Qualification Specifications

cobas p 680

Version 3.0

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Preface

Revision History

Version	Revision Date	Revision Information
1.0	07-May-2014	This is the first issue of this document
2.0	06-Jan-2015	1. General, corrected terminology and misspelling 2. Section OQ 3, Added TOOL WEIGHING ONBOARD SYSTEM 3. Section OQ 4, Macro – Check Arm X Diff range correction from 5 to 10.
3.0	27-Aug-2015	4. Change in criteria for Macros in OQ 4, OQ 5, OQ 6 and OQ 7 from “pass without errors” to “pass”.

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About this Document

This document summarizes the acceptance criteria for the **cobas p** 680 Installation Qualification and Operational Qualification procedures.

The document is organized to correspond to the Installation Qualification (IQ) and Operational Qualification (OQ) section numbers and names.

Scope

These specifications are only valid for the **cobas p** 680 Installation Qualification and Operational Qualification.

Abbreviations

AC	Alternating current
°C	Degree centigrade/Celsius
cLLD	Capacitive Liquid Level Detection
g	Gramm
GRIPS	Global Repository of Information about Products and Services
Hz	Hertz
IQ	Installation Qualification
iSDoc	integrated Service Documentation
IVD	In vitro diagnostics
ML	Microlab
OQ	Operational Qualification
PIP	Pipetting channel
PIM	Pooling Instrument Manager
Pa	Pascal
ppt	Parts per Thousand
STAR	Sequential Transfer and Aliquoting Robot
s	Second
µl	Micro liter
V	Volt

References

The following documents and tools are available from GRIPS and are the source of the related specifications:

Document / Tool	Version	Related Procedures
cobas® 6800/8800 SW Installation Manual	Current version available on GRIIPS	Installation Pooling Instrument Manager
cobas p 680 IQ OQ Guidelines	Current version available on GRIPS	IQ/OQ
cobas p 680 iSDoc	Current version available on GRIPS	Hardware Installation Procedure
Microlab® STAR Service Software	Version 4.8.0.618	IQ and OQ

IQ Specifications

IQ 4: Technical Specifications Verification

Item	Specification
Room Temperature	15°C - 30°C (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)
Line Voltage	100 VAC (-15%) to 240 VAC (+10%) 85 VAC to 264 VAC
Line Frequency	50 / 60 Hz $^{+}$/- 5%

OQ Specifications

OQ 3: Calibration Tool Certificates

The service tools for the **cobas p** 680 have to be calibrated in a given frequency to ensure proper adjustments. The frequency varies for the different tools between one and two years. The list below shows how often the calibration has to be performed and where this can be done.

Tool	Frequency	
Mettler Toledo Balance Included in VFV Balance &Accessories Box Material number: 05527350001 for Type WXS 04640560001 for Type SAG (110V) 04640578001 for Type SAG (230V) 05411025001 for TOOL WEIGHING ONBOARD SYSTEM	yearly	Contact the local Mettler Toledo Affiliate to schedule the calibration
Mettler Toledo Weight Included in VFV Balance &Accessories Box Material number: 05527350001	Every two years	Contact the local Mettler Toledo Affiliate to schedule the calibration
TESTO Temperature/Humidity meter Included in VFV Balance &Accessories Box Material number: 05527350001	yearly	Contact the local TESTO Affiliate to schedule the calibration
Wrench Torque ¼” Material number: 04635892001	yearly	Calibrate locally
WIKA Pressure transmitter Material number: 04636228001	yearly	Follow the repair process from Mannheim to calibrate this tool

OQ 4: Instrument check procedure

Test	Test Detail	Passed Criteria
Macro – Adjust Arm Z using PIP	Checks the X-arm against parallel alignment to the deck surface	Pass and correction value must be within +/- 5 counts
Macro – Check Arm X Diff	Checks the parallelism of the X-arm to the Y-axis	Pass and correction value must be within +/- 10 counts
Macro – Adjust PIP manual	Checks the adjustment in pivoting around the X-/Y-axis and shifting along the X-axis	Pass and values must be within: Tilt in Y: +/- 20 counts Tilt in X: +/- 20 counts Deviation: +/- 20 counts
Macro – Adjust PIP	Automatic adjustment of the Y-/Z-position of the channels, calculation of the X-mean for all channels and sets the pressure sensor to ambient.	Pass
Macro – Check PIP	Checks the correct position of the channels and confirms the macro “Adjust PIP”	Pass and values must be within: Deviation X: +/- 20 counts Deviation Y: +/- 20 counts Deviation Z: +/- 30 counts
Macro – Check PIP Tightness	Checks the tightness of the heads against over and under pressure.	Pass and all channels “OK”, Tolerance 400 Pa
Macro – Adjust PIP Pressure	Adjusts the pressure sensor on all pipetting heads against an external device	Pass
Macro – Check PIP Pressure	Checks the pressure sensor on all pipetting heads against an external device	Pass and value must be within: +/- 20ppt
Macro – Adjust Autoload	This procedure ensures all parts of the Autoload are correctly adjusted	Pass
Macro – Check Autoload	Checks if all used carriers can be loaded	Pass All carriers must be back on

		loading trays
Macro – Adjust RD5 Handler	Adjusts the Movable deck and all related components	Pass
Macro – Check RD5 Handler	Checks the Movable deck and all related components	Pass

OQ 5: Instrument Verification

Test	Test Detail	Passed Criterion
Weekly Maintenance	Weekly check of tightness (over and under pressure) and cLLD of all pipetting channels/heads	Pass
Channel Position Verification	Check of all channels for X- ,Y-, Z- position deviation	Pass
Barcode Verification	Check of barcode scanner alignment	Pass
Cover Safety Verification	Check of correct supervision of the covers	Pass
Volume Verification	· Check of the external calibration weight · 1000µl accuracy of all pipetting channel/heads · 1000µl precision of all pipetting channel/heads · 50µl accuracy of all pipetting channel/heads · 50µl precision of all pipetting channel/heads	· 20g +/- 0.00034g · +/- 5% · ≤ 1.5% · +/- 5% · ≤ 2.5%

OQ 6: Handheld barcode reader

Test	Test Detail	Passed Criterion
Handheld barcode reader	Handheld reader scans tube, rack and barcode.	Pass

OQ 7: Pool Communication Test Run

Test	Test Detail	Passed Criterion
Pool Communication Test Run	Data communication with Instrument Gateway	Pass