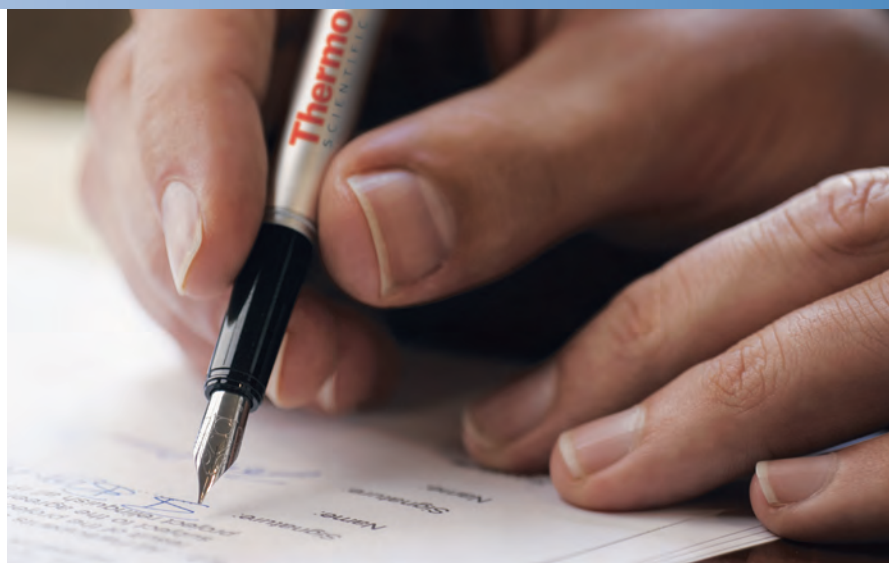
# Thermo Scientific ValPro System Qualification for FT-IR and Raman Spectrometers

Comprehensive spectrometer validation tools

Thermo Scientific ValPro System Qualification for FT-IR and Raman spectrometers is the most complete and cost effective method of addressing all of your regulatory compliance needs.




ValPro™ System Qualification for Thermo Scientific FT-IR, FT-Raman and dispersive Raman spectrometers provides the most complete set of system qualification tools in the industry. Designed to meet Code of Federal Regulations (CFR), systems qualified with ValPro can stand up to the most stringent governmental or industrial regulatory reviews. Thermo Scientific common system qualification methodology makes ValPro the fastest and most cost effective means of achieving complete system compliance.

ValPro gives you the ability to:

- ✓ **Qualify the spectrometer**
- ✓ **Qualify the sampling module**
- ✓ **Qualify the analysis software**

Its integrated approach allows you to get your system into commission quickly.

## Complete System Qualification

ValPro qualification tools cover the entire system by including standards and procedures for Thermo Scientific FT-IR and Raman spectrometers, as well as sampling accessories such as ATR and diffuse reflectance. ValPro significantly reduces the time and financial investment required for system qualification by providing:

- Traceable reference standards designed specifically for each system and accessory
- Comprehensive procedures documenting installation and operation in your laboratory
- Methods that comply with European and Japanese Pharmacopoeias or ASTM practices
- Expert qualification services delivered by certified personnel

These features make qualification simple and ensure proper installation of the system, giving you complete confidence in the results.

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## Installation Qualification

Detailed installation procedures, reports and certification documents are part of every ValPro system qualification package. This ensures that your spectrometer system installation complies with Installation Qualification (IQ) specifications. These procedures verify and document that the equipment is:

- Delivered as ordered and specified in the DQ
- Defect- and damage-free
- Properly installed in an appropriate environment

IQ procedures also verify proper installation of the software.

You can choose to implement these procedures using your own personnel, or have the procedures completed by trained and certified support personnel as part of our Installation Certification service which establishes traceability back to the factory.

## Design Qualification

The ValPro system qualification package includes extensive documentation explaining our product life cycle management to address Design Qualification (DQ). DQ documentation details our processes for:

- Qualifying suppliers
- Documenting projects
- Testing and releasing products
- Archiving test results
- Supporting products

Additionally, the package provides specific hardware and software information to help you determine if the products are fit-for-purpose.

The documentation provides detailed software DQ information. This information explains how the supplied software products comply with ISO 9001 protocols and Code of Federal Regulations for configurable off-the-shelf software. Procedures are documented for:

- Software coding
- Code archiving and off-site storage
- Algorithm documentation and verification
- Software revision control and issue tracking
- Software documentation

## Operational Qualification

Following successful completion of IQ, ValPro's Operational Qualification (OQ) provides assurance that:

- The system is operating correctly
- The software is operating correctly
- System operators are properly trained

OQ procedures may include the following tests† to assess instrument performance:

- Noise
- Wavelength accuracy
- Spectral resolution
- Precision
- Linearity

As with IQ procedures, you can have OQ completed by your own personnel or by trained and certified support personnel as part of our Installation Certification service which links system performance back to the original factory data.

