

EQUIPMENT QUALIFICATION

Incubating Rocking/Waving Shaker

Design, Installation, Operation and Performance



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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 Incubating Rocking/Waving Shakers. 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) – 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	

Incubating Rocking/Waving 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 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

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

Table 4.5.1

Item	Included in Delivery	Notes
Incubating Rocking/Waving Shaker	☐ Yes ☐ No ☐ N/A	
Power Cable	☐ Yes ☐ No ☐ N/A	
Instruction Manual (230V available on VWR.com)	☐ Yes ☐ No ☐ N/A	
Rubber Tray Mat	☐ 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)		
Safety Guide (230V models)		
Purchase order		
Delivery Documents		

4.7 Site Requirement

The proper performance of the equipment relies on installation of the unit in the appropriate environment. Environment 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 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)

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.

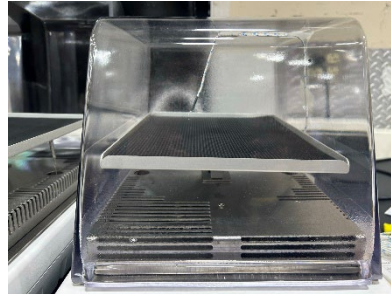
Test Parameter	Acceptance Criteria	Status	Comments
Plug in Power Cord	The Standby indicator light will illuminate, verifying power to the unit.	☐ Pass ☐ Fail	
Press Standby Button	The standby indicator light will turn off and the temperature, speed & timer displays will illuminate.	☐ Pass ☐ Fail	
Temperature setup	Making sure the temperature will adjust by press the up/down arrows below the temperature display.	☐ Pass ☐ Fail	
Tilt setup	Press speed / tilt button below the speed display. Making sure the angle will adjust by press the up/down arrows below the Speed display.	☐ Pass ☐ Fail	
Speed setup	Making sure the speed will adjust by press the up/down arrows below the speed display.	☐ Pass ☐ Fail	
Timer setup	Making sure the timer will adjust by press the up/down arrows below the time display.	☐ Pass ☐ Fail	
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	press the standby button. The temperature, speed and time displays will be blank, the standby indicator light will illuminate.	☐ Pass ☐ Fail	

5.3 Specification Tests

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



Images left to right: K Type temperature probe, Fluke digital thermometer, Location of the temperature probe.

Testing Procedure:

1. Place temperature probe on the center of the unit (on the lid). The end of the temperature probe should be placing no more then 1-1/2" down.
2. Input temperature settings for each test as defined in table 5.3.1.
3. Allow unit to heat up for the designated time stated in table.
4. Verify the actual temperature is equal to the set temperature if the unit has not reached its set temperature – wait 5 minutes and check again.
5. Using the thermometer, measure temperature as demonstrated in table 5.3.1
6. Ensure that the temperature measurement is between the allowable tolerances as defined in Tables 5.3.1. 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.

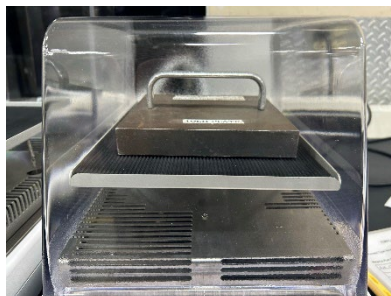
Table 5.3.1

	Temp. Input	Allowable Tolerance	Heating Time
Test 1	37°C	35°C - 39°C	60minutes
Test 2	65°C	61°C - 67°C	60 minutes

Speed Testing

Additional instruments required:

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



Images left to right: Extech Tachometer, reflective tape, Location of the tape.

Testing Procedure:

1. Leave the lid open during speed testing. Add reflective tape in the corner of the tray as shown in the image above.
2. Input speed & tilt setting testing for each test as defined in table 5.3.2. Test 1 & 2 are for rocking shakers and Test 3 & 4 are for waving Shakers.
3. Allow unit to run for the designated time stated in table.
4. Using the tachometer, measure speed as demonstrated in table 5.3.2.
5. Ensure that the speed measurement is between the allowable tolerances as defined in Tables 5.3.2. If speed is outside of the allowable range, record deviation in Section 5.6 OQ Deviation Log.

