Operations Manual

IMMAGE 800
Immunochemistry System

For *In Vitro* Diagnostic Use

A11403AF
January 2021

Beckman Coulter, Inc.
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BECKMAN COULTER

IMMAGE 800 Immunochemistry System
Operations Manual
PN A11403AF (January 2021)

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www.beckmancoulter.com

Original Instructions

Revision History

A11403AF, January 2021
Software version 2.1

Changes:

- Removed EC REP address.
- Removed CE mark.

Throughout Manual
- Removed references to the *Chemistry Information Manual*.

Chapter 1
- Added IMMAGE Symbols and Hardware Labels section to replace and enhance old Symbols and Labels section from the Safety section of the IMMAGE 800 Addendum.
- Added the Electromagnetic Compatibility section.
- Added Laser Labels.
- Updated Figure 2.15.
- Added the Legacy Hardware Labels section.

Chapter 2
- Updated Figure 2.16
- Updated the IMMAGE 800 Program Tree (4 of 5)

Chapter 10
- Updated several sections with information about placing the IMMAGE system in *Diagnostics* mode before attempting certain maintenance or parts replacement procedures.
- Removed the Sample and Reagent Crane Probe section.

A11403AE, September 2016
Software version 2.0

Changes:
Copyright page
- Revised EC REP address.

Appendix A, *Part Number List* was deleted.
- Refer to www.beckmancoulter.com or contact your Beckman Coulter representative.

A11403AD, October 2011
Software version 2.0

⚠ Safety Notice

Introduction

This safety notice summarizes information basic to the safe operation of the IMMAGE 800 Immunochemistry System described in this manual. The international symbol displayed above is a reminder that all safety instructions should be read and understood before installation, operation, maintenance, or repair of this instrument. When you see the symbol on other pages, pay special attention to the safety information presented. Observance of safety precautions will also help to avoid actions that could damage or adversely affect the performance of the instrument.

Other symbols may also be displayed on the equipment. These are reproduced and described in the Operating Precautions and Hazards section.

Safety During Installation and/or Maintenance

This instrument is designed to be installed by a Beckman Coulter Field Service representative. Installation by anyone other than authorized Beckman Coulter personnel invalidates any warranty covering the instrument.

Any servicing of this equipment that requires removal of any covers can expose parts which involve the risk of electric shock or personal injury. Make sure that the power switch is turned OFF and that the instrument is disconnected from the main power source. Refer such maintenance to qualified service personnel.

Electrical Safety

- To reduce the risk of electrical shock, this instrument uses a three-wire electrical cord and plug to connect to earth-ground. Make sure that the matching wall outlet receptacle is properly wired and earth-grounded.
- Never remove or install any circuit board, connect or disconnect any plug or cable, while the power is ON. Always use the antistatic wrist strap located in the electronic board compartment when removing or installing any circuit board.
- Do not place containers holding liquid on top of the instrument. If a spill occurs, liquid may get into the instrument and damage electrical or mechanical components.

Safety Against Risk of Fire

Fuses protect certain electrical circuits within this instrument against overcurrent conditions. For continued protection against the risk of fire, replace only with the same type and rating specified.

Mechanical Safety

For safe operation of the equipment, observe the following:

- Operate the system with reagent door and covers and shields in place.
- During power up, routine operation, and diagnostic procedures, keep hands and/or foreign objects out of the path of the carousels and probes.
- Do not attempt to clean around the carousels and probes while they are in motion. Wait until the instrument is in "standby" to perform cleaning procedure.

Chemical and Biological Safety

Normal operation may involve the use of solutions and test samples that are pathogenic or infectious. Observe all laboratory policies or procedures which pertain to the handling of these materials.

- The reagents and other chemical preparations used with the system will not normally cause adverse reactions; however, those persons with sensitive skin should wear protective gloves before attempting to work with reagents and other chemical preparations.
- Do not handle sample or solutions without proper protection. Body fluids and other infectious samples must be handled according to good laboratory practice to prevent spread of disease.
- When performing maintenance, service, or troubleshooting on elements of the system that have contacted sera or other biological fluids, observe standard laboratory precautions. It is always necessary to wash your hands thoroughly after performing any routine maintenance.

Dispose of all waste solutions according to appropriate environmental health and safety guidelines.

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General Information/Precautions and Hazards

Introduction

Intended Use

The Beckman Coulter IMMAGE 800 Immunochemistry System is a fully automated, computer controlled, bench-top analyzer designed for the in vitro quantitation of biological fluid components. The system methodologies are rate turbidimetry and rate nephelometry.

The IMMAGE 800 is a high throughput, random access analyzer that features bar code identification of samples and reagents to perform sample testing. It automatically dilutes the samples and delivers them to the reaction cuvette along with other reaction constituents. The system analyzes up to 72 samples per run with up to 24 analytes per sample.

How to Use This Manual

Scope of This Manual

This manual provides information on the operation of the IMMAGE 800. Diagnostic interpretation or the clinical significance of the assay results provided by the system are not discussed in this manual. Typical and actual results are shown only to demonstrate the operating procedures, parameters, and characteristics of the system.

IMMAGE Reagent Instructions For Use

This manual should be used in conjunction with the IMMAGE Immunochemistry Systems reagent *Instructions For Use* (for individual reagents) which contains specific chemistry information for the full range of analytes available on the IMMAGE 800.

Manual Conventions

The IMMAGE 800 Immunochemistry System *Operations Manual* uses the following printed and visual cues to guide the user in how to respond to printed directions.

Table 1.1 IMMAGE 800 Conventions

Convention	Description
Icon Buttons	Icon buttons are in bold with one letter underlined. The underline indicates which letter to press in combination with the Alt key to select the icon button from the keyboard.
Function Buttons [F1]	Function buttons are in bold with the corresponding function key in square brackets ([ ]).
<Buttons>	The "less than" (<) and "greater than" (>) symbols enclose a button's name in bold.
Options button < ▼ >	The "less than" (<) and "greater than" (>) symbols enclose a black triangle, preceded by the phrase "options button", all in bold.
Text field	Names of text fields are followed by the word "field", all in bold.
[X], [→] or [Tab]	Keyboard keys are in bold and enclosed by square brackets ([ ]).
[Alt + X]	Combination keys are in bold and enclosed by square brackets ([ ]) with a plus (+) between each key.

Manual Format

Information in this manual is presented in modular units. Each unit of information is described by a brief title in the left margin.

Many units consist of a table which presents a procedure, process, or description.

Procedure Tables

Procedure tables are the most common type of table in this manual. They list each step of a procedure by number with the corresponding action that is to be performed.

A "Refer to Figure x.x." instruction directs the operator to the screen that displays as a *result* of the action requested in the step.

Occasionally, a decision must be made at a step within a procedure. A smaller decision table is then presented which describes the variable conditions in the left column and the appropriate action for each condition in the right column.

Example of Procedure Table

The following table is an example of a procedure table that contains a decision table.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Rerun Samples [F6]. (Refer to Figure x.x.)</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To enter...</th><th>type...</th></tr>
<tr><td>individual Sample IDs,</td><td>the Sample IDs for rerun in the Sample IDs field.</td></tr>
<tr><td>a range of Sample IDs,</td><td>the Sample ID at the beginning of the range in the Range field.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select a button from the bottom of the dialog box.</td></tr>
</table>

Read the decision table as complete sentences, using the first heading to introduce the condition and the second heading to introduce the action. Step 2 of the table is read:

To enter individual Sample IDs, type the Sample IDs for rerun in the **Sample IDs** field.

To enter a range of Sample IDs, type the Sample ID at the beginning of the range in the **Range** field.

Warranty and Service Policy Information

Warranty Policy

The IMMAGE 800 Immunochemistry System is covered by and subject to the exceptions of the standard warranty enclosed with each system. Failure to operate the system in accordance with this manual voids the warranty.

Service Information

If any fault develops in the system, call the Beckman Coulter Clinical Support Center. Give full details of the difficulty. Be sure to have the model and serial number (located on the lower right side of the instrument near the front.)

For USA and Canadian customers only:
Call your local Beckman Coulter office toll-free from anywhere in the continental United States, Alaska, Hawaii, and Canada at (800) 854-3633.

For customers outside the USA and Canada:
Call the nearest Beckman Coulter Field Service Office.

Responsibility During the Warranty Period

The user is responsible for the routine preventive maintenance procedures described in the maintenance section of this manual. Repairs arising from failure to perform these maintenance procedures at the indicated time intervals will be made at the user's expense.

Shipping Damage

Each IMMAGE 800 System is carefully examined and checked by Beckman Coulter before it is shipped. When you receive your new IMMAGE 800 System, visually inspect the shipping container for any possible damage. If there is damage, notify the Beckman Coulter Service Representative before his/her arrival at your facility to install your system.

If no damage is found to the shipping container, the Beckman Service Representative will supervise the unpacking of your system. If it is damaged in any way, the customer should file a claim with the carrier. If no damage is found, a visual and operational check of your system will be performed.

Precautions

Introduction

The operational precautions below enable the user to avoid those actions which could result in an invalid quantitative determination.

Proper Handling of a USB Flash Drive

A USB flash drive requires special care in handling.

- Only connect the USB flash drive to the console.
- Do not plug the USB flash drive into the USB port when not is use.
- Protect it from moisture, cold, and heat.
- Do not carry the USB flash drive around in your clothing.
- Do not run software from the USB flash drive.
- Do not use the same USB flash drive on multiple IMMAGE systems in the lab. Each system should have its own designated USB flash drive, and it should be labeled with System ID/Serial Number on it to avoid confusion.

Proper Handling of Compact Disks

Compact disks (CD-ROMs) require special handling to prevent damage.

- Do not place a CD-ROM in direct sunlight or excessive heat or humidity.
- Hold a CD-ROM by the edges.
- Replace a CD-ROM in its case after use.

Sample Volumes

Sample containers must contain an adequate volume of test specimen to ensure accurate aspiration. Refer to the IMMAGE Immunochemistry Systems reagent *Instructions for Use* and the Systems Sampling Template for information regarding volume requirements.

CAUTION

Use extreme care when removing bar coded or labeled glass sample tubes from the IMMAGE 800 sample racks to avoid breakage. Rotating the tube slightly while pushing from the bottom of the tube may make removal easier.

Hazards

Introduction

The following hazards are identified to ensure maximum safety of the user.

Booting Up

Close reagent and sample carousel covers and keep clear of all mechanical assemblies when booting up the system.

Three-pronged Power Plugs

The three-pronged power plug from all system components of the IMMAGE 800 Immunochemistry System must be connected to a three-wire grounded power source.

- Do not use an adapter to connect the power plug to a two-pronged outlet.
- If the electrical outlet will not accept the three-pronged plug, notify qualified maintenance personnel; they will supply the required electrical ground.

DO NOT UNDER ANY CIRCUMSTANCES OPERATE THE SYSTEM UNTIL AN ELECTRICAL GROUND IS PROVIDED AND THE POWER CORD IS PROPERLY CONNECTED TO GROUND.

Emergency Stop

Turn the instrument main power switch off if the stop button on the screen is unavailable, and the instrument must be stopped immediately.

Cranes

Keep clear of both cranes while the instrument is running.

Covers

Keep all covers and shields in place while the instrument is running.

Adding Samples to an Operating Instrument

The instrument status must be in *Standby* when adding or changing reagents, buffers, diluents, or dilution segments. The instrument status must be in *Standby* or *Pausing-OK to load samples* when adding or removing samples. Keep reagent and sample carousel covers closed while the instrument is running.

Pausing the System to Load Samples

If you pause the system to load or remove samples while the system is running, DO NOT load or remove samples until the *OK to load samples* message appears on the screen. Failure to comply may cause personal injury.

Replacing Mechanical or Electrical Parts

Before replacing any defective mechanical or electrical part in the system, confirm that the power to the system is turned off.

Bar Code Readers

DO NOT tamper with or remove the housing of any bar code reader.

Disposal of Waste Liquids

All waste liquids from the IMMAGE 800 Immunochemistry System should be disposed of in an approved method for handling biohazardous material.

Biological Samples

Observe all laboratory policies or procedures pertaining to the handling of biological samples that may contain pathogens.

Preservatives

Sodium azide preservative may form explosive compounds in metal drain lines. See National Institute for Occupational Safety and Health bulletin: Explosive Azide Hazards (8/16/76).

Incineration of used reagent cartridges may produce toxic fumes.

Handling of Hazardous Substances

If a hazardous substance such as blood is spilled onto the IMMAGE 800 System, clean up the spill by using a 10% bleach solution, or use your laboratory decontamination solution. Then follow your laboratory procedure for disposal of hazardous materials. If the IMMAGE 800 System needs to be decontaminated, call your Beckman Coulter Service Representative for assistance.



A011460L.EPS

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.

IMMAGE Symbols and Hardware Labels

The following symbols and hardware labels are attached to the IMMAGE 800. Use caution, observe and follow all warning labels. Do not cover or remove these labels. If the labels peel off or become illegible, contact Beckman Coulter to replace the labels.

- Orange labels identify areas of the system where hazards exist and where caution should be taken to avoid serious injury or death.
- Yellow labels indicate that there is a risk of personal injury, fire, or damage.
- Instruction Labels are affixed on the system at relevant locations to alert the operator to operate the system correctly.

Caution Read Manual Symbol



This symbol indicates that all operators must read the instrument's IFU and operation manuals for an explanation of the Caution or Warning.

Reagent Compartment Cover Label



This label is located on the reagent compartment cover. The instrument will stop if the cover is opened.

Biohazard Symbol



This is the international symbol for biohazardous material. This label indicates the use of biohazardous materials in the area such as sample probes, mixer bars, sample racks, cuvettes, a sample probe wash well, and so forth. 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.

Caution Biohazard Label



This cautionary label is located between the sample and reagent carousels. Operate the system with all covers in place.

Moving Parts Symbol



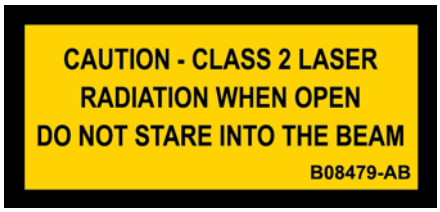
The Moving Parts Symbol indicates that there are moving parts in the area and that the system should be operated only when all covers are in place and caution is used to reduce risks of personal injury. Failure to properly seat covers could lead to erroneous results. Moving parts may include the sample probe, reagent probes, parts of the syringes, mixer bars, and so forth.

Laser Radiation Symbol



The Laser Radiation Symbol indicates that there may be laser light radiation in the area. Take precautions to prevent exposure.

Caution Class 2 Laser Panel Marking



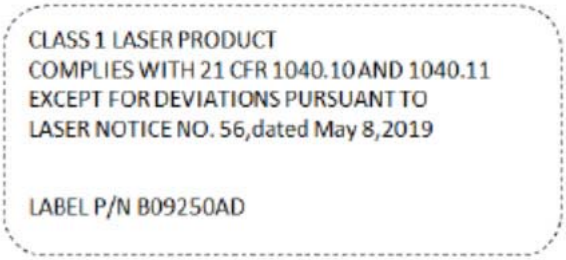
This Panel Marking indicates that there is Class 2 laser light radiation beyond the panel it is placed on. This label is placed inside the Sample Wheel Compartment, near the opening through which a bar code reading beam emits. Use caution and do not stare into the beam when laser light is in the area or when cover is opened or removed.

Bar Code Caution Label



This label is placed inside the Reagent Compartment near the opening through which a bar code reading beam emits. Do not stare into the laser light beam when the cover interlock is defeated.

Laser Certification Label



The Class 1 Laser Product Label indicates that the product contains a Class 1 laser that complies with US requirements (21 CFR 1040.10 and 1040.11). This label is located on the right side panel.

Chinese Laser Label



Caution Laser Class 2 Protective Housing Label



CE Mark

The CE mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and environmental protection requirements.

Regulatory Compliance Mark



This Regulatory Compliance Mark (RCM) indicates compliance with the ACMA requirements (safety and EM) for Australia and New Zealand.

Recycling Label



This label is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this label indicates that:

1. The device was put on the European Market after August 13, 2005 and,
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 local Beckman Coulter office for details on the take-back program that facilitates the correct collection, treatment, recovery, recycling and safe disposal of these products.

   For the Japan Market:

   This system is considered an industrial waste, subject to special controls for infectious waste. Prior to disposal of the system, refer to the “Waste Disposal and Public Cleaning Law” for compliance procedures.

Restrictions of Hazardous Substances (RoHS) Labels

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.

RoHS Caution Label



This logo 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.

QNX License



This symbol indicates the license number for the QNX software included in the computer.

Consult Instructions for Use



This symbol indicates that the user should read the product's Instructions For Use before using the system.

Manufacturer Identifier



This symbol indicates the location of the legal manufacturer.

Date of Manufacture



This symbol indicates the date of manufacture.

EC Representative



This symbol indicates the European Community Representative for the product.

CSA



This symbol indicates recognition by a nationally recognized testing laboratory that the instrument has met the relevant product safety standards for the US and Canada.

In Vitro Diagnostic Use



This symbol indicates that the instrument is an in vitro diagnostic medical device.

Keep Dry



This symbol indicates that the instrument must be kept dry.

Product or Reference Number



This symbol indicates the model number, catalog number or part number of the equipment.

Temperature Limitation



This symbol indicates storage requirement temperature limitations.

USB Port



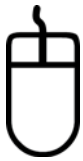
This symbol indicates a USB port.

Computer Power Switch



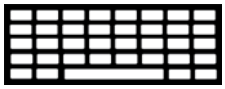
This symbol, located above the computer power button, indicates On or Standby conditions. A green light indicates the power to the computer is ON.

Connection Between Computer and Mouse



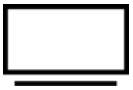
This symbol is located beside the connection between the computer and the mouse.

Connection Between Computer and Keyboard



This symbol is located beside the connection between the computer and the keyboard.

Connection Between the Computer and the Monitor



This symbol is located beside the connection between the computer and the monitor.

Instrument or Uninterruptible PowerSupply (UPS) Power Switch, ON



This symbol is located on the instrument and the UPS main power switches. When the portion of the switch that displays this symbol is depressed, the instrument is ON.

Instrument or UPS Power Switch, OFF



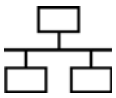
This symbol is also located on the instrument and the UPS main power switches. When the portion of the switch that displays this symbol is depressed, the instrument is OFF.

Monitor Power Switch



This symbol, located on the monitor power button, indicates On or Standby conditions. A green light indicates the power to the monitor is ON.

Network Port



This symbol indicates the location of a network connection port on the computer.

California Proposition 65



This product may contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to https://www.P65Warnings.ca.gov.

Legacy Hardware Labels

C-Tick Mark



The C-Tick mark is intended for use on products that comply with the applicable Electromagnetic Compatibility (EMC) standards in the Australian or New Zealand market.

Moving Parts Label



This label indicates moving parts that can pinch or crush. This label is found in several locations.

Caution parts move automatically.

While the system is in operation, do not touch or go close to any moving parts. Close protective guards and covers during operation. Failure to close covers correctly can cause injury or incorrect results.

Moving Parts Symbol



The moving parts symbol indicates that there are moving parts in the area. Only operate the system when all covers are in position and use caution to reduce the risk of personal injury. While the system is operating, do not touch the moving parts of the system. Do not insert fingers or hands into any system opening.

CHAPTER 2 System Description

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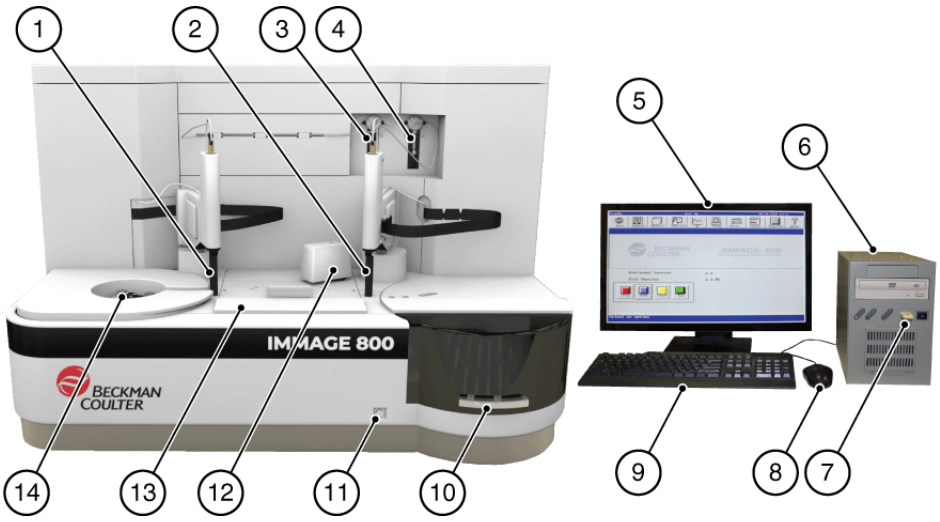
Hardware Components

Overview

Introduction

The IMMAGE 800 Immunochemistry System is a bench-top analyzer composed of the IMMAGE 800 instrument and computer. (Refer to Figure 2.1.) The system is shipped complete for installation. The system will be installed by a Beckman Coulter Representative.



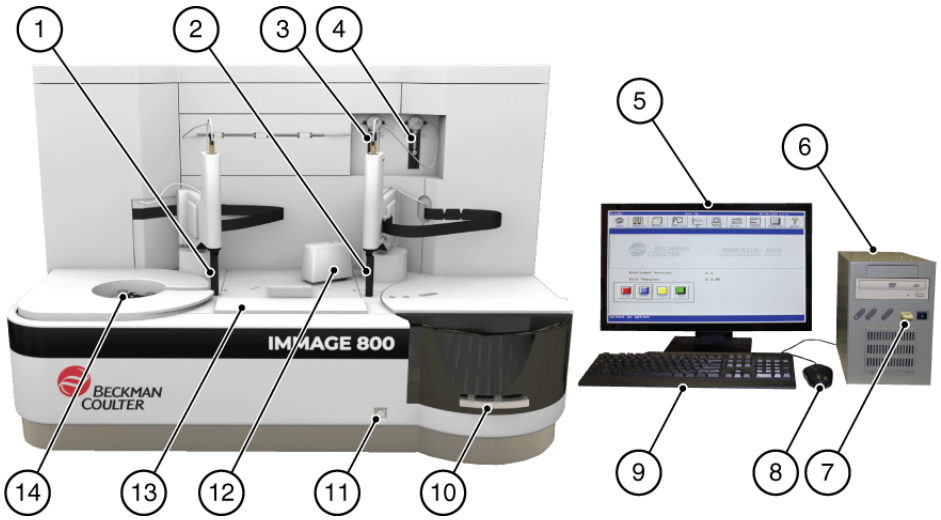
1. Reagent Probe and Mixer
2. Sample Probe and Mixer
3. Reagent Syringe
4. Sample Syringe
5. Monitor
6. Computer
7. USB Flash Drive
8. Mouse
9. Keyboard
10. Sample Carousel
11. Advance Button
12. Cuvette Wash Station
13. Reaction Module
14. Reagent Compartment

Figure 2.1 IMMAGE 800 Immunochemistry System

Instrument

Description

The IMMAGE 800 instrument is the analytical unit where the samples and reagents are loaded and where the chemical reactions take place.
(Refer to Figure 2.2.)



1. Reagent Probe and Mixer
2. Sample Probe and Mixer
3. Reagent Syringe
4. Sample Syringe
5. Monitor
6. Computer
7. USB Flash Drive
8. Mouse
9. Keyboard
10. Sample Carousel
11. Advance Button
12. Cuvette Wash Station
13. Reaction Module
14. Reagent Compartment

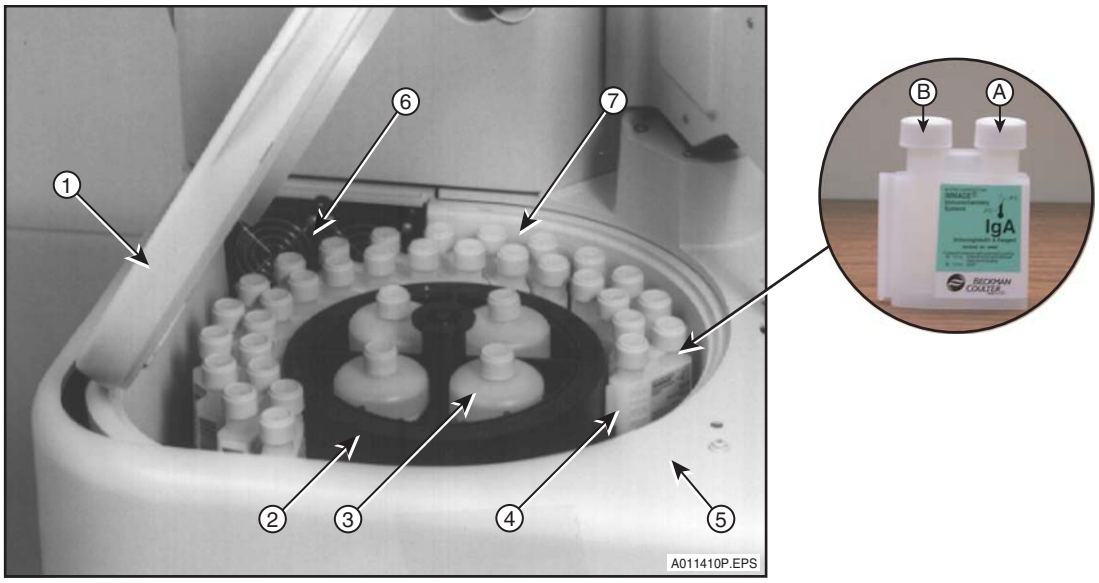
Figure 2.2 IMMAGE 800 Immunochemistry System

Reagent Compartment

Description

The reagent compartment is the area of the instrument where the removable reagent carousel is stored. The temperature of the compartment is maintained at approximately 15°C. (Refer to System Specifications and Characteristics, "Temperature and Humidity" in this chapter.)

Reaction buffer bottles are placed in the center of the reagent compartment. The bottles are maintained at room temperature. (Refer to Figure 2.3.)



1. Reagent Compartment Cover
2. Reagent Carousel
3. Reaction Buffer Bottle
4. Reagent Cartridges (Compartments A and B)
5. Reagent Bar Code Reader
6. Fans
7. Temperature Sensor

Figure 2.3 The Reagent Compartment

NOTICE
The instrument will stop if the reagent compartment cover is opened.

Component List

The following table lists each component of the reagent compartment with its function.

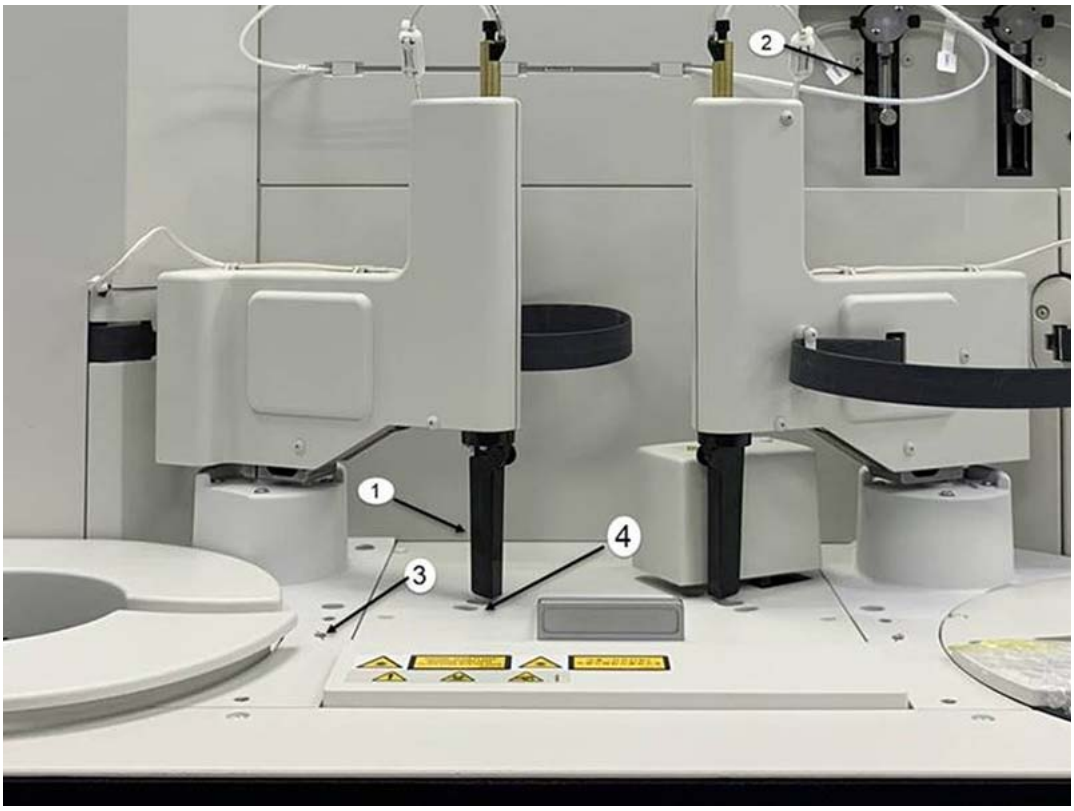
Table 2.1 Reagent Compartment Components

Number	Component	Function
1	Reagent Compartment Cover	Necessary to maintain temperature within compartment.
2	Reagent Carousel	Holds up to 24 reagent cartridges and 4 reaction buffer bottles.
3	Reaction Buffer Bottles	Contain reaction buffers.
4	Bar Coded Reagent Cartridges	Contain chemistry specific reagent including (where applicable): • Reagent • AGXS (antigen excess) Solution • Co-reagent • Conjugate • Evaporation Caps The cartridges are bar coded to allow for instrument identification of each cartridge.
5	Reagent Bar Code Reader	Reads bar codes on reagent cartridges.
6	Fans	Circulate cool air in reagent compartment.
7	Peltier Temperature Sensor	Helps control 15°C in reagent compartment.

Reagent Crane

Description

The reagent crane transfers reagents and buffers from the reagent compartment to the reaction wheel. (Refer to Figure 2.4.)



1. Reagent Probe/Mixer
2. Reagent Syringe Pump
3. Reagent Crane Wash Station
4. Reagent Addition Ports

Figure 2.4 Reagent Crane

Component List

The following table lists each component of the reagent crane with its function.

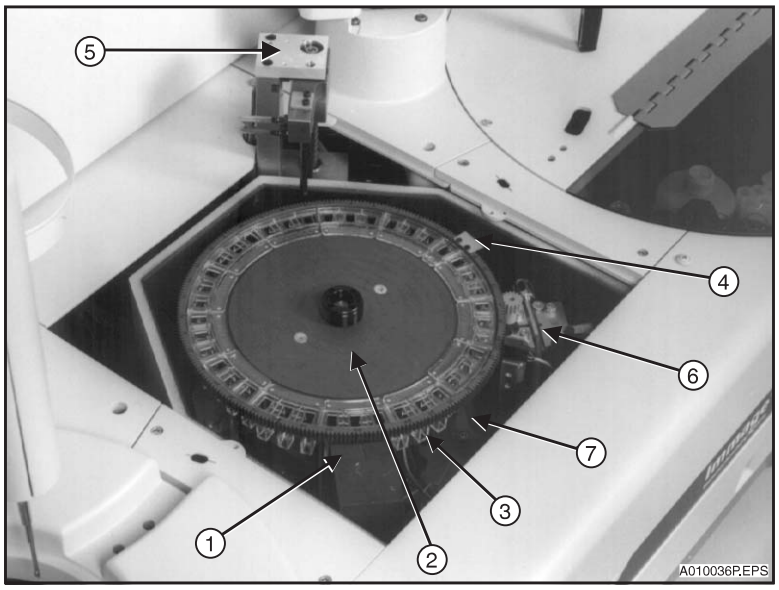
Table 2.2 Reagent Crane Components

Number	Component	Function
1	Reagent Probe	Aspirates reagents and buffer from the reagent compartment and dispenses them into a cuvette on the reaction wheel.
	Reagent Paddle Mixer	Mixes the contents of a cuvette after reagent or buffer has been dispensed.
2	Reagent Syringe Pump (500 µL)	Mechanism for accurate reagent and buffer aspiration and delivery through the reagent probe.
3	Reagent Crane Wash Station	Washes interior and exterior of reagent probe/ mixer.
4	Reagent Addition Ports	Two openings in reaction module cover to allow reagents to be added to one of two different cuvette locations.

Reaction Module

Description

The reaction module is the area of the instrument where the reaction takes place. The temperature of the reaction module is maintained at approximately 37°C. (Refer to Figure 2.5 and System Specifications and Characteristics, "Temperature and Humidity" in this chapter.)



1. Optics
2. Reaction Wheel
3. Cuvette
4. Reference Cuvette
5. Cuvette Wash Station
6. Heat Block Temperature Sensor
7. Status Monitor Temperature Sensor

Figure 2.5 Reaction Module

Component List

The following table lists each component of the reaction module with its function.

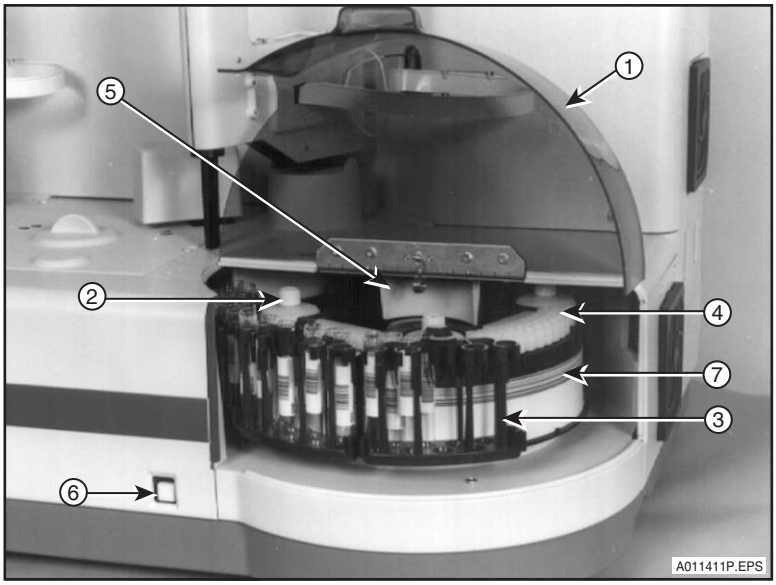
Table 2.3 Reaction Module Components

Number	Component	Function
1	Optics	Measures light scatter in nephelometric reactions (670 nm wavelength) and turbidimetric reactions (940 nm wavelength).
2	Reaction Wheel	Holds 39 reaction cuvettes and the reference cuvette. Spins to move individual cuvettes to correct positions for each stage of the analysis.
3	Cuvettes	Hold the combined reactants. The reaction being measured takes place in the clear, plastic cuvettes. The optics pass light through the cuvette to measure scatter.
4	Reference Cuvette	Has a known scatter value. The instrument measures the scatter from the on-board reference cuvette. It then adjusts the optics based on these measurements and the known reference values.
5	Cuvette Wash Station	Washes the cuvette after the reaction is complete.
6	Heat Block Temperature Sensor	Controls 37°C in reaction module.
7	Status Monitor Temperature Sensor	Monitors reaction module temperature.

Sample Carousel

Description

The sample carousel is the area of the instrument where the samples are loaded onto the system and where the diluents are placed. Samples are loaded onto the system via sample racks. All sample cups must be placed on the system using the Sample Cup Holder Kit. To ensure sufficient sample aspiration, do not place sample cups directly into the racks or use 1.0 mL sample cups. Sample dilutions are made in dilution wells. (Refer to Figure 2.6.)



1. Sample Carousel Cover
2. Sample Diluent Bottle
3. Sample Rack
4. Dilution Segment
5. Sample Bar Code Reader
6. Sample Carousel Advance Button
7. Background Bar Code Label

Figure 2.6 Sample Carousel

Component List

The following table lists each component of the sample carousel with its function.

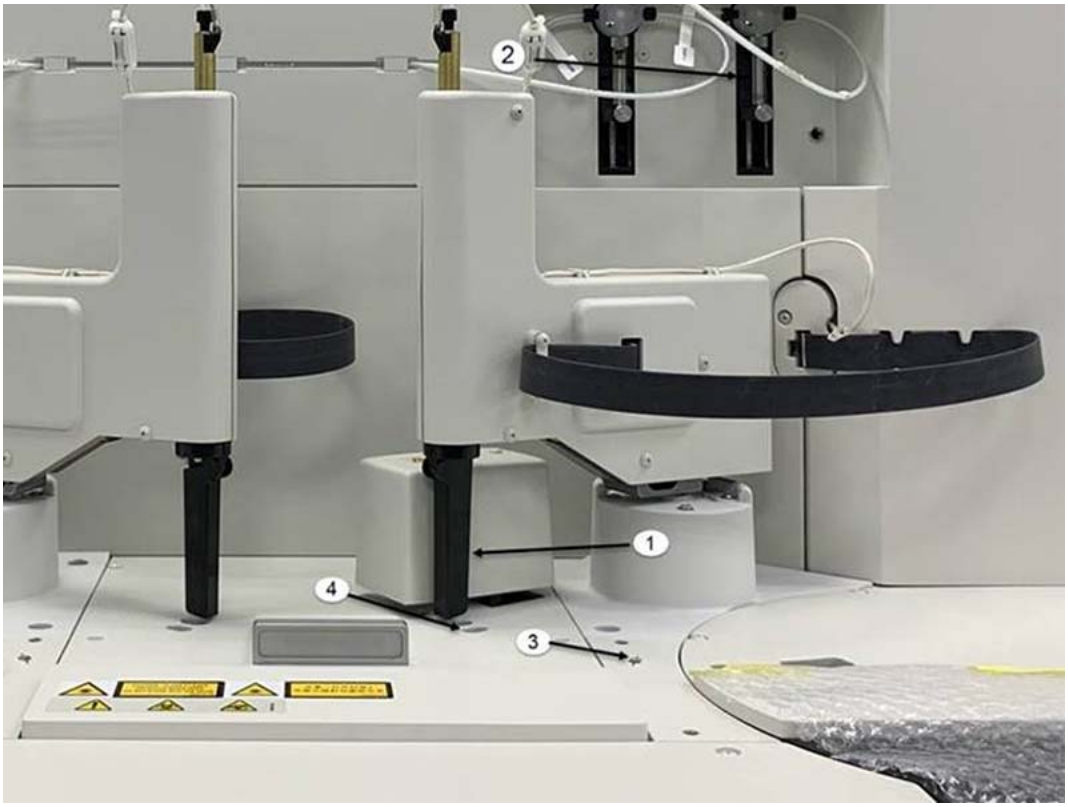
Table 2.4 Sample Carousel Components

Number	Component	Function
1	Sample Carousel Cover	Reduces evaporation of sample.
2	Sample Diluent Bottles	Contain sample diluents.
3	Sample Racks	Hold sample tubes. (Refer to Racks in this section of the manual.)
4	Dilution Segments	The various sample dilutions are automatically made in the wells of the dilution segments before delivery to the reaction wheel. The disposable dilution segments are placed on the system by the user.
5	Sample Bar Code Reader	Scans bar codes on the sample carousel including: • bar coded sample tubes • sample rack bar codes • background bar codes • calibrator bar codes • reagent bar code cards • calibrator bar code cards
6	Sample Carousel Advance Button	Rotates the Sample Carousel to allow access for loading sample racks, dilution segments, and sample diluent bottles.
7	Background Bar Code Label	Informs instrument of presence or absence of sample tube. When the sample bar code reader can read the background bar code, no sample tube is present at that position.

Sample Crane

Description

The sample crane transfers samples and diluents. Sample dilutions are made in the dilution wells and then delivered to the reaction wheel. The Sample Crane functions in the same manner as the Reagent Crane. (Refer to Figure 2.7.)



1. Sample Probe/Mixer
2. Sample Syringe Pump
3. Sample Crane Wash Station
4. Sample Addition Ports

Figure 2.7 Sample Crane

Component List

The following table lists each component of the sample crane with its function.

Table 2.5 Sample Crane Components

Number	Component	Function
1	Sample Probe	Aspirates sample and diluent and dispenses them into the dilution well. Aspirates diluted sample from the dilution well and dispenses it into a cuvette on the reaction wheel.
	Sample Paddle Mixer	Mixes the contents of a cuvette while diluted sample is dispensed. Also mixes in dilution wells.
2	Sample Syringe Pump (250 µL)	Mechanism for accurate sample, diluent, and diluted sample aspiration and delivery through the sample probe.
3	Sample Crane Wash Station	Washes interior and exterior of sample probe/ mixer.
4	Sample Addition Ports	Two openings in reaction module cover to allow samples to be added to one of two different cuvette locations.

Upper Instrument Subsystems

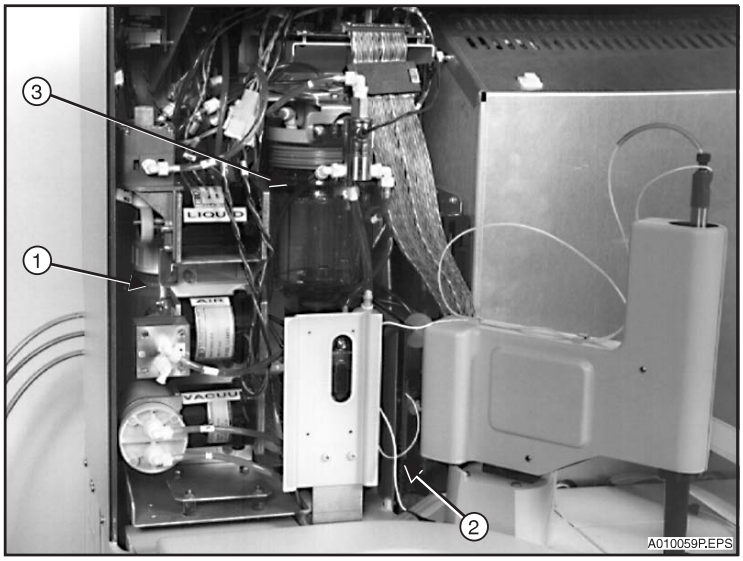
Upper Subsystem List

The upper portion of the instrument contains three subsystems.

- Hydro Pneumatics
- Electronics Control Compartment
- Power Supply Assembly

Hydro Pneumatics

The hydro pneumatics control the flow of wash solution through the system and the flow of waste out of the system. Pressure and vacuum control this fluid motion. (Refer to Figure 2.8.)

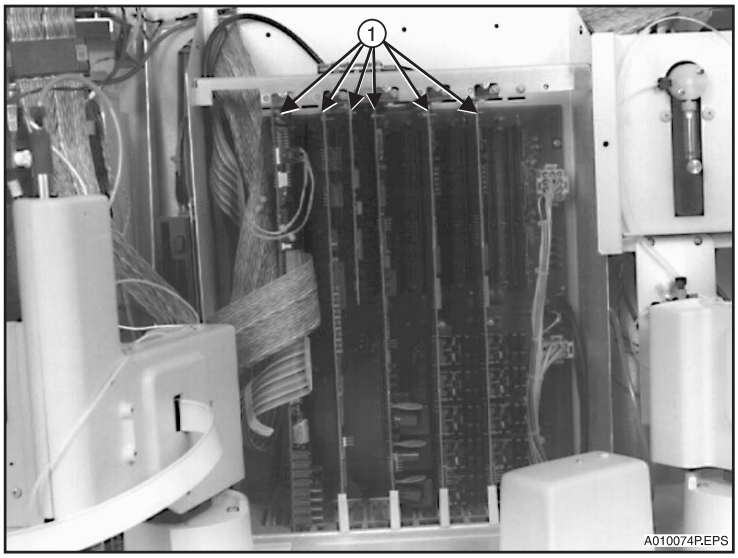


1. Pressure Reservoir-Liquid
2. Pressure Reservoir-Air
3. Vacuum Reservoir

Figure 2.8 Hydro Pneumatics

Electronics Compartment

The electronics compartment contains the electronic circuit boards. (Refer to Figure 2.9.) Electronic circuit boards should only be handled by a Beckman Coulter service representative.

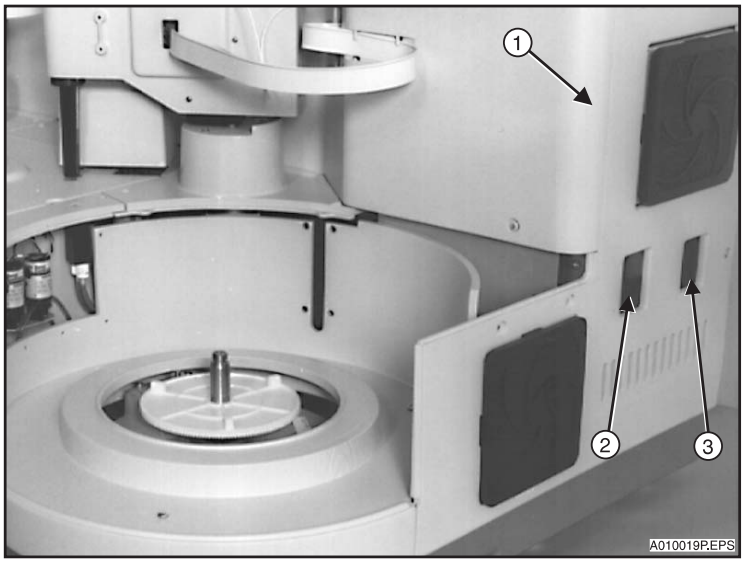


1. Circuit Boards

Figure 2.9 Electronics Compartment

Power Supply Assembly

All of the power supplies used by the IMMAGE 800 instrument are contained in this area of the instrument. (Refer to Figure 2.10.) Power supply assemblies should only be handled by a Beckman Coulter service representative.



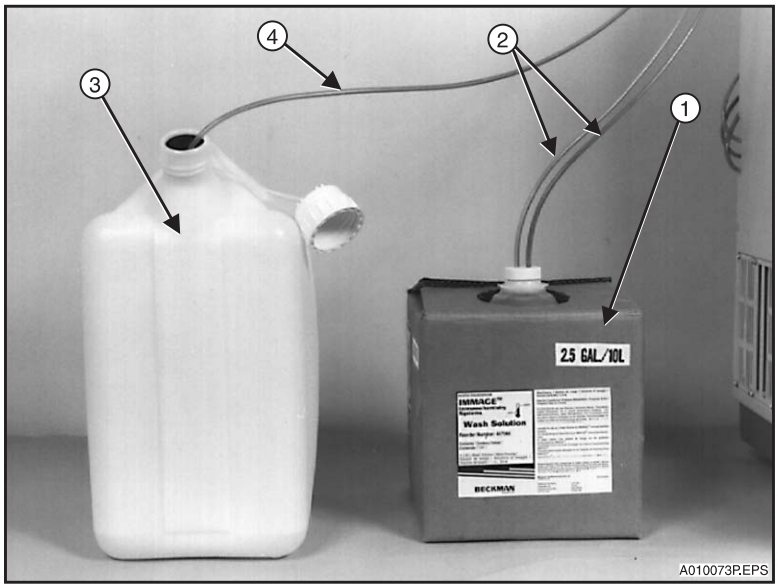
1. Power Tower
2. Power Switch
3. Electrical Outlet/Voltage Selector

Figure 2.10 Power Supply Assembly

Wash Solution Box and Waste Container

Description

The wash solution box and waste container are stored separately from the IMMAGE 800 instrument. (Refer to Figure 2.11.)



1. Wash Solution Box
2. Wash Solution Tubing
3. Waste Container
4. Waste Tubing

Figure 2.11 Wash Solution Box and Waste Container

Component List

The following lists the components depicted in Figure 2.11.

Table 2.6 Wash Solution Box and Waste Container Components

Item	Component	Function
1	Wash Solution Box	Holds wash solution.
2	Wash Solution Tubing (blue and orange)	Blue: Connects wash solution box to instrument. Orange: vents wash solution to box.
3	Waste Container	Holds waste. (A drain can be used instead.)
4	Waste Tubing (green)	Outlet for waste leading to waste container or drain.

Wash Solution

The wash solution is used to wash the probes, mixers, and cuvettes.

Wash Solution Box Placement

The wash solution box must be close enough to the instrument to allow connection of the wash solution tubing.

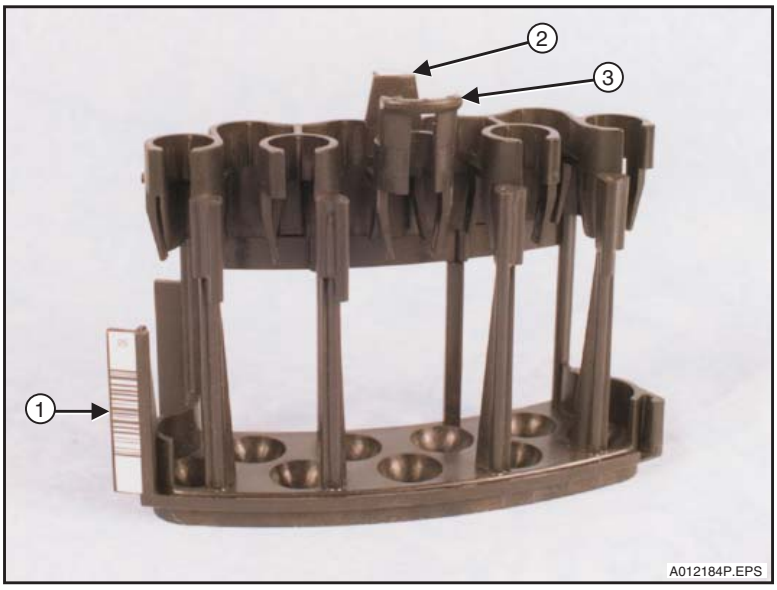
Waste Container Placement

The waste container must be placed with the opening of the waste container no higher than the top of the instrument.

Racks

Description

Each sample rack holds up to nine sample tubes. Each rack is bar coded to allow identification of the rack number by the instrument. (Refer to Figure 2.12.)



1. Rack Bar Code Label
2. Rack Number
3. Handle

Figure 2.12 Sample Rack

Types of Racks

There are four types of racks. They are identified by the size of sample tube that they hold.

- 16 × 100 mm
- 16 × 75 mm
- 13 × 100 mm
- 13 × 75 mm

Applying Rack Labels

Refer to CHAPTER 5, *System Setup*, Instrument Setup, Placing Labels on a Rack for a detailed procedure for label placement.

Loading Rack onto the Sample Carousel

Follow the steps below to load a rack onto the sample carousel. (Refer to Figure 2.13.)

Step	Action
1	Press the Advance button to advance the sample carousel to an empty slot.
2	Lift the rack by its handle.
3	Open the cover of the sample carousel.
4	Align rack pegs over holes in the sample carousel.
5	Lower rack pegs into carousel holes.



Figure 2.13 Loading Rack onto the Sample Carousel

Computer

Description

The computer supplies the user interface to the IMMAGE 800 Immunochemistry System and stores data.

The user performs all software interaction on the computer portion of the system. This software interaction is stored on the computer and is sent to the instrument at the appropriate time.

Additionally, patient results, control results, and setup parameters are stored on the computer.

NOTICE
Only the computer supplied by Beckman Coulter is to be used with the IMMAGE 800 Immunochemistry System.

Changing the Date on the PC

The PC supplied with some IMMAGE 800 systems contains a battery that provides power to the computer's internal clock during power off. The status of the battery is checked every time the Power On sequence is performed.

⚠ CAUTION

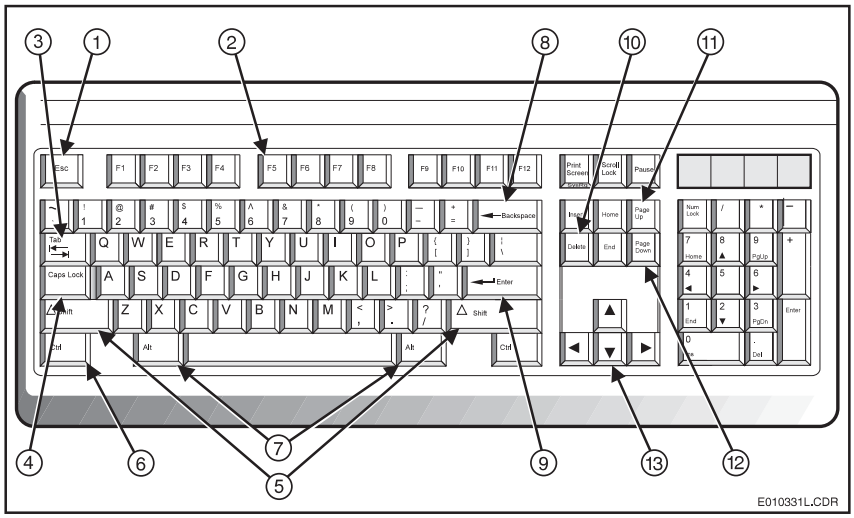
The date and time must be reset each time the Power On sequence is performed on a computer with a dead CMOS (Complementary Metal Oxide Semiconductor) battery. Contact Beckman Coulter Clinical Support or the nearest local Beckman Coulter Field Service office for assistance in replacing the battery.

Table 2.7 Computer Components

Number	Component	Description
1	Personal Computer (PC)	The PC contains the: • CPU (Central Processing Unit) • hard disk drive • USB port • CD-ROM Drive
2	USB Port	Where a USB flash drive is placed and read.
3	CD-ROM Drive	Where a CD-ROM is placed and read.
4	Keyboard	101- key enhanced keyboard.
5	Mouse	A two-button movable input device.
6	Monitor	Displays user interface (touch screen).
7	Uninterruptible Power Source (UPS)	The backup power source providing temporary power to the computer for a limited period of time in the event of brownouts or low line voltage conditions.

Keyboard

Figure 2.14 depicts the 101- key enhanced keyboard used on the IMMAGE 800.

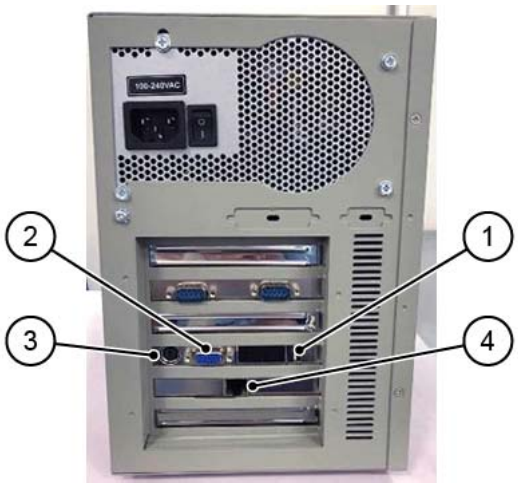


1. Escape Key
2. Function Keys
3. Tab Key
4. Caps Lock Key
5. Shift Keys
6. Control Keys
7. Alt Keys
8. Backspace Key
9. Enter Key
10. Delete Key
11. Page Up Key
12. Page Down Key
13. Arrow Keys

Figure 2.14 IMMAGE 800 Keyboard

Port Connections

Figure 2.15 shows the back of the computer and where each cable connects.



1. Printer Port
2. Monitor Port
3. Mouse/Keyboard Port
4. Instrument Port

Figure 2.15 CPU Ports

Proper Care and Handling of a USB Flash Drive

A USB flash drive requires special care in handling.

- Only connect the USB flash drive to the console.
- Do not plug the USB flash drive into the port when not in use.
- Protect it from moisture, cold, and heat.
- Do not carry the USB flash drive around in your clothing.
- Do not run software from the USB flash drive.
- Do not use the same flash drive on multiple IMMAGE systems in the lab. Each system should have its own designated USB flash drive, and it should be labeled with System ID/Serial Number on it to avoid confusion.

Proper Care and Handling of a Compact Disk

Compact disks (CD-ROMs) require special care in handling.

- Store away from direct sunlight, excessive heat, and humidity.
- Hold the CD-ROM by the edges.
- Replace the CD-ROM in its case after use.

Printer

Description

The printer supplied with the IMMAGE 800 Immunochemistry System is a USB printer. The printer is designed to use single sheet paper.

The printer is set up to use 8.5 × 11 inch paper. Paper size can be chosen in **Printer Setup**.

Refer to the manual that accompanies the printer for proper setup, care, and handling of the printer.

Software Overview

Overview

Introduction

The IMMAGE 800 is controlled through a graphical user interface (GUI). This section describes the basic functions within the interface. The concepts presented in this section should be understood by the user before attempting to use the IMMAGE 800. The Main Software screen is shown below.

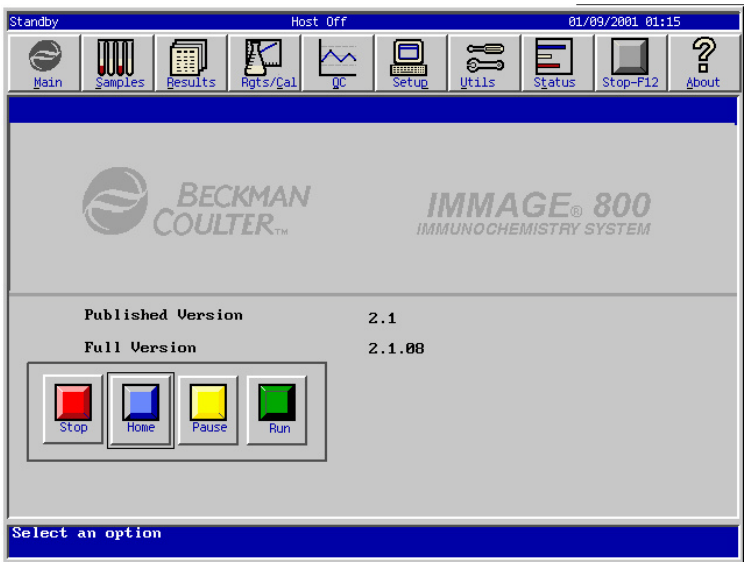


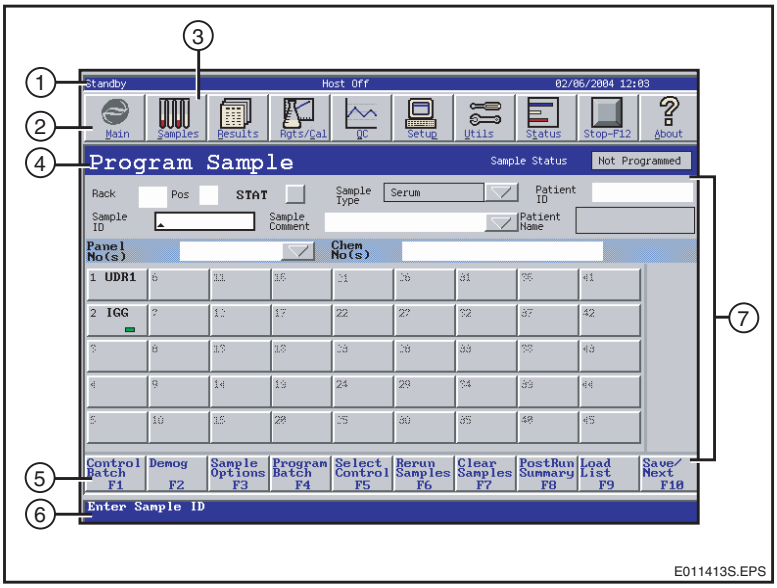
Figure 2.16 Main Screen

Screen Format

Introduction

The IMMAGE 800 Immunochemistry System is designed to have a user friendly interface. Figure 2.17 shows the sample programming screen of the IMMAGE 800 as an example of this interface. This screen is broken into six functional areas:

- Status Bar
- Menu Bar
- Title Bar
- Function Buttons
- Message Bar
- Working Area



1. Status Bar
2. Menu Bar
3. Icon Button
4. Title Bar
5. Function Buttons
6. Message Bar
7. Working Area

Figure 2.17 Sample Programming Screen

Status Bar

The blue bar at the top of the screen is the *status bar.* This bar shows the instrument status, date and time.

Menu Bar

Below the status bar is a row of *icon buttons* called the *menu bar.* These icon buttons can be *selected* to access various functional areas of the interface. These areas are:

- Main
- Samples
- Results
- Rgts/Cal (Reagent load and calibration)
- QC (Quality control)
- Setup
- Utils (Utilities)
- Status
- Stop - F12
- About

The menu bar consists of these specific icon buttons regardless of the current screen.

Title Bar

Below the menu bar is a bar containing the title of the current screen with some possible additional information.

Function Buttons

At the bottom of the screen is an area for up to ten *function buttons*. These function buttons perform functions that are specific to the particular screen. Each function button on the screen corresponds to a function key on the keyboard read from left to right (F1, F2, F3, etc.). The screen function buttons are labeled with the action the function button performs and the corresponding keyboard function key.

Options Button

Within the working area, and occasionally on screens or dialog boxes, are buttons that perform a different function than the "F" numbered function buttons. These buttons, called *options buttons*, appear triangular in shape (▼) and often accompany a text field. When an options button is selected, it presents a list of items, or options, from which a user may choose.

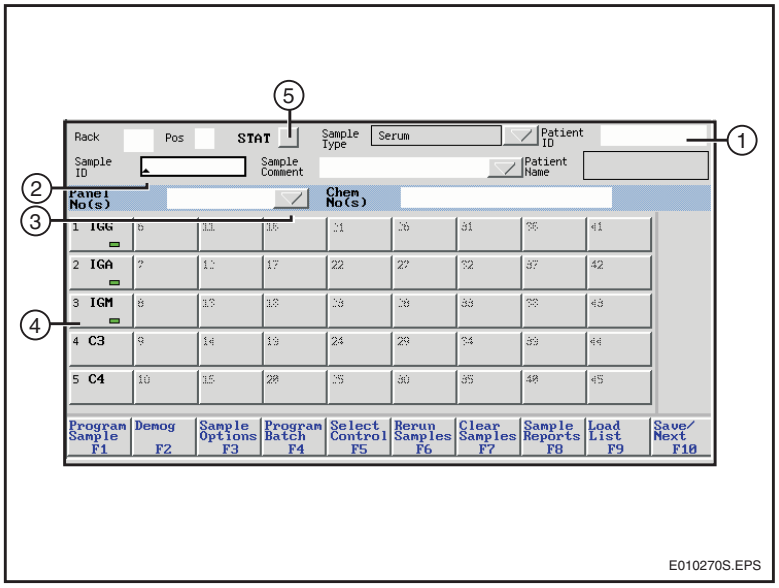
Message Bar

The blue bar at the bottom of the screen is the *message bar.* This bar is used for instructions and error messages. The first line displays instructions and the second line displays error messages. These messages are related to activities in the working area. (Refer to Figure 2.18.)

Working Area

The middle portion of the screen is referred to as the *working area.* The user enters data into the working area via:

- Text fields
- Buttons
- Toggle buttons
- Check boxes



1. Text Field
2. Cursor
3. Options Button
4. Toggle Button
5. Check Box

Figure 2.18 Working Area of Program Sample Screen

Text Fields

Definition of Text Field

Text fields are white areas on the screen in which the user types data.

Definition of Cursor

When a text field is chosen, a *cursor* displays in that field. This cursor indicates where text will be entered.

Characteristics of Text Fields

Unless otherwise noted, most text fields can accept any alphanumeric characters. This means that the user can type in any letter, number, or a space.

Each text field has a limited *number* of characters that can be entered. Most text fields have a restricted *set* of characters that can be entered.

Example: If the user attempts to enter anything other than a number in a numeric field the character will not be entered. A message will display which reads "Only numeric characters are allowed."

NOTICE

The alphanumeric characters "|" (piping bar), "\" (backslash), " ^" (caret), and "&" (ampersand) are not allowed because they are host interface delimiters.

Buttons

Function

Buttons on the screen perform as their name implies. When they are selected or "pressed" an action is performed in the software. Often this action will be used to access a new screen or dialog box.

The icons in the menu bar and the function buttons on the bottom of the screen operate like buttons.

Example

The options button < ▼ > next to the **Sample Comment** field on the Program Sample screen is an example of a button.

Toggle Buttons

Function

Toggle buttons function in the same manner as buttons, except when they are selected or "pressed", their state is changed.

Selected or Unselected

Toggle buttons may either be in the selected or unselected state. If a toggle button is selected it will be highlighted in blue.

Example

Each chemistry button in the list of chemistries on the Program Sample screen is an example of a toggle button.

Check Boxes

Function

Check boxes are similar to toggle buttons because they are either toggled on or off. When selected, a check box will change state.

States

A check box is either checked or unchecked. When checked, a check mark will appear in the check box.

Example

The **STAT** check box on the Sample Program screen is an example of a check box.

Performing Software Functions

Introduction

The IMMAGE 800 Immunochemistry System uses a graphical user interface. Functions can be performed by using a mouse to point and click, with *keyboard equivalents*, or with an optional touch screen.

Using the Mouse

The mouse is the recommended method for performing actions with the IMMAGE 800. When the mouse is moved, the arrow on the screen moves with it. This arrow is called the *pointer*. Movements of the pointer correspond to movements of the mouse. When the pointer tip is touching an item on the screen, the pointer is *pointing* to that item. Pressing the left button on the mouse and quickly releasing it is called *clicking*. Clicking a button on the screen that the pointer is pointing to will select that button. Clicking twice in rapid succession is called *double-clicking*. Pressing and holding down the left mouse button and moving the mouse is referred to as *dragging*.

Using Keyboard Equivalents

All actions on the IMMAGE 800 can be performed with keyboard equivalents as well. The screen navigation will be affected by the location of the cursor on the screen. The cursor movement is directed either within a partition (local movement), which is a logical grouping of data fields that may or may not be visually distinct from other groupings, or is directed globally, which is movement throughout the entire screen. Keyboard equivalent methods include:

- [Alt + Key]
- Function Buttons
- Tabs + Spacebar
- Arrow Keys + Spacebar
- Page Up/Page Down Keys
- Selecting a number from a list

[Alt + Key]

Icon buttons on the menu bar, at the top of the screen, can be selected by pressing and holding down the **[Alt]** key and then pressing the key that corresponds to the underlined letter in the title of that icon. For example, to show the **Main** screen, press the key combination **[Alt + m]**. Buttons in dialog boxes may be selected using the [Alt + key] method as well.

Function Buttons

Functions buttons on the bottom of the screen can be selected by pressing the function keys at the top of the keyboard (F1, F2, F3, ...). The function buttons on the screen are numbered from left to right just as they are on the keyboard.

Tab + Spacebar

The items in the working area of the screen can be chosen by using the **[Tab]** key. Pressing the **[Tab]** key moves the highlight forward (generally left to right and top to bottom) through the various text fields and screen buttons that may be chosen. If the item is a text field, data may be entered as soon as the item is chosen. If the item is a button, the button can be selected by pressing the **[Spacebar]**.

Arrow Keys + Spacebar

The Arrow Keys on the keyboard may also be used to move the highlight between the various items on the screen that may be chosen. The highlight moves in the direction of the arrow. If a text field is chosen, **[←]** and **[→]** will move through each letter in the field before moving to the next item. If the item is a text field, data may be entered as soon as the item is chosen. If the item is a button, the button can be selected by pressing the **[Spacebar]**.

Page Up/Page Down Buttons

An exception to the use of the **[Tab]** key or arrow keys are page up/page down buttons. These buttons cannot be chosen. The **[Page Up]** and/or **[Page Down]** keys on the keyboard are equivalent to the **<Page Up>** and **<Page Down>** buttons, respectively.

Selecting a Number from a List

If there is a list of items to choose from, the user may select an item by typing the number of the item in the text box and pressing **[Enter]**.

A range of numbers can be entered by entering the first number followed by a dash followed by the last number in the range (*Example*: 1-5 selects 1, 2, 3, 4, and 5).

A list of discontinuous numbers can be entered by separating the items with a comma (*Example*: 1, 5, 8-10 selects 1, 5, 8, 9, and 10).

Using the Touch Screen

When the touch screen is used, the screen can be touched with a finger or any other object. Any button on the screen can be selected by touching the button on the screen. Any text field can be chosen by touching the field on the screen.

Selecting vs. Choosing

Introduction

Selecting an item or field is different from *choosing* the item or field. Text fields can only be chosen. Buttons, toggle buttons, and check boxes can be chosen and selected.

"Choosing" Definition

Using the **[Tab]** key or arrow keys moves the user to the various items on the screen by highlighting one item at a time. An item is highlighted when a dark line appears around it. When the item is highlighted that item is *chosen* but no action occurs.

"Selecting" Definition

Pressing the **[Spacebar]** *selects* the chosen item on the screen. When an item is selected the software performs the appropriate action.

Text fields cannot be selected, only chosen.

Selecting/Choosing by Mouse or Touch screen

Buttons, toggle buttons, and check boxes are selected with the user's first action and the **[Spacebar]** is not needed when using the mouse or touch screen.

Dialog Boxes

Definition

Dialog boxes are smaller than the total size of the screen and generally do not include a bottom row of function keys. The purpose of a dialog box is to input a single piece of data. This piece of data may be as simple as confirming the user's request for the system to perform an action. (Refer to Figure 2.19.)

Data is entered into dialog boxes the same as it is entered into the working area of any screen.

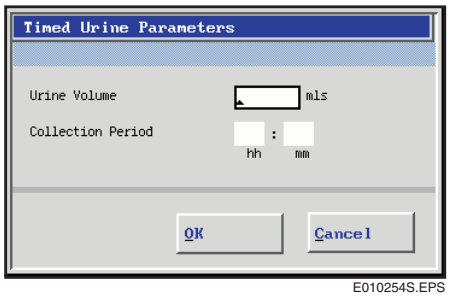


Figure 2.19 Dialog Box Example

<Cancel>

Most dialog boxes will have a **<Cancel>** button. This button closes the dialog box without entering the requested data or denies confirmation of an action. If this button is selected:

- no data is entered
- no action is performed
- the dialog box closes

This button can also be selected by pressing **[Alt + c]**.

<OK>

Some dialog boxes will have an **<OK>** button. This button accepts the data being entered or confirms a user's request for an action. If this button is selected:

- the data is entered into the system or the action is performed
- the dialog box closes

This button can also be selected by pressing **[Alt + o]**.

<Print> or <Display>

Some dialog boxes may contain **<Print>** or **<Display>** buttons.

Deleting Data From a Text Field and Printing Data from a Screen

Deleting Data from a Text Field

Follow the steps below to delete data from a text field.

Step	Action
1	Choose the text field.
2	Choose one: • Press the **[Delete]** key to delete the entire field. • Press the **[Backspace]** key to delete a single character prior to the cursor. • Drag through any portion of the text to highlight it and then press the **[Backspace]** key to delete the highlighted text.

Printing Data from a Screen

Many screens contain data that may be printed by selecting **Print [F10]**.

Printing a Screen

Any screen can be printed by pressing **[Ctrl]** + **[P]** simultaneously.

Page Up/Page Down

Definition of Multipage

Some screens contain lists of data. If this list contains more data than an individual screen can show the list is said to be *multipage*.

Example:

The chemistry list on the Program Sample screen is a multipage list.

Use of Page Up/Page Down

The user can access additional pages of data by selecting the page up and page down buttons on the right. The page numbers are shown above the buttons. Selecting the Page Down button will advance the page to the next page. Selecting the Page Up button will return the page to the previous page. These buttons only appear if more than one page of data exists.

Keyboard Equivalents

The keyboard equivalent of the screen Page Up and Page Down buttons are the **[Page Up]** and **[Page Down]** keys, respectively.

Program Structure

Introduction

The software or interface of the IMMAGE 800 Immunochemistry System is divided into functional areas based on different tasks. The icons in the menu bar at the top of the screen represent the various functional areas. The following menu tree displays an overview to the structure of the IMMAGE 800 software divided into its functional groups.

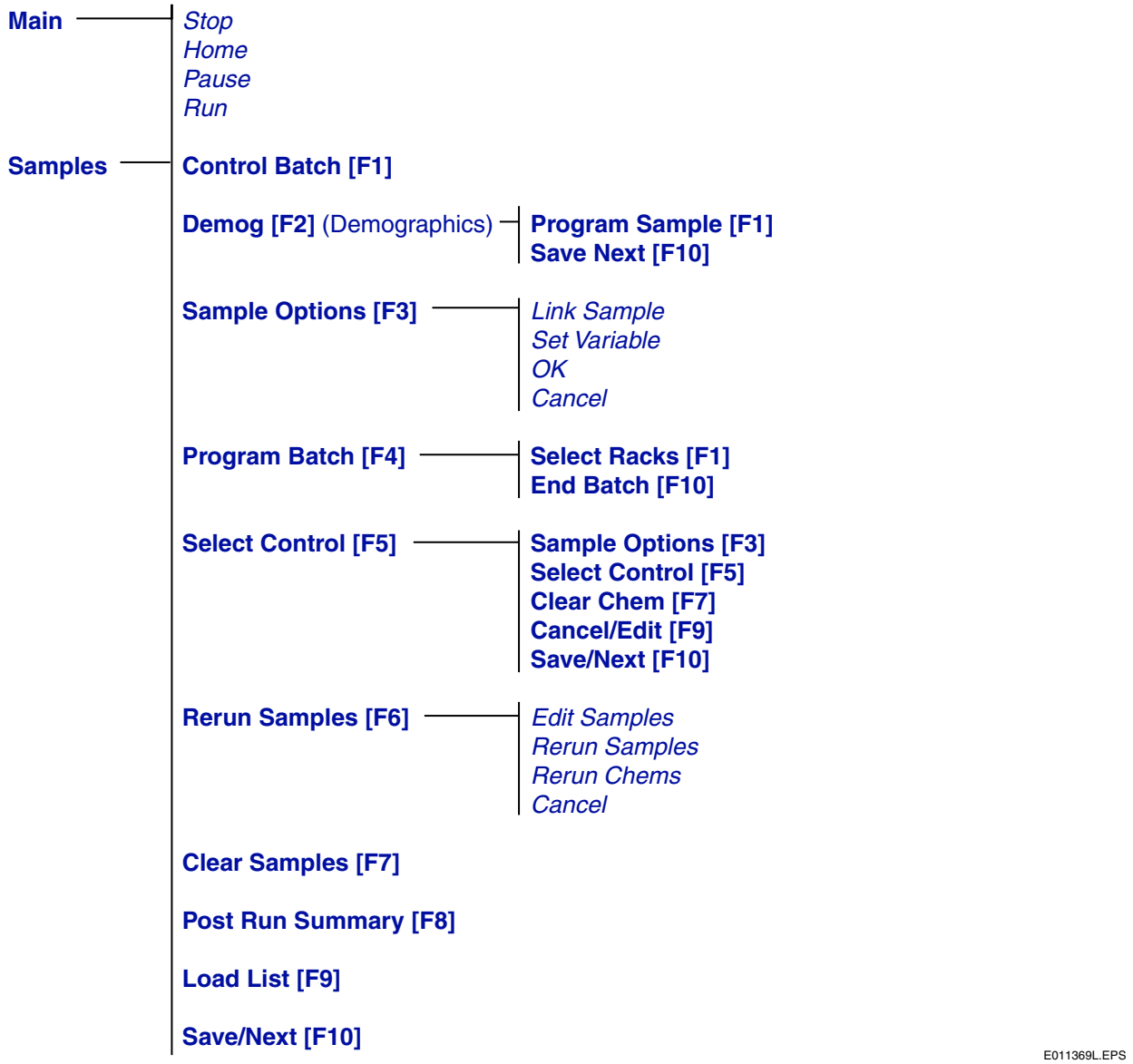


Figure 2.20 IMMAGE 800 Program Tree (1 of 5)



Figure 2.21 IMMAGE 800 Program Tree (2 of 5)

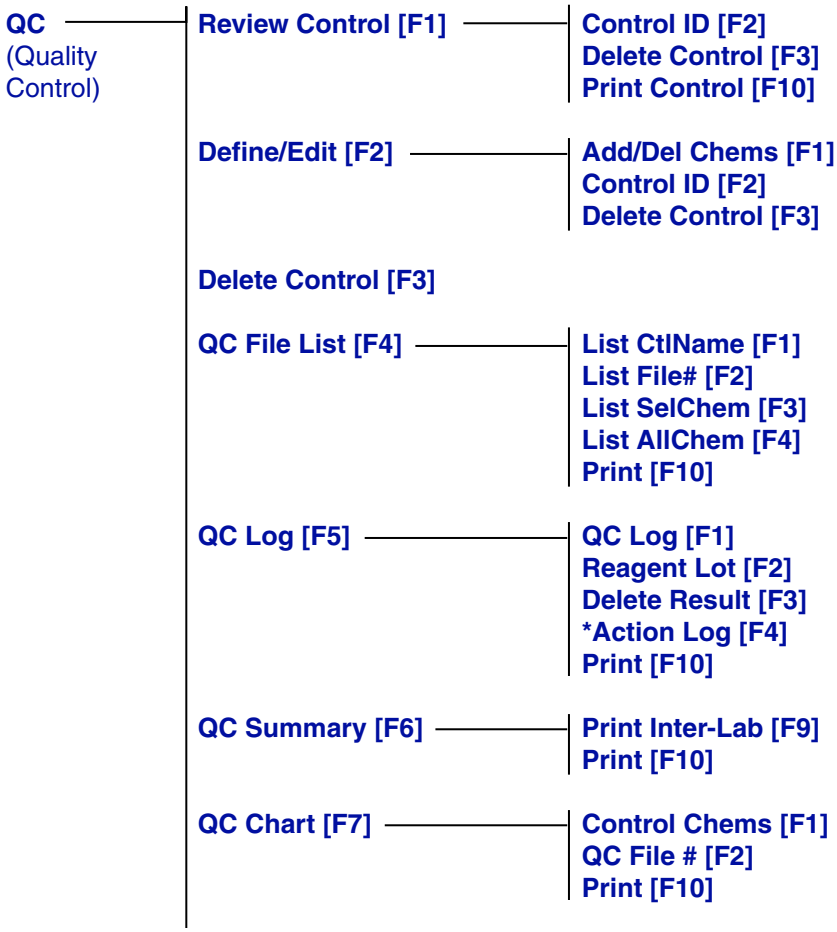


Figure 2.22 IMMAGE 800 Program Tree (3 of 5)

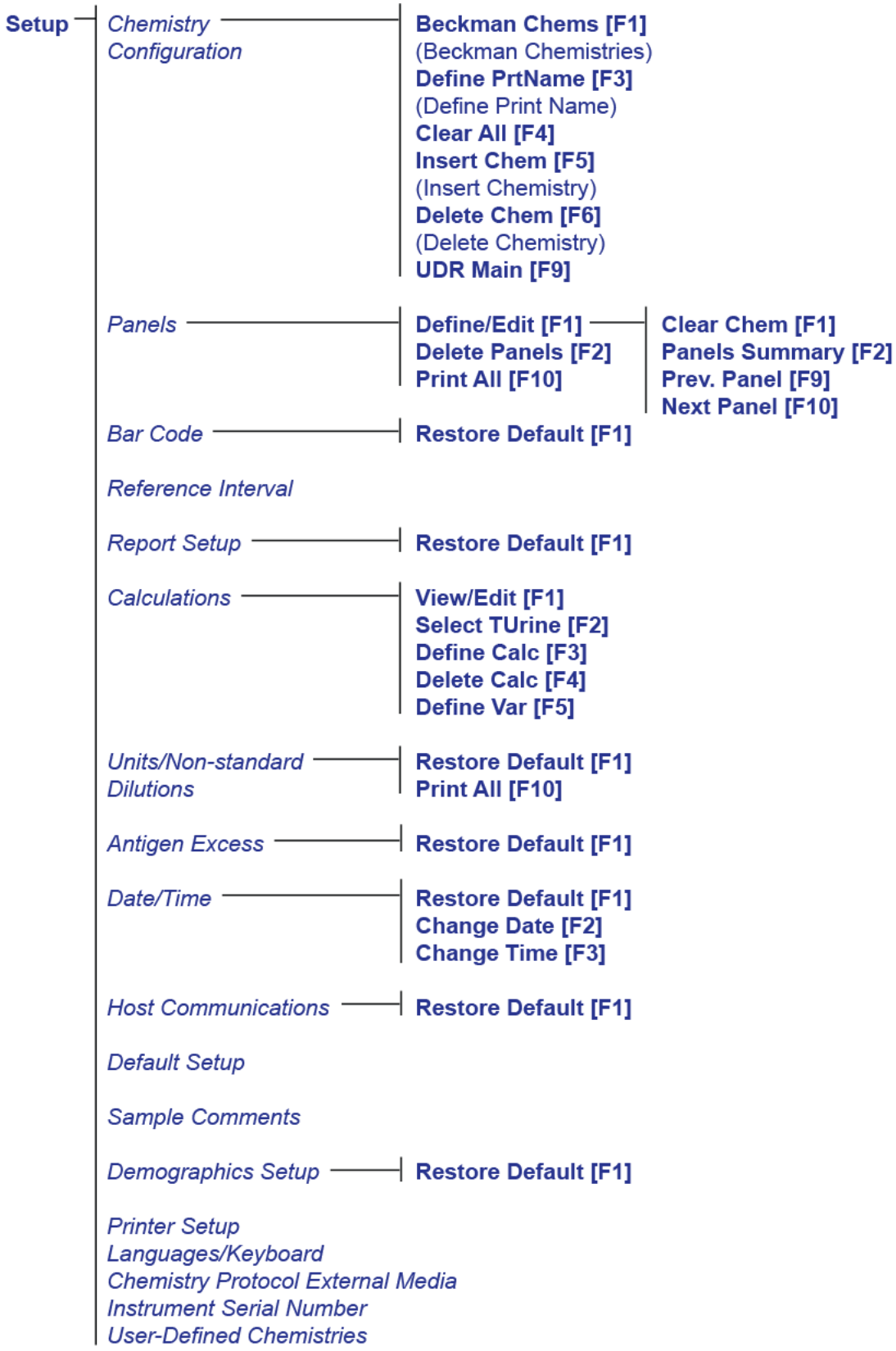


Figure 2.23 IMMAGE 800 Program Tree (4 of 5)

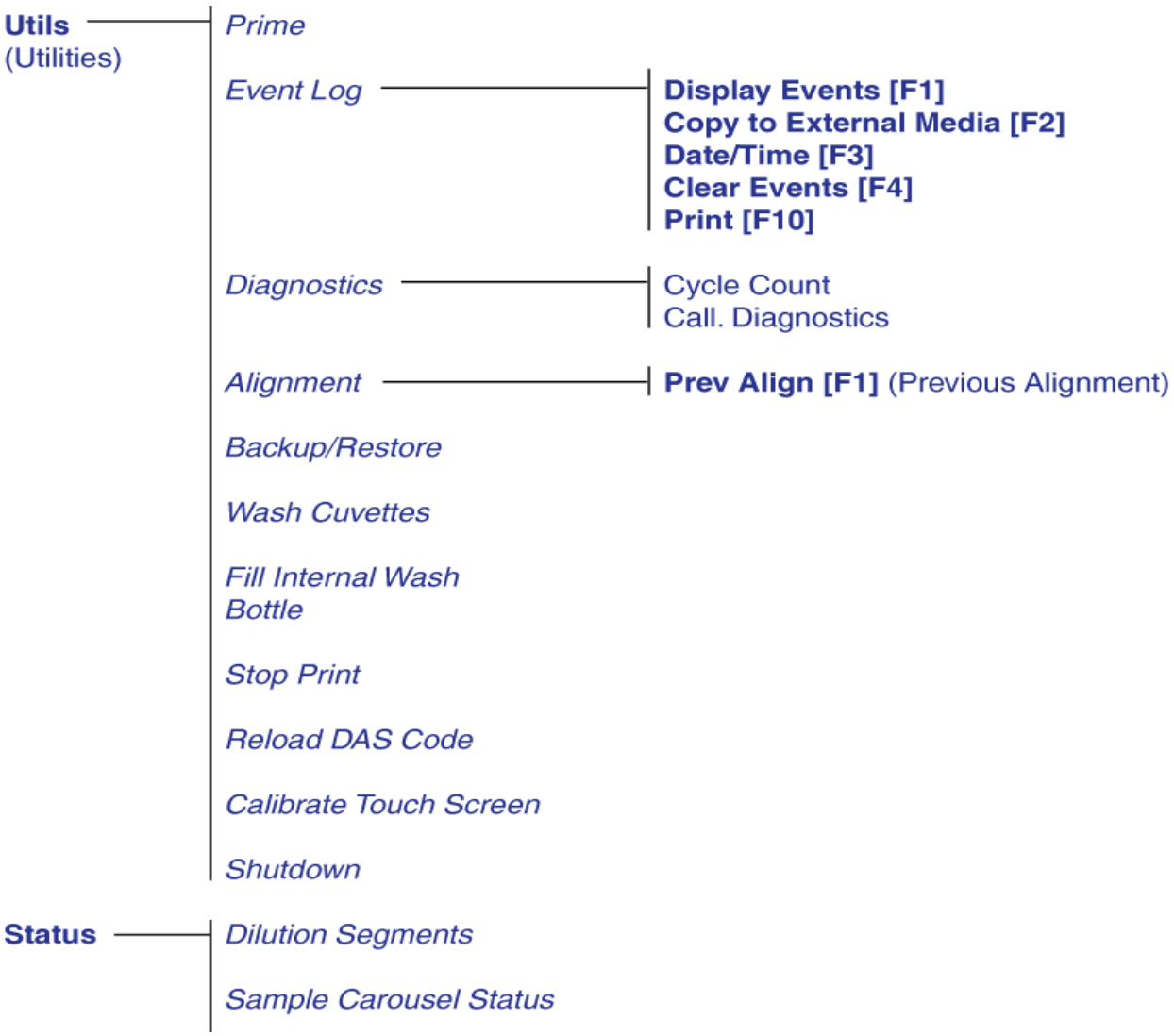


Figure 2.24 IMMAGE 800 Program Tree (5 of 5)

Sample Programming Overview

Introduction

This section summarizes the sample programming methods for the IMMAGE 800 Immunochemistry System.

Sample Programming Options

The following table will summarize the sample programming options based on the variables of bar coded samples and host interface. For detailed explanations of sample programming refer to CHAPTER 7, *Sample Programming*, of this manual.

Table 2.8 Sample Programming Options

Bar Coded Samples	Host Interface	Sample Programming
Yes	Host Query	None required. Load samples in any rack and position.
No	Bi-directional	None required. Load samples in rack and position assigned by host.
Yes	Bi-directional	None required. Load samples in any rack and position.
No	Unidirectional	Required. Enter rack and position number, sample ID, and chemistries. Load samples in assigned rack and position.
Yes	Unidirectional	Required. Enter sample ID, and chemistries. Load samples in any rack and position.
No	None	Required. Enter rack and position number, sample ID, demographics, and chemistries. Load samples in assigned rack and position.
Yes	None	Required. Enter sample ID, demographics, and chemistries. Load samples in any rack and position.

System Specifications and Characteristics

Instrument Specifications

Placement

The surface on which the unit rests must be free of vibration and must be level, 1° or <0.75 inch (1.9 cm) slope across the length and the width of the instrument. Do not place instrument in direct sunlight or drafts or near a heating or cooling duct.

Clearance
Sides - 6 inches (15.2 cm) minimum
Back - None
Front - 3 inches (7.6 cm) minimum
Top - 4 inches (10.1 cm) from top of instrument

Dimensions (Excluding Wash and Waste Bottles)

Height = 30 inches (76.2 cm)
Depth = 25.5 inches (64.8 cm)
Length = 43.5 inches (110.5 cm)

Weight

250 lb. (120 kg)

Power Requirements

Operating Range	100-120VAC, 200-240VAC Single Phase
Frequency Range	50/60 Hz
Transient Suppression	Recommended
BTU Generated	2,900 BTU/hour
Electrical Outlet	Grounded per Local Code
Surge Protector	Recommended
Current	8.0 Amps (normal) 12 Amps surge

Supplemental Specifications

Environment	Indoor use only
Installation Category	II
Pollution Degree	2
EN55011	Meets class A
Maximum Sound Pressure per IEC 61010-1	Normal: 82 dBA
	1 meter: 71 dBA

Maximum Leakage Current	120V, 60 Hz: 40 uA
	240V, 50 Hz: 68 uA

WARNING

IF THE EQUIPMENT IS USED IN A MANNER NOT SPECIFIED BY BECKMAN COULTER, INC., THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.

Temperature and Humidity

Ambient Temperature	+15°C to +32°C
Ambient Relative Humidity (RH)	15% to 85% (non-condensing)
Reagent Compartment Temperature	13-22°C (32°C Ambient, <45%RH)
Reaction Module Temperature	+37°C ± 0.5°C

Drain Requirements

Flow Rate: 3 Liters/hour minimum
Waste Container Placement: The opening should be no higher than the top of the instrument.

Regulatory Agency Approvals

The IMMAGE 800 meets the safety requirements for the following agencies: CE, UL, CSA, IEC and CENFLEC.

Environmental Conditions

System can operate up to 8000 ft. (2,438m) elevation.

Capacities

The following table lists various system capacities.

Table 2.9 System Capacities

Item	Capacity
Reagents	24 reagent cartridges can be loaded.
Reagent cartridge	150 or 300 tests per cartridge.
Reaction buffers	4 bottles can be loaded.
Buffer bottle	120 mL: 350 tests.
Samples	72 samples can be loaded.
Sample diluents	4 bottles can be loaded.
Diluent bottles	120 mL: number of dilutions is workload dependent.
Sample dilution segments	4 segments of 36 wells each.

