

Qualify Your Nicolet Summit Spectrometer

Your Thermo Scientific™ Nicolet™ Summit FTIR Spectrometer comes with standard tests and test samples that can be used to verify its operation. We refer to this process as “instrument qualification” and, whether performed formally or informally, it is often an important requirement for instrument installations.

Instrument qualification demonstrates the spectrometer is “fit for purpose,” properly maintained, and calibrated to national or international standards and published test limits. In the end, it ensures the integrity of any data you acquire with the spectrometer.

If you purchased a “qualified” installation, we perform initial qualification at the factory and ship the printed qualification test results with the spectrometer. A certified service person installs the spectrometer at the customer-designated location, reruns the factory qualification tests and certifies the installation. The service person provides a signed log of the installation steps, certificates of authentication for the test standards, qualification test results and other documentation. If you purchased re-certification, the service person returns regularly to repeat the qualification and re-certify the instrument.

The OMNIC Paradigm software includes the factory qualification test in addition to standard industry-wide qualification tests you most likely recognize (for example, European Pharmacopoeia, Japanese Pharmacopoeia, etc.). Any required qualification reference standards are supplied inside the instrument and controlled by the OMNIC Paradigm software.

Whether or not you purchased formal qualification and recertification, you can easily run the qualification tests yourself. We recommend that you store the test results in a common location so they can be used to verify and track instrument performance over time. Qualification test results can also be viewed at any time in the OMNIC Paradigm software.

When to Qualify

After the spectrometer is installed, we recommend that you select and run one of the standard qualification tests provided with OMNIC Paradigm software and repeat that test periodically, as needed, to verify spectrometer operation. You should always repeat qualification immediately after the following circumstances:

- if you moved the spectrometer to a new location
- if you replaced the source

- if you changed the type of sample compartment windows installed in the spectrometer (for example, from potassium bromide (KBr) to zinc selenide (ZnSe) or the reverse)
- if you updated the spectrometer's firmware

Note Users working in a regulated environment typically also requalify after a software upgrade.

What tests are available?

OMNIC Paradigm software includes the following performance and qualification tests. All of these tests are based on internationally recognized methods for testing FTIR spectrometer performance.

Table 1. Performance and Qualification Tests Included with OMNIC Paradigm Software

Abbreviated Test Name	Full Test Name and Source
PHEUR (or Ph. Eur.)	Nicolet FTIR-PHEUR Qualification <i>European Pharmacopoeia</i> , Ninth Edition, General Chapter 2.2.24, Absorption Spectrophotometry, Infrared (wavenumber accuracy and optical resolution tests)
USP	Nicolet FTIR-USP Qualification <i>US Pharmacopoeia</i> , 41 <854> Mid-Infrared Spectroscopy (wavenumber accuracy test)
JP	Nicolet FTIR-JP Qualification <i>Japanese Pharmacopoeia</i> , Seventeenth Edition, 2.25 Infrared Spectrophotometry/General Tests (wavenumber accuracy, optical resolution, and repeatability tests)
CP	Nicolet FTIR-CP Qualification <i>Chinese Pharmacopoeia</i> , 2015 Edition, 0402 Infrared Spectrophotometry (wavenumber accuracy and optical resolution tests)
ASTM	Nicolet FTIR-ASTM Test <i>International Annual Book of Standards</i> , Section 3, Metals Tests and Analytical Procedures, Volume 3.06, E1421-99 Standard Practice for Describing and Measuring Performance of Fourier Transform Mid-Infrared (FT-MIR) Spectrometers (energy ratio and noise level tests)

Table 1. Performance and Qualification Tests Included with OMNIC Paradigm Software

Abbreviated Test Name	Full Test Name and Source
Nicolet FTIR Factory	Nicolet FTIR-Factory Qualification Thermo Scientific factory qualification for FTIR spectrometers (combines the PHEUR, USP, JP and CP tests listed above with our own performance verification tests listed below)
Nicolet FTIR PV	Nicolet FTIR-PV Test Performance Verification test for Nicolet Series FTIR spectrometers. Runs the following tests to verify instrument performance and prints a standard test report: Energy ratio: Detects changes in energy distribution in the single beam spectrum. Used to verify performance of the source, as well as instrument alignment and optical integrity over time. Based on ASTM E1421-99, Level One test for energy ratio with an additional ratio of 2,000 cm ⁻¹ /1,000 cm ⁻¹ . Noise level: Measures the instrument's noise level for transmission analysis. Based on ASTM E1421-99 Level One test for noise level.
Algorithms Test	Algorithms Test Qualification test for the quantification algorithms used by OMNIC Paradigm software

