

**Simplify regulatory compliance and ensure complete, traceable documentation of all qualification procedures performed for your Thermo Scientific UV-Visible spectrophotometer with the UV Validator.**

## UV Validator

Qualification documentation and reference materials for spectrophotometers, software and accessories



Designed with the regulated laboratory in mind, the UV Validator provides support for system qualification and validation activities for Thermo Scientific UV-Visible spectrophotometers, software and accessories. It provides all the documentation and reference materials needed to facilitate compliance of your UV-Visible spectrophotometer system with the requirements of FDA, GMP, ISO 9001:2000 and ISPE 2001 guidelines and regulations.

### Streamlined for Efficiency

The UV Validator streamlines Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Re-Qualification (RQ) procedures for simple and efficient use by the end user. It provides all the tools you need for IQ/OQ qualification procedures, including the reference materials outlined in the UV Validator's qualification procedures. This kit includes the following:

- 4 Neutral Density Filters
- Holmium Oxide Filter
- Didymium Filter
- Chalk Solution (Kinetics)

Streamlining the qualification process with direct and specific protocols allows a complete qualification of the instrument to be completed in a few hours. Inclusion of the reference materials allows you to produce your own easy-to-follow and effective SOPs and PQ procedures.



For PQ procedures in accordance with Pharmacopeia regulations, our automated performance verification accessories provide error-free, unmatched efficiency designed to save you time and money. See Thermo Scientific specification sheet PS51731 *Accessories for Automated Performance Verification* for more information on these optional accessories.

### Complete System Qualification

The UV Validator offers detailed, step by-step procedures and documentation to provide evidence of control for the installation, operation and performance of the instrument and analysis software, including:

- Information on the validation process
- Information on Installation and Instrument Qualification
- Information on Pharmacopoeia requirements
- Recommended tests for specific instrument performance
- Documentation for manufacturer-verified IQ/OQ

When purchased with both the UV Validator and Installation Certification Service, spectrophotometers are installed by trained and certified service engineers who provide the following services:

- Perform the IQ and OQ Testing
- Complete the IQ and OQ Documentation
- Ensure that the instrument meets or exceeds all qualification performance test parameters

## Installation Qualification

The Installation Qualification (IQ) procedure includes documentation and verification that your instrument was received as ordered and specified in the Design Qualification (DQ) and is free of defect and damage. It also ensures that the instrument is installed properly in the correct environment and meets all of the manufacturer's specifications. IQ includes all of the following:

- Hardware Set-up
- Software Set-up
- System Power up
- Software Control
- Data Output
- Appropriate Documentation
- System Log Book

With the purchase of installation certification services, instrument qualification is performed by a trained and certified service technician. Alternatively, customers may perform qualification themselves following the step-by-step procedures outlined in the documentation provided with the UV Validator. When completed as part of our Installation Certification service, traceability back to the factory is established.

## Operational Qualification

Operational Qualification (OQ) includes a plan for verifying that both the hardware and software are operating in accordance with their specifications. It includes routine tests of the system to ensure that the spectrophotometer performs to specification and that the software functions as intended. As with IQ procedures, our Installation Certification service links the system's performance back to original factory specifications for complete traceability.

## Performance Qualification

Performance Qualification (PQ) tests and documents that the system is adequate for specific tasks. It is unique to every location and use; therefore, PQ is the responsibility of the user. It includes:

- Method validation and verification
- Fit-for-purpose testing
- Standard Operating Procedures (SOPs)
- On-going performance verification tests and Re-Qualification (RQ)

Performance Qualification, or Performance Verification, must be established and performed by the user and should be tailored to the specific user, experiment and instrument SOP requirements. For more information on performance verification testing see Thermo Scientific Technical Note TN51686 *Performance Verification of the Evolution 300 UV-Visible Spectrophotometer in the Regulated Laboratory*.

## Certified Qualification Experts

For simplified regulatory compliance and complete traceability, trained and certified support personnel are available to perform all installation and qualification procedures. Annual re-certification ensures that our qualification experts remain proficient to provide the most complete and consistent qualification support of your laboratory. The UV Validator, in conjunction with our certified support personnel, assures that your spectrophotometer system is properly installed and qualified, eliminating potential regulatory difficulties.

## Ordering Information

Description	Part Number
UV Validator	10030901
On-site Installation of Instrument with VISIONsecurity™ (U.S. and Canada)*	701-116400
On-site Installation Certification Service (U.S. and Canada)*	701-127800
Upgrade to On-site Service (U.S. and Canada)*	701-112500

\* For installation and warranty coverage outside the U.S. and Canada, please contact your local Thermo Scientific sales office or distributor.