




# Mastercycler® ep realplex

SOP - Performance Qualification

**eppendorf**



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# 1 PQ – Mastercycler ep realplex

## 1.1 Introduction

- The performance qualification (PQ) must be performed by a service specialist with the manufacturer's authorization.
- The PQ should be performed at least every 2 years.
- The following documents also apply with regard to the PQ:
  - The latest version of the service manual.
  - The operating instructions shipped with the device.
- ◊ Where needed, supplement the PQ with further documents, e.g. descriptions, print outs, records and reports. List these documents under remarks.

### 1.1.0.1 Abbreviations

PQ – Performance Qualification

SM – Service manual

OM – Operating Manual

## 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:

---

Installation date (day/month/year):

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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 PQ – Mastercycler ep realplex

## 1.3 Validation

No.	section SM/OM	Procedure	yes / OK	no / not OK
PQ 01		Validation plate permanently frozen until validation.		
PQ 02		No evaporation detectable in the individual wells of the validation plate.		
PQ 03		Lot number and shelf life of validation plate noted.		
PQ 04		Validation plate centrifuged.		
PQ 05		Validation performed successfully.		
PQ 06		For the evaluation, a maximum of 6 positions per unknown group were deactivated.		
PQ 07		Result: The Mastercycler ep realplex is capable of differentiating between 5,000 and 10,000 genomic units.		

Deactivated positions:

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												



The results of the validation should be printed out and included with the Performance Qualification documents.

# 1 PQ – Mastercycler ep realplex

Remarks:

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Place, date:

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Signature:

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# 1 PQ – Mastercycler ep realplex



## 2 List of tests – Mastercycler ep realplex

### 2.1 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): \_\_\_\_\_

### 2.2 Test list

<b>Recurring tests</b>				
<b>(Operation qualification / electrical test in accordance with checklist)</b>				
<b>Test type</b>	<b>Test date</b>	<b>Tester</b>	<b>Remarks</b>	<b>Next test</b>



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