

# Countess™ SAE Software Solution for 21 CFR Part 11 Support

for use with: Countess™ 3 and 3 FL Automated Cell Counters

Pub. No. MAN0025462 Rev. A.0

## Security Audit e-Signature (SAE) for the Countess™ 3/3FL Instruments

**IMPORTANT!** 21 CFR part 11 is a regulation that describes the criteria for acceptance by the U.S. Food and Drug Administration (FDA) for electronic records and electronic signatures. Part 11 is composed of procedural and technical requirements. Procedural requirements are the standard operating procedures instituted by the end user, and technical requirements are the functional characteristics of the compliance management software used.

This section is intended to provide instructions for using Security, Audit, and ElectronicSignature (SAE) on board Countess™ 3/3FL Instruments. Security, Audit, e-Signature (SAE) software provides the tools necessary for supporting 21 CFR Part 11 technical compliance including:

- Creating and maintaining user accounts
- Managing and enforcing password policies of all accounts
- Assigning, managing and enforcing access rights to all accounts
- Documenting and maintaining audit and e-Signature histories
- Permitting e-Signature approval for data verification

To implement the Countess™ 3/3FL SAE Software Solution for 21 CFR Part 11 support on Countess™ 3/3FL Instruments, you need the following components installed, activated, and communicating:

- SAE Administrator Console - With the Countess™ 3/3FL Imager Analysis Application Profile, used to configure the SAE settings for Countess™ 3/3FL Instruments
- Countess™ 3 SAE License - Used to activate the SAE settings for the Countess™ 3/3FL instrument software
- Countess™ 3/3FL Instrument - SAE Mode - Software connected with the SAE Administrator Console

**Note:** For details on accessing Countess™ 3/3FL SAE Software Solution downloads and resources, see the "Related documentation and references" section.

## Activate your license key

**Note:** Running an instrument qualification using Installation Qualification/Operational Qualification/Performance Qualification (IQ/OQ/PQ) is recommended before SAE mode is enabled on the Countess™ 3/3FL Instrument for the first time.

1. Touch **Settings** on the bottom-right side of the **Home** screen.
2. Touch **SAE Mode**.

**Note:** If no license has been activated, you will automatically be prompted to activate your license. Validate the serial number of your instrument listed in the software on this page, insert your USB stick with your license into the Countess™ 3/3FL instrument and click **Activate**.

3. Toggle the SAE mode to **Enable** and click **Next**.
4. Enter the IP address and port of the SAE console location, then touch **Next**.

**Note:** IP address and port location (e.g., 10.X.X.X:8201/adminconsole/index.html) are available in the address bar of the SAE Admin Console.

**Note:** The SAE Admin Console should be configured with a static IP address to ensure a reliable connection to the instrument.

5. Enter the username and password of the SAE Administrator and click **Enable** (by default, only an SAE Admin user can activate SAE mode on an instrument).

After successful connection, the instrument will restart.

## Enable SAE mode

1. Touch **Settings** located on the bottom-right side of the **Home** screen.
2. Touch **SAE mode**.
3. Move the slider to **Enable**, then touch **Next**.

- Enter the IP address and port of the SAE console location and then touch **Next**.  
**Note:** IP address and port location (e.g., 10.X.X.X:8201/adminconsole/index.html) are available in the address bar of the SAE Admin Console.
- The system will require the SAE Administrator to enter their credentials to complete the process. Enter credentials and touch **Enable** to complete the process.

## Disable SAE mode

- Log in as SAE Console Admin on the Countess™ 3/3FL instrument.
- Touch **Settings** on the bottom-right side of the **Home** screen.
- Touch **SAE mode**.
- Move the slider to **Disable**, then touch **Next**.
- At this point the SAE Admin may need to enter their credentials and touch **Disable** to continue or **Cancel** to leave the SAE mode enabled.
- If user touches **Disable**, then the following warning will display:

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**IMPORTANT!** "Are you sure? Disabling SAE mode will require you to reset your instrument to factory settings and will delete all of your data."

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**IMPORTANT!** We recommend saving all data externally before proceeding with the disable.

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## Sign in to the instrument in SAE mode

- Enter your SAE username and password in the SAE login window.  
**Note:** Your username and password must be created by the SAE Admin on the SAE Console prior to logging in.
- Touch **Sign In**. After signing in, you may be prompted to change your SAE password.

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**IMPORTANT!** The following symbols cannot be used in your password: + & %\

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**Note:** The following characters can be used in addition to letters and numbers for passwords: - \_ ( ) [ ] { } / - ! @ # \$ \* , .. = . , ' " : ; | < > ?

