

Getting Started with Security Suite Software

The Thermo Scientific™ Security Suite includes software applications to run your Thermo Scientific instrument with secure data storage. The Security Suite works in conjunction with your network's or computer's operating system and your Thermo Scientific instrument applications to provide a secure environment that will help you support the requirements of 21 CFR Part 11. The Security Suite uses the Windows™ Event Viewer to log application events and changes to acquired spectral data and associated files. When an instrument application configured with data security is running, it is in constant communication with the Security Suite software in order to enforce the defined security policies. For more information, refer to the *Security Administration User Guide* in the documentation set that came with this software.

Note Read this document and complete the accompanying System Owner Form before you install the Security Suite software.

Contents

[“Configuration Options” on page 1](#)
[“Installation Overview” on page 2](#)
[“Roles and Responsibilities” on page 4](#)
[“Default User Groups” on page 5](#)
[“Important Terms” on page 6](#)
[“Supporting Documents” on page 8](#)

Configuration Options

Single Computer Configuration



Instrument Control
+
Security Administration
+
Secure Data Storage

All Security Suite software components are installed on the computer attached to the Thermo Scientific instrument.

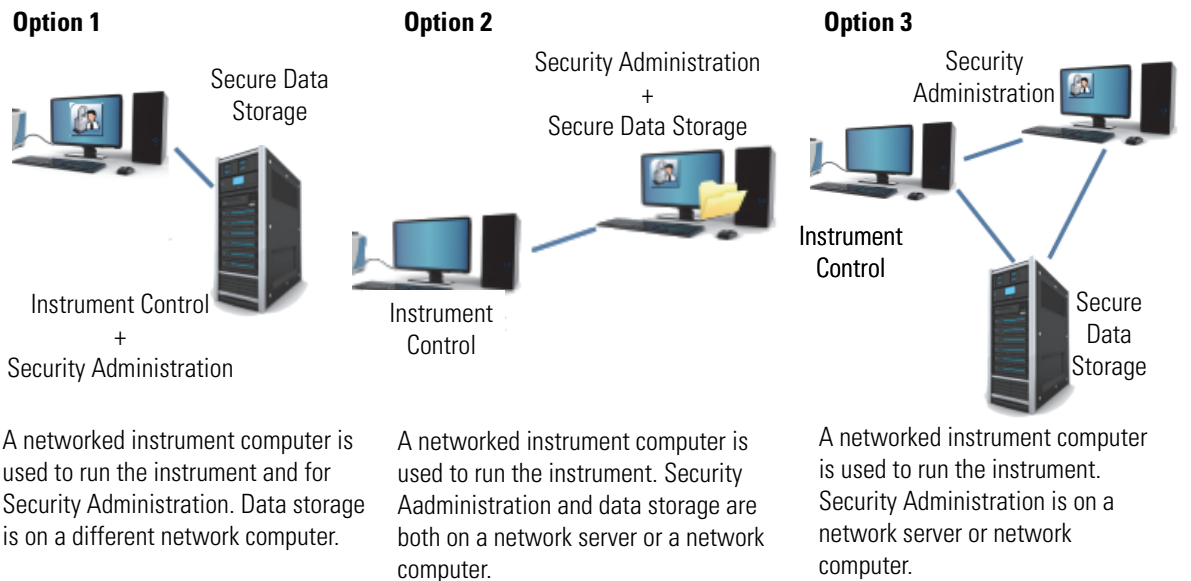
Note

- There are no centralized Security Administration configuration functions for this option, all computers must be individually configured
- This configuration centralizes all Security Administration and auditing functions to the Instrument Control computer.
- Single Computer Configurations, local security policies must be applied individually for each Thermo Scientific instrument

Components Distributed on a Network

Note Be prepared to provide a Domain Administrative login password for all Distributed Configurations.

Networked computers or servers in a shared domain are used to run the instrument, Security Administration and data storage. There are three Distributed Configurations options for installing the Security Suite software components. Only options 2 and 3 provide centralized Security Administration control.



Installation Overview

The following is an overview of the steps required to install and configure the Security Suite software.

Note You must be an administrator password login credentials on the computer attached to your Thermo Scientific instrument in order to install the Security Suite software.

Table 1. Security Suite installation overview

Step	Person	Task
1	Security Administrator	Coordinate with internal IT Administrator to complete the Thermo Scientific System Owner Form. A PDF version of the form is available in the documentation set.
2	IT Administrator	Complete any required Windows administration tasks such as creating a service account and adding user accounts to user groups (see the System Owner Form).
3	TFS Service Representative	Verify that the System Owner Form has been completed.
4	TFS Service Representative	Start the Security Suite installation on the computer attached to the Thermo Scientific instrument and select a Security Administration configuration option (see the System Owner Form).

