

Installation Qualification Procedure

cobas p 680

Version 3.0

Instrument Serial Number: _____



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Preface

Revision History

Version	Revision Date	Revision Information
0.1	30-Jan-2014	1. This is the first pre-launch issue of this document.
1.0	07-May-2014	1. This is the first launch version of this document. 2. Section 3 Changed "Calibration Weight 20g" to "Calibration Weight". 3. IOQ changed to mandatory upon installation or move. 4. Power line range corrected to: 100 VAC (-15%) to 5. 240 VAC (+10%) 85 VAC to 264 VAC. 6. Added in section 6 writing and comparing firmware versions from instrument configuration and iSDocs.
2.0	06-Jan-2015	1. Corrected general terminology. 2. Section 5: Installation Steps and Checks, step 2 and 3 combined in one step. 3. Sections 6 Software Components Check, Screenshot for version information removed.
3.0	25-Aug-2015	1. Section 2, Changed from "verify" to "record" for recording the relevant document information. Removed Acceptance Criteria and Conclusion accordingly.

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cobas p 680

Installation Qualification Procedure

About this Document

This document is to be used to perform an Installation Qualification on a **cobas p 680**, operated with **cobas p 680** software on a Pooling Instrument Manager.

The IQ and OQ procedure must be performed by a certified Roche Field Service Engineer / Field Service Representative (FSR) only.

The FSR must have attended **cobas p 680** service training.

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

GRIPS	Global Repository of Information about Products and Services
ID	Identification
iSDoc	Integrated Systems Documentation
IQ	Installation Qualification
IVD	In vitro diagnostics
LAN	Local Area Network
N/A	Not Applicable
PIM	Pooling Instrument Manager (Control Unit)
OQ	Operational Qualification
S/N	Serial Number
STAR	Sequential Transfer and Aliquoting Robot
USB	Universal Serial Bus
VAC	Voltage Alternative Current

General Information

Customer Information

Company: _____

Address: _____

System location and department: _____

Contact person: _____

Roche Representative

Installation Qualification performed by: _____

Job title: _____

Company: _____

Address: _____

Installation Qualification Procedure

1 Principal Components Check

Objective

Record the components listed below available during the installation.

Procedure

- Record the required information of the components in the table below

Results

Component	Model, Version or S/N
Hardware components	
cobas p 680	S/N
PIM (Control Unit)	Model: S/N:
Software components	
cobas p 680 OS Win7 Recovery	Version:
cobas p 680 SW Installation Disc	Version:
Microlab® STAR Service SW	Version:
Microlab® STAR Maintenance & Verification SW	Version:

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2 Document Verification

Objective

Record the versions of all documents available on GRIPS listed in the table below during the Installation Qualification

Procedure

- Record the available versions of the listed documents in the table below.

Results

Document	Version (according to GRIPS)
cobas® 6800/8800 SW Installation Manual	Version:
cobas p 680 IQ OQ Guidelines	Version:
cobas p 680 iSDoc	Version:
cobas p 680 Operator's Manual	Version:

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3 Tool Calibration Certificates

Objective

The tools used for the Installation Qualification must be calibrated according to manufacturers' instructions

Acceptance Criteria

The valid calibration certificates for the tools are available.

Procedure

- Record the valid calibration ID of the tool calibration certificates in the table below
- Record the corresponding calibration date of the tools in the table below
- Make copies of the calibration certificates and attach them to this document.

Results

Calibration Tool	Calibration ID	Availability Cal. Certificate		Calibration Dates
Balance		<input type="checkbox"/> Yes	<input type="checkbox"/> No	Last Calibration Valid through:
Calibration Weight (Balance)		<input type="checkbox"/> Yes	<input type="checkbox"/> No	Last Calibration Valid through:
Temp./Hum. Measuring Dev.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	Last Calibration Valid through:
Wrench Torque 1/4 Inch		<input type="checkbox"/> Yes	<input type="checkbox"/> No	Last Calibration Valid through:
Pressure Transmitter WIKA D-10-P		<input type="checkbox"/> Yes	<input type="checkbox"/> No	Last Calibration Valid through:

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature: _____ Date: _____

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4 Technical Specifications Verification

Objective

Verify that the current conditions on site meet the **cobas p 680** specifications

Acceptance Criteria

The current conditions on site meet the technical specifications of the **cobas p 680** instrument