Table 2. Qualification Standards Used for Nicolet Series FTIR Spectrometers

Standard	Description
1.5 mil polystyrene	NIST ^a -certified 1.5 mil polystyrene standard mounted inside the spectrometer and controlled by OMNIC Paradigm software
3.0 mil polystyrene	NIST-certified 3.0 mil polystyrene card-mounted (external) standard (used in the ASTM tests only)

^a National Institute of Standards and Technology

How to Run the Tests

Use the OMNIC Paradigm software that came with your spectrometer to run performance and qualification tests. Before you run one of these tests, make sure the spectrometer has been powered on for at least 1 hour.

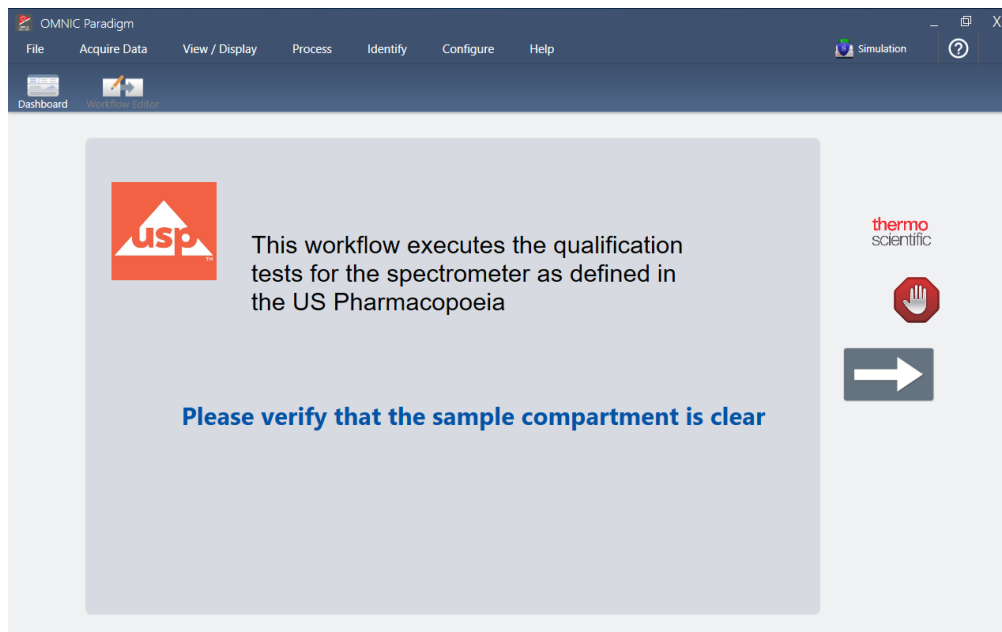
❖ **To run a performance or qualification test**

1. Open OMNIC Paradigm software.
2. From the OMNIC Paradigm main window, double-click a performance or qualification workflow provided with the software.

The provided performance and qualification workflows are shown below. You may need to scroll through the list to locate them.

