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Eppendorf BioSpectrometer® 6135/6136/6137

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

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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):

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 – Eppendorf BioSpectrometer

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.
Test filter			
Testo thermometer			

2.2 Visual inspection for damage

No.	SM/OM section	Check	Yes	No
OQ 01	_____	Can any damage be detected on the device or on the mains cable?		

2.3 Function tests



For the inspection, the room temperature must be between 20 °C and 23 °C.

2.3.1 Self test

No.	SM/OM section	Check	Yes	No
OQ 02	SM, Chapter 5.5	Was the self test carried out successfully?		

2.3.2 Calibrating the BioSpectrometer



Use the secondary test filter kit (order no. 6135 931.002) for calibration.

No.	SM/OM section	Check	Yes	No
OQ 03	SM, Chapter 5.5	Was the wavelength systematic error and photometric accuracy tested?		
	SM, Chapter 5.5	Are the test results within the limiting values?		
	SM, Chapter 5.5	Was a certificate of conformity issued?		
OQ 04	SM, Chapter 5.6.4.4	Was the fluorescence unit checked.		

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2.3.3 Function of the serial interfaces

No.	SM/OM section	Check	Yes	No
OQ 05	SM, chapter 5	Was the serial interface test completed successfully?		

2.3.4 Function of the key pad

No.	SM/OM section	Check	Yes	No
OQ 06	SM, chapter 5	Was the key pad test completed successfully?		

2.3.5 Function of the display

No.	SM/OM section	Check	Yes	No
OQ 07	————	Is the display damaged?		
OQ 08	SM, chapter 5	Was the color sample of the display test correctly displayed?		

2.3.6 Data backup

No.	SM/OM section	Check	Yes	No
OQ 09	SM, chapter 5	Was the "backup.bio" file created with more than 2 KB on the USB stick?		

2.3.7 Temperature control function of the BioSpectrometer kinetic

No.	SM/OM section	Check	Passed	Failed
OQ 10	SM, chapter 5	Is the status of the temperature calibration "OK"?		

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