Equipment Validation Guide

Installation/Operational/Performance Qualification

Pro Line Platelet Incubators

360412/A

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, 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

Note: The operation and service manuals were shipped with the product on a CD.

➤ 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	
Packaging materials and shipping inserts have been removed	YES NO
Grounded outlet(s) meets electrical requirements on the product specification label	YES NO
Rear standoff brackets have been installed	YES NO
Unit is clear of extreme temperature sources (including direct sunlight and HVAC vents)	YES NO
Minimum 24” (610 mm) above for ambient temperatures of 28 °C to 35 °C	YES NO n/a
Minimum 4” (102 mm) above for ambient temperatures of 15 °C to 28 °C	YES NO n/a
Minimum 12” (305 mm) behind for ambient temperatures of 28 °C to 35 °C	YES NO n/a
Minimum 4” (102 mm) behind for ambient temperatures of 15 °C to 28 °C	YES NO n/a
Unit is placed on a stable, sturdy, level surface	YES NO
Operating conditions as stated in the operation manual for ambient temperature and relative humidity are met	YES NO

Prior to Power-Up	
Verify incubator compatibility with agitator model	YES NO n/a
Pro Line Agitator is installed in an **Pro Line** incubator	YES NO n/a
Unit is at room temperature	YES NO
Pro Line backup battery for the monitoring system is installed and connected	YES NO n/a
Pro Line backup battery for the motion alarm is installed and connected	YES NO n/a
Full system backup battery is connected (PC100 - Pro; if installed)	YES NO n/a

Power Connection	
Power cord is plugged directly into incubator	YES NO
Power cord is plugged directly into a grounded outlet	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.

➤ 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 reaches the temperature setpoint		YES NO

Installation	Observed	Default	Acceptable	New Setting
Check high chamber temperature alarm setpoint		+24.0 °C	YES NO	
Check low chamber temperature alarm setpoint		+20.0 °C	YES NO	
Check **Pro Line** heat pump 1 alarm setpoint		+50.0 °C	YES NO	

Note: 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)			+22.0 °C	YES NO	

Note: Measure the chamber temperature with an independent thermometer after the cabinet temperature has reached the setpoint. Refer to the product service manual for instructions in calibrating the primary monitor probe and correct placement of the independent thermometer.

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

Note: The default calibration value varies. Calibrate the primary monitor probe (if necessary) to match the temperature reading recorded by an independent thermometer. Refer to the product service manual for instructions in calibrating the primary monitor probe and correct placement of the independent thermometer.

General Operational Testing	Observed	Default	Acceptable	New Setting
Check **Pro Line** 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		+24.0 °C	YES NO	
Perform low temperature alarm test		+20.0 °C	YES NO	

Power Alarm Testing	Observations	Acceptable
Perform **Pro Line** power failure alarm test [1]		YES NO n/a
Perform **Pro Line** no battery alarm test [2]		YES NO n/a

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

2 *"No Battery"* message is displayed.

Note: No battery alarm test is not applicable for PC100 -Pro with optional full system battery back-up.

Motion Alarm Testing	Observations	Acceptable
Perform the Agitator 1 motion alarm test [1]		YES NO n/a

1 *"Agitator 1 Low Speed"* message is displayed with audible alarm.
Applies to any **Pro Line** incubator with an **Pro Line** agitator installed as "Agitator 1".

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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 review 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

Contact Helmer

U.S. and Canada
Technical Service techservice@helmerinc.com
Customer Service sales@helmerinc.com

HELMER SCIENTIFIC
14400 Bergen Boulevard
Noblesville, IN 46060 USA

PH +1.317.773.9073
FX +1.317.773.9082
Toll Free 800.743.5637 (U.S. and Canada)

www.helmerinc.com

Outside U.S. and Canada
Contact a distributor or intlsales@helmerinc.com

Operation and Service Manuals

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

Helmer Scientific
14400 Bergen Boulevard, Noblesville, IN 46060 USA

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