*† Consult your Thermo Scientific representative to discuss the qualification needs for your instrument configuration.*



**Nicolet iS50 FT-IR spectrometer with iS50 Raman module and built-in iS50 ATR**

## Performance Qualification

The ValPro system qualification package provides guidelines for performance qualification, ensuring that your system is working properly for its intended use. ValPro qualification tools, used in conjunction with our consulting services, provide the flexibility needed to accommodate any qualification requirement. This approach allows independent qualification of the spectrometer, sampling technique, or analytical methods. It allows incorporation of any user-defined or industry-recommended qualification standards or methods into the package.

## Traceable Reference Materials

The ValPro system qualification package provides complete traceability for the reference materials used to run performance verification tests. Whether they are internationally recognized standards, or proprietary materials, these references follow our strict traceability process. ValPro standards include NIST and NPL traceable references, as well as proprietary references.

Standard reference materials are provided in convenient form factors for instrument sampling configurations. Motorized validation wheels are available for some system configurations to allow automated on-demand or scheduled system testing.

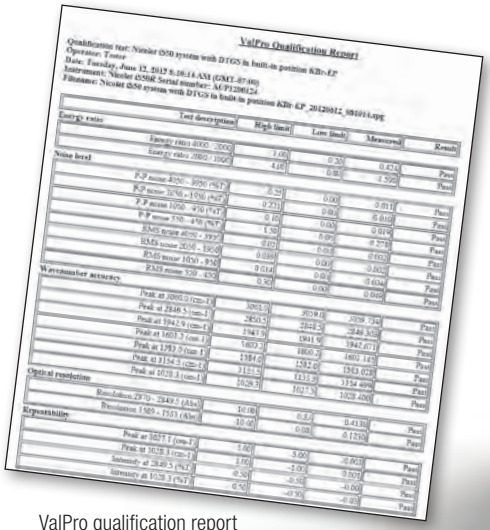
## ValPro Qualification Software

The ValPro Qualification software can run a variety of tests that support your specific instrument configuration†. This software allows you to run the same tests used for OQ at any time as part of your ongoing system performance verification SOP. It can also execute custom tests implemented to address PQ for your system.

The software:

- Provides selection of a variety of performance verification tests.
- Automatically archives spectral data and result history
- Generates a qualification report that can be printed and signed
- When combined with our 21 CFR Part 11 tools, provides additional security by controlling access and using digital signatures plus detailed audit trails.

*† Consult your Thermo Scientific representative to discuss the qualification needs for your instrument configuration.*




ValPro qualification report


**Thermo Scientific DXR SmartRaman spectrometer**


Polystyrene Reference Cards for FT-IR Spectrometers

Validation Wheel for Automated ValPro Testing

Raman Polystyrene Reference Accessory


**Nicolet iS10 FT-IR spectrometer with Smart Diffuse Reflectance accessory**

## Performance Verification Test Methods

The ValPro system qualification package uses performance verification tests prescribed by internationally recognized bodies.

These include:

- European pharmacopoeia
- Japanese pharmacopoeia
- ASTM standard practices

ValPro methods and standards are also compatible with the existing ASTM E 1421 tests used in our Val-Q system qualification package for those customers who have standardized on this approach.

## Certified Qualification Experts

For complete traceability and simplified regulatory compliance, we provide trained and certified support personnel to perform all installation and qualification procedures. Annual re-certification ensures that our qualification experts stay proficient to provide you with complete and consistent qualification support. ValPro system qualification, in conjunction with our certified support personnel, assures that your instruments are installed and qualified properly – eliminating potential regulatory difficulties. For third party verification and continuous compliance, we offer biannual and annual re-qualification services.

## ValPro System Qualification Package

The ValPro system qualification package provides you with:

- Complete instrument and software DQ
- Complete procedures and documentation for instrument IQ and OQ
- Test methodologies from European and Japanese Pharmacopoeias, as well as ASTM standard practices
- Instrument tests for wavelength accuracy, spectrophotometer noise, and photometric linearity for most systems
- Traceable NIST or proprietary standards
- Optional automated operation of tests
- Complete troubleshooting and diagnostic information
- Templates for recommended performance verification standard operating procedures (SOPs)
- Historical validation reports with audit trails
- Example PQ procedures
- Fully compatible with our 21 CFR Part 11 compliance tools

## Software & System Requirements

- OMNIC 7.2 or later version
- Windows® XP Professional or Windows 7 Professional
- OMNIC DS & Thermo Scientific Security Administration (optional for 21 CFR Part 11 compliance)

## Configurations

Consult your Thermo Scientific representative to discuss the qualification needs for your instrument configuration.

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*Thermo Electron Scientific Instruments LLC, Madison, WI USA is ISO Certified.*

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