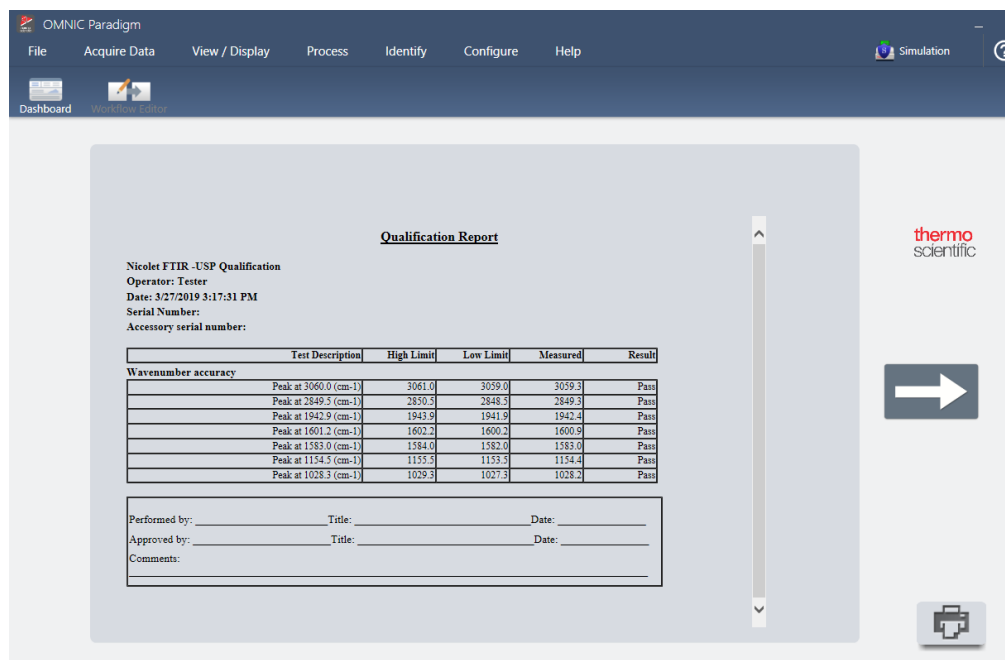
Workflows		
Name	Date Created	Last Modified
Nicolet FTIR -Factory Qualification	3/28/2019 1:53:29 PM	3/27/2019 9:33:50 PM
Nicolet FTIR - PHEUR Qualification	3/28/2019 1:53:15 PM	3/27/2019 9:33:49 PM
Nicolet FTIR - CP Qualification	3/28/2019 1:52:55 PM	3/27/2019 9:33:50 PM
ATR Accessory -PHEUR Qualification	3/28/2019 1:51:48 PM	3/27/2019 9:33:50 PM
Nicolet FTIR - JP Qualification	3/28/2019 1:50:52 PM	3/27/2019 9:33:51 PM
Nicolet FTIR -USP Qualification	3/27/2019 4:09:42 PM	3/27/2019 6:21:36 PM
Nicolet FTIR -PV Test	3/28/2019 1:53:46 PM	3/27/2019 9:33:51 PM

The workflow opens in the Play Workflow window.



Click the arrow button to continue and follow any on-screen instructions to complete the workflow.

When the workflow is completed, the results are displayed in a standard report. Here is an example:



The report is saved automatically in the OMNIC Paradigm database, along with the acquired spectra. Use the Print button if you need to print the report.

If one or more tests in the report show a “Fail” result, consult the troubleshooting information on our website or contact your local technical support representative for help in solving the problem. Once the problem has been solved, rerun the qualification test.

About the Test Results

The performance and qualification test results include the test type, operator name, date, serial number of the spectrometer and any sampling accessory used, along with descriptions of the individual tests, their high and low limits, the measured results and whether the results are within the specified limits (Pass if “yes” or Fail if “no”).

The report is saved automatically along with the acquired spectra. We recommend that you save each test report and store it in a known location, along with any previously run reports for this spectrometer.

Qualification test spectra are tagged with the following information:

Table 3. Search Tags used for OQ Spectra

Test Name	Associated Search Tag
Nicolet FTIR-PHEUR Qualification	“PHEUR” (displays all spectra created with the European Pharmacopoeia workflow)
Nicolet FTIR-USP Qualification	“USP” (displays all spectra created with the US Pharmacopoeia workflow)
Nicolet FTIR-JP Qualification	“JP” (displays all spectra created with the Japanese Pharmacopoeia workflow)
Nicolet FTIR-CP Qualification	“CP” (displays all spectra created with the Chinese Pharmacopoeia workflow)
Nicolet FTIR-ASTM Test	“ASTM” (displays all spectra created with the ASTM workflow)
Nicolet FTIR-Factory Qualification	“Factory” (displays all spectra created with the Nicolet FTIR Factory workflow)
Nicolet FTIR-PV Test	“PV” (displays all spectra created with the Nicolet FTIR PV workflow)
Algorithms Test	Algorithms (displays all spectra created with the Algorithms workflow)

To locate and open individual spectra, use the date selection box in the middle pane to locate the spectra, or enter a tag from the table above in the Search box. Double-click a spectrum in the list to open it.

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