

cobas[®] 6800/8800 Systems Software 1.3

Software Qualification (SWQ)

Version 3.0

Serial Numbers

IG server set: _____

cobas[®] 6800/8800: _____

Sample Supply Module: _____

Movable Platform: _____

cobas p 680: _____

Instructions on where to locate serial numbers are described in the iSDoc.



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Preface

Revision History

Version	Revision Date	Revision Information
1.0	01-Aug-2017	This is the first issue of this document
2.0	31-Sep-2018	- Added component User Assistance - Cover upgrade method SW 1.3.8
3.0	See GRIPS	Pool Communication Test Run and Check Run removed upon impact assessment DH-03406.12-047

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About this Document

This document has to be used to perform a Software Qualification on the **cobas[®] 6800/8800** and **cobas p 680** Systems Software 1.3. This document does not replace the respective instrument IQ/OQ procedure.

The Software Qualification must be performed by Roche personnel only.

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

DSS	Diagnostic and Service Software
IC	Instrument Control
ID	Identification
IG	Instrument Gateway
IM	Instrument Management
IPC	Industrial Personal Computer
IQ	Installation Qualification
N/A	Not Applicable
OQ	Operational Qualification
PIM	Pooling Instrument Management
SSM	Sample Supply Module
S/N	Serial Number
EULA	End-user license agreement



General Information

Customer Information

Company: _____

Address: _____

System location and department: _____

Contact person: _____

Roche Representative

Software Qualification performed by: _____

Job title: _____

Company: _____

Address: _____

Software Qualification (SWQ)

Document Verification

Objective

Record the versions of all documents listed below available on GRIPS during the Software Qualification.

Procedure

Record the version of the documents available on GRIPS listed in the table below.

Results

Document	Software Version	Document Version
cobas[®] 6800/8800 Software Installation Manual		
cobas[®] 6800/8800 User Access Information		
cobas[®] 6800/8800 Systems User Guide		
cobas[®] 6800/8800 Systems iSDoc	N/A	
cobas[®] 6800/8800 Qualification Guidelines	N/A	

Media Information

Objective

Record the versions of all software components to be installed in the list below.
 Note that the CHK ASAP is required for the Check Run and for the Pool Communication Test Run.

Procedure

- Record the version of the listed software components

Results

Component	SW Version
System Software Release	
FSR Tools Disc	
Maintenance Package (MP)	
Language Package (LP)	
CHK ASAP	

Component	Publication Version
User Assistance *	

* The integrated User Assistance **cannot** be installed with SW versions **1.3.8** or below.
 Only the User Assistance marked with “integrated” can be installed on **cobas[®] 6800/8800** Instruments.
 E.g. “cobas[®] 6800/8800 Systems User Assistance SW 1.3 (**integrated**) – English”.

The publication version will be displayed on GRIPS in the version field. Alternatively, the version can be found in the About section of the User Assistance.

SW Installation Method

Objective

Depending on the initial situation of the systems in the cluster the SW installation varies substantially. Record the installation method.

Procedure

Tick the SW installation method accordingly in the table below.

Result

SW Installation Method	
Software Installation (refers to a new installation)	<input type="checkbox"/>
Software Upgrade (from 01.01.xx)	<input type="checkbox"/>
Software Upgrade (from 01.02.xx)	<input type="checkbox"/>
Software Upgrade (from 01.03.xx)	<input type="checkbox"/>

Software Installation Steps Check

Objective

Verify that the installation steps are performed on all instruments in the cluster according to the appropriate SW installation method described in the Software Installation Manual.

Acceptance Criteria

All installation steps are performed according to the Software Installation Manual. The designated checkboxes in the Software Installation Manual are ticked.

Procedure

- Confirm the steps during the software installation/upgrade in the manual
- Verify that the acceptance criteria are met.

Results

Component	Performed
All installation steps are performed and confirmed in the SW Installation Manual.	<input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: No

Signature: _____ Date: _____

Sample Supply Module

Objective

Verify the installed SSM SW version(s) on the sample supply module(s) in the cluster. Perform the time synchronization and verify the sample supply module(s) in the cluster is within specification.

Attention

In case a full instrument IQOQ is planned or SSM SW version 003.0006.0112 is already installed select N/A accordingly.

Acceptance Criteria

The sample supply module time must be synchronized. In case of an SSM SW installation all module checks must pass successfully.

Procedure

- Perform the time synchronization of the sample supply module according to the procedure in iSDoc.
- Perform the sample supply module checks according to the procedure in iSDoc.
- Verify that the acceptance criteria are met.

Material Required

- Calibration rack
- 1 MPA Rack 13mm navy blue 6201-6250
- 1 **cobas omni** secondary tube 13x75

Results

Component	Performed
Check installed SSM SW version (003.0006.0112 or higher)	<input type="checkbox"/> Done
Sample supply module time synchronization In case an instrument OQ is planned select N/A	<input type="checkbox"/> N/A <input type="checkbox"/> Done
Sample supply module checks In case an instrument OQ is planned select N/A In case SSM SW version 003.0006.0112 (or higher) was already installed select N/A	<input type="checkbox"/> N/A <input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: No

Signature: _____ Date: _____

cobas® 6800/8800 Systems Software 1.3
Software Qualification (SWQ)

Conclusion

Conclusion A:

All Acceptance Criteria have been met. The Software 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 Software 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/>

Performed by Roche representative: _____

Signature: _____ Date: _____

Deviation Log

Record all deviations noticed during the Software 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:
