Installation, Operation, and Performance Qualification

UniCel DxH Series with System Manager Software

Coulter Cellular Analysis System

CE IVD

PN B75453AC
October 2018

Manufactured by
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

BECKMAN COULTER

UniCel DxH Connectivity Coulter Cellular Analysis System
Installation, Operation, and Performance Qualification
PN B75453AC (October 2018)

Find us on the World Wide Web at:
www.beckmancoulter.com

Symbols Glossary is available at **www.beckmancoulter.com**. See Related Documents for the part number.

Rx Only in the U.S.A.

EC REP

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Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to www.beckmancoulter.com and download the latest version of the manual or system help for your instrument.

Initial Issue AA, 10/2015

Issue AB, 6/2018
The following sections were modified:

- Branding was updated throughout the document
- EC REP address was updated on the UniCel DxH Connectivity Coulter Cellular Analysis System Installation, Operation, and Performance Qualification copyright page

Issue AC, 10/2018
Note: Changes that are part of the most recent revision are indicated by a change bar in the left margin of the page.
The following sections were modified:

- Copyright page
- Added DxH 800/DxH 600 throughout the manual
- Added DxH Slidemaker Stainer - IQ Checklist, DxH Slidemaker Stainer - Software and Documentation Checklist, DxH Slidemaker Stainer - System Components, and DxH Slidemaker Stainer - Interface Installation Checklist to CHAPTER 1, Installation Qualification (IQ)
- Added DxH Slidemaker Stainer - OQ Checklist to CHAPTER 2, Operation Qualification (OQ)
- Added DxH Slidemaker Stainer - PQ Checklist to CHAPTER 3, Performance Qualification (PQ)
- Related Documents

Contents

Introduction

Overview

This document provides a checklist guideline for the management of installation processes for a new hematology system.

The following definitions are excerpted from the Clinical and Laboratory Standards Institute's *QMS18, Process Management* guideline[1]:

Installation qualification (IQ) - a set of formal checks and records that confirms the equipment or process and its components, including any integral hardware or software, were supplied as ordered and properly installed in the laboratory or other environment; NOTE: IQ can be performed by the manufacturer's technical service engineer.

Operational qualification (OQ) - process and records to confirm that the equipment or process is operational for its intended use and operation; NOTE: OQ can be performed by the manufacturer's technical service engineer.

Performance qualification (PQ) - process and records to confirm that the equipment or process will perform to specified needs, producing acceptable results under normal operating conditions; NOTE: PQ must be performed by laboratory staff.

IQ, OQ, and PQ are validation activities.[2]

Facility	
Address/Location	
Instance Number	
Instrument Serial Number	
Laboratory Representative	

CHAPTER 1

Installation Qualification (IQ)

DxH 800/DxH 600 IQ Checklist

Instrument/SN:_____

See next page for approval signatures.

Table 1.1 DxH 800/DxH 600 IQ Checklist

Action	Select One	
	N/A*	✓
An operator is trained or scheduled to be trained within the next two weeks.		
All the cartons on the shipping list have arrived.		
All of the cartons are intact and undamaged. If any cartons are damaged, a claim was filed with the carrier.		
The shipping containers can clear the entrance doorways.		
The instrument area is easily accessible for maintaining and servicing the instrument.		
The space is sufficient for the placement of the floor stand and the System Manager.		
The ventilation fans are not obstructed.		
The female ac outlet for the Specimen Processing Module (SPM) is within 3 m (10 ft) of the area designated for the instrument.		
The main ac outlet is a three-wire outlet supplying 100 to 240 Vac, nominal; 8.0 to 2.8A; 48 to 62 Hz; single-phase power.		
The ground is a confirmed third-wire earth ground that can carry the full current of the circuit.		
The circuit is independent and protected.		
If the waste from the instrument will drain into an open drain instead of a waste container, the drain is chemically resistant and is appropriate for biohazardous waste.		
The drain or waste container is less than 76 cm (30 in.) above the floor and is within 3.7 m (12 ft) of the area designated for the SPM.		
The drain or waste container is located so that the waste drain tubing is always below the waste fitting at the base of the instrument.		
The typical ambient room temperature for this instrument is in agreement with the typical ambient room temperature indicated in the Instructions for Use (IFU).		
The relative humidity (non-condensing) and ambient temperature for this instrument is in agreement with the relative humidity (non-condensing) and ambient temperature indicated in the IFU.		
The peak thermal load for the DxH 800/DxH 600 is: DxH 800/DxH 600 instrument (SPM + PSM only) = 1,775 BTU/HOUR		
The peak thermal load for the DxH 800/DxH 600 is: Standard Computer = 546 BTU/HOUR		