Table 2.9 System Capacities, continued

Item	Capacity
Dilution well	300 µL.
Wash solution	1 box/10 L/approximately 1,000 tests.
Waste container	5 gallons (18.9 L).

Peripheral Devices Specifications

Introduction

Refer to the inserts which accompany the respective peripheral devices (computer, printer, etc.) for product specifications.

Sample Container Information

Sample Containers Allowed

Introduction

The following categories document specifications for sample containers that can run on the IMMAGE 800 Immunochemistry System.

Primary Tubes

16 × 100 mm (10 mL)
16 × 75 mm (7 mL)
13 × 100 mm (7 mL)
13 × 75 mm
16.5 × 92 mm

Secondary (Aliquot) Tubes

16 × 100 mm
16 × 75 mm
13 × 100 mm
12 × 75 mm

Microtubes

13 × 100 mm SYNCHRON Microtube

Sample Cups

NOTICE

Low humidity and high ambient temperature may cause evaporation when using small volumes of sample in sample cups. To minimize evaporation:

- Program samples in positions A or B on the sample carousel.

OR

- Program samples as STATS.

2 mL (placed into a sample cup holder)
0.5 mL (placed into a sample cup holder)

Bar Code Types and Options

Introduction

Four bar code types are supported by the IMMAGE 800:

- Code 39
- Code 128
- Interleaved 2 of 5
- Codabar

The bar code scanner will read any of these bar code types, provided the type is enabled in Bar Code Setup and the options match those defined for the bar code label. The scanner will also automatically discriminate between the symbologies, so tubes with bar code labels of different types may be intermixed in a run.

Code 39 Options

Check Digit: If a higher degree of data integrity is required, a check digit may be enabled and added to the bar code ID. The check digit used is a Modulus 43, which is the sum of all the character values and is the last digit of the bar code ID. Code 39 expects the check digit to be included in the final code length.

Large Intercharacter Gap: In Code 39, the intercharacter gap has a minimum value of *one times the width* of the narrow element and a maximum value of *three times the width* of the narrow element, or 0.06 inches (0.152 cm), whichever is greater. This feature should be enabled when the intercharacter gap exceeds four times the narrow element width.

Fixed Code Length: If the sample IDs being used are all of the same length, Fixed Code Length may be enabled to ensure that only one length of sample ID is accepted.

Define Code Length: When Fixed Code Length is enabled, the code length may be defined as from 1 to 15 characters.

Code 128 Options

The options for Code 128 bar codes are fixed in the software and cannot be reconfigured by the user. The IMMAGE 800 uses Code 128 formatting to read BECKMAN COULTER bar coded cards and rack ID.

Fixed Code Length: disabled.

Interleaved 2 of 5 Options

Check Digit: If a higher degree of data integrity is required, a check digit may be enabled and added to the bar code ID. The check digit used is a Modulus 10. Interleaved 2 of 5 expects the check digit to be included in the final code length.

Code Length One: An even number from 0 to 14 must be defined as the number of characters in the code.

Code Length Two: A second code length (an even number from 0 to 14) may be defined. Both lengths would then be recognized.

Codabar Options

Start and Stop Codes Match: When this option is enabled, the start code and stop code must be the same character for a valid read.

Large Intercharacter Gap: This option is used when reading Codabar labels with large gaps between bar code characters. The normal intercharacter gap cannot exceed one character element.

Fixed Code Length: If the sample IDs being used are all of the same length, Fixed Code Length may be enabled to ensure that only one length of sample ID is accepted.

Define Code Length: When Fixed Code Length is enabled, the code length may be defined as from 1 to 15 characters.

Bar Code Label Specifications

Industry Standards

American National Standards (ANSI X3.182.1990)
American Society for Testing Materials (ASTM E1466-92)

Symbol Size

Maximum overall length: 60 mm (2.36 inch)
(Includes bar code symbol with 5 mm (0.20 inch) quiet zone at each end.)
Minimum height: 10 mm (0.40 inch)

Symbol Content

Maximum of 15 characters.

Recommended symbol content printed on label in human-readable form. Square bracket ([or]), percentage sign (%), dollar sign ($), comma (,) quotation mark ("), ampersand (&), asterisk (*), semi-colon (;), question mark (?), back slash (\), caret (^), tilde (~), or piping bar (|) cannot be used as a character.

Margin of Reading Accuracy

Bar code symbol (narrow) element width of 0.19 to 0.51 mm (0.0075 to 0.02 inch)

Wide-element to narrow-element ratio of 2.2:1 to 3.0:1.

Placing a Tube into a Rack

Tubes should be seated to the bottom of the rack with the bar code label facing the same direction as the rack label.

Label Print Quality

Printed by direct thermal or thermal transfer.

Label Symbologies

Code 39
Interleaved 2 of 5
Codabar
Code 128

Check Characters

The use of check digits and fixed length codes is highly recommended where possible. This greatly reduces the possibility of scanning errors.

Label Sources

All patient and control sample labels are supplied by the customer. Preprinted labels can be used, or labels generated by a bar code printer. Beckman Coulter, Inc. recommends the following printers:

Execuport 2400	Computer Transceiver Systems P.O. Box 1117 23 Carol Street Clifton, NJ 07014-0996 Phone: (201) 473-4700
Intermec 3000A	Intermec Corporation 6001 36th Avenue West Everett, WA 98203 Phone: 1-800-755-5505
Zebra 130	Zebra Technologies Corp. 333 Corporate Woods Parkway Vernon Hills, IL 60061 Phone: (708) 634-6700

Please contact any of the above vendors or industry standard associations for any specific bar code application issues.

Applying Bar Code Labels

Correct Application of Bar Codes

Refer to the IMMAGE Sampling Template for the correct application of bar codes.

Sample Volume

Minimum Volumes

Refer to the IMMAGE Sampling Template for minimum volume requirements.

Primary Tube Sampling Template

Before running a primary tube on the IMMAGE 800, verify sample tube volume level with the IMMAGE Sampling Template.

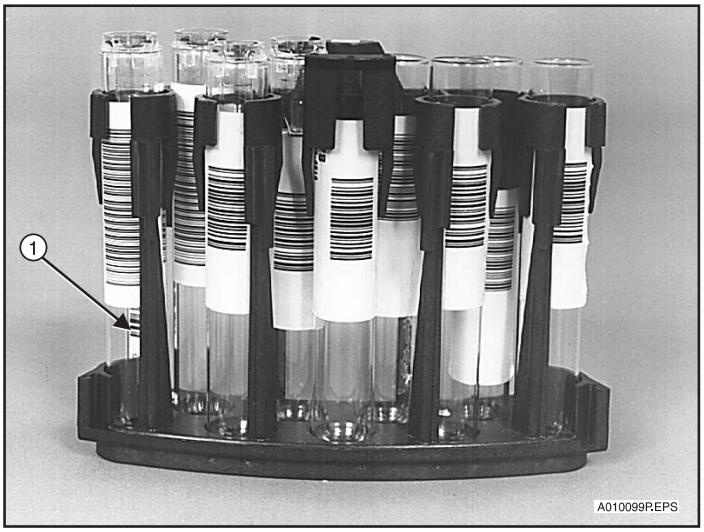
Loading Tubes Into Racks

Guidelines

- Remove stoppers from sample tubes before loading.
- Load the sample tubes onto the racks with the bar code labels facing the same direction as the sample rack bar code label. (Refer to Figure 2.25.)
- Confirm that the tube is properly seated in the bottom of the rack.
- Be sure the entire bar code symbol, including quiet zone, is visible through the rack.

NOTICE
The bar code must be visible to the Sample Bar Code Reader, otherwise the sample will not be identified or run.

Example



1. Rack Bar Code Label

Figure 2.25 Bar Coded Tube Orientation

Instrument Operation Overview

Instrument Operation

Introduction

The following tables describe instrument functions during start-up, sample processing, and data reduction.

Start-up

The following tables explain what happens after all reagents and samples have been loaded and Start Run has been selected.

Table 2.10 Start Up Functions

Stage	Description
1	The IMMAGE 800 will: • home moving parts • prime wash through the lines • wash the probes • perform internal diagnostic checks
2	A fluid level sense is performed on all Buffer and Diluent bottles. The % volume remaining is then calculated.
3	Sample and Reagent carousels are spun. Bar codes for both reagent and samples are read. If the reagent load procedure has been performed and the reagent cover has not been opened, the reagent carousel is not reread.
4	The on-board reference cuvette is read as part of optical quality control.

Sample Processing

The following table describes typical sample processing performed by the IMMAGE 800.

Table 2.11 Sample Processing Functions

Stage	Description
1	Buffer is added to the reaction cuvette, followed by a 5 minute incubation to allow temperature equilibrium.
2	Sample or diluted sample is added to the reaction cuvette with mixing.
3	Reagent is then dispensed with mixing.
4	The reaction is monitored from 90 seconds up to 5 minutes depending on the chemistry.

(1 of 2)

Table 2.11 Sample Processing Functions, continued

Stage	Description
5	Chemistries which utilize AGXS testing have antigen dispensed and their reaction monitored for an additional 20 seconds.
6	The instrument will automatically make the appropriate dilution for high or low samples to obtain the final answer. Samples which exceed the instrument range will be flagged as Out-of-Range Hi or Out-of-Range Lo. Note: During the run, the system tracks all reagent volumes and can switch to another bottle of the same lot number. If there are no additional reagents of that lot number, the test will be set to *Pending* prior to aspiration of sample or reagent.

(2 of 2)

Data Reduction

The following table describes the typical data reduction process performed by the IMMAGE 800.

Table 2.12 Data Reduction Functions

Stage	Description
1	The reaction wheel operates on a 5 second cycle time. During each cycle, the cuvettes are spun in front of the optics station and 200 data points are taken. These 200 points per cuvette are then calculated to a single value.
2	For each spin, the calculated value, the time the data was taken, and a calculated quality value is logged for each cuvette.
3	When the reaction incubation time has expired on each cuvette, the data logged for that cuvette is checked for certain mathematical bounds.
4	The data is then checked for an increasing signal, indicative of a reaction.
5	Passing the checks, the data is then mathematically curve fitted to a non-linear function. The rate of scatter intensity is calculated from the resulting curve.
6	The rate is directly related to the concentration.
7	A concentration test result is calculated based on the calibration factor, the rate, and any dilution factors used.
8	Results may be scaled into alternative reporting units defined by the user.

CHAPTER 3 Theory of Operations

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Signal Measurement and Reaction Dynamics 3-3
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Theory of Operations

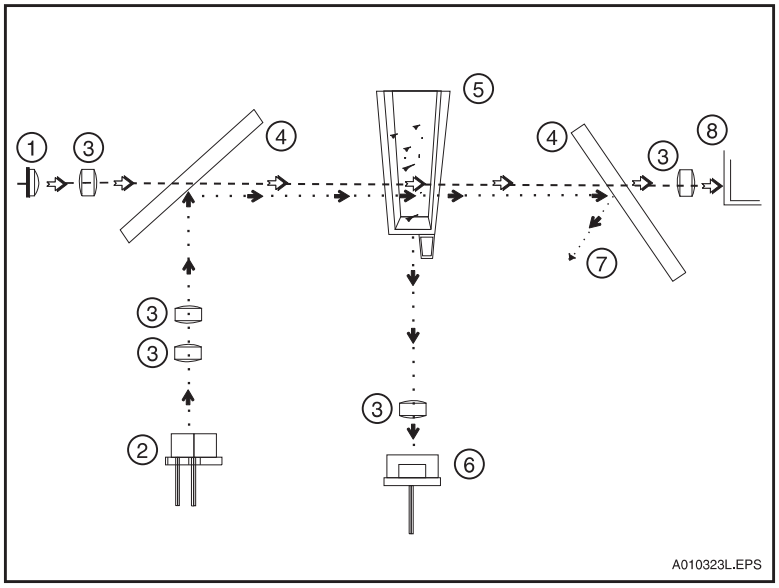
Principles of Methodologies

Principles of Rate Nephelometry

The rate nephelometer measures the increase in the intensity of light scattered by particles suspended in a cuvette. The light source for the rate nephelometer is a 670 nm laser. The detector is placed at a 90° angle from the laser beam to measure light scatter, as shown in Figure 3.1.

Principles of Rate Turbidimetry

The rate turbidimeter measures the decrease in the intensity of light as it passes through a solution of light scattering particles in a cuvette. The light source for the rate turbidimeter is an light emitting diode (LED) at a wavelength of 940 nm. Turbidimetric measurements are made at 0° from the incident beam as shown in Figure 3.1.



1. LED light source (turbidimetric)
2. Laser light source (nephelometric)
3. Focus lens
4. Beam splitter
5. Reaction cuvette
6. Nephelometric detector (90° angle to incident laser beam)
7. Laser light bounces into light trap
8. Turbidimetric detector (0° angle to the incident LED beam)

Figure 3.1 IMMAGE 800 Rate Nephelometer and Rate Turbidimeter Basic Components

Signal Measurement and Reaction Dynamics

Light Scatter Signal Development

During an antigen-antibody reaction, immunoprecipitin complexes are formed.

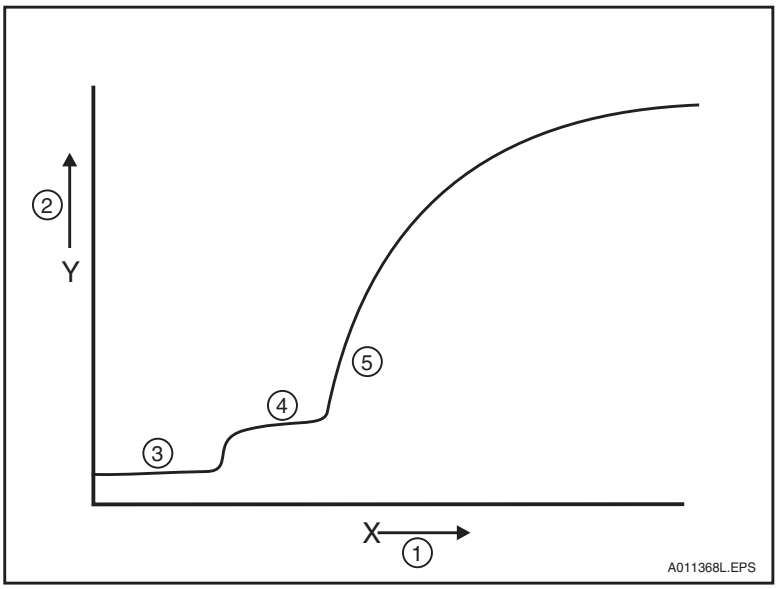
In rate nephelometry, the light scattered at 90° increases as the complexes are formed.

In rate turbidimetry, the light intensity at 0° decreases as the complexes are formed. This decrease is converted to an increasing scatter signal by the formula:

$$\text{scatter signal} = -\text{Log}_{10}\left[\frac{\text{light intensity}}{\text{initial light intensity}}\right]$$

E011367L.EPS

Rate nephelometry and rate turbidimetry give the same signal as illustrated in Figure 3.2.



1. X = Increasing time
2. Y = Increasing scatter signal
3. Buffer Addition
4. Sample Addition
5. Antibody Addition

Figure 3.2 Scatter Signal versus Time for Rate Nephelometry and Rate Turbidimetry

Rate Determination

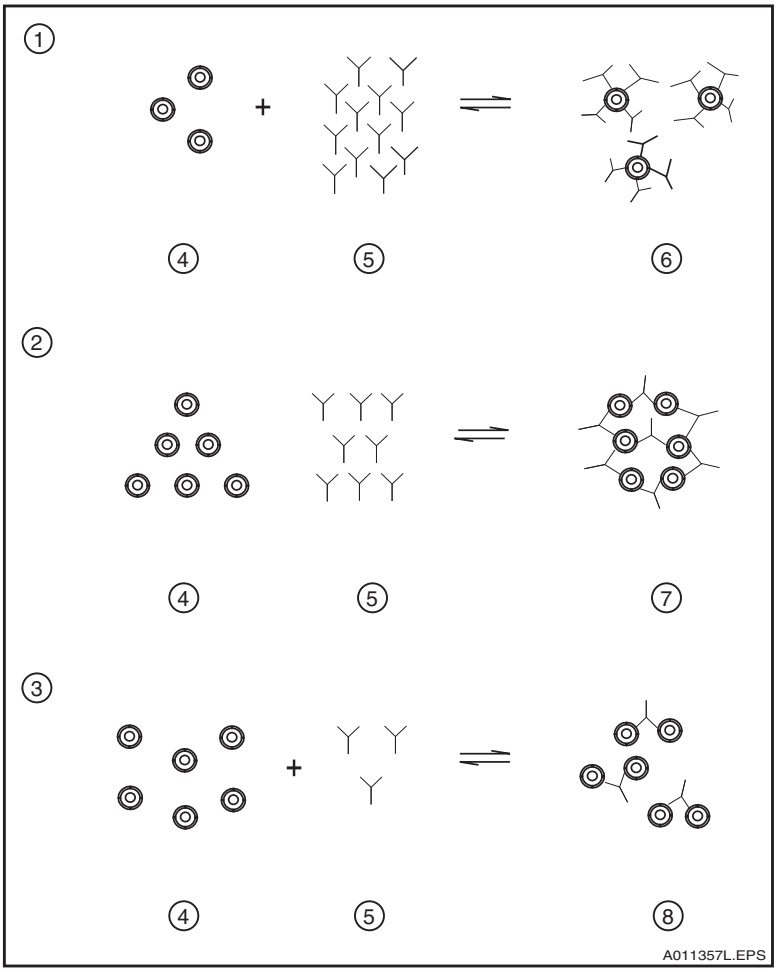
The system monitors scatter signal from the antigen antibody reaction at 5 second time intervals. At the end of the reaction, the system mathematically calculates the rate of change of the scatter signal.

Dynamic Blanking

The IMMAGE 800 automatically performs a patented dynamic blanking algorithm for selected analytes when testing at low serum dilutions. The results are improved by elimination of the nonspecific light scatter produced by the polymer enhanced reaction buffer interacting with the serum.

Dynamics of the Immunoprecipitin Reaction

The formation of light scattering complexes is dependent on the presence of antigen and antibody molecules in optimal proportions. In general, the reagent contains a fixed amount of antibody which binds with antigen in the sample to form light scattering complexes. (Refer to Figure 3.3.)

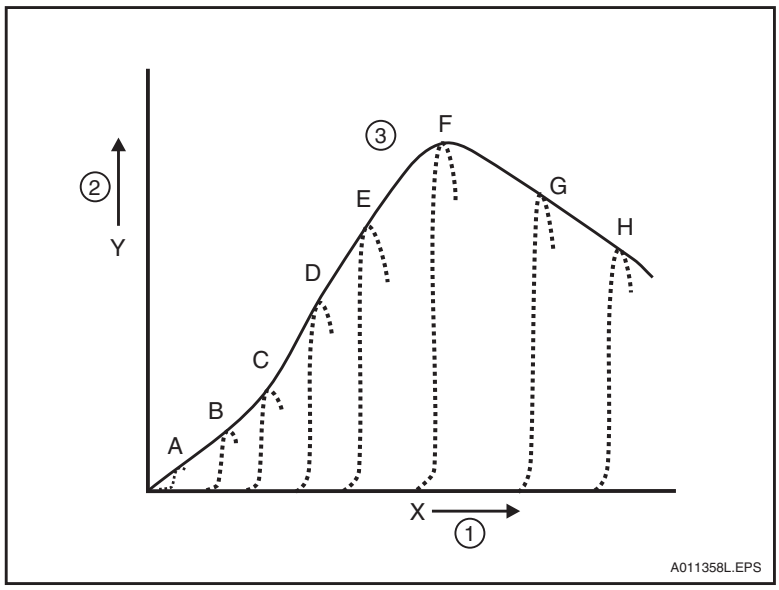


1. Antibody excess
2. Optimal proportion
3. Antigen excess
4. Antigen
5. Antibody
6. Soluble complexes
7. Insoluble complexes
8. Soluble complexes

Figure 3.3 Antigen-antibody Reaction Under Varying Concentrations Of Antigen And Antibody

Protein Rate Response Curve

Figure 3.4 illustrates the rate response for several test samples with various antigen concentrations. The antibody is maintained at a constant level. The magnitude of the rate response increases from test sample A to test sample F. The rate response for test sample G is less than for sample F, although the antigen concentration in sample G is greater than sample F. Test sample H illustrates a further reduction in the rate response due to the increase in antigen concentration in the sample.



1. X = Increasing Antigen Concentration
2. Y = Peak rate of scatter
3. A-H represent peak response values at varying antigen concentrations. The antibody is maintained at a constant level.

Figure 3.4 Protein Rate Response Curve

Antigen Excess Testing

Overview

Antigen excess (AGXS) testing is only necessary for some IMMAGE 800 protein reagents.

Immunoglobulin G (serum IGG, urine IGU), Immunoglobulin A (serum IGA, cerebrospinal fluid IGALC), Immunoglobulin M (serum IGM, cerebrospinal fluid IGMLC), Kappa (KAP), Lambda (LAM), Haptoglobin (HPT), Urine Transferrin (TRU), Alpha-1-Microglobulin (A1M), Microalbumin (MA) and Albumin (ALB) which are identified by the system as ambiguous, are tested for antigen excess condition if AGXS testing is enabled. A reaction is ambiguous if the rate response could represent either an antigen excess or an antibody excess reaction.

Antibody Excess

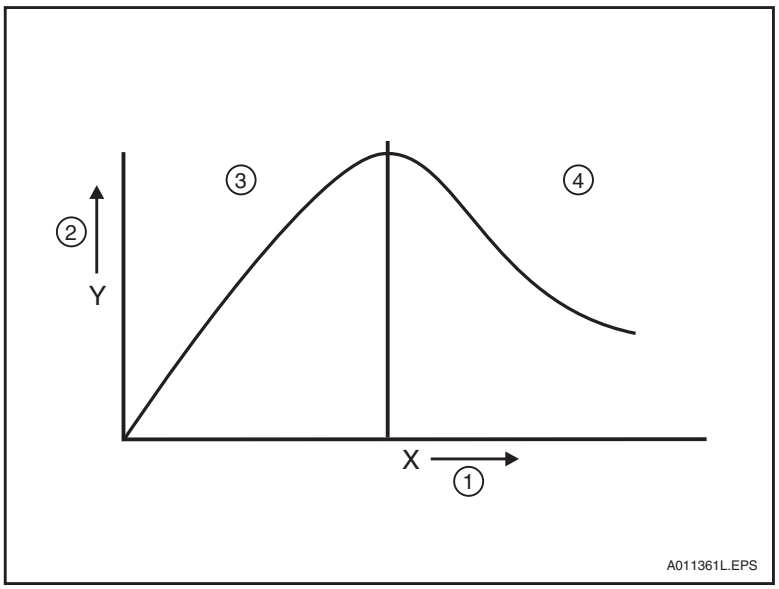
When the reaction is less than the optimal antibody-antigen proportions (center line), the reaction is in antibody excess (AbXS). (Refer to Figure 3.7.) This indicates all the antigen in the sample is bound, forming complexes. This is the ideal condition for the reaction to take place.

Antigen Excess

When the reaction is greater than the optimal antigen-antibody proportions (center line), the reaction is in antigen excess (AGXS) and the rate response will start to decrease due to excessive levels of antigen. (Refer to Figure 3.7.)

Ambiguous Response

It is possible for two significantly different sample concentrations of antigen to yield the same rate response. Either the rate response represents the correct concentration in the area of AbXS (left side) or the same rate response represents a concentration that is in the area of AGXS (right side) and requires further dilution. Antigen excess testing differentiates these two situations. (Refer to Figure 3.7.)



1. X = Increasing antigen concentration
2. Y = Rate response
3. Antibody excess (AbXS)
4. Antigen excess (AGXS)

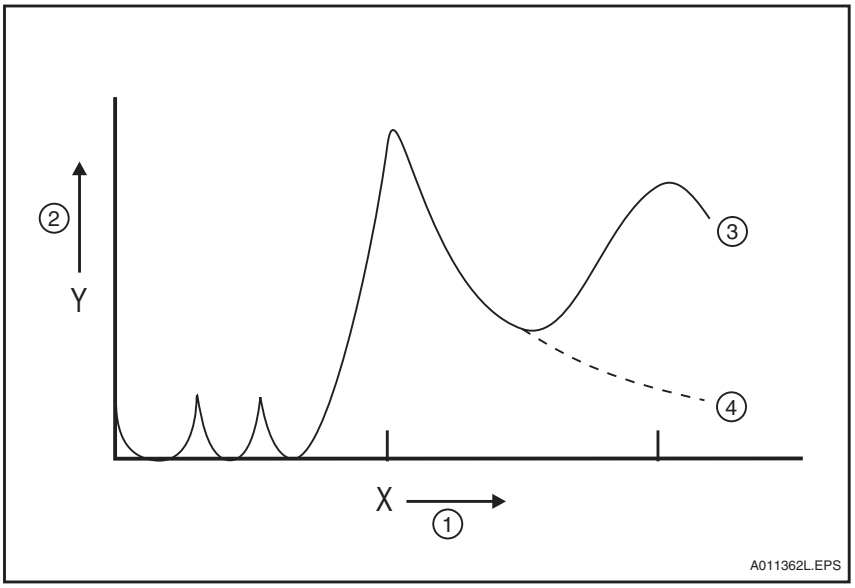
Figure 3.5 Antigen Excess Detection

How Antigen Excess Testing is Performed

The system performs antigen excess testing by adding additional antigen to the completed reaction.

Table 3.1 Antigen Excess Testing

If unbound Ab is...	the addition of more Ag will result in...	and the IMMAGE 800 will...
present	an increase in rate response, as indicated by the solid line in Figure 3.8	use the initial rate response to calculate the final result.
not present	*no* increase in rate response, as indicated by the broken line in Figure 3.8	automatically rerun the sample at the next higher dilution and test for antigen excess until a final result is obtained.



1. X = Reaction time (in seconds)
2. Y = Rate response
3. Response if antibody excess
4. Response if antigen excess

Figure 3.6 Rate Response versus Reaction Time

Out-of-range Testing

Description of Out-of-range Testing

The IMMAGE 800 reagents have been optimized so that the initial measuring range will include the majority of the expected concentration values. Each reagent bar code card contains information which defines the out-of-range high and out-of-range low limits. Samples above or below the initial measuring range will automatically be retested at the next appropriate dilution.

Calibration

Calibration Curve

The calibration curve for each lot of reagent is determined by Beckman Coulter, Inc. In general, the calibration curve is formed from eight to twelve standards of known analyte concentrations, with approximately thirty points per standard, tested on multiple systems. The calibration curve parameters are coded onto a lot specific reagent bar code card. When a reagent bar code card is read, the curve parameter information is transferred and stored by the system.

System Calibration

System calibration is accomplished by testing a single analyte concentration which is contained in a specific calibrator. To ensure a valid calibration, the system requires that the rate response of two replicates obtained during calibration is reproduced within a predefined percentage. The averaged rate of the two replicates is used to establish a calibration scale factor based on the assigned calibrator target value. The calibration scale factor is used to adjust the measured rate response to equal the theoretical response.

Protein Calibration Curve

When the antibody concentration is constant, the rate response will increase as antigen concentration increases. The maximum rate response occurs when the antibody and antigen are in optimal proportions. As antigen concentration increases further, the rate response will then progressively decrease. The regions at lower and higher antigen concentration are called antibody excess and antigen excess, respectively.

CHAPTER 4 System Power On/Off

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System Power On/Off

System Power On

Introduction

After the IMMAGE 800 Immunochemistry System installation, the system can be powered on.

Power On Sequence

To power on the IMMAGE 800 system.

Step	Action
1	Confirm that the USB port is empty.
2	Verify that the Uninterruptible (UPS) is on. (The UPS power switch is on and the power indicator light is on.)
3	Turn on the printer.
4	Turn on the monitor.
5	Turn on the CPU.
6	Turn on the instrument.
7	Close reagent and sample carousel covers.
8	When the note is displayed to check dilution segment status, select <**OK**>.
9	When the temperature warning note displays, select <**OK**>. • The system will continue to bring the reagent chamber and reaction cuvettes to the appropriate temperature range. • The system will not allow a run to start until the reaction cuvettes are within the appropriate temperature range.
10	Refer to CHAPTER 11, *System Status/Instrument Commands*, Checking Dilution Segment Status and Clearing Dilution Segments, and CHAPTER 7, *Sample Programming*, Checking Status and Clearing/Replacing Dilution Segments.
11	Refer to the appropriate chapters in this manual to operate the system.

Additional Information

- Refer to CHAPTER 1, *General Information/Precautions and Hazards* for a description of switches and port connections.
- Refer to CHAPTER 2, *System Description*, Computer, Printer, for the location of appropriate switches and connections.
- Refer to the instruction manual provided with the UPS for specific information on the UPS.

System Power Off

Introduction

It is recommended that the instrument remains powered on and in *Standby* when not in use.

Powering off the system is recommended for the following situations:

- when parts replacement procedures specify power to be turned off
- when moving the system to a new location
- when lab power goes off (the console is protected by the UPS)

Once the procedure is complete or lab power is restored, power on the system.

Power Off Sequence

The instrument status must be in *Standby* in order to proceed with the steps below to power off the IMMAGE 800 system.

NOTICE
The database may become corrupted if power is turned off before the Power Off sequence is completed.

Step	Action
1	Confirm that the USB port is empty.
2	Select **Utilities** from the menu bar.
3	Select <**Shutdown**>.
4	When the message *Shutdown Complete* is displayed, turn off the printer, monitor, CPU (computer), UPS, and instrument.

Emergency Stop

Turn the instrument main power switch off if the stop button on the screen is unavailable and the instrument must be stopped immediately.

NOTICE
When an emergency stop or unplanned power loss occurs during a run, and power is restored within 24 hours, the cuvettes must be washed 1 time before a run can be started. (Refer to CHAPTER 10, *Utilities*, As-Indicated Maintenance, "Washing Cuvettes.")

If power is restored after 24 hours, the cuvettes must be replaced. (Refer to CHAPTER 10, *Utilities*, As-Indicated Maintenance, "Replacing Cuvettes.")

Database Recovery

Introduction

In the event of a fatal system error or power outage, the system will attempt to recover files and databases which may have been affected.

Fatal Errors

When a fatal error note is displayed, call Beckman Coulter for assistance.

Information Retained

The following information will be retained in the database after power is restored.

- Chemistry protocols
- Reagent and calibrator bar coded parameters
- Current calibration status for each reagent
- Calibration requests that were not completed
- Completed results
- Sample programming for incomplete results and samples that have not been run
- Quality control files
- All system software setup configurations
- Event logs
- All instrument hardware settings

Information Changed

The following information and/or screens will be changed after power is restored.

Table 4.1 Information Changed After Power is Restored

Information/Screen	Change
Dilution Segments dialog box	All segments go to 0 *wells available*.
Sample Carousel Status monitor	Screen is blank.
Reagent Status/Calibration Status screen	Screen is blank. Calibration requests are deleted.
Sample Load List	Samples which were *In Process*, become *Incomplete*.
Instrument Status Monitor	Continuously updates all parameters.
Simulated calibrations	Calibration status changes to *Failed.*
Printing	Printouts will stop. From Results Recall, request printouts of patient and control reports if needed. Calibration reports *cannot* be recalled for printing.

Software Installation Instructions

Loading System Software

The IMMAGE 800 System Software is preloaded on the hard disk. If re-installation of software is required, contact Beckman Coulter Clinical Support or a local Beckman Coulter Field Service office for assistance.

CHAPTER 5 System Setup

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System Software Configuration

Overview

Introduction

In System Setup several features of the IMMAGE 800 Immunochemistry System interface can be customized for the individual laboratory's requirements. Setup maintains the default parameters used for configuring the IMMAGE 800 interface. These configurations can be changed when the system status is in *Standby*.

This chapter explains how to:

- configure the chemistry menu
- set up panels
- set up bar codes
- set up reference intervals
- set up reports
- set up special calculations
- set up units/non-standard dilutions
- configure antigen excess testing
- set up date and time
- set up host communications
- set up replicates/statistics
- set up sample comments
- set up demographics
- set up the printer
- set up the language
- read the chemistry protocol external media
- enter the instrument serial number
- set up user-defined reagent chemistries

Accessing Setup

The instrument status must be in *Standby* in order to proceed with the steps below to access the Setup screen.

Step	Action
1	Select **Setup** from the menu bar.
2	Choose the desired setup option from a numbered button. (Refer to Figure 5.1.)

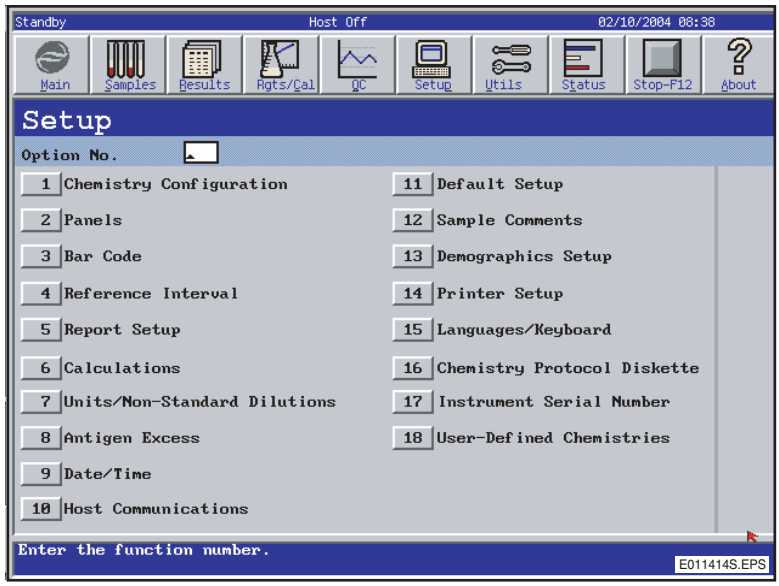

Figure 5.1 Setup Screen

Configuring the Chemistry Menu

Introduction

The chemistry menu available in the sample programming, quality control, panel definition and other screens is defined by the individual laboratory. The menu contains up to 72 chemistries.

Defining a Chemistry for a Position

The instrument status must be in *Standby* in order to proceed with the steps below to define a chemistry.

Step	Action
1	From the Setup screen, select **<1> Chemistry Configuration**. (Refer to Figure 5.2.)
2	Choose the position for the chemistry.
3	Choose one: • Type the Beckman Coulter chemistry acronym if known (e.g., IGG). OR • Select **Beckman Chems [F1]** to display a list of all Beckman Coulter chemistries that have a protocol on the system and select the appropriate chemistry.

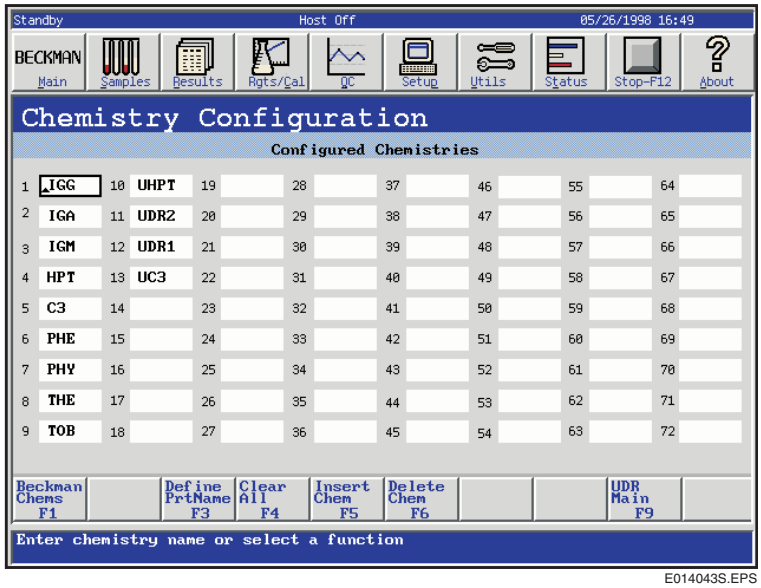

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Figure 5.2 Chemistry Configuration Screen

Clearing All 72 Positions

The instrument status must be in *Standby* in order to proceed with the steps below to clear all positions.

Step	Action
1	From the Setup screen, select **<1> Chemistry Configuration**.
2	Select **Clear All [F4]**.
3	Select **<OK>** to clear all of the configured chemistries. OR Select **<Cancel>** to return to the Chemistry Configuration screen without clearing all of the configured chemistries.

Inserting a Blank Position for Chemistry Insertion

This function is useful for inserting a chemistry into the menu. The subsequent chemistries will be incremented by one position. After a blank position is inserted, a chemistry can be defined for that position using the normal procedure. (Refer to "Defining a Chemistry for a Position" in this section.)

The instrument status must be in *Standby* in order to proceed with the steps below to insert a blank position.

Step	Action
1	From the Setup screen, select **<1> Chemistry Configuration**.
2	Select a position.
3	Select **Insert Chem [F5]** to insert a blank position and increment the subsequent chemistries by one position.
4	Define a chemistry for the new blank position as described in "Defining a Chemistry for a Position," in this section.

Deleting a Chemistry

This function deletes a chemistry from the menu and decrements the subsequent chemistries by one position. The chemistry protocol remains in the system. When the chemistry is deleted from the chemistry menu:

- the system automatically removes the chemistry from any configured control.
- the system automatically removes the chemistry from any configured panel in which it is defined.
- accumulated QC data for the chemistry is not deleted.

Step	Action
1	From the Setup screen, select **<1> Chemistry Configuration**.
2	Choose a position for the chemistry to be deleted.
3	Select **Delete Chem [F6]**.
4	Select **<OK>** to delete the chemistry. OR Select **<Cancel>** to return to the Chemistry Configuration screen without deleting chemistry. NOTICE If the error message *Unable to delete chemistry* is displayed, one of the following conditions exists: • The reagent is on board the instrument. • The chemistry is programmed for a sample. • The chemistry is configured in a programmed control. This condition must be corrected before the chemistry can be deleted.

Defining Print Names

This function allows definition of print names for each chemistry. A Print Name is any defined text that will print on the patient chartable report in place of the Beckman Coulter chemistry name.

The instrument status must be in *Standby* in order to proceed with the steps below to define a Print Name.

Step	Action
1	From the Setup screen, select **<1> Chemistry Configuration**.
2	Select **Define PrtName [F3]**. (Refer to Figure 5.3.) The chemistry menu will be displayed. If there are chemistries defined for positions greater than 20, the **<Page Up>** and **<Page Down>** buttons can be used to show additional pages of chemistries.
3	Choose the text field beside the desired chemistry.
4	Type the print name (up to 21 alphanumeric characters).
5	For additional chemistries repeat Steps 3-4.
6	Select **<OK>** to save the changes or additions. OR Select **<Cancel>** to return to the Chemistry Configuration screen without saving changes or making additions.

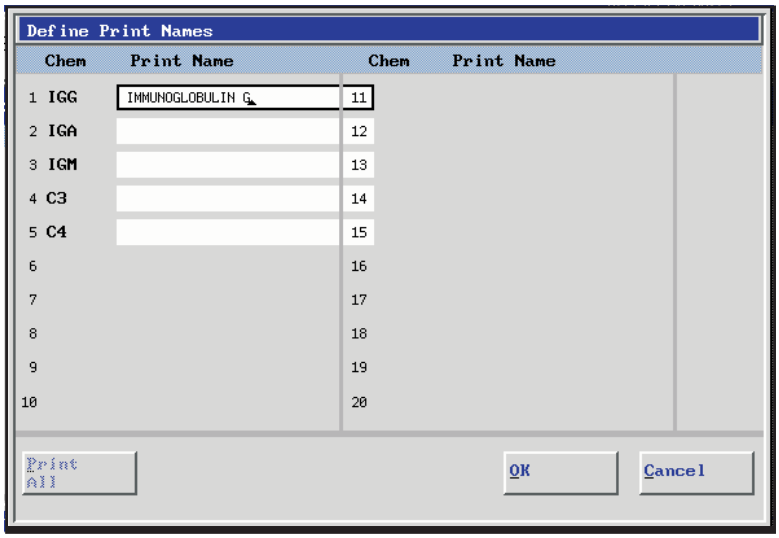

Figure 5.3 Define Print Names Dialog Box

Additional Information

Refer to CHAPTER 6, *Reagents/Calibration*, Loading/Unloading Reagent Cartridges for information on unloading chemistries.

Refer to CHAPTER 7, *Sample Programming*, Selecting Chemistry Tests by Panel and Selecting Chemistry Tests by Chemistry for information on removing chemistries from a programmed sample.

Refer to CHAPTER 7, *Sample Programming*, Programming a Control for information on removing chemistries from a programmed control.

Panel Setup

Introduction

The IMMAGE 800 holds up to 50 chemistry panels in its memory. Each panel is defined with a name and the chemistries that it contains.

Defining New Panels

The instrument status must be in *Standby* in order to proceed with the steps below to define a panel list.

Step	Action
1	From the Setup screen, select **<2> Panels**. (Refer to Figure 5.4.)
2	Select an available panel number for each panel to be defined from the multipage list of panel summaries. Available panels have blank Name and Chemistry fields.
3	Select **Define/Edit [F1]**. (Refer to Figure 5.4.)
4	Type the panel name in the **Panel Name** field (up to 15 alphanumeric characters). (Refer to Figure 5.5.)
5	Select the number beside each desired chemistry for the panel being defined. Selecting **Clear Chems [F1]** will deselect all of the selected chemistries.
6	Select the options button <▼ > beside **Sample Type**.
7	Select the sample type. The default sample type is determined by the sample type selected on the Default Setup screen. (Refer to Default Setup, "Setting the Default Sample Type" in this chapter to change the default sample type.)
8	Select the AGXS check box beside the desired chemistry to enable or disable antigen excess testing.
9	Select the options button <▼ > in the "Non-Std." column beside the desired chemistry. Select the number beside the desired dilution. OR Enter the number of the desired dilution and press **[Enter]**.
10	To define additional panels, select **Next Panel [F10]** to move to the next panel and return to Step 4.
11	Select **Panels Summary [F2]** to return to the list of panel summaries.

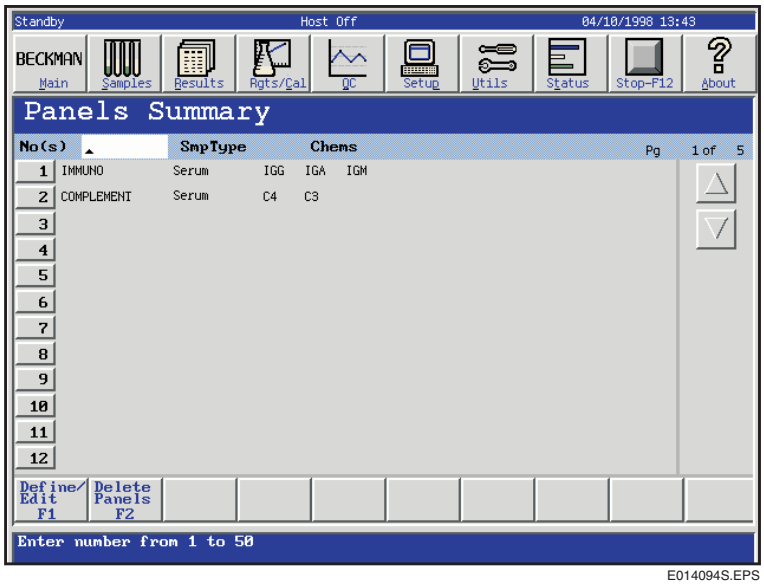

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Figure 5.4 Panels Summary Screen

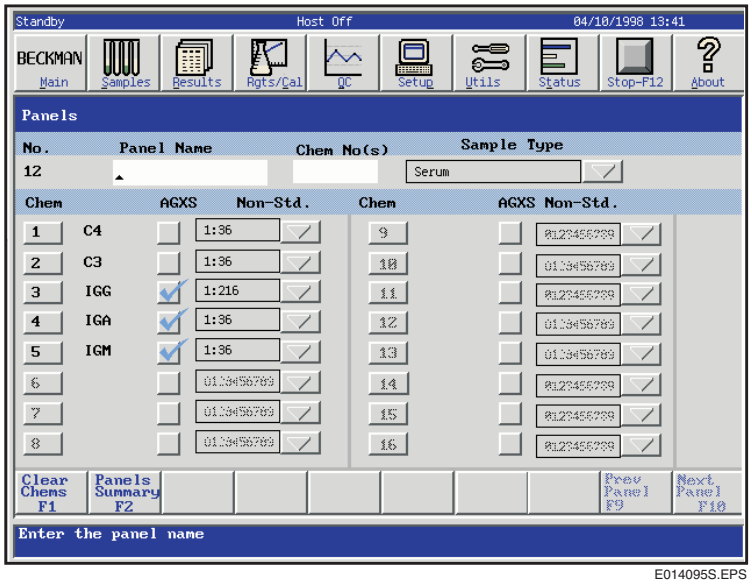

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Figure 5.5 Panels Screen

Editing Panels

The instrument status must be in *Standby* in order to proceed with the steps below to edit defined panels.

Step	Action
1	From the Setup screen, select **<2> Panels**. A multipage list of panel summaries will be displayed.
2	Select the numbers beside the panels to be edited.
3	Select **Define/Edit [F1]**.
4	Rename the panel if desired.
5	Select or deselect the numbers beside each chemistry as desired. Selecting **Clear Chems [F1]** will deselect all of the selected chemistries.
6	Select the options button <▼ > beside **Sample Type** to change the sample type.
7	Select the sample type. The default sample type is determined by the sample type selected in the Default Setup screen. (Refer to Default Setup, "Setting the Default Sample Type" in this chapter to change the default sample type.)
8	Select the AGXS check box beside the desired chemistry to enable or disable antigen excess testing.
9	Select the options button <▼ > in the "Non-Std." column beside the desired chemistry to change the dilution. Select the number beside the desired dilution. OR Enter the number of the desired dilution AND Press **[Enter]**.
10	To edit additional panels, select **Prev Panel [F9]** or **Next Panel [F10]** to display the previous or next panel. Repeat Steps 4-5.
11	Select **Panels Summary [F2]** to return to the list of panel summaries. (Refer to Figure 5.4.)

Deleting Panels

The instrument status must be in *Standby* in order to proceed with the steps below to delete defined panels.

Step	Action
1	From the Setup screen, select **<2> Panels**. A multipage list of panel summaries will be displayed.
2	Select the numbers beside the panels to be deleted.
3	Select **Delete Panels [F2]**.
4	Select **<OK>** at the *Delete ALL selected panels*? dialog box. OR Select **<Cancel>** to return to the list of panel summaries without deleting the panels.

Bar Code Setup

Introduction

The bar code symbologies recognized by the IMMAGE 800 can be selected. Additionally, the bar code parameters can be configured to match those of the sample bar codes being read.

Enabling/Disabling Bar Code Symbologies

The instrument status must be in *Standby* in order to proceed with the steps below to enable or disable bar code symbologies.

Step	Action
1	From the Setup screen, select **<3> Bar Code**. (Refer to Figure 5.6.)
2	To enable a bar code symbology select the check box beside the symbology. If the check box is checked, the symbology is enabled.
3	To disable a bar code symbology deselect the check box beside the symbology. If the check box is unchecked, the symbology is disabled. The default is all bar code types enabled.

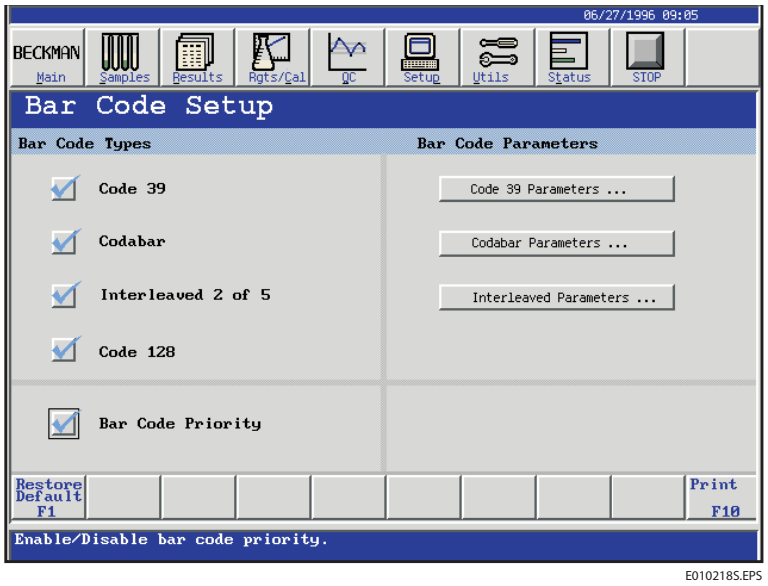

Figure 5.6 Bar Code Setup Screen

Bar Code Parameters

Each bar code type has different parameters that can be set. The parameters can include the following:

- range lengths
- enabling check digits
- large intercharacter gap
- fixed code lengths
- start and stop codes match.

The parameters available for each bar code type are shown in Table 5.1. Defaults are in **bold**.

NOTICE
The bar code parameters of the IMMAGE 800 must match the parameters of the printed bar code labels. Review the bar code printer setup to confirm that the parameters of the IMMAGE 800 match those of the bar code printer.

Code 128 is always enabled with variable code length. The parameters cannot be modified or changed. The Code 128 specification is 64 characters or less.

The defaults for bar code parameters are in **bold**.

Table 5.1 Bar Code Parameters

Parameter	Code 39	Codabar	Interleaved 2 of 5
Start & Stop Codes Match	NA[1]	Enabled or **Disabled**	NA
Check Digit	Enabled or **Disabled**	Enabled or **Disabled**	Enabled or **Disabled**
Large Intercharacter Gap	Enabled or **Disabled**	Enabled or **Disabled**	NA
Fixed Code Length	Enabled or **Disabled**	Enabled or **Disabled**	NA
Define Code Length	Any number (**10 digits**)	Any number (**10 digits**)	NA
Code Length One	NA	NA	Any even number from 0 to 14
Code Length Two	NA	NA	Any even number from 0 to 14

[1] Not applicable.

Setting Bar Code Parameters

The instrument status must be in *Standby* in order to proceed with the steps below to set bar code parameters.

Step	Action
1	From the Setup screen, select **<3> Bar Code**.
2	Select the appropriate **Bar Code Parameter** button. **Bar Code Parameter** buttons are available for selection only for enabled bar code types.
3	Select options appropriate for your bar code system.
4	Define any code lengths if necessary by typing the number in the appropriate field.
5	Select **<OK>** to save the parameters. OR Select **<Cancel>** to return to the Bar Code Setup screen without saving the parameters.
6	If additional bar code parameters are to be set, repeat Steps 2-5.

Bar Code Priority

If the Bar Code Priority is...	batch programming will...
disabled	autonumber the racks and positions.
enabled	not autonumber the racks and positions.

- The instrument reads bar coded samples whether or not the Bar Code Priority is enabled.
- Disabling the Bar Code Priority is recommended.

Enabling/Disabling Bar Code Priority

The instrument status must be in *Standby* in order to proceed with the steps below to enable or disable Bar Code Priority.

Step	Action
1	From the Setup screen, select **<3> Bar Code**.
2	To enable bar code priority select the check box beside **Bar Code Priority**. If the check box is checked, the bar code priority is enabled.
3	To disable bar code priority deselect the check box beside **Bar Code Priority**. If the check box is unchecked, bar code priority is disabled. The default is bar code priority enabled.

Restoring Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore bar code symbology defaults.

Step	Action
1	From the Setup screen, select **<3> Bar Code**.
2	Select **Restore Default [F1]** to return all bar code setups to their defaults.
3	Select **<OK>** at the confirmation screen to restore the defaults. OR Select **<Cancel>** to return to the Bar Code Setup screen without restoring the defaults.

Additional Information

CHAPTER 7, *Sample Programming*, Selecting Save/Next, Programming a Batch of Samples, Identifying a Batch

Reference Interval Setup

Introduction

When a reference interval and critical range are defined, they are printed beside the result on the report. A result outside of the reference interval or critical range is flagged. The interval and range are defined per chemistry or calculation with distinction made for sample type, sex, and age group.

Chemistries must be configured and calculations must be enabled before intervals can be defined.

The minimum entries necessary to save a reference interval are low age, low age unit, high age, high age unit, low reference interval number and high reference interval number.

Defining/Editing Sample Type and Sex

The instrument status must be in *Standby* in order to proceed with the steps below to define a sample type and sex for intervals and ranges.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation being defined. Multiple chemistries/calculations can be chosen.
3	Select **<Define Edit>** (Refer to Figure 5.8.)
4	Select the options button <▼ > below Sample Type.
5	Select the sample type. The default is serum.
6	Select the options button <▼ > below Sex.
7	Select the sex. The default is M/F (Male/Female).
8	Go to "Defining/Editing Intervals and Ranges."

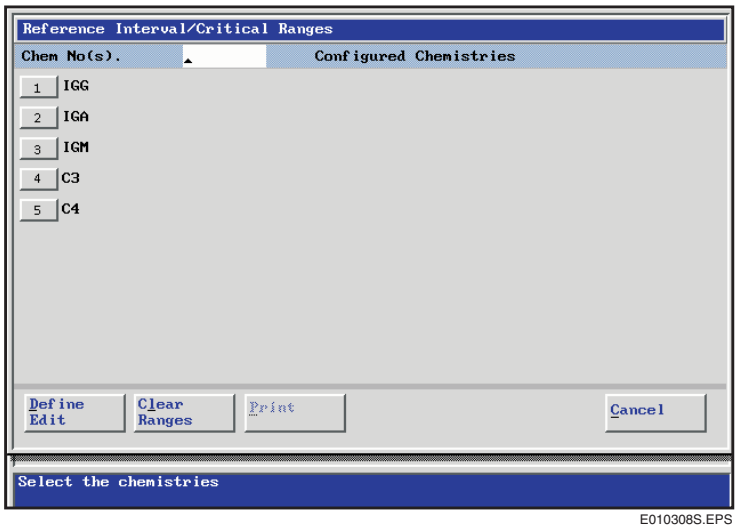

Figure 5.7 Reference Interval/Critical Ranges Dialog Box

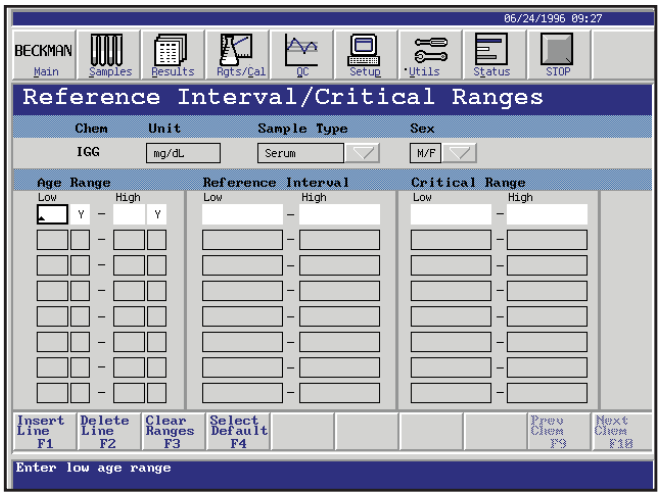

Figure 5.8 Reference Interval/Critical Ranges Screen

Choices for Age Field Entries

The following choices are available for the age field entries.

Table 5.2 Age Field Entries

Field	Entry choices
Low Age Range/High Age Range	0-999
Age unit field next to the low and high age fields	Y (Years) (default) H (Hours) D (Days) W (Weeks) M (Months)

Before Defining/Editing Intervals/Ranges

If more than one age-defined interval or range is to be entered, it must be entered from the lowest age range to the highest age range.

Example:

- 1-5 years on the first line
- 6-14 years on the second line
- 15-175 years on the third line

Age ranges cannot overlap.

Example of overlapping age ranges:

- 1-5 years
- 5-175 years

Defining/Editing Intervals and Ranges

The instrument status must be in *Standby* in order to proceed with the steps below to define reference intervals and critical ranges.

Step	Action
1	From the Reference Interval/Critical Ranges screen,type the low age in the **Low** field. Press **[Tab]**. (Refer to Figure 5.8.)
2	Type the age unit in the field next to the low age. Press **[Enter]**.
3	Type the high age in the **High** field. Press **[Tab]**.
4	Type the age unit in the field next to the high age. Press **[Enter]**.
5	Type the low and high reference interval numbers in the **Low** and **High Reference Interval** fields. The low reference interval number must be less than the high reference interval number rounded to the nearest hundredth. *Example:* Acceptable entry: Low-5.06, High-5.07 Unacceptable entry: Low-5.061, High-5.063
6	Optional entry: Type the low and/or high critical range numbers in the **Low** and/or **High Critical Range** fields. The critical range numbers must be outside of the reference interval.

(1 of 2)

Step	**Action**, continued
7	Repeat Steps 1-6 for additional interval and range definitions for the same chemistry/calculation. Use the **<Page Up>** or **<Page Down>** buttons to move to other pages of the same chemistry/calculation.
8	Select another sample type and/or sex to define additional groups of the chemistry/calculation. Repeat Steps 1-7. OR Select **Prev Chem [F9]** or **Next Chem [F10]** to define other chemistries. Repeat Steps 1-7. OR Select any icon from the menu bar to exit the screen.

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Selecting the Default

The default interval and range will be printed when an age is not specified in sample programming or when age is specified but the reference interval has not been defined for that age.

Only one default can be chosen for a particular interval and range definition grouped by chemistry/calculation, sample type and sex.

When the instrument status is in *Standby*, proceed with the steps below to select the default interval and range.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the desired chemistry/calculation. Multiple chemistries/calculations may be chosen.
3	Select **<Define Edit>** (Refer to Figure 5.7.)
4	Select a field on the interval/range line that is the chosen default.
5	Select **Select Default [F4]**. A **">"** symbol will mark the default range on the far left of the line.
6	Select another sample type and/or sex to move to other definitions within the same chemistry/calculation. Repeat Steps 4-5. OR Select **Prev Chem [F9]** or **Next Chem [F10]** to move to other chemistries/ calculations. Repeat Steps 4-5. OR Select any icon from the menu bar to exit the screen.

Deselecting a Default

When the instrument status is in *Standby*, proceed with the steps below to deselect the default interval and range.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the desired chemistry/calculation. Multiple chemistries/calculations may be chosen.
3	Select <**Define Edit**> (Refer to Figure 5.7.)
4	Select a field on the interval/range line that is the current default.
5	Select **Select Default [F3]**. The ">" symbol is removed from the far left of the line.
6	Select another sample type and/or sex to move to other definitions within the same chemistry/calculation. Repeat Steps 4-5. OR Select **Prev Chem [F9]** or **Next Chem [F10]** for other chemistries/ calculations. Repeat Steps 4-5. OR Select any icon from the menu bar to exit the screen.

Clearing Intervals/Ranges

Intervals and ranges can be cleared from either the Reference Interval/Critical Ranges dialog box or the Reference Interval/Critical Ranges screen.

When the instrument status is in *Standby*, proceed with the steps below to clear intervals and ranges from the Reference Interval/Critical Ranges dialog box.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation to be cleared. Multiple chemistries/calculations can be chosen.
3	Select <**Clear Ranges**>.
4	Select <**OK**> to clear all the intervals and ranges for the chemistry(ies)/ calculation(s) selected. OR Select <**Cancel**> to return to the Reference Interval/Critical Ranges dialog box without clearing intervals and ranges.

When the instrument status is in *Standby*, proceed with the steps below to clear intervals and ranges from the Reference Interval/Critical Ranges screen.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation to be cleared. Multiple chemistries/calculations can be chosen.
3	Select **<Define Edit>** (Refer to Figure 5.7.)
4	Select **Clear Ranges [F3]**.
5	Select **<OK>** to clear the intervals and ranges for the chemistry/ calculation, sample type and sex selected. OR Select **<Cancel>** to return to the Reference Interval/Critical Ranges screen without clearing intervals and ranges.
6	Select another sample type and/or sex to move to other definitions within the same chemistry/calculation. Repeat Steps 4-5. OR Select **Prev Chem [F9]** or **Next Chem [F10]** to move to other chemistries/ calculations. Repeat Steps 4-5. OR Select any icon from the menu bar to exit the screen.

Inserting a Line

This function is used to insert one line in a chemistry/calculation interval and range definition.

The instrument status must be in *Standby*, in order to proceed with the steps below to insert a line into an interval and range definition for a chemistry/calculation.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation where a line is being inserted.
3	Select **<Define Edit>** (Refer to Figure 5.7.)
4	Select a field on the line below where a line will be inserted.
5	Select **Insert Line [F1]**. A blank line will be inserted.

(1 of 2)

Step	**Action**, continued
6	Type ages, age units, intervals, and ranges on the blank line. Use the **<Page Up>** or **<Page Down>** buttons to move to other pages of the same chemistry/calculation.
7	Select another sample type and/or sex to insert lines from additional groups of the chemistry/calculation. Repeat Steps 4-5. OR Select **Prev Chem [F9]** or **Next Chem [F10]** to move to other chemistries/ calculations. OR Select any icon from the menu bar to exit the screen.

(2 of 2)

Deleting a Line

This function is used to delete one line of a chemistry/calculation interval and range definition.

The instrument status must be in *Standby*, in order to proceed with the steps below to delete a line from an interval and range definition for a chemistry/calculation.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation where a line is being deleted.
3	Select **<Define Edit>** (Refer to Figure 5.7.)
4	Select a field on the line being deleted.
5	Select **Delete Line [F2]**.
6	Select **<OK>** to delete the intervals and ranges. OR Select **<Cancel>** to return to the Reference Interval/Critical Ranges screen without deleting the line.

Printing Intervals and Ranges

When the instrument status is in *Standby*, proceed with the steps below to print the interval and range definitions.

Step	Action
1	From the Setup screen, select **<4> Reference Interval**. (Refer to Figure 5.7.)
2	Select the button beside the chemistry/calculation to be printed. Multiple chemistries/calculations can be chosen.
3	Select **<Print>**.
4	All definitions for each chemistry/calculation chosen will print.

Additional Information

Refer to Configuring the Chemistry Menu and to Calculations Setup in this chapter for chemistry and calculations setup information.

Report Setup

Introduction

Report formats can be selected for patient reports. A report header, including a facility name and address, can also be defined. Automatic printing of calibration, control, and patient reports can also be enabled.

Defining the Report Header

The report header can include the facility name and the facility address.

The instrument status must be in *Standby* in order to proceed with the steps below to define the report header.

Step	Action
1	From the Setup screen, select **<5> Report Setup**. (Refer to Figure 5.9.)
2	If desired, type the name of the facility in the **Facility Name** field (up to 60 alphanumeric characters).
3	If desired, type the address of the facility in the four **Facility Address** fields (4 lines of up to 60 alphanumeric characters each). The default report header is blank.

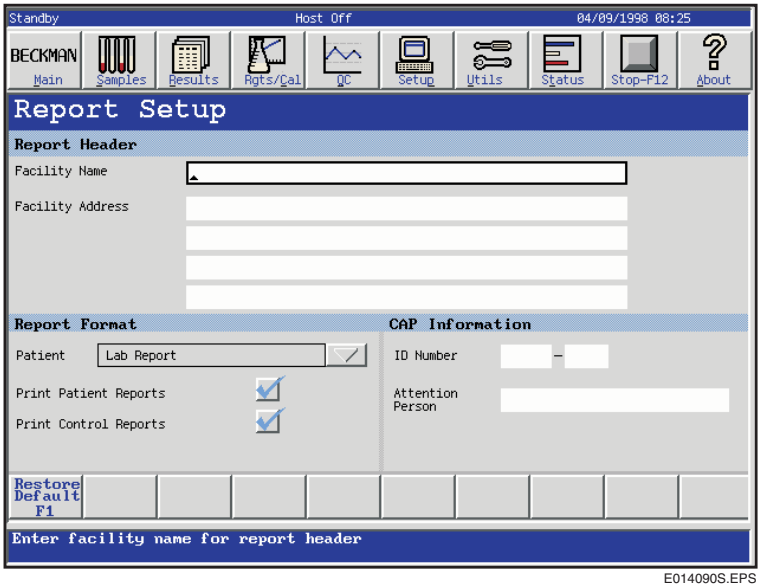


Figure 5.9 Report Setup Screen

Defining the Patient Report Format

The instrument status must be in *Standby* in order to proceed with the steps below to define the patient report format.

Step	Action
1	From the Setup screen, select **<5> Report Setup**. (Refer to Figure 5.9.)
2	Select the options button **<▼>** beside **Patient** under **Report Format**.
3	Select the number for the appropriate format. (Refer to APPENDIX B, *Reports* for format examples.) • **Lab Report** • **Lab Report - Dilutions** • **Patient Chartable Reports** The default patient report format is Lab Report.

Disabling Automatic Printing

Patient, calibration and control reports automatically print unless the print is disabled. The instrument status must be in *Standby* in order to proceed with the steps below to disable automatic printing.

Step	Action
1	From the Setup screen, select **<5> Report Setup**. (Refer to Figure 5.9.)
2	Select the check box next to **Patient Report** **Calibration Report** **Control Report** to disable the automatic printing of patient, calibration, or control reports respectively. The default is all three reports are automatically printed (checked).

Defining Inter-Lab Information

The instrument status must be in *Standby* in order to proceed with the steps below to define the Inter-Lab information for the report header.

Step	Action
1	From the **Setup** screen, select **<5> Report Setup**. (Refer to Figure 5.9.)
2	Type the laboratory Inter-Lab ID number beside the **ID Number** field (up to 9 numbers). The default is blank.
3	Type the name of the attention person beside **Attention Person** field (up to 30 alphanumeric characters). The default is blank.

Restoring Report Setup Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore report setup defaults.

Step	Action
1	From the Setup screen, select **<5> Report Setup**. (Refer to Figure 5.9.)
2	Select **Restore Default [F1]** to return all patient and control report setups to their defaults.
3	Select <**OK**> at the confirmation screen to restore the defaults. OR Select <**Cancel**> to return to the Report Setup screen without restoring the defaults.

Additional Information

For examples of report formats, refer to APPENDIX B, *Reports*.

Calculations Setup

Introduction

There are 12 Beckman Coulter defined calculations that can be enabled for the IMMAGE 800. The system will automatically calculate and print the final calculation on reports when the chemistries necessary for the calculation are run.

The system provides a maximum of 28 additional calculations that may be defined, edited, and/or deleted by the operator. The Custom Calculations feature provides for the reporting of operator-defined calculations using sample results when chemistries necessary for the calculations are run. The calculations may involve results from one sample or two linked samples.

The default for calculations is disabled.

Calculation Description

The following table describes the 12 calculations available on the IMMAGE 800.

Table 5.3 Calculations Available on IMMAGE 800

Calculation Name	Chemistries Run for Calculation	Formula
APA/APB	Apolipoprotein A, Apolipoprotein B	serum APA/serum APB
APB/APA	Apolipoprotein B, Apolipoprotein A	serum APB/serum APA
KAP/LAM	Kappa, Lambda	serum KAP/serum LAM
PRO +NAPA	Procainamide, N-acetylprocainamide	serum PRO + serum NAPA
PRI + PHE	Primidone, Phenobarbital	serum PRI + serum PHE
Excretion Rate	Any urine chemistry that is configured	[(Result in mg/dL) * 10 * (Volume in mL)]/Time in minutes
CSF Index	Immunoglobulin G (CSF and serum), Albumin (CSF and serum)	CSF IGG * serum ALB/CSF ALB * serum IGG
IGG Synth Rate	Immunoglobulin G (serum and CSF), Albumin (serum and CSF)	5 dL/day *[(CSF IGG - serum IGG/ 369) - ((CSF ALB - serum ALB/230) * (0.43 * serum IGG/serum ALB))]

(1 of 2)

Table 5.3 Calculations Available on IMMAGE 800, continued

Calculation Name	Chemistries Run for Calculation	Formula
ALB Index	Albumin (CSF and serum)	CSF ALB/serum ALB
IGG Index	IGG (CSF and serum)	CSF IGG/serum IGG
IGA Index	IGA (CSF and serum)	CSF IGA/serum IGA
IGM Index	IGM (CSF and serum)	CSF IGM/serum IGM

(2 of 2)

Units in Calculations

- The units of the calculation result are the units of the first chemistry encountered in the equation.
- Units will be converted within a calculation if the units belong in the same unit category. (Refer to Table 5.4.)
- When the units in the calculation are not in the same category, they cannot be converted and the calculation will be suppressed.

Units in Custom Calculations

- Changing the units of a chemistry may affect the calculation result defined with that chemistry.
- Units will be converted within a calculation if the units belong in the same unit category. (Refer to Table 5.4.)

Enabling a Calculation

The instrument status must be in *Standby*, in order to proceed with the steps below to enable a calculation.

Step	Action
1	From the Setup screen, select **<6> Calculations**. (Refer to Figure 5.10.)
2	Select the button beside the calculation desired. Multiple calculations can be selected.
3	Select **View [F1]**. The Calculations screen for the first calculation selected will be displayed. (Refer to Figure 5.11.)
4	Select the check box beside **Enable Calculation** to enable the calculation displayed. The default for all calculations is disabled (unchecked).

(1 of 2)

Step	**Action**, continued
5	Select **Prev Calc [F9]** or **Next Calc [F10]** to move to another Calculations screen. OR Select **Calc Summary [F1]** or an icon from the menu bar to return to the Calculations Summary screen.
6	If the Excretion Rate Calculation is enabled, go to "Selecting Urine Chemistries for Excretion Rate Calculations".

(2 of 2)

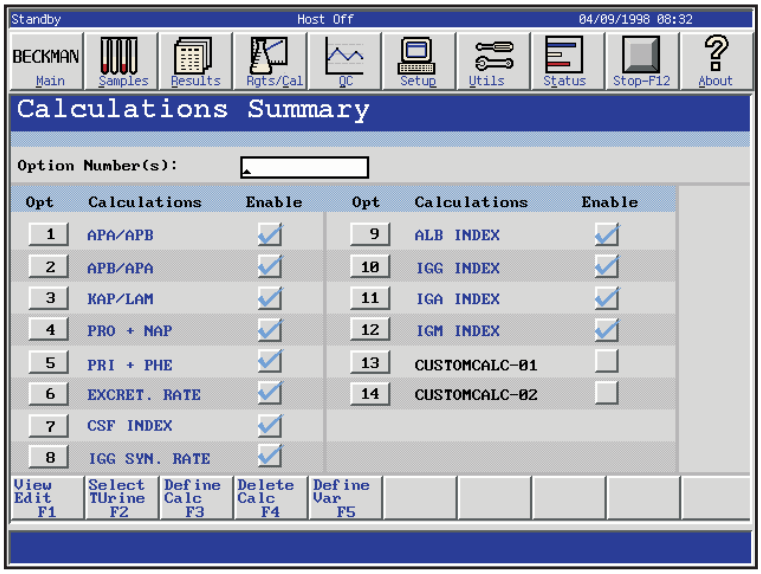


Figure 5.10 Calculations Summary Screen

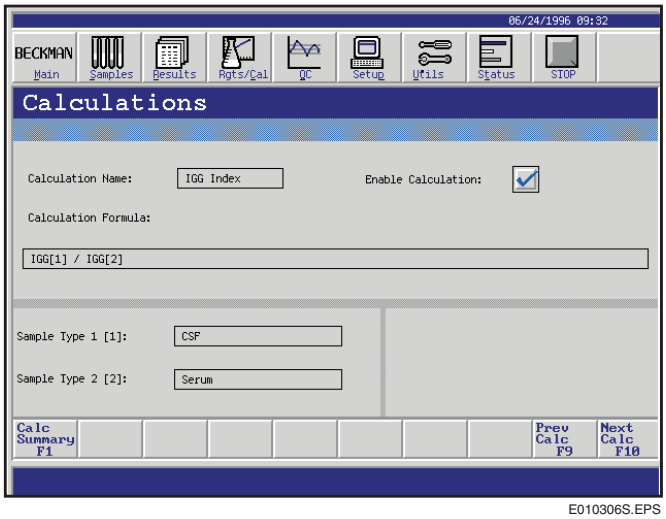


Figure 5.11 Calculations Screen

Selecting Urine Chemistries for Excretion Rate Calculations

After the excretion rate calculation is enabled, the urine chemistries for the calculation must be enabled. Once enabled, the excretion rate calculation will utilize the hours and volume entered for the urine sample.

When the instrument status is in *Standby*, proceed with the steps below to enable urine chemistries for excretion rate calculations.

Step	Action
1	From the Setup screen, select **<6> Calculations**. (Refer to Figure 5.10.)
2	Select **Select TUrine [F2]**. (Refer to Figure 5.12.)
3	Select the check box beside the urine chemistry desired for the excretion rate calculation. The default is disabled (unchecked).
4	Select **<OK>** to return to the Calculations Summary screen. OR Select **<Cancel>** to return to the Calculations Summary screen without changing the urine chemistry definition.

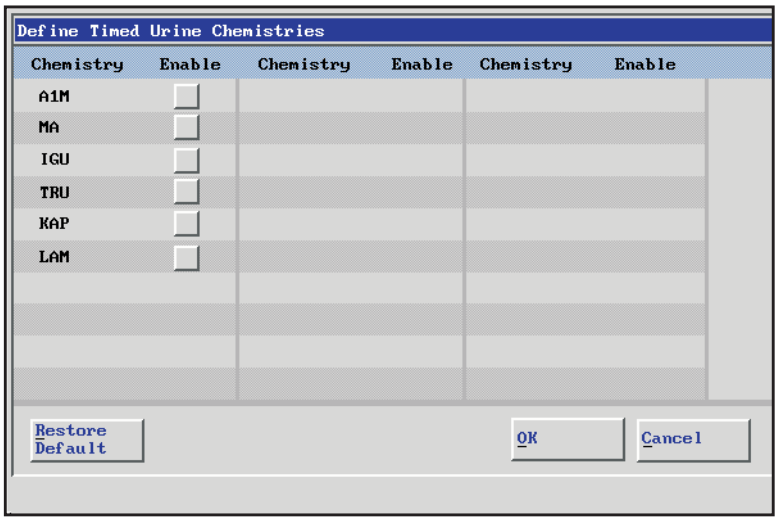


Figure 5.12 Define Timed Urine Chemistries Dialog Box

Selecting Units for Excretion Rate Calculations

The instrument status must be in *Standby* in order to proceed with the steps below to change the unit for Excretion Rate calculations.

Step	Action
1	From the Setup screen, select **<6> Calculations**.
2	Select **<6> Excretion Rate**. OR Enter the number beside Excretion Rate in the **Option** field.
3	Select **View/Edit [F1]**.
4	Select the options button **<▼ >** beside the **Unit** field. From the Calculation Unit screen, select the number next to the desired unit. OR Enter the number corresponding to the desired unit AND Press **[Enter]**.
5	Select **Calc Summary [F1]**. OR Select any icon from the menu bar.
6	From the Warning screen, select **<OK>** to change the unit. OR Select **<Cancel>** to exit without changing the unit.

Restoring Default Excretion Rate Calculations

When the instrument status is in *Standby*, proceed with the steps below to restore all default excretion rate calculations.

Step	Action
1	From the Setup screen, select **<6> Calculations**. (Refer to Figure 5.10.)
2	Select **Select TUrine [F2]**. (Refer to Figure 5.12.)
3	Select **<Restore Default>**. All the urine chemistry checkboxes will be unchecked and the timed urine calculations for those chemistries disabled.
4	Select **<OK>** to return to the Calculations Summary screen. OR Select **<Cancel>** to return to the Calculations Summary screen without changing the timed urine chemistry definition.

Variables

An IMMAGE 800 variable is a placeholder which may represent more than one number. A maximum of six variables may be defined for use in Custom Calculations. The numeric value for a variable is assigned during sample programming and that value will be used for the Custom Calculation on that particular sample. (Refer to CHAPTER 7, *Sample Programming*, Setting Variables.)

Defining and Editing Variables

The instrument status must be in *Standby* in order to proceed with the steps below to define or edit variables.

Step	Action
1	From the Setup screen, select **<6> Calculations**. OR Enter **6** in the **Option No.** field.
2	Select **Define Var [F5]**.
3	Enter the Variable name in the **Define Variables** fields. A maximum of six variables may be defined with up to five alphanumeric characters. NOTICE Variable names cannot begin with a numeric character.
4	Select <**OK**> to save the variable name. OR Select <**Cancel**> to return to the Calculations Summary screen.

Custom Calculations

- A Custom Calculation name must be unique with a maximum of 15 characters.
- Calculation formulas are not affected if the operator deletes the chemistries from the Chemistry Configuration.
- The operator must enable or disable each Custom Calculation individually.
- If the sample type defined for a calculation is serum, the calculation is applied to samples with a sample type of serum or plasma. If the sample type defined for a calculation is plasma, the calculation is applied to samples with a sample type of serum or plasma.
- Custom Calculations that require two samples must be linked through Sample ID. Each sample can only be linked to one other sample. (Refer to CHAPTER 7, *Sample Programming*, Linking/Unlinking Samples.)
- Slope-offset adjustments (if used) will be applied to the chemistry result before the calculation is performed.
- Custom calculation results are reported without units.

Defining a Custom Calculation

The instrument status must be in *Standby* in order to proceed with the steps below to define a Custom Calculation.

Step	Action
1	From the Setup screen, select **<6> Calculations**. OR Enter **6** in the **Option No.** field.
2	Select **Define Calc [F3]**.
3	Define the calculation name with a maximum of 15 characters.
4	Select the check box next to **Enable Calculation** to enable the use of the calculation.
5	Enter the calculation formula with a maximum total of six chemistries and/or variables per calculation. The order of precedence when using mathematical operations in a calculation formula are: 1st ( ) brackets 2nd ** exponent 3rd *, / multiplication, division 4th +, - addition, subtraction
6	Select the options button <▼ > beside Sample Type 1 [1] or Sample Type 2 [2] to select the sample type(s). NOTICE The same sample type cannot be defined for Sample Type 1 [1] and Sample Type 2 [2]. The default for Sample Type 1 [1] is the default sample type specified in System Setup. (Refer to Default Setup, "Setting the Default Sample Type" in this chapter.) The default sample type for Sample Type 2 [2] is None.
7	Select **Save Calc [F2]** To save the calculation defined.
8	Select **Calc Summary [F1]** to return to the Calculation Summary screen. OR Select any icon from the menu bar to exit.

Editing a Custom Calculation

The instrument status must be in *Standby* in order to proceed with the steps below to edit a Custom Calculation.

Step	Action
1	From the Setup screen, select **<6> Calculations**. OR Enter **6** in the **Option No.** field.
2	Select the number(s) beside the Custom Calculations desired. OR Enter the number(s) corresponding to the Custom Calculations in the **Option No.** field.
3	Select **View/Edit [F1]**.
4	To edit the calculation name, enter a name with a maximum of 15 characters and press **[Enter]** to continue.
5	Select the check box next to **Enable Calculation** to enable or disable the use of the calculation and press **[Enter]** to continue.
6	To edit the calculation formula, enter a formula with a maximum total of six chemistries and/or variables per calculation and press **[Enter]** to continue. The order of precedence when using mathematical operations in a calculation formula are: 1st ( ) brackets 2nd ** exponent 3rd *, / multiplication, division 4th +, - addition, subtraction
7	To edit the sample type, select the options button <▼ > beside Sample Type 1 [1] or Sample Type 2 [2] to select the sample types. NOTICE The same sample type cannot be defined for Sample Type 1 [1] and Sample Type 2 [2]. The default for Sample Type 1 [1] is the default sample type specified in System Setup. (Refer to Default Setup, "Setting the Default Sample Type" in this chapter.) The default sample type for Sample Type 2 [2] is None.

Step	**Action**, continued
8	

Select…	**to…**
Save Calc [F2]	save the calculation defined.
Calc Summary [F1]	return to the Calculations Summary screen.
Prev Calc [F9]	return to the previous calculation (if more than one Custom Calculation is chosen.)
Next Calc [F10]	advance to the next calculation (if more than one Custom Calculation is chosen.)

9	Select any icon from the menu bar to exit.

Deleting Custom Calculations

The instrument status must be in *Standby* in order to proceed with the steps below to delete a Custom Calculation.

Step	Action
1	From the Setup screen, select **<6> Calculations**. OR Enter **6** in the **Options No.** field.
2	Select the number(s) beside the Custom Calculations desired. OR Enter the number(s) corresponding to the Custom Calculations in the **Option No.** field.
3	Select **Delete Calc [F4]**.
4	Select **<OK>** to delete the Custom Calculations. OR Select **<Cancel>** to return to the Calculations Summary screen without deleting the Custom Calculations.

Units Setup

Introduction

Units can be selected for reporting with the results and displayed throughout the IMMAGE 800 system for each chemistry.

Selecting Units for Each Chemistry

The instrument status must be in *Standby* in order to proceed with the steps below to select the desired units for a chemistry.

Step	Action
1	From the Setup screen, select **<7> Units/Non-Standard Dilutions**. (Refer to Figure 5.13.)
2	Select the sample type, then select the options button < ▼ > beside the desired chemistry. (Refer to Figure 5.14.) The default units are displayed.
3	Select the number beside the units desired for the selected chemistry and sample type. OR Select <**Cancel**> to return to the Units screen without changing the units.
4	If the units selected are in a different category than the default units, a Units Conversion dialog box is displayed. (Refer to Figure 5.15 and Table 5.4.) The default units are displayed in the Units Conversion dialog box. Follow the steps below to enter a conversion factor. • Type the conversion factor to be multiplied by the default units in the **Conversion factor** field. • Select <**OK**> to save the conversion factor. OR • Select <**Cancel**> to return to the **Units** dialog box without saving the conversion factor.
5	Repeat Steps 2-4 for additional chemistries.

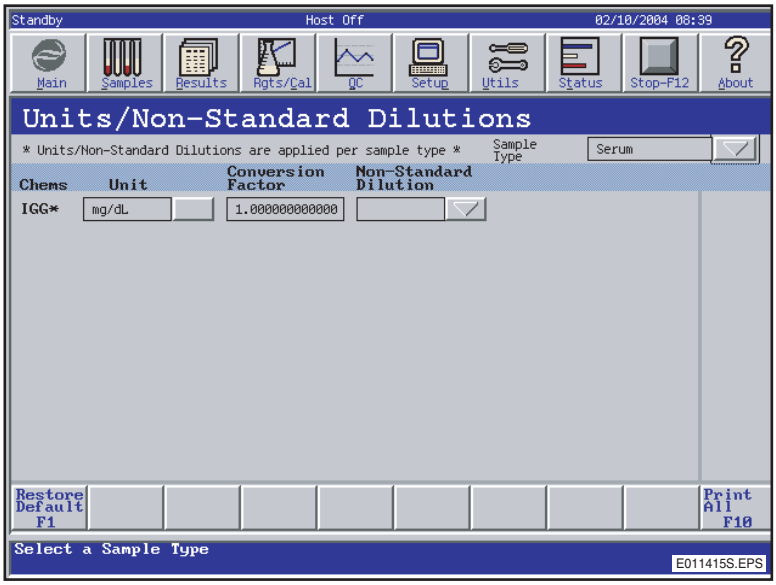


Figure 5.13 Units/Non-Standard Dilutions Screen

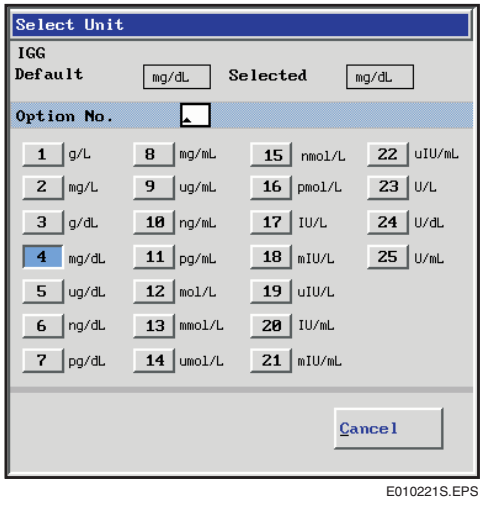


Figure 5.14 Units Dialog Box

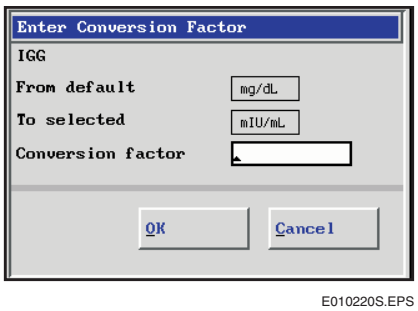


Figure 5.15 Units Conversion Dialog Box

Table 5.4 Units Categories

Weight/Volume	Mass/Volume	International Units/Volume	Units/Volume
g/L	mol/L	IU/L	U/L
mg/L	mmol/L	mIU/L	U/dL
g/dL	µmol/L	µIU/L	U/mL
mg/dL	nmol/L	IU/mL	
µg/dL	pmol/L	mIU/mL	
pg/dL		µIU/mL	
mg/mL			
µg/mL			
ng/mL			
pg/mL			

Restoring Defaults

The default units and standard dilutions for all of the chemistries can be restored with the following procedure. The default unit for each chemistry is shown in the Units Dialog Box (refer to "Selecting Units for Each Chemistry" above). The default dilution for each chemistry is shown in the Non-Standard Dilutions box. Refer to selecting non-standard dilutions for each chemistry. The instrument status must be in *Standby* to proceed with the steps below to restore defaults.

Step	Action
1	From the Setup screen, select **<7> Units/Non-Standard Dilutions**.
2	Select **Restore Default [F1]**.
3	Select **<OK>** to restore the defaults for units and standard dilutions. OR Select **<Cancel>** to return to the Units Setup screen without restoring the defaults.

Selecting Non-Standard Dilutions as Default for Each Chemistry

Introduction

The instrument status must be in *Standby* in order to select a non-standard dilution for a chemistry. The system allows the user to select a non-standard dilution to use as the initial dilution every time a particular assay is run.

Selecting a Non-Standard Dilution

Step	Action
1	From the Setup screen, select **<7> Units/Non-Standard Dilutions**. (Refer to Figure 5.13.)
2	Select the sample type. Then select the **options button** < ▼ > beside the desired chemistry. Standard and non-standard dilutions are displayed. (Refer to Figure 5.16.)
3	Select the number beside the desired dilution for the selected chemistry and sample type. Note that the current default dilution is highlighted. If the chosen dilution is a non-standard dilution, that dilution will appear on the Units/Non-Standard Dilutions screen. OR Select **<Cancel>** to return to the Units/Non-Standard Dilutions screen without changing the non-standard dilution. OR Select **<Default>** to return to the standard default dilution.
4	Repeat Steps 2-3 for additional chemistries.

When a non-standard dilution has been selected for a chemistry and sample type, whenever this chemistry is run in this sample type, the system uses the selected non-standard default dilution as the initial dilution. If the test is out of range at this dilution, the system will step up or step down to a different dilution.

If the original sample was programmed to run with a standard dilution, and later you changed the default dilution to a non-standard dilution, the sample will be rerun with the standard dilution.

The default dilution used for samples programmed as controls is unaffected.

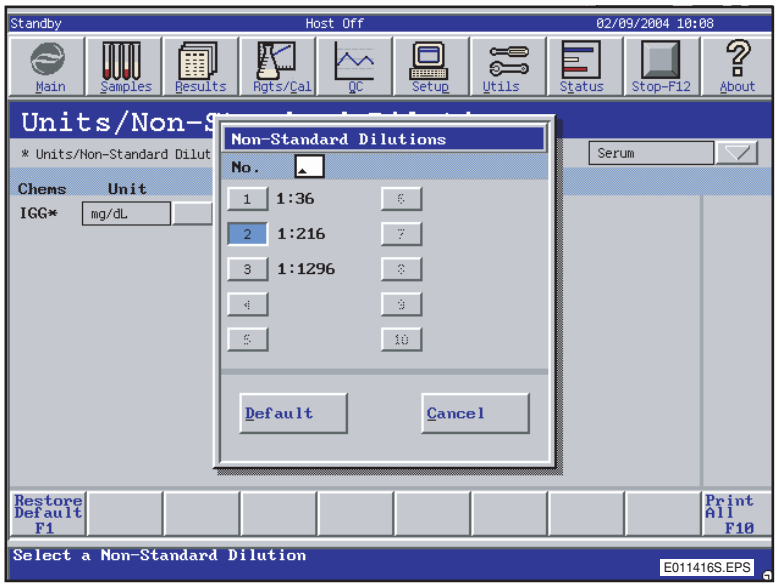


Figure 5.16 Non-Standard Dilutions Display

Configuring Antigen Excess Testing

Introduction

Antigen excess (AGXS) testing can be enabled or disabled for each appropriate chemistry configured on the chemistry menu.

