

EQUIPMENT QUALIFICATION

for Thermal Shakers

Design, Installation, Operation and Performance



Content	Page
1. Introduction	3
2. Identification of Equipment	3
3. Design Qualification (DQ)	4
4. Installation Qualification (IQ)	6
4.1 Purpose	6
4.2 Installation type	6
4.3 Safety Instructions	6
4.4 Description of Equipment	6
4.5 Unpacking	6
4.6 Technical Documents	8
4.7 Site Requirement	9
4.8 Location Identification	10
4.9 Installation Confirmation	10
4.10 Installation Qualification Deviation Log	12
4.11 Installation Qualification Completion	12
5. Operation Qualification (OQ)	12
5.1 Purpose	13
5.2 General Functionality Tests	13
5.3 Specifications Tests	16
5.4 Authorized Signature on Behalf of Customer	19
5.5 User Training	21
5.6 Operation Qualification Deviation Log	19
5.6 Operation Qualification Completion	19
6. Performance Qualification (PQ)	19
6.1 Purpose	19
6.2 General Functionality Tests	20
6.3 Specifications Tests	21
6.4 Performance Qualification Activity Log	22
6.5 Performance Qualification Deviation Log	29
6.6 Performance Qualification Completion	32
7. Appendices	33
7.1 Users Training Log	33
7.2 Service Activity Log	34

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 the manufacturer's specifications.

Defined in this document, are verification tests to be performed on the VWR Thermal Shaker. To ensure the validity of the tests and quality of the data collected from your equipment, the tests must be performed by a 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) – Details the user requirements drawn on that have come to define the specifications of the equipment.

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

Operational Qualification (OQ) – 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) – Covers the ongoing tests used to check the performance of the equipment throughout its life cycle. The performance checks help to ensure the equipment 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	

Thermal Shaker

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 either by 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 the 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

A 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
Thermal Shaker	☐ Yes ☐ No ☐ N/A	
Power Cable	☐ Yes ☐ No ☐ N/A	
Instruction Manual (230V available on VWR.com)	☐ Yes ☐ No ☐ N/A	
Safety Guide (230V models)	☐ 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 equipment successfully, it is important that the customer records and defines a specific location for the following documents:

Document Description	Document No.	Location
Instruction manual (230V available on VWR.com)		
Declaration of Conformity (230V available on VWR.com)		
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.

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°C	☐ Pass ☐ Fail	
Minimum space of 30 cm on all sides of the unit	☐ Pass ☐ Fail	
No explosive vapors within 15cm of 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 a 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
Switch toggle switch to "ON"	Verify splash screen turns on and brand matches on the front panel	☐ Pass ☐ Fail	
Temperature setup	Touch the far-left box to bring up the Temperature Setting Window. Touch the digit you wish to change the digit will be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Temperature can adjust in 0.1°C increments. Once the value for the temperature setting is complete, touch "set". To turn off temperature control, touch the temperature box and touch "off".	☐ Pass ☐ Fail	
Speed setup	Touch the center box to bring up the Speed Setting Window. Touch the digit you wish to change the digit will be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Speed can adjust in 10-RPM increments. Once the value for the speed setting is complete, touch "set". To turn off speed control, touch the RPM box and touch "off".	☐ Pass ☐ Fail	
Timer setup	Touch the right box to bring up the Time Setting Window. Touch the digit you wish to change the digit will now be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Time can adjust in 1-minute increments.	☐ Pass ☐ Fail	

	Once the value for the time setting is complete, touch “set”. Touching the “clear” button will allow the unit to run continuously while counting elapsed time.		
Turn off unit	Switch the toggle switch to “OFF”	☐ Pass ☐ Fail	

5.3 Specification Test

Temperature Testing

Additional instruments required:

1. *Fluke* digital thermometer model # 52I / 52II, or equivalent
2. *OMEGA* Type K temperature probe model # 5SC-GG-K-30 or equivalent, three probes required



Images left to right: Omega temperature probe, Fluke digital thermometer, 1.5mL Accessory Block

Testing Procedure:

1. Attach 1.5mL accessory block and verify "1.5/2.0 " displays on screen.
2. Place test probes into the three positions shown above. Thermocouple should be installed on the bottom of the well and secure with empty vial (1.5mL test tube).
3. Input temperature settings for each test as defined in table 5.3.1 (For ISTH Cool) and 5.3.2 (For ISTH Heat)
4. Allow unit to heat up for the designated time stated in table.
5. Using the thermometer, record the temperature of the unit.
6. Ensure that the temperature measurement is between the allowable tolerances as defined in Tables 5.3.1 and 5.3.2. 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.

