Instructions for Use

DxC 500 AU Chemistry Analyzer

For *In Vitro* Diagnostic Use

C24569AB
January 2024

Beckman Coulter, Inc.
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Brea, CA 92821 U.S.A.

Instructions for Use
DxC 500 AU Chemistry Analyzer
PN C24569AB (January 2024)

Trademarks

Find us on the World Wide Web at:
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EC REP

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Rx Only

Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

C24569AB, January 2024

Software version 1.4.0

Table 1 Changes Since Last Revision

Chapter	Topic	Description of Change
System Information	Navigation Bar	Added note to the description of the Print Screen button.
	Status Bar	Changed the description of the system state button.
Consumables	Status Tiles for Consumables	For the descriptions of Sample Diluent, DI Water, Wash Solution 2%, and Wash Solution 100% and Lipase Wash modified the descriptions in the Action Required column.
	Replacing the Sample Diluent in the Running (Standby) or Running (Sampling) State	• Changed the description of when you need to replace the consumable. • Added a warning note about a physical hazard in the guided instructions for the Replace Sample Diluent step.
	Replacing the Diluted Wash Solution (2%) in the Running (Standby) or Running (Sampling) State	• Changed the description of when you need to replace the consumable. • Added a warning note about a physical hazard in the guided instructions for the Replace Wash Solution (2%) step.
	Replacing the Diluted Wash Solution (2%) in the Paused State	• Changed the description of when you need to replace the consumable. • Added a warning note about a physical hazard. • Changed step 7 to reflect that you need to perform a reagent check.

Table 1 Changes Since Last Revision (Continued)

Chapter	Topic	Description of Change
	Replacing the Wash Solution (100%) and Lipase Wash in the Running (Standby) State	• Changed the description of when you need to replace the consumable. • In step 8, removed the statement that the reagent check only checks the newly loaded solution.
	Replacing the Wash Solution (100%) and Lipase Wash in the Running (Sampling) State	Changed the description of when you need to replace the consumable.
	Replacing the DI Water	Changed the description of when you need to replace the consumable.
Reagents	Reagent Details Pages	Changed the description of Total Count, which is now named Usable Count.
Calibration	Configuring Calibrators	Removed a note about having to cancel a reagent blank manually.
	Configuring Calibrators for Chemistry Tests Manually	Removed a note about having to cancel a reagent blank manually.
	Reviewing Calibration Data	• Added new step 6 about accessing the Reaction Detail page. • Removed the note from step 5b about exporting results.
	Rerunning a Calibration	Added a note that the Reorder button is not for reordering ISE calibrations.
Quality Control	Reviewing QC Data	• Modified step 3e with information about accessing the ISE Reaction Detail page. • Removed the note from step 3e about exporting results. • Added a note to step 2 about the display of QC results.
	Configuring Control Materials	Removed instructions from step 7b for selecting a result when a rule is violated.
Sample Processing	Exporting Patient Test, Reagent Blank, Calibration, and QC Test Results	Removed the topic.
	Reviewing Results	• Added information about accessing the Reaction Detail page. • Removed the note from step 3 about exporting results.

Table 1 Changes Since Last Revision (Continued)

Chapter	Topic	Description of Change
	Rerunning a Test	Added a note a that te procedure is only for barcoded samples.
Troubleshooting	#: Insufficient sample detected	Added a step for Corrective Action.
	%: Clot detected	Added a step for Corrective Action.
	R: Insufficient reagent detected	Added a step for Corrective Action.
	!: Unable to calculate concentration	Modified the list of operating parameters to review.
	Troubleshooting Sample Events	Added a note about dismissing events on the Sample Events page.
System Management	Exporting Metering Data	New topic for new feature.
	Changing the User Interface Language	New topic for new feature.
System Configuration	Assigning a Dedicated Position in the Reagent Refrigerator	• Added a note to step 4 that you can assign a maximum of two dedicated positions for each solution. • Added a note to step 4 about the starting time of expiration of the solutions.
	Configuring Chemistry Tests Manually	• Added a step 4c about deleting a test. • Added a note to the description of Use Settings From in the Chemistry Details: Use Parameters From table about deleting a sample type. • Added a note to step 6a about adding a sample type to a test.
	Configuring Calculated Results	Added a note to step 5a about adding a sample type to a test.
	Managing Tests	Added a note to step 3 about making sure not to change the selections for regions.
	Configuring Test Panels	Added two notes to step 5.
Other Important Information	Dimensions and Weight	Changed the description of the height of the analyzer.
Parts Lists and Ordering Information	Parts List for Keyboard and Mouse Kit Specifications	Changed the list of parts for keyboard and mouse kits.

Table 1 Changes Since Last Revision (Continued)

Chapter	Topic	Description of Change
Maintenance Tasks Appendix	Perform Electrode Selectivity Check	Added a new step 12 about viewing details about the selectivity check.
	Clean and Calibrate the ISE	Removed duplicate step 10.
	Replace the ISE Buffer Syringe	Removed the information about the recommended usage cycle for the syringe.

Initial Issue, C24569AA, November 2023

Software version 1.3.0

Additional Resources

Training and Education Resources

To access training and educational resources, go to the Beckman Coulter training website at www.beckmancoulter.com.

1 Move your cursor over **Resources**, and select **Training Courses**.
The Beckman Coulter Learning Lab website opens.

2 Select one of the following links:

- **Browse Courses**: to search for specific analyzer online training courses and the instructor-led training course schedule.
- **Tips & Tools**: to search for analyzer-specific job aids such as competency checklists, flowcharts for maintenance, and training manuals.

Related Manuals

Other documents are available with the System Help and on the Beckman Coulter website at www.beckmancoulter.com/support/tech-docs.

Manuals include:

- *Host Manual for DxI 9000 and DxC 500 AU Analyzers*
- Reagent Instructions for Use
- *DxC 500 AU Release Notes*

Printed Copy of IFU

- Search for, download, then print a copy of the manual from the Beckman Coulter website at www.beckmancoulter.com/support/tech-docs.
- Order a copy of the manual from Beckman Coulter: Contact Beckman Coulter Customer Support at 1-800-526-3821 from the United States and Canada, or your local Beckman Coulter Representative.
- Print an individual topic and its subtopics from the System Help.

Additional Resources

Printed Copy of IFU

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Glossary

CHAPTER 1

Introduction

Intended Use

The Beckman Coulter DxC 500 AU Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only.

Intended User

For professional use only.

Benefits and Limitations

This product measures the chemical components in the sample (serum, plasma, urine, and whole blood (HbA1c only)) by mixing (stirring) the sample and reagent. Refer to the reagent Instructions for Use for details of the measurement specifications.

CHAPTER 2

Safety

Safety Notice

- Read all product manuals and consult with Beckman Coulter-trained personnel before you operate the analyzer.
- Do not perform any procedure before you carefully read all instructions.
- Only perform procedures that are described in the Instructions for Use or System Help, or by direction of Beckman Coulter-trained personnel.
- Certain areas of the analyzer present a risk of personal injury or damage to the analyzer when safety procedures are not followed.
- Always follow the product labels and the recommendation from the manufacturer.
- For more information, contact Beckman Coulter.

This Safety Chapter describes the possible hazards of the analyzer. The specific hazards of individual procedures are included within the instructions.

Use Statement

The analyzer is for indoor use only.

Do not use the analyzer in a manner not specified by Beckman Coulter, as the protection provided by the analyzer can be impaired and incorrect results or analyzer failure can occur.

Notice to User

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Symbols Glossary

Table 2 Symbols Glossary

Symbol	Description
CE	**CE Marking** This symbol indicates conformity with the provisions of the applicable EU directives and regulations.
C SP® US	**cNRTLus Certification Mark** This symbol indicates recognition by a Nationally Recognized Testing Laboratory (NRTL) that the system has met the relevant product safety standards for the United States and Canada. *OSHA, CEC*
Made in *Country of Origin*	**Country of Origin Symbol** This symbol indicates the country that the product was manufactured in.
	**Warning; Crushing of hands** This symbol indicates a warning of a closing motion of mechanical parts of equipment. *ISO 7010. Graphical Symbols for electrical equipment in medical practices. #W024* **Supplemental Product-Specific Manufacturer Information** Use caution to avoid injury to hands when close to equipment with moving mechanical parts.
	**RCM Symbol** This symbol indicates compliance with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.
	**RoHS Caution Symbol** This symbol indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture. These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 *Marking for Control of Pollution Caused by Electronic Information Products* requirements.

Table 2 Symbols Glossary (Continued)

Symbol	Description
RxOnly	**RxOnly Symbol** This symbol is recognized by the US FDA as an alternative to the following statement: Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner. *21 CFR 801.109(b)(1)*
	**Recycling Symbol** This symbol is required by the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. This symbol indicates that: 1. The device was put on the European Market after August 13, 2005. 2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or your local Beckman Coulter Representative for more information on the take-back program that facilitates the correct collection, treatment, recovery, recycling, and safe disposal of these products. *EU Directive 2012/19/EC: waste electrical and electronic equipment (WEEE)* For the Japan market: This system is considered an industrial waste, subject to special controls for infectious waste. Before disposal of the system, refer to the *Waste Disposal and Public Cleaning Law* for compliance procedures.
	**"ON" (power)** This symbol indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5007* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the on position.
	**"ON"/"OFF" (push-push)** This symbol indicates connection to or disconnection from the mains. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5010* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate a switch that is used as an on and off switch, without disconnecting power.

Table 2 Symbols Glossary (Continued)

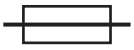
Symbol	Description
	**"ON" for a part of equipment** This symbol indicates the On condition for a part of equipment. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5264* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate on or reset conditions.
	**Stop** This symbol indicates the control or the indicator to stop the active function. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5110A* **Supplemental Product-Specific Manufacturer Information** This symbol indicates a stop button.
	**"OFF" (power)** This symbol indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5008* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the off position.
	**Fuse** This symbol indicates fuse boxes or their location. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5016* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate a fuse location and rating.
	**Dangerous voltage** This symbol indicates hazards arising from dangerous voltages. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5036* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate an area of the system to not access under any circumstances, due to possibility of high voltages and the risk of electrical shock.

Table 2 Symbols Glossary (Continued)

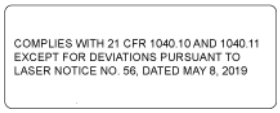
Symbol	Description
	**Protective earth; protective ground** This symbol indicates a terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5019*
	**Warning, Hot Surface** This symbol indicates a warning of a hot surface. *ISO 7010. Graphical Symbols – Safety colors and safety signs. #W017* **Supplemental Product-Specific Manufacturer Information** This symbol indicates that there is a hot surface or component (such as a lamp) in the area that, if touched, can cause a burn.
	**Warning; Laser Beam** This symbol indicates a warning of a laser beam. *ISO 7010. Graphical Symbols - Safety colors and safety signs. #W004* **Supplemental Product-Specific Manufacturer Information** This symbol indicates that there can be laser light radiation in the area. Take precautions to prevent exposure.
	**Laser Compliance** This symbol indicates that the product is a Class 1 Laser Product and is in compliance with international standard and US requirements. *21 CFR 1040*
	**Laser Compliance** This symbol indicates that the product is a Class 1 Laser Product and is in compliance with international standard and US requirements. *21 CFR 1040* *IEC 60825*

Table 2 Symbols Glossary (Continued)

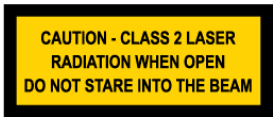
Symbol	Description
	**Laser Class 2 Panel Label** This symbol on a panel indicates that there is Class 2 laser light radiation beyond the panel it is placed on. Use caution and do not stare into the beam when laser light is in the area. *IEC 60825: Safety of laser products - Part 1: Equipment classification and requirements, clause 7.4*
	**Manufacturer** This symbol indicates the medical device manufacturer. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.1* **Supplemental Product-Specific Manufacturer Information** This symbol indicates who the legal manufacturer of the product is.
	**Authorised representative in the European Community** This symbol indicates the authorized representative in the European community. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.2*
	**Catalogue Number** This symbol indicates the manufacturer's catalogue number so that the medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.6*
	**In vitro diagnostic medical device** This symbol indicates a medical device that is intended to be used as an in vitro diagnostic medical device. *ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.5.1*
	**Caution** This symbol indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.4*

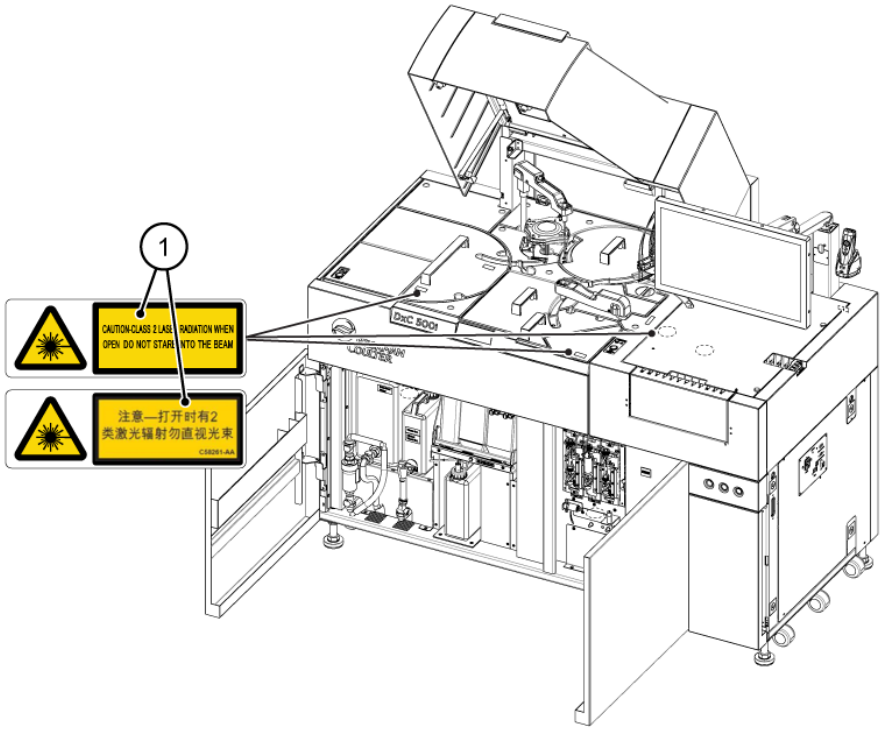
Table 2 Symbols Glossary (Continued)

Symbol	Description
	**Warning; Biological hazard** This symbol indicates a warning of a biological hazard. *ISO 7010. Graphical Symbols - Safety colors and safety signs. #W009* **Supplemental Product-Specific Manufacturer Information** This symbol indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard. This symbol indicates the use of biohazardous materials in the area. Use caution when working with possible infectious samples. Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.
	**Consult instructions for use** This symbol indicates the need for the user to consult the instructions for use. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.3*
	**Date of Manufacture** This symbol indicates the date when the medical device was manufactured. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.3*
	**California Proposition 65** This symbol indicates that this product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm. For more information go to https://www.P65Warnings.ca.gov.
	**Serial number** This symbol indicates the manufacturer's serial number so that a specific medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.7*

Laser Labels

This analyzer complies with IEC60825-1 and is classified as a Class 1 laser product.

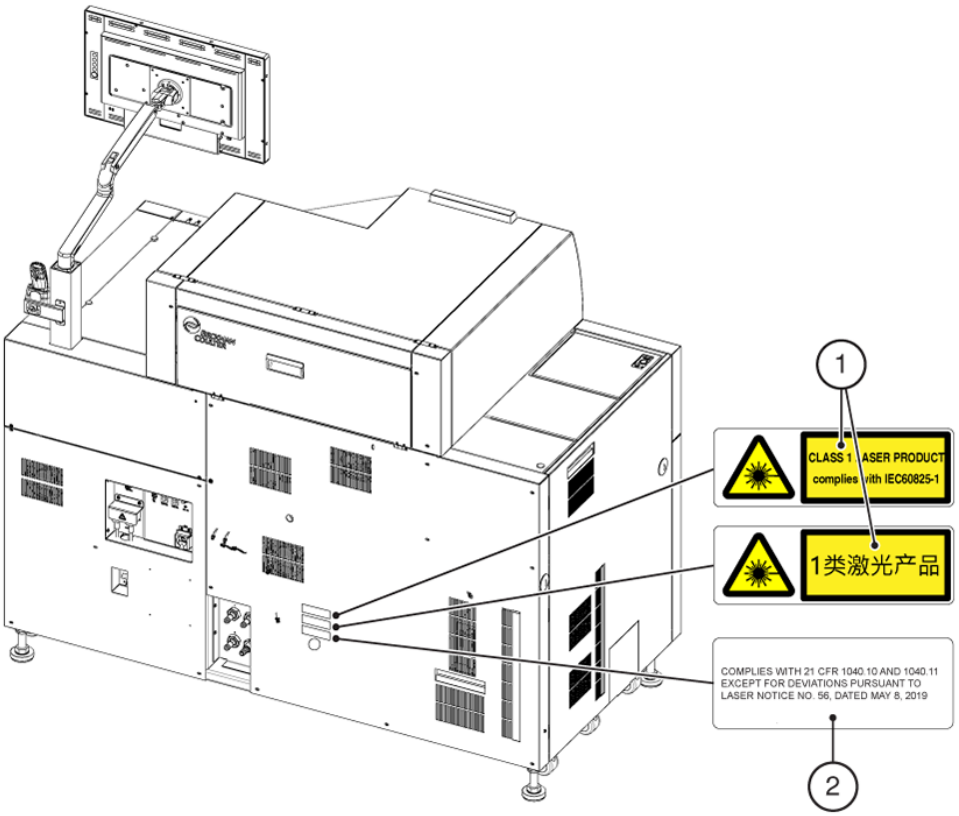
Figure 1 Laser Labels (Top of Analyzer)



1. CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM

   Bottom label is for China market only.

Figure 2 Laser Labels (Back of Analyzer)



1. CLASS 1 LASER PRODUCT complies with IEC60825-1
2. Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 56, dated May 8, 2019.

Safety Information

Electromagnetic Compatibility

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic

interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

Flammable Materials

Do not use flammable materials near the analyzer.

Moving Parts

Do not touch or go close to moving parts. Keep protective guards in position and covers closed during operation, except as directed by the system documentation. Failure to follow these instructions can cause injury.

Electrical Ground

A Beckman Coulter Representative must connect the power to the analyzer. It is your responsibility to prepare the power supply and facility according to applicable electrical codes and the specifications described in the Electrical Line Requirements of the System Specifications section.

Electrical Shock Hazard

Do not replace or service any components where you can contact hazardous parts that can cause electric shock. Beckman Coulter must perform this maintenance. For continued protection against electrical shock hazards, only perform procedures that are described in the Instructions for Use or System Help.

Main Power Disconnection

To completely turn off the power for the analyzer, turn off the main breaker that is located at the rear of the analyzer.

Biohazardous and Chemical Materials

Wear the required personal protective equipment (PPE) such as gloves, eye shields, and lab coats when performing any procedure.

Observe all biohazard precautions when doing maintenance, service, or troubleshooting on the analyzer. Biohazard precautions include, but are not limited to, wearing personal protective equipment (PPE), and washing hands after working on contaminated portions of the analyzer.

Follow all laboratory procedures and policies for handling potentially infectious and pathogenic materials.

Avoid skin contact with reagents and other chemical preparations. Wear personal protective equipment (PPE) to work with reagents and other chemical preparations used with the analyzer. For more information, refer to the related SDS (safety data sheet).

Clean spills of biohazardous or other potentially hazardous substances on the analyzer immediately. If the analyzer must be decontaminated, contact Beckman Coulter.

Follow your laboratory procedure for disposing of biohazardous and hazardous materials.

Waste

Handle and treat any liquid or solid waste that is generated by the analyzer as infectious materials.

Some liquid waste, solid waste, or mixtures might require special treatment before disposal. For correct disposal, refer to relevant federal, state, territory, and local laws.

Some substances in the reagents, control materials, sample diluents, and wash solutions are regulated under the pollution ordinance and effluent standard. Treat such substances according to the effluent standard applied to the facilities, consulting the relevant manufacturer or distributor. Also, federal, state, territory, and local laws might regulate these substances.

Handle and treat any used or replaced hardware (such as tubing or probes) as infectious waste materials.

Bar Code Reader

- Do not adjust or remove the housing of any bar code reader. The bar code readers use lasers and looking directly at the laser light can be hazardous. Assume that the laser is always on.
- Any modifications or performance of procedures other than these specified herein might result in hazardous radiation exposure.

Alerts for Warnings, Cautions, and Notes

This manual uses the following alert symbols:

Warning

Warning indicates a potentially hazardous situation which, if not avoided, could cause death or serious injury. Warning can indicate the possibility of erroneous results.

Caution

Caution indicates a potentially hazardous situation, which, if not avoided, could cause minor or moderate injury. Caution can indicate the possibility of damage to the analyzer, or a delay in results.

Important

Important indicates important information to follow.

Note

Note indicates notable information to follow.

Tip

Tip indicates information to consider.

Hazards

- A Beckman Coulter representative installs the analyzer. If the analyzer installation needs modification, contact Beckman Coulter.
- If the analyzer malfunctions, power off the analyzer completely using the main breaker located on the back of the analyzer before any repair service.
- If fluid is spilled on the analyzer, turn off the main breaker located on the back of the analyzer immediately. Wipe up the spill only after turning off the main analyzer breaker. If fluid enters the analyzer after a spill, contact Beckman Coulter before restarting the analyzer.
- Before transferring the analysis results to a Laboratory Information System, confirm that the sample IDs are correct.
- Substances such as Lipemia, Icterus, and Hemolysis can interfere with results. Refer to the reagent Instructions for Use (reagent IFU) for specific substance interference information.
- To be sure the analytical data is accurate:
  - — Confirm the quality of deionized (DI) water is within specifications.
  - — Confirm that all tests have passed calibration, and calibration is not expired.
  - — Inspect the quality control data.
- Use the correct reagent, calibrator, and control material to analyze samples.
- Avoid excessive reagent agitation, which can cause bubbles. If bubbles are visible on the surface of the reagent, remove them. Confirm that the reagent bottles are placed

securely on the reagent tray with the correct adapters. If the bottles are tilted, incorrect results can occur, or you can damage the reagent probe.

- Prepare reagents, wash solutions, calibrators, and control samples according to the product's IFU, paying particular attention to any reconstitution, mixing, and pretreatment instructions.
- Handling samples:
  - Precautions when using whole blood (HbA1c)
    - Use HbA1c with Beckman Coulter's HbA1c Advanced test (for automated sample preparation). Use of any other test can cause incorrect diagnostic results. Operation of the three tests HbA1c, T-Hb, and A1c, and some of the specific test parameters are pre-programmed and you cannot change them.
    - If the blood has coagulated, obtain a new sample.
    - If the blood cells have settled, mix the whole blood by inverting gently.
    - Do not process HbA1c whole blood patient samples on the STAT table.
  - Sample to sample carryover is one potential source of analytical error in the clinical laboratory. Do not use the same sample run on an AU Chemistry analyzer for analysis of analytes for which a small quantity of carryover could cause problems with the results.
  - The analyzer analyzes serum, urine, plasma, CSF and whole blood (for HbA1c only). Other can be used for sample types not listed in the Sample Type list. Some samples cannot be analyzed depending on the analysis test, reagent, and sample tubes used. For questions regarding reagent and sample tube type, contact Beckman Coulter.
  - Use serum or plasma that is clot free, or urine that is free from suspended matter. If serum or urine contains clots or suspended matter, the probe can clog and cause problems with the analysis results.
  - Chemicals present in the sample (such as medicine, anticoagulant, or preservative) can significantly interfere with the results. Refer to the reagent IFU for each test.
  - Highly viscous samples can interfere with the testing of the samples and the reliability of data.
  - Refer to the reagent IFU for each test for correct sample collection and storage. Incorrect storage of samples can alter the analyte in a sample.
  - Use only sample containers and sample tubes specified by Beckman Coulter.
  - To reduce the risk of interference, centrifuge and then separate serum and plasma samples adequately from blood cells immediately. Before analysis, confirm that samples are free from suspended matter, such as fibrin. While the analyzer has a sophisticated clot detection mechanism, this mechanism is not able to detect all clots. Carefully inspect the samples.
  - Collect urine samples using correct preservatives and remove any suspended matter using centrifugation before analysis (CLSI GP16-A3).
  - Confirm that any anticoagulants or collection devices that employ a barrier are compatible with the test reagent being used. Refer to the reagent IFU for suitable and validated sample types. Use caution when using sample tubes containing barriers or gels. Confirm the suitability of all collection devices in use.
  - For information about whether a serum separating agent is correct or not, contact the chemical reagent manufacturer or distributor.

  - When using sample containers or tubes containing a separating medium, confirm that there is enough serum to avoid contaminating or blocking the sample probe with the separating medium.
  - Confirm that there is enough sample for correct sampling to occur. The small amount of wash water left on the sample probe can dilute the volume of sample left in the sample tube.
- To prevent water leaks, confirm that Beckman Coulter has fitted water supply and drainage hoses according to local guidelines.
- To confirm analyzer performance, maintain and inspect the analyzer periodically by replacing the parts according to the instructions that display on the Task page for each maintenance task.
  - Have and follow a maintenance schedule for this analyzer.
  - Create a maintenance routine for the computer software and hardware, including frequent backing up of data containing analysis settings, results history, and the event log list file. To reduce the risk of computer infection, be sure that the media used for backing up is free from viruses.
  - Do not store backups on site. Keep one copy on site for reference and one copy off site.
- For open channel tests: before using the analyzer for the first time, configure parameters such as the reagent and sample quantity, measurement wavelength, and calibrator values. Enter test-specific parameters from the reagent setting sheet to have optimum analyzer performance. Enter any updates to these settings into the analyzer immediately.
- Dedicate the computer hardware to only running the analyzer software. Do not connect the computer hardware to the Internet, unless instructed to do so by Beckman Coulter.
- Keep the analyzer covers closed except for startup procedures and maintenance. If the covers are open for extended periods of time, excess condensation can be generated in the reagent refrigerator and cause errors.
- As a Perform Service user, you have access to the Chemistry Diagnostics pages and the ISE Analysis page in the Advanced menu. Except for the Custom Diag page, do not perform any actions on these pages unless directed to do so by Beckman Coulter Customer Support.

CHAPTER 3

System Information

System Requirements

The analyzer has specific requirements to operate correctly and avoid damage to the analyzer or other equipment. Examples include the following requirements:

- Placement requirements: The surface and surrounding area that is designated for the analyzer must be large enough to accommodate the analyzer and strong enough to support it. Sufficient clearance around the analyzer is required for safe installation and maintenance.
- Electrical line requirements: The electrical line and any line conditioners, and backup power supplies (UPS units) that are used with the analyzer must meet specific requirements. To prevent damage to the analyzer or other equipment, follow the electrical line requirements.
- Electrical Line connection: The analyzer can be connected using an industrial style plug or wired directly into a distribution box in the building installation. Beckman Coulter Customer Support will wire the analyzer according to the your site's requirements determined from the pre-installation evaluation.
- Environmental requirements: The analyzer requires specific environmental conditions to operate correctly. Also, the location must not be subject to direct sunlight, vibration, or corrosive gases.

For detailed requirements, refer to System Specifications.

Viewing Analyzer Version Information

You can view information about the current version of the analyzer software and hardware.

1 Select **Menu** > **About**.
The analyzer displays the About dialog, with the analyzer software version, and telephone numbers for service and sales representatives.

2 For more detailed information, select **Details**.
The analyzer displays the Product Version dialog with version information for software subsystems and the version of the IFU that is included in the System Help.

3 To exit each dialog, select the **X** in the upper right corner of the dialog.

Chemistry Theory of Operation

The chemistry analyzer employs a variety of analytical methods, depending on the particular tests being run. These include:

- End point reaction method
- Rate reaction method
- Photometric measurement
- Ion selective electrode (ISE) measurement

Reagent Blank

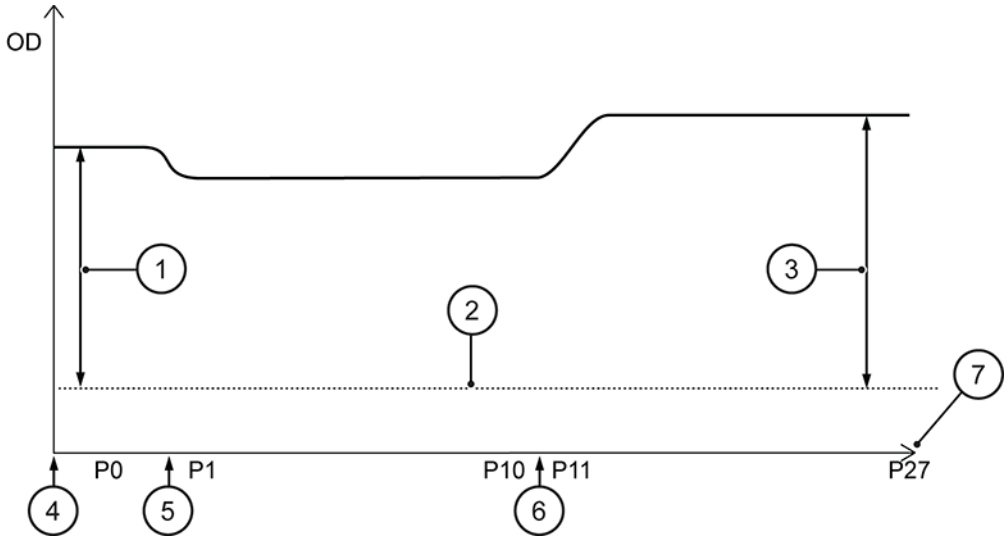
To calculate a measurement value (reaction OD), the system subtracts the reagent blank OD (reagent OD at each photometric point of P0 to P27) and the Deionized (DI) water blank OD values (photocal data) from the measured OD of a sample reacted with a reagent.

By performing a reagent blank measurement, the system obtains reagent blank OD values (RB) at all photometric points shown in the following chart.

The system measures up to four replicates of the sample and determines the reagent blank data (reagent blank OD value).

1 replicate: the OD value.
2 replicates: the mean value of two OD values.
3 replicates: the mean value of the two closest OD values.
4 replicates: discard the highest and lowest OD values and average the two remaining OD values.

Figure 3 Reagent Blank (Compared with Water Blank; Example of 2-step Analysis)



1. Reagent OD value at the first point (first data)
2. Deionized water blank (photocal data)
3. Reagent OD value at the last point (second data)
4. R1 (first reagent) dispensing
5. Sample (water) dispensing
6. R2 (second reagent) dispensing
7. Photometric point

First-point Reagent OD Value (First Data)

- First-point reagent OD value (RB) = {first point measured OD value} -{DI water blank (photocal data)}.
- If the first-point reagent OD value is outside the reagent OD range (Low and High) that you have programmed in **Reaction Blank OD Limit** of the Chemistry Details: General Parameters tab on the Tests page (**Menu** > **System Configuration** > **Test Menu**), the system generates a flag.

Last-point Reagent OD Value (Second Data)

- Last-point reagent OD value (RB) = {last point measured OD value} - {DI water blank (photocal data)}.
- If the last-point reagent OD value is out of the reagent OD range (Low and High) that you have programmed in **Reaction Blank OD Limit** of the Chemistry Details: General Parameters tab on the Tests page (**Menu** > **System Configuration** > **Test Menu**), the system generates a flag.

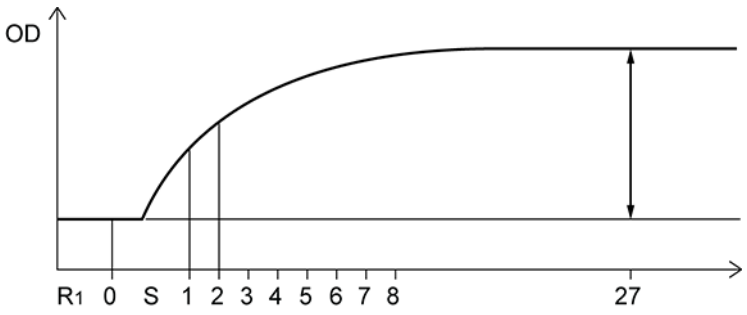
End Point Reaction Method

1-Point Reaction Method

This general type of end point reaction method determines the reaction mixture OD from the OD measured at a specified photometric position.

Reaction mixture OD = OD (at specified position) - OD0 (at position 0)

Figure 4 Reaction Curve for 1-Point Reaction Method



2-Point Reaction Method (Self-Blank Method)

This end point reaction method requires a sample blank adjustment. Eliminate the OD values before dispensing the reagent 2 as the blank channel. To obtain correct data without influences from turbidity or color of the serum, the OD values of the blank channel are subtracted from the OD values measured after dispensing the reagent 2.

The following expression represents the OD value in this reaction method:

K2 = {R1. V / (R1.V + R2.V + S.V)}

K3 = {(R1.V + S.V) / (R1.V + R2.V + S.V)}

Reaction OD value = (Px - K2 × P0) - (K3 × Pz - K2 × P0).

This calculation result is defined as the reaction OD value.

Figure 5 Reaction Curve for 2-Point Reaction Method (Self-Blank Method)

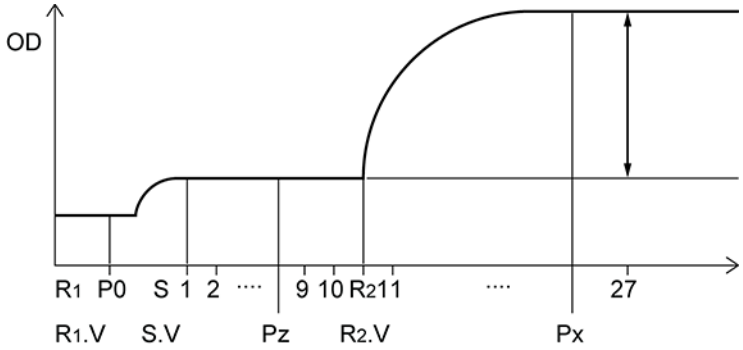


Table 3 2-Point Reaction Method (Self-Blank Method)

Item	Description
R1.V:	Reagent 1 dispense volume
R2.V:	Reagent 2 dispense volume
S.V:	Sample dispense volume
P0:	OD value at the first point
Pz:	OD value before dispensing reagent 2
Px:	OD value after dispensing reagent 2

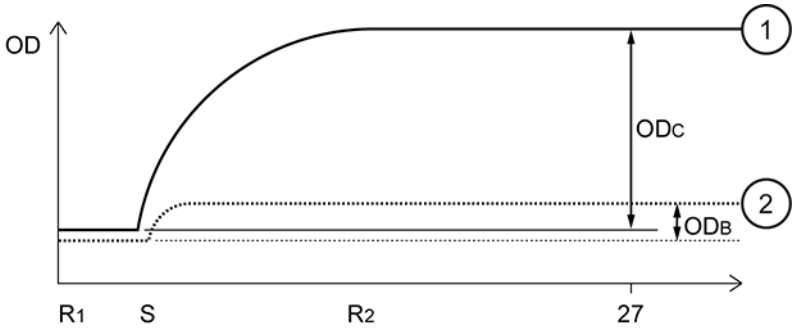
Sample Blank Correction Method

This type of reaction method uses two cuvettes, a cuvette for the color reaction and a cuvette for the sample blank. The analyzer measures blank item OD values, which include serum quality issues, first. Then, the analyzer subtracts the blank item value from the measured OD value of the actual sample (OD value of the color item).

With this end-point reaction method, you can obtain higher accuracy data than the 2-point reaction method even when you cannot avoid serum quality issues (dotted line in the following figure).

Reaction OD value = [Color item OD value (OD_C)] - [Blank item OD value (OD_B)]

Figure 6 Reaction Curve for Sample Blank Correction



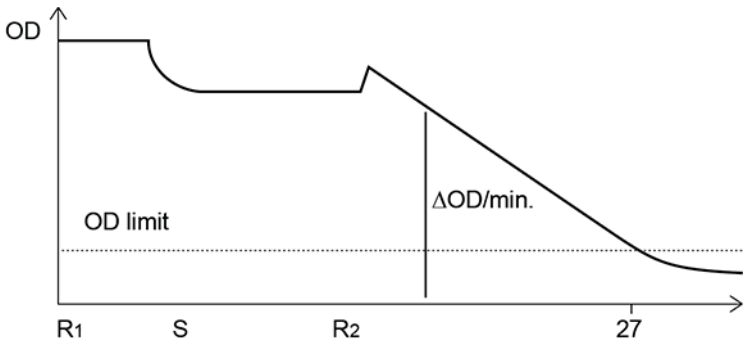
1. Color reaction channel
2. Sample blank channel

Rate Reaction Method

Rate Reaction Method

This reaction method determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method.

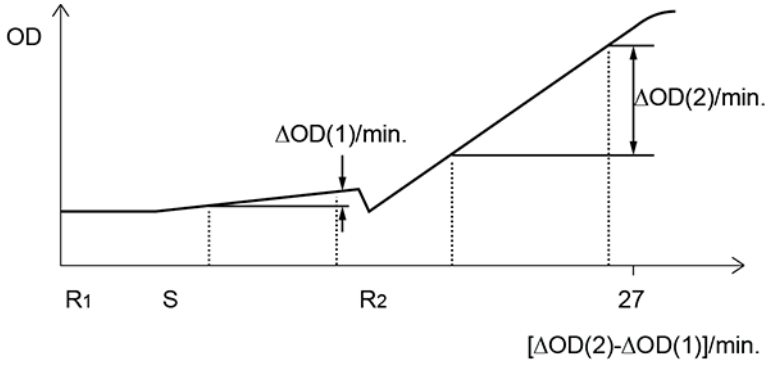
Figure 7 Reaction Curve for Rate Reaction Method



Double Rate Reaction Method

This reaction method determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method. Next, the system obtains the OD rate of the objective substance from the calculation expression.

Figure 8 Reaction Curve for Double Rate Reaction Method

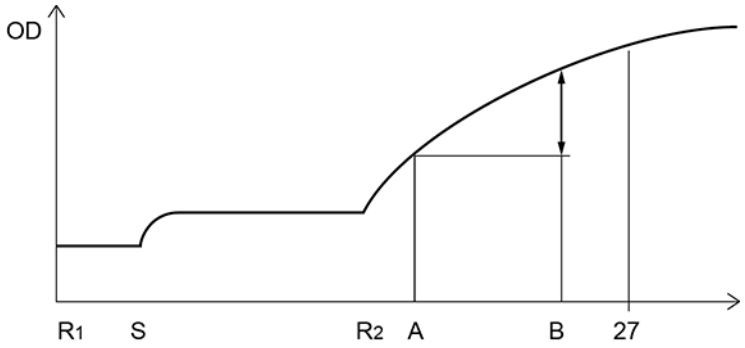


Fixed Point Reaction Method

The fixed point reaction method measures the OD value at two specified photometry points. The system measures the two photometry points after the beginning of reaction between sample and reagent.

Reaction OD value = OD_B - OD_A

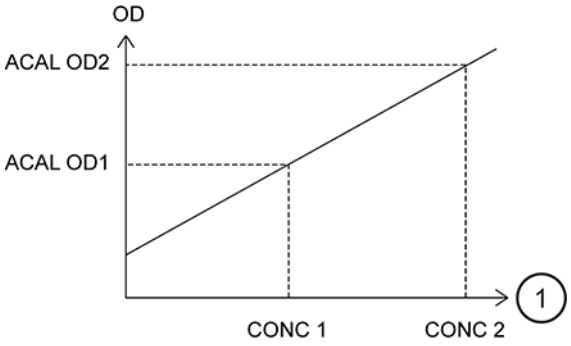
Figure 9 Reaction Curve for Fixed Point Reaction Method



Summary of Calibration Types

You can generate a maximum of 15 types of calibration curves. The following information describes the six major types of calibration curves.

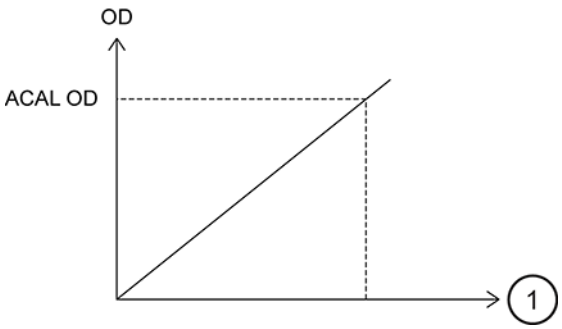
Figure 10 ACAL AA



1. CONC: Calibrator Concentration value

- Generate this calibration curve using two different calibrators. The Y intercept is above or below 0 but does not pass through 0 (reagent blank).
- Use this type of calibration curve for tests that use the fixed point reaction method.

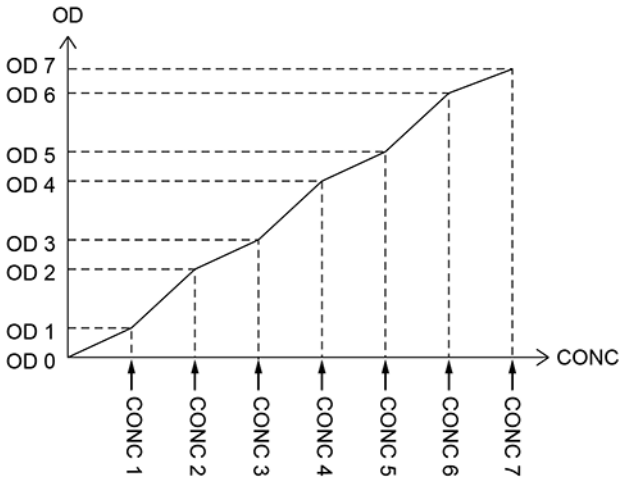
Figure 11 ACAL AB



1. CONC: Calibrator Concentration value

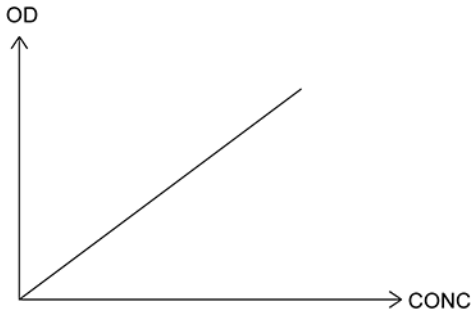
- Generate this calibration curve using a single calibrator and the reagent blank. The Y intercept passes through 0.
- Use this type of calibration curve for tests that use the end point reaction method. An example of a test using this type of calibration is Glucose.

Figure 12 ACAL 7AB



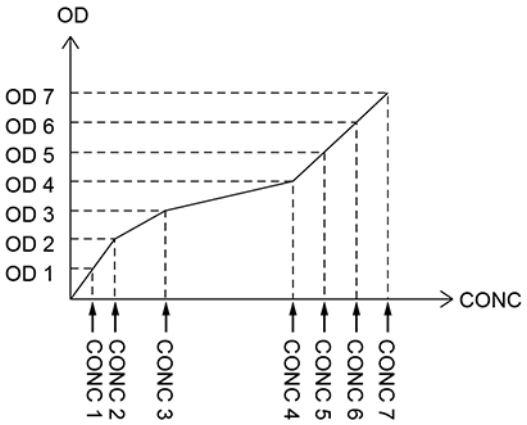
- Generate this calibration curve using a minimum of two calibrators up to a maximum of 7 calibrators. The Y intercept passes through 0.
- Use this type of calibration curve for immunoturbidimetric tests. An example of a test using this type of calibration is C-Reactive Protein.

Figure 13 MCAL MB



- Set the calibration coefficient with a theoretical or traceable reference method.
- MB factor derived from extinction coefficient or IFCC reference labs that is a derived factor.
- An example of a test using this type of calibration is Lactate Dehydrogenase.

Figure 14 MCAL 7 MB



- Generate this calibration curve by entering the OD and concentration for a maximum of 7 calibrators.
- Use this type of calibration curve for immunoturbidimetric tests with constantly curving characteristics.

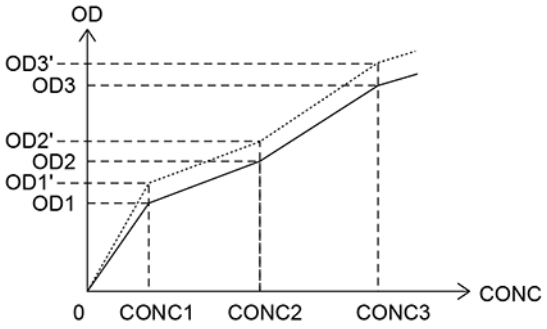
ACAL nAB (single-point correction)

First, analyze one of multiple standard solutions for 2AB to 7AB. By using the ratio between the reaction OD values of this standard solution and the previously measured standard solution, correct the reaction OD values of other standard solutions, and then recreate the calibration chart.

You can correct the calibration chart with two points of OD0 and another OD value, if the standard solution with a concentration of 0 is available.

Example 1: If none of multiple standard solutions has a concentration of 0.

Figure 15 Single-point Correction without a Standard Solution Concentration of Zero



You can perform a single point update to the calibration curve for calibrations defined as 2AB to 7AB. A single calibrator is used to obtain a new reaction OD. The ratio between the previously obtained OD and the current OD causes the OD of the other calibrators to be adjusted, and the new calibration curve is calculated.

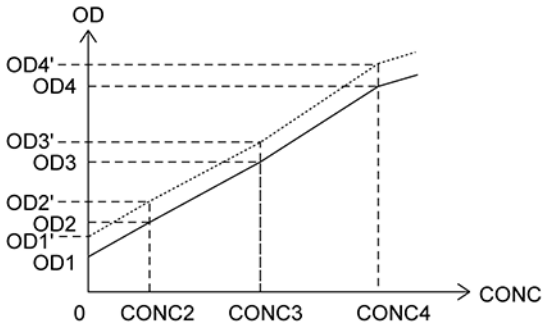
1. Perform the single-point correction.

$$ODn' = ODn \times \frac{OD2'}{OD2}$$

2. Recalculate for the calibration curve.

Example 2: If any standard solution has a concentration of 0.

Figure 16 Single-point Correction with a Standard Solution Concentration of Zero



ODn: previous OD value ODn': OD value after correction

If you perform a correction with two points of CONC1 and another (CONC3), execute the following calculation.

1. Use the reaction OD values of CONC1 and CONC3 (OD1' and OD3') as they are.
2. Correct each point:

$$ODn' = \alpha \times (ODn - OD1) + \beta$$

$$\alpha = \frac{OD3' - OD1'}{OD3 - OD1}$$

$$\beta = OD1'$$

Principles of the Real-time Water Blank Check

The real-time water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the deviation in the water blank reading on a cuvette exceeds a tolerance level, the system generates a `Photometry Error During Cuvette Wash` event.

The analyzer generates a `Photometry Error During Cuvette Wash` event when it detects a cuvette overflow or unstable photometry. The following conditions can cause unstable photometry:

- Incorrectly placed cuvettes in the cuvette wheel
- Dirty cuvettes
- Insufficient amount of wash solution being supplied to clean the cuvettes
- A deteriorating lamp

When the analyzer generates a `Photometry Error During Cuvette Wash` event, check to see if a cuvette overflow has occurred.

- If a cuvette overflow has occurred, refer to Recovering from a Cuvette Wheel Overflow. It is necessary to identify and rerun all samples affected by the cuvette overflow.
- If a cuvette overflow has not occurred, the system might have generated the `Photometry Error During Cuvette Wash` event because of unstable photometry. To determine the cause of the error and perform corrective actions refer to Recovering from an Unstable Photometry Error.

Photometric Measurement

Various chemical components in the sample and the reagents produce a color reaction in the cuvette. Light from a halogen lamp passes through the reaction mixture, and separates into specific wavelengths by a diffraction grating. A photodetector measures the optical density of the reaction mixture. The system performs measurements at 18-second intervals throughout the reaction period. The system uses the measured values for the reaction period and wavelengths that are defined in the Chemistry Details: General Parameters tab on the Tests page (**Menu** > **System Configuration** > **Test Menu**) for concentration calculation.

Principles of the ISE Measuring Method

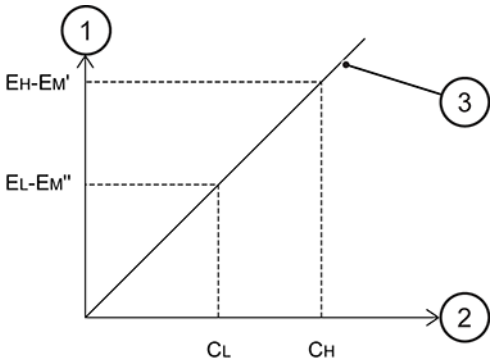
The system mixes sample and ISE Buffer Solution using a specified sample ratio in the sample pot of the ISE module (optional). The system aspirates the mixture and passes it to the Na, K, and Cl electrodes. The system measures the potential generated at the electrodes. The system cycles ISE MID Standard Solution between samples to measure the reference potential and to prevent carryover.

Calibration Processing on the ISE

During calibration of the ISE, the system measures both ISE MID Standard Solution and Standard Solution H and L, which have a known concentration. The system obtains the relationship between the electrode potential and ion concentration then, and calculates the Na, K, and Cl calibration setup coefficient S (slope).

Calibration

Figure 17 Calculation of Slope



1. Potential difference (mV)
2. CONC (logarithm) mmol/L
3. Calibration

C_H	A known concentration of Standard Solution H used for calibration
C_L	A known concentration of Standard Solution L used for calibration
E_H-E_M'	A potential difference between Standard Solution H and ISE MID Standard Solution
E_L-E_M''	A potential difference between Standard Solution L and ISE MID Standard Solution

The system creates a calibration using a potential difference between the two points of known concentration.

Correction by M-CAL

M-CAL at the ISE is data correction using a calculation formula, Y = AX + B.

Y: corrected value, X: measured value.

Coefficients A and B are obtained in the following way.

Correlation regression with a measurement (y) obtained from the system before correction and value (x) obtained from any conventional method or standard method.

You can obtain coefficients A and B by a 3-point regression calibration or Manual calculation.

y = ax + b

gives

x= (1/a)y - (b/a)

Therefore, A =-1/a, B = -b/a

The two methods to perform M-CAL are:

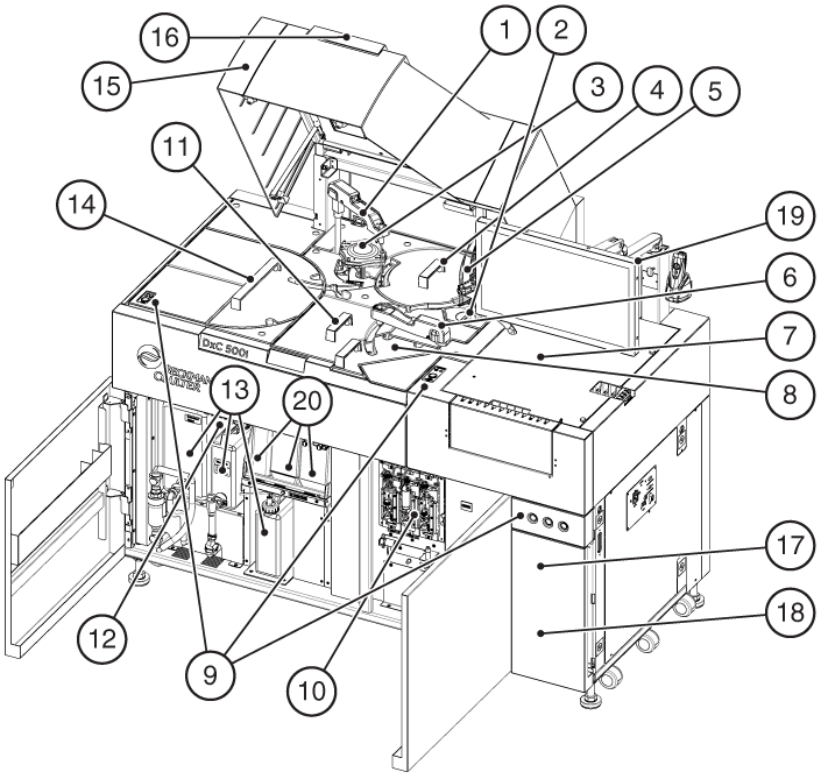
- Manual: Obtain A and B with the previously listed equations and enter them as the factors.
- CRS (3-point regression CAL): Optional.

Subsystem Functions

This section provides a description and diagram with location of each hardware subsystem and module.

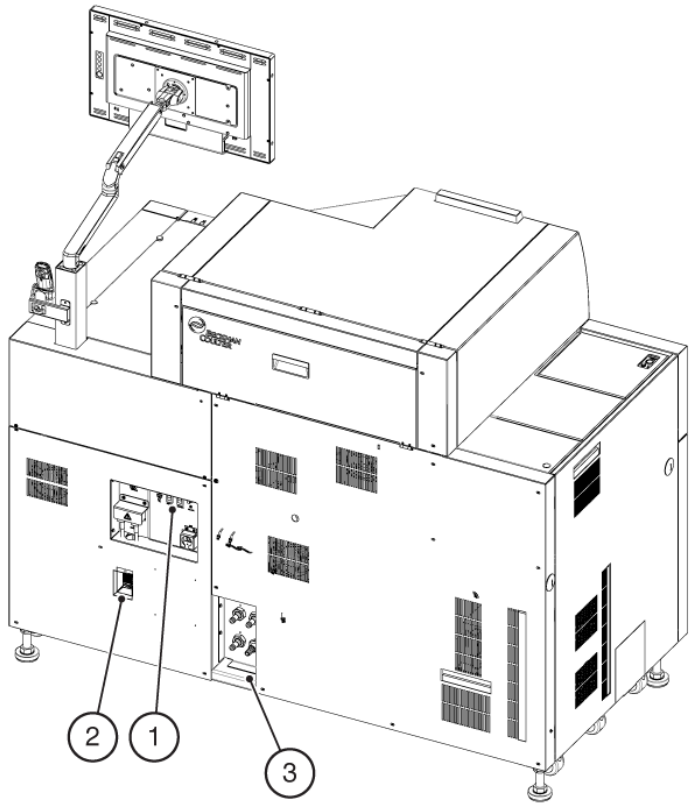
Hardware Overview

Figure 18 Hardware Overview (Top and Front View)



1. Reagent transfer subsystem
2. Photometer lamp
3. Mix bar subsystem
4. Cuvette wheel
5. Wash nozzle subsystem
6. Sample transfer subsystem
7. Sample handler
8. STAT table
9. Operation buttons and indicator lights
10. Syringe subsystem
11. ISE Module (optional)
12. Wash solution roller pump
13. Tank storage
14. Reagent refrigerator
15. Upper cover
16. Status light
17. Sub-breakers
18. Computer
19. Monitor
20. ISE solution bottles

Figure 19 Hardware Overview (Side and Rear View)

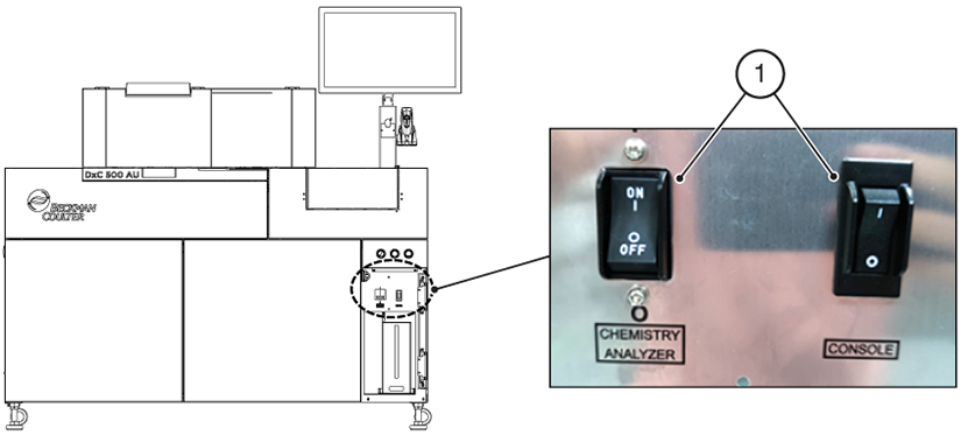


1. Sub-breakers and fuses
2. Main breaker
3. Water supply and drain connections

Breakers

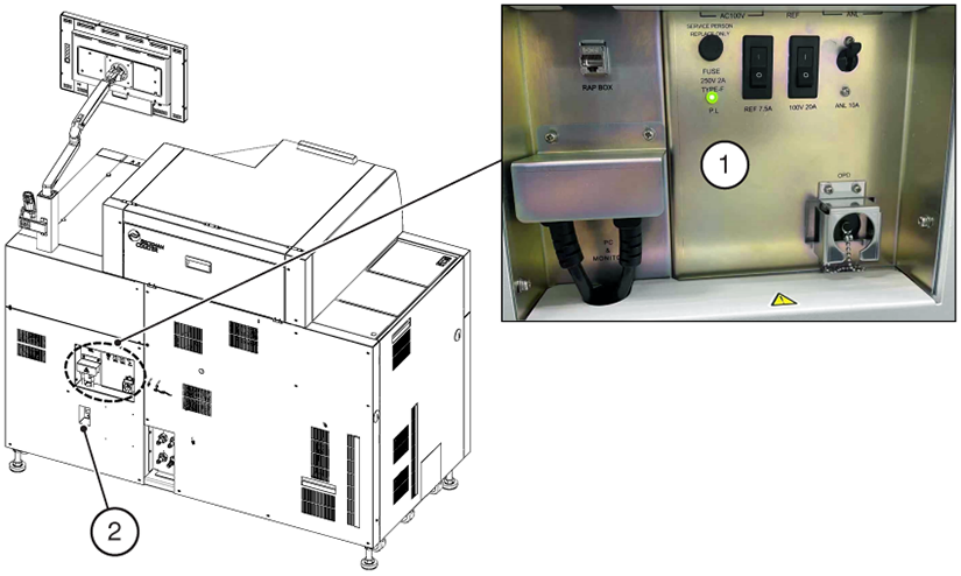
The main breaker (main power switch) allows the power in specific areas of the analyzer to be isolated. In normal conditions, all of the sub-breaker switches are in the on position.

Figure 20 Breakers at Front Panel



1. Sub-breakers

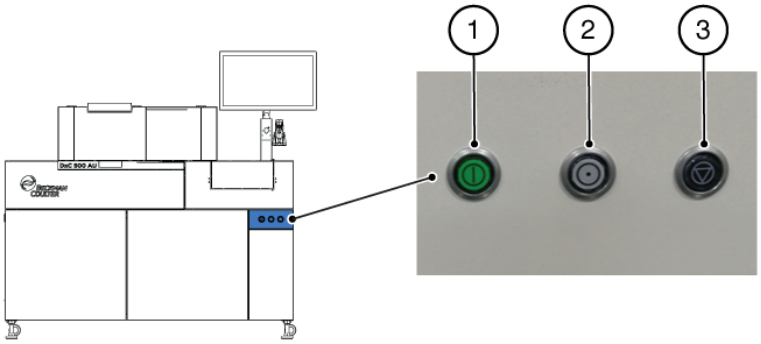
Figure 21 Breakers at Back Panel



1. Sub-breakers and fuses
2. Main breaker

Operation Buttons and Indicator Lights

Figure 22 Front Operation Buttons and Indicator Lights



1. On button with power indicator light (Green)
2. Reset button (White)
3. Analyzer Stop button (Black)

Figure 23 ROTATION LED (STAT Table) and TABLE ROTATION/DIAG Button with Indicator Light

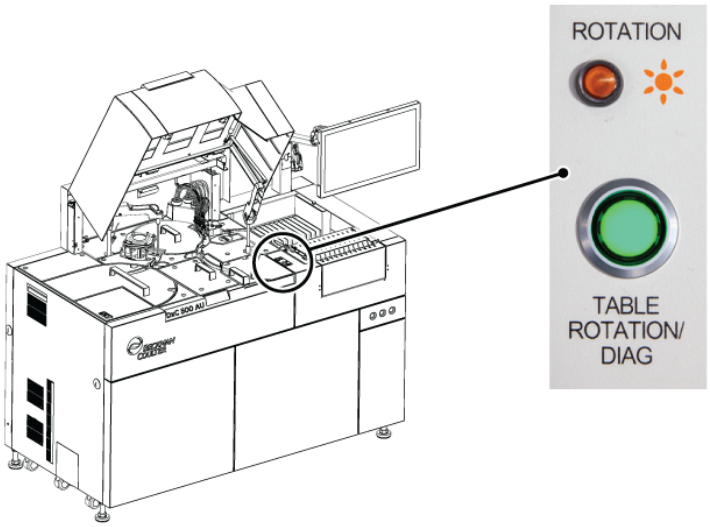


Figure 24 ROTATION LED (Reagent Tray) and TRAY ROTATION Button with Indicator Light

Table 5 Operation Buttons and Indicator Lights

Item	Description
On button with power indicator light (green)	The On button turns on the analyzer and computer, and the analyzer initializes. When the analyzer is fully powered up, the indicator light in the button turns on.
Reset button (white)	The Reset button restores the main power to the analyzer, and is used after the Analyzer Stop button is pressed or a power failure occurs.

Table 5 Operation Buttons and Indicator Lights (Continued)

Item	Description
Analyzer Stop button (black)	The Analyzer Stop button immediately stops the operation of the analyzer. Use this button to initiate an immediate stop, or to completely turn off the analyzer after shutting down the chemistry analyzer. The power to the computer is not turned off by pressing the button.
TABLE ROTATION/DIAG button with indicator light (Table Rotation and Diagnostics)	The TABLE ROTATION/DIAG button rotates the STAT table for loading samples on the STAT table. In the maintenance task pages, this button initiates the maintenance function. (To go to a maintenance task page, select **Maintenance**, then select a maintenance task from the list.) When you press this button to start an operation, the indicator light in the button turns off and is inactivated until the operation is complete. When the operation is complete, the indicator light in the button turns on and the button is activated again.
ROTATION LED (STAT table)	This light is located above the TABLE ROTATION/DIAG button, and blinks when the STAT table is busy.
TRAY ROTATION button with indicator light	The TRAY ROTATION button rotates the reagent tray for loading reagents. When this button is activated, the indicator light in the button turns on.
ROTATION LED (reagent tray)	This light is located above the TRAY ROTATION button, and blinks when the tray rotates.

Status Light

The status light, on top of the analyzer, changes color to display the operational status of the analyzer. For red, the LED blinks. For green, yellow, and blue, the LED is on steadily.

Figure 25 Status Light

1. Status light

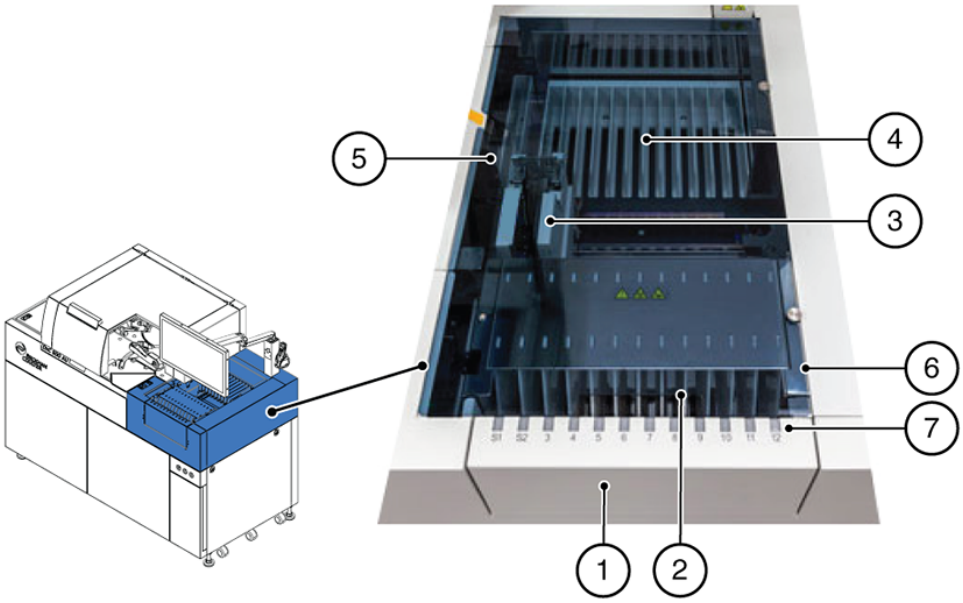
Table 6 Status Light Indication

Color of Status Light	Description
Red (LED is blinking)	The analyzer needs attention now. A condition exists so that the analyzer cannot process samples. The analyzer is in the *Error* (*Stopped*) state.
Green (LED is on)	The analyzer is running or pausing. • Running: The analyzer is ready to perform sample processing, or the analyzer is performing sample processing. • Pausing: The analyzer is entering the *Paused* state.
Yellow (LED is on)	The analyzer needs attention soon. During sample processing, consumables, not including reagent blank, are empty on the analyzer. If the wash solution tank is empty, the analyzer moves to the *Paused* state.
Blue (LED is on)	The analyzer is in the *Starting*, *Service*, or *Shut Down* state. Do not load samples.
Off (LED is off)	The analyzer power is off.

Sample Handler

The sample handler is the subsystem of the DxC 500 AU that handles racks for processing samples. Processing of samples begins in the rack input and output area.

Figure 26 Top View of Sample Handler



1. Door
2. Rack input and output area
3. Rack transfer subsystem
4. Rack buffer area
5. Sample aspiration lane
6. Sample handler top cover
7. Rack position status indicators

Table 7 Sample Handler Components

Item	Description
Door	The sample handler door allows access to the analyzer to load and unload racks. After loading racks and closing the door, the magnet sensor on the door triggers the rack transfer for calibration, QC, and patient sample processing. To prevent dirt and dust from getting into samples, keep the door closed during sample processing.
Rack input and output area	The rack input and output area has 12 positions for loading and unloading racks. An indicator on the door provides the status of racks in each position. **Note** Racks in the 1st and 2nd positions (labeled S1 and S2) have higher priority for transfer to the rack buffer area than racks in the other 10 positions. After being transferred to the rack buffer area, the priority for the racks to be moved to the sample aspiration position is determined by sample priority.
Rack transfer subsystem	The rack transfer subsystem transfers racks between the rack input and output area and the rack buffer area, and between the rack buffer area and the sample aspiration lane. When the racks are transferred from the rack input and output area to the rack buffer area, the analyzer reads sample IDs and rack IDs, and performs sample container detection.

Table 7 Sample Handler Components (Continued)

Item	Description
Rack buffer area	The rack buffer area has 12 positions that hold racks before and after sample processing. The analyzer transfers racks to the sample aspiration lane determined by priority. After samples are processed at the sample aspiration lanes, the analyzer transfers the racks to the rack buffer area. If a test has system configuration conditions set up for triggering a rerun or reflex test, the racks are held in the rack buffer area after sample aspiration. Refer to Configuring Reruns and Configuring Reflex Tests. After the initial results are obtained, the analyzer transfers racks that have samples requiring rerun or reflex analysis to the sample aspiration lane. If the racks are no longer required for processing, the analyzer returns them to the rack input and output area for unloading.
Sample aspiration lane	After the rack is transferred to the sample aspiration lane, the analyzer aspirates the sample from the sample container. After sample aspiration, the racks return to the rack buffer area and then return to the rack input and output area.
Sample handler top cover	The sample handler top cover prevents dirt or dust from getting into samples during analysis. Sample handler operation stops when the sample handler top cover is removed.

Table 8 Rack Position Status Indicators

Indicator Color	Rack Position Status	Guidelines for Accessing the Rack Position
Green (on)	The rack is waiting for processing. A green (on) indicator might also mean that the rack is ready for processing after a handling error at the sample handler (for example, a rack jam or an open sample handler cover), and that the sample handler has been reset. Samples in the rack have not been aspirated yet. Sample processing can start without re-ordering tests.	The operator can remove or move the rack to another available position.
Green (blinking)	Operation in progress. The rack is moving to or from the rack position.	Do not access the rack position.
Blue (on)	The rack has returned.	The operator can remove or move the rack to another available position.
Off	The rack position does not contain a rack.	The operator can load a rack in any of the open positions.

Sample Handler Ready Status

The sample handler can have a ready status of True (operational) or False (not operational).

Sometimes a system event will have the effect of causing the sample handler to go to a ready status of False.

To view the sample handler ready status on the Custom Diag page, select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.

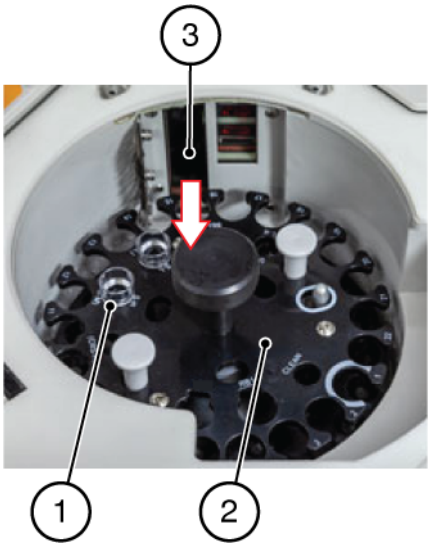
STAT Table

Use the STAT table to process priority STAT samples. The STAT table is the fastest method for processing a sample. STAT table samples always have higher priority than samples loaded on a rack. The STAT table compartment is maintained between 4 °C and 12 °C, even after shutting down the chemistry analyzer. The STAT table has 22 outer positions for processing patient samples, calibrators, and control samples, and 8 inner positions for performing ISE calibration, ISE maintenance procedures, and reagent blank.

Caution

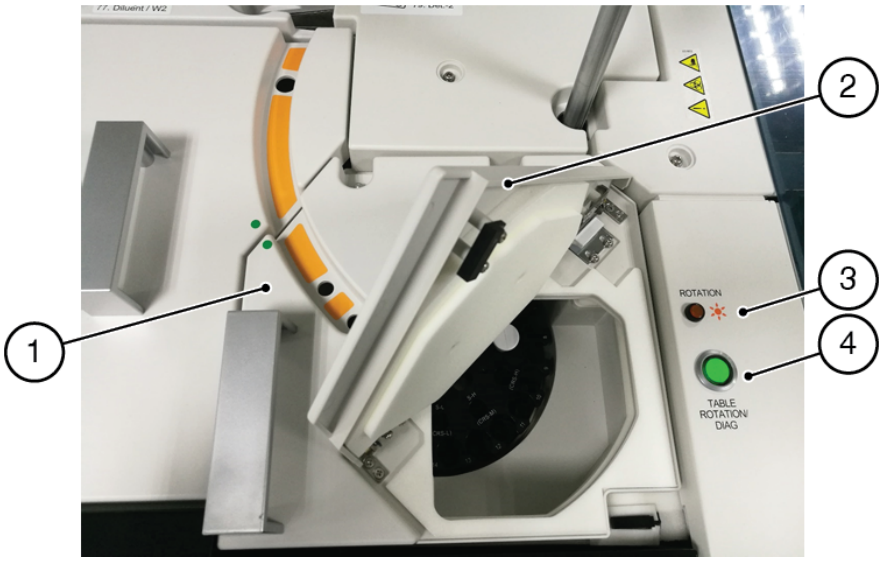
Do not process HbA1c whole blood patient samples on the STAT table.

Figure 27 STAT Table (with Large STAT Table Cover Removed)



1. Sample cup
2. STAT table
3. Window for sample ID bar code reader and direction of laser radiation

Figure 28 STAT Table (with Large STAT Table Cover in Place)



1. Large STAT table cover
2. Small STAT table cover (opened)
3. ROTATION LED
4. TABLE ROTATION/DIAG button with indicator light

Table 9 ROTATION LED Status

LED	Description
Blinking	The STAT table rotates before sample aspiration. The sample probe moves over to the STAT table. The STAT table is busy. **Caution** **To avoid injury, do not touch or open the large STAT table cover while the amber ROTATION LED is blinking.**
Off	The STAT table is in the idle state.

Caution

- **If the small STAT table cover is open at the start of reset or initialization, the analyzer moves to the *Error* (*Stopped*) state.**
- **If the small STAT table cover is open at the start of STAT analysis, the analyzer moves to the *Running* (*Standby*) state and generates an event.**
- **If the large STAT table cover is open when STAT table is rotating or sample probe is aspirating, the analyzer moves to the *Error* (*Stopped*) state.**

Figure 29 STAT Table (Top View)

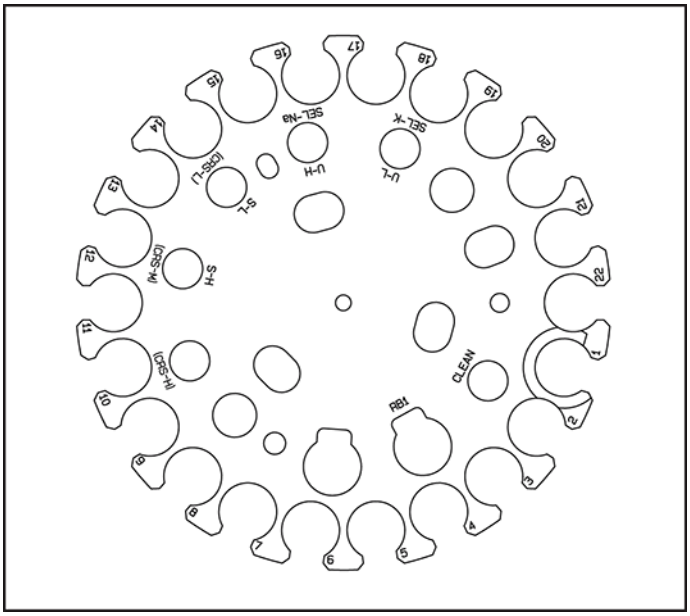


Table 10 STAT Table Positions

Position	Sample
No.1 to No.22	Patient samples, calibrators, and control samples
S-H	ISE High Serum Standard

Table 10 STAT Table Positions (Continued)

Position	Sample
S-L	ISE Low Serum Standard
U-H	ISE High Urine Standard
U-L	ISE Low Urine Standard
CLEAN	Beckman Coulter Cleaning Solution
SEL-K	ISE Selectivity Check Solution (K)
SEL-Na	ISE Selectivity Check Solution (Na)
RB1	Deionized water for Reagent Blank

Note

The STAT table can read bar code labels only on samples placed on the outer positions of the STAT table. In addition, the bar code labels must be facing outward.

Note

Always keep the large and small covers on the STAT table closed to maintain the temperature and sample integrity. Although the STAT table compartment is cooled, do not use the STAT table to store samples or leave samples in the STAT table for an extended time. Keep the samples in the STAT table only for as long as required for sample processing.

Note

Open the small cover on the STAT table only to add or remove samples as required. Excessive opening and closing can damage the cover hinges.

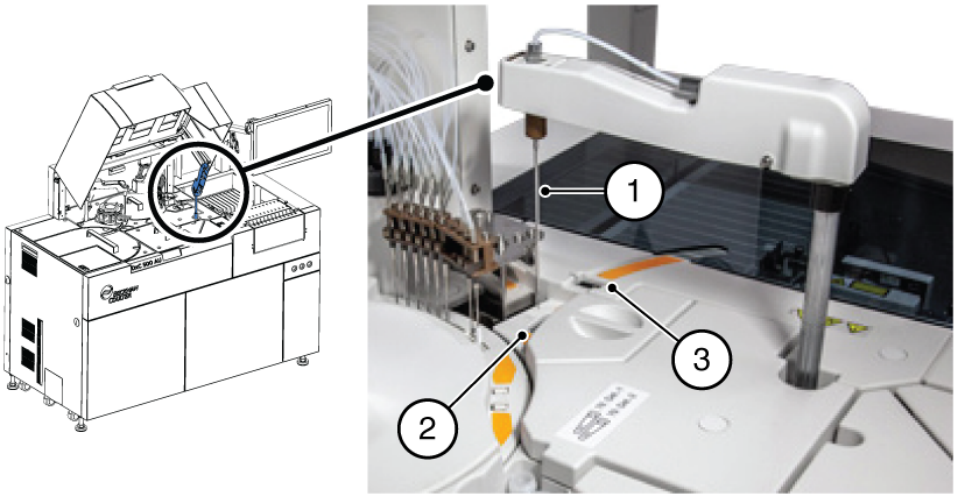
Sample Transfer Subsystem

The sample transfer subsystem moves the sample probe between the sample aspiration position, cuvette position, sample probe wash well position, whole blood wash well position, and the position that holds the diluted Beckman Coulter Wash Solution (2%) for cleaning the sample probe.

The sample probe detects the levels of liquid and dispenses samples and diluent. The sample probe can detect downward collisions and clots. The analyzer aspirates sample from the tube or cup and dispenses it into the cuvette. The analyzer rinses the sample probe with deionized water internally and externally in the sample probe wash well between each sample dispense. If whole blood sample is aspirated, the analyzer rinses the sample probe with deionized water internally and externally in the whole blood wash well that is dedicated for washing whole blood.

When an ISE module is installed, the analyzer aspirates sample from the tube or cup and dispenses it into the ISE sample pot for analysis.

Figure 30 Sample Transfer Subsystem



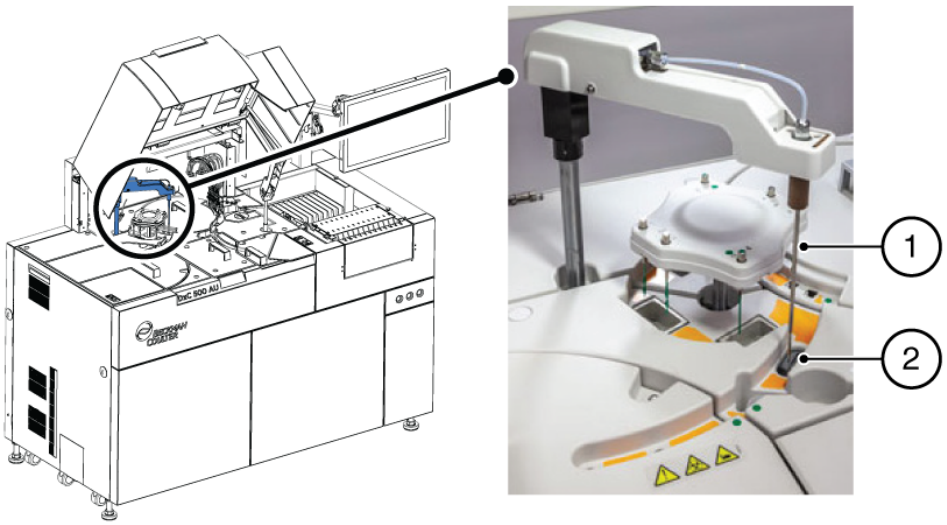
1. Sample probe
2. Sample probe wash well
3. Whole blood wash well

Reagent Transfer Subsystem

The reagent transfer subsystem moves the reagent probe between the reagent refrigerator position, cuvette position, reagent probe wash well position, and the position that holds the sample diluent.

The reagent probe detects the level of liquid and dispenses reagents and diluent. The reagent probe can detect downward collision. The analyzer aspirates reagent from the reagent bottle in the reagent refrigerator and dispenses it into the cuvette. The analyzer rinses the probe with deionized water internally and externally in the reagent probe wash well between each reagent dispense.

Figure 31 Reagent Transfer Subsystem

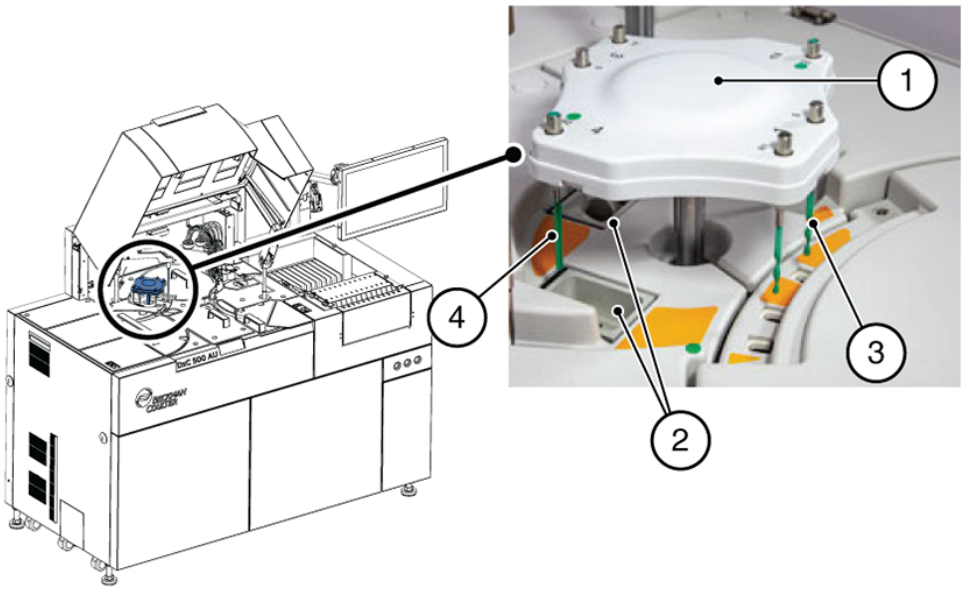


1. Reagent Probe
2. Reagent probe wash well

Mix Bar Subsystem

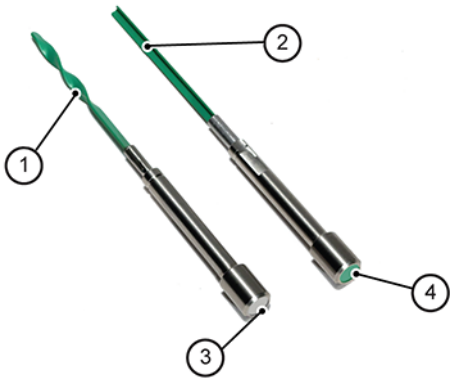
Mix bars are used to mix the reagent and sample in the cuvette. The mix bar subsystem contains four spiral-shaped mix bars for R1/S positions and two L-shaped mix bars for R2 positions. A first mix occurs after the analyzer dispenses R1. A second mix occurs after the analyzer dispenses sample. A third mix occurs after the analyzer dispenses R2. After mixing in the cuvette, the mix bars are cleaned in diluted Beckman Coulter Wash Solution, then rinsed in deionized water in the mix bar wash wells.

Figure 32 Mix Bar Subsystem



1. Mix bar subsystem
2. Mix bar wash wells
3. Spiral-shaped mix bar (R1/S position)
4. L-shaped mix bar (R2 position)

Figure 33 Mix Bars

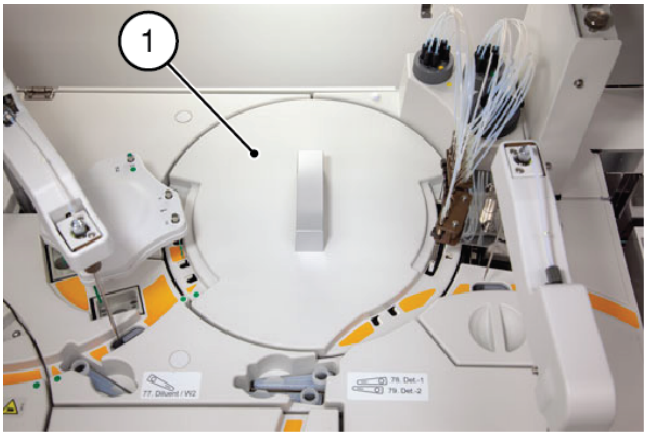


1. Spiral-shaped mix bar
2. L-shaped mix bar
3. Silver
4. Green

Cuvette Wheel

The incubation bath keeps the reaction temperature of the cuvettes at 37 °C. The cuvette wheel contains a total of 88 cuvettes. The wash nozzle subsystem automatically cleans the cuvettes. The weekly photocal maintenance procedure monitors the cuvette integrity.

Figure 34 Cuvette Wheel

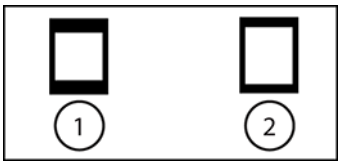


1. Cuvette wheel

Caution

Cuvettes with the same outer dimensions might have different interior dimensions. The analyzer uses cuvette part number MU846500 with an interior dimension of 5 mm x 5 mm. Use of any other cuvette can cause erroneous results.

Figure 35 Cuvette Interior Dimensions



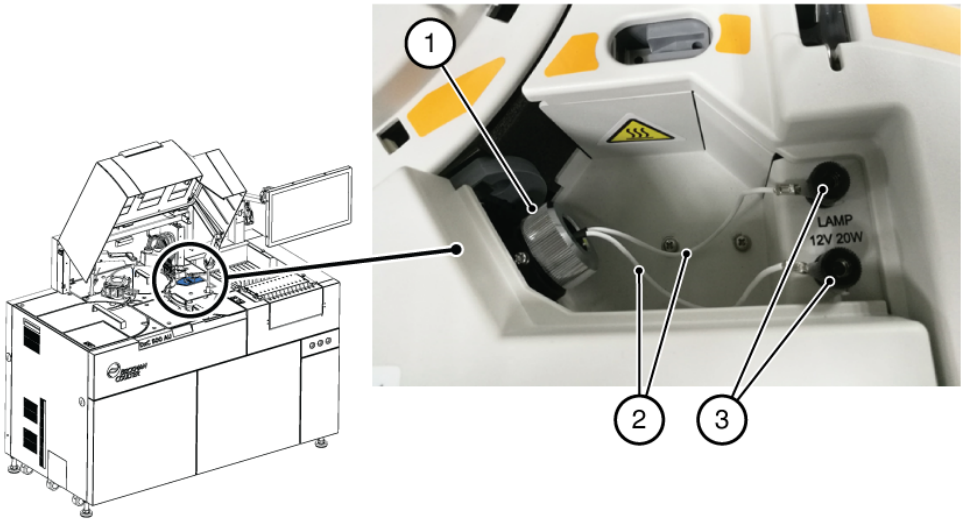
1. For DxC 500 AU (5 mm x 5 mm)
2. Example for other AU systems

The real-time water blank check method continuously monitors cuvettes in the *Running* state. The real-time water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the water blank reading check fails, or the analyzer detects a cuvette overflow or unstable photometry, the analyzer generates an event.

Photometry Subsystem

The photometry subsystem includes a halogen lamp, lenses, a diffraction grating, and a photodetector to measure the amount of light transmitted through the reaction mixture in the cuvette. The diffraction grating splits the light into 13 wavelengths.

Figure 36 Photometer Lamp



1. Lamp holder
2. Lamp lead wires
3. Knobs

Warning

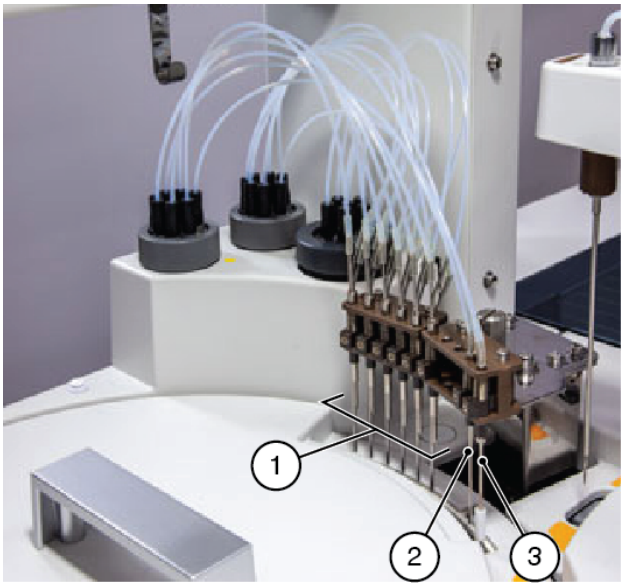
Never touch the photometer lamp or look directly into the photometer lamp when the lamp is illuminated. The lamp is hot when the analyzer is on. When you need to replace or check the status of the lamp, wait 5 minutes after the analyzer completes the shutdown process.

Wash Nozzle Subsystem

The wash nozzle subsystem cleans, rinses, and dries the cuvettes. The wash nozzle subsystem includes six wash nozzles, one aspiration nozzle, and one dry nozzle. Each wash nozzle is a 3-way nozzle. The longest nozzle aspirates liquid, the middle nozzle dispenses, and the shortest nozzle aspirates any overflow liquid. The aspiration nozzle aspirates any remaining liquid in the cuvette. The dry nozzle uses the fluorocarbon polymer tip to bring

any remaining moisture to the bottom of the cuvette, then aspirates to dry the interior of the cuvette completely.

Figure 37 Wash Nozzle Subsystem

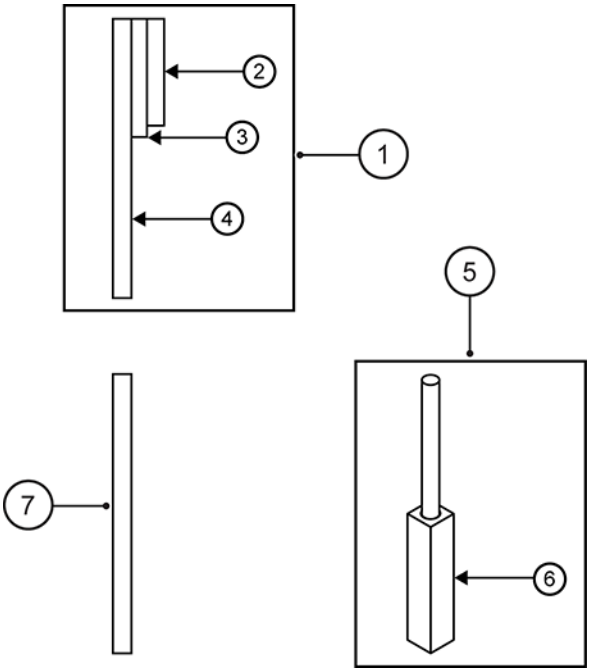


1. Wash nozzles (6)
2. Aspiration nozzle
3. Dry nozzle

The dispensing sequence of the wash nozzles, from left to right in the diagram:

- Nozzle 1 and 2 - Diluted Beckman Coulter Wash Solution
- Nozzle 3 to 6 - Warm deionized water
- Nozzle 7 - Aspiration
- Nozzle 8 - Drying

Figure 38 Wash Nozzle



1. Wash nozzle
2. Overflow nozzle
3. Liquid (diluted wash solution and warm deionized water) dispense nozzle
4. Liquid (reaction mixture, diluted wash solution, and warm deionized water) aspirating nozzle
5. Dry nozzle
6. Drying tip
7. Aspiration nozzle

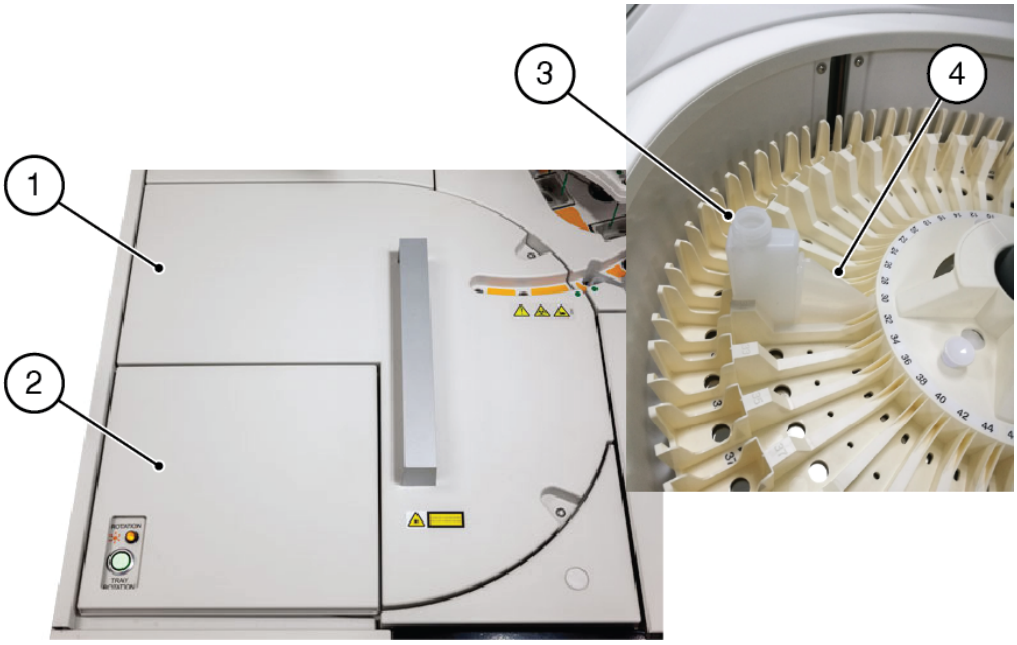
Reagent Refrigerator

The reagent refrigerator stores all reagent bottles for each reagent kit. It is maintained between 4°C (39.2 °F) and 12°C (53.6 °F), even after shutting down the chemistry analyzer. You can view the temperature of the reagent refrigerator on the Custom Diag page. Select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.

You can designate each bottle position as barcoded (with a bar code label), or if it does not have a bar code label you can enter the bar code manually when you replace the reagent. During a reagent check, the analyzer detects reagent bottles, reads reagent bar codes,

identifies the onboard expirations, and senses volume levels to calculate the reagent volumes.

Figure 39 Reagent Refrigerator



1. Large reagent refrigerator cover
2. Small reagent refrigerator cover
3. Reagent bottle
4. Adapter

Important

You must place reagent bottles in the reagent refrigerator with the reagent bar code labels facing outwards. You must remove all reagent bottle caps before placing the bottles in the reagent refrigerator. You must use the correct adapters to secure bottles, as required.

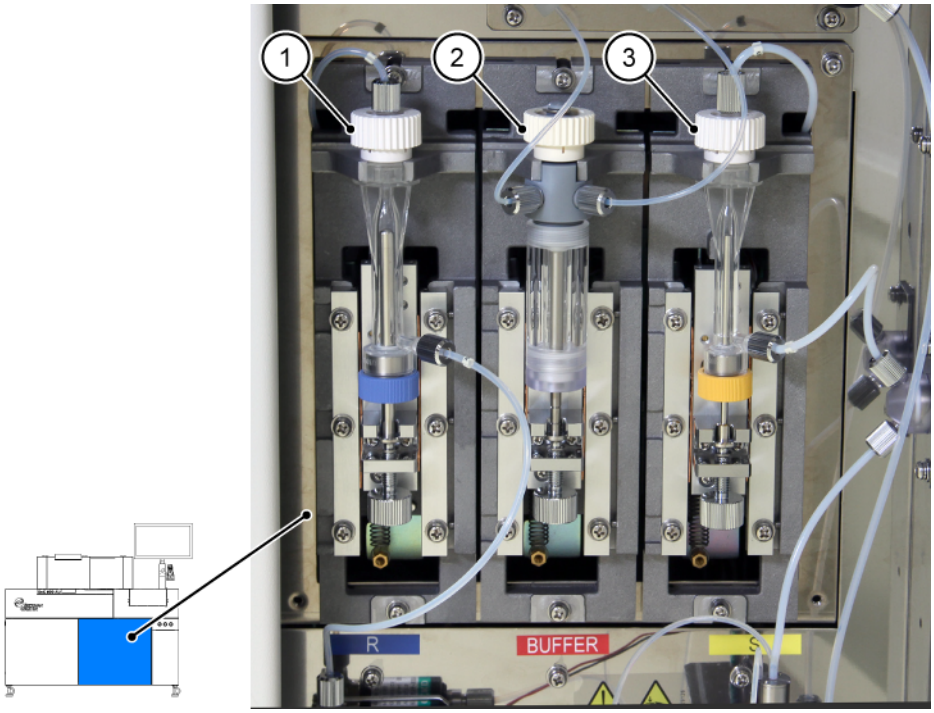
Caution

When you replace reagents during the *Paused* (*Reagent Paused*) state, you can open the small reagent refrigerator cover. When you replace reagents during the *Running* (*Standby*) state, you can open the large reagent refrigerator cover. In any other situation, do not open the large reagent refrigerator cover or small reagent refrigerator cover when the analyzer is in the *Running* state, which causes the analyzer to go to the *Error* (*Stopped*) state.

Syringe Subsystem

A sample syringe dispenses the required volume of sample and a reagent syringe dispenses the required volume of reagent. If the ISE module is installed, the analyzer has a buffer syringe to dispense the required volume of ISE Buffer Solution.

Figure 40 Location of Syringes



1. Reagent syringe (blue)
2. ISE buffer syringe (clear)
3. Sample syringe (yellow)

Tank Storage

The tank storage area has a deionized water tank, a wash solution tank, and a diluted wash solution tank. The analyzer uses diluted Beckman Coulter Wash Solution to clean the cuvettes and mix bars. The analyzer uses deionized water to dilute the wash solution, rinse analyzer components, and make dilutions.

Figure 41 Tank Locations

1. Deionized water tank
2. Diluted wash solution tank
3. Wash solution tank

Deionized Water Tank

The deionized water tank has a capacity of 10 liters. A float sensor detects when the volume in the tank is low and opens a valve to fill it automatically.

Diluted Wash Solution Tank

The diluted wash solution tank has a capacity of 2 liters. A float sensor indicates when the volume in the tank is low. The tank automatically fills with Beckman Coulter Wash Solution and deionized water to make the diluted Beckman Coulter Wash Solution.

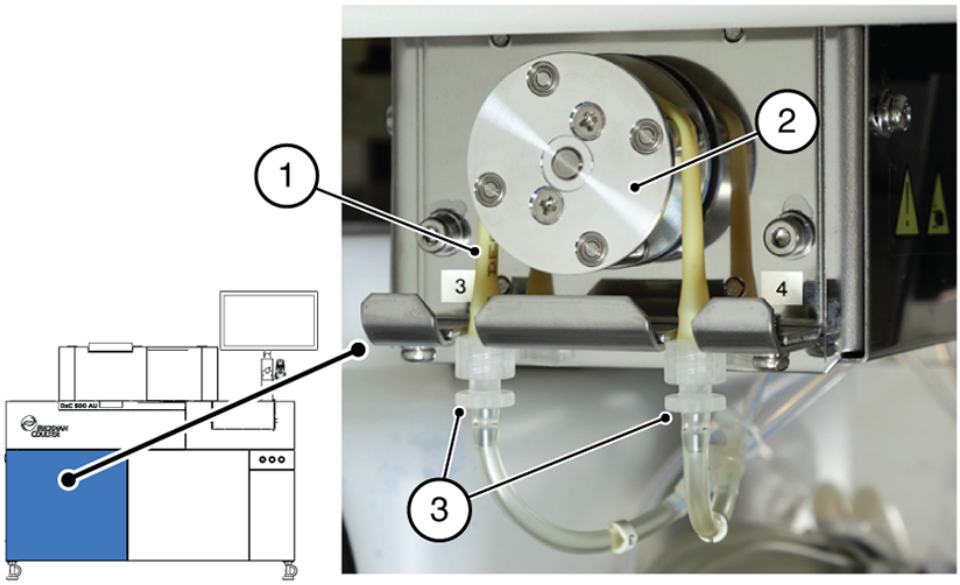
Wash Solution Tank

The wash solution tank has a capacity of 2 liters. When the volume of Beckman Coulter Wash Solution in the wash solution tank decreases to a certain level, the analyzer generates an event to alert the operator to replace the tank with a new tank.

Wash Solution Roller Pump

The wash solution roller pump supplies Beckman Coulter Wash Solution to the diluted wash solution tank from the wash solution tank.

Figure 42 Wash Solution Roller Pump

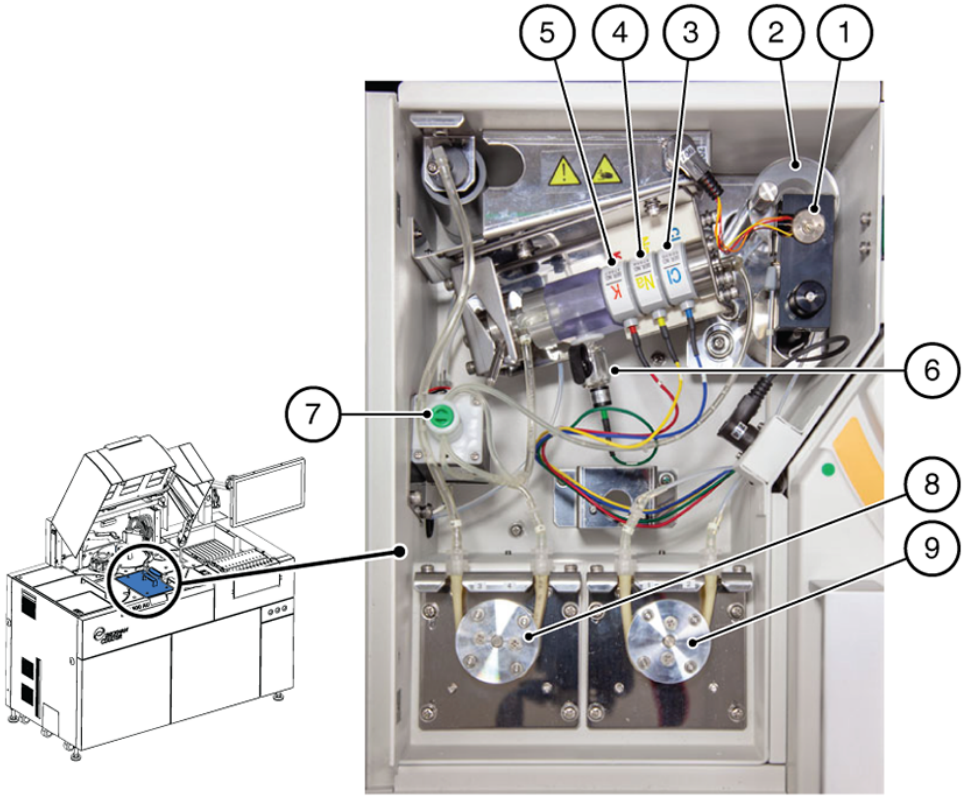


1. Roller pump tubing
2. Wash solution roller pump
3. Connectors

ISE Module (Optional)

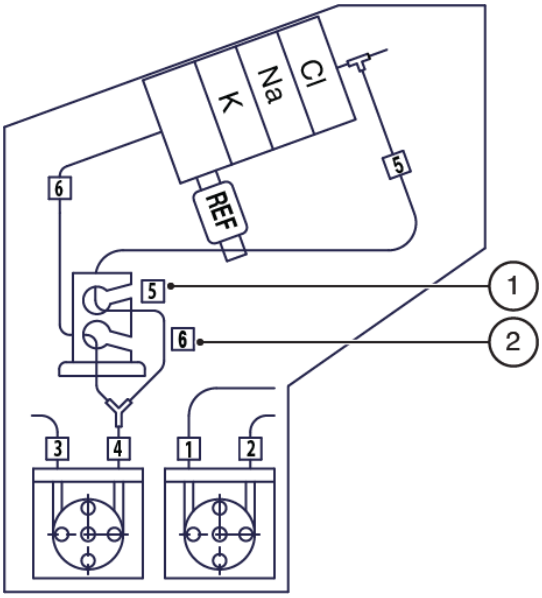
Diluted sample passes through the Na, K, and Cl ion-selective electrodes to determine the concentration by comparing the electrical potential difference to the REF electrode. The analyzer has a common sample probe and sample syringe for photometric and ISE analysis.

