Pipetting

Device qualification of the Finnpipette Novus electronic pipette (IQ/OQ/PQ)

Keywords

- Thermo Scientific Finnpipette Novus electronic pipette
- Device qualification
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Introduction

During device qualification, one verifies and documents whether the equipment, in this case a pipette, is reliable and capable of fulfilling the requirements of its intended use. All qualification activities are fully documented according to pertinent quality and regulatory requirements and signed by authorized personnel.

Installation qualification (IQ)

The main purpose of the IQ is to verify that the correct pipette has been delivered and that the electrical connections conform to the manufacturer's specifications and requirements.

IQ includes but is not limited to:

Verifications

- The catalog number on the label of the pipette shipping box corresponds to the purchase order.
- The pipette corresponds to the order specifications (volume range, number of channels, model).
- The catalog number stated on the Calibration Report corresponds to the purchase order.
- The serial number stated on the Calibration Report corresponds to the serial number on the pipette.
- The Instructions for Use corresponds to the purchased pipette model (either single channel or multichannel model as appropriate). The catalog number of the purchased model is stated in the Instructions for Use.
- The complete Thermo Scientific™ Finnpipette™

Novus™ product box contains the items stated in the Instructions for Use.

- The following environmental recommendations apply:
  - Operating temperature 15–35°C
  - Relative humidity during operation 20-85% and during storage 60 +/- 25%

Actions

- Confirm that the pipette charger is compatible with the local power supply and that the charger specifications correspond to the local power supply specifications.
- Fully charge the battery of the pipette, preferably for 2 hours, for the first charge.
- Confirm the existence of necessary SOPs (preventive maintenance, work instructions, etc.)
- Confirm that the required operator training has been conducted.

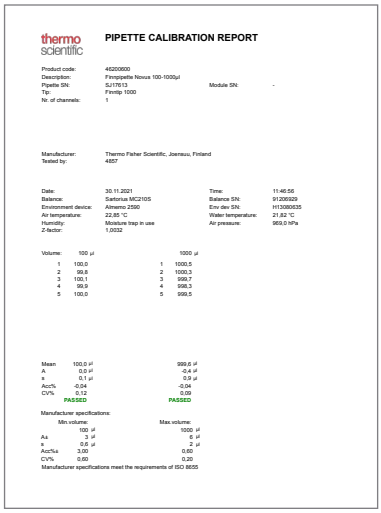
Operational qualification (OQ)

The OQ protocol verifies that the pipette is functioning in an acceptable manner. This includes testing the pipette to ensure that is capable of operating in accordance with the specifications and requirements defined by the manufacturer.

OQ shall be performed after IQ and shall be repeated throughout the life of the pipette and after service. OQ must be included in the SOPs.

OQ includes but is not limited to:

- Ensuring the pipette is operating properly by checking basic operations and functions defined in the Instructions for Use, e.g. the function of the display, tip ejector and menu.
- Verifying pipette operation either by the end user or by an authorized party, e.g. the manufacturer. The Calibration Report provided with the pipette verifies the OQ performed by the manufacturer. User verification should be performed in a controlled environment using water, e.g. in accordance with ISO 8655. We recommend that end users perform the verifications themselves because pipetting results obtained by the user may differ from the values stated in the Calibration Report.
- Ensuring repeatable results, the pipette must be regularly serviced according to the Instructions for Use.



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PIPETTE CALIBRATION REPORT

Product code: 46200600
Description: Finnpipette Novus 100-1000µl
Pipette SN: SJ17613
Tip: Finntip 1000
No. of channels: 1
Module SN: -

Manufacturer: Thermo Fisher Scientific, Joensuu, Finland
Tested by: 4857

Date: 30.11.2021
Balance: Sartorius MC210S
Environment device: Almemo 2590
Air temperature: 22,85 °C
Humidity: Moisture trap in use
Z-factor: 1,0032
Time: 11:46:56
Balance SN: 91206929
Env dev SN: H13080635
Water temperature: 21,82 °C
Air pressure: 969,0 hPa

Volume:	100 µl	1000 µl
1	100,0	1000,5
2	99,8	1000,3
3	100,1	999,7
4	99,9	998,3
5	100,0	999,5

Mean	100,0 µl	999,6 µl
A	0,0 µl	0,4 µl
s	0,1 µl	0,9 µl
Acc%	-0,04	-0,04
CV%	0,12	0,09
	PASSED	PASSED

Manufacturer specifications:

	Min volume:	Max volume:
	100 µl	1000 µl
As	3 µl	6 µl
s	0,5 µl	2 µl
Acc%s	3,00	0,60
CV%	0,60	0,20

Manufacturer specifications meet the requirements of ISO 8655

Example of Calibration Report.

Performance qualification (PQ)

The purpose of the PQ is to verify that the pipette is capable of properly accomplishing the task for its intended use. PQ relates to the daily use of the pipette and is designed to measure routine performance.

Note: Prior to shipment, the pipettes are tested under factory conditions. However, performance in a laboratory may vary due to temperature, pressure, humidity, operator, liquid, type of tip, etc. This should be taken into account when verification and validation tests are performed.

PQ includes but is not limited to:

- Determination by the user of the acceptance criteria required by the most critical pipette and tip application. Typically, this means setting acceptance limits for pipetting accuracy and precision and verifying that the pipette and tip fulfill these criteria.

Because the pipette typically is part of a broad application comprised of several instruments, system validation is recommended. This should be done after PQ has been performed for each instrument. In practice, system validation often requires the use of proven calibrators, samples or reference liquids.

Learn more at **thermofisher.com/finnpipette**

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