cobas® 6800/8800 Systems

Qualification Specifications

Version 4.0

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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	Spelling corrections Changed “instrument” into “Systems”
1.2	27-Aug-2015	Added the Software Qualification Procedure to the reference Added SWQ Specifications section
2.0	18-Aug-2016	SWQ Specifications are differentiated by their related SWQ documents for SW 1.1 and 1.2 Editorial changes
3.0	01-Aug-2017	Added DSS SW version specific sections. Removed numbering for consistency reasons. Removed document versions under *References*. Combined Module Connection Checks. Reduced set of OQ Checks with DSS SW 1.3.
4.0	See GRIPS	Added SWQ Specifications for for SW 1.4 Removed SWQ Specifications for SW 1.1 Removed Check Run and Pool Communication Test Run from SWQ Specifications for SW 1.3 (Impact Assessment DH-03406.12-047) IQ and OQ Specifications for SW 1.1 removed.

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About this Document

This document summarizes the acceptance criteria and specifications for the **cobas**® 6800/8800 Systems Installation Qualification (IQ), Operational Qualification (OQ) and Software Qualification (SWQ) for all supported software versions.

Complementary Information can be found in the IQ- and OQ-Certificate PDF files generated by the DSS Software.

Scope

These specifications are only valid for the **cobas**® 6800/8800 Installation Qualification and Operational Qualification.

Abbreviations

GRIPS	Global Repository of Information about Products and Services
iSDoc	integrated Service Documentation
SWQ	Software Qualification
IQ	Installation Qualification
OQ	Operational Qualification
Inacc.	Inaccuracy
Impr.	Imprecision
IG	Instrument Gateway Server
IC	Instrument Control
IM	Instrument Manager

References

The following documents are available on GRIPS and refer to the related specifications:

Document
cobas® 6800/8800 Systems - Installation Qualification (IQ)
cobas® 6800/8800 Systems - Operational Qualification (OQ)
cobas® 6800/8800 Systems Software 1.2 - Software Qualification (SWQ)
cobas® 6800/8800 Systems Software 1.3 - Software Qualification (SWQ)
cobas® 6800/8800 Systems Software 1.4 - Software Qualification (SWQ)

IQ Specifications DSS SW 1.2

IQ Technical Specifications Verification

Instrument Configuration	Conditions	Specifications
Stand-alone	Environmental Temperature	15°C – 32°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 32°C) (20% - 80%; 21.7°C – 32°C) (no condensation)
With IG	Environmental Temperature	15°C – 28°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 28°C) (20% - 80%; 21.7°C – 28°C) (no condensation)
With **cobas p** 680	Environmental Temperature	15°C – 30°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 30°C) (20% - 80%; 21.7°C – 30°C) (no condensation)
Line Voltage **cobas**® 6800/8800 instrument	Phase 1	180VAC – 264VAC
	Phase 2	
	Phase 3	
Line Voltage Sample Supply Module	Plug 1 (Main)	180VAC – 264VAC
	Plug 2 (UPS)	

IQ: Movable Check

Test	Test Detail	Specification
Set the IC configuration ID	Movable instrument configuration is set	Pass
Movable Platform	Movable functionalities working correctly	Pass

IQ: Instrument Belt Check

Module	Unit	Belt	Specification
Transfer Module	Transfer Module Handler	X-Belt	32.0 – 36.0 Hz
		Y-Belt (left/right)	27.5 – 30.5 Hz
	Sample Transfer	Y-Belt (left/right)	30.0 – 33.0 Hz
	Rack Handler	X-Belt	65.5 – 75.5 Hz
		Y-Belt	30.0 – 34.0 Hz
		IN-Belt	37.0 – 45.0 Hz
Processing Module	Processing Module Handler	X-Belt (front/rear)	37.5 – 42.5 Hz
		Y-Belt	20.5 – 23.5 Hz
	Processing Transfer Unit	X-Belt	33.0 – 37.0 Hz
	Reagent Transfer Unit	Y-Belt	20.0 – 23.0 Hz
	Solid Waste Station	Y-Belt	50.5 – 57.0 Hz
Consumable Loading Area (**cobas**® 6800)	Main Handler	X-Belt	22.5 – 25.5 Hz
Consumable Loading Area (**cobas**® 8800)	Main Handler	X-Belt	13.0 – 15.0 Hz