Figure 43 ISE Module



1. Mixing subsystem
2. Sample pot
3. Cl electrode
4. Na electrode
5. K electrode
6. REF electrode
7. Pinch valve
8. Mixture aspiration roller pump
9. ISE MID Standard Solution roller pump

Figure 44 ISE Tubing Flow Sequence



1. Top of pinch valve (tubing 5)
2. Bottom of pinch valve (tubing 6)

Table 11 ISE Module Components

Component	Description
Mixing subsystem	The mixing subsystem mixes sample and ISE Buffer Solution dispensed into the sample pot. It has two liquid-level sensors to detect correct drainage.
Sample pot	Sample and ISE Buffer Solution are dispensed into the sample pot and mixed. The following volumes are dispensed for serum and urine: • ISE Buffer Solution: 618 µL (fixed) • Sample: 20 µL (fixed) • Deionized water: 10 µL (fixed)
Cl electrode, Na electrode, and K electrode	These electrodes are used for measuring the potential of Cl, Na, and K ions in the sample and ISE MID Standard Solution. The concentrations of individual ions in the sample can be calculated from the potential differences between each ion in the sample and in the ISE MID Standard Solution.
REF electrode	This electrode is the reference electrode for the Cl, Na, and K electrodes.
Pinch valve	The pinch valve has the following two functions: • Allows sample in the sample pot to enter the flow cell for measurement by pinching off tubing 5. • Allows excess sample to pass through the bypass tubing to waste by pinching off tubing 6.

Table 11 ISE Module Components (Continued)

Component	Description
Roller pumps	• The Mixture Aspiration Roller Pump (pump is on the left) does the following: — Aspirates liquid from the sample pot through the flow cell or bypass tubing and out to waste. — Aspirates ISE Reference Solution from the ISE Reference Solution bottle past the REF electrode and out to waste. • The ISE MID Standard Solution Roller Pump (pump on right) aspirates ISE MID Standard Solution from the ISE MID Standard Solution bottle to the sample pot.
Roller pump tubing	The roller pump tubing is made of rubber and wraps around the roller pump. As the roller pump rotates, the rollers on the pump squeeze the tubing, and solution is supplied or removed.

ISE Solution Bottles

The ISE has an ISE Buffer Solution bottle, ISE MID Standard Solution bottle, and ISE Reference Solution bottle.

Figure 45 ISE Solution Bottles

1. ISE Reference Solution bottle
2. ISE MID Standard Solution bottle
3. ISE Buffer Solution bottle
4. ISE operation LED

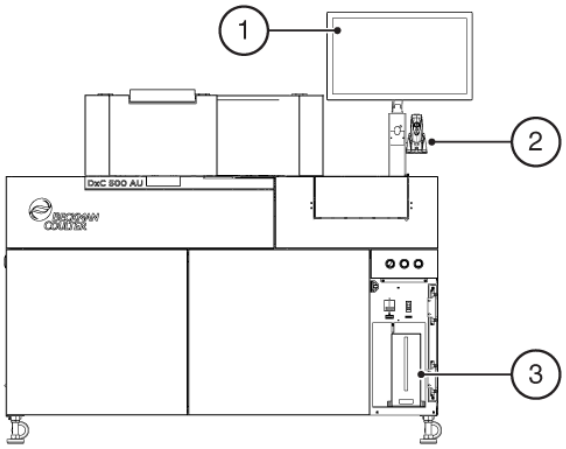
Table 12 ISE Solution Bottles

Item	Description
ISE Buffer Solution bottle	This bottle stores the ISE Buffer Solution. The analyzer uses the ISE Buffer Solution for diluting the sample. The capacity of this container is 2 liters.
ISE MID Standard Solution bottle	This bottle stores the ISE MID Standard Solution. The analyzer uses the ISE MID Standard Solution to condition the electrodes between analysis. The capacity of this container is 2 liters.
ISE Reference Solution bottle	This bottle stores the ISE Reference Solution. The analyzer uses the ISE Reference Solution as a reference point relative to the three electrodes. The capacity of this container is 1 liter.
ISE operation LED	This LED blinks while the ISE module is busy. You can replace ISE reagent bottles when the ISE operation LED is off.

Console

The computer is located behind the right front door under the front operation buttons and indicator lights, and the monitor and handheld bar code reader are attached to the side of the sample handler with a monitor arm.

Figure 46 Console



1. Monitor
2. Handheld bar code reader
3. Computer

Monitor

The monitor displays the operating software. The touch screen enables operator input.

Keyboard and Mouse

The keyboard and mouse are optional and can be ordered from Beckman Coulter. Refer to Parts List for Keyboard and Mouse Kit Specifications.

To install the keyboard, simply plug in the USB wireless adapter for the keyboard at the USB port on the back of the monitor.

Note

If the keyboard fails to connect with the console, contact Beckman Coulter Customer Support.

Tip

The inside of the left front door of the analyzer includes a shelf to store the keyboard and mouse when not in use.

Computer

The analyzer uses a personal computer to perform data processing. The computer includes a hard disk to store programs, analysis parameters, an analysis database, USB drives, and a DVD R/W component. An external hard disk option is also available.

Handheld Bar Code Reader

The wireless handheld bar code reader reads bar code labels for input to the software. You can perform the following types of scans:

- Scan a sample ID in the Sample ID field in the Test Order Entry page (**Order**).
- Scan the 2-dimensional bar code on the calibrator value assignment sheet to load the calibration information, including concentration values, on the analyzer.
- Scan the bar code label located on the ISE reagent bottle when you replace the ISE reagent.

Combination Tests

Combination tests determine the presence or concentration of two or more analytes in a sample, and are ordered as a single test.

Constituent tests determine the presence of a single analyte. For most combination tests, the analyzer uses an algorithm and the results of the constituent tests to calculate a result for the combination test.

For example, the HbA1c Advanced (hemoglobin A1c) test has two constituent tests: Total Hemoglobin (T-Hb) and Hemoglobin A1c (A1c). The concentrations of both T-Hb and A1c are determined, and are used in the calculation of the reported HbA1c (A1c/T-Hb ratio), which is expressed either as mmol/mol (IFCC) or % (DCCT/NGSP).

Combination test results are reported as a numerical value, a qualitative interpretation such as Positive or Negative, or a panel containing the result of each constituent test.

When you enter a test order for the combination test, the analyzer automatically performs all of the constituent tests.

You cannot enter a test order for a constituent test for a patient sample, but in some cases you can enter a test order for a constituent test for calibration or control samples.

All constituent tests within a combination test use the same reagent kit, and the same calibrator and control set, if applicable.

Performance Characteristics

Performance characteristics describe specific attributes or properties of the analyzer, such as sample capacity and sample throughput.

Table 13 Chemistry Analyzer Performance Characteristics

Characteristic	Description
Analytical method:	
Photometric points	28
Method of analysis	Discrete method Types of measurement: • End point reaction method • Rate reaction method • Fixed point reaction method • Electrode method (ISE) (option)

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Throughput	The analyzer throughput rate depends on individual test protocols and the mix of tests in any run. Maximum throughput rate: • 65 test results per hour for analysis of only HbA1c in batch mode • 200 samples per hour for analysis of only ISE • 400 photometric test results per hour or 800 test results per hour (photometric + ISE)
Number of simultaneous analytes	Maximum of 60 photometric + 3 ISE tests on board
Racks:	
Rack types	• DxLAB tube rack • DxLAB cup rack
Rack capacity, input area	12 racks **Note** The rack buffer area can hold an additional 12 racks.
Patient samples:	
Sample types	Serum, plasma, urine, CSF, and whole blood (HbA1c Advanced).
Sample capacity, rack	7 samples per rack
Sample capacity, STAT table	22 samples in outer positions of the STAT table
Sample dispensing system	Micro-syringe system with the following functions: • Liquid level detection • Clot detection • Adequate sample aspiration • Collision detection • Pre-dilution
Sample volumes	• Normal dispensing: 1.0 µL/test to 25.0 µL/test, in steps of 0.1 µL/test • Dispensing with dilution: 1.0 µL/test to 20.0 µL/test, in steps of 0.1 µL/test • Dispensing with condense: 1.0 µL/test to 20.0 µL/test, in steps of 0.1 µL/test

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Automated pre-dilutions	Automated sample dilution in a separate dilution cuvette before sample is dispensed into the test cuvette. Sample dilution factors: 1, 3, 5, 10, 15, 20, 25, 50, 75, 100
Reagents:	
Reagent dispensing system	Micro-syringe with collision detection function for the probe
Reagent setting method	Turntable method
Reagent refrigerator temperature	Maintained between 4°C (39.2 °F) and 12°C (53.6 °F), even after shutting down the chemistry analyzer
Reagent refrigerator capacity	76 reagent bottles: • Maximum of thirty-eight 15-mL, 30-mL, or 60-mL bottles in the inner ring • Maximum of thirty-eight 15-mL or 30-mL bottles in the outer ring
Reagent bottle sizes	15 mL, 30 mL, and 60 mL
Reagent bottle adapters	For 15-mL and 30-mL bottles
Number of reagent steps	Maximum 2 steps
Types of reagents	• Normal concentration reagent • Highly concentrated reagent
Reagent volumes	• Normal dispensing: 10 µL/test to 250 µL/test, in steps of 1.0 µL/test • Dispensing with dilution: 10 µL/test to 240 µL/test, in steps of 1.0 µL/test
Calibration:	
Calibration methods	• ACAL AA • ACAL AB • ACAL 2 AB to ACAL 7 AB • MCAL MB • MCAL 2 MB to MCAL 7 MB

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Calibration curve types	• Straight line • Polygonal line • Quadratic expression • Tertiary expression (2 types) • EIA-TYPE 1 to 4 • Spline
Calculation correction methods	• Water blank correction • Reagent blank correction • Sample blank correction
Quality control (QC):	
Control materials	No maximum that can be configured
Quality control methods	• Shewhart day-to-day management (Levey-Jennings method) • Multi-rule control (Westgard method)

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Sample processing order	• Samples processed in the STAT table have a higher priority than samples processed in racks. • Racks in the first and second positions (labeled S1 and S2) have a higher priority for being transferred from the rack input and output area to the rack buffer area than racks in the other 10 positions. After being transferred to the rack buffer area, the priority for the racks to be moved to the sample aspiration position is determined by sample priority. • Priority of samples in racks: 1. Rack containing STAT sample scheduled for auto rerun (reagents used for the test scheduled for the sample are available and have been calibrated) 2. Rack containing STAT samples (reagents used for the test scheduled for the sample are available and have been calibrated) 3. Rack containing calibrators for a STAT test (due or not) 4. Rack containing control samples for a STAT test (due or not) 5. Rack containing calibrators for a whole blood test (due or not) 6. Rack containing control samples for a whole blood test (due or not) 7. Rack containing whole blood samples (reagents used for the test scheduled for the sample are available and have been calibrated) 8. Rack containing calibrators (due or not) 9. Rack containing control samples (due or not) 10. Rack containing samples scheduled for auto rerun (reagents used for the test scheduled for the sample are available and have been calibrated) 11. Rack containing routine samples (reagents used for the test scheduled for the sample are available and have been calibrated)
Reaction system:	
Reaction incubation method	Dry bath system
Reaction temperature	Dry bath: 37 °C ± 0.3 °C (98.6 °F ± 0.5 °F)

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Reaction mixture volume	90 µL to 350 µL (5 mm x 5 mm cuvette)
Reaction time	Maximum 8 minutes, 37.5 seconds
Mixing system	Rotating mixing bar system
Reaction cell	Glass square cuvette Optical path length: 5 mm
Reaction line	Rotary disk system: 88 cuvettes
Optical system:	
Photometer	Multi-wavelength diffraction grating spectrophotometer
Photometric modes	Monochromatic or bichromatic
Photodetector	Silicon photodiode array
Light source	Halogen lamp 12 V/20 W
Measurable absorbance range	0 to 3.0 Abs (converted in units of 10 mm of optical path length)
Wavelengths	13 wavelengths: 340 nm, 380 nm, 410 nm, 450 nm, 480 nm, 520 nm, 540 nm, 570 nm, 600 nm, 660 nm, 700 nm, 750 nm, and 800 nm
Photometric resolution	0.0001 Abs
Lamp warmup time	The photometer lamp needs approximately 20 minutes to stabilize (warm up) after the analyzer starts up.
Temperatures:	
Dry bath incubation	37 °C ± 0.3 °C (98.6 °F ± 0.5 °F)
Reagent refrigeration	4 °C to 12 °C (39.2 °F to 53.6 °F)
Deionized water	5 °C to 28 °C (41 °F to 83 °F)
Generated noise level	<60 dB

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Hardware configuration	• Analyzer • Console
Hardware options	• ISE • Keyboard • Mouse
Sample ID bar code reader:	
Wavelength	660 nm
Maximum output	85 µW
Pulse width	112 µS
Frequency	500 Hz
Class	2
STAT table bar code reader:	
Wavelength	650 nm
Maximum output	< 1.0 mW
Frequency	100 scans/second
Class	2
Data processing configuration:	
Memory	• Hard disk: 500 GB or more • Memory capacity: 8 GB or more
Data input methods	• Touch screen monitor • Keyboard (option) • Mouse (option) • Online (TCP/IP) • Handheld bar code reader • DVD-RW drive • Remote service (option)

Table 13 Chemistry Analyzer Performance Characteristics (Continued)

Characteristic	Description
Data output methods	• Monitor display • Printer (option) • Online (TCP/IP) • External storage device (option) • Remote service (option) • Internal hard disk • DVD-RW drive
Data storage duration	• Calibrator data: > 2 years • Control data: > 2 years • Patient sample data: 30 days • Audit log entries: 2 years

Table 14 ISE Performance Characteristics

Characteristic	Description
Reagents	• ISE Buffer Solution: 2L bottle • ISE MID Standard Solution: 2L bottle • ISE Reference Solution: 1L bottle
Measurement method	Indirect (diluted) ion-selective electrode
Measurement items	Na, K, and Cl ions in serum or urine
Throughput	200 samples per hour
Sample volume	20 µL plus 10 µL deionized water
Dilution ratio	32.4 times (20 µL sample + 10 µL deionized water + 618 µL ISE Buffer Solution = 648 µL)
Analytical measuring range (mmol/L):	
Na	• Serum: 50 to 200 • Urine: 10 to 400
K	• Serum: 1.0 to 10.0 • Urine: 2.0 to 200
Cl	• Serum: 50 to 200 • Urine: 15 to 400
Calibration curve	Automatic calibration curve: measures the high-concentration calibrator and low-concentration calibrator to set two points on the chart.
Data correction	Enables manual calibration chart correction (MCAL).

Table 14 ISE Performance Characteristics (Continued)

Characteristic	Description
Drift correction	Automatic correction: measures the electrical potential of ISE MID Standard Solution for each sample to perform drift correction.
Approximate daily consumption of reagents and consumables:	
ISE Buffer Solution	Approximately 180 mL (if 200 serum samples/day)
ISE MID Standard Solution	Approximately 260 mL (if 200 serum samples/day)
ISE Reference Solution	Approximately 35 mL (if 200 serum samples/day)
Beckman Coulter Cleaning Solution	Approximately 1 mL (if 200 serum samples/day)

User Interface

The analyzer software includes an operating system, application software, and a user interface (UI). The application software controls all of the processing functions. The UI software enables you to interact with the application software.

The analyzer Home page contains the task indicators that you use to perform Daily Startup and to monitor the status of the analyzer throughout the day.

Home Page

The home page is the first page that you see when you log on. To get to this page from any other page, select **Home** in the navigation bar. The navigation bar and status bar operate the same way on the home screen as on any other screen.

Navigation Bar

The navigation bar is located at the top of the screen.

Table 15 Navigation Bar

Item	Description
Home button	Opens the Home page
Menu button	Opens the Menu list
Order button	Opens the Test Order Entry page
Calibration event indicator	Opens the Calibration Events page
QC event indicator	Opens the QC Events page
Samples event indicator	Opens the Sample Events page

Table 15 Navigation Bar (Continued)

Item	Description
System event indicator	Opens the System Events page
Sample Search field	The field for performing a sample search
Print Screen button 	Opens the Print Screen dialog for printing the screen or saving the screen to a PDF file **Note** The **Print Screen** button is inactive while dialogs are displayed. Many dialogs include the print screen icon in the upper left corner of the dialog. Selecting the icon on a dialog prints the dialog and the user interface page behind it.
Help button	Provides access to the context-sensitive System Help
User accounts button 	Displays the username of the operator who is logged on to the analyzer and opens the menu for logging on, logging off, changing the password, and managing user accounts
Date and time display	Displays the current date and time **Note** The date and time format are configured during installation, by a Beckman Coulter Customer Support representative. If you want to change the date and time format later, contact Beckman Coulter Customer Support.

Task Indicators

Task indicators are located on the Home page only and provide information about the materials and procedures for preparing the analyzer for sample processing.

Each task indicator displays a numerical value that indicates the items to address. If the value on the task indicator is 1 or greater, action is required.

In addition, each task indicator (not including the **Materials** or **Sample List** task indicator) might include a yellow or red vertical bar that indicates the following:

- No vertical bar: Address the item soon to avoid an impact on future throughput.
- Yellow vertical bar: Address the item immediately. The throughput of at least one specific test is currently impacted.
- Red vertical bar: Address the item immediately. The throughput of all tests is currently impacted.

Note

Overdue maintenance tasks do not include red vertical bars.

To view specific information about what to address, select the task indicator.

Table 16 Task Indicators

Indicator	Meaning
Materials	The total number of consumable, reagent, calibrator, and control materials to address to prepare the analyzer for sample processing
Maintenance	The number of maintenance tasks to address before processing samples
Consumables	The number of consumables that require replenishment or replacement before processing samples
Reagents	The number of tests that require reagents before processing samples
Calibration	The number of tests that require calibration before processing samples
QC	The number of tests that require QC
Sample List	The number of samples that have a status of Ordered

By default, selecting most task indicators from the Home page opens a new tab and displays a Due Now page related to the task indicator. For example, selecting the **Consumables** task indicator opens the Consumables tab and displays the Consumables Due Now page. Each Due Now page, in addition to displaying the materials or tasks that are due now or due soon, provides access to other pages related to the task indicator. For example, the Consumables Due Now page includes buttons that provide access to the Materials page and the All Consumables page.

If you select a task indicator from the Home page while the associated tab is already open, the tab becomes the active tab. If the Due Now page is not displayed on the tab, use the breadcrumb link or close the tab and select the task indicator again.

Status Bar

The status bar is located at the bottom of every screen.

Table 17 Status Bar Functions

Item	Description
System state	The color of the system state button indicates the current system state. Refer to Table 18 System States. Select this button to view options for shutting down the analyzer computer, stopping sample processing, and initializing the analyzer. Refer to Shutting Down the Chemistry Analyzer.
STAT Table state	Indicates the current condition for STAT table analysis. Refer to Table 19 STAT Table States. To start STAT table analysis in the *Running (Standby)* state or the *Running (Sampling)* state, select the Start button in the STAT Table state area.
System process	Indicates the process that the analyzer is performing. Refer to Table 19 System Processes.
Time remaining	Indicates the time remaining in the active process. The analyzer displays a blank value if it cannot predict the time remaining.

Table 18 System States

Color of System State Button and Status Light	System State
Blue	*Starting, Service, Shut Down*
Green	*Running*, *Pausing*
Yellow	*Paused*
Red (blinking status light)	*Error*

Table 19 System Processes

System State	System Process	Description
Starting (blue)	*Initializing*	The software is loading and the hardware is initializing.
	Warmup	After the analyzer initializes, the analyzer allows the lamp to warm up and for the temperature to stabilize. If initialization occurs after shutting down the system by selecting the system state button, warming up occurs for approximately 20 minutes. If initialization occurs after shutting down the system by pressing the Analyzer Stop button, warming up occurs for approximately 90 minutes.
Service (blue)	*Stopped*	The analyzer is entering *Diagnostics* mode.
	Photocal	The analyzer is performing a photocal.
	Cleaning Cuvettes	The analyzer is performing cleaning cuvettes with internal wash, or the analyzer is performing cleaning cuvettes with external solution (including performing ISE enhanced cleaning).
	Calibrating ISE	The analyzer is calibrating the ISE.
	Selectivity check	The analyzer is performing an ISE selectivity check.
	Cleaning ISE	The analyzer is cleaning the ISE.
	ISE Measurement	The analyzer is confirming performance of the ISE module.
Shut Down (blue)	*Shutting Down*	The chemistry analyzer is shutting down, and the console is shutting down.
Running (green)	*Standby*	The analyzer temperature is stable and the analyzer is ready to perform sample processing. You can start analysis.

Table 19 System Processes (Continued)

System State	System Process	Description
	Reagent Check	The analyzer is performing a reagent check.
	Sampling	After the start of sample processing, racks are in the rack input and output area, and the racks are moving to the sample aspiration position.
	Washing	Sample processing is complete, and the analyzer is washing the cuvettes.
	Stopping	The analyzer is stopping.
Pausing (green)	*Wait for Paused (Reagent Paused) state*	The analyzer is moving to the *Paused* state after the user initiates reagent loading during sample processing. The analyzer stops further samples from sampling, but if the R1 reagent for a test has been dispensed, the analyzer finishes dispensing the sample into the cuvette when you select **Continue**. The analyzer completes tests that are in progress, including reactions in the cuvette wheel, before shifting to the *Paused* state.
	Pausing	The analyzer is moving to the *Paused* state. The analyzer stops further samples from sampling, but if the R1 reagent for a test has been dispensed, the analyzer finishes dispensing the sample into the cuvette. The analyzer completes tests that are in progress, including reactions in the cuvette wheel, before shifting to the *Paused* state.
Paused (yellow)	*Reagent Paused*	The analyzer is moving to the *Paused* state. The analyzer stops further dispensing of samples, but continues to process samples that are already dispensed until tests are complete.

Table 19 System Processes (Continued)

System State	System Process	Description
	Paused	The analyzer has moved to the *Paused* state.
Error (red with blinking status light)	*Stopped*	The analyzer has moved to the *Error state.*
	Initializing	The analyzer is resetting. The analyzer initializes, then goes to the *Running* (*Standby*) state.

Table 20 STAT Table States

State	Description	Can Access?
Busy	The STAT table is rotating. The STAT table is performing sample processing, or a STAT table check is in progress.	No, do not open the large STAT table cover and the small STAT table cover.
(blank)	• The STAT table is idle. • STAT table analysis is paused.	Yes, the indicator light in the TABLE ROTATION/DIAG button on the analyzer is on. You can open the small STAT table cover, press the **TABLE ROTATION/DIAG** button to rotate the STAT table, and load samples.

Convention for Expressing System State and System Process

When the analyzer is in a particular system state, it can undergo one or more associated system processes.

This manual expresses system states and system processes in the following format:

system state (*system process*)

For example, *Running* (*Standby*) indicates that the analyzer is in the *Running* state and undergoing the *Standby* process.

Navigation Tools

The user interface includes navigation tools (such as, tabs, breadcrumb links, various page-specific command buttons, or selectable table rows) that help you to navigate between pages.

Table 21 Navigation Tools

Item	Description
Breadcrumb links	Breadcrumb links enable you to retrace the navigation steps that led you to the current page. Select any breadcrumb link to go back to a previous page. The name of the current page is displayed to the right of the breadcrumb links, if any. **Note** If you opened the current page from the Home page or from the Menu, the page name is displayed without any breadcrumb links.
Tabs	Each page opens in a new tab on the screen. Select any available tab to switch between pages. **Important** An excess number of open tabs can lead to system events that are associated with limitations on resource allocation and negatively impact analyzer performance (for example, causing slower response times for the user interface). To minimize the impact on analyzer performance, limit the number of open tabs.
Tiles	Tiles are similar in appearance to the task indicators found on the Home page (refer to Task Indicators for more information). Tiles are found on various user interface pages and provide information about the status of a specific object, such as a consumable, or a task, such as a calibration. In most instances, you can select a tile and then select a command button to view additional information or to manipulate the object.
Checkboxes	Checkboxes might be included at the beginning of a row. Select rows by selecting the associated checkboxes.
Rows	Information on a page can be arranged in a table with rows. Select a row to open a detail page about that item.
Command buttons	Select a page-specific button to complete a specific task.
Command menu buttons	Select a page-specific button with a down arrow to open a menu with options to select from.

Table 21 Navigation Tools (Continued)

Item	Description
Arrows in column headings	Select the arrow in a column heading to sort the rows in the table by the contents of that column. Select the arrow again to reverse the sort order.
Ellipsis (...) within user interface text	Some elements on the user interface, such as buttons and column headings, contain an ellipsis (...) at the end of the text label on the element. The ellipsis indicates that the full text does not fit within the boundaries of the user interface element and is not displayed. To display the full text, select and hold the user interface element with an ellipsis. The full text is hidden when you release the element.

On-Screen Keyboard

Some user interface pages, such as Test Order Entry, require you to enter data. When you select a text field, the analyzer may display an on-screen keyboard at the bottom of the screen, and a Text Input dialog above the keyboard.

To use the on-screen keyboard, touch the keys to type, and then select **Done** in the Text Input dialog.

System Help

The System Help provides the complete Instructions for Use on the console.

To locate context-sensitive information, use the **Help** button on the navigation bar. To locate topic-specific information, use the **Help** button to open System Help and then use the System Help navigation tools to locate the information.

Tip

On the monitor's touch screen, touch the screen and place two fingers next to each other. Spread them apart to zoom in on the view of the system help, or move them closer together to zoom out of the view.

Navigation Pane

The navigation pane contains the table of contents for System Help. When System Help is open in a new tab, the navigation pane is located on the left side of the System Help page. When System Help is docked left or docked right, select the icon in the upper left corner to display the navigation pane.

System Help Display Options

Display options are located at the top of the screen when you first open System Help. Changing the display option changes where System Help is located on the screen.

Table 22 System Help Display Options

Button	Function
Dock left or **Dock right**	The button name switches between **Dock left** and **Dock right** each time you select it. • **Dock left** moves System Help to the left side of the screen. The analyzer user interface is visible on the right side of the screen. • **Dock right** moves System Help to the right side of the screen. The analyzer user interface is visible on the left side of the screen.
Open in new tab	Opens System Help as a new tab within the analyzer user interface. You can use the tabs to switch between the user interface and System Help.
Hide	Closes System Help.
On-screen keyboard 	Displays the on-screen keyboard. You can use the on-screen keyboard to enter text in the search field.

System Help Navigation Tools

The System Help includes tools that help you to navigate through the content. You can locate information using the table of contents in the navigation pane, entering a key word or phrase in the search field, selecting a related link, or following a breadcrumb link.

Table 23 Navigation Tools

Item	Description
Show menu icon 	Select to display the Table of Contents if it is not displayed.
Breadcrumb links	Breadcrumb links indicate the location of the current topic within System Help. Select any breadcrumb link to open the associated topic.

Table 23 Navigation Tools (Continued)

Item	Description
Search field	Enter one or more words in the search field and press the **Enter** key to find related content in the System Help. Select a topic from the list provided in the search results. When you open a topic from the search results, the search words are highlighted in the text. **Tip** When two or more words are entered in the search field, every instance of each word is displayed in the search results. To limit the search results to instances of the exact phrase entered into the search field, place quotation marks before and after the phrase.
• Previous Topic button  • Next Topic button 	Select to view the previous topic or the next topic in the System Help.
Toggle Search Highlighting button 	Select to hide or show highlighted search terms.
Print button 	Select to print the current topic.
Related links	Related links at the bottom of the page allow you to access information that is related to the current topic. • Parent Topic: A link to the higher-level topic (such as summary or overview topics) • Child Topics: A list of links to lower-level topics (such as specific tasks or reference items)

Videos

System Help includes videos for some topics and procedures.

To view the video, select the play button at the bottom of a video window.

Note

Videos do not have audio.

In the PDF version of the IFU, the following message is displayed to indicate where video is available in System Help:

Refer to the video in System Help.

Limitations of Use

The analyzer is limited to the purpose of analyzing samples and reporting results. Never install unauthorized software on the analyzer.

Hardware Configuration

The analyzer is a complete and self-contained device that requires no additional hardware in order to function as designed.

Software Environment

All software required for the proper operation of the analyzer is installed in the factory. No additional software is required or recommended. The system software may be updated from time to time.

Installed software includes the following functions:

- Computer operating system: The software and utilities that enable applications to run and to store and retrieve data
- Analyzer control: Controls the mechanical aspects of the analyzer
- Result processing: Converts raw result data into reportable result data
- Database: Stores and manages all data on the analyzer
- User interface: The system console
- Networking: Controls the flow of data to and from host systems (LIS or middleware), printers, and Beckman Coulter Customer Support (through RMS)
- Security: Protects against the introduction of malicious software
- Process monitoring: Monitors the performance of pipetting subsystems, to detect obstructions such as clots
- Fault detection: Identifies error conditions and reports them as events (system events, sample events, QC events, and calibration events)
- Diagnostics: Software routines used to diagnose problems with the analyzer

LIS Interface

The analyzer can be directed by a laboratory information system (LIS) through the LIS interface. When connected to an LIS, the analyzer receives test requests from, and sends test results to, the LIS. The LIS interface consists of two major components:

- The physical, or hardware, interface, which is a port located on the external computer
- The logical, or software, interface, which includes the frame-layer protocols and message formats for sending and receiving messages

For information about setting up the LIS interface on the analyzer, refer to Configuring the LIS Interface.

CHAPTER 4

Daily Startup

Daily Startup Overview

Daily startup is the process of preparing the analyzer to run tests on patient samples.

Preparing the analyzer to run tests on patient samples includes completing maintenance, having a sufficient supply of consumables and reagents on board the analyzer, and running required calibration and QC. Performing daily startup each day helps to maximize the time until the analyzer requires attention again. After performing daily startup, monitor the task indicators on the Home page and address issues as they occur to keep the analyzer prepared to run tests on patient samples.

You can configure when the analyzer provides a notification to perform some daily startup activities, such as the performance of QC and Calibration tests, to align with your daily shift schedule. Refer to Configuring Daily Startup for more information.

Materials for Daily Startup

To enhance the efficiency of daily startup, the Materials page contains a list of the consumables, reagents, calibrators, and control materials that are needed. It also includes buttons for loading consumables and reagents and for accessing pages to view calibration and QC orders. To view the Materials page, select the **Materials** task indicator on the Home page.

Performing Daily Startup

Perform daily startup to prepare the analyzer for sample processing.

When a task indicator displays a value greater than zero, select the indicator and perform the associated task described in this procedure. When the task is complete, return to the Home page and evaluate the next task indicator with a value greater than 0 (zero).

1 Select **Home** on the navigation bar.

2 Resolve the maintenance tasks that are due now.

- **a.** Select the **Maintenance** task indicator.
- **b.** Review the list of tasks in the Maintenance Due Now section of the Maintenance page to identify the required maintenance.
- **c.** Perform the required maintenance tasks.

  Refer to Performing a Maintenance Task.

3 Gather the materials that will be needed to perform the daily startup tasks.

- **a.** Select the **Materials** task indicator.
- **b.** Review the materials listed on the page to identify the materials that are required to perform the daily startup tasks.
- **c.** Gather the required materials.

4 Resolve the consumable tasks that are due now.

a. Select the **Consumables** task indicator.

b. Review the tiles on the Consumables Due Now page to identify the consumables that are needed.

c. Perform the required tasks.

Table 24 Determining Required Tasks for Chemistry Consumables

If this tile is displayed	Perform this task
DI Water	Replacing the DI Water
Wash (100%) or Lipase Wash	Replacing the Wash Solution (100%) and Lipase Wash in the Running (Standby) State **Note** Lipase wash is available only outside the United States.
Sample Diluent	Replacing the Sample Diluent in the Running (Standby) or Running (Sampling) State
Wash (2%)	Replacing the Diluted Wash Solution (2%) in the Running (Standby) or Running (Sampling) State
Wash Solution	Replacing the Wash Solution Tank in Running (Standby) or Running (Sampling) State

5 Resolve the reagent tasks that are due now.

a. Select the **Reagents** task indicator.

b. Review the tiles on the Reagents Due Now page to identify the reagents that are needed.

Note

At initialization, the analyzer performs a reagent check of all positions in the reagent refrigerator.

c. Load the chemistry reagents that are needed.

Refer to Replacing Chemistry Reagents in the Running (Standby) State or the Starting (Warmup) State.

d. If your analyzer includes an ISE module, load the ISE reagents that are needed.

Refer to Replacing ISE Reagents in the Running (Standby) or Running (Sampling) State.

6 Resolve the calibration tasks that are due now.

a. Select the **Calibration** task indicator.

b. Review the tiles on the Calibrations Due Now page to identify the calibration tests to run.

c. Run the required calibrations.

Refer to Running Calibrations.

7 Resolve the QC tasks that are due now.

a. Select the **QC** task indicator.

b. Review the tiles on the QC Due Now page to identify the QC tests to run.

c. Run the required QC tests.

Refer to Running QC Tests.

CHAPTER 5
Consumables

Consumables Overview

Consumables are a type of materials that are used when the analyzer processes samples. Consumables are not test-specific and do not require calibration.

The analyzer evaluates the status of each consumable and adds a tile to the Consumables Due Now page when it is time to add or replace the consumable. When a red vertical bar is displayed on the tile, the level of the consumable stops test processing.

The level of consumables that trigger these notifications may be configured on the Supplies page. (Refer to Configuring Thresholds for Supplies.) The Due Soon Threshold sets the level for a notification when consumables are low. For most consumables, the Due Soon Threshold is based on the percentage of the usable consumable on board the analyzer. The Due Now Threshold is set at 0 or empty.

Description of Consumables

Table 25 Description of Consumables

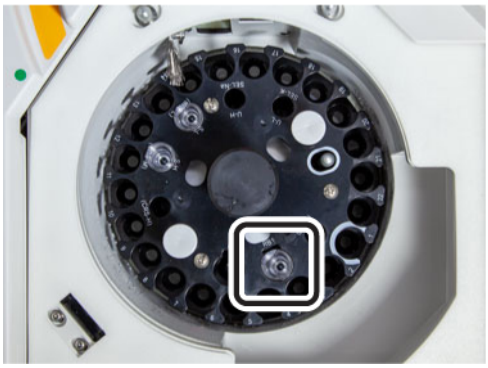
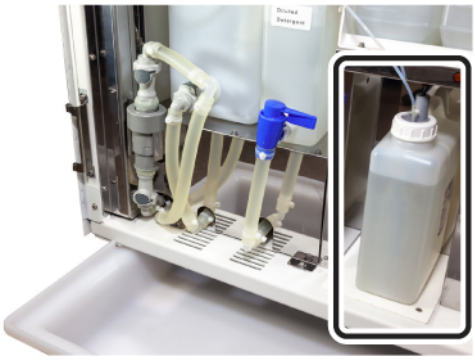
Consumable	Description
DI Water 	The analyzer uses deionized water for reagent blank. The DI water is located in the inner circle of the STAT table at the position for RB1.
Wash Solution (100%) or Lipase Wash 	The analyzer uses Beckman Coulter Wash Solution (100%) or lipase wash to wash the reagent probe to prevent contamination between specified reagents. The wash solution is located inside the reagent refrigerator at the positions assigned to Wash (100%) and Lipase Wash. A maximum of two bottles are allowed for wash solution (100%) and two bottles for lipase wash. Refer to Assigning a Dedicated Position in the Reagent Refrigerator. **Note** Lipase wash is available only outside the United States.
Sample Diluent 	The analyzer uses deionized water or diluent to dilute samples. The sample diluent is located at position 77 next to the reagent refrigerator. Position 77 is also used for the bottles of 1N hydrochloric acid or diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite) that are used during the maintenance procedure for cleaning cuvettes with external solution.

Table 25 Description of Consumables (Continued)

Consumable	Description
Wash Solution (2%) 	The analyzer uses diluted Beckman Coulter Wash Solution (2%) to wash the sample probe. The diluted wash solution is located at position 78 next to the cuvette wheel.
Wash Solution 	The wash solution tank contains Beckman Coulter Wash Solution, which the analyzer uses to prepare the diluted wash solution when the diluted wash solution reaches insufficient level. The analyzer uses diluted wash solution to wash the cuvettes, mix bars, and analyzer tubing. The wash solution tank is located in the tank storage area behind the front left door.

Status Tiles for Consumables

The analyzer communicates the status of consumables using consumable-specific tiles. The tiles are located on the All Consumables page and, when your attention is required, the tiles appear in the Consumables Due Now page.

Table 26 Status Tiles for Consumables

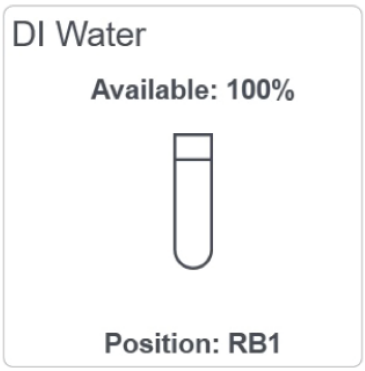
Tile	Description	Action Required
DI Water 	The value for Available: x % above the icon indicates the amount of solution remaining. The text below the icon indicates the location of this consumable.	Deionized water for reagent blank is needed soon or urgently under the following conditions: • When the tile is displayed on the Consumables Due Now page, the solution is empty, will be empty soon, or will expire soon. The remaining solution is empty or below the Due Soon or Expiring Soon threshold level. • When the tile includes a yellow vertical bar, the volume is insufficient or the solution is expired. When the tile is displayed on the Consumables Due Now page, replace the solution. Refer to Replacing the DI Water.

Table 26 Status Tiles for Consumables (Continued)

Tile	Description	Action Required
Wash (100%)  Lipase Wash  	The value for Available: x % above the icon indicates the amount of solution remaining. The text below the icon indicates the location of this consumable.	Beckman Coulter Wash Solution (100%) or lipase wash for cleaning the reagent probe is needed soon or urgently under the following conditions: • When the tile is displayed on the Consumables Due Now page, the solution will be empty or will expire soon. The remaining solution is below the Due Soon or Expiring Soon threshold level. • When the tile includes a red vertical bar, the volume is empty or the solution is expired for all (one or two) bottles in the reagent refrigerator. When the tile is displayed on the Consumables Due Now page, replace the solution. Refer to Replacing the Wash Solution (100%) and Lipase Wash in the Running (Standby) State or Replacing the Wash Solution (100%) and Lipase Wash in the Running (Sampling) State. **Note** Lipase wash is available only outside the United States.

Table 26 Status Tiles for Consumables (Continued)

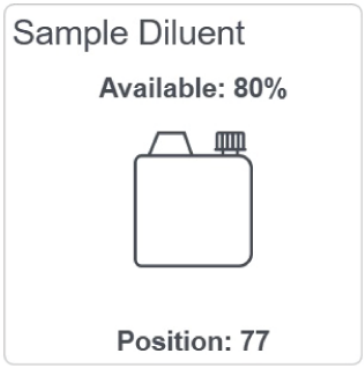
Tile	Description	Action Required
Sample Diluent 	The value for Available: x % above the icon indicates the amount of solution remaining. The text below the icon indicates the location of this consumable.	Deionized water or diluent in the sample diluent bottle is needed soon or urgently under the following conditions: • When the tile is displayed on the Consumables Due Now page, the solution will be empty or will expire soon. The remaining solution is below the Due Soon or Expiring Soon threshold level. • When the tile includes a yellow vertical bar, the volume is empty. • When the tile includes a red vertical bar, the solution is expired. When the tile is displayed on the Consumables Due Now page, replace the solution. Refer to Replacing the Sample Diluent in the Running (Standby) or Running (Sampling) State.

Table 26 Status Tiles for Consumables (Continued)

Tile	Description	Action Required
Wash (2%) 	The value for Available: x % above the icon indicates the amount of solution remaining. The text below the icon indicates the location of this consumable.	Diluted Beckman Coulter Wash Solution (2%) for cleaning the sample probe is needed soon or urgently under the following conditions: • When the tile is displayed on the Consumables Due Now page, the solution will be empty or will expire soon. The remaining solution is below the Due Soon or Expiring Soon threshold level. • When the tile includes a red vertical bar, the volume is empty or the solution is expired. When the tile is displayed on the Consumables Due Now page, replace the solution. Refer to Replacing the Diluted Wash Solution (2%) in the Running (Standby) or Running (Sampling) State or Replacing the Diluted Wash Solution (2%) in the Paused State.

Table 26 Status Tiles for Consumables (Continued)

Tile	Description	Action Required
Wash Solution 	The text `Available` and `Empty` above the tank icon indicates the status of the volume of Beckman Coulter Wash Solution.	Beckman Coulter Wash Solution in the wash solution tank is needed soon or urgently under the following conditions: • When the tile is displayed on the Consumables Due Now page and includes a red vertical bar, the solution is empty. When the tile is displayed on the Consumables Due Now page, replace the solution. Refer to Replacing the Wash Solution Tank in Running (Standby) or Running (Sampling) State or Replacing the Wash Solution Tank when the Analyzer Moves from the Running (Sampling) State to the Paused State.

Monitoring the Status of Consumables

Monitor consumables to identify the consumables that require attention, the status of all consumables, or the expiration dates or quantity of a specific consumable that is onboard the analyzer.

1 To identify consumable tasks that are due, view the **Consumables** task indicator on the Home page.

   a. If the value on the task indicator is not 0, select the task indicator.
   The analyzer displays the Consumables Due Now page. If the All Consumables page is displayed when the **Consumables** task indicator is selected, select **Consumables Due Now** in the breadcrumb links.

   b. Review the tiles on the Consumables Due Now page and perform the task that is associated with each tile that is displayed.

If this tile is displayed	Perform this task
DI Water	Replacing the DI Water
Wash (100%) or Lipase Wash	Replacing the Wash Solution (100%) and Lipase Wash in the Running (Standby) State or Replacing the Wash Solution (100%) and Lipase Wash in the Running (Sampling) State **Note** Lipase wash is available only outside the United States.
Sample Diluent	Replacing the Sample Diluent in the Running (Standby) or Running (Sampling) State
Wash (2%)	Replacing the Diluted Wash Solution (2%) in the Running (Standby) or Running (Sampling) State or Replacing the Diluted Wash Solution (2%) in the Paused State
Wash Solution	Replacing the Wash Solution Tank in Running (Standby) or Running (Sampling) State or Replacing the Wash Solution Tank when the Analyzer Moves from the Running (Sampling) State to the Paused State

2 To view the status of all consumables at any time, open the All Consumables page.

   a. Select the **Consumables** task indicator on the Home page.
   The analyzer displays the Consumables Due Now page.

   b. From the Consumables Due Now page, select **All Consumables**.
   The analyzer displays the All Consumables page.

   c. Review the tiles to confirm the status of each consumable that the analyzer uses.

Replacing the Sample Diluent in the Running (Standby) or Running (Sampling) State

To avoid interruptions in sample processing, replace the deionized water or diluent in the sample diluent bottle when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours.

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

1. Select the **Materials** task indicator on the Home page.
   The Materials page is displayed.
2. Select **Load Deck**.
3. Follow the instructions that are displayed.
   When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing the Diluted Wash Solution (2%) in the Running (Standby) or Running (Sampling) State

To maintain effective performance of the diluted Beckman Coulter Wash Solution (2%) for washing the sample probe, and avoid interruptions in sample processing, replace the wash solution when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours.

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle wash solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

1. Select the **Materials** task indicator on the Home page.
   The Materials page is displayed.
2. Select **Load Deck**.
3. Follow the instructions that are displayed.
   When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing the Diluted Wash Solution (2%) in the Paused State

To maintain effective performance of the diluted Beckman Coulter Wash Solution (2%) for washing the sample probe, and avoid interruptions in sample processing, replace the wash

solution when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours.

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle wash solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Warning

There is a physical hazard when replacing the bottle for diluted wash solution (2%) in the on-deck position. Make sure that when you attempt to replace the diluted wash solution (2%) at on-deck position 78, that a reagent check is not in progress. A reagent check is in progress when the status bar indicates that the analyzer is in the *Running* (*Reagent Check*) state.

When the diluted wash solution (2%) for washing the sample probe becomes empty during sample processing, the analyzer generates an event and moves to the *Paused* state.

1. Open the upper cover.
2. Remove the bottle of diluted wash solution (2%) at position 78, and discard the solution in the bottle.
3. Rinse the bottle with deionized water.
4. Fill the bottle with approximately 50 mL of the freshly prepared diluted wash solution (2%).
5. Put the bottle back in position 78.

   Caution

   To prevent rust or corrosion of the inner surface of the bottle holder, be sure to wipe the outside of the bottle clean before placing the bottle back into position.
6. Close the upper cover.
7. Perform a reagent check.
   Refer to Performing a Chemistry Reagent Check.

   After the reagent check, the analyzer removes the tile from the Consumables Due Now page.

8 Select **All Consumables** in the Consumables Due Now page, and confirm that the volume on the tile is updated.

9 To move the analyzer to the *Running* (*Sampling*) state, open and close the sample handler door.

Replacing the Wash Solution (100%) and Lipase Wash in the Running (Standby) State

To maintain effective performance of the Beckman Coulter Wash Solution (100%) and Beckman Coulter Lipase Wash for washing the reagent probes, replace the solutions when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours.

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

Note

Lipase wash is available only outside the United States.

If you configure contamination prevention parameters and use wash solution (100%) or lipase wash, perform this procedure. Refer to Configuring Contamination Prevention Parameters for the correct solutions to use.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle wash solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

When wash solution (100%) or lipase wash becomes empty during sample processing, the analyzer generates an event and moves to the *Paused* state. If wash solution becomes insufficient during sample processing, you can put the analyzer in the *Paused* state and then replace the wash solution bottle.

The bottle of wash solution (100%) and the bottle of lipase wash must be assigned dedicated positions on the Dedicated Positions page. Refer to Assigning a Dedicated Position in the Reagent Refrigerator.

1 Open the upper cover and reagent refrigerator large cover.

2 Remove the bottle of wash solution (100%) and the bottle of lipase wash from their dedicated positions in the reagent refrigerator.

3 Discard the wash solution in each bottle that you removed from the reagent refrigerator.

4 Rinse the bottles with deionized water.

5 Fill the bottle of wash solution (100%) with approximately 50 mL of freshly prepared wash solution (100%).

6 Fill the bottle of lipase wash with approximately 50 mL of freshly prepared lipase wash.

7 Place the bottles back into the reagent refrigerator in the assigned dedicated positions on the Dedicated Positions page.

8 Close the upper cover and reagent refrigerator large cover.
The analyzer starts a reagent check automatically to check the consumables. After the reagent check, the analyzer removes the tile from the Consumables Due Now page.

9 Select **All Consumables** in the Consumables Due Now page, and confirm that the volume on the tile is updated.

Replacing the Wash Solution (100%) and Lipase Wash in the Running (Sampling) State

If you configure contamination prevention parameters and use wash solution (100%) or lipase wash, perform this procedure. Refer to Configuring Contamination Prevention Parameters for the correct solutions to use.

Note

Lipase wash is available only outside the United States.

To maintain effective performance of the Beckman Coulter Wash Solution (100%) and lipase wash for washing the reagent probes, replace the solutions when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours. .

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle wash solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

When wash solution (100%) or lipase wash becomes empty during sample processing, the analyzer generates an event and moves to the *Paused* state. If wash solution becomes insufficient during sample processing, you will have an opportunity to move the analyzer into the *Paused* state, and then you can replace the wash solution (100%) or lipase wash.

1 Select the **Materials** task indicator on the Home page.
The Materials page is displayed.

2 Select **Manage CC Reagent Refrigerator**.

3 Follow the instructions that are displayed.

When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing the DI Water

Deionized water is used for reagent blank. To avoid interruptions in sample processing, replace the deionized water when the tile is displayed on the Consumables Due Now page. The default Expiring Soon threshold is 8 hours. The solution expires every 24 hours.

To change the Expiring Soon threshold, refer to Configuring Thresholds for Supplies.

When the tile is displayed on the Consumables Due Now page, replace the deionized water.

1 Select the **Materials** task indicator on the Home page.
The Materials page is displayed.

2 Select **Load STAT Table**.

3 Follow the instructions that are displayed.

When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing the Wash Solution Tank in Running (Standby) or Running (Sampling) State

The analyzer consumes the Beckman Coulter Wash Solution in the wash solution tank at a rate of 0.25 L per 2,000 tests. The analyzer is able to continue the analysis approximately 2,000 tests after detecting an insufficient volume of wash solution.

If wash solution becomes empty during sample processing, the analyzer automatically moves to the *Paused* state. In this case, you must perform the following procedure instead of this procedure: Replacing the Wash Solution Tank when the Analyzer Moves from the Running (Sampling) State to the Paused State.

When the tile is displayed on the Consumables Due Now page, replace the wash solution tank.

Caution

Use the wash solution listed in Parts List for Chemistry Consumables. If you do not use this wash solution, cleaning performance cannot be ensured.

Warning

Wear Personal Protective Equipment (PPE), such as gloves, eye shields, and lab coats, to handle wash solution. Refer to the Safety Data Sheets (SDS) for more information.

- **If the wash solution contacts the eyes or mouth, immediately flush with water. Seek medical attention.**
- **If the wash solution contacts skin or clothes, rinse the affected area thoroughly with water.**
- **If the wash solution splashes or spills outside the tank, follow your laboratory procedure to wipe up spills immediately.**
- **If any spill is left untreated, it can generate toxic gas and can cause parts of the analyzer to corrode.**

1 Select the **Materials** task indicator on the Home page.
The Materials page is displayed.

2 Select **Load Cabinet**.

3 Follow the instructions that are displayed.

When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing the Wash Solution Tank when the Analyzer Moves from the Running (Sampling) State to the Paused State

The analyzer consumes the Beckman Coulter Wash Solution in the wash solution tank at a rate of 0.25 L per 2,000 tests. The analyzer is able to continue the analysis approximately 2,000 tests after detecting an insufficient volume of wash solution.

If wash solution becomes empty during sample processing, the analyzer automatically moves to the *Paused* state. When it does, you can replace the wash solution tank using this procedure.

Caution

Use the wash solution listed in Parts List for Chemistry Consumables. If you do not use this wash solution, cleaning performance cannot be ensured.

Warning

Wear Personal Protective Equipment (PPE), such as gloves, eye shields, and lab coats, to handle wash solution. Refer to the Safety Data Sheets (SDS) for more information.

- **If the wash solution contacts the eyes or mouth, immediately flush with water. Seek medical attention.**
- **If the wash solution contacts skin or clothes, rinse the affected area thoroughly with water.**
- **If the wash solution splashes or spills outside the tank, follow your laboratory procedure to wipe up spills immediately.**
- **If any spill is left untreated, it can generate toxic gas and can cause parts of the analyzer to corrode.**

1 Confirm that the analyzer is in the *Paused* state.

2 Open the left front door of the analyzer.

3 Place a new wash solution tank next to the analyzer and remove the cap.

4 Carefully pull the wash solution tank forward until you can reach the tank cap.

5 Loosen the tank cap, and remove the tank cap, tubing, and sensor from the tank.

Important

To prevent damage to the sensor cable, when loosening the tank cap be sure that the sensor cable does not become twisted.

Important

The tubing and sensor can drip when you remove it from the tank. Follow your laboratory procedure to wipe up spills immediately.

6 Replace the tank with a new wash solution tank.

7 Insert the tubing and sensor in the tank, and tighten the cap.

Important

To prevent damage to the sensor cable, when tightening the tank cap be sure that the sensor cable does not become twisted.

8 Put the wash solution tank back in the analyzer.

9 Close the left front door of the analyzer.

10 Select **All Consumables** in the Consumables Due Now page, and confirm that the tile indicates Available.

11 To move the analyzer to the *Running* (*Sampling*) state, open and close the sample handler door.

Consumables

Consumables Overview

CHAPTER 6

Reagents

Reagents Overview

Reagents are the test-specific solutions that are used by the analyzer to process samples. Each reagent lot or bottle must be calibrated before it can be used to generate results.

The analyzer evaluates the status of the reagent for each test that is enabled. As the analyzer uses the reagent to process tests, or as expiration thresholds approach, the analyzer displays a tile on the Reagents Due Now page. When a reagent tile is displayed on the Reagents Due Now page, load more reagent. When you load more reagent, the tile is removed from the Reagents Due Now page.

A yellow vertical bar on the reagent tile means that the reagent volume is critically low or empty, that the reagent lot or onboard stability has expired, or that the test was enabled but the reagent container is not on board.

When a tile appears on the Reagents Due Now page but does not include a yellow vertical bar, reagents are needed soon because of the remaining volume or time before expiration.

The number of tests or the time before expiration of a reagent that triggers the addition of a tile is set as part of the system configuration on the Supplies page. (Refer to Configuring Thresholds for Supplies.) The Due Soon threshold sets the level for the tile to appear on the Reagents Due Now page. The Due Now threshold is the volume of reagent that triggers the addition of the yellow vertical bar to the tile, and is fixed at 0. The Expiring Soon threshold sets the number of hours before reagent expiration that triggers the addition of a tile.

For more information about the status of reagents, refer to Monitoring the Status of Reagents.

Description of Reagents

Each test that is available on the analyzer requires a test-specific reagent bottle to produce results. The analyzer uses the contents in the reagent bottle to process tests.

The analyzer scans bar code labels on reagent bottles to identify individual reagent bottles. Reagent bottles without a bar code label must be assigned to dedicated positions. Refer to Assigning a Dedicated Position in the Reagent Refrigerator. The number of tests that can be processed per reagent bottle depends on the test.

A maximum of five bottles of the same reagent can be placed in the reagent refrigerator for additional test volume. The analyzer sequences the bottles (1 to 5) during the reagent check.

More than one test can be assigned to a single reagent by programming the same reagent ID for each test.

Most Beckman Coulter reagents are liquid and ready to place in the reagent refrigerator after removing the cap on the reagent bottle. Refer to the reagent IFU to determine if a reagent requires preparation and for the reagent preparation procedure.

Monitoring the Status of Reagents

Monitor reagents to determine the reagent issues to address, the status of all onboard reagents, expiration dates, or the quantity of a reagent that is on board the analyzer.

Note

The analyzer displays ISE tests on the Reagents Due Now page and the All Reagents page as individual tiles for Na, Cl, and K.

---

1 To identify reagent tasks that are due now, view the **Reagents** task indicator on the Home page.

- **a.** If the value on the task indicator is 1 or greater, select the task indicator.
  The analyzer displays the Reagents Due Now page.
- **b.** Review the tiles on the page and identify the reagents that are needed.
  Each tile includes the test name, the number of tests that can be run with the remaining reagent, and the reason the tile appears on the Reagents Due Now page.
- **c.** Load the reagents that are needed.

---

2 To view the reagent tiles for each enabled test, open the All Reagents page.

- **a.** Select the **Reagents** task indicator on the Home page.
  The analyzer displays the Reagents Due Now page.
- **b.** From the Reagents Due Now page, select **All Reagents**.
  The analyzer displays the All Reagents page.
- **c.** Review the reagent information for all enabled tests.

---

3 To view the reagent tile for each reagent container that is on board the analyzer, open the Reagent Position List page.

- **a.** Select the **Materials** task indicator on the Home page.
  The Materials page is displayed.
- **b.** Select **Reagent Position List**.
  The Reagent Position List page is displayed.
- **c.** View the tile for each reagent container that is on board the analyzer.
  Each tile displays the test name, reagent refrigerator position, expiration date, test count, and if an error has occurred with the reagent and needs your attention, the reason for the error.

---

4 To view detailed reagent information for a selected test, open the Reagent Review Details page or (for ISE reagents) the ISE Reagent Details page.

- **a.** Select the **Reagents** task indicator on the Home page.
  The analyzer displays the Reagents Due Now page.
- **b.** Select a tile from the Reagents Due Now page, or select **All Reagents** and then select a tile.

c. Select the **Details** button.
The analyzer displays the Reagent Review Details page or the ISE Reagent Details page.

d. View the detailed reagent information for the selected test.

Note

Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.

Reagent Details Pages

You can open the Reagent Review Details page or the ISE Reagent Details page by selecting a tile on the Reagents Due Now page or All Reagents page and selecting **Details**.

Note

When you change the configuration of reagents in the System Configuration menu, the analyzer automatically starts a reagent check and then updates the information on the tiles on the All Reagents page and in the tables on the Reagent Review Details page or the ISE Reagent Details page.

Table 28 Information on the Reagent Review Details Page

Item	Description
Test	The test name.
Sample Type	The sample type for the test.
On Board	The number of onboard bottles physically on the analyzer. **Note** Even if two bottles have the same lot number, they are counted separately.
Usable Count	The number of tests that can be performed with the remaining reagent in all of the bottles on board, displayed in real time.
Supply Name	The reagent name.

Table 28 Information on the Reagent Review Details Page (Continued)

Item	Description
Test Count	The number of tests that can be performed by a bottle of reagent (R1) or a pair of reagents (R1 and R2). **Note** Does not include expired reagents that are on the analyzer.
Positions	The reagent bottle position in the reagent refrigerator.
Expiration	The reagent expiration date or the reagent onboard stability date, whichever is earlier.
Calibration Expiration	The expiration date of the calibration.
Lot Number	The lot number of the reagent bottle.
Serial Number	The unique serial number for the reagent bottle.
Sequence Number	The sequence number (1 to 5) of the same test in the R1 or R1/R2 pair.
RB History	The history of reagent blank results for the reagent. To view detailed information about a reagent blank result, select the reagent blank result and select **RB Result Details**. The analyzer displays the Chemistry Results page, which includes all replicates for the reagent blank result.
Calibration Curve	The calibration curve for the test. To view detailed information about the calibration curve, select **Details**. The analyzer displays the Calibration Curve Details page. **Note** If a reagent blank or calibration is in progress, the analyzer waits until the reagent blank or calibration is complete before calculating the calibration curve. **Note** Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.
Levey-Jennings Chart	The Levey-Jennings chart for the QC test results for the reagent.

Table 28 Information on the Reagent Review Details Page (Continued)

Item	Description
Order RB button	Manually orders the reagent blank for the selected reagent bottle. Selecting the button causes the reagent blank to be selected on the Edit Calibration Order page.
Order Calibration button	Manually orders both the calibration and reagent blank for the selected reagent bottle. Selecting the button causes the calibration and reagent blank to be selected on the Edit Calibration Order page. **Note** Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.
Order QC button	Manually orders the QC test. Selecting the button causes the QC test to be selected on the Edit QC Order page.

Table 29 Information on the ISE Reagent Details Page

Item	Description
Test	The test name.
Sample Type	The sample type for the test.
Test Count	The number of tests that can be performed by the bottle of ISE reagent (ISE Buffer Solution, ISE MID Standard Solution, or ISE Reference Solution) with the lowest volume. **Note** Does not include expired reagents that are on the analyzer.
Bulk Solution Details: Solution	ISE Buffer Solution, ISE MID Standard Solution, or ISE Reference Solution.
Bulk Solution Details: Cycle Count	The number of tests that can be performed with the ISE solution.
Bulk Solution Details: Lot Number	The lot number of the ISE solution bottle.
Bulk Solution Details: Expiration	The expiration date for the ISE solution bottle.
Electrode Details: Electrode	The Na, K, Cl, or REF electrode.

Table 29 Information on the ISE Reagent Details Page (Continued)

Item	Description
Electrode Details: Cycle Count	The number of tests that have been performed with the electrode.
Electrode Details: Lot Number	The lot number of the electrode.
Electrode Details: Expiration	The electrode expiration date.
Electrode Details: Calibration Expiration	The expiration date of the calibration.
Calibration Slope	The calibration slope for the test. To view detailed information about the calibration slope, select a row in the table and select **Calibration Details**. The analyzer displays the Calibration Curve Details page. **Note** If a calibration is in progress, the analyzer waits until the calibration is complete before calculating the calibration slope.
MID Solution Factor	The values that the analyzer obtains from the concentration of the ISE MID Standard Solution to establish a reference for measuring Na, K, and Cl ion concentrations.
Levey-Jennings Chart	The Levey-Jennings chart for the QC test results for the reagent.

Performing a Chemistry Reagent Check

The analyzer automatically performs a reagent check at daily startup and when you replace reagents.

The automatic reagent check occurs when you perform the following actions in the following order:

1. Open analyzer top cover.
2. Open the large reagent refrigerator cover.
3. Load reagents into the reagent refrigerator.
4. Close the large reagent refrigerator cover.
5. Close the analyzer top cover.

To manually update the status of reagents on the Reagents Due Now and All Reagents pages, perform this procedure.

1 Select the **Reagents** task indicator on the Home page.
The analyzer displays the Reagents Due Now page.

2 Select **Reagent Check**.
The analyzer displays the Reagent Check dialog with **Check all positions** selected.

3 Select (or leave selected) one of the following options:

- **Check all positions**: Determines the remaining volume of reagent at all positions, including the bottle positions for consumables on deck and the RB1 position in the STAT table. Leave this option selected when loading numerous reagents.
- **Check specified positions**: Determines the remaining volumes of reagent at the specified positions. Select this option when replacing a reagent bottle. If the reagent is an R1/R2, perform a reagent check for both the R1 and R2 reagent.
- **Reset only**: Select this option when the reagent refrigerator cover was only opened and closed, or when changing any settings, without changing any reagent. The system resets to the latest volumes (tests) in the system memory.

4 Select **OK**.

- If you selected **Check all positions** or **Reset only**, the analyzer performs the reagent check or reset operation.
- If you selected **Check specified positions**, the analyzer displays a dialog that shows the empty positions and the test name, reagent type (R1/R2), test count, and onboard expiration for the reagents that are loaded in each position in the reagent refrigerator.

5 If you selected **Check specified positions**:

a. Select the positions for the analyzer to perform a reagent check on.

b. Select **OK**.
The analyzer performs the reagent check for the specified positions.

After the reagent check is complete, the analyzer increases the number in the **Calibration** task indicator and adds a tile to the Calibrations Due Now page for the reagents that need it.

Chemistry Reagent Bottles and Adapters

The analyzer can use three sizes of reagent bottles:

- 15 mL
- 30 mL
- 60 mL

Table 30 Reagent Bottle Part Numbers

Bottle	Part Number	Packing Quantity
60-mL reagent bottle	63093	20 bottles
30-mL reagent bottle	63094	20 bottles
15-mL reagent bottle	63165	20 bottles

Table 31 Reagent Bottle Adapter Part Numbers

Adapter	Location	Part Number	Part Name on Package	Packing Quantity
30-mL bottle adapter	Inner ring	MU998600	Separate plate	2 pieces
		MU826200	Partition plate for 30-mL bottle	20 pieces
15-mL bottle adapter	Inner ring	MU812400	Partition plate for 15-mL bottle, Inside	2 pieces
		MU823200	Partition for 15-mL bottle	20 pieces
15-mL bottle adapter	Outer ring	MU812300	Adapter set for 15-mL bottle, Outside	2 pieces
		MU823100	15-mL Outside partition plate	20 pieces

The reagent tray uses adapters to hold 15-mL and 30-mL reagent bottles securely in position.

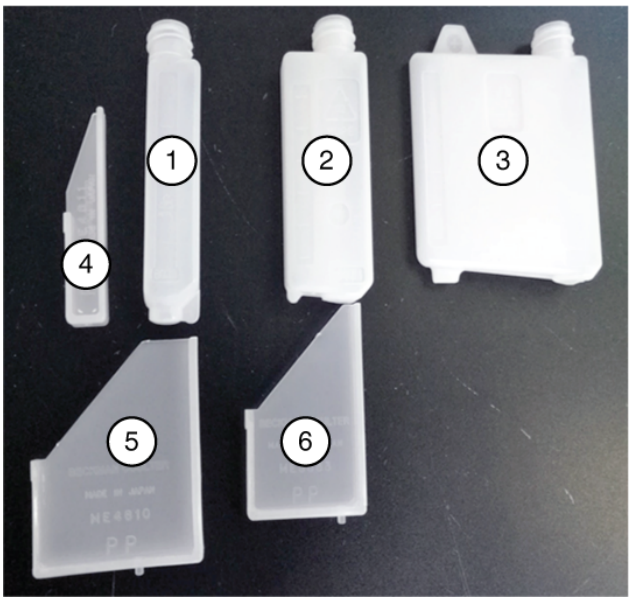
Important

You must place reagent bottles in the reagent refrigerator with the reagent bar code labels facing outwards. You must remove all reagent bottle caps before placing the bottles in the reagent refrigerator. You must use the correct adapters to secure bottles, as required.

The DxC 500 AU contains a single reagent refrigerator that holds up to 76 reagent bottles.

Adding Adapters to the Reagent Tray

Figure 47 Reagent Bottles and Adapters



1. 15-mL bottle
2. 30-mL bottle
3. 60-mL bottle
4. 15-mL bottle adapter for outer ring
5. 15-mL bottle adapter for inner ring
6. 30-mL bottle adapter for inner ring

Place the reagent bottle with the correct adapter.

Figure 48 Placing Adapter for 15-ml Bottle in Outer Ring

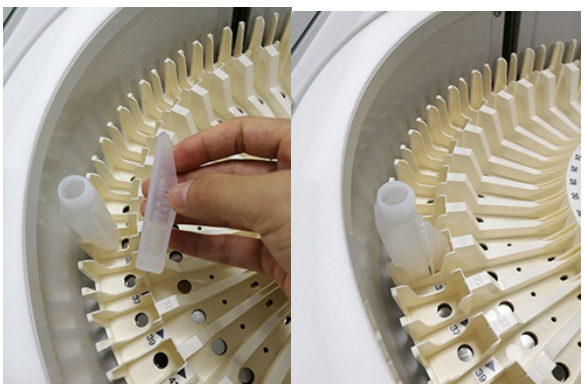


Figure 49 Placing Adapter for 15-ml Bottle in Inner Ring

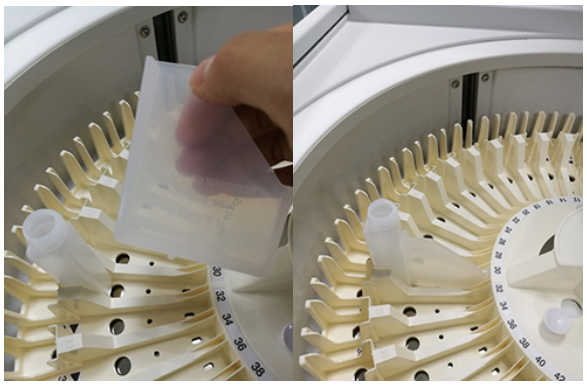


Figure 50 Placing 30-ml Bottle in Outer Ring

Figure 51 Placing Adapter for 30-ml Bottle in Inner Ring

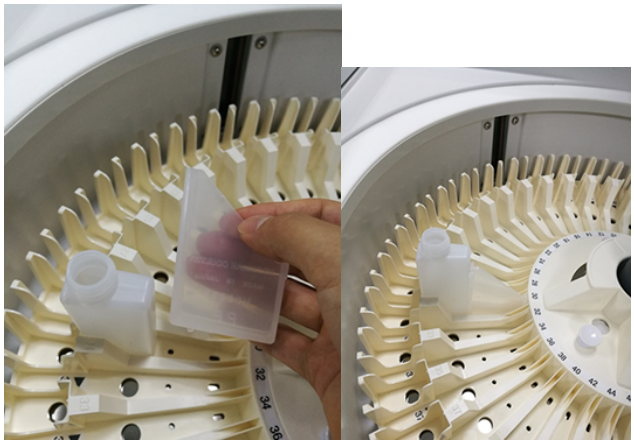


Figure 52 Placing 60-ml Bottle in Inner Ring

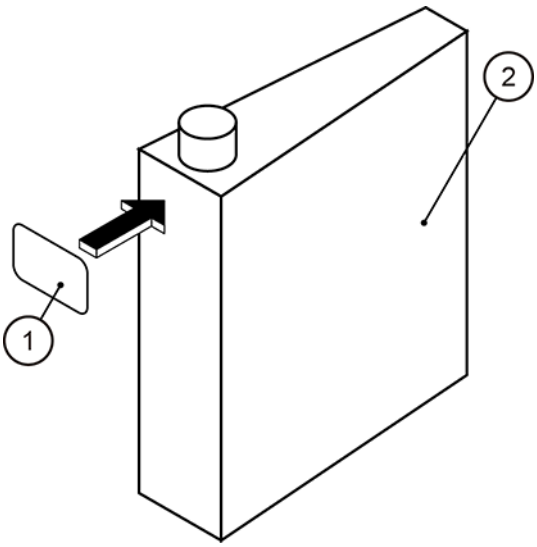
Commercial Reagent Bottles

When you use commercial reagent bottles, the test count displayed on the Reagents page can differ from the remaining actual test count. The analyzer uses the liquid level in the bottle to calculate the test count. Because the bottle is different from the Beckman Coulter reagent bottles, the calculation might be incorrect.

Commercial reagent bottles that are not sold by Beckman Coulter are available in some markets.

If the transparency of the commercial reagent bottle is too high for the bottle sensor to detect the bottle, apply an opaque label as shown in the following figure:

Figure 53 Applying a Label to a Reagent Bottle



1. Label
2. Reagent bottle

Filling Reagent Bottles

Caution

If bubbles are present in the bottles, correct analysis might not occur. Check the bottles for bubbles, and remove any bubbles before placing bottles in the reagent refrigerator. Be careful to avoid contamination.

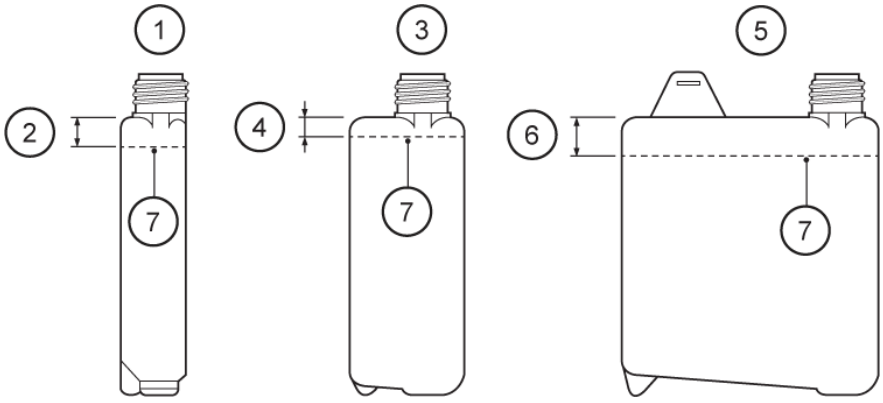
Caution

Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

Caution

When you fill Beckman Coulter bottles with reagent, Beckman Coulter Wash Solution (100%), lipase wash, or deionized water, do not exceed the maximum liquid level. The maximum liquid level depends on the bottle size. If a reagent bottle is filled over the maximum liquid level, bubbles can occur and cause a level detection error.

Figure 54 Maximum Liquid Level



1. 15-mL bottle
2. 8 mm
3. 30-mL bottle
4. 4 mm
5. 60-mL bottle
6. 12 mm
7. Maximum liquid level

Note

Lipase wash is available only outside the United States.

Creating and Printing Bar Code Labels for Reagent Bottles

This procedure is appropriate for reagent bottles used on DxC 500 AU analyzers for customers in the United States.

Perform this procedure on your personal computer.

1 Set up an Avery account.

a. Go to www.avery.com.

b. Create an Avery account.

2 Select **Start a New Project**.

3 For **Template Number** enter **94221** for the US or **60x25-R** for outside the US.

The 94221 template is 1 inch (25.4 mm) x 2.5 inches (63.5 mm), 24 per sheet.

The 60x25-R template is 2.4 inches (60 mm) x 0.98 inches (25 mm), 27 per sheet.

4 For the US, use the Presta 94221 template, and for outside the US, use the 60x25-R template, and start with a blank label.

5 In the left tool bar, select **QR and Barcodes**.

If it is not viewable, first select **... More** to view the QR and Barcodes option.

6 Select **Add Barcode or QR code**.

7 In the dialog that displays, Select **Spreadsheet or Sequential Number**, and then select **Next**.

8 In the dialog that displays, Select **Sequential Numbers**,

9 In Type, select **Numbers (1, 2, 3, ...)**.

10 Enter the first bottle number, a 4-digit number from 9000 to 9999, in **Start Value**.

11 Enter the last bottle number, a 4-digit number from 9000 to 9999, in **End Value**.

The end value depends on the number of bar codes you want to print. For example, if the first bottle number is 9000, and you want to print 12 bar codes, the end value would be 9011.

12 Enter **1** for **Increments**.

13 Enter **4** for **Leading Zeros**.

14 In **Prefix** enter a 13-digit number according the following guidelines:

Digit	Description
1, 2, and 3	The 3-digit reagent ID
4	The bottle type. — **1** for 30 mL — **3** for 60 mL — **5** for 15 mL

Digit	Description
5	The reagent type. — **1** for R1 — **2** for R2
6, 7, 8, and 9	Expiration date in the format MMYY.
10, 11, 12, 13	The 4-digit lot number

15 Select **Add**.

16 In the Step 1 - prepare data page, select **SN2**.

17 In the dialog that displays, select **Select format and enter data**.

18 In **Industry Standard Format**, select **2/5 Interleaved**.

19 Drag and drop **SN2 Gray Box** to the Enter Only Numeric characters field.

20 Keep **Use check digit** and **Display text below the code** selected.

21 In the dialog that displays, enter **10** for **X Dimension**.

22 Keep **Use check digit** and **Display text below the code** selected.

23 Select **Finish**.

24 In the dialog that displays, enter **55** for **Code width**.

25 Select **mm**.

26 Enter **10** for **X Dimension**.

27 Enter **30** for **Bar Height %**.

28 In the left tool bar, select **Text**.

29 Select **Add Text Box**, and enter a name for the label.

Beckman Coulter recommends using the assay name and bottle type, for example GLU, R1.

30 If necessary, drag the bar code label so that it fits on the page.

31 Drag the text box to a desired location on the label.

32 To preview and print the label, select **Preview and Print** at the bottom of the page.

33 To save the label template for future use, select **Save** at the top of the page.

34 The template can be found under your login. Select Profile and under Projects. select the template, for example: 20200722a Create Barcode Labels.docx

Tip

If help is needed, call Avery support.

Replacing Chemistry Reagents in the Running (Standby) State or the Starting (Warmup) State

Replace any reagent that displays on the Reagents Due Now page or that satisfies any of the following conditions:

- Onboard remaining time less than your laboratory requirements
- Other conditions specified in your laboratory requirements
- Expired

For more information about determining the status of reagents, refer to Monitoring the Status of Reagents.

Note

You can replace reagents when running patient samples, but not when running reagent blank, calibration, or QC samples.

Caution

If bubbles are present in the bottles, correct analysis might not occur. Check the bottles for bubbles, and remove any bubbles before placing bottles in the reagent refrigerator. Be careful to avoid contamination.

Caution

Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

Important

Condensation can form on refrigerated reagent bottles. Inspect the reagent bottle opening and the bar code label area for condensation. Remove condensation with a clean, dry, lint-free absorbent tissue before loading the reagent.

If the bar code label is dirty or has moisture on it, the analyzer cannot read the label. Inspect the bar code label and wipe off any dirt or moisture. If the analyzer still cannot read the label, enter the reagent bar code manually. Refer to Assigning a Dedicated Position in the Reagent Refrigerator.

For two-part reagents, the reagent label indicates whether the reagent is an R1 or R2 reagent.

The analyzer checks the volumes remaining in the reagent bottles at every aspiration. When the volumes reach the event test level, the analyzer generates an `Insufficient R1 Reagent` or `Insufficient R2 Reagent` event on the System Events page and a tile for the reagent on the Reagents Due Now page.

Confirm that the reagent is configured to trigger an alert when levels are insufficient for tests. Refer to Configuring Thresholds for Supplies.

---

1 Confirm that the analyzer is not in the *Running* (*Sampling*) state.

---

2 To identify the reagents to replace, view the **Reagents Due Now** page.

a. Select the **Reagents** task indicator on the Home page.
The analyzer displays the Reagents Due Now page.

b. Review the tiles on the page and identify the reagents that are needed.

Each tile includes the test name, and the number of tests that can be run with the remaining reagent.

c. To view the positions for loading the reagents, select **Materials List**, and on the Materials page select **Reagent Position List**.
The analyzer displays the Reagent Position List page.

---

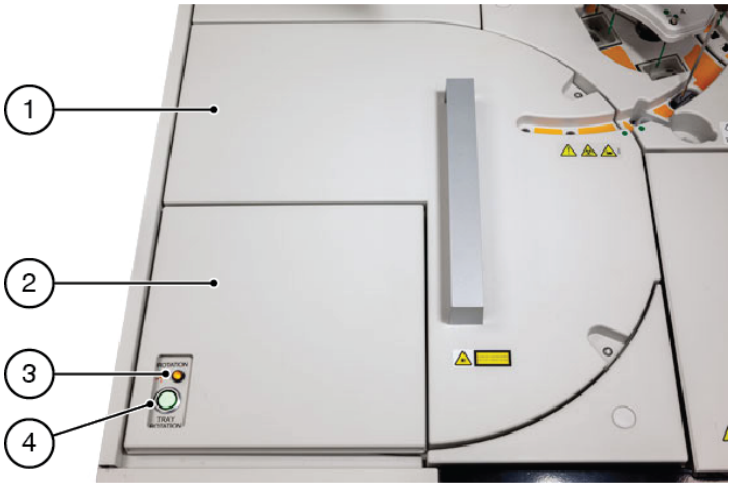
3 Open the upper cover.

---

4 Replace or add the reagent bottles.

a. Remove the large reagent refrigerator cover.

Figure 55 Reagent Refrigerator



1. Large reagent refrigerator cover
2. Small reagent refrigerator cover
3. ROTATION LED
4. TRAY ROTATION button with indicator light

b. Remove the reagent bottles that are expired, have insufficient volume, or are empty from the reagent refrigerator.

c. Place the new bottles in the reagent refrigerator. Use adapters as needed. For more information, refer to Chemistry Reagent Bottles and Adapters.

Caution

Confirm that 15-mL reagent bottles are placed on the reagent tray with the bar code label facing out. Incorrectly loaded bottles can damage the bottle or the reagent probe.

Note

If the bottle has a reagent bar code, place the bottle in any available (not assigned) position in the reagent refrigerator.

If the bottle does not have a reagent bar code, place the bottle in the correct assigned position. For more information, refer to Assigning a Dedicated Position in the Reagent Refrigerator.

d. Put back the large reagent refrigerator cover.

5 Close the upper cover.
The analyzer starts the reagent check automatically.

In the *Running* (*Standby*) state or the *Starting* (*Warmup*) state, if you remove the large reagent refrigerator cover, and then put back the large reagent refrigerator cover and close the upper cover, a reagent check starts automatically.

6 If the reagent check does not start automatically (because you opened and closed the small reagent refrigerator cover instead of using the large reagent refrigerator cover), perform a reagent check.
Refer to Performing a Chemistry Reagent Check.

Replacing Chemistry Reagents in Running (Sampling) State

Replace any reagent that displays on the Reagents Due Now page or that satisfies any of the following conditions:

- Onboard remaining time less than your laboratory requirements
- Other conditions specified in your laboratory requirements
- Expired

For more information about determining the status of reagents, refer to Monitoring the Status of Reagents.

Note

You can replace reagents when running patient samples, but not when running reagent blank, calibration, or QC samples.

Caution

If bubbles are present in the bottles, correct analysis might not occur. Check the bottles for bubbles, and remove any bubbles before placing bottles in the reagent refrigerator. Be careful to avoid contamination.

Caution

Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

Important

Condensation can form on refrigerated reagent bottles. Inspect the reagent bottle opening and the bar code label area for condensation. Remove condensation with a clean, dry, lint-free absorbent tissue before loading the reagent.

If the bar code label is dirty or has moisture on it, the analyzer cannot read the label. Inspect the bar code label and wipe off any dirt or moisture. If the analyzer still cannot read the label, enter the reagent bar code manually. Refer to Assigning a Dedicated Position in the Reagent Refrigerator.

For two-part reagents, the reagent label indicates whether the reagent is an R1 or R2 reagent.

If the analyzer is in the *Running* (*Sampling*) state, more than one sequence of bottles is on board, and the calibration and reagent are not expired, the analyzer switches to the next bottle sequence when the current bottle sequence is empty. If the reagent becomes empty or the next bottle sequence is not available, you will have an opportunity to move the analyzer into the *Paused* state, and then you can replace the reagent. During reagent blank, calibrator, or control sample processing, you cannot shift the analyzer to the *Paused* state to replace or add reagents.

The analyzer checks the volumes remaining in the reagent bottles at every aspiration. When the volumes reach the event test level, the analyzer generates an `Insufficient R1 Reagent` or `Insufficient R2 Reagent` event on the System Events page and a tile for the reagent on the Reagents Due Now page.

Confirm that the reagent is configured to trigger an alert when levels are insufficient for tests. Refer to Configuring Thresholds for Supplies.

1. Select the **Materials** task indicator on the Home page.
   The Materials page is displayed.
2. Select **Manage CC Reagent Refrigerator**.
3. Follow the instructions that are displayed.
   When you finish each step, select the button at the end of the step to proceed to the next step.

Replacing ISE Reagents in the Running (Standby) or Running (Sampling) State

If your analyzer includes an ISE module, replace ISE reagents when the onboard stability expires, the reagent expires, or the quantity of reagent is insufficient.

For onboard stability claims for the ISE reagents, refer to the reagent IFU.

If you need to replace all three reagents, replace them in this order:

1. ISE Buffer Solution
2. ISE MID Standard Solution
3. ISE Reference Solution

Caution

Do not allow the ISE Reference Solution (including what is left in the bottle, cap, and aspiration tubing) to contact the ISE Buffer Solution or ISE MID Standard Solution. ISE Reference Solution is highly concentrated. Any amount of cross contamination can affect results.

Caution

Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

You can replace ISE reagents in the *Running* (*Sampling*) state if the number of tests remaining becomes insufficient. Replace the reagent before the bottle empties.

Note

Be sure that the reagent is configured to trigger a tile to appear on the Reagents Due Now page when levels are insufficient for tests. Refer to Configuring Thresholds for Supplies.

Note

If an ISE reagent becomes insufficient when the analyzer is in the *Running* (*Sampling*) state, you will have an opportunity to move the analyzer into the *Paused* state. It takes

approximately 22 minutes to complete the transition to the *Paused* state, then the analyzer turns off the ISE operation LED.

For more information about the ISE operation LED, refer to ISE Solution Bottles.

Caution

Do not remove an ISE reagent bottle from the analyzer while the analyzer is in *Running* (*Sampling*) state (while the ISE operation LED is blinking). If you remove an ISE reagent bottle, the analyzer pauses the ISE analysis.

Materials Required:

- ISE Buffer Solution
- ISE MID Standard Solution
- ISE Reference Solution

1 Select the **Materials** task indicator on the Home page.
The Materials page is displayed.

2 Select **Load Cabinet**.

3 Follow the instructions that are displayed.

When you finish each step, select the button at the end of the step to proceed to the next step.

Important

When following the guided instructions in the *Running* (*Sampling*) state, do not close the sample handler door in an attempt to start sample processing, because doing so would terminate the guided instructions.

CHAPTER 7

Chemistry Analyzer Maintenance Tasks

Maintenance Overview

Periodic maintenance of the analyzer is required to maintain analyzer performance and reliability.

The user interface notifies you when maintenance tasks are due, provides instructions for performing the maintenance tasks, and contains a maintenance log to record that the maintenance was performed.

Periodic maintenance includes the following types of maintenance:

- Time-Interval Maintenance: Maintenance that is scheduled to occur after a specified period, such as daily, weekly, monthly, or yearly.
- Test-Interval Maintenance: Maintenance that is scheduled to occur after a specified number of tests or operations.

After any part replacement or significant maintenance, Beckman Coulter recommends that you perform QC analysis. If any shifts are observed, calibrate all onboard tests.

A trained service representative will coordinate periodic maintenance activities for your analyzer according to the terms of your service agreement, if applicable.

The maintenance frequencies displayed on the Maintenance page are determined by analysis of 2,000 or fewer tests per day. Manage the ISE maintenance schedule either periodically or by the quantity of samples analyzed. The ISE maintenance frequencies displayed on the Maintenance page are determined by analysis of 200 ISE samples per day.

Increase the amount of maintenance required depending on the quantity of tests and local environmental conditions.

Monitoring Maintenance Status

Monitor maintenance status to identify the maintenance tasks that are due or to view the status of all scheduled maintenance tasks.

When maintenance is due, the analyzer increases the number in the **Maintenance** task indicator.

1 To identify maintenance tasks that are due, view the **Maintenance** task indicator on the Home page.

   a. If the value on the task indicator is 1 or greater, select the task indicator.
   The analyzer displays the Maintenance page.

   b. Review the tasks in the Maintenance Due Now section and identify the required maintenance.

   The amount of time since the task was due is listed for each task. If the task includes a yellow vertical bar, the task is overdue.

2 To view the status of maintenance tasks that are not due, select the gray bar that is labeled **Scheduled** or **As Needed** on the Maintenance page.

   Scheduled tasks are maintenance tasks that will be due at some point. The frequency and the date and time when each task is due is listed for each task.

   As Needed tasks are optional tasks or tasks that Beckman Coulter Customer Support periodically recommends.

Reviewing the Maintenance Log

The maintenance log includes a list of all the maintenance tasks that have been completed. You can add entries to the maintenance log. You can also print or export entries from the log for review and retention.

Each record of a completed task in the maintenance log includes the Username of the person who performed the maintenance, and the status of the maintenance. A history of changes to the record is also included.

1 Open the Maintenance Log page.

   a. Select the **Maintenance** task indicator on the Home page.

   b. Select **Maintenance Log** on the Maintenance page.

   c. To find a maintenance task or tasks, enter a date range using the **From** field and **To** field at the top of the page. Select the field, make selections in the Date Entry dialog, and then select **Done**.
   The analyzer displays a list of maintenance tasks that match the selected criteria.

   d. To view the Log page for a specific task, select the task from the list.

2 To save the maintenance records in a format that is compatible with a spreadsheet, insert a USB device into one of the USB ports on the front of the console computer.

   a. Select the down arrow on **Export to File** on the Maintenance Log page.

   b. Select **Export to File**.

   c. In the Save As dialog, enter a file name for the .csv file and select the location on the USB device.

   d. Select **Save**.

3 To print a copy of the maintenance records, select the down arrow on **Export to File** on the Maintenance Log page, and then select **Print**.

4 To save the maintenance records as a .pdf file, insert a USB device into a USB port on the front of the console computer.

   a. Select the down arrow on **Export to File** on the Maintenance Log page, and then select **Save**.

   b. In the Save Maintenance Log dialog, enter a file name for the .pdf file and select the location on the USB device.

   c. Select **Save**.

5 Enter any maintenance notes on the Log page (optional).

   a. To access the Log page from the Maintenance Log page, select a task from the maintenance log.

   b. Enter your note in the Add to Notes and History field, and then select **Save**.

   c. If the analyzer displays the Enter Username dialog, enter a user name, and then select **Save**.

   Note

   The analyzer does not display the Enter Username dialog for a maintenance task that has a task status of Complete.

   The analyzer displays the Maintenance page.

6 To change the status of a maintenance task that has not been completed, select an option from the **Task Status** list on the Log page, select a user from the drop-down list in the Select User dialog, and then select **Save**.

   Note

   You cannot change the status of a maintenance task that has a status of Complete.

   The analyzer updates the status in the maintenance log, adds an entry of the change, and then displays the Maintenance page.

Performing a Maintenance Task

Selecting a task from the lists on the Maintenance page displays the Task page with steps for performing the task.

The Maintenance page displays the following types of maintenance tasks:

- Maintenance Due Now: Tasks that are due.
- Scheduled: Tasks that are scheduled, but are not due now.
- As Needed: Tasks that are not scheduled, but can be completed on an as-needed basis.

To display the list for a type of maintenance task, select the gray bar that is labeled with the type.

1 Select the **Maintenance** task indicator on the Home page.
The analyzer displays the Maintenance page.

2 To perform maintenance that is due now, select a task from the Maintenance Due Now list, and then follow the steps on the Task page.

Important

Do not select the checkbox, which is used for selecting tasks to mark as completed. Select any other part of the row containing the task that you want to perform.

3 To perform other scheduled or as-needed maintenance, select a task from the Scheduled or As Needed list, and then follow the steps on the Task page.

Important

Do not select the checkbox, which is used for selecting tasks to mark as completed. Select any other part of the row containing the task that you want to perform.

4 To register completion, add an entry for the task to the Maintenance Log page.

a. On the Task page, select **Task Completed**, or on the Maintenance page, select the checkbox next to the task and select **Task Completed**.

b. In the Enter Username dialog, enter a user name, and then select **Save**.

5 Enter any maintenance notes on the Log page (optional).

a. To access the Log page from the Maintenance Log page, select a task from the maintenance log.

b. Enter your note in the Add to Notes and History field, and then select **Save**.

c. If the analyzer displays the Enter Username dialog, enter a user name, and then select **Save**.

Note

The analyzer does not display the Enter Username dialog for a maintenance task that has a task status of Complete.

The analyzer displays the Maintenance page.

Creating a Custom Maintenance Task

Create a custom entry on the Maintenance Log page.

1 Select the **Maintenance** task indicator on the Home page.

2 Select **Maintenance Log** on the Maintenance page.

3 Select **Create Entry** on the Maintenance Log page.
The analyzer displays the Maintenance Task Information dialog.

4 Enter a name for the task, and select **Save**.
The analyzer displays the Log page.

5 Enter a note in the Add to Notes and History field (optional).

6 In **Task Status**, select a status for the task, and then select **Save**.

7 In the Enter Username dialog, enter a user name, and then select **Save**.

Maintenance Warnings and Cautions

Warning

Operate the analyzer with the covers down. If you need the covers up during maintenance, keep all body parts away from the probes and other moving parts of the analyzer. Serious injury can occur and you can damage the analyzer.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats when performing any procedure. To avoid injury, observe and follow all the warnings and cautions throughout this manual.

Caution

Failure to perform maintenance according to the instructions that display on the Task page for each maintenance task can cause problems with analyzer performance and invalidate the service agreement.

Caution

Perform all scheduled maintenance along with regular preventive maintenance. If you do not perform scheduled maintenance or maintenance is overdue, abnormal data can result.

Caution

When you press the TABLE ROTATION/DIAG button with indicator light on the analyzer the first time after you select a maintenance procedure option, the analyzer initializes. To avoid injury, do not touch any moving parts until the analyzer indicates that the analyzer is ready (as indicated by events, system states, and LEDs).

Opening and Closing the Upper Cover on the Chemistry Analyzer

⚠ Caution

To prevent fingers or hands from being pinched, avoid putting your hands near the edges of the upper cover (except for at the handle) when opening and closing the upper cover.

1 To open the upper cover, use the hidden handle located under the front edge of the cover, approximately in the center.

Figure 56 Correct Way to Grasp Analyzer Cover While Opening and Closing

2 To close the upper cover: with one hand, use the handle located under the front edge of the cover, and pull downward. If necessary, with the other hand, push down on the top part of the upper cover.

Dilution Ratios for Detergents

⚠ Caution

Prepare fresh detergents to maintain effective cleaning. Without effective cleaning, analysis results can be affected. Beckman Coulter recommends replacing diluted and

undiluted Beckman Coulter Wash Solution and Beckman Coulter Cleaning Solution daily.

However, the wash solution in the wash solution tank and the diluted wash solution in the diluted wash solution tank do not need to be replaced daily. To replenish the wash solution in the wash solution tank, replace the entire tank. The analyzer replenishes the diluted wash solution in the diluted wash solution tank automatically.

Note

Use only Beckman Coulter Wash Solution and Beckman Coulter Cleaning Solution. Refer to Parts List for Chemistry Analyzer Maintenance.

The following table includes dilution ratios for all detergents used for chemistry analyzer maintenance, except for the wash solution in the wash solution tank and the diluted wash solution in the diluted wash solution tank.

Table 33 Dilution Ratios for Detergents Used for Chemistry Analyzer Maintenance

Solution	Example Dilution	Also Used for ISE Maintenance?
Wash solution (100%)	No dilution.	No
Lipase wash **Note** Lipase wash is available only outside the United States.	No dilution.	No
Diluted wash solution (2%)	2 mL of wash solution + 98 mL of deionized water	Yes
Diluted wash solution (5%)	5 mL of wash solution + 95 mL of deionized water	No
Cleaning solution (5% sodium hypochlorite)	No dilution.	Yes
Diluted cleaning solution (1% sodium hypochlorite)	20 mL of cleaning solution + 80 mL of deionized water	No

Table 33 Dilution Ratios for Detergents Used for Chemistry Analyzer Maintenance (Continued)

Solution	Example Dilution	Also Used for ISE Maintenance?
Diluted cleaning solution (0.5% sodium hypochlorite)	10 mL of cleaning solution + 90 mL of deionized water	Yes
Commercial 1N hydrochloric acid	No dilution.	No

About the Exit Maintenance Button

The Exit Maintenance button appears on the Task pages for all maintenance tasks. It shifts the analyzer from a maintenance condition (blue) to the *Running* (*Standby*) state (green). For most maintenance tasks, it is not needed.

For those maintenance tasks that do require you to select the Exit Maintenance button, it is identified as a step in the instructions that display on the Task page.

In some instances, you might want to the use the Exit Maintenance button without performing the maintenance task in its entirety. For example, you might want to prime a syringe by selecting **Prime Reagent Probe and Syringe** on the Task page for the Replace a Reagent Probe maintenance task. After priming the syringe, you would select **Exit Maintenance** to return to the *Running* (*Standby*) state without selecting **Task Completed**. (Selecting **Task Completed** would reset the syringe usage cycle.)

Important

If you are performing a maintenance task in its entirety, try to avoid selecting the **Exit Maintenance** button, unless It is identified as a step in the instructions that display on the Task page. In many cases, you would need to restart the maintenance task from the beginning.

Confirm Selectivity Check Data

1 Confirm the selectivity check data is below the acceptable limits of 160.0 mmol/L for Na and 6.00 mmol/L for K.

a. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Perform Electrode Selectivity Check**.

b. Follow the steps on the Task page.

You do not have to perform steps 1 to 9 of the Perform Electrode Selectivity Check procedure, because they have been performed already in this procedure.

2 Open the upper cover and small STAT table cover, and remove all maintenance materials used for the procedure. Put the diluent bottle back in position 77.

Caution

To prevent rust or corrosion of the inner surface of the bottle holder, be sure to wipe the outside of the bottle clean before placing the bottle back into position.

3 Close the upper cover and small STAT table cover.

4 Calibrate the ISE.

a. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Calibrate the ISE**.

b. Follow the steps on the Task page.

View Photocal Results

If a cuvette fails the photocal, perform the following corrective action.

1 To view the details and status of the photocal performed most recently, go to the Task page for the Perform a Photocal maintenance task and select **Photocal Results**.
The analyzer displays the Photocal Results page.

Note

To view a detailed history of photocal results for a cuvette in the Cuvette Details dialog, select the cuvette number in the Unit section and select **Details**.

2 Clean or replace any cuvettes identified with Mean Check Error or Cuvette Check Error.

a. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean or Replace Individual Cuvettes**.

b. Follow the steps on the Task page.

3 Replace the photometer lamp if any cuvettes fail the Lamp Check.

The analyzer displays cuvettes with a Lamp Check Error in red. The photometer lamp is deteriorating and needs replacement.

a. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the Photometer Lamp**.

b. Follow the steps on the Task page.

Important

If you replaced the lamp due to a Lamp Check failure, wait for the lamp to come up to the correct temperature before performing another photocal during the Replace the Photometer Lamp procedure.

— Wait for the lamp to reach the correct temperature.
— Repeat the photocal on each cuvette that failed the Mean Check or Cuvette Check.
— Repeat the photocal on all cuvettes if any cuvettes failed the Lamp Check and the lamp was replaced, or numerous cuvettes failed the Mean Check or Cuvette Check.

4 If any cuvettes fail the photocal again, repeat steps 2 to 3.

Note

If a cuvette fails the photocal after cleaning, replace the cuvette with a new cuvette and repeat the photocal.

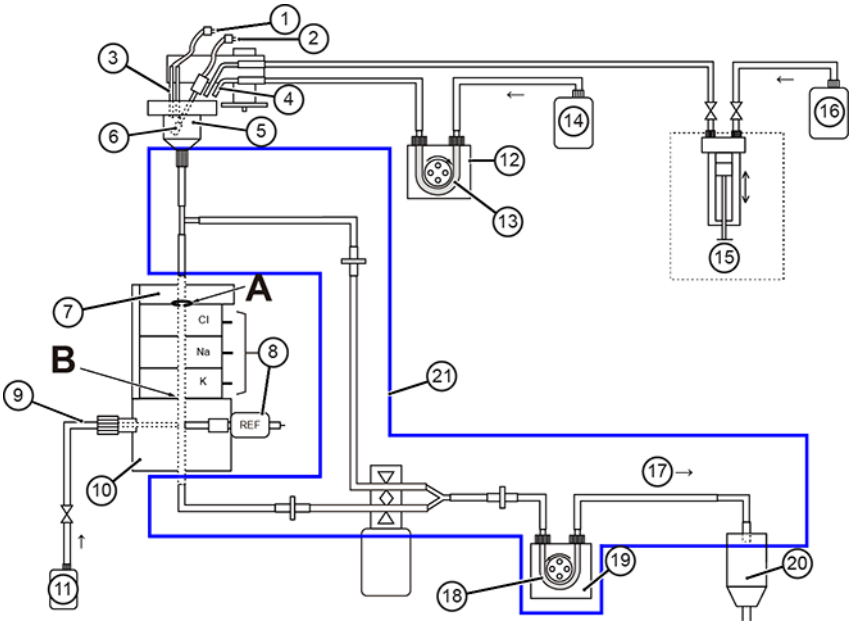
5 Perform QC, inspect the data, and recalibrate if necessary.

ISE Maintenance

ISE Tubing Block Diagram

Various maintenance procedures refer to this ISE tubing block diagram.

Figure 57 ISE Tubing Block Diagram



1. Level sensor connector
2. Mixing motor connector
3. Liquid level sensor
4. ISE MID Standard Solution and ISE Buffer Solution nozzles
5. Sample pot
6. Mix bar
7. Electrode block (inlet)
8. Electrode
9. ISE Reference Solution tubing
10. ISE REF electrode block
11. ISE Reference Solution
12. ISE MID Standard Solution roller pump
13. ISE MID Standard Solution roller pump tubing
14. ISE MID Standard Solution
15. ISE buffer syringe
16. ISE Buffer Solution
17. Waste solution
18. Mixture aspiration roller pump tubing
19. Mixture aspiration roller pump
20. Drain well
21. Flow cell tubing

CHAPTER 8

Calibration

Calibration Overview

Calibrations establish values that the analyzer uses to calculate results.

Calibrations are generated from tests that are run on a defined set of samples, called calibrators, that have known concentrations of analyte. Calibrations either pass or fail according to the calibration acceptance criteria that are defined in the calibration parameters. When a calibration passes, the calibration result becomes the active calibration for processing samples. An active calibration remains active for the duration of the calibration stability period, at which point the calibration expires and can no longer be used to calculate results.

To report a result, the analyzer requires an active calibration for each test that is requested.

Calibration Orders

The analyzer increases the number in the **Calibration** task indicator and adds a tile to the Calibrations Due Now page:

- When a calibration or reagent blank for an onboard reagent expires
- At the start of a shift during which a calibration or reagent blank for an onboard reagent will expire
- When a new reagent bottle or a new reagent lot is loaded (depending on the test configuration)
- When a new test is enabled and the corresponding calibrator is configured.

Note

For information about scheduling shifts, refer to Configuring Daily Startup.

You can also order calibrations manually that are not yet due, from the Edit Calibration Order page.

The analyzer can calibrate a maximum of 5 bottles or lot numbers of the same usable on-board reagent before the analyzer uses the reagent. To calibrate by lot or by bottle, you must select **Lot** or **Bottle** in the Stability and Interval parameters in the Calibration Parameters section of the Tests system configuration page.

Calibration Process Flow

1. Configure calibrators.
2. Run a calibration.
3. Review results.
   - If the calibration passes, the analyzer uses the calibration to assign values to samples until the calibration expires.
   - If the calibration fails, review the calibration data and troubleshoot. Refer to Troubleshooting Calibration Events.

Monitoring the Status of Calibrations

Monitor calibration status to identify the calibrations that must be performed, or to view the status of all calibrations.

When a calibration for an onboard reagent is due, or will become due soon, the analyzer increases the number in the **Calibration** task indicator.

A calibration becomes due when the calibration curve expires. A calibration is due soon if the curve will expire during the current shift. For information about scheduling shifts, refer to Configuring Daily Startup.

Note

In cases where the shift is configured for 24 hours and the calibration stability time is less than 24 hours, the calibration will be marked Due Soon 8 hours before the curve expiration.

1. To identify calibrations that are due, or will become due soon, view the **Calibration** task indicator on the Home page.
   a. If the value on the task indicator is 1 or greater, select the task indicator.
   The analyzer displays the Calibrations Due Now page.
   b. Review the tiles on the page and identify the calibration tests to run.
   For calibrations that are due soon, the tile displays the number of hours before the calibration will be due (for example, in 4 hours) and the reason that it will be due soon. For calibrations that are past due, the tile displays a yellow vertical bar and the reason that it is past due.
2. To view the status of all calibrations (due and not due), select **All Calibrations** to open the All Calibrations page.
   For calibrations that are not due, the tile displays the number of hours or days before the calibration will be due (for example, in 4 hours or in 5 days). For calibrations that are due soon, the tile displays the number of hours before the calibration will be due (for example, in 4 hours) and the reason that it will be due soon. For calibrations that are past due, the tile displays a yellow vertical bar and the reason that it is past due.
3. To view the status of all configured calibrator lots, select **Calibrators** on the Calibrations Due Now page or the All Calibrations page.
   The analyzer displays the Calibration Material List page.

Configuring Calibrators

You must configure calibrators before running calibrations.

To configure a new calibrator lot, enter the information for the new lot.

Note

When a calibrator lot expires, or if you load a reagent for a test that does not have a configured calibrator, the number on the Calibration events indicator increases.

Note

If a calibrator lot expires, calibrations for which the calibrator has been configured are canceled. The calibration order is canceled on the Edit Calibration Order page and removed from the Sample List page. You must configure a new calibrator and reorder the calibration from the Reagent Review Details page.

1 Open the Calibration Materials List page.

- To configure a calibrator that is identified in a Calibration event, select the **Calibration** event indicator in the navigation bar, and then select the event for the calibrator to configure.
- If there is no calibration event, select the **Calibration** task indicator on the Home page, and then select **Calibrators**.

2 Locate the calibrator that you want to configure, and then select **Scan**.

Note

When scanning the bar code, confirm that the values are displayed on the screen before putting back the scanner into its holder. It might take up to 10 seconds for the values to be displayed on the screen.

3 Follow the instructions that are displayed. When you finish each step, select the button at the end of the step to proceed to the next step.

4 Confirm the accuracy of the scanned information by comparing it to the calibrator's Value Assignment Sheet. If it is incorrect, scan the calibrator again. If it is still incorrect, enter the correct information in the Details page. (From the Calibration Material List page, select the calibrator and select **Details**.)

Defining a New Calibrator for a Chemistry Test

This procedure applies only to open chemistry tests.

When you are configuring a test manually or editing a configured test, define a new calibrator with a name and the number of calibrator levels. Defining a calibrator associates the calibration measuring points with the correct calibrator levels for the specified calibrator.