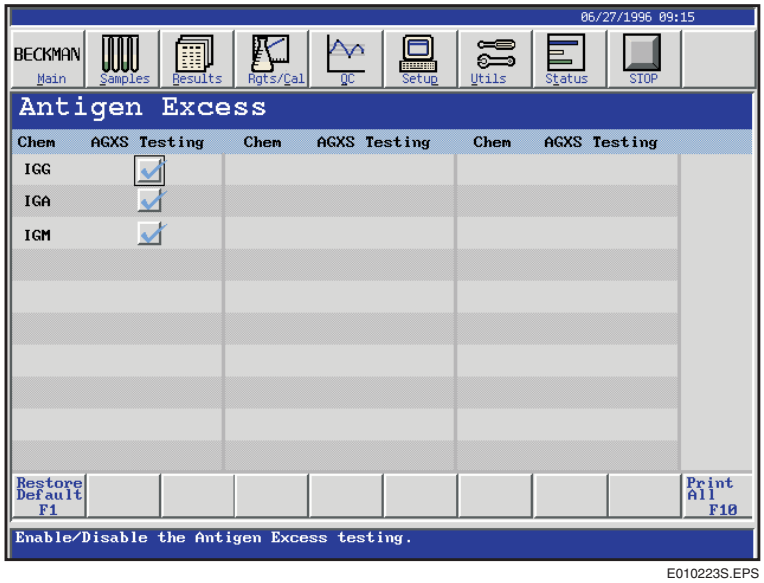
The default for AGXS testing is enabled for all the appropriate chemistries.

If AGXS testing is enabled, AGXS testing is always performed for the associated chemistry. If AGXS testing is disabled, AGXS testing will not be performed for the associated chemistry. AGXS can be enabled or disabled for an individual sample in Sample Programming.

How to Configure AGXS Testing

The instrument status must be in *Standby* in order to proceed with the steps below to configure AGXS testing.

Step	Action
1	From the Setup screen, select **<8> Antigen Excess**. A multipage list of chemistries will be displayed. (Refer to Figure 5.17.)
2	A checkmark in the box indicates AGXS is enabled for that chemistry. Select the check box to remove the check and disable the AGXS testing.



E010223S.EPS

Figure 5.17 Antigen Excess Screen

Restoring Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore the default.

Step	Action
1	From the Setup screen, select **<8> Antigen Excess**.
2	Pressing **Restore Default [F1]** will set AGXS testing to enabled for all appropriate chemistries requiring AGXS testing.

Date and Time Setup

Introduction

At installation the system requires the date and time to be set. After this, changing the date or time is optional. The format of the date and time for the appropriate screens and printouts may be changed as well.

Formatting the Date

The instrument status must be in *Standby* in order to proceed with the steps below to format date parameters.

Step	Action
1	From the Setup screen, select **<9> Date/Time**. (Refer to Figure 5.18.)
2	Format the order of the date by selecting the button beside **Order**. Select either: **<1> Month Day Year** **<2> Day Month Year** **<3> Year Month Day**
3	Format the day by selecting the button beside **Day Format**. Select either: **<1> Leading Zero (01)** **<2> No Leading Zero (1)**
4	Format the month by selecting the button beside **Month Format**. Select one: **<1> Leading Zero (01)** **<2> No Leading Zero (1)** **<3> Abbreviated Month (Jan)** **<4> Full Month (January)**
5	Format the year by selecting the button beside **Year Format**. Select either: **<1> 2 Digits** **<2> 4 Digits**

(1 of 2)

Step	**Action**, continued
6	Determine the appropriate date separator, then: • delete the current separator in the **Separator** field. • type in the appropriate separator (any non-alphabetic character). *Example:* "/".

(2 of 2)

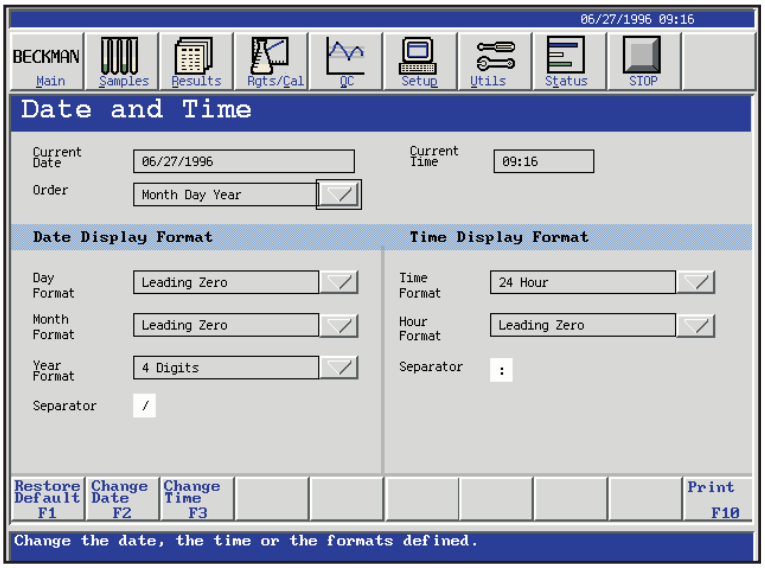


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Figure 5.18 Date and Time Screen

Formatting the Time

The instrument status must be in *Standby* in order to proceed with the steps below to format the time.

Step	Action
1	From the Setup screen, select **<9> Date/Time**. (Refer to Figure 5.18.)
2	Format the time by selecting the button beside **Time Format**. Select either: **<1> 24 Hour** **<2> 12 Hour**
3	Format the hour by selecting the button beside **<Hour Format>**. Select either: **<1> Leading Zero (01)** **<2> No Leading Zero (1)**
4	Determine the appropriate time separator, then: • delete the current separator in the **Separator** field. • type in the appropriate separator.

Restoring Default Formats

To restore the date and time formats to their defaults, select **Restore Default [F1]**. The format defaults are:

Date Display Format Defaults

Order	month day year
Day Format	Leading Zero (01)
Month Format	Leading Zero (01)
Year Format	1996 (four-digit year)
Separator	/

Time Display Format Defaults

Time Format	24 Hour
Hour Format	Leading Zero (01)
Separator	:

Changing the Date

The instrument status must be in *Standby* in order to proceed with the steps below to change a date.

Step	Action
1	From the Setup screen, select **<9> Date/Time**. (Refer to Figure 5.18.)
2	Select **Change Date [F2]**. (Refer to Figure 5.19.)
3	Correct the month (displayed above the mm), if needed. • delete the currently displayed month • type the correct month in its place The digits for "month" can be entered with or without a leading zero. For example, "4" or "04" may by entered for April.
4	Correct the day (displayed above the dd), if needed. • delete the currently displayed day • type the correct day in its place The digits for "day" can be entered with or without a leading zero for numbers less than ten. For example, "4" or "04" may by entered for the fourth day of the month.
5	Correct the year (displayed above the yyyy), if needed. • delete the currently displayed year • type the correct year in its place The digits for "year" must contain all four digits. For example "1996" may be entered but not "96".
6	Select **<OK>** to save the changes. OR Select **<Cancel>** to return to the Date and Time screen without saving the changes.

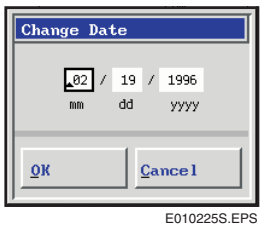


Figure 5.19 Change Date Dialog Box

Changing the Time

The instrument status must be in *Standby* in order to proceed with the steps below to change the time.

Step	Action
1	From the Setup screen, select **<9> Date/Time**. (Refer to Figure 5.18.)
2	Select **Change Time [F3]**. (Refer to Figure 5.20.)
3	Correct the hour (displayed above the hh), if needed. • delete the currently displayed hour • type the correct hour in its place The digits for "hour" can be entered with or without a leading zero for numbers less than ten. For example, "4" or "04" may by entered for four o'clock.
4	Correct the minute (displayed above the mm) if needed. • delete the currently displayed minute • type the correct minute in its place The digits for "minute" can be entered with or without a leading zero for numbers less than ten. For example, "4" or "04" may by entered for four minutes after the hour.
5	If the time format is set to twelve hour mode correct the AM/PM setting, if necessary. 1. Select the button beside the AM or PM. 2. Select **1** for AM or **2** for PM.
6	Select **<OK>** to save the changes. OR Select **<Cancel>** to return to the Date and Time screen without saving the changes.

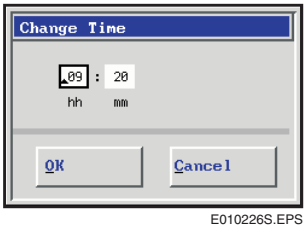


Figure 5.20 Change Time Dialog Box (24 hour format)

Setting Back the Date/Time

After the date/time is set back, an overlapping time period is created.

Example:

Old time: 11 PM
New set time: 10 PM

The overlapping time period is 1 hour.

If a run is finished at 11 PM old time and another is run finished by11 PM new time, the overlapping time period of 1 hour will have results and load lists from both runs. If these results and load lists are recalled by date and time, both sets of results and load lists will display.

Host Communications Setup

Introduction

When connecting a laboratory information system (LIS) to the IMMAGE 800, several parameters must be set. Refer to Restoring Defaults in this section for default settings. These parameters should be set by the person configuring the connection between the IMMAGE 800 and the LIS. Further information about all of the host communications parameters is found in the IMMAGE Immunochemistry Systems *Host Interface Specifications*.

Entering Sender ID

The Sender ID is a free text field sent with each message header record to the host if the Message Header Mode is set to Full Header. The instrument status must be in *Standby* in order to proceed with the steps below to enter the Sender ID.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Type the sender ID in the **Sender ID** field. (Up to 80 alphanumeric characters)

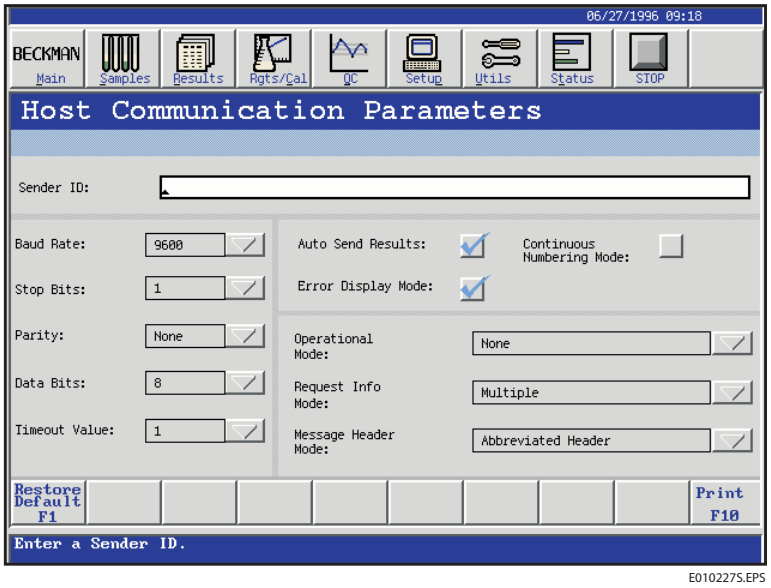


Figure 5.21 Host Communications Parameters Screen

Setting Computer Port Parameters

The communications port parameters must be set to match those of the LIS. The instrument status must be in *Standby* in order to proceed with the steps below to set the computer port parameters for communications of the IMMAGE 800 to a host computer.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the options button < ▼ > next to one of the following parameters (refer to Table 5.5): • Baud Rate • Stop Bits • Parity • Data Bits
3	Select the choice that matches the parameter of the host. OR Select **<Cancel>** to exit the dialog box without setting a parameter. The choices are shown in Table 5.5.
4	Repeat Steps 2-3 to set additional parameters.

Table 5.5 Computer Port Parameter Choices

Baud Rate	Stop Bits	Parity	Data Bits
<1> 2400	<1> 1	<1> None	<1> 8
<2> 4800	<2> 2	<2> Even	<2> 7
<3> 9600		<3> Odd	
<4> 19200			

Setting the Timeout Value

The timeout value is the time the IMMAGE 800 will wait for an answer to a query of the host before timing out and canceling the query.

The instrument status must be in *Standby* in order to proceed with the steps below to set the timeout value.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the options button **< ▼ >** beside **Timeout Value:** to enter the Timeout Value dialog box.
3	Select the number next to one of the timeout values below: **<1> 1 minute** **<2> 2 minutes** **<3> 4 minutes** **<4> 7 minutes** **<5> 10 minutes** OR Select **<Cancel>** to exit the Timeout Value dialog box without selecting an timeout value.

Enabling/Disabling Auto Send Results

If Auto Send is enabled, results are sent to the LIS automatically. No additional actions are required to send the results.

If the Auto Send is disabled, the results must be approved and sent to the LIS from the Recall Results By screen. (Refer to CHAPTER 8, *Results Recall*.)

The instrument status must be in *Standby* in order to proceed with the steps below to enable or disable auto send results.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the check box next to **Auto Send Results:** to enable auto send. OR Deselect the check box to disable auto send.

Enabling/Disabling Error Display Mode

When fatal errors are generated, there is a problem with transmission to or from the host system. If the error display mode is enabled, these errors will be displayed on the screen. If the error display mode is disabled, these errors will not be displayed on the screen but can be found in the Error Log. (Refer to CHAPTER 10, *Utilities*.)

The instrument status must be in *Standby* in order to proceed with the steps below to enable or disable error display mode.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the check box next to **Error Display Mode:** to enable error display mode. OR Deselect the check box to disable error display mode.

Enabling/Disabling Continuous Numbering Mode

The frame is a basic unit of data transmission. When the continuous numbering mode is checked (enabled), frame numbers from the host will not be reset at "1" with the next header record.

The instrument status must be in *Standby* in order to proceed with the steps below to enable or disable the continuous numbering mode.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the check box next to **Continuous Numbering Mode** to enable continuous numbering. OR Deselect the check box to disable Continuous Numbering Mode.

Selecting an Operational Mode

One of three operational modes can be selected or host communications can be turned off completely. The three operational modes are described in the IMMAGE Immunochemistry Systems *Host Interface Specifications*.

The instrument status must be in *Standby* in order to proceed with the steps below to select the operational mode.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the options button **< ▼ >** beside **Operational Mode:** to enter the **Operational Mode** dialog box.
3	Select the number next to one of the operational modes below: **<1> None** **<2> UniDirectional** **<3> BiDirectional** **<4> BiDirectional with Host Query** OR Select **<Cancel>** to exit the Operational Mode dialog box without selecting an operational mode.

Selecting Request Information Mode

The request information mode determines whether the IMMAGE 800 queries for one or multiple samples at a time. The optimal setting for this mode is determined by how the LIS processes the requests (real-time vs. batch processing).

The instrument status must be in *Standby* in order to proceed with the steps below to select the request information mode.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the options button **< ▼ >** beside **Request Info. Mode:** to enter the Request Information Mode dialog box.
3	Select the number next to one of the operational modes below: **<1> Single** **<2> Multiple** OR Select **<Cancel>** to exit the Request Information Mode dialog box without selecting the request information mode.

Selecting Message Header Mode

The message header mode determines if the message headers sent to the host will include the Sender ID, Version No., and Date and Time of Message fields.

The instrument status must be in *Standby* in order to proceed with the steps below to select the message header mode.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select the options button < ▼ > beside **Message Header Mode:** to enter the Message Header Record Mode dialog box.
3	Select the number next to one of the operational modes below: **<1> Full Header** **<2> Abbreviated Header** OR Select <**Cancel**> to exit the Message Header Record Mode dialog box without selecting a message header mode.

Restoring Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore the host communication parameter defaults.

Step	Action
1	From the Setup screen, select **<10> Host Communications**. (Refer to Figure 5.21.)
2	Select **Restore Default [F1]**. (Refer to Table 5.6.)
3	Select <**OK**> to restore the defaults. OR Select <**Cancel**> to return to the Host Communications Parameters screen without restoring the defaults.

Table 5.6 Host Communication Parameter Defaults

Parameter	Default
Sender ID	blank
Baud Rate	9600
Stop Bits	1
Parity	None
Data Bits	8
Timeout Value	1 minute
Auto Send Results	Enabled
Error Display Mode	Enabled
Continuous Numbering Mode	Enabled
Operational Mode	None
Request Information Mode	Single
Message Header Mode	Abbreviated Header

Additional Information

For additional information refer to IMMAGE Immunochemistry Systems *Host Interface Specifications.*

Default Setup

Introduction

Default Setup is used to:

- define the default sample type for all samples programmed. The sample type can be changed for individual samples from the Program Sample screen.
- define the default number of replicates to be run for each sample and what statistics to run on replicates.
- enable or disable statistics to run on replicates.
- define the default setup of the Calibration Halt function.

Setting the Default Sample Type

The instrument status must be in *Standby* in order to proceed with the steps below to define default sample types.

Step	Action
1	From the Setup screen, select **<11> Default Setup**. (Refer to Figure 5.22.)
2	Select options button < ▼ > beside **Default Sample Type**.
3	Select the button beside desired default sample type from the choices below: • **Serum** • **CSF** • **Plasma** • **Random Urine** • **Timed Urine** The default is serum. The selection will be shown in the Default Sample Type field. Select **<OK>** to return to the Setup dialog box and change the sample type. OR Select **<Cancel>** to return to the Setup dialog box without changing the sample type.

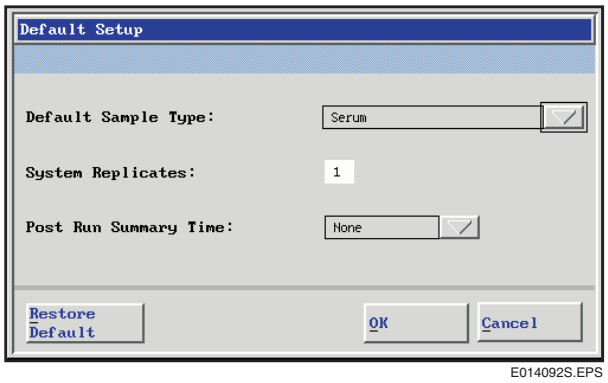


Figure 5.22 Default Setup Dialog Box

Definition of Replicates

System Replicates – The number of times each test will be performed on each sample.

Setting System Replicates

The instrument status must be in *Standby* in order to proceed with the steps below to set the desired number of system replicates.

Step	Action
1	From the Setup screen, select **<11> Default Setup**. (Refer to Figure 5.22.)
2	Type the desired number of system replicates (1 to 9) in the System **Replicates** field.
3	Select **<OK>** to return to the Chemistry Configuration screen. OR Select **<Cancel>** to return to the Chemistry Configuration screen without changing the statistics setup.

Setting the Default Post Run Summary Time Search

The instrument status must be in *Standby* in order to proceed with the steps below to set the time limit for the Post Run Summary.

Step	Action
1	From the **Setup** screen, select **<11> Default Setup**.
2	Select the options button < ▼ > beside **Post Run Summary Time**.
3	Select the number beside the desired time search option. OR Enter the number of the desired time search in the **Option No.** field and press **[Enter]**. OR Select **<Cancel>** to return to the Default Setup screen without changing the Post Run Summary Time search. The default Post Run Summary time has no time restriction.
4	Select **<OK>** to return to the Setup dialog box and change the Post Run Summary Time Search. OR Select **<Cancel>** to return to the Setup dialog box without changing the Post Run Summary Time Search.

Restoring Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore replicate/statistic defaults.

Step	Action
1	From the Setup screen, select **<11> Default Setup**. (Refer to Figure 5.22.)
2	Select **<Restore Default>**. The defaults are: Default Sample Type: serum System Replicates: 1 Post Run Summary Time: none
3	Select **<OK>** to restore defaults. OR Select **<Cancel>** to return to the Setup dialog box without restoring the defaults.

Sample Comments Setup

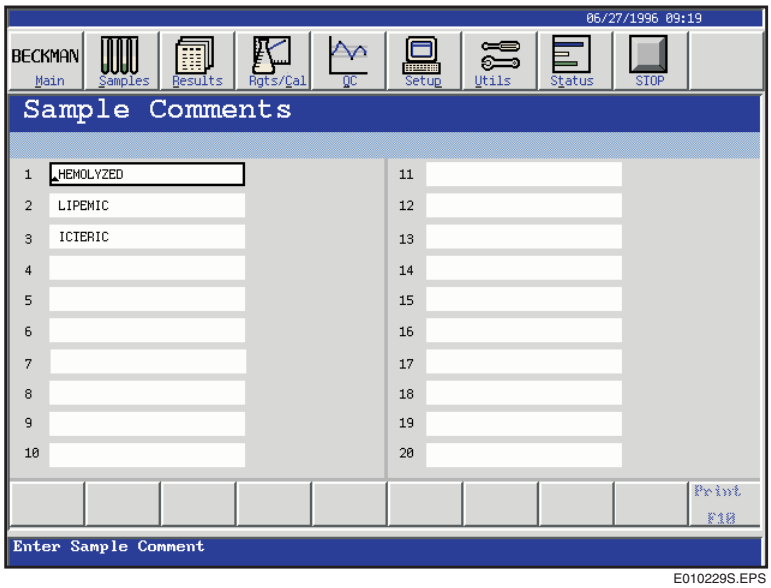
Introduction

Up to 20 sample comments may be predefined on the IMMAGE 800 Immunochemistry System for use when programming samples on the instrument. These will be presented in a numbered menu when programming samples.

Defining New Sample Comment

The instrument status must be in *Standby* in order to proceed with the steps below to define samples comments.

Step	Action
1	From the Setup screen, select **<12> Sample Comments**. (Refer to Figure 5.23.)
2	Choose a text field beside a comment number.
3	Type a comment up to 25 characters long including spaces and punctuation.
4	Return to Step 2 for additional comments.



E010229S.EPS

Figure 5.23 Sample Comments Screen

Editing a Sample Comment

The instrument status must be in *Standby* in order to proceed with the steps below to edit a sample comment.

Step	Action
1	From the Setup screen, select **<12> Sample Comments**. (Refer to Figure 5.23.)
2	Choose the comment to be edited.
3	Edit the comment.

Demographics Setup

Introduction

The fields which are accessible in the demographics screen of sample programming can be selected. (Refer to CHAPTER 7, *Programming a Sample*, Entering Patient Demographics.)

Selecting Fields to be Displayed in Sample Programming

The instrument status must be in *Standby* in order to proceed with the steps below to select fields for display in sample programming.

Step	Action
1	From the Setup screen, select **<13> Demographics Setup**. (Refer to Figure 5.24.)
2	Select the check boxes beside the fields to be accessible in the Demographics screen of sample programming. Checked fields will be accessible, unchecked fields will not be accessible in sample programming.

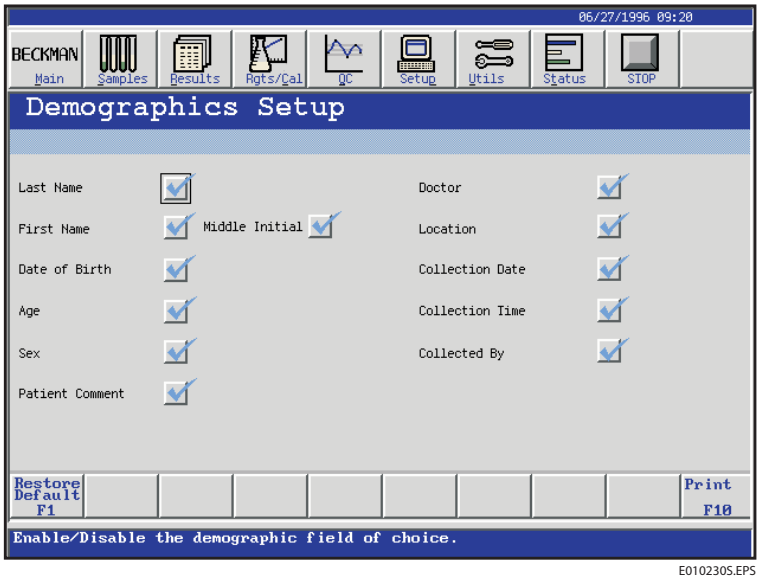


Figure 5.24 Demographics Setup Screen

Restoring Defaults

The instrument status must be in *Standby* in order to proceed with the steps below to restore defaults to the Demographics Setup.

Step	Action
1	From the Setup screen, select **<13> Demographics Setup**.
2	Select **Restore Default [F1]**. The default is all fields accessible.
3	Select **<OK>** to restore defaults. OR Select **<Cancel>** to return to the Demographics Setup screen without restoring the defaults.

Printer Setup

Introduction

The printer type is a USB printer or compatible. The paper size can be selected.

Selecting Paper Size

The instrument status must be in *Standby* in order to proceed with the steps below to select the paper size.

Step	Action
1	From the Setup screen, select **<14 > Printer Setup** (Refer to Figure 5.25.)
2	Select the options button < ▼ > beside **Paper Size**.
3	Select the option number for the desired paper size. OR Select **<Cancel>** to return to the Printer Setup dialog box.
4	Select **<OK>**. OR Select **<Cancel>** to return to the Printer Setup dialog box without changing the paper size. Default is U.S. Domestic (8 ½ × 11 inches).

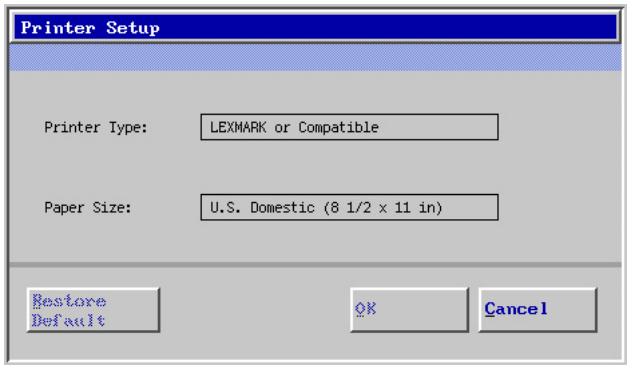


Figure 5.25 Printer Setup Dialog Box

Restoring Default

To restore the paper size default, select **<Restore Default>** from the Printer Setup dialog box.

Language Setup

Introduction

A language can be selected for use for system operations and printouts on the IMMAGE 800. The keyboard should match the language.

Changing the Displayed/Printed Language

The instrument status must be in *Standby* in order to proceed with the steps below to change the language.

Step	Action
1	From the Setup screen, select **<15> Languages/Keyboard**. (Refer to Figure 5.26.)
2	Select a language from the options button < ▼ >. NOTICE Selecting Japanese from the Language options will cause the Language/Keyboard selection to become unavailable. Reloading of the software is necessary to restore the Language/Keyboard Selection option. OR Select **<Cancel>** to return to the Setup screen without changing the language.
3	Perform the power off sequence and then the power on sequence. (Refer to CHAPTER 4, *System Power On/Off*, Power On Sequence, Power Off Sequence.)

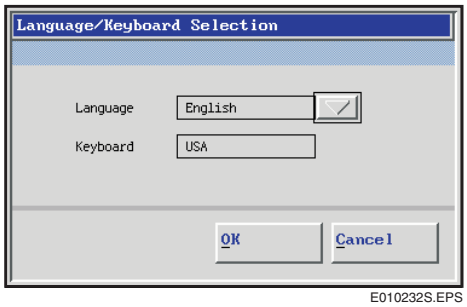


Figure 5.26 Languages/Keyboard Selection Dialog Box

Loading the Chemistry Protocol External Media

Description

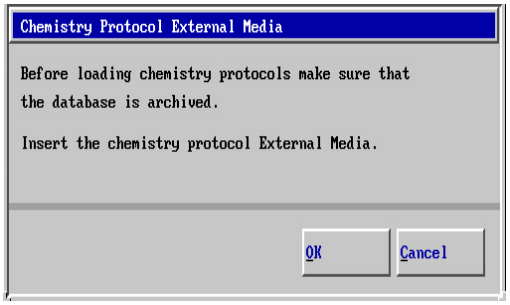
The chemistry protocol external media is provided with each IMMAGE 800 Immunochemistry system. It contains essential non-lot specific information about how to run each chemistry.

When to Load the Protocol External Media

The chemistry protocol external media is loaded when the IMMAGE 800 is installed. When new chemistries become available, new external media is provided.

Loading the Protocol External Media

The instrument status must be in *Standby* in order to proceed with the steps below to load the chemistry protocols onto the hard drive of the computer.

Step	Action
1	Select **Setup** from the menu bar.
2	Select **<16> Chemistry Protocol External Media** from the Setup screen.
3	Insert the chemistry protocol CD-ROM into the CD-ROM drive.  Figure 5.27 Chemistry Protocol External Media Dialog Box NOTICE Once the Protocol CD has been inserted into the CD-ROM drive, wait for the light on the CD_ROM drive to go out before selecting **<OK>**.
4	Select **<OK>** if the database has been archived. OR Select **<Cancel>** to return to the Setup screen without loading the external media.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>5</td><td>
<table>
<tr><th>If the CD-ROM is...</th><th>the screen...</th></tr>
<tr><td>successfully read</td><td>returns to the Setup menu.</td></tr>
<tr><td>unsuccessfully read</td><td>displays an appropriate error message. (Refer to CHAPTER 10, Utilities).</td></tr>
</table>
</td></tr>
<tr><td>6</td><td>Select Main to return to the main display.</td></tr>
</table>

Instrument Serial Number Setup

Introduction

The serial number of the instrument is entered through the Instrument Serial Number option. The instrument serial number will be printed on all reports.

How to Enter the Serial Number

When the instrument status is in *Standby*, proceed with the steps below to enter the serial number of the instrument.

Step	Action
1	From the Setup screen, select **<17> Instrument Serial Number**. (Refer to Figure 5.28.)
2	Type the instrument serial number in the **Serial Number** field (up to 7 alphanumeric characters).
3	Select **<OK>** to enter the serial number. OR **<Cancel>** to return to the Setup screen without entering the serial number.

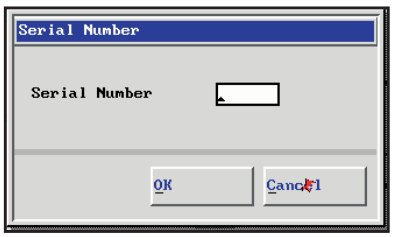


Figure 5.28 Serial Number Dialog Box

User-Defined Reagent Chemistry Setup

UDR Chemistry Overview and Precautions

Introduction

Each laboratory can define its own user-defined reagent (UDR) chemistry protocols using the templates from the chemistry protocol external media. After the chemistry protocol external media is loaded and the UDR protocol is defined, the UDR chemistry name is available for placement on the list of configured chemistries for selection in UDR rate mode programming, reference intervals, UDR calibration, sample programming, control definitions and panels.

Precautions

⚠ CAUTION

Since Beckman Coulter does not manufacture or otherwise control the sample and reagents that may be used in user-defined reagent applications, Beckman Coulter makes no warranty whatsoever with respect to such sample and reagent performance (including sample carryover, test results, reagent and cartridge handling), their effect on the system or required system maintenance or the frequency thereof, or their effect on operator safety. User assumes full responsibility for use of the proper test protocol and test result generation for the reagent(s) selected by the user and for any errors or omissions associated therewith. BECKMAN COULTER EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO THIS PRODUCT WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

⚠ CAUTION

Non-Beckman Coulter reagents, calibrators, and controls can contain components, not listed on the insert, which may carry over into the system causing chemical or optical interference. This carryover could adversely affect results on a properly performing system. Manufacturers of user-defined reagents should be contacted for disclosure of potentially interfering substances, such as preservatives.

Setting Up a UDR Chemistry

Loading the Protocol External Media

Follow the instructions under Loading the Chemistry Protocol External Media, earlier in this chapter, to load the user-defined reagent chemistry protocol templates.

Password Setup Procedure

Once a UDR chemistry has been defined and saved, the user must log in and perform a password setup procedure. This password protection feature is recommended for security purposes. A database backup will not backup passwords. Therefore, restoring a database will reset the password to default. The password setup is used to identify specific information, such as:

- who logged in
- which field was updated
- what screen was entered
- what field was changed

This and other information are described in the Display Events log. The password setup is described in the following steps.

Step	Action
1	Select the **Password Setup** box near upper right corner of the User-Defined Chemistries screen. Refer to Figure 5.29.
2	The User **Log in** screen appears. Refer to Figure 5.30. Note that the **Username** field defaults to ADMIN. Enter ADMIN in the Password field and select **<OK>**. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
3	If **<OK>** was selected above, the UDR User Setup/Password Protection Mode screen appears. Refer to Figure 5.31. This screen is used to add or delete a user. Up to 16 users are allowed. Password protection is enabled by default (i.e., the Password Protection Mode box is checked.) If the Password Protection Mode box is disabled (not checked), the password protection feature is not available (i.e., no prompt after Define and Save.) To add another user, select a new user name number. Then select **<Define Edit User>** and proceed to Step 4.
4	A Define/Edit User screen appears. Refer to Figure 5.32. Enter a new user name in the **Username** field. Enter your password in the **Password** field. Enter the same password in the **Confirm Password** field.

Step	**Action**, continued
5	To delete a user, select the username number and select <**Delete User**>. OR Select <**Cancel**> to return to the Password Protection Mode Screen.
6	Select <**Exit**> to return to the User Defined Chemistries screen.

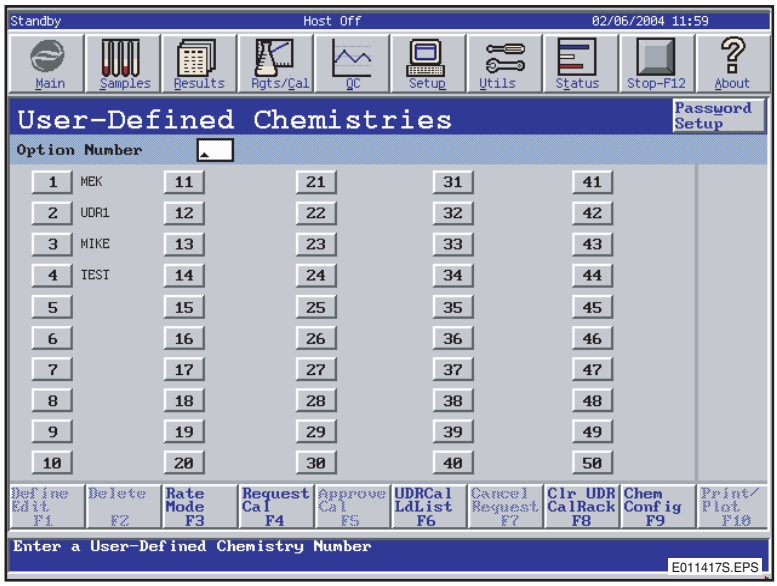


Figure 5.29 User-Defined Chemistries Screen

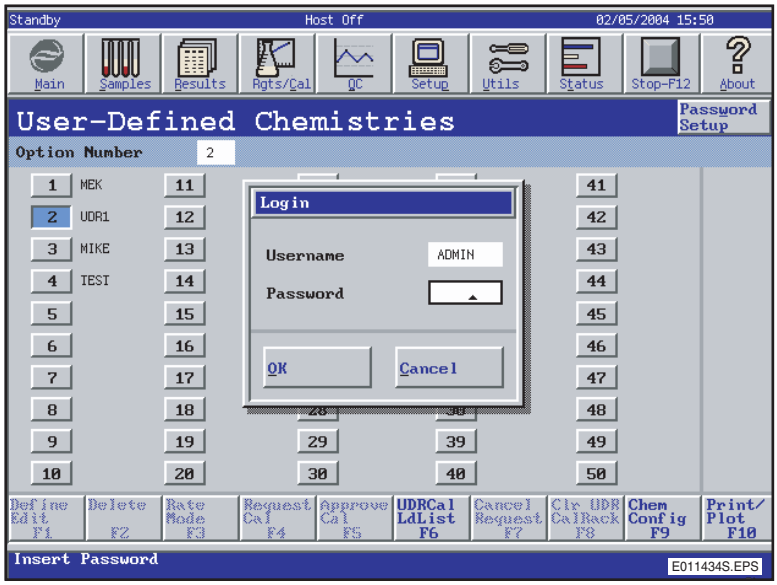


Figure 5.30 User Login Screen

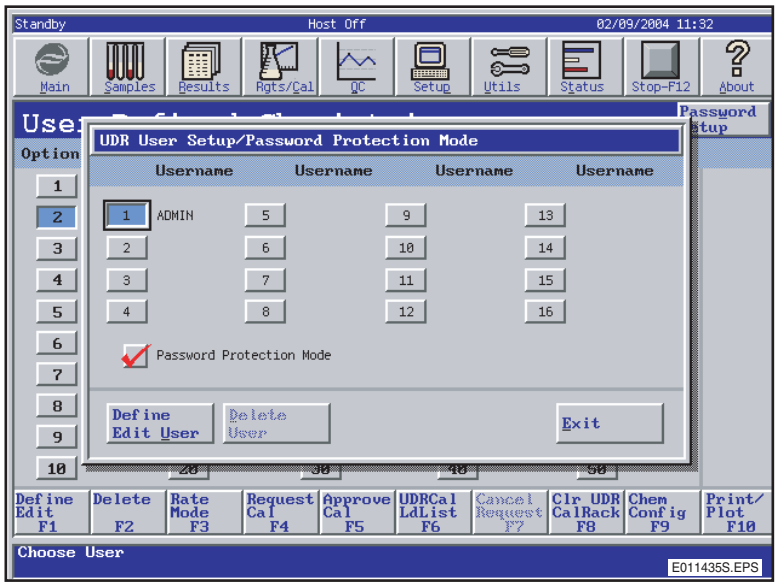


Figure 5.31 UDR User Setup/Password Protection Mode Screen

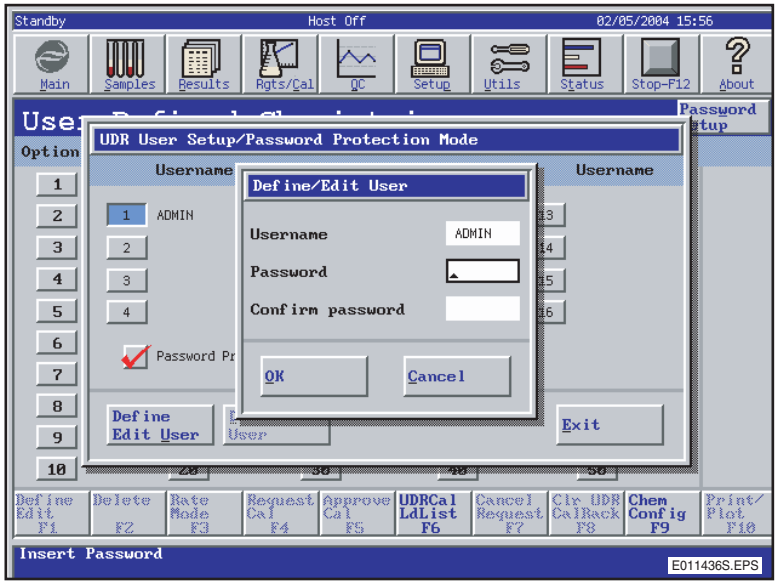


Figure 5.32 Define/Edit User Screen

Accessing Define/Edit

The instrument status must be in *Standby* in order to proceed with the steps below to access the Define/Edit screen.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Select the UDR Option Number. (Refer to Figure 5.29.)
3	Select **Define/Edit [F1]**. (Refer to Figure 5.33 and Figure 5.34.) Continue to "Beginning a New UDR Protocol Definition" in this chapter.

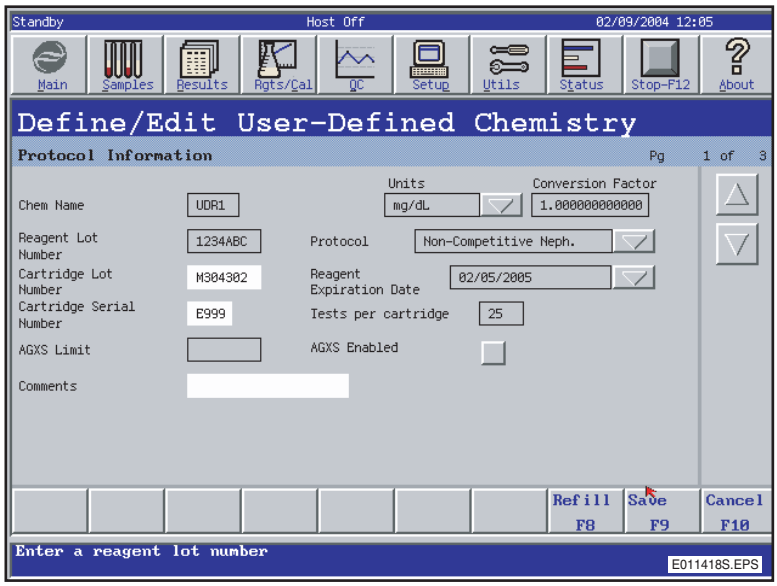


Figure 5.33 Define/Edit User-Defined Chemistry Screen, Page 1

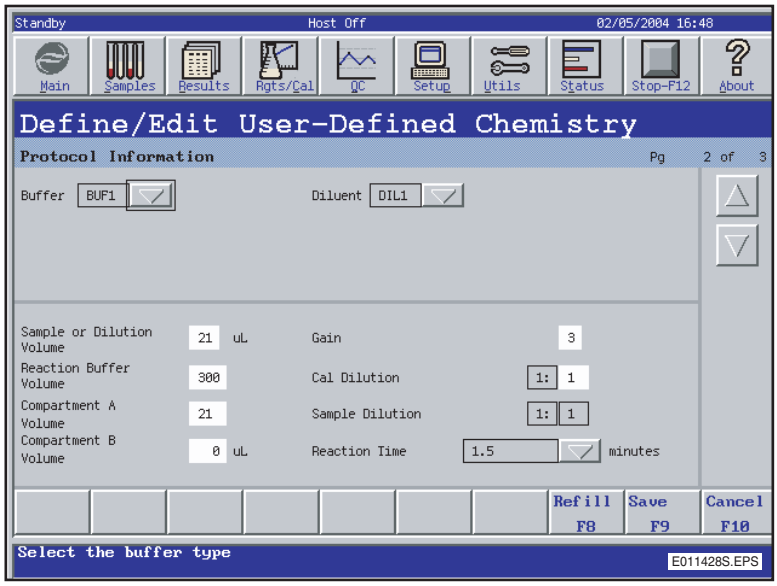


Figure 5.34 Define/Edit User-Defined Chemistry Screen, Page 2

Defining a UDR Chemistry

Description of Definition Fields

The following table describes the fields of the Define/Edit User-Defined Chemistry screen, Page 1. (Refer to Figure 5.33.) Use the tab key to navigate.

Table 5.7 Protocol Definition Fields, Page 1

Field	Entries Allowed	Function
Chem Name	Two to five alphanumeric characters	Unique name for chemistry.
Reagent Lot Number	A maximum of eight alphanumeric characters	Identifies reagent lot number.
Cartridge Lot Number	A maximum of eight alphanumeric characters	Identifies cartridge lot number.
Cartridge Serial Number	A maximum of four alphanumeric characters	Identifies unique serial number of UDR cartridge.
AGXS Limit	1-9999	Identifies Antigen Excess limit rate.
Comments	A maximum of 20 alphanumeric characters	Provides additional vendor information, or other comments.
Units	Selection from list	Concentration Units of UDR results.
Conversion Factor	Not applicable	• Displays the conversion factor input from the Units option button.
Protocol	Selection from list: • Non-Competitive nephelometric • Competitive nephelometric • Non-Competitive NIPIA • Competitive NIPIA	• Immunoprecipitin reaction detected by rate nephelometry. • Inhibition immunoprecipitin reaction detected by rate nephelometry. • Immunoprecipitin reaction detected by rate turbidimetry. • Inhibition immunoprecipitin reaction detected by rate turbidimetry.
Reagent Expiration Date	Date in order as defined in Date Setup	Reagent will be flagged on reports as expired after this date.

(1 of 2)

Table 5.7 Protocol Definition Fields, Page 1, continued

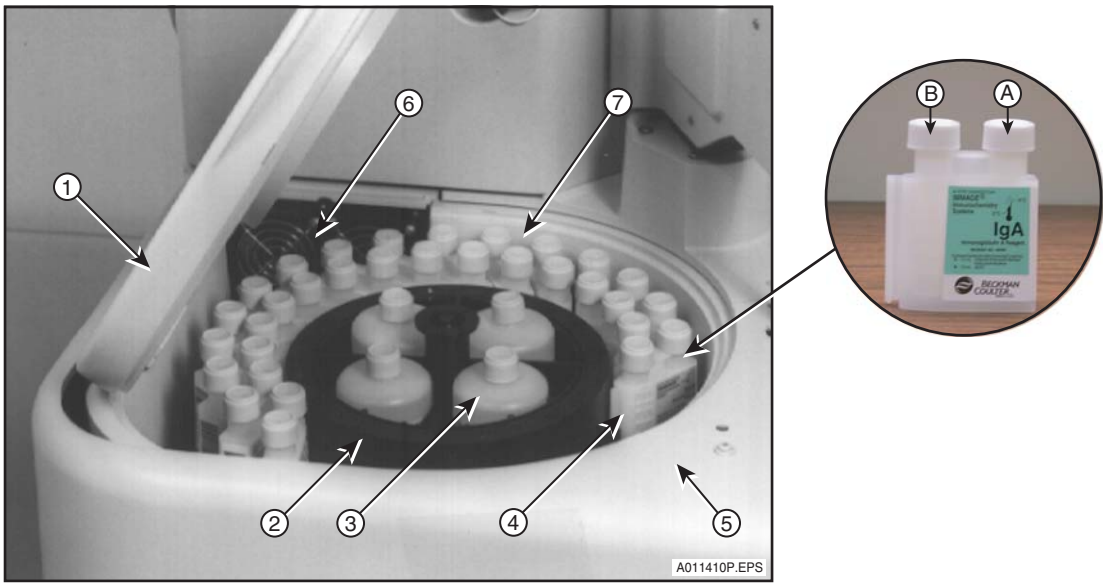
Field	Entries Allowed	Function
Tests per Cartridge	1-300	Identifies the number of tests available in the reagent cartridge.
AGXS Enabled	Select (check) to enable	Allows usage of AGXS Limit field.

(2 of 2)

The following table describes the protocol fields of the Define/Edit User-Defined Chemistry screen, Page 2. (Refer to Figure 5.34.)

Table 5.8 Protocol Definition Fields, Page 2

Field	Entries Allowed	Function
Buffer	BUF 1 to 4, or BUF 10 to 15	Identifies type of buffer used in test.
Diluent	DIL 1 to 4, or DIL 10 to 15	Identifies type of diluent used in test.
Sample or Dilution Volume	3 µL to 21 µL or 3 µL to 75 µL, depending on the sample dilution	Sample or dilution volume dispensed to reaction cuvette.
Reaction Buffer Volume	"0"; or from 195 µL to 300 µL	Reaction buffer volume dispensed.
Compartment A Volume (Refer to Figure 5.35.)	5 µL to 235 µL	Reagent volume aspirated from cartridge, compartment A.
Compartment B Volume (Refer to Figure 5.35.)	"0" ; or from 5 µL to 235 µL	Reagent volume aspirated from cartridge, compartment B.
Gain	1, 2, 3, 4	Signal amplification. As gain number increases, signal amplification increases.
Cal Dilution	1:1; or 1:5 to 1:50	Determines dilution ratio for calibration.
Sample Dilution	1:1; or 1:5 to 1:50	Determines dilution ratio for sample predilution.
Reaction Time	Select from list: 1.5 to 10 minutes	Interval in which reaction readings are taken after addition of the last reagent to the reaction mixture.



1. Reagent Compartment Cover
2. Reagent Carousel
3. Reaction Buffer Bottle
4. Reagent Cartridges (Compartments A and B)
5. Reagent Bar Code Reader
6. Fans
7. Temperature Sensor

Figure 5.35 The Reagent Compartment

The following table describes the calibration fields of the Define/Edit User-Defined Chemistry screen, Page 3. (Refer to Figure 5.36.)

Table 5.9 Calibration Definition Fields, Page 3

Field	Entries Allowed	Function
Levels	4 to 9	Identifies the number of calibrators used in test.
Replicates	1 to 9	Allows a number of tests to be repeated for each calibration level.
Update Level	1 to 9	Single-point calibration setpoint update level.
Replicates	1 to 9	Set point update replicate.
Cal Level Setpoints	Up to 6 digits with a decimal point, or seven digits.	Identifies concentration value for each calibration level in ascending order where Level 1 is the lowest concentration value.

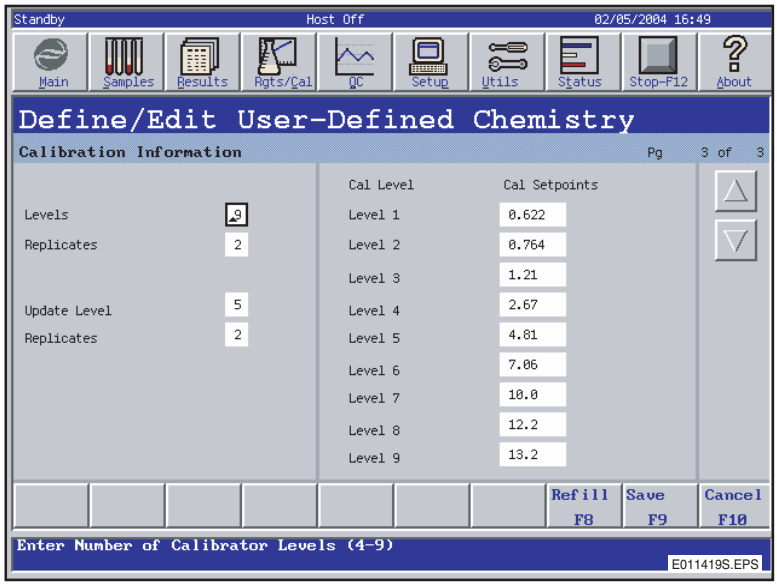


Figure 5.36 Define/Edit User-Defined Chemistry Screen, Page 3

Order of Reaction

The following table describes the order of reaction as determined by the type and volume of reaction components defined.

Table 5.10 Order of Reaction

If the Reaction Buffer Volume is…	and the Compartment B Volume is…	the Order of Reaction is…
Between 195-300 µL	0 µL	UDR buffer > Incubate > Neat or Diluted Sample > Compartment A Reagent starts reaction
Between 195-300 µL	Between 5-235 µL	UDR buffer > Compartment B Reagent > Incubate > Neat or Diluted Sample > Compartment A Reagent starts reaction
0 µL	Between 195-235 µL	Compartment B Reagent > Neat or Diluted Sample > Incubate > Compartment A Reagent starts reaction

Recommended Order for UDR AGXS Flagging Limit Use

Step	Action
1	Define UDR parameters
2	Perform UDR multi-point calibration.
3	Approve UDR multi-point calibration. Note: If calibration verification is desired, run the calibration verification BEFORE changing the sample dilution.
4	Change UDR sample dilution (optional).
5	Perform UDR AGXS Limit determination testing using UDR Rate Mode.
6	Enter UDR AGXS Limit (rate value) and select (check) the AGXS Enable box to begin UDR AGXS flagging. The AGXS Enable box is located in the Define/Edit User-Defined Chemistry screen (Refer to Figure 5.33).
7	Run UDR samples and perform single-point UDR calibration updates.

Additional Information

Refer to IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 3, *Theory of Operations*, Principles of Methodologies for theory of operation information.

Beginning a New UDR Protocol Definition

The instrument status must be in Standby to proceed with the steps below. Refer to the Define/Edit User-Defined Chemistry screen shown in Figure 5.33.

Step	Action
1	From Page 1 of the Define/Edit User-Defined Chemistry screen, enter the UDR chemistry name in the **Chem Name** field. This field is limited to 2-5 alphanumeric characters. The chemistry name must not be in use for any other chemistry or calculation.
2	Select the options button < ▼ > beside the **Units** field.
3	Select the number for the desired unit.
4	Enter the reagent lot number in the **Reagent Lot Number** field.
5	Select the options button < ▼ > beside the **Protocol** field.
6	Select the number for the desired protocol.
7	Select the **Cartridge Lot Number** field.
8	Enter the cartridge lot number from the UDR cartridge. The lot number is found on the bar code label of the UDR cartridge supplied by Beckman Coulter.

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Step	**Action**, continued
9	Select the options button < ▼ > beside the **Reagent Expiration Date** field.
10	Enter the reagent expiration date. NOTICE The expiration date must not be the current date. Recalibration will be necessary when the expiration date is changed.
11	Select **<OK>** to enter the expiration date into system. OR Select **<Cancel>** to exit the dialog box without entering the date. Continue to “Defining UDR Sample/Reagent Volumes.”
12	Enter the reagent cartridge serial number in the **Cartridge Serial Number** field. The serial number is found on the bar code label of the UDR cartridge supplied by Beckman Coulter.
13	Enter the number of tests in the **Tests per Cartridge** field. The maximum number of tests is 300.
14	If desired, select the **Comments** field and enter vendor information or other comments. This field is limited to 20 alphanumeric characters.

(2 of 2)

Defining an AGXS Limit

The AGXS Limit is a user-defined value. The AGXS Limit feature will only be available if the UDR has a status of "calibrated" and uses a "Non-Competitive Nephelometric" or "Non-Competitive NIPIA" protocol. Entry of this value in the AGXS Limit field is only available after a UDR multi-point calibration has been performed and approved.

Entering an AGXS Limit value into the UDR definition will clear the calibration program of the defined UDR. The AGXS limit is calibration specific; therefore, recalibrating a UDR using a multi-point calibration will clear the AGXS Limit field and disable AGXS flagging.

During the sample run, if the calibrated rate for a UDR sample reaction is equal to or greater than the value entered for the AGXS Limit in the UDR definition, the system will suppress the results and display ******* in the results column on the results display and printout instead of a numerical result. AGXS flagging shall not apply during UDR Rate Mode runs.

Refer to follow the steps to enter an AGXS flagging rate value.

Step	Action
1	From the User-Defined Chemistries screen, select the chemistry for AGXS flagging. Refer to Figure 5.29.
2	Select **Define Edit**.
3	A user defined warning message appears. Read the message and select **<OK>**.
4	Select the **AGXS Enable** box.
5	Enter Rate Units into AGXS Limit field.
6	Select **Save [F9]**.
7	If your password is protected, then refer to the Password Setup Procedure in this chapter and enter your user name and password.
8	Select **<OK>**.

Defining UDR Sample/Reagent Volumes

The minimum total cuvette volume of reagent(s) and sample is 195 µL.

The maximum total cuvette volume of reagent(s) and sample is 365 µL.

The instrument status must be in *Standby* in order to proceed with the steps below to define UDR sample and reagent volumes. Refer to Figure 5.34

Step	**Action**
1	From Page 2 of the Define/Edit User-Defined Chemistry screen, select the **Buffer** options button beside the Buffer field.
2	Select the buffer type from the list.
3	Select the **Diluent** options button < ▼ > beside the Diluent field.
4	Select the diluent type from the list.

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<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>5</td><td>Enter the volume of sample or sample dilution to be aspirated and dispensed in the Sample or Dilution Volume field.
<table>
<tr><th>If the Sample Dilution field entry is...</th><th>the Sample or Dilution Volume field may be...</th></tr>
<tr><td>1:5 to 1:50</td><td>3 µL to 75 µL</td></tr>
<tr><td>1:1 (undiluted)</td><td>3 µL to 21 µL</td></tr>
</table>
NOTICE
Aspiration of neat serum and/or plasma sample volumes greater than 15 µL may result in carryover and is not recommended.</td></tr>
<tr><td>6</td><td>Enter the reaction buffer volume to be aspirated and dispensed in the Reaction Buffer Volume field. Entries may be "0" or from 195 µL to 300 µL.</td></tr>
<tr><td>7</td><td>Enter the volume of reagent to be aspirated and dispensed from Compartment A in the Compartment A Volume field. Entries may be from 5 µL to 235 µL.</td></tr>
<tr><td>8</td><td>Enter the volume of reagent to be aspirated and dispensed from Compartment B in the Compartment B Volume field.
<table>
<tr><th>If the Reaction Buffer Volume field entry is...</th><th>the Compartment B Volume field entry may be...</th></tr>
<tr><td>0</td><td>195 µL to 235 µL</td></tr>
<tr><td>195 µL to 300 µL</td><td>0 or 5 µL to 235 µL</td></tr>
</table></td></tr>
<tr><td>9</td><td>Enter the gain in the Gain field. Entries may be 1, 2, 3, or 4. The gain increases as the number increases.</td></tr>
<tr><td>10</td><td>Enter the calibration dilution in the Cal Dilution field. Entries may be from 1:5 to 1:50.
OR
Enter 1:1 for an undiluted sample.
The Sample Dilution field automatically displays the same value as the Cal Dilution field. No input is allowed until after calibration and approval.</td></tr>
</table>

(2 of 3)

Step	**Action**, continued
11	After calibration and approval, if the desired sample dilution is different from the calibration dilution, enter the sample dilution in the **Sample Dilution** field. Entries may be from 1:5 to 1:50. OR Enter 1:1 for an undiluted sample.
12	Select the options button < ▼ > beside the **Reaction Time** field.
13	Select the reaction time number from the list.
14	Select the **<Page Down>** button to go to Page 2 of the Define/Edit User-Defined Chemistry screen.
15	Continue to "Defining UDR Calibration Information."

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Defining UDR Calibration Information

Defining UDR Calibration Information

The out-of-range low value for the protocol is the lowest non-zero calibrator setpoint concentration. The out-of-range high value for the protocol is the highest calibrator setpoint concentration.

The instrument status must be in *Standby* in order to proceed with the steps below to define the calibration information on Page 3 of the Define/Edit User-Defined Chemistry screen. Refer to Figure 5.36

Step	Action
1	From Page 3 of the Define/Edit User-Defined Chemistry screen, enter the number of Cal Setpoint levels in the **Levels** field. Entries may be from four to nine.
2	Enter the number of replicates to be run per Cal Setpoint level in the **Replicates** field. Entries may be from one to nine.
3	Enter a Cal Level number in the **Update Level** field for a single-point calibration update. Entries may be from one to nine.
4	Enter the number of replicates to be run for the Update Level in the **Replicates** field. Entries may be from one to nine.
5	Enter the concentration value in each of the **Cal Setpoint** fields. The concentration values must be in ascending order with Level 1 being the lowest concentration. Each field entry is limited to seven digits or six digits with a decimal point. NOTICE The number of calibration levels limits the type of curve-fit model applicable to the UDR. (Refer to Approving a Calibration, "Curve-Fit Model Descriptions", later in this chapter.)
6	Select **Save [F9]** to save the protocol and calibration information. OR Select **Cancel [F10]** to exit the screen without saving the protocol.
7	Go to the User-Defined Chemistries screen (Figure 5.29) and select **Chem Config [F9]** to configure the UDR chemistry. (Refer to Configuring the Chemistry Menu in this chapter.)
8	From the Chemistry Configuration screen, select **UDR Main [F9]** to return to the User-Defined Chemistries screens.

Deleting UDR Chemistries

Removing a UDR Chemistry from the Chemistry Menu

This function removes the UDR chemistry from the chemistry configuration menu, from any configured control, and from any configured panel. Refer to Configuring the Chemistry Menu, "Deleting a Chemistry" earlier in this chapter.

Deleting a UDR Definition

The Delete function deletes a UDR definition only if the chemistry has been removed from the chemistry menu. When the UDR definition is deleted, the UDR reference intervals and all associated, non-archived patient results are deleted. Refer to IMMAGE 800 Immunochemistry System *Operation Manual* CHAPTER 10, *Utilities*, Backup/Restore.

The instrument status must be in *Standby* in order to proceed with the steps below to delete a UDR definition.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Choose a number beside the chemistry to be deleted.
3	Select **Delete [F2]**. (Refer to Figure 5.37.)
4	Select **<OK>** to delete the chemistry. OR Select **<Cancel>** to return to the User-Defined Chemistries screen without deleting the chemistry.
5	Remove the reagent cartridge from the reagent carousel.

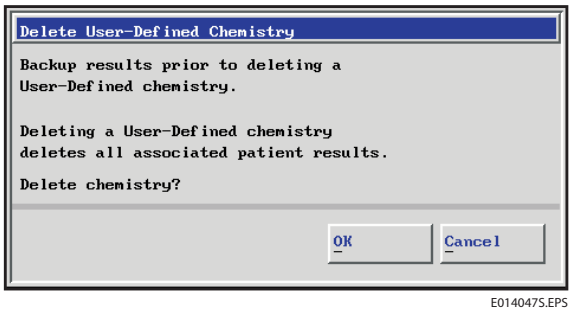

Figure 5.37 Delete User-Defined Chemistry Dialog Box

Editing UDR Definitions

Introduction

A previously defined UDR definition may be recalled and edited. Editing the sample dilution and/or AGXS Limit of a defined UDR clears the calibration programs for the UDR. Editing Comments, the Cartridge Serial Number and/or refilling a cartridge will not affect calibration. Editing anything else clears the calibration programs, cancels the calibration, clears the AGXS Limit, and disables AGXS flagging. The edited UDR definition is saved with the same chemistry name. Refer to Table 5.11 for further information.

Table 5.11 UDR Editing Function

Editing Function	Calibration Rack	Calibration Status	Curve-Fit Model
Clears calibration programs	Cleared	Calibrated	Cannot Change
Clears calibration programs and Cancels the calibration	Cleared	Uncalibrated	Cannot Change

Editing a UDR Definition

The units and chemistry name of the UDR cannot be changed unless the UDR is first removed from the chemistry menu.

The instrument status must be in *Standby* in order to proceed with the steps below to edit a UDR definition.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	Select a number beside a defined UDR position. (Refer to Figure 5.29.)
3	Select **Define/Edit [F1]**.
4	Refer to Defining a UDR Chemistry to edit the UDR definition and calibration information. NOTICE Editing the sample dilution or AGXS Limit of a defined UDR clears the calibration programs for that UDR. Editing Comments, Cartridge Serial and/or Refill numbers does not affect calibration. Editing anything else clears the calibration programs, cancels the calibration, clears the AGXS Limit and disables AGXS flagging. If the serial number is changed in the protocol definition, the cartridge identified by the overwritten serial number is no longer usable, regardless of the number of tests remaining.

Editing a UDR Definition is summarized in Table 5.12 below.

Table 5.12 Editing a UDR Definition

Edited UDR Definition	Effect on Calibration	Effect on AGXS Flagging
Comments Serial Number Refill Cartridge	No Effect Status: Calibrated	No Effect
Sample Dilution AGXS Limit	Clears Program Status: Calibrated	No Effect
All Other Parameters	Clears Program Cancels Calibration Status: Uncalibrated	Clears AGXS Limit Disable Flagging

Loading UDR Reagent Cartridges

Introduction

The UDR reagent cartridges must be loaded before performing a run.

Description of Cartridge

The UDR cartridge provided by Beckman Coulter contains the following information:

- Cartridge lot number
- Cartridge serial number.

Limits

- Twelve cartridges may be loaded in the reagents carousel at one time.
- Each UDR cartridge has a set number of 300 tests. When the 300 tests count down to zero, a new UDR serial number and/or cartridge lot number must be defined and loaded.
- When the cartridge is level sensed as empty, but more tests are available on the Reagent/Calibration Status screen, the UDR cartridge may be refilled and reused until the tests remaining is zero.

Loading UDR Cartridges

Follow the instructions in CHAPTER 6, *Reagents/Calibration*, Loading/Unloading Reagent Cartridges, "Loading Reagent Cartridges."

Refilling UDR Cartridges

A UDR can be programmed to run a maximum of 300 tests. If the cartridge holds less than 300 tests, the cartridge may be refilled to reach the maximum 300 tests. Follow the steps below to refill the UDR cartridge.

Step	Action
1	Go to the **User-Defined Chemistry** screen. (Refer to Figure 5.29.)
2	Select a UDR.
3	Select **Define/Edit [F1]**.
4	Select **<OK>** to close the warning message.
5	Select **Refill [F8]** at the Defined/Edit-User Defined Chemistry screen. (Refer to Figure 5.33.)
6	Select the **Cartridge Serial Number** on the UDR Cartridge Refill screen. (Refer to Figure 5.38.)

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Step	**Action**, continued
7	Select **<Refill>**. The system will update tests remaining in the cartridge to the number of tests defined in the Defined/Edit-User Defined Chemistry screen. OR Select **<Exit>** to return to the Defined/Edit-User Defined Chemistry screen without refilling the cartridge.
8	Refill the cartridge.

(2 of 2)

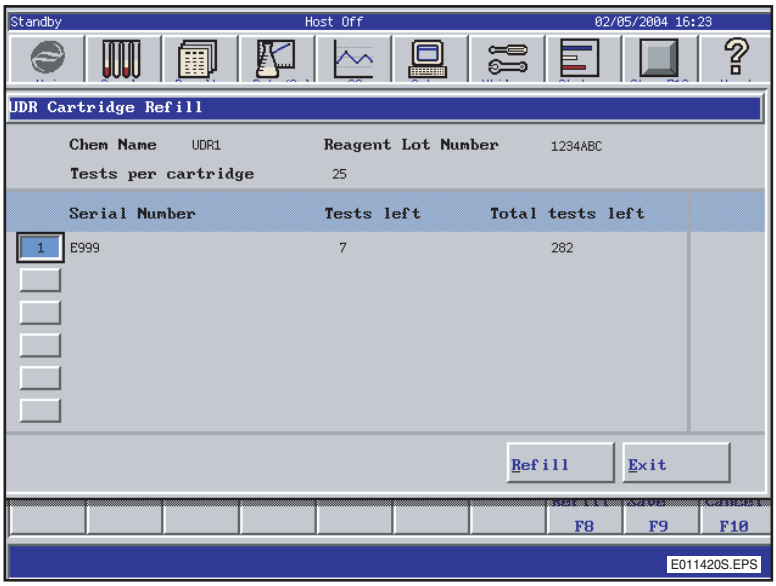

Figure 5.38 UDR Cartridge Refill Screen

The UDR Cartridge Refill screen (Figure 5.38) is defined in Table 5.13:

Table 5.13 UDR Cartridge Refill Screen

Screen Item	Screen Definition
Chem Name	Chemistry Name as defined in Figure 5.33.
Reagent Lot Number	Reagent Lot Number as defined in Figure 5.33.
Tests per cartridge	Tests per cartridge as defined in Figure 5.33.
Serial Number	Cartridge Serial number as defined in Figure 5.33
Tests left	Number of tests remaining from tests per cartridge defined in Figure 5.33.
Total tests left	Number of tests remaining from 300 total tests per cartridge.

Removing UDR Cartridges

Follow the instructions in CHAPTER 6, *Reagents/Calibration*, Loading/Unloading Reagent Cartridges, "Removing Cartridges from The Reagent Carousel."

Loading/Clearing UDR Buffer and Diluent

Introduction

Beckman Coulter IMMAGE 800 buffers and diluents, or user-prepared solutions, may be used as UDR buffer and diluent. However, the UDR buffer and diluent are given a specific name on the sample or reagent carousel. The positions and lot numbers of UDR buffer and diluent must be entered into the computer.

- Up to 4 bottles of UDR buffers may be placed on the inner section of the reagent carousel.
- Up to 4 bottles of UDR sample diluents may be placed on the inner section of the sample carousel.

Checking UDR Buffer/Diluent Status

The instrument status must be in *Standby* in order to proceed with the steps below to check the buffer and diluent status before a run.

Step	Action
1	Select **Reagents/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**. (Refer to Figure 5.39.)
3	Check the **% Remaining** for a sufficient amount to complete a run. • The designation for a UDR buffer is BUF 1-4 and BUF 10-15. BUF 1-4 is designated for system buffer. BUF 10-15 is designated for user-defined buffer. • The designation for a UDR diluent is DIL 1-4 and DIL 10-15. DIL 1-4 is designated for system diluent. DIL 10-15 is designated for user-defined diluent.

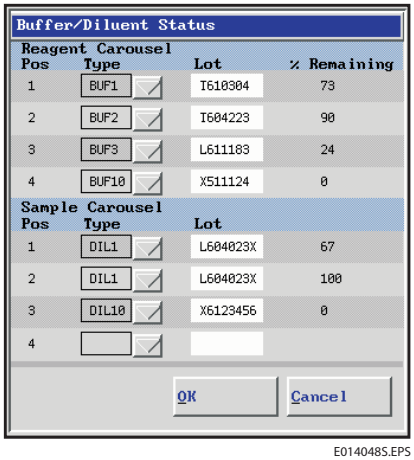

Figure 5.39 Buffer/Diluent Status Dialog Box

Loading a New Lot of UDR Buffer/Diluent or Changing a Position

Follow the instructions in CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Loading A New Lot Or Changing A Position."

Replacing the Same Lot of UDR Buffer/Diluent

Follow the instructions in CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Replacing the Same Lot."

After Loading Buffers and Diluents

NOTICE

Recalibration of affected reagents may be necessary when buffer or diluent lot numbers are changed.

The system assumes that lot numbers and position numbers for buffers or diluents remain the same from run to run until changed by the user.

The **% Remaining** volume on the Buffer/Diluent Status dialog box is updated during a sample run.

Clearing a UDR Buffer/Diluent Position

Refer to CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, "Clearing a Buffer or Diluent Position."

Programming Rate Mode

Introduction

After the UDR chemistry protocol is defined and the chemistry is configured, Rate Mode is used to optimize UDR parameters. After running the UDR chemistry, a report with only instrument responses (IR) is automatically generated. A maximum of six UDRs may be programmed at one time in rate mode. Rate Mode can be run on a calibrated or uncalibrated UDR.

Programming Rate Mode

The instrument status must be in *Standby* in order to proceed with the steps below to program a UDR for rate mode.

Step	Action
1	From the User-Defined Chemistry screen, select **Rate Mode [F3]**. (Refer to Figure 5.40.)
2	Select up to six of the UDR chemistries.
3	Select **<OK>** to continue. Rate Mode may be run on a calibrated or uncalibrated UDR. NOTICE Rate results are always uncalibrated rate, whether the UDR is calibrated or uncalibrated. OR Select **<Cancel>** to exit rate mode and return to the User-Defined Chemistry screen.
4	From the UDR Rate Mode Assign screen (Refer to Figure 5.41.), enter an *available* rack number in the **Rack** field. OR Select **Clear Racks [F1]** and Enter the racks and/or positions to clear. Select **<OK>** to clear or **<Cancel>** to exit without clearing.
5	Enter a position number in the **Pos** field. Up to nine positions may be entered.
6	Enter a Sample ID in the **Sample ID** field for each position assigned. Up to 15 characters may be entered.
7	Select **Save [F9]** to save the program. OR Select **Cancel [F10]** to exit the screen without saving the program.
8	Repeat Steps 1-7 to program additional racks for rate mode.
9	Print a Load List from Sample Programming.
10	Load the samples on the sample carousel.

(1 of 2)

Step	**Action**, continued
11	Select **Main** from the menu bar and **Run**.
12	Select <**OK**> in the Check Dilution Segments dialog box to start the run. OR Select <**Cancel**> to exit without starting the run.

(2 of 2)

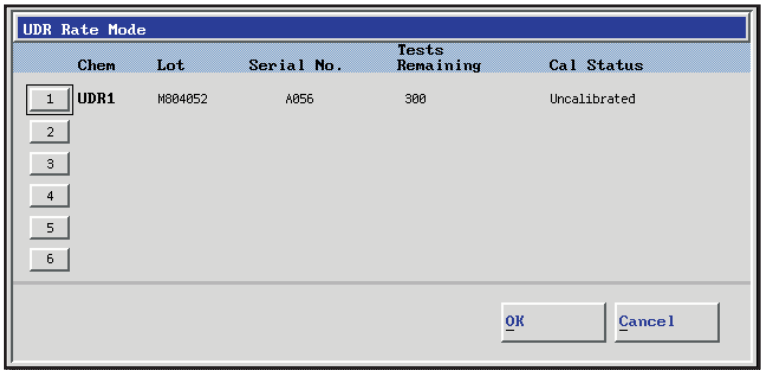

Figure 5.40 UDR Rate Mode Dialog Box

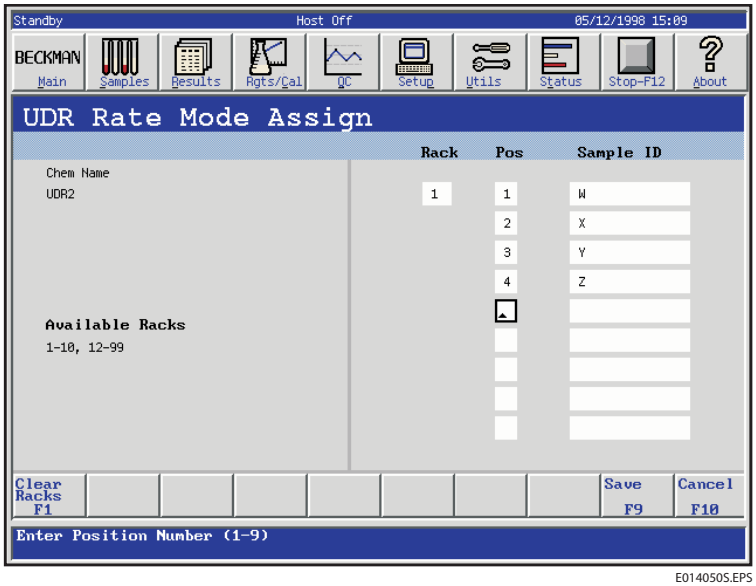

Figure 5.41 UDR Rate Mode Assign Screen

Additional Information

Refer to CHAPTER 7, *Sample Programming*, Clearing a Sample and Requesting a Load List.

Refer to CHAPTER 8, *Results Recall*, Printing Recalled Results to reprint UDR rate mode results.

Refer to APPENDIX B, *Reports* for an example of a Rate Mode report.

Calibrating a UDR Chemistry

Introduction

A UDR can be calibrated by using a multi-point calibration. Subsequently, this calibration may be updated using a single-point update calibration. The UDR chemistry calibration, using a multi-point calibration or single-point update, requires that the protocol definition be completed and the chemistry name configured. The calibration is programmed from the User-Defined Chemistries screen shown in Figure 5.29. The calibrators are run as routine test samples using the defined protocol. A UDR calibration must be on a separate run from samples for that UDR chemistry. The instrument response (IR) for each calibrator replicate is generated.

Once the calibration is approved, the UDR cal status is in *Calibrated* and UDR chemistries can be run with other Beckman Coulter chemistries. Using the UDR calibration data, the system will calculate a final result in the concentration units selected in the protocol.

Programming a UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to program a UDR calibration.

Step	Action
1	From the User-Defined Chemistries screen, select **Request Cal [F4]**. The UDR chemistries on the reagent carousel will be displayed. (Refer to Figure 5.42.)
2	Select up to six UDR chemistries for calibration.
3	Select <**OK**> to continue. OR Select <**Cancel**> to return to the User-Defined Chemistries screen.
4	From the UDR Cal Assign screen, enter an *available* rack number in the **Rack** field. (Refer to Figure 5.43.) OR Select **Clear Racks [F1]** and enter the racks and/or positions to clear. Select <**OK**> to clear or <**Cancel**> to exit without clearing.
5	After a rack number is entered, the position numbers will automatically fill in the **Pos** field according to the levels defined for the chemistry displayed. The calibrators must be programmed in ascending concentration, with Level 1 being the lowest concentration.
6	Enter a Cal ID in the **Cal ID** field (optional). Up to 18 characters may be entered.

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Step	**Action**, continued
7	Select **Save [F9]** or a menu bar icon to save the calibration program for the displayed chemistry. OR Select **Cancel [F10]** to exit the screen without saving any calibration programs.
8	Repeat Steps 4-7 to program additional racks for calibration of other UDR chemistries.

(2 of 2)

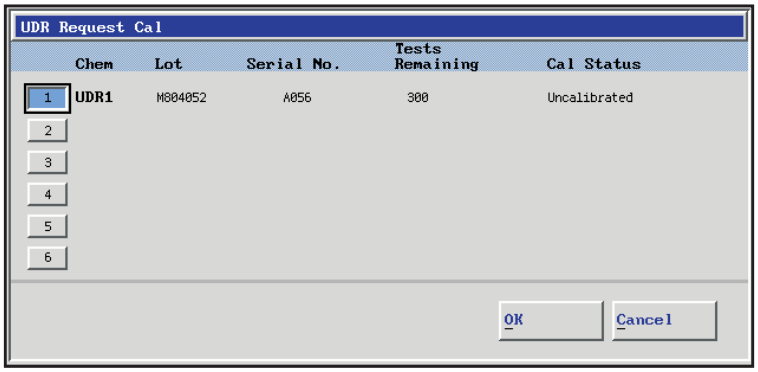


Figure 5.42 UDR Request Cal Dialog Box

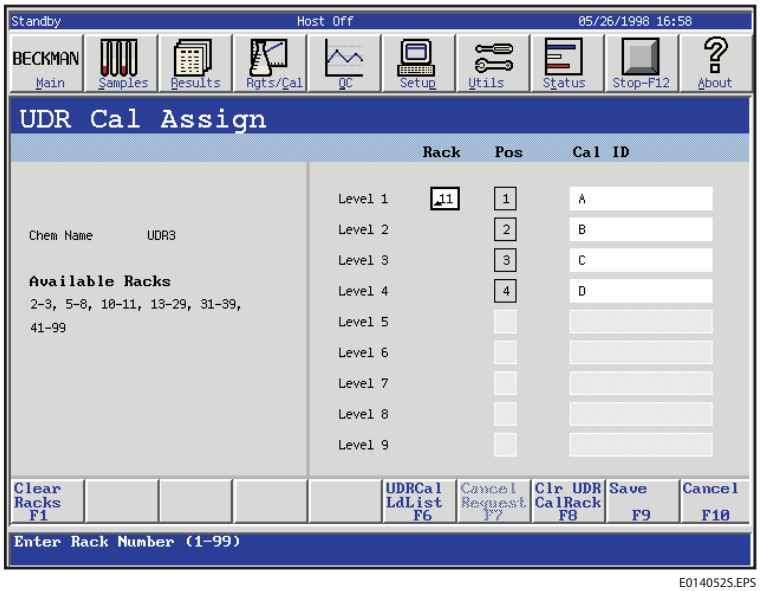


Figure 5.43 UDR Multi-point Cal Assign Screen

Programming a Single-Point UDR Calibration

A single-point calibration update can be performed on a UDR after a multi-point calibration has been performed and approved. This option is not available prior to multi-point calibration. The single-point calibration update result is compared to the multi-point calibration and the system calculates a scale factor. After the update is approved, the scale factor is applied to quality control results and patient results.

The instrument status must be in *Standby* in order to program a single-point UDR calibration. Program a single-point calibration as follows:

Step	Action
1	From the User-Defined Chemistries screen, select **Request Cal [F4]**. (Refer to Figure 5.29.) The UDR chemistries on the reagent carousel will be displayed.
2	Select up to six UDR chemistries for calibration.
3	Select <**OK**> to continue. OR Select <**Cancel**> to return to the User-Defined Chemistries screen.
4	From the UDR Cal Assign screen, select (check) the single-point update box. The predefined update single-point level and the **Cal ID** fields will be enabled. (Refer to Figure 5.44.)
5	From the UDR Cal Assign screen, enter an *available* rack number in the **Rack** field. OR Select **Clear Racks [F1]** and enter the racks and/or positions to clear. Select <**OK**> to clear or <**Cancel**> to exit without clearing.
6	After a rack number is entered, fill in the **Pos** field according to the level defined for the chemistry displayed.
7	Enter a Cal ID in the **Cal ID** field (optional). Up to 18 characters may be entered.
8	Select **Save [F9]** or a menu bar icon to save the calibration program for the displayed chemistry. OR Select **Cancel [F10]** to exit the screen without saving any calibration programs.
9	Repeat Steps 1-7 to program additional racks for calibration of other UDR chemistries.

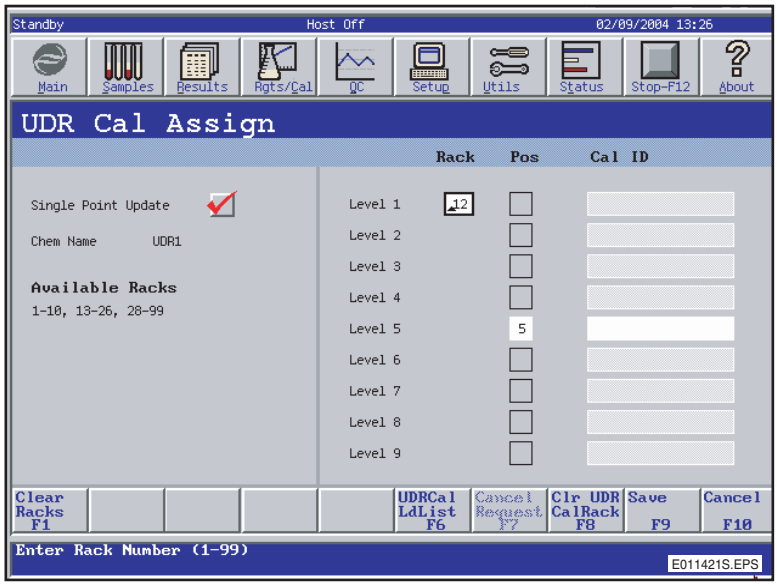


Figure 5.44 UDR Cal Assign Screen

Requesting a UDR Cal Load List

The instrument status must be in *Standby* in order to proceed with the steps below to request a UDR load list.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **UDRCal LdList [F6]**. (Refer to Figure 5.45.)
2	Select **Print [F10]** to print the load list or **UDRCal [F9]** to return to the UDR Cal screen. (Refer to APPENDIX B, *Reports* for an example of a Calibration Load List.)

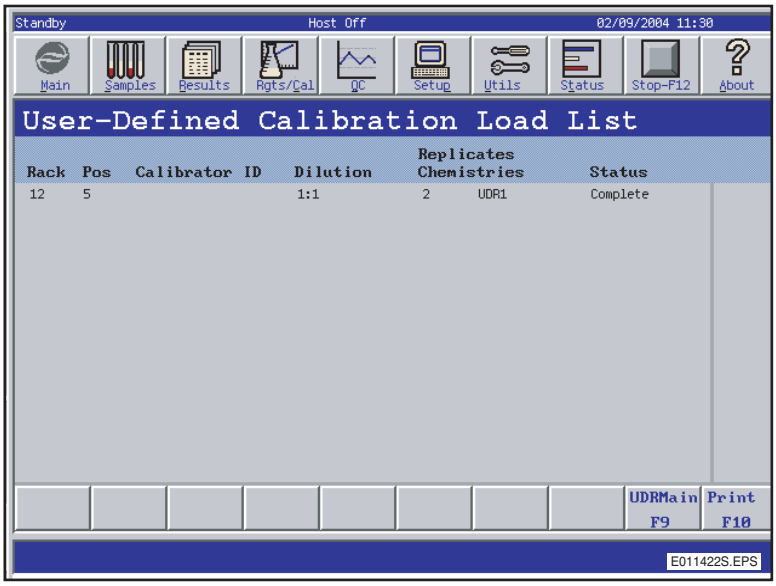


Figure 5.45 User-Defined Calibration Load List Screen

Running the UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to run a UDR calibration.

Step	Action
1	Load the calibration samples in the appropriate racks.
2	Select **Main** from the menu bar and **Run**.
3	Select <**OK**> in the Check Dilution Segments dialog box to start the run. OR Select <**Cancel**> to exit without starting the run.
4	When the calibration run is finished, a multi-point or single-point UDR Calibration Results report is printed. Continue to "Approving a UDR Calibration."

Canceling a UDR Cal Request

The instrument status must be in *Standby* in order to proceed with the steps below to cancel a UDR cal request.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **Cancel Request [F7]**. (Refer to Figure 5.46.)
2	Select the requested chemistries to be canceled.
3	Select <**OK**> to cancel the calibration request. The Cal Status of the canceled chemistries will return to the status prior to the calibration request. OR Select <**Cancel**> to return to the User-Defined Chemistries screen.

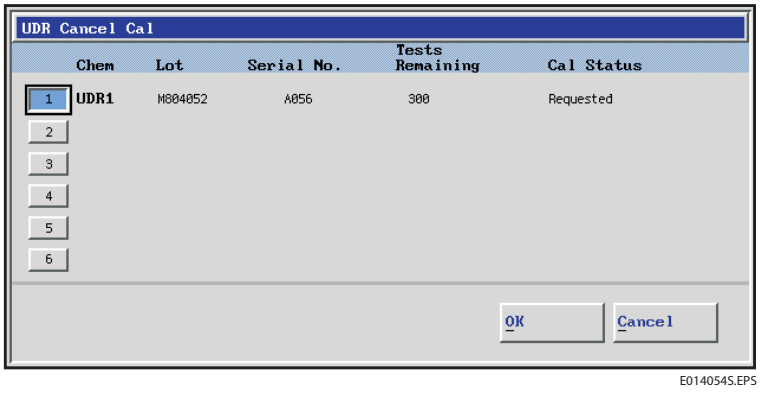


Figure 5.46 UDR Cancel Cal Dialog Box

Clearing a UDR Cal Rack

The instrument status must be in *Standby* in order to proceed with the steps below to clear a UDR Cal rack.

Clearing the rack used for a UDR Single Point Calibration Update before approving it will also clear the previous UDR calibration (Multipoint or Single Point Update). Therefore, if you choose to repeat a Single Point Calibration Update, do it without clearing the current calibration rack.

NOTICE
Do not clear a UDR Cal rack until the final curve-fit model for the calibration has been selected.

Step	Action
1	From either the User-Defined Chemistries screen or the UDR Cal Assign screen, select **Clear UDR Cal Rack [F8]**. (Refer to Figure 5.47.)
2	Enter the racks to clear in the **Rack(s)** field.
3	Select <**OK**> to clear the rack. OR Select <**Cancel**> to exit without clearing. NOTICE Clearing the User-Defined Calibration Rack will clear the rack positions. The calibration results for this rack will be deleted. After clearing the rack, the calibration results cannot be displayed with the current model, with a different model, or be printed.

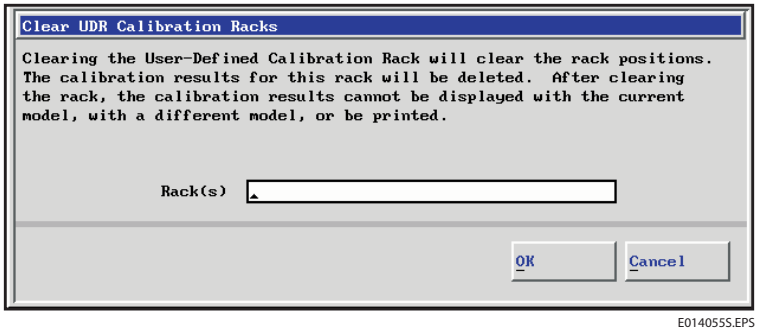


Figure 5.47 Clear UDR Calibration Racks Dialog Box

Approving a Calibration

Introduction

After the calibration run, the instrument response (IR) for each calibrator replicate is generated. The IR versus calibrator set point concentration, as well as curve-fit, is displayed as a plot using various curve-fit models. The calibration model can be selected for the UDR. The model and associated calibration parameters are saved for the reagent lot numbers defined for this UDR, or until another calibration is requested.

The four models available are First Order Polynomial, Second Order Polynomial, Third Order Polynomial, and Four Parameter Logistic.

Curve-Fit Model Descriptions

The following table describes the four curve-fit models. Refer to Figure 5.48 to Figure 5.54.