Table 1.1 DxH 800/DxH 600 IQ Checklist *(Continued)*

Action	**Select One**	
	N/A*	✓
The peak thermal load for the DxH 800/DxH 600 is: Power Computer = 632 BTU/HOUR		
The peak thermal load for the DxH 800/DxH 600 is: POWERWARE UPS add additional 2,066 BTU/HOUR		
The peak thermal load for the DxH 800/DxH 600 is: POWERVAR UPS add additional 220 BTU/HOUR		
The instrument reagents, calibrators, and controls are available and within expiration limits.		
The paper supplies and blood collection tubes are available.		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for IQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign):*	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH 800/DxH 600 Software and Documentation Checklist

Instrument/SN:_____

Table 1.2 DxH 800/DxH 600 Software and Documentation Checklist

Action	**Select one**	
	N/A*	✓
All appropriate software, manuals, letters, and installation instructions are available on the Beckman Coulter website. Replacements for missing components have been ordered.		
Required Safety Data Sheet (SDS) documents are available.		

Approvals for Software and Documentation Checklist:

Date:	
Beckman Coulter Representative and Title *(sign):*	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH 800/DxH 600 System Components

Instrument/SN:_____

See next page for approval signatures.

Table 1.3 DxH 800/DxH 600 System Components

Instrument	
Model:	
Serial Number:	
Report Printer	
Model:	
Serial Number:	
IP Address:	
Verify default printer;	
Print test page from printer:	
Computer	
Model:	
Serial Number:	
IP Address (if applicable):	
UPS (optional)	
Model:	
Serial Number:	
Handheld Bar-Code Scanner	
Model:	
Serial Number:	
Ethernet (optional)	
Model:	
Serial Number:	
Router (optional)	
Model:	
Serial Number:	
Software	
Version:	

Approvals for System Components:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH 800/DxH 600 Interface Installation Checklist

Instrument/SN:_____

Table 1.4 DxH 800/DxH 600 Interface Installation Checklist

Action	**Select one**	
	N/A*	✓
Connect the Ethernet cable to the System Manager.		
Power ON the instrument.		
Check that the instrument is communicating with the network.		
Configure the interface device.		
Configure the external device.		
Check that the LAN connection to the system is set up.		
Check that the LAN connection to the LIS system is set up.		
Check the communication between the instrument and the system.		

Approvals for Interface Installation Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - IQ Checklist

Instrument/SN:_____

See next page for approval signatures.