1 Confirm that the analyzer is in the *Running* (*Standby*) state.

2 Select **Menu** > **System Configuration**.

3 Select **Test Menu**.
The analyzer displays the Tests page.

4 In the Tests section, select the test.
The analyzer displays the Test Configuration and Chemistry Details tabs in the Tests page.

5 In the Chemistry Details tab, select **Calibration Parameters**.

6 Select **Add**.
The analyzer displays the Calibrator dialog.

7 Enter a name for the calibrator.

8 Select the number of levels that are available for the calibrator.

9 Enter a name for each level of the calibrator.

10 Select **Create**.

11 Activate the draft configuration.
Refer to Activating a Draft Configuration.

12 To view the details for the newly created calibrator, select **Calibrators** on the Calibrations Due Now page or the All Calibrations page.
The analyzer displays the Calibration Material List page.

Configuring Calibrators for Chemistry Tests Manually

You can configure a new lot of an existing chemistry calibrator without using the bar code reader.

Note

You can only configure chemistry calibrators manually. Immunoassay calibrators must be configured by scanning the calibrator card. Refer to Configuring Calibrators.

1 From the Home page, select the **Calibration** task indicator, then select **Calibrators**.
The analyzer displays the Calibration Material List page.

2 Select **Add**.
The analyzer displays Step 1 - Lot of the New Calibrator page.

3 Select a calibrator from the list in **Calibrator Name**.

4 Enter the new lot number in **Lot Number**.

5 Select the expiration date in **Expiration**.

6 Select the status (**Active** or **Not Active**) in **Status**.

7 Select a configuration option from the Load Type list box.
The analyzer displays fields for entering assignment information to each calibrator level.

8 If you selected **None Configured** from the list box, no load type is configured.

Note

If you select this option, you must specify the rack ID and cup position in the Rack View each time you run the calibrator.

a. Select **Next**.
The analyzer displays Step 2 - Tests of the New Calibrator page.

b. Enter the concentrations for each level of the calibrator.

Note

If the calibrator is for an open test, you must first define the calibrator in the Chemistry Details tab of the Tests configuration page. Refer to Defining a New Calibrator for a Chemistry Test.

c. Select **Next** again.
The analyzer displays Step 3 - Review and Save of the New Calibrator page.

d. Review the information for the calibrator, and select **Save**.
The calibrator lot is not associated with any rack or calibrator ID.

9 If you selected **Bar Code Configuration** from the list box, enter calibrator IDs for each level of the calibrator.

a. In the Bar Code column, select the field for a level of the calibrator, and scan or type the calibrator ID for the calibrator level in the Text Input dialog.

b. Use the Previous and Next buttons in order to scan or type the sample IDs for other calibrator levels, and select **Done**.

c. Select **Next**.
The analyzer displays Step 2 - Tests of the New Calibrator page.

d. Enter the concentrations for each level of the calibrator.

Note

If the calibrator is for an open test, you must first define the calibrator in the Chemistry Details tab of the Tests configuration page. Refer to Defining a New Calibrator for a Chemistry Test.

e. Select **Next** again.
The analyzer displays Step 3 - Review and Save of the New Calibrator page.

f. Review the information for the calibrator, and select **Save**.
The calibrator lot is associated with the selected calibrator IDs.

---

10 If you selected **Rack and Position Configuration** from the list box, enter rack IDs and position numbers for each level of the calibrator.

a. In Rack Type, select the type of rack you are using, or select **STAT Table**.

b. (If you selected **STAT Table** in Rack Type, skip this step.) If you selected a rack in Rack Type, select a field to the right of the first level of the calibrator, and scan or type the rack ID in the Rack ID field.

c. Enter the cup position in the Position Number field, and select **Done**.
The analyzer duplicates the specified rack ID for the other calibrator levels and assigns cup numbers sequentially to the other calibrator levels, starting with the specified cup position.

d. Select **Next**.
The analyzer displays Step 2 - Tests of the New Calibrator page.

e. Enter the concentrations for each level of the calibrator.

Note

If the calibrator is for an open test, you must first define the calibrator in the Chemistry Details tab of the Tests configuration page. Refer to Defining a New Calibrator for a Chemistry Test.

f. Select **Next** again.
The analyzer displays Step 3 - Review and Save of the New Calibrator page.

g. Review the information for the calibrator, and select **Save**.
The calibrator lot is associated with the selected rack.

Assigning Racks or Calibrator IDs to Calibrators

You can permanently assign racks or calibrator IDs to specific calibrators or calibrator levels.

When you load a rack or container with a calibrator ID that is assigned to a calibrator or calibrator level, the analyzer recognizes the rack or calibrator ID and runs the associated calibration test. You can assign racks or calibrator IDs using one of the following configuration options:

- **None Configured**: If you do not assign a rack or calibrator ID to a calibrator, you must specify a rack ID and cup position in the Rack View each time that you run the calibration.
- **Rack and Position Configuration**: When the analyzer scans the bar code label on the rack, the analyzer recognizes the rack ID and runs the assigned calibration tests.

Caution

When running calibrations using assigned racks, use the correct calibrator in the correct rack and position for the specific calibration. The analyzer runs the calibration assigned to the rack regardless of what samples are in the rack.

Note

If you assign a rack ID and position to a calibrator, the rack must only be used for the associated calibration. The analyzer will attempt to run a calibration with any container in an assigned rack.

If you expect the associated calibration to run infrequently, it might be better to use the None Configured or Bar Code Configuration option instead.

- **Bar Code Configuration**: When the analyzer scans the bar code on the sample container, the analyzer recognizes the calibrator ID and runs the assigned calibration test.

1 From the Home page, select the **Calibration** task indicator, then select **Calibrators**.
The analyzer displays the Calibration Material List page.

2 Select the calibrator that you want to associate with a rack or calibrator ID.

The calibrator name is listed in the Calibrator Name column.

3 Select **Details**.
The analyzer displays Step 1 - Lot of the Details page.

4 Select a configuration option from the Load Type list box.
The analyzer displays fields for entering assignment information to each calibrator level.

5 If you selected **None Configured** from the list box, no load type is configured.

Note

If you select this option, you must specify the rack ID and cup position in the Rack View each time you run the calibrator.

a. Select **Next**.
The analyzer displays Step 2 - Tests of the Details page.

b. Select **Next** again.
The analyzer displays Step 3 - Review and Save of the Details page.

c. Review the information for the calibrator, and select **Save**.
The calibrator lot is not associated with any rack or calibrator ID.

6 If you selected **Bar Code Configuration** from the list box, enter calibrator IDs for each level of the calibrator.

   a. In the Bar Code column, select the field for a level of the calibrator, and scan or type the calibrator ID for the calibrator level in the Text Input dialog.

   b. Use the Previous and Next buttons in order to scan or type the sample IDs for other calibrator levels, and select **Done**.

   c. Select **Next**.
   The analyzer displays Step 2 - Tests of the Details page.

   d. Select **Next** again.
   The analyzer displays Step 3 - Review and Save of the Details page.

   e. Review the information for the calibrator, and select **Save**.
   The calibrator lot is associated with the selected calibrator IDs.

7 If you selected **Rack and Position Configuration** from the list box, enter rack IDs and position numbers for each level of the calibrator.

   a. In Rack Type, select the type of rack you are using, or select **STAT Table**.

   b. (If you selected **STAT Table** in Rack Type, skip this step.) If you selected a rack in Rack Type, select a field to the right of the first level of the calibrator, and scan or type the rack ID in the Rack ID field.

   c. Enter the cup position in the Position Number field, and select **Done**.
   The analyzer duplicates the specified rack ID for the other calibrator levels and assigns cup numbers sequentially to the other calibrator levels, starting with the specified cup position.

   d. Select **Next**.
   The analyzer displays Step 2 - Tests of the Details page.

   e. Select **Next** again.
   The analyzer displays Step 3 - Review and Save of the Details page.

   f. Review the information for the calibrator, and select **Save**.
   The calibrator lot is associated with the selected rack.

Running Calibrations

When a test requires a calibration, the analyzer automatically increases the number in the **Calibration** task indicator and adds a tile to the Calibrations Due Now page. To run a calibration, you must add a calibration order manually.

Calibrations become due in the following instances:

- When a calibration or reagent blank for an onboard reagent expires
- At the start of a shift during which a calibration or reagent blank for an onboard reagent will expire

- When a new reagent bottle or a new reagent lot is loaded (depending on the test configuration)
- When a new test is enabled and the corresponding calibrator is configured.

Note

Individual calibrators can be assigned to specific rack IDs or specific calibrator bar codes, or not assigned. To determine how a calibration has been assigned, open the Calibration Material List page for the calibrator. From the Home page, select the **Calibration** task indicator, then select **Calibrators**. The Loading Configuration column displays the configuration of the calibrator.

Note

Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.

Note

You can view information about the calibrator and reagents that are associated with a calibration order on the Calibration Order Details page. Refer to Reviewing Calibration Order Details. The Rack View section of the Edit Calibration Order page displays a diagram for each calibration that is ordered.

Note

The Tests section of the Edit Calibration Order page displays a list of enabled calibrations. Calibrations that are due are marked with a yellow vertical bar in the Name column.

Note

It is recommended that the setting for Loading Configuration (Rack and Position Configuration, None Configured, or Bar Code Configuration) for your lab is consistent for all analyzers in your lab. If the setting is consistent, only one of the three steps, which depend on the setting, will be applicable to you.

---

1 Select the **Calibration** task indicator on the Home page.
The analyzer displays the Calibrations Due Now page.

---

2 Select **Orders**.
The analyzer displays the Edit Calibration Order page.

3 For each test that you want to calibrate, select the checkbox in the Calibrate column. Confirm that the checkbox in the RB column is selected to run a reagent blank for that test.

Note

If there are multiple onboard lots or bottles of the same reagent, and you have configured Lot or Bottle in the Stability and Interval parameters in the Calibration Parameters section of the Tests system configuration page, each lot or bottle will be calibrated according the setting.

4 If the Loading Configuration of the calibration is None Configured, place the sample containers in a rack that is not assigned to a calibration, control sample, or test order, and then enter a rack ID.

a. Enter the rack ID in the field below the rack diagram (type the ID or scan the bar code label).

The rack ID can be found on the rack ID label affixed to the handle of the rack.

Note

If you enter or change any rack IDs in the Rack View section, you must provide rack IDs for every rack in the Rack View section.

b. Save the rack ID by selecting **Save** and then **OK**.

5 If the Loading Configuration of the calibration is Rack and Position Configuration, place the sample containers in the rack and position that is indicated in the rack diagram. Be sure that the rack ID label on the rack matches the rack ID displayed below the rack diagram. Select **Save** and then **OK**.

6 If the Loading Configuration of the calibration is Bar Code Configuration, place the sample containers in a rack that is not assigned to a calibration, control sample, or test order. Select **Save** and then **OK**.

7 Fill each sample container with the quantity of the calibrator level that is specified in the diagrams.

8 Place the racks in the sample handler and close the sample handler door.

Note

When multiple calibrators for two or more tests are placed in one rack, if any level of a calibrator is mistakenly not placed in the rack, the rack is returned and the analyzer does not perform calibrations for any tests in the rack.

Running a Calibration Using the STAT Table

When a test requires a calibration, the analyzer automatically increases the number in the **Calibration** task indicator and adds a tile to the Calibrations Due Now page. You can also add a calibration order manually to run a calibration that the analyzer has not ordered.

Calibrations become due in the following instances:

- When a calibration or reagent blank for an onboard reagent expires
- At the start of a shift during which a calibration or reagent blank for an onboard reagent will expire
- When a new reagent bottle or a new reagent lot is loaded (depending on the test configuration)
- When a new test is enabled and the corresponding calibrator is configured.

Note

You can view information about the calibrator and reagents that are associated with a calibration order on the Calibration Order Details page. Refer to Reviewing Calibration Order Details. The Rack View section of the Edit Calibration Order page displays a diagram for each calibration that is ordered.

Note

The Tests section of the Edit Calibration Order page displays a list of enabled calibrations. Calibrations that are due are marked with a yellow vertical bar in the Name column.

1. Select the **Calibration** task indicator on the Home page.
   The analyzer displays the Calibrations Due Now page.
2. Select **Orders**.
   The analyzer displays the Edit Calibration Order page.
3. For a test that you want to calibrate using the STAT table, select the checkbox in the Calibrate column. Confirm that the checkbox in the RB column is selected to run a reagent blank for that test.
4. If the calibrator is configured for DxLAB Rack, or for Bar Code Configuration, change the rack type to **STAT Table**.
   a. In the Rack View section, if it is not already selected, select the rack for the calibration, and select **Change Rack**.
   b. In the Change Rack dialog, select **OK**.
   The analyzer changes the diagram of the calibration in a rack to a diagram of the calibration in the STAT table.

   Note

   If you assigned the individual calibrator levels to specific tube IDs, both the rack and STAT table options are available in the Rack View section.

5 Select **Save** and then **OK**.

6 Confirm that the analyzer is in the *Running (Standby)* state and that the ROTATION LED is off.

7 Open the small STAT table cover and place the calibrators in the STAT table.

   a. Fill each sample container with the calibration level and volume that is specified on the diagram.

   b. Place sample containers in the positions that are highlighted on the diagram in the Rack View section.

8 Close the small STAT table cover.

9 Select the Start button in the STAT Table state area of the status bar.
The analyzer displays the STAT Start dialog.

10 Select **OK**.

   The analyzer performs a STAT table check and performs a reagent blank for all reagent blank orders with a status of Ordered. If the STAT table check does not identify any errors, the analyzer starts analysis. If there are errors, the analyzer displays events on the System Events page.

   a. If the STAT table check identifies errors, review the event on the System Events page.

   b. After performing corrective actions, repeat this step.

Note

When multiple calibrators for two or more tests are placed in the STAT table, or when calibrators and patients samples are placed in the STAT table at the same time, if any level of a calibrator is mistakenly not placed in the STAT table, the analyzer does not perform calibrations or patient sample processing for any tests in the STAT table.

Canceling a Manually Ordered Calibration

Cancel manually ordered calibrations on the Edit Calibration Order page. You can cancel more than one calibration at a time.

1 Select the **Calibration** task indicator on the Home page.
The analyzer displays the Calibrations Due Now page.

2 Select **Orders**.
The analyzer displays the Edit Calibration Order page.

3 Cancel one or more calibration orders.

a. Scroll through the list of available test calibrations or enter the full or partial test name in the **Test Name** search field.

b. Clear the **Calibrate** checkboxes for the calibrations to cancel.
The analyzer removes the rack diagram from the Edit Calibration Order page.

c. Select **Save**.

Manually Calibrating a Specific Reagent by Lot or by Bottle

The analyzer can calibrate a maximum of 5 lot numbers or bottles (serial numbers) of the same usable on-board reagent before the analyzer uses the reagent. This is useful when you have multiple reagents for the same test on the analyzer.

The analyzer must be configured to perform calibrations by lot or by bottle. Refer to Configuring Calibrations by Lot or by Bottle.

Note

Individual calibrators can be assigned to specific rack IDs or sample container bar codes, or not assigned. To determine how a calibration has been assigned, open the Calibration Material List page for the calibrator. Select **Menu** > **Calibration Material List**. The Loading Configuration column displays the configuration of the calibrator.

Note

It is recommended that the setting for Loading Configuration (Rack and Position Configuration, None Configured, or Bar Code Configuration) for your lab is consistent for all analyzers in your lab. If the setting is consistent, only one of the three steps, which depend on the setting, will be applicable to you.

1 Open the Reagent Review Details page.

a. Select the **Reagents** task indicator on the Home page.
The analyzer displays the Reagents Due Now page.

b. Select a tile from the Reagents Due Now page, or select **All Reagents** and then select a tile.

c. Select the **Details** button.
The analyzer displays the Reagent Review Details page.

2 Select the reagent lot or bottle (serial number) that you want to calibrate.

3 Order a calibration or reagent blank for the test.

a. Select **Order Calibration**.
When you select **Order Calibration**, the corresponding reagent blank is ordered too.

b. To order only a reagent blank, select **Order RB**.

The analyzer orders the calibration.

4 Select the **Calibration** task indicator on the Home page.
The analyzer displays the Calibrations Due Now page.

5 Select **Orders**.
The analyzer displays the Edit Calibration Order page.

6 If the Loading Configuration of the calibration is Rack and Position Configuration, place the sample containers in the rack and position that is indicated in the rack diagram. Be sure that the rack ID label on the rack matches the rack ID displayed below the rack diagram.

7 If the Loading Configuration of the calibration is None Configured, place the sample containers in a rack that is not assigned to a calibration, control sample, or test order.

a. Enter the rack ID in the field below the rack diagram (type the ID or scan the bar code label).

The rack ID can be found on the rack ID label affixed to the handle of the rack.

Note

If you enter or change any rack IDs in the Rack View section, you must provide rack IDs for every rack in the Rack View section.

b. Save the rack ID by selecting **Save** and then **OK**.

8 If the Loading Configuration of the calibration is Bar Code Configuration, place the sample containers in a rack that is not assigned to a calibration, control sample, or test order.

9 Fill each sample container with the quantity of the calibrator level that is specified in the diagrams.

10 Place the racks in the sample handler and close the sample handler door.

Note

The calibrations are performed before any samples that are in Ordered status, but any samples that are already in Presented or In Progress status must be processed first.

Changing the Active Calibrator Lot

You can change the calibrator lot that will be used for calibrating tests.

The active calibrator lot is the lot that is used when running calibration tests. Only one calibrator lot for a specific test can be active. To use a different configured calibrator lot, you must change the active lot.

Note

You can only change the calibrator lot that will be used for future calibrations. You cannot change the active calibration curve used for calculating test results.

1 From the Home page, select the **Calibration** task indicator to open the Calibrations Due Now page.

2 Select **Calibrators**.
The analyzer displays a list of configured calibrators.

3 Select the calibrator lot that you want to use, and then select **Set Active**.
The status of the selected lot is changed to Active, and the status of the previously active lot is changed to Not Active.

Reviewing Calibration Order Details

Use the Calibration Order Details page to view information about the calibrator and reagents that are associated with a calibration order.

The Calibration Order Details page displays information such as the calibrator name, lot number and expiration date, the reagent lot and serial number, completion time for the calibration, and the status (Passed, Failed, Ordered, Presented, or In Progress) of the calibration curve.

1 To view the Calibration Order Details page, select the **Sample List** task indicator on the Home page, and then select the calibration order to view. If the calibration order that you want to view is not displayed in the **Ordered** view, select the **Active** or **All** views to locate an order that is in progress or completed.

2 To view the Calibration Curve Details page, select the **View** link in the Curve Details column.

For more information about the Calibration Curve Details page, refer to Reviewing Calibration Data.

Reviewing Calibration Data

The Calibration Curve Details page provides information about calibrations.

The Calibration Curve Details page is divided into the following three sections:

- Calibration Summary: Displays general information about the calibration, including the Passed or Failed status of the calibration.
- Calibration Summary Details: Displays information about each calibration level.
- Chart Details: Displays the calibration curve and the Replicate Details.

Note

For failed calibrations, the chart displays data points in red.

1 Select the **Calibration** task indicator on the Home page.
The analyzer displays the Calibrations Due Now page.

2 Select **All Calibrations**.
The analyzer displays the All Calibrations page.

3 Select the tile for the calibration that you want to view, and then select **Details**.
The analyzer displays the Calibration Curve Details page.

Note

Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.

4 To view the Calibration Summary, the Calibration Summary Details, and the Chart Details for a specific calibration, select the calibration record in **Select Calibration Record**.

5 For chemistry tests, view additional details for each calibration, such as sample information, reagent information, reaction data, and cuvettes used.

a. Select **Reaction Detail**.
The analyzer displays the Chemistry Results page.

b. Use the Previous and Next buttons to view the details for each calibration replicate.

6 For ISE tests, to view additional details for each calibration, such as sample information, reagent information, reaction data, and electrode information, select **Reaction Detail**.
The analyzer displays the ISE Reaction Detail page.

Rerunning a Calibration

To confirm results from a calibration that failed, rerun the test from the Calibration Events page.

You can rerun a calibration if the event occurred because of a calibration failure, but not if the event occurred because of an expired calibrator.

Note

The Reorder button is not for reordering ISE calibrations. To rerun an ISE calibration, perform the Calibrate the ISE maintenance task.

1 Select the checkbox for the calibration on the Calibration Events page.

2 Select **Reorder**.

3 Enter any text into the Text Input dialog, and then enter comments about the reorder in the Calibration Failure: Add Comments dialog.

Note

Deselecting the **Reorder** checkbox in the dialog, removes the test from the calibration order.

The analyzer dismisses the calibration event and adds the test to the calibration orders.

CHAPTER 9
Quality Control

Quality Control Overview

In clinical laboratory testing, Quality Control (QC) includes monitoring the performance of a test to confirm that results are valid and can be released to the requesting health care provider.

Run control samples as recommended in the reagent Instructions for Use. After installing new software, run control samples for all tests that you use to report patient results, then recalibrate any tests that have out-of-range control results. You may choose to run control samples more frequently based on good laboratory practices or laboratory accreditation requirements and applicable laws.

Monitoring test performance is done using control materials from a single control lot. A control lot designates a quantity of control material manufactured in one process, with the same concentration values and the same expiration date. A control lot can include multiple concentration levels (multilevel control material).

The analyzer provides a QC management system to help the clinical lab monitor test performance. You must configure the QC information to use the software. Before using the analyzer to run a specific QC test, the control material must be configured.

QC tests generate alerts based on the Westgard rules that are configured for the control lot or test.

QC Test Orders

The analyzer orders QC tests automatically when the QC tests are due. The frequency of QC tests is configured in System Configuration. The QC Due Now page displays the QC tests that have been automatically ordered. The Edit QC Order page displays diagrams of racks or of the STAT table with the QC tests and levels that have been ordered. If racks have been assigned to a control material lot, the rack ID is displayed below the rack diagram. You can also order QC tests that are not due from the Edit QC Order page.

The analyzer can also automatically order QC tests by reagent pack. The analyzer must be configured to allow QC by reagent pack in System Configuration. The first time QC by reagent pack is enabled, the analyzer orders QC tests for all reagent packs currently loaded on the analyzer. After that, the analyzer adds QC test for any new reagent packs that are added. The QC tests for reagent packs are scheduled according to the frequency that was configured in System Configuration.

Westgard Rules

Westgard rules are the statistical criteria used to monitor the performance of a specific test or group of tests.

Applying Westgard rules enables the analyzer to report an event when there could be a problem with an analyzer, laboratory process, reagent, or control material, and investigation is warranted. Multiple rules can be applied to create a rule set. Each rule set applies to one or more tests on a single control material. Multiple rule sets can be applied to a single control material or test.

The analyzer includes a default rule set (all of the selectable Westgard rules except for 3_{1S}) for control materials that do not have a specified rule set. You can specify a new rule set by selecting which rules to apply. You can select from the following rules:

- 1_{2S}: A result that exceeds the target by ±2 SD violates the 1_{2S} rule. Approximately 5% of results will be rejected by this rule.
- 1_{3S}: A result that exceeds the target by ±3 SD violates the 1_{3S} rule. Results that break this rule indicate random errors.
- 2_{2S}: Two consecutive results that exceed the same target +2 SD or the same target -2 SD violate the 2_{2S} rule. Results that break this rule indicate systematic errors.
- 3_{1S}: Three consecutive results that exceed the same target ±1 SD on one side of the target violate the 3_{1S} rule. Results that break this rule indicate systematic errors.
- 4_{1S}: Four consecutive results that exceed the same target ±1 SD on one side of the target violate the 4_{1S} rule. Results that break this rule indicate systematic errors.
- 10_x: Ten consecutive results that are on one side of the target violate the 10_x rule. Results that break this rule indicate systematic errors.
- 12_x: Twelve consecutive results that are on one side of the target violate the 12_x rule. Results that break this rule indicate systematic errors.

Monitoring QC Status

Monitor QC status to identify the tasks to be performed, the status of all QC tests, and the control materials that are configured for the analyzer.

When a QC test is due, or due soon, the analyzer orders the QC test automatically and increases the number in the **QC** task indicator.

The tiles for the QC tests on the QC Due Now page and the All QC page provide the following status information about QC tests:

- For tests that are not due, the tile (on the All QC page only) displays the number of hours or days before the test is due. For example, in 4 hours or in 5 days.
- For tests that are due soon, the tile displays a yellow vertical bar and the number of hours before the test is due. For example, in 4 hours.
- For tests that are past due for less than 1 day, the tile displays a yellow vertical bar and the number of hours since the test was due. For example, 4 hours ago.
- For tests that are past due for more than 1 day, the tile displays a red vertical bar and the number days since the test was due. For example, 5 days ago.

---

1 To identify QC tasks that are due, view the **QC** task indicator on the Home page.

a. If the value on the task indicator is 1 or greater, select the task indicator. The analyzer displays the QC Due Now page.

b. Review the tiles on the page and identify the QC tests to run.

---

2 To view the status of all QC tests (due and not due), select **All QC** on the QC Due Now page to go to the All QC page.

---

3 To view all control materials that are configured for the analyzer, select **Control Materials** on the All QC page or the QC Due Now page.

Configuring Control Materials

Before using a new control material or a new control material lot, configure the new control material or control material lot.

For a new control material, enter the information about the manufacturer, lot number, expiration date, levels, QC rules and alerts, and tests. To configure a new lot of a previously configured control material, you still must perform the steps in this procedure.

You can define multiple control levels for a control lot, and each control level can apply to different tests. You can include level-specific lot numbers for each level using the information on the package insert. A control material can include analytes for multiple tests at various concentration levels.

---

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

---

2 Select **Control Materials** from the QC Due Now page.
The analyzer displays the Control Materials page.

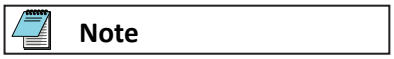
---

3 Select **Add**.
The analyzer displays Step 1- Lot of the New Control Material page.

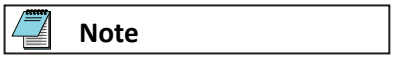
---

4 Enter the information for the control material lot.

a. Enter information in the **Control Material Name**, **Manufacturer**, and **Master Lot Number** fields.



Manufacturer and **Master Lot Number** are optional.



Unless you also enter a master expiration date, entering a master lot number is optional.

b. Select an option for Status.

Select **In Evaluation** when you want to use a new control material to determine the expected mean and SD values for future QC testing. Select **In Use** to begin using this control material lot for QC testing. You cannot select **Not Used** when configuring a new lot (either adding or copying information). You can select this option only when you are editing an existing lot.

The option Not Used prevents the control material lot from being used for QC testing. Once Not Used is selected, it cannot be changed, and the control material lot cannot be used.

c. For Load Type, select **Sample with bar code** or **Sample with no bar code**.

Note

If **Sample with no bar code** is selected, a sample rack must be dedicated for use with the controls being configured. The specific rack ID must be entered later in this procedure.

d. If you selected **Sample with no bar code** in Load Type, then for Rack Type select **DxLAB Rack** or **STAT Table**.

e. Select an option from Sample Type.

---

5 Enter the information for each level of the control material.

Note

The master lot number and expiration date are used to enter the lot number and expiration date for each level automatically. The analyzer generates lot numbers for new levels in increments of 1 after the master lot number. If the level has a different lot number or expiration date than the new one generated by the analyzer, change the lot number or expiration date for that level. If the **Lot Number** and **Expiration Date** fields for the level are empty, add a lot number and expiration date.

a. If you selected **Sample with no bar code** for the load type, and **DxLAB Rack** for the rack type, enter information in the **Level Name**, **Rack ID**, and **Rack Position** fields.

b. If you selected **Sample with no bar code** for the load type, and **STAT Table** for the rack type, enter information in the **Level Name** and **Rack Position** fields.

c. If you selected **Sample with Bar Code** for the load type, enter the information in the **Level Name** and **Sample ID** fields.

d. To add a lot number for a control level, enter a new number in the **Lot Number** field. To change a lot number for a control level, delete the old number in the **Lot Number** field and enter the new number.

e. To add or change the expiration date for a control level, select the **Expiration Date** field and use the calendar dialog to enter the expiration date. Then select **Done**.

f. To add more levels, select **Add Level**, and then enter the information for the new level.

g. To delete a level, select the level, and then select **Delete Level**.

---

6 Configure Westgard rules for all samples in the lot by selecting the button for Westgard Rules.

Note

A default set of Westgard rules is applied to a new control material. When the default set of Westgard rules is applied, the analyzer displays the **Default** button for the Westgard Rules. When a custom set of rules is applied to a control material, the analyzer displays the **Custom** button for the Westgard Rules.

The analyzer displays the Westgard Rules Configuration dialog.

---

7 Select the Westgard rules that you want from the Westgard Rules Configuration dialog.

a. To view the definition of a rule and an example of a chart, select the rule name.

b. To use a rule, select the **Apply** checkbox for that rule.

c. To not use a rule, clear the **Apply** checkbox for that rule.

d. To save your changes, select **Save**.

The analyzer closes the Westgard Rules Configuration dialog.

---

8 To return to the default Westgard rules, select the **Custom** Westgard Rules button, and then select **Apply Default Rules** in the Westgard Rules Configuration dialog.
The analyzer applies the default rules to the control and closes the Westgard Rules Configuration dialog.

---

9 After entering the information, select **Next**.
The analyzer displays the Step 2 - Tests of the New Control Material page.

---

10 Select the tests and enter the test information for the control material.

a. Select the box next to the name of each test that you want to include.

b. Enter an expected mean in **Expected Mean** and standard deviation in **SD** for each test and control level. Then select **Done**.

---

11 Configure Westgard rules for specific tests by selecting the button in Westgard Rules for the specific test.

Note

Default Westgard rules are applied to a new control material. When default Westgard rules are applied, the **Default** button is displayed. When custom rules are applied to a control material, the **Custom** button is displayed.

The analyzer displays the Westgard Rules Configuration dialog.

---

12 Select the Westgard rules that you want from the Westgard Rules Configuration dialog.

a. To view the definition of a rule and an example of a chart, select the rule name.

b. To use a rule, select the **Apply** checkbox for that rule.

c. To not use a rule, clear the **Apply** checkbox for that rule.

d. To save your changes, select **Save**.

The analyzer closes the Westgard Rules Configuration dialog.

---

13 To return to the default Westgard rules, select the **Custom** Westgard Rules button, and then select **Apply Default Rules** in the Westgard Rules Configuration dialog.
The analyzer applies the default rules to the control and closes the Westgard Rules Configuration dialog.

14 After entering the information, select **Next**.
The analyzer displays Step 3 - Review and Save of the New Control Material page.

15 Review the information for the control material.

a. Confirm that the information on the page is correct.

b. To return to a previous step and modify the information, select **Previous**.

c. To accept and save the information, select **Save**.
The analyzer displays the Control Materials page, which lists all the control materials that are configured for the analyzer.

Copying Information from a Control Material Lot

To configure a new lot of a control material that was configured previously, you can use the Copy feature to copy the information from the previous lot.

When you use the Copy feature, the analyzer copies all the information from the previously configured control material except for the master lot number and expiration date. The analyzer also changes the status of the new control material lot to In Evaluation.

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

2 Select **Control Materials** from the QC Due Now page.
The analyzer displays the Control Materials page.

3 Select the control material lot to copy.

4 Select **Copy**.
The analyzer displays Step 1 - Lot of the Copy Control Lot page.

5 Enter and review the information for the new lot.

Follow the instructions for configuring control materials, starting with the step for entering the information for the control material lot in Step 1 - Lot of the New Control Material page. Refer to Configuring Control Materials.

Editing a Control Material Lot

You can edit information for a control material lot, such as change rack configuration, expected SD values, or Westgard rules, or add or remove tests.

Note

If a QC test order has a status of Ordered or In Progress for a control material lot, you cannot edit the lot information. To edit lot information, cancel the QC test order or wait until the QC test order is complete.

1. Select the **QC** task indicator on the Home page.
   The analyzer displays the QC Due Now page.
2. Select **Control Materials** from the QC Due Now page.
   The analyzer displays the Control Materials page.
3. Select the control material to edit.
4. Select **Edit**.
   The analyzer displays Step 1 - Lot of the Edit Control Lot page.
5. Make any required changes to the information for the control material lot, control levels, or lot-specific Westgard rules.
6. Select **Next**.
   The analyzer displays Step 2 - Tests of the Edit Control Lot page.
7. Make any required changes to the tests that use this control material, a test SD or mean, or test-specific Westgard rules.
8. Select **Next**.
   The analyzer displays Step 3 - Review and Save of the Edit Control Lot page.
9. Review the information for the control material.
   a. Confirm that the information on the page is correct.
   b. To return to a previous step and modify the information, select **Previous**.
   c. To accept and save the information, select **Save**.
   The analyzer displays the Control Materials page, which lists all the control materials that are configured for the analyzer.

Deleting a Control Material

A control material can be removed from the list of configured control materials to prevent the control material from being used.

Note

To delete a control material, the status of the control material lot must be Not Used. You can edit the status of the control material. Refer to Editing a Control Material Lot.

Caution

The option Not Used prevents the control material lot from being used for QC testing. Once Not Used is selected, it cannot be changed, and the control material lot cannot be used.

1. Select the **QC** task indicator on the Home page.
   The analyzer displays the QC Due Now page.
2. Select **Control Materials** from the QC Due Now page.
   The analyzer displays the Control Materials page.
3. Select a control material lot to delete that has a status of Not Used.
4. Select **Delete**.
   The analyzer displays a confirmation dialog.
5. Select **Yes** to delete the control material.
   The analyzer deletes the control material from the Control Materials page.

Running QC Tests

When a QC test is required, the analyzer increases the number in the **QC** task indicator and orders the QC test automatically. The analyzer also generates a loading guide that indicates where to place the samples in the rack.

Before the analyzer can order QC tests, the control material must be configured. If the control material was configured with a Load Type of **Sample with Bar Code**, the rack ID must be entered in the **Rack ID** field before running the QC test.

If the control material was configured with a Rack Type of **DxLAB Rack**, the rack ID that was configured is displayed in the **Rack ID** field. If the control material was configured with a Rack Type of **STAT Table**, the positions for each sample are displayed in the Rack View.

1. Select the **QC** task indicator on the Home page.
   The analyzer displays the QC Due Now page.
2. To access the Edit QC Order page, select **Orders**.

   Note

   Checkboxes that are filled with solid blue squares indicate selections that were made automatically by the analyzer. Checkboxes with checkmarks indicate manual selections.
3. Select the test that you want to order by selecting the box in the Tests section.

   A filled-in checkbox indicates that a test is selected.

   The analyzer displays the associated control materials in the Materials section of the page.
4. Select the control materials and levels that you want to include in the order by selecting the boxes in the Materials section.
   The analyzer adds the control samples to the rack diagram in the Rack View section.

5 To include control materials that are In Evaluation, select the **In Evaluation** box at the bottom of the Materials section.

Materials that are In Evaluation are displayed in the list with an asterisk.

6 Place the control samples in the rack and confirm the rack ID in the rack diagram.

Repeat for each rack.

a. Place sample containers in the rack positions that are highlighted in Rack View.

b. Fill each sample container with the control sample level that is specified on the diagrams.

c. If a rack diagram does not have a rack ID under the rack diagram, enter the rack ID in the field.

The rack ID can be found on the rack ID label that is on the rack. Select the field and then either type the rack ID or use the handheld bar code reader to scan the bar code label that is on the rack.

7 Select **Save**.

8 Place the racks in the sample handler and close the sample handler door.

Running QC Tests Using the STAT Table

If you selected **Sample with no bar code** in Load Type and **STAT Table** for Rack Type when configuring the control material, when a QC test is required, the analyzer increases the number in the **QC** task indicator and orders the QC test on the STAT table automatically. The analyzer also displays a Rack View that indicates where to place the samples in the STAT table.

Note

If the analyzer goes to the *Error* (*Stopped*) state when a sample is still in the *Presented* sample state (the analyzer has started scanning the sample bar codes but has not started aspirating the sample), you can resume processing the sample without re-ordering tests. To resume processing the sample, either reload it or restart the STAT table.

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

2 To access the Edit QC Order page, select **Orders**.

Note

Checkboxes that are filled with solid blue squares indicate selections that were made automatically by the analyzer. Checkboxes with checkmarks indicate manual selections.

3 Select the test that you want to order by selecting the box in the Tests section.

A filled-in checkbox indicates that a test is selected.

The analyzer displays the associated control materials in the Materials section of the page.

4 Select the control materials and levels that you want to include in the order by selecting the boxes in the Materials section.
The analyzer adds the control samples to the rack diagram in the Rack View section.

5 To include control materials that are In Evaluation, select the **In Evaluation** box at the bottom of the Materials section.

Materials that are In Evaluation are displayed in the list with an asterisk.

6 If the Rack View section does not already display a diagram of the QC test in the STAT table, in the Rack View section, select the rack for the QC test, and select **Change Rack**.
The analyzer changes the diagram of the QC test in a rack to a diagram of the QC test in the STAT table.

7 Select **Save**.

8 Confirm that the analyzer is in the *Running (Standby)* state and that the ROTATION LED is off.

9 Open the small STAT table cover and place the control samples in the STAT table.

a. Fill each sample container with the control sample level and volume that is specified on the diagram.

b. Place sample containers in the positions that are highlighted on the diagram in the Rack View section.

10 Close the small STAT table cover.

11 Select the Start button in the STAT Table state area of the status bar.
The analyzer displays the STAT Start dialog.

12 Select **OK**.

The analyzer performs a STAT table check and performs a reagent blank for all reagent blank orders with a status of Ordered. If the STAT table check does not identify any errors, the analyzer starts analysis. If there are errors, the analyzer displays events on the System Events page.

a. If the STAT table check identifies errors, review the event on the System Events page.

b. After performing corrective actions, repeat this step.

Adding a QC Test

Add QC tests to a QC test order on the Edit QC Order page. You can add more than one QC test at a time.

Note

You can run QC tests that are not due by adding the test to a QC test order.

Note

Before you can add QC tests to a QC order, the control material must be configured.

The left side of the Edit QC Order page displays a list of available QC tests. A filled-in checkbox next to the QC test indicates that the test is due and has been ordered automatically.

1. Select the **QC** task indicator on the Home page.
   The analyzer displays the QC Due Now page.

2. To access the Edit QC Order page, select **Orders**.

   Note

   Checkboxes that are filled with solid blue squares indicate selections that were made automatically by the analyzer. Checkboxes with checkmarks indicate manual selections.

3. Select the test that you want to order by selecting the box in the Tests section.
   A filled-in checkbox indicates that a test is selected.
   The analyzer displays the associated control materials in the Materials section of the page.

4. Select the control materials and levels that you want to include in the order by selecting the boxes in the Materials section.
   The analyzer adds the control samples to the rack diagram in the Rack View section.

5. To include control materials that are In Evaluation, select the **In Evaluation** box at the bottom of the Materials section.
   Materials that are In Evaluation are displayed in the list with an asterisk.

6. Place the control samples in the rack and confirm the rack ID in the rack diagram.
   Repeat for each rack.

a. Place sample containers in the rack positions that are highlighted in Rack View.

b. Fill each sample container with the control sample level that is specified on the diagrams.

c. If a rack diagram does not have a rack ID under the rack diagram, enter the rack ID in the field.

The rack ID can be found on the rack ID label that is on the rack. Select the field and then either type the rack ID or use the handheld bar code reader to scan the bar code label that is on the rack.

7 Select **Save**.

8 Place the racks in the sample handler and close the sample handler door.

Canceling a QC Test Order

You can cancel a QC test order on the Edit QC Order page. You can cancel more than one QC test at a time.

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

2 To access the Edit QC Order page, select **Orders**.

Note

Checkboxes that are filled with solid blue squares indicate selections that were made automatically by the analyzer. Checkboxes with checkmarks indicate manual selections.

3 To cancel one or more control samples for a selected test, clear the checkbox for the control material in the Materials section.
The analyzer removes the samples from the rack diagram in the Rack View section.

4 Select **Save**.

Dismissing a QC Test Order

You can skip a QC test by selecting **Dismiss** from the QC Due Now page.

When you dismiss a QC test, the tile is removed from the QC Due Now page. On the Home page, the analyzer decreases the number on the **QC** task indicator by the number of QC tests that were deferred. The dismissed test remains on the All QC page and shows the expiration status of the test. The test will be displayed on the QC Due Now page the next time that QC test is due (based on the configured frequency of that QC test).

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

2 Select the tile for the QC test that you want to dismiss.

3 Select **Dismiss**.
The QC test is removed from the QC Due Now page.

4 To reinstate all dismissed QC test orders, select **Restore All** on the QC Due Now page.
The times until due will be the same as they were prior to dismissing the QC test orders.

Reviewing QC Data

The Levey-Jennings chart for each control material is located on the QC Result Review page.

A Levey-Jennings chart represents control results. Each point on the chart represents a result. The difference between the result and the expected mean result (measured in units of standard deviation between -3 SD and +3 SD) is determined, and then plotted on the chart. You can view a Levey-Jennings chart to determine whether control results, over time, are within range or out of range. Control results that are within range form a normal distribution with equal numbers of points above and below the mean. A normal distribution has the following characteristics:

- 70% of the points are between +1 SD and -1 SD
- 25% of the points are between +1 SD and +2 SD and between -1 SD and -2 SD
- 5% of the points are between +2 SD and +3 SD and between -2 SD and -3 SD

The analyzer stores all results and calculations for each control sample. The information about the control sample is displayed in the Summary section on the QC Result Review page. The information includes the name of the control material, level, lot number, expiration, and sample ID. The calculated statistics for the test are located in the table under Status. The data table below the statistical values displays a list of the QC results that are specific to each data point within the selected date range.

You can also view result details for a specific QC test from the Sample List page.

The Levey-Jennings chart on the QC Result Review page is a graph of the data points from the selected QC test. The symbols on the Levey-Jennings chart have the following meanings:

- Circle: The data point is within the 3 SD limits.
- Triangle: The data point is outside the 3 SD limits, but inside the 4 SD limits.
- Double triangle: The data point is outside the SD limits.
- Green: The data point is in control according to the applied Westgard rules.
- Red: The data point is not in control according to an applied Westgard rule.
- Gray: The data point is for a control material that has the status of In Evaluation or the data point has been excluded from the calculations.

Tip

On the touch screen of the monitor, touch the screen and place two fingers next to each other. Spread them apart to zoom in on the view of the Levey-Jennings chart, or move them closer together to zoom out on the view.

Note

The analyzer displays QC results as out of control when any level of the QC result is out of control. The analyzer displays QC results as in control only when all levels of the QC result are in control. To identify the QC level that is out of control, check the result for each level.

Note

Note the following when QC by reagent pack has been configured:

- For multiple reagent packs in the same run (when multipoint rules are selected), an event is created when a single result in that run is out of control. An event could be created even when the last result in that run is in control. Review all results for that run to determine the result that is out of control.
- When QC data is evaluated from multiple runs, the most recent QC result determines whether the results are in control or not. If a result is out of control and a QC event occurs, the event is dismissed when the next data point brings the results back in control.

---

1 Select the **QC** task indicator on the Home page.
The analyzer displays the QC Due Now page.

---

2 Open the QC Result Review page to review results.

a. To review results for a QC test from the QC Due Now page, select a tile, and then select **Chart**.

b. To review results for a test from the Control Materials page, select **Control Materials**, select a control material from the list, and then select **Chart**.

c. To review results for a QC test from the All QC page, select **All QC**, select a tile, and then select **Chart**.

---

3 Select the QC results that you want to display on the QC Result Review page.

a. To scroll between tests that use this control material, use the next and previous buttons at the top of the QC Result Review page.

b. Select a control level from the list in **Level**.

c. Enter a date range by selecting **From** and **To** and using the calendars in each dialog to select a year, month, and date, and then selecting **Done**.

d. To view more detail about a result, select the data point on the Levey-Jennings chart. The corresponding data row in the table is highlighted.

e. To view more details about a result on the QC Result Review page, locate the data point in the data table, and then select **View** in the Details column.
The analyzer displays the Result Details page or the ISE Reaction Detail page for the QC test. For ISE tests, select the QC test result in the Other Processes section of the ISE Reaction Detail page.

4 To exclude a QC result, display the result on the QC Result Review page.

Note

The excluded data point will be greyed out on the chart, and the cumulative mean and SD will be recalculated.

a. Select the data point on the Levey-Jennings chart or the result in the corresponding data table.
The data row in the table is highlighted.

b. Select **Exclude**.

c. Enter comments about the data point in the **Comments** field in the QC Failure: Add Comments dialog.

d. You can choose to reorder the QC test by selecting the **Reorder** checkbox in the QC Failure: Add Comments dialog.

Note

Deselecting the **Reorder** checkbox in the dialog removes the test from the QC test order.

e. Select **Save** in the QC Failure: Add Comments dialog.

5 To save the QC results in a format that is compatible with a spreadsheet, export the file to a USB device.

a. Select **Menu** > **Control Materials List**.

b. Insert a USB device into one of the USB ports on the front of the console computer.

c. Select **Export** on the Control Materials page.

d. If a Restrictions dialog is displayed, select **OK** and continue.

e. In the Save As dialog, enter a file name for the .csv file and select the location on the USB device.

f. Select **Save**.

Rerunning a QC Test

To confirm results from a QC test that failed, rerun the test from the QC Events page.

1 Select the **QC** event indicator in the navigation bar.

2 Select the checkbox for the QC test on the QC Events page.

3 Select **Reorder**.

4 Enter any text into the Text Input dialog, and then enter comments about the reorder in the QC Failure: Add Comments dialog.

Note

Deselecting the **Reorder** checkbox in the dialog, removes the test from the QC test order.

The analyzer dismisses the QC event and adds the test to the QC test orders.

CHAPTER 10

Sample Processing

Sample Processing Overview

Sample processing begins when the analyzer receives a test order.

When you load a sample on the analyzer, the analyzer reads the bar code label on the sample container and attempts to associate the bar code with a test order. If the analyzer has not received a test order, the analyzer queries the host system for an order and waits for a response. When the sample is successfully associated with a test order, the analyzer confirms that all required reagents, supplies, calibrations, and hardware conditions (for example, temperatures) are sufficient to process the ordered tests. If all conditions are met, the analyzer runs the ordered tests. If the analyzer cannot run the tests due to missing or expired reagents, supplies, or calibrations, or if there is a problem with the placement of samples in racks, the system generates an event on the Sample Events page. If there is a hardware problem, it generates an event on the System Events page.

When you enter test orders manually for a sample in a rack, you specify the rack ID, the sample ID, and the position of the container in the rack.

For manually entered orders, a bar code label on the sample container is not required. The analyzer recognizes the rack ID and runs the ordered tests. Results are associated with the sample ID entered with the test order.

Note

If you load a tube with a bar code label that is different from the sample ID in the manual order, the analyzer will generate a Samples event, and no tests will be run on the sample. This is to prevent a sample from an LIS order being mistaken for the manually-ordered sample.

You can also load unlabeled sample containers on the STAT table (this function is available only for test orders that are entered manually). When you enter a test order for a container to be loaded on the STAT table, specify the position of the sample container on the STAT table. When you select the Start button in the STAT Table state area on the status bar, the analyzer runs the ordered tests.

Test Orders

The analyzer typically receives test orders from a connected host system, such as an LIS (laboratory information system). You can also enter test orders manually on the analyzer using the Test Order Entry page on the user interface.

STAT Samples

Test orders for STAT samples are given a higher priority when the analyzer schedules these tests.

When loading racks containing STAT samples, place the racks in lane S1 or lane S2 of the sample handler. Racks in these positions have higher priority for being transferred to the rack buffer area than racks in the other 10 positions. You can also load individual sample

tubes on the STAT table for priority processing over samples loaded on racks. When you start STAT table analysis, the analyzer interrupts running rack analysis, and processes the samples loaded in the STAT table first. After completing dispensing from the STAT table, the analyzer continues running the samples in racks.

Note

The analyzer cannot process whole blood samples on the STAT table.

Sample Preparation

Perform initial sample preparation (for example, collection, centrifugation, and removing caps) according to your laboratory procedures.

When you use DxLAB tube racks or DxLAB cup racks, you can load uncapped primary and secondary sample containers directly on the analyzer.

Monitoring Sample Status

The Sample List page, available from the Home page or from the Test Order Entry page, displays the status of samples in the Status column. You can view samples that have a status of Ordered, active samples, or all samples by selecting the **Ordered**, **Active**, or **All** options. The Sample List page only displays samples that have not been completed, or have been completed within the last 24 hours. To view samples that were completed more than 24 hours ago, enter the sample ID in the search field to display the Sample page for a specific sample.

Monitoring Result Status

The Sample page for a sample, available by selecting a sample on the Sample List page, or by entering a sample ID in the search field, displays the status of test results in the Result column. After a test is complete, the result is displayed instead of the status.

Reviewing Results

If the analyzer is connected to a host system, the analyzer reports the results of completed tests to the host system. The analyzer also displays the results on the Sample page for the sample. The Sample page displays results, any flags associated with the results such as H (high), L (low), HH (critically high), or LL (critically low), and information about test processing. Links on the Sample page open subsequent pages that provide greater detail about the test processing.

Entering Test Orders

Most patient test orders originate from a host system (LIS), but it is sometimes necessary to enter test orders manually from the console. For example, if the Laboratory Information

System (LIS) is not available to download sample information, tests can be ordered from the console.

Important

For manual orders, do not load samples before completing and saving the test order. When the analyzer scans a rack bar code, it checks for existing orders. If no order is found, the analyzer does not schedule tests or process the sample.

---

1 Select **Order** in the navigation bar.

The analyzer displays the Test Order Entry page.

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2 In **Rack Type**, select **DxLAB Rack** or **STAT Table**.
The Rack View section displays an image of the rack, or the STAT Table.

---

3 If you selected **DxLAB Rack**, enter the rack ID in **Rack ID**. The rack ID can be found on the bar code label affixed to the rack. Select the Rack ID field, and in the Text Input dialog either scan the bar code label with the handheld bar code reader or enter the rack ID, and then select **Done**.

---

4 Enter information in the Rack and Position table.

a. Select a text field to the right of any available position in the Rack and Position table. The analyzer displays the Text Input dialog.

b. Select the **Sample ID** field and either scan the bar code label, or type the sample ID. The analyzer displays the sample ID next to the corresponding position in the loading guide.

c. Select the sample type in **Sample Type**.
The Test and Panel Selection table displays available tests for the selected sample type.

d. If the sample has been manually diluted, enter the dilution factor, from 1 to 999, in **Dilution Factor**.

Important

Always refer to the reagent Instructions for Use before diluting a sample or applying a dilution factor.

Note

The dilution factor is the total number of parts of a sample, including 1 part of the undiluted sample. For example, a dilution factor of 3 indicates 1 part of undiluted sample and 2 parts of diluent.

e. If the sample is a STAT sample, select **STAT**.

STAT samples have a higher priority when the analyzer schedules tests to run.

For example, within a rack with STAT samples, the STAT samples are processed before the other samples in the rack. Racks with STAT samples are processed before racks without STAT samples.

Note

If the Rack Type is **STAT Table**, selecting **STAT** is not necessary, because samples on the STAT table are already recognized as STAT samples.

f. Select **Done**.

---

5 To add patient demographic information to the sample, select **Demographics** below the Rack and Position table, and then enter the information in the Demographics dialog. Select **Save** to add the demographic information to the sample and close the dialog.

Note

Patient information is optional, but when you enter any patient information, you must enter a patient ID also.

---

6 In the Test and Panel Selection table, select the tests to run on the sample.

a. To order individual tests, select the **Test** option, and then select the tests to run.

b. To order a panel, select the **Panel** option, and then select one or more panels from the Panel list.

When you select a panel, all of the tests in the panel are automatically added to the order.

Note

You can use these steps to add panels and individual tests to the same order.

---

7 To run multiple replicates of a test, enter the number of replicates in **Replicates**. You can also increase or decrease the number of replicates by selecting the **+** or **-** icons in the Replicates column.

The maximum number of replicates for ISE tests and LIH tests is 1. For all other Chemistry tests, the maximum number of replicates is 20. The hint text in the **Replicates** control indicates the maximum for the associated test.

Note

To see the hint text, delete the contents of the Replicates field.

Note

Be sure that rerun and reflex rules are not enabled for tests that are programmed for multiple replicates, because the tests with rerun or reflex rules would run multiple times.

8 Select a prep type in the Prep Type column.

- To run the sample with the standard undiluted version of the test, leave **Neat** selected.
- To dilute the sample automatically for an individual test, select **Dilute**. A diluted sample uses a smaller sample volume by decreasing the sample dispensing volume or increasing the dilution ratio.

Note

The **Dilute** option is available only for tests that support automated dilution. To determine whether a particular test supports automated dilutions and to find the preset dilution factor, refer to the reagent Instructions for Use.

Note

Automated dilution creates a dilution for use with a single test. The sample in the rack is not affected.

Note

Before you can select this option, you must select **Enable Prep Type on Test Order Entry page** and enter values for sample volume and predilution rate in the customer configurable options on the Tests configuration page. Refer to Setting Customer Configurable Options.

- To condense the sample automatically for an individual test, select **Condense**. A condensed sample uses a larger sample volume by increasing the sample dispensing volume or decreasing the dilution ratio.

Note

The **Condense** option is available only for tests that support automated condensing. To determine whether a particular test supports automated condensing and to find the preset dilution factor, refer to the reagent Instructions for Use.

Note

Before you can select this option, you must select **Enable Prep Type on Test Order Entry page** and enter a value for sample volume in the customer configurable options on the Tests configuration page. Refer to Setting Customer Configurable Options.

9 For each sample container, enter the Sample ID and associated information in the next available position in the Rack and Position table.

10 Select **Save**.

11 To confirm that the tests have been ordered:

a. Select **Sample List**.
The analyzer displays the Sample List page.

b. Select the sample.
The analyzer displays the Sample page.

c. Confirm that the tests are displayed in the table.

Note

Any tests that have not completed within 24 hours of the last time that a test was ordered for the sample, which is displayed in Ordering Time on the Sample page, have been canceled.

Editing a Manual Test Order

You can edit manual test orders to add or remove tests, to add or remove samples, or to edit patient demographics.

Note

You can only edit test orders that have a status of Ordered. Test orders cannot be edited after the analyzer begins processing the samples. You cannot edit LIS orders.

1 Select the **Sample List** task indicator on the Home page.
The analyzer displays the Sample List page.

2 Select **Rack View**.
The analyzer displays the Rack View page. A rack diagram shows all racks with samples that have a status of Ordered. Each rack in the diagram shows the sample IDs for the samples that are loaded in each position of the rack.

3 If it is not already selected, select the rack containing the sample to edit.
The outline of the rack turns blue.

4 Select **Details**.
The analyzer displays the Test Order Entry page, with all of the information for the existing test order already filled in.

5 Edit the test order. You can add or remove tests, replicates, and panels, add or remove samples, change the rack ID, and edit demographic information. For more information, refer to Entering Test Orders.

6 When you have finished editing the order, select **Save**.

Ordering Tests in Batch

To perform the same tests on a group of samples, enter the orders in a single batch.

The analyzer orders the same tests for all of the samples in the batch.

Note

Batch orders can be run only on racks.

1 Select **Order** > **Batch Order**.
The analyzer displays the Batch Order Entry page.

2 Enter information in the Rack Information section.

a. Select a text field in the Rack Information section.

b. Enter the number of samples in **Number of Samples**.
The Rack View section displays images of the racks that are required for the batch test order.

c. In **Rack ID**, scan or type the ID of the initial rack that contains the samples.
In the Rack View section, the analyzer generates new rack IDs in increments of 1 after the initial rack ID.

d. In **Starting Sample ID**, enter the sample ID for the first sample in the batch, and select **Done**.
In the Sample Information table and Rack View section, the analyzer generates new sample IDs in increments of 1 after the starting sample ID.

e. In **Sample Type**, select the sample type for the samples.
The Test and Panel Selection table displays all tests that are available for the specified sample type.

3 In the Test and Panel Selection table, select the tests to run on the sample.

a. To order individual tests, select the **Test** option, and then select the tests to run.

To remove a test or panel from the order, clear the checkbox for it.

b. To order a panel, select the **Panel** option, and then select one or more panels from the Panel list.

Selecting a panel automatically adds all of the tests in the panel to the order.

c. To run multiple replicates of a test, select the field for replicates and enter the number of replicates in **Replicates** in the Text Input dialog. You can also increase or decrease the number of replicates by selecting the **+** or **-** icons.

The maximum number of replicates for ISE tests and LIH tests is 1. For all other Chemistry tests, the maximum number of replicates is 20. The hint text in the **Replicates** control indicates the maximum for the associated test.

Note

To see the hint text, delete the contents of the Replicates field.

d. Select a prep type in the Prep Type column.

— To run the sample with the standard undiluted version of the test, leave **Neat** selected.

— To dilute the sample automatically for an individual test, select **Dilute**. A diluted sample uses a smaller sample volume by decreasing the sample dispensing volume or increasing the dilution ratio.

Note

The **Dilute** option is available only for tests that support automated dilution. To determine whether a particular test supports automated dilutions and to find the preset dilution factor, refer to the reagent Instructions for Use.

Warning

Batch test orders do not support manual dilutions. Always refer to the reagent Instructions for Use before diluting a sample or applying a dilution factor.

Note

Automated dilution creates a dilution for use with a single test. The sample in the rack is not affected.

Note

Before you can select this option for chemistry tests, you must select **Enable Prep Type on Test Order Entry page** and enter values for sample volume and predilution rate in the customer configurable options on the Tests configuration page. Refer to Setting Customer Configurable Options.

— To condense the sample automatically for an individual test, select **Condense**. A condensed sample uses a larger sample volume by increasing the sample dispensing volume or decreasing the dilution ratio.

Note

The **Condense** option is available only for chemistry tests that support automated condensing. To determine whether a particular test supports automated condensing and to find the preset dilution factor, refer to the reagent Instructions for Use.

Note

Before you can select this option, you must select **Enable Prep Type on Test Order Entry page** and enter a value for sample volume in the customer configurable options on the Tests configuration page. Refer to Setting Customer Configurable Options.

Note

You can use these steps to add panels and individual tests to the same order.

4 If you want to change any of the sample IDs, in the Sample Information section select the field for the sample ID and scan or type the sample ID in the Text Input dialog.

If you are testing more than seven samples, requiring multiple racks, use the arrow buttons at the top of the Sample Information section to cycle through the racks.

5 If you want to change any of the rack IDs, in the Rack View section select the field below the rack diagram and scan or type the rack ID in the Text Input dialog.

6 Select **Save** to order the tests.

7 To confirm that the tests have been ordered:

a. Select **Sample List**.
The analyzer displays the Sample List page.

b. Confirm that the tests are displayed in the table.

Sample Preparation

Sample preparation includes labeling sample containers, confirming sample volumes, and placing containers in racks.

Perform initial sample preparation (centrifugation, pipetting, dilution, and so on) according to your laboratory procedures.

The analyzer accepts uncapped primary tubes and secondary containers, including cups and insert cups.

Warning

- **Confirm that the sample tube contains the required minimum volume of sample. If a primary tube does not contain enough sample, the analyzer might aspirate the gel, clot, buffy coat, or cells, which can cause a sample error or produce erroneous results.**
- **Remove or break any bubbles in the samples. Air bubbles in samples can affect level sensing by the analyzer and produce erroneous results. Carefully aliquot samples into secondary containers and inspect the samples before loading them on the analyzer.**
- **The sample handler is not thermally controlled. To minimize sample evaporation, which can cause erroneous results, ensure that the sample does not sit in the sample handler for an extended period.**

Warning

If the following requirements are not met, results are affected and system errors occur.

- **Do not have fibrous material or fibrin in the sample, except for whole blood.**
- **Confirm that no air bubbles are in the samples.**
- **Dispense sample volume in the quantity required for analysis and the dead volume.**
- **In the Tests page (System Configuration > Test Menu), you can set the sample volume dilution to 0 µL (default) or 10 µL. When the Dilution is 0 µL, the system does not dilute the sample and it adds an extra 3 µL per test to the sample volume to ensure dispensing accuracy. For example, if the sample volume of a test is 3 µL, the system aspirates 6 µL per test and dispenses 3 µL. If 10 tests are ordered on a sample, the system adds a total of 30 µL to the sample volume. When the Dilution is 10 µL, the system adds 10 µL of water to the sample and does not aspirate any extra sample volume per test.**
- **After sample aspiration, the sample probe is rinsed in the wash well, and a small amount of water is transferred to the sample when the next test is aspirated. If the initial sample volume is small, and 20 or more tests are being analyzed on the sample, add an extra 200 µL to the required sample volume to avoid diluting the sample.**
- **Confirm that a sufficient sample volume for analysis plus the needed dead volume is in a primary tube. The dead volume required in a primary tube is 4 mm above the nonsample (cells or gel) layer.**
- **If the sample volume is insufficient, perform analysis after transferring the sample to a smaller cup or cup nested (inserted) in a tube.**
- **If the sample volume is insufficient, the system can aspirate the non-sample (cells or gel) layer below the sample and results can be affected.**
- **Prevent sample evaporation and contamination before analysis.**

Sample Handler

The sample handler accepts DxLAB racks for presentation of samples to the analyzer. The first two positions in the sample handler, labeled S1 and S2, have a higher priority for sample loading than the racks in the other sample handler positions.

DxLAB Racks

DxLAB tube and cup racks are used to present samples to the analyzer. The analyzer identifies racks by scanning bar code labels that are attached to the racks.

STAT Table

You can load samples directly on the analyzer by placing the sample containers in the STAT table.

Preparing Sample Containers

Prepare samples for analysis by placing a bar code label on the sample container, confirming sample dilutions and volumes, and placing the sample container in a rack.

Sample racks are used to present samples to the analyzer. Bar code labels on sample containers enable the analyzer to read sample IDs.

Note

The internal bar code reader automatically recognizes all supported symbologies. Except for with bar codes that use the ISBT 128 symbology, you can place sample containers with different symbologies in the same rack.

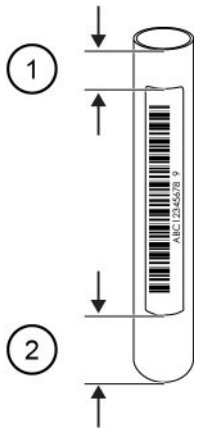
Note

Bar code labels are required only for samples that are ordered by the LIS. Orders that are entered manually include the rack ID and position or are assigned to a position in the STAT table, so bar code labels are not necessary for sample identification.

---

1 Attach the bar code label to the sample container so that the label is a minimum of 0.6 inches (14 mm) from the top and a minimum of 0.8 inches (20 mm) from the bottom of the container. Confirm that the label is securely fastened.

Figure 58 Bar Code Label Placement



1. 0.6 inches (14 mm)
2. 0.8 inches (20 mm)

---

2 If the sample requires dilution, follow your laboratory procedures to dilute the sample.

Dilutions must be 1 part of sample to *n* parts of diluent, where *n* is an integer. When ordering tests for the sample, specify a dilution factor of *n*+1.

---

3 Confirm that the volume of sample in the sample container is sufficient to process all of the tests that have been ordered for the sample.

Note

If you are transferring sample to a new sample container, carefully pipette the sample into the sample container. Avoid creating air bubbles.

Note

If the sample level is above the maximum sample volume limit, Beckman Coulter recommends removing sample until the sample level in the tube or cup is at or below the volumes specified in Maximum Sample Volume Limits for Tubes in Racks and Maximum Sample Volume Limits for Other Containers in Racks. If a sample exceeding the maximum sample volume limit was not removed before analysis, inspect the sample handler after analysis to determine whether any sample spilled onto the sample handler. If any sample spilled onto the sample handler or racks, clean the area by wiping with an alcohol prep pad (70% isopropyl alcohol) or lint-free absorbent tissue moistened with hot water. Check whether any sample has spilled onto the anti-static brushes, and if it has, replace them.

4 Remove the cap and place the sample container in the rack. Push the container down into the rack completely, and confirm that the label is visible through the slot.

Caution

Do not rotate a sample tube while it is in the rack. Rotating the tube while it is the rack can damage the bar code label, and cause errors when reading the bar code label. To rotate a tube, first remove the tube from the rack.

Tip

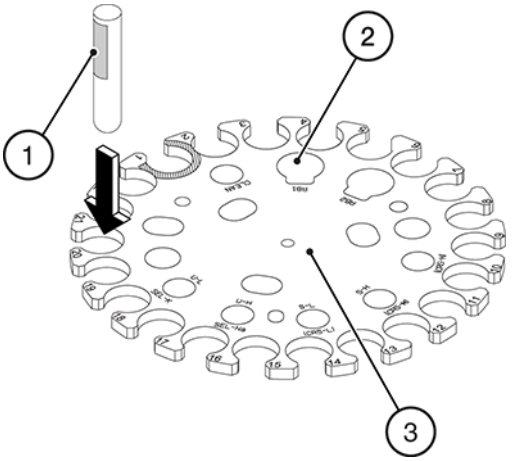
You can use the DxLAB rack holder to hold the racks upright while loading samples. Refer to Parts List for Sample Racks and Accessories.

Figure 59 Placing a Sample Container in a Rack

Bar Code Labels for STAT Table Analysis

The outer positions (1 to 22) are used for STAT analysis. Place the tube on the table with the bar code label facing out from the center of the table.

Figure 60 Placing Tubes with Bar Code Labels on the STAT Table



1. Place the tube in outer position 1-22 with the label facing out from the center of the table.
2. Inner positions are not available for bar code mode.
3. STAT table

Sample Containers

Sample containers are the tubes and cups that you load on the analyzer to provide sample material for testing.

Sample containers are divided into two main types:

- Primary tubes—Used for sample collection, and available in various sizes and configurations.

  Commercial tube sizes that can be used on the analyzer are 13 x 75 mm, 13 x 100 mm, and 16 x 100 mm.

  Dead volumes are listed in the following table. In addition to usable sample, primary tubes contain other materials such as gel, clot, buffy coat, and packed cells.
- Secondary containers— Sample tubes and sample cups for low volume samples. The sample material in secondary containers is aliquotted from primary tubes.

The analyzer scans the bar code label on each sample container to identify the sample and the test orders that are associated with that sample.

The analyzer supports a variety of sample tubes and sample cups.

Warning

Use only sample cups and tubes listed in the specifications and vailidated by Beckman Coulter. If other cups or tubes are used, analysis cannot be performed or errors can result.

Important

If the analyzer is programmed to use the pre-dilution option with a dilution factor of 3 or 5, a larger dead volume is required to ensure accurate sample dispensing. Refer to the following table for the sample volumes required for each dilution factor. The analyzer can be programmed for dilution factors other than 3 and 5, or to dispense a smaller rerun sample volume than the first-run sample volume without affecting the dead volume requirement. Refer to Entering Test Orders and Rerunning a Test with a Diluted Sample for more information.

Important

For guidance on which sample tubes can be used for which sample cups, contact Beckman Coulter Customer Support.

Table 34 Cups or Tubes Available for DxLAB Racks or STAT Table

Cup or Tube	PN	Locations	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Dilution Factor
Access Sample Container (3.0 mL)	81914	DxLAB cup rack	150	150
Commercial sample tube • Height: 55 mm to 102 mm • Outer diameter (OD): 11.5 mm to 16mm • Inner diameter: 9 mm to 15 mm • Maximum diameter of sample tube flange: < 17.5 mm (An adapter conforming to the outer diameter is required.)	N/A	• DxLAB tube rack • STAT table - outer • STAT table - inner (ISE) (OD 12.3 mm only) • STAT table - inner (RB) (13 mm x 75 mm only)[1]	200 (OD 12.3 mm)	250 (OD 15.4 mm)
Auto aliquot tube	2910034	STAT table - outer	80	300
Serum Separator Tube (16 mm x 100 mm)	N/A	• DxLAB tube rack • STAT table - outer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Primary tube (13 mm x 75 mm)	N/A	• DxLAB tube rack • STAT table - outer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Primary tube (13 mm x 100 mm)	N/A	• DxLAB tube rack • STAT table - outer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Primary tube, red top (13 mm x 75 mm)	N/A	• DxLAB tube rack • STAT table - outer	140	140

[1] If performing a reagent blank during sample processing, make sure that there is at least 1.5 mL of deionized water in the sample container.

Table 34 Cups or Tubes Available for DxLAB Racks or STAT Table (Continued)

Cup or Tube	PN	Locations	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Dilution Factor
Primary tube, red top (13 mm x 100 mm)	N/A	• DxLAB tube rack • STAT table - outer	140	140
Sample Cup (2.5 mL)	MU853200	• DxLAB cup rack • STAT table - outer • STAT table - inner (ISE)	50	80
Sarstedt S-Monovette (4.9 mL)	N/A	• DxLAB tube rack	3400	3400
Sarstedt S-Monovette (5.5 mL)	N/A	• DxLAB tube rack • STAT table - outer	3600	3600
Sarstedt S-Monovette (7.5 mL)	N/A	• DxLAB tube rack • STAT table - outer	5000	5000

Table 35 Cups Nested (Inserted) in Tubes Available for Racks or STAT Table

Cup	Cup PN	Tube	Tube PN	Locations	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Dilution Factors
DxC cup (2.0 mL)	652730	5.0 mL Screw Cap Tube	979272	STAT table - outer	50	200
Access 2 cup (1.0 mL)	81915	Primary tube (13 mm x 75 mm) or Primary tube, red top (13 mm x 75 mm)	N/A	• DxLAB tube rack • STAT table - outer	140	140

Table 35 Cups Nested (Inserted) in Tubes Available for Racks or STAT Table (Continued)

Cup	Cup PN	Tube	Tube PN	Locations	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Dilution Factors
Access 2 cup (1.0 mL)	81915	Primary tube (13 mm x 100 mm) or Primary tube, red top (13 mm x 100 mm)	N/A	DxLAB tube rack	140	140
EZ Nest cup	1270013000	Primary tube (13 mm x 75 mm) or Primary tube, red top (13 mm x 75 mm)	N/A	• DxLAB tube rack • STAT table - outer	50	150
EZ Nest cup	1270013000	Primary tube (13 mm x 100 mm) or Primary tube, red top (13 mm x 100 mm)	N/A	DxLAB tube rack	50	150
EZ Nest cup	1270016000	Serum Separator Tube (16 mm x 100 mm)	N/A	DxLAB tube rack	50	120
Sample Cup (2.5 mL)	MU853200	Primary tube (16 mm x 100 mm)	N/A	DxLAB tube rack	50	80

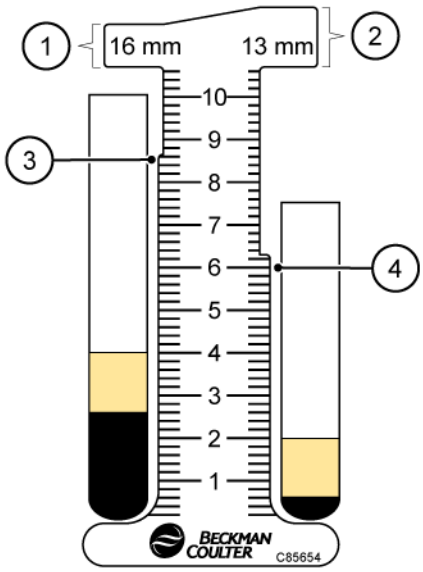
Checking Sample Volumes with the Sample Volume Tool

The sample volume tool is used to determine if primary tube samples have at least 1000 µL of sample available for testing. This amount of sample is sufficient to run most clinical chemistry and immunoassay tests.

In addition, use the tool to determine if the height of the sample does not exceed the maximum height, which is 15 mm from the top of the tube. Filling tubes below the maximum height helps to prevent sample from spilling. For more information, refer to Maximum Sample Volume Limits for Sample Tubes and Cups in Racks.

Use the tool to determine if the height of the sample exceeds the minimum height. Filling tubes above the minimum height helps to ensure that the sample probe can reach the sample layer.

Figure 61 Sample Volume Tool



1. Minimum volume of sample serum or plasma (16 mm diameter tubes)
2. Minimum volume of sample serum or plasma (13 mm diameter tubes)
3. Maximum height of sample (85 mm for 100 mm length tubes)
4. Maximum height of sample (60 mm for 75 mm length tubes)

1 Determine if primary tube samples have at least 1000 µL of sample available for testing.
   a. Align the sample in the tube with the tab at the top of the tool (section 1 or 2 in the figure).
      Align the bottom of the sample with the bottom of the tab.
   b. Confirm that the bottom of the sample meniscus is higher than the top of the tab.

2 Fit the tube in the contour of the tool, with the bottom of the tube positioned firmly against the bottom contour of the tool.
   The left side of the tool is for 100 mm length tubes, and the right side of the tool is for 75 mm length tubes.

3 Confirm that the top of the sample is not higher than the maximum height of the sample (line 3 or 4 in the figure).

After confirming the sample volumes, the tubes are ready to be placed in racks.

Note

When placing tubes in racks, make sure that all tubes are pushed completely down into the racks.

Maximum Sample Volume Limits for Sample Tubes and Cups in Racks

Maximum sample volume limits are provided to prevent sample from spilling when racks are being transferred in the sample handler. If sample spills out of the containers, sample carryover and erroneous result might occur. Determine the maximum sample volume limits for the validated sample tubes and cups used in your laboratory.

Use the following instructions to confirm that the sample levels in the tubes and cups do not exceed the maximum sample volume limits before placing the tubes or cups in racks for analysis.

1 Confirm the sample tubes and cups that are being used in your laboratory.

2 Confirm the maximum sample volume limit of the tube by using the sample volume tool.
   Refer to Checking Sample Volumes with the Sample Volume Tool.

3 Confirm the maximum sample volume limit of the cup by using the applicable dimensions or volumes specified in Maximum Sample Volume Limits for Other Containers in Racks.

Maximum Sample Volume Limits for Tubes in Racks

The maximum sample volume limit is defined as 15 mm from the top of the tube to the sample level in the tube due to the volume differences in various commercial tubes.

Use the sample volume tool to confirm that there is 15 mm of space between the sample level and the top of the tube. Refer to Checking Sample Volumes with the Sample Volume Tool.

Maximum Sample Volume Limits for Other Containers in Racks

Table 36 Maximum Sample Volume Limits for Other Containers in Racks

Cup	Cup REF	Maximum Volume
DxC cup (2.0 mL)	652730	970 µL
Access 2 cup (1.0 mL)	81915	840 µL
Access cup (3.0 mL)	81914	3.0 mL
EZ Nest cup	1270013000	560 µL
EZ Nest cup	1270016000	800 µL
Sample Cup (2.5 mL)	MU853200	2.0 mL

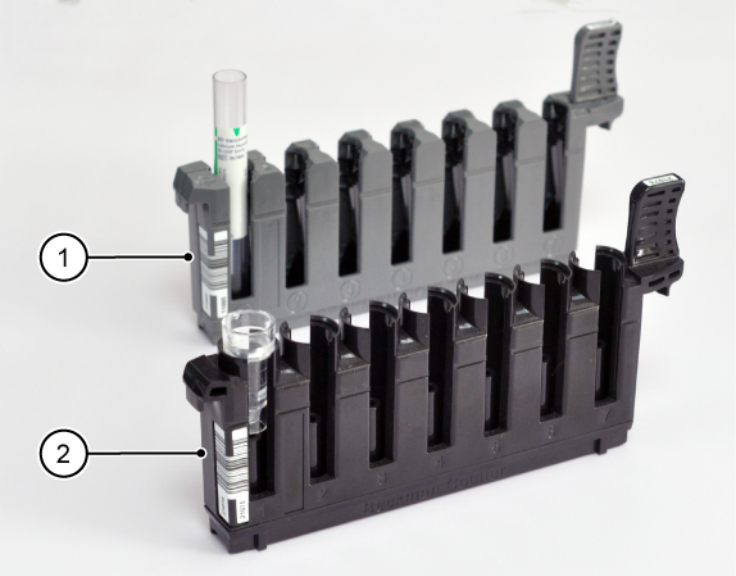
DxLAB Racks

The sample handler on the analyzer accepts DxLAB racks for presenting samples to the analyzer.

There are two types of DxLAB racks.

- DxLAB tube racks (gray) accept any supported sample tube, including insert cups in sample tubes. You can load up to seven sample tubes in the rack. You can include secondary containers with primary tubes in a single rack, only if the secondary containers match the dimensions for commercial sample tubes listed in the table Cups or Tubes Available for Racks or STAT Table.
- DxLAB cup racks (black) accept any supported sample cup. Sample cups are primarily used for calibration, QC, pediatric patient samples, and other low-volume samples. You can load up to seven sample cups in the rack, and you can use a mixture of cup types and dimensions in a single rack.

Figure 62 DxLAB Racks



1. DxLAB tube rack
2. DxLAB cup rack

The location of the rack ID bar code label is the front of the rack (enters first into the sample handler).

Cleaning Sample Racks

Clean sample racks as necessary.

1	Soak sample racks in a 0.6% solution of sodium hypochlorite for at least 30 minutes, or up to 24 hours.
2	Rinse the sample racks with deionized water.
3	Dry the sample racks completely.

Placing Labels on a DxLAB Rack

DxLAB racks have two labels: A bar code label that is read by the analyzer, and a rack ID label that can be read by the operator.

Warning

The system might read bar code labels in bad condition incorrectly. If you observe any of the following conditions, replace bar code labels:

- **The bar code label is smudged, scratched, or damaged.**
- **The bar code label is stained or dirty.**
- **The bar code label is torn or peeling.**

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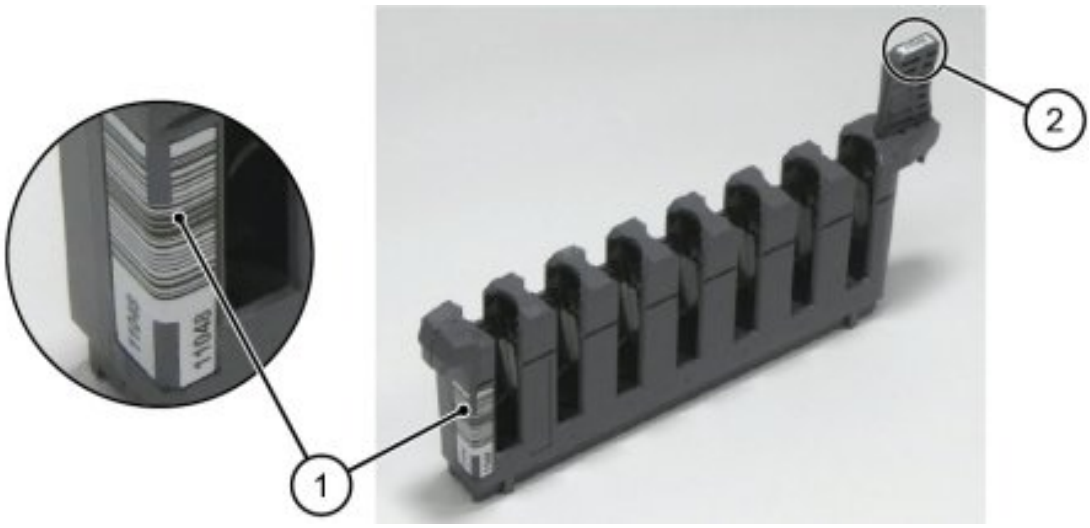
1 Place the rack on the table in front of you, with the handle on the rack oriented away from you.

Figure 63 Applying Rack Labels



1. Bar code label
2. Rack ID label

Important

Be sure to apply the correct label type to the rack. Labels for tube racks have rack IDs that begin with 1. Labels for cup racks have rack IDs that begin with 2.

---

2 Use a clean, lint-free absorbent tissue soaked in isopropyl alcohol (70%) to wipe the areas for the bar code label and rack ID label as shown in the figure.

---

3 Apply the bar code label to the recess in the corner of the rack as shown in the figure.

a. Orient the label so that the numbers are at the bottom.

b. Attach the label to the left side first (end of the rack), and hold for 30 seconds. Be sure that the label fits in the recess, and is aligned with the edge of the recess.

c. Fold the label around the corner and hold for an additional 30 seconds.

4 Apply the rack ID label to the top of the rack handle, and hold for 30 seconds.

Note

Be sure that the numbers on the bar code label and on the rack ID label are the same.

5 For best results, allow the label adhesive to cure for 24 hours before using the rack.

Placing Racks in the Sample Handler

The rack input area can hold a maximum of 12 racks (84 samples). Loading a rack in the rack input and output area and closing the sample handler door triggers the start of processing automatically. After the start of processing, you can open the sample handler door and put other racks into the rack input and output area. The rack moves to the rack buffer area.

Warning

Never look directly into the bar code readers. The laser light can cause serious eye damage.

Note

Prior to loading patient samples, confirm calibration has passed for the tests. If calibration fails and there is no valid calibration curve, the analyzer cannot process the patient samples. To confirm results for a calibration, refer to Reviewing Calibration Data.

Note

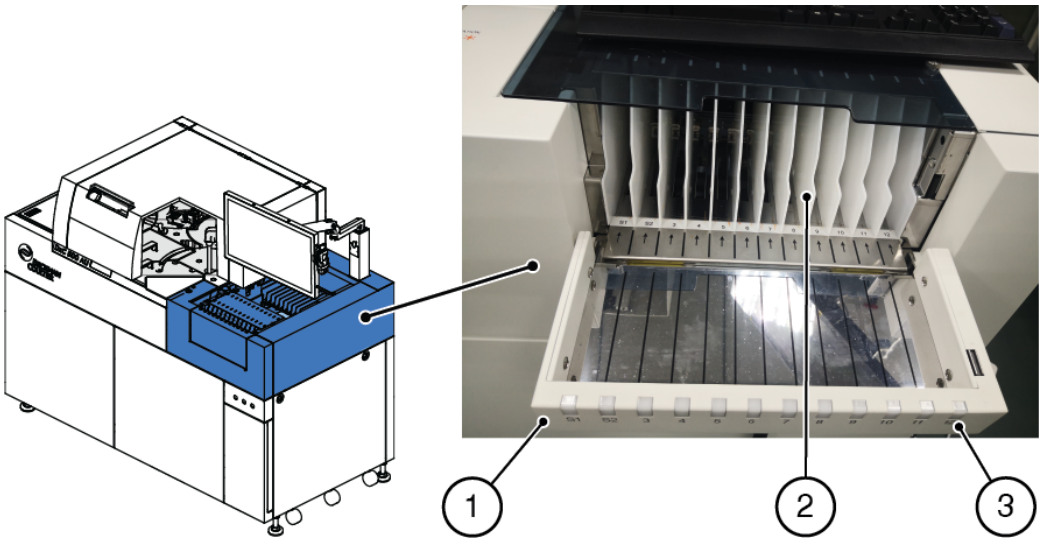
If the analyzer goes to the *Error* (*Stopped*) state when a sample is still in the *Presented* sample state (the analyzer has started scanning the sample bar codes but has not started aspirating the sample), you can resume processing the sample without re-ordering tests. To resume processing the sample, reload the rack and restart sample processing.

1 Open the sample handler door.

2 Remove racks from positions indicated by blue LEDs.

3 Place the racks in positions where the indicator LEDs are off.

Figure 64 Placing Racks in the Rack Input Area



1. Door
2. Rack input and output area
3. LED indicators and rack position status indicators

Note

You can use the DxLAB rack tray to place the racks in the sample handler. For more information, refer to Using the DxLAB Rack Tray to Place Racks in the Sample Handler.

4 Close the sample handler door.
The analyzer performs a reagent blank for all pending reagent blank orders and starts the sample processing.

Using the DxLAB Rack Tray to Place Racks in the Sample Handler

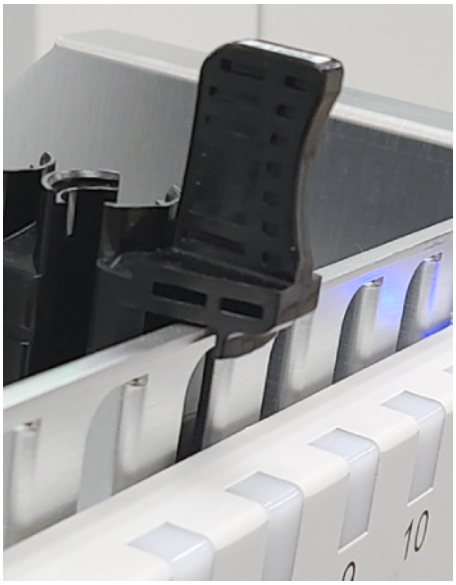
To help to avoid spillage of sample when loading racks in the sample handler, use the DxLAB rack tray.

With the DxLAB rack tray, you do not need to carry each rack loaded with samples individually to the sample handler.

1 Place the rack tray on a level surface.

2 Place empty racks in the rack tray. Make sure the racks are secured in place by the tab at the rear of each rack.

Figure 65 Secured Rack in Rack Tray



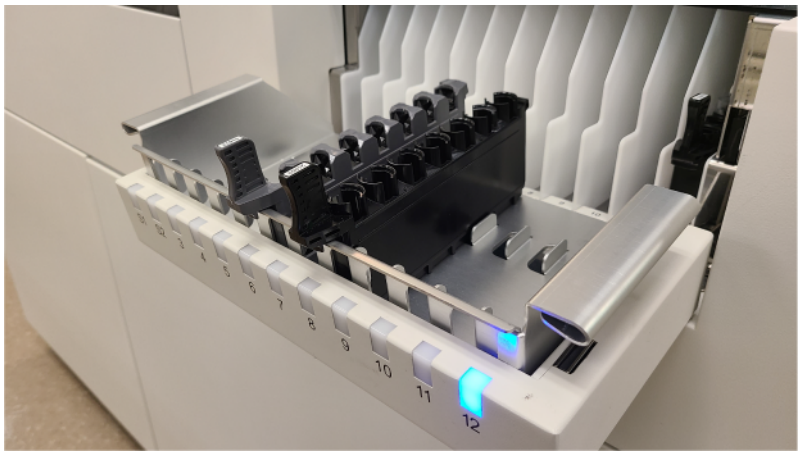
3 Prepare the sample containers and put them in the racks.

4 Place the rack tray on top of the closed sample handler top cover.

5 Open the sample handler door.

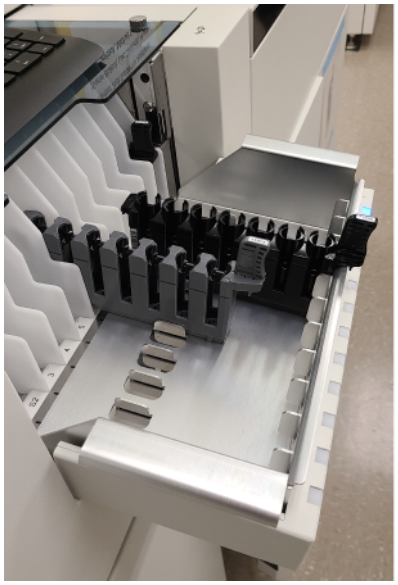
6 Place the rack tray inside the open sample handler door.

Figure 66 Rack Trays Inside Sample Handler Door



7 For each rack, hold the handle at the rear of the rack and gently lift the handle from the rack holder, and push the rack into its channel in the rack input and output area.

Figure 67 Pushing Racks into Rack Input and Output Area



Unloading DxLAB Racks

You can remove racks from lanes in the sample handler any time the rack position status indicator on the sample handler door is not green (blinking).

1 Open the sample handler door.

2 Identify racks that can safely be removed by observing the LED indicators for each position.

- If the LED indicator for a position is blue, the analyzer has completed processing the samples in the rack. The position is inactive and it is safe to remove the rack.
- If the LED indicator for a position is green, the samples in the rack have not yet been processed. The position is inactive and it is safe to remove the rack, but the rack must be placed back in the sample handler for the samples to be processed.
- If the LED indicator for a position is green and blinking, do not remove the rack. The sample handler is moving the rack.

3 Remove racks from inactive positions.

4 Close the sample handler door.

Processing STAT Chemistry Samples on the STAT Table

Before processing priority STAT samples on the STAT table, order the tests manually or configure the LIS to order the tests.

Important

If the STAT table is paused for an extended time, the chemistry analyzer changes to the *Paused* state.

Note

If the analyzer goes to the *Error* (*Stopped*) state when a sample is still in the *Presented* sample state (the analyzer has started scanning the sample bar codes but has not started aspirating the sample), you can resume processing the sample without re-ordering tests. To resume processing the sample, restart the STAT table.

Important

Do not remove reagent blank, calibrators, control samples, or patient samples with a status of Ordered from the STAT table. If you remove such samples from the STAT table, the analyzer generates an event after you select the Start button in the STAT Table state area of the status bar.

Note

Prior to loading patient samples, confirm calibration has passed for the tests. If calibration fails and there is no valid calibration curve, the analyzer cannot process the patient samples. To confirm results for a calibration, refer to Reviewing Calibration Data.

1 Confirm that the analyzer is in the *Running (Standby)* state and that the ROTATION LED is off.

2 Open the small STAT table cover.

Caution

When you open the small STAT table cover to load STAT samples, keep the upper cover closed. This precaution prevents injury and prevents the entire STAT table from opening.

3 Load the samples in the positions specified when entering the test orders.

Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table as required.

4 Close the small STAT table cover.

5 Select the Start button in the STAT Table state area of the status bar.
The analyzer displays the STAT Start dialog.

6 Select **OK**.

The analyzer performs a STAT table check and performs a reagent blank for all reagent blank orders with a status of Ordered. If the STAT table check does not identify any errors, the analyzer starts analysis. If there are errors, the analyzer displays events in the System Events page.

a. If the STAT table check identifies errors, review the event on the System Events page.

b. After performing corrective actions, repeat this step.

The amber ROTATION LED blinks until the analyzer completes sample aspiration. You can open the small STAT table cover when the amber ROTATION LED is not blinking to remove existing samples and load new samples. If you open the small STAT table cover when the amber ROTATION LED is blinking, the analyzer generates a `STAT Table Small Cover Open` event.

Monitoring Sample Status

Monitor sample status to determine the status of ordered or active samples or to review the patient information, tests, or results for a completed sample.

The Sample List page displays the status of Patient, QC, and calibration test orders. The Sample List page has three views, which you select from options in the upper left corner of the page: **Ordered**, **Active**, and **All**.

- Ordered: This is the default view. It includes samples for which orders exist, but processing has not yet begun.
- Active: Includes all samples that have tests with a status of In Progress or Presented.
- All: All samples, including completed samples.

The Status column displays the status of each sample.

- Ordered: An order exists for the sample, but the analyzer has not started processing the sample.
- Presented: The sample handler has acquired the sample rack and has scanned the sample bar codes, or the rack has been scanned and is in the rack buffer waiting for the analyzer to aspirate the sample.
- In Progress: The analyzer has started aspirating the sample.
- Completed: The analyzer has finished processing the sample.
- Canceled: The test order for the sample has been canceled.

The Flags column displays any flags associated with the sample. Select a flag to display the meaning of the flag.

The Estimated Completion column displays estimated completion time in italics and actual completion times in plain text (without italics).

Note

To keep the list of samples from growing too large, completed samples are removed from the Sample List page after 24 hours. Ordered samples are canceled and removed from the page if they have not been loaded on the analyzer within 24 hours. Samples that have been removed from the Sample List page remain in the database, and can be viewed by using the sample search feature.

1 To determine the status of test orders, open the Sample List page by selecting the **Sample List** task indicator on the Home page.

2 To view only ordered samples, select **Ordered**.

3 To view only active samples, select **Active**.

4 To view all samples, including completed samples, open the All Samples view. Select **All**.

5 To view detailed information about a patient sample, select the sample from the list to open the Sample page for that sample.

6 To view detailed information about a QC order, select the sample from the list to display the QC Order Details page.

7 To view detailed information about a calibration order, select the sample from the list to display the Calibration Order Details page.

8 Open the Sample page for the sample to determine the status of a specific sample and each test associated with that sample, including samples that have been removed from the Sample List page.

   a. If the sample is displayed on the Sample List page, select the sample.
   The analyzer displays the Sample List page for the selected sample.

   b. If the sample is not displayed on the Sample List page, enter the sample ID or the patient name in the sample search field, located in the navigation bar.
   As you begin typing, the analyzer displays a list of samples that correspond to the typed characters.

   c. Select the sample from the list.
   The analyzer displays the Sample page for the selected sample.

Changing the Priority of a Test Order

If the analyzer has not started processing a test order, you can change the priority of the test order.

1 Open the Sample page for the sample.

   a. From the Home page, select the **Sample List** task indicator to display the Sample List page.

   b. Select the sample from the list.
   The analyzer displays the Sample page for the selected sample.

2 To change the priority to STAT, select **Sample Actions** > **Change Priority to STAT**.

3 To change the priority to Routine, select **Sample Actions** > **Change Priority to Routine**.

Canceling a Test Order

If the analyzer has not started processing the sample associated with a test order, you can cancel the test from the Sample page for the associated sample.

1 Open the Sample page for the sample.
   a. From the Home page, select the **Sample List** task indicator to display the Sample List page.
   b. Confirm that the status of the sample status is Ordered.

   Note

   You cannot cancel a test if the sample status is Presented.

   c. Select the sample from the list.
   The analyzer displays the Sample page for the selected sample.

2 Select the checkbox for the test to cancel.

   Note

   You can only cancel a test when both the sample and the result have the status: Ordered.

3 Select **Cancel**.
   The analyzer displays the Cancel Test Confirmation dialog.

4 Optional: Enter a comment about the cancellation in **Lab Note**.

5 Select **Yes, cancel test.** to confirm the cancellation.

Reviewing Results

The analyzer automatically sends patient results to the connected host (LIS). You can also review results at the analyzer console by opening the Sample page for the sample.

The Sample page displays results numerically and displays any flags associated with the result. If the result is critically high or low, an exclamation point (!) is displayed next to a red vertical bar in the Critical column.

The Result column provides a summary of the results:

- (Numerical test result): Sample processing is complete, and the result has been calculated.
- `No result`: An error has occurred, and results cannot be calculated.
- `Running`: Sample processing is in progress, and results have not been calculated yet. The analyzer displays how long sample processing has been running.
- `Ordered`: Sample processing has not started for an ordered test.
- `Canceled`: Sample processing has been canceled for an ordered test.

1 Open the Sample page for the sample.

   a. In the sample search field in the navigation bar, enter the sample ID, patient name, or patient ID.

      As you begin typing, the analyzer displays a list of samples that correspond to the typed characters.

   b. Select the sample from the list.
      The analyzer displays the Sample page for the selected sample.

2 If the result has a flag, select the link in the Flags column.
The analyzer displays the interpretation of the flag. Review the flag and, if necessary, rerun the sample.

3 To view detailed information about the results of a test for the sample, select **View** in the Processing Details column.
The analyzer displays the Result Details page or the ISE Reaction Detail page.

4 To view the history of a test for the sample and patient, select the test name in the Test column.
The analyzer displays details about each run of the test for the sample, and for the patient (including test details for all samples associated with the patient).

The Sample Page

The Sample page displays all results for the sample ID displayed at the top of the page.

If results are not available, the Sample page displays the status of the tests that have been ordered for the sample (for example, Ordered, In Progress, Running, or Canceled).

To open the Sample page, enter the sample ID in the sample search field and then select the sample from the list, or select the sample on the Sample List page.

Note

By default, the Sample List page (select the **Sample List** task indicator on the Home page) only shows samples for orders that are pending. Select **All** on the Sample List page to include completed samples.

Patient Information

The patient information section displays the name of the patient, the patient ID, and other information about the patient, if available.

Test Information

The table of test information includes the following information for the sample:

- Checkbox: The left column of the test table contains checkboxes for selecting results on which to perform an action. Actions include **Cancel**, **Rerun**, **Dilute and Rerun**, and **Resend to LIS**. A checkmark is displayed in the checkbox when the checkbox is selected.
- Test: The Test column displays the test name. The test name is a link for viewing the details about the test. The details include reagent information, and a history of all test runs for the sample and for the patient.
- Result: The Result column displays the result numerically.
- Reference Range: The Reference Range column displays the reference range defined in the test configuration.
- Dilution Factor: The Dilution Factor column displays the dilution factor.
- Critical: The Critical column displays an exclamation point (!) next to a red bar for results that are outside of the critical limits defined in the test configuration.
- Flags: The Flags column displays any flags that are associated with the result. The flags are links for viewing an explanation of the flag.
- To LIS: The To LIS column displays Transmitting, Completed, or Transmission Failed.
- Processing Details: The Processing Details column displays a **View** link for each test. Select the link for additional information about the processing of the test.

Sample Information

The sample information section displays the sample type, the priority of the sample, and other information about the sample, when available.

Sample Actions Menu

The **Sample Actions** menu includes the following options:

- **Change Priority to STAT** (or **Change Priority to Routine**): Select to change the priority of the sample from Routine to STAT, or from STAT to Routine.
- **Add Sample Comment**: Select to add a comment about the sample.
- **Edit Patient Demographics**: Select to add or change information about the patient.

Note

You can edit patient demographics only for manually ordered samples, and only before the analyzer processes the sample. Patient demographics from a host system (LIS) cannot be edited.

- **View Sample History**: Select to view a history of all results for the sample, and all actions that have been performed for the sample.

Viewing Patient Test Results

View results for all completed patient tests on the Test Results page.

1 Select **Menu** > **Advanced** > **Test Results**.
The analyzer displays the Test Results page.

2 To view the Sample page for a sample, select the row for the sample.
Refer to The Sample Page.

Viewing Test-Specific Result Statistics

Filter all test results by date and time range and sample type on the Result Data Statistics page. View statistics for a specific test on the Result Detail Statistics page.

1 Select **Menu** > **Advanced** > **Result Data Statistics**.
The analyzer displays the Result Data Statistics page.

2 Select a date and time range using the drop-down lists in **Start Date** and **End Date**.

Note

You cannot set a time range for the statistics that ends more than a year earlier than the current time.

3 Select filters for the results.

a. Select a sample type in **Sample Type**.

b. Enter a sample ID range in **Start** and **End**.

Tip

Enter the asterisk character (*) to search for zero or more characters in a string of characters, and the question mark character (?) to substitute for a single character in a sample ID.

c. Select **OK**.
The analyzer displays detailed information for the selected date and time range, sample type, and sample ID range.

4 Select a row for one of the tests.
The analyzer displays the Result Detail Statistics page for the selected test, which includes detailed information for each instance of the test.

Rerunning a Test

You can manually rerun a test from the Sample page or from the Test Results page.

Note

This procedure is only for samples with bar codes. To rerun a test for a sample without a bar code, submit the test again manually. Refer to Entering Test Orders.

Tip

To configure the analyzer to rerun tests automatically when the test results meet specified criteria, refer to Configuring Reruns.

1 Open the Sample page for the sample.
   a. In the sample search field in the navigation bar, enter the sample ID, patient name, or patient ID.

      As you begin typing, the analyzer displays a list of samples that correspond to the typed characters.
   b. Select the sample from the list.
      The analyzer displays the Sample page for the selected sample.

2 Select the tests to rerun.

3 Select **Rerun**.
   The analyzer orders the test. The sample status changes to Ordered.

4 If you ran the original test on a rack in a sample container with a bar code, load the sample, and start sample processing.
   a. Load the sample in any position on the rack, and put the rack in the rack input area.
   b. Close the sample handler door.
      The analyzer starts processing the sample.

5 If you ran the original test on the STAT table, load the sample, and start sample processing.
   a. If you ran the original test on the STAT table in a sample container with a bar code, load the sample in any position in the outer circle of the STAT table.
   b. Select the Start button in the STAT Table state area on the status bar.
      The analyzer displays the STAT Start dialog.
   c. Select **OK**.

      The analyzer performs a STAT table check and performs a reagent blank for all reagent blank orders with a status of Ordered. If the STAT table check does not identify any errors, the analyzer starts analysis. If there are errors, the analyzer displays events on the System Events or Sample Events page.

      1. If the STAT table check identifies errors, review the event on the System Events or Sample Events page.
      2. After performing corrective actions, repeat this step.

Rerunning a Test with a Diluted Sample

After a test is complete, you can rerun the test with a manual dilution of the sample.

Note

You can rerun a test only if it has been completed. If a test has a status of Ordered, either wait for the completion of the test, or order a new test for the sample.

1 Prepare a secondary container for the diluted sample according to your laboratory procedures.

Note

For information about allowable dilutions for a particular test, refer to the reagent Instructions for Use.

Note

Dilutions must be 1 part of sample plus *n* parts of diluent, where *n* is an integer from 1 to 999. The analyzer will only accept integer values for the dilution factor or number of parts of diluent. For example, you cannot use a 2:3 dilution, because that would require 1 part of sample to 1.5 parts of diluent, or a dilution factor of 2.5.

2 Optional: Label the secondary container with a unique bar code label.

Note

If you do not place a bar code label on the container, you must specify a rack ID and position, or the analyzer will not rerun the test.

3 Open the sample page for the sample ID used in the original order.

a. In the sample search field in the navigation bar, enter the sample ID, patient name, or patient ID.

As you begin typing, the analyzer displays a list of samples that correspond to the typed characters.

b. Select the sample from the list.
The analyzer displays the Sample page for the selected sample.

4 Select the tests to rerun with a manual dilution.

5 Select **Dilute and Rerun**.
The analyzer displays the Manual Dilution dialog for the selected tests.

6 Enter the ID of the new secondary container in **Dilution Tube ID**.
The analyzer will associate the dilution tube ID, which is the sample ID for the diluted sample, with the sample ID from the original order.

7 Optional: Enter the rack ID and the position of the secondary container in the rack. The rack ID can be found on the rack ID label affixed to the rack.

a. Select the **Rack ID** field and then either type the rack ID, or scan the rack ID label with the handheld bar code reader.

b. Enter the rack position of the secondary container in **Position**.

Note

If the sample container does not include a bar code label with the dilution tube ID, you must specify the rack ID and position, or the analyzer will not rerun the test.

8 Select the diluent type from **Diluent Type**.

9 Enter the dilution information.

Enter either the number of parts of diluent, or the dilution factor.

a. To specify the number of parts of diluent to one part of sample, enter the number (an integer from 1 to 999) in **Sample = 1 part. Diluent =**<*value*>.
The analyzer calculates the dilution factor and displays the value in **Factor**.

b. To specify the dilution factor, enter the number (an integer from 2 to 1000) in **Factor**.
The analyzer calculates the number of parts of diluent to one part of sample and displays the value in **Sample = 1 part. Diluent =**<*value*>.

10 Select **Order Rerun**.
The analyzer orders the test and runs the test when the secondary container is loaded.
The sample status is changed to: Ordered.

Printing or Saving Results Reports

You can print results reports for a patient sample from the Sample page. Alternatively, you can save the reports to a USB drive in PDF format.

1 Use the sample search feature to locate the sample for which to print results.

a. In the sample search field in the navigation bar, enter the sample ID, patient name, or patient ID.

As you begin typing, the analyzer displays a list of samples that correspond to the typed characters.

b. Select the sample from the list.
The analyzer displays the Sample page for the selected sample.

2 To print the report, select the arrow on the button with the printer icon, and then select **Print**.

3 To save a PDF version of the report to a USB drive:

a. Plug a USB drive into one of the USB ports on the rear of the monitor.

b. Select the arrow on the button with the printer icon, and then select **Save to PDF**.

c. In the Save Result Review Report dialog, select a folder in the USB drive to save the report in. Create a new folder if necessary.

d. If you do not want to use the default file name, enter a new name.

e. Select **Save**.

