

Validated systems for pharmaceutical environments

Thermo Scientific Evolution Series
UV-Visible Spectrophotometers



Advanced tools for pharmaceuticals and high-value QA/QC testing

For over 60 years, customers in world-renowned research, QA/QC and educational laboratories have relied on the high-performance and exceptional value provided by Thermo Scientific™ UV-Visible spectrophotometers. The Thermo Scientific™ Evolution™ 201 and 220 UV-Visible Spectrophotometers provide simplified workflows; cutting-edge technology and an array of accessories to consistently deliver the high-quality results you depend on. If pre-programmed Life Science methods are needed, the Thermo Scientific™ Evolution™ 260 Bio UV-Visible Spectrophotometer adds methods for quantifying nucleic acids and proteins and performing thermal denaturation studies. If advanced performance and additional operational flexibility is required, The Thermo Scientific™ Evolution™ 350 UV-Visible Spectrophotometer offers solutions designed to simplify the sophisticated for your advanced applications.



Evolution UV-Visible pharmacopeia performance requirements

Performance Verification at installation and at set intervals thereafter is required for UV-Visible spectrophotometers in regulated laboratories. In the pharmaceutical industry, national pharmacopoeias with international reach define specific performance levels for several criteria. With superior specifications the Evolution 350 will meet the performance requirements for all global pharmacopoeias including United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP). Due to changes in manufacturing to improve the specifications, the Evolution 200 series will now meet all requirements for USP and EP.

Instrument	USP	EP	JP
Evolution 201	✓	✓	
Evolution 220	✓	✓	
Evolution 260 Bio	✓	✓	
Evolution 350	✓	✓	✓

Pharmacopeia performance verification testing

No matter the operational range, Thermo Scientific has the appropriate standards options for any pharmacopeia requirement. For qualification in the UV region, the new **USP and EP UV Standards Set** includes the full list of standards needed for performance verification. If evaluating the performance of the instrument in the visible region is required, add the new **USP and EP Visible Standards Set**.

	222-327200 USP and EP UV Standards Set	222-327300 USP and EP Visible Standards Set
Operating Range	< 400nm	≥ 400nm
Wavelength Accuracy and Precision	Holmium Oxide Solution	Didymium Glass
Photometric Accuracy, Precision and Linearity	Three Potassium Dichromate Standards	Four Neutral Density Glass Standards
Resolution	Toluene in Hexane Solution	N/A
Stray Light	Potassium Chloride Solution Sodium Iodide Solution Sodium Nitrate Solution	N/A

If only general instrument qualification is needed rather than full pharmacopeia performance verification, our **Qualification Filter Kit for UV-Visible** can be used to fully qualify your spectrophotometer. The Qualification Filter Kit for UV-Visible contains some of the standards used for USP and EP performance verification, so additional standards can be purchased later to supplement this kit.



An optional Mercury lamp accessory can also be purchased for each class of instrument.

- A pre-installed mercury lamp option is available for the Evolution 350. Stand-alone mercury lamp accessories are also available for the Evolution 350 and Evolution 200 series.
- Both US and European Pharmacopoeias call out low pressure mercury emission lamps as the preferred choice for establishing wavelength accuracy.
- Choosing the mercury lamp accessory frees customers who perform routine performance verification tests from the burden or purchasing and re-certifying standard solutions for measuring these parameters. As a fundamental physical standard, a mercury lamp never needs calibration.

Complete IQ/OQ Validation package

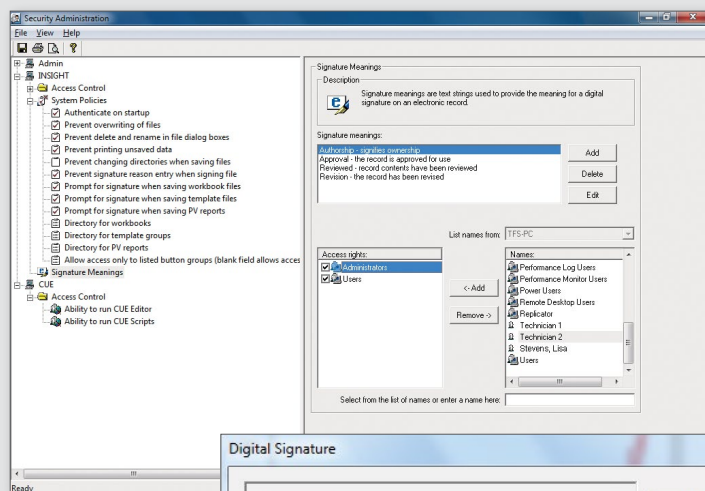
Thermo Scientific Validator packages provide support for system qualification and validation activities for instruments, software and accessories. All of the documentation and reference materials needed to facilitate compliance of your Thermo Scientific spectrophotometer system with the requirements of FDA, GxP, ISO 9001:2008 and ISPE 2001 guidelines and regulations are included for your convenience. Validator packages streamline Installation Qualification (IQ), Operational Qualification (OQ) and assist in Performance Qualification (PQ) procedures and development for simple and efficient use.