Table 5.14 Curve-fit Models

Model	Minimum number of calibrator levels to plot graph	Formula	Parameter Displayed
First Order Polynomial	4	$y = A + Bx$ A011363L.EPS	A B
Second Order Polynomial	5	$y = A + Bx + Cx^2$ A011364L.EPS	A B C
Third Order Polynomial	6	$y = A + Bx + Cx^2 + Dx^3$ A011365L.EPS	A B C D
Four Parameter Logistic	6	$y = \frac{A - D}{1 + \left[\frac{x}{C}\right]^B} + D$ A011366L.EPS	A B C D

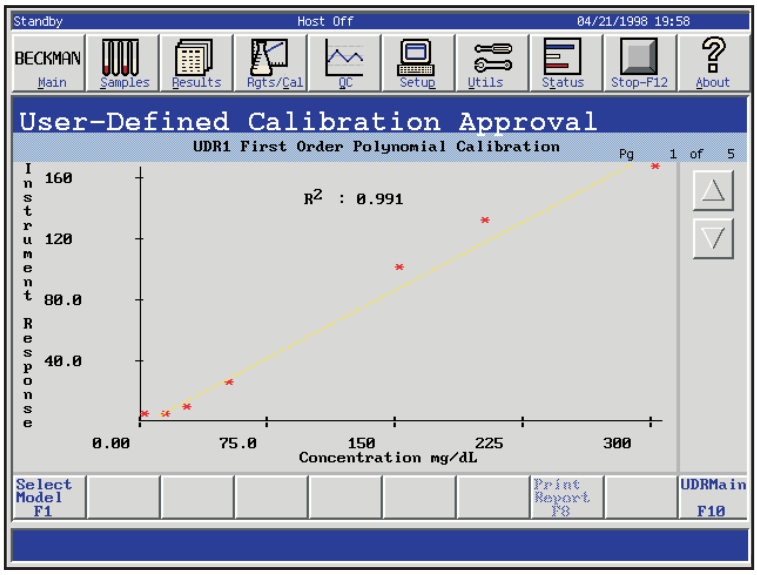


Figure 5.48 Example of First Order Polynomial Calibration

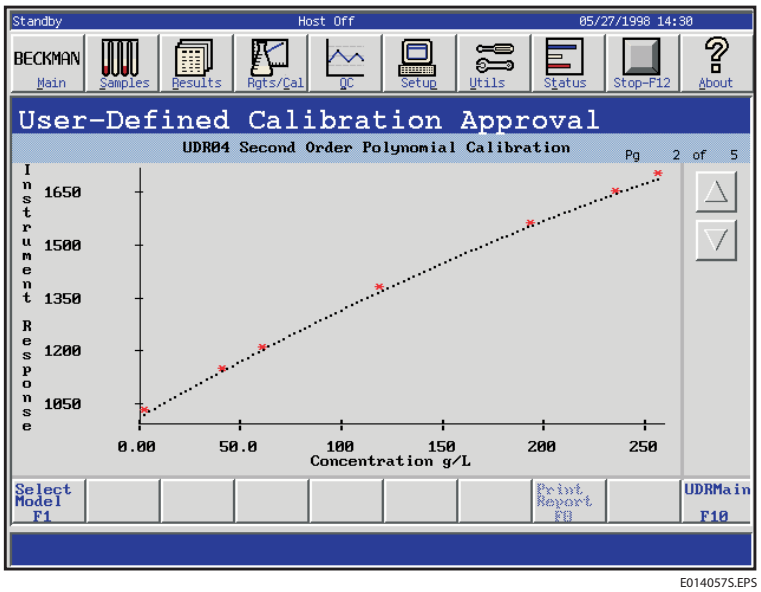


Figure 5.49 Example of Second Order Polynomial Calibration

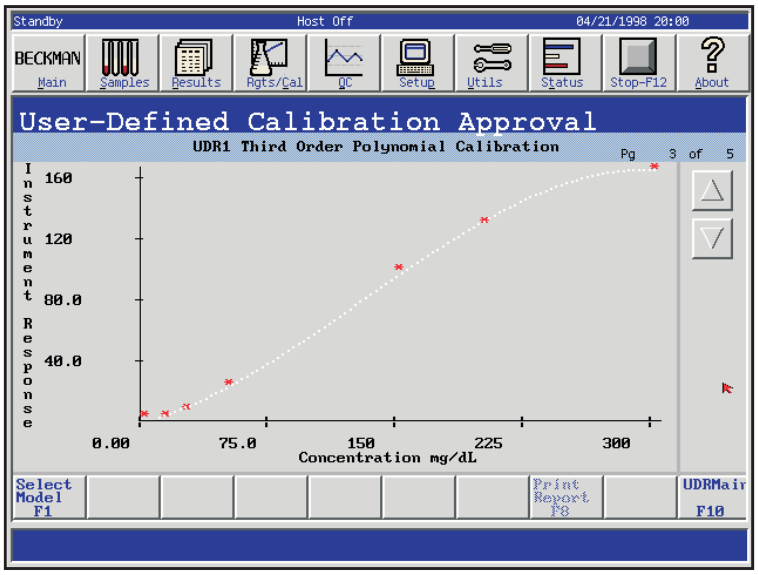


Figure 5.50 Example of Third Order Polynomial Calibration

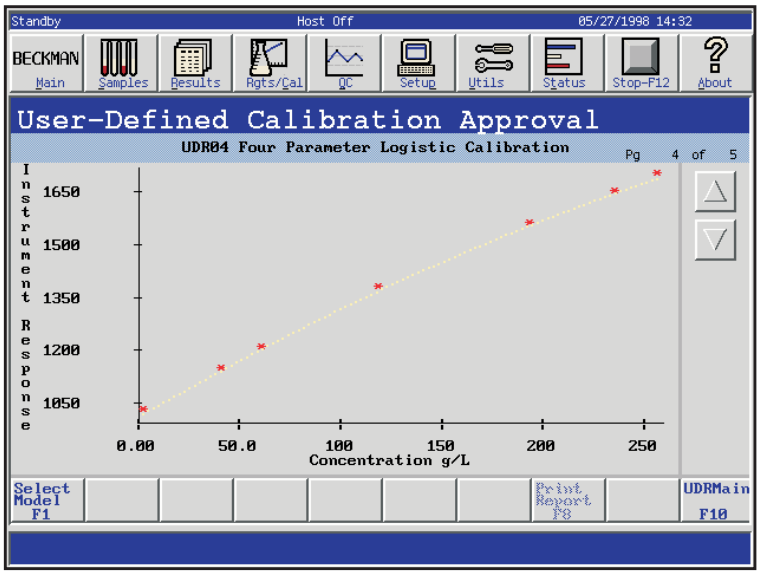


Figure 5.51 Example of Four Parameter Logistic Calibration

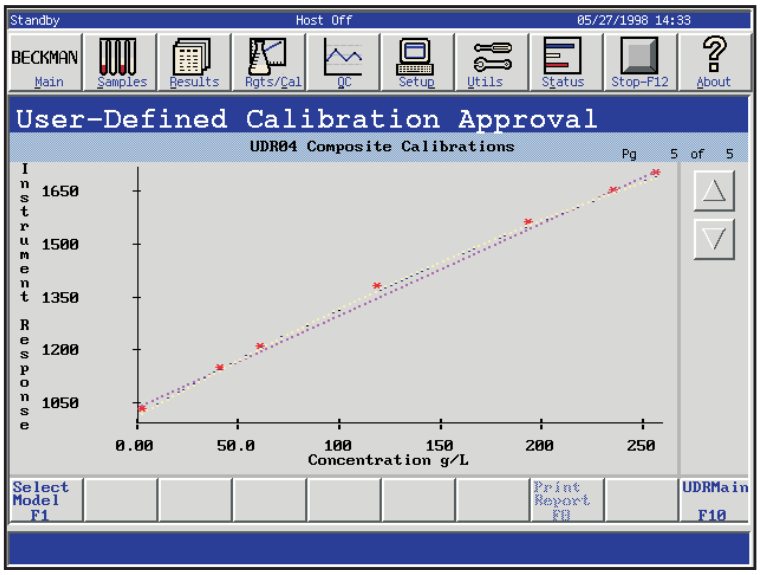


Figure 5.52 Example of Composite Calibration

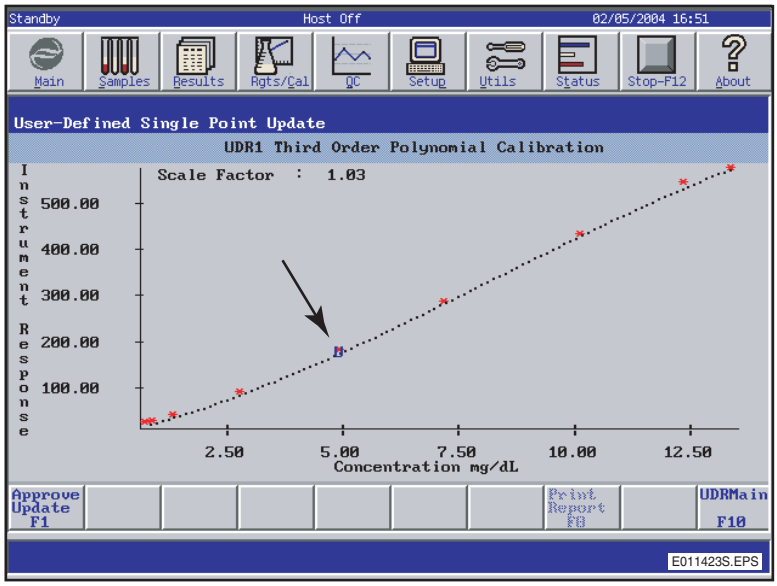


Figure 5.53 User-Defined Single-Point Update Screen

Plot Descriptions

The following table describes the plots.

Table 5.15 Plot Descriptions

Part	Description
X-axis	Calibrator setpoint concentrations and units defined by the protocol.
Y-axis	Instrument responses (IR) for each calibrator replicate.
Asterisks (*)	Each calibration data point.
Dotted line (.)	Calibration curve.
Letter U	Single-point update level.

Approving a UDR Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to approve a UDR calibration model.

The Multi-Point UDR Calibration Result report must show at least one instrument response (IR) for each calibrator level. If not, the entire calibration run must be repeated. The exception to rerunning the entire calibration occurs when one of the calibrator levels has a status of *Incomplete*. The incomplete sample may be rerun as part of the same calibration rack and its results added to the rest of the calibration data.

NOTICE

A Calibration for a UDR reagent may be approved with the status of "Incomplete" for some of the calibrator samples. This calibration will include only the completed replicates for each calibrator level. The incomplete replicates will be completed in a subsequent run if the calibration rack has not been cleared or removed from the system. These calibration replicates will be performed using the sample dilution defined for the UDR.

NOTICE

At the end of this run the UDR reagent will again have a status of "Unapproved" and require approval to return to "Calibrated". This calibration will now include all the completed replicates from both runs. If the calibration dilution and sample dilution are not the same, these replicates could be significantly different. In this case it is recommended that UDR calibration racks with incomplete replicates be removed from the system following calibration approval.

Step	Action
1	From the User-Defined Chemistries screen, select **Approve Cal [F5]**.
2	Use **<Page Up>** or **<Page Down>** to review the plots of the models for the calibration. The last page has a composite plot of all the models.
3	To print a curve-fit model plot, press **[Ctrl, P]** on the keyboard.
4	Select **Model [F1]** to display the curve-fit model options. (Refer to Figure 5.54.)
5	Select the number beside the model desired and select **<OK>** to approve the UDR calibration. OR Select **<Cancel>** to exit the User-Defined Model dialog box.
6	Select **Print Report [F8]** to print the data and statistics for a curve-fit model.
7	Program controls on the UDR through Sample Programming to see if they are acceptable with the chosen calibration model before clearing the UDR cal rack. To test another model with controls, repeat Steps 1-7.
8	When the final calibration model has been selected, clear the UDR calibration rack. Refer to "Clearing a UDR Cal Rack" in this chapter.

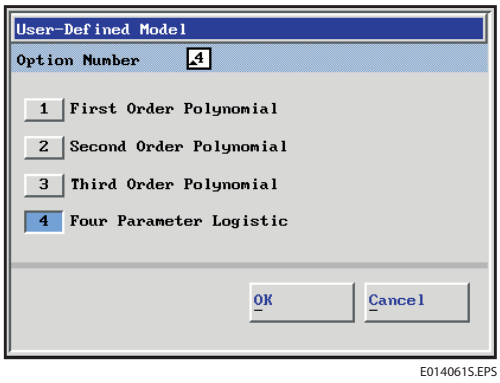


Figure 5.54 User-Defined Model Dialog Box

Approving a Single-Point UDR Calibration

The instrument status must be in *Standby* to proceed with the steps below to approve a UDR calibration model.

The single-point UDR Calibration Result report must show at least one instrument response (IR) for the single-point calibrator level. If not, a calibration run must be repeated.

Step	Action
1	From the User-Defined Chemistries screen (Figure 5.29), select the UDR chemistry and **Approve Cal [F5]**. NOTICE If a single-point calibration is approved with a scale factor that is not within the range (0.6667 - 2.0), the sample run will produce no concentration results. In this case, first rerun the single-point calibration. If the results are the same, run a multi-point calibration. Target instrument response +/- 50% for calibration update level.
2	Select **Approve Update [F1]** to approve the scale factor. (Refer to Figure 5.53). The only curve-fit model available is the approved multi-point calibrated curve-fit model. Note: The letter 'U' appears on the plot at the update level. A scale factor is also displayed on the plot window. (Refer to Figure 5.53.) NOTICE After programming and saving, a single-point calibration request, the curve-fit model cannot be changed. Each single-point calibration can only use the model from the last approved mult-point calibration. If the update level (letter U) does not appear on the plot window, the single-point calibration is not reliable. Repeat the single-point calibration. If the results are the same, perform a multi-point calibration.
3	To print a curve-fit model plot, press **[Ctrl, P]** on the keyboard.
4	Select **Print Report [F8]** to print the data and statistics for a curve-fit model.
5	Select **UDR Main [F10]** to return to the User-Defined Chemistries screen.
6	Program controls on the UDR through Sample Programming to see if the single-point calibration is acceptable. Another model cannot be tested.
7	When the calibration model has been approved, clear the UDR calibration rack. Refer to "Clearing a UDR Cal Rack" in this chapter.

Plotting a Robust Means Data Curve

The Robust Means Data Curve plots a Robust Means/Time curve for reagent development purposes. A Robust Means Data Curve may be plotted for UDR rate and calibration runs only. When a Plot Robust Means Data is requested, the number of actual replicates run by the instrument is displayed within the parentheses next to the Replicates box. This will include accepted and rejected replicates. For further details, refer to Programming Rate Mode and Calibrating a UDR Chemistry in this chapter. Refer to the following steps to plot a Robust Means Data Curve.

Step	Action
1	Go to the User-Defined Chemistries screen and select a UDR chemistry. (Refer to Figure 5.29.)
2	Select **Print Plot (F10)**. A User-Defined Reports screen appears. (Refer to Figure 5.55.)
3	From the User Defined Reports screen, select option **<6> Plot Robust Means Data Curve** and **<OK>**. The Plot Robust Means Data Curve window appears as shown in Figure 5.56. OR Select **<Cancel>** to return to the User-Defined Chemistries screen.
4	From the Plot Robust Means Data Curve window, enter the rack number, position number, and replicate number. Select **Plot** to plot the curve. A typical Robust Means Data Curve is shown in Figure 5.57. OR Select **<Exit>** to return to the previous screen.

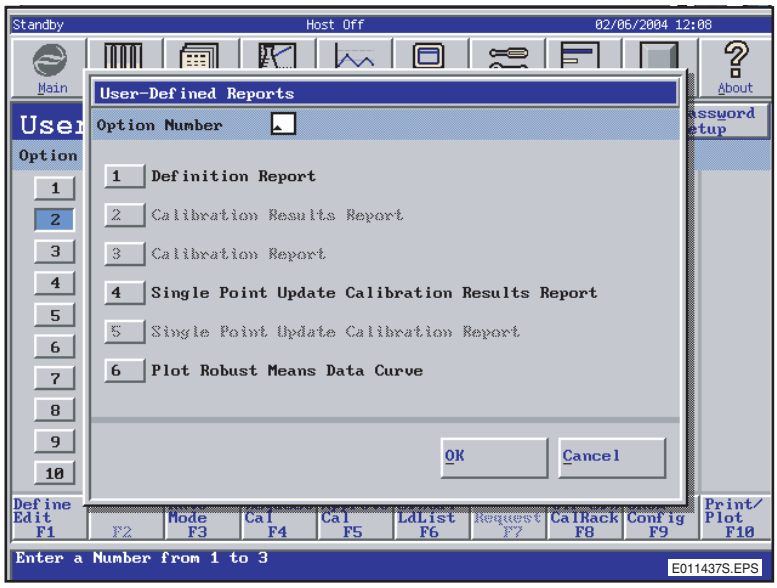


Figure 5.55 User-Defined Reports Screen

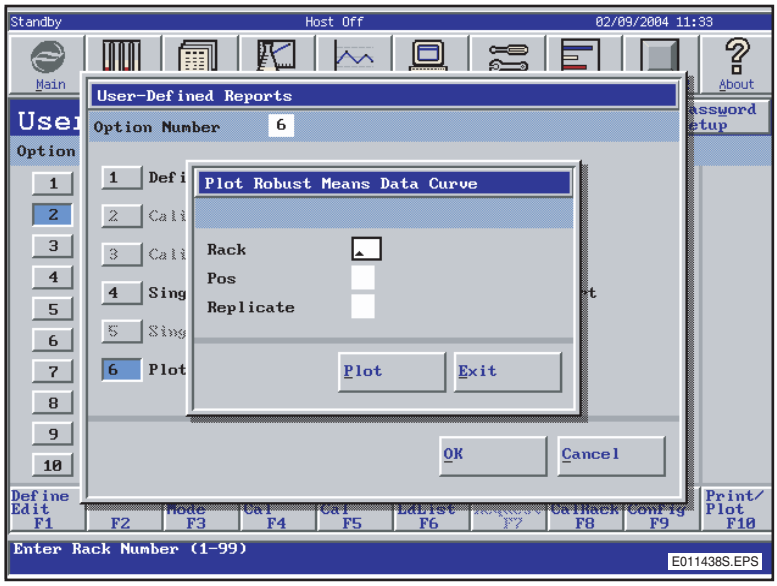


Figure 5.56 Plot Robust Means Data Curve Window

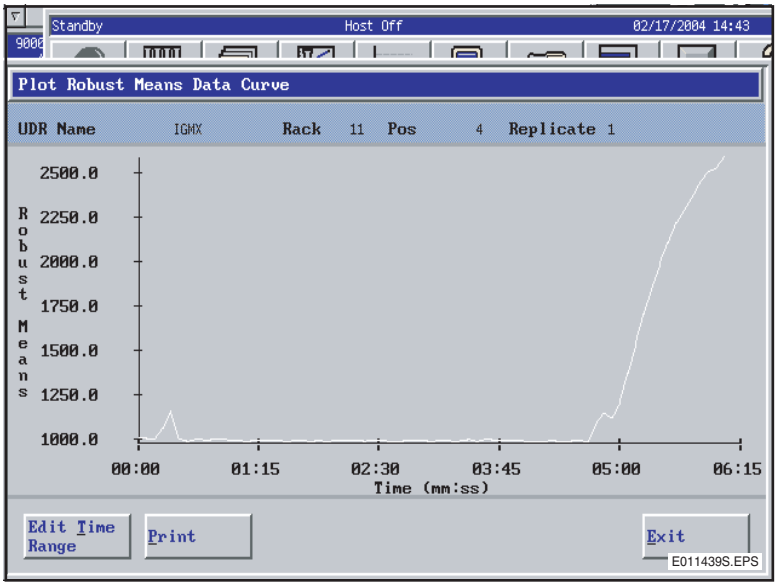


Figure 5.57 Plot Robust Means Data Curve

Editing the Time Range on a Robust Means Data Curve

The time range can be edited on a Robust Means Data curve in order to focus on a particular area of the curve. Perform the following steps to edit the time range.

Step	Action
1	Refer to Figure 5.57 and select **Edit Time Range** on the Robust Means Data Curve. A Time Range window appears as shown on Figure 5.58.
2	Enter the new starting time and ending time in the Time Range window. The new starting/ending times must be within the original time range as shown on the initial data curve.
3	A new Time Range screen appears that shows the edited times. Select <**OK**> to plot the new curve, and proceed to Step 4. OR Select **Default** to return to the original curve and time range. OR Select <**Cancel**> to return to the previous screen.
4	Select <**Exit**> to return to the Plot Robust Means Data Curve screen (Figure 5.56). OR Select <**Edit Time Range**> again and repeat this procedure. OR Select <**Print**> to print the the Plot Robust Means Data Report. OR Select **[Ctrl, P]** on the keyboard to print the Plot Robust Means Data Curve.

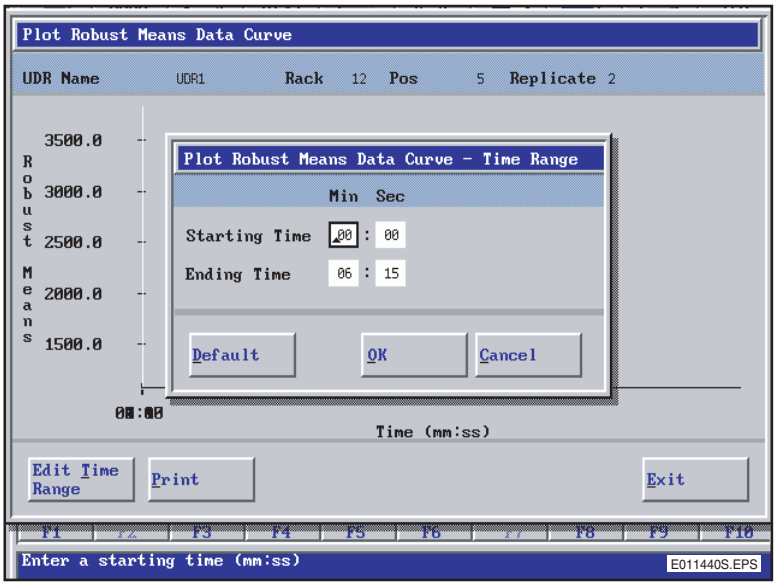


Figure 5.58 Plot Robust Means Data Curve - Time Range Window

Printing UDR Reports

Description of UDR Reports

The following table describes the UDR report options. Refer to APPENDIX B, *Reports* for examples of the UDR Reports.

Table 5.16 UDR Reports

Report	Description
Definition Report	Identifies UDR chemistry definition protocol and calibration information.
Calibration Results Report	Identifies UDR instrument response results per replicate of each UDR calibrator for the selected chemistry.
Calibration Report	Identifies UDR mean instrument responses per replicate of each UDR calibrator for the selected chemistry, the curve-fit model, and associated parameters. A calibration report can be printed once a UDR chemistry is defined and before a calibration is requested. The printed report will be blank.
Single-Point Update Calibration Results Report	Identifies UDR instrument response results per replicate of single-point update calibrator for the selected chemistry.
Single-Point Update Calibration Report	Identifies UDR mean instrument responses per replicate of single-point update calibrator for the selected chemistry, the curve-fit model, associated parameters, and scale factor.
Plot Robust Means Data Report	Identifies UDR robust means data for a single replicate of a selected UDR calibrator or rate mode report.
Rate Mode Results	Identifies UDR instrument responses per replicate of each UDR sample for the selected chemistry.
Patient Results	Identifies UDR concentrations per replicate of patient sample programmed.

Printing UDR Reports

The instrument status must be in *Standby* in order to proceed with the steps below to print UDR reports.

Step	Action
1	From the Setup screen, select **<18> User-Defined Chemistries**.
2	From the User-Defined Chemistries screen, choose one of the defined UDR positions.
3	Select **Print/Plot [F10]** to display the report options.
4	Select the number beside the report desired.
5	Select **<OK>** to print the report. OR Select **<Cancel>** to return to the User-Defined Chemistry screen.

Printing UDR Rate Mode and Patient Results

Follow the instructions in CHAPTER 8, *Results Recall*, Printing Recalled Results to reprint UDR rate mode and patient results.

Setting Up UDR Reference Intervals and Panels

UDR Reference Interval and Panel Setup

UDR reference intervals and panels are defined like other Beckman Coulter chemistries from the Reference Interval Setup and Panel Setup screens. (Refer to Reference Interval Setup, "Defining/Editing Intervals and Ranges" and Panel Setup, "Defining New Panels" in this chapter.)

Defining UDR Quality Control

UDR Quality Control Definition

UDR quality controls are defined like other Beckman Coulter chemistries from the Quality Control screen. (Refer to CHAPTER 9, *Quality Control*, Defining a Control.)

Programming a UDR Sample

UDR Programming Reference

The UDR chemistry is programmed like an other Beckman Coulter chemistry from the Program Sample screen except that AGXS check cannot be chosen. (Refer to CHAPTER 7, *Sample Programming*.)

Instrument Setup

Overview

Introduction

Some parts of the instrument hardware require a one-time setup prior to a sample run.

This section explains:

- Rack bar code label placement
- Wash solution box placement
- Waste container placement

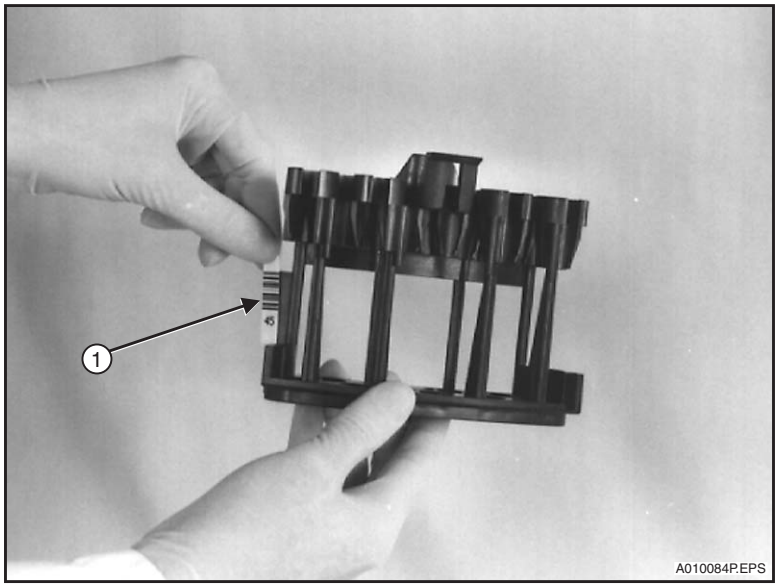
Placing Labels on a Rack

Introduction

Two labels must be placed on each rack. The labels identify the rack number. One label is bar coded, the other label is a numbered label.

Placing the Bar Coded Label on the Rack

Place the bar coded rack label on the side of the rack as pictured in Figure 5.59.

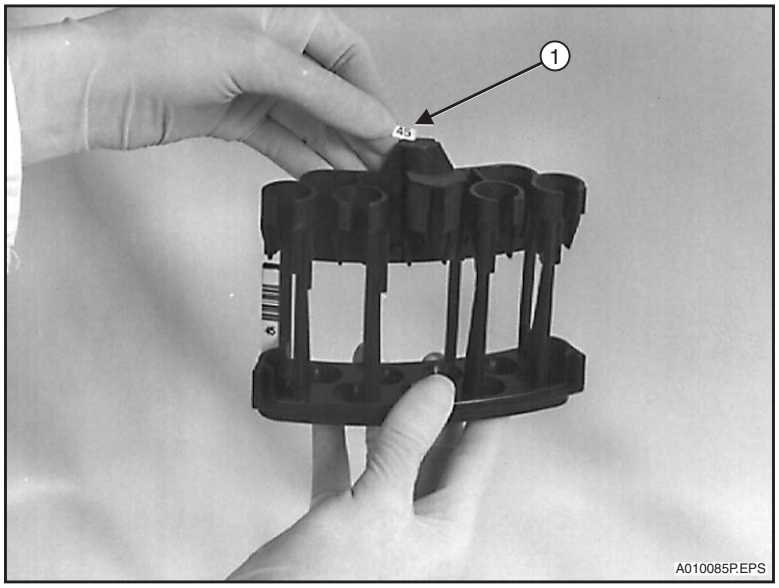


1. Rack bar code label

Figure 5.59 Rack Bar Code Label Placement

Placing the Rack Number Label on the Rack

Place the rack number label on the top of the rack as pictured in Figure 5.60.



1. Rack number label

Figure 5.60 Rack Number Label Placement

Wash Solution Box and Waste Container Placement

Introduction

The wash solution box and waste container are placed by the instrument in specific locations.

Wash Solution Box Placement

The wash solution box is placed close enough to the instrument to allow connection of the wash solution tube.

Waste Container Placement

The waste container must be placed with the opening of the waste container no higher than the top of the instrument.

CHAPTER 6 Reagents/Calibration

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Reagents

Overview

Introduction

This section explains:

- Reagent Status/Calibration Status Screen
- Loading Reagent/Calibrator Bar Coded Parameters
- Displaying/Deleting Reagent Parameters
- Loading/Clearing Buffers and Diluents
- Loading Wash Solution
- Loading/Unloading Reagent Cartridges

Reagent Status/Calibration Status Screen

Displaying the Screen

Select **Rgts/Cal** from the menu bar. (Refer to Figure 6.1.)

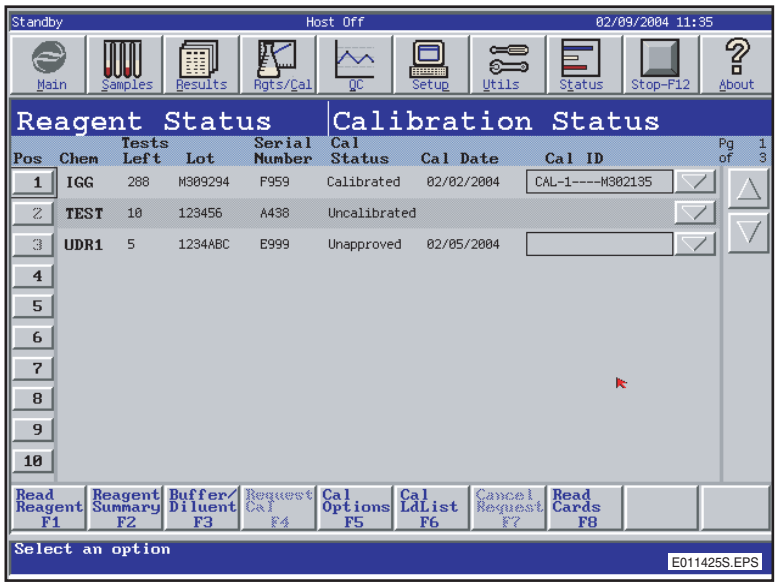

Figure 6.1 Reagent Status/Calibration Status Screen

Screen Headings Description

The following table describes the headings of the Reagent Status/Calibration Status screen for Beckman Coulter chemistries.

Table 6.1 Screen Headings

Heading	Description
Pos	Position of the reagent cartridge on the reagent carousel
Chem	Name of chemistry
Tests Left	Number of tests remaining in the reagent cartridge
Lot	Lot number of the reagent
Serial Number	Serial number of the reagent cartridge
Cal Status	Current calibration status of the reagent cartridge
Cal date	Date of calibration
Cal ID	Name of calibrator
Options button < ▼ > beside the Cal ID	Calibrator information

Function Button Description

The following table describes the function buttons at the bottom of the Reagent Status/ Calibration Status screen.

Table 6.2 Function Buttons

Name	Button	Function
Read Reagent	**[F1]**	Reads the bar coded label on the reagent cartridges that are loaded on the reagent carousel.
Reagent Summary	**[F2]**	Lists the chemistry name, reagent lot, reagent expiration date, calibration status, calibration date, and calibrator lot for all reagents which have had bar code parameters loaded into the database.
Buffer/Diluent	**[F3]**	Allows set up of buffer or diluent positions on reagent or sample carousel. Displays the **% Remaining** volume of buffer or diluent.
Request Cal	**[F4]**	Requests calibration of selected chemistries.
Cal Options	**[F5]**	Allows the selection of one of the following options: • Calibrator Summary • Slope and Offset Adjustments
Cal LdList	**[F6]**	Displays a load list of requested calibrations.
Cancel Request	**[F7]**	Cancels a calibration after it has been requested.
Read Cards	**[F8]**	Reads reagent or calibrator bar code cards when cards are placed on the sample carousel racks.

Loading Reagent/Calibrator Bar Coded Parameters

Introduction

- A reagent bar code card is provided with every reagent kit. The reagent bar code card contains lot specific parameters for each reagent.
- A calibrator bar code card is provided with every calibrator. The calibrator bar code card contains lot specific parameters for each calibrator.

When to Load

Prior to reagent calibration, the reagent and calibrator bar code cards must be scanned into the database. If a reagent or calibrator lot was previously used, the bar code card does not need to be rescanned.

Limits

- Up to 8 reagent or calibrator bar code cards can be loaded on the sample carousel at one time.
- Up to 6 different lots of the same reagent or calibrator ID can be stored at one time. When more than 6 different lots are scanned, the oldest, by date of scan, is removed from the database.
- Up to 50 different calibrator names can be stored in the database.

Loading Bar Code Cards

The instrument status must be in *Standby* in order to proceed with the steps below to load reagent and calibrator bar code cards.

Step	Action
1	Place the reagent or calibrator bar code card(s) on an EMPTY rack(s). (Refer to Figure 6.2.)
2	Open the sample compartment cover. Rotate the sample carousel by pressing the advance button on the instrument.
3	Place the rack(s) on the sample carousel.
4	Close the sample compartment cover.
5	Select **Rgts/Cal** from the menu bar.
6	Select **Read Cards [F8]**.
7	Select <**OK**> to start the bar code read and go to Step 8. OR Select <**Cancel**> to return to the Reagent Status/Calibration Status screen without reading the bar code cards.

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>8</td><td>
<table>
<tr><th>If the bar code card is..</th><th>the screen will display...</th></tr>
<tr><td>successfully read</td><td>the Rack, reagent/calibrator Name, and Lot for each scanned bar code card in the Cards Read window.</td></tr>
<tr><td>misread</td><td>an error message appears with the rack and position where the bar code was misread. (Refer to CHAPTER 10, Utilities, Troubleshooting.)</td></tr>
</table>
</td></tr>
<tr><td>9</td><td>To exit the Cards Read dialog box, even if the bar code read is not finished, select <OK>.</td></tr>
</table>

(2 of 2)

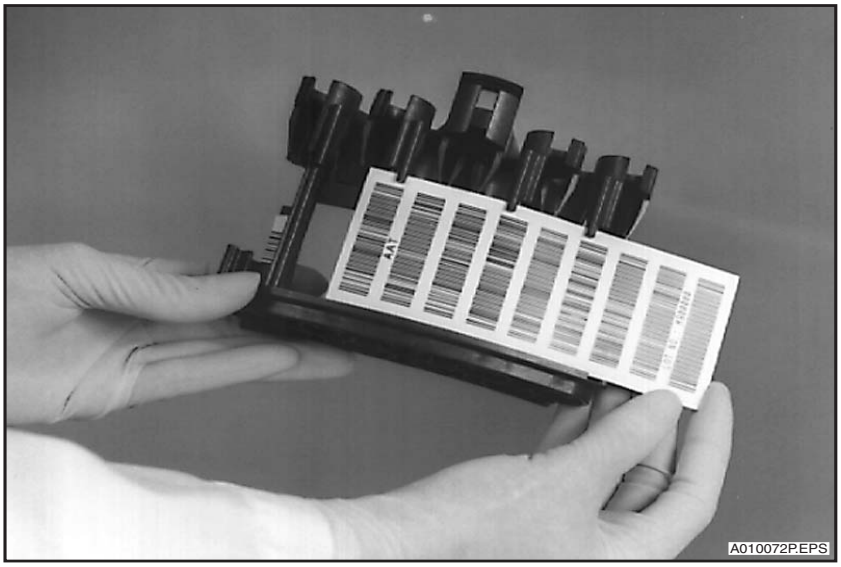

Figure 6.2 Loading Reagent/Calibrator Bar Code Cards on a Rack

Displaying/Deleting Reagent Parameters

Introduction

Reagent parameters may be displayed and/or deleted from the Reagent Summary.

Displaying Reagent Parameters

The instrument status must be in *Standby* in order to proceed with the steps below to display reagent parameters.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Reagent Summary [F2]**. (Refer to Figure 6.3.)
3	Select a button beside the Chem lot to be displayed. THEN Select the <**Display**> button to view the reagent lot parameters. OR Select <**Go To**> and type the Chem and Lot number.
4	Select <**OK**> from the Reagent Lot Parameters dialog box when finished viewing the reagent lot parameters.

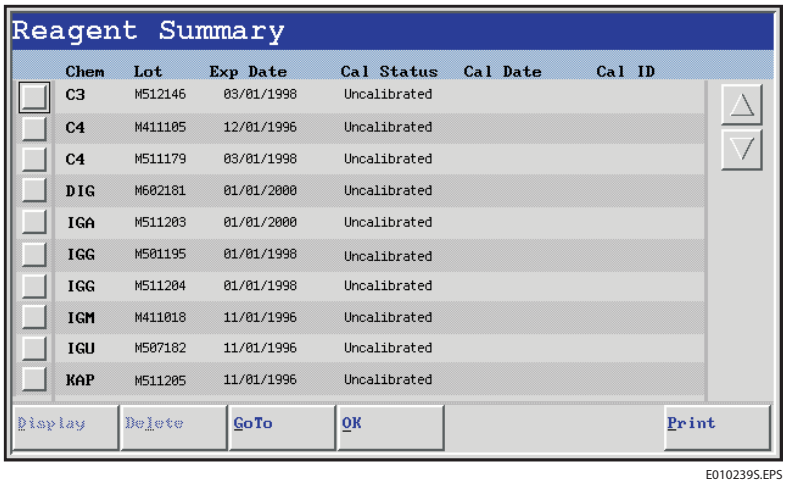

Figure 6.3 Reagent Summary Dialog Box

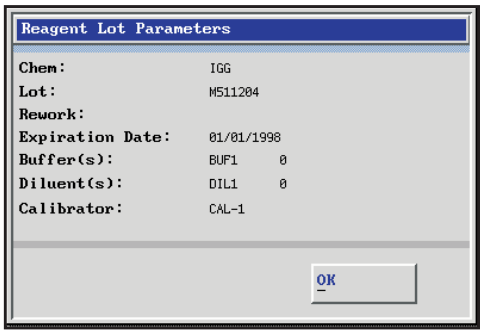

Figure 6.4 Reagent Lot Parameters Dialog Box

Deleting Reagent Parameters

The instrument status must be in *Standby* in order to proceed with the steps below to delete reagent parameters.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Reagent Summary [F2]**. (Refer to Figure 6.3.)
3	Select a button beside the Chem lot to be deleted. OR Select **<Go To>** and type the Chem and Lot number.
4	Select **<Delete>**.
5	Select **<OK>** from the Delete Reagent Lot Confirmation dialog box to delete the parameters. OR Select **<Cancel>** to return to the Reagent Summary dialog box without deleting parameters.

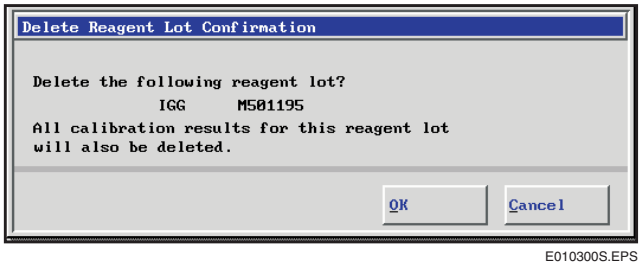

Figure 6.5 Delete Reagent Lot Confirmation Dialog Box

Loading/Clearing Buffers and Diluents

Introduction

Reaction buffers and sample diluents must be placed on the IMMAGE 800 and their positions and lot numbers must be entered into the computer.

- Up to 4 bottles of reaction buffer may be placed on the inner section of the reagent carousel.
- Up to 4 bottles of sample diluent may be placed on the inner section of the sample carousel.
- For certain chemistries, a buffer is used as sample diluent and is placed on the inner section of the sample carousel.

Limits

- Only one lot number of each buffer type and one lot number of each diluent type may be loaded onto the system at one time.
- Multiple bottles of the same lot can be loaded at different positions.
- When multiple positions are defined for the same buffer or diluent, the lot number will be automatically copied to each position.

Checking Buffer/Diluent Status

The instrument status must be in *Standby* in order to proceed with the steps below to check the buffer and diluent status before a run.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**. (Refer to Figure 6.6.)
3	Check the **% Remaining** for a sufficient amount to complete a run. Approximately 350 tests per bottle of reaction buffer.

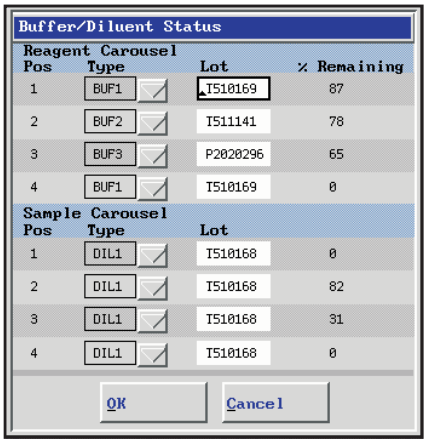

Figure 6.6 Buffer/Diluent Status Dialog Box

Loading a New Lot or Changing a Position

The instrument status must be in *Standby* in order to proceed with the steps below to change the lot or position of a buffer or diluent.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**. (Refer to Figure 6.6.)
3	Select the options button < ▼ > beside the desired position.
4	Select the desired buffer or diluent to place in the position. Press <**OK**>. OR Select <**Cancel**> to return to the Reagents Status/Calibration Status screen without selecting a buffer or diluent.
5	Enter the buffer or diluent lot number.
6	Repeat steps 3-5 for each buffer and diluent to be loaded.
7	Select <**OK**> to accept any changes made. OR Select <**Cancel**> to return to the Reagent Status/Calibration Status screen without entering any changes.
8	Follow "Replacing the Same Lot," in this section, to place bottles on the carousel(s). NOTICE Recalibration of affected chemistries may be necessary when buffer or diluent lots are changed.

Replacing the Same Lot

The instrument status must be in *Standby* in order to proceed with the steps below to replace the same lot of buffer or diluent in the same position.

Step	Action
1	Mix each buffer or diluent bottle by inversion; remove the screw cap.
2	Check each container for bubbles and remove bubbles if present.
3	Place an evaporation cap on each bottle.
4	Open the reagent or sample compartment cover. Rotate the sample carousel by pressing the advance button on the instrument.
5	Place buffer and diluent bottles in their defined positions on the sample or reagent carousel according to the Buffer/Diluent Status dialog box.
6	Close the reagent or sample compartment cover. The IMMAGE 800 retains the lot and position number. The **% Remaining** will be updated when the next run is started.

After Loading Buffers and Diluents

- Recalibration of affected reagents may be necessary when reaction buffer or diluent lots are changed.
- The system assumes that lot numbers and position numbers for buffers or diluents remain the same from run to run until changed by the operator.
- The **% Remaining** volume on the Buffer/Diluent Status dialog box is updated during a sample run.

Clearing a Buffer or Diluent Position

The instrument status must be in *Standby* in order to proceed with the steps below to clear a buffer or diluent position.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**.
3	Open the reagent or sample compartment cover.
4	Remove the buffer or diluent from the carousel.
5	Close the reagent or sample compartment cover.
6	Select the options button < ▼ > beside the position to be cleared.
7	Select <**Clear**> to clear the position. OR Select <**Cancel**> to return to the Reagent Status/Calibration Status screen without clearing the position.

Loading Wash Solution

Introduction

The wash solution is used for rinsing the probes, mixers and cuvettes on the IMMAGE 800.

When to Load

Load a new box of wash solution when the volume of the solution is low (approximately 1000 tests/10 liter box).

Loading the Wash Solution

The instrument status must be in *Standby* in order to proceed with the steps below to load the wash solution.

Step	Action
1	Remove the screw cap, with the tubings and straw attached, from the wash solution container in use.
2	Remove the screw cap from the new container of wash solution.
3	Place the cap with the tubings and straw attached into the new wash solution and screw on the cap. The blue tubing is attached to the side with a straw, the orange tubing is not attached to a straw.
4	Verify that the blue and orange tubings are attached to the top of the cap.
5	No software intervention is required. Priming is not required.

Loading/Unloading Reagent Cartridges

Introduction

The reagent cartridges must be loaded before performing a run.

Description of Cartridge Bar Code

The Beckman Coulter reagent cartridge bar code contains the following information:

- Chem ID
- Reagent lot number
- Reagent cartridge serial number

Limits

- Up to 24 cartridges can be loaded on the reagent carousel.
- Only one lot of any reagent may be placed on the reagent carousel.
- Multiple cartridges of the same lot may be placed on the carousel.

Loading Reagent Cartridges

The instrument status must be in *Standby* in order to proceed with the steps below to load the reagent cartridge(s).

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Invert each cartridge gently before removing screw caps. Remove the screw caps from the cartridge(s). Check each compartment for bubbles and remove bubbles if present. Place evaporation caps on each cartridge compartment. Note: Some cartridges do not have reagent in compartment B.
3	Open the reagent compartment cover.
4	Place the reagent cartridges onto the reagent carousel. Ensure that the reagent cartridge is correctly placed into the groove on the carousel. (Refer to Figure 6.7.)
5	Close the reagent compartment cover. Note: If calibration and reagent status do not need to be reviewed, proceed to sample programming. (Refer to CHAPTER 7, *Sample Programming*).
6	Select **Read Reagents [F1]**.
7	Select **<OK>** to initiate the reagent cartridge read and go to Step 8. OR Select **<Cancel>** to return to the Reagent Status/Calibration Status screen without reading the reagent cartridges.

(1 of 2)

Step	**Action**, continued
8	

If...	**the screen will display...**
the load is successful	updated reagent status information.
the load is unsuccessful	an error message. (Refer to CHAPTER 10, *Utilities*, Troubleshooting.)
the cartridge is expired	a warning message.
the cartridge is exhausted	"Tests Left" as zero.

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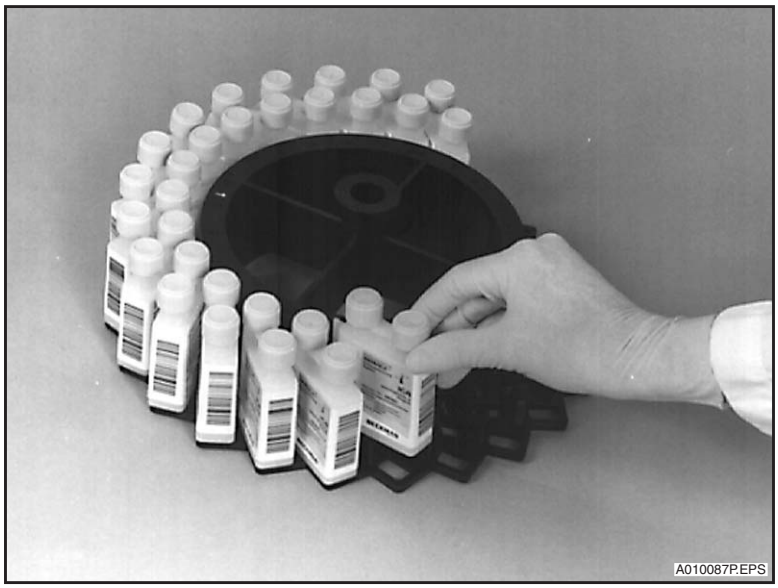

Figure 6.7 Loading Reagent Cartridges on the Reagent Carousel

Removing the Reagent Carousel

The instrument status must be in *Standby* in order to proceed with the steps below to remove the reagent carousel from the IMMAGE 800 upon completion of the daily workload.

Step	Action
1	Open the reagent compartment cover.
2	Lift the reagent carousel from the center and remove.
3	Store the loaded reagent carousel in the refrigerator. No software intervention is required.

Removing Cartridges from the Reagent Carousel

The instrument status must be in *Standby* in order to proceed with the steps below to remove reagent cartridges from the reagent carousel.

Step	Action
1	Open the reagent compartment cover.
2	Lift the reagent cartridge up from the reagent carousel.
3	Store the cartridge in the refrigerator. No software intervention is required.
4	Close the reagent compartment cover.

Calibration

Overview

Introduction

This section explains the following topics:

- Checking Calibration Status
- Requesting and Canceling Calibration
- Loading Calibrators on the Sample Carousel
- Starting a Calibration Run
- Calibration Results
- Re-enabling Calibration
- Cal Options

Checking Calibration Status

Introduction

The calibration status of each chemistry can be checked prior to performing a run.

Explanation of Terms

The following table explains the different calibration status terms.

Table 6.3 Calibration Status Terms

Term	Explanation
Uncalibrated	the reagent has never been calibrated
Calibrated	the reagent is calibrated
Requested	calibration is requested
Cal Failed	calibration failed
Cal Re-enabled	the previous calibration is re-enabled

Checking On-Board Reagent Cal Status

Follow the steps below to check the calibration status of the on-board reagent cartridges.

Step	Action
1	Place reagent cartridges on the reagent carousel, and read the cartridge bar codes. (Refer to Reagents, Loading/Unloading Reagent Cartridges, in this chapter.)
2	Check the calibration status of the reagents from the Reagent Status/ Calibration Status screen under the Cal Status heading. (Refer to Figure 6.8.)
3	Select **Control [P]** to print the Reagent Status/Calibration Status screen(s).

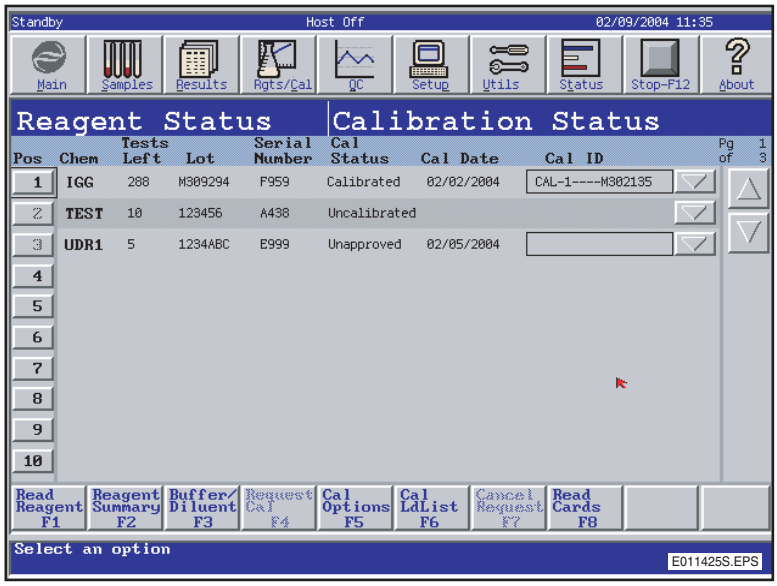

Figure 6.8 Reagent Status/Calibration Status Screen

Verifying the Cal Status of Reagent Parameters in the Database

Follow the steps below to verify the calibration status of any reagent loaded in the database.

Step	Action
1	From the Reagent Status/Calibration Status screen, select **Reagent Summary [F2]**. (Refer to Figure 6.8.)
2	Verify the calibration status under the Cal Status heading for the desired reagent.
3	For further information about the reagent, complete the following steps. From the Reagent Summary dialog box, select a button beside a desired reagent. THEN Select the <**Display**> button to view the reagent lot parameters. (Refer to Figure 6.4.) OR Select <**Go To**> and type the Chem and Lot number.
4	Select <**OK**> from the Reagent Lot Parameters dialog box when finished viewing the reagent lot parameters.

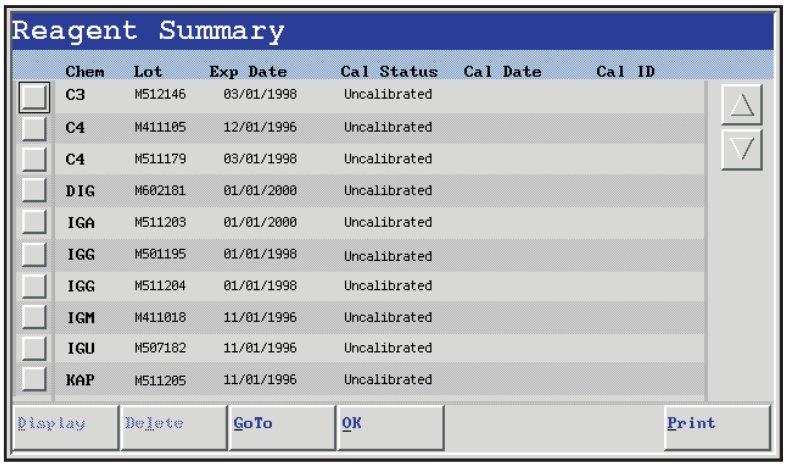

Figure 6.9 Reagent Summary Dialog Box

Calibration History

Introduction

The Calibration History window allows the operator to review the previous four calibrations and displays the following information:

- chemistry name
- reagent lot number
- date
- time
- Cal ID
- scale factor
- reaction buffer
- sample diluent

Displaying Calibration History

Calibration history is not available for User-Defined Reagents. Up to four successful calibrations will be displayed. Failed calibrations will not be displayed.

Step	Action
1	Select **Rgts/Cal** icon.
2	From the Reagent Status/Calibration Status screen, select the pull-down on the **Cal ID** field to display the Calibration History window. Refer to Figure 6.1.
3	The calibrations display ascending date/time order, with the oldest calibration listed first.
4	Select **<OK>** to return to the Reagent/Status/Calibration screen.

Re-Enable Calibration

If the most recent calibration failed and there was a previous successful calibration, the user has the option to re-enable the previous calibration.

Step	Action
1	From the Reagent Status/Calibration Status screen, select Re-enable Calibration. The calibration status of the test changes to Cal Re-enable.
2	The calibrations display ascending date/time order, with the oldest calibration listed first.
3	Select **<OK>** to return to the Reagent/Status/Calibration screen.

Cartridge-Specific Calibration

Introduction

The cartridge-specific calibration option provides calibration of partially used cartridges.

The calibration factor established from a fresh cartridge can be stored and applied to all subsequently loaded cartridges of the same lot.

Explanation of Terms

The table below defines terms specific to cartridge-specific calibration for the IMMAGE 800.

Cartridge-Specific Calibration Terms

Term	Explanation
Reagent Lot:	Calibration of a fresh cartridge to be applied to all cartridges with the same lot number.
Cartridge-specific:	Calibration of a partially used cartridge to be applied to that cartridge only. The system determines the cartridge to be used for this calibration based on criteria described below. Refer to "Cartridge-Specific Calibration Criteria."
Predetermined number of tests:	The number of tests remaining in a cartridge to allow a cartridge-specific calibration. This number is determined by Beckman Coulter on a per chemistry basis and is coded into the reagent bar code card.
**Requested*:	Calibration status of a requested chemistry that will become a cartridge-specific calibration.

Cartridge-Specific Calibration Criteria

The criteria for cartridge-specific calibration is defined as follows:

- Reagent bar code card indicates the potential for this classification.
- Reagent cartridge on carousel contains less than predetermined number of tests remaining.
- Calibration is requested for a specific chemistry.

If…	Then…
more than one cartridge on carousel has less than the predetermined number of tests remaining,	the system uses the cartridge with the least number of tests remaining.
two or more cartridges, with the same number of tests remaining, are on the system at the same time,	the system uses the cartridge loaded at the lowest carousel position.
all the cartridge-specific calibration criteria are met when a calibration is requested,	the system automatically runs a cartridge-specific calibration on the appropriate cartridge.

Calibration Status

Each cartridge with a cartridge-specific calibration will have its own calibration values. There can be only one cartridge-specific calibration per cartridge. Any time the same cartridge is recalibrated for cartridge-specific use, the previous cartridge-specific calibration (for that cartridge) will be overwritten. Follow the steps below to access the Calibration Information screen that summarizes calibration status.

Step	Action
1	From the Reagent Status/Calibration Status screen, select the options button < ▼ > beside Cal ID for the desired chemistry.
2	View the Calibration Information dialog box for the desired information.

If...	Then...
recalibration is requested for a chemistry, and one of the cartridges meets the cartridge-specific calibration criteria,	calibration status is **Requested* for that cartridge only.
a newly loaded cartridge has the same lot number as a cartridge with previous cartridge-specific calibration,	the reagent lot calibration (not cartridge-specific) applies to the new cartridge. Calibration status is the same as the reagent lot calibration status prior to loading the new cartridge.
the lot number of the reagent is new to the system,	calibration status is *Uncalibrated* for all cartridges of that lot on the system.

Calibration Events

Reagents selected for cartridge-specific calibration should be calibrated using the same method as that used to calibrate other reagents. The table below presents a set of varying conditions and their corresponding events.

If…	Then…
a cartridge: • is designated by a reagent parameter bar code, • is loaded on the carousel with a predetermined, number of tests remaining • has a chemistry requested for calibration,	it may be used to establish a cartridge-specific calibration.
a calibration is requested,	the status of only the cartridge designated for cartridge-specific calibration changes to **Requested*. All other cartridges of that chemistry maintain the same calibration status prior to the request.
additional cartridges of the same lot with greater than the predetermined number of remaining tests are loaded on the system,	those cartridges maintain the reagent lot calibration.
the calibration is successfully completed,	the Cal Status of that cartridge goes to *Calibrated*: • a new cartridge-specific calibration is applied. • the reagent lot calibration is no longer associated with this cartridge • the cartridge-specific calibration does not affect any other cartridge with the same lot number.
the calibration fails,	the status of only the **Requested* cartridge changes to *Cal Failed*. The Cal Status of all additional cartridges will not change.
cancellation of the cartridge-specific calibration request is desired,	cancel the calibration request. Refer to Requesting and Canceling Calibration in this chapter.
reestablishment of cartridge-specific calibration is desired,	reenable calibration. Refer to Re-Enabling Calibration in this chapter.

(1 of 2)

If…	**Then…**, continued
a new reagent lot calibration is desired,	recalibrate with a fresh cartridge (greater than predetermined number of tests remaining). • remove cartridge-specific cartridge • place a "fresh" cartridge on carousel • request and recalibrate chemistry • replace used cartridge on carousel after successful calibration
specific calibration information is desired,	select the options button < ▼ > beside Cal ID for the calibrator of the specific chemistry. The Calibration Information screen will indicate whether the calibration was cartridge-specific.

(2 of 2)

Requesting and Canceling Calibration

Introduction

- Reagent and calibrator bar code parameters must be loaded prior to requesting a calibration. (Refer to Reagents, Loading Reagent/Calibrator Bar Coded Parameters in this chapter.)
- Calibration must be requested for a reagent lot which has a status of *Uncalibrated* before patient samples can be run with that reagent lot.
- Calibration may be requested regardless of the current calibration status for any reagent lot.
- If the calibration status is *Cal Failed*, request either a new calibration or Cal Re-enable. (Refer to Re-Enabling Calibration in this section.)

Requesting Calibration

Follow the steps below to request calibration.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Load the reagent cartridges if necessary. (Refer to Reagents, Loading/Unloading Reagent Cartridges, in this chapter.)
3	Select the button(s) to the left of the chemistries to be calibrated. If selecting a chemistry where more than one cartridge of the same lot number is on the reagent carousel: • each cartridge of that lot is automatically given a status of *Requested.* • only the cartridge with the lowest volume will be calibrated
4	Select **Request Cal [F4]**. • The Request Calibration screen is displayed. (Refer to Figure 6.10.) • Requested Chems appear next to the appropriate Calibrator for the chemistry.
5	To run a calibrator as a STAT, select the STAT checkbox for the calibrator at the right of the screen. • ALL chemistries requested for a STAT calibrator will be calibrated STAT. • A STAT calibrator will be run before any other calibrator or sample.
6	Go to Checking and Clearing Racks.

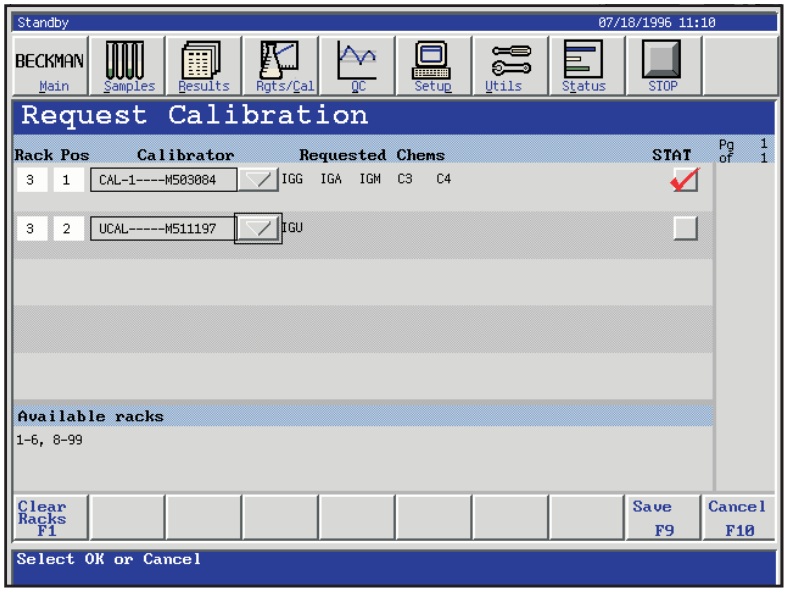

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Figure 6.10 Request Calibration Screen

Checking and Clearing Racks

The rack position used for a calibrator must be *Available* before it is used for calibration.

Follow the steps below to check the rack status and clear racks.

Step	Action
1	On the Request Calibration screen, check the **Available Racks** section to see if the rack to be used is *Available*. *Available* racks have at least one position that is not programmed.
2	If the rack is *Not Available*, select **Clear Racks [F1]**. (Refer to Figure 6.11.)

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>3</td><td>
<table>
<tr><th>If...</th><th>then...</th></tr>
<tr><td>one rack number is entered,</td><td>Press [Enter] to access the Pos(s) field.

Type the position numbers desired to clear (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range.

Note: If one rack number and no position number is entered, all positions on the rack are automatically cleared.</td></tr>
<tr><td>more than one rack number is entered,</td><td>• all positions on each rack are automatically cleared.
• the Pos(s) field cannot be accessed.</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Select <OK> to clear the racks and positions.
OR
Select <Cancel> to return to the Reagent Status/Calibration Status screen without clearing.</td></tr>
<tr><td>5</td><td>
<table>
<tr><th>If the calibrator sample is...</th><th>then...</th></tr>
<tr><td>bar coded</td><td>Select Save [F9] to save the request.
OR
Select Cancel [F10] to return to the Reagent Status/Calibration Status screen without saving.</td></tr>
<tr><td>not bar coded</td><td>Go to Assigning Calibrator Rack and Position in this section.</td></tr>
</table>
</td></tr>
</table>

(2 of 2)

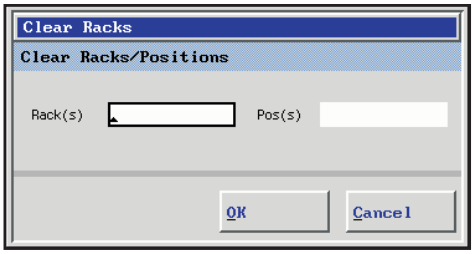

Figure 6.11 Clear Racks Dialog Box

Assigning Calibrator Rack and Position

A non-bar coded calibrator must be assigned a rack and position when requesting calibration.

Follow the steps below to assign rack and position to a non-bar coded calibrator sample.

Step	Action
1	From the Request Calibration screen type the *Available* rack and position for the calibrator in the **Rack** and **Position** fields.
2	Select the options button < ▼ > beside the desired position for the calibrator.
3	From the Calibrator Lots dialog box, select the appropriate calibrator lot number. OR Select <**Cancel**> to return to the Request Calibration screen without selecting a calibrator lot number.
4	Select **Save [F9]** to save the calibration request and assignment. OR Select **Cancel [F10]** to return to the Reagent Status/Calibration Status screen without saving.

Canceling a Requested Calibration

Follow the steps below to cancel a requested calibration.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select the button(s) to the left of the requested chemistries to be canceled.
3	Select **Cancel Request [F7]**. The Cal Status of the canceled chemistries will return to the status prior to calibration request.

Loading Calibrators on the Sample Carousel

Introduction

When calibration is requested, calibrators are placed on the sample carousel.

Placing Bar Coded Calibrators on the Carousel

Calibration status must be *Requested* in order to proceed with the steps below to place bar coded calibrators on the sample carousel prior to automatic assignment.

Step	Action
1	Locate the calibrator bar code label provided with the calibrator.
2	Place the appropriate label on an empty test tube. (Refer to CHAPTER 2, *System Description*, Sample Container Information for various test tube and sample cup sizes and instructions for applying bar code labels.) Note: The labeled test tube should be saved for re-use.
3	Place the tube into a sample rack.
4	Place the appropriate sample cup in the labeled test tube.
5	Place the appropriate calibrator in the sample cup.
6	Repeat steps 1-5 for any additional calibrators. Continue placing calibrators into the same sample rack.
7	Open the sample compartment cover.
8	Place the rack(s) containing calibrators on the sample carousel. Rotate the sample carousel by pressing the advance button on the instrument. NOTICE Place racks containing calibrators in position A and B. Controls and/or patient samples may be placed in other positions on the sample carousel. (Refer to CHAPTER 7, *Sample Programming*.)
9	Close the sample compartment cover.

Displaying/Printing Cal Load List

After the calibrators are manually assigned, follow the steps below to display or print the Calibrator Load List and to load calibrators.

Step	Action
1	From the Reagent Status/Calibration Status screen, select **Cal LdList [F6]**. (Refer to Figure 6.12.)
2	Select **<Print>** to print a Cal Load List. OR Select **<OK>** to return to the Reagent Status/Calibration Status screen. (Refer to APPENDIX B, *Reports* for an example printout).

Placing Non-bar Coded Calibrators on the Carousel

Follow the steps below to place non-bar coded calibrators on the sample carousel.

Step	Action
1	According to the Cal Load List, place a test tube into the appropriate rack and position.
2	Place the appropriate sample cup in the test tube.
3	Place the appropriate calibrator in the sample cup.
4	Repeat steps 1-3 for any additional calibrators. Continue placing calibrators into the same sample rack.
5	Open the sample compartment cover.
6	Place the rack(s) containing calibrators on the sample carousel. Rotate the sample carousel by pressing the advance button on the instrument. NOTICE Place racks containing calibrators in position A and B. Controls and/or patient samples may be placed in any other positions on the sample carousel. (Refer to CHAPTER 7, *Sample Programming*.)
7	Close the sample compartment cover.

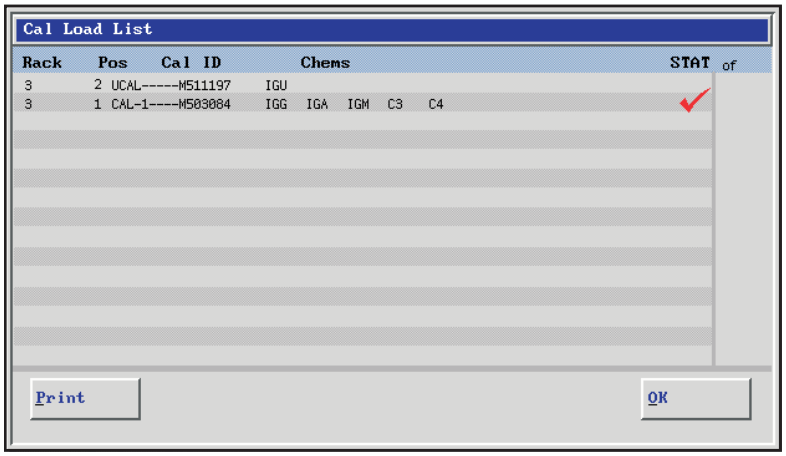

Figure 6.12 Cal Load List Dialog Box

Programming Samples and Controls

Samples and controls may be programmed on a calibration run. (Refer to CHAPTER 7, *Sample Programming*.)

Starting a Calibration Run

Introduction

After the calibration has been requested and calibrators are placed into position, the calibration run is started.

Starting a Calibration Run

Follow the steps below to start the calibration run.

Step	Action
1	Select **Main** from the menu bar.
2	Select **Run**.

Additional Information

Refer to CHAPTER 2, *System Description* for information on how the IMMAGE 800 processes a calibrator and for test tube and sample cup sizes.

Refer to CHAPTER 3, *Theory of Operations* for the theory of calibration.

Calibration Results

Introduction

The following information may be printed on the Calibration Report for a successful calibration result: (Refer to APPENDIX B, *Reports* for an example report.)

- Chemistry ID
- Chemistry Lot
- Calibrator ID
- Reaction Buffer Lot
- Sample Diluent Lot
- Date and Time of Calibration
- Units
- Instrument Response
- Target Response
- Cal Value
- Dilution
- Rack/Position of the calibrator
- Reagent Position
- STAT/Rerun flags
- Instrument Errors/Codes
- Calibrated to Value

Calibration Time Limit

No time limit is imposed by the system for expiration of a calibration result. Recalibration of affected reagents may be necessary when reaction buffer or diluent lots are changed.

After Calibration

Rack positions used for calibration are automatically cleared to a status of *Available* after the calibration is run whether the calibration passed or failed.

Failed Calibration

When calibration fails:

- Samples programmed for a reagent that fails calibration will be displayed and printed on the report as *Pending*.
- Refer to CHAPTER 10, *Utilities*, Troubleshooting.

Re-Enabling Calibration

Introduction

The previous successful calibration can be re-enabled only when a calibration fails.

Re-enabling Calibration

The instrument status must be in *Standby* in order to proceed with the steps below to re-enable a calibration.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select the options button < ▼ > to the right of the Cal ID of the failed calibration.
3	From the Re-enable Previous Calibration dialog box, select **<OK>** to re-enable the calibration. OR **<Cancel>** to return to the Reagent Status/Calibration Status screen without re-enabling the calibration.

After Calibration is Re-enabled

- The previous calibration is re-enabled for all reagent cartridges of the same lot.
- Results generated by a re-enabled calibration are flagged on the laboratory and patient chartable reports under the Instrument Code. (Refer to APPENDIX A, *Instrument Codes* for instrument codes.)

Cal Options

Introduction

Cal Options is used to access Calibrator Summary (calibrator lot parameters), Slope and Offset Adjustments, or Print Last Calibration Results.

Displaying Calibrator Lot Parameters

The instrument status must be in *Standby* in order to follow the steps below to display calibrator lot parameters.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Cal Options [F5]**.
3	Select **<1> Calibrator Summary**. (Refer to Figure 6.13.)
4	Select a button beside the Calibrator to be displayed. THEN Select the **<Display>** button to view the calibrator lot parameters. (Refer to Figure 6.13.) OR Select **<Go To>** and type the Cal and Lot number. Select **<OK>** from the Calibrator Lot Display dialog box when finished viewing the calibrator lot parameters.

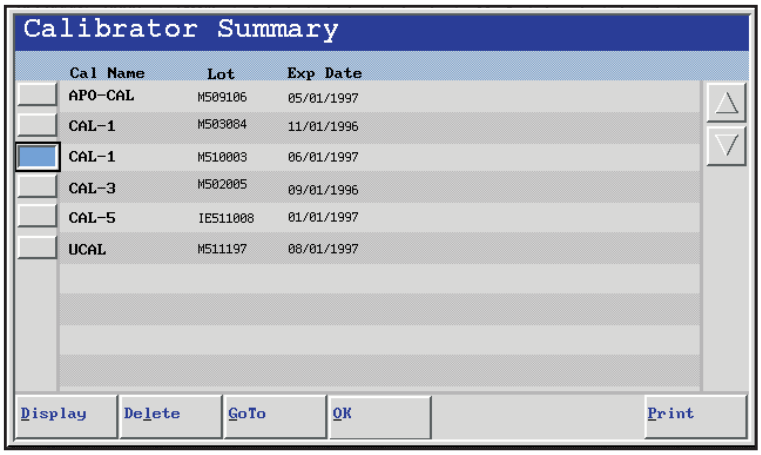

Figure 6.13 Calibrator Summary Dialog Box

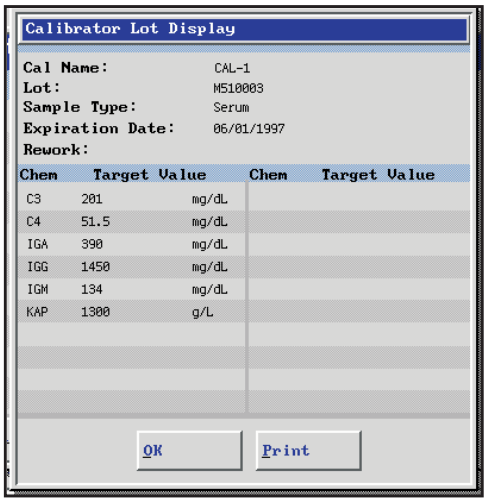

Figure 6.14 Calibrator Lot Display Dialog Box

Printing Calibrator Target Values

Follow the steps below to print calibrator target values.

Step	Action
1	Display the Calibrator Lot Display dialog box for the calibrator that is to be printed. (Refer to "Displaying Calibrator Lot Parameters.")
2	Select <**Print**> to print the calibrator lot parameters OR <**OK**> to return to the Calibrator Summary Dialog box.

Deleting Calibrator Parameters

The instrument status must be in *Standby* in order to follow the steps below to delete calibrator parameters.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Cal Options [F5]**.
3	Select <**1**> **Calibrator Summary**. (Refer to Figure 6.13.)
4	Select a button beside the Cal lot to be deleted. OR Select <**Go To**> and type the Cal and Lot number. Select <**Delete**> to delete the calibrator parameters.

(1 of 2)

Step	**Action**, continued
5	Select **<OK>** from the Delete Calibrator Lot Confirmation dialog box to delete the parameters OR **<Cancel>** to return to the Calibrator Summary dialog box without deleting parameters.

(2 of 2)

Definition of Slope and Offset

Slope and offset values are entered to scale a result from the IMMAGE 800 to correlate with other systems.

Acceptable slope entries: 0.001 - 9999.0
Acceptable offset entries: -9999.0 - +9999.0

The result is multiplied by the slope, then the offset is added or subtracted.

Entering Slope and Offset Adjustment

The instrument status must be in *Standby* in order to follow the steps below to enter Slope and Offset Adjustment.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Cal Options [F5]**.
3	Select **<2> Slope/Offset Adjustment**.
4	Select the **Slope** or **Offset** field beside the chemistry desired.
5	Type the slope and/or offset number in the **Slope** and **Offset** fields.
6	Select an icon from the menu bar to save the slope/offset number and go to another screen.

Restoring Default Slope and Offset Adjustments

The instrument status must be in *Standby* in order to follow the steps below to restore the default slope and offset adjustments.

Step	Action
1	From the Slope/Offset screen select **Restore Default [F1]**.
2	Select **<OK>** to restore all the defaults. (The default for each slope is 1.000 and each offset is 0.000.) OR Select **<Cancel>** to return to the Slope/Offset screen without restoring the default.

Printing Slope and Offset Adjustments

From the Slope/Offset screen select **Print [F10]** to print all of the slope and offset adjustments.

CHAPTER 7 Sample Programming

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Preparing for Programming/Running

Overview

Introduction

Before programming samples and/or starting a run:

- all racks to be used must have a status of *Available*. If the status of a rack is not *Available*, the rack must be cleared before it can be used for programming samples.
- the dilution segments status should be checked. Segments can be cleared or left unchanged.
- reagents, reaction buffers, and sample diluents should be checked.
- wash solution volume should be checked.

Checking and Clearing Sample Racks

Introduction

If sample racks were programmed for a previous run, the racks must be cleared before they can be used again.

> NOTICE
> If only bar coded samples are used (racks and positions are automatically assigned), it is not necessary to clear racks.

Checking Rack Status

Follow the steps below to determine whether a rack is *Available*.

Step	Action
1	Select **Samples** from the menu bar.
2	Select **Load List [F9]**.
3	Type the rack numbers(s) to be checked in the **Rack(s)** field (up to 15 alphanumeric characters). Numbers can be separated by a comma as a series and/or by a dash as a range (*Example*: 1, 2, 5-8).
4	Select **Display**. If a Load List cannot be displayed for a requested rack, the rack is *Available.*

Clearing Racks

Follow the steps below to clear sample racks.

Step	Action
1	Select **Samples** from the menu bar.
2	Select **Clear Samples [F7]**.
3	Choose the **Rack(s)** field.
4	Type the rack numbers to be cleared. Numbers can be separated by a comma as a series and/or by a dash as a range (*Example*: 1, 2, 5-8).
5	Select <**OK**> to clear the racks. OR Select <**Cancel**> to return to the Program Sample screen without clearing racks.
6	Select <**OK**> to confirm the racks to be cleared. OR Select <**Cancel**> to return to the Clear Samples dialog box.

After Racks are Cleared

After sample racks are cleared:

- the rack status becomes *Available*.
- associated sample programs and results remain in the database. Both can be accessed through Results Recall, by any option except Rack and Position.

Additional Information

Refer to Requesting a Load List in this chapter for more information on the Load List function.

Refer to Clearing a Sample in this chapter for more information on the Clear Samples function.

Checking Status and Clearing/Replacing Dilution Segments

Introduction

Prior to starting every run, the Dilution Segments status should be checked.

Options

There are two options from the Dilution Segments status screen:

- The status of the dilution segments can be left unchanged.
- Up to four dilution segments can be cleared. The cleared segments must be replaced with unused segments on the sample carousel.

Checking Status and Clearing Segments

The instrument status must be in *Standby* in order to proceed with the steps below to check the status of the dilution segments.

Step	Action
1	Select **Status** from the menu bar.
2	Select **<1> Dilution Segments**.
3	<table><tr><th>**If dilution segments are...**</th><th>**then...**</th></tr><tr><td>to be cleared</td><td>Type the segment number(s) in the **Clear Segment(s)** field. Numbers can be separated by a comma as a series or by a dash as a range. OR Select the numbered button beside each appropriate segment AND Select <**OK**>.</td></tr><tr><td>*not* to be cleared</td><td>Select <**Cancel**>.</td></tr></table>

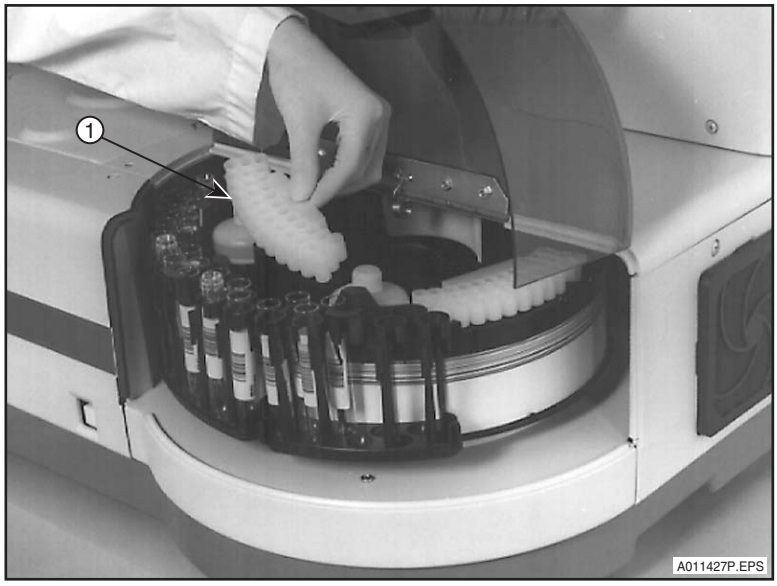
After Clearing Segments

Always replace the cleared dilution segments with unused segments on the sample carousel before a run is started.

Replacing Dilution Segments

The instrument status must be in *Standby* in order to proceed with the steps below to replace dilution segments.

Step	Action
1	Lift the cover of the sample carousel.
2	Rotate the sample carousel by pressing the advance button in order to access the desired dilution segment, if necessary.
3	Lift the segment to be replaced off of the sample carousel. (Refer to Figure 7.1.)
4	Dispose of the used segment in a manner appropriate for biohazardous materials.
5	Place an unused segment in the empty position on the sample carousel.
6	Repeat Steps 2-5 until all desired segments are replaced.



1. Dilution Segment

Figure 7.1 Replacing a Dilution Segment

Additional information

Refer to CHAPTER 11, *System Status/Instrument Commands* for more information on Dilution Segments status.

Checking Reagents, Buffers, and Diluents

Introduction

Before starting a run, the Reagent Status/Calibration Status and Buffer/Diluent Status should be checked to ensure that:

- the appropriate chemistries, buffers, and diluents are on the system.
- the volume of reagents, buffers, and diluents seem adequate to complete the run.
- the chemistries are calibrated.

Checking Reagent Status

Follow the steps below to check the status of reagents.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Read Reagents [F1]** to update the status information if reagent cartridges were loaded or removed since the last run.
3	Determine if the chemistries on the carousel and the number of tests remaining are appropriate for the run. Note any chemistries that require calibration. (Refer to CHAPTER 6, *Reagents/Calibration* for further information on loading reagent cartridges and calibration.)

Checking Buffer/Diluent Status

Follow the steps below to check the status of buffers and diluents.

Step	Action
1	Select **Rgts/Cal** from the menu bar.
2	Select **Buffer/Diluent [F3]**.
3	Determine if the buffer and diluent types and the volume **% Remaining** are appropriate for the run. (Refer to CHAPTER 6, *Reagents/Calibration*, Loading/Clearing Buffers and Diluents, for more information.)

Checking Wash Solution Volume

Introduction

Before starting a run, the wash solution should be checked to ensure that there is sufficient volume to complete the run.

Each wash solution box will perform approximately 1,000 tests. The instrument also has an internal reservoir of wash solution, so a run can continue for a short time after the box is empty; however, the box should be replaced as soon as possible.

Checking Wash Solution

Follow the steps below to check the wash solution volume.

Step	Action
1	Visually inspect the wash solution level through the perforated cut-outs at the top of the box and/or lift and swirl the box.
2	Replace the box if the wash solution volume does not appear sufficient to complete the run. (Refer to CHAPTER 6, *Reagents/Calibration*, Loading Wash Solution for more information.) Wash solution can be pooled.

NOTICE

For a more accurate estimation of wash solution usage, record the cycle count when a new wash solution box is placed on the system. Replace the box when the cycle count nears 1,000 additional tests.

Programming a Sample

Overview

Introduction

The following sample information can be programmed:

- sample identification
- test selection
- sample description, which consists of sample type, sample comment, patient ID, and patient demographics
- sample options, which consist of sample replicates, test replicates, off-line dilution ratio, antigen excess testing, non-standard dilutions, and linking samples
- control samples
- STAT samples

Additional Information

Refer to CHAPTER 2, *System Description*, Sample Container Information, Sample Containers Allowed, "Sample Cups," when using a sample cup.

Program Sample Screen

Accessing Program Sample Screen

Select **Samples** from the menu bar to access the Program Sample screen. (Refer to Figure 7.2.)

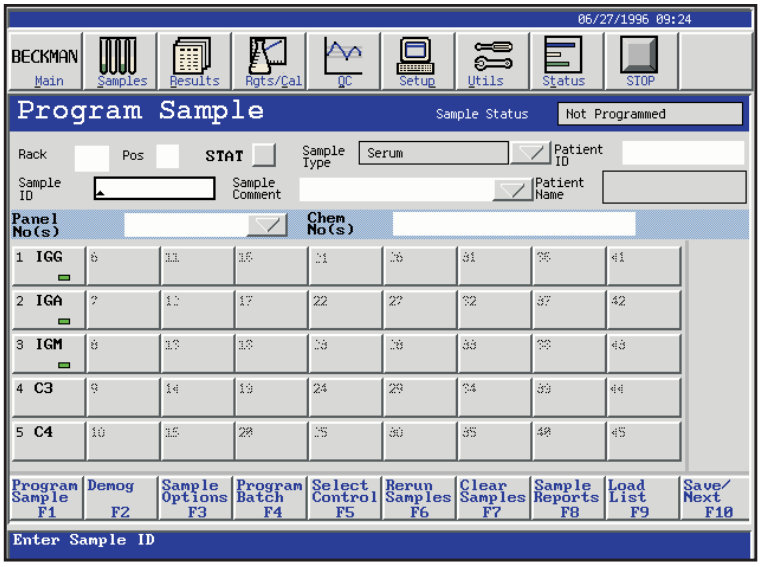


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Figure 7.2 Program Sample Screen

Sample Status

The status of the current sample is displayed on the right side of the title bar. The following table decribes each status and which sample programming fields or functions are accessible while the status is displayed.

Table 7.1 Sample Status

Status	Description	Accessible Fields/ Functions
Not Programmed	Sample is not programmed or saved.	All
Sample Required	Sample program is saved.	All
Waiting to Run	The sample carousel was scanned and the sample program is recognized by the system.	Demographics Add chemistries and any options related to them
Running	One or more tests requested for the sample are running.	Sample Comment Demographics Add chemistries and any options related to them

(1 of 2)

Table 7.1 Sample Status, continued

Status	Description	Accessible Fields/ Functions
Complete	All tests requested for the sample are completed.	Demographics Rerun
Incomplete	At least one test result for the sample is pending.	Patient ID Sample Comment Demographics Rerun

(2 of 2)

Program Sample Working Area

The Program Sample screen working area is divided into three sections. The following table lists the functions available in each section of the working area.

Table 7.2 Working Area Functions

Section	Functions
Upper	Allows entry of the following information associated with a sample: Rack — STAT Designation — Sample Comment Position — Sample Type Sample ID — Patient ID Patient Name can only be accessed through Demographics.
Middle	Allows the selection of panel numbers and/or chemistry numbers.
Lower (chemistry menu)	• Displays the chemistries which were configured in Setup. • Allows the selection of chemistries. • Indicates that antigen excess testing is enabled for a chemistry by displaying a small green box. • Displays **<Page Up>** and **<Page Down>** buttons so chemistries with numbers greater than 45 can be accessed.

Program Sample Function Buttons

The following table describes the function buttons at the bottom of the screen.

Table 7.3 Program Sample Function Buttons

Name	Button	Description
Demog	**[F2]**	Allows the entry of patient demographic information.
Sample Options	**[F3]**	Allows the selection of sample or chemistry replicates, off-line or non-standard dilutions, antigen excess testing, and linking samples.
Program Batch	**[F4]**	Allows a sample program to be automatically repeated for multiple samples.
Program Control	**[F5]**	Allows the selection of a control from a pre-defined list.
Rerun Samples	**[F6]**	Allows the selection of samples or chemistries to be rerun.
Clear Samples	**[F7]**	Allows sample programs or racks to be cleared.
Post Run Summary	**[F8]**	Provides a list of pending or incomplete samples.
Load List	**[F9]**	Requests a load list.
Save/Next	**[F10]**	Saves the current sample program and allows programming of the next sample.

Additional Information

Refer to CHAPTER 2, *System Description*, Performing Software Functions, for general information on using the software.

Entering Sample Identification

Introduction

Every sample must be identified by either Rack and Position or Sample ID. Both Rack and Position and a Sample ID can be entered for a sample.

Minimum Sample Program Required

The minimum information required for a sample to be saved is:

Rack and Position and at least one chemistry

OR

Sample ID and at least one chemistry.

Assigning a Rack and Position

Follow the steps below to assign a Rack number and Position number.

NOTICE
A Rack number and Position number must be assigned if a sample is not bar coded or if a sample bar code is unreadable.

Step	Action
1	Select **Samples** from the menu bar.
2	Choose the **Rack** field if the cursor is in another field.
3	Type an available Rack number (1-99) and press **[Enter]**.
4	Type a Position number (1-9).

Entering a Sample ID

Follow the steps below to enter a Sample ID.

Step	Action
1	Select **Samples** from the menu bar.
2	Choose the **Sample ID** field if the cursor is in another field.
3	Type a Sample ID (up to 15 alphanumeric characters; a space is not allowed).

NOTICE

Every Sample ID must be unique. A Sample ID can only be reused by:

- rerunning the sample. The original and rerun results will be collated.

  Example:
  A sample is programmed for tests A and B. Test B requires pretreatment of the sample. The untreated sample can be run first for test A, and the pretreated sample can then be rerun for Test B only.

  OR

- clearing the Sample ID and reprogramming it. The original and reprogrammed Sample IDs will be treated as two different samples.

  Example:
  A lab receives two different samples with identical Sample IDs. One of the samples can be run first and cleared by Sample ID, and the remaining sample can then be run.

Displaying/Editing a Sample Program

A previously saved sample program can be displayed by entering either the Rack and Position or the Sample ID. The program can then be edited.

Selecting Chemistry Tests by Panel

Introduction

A panel containing one or multiple chemistry tests can be selected. Panels are defined by the user in Setup.

A panel can be selected by typing the number of the panel in the **Panel No(s)** field or by selecting the panel from the Panels list.

The maximum number of panels which can be selected is the number that was defined in Setup.

NOTICE

Panels defined using previous versions of software and restored to version 1.5 will have a sample type of Unknown.
Panels having a sample type of Unknown cannot be used in Sample Programming. (Refer to CHAPTER 5, *System Setup*, Panel Setup, "Editing Panels" to edit a sample type.)

Selecting a Panel by Number

Follow the steps below to select a panel by number.

Step	Action
1	Select **Samples** from the menu bar.
2	From the Program Sample screen, choose the **Panel No(s)** field.
3	Type the desired panel number(s) in the **Panel No(s)** field. Numbers can be separated by a comma as a series and/or by a dash as a range (*Example*: 1, 2, 5-8).
4	Press **[Enter]**.

Selecting a Panel from Panels List

Follow the steps below to select a panel from the Panels list. (Refer to Figure 7.3.)

Step	Action
1	Select the options button < ▼ > beside the **Panel No(s)** field.
2	Type the desired panel number(s). Numbers can be separated by a comma as a series and/or by a dash as a range (*Example*: 1, 2, 5-8). Press **[Enter]**. OR Select the number beside the desired panel(s).
3	Select <**OK**> to program the panel(s). OR Select <**Cancel**> to return to the Program Sample screen without programming the panels.

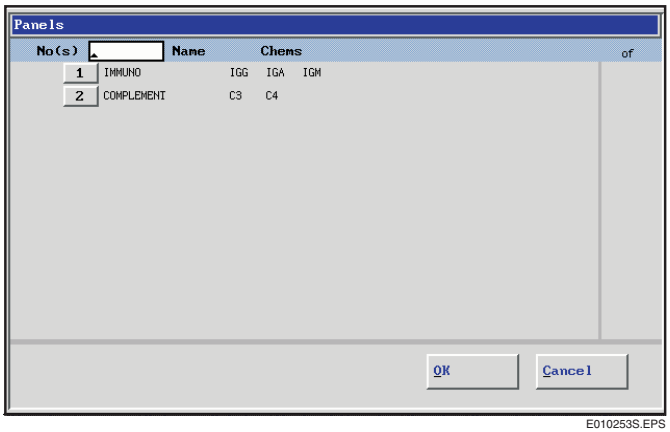

Figure 7.3 Panels Dialog Box

After Panel Selection

After a panel is selected:

- the panel number will remain displayed.
- the chemistries in that panel will be selected in the Chemistry Menu.
- the sample type defined for the panel will be displayed.
- any off-line or non-standard dilution defined for the panel will be applied.