## Change your password in SAE mode

- Touch the user icon on the bottom-left side of the **Home** screen.
- Touch **Change Password** and enter your old password, your new password, and then confirm your new password.

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**IMPORTANT!** The following symbols cannot be used in your password: + & %\

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**Note:** The following characters can be used in addition to letters and numbers for passwords: - \_ ( ) [ ] { } / - ! @ # \$ \* , .. = . , ' " : ; | < > ?

**Note:** Your new password must meet the complexity requirements set by the SAE Console Admin.

**Note:** If you exceed the maximum number of sign-in attempts, you will be temporarily locked out of your account. See the SAE Console Admin.

**Note:** You may have limited access to Countess™ 3/3FL instrument functions based on your user role set by the SAE Console Admin. in the SAE Console.

## SAE user roles

Role	Description
SAE Console Administrator (SAE Console Admin)	A default system role with full access privileges to the SAE Console. The SAE Console Admin creates new SAE user accounts, defines what privileges are granted to each SAE user role, and assigns user roles to all other SAE users.
Countess™ Admin	A default SAE role with privileges to use and manage the Countess™ 3/3FL instrument and Countess™ 3/3FL Analysis Software—Secure.
Countess™ Lead Scientist	A default SAE role with privileges to use the Countess™ 3/3FL instrument and Countess™ 3/3FL Analysis Software—Secure.
Countess™ Technologist	

## Permissions and default user roles

To determine the permissions for a default role or to edit it, select the role then click **Edit**.

The following table shows all user-configurable permissions and the settings for the default user accounts.

**Table 1** Conferrable permissions and default user roles

Permissions		Default roles		
Category	Function	Lead Scientist	Technologist	Admin
Setup	Sign in To Thermo Fisher™ Connect	No	No	Yes
	Create Thermo Fisher™ Connect profile on-device	No	No	Yes
	Unlink Thermo Fisher™ Connect profile on-device	No	No	Yes
	Load Protocol	Yes	Yes	Yes
	Import Protocol	Yes	No	Yes
	Export Protocol	Yes	No	Yes
	Delete Protocol	Yes	No	Yes
	Edit Protocol	Yes	No	Yes
	Change save settings	Yes	No	Yes
	Create Protocol	Yes	No	Yes
Run	Adjust light intensity	Yes	No	Yes
	Adjust focus	Yes	No	Yes
	Select capture channels	Yes	No	Yes
	Capture selected channels	Yes	Yes	Yes
Calculators	Pre-dilution calculator	Yes	No	Yes
	Cell-splitting calculator	Yes	Yes	Yes
View	Turn on/off channel images	Yes	Yes	Yes
	Turn on/off channel contours	Yes	Yes	Yes
	Open/close histogram	Yes	Yes	Yes
Adjust Count	Adjust gating parameters	Yes	No	Yes
	Save images/results	Yes	Yes	Yes
	Adjust save options	Yes	No	Yes
	Adjust save name	Yes	No	Yes
Instrument Settings	Change light cubes	Yes	No	Yes
	Adjust Date/Time	Yes	No	Yes
	Connect to WiFi network	Yes	Yes	Yes
	Reset instrument	No	No	Yes
	Update software	Yes	No	Yes
	View About software	Yes	Yes	Yes
	Copy error logs	Yes	Yes	Yes

## Acquire images in SAE mode

Image acquisition in SAE mode is the same as in non-SAE mode.

For Countess™ 3, refer to the *Countess™ 3 Automated Cell Counter User Guide* (Pub. No. MAN0019566).

For Countess™ 3 FL, refer to the *Countess™ 3 FL Automated Cell Counter User Guide* (Pub. No. MAN0019567).

**Note:** In SAE mode, data is committed to the audit log as v1 at image acquisition.


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## Documentation and support

### Related documentation

Document	Publication number	Description
<i>Countess™ 3 Automated Cell Counter User Guide</i>	MAN0019566	User guide for Countess™ 3 Automated Cell Counter detailing use of the instrument with SAE enabled and disabled
<i>Countess™ 3 FL Automated Cell Counter User Guide</i>	MAN0019567	User guide for Countess™ 3 FL Automated Cell Counter detailing use of instrument with SAE enabled and disabled

### Obtain information from the Help System

The SAE Admin Console has a Help system that describes how to use each feature of the user interface. Click  to access the Help system.

**Note:** This Help is not specific for the Countess™ 3/3 FL instruments and should only be used as a general guide.

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

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Revision	Date	Description
A.0	09 June 2021	New document.

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