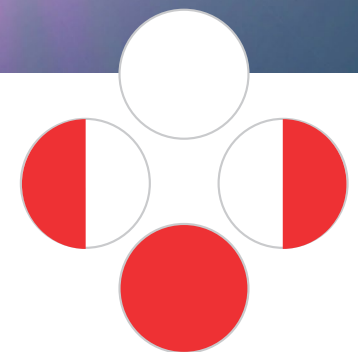# Thermo Scientific SolstiX XRD Software with Security Suite

For ARL EQUINOX XRD
Enables 21 CFR Part 11 compliance

Security Suite Software, a proven compliance component of many other Thermo Scientific systems, integrates directly into SolstiX Software so analysts can confidently operate the trusted Thermo Scientific™ ARL™ EQUINOX X-ray Diffractometer range in compliance with regulatory requirements.

In the quest for 21 CFR Part 11 compliance, Thermo Scientific™ SolstiX™ Software with Security Suite Software makes your job easy. The package provides maximum security and data integrity assurance for the varying analytical needs of your laboratory.

SolstiX Software with Security Suite logs changes to files associated with the software, even when SolstiX Software is not running.

Thermo Fisher
SCIENTIFIC

Thermo Scientific SolstiX Software with Security Suite

Thermo Scientific SolstiX Software with Security Suite 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 XRD Software, it combines security and data integrity assurance with the full-featured flexibility to address the varying analytical needs of your laboratory. Because SolstiX Software with Security Suite can be configured on a per user basis, on one system or across your enterprise, you can ensure 21 CFR Part 11 compliance. SolstiX™ Software with Security provides:

Full system access control

• Works with Windows security to authenticate operators

• Software access is controlled on a per user basis on single or multiple instruments

Flexible record storage and retrieval

• Original data is saved automatically to allow reproduction of results

• Retrieval and review in Thermo Scientific™ OMNIC™ Software, or with database or graphical programs

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
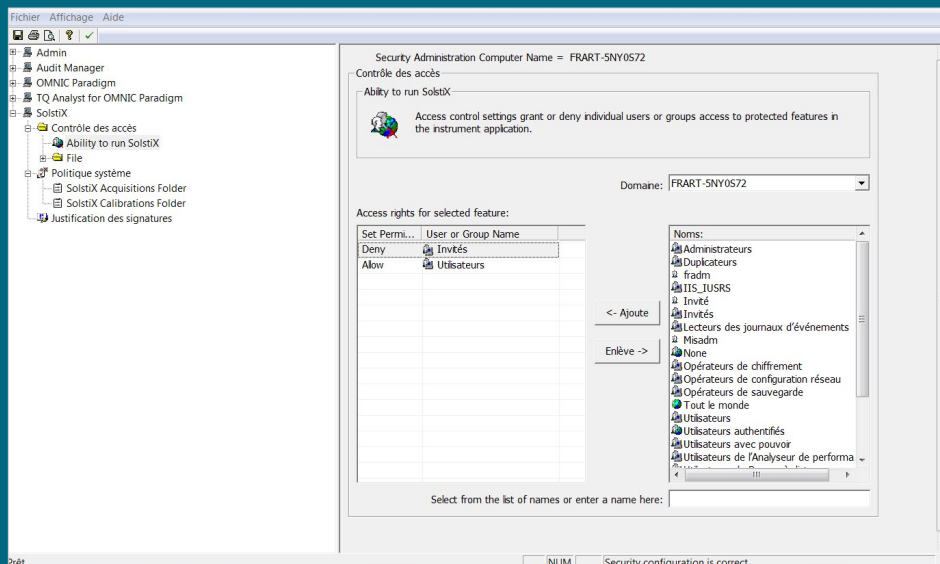
Security Suite, a maximum control with minimum effort.

# Thermo Scientific Security Administration abilities

Set system policies

- 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 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 software when a user logs on
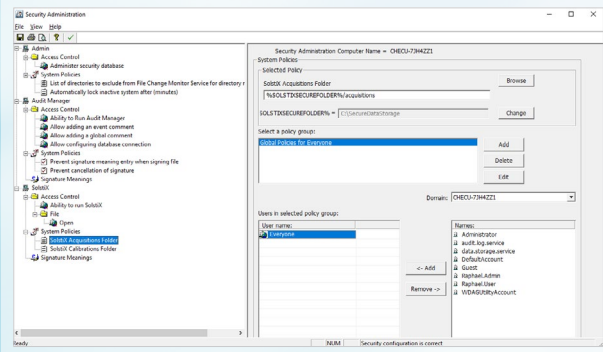
Control access to software features

