

Compleo™ SAE Software Solution

USER GUIDE

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Revision A



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A	30 December 2025	New document for Compleo™ SAE Software Solution.

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

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Chapter 1 Installation

1.1 Overview

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. Thermo Fisher Scientific products help to enable 21 CFR Part 11 compliance by providing functionality for their respective components, but customers own final responsibility for ensuring 21 CFR Part 11 compliance for their processes.

This document is intended to provide instructions for using CTST[™] Compleo[™] (Compleo[™]) SAE software for Security, Audit, and Electronic Signature (SAE) functionality with Compleo[™] instruments. Compleo[™] SAE software and SAE Administrator (Admin) Console software work together to provide the tools necessary to enable 21 CFR Part 11 technical compliance, including:

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

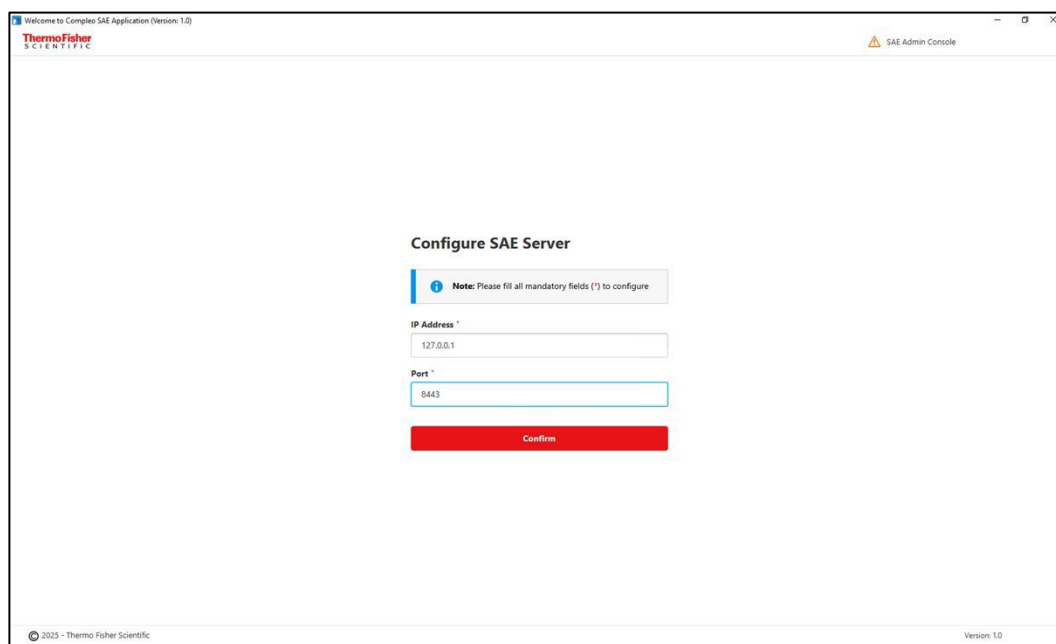
1.2 Installation

To use the SAE Software Solution on Compleo[™] instruments, you need the following components installed and activated:

- Compleo[™] system (instrument and computer).
- Compleo[™] GUI software: Instrument control software. Serves as the 'bridge' for communication between the instrument and the Compleo[™] SAE Software.
- Compatible firmware versions should be installed for optimal performance.
- SAE Administrator Console Software: This software will use the Compleo[™] SAE Software Profile and apply SAE settings configured by the user.
- Compleo[™] SAE License Activation Key: This activates the Compleo[™] SAE software. Keep this license to apply future updates.
- Compleo[™] SAE Software: Local SAE software that utilizes configured settings from the SAE Administrator Console software.
 - The Compleo[™] SAE Software overlays the Compleo[™] GUI software to monitor the security, auditing, and e-signature preferences selected.

1.3 Configure communication with SAE Administrator Console

- Once the Compleo™ SAE Software has been installed, the user will be taken to the SAE server configuration page for connecting the Compleo™ SAE Software module to the SAE Admin Console software.
- User must enter the valid IP address and port number of the system where 'SAE Admin Console' is installed and then click Confirm.
- The localhost IP address used is 127.0.0.1, and the port number is 8443. Please contact your IT department for the IP address if a remote server will be used to host the SAE Admin Console. Note that the port number must remain as 8443.
- Once the configuration is complete, the user will be taken to the login page.



