**In the quest for 21 CFR Part 11 compliance, Thermo Scientific OMNIC™ DS software makes your job easy. The package provides maximum security and data integrity assurance for the varying analytical needs of your laboratory. OMNIC DS software logs changes to files associated with the software, even when OMNIC software is not running.**

OMNIC DS Software

Versatile data security and integrity tools for your OMNIC Spectroscopy Software
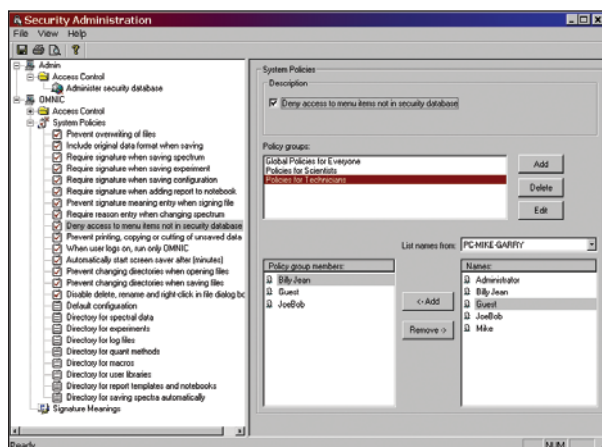
Thermo Scientific Security Administration Server gives you maximum control with minimal effort

Thermo Scientific OMNIC DS software provides advanced data security and integrity tools that allow you to meet the requirements of the Food and Drug Administration's Code of Federal Regulations Title 21, Part 11 Electronic Records/Electronic Signatures rule.

Designed to run with Thermo Scientific OMNIC spectroscopy software, it combines security and data integrity assurance with the full-featured flexibility to address the varying analytical needs of your laboratory.

Because OMNIC DS software can be configured on a per user basis, on one system or across your enterprise, you can ensure 21 CFR Part II compliance.

OMNIC DS Software Provides:

Full System Access Control
- Works with Windows Vista® or Windows® XP security to authenticate operators
- Software access is controlled on a per user basis on single or multiple instruments

True Digital Signatures
- Establishes record responsibility using cryptographic user authentication
- Assures the highest level of data integrity with encryption to detect tampering

Complete Audit Trails
- Non-editable spectral histories stay with the data and provide traceability
- File events and program use are logged for administrative review

Flexible Record Storage and Retrieval
- Original data is saved automatically to allow reproduction of results
- Retrieval and review in OMNIC software, or with database or graphical programs

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Designed with the Regulations in Mind

OMNIC DS software was designed from the ground up using our strictly controlled Product Development Process (PDP) to ensure compliance with our ISO 9001 Certification, and in accordance with cGMP, GLP, and GAMP design, development, and manufacturing guidelines. We maintain complete traceability in our development process, including specification, revision control, and software validation.

OMNIC DS software can be used with any Thermo Scientific Nicolet™ FT-IR or Thermo Scientific Nicolet Raman laboratory spectrometer that uses full-featured OMNIC software.*

*EZ OMNIC is not compatible with OMNIC DS software.

Thermo Scientific Security Administration Server

At the heart of the OMNIC DS software data security and integrity is the Thermo Scientific Security Administration Server. This versatile server application gives your system administrator control over OMNIC software access, policies, and digital signature meanings in an easy-to-use interface. The Thermo Scientific Security Administration application can be run stand-alone on your spectrometer workstation, or as a server application to administer OMNIC software on one or all of the instruments at your facility.

Thermo Scientific Security Administration gives the system administrator the ability, on a per user basis, to...