CHAPTER 11

Troubleshooting

Troubleshooting Overview

The user interface on the analyzer notifies you of an event when an error or problem occurs that requires attention. Troubleshooting involves identifying the issue, locating important information about the issue, and performing the corrective actions to resolve the issue.

Event Indicators

Four event indicators are located in the navigation bar at the top of every page. Each event indicator displays a numerical value that indicates the number of active events.

- **Calibration**: Indicates the number of calibration events that require attention
- **QC**: Indicates the number of QC events that require attention
- **Samples**: Indicates the number of sample events that require attention
- **System**: Indicates the number of system events that require attention

Except for sample event indicators, each event indicator displays a color that indicates the type of event that has occurred. Red and yellow indicate that the analyzer needs attention now. Red indicates an event that has stopped the analyzer from processing samples. Yellow indicates an event that has not stopped sample processing, but if action is not taken, processing could stop.

The event indicators are continuously updated.

Event Information

To identify the issue that requires attention, select the event indicator to view the event page. The event page lists the active events for that indicator. The list provides a description of the event, the effect the event has on sample processing or the analyzer, and when the event occurred.

Corrective Actions

Review the information that is provided and take action to correct the issue. When the issue has been resolved, the event is removed from the event page.

Technical Support

If the problem persists after performing the recommended corrective actions, contact Beckman Coulter Customer Support.

Troubleshooting System Events

When the **System** event indicator is red or yellow, or the number on the indicator increases, a system event has occurred that requires attention.

Select the event from the System Events page and then refer to the user interface to complete the troubleshooting steps.

1 Select the **System** event indicator in the navigation bar.
The analyzer displays the System Events page.

2 Select an event from the list on the System Events page.
The analyzer displays the troubleshooting page for the event.

Note

Address the critical (red) system events first.

3 Follow the instructions on the troubleshooting page.

Troubleshooting Reagent Blank Tests

A reagent blank is a confirmation of the reagent system. The reagent system includes reagents, the reagent probes, and the reagent syringes.

1 Review flags on the Chemistry Results page for the reagent blank result.

— Look for flag u or y when the RB data of the first read point of the test fails.
— Look for flag U or Y when the RB data of the last read point of the test fails.

(Limits are programmed in the Tests system configuration page).

2 Review the calibration events for RB Data Error events.

3 Review reagent blank data on the Reagent Review Details page.

4 Inspect the reagents.

a. Inspect the reagent expiration date.

b. Inspect the reagent onboard expiration date.

c. Confirm the correct reagent preparation.

d. Confirm that fixed reagents are in the correct position.

e. Put on a new bottle of reagent and perform a reagent blank or calibration.

f. Confirm that a reagent with a bar code label is not in a position fixed for a different test.

5 Inspect the reagent probes and reagent syringes.

a. If necessary, clean the reagent probes and wash wells.

b. If necessary, replace the reagent probes.

c. If necessary, replace the reagent syringes.

Troubleshooting Calibration Events

Begin troubleshooting calibrations from the Calibration Events page, which is accessed by selecting the **Calibration** event indicator in the navigation bar.

The Calibration Events page contains a list of the active events. The list provides information about the calibrator associated with the event and a description of the event.

1. Select the **Calibration** event indicator in the navigation bar.
   The analyzer displays the Calibration Events page.
2. Select the event on the Calibration Events page.
3. If the event is an expired calibrator, the analyzer displays the Calibration Material List page where you can configure a new calibrator lot. Refer to Configuring Calibrators.
4. If the event is a calibration failure, review the Calibration Curve Details page. Refer to Reviewing Calibration Data.

   Note

   Even if the calibration failed, you can use a previous valid calibration curve to run the test, instead of performing the following troubleshooting steps. However, results might be erroneous and must not be reported. The analyzer attaches a bh flag to the test result.

5. Troubleshoot the analyzer.
   a. Identify and resolve any other events.
   b. Confirm that all required maintenance has been performed.
6. Troubleshoot the calibrator.
   a. Confirm the material has been handled per the product-specific instructions for use.
      For example, open vial, expiration, reconstitution, and freeze and thaw cycles.
   b. Confirm that the correct material and lot number were selected for the test.
   c. Confirm that the sample container has sufficient volume.
   d. Confirm that the sample container has been loaded in the correct rack and in the correct position.
   e. Confirm that the information entered when the calibrator was configured is correct.
7. Repeat the calibration using the same calibrator that was used during the failed calibration.
   a. Select the checkbox for the calibrator on the Calibration Events page and then select **Reorder**.
   b. If the QC results for the repeat calibration are out of range, contact Beckman Coulter Customer Support.

8 If the calibration still fails, repeat the calibration using a new reagent pack.

   a. Unload the reagent bottle and load a new reagent bottle.

   If the new reagent bottle is from a different lot number than the original bottle, calibrate the test.

   b. Select the checkbox for the calibrator on the Calibration Events page and then select **Reorder**.

   c. If the QC results for the repeat calibration are out of range, contact Beckman Coulter Customer Support.

9 If the calibration still fails, repeat the calibration with a new calibrator set from the same calibrator lot as the previous calibrator set.

   a. Select the checkbox for the calibrator on the Calibration Events page and then select **Reorder**.

   b. If the QC results for the repeat calibration are out of range, contact Beckman Coulter Customer Support.

Troubleshooting Chemistry Calibrations

Calibration is a confirmation of the sampling system. The sampling system includes calibrators, the sample probe, the sample syringe, and the wash syringe.

- Calibrator:
  - Confirm that the correct calibrator was poured for the calibration.
  - Confirm the integrity of the calibrator (expiration date, open-bottle stability, time at room temperature, and contamination).
  - Confirm that the calibrator lot number in use and the lot number concentration programmed in the Calibration Parameters tab of the Tests configuration page are the same.
- Sample Probe:
  - Inspect the sample probe.
  - Clean the sample probe.
  - Clean the sample probe wash wells.
  - Replace the sample probe.
- Sample Syringe and Wash Syringe:
  - Inspect the sample syringe and wash syringe.
  - Replace the sample syringe and wash syringe.

Troubleshooting QC Events

Begin troubleshooting QC results from the QC Events page, which is accessed by selecting the **QC** event indicator.

The QC Events page contains a list of the active QC events. The list provides information about the control material associated with the event.

1. To review the QC data, select the row with the QC test to view the QC Result Review page. Refer to Reviewing QC Data.
2. To reorder a QC test, select the checkbox for the test, and then select **Reorder**.

   Enter comments about the reorder in the QC Failure: Add Comments dialog.

   The analyzer dismisses the QC event and adds the test to the QC test orders and loading guide.
3. Troubleshoot the analyzer.
   a. Identify and resolve any other events.
   b. Confirm that all required maintenance has been performed.
4. Troubleshoot the QC material.
   a. Confirm that the correct material and lot number were selected for the test.
   b. Confirm the material has been handled per the product-specific instructions for use.

      For example, open vial, expiration, reconstitution, and freeze-thaw cycles.
   c. Confirm that the sample container has sufficient volume.
   d. Confirm that the sample container has been loaded in the correct rack and in the correct position.
5. Repeat the QC test.
   a. Confirm that the mean and SD for the control lot are correct.

      Refer to your laboratory procedure for setting the mean and SD for the control lot.
   b. To eliminate random errors as a cause of the QC failure, pipette a fresh sample from the container in use and rerun the QC test.

      Note

      Statistically, even with an appropriate mean and 2SD range, 1 of 20 QC results are out of range, and 1 of 333 QC results are out of the 3SD range.
   c. Prepare new control material according to the procedure provided by the manufacturer, and then repeat the test using the new control material.
   d. Recalibrate the test to compensate for subtle changes in the analyzer or reagent, and then repeat the QC test.
   e. If the results from the repeated QC test are out of range, contact Beckman Coulter Customer Support.

Troubleshooting QC Data

QC validates calibration.

1. Troubleshoot any QC events on the QC events page.
2. Review QC flags on the Result Details page for the QC test.
3. Review the daily QC charts.
   - If all QC is increasing or decreasing (one direction only), the problem could be related to the calibration factor and calibration.
   - If you perform QC on multiple tests from the same control sample, but QC is only out of range for a specific test, the problem could be the QC test parameters, reagent, or calibration.
   - If tests from only one level of QC are out of range, the problem could be incorrect control sample in the cup.

Troubleshooting Sample Events

Begin troubleshooting sample events from the Sample Events page, which is accessed by selecting the **Samples** event indicator.

The Sample Events page contains a list of the active sample events. The list provides information about the sample associated with the event.

Note

If a QC result generates a flag, the flag triggers a sample event on the Sample Events page. When you rerun the QC test and the QC result generates the same flag, no new sample event is displayed on the Sample Events page. Be aware that on the Sample Events page, only the first event for the QC test is displayed until you dismiss the event by selecting the event and selecting **Dismiss**.

1. To review results for a sample with an event, select a sample ID from the list to view the Result Details page.
2. Troubleshoot the analyzer.
   a. Identify and resolve any other events.
   b. Confirm that all required maintenance has been performed.
3. Troubleshoot the sample.
   a. Confirm that the sample volume is sufficient for all the tests that are ordered for the sample.
   b. Confirm that the sample type is correct for the test.
   Refer to the reagent Instructions for Use.
   c. Confirm that the sample was not evaporated from being on the analyzer too long.
   d. Confirm that the bar code label on the sample container is in the correct location on the container and the label is not damaged.
   e. Confirm that the correct sample container and the correct rack were used to process the sample.

4 Troubleshoot the test by confirming that the calibration is not expired.

5 Troubleshoot the reagents.

   a. Confirm that the correct reagent bottle was used and that the bottle is in the correct location on the analyzer.

   b. Confirm that the reagent bottle is not expired.

6 To dismiss a specific event, select **Dismiss** for the specific event in the list.

7 To dismiss all sample events, select **Dismiss All** at the bottom of the page.

Troubleshooting Sample Issues

This system analyzes serum, urine, plasma, other sample types, and whole blood (for HbA1c only). If problems are encountered when analyzing a specific test, or when using a specific reagent, refer to the relevant reagent Instructions for Use or contact Beckman Coulter Customer Support.

Note the following sample requirements:

- Use serum or plasma that is adequately separated from cells, and urine that is free of suspended matter, to prevent the sample probe from becoming blocked, and adversely affecting analysis.
- Confirm that blood samples are sufficiently coagulated before serum separation. Remove any suspended fibrin before placing serum on the system.
- If there is any suspended matter present in urine to be tested, centrifuge the sample before testing.
- Inspect the serum for the extent of hemolysis, lipemia, bilirubin, and other sample quality issues according to your laboratory procedure.
- Precautions when using whole blood (HbA1c):
  - Clean the outside of the sample probe with an alcohol prep (70% Isopropyl alcohol) as required to remove coagulated blood adhering to the outside of the sample probe. Coagulated blood causes increased water being carried on the outside of the sample probe.
  - If the blood has coagulated, obtain a new sample.
  - If the blood cells have precipitated, mix the whole blood by inverting gently.

Troubleshooting Wash Solution Issues

1 Confirm that Beckman Coulter Wash Solution is in the wash solution tank.

2 If the diluted wash solution tank is contaminated, contact Beckman Coulter Customer Support.

3 If the analyzer does not seem to be using the diluted wash solution in the diluted wash solution tank, contact Beckman Coulter Customer Support.

Troubleshooting Deionized Water Related Issues

- Confirm the deionized water supply source for the analyzer does not require service.
- If the deionized water tank is contaminated, clean the deionized water tank.
- If the deionized water filter is dirty, clean the deionized water filter.

Chemistry Result Flags

The analyzer generates flags when the system encounters a condition that can affect the result. This condition can range from minor warnings to severe errors that require attention immediately. Review each flag and identify the root cause, and perform the corrective action.

Do not report any result with an unresolved or unexpected flag. When in doubt, always consider rerunning the sample analysis, and diluting or condensing the sample if necessary.

This section contains a list of all flags in alphabetical order, suggestions of their cause, and action to take.

Table 37 Summary of Flags (Alphabetical Order)

Flag	Definition
#	#: Insufficient sample detected
%	%: Clot detected
(	(: Insufficient reagent probe wash solution
*	*: Linearity error in rate reaction method
$	$: Not enough data to determine linearity of reaction
?	?: Unable to calculate a result
&	&: Prozone test data is abnormal
!	!: Unable to calculate concentration
@	@: OD is higher than 3.0
/	/: Test pending or not analyzed
a	a: Reagent expired
ba	ba: No calibration data or expired
bh	bh: Reagent blank or calibration failed, and the result was calculated with historical data
B	B: OD of reaction is lower than the minimum OD range
D	D: OD of reaction is higher than the maximum OD range
E	E: Error in reaction rate for test using rate reaction method
F	F: Result is higher than the analytical measuring range
Fx	Fx: Result (OD) is higher than the analytical measuring range
G	G: Result is lower than the analytical measuring range

Table 37 Summary of Flags (Alphabetical Order) (Continued)

Flag	Definition
Gx	Gx: Result (OD) is lower than the analytical measuring range
h	h: Result might be affected by hemolysis
H	H: The result is above the upper limit of the reference range
HH	HH: The result is greater than the configured critically high threshold
i	i: Result might be affected by icterus
l	l: Result might be affected by lipemia
L	L: The result is below the low limit of the reference range
LL	LL: The result is less than the configured critically low threshold
n	n: LIH test not performed
NRT	NRT: No result obtained. Timeout occurred waiting for result
R	R: Insufficient reagent detected
Tx	Tx: Result of T-Hb or A1c is outside the analytical measuring range
u	u: OD at the first photometric point for reagent blank or patient sample is low
U	U: Reagent Blank OD exceeds the lower limit set at the last photometric read point
Va	Va: Deviation of multiple measurements check is out of range
Wa	Wa: Test has been analyzed with an erroneous cuvette
y	y: OD at the first photometric point for reagent blank or patient sample is high
Y	Y: Reagent Blank OD exceeds the high limit set at the last photometric read point
Z	Z: Prozone error

#: Insufficient sample detected

Possible Cause	Corrective Action
The sample probe cannot detect sufficient sample volume. • Insufficient sample volume • Malfunction of the sample level detection system • Inappropriate sample cup or tube	1. Review the associated sample event on the Sample Events page. 2. Review all other results that were generated on the same sample before the flag was generated to confirm data validity and consistency (no extremely low or high values). 3. Wipe the probe with an alcohol prep pad (70% Isopropyl alcohol) and inspect the probe to confirm that it is installed correctly. 4. Replace the sample probe. 5. Add more sample to the sample cup, and rerun the test. 6. Confirm that the correct sample cup or tube is in use.

%: Clot detected

Possible Cause	Corrective Action
The sample probe is blocked or partially blocked during sample aspiration.	1. Review the associated sample event on the Sample Events page. 2. Review all other results that were generated on the same sample before the flag was generated to confirm data validity and consistency (no extremely low or high values). 3. Confirm that the sample is free of clots. If that sample has clots, remove the clots and if necessary, centrifuge the sample and rerun the analysis. 4. If the error still occurs, clean or replace the sample probe.

(: Insufficient reagent probe wash solution

Possible Cause	Corrective Action
One or more solutions that were programmed in the Contamination Parameters Configuration page are empty at the positions assigned to Wash (100%) or Lipase Wash in the reagent refrigerator. Contamination parameters are suspended for the related Beckman Coulter Wash Solution. Carryover might have occurred on tests that have this flag. **Note** Lipase wash is available only outside the United States.	1. Fill the bottles for Wash (100%) or Lipase Wash with wash solution (100%) or lipase wash. 2. Perform a reagent check on the bottles. 3. Rerun the analysis for the flagged tests.

***: Linearity error in rate reaction method**

Possible Cause	Corrective Action
The rate of a reaction varies by more than the configured % variance (**Menu** > **System Configuration** > **Test Menu**) and is therefore deemed non-linear, or the reverse reaction check on a test using the rate reaction method fails. • Unusually high result • Contaminated reagent • Dirty or defective mix bars • Reagent or sample probe alignment problem • Outer cuvette walls or the cuvette wheel is wet • Defective cuvettes • Deteriorated lamp • Concentration is close to zero for toxicology analysis using the rate reaction method	1. Dilute the sample and rerun the analysis. 2. Replace a reagent if you suspect contamination, or if the reagent is expired or onboard expired. 3. Clean all mix bars and inspect them for damage. For more information, refer to the Task page for the Perform Weekly Manual Cleaning maintenance task. 4. Confirm the alignment of the sample probe and reagent probe. If the probe is bent, replace the probe. 5. Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, clean the cuvettes and the cuvette wheel. 6. Perform a photocal to assess the lamp and cuvette integrity. Replace the lamp or cuvettes as required and perform another photocal. 7. If using the rate reaction method, the reverse reaction check is performed. If the concentration is close to zero, the reaction curve is flat and triggers the * flag. Confirm that there is no other cause for the * flag before reporting the result. No other action is required.

$: Not enough data to determine linearity of reaction

Possible Cause	Corrective Action
Fewer than three read points of a test using the rate reaction method are within the acceptable optical density range specified. To calculate a test using the rate reaction method correctly, a minimum of three readings must be taken before reaching maximum or minimum optical density. If these optical density limits are exceeded, the reaction might go into substrate depletion caused by a high concentration or a problem with the condition of the reagent. Linearity calculations are not made when this flag occurs.	1. If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic. or can contain excessively large concentration of the analyte being tested. Dilute the sample and rerun analysis. 2. Confirm that the probes and syringes are functioning correctly. For more information, refer to the Task pages for the Perform Daily Checking and Priming and Perform Daily Inspection maintenance tasks. 3. Analyze the reaction data including the reaction data processed immediately before and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow.

?: Unable to calculate a result

Possible Cause	Corrective Action
A result cannot be calculated for this sample:. • In a testing using the rate reaction method, fewer than three photometric readings satisfy the configured test criteria (**Menu** > **System Configuration** > **Test Menu**). • Outer cuvette walls or the cuvette wheel is wet • Mechanical error	1. If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and rerun analysis. 2. Confirm the reagent condition. 3. If the analyzer generates a flag or event identifying the malfunction, select the **Sample** events indicator in the navigation bar for a description of the event and corrective actions. When the problem is solved, rerun the analysis. If the issue persists, contact Beckman Coulter Customer Support. 4. Analyze the reaction data including the reaction data processed immediately before and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, clean the cuvettes and the cuvette wheel.
Diluted Beckman Coulter Wash Solution (2%) was programmed in the Contamination Parameters Configuration page and became empty during sample processing. Carryover prevention parameters are suspended for the diluted wash solution (2%). Carryover might have occurred on tests that have this flag. There are no results for the affected tests.	1. Replace the diluted wash solution (2%) in the bottle at position 78. 2. Rerun the tests that have this flag.

&: Prozone test data is abnormal

Possible Cause	Corrective Action
The data for prozone judgement is abnormal.	Dilute the sample and rerun analysis. If the issue persists, contact Beckman Coulter.

!: Unable to calculate concentration

Possible Cause	Corrective Action
The system has failed to calculate a result.	1. If the flag is a single sample issue, rerun and dilute if necessary. 2. If multiple samples are affected, review all operating parameters such as: — The Decimal Places setting for reporting test results (one recently added test on multiple samples that had that test ordered) — Reagent quality — Calibration — General system issues 3. Analyze the reaction data including the reaction data processed immediately before and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow. 4. If the flag is generated on Na, K, or Cl, rerun a sufficient number of samples which preceded the appearance of the **!** flag in order to confirm that the system did not report incorrect results. It is possible that air in the flow cell affected samples before the system generated the **!** flag. — To ensure that there are no obstructions in the flow cell, prime with ISE MID Standard Solution or ISE Reference Solution and confirm that no bubbles are in the tubing at the bottom of the flow cell. — Confirm that all tubing is connected correctly.

@: OD is higher than 3.0

Possible Cause	Corrective Action
An abnormally high value. A reaction OD has exceeded 3.0. In a dual wavelength measurement, an error occurs if either of the two wavelengths exceed 3.0 OD. This error occurs if one of the following three conditions is met: • Primary wavelength is over the limit (3.0) • Secondary wavelength is over the limit (3.0) • Reaction wavelength is over the limit (3.0) This error only occurs with end point or fixed point reaction methods, not with rate reaction methods. • Sample quality. The sample is severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. • Faulty photometer lamp. • Cuvette overflow.	1. Dilute the sample and rerun analysis. 2. Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range. For more information, refer to the Task pages for the Perform a Photocal and Replace the Photometer Lamp maintenance tasks. 3. Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow.

/: Test pending or not analyzed

Possible Cause	Corrective Action
The test was not performed, even though it was ordered (generally because a reagent bottle is empty), or the testing is still in process.	Review all results generated immediately before this flag for consistency and validity (especially low or high results) and rerun if necessary. 1. If the reagent is empty, place new reagent onto the system and rerun analysis. 2. Confirm that dedicated reagents are in the correct position. 3. Inspect the reagent probe and clean or replace as required. For more information, refer to the Task page for the Perform Daily Checking and Priming maintenance task. 4. Confirm that the reagent probe is correctly installed and connected.

a: Reagent expired

Possible Cause	Corrective Action
The reagent has either expired or has been on board beyond the period defined in the Test page (**Menu** > **System Configuration** > **Test Menu**).	Replace the reagents and perform a reagent check and a calibration if necessary.

ba: No calibration data or expired

Possible Cause	Corrective Action
No reagent blank or calibration data, or the data is expired.	1. Perform a calibration. 2. Review the calibration results. Refer to Reviewing Calibration Data. 3. Carefully review any results generated with this flag and rerun if necessary.

bh: Reagent blank or calibration failed, and the result was calculated with historical data

Possible Cause	Corrective Action
Reagent blank or calibration failed, and the result was calculated with historical data. Results can be erroneous and must not be reported.	1. Perform a calibration. 2. Review calibration results on the Calibration Curve Details page. Refer to Reviewing Calibration Data. 3. Rerun samples using a valid calibration.

B: OD of reaction is lower than the minimum OD range

Possible Cause	Corrective Action
The OD of a test using the rate reaction method or fixed point reaction method cannot meet the minimum OD criteria for the configured OD Limit for the test (**Menu** > **System Configuration** > **Test Menu**). • Specified read point FST+2 (first photometry point plus two) in a negative rate reaction method: High concentration • Photometry read point in a negative fixed point reaction method: High concentration • Photometry read point in a positive fixed point reaction method: Low concentration.	• If this flag is only generated on one or a few samples, inspect the sample quality: — If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and rerun analysis. — If the sample has a low concentration, no reaction occurs in the cuvette. Confirm that there is enough sample volume in the tube. • If this flag is only generated on one reagent, inspect the reagent quality: — Inspect the reagent for contamination. — Inspect the reagent expiration, onboard expiration, and reagent blank expiration. — Confirm that the reagent was prepared correctly. — Confirm that fixed reagents are in the correct position. • If this flag is generated randomly on several samples and several different tests: — Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, clean the cuvettes and the cuvette wheel. — Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range.

D: OD of reaction is higher than the maximum OD range

Possible Cause	Corrective Action
The OD of a test using the rate reaction method or fixed point reaction method cannot meet the maximum OD criteria for the configured OD Limit for the test (**System Configuration** > **Configure Tests**). • Specified read point FST+2 (first photometry point plus two) in a positive rate reaction method: High concentration • Specified read point LST-2 (last photometry point minus two) in a negative rate reaction method: Low concentration • Photometry read point in a positive fixed point reaction method: High concentration • Photometry read point in a negative fixed point reaction method: Low concentration	• If this flag is only generated on one or a few samples, inspect the sample quality: — If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and rerun analysis. — If the sample has a low concentration, no reaction occurs in the cuvette. Confirm that there is enough sample volume in the tube. • If this flag is only generated on one reagent, inspect the reagent quality: — Inspect the reagent for contamination. — Inspect the reagent expiration, on-board expiration, and reagent blank expiration. — Confirm that the reagent was prepared correctly. — Confirm that fixed reagents are in the correct position. • If this flag is generated randomly on several samples and several different tests: — Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, clean the cuvettes and the cuvette wheel. — Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range.

E: Error in reaction rate for test using rate reaction method

Possible Cause	Corrective Action
In the test using the rate reaction method, the result is judged as an error because the reaction was finished in an excessively short time. • Abnormally high concentration of analyte in a sample	Dilute the sample and rerun the analysis.

F: Result is higher than the analytical measuring range

Possible Cause	Corrective Action
The concentration of the sample is above the high limit for the configured analytical measuring range for the test (**Menu** > **System Configuration** > **Configure Tests**).	1. Confirm that the correct analytical measuring range is configured. 2. Dilute the sample and rerun the analysis. Dilute the sample so that the sample yields a value in the middle of the analytical measuring range.

Fx: Result (OD) is higher than the analytical measuring range

Possible Cause	Corrective Action
No concentration could be calculated. The OD of the sample exceeded the OD of the upper limit of the analytical measuring range.	Dilute the sample and rerun analysis.

G: Result is lower than the analytical measuring range

Possible Cause	Corrective Action
The concentration of the sample is below the low limit for the configured analytical measuring range for the test (**Menu** > **System Configuration** > **Configure Tests**), or the reagent was not dispensed correctly. • Incorrect analytical measuring range is programmed • Clinical context of the patient • Insufficient reagent dispensing • Insufficient sample dispensing	1. Confirm that the correct analytical measuring range is configured. 2. Review the result in the clinical context of the patient and rerun if necessary. 3. Confirm the correct operation of the reagent probe. 4. Confirm that the reagent bottles are in the correct position. 5. Inspect the sample for bubbles.

Gx: Result (OD) is lower than the analytical measuring range

Possible Cause	Corrective Action
No concentration could be calculated. The OD of the sample is lower than the OD of the low limit of the analytical measuring range.	1. Review the result in the clinical context of the patient and rerun if necessary. 2. Confirm the correct operation of the reagent probes. 3. Confirm that the reagent bottles are in the correct position. 4. Inspect the reagents for bubbles.

h: Result might be affected by hemolysis

Possible Cause	Corrective Action
The result might be affected by hemolysis.	Follow laboratory procedure for hemolytic samples.

H: The result is above the upper limit of the reference range

Possible Cause	Corrective Action
The sample result is higher than the configured high value for the test (**Menu** > **System Configuration** > **Configure Tests**).	Follow laboratory procedures for abnormal results.

HH: The result is greater than the configured critically high threshold

Possible Cause	Corrective Action
The sample result is higher than the configured critical upper value for the test (**Menu** > **System Configuration** > **Configure Tests**).	Follow laboratory procedures for abnormal results.

i: Result might be affected by icterus

Possible Cause	Corrective Action
The result might be affected by bilirubin.	Follow laboratory procedure for icteric samples.

l: Result might be affected by lipemia

Possible Cause	Corrective Action
The result might be affected by lipemia or samples are turbid.	Follow laboratory procedure for lipemic samples.

L: The result is below the low limit of the reference range

Possible Cause	Corrective Action
The sample result is lower than the configured low value for the test (**Menu** > **System Configuration** > **Configure Tests**).	Follow laboratory procedure for abnormal results.

LL: The result is less than the configured critically low threshold

Possible Cause	Corrective Action
The sample result is lower than the configured critical lower value for the test (**Menu** > **System Configuration** > **Configure Tests**).	Follow laboratory procedures for abnormal results.

n: LIH test not performed

Possible Cause	Corrective Action
The LIH test has not been performed for tests configured with **LIH Influence Check** in the Chemistry Details: General Parameters section of the Tests page (**Menu** > **System Configuration** > **Test Menu**).	1. Examine the sample and rerun if necessary. 2. Confirm the LIH reagent.

NRT: No result obtained. Timeout occurred waiting for result

Possible Cause	Corrective Action
No result was obtained. A timeout occurred after waiting 3 hours for the result.	1. Check the quality of the sample. 2. If the quality of the sample is okay, run the test again.

R: Insufficient reagent detected

Possible Cause	Corrective Action
Level detection indicates the reagent volume is not sufficient for analysis.	1. Review the associated sample event on the Sample Events page. 2. Review all results generated immediately before this flag for consistency and validity (in particular the low or high results), and rerun the analysis, if necessary. 3. Place new reagent onto the analyzer and rerun the analysis. 4. If the flag occurs even though there is sufficient reagent, the reagent bottle can contain bubbles. Remove the bubbles and perform another reagent check. 5. If the reagent bottle opening is wet, dry the opening. Inspect the reagent probe, and clean or replace the probe as required. 6. Confirm that the reagent probe is correctly installed.

Tx: Result of T-Hb or A1c is outside the analytical measuring range

Possible Cause	Corrective Action
The result of T-Hb or A1c is outside the analytical measuring range programmed in the Chemistry Details: General Parameters section of the Tests page (**Menu** > **System Configuration** > **Test Menu**).	1. Rerun analysis. 2. If the result is confirmed, report according to the reagent Instructions for Use. For whole blood samples, remix the whole blood and rerun the analysis.

u: OD at the first photometric point for reagent blank or patient sample is low

Possible Cause	Corrective Action
The first photometric point OD of the reagent blank or the OD at P0 of the patient sample is lower than the configured Reagent OD Limit for the test (**Menu** > **System Configuration** > **Configure Tests** > **Chemistry Details**). • Reagent expired • Reagent contamination • Incorrectly prepared reagents • Incorrectly configured range	1. Inspect the reagent expiration and onboard expiration date. 2. Confirm that the reagent has been prepared correctly. 3. Replace the reagent and rerun the analysis. 4. Confirm that the configured Reagent OD Limit is correct.

U: Reagent Blank OD exceeds the lower limit set at the last photometric read point

Possible Cause	Corrective Action
Reagent blank OD is lower than the configured Reagent OD Limit for the test (**Menu** > **System Configuration** > **Configure Tests** > **Chemistry Details**). • Reagent expired • Reagent contamination • Incorrectly prepared reagents • Incorrectly configured range	1. Inspect the reagent expiration and onboard expiration date. 2. Confirm that the reagent has been prepared correctly. 3. Replace the reagent and rerun analysis. 4. Confirm that the configured Reagent OD Limit is correct.

Va: Deviation of multiple measurements check is out of range

Possible Cause	Corrective Action
The precision of replicates for the reagent blank or calibration exceeds the allowable range.	1. Perform the corresponding maintenance: — Inspect the syringes. — Inspect the sample probe. For more information, refer to the Task pages for the Perform Daily Checking and Priming and Perform Daily Inspection maintenance tasks. 2. Confirm the correct sample material was used for the reagent blank or calibration. 3. Inspect for evidence of system contamination.

Wa: Test has been analyzed with an erroneous cuvette

Possible Cause	Corrective Action
The test has been analyzed using a cuvette which failed photocal criteria.	1. Clean the affected cuvette and perform a photocal. For more information, refer to the Task pages for the Clean or Replace Individual Cuvettes and Perform a Photocal maintenance tasks. 2. If the error still occurs, replace the cuvette. For more information, refer to the Task page for the Clean or Replace Individual Cuvettes maintenance task. 3. Rerun analysis.

y: OD at the first photometric point for reagent blank or patient sample is high

Possible Cause	Corrective Action
The first photometric point OD of the reagent blank or the OD at P0 of patient sample is higher than the configured Reagent OD Limit for the test (**Menu** > **System Configuration** > **Configure Tests** > **Chemistry Details**). • Reagent expired • Reagent contamination • Incorrectly prepared reagents • Incorrectly configured range	1. Inspect the reagent expiration and onboard expiration date. 2. Confirm that the reagent has been prepared correctly. 3. Replace the reagent and rerun analysis. 4. Confirm that the configured Reagent OD Limit is correct.

Y: Reagent Blank OD exceeds the high limit set at the last photometric read point

Possible Cause	Corrective Action
Reagent blank OD is higher than the configured Reagent OD Limit for the test (**Menu** > **System Configuration** > **Configure Tests** > **Chemistry Details**). • Reagent expired • Reagent contamination • Incorrectly prepared reagents • Incorrectly configured range	1. Inspect the reagent expiration and onboard expiration date. 2. Confirm that the reagent has been prepared correctly. 3. Replace the reagent and rerun analysis. 4. Confirm that the configured Reagent OD Limit is correct.

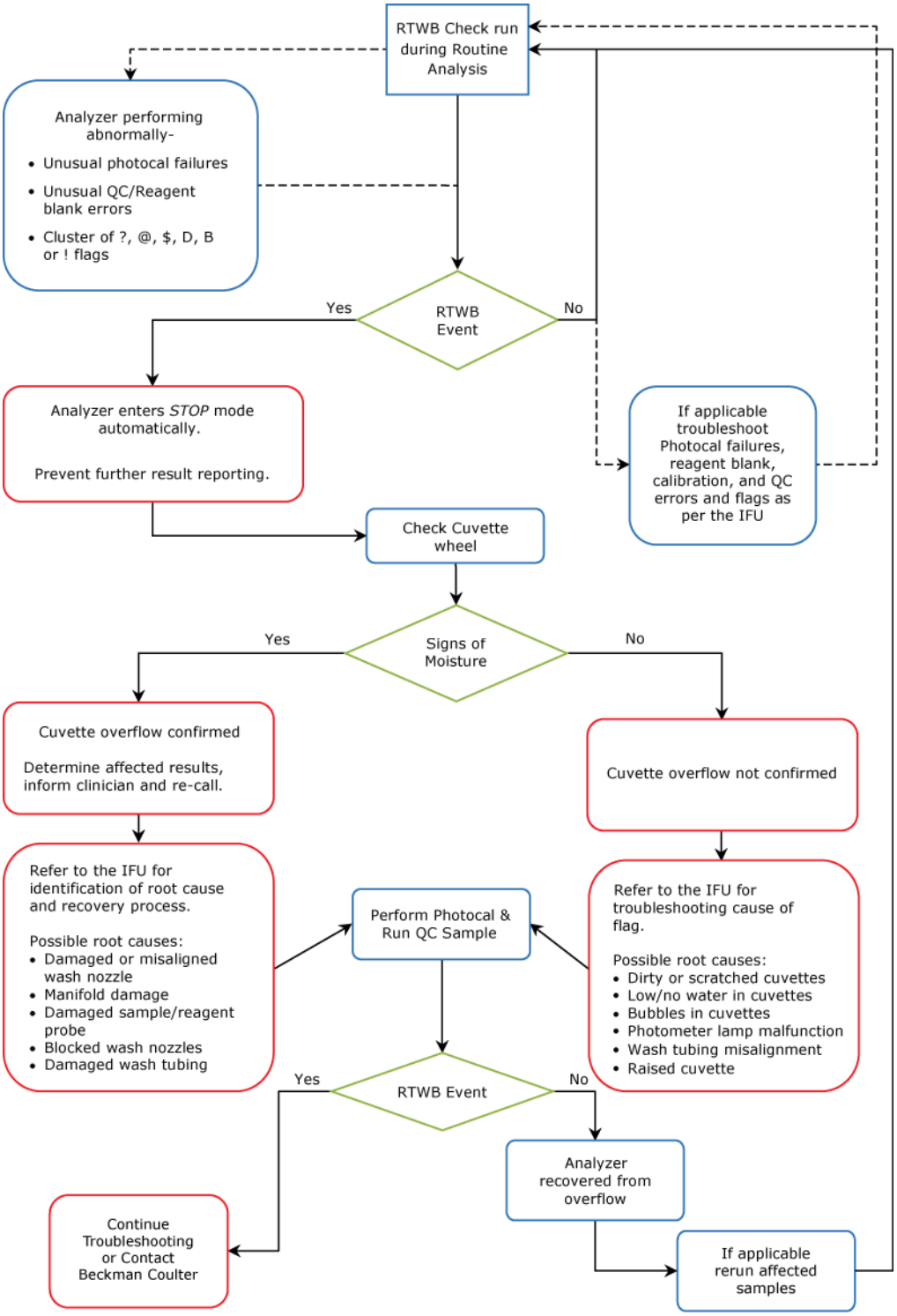
Z: Prozone error

Possible Cause	Corrective Action
A configured mathematical logic check for the test failed (**System Configuration** > **Configure Tests**). • Abnormally high concentration of analyte in a sample	Dilute the sample and rerun the analysis.

RTWB Troubleshooting Overview Flowchart

The flowchart shows an overview of errors and corrective actions for monitoring the automatic RTWB check function while the system is in operation.

Figure 68 RTWB Troubleshooting Overview Flowchart



Recovering from a Photometry Error During a Cuvette Wash Event

Inspect the cuvettes to determine if a cuvette overflow occurred when the system generated a `Photometry Error During a Cuvette Wash` event. The recovery procedures are different if a cuvette overflow occurred, or if unstable photometry caused the error.

The analyzer goes to *Stopped* state immediately after the system generates a `Photometry Error During a Cuvette Wash` event.

Inspecting the Cuvettes to Determine if an Overflow Occurred

To confirm that a cuvette overflow has occurred, remove the cuvette wheel cover after initializing system. The cuvettes are frosty or white. If the cuvettes are dark, black, or are wet when removed, a cuvette overflow has occurred. In addition, remove the cuvette identified in the `Photometry Error During a Cuvette Wash` event. The number at the end of the event description identifies the cuvette number that generated this event (cuvette number 1 to 88). Visually inspect the cuvette to determine if it is wet. If the cuvette is wet on the outside, refer to Recovering from a Cuvette Wheel Overflow and perform all system recovery procedures. If the cuvette is not wet on the outside, refer to Recovering from an Unstable Photometry Error and perform the required system recovery procedures determined by the cause of the error.

For more information on how to remove the cuvette wheel, refer to the Task page for the Clean the Cuvettes and the Cuvette Wheel maintenance task.

Recovering from a Cuvette Wheel Overflow

Performing scheduled maintenance reduces the chances of a cuvette wheel overflow.

Indications that a cuvette wheel overflow has occurred include the following items:

- Sample flags *, ?, D, or B
- QC flags or events
- Reagent blank flags
- Analyzer not performing normally
- Numerous cuvettes failing after a photocal

The data, events, or flags vary depending on the severity of the overflow. An overflow can affect one or all tests.

Also, if a cuvette wheel overflow has occurred, the cuvettes will be dark, black, or wet when removed.

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1 Align the wash nozzle subsystem over the cuvettes and confirm that the wash nozzles are centered over the cuvettes.

A bent or damaged wash nozzle can cause overflow.

---

2 Sonicate and clean the wash nozzles with a stylet to remove any debris.

When the wash nozzle is clogged, liquid is not aspirated from the cuvette completely and eventually liquid spills over the side. A clogged wash nozzle can occur when the wash nozzles are not cleaned correctly, or when particles such as glass are aspirated into the nozzle.

3 Rotate the sample and reagent probes over the cuvette wheel and confirm that the probes are correctly aligned.

A bent probe could be dispensing outside of the cuvette.

4 Inspect the cuvettes and replace any that are chipped or cracked.

Chipped or cracked cuvettes can be caused by alignment problems with the reagent probe or wash nozzels.

5 Inspect the wash nozzle tubing connections and confirm that the connections are secure.

Leaking connections can cause overflow.

6 Inspect the O-rings inside the mounting joint of the water supply tube and confirm that the o-rings are in position and not damaged.

Damaged or out-of-position O-rings can cause overflow.

7 After the cuvette wheel overflow has been corrected, clean the cuvettes and the cuvette wheel.

8 If the analyzer generated a `Photometry Error During Cuvette Wash` event, rerun all tests with results that were obtained during the 60 minutes before the event was generated.

The overflow might have occurred 60 minutes before the event was generated. (The 60-minute time frame is the possible time that the analyzer was in the *Running* (*Sampling*) state.) Results obtained during the 60 minutes before the event was generated are invalid and need to be obtained again. For detailed instructions, refer to Identifying and Reanalyzing Samples after a Cuvette Wheel Overflow.

Identifying and Reanalyzing Samples after a Cuvette Wheel Overflow

A cuvette overflow could have occurred 60 minutes before the system generates the `Photometry Error During a Cuvette Wash` event. The results measured during the 60 minutes before the event are invalid and must be reanalyzed.

The analyzer changes to the *Error* (*Stopped*) state immediately after the system generates the `Photometry Error During a Cuvette Wash` event. The number at the end of the event description identifies the cuvette number that generated this event (cuvette number 1 to 88).

Warning

The 60-minute time frame is the time that the analyzer was in the *Running* (*Sampling*) state. If the analyzer went into the *Running* (*Standby*) state and did not remain in the *Running* (*Sampling*) state for 60 consecutive minutes before the event, add the *Running* (*Standby*) state time to the 60-minute time frame. For example, if the analyzer was in the *Running* (*Standby*) state for 20 minutes total, add 20 minutes to

the 60 minutes and search for samples affected by the overflow in the past 80 minutes.

Search for samples affected by the overflow.

1. Select the **System** event indicator in the navigation bar.
   The analyzer displays the System Events page.
2. Search for the event message `Photometry Error During a Cuvette Wash`.
3. Note the date and time of the event.
4. Search for the `MEASURE START` messages on the Audit Log page.
   Refer to Viewing the Audit Log Page.
5. Calculate the time between the `Photometry Error During a Cuvette Wash` event and the most recent `MEASURE START` message.
   - If the time between the system event and audit log message is 60 minutes or longer, the time frame for searching samples with invalid data is 60 minutes.
   - If the time between the system event and audit log message is shorter than 60 minutes, determine the time in the *Running* (*Sampling*) state, and add it to the next time in the *Running* (*Sampling*) state, and continue adding the time until the total time in the *Running* (*Sampling*) state is 60 minutes. Add the total time in the *Running* (*Standby*) state between the *Running* (*Sampling*) states and the `Photometry Error During a Cuvette Wash` event, and add it to 60 minutes. The result is the time frame for searching samples with invalid data.
6. Calculate the start date and time for the search to identify all the affected samples. Calculate backwards from the `Photometry Error During a Cuvette Wash` event by the time frame calculated in the previous step.
   The ending date and time for the search is the time when the system generated the `Photometry Error During a Cuvette Wash` event.
7. Find the affected samples within the time frame between the start and ending date and time for the search.
   Refer to Viewing Test-Specific Result Statistics.

Recovering from an Unstable Photometry Error

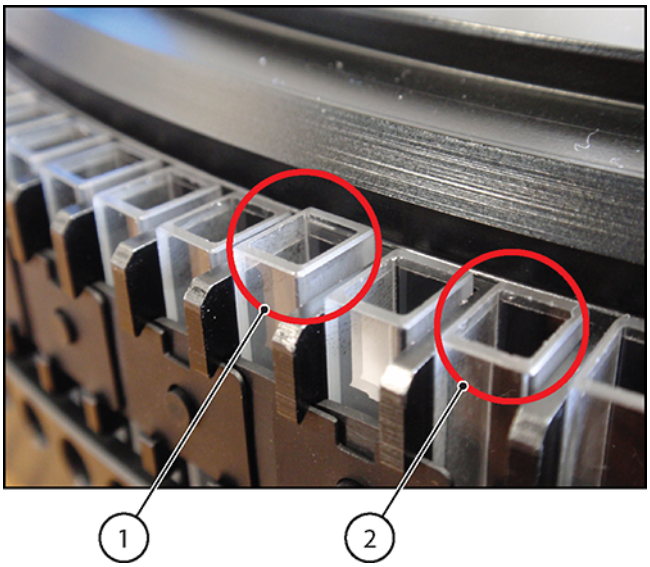
When the analyzer generates a `Photometry Error During a Cuvette Wash` event, and a cuvette overflow did not occur, unstable photometry causes the event. Incorrectly placed cuvettes in the cuvette wheel, an insufficient amount of diluted wash solution being supplied to clean the cuvettes, bubbles in the bottom of the cuvettes, dirty or scratched cuvettes, or a deteriorating lamp can cause unstable photometry.

Perform the following procedures in this section. After the error is identified and corrected, perform a photocal. For general information that you can use to locate and perform the Perform a Photocal maintenance task, refer to Performing a Maintenance Task. If the error still occurs, contact Beckman Coulter Customer Support.

Inspecting the Cuvette Placement

Inspect the cuvette identified by the `Photometry Error During a Cuvette Wash` event to determine if it is placed in the cuvette wheel correctly. Push the cuvette down into the cuvette wheel until the top of the cuvette is even with the cuvette wheel.

Figure 69 Incorrect and Correct Cuvette Placement

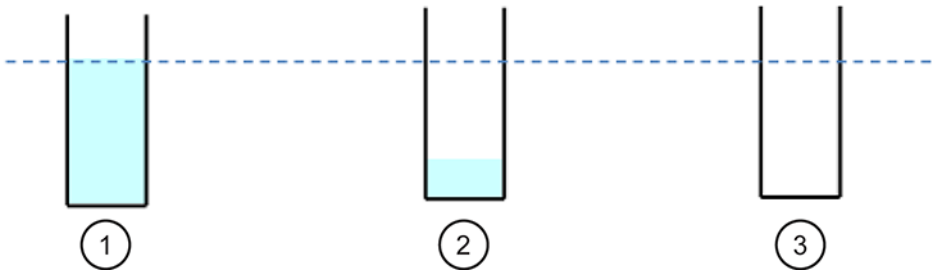


1. Incorrect cuvette placement
2. Correct cuvette placement

Inspecting the Cuvette Condition

1 Inspect the cuvettes identified by the `Photometry Error During a Cuvette Wash` event to determine if there is sufficient diluted wash solution in the cuvette.
If the remaining diluted wash solution volume is insufficient or empty, there is a possibility of system malfunction. Contact Beckman Coulter Customer Support.

Figure 70 Diluted Wash Solution Level in Cuvette



1. Sufficient: OK
2. Insufficient: Not Good
3. Empty: Not Good

---

2 Inspect the cuvette to determine if there are any bubbles at the bottom of the cuvette.

Figure 71 Bubbles in Cuvette

1. Not good
2. Not good

---

3 If bubbles exist in the cuvette, inspect the water and wash solution supply tubing on the wash nozzle component to determine if there are bubbles. The aspiration tubing has bubbles in normal operation.

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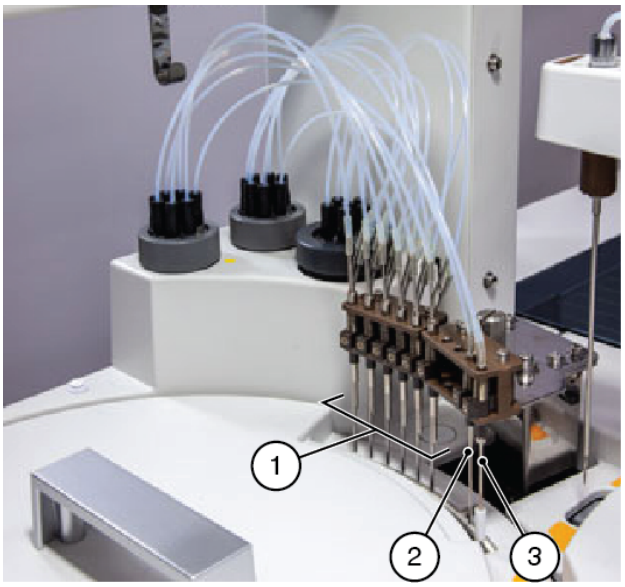
4 If bubbles exist in the water and wash solution supply tubing on the wash nozzle component, tighten the tube mounting joints and remove the bubbles by performing the Clean Cuvettes with Internal Wash maintenance task or by priming the wash nozzle.

For general information that you can use to locate and perform the Perform a Photocal maintenance task, refer to Performing a Maintenance Task.

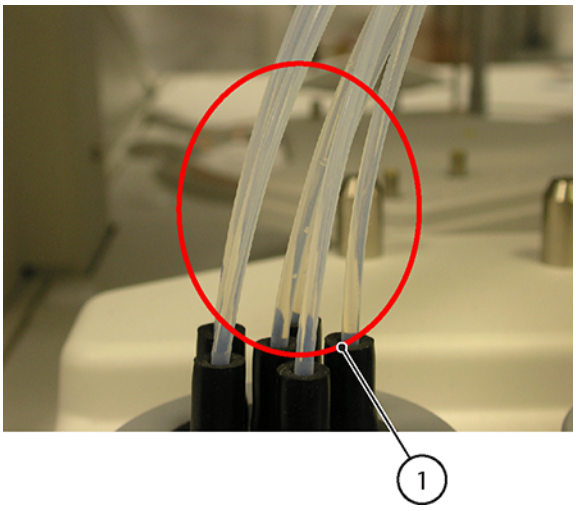
For instructions on priming the wash nozzle, refer to the instructions that appear on the Task page for the Replace the O-rings in the Water Supply Tube Mounting Joint maintenance task.

Figure 72 Tube Mounting Joint Manifolds



1. Water supply tube mounting joint manifold (A total of six O-rings are used inside)
2. Wash nozzle tube mounting joint manifolds
3. Wash nozzle component

Figure 73 Water Supply Tubing



1. Inspect water supply tubing for bubbles

5 Inspect the cuvette to determine if it is dirty or scratched. Clean or replace the cuvette as required. For general information that you can use to locate and perform the Clean or Replace Individual Cuvettes maintenance task, refer to Performing a Maintenance Task.

Inspecting the Photometer Lamp

Confirm the number of hours that the photometer lamp has been in use.

To view the lamp usage hours on the Photocal Results page, go to the Task page for the Perform a Photocal maintenance task and select **Photocal Results**.

If the lamp has been in use for over 1,000 hours, replace the lamp.

For general information that you can use to locate the Perform a Photocal maintenance task, refer to Performing a Maintenance Task.

Resetting the Sample Handler

Sometimes you will need to reset the sample handler in order to perform troubleshooting.

1. Select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.
2. Select **Sample Handler Reset**.
   The sample handler ready status moves to *True*.

Resetting the ISE Module

You can view the status of the ISE module, or reset the ISE module when it has an error and you want to run photometric tests, on the Custom Diag page.

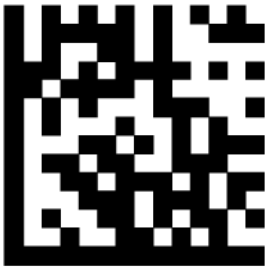
1. Select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.
2. Select **ISE Reset**.
   The ISE module moves to Stopped status.

Relinking the Wireless Handheld Bar Code Reader

If the wireless handheld bar code reader was moved for an extended time to a location outside of its communication range with the charger base, the reader might lose its link to the charger base.

To relink the reader with the charger base, scan the following bar code with the reader.

Figure 74 Bar Code for Relinking the Wireless Handheld Bar Code Reader



Unlink

CHAPTER 12

System Management

System Management Overview

System management includes managing user access, configuring the user interface language, shutting down the analyzer, and restarting the analyzer.

Managing User Access

You can set up individual accounts for users of the analyzer, including access levels and passwords.

Changing the User Interface Language

The user interface can be displayed in a variety of languages.

Shutting Down and Restarting the Analyzer

Shutting down and restarting includes the following tasks:

- Shutting down the analyzer
- Restarting the analyzer

Accounts and Passwords

Accounts and passwords help provide security and traceability for your analyzer.

If you are an administrator, Beckman Coulter recommends that you create an account with a required user name and password for each person who will use the analyzer. Accounts help to manage access to various features, and prevent unauthorized access to the analyzer. The analyzer records which operator ordered tests, edited patient information, performed maintenance activities, and so on.

Note

You must configure at least one user as a Super User. Users with Super User authorization can perform any action on the analyzer, including managing user accounts, and performing service activities.

Authorizations

You can assign one or more authorizations to each user account. The following authorizations are available:

- Super User: User can perform all activities on the analyzer
- Manage Users: User can create or delete users, and assign temporary passwords
- System Configuration: User can edit the system configuration
- View Patient Information: User can see patient ID and name, sample IDs, and demographic information
- Perform Maintenance: User can perform maintenance activities
- Perform Service: User can perform service activities

Caution

As a Perform Service user, you have access to the Chemistry Diagnostics pages and the ISE Analysis page in the Advanced menu. Except for the Custom Diag page, do not perform any actions on these pages unless directed to do so by Beckman Coulter Customer Support.

Passwords

Users with an account on the analyzer can change their password. You must have the Manage Users authorization to reset passwords for other users.

You can configure the requirements for password complexity, and set when passwords expire.

Automatic Logout Options

To ensure that each user is logged in under the correct username and password, you can enable automatic logout. Automatic logout locks the console and logs out the user after a period of inactivity.

When users are automatically logged out, they do not lose any data or work that was in process at the time. When they log in again, they see the analyzer as it was when they were logged out, provided that another user has not logged in and made changes. However, if a different user logs in, all pages opened by the previous user are closed and any unsaved data is lost.

Deactivated Accounts

You must have the Manage Users authorization to deactivate the accounts of other users, including other users with the Manage Users authorization. When an account is deactivated, the user associated with that account cannot log in. A deactivated account remains visible on the User Account Management page. You must have the Manage Users authorization to reactivate the account.

Creating User Accounts

Create a user account for each person that is authorized to use the analyzer.

Note

You must have the Manage Users authorization to perform this task.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 75 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select **Create User Account**.
The analyzer displays the Create User Account dialog.

4 Enter a username and temporary password for the new user, and then select **Done**.

The new user account is added to the list, but no authorizations are selected by default.

Note

Temporary passwords are not subject to password requirements, because the user must enter a new password that meets requirements when they log in.

5 Under Authorizations, select the checkboxes for the authorizations that you want to assign to the user. Clear the checkboxes for any authorizations that you do not want to assign to the user.

Note

Selecting **Super User** automatically selects all authorizations.

Important

There must always be at least one active account with Super User authorization. The first account that you create must be a Super User account.

6 Select **Save**.
The account information is saved.

Editing User Authorizations

You must have the Manage Users authorization to edit user accounts.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 76 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select the line for the user account to edit.

4 Under Authorizations, select the checkboxes for the authorizations that you want to assign to the user. Clear the checkboxes for any authorizations that you do not want to assign to the user.

Note

Selecting **Super User** automatically selects all authorizations.

Important

There must always be at least one active account with Super User authorization. The first account that you create must be a Super User account.

5 Select **Save**.
The account information is saved.

Unlocking a Locked User Account

When a user enters an incorrect password five consecutive times, the account is locked for 30 minutes.

Note

You must have the Manage Users authorization to perform this task.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 77 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select **Unlock** on the line for the user with the locked account.
The account is unlocked.

Deactivating User Accounts

When you deactivate a user account, the user is prevented from logging in.

Note

You must have the Manage Users authorization to perform this task.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 78 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Clear the checkbox in the Active column for the user account that you want to deactivate.

4 Select **Save**.
The account information is saved.

Configuring Automatic Logout

You can configure when users are automatically logged out of the analyzer due to inactivity.

Note

You must have the Manage Users authorization to perform this task.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 79 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select the **Activate** checkbox next to the **Unattended time before automatic logout** field, if it does not already contain a checkmark.

4 At the top of the page, select the text field for **Unattended time before automatic logout**, and in the Text Input dialog enter the number of minutes to keep a user logged in after user's last action at the console.

5 Select **Save**.
The account information is saved.

Configuring Password Expiration

You can configure the number of days before a password expires. When a password expires, the user must create a new password.

Note

You must have the Manage Users authorization to perform this task.

1. Select the user accounts icon in the upper right corner of the screen.

   Figure 80 User Accounts Icon

2. Select **Manage User Accounts** from the menu.
   The analyzer displays the User Account Management page.
3. Select the **Activate** checkbox next to the **Password Expiration** field, if it does not already contain a checkmark.
4. At the top of the page, select the text field for **Password Expiration**, and in the Text Input dialog enter the number of days for a password to remain valid.
5. Select **Save**.
   The account information is saved.

Configuring Password Requirements

You can increase the security of the analyzer by defining rules for the complexity of passwords.

Note

You must have the Manage Users authorization to perform this task.

You can select from the following options for password requirements:

- **Must contain a minimum number of characters:** (*Specify a number from 1 to 100.*)
- **Must contain at least one uppercase letter.**
- **Must contain at least one lowercase letter.**
- **Must contain at least one numeral.**
- **Must contain at least one special character.** (Any character that is not a letter or numeral.)
- **Must not contain the user name in uppercase, lowercase or mixed-case representations.**
- **Must differ from previous passwords:** (*Specify a number from 1 to 100.*)

1 Select the user accounts icon in the upper right corner of the screen.

Figure 81 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select **Set Password Requirements**.
The analyzer displays the Set Password Requirements dialog.

4 Select the options that you want to enforce when users create passwords.

For the options **Must contain a minimum number of characters:** and **Must differ from previous passwords:** enter the minimum number (up to 100) of characters or previous passwords in the field.

Note

Each option that you select from the requirements for uppercase letter, lowercase letter, numeral, and special character increases the lowest number that you can specify for the **Must contain a minimum number of characters:** option. For example, if you select all four options, you must specify a value of at least 4.

5 Select **Done**.
The analyzer saves the changes and closes the dialog.

6 Select **Save**.
The account information is saved.

Resetting Passwords

If a user forgets their password, you can reset it to a temporary password. The next time the user logs in, they must create a permanent password that meets the password requirements.

Note

You must have the Manage Users authorization to perform this task.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 82 User Accounts Icon

2 Select **Manage User Accounts** from the menu.
The analyzer displays the User Account Management page.

3 Select **Reset** next to the username with the password to reset.
The analyzer displays the Reset Password dialog.

4 Enter a temporary password in the **Password** field.

Note

Temporary passwords are not subject to password requirements, because the user must enter a new password that meets requirements when they log in.

5 Select **Done**.
The password is reset to the temporary password.

Changing Your Password

You can change your password at any time.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 83 User Accounts Icon

2 Select **Change Password** from the menu.
The analyzer displays the Change Password dialog.

3 Enter your current password in **Current Password**.

4 Enter a new password in **New Password**.
As you enter the password, each red x in the Password Rules box changes to a green checkmark when the associated rule has been satisfied.

5 Enter the password again in **Confirm Password**.
If the passwords match, the final red x changes to a green checkmark.

6 Select **Save**.
Your password is changed.

Logging In

You must log in to gain access to analyzer functions.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 84 User Accounts Icon

2 Select **Log In** from the menu.
The analyzer displays the Log In dialog.

3 Enter your username in **Username**.

4 Enter your password in **Password**.

5 Select **Log In**.

Logging Out

When you leave the analyzer, log out to prevent other users from performing actions in your name.

1 Select the user accounts icon in the upper right corner of the screen.

Figure 85 User Accounts Icon

2 Select **Log Out** from the menu.

3 Select **Log Out** in the Confirm dialog.
You are logged out.

Note

When you log out, the analyzer automatically logs in to the Guest account, which has limited access. The Guest account prevents access to any patient information and Maintenance tasks, but allows users to perform tasks on the Consumables, Reagents, Calibration, and QC pages.

Changing the User Interface Language

The analyzer user interface and System Help are available in different languages.

You can change the language that the analyzer uses for the System Help and the user interface. When you change the language, all open tabs close, and the user interface restarts.

Note

It is recommended not to the change the user interface language when tests are in progress.

Note

Only the user interface is restarted. Tests in progress and other analyzer functions continue to run. However, when the tabs close, incomplete user interface workflows (such as ordering tests or reviewing results) are canceled and must be restarted.

Note

Changing the language does not change the date and time format or the on-screen keyboard. To change the date and time format or the on-screen keyboard, contact Beckman Coulter Customer Support.

1 Select **Menu** > **Languages**.
The analyzer displays a list of available languages.

2 Select your preferred language from the list.

Important

Do not select **Language Pack**. The **Language Pack** option is for use by Beckman Coulter service personnel only.

Note

Selecting a language included in the table below displays the System Help and the user interface in the chosen language. Selecting any other language, if available, displays the System Help in the chosen language and the user interface in English.

— Chinese (simplified) — English — French — German	— Greek — Hungarian — Italian — Japanese	— Polish — Portuguese (continental) — Russian — Spanish — Turkish

The analyzer displays a confirmation dialog.

3 To confirm your selection, select **Yes**.
The user interface closes and restarts.

Viewing the Audit Log Page

The Audit Log page is a record of significant events and actions performed on the analyzer.

You can filter the events and actions recorded in the Audit Log page by the following parameters.

- Category—Categories include Configuration, Events, Sample, QC, User, System, Calibration, and Reagent Blank.
- Subsystem—The software or hardware subsystem
- Initiated By—Who performed the action, or System, in the case of a software-generated event.
- Date Range—The date and time in which the action or event occurred.

You can combine filtering parameters to further narrow the scope of the Audit Log page display.

1 Select **Menu** > **Audit Log**.
The analyzer displays the Audit Log page.

2 To view only entries for a certain category, select the **Category** list box, and then select a category from the list.
The Audit Log page displays only entries for the selected category.

3 To view only entries for a certain subsystem, select the **Subsystem** list box, and then select a subsystem from the list.
The Audit Log page displays only entries for the selected subsystem.

4 To view only entries for a certain user (or the system), select the **Initiated By** list box, and then select a user from the list.
The Audit Log page displays only entries associated with the selected user.

5 To view entries from a certain date range, select **From** and **To** dates and times in the Date Range selector, and then select the date and time for each end of the range.

a. Select the date and time in the **From** or **To** fields.
The analyzer displays the Date Entry dialog. The dialog defaults to the current date and time. Buttons across the top of the dialog enable you to select the **Year**, **Month**, **Day**, **Hour**, and **Minute**. You can switch from one view to another at any time.

b. Select the button for the unit of time that you want to change.
The analyzer displays options for selecting date and time units.

c. Select a date and time unit.
The analyzer updates the date and time range according to your selection.

d. Continue these steps until the analyzer displays the date and time that you want to use.

e. Select **Done** to save the range and exit the dialog.
The Audit Log page now shows only entries from the specified date and time range.

6 To refresh the data displayed on the Audit Log page, select **Refresh Log**.
The analyzer updates the display with any entries that were generated after you opened the Audit Log page, or since the last time you selected **Refresh Log**.

7 To create a file containing the Audit Log page entries, export the audit log.

a. Plug a USB drive into one of the USB ports on the front of the computer.

b. Select **Export**.
The analyzer displays the Save As dialog.

c. Open the folder in the USB drive to which you want to save the file, or select **New folder** to create a new folder.

d. Enter the file name to use for the file, and select **Save**.
The analyzer saves the audit log entries as a CSV (comma-separated value) file in the selected folder.

Shutdown and Restart

The procedures in this section explain how to shut down and restart the analyzer and the analyzer computer correctly.

Caution

Failure to follow the correct shutdown procedures can damage the analyzer or corrupt the system database. Perform the shutdown procedures only when you are directed to do so by Beckman Coulter Customer Support or by the system documentation.

Stopping Test Processing

Stopping cancels all tests that are in progress and prevents new tests from starting.

In some cases, it is necessary to stop tests that are in progress before correcting problems with the analyzer.

Note

After stopping test processing, the analyzer cannot run again until it is initialized. If you stopped test processing because of an error condition, correct that condition before initializing.

1 Select the **System** state button in the lower left corner of the user interface.

2 Select **Stop**.
A confirmation dialog informs you that the analyzer will be stopped, all unsaved data will be lost, and that tests in progress will be canceled.

3 Select **OK**.
A progress dialog is displayed while tests are canceled. When the process is complete, the analyzer is placed in a red, *Error* state.

Initializing the Analyzer

Initializing brings all devices to a known safe state and returns the analyzer to a green *Running* state.

When initializing, the analyzer goes from the *Error* (*Initializing*) state to the *Running* (*Standby*) state.

The analyzer must be in an *Error* state to complete this procedure.

1 Select the **System** state button in the lower left corner of the user interface.

2 Select **Initialize**.
A confirmation dialog is displayed.

3 Select **OK**.
When initialization is complete, the analyzer returns to the *Running* (*Standby*) state.

If the analyzer does not return to the *Running* state after initialization, contact Beckman Coulter Customer Support for assistance.

Shutting Down the Chemistry Analyzer

Shutting down the analyzer turns off the analyzer lamp and the computer.

The analyzer maintains the refrigerator, incubation bath, and STAT table temperatures. The fans remain on. The ISE module performs an automatic prime with ISE MID Standard Solution every hour to keep the electrodes conditioned.

The analyzer must be in a *Running* (*Standby*) or *Error* (*Stopped*) state to complete this procedure. If you perform this procedure when the analyzer is not in a *Running* (*Standby*) or *Error* (*Stopped*) state, you will be instructed to stop the analyzer first, or wait until the current process is complete, before performing a shut down.

Note

If the analyzer is not in either of those two system states, for example if the analyzer and console are disconnected, you can use the Analyzer Stop button to shut down the analyzer. Refer to Shutting Down the Chemistry Analyzer by Pressing the Analyzer Stop Button.

1 Select the system state button in the lower left corner of the user interface.

2 Select **Shut Down**.
A confirmation dialog is displayed.

3 Select **OK**.

Restoring Power to the Chemistry Analyzer

Perform this procedure to restore power to the analyzer and the analyzer computer after shutting down them down by selecting the system state button in the lower left corner of the user interface.

Press the On button with power indicator light (green) on the front of the analyzer.

Shutting Down the Chemistry Analyzer by Pressing the Analyzer Stop Button

When the analyzer is in operation, if you urgently need to turn off the analyzer power, you can press the Analyzer Stop button. If you press the Analyzer Stop button, or there is a power failure, the analyzer immediately stops operation. Power to the incubator and reagent refrigerator is also turned off.

Caution

If you press the Analyzer Stop button, or if there is a power failure during *Running* (*Sampling*) state, any data that is not complete is lost and you must perform sample processing again.

Caution

If you press the Analyzer Stop button, or if there is a power failure, sample can remain in the sample probe, and reagents can remain in the cuvettes. Perform the Clean Cuvettes with Internal Wash maintenance task to clean the sample probe and cuvettes after you restart the system.

1 Press the Analyzer Stop button on the front of the analyzer.
The operation of the analyzer and the ISE module immediately stop.

2 Turn off the chemistry analyzer computer.

a. Select the system state button in the lower left corner of the user interface.

b. Select **Shut Down**.
A confirmation dialog is displayed.

c. Select **OK**.

3 Remove all racks from the sample handler.

4 To turn off the system power completely, turn off the main breaker, which is located on the left side of the analyzer.

Restoring Power to the Chemistry Analyzer after Pressing the Analyzer Stop Button

Turning on power to the analyzer restores power to all analyzer devices, resets the software, initializes the analyzer (returns all analyzer devices to their home positions), and prepares the analyzer for operation.

After turning off the analyzer with the Analyzer Stop button or turning on the main breaker, the analyzer takes 90 minutes to go to the *Running* (*Standby*) state.

Tip

To bypass the *Starting* (*Warmup*) state after confirming that there is no impact on the temperatures in the analyzer due to pressing the Analyzer Stop button, select **Stand By** on the Custom Diag page (**Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**).

1 If you turned off power to the chemistry analyzer completely by using the main breaker, which is located on the left side of the analyzer, turn on the main breaker.

2 Press the Reset button (white) on the front of the analyzer.

3 Press the On button with power indicator light (green) on the front of the analyzer.

Important

If the system was without power for a lengthy time after you pressed the Analyzer Stop button, or if there was a power failure, confirm the reagent integrity before resuming sample processing.

Exporting Metering Data

You can export data about the testing performed by the analyzer during a period of time.

The following types of data are exported to a .csv file:

- Analyzer serial number
- Test name
- Test count for routine patient samples
- Test count for STAT patient samples
- Test count for reruns triggered by rules system configuration
- Test count for reflex tests
- Test count for QC samples

1 Select **Menu** > **Advanced** > **Metering Data Export**.
The analyzer displays the Metering Data Export page.

2 Select a date range using the Date Entry dialogs for **From Date** and **To Date**.

Note

The date range must be 60 days or less.

3 Select **Export**.

4 Select a location for saving the .csv file, either to the analyzer computer or to an external media device, and select **Save**.

CHAPTER 13

System Configuration

System Configuration Overview

A Beckman Coulter Customer Support representative helps you to establish a custom configuration when the analyzer is installed. This configuration can be modified, updated, or customized at any time.

Configuration settings are stored and used as a collection. When you customize the behavior of one part of the analyzer, the new setting is stored with the settings for all of the other configuration options. The analyzer confirms that the individual settings within a configuration collection are mutually consistent before the configuration can be activated.

The analyzer can use only one collection of configuration settings at a time. The configuration in use is called the active configuration. The analyzer creates a draft configuration when you modify one or more settings in the active configuration.

Configuring the Analyzer

Configuration includes the following tasks:

- Configuring tests and test panels
- Configuring ranges for quantitative tests
- Configuring the frequency of QC tests
- Configuring result processing rules
- Configuring the LIS interface
- Configuring sample comments
- Configuring supply thresholds
- Configuring laboratory shift times
- Configuring contamination prevention settings
- Configuring the sample bar code reader
- Configuring dedicated positions in the reagent refrigerator

Draft Configurations

Initially, the draft configuration is an exact copy of the active configuration. As you modify the draft configuration, the differences between the draft and active configurations are shown in the Draft Configuration section of the System Configuration page.

You can change the draft configuration by using one of the following methods:

- Editing configuration items on one or more configuration pages.
- Loading a previously saved draft.
- Opening a previous active configuration by using the Roll Back feature.

If you are making multiple changes to the configuration, or if your new configuration is complex, you can save your working copy to a disk file. You can then retrieve this draft later to continue working. Interim drafts can be saved to the system disk drive, or to an external USB drive.

You can start a new draft by directly selecting and editing any configuration setting, or you can load a previously saved draft and edit the settings in that draft. In either case, no changes are made to the analyzer behavior until you activate the draft. When you activate the draft, it becomes the active configuration.

Note

If you discover an error in your new configuration, you can always use the Roll Back feature to recover a previous configuration.

Authorization

You must be logged in as a user with Super User or System Configuration authorization to load a configuration and change the configuration settings, or to activate a new configuration. Refer to Logging In.

Confirming Changes in the Draft Configuration

The System Configuration page displays the differences between your draft configuration and the current active configuration. You can review the pending changes to confirm that the new configuration is correct.

The analyzer confirms that the draft configuration has no errors, inconsistencies, or incomplete settings. Such issues are displayed at the bottom of the System Configuration page. You cannot activate the configuration until all issues are resolved.

Roll Back

When you activate a new configuration, that configuration is stored permanently in the system database. Because each activated configuration collection is stored in the database, you can audit, retrieve, and review details of any previously activated configuration. You can also select a previously activated configuration and activate that configuration again.

Audit Support

For audit purposes, the analyzer records the active configuration for each sample result that is reported. You can review each of the configuration settings that were in use when any sample result was obtained and reported.

Note

To be sure that all activities are logged for audit purposes, configure accounts and require operators to log in. You can then identify who performed each sample review or activated a new configuration.

You can use the Audit Log page to determine which configuration was active when a specific sample was processed. Use the Roll Back feature to load that previous configuration as a draft and view the settings.

Saving a Draft Configuration

You can save your draft configuration to the system disk drive or to an external USB drive at any time without activating the configuration.

You can open a saved draft later to continue editing it or to activate it.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Look at the Draft Configuration to confirm that the draft has all of the changes that you want to save.

3 Select **Save Draft**.
The analyzer displays the last folder in which you saved a draft or the last folder from which you loaded a draft.

4 If necessary, open the folder to which you want to save the draft.

5 Enter a name for the draft in **File name** and select **Save**.

6 Discard the draft, or activate it.

Note

You must either discard or activate the draft after saving, or the draft remains on the System Configuration page. If you attempt to close the page, the analyzer prompts you either discard the draft or cancel closing the page.

Loading a Draft Configuration

You can load a saved draft configuration from a local file or from an external USB drive.

Caution

Before performing this procedure, contact Beckman Coulter Customer Support.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

Note

The saved draft configuration that you load must be from the same analyzer.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Load Draft**.

3 Open the folder that contains the draft that you want to load.

4 Select the configuration file and then select **Open**.
The analyzer loads the selected file and displays the differences between the active configuration and the draft configuration in the Draft Configuration section of the System Configuration page.

Loading a Previously Active Configuration into the Draft Configuration

You can load any previously activated configuration into the draft configuration to view, edit, or activate the configuration.

Note

When you load a draft or a previously active configuration, any changes that were made to the existing draft configuration must be discarded. To preserve those changes, save the draft configuration before loading a draft or restoring a previously active configuration.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Roll Back**.

Note

If there are any changes in the current draft, a dialog will inform you that you must save or discard the draft before you can perform this step.

The analyzer displays the Roll Back Configuration dialog with the effective date of all previous configurations, who activated the configuration, a summary of changes, and comments about each configuration.

3 Select the configuration to view or restore.

4 Select **OK**.
The analyzer updates the Draft Configuration section to show the differences between the active configuration and the previously activated configuration.

5 To review the differences between the draft configuration and the active configuration, select the links in the Draft Configuration section.

You can also make more changes to the configuration in this step, and the changes become part of the draft configuration.

6 Activate the draft configuration.

a. Select **Activate Draft**.
The Activate Configuration dialog is displayed.

b. Enter a comment about the changes in the **Activation Comments** field.
The analyzer displays the comment in the Active System Configuration section and the Audit Log (**Menu** > **Audit Log**).

c. Select **OK**.
The configuration is activated, and the Draft Configuration section is cleared.

The analyzer displays details about the active configuration in the Active System Configuration section.

d. To save the active configuration in a format that is compatible for loading as a draft configuration later, select **Export to File** in the Active System Configuration section. Then select a file location in the Save As dialog, enter a file name for the .json file, and select **Save**.

Discarding a Draft Configuration

You can discard a draft configuration if you determine that the changes are not needed, or if it has errors that you are unable to resolve.

After you discard the draft, the Draft Configuration section will be empty.

1 If you are not already on the System Configuration page, select the System Configuration tab, and then select **System Configuration** in the breadcrumb links.

Note

If there is no open System Configuration tab, then this procedure is not applicable, because the tab cannot be closed when there is a draft configuration.

2 Select **Discard Draft**.
The analyzer displays a confirmation dialog.

3 To discard the draft, select **Yes, Discard**.

Activating a Draft Configuration

A draft configuration must be activated before the changes become effective.

Before you can activate a configuration, you must resolve all configuration errors. Errors are shown at the bottom of the System Configuration page. Select the link in the error message to go to the configuration page that has the error.

1 If you are not already on the System Configuration page, select the System Configuration tab, and then select **System Configuration** in the breadcrumb links.

Note

If there is no open System Configuration tab, then this procedure is not applicable, because the tab cannot be closed when there is a draft configuration.

2 Examine the list in the Draft Configuration section to confirm that the draft configuration has all of the intended changes.

3 Activate the draft configuration.

a. Select **Activate Draft**.
The Activate Configuration dialog is displayed.

b. Enter a comment about the changes in the **Activation Comments** field.
The analyzer displays the comment in the Active System Configuration section and the Audit Log (**Menu** > **Audit Log**).

c. Select **OK**.
The configuration is activated, and the Draft Configuration section is cleared.

The analyzer displays details about the active configuration in the Active System Configuration section.

d. To save the active configuration in a format that is compatible for loading as a draft configuration later, select **Export to File** in the Active System Configuration section. Then select a file location in the Save As dialog, enter a file name for the .json file, and select **Save**.

Test and Test Panel Configurations

Configure tests to specify ranges and codes for ordering tests, and to enable tests.

Test configuration is part of the overall system configuration. You configure tests on the Tests configuration page using the following options:

- Enabled: You can enable or disable a test. A test must be enabled before it can be run. You can disable a test that is run infrequently, to prevent the analyzer from prompting you to load reagents, perform calibrations, or run QC for that test.
- Units and Range Settings for quantitative tests: You can define the reference ranges and critical limits for a test, and specify separate ranges for different sexes and age groups.
  - Reference ranges: Results that fall outside the defined reference range are flagged. The flags are L for low, and H for high.
  - Critical Limits: Results that fall outside the critical limits are flagged. The flags are LL for critically low, and HH for critically high. In addition, critical results are identified on the Sample page by an exclamation point next to a red bar in the Critical column.
- LIS Code: You can specify the code used by the LIS to order the test.

Keep the remaining settings on the Tests configuration page at their default values.

You configure test panels on the Configure Test Panels page. You can add any combination of tests to a test panel.

Enabling and Disabling Tests

Tests must be enabled before they can be run.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1. Select **Menu** > **System Configuration**.
   The analyzer displays the System Configuration page.
2. Select **Test Menu** from the System Configuration menu.
   The analyzer displays the Tests configuration page.
3. In the list of tests on the left side of the page, select the **Enabled** checkbox for each test to enable. To disable a test, clear the checkbox.
4. Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Ranges for Quantitative Results

Configure ranges for tests to enable the analyzer to flag results that are outside the defined ranges.

You can configure reference ranges and critical limits for each quantitative test on the analyzer. You can configure different ranges for different demographic groups.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1. Select **Menu** > **System Configuration**.
   The analyzer displays the System Configuration page.
2. Select **Test Menu** from the System Configuration menu.
   The analyzer displays the Tests configuration page.
3. Select the test from the list on the left side of the page.
4. In the Units and Range Settings section, select **New**.
5. To assign a range to a specific sex, select the list in the Sex column, and then select from the list. Available options are **Any**, **Male**, **Female**, and **Unknown.**

6 Specify the range settings.

a. Select a text field in a row of the Range Settings section.
The analyzer displays the Text Input dialog.

b. To assign a range to a specific age range, clear the **Unknown** checkbox, and then enter the age range in the **From** and **To** fields. Select **Days**, **Months**, or **Years** for the starting and ending ages.

c. To assign a range to all ages, select 0 **Days** in the **From** fields, and select **No Maximum** in the **To** list.

d. To assign a range only to patients for whom no age has been specified in the patient demographics, select **Unknown**.

e. Set the Reference range by entering values in the **From** and **To** fields.

f. Set the Critical Limits by entering values in the **Below** and **Above** fields.

Note

The value in the **Below** field must be less than or equal to the **From** value of the Reference range. The value in the **Above** field must be greater than or equal to the **To** value of the Reference range.

g. Select **Done**.

7 To configure another range, select **New**, and assign and set the ranges.

Note

Age ranges must not overlap, and there must not be gaps between age ranges.

8 To delete a range, select the checkbox to the left of the range to delete, and then select **Delete**.

9 Activate the draft configuration. Refer to Activating a Draft Configuration.

Changing the LIS Code

You can change the code that the LIS uses to order tests. This might be necessary when the same LIS code is assigned to a different test on another analyzer.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Test Menu** from the System Configuration menu.
The analyzer displays the Tests configuration page.

3 Select the test from the list on the left side of the page.

4 Enter the new LIS code.

a. Select the field for LIS Code.
The analyzer displays the Text Input dialog.

b. Enter the new LIS code in **LIS Code**.

c. Select **Done**.

5 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Chemistry Tests Manually

For closed tests (parameter settings imported into the software), only customer editable settings are accessible and these values cannot be increased. For open tests, all parameter fields are available for manual entry based on the settings supplied by the reagent manufacturer.

1 Select **Menu** > **System Configuration**.

2 Select **Test Menu**.
The analyzer displays the Tests page.

3 If you want to configure a new (open) test:

a. In the Tests section, select **New**.
The analyzer displays the Add Item dialog.

b. Enter a test name in **Name**.

Note

A test name cannot contain any of the following characters: \ / : * ? " < > |

c. Select **Chemistry** in **Discipline**.

d. Select **OK**.

The analyzer displays the new test as enabled in the Tests section.

The analyzer displays the Test Configuration and Chemistry Details tabs on the right side of the Tests page.

4 If you want to edit an existing test:

a. In the Tests section, select the test.
The analyzer displays the Test Configuration and Chemistry Details tabs on the right side of the Tests page.

b. To enable the test, select the box next to the test in the Enabled column.

Note

You can enable only 60 chemistry tests (including 3 HbA1c tests, 2 sample blank tests, and 1 LIH test) and only 3 ISE tests.

c. To delete the test, select **Delete**.

Note

When you delete a test, all results for the test are removed from the Result Data Statistics page.

5 Enter or select values in the Test Configuration tab:

Table 76 Test Configuration Tab

Parameter	Description
Test ID	The unique identifier for the test. Provided by Beckman Coulter Customer Support. You can associate up to five different test IDs with a reagent ID. Each of the tests with a different test ID has a unique set of test parameters.
LIS Code	The LIS code for the test. Provided by Beckman Coulter Customer Support.
Calculated Result	Select this checkbox as a part of the process of defining calculated result rules. Refer to Configuring Calculated Results. Otherwise, do not select. Leave as-is.

6 Configure the units and ranges in the Test Configuration tab:

Repeat this step to add additional sample types and ranges.

a. Add a sample type by selecting an option from the **Add Sample Type** menu.
The analyzer displays the Units and Range Settings for the selected sample type.

If you want to use the same units and range settings as another sample type, without specifying them manually, select the sample type in **Use Ranges From**.

Note

If you add a sample type to the test, it shares the calibration curve with the primary sample type, and it is configured with the same calibration parameters

as the primary sample type. When you run the calibration for the test, the analyzer generates a single calibration curve (for the primary sample type).

Note

If you delete a sample type for the test by selecting **Remove Sample Type**, and then later add the sample type again, the unit and ranges settings that you set for the sample type are restored.

b. Select the units to use for reporting results in **Units**.

c. Select the number of decimal places for reporting results in **Decimal Places**.

You can select **X** (integer results), **X.X** (one decimal place), **X.XX** (two decimal places), and so on.

Note

The selected number of decimal places does not change the precision of the test. It only affects how results are displayed and reported.

d. Configure the ranges, add a new set of ranges for a sample type, and delete a set of ranges from a sample type.

Refer to Configuring Ranges for Quantitative Results.

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7 Enter or select values in the Chemistry Details tab:

Table 77 Chemistry Details Tab

Parameter	Description
Test Kind	General, color, or blank test. When the color test is selected, select the blank test name in **Blank Test**.
Reagent Name	The reagent name. The maximum is 50 characters. You can program a maximum of 120 assays associated with the same reagent name.
Revision	The reagent setting sheet version, starting at 01.
Reagent ID	The first three digits of the reagent ID on the reagent bottle. A reagent ID is required. You can enter a value from **422** to **439**, but do not enter other numbers. because they might be assigned already to other reagents.
Regions	The locations of analyzers that use this test configuration.

Table 78 Chemistry Details: Use Parameters From

Parameter	Description
Use Settings From	If you want to use the same parameter values as another sample type that is associated with the test without specifying them manually, select the sample type in the drop-down menu. If the test is not configured with a functional sample type (serum, urine, CSF, or other), such as with plasma as the sample type, select a functional sample type from the drop-down menu. Patient test results are reported only for the selected sample type. Reagents and calibrations become due only for the selected sample type. If you select another sample type, the following sections in the Chemistry Details tab are hidden for the sample type that is using the same parameter values as a functional sample type: Application Detail, General Parameters, Calibration Parameters, Prozone Check Parameter, and Customer Configurable Options. **Note** Plasma is a non-functional sample type. Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages. **Note** If you deleted a sample type for the test by selecting **Remove Sample Type** in the Test Configuration tab, it is still selectable for the Use Settings From parameter. Ignore this value for selection.

Table 79 Chemistry Details: General Parameters

Parameter	Description
Sample Volume	You can set sample volume in increments of 0.1 µL. The minimum sample volume is 1.0 µL. The maximum sample volume is 25.0 µL. Refer to the description of Dilution below for ranges of sample volumes for specific dilutions.
Dilution	The analyzer uses deionized water (0 or 10 µL) dispensed for a sample dilution following the sample dispense. If Dilution is 0 µL, then you can set the sample volume between 1.0 µL and 25.0 µL. If Dilution is 10 µL, then you can set the sample volume between 1.0 µL and 20.0 µL. If you set Dilution to 0 µL, then the system aliquots an extra 2.9 µL of sample for dispensing accuracy.
Predilution Rate	Defines the automatic dilution factor. The system uses two cuvettes for dilution and reaction for a test. First the analyzer performs sample dilution with deionized water or other diluent in a dilution cuvette, then dispenses the test sample volume from the dilution cuvette into a reaction cuvette. **Note** The dilution factor is the total number of parts of a sample, including 1 part of the undiluted sample. For example, a dilution factor of 3 indicates 1 part of undiluted sample and 2 parts of diluent. Select 1, 3, 5, 10, 15, 20, 25, 50, 75, or 100.
Reagent Volume	You can set reagent volumes in increments of 1.0 µL. The total maximum reagent volume and dilution is 250 µL. R1-1: Reagent volume 10 to 250 µL, with dilution 0, 10 to 240 µL. R2-1: Reagent volume 0, 10 to 250 µL, with dilution 0, 10 to 240 µL.
Wavelength	— Primary: 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, or 800 nm. — Secondary: None, 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, or 800 nm.

Table 79 Chemistry Details: General Parameters (Continued)

Parameter	Description
Method	The type of reaction measurement: RATE, RATE1, FIXED, FIXED1, END, END1 **Note** The 1 at the end of a method name indicates a method not using a reagent blank correction. The system does not subtract the reagent blank from the measuring points.
Reaction Slope	Select **+** for an increasing reaction curve. Select **-** for a decreasing reaction curve.
Measuring Point	End point reaction method or fixed point reaction method: — First: 0 to 26 — Last: 1 to 27 Rate reaction method: — First: 1 to 25 — Last: 3 to 27 Self blank: The system subtracts the absorbance of Point 2 data (caused by sample) from Point 1 data (reaction data). **Note** If the test only has one set of measuring points, then Point 2 First and Last text boxes can be left blank.
Linearity Limit	Applies to rate reaction method only. A check by rate reaction method to confirm if the reaction is non-linear caused by exceeding the defined % variance or OD limits between photometer read points. If the limits are exceeded, the analyzer generates a * flag. Enter a value from **0** to **100**. For end point reaction method and fixed point reaction method leave it blank.
Lag Time Check	Applies to rate reaction method only. *Lag time* is the time after the system adds all reagents to the sample and before it takes any read points to determine the reaction rate. Select **Lag Time Check** to enable.

Table 79 Chemistry Details: General Parameters (Continued)

Parameter	Description
Reaction OD Limit	-2.0000 (Low) to 3.0000 (High). Remains blank for end point reaction methods. If the limits are exceeded, the analyzer generates a B flag for less than the minimum OD and a D flag for greater than the maximum OD.
Reaction Blank OD Limit	Reagent blank OD limits at the first and last read points. -2.0000 (Low) to 3.0000 (High). If the limits are exceeded, the analyzer generates a u flag or a U flag for less than the minimum reagent OD and a y flag or a Y flag for greater than the maximum reagent OD.
Analytical Measuring Range	The range the analyzer can measure for a reagent. Low: -9999999 to 9999999. High: Low value to 9999999. A maximum of 7 total digits before and after the decimal point (if at least one decimal place is selected in Decimal Places), can be entered. The analyzer generates an Fx Flag for an OD value greater than the OD of the upper limit of the analytical measuring range. It generates a Gx Flag for an OD value less than the OD of the lower limit of the analytical measuring range.
Manufacturer Factor	This coefficient corrects the concentration value with the equation of Y=AX+B. Enter values for **A** and **B**. The analyzer corrects the value before checking the analytical measuring range.
Reagent Onboard Stability	Days (0 to 999) and hours (0 to 23). The onboard stability period starts when the system performs the reagent check, even if the system does not use the reagent.
LIH Influence Check	Select **Perform LIH Check** to enable. When performing the check, the analyzer generates a flag if the level of LIH exceeds the specific limits of the test. If the LIH check is enabled, but the system does not perform LIH testing on the sample, the system generates an n flag.
Lipemia, Icterus, and Hemolysis	+, ++, +++, ++++, or +++++ for the number of interferents. If you enabled LIH Influence Check, program test-specific LIH criteria from the test-specific reagent setting sheet.

Table 80 Chemistry Details: Calibration Parameters

Parameter	Description
Calibration Type	Select the calibration type from the reagent setting sheet. MB to 7 MB, AA, AB to 7 AB.
Formula	The interpolation formula for the calibration curve. Select the formula from the reagent setting sheet. The calibration type limits the formulas that you can select for a test.
Calibrator Name	The calibrator name. Select **Add**, and in the Calibrator dialog enter the calibrator name and select the number of levels for the calibrator. Even if not all levels are used, select the number that reflects all levels of the calibrator. Select **Create**. **Note** A calibrator name cannot contain any of the following characters: \ / : * ? " < > |
Slope Check	Applies to multi point calibration tests. Refer to the predicate setting sheets. Select to enable. If enabled, select **+** or **–**.
Stability and Interval	Enter the number of days and hours for the stability of the reagent blank and calibration. For reagent blank, select **Lot** or **Bottle** in **Interval**. For calibration, select **None**, **Lot**, or **Bottle** in **Interval**.
Counts	The quantity of reagent blank and calibration replicates used for calculation. If you select **1**, the analyzer uses the reagent blank or calibrator OD for calculation. If you select **2**, the analyzer uses the mean value of the replicates. If you select **3**, the analyzer use the mean value of the two closest replicates. If you select **4**, the analyzer discards the highest and lowest replicate values, and it uses the mean value of the remaining replicates. The default is 4.
MB Factor	Applies to MB calibrations only. Defaults to 10000. Enter the correct MB factor for the MB calibration according to the reagent setting sheet. **Note** If you selected **Use highest calibrator for Upper AMR**, you cannot define MB Factor.
Positive Cutoff	Applies to semi-quantitative assays only. A result is shown as positive when the result is equal to or greater than the Positive Cutoff value. Enter a concentration value or leave blank.

Table 80 Chemistry Details: Calibration Parameters (Continued)

Parameter	Description
Use highest calibrator for Upper AMR	Select to enable the analytical measuring range to be updated by the highest calibrator value. Refer to the predicate setting sheet, for example, for HbA1c. **Note** Do not select **Use highest calibrator for Upper AMR** if you are going to define MB Factor.
Calibration OD and Concentration Parameters	Does not affect the MB Factor for MB assays. Depending on the calibration type you might have to run up to 7 calibrators. For example, Point 1 to Point 5 is required for a 5AB calibration. For AB calibrations: — Calibrator Name: The calibrator level name. Unused boxes can be left blank. — Factor Range Low: -9999999 to 9999999. Refer to the reagent setting sheet. — Factor Range High: The Factor Low Range to 9999999. Refer to the reagent setting sheet. For MB calibrations: — OD: The OD value. -2.0000 to 3.0000. — Conc (outside US only): The calibrator concentration. A maximum of 9 digits, including the decimal point and minus sign, from -9999999 to 9999999. — OD Range High: The OD value to 3.0000.
OD Delta Check	A measure of system precision during reagent blank or calibration. It is the difference between two usable replicate values. If the limit is exceeded, the calibration fails. Select to enable and enter a value, or leave unselected and blank. The default is not selected.

Table 81 Chemistry Details: Prozone Check Parameter

Parameter	Description
Logic Check 1 to Logic Check 3	Select the logic checks to perform.
Logic Check 1: Check Points	The photometric measuring point for evaluation or the photometric measuring point for start of evaluation.
Limit Points	The evaluation points other than check points. When the low concentration reaction and Prozone draw similar curves, this can be used to cancel low concentration.

Table 81 Chemistry Details: Prozone Check Parameter (Continued)

Parameter	Description
Check Pattern	— **Pattern 1**: application of both evaluation formulas 1 and 2 — **Pattern 2**: application of only evaluation formula 1 — **Pattern 3**: application of only evaluation formula 2 — **Pattern 4**: neither evaluation formula 1 nor 2 applied
Decision Values	The ODs to use for evaluation.
Logic Check 2 and Logic Check 3: Check Points	— Point 1: The evaluation start point for the check. — Interval: The point interval from the evaluation start point for the check.

8 Activate the draft configuration.

a. Select **Activate Draft**.
The Activate Configuration dialog is displayed.

b. Enter a comment about the changes in the **Activation Comments** field.
The analyzer displays the comment in the Active System Configuration section and the Audit Log (**Menu** > **Audit Log**).

c. Select **OK**.
The configuration is activated, and the Draft Configuration section is cleared.

The analyzer displays details about the active configuration in the Active System Configuration section.

d. To save the active configuration in a format that is compatible for loading as a draft configuration later, select **Export to File** in the Active System Configuration section. Then select a file location in the Save As dialog, enter a file name for the .json file, and select **Save**.

9 Run the test to confirm the programming.

a. Load the reagent and any required cleaning solution on the analyzer.

b. Perform a reagent check.

c. Confirm that the analyzer orders calibration for the new test.

d. Add the test to an existing configured QC material or create a new QC material for the test, and order QC on the new test.

Refer to Editing a Control Material Lot or Configuring Control Materials.

e. Perform a reagent blank, calibration, and QC on the new test.

f. Review the Chemistry Results page (reagent blank and calibration) or Result Details page (QC), and confirm that the data are correct.

Setting Customer Configurable Options

For closed tests (Beckman Coulter assays), the values for the parameters in the General Parameters and Calibration Parameters sections of the Chemistry Details tab are default

values. Some of those parameters can be updated with narrower ranges in the Customer Configurable Options section of the Chemistry Details tab.

Note

There are no customer configurable options for ISE or HbA1c tests.

Some open tests (Beckman Coulter-authorized third party assays) might not have claims for many or all of these fields, which will be left blank when imported from the parameter package. If the field is mandatory, for example in the case of Reagent Onboard Stability, a value for the field must be entered by the operator before the configuration can be activated.

Note

If you update the values for these parameters in the General Parameters and Calibration Parameters sections with a parameter package, the analyzer does not update the values for these parameters in the Customer Configurable Options section.

1 Select **Menu** > **System Configuration**.

2 Select **Test Menu**.
The analyzer displays the Tests page.

3 In the Tests section, select the test.
The analyzer displays the Test Configuration and Chemistry Details tabs on the right side of the Tests page.

4 Enter or select values in the Customer Configurable Options section of the Chemistry Details tab.
Except for Correlation Factor and the parameters in the Prep Type subsection of the Customer Configurable Options section, these new values override the default values. For a description of the parameters, refer to Table 77 Chemistry Details: General Parameters and Table 77 Chemistry Details: Calibration Parameters. For Correlation Factor and the parameters in the Prep Type subsection, default values are not yet set, and the Customer Configurable Options section is the only place where values for these parameters can be set.

Table 82 Guidelines for Setting New Values for Customer Configurable Options

Parameter	Guidelines	Overrides Existing Default Value?
Perform LIH Check	If LIH Influence Check: Perform LIH Check in the General Parameters section is not selected, you can select **Perform LIH Check**. If LIH Influence Check: Perform LIH Check in the General Parameters section is selected, you cannot deselect **Perform LIH Check**.	Yes
Lipemia, Icterus, or Hemolysis	Select a value for Lipemia, Icterus, or Hemolysis that is lower than or equal to the values for those parameters in LIH Influence Check in the General Parameters section.	Yes
Enable Prep Type on Test Order Entry page	Select to make prep types selectable on the Test Order Entry page. Refer to Entering Test Orders.	No
Prepare with Diluent: Sample Volume	You can set sample volume in increments of 0.1 µL. The minimum sample volume is 1.0 µL. The maximum sample volume is 25.0 µL. Refer to the description of Prepare with Diluent: Dilution below for ranges of sample volumes for specific dilutions.	No
Prepare with Diluent: Dilution	The analyzer uses deionized water (0 or 10 µL) dispensed for a sample dilution following the sample dispense. If Dilution is 0 µL, then you can set the sample volume between 1.0 µL and 25.0 µL. If Dilution is 10 µL, then you can set the sample volume between 1.0 µL and 20.0 µL. If you set Dilution to 0 µL, then the system aliquots an extra 2.9 µL of sample for dispensing accuracy.	No

Table 82 Guidelines for Setting New Values for Customer Configurable Options (Continued)

Parameter	Guidelines	Overrides Existing Default Value?
Prepare with Diluent: Predilution Rate	Defines the automatic dilution factor. The system uses two cuvettes for dilution and reaction for a test. First the analyzer performs sample dilution with deionized water or other diluent in a dilution cuvette, then dispenses the test sample volume from the dilution cuvette into a reaction cuvette. **Note** The dilution factor is the total number of parts of a sample, including 1 part of the undiluted sample. For example, a dilution factor of 3 indicates 1 part of undiluted sample and 2 parts of diluent. Select 1, 3, 5, 10, 15, 20, 25, 50, 75, or 100.	No
Prepare with Condense: Sample Volume	You can set sample volume in increments of 0.1 µL. The minimum sample volume is 1.0 µL. The maximum sample volume is 20.0 µL.	No
Analytical Measuring Range: Low	Set a value that is higher than or equal to Analytical Measuring Range: Low in the General Parameters section.	Yes
Analytical Measuring Range: High	Set a value that is lower than or equal to Analytical Measuring Range: High in the General Parameters section.	Yes
Reagent Onboard Stability: Stability	Set an amount of time that is shorter than or equal to Reagent Onboard Stability: Stability in the General Parameters section.	Yes
Manufacturer Factor	Set values for **A** and **B** that are less than or equal to those values for Manufacturer Factor in the General Parameters section.	Yes
Stability and Interval: Stability	— Set an amount of time for Reagent Blank: Stability that is shorter than or equal to Stability and Interval: Reagent Blank: Days and Stability and Interval: Reagent Blank: Hours in the Calibration Parameters section. — Set an amount of time for Calibration: Stability that is shorter than or equal to Stability and Interval: Calibration: Days and Stability and Interval: Calibration: Hours in the Calibration Parameters section.	Yes

Table 82 Guidelines for Setting New Values for Customer Configurable Options (Continued)

Parameter	Guidelines	Overrides Existing Default Value?
Stability and Interval: Interval	— If Stability and Interval: Reagent Blank: Interval in the Calibration Parameters section is set to **Lot**, you can set Reagent Blank: Interval to either **Lot** or **Bottle**. — If Stability and Interval: Calibration: Interval in the Calibration Parameters section is set to **None**, you can set Calibration: Interval to **None**, **Lot**, or **Bottle**. If the value in the Calibration Parameters section is set to **Lot**, you can set Calibration: Interval to **Lot** or **Bottle**. — Further restrictions for Calibration: Interval based on the value set for Reagent Blank: Interval: If Reagent Blank: Interval is set to **Lot**, you can set Calibration: Interval to **None** or **Lot**. If Reagent Blank: Interval is set to **Bottle**, you can set Calibration: Interval to **None**, **Lot**, or **Bottle**.	Yes
Correlation Factor	This coefficient corrects the concentration value with the equation of Y=AX+B. The analyzer performs the correlation correction after checking the analytical measuring range. Enter values for **A** and **B**: — A: -9999999 to 9999999 — B: -9999999 to 9999999	No

5 Activate the draft configuration.

a. Select **Activate Draft**.
The Activate Configuration dialog is displayed.

b. Enter a comment about the changes in the **Activation Comments** field.
The analyzer displays the comment in the Active System Configuration section and the Audit Log (**Menu** > **Audit Log**).

c. Select **OK**.
The configuration is activated, and the Draft Configuration section is cleared.

The analyzer displays details about the active configuration in the Active System Configuration section.

d. To save the active configuration in a format that is compatible for loading as a draft configuration later, select **Export to File** in the Active System Configuration section.

Then select a file location in the Save As dialog, enter a file name for the .json file, and select **Save**.

6 Run the test to confirm the programming.

a. Load the reagent and any required cleaning solution on the analyzer.

b. Perform a reagent check.

c. Confirm that the analyzer orders calibration for the new test.

d. Add the test to an existing configured QC material or create a new QC material for the test, and order QC on the new test.

Refer to Editing a Control Material Lot or Configuring Calibrators.

e. Perform a reagent blank, calibration, and QC on the new test.

f. Review the Chemistry Results page (reagent blank and calibration) or Result Details page (QC), and confirm that the data are correct.

Configuring Calibrations by Lot or by Bottle

You can configure the analyzer to calibrate a maximum of 5 lot numbers or bottles (serial numbers) of the same usable on-board reagent before the analyzer uses the reagent. This is useful when you have multiple reagents for the same test on the analyzer.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Test Menu** from the System Configuration menu.
The analyzer displays the Tests configuration page.

3 Select the test from the list on the left side of the page.

4 In the Chemistry Details tab, in the Calibration Parameters section, in the Stability and Interval parameters, select **Lot** or **Bottle** in Interval for the calibration or reagent blank.

5 Activate the draft configuration. Refer to Activating a Draft Configuration.

Managing Tests

Use the Menu Management page to confirm that tests from a parameter package can be enabled for use on the analyzer.

The right side of the Menu Management page includes the tests that appear on the Tests configuration page as selectable to be enabled on the analyzer. When you select a test on the left side of the page in the Name section, it gets added to the right side of the page and as a selectable test on the Tests configuration page.

When the maximum of 120 tests that are configured on the analyzer is exceeded, the analyzer displays an error dialog.

1 Select **Menu** > **System Configuration**.

2 Select **Menu Management**.
The analyzer displays the Menu Management page.

3 In the Regions section, do not change the automatic selection that has been implemented on the analyzer. This region selection is aligned with the location of the analyzer and the tests and applications that are registered in that region.
The analyzer displays the tests used in those regions in the Name section.

Warning

Changing regions can cause incorrect test parameters to become available. Incorrect test parameters cause errors in analysis results and can cause an incorrect diagnosis.

4 Select the tests that you want to add to the analyzer configuration.

You can enter text in the Search by test name field to filter the list.

The analyzer adds the tests to the right side of the Menu Management page.

If the maximum of 120 is exceeded, the analyzer displays an error dialog.

5 If the analyzer displays an error dialog, deselect some of the tests on the left side of the page in the Name section, or delete some of the tests that appear on the Tests configuration page.

6 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Test Panels

You can group related tests into panels. When you order a panel, all tests in the panel are ordered automatically.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Panels**.
The analyzer displays the Configure Test Panels page.

3 Select **New**.
The analyzer displays the Add Item dialog.

4 Enter a name for the test panel in **Name**, and then select **OK**.

Tip

Avoid using commas in panel names. Names with commas might be mistaken for multiple panels.

The analyzer displays the Details for the Panel for the new panel. All fields are empty.

5 Select a sample type in **Sample Types**.
The analyzer displays a list of tests that can be run on the selected sample type.

Note

If no tests are displayed for the selected sample type, no tests are enabled for that sample type. Confirm that the tests that you want to include in the panel are enabled and configured for that sample type.

Note

A panel must be configured for each sample type.

Note

QC cannot be programmed using panels.

6 Select the tests that you want to include in the panel. You can scroll through the list of tests, or enter the test name in the **Search by name** field.

7 To edit an existing test panel, select the panel in the Name section, and make the necessary changes. You can scroll through the list of panels, or enter the panel name in the **Search by the name.** field.

8 To add a new panel with the same details as an existing panel:

a. Select the panel that you want to copy.

b. Select **Copy**.

c. Enter a name for the new panel in the Copy Item dialog.

d. Select **OK**.

9 To rename a panel, select **Rename**, enter a new name in the Rename Item dialog, and then select **OK**.

10 To delete a panel, select **Delete**, and then select **OK** in the Delete Item dialog.

11 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring the Frequency of QC Tests

You can configure the frequency of automatic QC test orders. You can also configure specific frequencies for individual QC tests.

You configure the frequency of QC tests by specifying an interval in hours. The first QC test each day is ordered at the Start Time specified in Daily Startup Configuration. Subsequent QC tests are ordered automatically after each occurrence of the specified interval. Refer to Configuring Daily Startup.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **QC**.
The analyzer displays the QC Configuration page.

