

Security, Audit, and E-Signature (SAE) Administrator Console v1.0.2

USER GUIDE

for use with AccuSEQ™ Real-Time PCR Software v3.0 or later

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C.0	26 June 2023	Updates for the AccuSEQ™ Software v3.2 launch
B.0	16 June 2020	Updates to the sign in procedure, the network and password security requirements, and additional information about default roles and permissions for the AccuSEQ™ Software v3.1 launch.
A.0	18 September 2019	New user guide for the Security, Audit, and E-Signature (SAE) Administrator Console v1.0 for the AccuSEQ™ Software v3.0 or later (for use with the QuantStudio™ 5 Real-Time PCR System).

The information in this guide is subject to change without notice.

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Get started with the SAE Administrator Console

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About the SAE Administrator Console

The Security, Audit, and E-Signature (SAE) Administrator Console is the tool that administrators use to configure the SAE module in the AccuSEQ™ Software.

The SAE module includes three components:

- The Security, Audit, and E-Signature (SAE) Administrator Console that an administrator uses to configure the module.
- The internal SAE server that stores settings, user accounts, audit records, and e-signature records. By default, the SAE server is installed on the same computer as the Security, Audit, and E-Signature (SAE) Administrator Console. You do not directly access the SAE server.
- The sign in, e-signature, and log screens that users interact with in the AccuSEQ™ Software.

The SAE module in the AccuSEQ™ Software includes the following functions.

Function	Description
System security	Requires users to sign in to the AccuSEQ™ Software and the SAE module. A default administrator account is provided in the software. You can set up additional user accounts and customize the permissions that are assigned to an account.
Auditing	Automatically audits changes to experiments in the AccuSEQ™ Software and modification to settings in the SAE module.
Electronic signature (e-signature)	Determines if users can e-sign experiments. After e-signature requirements are fully met, an experiment cannot be modified. Note: While partially signed , users with the e-signature permission can revert the e-sign of an experiment. This unlocks the experiment.

The SAE module also includes two default Administrator roles.

- System Administrator—full set of permissions
- IT Administrator—has permission to edit SAE settings, but not to E-sign in the AccuSEQ™ Software.

For more information, see “Default user roles and permissions—AccuSEQ™ Software” on page 12.

Workflow: Configure the SAE module using the SAE Administrator Console

Get started with the SAE Administrator Console (before first use)

“Start the SAE Administrator Console” on page 7



“Change your SAE user account password” on page 7



Configure the SAE Administrator Console (if needed)

Chapter 2, “Manage SAE user accounts”

A default system administrator user account is provided in the software. Complete this step of the workflow to add more user accounts or to enable/disable e-signature function for a user.



Chapter 3, “Manage the system security function”

Complete this step of the workflow to manage system security policies and set user name and password requirements for all user accounts.



Chapter 5, “Manage the e-signature function and logs”

Complete this step of the workflow to create e-signature reasons and view e-signature logs.



View logs (if needed)


“View and print object audit logs” on page 17

“View and print event audit logs” on page 18

“View and print the e-signature log” on page 20

Start the SAE Administrator Console

The SAE Administrator Console is automatically installed with the AccuSEQ™ Software.

1. Close the AccuSEQ™ Software, if it is open.
2. Double-click the **SAE Admin**  icon to open the SAE Admin console.
3. Enter the administrator **User Name** and **Password**, then click **OK**.

Change your SAE user account password

1. Click the name of the logged in user in the top right corner of any screen.
2. Click **Profile**.
3. Click **Change Password**.
4. Enter the old password, then enter a new password 2 times. Click **OK**.
5. *(If needed)* Enter a new **First Name**, **Middle Name**, **Last Name**, **Phone**, and/or **E-mail**.
You cannot change any of the remaining fields in the **Profile** dialog box. To make other changes, see “Edit a user account” on page 10.
6. Click **Update**.

Optional tasks

Determine the signed-in user

The name of the signed-in user is displayed in the top-right corner of the SAE Administrator Console window.

Display the software version

The software version is displayed on the sign in screen.

If you are signed in to the software, exit the application, then start the software to display the sign in screen.

Change your SAE user account password

1. Click the name of the logged in user in the top right corner of any screen.
2. Click **Profile**.
3. Click **Change Password**.
4. Enter the old password, then enter a new password 2 times. Click **OK**.
5. *(If needed)* Enter a new **First Name, Middle Name, Last Name, Phone, and/or E-mail**.
You cannot change any of the remaining fields in the **Profile** dialog box. To make other changes, see “Edit a user account” on page 10.
6. Click **Update**.