Configure SAE Server

Note: Please fill all mandatory fields (*) to configure

IP Address *
127.0.0.1

Port *
8443

Confirm

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Note: The color of the SAE Admin Console icon changes from orange to green on the login page, indicating a successful connection. Configuration of the SAE Admin Console is required only once per installation.

1.4 Activate your license key

Activation of Compleo™ SAE software using the license key can be done by a Thermo Fisher Scientific Global Service and Support representative upon installation of the Compleo™ SAE software module. If qualification services were purchased, the qualification will be performed by the Field Service representative following the SAE installation. Please follow these steps to activate Compleo™ SAE software.

- Launch the Compleo™ SAE software using the Compleo™ SAE launch icon on the desktop or from the Start menu.
- When Compleo™ SAE is launched for the first time after installation, it needs to be activated using the activation license key.
- The serial number of the instrument will be automatically read and displayed to the user via the computer provided with the system.

- The user needs to enter the Sales Order number, followed by the License Key, and then click on the Activate button.
 - If any of the inputs are incorrect, an error message (ex., 'Invalid sales order and/or license key for this Compleo™ device') will be displayed.
 - If the activation is successful, then the user will be taken to the next screen to configure the SAE Admin Console.

Welcome to Compleo SAE Application (Version: 1.0)

ThermoFisher
SCIENTIFIC

SAE Admin Console Compleo GUI App

Welcome to Compleo SAE

Activate to enable 21 CFR Part 11 Compliance for your Compleo Instrument

Note: Please fill all mandatory fields (*) to activate. Click the refresh icon if you do not see the appropriate serial number matching the instrument.

Serial Number *
SN1234567890

Sales Order Number *
123

License Key *
.....

Activate

© 2023 - Thermo Fisher Scientific Version: 1.0

Welcome to Compleo SAE Application (Version: 1.0)

ThermoFisher
SCIENTIFIC

SAE Admin Console Compleo GUI App

Welcome to Compleo SAE

Activate to enable 21 CFR Part 11 Compliance for your Compleo Instrument

Success: License Activated

Congratulations! Your license has been activated successfully. Please click on "Continue" to sign in and launch the dashboard.

Continue

License Key *
.....

Activate

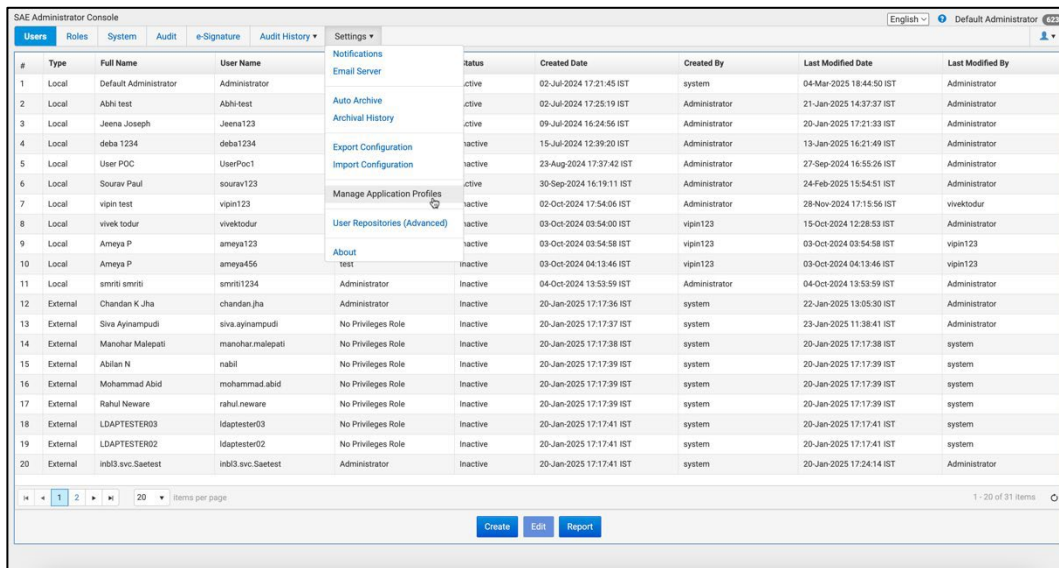
© 2023 - Thermo Fisher Scientific Version: 1.0

Note: Activation of Compleo™ SAE is only required once for each instrument. The license information is saved in the installation directory of Compleo™ SAE. However, you will need to activate the software again if you install Compleo™ SAE or upgrade from a previous version without retaining user data. This process is detailed in section 1.6, titled "Uninstalling the Compleo™ SAE Software".

1.5 Basic SAE Administrator Console Configuration

To log in to the SAE admin console, visit the URL provided by your system administrator (by default, the URL is <https://localhost:8443/admin-console/login>). Use "Administrator" as the username along with the provided default password. After successfully logging in, you will be prompted to change your password; this is highly recommended.

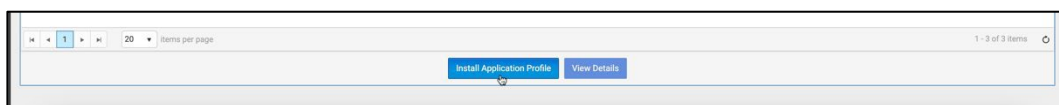
Once you are logged in, you need to install the provided .dat file along with the Compleo™ SAE installer. To do this, navigate to the Settings tab and select "Manage Application Profiles" from the drop-down menu.



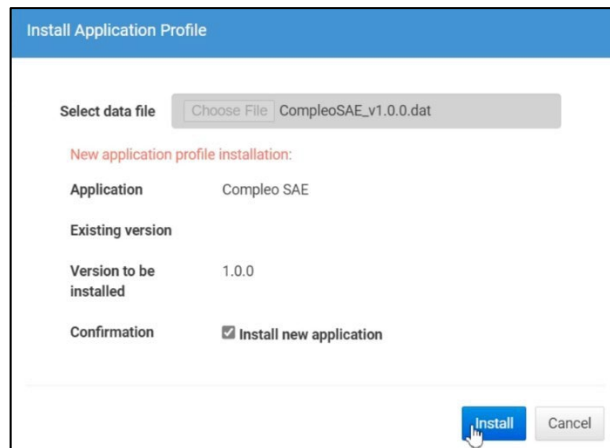
The screenshot shows the SAE Administrator Console interface. At the top, there are navigation tabs: Users, Roles, System, Audit, e-Signature, and Audit History. A Settings dropdown menu is open, showing options like Notifications, Email Server, Auto Archive, Archival History, Export Configuration, Import Configuration, Manage Application Profiles (highlighted), User Repositories (Advanced), and About. Below the menu is a table of users with columns for #, Type, Full Name, User Name, Status, Created Date, Created By, Last Modified Date, and Last Modified By. The table contains 20 rows of user data. At the bottom of the table, there are buttons for Create, Edit, and Report.

#	Type	Full Name	User Name	Status	Created Date	Created By	Last Modified Date	Last Modified By
1	Local	Default Administrator	Administrator	Active	02-Jul-2024 17:21:45 IST	system	04-Mar-2025 18:44:50 IST	Administrator
2	Local	Abhi test	Abhi-test	Active	02-Jul-2024 17:25:19 IST	Administrator	21-Jan-2025 14:37:37 IST	Administrator
3	Local	Jeena Joseph	Jeena123	Active	09-Jul-2024 16:24:56 IST	Administrator	20-Jan-2025 17:21:33 IST	Administrator
4	Local	deba 1234	deba1234	Inactive	15-Jul-2024 12:39:20 IST	Administrator	13-Jan-2025 16:21:49 IST	Administrator
5	Local	User POC	UserPoc1	Active	23-Aug-2024 17:37:42 IST	Administrator	27-Sep-2024 16:55:26 IST	Administrator
6	Local	Sourav Paul	sourav123	Active	30-Sep-2024 16:19:11 IST	Administrator	24-Feb-2025 15:54:51 IST	Administrator
7	Local	vipin test	vipin123	Inactive	02-Oct-2024 17:54:06 IST	Administrator	28-Nov-2024 17:15:56 IST	vivektodur
8	Local	vivek todur	vivektodur	Inactive	03-Oct-2024 03:54:00 IST	vipin123	15-Oct-2024 12:28:53 IST	Administrator
9	Local	Ameya P	ameya123	Inactive	03-Oct-2024 03:54:58 IST	vipin123	03-Oct-2024 03:54:58 IST	vipin123
10	Local	Ameya P	ameya456	Inactive	03-Oct-2024 04:13:46 IST	vipin123	03-Oct-2024 04:13:46 IST	vipin123
11	Local	smriti smriti	smriti1234	Administrator	Inactive	04-Oct-2024 13:53:59 IST	Administrator	Administrator
12	External	Chandan K Jha	chandan.jha	Administrator	Inactive	20-Jan-2025 17:17:36 IST	system	Administrator
13	External	Siva Aynampudi	siva.aynampudi	No Privileges Role	Inactive	20-Jan-2025 17:17:37 IST	system	Administrator
14	External	Manohar Malepati	manohar.malepati	No Privileges Role	Inactive	20-Jan-2025 17:17:38 IST	system	system
15	External	Abilan N	nabil	No Privileges Role	Inactive	20-Jan-2025 17:17:39 IST	system	system
16	External	Mohammad Abid	mohammad.abid	No Privileges Role	Inactive	20-Jan-2025 17:17:39 IST	system	system
17	External	Rahul Neware	rahul.neware	No Privileges Role	Inactive	20-Jan-2025 17:17:39 IST	system	system
18	External	LDAPTESTER03	ldaptester03	No Privileges Role	Inactive	20-Jan-2025 17:17:41 IST	system	system
19	External	LDAPTESTER02	ldaptester02	No Privileges Role	Inactive	20-Jan-2025 17:17:41 IST	system	system
20	External	inb3.svc.Saetest	inb3.svc.Saetest	Administrator	Inactive	20-Jan-2025 17:17:41 IST	system	Administrator

At the bottom of the page, click the "Install Application Profile" button and follow the instructions provided. After selecting the .dat file, ensure that you check the option for "Install Application Profile," as shown in the accompanying image.



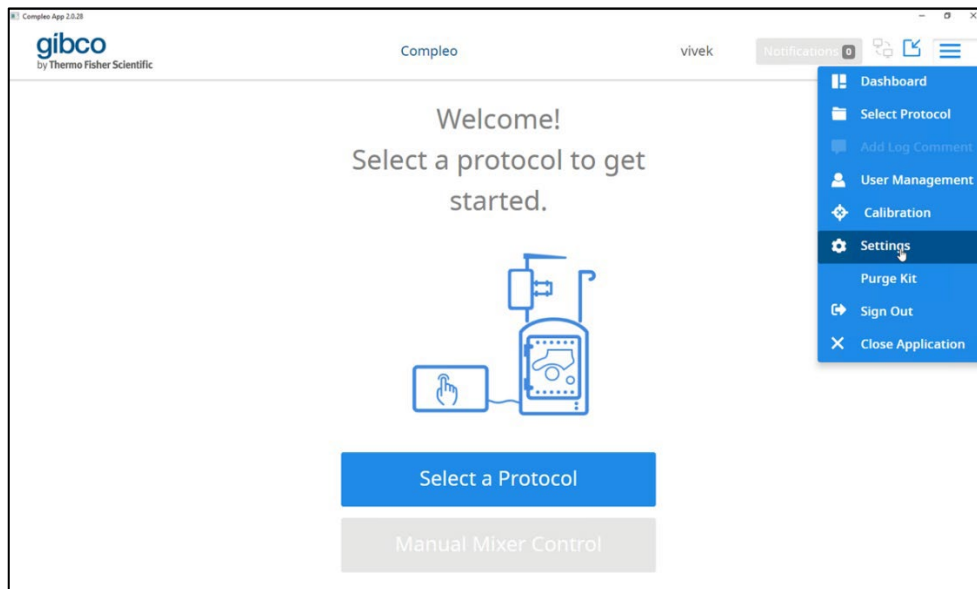
Once the installation is complete, you will notice new options available under the Audit and e-Signature tabs that are applicable to Compleo™ SAE. Now you can add new roles with relevant permissions and create new users, activating them as needed.