Table 5.3.2

	Speed Input	Allowable Tolerance	Time
Test 1	10 RPM	9 RPM – 11 RPM	5 minutes
Test 2	50 RPM	49 RPM – 51 RPM	5 minutes
Test 3	10 RPM	9 RPM – 11 RPM	5 minutes
Test 4	30 RPM	29 RPM – 31 RPM	5 minutes

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 meeting 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	The Standby indicator light will illuminate, verifying power to the unit.	☐ Pass ☐ Fail	
Press Standby Button	The standby indicator light will turn off and the temperature, speed & timer displays will illuminate.	☐ Pass ☐ Fail	
Temperature setup	Making sure the temperature will adjust by press the up/down arrows below the temperature display.	☐ Pass ☐ Fail	
Tilt setup	Press speed / tilt button below the speed display. Making sure the angle will adjust by press the up/down arrows below the Speed display.	☐ Pass ☐ Fail	
Speed setup	Making sure the speed will adjust by press the up/down arrows below the speed display.	☐ Pass ☐ Fail	
Timer setup	Making sure the timer will adjust by press the up/down arrows below the time display.	☐ Pass ☐ Fail	

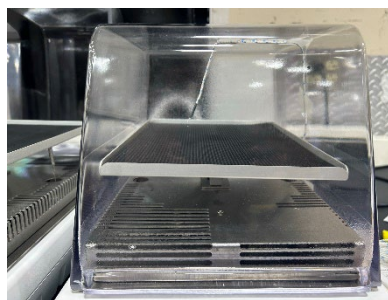
Turn off unit	Press the standby button. The temperature, speed and time displays will be blank, the standby indicator light will illuminate.	☐ Pass ☐ Fail	
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6.3 Specification Test

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



Images left to right: K Type temperature probe, Fluke digital thermometer, Location of the temperature probe.

Testing Procedure:

1. Place temperature probe on the center of the unit (on the lid). The end of the temperature probe should be placed no more than 1-1/2" down.
2. Input temperature settings for each test as defined in table 6.3.1.
3. Allow unit to heat up for the designated time stated in table.
4. Verify the actual temperature is equal to the set temperature if the unit has not reached its set temperature – wait 5 minutes and check again.
5. Using the thermometer, measure temperature as demonstrated in table 6.3.1
6. Ensure that the temperature measurement is between the allowable tolerances as defined in Tables 6.3.1.
7. If the temperature are within the allowable range, note the date PQ testing was performed in Section 6.4 PQ Activity Log
8. If the temperature is outside of the allowable range, record deviation in Section 6.5 PQ Deviation Log.

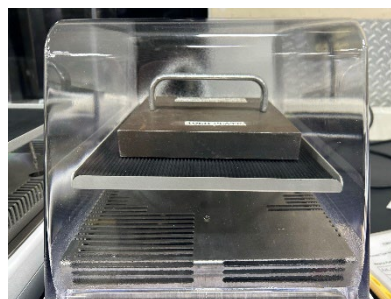
Table 6.3.1

	Temp. Input	Allowable Tolerance	Heating Time
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Speed Testing

Additional instruments required:

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



Images left to right: Extech Tachometer, reflective tape, Location of the tape.

Testing Procedure:

1. Leave the lid open during speed testing. Add reflective tape in the corner of the tray as shown in the image above.
2. Input speed & tilt setting testing for each test as defined in table 6.3.2. Test 1 & 2 are for rocking shakers and Test 3 & 4 are for waving Shakers.
3. Allow unit to run for the designated time stated in table.
4. Using the tachometer, measure speed as demonstrated in table 6.3.2.
5. Ensure that the speed measurement is between the allowable tolerances as defined in Tables 6.3.2.
6. If the speed 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 6.3.2

	Speed Input	Allowable Tolerance	Time
Test 1	10 RPM	9 RPM – 11 RPM	5 minutes
Test 2	50 RPM	49 RPM – 51 RPM	5 minutes
Test 3	10 RPM	9 RPM – 11 RPM	5 minutes
Test 4	30 RPM	29 RPM – 31 RPM	5 minutes

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]

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. Appendices

7.1 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	
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	
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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	