Network and password security requirements

Network configuration and security

The network configuration and security settings of your laboratory or facility (such as firewalls, anti-virus software, network passwords) are the sole responsibility of your facility administrator, IT, and security personnel. This product does not provide any network or security configuration files, utilities, or instructions.

If external or network drives are connected to the software, it is the responsibility of your IT personnel to ensure that such drives are configured and secured correctly to prevent data corruption or loss. It is the responsibility of your facility administrator, IT, and security personnel to prevent the use of any unsecured ports (such as USB, Ethernet) and ensure that the system security is maintained.

Note: The AccuSEQ™ Software cannot connect to an Active Directory (to use existing domain usernames/passwords).

Password security

Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

It is the sole responsibility of your IT personnel to develop and enforce secure use of passwords.



Manage SAE user accounts

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Create a user account

1. Click the **User Management** tab at the top of the screen.
2. Click **Users** on the left of the screen.
3. Click **Add New User**, then enter the user name, first name, (optional) middle name, and last name. The field limits are specified in the **SAE Settings** tab (see “Configure user name and password settings” on page 16).

Note: The first name and last name are displayed as the name of the signed-in user in the top-right corner of the SAE Administrator Console window.

Note: You cannot change the user name after you save the user account.

4. Enter a **Password**, then re-enter it for confirmation.
5. Select **Active** as the status.
6. Select a role for the user account.

Note: Each role assigns specific permissions to the user. For information on roles and associated permissions, see “Default user roles and permissions—AccuSEQ™ Software” on page 12.

7. Select or deselect **Pre-Expire**.
If selected, the user must specify a new password the first time they sign in.

Note: The user account password automatically expires after the number of days specified in the **SAE Settings** tab.

8. Select or deselect **E-signature Authority**.
If selected, the user is allowed to e-sign experiments or revert e-signatures in the AccuSEQ™ Software.
9. (Optional) Enter phone, email (for information only), and comments.
10. Click **Save**.

Edit a user account

1. Click the **User Management** tab at the top of the screen.
2. Click **Users** on the left of the screen.
3. Select the user account to edit, then click **Edit User**.
4. Edit the settings if needed.

Note: You cannot change the username after the user account is saved.

5. Click **Save**.

Activate a suspended SAE user account

If a user makes too many unsuccessful login attempts, the user account will be suspended and the user will be temporarily locked out of the software.

Note: The allowed login attempts are specified in the **SAE Settings** tab.

1. Click the **Users** tab.
2. Select a user account, then click **Edit User**.
3. Change the status from **Suspended** to **Active**.
4. Click **Save**.

Inactivate (disable) a user account

Note: You cannot delete a user account. Instead, set the account status to **Inactive**. An inactive user cannot sign in to the software.

1. Click the **User Management** tab at the top of the screen.
2. Click **Users** on the left of the screen.
3. Select a user account, then click **Edit User**.
4. Change the status from **Active** to **Inactive**.
5. Click **Save**.

Reset a user account password

1. Click the **User Management** tab at the top of the screen.
2. Click **Users** on the left of the screen.
3. Select the affected user account, then click **Edit User**.
4. Enter a replacement password for the user account, then re-enter the password for confirmation.
5. If you want the password to be temporary, select **Pre-Expire** to require the user to enter a new password the first time they sign in.
6. Click **Save**.

View a user role

1. Click the **User Management** tab at the top of the screen. .
2. Select the **Role** of interest, then click **View Role**
The **Permissions** for the selected Role are displayed.
3. Click **Close** to close the window.

Create a user role

A user role defines a set of permissions that you can assign to user accounts. If the default user roles do not define the set of permissions that you require, you can create a new user role with the necessary permissions.

For a description of default user roles and permissions, see “Default user roles and permissions—AccuSEQ™ Software” on page 12.

1. Click the **User Management** tab at the top of the screen.
2. Click **Roles** on the left of the screen.
3. Click **Add New Role**, then enter the role name and description.
4. Select the permissions for the role.
5. Click **Save**.

Default user roles and permissions—AccuSEQ™ Software

Note: The e-signature function is enabled/disabled at the user-account level. It is not a permission that is associated with a role.

Two types of roles are provided:

- **User roles** (editable)—For use by individuals in various laboratory roles (**Analyst**, **Scientist**, and **System Administrator**).
- **Special roles** (not editable)
 - **IT Administrator**—Has only the edit **Security, Auditing, and E-Signature settings** permission. The **IT Administrator** role is not authorized to sign in to the AccuSEQ™ Software.
 - **Thermo Fisher Scientific Service**—Has the **Associate Generic Properties** permission (specific to this role) and is for service use only. This role cannot be selected for new user accounts.

