

If your laboratory requires 21 CFR Part 11 compliance, VISIONsecurity™ software makes your job easy. Integrating with the security features of the Windows® operating system, VISIONsecurity provides maximum security and data integrity assurance. Changes to all files associated with VISIONsecurity are monitored and logged even when the software is not running.

VISIONsecurity Software

Powerful, easy-to-use and customize for all UV-Visible applications



The Thermo Scientific VISIONsecurity software provides advanced data security and integrity tools allowing you to meet the requirements of the Food and Drug Administration's Code of Federal Regulations Title 21, Part 11 for Electronic Records and Electronic Signatures. Using the same easy-to-use and powerful interface as the VISIONpro software, VISIONsecurity combines security and data integrity assurance with flexibility for your multi-user laboratory. VISIONsecurity software can be configured on a per user basis, on one system, or across your entire enterprise, allowing easy administration from one user to tens of thousands.

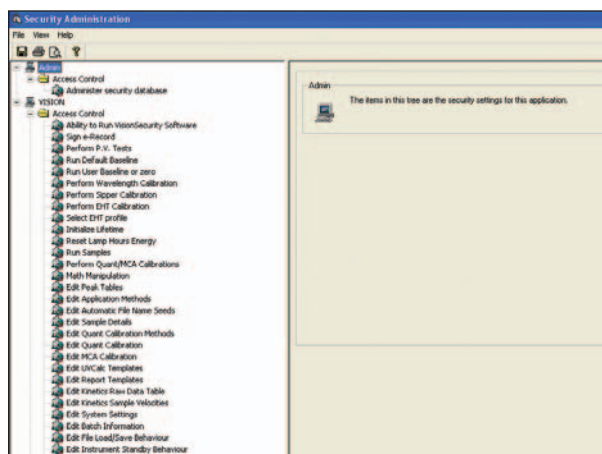
VISIONsecurity Software Provides the Following Features:

Full System Access Control

- Set up users once either on a local computer or a network, no need to configure each computer running each instrument
- User and User Group settings are applied across all computers on the network, automatically
- Works with Windows security features to authenticate operators
- Software access is controlled on a per user basis on single or multiple instruments

Electronic Signatures

- Establishes record responsibility using user authentication
- Assures the highest level of data integrity to detect tampering



The Thermo Scientific Security Administration Server gives you maximum control with minimal effort

Complete Audit Trails

- Even when VISIONsecurity is not running, events for all VISIONsecurity files are audited
- Non-editable audit trail 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 automatically saved to allow reproduction of results
- Retrieval and review in VISIONsecurity software, or with other third-party statistical or graphical analysis programs

Designed with the Regulations in Mind

VISIONsecurity software was designed from the ground up using our strictly controlled Product Development Process 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.

Total Solutions for UV-Visible, FT-IR, Raman, and Imaging Software

The Thermo Scientific Security Administration program that controls user access to VISIONsecurity software also administers security for the OMNIC™ software suite. This allows a single administration point for your UV-Visible spectrophotometer, as well as an FT-IR, Near-Infrared, and Raman spectrophotometer running OMNIC software.

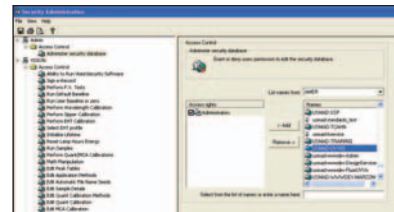
Running Thermo Scientific Security Administration Software on a Server

At the heart of the VISIONsecurity software data security and integrity is the Thermo Scientific Security Administration Software. This versatile server application gives your system administrator control over VISIONsecurity software access, policies, and digital signature meanings in an easy-to-use interface. The Security Administration application can be run stand-alone on your spectrophotometer workstation, or as a server application to administer VISIONsecurity software on one or all of the instruments connected to that server, anywhere. Settings can be applied to single users or groups of users as assigned in the Windows operating system.

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

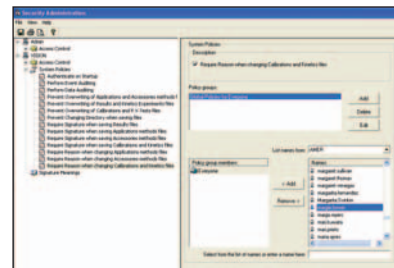
1. Control access to VISIONsecurity software features, including:

- Ability to run VISIONsecurity software
- Ability to change default instrument parameters
- Complete control to allow or prevent changes to
 - *method files*
 - *report templates*
 - *stored calibration files*
- Complete control to allow or prevent executing Performance Verification tests
- Control with over 30 individual software features



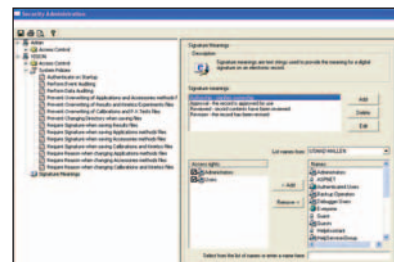
2. Set system policies for VISIONsecurity software to:

- 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 changing directories when opening or saving files



3. Control signature meaning use in VISIONsecurity software:

- Add, delete, or edit signature meanings
- Set which meanings are available to specific users



Thermo Scientific Security Administration Server lets you:

Audit-Proof Compliance

The Thermo Scientific Security Administration Server gives you the peace of mind that your results are stored in a way that you can be comfortable presenting to any auditor. 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.