3 To set the frequency for all QC tests, select options in the Automatic QC Test Order Settings section.

Note

You can also set frequencies for individual tests. Individual frequency settings take precedence over the settings for all QC tests.

a. Select **Enable Automatic QC**, if it is not already selected.

b. Select the interval in **Interval (Hours)**.

Note

Do not select 48. QC is automatically ordered at the start of each day (every 24 hours).

4 To set the QC interval for one or more individual tests, specify the QC interval in the Test-Specific Settings section.

a. To filter the list of tests in the Test-Specific Settings section, select the sample type in **Sample Type**.
The Test-Specific Settings section displays available tests for the selected sample type.

b. Locate the test in the Test Name column.

c. In the Cycle Type column, select the interval unit (for example, **Hours**).

d. Select the text field in the Count column, and in the Text Input dialog enter the number of interval units for one QC cycle.

For example, if the Cycle Type is **Hours**, and the Count is **24**, the QC test will be ordered every 24 hours.

e. Select **Done**.

5 Activate the draft configuration. Refer to Activating a Draft Configuration.

Result Processing Rules

The analyzer uses rules to trigger operations such as rerunning a test, running a reflex test, or calculating a derived result.

The Rules page is available from the System Configuration page.

A rule includes one or more conditions, one or more actions that are triggered when all of the conditions are true, and one or more exclusions that can prevent the rule from being triggered.

A rule-building section at the bottom of the page displays the rule as a Boolean expression of the form: **IF** <condition> **AND IF** <additional condition, if defined> **THEN** <action> **EXCEPT IF** <exclusion> **OR IF** <additional exclusion, if defined>.

General

The General section includes the **Description** field, in which you enter a description of the rule. The description has no effect on the operation of the rule, but should describe the intended function in terms that an operator can understand.

Conditions

In the Conditions section, you can specify one or more conditions to trigger the rule. When the rule is triggered, the analyzer performs the actions identified in the Actions section. When you specify more than one condition, all specified conditions must be true to trigger the rule.

Some conditions include parameters, which are displayed in brackets ([ ]). When you add one of these conditions, the parameter name is displayed in the rule-building section as a link. Select the link to open a dialog and define the parameter. A parameter can be a logical expression such as ">10" which is true when the result is greater than 10. Other examples of parameters include lists of tests, lists of flags, and patient age expressions.

You can select the following conditions:

- **The result value is critical**—Triggers the action when the result of a test is outside of the Critical Limits, as defined on the Tests configuration page.
- **The result has the flag: [Flag]**—Triggers the action when the result of a test has one or more of the flags that are identified in this condition.
- **The result value satisfies: [Logical Expression]**—Triggers the action when the logical expression defined in this condition is true.
- **The patient: [Age Expression]**—Triggers the action when the age of the patient falls in the range of ages defined by the logical expression identified in this condition.
- **The sex of the patient is: [Value]**—Triggers the action when the sex of the patient, identified in the test order, matches the value identified in this condition. Possible values are **Male**, **Female**, or **Unknown**.
- **The test code is: [Test]**—Triggers the action when a result is received from a test identified in this condition. You can identify one or more tests. This condition is true when a result is received from any one test in the list.

Actions

In the Actions section, you can select one or more actions for the analyzer to perform when a rule is triggered. The following actions are available:

- **Rerun with prep type: [Prep Type]**—Rerun the test that triggered the rule with the original sample volume (neat), a smaller sample volume by decreasing the sample dispensing volume or increasing the dilution ratio (dilute), or a larger sample volume by increasing the sample dispensing volume or decreasing the dilution ratio (condense).
- **Run reflex tests: [Tests]**—Run the specified tests when all of the conditions in the rule are true.
- **Add calculated result: [Expression]**—Perform a mathematical calculation on the results of any test identified in Actions, to produce a calculated result.
- **Rerun the test**—Rerun the test that triggered the rule.

Exclusions

In the Exclusions section, you can specify exclusions that will prevent the rule from being triggered and the analyzer from performing the specified action. The list of available exclusions is the same as the list of conditions for triggering a rule. However, only one exclusion must be true to prevent the rule from being triggered.

Configuring Calculated Results

Calculated results are created by applying a mathematical formula to the results of one or more tests.

Defining a calculated result requires the following two separate operations:

- Creating the calculated result test—The test name that is used to report results.
- Defining the calculated result rules—The formula that is used to calculate a calculated result from one or more results.

You cannot order a calculated result test directly. When you order all of the constituent tests that are used to calculate the result, the analyzer automatically calculates the result and displays it with the constituent results.

Note

If any of the constituent tests are canceled or fail to produce results, the calculated result test is automatically canceled.

---

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

---

2 Select **Test Menu** from the System Configuration menu.
The analyzer displays the Tests configuration page.

---

3 Create the calculated result test.

a. Select **New**, in the lower left corner of the Tests list.
The analyzer opens the Add Item dialog.

b. Enter a unique name for the test in the **Name** field.

c. Select the discipline from the **Discipline** list.

d. Select **OK**.

---

4 Configure the test.

a. Select the field for Test ID or LIS Code.

The analyzer displays the Text Input dialog.

b. In **Test ID**, enter a unique test ID.

c. In **LIS Code**, enter the code that the LIS will use for receiving results.

d. Select **Done**.

e. Select the **Calculated Result** checkbox.

---

5 Configure the units and ranges.

Repeat this step to add additional sample types and ranges.

a. Select an option from the **Add Sample Type** menu.
The analyzer displays the Units and Range Settings for the selected sample type.

b. Select the units to use for reporting results from the **Units** list.

c. Select the number of decimal places to report in **Decimal Places**.

You can select **X** (integer results), **X.X** (one decimal place), **X.XX** (two decimal places), and so on.

Note

The selected number of decimal places does not change the precision of the test. It only affects how results are displayed and reported.

d. Configure the ranges. Refer to Configuring Ranges for Quantitative Results for information about configuring ranges.

---

6 When you have finished configuring ranges, select **System Configuration** in the breadcrumb links to return to the System Configuration page.

The System Configuration page displays errors at the bottom, because no rules have been defined. These errors are resolved when you add a Calculated Result rule.

---

7 Add a new rule.

a. Select **Rules**.
The analyzer displays the Rules page.

b. Select **New**.
The analyzer opens the Add Item dialog.

c. Enter a unique name for the rule in **Name**.

d. Select **OK**.
The Rule Details section displays four categories: General, Conditions, Actions, and Exclusions. At first, only the General settings are available.

8 Configure the general settings for the rule.

a. In the General settings, select the Description field, and in the Text Input dialog, enter a description of the rule in **Description**.

b. Select **Done**, and select **Next**.
The analyzer displays the Conditions settings.

Note

Do not select any conditions. Conditions are not supported for calculated results.

c. Select **Next**.
The analyzer displays the available Actions.

9 Configure the action for the calculated result rule.

a. Select **Add calculated result: [Expression]**.

Note

Do not select any other actions. Calculated results cannot be combined with other rule actions.

The bottom part of the page displays Add calculated result: Expression, with **Expression** displayed as a link.

b. Select the **Expression** link.
The analyzer displays the Set Value dialog.

c. In **Name of the calculated result**, select the calculated result test that you created in step 3.

d. In **Sample Type**, select the sample type.
The analyzer displays buttons for the tests that support the selected sample type.

e. Define the calculated result expression. Select from the test buttons to add a test result, and type mathematical operators to create an arithmetic expression.

Note

You can use the following mathematical operators: +, -, *, /, (,), Log(a,b), Exp(c), Pow(x,y), Sqrt(z), Pl, and E.

f. Select **OK** to close the Set Value dialog.

g. Select **Next**.
The analyzer displays the available Exclusions.

Note

Do not select any exclusions. Exclusions are not supported for calculated results.

10 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Reflex Tests

The analyzer uses a system of rules to automatically trigger reflex tests if a test result meets specified criteria.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Add a new rule.

a. Select **Rules**.
The analyzer displays the Rules page.

b. Select **New**.
The analyzer opens the Add Item dialog.

c. Enter a unique name for the rule in **Name**.

d. Select **OK**.
The Rule Details section displays four categories: General, Conditions, Actions, and Exclusions. At first, only the General settings are available.

3 Configure the general settings for the rule.

a. In the General settings, select the Description field, and in the Text Input dialog, enter a description of the rule in **Description**.

b. Select **Done**, and select **Next**.
The analyzer displays the Conditions settings.

4 Configure the conditions for the rule.

a. In the Conditions section, select the checkbox for **The test code is: [Test]**.
In the rule-building section at the bottom of the page, the analyzer displays IF the test code is: Test, with **Test**, displayed as a link.

b. Select the **Test** link.
The analyzer displays the Set Value dialog, which contains a list of available tests.

c. Select the test or tests that you want the rule to be applied to, and then select **OK**.
The selected tests are displayed in the rule-building section.

d. In the Conditions section, select the conditions to trigger the rule.
Each condition that you select adds an AND IF line to the rule-building section. Conditions that include text in brackets are displayed with a blue link.

— If you select **The result value is critical**, the rule is triggered when the result is critical (as defined in the Tests configuration page for the test).
— If you select **The result has the flag: [Flag]**, the blue **Flags** link in the rule-building section opens the Set Value dialog. The Set Value dialog contains options for selecting one or more flags to trigger the rule.

- If you select **Result value satisfies: [Logical Expression]**, the blue **Logical Expression** link in the rule-building section opens the Set Value dialog. The Set Value dialog has options for selecting operators and result values for either **Quantitative** or **Qualitative** results. The rule is triggered when the logical expression is true.
- If you select **The patient: [Age Expression],** the blue **Age Expression** link opens the Set Value dialog. The Set Value dialog contains options for defining an age range expression to trigger the rule.
- If you select **The sex of the patient is: [Value]**, the blue **Value** link opens the Set Value dialog. The Set Value dialog contains options for **Unknown**, **Male**, and **Female**. The rule is triggered if the sex of the patient matches the selection in the rule.
- If you select **The test code is: [Test]**, the blue **Test** link opens the Set Value dialog. The Set Value dialog contains a list of available tests. The rule is triggered when a selected test is run.

e. Select **Next**.
The analyzer displays the available Actions.

---

5 Configure the actions for the reflex test rule.

a. Select **Run reflex tests: [Tests]**.
The analyzer displays THEN Run reflex tests: Tests in the rule-building section, with **Tests** displayed as a link.

b. Select the **Tests** link.
The analyzer displays the Set Value dialog, which contains a list of available tests.

c. Select one or more tests to run when one or more of the conditions that are defined in the Conditions settings triggers the rule.

d. Select **OK** to close the Set Value dialog.

e. Select **Next**.
The analyzer displays the available Exclusions.

---

6 Configure the exclusions for the rule.

If you select one or more exclusions, the analyzer displays an EXCEPT IF line in the rule-building field. Configure exclusions in the same way that you configured conditions for the rule earlier in this procedure. If you select more than one exclusion, OR IF precedes each additional exclusion. OR IF indicates that satisfying any one of the exclusions prevents the rule from being triggered.

---

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Reruns

The analyzer uses a system of rules to automatically trigger a rerun when a test result meets specified criteria.

---

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

---

2 Add a new rule.

a. Select **Rules**.
The analyzer displays the Rules page.

b. Select **New**.
The analyzer opens the Add Item dialog.

c. Enter a unique name for the rule in **Name**.

d. Select **OK**.
The Rule Details section displays four categories: General, Conditions, Actions, and Exclusions. At first, only the General settings are available.

---

3 Configure the general settings for the rule.

a. In the General settings, select the Description field, and in the Text Input dialog, enter a description of the rule in **Description**.

b. Select **Done**, and select **Next**.
The analyzer displays the Conditions settings.

---

4 Configure the conditions for the rule.

a. In the Conditions section, select the checkbox for **The test code is: [Test]**.
In the rule-building section at the bottom of the page, the analyzer displays IF the test code is: Test, with **Test**, displayed as a link.

b. Select the **Test** link.
The analyzer displays the Set Value dialog, which contains a list of available tests.

c. Select the test or tests that you want the rule to be applied to, and then select **OK**.
The selected tests are displayed in the rule-building section.

d. In the Conditions section, select the conditions to trigger the rule.
Each condition that you select adds an AND IF line to the rule-building section. Conditions that include text in brackets are displayed with a blue link.

- If you select **The result value is critical**, the rule is triggered when the result is critical (as defined in the Tests configuration page for the test).
- If you select **The result has the flag: [Flag]**, the blue **Flags** link in the rule-building section opens the Set Value dialog. The Set Value dialog contains options for selecting one or more flags to trigger the rule.
- If you select **Result value satisfies: [Logical Expression]**, the blue **Logical Expression** link in the rule-building section opens the Set Value dialog. The Set Value dialog has options for selecting operators and result values for either **Quantitative** or **Qualitative** results. The rule is triggered when the logical expression is true.
- If you select **The patient: [Age Expression],** the blue **Age Expression** link opens the Set Value dialog. The Set Value dialog contains options for defining an age range expression to trigger the rule.

— If you select **The sex of the patient is: [Value]**, the blue **Value** link opens the Set Value dialog. The Set Value dialog contains options for **Unknown**, **Male**, and **Female**. The rule is triggered if the sex of the patient matches the selection in the rule.
— If you select **The test code is: [Test]**, the blue **Test** link opens the Set Value dialog. The Set Value dialog contains a list of available tests. The rule is triggered when a selected test is run.

e. Select **Next**.
The analyzer displays the available Actions.

---

5 Configure the rule action for a rerun.

a. Select **Rerun the test**.
The analyzer displays THEN Rerun the test in the rule-building section.

b. Select **Next**.
The analyzer displays the available Exclusions.

---

6 Configure the exclusions for the rule.

If you select one or more exclusions, the analyzer displays an EXCEPT IF line in the rule-building field. Configure exclusions in the same way that you configured conditions for the rule earlier in this procedure. If you select more than one exclusion, OR IF precedes each additional exclusion. OR IF indicates that satisfying any one of the exclusions prevents the rule from being triggered.

---

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Reruns with Prep Type

The analyzer uses a system of rules to automatically trigger a rerun with a Prep Type of Dilute or Condense when a test result meets specified criteria.

When the Rerun with prep type: Dilute rule is triggered, the analyzer creates a dilution of the sample according to the dilution factor defined in the APF or parameter package, and reruns the test on the diluted sample.

When the Rerun with prep type: Condense rule is triggered, the analyzer draws extra sample according to the specifications in the parameter package, and reruns the test as a condensed sample.

---

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

---

2 Add a new rule.

a. Select **Rules**.
The analyzer displays the Rules page.

b. Select **New**.
The analyzer opens the Add Item dialog.

c. Enter a unique name for the rule in **Name**.

d. Select **OK**.
The Rule Details section displays four categories: General, Conditions, Actions, and Exclusions. At first, only the General settings are available.

---

3 Configure the general settings for the rule.

a. In the General settings, select the Description field, and in the Text Input dialog, enter a description of the rule in **Description**.

b. Select **Done**, and select **Next**.
The analyzer displays the Conditions settings.

---

4 Configure the conditions for the rule.

a. In the Conditions section, select the checkbox for **The test code is: [Test]**.
In the rule-building section at the bottom of the page, the analyzer displays IF the test code is: Test, with **Test**, displayed as a link.

b. Select the **Test** link.
The analyzer displays the Set Value dialog, which contains a list of available tests.

c. Select the test or tests that you want the rule to be applied to, and then select **OK**.
The selected tests are displayed in the rule-building section.

d. In the Conditions section, select the conditions to trigger the rule.
Each condition that you select adds an AND IF line to the rule-building section. Conditions that include text in brackets are displayed with a blue link.

- If you select **The result value is critical**, the rule is triggered when the result is critical (as defined in the Tests configuration page for the test).
- If you select **The result has the flag: [Flag]**, the blue **Flags** link in the rule-building section opens the Set Value dialog. The Set Value dialog contains options for selecting one or more flags to trigger the rule.
- If you select **Result value satisfies: [Logical Expression]**, the blue **Logical Expression** link in the rule-building section opens the Set Value dialog. The Set Value dialog has options for selecting operators and result values for either **Quantitative** or **Qualitative** results. The rule is triggered when the logical expression is true.
- If you select **The patient: [Age Expression],** the blue **Age Expression** link opens the Set Value dialog. The Set Value dialog contains options for defining an age range expression to trigger the rule.
- If you select **The sex of the patient is: [Value]**, the blue **Value** link opens the Set Value dialog. The Set Value dialog contains options for **Unknown**, **Male**, and **Female**. The rule is triggered if the sex of the patient matches the selection in the rule.
- If you select **The test code is: [Test]**, the blue **Test** link opens the Set Value dialog. The Set Value dialog contains a list of available tests. The rule is triggered when a selected test is run.

e. Select **Next**.
The analyzer displays the available Actions.

5 Configure the rule action for a rerun with a prep type.

a. Select **Rerun with prep type [Prep Type]**.
The analyzer displays THEN Rerun with prep type: in the rule-building section.

b. Select **Prep Type**.

c. In the Set Value dialog, select **Dilute** or **Condense**, and then select **OK**.

Note

In order for this setting to be functional, you must enter values for sample volume and predilution rate in the customer configurable options on the Tests configuration page. Refer to Setting Customer Configurable Options. (Predilution rate applies only to dilutions.)

d. Select **Next**.
The analyzer displays the available exclusions.

6 Configure the exclusions for the rule.

If you select one or more exclusions, the analyzer displays an EXCEPT IF line in the rule-building field. Configure exclusions in the same way that you configured conditions for the rule earlier in this procedure. If you select more than one exclusion, OR IF precedes each additional exclusion. OR IF indicates that satisfying any one of the exclusions prevents the rule from being triggered.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring the LIS Interface

You can configure communication and protocol settings that are used for communicating with the host system (LIS).

The LIS sends test orders and sample information to the analyzer and receives results from the analyzer. The LIS can use a single connection or two separate connections for sending and receiving. Consult your LIS vendor or Beckman Coulter Customer Support for assistance.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **LIS**.
The analyzer displays the LIS page.

Note

Do not change the Individual Message Transmission settings.

3 To enable communications with the LIS, select **CLSI LIS01-A/LIS02-A (ASTM)** in the LIS Protocol section of the page.

To disable communications, select **Disabled**.

4 Configure the Device Identification settings.

a. Select the text field for **Sender Name**. Enter the device name that identifies the analyzer to the LIS in **Sender Name** in the Text Input dialog.
When results are uploaded to the LIS, this name is listed as the device name.

b. Select the text field for **Sender ID**. Enter the unique identifier that identifies the analyzer to the LIS in **Sender ID** in the Text Input dialog.

c. Select **Done**.

5 Configure the Text Encoding method. Select either **UTF-8** or **GB18030**.

6 Configure the General Settings.

a. To create a sample event when the LIS orders a test that has not been configured on the analyzer, select **Notify of LIS orders for tests that have not been configured**.

To ignore LIS orders for tests that have not been configured on the analyzer, clear this option.

b. To upload results to the LIS when the results are available, select **Enable partial upload**.

To not upload results until all results for a test order are available, clear this option.

c. To transmit reagent lot and expiration information with results, select **Transmit reagent information with results**.

d. To notify the LIS when a test order has been canceled, select **Send message when test order is canceled**.

e. To send a query to the LIS when a sample is loaded without a test order, select **Issue host queries**. Then select the text field for Host query response timeout, and in the Text Input dialog enter the number of seconds to wait for a response from the LIS in **Host query response timeout**.

f. Select **Done**.

7 Configure the communication connection settings.

a. In Connection Type, select **Serial** for an RS-232 connection, or select **TCP/IP** for a network connection.

b. To use the same connection for upload and download, select **One** in Physical Connections. To use one connection for downloading orders and another connection for uploading results, select **Two**.

8 If you selected **Serial** in Connection Type, configure the serial port settings.

Note

If you selected **Two** in Physical Connections, each of the following substeps must be performed for both the Download and Upload ports.

a. In **Baud Rate**, select the transmission speed for the port.

b. In **Parity**, select **None**, **Even**, or **Odd**.

c. In **Flow Control**, select **None** or **Xon/Xoff**.

9 If you selected **TCP/IP** in Connection Type, configure the network settings.

Note

If you selected **Two** in Physical Connections, each of the following substeps must be performed for both the Download and Upload ports.

a. Enter the port number in **TCP Port**.

b. Enter the IP address for the connection in **IP Address**.

c. Select **Done**.

10 In Records per Frame, select **One record per frame** or **Multiple records per frame**.

11 Enter the maximum number of bytes to support.

a. Select the text field for Maximum bytes per frame.

b. in the Text Input dialog enter the maximum number of bytes to support in **Maximum Bytes per Frame**.

c. Select **Done**.

12 Configure LIS Codes for Sample Type.

a. Select the field for a sample type that you want to change.

b. Enter the code that you want to use for the selected sample type.

c. Edit any other sample types that you want to change.

d. Select **Done**.

13 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Sample Comments

You can create standard comments to add to samples.

When you create standard sample comments, they can be quickly selected from a list on the Sample page.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Sample Comments**.
The analyzer displays the Sample Comments page.

3 To enter a new comment, select **New**, type the comment in the dialog, and then select **OK**.

4 To create a new comment that is very similar to another comment, copy the other comment and then edit it to create the new comment.

   a. Select the comment to copy.

   b. Select **Copy**.
   The analyzer displays the Copy Item dialog.

   c. In **Copy to:**, edit the comment, and then select **OK**.

5 To edit a comment, open the Edit Item dialog to enter the new text.

   a. Select the comment to edit.

   b. Select **Edit**.
   The analyzer displays the Edit Item dialog.

   c. In **New value:**, edit the comment, and then select **OK**.

6 To delete a comment, perform these steps:

   a. Select the comment to edit.

   b. Select **Delete**.
   The analyzer displays a confirmation dialog.

   c. Select **OK**.
   The analyzer deletes the comment.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Thresholds for Supplies

You can configure the supply levels that trigger notifications for the Due Soon Threshold and, for some supplies, the Expiring Soon threshold.

When a supply is due soon, the tile for that supply appears on the Consumables Due Now page or Reagents Due Now page.

- When a consumable is due now, or exhausted, the tile includes a red vertical bar on the left side. When a consumable is exhausted, the analyzer cannot process samples until the consumable has been replenished.
- When a reagent is due now, the tile includes a yellow vertical bar on the left side.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Supplies**.
The analyzer displays the Supplies configuration page.

3 Select a text field, and in the Text Input dialog enter numbers in the **Due Soon** field for each supply. For fields that include an **Expiring Soon** setting, select the number of hours from the drop-down menu.

The units for each supply (such as Percent or Test Count) are displayed in the Unit column. The numbers indicate when an alert is triggered for each supply.

4 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Daily Startup

You can configure the analyzer to coordinate certain activities with your daily shift schedule.

You can specify the duration of work shifts in your laboratory, as well as the starting time for the first shift of the day. The analyzer will then coordinate activities such as QC and calibration based on the shift schedule.

For calibrations, calibrations and reagent blanks that would normally become due during a particular shift will become due at the start of that shift based on the start time and the shift length configured in Daily Startup.

For QC, QC tests become due at the start of each day that is specified in **Start Time** when you configure daily startup. If the frequency of a QC test has been configured for an interval less than 24 hours, then the QC test will also become due at the beginning of each interval.

Note

When you edit the configuration, you are editing it in the draft configuration. You must activate the draft configuration to make the changes effective.

1 Select **Menu** > **System Configuration**.
The analyzer displays the System Configuration page.

2 Select **Daily Startup**.
The analyzer displays the Daily Startup Configuration page.

3 Use the drop-down menus in **Start Time** to select the starting time of your first daily shift.

4 Select the shift length in **Hours**.

5 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Contamination Prevention Parameters

Contamination prevention parameters are predefined by Beckman Coulter. For open tests, you can add or modify settings based on your lab's carryover verification testing.

Although the analyzer has sufficient washing capability, cross contamination can occur in readily affected samples or in analysis tests with high sensitivity. You can program extra washing conditions and avoidance parameters to prevent such contamination.

Caution

Sample processing throughput might be decreased when contamination prevention is configured. Consult the reagent Instructions for Use or the reagent manufacturer.

Program reagent, mix-bar, and cuvette contamination avoidance conditions.

Important

If you modify or remove existing contamination prevention parameters, perform the procedure for Cleaning Cuvettes With External Solution to prevent cuvette contamination. Use Beckman Coulter Wash Solution (100%) or lipase wash instead of 1N hydrochloric acid or diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite). Refer to the Task page for the Cleaning Cuvettes With External Solution maintenance task.

Note

Lipase wash is available only outside the United States.

1. Select **Menu** > **System Configuration**.
2. Select **Contamination**.
   The analyzer displays the Contamination Parameters Configuration page.
3. Select **Contamination Prevention**.
   The analyzer displays the Contamination Prevention section.
4. Select **Add**.
   The analyzer displays the New Contamination Prevention dialog.

5 Enter values in the dialog and select **OK**.

Table 83 Contamination Prevention Parameters in the New Contamination Prevention Dialog

Item	Contents	Description	Limitations
Preceding Test Name	Test name	Select the test and type to perform extra washing before the test analysis. You can also select the Beckman Coulter Wash Solution (**Wash (100%)**, **Lipase Wash**), or **All** for the preceding test.	— If Prevent Using Cuvette is **Yes**, **Wash (100%)** or **Lipase Wash**, you can only select **DENAT**, **A1c**, or **T-Hb** individually for Preceding Test Name. — If Prevent Using Cuvette is **Yes**, **Wash (100%)** or **Lipase Wash**, you cannot select **Wash (100%)** or **Lipase Wash** for Preceding Test Name. — If Prevent Using Cuvette is **No**, you can only select **DENAT** for Preceding Test Name.
Following Test Name	Test name	Select the test that the preceding test affects, or select **All**.	— If Prevent Using Cuvette is **Yes**, **Wash (100%)** or **Lipase Wash**, you can only select **DENAT**, **A1c**, or **T-Hb** individually for Following Test Name. — If Prevent Using Cuvette is **No**, you can only select **DENAT** for Following Test Name.
Preceding Reagent Type	R1 or R2	The type of reagent for the preceding test.	
Following Reagent Type	R1 or R2	The type of reagent for the following test.	

The analyzer adds the parameters for the test to the list on the Contamination Prevention section.

6 Adjust the values for the parameters.

Table 84 Contamination Prevention Parameters

Item	Contents	Description	Limitations
Solution	Water, Wash (100%) or Lipase Wash	The analyzer cleans the reagent probe with water, Beckman Coulter Wash Solution (100%), or lipase wash. Place the required solution on the analyzer. The bottle positions for wash solution (100%) or lipase wash are in the reagent refrigerator.	If Prevent Using Cuvette is **Yes**, **Wash (100%)**, or **Lipase Wash**, you must select **Water**.
Wash Count	0 to 5	Select the number of times that the analyzer washes the reagent probe in water, wash solution (100%), or lipase wash.	If Prevent Using Cuvette is **Yes**, **Wash (100%)**, or **Lipase Wash**, you must select **0**.
Water Cleaning Effective	No or Yes	**No**: Cleaning 5 times with wash solution (100%) always occurs before the affected test, even if you run 5 or more tests between the two affected tests. **Yes**: The normal rinsing of the reagent probe with deionized water between tests has the same cleaning effect as the programmed contamination avoidance cleaning. If you select **5** for **Wash Count** for Wash (100%), and you run 5 or more tests between the two affected tests, the analyzer does not perform the additional cleaning with wash solution (100%).	If Prevent Using Cuvette is **Yes**, **Wash (100%)**, or **Lipase Wash**, you must select **No**.

Table 84 Contamination Prevention Parameters (Continued)

Item	Contents	Description	Limitations
Prevent Using Mixer	No or Yes	**No**: The analyzer uses the mix bar for processing of the following test immediately after the preceding test. **Yes**: The analyzer does not use the mix bar for the following test immediately after the preceding test.	If Prevent Using Cuvette is **Yes**, **Wash (100%)**, or **Lipase Wash**, you must select **No**.
Prevent Using Cuvette	Yes, Wash(100%), Lipase Wash, or No	**Yes**: The analyzer does not use the cuvette or uses it for a test other than the following test after the preceding test. **Wash (100%)** or **Lipase Wash**: The analyzer washes the cuvette with wash solution (100%) or lipase wash after the preceding test or uses it for a test other than the following test after the preceding test. **No**: The analyzer can use the cuvette for processing the following test.	

7 Assign positions to Wash (100%) and Lipase Wash in the reagent refrigerator.
Refer to Assigning a Dedicated Position in the Reagent Refrigerator.

8 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Carryover Prevention Parameters Between Sample Types

Program extra cleaning of the sample probe between different sample types.

1 Select **Menu** > **System Configuration**.

2 Select **Contamination**
The analyzer displays the Contamination Parameters Configuration page.

3 Select **Carryover Prevention - Sample Type**.
The analyzer displays the Carryover Prevention - Sample Type section.

4 Select **Add**.
The analyzer displays the New Carryover Prevention - Sample Type dialog.

5 Select the sample-type combination and select **OK**.
The analyzer adds the sample-type combination to the list on the Carryover Prevention - Sample Type section.

6 In the lists under Wash Count, select the number of times that the analyzer cleans the sample probe with water and diluted Beckman Coulter Wash Solution (2%) when changing between sample types.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Carryover Prevention Parameters for Specific Tests

Configure extra sample probe washes before or after highly sensitive tests.

Configure the wash count for sensitive tests that might be affected by other tests.

1 Select **Menu** > **System Configuration**.

2 Select **Contamination**.
The analyzer displays the Contamination Parameters Configuration page.

3 Select **Carryover Prevention - Test Type**.
The analyzer displays the Carryover Prevention - Test Type section.

4 Select **Add**.
The analyzer displays the New Carryover Prevention - Test Type dialog.

5 Select the test in **Test Name** and select **OK**.
The analyzer adds the test to the list in the Carryover Prevention - Test Type section.

6 In the lists under Wash Count, select the number of times that the analyzer cleans the sample probe with diluted Beckman Coulter Wash Solution (2%) and water before and after dispensing the test.

Table 85 Carryover Prevention - Test Type Parameters

Item	Contents	Input Notes
Pre Dispense Wash Count: Wash Solution (2%) and Water	0 to 6	Select the number of times that the analyzer cleans the sample probe with water and diluted wash solution (2%) before dispensing the test.
Post Dispense Wash Count: Wash Solution (2%) and Water	0 to 6	Select the number of times that the analyzer cleans the sample probe with water and diluted wash solution (2%) after dispensing the test.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Configuring Sample ID Bar Code Settings

You can configure the bar code type, the number of digits, and the check mode for sample IDs.

1 Select **Menu** > **System Configuration**.

2 Select **Sample Bar Code**.
The analyzer displays the Sample Bar Code page.

3 Select the bar code type in **Bar Code Type**.

You can select one of the following bar code types:

— Multi Code
— ISBT 128

4 If you selected **Multi Code** for the bar code type, select the Digits field, and in the Text Input dialog enter the number of digits for the sample ID in **Digits**.

Note

If you enter **0**, any numbers of digits that are in the supported range of digits are permitted.

5 Select the check mode in **Check Character**.

You can select **None**, **Exists Only**, or **Exists and is Valid**.

6 Select **OK**.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

Assigning a Dedicated Position in the Reagent Refrigerator

Reagent bottles that have a bar code label can be placed in any available (not assigned) position on the reagent tray. Reagent bottles without a bar code label, and the bottles of Beckman Coulter Wash Solution (100%) and lipase wash for washing the reagent probes, must be assigned to dedicated positions.

Note

Lipase wash is available only outside the United States.

Caution

Make sure to place the correct reagent in the dedicated position that you assign. If the wrong reagent {with or without a bar code} is placed in the dedicated position, it will be recognized as the reagent that is configured for that dedicated position. This situation can cause incorrect results.

1 Select **Menu** > **System Configuration**.

2 Select **Dedicated Positions**.

The analyzer displays the Dedicated Positions page.

Note

If a reagent, the wash solution (100%), or the lipase wash has already been configured with a dedicated position, it appears in the list on the page.

3 To assign a reagent, the wash solution (100%), or the lipase wash to a dedicated position, select **Add**.

The analyzer displays the Add Dedicated Position dialog.

4 Enter or select values in **Position**, **Test Name**, **Type**, **Bottle Size**, **Lot Number**, and **Bottle Number**, and select **OK**.

The value for **Lot Number** and the value for **Bottle Number** are each limited to 4 alphanumeric characters.

Note

For wash solution (100%) and lipase wash, values for **Type**, **Lot Number**, and **Bottle Number** do not apply.

Note

For wash solution (100%) and lipase wash, you can assign a maximum of two dedicated positions for each solution.

Note

For wash solution (100%) and lipase wash, countdown to the time of expiration of the solutions starts when you assign them to dedicated positions.

The analyzer displays the specified values on the Dedicated Positions page.

5 To delete a reagent, the wash solution (100%), or the lipase wash from the list, select the entry, select **Delete**, and select **OK** in the Delete Item dialog.

6 To edit an entry in the list, select the entry, select **Edit**, change values in the Edit Dedicated Position dialog, and select **OK**.

7 Activate the draft configuration. Refer to Activating a Draft Configuration.

CHAPTER 14

Other Important Information

Service

Coverage

If any problems occur in the system during the warranty period, contact your Beckman Coulter representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, call Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

System Specifications

This section summarizes requirements for the DxC 500 AU such as placement, electrical, and environmental.

For more information on other configurations, contact Beckman Coulter Customer Support.

Storage and Handling

Temperature and Humidity Conditions When Not in Use

- The temperature is between 5 °C (41° F) and 40 °C (104° F).
- The humidity is between 15% RH and 90% RH.

Temperature and Humidity Conditions When Analyzer is Being Transported

- The temperature is between -30 °C (22° F) and 60 °C (140° F).
- The humidity is between 10% RH and 95% RH.

Electrical Line Requirements

For the electrical line connection, the analyzer can be connected using an industrial style plug or wired directly into a distribution box in the building installation.

Important

A Beckman Coulter Representative must connect the power supply cable to the analyzer. It is your responsibility to prepare the power supply and facility according to applicable electrical codes and the specifications described in this section.

Table 86 Electrical Line Requirements

Parameter	Requirement
Position of distribution panel (if wired to the building installation)	Power cable with a length of 10 m can reach the analyzer
External mains disconnect in the building installation	Recommended
Maximum voltage fluctuations of power source	± 10%
Transient overvoltage of power source	Less than 2500 V (overvoltage category II)
Analyzer is grounded	Required
Grounding resistance of grounding terminal	Less than 100 Ω of grounding resistance defined in the technical standards for electrical facilities
Voltage, Frequency	AC 208 V 50/60 Hz (USA) AC 230 V 50/60 Hz (Europe) AC 220 V 50/60 Hz (Asia) AC 240 V 50/60 Hz (Australia) AC 200 V 50/60 Hz (Japan)
Maximum rated power consumption (The analyzer must be connected to a dedicated branch circuit with a rating of 20 A.)	3500 VA (dedicated circuit required)

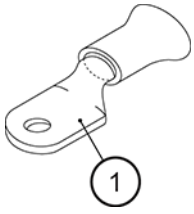
Caution

To avoid electrical damage to the analyzer caused by uneven current, use an uninterruptible power supply (UPS) and wiring configuration to connect the analyzer to electrical power. For more information, contact Beckman Coulter.

Warning

For analyzers being wired into the building installation, connect all the grounding terminals provided for the distribution panel to ground. Failure to ground the terminals can cause electric shock and analyzer malfunction.

Figure 86 Crimp Terminal Hole



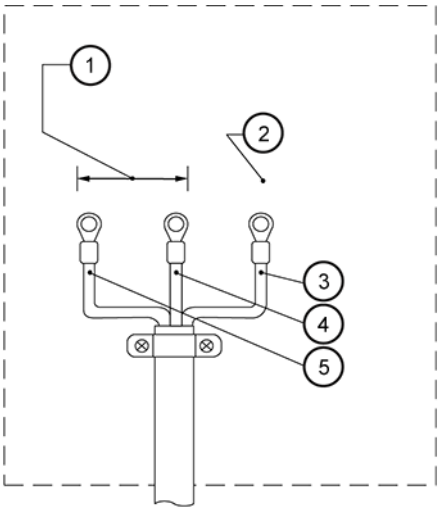
1. Crimp terminal hole diameter 5.4 mm

Caution

Only a Beckman Coulter Representative can connect the power cable inside the analyzer.

- **The power cable for the analyzer can be an industrial style plug or be hardwired to the laboratory's electrical network.**
- **For a hardwired configuration, connect the power cables to the distribution panel.**

Figure 87 Distribution Panel



1. Connect these terminals to the power source specified for the analyzer
2. Connect this terminal to a grounding terminal that measures less than 100 Ω
3. Yellow/Green
4. Black (NEUTRAL)
5. Black (LIVE)

Environmental Requirements

To operate this analyzer safely and accurately, confirm the following requirements for the location in the laboratory:

Table 87 Environmental Requirements for Operation

Parameter	Requirement
Can be placed in direct sunlight?	No
Can be subject to vibration?	No
Maximum pollution (including dust and airborne particles) degree, as defined by IEC and UL standards	2
Maximum gradient	1/200
Minimum weight that the floor can support	700 kg (1,543 pounds)
Maximum altitude	2,000 m (6,561 ft) above sea level

Table 87 Environmental Requirements for Operation (Continued)

Parameter	Requirement
Location can contain corrosive gases?	No
Temperature	18 °C to 32 °C (64 °F to 90 °F)
Temperature fluctuation	Within 4 °C during analysis
Humidity	20% to 80% RH (without condensation)
Can be exposed to direct airflow from air conditioners?	No

Caution

Do not move or adjust the computer from the original position. During installation, Beckman Coulter installs the computer in the correct position. For proper ventilation, the space requirement around the computer is at least 76 mm.

Caution

Heat output by the analyzer during operation is approximately 7,238 kJ/h (8,820 BTU). When the specified room temperature and humidity ranges fluctuate, the analyzer data might not be reliable. When the analyzer is in operation, confirm that the requirements for temperature and humidity are met.

Note

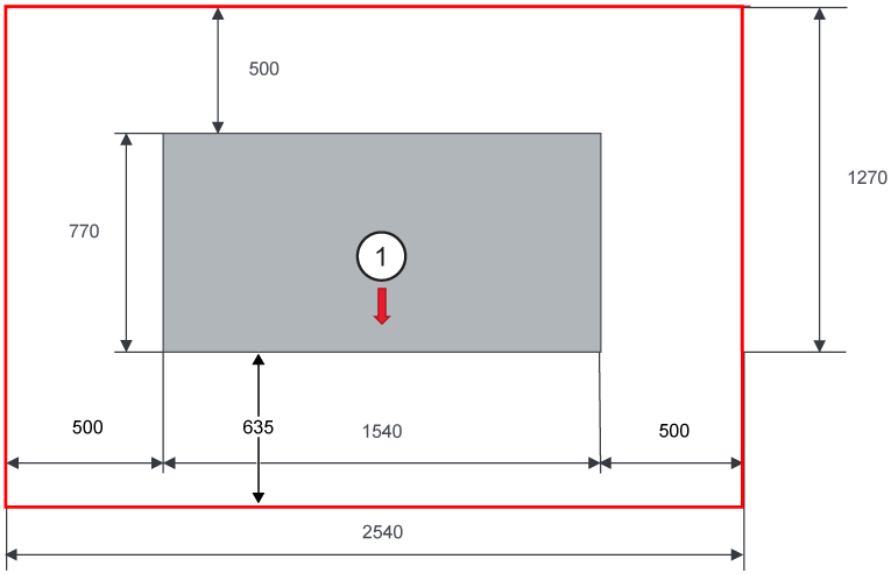
The installation site must be well ventilated. For more information, refer to Clearance Requirements.

Clearance Requirements

The system includes the analyzer and its subsystems.

This analyzer requires space of a minimum of 500 mm (20 inches) from the wall around it for safe installation and maintenance.

Figure 88 System Clearance



1. DxC 500 AU analyzer (without monitor mounted on analyzer)

   (Red arrow points to the front of the analyzer.)

Dimensions and Weight

Table 88 Dimensions

Module	Length	Height	Depth
Analyzer with monitor mounted on analyzer	2100 mm (6.9 ft)	1602 mm (5.3 ft)	770 mm (2.5 ft)
Analyzer only (including status light)	1540 mm (5.0 ft)	124.0 cm (4.1 ft)	770 mm (2.5 ft)

The weight of the analyzer with monitor is less than or equal to 450 kg (992 pounds).

Water Supply Requirements

Table 89 Water Supply Requirements

Specification	Requirement
Type	Deionized CAP type II or better, bacteria free
Supply	Continuous flow
Resistivity	> 0.5 MΩ·cm
Mechanical filtration	0.5 µm
Deionized water conductivity	2.0 µS/cm or less (water transmitted through a filter of 0.5 µm or less)

Table 89 Water Supply Requirements (Continued)

Specification	Requirement
Water pressure	0.49×10^5 to 3.92×10^5 Pa (7 psi to 57 psi) Greater than this range, connection to an external water supply valve unit is required.
Water consumption	Maximum: 20 L/hour
Water demand	Maximum: 0.6 L/minute
Deionized water temperature	5 to 28 °C (41 °F to 83 °F)
Water-supply facility	More requirements for the water supply: • The analyzer is located within 10 m (33 ft) of the deionized water outlet. • Deionized water supplied to the analyzer does not contain excessive air bubbles. The analyzer includes the following tubing: • Water supply hose: Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 ft), 1 piece.

Caution

If the tap water temperature exceeds the optimal temperature range for the deionizer, consult the deionizer manufacturer. When using the existing water supply tubing and deionizer, confirm that it is micro-organism free.

Note

The water pressure for this analyzer operates at a range from 0.49 x 10^5 to 3.92 x 10^5 Pa. For the correct water pressure for the deionizer, contact the deionizer manufacturer. Beckman Coulter recommends use of a reverse osmotic membrane as the deionizer. For more information, contact Beckman Coulter.

Drainage and Exhaust Requirements

Table 90 Drainage and Exhaust

Specification	Requirement
Concentrated liquid waste hose, diluted liquid waste hose	Braided hose 15 mm (ID) x 22 mm (OD), L=10 m (33 ft), 2 pieces
Exhaust hose	Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 ft), 1 piece
Maximum distance of drain hole from the analyzer	10 m (33 ft)
Connecting drain to an infectious waste collection tank	As required by law

Table 90 Drainage and Exhaust (Continued)

Specification	Requirement
Location of drain above the analyzer installation floor	No higher than 1.5 m (5 ft)
Location of exhaust above the analyzer installation floor	No higher than 0.1 m (0.33 ft)
Placement of ends of exhaust air hoses, which are inserted into the drain	Above the liquid level of the drain
Placement of ends of liquid waste hoses, which are inserted into the drain	Above the liquid level of the drain
Liquid waste hoses	Not bent or crushed
Drainage capability for concentrated liquid waste	• 5.5 L/hour (normal) • 7.5 L/hour (HbA1c)
Drainage capability for diluted liquid waste	12 L/hour

Note

A damaged or disconnected waste hose may discharge potentially infectious waste inside or near the analyzer, causing damage to the analyzer or posing a slip hazard and contact with biohazardous waste. Do not kink or crush the waste hose.

Warning

Follow your laboratory procedure for disposal of all liquid and infectious waste.

The analyzer discharges liquid waste by forced drain and moist air containing the components of liquid waste.

- Concentrated liquid waste: Compound liquid of sample and reagent retrieved from cuvettes and diluted Beckman Coulter Wash Solution.
- Diluted liquid waste: Liquid waste used for components such as washing cuvettes and mix bars.

Installation

Before installation of the analyzer, refer to System Specifications.

A Beckman Coulter Field Service Engineer must be present when the analyzer is removed from the shipping crate.

A qualified Beckman Coulter Field Service Engineer must install the analyzer.

If the analyzer must be relocated, contact Beckman Coulter Customer Support.

Warranty

The DxC 500 AU Chemistry Analyzer is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents. The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals will be made at the discretion of Beckman Coulter, and at the customer's expense.

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Other Important Information

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APPENDIX A

Parts Lists and Ordering Information

Parts List for Chemistry Analyzer Maintenance

Table 91 Parts List for Chemistry Analyzer Maintenance

Part	Part Number
1N hydrochloric acid	Commercial item
15-mL reagent bottle (20 bottles)	63165
30-mL reagent bottle (20 bottles)	63094
60-mL reagent bottle (20 bottles)	63093
Adapter A for STAT table, 11.5 mm to 14 mm cup (package of 22)	MU811800
Adapter B for STAT table, 13.5 mm to 16 mm cup (package of 22)	MU811900
Adapter C for STAT table, ACA cup (package of 22)	MU811700
Air filter kit (2 square filters, 2 rectangular filters)	C64277
Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Analyzer Maintenance Kit	C79482
Anti-static brush 1 (for right side of rack transfer subsystem)	C64233
Anti-static brush 2 (for left side of rack transfer subsystem)	C64234
Basin	Commercial item
Cleaning solution (5% sodium hypochlorite)	66039
Clean, dry, lint-free absorbent tissue	Commercial item
Cotton-tipped applicator	Commercial item
Cuvettes (5 mm x 5 mm) (package of 10)	MU846500
Cuvette Maintenance Holder	C92126
Deionized water filter	ZM307900
Disposable pipette	Commercial item
Deionized water tank (10 L)	MU810600
Deionized water tank (10 L) (China)	B80708
Diluted wash solution tank (2L)	MU853500
Diluted wash solution tank (2L) (China)	B80710
Label for bottle detection (package of 360)	MU987900
O-ring (for sample probe filter)	MU963700
O-rings (for wash nozzle subsystem)	MU963800
Packing in the wash nozzle tube mounting joints	MU842700
Pair of tweezers	Commercial item

Table 91 Parts List for Chemistry Analyzer Maintenance (Continued)

Part	Part Number
Photometer lamp	MU988800
R Syringe	B69039
R2: L-shaped mix bar (package of 3)	MU826700
Reagent probe	MU995800
Reagent probe tubing	MU854100
Reagent tray	C64241
Roller pump tubing (package of 2)	MU962300
S and R1: Spiral-shaped mix bar (package of 3)	MU959900
S Syringe	B44676
Sample Cup (2.5 mL) (package of 100)	MU853200
Sample Cup (2.5 mL) (package of 1000)	ZM160600
Sample probe	MU993400
Sample probe tubing	MU854200
Sample Tube Template	C99600
Sonicator	Commercial item
Stylet 0.14 mm diameter	MU941300
Stylet 0.3 mm diameter	ZM022700
Vacuum cleaner	Commercial item
Wash nozzle joint (package of 3)	ZM113100
Wash solution tank (2 L)	MU853400
Wash solution tank (2 L) (China)	B80709

Parts List for ISE Maintenance

Table 92 Parts List for ISE Maintenance

Part	Part Number
Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Beaker	Commercial item
Cl electrode	MU919600
Clean, dry, lint-free absorbent tissue	Commercial item
Cleaning solution (5% sodium hypochlorite)	66039
Deionized water	-
Disposable pipette (2 pieces) (that can collect more than 1 mL of liquid)	Commercial item

Table 92 Parts List for ISE Maintenance (Continued)

Part	Part Number
ISE buffer syringe case	B91297
ISE High Serum Standard	• AUH1015 (US) • 66316 (Outside US)
ISE High Urine Standard	• AUH1016 (US) • 66315 (Outside US)
ISE Internal Reference Solution	• AUH1017 (US) • 66314 (Outside US)
ISE (K+) and (Na+) Selectivity Check Solution	• AUH1018 (US) • 66313 (Outside US)
ISE Low Serum Standard	• AUH1014 (US) • 66317 (Outside US)
ISE Low Urine Standard	• AUH1016 (US) • 66315 (Outside US)
ISE Maintenance Kit	C79484
ISE MID Standard Solution	• AUH1012 (US) • 66319 (Outside US)
ISE mix bar	MU962800
ISE REF Electrode Block	MU824500
ISE REF Electrode Packing	MU920200
ISE REF Electrode (with the packing)	MU919700
ISE Tubing 4	B97644
K electrode	MU919500
Na electrode	MU919400
O-ring (for ISE)	MU990000
Plastic tweezers	Commercial item
R Syringe	ZM011200
Sample Cup (2.5 mL)	MU853200
Sample pot	MU962700
Sonicator	Commercial item
Squeeze bottle with disposable pipette tip or syringe with disposable pipette tip	Commercial item

Table 92 Parts List for ISE Maintenance (Continued)

Part	Part Number
Wash solution tank (2 L)	MU853400
Wash solution tank (2 L) (China)	B80709

Parts List for Chemistry Consumables

Table 93 Parts List for Chemistry Consumables

Consumable	Part	Part Number
Diluted Wash Solution (2%)	Deionized water	-
	Wash solution tank (2 L)	MU853400
	Wash solution tank (2 L) (China)	B80709
	60-mL reagent bottle (20 bottles)	63093
Sample Diluent	Deionized water or diluent	-
	60-mL reagent bottle (20 bottles)	63093
Wash Solution (100%) and Lipase Wash	Deionized water	-
	Wash solution tank (2 L)	MU853400
	Wash solution tank (2 L) (China)	B80709
	60-mL reagent bottle (20 bottles)	63093
	Lipase wash (Outside US)	ODR20067
DI Water	Deionized water	-
	Commercial sample tube	-
Wash Solution Tank	Wash solution tank (2 L)	MU853400
	Wash solution tank (China)	B80709

Parts List for Keyboard and Mouse Kit Specifications

Table 94 Parts List for Keyboard and Mouse Kit Specifications

Part	Part Number
Keyboard and Mouse Kit Specification - English (Optional)	D09590
Keyboard and Mouse Kit Specification - French (Optional)	D09591
Keyboard and Mouse Kit Specification - German (Optional)	D09592
Keyboard and Mouse Kit Specification - Japanese (Optional)	D09593
Keyboard and Mouse Kit Specification - Spanish (Optional)	D09594
Keyboard and Mouse Kit Specification - Italian (Optional)	D09595

Parts List for Sample Racks and Accessories

Table 95 Sample Racks and Accessories

Item	Part Number	Description	Quantity Included
DxLAB tube rack	C22708	Rack for loading sample tubes	10
DxLAB cup rack	C22709	Rack for loading sample cups	10
DxLAB tube rack labels with bar codes 11001 to 11100	C77918	Bar code labels for tube racks	100
DxLAB tube rack labels with bar codes 11101 to 11200	C77919	Bar code labels for tube racks	100
DxLAB cup rack labels with bar codes 21001 to 21100	C77920	Bar code labels for cup racks	100
DxLAB cup rack labels with bar codes 21101 to 21200	C77921	Bar code labels for cup racks	100
DxLAB rack tray (12 position)	C99601	Container for carrying multiple racks	1

APPENDIX B

Chemistry Analyzer Maintenance Tasks

Maintenance Tasks Overview

Important

The maintenance tasks included in this appendix are included for reference only. When performing the procedures, you should only use the on-screen instructions for each task, unless otherwise instructed. The maintenance tasks cannot be performed without opening the appropriate maintenance task page.

The Maintenance page displays the following types of maintenance tasks:

- Maintenance Due Now: Tasks that are due.
- Scheduled: Tasks that are scheduled, but are not due now.
- As Needed: Tasks that are not scheduled, but can be completed on an as-needed basis.

To display the list for a type of maintenance task, select the gray bar that is labeled with the type.

1 Select the **Maintenance** task indicator on the Home page.
The analyzer displays the Maintenance page.

2 To perform maintenance that is due now, select a task from the Maintenance Due Now list, and then follow the steps on the Task page.

Important

Do not select the checkbox, which is used for selecting tasks to mark as completed. Select any other part of the row containing the task that you want to perform.

3 To perform other scheduled or as-needed maintenance, select a task from the Scheduled or As Needed list, and then follow the steps on the Task page.

Important

Do not select the checkbox, which is used for selecting tasks to mark as completed. Select any other part of the row containing the task that you want to perform.

4 To register completion, add an entry for the task to the Maintenance Log page.

   a. On the Task page, select **Task Completed**, or on the Maintenance page, select the checkbox next to the task and select **Task Completed**.

   b. In the Enter Username dialog, enter a user name, and then select **Save**.

5 Enter any maintenance notes on the Log page (optional).

   a. To access the Log page from the Maintenance Log page, select a task from the maintenance log.

   b. Enter your note in the Add to Notes and History field, and then select **Save**.

   c. If the analyzer displays the Enter Username dialog, enter a user name, and then select **Save**.

   Note

   The analyzer does not display the Enter Username dialog for a maintenance task that has a task status of Complete.

The analyzer displays the Maintenance page.

Perform Daily Inspection

Inspect the Syringes and Wash Solution Roller Pump for Leaks

The analyzer includes a sample syringe and a reagent syringe. If your analyzer includes an ISE, the analyzer includes an ISE buffer syringe. All syringes are located inside the middle front door of the analyzer.

The sample and reagent syringes measure the volume of sample or reagent to use in a reaction. The ISE buffer syringe measures the volume of buffer to use to dilute the ISE sample. A leak in a syringe can cause the syringe or probe to fail and affect test results.

Although the syringes are different sizes and serve different functions, you can inspect for correct performance using the same methods.

The wash solution roller pump supplies the required amount of Beckman Coulter Wash Solution (100%) to the diluted wash solution tank. If the wash solution roller pump tubing leaks, the concentration of diluted wash solution can be incorrect, or problems can occur with the wash solution roller pump.

Materials Required:

- Clean, dry, lint-free absorbent tissue

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the middle and left front doors of the analyzer.

Caution

Do not allow a strong alkali, such as Beckman Coulter Wash Solution, to contact the syringe. If a strong alkali contacts the syringe, cracks can occur. If a strong alkali contacts the syringe, remove the syringe and rinse it with water.

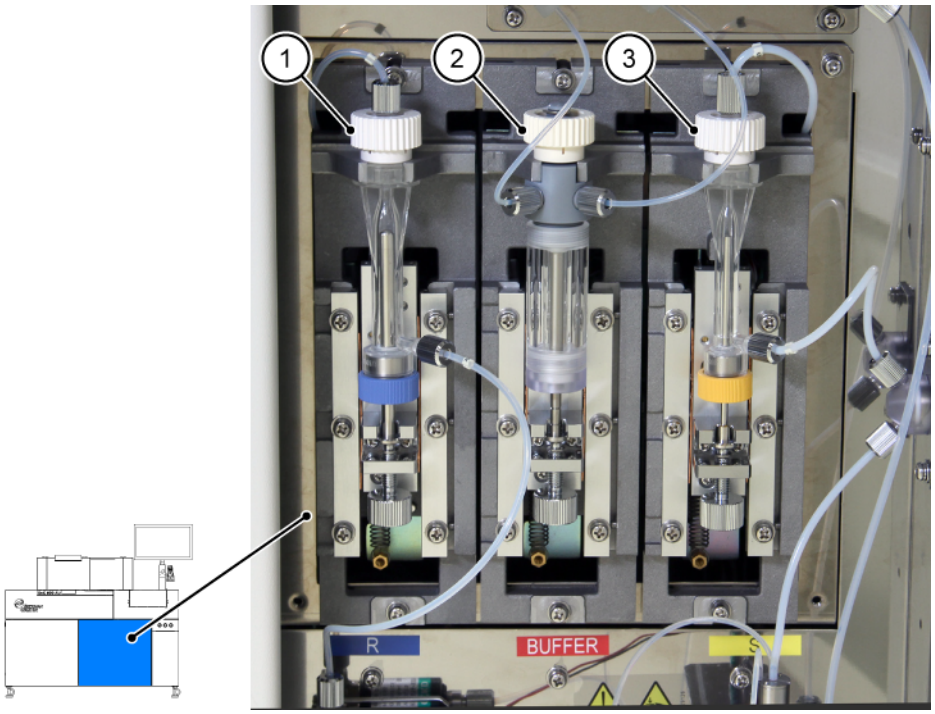
3 Inspect each syringe.

a. Look for any cracks or leaks in the syringe.

b. Use the clean, dry, lint-free absorbent tissue to confirm that the top and bottom connections for the syringe and the bottom fixing screw have no leaks.

c. If you find a crack or a leak, replace the syringe after completing this maintenance task.

Figure 89 Location of Syringes



1. Reagent syringe (blue)
2. ISE buffer syringe (clear)
3. Sample syringe (yellow)

Figure 90 Sample and Reagent Syringe Parts

1. Reagent syringe
2. Sample syringe
3. Top fixing nut (possible leakage location)
4. Connector to side tubing (possible leakage location)
5. Bottom piston fixing screw (possible leakage location)

4 Confirm that the fixing nuts and piston fixing screws are tight. If a leak persists after you tighten the screws, replace the syringe.

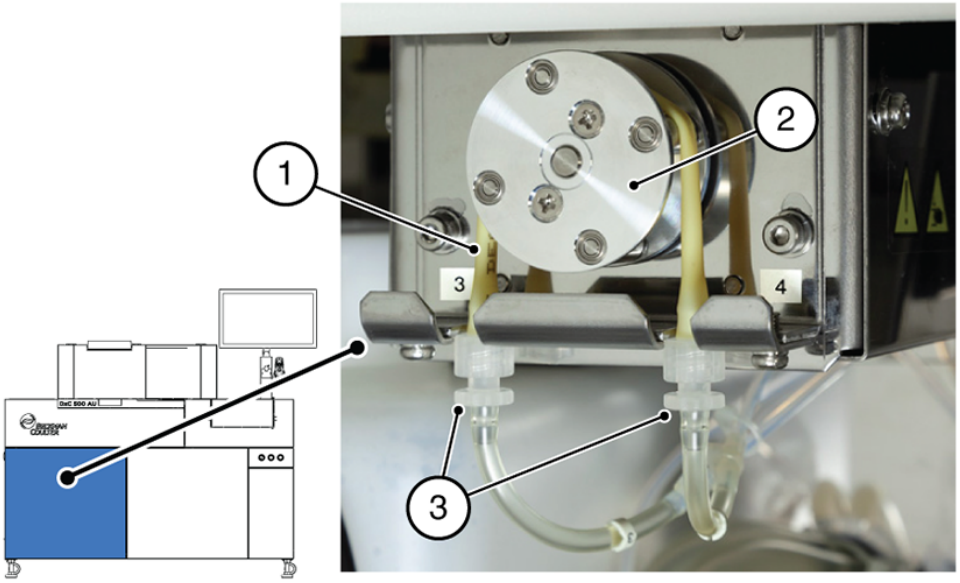
5 Inspect the wash solution roller pump tubing.

a. Look for any cracks or leaks in the roller pump tubing.

b. Use the clean, dry, lint-free absorbent tissue to wipe the peripheral part of the tubing and the roller pump to inspect for leaks. Wipe any fluid with the clean, dry, lint-free absorbent tissue.

c. If you find a crack or a leak, replace the tubing after completing this maintenance task.

Figure 91 Wash Solution Roller Pump



1. Wash solution roller pump
2. Roller pump tubing
3. Connectors

6 Confirm that the tubing connectors are tight. If a connector is loose, turn it clockwise to tighten. Wait 5 minutes, then inspect for leaks again. If the leak persists, replace the tubing.

7 Close all analyzer doors and covers.

8 Select **Task Completed**.

Important

If you found a crack or a leak in a syringe during this maintenance task, replace the syringe after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace the Sample Syringe**, **Replace the Reagent Syringe**, or **Replace the ISE Buffer Syringe**.
2. Follow the steps on the Task page.

Important

If you found a crack or a leak in the roller pump tubing during this maintenance task, replace the tubing after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the Wash Solution Roller Pump Tubing**.
2. Follow the steps on the Task page.

Perform Daily Checking and Priming

Inspect and Perform Basic Cleaning of the Sample Probe, Reagent Probe, and Mix Bars

The probes deliver precise quantities of reagent or sample to the cuvettes. The mix bars mix the contents in the cuvettes. If the mix bars or probes become bent or damaged, or if the probes become clogged, correct analysis cannot be achieved.

Before you begin analysis, inspect the sample probe, reagent probe, and mix bars for damage or deterioration.

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)

Inspect and Perform Basic Cleaning of the Sample Probe and Reagent Probe

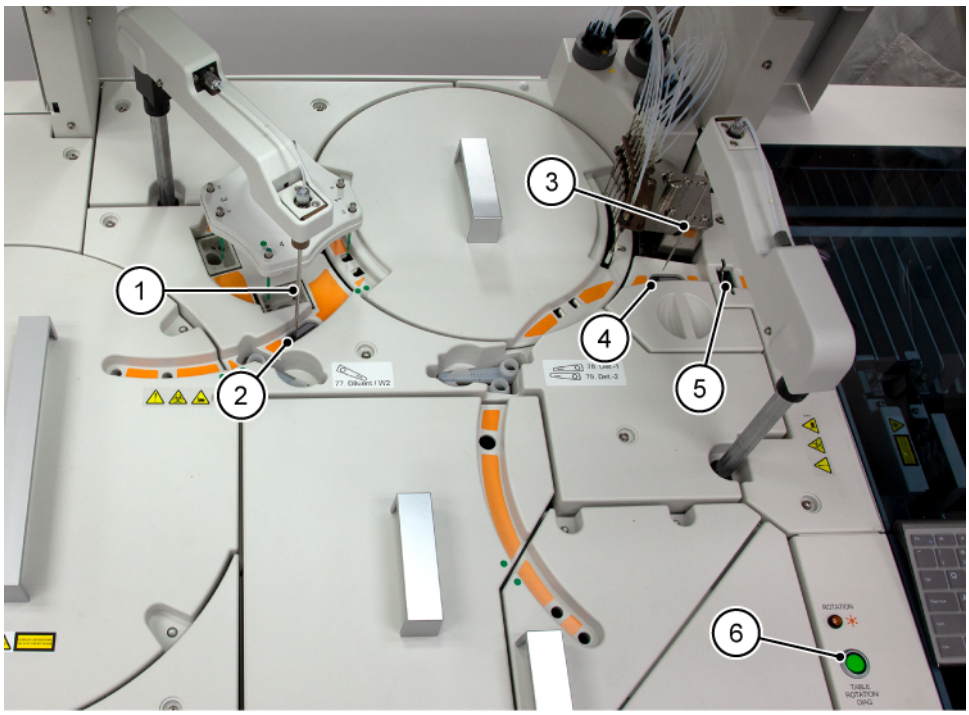
Confirm that each probe operates correctly.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Inspect each probe for damage.

Figure 92 Sample Probe, Reagent Probe, and Whole Blood Wash Wells



1. Reagent probe
2. Reagent probe wash well
3. Sample probe
4. Sample probe wash well
5. Whole blood wash well
6. TABLE ROTATION/DIAG button

If a probe is bent or damaged, replace the probe after completing this maintenance task.

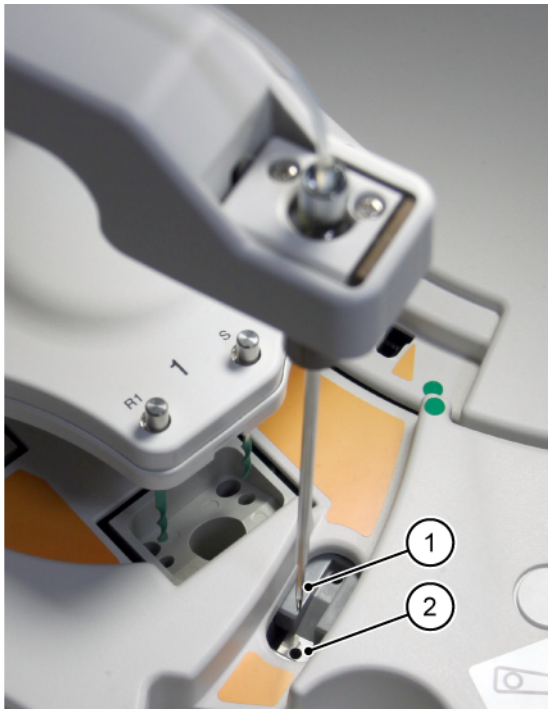
4 Inspect each probe for contaminants or crystallization. If a probe is dirty, wipe the surface with an alcohol prep pad (70% Isopropyl alcohol).

Important

Do not bend the probe when cleaning.

5 Confirm that the probe is aligned to the center of the wash well directly above the small hole in the metal. If the probe is not aligned correctly, contact Beckman Coulter.

Figure 93 Alignment of Probe with Wash Well Hole

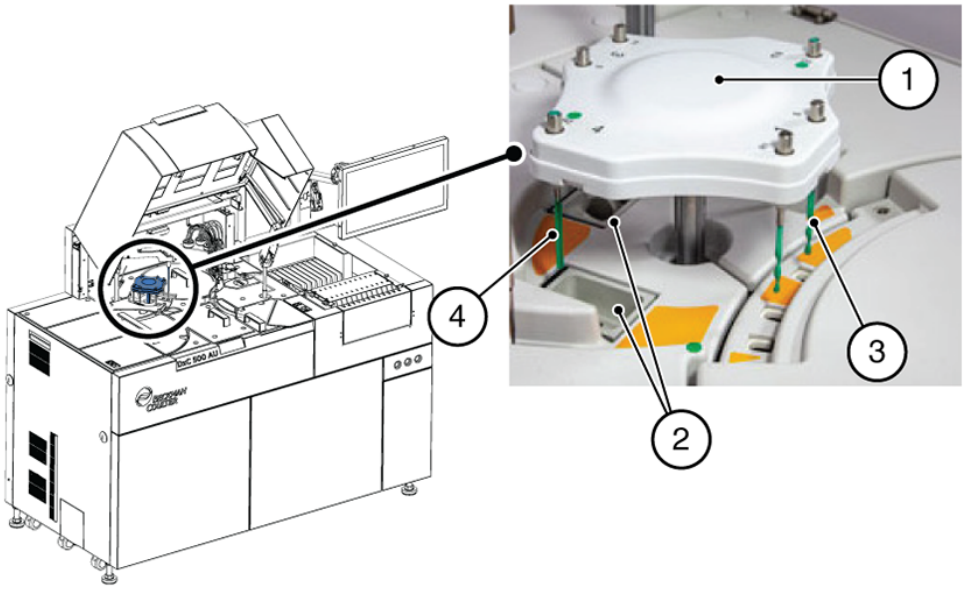


1. Probe
2. Hole in metal

Inspect and Perform Basic Cleaning of the Mix Bars

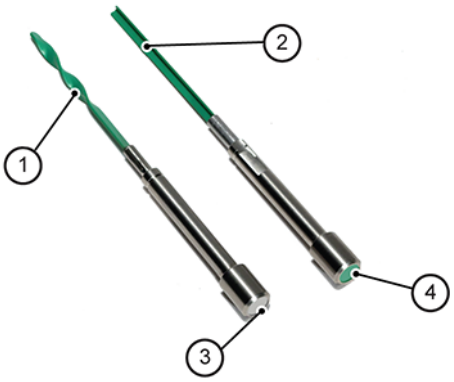
1 Inspect each mix bar for damage.

Figure 94 Mix Bar Subsystem



1. Mix bar subsystem
2. Mix bar wash wells
3. Spiral-shaped mix bar (R1/S position)
4. L-shaped mix bar (R2 position)

Figure 95 Mix Bars



1. Spiral-shaped mix bar
2. L-shaped mix bar
3. Silver
4. Green

If a mix bar is bent, scratched, or there are chips in the fluororesin coating, replace the mix bar after completing this maintenance task.

2 Remove and inspect each mix bar for contaminants, crystallization, or damage. If the mix bar is dirty, wipe the mix bar with an alcohol prep pad (70% Isopropyl alcohol).

Confirm Operation of the Probes and Mix Bars

Prime the analyzer to confirm the operation of the probes and mix bars.

1 Select **Prime Washing Line**.
The analyzer displays the Prime Washing Line dialog.

2 In **Repetitions**, confirm that the value is 1.

3 Select **OK**.

4 Press the **TABLE ROTATION/DIAG** button on the analyzer.
The analyzer initializes the probes and mix bar subsystem, then performs the following actions:

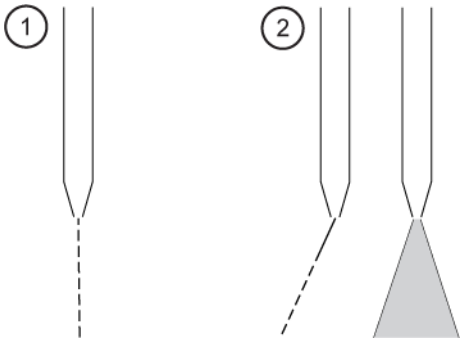
1. Dispenses deionized water from the sample probe
2. Dispenses deionized water from the reagent probe
3. Activates the mix bar subsystem and the wash nozzle subsystem

5 As the analyzer dispenses water, confirm that each probe dispenses a thin, straight stream of water, and that water flows in the wash wells.

The analyzer dispenses water in the following order:

1. Sample probe
2. Reagent probe

Figure 96 Sample and Reagent Probes



1. Correct Flow
2. Incorrect Flow

a. If the water is spraying or dispensing at an angle, clean the probe.

For more information, refer to step 4.

b. If cleaning does not correct the problem, replace the probe after completing this maintenance task.

6 When the analyzer activates the mix bars, confirm that the mix bars align correctly in the wash wells. If a mix bar does not align correctly, contact Beckman Coulter.
After priming is complete, the indicator light in the TABLE ROTATION/DIAG button on the analyzer turns on.

7 Repeat steps 4 to 6 as required to inspect all probes and mix bars.

8 Close the upper cover.

9 Select **Task Completed**.

Important

If you found during this maintenance task that a probe was bent or damaged, replace the probe after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace a Sample Probe** or **Replace a Reagent Probe**.
2. Follow the steps on the Task page.

Important

If you found during this maintenance task that a mix bar was bent, scratched, or there were chips in the fluororesin coating, replace the mix bar after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace the Mix Bars**.
2. Follow the steps on the Task page.

Important

If during this maintenance task cleaning did not correct the problem with dispensing of water by a probe, replace the probe after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace a Sample Probe** or **Replace a Reagent Probe**.
2. Follow the steps on the Task page.

Clean and Calibrate the ISE

If your analyzer includes an ISE module, clean and calibrate the ISE.

Clean the ISE

Clean the sample pot and the electrode lines daily to prevent contamination and inaccurate results. This procedure requires approximately 5 minutes to complete.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle Beckman Coulter Cleaning Solution (sodium hypochlorite). If the cleaning

solution contacts skin or clothes, rinse the affected area thoroughly with water. If the cleaning solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Note

If you do not plan to use the analyzer for a long period, clean the ISE before the period of inactivity.

Tip

It is a requirement to calibrate the ISE just before starting the weekly Perform Automatic Washing procedure. To avoid calibratiing the ISE multiple times in 1 day, you can plan to perform this daily task just before starting the Perform Automatic Washing procedure.

Materials Required:

- Beckman Coulter Cleaning Solution (5% sodium hypochlorite)
- Sample Cup (2.5 mL)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the small STAT table cover.

3 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table until the **Clean** position is accessible.

4 Fill the Sample Cup (2.5 mL) with a minimum of 1 mL of cleaning solution (5% sodium hypochlorite).

5 Place the Sample Cup (2.5 mL) in the **Clean** position on the STAT table.

Caution

Wipe up cleaning solution spills immediately. Follow your laboratory procedure.

6 Close the small STAT table cover.

7 Select **Wash ISE**.
The analyzer starts the cleaning operation. After the priming is complete, the indicator light in the TABLE ROTATION/DIAG button turns on.

8 When the cleaning operation is complete, open the small STAT table cover, rotate the STAT table to Clean position, remove the Sample Cup (2.5 mL) from the STAT table, and discard it.

9 Close the small STAT table cover.

10 Select **ISE Total Prime**.
The ISE total prime clears the lines of the ISE Cleaning Solution before ISE calibration.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
After the priming is complete, the indicator light in the TABLE ROTATION/DIAG button turns on.

12 Select **Exit Maintenance**.

Calibrate the ISE

Calibrate the ISE every 24 hours, after performing particular maintenance procedures, and after replacing the ISE reagents.

Caution

When the analysis is in progress or the ISE state is *Busy*, do not open the STAT table covers to add Standard Solutions to the STAT table or place hands in the path of the sample probe.

Note

Calibrating only serum or urine requires approximately 4 minutes to complete.
Calibrating serum and urine together requires approximately 7 minutes to complete.

Materials Required:

- ISE High Serum Standard
- ISE Low Serum Standard
- ISE High Urine Standard
- ISE Low Urine Standard
- Sample Cup (2.5 mL) (4 cups)

1 Open the small STAT table cover.

2 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table until the **S-H**, **S-L**, **U-H**, and **U-L** positions are accessible.

3 Fill a Sample Cup (2.5 mL) with approximately 500 µL of Standard Solution as required for processing (determined by your laboratory processing serum, urine, or both sample types).

Table 96 Position Labels for ISE Serum and Urine Standard Solutions

Solution	Position Label
ISE High Serum Standard	**S-H**
ISE Low Serum Standard	**S-L**

Table 96 Position Labels for ISE Serum and Urine Standard Solutions (Continued)

Solution	Position Label
ISE High Urine Standard	**U-H**
ISE Low Urine Standard	**U-L**

4 Place the Sample Cups (2.5 mL) into the corresponding positions on the STAT table.

5 Close the small STAT table cover.

6 Select **Calibrate Serum**, **Calibrate Urine**, or **Calibrate Serum and Urine** depending on the sample types to calibrate.
The analyzer starts calibration.

7 When calibration is complete, confirm that the result for each electrode is within the ranges for the calibrated sample types in the ISE Reagent Details page (Select **Home** > **Reagents** > **All Reagents**. Select the correct tile, and then select **Details**.).

To determine calibration quality, compare the current results with previous results for consistency, in the ISE Reagent Details page.

8 Open the small STAT table cover, remove the Sample Cups (2.5 mL) from the STAT table, and discard them.

9 Close the small STAT table cover.

10 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Perform Automatic Washing

Before performing this procedure, print a copy of Confirm Selectivity Check Data (if your analyzer includes an ISE module) and View Photocal Results from the Maintenance chapter of the PDF version of the DxC 500 AU Instructions for Use. You will need to perform the steps in Confirm Selectivity Check Data (if your analyzer includes an ISE module) and View Photocal Results after you select **Task Completed**.

If your analyzer includes an ISE module, this procedure cleans cuvettes with external solution, performs a photocal, performs enhanced cleaning of the ISE, and checks selectivity for the Na and K electrodes.

If your analyzer does not include an ISE module, this procedure cleans cuvettes with external solution and performs a photocal only.

Overview of Cleaning Cuvettes with External Solution

To obtain correct analysis results, clean the cuvettes once a week. The sample probe, reagent probe, mix bars, and waste lines are thoroughly cleaned during the procedure.

The procedure prepares the cuvettes for the photocal by thoroughly cleaning them. The sample probe, reagent probe, mix bars, and waste lines also benefit from the cleaning procedure.

The procedure is accomplished by running 1N hydrochloric acid or diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite) through the analyzer.

- Each week, alternate the solution for use.
  - The diluted cleaning solution removes stains formed by protein deposits left in the cuvettes.
  - The 1N hydrochloric acid removes a small quantity of inorganic substances such as metallic ions.

Warning

Do not mix diluted cleaning solution and hydrochloric acid. Confirm that all containers on the analyzer that are designated for cleaning cuvettes contain the same solution. Clearly label containers designated for diluted cleaning solution and hydrochloric acid and confirm that all positions requiring these cleaners contain the same solution. The mixing of sodium hypochlorite solution and hydrochloric acid causes the formation of chlorine gas, which is highly toxic.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle diluted cleaning solution or hydrochloric acid. If the diluted cleaning solution or hydrochloric acid contacts skin or clothes, rinse the affected area thoroughly with water. If the diluted cleaning solution or hydrochloric acid contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Warning

Do not spill diluted cleaning solution on the analyzer. If diluted cleaning solution is spilled on the analyzer, follow your laboratory procedure to wipe up spills immediately.

Caution

For each procedure, prepare fresh diluted cleaning solution (0.5% sodium hypochlorite). Prepare a fresh solution to maintain effective cleaning. Without effective cleaning, analysis results can be affected.

Materials Required:

- Two 60-mL bottles labeled with either of the following descriptions:
  - 1N hydrochloric acid
  - Diluted cleaning solution (0.5% sodium hypochlorite)
- Either of the following solutions:
  - Approximately 120 mL of 1N hydrochloric acid
  - Approximately 120 mL of freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)

For information about preparing for cleaning cuvettes with external solution, refer to step 3.

Overview of Performing a Photocal

The photocal detects dirt, stains, or scratches, and identifies cuvettes that require cleaning or replacing. Clean or replace cuvettes that show an abnormal value during the photocal.

Important

For optimal results, only perform a photocal measurement when the photometer lamp is stabilized after the analyzer starts up. The photometer lamp needs approximately 20 minutes to stabilize (warm up) after the analyzer starts up.

Overview of Performing Enhanced Cleaning of the ISE

Performing enhanced cleaning of the ISE is applicable only If your analyzer includes an ISE module.

If you do not perform the ISE enhanced cleaning cycle, contamination or inaccurate results can occur.

Materials Required:

- Beckman Coulter Cleaning Solution (5.0% sodium hypochlorite)
- Sample Cup (2.5 mL)

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle Beckman Coulter Cleaning Solution (sodium hypochlorite). If the cleaning solution contacts skin or clothes, rinse the affected area thoroughly with water. If the cleaning solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

For information about preparing for performing enhanced cleaning of the ISE, refer to step 4.

Overview of Checking Selectivity for the Na and K Electrodes

Checking selectivity for the Na and K electrodes is applicable only If your analyzer includes an ISE module.

The Na electrode and K electrode are ion-selective electrodes. If the selectivity of the electrodes deteriorates, ions other than Na or K can affect the electrodes, and results can be affected.

To confirm the ion selectivity of the electrodes, perform a selectivity check of the Na and K electrodes every week.

Important

Do not leave the bottle of ISE Selectivity Check Solution open. Concentration or crystallization of the ISE Selectivity Check Solution can occur.

Materials Required:

- ISE (K+) and (Na+) Selectivity Check Solution
- Sample Cup (2.5 mL) (2 cups)

For information about preparing for checking selectivity for the Na and K electrodes, refer to step 5.

Perform Automatic Washing Procedure

1 If your analyzer includes an ISE module, if you have not just done so, calibrate the ISE.

2 Confirm that the analyzer is in the *Running* (*Standby*) state.

3 Prepare for cleaning cuvettes with external solution.

a. Fill the 60-mL bottles with approximately 60 mL of the solution for cleaning the cuvettes selected for the week. If diluted cleaning solution (0.5% sodium hypochlorite) was used previously for the procedure, use 1N hydrochloric acid for the current procedure.

Tip

Do not fill into the neck of the bottle.

Warning

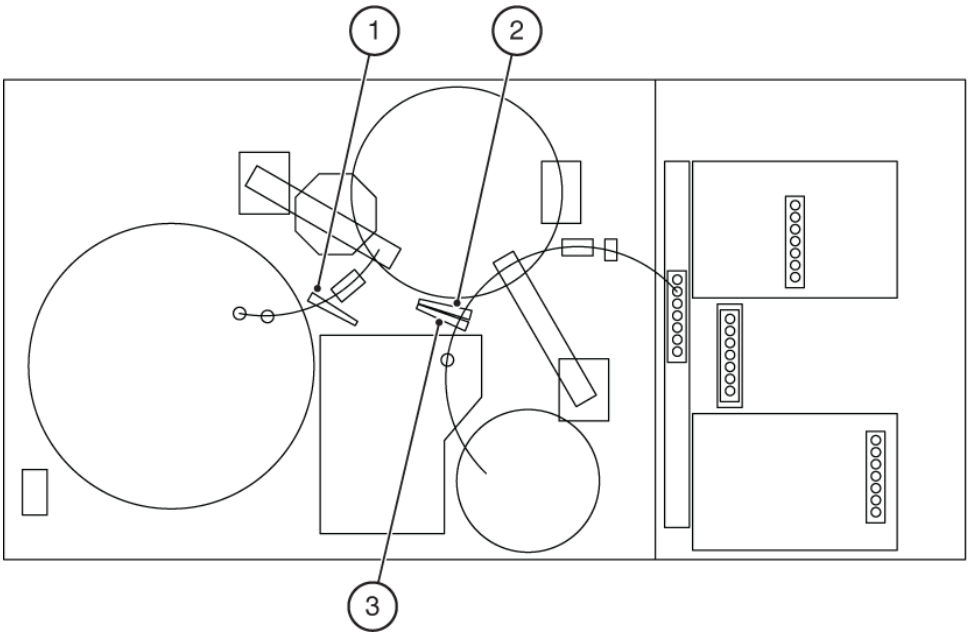
Do not mix diluted cleaning solution and hydrochloric acid. Confirm that all containers on the analyzer that are designated for cleaning cuvettes contain the same solution. Clearly label containers designated for diluted cleaning solution and hydrochloric acid and confirm that all positions requiring these cleaners contain the same solution. The mixing of sodium hypochlorite solution and hydrochloric acid causes the formation of chlorine gas, which is highly toxic.

b. Open the upper cover.

c. Remove the diluent bottle from position 77.

d. Place the bottles of solution for cleaning cuvettes in positions 77 and 79.

Figure 97 Positions for Cleaning Cuvettes with External Solution



1. 77
2. 78 (not for cleaning cuvettes with external solution)
3. 79

Warning

Do not spill diluted cleaning solution on the analyzer. If diluted cleaning solution is spilled on the analyzer, follow your laboratory procedure to wipe up spills immediately.

Caution

To prevent rust or corrosion of the inner surface of the bottle holder, be sure to wipe the outside of the bottle clean before placing the bottle back into position.

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4 If your analyzer includes an ISE module, prepare for performing enhanced cleaning of the ISE.

a. Open the small STAT table cover.

b. Fill a Sample Cup (2.5 mL) with 1.5 mL of cleaning solution (5% sodium hypochlorite).

c. Press the **TABLE ROTATION/DIAG** button on the analyzer to rotate the STAT table until the CLEAN position is accessible.

d. Place the cup in the CLEAN position on the STAT table.

5 If your analyzer includes an ISE module, prepare for checking selectivity for the Na and K electrodes.

   a. Press the **TABLE ROTATION/DIAG** button on the analyzer to rotate the STAT table until the Sel-Na, and Sel-K positions are accessible.

   b. Fill the Sample Cups (2.5 mL) with approximately 500 µL of ISE (Na+) Selectivity Check Solution and 500 µL of ISE (K+) Selectivity Check Solution separately.

   c. Place the ISE (Na+) Selectivity Check Solution in the Sel-Na position. Place the ISE (K+) Selectivity Check Solution in the Sel-K position.

   d. Close the small STAT table cover.

   e. Close the upper cover.

6 Select **Start**. The procedure starts.

   The analyzer cleans cuvettes (and the sample probe, reagent probe, mix bars, and waste lines) with external solution, then performs a photocal, and then (if your analyzer includes an ISE module) checks selectivity for the Na and K electrodes.

   You can view the remaining time in the Process area of the status bar.

   Caution

   After the procedure completes, immediately remove the two 60-mL bottles of cleaning solution from positions 77 and 79. The bottles of cleaning solution can generate gas.

7 Select **Task Completed**.

   Important

   After you select **Task Completed**, use your printed instructions to perform the steps for Confirm Selectivity Check Data (if your analyzer includes an ISE module) and View Photocal Results.

Perform Weekly Manual Cleaning

Clean the Sample Probe

Caution

Clean the sample probe weekly to prevent contamination and to provide correct analysis and results. If the sample probe is dirty or clogged, carryover between samples can occur.

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- Stylet 0.14 mm diameter

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

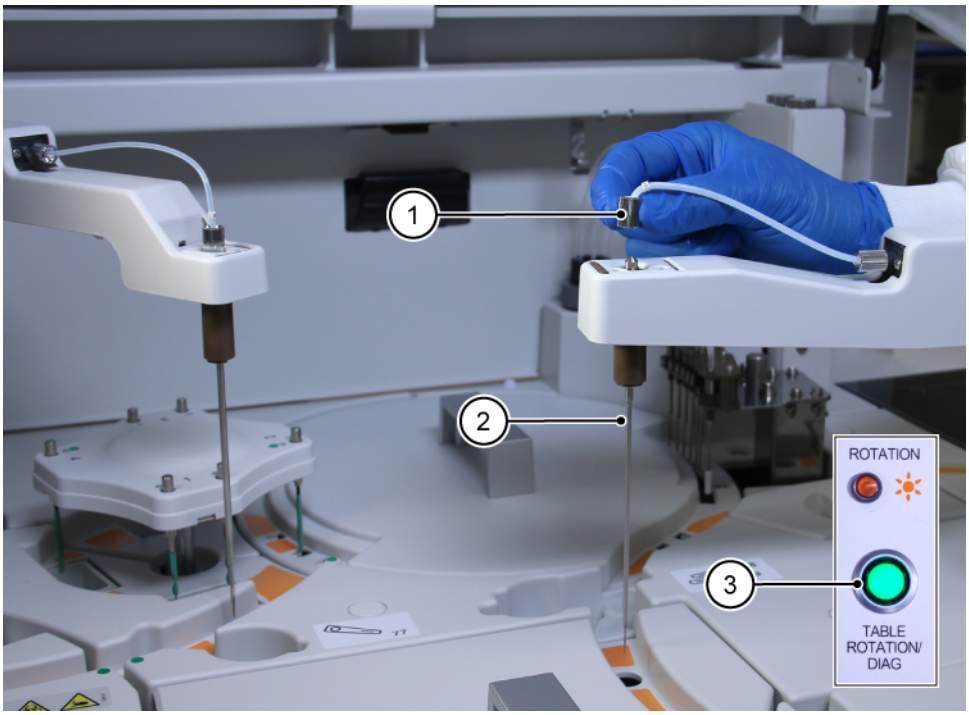
3 Clean the sample probe.

a. Unscrew the connector above the sample probe.

Important

Do not bend or damage the sample probe when you replace it.

Figure 98 Remove the Sample Probe for Cleaning



1. Connector
2. Sample probe
3. TABLE ROTATION/DIAG button with indicator light

b. After all the liquid drips from the probe, lift the probe from the arm.

c. Wipe the tip of the probe with an alcohol prep pad (70% Isopropyl alcohol).

d. Carefully insert the stylet into the probe to remove any potential obstruction.

e. Reinstall the probe into the arm, connect the connector to the top of the probe, and tighten the connector.

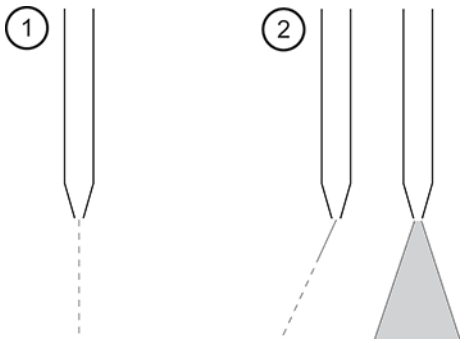
4 Confirm the performance of the probe.

a. Select **Prime Sample Probe**.
The analyzer displays the Prime Sample Probe dialog.

b. For **Repetitions**, confirm that the value is **3**, and then select **OK**.

c. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Confirm that a thin straight stream of water is dispensed from the probe, and that the water does not spray or dispense at an angle. If the water sprays or dispenses at an angle, replace the probe after completing this maintenance task.

Figure 99 Sample and Reagent Probes



1. Correct flow
2. Incorrect flow

d. If HbA1c is enabled, select **Clean Sample Probe**.
The analyzer displays the Clean Sample Probe dialog.

e. For **Repetitions**, confirm that the value is **3**, and then select **OK**.

f. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The sample probe moves to the whole blood wash well for washing.

Clean the Mix Bars

Caution

Clean the mix bars weekly to prevent contamination and to provide correct analysis and results. If the mix bars are contaminated or stained, carryover between samples can occur.

Materials Required:

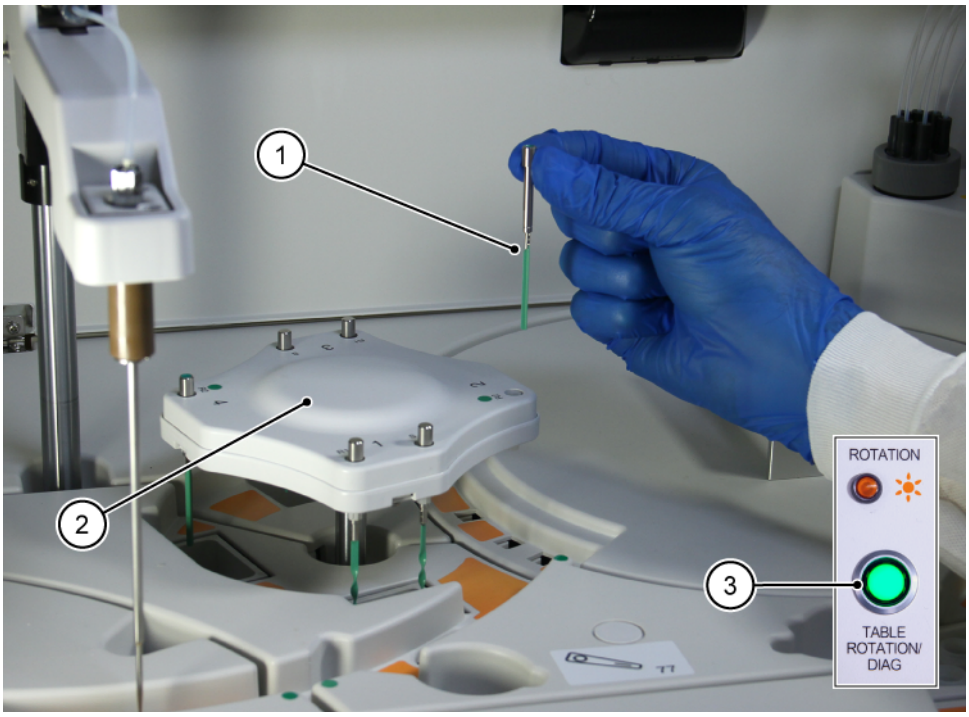
- Alcohol prep pads (70% Isopropyl alcohol)

---

1 Clean the mix bars.

a. Lift the mix bars up to remove them and wipe them with an alcohol prep pad (70% Isopropyl alcohol).

Figure 100 Remove the Mix Bars for Cleaning



1. Mix bar
2. Mix bar subsystem
3. TABLE ROTATION/DIAG button with indicator light

Caution

When cleaning the mix bars, confirm that the mix bars are not bent and that the coating is not scratched. Replace the mix bars if they are damaged. When inserting the mix bars into the mix bar subsystem, do not scratch the mix bars. Scratched or damaged mix bars can cause sample and/or reagent carryover and affect results.

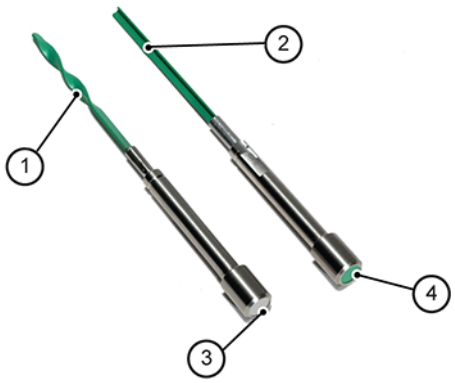
b. Insert the four spiral-shaped mix bars in the positions labeled R1/S and the two L-shaped mix bars in the positions labeled R2.

Caution

Do not scratch the mix bar when inserting the mix bar into the mix bar subsystem. Scratched or damaged mix bars can cause sample or reagent carryover and affect results.

Rotate each mix bar slightly to insert completely.

Figure 101 Mix Bars



1. Spiral-shaped mix bar
2. L-shaped mix bar
3. Silver
4. Green

Caution

The shapes of the mix bars differ between mix types. If the spiral and L-shaped mix bars are not placed in the correct mix bar subsystem, analysis results can be affected. The placement of each mix bar shape:

- **R1 and S positions: Spiral-shaped mix bar**
- **R2 positions: L-shaped mix bar**

2 Confirm the performance of the mix bars.

a. Select **Confirm Mix Bars**.
The analyzer displays the Confirm Mix Bars dialog.

b. For **Repetitions**, confirm that the value is **3**, and then select **OK**.

c. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

Watch the mix bar subsystem perform a sequence to confirm correct operation. If an abnormal noise occurs during mixing, replace the mix bar after completing this maintenance task.

Clean the Pre-dilution Bottle

When the pre-dilution bottle remains on the analyzer without being periodically cleaned, bacterial contamination can occur.

To maintain the reliability of the analyzer and prevent contamination, clean the pre-dilution bottle once each week.

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Extra 60-mL bottle (optional)

1 Remove the pre-dilution bottle from the analyzer and discard the deionized water. The pre-dilution bottle is located outside of the reagent refrigerator in the position labeled 77.

2 Wash the pre-dilution bottle by filling it with freshly prepared diluted cleaning solution (0.5% sodium hypochlorite).

3 Rinse the bottle well using deionized water to remove any diluted cleaning solution residue which can affect analysis results.

Note

Beckman Coulter recommends allowing the pre-dilution bottle to air dry completely before reuse. Use two 60-mL bottles for pre-dilution and alternate the bottles weekly.

4 Fill the bottle with deionized water and place it on the analyzer.

Caution

To prevent rust or corrosion of the inner surface of the bottle holder, be sure to wipe the outside of the bottle clean before placing the bottle back into position.

5 Close the upper cover.

6 Select **Task Completed**.

Important

If the water sprayed or dispensed at an angle when confirming the performance of the sample probe, replace the probe after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace a Sample Probe**.
2. Follow the steps on the Task page.

Important

If an abnormal noise occurred during mixing when confirming the performance of the mix bars, replace the mix bar after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace the Mix Bars**.
2. Follow the steps on the Task page.

Perform ISE Cleaning

If your analyzer includes an ISE module, perform ISE cleaning.

Manually Clean the ISE Mix Bar, Liquid Level Sensors, Nozzles, and Sample Pot

To obtain accurate results and optimum analyzer performance without unexpected analyzer downtime, perform the following ISE maintenance procedure every two weeks or every 3,000 samples, whichever comes first. Clean according to your laboratory procedures and after careful monitoring of calibration and QC data.

For more information, refer to ISE Tubing Block Diagram.

Important

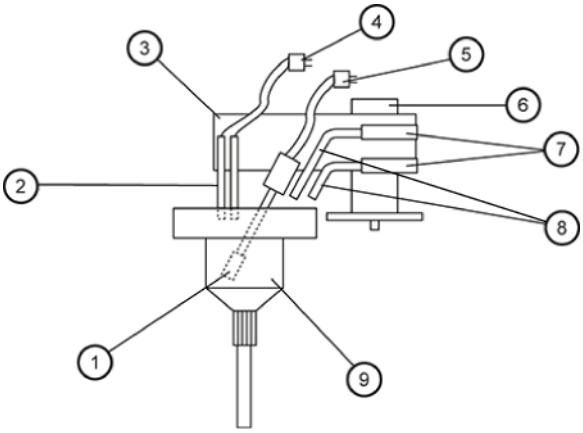
By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Figure 102 ISE Mix Bar, Liquid Level Sensors, Nozzles, and Sample Pot



1. Mix bar
2. Liquid level sensor
3. Mixing subsystem
4. Level sensor connector
5. Mixing motor connector
6. Mixing subsystem knob
7. Connecting Tubing
8. ISE MID Standard Solution and ISE Buffer Solution nozzles
9. Sample pot

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1. Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.
2. Select **Drain Bypass Tubing**.
3. Open the upper cover.
4. Open the ISE cover.
5. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the bypass tubing.

Clean the Nozzles, Mix Bar, and Liquid Level Sensors

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- Clean, dry, lint-free absorbent tissue

1. Disconnect the liquid level sensor connector 714 and mixing motor connector 706.
2. Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to unseat it.

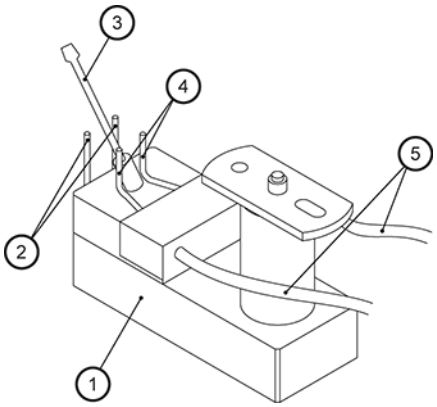
Important

Do not bend or break the liquid level sensors when cleaning.

3 Use an alcohol prep pad (70% Isopropyl alcohol) to wipe the two nozzles, the liquid level sensors, and the mix bar.

Figure 103 Wiping the Nozzles, the Liquid Level Sensors, and the Mix Bar

Figure 104 Mixing Subsystem



1. Mixing subsystem
2. Liquid level sensors
3. Mix bar
4. Nozzle
5. Connecting tubing

4 Place the mixing subsystem on the mixing subsystem holder.

Important

Do not change the orientation position of the two nozzles attached to the mixing subsystem. Do not apply excess pressure to the tubing.

Clean the Sample Pot

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

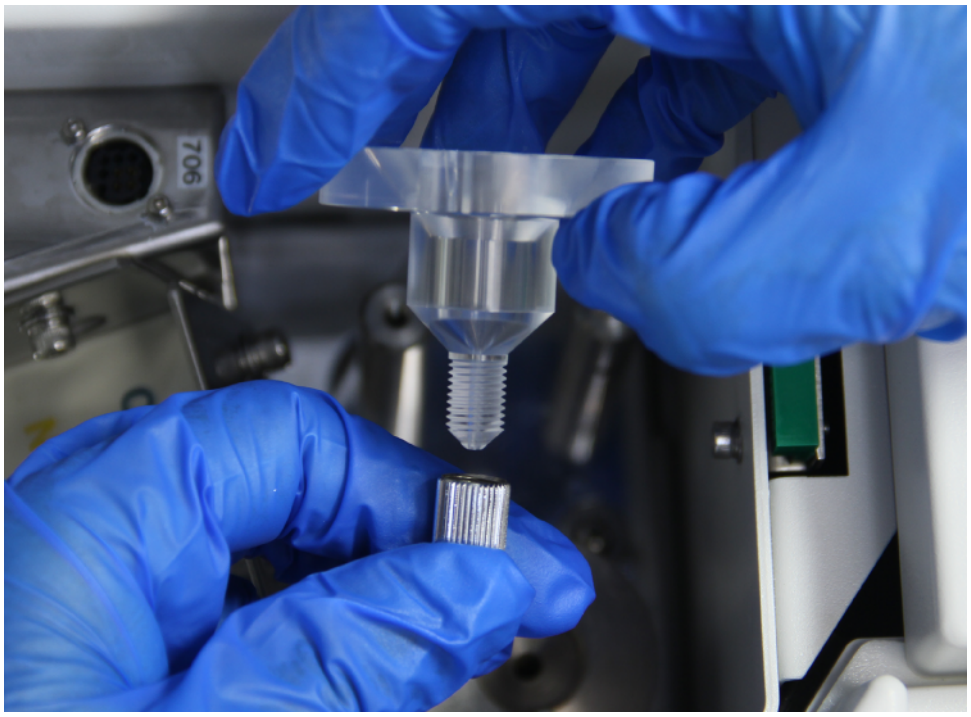
Materials Required:

- Freshly prepared diluted Beckman Coulter Wash Solution (1%)
- Deionized water
- Clean, dry, lint-free absorbent tissue
- Sonicator
- Beaker

1 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.

2 Disconnect the sample pot tubing from the sample pot by unscrewing the connector.

Figure 105 Unscrew the Connector



3 Submerge the sample pot into a beaker filled with freshly prepared diluted wash solution (1%).

4 Place the beaker in the sonicator filled with deionized water and sonicate for 10 minutes.

5 Rinse the sample pot with deionized water.

6 Use a clean, dry, lint-free absorbent tissue to dry the sample pot before putting it back in the original position.

Reinstall the Sample Pot and Mixing Subsystem

1 Reattach the sample pot tubing to the sample pot by screwing the connector.

2 Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.

3 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

Figure 106 Reinstalling the Mixing Subsystem

4 Reconnect the level sensor connector 714 and mixing motor connector 706.

5 Select **ISE Total Prime**.

6 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The indicator light of the TABLE ROTATION/DIAG button turns on after the prime is complete.

7 During the prime, confirm that ISE Buffer Solution and ISE MID Standard Solution are correctly dispensed into the sample pot and flow to waste without generating events.

8 Close all analyzer doors and covers.

9 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

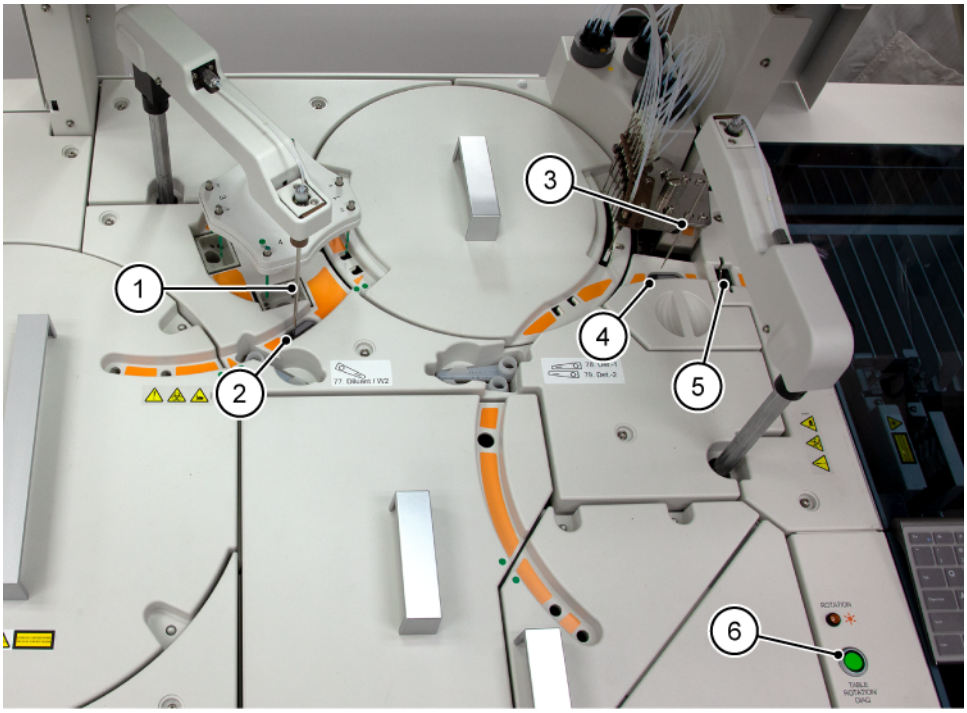
Clean the Wash Wells

Clean the Sample Probe Wash Well, Reagent Probe Wash Well, and Whole Blood Wash Well

Dirty wash wells can cause incorrectly cleaned probes, which can then contaminate reagents or samples.

To maintain the reliability of the analyzer and prevent contamination, clean the wash wells monthly.

Figure 107 Sample Probe, Reagent Probe, and Whole Blood Wash Wells



1. Reagent probe
2. Reagent probe wash well
3. Sample probe
4. Sample probe wash well
5. Whole blood wash well
6. TABLE ROTATION/DIAG button with indicator light

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 If HbA1c is enabled, clean the whole blood wash well.

a. Select **Clean Sample Probe**.
The analyzer displays the Clean Sample Probe dialog.

b. For **Repetitions**, confirm that the value is **3**, and then select **OK**.

c. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The sample probe moves to the whole blood wash well for washing.