Table 1 Permissions associated with default user and specialty roles

Permissions		User roles (editable)			Specialty roles (not editable)	
Category	Function	Analyst	Scientist	System Administrator	IT Administrator	Thermo Fisher Scientific Service
Experiments	Create	Yes	Yes	Yes	No	No
	Delete	No	No	Yes	No	No
	Edit experiment properties	Yes	Yes	Yes	No	No
	Edit plate setup	Yes	Yes	Yes	No	No
	Edit qPCR method	Yes	Yes	Yes	No	No
	Import or export	Yes	Yes	Yes	No	No
Experiments created by other users	Create or delete	No	No	Yes	No	No
	Edit plate properties	No	No	Yes	No	No
	Edit plate setup	No	No	Yes	No	No
	Edit qPCR method	No	No	Yes	No	No
	Import or export	Yes	Yes	Yes	No	No
Template	Create or edit an admin defined template	No	No	Yes	No	Yes
	Delete an admin defined template	No	No	Yes	No	No
	Create a locked template	Yes	Yes	Yes	No	No
	Publish an admin-defined or factory default template	No	No	Yes	No	No
	Unpublish an admin-defined or factory default template Unpublishing hides the template from users who do not have "View unpublished template" permission.	No	No	Yes	No	No
	View an unpublished template	No	No	Yes	No	Yes

Table 1 Permissions associated with default user and specialty roles (continued)

Permissions		User roles (editable)			Specialty roles (not editable)	
Category	Function	Analyst	Scientist	System Administrator	IT Administrator	Thermo Fisher Scientific Service
Template	Import or export a template	Yes	Yes	Yes	No	No
	Associate Assay Properties For use by Thermo Fisher Scientific Service personnel only.	No	No	No	No	Yes
Run	Start or stop	Yes	Yes	Yes	No	No
Analysis settings	Edit	Yes	Yes	Yes	No	Yes
Analysis	Omit wells during re-analysis	Yes	Yes	Yes	No	No
Plot settings	Modify plot properties	No	Yes	Yes	No	No
Results (from Report screen)	Export	No	Yes	No	No	No
Report	Print Experiment Report	Yes	Yes	Yes	No	No
	Print Audit Logs Report	No	No	Yes	No	No
	Print E-signature Report	No	No	Yes	No	No
Security, Auditing, and E-Signature settings	Edit	No	No	Yes	Yes	Yes



Manage the system security function

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Use the system security function

The system security function is always enabled and cannot be disabled. All users are required to sign in to the AccuSEQ™ Software.

However, the SAE IT Administrator or System Administrator can change security policies, user name requirements, and password requirements.

Configure the security policies

Configure the security policy for passwords, account suspension, and session lockout.

1. Click the **SAE Settings** tab at the top of the screen.
2. Click **Security Policy** on the left of the screen.
3. Enable or disable **Password Expiration**.
If enabled (**On**), set the remaining parameters:
 - a. Select the number of days for which the password is valid.
 - b. Select the number of days to notify a user before password expiration.
4. Enable or disable **Account Suspension on Incorrect Login Attempts**.
If enabled (**On**), set the remaining parameters:
 - a. Select the number of hours that the account will be suspended.
 - b. Select the number of times that a user can enter an incorrect password (**Consecutive Password Failure**) within the selected number of minutes.
5. Enable or disable **Session Lockout**.
If enabled (**On**), select the number of minutes that the session will be locked.
6. Click **Save Settings**.

To restore all settings to the default values:

1. Click **Restore Default** to restore all settings to the default values.
2. Click **Save Settings** to save the default settings.

Configure user name and password settings

Configure the settings for user names and passwords.

Note: New settings are applied only to new user accounts. To apply new settings to existing user accounts, you must manually edit the accounts (see “Edit a user account” on page 10).

1. Click the **SAE Settings** tab at the top of the screen.
2. Click **User Name & Password** on the left of the screen.
3. Select the minimum and maximum number of characters for a user name.
4. Select the minimum and maximum number of characters for a password.
5. Select the required characters for a password.

Note: Allowed special characters: `~!@#\$%^&*

6. Select the number of previous (most recent) passwords that the user cannot reuse.
7. Enable or disable **Pasting Password**.
8. Click **Save Settings**.

To restore all settings to the default values:

1. Click **Restore Default** to restore all settings to the default values.
2. Click **Save Settings** to save the default settings.



View audit logs

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You can view the following audit logs from the **Logs** tab:

- **Object audit logs**—Object audits capture information that has changed (in templates and experiments). For example, updates to values like run method and plate setup.
- **Event audit logs**—Event audits capture user actions such as signing in/out, saving, or running the instrument.