1. Control access to OMNIC software features, including:
- Ability to run OMNIC software
- Complete menu item control
- Detailed control of experiment and spectral library subroutines
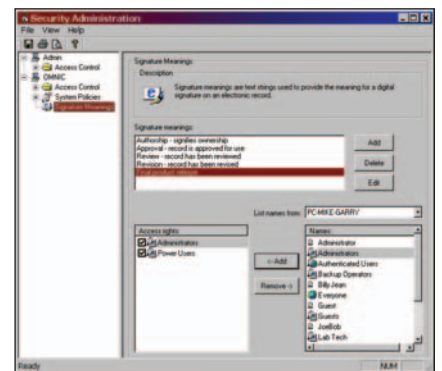- Ability to run macros and external programs
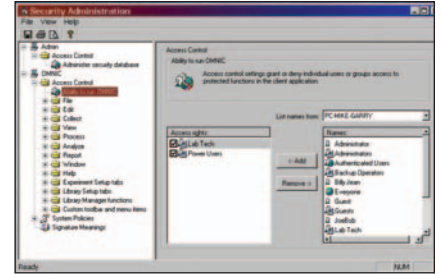
2. Set system policies for OMNIC software to:
- Prevent overwriting of files
- Save all raw data
- Require digital signatures on file saves
- Prevent changing signature meanings when saving
- Require reason entry when data is changed
- Prevent access to OMNIC software add-on packages
- Automatically lock workstation after a set period of inactivity
- Prevent changing directories when opening or saving files
- Set default configurations and directories
- Prevent copying or printing of unsaved data to external applications
- Only run OMNIC software when a user logs on
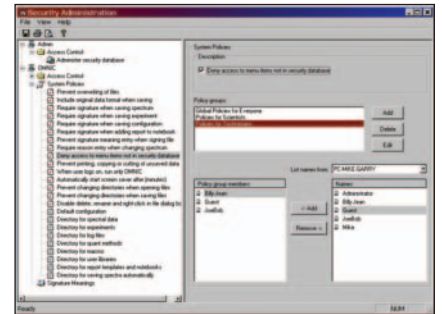
3. Control signature meaning use in OMNIC software:
- Add, delete, or edit signature meanings
- Set which meanings are available to specific users

Thermo Scientific Security Administration Server lets you:

Show Your Stuff

Thermo Scientific Security Administration Server gives you the peace of mind that your spectrometer's results are being generated in a way that you can be comfortable presenting to any auditor. And to comply with the 21 CFR Part 11 regulation's requirement to recall records in a human readable format for inspection, review, and copying, the Security Administration Server allows you to preview and print all of the settings for all of the users being administered.

Expand

Thermo Scientific Security Administration Server software now controls OMNIC, OMNIC for Thermo Scientific Nicolet Almega™, and OMNIC for Nicolet Raman software. Additional Thermo Scientific application software control can be added as they become available.

Provide High Security Without Losing Productivity

Beyond the security controls, you can still configure OMNIC software to your specific needs and obtain the best usable information from your analyses. Toolbar buttons and software options can be set through OMNIC software. This provides your users with a consistent software interface that allows them to be as productive as possible and ensures they follow established procedures. Once set, these features can be locked through the Security Administration Server to prevent modification.

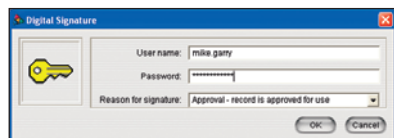## OMNIC DS Software Features

User Authentication and Digital Signatures

OMNIC DS software requires the use of a closed system to provide the appropriate level of security. It works with Windows 2000 or XP Professional security to re-authenticate the logged on user's Windows account using Microsoft® authentication. This authentication occurs whenever the logged on user launches OMNIC DS software or applies a digital signature to a file. This provides several advantages to the user and the system

administrator. First, there is no need to remember different passwords. Also, policy settings, such as password aging and the allowed number of log-on attempts are those set for the computer.

As part of its file security, OMNIC DS software uses digital signatures, even though they are not required for a closed system. The contents of the digitally signed file are validated with a secure hash that is then encrypted. This provides extra protection for file tampering detection.

It is important to keep in mind that even with the features provided in the Thermo Scientific Security Administration Server and OMNIC DS software, compliance with 21 CFR Part 11 requires additional effort. Best practices for computer security should be applied, and written policies must exist and be adhered to so accountability is ensured and electronic record falsification avoided.

Audit Trails

OMNIC DS software provides complete data and event tracking that allows you to establish thorough audit trails. The two aspects of tracking and logging include:

Spectral Data Processing History

Spectral data processing histories provide complete data traceability, which include:

a. Any changes to data in OMNIC software by any operator
b. Digital signature history
c. Comments added to collection information
d. Data collection information
e. Errors that may have occurred during data collection

Entries to the spectral data processing history include the user's name, date and time with GMT reference for global use, and reason for change. The history is not editable, and is embedded as an integral part of the spectral data file, so it goes wherever the data file goes.
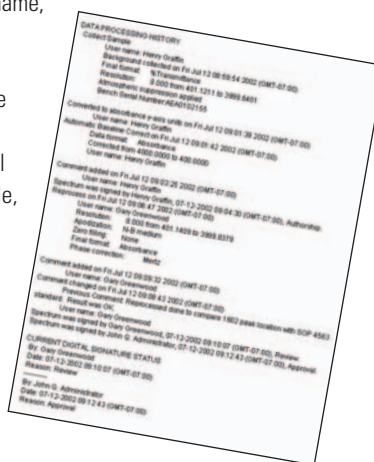
Event Logging