Table 1. Security Suite installation overview

Step	Person	Task
5	TFS Service Representative	If using a Distributed configuration option , browse to an IT-accessible location for the Network Installation Package(s) (i.e., network computer or flash drive) and copy the package to that location.  WAIT! Leave the Security Suite installation wizard open until the IT Administrator completes the next step!
6	IT Administrator	Run any required Network Installation Package(s) on the selected network server or network computer as defined in the System Owner Form.
7	TFS Service Representative	Verify that any required network installation packages have been installed. Then follow the steps in the installation wizard to complete the Security Suite installation on the instrument computer.
8	Sec Administrator/TFS Service Representative	Perform installation qualification (IQ).
9	TFS Service Representative	Open the Security Administration program. A warning message may indicate that the event log(s) are not set to archive. If the message appears, choose OK to close the message and complete the steps below to set both event logs to archive when full. (Windows default settings are to overwrite Event logs when full.) ❖ To set the event logs to archive when full 1. From the Security Administration main screen, choose View (menu) > View Event Log to open the Event Viewer window. 2. In the Event Viewer left pane, right-click Thermo Electron in the Applications and Services Logs group, choose Properties and set “When maximum event log size is reached:” to “Archive the log when full, do not overwrite events” and click OK. 3. In the Windows Logs group, right-click Security, choose Properties, make the same change described in step 2 above and click OK. 4. Click Close to close the Event Viewer window. 5. In Security Administration, choose File (menu) > Save Settings.

Table 1. Security Suite installation overview

Step	Person	Task
10	IT Administrator	Specify the location for secure data storage (i.e., the folder that is fully accessible only to the service account specified in the System Owner Form). Follow these steps: ❖ To specify the location for secure data storage 1. In the Security Administration navigation (left) pane, click the plus (+) sign at the left of the icon for the first instrument application. 2. Click the + sign at the left of the System Policies icon to open the group. 3. Click to select the Directory for spectral data policy. 4. Click the Change button at the top of the right pane. 5. Enter or browse to the location of the folder designated for secure data storage in the System Owner Form and choose Select. 6. Choose OK to close the message box. 7. Choose File (menu) > Save Settings. The variable name in the “Directory for spectral data” box in the right pane is unchanged. However, the variable is now set to the specified folder and path. All of the remaining “directory” policies (for example, for experiments, log files, etc.) in all the remaining instrument application groups are automatically set to specified folder and path. This sets the default storage location for all acquired spectral data and associated files will be stored in this folder and path.
11	Security Administrator	Set access rights, policy permissions and signature meanings for the Security Administration authorization groups and the Thermo Scientific instrument applications that will be controlled by Security Administration software.

Roles and Responsibilities

The Security Suite software installation requires a coordinated effort between the person performing the installation (normally a Thermo Scientific service representative) and the administrators at the installation site (one or more for the instrument and one from the company’s IT department). In this documentation set, we use the following terms to designate these roles.

Table 2. Roles and responsibilities to perform Security Suite installation

Role	Responsibilities
System Owner	A user (most likely a scientist or lab manager) responsible for the use and management of the Thermo Scientific instrument and its associated computer at the customer site. This person is responsible for completing the System Owner Form before the TFS Service Representative arrives to perform the installation.

Table 2. Roles and responsibilities to perform Security Suite installation

Role	Responsibilities
Security Administrator	One or more users (or a group of users) responsible for administration of policies and access control of instrument applications managed by Security Administration software . These users should have full access to the Security Administration program.
Instrument Operators	One or more users (or a group of users) responsible for running Thermo Scientific instruments at the installation site. These users typically have restricted access to the software applications used to run the instrument.
TFS Service Representative	A factory-trained and certified service representative from Thermo Fisher Scientific responsible for installing and servicing the Thermo Scientific instrument and for installing software and configuring the instrument to operate with secure data storage as defined in the System Owner Form.
IT Administrator	IT (Information Technology) administrator responsible for the upkeep, configuration, and operation of the instrument computer and any networked multi-user computers and servers at the customer site. This person must be available during the installation in order to install any required Network Installation Package(s). The type of network installation package(s) required depends on the installation configuration specified in the System Owner Form. An IT administrator is typically also responsible for the <i>service account</i> used for secure storage of instrument data and associated files. This account must have full access to the data storage folder. The service account name must be specified during the Security Suite installation. The data storage folder must be specified once, after the Security Administration program is started for the first time. The specified location is used for all the installed instrument applications. An IT administrator also typically creates any required user accounts and authorization groups on the network. These groups represent the user roles for the Thermo Scientific instrument.

Default User Groups

The Security Suite automatically uses two default groups with recommended compliance assignments, such as to allow or deny access to Security Administration software, or to require the use of electronic signatures and/or comments. The default group names represent the two main types of users who will be using the Security Suite software (that is, administrators of Security Administration software (Administrators) and instrument operators (Users)). Accounts for individual users can then be assigned to one of these user groups, or set up individually as needed.

Table 3. Default user groups for Security Suite software

Authorization Group	Description
Administrators	Windows group that has full access to all the features of the Security Administration program , including system configuration. These users will be responsible for administration of system policies and access control of instrument applications managed by Security Administration software.