4 Open the upper cover.

5 Select **Move Probes**.

6 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

Important

While cleaning the interior of the wash well, avoid touching the sample probe and reagent probe.

7 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into each sample probe wash well, reagent probe wash well, and whole blood wash well.

8 Use a cotton-tipped applicator to clean each well. Use a different cotton-tipped applicator for each wash well to avoid any contamination.

9 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. All probes move back to the home position over the wash wells.

10 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

11 In **Repetitions**, confirm that the value is 1.

12 Select **OK**.

13 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
After initialization, the analyzer primes water through the probes and wash wells. Inspect the probe wash wells visually for correct drainage. If drainage is poor, repeat steps 5 to 13.

Clean the Mix Bar Wash Wells

In normal operation, the mix bar wash wells clean the outside surface of each mix bar by washing in diluted Beckman Coulter Wash Solution (1%) and then rinsing with deionized water.

Dirty wash wells can cause incorrectly cleaned mix bars, which can cause carryover problems.

To maintain the reliability of the analyzer and prevent contamination, clean the wash wells monthly.

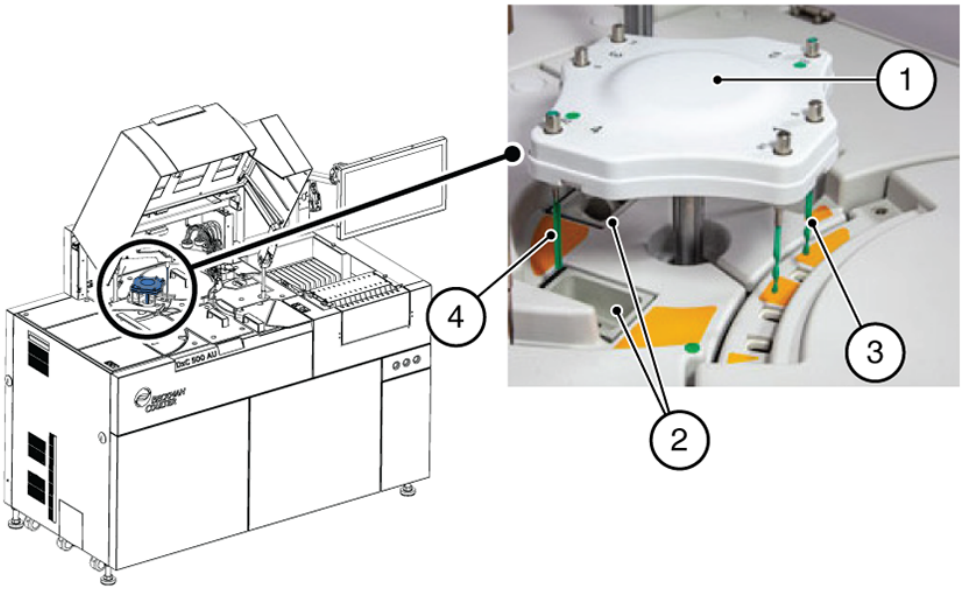
Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or *Running* (*Standby*) state.

2 Manually turn the mix bar subsystem so that the mix bars are not over the wash wells.

Figure 108 Mix Bar Wash Wells



1. Mix bar subsystem
2. Mix bar wash wells
3. Spiral-shaped mix bar (R1/S position)
4. L-shaped mix bar (R2 position)

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

3 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into each mix bar wash well.

4 Use a cotton-tipped applicator to clean each well. Use a different cotton-tipped applicator for each wash well to avoid any contamination.

5 Turn the mix bar subsystem so that the mix bars are over the mix bar wash wells.

6 Select **Confirm Mix Bars**.
The analyzer displays the Confirm Mix Bars dialog.

7 For **Repetitions**, confirm that the value is **3**, and then select **OK**.

8 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The mix bar subsystem initializes and performs a sequence.

9 Visually inspect the mix bar wash wells for correct water drainage. If drainage is poor, repeat steps 2 to 8.

10 Close the upper cover.

11 Select **Task Completed**.

Perform Monthly Manual Cleaning

Clean the Wash Nozzle Subsystem and Inspect the Tube Mounting Joints

Before performing this procedure, print a copy of the procedure from the PDF version of the DxC 500 AU Instructions for Use. During the procedure, you will need to shut down the chemistry analyzer, and the on-screen instructions will no longer be available.

The wash nozzle subsystem includes eight nozzles that aspirate liquid out of the cuvettes, dispense diluted Beckman Coulter Wash Solution and deionized water into the cuvettes, and dry the cuvettes.

If any of the nozzles become clogged, their functionality can suffer, resulting in inefficient cleaning of the cuvettes.

Inspect the mounting joints for cracks or leaks. If any damage exists, the aspiration and dispense by nozzles can be affected.

Materials Required:

- Clean, dry, lint-free absorbent tissue
- Sonicator filled with deionized water
- Stylet 0.3 mm diameter when the sonicator is not available

Remove the Wash Nozzle Subsystem and Inspect the Tube Mounting Joints

1 Select the **Maintenance** task indicator on the Home page.
The analyzer displays the Maintenance page.

2 Select **Perform Monthly Manual Cleaning**.

3 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

4 Open the upper cover.

5 Open the rear cover of the analyzer.

6 Select **Drain Wash Nozzles**.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The liquid drains from the tubing.

Note

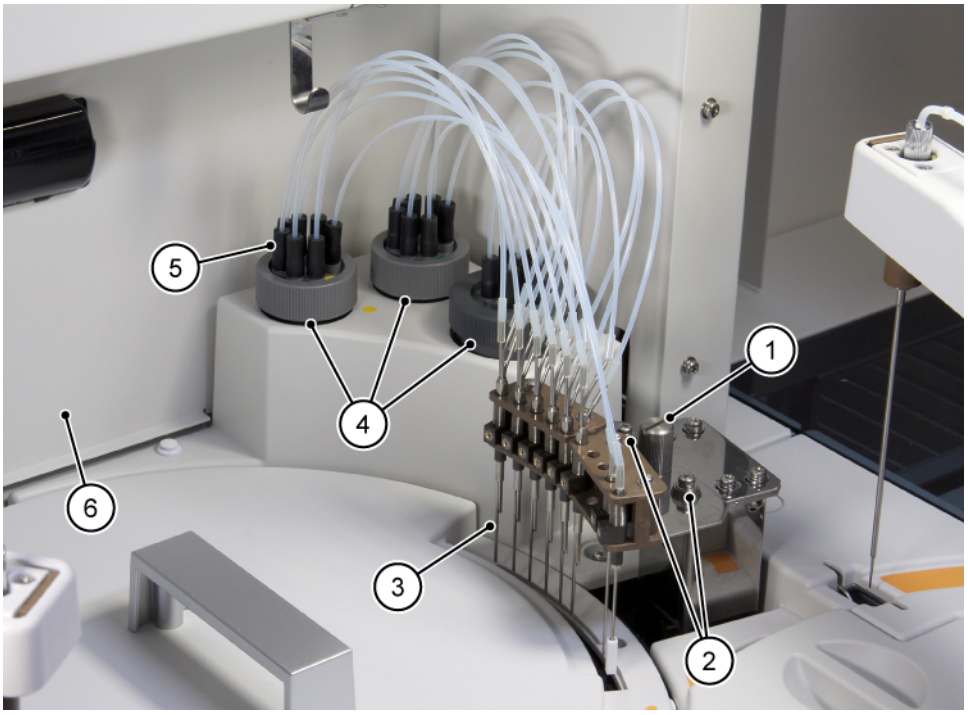
Each subsequent pressing of the TABLE ROTATION/DIAG button continues to drain liquid from the tubing.

Caution

Drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water beforehand, the water spills out of the nozzle.

If the water spills onto the cuvettes, clean the cuvettes and the cuvette wheel after completing this maintenance task.

Figure 109 Wash Nozzle Subsystem and Tube Mounting Joints



1. Knob
2. Positioning screws
3. Wash nozzle
4. Manifolds
5. Water supply tube mounting joint (Six O-rings installed inside the joint)
6. Rear cover

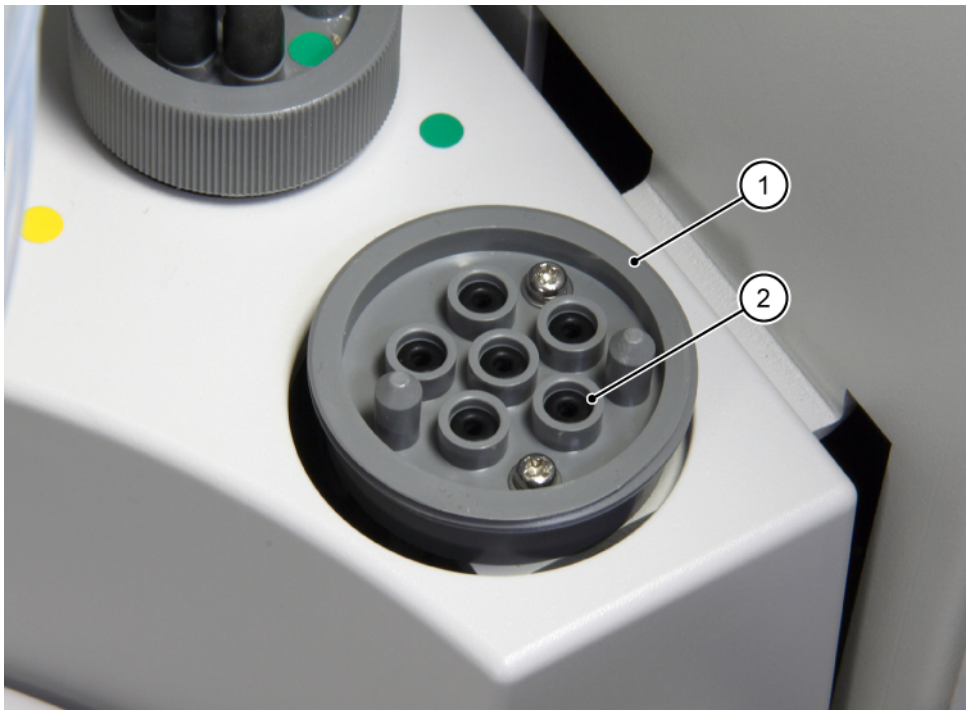
8 Loosen the three manifolds, and remove them from their mounting positions.

Figure 110 Loosening Manifolds

Important

Six O-rings are inside the water supply tube mounting joint of the wash nozzle subsystem. After removing the manifold, confirm that all six O-rings are seated inside the six grooves in the manifold base.

Figure 111 Manifold Base of the Water Supply Tube Mounting Joint



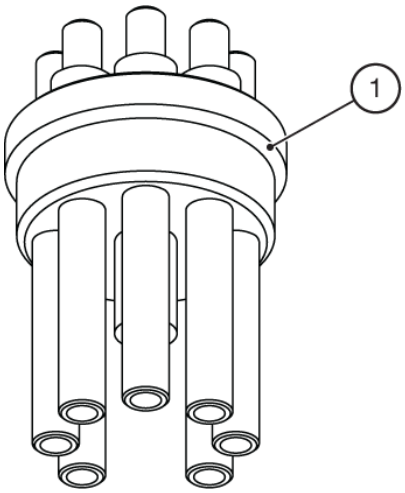
1. Manifold base
2. O-ring

If an O-ring is missing, inspect the manifold to confirm that the O-ring is not attached to the surface of the manifold. If it cannot be found, install a new O-ring in the groove in the manifold base after completing this maintenance task.

Important

Inspect the packing inside each manifold of the three tube mounting joints. If the packing is damaged, replace the packing after completing this maintenance task.

Figure 112 Wash Nozzle Tube Mounting Joint

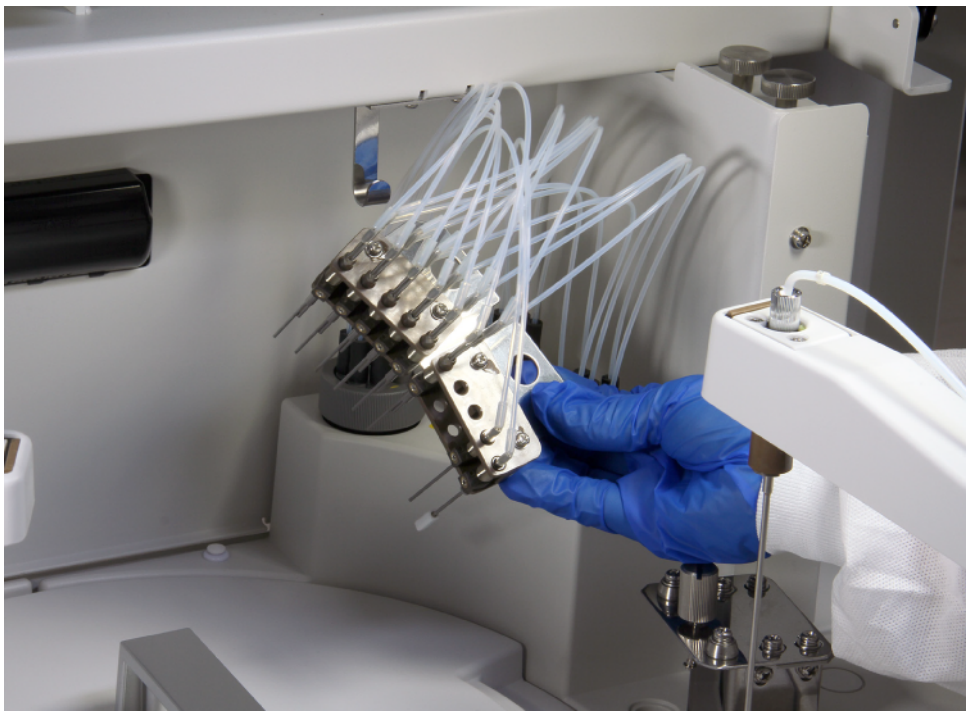


1. Packing of the tube mounting joint

9 Loosen the knob holding the wash nozzle subsystem in position.

10 Lift the wash nozzle subsystem up over the positioning screws. Do not bump or bend the nozzles.

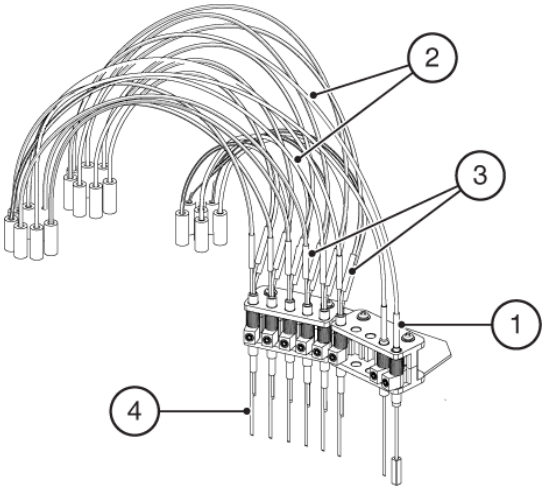
Figure 113 Lifting the Wash Nozzle Subsystem



Important

Do not loosen or remove the positioning screws on either side of the knob when you loosen the knob on the wash nozzle subsystem. The positioning screws are used for positioning the wash nozzle subsystem.

Figure 114 Wash Nozzle Subsystem



1. Wash nozzle joint
2. Tubing
3. Wash nozzle joint
4. Wash nozzle

11 Remove the wash nozzle subsystem along with the tubing and inspect the joints for cracks. If a crack is found, contact Beckman Coulter to have the cracked joint replaced.

Clean and Inspect the Wash Nozzle Subsystem

Important

Do not damage the nozzles when using a sonicator to clean the wash nozzle subsystem.

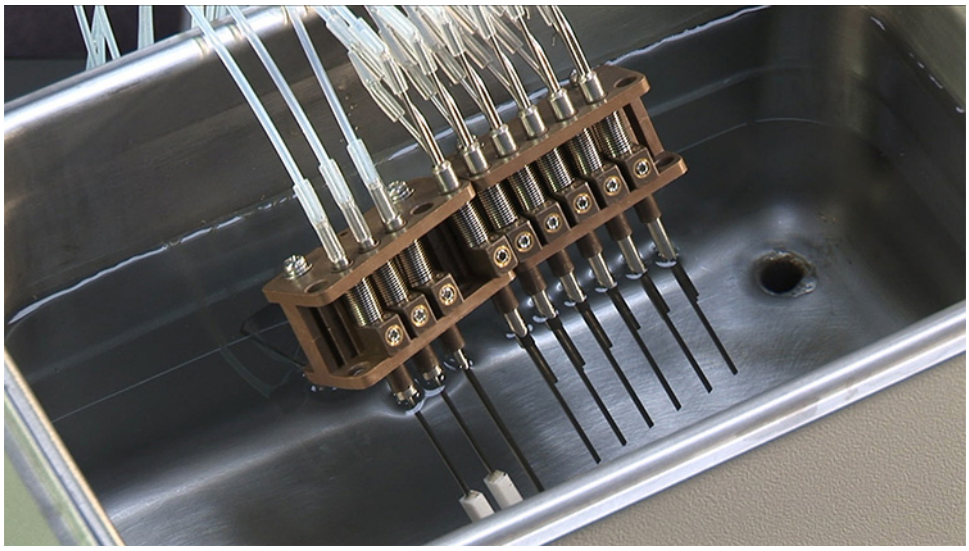
1 Sonicate the wash nozzle subsystem in deionized water for 15 minutes. Submerge only the nozzle portion. Do not get the springs above the nozzles wet. If water does get into the springs, dry them well using a clean, dry, lint-free absorbent tissue, or canned air.

After cleaning the nozzles in water, wipe any drops using a clean, dry, lint-free absorbent tissue.

Note

Beckman Coulter recommends using a sonicator for cleaning the nozzles. If a sonicator is not available, clean the interior of each nozzle using the supplied stylet and deionized water.

Figure 115 Sonicating the Wash Nozzle Subsystem



2 Remove the wash nozzle subsystem from the sonicator, and dry thoroughly with a clean, dry, lint-free absorbent tissue.

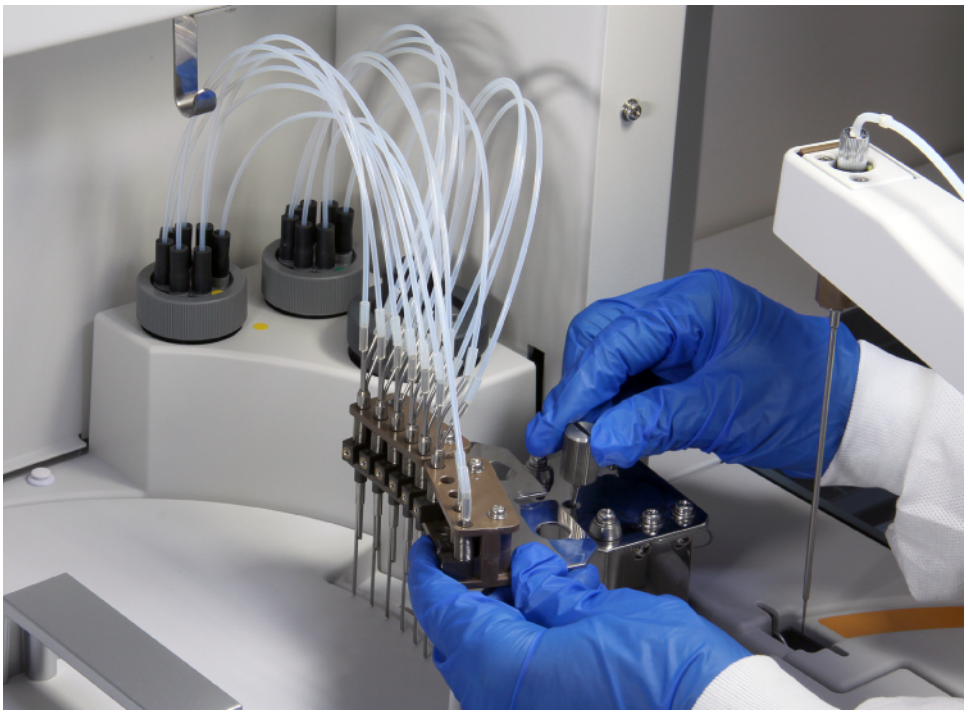
3 Inspect the O-rings inside the water supply tube mounting joint. Confirm that all six O-rings are correctly inserted in individual grooves. Confirm that the O-rings are not ripped or over-stretched. Look for dust or wash solution crystals around each O-ring. If faults are found with the O-rings, replace the O-rings after completing this maintenance task.

4 Return the wash nozzle subsystem to its original position. Place the wash nozzle subsystem over the positioning screws, then tighten the knob to hold the wash nozzle subsystem in position.

Important

Do not hit the nozzle tips on the cuvette wheel cover when installing the wash nozzle subsystem.

Figure 116 Returning the Wash Nozzle Subsystem to Original Position



5 Return each of the manifolds to their original position. Match the colored dot on the manifold with the one next to its position. Tighten the manifolds without cross

threading them. Confirm that the manifolds are finger-tight to prevent a cuvette wheel overflow, but do not over-tighten.

Figure 117 Returning Manifolds to Original Positions

Important

To avoid analyzer damage and to perform tests correctly:

- When you install the manifolds, confirm that the manifolds are in the correct, color-coded positions. Firmly tighten the manifolds.
- Confirm that all tubing from the nozzles to the tube mounting joints are connected.
- Do not damage any of the joints or tubing. Damaged components can cause leaks and can contaminate or flood the cuvette wheel.

6 Select **Prime Wash Nozzle**.
The analyzer displays the Prime Wash Nozzle dialog.

7 For **Repetitions**, enter a value of **5**, and then select **OK**.

8 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The air in the tubing is purged as the wash nozzle subsystem moves up and down.

Important

Confirm that the wash nozzle subsystem moves freely without interference and that no leaks occur. If leaks occur, remove the water supply manifold, and confirm that

six O-rings are correctly placed in the grooves. Inspect each O-ring, and replace damaged O-rings after completing this maintenance task.

9 Close the upper and rear covers.

Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter

The deionized water filter and sample probe filter are used to prevent particles from entering the internal deionized water system. Clean the deionized water tank to avoid bacterial contamination of the analyzer.

Materials Required:

- Clean, dry, lint-free absorbent tissue
- Basin
- Sonicator filled with deionized water
- Deionized water tank
- Freshly prepared diluted Beckman Coulter Cleaning Solution (1.0% sodium hypochlorite)

Important

Turn off the analyzer before you start this procedure. If this procedure is performed with the analyzer on (in the *Running* (*Standby*) state), the analyzer supplies deionized water through the supply tubing, the float sensor in the deionized water tank activates, and water drains continuously from the tubing.

Important

Always use clean gloves for this procedure to prevent the deionized water tank from becoming contaminated from previously dirty gloves.

Clean the Deionized Water Tank and Remove the Deionized Water Filter and Sample Probe Filter

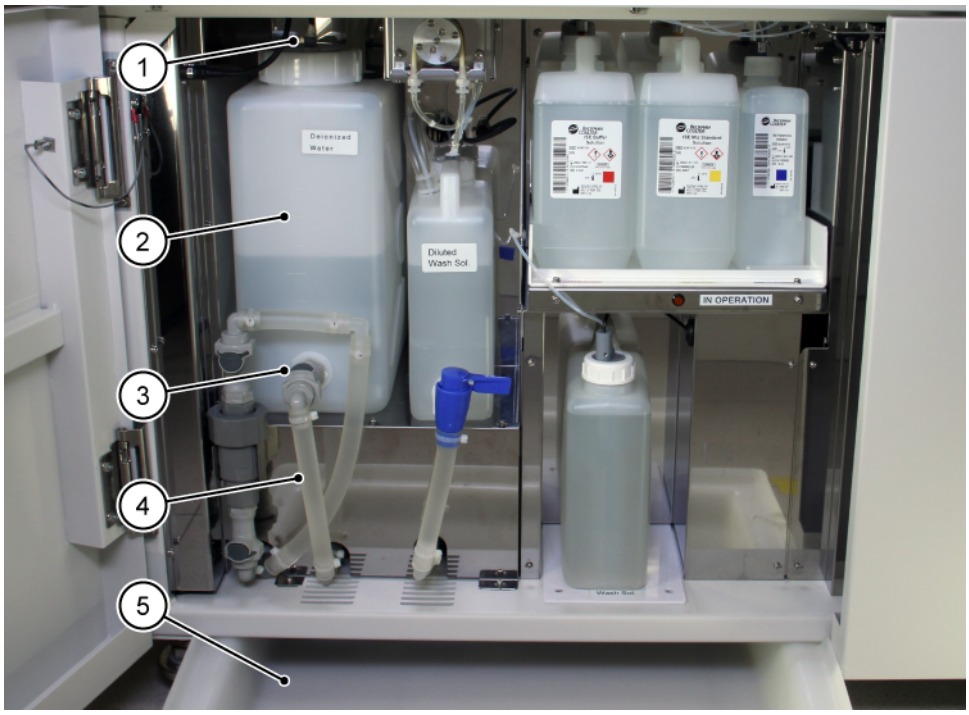
1 Select **Exit Maintenance**.
The analyzer goes to the *Running* (*Standby*) state.

2 Shut down the chemistry analyzer.
Refer to Shutting Down the Chemistry Analyzer.

3 Open the left front door of the analyzer.

4 Position a basin on the floor under the deionized water tank to catch spilled water.

Figure 118 Deionized Water Tank



1. Float sensor connector
2. Deionized water tank
3. Quick disconnect joint
4. Deionized water drainage tubing
5. Basin

5 Unplug the black float sensor connector 879.

6 Press the gray button of the quick disconnect joint on the front of the tank and remove the tubing.

Important

When the float sensor and tubing are removed from the tank, deionized water can drip. If the deionized water drips, immediately wipe off the water with a clean, dry, lint-free absorbent tissue.

7 Pull the deionized water tank out of the analyzer. Confirm that the tubing clears the top of the tank and wrap them in a clean, dry, lint-free absorbent tissue.

8 Unscrew the cap of the tank and remove the float sensor and water supply tubing.

Figure 119 Float Sensor and Water Supply Tubing

1. Cap
2. Float sensor
3. Deionized water tank
4. Water supply tubing

9 Discard the deionized water in the tank.

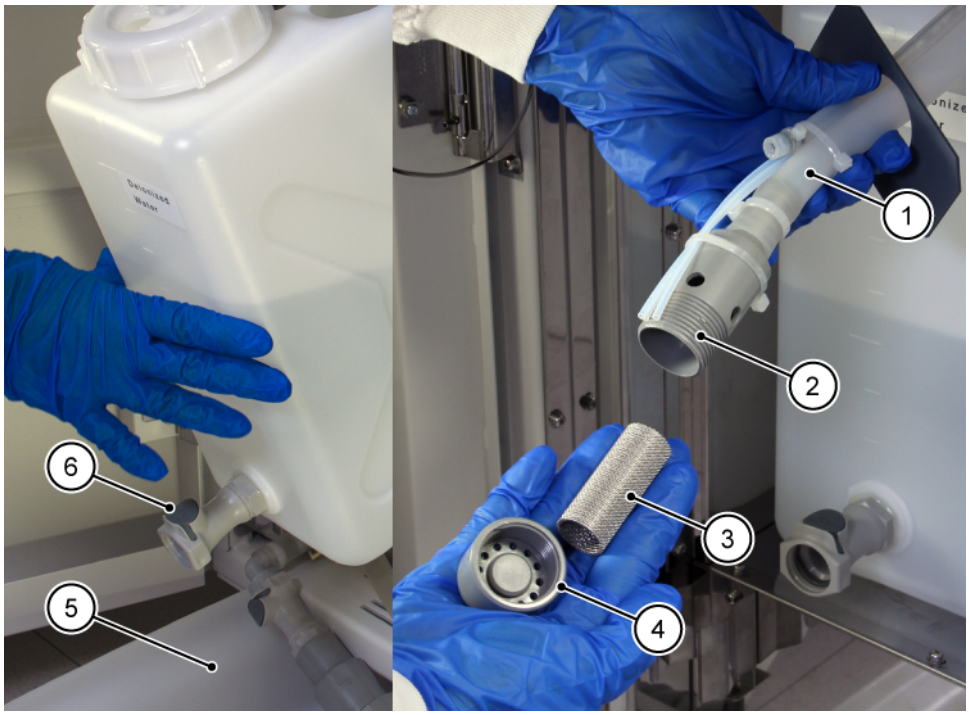
10 Clean the tank with freshly prepared diluted cleaning solution (1.0% sodium hypochlorite).

11 Rinse the tank thoroughly using deionized water and set aside to allow the tank to dry.

12 Clean the float sensor and the exterior part of the tubing with deionized water.

13 Remove the deionized water filter from the case attached to the water supply tubing over the basin by unscrewing it. Water drips from it.

Figure 120 Deionized Water Filter



1. Water supply tubing
2. Filter case
3. Deionized water filter
4. Filter case cap
5. Basin
6. Quick disconnect joint

14 Locate the sample probe filter case directly to the left of the deionized water tank and remove it from the bracket.

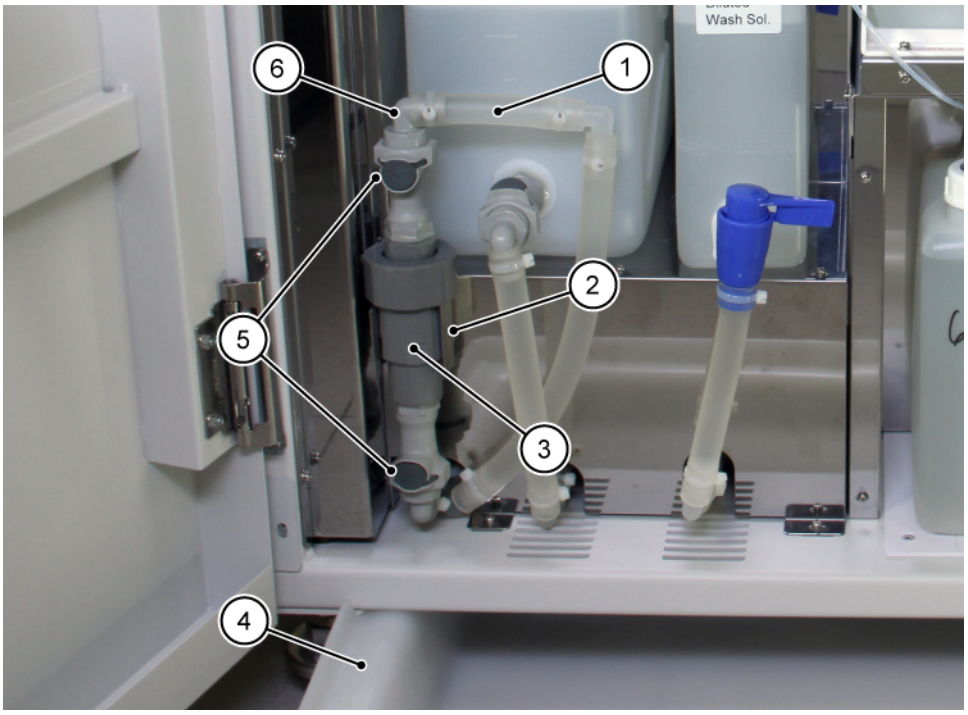
15 Press the gray button of the quick disconnect joints and pull to remove the tubing from the top and bottom of the filter case.

16 Unscrew the filter case over the basin and remove the sample probe filter.

Important

When working with the sample probe filter, do not lose the O-ring.

Figure 121 Sample Probe Filter



1. Tubing
2. Bracket
3. Filter case
4. Basin
5. Quick disconnect buttons
6. Quick disconnect joint

Clean the Deionized Water Filter and Sample Probe Filter

1 Place the deionized water filter and the sample probe filter in the sonicator filled with deionized water.

2 Sonicate the filters for 10 minutes.

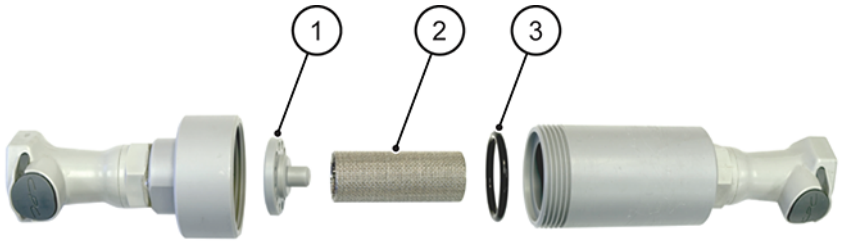
3 Reinsert the clean deionized water filter into its case and tighten the cap.

4 Reinsert the clean sample probe filter into the filter case.

Important

When working with the sample probe filter, do not lose the O-ring.

Figure 122 Disassembled Sample Probe Filter



1. Filter positioning insert
2. Sample probe filter
3. O-ring

5 Tighten the filter case firmly.

Caution

Do not connect the filter case to the joints upside down. If you connect the filter case upside down, debris can cause data errors.

6 Reconnect the quick disconnects by forcing the tubing into their connections until you hear a distinct click.

7 Push the filter case into the metal bracket.

Return the Deionized Water Tank to its Original Position

1 Fill the clean tank with 5 L of deionized water.

Important

Fill the deionized water tank with 5 L of deionized water before turning the analyzer on. If the deionized water tank is empty and the pump turns on, a malfunction can result when the analyzer is turned on.

2 Place the float sensor into the deionized water tank. Tighten the cap.

3 Place the tank into the analyzer and reinsert all water supply tubing into the top of the tank. Push the tank into place.

4 Reconnect each quick disconnect to the tank by pressing the tubing into its connection until you hear a distinct click.

5 Reconnect the float sensor connector 879.

6 Wipe any spilled water from the analyzer surface and remove the basin.

7 Press the On button (green).
The analyzer powers on and initializes, enters into the *Starting* state for 20 minutes, and then enters the *Running* (*Standby*) state.

Perform a Prime Washing Line

1 Go back to the Perform Monthly Manual Cleaning task page.

a. Select the **Maintenance** task indicator on the Home page.
The analyzer displays the Maintenance page.

b. Select the gray bar that is labeled Maintenance Due Now or the gray bar that is labeled Scheduled.
The analyzer displays the Maintenance Due Now maintenance tasks or the Scheduled maintenance tasks.

c. Select **Perform Monthly Manual Cleaning**.
The analyzer displays the Task page.

2 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

3 In **Repetitions**, enter 3.

4 Select **OK**.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Watch the sample probe tubing, reagent probe tubing, and water supply tubing for the wash nozzle subsystem as the analyzer performs the prime. Repeat the prime until all bubbles are removed from the tubing by pressing the **TABLE ROTATION/DIAG** button.

Note

Each time you press the TABLE ROTATION/DIAG button, the analyzer performs 3 repetitions of the prime.

6 Close all analyzer doors and covers.

7 Select **Task Completed**.

Important

If the water spilled onto the cuvettes when draining the wash nozzles, clean the cuvettes and cuvette wheel after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean the Cuvettes and Cuvette Wheel**.
2. Follow the steps on the Task page.

Important

If an O-ring was missing, damaged, or faulty, replace the O-rings in the water supply tube mounting joint after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the O-rings in the Water Supply Tube Mounting Joint**.
2. Follow the steps on the Task page.

Important

If you found that the packing was damaged after removing the manifold, replace the packing in the wash nozzle tube mounting joints after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Replace the Packing in the Wash Nozzle Tube Mounting Joints**.
2. Follow the steps on the Task page.

Inspect and Add ISE Internal Reference Solution

If your analyzer includes an ISE module, inspect and add ISE internal reference solution.

Visually inspect the ISE REF electrode. Add ISE Internal Reference Solution when it is less than the reference line.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

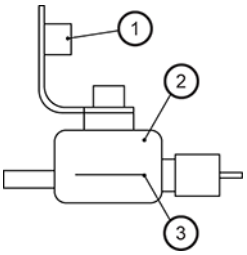
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 123 ISE REF Electrode



1. ISE REF electrode cap
2. ISE REF electrode
3. Reference line

Materials Required:

- ISE Internal Reference Solution

---

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

---

2 Open the upper cover.

---

3 Open the ISE cover.

---

4 Inspect the ISE Internal Reference Solution level. If the level is on or above the reference line, no further action is required. If the level is below the reference line, open the ISE REF electrode cap and add ISE Internal Reference Solution above the reference line.

Important

Do not break or damage the glass ISE REF electrode.

---

5 Close the ISE REF electrode cap.

---

6 Wait 15 minutes to allow the solution to equilibrate.

---

7 Select **ISE Total Prime**.

---

8 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime. The indicator light of the TABLE ROTATION/DIAG button turns on after the prime is complete.

9 Close all analyzer doors and covers.

10 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Clean the Air Filters

Before performing this procedure, print a copy of the procedure from the PDF version of the DxC 500 AU Instructions for Use. During the procedure, you will need to shut down the chemistry analyzer, and the on-screen instructions will no longer be available.

The air filters prohibit dust and other contaminates from entering the analyzer.

Caution

Do not run the analyzer without filters in position. If filters are missing, heaters and the power supplies get dusty, which can cause a short circuit and fire.

Materials Required:

- Air filters
- Vacuum cleaner

1 Shut down the chemistry analyzer by pressing the Analyzer Stop button (black) to completely turn off the power, including the fans. Refer to Shutting Down the Chemistry Analyzer by Pressing the Analyzer Stop Button.

An analyzer stop is necessary to avoid the risk of the fans bringing dust into the analyzer while the filters are removed.

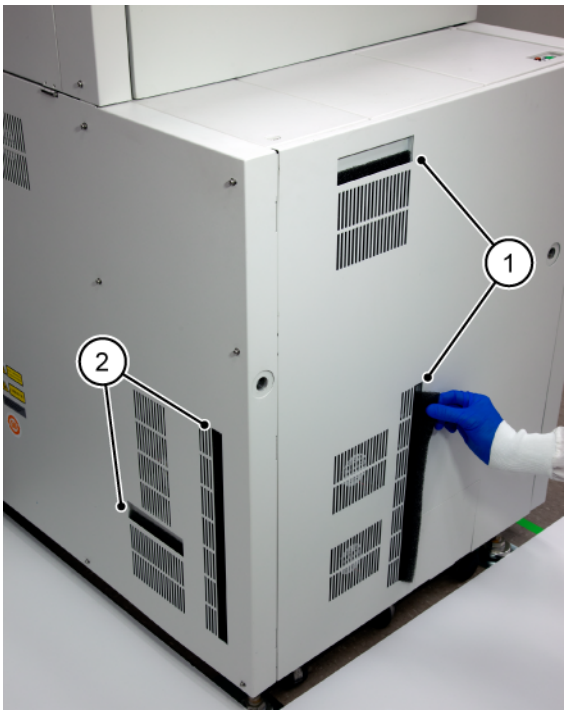
Note

If you are going to clean the air filters by vacuum, without using water, you can skip the steps to remove the filters. It is only necessary to remove the filters if you are cleaning them with water.

2 Remove the two air filters at the back of the analyzer.

3 Remove the air filters from the back and left side of the analyzer.

Figure 124 Air Filter Locations



1. Air filters (on the side of the analyzer)
2. Air filters (at the back of the analyzer)

4 Vacuum the dust from the filters or clean the filters with water and allow the filters to completely dry.

If a filter is torn, replace the air filters after completing this maintenance task.

Important

If you are cleaning the filters with water, confirm that the filters are completely dry before replacing them on the analyzer to avoid moisture from getting into the analyzer.

5 Put the filters back in their original positions.

6 Press the Reset button (white) to turn on the main power, and then wait 5 seconds.

7 Press the On button (green).
The lamp turns on and the software loads. The analyzer is in the *Starting* (*Warmup*) state for a maximum of about 1.5 hours.

8 After the required 20-minute lamp warm-up time, wait until the temperature of the cuvette wheel is 37 °C.

To view the cuvette wheel temperature on the Custom Diag page, select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.

Tip

To bypass the *Starting* (*Warmup*) state after the required 20-minute lamp warm-up time and the temperature of the cuvette wheel reaches 37 °C. select **Stand By**.

9 Select **Task Completed**.

Important

If you found that a filter was torn when vacuuming the dust from the filters or cleaning the filters with water, replace the air filter after you select **Task Completed**.

1. Select the **Maintenance** task indicator on the Home page.

   The analyzer displays the Maintenance page.
2. Select the gray bar that is labeled As Needed, and select **Replace the Air Filters**.
3. Follow the steps on the Task page.

Replace the Wash Solution Roller Pump Tubing

The roller pump tubing deteriorates gradually caused by abrasion and vibration by the roller pump. If the roller pump tubing is used for an extended period, it does not function correctly. Replace the roller pump tubing with a new one every 3 months.

Caution

When replacing the roller pump tubing, take the following precautions:

- **Wear appropriate personal protective equipment (PPE) to prevent your hands from contacting the Beckman Coulter Wash Solution.**
- **Do not let the wash solution drip on the surrounding area. If the solution contacts skin or clothes, rinse the affected area thoroughly with water.**
- **If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention.**
- **Refer to the safety data sheets (SDS) for more information.**
- **Follow your laboratory procedure to wipe up spills immediately.**

Materials Required:

- Roller pump tubing

Perform the following procedure to avoid wash solution leaking from the connection tubing while the wash solution roller pump tubing is disconnected.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

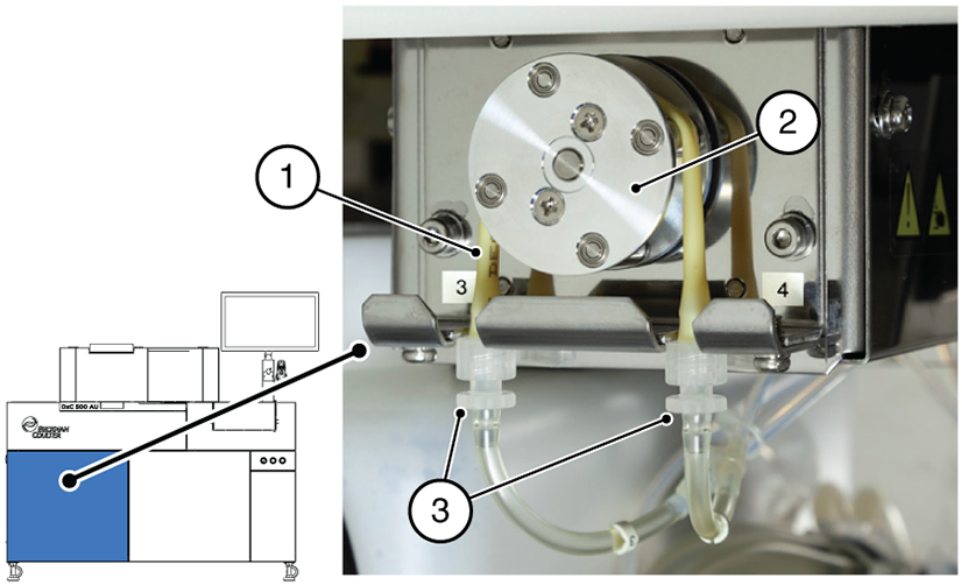
2 Open the left front door of the analyzer.

3 Select **Drain and Prime Tubing**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The roller pump rotates in the reverse direction to drain the wash solution back to the wash solution tank.

5 Remove the tubing from the roller pump.

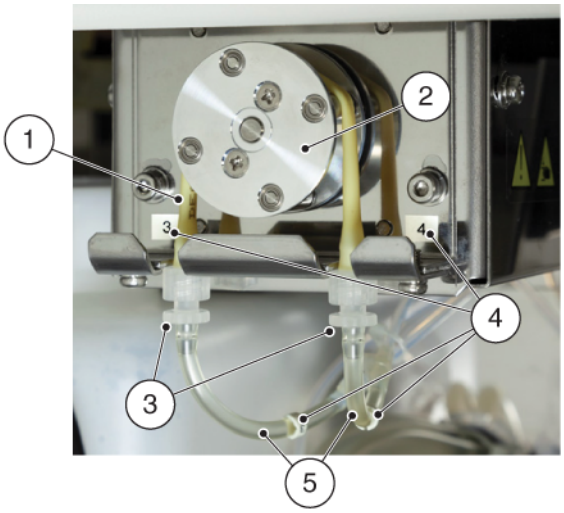
Figure 125 Wash Solution Roller Pump



1. Roller pump tubing
2. Roller pump
3. Normal rotation direction of roller pump = from right connector to left connector (counterclockwise)

6 Remove the roller pump tubing from the relay tubing by unscrewing the connectors.

Figure 126 Wash Solution Roller Pump Tubing



1. Roller pump tubing
2. Roller pump
3. Connectors
4. ID numbers

5. Relay tubing

7 Connect the connectors of the new roller pump tubing to each relay tubing.

8 Stretch the roller pump tubing around the roller pump, and slide the connectors into the grooves under the roller pump. Confirm that the ID numbers on the relay tubing match the ID numbers on the roller pump plate.

9 Press the **TABLE ROTATION/DIAG** button with indicator light again. The roller pump rotates in the normal direction to fill the tubing with wash solution.

10 Close all analyzer doors and covers.

11 Select **Task Completed**.

Manually Clean the ISE Drain Well

If the analyzer analyzes samples that contain large amounts of fibrin and protein, the fibrin and protein can accumulate by the drain tubing outlet and drain well, possibly causing errors.

Perform the following procedure every 3 months or every 20,000 samples, whichever comes first.

For more information, refer to ISE Tubing Block Diagram.

Important

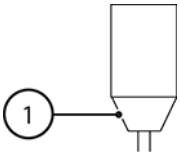
By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Figure 127 Drain Well



1. Drain well

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Clean the Drain Well

1 Remove the drain tubing from the hook over the drain well.

Figure 128 Removing the Drain Tubing

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle diluted cleaning solution or hydrochloric acid. If the diluted cleaning solution or hydrochloric acid contacts skin or clothes, rinse the affected area thoroughly with water. If the diluted cleaning solution or hydrochloric acid contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

2 Prepare approximately 50 mL of diluted cleaning solution (0.5% sodium hypochlorite). For more information, refer to Dilution Ratios for Detergents.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

— If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

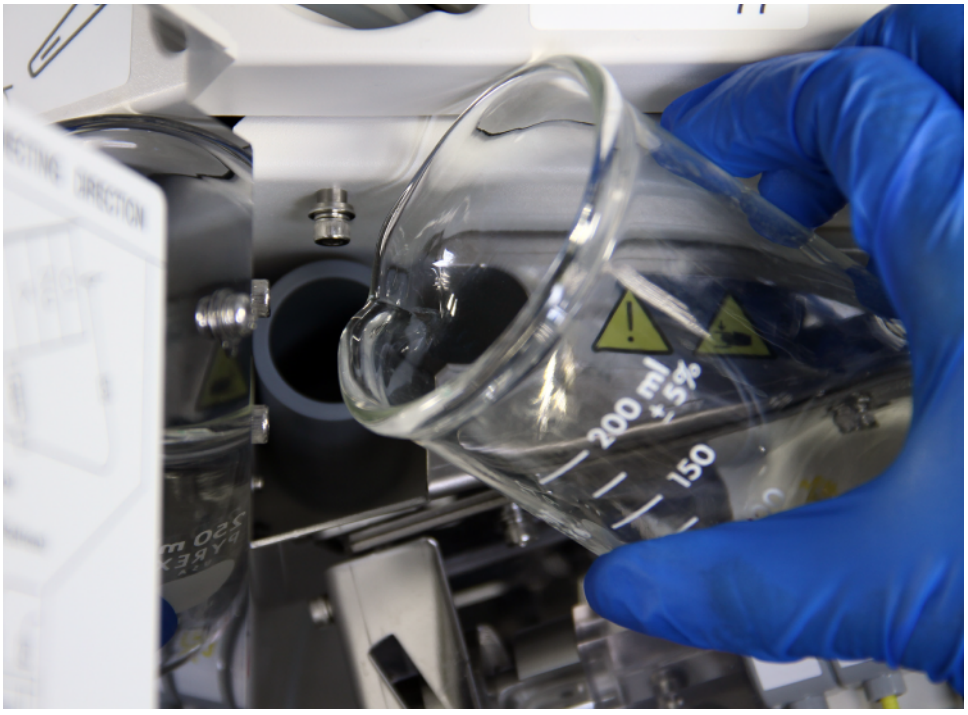
— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

3 Pour the diluted cleaning solution (0.5% sodium hypochlorite) into the drain well directly from the top.

Figure 129 Pouring Diluted Cleaning Solution Into the Drain Well



4 Allow the diluted cleaning solution (0.5% sodium hypochlorite) to sit for approximately 10 minutes.

5 Pour deionized water into the drain well to rinse out the diluted cleaning solution.

6 Put the drain tubing on the hook over the drain well.

Figure 130 Putting the Drain Tubing on the Hook

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

8 Close all analyzer doors and covers.

9 Select **Task Completed**.

Replace ISE Tubing

If your analyzer includes an ISE module, replace ISE tubing.

To obtain accurate results and optimum analyzer performance without unexpected analyzer downtime, replace the tubing every 22,500 ISE samples. Use the following maintenance frequencies to perform this procedure.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Table 97 Criterion for Frequency of Replace ISE Tubing

Frequency	Patient Samples (with ISE Tests) Throughput per Day
Monthly	501 or more
Every Two Months	301 - 500
Every Three Months	1 - 300

Important

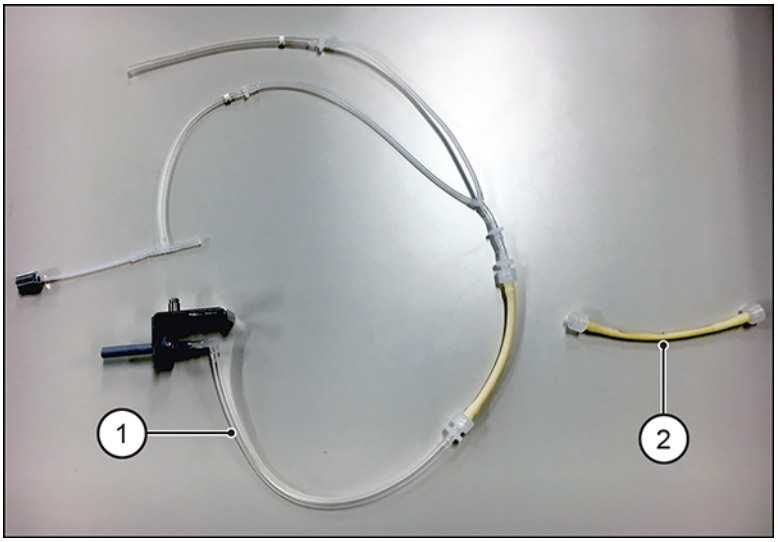
You may need to replace the ISE tubing more frequently than specified in the preceding table after running more than 1,000 samples or large volumes of dialysis samples, LIH (lipemic, icteric, or hemolyzed) samples, or serum samples containing separator material.

Materials Required:

- ISE Tubing 4

ISE Tubing 4 contains a flow cell tubing and an ISE MID Standard Solution roller pump tubing.

Figure 131 ISE Tubing 4



1. Flow cell tubing
2. ISE MID Standard Solution roller pump tubing

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

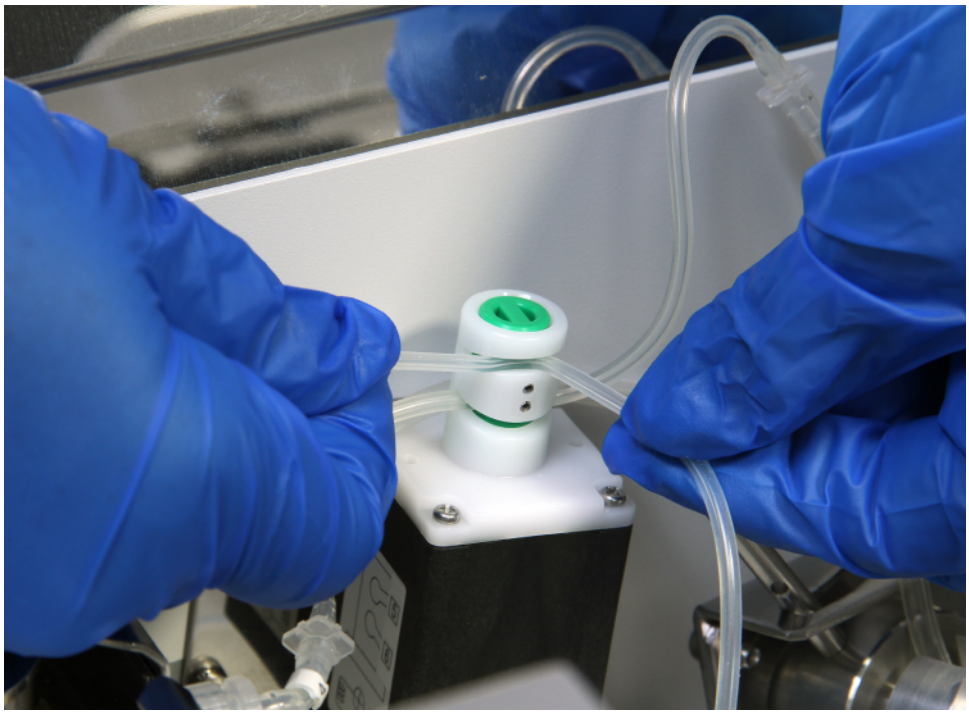
Remove Flow Cell Tubing

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

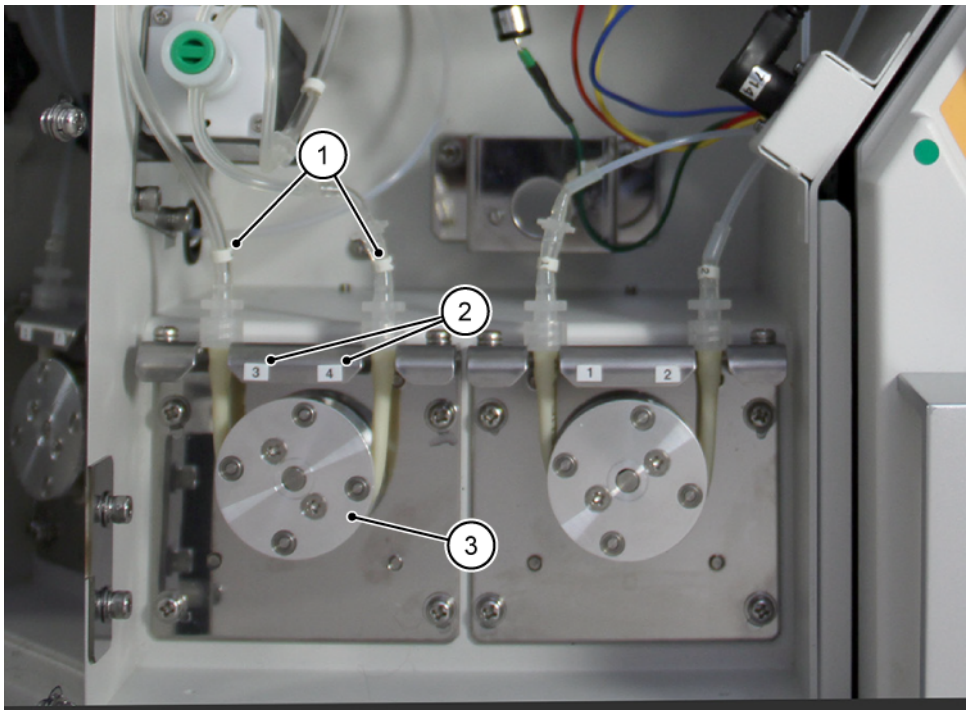
1 Remove the tubing from the pinch valve grooves by pulling it out and then up.

Figure 132 Pinch Valve Grooves



2 Remove the roller pump tubing from the bracket of the mixture aspiration roller pump.

Figure 133 Mixture Aspiration Roller Pump Tubing



1. Tubing connector numbers
2. Numbers on pump bracket
3. Mixture aspiration roller pump

3 Disconnect the liquid level sensor connector 714 and mixing motor connector 706.

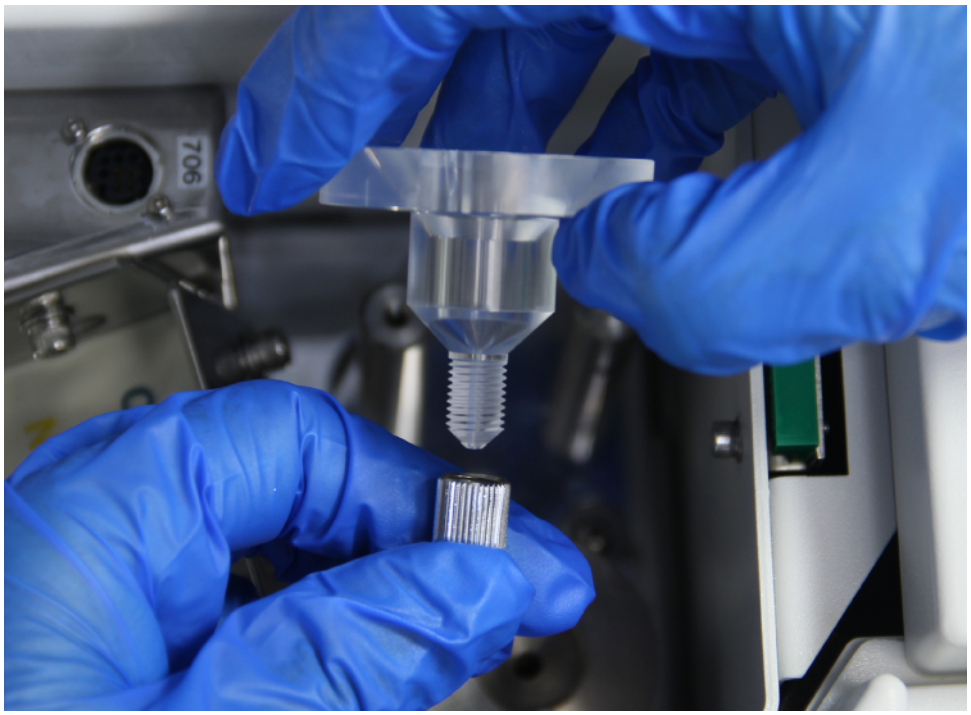
4 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to remove it.

Figure 134 Mixing Subsystem

5 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.

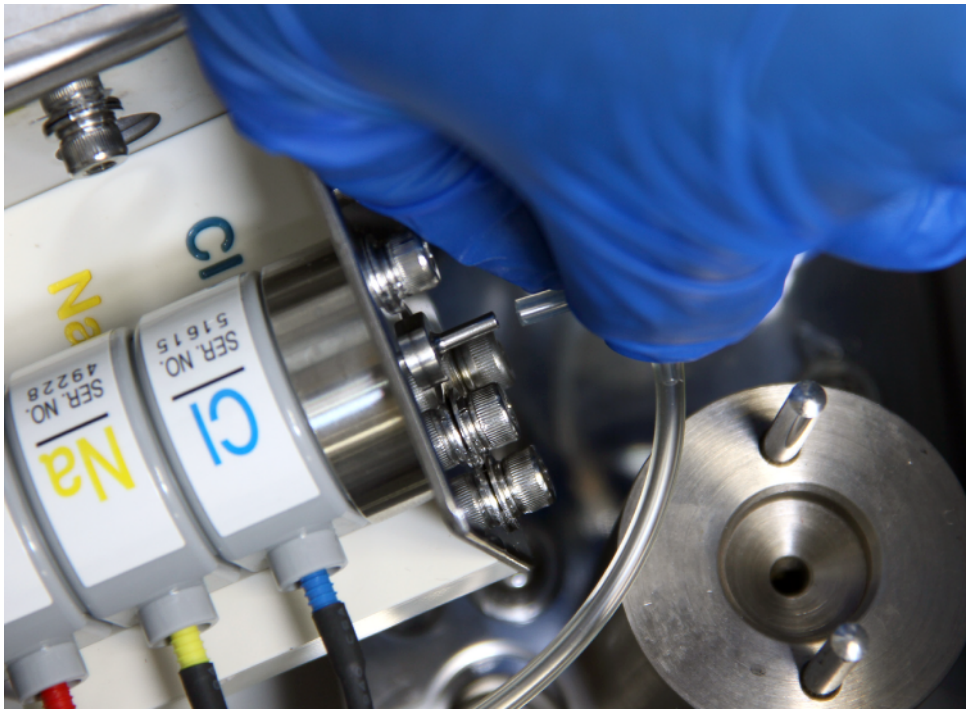
6 Disconnect the sample pot tubing from the sample pot by unscrewing the connector.

Figure 135 Sample Pot



7 Disconnect the other end of the sample pot tubing from the electrode block inlet.

Figure 136 Electrode Block Inlet

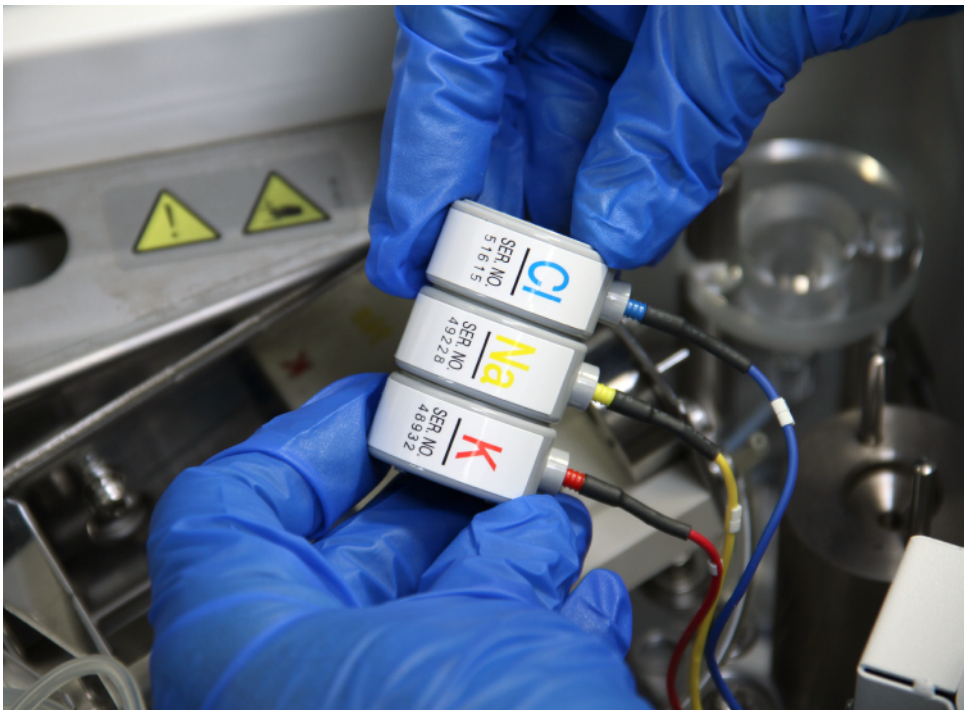


8 Disconnect the green ISE REF electrode wire.

9 Push the lock lever forward to release the electrodes.

10 Remove the Na, K, and Cl electrodes from the electrode block to keep these electrodes away from the ISE REF electrode. Any contact with the ISE Reference Solution can deteriorate the Na, K, and Cl electrodes.

Figure 137 Na, K, and Cl Electrodes



Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrodes.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

   — If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

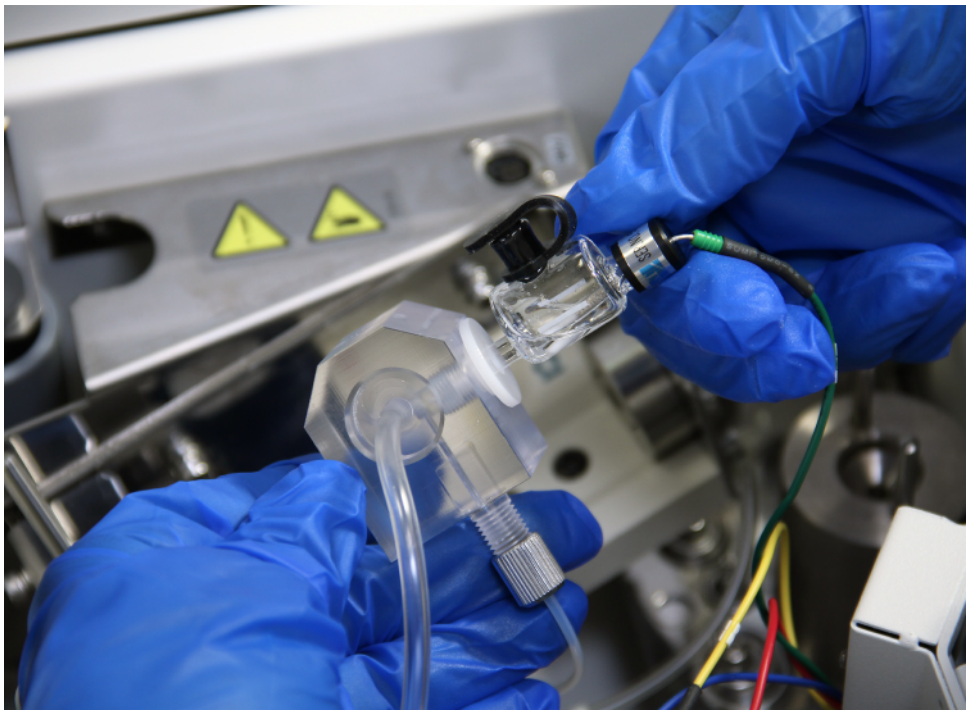
2. Continue this procedure by going to the next step.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

11 Gently lift up the ISE REF electrode block.

Figure 138 ISE REF Electrode Block



12 While holding the ISE REF Electrode block, disconnect the tubing (labeled 6) from the ISE REF Electrode block.

Figure 139 ISE REF Electrode Block

13 Remove the drain tubing with metal plate from the hook over the drain well.

Connect New Flow Cell Tubing

Materials Required:

- Flow cell tubing contained in ISE Tubing 4

1 Obtain the new flow cell tubing from ISE Tubing 4 .

2 Confirm that all joints and connectors of the new flow cell tubing are secured.

3 Place the metal plate with drain tubing on the hook over the drain well.

4 Attach the flow cell tubing (labeled 6) to the ISE REF Electrode block.

5 Place the ISE REF Electrode block in the original position and reconnect the green ISE REF Electrode wire.

6 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF Electrode block side.

Important

Confirm that all four O-rings are in position before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flow cell.

7 Align the electrodes in a straight stack with the pegs in the holes.

8 Pull the lock lever backward to lock the electrodes in position.

9 Connect the sample pot tubing of the flow cell tubing to the electrode block inlet.

10 Connect the sample pot tubing of the flow cell tubing to the sample pot by screwing on the connector.

Important

To attach the sample pot tubing to the sample pot, finger-tighten the connector.

11 Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.

12 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

Important

Do not change the orientation position of the two nozzles attached to the mixing subsystem. Do not apply excess pressure to the tubing.

13 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

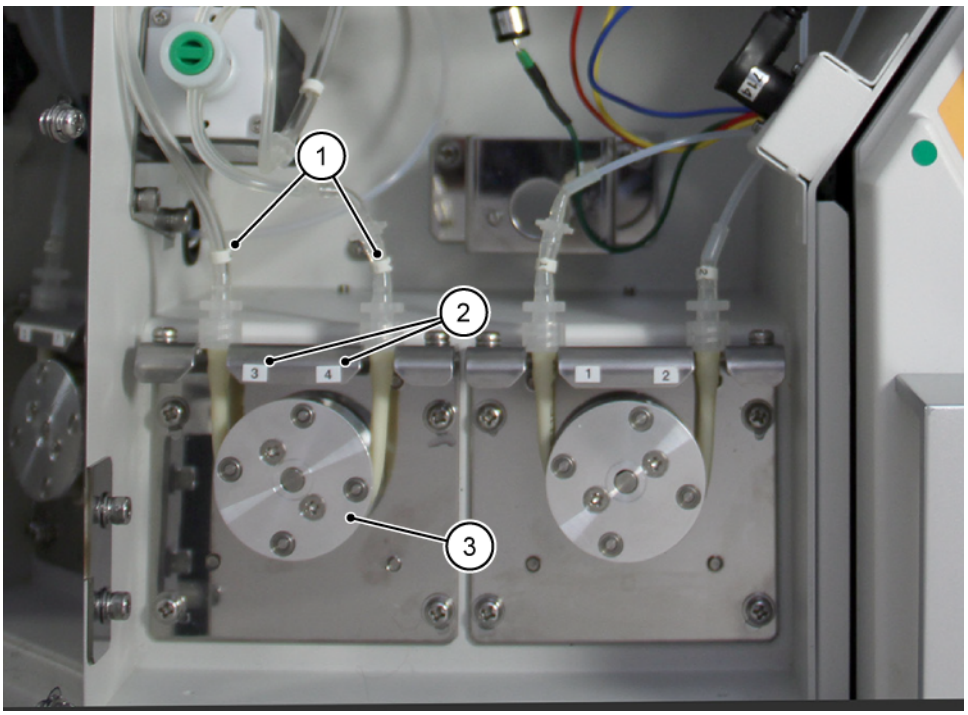
Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

14 Place the roller pump tubing of the flow cell tubing on the mixture aspiration roller pump. Confirm that the tubing connector numbers match to their corresponding

numbers on the pump bracket. Hook one end of the tubing to the bracket, stretch the tubing around the pump, and hook the other end in the bracket.

Figure 140 Mixture Aspiration Roller Pump Tubing



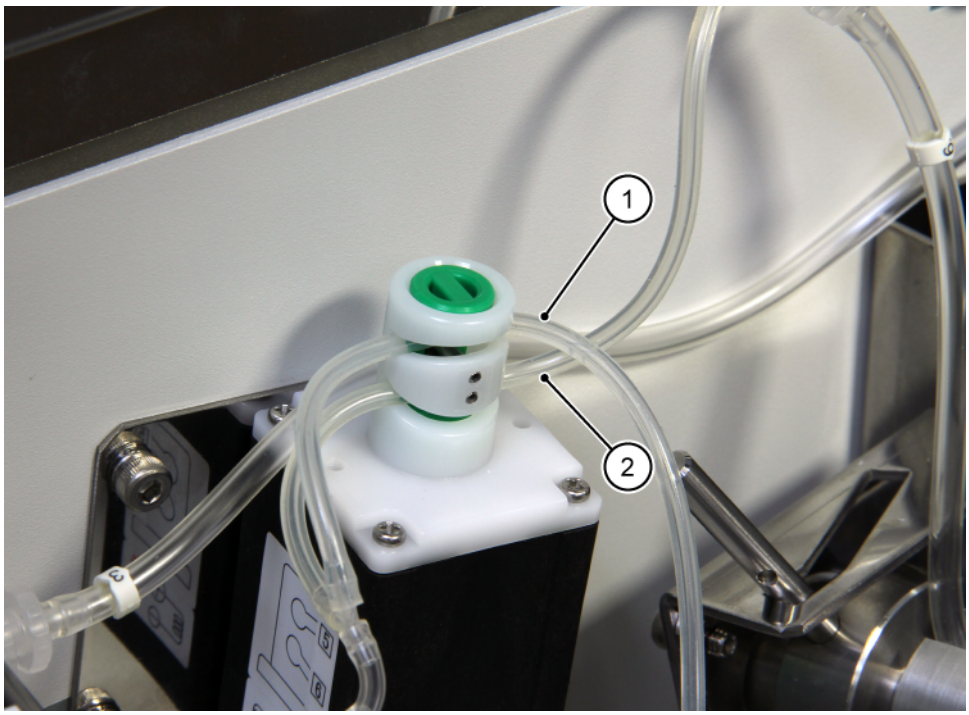
1. Tubing connector numbers
2. Numbers on pump bracket
3. Mixture aspiration roller pump

Important

Confirm that the tubing is not twisted on the roller pump.

15 Insert the tubing into the grooves of the pinch valve. Confirm that the tubing is inserted completely into the groove. Put tubing labeled 6 in the bottom groove of the pinch valve, and put tubing labeled 5 in the top groove of the pinch valve.

Figure 141 Pinch Valve



1. Tubing labeled 5 in top groove of pinch valve
2. Tubing labeled 6 in bottom groove of pinch valve

Replace the ISE MID Standard Solution Roller Pump Tubing

Materials Required:

- ISE MID Standard Solution roller pump tubing contained in ISE Tubing 4 .

1 Remove the roller pump tubing from the bracket of the ISE MID Standard Solution roller pump.

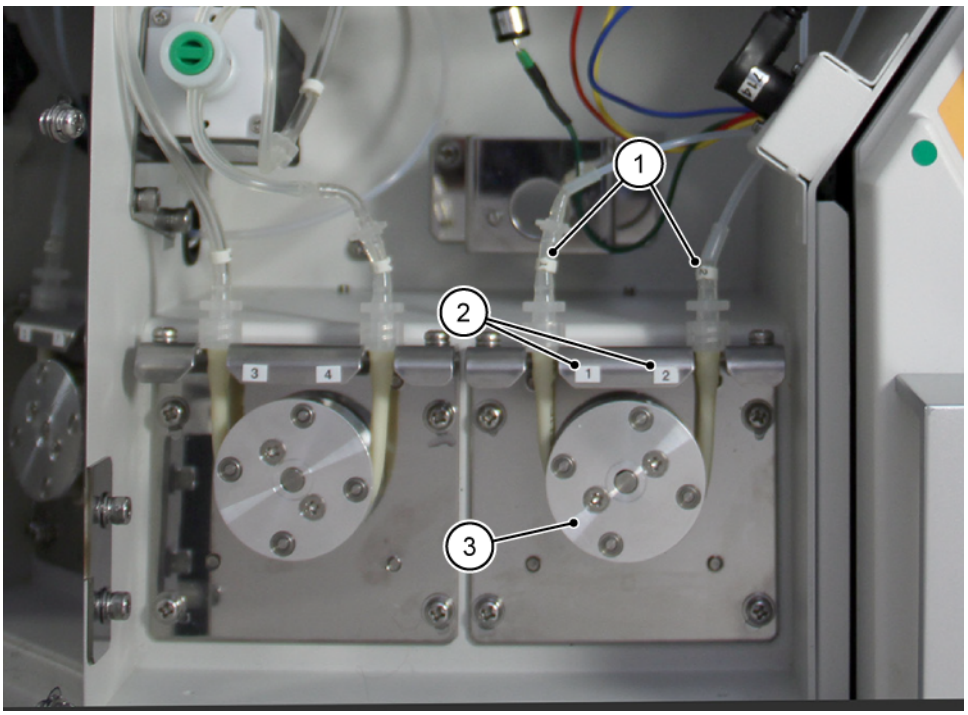
2 Disconnect the roller pump tubing by twisting apart the connectors at each end.

3 Connect a new roller pump tubing. Turn the connectors at both ends to secure it.

4 Place the roller pump tubing on the ISE MID Standard Solution roller pump. Confirm that the tubing connector numbers match their corresponding numbers on the pump

bracket. Hook one end of the tubing to the bracket, stretch the tubing around the pump, and hook the other end to the bracket.

Figure 142 ISE MID Standard Solution Roller Pump



1. Tubing connector numbers
2. Numbers on pump bracket
3. ISE MID Standard Solution roller pump

Important

Confirm that the tubing is not twisted on the roller pump.

Prime the Tubing

1 Select **Prime Bypass Tubing**.

2 Press the **TABLE ROTATION/DIAG** button on the analyzer to start the prime. The two roller pumps are activated to prime liquid through the ISE. The roller pumps rotate for approximately one minute to remove air from the tubing.

3 Select **ISE Total Prime**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed

from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

5 Close all analyzer doors and covers.

6 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Clean the Cuvettes and the Cuvette Wheel

To maintain correct operation of the photometry subsystem, the cuvettes and the wheel must be clean. The cuvette wheel has 88 cuvettes.

The cuvettes are checked weekly during the photocal procedure. This procedure is performed every 6 months to keep the cuvettes in optimal condition. Perform this procedure every 6 months or if a wheel overflow occurs. In the US market, Beckman Coulter performs this procedure as part of the preventive maintenance.

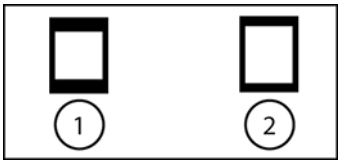
Materials Required:

- Cotton-tipped applicator
- Freshly prepared diluted Beckman Coulter Wash Solution (2%)
- Sonicator
- Clean, dry, lint-free absorbent tissue
- Plastic containers to hold cuvettes in the sonicator

Caution

Cuvettes with the same outer dimensions might have different interior dimensions. The DxC 500 AU uses cuvette PN MU846500 with an interior dimension of 5 mm x 5 mm. Do not use a cuvette from another AU analyzer on the DxC 500 AU. Use of a cuvette other than the DxC 500 AU cuvette on the DxC 500 AU causes erroneous results.

Figure 143 Cuvette Interior Dimensions



1. For DxC 500 AU (5 mm x 5 mm, PN MU846500)
2. Example for other AU analyzer

Remove the Cuvette Wheel

Perform this procedure on a work surface protected with clean, dry, lint-free absorbent tissue or absorbent paper designed to protect laboratory countertops.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Open the rear cover of the analyzer.

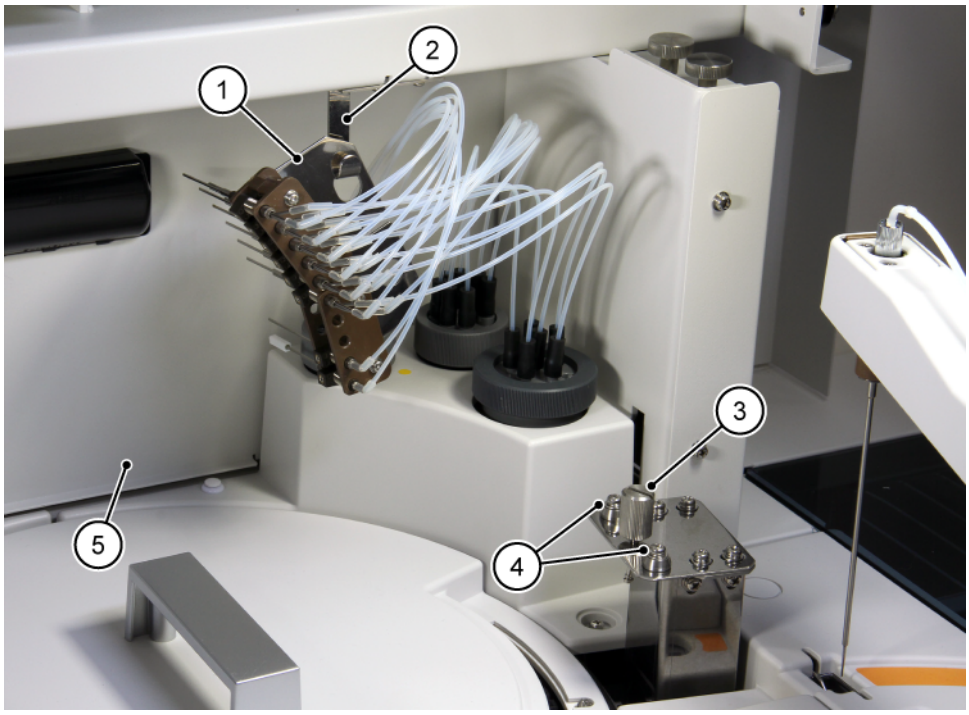
4 Loosen the knob of the wash nozzle subsystem. Without disconnecting the tubing, remove the nozzle portion and hang it on the hook.

Important

When hanging the wash nozzle subsystem on the hook, do not damage the wash nozzles. Avoid contact between the wash nozzles and the cuvette wheel cover.

Do not loosen or remove the positioning screws on either side of the knob when you loosen the knob on the wash nozzle subsystem. The positioning screws are used for positioning the wash nozzle subsystem.

Figure 144 Remove Wash Nozzle Subsystem

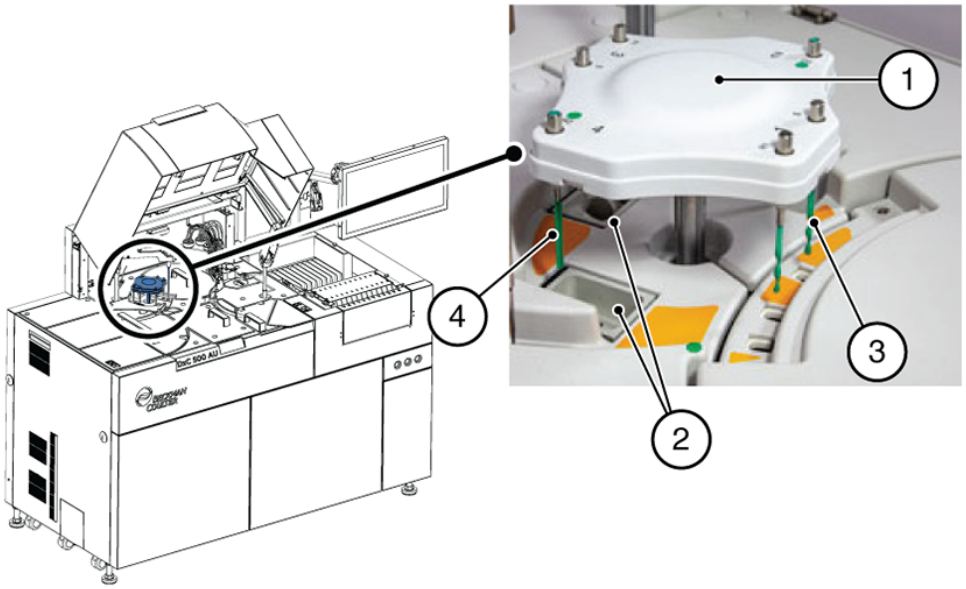


1. Wash nozzle subsystem
2. Hook
3. Knob
4. Positioning screws
5. Rear cover

---

5 Remove the two mix bars that are above the cuvette wheel from the mix bar subsystem.

Figure 145 Remove Mix Bars from Mix Bar Subsystem



1. Mix bar subsystem
2. Mix bar wash wells
3. Spiral-shaped mix bar (R1/S position)

4. L-shaped mix bar (R2 position)

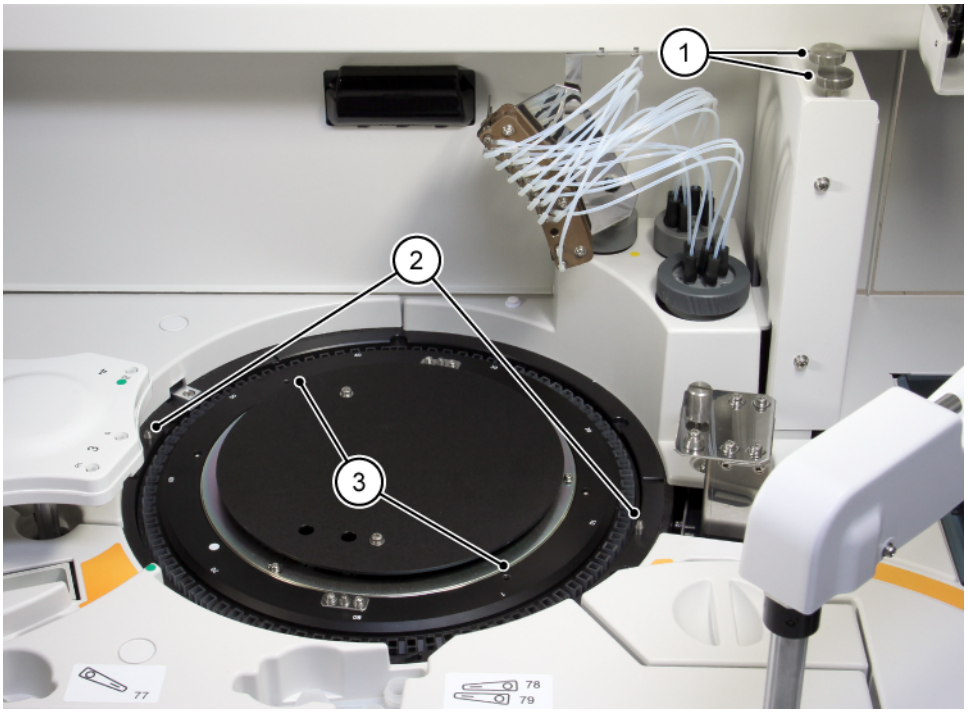
6 Carefully lift the cuvette wheel cover and remove it from the analyzer.

Important

When removing the cuvette wheel cover, do not damage the sample probe, reagent probe, or mix bars.

7 Remove the two silver screws located on the top of the right pillar under the upper cover, and tighten the screws into the two holes in the cuvette wheel.

Figure 146 Remove the Cuvette Wheel



1. Silver screws
2. Screws securing the cuvette wheel
3. Holes for the silver screws (one hole is near cuvette number 1, and the other hole is between cuvette numbers 40 and 50)

8 Use the two screws as handles, and lift the cuvette wheel carefully from the analyzer.

Caution

When removing the cuvette wheel, do not touch the peripheral components.

Caution

When handling cuvettes, do not scratch the cuvettes. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.

Caution

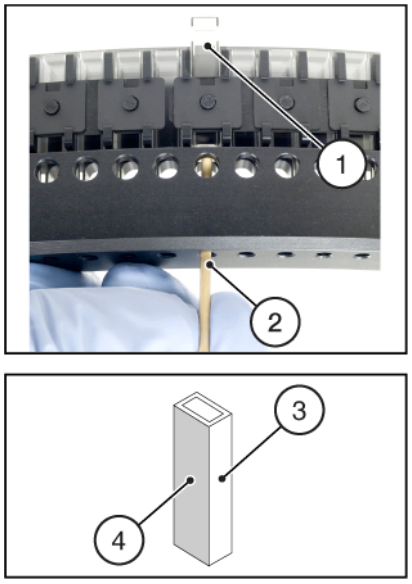
To maintain correct photometric analysis, do not get fingerprints on the photometric surface of the cuvettes. Always wear gloves when handling the cuvettes.

Remove the Cuvettes from the Wheel

Perform this procedure on a work surface protected with clean, dry, lint-free absorbent tissue or absorbent paper designed to protect laboratory countertops.

Use the reverse end of a cotton-tipped applicator to push each cuvette from the bottom to remove it from the wheel. Remove all 88 cuvettes.

Figure 147 Remove a Cuvette



1. Cuvette
2. Cotton-tipped applicator
3. Photometric face of cuvette
4. Frosted glass face of cuvette

Clean the Cuvettes and the Cuvette Wheel Procedure

Caution

When handling cuvettes, do not scratch the cuvettes. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.

1 Submerge all cuvettes in a plastic container filled with freshly prepared diluted wash solution (2%).

Important

Do not use diluted wash solution to clean the cuvette wheel. Using diluted wash solution to clean the cuvette wheel can cause the metallic plating on the wheel to be removed.

2 Sonicate for 15 minutes.

3 Thoroughly rinse the cuvettes in deionized water, or sonicate them in deionized water for 10 minutes to remove any residual diluted wash solution.

4 Allow the cuvettes to dry completely.

Important

Use one of the following cuvette drying methods:

— Allow cuvettes to air dry.
— Use an oven with the heat set under 50 °C (122 °F).
— Use a clean, dry, lint-free absorbent tissue.

5 Rinse the cuvette wheel with deionized water and dry thoroughly with a clean, dry, lint-free absorbent tissue.

6 Insert the cuvettes into the wheel. Confirm that each cuvette is gently pushed down completely into the wheel.

Caution

Confirm that 88 cuvettes are correctly installed in the cuvette wheel. If one of the cuvettes is missing, the mixture, reagent, or diluted wash solution spills into the cuvette wheel, causing a cuvette wheel overflow and preventing successful analysis.

Caution

Do not scratch the cuvettes when putting back the cuvettes on the cuvette wheel. Never touch the photometric surface of a cuvette. Wear gloves when handling the cuvettes. If the photometric surface is stained, analysis data is inaccurate.

7 If the incubation bath is wet, dry the incubation bath with a clean, dry, lint-free absorbent tissue.

(The incubation bath is wet only if a cuvette overflow occurs.)

8 Return the cuvette wheel to the original position by aligning the cuvette numbers on the wheel with the cuvette numbers on the incubation bath of the analyzer.

Tip

To aid in correct orientation of the cuvette wheel, you can align the white spot on the wheel with the white spot on the incubator bath. Also, there are offset locating pins that make it impossible for the cuvette wheel to fit except for in the correct position.

9 Remove the two screws used as handles to remove the wheel and return to the positions on the top of the right pillar under the upper cover.

10 Return the cuvette wheel cover and wash nozzle subsystem back to the original positions, and return the R1 and S mix bars to the mix bar subsystem.

11 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

12 For **Repetitions**, confirm that the value is 1, and then select **OK**.

13 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Watch as the wash nozzle subsystem moves, and confirm that the downward motion is not inhibited.

14 Close the upper and rear covers.

15 Select **Task Completed**.

Important

After you select **Task Completed**, perform a photocal to confirm that the cuvettes were cleaned correctly.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Perform a Photocal**.
2. Follow the steps on the Task page.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

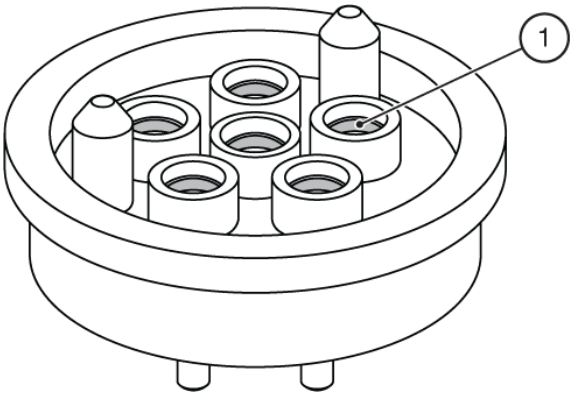
Replace the O-rings in the Water Supply Tube Mounting Joint

Replace each O-ring in the water supply tube mounting joint with a new one yearly.

When installing the water supply tube mounting joint of the wash nozzle subsystem, inspect the following items.

- All six O-rings are seated in a groove. Refer to the following figure.
- Confirm that particles such as dust or wash solution crystals are not observed on or around the O-rings.

Figure 148 Manifold Base of the Water Supply Tube Mounting Joint



1. O-ring

Materials Required:

- O-rings
- Clean, dry, lint-free absorbent tissue
- Pair of tweezers

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the rear cover of the analyzer.

3 Select **Drain Wash Nozzles**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the tubing.

Caution

Drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water beforehand, the water spills out of the nozzle.

If the water spills onto the cuvettes, clean the cuvettes and cuvette wheel after completing this maintenance task.

5 Loosen the three manifolds, and remove them from their mounting positions.

Figure 149 Loosening Manifolds

6 Using a pair of tweezers, remove each O-ring from the groove. Wipe away any crystallization or foreign matter found around O-ring grooves.

7 Set new O-rings into the grooves.

8 Put the manifold back into its position on the analyzer. Match the colored dot on the manifold with the one next to its position. Tighten the manifolds without cross

threading them. Confirm that the manifolds are finger-tight to prevent a cuvette wheel overflow, but do not over-tighten.

Figure 150 Returning Manifolds to Original Positions

Important

To avoid analyzer damage and to perform tests correctly:

- When you install the manifolds, confirm that the manifolds are in the correct, color-coded positions. Firmly tighten the manifolds.
- Confirm that all tubing from the nozzles to the tube mounting joints are connected.
- Do not damage any of the joints or tubing. Damaged components can cause leaks and can contaminate or flood the cuvette wheel.

9 Select **Prime Wash Nozzle**. The analyzer displays the Prime Wash Nozzle dialog.

10 For **Repetitions**, enter **5**, and then select **OK**.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

12 Confirm that there are no leaks from the tube mounting joint. If you detect a leak, unscrew the manifold for the water supply tube mounting joint, and confirm that the O-rings are installed correctly.

Important

If you use the O-rings for a long time without cleaning or if you put the joint manifold back without the O-rings correctly set, wash solution crystals can form, causing errors with the cuvettes. Inspect the O-rings along with the monthly maintenance of the wash nozzle subsystem.

13 Close all analyzer doors and covers.

14 Select **Task Completed**.

Important

If the water spilled onto the cuvettes when draining the wash nozzles, clean the cuvettes and cuvette wheel after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean the Cuvettes and Cuvette Wheel**.
2. Follow the steps on the Task page.

Replace the Na Electrode

If your analyzer includes an ISE module, replace the Na electrode.

Tip

You can find the Lot No. and the bar code containing both the electrode ID and lot No. on the electrode package. You need this information to document on the maintenance log.

Replace the electrode when calibration or Selectivity Check results are out of range, and troubleshooting has been performed. Replacement of the electrode at every 40,000 samples or every six months ensures continuous and reliable electrode performance without unexpected analyzer down-time. If the electrode has deteriorated, the analyzer cannot obtain accurate analysis results. You can view the number of months remaining or number of samples remaining on the Task page for this task.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Materials Required:

- Na electrode
- O-ring

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Replace the Na Electrode Procedure

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

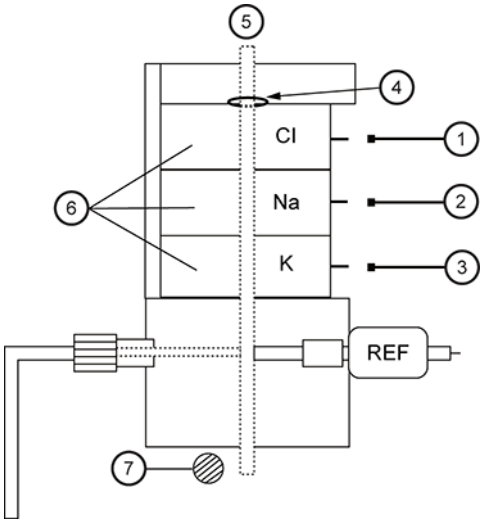
1 Push the lock lever forward to release the electrodes.

2 Remove the electrodes.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

Figure 151 Na, K, and Cl Electrodes



1. Cl electrode wire (blue)
2. Na electrode wire (yellow)
3. K electrode wire (red)
4. O-ring
5. Sample pot
6. Electrodes
7. Lock lever

3 Disconnect the lead wire of the Na electrode.

Figure 152 Disconnecting the Lead Wire of the Na Electrode

Caution

Handle the lead wire from the very end so it does not come apart.

4 Replace the failed electrode with a new one.

Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

— If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

5 Connect the yellow wire to the Na electrode.

Figure 153 Connecting the Yellow Wire to the Electrodes

6 Confirm that the green wire connects to the ISE REF electrode.

7 Before installing the electrodes, wipe the electrode block with a clean, dry, lint-free absorbent tissue.

8 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF electrode block side.

Important

Confirm that all four O-rings are in position before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flow cell.

9 Pull the lock lever backward to lock the electrodes in position.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

11 Close all analyzer doors and covers.

12 Register information about the electrode package.

a. Select **Replace Electrode**.
The analyzer displays the Electrode Information dialog.

b. Enter the lot number and expiration date in the Lot Number and Expiration Date fields.

c. Select **Save**.

13 Select **Task Completed**.

Important

Wait a minimum of 5 minutes after closing the covers, and then perform calibration and QC for all ISE tests.

Important

After you select **Task Completed**, to obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 98 Acceptable Differences Between First and Second MID Solution Factors (Serum or Urine)

	Na
Difference between 1st and 2nd factors	0.020

Replace the K Electrode

If your analyzer includes an ISE module, replace the K electrode.

Tip

You can find the Lot No. and the bar code containing both the electrode ID and lot No. on the electrode package. You need this information to document on the maintenance log.

Replace the electrode when calibration or Selectivity Check results are out of range, and troubleshooting has been performed. Replacement of the electrode at every 40,000 samples or every six months ensures continuous and reliable electrode performance without unexpected analyzer down-time. If the electrode has deteriorated, the analyzer cannot obtain accurate analysis results. You can view the number of months remaining or number of samples remaining on the Task page for this task.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Materials Required:

- K electrode
- O-ring

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Replace the K Electrode Procedure

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

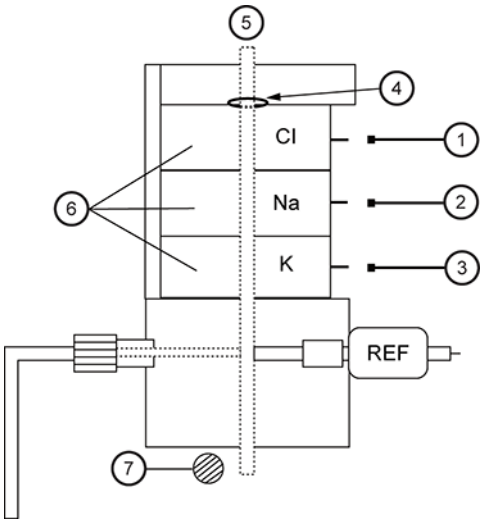
1 Push the lock lever forward to release the electrodes.

2 Remove the electrodes.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

Figure 154 Na, K, and Cl Electrodes



1. Cl electrode wire (blue)
2. Na electrode wire (yellow)
3. K electrode wire (red)
4. O-ring
5. Sample pot
6. Electrodes
7. Lock lever

3 Disconnect the lead wire of the K electrode.

Figure 155 Disconnecting the Lead Wire of the K Electrode

Caution

Handle the lead wire from the very end so it does not come apart.

4 Replace the failed electrode with a new one.

Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

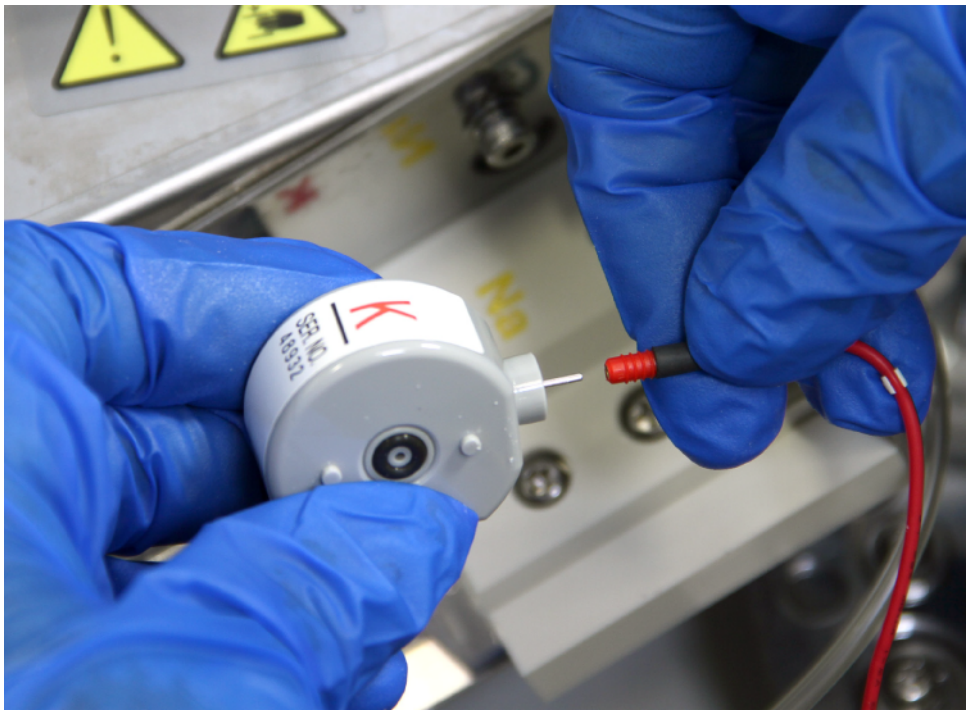
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

5 Connect the red wire to the K electrode.

Figure 156 Connecting the Red Wire to the Electrodes



6 Confirm that the green wire connects to the ISE REF electrode.

7 Before installing the electrodes, wipe the electrode block with a clean, dry, lint-free absorbent tissue.

8 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF electrode block side.

Important

Confirm that all four O-rings are in position before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flow cell.

9 Pull the lock lever backward to lock the electrodes in position.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed

from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

11 Close all analyzer doors and covers.

12 Register information about the electrode package.

a. Select **Replace Electrode**.
The analyzer displays the Electrode Information dialog.

b. Enter the lot number and expiration date in the Lot Number and Expiration Date fields.

c. Select **Save**.

13 Select **Task Completed**.

Important

Wait a minimum of 5 minutes after closing the covers, and then perform calibration and QC for all ISE tests.

Important

After you select **Task Completed**, to obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 99 Acceptable Differences Between First and Second MID Solution Factors (Serum or Urine)

	K
Difference between 1st and 2nd factors	0.045

Replace the Cl Electrode

If your analyzer includes an ISE module, replace the Cl electrode.

Tip

You can find the Lot No. and the bar code containing both the electrode ID and lot No. on the electrode package. You need this information to document on the maintenance log.

Replace the electrode when calibration or Selectivity Check results are out of range, and troubleshooting has been performed. Replacement of the electrode at every 40,000 samples

or every six months ensures continuous and reliable electrode performance without unexpected analyzer down-time. If the electrode has deteriorated, the analyzer cannot obtain accurate analysis results. You can view the number of months remaining or number of samples remaining on the Task page for this task.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Materials Required:

- Cl electrode
- O-ring

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Replace the Cl Electrode Procedure

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

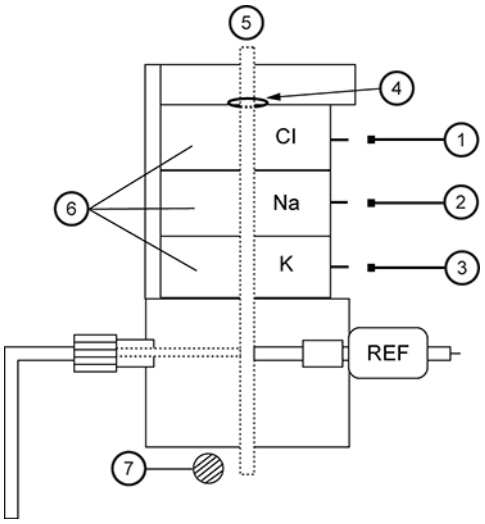
1 Push the lock lever forward to release the electrodes.

2 Remove the electrodes.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

Figure 157 Na, K, and Cl Electrodes



1. Cl electrode wire (blue)
2. Na electrode wire (yellow)
3. K electrode wire (red)
4. O-ring
5. Sample pot
6. Electrodes
7. Lock lever

3 Disconnect the lead wire of the Cl electrode.

Figure 158 Disconnecting the Lead Wire of the Cl Electrode

Caution

Handle the lead wire from the very end so it does not come apart.

4 Replace the failed electrode with a new one.

Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

5 Connect the blue wire to the Cl electrode.

Figure 159 Connecting the Blue Wire to the Electrodes

6 Confirm that the green wire connects to the ISE REF electrode.

7 Before installing the electrodes, wipe the electrode block with a clean, dry, lint-free absorbent tissue.

8 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF electrode block side.

Important

Confirm that all four O-rings are in position before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flow cell.

9 Pull the lock lever backward to lock the electrodes in position.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed

from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

11 Close all analyzer doors and covers.

12 Register information about the electrode package.

a. Select **Replace Electrode**.
The analyzer displays the Electrode Information dialog.

b. Enter the lot number and expiration date in the Lot Number and Expiration Date fields.

c. Select **Save**.