Provide High Security Without Losing Productivity

Beyond the security controls, you can still configure VISIONsecurity software to your specific needs and set up the most efficient methods for your analyses. Toolbar buttons and software options can be set through the software. This provides users with a consistent software interface that allows them to be as productive as possible and makes compliance with established procedures easy. Once set, these features can be locked through the Security Administration software to prevent modification.

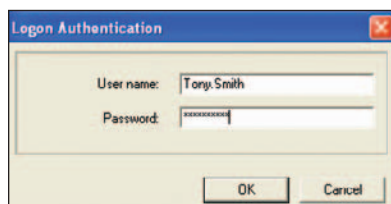
Expand

The Thermo Scientific Security Administration Server software controls VISIONsecurity and the OMNIC suite of software for UV-Visible spectrophotometers, FT-IR, Near-Infrared, and Raman instruments. Additional Thermo Scientific application software controls can be added as they become available.

VISIONsecurity Software Features

User Authentication and Digital Signatures

VISIONsecurity software requires the use of a closed system to provide the appropriate level of security. It works with Windows security to re-authenticate the logged on user's Windows account using Microsoft® authentication. This authentication occurs whenever the logged on user launches VISIONsecurity 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 set for the computer by the server, not the individual computer.

As part of its file security, VISIONsecurity software uses electronic signatures, even though they are not required for a closed system. 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 VISIONsecurity 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 is avoided.

Audit Trails

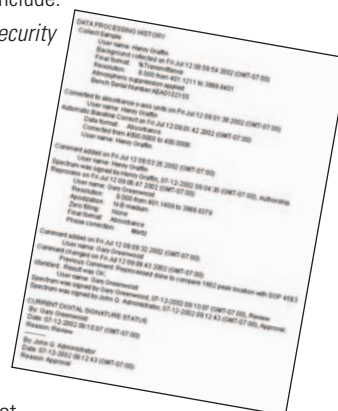
VISIONsecurity software provides complete data and event tracking that allows you to establish thorough audit trails. The two aspects of tracking and logging include:

Spectral Data Processing History

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

- Any changes to data in VISIONsecurity software by any operator
- Digital signature history
- Comments added to data or calibration information
- Method parameters for data collection
- Errors that may have occurred during data collection

Entries to the spectral data processing history include the user's name, date and time, 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.

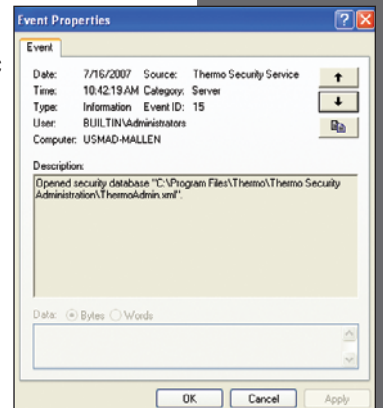
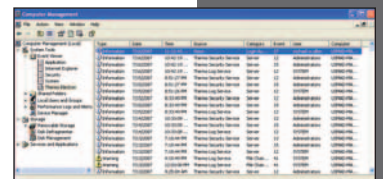


Event Logging

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

- Changes to files associated with the VISIONsecurity software application, even when the software is not running, including creation, modification, renaming, and deletion
- Changes to the Security Administration's application database
- Activity of the Thermo Scientific Security Server
- Program activity and detailed changes to files are tracked while VISIONsecurity 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 Thermo Scientific spectrophotometer, 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

VISIONsecurity software gives you the ability to store and retrieve data ensuring your ability to prove the quality of the work you perform using your Thermo Scientific spectrophotometer. 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:

- Easy access to method information and instrument parameters
- One-click access to original data, allows you to revert to data as it was originally collected.

Access to original data allows you to fine-tune your analysis method, without losing information or to troubleshoot problems with your data analysis routine.

Many data archival, retrieval, and output Options

VISIONsecurity gives you many options for storing, archiving, and retrieving data including:

- AutoSave – automatically save data without operator intervention.
- Auto-Print function allows data to be “printed” to an Adobe PDF file without operator intervention.
- Combining Auto-Print using the PDF file output and AutoSave allow you to save data in two formats to two physical storage locations simultaneously.
- Archive data on network drives with Thermo Scientific Log Service file security
- Save, export, or copy results, spectra, and data to external applications for further analysis
- Copy report data to the Windows clipboard for use in other external applications

Keeping Your Analysis Process in Control

Thermo Scientific UV-Visible spectrophotometers include pre-programmed performance verification tests to give you the assurance that the system is working properly at all times. Featuring the widest range of standards and Certified Reference Materials traceable to NIST and NPL, Thermo Scientific UV-Visible products allow complete Installation, Operational, and Performance Qualification.

Our Smart Accessories™ have built-in recognition routines for easy method development and execution. With over 25 accessories for our Evolution line of spectrophotometers, we have a solution to meet your analysis needs.



Operating System Requirements

Windows 2000 or XP Professional

Additional Information

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

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PS51414_E 09/07M

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