> NOTICE
> If multiple panels are selected, their defined sample types non-standard dilutions, antigen excess and any off-line dilutions must be the same.

Canceling a Panel

A selected panel can be canceled by deselecting it in the Panels list. The highlight will be removed.

A panel cannot be canceled after the sample program is saved and/or the run is started.

Additional Information

Refer to CHAPTER 5, *System Setup*, Panel Setup for more information on defining panels.

Selecting Chemistry Tests by Chemistry

Introduction

A chemistry test can be selected individually from the chemistry menu. Chemistries are configured on the chemistry menu by the user in Setup.

A chemistry can be selected by typing the number of the chemistry in the **Chem No(s)** field or by selecting the appropriate button in the chemistry menu.

The maximum number of chemistries which can be selected is the number of chemistries configured in the chemistry menu.

Selecting a Chemistry by Number

Follow the steps below to select a chemistry by number.

Step	Action
1	Select **Samples** from the menu bar.
2	Choose the **Chem No(s)** field.
3	Type the desired chemistry number(s) in the **Chem No(s)** field. Numbers can be separated by a comma as a series and/or by a dash as a range (*Example*: 1, 2, 5-8).
4	Press **[Enter]**.

Selecting a Chemistry from Chemistry Menu

Follow the steps below to select a chemistry from the chemistry menu.

Step	Action
1	Select **Samples** from the menu bar.
2	Select the button corresponding to the desired chemistry. Chemistries with numbers greater than 45 can be accessed by paging down.

NOTICE

If both panels and individual chemistries are selected for a sample, their Sample Types and any off-line dilutions must be the same.

After Chemistry Selection

After a chemistry is selected, the button is highlighted in the chemistry menu.

Canceling a Chemistry

A selected chemistry can be canceled by deselecting the button from the chemistry menu. The highlight is removed.

A chemistry cannot be canceled after the run is started.

Additional Information

Refer to CHAPTER 5, *System Setup*, Configuring the Chemistry Menu for more information on configuring the chemistry menu.

Selecting a Sample Type

Introduction

Sample Type is selected from a list which contains:

- Serum
- CSF
- Plasma
- Random Urine
- Timed Urine

The default Sample Type is defined in Setup and is initially displayed in the **Sample Type** field.

NOTICE
If a sample type is selected that is not applicable to specific chemistries, those chemistries are unavailable and appear dimmed on the chemistry menu.

Selecting a Sample Type

Follow the steps below to select a Sample Type.

Step	Action
1	Select **Samples** from the menu bar.
2	Select the options button < ▼ > beside the **Sample Type** field.
3	Type the number of the desired Sample Type and press **[Enter]**. OR Select the number beside the desired Sample Type.

Panel or Control Sample Type

If a panel or control is selected, the Sample Type defined for the panel or control will automatically appear.

Timed Urine Parameters

If Timed Urine is selected as the Sample Type, a dialog box will appear. (Refer to Figure 7.4.) If the parameters are not entered, the sample program cannot be saved. Information must be entered as follows:

Step	Action
1	Type the urine volume (in milliliters, 1-99999.0) and press **[Enter]**.
2	Enter the total time in which the urine was collected: • Type the number of hours (0-99) and press **[Enter]** • Type the number of minutes (0-59) and press **[Enter]**
3	Select <**OK**> to program the urine parameters. OR Select <**Cancel**> to return to the Program Sample screen. The Sample Type must be changed or the urine parameters must be entered to save the sample program.

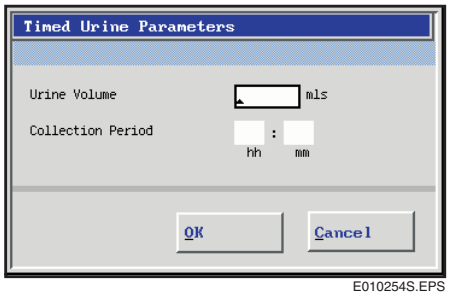

Figure 7.4 Timed Urine Parameters Dialog Box

Additional Information

Refer to CHAPTER 5, *System Setup*, Default Setup for more information on defining a default Sample Type.

Entering a Sample Comment

Introduction

A Sample Comment can be selected from a list defined in Setup or can be entered in the **Sample Comment** field.

Selecting Comment from List

Follow the steps below to select a Sample Comment from the Sample Comment list. (Refer to Figure 7.5.)

Only one comment can be selected for a sample. After a comment is selected, it can be edited in the **Sample Comment** field.

Step	Action
1	Select **Samples** from the menu bar.
2	<table><tr><th>To select comment from list...</th><th>To enter comment number...</th></tr><tr><td>Select the options button < ▼ > beside the **Sample Comment** field AND Type the number of the desired comment, and press **[Enter]**. OR Select the number beside the desired comment.</td><td>Choose the **Sample Comment** field AND Type the number of the desired comment, and press **[Enter]**.</td></tr></table>

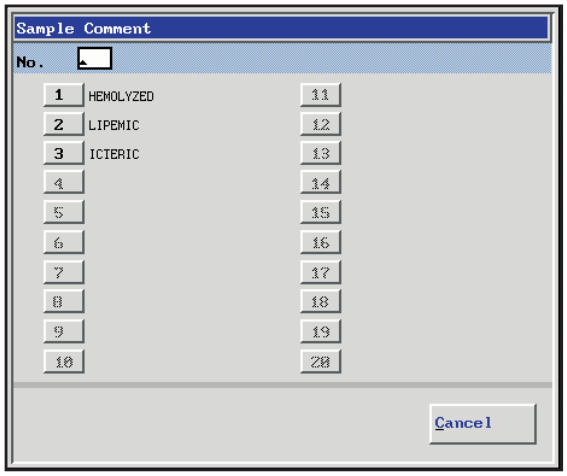

Figure 7.5 Sample Comment Dialog Box

Entering a Comment

Follow the steps below to enter a Sample Comment.

Step	Action
1	Select **Samples** from the menu bar.
2	Choose the **Sample Comment** field.
3	Type a Sample Comment (up to 25 alphanumeric characters).

Additional Information

Refer to CHAPTER 5, *System Setup*, Sample Comments Setup, for more information on defining a list of Sample Comments.

Entering a Patient ID

Introduction

A Patient ID can be entered in the **Patient ID** field.

The Patient ID can be used as a link to recall demographics (refer to Table 7.4):

Table 7.4 Patient ID Field

If...	and...	then...
a Patient ID is entered along with demographic information for a sample,	the same Patient ID is entered later for a new sample,	• the demographic information will be displayed automatically for the new sample. • the patient name will appear in the **Patient Name** field.

Entering a Patient ID

Follow the steps below to enter a Patient ID.

Step	Action
1	Select **Samples** from the menu bar.
2	Choose the **Patient ID** field.
3	Type a Patient ID (up to 15 alphanumeric characters).

Entering Patient Demographics

Introduction

Patient Demographics can be entered for each sample.

Select **Demog [F2]** to access the Demographics screen.

The upper section of the Program Sample screen also appears on the Demographics screen. (Refer to Figure 7.6.) Only the **STAT** check box and the **Sample Type** and **Sample Comment** fields can be accessed.

Individual patient demographic fields can be disabled from Setup. Disabled demographic fields cannot be accessed.

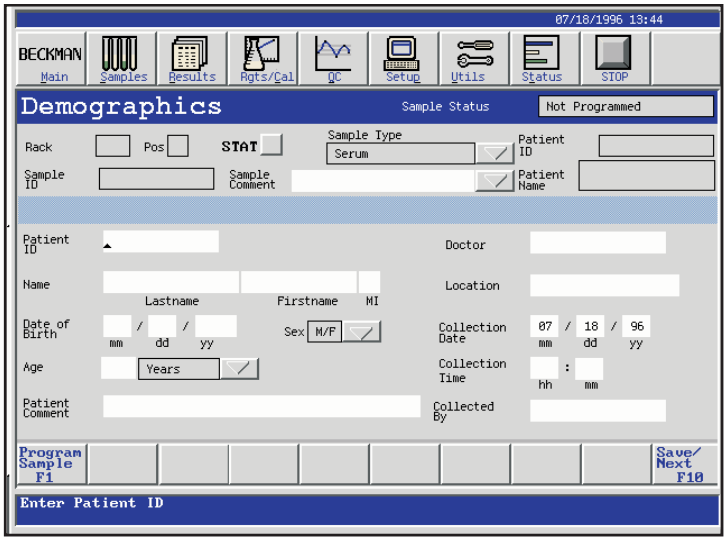

Figure 7.6 Demographics Screen

Entering Demographics

Follow the steps below to enter patient demographics from the Demographics screen.

Step	Action
1	Type or select the appropriate information in each field. (Refer to Table 7.5 for a description of field entries.)
2	When all desired Demographics are entered: **To...** — **Select...** return to the same sample, — **Program Sample [F1].** advance to the next sample, — **Save/Next [F10].**

Table 7.5 Demographic Field Entries

Field	Entries	Notes
Patient ID	15 alphanumeric characters	Patient ID may be entered from the Program Sample screen.
Name	Last name: 18 alphanumeric characters First name: 15 alphanumeric characters MI (Middle Initial): 1 alphabetic character	
Date of Birth	mm: 1-12 dd: 1-31 yyyy: 1850-2035	The order and the separator character are defined in Setup.
Sex	• Select the options button < ▼ > beside the **Sex** field. • Select an option from the list.	• The options are: Male, Female, M/F • The default is M/F.
Age units	• Select the options button < ▼ > beside the **Age** field. • Select an option from the list.	• The options are: Hours, Days, Weeks, Months, Years • The default is Years.
Age	Hours: 0-999 Days: 0-999 Weeks: 0-999 Months: 0-999 Years: 0-999	• Age is automatically calculated if Date of Birth is entered. • Age is automatically recalculated if Age units are changed.

(1 of 2)

Table 7.5 Demographic Field Entries, continued

Field	Entries	Notes
Patient Comment	45 alphanumeric characters	
Doctor	18 alphanumeric characters	
Location	20 alphanumeric characters	
Collection Date	mm: 1-12 dd: 1-31 yy: 0-99	• The order and the separator character are defined in Setup. • The default date is the current date.
Collection Time (24-hour format)	hh: 0-23 mm: 0-59	• The time format is defined in Setup as 12-hour or 24-hour. • The separator character is defined in Setup.
Collection Time (12-hour format)	hh: 1-12 mm: 0-59 AM/PM: • Select the options button < ▼ > beside the **Collection Time** field. • Select **AM** or **PM**.	• The time format is defined in Setup as 12-hour or 24-hour. • The separator character is defined in Setup. • The default is AM.
Collected By	18 alphanumeric characters	

(2 of 2)

Additional Information

Refer to CHAPTER 5, *System Setup*, Demographics Setup for more information on disabling demographic fields and Date and Time Setup for more information on defining date and time formats.

Selecting Sample Options

Introduction

To access the Sample Options dialog box, chemistries must first be selected from the Program Sample screen. (Refer to Figure 7.7.)

Sample Options allows:

- the designation of the number of replicates for an entire sample or for individual tests.
- the enabling or disabling of antigen excess testing.
- the selection of non-standard dilutions.
- the entering of an off-line dilution factor.
- the linking and unlinking of two samples for a calculation.
- the setting of variables for use in Custom Calculations.

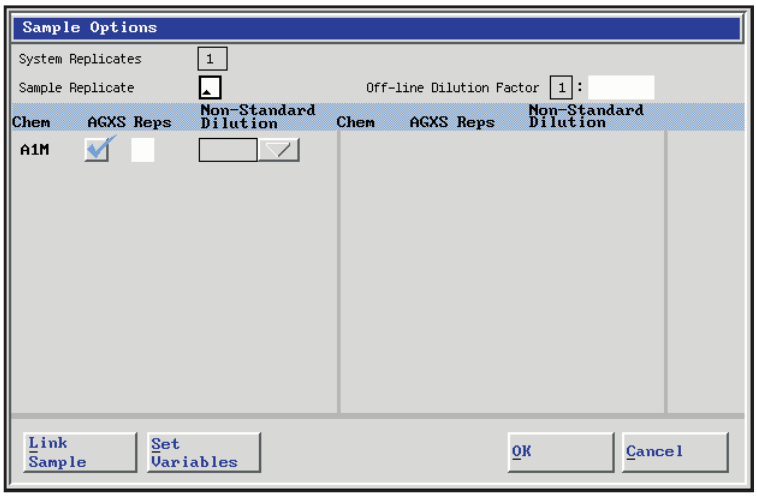

Figure 7.7 Sample Options Dialog Box

Exiting the Sample Options Dialog Box

Select <**OK**> to save the information and return to the Program Sample screen.

OR

Select <**Cancel**> to return to the Program Sample screen without accepting any changes.

Selecting Replicates

Introduction

A Sample Replicate number can be entered in the **Sample Replicate** field. The Sample Replicate number defines the number of times all tests selected for the sample will be repeated. (1-9 Sample Replicates are available.) It applies only to the current sample.

The default number of sample replicates defined in Setup is displayed in the **System Replicates** field. This field is for display only and cannot be accessed, except from Setup.

A test replicate number can be entered for each test that is selected for a sample. The test replicate number defines the number of times an individual test will be repeated. (1-9 test replicates are available). It applies only to the current sample.

NOTICE
The test replicates function is available only when the Sample Replicate is set to 1.

Entering Sample Replicates

Follow the steps below to enter a Sample Replicate number.

Step	Action
1	Select chemistry(ies) from the Program Sample screen.
2	Select **Sample Options [F3]**.
3	Choose the **Sample Replicate** field.
4	Type the number of replicates for the sample (1-9).

Entering Test Replicates

Follow the steps below to enter a test replicate number.

Step	Action
1	Select chemistry(ies) from the Program Sample screen.
2	Select **Sample Options [F3]**.
3	Choose the **Reps** field beside the desired chemistry.
4	Type the number of replicates for the test (1-9).

Additional Information

Refer to CHAPTER 5, *System Setup*, Default Setup, for more information on defining System Replicates.

Antigen Excess (AGXS) Testing

Introduction

Antigen excess (AGXS) testing can be enabled or disabled for an individual chemistry. The enabling or disabling of AGXS from Sample Options applies only to the current sample.

If AGXS testing is applicable to a chemistry, a check box appears beside that chemistry in the Sample Options dialog box.

AGXS Testing Default

The default for AGXS testing is defined in Setup and indicated by the check box. (Refer to Table 7.6.)

Table 7.6 AGXS Testing

When the check box is...	AGXS testing is...	And on the Program Sample screen...
checked,	enabled for the chemistry. Every time the test is run it will be tested for antigen excess.	a small green box appears on the chemistry button on the chemistry menu.
unchecked,	disabled for the chemistry. The chemistry will not be tested for antigen excess.	there is no green box on the chemistry button on the chemistry menu.

Enabling/Disabling AGXS Testing

Follow the steps below to enable or disable AGXS testing.

Step	Action
1	Select **Sample Options [F3]** from the Program Sample screen.
2	Choose the AGXS check box beside the desired chemistry.
3	Select the check box to toggle it to "checked" or "unchecked".

Additional Information

Refer to CHAPTER 3, *Theory of Operation*, Antigen Excess Testing for more general information on antigen excess.

Refer to CHAPTER 5, *System Setup*, Configuring Antigen Excess Testing for more information on defining the default for AGXS testing.

Selecting Non-Standard Dilutions

Introduction

A Non-Standard Dilution can be selected for an individual chemistry from a pre-defined list. The list contains Non-Standard Dilutions that are specific for each chemistry. The default starting dilution is indicated as selected when the Non-Standard Dilutions screen is first displayed. (Refer to Figure 7.8.)

When a Non-Standard Dilution is selected for a chemistry:

- it is used as the starting dilution for the chemistry.
- it applies only to the chemistry for the current sample.
- it is displayed beside the chemistry on the Sample Options dialog box.
- it will remain selected if the Non-Standard Dilution dialog box is displayed again for the same sample.

If antigen excess testing is enabled for a chemistry, it will still be performed when a Non-Standard Dilution is selected.

Sample programming from a host computer assumes the default starting dilution for each chemistry. A Non-Standard Dilution can be selected by editing the sample program before the run begins. Alternatively, a Non-Standard dilution can be programmed to be the default starting dilution. Refer to CHAPTER 5, *System Setup*, Selecting Non-Standard Dilutions as Default for Each Chemistry. This would allow sample programming from the host computer to begin at a dilution defined by the user.

A Non-Standard Dilution can be useful when a specific sample is known to have unusually low or high test results.

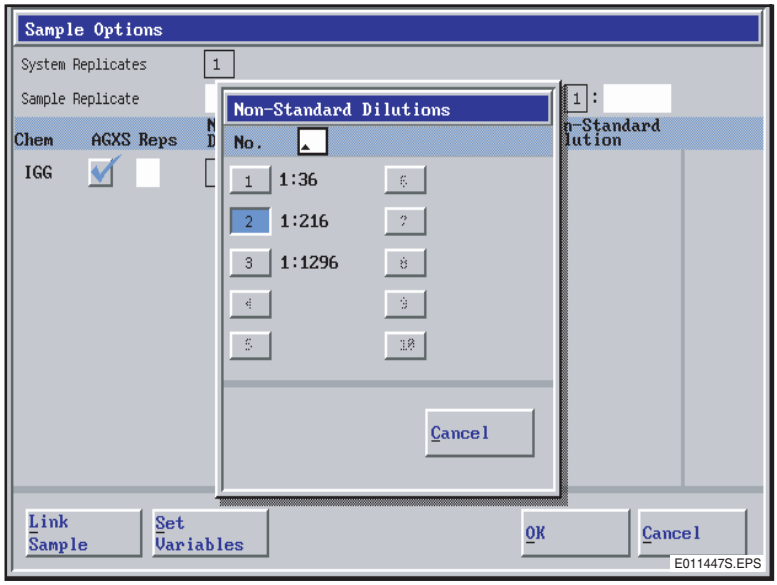

Figure 7.8 Non-Standard Dilutions Dialog Box

Selecting a Non-Standard Dilution

Follow the steps below to select a Non-Standard Dilution from the Non-Standard Dilution list.

Step	Action
1	Change the Sample Type if different from the default Sample Type. (Refer to Selecting a Sample Type in this chapter.)
2	Select the chemistry desired.
3	Select **Sample Options [F3]** from the Program Sample screen.
4	Select the options button < ▼ > in the "Non-Standard Dilution" column that is beside the desired chemistry.
5	Type the number of the desired dilution and press **[Enter]**. OR Select the number beside the desired dilution.

Entering an Off-line Dilution Factor

Introduction

An Off-line Dilution Factor may be entered for a sample through the Sample Options screen. This factor represents a user prepared dilution of the sample. The Default Dilution normally used in the calculation of concentration for an analyte should be considered in the creation of a user prepared dilution.

The Off-Line Dilution Factor applies to the current sample only. When a sample using an off-line dilution factor is run, the system makes **no** further dilutions. It runs the sample "as is"; it does **not** create the default dilution or any out-of-range dilutions. Each result is automatically multiplied by the user-entered off-line dilution factor.

Example:
To assay an IGA sample at twice the default dilution:

- To make twice the dilution of the analyte being assayed the user must know the Default Dilution and appropriate diluting fluid for the analyte.
- Find the Default Dilution and diluting fluid for IGA in the IMMAGE Immunochemistry Systems *IGA Instructions For Use*.
  - The Default Dilution for IGA is 1:36.
  - The diluting fluid for IGA is DIL1.
- Prepare the Default Dilution for the analyte being tested.
  - For IGA, make a 1:36 dilution by diluting 1 part serum in 35 parts of DIL1.
- Prepare a 1:2 dilution of the previously prepared Default Dilution.
  - Dilute 1 part of Default Dilution in 1 part of DIL1.
  - The final dilution factor is now 1:72.
- Enter an Off-line Dilution Factor of 72 during sample programming.
- The system will produce a final result by automatically multiplying each test result from the sample by 72.

Alternatively the user may run an off-line dilution without selecting to use this feature. The system will perform tests using the default dilution and out-of-range dilutions as required. The user would then need to manually multiply all test results for the sample by the user-prepared dilution factor.

Entering Off-line Dilution Factor

Follow the steps below to enter an Off-line Dilution Factor.

Step	Action
1	Select **Sample Options [F3]** from the Program Sample screen.
2	Choose the **Off-line Dilution Factor** field.
3	Enter the factor by typing the number of total parts of diluent + sample (1.01-9999.99), and press **[Enter]**.

CAUTION

If a non-standard or off-line dilution is selected, a condition of antigen excess could exist which may not be detected by the IMMAGE 800 System.

When an off-line dilution is selected, diluent incompatibility is not detected by the IMMAGE 800 System. Only chemistries using the same diluent type should be run on a sample with an off-line dilution preparation.

Linking/Unlinking Samples

Introduction

Some special calculations use the test results from two different samples. The Sample IDs of both samples must be linked so the calculation can be performed.

Samples can also be unlinked.

Linking Samples

Follow the steps below from the Sample Program screen to link two samples.

Step	Action
1	Program one of the samples to be linked. Select **Save/Next [F10]**.
2	Enter a Sample ID, select chemistries, and program any additional information for the other sample to be linked.
3	Select **Sample Options [F3]**.
4	Select <**Link Samples**>. (Refer to Figure 7.9.)
5	Type the Sample ID of the saved sample to be linked to the sample being programmed.
6	Select <**OK**> to save the link and return to the Sample Options dialog box. OR Select <**Cancel**> to return to the Sample Options dialog box without linking the samples.

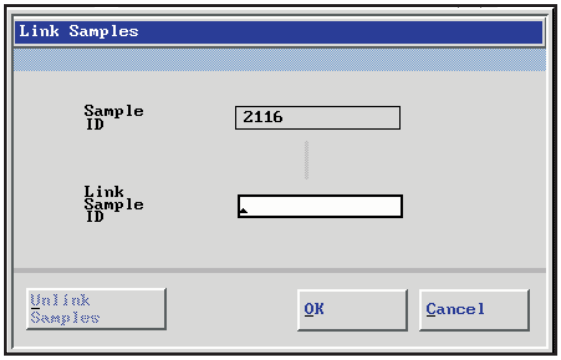

Figure 7.9 Link Samples Dialog Box

Unlinking Samples

Follow the steps below to unlink two samples.

Step	Action
1	Display one of the linked samples by entering the Sample ID in the Program Sample screen.
2	Select **Sample Options [F3]**.
3	Select **<Link Samples>**.
4	Select **<Unlink Samples>**.
5	Select **<OK>** to unlink the samples and return to the Link Samples dialog box. OR Select **<Cancel>** to return to the Link Samples dialog box without unlinking the samples.

Running Linked Samples

Follow the steps below to run linked samples.

Step	Action
1	Load the linked samples onto the instrument.
2	Select **Main** from the menu bar. AND Select **Run**.
3	Select **<OK>** in the Check Dilution Segments dialog box to start the run. OR Select **<Cancel>** to exit without starting the run.

Setting Variables

Introduction

Variables are used in Custom Calculations as placeholders in formulas to represent more than one number (value). The numeric value of the variables can be entered on the Set Variables screen.

A maximum of six variable values may be entered. The values apply only to the current sample.

Setting the Variables

Follow the steps below to set the variables.

Step	Action
1	Select the desired chemistry(ies) from the Program Sample screen.
2	Select **Sample Options [F3]**.
3	Select <**Set Variables**>.
4	Select an options button < ▼ > from the Set Variables dialog box.
5	Select the number beside the desired variable. OR Enter the number of the desired variable in the **Option No.** field. OR Select <**Cancel**> to return to the Set Variables dialog box.
6	Enter the value of the variable in the **Value** field and press **[Enter]**.
7	Select <**OK**> to set the variable and return to the Sample Options dialog box. OR Select <**Cancel**> to return to the Sample Options dialog box without setting the variable.

Additional Information

Refer to CHAPTER 5, *System Setup*, Calculations Setup, for more information on special calculations.

Programming a Control

Introduction

Control names and lot numbers are defined in QC, along with information including:

- Sample Type
- Control chemistries
- Up to eight unique Control IDs
- Mean and Standard Deviation

Controls may be identified by bar code labels or by Rack and Position.

Control results are compared to the ranges defined by the mean and standard deviation.

Controls cannot be included during batch programming of patient samples.

Control IDs

Control IDs, like Sample IDs, must be unique for each sample within a run.

Control Batch [F1] cannot be accessed when control definitions do not include Control IDs.

Sample Control IDs must be used when programming controls in batch.

Control IDs, unlike Sample IDs, can be reused after the control sample is run. When the sample status of a Control ID is *Complete* or *Incomplete*:

- the Control ID can be selected to run again.
- the status will automatically change to *Sample Required*.
- any *Pending* tests are deleted from an *Incomplete* control sample program.

Exception: if controls are programmed by bar code, the system will try to run *Pending* tests from an *Incomplete* sample.

Control Chemistries

When a control is selected, only the chemistries defined for the Control Name are available. The defined chemistries can be selected and deselected from the Program Control screen.

A manually programmed control will always be programmed for the chemistries that were selected last.

Example:

- Control X is defined for IGG, IGA, and IGM.
- IGA and IGM are deselected before the control is run.
- The next time the control is programmed, only IGG will be selected.

Bar Coded Controls

Bar code labels can be used to identify control samples. The bar code must encode a defined Control ID.

If the same control is repeated in different positions during a run, each control sample must have a different bar coded Control ID.

All defined control chemistries will be run automatically when a Control ID is identified by bar code.

Exception: the system will try to run *Pending* tests from an *Incomplete* sample.

> NOTICE
> After pausing or stopping the system, completed bar coded control samples will be run again when the system is started.

When using a barcoded QC, the control will rerun during Pause/Resume.

Host Programming of a Control

If a control is programmed by a host computer, the Control ID sent from the host:

- must be programmed for only the chemistries defined for that control.
- must not match any patient Sample ID that is sent for the same run.

Programming a Non-bar Coded Control

Follow the steps below to program a non-bar coded control.

Step	Action
1	Select **Select Control [F5]** from the Program Sample screen.
2	Type the number of the desired control and press **[Enter]**. (Refer to Figure 7.10.) OR Select the number beside the desired control. OR Select **<Cancel>** to return to the Program Sample screen without selecting a control.
3	Enter a Rack and Position number. (Refer to Figure 7.11.) AND Select the options button < ▼ > beside the Control ID field to select a Control ID. (A Control ID is optional.) NOTICE If a control is programmed with a Control ID and the host sends a patient sample with an ID identical to the control, the programmed control will be deleted.
4	Select or deselect panels and/or chemistries if necessary. Select **Clear Chems [F7]** to deselect all chemistries. (Refer to Selecting Chemistry Tests by Panel and Selecting Chemistry Tests by Chemistry in this Section.)
5	Select **Sample Options [F3]** if needed. (Refer to Selecting Sample Options in this Section.)
6	Select **Select Control [F5]** to return to the Select Control dialog box without saving the control program. OR Select **Save [F10]** to save the control program and return to the Program Sample screen. OR Select **Cancel Edit [F9]** to return to the Program Sample screen without saving the control program.

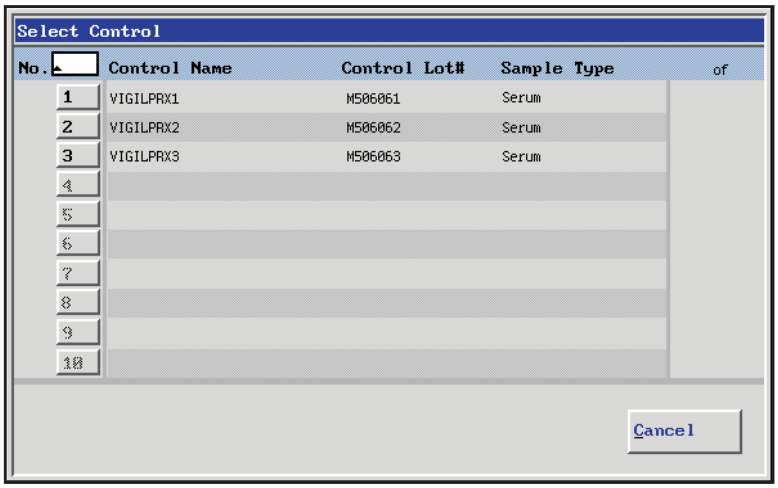

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Figure 7.10 Select Control Dialog Box

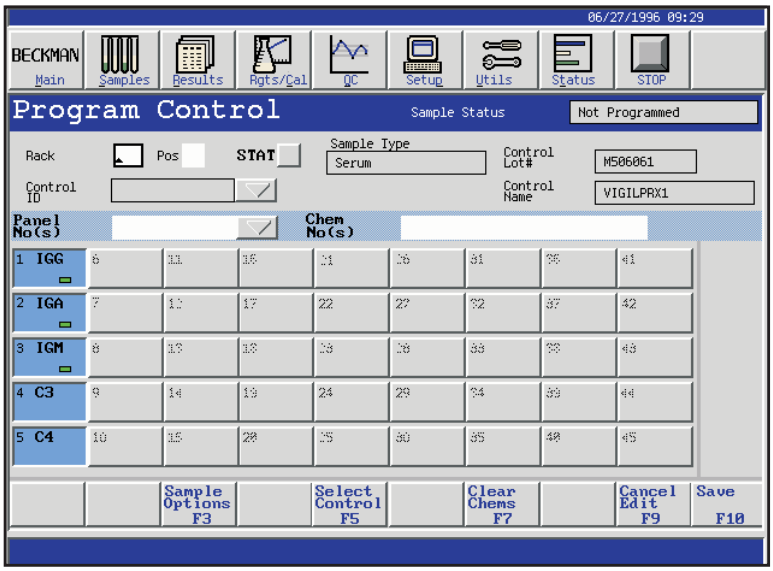

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Figure 7.11 Program Control Screen

Alternative Methods of Selecting Controls

In addition to using **Select Control [F5]**, the following methods can be used to select a control:

Table 7.7 Alternative Methods of Selecting Controls

Method	If...	then...
1	the Control ID is known,	type the Control ID in the **Sample ID** field of the Program Sample screen.
2	the Rack and Position of a completed control is known,	type the Rack and Position number in the **Rack** field and **Pos** field of the Program Sample screen.

Additional Information

Refer to CHAPTER 9, *Quality Control*, Defining a Control for more information on defining controls.

Programming a STAT

Introduction

A sample which requires priority can be programmed as a STAT. The running priority for samples is:

1. STAT calibration
2. STAT samples/controls
3. Routine calibration
4. Routine samples/controls

A STAT sample is run before any routine patient or control sample on the carousel, regardless of the Rack and Position numbers.

A STAT calibration is run before a STAT sample. A STAT calibration must be programmed when the calibration is requested.

If multiple STAT samples are programmed, they will be run in the order they are placed around the sample carousel, in a counter-clockwise direction.

Programming a STAT Sample

Follow the steps below to program a STAT sample.

Step	Action
1	Select **Samples** from the menu bar.
2	Select the **STAT** check box. This can be done at any time while programming a sample.

Additional Information

Refer to CHAPTER 6, *Reagents/Calibration,* Requesting and Canceling Calibration, for more information on programming a STAT calibration.

Selecting Save/Next

Introduction

When all desired information is programmed for a sample, select **Save/Next [F10]** to program additional samples.

A message will display if there is not enough information entered to save the sample program.

If a minimum of a sample identifier (Rack and Position or Sample ID) and a chemistry is programmed for a sample, the sample program will be automatically saved if the Program Sample screen is exited without selecting **Save/Next [F10]**.

Automatic Incrementing

If a Rack number and Position number are entered for the current sample, selecting **Save/Next [F10]** will automatically increment to the next position within the rack according to the following guidelines.

Table 7.8 Automatic Incrementing

If the next position on the rack is...	then Save /Next will display...
not programmed,	a blank Program Sample screen with the current Rack and a new Position.
programmed, but not run,	the corresponding sample program.
complete, incomplete, or programmed for a rerun or calibrator,	the next position on the rack that is not programmed or is programmed but not run.

Selecting **Save/Next [F10]** from the last position on a rack will display a blank Program Sample screen.

Programming a Batch of Samples

Overview

Introduction

Multiple samples can be programmed as a batch with the same chemistries, Sample Type, Sample Comment, and Sample Options.

Up to 100 samples can be programmed in a batch. A maximum of 72 samples can be placed on the sample carousel at one time. Additional samples in a batch can be placed on a subsequent run.

Batches and individual samples can be programmed in the same run.

Entering/Editing a Batch Sample Program

Introduction

The information to be applied to all samples in a batch is entered in the Program Sample screen. This information can be edited later for individual samples within the batch.

Entering a Batch Program

Follow the steps below to enter a sample program to be applied to a batch of samples.

Step	Action
1	Select **Samples** from the menu bar.
2	Select chemistries from the Program Sample screen. (Refer to Programming a Sample, Selecting Chemistry Tests by Panel and Selecting Chemistry Tests by Chemistry, in this chapter for more information.)
3	Select Sample Type if the Sample Type default is to be changed for the batch. (Refer to Programming a Sample, Selecting a Sample Type, in this chapter for more information.)
4	Select Sample Comment if a Sample Comment is to be entered for the batch. (Refer to Programming a Sample, Entering a Sample Comment, in this chapter for more information.)
5	Select **Sample Options [F3]** if replicate, AGXS testing, or dilution defaults are to be changed for the batch. (Refer to Programming a Sample, Selecting Sample Options, in this chapter for more information.)

Identifying Batch Samples

Introduction

After a sample program is entered for a batch, the samples in the batch must be identified.

The procedure for identifying samples in a batch is different when Bar Code Priority is enabled in Setup than when Bar Code Priority is disabled.

Identifying Batch Samples, Bar Code Priority Enabled

Follow the steps below to identify which samples are to be included in a batch if bar code priority is enabled in Setup.

Step	Action
1	Select **Program Batch [F4]** when all information to be applied to the batch is programmed.
2	Type the Sample ID for each sample in the batch. (Refer to Figure 7.12.) Rack and Position numbers can be entered for samples that are not bar coded.
3	Select **End Batch [F10]** when all Sample IDs are entered.

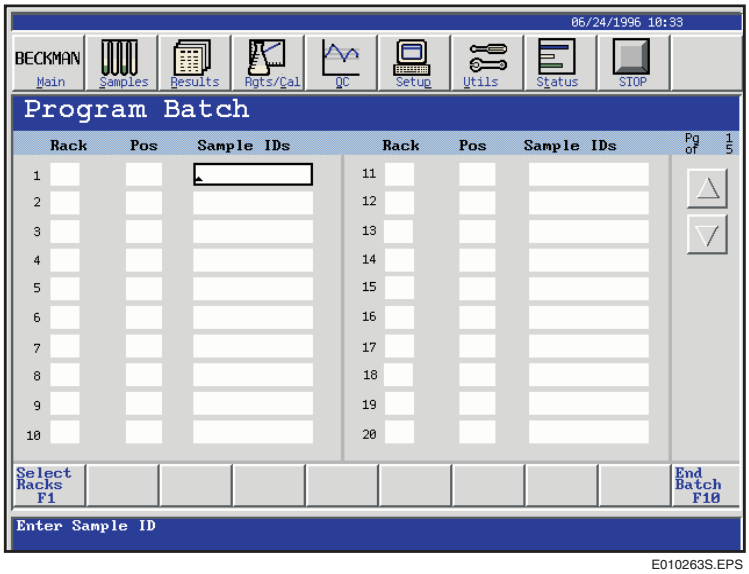


Figure 7.12 Program Batch Screen, Bar Code Priority Enabled

Identifying Batch Samples, Bar Code Priority Disabled

Follow the steps below to identify which samples are to be included in a batch if Bar Code Priority is disabled in Setup.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Program Batch [F4] when all information to be applied to the batch is programmed.</td></tr>
<tr><td>2</td><td>Type the rack numbers to be used for the batch. Numbers can be separated by a comma as a series and/or by a dash as a range. (Example: 1, 2, 5-8) (Refer to Figure 7.13.)
<table>
<tr><th>If the racks are...</th><th>then...</th></tr>
<tr><td>listed as "available"</td><td>Press [Enter] and proceed to Step 3.</td></tr>
<tr><td>not listed as "available"</td><td>Type the rack numbers that need to be cleared.

Select <Clear Racks>.
AND
Select <OK> to confirm the racks and repeat Step 2 for "available" racks.
OR
Select <Cancel> to return to the Select/ Clear Racks dialog box without clearing the racks.</td></tr>
</table></td></tr>
<tr><td>3</td><td>Type the number of samples to be included in the batch. This number must be less than or equal to the number displayed beside Samples available to program.</td></tr>
<tr><td>4</td><td>Select <OK> to proceed to the Program Batch screen.

Rack and position numbers will be displayed, corresponding to the racks selected and the number of samples entered. (Refer to Figure 7.14.)</td></tr>
<tr><td>5</td><td>Type the desired Sample ID beside each Rack and Position.</td></tr>
<tr><td>6</td><td>Select End Batch [F10] when all Sample IDs are entered.</td></tr>
</table>

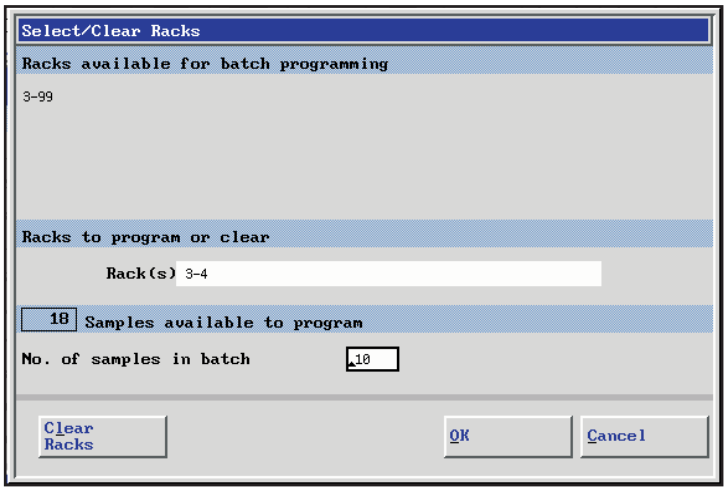


Figure 7.13 Select/Clear Racks Dialog Box

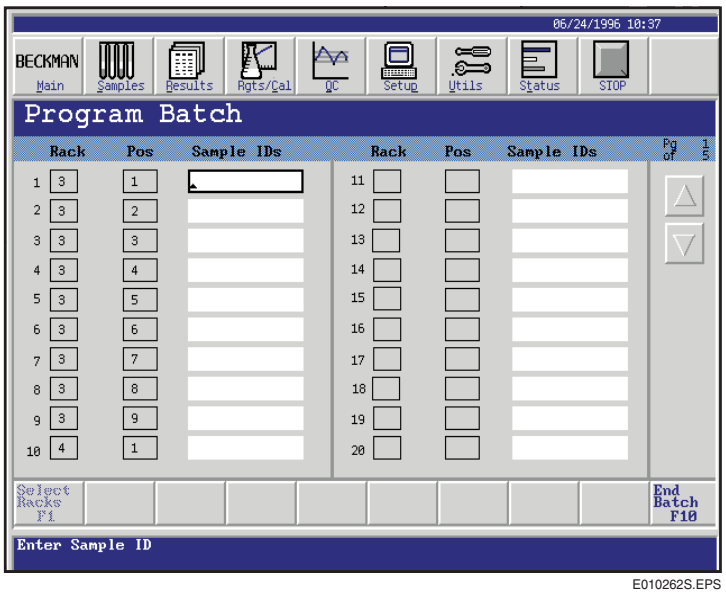


Figure 7.14 Program Batch Screen, Bar Code Priority Disabled

Additional Information

Refer to CHAPTER 5, *System Setup*, Bar Code Setup, for more information on enabling and disabling Bar Code Priority.

Editing Samples Within a Batch

Individual samples within a batch can be edited after the batch samples are identified. Editing can include entering patient demographic information. Follow the steps below to edit an individual sample within a batch.

Step	Action
1	Select **Samples** from the menu bar.
2	Type the Rack number and Position number. OR Type the Sample ID of the desired sample.
3	Edit the desired information for the sample.
4	Select **Save/Next [F10]**.
5	Repeat Steps 2-4 to edit additional samples.

Loading and Starting a Run

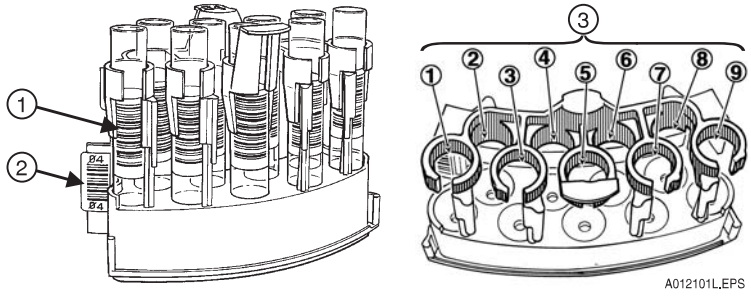
Loading Samples

Load Samples

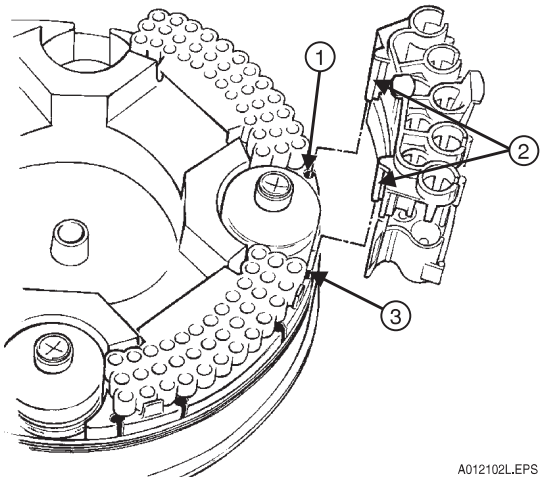
To load prepared sample containers into racks and onto the IMMAGE 800, follow these steps.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Determine in which rack and position to place sample containers.
<table>
<tr><th>If the sample container...</th><th>Then...</th></tr>
<tr><td>is bar code labeled,</td><td>Samples may be placed in any position of any rack of the proper size (no Load List is required).</td></tr>
<tr><td>is not bar code labeled,</td><td>• Select Samples from the menu bar,
• Select Load List [F9] from the Program Samples screen,
• Type the number(s) of the rack(s) programmed for the samples to be processed, and
• Print or display the Load List to identify the proper position for each sample.</td></tr>
</table></td></tr>
</table>

(1 of 3)

Step	**Action**, continued
2	Place prepared sample containers into sample racks and verify that each container is: • placed into a rack which matches the container size (four rack sizes are available: 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, and 16 × 100 mm), • seated in the depression at the bottom of the rack, and • positioned so that bar code labels (1), if used, face in the same direction as the rack bar code label (2). Position numbers (3).  Figure 7.15

(2 of 3)

Step	**Action**, continued
3	• Confirm the instrument status is in *Standby*. • Place the sample rack in any position on the sample carousel. Notes: Position the rack so that both rack pegs (2) slide into holes in the carousel (1), (3). Press the advance button to rotate the carousel to additional positions. Racks containing calibrators must be placed in sample carousel positions A and/or B only.  Figure 7.16

(3 of 3)

Pre-run Checklist

Pre-run Checklist

With the IMMAGE 800 in *Standby*, prepare for the start of a run by performing these tasks or verifying they have been performed. Refer to appropriate sections of this guide for instructions on how to perform each task.

- Perform daily maintenance.
- Check status of dilution segments, clear and replace if necessary.
- Check status of reagent cartridges, load if necessary.
- Check status of reaction buffers and sample diluents, replace if necessary.
- Check sample rack status, clear racks if necessary.
- Check calibration status, calibrate if necessary.
- Prepare sample containers.
- Program control or patient requests, if necessary.
- Load samples.

Starting the Run

When all sample racks are on the sample carousel and the run is ready to be processed, follow the steps below.

Step	Action
1	Close the covers.
2	Select **Main** from the menu bar.
3	Select <**Run**>.
4	Select <**OK**> if dilution segment status is *OK*, AND Observe the instrument occasionally during the first 5 minutes of operation to respond to any messages that might be displayed.

Pausing a Run

Overview

Introduction

When the system is running the user may select the pause option to load samples without waiting for the entire system to complete all actions.

When pausing a run:

- The user can pause the system for a sample load.
- The user can pause the system completely.
- The user can cancel the pause request.

System Pause

Introduction

If the system is running and the user selects the pause option from the IMMAGE 800 main screen, the user may choose to completely pause the system. When the user selects pause, the system completes any sample that is in process and goes into *Standby* after the pause.

Step	Action
1	During the run, select **Pause** at the main screen.
2	Select **System Pause** at the Request Pause screen. (Refer to Figure 7.17.) The system status changes to *Pausing*. The system completes any sample that is in process, then goes into Standby mode.

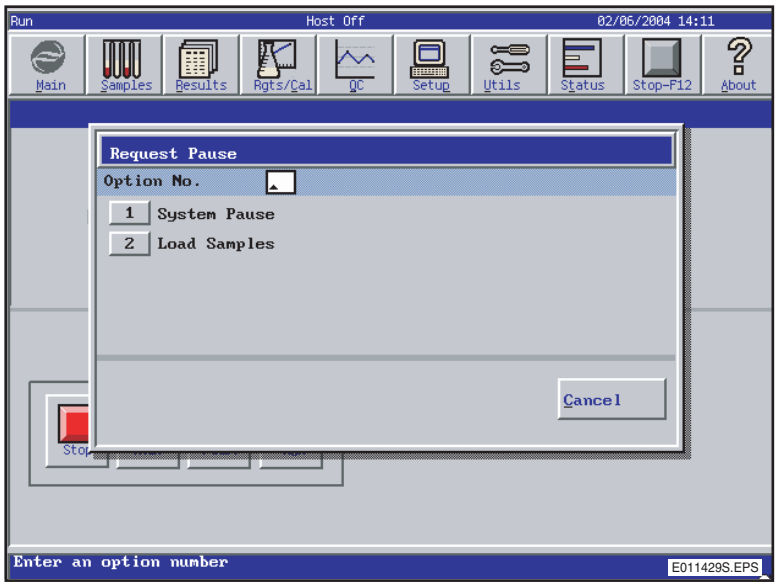


Figure 7.17 Request Pause Screen

Canceling a Pause Request

Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.17.)

Restarting a Run

Select the **<RUN>** button to restart the paused run.

Pausing to Load Samples

Introduction

If the system is running and the user selects the pause option from the IMMAGE 800 main screen, the user may choose to pause the system for a sample load. This type of pause allows the user to load samples without waiting for the entire sytem to complete all actions. The system provides an estimated time period before samples can be loaded, based on the time when sample additions/removal is allowed.

Tests currently running on the reaction wheel will continue. No further dilutions are created. While the remaining tests continue, samples may be added or removed. The user has the option to resume operations or let the system pause to *Standby*.

Pausing-Load Samples

Step	Action
1	Program new samples on a rack that is not on the system.
2	During the run, select **<Pause>** from Main screen. It is recommended not to pause the system during calibration because it may result in a calibration failure.
3	Select **Load Samples** at the Request Pause screen. (Refer to Figure 7.17.) Note that the status screen shows "Pausing-Load Samples" and the estimated time period before you can add or remove samples. The time counts down in 5 second increments to zero. OR Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.17.)
4	Wait until the "OK to load samples" message appears on the screen. (Refer to Figure 7.18.) **CAUTION** **To avoid personal injury, DO NOT load or remove samples until the "OK to load samples" message appears on the screen.** When the message appears, select **<OK>**. The system status changes to "Pausing-OK to load sample."

(1 of 2)

Step	**Action**, continued
5	Advance the sample wheel and load samples. NOTICE The amount of time to load new samples and to resume the run depends on the number of samples being processed. If a small number of samples are being processed, there may not be enough time to resume the run. In this case, the sytem will return to *Standby*. Select **<RUN>** to restart the system.
6	Go the the Main screen and select **<RUN>**. The system status will change to *Resuming* and *Run*. **CAUTION** **To avoid personal injury, DO NOT load samples once the RUN button is selected.**

(2 of 2)

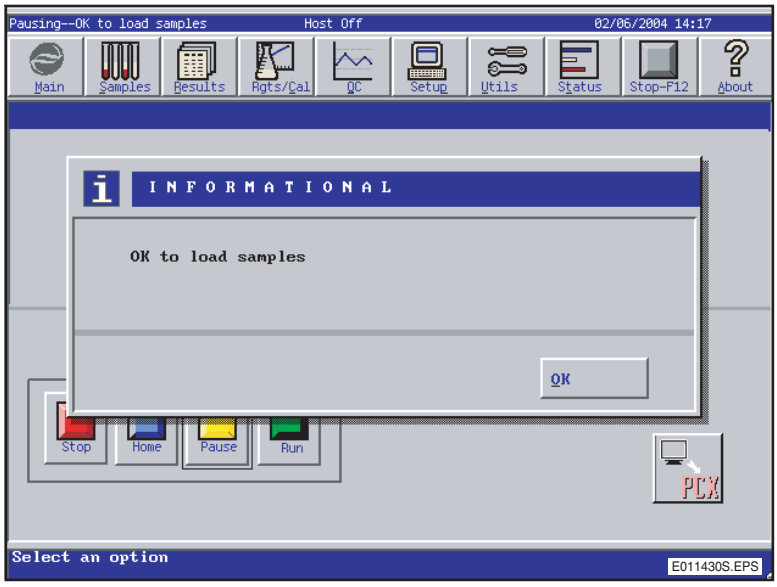


Figure 7.18 OK to Load Samples Message

Canceling a Pause

Select the **<Cancel>** button to cancel the pause request. This will not affect the current run. (Refer to Figure 7.17.)

Resume Operations

If the user chooses to resume operations before the system goes to *Standby*, the system continues the pause process until all currently running tests are complete. When all operations are complete, the system reinventories the sample wheel and automatically returns to the running state. If the user resumes operations after the system goes to *Standby*, the system reinventories the sample wheel and returns to a running state. Incomplete samples requiring additional dilutions continue processing at the next required sample dilution.

Dilutions created before selecting *Pause*, will not be reused. In some instances, the system may have to remake previously made dilutions, and additional sample volume may be required.

When using a barcoded QC, the control will rerun during Pause/Resume.

Rerunning a Sample

Overview

Introduction

A sample can be rerun when it has a status of *Complete* or *Incomplete*. If the system is running, a sample programmed to be rerun will be added to the current run. If the system has returned to a *Standby* status, a new run must be started.

Several options are available when rerunning samples:

- The original sample programs can be edited before rerunning.
- The original sample programs can be rerun.
- Selected chemistries can be rerun for a group of samples.
- The initial dilution made in the dilution well can be reused. The default is to remake a dilution.

Rerun Results

When tests are rerun:

- The rerun results replace the original results.
- Rerun results are indicated by a flag (R) on the Laboratory Report.
- After a sample is rerun, all results will be collated on the result report.

Selecting Samples to be Rerun

Introduction

Samples can be selected for rerunning by Sample ID and/or a range of Sample IDs, or by Rack and Position. (Refer to Figure 7.19.)

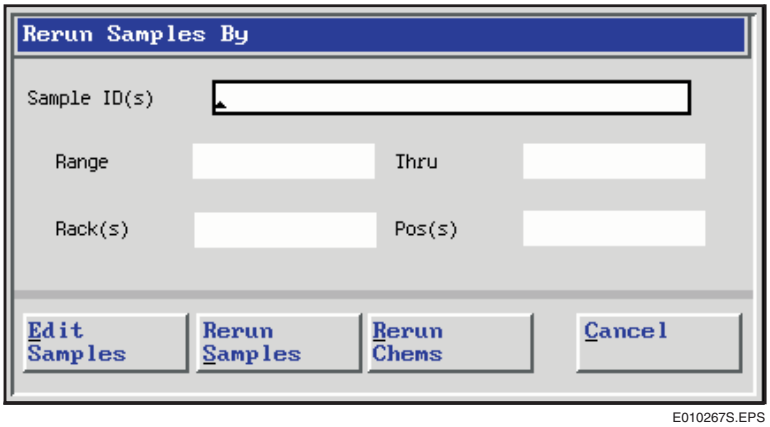


Figure 7.19 Rerun Samples Dialog Box

Rerunning by Sample ID

Follow the steps below to enter Sample IDs for rerun. Both individual Sample IDs and a range of Sample IDs can be entered.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Rerun Samples [F6] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To enter...</th><th>type...</th></tr>
<tr><td>individual Sample IDs,</td><td>the Sample IDs for rerun in the Sample ID(s) field (up to 43 characters, spaces are not allowed).

Sample IDs can be separated by a comma as a series.</td></tr>
<tr><td>a range of Sample IDs,</td><td>the Sample ID at the beginning of the range in the Range field.

Press [Enter].

Type the Sample ID at the end of the range in the Thru field.</td></tr>
<tr><td>a range of alphanumeric Sample IDs,</td><td>the individual Sample IDs to be rerun in the Sample IDs field, separated by a comma.</td></tr>
<tr><td>all Sample IDs,</td><td>"0" in the Range field.

Press [Enter].

Type zzzzzzzzzzzzzzz in the Thru field.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select a button from the bottom of the dialog box.</td></tr>
</table>

Rerunning by Rack and Position

Follow the steps below to enter Rack(s) and Position(s) for rerun.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Rerun Samples [F6] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>Type the rack number(s) desired for rerun in the Rack(s) field (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range. (Example: 1, 2, 5-8)</td></tr>
<tr><td>3</td><td>
<table>
<tr><th>If...</th><th>then...</th></tr>
<tr><td>one rack number is entered,</td><td>Press [Enter] to access the Pos(s) field.

Type the position numbers desired for rerun (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range.

Note: If one rack number and no position number is entered, all positions on the rack are automatically selected.</td></tr>
<tr><td>more than one rack number is entered,</td><td>• All positions on each rack are automatically selected.
• The Pos(s) field cannot be accessed.</td></tr>
</table>

A sample in a bar coded container, originally programmed by entering the Sample ID or the Control ID only, cannot be rerun by Rack and Position when sample is, later, placed in a non-bar coded container. The label must be recognized to rerun the sample.

If the Rack and Position was programmed but not scanned from the sample carousel, rerun of the sample is allowed using a non-bar coded container.</td></tr>
<tr><td>4</td><td>Select a button from the bottom of the dialog box.</td></tr>
</table>

NOTICE

When rerunning samples by Rack and Position, the samples must be kept in their original rack number and position number on the sample carousel.

Rerunning with Non-Standard Dilutions

If the original sample was programmed to run with a standard dilution, and later you changed the defaulted standard to a non-standard dilution, the sample will be rerun with the standard dilution.

Editing Sample Programs Before Rerunning

Introduction

After samples are selected to be rerun, the individual sample programs can be edited. The following sample program information is allowed to be edited:

- chemistries (may be added or deleted)
- STAT check box
- Sample Comment
- Test Replicates
- AGXS testing
- Non-standard dilutions

Reuse Dilution Option

There is an option to reuse the dilution made in the dilution well when a sample was originally run. (Refer to "Editing Programs Before Rerun," Step 3.) This option can be useful when sample volume is limited.

Reuse Dilution cannot be used if the necessary dilution segments were cleared or removed from the sample carousel.

If Reuse Dilution is selected and there is not enough diluted sample available in the dilution well, the dilution will be remade in a new well.

Note: The default is to remake a dilution.

CAUTION

Due to the possibility of sample evaporation over time, the Reuse Dilution feature should be used with discretion.

Clear Chems Option

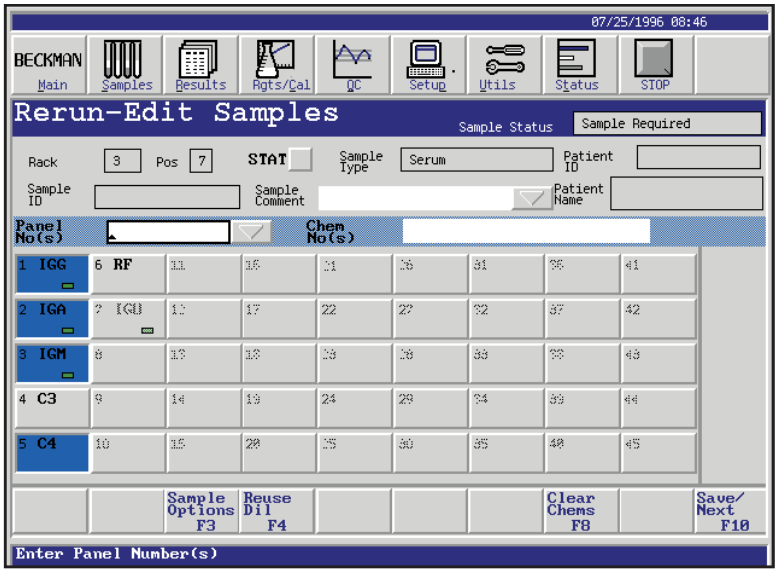
There is an option to clear all of the chemistries originally selected for a sample. (Refer to "Editing Programs Before Rerun," Step 3.)

This option can be useful when the original sample program had several chemistries selected, and only one or two chemistries are to be rerun.

Editing Programs Before Rerun

Follow the steps below to edit individual sample programs before rerunning.

Step	Action
1	Select **Rerun Samples [F6]** from the Program Sample screen and select samples to be rerun. (Refer to Rerunning a Sample, Selecting Samples to be Rerun in this Section for more information.)
2	Select **Edit Samples**.
3	Perform any of the following: (Refer to Figure 7.20.) • Edit the desired sample program information. (Refer to Programming a Sample in this chapter for more information.) • Select **Reuse Dil [F4]** to reuse the original dilution. Select **<OK>** to confirm. • Select **Clear Chems [F8]** to clear all original chemistry selections. Then select the desired chemistry(s) to be rerun.
4	Select **Save/Next [F10]** to: edit the next sample. OR return to the Sample Program screen when all samples selected for rerun are edited.



E010304S.EPS

Figure 7.20 Rerun-Edit Samples Screen

Rerunning Original Sample Programs

Introduction

Samples can be rerun with no change to the original sample programs.

All initial dilutions will be remade when original sample programs are rerun. The Reuse Dilution option is only available through **Edit Samples**.

Rerunning Original Programs

Follow the steps below to rerun original sample programs.

Step	Action
1	Select **Rerun Samples [F6]** from the Program Sample screen and select samples to be rerun. (Refer to Rerunning a Sample, Selecting Samples to be Rerun in this section for more information.)
2	Select **Rerun Samples**. The Rerun Samples dialog box will close and the Program Sample screen will appear.

Rerunning Selected Chemistries

Introduction

Through Rerun Chem, one or more chemistries can be selected for all samples which are to be rerun. The samples will then be programmed for only those selected chemistries.

Only a chemistry which was selected in the original sample program can be selected in Rerun Chem. The ability to add a new chemistry is only available through Edit Samples.

Selecting Chemistries for Rerun

Follow the steps below to select chemistries to be rerun.

Step	Action
1	Select **Rerun Samples [F6]** from the Program Sample screen and select samples to be rerun. (Refer to Rerunning a Sample, Selecting Samples to be Rerun in this section for more information.)
2	Select <**Rerun Chem**>.
3	Select the chemistry(s) to be rerun. (Refer to Figure 7.21.) (Refer to Programming a Sample, Selecting Chemistry Tests by Chemistry in this chapter for more information.)
4	Select <**OK**> to run the chemistry(s). OR Select <**Cancel**> to return to the Program Sample screen without rerunning.

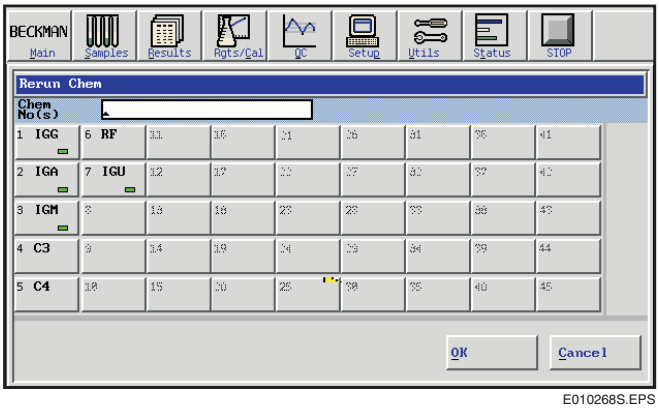


Figure 7.21 Rerun Chem Dialog Box

Rerunning Controls

Introduction

Bar coded and non-bar coded controls can be rerun. These controls are defined in the QC program.

Rerunning Original Control Programs

Follow the steps below to rerun original control programs.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Choose one of the following types of control samples.
<table>
<tr><th>If the control sample has been run and…</th><th>then…</th></tr>
<tr><td>is not bar coded,</td><td>all chemistries defined for the control may be rerun. Go to Step 2.</td></tr>
<tr><td>has completed results and is bar coded,</td><td>all chemistries defined for the control may be rerun. Go to Step 3.</td></tr>
<tr><td>has incomplete results and is bar coded,</td><td>only the incomplete chemistries defined may be rerun. Go to Step 3.</td></tr>
</table></td></tr>
<tr><td>2</td><td>Enter the rack and position of the previously run non-bar coded control.</td></tr>
<tr><td>3</td><td>Place the sample on the sample carousel.

Select Run from the main menu.</td></tr>
<tr><td>4</td><td>Select <OK> in the Check Dilution Segments dialog box to start the run.
OR
Select <Cancel> to exit without starting the run.</td></tr>
</table>

Requesting a Load List or Post-run Summary

Overview

Introduction

A Load List or Post-run Summary can be requested at any time.

A Load List contains the following information for each sample, when applicable:

- Rack/Position
- Sample ID
- Patient Name
- Sample Type
- Off-line Dilution Factor
- Chemistries, including replicates
- Sample status
- STAT designation
- Rerun designation

A Post-run Summary contains the following information for each sample:

- Rack/Position
- Sample ID
- Date and time programmed
- Pending tests
- Test status
- Reason for each incomplete test

Requesting a Load List

Introduction

A Load List can be requested by one of the following options:

- Sample ID and/or a range of Sample IDs
- Rack/Position
- Date/Time
- Sample Status

When a Load List is requested, it can be displayed and/or printed. (Refer to Figure 7.22.)

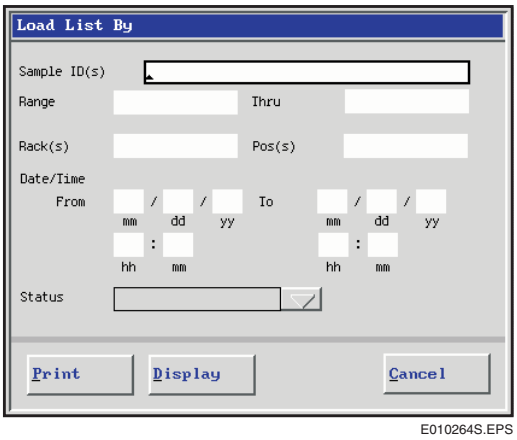


Figure 7.22 Load List Dialog Box

Requesting Load List by Sample ID

Follow the steps below to request a Load List by Sample ID. Both individual Sample IDs and a range of Sample IDs can be entered.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Load List [F9] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To enter...</th><th>type...</th></tr>
<tr><td>individual Sample IDs</td><td>the Sample IDs desired for the Load List in the Sample ID(s) field (up to 43 characters, spaces are not allowed).

Sample IDs can be separated by a comma as a series.</td></tr>
<tr><td>a range of Sample IDs</td><td>the Sample ID at the beginning of the range in the Range field.

Press [Enter].

Type the Sample ID at the end of the range in the Thru field.</td></tr>
<tr><td>a range of alphanumeric Sample IDs,</td><td>the individual Sample IDs to be requested in the Sample IDs field, separated by a comma.</td></tr>
<tr><td>all Sample IDs,</td><td>"0" in the Range field.

Press [Enter].

Type zzzzzzzzzzzzzzz in the Thru field.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select a button from the bottom of the dialog box.</td></tr>
</table>

Requesting Load List by Rack and Position

Follow the steps below to request a Load List by Rack and Position.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Load List [F9] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>Type the rack number(s) desired for the Load List in the Rack(s) field (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range. (Example: 1, 2, 5-8)</td></tr>
<tr><td>3</td><td>
<table>
<tr><th>If...</th><th>then...</th></tr>
<tr><td>one rack number is entered,</td><td>Press [Enter] to access the Pos(s) field.

Type the position numbers desired for the Load List (up to 15 alphanumeric characters). Numbers can be separated by a comma as a series and/or by a dash as a range.

Note: If one rack number and no position number is entered, all positions on the rack are automatically selected.</td></tr>
<tr><td>more than one rack number is entered,</td><td>• All positions on each rack are automatically selected.
• The Pos(s) field cannot be accessed.</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Select a button from the bottom of the dialog box.</td></tr>
</table>

Requesting Load List by Date/Time

Follow the steps below to request a Load List by Date/Time.

Step	Action
1	Select **Load List [F9]** from the Program Sample screen.
2	Type the desired date and time ranges in the **From** fields and **To** fields. (Refer to Table 7.9 for a description of the Date/Time field entries.)
3	Select a button from the bottom of the dialog box.

Table 7.9 Date/Time Field Descriptions

Field	Entries	Notes
Date: From and To	mm: 1-12 dd: 1-31 yy: 0-99	• If only a From date is entered, the load list be requested for the 24-hour period of that date. • The order and the separator character are defined in Setup.
Time: From and To (12-hour format)	hh: 1-12 mm: 0-59 AM/PM: • Select the options button < ▼ > beside the **AM/PM** field. • Select **AM** or **PM**.	• A time entry is optional. If only a date is entered, the load list will be requested for the each 24-hour period in the date range. • Time is not allowed to be entered unless date is entered. • The time format is defined in Setup as 12-hour or 24-hour. • The separator character is defined in Setup. • The 12-hour default is AM.
Time: From and To (24-hour format)	hh: 0-23 mm: 0-59	

Requesting Load List by Status

Follow the steps below to request a Load List by Sample Status.

Step	Action
1	Select **Load List [F9]** from the Program Sample screen.
2	Select the options button < ▼ > beside the **Status** field.
3	Type the number of the desired status. OR Select the number beside the desired status.

Printing a Load List

After an option to request a Load List is entered, the Load List can be printed by selecting **Print**. The Program Sample screen will appear. The Load List will not be displayed.

(Refer to APPENDIX B, *Reports* for an example of a printed Load List.)

Displaying a Load List

After an option to request a Load List is entered, the Load List can be displayed by selecting **Display**. The Load List screen will appear. (Refer to Figure 7.23.)

Page Up and Page Down buttons appear when a displayed Load List covers more than one screen.

A displayed Load List can also be printed from the Load List screen by selecting **Print [F10]**.

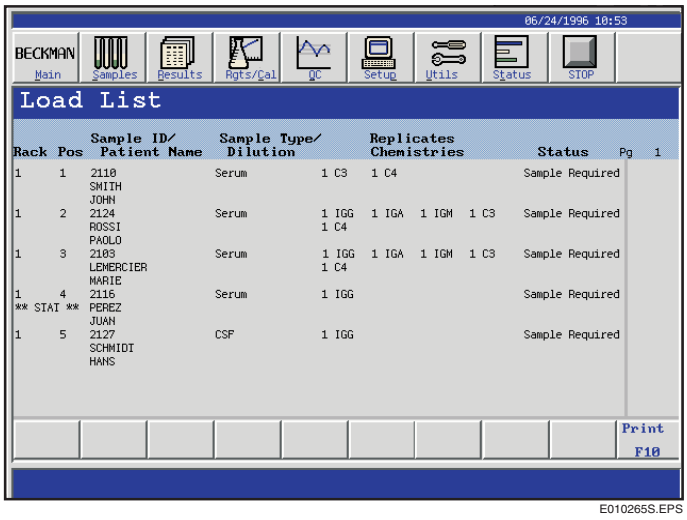


Figure 7.23 Load List Screen

Additional Information

Refer to CHAPTER 5, *System Setup*, Date and Time Setup for more information on defining date and time formats.

Requesting a Post-run Summary

Introduction

The Post Run Summary feature provides a list of samples that are pending or incomplete in reverse chronological order. The summary includes:

- Run date and time
- Rack and position
- Sample ID
- Chemistry name
- Remarks.

The operator has the option to choose the time frame for the Post Run Summary report. The Post Run Summary Time Search includes:

- None
- 12 Hour
- 24 Hour
- 48 Hour
- 72 Hour.

Accessing the Post Run Summary

Follow the steps below to access the Post Run Summary.

Step	Action
1	Select **Samples** from the menu bar.
2	Select **Post Run Summary [F8]**.
3	Select **Print [F10]** to print the Post Run Summary. OR Select an icon from the menu bar to exit the screen.

Setting the Post Run Summary Time Limit

Refer to CHAPTER 5, *System Setup*, Default Setup, "Setting the Default Post Run Summary Time Search."

Clearing a Sample

Overview

Introduction

A sample can be cleared by Sample ID and/or a range of Sample IDs, or by Rack and Position. (Refer to Figure 7.24.) Up to 10,000 Sample IDs can be stored in the database.

When a sample is cleared by Sample ID:

- the associated Position on the Rack becomes available for programming.
- the Sample ID can be reused.
- the Sample Program cannot be recalled by Rack and Position or Sample ID.

When a sample is cleared by Rack and Position:

- the associated Position on the Rack becomes available for programming.
- the Sample ID cannot be reused.
- the sample program cannot be recalled by Rack and Position.

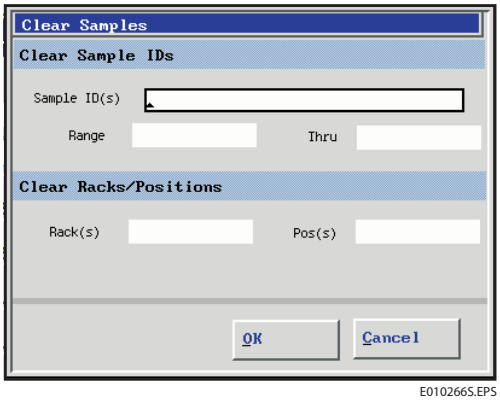


Figure 7.24 Clear Samples Dialog Box

Clearing a Sample by Sample ID

Clearing by Sample ID

Follow the steps below to enter Sample IDs to be cleared. Both individual Sample IDs and a range of Sample IDs can be entered.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Clear Samples [F7] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To enter...</th><th>type...</th></tr>
<tr><td>individual Sample IDs,</td><td>the Sample IDs to be cleared in the Sample ID(s) field (up to 42 characters, spaces are not allowed).

Sample IDs can be separated by a comma as a series.</td></tr>
<tr><td>a range of Sample IDs,</td><td>the Sample ID at the beginning of the range in the Range field.

Press [Enter].

Type the Sample ID at the end of the range in the Thru field.</td></tr>
<tr><td>a range of alphanumeric Sample IDs,</td><td>the individual Sample IDs to be cleared in the Sample IDs field, separated by a comma.</td></tr>
<tr><td>all Sample IDs,</td><td>"0" in the Range field.

Press [Enter].

Type zzzzzzzzzzzzzzz in the Thru field.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select <OK>.

Select <OK> again to confirm the Sample IDs or <Cancel> to return to the Clear Samples dialog box.
OR
Select <Cancel> to return to the Program Sample screen without clearing samples.</td></tr>
</table>

Clearing a Sample by Rack and Position

Clearing by Rack and Position

Follow the steps below to enter Rack(s) and Position(s) to be cleared.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Clear Samples [F7] from the Program Sample screen.</td></tr>
<tr><td>2</td><td>Type the rack number(s) desired to be cleared in the Rack(s) field (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range.</td></tr>
<tr><td>3</td><td>
<table>
<tr><th>If...</th><th>then...</th></tr>
<tr><td>one rack number is entered,</td><td>Press [Enter] to access the Pos(s) field.

Type the position numbers desired to be cleared (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range. (Example: 1,2,5-8)

Note: If one rack number and no position number is entered, all positions on the rack are automatically selected.</td></tr>
<tr><td>more than one rack number is entered,</td><td>• All positions on each rack are automatically selected.
• The Pos(s) field cannot be accessed.</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Select <OK>.

Select <OK> again to confirm the Racks and Positions or <Cancel> to return to the Clear Samples dialog box.
OR
Select <Cancel> to return to the Program Sample screen without clearing samples.</td></tr>
</table>

Routine Operation

Overview

Introduction

The following tables summarize routine operating procedures for various bar code and host computer capabilities. Bar Code Setup and Host Communications Setup should first be appropriately defined. (Refer to CHAPTER 5, *System Setup*.)

Operating in Host Query Mode

Follow the steps below for routine operation of the IMMAGE 800 Immunochemistry System using host query.

Step	Action
1	Check and clear as necessary: • sample racks Check, clear, and replace as necessary: • dilution segments Check: • reagents, buffers, and diluents • wash solution volume (Refer to Preparing for Programming/Running in this chapter.)
2	Request calibrations if necessary. (Refer to CHAPTER 6, *Reagents/ Calibration.*)

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>3</td><td>
NOTICE
If a position is programmed by a bar coded tube with host query, the position will automatically clear when a new bar coded tube is read in that position. The new bar coded tube can then run as a result of the host query for that position.

All manually programmed positions must be cleared manually in order to run any other samples in those positions. If a bar coded tube with a host query is run in a position previously manually programmed, the position will not automatically clear. A conflict warning message will display.

<table>
<tr><th>If samples are...</th><th>then...</th></tr>
<tr><td>bar coded</td><td>load samples in any rack and position.</td></tr>
<tr><td>not bar coded</td><td>program rack and position, and sample ID for each sample. Load samples in the programmed racks and positions. (Refer to Programming a Sample in this chapter.)</td></tr>
</table>

(Refer to CHAPTER 2, *System Description*, Sample Container Information.)
</td></tr>
<tr><td>4</td><td>Select Main from the menu bar.
AND
Select Run.</td></tr>
<tr><td>5</td><td>Select <OK> in the Check Dilution Segments dialog box to start the run.
OR
Select <Cancel> to exit without starting the run.</td></tr>
</table>

(2 of 2)

Operating in Bi-directional Mode

Follow the steps below for routine operation of the IMMAGE 800 Immunochemistry System using bi-directional mode.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Check and clear as necessary:
• sample racks

Check, clear, and replace as necessary:
• dilution segments

Check:
• reagents, buffers, and diluents
• wash solution volume

(Refer to Preparing for Programming/Running in this chapter.)</td></tr>
<tr><td>2</td><td>Request calibrations if necessary. (Refer to CHAPTER 6, Reagents/ Calibration.)</td></tr>
<tr><td>3</td><td>Send sample programming from the host computer according to the laboratory’s procedure.</td></tr>
<tr><td>4</td><td><table><tr><th>If samples are...</th><th>then...</th></tr><tr><td>bar coded</td><td>load samples in any rack and position.</td></tr><tr><td>not bar coded</td><td>load samples in racks and positions assigned by the host.</td></tr></table>
(Refer to CHAPTER 2, System Description, Sample Container Information.)</td></tr>
<tr><td>5</td><td>Select Main from the menu bar.
AND
Select Run.</td></tr>
<tr><td>6</td><td>Select <OK> in the Check Dilution Segments dialog box to start the run.
OR
Select <Cancel> to exit without starting the run.</td></tr>
</table>

Operating Without Host Communications

Follow the steps below for routine operation of the IMMAGE 800 Immunochemistry System using unidirectional mode.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Check and clear as necessary:
• sample racks

Check, clear, and replace as necessary:
• dilution segments

Check:
• reagents, buffers, and diluents
• wash solution volume

(Refer to Preparing for Programming/Running in this chapter.)</td></tr>
<tr><td>2</td><td>Request calibrations, if necessary. (Refer to CHAPTER 6, Reagents/ Calibration.)</td></tr>
<tr><td>3</td><td><table><tr><th>If samples are...</th><th>then...</th></tr><tr><td>bar coded,</td><td>program sample ID, chemistries, and any additional information needed for each sample. Load samples in any rack and position.</td></tr><tr><td>not bar coded,</td><td>program rack and position, sample ID, chemistries, and any additional information needed for each sample. Load samples in the programmed racks and positions.</td></tr></table>
(Refer to Programming a Sample in this chapter and CHAPTER 2, System Description, Sample Container Information.)</td></tr>
<tr><td>4</td><td>Select Main from the menu bar.
AND
Select Run.</td></tr>
<tr><td>5</td><td>Select <OK> in the Check Dilution Segments dialog box to start the run.
OR
Select <Cancel> to exit without starting the run.</td></tr>
</table>

Host Communication Status

Introduction

The following table explains the host communications messages displayed at the top, center of the screen during a run.

Table 7.10 Host Communications Messages

Host Setup	Message	Status
None	*Host off*	IMMAGE 800 host communications is set for no host.
Unidirectional	*Host Up*	IMMAGE 800 host communications is set for transfer of data from the IMMAGE 800 to the host only.
Bidirectional	*Host Up*	IMMAGE 800 is able to communicate with the host.
	Host Down	IMMAGE 800 is unable to communicate with the host, but is still trying.
Bidirectional with Host Query	*Host Up*	IMMAGE 800 is able to communicate with the host.
	Host Down	IMMAGE 800 is unable to communicate with the host, but is still trying.
	Host Up - Query in Progress	IMMAGE 800 is querying for samples from the host.
	Host Down - Query in Progress	IMMAGE 800 is unable to communicate, but is still attempting to query for samples from the host.

Checking for a Successful Host Query

For the Bidirectional and Bidirectional With Host Query setups, review the load list for any samples that have not been received from the host after the run is in progress.

Operating IMMAGE 800 in Japanese

Overview

Introduction

There are several features available when the IMMAGE 800 is enabled in the Japanese language. These features are:

- Keyboard entry mode selection in English or Japanese (Romaji) by use of a Japanese keyboard.
- Data entry and edit in English, Hiragana, Katakana, and Kanji within some functions.
- Static and dynamic display of Japanese characters on screens and fields that can be edited.
- Data storage and retrieval through the Archive/Restore screen.
- Data recall through the Results Recall screen.
- Patient information through the Sample/Demographics screen.
- Data output in Japanese, including printer output of reports and results.
- Host interface with the Laboratory Information System (LIS) to transfer Japanese characters.
- A basic Kanji character dictionary and an expanded dictionary to include additional Kanji characters for names, places, and technical/medical terms.
- Pop-up messages, including error messages, are displayed in mixed scripts of Kanji, Hiragana, Katakana, and English, as appropriate for the message.
- Barcode labels, parameters, and data will be read, and stored, in English.
- Reagent lot parameter data will be stored and displayed in English.

Note: Japanese language capability requires a Japanese keyboard.

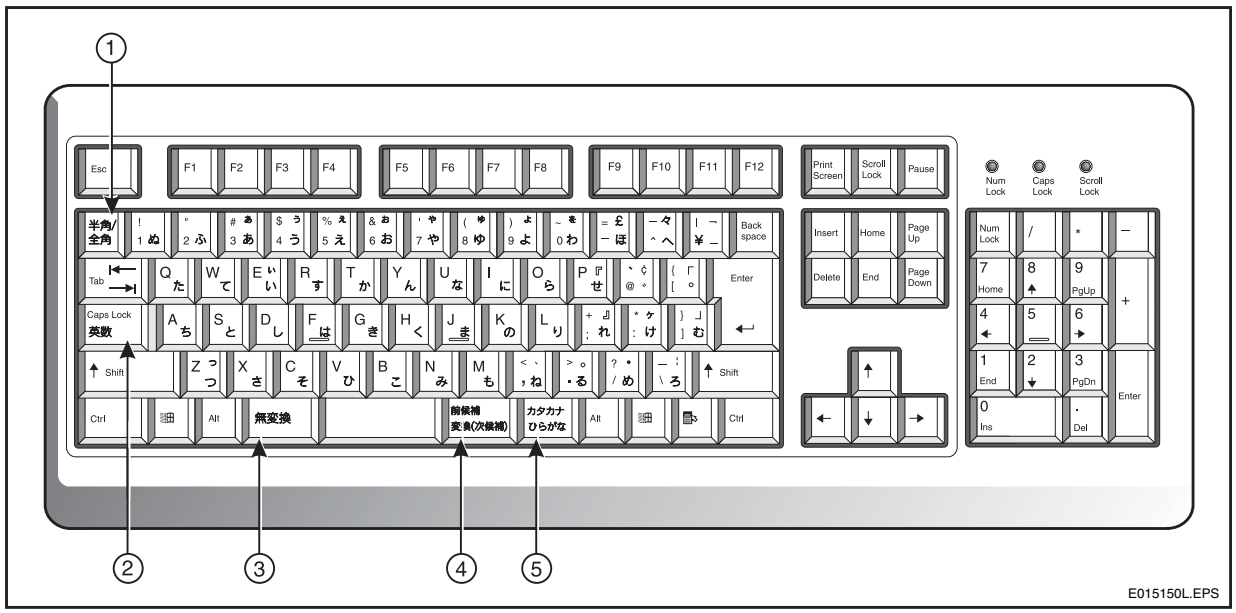
NOTICE

Other languages will be disabled when the IMMAGE 800 is running in the Japanese language. In order to access another language, the IMMAGE 800 software must be reinstalled. It is recommended that the database be archived before switching languages.

Computer

The Japanese Keyboard

Figure 7.25 depicts the IBM Japanese terminology translation keyboard used with the IMMAGE 800. The function of the normal keyboard keys (For example, [Esc], [Page Up/Down], [Delete], [Tab]) remain the same.



1. One Byte (Half-width)/Two Byte (Full-width)
2. Roman Character
3. (Not Used)
4. (Not Used)
5. Katakana Mode/Hiragana Mode

Figure 7.25 IMMAGE 800 Japanese Keyboard

Keyboard Entry

Data may be entered from the keyboard in the following writing modes:

- Eigo Zenkaku[1]
- Eigo Hankaku[2]
- Hiragana
- Katakana Zenkaku[1]
- Katakana Hankaku[2]
- Kanji (Translation from Romaji to Hiragana conversion)

The following writing modes and character widths may be selected, from field to field, or screen to screen:

- English (Full-width or half-width)

[1] = Full-width

[2] = Half-width

- Hiragana (Full-width)
- Katakana (Full-width, or half-width)

Note: Kanji characters converted from Hiragana are full-width.

When a change in the writing mode, and/or character width, is selected using the keyboard, the change is displayed on the screen. The character width and type mode symbol are displayed in the lower right corner of the screen.

- To switch from Japanese entry mode to English entry mode (Roman), press the **[Shift + Caps Locks]** keys at the same time.
- To return to Hiragana, press the **[Katakana/Hiragana]** key.
- To change from Hiragana to Katakana, press the **[Shift + Katakana/Hiragana]** keys at the same time.
- To return to Hiragana, press the **[Katakana/Hiragana]** key.
- The **[one byte/two byte]** key is used as a toggle to switch between half-width and full-width characters.

Data/Text Entry

Introduction

Data/text entry of Japanese characters are only available from the Japanese keyboard provided. Japanese words are entered in Romaji for translation to Hiragana, Katakana, and/or Kanji.

Screens and Fields

The screens and fields available for text entry of Japanese characters are:

Main Sample Program Screen (Refer to Figure 7.26.)

- Sample Comment

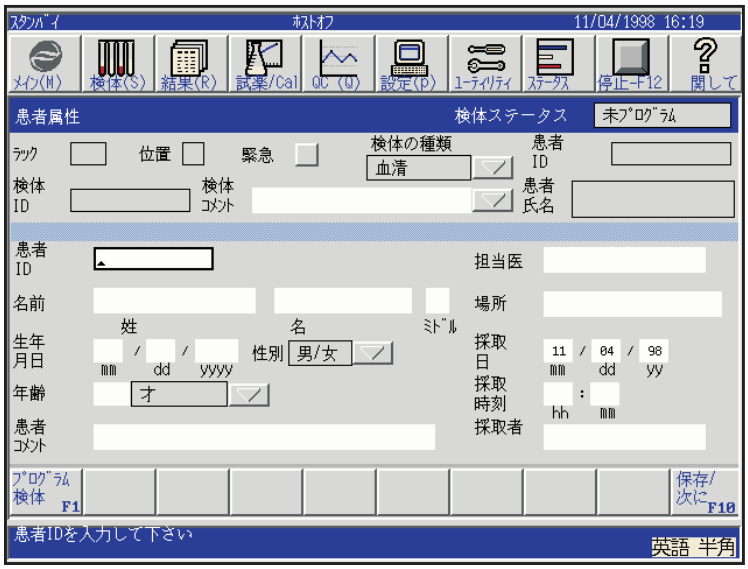


J015148S.EPS

Figure 7.26 Sample Programming Screen

Demographics Screen (Refer to Figure 7.27)

- Sample Comment
- Patient Last Name, First Name, MI[1]
- Patient Comment
- Physician Name
- Location
- Collected By



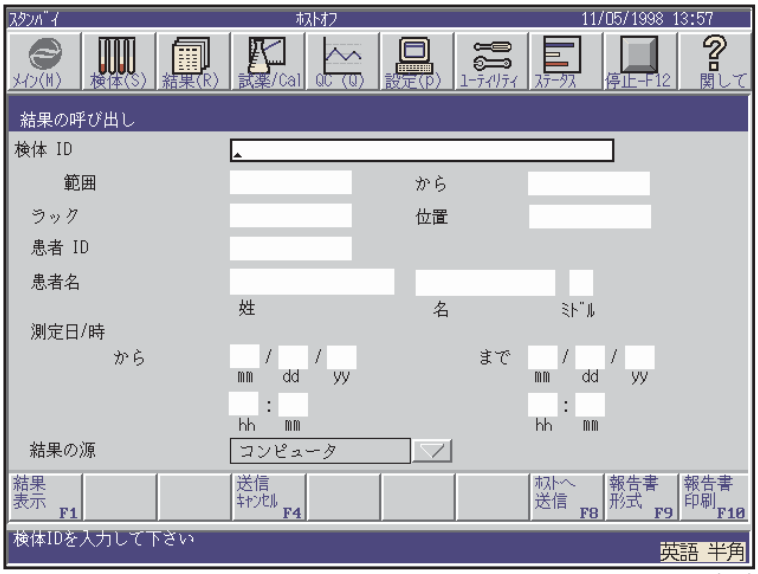
J010256S.EPS

Figure 7.27 Patient Demographic Screen

[1] MI= Middle Initial. It is recommended that the MI field be disabled in the demographics screen setup (Refer to Chapter 5, System Setup) when running the IMMAGE 800 in the Japanese language mode.

Recall Results Screen (Refer to Figure 7.28)

- Patient Last Name, First Name, MI[1]

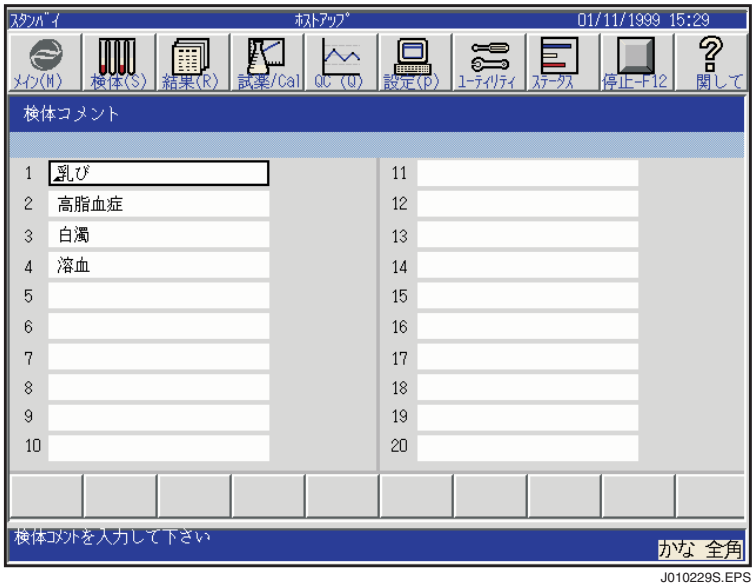


J014099S.EPS

Figure 7.28 Recall Results Screen

Setup

- **Sample Comments Screen** (Refer to Figure 7.29)



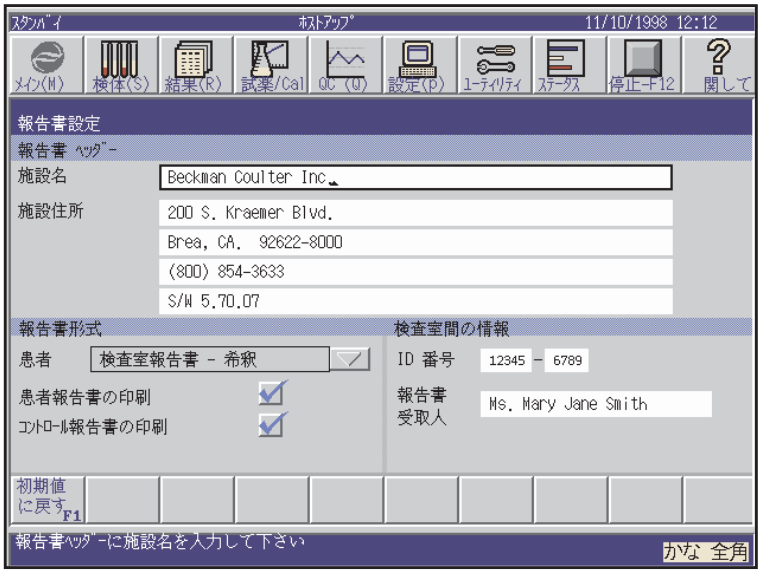
J010229S.EPS

Figure 7.29 Sample Comments Screen

[1] MI= Middle Initial. It is recommended that the MI field be disabled in the demographics screen setup (Refer to Chapter 5, *System Setup*) when running the IMMAGE 800 in the Japanese language mode.