This information is automatically recorded by the software and cannot be modified.

View and print object audit logs

The object audit log for an experiment is also accessible in the AccuSEQ™ Software.

1. Click the **Logs** tab at the top of the screen.
2. Click **Audit Logs** on the left of the screen.
3. Click **Filters**, then select the **Application** for the audit log (on far right of screen): **SAE** or **AccuSEQ**. Enter other filter criteria if needed, then click **Apply Filter** to display the filtered list.
4. Click the **Objects** tab.
5. Click **Refresh** to synchronize the SAE Administrator Console with the AccuSEQ™ Software.
6. Generate or print the log:

If you want to...	Then...
Generate summary information	Click Summary Report to generate and open a PDF file.
Generate detailed information	Select the objects of interest in the list, then click Detailed Report to generate and open a PDF file.
Print the log	Click Print .

View and print event audit logs

1. Click the **Logs** tab at the top of the screen.
2. Click **Audit Logs** on the left of the screen.
3. Click **Filters**, then select the **Application** for the audit log (on far right of screen): **SAE** or **AccuSEQ**. Enter other filter criteria if needed, then click **Apply Filter** to display the filtered list.
4. Click the **Events** tab.
5. Click **Refresh** to synchronize the SAE Administrator Console with the AccuSEQ™ Software.
6. Generate or print the log:

If you want to...	Then...
Generate summary information	Click Summary Report to generate and open a PDF file.
Print the log	Click Print .



Manage the e-signature function and logs

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The e-signature log contains e-signature records from the AccuSEQ™ Software or the SAE Administrator Console.

Enable or disable the e-signature function

This procedure enables or disables the e-signature function for a *software feature*. To enable or disable the e-signature function for a *user*, see “Edit a user account” on page 10.

1. Click the **SAE Settings** tab at the top of the screen.
2. Click **E-signature Settings** on the left of the screen.
3. Under **Require E-signatures for document locking**, select or deselect **Enable**. If enabled, select the number of signatures that are required to lock a document.

Note: *Document* refers to an experiment in the AccuSEQ™ Software. A locked document cannot be modified by any user.

4. Click **Save Settings**, then click **OK**.

To restore all settings to the default values:

1. Click **Restore Default** to restore all settings to the default values.
2. Click **Save Settings** to save the default settings.

Manage the e-signature reasons

Create an e-signature reason

1. Click the **SAE Settings** tab, then click **E-signature Settings**.
2. Click **New E-signature Reason**.
3. Enter a reason for the e-signature (for example, **Approve**), then enter a meaning (that is, a detailed description of the reason).
4. Click **Save**, then click **OK**.

The new e-signature reason is available for user selection when the **E-Sign** button is clicked in the AccuSEQ™ Software.

Edit an e-signature reason

1. Click the **SAE Settings** tab, then click **E-signature Settings**.
2. In the table, select the reason to edit, then click **Edit Selected Reason**.
3. Edit the meaning if needed.
4. Click **Save**, then click **OK**.

The updated e-signature reason is available for user selection when the **E-Sign** button is clicked in the AccuSEQ™ Software. The change is not applied to experiments and results that have already been signed.

Delete an e-signature reason

1. Click the **SAE Settings** tab, then click **E-signature Settings**.
2. In the table, select the reason to delete, then click **Delete Selected Reason**.
3. Click **OK**.

The deleted e-signature reason is not available for user selection when the **E-Sign** button is clicked in the AccuSEQ™ Software. The e-signature reason is not deleted from experiments and results that have already been signed.

View and print the e-signature log

The e-signature log contains e-signature records from the AccuSEQ™ Software.

The log information is automatically recorded by the software and cannot be modified.

The e-signature log for an experiment is also accessible in the AccuSEQ™ Software.

1. Click the **Logs** tab, then click **E-signature Logs**.
2. (Optional) Click **Filters**, select or enter the filter criteria if needed, then click **Apply Filter** to display the filtered list.

Note: To remove the filters, click **Reset Filter**.

3. Click **Refresh** to synchronize the SAE module with the AccuSEQ™ Software.
4. Generate, export, or print the log:

Option	Description
Generate summary information	Click Summary Report to generate and open a PDF file.
Print the log	Click Print .

Documentation and support

Related documents

The following related documents are available:

Document	Publication Number
<i>AccuSEQ™ Real-Time PCR Software v3.2 User Guide</i>	MAN0029199
<i>AccuSEQ™ Real-Time PCR Software v3.2 Quick Reference</i>	MAN0029200

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 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

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