




Mastercycler® ep realplex

SOP - Installation Qualification

eppendorf



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1 IQ – Mastercycler ep realplex

1.1 Introduction

- The following documents also apply with regard to the IQ:
 - The operating instructions shipped with the device.
- ⇒ Where needed, supplement the IQ with further documents, e.g. descriptions, print outs, records and reports. List these documents under remarks.

1.1.1 Abbreviations

IQ – Installation Qualification

SM – Service manual

OM – Operating Manual

1.2 Device data

Organization/operator:

Place of use of the device (building, floor, room, lab etc.):

Storage location of the operating manual:

Storage location of the service manual:

Device stock number:

Manufacturer: Eppendorf AG

Type designation:

Serial number:

Power in volts:

Frequency in Hz:

Installation date (day/month/year):

realplex module, firmware version:

Cycler module, firmware version:

realplex software, version:

Color Calibration Kit, batch:

Color Calibration Kit, shelf life:

real-time PCR validation kit, batch:

real-time PCR validation kit, shelf life:

1 IQ – Mastercycler ep realplex

1.3 Delivery condition and delivery package

1.3.1 Check packaging for damage

No.	Section SM/OM	Procedure	yes	no
IQ 01	————	The packaging shows no signs of damage on the outside. (Further details as comment)		
IQ 02	————	The details of the packaging label correspond with the order.		



Attention! Have a careful look at the assembly of the packaging. Older packaging versions consist of two boxes inserted into one another. As soon as the straps are cut open, the inner box together with the Mastercycler ep realplex may slip out of the casing and fall to the ground.

No.	Section SM/OM	Procedure	yes	no
IQ 02a	————	Mastercycler module and realplex module have the same LOT number.		
IQ 02b	OM, Chapter 2	The temperature indicators display less than 55 °C. (Temperatures above 55 °C destroy the Multiplier.)		

1.3.2 Check Mastercycler ep realplex and accessories for damage

No.	Section SM/OM	Procedure	yes	no
IQ 03	————	The Mastercycler ep realplex shows damage on the outside.		
IQ 04	————	The accessories do not show any signs of damage on the outside.		

1.3.3 Check delivery package



Note: Keep transport box!

Only use the original transport box when sending the Mastercycler ep realplex in for repairs.

No.	Section SM/OM	Procedure	yes	no
IQ 05	OM, Chapter 2	The delivery package matches the details described in the operating manual and is complete.		

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1.4 Setup

1.4.1 Setting up the Mastercycler ep realplex



Risk of explosion!

- ⚠ Do not operate the device in rooms where work is being carried out with explosive substances.
- ⚠ Do not use this device to process any explosive or highly reactive substances.
- ⚠ Do not use this device to process any substances which could create an explosive atmosphere.



Follow the instructions in the operating manual for commissioning the Mastercycler ep realplex

No.	Section SM/OM	Procedure	yes	no
IQ 06	_____	Is the setup location solid, flat and resonance-free? Weight of the Mastercycler ep realplex: 24 kg.		
IQ 07	_____	Ensure free circulation of air by maintaining a distance of at least 10 cm on all sides of the device from adjacent devices or walls and keep the underside of the device clear.		
IQ 08	_____	Do the mains voltage and mains frequency match the details on the nameplate?		
IQ 09	_____	Are the ambient conditions listed below met? Temperature: 15 °C to 35 °C rel. humidity to 70 %		

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1.5 Check device functions and give instructions to customer



Warning! Injury from trapping or crushing.

- Do not place your fingers between the *realplex* module and cycler module when opening and closing the device or when opening it into the cleaning position.
- Do not reach in under the opened *realplex* module.
- Take care that the stand is properly engaged so that the *realplex* module stays in the opened position.



Warning! Risk to health if used incorrectly.

If the temperature control is performed incorrectly, sample material may be released and the thermoblock and the frame with heating foil may get damaged.

- Ensure that the PCR plates are correctly inserted in the thermoblock.
- Always close the *realplex* module before temperature-controlling the samples. This avoids the tube lid from bursting.

No.	Section SM/OM	Procedure	yes	no
IQ 12	OM, Section 2	The <i>realplex</i> module is mounted.		
IQ 13	OM, Section 2	The Rollflex cable is connected and fixed.		
IQ 14	OM, Section 2	CANBUS cable and adapter are connected.		
IQ 15	OM, Section 2	Address and terminating resistor are set correctly.		
IQ 16	OM, Section 2	The Mastercycler is connected and ready for operation.		
IQ 17	OM, Section 2	The energy save functions of the PC are deactivated.		
IQ 18	OM, Section 2	The <i>realplex</i> software is installed.		
IQ 19	OM, Section 2	The database is set up.		
IQ 20		The current version of the firmware and the <i>realplex</i> software is installed.		



Carry out the Operating Qualification and the Performance Qualification to complete the installation of Mastercycler ep *realplex*.



The log file of the *realplex* software should be printed out and the Installation Qualification documents added.

1 IQ – Mastercycler ep realplex

No.	Section SM/OM	Procedure	yes	no
IQ 21		The operator is instructed in all functions described in the IQ, OQ and PQ.		

Remarks:

Place, date:

Signature:

The user hereby confirms that he has been briefed on the aforementioned instrument functions.

Place, date:

Signature:

1 IQ – Mastercycler ep realplex

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