13 Select **Task Completed**.

Important

Wait a minimum of 5 minutes after closing the covers, and then perform calibration and QC for all ISE tests.

Important

After you select **Task Completed**, to obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 100 Acceptable Differences Between First and Second MID Solution Factors (Serum or Urine)

	Cl
Difference between 1st and 2nd factors	0.025

Replace the ISE REF Electrode and Packing

If your analyzer includes an ISE module, replace the ISE REF electrode and packing.

Tip

You can find the Lot No. and the bar code containing both the electrode ID and lot No. on the electrode package. You need this information to document on the maintenance log.

Replace the ISE REF electrode when calibration or Selectivity Check results are out of range for Na, K, and Cl, or the Na, K, and Cl results fluctuate significantly higher or lower than the

previous measurement, and troubleshooting has been performed. Replacement of the electrode at 150,000 samples or 2 years, whichever comes first, ensures continuous and reliable electrode performance without unexpected analyzer down-time.

If all calibration measurement values of Na, K, and Cl fluctuate, higher or lower than previous measurements, or if the analyzer displays an event message after replacing the ISE REF electrode, contact Beckman Coulter.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Materials Required:

- ISE REF Electrode (with the packing)
- ISE REF Electrode Packing
- Plastic tweezers

Important

Do not use force to install or uninstall the ISE REF electrode. When installing or uninstalling the electrode, do not break the electrode.

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1. Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.
2. Select **Drain and Prime Flow Cell**.
3. Open the upper cover.
4. Open the ISE cover.
5. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Remove the ISE REF Electrode and Packing

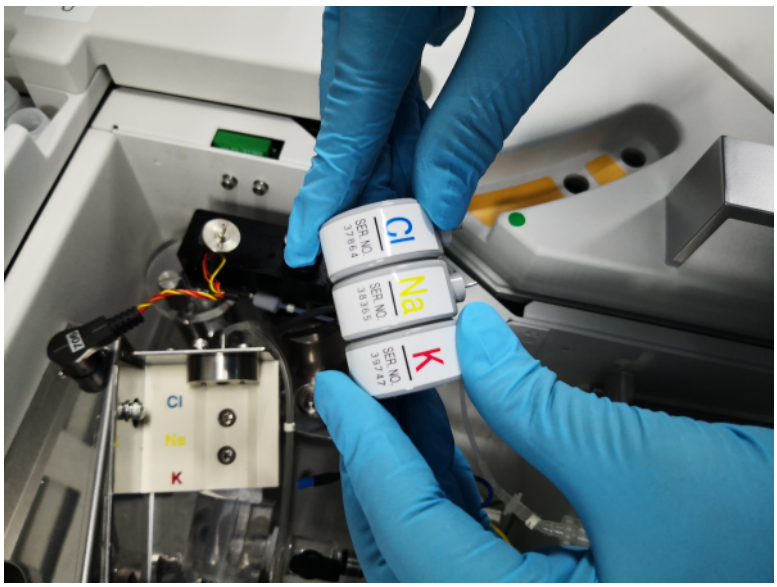
Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

1 Push the lock lever forward to release the electrodes.

2 Remove the Na, K, and Cl electrodes from the electrode block to keep these electrodes away from the ISE REF electrode. Any contact with the ISE Reference Solution can deteriorate the Na, K, and Cl electrodes.

Figure 160 Removing the Na, K, and Cl Electrodes From the Electrode Block



Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

3 Disconnect the green wire from the ISE REF electrode.

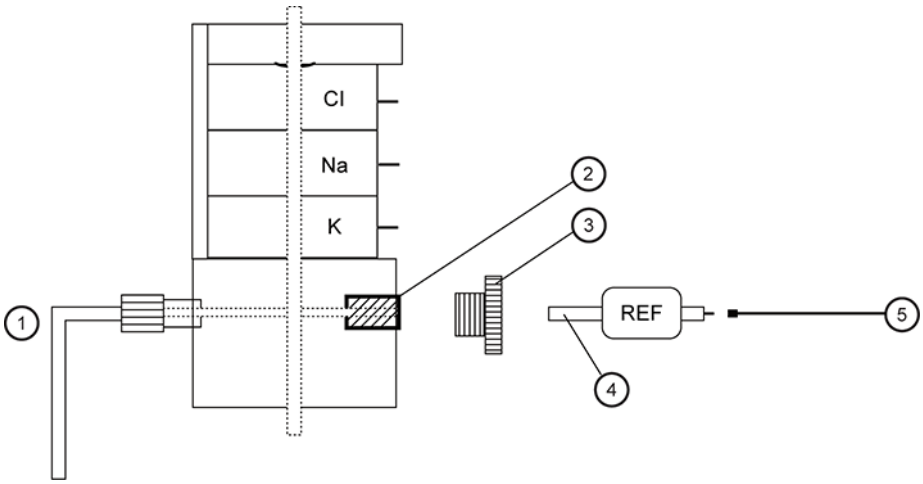
4 Gently lift the ISE REF electrode block.

5 Carefully unscrew the ISE REF electrode cap screw, then gently remove the ISE REF electrode along with the cap screw.

Figure 161 Removing the ISE REF Electrode

6 Remove the ISE REF electrode packing with a pair of plastic tweezers.

Figure 162 ISE REF Electrode and Packing



1. ISE Reference Solution tubing
2. ISE REF electrode packing
3. Cap screw
4. ISE REF electrode
5. ISE REF electrode wire (green)

Replace the ISE REF Electrode and Packing Procedure

1 Confirm that no air bubbles are in the ISE REF electrode tip. If air bubbles are found in the tip, remove the bubbles by pointing the electrode tip downward while tapping it with a finger.

2 Insert new packing into the ISE REF electrode block.

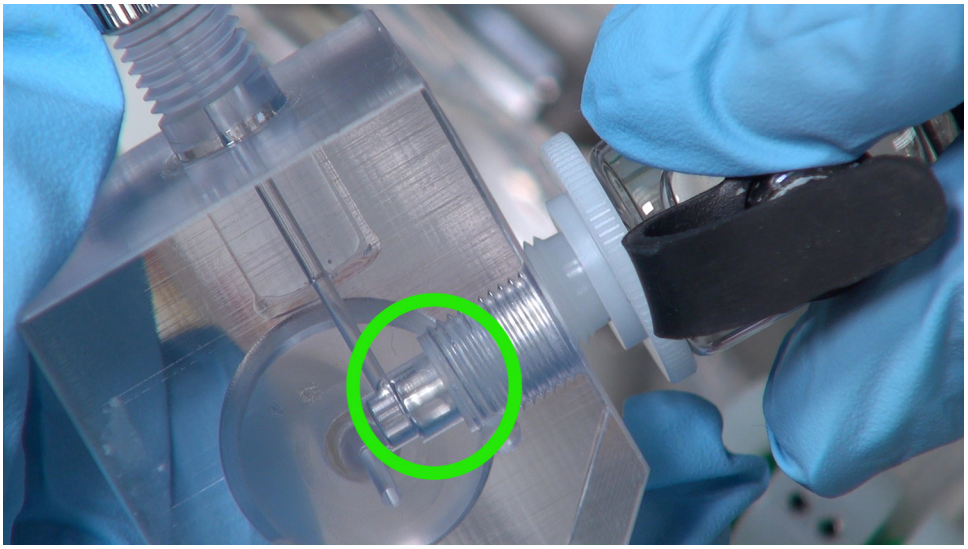
3 Place the cap screw on the ISE REF Electrode, then place the ISE REF Electrode in the ISE REF Electrode block so that the electrode tip is centered in the packing.

Note

Dampen the ISE REF Electrode tip with deionized water if you have difficulty inserting the ISE REF Electrode into the ISE REF Electrode block.

4 Insert the cap screw into the ISE REF electrode block and screw it in carefully. Finish tightening the cap screw by a quarter or half turn to orient the ISE REF electrode correctly.

Figure 163 Tightening the Cap Screw



5 Reinstall the ISE REF electrode block.

6 Connect the green ISE REF electrode wire to the ISE REF electrode.

7 Wipe the top of the block with a clean, dry, lint-free absorbent tissue. Always wear gloves when handling the ISE Reference Solution.

8 Reinstall the Na, K, and Cl electrodes.

9 Pull the lock lever backward to lock the electrodes in position.

10 Select **Prime MID and REF Solutions**.

11 Press the **TABLE ROTATION/DIAG** button on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

12 Close all analyzer doors and covers.

13 Register information about the electrode package.

a. Select **Replace Electrode**.
The analyzer displays the Electrode Information dialog.

b. Be sure the Lot Number field is selected.

c. Scan the bar code label on the electrode package.
The analyzer populates the Lot Number field with the scanned bar code ID.

Figure 164 Example of Correct Electrode Bar Code to Scan

1. Scan the longer bar code.

d. Press the Tab key.
The analyzer populates the Expiration Date field.

e. If the bar code is not read successfully, manually enter the lot number and expiration date in the Lot Number and Expiration Date fields.

f. Select **Save**.

14 Select **Task Completed**.

Important

Wait a minimum of 5 minutes after closing the covers, and then perform calibration and QC for all ISE tests.

Important

After you select **Task Completed**, to obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 101 Acceptable Differences Between First and Second MID Solution Factors (Serum or Urine)

	Na	K	Cl
Difference between 1st and 2nd factors	0.020	0.045	0.025

Clean the Interior of the Reagent Refrigerator

Exposure to the outside air causes condensation forms inside the reagent refrigerator.

To diminish the amount of condensation formed, keep the reagent refrigerator cover in position.

Clean the interior of the refrigerator when a reagent or sample is spilled, or as needed after inspection.

If bacterial contamination is suspected, or mold is observed, contact Beckman Coulter Customer Support for the decontamination procedure.

Caution

When you wipe the glass window on the bar code reader that is inside the reagent refrigerator, clean and dry the glass window completely.

Materials Required:

- Clean, dry, lint-free absorbent tissue
- Alcohol prep pads (70% Isopropyl alcohol)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Remove the reagent refrigerator large cover.

4 Remove the reagent tray with its reagents from the refrigerator.

a. Lift the white securing pins until they unclip from the base.

b. Lift the tray up from the center.

c. Gently place the tray in a safe place.

5 Clean the wall, bottom, and central area inside the reagent refrigerator.

a. Wipe off any condensation inside the refrigerator using an absorbent tissue.

b. Clean the inside of the refrigerator using an alcohol prep pad.

c. Rinse the inside of the refrigerator using deionized water.

d. Dry the inside of the refrigerator using an absorbent tissue.

6 Put back the reagent tray with its reagents into the reagent refrigerator.

a. Set the tray onto the metal pin.

b. Press down on the white securing pins to secure the tray.

7 Replace the reagent refrigerator large cover.

8 Close the upper cover.

9 Select **Task Completed**.

Clean the Interior of the STAT Table Compartment

Condensation forms inside the STAT table compartment, caused by exposure to the outside air.

Keep the STAT table compartment cover in position to diminish the amount of condensation formed.

Clean the interior of the compartment when a reagent or sample is spilled, or as needed after inspection.

If bacterial contamination is suspected, or mold is observed, contact Beckman Coulter for the decontamination procedure.

⚠ Caution

When you wipe the bar code reader glass window inside the STAT table compartment, clean up and dry the glass window completely.

Materials Required:

- Clean, dry, lint-free absorbent tissue
- Alcohol prep pads (70% Isopropyl alcohol)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Remove the large STAT table cover.

4 Remove the STAT table by lifting the white securing pins until they unclip from the base. Lift the table up from the center, and gently place the table in a safe place.

5 Wipe off the condensation and stains on the wall, bottom, and central area inside the STAT table compartment with a clean, dry, lint-free absorbent tissue. Also wipe off the condensation and stains on the removed STAT table.

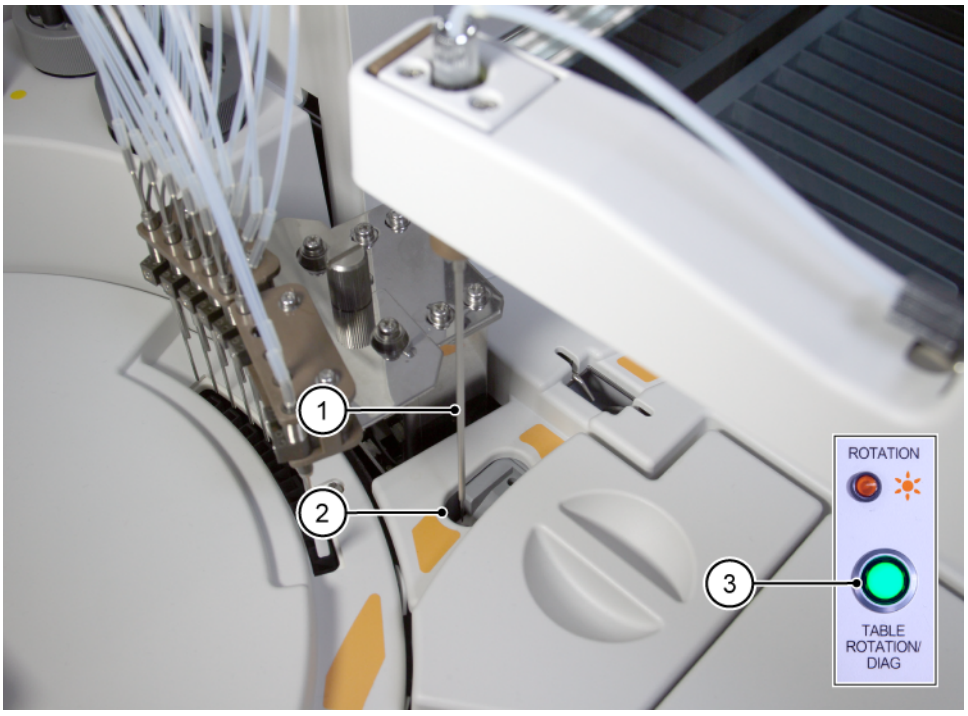
6	Wipe the wall, bottom, and central area inside the STAT table compartment and the STAT table with an alcohol prep pad (70% Isopropyl alcohol).
7	Place the STAT table in the STAT table compartment. Align the guide hole on the STAT table with the guide pin and then press down on the white securing pins to secure the STAT table.
8	Place the large STAT table cover in the original position.
9	Close the upper cover.
10	Select **Task Completed**.

Clean the Sample Probe Wash Well

A dirty sample probe wash well can cause an incorrectly cleaned sample probe, which can then contaminate samples.

To maintain the reliability of the analyzer and prevent contamination, clean the sample probe wash well as needed.

Figure 165 Sample Probe Wash Well



1. Sample probe
2. Sample probe wash well
3. TABLE ROTATION/DIAG button with indicator light

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Select **Move Probes**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

Important

While cleaning the interior of the wash well, avoid touching the sample probe.

5 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into the sample probe wash well.

6 Use a cotton-tipped applicator to clean the well.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. All probes move back to the home position over the wash wells.

8 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

9 For **Repetitions**, confirm that the value is 1, and then select **OK**.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. After initialization, the analyzer primes water through the probes and wash wells. Inspect the sample probe wash well visually for correct drainage. If drainage is poor, repeat steps 3 to 9.

11 Close the upper cover.

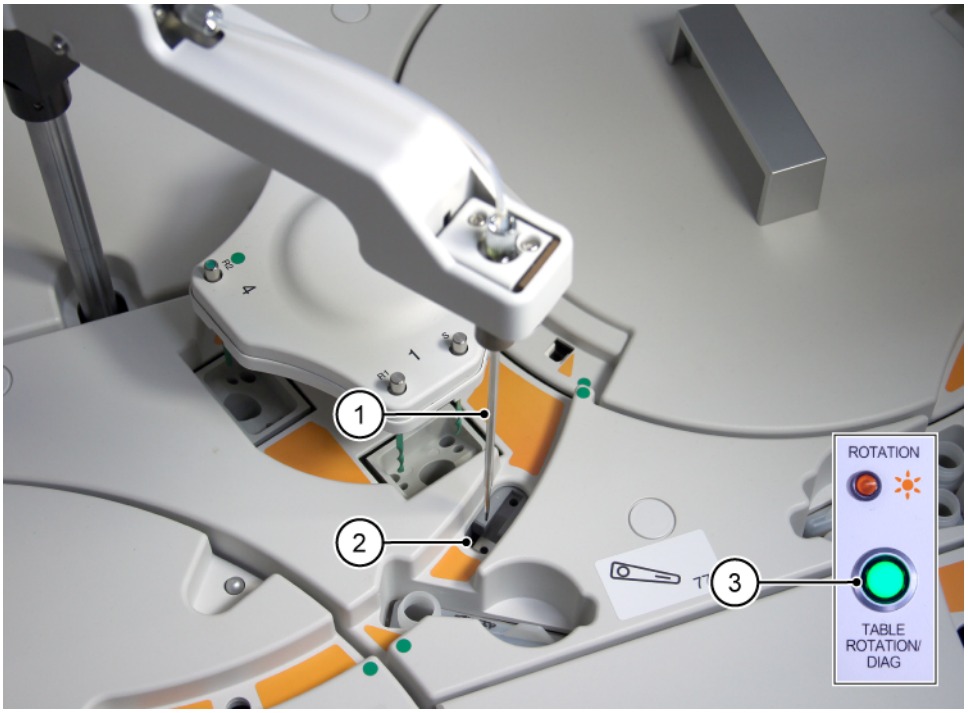
12 Select **Task Completed**.

Clean the Reagent Probe Wash Well

Dirty reagent probe wash well can cause an incorrectly cleaned reagent probe, which can then contaminate reagents.

To maintain the reliability of the analyzer and prevent contamination, clean the reagent probe wash well as needed.

Figure 166 Reagent Probe Wash Well



1. Reagent probe
2. Reagent probe wash well
3. TABLE ROTATION/DIAG button with indicator light

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Select **Move Probes**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

Important

While cleaning the interior of the wash well, avoid touching the reagent probe.

5 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into the reagent probe wash well.

6 Use a cotton-tipped applicator to clean the well.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. All probes move back to the home position over the wash wells.

8 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

9 For **Repetitions**, confirm that the value is 1, and then select **OK**.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
After initialization, the analyzer primes water through the probes and wash wells. Inspect the probe wash wells visually for correct drainage. If drainage is poor, repeat the previous steps.

11 Close the upper cover.

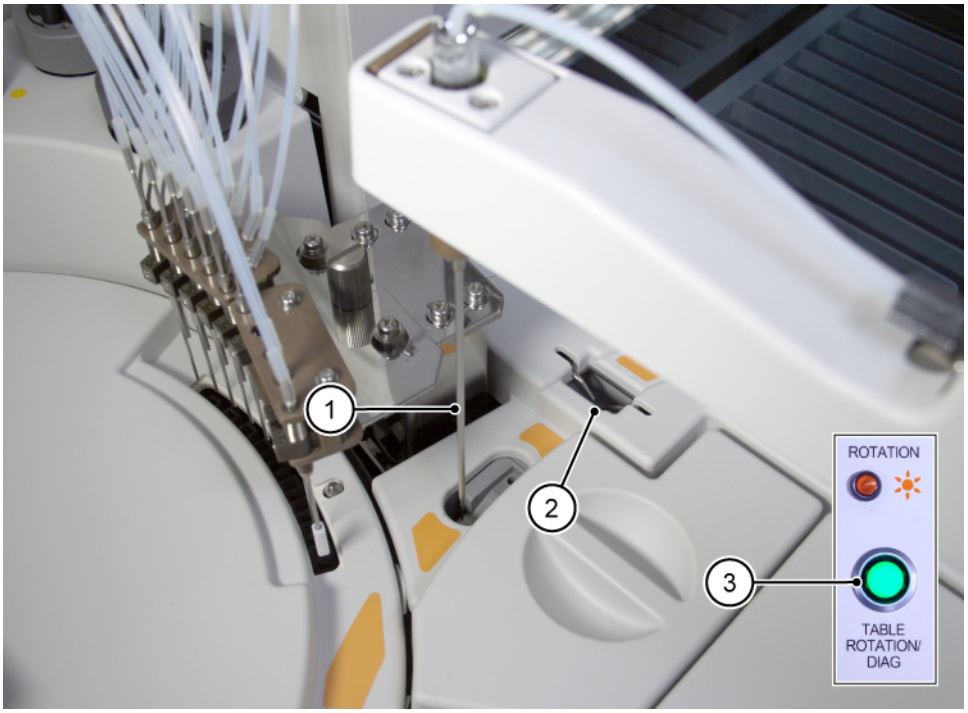
12 Select **Task Completed**.

Clean the Whole Blood Wash Well

A dirty whole blood wash well can cause an incorrectly cleaned sample probe, which can then contaminate samples.

To maintain the reliability of the analyzer and prevent contamination, clean the whole blood wash well as needed.

Figure 167 Whole Blood Wash Well



1. Sample probe
2. Whole blood wash well
3. TABLE ROTATION/DIAG button with indicator light

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Select **Move Probes**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

Important

While cleaning the interior of the wash well, avoid touching the sample probe.

5 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into the whole blood wash well.

6 Use a cotton-tipped applicator to clean the well.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. All probes move back to the home position over the wash wells.

8 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

9 For **Repetitions**, confirm that the value is 1, and then select **OK**.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. After initialization, the analyzer rotates the sample probe to the whole blood wash well position, and then primes water through the probe and whole blood wash well. The sample probe moves deeply into the wash well for cleaning. Inspect the whole blood wash well visually for correct drainage. If drainage is poor, repeat steps 3 through 9.

11 Close the upper cover.

12 Select **Task Completed**.

Clean the Mix Bar Wash Wells

In normal operation, the mix bar wash wells clean the outside surface of each mix bar by washing in diluted Beckman Coulter Wash Solution (1%) and then rinsing with deionized water.

Dirty wash wells can cause incorrectly cleaned mix bars, which can cause carryover problems.

To maintain the reliability of the analyzer and prevent contamination, clean the wash wells as needed.

Materials Required:

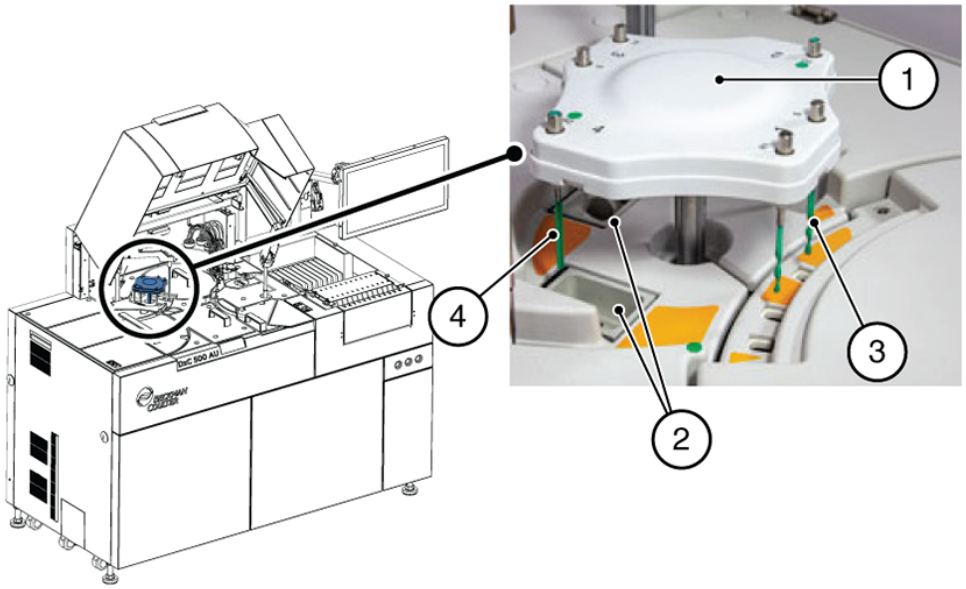
- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- Cotton-tipped applicator
- Disposable pipette

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Manually turn the mix bar subsystem so that the mix bars are not over the wash wells.

Figure 168 Mix Bar Wash Wells



1. Mix bar subsystem
2. Mix bar wash wells
3. Spiral-shaped mix bar (R1/S position)
4. L-shaped mix bar (R2 position)

Caution

Do not spill diluted cleaning solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

4 Using a pipette, dispense freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into each mix bar wash well.

5 Use a cotton-tipped applicator to clean each well. Use a different cotton-tipped applicator for each wash well to avoid any contamination.

6 Turn the mix bar subsystem so that the mix bars are over the mix bar wash wells.

7 Select **Confirm Mix Bars**.
The analyzer displays the Confirm Mix Bars dialog.

8 For **Repetitions**, confirm that the value is **3**, and then select **OK**.

9 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The mix bar subsystem initializes and performs a sequence.

10 Visually inspect the mix bar wash wells for correct water drainage. If drainage is poor, repeat steps 3 to 9.

11 Close the upper cover.

12 Select **Task Completed**.

Clean the Reagent Probe

Caution

If the reagent probe is contaminated or stained, carryover between reagents can occur. To prevent contamination and to provide correct analysis and results, clean the reagent probe as needed.

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- Stylet 0.3 mm diameter

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

3 For **Repetitions**, confirm that the value is 1, and then select **OK**.

4 Open the upper cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. When you press the **TABLE ROTATION/DIAG** button, the reagent probe initializes, then drains the deionized water in the probe.

6 Unscrew the connector above the probe. Allow the fluid to drain completely.

Important

When handling the probe, do not bend or damage the probe tip.

7 Lift the probe from the arm.

8 Wipe the tip of the probe with an alcohol prep pad.

9 Carefully insert the stylet into the probe tip to remove the obstruction.

10 Return the probe to its arm and tighten the connector over the top.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Watch the dispense to confirm that you reinstalled the probe correctly.

12 If the water is spraying or not dispensing straight from the probe tip, replace the probe after completing this maintenance task.

13 Close the upper cover.

14 Select **Task Completed**.

Important

If the water was spraying or not dispensing straight from the probe tip, replace the reagent probe after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace a Reagent Probe**.
2. Follow the steps on the Task page.

15 Perform QC, inspect the data, and recalibrate if necessary.

Clean the Rack Input and Output Area and the Rack Buffer Area

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)

Note

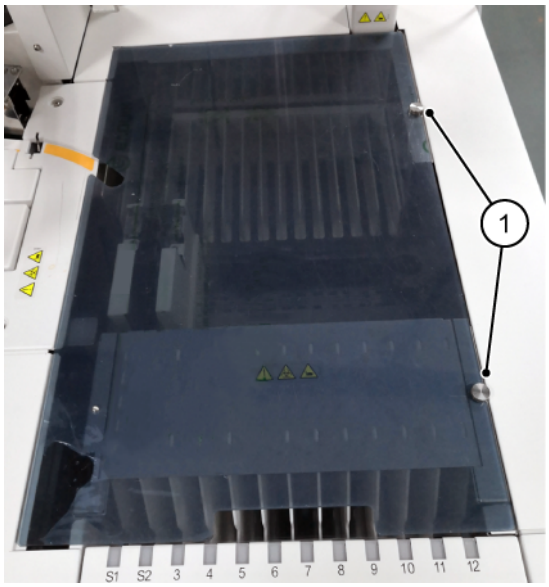
When you clean the rack input and output areas, do not touch the sensors.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Loosen the two thumbscrews on the right that are holding the sample handler top cover, and remove the sample handler top cover.

Figure 169 Thumbscrews Holding the Sample Handler Top Cover

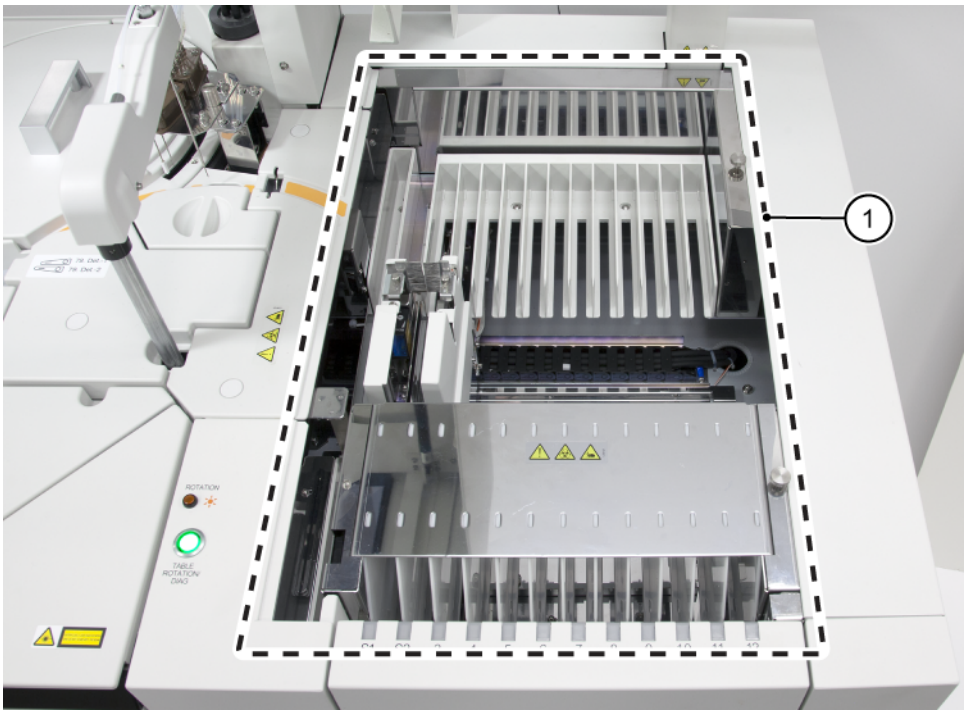


1. Two thumbscrews holding the sample handler top cover

4 Open the sample handler door.

5 Wipe the areas with an alcohol prep pad (70% Isopropyl alcohol).

Figure 170 Rack Input and Output Area and Rack Buffer Area



1. Wipe these areas.

6 Put the top cover on the sample handler, and tighten the screws.

7 Close the sample handler door.

8 Close the upper cover.

9 Select **Task Completed**.

Perform a Photocal

When the procedure for cleaning cuvettes with external solution is finished, perform a photocal to confirm the integrity of the cuvettes. The photocal detects dirt, stains, or scratches, and identifies cuvettes that require cleaning or replacing. Clean or replace cuvettes that show an abnormal value during the photocal.

When performing the Clean Cuvettes with External Solution task, you can start the photocal from the Deep Clean Cuvettes dialog. If you selected **After the procedure is complete, perform a photocal** in the Deep Clean Cuvettes dialog, skip the first four steps and start at View Photocal Results. For more information, refer to Clean Cuvettes with External Solution.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

If you did not select the photocal with the procedure for cleaning cuvettes with external solution, you can start the photocal using the following procedure.

Important

For optimal results, only perform a photocal measurement when the photometer lamp is stabilized after the analyzer starts up. The photometer lamp needs approximately 20 minutes to stabilize (warm up) after the analyzer starts up.

1 Confirm that the analyzer is in the *Running* (*Standby*) state.

2 Close the upper cover.

3 Select **Photocal**.
The analyzer displays the Photocal dialog.

4 Make sure **Check All Cuvettes** is selected and select **OK**.
The analyzer starts photocal for all cuvettes.

Note

If you are performing a photocal after performing the Clean or Replace Individual Cuvettes maintenance task, you can perform the photocal on an individual cuvette instead.

The photocal takes approximately 24 minutes to complete for all cuvettes. The analyzer automatically moves to the *Running* state after the photocal is complete.

View Photocal Results

If a cuvette fails the photocal, perform the following corrective action.

1. To view the details and status of the photocal performed most recently, select **Photocal Results**
   The analyzer displays the Photocal Results page.

   Note

   To view a detailed history of photocal results for a cuvette in the Cuvette Details dialog, select the cuvette number in the Unit section and select **Details**.

2. Clean or replace any cuvettes identified with Mean Check Error or Cuvette Check Error after completing this maintenance task.

3. If any cuvettes fail the Lamp Check, replace the photometer lamp after completing this maintenance task.

   The analyzer displays cuvettes with a Lamp Check Error in red. The photometer lamp is deteriorating and needs replacement.

4. Perform QC, inspect the data, and recalibrate if necessary.

5. Select **Task Completed**.

   Important

   Clean or replace any cuvettes identified with Mean Check Error or Cuvette Check Error after you select **Task Completed**.

   1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean or Replace Individual Cuvettes**.
   2. Follow the steps on the Task page.

   Important

   If any cuvettes failed the Lamp Check, replace the photometer lamp after you select **Task Completed**.

   1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the Photometer Lamp**.
   2. Follow the steps on the Task page.

   Wait for the lamp to come up to the correct temperature before performing another photocal during the Replace the Photometer Lamp procedure.

   — Wait for the lamp to reach the correct temperature.
   — Repeat the photocal on each cuvette that failed the Mean Check or Cuvette Check.
   — Repeat the photocal on all cuvettes if any cuvettes failed the Lamp Check and the lamp was replaced, or numerous cuvettes failed the Mean Check or Cuvette Check.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Air Filters

Before performing this procedure, print a copy of the procedure from the PDF version of the DxC 500 AU Instructions for Use. During the procedure, you will need to shut down the chemistry analyzer, and the on-screen instructions will no longer be available.

The air filters prohibit dust and other contaminates from entering the analyzer. If a filter is torn, replace it.

Caution

Do not run the analyzer without filters in position. If filters are missing, heaters and the power supplies get dusty, which can cause a short circuit and fire.

Materials Required:

- Air filters

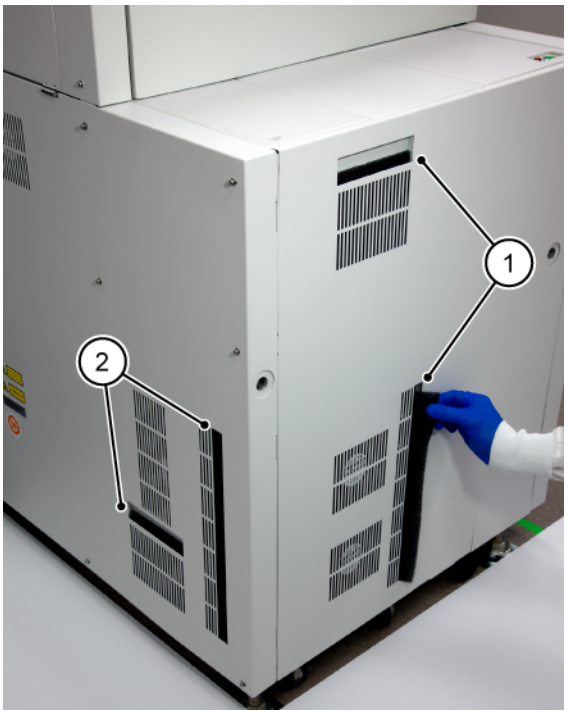
1. Shut down the chemistry analyzer by pressing the Analyzer Stop button to completely turn off the power, including the fans. Refer to Shutting Down the Chemistry Analyzer by Pressing the Analyzer Stop Button.

   An analyzer stop is necessary to avoid the risk of the fans bringing dust into the analyzer while the filters are removed.

2. Remove the two air filters at the back of the analyzer.

3 Remove the two air filters on the left side of the analyzer.

Figure 171 Air Filter Locations



1. Air filters (on the side of the analyzer)
2. Air filters (at the back of the analyzer)

4 Replace the filters that are torn.

5 Press the Reset button (white) to turn on the main power, and then wait 5 seconds.

6 Press the On button with power indicator light (green).
The lamp turns on and the software loads. The analyzer is in the *Starting* (*Warmup*) state for a maximum of about 1.5 hours.

7 After the required 20-minute lamp warm-up time, wait until the temperature of the cuvette wheel is 37 °C.

To view the cuvette wheel temperature on the Custom Diag page, select **Menu** > **Advanced** > **Chemistry Diagnostics** > **Custom Diag**.

Tip

To bypass the *Starting* (*Warmup*) state after the required 20-minute lamp warm-up time and the temperature of the cuvette wheel reaches 37 °C. select **Stand By**.

8 Select **Task Completed**.

Clean or Replace Individual Cuvettes

Caution

Confirm that 88 cuvettes are correctly installed in the cuvette wheel. If one of the cuvettes is missing, the mixture, reagent, or diluted wash solution spills into the cuvette wheel, causing a cuvette wheel overflow and preventing successful analysis.

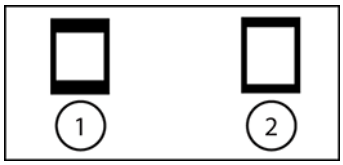
Caution

Do not scratch the cuvettes when replacing cuvettes on the cuvette wheel. Never touch the photometric surface of a cuvette. If the photometric surface is stained, analysis data is inaccurate. Wear gloves when handling the cuvettes.

Caution

Cuvettes with the same outer dimensions might have different interior dimensions. The DxC 500 AU uses cuvette part number MU846500 with an interior dimension of 5 mm x 5 mm. Do not use a cuvette from another AU analyzer on the DxC 500 AU. Use of a cuvette other than the DxC 500 AU cuvette causes erroneous results.

Figure 172 Cuvette Interior Dimensions



1. For DxC 500 AU (PN MU846500 5 mm x 5 mm)
2. Example for other AU systems

Clean or replace individual cuvettes that fail the weekly photocal procedure. If only a few cuvettes need cleaning or replacing after a cuvette wheel overflow, you can use this procedure.

Materials Required:

- Cuvettes
- Cotton-tipped applicator
- Clean, dry, lint-free absorbent tissue
- Freshly prepared diluted Beckman Coulter Wash Solution (2%)
- Plastic container
- Sonicator

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Open the rear cover of the analyzer.

4 Loosen the knob of the wash nozzle subsystem. Without disconnecting the tubing, remove the nozzle portion from its stand and hang it on the nearby hook.

Refer to the video in system help.

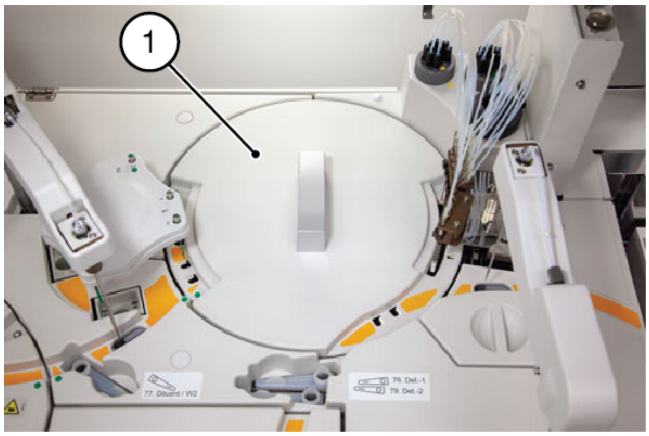
Figure 173 Removing the Wash Nozzle Subsystem

5 Remove the two mix bars that are above the cuvette wheel from the mix bar subsystem.

6 Lift the cuvette wheel cover, carefully remove it from the analyzer, and set it aside.

Refer to the video in system help.

Figure 174 Removing the Cuvette Wheel Cover



1. Cuvette wheel cover

7 Locate the failed cuvettes. Every 10th cuvette is numbered.

8 Using two cotton-tipped applicators, gently insert them in the cuvette to be removed and pull up.

An alternate method is to use two applicators to pinch the cuvette and pull up.

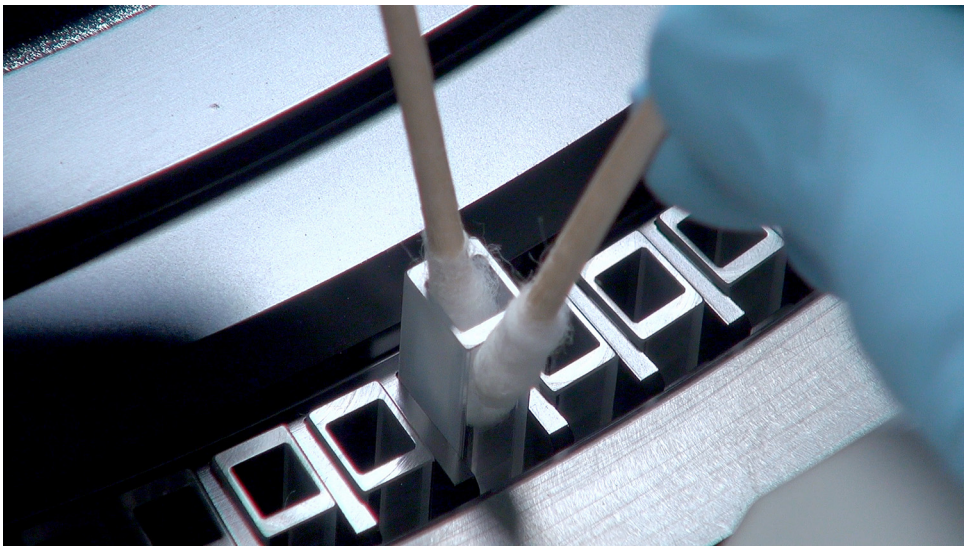
Note

If you have difficulty inserting the applicators into the cuvette or lifting the cuvette with the applicators, dampen the cotton tip with deionized water before using the applicators.

Refer to the video in system help.

Figure 175 Removing the Cuvette

Figure 176 Cotton-tipped Applicators



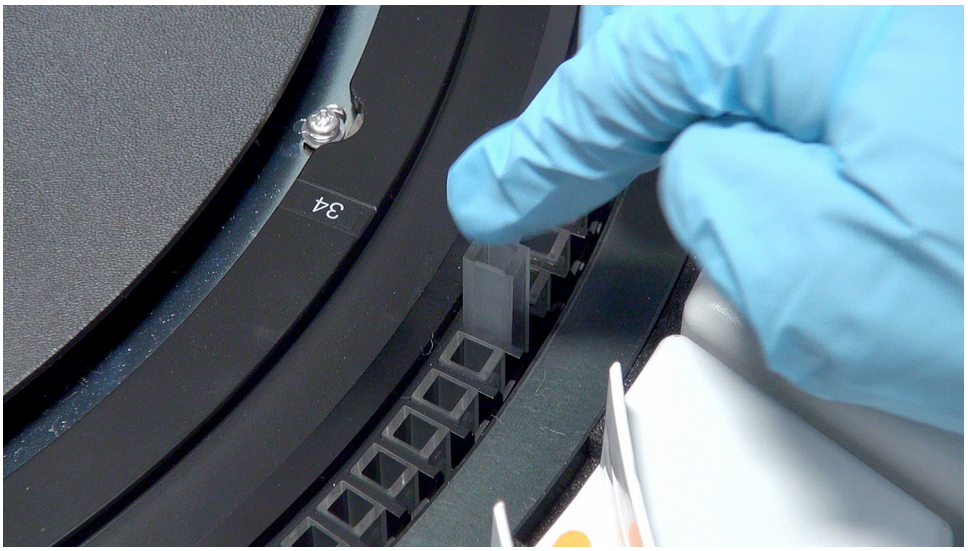
9 Determine if the cuvettes need replacing or cleaning.

— To replace individual cuvettes: Insert the new cuvette into the wheel. Gently push the cuvette completely into the wheel.
— To clean individual cuvettes: Sonicate cuvettes in freshly prepared diluted wash solution (2%) for 15 minutes. If a sonicator is not available, soak them in freshly prepared diluted wash solution (5%) overnight. Rinse the cuvette in deionized water. Allow the cuvettes to completely dry.

10 Put the new or cleaned cuvettes into their positions. Gently push the cuvettes completely into the wheel.

Refer to the video in system help.

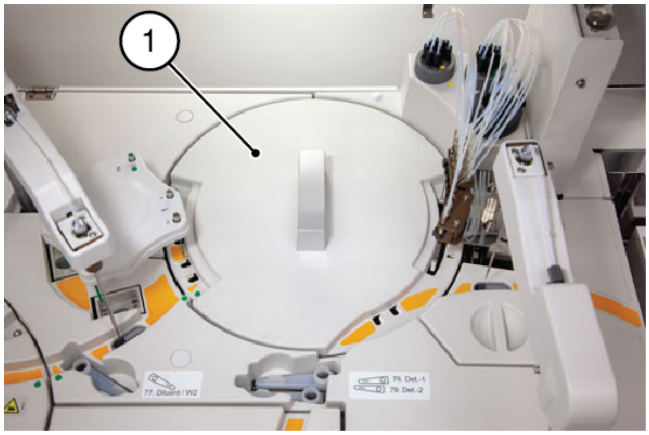
Figure 177 Putting a Cuvette Into Position



11 Put the cuvette wheel cover back in its original position.

Refer to the video in system help.

Figure 178 Putting the Cuvette Wheel Cover Back in its Original Position



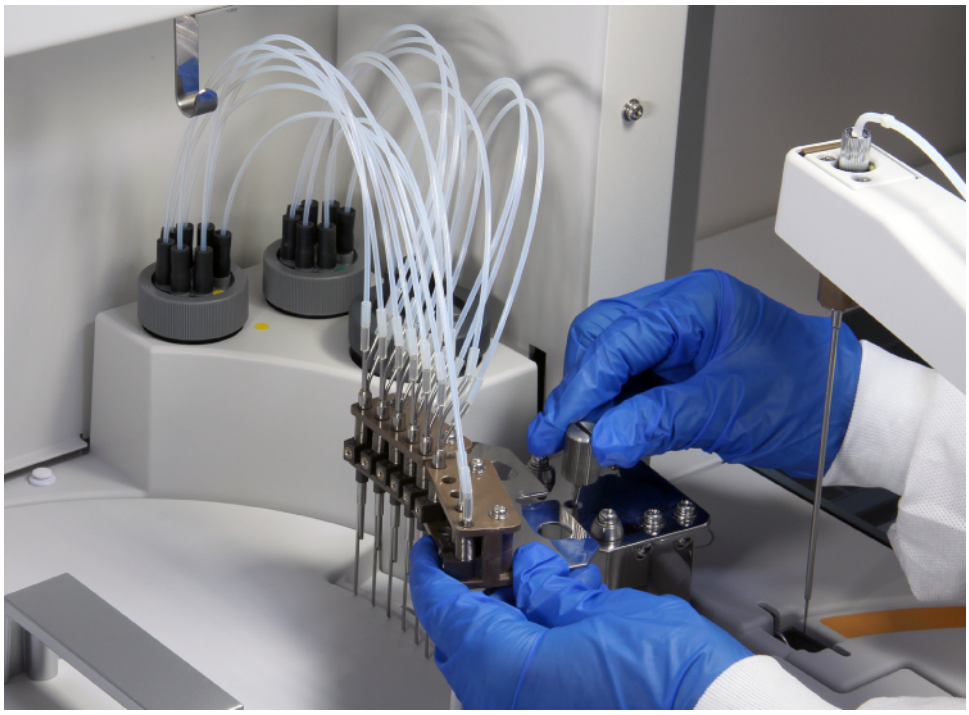
1. Cuvette wheel cover

12 Put the R1 and S mix bars back into the mix bar subsystem.

13 Put the wash nozzle subsystem back in its original position.

Refer to the video in system help.

Figure 179 Putting the Wash Nozzle Subsystem Back in its Original Position



14 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

15 For **Repetitions**, confirm that the value is 1, and then select **OK**.

16 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Watch as the wash nozzle subsystem moves, and confirm that the downward motion is not inhibited.

17 Select **Task Completed**.

Important

After you select **Task Completed**, perform a photocal on the individual cuvette.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Perform a Photocal**.
2. Follow the steps on the Task page.

Replace the Deionized Water Filter, Sample Probe Filter, and O-ring

Materials Required:

- Sample probe filter
- Deionized water filter
- O-ring

1 Remove the filters.

For information on how to remove the filters, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

Important

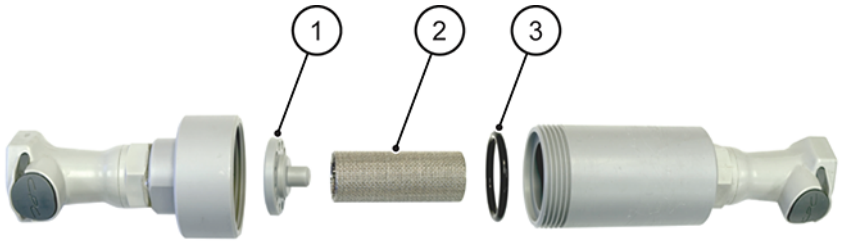
By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

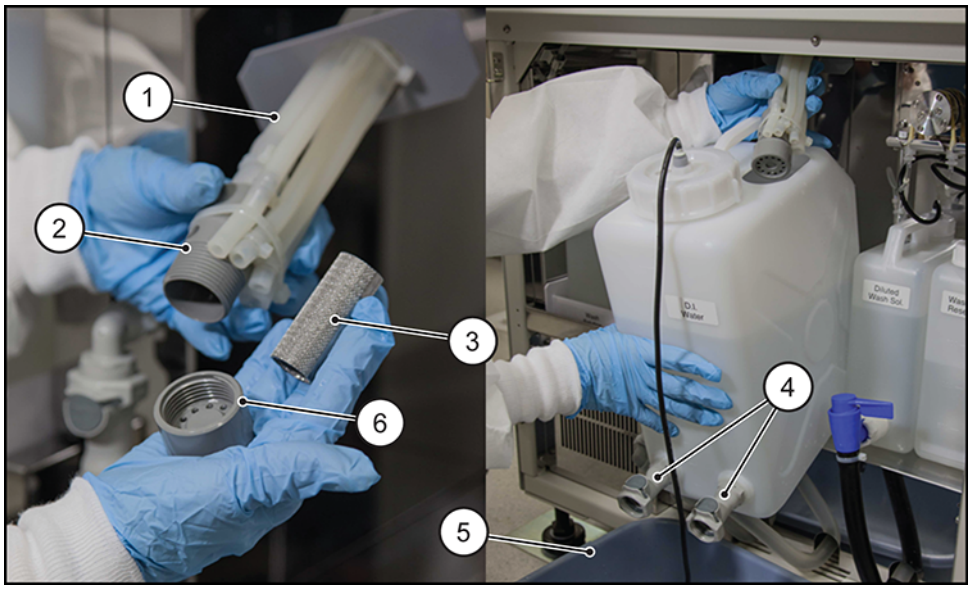
     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Figure 180 Parts in the Sample Probe Filter Case



1. Filter positioning insert
2. Sample probe filter
3. O-ring

Figure 181 Deionized Water Filter



1. Water supply tubing
2. Sample probe filter case
3. Deionized water filter
4. Quick disconnect joint
5. Basin
6. Filter case cap

2 When the filters are removed for cleaning, inspect them. If the filters cannot be cleaned successfully, replace them.

3 Select **Task Completed**.

Important

After you select **Task Completed**, replace the O-ring.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the O-rings in the Water Supply Tube Mounting Joint**.
2. Follow the steps on the Task page.

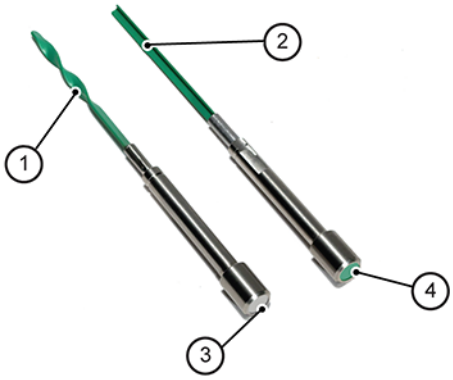
Replace the Mix Bars

Replace the mix bars if they are stained, damaged, or if the fluororesin coating is chipped.

Materials Required:

- S and R1: Spiral-shaped mix bar
- R2: L-shaped mix bar

Figure 182 Mix Bars



1. Spiral-shaped mix bar
2. L-shaped mix bar
3. Silver
4. Green

Caution

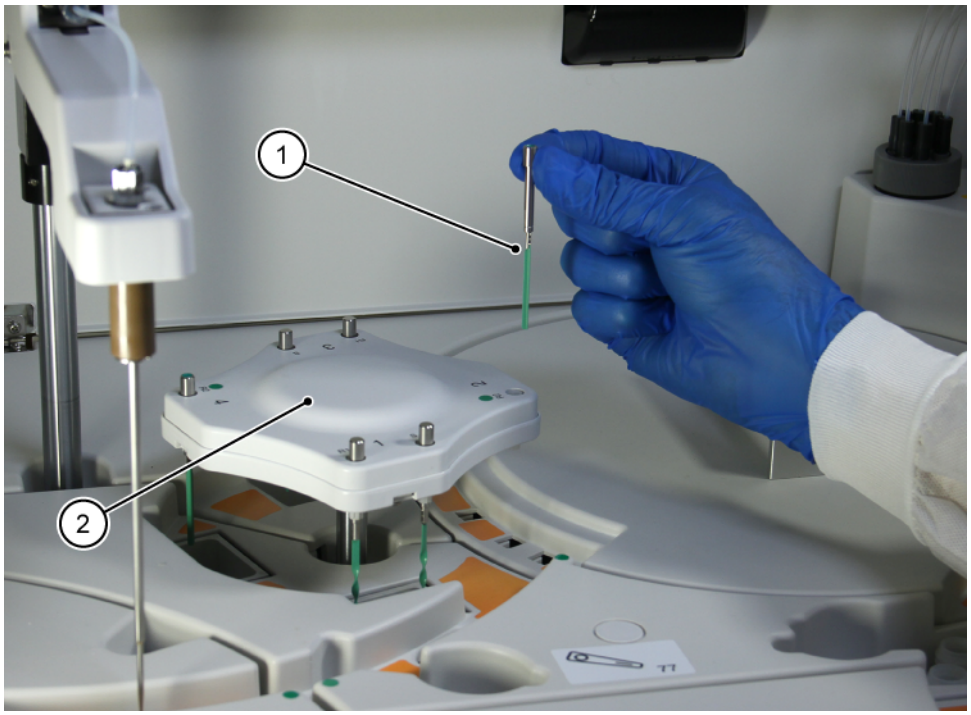
Do not operate the mix bar subsystem when replacing a mix bar. Replacement of the mix bar during operation can cause an injury.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Pull out the mix bar to be replaced.

Figure 183 Remove a Mix Bar



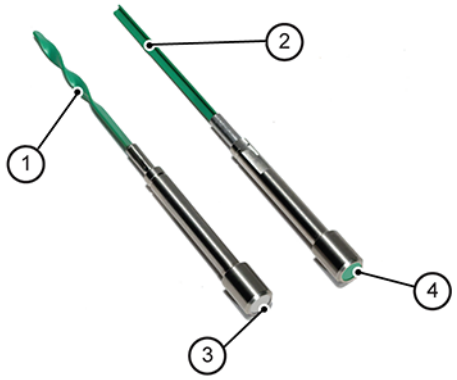
1. Mix bar
2. Mix bar subsystem

4 Insert a new mix bar in the correct position: the spiral-shaped mix bar in the position labeled R1/S and the L-shaped mix bar in the position labeled R2. Rotate the mix bar slightly to insert it completely.

Caution

Do not scratch the mix bar when inserting the mix bar into the mix bar subsystem. Scratched or damaged mix bars can cause sample or reagent carryover and affect results.

Figure 184 Mix Bars



1. Spiral-shaped mix bar
2. L-shaped mix bar
3. Silver
4. Green

Caution

The shapes of the mix bars differ between mix bar subsystem. Placing the spiral and L-shaped mix bars in the wrong mix bar subsystem can affect analysis results. The following are the correct placements of each type of mix bar:

- **R1 and S positions: Spiral-shaped mix bar**
- **R2 positions: L-shaped mix bar**

5 Select **Confirm Mix Bars**. The analyzer displays the Confirm Mix Bars dialog.

6 For **Repetitions**, enter **3**, and then select **OK**.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The mix bar subsystem initializes and performs a sequence three times.

8 Close the upper cover.

9 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Packing in the Wash Nozzle Tube Mounting Joints

When inspecting the wash nozzle tube mounting joints, replace the packing if it is overstretched, cracked, or torn.

Materials Required:

- Packing
- Pair of tweezers

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the rear cover of the analyzer.

3 Select **Drain Wash Nozzles**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

The liquid drains from the tubing.

Caution

Drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water beforehand, the water spills out of the nozzle.

If the water spills onto the cuvettes, clean the cuvettes and cuvette wheel after completing this maintenance task.

5 Remove all the wash nozzle tube mounting joints.

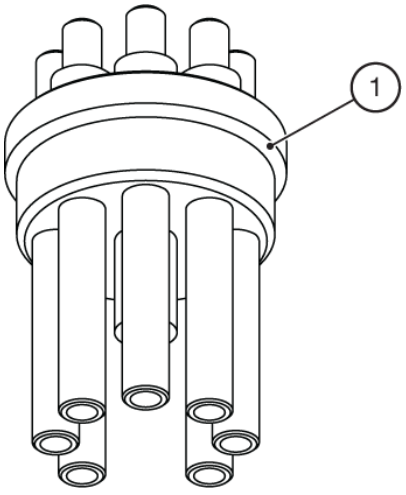
6 Remove the packing with tweezers from each tube mounting joint.

7 Install new packing on each tube mounting joint.

Important

Place the packing in the groove of each tube mounting joint.

Figure 185 Wash Nozzle Tube Mounting Joint



1. Packing of the tube mounting joint

8 Install all the wash nozzle tube mounting joints into their original positions.

Important

Install the tube mounting joints in the correct positions. The tube mounting joints are color-coded to match where the placement of each joint belongs on the analyzer.

Important

Tighten the cap of each tube mounting joint firmly when replacing the tube mounting joints, otherwise leaks can result.

9 Select **Prime Wash Nozzle**. The analyzer displays the Prime Wash Nozzle dialog.

10 For **Repetitions**, enter **5**, and then select **OK**.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Confirm that the wash nozzle subsystem is operating correctly.

12 Close the rear cover.

13 Select **Task Completed**.

Important

If the water spilled onto the cuvettes when draining the wash nozzles, clean the cuvettes and cuvette wheel after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean the Cuvettes and Cuvette Wheel**.
2. Follow the steps on the Task page.

Replace a Reagent Probe

The reagent probe delivers precise quantities of reagent to the cuvettes. A clogged, bent, or damaged probe affects correct analysis.

If cleaning does not remove contamination from the probe, replace the probe.

Materials Required:

- Reagent probe

Important

Confirm that the reagent probe is above the wash well and then replace it with a new one. Deionized water drips from the probe tip as the connector is unscrewed.

Important

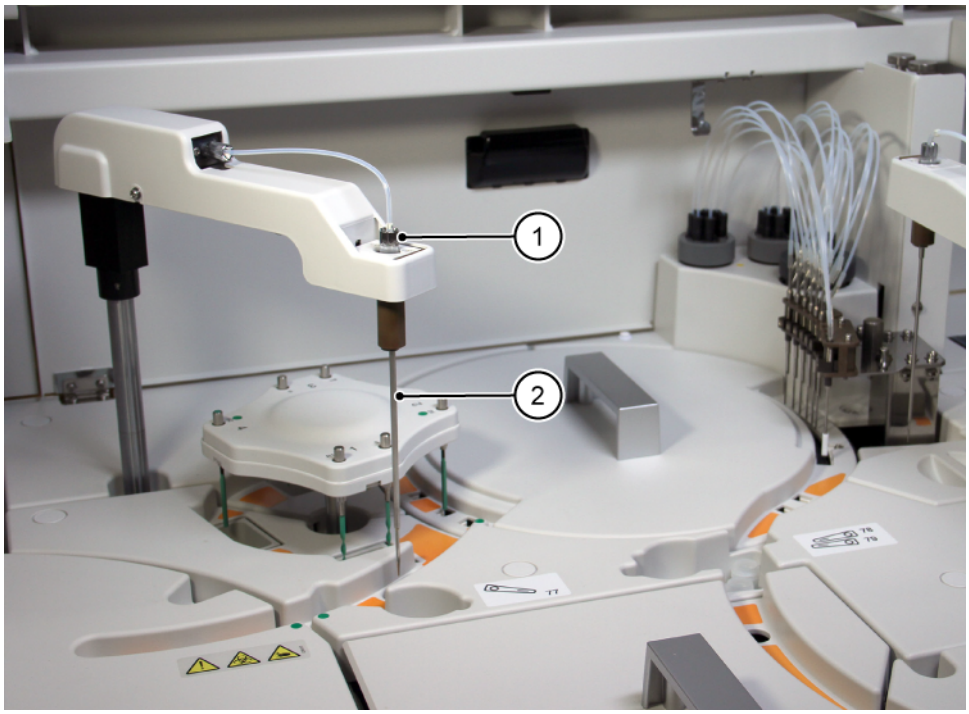
When handling the probe, do not bend or damage the probe tip.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Unscrew the connector above the probe.

Figure 186 Remove a Reagent Probe



1. Reagent probe connector
2. Reagent probe

4 Allow water to drip from the probe, then lift the probe from the arm.

5 Place the new probe into its position and tighten the connector over the top. Firmly tighten the connector so that no leaks occur.

Note

If the probe connector does not fit, confirm that you are replacing the correct probe type. The sample probe has a smaller diameter than the reagent probe.

6 Select **Prime Reagent Probe and Syringe**.
The analyzer displays the Prime Reagent Probe and Syringe dialog.

7 For **Repetitions**, enter **3**, and then select **OK**.

8 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Deionized water is dispensed from the probe tip. Confirm that the deionized water dispenses in a thin straight stream, and does not spray or dispense at an angle.

9 Close the upper cover.

10 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Reagent Probe Tubing

Replace the reagent probe tubing if the tubing leaks or breaks.

Materials Required:

- Reagent probe tubing

Important

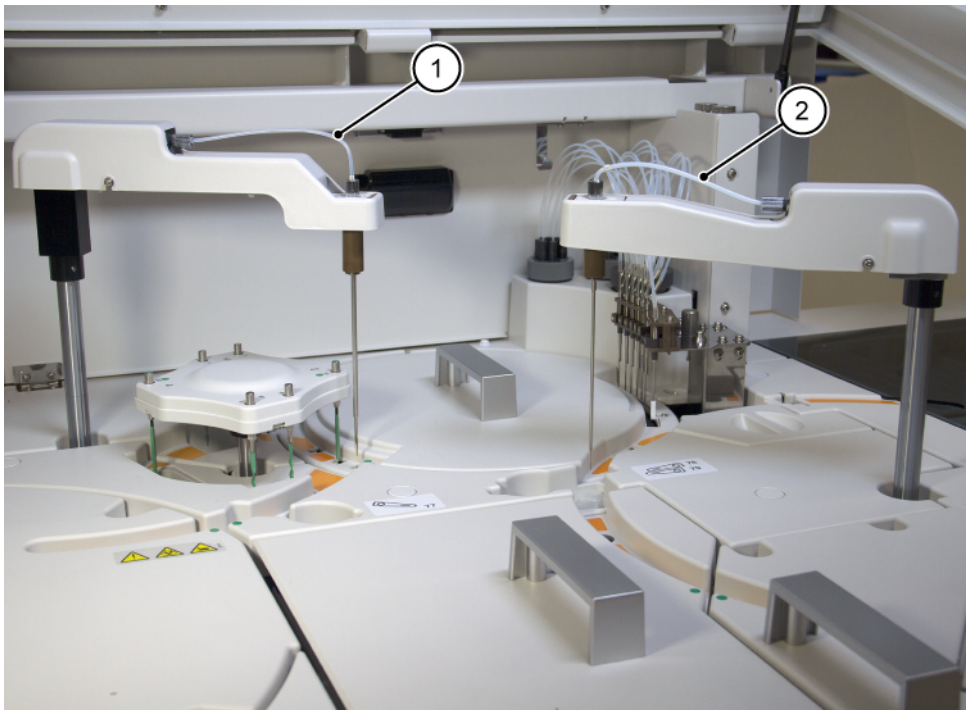
Before disconnecting the tubing, confirm that the probe is positioned over the wash well. Fluid from the probe can drip.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Loosen the connectors on both sides of the probe tubing to remove it.

Figure 187 Probe Tubing



1. Reagent probe tubing
2. Sample probe tubing

4 Tighten the new tubing connectors to secure both ends of the probe tubing. Tighten the connectors firmly so that no liquid leaks.

5 Select **Prime Reagent Probe and Syringe**.
The analyzer displays the Prime Reagent Probe and Syringe dialog.

6 For **Repetitions**, confirm that the value is **3**, and then select **OK**.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Confirm that the tubing is not leaking and that the probe is dispensing correctly.

8 Close all analyzer doors and covers.

9 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Reagent Syringe

If a leak, crack, or any other damage is found with the reagent syringe, replace the syringe.

If syringe performance is questionable because of abnormal data, remove and inspect the syringe.

Replace the reagent syringe if:

- There is not smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that is too hard or too loose.
- The syringe leaks even after correct installation.

Beckman Coulter recommends replacing syringes every 400,000 cycles. Replacement of syringes every 400,000 cycles provides continuous and reliable syringe performance without unexpected analyzer down-time. To view the number of cycles that a syringe has been used, select **Cycles Used**.

Replace a damaged syringe immediately, even if 400,000 cycles have not passed since the syringe was replaced.

Beckman Coulter recommends performing QC after replacing a syringe to confirm the performance of the new syringe.

Materials Required:

- Reagent syringe (R syringe)
- Clean, dry, lint-free absorbent tissue

⚠ Caution

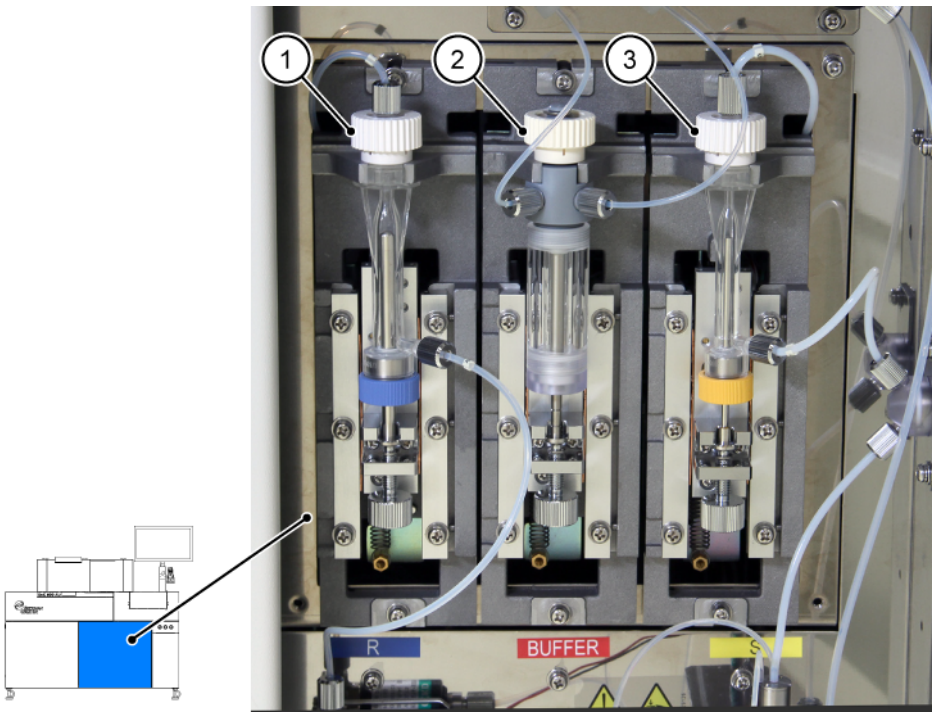
If you install the incorrect syringe, you obtain incorrect results.

Remove the Reagent Syringe

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the middle front door of the analyzer.

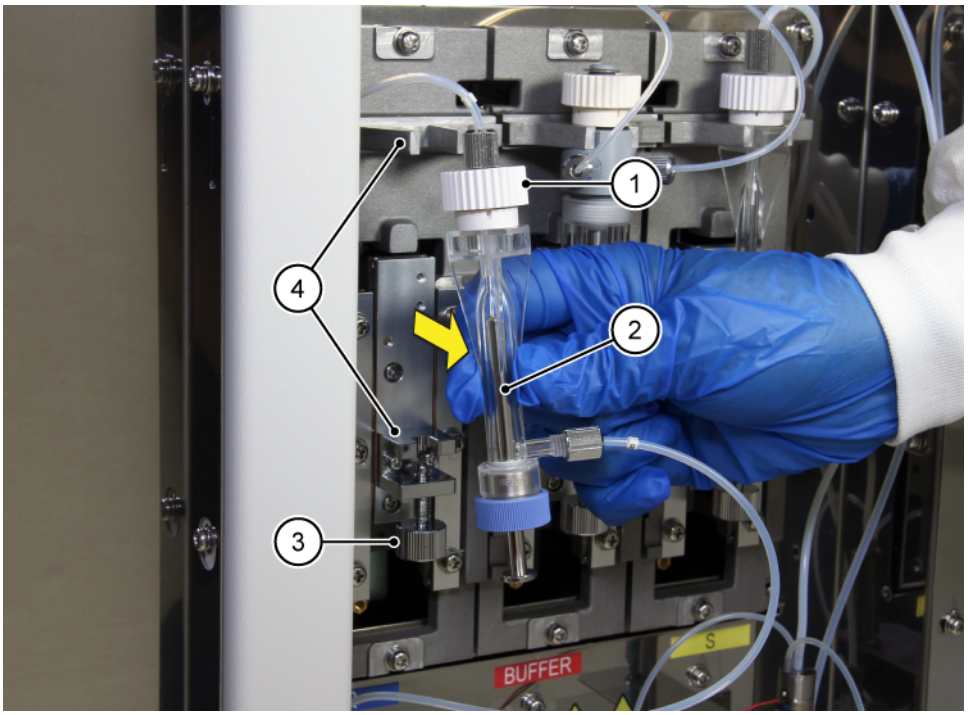
Figure 188 Location of Syringes



1. Reagent syringe (blue)
2. ISE buffer syringe (clear)
3. Sample syringe (yellow)

3 Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe from the mounting grooves.

Figure 189 Remove the Syringe



1. Top fixing nut
2. Syringe
3. Bottom piston fixing screw
4. Mounting grooves

4 Pull the syringe forward to remove it from the mounting grooves.

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

When removing the syringe, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe.

5 Loosen the connectors on the top and side of the syringe to remove the tubing.

Note

Some fluid might drip.

Install a New Reagent Syringe

1 Obtain a new syringe.

2 Screw the connectors on the top and side tubing. Do not over-tighten.

3 Install the syringe into the mounting groove. Align the syringe piston into the drive shaft.

Figure 190 Installing the Reagent Syringe Into the Mounting Groove

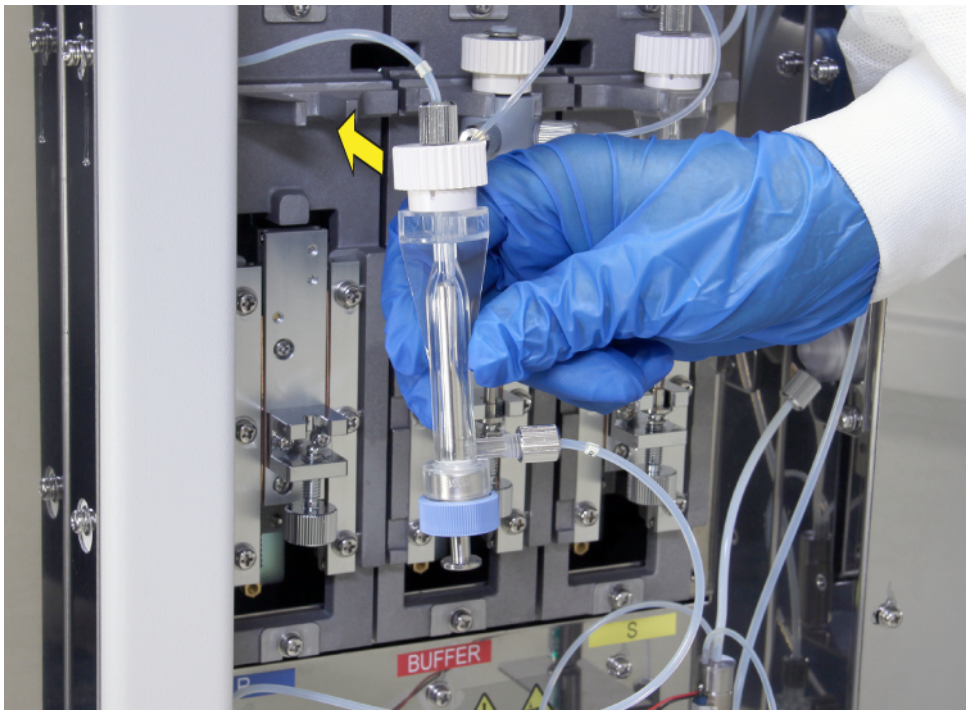
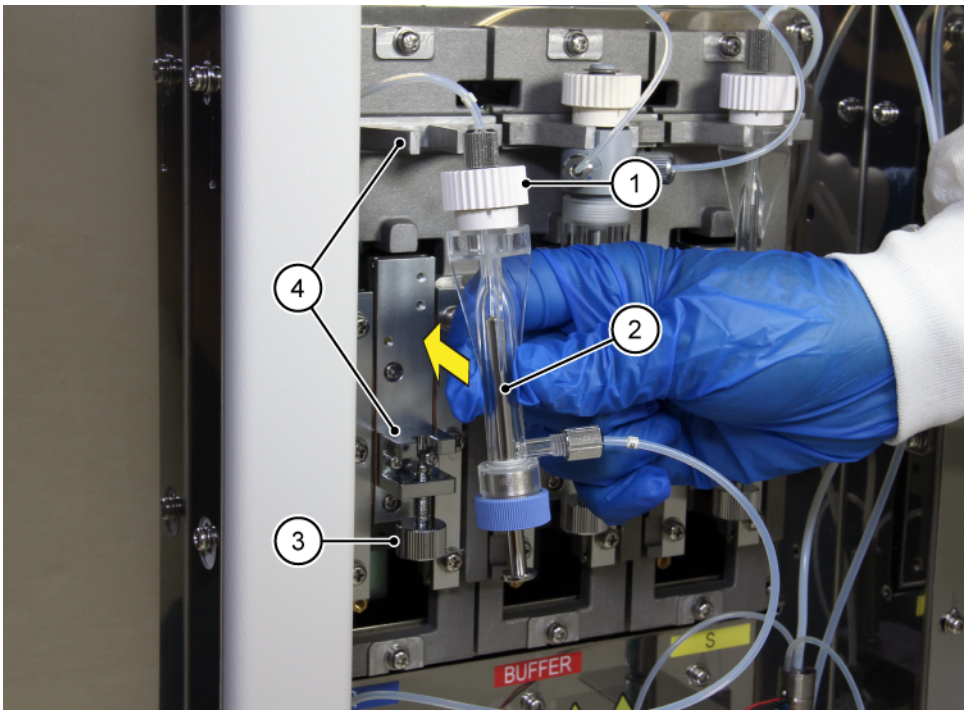


Figure 191 Installing the Syringe



1. Top fixing nut
2. Syringe
3. Bottom piston fixing screw
4. Mounting grooves

Caution

Do not allow a strong alkali, such as Beckman Coulter Wash Solution, to contact the syringe. If a strong alkali contacts the syringe, cracks can occur. If a strong alkali contacts the syringe, remove the syringe and rinse it with water.

4 Tighten the top fixing nut until you hear a clicking sound.

5 Tighten the bottom piston fixing screw.

Caution

Do not tighten the bottom piston fixing screw first, and do not press the piston when you tighten the bottom fixing screw.

Prime the New Reagent Syringe

1 After replacing the syringe, select **Prime Reagent Probe and Syringe**.
The analyzer displays the Prime Reagent Probe and Syringe dialog.

2 For **Repetitions**, confirm that the value is **3**, and then select **OK**.

3 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

4 Press the **TABLE ROTATION/DIAG** button again.

5 If there are bubbles in the syringe after the prime, repeat the prime until all bubbles are cleared.

If you cannot clear the bubbles after the prime, perform the corrective actions. For more information, refer to the following section on corrective actions if prime fails for the reagent syringe.

6 Close the middle front door of the analyzer.

7 Select **Exit Maintenance**.

8 Perform QC, inspect the data, and recalibrate if necessary.

Corrective Actions if Prime Fails for the Reagent Syringe

1 Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe from the mounting grooves.

2 Pull the syringe forward to remove it from the mounting grooves.

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

When removing the syringe, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe.

3 Slowly move the syringe piston up and down by hand. Confirm that there are no bubbles on the syringe tip.

If bubbles are there, move the piston up and down until the bubbles are purged.

Figure 192 Moving the Syringe Piston Up and Down

4 Reinstall the syringe into the mounting groove. Align the syringe piston into the drive shaft.

5 Tighten the top fixing nut until you hear a clicking sound.

6 Tighten the bottom piston fixing screw.

Caution

Do not tighten the bottom piston fixing screw first, and do not press the piston when you tighten the bottom fixing screw.

7 Close the middle front door of the analyzer.

8 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace a Sample Probe

The sample probe delivers precise quantities of sample to the cuvettes. A clogged, bent, or damaged probe affects correct analysis.

If cleaning does not remove contamination from the probe, replace the probe.

Materials Required:

- Sample probe

Important

Confirm that the sample probe is above the wash well and then replace it with a new one. Deionized water drips from the probe tip as the connector is unscrewed.

Important

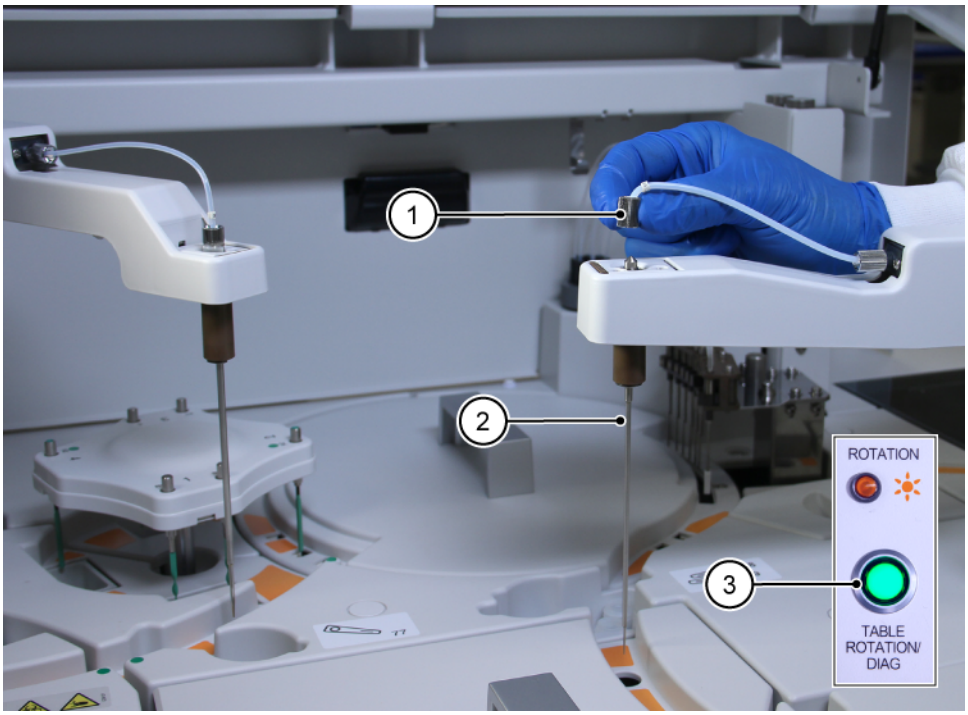
When handling the probe, do not bend or damage the probe tip.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Unscrew the connector above the probe.

Figure 193 Remove a Sample Probe



1. Sample probe connector
2. Sample probe
3. TABLE ROTATION/DIAG button with indicator light

4 Allow water to drip from the probe, then lift the probe from the arm.

5 Place the new probe into its position and tighten the connector over the top. Firmly tighten the connector so that no leaks occur.

Note

If the probe connector does not fit, confirm that you are replacing the correct probe type. The sample probe has a smaller diameter than the reagent probe.

6 Select **Prime Sample Probe**.
The analyzer displays the Prime Sample Probe dialog.

7 For **Repetitions**, enter **3**, and then select **OK**.

8 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Deionized water is dispensed from the probe tip. Confirm that the deionized water is dispensed in a thin straight stream, and does not spray or dispense at an angle.

9 Close the upper cover.

10 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Sample Probe Tubing

Replace the sample probe tubing if the tubing leaks or breaks.

Materials Required:

- Sample probe tubing

Important

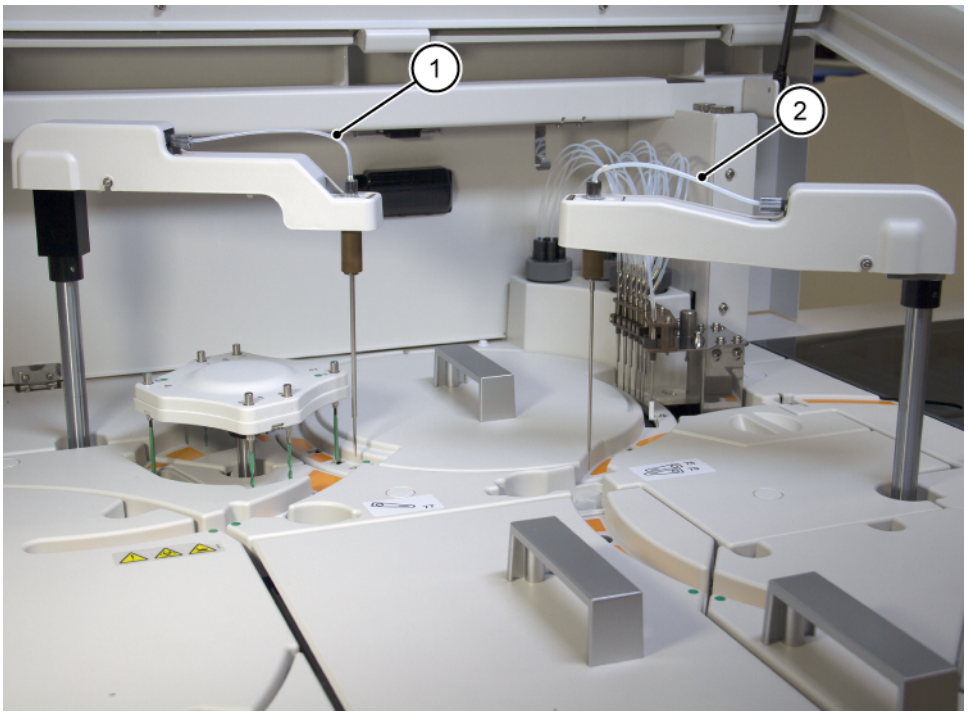
Before disconnecting the tubing, confirm that the probe is positioned over the wash well. Fluid from the probe can drip.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Loosen the connector farthest from the probe first, then loosen the connector closest to the probe, and remove the probe tubing.

Figure 194 Probe Tubing



1. Reagent probe tubing
2. Sample probe tubing

4 Tighten the new tubing connectors to secure both ends of the probe tubing. Tighten the connectors firmly so that no liquid leaks.

5 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

6 For **Repetitions**, enter 3, and then select **OK**.

7 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. Confirm that the tubing is not leaking and that the probe is dispensing correctly.

8 Close all analyzer doors and covers.

9 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Sample Syringe

If a leak, crack, or any other damage is found with the sample syringe, replace the syringe.

If syringe performance is questionable because of abnormal data, remove and inspect the syringe.

Replace the sample syringe if:

- There is not smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that is too hard or too loose.
- The syringe leaks even after correct installation.

Beckman Coulter recommends replacing syringes every 400,000 cycles. Replacement of syringes every 400,000 cycles provides continuous and reliable syringe performance without unexpected analyzer down-time. To view the number of cycles that a syringe has been used, select **Cycles Used**.

Replace a damaged syringe immediately, even if 400,000 cycles have not passed since the syringe was replaced.

Beckman Coulter recommends performing QC after replacing a syringe to confirm the performance of the new syringe.

Materials Required:

- Sample syringe (S syringe)
- Clean, dry, lint-free absorbent tissue

Caution

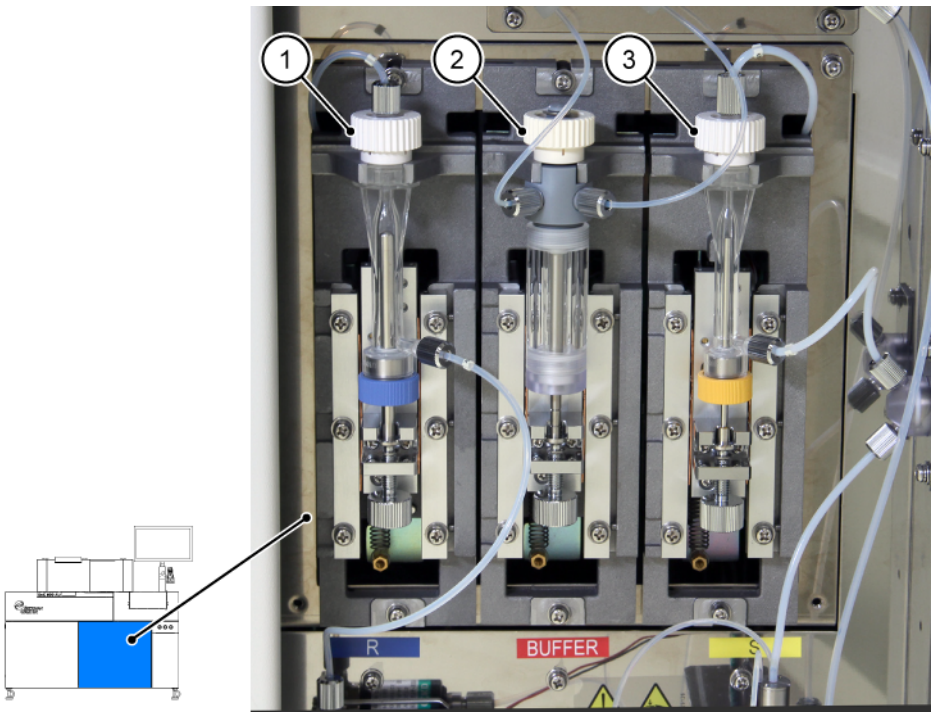
If you install the incorrect syringe, you obtain incorrect results.

Remove the Sample Syringe

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the middle front door of the analyzer.

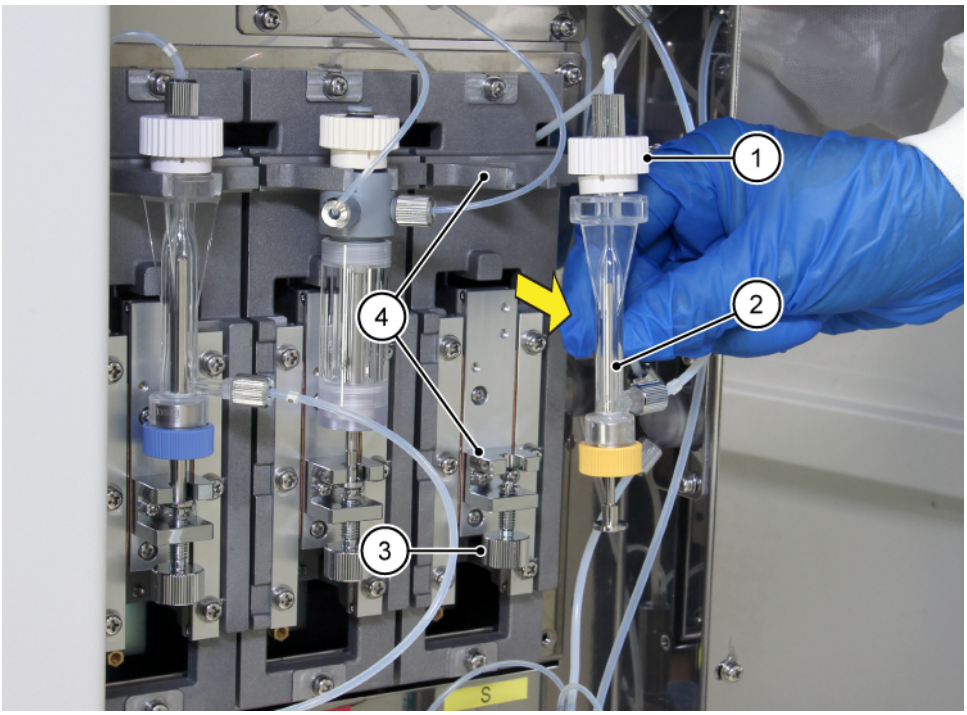
Figure 195 Location of Syringes



1. Reagent syringe (blue)
2. ISE buffer syringe (clear)
3. Sample syringe (yellow)

3 Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe from the mounting grooves.

Figure 196 Remove the Syringe



1. Top fixing nut
2. Syringe
3. Bottom piston fixing screw
4. Mounting grooves

4 Pull the syringe forward to remove it from the mounting grooves.

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

When removing the syringe, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe.

5 Loosen the connectors on the top and side of the syringe to remove the tubing.

Note

Some fluid might drip.

Install a New Sample Syringe

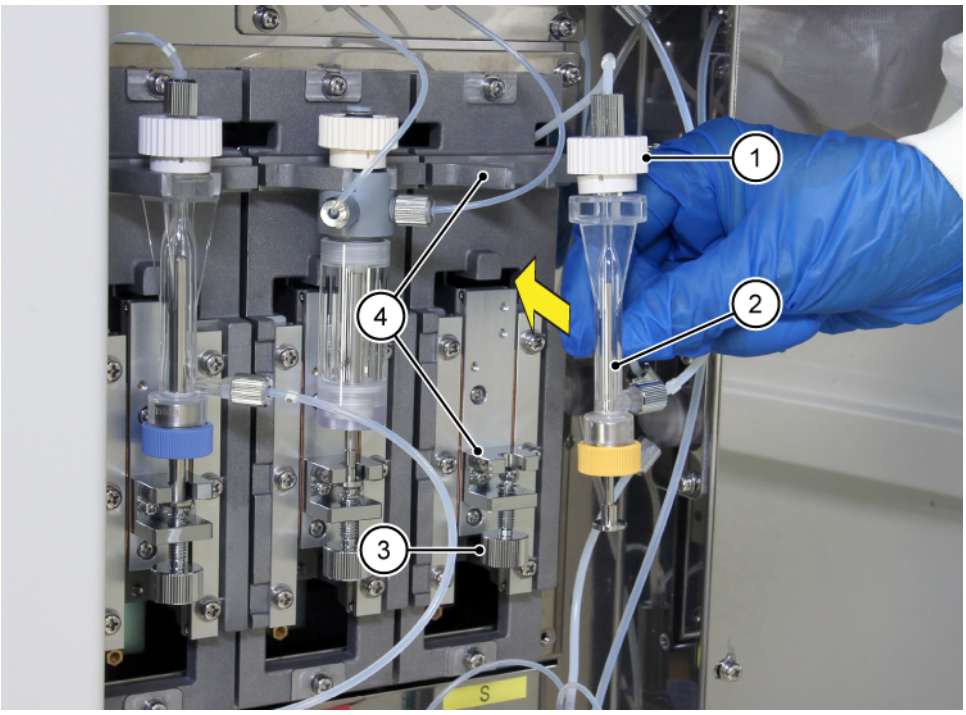
1 Obtain a new syringe.

2 Screw the connectors on the top and side tubing. Do not over-tighten.

3 Install the syringe into the mounting groove. Align the syringe piston into the drive shaft.

Figure 197 Installing the Sample Syringe Into the Mounting Groove

Figure 198 Installing the Syringe



1. Top fixing nut
2. Bottom piston fixing screw
3. Syringe
4. Mounting grooves

Caution

Do not allow a strong alkali, such as Beckman Coulter Wash Solution, to contact the syringe. If a strong alkali contacts the syringe, cracks can occur. If a strong alkali contacts the syringe, remove the syringe and rinse it with water.

4 Tighten the top fixing nut until you hear a clicking sound.

5 Tighten the bottom piston fixing screw.

Caution

Do not tighten the bottom piston fixing screw first, and do not press the piston when you tighten the bottom fixing screw.

Prime the New Sample Syringe

1 After replacing the syringe, select **Prime Sample Syringe**.
The analyzer displays the Prime Sample Syringe dialog.

2 For **Repetitions**, confirm the value is 260, and then select **OK**.

3 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

4 If the prime fails (air is still detected), the analyzer displays a `Sample Syringe Prime Incomplete` event. Repeat the prime. If the analyzer generates the event again, replace the syringe.

Note

The sample syringe prime can take from 12 to 44 minutes to complete. The sample syringe primes until the analyzer detects no air using pressure changes.

5 Close the middle front door of the analyzer.

6 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace Rack Labels

If a DxLAB rack bar code label is scratched, stained, or deteriorated, an ID read error results. Replace the bar code label and with a new one. In order to match the bar code label, replace the DxLAB rack ID label also.

Important

DxLAB rack bar code labels can deteriorate with time. If a rack ID read error occurs on an older label and the label shows no anomalies, the label is assumed to have deteriorated from discoloration or reduction in reflectivity. If the DxLAB rack bar code label is deteriorated, replace both rack labels.

- The bar code label is faint, or scratched caused by abrasion or scraping.
- A label is stained or blurred caused by adhesion of foreign matters (liquid or solid).
- A label is peeled or torn.

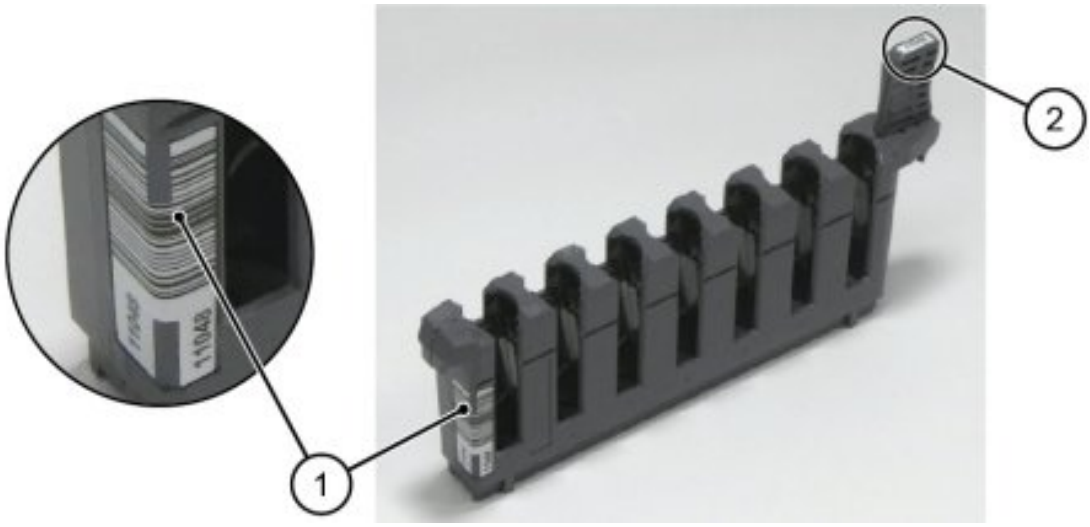
Materials Required:

- New DxLAB rack labels

---

1 Remove the DxLAB rack labels.

Figure 199 DxLAB Rack Labels



1. Bar code label
2. Rack ID label

Important

If it is difficult to remove a label, dampen the label with water and use a tool to scrape it off, such as a razor blade or scissors.

— Never use an organic solvent such as ethyl alcohol (ethanol). Organic solvents alter the quality of the plastic surface on a rack.
— If you use water, wipe the water off completely so that no moisture remains on the rack.
— Do not scratch the rack surface.

---

2 Attach new labels on the rack.

For more information, refer to Placing Labels on a DxLAB Rack.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

— If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

3 Select **Task Completed**.

Replace a Wash Nozzle Joint

If a wash nozzle joint is damaged or cracked, leaks or insufficient aspiration of a cuvette can occur. To avoid errors, immediately replace the damaged wash nozzle joint.

Materials Required:

- Wash nozzle joint

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the rear cover of the analyzer.

3 Select **Drain Wash Nozzles**.

4 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

The liquid drains from the tubing.

Caution

Drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water beforehand, the water spills out of the nozzle.

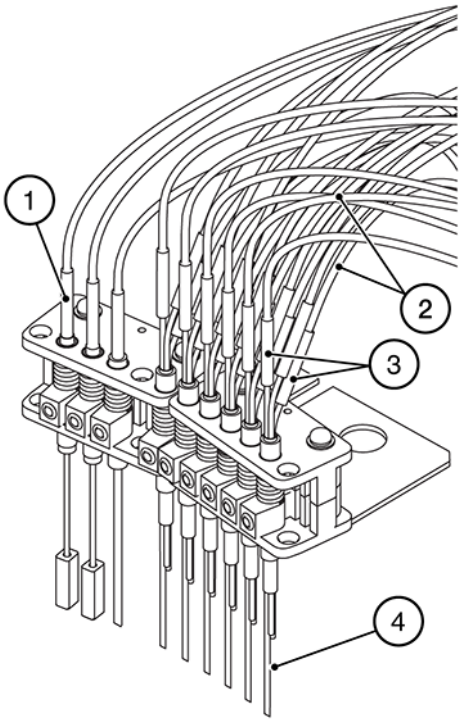
If the water spills onto the cuvettes, clean the cuvettes and cuvette wheel after completing this maintenance task.

5 Remove the wash nozzle component along with the tubing and place it on a clean surface.

Caution

Replace one wash nozzle joint at a time. If the tubing is not connected to the correct nozzle by the wash nozzle joint, correct analysis is not performed.

Figure 200 Wash Nozzle Component



1. Wash nozzle joint
2. Tubing
3. Wash nozzle joint
4. Wash nozzle

Important

When handling the wash nozzle component, do not damage the wash nozzles.

Important

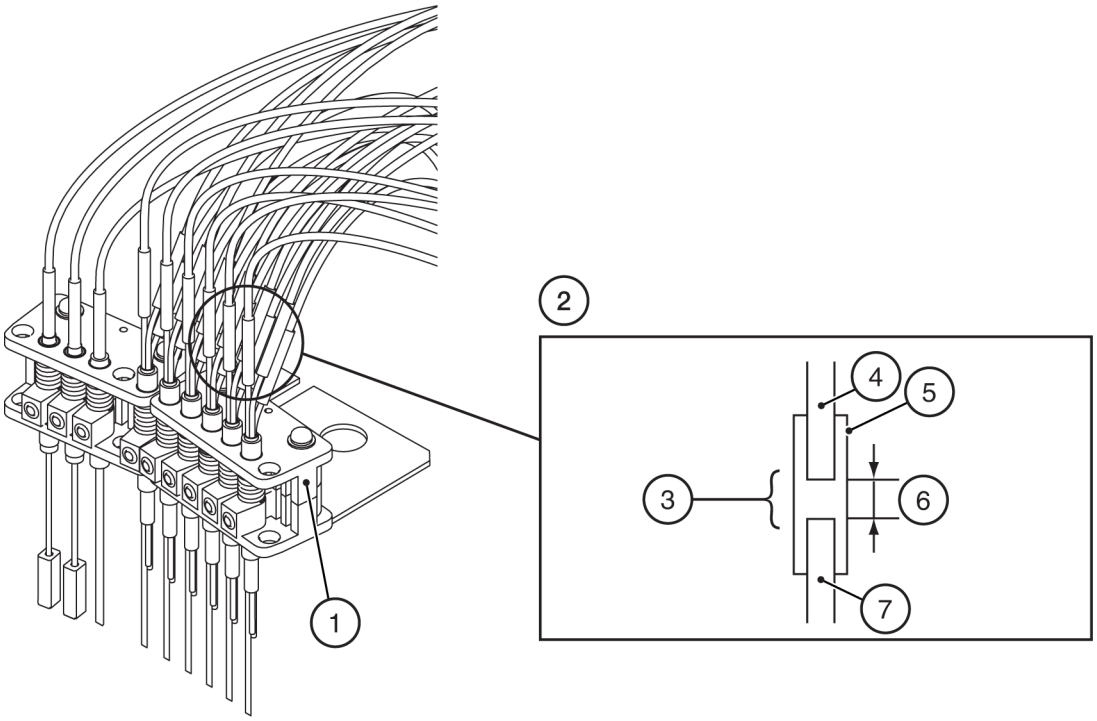
When removing the wash nozzle component, do not touch the nozzle tips to the cuvette wheel cover.

6 Remove the wash nozzle joint to be replaced.

7 Insert the new wash nozzle joint onto the open end of the tube, and then insert the nozzle into the other end of the wash nozzle joint.

Center the tube and nozzle in the joint, allowing approximately 1 mm between them.

Figure 201 Replace a Wash Nozzle Joint



1. Wash nozzle component
2. Cross-sectional view
3. Position both ends of the tube and nozzle in the center of the wash nozzle joint
4. Tube
5. Wash nozzle joint
6. Approximately 1 mm
7. Nozzle

Caution

Confirm that the tubing does not cross. If the tubing crosses, it can pull out from the wash nozzle joint and affect correct functioning of the wash nozzle and cause a cuvette overflow and affect results.

Important

When installing the wash nozzle component, do not touch the nozzle tips to the cuvette wheel cover.

8 Replace the wash nozzle component.

9 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

10 Confirm that the wash nozzle component is placed correctly on the analyzer.

11 Select **Prime Washing Line**. The analyzer displays the Prime Washing Line dialog.

12 For **Repetitions**, enter a value of **5**, and then select **OK**.

13 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
The air in the tubing is purged as the wash nozzle component moves up and down. Confirm that the analyzer moves the wash nozzle component up and down without interference.

14 Close the rear cover.

15 Select **Task Completed**.

Important

If the water spilled onto the cuvettes when draining the wash nozzles, clean the cuvettes and cuvette wheel after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Clean the Cuvettes and Cuvette Wheel**.
2. Follow the steps on the Task page.

Clean Cuvettes with Internal Wash

If the analyzer was put into the *Error* (*Stopped*) state during analysis, reagents and sample remain in the cuvettes. Cleaning cuvettes with internal wash cleans the entire cuvette wheel automatically using the wash nozzle subsystem.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Clean Cuvettes**.
The analyzer displays the Clean Cuvettes dialog.

3 Select **Start**.
The analyzer starts cleaning cuvettes with internal wash. The procedure takes approximately 10 minutes.

4 Select **Task Completed**.

Clean Cuvettes with External Solution

To obtain correct analysis results, clean the cuvettes as needed. The sample probe, reagent probe, mix bars, and waste lines are thoroughly cleaned during the procedure.

The procedure prepares the cuvettes for the photocal by thoroughly cleaning them. The sample probe, reagent probe, mix bars, and waste lines also benefit from the cleaning procedure.

The procedure is accomplished by running 1N hydrochloric acid or diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite) through the analyzer.

Each week, alternate the solution for use.

- The diluted cleaning solution (0.5% sodium hypochlorite) removes stains formed by protein deposits left in the cuvettes.
- The 1N hydrochloric acid removes a small quantity of inorganic substances such as metallic ions and any bacterial contamination.

A procedure takes about 23 minutes to complete from start to finish.

Warning

Do not mix diluted cleaning solution and hydrochloric acid. Confirm that all containers on the analyzer that are designated for cleaning cuvettes contain the same solution. Clearly label containers designated for diluted cleaning solution and hydrochloric acid and confirm that all positions requiring these cleaners contain the same solution. The mixing of sodium hypochlorite solution and hydrochloric acid causes the formation of chlorine gas, which is highly toxic.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle diluted cleaning solution or hydrochloric acid. If the diluted cleaning solution or hydrochloric acid contacts skin or clothes, rinse the affected area thoroughly with water. If the diluted cleaning solution or hydrochloric acid contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Warning

Do not spill diluted cleaning solution on the analyzer. If diluted cleaning solution is spilled on the analyzer, follow your laboratory procedure to wipe up spills immediately.

