

cobas[®] 6800/8800 Systems

Installation Qualification (IQ)

Version 3.0

Instrument Serial Number: _____

Instrument Type:

- ☐ **cobas[®] 6800**
- ☐ **cobas[®] 6800 movable**
- ☐ **cobas[®] 8800**

Sample Supply Module Serial Number: _____

Instrument Gateway Serial Number: _____

Platform Serial Number (movable only): _____

Instructions to locate serial numbers are described in the iSDoc.



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Preface

Revision History

Version	Revision Date	Revision Information
1.0	10-Jun-2014	This is the first issue of this document
1.1	01-Dec-2014	Chapter 1, Add Software Installation Manual. Over all, change Instrument into Systems
1.2	27-Aug-2015	Chapter 1, Modified the document list. Chapter 1, Changed from “verify” to “record” for recording the relevant document information. Removed Acceptance Criteria and Conclusion accordingly.
1.3	10-Jun-2016	Editorial Changes
2.0	01-Aug-2017	Adaption to divergent DSS SW Versions Removed numbering for consistency reasons Document name changed from <i>Installation Qualification Procedure</i> to <i>Installation Qualification (IQ)</i> Editorial Changes
3.0	See GRIPS	Editorial Changes Removed SSM and System SW Release from section software information

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About this document

This document has to be used to perform an Installation Qualification (IQ) on a **cobas[®] 6800/8800 System**.

The IQ must be performed by trained Roche personnel only.

This Installation Qualification (IQ) document has to be filled out completely and truthfully. Where required it has to be signed by the RSR or by the customer respectively.

All checks performed in the specific product in the DSS Software (IQ cobas 6800, IQ cobas 6800 movable or IQ cobas 8800) have to be completed successfully.

The DSS Software records all results and generates an Installation Qualification Certificate which has to be printed out and added to this document. The DSS Software tests all required specifications and returns a “Passed” or “Failed”.

A “Failed” test has to be followed by the appropriate correction/repair. It has to be documented in the deviation log in the appendix of this document. Additionally, each deviation has to be described in detail in a separate Deviation Report.

Documentation of deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

Abbreviations

S/N	Serial Number
N/A	Not Applicable
DSS	Diagnosis and Service
IC	Instrument Control
ID	Identification
IPC	Industrial Personal Computer
IQ	Installation Qualification
IG	Instrument Gateway Server
IM	Instrument Manager

General Information

Customer Information

Company:

Address:

System location and department:

Contact person:

Roche Representative

Installation Qualification performed by:

Job title:

Company:

Address:

Installation Qualification (IQ)

Document Verification

Objective

Make sure that the latest version of the respective document is used during the installation and the IQ. All documents are available on GRIPS.

Procedure

- Record the document versions of the used documents in the table below.

Results

Document	Document Version
cobas[®] 6800/8800 Instrument Installation Manual	
cobas[®] 6800/8800 IG server set Installation Manual	
cobas[®] 6800/8800 Systems iSDoc	
cobas[®] 6800/8800 Systems Qualification Guideline	
cobas[®] 6800/8800 Systems Qualification Specifications	

Tool Calibration Certificates

Objective

The tools used for the Installation Qualification must be calibrated.

Acceptance Criteria

Valid Calibration Certificates are available for tools that require calibration.

Procedure

- Record the model, serial and calibration ID numbers of the tools in the table below.
- Check the Belt Tension Meter parameters. *Mass M: 100.0g/m; Width W: 100.0mm/R; Span S 0010mm.*
- Record the corresponding calibration dates of the tools in the table below.
- Verify that the acceptance criteria are met.

Results

Tool	Model & Serial Number	Calibration ID	Calibration Dates
Belt tension meter		<input type="checkbox"/> N/A	Last calibration: Valid until:
Thermometer		<input type="checkbox"/> N/A	Last calibration: Valid until:
Humidity meter		<input type="checkbox"/> N/A	Last calibration: Valid until:
Voltage meter		<input type="checkbox"/> N/A	Last calibration: Valid until:

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Technical Specifications Verification

Objective

Verify that the current conditions on site meet the technical specifications according to the instrument configuration.