Table 1.5 DxH Slidemaker Stainer - IQ Checklist

Action	**Select One**	
	N/A*	✓
An operator is trained or scheduled to be trained within the next two weeks.		
All the cartons on the shipping list have arrived.		
All of the cartons are intact and undamaged. If any cartons are damaged, a claim was filed with the carrier.		
The shipping containers can clear the entrance doorways.		
The instrument area is easily accessible for maintaining and servicing the instrument.		
The space is sufficient for the placement of the floor stand and the System Manager.		
The ventilation fans are not obstructed.		
The female ac outlet for the Specimen Processing Module (SPM) is within 3 m (10 ft) of the area designated for the instrument.		
The main ac outlet is a three-wire outlet supplying 100 to 240 Vac, nominal; 8.0 to 2.8A; 48 to 62 Hz; single-phase power.		
The ground is a confirmed third-wire earth ground that can carry the full current of the circuit.		
The circuit is independent and protected.		
If the waste from the instrument will drain into an open drain instead of a waste container, the drain is chemically resistant and is appropriate for biohazardous waste.		
The drain or waste container is less than 76 cm (30 in.) above the floor and is within reach of 3.7 m (12 ft) of tubing from the area designated for the SPM.		
The drain or waste container is located so that the waste drain tubing is always below the waste fitting at the base of the instrument.		
The typical ambient room temperature for this instrument is in agreement with the typical ambient room temperature indicated in the Instructions for Use (IFU).		
The relative humidity (non-condensing) and ambient temperature for this instrument is in agreement with the relative humidity (non-condensing) and ambient temperature indicated in the IFU.		
The peak thermal load for the DxH Slidemaker Stainer is: DxH Slidemaker Stainer instrument (SPM) = 878 BTU/HOUR		
The peak thermal load for the DxH Slidemaker Stainer is: Ultra Small Form Factor (USFF) Computer = 666 BTU/HOUR		
The peak thermal load for the DxH Slidemaker Stainer is: Powerful Ultra Form Factor (PUFF) Computer = 666 BTU/HOUR		
The peak thermal load for the DxH Slidemaker Stainer is: POWERVAR UPS add additional 220 BTU/HOUR		
The instrument reagents, calibrators, and controls are available and within expiration limits.		
The paper supplies and blood collection tubes are available.		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for IQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign):*	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - Software and Documentation Checklist

Instrument/SN:_____

Table 1.6 DxH Slidemaker Stainer - Software and Documentation Checklist

Action	**Select one**	
	N/A*	✓
All appropriate software, manuals, letters, and installation instructions are available on the Beckman Coulter website. Replacements for missing components have been ordered.		
Required Safety Data Sheet (SDS) documents are available.		

Approvals for Software and Documentation Checklist:

Date:	
Beckman Coulter Representative and Title *(sign):*	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - System Components

Instrument/SN:_____

See next page for approval signatures.

Table 1.7 DxH Slidemaker Stainer - System Components

Instrument	
Model:	
Serial Number:	
Report Printer	
Model:	
Serial Number:	
IP Address:	
Verify default printer;	
Print test page from printer:	
Computer	
Model:	
Serial Number:	
IP Address (if applicable):	
UPS (optional)	
Model:	
Serial Number:	
Handheld Bar-Code Scanner	
Model:	
Serial Number:	
Ethernet (optional)	
Model:	
Serial Number:	
Router (optional)	
Model:	
Serial Number:	
Software	
Version:	

Approvals for System Components:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - Interface Installation Checklist

Instrument/SN:_____

Table 1.8 DxH Slidemaker Stainer - Interface Installation Checklist

Action	**Select one**	
	N/A*	✓
Connect the Ethernet cable to the System Manager.		
Power ON the instrument.		
Check that the instrument is communicating with the network.		
Configure the interface device.		
Configure the external device.		
Check that the LAN connection to the system is set up.		
Check that the LAN connection to the LIS system is set up.		
Check the communication between the instrument and the system.		

Approvals for Interface Installation Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

CHAPTER 2

Operation Qualification (OQ)

DxH 800/DxH 600 OQ Checklist

Instrument/SN:_____

See next page for approval signatures.

Table 2.1 DxH 800/DxH 600 OQ Checklist

Action	Select one	
	N/A*	✓
Ensure that all the SPM panels and covers are installed.		
Perform a daily checks cycle and verify that the results are acceptable.		
Run the following controls and verify that all the parameters are within acceptable limits:		
• COULTER LATRON CP-X Control		
• COULTER 6C Cell Control (all three levels)		
• COULTER Retic-X Cell Control		
• COULTER Body Fluid Controls		
Retain printouts of the control results. **NOTE** If this is a new installation, retain printouts of the carryover, repeatability, control results, and current calibration factors.		
If this is a system upgrade, verify the instrument's whole-blood performance		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for OQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - OQ Checklist

Instrument/SN:_____

Table 2.2 DxH Slidemaker Stainer - OQ Checklist

Action	**Select one**	
	N/A*	✓
Ensure that all the SPM panels and covers are installed.		
Perform a daily checks cycle and verify that the results are acceptable.		
Run 10 fresh whole-blood samples in the Make and Stain cycle:		
• Verify the smear quality with your Beckman Coulter Representative.		
• Verify the print quality of the bar code on the microscopic slide.		
• Verify the stain quality with your Beckman Coulter Representative.		
If this is a new installation, retain the envelope from the DxH Slidemaker Stainer that contains the software alignments for all modules.		
If this is a system upgrade, your Beckman Coulter Representative will perform a system verification as directed under Section 5.1 in the UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System Service Manual.		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for OQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

CHAPTER 3

Performance Qualification (PQ)

DxH 800/DxH 600 PQ Checklist

Instrument/SN:_____

See next page for approval signatures.