System use and file event logging is output in a custom Thermo Scientific log within the Microsoft Event Viewer, which include:

a. Changes to the Security Administration's application database
b. Activity of the Thermo Scientific Security Server
c. Changes to files associated with the OMNIC software application, **even when OMNIC software is not running**, including creation, modification, renaming, and deletion
d. Program activity and detailed changes to files are tracked while OMNIC software is running; including log-on, log-off and failed log-on; file signing and failed signing events and file creation or modification events

This comprehensive activity tracking and logging assures you the ability to create detailed audit trails for your Nicolet FT-IR or Nicolet Raman spectrometer, and the data it generates. This audit trail can be contained on a single workstation or run enterprise-wide by installing Thermo Scientific Security Administration as a server application.
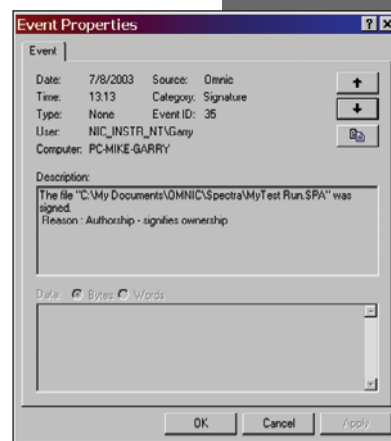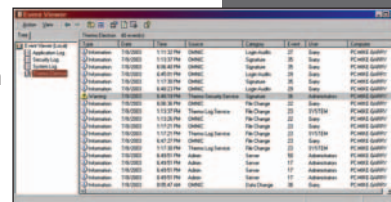
Record Storage and Retrieval

OMNIC DS software gives you the ability to store and retrieve data to ensure your ability to prove the quality of the work you perform using your Nicolet FT-IR or Nicolet Raman spectrometer. With raw data storage and many storage and retrieval formats, you can get the information you need at critical times.

Raw data storage gives you the ability to reproduce the experiment. This includes:

a. Final format data used to analyze data and generate results
b. Sample interferogram
c. Background interferogram

Interferograms represent the raw data which can be used to reproduce the data or troubleshoot problems with your data.

### Many data archival, retrieval, and output options, including:

a. Automatically save data without operator intervention
b. Archive data and other information in OMNIC Digital Laboratory Notebooks
c. Archive data to analytical data archiving software, like eRecordManager™ from Thermo Scientific
d. Archive data on network drives with Thermo Scientific Log Service file security
e. Copy spectra and reports in graphical format to external programs

Keeping Your Analysis Process in Control

Standard features on our laboratory spectrometers provide feedback to let you know the system is working properly at all times. The system status monitor has active checking of instrument performance and data collection quality. And integrated Performance Verification and System Suitability tests provide an even higher level of confidence in your results.
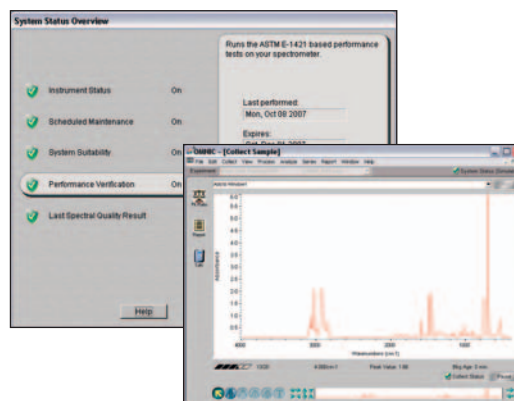
At the operator level, if you need more control of the analytical process during routine operation, our OMNIC Macros\Basic™ program can be used to create analysis workflows. These workflows ensure that the operator is taking the proper steps, according to your Standard Operating Procedures (SOP's), to get the results you expect from your spectrometer.
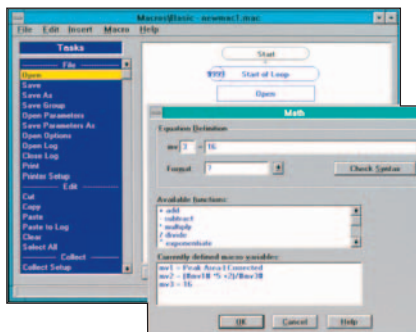
Operating System Requirements

Windows XP Professional or Windows Vista Business

Additional Information

If you would like more detailed information about how we provide for the requirements of this regulation, request a copy of the *OMNIC Software: 21 CFR Part 11 Compliance manual.*

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

ISO 9001

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