Reliable data security for your electronic records

If your laboratory requires 21 CFR Part 11 compliance, Insight Security software is here to make your life easier. Using the same easy-to-use interface, Insight Security software combines security and data integrity assurance with the versatility required for your multi-user laboratory.

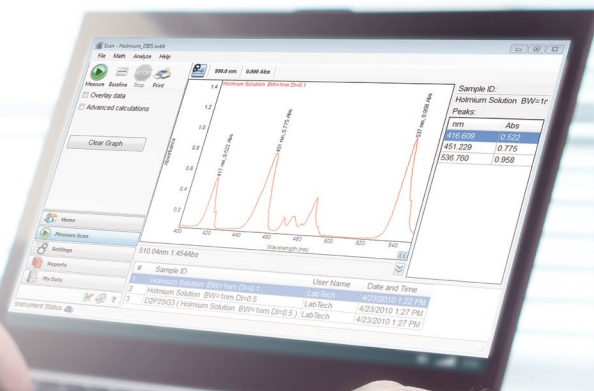
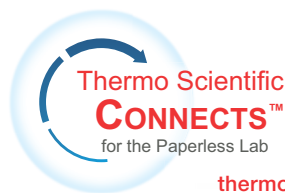
- Achieve clear traceability with sample history and electronic signature details that are stored directly within your protected data files
- Ensure that any changes to files associated with Insight Security are monitored and logged, even when the software is not running, with software that is seamlessly integrated with Microsoft® Windows® security features
- Manage your users' access and privileges quickly and easily from one central server location with our cross-platform Thermo Scientific Security Suite software.



Integrated informatics solutions

Laboratory informatics are a critical part of any laboratory, facilitating end-to-end traceability of samples and associated laboratory processes, providing a central repository for data and test results and ensuring regulatory compliance. Thermo Scientific Lab Information Management Systems (LIMS) deliver a complete informatics solution for method execution, laboratory and data management.

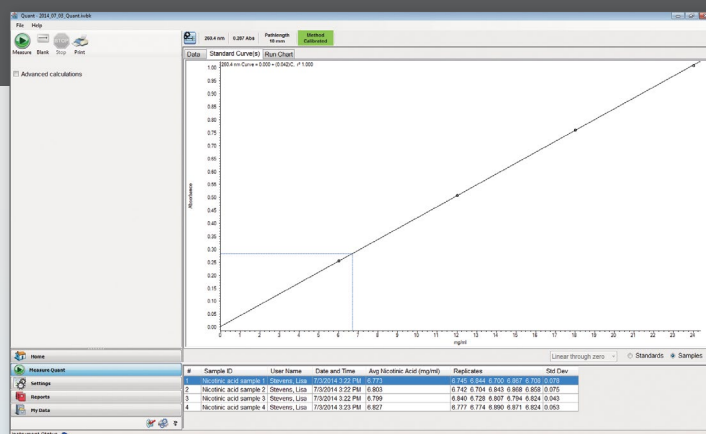
In combination with our Laboratory Execution System (LES), Scientific Data Management System (SDMS) and Integration Manager (IM), Thermo Scientific LIMS deliver the most comprehensive paperless lab solution available today. Now lab managers and scientists across all industries can achieve full instrument integration, manage methods and workflow, retrieve and archive any kind of raw scientific data, and export results across the organization.



Reliable precision for quantitative analysis

Reliable results are an essential component of quality control analyses. From simple, single-standard comparisons to standard curves based on peak area, we have the tools to get the answers you need every time. Evolution UV-Visible spectrophotometer's double beam optical design delivers outstanding reliability, precision performance and minimal downtime.

- Get more done each day. The instant-on xenon flash lamp requires no warm-up time and is guaranteed for three years of continuous use.
- Enjoy long-term stability during data acquisition with double-beam optics and a reference position detector for monitoring control samples



Complete pharma solution bundles available

With various bundles available, we have the ideal configuration to meet every need.

Each bundle will include:

- Choice of Evolution UV-Visible spectrophotometer
- INSIGHT with Security software
- Validator 2 IQ/OQ Qualification Documentation
- Choice of USP and EP Standards Set or general Qualification Filter Kit



Pharma UV-Visible instrumentation checklist

- Meets pharmacopeia performance requirements
- IQ/OQ qualification package
- Validated installation
- 21CFR Part 11 for data integrity
- LIMS compatibility
- Advanced QA/QC software functionality

Find out more at thermofisher.com/evolution350

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