Table 3.1 DxH 800/DxH 600 PQ Checklist

Action	Select one	
	N/A*	✓
Reference: Hematology Performance Verification (HPVM) Manual (4277076)		
Hardware installation data qualified		
Precision qualified		
Accuracy qualified		
Carryover qualified		
Calibration		
DMS/Workstation/System Manager set up		
QC files set up		
IQAP/eIQAP participant # for new instrument set up/enrolled		
Interfacing to LIS (IT/LIS contact) set up		
Patient flagging limits and review criteria set up		
Decision rules set up		
Comparisons performed by laboratory staff:		
• Samples run on new instrument and comparison method completed		
• CBC/DIFF		
• Manual differentials for truth tables		
• Reticulocytes		
• Body fluids		
Comparison data collated and submitted for data analysis		
Measuring range (linearity) qualified		
Reference interval (normal ranges) qualified		
QC lab limits (per lab protocol) established		
Primary instrument verified (comparability) with backup instrument		
Specimen mixing study verified		
Interfacing (trained operator and lab IT contact) tested		

Table 3.1 DxH 800/DxH 600 PQ Checklist *(Continued)*

Action	Select one	
	N/A*	✓
Data analysis reports reviewed with appropriate lab staff		
Pathology/Lab Director sign-off		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for PQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

DxH Slidemaker Stainer - PQ Checklist

Instrument/SN:_____

Table 3.2 DxH Slidemaker Stainer - PQ Checklist

Action	**Select one**	
	N/A*	✓
Slide quality verified		
Smear quality verified		
Stain protocol verified (see the Stain Protocol Optimization appendix available from the System Help)		
DMS/Workstation/System Manager is set up		
Primary stainer protocol verified with backup instrument		
Maintenance procedures and checklist reviewed by laboratory staff		
Staff training/competence checklist with key operator completed		
Review consumable part numbers with key operator		
If CellaVision is present:		
• Performed SmearChecker on SMS stained slides		
• Verified minimal presence of debris/artifact		
• Verified SMS slide label setup properly for CellaVision to read SMS bar codes		

***** Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for PQ Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

CHAPTER 4

Additional Qualifications

Additional Qualifications Checklist

The items included in the Additional Qualifications Checklist may include items that are your laboratory's responsibility. They may be processes/procedures that are not included in the Implementation Guide, but are agreed to by Beckman Coulter and your laboratory for which Beckman Coulter will provide assistance.

Instrument/SN:_____

See next page for approval signatures.

Table 4.1 Additional Qualifications Checklist

Action	Select one	
	N/A*	✓

***** Some items may not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for Additional Qualifications Checklist:

Date:	
Beckman Coulter Representative and Title *(sign)*:	
Beckman Coulter Representative and Title *(print)*:	
Date:	
Laboratory Representative and Title *(sign)*:	
Laboratory Representative and Title *(print)*:	
Comments:	

References

1. QMS18 Process management; 2015. Clinical and Laboratory Standards Institute (CLSI), Wayne, PA.
2. QMS01-A4 Process management; 2011. Clinical and Laboratory Standards Institute (CLSI), Wayne, PA.

Related Documents

Your DxH documentation can be found on our website at www.beckmancoulter.com.

Instructions for Use

PN B26647

- System Overview
- Operation Principles
- Daily Checks
- Quality Control
- Sample Analysis
- Data Review
- Workload
- Shutdown
- Setup
- Troubleshooting
- Quality Assurance
- Cleaning Procedures
- Replacement/Adjustment Procedures
- Appendices
- Abbreviations and Acronyms
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Host Transmission

PN B26711

Hematology Tube List

PN A70017

Symbols Glossary

PN C29230

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