




# Mastercycler® ep realplex

SOP - Operational Qualification



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# 1 Introduction

- The operational qualification (OQ) must only be carried by a technician who has been authorized by the manufacturer.
- The electrical safety check must only be carried out by a qualified electrician.
- The following documents are also valid for carrying out the OQ:
  - The current version of the service manual.
  - The operating manual supplied with the device.
- ◊ Include other documents, such as explanations, printouts, recordings and results, with the OQ. Label these documents accordingly.
- At the end of the SOP you will find a list containing a documentation of all tests which were carried out on the device. Enter the test you have carried out and the date of the next test into this list.
- If there is already a list available at the customer's premises then enter the test you have carried out into this list. Do not use a new list for each test.

## 1.1 Abkürzungen

OQ – Operational Qualification

SM – Service Manual

BA – Operating Manual

SF – Service funktion

BA TV – Operating Manual temperature validation

## 1.2 Device data

Organization/operator:

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

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Storage location of the operating manual:

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Storage location of the service manual:

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Device stock number:

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Manufacturer: Eppendorf AG

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Type designation:

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Serial number:

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Power in volts:

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Frequency in Hz:

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Installation date (day/month/year):

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*realplex* module, firmware version:

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*realplex* module, firmware version:

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Cycler module, firmware version:

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*realplex* software, version:

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Color Calibration Kit, batch:

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Color Calibration Kit, shelf life:

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real-time PCR validation kit, batch:

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real-time PCR validation kit, shelf life:

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# 1 Introduction

## 2 Electrical test – Mastercycler ep realplex



The test can be conducted in accordance with either IEC 61010-1 (corresponds to EN 61010-1) or VDE 701/702.

In the U.S., the protective earth current is measured in accordance with NFPA 99.

### 2.1 Test in accordance with IEC 61010-1 (EN 61010-1)

No.	Section SM/OM	Procedure	Measured value	passed	failed
EP 01	_____	Leakage current max. 3.5 mA in single fault condition.			
EP 02	_____	Accessible current max. 0.5 mA in normal case.			

### 2.2 Test in accordance with VDE 701/702

No.	Section SM/OM	Procedure	Measured value	passed	failed
EP 03	_____	Protective earth resistance max. 0.3 Ω, up to 5 m cable length.			
EP 04	_____	Protective earth current max. 3.5 mA.			
EP 05	_____	Accessible current max. 0.5 mA.			

### 2.3 Test in accordance with NFPA 99 (U.S. only)

No.	Section SM/OM	Procedure	Measured value	passed	failed
EP 06	_____	Protective earth current max. 0.5 mA.			

Remarks:

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Place, date: \_\_\_\_\_

Signature: \_\_\_\_\_

## 2 Electrical test – Mastercycler ep realplex



## 3 Function test – Mastercycler ep realplex

### 3.1 Check device functions



If during the inspection of the service functions an error occurs do not abort the OQ.  
Mark the test of this service function as failed and continue with the OQ.

#### 3.1.1 Functional test of the realplex module with the software version 1.5

No.	Section SM/OM	Procedure	passed	failed
OQ 01	SM, Chapter 3, SF Filterwheels	Perform a filter rotor test.		
OQ 02	SM, Chapter 3, SF LED array	Perform LED array test.		
OQ 03	SM, Chapter 3, SF Multiplier	Perform Multiplier dark current test.		
OQ 04	SM, Chapter 3, SF Optical Path	Check light path with dark plate.		
OQ 05	SM, Chapter 3, SF Calibration	Check Multiplierdrift.		
OQ 06	SM, Chapter 3, SF Well State	Check light path with lumogen plate.		
OQ 07	SM, Chapter 3.8.1	Perform background calibration.		
OQ 08	BA, Chapter 3.8.2	Perform dye calibration.		

#### 3.1.2 Functional test of the realplex module with the software version 2.0

No.	Section SM/OM	Procedure	passed	failed
OQ 09	SM, Chapter 3, SF Filterwheels	Perform a filter rotor test.		
OQ 10	SM, Chapter 3, SF LED array	Perform LED array test.		
OQ 11	SM, Chapter 3, SF Detector	Perform Multiplier dark current test.		
OQ 12	SM, Chapter 3, SF Optical Path	Check light path with dark plate.		
OQ 13	SM, Chapter 3, SF Calibration	Check Multiplierdrift.		
OQ 14	SM, Chapter 3, SF Well State	Check light path with lumogen plate.		
OQ 15	SM, Chapter 3.8.1	Perform background calibration.		
OQ 16	BA, Chapter 3.8.2	Perform dye calibration.		

## 3 Function test – Mastercycler ep realplex

### 3.1.3 Functional test of the Mastercycler module with the software version 1.5 or higher

No.	Section SM/OM	Procedure	passed	failed
OQ 17	SM, Chapter 3, SF Settings	Check fan function.		
OQ 18	SM, Chapter 3, SF Settings	Check thermoblock segments.		
OQ 19	BA TV	Thermal test of the thermoblock.		
OQ 20	SM, Chapter 3, SF Lid Drive	Check frame with heating foil function.		

### 3.1.4 Color calibration data

	Sensitivity code			
SYBR				
FAM				
VIC				
JOE				
NED				
TAMRA				
ROX				



The log file of the *realplex* software is to be printed out and to be added to the Operation Qualification documents.

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## 3 Function test – Mastercycler ep realplex

### 3.1.5 Completion of the OQ

No.	Section SM/OM	Procedure	yes	no
OQ 21	_____	Was the OQ performed completely?		
OQ 22	_____	Has the device withstood all tests?		

Remarks:

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Place, date:

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Signature:

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## 3 Function test – Mastercycler ep realplex





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