Analytic Module (**cobas**® 6800)	Amplification Plate Handler	X-Belt	54.0 – 66.0 Hz
		Y-Belt	40.0 – 50.0 Hz
		Z-Belt	18.0 – 22.0 Hz
Analytic Module (**cobas**® 8800)	Amplification Plate Handler	X-Belt	20.0 – 24.0 Hz
		Y-Belt	40.0 – 50.0 Hz
		Z-Belt	18.0 – 22.0 Hz

IQ :Module Connection Checks

Test	Test Detail	Specification
Transfer module connection check	All transfer module units reacting and communicating	Pass
Processing module A connection check	All processing module A units reacting and communicating	Pass
Processing module B connection check (**cobas**® 8800)	All processing module B units reacting and communicating	Pass
Analytic module connection check	All analytic module units reacting and communicating	Pass
Consumable loading Area connection check	All consumable loading area units reacting and communicating	Pass

IQ Specifications DSS SW 1.3 and 1.4

IQ Technical Specifications Verification

Instrument Configuration	Conditions	Specifications
Stand-alone	Environmental Temperature	15°C – 32°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 32°C) (20% - 80%; 21.7°C – 32°C) (no condensation)
With IG	Environmental Temperature	15°C – 28°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 28°C) (20% - 80%; 21.7°C – 28°C) (no condensation)
With **cobas p** 680	Environmental Temperature	15°C – 30°C
	Relative Humidity	30% - 80% (25% - 80%; 18.2°C – 30°C) (20% - 80%; 21.7°C – 30°C) (no condensation)
Line Voltage **cobas**® 6800/8800 instrument	Phase 1	180VAC – 264VAC
	Phase 2	
	Phase 3	
Line Voltage Sample Supply Module	Plug 1 (Main)	180VAC – 264VAC
	Plug 2 (UPS)	

IQ Movable Check

Test	Test Detail	Specification
Set the IC configuration ID	Movable instrument configuration is set	Pass
Movable platform	Movable functionalities working correctly	Pass

IQ Instrument Belt Check

Module	Unit	Belt	Specification
Transfer Module	Transfer Module Handler	X-Belt	32.0 – 36.0 Hz
		Y-Belt (left/right)	27.0 – 31.0 Hz
	Sample Transfer	Y-Belt (left/right)	30.0 – 33.0 Hz
Processing Module	Processing Module Handler	X-Belt (front/rear)	37.0 – 43.0 Hz
		Y-Belt	21.0 – 23. Hz
	Reagent Transfer Unit	Y-Belt	20.0 – 23.0 Hz
Consumable Loading Area (**cobas**® 6800)	Main Handler	X-Belt	22.0 – 26.0 Hz
Consumable Loading Area (**cobas**® 8800)	Main Handler	X-Belt	12.0 – 16.0 Hz
Analytic Module (**cobas**® 6800)	Amplification Plate Handler	X-Belt	54.0 – 66.0 Hz
		Y-Belt	40.0 – 50.0 Hz
		Z-Belt	18.0 – 22.0 Hz
Analytic Module (**cobas**® 8800)	Amplification Plate Handler	X-Belt	20.0 – 24.0 Hz
		Y-Belt	40.0 – 50.0 Hz
		Z-Belt	18.0 – 22.0 Hz

IQ Module Connection Check

Test	Test Detail	Specification
Module Connection Check	The communication to all modules is verified	Pass

OQ Specifications DSS SW 1.2

OQ Transfer Module

OQ Infrastructure

Test	Test Detail	Specification
Fan speed	Ventilation fan transfer module	>=2000
Service light	Service light rotating	Pass
Module light	All light colors are visible.	Pass
Global indicator	All light colors are visible.	Pass
Airflow screen	Can move down and up	Pass
Fuses	All fuses are good	Pass
Temperature sensor	Temperature changed	Pass

