Equipment Validation Guide

Installation/Operational/Performance Qualification

Refrigerators

360410/B

Contents

About this Guide

The equipment validation guide has been developed to provide the end user documented evidence that their device has been installed correctly and is operating as intended.

⚠ ***Warning: To avoid injury—before using the equipment, read all instructions in the associated operation and service manuals.***

Validation Applicability

Upon receipt of new equipment; when existing equipment is modified; when service is performed that will affect critical operating functions; or when equipment is moved to a new location, perform the validation procedures in the following chapters. Record the product model number, version letter, and serial number below, as displayed on the product specification label.

- Model: _____
- Serial number: _____

Validation Responsibility

The end user of Helmer equipment; an individual within the end user's organization; or an individual or organization designated by the end user is responsible for the execution, review, filing, maintenance, and approval of any validation (and specifically, performance qualification) deemed appropriate by the end user's organization. Acceptable outcomes as manifested in the validation documentation are those defined by the end user's organization.

Required Documents

- Installation and operational qualification instructions (included within this document), and user-generated performance qualification
- Helmer equipment operation and service manuals

➤ The operation and service manuals can be downloaded from Helmer's website (info.helmerinc.com/manuals).

Installation Qualification

Installation qualification demonstrates that the equipment is properly installed in environmental conditions that meet Helmer's specifications. The installation qualification must be completed prior to execution of the operational qualification phase.

Operational Qualification

Operational qualification demonstrates that the installed equipment is functioning within established limits as specified by Helmer. The operational qualification must be completed prior to the execution of the performance qualification phase.

Performance Qualification

Performance qualification demonstrates that the equipment performs as expected for its intended use in the processes established by the end user's facility and that the output meets the facility's specifications. It evaluates the adequacy of the equipment as used in specific processes that rely on the facility's own personnel, procedures, and supplies, in a normal working environment.

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Chapter 1: Installation Qualification

Objective: To show that the equipment has been installed in compliance with Helmer's Technical specifications and requirements.

➤ Perform the installation qualification using the checklist below.

Location	
Grounded outlet(s) meets electrical requirements on the product specification label	YES NO
Unit is clear of extreme temperature sources (including direct sunlight and HVAC vents)	YES NO
Minimum of 8" (200mm) unobstructed space above unit (upright units and ante-room side of pass-thru units only)	YES NO n/a
Minimum 0" clearance above clean room side (pass-thru units only)	YES NO n/a
Minimum of 3" (80mm) unobstructed space behind unit	YES NO
Minimum 0" clearance between cabinet and wall (pass-thru units only)	YES NO n/a
Floor is level (to allow door self-closing and proper drainage from evaporator)	YES NO
Operating conditions as stated in the Operation Manual or Instructions for Use for ambient temperature and relative humidity are met	YES NO

Prior to Power-Up	
Unit is at room temperature	YES NO
i.Series rechargeable backup battery for the monitoring system is installed and switched ON	YES NO n/a
Horizon Series 9 V backup battery for the monitoring system is installed and connected	YES NO n/a
Probe is properly secured in solid ballast (if equipped)	YES NO n/a
Probe bottle(s) contain glycerin solution (if equipped)	YES NO n/a
Probes are immersed 2" (51mm) into glycerin solution (if equipped)	YES NO n/a
Product model number and serial number have been recorded	YES NO
Power cord strain relief is installed	YES NO n/a
Casters are locked (if equipped)	YES NO n/a

Power Source		Acceptable
Test and record outlet voltage and frequency	_____ Volts (± 10%) _____ Hz	YES NO

Power Connection	
Power cord is plugged directly into a grounded outlet	YES NO
ON/OFF AC power switch is switched ON	YES NO
The display initializes	YES NO

Acceptable results (if all answers are Yes or n/a)

Results acceptable (initial): _____ Not acceptable (initial): _____

Not Acceptable / Corrective Action

Performed by (print): _____

Signature: _____ Date: _____

Reviewed by (print): _____

Signature: _____ Date: _____

Accept (initial): _____ Reject (initial): _____

Chapter 2: Operational Qualification

Objective: To show that operational functions, when tested, meet Helmer's specifications and/or requirements under stated conditions of use as stated in the Operation Manual or Instruction for Use.

➤ Perform the installation qualification prior to performing the operational qualification.

Note: The following settings correspond with Helmer default values for the equipment. These settings may be different than settings specified by the end user's organization.

Note: Operational qualification may be modified or expanded to meet organizational requirements.

Record the serial number of the independent thermometer used for testing: _____

Start-Up	Observations	Acceptable
Chamber temperature pulls down to temperature setpoint		YES NO

Note: Temperature setpoint is +4.0 °C for blood bank and laboratory refrigerators of +5.0 °C for pharmacy models.

Installation	Observed	Default	Acceptable	New Setting
Check high chamber temperature alarm setpoint		+5.5 °C *or* +6.5 °C	YES NO	
Check low chamber temperature alarm setpoint		+1.5 °C *or* 2.0 °C	YES NO	

Note: Low temperature alarm setpoint is +1.5 °C for blood bank refrigerators and +2.0 °C for laboratory/pharmacy models. High temperature alarm setpoint is +5.5 °C for blood bank and laboratory refrigerators or +6.5 °C for pharmacy models. Refer to the product service manual for instructions in changing the temperature alarm setpoints.

