

Thermo Scientific iCE 3000 Series Validator Packages

Validator Packages for the Thermo Scientific iCE 3000 Series enable instrument verification for all stages of qualification. This ensures that your instrument is always operating to the optimum specification



Analytical laboratories are continuing to implement increasingly stringent compliance systems. In general, most laboratories operate internal systems and processes based on the requirements of, and normally formally accredited in accordance with, a standard such as ISO 9000, Good Laboratory Practice (GLP), or the requirements of an industry-specific body such as the US Food and Drug Administration (FDA). Whichever system is in place will, without doubt, include instrument and system suitability testing.

Often there is no assistance for analysts to determine and verify that an AA spectrometer is operating as it was designed to. This can cause confusion and uncertainty about the quality and reliability of results obtained. The documentation associated with this verification can be lengthy and incredibly time consuming to produce. This is where the unique Thermo Scientific Validator Packages can assist.

The Validator Packages provide the documentation and equipment needed to ensure that the spectrometer is operating to specifications set by the manufacturer. It is a step-by-step quality assurance examination designed to provide confidence for managerial and regulatory personnel that the system is under control and operating correctly.

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Validation Process

The process of validation is far greater than simply verifying the performance of instruments being used and extends to all areas of laboratory operation and management. The iCE 3000 Series Validator Packages can be used to help with verification of all stages of qualification.

Stages of AA Instrument Verification

The necessary stages which make up instrument verification are listed below with explanations of their function.

- **Specification Qualification and Design Qualification (SQ/DQ)**

Specification Qualification and Design Qualification provide evidence that quality is formally specified and designed into a product.

The Thermo Fisher Scientific Atomic Absorption Research & Development and Manufacturing facility have been awarded accreditation to the ISO 9001 Quality Standard. All Thermo Scientific iCE 3000 Series Atomic Absorption products are designed and manufactured in accordance with the requirements of this standard. ISO 9001 accreditation is regularly audited by accredited external assessors.

- **Installation Qualification (IQ)**

Installation Qualification requires that the equipment and control systems are checked against specified standards of operating environment, physical connection, safety parameters and functional parameters, prior to the initial utilization of the system.

- **Operational Qualification (OQ)**

Operational Qualification requires evidence that the equipment performs consistently, as specified, over the intended operating ranges and confirmation that the instrument is in calibration.

- **Performance Qualification (PQ)**

Performance Qualification requires evidence that the results of analyses performed on the installed instrument possess acceptable sensitivity, accuracy and short and long term precision.

The responsibility of these Qualification stages are outlined in Table 1.

Qualification Stage	Responsibility
Specification Qualification	Thermo Fisher Scientific
Design Qualification	Thermo Fisher Scientific
Installation Qualification	Thermo Fisher Scientific
Operational Qualification	On installation – Thermo Fisher Scientific Post Installation – Analyst / Customer
Performance Qualification	On installation – Thermo Fisher Scientific Post Installation – Analyst / Customer
Laboratory Validation Compliance	Analyst / Customer Organization

Table 1: Responsibilities for Verification processes

Validator Packages

There are 3 packages available, tailored to a particular configuration of instrument, each with a unique automated OQ functionality, comprehensive logbook, certified standard solutions and other necessary hardware.

iCE 3000 Series Flame AAS Validator Package – for use with flame systems.

iCE 3000 Series Graphite Furnace Validator Package – for use with furnace systems.

iCE 3000 Series Flame & Furnace Validator Package – for use with both flame and furnace systems.

(All packages require an appropriate accessory mount)

Time Saving Automated Operational Qualification

The work required to perform the OQ tests is dramatically reduced with the automated OQ functionality. This unique feature, included with all packages, allows OQ tests to be performed automatically with the use of a Calibrated Validation Unit (CVU). The CVU is an automated, motor-driven wheel of absorbance filters, mounted in to the spectrometer and controlled by the SOLAAR software. Testing can be carried out unattended and at a pre-set time as defined by the user. Imagine entering your laboratory first thing in a morning and finding that your AA has completed all the OQ tests and is ready to start work – how much time would you save? Results are automatically stored to a database and can be printed for inclusion in the Validator Logbook.

Comprehensive Validator Logbook

A full set of documentation for AA system verification is provided with the Validator Packages. The AA Validator Logbook is a comprehensive manual of the tools and operating procedures needed to achieve instrument verification. It contains detailed information on how to perform the required tests, and test record sheets on which to document the results. Test incident sheets are also included to document any encountered problems.

Dependable Certified Reference Standards

A set of master standards and a blank specific to the tests required are supplied. All standards are supplied with a traceable certificate of analysis.

Additional Hardware

To perform the OQ/PQ tests a dedicated Ca/Mg hollow cathode lamp is required and is included in the package. For Furnace systems a dedicated set of graphite cuvettes is included.

Summary

The unique, automated Thermo Scientific Validator Packages can save time, money and energy for any laboratory which requires their Thermo Scientific iCE 3000 Series instrument to be verified. Whether this is required for formal quality procedures, regulatory compliance or just as good practice, the Validator Packages offer all you need.

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