OQ Teaching and Calibration

Test	Test Detail	Specification
Transfer module handler teach	Teach the transfer module handler	Pass
Rack handler teach	Teach the rack handler	Pass
Sample pipetters teach	Teach the sample pipetters	Pass
Rack handler calibration	Calibrate the rack handler camera	Pass

OQ Rack handler

Test	Test Detail	Specification
Rack handler check	All racks are read and moved	Pass

OQ Sample transfer head

Test	Test Detail	Specification
Sample transfer head tightness check	Sample transfer head has no leaks	Pass

OQ Processing Module A/B

OQ Infrastructure

Test	Test Detail	Specification
Fan speed	Ventilation fan processing module	>=2000
Service light	Service light rotating	Pass
Module light	All light colors are visible.	Pass
Global indicator	All light colors are visible.	Pass
Airflow screen	Can move down and up	Pass
Fuses	All fuses are good	Pass
Temperature sensor	Temperature changed	Pass

OQ Processing Module Fluidics

Test	Test Detail	Specification
Extended prime	Prime without error and leaks	Pass without any leaks

OQ Teachings

Test	Test Detail	Specification
Processing module handler teach	Teach processing module handler	Pass
Reagent transfer head teach	Teach reagent transfer head	Pass
Processing transfer head teach	Teach processing transfer head	Pass
Interim reagent storage	Teach interim reagent storage	Pass

OQ Processing module heads

Test	Test Detail	Specification
Reagent transfer tightness check	Perform tightness check	Pass
Processing transfer 1/2 tightness check	Perform tightness check	Pass
Reagent head balance calibration	The OWS is calibrated with a 10g weight	Calibration is OK
Reagent head pipetting check (Reagent head pipetting A-H)	Initial pipetting 800µl	Inacc: <3%
	Pipetting 50µl (high volume)	Inacc: <3.8% Impr: <1.25%
	Pipetting 10µl (low volume)	Inacc: <7.5% Impr: <3.75%

OQ Analytic Module

OQ Teaching

Test	Test Detail	Specification
Amplification plate handler teach	Teach the plate handler	Pass

OQ Handling Checks

Test	Test Detail	Specification
Analytic module handling check	Move the amplification plate to the different position in the analytic module	Pass

OQ Analytic Unit A1/A2/B1/B2

Test	Test Detail	Specification
Analytic unit ramp check	Check the cycler block functionality	Pass
Analytic unit functional check	Channels imprecision	<0.5%
	Channels inhomogeneity	<35%
	Min Excitation power channel 1	>=5170
	Max Excitation power channel 1	<=35159
	Min Excitation power channel 2	>=1650
	Max Excitation power channel 2	<=5552
	Min Excitation power channel 3	>=5830
	Max Excitation power channel 3	<=18426
	Min Excitation power channel 4	>=11770
	Max Excitation power channel 4	<=35637
	Min Excitation power channel 5	>=1980
	Max Excitation power channel 5	<=5866

OQ Consumable Loading Area

OQ Handling Checks

Test	Test Detail	Specification
Reagent drawer adjustment	Drawer adjustment	Pass
Reagent storage check	Checks the reagent and control cassette handling in the reagent storage	Pass

OQ Teaching

Test	Test Detail	Specification
Calibrate main handler	Calibrates the main handler	Pass
Consumable loading area teach	Teach the consumable area on all positions	Pass

OQ Handling

Test	Test Detail	Specification
Main handler handling check	Handling of the different consumables through the instrument	Pass

OQ Instrument

OQ Safety interlock

Test	Test Detail	Specification
Safety interlock check	All interlock unit are functioning correctly	Pass

OQ Handheld barcode reader

Test	Test Detail	Specification
Handheld barcode reader	Read tube and rack barcode	The information read corresponds to the tube and rack barcode

OQ Sample Supply Module

Test	Test Detail	Specification
Sample supply module time synchronization	Synchronize the sample supply module	Time of the sample supply module corresponds to the IM.
Sample supply module check	Check all sensor and mechanical checks	Pass

OQ Check Run

Test	Test Detail	Specification
Check Run	System mechanical, electrical, and communication test.	Run completed without error messages, batch, control, and final sample results communicated throughout the system.