Caution

For each procedure, prepare fresh diluted cleaning solution (0.5% sodium hypochlorite). Prepare a fresh solution to maintain effective cleaning. Without effective cleaning, analysis results can be affected.

The ISE Enhanced Cleaning procedure is optional during the procedure.

To run the ISE Enhanced Cleaning procedure separately from the procedure, refer to Perform Automatic Washing.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

   — If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

   If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

   — If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

   If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Materials Required:

- Two 60-mL bottles labeled with either of the following descriptions:
  — 1N hydrochloric acid
  — Diluted cleaning solution (0.5% sodium hypochlorite)
- Either of the following solutions:
  — Approximately 120 mL of 1N hydrochloric acid
  — Approximately 120 mL of freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)

Materials required for ISE (optional module) Enhanced Cleaning during the procedure:

- Sample Cup (2.5 mL)
- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)

---

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

---

2 Fill the 60-mL bottles with approximately 60 mL of the solution for cleaning cuvettes selected for the week. If diluted cleaning solution (0.5% sodium hypochlorite) was used previously for the procedure, use hydrochloric acid for the current procedure.

Tip

Do not fill into the neck of the bottle.

Warning

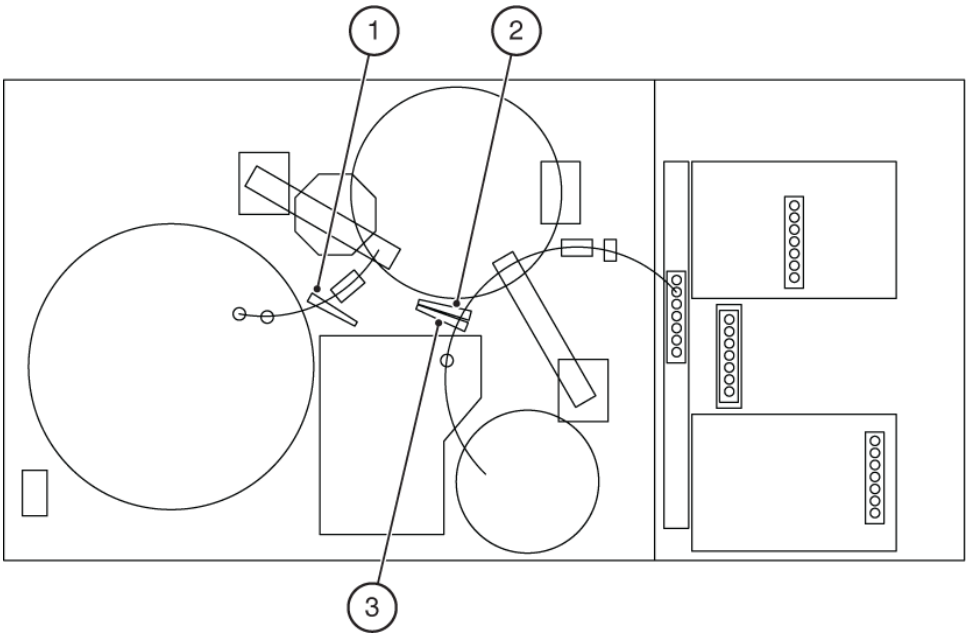
Do not mix diluted cleaning solution and hydrochloric acid. Confirm that all containers on the analyzer that are designated for cleaning cuvettes contain the same solution. Clearly label containers designated for diluted cleaning solution and hydrochloric acid and confirm that all positions requiring these cleaners contain the same solution. The mixing of sodium hypochlorite solution and hydrochloric acid causes the formation of chlorine gas, which is highly toxic.

---

3 Open the upper cover.

4 Place the bottles in the positions labeled 77 and 79. If a photocal is also selected, close the upper cover.

Figure 202 Positions for Cleaning Cuvettes with External Solution



1. 77
2. 78 (not for cleaning cuvettes with external solution)
3. 79

Warning

Do not spill diluted cleaning solution on the analyzer. If diluted cleaning solution is spilled on the analyzer, follow your laboratory procedure to wipe up spills immediately.

Caution

To prevent rust or corrosion of the inner surface of the bottle holder, be sure to wipe the outside of the bottle clean before placing the bottle back into position.

5 If you want to perform enhanced cleaning of the ISE, fill a Sample Cup (2.5 mL) with 1.5 mL cleaning solution (5% sodium hypochlorite). Place the cup in the **CLEAN** position on the STAT table.

6 Select **Deep Clean Cuvettes**.
The analyzer displays the Deep Clean Cuvettes dialog.

7 Decide whether to start the photocal immediately when the procedure is complete, without operator input. Also, the weekly ISE Cleaning (Enhanced) procedure can be run with the procedure without adding any time to the procedure.

- If you want to start the photocal after the procedure completes, select **After the procedure is complete, perform a photocal**.
- If your analyzer includes an ISE module and you want to start the ISE cleaning procedure during the procedure, select **During the procedure, perform ISE Cleaning (Enhanced)**.

8 Select **Start**. The procedure starts and takes 23 minutes (and an additional 24 minutes if you selected the option to perform a photocal after this procedure) to complete. You can view the remaining time in the Process area of the status bar. If you selected **After the procedure is complete, perform a photocal**, the photocal starts automatically.

Caution

After the procedure completes, immediately remove any bottles of cleaning solution from the analyzer. The bottles of cleaning solution can generate gas.

9 Open the upper cover and remove all maintenance materials used for the procedure. Put the diluent bottle back on the analyzer.

10 Select **Task Completed**.

Clean the ISE

If your analyzer includes an ISE module, clean the ISE.

Clean the sample pot and the electrode lines daily to prevent contamination and inaccurate results. This procedure requires approximately 5 minutes to complete.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle Beckman Coulter Cleaning Solution (sodium hypochlorite). If the cleaning solution contacts skin or clothes, rinse the affected area thoroughly with water. If the cleaning solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Note

If you do not plan to use the analyzer for a long period, clean the ISE before the period of inactivity. You do not have to perform the last step of this procedure (perform calibration and QC for all ISE tests).

Materials Required:

- Beckman Coulter Cleaning Solution (5% sodium hypochlorite)
- Sample Cup (2.5 mL)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the small STAT table cover.

3 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table until the **Clean** position is accessible.

4 Fill the Sample Cup (2.5 mL) with a minimum of 1 mL of cleaning solution (5% sodium hypochlorite).

5 Place the Sample Cup (2.5 mL) in the **Clean** position on the STAT table.

Caution

Wipe up cleaning solution spills immediately. Follow your laboratory procedure.

6 Close the small STAT table cover.

7 Select **Wash ISE**.
The analyzer starts the cleaning operation.

8 When the cleaning operation is complete, open the small STAT table cover, rotate the STAT table to Clean position, remove the Sample Cup (2.5 mL) from the STAT table, and discard it.

9 Close the small STAT table cover.

10 Select **ISE Total Prime**.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.
After the priming is complete, the indicator light in the TABLE ROTATION/DIAG button turns on.

12 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Calibrate the ISE

If your analyzer includes an ISE module, calibrate the ISE for the serum sample type.

Calibrate the ISE every 24 hours, after performing particular maintenance procedures, and after replacing the ISE reagents.

Caution

When the analysis is in progress or the ISE state is *Busy*, do not open the STAT table covers to add Standard Solutions to the STAT table or place hands in the path of the sample probe.

Note

Calibrating only serum or urine requires approximately 4 minutes to complete. Calibrating serum and urine together requires approximately 7 minutes to complete.

Materials Required:

- ISE High Serum Standard
- ISE Low Serum Standard
- ISE High Urine Standard
- ISE Low Urine Standard
- Sample Cup (2.5 mL) (4 cups)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the small STAT table cover.

3 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table until the **S-H**, **S-L**, **U-H**, and **U-L** positions are accessible.

4 Fill a Sample Cup (2.5 mL) with approximately 500 µL of Standard Solution as required for processing (determined by your laboratory processing the serum, urine, or both sample types).

Table 102 Position Labels for ISE Serum Standard Solutions

Solution	Position Label
ISE High Serum Standard	**S-H**
ISE Low Serum Standard	**S-L**
ISE High Urine Standard	**U-H**
ISE Low Urine Standard	**U-L**

5 Place the Sample Cups (2.5 mL) into the corresponding positions on the STAT table.

6 Close the small STAT table cover.

7 Select **Calibrate Serum**, **Calibrate Urine**, or **Calibrate Serum and Urine**, depending on the sample types to calibrate.
The analyzer starts calibration.

8 When calibration is complete, confirm that the result for each electrode is within the ranges for the calibrated sample types in the ISE Reagent Details page (Select **Home** > **Reagents** > **All Reagents**. Select the correct tile, and then select **Details**.).

To determine calibration quality, compare the current results with previous results for consistency, in the ISE Reagent Details page.

9 Open the small STAT table cover, remove the Sample Cups (2.5 mL) from the STAT table, and discard them.

10 Close the small STAT table cover.

11 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Photometer Lamp

Before performing this procedure, print a copy of the procedure from the PDF version of the DxC 500 AU Instructions for Use. During the procedure, you will need to shut down the chemistry analyzer, and the on-screen instructions will no longer be available.

Over time, the intensity of the photometer lamp diminishes, and results are affected.

Beckman Coulter recommends replacing the photometer lamp every 1,000 hours. Replacement of the lamp at 1,000 hours ensures continuous and reliable lamp performance without unexpected analyzer down-time. To view the lamp usage hours on the Photocal Results page, go to the Task page for the Perform a Photocal maintenance task and select **Photocal Results**.

Replace the lamp when a cuvette displays in red for a `Lamp Check Error` on the Photocal Results page, or when troubleshooting indicates the need for a new lamp, even if 1,000 hours have not passed since the lamp was replaced.

After replacing the lamp, the analyzer requires a photocal to evaluate the quality and intensity of the new lamp.

Warning

To prevent electric hazards, shut down the chemistry analyzer before replacing the photometer lamp. For more information, refer to Shutting Down the Chemistry Analyzer.

Wait a minimum of 5 minutes after the analyzer completes the shutdown process. Do not touch the lamp with your bare hands until the photometer lamp has cooled down completely. The lamp is hot and can cause burns.

Important

Never touch the glass of the photometer lamp with your bare hands. If oil from skin or fingerprints are left on the glass, wipe them off with a clean, dry, lint-free absorbent tissue.

Materials Required:

- Photometer lamp

1 Shut down the chemistry analyzer.
Refer to Shutting Down the Chemistry Analyzer.

2 Allow the lamp to cool for a minimum of 5 minutes.

3 Open the upper cover.

4 Remove the lamp cover.

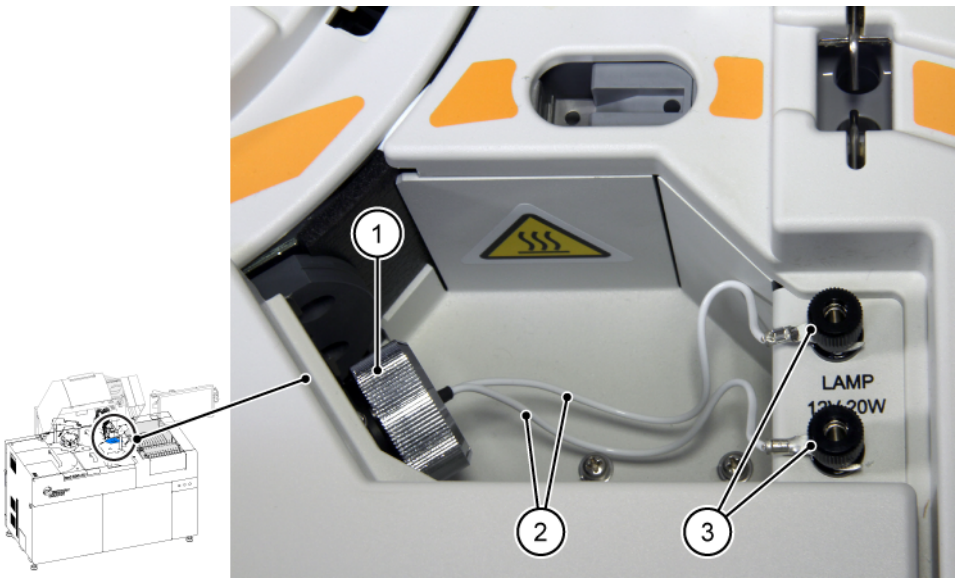
Important

Do not bump the cover against the reagent probe when removing the lamp cover.

5 Loosen the two knobs on the terminals, then disconnect the lamp lead wires.

Refer to the video in system help.

Figure 203 Photometer Lamp



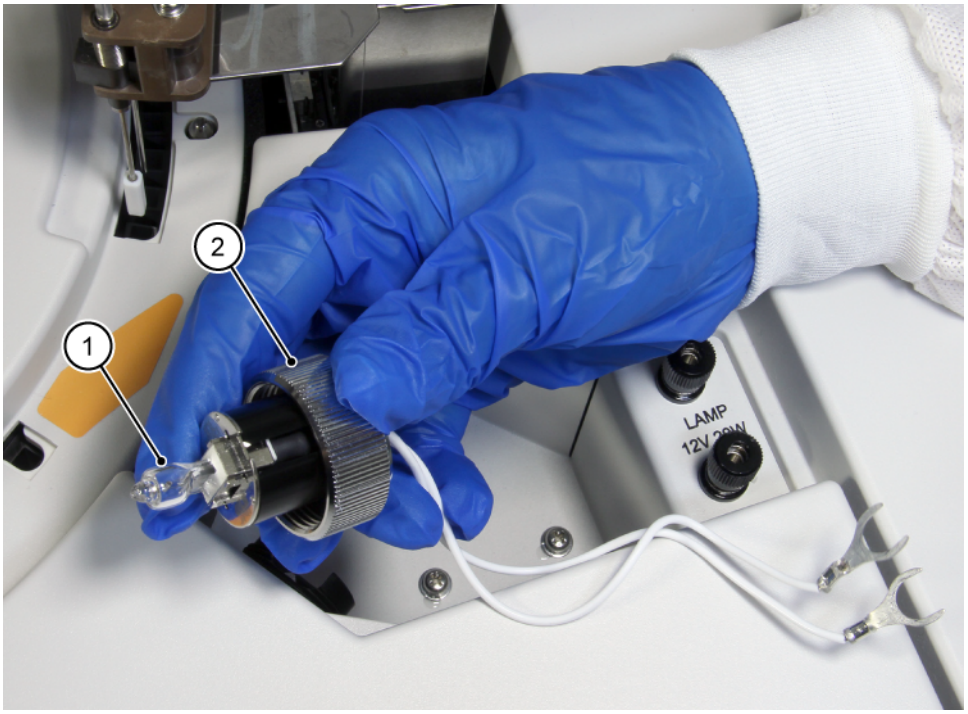
1. Lamp holder
2. Lamp lead wires

3. Knobs

6 Remove the lamp by turning the lamp holder counterclockwise, then pulling the lamp from the lamp receptacle. Handle the lamp by the lead wires.

Refer to the video in system help.

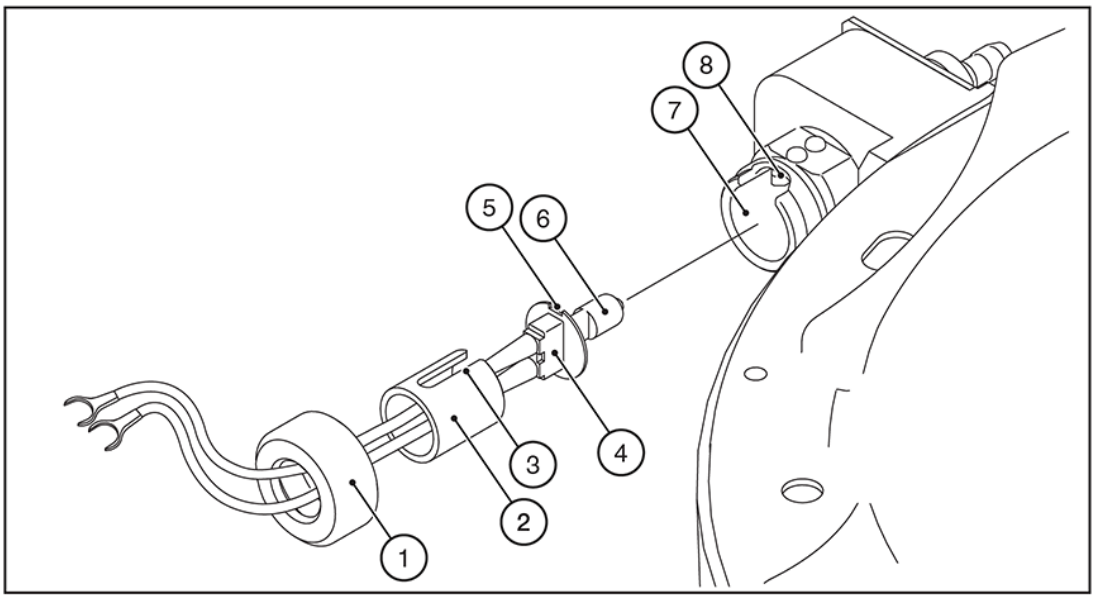
Figure 204 Photometry Subsystem



1. Photometer lamp
2. Lamp holder

7 Remove the lamp holder and collar from the lamp and keep them for future use.

Figure 205 Photometry Subsystem



1. Lamp holder
2. Collar
3. Collar notch
4. Guide key
5. Notch
6. Lamp
7. Lamp receptacle
8. Protrusion

8 Obtain a new lamp. Handle the lamp using only the wires. If you touch the bulb, you can damage it.

9 Slide the collar along the lead wires with the opening of the notch toward the rear of the lamp. Align the notched collar with the notch of the guide key of the lamp.

Refer to the video in system help.

Figure 206 Aligning the Notched Collar of the Photometer Lamp

10 Insert the lamp into the receptacle with the notches lined up on the top. Slide the notches into the keyed protrusion of the receptacle.

11 Slide the lamp holder along the wires behind the lamp and tighten to hold it in position.

Caution

Confirm that the lamp holder is securely in position. If the holder is loose, accurate analysis data is not obtained.

12 Connect the lead wires to the terminals and tighten with the knobs. Each lead wire can be connected to either terminal.

Refer to the video in system help.

Figure 207 Connect the Lead Wires of the Photometer Lamp

13 Put the lamp cover back in its original position.

14 Close the upper cover.

15 Press the On button with power indicator light (green). The analyzer powers up and initializes.

Important

After replacing the lamp, perform a photocal to confirm that the lamp does not have any defects. To obtain accurate analysis data, wait 20 minutes to stabilize the lamp after turning on the analyzer, then perform the photocal.

16 Select the **Maintenance** task indicator on the Home page.
The analyzer displays the Maintenance page.

17 On the Maintenance page, select the gray bar that is labeled As Needed, and then select **Replace Photometer Lamp**. The analyzer displays the Replace Photometer Lamp dialog.

18 Select **OK** to indicate the lamp was replaced and reset the lamp used time.

19 Allow the lamp 20 minutes to warm up and come to the correct intensity before continuing to the next step.

It takes 20 minutes for the analyzer to go from the *Starting* (*Warmup*) state to the *Running* (*Standby*) state.

20 Select **Task Completed**.

Important

After you select **Task Completed**, perform a photocal.

1. On the Maintenance page, select the gray bar that is labeled As Needed, and select **Perform a Photocal**.
2. Follow the steps on the Task page.

Errors can occur after the photocal. If numerous cuvettes fail the photocal, the lamp was incorrectly replaced or the lamp is defective. If only a few cuvettes fail the photocal, the cuvettes are dirty or stained. Clean the cuvettes. If the analyzer still reports an error after cleaning, replace the cuvettes.

Manually Clean the Sample Pot Tubing and Bypass Tubing

If your analyzer includes an ISE module, manually clean the sample pot tubing and bypass tubing.

Clean the sample pot tubing and bypass tubing if the sample pot tubing or bypass tubing becomes clogged or if you obtain erroneous calibration or QC results.

Note

You can perform Replace ISE Tubing instead of performing Manually Clean the Sample Pot Tubing and Bypass Tubing procedure.

For more information, refer to Replace ISE Tubing.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Note

The sample pot tubing and bypass tubing can become clogged and cause erroneous calibration or QC results after running the following samples:

- Large-volume dialysis patient samples
- LIH (lipemic, icteric, or hemolyzed) sample
- Serum sample that contains fibrin because centrifugal separation was not correctly conducted
- Serum sample that contains separator material which was aspirated because the serum volume was too low, or centrifugal separation was not correctly conducted.

Note

If the sample pot tubing or bypass tubing frequently becomes clogged, confirm that samples are correctly prepared.

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

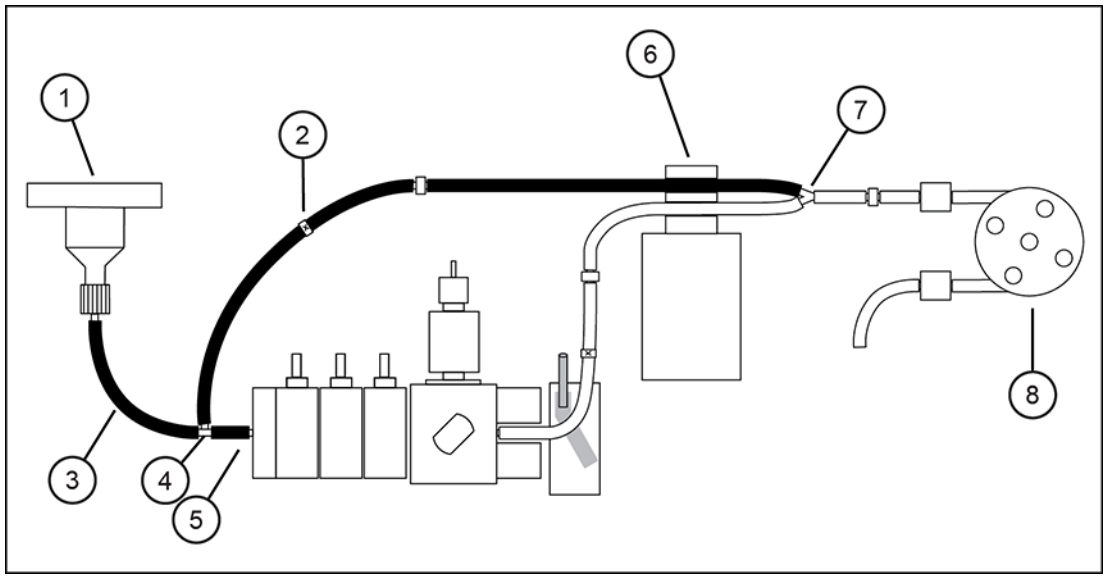
5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Remove the Sample Pot Tubing and Bypass Tubing

Figure 208 Sample Pot Tubing and Bypass Tubing



1. Sample pot
2. Bypass tubing labeled 5
3. Sample pot tubing
4. T-connector
5. Electrode block inlet
6. Pinch valve
7. Y-connector
8. Mixture aspiration roller pump

1 Disconnect the level sensor connector 714 and mixing motor connector 706.

2 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to remove it and place it on the mixing subsystem holder.

3 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.

4 Disconnect the sample pot tubing from the sample pot by unscrewing the connector. Put the sample pot aside.

5 Disconnect the other end of the sample pot tubing from the electrode block inlet.

6 Remove the bypass tubing labeled 5 from the top groove of the pinch valve.

7 Disconnect the bypass tubing from the Y-connector near the mixture aspiration roller pump.

Clean the Sample Pot Tubing and Bypass Tubing

Materials Required:

- Freshly prepared diluted Beckman Coulter Wash Solution (1%)
- Deionized water
- Clean, dry, lint-free absorbent tissue
- Sonicator
- Beaker
- Squeeze bottle with disposable pipette tip or syringe with disposable pipette tip

1 Fill the sample pot tubing and bypass tubing with freshly prepared diluted wash solution (1%). Use a disposable pipette tip attached to a squeeze bottle or a syringe to fill the sample pot tubing and bypass tubing.

a. Attach the pipette tip or syringe to either end of the sample pot tubing.

b. Force the diluted wash solution (1%) through the sample pot tubing.

c. Attach the pipette tip or syringe to the end of the bypass tubing.

d. Force the diluted wash solution (1%) through the bypass tubing.

Figure 209 Sample Pot Tubing and Bypass Tubing

2 Submerge the sample pot tubing and bypass tubing into a beaker filled with freshly prepared diluted wash solution (1%).

3 Place the beaker in the sonicator filled with deionized water and sonicate for 10 minutes.

4 Rinse the sample pot tubing and bypass tubing with deionized water.

a. Attach the pipette tip or syringe to either end of the sample pot tubing.

b. Force deionized water through the sample pot tubing.

c. Attach the pipette tip or syringe to the end of the bypass tubing.

d. Force deionized water through the bypass tubing.

e. Confirm that the lines have been flushed thoroughly.

5 Use a clean, dry, lint-free absorbent tissue to dry the sample pot tubing and bypass tubing before reconnecting them.

Note

If the sample pot tubing or bypass tubing remains clogged, or the analyzer continues to generate erroneous calibration or QC results, replace the ISE tubing after completing this task. .

For more information, refer to Replace ISE Tubing.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Attach the Sample Pot Tubing and Bypass Tubing

1 Connect the sample pot tubing to the electrode block inlet.

2 Attach the tubing to the sample pot by screwing on the connector.

3 Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.

4 Connect the bypass tubing to the Y-connector located near the mixture aspiration roller pump.

5 Insert the bypass tubing in the top groove of the pinch valve. Confirm that the tubing is inserted completely into the groove.

6 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

7 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

Prime the Tubing

1 Reprime the lines with ISE MID Standard Solution.

2 Press the **TABLE ROTATION/DIAG** button on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the REF electrode block side drain tubing labeled 6.

Note

You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly, and the electrodes are secured with the lock lever.

3 Select **ISE Total Prime**.

4 Press the **TABLE ROTATION/DIAG** button on the analyzer to start the prime. The TABLE ROTATION/DIAG LED turns on after the prime is complete.

5 Close all the analyzer doors and covers.

6 Select **Task Completed**.

Important

If the sample pot tubing or bypass tubing remained clogged, or the analyzer continued to generate erroneous calibration or QC results, when using a clean, dry, lint-free absorbent tissue to dry the sample pot tubing and bypass tubing before reconnecting them, replace the ISE tubing after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace ISE Tubing**.
2. Follow the steps on the Task page.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Manually Clean and Replace the ISE REF Electrode Block

If your analyzer includes an ISE module, manually clean and replace the ISE REF electrode block.

The accumulation of contaminants or crystals, a reduction in the flow rate, or noise interference can cause data problems. Manually clean or replace the ISE REF electrode block if the data indicates that it is needed.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

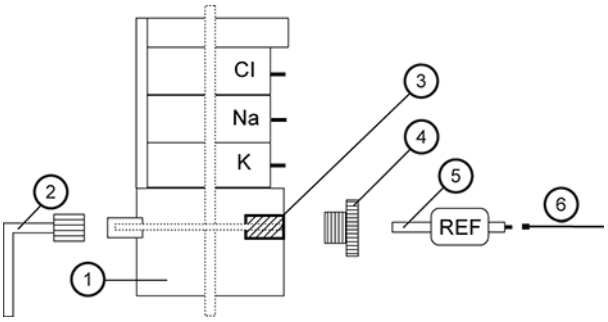
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 210 ISE REF Electrode Block



1. ISE REF electrode block
2. ISE Reference Solution tubing
3. ISE REF electrode packing
4. Cap screw
5. ISE REF electrode
6. ISE REF electrode wire (green)

Materials Required:

- ISE REF Electrode Block
- Freshly prepared diluted Beckman Coulter Wash Solution (2%)
- Plastic tweezers

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Manually Clean and Replace the ISE REF Electrode Block Procedure

Important

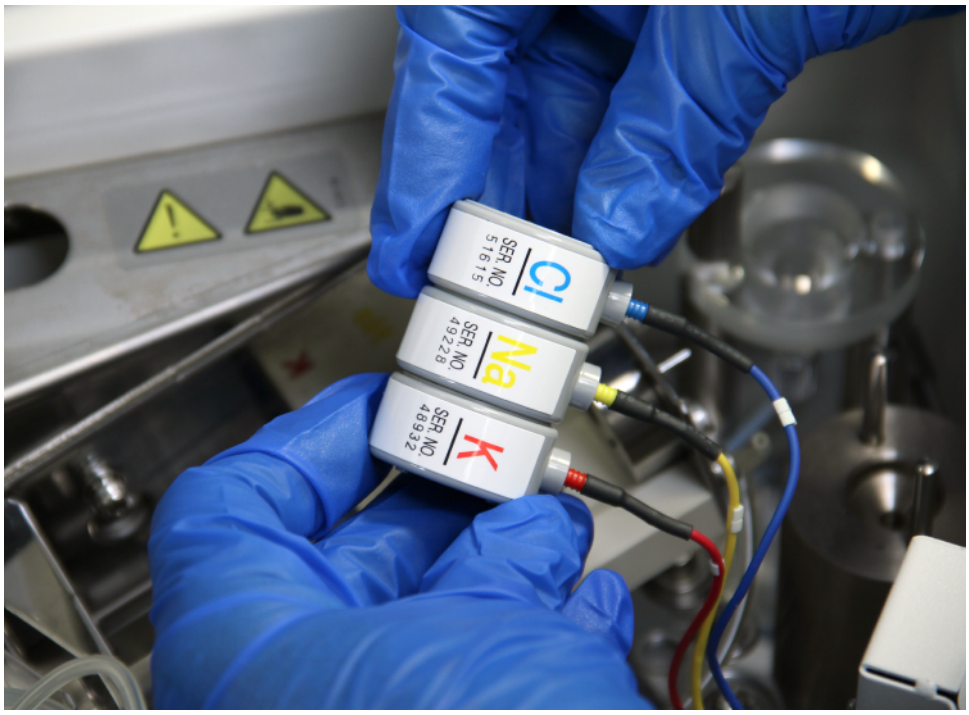
Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

1 Push the lock lever forward to release the electrodes.

2 Remove the Na, K, and Cl electrodes from the electrode block to keep these electrodes away from the ISE REF electrode. Any contact with the ISE Reference Solution can deteriorate the Na, K, and Cl electrodes.

Refer to the video in system help.

Figure 211 Removing the Electrodes from the Electrode Block



Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

3 Disconnect the ISE REF electrode wire (green) from the ISE REF electrode.

Caution

Handle the ISE REF electrode wire (green) from the end to avoid damage to the wire.

4 Gently lift up the block on which the ISE REF electrode is installed.

5 Loosen the cap screw on the ISE REF electrode and gently remove the electrode along with the cap screw.

Refer to the video in system help.

Figure 212 Removing the Electrode along with the Cap Screw

6 Remove the ISE REF electrode packing in the block with a pair of plastic tweezers.

7 While holding the ISE REF electrode block by hand, pull the ISE REF electrode block-side drain tubing (labeled 6) out of the ISE REF electrode block.

8 Remove the ISE Reference Solution tubing connected to the lower side of the ISE REF electrode block.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

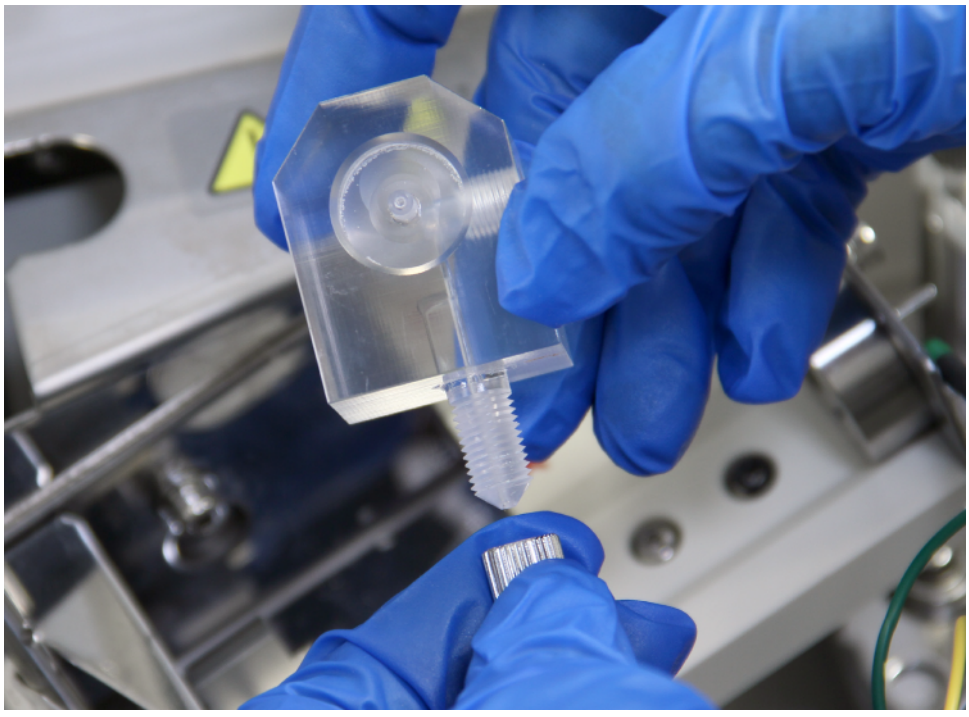
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Refer to the video in system help.

Figure 213 Removing the ISE Reference Solution Tubing



Important

To prevent the ISE REF electrode block from becoming deformed from ultrasonic cleaning, follow these precautions. If the ISE REF electrode block has been deformed or cracked, replace it.

— Do not perform ultrasonic cleaning for more than 10 minutes.
— Use a cleaning liquid at room temperature.
— Use a sonicator rated at 600 W or less. If the output of the sonicator is uncertain, contact the manufacturer of the sonicator.

9 To clean the ISE REF electrode block, do one of the following:

— Sonicate for 10 minutes in freshly prepared diluted wash solution (2%).

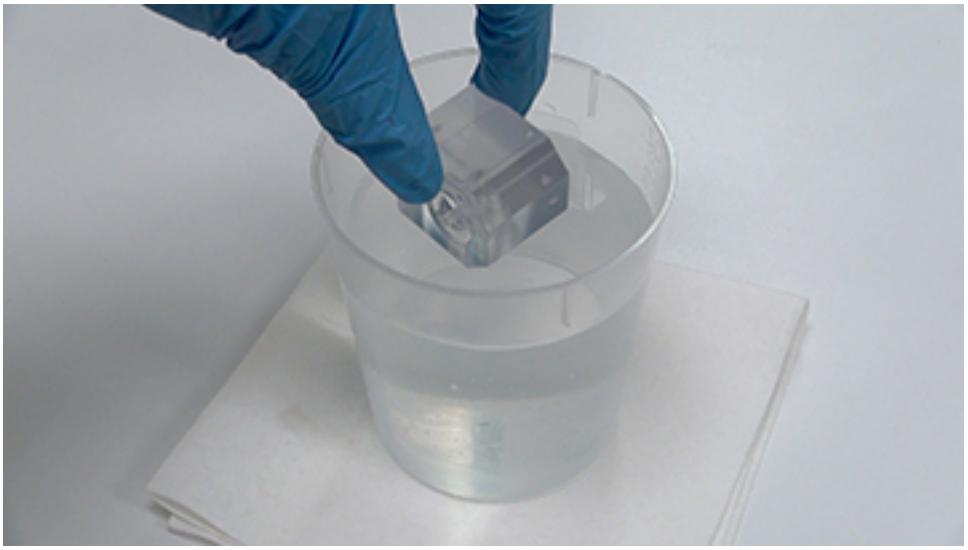
Refer to the video in system help.

Figure 214 Sonicating the ISE REF Electrode Block

— If a sonicator is not available, soak it in the freshly prepared diluted wash solution (2%) for more than 30 minutes.

Refer to the video in system help.

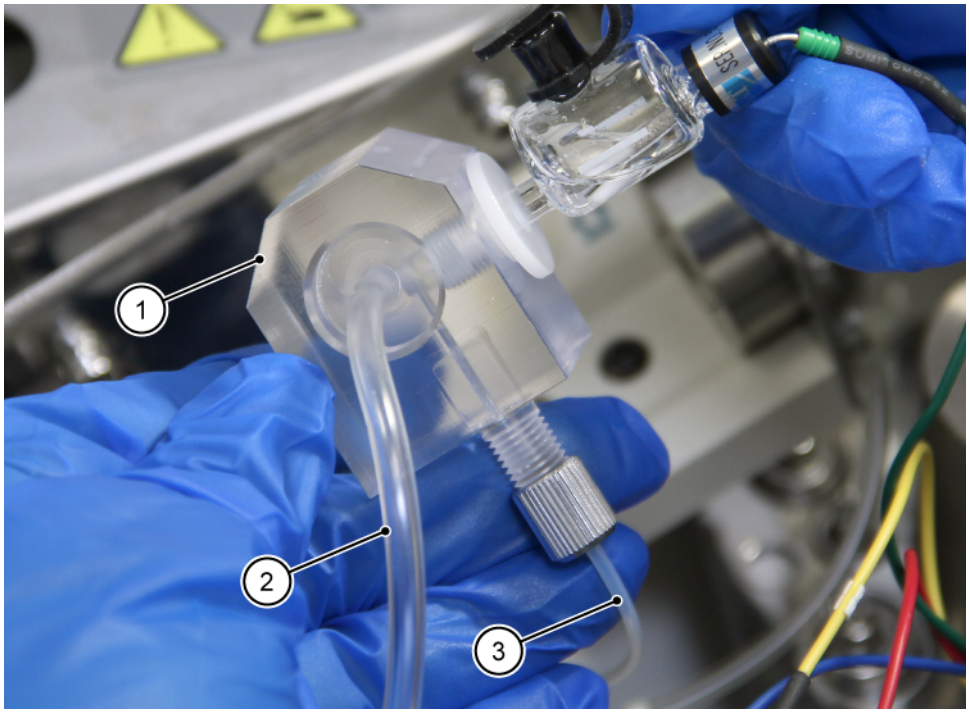
Figure 215 Soaking the ISE REF Electrode Block



Confirm that diluted wash solution (2%) can flow through the flow path in the ISE REF electrode block.

10 Thoroughly rinse the ISE REF electrode block in deionized water, and dry with a clean, dry, lint-free absorbent tissue. If you are replacing the ISE REF electrode block, obtain a new ISE REF electrode block.

Figure 216 ISE REF Electrode Block



1. ISE REF electrode block
2. ISE REF electrode block-side drain tubing (labeled 6)
3. ISE Reference Solution tubing

11 Attach the ISE REF electrode block-side drain tubing (labeled 6) and the ISE Reference Solution tubing to the cleaned or a new ISE REF electrode block.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

   — If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

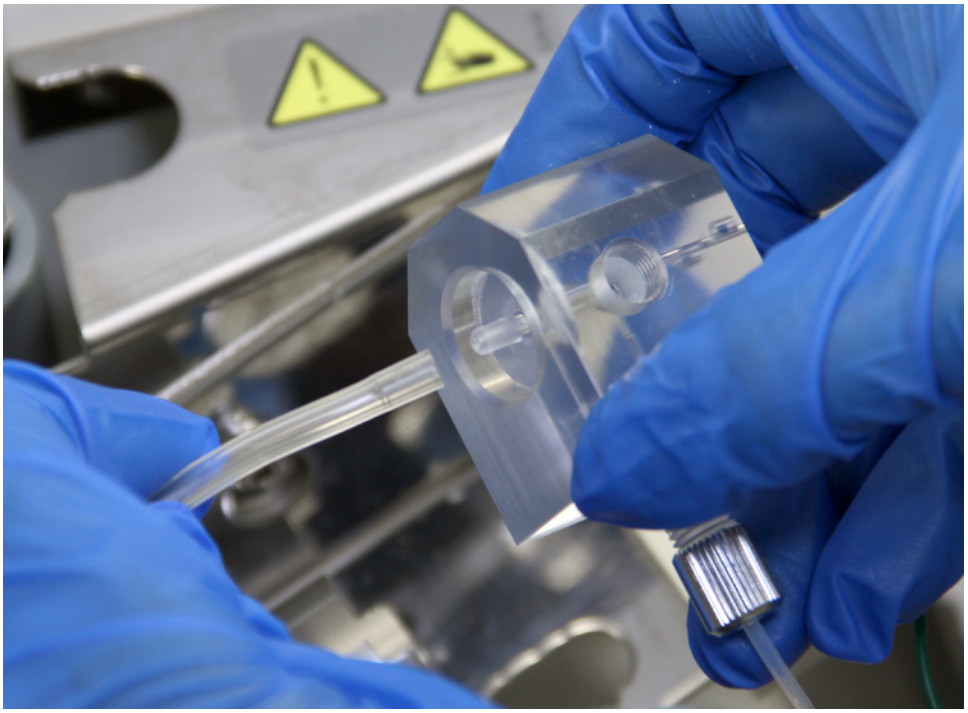
If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.

— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 217 Attaching the ISE REF Electrode Block-side Drain Tubing (Labeled 6) and the ISE Reference Solution Tubing



12 Confirm that no air bubbles are in the ISE REF electrode tip. If air bubbles are found in the tip, remove the bubbles by pointing the electrode tip downward while tapping it with a finger.

13 Insert the ISE REF electrode packing into the ISE REF electrode block. Confirm that the packing is not cracked or broken. If so, replace the packing.

14 Place the cap screw on the ISE REF electrode, then place the ISE REF electrode in the ISE REF electrode block so that the electrode tip is centered in the packing.

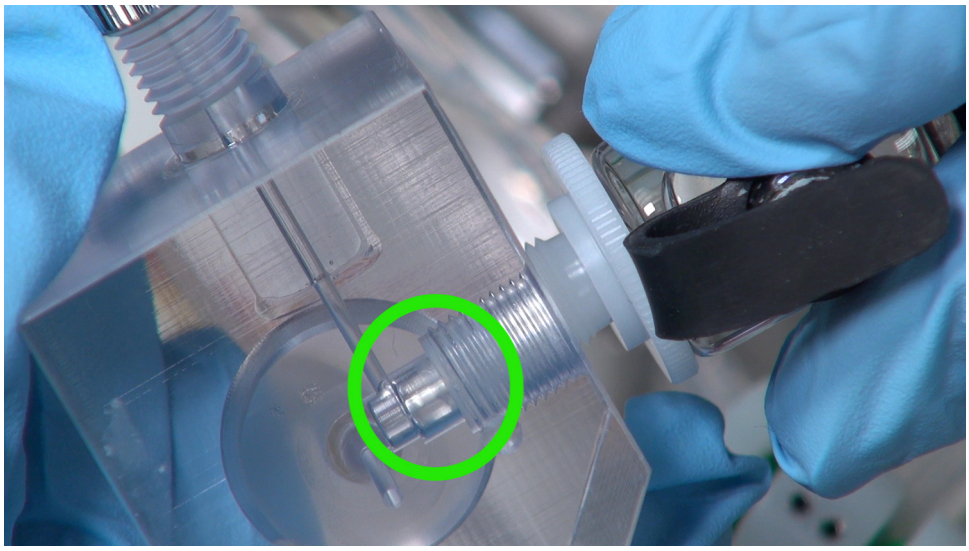
Note

If you have difficulty inserting the ISE REF electrode into the ISE REF electrode block, dampen the ISE REF electrode tip with deionized water.

15 Insert the cap screw into the ISE REF electrode block and screw it in carefully. Finish tightening the cap screw by a quarter or half turn to orient the ISE REF electrode correctly.

Refer to the video in system help.

Figure 218 Tightening the Cap Screw



16 Reinstall the ISE REF electrode block.

17 Connect the green ISE REF electrode wire to the ISE REF electrode.

18 Wipe the top of the block with a clean, dry, lint-free absorbent tissue. Always wear gloves when handling the ISE Reference Solution.

19 Reinstall the Na, K, and Cl electrodes.

20 Pull the lock lever backward to lock the electrodes in position.

21 Connect the blue wire to the Cl electrode, yellow wire to the Na electrode, and red wire to the K electrode.

22 Reprime the lines with ISE MID Standard Solution.

23 Press the **TABLE ROTATION/DIAG** button on the analyzer. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

24 Close all analyzer doors and covers.

25 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Clean the Inlet Side of ISE Electrode Block

If your analyzer includes an ISE module, clean the inlet side of ISE electrode block.

Inspect the inlet side of the electrode block for contaminants that have accumulated. Perform maintenance to clean the inlet side of the electrode block as needed.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

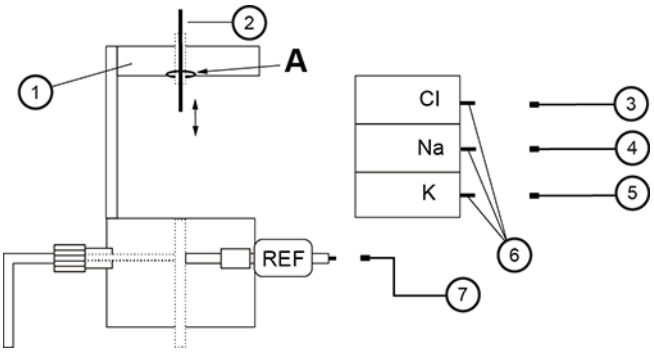
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 219 Electrode Block

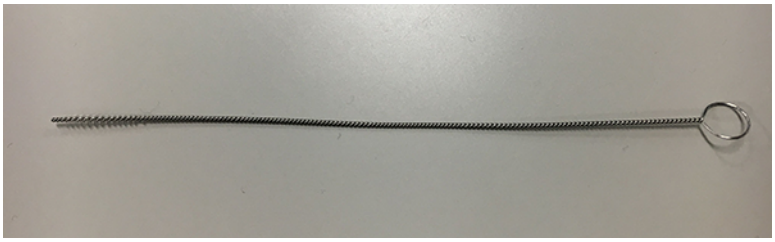


1. Electrode block (inlet side)
2. Brush
3. Cl electrode wire (blue)
4. Na electrode wire (yellow)
5. K electrode wire (red)
6. Electrodes
7. ISE REF electrode wire (green)

Materials Required:

- Brush

Figure 220 Brush



Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Clean the Inlet Side of ISE Electrode Block Procedure

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

1 Disconnect the liquid level sensor connector 714 and mixing motor connector 706.

2 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to unseat it.

3 Place the mixing subsystem on the mixing subsystem holder.

4 Remove the sample pot tubing from the electrode block inlet.

Refer to the video in system help.

Figure 221 Removing the Sample Pot Tubing From the Electrode Block Inlet

5 Push the lock lever forward to release the electrodes.

6 Remove the Na, K, and Cl electrodes from the electrode block.

Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrode.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

7 Pass the brush through the hole in the metal part that contacts the Cl electrode.

(location A in ISE Tubing Block Diagram). Contamination can lodge in the flow cell of the electrode block.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

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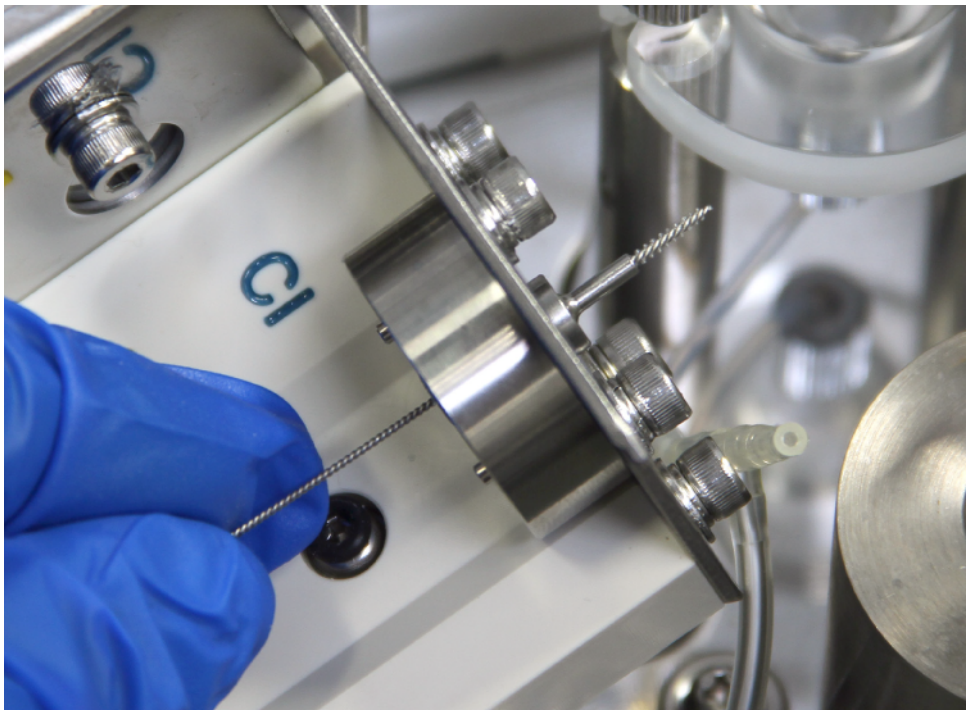
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Refer to the video in system help.

Figure 222 Electrode Block Inlet



8 Remove contamination in the block by turning the brush.

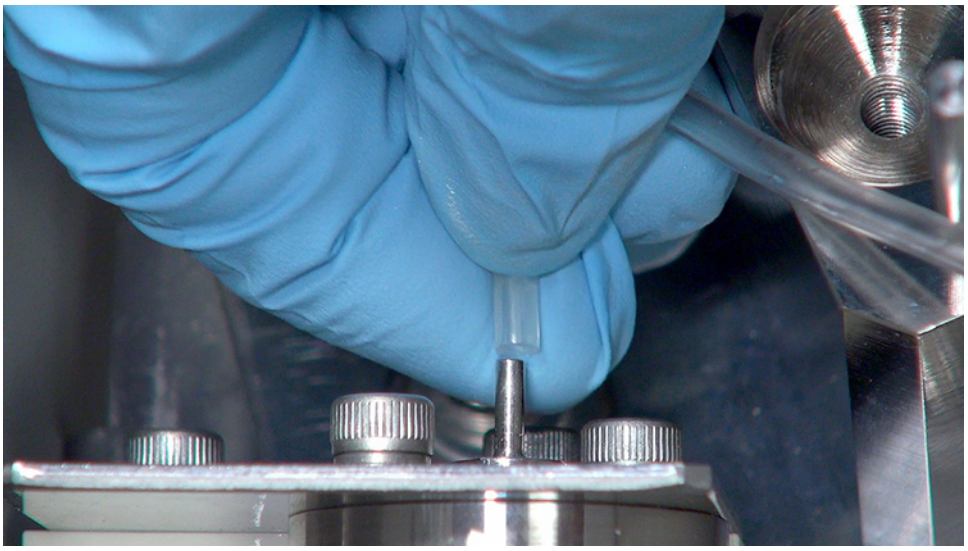
9 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF electrode block side.

10 Pull the lock lever backward to lock the electrodes in position.

11 Attach the sample pot tubing to the electrode block inlet.

Refer to the video in system help.

Figure 223 Attaching the Sample Pot Tubing to the Electrode Block Inlet



12 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

13 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

14 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

15 Close all analyzer doors and covers.

16 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Manually Clean the ISE K Electrode

If your analyzer includes an ISE module, manually clean the ISE K electrode.

If calibration errors, such as slope readings of 0, occur frequently for the K electrode only, the ISE Reference Solution might have contaminated the K electrode. In this situation, perform the manual cleaning of the K electrode.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
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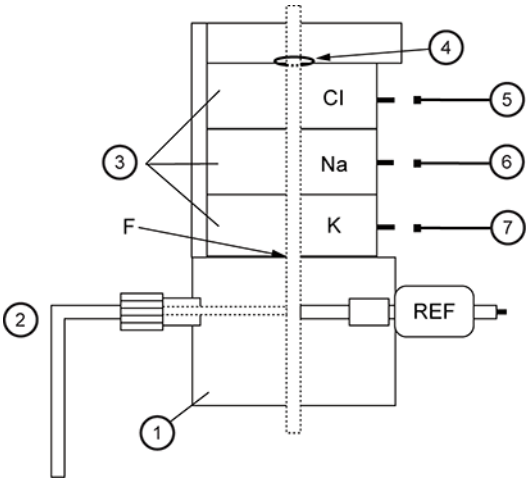
     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 224 Electrode Block



1. ISE REF electrode block
2. ISE Reference Solution tubing
3. Electrodes
4. O-ring
5. Cl electrode wire (blue)
6. Na electrode wire (yellow)
7. K electrode wire (red)

Materials Required:

- Clean, dry, lint-free absorbent tissue

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Manually Clean the ISE K Electrode Procedure

Important

Always drain the flow cell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the ISE REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flow cell.

1 Push the lock lever forward to release the electrodes.

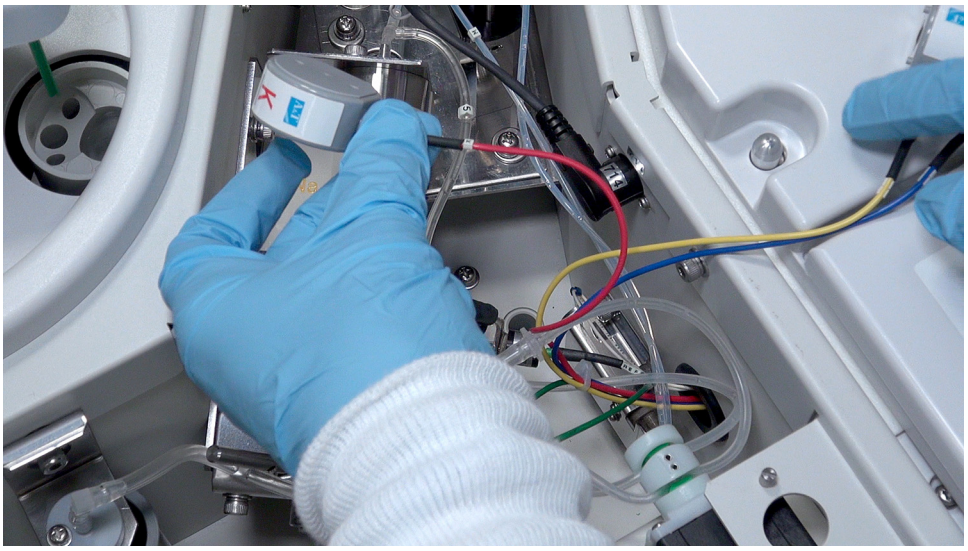
2 Remove the K electrode from the electrode block.

Caution

When lifting the electrodes, use your hand to support the electrodes. Do not lift out the electrodes by the wires when they are still connected.

Refer to the video in system help.

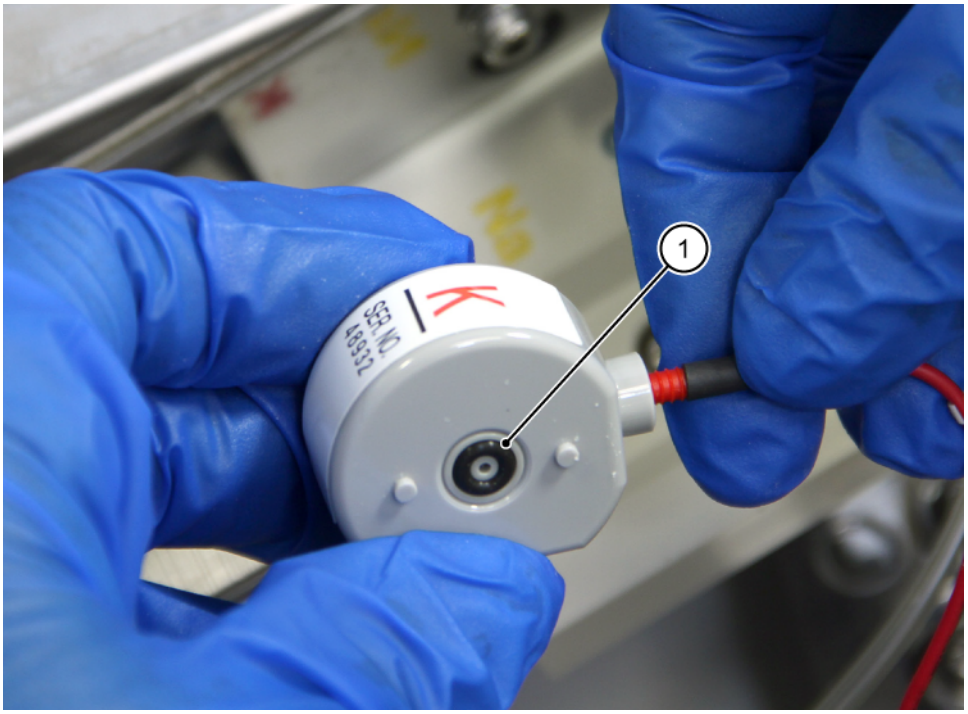
Figure 225 Removing the K Electrode From the Electrode Block



3 Disconnect the lead wire of the K electrode.

4 Remove the O-ring of the K electrode.

Figure 226 K Electrode



1. O-ring

5 Use a squeeze bottle to dispense deionized water to clean the O-ring and O-ring groove of the electrode.

If deionized water enters the electrode flow cell, it will not cause any problems for ISE measurement.

6 Wipe the side face of the ISE REF electrode block that contacts the K electrode using a clean, dry, lint-free absorbent tissue dampened with deionized water.

(The side face is at location B in ISE Tubing Block Diagram.)

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
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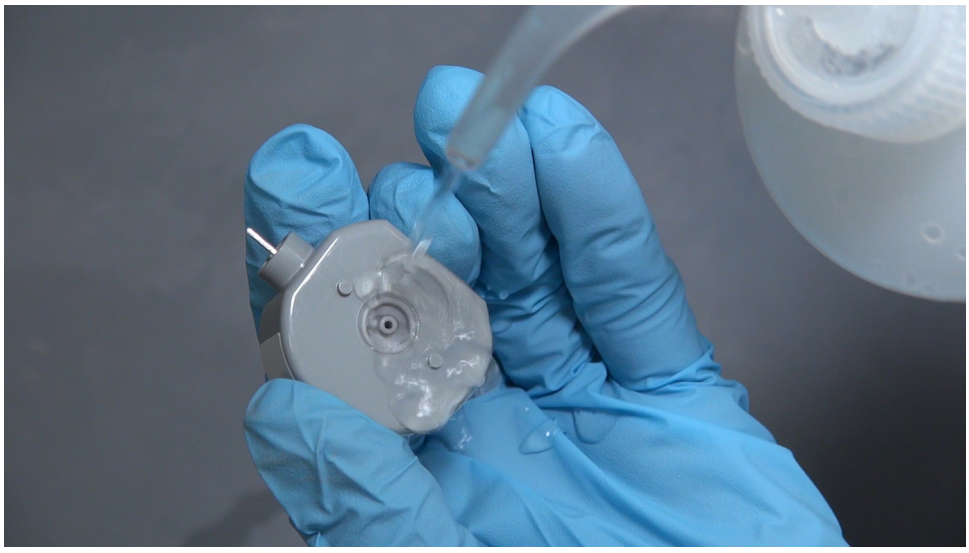
     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.
2. Continue this procedure by going to the next step.

Refer to the video in system help.

Figure 227 Cleaning the O-ring and O-ring Groove of the Electrode

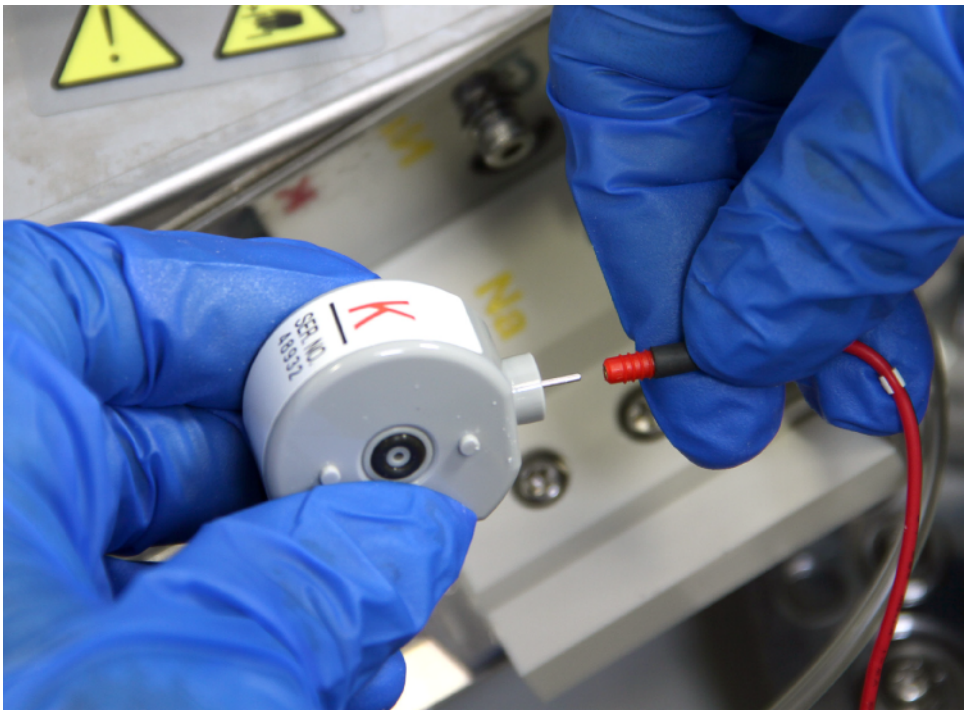


7 Using a clean, dry, lint-free absorbent tissue, sufficiently dry the K electrode, O-ring, and ISE REF electrode block surfaces.

8 Connect the red lead wire to the K electrode.

Refer to the video in system help.

Figure 228 Connecting the Red Lead Wire to the K Electrode



9 Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the electrode block inlet side to the ISE REF electrode block side.

Important

The analyzer uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location A in ISE Tubing Block Diagram). Do not lose the O-rings when replacing the electrodes.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:

— If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

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— If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

10 Pull the lock lever backward to lock the electrodes in position.

11 Select **Drain and Prime Flow Cell**.

12 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flow cell and that there are no bubbles in the ISE REF Electrode block side drain tubing labeled 6.

Note

You might need to repeat this step five times. If bubbles are in the tubing after the prime, confirm that the electrodes and tubing are installed correctly and that the lock lever secures the electrodes.

13 Close all analyzer doors and covers.

14 Select **Task Completed**.

Important

Wait a minimum of 5 minutes after closing the covers, and then perform calibration and QC for all ISE tests.

Important

After you select **Task Completed**, to obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 103 Acceptable Differences Between First and Second MID Solution Factors (Serum or Urine)

	Na	K	Cl
Difference between 1st and 2nd factors	0.020	0.045	0.025

Perform Electrode Selectivity Check

If your analyzer includes an ISE module, check selectivity for the Na and K electrodes.

The Na electrode and K electrode are ion-selective electrodes. If the selectivity of the electrodes deteriorates, ions other than Na or K can affect the electrodes, and results can be affected.

Checking selectivity of the electrodes is performed as part of the weekly task to perform automatic washing. To confirm the ion selectivity of the electrodes apart from the weekly task to perform automatic washing, perform a selectivity check of the Na and K electrodes as needed. The ISE selectivity check takes about 4 minutes complete.

Important

Do not leave the bottle of ISE Selectivity Check Solution open. Concentration or crystallization of the ISE Selectivity Check Solution can occur.

Materials Required:

- ISE (K+) and (Na+) Selectivity Check Solution
- Sample Cup (2.5 mL) (2 cups)

1 If you have not just done so, calibrate the ISE.

2 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

3 Open the upper cover.

4 Open the small STAT table cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to rotate the STAT table until the Sel-Na, and Sel-K positions are accessible.

6 Fill the Sample Cups (2.5 mL) with approximately 500 µL of ISE (Na+) Selectivity Check Solution and 500 µL of ISE (K+) Selectivity Check Solution separately.

7 Place the ISE (Na+) Selectivity Check Solution in the Sel-Na position. Place the ISE (K+) Selectivity Check Solution in the Sel-K position.

8 Close the small STAT table cover.

9 Select **Check Selectivity**. The analyzer displays the Selectivity Check dialog.

10 Select **Start Check**.

11 Confirm the selectivity check data is below the acceptable limit of 160.0 mmol/L for Na and 6.00 mmol/L for K.

If the Na or K selectivity check test result is over the acceptable selectivity check limit, the background for the Na or K result displays in yellow.

If the Na or K selectivity check test result is over the acceptable selectivity check limit, first confirm the ISE (Na+) Selectivity Check Solution and ISE (K+) Selectivity Check

Solution open bottle stability and expiration with the ISE reagent IFU. Repeat the procedure with new or freshly filled cups of ISE (Na+) Selectivity Check Solution and ISE (K+) Selectivity Check Solution. Confirm the ISE calibration results.

If the ISE calibration passes and the selectivity check fails, replace the Na or K electrode after completing this maintenance task.

12 To view details about the selectivity check in the Data section of the ISE Reaction Detail page, select **Detail**.

13 To exit the Selectivity Check dialog, select the X in the upper right corner of the dialog.

14 Perform a MID/REF prime three times to clear the electrode flow cell of any ions remaining from the selectivity check procedure.

a. Select **Prime MID and REF Solutions**.

b. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime.
After the priming is complete, the indicator light in the TABLE ROTATION/DIAG button turns on.

c. Initiate the MID/REF prime two more times by pressing the **TABLE ROTATION/DIAG** button with indicator light on the analyzer.

15 After completing the operation, open the small STAT table cover, and then remove the Sample Cups (2.5 mL) from the STAT table.

16 Close the small STAT table cover.

17 Select **Task Completed**.

Important

If the ISE calibration passed and the selectivity check failed, replace the Na or K electrode after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace the Na Electrode** or **Replace the K Electrode**.
2. Follow the steps on the Task page.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Perform Manual Enhanced ISE Cleaning

If your analyzer includes an ISE module, perform manual enhanced ISE cleaning.

Use this method when the ISE calibration slopes are in the mid-to-low forties, or if there is a residue when you inspect the sample pot or T-tubing.

Materials Required:

- Freshly prepared diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite)
- ISE MID Standard Solution
- Pipette (2 pieces) (that is commercially available and can collect more than 1 mL of liquid)

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1. Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.
2. Select **Drain and Prime Flow Cell**.
3. Open the upper cover.
4. Open the ISE cover.
5. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

Perform Manual Enhanced ISE Cleaning Procedure

Warning

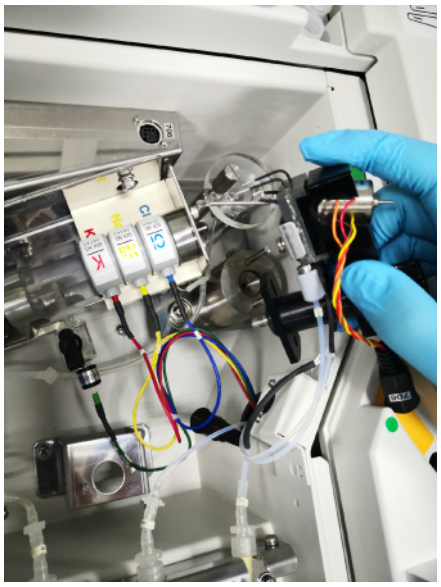
Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle Beckman Coulter Cleaning Solution (sodium hypochlorite). If the cleaning solution contacts skin or clothes, rinse the affected area thoroughly with water. If the cleaning solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

1 Disconnect the liquid level sensor connector 714 and mixing motor connector 706.

2 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to unseat it.

Refer to the video in system help.

Figure 229 Unseating the Mixing Subsystem

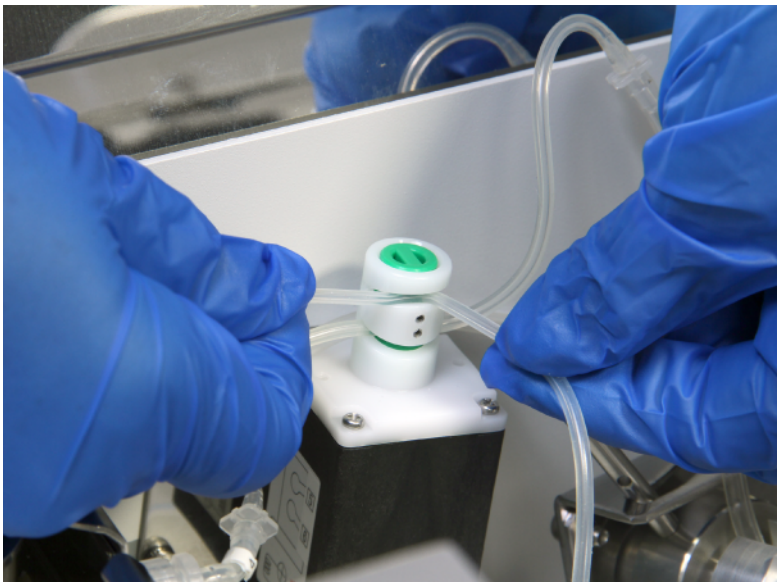


3 Place the mixing subsystem on the mixing subsystem holder.

4 Remove the tubing (labeled 5 and 6) from the pinch valve.

Refer to the video in system help.

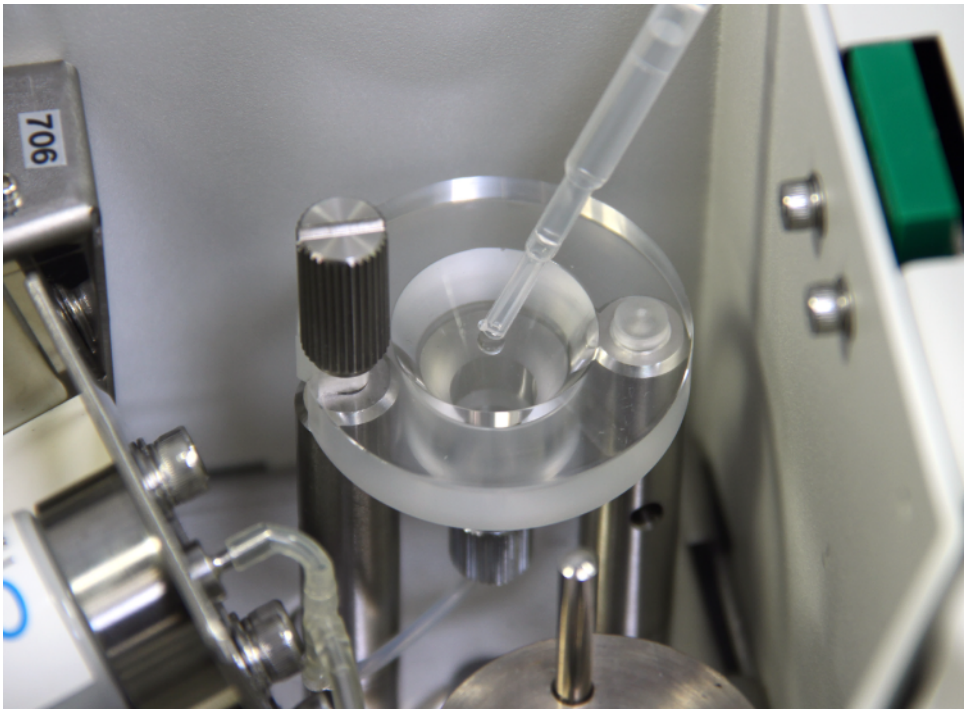
Figure 230 Removing the Tubing (Labeled 5 and 6) From the Pinch Valve



5 For the first 2 minutes, pipette the freshly prepared diluted cleaning solution (0.5% sodium hypochlorite) into the sample pot while manually turning the left roller pump component clockwise until most of the diluted cleaning solution empties from the sample pot into the tubing. Continue filling the sample pot with the diluted cleaning solution while turning the roller pump component.

Refer to the video in system help.

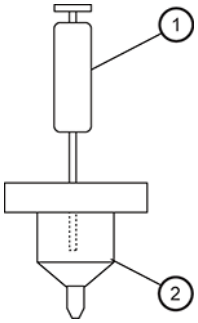
Figure 231 Filling the Sample Pot With Diluted Cleaning Solution



Do not completely empty the sample pot before adding more diluted cleaning solution (0.5% sodium hypochlorite).

Confirm that the tubing is filled with the diluted cleaning solution.

Figure 232 Filling the Sample Pot



1. Pipette
2. Sample pot

---

6 Let the diluted cleaning solution remain in the tubing for 5 minutes.

---

7 Manually turn the roller pump on the left clockwise to clear the diluted cleaning solution from the tubing.

Refer to the video in system help.

---

8 Pipette 10 mL of ISE MID Standard Solution into the sample pot, and manually turn the roller pump on the left clockwise to clear the ISE MID Standard Solution. Repeat 3 times.

Refer to the video in system help.

Figure 233 Pipetting ISE MID Standard Solution Into the Sample Pot

9 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

Refer to the video in system help.

Figure 234 Putting the Mixing Subsystem Back Into Position

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

10 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

11 Insert the tubing into the grooves of the pinch valve. Confirm that the tubing is inserted completely into the groove. Put tubing labeled 6 in the bottom groove of the pinch valve, and put tubing labeled 5 in the top groove of the pinch valve.

Note

Refer to the label on the back of the ISE cover for placement of the pinch valve tubing. Install the tubing (labeled 5 and 6) in the correct grooves of the pinch valve.

Refer to the video in system help.

12 Select **Prime MID and REF Solutions**.

13 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime.

14 Repeat the prime two times using the **TABLE ROTATION/DIAG** button on the analyzer.

15 Select **ISE Total Prime**.

16 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime.

17 Close all analyzer doors and covers.

18 Select **Task Completed**.

Important

If the tubing is not clean after performing this procedure, replace the tubing after you select **Task Completed**.

1. On the Maintenance page, select the gray bar that is labeled Scheduled, and select **Replace ISE Tubing**.
2. Follow the steps on the Task page.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the ISE Buffer Syringe

If your analyzer includes an ISE module, replace the ISE buffer syringe.

If a leak, crack, or any other damage is found with the syringe, replace the syringe.

If syringe performance is questionable because of abnormal data, remove and inspect the syringe.

Replace the syringe if:

- There is not smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that is too hard or too loose.
- The fluorocarbon polymer tip is worn, damaged or there is evidence of the fluorocarbon polymers flaking.
- The syringe or case head leaks even after correct installation.
- The head of the syringe is cracked.

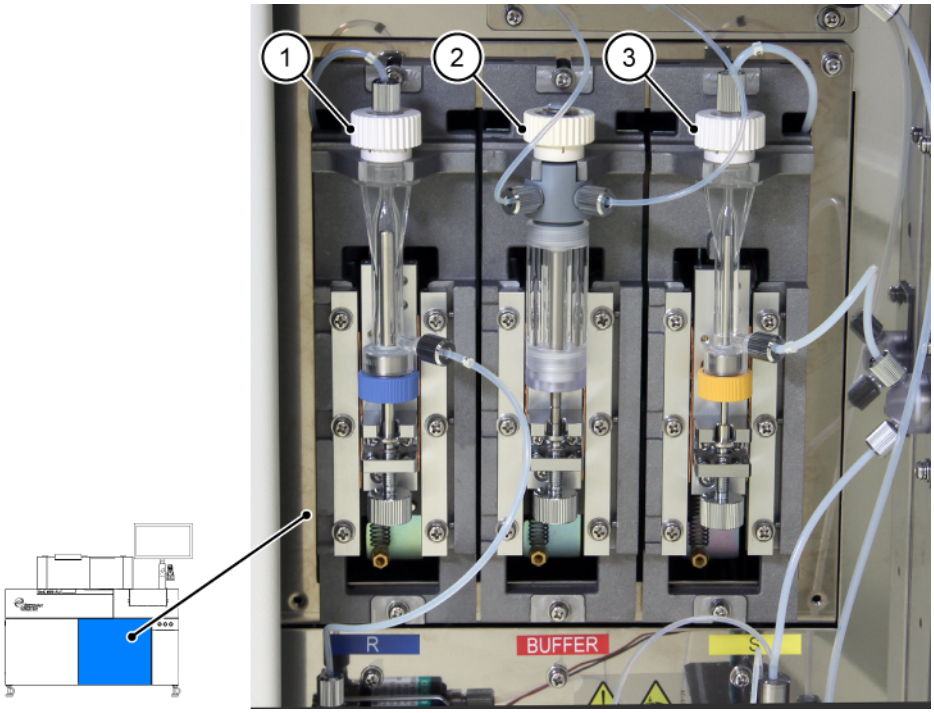
Materials Required:

- ISE buffer syringe
- Clean, dry, lint-free absorbent tissue

Caution

Do not remove the piston from a new syringe. If you remove the piston, the performance of the syringe can be unreliable.

Figure 235 Location of Syringes



1. Reagent syringe (blue)
2. ISE buffer syringe (clear)
3. Sample syringe (yellow)

Remove the ISE Buffer Syringe

1	Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.
2	Open the middle front door of the analyzer.
3	Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.

4 Pull the syringe case forward to remove it from the mounting grooves.

Figure 236 ISE Buffer Syringe

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

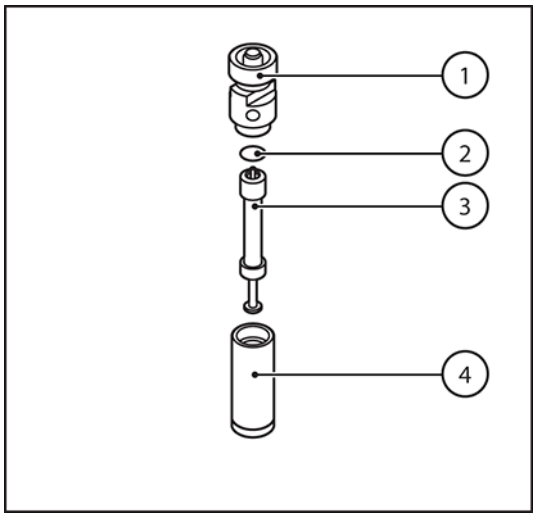
When removing the syringe case, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe case.

5 Tilt the syringe case upside down before removing the syringe. Tilting the syringe case prevents air from entering the tubing lines and keeps the water from leaking into the syringe case.

6 Remove the case body by turning it counterclockwise while holding the case head. Pull the syringe from the case head.

Do not lose the O-ring, which can drop from the case head. If the O-ring remains in the case head, carefully remove it with a pair of tweezers.

Figure 237 Remove the Syringe



1. Case head
2. O-ring
3. Syringe
4. Case body

Install a New ISE Buffer Syringe

1 Obtain a new syringe.

2 Insert the new syringe into the case head.

3 Dry excess water from the syringe and case head to prevent condensation from forming in the case. Screw the case body into the case head by twisting clockwise. Do not over-tighten. Tighten the case body by 45 to 60 degrees from the position that it becomes tight.

4 Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.

5 Tighten the top fixing nut until you hear a clicking sound.

6 Tighten the bottom piston fixing screw.

Prime the New ISE Buffer Syringe

1 Select **Prime Buffer Solution**.

2 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime.

3 If there are bubbles in the syringe after priming, repeat the prime until all bubbles are cleared. If you cannot clear the bubbles after the prime, perform the corrective actions.

For more information, refer to the following section on performing corrective actions if priming fails for the ISE buffer syringe.

4 Close all analyzer doors and covers.

5 Select **Exit Maintenance**.

6 Perform QC, inspect the data, and recalibrate if necessary.

Corrective Actions if Priming Fails for the ISE Buffer Syringe

1 Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.

2 Pull the syringe case forward to remove it from the mounting grooves.

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

When removing the syringe, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe.

Important

Do not apply excessive force to the fixing screws when you remove the syringe case. Excessive force to the fixing screws damages the syringe case.

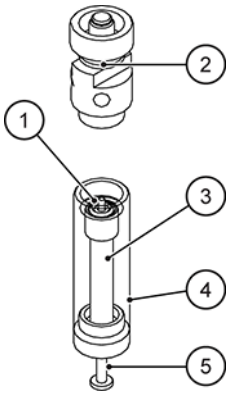
3 Slowly move the syringe piston up and down by hand. Confirm that there are no bubbles on the syringe tip.

If you see bubbles, move the piston up and down until the bubbles are purged.

Caution

Do not move the piston by hand with the case body and case head disconnected. If you move the syringe piston with the case body and case head disconnected, the accuracy is not retained because of the deformation of the piston. This deformation can decrease the time a syringe is in use before requiring replacement.

Figure 238 Confirm No Bubbles are on the Syringe Tip



1. Confirm that no bubbles are attached to the fluorocarbon polymer tip.
2. Case head
3. Syringe
4. Case body
5. Piston

Note

This figure illustrates the disconnected case body and case head to show the location to inspect for bubbles. Do not disconnect the case body from the case head to confirm that there are no bubbles.

4 Reinstall the syringe by placing the syringe case into the mounting groove. Align the syringe piston into the drive shaft.

5 Tighten the top fixing nut until you hear a clicking sound.

6 Tighten the bottom fixing nut.

7 Select **Task Completed**.

Replace the ISE Buffer Syringe Case

If your analyzer includes an ISE module, replace the ISE buffer syringe case.

Replace the ISE buffer syringe case if:

- The case body or case head is chipped, worn, or damaged in any way.

Materials Required:

- ISE buffer syringe case
- Clean, dry, lint-free absorbent tissue

Figure 239 ISE Buffer Syringe Case

1. ISE buffer syringe case (gray)

Install a New ISE Buffer Syringe Case

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Remove the ISE buffer syringe.

Refer to Replace the ISE Buffer Syringe.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

3 Obtain a new syringe case.

4 Insert the syringe into the case head.

5 Dry excess water from the syringe and case head to prevent condensation from forming in the case. Screw the case body into the case head by twisting clockwise. Do not over-tighten. Tighten the case body by 45 to 60 degrees from the position that it becomes tight.

6 Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.

7 Tighten the top fixing nut until you hear a clicking sound.

8 Tighten the bottom piston fixing screw.

9 Select **Prime Buffer Solution**.

10 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime.

11 If there are bubbles in the syringe after priming, repeat the prime until all bubbles are cleared. If you cannot clear the bubbles after the prime, perform the corrective actions.

For more information, refer to the following section on performing corrective actions if priming fails for the ISE buffer syringe.

12 Close all analyzer doors and covers.

13 Select **Exit Maintenance**.

14 Perform calibration and QC for all ISE tests.

Corrective Actions if Priming Fails for the ISE Buffer Syringe

1 Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.

2 Pull the syringe case forward to remove it from the mounting grooves.

Caution

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

Important

When removing the syringe, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe.

Important

Do not apply excessive force to the fixing screws when you remove the syringe case. Excessive force to the fixing screws damages the syringe case.

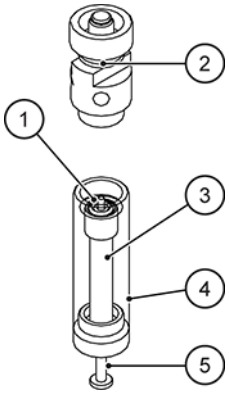
3 Slowly move the syringe piston up and down by hand. Confirm that there are no bubbles on the syringe tip.

If you see bubbles, move the piston up and down until the bubbles are purged.

Caution

Do not move the piston by hand with the case body and case head disconnected. If you move the syringe piston with the case body and case head disconnected, the accuracy is not retained because of the deformation of the piston. This deformation can decrease the time a syringe is in use before requiring replacement.

Figure 240 Confirm No Bubbles are on the Syringe Tip



1. Confirm that no bubbles are attached to the fluorocarbon polymer tip.
2. Case head
3. Syringe
4. Case body
5. Piston

Note

This figure illustrates the disconnected case body and case head to show the location to inspect for bubbles. Do not disconnect the case body from the case head to confirm that there are no bubbles.

4 Reinstall the syringe by placing the syringe case into the mounting groove. Align the syringe piston into the drive shaft.

5 Tighten the top fixing nut until you hear a clicking sound.

6 Tighten the bottom fixing nut.

7 Select **Task Completed**.

Replace the ISE Mix Bar

If your analyzer includes an ISE module, replace the ISE mix bar.

If the ISE mix bar is bent or damaged, you cannot achieve correct analysis. Replace the ISE mix bar.

Warning

Wear personal protective equipment (PPE) such as gloves, eye shields, and lab coats, to handle Beckman Coulter Cleaning Solution (sodium hypochlorite). If the cleaning solution contacts skin or clothes, rinse the affected area thoroughly with water. If the cleaning solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the safety data sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

Materials Required:

- Mix bar

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain and Prime Flow Cell**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the flow cell.

Note

The first time you press the **TABLE ROTATION/DIAG** button on the analyzer, liquid is drained from the flow cell. Each additional time you press the **TABLE ROTATION/DIAG** button, the analyzer primes ISE MID Standard Solution through the flow cell.

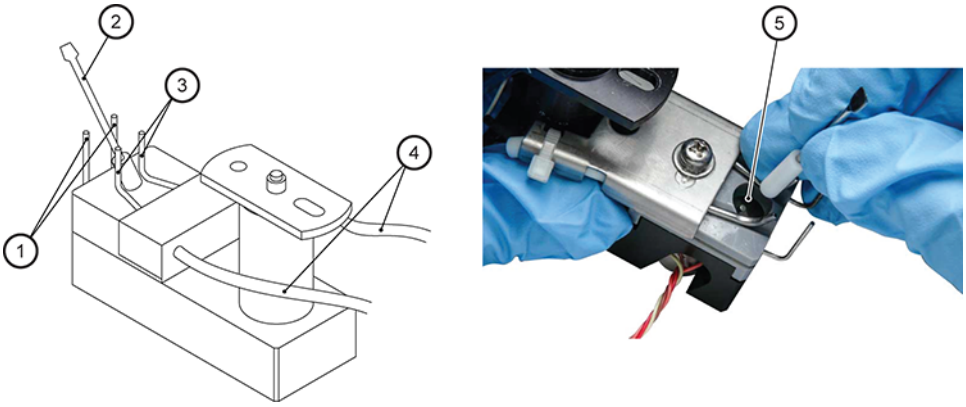
Replace the ISE Mix Bar Procedure

1 Disconnect the liquid level sensor connector 714 and mixing motor connector 706.

2 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to unseat it.

Refer to the video in system help.

Figure 241 Mixing Subsystem



1. Liquid level sensors
2. Mix bar
3. Nozzle
4. Connecting tubing
5. Shaft

3 Pull the mix bar to remove it.

Important

When removing the mix bar, hold the connecting tubing in position on the mixing subsystem.

4 Obtain a new mix bar.

5 Insert the new mix bar into the shaft on the mixing subsystem. Gently push the mix bar until it reaches the end of the shaft.

Figure 242 Inserting the New Mix Bar into the Shaft on the Mixing Subsystem

Reinstall the Mixing Subsystem

1 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

Refer to the video in system help.

2 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

3 Perform a total prime to prime the ISE with fresh ISE Buffer Solution, ISE MID Standard Solution, and ISE Reference Solution.

During the prime, confirm that ISE Buffer Solution and ISE MID Standard Solution are correctly dispensed into the sample pot and flow to waste without generating events.

Also, confirm that the mix bar rotates without contacting the sample pot. The mix bar makes a mechanical noise when it contacts the sample pot.

a. Select **ISE Total Prime**.

b. Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer to start the prime. The indicator light of the TABLE ROTATION/DIAG button turns on after the prime is complete.

4 Close all analyzer doors and covers.

5 Select **Task Completed**.

Important

After you select **Task Completed**, perform QC, inspect the data, and recalibrate if necessary.

Replace the Sample Pot

If your analyzer includes an ISE module, replace the sample pot.

If cleaning the sample pot every 2 weeks does not remove accumulated contaminants, replace the sample pot. Also replace the pot if any cracks or flaws are found in the pot.

For more information, refer to ISE Tubing Block Diagram.

Important

By selecting the link, you will be navigating to another page in the system help. Follow these guidelines:

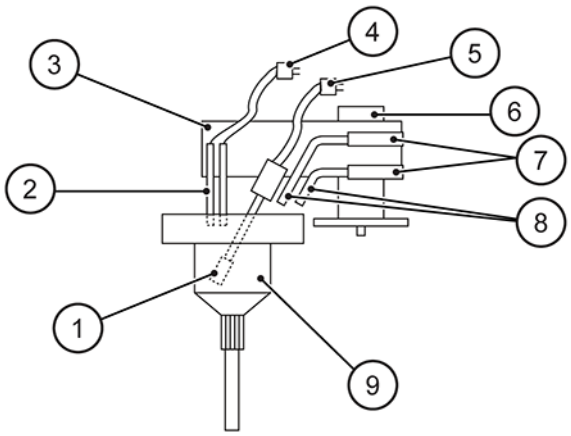
1. After viewing the linked-to task, navigate back to this page in the system help:
   - If you are using a physical mouse, right-click the page in the system help to display the context menu, and then select **Back**.

     If the analyzer does not navigate back to this page, right-click the page in the system help to display the context menu, and then select **Refresh**.
   - If you are using the touch screen, long press on the screen to display the context menu, and then select **Back**.

If the analyzer does not navigate back to this page, long press on the screen to display the context menu, and then select **Refresh**.

2. Continue this procedure by going to the next step.

Figure 243 Sample Pot and Mixing Subsystem



1. Mix bar
2. Liquid level sensor
3. Mixing subsystem
4. Level sensor connector
5. Mixing motor connector
6. Mixing subsystem knob
7. Connecting tubing
8. Nozzles
9. Sample pot

Materials Required:

- Sample pot

Prepare the ISE for Maintenance

Important

Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Select **Drain Bypass Tubing**.

3 Open the upper cover.

4 Open the ISE cover.

5 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The liquid drains from the bypass tubing.

Replace the Sample Pot Procedure

1 Disconnect the liquid level sensor connector 714 and mixing motor connector 706.

2 Loosen the knob securing the mixing subsystem. Gently lift the mixing subsystem to unseat it.

Refer to the video in system help.

Figure 244 Unseating the Mixing Subsystem

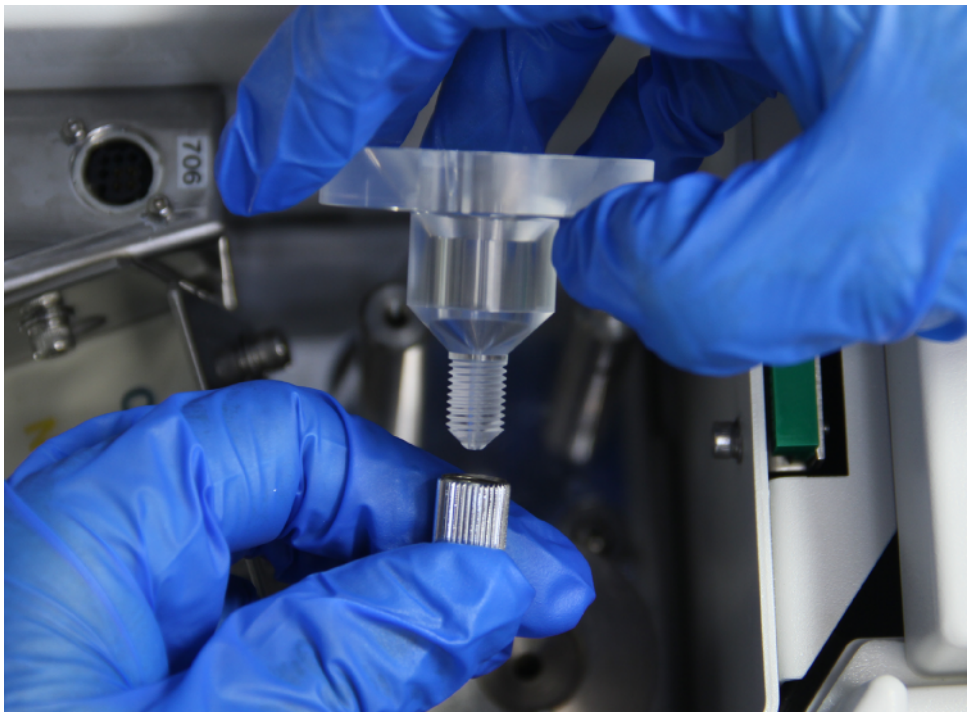
3 Place the mixing subsystem on the mixing subsystem holder.

4 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.

5 Disconnect the sample pot tubing from the sample pot by unscrewing the connector.

Refer to the video in system help.

Figure 245 Disconnecting the Sample Pot Tubing From the Sample Pot



6 Reattach the sample pot tubing to the new sample pot by screwing the connector.

7 Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.

8 Put the mixing subsystem back on the two positioning pins. Tighten the knob to secure the mixing subsystem.

Important

When reinstalling the mixing subsystem, confirm that the tubing is not pinched between the mixing subsystem and its stand.

Refer to the video in system help.

Figure 246 Reinstalling the Mixing Subsystem

9 Reconnect the level sensor connector 714 and mixing motor connector 706.

Important

The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.

10 Select **ISE Total Prime**.

11 Press the **TABLE ROTATION/DIAG** button with indicator light on the analyzer. The indicator light of the TABLE ROTATION/DIAG button turns on after the prime is complete.

12 During the prime, confirm that ISE Buffer Solution and ISE MID Standard Solution are correctly dispensed into the sample pot and flow to waste without generating events.

13 Close all analyzer doors and covers.

14 Select **Task Completed**.

Important

After you select **Task Completed**, perform calibration and QC for all ISE tests.

Clean or Replace the Anti-Static Brushes

Anti-static brushes reduce the chance of static electricity affecting a sample by removing static electricity before sampling takes place.

Caution

To avoid infection, always wear gloves to clean or replace the anti-static brushes.

Materials Required:

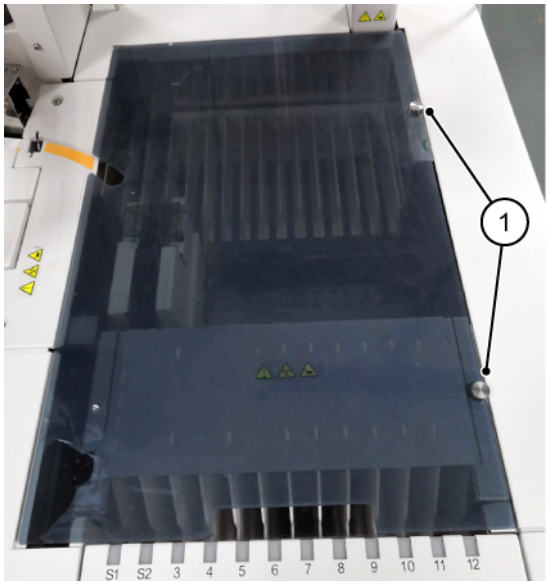
- Anti-static brushes
- Alcohol prep pads (70% Isopropyl alcohol)

1 Confirm that the analyzer is in the *Starting* (*Warmup*) state or the *Running* (*Standby*) state.

2 Open the upper cover.

3 Loosen the two thumbscrews on the right that are holding the sample handler top cover, and remove the sample handler top cover.

Figure 247 Thumbscrews Holding the Sample Handler Top Cover



1. Two thumbscrews holding the sample handler top cover

4 Loosen the fixing screw at the top of one of the anti-static brushes, and remove the anti-static brush.

Figure 248 Fixing Screws for Anti-Static Brushes

1. Fixing screws

5 Repeat the previous step for the anti-static brush that is located on the opposite side of the rack transfer subsystem.

6 Clean any stains on the brushes with an alcohol prep pad (70% Isopropyl alcohol) from the base to the end of the bristle tips.

7 If the anti-static brushes are still stained after cleaning or indicate wear, replace them.

8 Dispose the old brushes in a container for biohazardous waste.

9 Install the cleaned or new anti-static brushes and tighten the fixing screws on top.

10 Put the top cover on the sample handler, and tighten the screws.

11 Close the upper cover.

12 Select **Task Completed**.

Glossary

1-Point Reaction Method — A type of end point reaction method. A general end-point reaction method that determines the optical density of the reaction mixture from the optical density measured at a specified photometric measuring point.

2-Point Reaction Method — A type of end point reaction method. Self-blank method. Provides sample blank adjustment. The optical density values before dispensing reagent are eliminated as the sample blank. This optical density value is then subtracted from the values calculated after dispensing the second reagent. Any contribution to the final reaction optical density from the sample (such as turbidity or icterus) is removed to improve measurement reliability.

ACAL (Auto Calibration) — The AB type (or ACAL) uses calibrator to calculate a calibration factor automatically and create a calibration curve each time the analyzer calibrates. The calibration types are defined in parameters as AB (single point), AA, or 2AB-7AB (multi-point) for each test.

Advanced Calibration — The analyzer can calibrate a maximum of 5 bottles or lot numbers of the same reagent before the analyzer uses the reagent.

Analytical Measuring Range — The range the analyzer can measure for a reagent. If the range is exceeded, the analyzer generates an F (over) or G (under) flag.

Calibration Curve — A curve calculated from the absorbance and concentration of the calibrator. The analyzer then calculates the analyte concentration for a sample using the calibration curve and sample OD.

Calibration History — The analyzer saves a maximum of 100 points of calibration data per sample type per test. View calibration data and status in the Calibration Monitor screen.

Calibrator — Material with a known value that the analyzer uses to establish the measurement relationship.

Cleaning Cuvettes with External Solution — A maintenance procedure that automatically cleans cuvettes, the sample probe, reagent probes, and mix bars using either diluted Beckman Coulter Cleaning Solution (0.5% sodium hypochlorite) or 1N hydrochloric acid. After performing this procedure, perform a photocal.

Cleaning Cuvettes with Internal Wash — A maintenance procedure that automatically cleans cuvettes using the wash nozzle subsystem before and after analysis in routine operation.

Consumable — Supply that is used when the analyzer processes samples.

Control Material — Material used to confirm the performance characteristics of an in vitro diagnostic medical device.

Critical Limits — Operator-defined boundaries of critical values. If the limit is exceeded, the analyzer generates an audible alert and a HH (high) or LL (low) flag.

Cuvette — A glass vessel that the analyzer uses as the reaction vessel, containing the sample and reagent.

Dead Volume (Reagent) — Reagent volume that the reagent probe cannot aspirate, and remains in the bottle. The dead volume depends on the size of the reagent bottle.

Dead Volume (Sample) — Sample volume that the sample probe cannot aspirate, and remains in the tube or cup. The dead volume depends on the type of cup or tube.

Dilution Factor — Specifies the total number of parts of a sample, including 1 part of the undiluted sample.

For example, a dilution factor of 50 indicates 1 part of undiluted sample and 49 parts of diluent. A dilution factor of 1 means no dilution.

End Point Reaction Method (END) — The three types of end point reaction methods:

- 1-point reaction method. Refer to 1-Point Reaction Method .
- 2-point reaction method. Refer to 2-Point Reaction Method .
- Sample blank correction. Refer to Sample Blank Correction .

END1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Event — Any significant occurrence in the system or in a program that requires users to be notified or an entry to be added to a log.

Event Level — The number of tests that can be performed using the remaining reagent. The analyzer generates a Reagent Insufficient event when the remaining reagent volume decreases to the number of tests.

Fixed Point Reaction Method (FIXED) — A method of calculation that determines the difference between the optical densities at two specific time points within a reaction. FIXED1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Flag — Symbols that display on analysis results, indicating that a problem or an error has occurred during analysis. A result with a flag must be reviewed and have corrective actions performed before reporting results. For more information, refer to Chemistry Result Flags.

Functional Sample Type — A sample type that contains all parameters required to process a test. Tests can have a number of functional sample types (serum, urine, CSF, whole blood or other).

LAG_TIME Check — If a reaction is terminated too quickly, effective data at two points or more may not be acquired. In this situation, the analyzer can be set up to calculate the analysis result using the data in the lag phase. Used for tests that use the rate reaction method. Refer to the individual method parameters to determine the correct setting for the test.

LIH Testing - Serum Index — Evaluates and performs test of lipemia (L), icterus (I), and hemolysis (H) in serum and plasma. LIH is the symbol used for testing lipemia (L), icterus (I), and hemolysis (H).

Linearity — Ability of a measuring method to generate results that are proportional to the analyte concentration in a sample.

MCAL (MB) — A type of calibration that does not use any calibrator material. A preset MB factor has been determined and is entered per the reagent setting sheet provided for this type of test.

Optical Density (OD) — The measurement of the amount of light absorbed by a solution in the cuvette with the use of a photometer. The higher the optical density the lower the transmittance.

Non-Functional Sample Type — A sample type that uses all parameters from a functional sample type, including its calibration. Tests can have a number of non-functional sample types (plasma or any user-defined label). Refer to Functional Sample Type .

Note

Tests with a plasma sample type will use parameters from serum. The plasma sample type will be labeled as serum on the All Calibrations, Edit Calibration Order, Calibration Curve Details, Reagent Review Details, and RB Result Details pages.

Photocal Measurement — Evaluates the integrity of the cuvettes used to obtain accurate analysis results. Confirm the photocal data obtained from a photocal measurement in the Photocal dialog.

QC Test — The process of analyzing samples with known concentrations of analytes to test the quality of reagents, calibrators, analyzer, and procedures.

Rate Reaction Method (RATE) —

- Normal rate reaction method measures the variation in the rate of absorbance per minute by calculating the average change in absorbance between two photometric points, using the least squares method.
- Double rate reaction method determines the rate of absorbance variation per minute by calculating the average of the absorbance variations between two measuring points, using the least squares method. The rate of absorbance before dispensing reagent 2 is subtracted from the value calculated after dispensing the second reagent.

RATE1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Reagent — A combination of chemicals that react with the target analyte in the sample. The DxC 500 AU uses one (R1), two (R1 and R2), or more than two reagents per analyte.

Reagent Blank (RB) — In the analysis, the reagent blank serves as the reference value for the reagents at each photometric point of individual analysis tests. It also becomes the Y-intercept of calibration curves created by ACAL.

Reagent ID — The analyzer identifies reagents placed on board the analyzer using the bar code label.

Reflex Testing — A function to generate a rerun order automatically for the Related Test by linking the Related Test to the Deciding Test. Reflex testing occurs when the Deciding Test has resulted in a rerun through result processing rules in the system configuration.

Related Test — The analyzer automatically orders the test for rerun when the Deciding Test has resulted in a rerun through result processing rules in the system configuration. A maximum of five tests can be programmed as Related Test in combination with a Deciding Test.

Rerun — A process whereby the analyzer tests the samples again, either manually or automatically.

Sample Blank Correction — A type of end point reaction method. Measures the blank item and then subtracts the value from the measured optical density, to calculate the optical density of the reaction. This method requires an extra blank.

Sample Diluent — Solution the analyzer uses for a manual or automatic dilution of samples.

Sample ID — An alphanumeric code assigned and used to identify each sample. The analyzer reads the sample bar code label attached to the sample cup to identify the sample ID.

Shut Down — Shutting down the analyzer turns off the analyzer lamp and the computer. The analyzer maintains the refrigerator, incubation bath, and STAT table temperatures. The ISE module performs an automatic prime with ISE MID Standard Solution every hour to keep the electrodes conditioned.

Standard Deviation — Measurement of statistical dispersion. In multiple measurements of the same sample, the standard deviation measures how spread out the values are.

Test Order — An instruction to perform tests on a sample. When a sample is placed on the analyzer, the analyzer uses the test order information to link the sample to the required tests.

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