- Ability to run XRD software

- Complete menu item control

- Detailed control of experiment and spectral library subroutines

- Ability to run macros and external programs
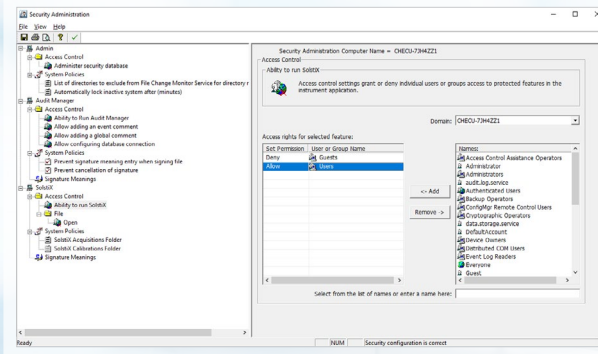
Control signature meaning use

- Add, delete, or edit signature meanings

- Set which meanings are available to specific users

3
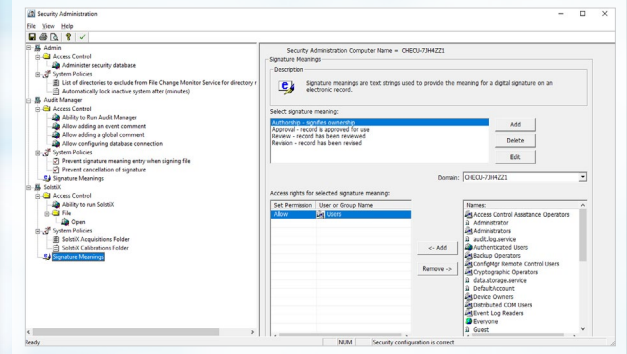
Designed with the regulations in mind

SolstiX Software with Security Suite was designed from the ground up using our strictly controlled Product Development Process (PDP) to ensure a full compliance. We maintain complete traceability in our development process, including specification, revision control and software validation.

Thermo Scientific Security Administration Server

At the heart of the SolstiX Software with Security Suite the Thermo Scientific Security Administration Server. This versatile application gives your system administrator control over SolstiX 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 XRD workstation, or as a server application to administer SolstiX Software. Thermo Scientific Security Administration Server lets you:

Show your stuff
Thermo Scientific Security Administration Server gives you the peace of mind that your X-ray diffractometer'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 XRD software.

Provide high security without losing productivity
Beyond the security controls, you can still configure software to your specific needs and obtain the best usable information from your analyses. 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.
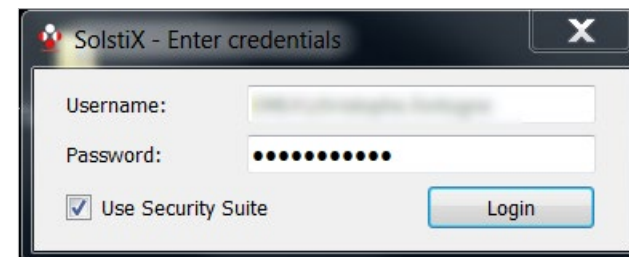
SolstiX Software with security suite features

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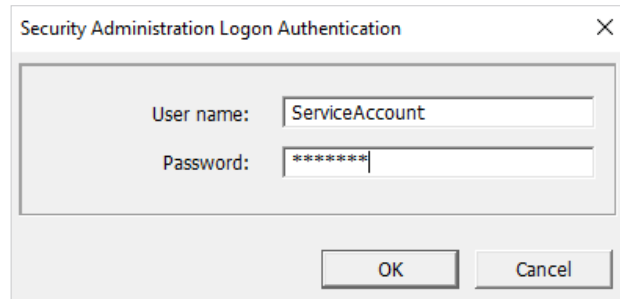
It is important to keep in mind that even with the features provided in the Thermo Scientific Security Administration Server and SolstiX Software with Security Suite, compliance with 21CFR Part 11 requires additional effort. Best practices for computer security should be applied, and written policies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

Audit trails
SolstiX Software with Security Suite 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 SolstiX 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.

Event logging

System use and file event logging is output in a custom Thermo Scientific file, 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 SolstiX Software application, even when the software is not running, including creation, modification, renaming, and deletion

d. Program activity and detailed changes to files are tracked while SolstiX Software is running; including log-on, log-off and failed log-on; file signing and failed signing events and file creation or modification events.