OQ Specifications DSS SW 1.3 and 1.4

OQ Processing module A/B extended prime

Test	Test Detail	Specification
Processing module A/B extended prime	Prime without error and leaks	Pass without any leaks

OQ Reagent Drawer Adjustment

Test	Test Detail	Specification
Reagent Drawer Adjustment	Drawer adjustment	Pass

OQ Instrument Teach

Test	Test Detail	Specification
Instrument Teach	Teaches all reference points in all modules	Pass

OQ Instrument Tightness check

Test	Test Detail	Specification
Instrument Tightness check	Checks the tightness of the Sample transfer, the Processing transfer Reagent transfer	Pass

OQ Rack handler calibration

Test	Test Detail	Specification
Rack handler calibration	Calibrates the rack handler camera	Pass

OQ Reagent transfer A/B pipetting checks

Test	Test Detail	Specification
Reagent head pipetting intro	OWS is positioned	Pass
Reagent head balance calibration	The OWS is calibrated with a 10g weight	Pass
Reagent head A/B pipetting checks (Reagent head pipetting A-H)	Initial pipetting 800µl	Inacc: <3%
	Pipetting 50µl (high volume)	Inacc: <3.8% Impr: <1.25%
	Pipetting 10µl (low volume)	Inacc: <7.5% Impr: <3.75%

OQ Analytic unit A1/A2/B1/B2 ramp check

Test	Test Detail	Specification
Analytic unit ramp check	Check the cycler block functionality	Pass

OQ Analytic unit A1/A2/B1/B2 functional check

Test	Test Detail	Specification
Analytic unit functional check	Channels imprecision	<0.5%
	Channels inhomogeneity	<35%
	Min Excitation power channel 1	>=5170
	Max Excitation power channel 1	<=35159
	Min Excitation power channel 2	>=1650
	Max Excitation power channel 2	<=5552
	Min Excitation power channel 3	>=5830
	Max Excitation power channel 3	<=18426
	Min Excitation power channel 4	>=11770
	Max Excitation power channel 4	<=35637
	Min Excitation power channel 5	>=1980
	Max Excitation power channel 5	<=5866

OQ Main handler handling check

Test	Test Detail	Specification
Main handler handling check	Handling of the different consumables through the instrument	Pass

OQ Safety interlock check

Test	Test Detail	Specification
Safety interlock check	All interlock unit are functioning correctly	Pass

OQ Handheld barcode reader

Test	Test Detail	Specification
Handheld barcode reader	Read tube and rack barcode	The information read corresponds to the tube and rack barcode

OQ Sample Supply Module

Test	Test Detail	Specification
Sample supply module time synchronization	Synchronize the sample supply module	Time of the sample supply module corresponds to the IM.
Sample supply module check	Check all sensor and mechanical checks	Pass

OQ Check Run

Test	Test Detail	Specification
Check Run	System mechanical, electrical, and communication test.	Run completed without error messages, batch, control, and final sample results communicated throughout the system.

SWQ SW 1.2 Specifications

SWQ: Sample Supply Module

Test	Test Detail	Specification
Sample supply module time synchronization	Synchronize the sample supply module	Time of the sample supply module corresponds to the IM.
Sample supply module check	Check all sensor and mechanical checks	Pass

SWQ: Check Run

Test	Test Detail	Specification
Check Run	System mechanical, electrical, and communication test.	Run completed without error messages, batch, control, and final sample results communicated throughout the system.

SWQ: Pool Communication Test Run

Test	Test Detail	Specification
Pool Communication Test Run	Data communication with Instrument Gateway	Pass

SWQ SW 1.3 Specifications

SWQ: Sample Supply Module

Test	Test Detail	Specification
Sample supply module time synchronization	Synchronize the sample supply module	Time of the sample supply module corresponds to the IM.
Sample supply module check	Check all sensor and mechanical checks	Pass

SWQ SW 1.4 Specifications

SWQ: Sample Supply Module

Test	Test Detail	Specification
Sample supply module time synchronization	Synchronize the sample supply module	Time of the sample supply module corresponds to the IM.