Report Setup Screen (Refer to Figure 7.30)

- Facility Name
- Facility Address
- Attention Person



J014090S.EPS

Figure 7.30 Report Setup Screen

Language Conversions

Romaji Text

When the sound of the Japanese word is entered in Romaji, the operator can choose the display mode of Hiragana or Katakana.

When a phonetic character is entered in Romaji, a conversion process automatically replaces the entry with a Hiragana or Katakana character.

For example, "ma" is a phonetic sound entered in Romaji. Conversion to Hiragana (or Katakana) characters occurs immediately following the keystrokes [m] and [a]. (Refer to the end of this section for the Hiragana and Katakana conversions.)

Kanji Text

The sound of the Kanji word is entered in Romaji by the operator. As the sound of the Kanji word is entered in Romaji, each phonetic entry in Romaji is converted to the equivalent Hiragana sequences for the Kanji word. The Hiragana sequence converted from Romaji, will be highlighted with a blue background for translation to Kanji characters.

The **SPACE BAR** is used to display the Kanji candidates:

- The first time the **SPACE BAR** is pressed, the Hiragana sequence for the Kanji word is replaced with the first Kanji character(s) choice from a candidate list.
- The second time the **SPACE BAR** is pressed, the Kanji candidate list is displayed, and the first Kanji character(s) that was previously displayed, is replaced with the second Kanji character(s) choice from the candidate list.
- Each subsequent time the **SPACE BAR** is pressed, the highlighted Kanji character(s) is replaced by the first character(s) on the next available candidate list, until there are no more choices left.

Note: There can be one (1), or over one hundred (100), Kanji candidates, on a case by case basis. The maximum number of Kanji choices displayed at any time is nine (9).

Kanji Text, Additional Information

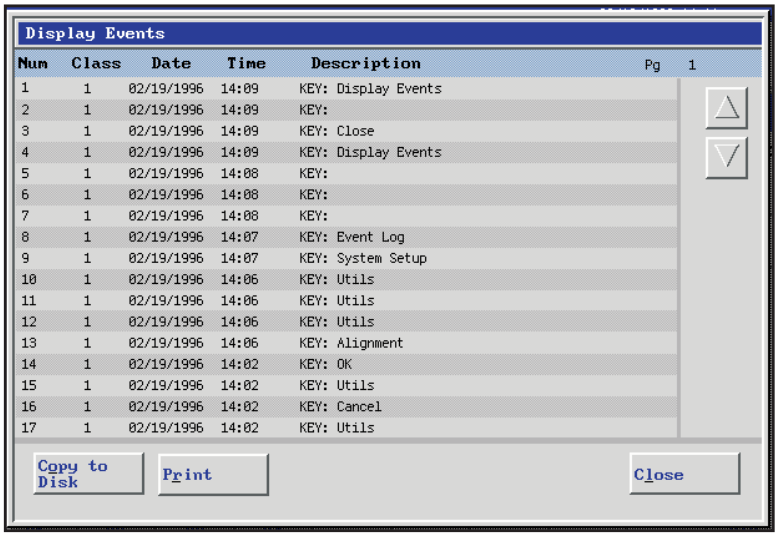
- To view the next set of Kanji candidates, press the **SPACE BAR**, or the down (↓) arrow key.
- To view the previous set of Kanji candidates, press the up (↑) arrow key.
- The last Kanji character used always appears as candidate number one, until the IMMAGE 800 system is rebooted.
- The number of Kanji choices found is displayed to the *right* of the Kanji choices displayed, and the number associated with the numeric order is displayed to the *left* of the Kanji choices.
- The candidate Kanji character(s), displayed in the text field, is highlighted with yellow until it is approved/inserted by the user.
- The candidate Kanji character(s) is entered into text when the **ENTER** key is pressed, or the selection number for the Kanji choice, displayed at the bottom of the screen, is entered by the user.

Note: If none of the Kanji character candidates are suitable, choosing the "0" option will automatically cause the text to revert back to Hiragana.

Display Language

Display and Output

Display output is mixed scripts of Japanese and English characters, with the exception of the messages captured in the Event Log, which appear in English. (Refer to Figure 7.31.)



E010274S.EPS

Figure 7.31 Display Events Dialog Box

English characters appear where Japanese characters are not appropriate, such as:

- Reagent Name or Control Name
- Reagent, Buffer, or Diluent Lot Number
- Calibration ID, Sample ID, Patient ID, Control ID
- Button/Function Label or Abbreviation

Reports and Summaries are displayable and printable in mixed scripts of Japanese and English characters. These include, but are not limited to:

- Calibration- Reports and Load Lists
- Post-Run Summary
- Sample Load List
- Results Recall

Data Storage/Retrieval

The IMMAGE 800 system has the capability of retrieving samples and results by patient names, in Japanese.

Data entered in Japanese is stored and retrieved in the Japanese language mode.

Databases stored/archived in Japanese are not displayable with Japanese characters in other languages.

Databases stored/archived in other languages are retrievable in the Japanese language mode (but not translated).

Kanji characters from the main Kanji dictionary are retrieved automatically, as needed.

Host Communication Interface

Japanese Character Transfer

Special provisions are necessary to accommodate the transfer of Japanese characters over the customer communication network. The baseline IMMAGE 800 host communication protocol uses the specifications of ASTM E1381-91.

The optimal use of escape delimiters is implemented to allow sending and receiving of Japanese characters.

For further information refer to IMMAGE Immunochemistry Systems *Host Interface Specifications* (Revision AD or greater).

Hiragana Conversions From Romaji



Figure 7.32 Hiragana Conversions From Romaji

Katakana Conversions From Romaji



Figure 7.33 Katakana Conversions From Romaji

CHAPTER 8 Results Recall

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Results Recall

Overview

Introduction

This chapter discusses how to recall and print patient and control results. Results can be recalled by sample ID, rack and position, patient ID, or run date and time. Results which have been recalled can be sent to a host computer. Up to 10,000 patient samples may be stored by the IMMAGE 800 database.

Recalling Results by Sample ID

Introduction

Results can be recalled by Sample ID and/or a range of Sample IDs.

Recalling by Sample ID

Follow the steps below to enter Sample IDs for recall. Both individual Sample IDs and a range of Sample IDs can be entered.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Results from the menu bar. (Refer to Figure 8.1.)</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To enter...</th><th>type...</th></tr>
<tr><td>an individual Sample ID or a series of Sample IDs,</td><td>the Sample IDs desired for recall in the Sample ID(s) field (up to 42 characters, spaces are not allowed). A single Sample ID has a maximum of 15 characters.

Sample IDs can be separated by a comma as a series.</td></tr>
<tr><td>a range of Sample IDs,</td><td>the Sample ID at the beginning of the range in the Range field.

Press [Enter].

Type the Sample ID at the end of the range in the Thru field.</td></tr>
<tr><td>a range of alphanumeric Sample IDs,</td><td>the individual Sample IDs to be recalled in the Sample IDs field, separated by a comma.</td></tr>
<tr><td>all Sample IDs,</td><td>"0" in the Range field. Press [Enter]. Type zzzzzzzzzzzzzz in the Thru field.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select the options button <▼ > beside the Data Source field.</td></tr>
</table>

(1 of 2)

Step	**Action**, continued
4	Select **Computer** to recall results in the current database stored on the hard disk. OR Select **External Media** to recall results from the USB flash drives that have been restored onto the hard disk. (Refer to CHAPTER 10, *Utilities*, Backup/Restore for instructions on how to back up and restore the database.) **CAUTION** **Before sending a range of results to the Host via Results Recall, clear any pending Calibration programming and any UDR Calibration racks.** NOTICE Do not clear a UDR rack until the final curve-fit model for the calibration has been selected. NOTICE Patient results restored from the external media cannot be sent to the host.
5	Select a function button from the bottom of the screen.
6	Refer to Displaying Recalled Results on the Screen and Printing a Recalled Result in this chapter to display or print results.

(2 of 2)

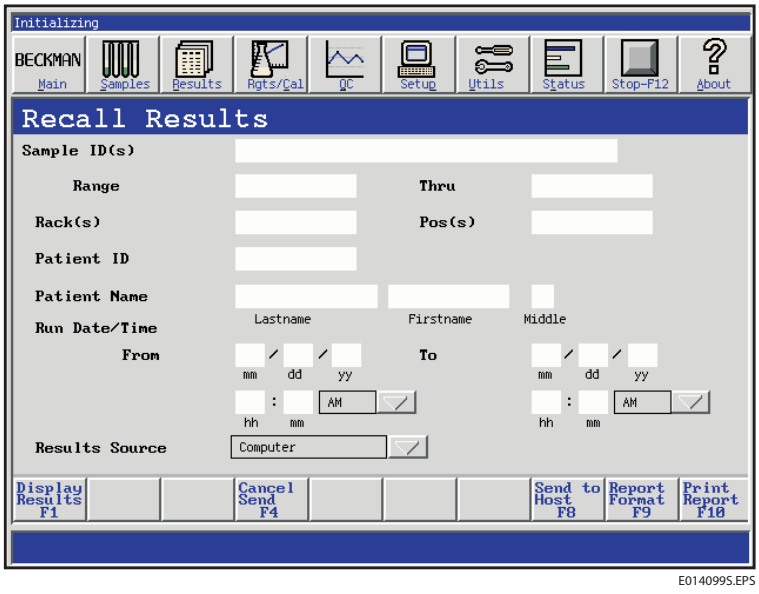

Figure 8.1 Recall Results Screen

Recalling Results by Rack and Position

Introduction

Results can be recalled by Rack and Position.

Recalling by Rack and Position

Follow the steps below to enter Rack and Position for recall.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select Results from the menu bar. (Refer to Figure 8.1.)</td></tr>
<tr><td>2</td><td>Type the rack number(s) desired for recall in the Rack(s) field (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range.</td></tr>
<tr><td>3</td><td>
<table>
<tr><th>If...</th><th>then...</th></tr>
<tr><td>one rack number is entered,</td><td>Press [Enter] to access the Pos(s) field.

Type the position numbers desired for recall (up to 15 characters). Numbers can be separated by a comma as a series and/or by a dash as a range.

Note: If one rack number and no position number is entered, all positions on the rack are automatically selected.</td></tr>
<tr><td>more than one rack number is entered,</td><td>• All positions on each rack are automatically selected.
• The Pos(s) field cannot be accessed.</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Select the options button <▼ > beside the Data Source field.</td></tr>
</table>

(1 of 2)

Step	**Action**, continued
5	Select **Computer** to recall results in the current database stored on the hard disk. OR Select **External Media** to recall results from the USB flash drives that have been restored onto the hard disk. (Refer to CHAPTER 10, *Utilities*, Backup/Restore for instructions on how to back up and restore the database.) **CAUTION** **Before sending a range of results to the Host via Results Recall, clear any pending Calibration programming and any UDR Calibration racks.** NOTICE Do not clear a UDR rack until the final curve-fit model for the calibration has been selected. NOTICE Patient results restored from the external media cannot be sent to the host.
6	Select a function button from the bottom of the screen.
7	Refer to Displaying Recalled Results on the Screen and Printing Recalled Results in this chapter to display or print results.

(2 of 2)

Recalling Results by Patient ID

Introduction

Results can be recalled by Patient ID or by Control ID.

Recalling by Patient ID

Follow the steps below to Recall a result by Patient or Control ID. Only one Patient or Control ID may be requested at a time.

Step	Action
1	Select **Results** from the menu bar. (Refer to Figure 8.1.)
2	Enter the Patient or Control ID (up to 15 alphanumeric characters) in the **Patient ID** field.
3	Select the options button <▼ > beside the **Data Source** field.
4	Select **Computer** to recall results in the current database stored on the hard disk. OR Select **External Media** to recall results from USB flash drives that have been restored onto the hard disk. (Refer to CHAPTER 10, *Utilities*, Backup/ Restore for instructions on how to back up and restore the database.) **CAUTION** **Before sending a range of results to the Host via Results Recall, clear any pending Calibration programming and any UDR Calibration racks.** NOTICE Do not clear a UDR rack until the final curve-fit model for the calibration has been selected. NOTICE Patient results restored from the external media cannot be sent to the host.
5	Select a function button from the bottom of the screen.
6	Refer to Displaying Recalled Results on the Screen and Printing Recalled Results in this chapter to display or print results.

Recalling Results by Patient Name

Introduction

Results can be recalled by Patient Name.

Recalling by Patient Name

Follow the steps below to recall a result by Patient Name.

Step	Action
1	Select **Results** from the menu bar. (Refer to Figure 8.1.)
2	Enter the Patient Name in the **Patient Name** field. NOTICE The results are recalled only when there are exact matches of the last name, first name and middle initial. A wildcard (*) is allowed for middle initial entry. In this case, samples are retrieved based on exact matches of the last name, first name with any or no middle initial.
3	Select the options button <▼ > beside the **Data Source** field.
4	Select **Computer** to recall results in the current database stored on the hard disk. OR Select **External Media** to recall results from USB flash drives that have been restored onto the hard disk. (Refer to CHAPTER 10, *Utilities*, Backup/ Restore for instructions on how to back up and restore the database.) **CAUTION** **Before sending a range of results to the Host via Results Recall, clear any pending Calibration programming and any UDR Calibration racks.** NOTICE Do not clear a UDR reck until the final curve-fit model for the calibration has been selected. NOTICE Patient results restored from the external media cannot be sent to the host.
5	Select a function button from the bottom of the screen.
6	Refer to Displaying Recalled Results on the Screen and Printing Recalled Results in this chapter to display or print results.

Recalling Results by Run Date/Time

Introduction

Results can be recalled by Run Date/Time.

Recalling by Run Date/Time

Follow the steps below to recall results by Run Date/Time.

Step	Action
1	Select **Results** from the menu bar. (Refer to Figure 8.1.)
2	Enter the desired date and time ranges in the **From** fields and **To** fields. (Refer to Table 8.1.)
3	Select the options button <▼ > beside the **Data Source** field.
4	Select **Computer** to recall results in the current database stored on the hard disk. OR Select **External Media** to recall results from USB flash drives that have been restored onto the hard disk. (Refer to CHAPTER 10, *Utilities*, Backup/ Restore for instructions on how to back up and restore the database.) **CAUTION** **Before sending a range of results to the Host via Results Recall, clear any pending Calibration programming and any UDR Calibration racks.** NOTICE Do not clear a UDR rack until the final curve-fit model for the calibration has been selected. NOTICE Patient results restored from the external media cannot be sent to the host.
5	Refer to Displaying Recalled Results on the Screen and Printing a Recalled Result in this chapter to display or print results.

Table 8.1 Run Date/Time Field Entry Options

Field	Entries	Notes
Date: From and To	mm: 1-12 dd: 1-31 yy: 0-99	• If only a **From** date is entered, the results will be recalled for the 24-hour period of that date. • The order and the separator character are defined in Setup. • An entry in the **From** field is required.
Time: From and To (12-hour format)	hh: 1-12 mm: 0-59 AM/PM: • Select the options button < ▼ > beside the **AM/PM** field. • Select **AM** or **PM**	• A time entry is optional. If only a date is entered, results will be recalled for each 24-hour period in the date range. • Time is not allowed to be entered unless date is entered. • The time format is defined in Setup as 12-hour or 24-hour. • The separator character is defined in Setup. • The 12-hour default is AM.
Time: From and To (24-hour format)	hh: 0-23 mm: 0-59	

Additional Information

Refer to CHAPTER 5, *System Setup*, Date and Time Setup.

Displaying Recalled Results on the Screen

Introduction

All recalled results may be viewed on the screen.

Displaying Results

Follow the steps below to display results on the screen.

Step	Action
1	From the Recall Results screen, select the results to be viewed.
2	Select **Display Results [F1]**. (Refer to Figure 8.2.)
3	Select **<Page Up>** or **<Page Down>** to view other pages of the same sample. Each sample generates at least two report pages.
4	Select **Prev Sample [F9]** or **Next Sample [F10]** to view other samples if more than one sample result was recalled.

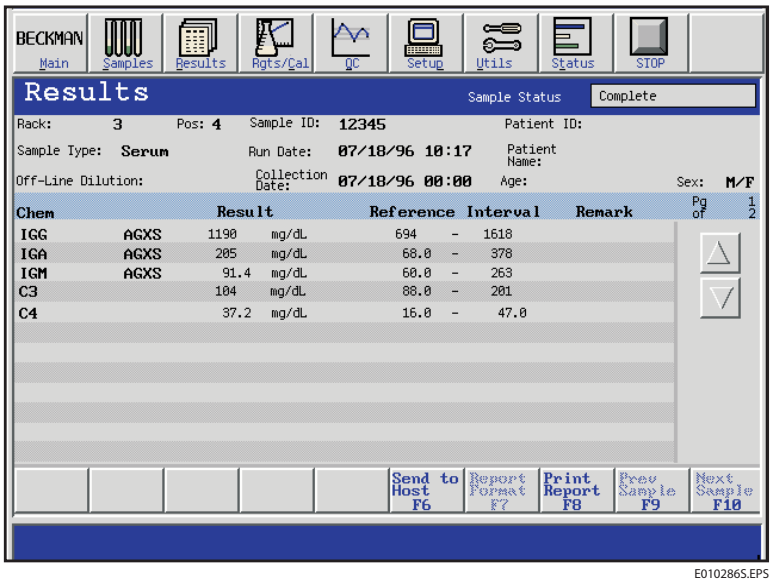

Figure 8.2 Results Screen

Printing Recalled Results

Introduction

All recalled results may be printed.

Printing a Recalled Result

Follow the steps below to print a recalled result.

Step	Action
1	From the Recall Results screen, select the results to be viewed, as described previously in this chapter.
2	<table><tr><th>To print using...</th><th>then...</th></tr><tr><td>default report format</td><td>Go to Step 5.</td></tr><tr><td>non-default report format</td><td>Continue to Step 3.</td></tr></table>
3	Select **Report Format [F7]**. A **Patient Report Format** dialog box is displayed with the following choices: • Lab Report • Lab Report-Dilutions • Patient Chartable Reports.
4	Select a Report Format. OR Select **<Cancel>** to return to the previous screen without selecting a report format.
5	Select **Print Reports [F8]**. The selected results will be printed in the format desired.

Stopping a Print Request

Printing of recalled results can be stopped from the Results Recall Screen by selecting **Utilities** from the menu bar and **<10> Stop Print**.

Additional Information

For information on the default report format setup refer to CHAPTER 5, *System Setup*, Report Setup.

For examples of result report formats, refer to APPENDIX B, *Reports*.

Sending Results to the Host

Introduction

Results from the IMMAGE 800 are automatically sent to the host computer when the autosend is enabled in Host Communications setup.

Results can be sent manually to the host computer whether autosend is enabled or disabled.

Manually Sending Results to the Host

Follow the steps below to manually send results to the host computer.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>From the Recall Results By screen, select a single sample or range of samples to send to the host computer.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>To...</th><th>select...</th></tr>
<tr><td>send results to the host computer without displaying them,</td><td>Send to Host [F8].</td></tr>
<tr><td>display results and send them to the host computer,</td><td>Display Results [F1], then Send to Host [F6].

Select Prev Sample [F9] or Next Sample [F10] to display other samples if more than one sample was recalled.

Select Send to Host [F6] for each sample displayed to send it to the host computer.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Select Cancel Send [F4] to stop sending results to the host.</td></tr>
</table>

Additional Information

Refer to CHAPTER 5, *System Setup*, Host Communications Setup, for information about autosend.

CHAPTER 9 Quality Control

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Quality Control

Overview

Introduction

The Quality Control (QC) program summarizes quality control results generated on the IMMAGE 800 Immunochemistry System. The control program uses the Westgard Rules[1] to monitor statistics for up to 100 controls. Rule violations 1-2S and 1-3S are flagged on a real-time basis and can be displayed on the console monitor.

The QC program provides the following features:

- Review Control
- Define/Edit
- Delete Control
- QC File List
- QC Log
- QC Summary
- QC Chart (Levey-Jennings)
- Backup QC
- Print Control

Recommended QC and Analysis Intervals

Beckman Coulter recommends that at least two levels of control material be analyzed daily. In addition, these controls should be run with each new calibration, with each new lot of reagent, and run after specific maintenance or troubleshooting, as detailed in CHAPTER 10, *Utilities*. More frequent use of controls, or the use of additional controls, is left to the discretion of the user based on individual laboratory practice.

QC Data Source

The system allows the operator to review and print QC data stored on:

- Hard Disk
- External Media (USB Flash Drive)

Additional Information

Refer to APPENDIX B, *Reports* for a QC Report Sample.

[1] Westgard, J. O.; Barry, P. L.; Hunt, M.R.; Groth, T. A., *A Multirule Shewhart Chart for Quality Control in Clinical Chemistry*. Clinical Chemistry 1981; 27:493-501.

Also, http://www.westgard.com/pdf

QC Statistics and Rules

Introduction

The following section describes the QC rules used by the Quality Control feature.

Determination of QC Flags

The IMMAGE 800 uses the Z-score method for standardizing the scale of a normally distributed measurement variable. For an individual control result, the Z-score represents the distance in standard deviations from the assigned mean. The Z-score is calculated from the following equation where:

X	=	the individual control result
$\overline{X}$	=	the assigned mean for the control
SD	=	the assigned standard deviation for the control

$$Z = \frac{X - \overline{X}}{SD}$$

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Each time a control result is received, the Z-score is calculated. If the Z-score is less than ± 2 SD, the result is within the assigned control range (the assigned mean ± 2 assigned standard deviations) and is considered acceptable.

Results are flagged at time of run. Flagging is not changed if the operator modifies the assigned mean and/or SD.

If the operator chooses to use a QC program other than the IMMAGE 800 QC program, assigning a mean of "0" and an SD of "99999" for a chemistry prevents additional flagging of the results in the IMMAGE 800 QC database and on the IMMAGE 800 screen.

Accuracy and Precision Flags

The IMMAGE 800 utilizes the following Westgard rules for evaluation of QC data.

1-2S: Result Between ± 2SD and ± 3SD From the Assigned Mean

If the result is between ± 2 and ± 3 standard deviations from the assigned mean, the result:

- is flagged as > 2SD on the QC Log report.
- is marked with a yellow warning symbol beside the value on the QC Log and QC Chart screens.
- is highlighted in a real-time pop-up window on the monitor as the system is running.

1-3SD: Result Greater Than 3SD From the Assigned Mean

If the result is greater than ± 3 SD from the assigned mean, the result:

- is flagged as > 3SD on the QC Log report.
- is marked with a red warning symbol beside the value on the QC Log and QC Chart screens.
- is highlighted in a real-time pop-up window on the monitor as the system is running.

2-2S and R-4S: Results Between 2 SD and 3 SD as Compared to the Previous Result

In addition, the Z-score for the current result is compared with the Z-score of the previous result in the same QC file. If both Z-scores are beyond 2 SD on the same side of the assigned mean, the current result receives an "Accuracy" flag on the QC Log report; this flag signifies a violation of the 2-2S rule. These values appear with a red warning symbol in the QC Log and QC Chart.

If the two results being compared are greater than 2 SD on opposite sides of the assigned mean, the current result receives the "Precision" flag on the QC Log report, signifying a violation of R-4S rule. These values appear with a red warning symbol in the QC Log and QC Chart.

- **Results Greater Than 4 SD From the Assigned Mean**

Results greater than 4 SD are included in the QC Log and QC Chart, but are not used to calculate statistics.

Flags Generated on Printed QC Reports

These flags appear in the remarks column of the QC results report:

- Greater than 2SD.
- Greater than 3SD.
- Two successive controls greater than 2SD (Accuracy).
- Two successive controls greater than 2SD on opposite sides of the assigned mean (Precision).

Additional QC Precision Rules

Some additional Westgard QC rules are helpful when determining whether the system is in control. These are not flagged by the IMMAGE 800 QC program but can help in determining system performance. (Refer to Figure 9.1.)

- **4-1S Within or Across: Last Four Results of One or Two Levels of Control Were More than 1 SD From the Mean on the Same Side**

  This rule judges the result out-of-control if the last four results from one or two levels were more than 1 SD from the mean in the same direction.

10X Within or Across: Last Ten Results of One or Two Levels of Control Were All on the Same Side of the Mean

This rule judges the result out-of-control if the last ten results from one or two levels were all on the same side of the mean.

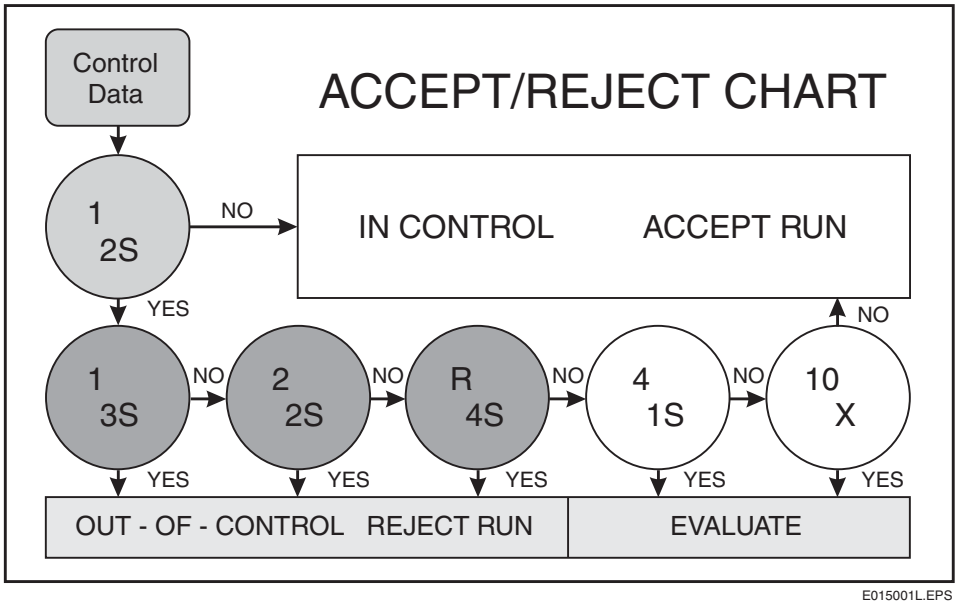

Figure 9.1 QC Accept/Reject Chart Using Westgard Rules

Defining a Control

Introduction

The Define/Edit option allows definition of up to 100 control names. The minimum information required to save a control definition is:

- control name
- lot number
- sample type
- one chemistry selection
- QC file number
- Mean
- Standard Deviation (SD)

In addition, the assigned mean, standard deviation (SD), and constituent code can be defined for each chemistry in a control. Control IDs can also be assigned to a control.

Grouping Chemistries Under a Control Name

All chemistries appearing in a control definition must be of the same sample type and have the same sample preparation.

QC File Number

The QC file number is a number from 1-999 which is unique to a chemistry defined within a control name. If the QC file number has already been assigned, the database will not accept it a second time. The file number can be reused after a chemistry in a control is deleted.

Assigned Mean and Assigned SD

For initial setup of control definitions, the mean and standard deviation (SD) values from commercial quality control inserts may be used. When the laboratory establishes its own mean and SD ranges, these values should be used instead of the insert values.

The mean and SD values may be edited, as data is collected for the individual laboratory.

Each laboratory should establish its own precision parameters which more accurately reflect individual laboratory quality control criteria.

Entering the Minimum Control Definition

When the instrument status is *Standby*, follow the steps below to enter the minimum information to define a control.

Step	Action
1	Select **QC** from the menu bar. (Refer to Figure 9.2.)
2	Select a number beside a blank line under the Control Name column.
3	Select **Define/Edit [F2]**. (Refer to Figure 9.3.)
4	Enter the name of the control in the **Control Name** field. Press **[Enter]**. The Control Name must be unique and can contain up to 20 alphanumeric characters. (Spaces are allowed.)
5	Enter the control lot number in the **Control Lot** field. The lot number can contain up to 12 alphanumeric characters. (No spaces are allowed). Press **[Enter]**.
6	Select the Sample Type from the options button < ▼ >. The default sample type is serum.
7	Select **Add/Del Chem [F1]** to select chemistries for the control. (Refer to Figure 9.4.) Use the <**Page Up**>/<**Page Down**> buttons to view additional chemistries.
8	Select the desired chemistries. Deselecting a selected chemistry will delete the chemistry from the control definition.
9	Select <**OK**> to accept chemistries OR <**Cancel**> to return to the Define/Edit Controls screen without accepting the chemistries.
10	The system automatically assigns a QC File number in the **QC File Number** field. Press **[Enter]** to accept the Auto-increment QC File number. OR Enter a unique file number beside each of the chemistries being defined in the **QC File Numbe**r field (up to 3 numeric characters).

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>11</td><td>Enter the Mean value beside the chemistry it corresponds to in the Assigned Mean field. Press [Enter].

NOTICE
The Assigned Mean is set to "0" and the Assigned SD is set to "99999" if "0" is entered in the Assigned Mean field.</td></tr>
<tr><td>12</td><td>Enter the "1" SD value beside the chemistry it corresponds to in the Assigned SD field. Press [Enter].</td></tr>
<tr><td>13</td><td>Proceed to Defining More Information on a Control to continue adding information to the control definition.
OR
Select any icon from the menu bar to exit the Define/Edit Controls screen and save the control definition.</td></tr>
<tr><td>14</td><td>A message will display upon exiting the screen if there is any missing information for the control definition. (Refer to Figure 9.4.)

Select <OK> to exit without saving the control.
OR
Select <Cancel> to return to the Define/Edit screen to add the necessary information.</td></tr>
<tr><td>15</td><td>A Define/Edit Controls dialog box is displayed when:

• the Assigned Mean field and/or Assigned SD field are set to "0", or
• there are no values entered in the Assigned Mean field and/or Assigned SD field.

<table>
<tr><th>Select…</th><th>to…</th></tr>
<tr><td><1> Save file(s) with Mean = 0.0, SD = 99999</td><td>set the mean to "0" and the SD to "99999" for the chemistries in question.</td></tr>
<tr><td><2> Delete undefined file(s) from this control</td><td>delete the chemistries in question from the control.</td></tr>
<tr><td><Cancel></td><td>to return to the Define/Edit screen and enter the mean and/or SD.</td></tr>
</table>
</td></tr>
</table>

(2 of 2)

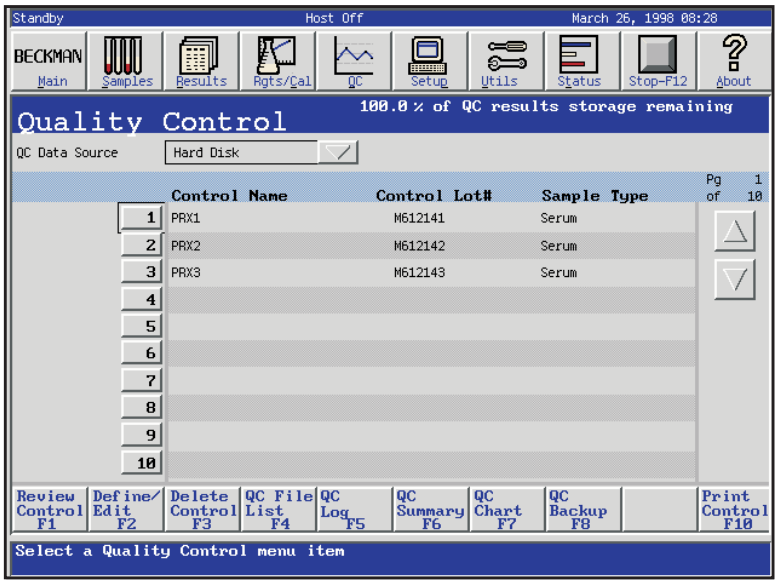

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Figure 9.2 Quality Control Screen

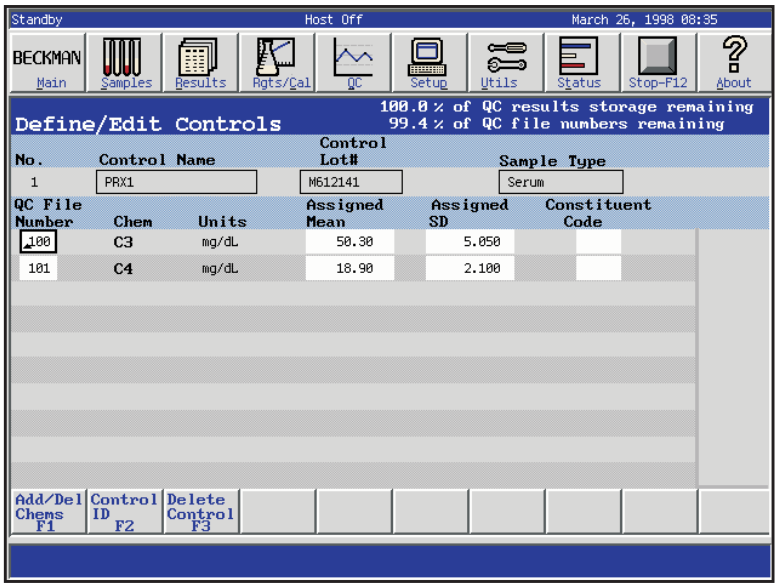

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Figure 9.3 Define/Edit Controls Screen

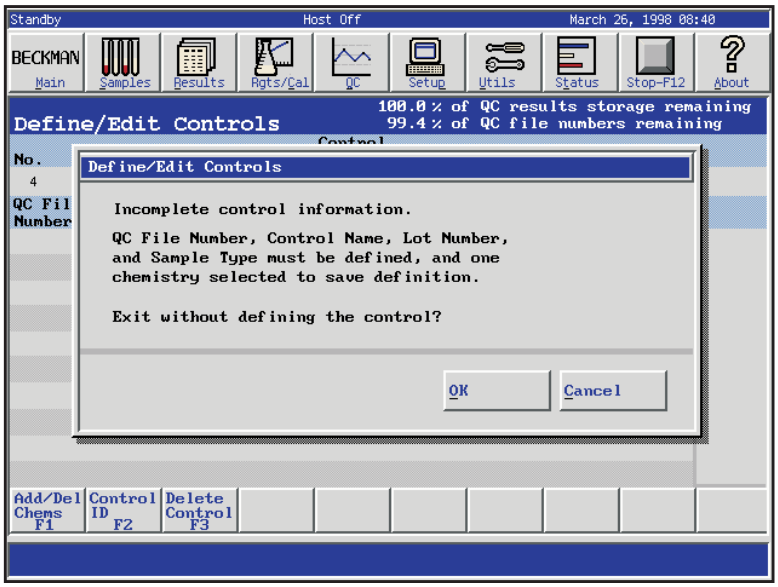

Figure 9.4 Define/Edit Controls Dialog Box

Control ID

- Control IDs must be part of the control definition if controls are identified by bar code on a run.
- Each Control Name can be defined with up to eight different Control IDs.
- The same bar coded control can be repeated in different positions during a run, if a different Control ID is assigned.
- Control IDs, like Sample IDs, must be unique for each sample within a run.
- Control IDs, unlike Sample IDs, can be reused without being cleared, after the control sample is run.
- Results from all Control IDs for a chemistry are collected under the same Control Name.

Assigning Control ID

After entering the minimum information to define a control, follow the steps below to further define a control.

Step	Action
1	From the Define/Edit Control screen, select **Control ID [F2]**.
2	**CAUTION** **When creating *Control* IDs, use a format that is distinctly different from *Sample* IDs. This will prevent the reporting of erroneous results due to controls being run as patient samples, or patient samples being run as controls.** **The Control ID dialog box will display. Up to eight unique IDs, each with a maximum of 15 alphanumeric characters may be entered.** Press **[Tab]**, **[Enter]**, or use the arrow keys after each bar code ID entry to move between fields.
3	Select <**OK**> to exit the screen and save the Control IDs. OR Select <**Cancel**> to exit the screen without saving the Control IDs.

Defining More Information for a Control

After entering the minimum information to define a control, follow the steps below to further define a control.

Step	Action
1	Enter the constituent code (a quality assurance program code) beside the chemistry it corresponds to in the **Constituent Code** field (4 alphanumeric characters; type leading zeroes if they are part of the constituent code).
2	Select any icon from the menu bar to exit the Define/Edit Controls screen and save the control definition.

Editing a Control

Introduction

The assigned mean, standard deviation (SD), constituent code and control ID of a previously defined control can be edited. In addition, individual chemistries can be added or deleted.

Editing Precautions

When editing control information, the following should be considered:

- Changing the mean and/or SD may affect subsequent QC statistical data.
- Changing previously defined mean and/or SD to zero will set the mean to zero and the SD to 99999.
- Subsequent data points will be compared to the new mean and SD.

Accessing a Control to Edit

When the instrument status is *Standby*, follow the steps below to access a previously defined control and to edit an assigned mean, SD, constituent code or control ID of a previously defined control.

Step	Action
1	From the Quality Control screen select the button beside the control name to be edited.
	Select **Define/Edit [F2]**. (Refer to Figure 9.3.)

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>2</td><td>Enter the new Mean value beside the chemistry it corresponds to in the Assigned Mean field. Press [Enter].

Enter the "1" SD value beside the chemistry it corresponds to in the Assigned SD field. Press [Enter].

A Define/Edit Controls dialog box is displayed when there are new values entered in the Assigned Mean and/or Assigned SD fields.

<table>
<tr><th>Select…</th><th>to…</th></tr>
<tr><td><1> Restore previously defined mean/SD and continue</td><td>exit the Define/Edit dialog box and restore the previously defined mean and/or SD value and continue.</td></tr>
<tr><td><2> Apply new mean/SD and continue statistical database</td><td>change the mean and/or SD to the new values. The previous results and cumulative statistics are saved.</td></tr>
<tr><td><3> Delete existing data and start new statistical database</td><td>change the mean and/or SD to the new values. The previous results and cumulative statistics are deleted.

This option is not available if the control is programmed for a run.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Enter the revised constituent code beside the chemistry it corresponds to in the Constituent Code field (4 alphanumeric characters; type leading zeroes if they are part of the constituent code).</td></tr>
<tr><td>4</td><td>Select Control ID [F2].</td></tr>
<tr><td>5</td><td>Enter the revised control ID into the Control ID field. (Up to 15 alphanumeric characters per field.) At least one Control ID and up to 8 different control IDs may be defined for each control name.</td></tr>
<tr><td>6</td><td>Select <OK> to save the Control IDs.
OR
Select <Cancel> to return to the Define/Edit Controls screen without saving the Control ID.</td></tr>
<tr><td>7</td><td>Select any icon from the menu bar to exit the Define/Edit Controls screen and save the edited control definition.</td></tr>
</table>

(2 of 2)

Adding or Deleting Individual Chemistries

Follow the steps below to add or delete an individual chemistry definition from a control definition.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>From the Quality Control screen select the button beside the control name to be edited.</td></tr>
<tr><td>2</td><td>Select Define/Edit [F2].</td></tr>
<tr><td>3</td><td>Select Add/Del Chem [F1].</td></tr>
<tr><td>4</td><td>Select the button beside the chemistry to be added or deleted.</td></tr>
<tr><td>5</td><td>
<table>
<tr><th>If deleting a chemistry without results…</th><th>If deleting a chemistry with results…</th></tr>
<tr><td>Select <OK> to delete the chemistry from the control.
OR
Select <Cancel> to return to the Define/Edit Controls screen without deleting the chemistry.</td><td>Select <OK> to delete the results, cumulative statistics, and chemistry.
OR
Select <Cancel> to delete the results and cumulative statistics but not the chemistry.

Enter a maximum of 3 alphanumeric characters in the Operator ID field. Press [Enter].</td></tr>
</table>
</td></tr>
</table>

Changing Units for a Defined Chemistry

Follow the steps below to change the units for a chemistry defined in a control.

Step	Action
1	Delete the chemistry from all controls. (Refer to "Adding or Deleting Individual Chemistries" in this chapter.)
2	Change the units for the chemistry. (Refer to CHAPTER 5, *System Setup*, Units Setup.)
3	Add the chemistry back into the control definition. (Refer to "Adding or Deleting Individual Chemistries.")
4	Redefine the chemistry. (Refer to "Entering the Minimum Control Definition" or "Defining More Information for a Control.")

Additional Information

Refer to CHAPTER 5, *System Setup*, Report Setup for information on setting up a report format for surveys.

Reviewing a Control Definition

Introduction

The Review Control function allows the operator to review control definitions for 100 controls.

Reviewing, Deleting, and Printing a Control Definition

Follow the steps below to review, delete, or print a control definition.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>From the Quality Control screen, select the button beside the Control Name to be reviewed.</td></tr>
<tr><td>2</td><td>Select Review Control [F1]. (Refer to Figure 9.5.)</td></tr>
<tr><td>3</td><td>The information about the control is displayed.
<table>
<tr><th>Select…</th><th>to…</th></tr>
<tr><td>Control ID [F2]</td><td>View the Control IDs defined for the Control name. Select <OK> to return to the Review Controls screen.</td></tr>
<tr><td>Delete Control [F3]</td><td>Clear the control. Select <OK> to delete the control.
OR
Select <Cancel> to return to the Review Controls screen.</td></tr>
<tr><td>Print Control [F10]</td><td>Print a comprehensive control listing. A comprehensive control listing includes the control name, control lot number, sample type, chemistry name, units, assigned mean, performance range, QC file number, and constituent code.</td></tr>
</table></td></tr>
<tr><td>4</td><td>Select any icon from the menu bar to exit the Review Controls screen.</td></tr>
</table>

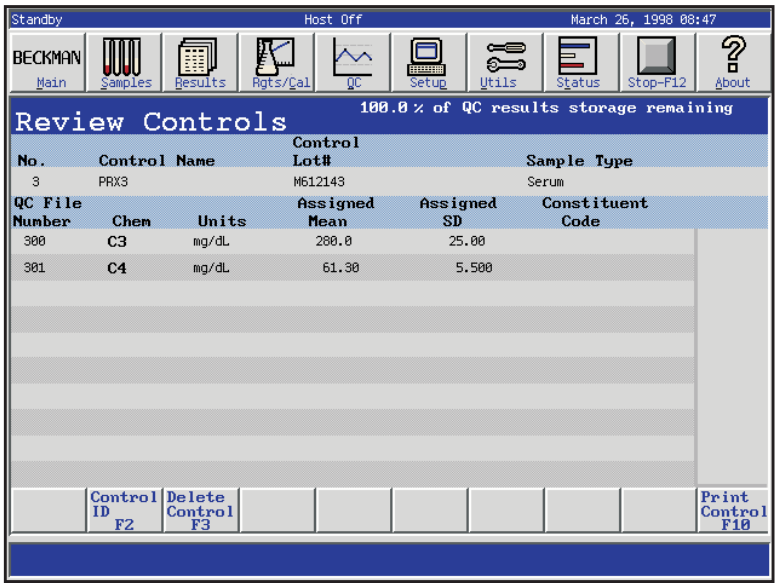

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Figure 9.5 Review Controls Screen

Deleting a Control Definition

Introduction

A previously defined control may be deleted from any of three locations:

- the Quality Control screen
- the Review Controls screen
- the Define/Edit Controls screen

The entire control definition (all chemistries) is deleted.

Deleting from the Quality Control Screen

Follow the steps below to delete a control definition from the Quality Control screen.

Step	Action
1	Select **QC** from the menu bar.
2	From the Quality Control screen, select the button beside the Control Name to be deleted.
3	Select **Delete Control [F3]**.
4	Select **<OK>** to delete the control. OR Select **<Cancel>** to return to the Quality Control screen without deleting the control.
5	Enter a maximum of 3 alphanumeric characters in the **Operator ID** field. Press **[Enter]**.

Deleting from the Review Control Screen

Follow the steps below to delete a control from the Review Controls screen.

Step	Action
1	Select **QC** from the menu bar.
2	From the Quality Control screen, select the button beside the Control Name to be deleted.
3	Select **Review Control [F1]**.
4	Select **Delete Control [F3]**.
5	Select **<OK>** to delete the control. OR Select **<Cancel>** to return to the Quality Control screen without deleting the control.

(1 of 2)

Step	**Action**, continued
6	Enter a maximum of three alphanumeric characters in the **Operator ID** field. Press **[Enter]**.

(2 of 2)

Deleting from the Define/Edit Controls Screen

Follow the steps below to delete a control from the Define/Edit Controls screen.

Step	Action
1	Select **QC** from the menu bar.
2	From the Quality Control screen, select the button beside the Control Name to be deleted.
3	Select **Define/Edit [F2]**.
4	Select **Delete Control [F3]**.
5	Select **<OK>** to delete the control. OR Select **<Cancel>** to return to the Quality Control screen without deleting the control.
6	Enter a maximum of three alphanumeric characters in the **Operator ID** field. Press **[Enter]**.

Displaying the QC File List

Introduction

The operator can display and/or print a list of QC files by control name, chemistry name, or QC File number.

A QC File is a grouping of control information for a particular chemistry in a particular control (e.g., control lot number, mean, SD, cumulative sums).

A QC File number is the unique number assigned by the operator to identify a particular QC File. (Refer to Defining a Control in this chapter.)

Displaying QC File Lists

Follow the steps below to list QC files.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select QC from the menu bar.</td></tr>
<tr><td>2</td><td>Select a number beside a defined control. If a Control Name is not selected, the QC File List by Control Name is displayed with all defined controls.</td></tr>
<tr><td>3</td><td>Select QC File List [F4]. (Refer to Figure 9.6.)</td></tr>
<tr><td>4</td><td>
<table>
<tr><th>Select...</th><th>to display the QC list by...</th></tr>
<tr><td>List CtlName [F1]</td><td>Control name</td></tr>
<tr><td>List File [F2]</td><td>File number</td></tr>
<tr><td>List SelChem [F3]</td><td>Selected chemistries. Choose the chemistries and select <OK> to display the QC List
OR
Select <Cancel> to exit without displaying the QC List.</td></tr>
<tr><td>List All Chem [F4]</td><td>Chemistry name in alphabetical order</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>Select Print [F10] to print the File List.
OR
Select any icon from the menu bar to exit.</td></tr>
</table>

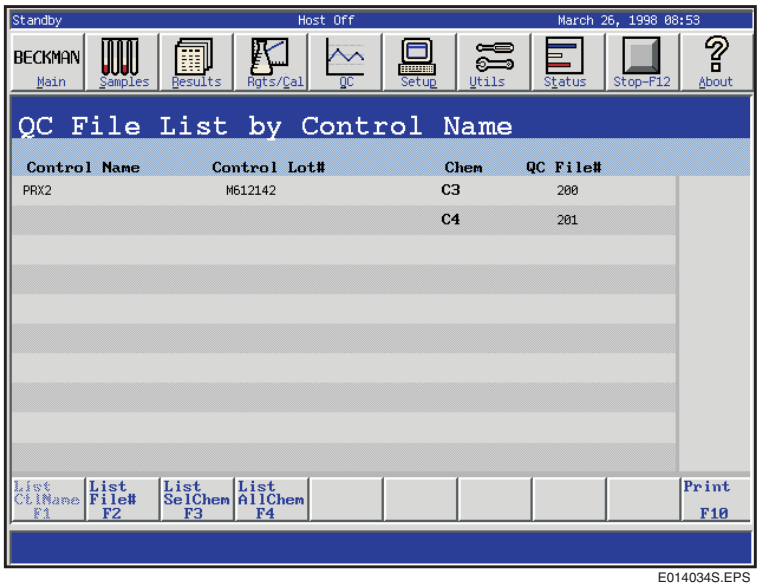


Figure 9.6 QC File List

QC Log

Introduction

The QC Log displays results from a specified period with interpretations regarding the relationship between QC results, using the assigned mean and standard deviation. Data points can be deleted from the hard disk only and the cumulative statistics will update automatically. The deleted data points are marked as deleted, with the operator's initials and the date and time of deletion. The operator may view or print the QC Log from either the hard disk or the external media (USB flash drive). The Action Log within the QC Log function allows comments to be attached to specific data points.

Description of Symbols on the QC Log

The following table describes the symbols and flags displayed on the QC Log.

Table 9.1 QC Log Symbols and Flags

Symbol/Flag	QC Result Interpretation	Westgard Rule Violation
Result and yellow Warning symbol	Result is > ±2 SD and <± 3 SD from the assigned mean.	1-2S
Result and red Warning symbol	Result is > ±3 SD from the assigned mean.	1-3SD
Result, red Warning symbol and "Accuracy" flag	Current result and previous result >±2 SD on the same side of the assigned mean.	2-2S
Result, red Warning symbol and "Precision" flag	Current result and previous result >±2 SD on the opposite sides of the assigned mean.	R-4S
Result flagged >± 4S.D.	Result is included in the QC Log and QC Chart, but is not used to calculate statistics.	
Deleted	QC data point was deleted. The date, time and operator are displayed beside the deletion.	
*	An Action Log comment is associated with the data point.	

Accessing QC Logs

Follow the steps below to access QC logs.

Step	Action
1	From the Quality Control screen, select the control desired. Use the <**Page Up**>/<**Page Down**> buttons to access additional controls.
2	Select **QC Log [F5]**.
3	Enter a Start date and an End date in the date range fields. The default Start/End date is the current date. Select <**OK**> to choose the default. Use **[Tab]** to toggle between fields. Select <**OK**> to continue. OR Select <**Cancel**> to exit.
4	The QC Log may be displayed by Chemistry or by Reagent Lot. (The default display is by chemistry in alphabetical order.) To display the QC Log by Reagent Lot, select **Rgt Lot [F2]**. (Refer to Figure 9.7.)
5	Enter the date range in the date range fields. Select <**OK**> to continue. Data is displayed by chemistry with reagent lot listed in descending order. (Use the <**Page Up**>/<**Page Down**> buttons to access additional data.) OR Select <**Cancel**> to exit.
6	To print the QC Log select **Print [F10]**.

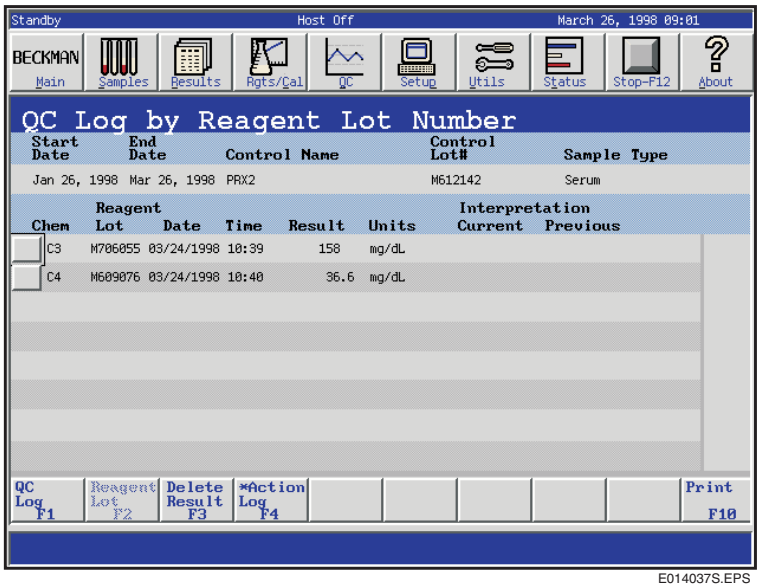


Figure 9.7 QC Log by Reagent Lot

Deleting a Result

The instrument status must be in *Standby* in order to proceed with the steps below.

Follow the steps below to delete results from the QC Log cumulative statistics.

Step	Action
1	From the Quality Control screen, select the control desired. Use the **<Page Up>**/**<Page Down>** buttons to access additional controls.
2	Select **QC Log [F5]**.
3	Enter a Start date and an End date in the date range fields. The default Start/End date is the current date. Select **<OK>** to choose the default. Use **[Tab]** to toggle between fields. Select **<OK>** to continue. OR Select **<Cancel>** to exit.
4	Select the result by selecting the check box next to the result.
5	Select **Delete Result [F3]**.
6	Enter a maximum of 3 alphanumeric characters in the **Operator ID** field. Press **[Enter]**.

(1 of 2)

Step	**Action**, continued
7	A message appears to confirm the deletion of the result. *QC result will be deleted. Backup is suggested. Delete QC result?* Select <**OK**> to delete the result. OR Select <**Cancel**> to exit without deleting the result. The deleted result is still displayed within the QC Log. It is marked as deleted with the initials of the operator who deleted it. However, the data point will no longer be included in any calculations or summaries.

(2 of 2)

Action Log

An Action Log comment, to be associated with a particular result, can be defined by the operator.

The instrument status must be in *Standby* in order to proceed with the steps below.

Follow the steps below to associate a comment with a result.

Step	Action
1	From the Quality Control screen, select the control desired. Use the <**Page Up**>/<**Page Down**> buttons to access additional controls.
2	Select **QC Log [F5]**.
3	Enter a Start date and an End date in the date range fields. The default Start/End date is the current date. Select <**OK**> to choose the default. Use **[Tab]** to toggle between fields. Select <**OK**> to continue. OR Select <**Cancel**> to exit.
4	Select the result by selecting the check box next to the result.
5	Select ***Action Log [F4]**.
6	The QC Action Log dialog box appears. Enter a maximum of 30 alphanumeric characters in the **Comment** field. Select <**OK**> to save the comment in the database. OR Select <**Cancel**> to exit without saving the comment.

(1 of 2)

Step	**Action**, continued
7	Select **Print [F10]** to print the QC Log.

(2 of 2)

Displaying QC Summaries

Introduction

The QC Summary report contains the cumulative mean, SD, CV and number of results (N) for any control within a specified date interval. The printed report contains the cumulative mean, SD, CV and Number of accumulated results.

A report can be printed in the Inter-Lab format for submission to Beckman Coulter. The constituent code must be defined in order for a chemistry to be included in the Inter-Lab QC Summary.

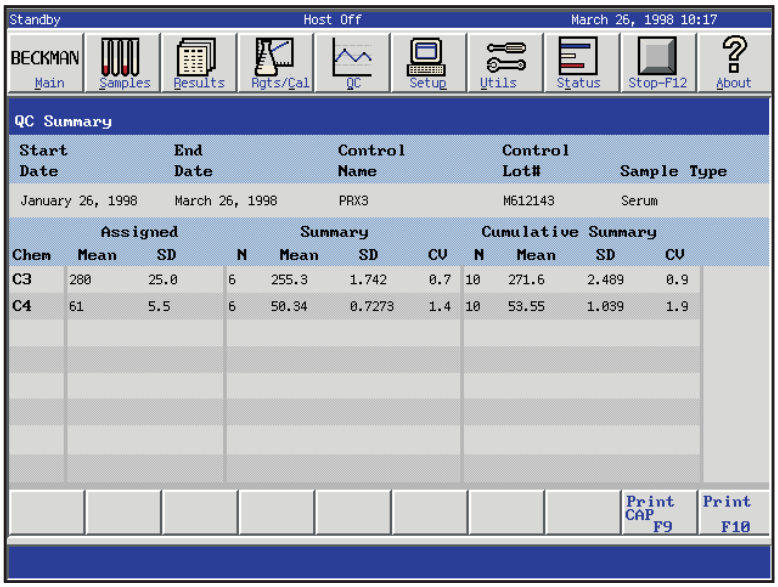
Accessing the QC Summary

Follow the steps below to access the QC Summary.

Step	Action
1	From the Quality Control screen, select the control desired. Use the **<Page Up>**/**<Page Down>** buttons to access additional controls.
2	Select **QC Summary [F6]** from the Quality Control screen. (Refer to Figure 9.8.)
3	Enter a Start date and an End date in the date range fields. The default Start/End date is the current date. Select **<OK>** to choose the default. Use **[Tab]** to toggle between fields. Select **<OK>** to continue. OR Select **<Cancel>** to exit.
4	Select **Print [F10]** to print the QC Summary. OR Select **Inter-Lab [F9]** to print a QC Summary report in the Inter-Lab format.

Additional information

Refer to CHAPTER 5, *System Setup*, Report Setup, Defining Inter-Lab Information for information on setting up a Inter-Lab reference number and contact person for the Inter-Lab QC Summary.



E014038S.EPS

Figure 9.8 QC Summary

QC Chart (Levey-Jennings)

Introduction

QC Chart displays the results in a control file for a specified period (default is current date) in graphic form, showing the position of data points relative to the assigned mean and standard deviation. The results are listed by date and time, most recent results first. QC Chart is available for either the hard disk or the external media (USB flash drive).

> NOTICE
> Flagging is based on assigned mean and SD at time of run and will not change if the assigned mean and/or SD are modified.

Accessing QC Chart

Follow the steps below to access QC chart.

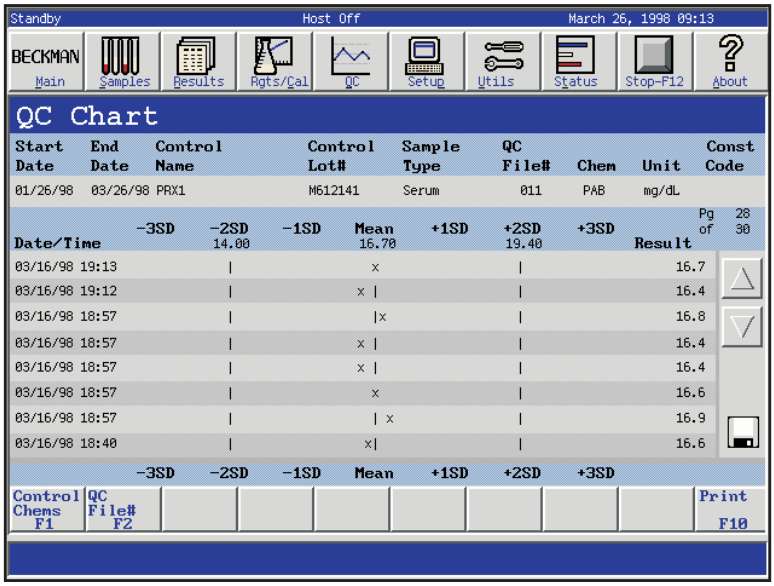
Step	Action
1	From the Quality Control screen, select the control desired. Use the <**Page Up**>/<**Page Down**> buttons to access additional controls.
2	Select **QC Chart [F7]**. (Refer to Figure 9.9.)
3	Enter a Start date and an End date in the date range fields. The default Start/End date is the current date. Select <**OK**> to choose the default. Use **[Tab]** to toggle between fields. Select <**OK**> to continue. OR Select <**Cancel**> to exit.
4	All chemistries for the control are selected by default. Deselect defined chemistries that should not be charted. Multiple selections are allowed. Select the <**Page Up**>/<**Page Down**> buttons to access additional chemistries.
5	Select <**OK**> to display the QC Chart(s) OR Select <**Cancel**> to cancel the Chart request.
6	Select the <**Page Up**>/<**Page Down**> buttons to access all requested QC charts.

(1 of 2)

Step	**Action**, continued
7	

Select...	**to…**
Control Chems [F1]	specify other chemistries for charting.
QC File# [F2]	specify other File Numbers for charting.
Print [F10]	print a copy of the QC Chart(s).

(2 of 2)



E014039S.EPS

Figure 9.9 QC Chart

QC Backup

Introduction

The QC Backup function saves the control information and QC View data on an external media (USB flash drive) for future review. The archived data can be reviewed in the following functions:

- Review Control
- QC File List
- QC Log
- QC Summary
- QC Chart
- QC Print

The control information consists of the inputs used to define a control. (Refer to Defining a Control in this chapter.)

The QC View data consist of the result date, result value, QC rule flags, deleted data point date, action log comment, deleted result, operator ID, and reagent lot number.

QC results that are archived on the external media (USB flash drives) may be deleted from the QC Result database on the hard disk. The cumulative statistics are not affected by this deletion.

Why Perform Routine QC Backup

The IMMAGE 800 database can store up to 35,000 QC results from 999 QC files. Upon exceeding 999 QC Files, a pop-up window appears notifying the operator that the QC database is full. Some QC Files must be deleted to make room for new QC Files. Upon reaching 35,000 QC results, a result associated with a File Number overwrites the oldest result related to the File Number. If there are no results associated with the File Number, the new result is not stored. A message appears notifying the operator that the new result was not saved.

To avoid loss of QC results, it is necessary to perform routine QC Backup. The interval will vary depending on the number of controls run.

The system also monitors the database and reports the remaining hard disk storage space for QC. This is displayed on the Quality Control screen just below the menu toolbar. Backup should be considered when less than 5% of QC storage space remains.

QC Backup

Follow the steps below to back up QC to an external media (USB flash drive).

Step	Action
1	From the Quality Control screen, select **QC Backup [F8]**. (Refer to Figure 9.10.)
2	Select **<1> Backup to External Media**. OR Enter "**1**" on the **Option No.** field.
3	Enter a maximum of 3 alphanumeric characters in the **Operator ID** field. Press **[Enter]**.
4	Place a USB flash drive into the USB port.
5	Select <**OK**> to back up the QC. OR Select <**Cancel**> to return to the Quality Control screen without archiving the QC. NOTICE If you wish to archive more than 30 QC files, you will need an additional USB drive to do so.
6	At the Backup/Restore dialog box, select <**OK**> to continue.
7	Select <**OK**> to delete the QC results from the hard disk. OR Select <**Cancel**> to return to the Quality Control screen without deleting the results from the hard disk. NOTICE Once the QC data is deleted from the hard disk, modifications are no longer allowed.
8	Enter a date range in the QC Date Range dialog box. Select <**OK**> to delete the QC results from the hard disk. OR Select <**Cancel**> to return to the Quality Control screen without deleting the QC results from the hard disk.

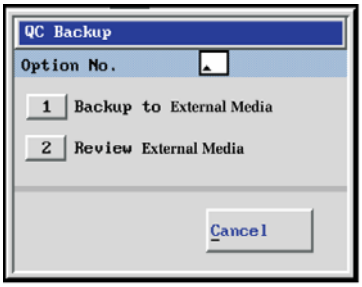


Figure 9.10 QC Backup Dialog Box

Restoring and Reviewing Backup Data

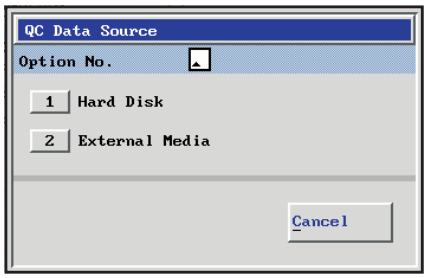
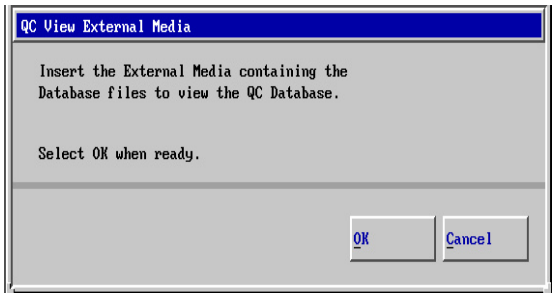
Introduction

Archived data can be reviewed from an external media (USB flash drive). Review options available from the USB flash drive include:

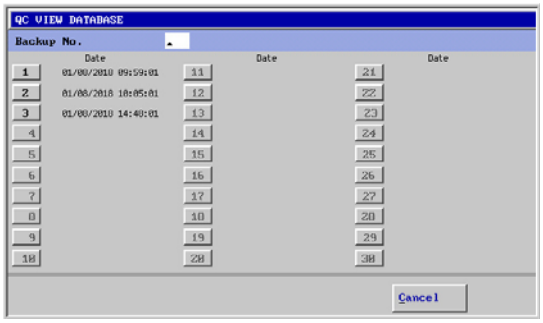
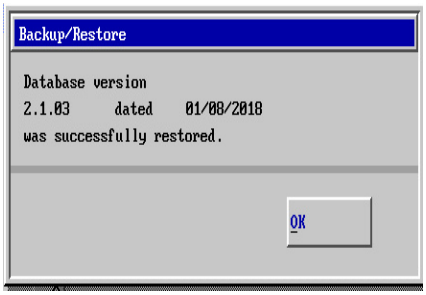
- Review of control definition and cumulative statistics for a control file.
- Display and printing of QC File List.
- QC Log, QC Summary and QC Chart.

Modifications to the control files that have been backed up are not allowed.

Reviewing Archived Data

Step	Action
1	From the Quality Control screen, select the options button <▼ > beside **QC Data Source** field.  E014041S.EPS Figure 9.11 QC Source Dialog Box Select **External Media**. The following screen is displayed.  Figure 9.12 QC View External Media Dialog Box

(1 of 3)

Step	**Action**, continued
2	Insert the archived USB flash drive, and then select <**OK**>. The following screen is displayed.  Figure 9.13 QC View Database Dialog Box
3	Select the specific archived file you want to see and then select <**OK**>. OR Select <**Cancel**> to exit the dialog box. NOTICE If there is only one backup, then there is no selection. The software has already selected it for you. The following screen is displayed.  Figure 9.14 Backup/Restore Dialog Box
4	Select <**OK**> when the database is successfully restored.

(2 of 3)

Step	**Action**, continued
5	

Select…	**to…**
Review Control [F1]	review backed up control definitions
QC File List [F4]	display and print backed up QC file lists. (Refer to "Displaying the QC File List" in this chapter.)
QC Log [F5]	display the backed up QC log. (Refer to "Accessing QC Logs" in this chapter.)
QC Summary [F6]	display and print a summary of the backed up data. (Refer to "Accessing the QC Summary" in this chapter.)
QC Chart [F7]	view a specific backed up control chart. (Refer to "Accessing QC Chart" in this chapter.)
Print Control [F10]	print backed up control ranges.

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CHAPTER 10 Utilities

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Utilities

Overview

Introduction

Utilities is divided into three sections: Maintenance, Troubleshooting, and Replacing Parts/User Servicing. These tasks are designed for performance at the operator level.

Utilities Dialog Box

Utilities menu items displayed in the IMMAGE 800 systems using software version 2.1 are numbered differently than the items displayed in earlier versions of the software. The Operations Manual and Instructions For Use reflect the display before version 2.1.

The differences occur because systems using version 2.1 software are configured with a USB drive, not a Floppy Disk Drive (FDD). The FDD is no longer applicable, and the Format QNX Diskettes menu item (number 5 in software versions before 2.1) is only applicable for systems with a FDD.

Following are the *Utilities* menu items found in Software v2.0 (and earlier version) and v2.1:

NOTICE

When following instructions related to the Utilities menu, choose functions based on the text description of the item and not the item number.

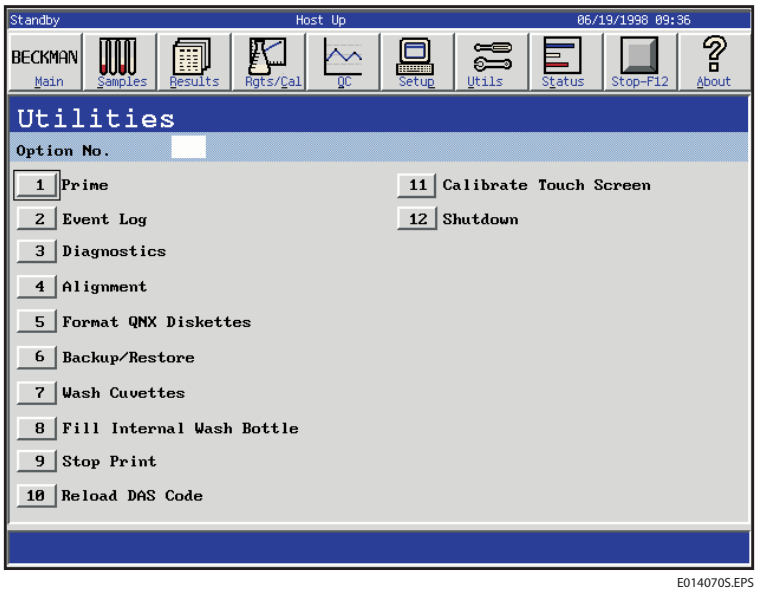


Figure 10.1 Software v2.0 (and earlier versions)

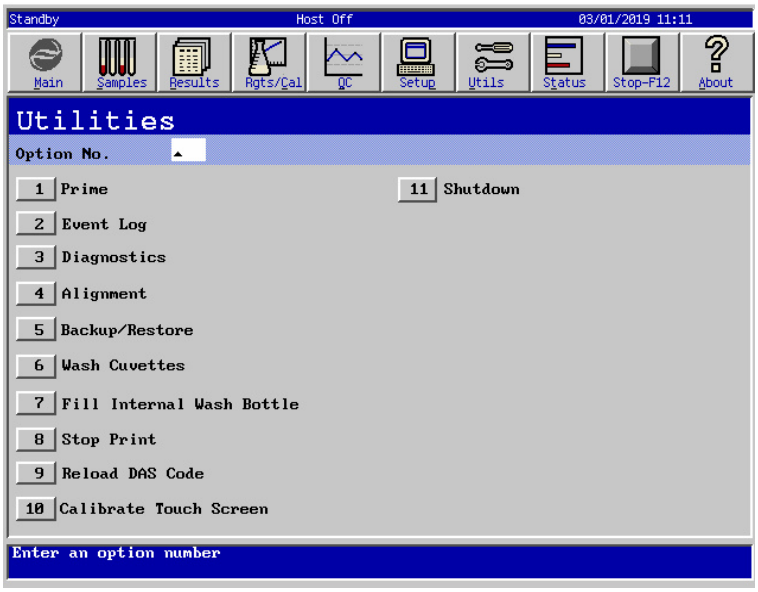


Figure 10.2 Software v2.1

Maintenance

This section will be helpful in performing required maintenance essential to:

- obtain accurate results
- meet inspection and accreditation requirements

This section explains how to:

- perform daily maintenance
- perform monthly maintenance
- perform as-indicated maintenance
- prime system fluids
- wash cuvettes

Troubleshooting

This section will be helpful in:

- diagnosing instrument problems
- initiating appropriate solutions for problems identified

This section explains how to use:

- Error messages for troubleshooting
- Event Log
- Callable Diagnostics
- alignment

- backup/restore
- internal wash bottle fill
- touch screen calibration

Replacing Parts/ User Servicing

For help with any system issues, call Beckman Coulter Clinical Support. The following information will assist the troubleshooting process: the model number, part number or serial number of the affected system and diagnostic printouts containing full details of the difficulty encountered.

Maintenance

Recommended Tools and Supplies

Beckman Coulter Tools and Supplies

The following items can be acquired from Beckman Coulter, Inc.

Table 10.1 Beckman Coulter Tools and Supplies

Item	Part Number
Maintenance Logbook	962324
IMMAGE Optics/Wash Head Alignment Tool	970456

Additional Tools/Supplies

The following items should be available in the laboratory.

- Straight-slotted screwdrivers
- Phillips-head screwdrivers
- Allen wrench - 9/64 inch
- Isopropyl alcohol swabs
- Household bleach solution
- Cotton-tipped applicators
- Deionized water
- Paper towels
- Lint-free tissues
- Surgical blade

Maintenance Precautions

Introduction

To ensure the safe operation of the IMMAGE 800, and the safety of the operator, please follow the precautions listed below.

Precautions

1. Do not remove or install a circuit board, connect or disconnect any plug or cable while the power cord is connected.
2. Always use the antistatic wrist strap located behind the front panel when handling any circuit board.
3. Observe procedures pertaining to safe handling of biological hazards while performing system maintenance or repair.
4. The instrument status must be in *Standby* before attempting to clean any part of the instrument.
5. Keep clear of all mechanical assemblies when booting up the system or when exiting the Diagnostics function.
6. The *Auto-Maintenance* function, which washes all cuvettes not washed or used within the previous 12 hours, may cause the system probes to move to *Home* position without warning. In order to disable this function while performing system maintenance tasks, alignments, troubleshooting, or parts replacment requiring physical manipulation near the sample or reagent cranes, it is recommended to select **Diagnostics** from the *Utilities* menu. *Auto-Maintenance* will not start while the system is in *Diagnostics* mode.

CAUTION

Sodium Azide preservative in diagnostic reagents may react with lead or copper in drain lines and form explosive compounds. Means of decontamination and control are described in Current Intelligence Bulletin: Explosive Azide Hazard, August 16, 1976 prepared by the National Institute for Occupational Safety and Health. A copy may be obtained from your Beckman Coulter Sales and Service Office.

Maintenance Schedule

Introduction

Follow the schedule of auto, daily, monthly, and as-indicated maintenance to keep the IMMAGE 800 in proper operating condition. For higher volume laboratories, maintenance frequency, when appropriate, will be indicated based on the number of tests. To keep a log of performed maintenance, use the IMMAGE Immunochemistry Systems *Maintenance Logbook.*

Auto Maintenance Procedures

Auto

The Auto Maintenance cycle washes all cuvettes (1-39). This cycle is performed automatically when:

- The system is in *Standby* and one or more of the cuvettes has not been washed in the preceding 12 hours.
- The system is in *Standby* and one or more of the cuvettes has not been used in the preceding 12 hours.

If the system is active when one of the above situations occur, or the system is interrupted during the Auto Maintenance cycle, the wash will run again in one hour.

- The *Auto-Maintenance* function may cause the system probes to move to *Home* position without warning. In order to disable this function while performing system maintenance tasks, alignments, troubleshooting, or parts replacment requiring physical manipulation near the sample or reagent cranes, it is recommended to select **Diagnostics** from the *Utilities* menu. *Auto-Maintenance* will not start while the system is in *Diagnostics* mode.

Daily Maintenance Procedures

Daily

The following table lists the scheduled daily maintenance for the IMMAGE 800 System.

Table 10.2 Daily Maintenance

Check	Clean
Wash Volume and Tubings	Reagent and Sample Probes/Mixers
Waste Volume and Tubing	
Fluid spills	
Syringes: tubings, tips, and valves	

Observe and Check

As part of daily maintenance perform the following steps.

Visual Maintenance

Visually confirm that the...	is...
Wash Solution (1) volume	sufficient to perform the laboratory's daily workload. (Each box will perform approximately 1,000 tests.)
Blue (Wash Solution) tubing (2)	free of sharp bends or obstructions and is attached to blue fitting. (Refer to Figure 10.3.)
Orange (Wash Solution) tubing (3)	free of sharp bends or obstructions and is attached to orange fitting.
Green waste tubing (4)	free of any sharp bends or obstructions and is routed to the drain or waste container. If the waste is collected in a waste container (5), decontaminate according to local regulatory guidelines and empty as needed.

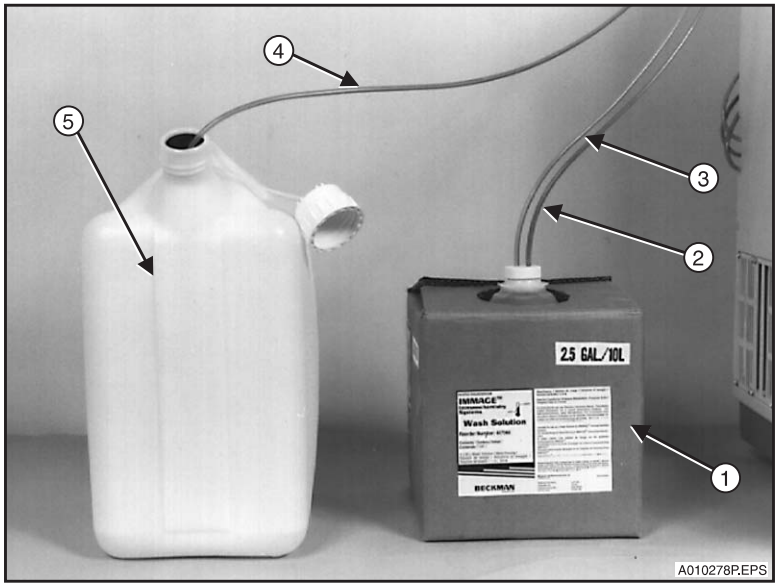
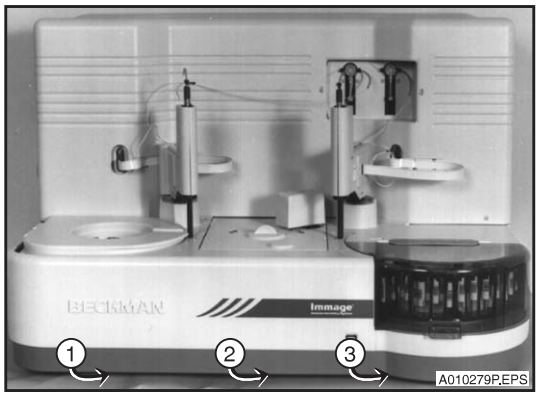
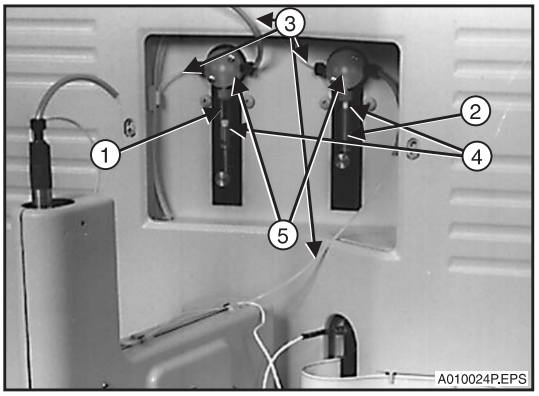


Figure 10.3 Wash Solution and Waste Containers

Observe and Check

If...	then...
fluid spills are present at location (1), (2), or (3) (Refer to Figure 10.4)	cover spills with 10% bleach solution and wipe with an absorbent towel. (Call Beckman Coulter Clinical Support.)  Figure 10.4

(1 of 2)

If...	then..., continued
while priming, or during routine operations, fluid leaks or bubbles are present,	remove bubbles from reagent (1) and sample (2) syringes, syringe lines (3), tips (4), and shear valves (5). (Refer to Figure 10.5) Bubbles may be removed by gently tapping on the tubing or syringe during the prime function. Refer to As-Indicated Maintenance in this section for syringe replacement.  Figure 10.5

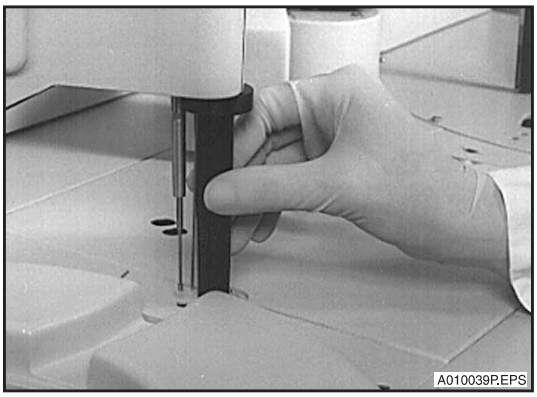
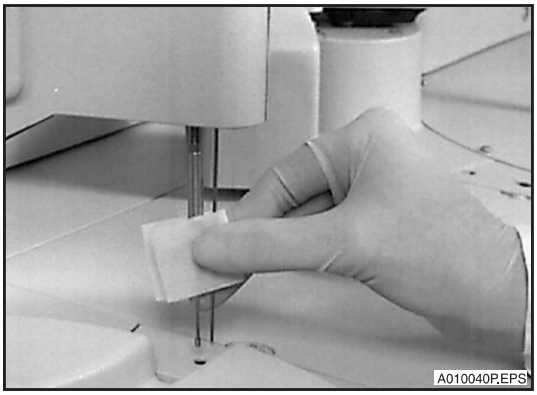
(2 of 2)

Cleaning Instrument Parts

The instrument status must be in *Standby* in order to proceed with the steps below to clean the reagent/sample probes and mixer paddles.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **Diagnostics** from the *Utilities* menu.

(1 of 2)

Step	**Action**, continued
3	Raise reagent/sample crane prob covers as shown.  Figure 10.6
4	Carefully wipe probe and mixer, the full length exposed, with an alcohol swab.  Figure 10.7
5	Lower probe covers.
6	Select **Main** from the menu bar.
7	Select <**OK**> to exit *Diagnostics*.
8	Select <**OK**> to clear *Warning*.

(2 of 2)

Priming

To prime, perform the following steps.

Step	Action
1	Select **Utilities** from the menu bar.

Step	Action
2	Select **<1> Prime** from the Utilities dialog box. OR Type **1** in the **Option No.** field and press **[Enter]**.
3	Enter number of primes desired.
4	Select <**OK**>.

Monthly Maintenance Procedures

Monthly

The following table lists the scheduled monthly maintenance for the IMMAGE 800 System.

Table 10.3 Monthly Maintenance

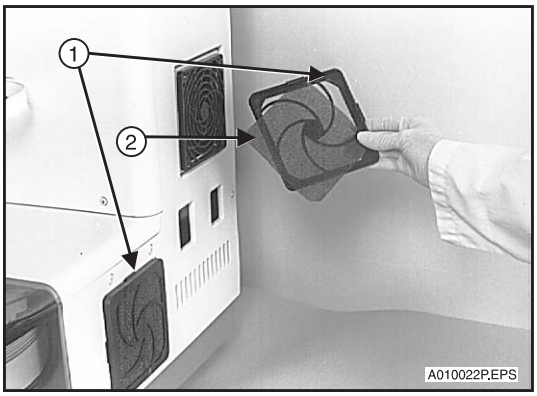
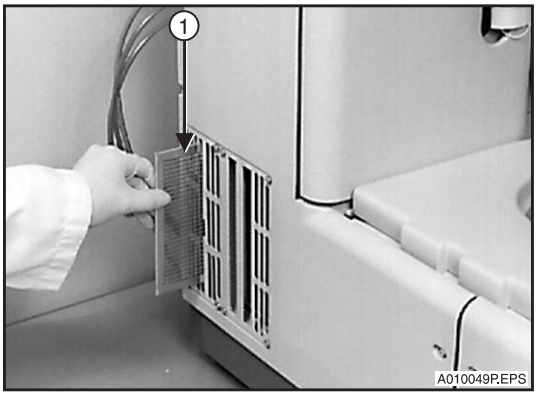
Clean	Perform
Exterior surfaces	Record the cycle count.
Fan Filters	

Cleaning Surfaces

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **Diagnostics** from the *Utilities* menu.
3	Wipe all exposed surfaces on the system and table surfaces with a fresh 10% bleach solution.
4	Select **Main** from the menu bar.
5	Select **<OK>** to exit *Diagnostics*.
6	Select **<OK>** to clear *Warning*.

Cleaning Filters

To clean fan filters, perform the following the steps.

Step	Action
1	Grasp and pull both fan covers (1) from right side of instrument and remove filters (2).  Figure 10.8
2	Remove filter (1) from the left side of the instrument.  Figure 10.9
3	Wash the filters with deionized water to remove lint or clean the filters with pressurized air, if available.
4	Use paper towels or lint-free tissues to dry the filter.
5	Reinsert filters and replace covers.

Cycle Count

The cycle count is the total number of tests started by the IMMAGE 800. Obtaining the cycle count is necessary to determine the number of tests performed. Follow the steps below to obtain the cycle count.

Step	Action
1	Select **Status** from the menu bar.
2	Select **<3> Instrument Status Monitor** from the Status screen. OR Type **3** in the **Option No.** field and press **[Enter]**.
3	Record the results on the maintenance log sheet.

As-Indicated Maintenance

As-Indicated

The following table lists the As-Indicated maintenance for the IMMAGE 800 System.

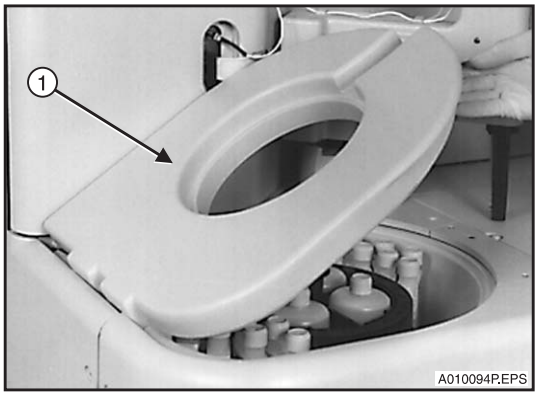
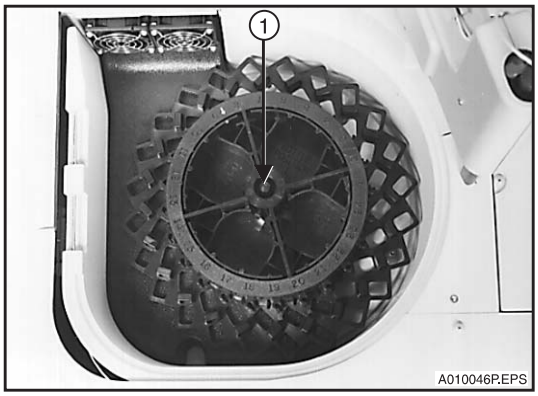
Table 10.4 As-Indicated Maintenance

Clean	Perform
Clean or replace printer cartridge (Refer to Printer Manual.)	Replace all Cuvettes every 10,000 tests. For systems using DIL2, cuvettes may need to be replaced more frequently.
Decontaminate Sample/Reagent Carousels and Sample Racks	Cuvette Wash.
	Replace syringes if leaking occurs, or as needed.
	Replace UPS battery when "battery low" light or audible alarm is activated. (Refer to UPS User's Manual.)

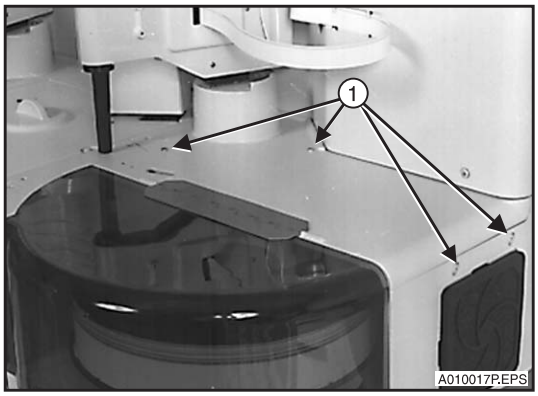
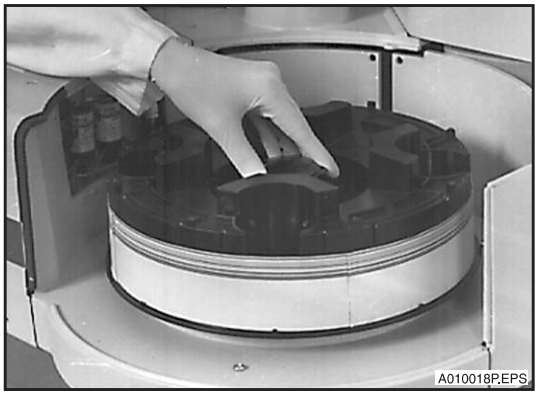
Decontaminating Carousels and Racks

To decontaminate the sample or reagent carousels or sample racks, perform the following steps. Verify from the status bar that the instrument status is in *Standby*.

NOTICE
DO NOT Autoclave Carousels or Sample Racks

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **Diagnostics** from the *Utilities* menu.
3	To remove the reagent carousel, lift the reagent cover (1).  Figure 10.10
4	Pull up on the carousel (1).  Figure 10.11

(1 of 3)

Step	**Action**, continued
5	To remove the sample carousel, unscrew the two top and two side screws (1) of the sample carousel cover.  Figure 10.12
6	Unscrew the sample carousel cap. Remove the sample carousel.  Figure 10.13
7	Prepare a 10% bleach solution (approximately 0.5% final hypochlorite solution) in deionized water.
8	Immerse carousels or sample racks into a large container or sink filled with the bleach solution. Allow carousels or racks to soak at room temperature for 15 to 20 minutes.
9	Remove the carousels or racks and rinse with deionized water or tap water and let stand until dry.
10	Observe rack labels for bubbling, peeling, or fading. Remove and replace with a new label if necessary according to instructions in CHAPTER 5, *System Setup*, Placing Bar Code Label on Rack.
11	Select **Main** from the menu bar.

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Step	**Action**, continued
12	Select **<OK>** to exit *Diagnostics*.
13	Select **<OK>** to clear *Warning*.

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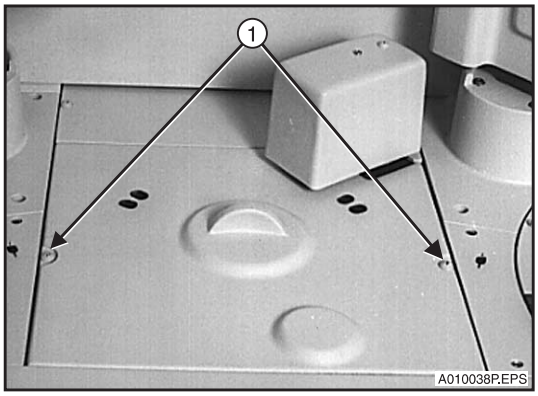
Replacing Cuvettes

Cuvettes are clustered in sectors of three for efficient handling. Handle cuvettes by the top edges only. Do not remove or touch Reference Cuvette (number 40).