Record storage and retrieval

SoltiX Software with Security Suite gives you the ability to store and retrieve data to ensure your ability to prove the quality of the work you perform using your ARL EQUINOX XRD. With raw data storage and many storage and retrieval formats, you can get the information you need at critical times.
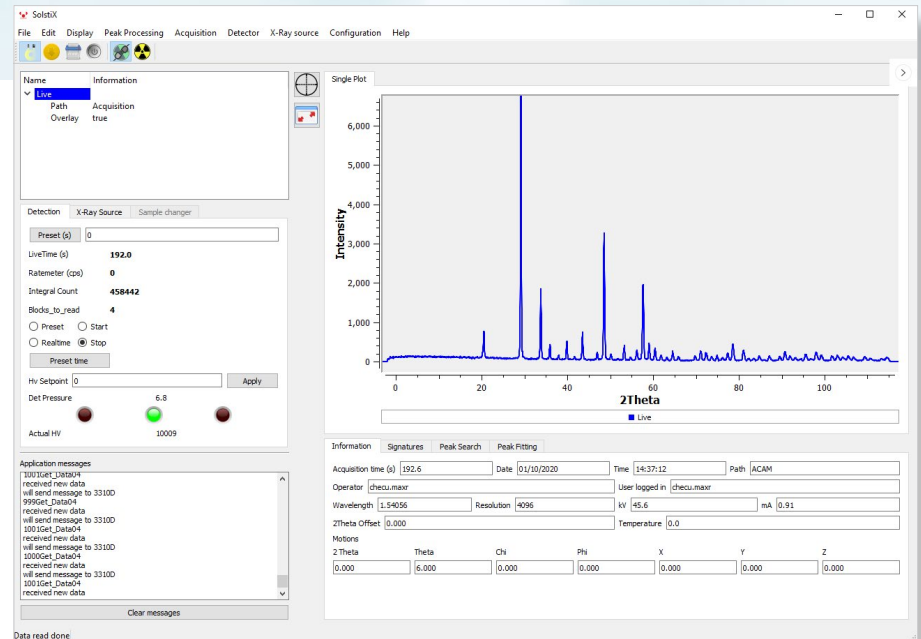
Y2O3 powder diffractogram.

This comprehensive activity tracking and logging assures you the ability to create detailed audit trails for your XRD instrument, and the data it generates.

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

c. Copy spectra and reports in graphical format to external programs

<?xml version="1.0" standalone="yes"?>
<TXL major="0" minor="7">
        <Signatures count="2"
masterhash="8d4920b74a9bbc67d7a0a7c401f36bca9cfe9e746912eef3f1c6dce11272d204" hashfunction="SHA-256">
        <Signature>
                <TxlVersion major="0" minor="7"/>
                <SequenceNumber>1</SequenceNumber>
                <SignatureMeaning>Record created</SignatureMeaning>
                <Timestamp>12/10/20 15:27:38</Timestamp>
                <SigningUser>EMEA\ServiceAccount</SigningUser>
                <SigningUserComment>Record creation</SigningUserComment>
                <Hash
hashfunction="SHA-256">8d0dd65a659c3944593a51db10c78b92e22be3366c16a5d1403a79ba9639de17</Hash>
        </Signature>
        <Signature>
                <TxlVersion major="0" minor="7"/>
                <SequenceNumber>2</SequenceNumber>
                <SignatureMeaning>Record reviewed</SignatureMeaning>
                <Timestamp>12/10/20 15:27:50</Timestamp>
                <SigningUser>EMEA\ServiceAccount</SigningUser>
                <SigningUserComment>Review1</SigningUserComment>
                <Hash
hashfunction="SHA-256">21122da851ab9795219ed57010f8dddc4f3075eae2191cd5dcaaf79ed2827b8e</Hash>
        </Signature>
        </Signatures>
        <Header>
                <Resolution>4096</Resolution>
                <OperatorName>ServiceAccount</OperatorName>
                <Wavelength>0x1.8a6223e186983p+0</Wavelength>
                <Radius>0x1.f400000000000p+7</Radius>
                <Detector>Detector_2D_IP</Detector>
                <DetectorOffset>123456</DetectorOffset>
                <DetectorRange>123456</DetectorRange>
                <DetectorTDC>123456</DetectorTDC>
                <XRaySource>Unreferenced</XRaySource>
                <XRayTargetType>OtherTarget</XRayTargetType>
                <FrontOpticType>Unreferenced_Optic</FrontOpticType>
                <BackOpticType>Unreferenced_Optic</BackOpticType>
                <Ru>0x1.edd2f1a9fbe77p+6</Ru>
                <Rv>0x1.edd2f1a9fbe77p+6</Rv>
                <Rw>0x1.edd2f1a9fbe77p+6</Rw>
                <Rx>0x1.edd2f1a9fbe77p+6</Rx>
                <Ry>0x1.edd2f1a9fbe77p+6</Ry>
        </Header>
        <Calibration major="0" minor="1"
hash="d7066ef571526db1a384399cf351d03b4d3a25e692c363cb3d4606e98fb5b437" hashfunction="SHA-256">
                <OrigFilename/>
                <RefPatternName/>
                <NumberOfPoints>0</NumberOfPoints>
                <Xpos count="0"/>
                <ASPL rows="4"
columns="100">000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000
0000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000

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.

thermo scientific

Thermo Scientific SolstiX XRD Software with Security Suite

For ARL EQUINOX XRD
Enables 21 CFR Part 11 compliance

Find out more on SolstiX XRD Software at **thermofisher.com/solstix**

Thermo Fisher
SCIENTIFIC