Table 5.3.1 (For ISTH Cool)

	Temp. Input	Speed Input	Allowable Tolerance	Heating / Cooling Time
Test 1	0°C	0 RPM	0°C - 13°C below ambient	30 minutes
Test 2	15°C	0 RPM	14°C - 16°C	30 minutes
Test 3	45°C	0 RPM	44.5°C – 45.5°C	30 minutes
Test 4	70°C	0 RPM	68°C - 72°C	30 minutes
Test 5	100°C	0 RPM	98°C - 102°C	30 minutes

Table 5.3.2 (For ISTH Heat)

	Temp. Input	Speed Input	Allowable Tolerance	Heating / Cooling Time
Test 1	45°C	0 RPM	44.5°C – 45.5°C	30 minutes
Test 2	70°C	0 RPM	68°C - 72°C	30 minutes
Test 3	100°C	0 RPM	98°C - 102°C	30 minutes

Speed Testing

Additional instruments required:

1. Digital Tachometer Extech model # 461920 / 461825 or equivalent.
2. Reflective tape.



Images left to right: Extech Tachometer #461920, Extech Tachometer #461825, Placement location of the reflective tape on block as circled in red.

Testing Procedure:

1. Attach desired Test block & verify desired block displayed on screen. (See below for table of block and maximum speed capacity of the block).
2. Attached reflected tape on the front right side of the block as shown in the third picture above.
3. Input speed testing for each test as defined in table 5.3.3 (for ISTH Cool) & table 5.3.4 (for ISTH Heat).
4. Allow unit to run for the designated time stated in table.
5. Using the tachometer, measure speed as by aiming at the reflective tape.
6. Ensure that the speed measurement is between the allowable tolerances as defined in Tables 5.3.3 & 5.3.4. If speed is outside of the allowable range, record deviation in Section 5.6 OQ Deviation Log.

Table 5.3.3 (for ISTH Cool Only, below speed setting are based on 0.5mL Tube Block)

	Speed Input	Temp. Input	Allowable Tolerance	Time
Test 1	300 RPM	0°C	290 – 310 RPM	30 minutes
Test 2	1000 RPM	100°C	980 – 1020 RPM	20 minutes
Test 3	1500 RPM	0°C	1470 – 1530 RPM	20 minutes
Test 4	2500 RPM	100°C	2450 – 2550 RPM	20 minutes
Test 5	3000 RPM	0°C	2940 – 3060 RPM	60 minutes

Table 5.3.4 (for ISTH Heat Only, speed settings below are based on 0.5mL Tube Block)

	Speed Input	Temp. Input	Allowable Tolerance	Time
Test 1	300 RPM	30°C	290 – 310 RPM	30 minutes
Test 2	1000 RPM	100°C	980 – 1020 RPM	20 minutes
Test 3	1500 RPM	30°C	1470 – 1530 RPM	20 minutes
Test 4	2500 RPM	100°C	2450 – 2550 RPM	20 minutes
Test 5	3000 RPM	30°C	2940 – 3060 RPM	60 minutes

Table 5.3.5 Other blocks & maximum speed settings

Block	Max. Speed
384 Well Plate Block	1400 RPM
0.2mL PCR Plate Block	1400 RPM
0.5mL Tube Block	3000 RPM
1.5mL Tube Block	2200 RPM
2.0mL Tube Block	2200 RPM
15mL Conical Tube Block	800 RPM
50mL Conical Tube Block	800 RPM
Microplate Thermal Block	2400 RPM
5mL Eppendorf Tube Block	2200 RPM

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 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: _____

5.6 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
Switch toggle switch to "ON"	Verify splash screen turns on and brand matches on the front panel	☐ Pass ☐ Fail	
Temperature setup	Touch the far-left box to bring up the Temperature Setting Window. Touch the digit you wish to change the digit will be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Temperature can adjust in 0.1°C increments. Once the value for the temperature setting is complete, touch "set". To turn off temperature control, touch the temperature box and touch "off".	☐ Pass ☐ Fail	
Speed setup	Touch the center box to bring up the Speed Setting Window. Touch the digit you wish to change the digit will be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Speed can adjust in 10-RPM increments. Once the value for the speed setting is complete, touch "set". To turn off speed control, touch the RPM box and touch "off".	☐ Pass ☐ Fail	
Timer setup	Touch the right box to bring up the Time Setting Window. Touch the digit you wish to change the digit will now be highlighted and ready to set. Tap the number above or below the blue box to select the desired value. Time can adjust in 1-minute increments. Once the value for the time setting is complete, touch "set".	☐ Pass ☐ Fail	

	Touching the “clear” button will allow the unit to run continuously while counting elapsed time.		
Turn off unit	Switch toggle switch to “OFF”	☐ Pass ☐ Fail	

6.3 Specification Test

Temperature Testing

Additional instruments required:

1. *Fluke* digital thermometer model # 52I / 52II, or equivalent
2. *OMEGA* Type K temperature probe model # 5SC-GG-K-30 or equivalent, three probes required



Images left to right: Omega temperature probe, Fluke digital thermometer, 1.5mL Accessory Block

Testing Procedure:

1. Attach 1.5mL accessory block and verify "1.5/2.0" displays on screen.
2. Place test probes into the three positions shown in the third photo above. Thermocouple should be installed at the bottom of the well and secured with an empty vial (1.5mL test tube).
3. Input temperature settings for each test as defined in table 6.3.1 (For ISTH Cool) and 6.3.2 (For ISTH Heat)
4. Allow unit to heat up for the designated time stated in table.
5. Using the thermometer, record the temperature of the unit.
6. If the temperatures are within the allowable range, note the date PQ testing was performed in Section 6.4 PQ Activity Log
7. If 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.

