

Validation Protocols for Laboratory Equipment Qualification

Multi- Qualification and validation services

Thermo Fisher Scientific helps you keep pace with the growing challenges facing today's labs. Our specialty is helping you to improve your productivity while meeting today's regulatory compliance needs. Our equipment qualification and validation service supports a broad range of equipment types.

Our suite of validation option packages will ensure that you comply with applicable Installation, Operational and Performance Qualification standards (IQ/OQ/PQ). Our certified validation engineers will verify that your equipment meets designated acceptance criteria at time of installation and throughout its operational life. We can provide you with all the supporting documentation you need to meet today's increasingly stringent regulatory requirements.

Why Thermo Scientific?

- Peace of mind... As the manufacturer, we should be the preferred supplier to validate your Thermo Scientific product.
- Time saving and convenient... Validation can be planned and scheduled for you at the time of instrument purchase or at a later date to meet your project timeline.
- Exclusive validation warranty policy... As product manufacturer, we can offer you our exclusive re-validation policy. If we validate your Thermo Scientific product and it experiences any failure during warranty period, we cover the cost of any subsequent re-validation at no further charge.
- Cost Saving... Discounts apply to validation and other services for Thermo Scientific service contract customers.

Worldwide support

Compliance services can be arranged in all major countries across the world for the following product lines:

- | | | |
|---|---------------------|------------------------------|
| • Centrifuges | • Ovens | • CO ₂ incubators |
| • Freezers | • Lab Refrigerators | • Cryomed freezers |
| • Freeze dryers | • LN ₂ | • Vacuum concentrators |
| • Shakers | • Thermocycler PCR | • Autoclaves |
| • Laminar-flow cabinets | | |
| • Biological safety cabinets (Type I and Type II NF, EN, & NSF) | | |

Contact your Thermo Fisher representative to learn more about these services or to develop a customized plan to meet your specific needs.

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Other Asian countries +852 2885 4613

Countries not listed: +49 6184 90 6940 or +33 2 2803 2000

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BRO-TLS-Compliance-0007

Qualification on Incubator

Qualification operation list

- Qualification protocol review and approval
- Qualification content review
- Verifier and client responsibilities review

Installation qualification content list* - Protocol E89003212 DELIVERED WHEN IQ / OQ ORDERED

- Reference instrument required:
(Calibrated at the "setting" with uncertainty at least 2 times better than the "acceptance criteria")
 - o Thermometer for ambient air temperature
 - o Multimeter for main voltage and hertz
- Verification of order form and deliveries
- Verification of goods received
- Verification of installation site and ambient condition
- Verification of equipment power supply
- Verification of equipment and associated accessories installation
- Verification of equipment power on
- Delivery of user training if requested
- List of components, service contract and documentation
- Test equipment calibration certificate or verification report
- Verifier training certificate
- Installation qualification report review and approval

*** For additional test, please contact us**

Qualification on Incubator

Operational qualification content list* - Protocol E89003213 DELIVERED WHEN IQ / OQ or IQ / OQ / PQ or MQ ORDERED

- Reference instrument required:
(Calibrated at the "setting" with uncertainty at least 2 times better than the "acceptance criteria")
 - o 1 probe temperature thermometer
- Verification of the general functionalities
- Verification of the alarms
- Verification of the unit temperature instrumentation, against here under specification, placing a calibrated reference probe at the center of the chamber
- Adjustment (calibration) if required
- Test equipment calibration certificate or verification report
- Verifier authorization certificate
- Operational qualification report review and approval

Product	Setting	Acceptance criteria
Cold Incubator	Default set temperature	+/-1 °C
Microbiology Incubator	+37 °C	+/-0,5 °C
Hybridization Incubator	+37 °C	+/-0,5 °C

The unit passes the test if, at the setting, the difference between the average unit display and the corrected average reference display is within the above specified acceptance criteria.

*** For additional test, please contact us**

Qualification on Incubator

Performance qualification content list* - Protocol E89003469 DELIVERED WHEN IQ / OQ / PQ ORDERED

- Reference instrument required:
(Calibrated at the "setting" with uncertainty at least 2 times better than the "acceptance criteria")
 - o Multi probes temperature thermometer & data logger
 - o Computer
- Customer specific test condition requirements, here under default values, review and approval to perform the following:
 - o Verification of the temperature stability and homogeneity performance at stable operation (including temperature mapping - max 15 probes, max 24 hours)
 - o Verification of the temperature stability and homogeneity after a door opening (including temperature mapping)
 - o Verification of the temperature stability and homogeneity during a power failure (including temperature mapping)
- Test equipment calibration certificate or verification report
- Verifier authorization certificate
- Performance qualification report review and approval

Product	Setting	Acceptance criteria	Test condition
Cold Incubator	+22,5 °C	[+20 °C, +25 °C]	9 probes (corners and center at 10% from the walls) Probes placed in air Acquisition interval 1min Acquisition duration from 30min to 24hours at stable operation Empty unit test condition
Microbiology Incubator	+37 °C	[+36 °C, +38 °C]	
Hybridization Incubator	+37 °C	[+36 °C, +38 °C]	

* For additional test, please contact us

SPECIFICATION SHEET

E89003499f

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Qualification on Incubator

Catalogue number

Product	Qualification	Document English	Package English
Incubator	IQ / OQ	IOQDOCE89003499	Please contact your local Thermo Fisher representative
	IQ / OQ / PQ	IOPQDOCE89003499	
	MQ	OQDOCE89003499	

Document] You receive the qualification binder customized for your equipment (protocols included), you complete the document.

Package] The local Thermo Fisher Scientific representative authorized verifier completes the customized document on site (document and labor included).

Change control

Version	Author	Date	Summary of Change
a	Benoit Limon	01-Jan-06	Original Document
b	Benoit Limon	15-Nov-06	Reformatting lay out
c	Benoit Limon	21-Dec-06	Added test equipment
d	Benoit Limon	14-Fev-07	Reformatting lay out
e	Benoit Limon	27-Apr-07	MQ reference added
f	Benoit Limon	17-Mar-08	Deleting RH section Deleting Environmental incubator

SPECIFICATION SHEET

E89003499f

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Qualification on Incubator

Customer overall responsibilities:

Provide one dedicated professional representative to obtain all necessary records and documentation
Provide and assure ready access to all relevant equipment, related documentation, work orders, etc
Provide training on the required policies and procedures
Provide with the appropriate workspace, computers and building access
Provide installation site meeting unit ambient condition requirements listed on user manual.
Approve all documents as soon as possible

Thermo Fisher Scientific qualification warranty policy:

Product Age & Qualification Performance	Repair Cost Responsibility	Re-Qualification Cost
Unit is under warranty, but failed the qualification test due to the unit	Thermo Fisher representative	Thermo Fisher representative
Passed qualification, but a performance component fails during warranty period	Thermo Fisher representative	Thermo Fisher representative
Not under warranty, not under service contract including qualification	Customer	Customer
Not under warranty, under service contract including qualification	Thermo Fisher representative	Thermo Fisher representative
Qualification test is interrupted due to customer intervention or power loss	---	Customer
<i>All other scenarios will be based on the discretion of Thermo Fisher Scientific representative Regional Service Manager & Qualification Manager</i>		

Customer signoff:

Customer reviewed / approved terms for qualification listed on that specification sheet:

Customer Name

Date

Customer Signature