The instrument status must be in *Standby* in order to proceed with the steps below.

Step	Action
1	Verify that the cuvette washer is raised into the cuvette wash station. If the cuvette washer is lowered into a cuvette, select **<Home>** from the Main screen to raise the cuvette washer.
2	Select **Utilities** from the menu bar.
3	Select **Diagnostics** from the *Utilities* menu.
4	Remove the two reaction module cover screws (1).  Figure 10.14

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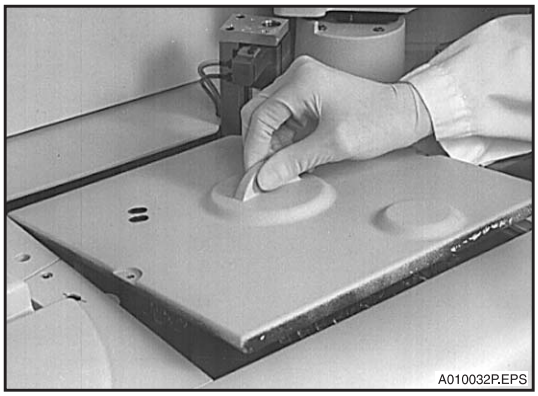
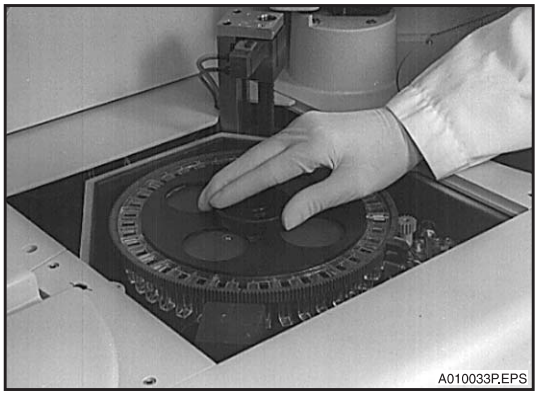
Step	**Action**, continued
5	Slide reaction module cover forward from under cuvette wash station as shown.  Figure 10.15
6	Unscrew cuvette cover plate counterclockwise. Remove cover plate.  Figure 10.16
7	Remove cuvettes by lifting upward. Rotate the wheel as necessary to access all the cuvettes. Dispose of the used cuvettes in a manner appropriate for biohazardous materials.
8	Wipe the wheel with lint-free tissue moistened with DI water.

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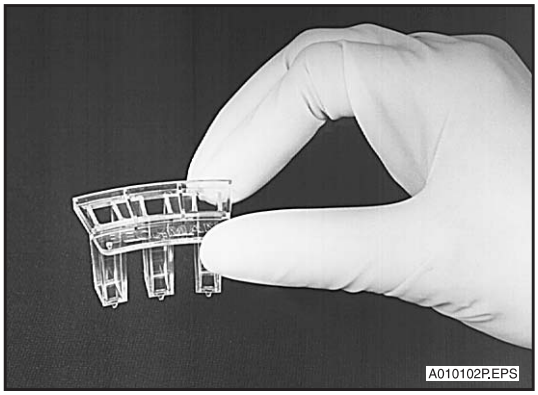
Step	**Action**, continued
9	Replace all cuvettes, handling by the top edges only. (Refer to Figure 10.17.) Confirm that all cuvettes are seated in the reaction carousel.  Figure 10.17
10	Replace the covers.
11	Select **Utilities** from the menu bar.
12	Select **<OK>** to exit *Diagnostics*.
13	Select **<OK>** to clear *Warning*.
14	Select **<7> Wash Cuvettes** from the *Utilities* dialog box. OR Enter **7** in the **Option No.** field and press **[Enter]**.
15	Type the first cuvette number (1) to begin the wash in the **Starting Range** field and press **[Enter]**.
16	Type the last cuvette number (39) in the **Cuvette** field to stop the wash in the **Ending Range** field.
17	Select **<OK>** to start washing the cuvettes.

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Washing Cuvettes

Washing the cuvettes may become necessary when performing maintenance or when troubleshooting. To access cuvette washing, perform the following steps.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<7> Wash Cuvettes** from the Utilities dialog box. OR Enter **7** in the **Option No.** field and press **[Enter]**.

Step	Action
3	Type the first cuvette number (1) to begin the wash in the **Starting Range** field and press **[Enter]**.
4	Type the last cuvette number (39) to stop the wash in the **Ending Range** field.
5	Select **<OK>** to start washing the cuvettes. NOTICE If **<Stop>** is selected to discontinue the cuvette wash, Homing of the system is necessary prior to using the Sample Carousel Advance button. OR Select **<Cancel>** to return to Utilities dialog box without starting the wash.

Replacing Syringes

To replace the reagent or sample syringes, perform the following steps.

Step	Action
1	Select **Utilities** from menu bar.
2	Select **<3> Diagnostics**.
3	Select **<2> Callable Diagnostics**.
4	Select **<1> Electro-mechanical motion**.
5	Select **Home All [F3]**.
6	Select **Devices [F2]**.
7	Select either **<11> Sample syringe** or **<12> Reagent syringe**.
8	Select **<3> Aspirate volumes**.
9	Enter "125" for the sample syringe or enter "250" for the Reagent Syringe, select **<OK>**.

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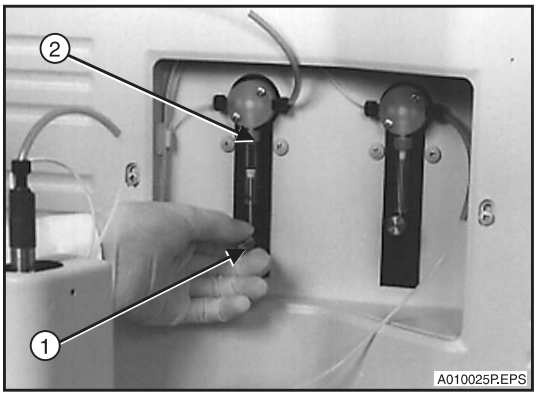
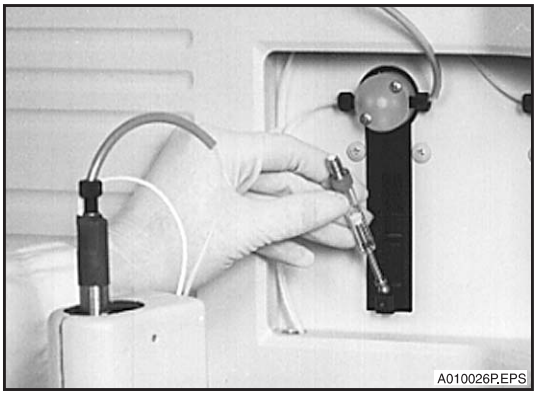
Step	**Action**, continued
10	Unscrew bottom syringe screw (1) and top syringe screw (2). (Refer to Figure 10.18.)  Figure 10.18
11	Remove syringe for replacement.  Figure 10.19
12	Insert new syringe.
13	Select **Main** from the menu bar.
14	After the status returns to *Standby*, prime the system and observe syringes for leaks or bubbles. Refer to Daily Maintenance Procedures, "Priming," in this chapter.
15	Run controls to verify system performance.

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Troubleshooting

Errors

Error Messages

The following table describes the types of error messages generated by the system. Error messages contain an explanation of the problem as well as an error number for reference in the Error Table. Errors are also logged in the Event log. For retrieval of events, refer to Event Log in this section.

Table 10.5 Error Messages

Location	Explanation
Remarks column of patient report	System is unable to obtain a valid answer.
Instrument errors on patient report	A code to indicate that the system is operating in a user-modified mode.
Green border pop-up window on screen	INFORMATIONAL MESSAGE only.
Yellow border pop-up window on screen	WARNING MESSAGE, system performance may need to be reviewed. Operation will continue unless startup checks have failed.
Red border pop-up window on screen	FATAL WARNING message, system performance must be reviewed and operation will cease.

Using the Error Table

Table 10.6 is useful to look up an explanation of any displayed or printed error messages.

- Error messages with the prefix "E" are found on patient reports (e.g., E10).
- Error messages without a prefix are displayed as pop-up windows (e.g., 10).

The "Action" column is prioritized with the most likely solutions appearing first. Call Beckman Coulter Clinical Support as a final resolution.

NOTICE

The Status Monitor screen updates every three seconds with out-of-range results highlighted in red and should, therefore, be observed for several minutes to verify proper instrument performance. (Refer to CHAPTER 11, *System Status/Instrument Command*, Checking the Instrument Status Monitor.)

Error Table

Table 10.6 Displayed or Printed Error Messages

Error #	Abbreviation/ Message	Explanation	Action
E1	No AGXS Data	No Antigen Excess Data Points	CALL BECKMAN COULTER CLINICAL SUPPORT
E2	No AGXS Data	No Antigen Excess Data Points High	CALL BECKMAN COULTER CLINICAL SUPPORT
E3	Motion Error	Motion Error	1. Remove any obstructions from moving parts. 2. Home system. 3. Follow Event Log directions to display the Motion Error Event Log. 4. Restart the run. Report any failed devices to Beckman Coulter Clinical Support.
E4	No Dil Wells	Out of Dilution Wells	From Status menu, check status of dilution segments and replace segments showing zero ("0") status.
E5	RGT Cart N/A	Insufficient Chemistry Reagent and/or Uncalibrated Reagent	If reagent volume is low, load a new reagent cartridge, and Read Reagents from the Rgts/Cal screen. If reagent is uncalibrated, calibrate.
E6	Back to Back	Excessive Calibrator Replicate Spread	Repeat calibration.
E7	Scale Fct	Scale Factor Range Error	Repeat calibration.
E8	Unstable RXN	Unstable Reaction	CALL BECKMAN COULTER CLINICAL SUPPORT
E9	RGT Cart N/A	Insufficient Chemistry Reagent	Reagent not on board. Load a new reagent cartridge, and Read Reagents from the Rgts/Cal screen.
E10	Chk Optics	Optics Error for AGXS, excessive Q Values	CALL BECKMAN COULTER CLINICAL SUPPORT
10	Code Segment CRC Failure	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E11	Chk Optics	Optics Error, excessive scatter	1. Dilute and rerun sample. 2. Check and remove bubbles from reagent cartridge/sample container.
E12	Chk Optics	Excessive Q Values Detected	1. Check and remove bubbles from reagent cartridge/sample container. 2. Check and remove bubbles from buffers and diluents. 3. Rerun sample.
E13	Chk Optics	Optics Error Divide-by-Zero or Log 10 Domain	CALL BECKMAN COULTER CLINICAL SUPPORT
E14	Chk Optics	Optics Error for AGXS, Divide-by-Zero or Log 10 Domain	CALL BECKMAN COULTER CLINICAL SUPPORT
E15	Chk Optics	Optics Error, Bad Data	CALL BECKMAN COULTER CLINICAL SUPPORT
E16	Chk Optics	Optics Error for AGXS, excessive scatter	CALL BECKMAN COULTER CLINICAL SUPPORT
E17	Chk Optics	Optics Error for AGXS, Bad Data	CALL BECKMAN COULTER CLINICAL SUPPORT
E18	RGT Temp OR	Reagent Temperature Out of Range	1. Verify reagent fans are turning. 2. Close reagent cover. 3. Check Status Monitor to verify reagent temperature is within range.
E19	Anlg Gnd OR	Analog Ground Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E20	Ref Volt OR	Reference Voltage Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E21	PSVE PS OR	P5VE Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E22	P12V PS OR	P12V Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E23	N12V PS OR	N12V Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E24	P24VD PS OR	P24VD Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E25	P24VE PS OR	P24VE Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E26	P24VH PS	P24VH Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E27	P24VS PS	P24VS Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E28	P24VP PS	P24VP Power Supply Out of Range	CALL BECKMAN COULTER CLINICAL SUPPORT
E29	Hi Press	High Pressure Out of Range	With system running samples: 1. Check Status Monitor. 2. Verify high pressure is in range.
E30	Lo Press	Low Pressure Out of Range	With system running samples: 1. Check Status Monitor. 2. Verify low pressure is in range.
E31	Vac	Vacuum Out of Range	With system running samples: 1. Check Status Monitor. 2. Verify vacuum is in range.
E32	RGT A LVL	Level Sense Failure, Reagent Compartment A	1. Check and remove bubbles from Reagent Compartment A. 2. Rerun sample.
E33	RGT B LVL	Level Sense Failure, Reagent Compartment B	1. Check and remove bubbles from Reagent Compartment B. 2. Rerun sample.
E34	Buff LVL	Level Sense Failure on Buffer	1. Check and remove bubbles from buffer. 2. Observe that reagent probe enters buffer. 3. Rerun sample.
E35	Dil LVL	Level Sense Failure on Diluent	1. Check and remove bubbles from diluent. 2. Rerun sample.

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E36	Sample LVL	Level Sense Failure on Sample	1. Check and remove bubbles from sample. 2. Verify sufficient sample volume is present. 3. Rerun sample.
E37	RGT A N/A	Reagent Compartment A Unavailable	Calibrate reagent.
E38	RGT B N/A	Reagent Compartment B Unavailable	Calibrate reagent.
E39	Buff N/A	Buffer Unavailable	Load a new buffer bottle, and verify that buffer position is defined correctly.
E40	Dil N/A	Diluent Unavailable	Load a new diluent bottle, and verify that diluent position is defined correctly.
E41	Hrdwr N/A	Hardware Unavailable	Home system.
E42	Excess Scat	Excessive Scatter	CALL BECKMAN COULTER CLINICAL SUPPORT
E43	Blank Term	Assoc. Blank Terminated	CALL BECKMAN COULTER CLINICAL SUPPORT
E44	S/W Error	Bad Test Object Address	CALL BECKMAN COULTER CLINICAL SUPPORT
E45	Uncal RGT	Uncalibrated Reagent	Recalibrate reagent.
E46	DilWell Err	Dilution Segments not Defined or Cleared	1. Clear dilution segments. 2. Rerun sample.
E47	S/W Error	Scheduling Failed	CALL BECKMAN COULTER CLINICAL SUPPORT
E48	No Param	No Valid Reagent Parameters A-G	1. Reload reagent card. 2. Reload reagent.
E49	Buff N/A	Insufficient Buffer	Load a new buffer bottle, and verify that buffer position is defined correctly.
50	Process Exception	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E50	Dil N/A	Insufficient Diluent	Load a new diluent bottle, and verify that diluent position is defined correctly.
E51	Sample N/A	Insufficient Sample	Verify sufficent sample.
E52	Cal Fail	Calibration Failure	Repeat calibration.
E53	Pause	Pause	CALL BECKMAN COULTER CLINICAL SUPPORT
E54	RGT Handler	Reagent Handler Error	CALL BECKMAN COULTER CLINICAL SUPPORT
E55	WASH N/A	Insufficient Wash Fluid	1. Verify wash line is not pinched. 2. From Utilities menu, select **<8> Fill Internal Wash Bottle**. 3. Rerun samples.
E56	No Model	No Model	CALL BECKMAN COULTER CLINICAL SUPPORT
E57	RXN Temp	Reaction Temperature Out of Range	1. Verify cover is in place. 2. Check Status Monitor for stable temperature.
E58	ORLO	Low Result	Refer to IMMAGE Immunochemistry Systems reagent *Instructions For Use* for appropriate measuring range.
E59	ORHI	High Result	Refer to IMMAGE Immunochemistry Systems reagent *Instructions For Use* for appropriate measuring range.
E60	RXN Error	No Reaction, AGXS failed	CALL BECKMAN COULTER CLINICAL SUPPORT
E61	ORLO	No Reaction (excluding Competitive)	Refer to IMMAGE Immunochemistry Systems reagent *Instructions For Use* for appropriate measuring range.
E62	RXN Error	No Reaction (Competitive)	CALL BECKMAN COULTER CLINICAL SUPPORT
E63	ORLO	Unstable Reaction (excluding Competitive)	Refer to IMMAGE Immunochemistry Systems reagent *Instructions For Use* for appropriate measuring range.

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E64	RXN Error	Unstable Reaction (Competitive)	1. Verify all constituents (reagents, samples, buffer, diluents, and segments) are available. 2. Rerun sample.
E65	ORHI	High Result	Refer to IMMAGE Immunochemistry Systems reagent *Instructions For Use* for appropriate measuring range.
E66	RXN Error	Unstable Reaction	CALL BECKMAN COULTER CLINICAL SUPPORT
E70	Invalid Cal	Invalid Calibration Type, Incorrect Reagent Card or Bad Read	1. Reread reagent card. 2. Reread calibration card.
E71	Cal Reps	Too Few Calibrators: Need Two or More Replicates for Calculation (Only one Replicate Calculation)	Repeat calibration.
E72	No Param	No Valid Reagent Parameters A-G, Reagent Card with no Parameters or Bad Read	Reread reagent card.
E73	RGT Handler	Reagent Handler Error	CALL BECKMAN COULTER CLINICAL SUPPORT
E76	Loop Error	Out of range result failed to reach final dilution level	Rerun pending test.
E77	DilWell LVL	Level sense failure on a dilution well	Rerun sample.
E79	S/W Error	No memory available	Reboot Instrument.
E80	Bad Data	Bad Data	CALL BECKMAN COULTER CLINICAL SUPPORT
E81	Bad Data	Bounds Failure	CALL BECKMAN COULTER CLINICAL SUPPORT
E82	Bad Data	Divide by Zero	CALL BECKMAN COULTER CLINICAL SUPPORT
E83	Bad Data	Excessive Q Values	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
E84	Bad Data	Log 10 Domain Error	CALL BECKMAN COULTER CLINICAL SUPPORT
E85	Bad Data	Divide by Zero Error (Cal/Actual, Actual = Zero)	CALL BECKMAN COULTER CLINICAL SUPPORT
101	Queue Send Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
102	Queue Receive Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
103	Event Send Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
104	Event Receive Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
105	P Semaphore Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
106	V Semaphore Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
107	Partition Return Buffer Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
108	Partition Get Buffer Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
109	Partition Ident Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
110	Queue Ident Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
111	Segment Get Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
112	Partition Create Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
113	Partition Delete Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
114	Timer Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
115	Ident Semaphore Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
150	Operating System Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
500	Motion Error Sample Carousel (or some other device) not functional	WARNING:	Home system.
501	Now Homing Reagent Section	WARNING:	No action required.
502	Now Homing Sample Section	WARNING:	No action required.
503	Reagent Section is Inoperable	WARNING:	Home system.
504	Sample Section is Inoperable	WARNING:	Home system.
505	DAS Reload Error	WARNING:	1. Select **Utils**. 2. Select **<10>. Reload DAS code**. 3. Reboot instrument.
801	Level Sense Failure at Buffer Bottle	WARNING:	1. Check and remove bubbles from buffer. 2. Observe that reagent probe enters buffer. 3. Rerun sample.
802	Level Sense Failure on Reagent A at Position	WARNING:	1. Check and remove bubbles from Reagent Compartment A. 2. Rerun sample.
803	Level Sense Failure on Reagent B at Position	WARNING:	1. Check and remove bubbles from Reagent Compartment B. 2. Rerun sample.
804	Level Sense Failure at Diluent Bottle	WARNING:	1. Check and remove bubbles from diluent. 2. Rerun sample.
805	Level Sense Failure at Dilution Well	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
806	Level Sense Failure at Sample Position	WARNING:	1. Check and remove bubbles from sample. 2. Verify sufficient sample volume is present. 3. Rerun sample.
811	Level Sense False Trigger at Buffer Bottle	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
812	Level Sense False Trigger on Reagent A at Position	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
813	Level Sense False Trigger on Reagent B at Position	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
814	Level Sense False Trigger at Diluent Bottle	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
815	Level Sense False Trigger at Dilution Well	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
816	Level Sense False Trigger at Sample Rack	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
900	Software Initialization Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
901	Error Downloading DAS	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1010	Unexpected XCOM Error Detected	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1020	XCOM Error during Socket Create	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1021	XCOM Error during Connect	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1022	XCOM Error during Setsockopt	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1023	XCOM Error during Ioctl	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1024	XCOM Error during Bind	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1025	XCOM Error during Listen	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1026	XCOM Error during Select	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1027	XCOM Error during Accept	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1030	Console to CAU Communications Failure (Alive Task)	FATAL:	Check cables between console and instrument. CALL BECKMAN COULTER CLINICAL SUPPORT
1201	Invalid Test Image Element	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1202	Error Scheduling Next Transaction	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1203	Start cycle does not match current cycle	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1204	Invalid Next Test Status	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1205	Sequencer Cycle Buffer Unavailable	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1206	Scheduled Cuvette is Already in Use	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1207	Scheduled Cuvette is Out of Range	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1208	The Command has Exceeded the Command Buffer size	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1209	Maximum Number of Cycles Exceeded	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1210	Sub-Sequence Time Tick Not in Ascending Order	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1212	DAS Buffer Overflow Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1213	Calculations Buffer Overflow Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1215	Cuvette Selected for Opportunistic Wash is Out of Range	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1216	Cuvette Selected for Preferred Wash is Out of Range	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1217	Preferred Wash Selection Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1218	Bad Return Status for Preferred Wash	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1219	Cycler Timed Out on Scheduler Stop	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1220	Dilution Handler Return Code Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1223	Error Reporting Wash Complete Status	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1227	Received Unexpected Level Sense Notification	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
1228	Received Unexpected Level Sense Failure Notification	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
1601	OMT Detected Invalid Request	WARNING:	Verify instrument is in proper mode for functions selected (e.g., *Standby*.)
1602	Optics Check-Nia Offset Quality High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1603	Optics Check-Nia Range Quality High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1604	Optics Check-Nia Range High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1605	Optics Check-Nia Range Low	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1606	Optics Check-Lpia Offset Quality High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1607	Optics Check-Lpia Range Quality High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1608	Optics Check-Lpia Range High	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1609	Optics Check-Lpia Range Low	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1610	Optics Check-Too Much Optics Data	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1611	Optics Check-Optics Check Not Done	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
1612	OMT Detected Invalid Barcode Setup	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
1613	Offline Sequence has Timed Out	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
1614	Cannot Start Run - Internal Wash Bottle Fill Procedure has Timed Out (LLS1)	WARNING:	Verify that volume in external wash solution container is sufficient. CALL BECKMAN COULTER CLINICAL SUPPORT
1615	Cannot Start Run - Internal Wash Bottle Fill Procedure has Timed Out (LLS2)	WARNING:	Verify that volume in external wash solution container is sufficient. CALL BECKMAN COULTER CLINICAL SUPPORT
1616	Cannot Start Run - Reaction Temperature is out of Range	WARNING:	Verify that reaction module cover is properly seated. CALL BECKMAN COULTER CLINICAL SUPPORT
1617	Cannot Start Run - Internal Wash Bottle is Empty	WARNING:	Verify that volume in external wash solution container is sufficient. CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1620	Mechanical Devices are inoperable. Go to Diagnostics or Alignment to correct the problem.	WARNING: Reagent or reaction cover may have been opened during power on.	1. Check that the reagent cover is on the instrument. 2. Close reagent cover if open. 3. Select **Utils**. 4. Select **Diagnostics**. 5. Select **Main**. 6. Select **<OK>** to exit the Diagnostics message. 7. Observe that the probes home. 8. Select **Home**. 9. If the probes home, then proceed to the next step. If the WARNING is displayed again, CALL BECKMAN COULTER CLINICAL SUPPORT. 10. Wash the cuvettes twice.
1625	CAU Optics Post Run Check Failed: NIA Channel	WARNING:	Repeat all chemistries run on the NIA Optics.
1626	CAU Optics Post Run Check Failed: LPIA Channel	WARNING:	Repeat all chemistries run on the LPIA Optics.
1627	Cannot Start Run-Alignment Checksum	WARNING:	Reboot the instrument.
1628	Cannot Start Run-UDS File Not Loaded	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
1629	File Gets Error:	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
1630	Download Error: UDS File Exceeded Limit of 1024 Lines	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
1800	Fatal Results Calculation Task Error	WARNING: Will STOP Run	Record what is displayed on pop-up screen. CALL BECKMAN COULTER CLINICAL SUPPORT
1801	Calibration Failed for Reagent	WARNING:	Repeat calibration.
2001	Unrecognized Bulk Name	WARNING: Will STOP Run	Verify that buffer and diluent positions are defined correctly.
2002	Size of memory allocation mismatch. No Chemistry Protocol Available for this dilution.	FATAL:	Check Sample Type for programmed chemistries.
2003	Buffer Detected but Not Defined	WARNING:	Define buffer positions for all loaded buffers.
2004	Buffer Defined but Not Detected	WARNING:	Load buffers for all defined buffer positions.
2005	Diluent Detected but Not Defined	WARNING:	Define diluent positions for all loaded diluents.
2006	Diluent Defined but Not Detected	WARNING:	Load diluents for all defined diluent positions.
2007	Invalid Card Type Received from MPC	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2008	Reagent Handler Invalid Parameters	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
2201	Illegal Protocol Tree Address	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2202	Scheduler Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2204	Corrupt Cycle Stack	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2205	Cycle Stack Empty	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2206	Cycle Stack Full	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2207	Frame Stack Full	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2208	Frame Stack Empty	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2209	Cuvette Handler Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2210	Attempt to Enable a Disabled Cuvette	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2211	Attempt to Recover an Expired Cuvette	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2212	Dilution Handler Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2214	Image Handler Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2215	Memory Allocation Error for Image Stack	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2216	Scheduler Supervisor Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2217	No Dilution Wells Available	WARNING:	1. From Status menu, check status of dilution segments and replace segments showing zero ("0") status. 2. Rerun sample.
2219	TDB Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2221	Failed to Schedule Test	WARNING:	1. Verify all constituents (reagents, samples, buffers, diluents, and segments) are available. 2. Rerun sample.

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2222	Task Fatal Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2223	Error with Scheduler Queue	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
2224	Illegal Queue Message Received	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
2225	Error in Cycle Count Conversion	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2402	Reaction Compartment Temperature Out of Range Low	WARNING: Will STOP Run	1. Verify cover is closed. 2. Check Status Monitor for stable reaction temperature in acceptable range.
2403	Reaction Compartment Temperature Out of Range High	WARNING: Will STOP Run	1. Verify cover is closed. 2. Check Status Monitor for stable reaction temperature in acceptable range.
2404	Reagent Compartment Temperature Out of Range Low	WARNING:	1. Verify reagent fans are working. 2. Verify cover is closed. 3. Check Status Monitor for stable reagent compartment temperature in acceptable range.
2405	Reagent Compartment Temperature Out of Range High	WARNING:	1. Verify reagent fans are working. 2. Verify cover is closed. 3. Check Status Monitor for stable reagent compartment temperature in acceptable range.
2406	Excessive temperature difference in the reaction chamber	WARNING:	1. Verify reagent fans are working. 2. Verify cover is closed. 3. Check Status Monitor for stable reagent compartment temperature in acceptable range.
2408	Analog Ground Out of Range Low	WARNING:	Observe Status Monitor

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2409	Analog Ground Out of Range High	WARNING:	Observe Status Monitor
2410	Reference Voltage Out of Range Low	WARNING:	Observe Status Monitor
2411	Reference Voltage Out of Range High	WARNING:	Observe Status Monitor
2416	5 Volt Power Supply ‘E’ Out of Range Low	WARNING:	Observe Status Monitor
2417	5 Volt Power Supply ‘E’ Out of Range High	WARNING:	Observe Status Monitor
2418	12 Volt Power Supply Out of Range Low	WARNING:	Observe Status Monitor
2419	12 Volt Power Supply Out of Range High	WARNING:	Observe Status Monitor
2420	Negative 12 Volt Power Supply Out of Range Low	WARNING:	Observe Status Monitor
2421	Negative 12 Volt Power Supply Out of Range High	WARNING:	Observe Status Monitor
2422	24 Volt Power Supply ‘D’ Out of Range Low	WARNING:	Observe Status Monitor
2423	24 Volt Power Supply ‘D’ Out of Range High	WARNING:	Observe Status Monitor
2424	24 Volt Power Supply ‘E’ Out of Range Low	WARNING:	Observe Status Monitor

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2425	24 Volt Power Supply ‘E’ Out of Range High	WARNING:	Observe Status Monitor
2426	24 Volt Power Supply ‘H’ Out of Range Low	WARNING:	Observe Status Monitor
2427	24 Volt Power Supply ‘H’ Out of Range High	WARNING:	Observe Status Monitor
2428	24 Volt Power Supply ‘S’ Out of Range Low	WARNING:	Observe Status Monitor
2429	24 Volt Power Supply ‘S’ Out of Range High	WARNING:	Observe Status Monitor
2430	24 Volt Power Supply ‘P’ Out of Range Low	WARNING:	Observe Status Monitor
2431	24 Volt Power Supply ‘P’ Out of Range High	WARNING:	Observe Status Monitor
2432	High Pressure Out of Range Low	WARNING:	With system running samples: 1. Check Status Monitor. 2. Verify high pressure is in range.
2433	High Pressure Out of Range High	WARNING:	With system running samples: 1. Check Status Monitor. 2. Verify high pressure is in range.
2434	Low Pressure Out of Range Low	WARNING:	With system running samples: 1. Check Status Monitor. 2. Verify low pressure is in range.
2435	Low Pressure Out of Range High	WARNING:	With system running samples: 1. Check Status Monitor. 2. Verify low pressure is in range.
2436	Vacuum Out of Range Low	WARNING:	With system running samples: 1. Check Status Monitor. 2. Verify vacuum is in range.

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2438	Internal Wash Bottle is Not Filling	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
2439	Internal Wash Bottle has Exceeded Maximum Fill Time	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
2440	Reagent Compartment Lid is Open	WARNING: Will STOP Run	Close reagent compartment cover.
2441	Reaction Compartment Lid Open	WARNING: Will STOP Run	Close reaction compartment cover.
2442	Thermal Flag Failure	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
2443	Card Cage Temperature Out of Range Low	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
2444	Card Cage Temperature Out of Range High	WARNING:	CALL BECKMAN COULTER CLINICAL SUPPORT
2445	Vacuum Reservoir Full	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
2446	Internal Wash Bottle float switch is disconnected	WARNING: Will STOP Run	CALL BECKMAN COULTER CLINICAL SUPPORT
2447	New failed Sending Status Monitor message to Console	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2800	SS Semaphore Create Error	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT
2801	Test Object Pointer and Tog Mismatch	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Table 10.6 Displayed or Printed Error Messages, continued

Error #	Abbreviation/ Message	Explanation	Action
2802	Invalid Reagent Type from Reagent Handler	FATAL:	CALL BECKMAN COULTER CLINICAL SUPPORT

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Backup and Restore Error Messages

The following table describes the backup and restore error messages generated by the system. Error messages contain an explanation and a corrective action the user must take to correct the error. Errors are also logged in the Event log. For retrieval of events, refer to Event Log in this section.

Table 10.7 Backup and Restore Error Messages

Error Message	Explanation	Corrective Action
Cannot create directories on External Media. Unable to continue processing.	Possible corrupted USB.	Confirm that USB is FAT32 formated or use a new USB.
The External Media does not contain enough space. Unable to continue processing.	Backing up greater than 30 full databases or 30 QC databases.	Use a new USB or remove files to create space.
You have reached the Maximum number of backups allowed on this External Media. Unable to continue processing.	Backing up greater than 30 full databases or 30 QC databases.	Use a new USB or remove files to create space.
The External Media was removed before completion of the task.	USB was removed before the transfer of data was completed.	Wait for success or failure dialog before removing the USB.
An error occurred while backing up the Alignment file. Inspect the Event Log.	Unexpected error while processing.	Inspect Event Log and/or use a new USB to retry.
This is not an Alignment file. Unable to continue processing.	Missing or corrupted file.	Confirm that the USB contains the Alignment file.

Table 10.7 Backup and Restore Error Messages

Error Message	Explanation	Corrective Action
An error occurred restoring the Alignment file. Inspect the Event Log.	Unexpected error while processing.	Inspect Event Log and/or use a new USB to retry.
No copying to External Media will occur until the printer queue is empty. Clear the printer queue?	Report printing in process.	Wait for printing to complete or select **<OK>** to clear the printer queue and retry.
Warning: An unrecognized External Media error has been detected. Inspect the External Media.	No USB present or trouble reading the USB.	Retry or use a new FAT32 formatted USB.
The instrument must be in Standby before copying to External Media.	System not in Standby.	Wait for system to be in Standby and retry.
No QC Review of External Media will occur until the printer queue is empty. Clear the printer queue?	Report printing in process.	Wait for printing to complete or select **<OK>** to clear the printer queue and retry.
The instrument must be in Standby before reviewing the QC Backup.	System not in Standby.	Wait for system to be in Standby and retry.
The External Media cannot be recognized. Reinsert or try another External Media	No USB present or trouble reading the USB.	Retry or use a new FAT32 formatted USB.
Unable to mount the External Media. Insert different External Media or reboot the system if the error persists.	Corrupted or incorrectly formatted USB.	Confirm that USB is FAT32 formatted or use a new USB.

Event Log

Introduction

The Event Log is a record of system events, such as an error or system status information that is logged (e.g., "The time has changed"). This logged information can be used as a troubleshooting tool if a problem is encountered while operating the instrument.

Event Information

The following information displays as part of the event log description.

Table 10.8 Event Log

Event Information	Definition
Number	Sequential number identifying the "order", with number one representing the most recent event.
Class	Number corresponding to the 1-25 event classes listed on the event log main screen (e.g., Input Device Events).
Date	Event searches specified for the appropriate Month, Day, and Year.
Time	Event searches specified for the appropriate Hours and Minutes.
Description	Identifies previous condition of the event logged.

Accessing the Event Log

The instrument status must be in *Standby* in order to proceed with the steps below to access the Event Log.

Step	Action
1	Select **Utilities** from the menu bar. (Refer to Figure 10.20.)
2	Select **<2> Event Log**. (Refer to Table 10.9 for a list of the Option Numbers.) OR Enter **2** in the **Option No.** field and press **[Enter]**. NOTICE It may be useful to select a specific time period for retrieval. This may be done before or after selecting the event option number. Refer to **Date/Time** option instructions.

(1 of 2)

Step	**Action**, continued
3	Select the desired option number(s). OR Type the option number(s) in the **Option No.** field and press **[Enter]**. Numbers can be separated by a comma as a series and/or by a dash as a range. (*Example:* 2, 3, 5-9, 17.)

(2 of 2)

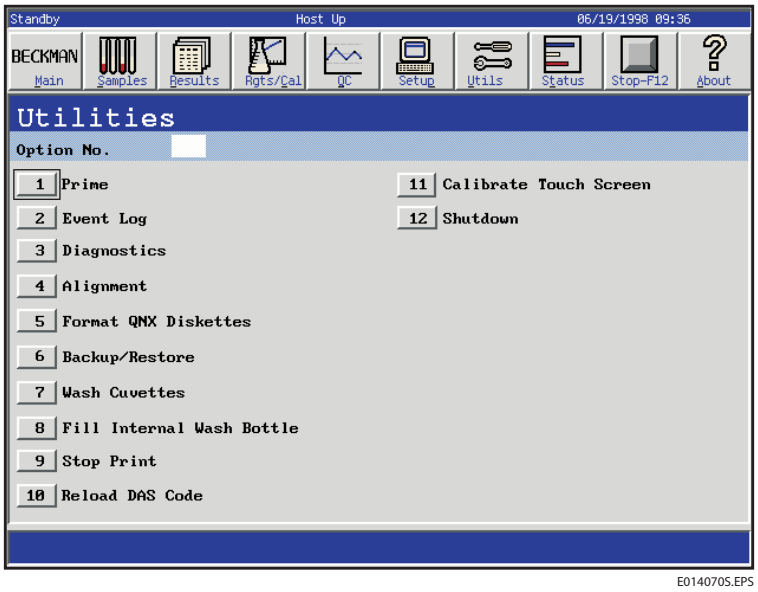


Figure 10.20 Utilities Dialog Box

Information Options

After the **Event Log Option(s)** has been selected, the information can be formatted using the following options. (Refer to Table 10.9 and Table 10.10.)

Table 10.9 Event Log Options

Option	Description
Display events [F1]	For reviewing events on the screen.
Copy to Disk [F2]	For saving events to a disk for permanent records.
Date/Time [F3]	For selecting events for a specified date and time.
Clear events [F4]	For removing unwanted event information.
Print [F10]	For creating a paper copy. To save paper, before selecting **Print**, verify only the desired event option(s) for the appropriate time period selected.

Table 10.10 Event Log Option Numbers

Option Number	Event Log
1	Input Device Events
2	Database
3	Printer
4	Reagent Load
5	QC
6	System/Sample Status
7	Calibration Results
8	Results
9	Maintenance/Diagnostics
10	Console
11	Motion
12	Status Monitor
13	Instrument
14	LIS Errors
15	LIS Data Stream

Displaying Events

After selecting the desired Event Log, follow the steps below to display the events.

Step	Action
1	Select **<2> Event Log** from the Utilities dialog box.
2	Select the desired option number(s). OR Type the option number(s) in the **Option No.** field and press **[Enter]**.
3	Select **Display Events [F1]** from the Event Log Screen. (Refer to Figure 10.21.)
4	To transfer information to a USB flash drive select **<Copy to External Media>** from the Display Events dialog box and follow the steps under "Copying to External Media."
5	To print the information, select **<Print>**.
6	If finished viewing displayed information, select **<Close>**.

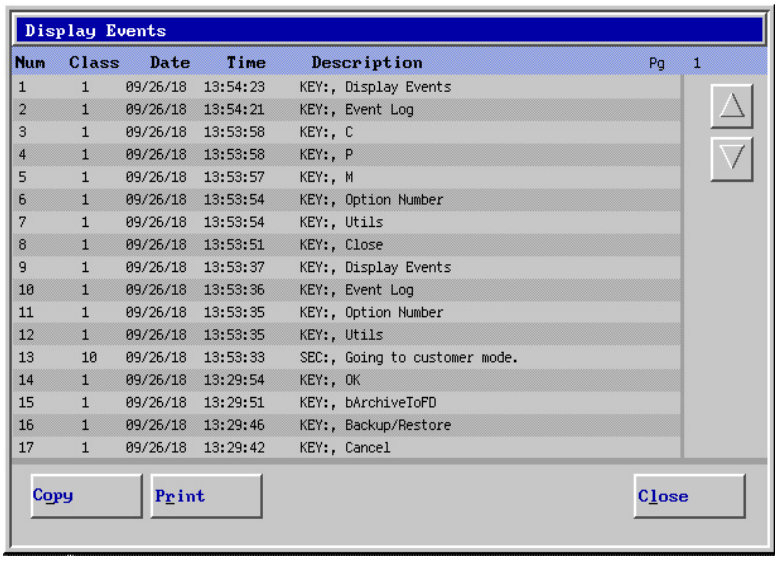
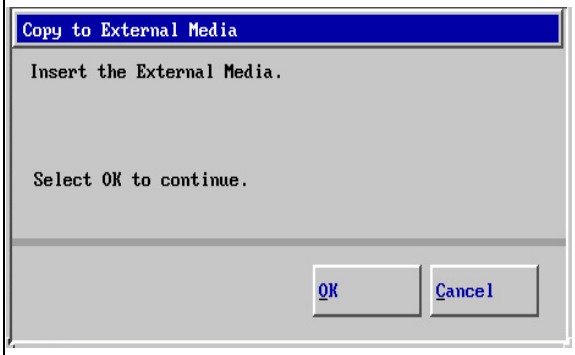


Figure 10.21 Display Events Dialog Box

Copying to External Media

After selecting the desired Event Log, follow the steps below to copy the events to an external media (USB flash drive).

Step	Action
1	Select the desired event log.
2	Select **Copy [F2]** from the Event Log Screen. The following screen is displayed.  Figure 10.22 Copy to External Media
3	Insert a USB flash drive into the USB port.
4	Select <**OK**> to transfer information to a USB flash drive. OR Select <**Cancel**> to return to the Event Log Screen without copying the information.

Specifying Date/Time

After selecting the desired event log follow the steps below to specify the desired date and time period.

Step	Action
1	Select **Date/Time [F3]** from the Event Log Screen.
2	Type in desired time period. Press the **[Enter]** key to advance the cursor to each field.
3	Select <**OK**> to return to the Event Log Screen. Select **Display Events [F1]** to view events that occurred during the selected time period. (Refer to Figure 10.23.) OR Select <**Cancel**> to exit the Date/Time screen without specifying a date/ time period.

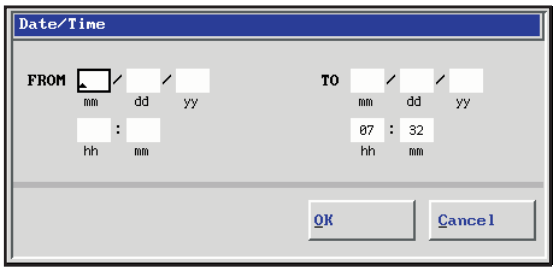


Figure 10.23 Date/Time Dialog Box

Clearing Events

After selecting the desired event log, follow the steps below to clear the desired events.

Step	Action
1	Select **Clear Events [F4]** from the Event Log Screen.
2	Verify events to be cleared.
3	Select <**OK**> to remove specified events. OR Select <**Cancel**> to exit the Clear Events screen without clearing events.

Printing an Event Log

Follow the steps below to print an Event Log.

Step	Action
1	Select a desired event from the Event Log Screen.
2	Select **Display Events [F1]**.
3	Select <**Print**>.

Callable Diagnostics

Introduction

The Callable Diagnostics option provides procedures directed toward identifying and isolating specific IMMAGE 800 malfunctions. This section describes:

- Home All
- Disable All
- Sample Stir Motor
- Reagent Stir Motor

The instrument status must be in *Standby* in order to proceed with the procedures described below.

Home All and Disable All

Follow the steps below to home the system or to disable all instrument motors.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<3> Diagnostics**. OR Enter **3** in the **Option No.** field.
3	Select **<2> Callable Diagnostics** from the Diagnostics dialog box. (Refer to Figure 10.24.) OR Enter **2** in the **Option No.** field and press **[Enter]**.
4	Select **<1> Electro-Mechanical Motion** from the Callable Diagnostics screen. OR Enter **1** in the **Option No.** field and press **[Enter]**.
5	

Select…	to…
Call. Diag [F1]	return to the Callable Diagnostics screen.
Home All [F3]	home the system.
Disable All [F4]	disable all instrument motors.

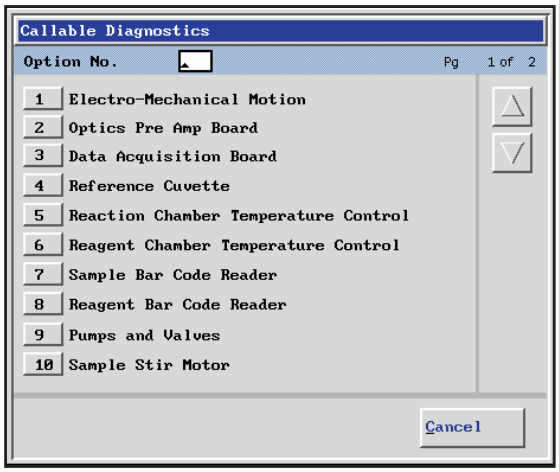


Figure 10.24 Callable Diagnostics Dialog Box

Sample Stir Motor and Reagent Stir Motor

The Sample and Reagent Stir Motor option is used to test or to verify:

- The revolutions per minute of the Sample and Reagent Stir Motors.
- The straightness of the Sample and Reagent Mixer/Paddle.

Follow the steps below to measure motor speed or test paddle straightness.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<3> Diagnostics** from the Utilities screen. OR Enter **3** in the **Option No.** field.
3	Select **<2> Callable Diagnostics** from the Diagnostics dialog box. OR Enter **2** in the **Option No.** field and press **[Enter]**.

(1 of 2)

<table>
<tr><th>Step</th><th>Action, continued</th></tr>
<tr><td>4</td><td>
<table>
<tr><th>If…</th><th>then...</th></tr>
<tr><td>Sample Stir Motor is desired,</td><td>Select <10> Sample Stir Motor from the Callable Diagnostics screen.
OR
Enter 10 in the Option No. field and press [Enter].</td></tr>
<tr><td>Reagent Stir Motor is desired,</td><td>Select <11> reagent stir motor from the callable diagnostics screen.
OR
Enter 11 in the Option No. field and press [Enter].</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>Observe the Mixer/Paddle for sway or wobble during motor exercise. Replace the Mixer/Paddle if necessary. (Refer to Replacing Parts/User Servicing, Sample and Reagent Crane Mixer/Paddle in this chapter.)</td></tr>
<tr><td>6</td><td>Verify that the Speed of Motor displayed at the end of the motor exercise is within 6000 to 10000 Revolutions per minute.

Call Beckman Coulter Clinical Support if the "Revolutions per minute" is out of specifications.</td></tr>
<tr><td>7</td><td>
<table>
<tr><th>Select…</th><th>to…</th></tr>
<tr><td>Call. Diag [F1]</td><td>Return to the Callable Diagnostics screen.</td></tr>
<tr><td>Start Motor [F2]</td><td>Run the motor continuously.</td></tr>
<tr><td>Stop Motor [F3]</td><td>Stop the motor.</td></tr>
</table>
</td></tr>
</table>

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Alignment

Introduction

The Alignment option contains procedures for alignment for the IMMAGE 800. Alignment procedures are performed on hardware components classified into different Functional Areas.

The instrument status must be in *Standby* in order to proceed with the alignments described below.

Functional Area

There are 11 hardware components on the IMMAGE 800 that require alignment. The operator can perform alignments on the Sample and Reagent Probes, and the Optics Functional Areas.

The alignment procedures described below will adjust the following:

- Straightness of the Sample and Reagent Probe
- Sample Crane Probe Height/Depth
- Reagent Crane Probe Height/Depth
- Optics
- Wash Head - Automatic Depth Alignment

NOTICE
Alignment procedures for all other Functional Area require assistance from Beckman Coulter Service personnel. Contact Beckman Coulter Clinical Support or a local Beckman Coulter Field Service office for assistance.

Prerequisite Alignment Steps

Prerequisite steps are noted on the IMMAGE 800 alignment screens as Step 1 for each alignment procedure. These prerequisites are required when aligning a new system or realigning an entire system. The prerequisites can be ignored when performing an alignment of a specific functional area.

Straightness of the Sample and Reagent Probe (from front)

Follow the steps below to verify the "straightness" (trueness) of the Sample Probe or Reagent Probe looking at the front of the probe. The instrument status must be in *Standby*.

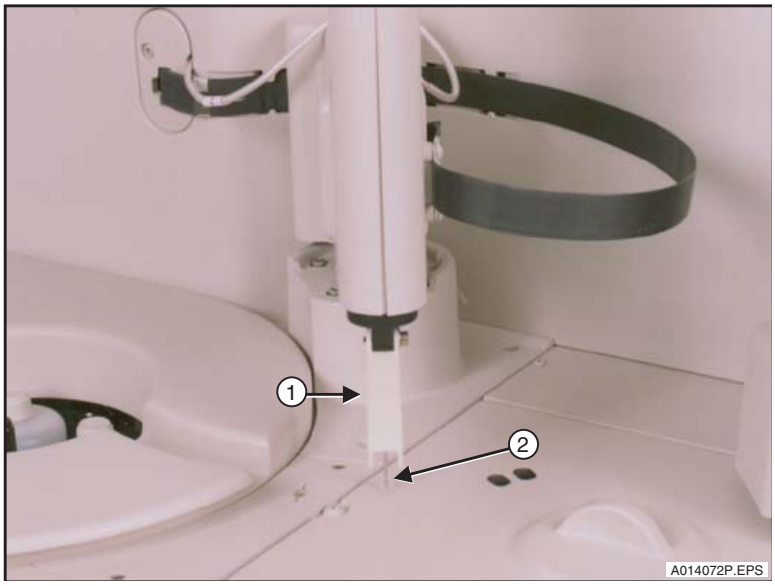
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Verify that the Sample or the Reagent Crane Mixer/Paddle is straight. (Refer to Callable Diagnostics, "Sample Stir Motor and Reagent Stir Motor" in this chapter.)</td></tr>
<tr><td>2</td><td>Rotate the Crane Assembly so that the crane assembly is facing towards the front of the instrument.</td></tr>
<tr><td>3</td><td>Raise the probe guard (1) to expose the probes and verify that the probe is aligned with the Crane Mixer/Paddle (2). (Refer to Figure 10.25.)
<table>
<tr><th>If the probe is…</th><th>then…</th></tr>
<tr><td>aligned with the Crane Mixer/Paddle,</td><td>proceed to "Straightness of Sample and/ or Reagent Probe (from the side)."</td></tr>
<tr><td>not aligned with the Crane Mixer/Paddle,</td><td>adjust the probe by gently bending it to align with the Crane Mixer/Paddle.</td></tr>
</table>


Figure 10.25</td></tr>
</table>

Straightness of the Sample or Reagent Probe (from side)

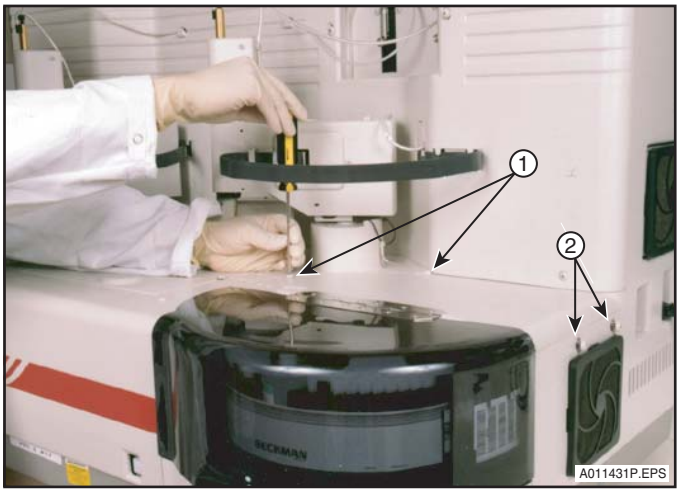
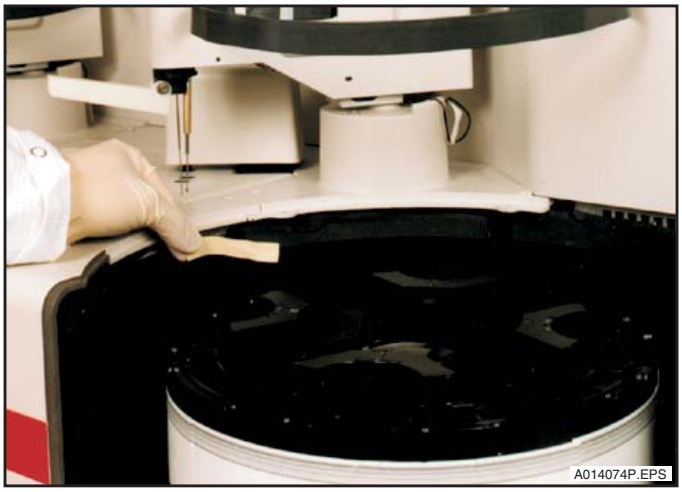
Follow the steps below to verify the "straightness" (trueness) of the Sample Probe viewing it from the side of the probe.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Disable all Electro-Mechanical Motion. Refer to Home All and Disable All in this chapter.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>If aligning the Sample Probe, follow the steps below...</th><th>If aligning the Reagent Probe, follow the steps below...</th></tr>
<tr><td>Remove the sample carousel cover by:

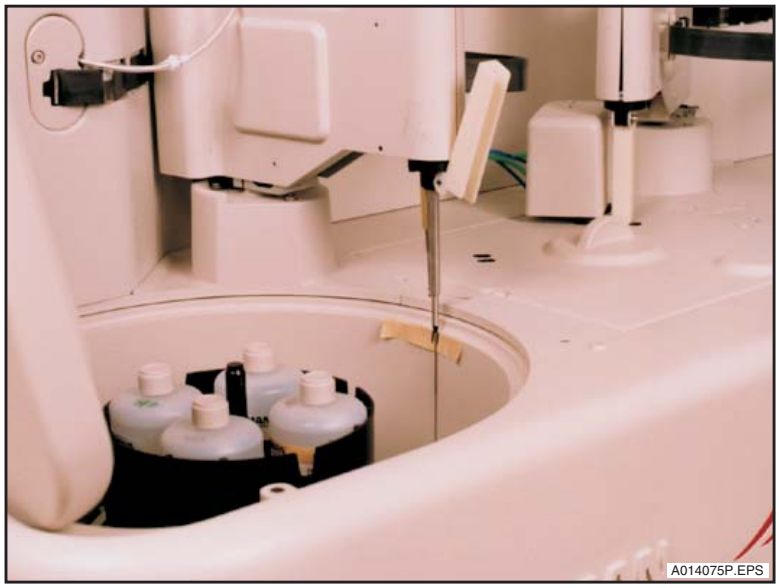
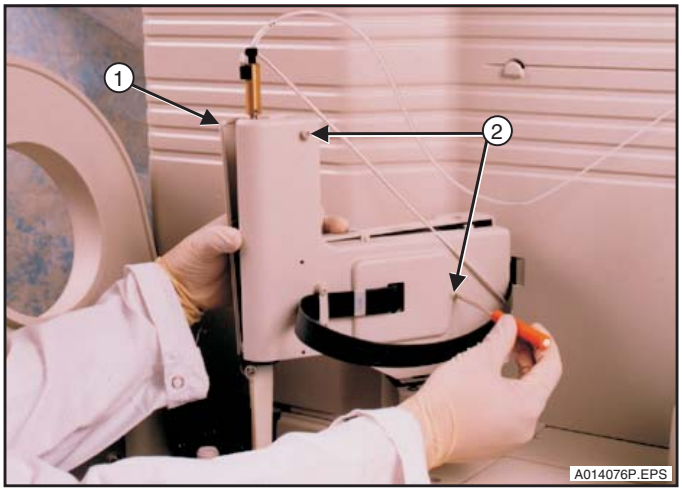
• removing the two hex screws (1) on top of the carousel cover.
• removing the two Phillips screws (2) on the right side just above the fan.

(Refer to Figure 10.26.)</td><td>Open the Reagent Carousel lid.</td></tr>
<tr><td>Place a piece of tape along the top left edge of the sample carousel tub. (Refer to Figure 10.27.)</td><td>Place a piece of tape along the top right edge of the reagent carousel tub. (Refer to Figure 10.28.)</td></tr>
</table>
</td></tr>
</table>

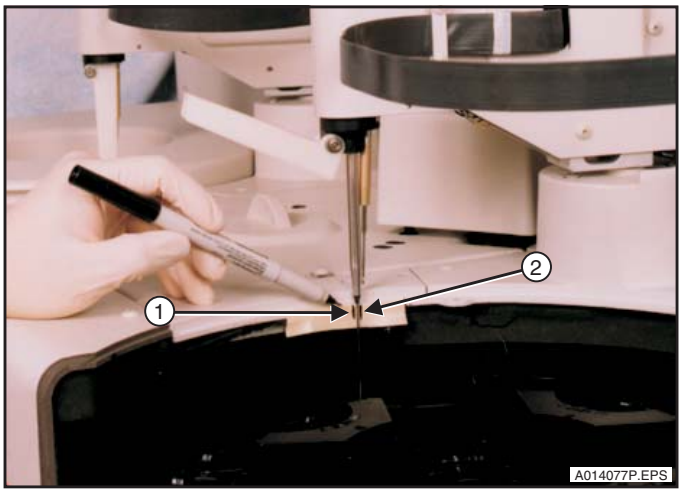
(1 of 6)

Step	**Action**, continued
	 Figure 10.26  Figure 10.27

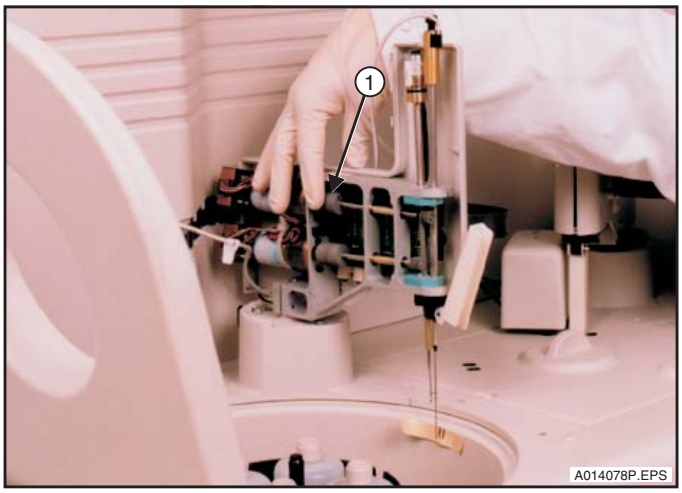
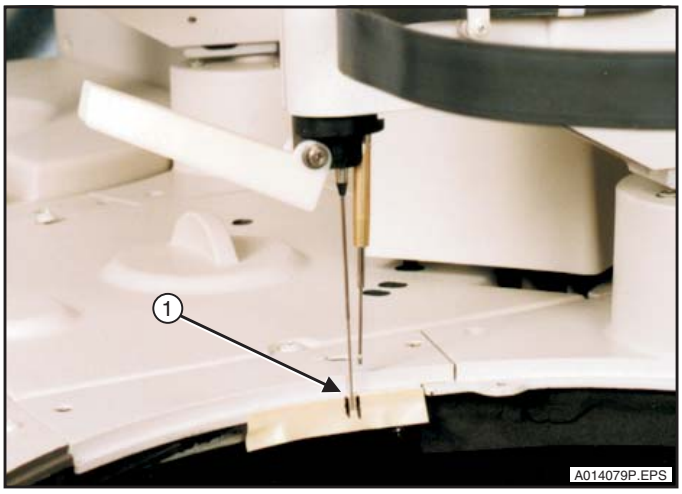
(2 of 6)

Step	**Action**, continued
	 Figure 10.28
3	Remove the left access cover (1) of the Crane Assembly by removing the two Phillips screws on the left side. Loosen the Phillips screws on the right side (2) of the assembly. (Refer to Figure 10.29.)  Figure 10.29
4	Rotate the assembly towards the appropriate compartment and raise the probe guard to expose the probes.

(3 of 6)

Step	**Action**, continued
5	Use the flex coupling to lower the probe so that the upper, large diameter portion of the probe falls just inside the compartment and is centered on the tape.
6	From the side of the instrument, make marks (1) and (2) on the piece of tape where the sides of the probe line up. (Refer to Figure 10.30.)  Figure 10.30

(4 of 6)

Step	**Action**, continued
7	Use the flex coupling (1) to raise the probe so that the tip of the probe is lined up with the piece of tape. (Refer to Figure 10.31.)  Figure 10.31 **If the tip of the probe is…** / **then…** centered (1) between the tape marks, / the probe is straight. (Refer to Figure 10.32.) *not* centered between the tape marks, / align probe by gently bending it to center of the tape marks.  Figure 10.32
8	Reinstall the sample carousel cover.

(5 of 6)

Step	**Action**, continued
9	Reinstall the access cover of the Crane Assembly. Position the tubing in the grooves before tightening the screws.

(6 of 6)

Sample and Reagent Crane Probe Height/Depth

Follow the steps below to align the Sample or Reagent Crane Probe height/depth.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<4> Alignment**. OR Enter **4** in the **Option No.** field and press **[Enter]**.
3	

If...	then...
aligning the Sample Probe,	1. Select **<9> Sample Crane Probe** from the Functional Areas dialog box. OR Enter **9** in the **Area No.** field and press **[Enter]**. 2. Select **<1> Sample Crane Probe** from the Alignment dialog box. OR Enter **1** in the **Procedure No.** field and press **[Enter]**.
aligning the Reagent Probe,	1. Select **<10> Reagent Crane Probe** from the Functional Areas dialog box. OR Enter **10** in the **Area No.** field and press **[Enter]**. 2. Select **<1> Reagent Crane Probe** from the Alignment dialog box. OR Enter **1** in the **Procedure No.** field and press **[Enter]**.

(1 of 2)

Step	**Action**, continued
4	Complete Steps 1-3 as described on the screen, selecting **<Continue>** after performing each step. OR Select **<Stop>** to exit. Select **<Close>** to return to the Alignment screen or select **<Repeat>** to restart the alignment procedure.
5	Select **<Yes>** from the Alignment dialog box to save the alignment data to a temporary file. OR Select **<No>** to return to the Alignment: Reagent Crane Probe screen without saving the alignment data.
6	Select any icon from the menu bar. (Refer to Figure 10.33.) Select **<Yes>** from the Alignment dialog box to save the new alignment data to the database. **[F1] Prev Align** allows the operator to overwrite this alignment data with the previous alignment data. OR Select **<No>** to restore the previous alignment data.

(2 of 2)

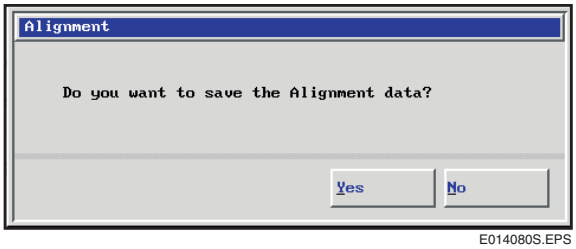


Figure 10.33 Alignment Dialog Box

Optics Alignment

Follow the steps below to perform the Optics Alignment.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<4> Alignment**. OR Enter **4** in the **Option No.** field and press **[Enter]**.
3	Use the **<Page Up>** and **<Page Down>** buttons to view additional Utilities options. Select **<11> Optics** from the Functional Areas dialog box. OR Enter **11** in the **Area No.** field and press **[Enter]**.
4	Select **<1> Optics** from the Alignment dialog box. OR Enter **1** in the **Procedure No.** field and press **[Enter]**.
5	Complete Steps 1-3 as described on the screen, selecting **<Continue>** after performing each step. OR Select **<Stop>** to exit. Select **<Close>** to return to the Alignment screen or select **<Repeat>** to restart the alignment procedure.
6	Select **<Yes>** from the Alignment dialog box to save the alignment data to a temporary file. OR Select **<No>** to return to the Alignment: Optics screen without saving the alignment data.
7	Select an icon from the menu bar. Select **<Yes>** from the Alignment dialog box to save the new alignment data to the database. **[F1] Prev Align** allows the operator to overwrite this alignment data with the previous alignment data. OR Select **<No>** to restore the previous alignment data.

Wash Head – Automatic Depth Alignment

Follow the steps below to perform the automatic depth alignment.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<4> Alignment**. OR Enter **4** in the **Option No.** field and press **[Enter]**.
3	Use the **<Page Up>** and **<Page Down>** buttons to view additional Utilities options. Select **<4> Cuvette Wash** from the Functional Areas dialog box. OR Enter **4** in the **Area No.** field and press **[Enter]**.
4	Select **<3> Automatic Depth Alignment**. OR Enter **3** in the **Procedure No.** field and press **[Enter]**.
5	Complete steps 1-3 as described on the screen, selecting **<Continue>** after performing each step. OR Select **<Stop>** to exit. Select **<Close>** to return to the Alignment screen or select **<Repeat>** to restart the alignment procedure.
6	Select **<Yes>** from the Alignment dialog box to save the alignment data to a temporary file. OR Select **<No>** to return to the Alignment screen without saving the alignment data.
7	Select an icon from the menu bar. Select **<Yes>** from the alignment dialog box to save the new alignment data to the database. **[F1] Prev Align** allows the system to overwrite this alignment data with the previous alignment data. OR Select **<No>** to restore the previous alignment data.

Backup/Restore

Introduction

The Backup/Restore option provides the ability to store data to a USB flash drive or hard disk for use at a later time.

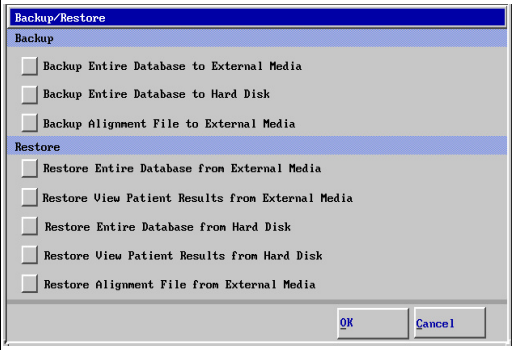
Backup saves data to the hard disk or to a USB flash drive for safe storage.

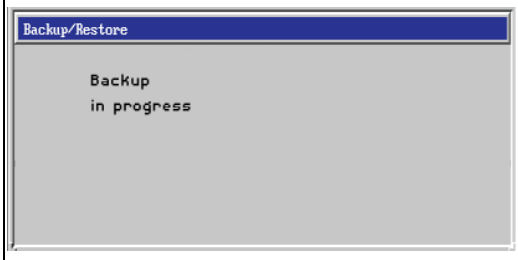
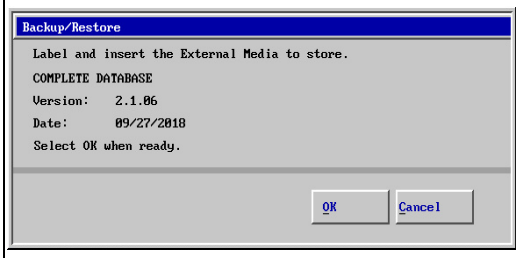
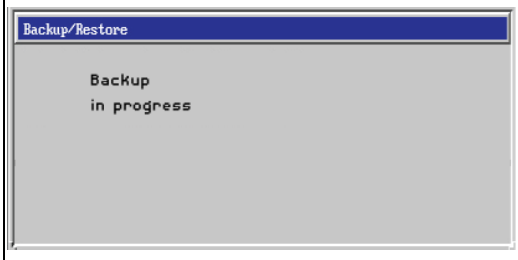
Restore takes previously backed up data from the hard disk or USB flash drive and places it back onto the system.

The instrument status must be in *Standby* in order to proceed with the steps below to back up or restore data.

Backup

Follow the steps below to back up the database.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<5> Backup/Restore** from the Utilities dialog box. OR Enter **5** in the **Option No.** field and press **[Enter]**. The following screen is displayed.  Figure 10.34 Backup/Restore Dialog Box NOTICE You can only back up 30 databases to a USB flash drive.
3	Select **Backup Entire Database to External Media** to copy the entire database to a USB flash drive. OR Select **Backup Entire Database to Hard Disk** to copy the entire database to the hard disk.

Step	Action
4	Select <**OK**> to back up the database. OR Select <**Cancel**> to exit and return to the Utilities screen. The following screen is displayed.  Figure 10.35 Backup in Progress The following screen is displayed.  Figure 10.36 Label and insert the External Media
5	Insert a USB flash drive into the USB port and then select <**OK**>. The following screen is displayed.  Figure 10.37 Backup in Progress When Backup is complete, a confirmation is displayed on the screen. (Refer to the Figure 10.38.)
6	Select <**OK**> to exit.

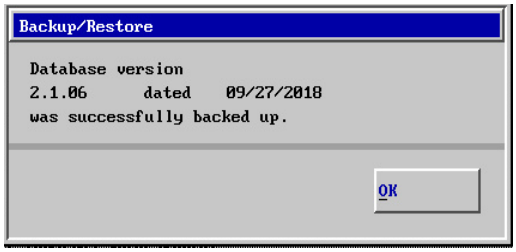
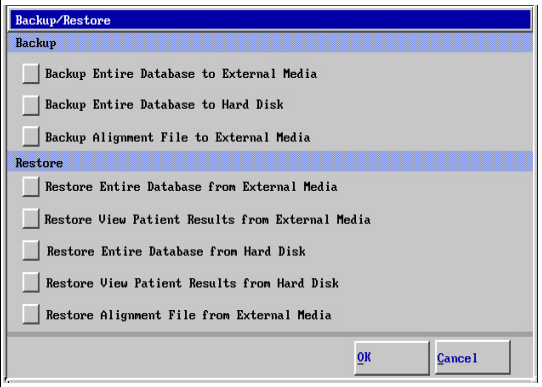


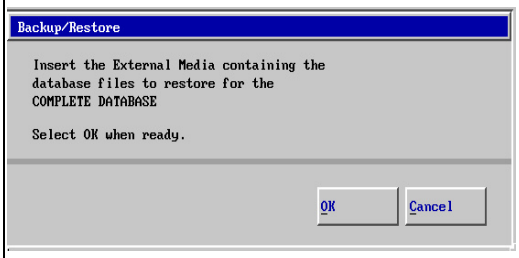
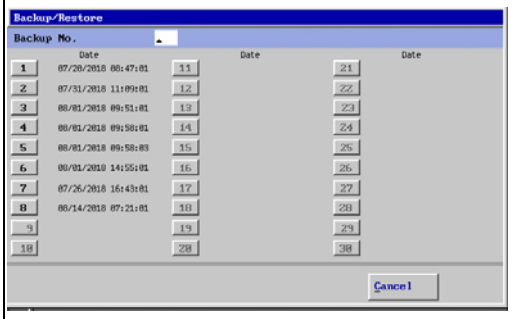
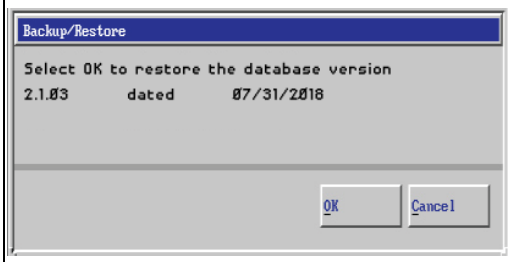
Figure 10.38 Backup Complete Confirmation Dialog Box

Restore

Follow the steps below to restore the database.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<5> Backup/Restore** from the Utilities dialog box. OR Select **5** in the **Option No.** field and press **[Enter]**. NOTICE Restoring the entire database will overwrite the current database and replace it with the backed up database. The following screen is displayed.  Figure 10.39 Backup/Restore Dialog Box

(1 of 3)

Step	**Action**, continued
3	Select **Restore Entire Database from External Media** and then select **<OK>**. The following screen is displayed.  Figure 10.40 Insert the External Media
4	Insert the USB flash drive that has the backed up databases into the USB port and then select **<OK>** . OR Select **<Cancel>** to exit and return to the Utilities screen. The following screen is displayed.  Figure 10.41 Backup No. Screen NOTICE The above screen will not appear if only 1 database is on the USB.
5	Select the database you want to restore. The following screen is displayed.  Figure 10.42 Select OK to restore Screen

(2 of 3)

Step	**Action**, continued
6	Select <**OK**>. The following screen is displayed.  Figure 10.43 Restore in progress Screen When Restore is complete, a confirmation is displayed on the screen. (Refer to Figure 10.44.)
7	Select <**OK**> to exit. You will be asked to reboot the system.

(3 of 3)

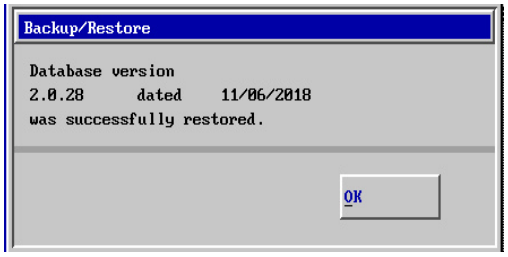


Figure 10.44 Restore Complete Confirmation Dialog Box

Backup/Restore Alignment Files

We recommend that a Beckman Coulter Service Representative performs the backup/ restore of alignment files.

Fill Internal Wash Bottle

Introduction

The IMMAGE 800 is equipped with an internal wash bottle that supplies wash solution to the system where needed.

The internal wash bottle is pressurized and is constantly replenished with wash solution from the Wash Solution Container. When the source runs out of wash solution, it may be necessary to fill the internal wash bottle after replacing the empty Wash Solution Container.

Filling the Internal Wash Bottle

Follow the steps below to fill the internal wash bottle. The instrument status must be in *Standby*.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<8> Fill Internal Wash Bottle** from the Utilities dialog box. OR Enter **8** in the **Option No.** field and press **[Enter]**.
3	Select an icon from the menu bar to exit. NOTICE The level of wash solution in the internal wash bottle can be verified through the Instrument Status Monitor. (Refer to CHAPTER 11, *System Status/Instrument Commands*, Checking the Instrument Status Monitor.)

Calibrate Touch Screen

Introduction

The IMMAGE 800 system can access screen components with the optional touch screen monitor. After calibration of the touch screen, software functions can be activated by the touch of a finger or other object. Any icon, button, or field on the screen can be selected by touching the icon, button, or field on the screen.

Calibrating the Touch Screen

The instrument status must be in *Standby* in order to proceed with the steps below to calibrate the touch screen.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **<11> Calibrate Touch Screen** from the Utilities dialog box. OR Enter **11** in the **Option No.** field and press **[Enter]**. (Refer to Figure 10.45.)
3	To calibrate and enable the touch screen, with one finger or an appropriate object, touch the crosshairs in the upper, left quadrant of the display area twice. Next, touch the crosshairs in the lower, right quadrant of the display area twice. OR To exit without saving the calibration, select **<Cancel>** or any key on the keyboard. NOTICE The touch screen will not be activated if the first calibration attempt is canceled prior to touching both crosshairs. If a previous calibration exists, canceling a calibration attempt retains the previous calibration data.
4	After calibration, software functions can be activated by the touch of a finger or other object. Any icon, button, or field on the screen can be selected by touching the icon, button, or field on the screen. Once the touch screen is activated, it cannot be turned off.

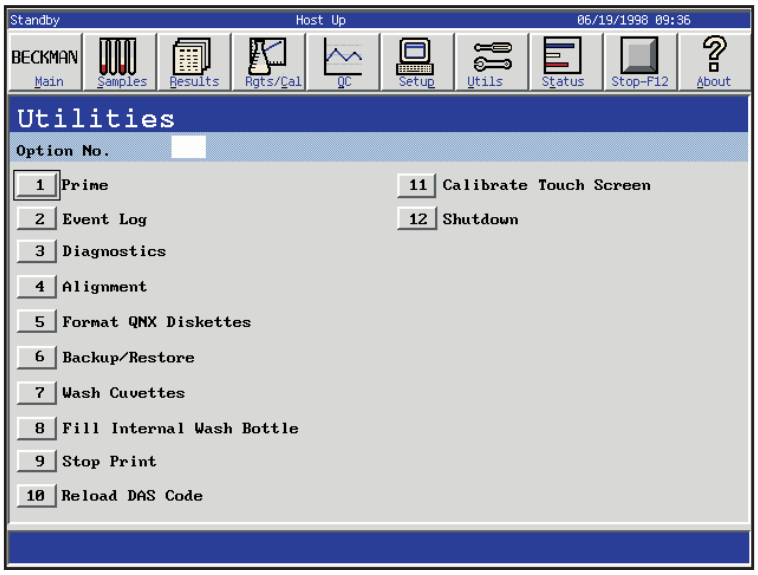


Figure 10.45 Utilities Screen with Touch Screen Option

Replacing Parts/User Servicing

Overview

Introduction

This section describes the customer-replaceable parts on the IMMAGE 800:

- Syringe
- Sample and Reagent Crane Mixer/Paddle

The instrument status must be in *Standby* in order to proceed with the parts replacement described below.

The *Probe Replacement* procedure is now performed by a Beckman Coulter Service Representative.

Syringe

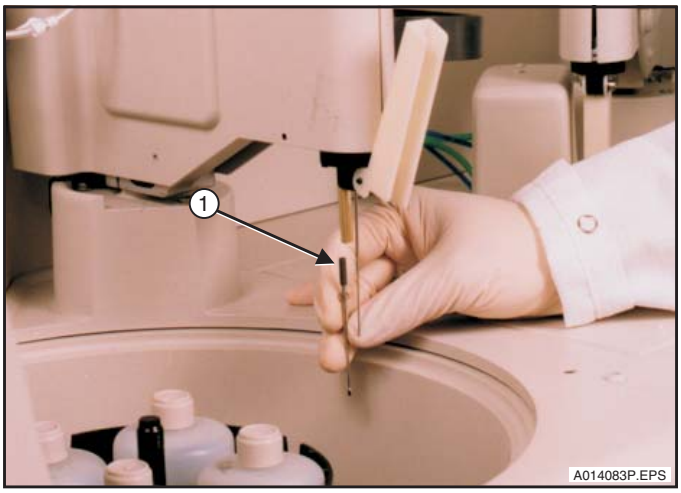
Replacing Syringes

Refer to As-Indicated Maintenance, "Replacing Syringes," in this chapter.

Sample and Reagent Crane Mixer/Paddle

Replacing Sample and Reagent Crane Mixer/Paddle

Follow the steps below to replace the Sample or Reagent Crane Mixer/Paddle.

Step	Action
1	Select **Utilities** from the menu bar.
2	Select **Diagnostics** from the *Utilities* menu.
3	Rotate the Crane Assembly toward the sample carousel.
4	Remove the Crane Mixer/Paddle (1) by gently pulling it down and out from the crane assembly. (Refer to figure below.)  Figure 10.46
5	Install the new mixer/paddle, making sure that it is pushed all the way up and properly seated.
6	Verify the straightness of the mixer/paddle. (Refer to Troubleshooting, Callable Diagnostics, "Sample Stir Motor and Reagent Stir Motor" in this chapter.)

CHAPTER 11 System Status/Instrument Commands

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System Status/Instrument Commands

Checking Dilution Segment Status and Clearing Dilution Segments

Introduction

Prior to starting every run, the Dilution Segments status should be checked.

Options

There are two options from the Dilution Segments dialog box:

- The status of the dilution segments can be left unchanged.
- Up to four dilution segments can be cleared. The cleared segments must be replaced with unused segments on the sample carousel.

Checking Status and Clearing Segments

The instrument status must be in *Standby* in order to proceed with the steps below to check the status of the dilution segments.

Step	Action
1	Select **Status** from the menu bar.
2	Select **<1> Dilution Segments**. (Refer to Figure 11.1.)
3	

If dilution segments are...	Then...
to be cleared	Type the segment number(s) in the **Clear Segment(s)** field. Numbers can be separated by a comma as a series or by a dash as a range. OR Select the number beside each appropriate segment AND Select <**OK**>.
not to be cleared	Select <**Cancel**>.

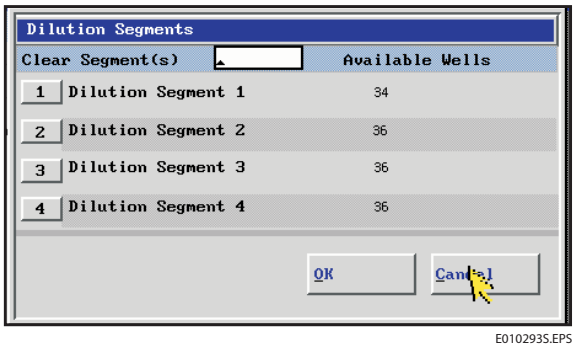

Figure 11.1 Dilution Segments Dialog Box

After Clearing Segments

Always replace the cleared dilution segments with unused segments on the sample carousel before a run is started.

Replacing Dilution Segments

The instrument status must be in *Standby* in order to proceed with the steps below to replace dilution segments.

Step	Action
1	Lift the cover of the sample carousel.
2	Rotate the sample carousel by pressing the advance button in order to access the desired dilution segment, if necessary.
3	Lift the segment to be replaced off the sample carousel.
4	Dispose of the used segment in a manner appropriate for biohazardous materials.
5	Place an unused segment in the empty position on the sample carousel.
6	Repeat steps 2-5 until all desired segments are replaced.

Additional Information

Refer to CHAPTER 7, *Sample Programming* for more information on Dilution Segments status.

Checking Sample Carousel Status

Introduction

The status of each sample on a run can be monitored during the run through Sample Carousel Status. The status is indicated by the colored indicator beside the Position Number/Sample ID.

Accessing Sample Carousel Status

Follow the steps below to access the sample carousel status.

Step	Action
1	Select **Status** from the menu bar.
2	Select **<2> Sample Carousel Status**. (Refer to Figure 11.2.)

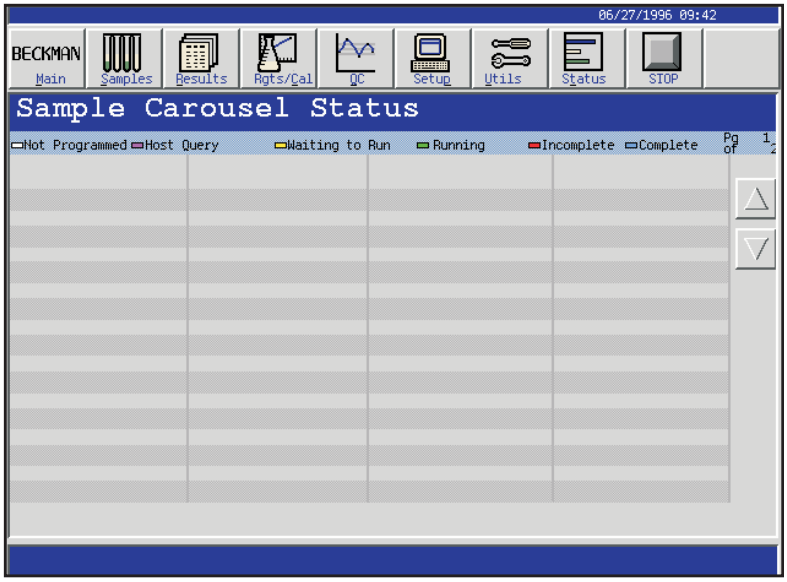

Figure 11.2 Sample Carousel Status Screen

Description of Sample Carousel Status

The following table describes the sample carousel status indicator colors and sample carousel status terms.

Table 11.1 Sample Carousel Status

Indicator Color	Status	Description
White	Not Programmed	Sample is not programmed or saved.
Purple	Host Query	Sample ID queries the host for programming.
Yellow	Waiting to Run	The sample carousel was scanned and the sample program is recognized by the system.
Green	Running	One or more tests requested for the sample are running.
Red	Incomplete	At least one test result for the sample is pending.
Blue	Complete	All tests requested for the sample are complete.

Sample IDs and Bar Code Reads

The sample bar code reader will read either the sample bar code label or the background bar code label on the rack. After a bar code is read, the database is checked for a program.

The following table describes the possible displays for Sample ID and Status on the Sample Carousel status screen based on the bar code read and program.

Table 11.2 Sample ID and Status

Displayed next to rack position	Displayed Sample Carousel Status	Bar Code Read	Is there a program for the rack and position or for the sample ID?
SAMPLE ID	Programmed	Valid sample bar code	Yes
	Host Query or Not Programmed	Valid sample bar code	No
	Not Programmed	Valid sample bar code	Sample ID or rack and position conflict
<*blank*>	Programmed	Background bar code	Yes
	Not Programmed	Background bar code	No
NO READ	Programmed	Invalid or no bar code	Yes
	Not Programmed	Invalid or no bar code	No

Checking the Instrument Status Monitor

Introduction

The instrument status monitor displays the instrument parameters which are continuously monitored.

Accessing Instrument Status Monitor

Follow the steps below to access the instrument status monitor.

Step	Action
1	Select **Status** from the menu bar.
2	Select **<3> Instrument Status Monitor**. (Refer to Figure 11.3.)
3	Verify acceptable status monitor parameters. Parameters which are out of range display in red.

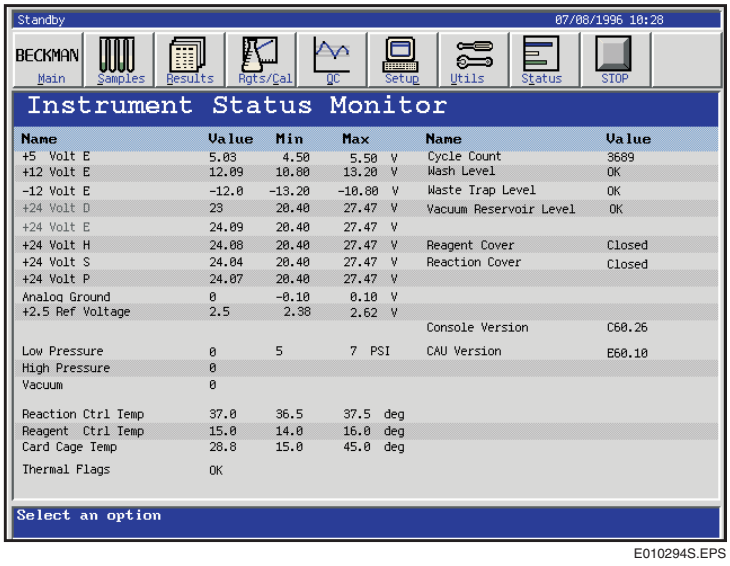

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Figure 11.3 Status Monitor Screen

Accessing Instrument Commands

Introduction

The "Main" icon can be used to access the instrument commands Stop, Home, Pause, and Run. The Stop command is also available from the menu bar or by selecting **[F12]**.

Command Description

The following table describes the function of each instrument command.

Table 11.3 Instrument Commands

Command	Function
Stop	Stops instrument immediately; current samples being run will be incomplete and must be rerun. All sample programming is saved.
Home	Reagent and sample carousels, cuvettes, and probes return to their home position.
Pause	Stops instrument after current samples that are running are completed. All sample programming is saved. OR Pauses instrument to load samples during a run.
Run	Starts a run.

Accessing Instrument Commands

Follow the steps below to access the instrument command buttons.

Step	Action
1	Select **Main** from the menu bar.
2	Select the desired command.

The Stop Command and Cuvette Maintenance

The following steps are recommendations for maintenance of the cuvettes after the **Stop** command is selected.

Table 11.4 Recommended Maintenance After Stop Command Selected

After Stop is selected during a run and before Run is selected...	**the cuvettes...**
immediately (<1 hour)	do not require maintenance.
less than 24 hours later	should be washed (Refer to CHAPTER 10, *Utilities*, As-Indicated Maintenance, "Washing Cuvettes".)
more than 24 hours later	should be replaced. (Refer to CHAPTER 10, *Utilities*, As-Indicated Maintenance, "Replacing Cuvettes".)

APPENDIX A Instrument Codes

Introduction

When the instrument code appears on a report, the first two digits represent the chemistry and the letter(s) that follow represent the condition(s).

Example: the instrument code 01J means that a slope/offset adjustment was applied to the chemistry IGG.

Chemistry Codes

The codes for chemistries are shown in the following table.

Table A.1 Chemistry Codes

Code	Chemistry	Code	Chemistry	Code	Chemistry
01	IGG	16	PAB	64	LPAX
02	IGA	17	ALB	65	CRPH
03	IGM	19	TRU	67	CCRP
04	C3	20	A1M		
05	AAT	25	APA		
06	KAP	26	APB		
07	TRF	27	RF		
08	HPT	29	AT3		
09	C4	30	ASO		
10	AAG	32	FER		
11	LAM	33	IGU		
12	AMG	57	DNB		
13	PFB	58	IGE		
14	CER	61	IGALC		
15	MA	62	IGMLC		

Condition Codes

The codes for conditions are shown in the following table.

Table A.2 Condition Codes

Condition	Code
Slope/offset adjustment	J
Calibration re-enabled	C
Reagent expired	R
Simulated result	S
Dilution well reused	W

APPENDIX B Reports

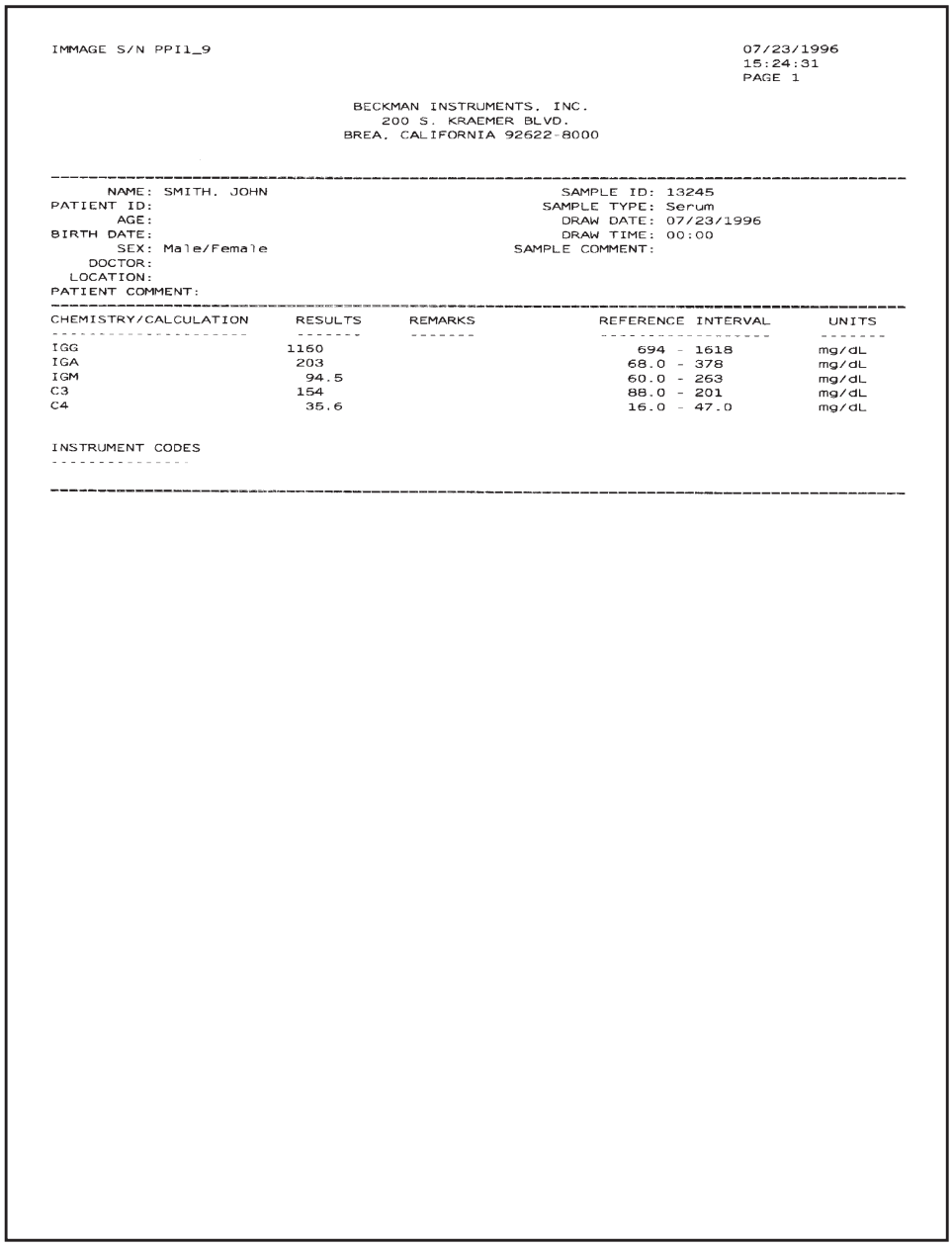
Introduction

Examples of reports that can be generated by the IMMAGE 800 Immunochemistry System are shown on the following pages. The reports are in the order listed in Table B.1 and Figure B.1 through Figure B.25.