Procedure

- Record the location of the **cobas p 680** installation in the space below
- Verify that the Acceptance Criteria are met

Location:	Building/floor:	Room number:
-----------	-----------------	--------------

Results

Condition	Specification	Measured Values (with Unit)
Environmental Temperature	15°C to 30°C (59 - 86°F) (operating conditions)	
Relative Humidity	30% to 80% (25% to 80%; 18.2°C to 30°C) (20% to 80%; 21.7°C to 30°C) (no condensation)	
Power Line Voltage	100 VAC (-15%) or 240 VAC (+10%) 85 VAC to 264 VAC	
Line Frequency	50 / 60 Hz +/- 5%	

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature: _____ Date: _____

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Installation Qualification Procedure

5 Installation Steps and Checks

Objective

Verify the installation of the **cobas p** 680 components

Acceptance Criteria

The **cobas p** 680 instrument installation is completed without any deviation or non-conformance

Procedure

- Perform the installation of all **cobas p** 680 instrument components according to the procedure described in iSDoc and the Installation Manual listed in section 2 "Document Verification"
- Verify that the Acceptance Criteria are met

Results

Installation Step	Performed
1. Check the content of the cobas p 680 shipment against the packing list	<input type="checkbox"/> Done
2. The cobas p 680 components were inspected and installed as specified in the corresponding iSDoc	<input type="checkbox"/> Done
3. The software components were installed as specified in the cobas® 6800/8800 SW Installation Manual	<input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature: _____ Date: _____

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Installation Qualification Procedure

6 Software Components Check

Objective

To verify the installed software

Acceptance Criteria

The correct versions of the **cobas p 680** software components are installed

Procedure

- Verify that all software components of the **cobas p 680** are installed according to the **cobas® 6800/8800 SW Installation Manual** and **cobas p 680 iSDoc**.
- Power up the system and record the required information in the table below.
- Make a printout of the Microlab® STAR Service SW instrument data and attach it to this document (Settings>Inst. Configuration>Read instrument data>print).
- Enter the **cobas p 680** firmware versions in the table below (listed in the instrument data printout).
- Enter the **cobas p 680** firmware versions in the table below (listed in iSDocs).
- Compare both versions.
- Verify that the Acceptance Criteria are met.

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Results

Component	Version / Configuration / Name / ID	
PIM UI Software	Version:	
Microlab® STAR Service SW	Version:	
Microlab® STAR Maintenance & Verification SW	Version:	
cobas p 680 Firmware for <ul style="list-style-type: none"> Master Autoload Pipetting channel X-Drive RD5 Loading Unit RD5 Process Unit 	Listed in the instrument configuration: Master Version: Autoload Version: Pipetting channel Version: X-Drive Version: RD5 Loading Unit Version: RD5 Process Unit Version:	listed in the iSDocs: Master Version: Autoload Version: Pipetting channel Version: X-Drive Version: RD5 Loading Unit Version: RD5 Process Unit Version

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature: _____ Date: _____

cobas p 680

Installation Qualification Procedure

7 Initialization Check

Objective

Verify the basic functionality of the installed **cobas p 680** instrument.

Acceptance Criteria

No error message occurs during initialization and the **cobas p 680** instrument goes into standby mode.

Procedure

- Power up the **cobas p 680** instrument and check the status after the initialization.
- Verify that the Acceptance Criteria are met.

Results

Test	Performed
1. Power up the system (cobas p 680 , PIM). No error message or failure has occurred.	<input type="checkbox"/> Done
2. Run the weekly Maintenance under "Maintenance and Verification". Weekly Maintenance passes successfully.	<input type="checkbox"/> Done
3. Shut down the system (cobas p 680 , PIM) and power it up again. No error message or failure has occurred.	<input type="checkbox"/> Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No: ☐

Signature: _____

Date: _____

8 Notes

[illegible]

Signature:

Date:

9 Conclusion

Conclusion A:

All Acceptance Criteria have been met. The Installation Qualification of the respective equipment was performed successfully

☐ Yes☐ 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.

☐ Yes☐ No

Comments:

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

Authorized Roche Representative:

Signature: _____

Date: _____

Reviewed and acknowledged by the customer:
(2 signatures required)

Signature: _____

Date: _____

Signature: _____

Date: _____

Appendix

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:
