EQUIPMENT QUALIFICATION

Hotplate-Stirrers

Design, Installation, Operation and Performance

Revision A 5/2026

Content Page

1. Introduction

This document serves to fulfill quality management requirements set forth by organizations such as the FDA, ISO and EU. Provided within, is the qualified assurance that your equipment performs correctly, in accordance with manufacturer's specifications.

Defined in this document, are verification tests to be performed on the VWR Hotplate-Stirrers. To ensure the validity of the tests and quality of the data collected from your equipment, the tests must be performed by an VWR trained and authorized service technician. The tests will take place at the site of installation. Customers may use this document to log all ongoing maintenance and service activities for the equipment.

The document is divided into the following sections:

Design Qualification (DQ) – This section details the user requirements drawn on that have come to define the specifications of the equipment.

Installation Qualification (IQ) – This section outlines the installation qualification procedures; it will cover delivery, unpacking and initial installation of the new equipment. The installation qualification must be performed before operational qualification.

Operational Qualification (OQ) – This section goes over the tests which will verify that the equipment is ready to be put into operation. Operational Qualification is specific to the current location of the equipment. If the location is changed, equipment must be re-qualified before putting back into routine operation.

Performance Qualification (PQ) – This section covers the ongoing tests used to check the performance of the centrifuge throughout its life cycle. The performance checks help to ensure the centrifuge is operating in accordance with the specifications. It is recommended that these periodic tests be performed by trained VWR service technicians.

2. Identification of Equipment

Manufacturer

Company	
Address	
City	
Post Code	
Country	
Telephone	

Supplier

Company	
Address	
City	
Post Code	
Country	
Telephone	

Hotplate-Stirrer

Model	
Serial Number	
Firmware version	
Internal Identification number	

Purchase order

Equipment purchase order number: _____

A copy of purchased order can be found here: _____

3. Design Qualification (DQ)

If a design qualification is required, please insert the appropriate documents behind this page and fill in the table below. If not applicable, please select N/A

☐ N/A

Equipment Model Number	Filed by	Date

4. Installation Qualification (IQ)

4.1 Purpose

The installation qualification serves to

- Confirm equipment is delivered as purchased.
- Check that all documents and certificates are included.
- Inspect for damages.
- Ensure installation conditions are appropriate, and the site meets the requirement according to the instruction manual.
- Confirm unit can be installed and put into operation successfully.

The installation qualification may be performed by either the supplier or the purchaser.

4.2 Installation Type

☐ Initial installation

☐ Relocation

☐ Qualification of previously installed equipment

4.3 Safety Instructions

Do not begin operation of the unit before reading user manual or being trained on the system. Do not attempt to service components. In the undesirable case of problems with your unit, please contact your local VWR authorized dealer.

4.4 Description of Equipment

Full description of the unit may be found in the user manual, including detailed technical data and optional accessories.

4.5 Unpacking

Table 4.5.1 lists all standard items included in the packaging with unit. Check the table for completeness of delivery. Record any missing items in table 4.5.2.

Table 4.5.1

Item	Included in Delivery	Notes
Hotplate-Stirrer	☐ Yes ☐ No ☐ N/A	
Power Cable	☐ Yes ☐ No ☐ N/A	
Instruction Manual (230V available on VWR.com)	☐ Yes ☐ No ☐ N/A	
Stir Bar	☐ Yes ☐ No ☐ N/A	

Table 4.5.2

Missing Item	Quantity	Notes
1.		
2.		
3.		
4.		
5.		

4.6 Technical Documents

To complete the installation of the centrifuge successfully, it is important that the customer records and defines a specific location for the following documents:

Document Description	Document No.	Location
Instruction manual (available on VWR.com)		
Declaration of Conformity (available on VWR.com)		
Safety Guide (230V)		
Purchase order		
Delivery Documents		

4.7 Site Requirement

The proper performance of the equipment relies on the installation of the unit in the appropriate environment. Environmental conditions such as power supply, air supply and temperature conditions must be suitable for the equipment as detailed in the instruction manual. Site requirements and actual site conditions should be verified with the reviewer. Check off the status of each site requirement as "Pass" or "Fail" and take notes as needed. If no comments, check "N/A"

Installation Requirements	Status	Comments
Flat and solid table (appropriated to the weight of the unit)	☐ Pass ☐ Fail	
Surface of table is skid-proofed	☐ Pass ☐ Fail	
Separate access to a plug socket (especially for refrigerated units)	☐ Pass ☐ Fail	
No direct solar radiation	☐ Pass ☐ Fail	
No heater in the direct surroundings	☐ Pass ☐ Fail	
Ambient temperature of 23℃	☐ Pass ☐ Fail	
Minimum space of 30 cm on all sides of the unit	☐ Pass ☐ Fail	
No explosive vapors within 15cm of the unit	☐ Pass ☐ Fail	

Additional comments: _____

4.8 Location Identification

Company	
Address	
City	
Post Code	
Country	
Building	
Room	
Department	
Telephone	

Describe the location of the system below; please include a photograph if possible.

Description of Installation Location (and photo if available)

4.9 Installation Confirmation

Once the unit is placed in the installation location, ensure complete and error free installation by checking the criteria below. Complete the below table by checking the status as “Pass” or “Fail”. Note comments as required.

Installation Criteria	Status	Comments
Verify that there is no physical damage to equipment, power cable or accessories	☐ Pass ☐ Fail	
Confirm voltage of power supply matches that of the equipment requirements	☐ Pass ☐ Fail	
Ensure all security labels are fixed and legible	☐ Pass ☐ Fail	

Additional comments: _____

4.10 Installation Qualification Deviation Log

Log any deviations which occurred during installation qualification in the table below. If there were no deviations, check "N/A".

	Deviation 1
Installation step	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 2
Installation step	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 3
Installation step	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 4
Installation step	
Deviation description	
Corrective action	
Customer comments	
Status	

4.11 Installation Qualification completion

Installation qualification has been performed, reviewed, and approved according to the procedures outlined in this section. All results meeting the specified parameters as detailed in the instruction manual.

Results

☐ Pass ☐ Fail ☐ N/A

Comments: _____

Performed by

Name _____

Company _____

Signature _____

Date _____

Reviewed by

Name _____

Company _____

Signature _____

Date _____

5. Operation Qualification (OQ)

5.1 Purpose

The operational qualification serves to demonstrate that the product meets all specifications as defined in the user manual and is able to be placed into routine operation.

5.2 General Functionality Tests

The table below lists the parameters that must be tested and the criteria that must be met in order for the unit to be deemed acceptable to be placed into routine operation.

Test Parameter	Acceptance Criteria	Status	Comments
Plug in Power Cord	Plug the female end of the provided power cord into PEM on the rear side of the unit. For the 10x10-120V unit, this end of the power cord fixed on the rear side of the unit. Plug the male end of the power cord into a matching standard grounded outlet.	☐ Pass ☐ Fail	
Standby Mode	The rocker switch on the right side of the unit controls standby mode. When the unit is switch on - All heating and stirring functions will remain off. The main operating screen will return. Previous heating and stirring settings will be displayed. The unit is ready for normal use	☐ Pass ☐ Fail	
Temperature setup	Rotate the left knob to control the heat setting. Clockwise rotation will increase the heat setting. Counterclockwise rotation will decrease the heat setting. To turn on the heater, press and hold the left knob until the unit beeps and the heater indicator illuminates. To turn off the heater, press and hold the left knob until the unit beeps and the heater indicator disappears.	☐ Pass ☐ Fail	
Speed setup	Rotate the right knob to control the speed setting. Clockwise rotation will increase the speed setting. Counterclockwise rotation will decrease the speed setting. To turn on the stirrer, press and hold the right knob until the unit	☐ Pass ☐ Fail	

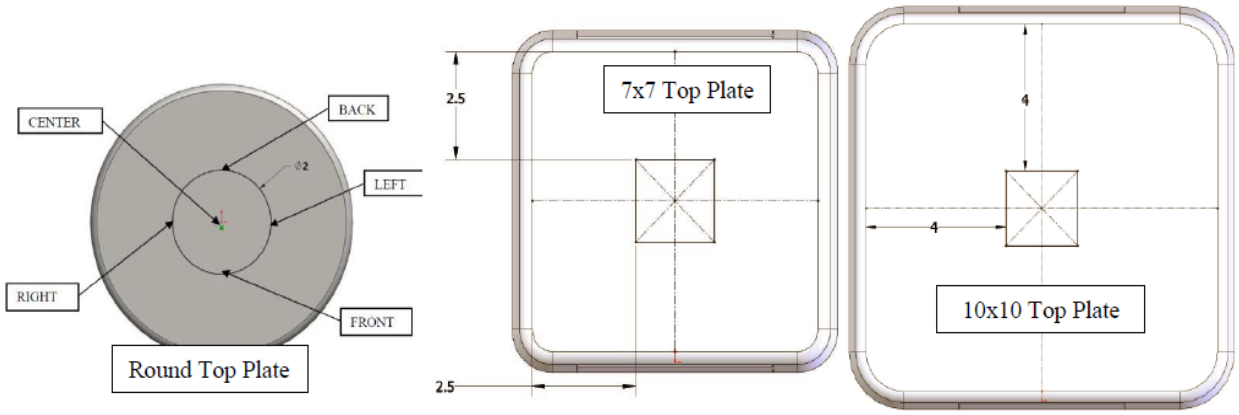
	beeps and the stirrer indicator illuminates. To turn off the stirrer, press and hold the right knob until the unit beeps and the stirrer indicator disappears		
Timer countdown	Set timer to 15 seconds, turn the unit to continuous mode, ensure the unit shuts off when time reaches zero	☐ Pass ☐ Fail	
Turn off unit	The rocker switch on the right side of the unit controls standby mode. To turned off the unit toggle switch to the opposite direction. Unplug the unit.	☐ Pass ☐ Fail	

5.3 Specification Tests

Temperature Testing

Additional instruments required:

1. *Fluke* digital thermometer model # 52I / 52II, or equivalent
2. *OMEGA* Surface Type K temperature probe model # 88107K & 88006K, or equivalent



Images left to right: OMEGA temperature probe, Fluke digital thermometer, Location for the temperature measurement.

Testing Procedure:

1. This test procedure is for (HPS & HP) units.
2. Input temperature settings for each test as defined in table 5.3.1 for Round top units, 5.3.2 for 7 x 7 Square top units & 5.3.3 for 10 x 10 Square top units.
3. Allow unit to heat up for the designated time stated in table.
4. Verify the actual temperature is equal to the set temperature.
5. Using the thermometer, measure temperature as demonstrated in table 5.3.1, 5.3.2, & 5.3.3. Take temperature inside 2" area around the center of the plate.
6. Ensure that the temperature measurement is between the allowable tolerances as defined in Tables 5.3.1, 5.3.2, & 5.3.3. If temperature is outside of the allowable range, record deviation in Section 5.6 OQ Deviation Log.

*Note: See user manual for Single Point Calibration process if required and additional information.

Table 5.3.1

For Round Top HPS unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	183°C - 310°C	30minutes
Test 2	Max Temp	300°C - 390°C	30 minutes

Table 5.3.2

For 7 x 7 HPS/HP unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	190°C - 310°C	30minutes
Test 2	Max Temp	330°C - 475°C	30 minutes

Table 5.3.3

For 10 x 10 HPS/HP unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	190°C - 310°C	30minutes
Test 2	Max Temp	360°C - 475°C	30 minutes

Speed Testing

Additional instruments required:

1. Round Top Units: 400mL water in 1,000mL Erlenmeyer Flask
2. 7 x 7 & 10 x 10 Units: 1,000mL water in 2,000mL Erlenmeyer Flask
3. Stir Bar: All Units – 40 x 10mm Stir bar.

Testing Procedure:

1. Turn on Stir function and set to the minimum setting (60 RPM). The stir bar should turn at a very slow speed without any hesitation.
2. Set Stirrer on to max setting of 1,600 RPM. Make sure the magnet speed gradually increases to the maximum speed. Stirrrer bar should not decouple.
3. Turn off stirrer function and when stir bar stops turning, turn on stirrer to 60RPM. Wait 5-10 seconds, turn off stirrer for several seconds, and then turn it on again to 60RPM. Do this a total of 5 times. Make sure the stir bar rotates smoothly after several rotations.
4. Ensure that the stir bar rotates smoothly at slow speed. If stir bar does not rotate smoothly at slow speed or stir bar decouples at high speed, record deviation in Section 5.6 OQ Deviation Log.

5.4 Authorized Signature on Behalf of Customer

By signing below, the customer is indicating responsibility for making any decision regarding applicable test procedures for specification testing not defined in this document. The customer takes full responsibility for test procedures applied that were not specified by the manufacturer as well as for the evaluation of measuring results.

Company _____

Approved by _____

Title _____

Department _____

Date _____

Signature _____

5.5 User Training

It is imperative that the user receives appropriate training to allow for productive and safe usage of the unit defined in this document. To qualify, the user will receive basic product familiarization and instructions on operations, maintenance, cleaning procedures, and use of the instruction manual.

Please contact your local VWR authorized dealer if you have more specific training requirements.

Users listed in Appendix “7.1 Training Logs of User(s)” have received basic equipment familiarization as documented in the table below.

Training Date: _____

Trainer: _____

Title: _____

Date: _____

Signature: _____

OQ Deviation Log

Log all deviations which occurred during the operational qualification tests in the tables below. Report the section where test is described, description of the deviation, corrective actions taken, customer comments and the current status of the deviation. The status field should include whether the customer approved of the corrective action taken to eliminate the deviation.

	Deviation 1
Operational Qualification Test Section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 2
Operational Qualification Test Section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 3
Operational Qualification Test Section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 4
Operational Qualification Test Section	
Deviation description	
Corrective action	
Customer comments	
Status	

5.7 Operational Qualification Completion

Operational qualification has been performed, reviewed, and approved by the customer according to the procedures outlined in this section. All results meet the specified parameters.

Results

- ☐ Compliance to requirements
- ☐ Conditional
- ☐ N/A

Comments: _____

Performed by

Name _____

Department _____

Signature _____

Date _____

Reviewed by

Name _____

Department _____

Signature _____

Date _____

6. Performance Qualification (PQ)

6.1 Purpose

Performance Qualification is the ongoing process of demonstrating that the unit continues to perform consistently according to the specifications laid out in the user manual, as performed by the user. Users must define their standard operating procedure for periodic checks to monitor the accurate performance of the unit.

6.2 General Functionality Test

Test Parameter	Acceptance Criteria	Status	Comments
Plug in Power Cord	Plug the female end of the provided power cord into PEM on the rear side of the unit. For the 10x10-120V unit, this end of the power cord is fixed on the rear side of the unit. Plug the male end of the power cord into a matching standard grounded outlet.	☐ Pass ☐ Fail	
Standby Mode	The rocker switch on the right side of the unit controls standby mode. When the unit is switch on - All heating and stirring functions will remain off. The main operating screen will return. Previous heating and stirring settings will be displayed. The unit is ready for normal use	☐ Pass ☐ Fail	
Temperature setup	Rotate the left knob to control the heat setting. Clockwise rotation will increase the heat setting. Counterclockwise rotation will decrease the heat setting. To turn on the heater, press and hold the left knob until the unit beeps and the heater indicator illuminates. To turn off the heater, press and hold the left knob until the unit beeps and the heater indicator disappears.	☐ Pass ☐ Fail	
Speed setup	Rotate the right knob to control the speed setting. Clockwise rotation will increase the speed setting. Counterclockwise rotation will decrease the speed setting. To turn on the stirrer, press and hold the right knob until the unit beeps and the stirrer indicator illuminates. To turn off the stirrer, press and hold the right knob until the unit	☐ Pass ☐ Fail	

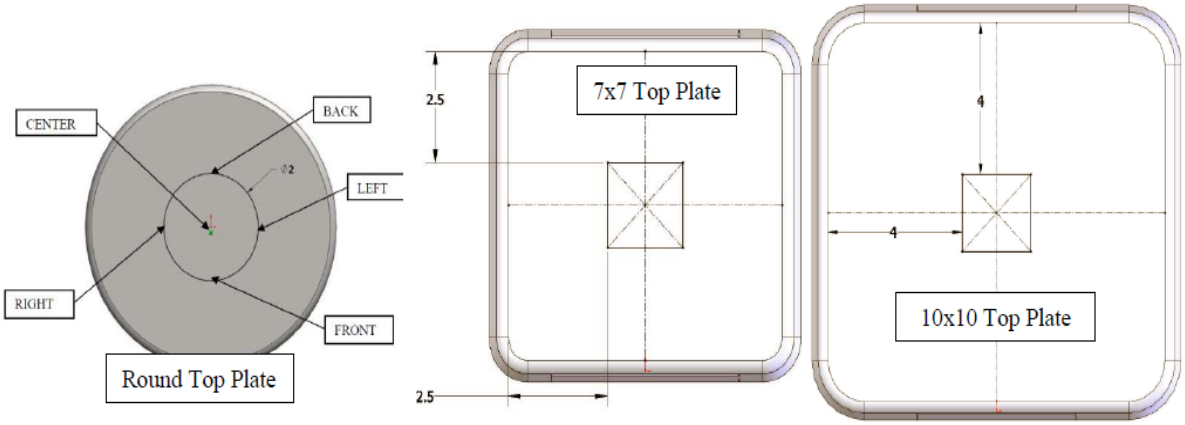
	beeps and the stirrer indicator disappears		
Timer countdown	Set timer to 15 seconds, turn the unit to continuous mode, ensure the unit shuts off when time reaches zero	☐ Pass ☐ Fail	
Turn off unit	The rocker switch on the right side of the unit controls standby mode. To turn off the unit toggle switch to the opposite direction. Unplug the unit.	☐ Pass ☐ Fail	

6.3 Specification Test

Temperature Testing

Additional instruments required:

1. *Fluke* digital thermometer model # 52I / 52II, or equivalent
2. *OMEGA* Surface Type K temperature probe model # 88107K & 88006K, or equivalent



Images left to right: OMEGA temperature probe, Fluke digital thermometer, Location for the temperature measurement.

Testing Procedure:

1. This test procedure is for (HPS & HP) units.
2. Input temperature settings for each test as defined in table 6.3.1 for Round top units, 6.3.2 for 7 x 7 Square top units & 6.3.3 for 10 x 10 Square top units.
3. Allow unit to heat up for the designated time stated in table.
4. Verify the actual temperature is equal to the set temperature.
5. Using the thermometer, measure temperature as demonstrated in table 6.3.1, 6.3.2 & 6.3.3. Take temperature inside 2" area around the center of the plate.
6. Ensure that the temperature measurement is between the allowable tolerances as defined in Tables 6.3.1, 6.3.2, & 6.3.3. If the temperature are within the allowable range, note the date PQ testing was performed in Section 6.4 PQ Activity Log

7. If the temperature is outside of the allowable range, record deviation in Section 6.5 PQ Deviation Log

*Note: See user manual for Single Point Calibration process if required and additional information.

Table 6.3.1

For Round Top HPS unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	183°C - 310°C	30minutes
Test 2	Max Temp	300°C - 390°C	30 minutes

Table 6.3.2

For 7 x 7 HPS/HP unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	190°C - 310°C	30minutes
Test 2	Max Temp	330°C - 475°C	30 minutes

Table 6.3.3

For 10 x 10 HPS unit

	Temp. Input	**Allowable Tolerance**	**Heating Time**
Test 1	250°C	190°C - 310°C	30minutes
Test 2	Max Temp	360°C - 475°C	30 minutes

Speed Testing

Additional instruments required:

1. Round Top Units: 400mL water in 1,000mL Erlenmeyer Flask
2. 7 x 7 & 10 x 10 Units: 1,000mL water in 2,000mL Erlenmeyer Flask
3. Stir Bar: All Units – 40 x 10mm Stir bar.

Testing Procedure:

1. This test procedure is for (S / HPS) units.
2. Turn on Stir function and set to the minimum setting (60 RPM). The stir bar should turn at a very slow speed without any hesitation.
3. Set Stirrer on to max setting of 1,600 RPM. Make sure the magnet speed gradually increases to the maximum speed. Stirrrer bar should not decouple.
4. Turn off stirrer function and when stir bar stops turning, turn on stirrer to 60 RPM. Wait 5-10 seconds, turn off stirrer for several seconds, and then turn it on again to 60 RPM. Do this a total of 5 times. Make sure the stir bar rotates smoothly after several rotations.
5. If the stir bar rotates smoothly at slow speed and stir bar does not decouple at high speed, note the date PQ testing was performed in Section 6.4 PQ Activity Log
6. If stir bar does not rotate smoothly at slow speed or stir bar decouples at high speed, record deviation in Section 6.5 PQ Deviation Log.

PQ Deviation Log

Log any deviations which occur during performance qualifications in the tables below. The log should cover test section number, deviation description, corrective action and customer comment. The status should include whether the customer accepted the corrective action and the final status.

	Deviation 1
Performance Qualification test section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 2
Performance Qualification test section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 3
Performance Qualification test section	
Deviation description	
Corrective action	
Customer comments	
Status	

	Deviation 4
Performance Qualification test section	
Deviation description	
Corrective action	
Customer comments	
Status	

6.5 Performance Qualification Completion

Performance qualifications have been performed, reviewed, and approved according to the procedures outlined in this section. All results meet the specified parameters.

Results

- ☐ Compliance to requirements
- ☐ Conditional
- ☐ N/A

Comments: _____

Performed by

Name _____

Department _____

Signature _____

Date _____

Reviewed by

Name _____

Department _____

Signature _____

Date _____

7. Appendices

Training Log of Users

Equipment Model		Date	
Type of Training			
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	

Equipment Model		Date	
Rotor Model			
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	

Equipment Model		Date	
Type of Training			
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	

Equipment Model		Date	
Type of Training			
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	
Name of Trainee		Signature of Trainee	

7.2 Service Activity Log

Activity	
Date	
Service Report No.	
Technician Name	
Technician Signature	
Notes	

Activity	
Date	
Service Report No.	
Technician Name	
Technician Signature	
Notes	

Activity	
Date	
Service Report No.	
Technician Name	
Technician Signature	
Notes	

Hotplate-Stirrer Series IQOQPQ
31185041