Table B.1 Generated Reports

Report Type	Report Name
Results	Patient Chartable Report
	Control Report
	Laboratory Report
	Laboratory Report with Dilutions
Calibration	Calibration Load List
	Calibration Report
Sample Programming	Sample Load List
	Post Run Summary
Setup	Units, Slope, and Offset Summary
	Reference Interval and Critical Range Summary
User-Defined Reagent Chemistries	User-Defined Chemistry Definition Report
	User-Defined Calibration Results Report
	User-Defined Calibration Report
	User-Defined Single-Point Calibration Result
	User-Defined Single-Point Calibration Update Report
	Plot Robust Means Data Report
Quality Control	QC File List by Control Name
	QC File List by QC File Number
	QC File List by Chemistry Name
	QC Log Report
	QC Log by Reagent Lot Report
	QC Chart Report
	QC Summary Report
	Inter-Lab Summary Report
Utilities	Event/Error Log

Patient Chartable Report



IMMAGE S/N PPI1_9 07/23/1996
15:24:31
PAGE 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

NAME: SMITH, JOHN
PATIENT ID:
AGE:
BIRTH DATE:
SEX: Male/Female
DOCTOR:
LOCATION:
PATIENT COMMENT:

SAMPLE ID: 13245
SAMPLE TYPE: Serum
DRAW DATE: 07/23/1996
DRAW TIME: 00:00
SAMPLE COMMENT:

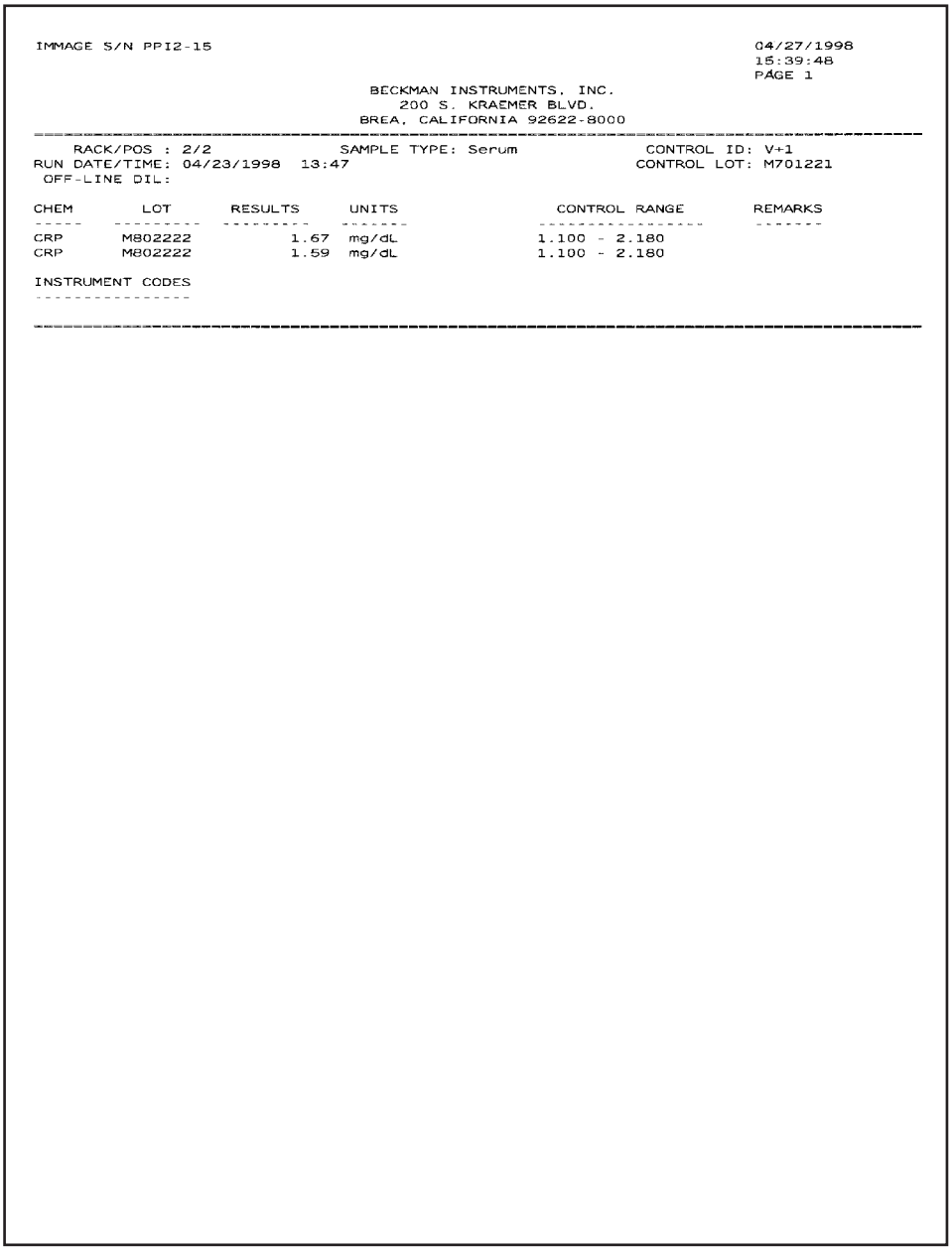
CHEMISTRY/CALCULATION	RESULTS	REMARKS	REFERENCE INTERVAL	UNITS
IGG	1160		694 - 1618	mg/dL
IGA	203		68.0 - 378	mg/dL
IGM	94.5		60.0 - 263	mg/dL
C3	154		88.0 - 201	mg/dL
C4	35.6		16.0 - 47.0	mg/dL

INSTRUMENT CODES

E010310L.EPS

Figure B.1 Patient Chartable Report

Control Report



IMMAGE S/N PPI2-15 04/27/1998
15:39:48
PAGE 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

RACK/POS : 2/2 SAMPLE TYPE: Serum CONTROL ID: V+1
RUN DATE/TIME: 04/23/1998 13:47 CONTROL LOT: M701221
OFF-LINE DIL:

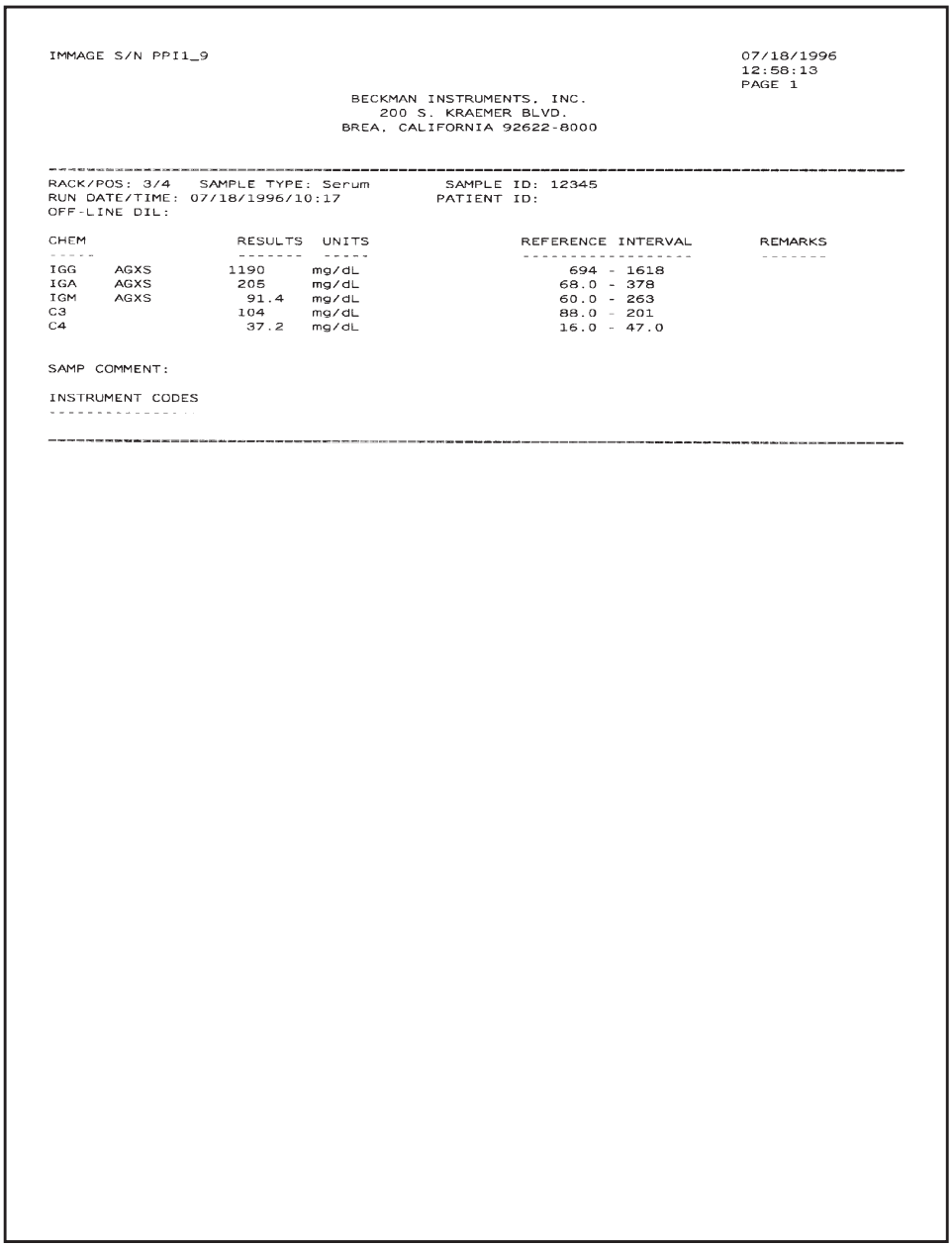
CHEM	LOT	RESULTS	UNITS	CONTROL RANGE	REMARKS
CRP	M802222	1.67	mg/dL	1.100 - 2.180	
CRP	M802222	1.59	mg/dL	1.100 - 2.180	

INSTRUMENT CODES

E014102L.EPS

Figure B.2 Control Report

Laboratory Report



IMMAGE S/N PPI1_9 07/18/1996
12:58:13
PAGE 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

RACK/POS: 3/4 SAMPLE TYPE: Serum SAMPLE ID: 12345
RUN DATE/TIME: 07/18/1996/10:17 PATIENT ID:
OFF-LINE DIL:

CHEM		RESULTS	UNITS	REFERENCE INTERVAL	REMARKS
IGG	AGXS	1190	mg/dL	694 - 1618	
IGA	AGXS	205	mg/dL	68.0 - 378	
IGM	AGXS	91.4	mg/dL	60.0 - 263	
C3		104	mg/dL	88.0 - 201	
C4		37.2	mg/dL	16.0 - 47.0	

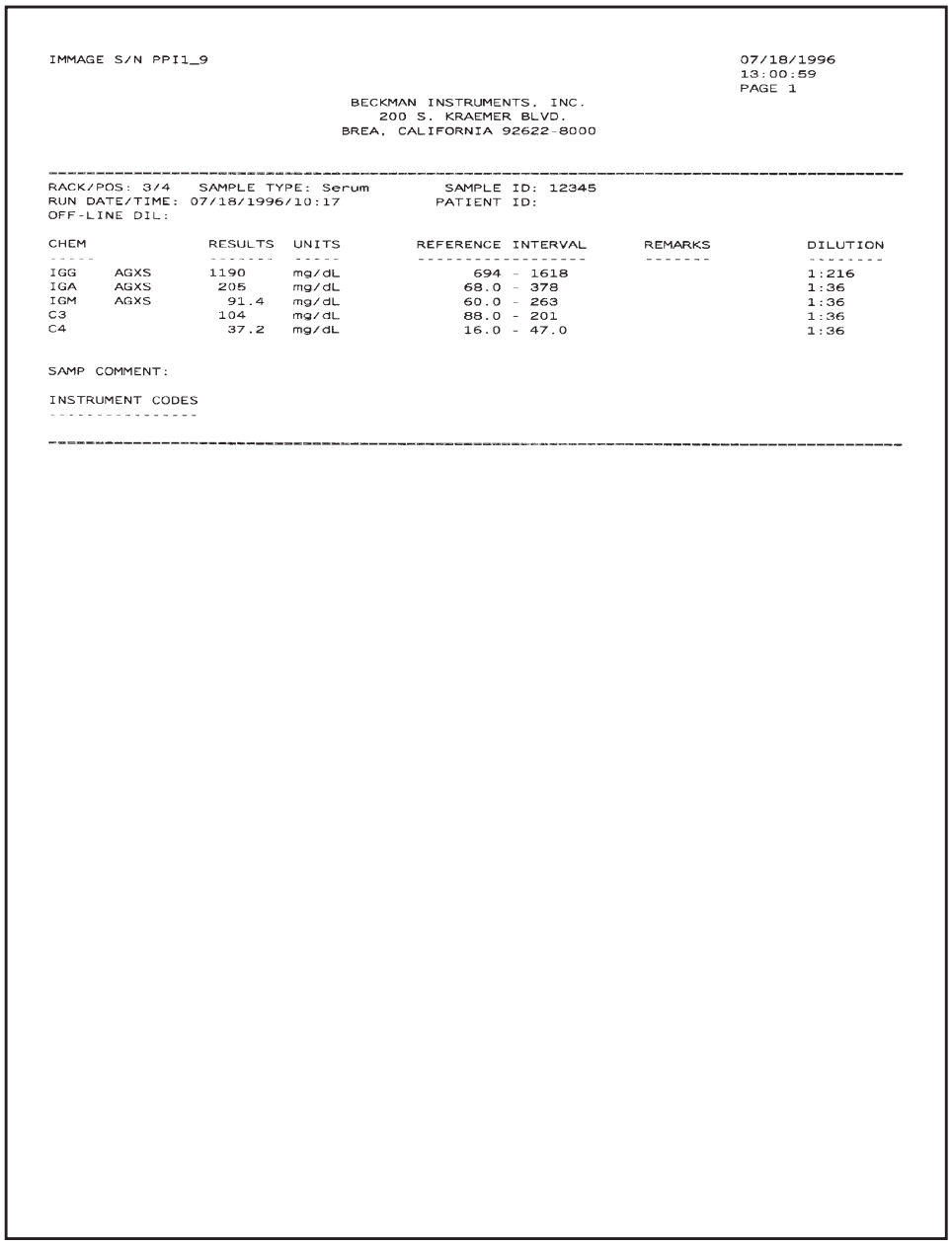
SAMP COMMENT:

INSTRUMENT CODES

E010312L.EPS

Figure B.3 Laboratory Report

Laboratory Report with Dilutions



IMMAGE S/N PPI1_9 07/18/1996
13:00:59
PAGE 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

RACK/POS: 3/4 SAMPLE TYPE: Serum SAMPLE ID: 12345
RUN DATE/TIME: 07/18/1996/10:17 PATIENT ID:
OFF-LINE DIL:

CHEM		RESULTS	UNITS	REFERENCE INTERVAL	REMARKS	DILUTION
IGG	AGXS	1190	mg/dL	694 - 1618		1:216
IGA	AGXS	205	mg/dL	68.0 - 378		1:36
IGM	AGXS	91.4	mg/dL	60.0 - 263		1:36
C3		104	mg/dL	88.0 - 201		1:36
C4		37.2	mg/dL	16.0 - 47.0		1:36

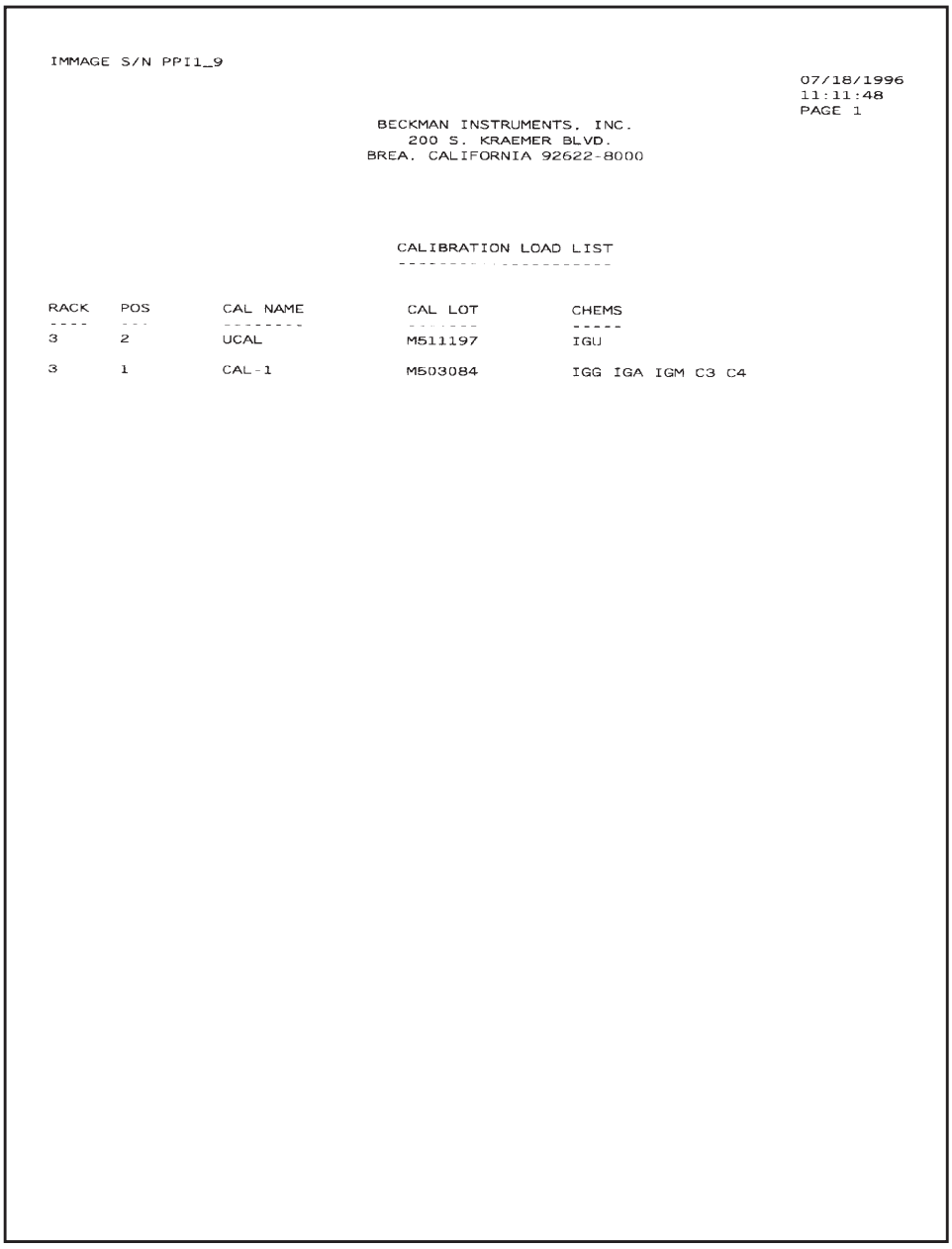
SAMP COMMENT:

INSTRUMENT CODES

E010313L.EPS

Figure B.4 Laboratory Report with Dilutions

Calibration Load List



IMMAGE S/N PPI1_9

07/18/1996
11:11:48
PAGE 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

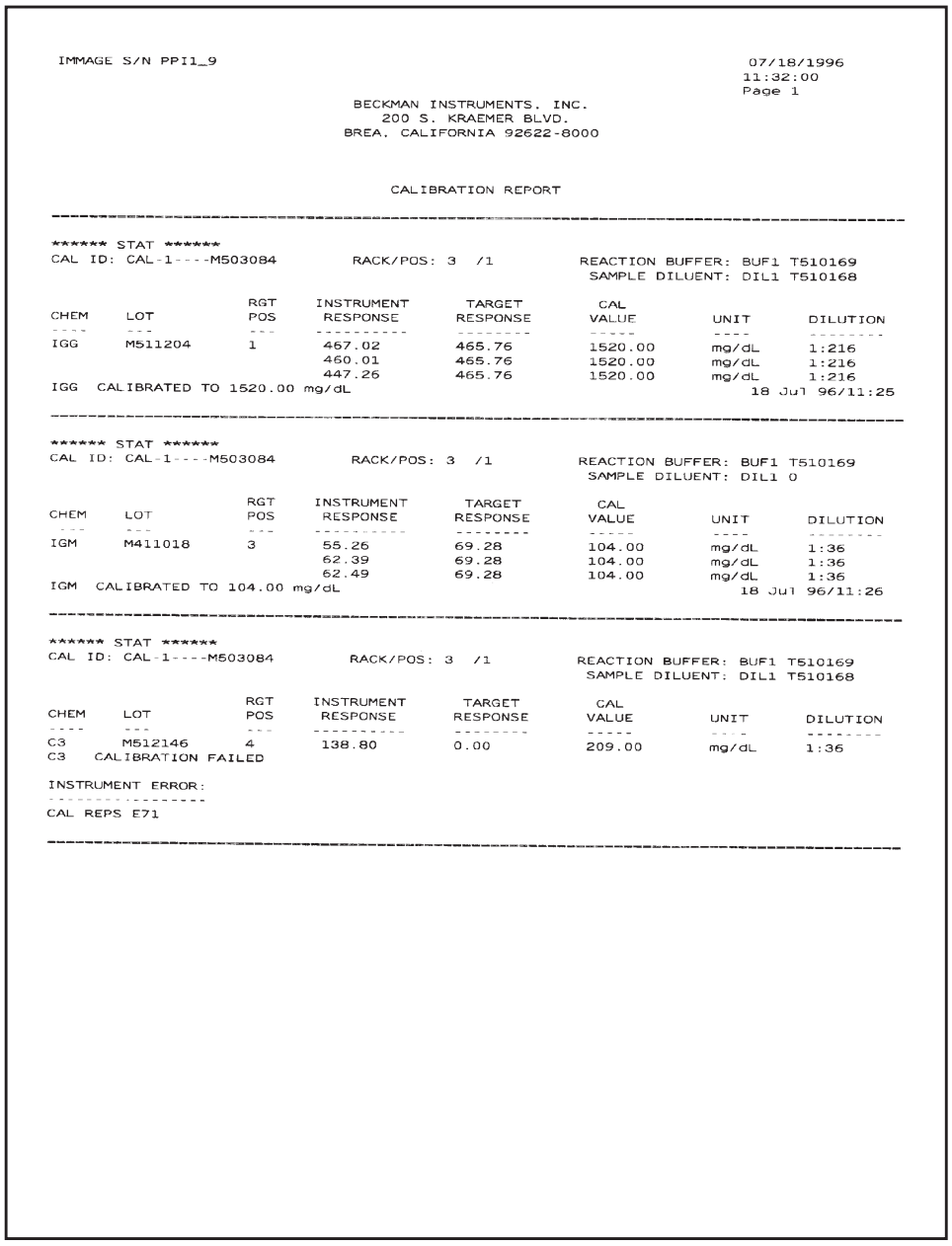
CALIBRATION LOAD LIST

RACK	POS	CAL NAME	CAL LOT	CHEMS
3	2	UCAL	M511197	IGU
3	1	CAL-1	M503084	IGG IGA IGM C3 C4

E010314L.EPS

Figure B.5 Calibration Load List

Calibration Report



IMMAGE S/N PPI1_9

07/18/1996
11:32:00
Page 1

BECKMAN INSTRUMENTS, INC.
200 S. KRAEMER BLVD.
BREA, CALIFORNIA 92622-8000

CALIBRATION REPORT

****** STAT ******
CAL ID: CAL-1----M503084 RACK/POS: 3 /1 REACTION BUFFER: BUF1 T510169
SAMPLE DILUENT: DIL1 T510168

CHEM	LOT	RGT POS	INSTRUMENT RESPONSE	TARGET RESPONSE	CAL VALUE	UNIT	DILUTION
IGG	M511204	1	467.02	465.76	1520.00	mg/dL	1:216
			460.01	465.76	1520.00	mg/dL	1:216
			447.26	465.76	1520.00	mg/dL	1:216

IGG CALIBRATED TO 1520.00 mg/dL
18 Jul 96/11:25

****** STAT ******
CAL ID: CAL-1----M503084 RACK/POS: 3 /1 REACTION BUFFER: BUF1 T510169
SAMPLE DILUENT: DIL1 0

CHEM	LOT	RGT POS	INSTRUMENT RESPONSE	TARGET RESPONSE	CAL VALUE	UNIT	DILUTION
IGM	M411018	3	55.26	69.28	104.00	mg/dL	1:36
			62.39	69.28	104.00	mg/dL	1:36
			62.49	69.28	104.00	mg/dL	1:36

IGM CALIBRATED TO 104.00 mg/dL
18 Jul 96/11:26

****** STAT ******
CAL ID: CAL-1----M503084 RACK/POS: 3 /1 REACTION BUFFER: BUF1 T510169
SAMPLE DILUENT: DIL1 T510168

CHEM	LOT	RGT POS	INSTRUMENT RESPONSE	TARGET RESPONSE	CAL VALUE	UNIT	DILUTION
C3	M512146	4	138.80	0.00	209.00	mg/dL	1:36

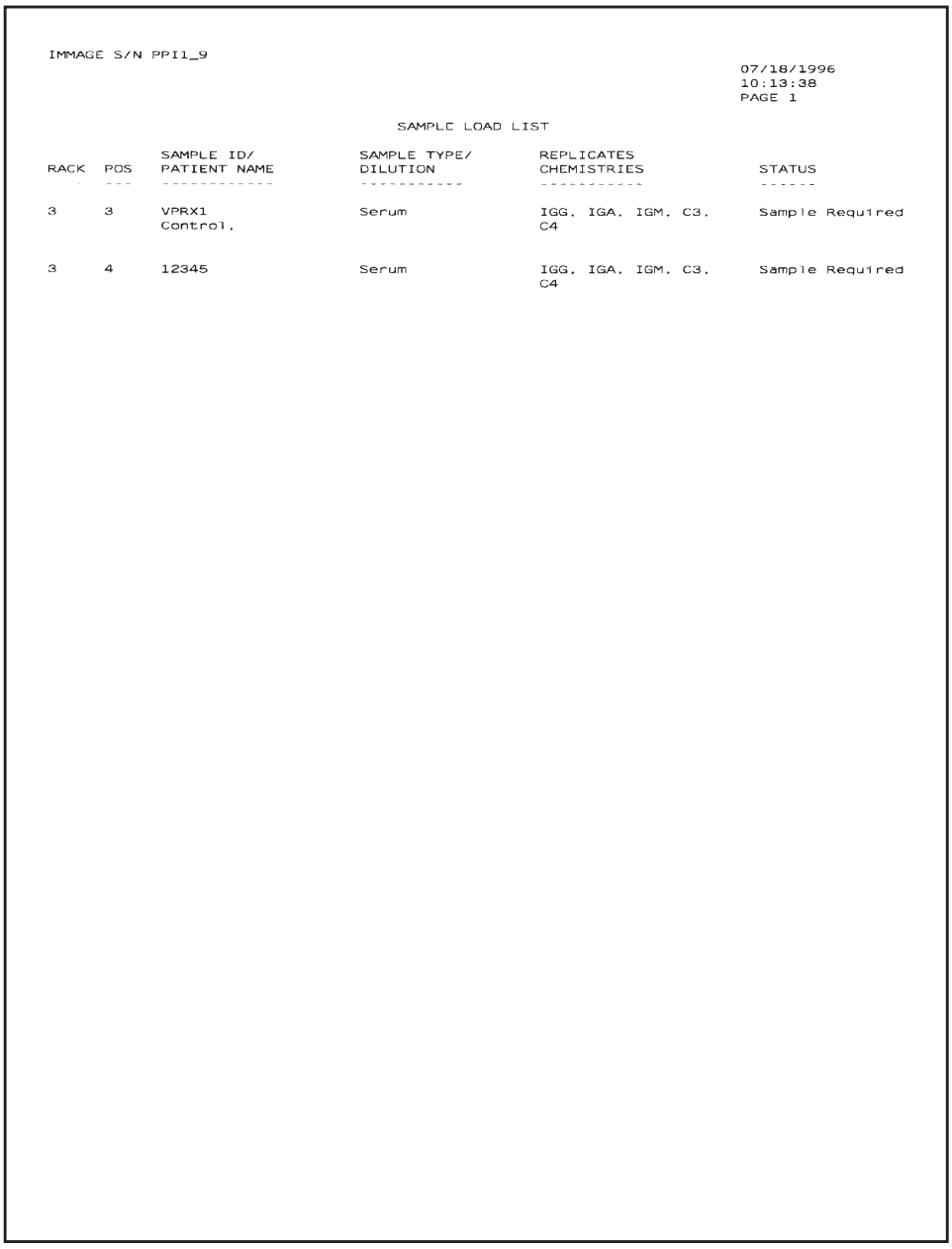
C3 CALIBRATION FAILED

INSTRUMENT ERROR:
CAL REPS E71

E010315L.EPS

Figure B.6 Calibration Report

Sample Load List



IMMAGE S/N PPI1_9

07/18/1996
10:13:38
PAGE 1

SAMPLE LOAD LIST

RACK	POS	SAMPLE ID/ PATIENT NAME	SAMPLE TYPE/ DILUTION	REPLICATES CHEMISTRIES	STATUS
3	3	VPRX1 Control,	Serum	IGG, IGA, IGM, C3, C4	Sample Required
3	4	12345	Serum	IGG, IGA, IGM, C3, C4	Sample Required

E010316L.EPS

Figure B.7 Sample Load List

Post-run Summary

IMMAGE S/N PPI2-15

04/22/1998
12:45:11
PAGE 1

POST-RUN SUMMARY

RUN DATE/TIME	RACK/POS	SAMPLE ID	CHEM	REMARKS
04/22/1998 12:03	34 8	V+1	RF	ORLO E61
04/22/1998 12:03	34 8	V+1	RF	ORLO E63
04/22/1998 12:01	34 5	46522	KAP	RGT CART N/A E9
04/22/1998 12:01	34 5	46522	KAP	TEST PENDING
04/22/1998 12:01	34 5	46522	VPA	ORLO E58
04/22/1998 12:01	34 5	46522	VPA	ORLO E58
04/22/1998 11:43	57 6	48292	LAM	RGT CART N/A E9
04/22/1998 11:43	57 6	48292	LAM	TEST PENDING
04/22/1998 11:43	57 4	62853	KAP	RGT CART N/A E9
04/22/1998 11:43	57 4	62853	KAP	TEST PENDING
04/22/1998 11:43	57 3	46548	ALB	RGT CART N/A E9
04/22/1998 11:43	57 3	46548	ALB	TEST PENDING
04/22/1998 11:43	34 6	23922	KAP	RGT CART N/A E9
04/22/1998 11:43	34 6	23922	KAP	TEST PENDING
04/22/1998 11:43	34 6	23922	LAM	RGT CART N/A E9
04/22/1998 11:43	34 6	23922	LAM	TEST PENDING

E014103L.EPS

Figure B.8 Post-run Summary

Units, Slope and Offset Summary

IMMAGE S/N 1343

02/06/2004
14:35:44
PAGE 1

UNITS, DILUTION, SLOPE AND OFFSET SUMMARY

CHEM	SAMPLE TYPE	UNITS	DILUTION	SLOPE VALUE	OFFSET VALUE
ALB	Serum	mg/dL	1:1296	1.000	0.000
ALB	CSF	mg/dL	1:6	1.000	0.000
ALB	Plasma	mg/dL	1:1296	1.000	0.000
CRPH	Serum	mg/dL	1:1	1.000	0.000
CRPH	Plasma	mg/dL	1:1	1.000	0.000
GEN	Serum	ug/mL	1:36	1.000	0.000
GEN	Plasma	ug/mL	1:36	1.000	0.000
IGA	Serum	mg/dL	1:36	1.000	0.000
IGA	CSF	mg/dL	1:1	1.000	0.000
IGA	Plasma	mg/dL	1:36	1.000	0.000
IGE	Serum	IU/mL	1:1	1.000	0.000
IGE	Plasma	IU/mL	1:1	1.000	0.000
IGM	Serum	mg/dL	1:36	1.000	0.000
IGM	CSF	mg/dL	1:1	1.000	0.000
IGM	Plasma	mg/dL	1:36	1.000	0.000
IGMX1	Serum	mg/dL	1:36	1.000	0.000
IGMX1	CSF	mg/dL	1:36	1.000	0.000
IGMX1	Plasma	mg/dL	1:36	1.000	0.000
IGMX1	Urine	mg/dL	1:36	1.000	0.000
PHE	Serum	ug/mL	1:36	1.000	0.000
PHE	Plasma	ug/mL	1:36	1.000	0.000
THE	Serum	ug/mL	1:36	1.000	0.000
THE	Plasma	ug/mL	1:36	1.000	0.000

E011432L.EPS

Figure B.9 Units, Slope and Offset Summary

Reference Interval and Critical Range Summary

IMMAGE S/N PPI2-15

04/21/1998
10:55:35
PAGE 1

REFERENCE INTERVAL AND CRITICAL RANGE SUMMARY

* = Default range

CHEM/ CALC	SEX	SAMPLE TYPE	AGE RANGE	REFERENCE INTERVAL	UNITS	CRITICAL RANGE
ALB						
	M/F	CSF	0D-30D	20.0-150	mg/dL	<10.0 >200
			31D-90D	20.0-100	mg/dL	<10.0 >150
			3M-6M	15.0-50.0	mg/dL	<5.00 >80.0
			7M-10Y	10.0-30.0	mg/dL	<5.00 >60.0
			11Y-40Y	15.0-45.0	mg/dL	<5.00 >150
			41Y-100Y	20.0-60.0	mg/dL	<5.00 >150

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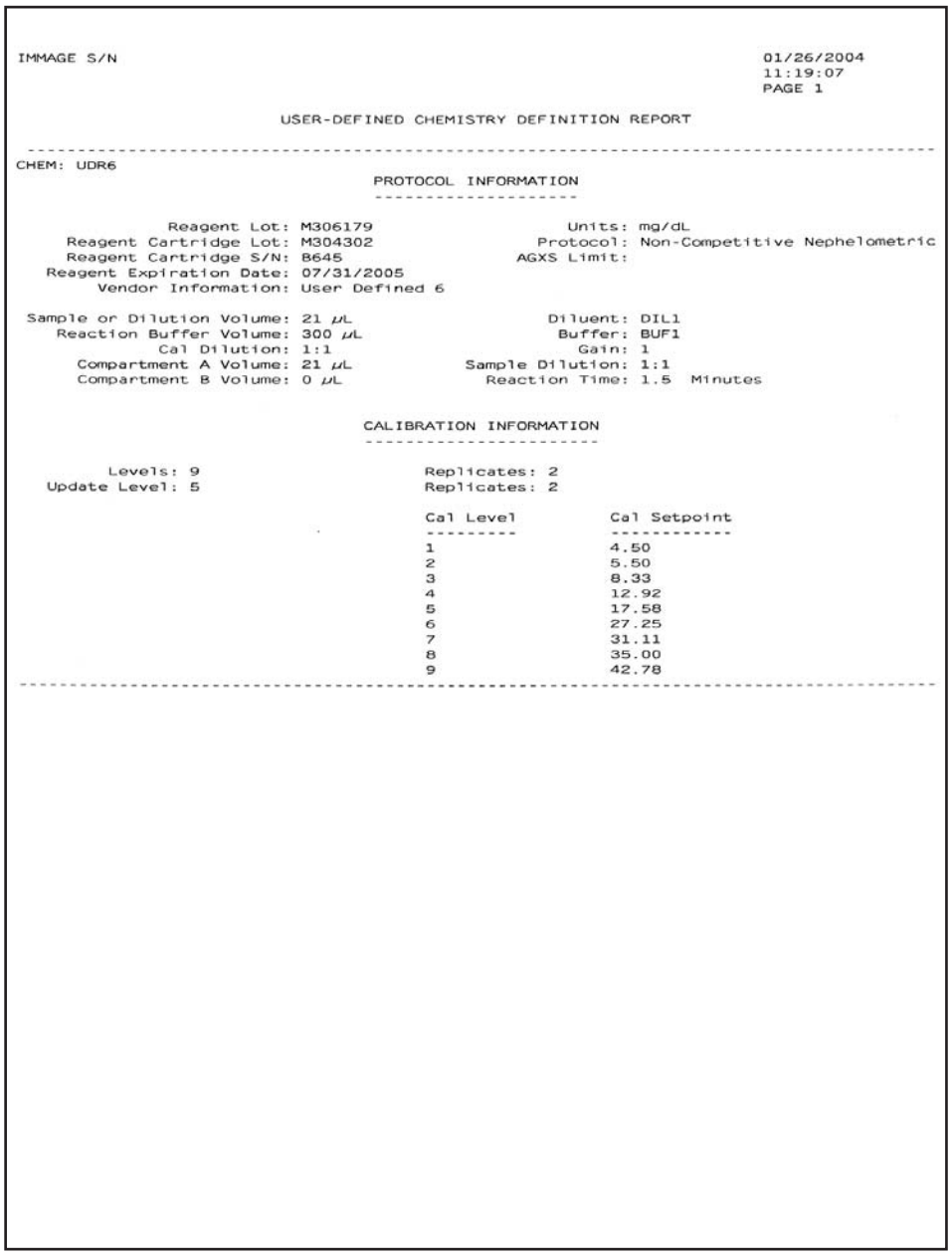
Figure B.10 Reference Interval and Critical Range Summary

User-Defined Chemistry Definition Report



IMMAGE S/N

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11:19:07
PAGE 1

USER-DEFINED CHEMISTRY DEFINITION REPORT

CHEM: UDR6

PROTOCOL INFORMATION

Reagent Lot:	M306179	Units:	mg/dL
Reagent Cartridge Lot:	M304302	Protocol:	Non-Competitive Nephelometric
Reagent Cartridge S/N:	B645	AGXS Limit:	
Reagent Expiration Date:	07/31/2005		
Vendor Information:	User Defined 6		
Sample or Dilution Volume:	21 µL	Diluent:	DIL1
Reaction Buffer Volume:	300 µL	Buffer:	BUF1
Cal Dilution:	1:1	Gain:	1
Compartment A Volume:	21 µL	Sample Dilution:	1:1
Compartment B Volume:	0 µL	Reaction Time:	1.5 Minutes

CALIBRATION INFORMATION

Levels: 9
Update Level: 5

Replicates: 2
Replicates: 2

Cal Level	Cal Setpoint
1	4.50
2	5.50
3	8.33
4	12.92
5	17.58
6	27.25
7	31.11
8	35.00
9	42.78

E011446L.EPS

Figure B.11 User-Defined Chemistry Definition Report

User-Defined Calibration Results Report

IMMAGE S/N 123

04/22/1998
08:16:34
PAGE 1

USER-DEFINED CALIBRATION RESULTS

CHEM: UDR1 REAGENT SERIAL NUMBER: A056 UDR BUFFER: BUF10 L123456
RGT POS: 2 REAGENT LOT NUMBER: M804052 UDR DILUENT: DIL10 L678901

RACK	POS	CAL ID	REP	INST RESP	CAL SETPT	UNIT	ERROR
11	1	A	1	0.186	0.00	mg/dL	
11	1	A	2	0.180	0.00	mg/dL	
11	1	A	3	0.131	0.00	mg/dL	
11	1	A	4	0.0439	0.00	mg/dL	
			MEAN -0.1352		SD -0.06568		CV -48.6
11	2	A	1	0.489	12.5	mg/dL	
11	2	A	2	0.460	12.5	mg/dL	
11	2	A	3	0.517	12.5	mg/dL	
11	2	A	4	0.725	12.5	mg/dL	
			MEAN -0.5478		SD -0.1204		CV -22.0
11	3	A	1	5.15	25.0	mg/dL	
11	3	A	2	5.32	25.0	mg/dL	
11	3	A	3	5.16	25.0	mg/dL	
11	3	A	4	5.04	25.0	mg/dL	
			MEAN -5.17		SD -0.1153		CV -2.23
11	4	A	1	21.3	50.0	mg/dL	
11	4	A	2	21.5	50.0	mg/dL	
11	4	A	3	21.1	50.0	mg/dL	
11	4	A	4	21.4	50.0	mg/dL	
			MEAN -21.32		SD -0.1708		CV -0.801
11	5	A	1	96.3	150	mg/dL	
11	5	A	2	97.2	150	mg/dL	
11	5	A	3	95.9	150	mg/dL	
11	5	A	4	96.5	150	mg/dL	
			MEAN -96.22		SD -0.7274		CV -0.756
11	6	A	1	126	200	mg/dL	
11	6	A	2	127	200	mg/dL	
11	6	A	3	129	200	mg/dL	
11	6	A	4	126	200	mg/dL	
			MEAN -127.0		SD -1.41		CV -1.11
11	7	A	1	167	300	mg/dL	
11	7	A	2	168	300	mg/dL	
11	7	A	3	154	300	mg/dL	
11	7	A	4	162	300	mg/dL	
			MEAN -162.8		SD -6.40		CV -3.93

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Figure B.12 User-Defined Calibration Results Report

User-Defined Calibration Report

IMMAGE S/N 123 04/22/1998
08:14:44
PAGE 1

USER-DEFINED CALIBRATION REPORT

CHEM: UDR1 REAGENT SERIAL NUMBER: A056 UDR BUFFER: BUF10 L123456
RGT POS: 2 REAGENT LOT NUMBER: M804052 UDR DILUENT: DIL10 L678901

RACK	POS	CAL ID	REPS	MEAN INST RESP	SD	%CV	SETPT	UNIT
11	1	A	4	0.135	0.0657	48.6	0.00	mg/dL
11	2	B	4	0.548	0.120	22.0	12.5	mg/dL
11	3	C	4	5.17	0.115	2.23	25.0	mg/dL
11	4	D	4	21.3	0.171	0.801	50.0	mg/dL
11	5	E	4	96.2	0.727	0.756	150	mg/dL
11	6	F	4	127	1.41	1.11	200	mg/dL
11	7	G	4	163	6.40	3.93	300	mg/dL

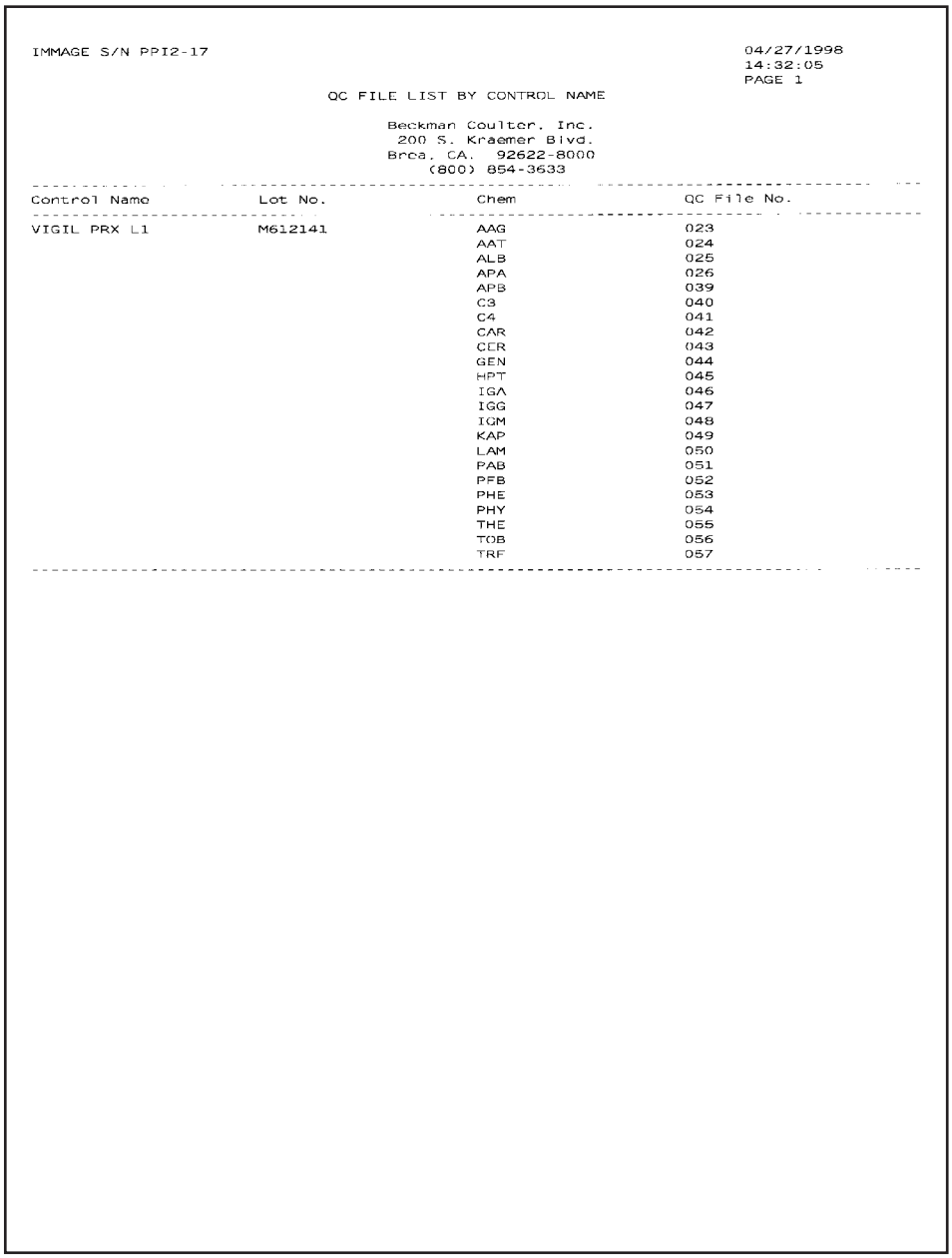
UDR1 CALIBRATED 04/21/1998 13:03

MODEL: Four Parameter Logistic Calibration
INSTRUMENT RESPONSE LOW = 0.130
INSTRUMENT RESPONSE HIGH = 168
A = -0.595709
B = 1.830002
C = 171.291351
D = 221.614227

E014064L.EPS

Figure B.13 User-Defined Calibration Report

QC File List by Control Name



IMMAGE S/N PPI2-17

04/27/1998
14:32:05
PAGE 1

QC FILE LIST BY CONTROL NAME

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

Control Name	Lot No.	Chem	QC File No.
VIGIL PRX L1	M612141	AAG	023
		AAT	024
		ALB	025
		APA	026
		APB	039
		C3	040
		C4	041
		CAR	042
		CER	043
		GEN	044
		HPT	045
		IGA	046
		IGG	047
		IGM	048
		KAP	049
		LAM	050
		PAB	051
		PFB	052
		PHE	053
		PHY	054
		THE	055
		TOB	056
		TRF	057

E014106L.EPS

Figure B.14 QC File List by Control Name

QC File List by QC File Number

IMMAGE S/N PPI2-17

04/27/1998
14:34:33
PAGE 1

QC FILE LIST BY QC FILE NUMBER

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

QC File No.	Chem	Control Name	Lot No.
058	AAG	VIGIL PRX 2	M612142
059	AAT	VIGIL PRX 2	M612142
060	ALB	VIGIL PRX 2	M612142
061	APA	VIGIL PRX 2	M612142
062	APB	VIGIL PRX 2	M612142
063	C3	VIGIL PRX 2	M612142
064	C4	VIGIL PRX 2	M612142
065	CAR	VIGIL PRX 2	M612142
066	CER	VIGIL PRX 2	M612142
067	GEN	VIGIL PRX 2	M612142
068	HPT	VIGIL PRX 2	M612142
069	IGA	VIGIL PRX 2	M612142
070	IGG	VIGIL PRX 2	M612142
071	IGM	VIGIL PRX 2	M612142
072	KAP	VIGIL PRX 2	M612142
073	LAM	VIGIL PRX 2	M612142
074	PAB	VIGIL PRX 2	M612142
075	PFB	VIGIL PRX 2	M612142
076	PHE	VIGIL PRX 2	M612142
077	PHY	VIGIL PRX 2	M612142
078	THE	VIGIL PRX 2	M612142
079	TOB	VIGIL PRX 2	M612142
080	TRF	VIGIL PRX 2	M612142

E014107L.EPS

Figure B.15 QC File List by QC File Number

QC File List by Chemistry Name

IMMAGE S/N PPI2-17

04/27/1998
15:52:47
PAGE 1

QC FILE LIST BY CHEMISTRY NAME

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

Chem	Control Name	Lot No.	QC File No.
AAG	VIGIL PRX L1	M612141	023
AAT	VIGIL PRX L1	M612141	024
ALB	VIGIL PRX L1	M612141	025
APA	VIGIL PRX L1	M612141	026
APB	VIGIL PRX L1	M612141	039
C3	VIGIL PRX L1	M612141	040
C4	VIGIL PRX L1	M612141	041
CAR	VIGIL PRX L1	M612141	042
CER	VIGIL PRX L1	M612141	043
GEN	VIGIL PRX L1	M612141	044
HPT	VIGIL PRX L1	M612141	045
IGA	VIGIL PRX L1	M612141	046
IGG	VIGIL PRX L1	M612141	047
IGM	VIGIL PRX L1	M612141	048
KAP	VIGIL PRX L1	M612141	049
LAM	VIGIL PRX L1	M612141	050
PAB	VIGIL PRX L1	M612141	051
PFB	VIGIL PRX L1	M612141	052
PHE	VIGIL PRX L1	M612141	053
PHY	VIGIL PRX L1	M612141	054
THE	VIGIL PRX L1	M612141	055
TOB	VIGIL PRX L1	M612141	056
TRF	VIGIL PRX L1	M612141	057

E014108L.EPS

Figure B.16 QC File List by Chemistry Name

QC Log Report

IMMAGE S/N PPI2-17 04/24/1998
09:12:14
PAGE 1

QC LOG REPORT

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

Control Name: VIGIL PRX L2 Start Date: 04/01/1998
Lot Number: M612142 End Date: 04/24/1998
Sample Type: Serum

AAG
QC File Number: 027 Constituent Code:
Assigned Mean: 0.000 Cumulative Mean: 73.72
Assigned +/-1 SD: 99999 Cumulative SD: 2.789

Date	Time	Result	Units	Flag	Comments
04/23/1998	15:10:20	71.0	mg/dL		
04/23/1998	15:07:00	75.1	mg/dL		
04/23/1998	15:05:20	74.1	mg/dL		
04/23/1998	15:05:10	74.4	mg/dL		
04/23/1998	14:43:19	70.3	mg/dL		
04/23/1998	14:42:39	70.6	mg/dL		
04/23/1998	14:42:29	71.2	mg/dL		
04/23/1998	14:42:19	71.1	mg/dL		
04/23/1998	14:16:28	72.0	mg/dL		
04/23/1998	14:16:18	73.2	mg/dL		
04/23/1998	14:15:58	72.1	mg/dL		
04/23/1998	14:15:48	73.2	mg/dL		
04/23/1998	13:53:36	78.7	mg/dL		
04/23/1998	13:53:26	77.4	mg/dL		
04/23/1998	13:53:16	77.5	mg/dL		
04/23/1998	13:53:07	77.4	mg/dL		

C3
QC File Number: 028 Constituent Code: 28
Assigned Mean: 164.0 Cumulative Mean: 137.4
Assigned +/-1 SD: 15.00 Cumulative SD: 10.20

Date	Time	Result	Units	Flag	Comments
04/23/1998	15:02:20	121	mg/dL	2SD ACC	
04/23/1998	15:01:59	122	mg/dL	2SD ACC	
04/23/1998	15:01:49	124	mg/dL	2SD ACC	
04/23/1998	15:01:40	123	mg/dL	2SD ACC	
04/23/1998	14:39:18	133	mg/dL	2SD	
04/23/1998	14:39:08	136	mg/dL		
04/23/1998	14:38:58	134	mg/dL		
04/23/1998	14:38:28	139	mg/dL		
04/23/1998	14:13:07	146	mg/dL		
04/23/1998	14:12:07	139	mg/dL		
04/23/1998	14:11:57	147	mg/dL		
04/23/1998	14:11:07	147	mg/dL		
04/23/1998	13:50:06	148	mg/dL		
04/23/1998	13:49:56	148	mg/dL		
04/23/1998	13:49:46	146	mg/dL		
04/23/1998	13:49:36	145	mg/dL		

HPT
QC File Number: 029 Constituent Code:
Assigned Mean: 0.000 Cumulative Mean: 124.8
Assigned +/-1 SD: 99999 Cumulative SD: 7.720

Date	Time	Result	Units	Flag	Comments
04/23/1998	15:04:19	117	mg/dL		
04/23/1998	15:03:50	119	mg/dL		
04/23/1998	15:03:40	106	mg/dL		
04/23/1998	15:03:20	117	mg/dL		
04/23/1998	14:41:08	123	mg/dL		
04/23/1998	14:40:39	123	mg/dL		
04/23/1998	14:40:28	122	mg/dL		
04/23/1998	14:40:18	123	mg/dL		
04/23/1998	14:14:57	127	mg/dL		
04/23/1998	14:14:47	128	mg/dL		
04/23/1998	14:14:37	132	mg/dL		

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Figure B.17 QC Log Report

QC Log by Reagent Lot

IMMAGE S/N PPI2-17 04/24/1998
09:18:39
PAGE 1

QC LOG REPORT

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

Control Name: VIGIL PRX L1 Start Date: 04/01/1998
Lot Number: M612141 End Date: 04/24/1998
Sample Type: Serum

AAG
QC File Number: 023 Constituent Code:
Assigned Mean: 0.000 Cumulative Mean: 78.29
Assigned +/-1 SD: 99999 Cumulative SD: 32.01
Reagent Lot Number: M610013

Date	Time	Result	Units	Flag	Comments
04/23/1998	15:01:40	118	mg/dL		
04/23/1998	15:01:20	116	mg/dL		
04/23/1998	15:01:10	112	mg/dL		
04/23/1998	15:01:00	117	mg/dL		
04/23/1998	14:34:38	104	mg/dL		
04/23/1998	14:33:48	100	mg/dL		
04/23/1998	14:33:38	98.4	mg/dL		
04/23/1998	14:33:19	105	mg/dL		
04/23/1998	14:10:17	46.3	mg/dL		
04/23/1998	14:09:37	45.8	mg/dL		
04/23/1998	14:09:27	45.7	mg/dL		
04/23/1998	14:08:27	45.2	mg/dL		
04/23/1998	13:44:36	49.1	mg/dL		
04/23/1998	13:44:16	50.0	mg/dL		
04/23/1998	13:44:06	50.2	mg/dL		
04/23/1998	13:43:56	50.0	mg/dL		

C3
QC File Number: 024 Constituent Code: 024
Assigned Mean: 50.30 Cumulative Mean: 41.26
Assigned +/-1 SD: 5.050 Cumulative SD: 2.206
Reagent Lot Number: M706055

Date	Time	Result	Units	Flag	Comments
04/23/1998	14:53:09	218	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:52:49	215	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:52:39	216	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:52:30	202	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:30:28	232	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:30:18	254	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:29:58	247	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:29:48	254	mg/dL	DELETED	04/24/1998 09:16 jis poured wrong control
04/23/1998	14:03:47	37.4	mg/dL	2SD	
04/23/1998	14:03:27	40.4	mg/dL		
04/23/1998	14:02:58	40.4	mg/dL		
04/23/1998	14:02:47	39.5	mg/dL	2SD	
04/23/1998	13:48:46	43.2	mg/dL		
04/23/1998	13:40:46	42.2	mg/dL		
04/23/1998	13:40:36	43.7	mg/dL		
04/23/1998	13:40:26	43.3	mg/dL		

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Figure B.18 QC Log by Reagent Lot

QC Chart Report

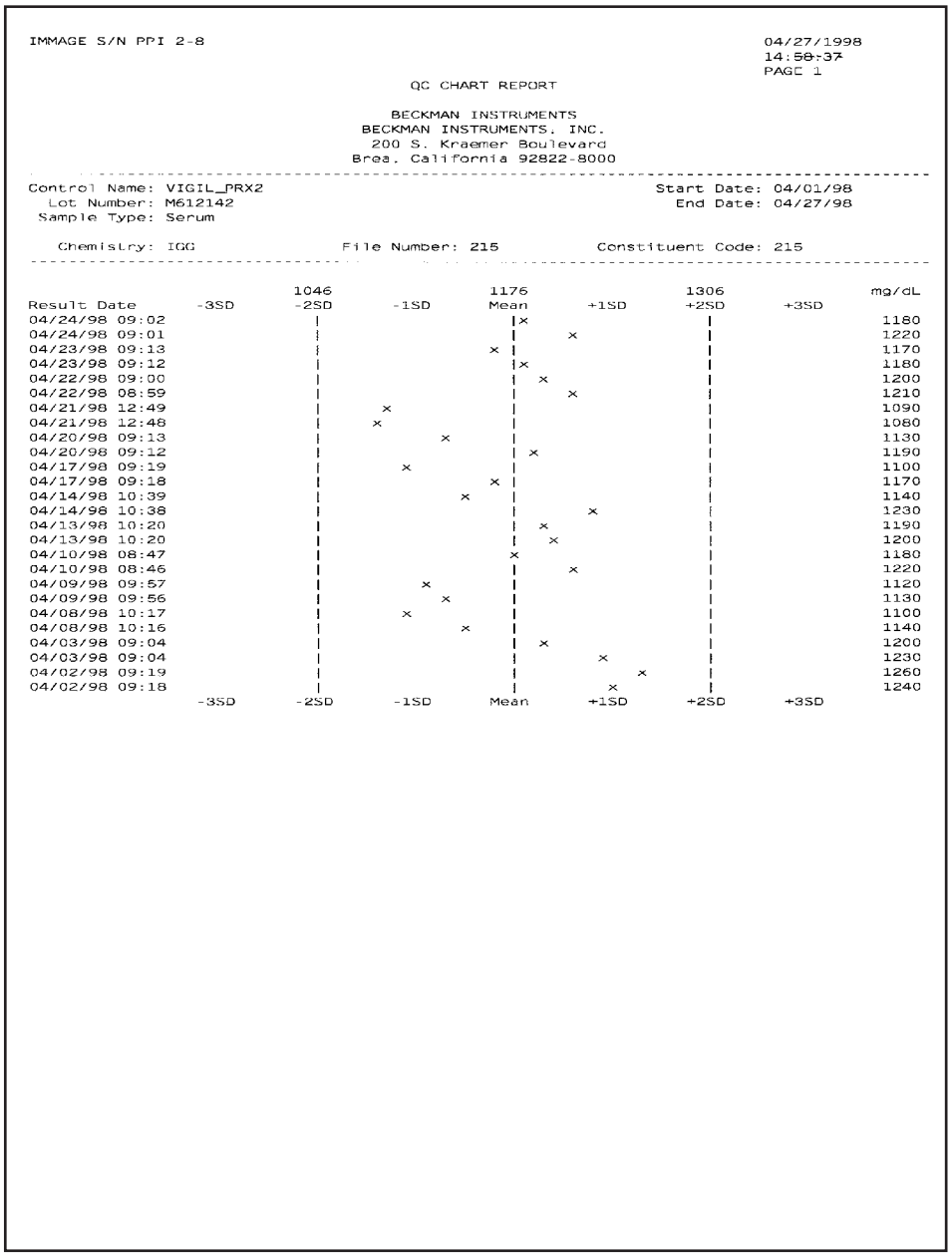

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Figure B.19 QC Chart Report

QC Summary Report

IMMAGE S/N PPI2-17 04/23/1998
18:23:16
PAGE 1

QC SUMMARY REPORT

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

Control Name: VIGIL PRX L3 Start Date: 04/01/1998
Lot Number: M612143 End Date: 04/23/1998
Sample Type: Serum

File		Summary				Cumulative Summary			
No	Chem	N	Mean	SD	CV	N	Mean	SD	CV
031	AAG	12	82.34	27.63	33.6	12	82.34	27.63	33.6
032	C3	8	253.2	6.730	2.7	8	253.2	6.730	2.7
033	HPT	12	152.1	70.49	46.3	12	152.1	70.49	46.3
034	IGG	8	1915	54.88	2.9	8	1915	54.88	2.9

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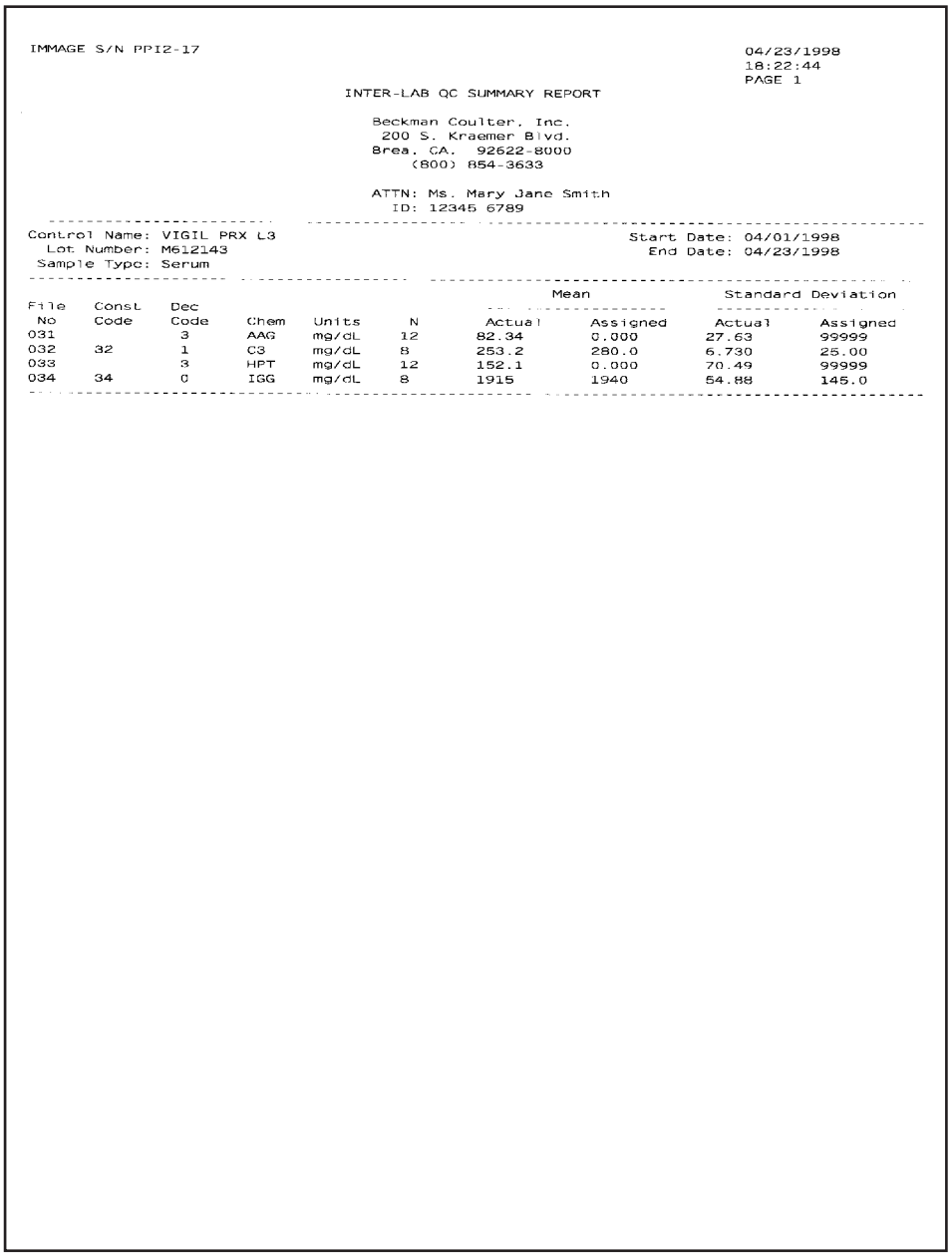
Figure B.20 QC Summary Report

Inter-Lab QC Summary Report



IMMAGE S/N PPI2-17

04/23/1998
18:22:44
PAGE 1

INTER-LAB QC SUMMARY REPORT

Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA. 92622-8000
(800) 854-3633

ATTN: Ms. Mary Jane Smith
ID: 12345 6789

Control Name: VIGIL PRX L3
Lot Number: M612143
Sample Type: Serum

Start Date: 04/01/1998
End Date: 04/23/1998

File No	Const Code	Dec Code	Chem	Units	N	Mean Actual	Mean Assigned	Standard Deviation Actual	Standard Deviation Assigned
031		3	AAG	mg/dL	12	82.34	0.000	27.63	99999
032	32	1	C3	mg/dL	8	253.2	280.0	6.730	25.00
033		3	HPT	mg/dL	12	152.1	0.000	70.49	99999
034	34	0	IGG	mg/dL	8	1915	1940	54.88	145.0

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Figure B.21 Inter-Lab QC Summary Report

Event/Error Log

IMMAGE S/N PPI1_9

07/18/1996
13:05:25
PAGE 1

EVENT/ERROR LOG

NUM	CLASS	DATE / TIME OCCURRED	DESCRIPTION
1	8	18 Jul 96 11:32:34	WLM: Change of state from CAU: <Standby>. (/mpcnim/src/wlm/wlm_log.c:897)
2	8	18 Jul 96 11:32:34	WLM: Message 2602 was received by the WLM COMM Agent.
3	8	18 Jul 96 11:32:34	WLM: Change of state from CAU: <Stopped>. (/mpcnim/src/wlm/wlm_log.c:897)
4	8	18 Jul 96 11:32:34	WLM: Message 2602 was received by the WLM COMM Agent.
5	8	18 Jul 96 11:32:34	WLM: Message 2611 was received by the WLM COMM Agent.
6	8	18 Jul 96 11:32:00	WLM: Change of state from CAU: <Stopping>. (/mpcnim/src/wlm/wlm_log.c:897)
7	4	18 Jul 96 11:31:59	SCRMGR: Internal Error: description: SM_ELANG filename: sm_wndutls.c linenum: 2063
8	18	18 Jul 96 11:31:59	INSTRUMENT: CAU Calibration Failed for Reagent - Chemistry: IGU, Index: 2, Error Status: 1 (error_id: 1801).
9	8	18 Jul 96 11:31:59	WLM: Message 2602 was received by the WLM COMM Agent.
10	8	18 Jul 96 11:31:59	WLM: Message 2202 was received by the WLM COMM Agent.
11	8	18 Jul 96 11:31:59	WLM: Message 2303 was received by the WLM COMM Agent.
12	8	18 Jul 96 11:31:59	WLM: Message 2301 was received by the WLM COMM Agent.
13	8	18 Jul 96 11:31:39	WLM: Message 2301 was received by the WLM COMM Agent.
14	8	18 Jul 96 11:31:19	WLM: Message 2301 was received by the WLM COMM Agent.
15	8	18 Jul 96 11:27:54	WLM: Message 2202 was received by the WLM COMM Agent.
16	8	18 Jul 96 11:27:54	WLM: Message 2303 was received by the WLM COMM Agent.
17	8	18 Jul 96 11:27:54	WLM: Message 2301 was received by the WLM COMM Agent.
18	8	18 Jul 96 11:27:54	WLM: Message 2303 was received by the WLM COMM Agent.
19	8	18 Jul 96 11:27:54	WLM: Message 2301 was received by the WLM COMM Agent.
20	8	18 Jul 96 11:27:44	WLM: Message 2301 was received by the WLM COMM Agent.
21	8	18 Jul 96 11:27:44	WLM: Message 2301 was received by the WLM COMM Agent.
22	1	18 Jul 96 11:27:37	KEY:
23	8	18 Jul 96 11:27:34	WLM: Message 2301 was received by the WLM COMM Agent.
24	8	18 Jul 96 11:27:34	WLM: Message 2301 was received by the WLM COMM Agent.
25	4	18 Jul 96 11:27:24	SCRMGR: Internal Error: description: SM_ELANG filename: sm_wndutls.c linenum: 2063
26	18	18 Jul 96 11:27:24	INSTRUMENT: CAU Calibration Failed for Reagent - Chemistry: C3, Index: 2, Error Status: 32 (error_id: 1801).
27	8	18 Jul 96 11:27:24	WLM: Message 2303 was received by the WLM COMM Agent.
28	8	18 Jul 96 11:27:24	WLM: Message 2301 was received by the WLM COMM Agent.
29	8	18 Jul 96 11:27:13	WLM: Message 2301 was received by the WLM COMM Agent.
30	8	18 Jul 96 11:27:04	WLM: Message 2301 was received by the WLM COMM Agent.
31	8	18 Jul 96 11:26:54	WLM: Message 2303 was received by the WLM COMM Agent.
32	8	18 Jul 96 11:26:54	WLM: Message 2301 was received by the WLM COMM Agent.
33	8	18 Jul 96 11:26:44	WLM: Message 2301 was received by the WLM COMM Agent.
34	8	18 Jul 96 11:26:34	WLM: Message 2301 was received by the WLM COMM Agent.
35	8	18 Jul 96 11:25:54	WLM: Message 2303 was received by the WLM COMM Agent.
36	8	18 Jul 96 11:25:54	WLM: Message 2301 was received by the WLM COMM Agent.
37	8	18 Jul 96 11:25:44	WLM: Message 2301 was received by the WLM COMM Agent.
38	8	18 Jul 96 11:25:14	WLM: Message 2301 was received by the WLM COMM Agent.
39	8	18 Jul 96 11:21:09	WLM: Message 2202 was received by the WLM COMM Agent.
40	1	18 Jul 96 11:20:31	KEY: OK
41	1	18 Jul 96 11:20:28	KEY: OK
42	1	18 Jul 96 11:20:23	KEY: Display
43	1	18 Jul 96 11:20:21	KEY: bPos02
44	1	18 Jul 96 11:20:18	KEY: Calibrator Summary
45	1	18 Jul 96 11:20:17	KEY: Cal Options
46	1	18 Jul 96 11:20:14	KEY: Reagent Load/Calibration
47	1	18 Jul 96 11:18:55	KEY: ENTER
48	1	18 Jul 96 11:18:55	KEY: ENTER
49	1	18 Jul 96 11:18:54	KEY: ENTER
50	1	18 Jul 96 11:18:53	KEY: ENTER
51	8	18 Jul 96 11:18:23	WLM: Message 2202 was received by the WLM COMM Agent.
52	18	18 Jul 96 11:18:23	INSTRUMENT: LPIA Optics Check - LPIA Offset: 20, LPIA Offset Quality: 30, LPIA Range: 112074, LPIA Range Quality: 131 (error_id: 5001).
53	18	18 Jul 96 11:18:23	INSTRUMENT: NIA Optics Check - NIA Offset: 3, NIA Offset Quality: 15, NIA Range: 54932, NIA Range Quality: 2248 (error_id: 5000).
54	8	18 Jul 96 11:18:23	WLM: Invalid rack ID detected, 0. (/mpcnim/src/wlm/wlm_verify.c:84)

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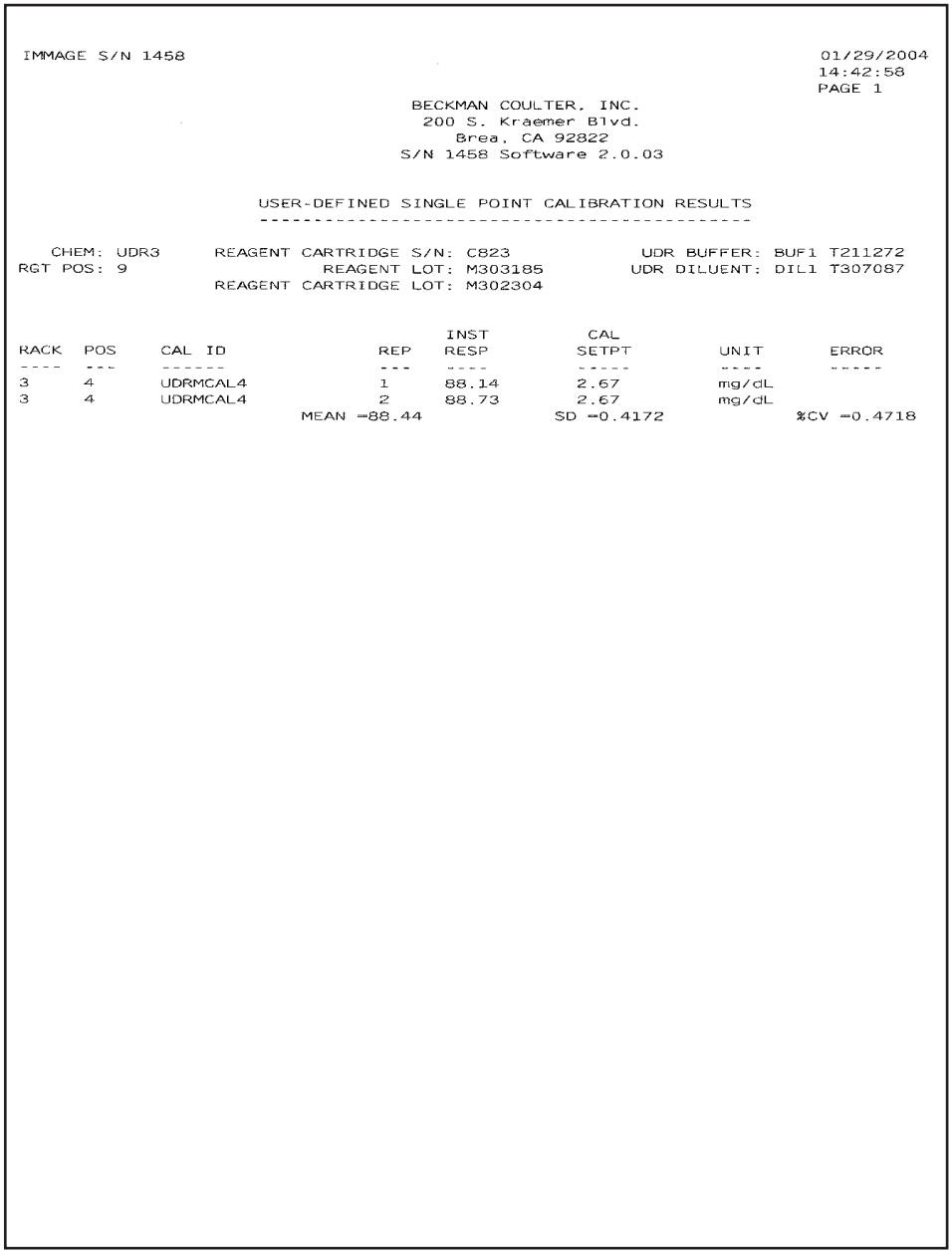
Figure B.22 Event/Error Log

User-Defined Single-Point Calibration Results



IMMAGE S/N 1458

01/29/2004
14:42:58
PAGE 1

BECKMAN COULTER, INC.
200 S. Kraemer Blvd.
Brea, CA 92822
S/N 1458 Software 2.0.03

USER-DEFINED SINGLE POINT CALIBRATION RESULTS

CHEM: UDR3 REAGENT CARTRIDGE S/N: C823 UDR BUFFER: BUF1 T211272
RGT POS: 9 REAGENT LOT: M303185 UDR DILUENT: DIL1 T307087
REAGENT CARTRIDGE LOT: M302304

RACK	POS	CAL ID	REP	INST RESP	CAL SETPT	UNIT	ERROR
3	4	UDRMCAL4	1	88.14	2.67	mg/dL	
3	4	UDRMCAL4	2	88.73	2.67	mg/dL	
			MEAN =88.44		SD =0.4172		%CV =0.4718

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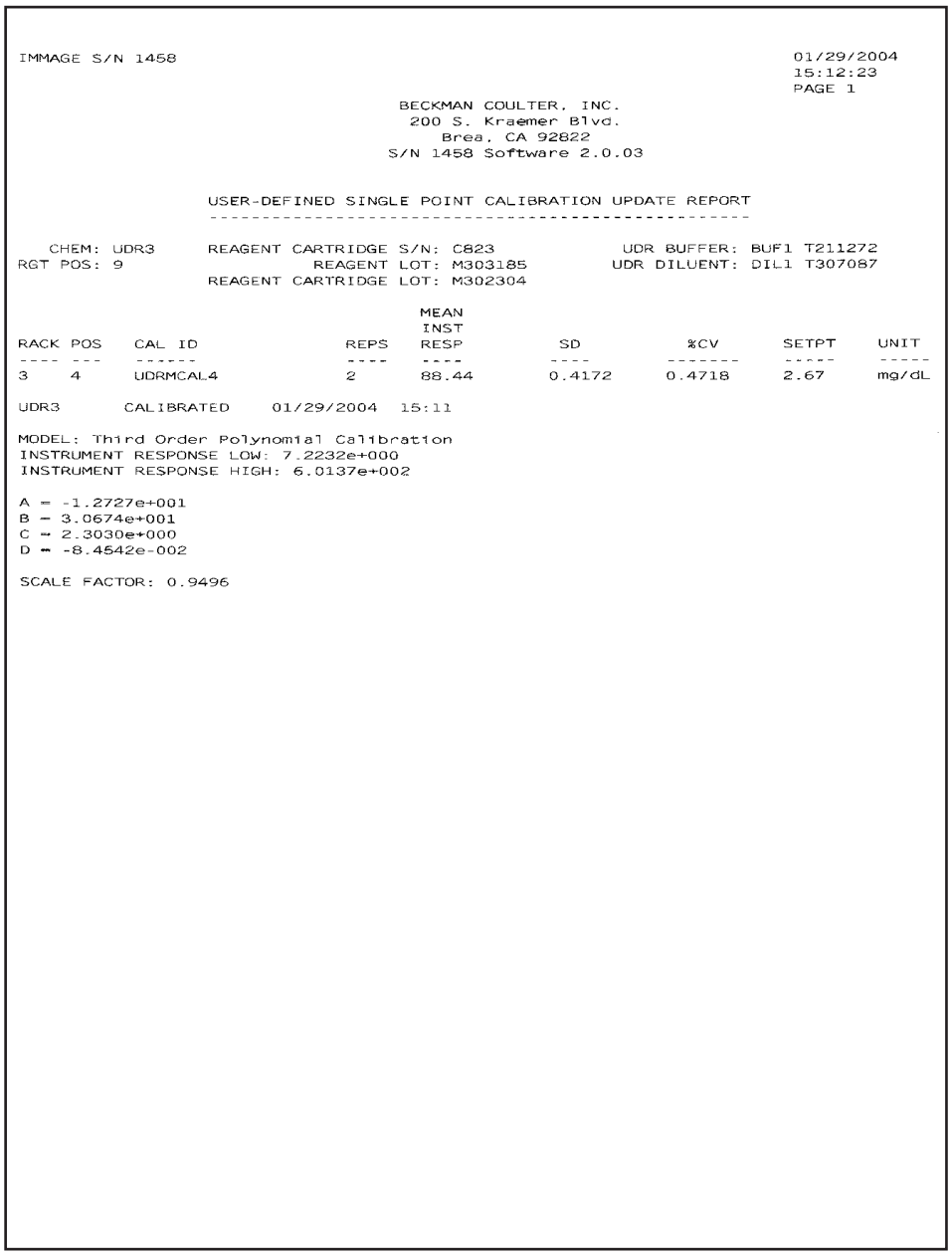
Figure B.23 User-Defined Single-Point Calibration Results

User-Defined Single-Point Calibration Update Report



```
IMMAGE S/N 1458                                                    01/29/2004
                                                                   15:12:23
                                                                   PAGE 1
                                   BECKMAN COULTER, INC.
                                    200 S. Kraemer Blvd.
                                       Brea, CA 92822
                                  S/N 1458 Software 2.0.03

                  USER-DEFINED SINGLE POINT CALIBRATION UPDATE REPORT
                  ---------------------------------------------------

   CHEM: UDR3     REAGENT CARTRIDGE S/N: C823          UDR BUFFER: BUF1 T211272
RGT POS: 9                  REAGENT LOT: M303185      UDR DILUENT: DIL1 T307087
                  REAGENT CARTRIDGE LOT: M302304

                                        MEAN
                                        INST
RACK POS   CAL ID              REPS     RESP        SD          %CV       SETPT    UNIT
---- ---   ------              ----     ----        ----        -------   -----    -----
3    4     UDRMCAL4            2        88.44       0.4172      0.4718    2.67     mg/dL

UDR3       CALIBRATED    01/29/2004  15:11

MODEL: Third Order Polynomial Calibration
INSTRUMENT RESPONSE LOW: 7.2232e+000
INSTRUMENT RESPONSE HIGH: 6.0137e+002

A = -1.2727e+001
B = 3.0674e+001
C = 2.3030e+000
D = -8.4542e-002

SCALE FACTOR: 0.9496
```

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Figure B.24 User-Defined Single-Point Calibration Update Report

Plot Robust Means Data Report

IMMAGE S/N pp1210

01/28/2004
06:43:52
PAGE 2

UDR DATA CURVE

Chem name: THE2

Rack: 15
Position: 1
Repeat: 1

TIME	MEAN DATA
06:40	2811
06:41	3160
06:42	3469
06:43	3746
06:44	3981
06:45	4203
06:46	4404
06:47	4581
06:48	4724
06:49	4866
06:50	4982
06:51	5086
06:52	5176
06:53	5260
06:54	5335

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Figure B.25 Plot Robust Means Data Report

Glossary

Alphanumeric character

A-Z, a-z, 0-9.

Analyte

The component being measured.

Antibody (Ab)

A protein made by the body to defend itself against a foreign substance (antigen). Antibody molecules bind noncovalently to the antigen that triggers their production.

Antigen (Ag)

A foreign substance that triggers an antibody response from the body's immune system.

Antigen excess (AGXS) testing

A test for unbound (excess) antibody remaining in solution after the primary reaction with antigen. Excess antibody is detected by the further addition of antigen and measurement of reaction rate.

Assay

A test. A single concentration determination.

Assigned mean

The mean value defined for a control.

ASTM protocol

A standardized computer interface specification following the guidelines from the American Society for Testing and Materials.

Bar code card

A Beckman Coulter-provided card which is imprinted with bar codes. The card contains either Reagent Parameters or Calibrator Parameters to input lot-specific information into the IMMAGE 800 system.

Bar code reader

A device on the instrument that scans and decodes bar codes.

Batch

A group of samples with the same sample programming information except for Sample ID.

Baud rate

The serial data transfer speed between two or more communication devices. One baud equals one signal event (change in frequency, phase angle, or voltage transmitted) per second.

Bidirectional interface

Two-way transmission of information from the host computer to the instrument (usually sample programming) and from the instrument to the host computer (usually results).

Buffer

Reaction medium for most protein chemistry reactions.

Buffer type

A specific type of reaction medium, such as Buffer 1 (BUF 1).

CMOS

An acronym for Complementary Metal Oxide Semiconductor, the components of the computer battery that stores the internal clock and PC configurations.

Calculation, Beckman Coulter-defined

A calculation formula supplied by Beckman Coulter which is uneditable and undeletable.

Callable diagnostics

Diagnostic routines initiated by the user from the software.

CAP information

Information consisting of an ID number and a designated laboratory contact person (based on the College of American Pathology standard).

Check digit

A character which is used to mathematically check that a bar code is read accurately.

Chemistry list

The comprehensive list of all chemistries with protocols loaded into the system.

Chemistry menu

The collection of chemistries configured by the user from the chemistry list for display/selection in sample programming and panel configuration.

Code length

A parameter which may be defined by the user so that only one bar code length will be accepted.

Constituent code

A quality assurance program code that can be defined for a control chemistry.

Control ID

The equivalent of a Sample ID for a control. Up to 8 unique Control IDs can be defined for each Control Name.

Conversion factor

The value that a user may define to apply to a result to convert from one category of units to another.

Critical range

A user-defined range consisting of low and high values that are used to flag patient results as "critical low" or "critical high".

Cuvette

One of the receptacles on the IMMAGE 800 reaction carousel in which sample and reactants are mixed and the reaction is measured.

DAS

Data Acquisition Software.

Data bits

Low or high voltage signals transmitted through the serial communication data line. Data bits are transmitted after a Start bit and before the Parity bit and Stop bit. The user can configure the number of bits to be transmitted between the Start bit and Stop bit.

Database

A collection of data stored and organized for rapid access and retrieval.

Diluent

Sample dilution medium for most protein dilutions.

Diluent type

A specific type of sample dilution medium, such as Diluent 1 (DIL1).

Dilution, off-line

A dilution factor defined by the user by which the sample result will be multiplied.

Dilution segment

A disposable tray of 36 dilution wells.

Dilution, starting

The Beckman Coulter-defined default dilution ratio from the system's predefined list for an individual chemistry.

Dilution well

A container within a dilution segment that holds sample with its diluent.

Dilutions, non-standard

A chemistry-dependent list of dilutions from which the starting dilution of a chemistry may be selected. The sample chemistry runs automatically based on the selected non-standard dilution instead of the default dilution.

File number (QC)

A unique number that must be assigned to each chemistry defined for a control.

Host query

A form of bidirectional interface communication. When the instrument reads a bar coded sample ID for which it has no program, the host computer is queried for the program associated with that sample. The host then sends the queried information to the system.

Icon

A small pictorial representation of a functional area. The icons are found on the menu bar at the top of the screen.

Intercharacter gap

The space that separates two characters in a bar code.

Inter-lab

A Beckman Coulter QC program.

Laboratory information system (LIS)

A laboratory host computer that can be interfaced to an IMMAGE 800 System.

Microtube™

A sample tube manufactured by Beckman Coulter which is intended for low-volume samples and can be bar coded.

Multipage list

A feature of the IMMAGE 800 interface that lists more than one screen page of information (e.g., chemistries). The multipage list includes Page-Up and Page-Down keys for next-page scrolling.

Numeric character

0-9.

Offset

A value which is added or subtracted following the application of a slope value to a chemistry result.

On-board reagent

The chemistries, buffers, and diluents that are currently loaded onto the system.

Panel

A group of tests that are ordered together.

Parity

A method of detecting serial data transmission errors.

Patient demographics

Information that is associated with a patient, such as name, ID, age or sex.

Pause

An instrument command which allows results to be generated for all samples in progress and then returns the instrument to *Standby* status.

Peltier

A temperature control system that heats or cools depending on the ambient temperature.

Primary tube

A tube into which the patient sample is collected.

Range length, bar code

The limits of the code length which may be defined for a symbology.

Reagent name

The two to five-character abbreviation of the chemistry name.

Reference interval (normal range)

A user-defined range consisting of low and high values that are used to flag patient results as "low" or "high".

Replicates

The number of repetitions performed for a test or sample.

Secondary tube

A tube which contains a portion of patient sample, control, or calibrator from another container.

Slope

A value by which a result is multiplied.

Special character

Any displayable or printable keyboard character that is not an alphanumeric character, including the following:

` ~ ! @ # $ % ^ & * ( ) - _ = + \ | [ ] { } ; : ' " , < > . / ?

Standby

An instrument mode where all motion is stopped and motors are turned off.

Start/Stop bits

Synchronization method that signals the start and end of data transmission in serial communication. The Data bits are preceded by the Start bit and followed by the Stop bit.

Symbology, bar code

A set of rules for encoding and decoding information contained in a bar code symbol. Examples of symbologies are Code 39, Code 128, Codabar, and Interleaved 2 of 5.

Target value

The known concentration of a calibrator.

Unidirectional interface

One-way communication. Results are communicated from the instrument to the host computer only.

Unit category

An expression of concentration, such as weight/volume (e.g., mg/dL), mass/volume (e.g., mol/L), and International Units/volume (e.g., IU/mL).

Index

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