Acceptance Criteria

The current conditions on site meet the technical specifications according to the Qualification Specifications document.

Procedure

- Record the environmental conditions at the installation site on the date of the installation in the table below.
- Compare the values against the technical specifications in the Qualification Specification document.
- Verify that the acceptance criteria are met.

Material required

- Voltmeter
- Thermometer
- Humidity meter

Installation Qualification (IQ)

Results

Instrument Configuration	Temperature and Humidity	Measured Values (with Unit)
Stand-alone	Environmental Temperature	<input type="checkbox"/> N/A
	Relative Humidity	<input type="checkbox"/> N/A
With IG	Environmental Temperature	<input type="checkbox"/> N/A
	Relative Humidity	<input type="checkbox"/> N/A
With cobas p 680	Environmental Temperature	<input type="checkbox"/> N/A
	Relative Humidity	<input type="checkbox"/> N/A

Line Voltage		Measured Values (with Unit)
Line Voltage cobas[®] 6800/8800 instrument	Phase 1	
	Phase 2	
	Phase 3	
Line Voltage Sample Supply Module	Plug 1 (Main)	
	Plug 2 (UPS)	

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Transport and Installation

Objective

Inspect the instrument shipment, verify the instrument delivery and verify the installation of all principal components.

Acceptance Criteria

The installation steps are successfully completed.

Procedure

- Inspect the delivery as mentioned in the installation manual.
- Check the instrument packing according the installation manual.
- Perform the installations according to the installation manuals.
- Verify that the acceptance criteria are met.

Results

Installation Step	Performed
Inspect the cobas[®] 6800/8800 instrument shipment for any damages.	<input type="checkbox"/> Done
Check the content of the cobas[®] 6800/8800 instrument shipment against the packing list in the Installation Manual.	<input type="checkbox"/> Done
The cobas[®] 6800 / 8800 instrument and its auxiliary components were installed as specified in the corresponding installation manual.	<input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Software Information

Objective

Record the Service Software (DSS) version.

Procedure

- Record the version of the used Service Software (DSS) below.

Results

Component	Version
DSS Software	

DSS IQ checks for cobas[®] 6800/8800

The DSS checks are specified in the Qualification Specifications document. The checks can differ substantially between the released DSS SW versions.

The DSS SW guides the RSR through the checks.

For a detailed description consult the according section in iSDoc.

Objective

The IQ checks in the DSS verify the functionality, accuracy and precision of the installed instrument.

Acceptance criteria

All IQ checks have to be passed according to the detailed Acceptance Criteria in the cobas[®] 6800/8800 Systems Qualification Specifications document.

Procedure

Perform all checks in the respective IQ product of the DSS SW.

Material required

- Belt tension meter

Results

DSS Product	Performed
cobas 6800 IQ	<input type="checkbox"/> N/A <input type="checkbox"/> Done
cobas 6800 movable IQ	<input type="checkbox"/> N/A <input type="checkbox"/> Done
cobas 8800 IQ	<input type="checkbox"/> N/A <input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature:

Date:

Certificates

Objective

Add the Installation Qualification Certificate to this document.

Acceptance Criteria

The Installation Qualification Certificate is attached to the IQ documentation.

Procedure

- Generate a Certificate on the DSS SW.
- Follow the instruction in iSDoc how to get the DSS Certificate.
- Print and attach the Installation Qualification Certificate to this document.
- Verify that the acceptance criteria are met.

Results

Test	Performed
Print and attach the Installation Qualification Certificate	<input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

[illegible]

Installation Qualification (IQ)**Conclusion****Conclusion A:**

All Acceptance Criteria have been met. The Installation Qualification of the respective equipment was performed successfully	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If No → continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Installation Qualification of the respective equipment was performed successfully.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
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Comments:

<hr/> <hr/> <hr/>

Authorized Roche Representative:

Signature: _____	Date: _____
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Reviewed and acknowledged by the customer: (2 signatures required)	_____
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Signature: _____	Date: _____
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Signature: _____	Date: _____
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Deviation Log

Record all deviations noticed during the Installation Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Performed by Roche representative:

Signature:

Date:

Reviewed and approved by customer:

Signature:

Date: