

Installation Qualification qTOWER³ Product Family

- qTOWER³
- qTOWER³ G
- qTOWER³ touch
- qTOWER³ G touch
- qTOWER³ 84
- qTOWER³ 84 G



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1 Customer and Service data

Customer address

Company	
Department	
Name	
Address (Street, Number, City, Zip code, Country)	
Phone	
E-mail	
Customer number	
Order number	

Device data

Device type	Serial number
PC (serial number, operating system)	Firmware version (Extras ► Device Identification) Exp.: QTower 3.x: Vers: 1.0.6.0, Jun 19 2018 10:51:12, #01 !1.0.4.0! 1.46
Software version (Help ► Info)	<ul style="list-style-type: none">▪ Optics (1.0.6.0)
Instrument location	<ul style="list-style-type: none">▪ Circuit board (1.46)▪ Power module (1.0.4.0)

Data of the AJ representative for the Installation Qualification

Name, company	
Date of Installation Qualification	

Installation Qualification

2 General information

The models of the qTOWER³ product family are thermal cyclers amplifying DNA by way of the polymerase chain reaction (PCR) developed for real-time PCR experiments. The devices are controlled using the qPCRsoft/qPCRsoft384/qPCRsoft *touch* program. A fluorescence photometer is used as detector.

3 Purpose of the IQ and OQ

Installation Qualification (IQ) and Operational Qualification (OQ) are central components of analytical instrument qualification.

The IQ establishes that the instrument is delivered as designed and specified, that it is installed properly in the selected environment, and that this environment is suitable for the instrument.

The OQ verifies that the instrument meets the specifications guaranteed by Analytik Jena in the user's environment and demonstrates fitness for the intended and selected use.

Please note that IQ and OQ must be carried out by personnel qualified by Analytik Jena.

The IQ and OQ documentation is prepared and completed by the Analytik Jena commissioner. The conditions in the selected environment are recorded and the exactness of the generated test data is documented and confirmed.

The responsible laboratory personnel or his/her deputy must review the documents and assure themselves of the scientific soundness of the tests. The user must approve the performed tests after execution to ensure completeness and accuracy of the finished documents. Both the user and the Analytik Jena commissioner must sign the documentation.

The tests and measurements performed during the IQ and OQ ensure that the instrument generates reliable and consistent data. When the instrument undergoes major repairs and modifications or if an instrument is moved to another location, relevant IQ and OQ tests should be repeated to verify that the instrument continues to operate satisfactorily.

Within the IQ, the software installation is documented. The laboratory head or his/her deputy are responsible to ascertain if involvement of information technology (IT) is required.

4 Documentation of the device to be qualified

In accordance with the existing order, the following real-time PCR thermocycler is examined during the installation qualification:

qTOWER ³	<input type="checkbox"/>
qTOWER ³ G	<input type="checkbox"/>
qTOWER ³ touch	<input type="checkbox"/>
qTOWER ³ G touch	<input type="checkbox"/>
qTOWER ³ 84	<input type="checkbox"/>
qTOWER ³ 84 G	<input type="checkbox"/>

Devices that are not included in the delivery are not subjected to the IQ.

In the text below, these devices are collectively called qTOWER³. Differences are explained in the corresponding section.

Note: A separate PC/Laptop is required for IQ and OQ of qTOWER³ (G) touch devices (for the read-out of firmware and raw fluorescence data).

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5 Installation qualification (IQ)

5.1 Installation and connection conditions

Installation conditions

	Compliant	Not compliant
Biological or medical laboratory	<input type="checkbox"/>	<input type="checkbox"/>
Table:		
<ul style="list-style-type: none"> ▪ wipe, scrape, heat and corrosion resistant, does not absorb moisture ▪ Min. load capacity of 30 kg (must be confirmed by the customer) ▪ Space required by the device (H x W x D): 59 x 27.5 x 27.5 cm + space for an external PC (if necessary) ▪ Adequate space to open the device space required by the open device (H x W x D): 70 x 27.5 x 50 cm 	<input type="checkbox"/>	<input type="checkbox"/>
The installation location is free of:		
<ul style="list-style-type: none"> ▪ Direct sunlight and radiation from heaters ▪ High dust contamination ▪ Heavy mechanical vibration ▪ Magnetic fields ▪ Drafts ▪ Corrosive gases 	<input type="checkbox"/>	<input type="checkbox"/>
The customer has to ensure, that the installation location meets the following environmental conditions:		
<ul style="list-style-type: none"> ▪ + 15 to 35 °C (air-conditioning recommended) ▪ max. 70 % relative humidity ▪ Air pressure: 0.7 to 1.06 bar ▪ Maximum altitude above mean sea level 2000 m 	<input type="checkbox"/>	<input type="checkbox"/>

Date

Signature of AJ Representative

Reviewed by user

Version 01.18
TecDoc

6/14

Electrical connection conditions

The qTOWER³ is operated with single-phase alternating current. Prior to making the connection, check that the voltage selection switch of the device is set to the correct value.

		Compliant	Not compliant
Voltage (according to the type label)	<input type="checkbox"/> 100 V ~		
	<input type="checkbox"/> 115 V ~	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/> 230 V ~		
Frequency	50 to 60 Hz	<input type="checkbox"/>	<input type="checkbox"/>
Power consumption	850 VA	<input type="checkbox"/>	<input type="checkbox"/>
Mains fuse (installation in the building)	16 A	<input type="checkbox"/>	<input type="checkbox"/>

5.2 Delivery scope

The completeness of the delivery is checked and the components are inspected for damage. Incomplete or damaged components must be marked as "Not compliant" and specified in more detail in section "Assessment of missing or damaged items".

Description	Amount	Compliant	Not compliant
qTOWER ³ Model: _____ S/N: _____	1	<input type="checkbox"/>	<input type="checkbox"/>
Protective cover	1	<input type="checkbox"/>	<input type="checkbox"/>
Main cable	1	<input type="checkbox"/>	<input type="checkbox"/>
qTOWER ³ operating instructions (DE/EN)	1	<input type="checkbox"/>	<input type="checkbox"/>
Operating instructions (DE/EN) qPCRsoft / qPCRsoft touch / qPCRsoft384 software	1	<input type="checkbox"/>	<input type="checkbox"/>
CD with qPCRsoft software	1	<input type="checkbox"/>	<input type="checkbox"/>
Screw driver	1	<input type="checkbox"/>	<input type="checkbox"/>
USB cable to connect device and PC	1	<input type="checkbox"/>	<input type="checkbox"/>

Installed color modules

	Color module	Position on filter wheel*
<input type="checkbox"/>	Color module 1 Blue (470 nm/520 nm)	
<input type="checkbox"/>	Color module 2 Green (515 nm/545 nm)	
<input type="checkbox"/>	Color module 3 Yellow (535 nm/580 nm)	
<input type="checkbox"/>	Color module 4 Orange (565 nm/605 nm)	
<input type="checkbox"/>	Color module 5 Red (630 nm/670 nm)	
<input type="checkbox"/>	Color module 6 NIR (660 nm/705 nm)	
<input type="checkbox"/>	FRET module 1 (470 nm/580 nm)	
<input type="checkbox"/>	FRET module 2 (470 nm/670 nm)	
<input type="checkbox"/>	FRET module 3 (470 nm/705 nm)	
<input type="checkbox"/>	FRET module 4 (515 nm/670 nm)	
<input type="checkbox"/>	FRET module 5 (470 nm/605 nm)	
<input type="checkbox"/>	Color Protein 1 Sypro (490 nm/580 nm)	
<input type="checkbox"/>	Customized module: _____	

* For color modules, which are not installed in the device, leave the field "Position on filter wheel" empty.

The integrated tablet controls the qTOWER³ *touch* and qTOWER³ G *touch*. For redundant PC and PC accessories, check the box in the "Not applicable" column.

Description	Amount	Not applicable	Compliant	Not compliant
Optional accessories				
PC Model: _____ S/N: _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Monitor Model: _____ S/N: _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Keyboard		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mouse		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Description	Amount	Not applicable*	Compliant	Not compliant
Further optional accessories:				
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Not applicable, if not included in the order.

Assessment of missing or damaged items

Any missing or damaged items are to be noted in this section:

Missing or damaged item, description of the damage

	Compliant	Not compliant
All missing or damaged items are documented.	<input type="checkbox"/>	<input type="checkbox"/>
The shipment incl. all components, except items listed above, is complete and is without visible damage.	<input type="checkbox"/>	<input type="checkbox"/>
The device installation can continue.	<input type="checkbox"/>	<input type="checkbox"/>
The device installation cannot continue due to missing or damaged articles. The next date for the installation is: _____	<input type="checkbox"/>	<input type="checkbox"/>

Date

Signature of AJ Representative

Reviewed by user

Installation Qualification

5.3 On-site Installation

The steps of on-site installation include the device placement, removal of transport locks, commissioning and functional test of the real-time PCR thermocycler, tablet/PC and accessories.

5.3.1 Device assembly

		Compliant	Not compliant
The qTOWER ³ has been set up by the Analytik Jena commissioner. The transport lock has been removed.		<input type="checkbox"/>	<input type="checkbox"/>
The PC (if included in the scope of delivery) has been set up by the Analytik Jena commissioner.		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	For qTOWER ³ (G) and qTOWER ³ 84 (G): The control and analysis software qPCRsoft / qPCRsoft 384 have been installed by the Analytik Jena commissioner.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	The qTOWER ³ (G) <i>touch</i> was delivered with pre-installed control and evaluation software qPCRsoft <i>touch</i> .	<input type="checkbox"/>	<input type="checkbox"/>
The accessories (if included in the scope of delivery)		<input type="checkbox"/>	<input type="checkbox"/>

have been set up by the Analytik Jena commissioner.			

Date

Signature of AJ Representative

Reviewed by user

5.3.2 Functional test of the device periphery and basic device functions

	Compliant	Not compliant
Functionality of the hardware		
After switching on the qTOWER ³ , the device commences the automatic initialization.	<input type="checkbox"/>	<input type="checkbox"/>
During initialization, the status LED on the front of the device flashes red and green.		
After initialization, the status LED is lit green. The device is operational.		
Hardware and software communication		
The review of the communication between the device hardware and the control software is verified by starting the control software.		
<ul style="list-style-type: none"> qTOWER³ (G) and qTOWER³84 (G): Communication is ensured if the system can be initialized correctly by actuating the command EXTRAS ► DEVICE INITIALIZATION without any error messages. The connection to the device is displayed in the lower left corner of the software window qPCRsoft / qPCRsoft 384. qTOWER³ (G) touch: Communication is ensured if the system is initialized correctly by switching on the device without any error messages. 	<input type="checkbox"/>	<input type="checkbox"/>

5.4 Nonconformities ascertained during the Installation Qualification

This page is intended to list any nonconformities that may have occurred during the installation qualification procedure. If possible, corrective measures should be recorded. If no nonconformities have occurred, the document should be signed by the Analytik Jena commissioner and by the responsible laboratory manager or his deputy.

Nonconformities

Measures and actions for elimination of nonconformities

	Compliant	Not compliant
All nonconformities during the installation qualification are documented in this section.	<input type="checkbox"/>	<input type="checkbox"/>
The instrument did not show any further recognizable complaints.		

5.5 Completion of the installation qualification

	Compliant	Not compliant
The installation qualification has been successfully performed and completed.	<input type="checkbox"/>	<input type="checkbox"/>

This documents that the qTOWER³ incl. the components supplied with it, conform to the customer's order. The qTOWER³ has been properly installed in the selected environment, and this environment is suitable for the instrument.

Date

Signature of AJ Representative

Reviewed by user

6 Revision Overview

Version	Coming into force of the revision	Changes
IQ.AJ.EN.01.18	10.04.2019	New document creation