

Security and Compliance

Nicolet Summit FTIR Spectrometer and OMNIC Paradigm Software

Making sure your data is safe and secure doesn't have to be hard. A fully secured system, like the Thermo Scientific™ Nicolet™ Summit FTIR spectrometer, consists of three software applications:



1 Security Administration – This program gives lab managers the ability to control who has access to what data, can enable or disable certain commands and features within the instrument software, and can require scientists or technicians to digitally sign their data to comply with 21 CFR Part 11 regulations.



Security Administration

System policies

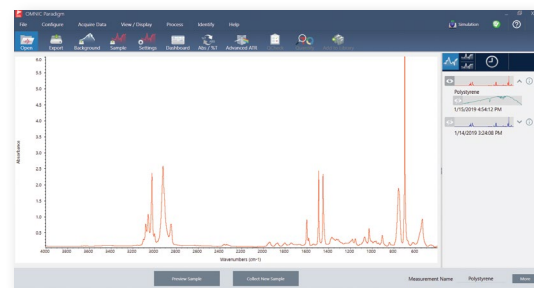
- Prevent overwriting of files
- Require signature when saving a spectrum
- Create records with Administrator specified Secure Tag

2 Audit Manager – This software captures system event information (when a user logged on, when a spectrum was collected, when data was saved, etc...) and provides easy filtering tools to quickly find events by date, user name, computer ID, and more. Audit Manager even includes additional event details like specific spectral processing information, which provides a single location for an auditor to review. All audit trail information is stored in an SQL or user-specific database.



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3 Thermo Scientific™ OMNIC™ Paradigm Software – The instrument control software is used to collect data, analyze samples, and create workflows. Like Audit Manager, OMNIC Paradigm Software stores all spectral data in a database, which provides more data storage flexibility and security. Users can even assign tags to measurements to make querying their data easy. OMNIC Paradigm Software uses MariaDB® relational database by default, but users can define the database of their choice from a supported list (Table 1).



User Name	Severity	Timestamp (Local - 5:00)	Category	Description
Anderson, Brian	Information	23-May-2019 11:39:27	Login Audits	Successful logon.
Croft, Lisa	Information	23-May-2019 11:54:32	Data Change	A workflow has started execution.
Yi, Wei	Information	24-May-2019 8:31:57	Data Change	Conversion Measurement Name: Batch5286

Compliance services

It's important to have documented evidence to show that the hardware and software have been installed correctly and are functioning as intended. Trained service engineers can provide IQ/OQ services during the installation of a new instrument or at any other time you might request, such as after an instrument is moved to a new location.

- **Installation Qualification (IQ)** – These documents verify that the system has arrived and is installed correctly. We check to make sure all the parts are included, the instrument has arrived undamaged, everything is connected properly, and that the environment is suitable for the instrument. We also double-check that the software is installed correctly, so all security policies will work as expected.
- **Operational Qualification (OQ)** – OQ documents verify the system functions as intended. Here, we check to make sure the hardware and software are working well together and spectral data is being accurately collected.

Learn about our instrument validation and qualification services offered through Unity Lab Services at unitylabservices.com/compliance.

System Qualification

Operating in a regulated environment requires you to make sure your instrument is performing as expected, usually once per day. Conducting this performance check is referred to as "System Qualification", and like everything else, we make that easy for you, too. System Qualification workflows are available for the most common methods referred to in the European, US, Japanese, and Chinese Pharmacopeias. The OMNIC Paradigm Software includes automated analysis procedures that make sure your spectrometer is compliant with the performance requirements outlined in the Pharmacopeia documents. Each instrument includes its own traceable internal polystyrene standard, so testing your instrument performance is as easy as clicking a button.



Our commitment to quality

Thermo Fisher Scientific operates under ISO 9001 certified product development and manufacturing procedures, assuring users a high level of confidence in the design and development of our software. We maintain complete traceability in our development process, including specifications, revision control and software validation.

Database	Supported Versions
Aurora DB	MySQL 5.6 MySQL 5.7
MariaDB	10.0 10.1 10.2 10.3
Oracle	11g Release 2 12c Release 1 12c Release 2 18c
SQL Server	2012 2014 2016 2017

Table 1. Relational databases compatible with OMNIC Software.



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