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Mastercycler[®] pro

SOP - Operational Qualification - English

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1 Introduction

1.1 Using this manual

- ▶ Ensure that you have a copy of the latest versions of the service manual and operating instructions. Check this using the version numbers at www.eppendorf-support.com and www.eppendorf.com.
- ▶ Read the service manual before starting work on the device.
- ▶ Read the chapters "Installation" and "Operation" of the operating manual.
- ▶ Observe the safety instructions in the operating manual.

1.2 Liability

The Eppendorf service partner entrusted with maintenance, servicing or testing is liable for ensuring that all work is carried out in a professional manner.

- ▶ The constructional features of the device must not be modified by servicing, maintenance or testing. The device must always be as safe as in its original state.
- ▶ Only accessories and original spare parts recommended by Eppendorf as well as measuring and test equipment recommended by Eppendorf may be used for any maintenance, servicing or testing work.

1.3 User profile

The specialist entrusted with maintenance, repair or testing must meet the following prerequisites:

- Successful participation in service trainings with certification by Eppendorf AG for the product that is to be maintained, repaired or tested.
- Qualification as a specialist with knowledge of the applicable local and international standards.
- Qualification to evaluate the work assigned to him.
- Recognition of potential hazards and how to prevent or correct them.

1.4 Notes on this document

- ▶ Include other documents, such as explanations, printouts, recordings and results, with the OQ. List these documents under "Appendices".
- ▶ At the end of this OQ, you will find a list for documenting all inspections which were completed on a device. Enter the test you performed, and the date of the next test, into this list.
- ▶ If a list is already available at the customer's premises, enter the test you have performed into this list. Do not use a new list for each test.

1.5 Abbreviations

OQ – Operational Qualification
SM – Service Manual
OM – Operating Manual

Introduction

Mastercycler® pro
English (EN)

1.6 Device data

Company / Operator:

Location where the device is used (building, floor, room, lab etc.):

Place where the operating manual is kept:

Operating Manual version (index number on the inside of the title page):

Place where the service manual is kept:

Service Manual version (index number on the inside of the title page):

Inventory number of the device:

Manufacturer: Eppendorf AG

Type designation:

Serial number:

Software/Firmware version:

Voltage in volts:

Frequency in Hz:

Installation date (day/month/year):

Device ID:

1.7 Responsible persons**Responsible technician**

Name, first name:

Company:

Certificate (issued on ... / valid until ...):

Signature:



Copies of the technician's certificates can be enclosed as appendices. List these documents at the end, under "Appendices".

User / Responsible for quality

Name, first name:

Company:

Signature:

2 OQ – Mastercycler pro

2.1 Test equipment



- You can find information on the test equipment specification in the Service Manual.
- Copies of the calibration certificates for this test equipment can be added as appendices to this OQ. List these documents at the end of this OQ, under “Appendices”.

Type	Type/serial number	Calibration on	Calibration certificate no.
Temperature Verification System Single-Channel, Order No. 0055 000.298			

2.2 Function tests

No.	SM/OM section	Check	Yes	No
OQ 01	SM chapter 5, "Settings"	The fan below the thermal module has been tested successfully.		
OQ 02	SM chapter 5, "Settings"	The three thermosegments (left, center, right) are heating and cooling properly. The sensors display the temperature correctly.		
OQ 03	—————	The mechanical heated lid can be completely moved to the front and back.		
OQ 04	—————	The lever for opening and closing the heated lid is working.		
OQ 05	SM, chapter 5, SF "Service Lid"	The heated lid reaches the preset temperature.		
OQ 06	SM, chapter 5, SF "Service Lid"	Only for the thermal block with 96 Wells: The "plate switch" of the heated lid is working.		
OQ 07	SM, chapter 5, SF "Service Lid"	The "lever switch" on the heated lid is working.		
OQ 08	SM, chapter 5, SF "Service Lid"	The 7-segment display was tested successfully.		
OQ 09	—————	The thermal block is capable of producing the predefined temperature. The test must be performed with the single channel temperature verification system.		
OQ 10	—————	A test run with a user program has been carried out successfully.		

Remarks

Appendices (e.g., calibration certificates, technician's certificates)

1:

2:

3:

4:

5:

City, date

Signature of technician

City, date

Signature of user

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Eppendorf AG · 22331 Hamburg · Germany

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