Table 6.3.1 (For ISTH Cool)

	Temp. Input	Speed Input	Allowable Tolerance	Heating / Cooling Time
Test 1	0°C	0 RPM	0°C - 13°C below ambient	30 minutes
Test 2	15°C	0 RPM	14°C - 16°C	30 minutes
Test 3	45°C	0 RPM	44.5°C – 45.5°C	30 minutes
Test 4	70°C	0 RPM	68°C - 72°C	30 minutes
Test 5	100°C	0 RPM	98°C - 102°C	30 minutes

Table 6.3.2 (For ISTH Heat)

	Temp. Input	Speed Input	Allowable Tolerance	Heating / Cooling Time
Test 1	45°C	0 RPM	44.5°C – 45.5°C	30 minutes
Test 2	70°C	0 RPM	68°C - 72°C	30 minutes
Test 3	100°C	0 RPM	98°C - 102°C	30 minutes

Speed Testing

Additional instruments required:

1. Digital Tachometer Extech model # 461920 / 461825 or equivalent.
2. Reflective tape.



Images left to right: Extech Tachometer #461920, Extech Tachometer #461825, Placement location of the tape on block, circled in red.

Testing Procedure:

1. Attach desired test block & verify selected block displayed on the screen. (See table 6.3.5 below for additional blocks and maximum speed capacities).
2. Attached reflected tape on the front right side of the block as shown in the third picture above.
3. Input speed testing for each test as defined in table 6.3.3 (for ISTH Cool) & table 6.3.4 (for ISTH Heat).
4. Allow unit to run for the designated time stated in table.
5. Using the tachometer, measure speed as demonstrated by aiming at the reflective tape.
6. If the speeds are within the allowable range, note the date PQ testing was performed in Section 6.4 PQ Activity Log
7. If speed is outside of the allowable range, record deviation in Section 6.5 PQ Deviation Log.

Table 6.3.3 (for ISTH Cool Only, below speed setting are based on 0.5mL Tube Block)

	Speed Input	Temp. Input	Allowable Tolerance	Time
Test 1	300 RPM	0°C	290 – 310 RPM	30 minutes
Test 2	1000 RPM	100°C	980 – 1020 RPM	20 minutes
Test 3	1500 RPM	0°C	1470 – 1530 RPM	20 minutes
Test 4	2500 RPM	100°C	2450 – 2550 RPM	20 minutes
Test 5	3000 RPM	0°C	2940 – 3060 RPM	60 minutes

Table 6.3.4 (for ISTH Heat Only, below speed setting are based on 0.5mL Tube Block)

	Speed Input	Temp. Input	Allowable Tolerance	Time
Test 1	300 RPM	30°C	290 – 310 RPM	30 minutes
Test 2	1000 RPM	100°C	980 – 1020 RPM	20 minutes
Test 3	1500 RPM	30°C	1470 – 1530 RPM	20 minutes
Test 4	2500 RPM	100°C	2450 – 2550 RPM	20 minutes
Test 5	3000 RPM	30°C	2940 – 3060 RPM	60 minutes

Table 6.3.5 Additional blocks & maximum speed settings

Block	Max. Speed
384 Well Plate Block	1400 RPM
0.2mL PCR Plate Block	1400 RPM
0.5mL Tube Block	3000 RPM
1.5mL Tube Block	2200 RPM
2.0mL Tube Block	2200 RPM
15mL Conical Tube Block	800 RPM
50mL Conical Tube Block	800 RPM
Microplate Thermal Block	2400 RPM
5mL Eppendorf Tube Block	2200 RPM

6.4 Performance Qualification Activity Log

Log all PQ tests performed in the tables below and check whether the tests were a pass or fail. If the test was a failure, record the failure in the following PQ deviation section. Record notes as applicable.

[illegible]

6.5 Performance Qualification 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	

6.6 Performance Qualification Completion

Performance qualification has been performed, reviewed, and approved according to the procedures outlined in this section. All results meeting the specified parameters.

Results

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

Comments: _____

Performed by

Name _____

Department _____

Signature _____

Date _____

Reviewed by

Name _____

Department _____

Signature _____

Date _____

7.1 Training Log of Users

[illegible][illegible]

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	

