



MixMate

SOP - Operational Qualification - English

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1 Introduction

1.1 Using this manual

- ▶ Make sure that the service manual and the operating manual are available in the latest versions. To do so, compare the version numbers. The latest versions of the manuals can be downloaded from www.eppendorf-support.com and www.eppendorf.com.
- ▶ Read the service manual before commencing work on the device.
- ▶ Read the chapters "Installation" and "Operation" of the operating manual.
- ▶ Observe the safety instructions in the operating manual.

1.2 Notes on liability

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

- ▶ Repair, maintenance and testing may not change the existing construction of the device. The device must always be as safe as it is in its original state.
- ▶ Only accessories and original spare parts recommended by Eppendorf, and 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

1.6 Device data

Company/owner	
Operation site of device (building, floor, room, laboratory, etc.)	
Storage site of the operating manual	
Operating manual version (index number on the inside of the front cover)	
Storage site of the service manual	
Service manual version (index number on the inside of the front cover)	
Inventory number of the device	
Manufacturer: Eppendorf AG	
Type designation	
Serial number	
Software/firmware version	
Voltage in volts	
Frequency in Hz	
Date of installation (day/month/year)	

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 – MixMate

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.
RPM-Tester			
Stopwatch			

2.2 OQ Checklist

2.2.1 Visual check

No.	SM/OM section	Check	Yes	No
OQ01		Is the MixMate free from damage?		
OQ02		Are the accessories (e.g. tube holders) free from damage?		

2.2.2 Functional check

No.	SM/OM section	Check	Measured value	Yes	No
OQ 3	SM chapters 9 and 10	Speed • 500 rpm ± 20 rpm • 1000 rpm ± 20 rpm • 2000 rpm ± 20 rpm • 3000 rpm ± 20 rpm		
OQ 4	SM chapters 9 and 10	Timer • 5 min ± 2 s		
OQ 5	OM, Chapter 5	Vortex function The vortex function is working properly.			
OQ 6	SM Chapter 9	Overload protection The overload protection is working properly.			

Remarks

Appendices (e.g.: calibration certificates, Technician's certificates,):

1:

2:

3:

4:

5:

City, date

Technician's signature

City, date

User signature

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