Table 3. Default user groups for Security Suite software

Authorization Group	Description
Users	Windows group that has limited access to the instrument applications that are controlled by the Security Administration software (i.e., only those features needed to operate the instrument with secure data storage).

Note

- The default groups are intended to save you time in setting system policies for each instrument application. The access rights and policy settings for the default groups are based on typical use. You can easily change the default rights and settings to customize security administration for your needs.
- You can keep the default group names or replace them with group names that are more meaningful to your organization. Before you can use new groups in Security Administration software, they must first be set up on the network domain or local computer. For more information, see “Replacing a Group Name for All Protected Features of an Application” in the Security Administration User Guide.

Important Terms

These terms are used in the Security Suite installation wizard and throughout the documentation set.

Table 4. Terms used in the Security Suite installation wizard and documentation set

Term	Meaning
instrument	Thermo Scientific instrument and any accessories it came with.
instrument applications	Thermo Scientific software applications used to run the Thermo Scientific instrument and accessories and for data analysis.
Security Administration program	Thermo Scientific software program that works in conjunction with your network's or computer's operating system and your instrument applications to provide a secure environment that will help you support the requirements of 21 CFR Part 11.
security policies	Access control, system policy and signature meaning requirements for each Thermo Scientific instrument application covering such things as access to menu commands and requiring electronic signatures. Security policies for all instrument applications are defined in the Thermo Scientific Security Administration program and described in the security setup guide for each instrument application.
Security Suite installation wizard	Thermo Scientific application that walks the operator (typically a Thermo Scientific service representative) through the Security Suite installation, starting and ending on the computer attached to the Thermo Scientific instrument. Run setup from the folder.

Table 4. Terms used in the Security Suite installation wizard and documentation set

Term	Meaning
Network Installation Package	Installation information for the specified network components of a distributed security administration configuration . The Security Suite installation wizard prompts the operator to copy the Network Installation Package (or packages) to an accessible network location or flash drive for the on-site IT administrator to install. The Network Installation Package(s) must be installed before the installation wizard can be completed on the instrument computer.
service account	Microsoft Windows account that provides automatic password management that can be delegated to other administrators (for example, to the Data Storage Manager for the Thermo Scientific Security Administration program). We recommend that you set up a managed service account for secure data storage with our Security Administration software. However, this is not a strict requirement and any password-protected account that has the “Logon as Service” right and Full Access to the data storage location. This account must also be a member of the Local Users group on each instrument computer. The service account name is required to complete the System Owner Form and must be entered during the Security Suite Installation. Note: Users in the Instrument Operators group should not have access to this service account.
data storage manager (also referred to as Thermo Scientific File Service)	A component of the Thermo Scientific Security Suite that manages secure storage of instrument data. The Thermo Scientific File Service allows an instrument application to write data to the specified secure data storage location. The data storage folder location must be specified once, after the Security Administration program is started for the first time. The specified location is used for all the installed instrument applications.
network computer	A computer connected to a multi-user network or domain. If a network computer is used to install the Security Administration program and services or as the data storage location, the computer can be connected to the same domain as the Thermo Scientific instrument or a different trusted domain.
network server	A networked computer dedicated to managing, storing, sending, and processing data 24-hours a day. If a network server is used to install the Security Administration program and services, the server can be connected to the same multi-user network (i.e., domain) as the Thermo Scientific instrument or a different trusted domain at the customer site. Note: A server running the Windows Server operating system is preferred over one running the Professional version of Microsoft™ Windows operating system software.
installation qualification (IQ)	Verifies the proper installation and configuration of a system. This can include ensuring that necessary files have been loaded, all instrument components and accessories have arrived at the customer site, and the equipment has been installed.

Table 4. Terms used in the Security Suite installation wizard and documentation set

Term	Meaning
Thermo Software IQ	Thermo Scientific software application that can be used to verify that the correct software files were installed on the computer connected to the Thermo Scientific instrument and that the files have not been changed, deleted or overwritten since they were installed. The Thermo Software IQ program is installed with all Thermo Scientific instrument applications. For more information, see the <i>Thermo IQ User Guide</i> available from the Help menu on the application's Home screen.

Supporting Documents

The following documents are included with this software installation package. PDF versions are provided in the documentation set, which is on separate media from the software.

Table 5. Security Suite documentation set main components

Document Name	Description
System Owner Form	Intended to facilitate communication between the System Owner and the on-site IT Administrator to identify, document and complete the Windows administrative tasks required to ensure successful installation. This document must be completed before the Thermo Scientific Service Representative can install the Security Suite software.
Security Administration User Guide	Describes the components and underlying concepts of the Security Suite and explains how to use the Security Administration program.
Security Administration Help System	Explains how to use the Security Administration application in a format that is accessible while using the software.
Security setup guides (for example, Setting Up OMNIC Spectra with Data Security)	A quick reference guide to setting security policies for each Thermo Scientific instrument application. These guides provide default settings for the included Security Administration user groups (Administrators and Users).