Chamber Temperature	Measured	Observed	Default	Acceptable	New Setting
Chamber temperature (after temperature stabilization)			+4.0 °C *or* +5.0 C	YES NO	

Note: Measure the chamber temperature with an independent thermometer after the chamber temperature has reached the setpoint.

Calibration	Measured	Observed	Default	Acceptable	New Setting
Check primary monitor probe temperature reading			VARIES	YES NO n/a	
Check secondary monitor probe temperature reading			VARIES	YES NO n/a	

Note: The default calibration value varies. Calibrate chamber probes (if necessary) to match the temperature reading recorded by an independent thermometer. Refer to the product service manual for instructions in calibrating the chamber probe(s), if equipped.

Note: Secondary probe setting does not apply to the following units:

- **i.Series** undercounter refrigerators
- **Horizon Series** upright, undercounter and pass-thru refrigerators

Testing	Observed	Default	Acceptable	New Setting
Check **i.Series** compressor temperature alarm setpoint		+50.0 °C	YES NO	
Check **i.Series** power failure alarm time delay		1 min ± 5 sec	YES NO n/a	
Perform door alarm test (change duration if desired, then test)		3 min ± 5 sec	YES NO	
Perform high temperature alarm test		+5.5 °C *or 6.5 °C*	YES NO	
Perform low temperature alarm test		+1.5 °C *or* 2.0 °C	YES NO	
Perform **i.Series** power failure alarm test		Display/audio [1]	YES NO n/a	
Perform **Horizon Series** power failure alarm test		Display/audio [2]	YES NO n/a	

Note: Low temperature alarm setpiont is +1.5 °C for blood bank refrigerators and +2.0 °C for laboratory/pharmacy models. High temperature alarm setpoint is +5.5 °C for blood bank and laboratory refrigerators or +6.5 °C for pharmacy models. Refer to the product service manual for instructions in changing the temperature alarm setpoints.

1 *"Power Failure"* message is displayed with audible alarm.

2 *"PoFF"* message is displayed with audible alarm.

Acceptable results (if all answers are Yes or n/a)

Results acceptable (initial): _____ Not acceptable (initial): _____

Not Acceptable / Corrective Action

Performed by (print): _____

Signature: _____ Date: _____

Reviewed by (print): _____

Signature: _____ Date: _____

Accept (initial): _____ Reject (initial): _____

Chapter 3: Performance Qualification

Objective: To demonstrate the equipment consistently produces acceptable outcomes under normal operating conditions in the end user's facility.

➤ Perform the installation qualification first, the operational qualification second, followed by the performance qualification.

Note: The following is a general outline of suggested topics for inclusion in an organization's performance qualification validation plan, to be developed in detail by the appropriate personnel within the end user's organization. The performance qualification validation plan is used to test the equipment against the organization's user requirement specification, under simulated real-world operating and usage conditions.

- Purpose and scope
- Action description
- Expected outcomes
- Actual outcomes
- Acceptance and rejection of outcomes by an authorized reviewer
- Outcome failure and problem resolution

Purpose and Scope

The reason(s) for performing a specific test case(s) for the purpose of performance qualification. In addition, the scope describes the parameters of each performance qualification test case, and whether the test case applies to a single or multiple validation tasks.

Action Description

This item is usually instruction on how to perform the validation test case(s). In general, other documentation, such as standard operating procedures, manuals, or training guides are required or otherwise referred to for such instruction.

Expected Outcomes

This section describes the expected validation test case(s) outcome(s).

Actual Outcomes

Space in the performance qualification is needed to record the actual results of test case outcomes, and any calculations, comments, or other pertinent information. In general, an operator permanently documents the actual results, often as either **pass** or **fail**. Should a test case result fail, the operator then refers to the appropriate problem resolution protocol used by end user's organization.

Acceptance and Rejection of Outcomes by an Authorized Reviewer

This section is a short comparison or summary of the actual outcomes when compared to the expected outcomes. The reviewer permanently documents the review of the actual outcome(s) as either **accept** or **reject**, and then refers to the appropriate problem resolution protocol in case of rejection.

Outcome Failure and Problem Resolution

Where expected outcomes are not achieved, then an outcome failure has occurred. Outcome failures result from numerous sources. On an outcome failure or rejection, the operator and the reviewer must refer to the appropriate problem resolution protocol(s) to document the corrective action(s) taken as well as the subsequently expected outcome(s) from corrective action(s). Finally, the reviewer permanently documents the actual outcome(s) of the corrective action(s), as either **accept** or **reject**. Actions beyond this point are a matter of protocol pertinent to end user's organization.

Acceptable results (if all answers are Yes or n/a)

Results acceptable (initial): _____ Not acceptable (initial): _____

Not Acceptable / Corrective Action

Performed by (print): _____

Signature: _____ Date: _____

Reviewed by (print): _____

Signature: _____ Date: _____

Accept (initial): _____ Reject (initial): _____

Chapter 4: Support and Other Information

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Operation and Service Manuals

Manuals are available at info.helmerinc.com/manuals.

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