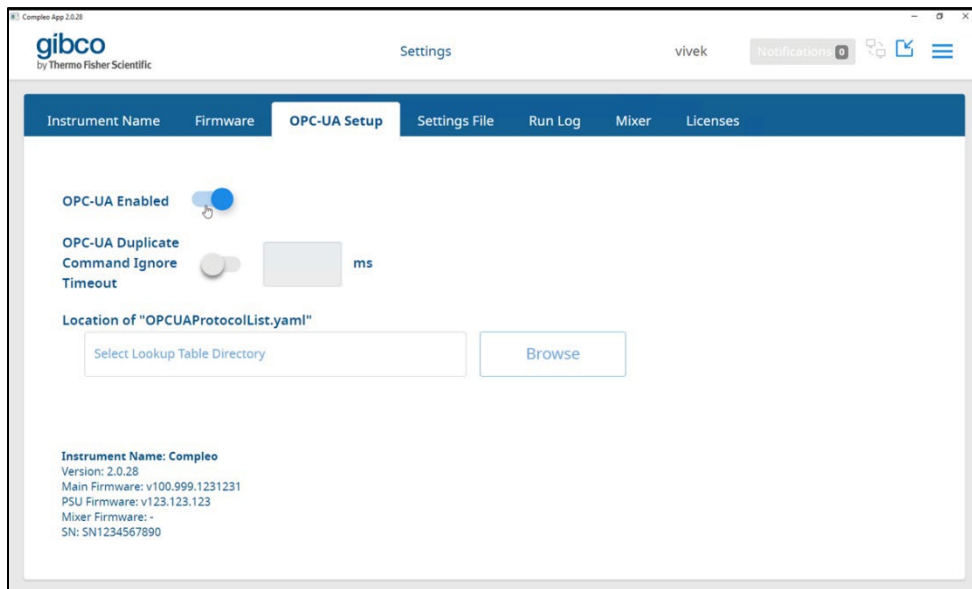


1.6 Connect Compleo™ SAE to the instrument

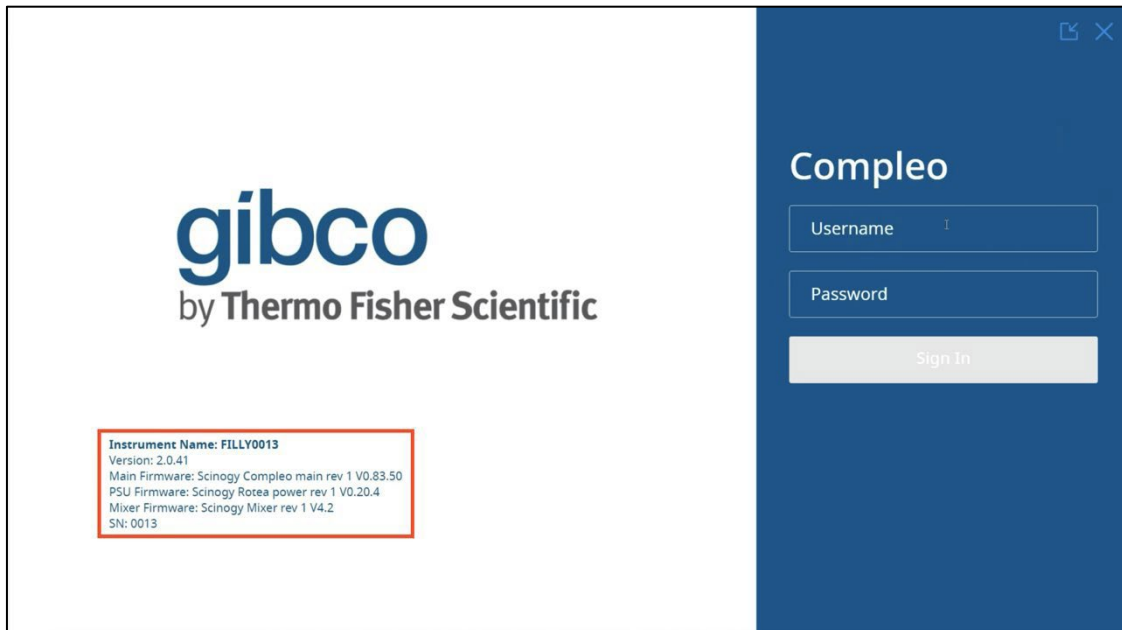
Note: The Compleo™ GUI software must be launched and running to enable Compleo™ SAE functionality.

1. Power on the Compleo™ instrument.
2. Launch the Compleo™ GUI software and ensure a successful connection to the instrument.
3. Log in using an administrator-level user.
4. Within the Compleo™ GUI software Settings navigate to the OPC-UA Setup tab. Enable OPC-UA connectivity by sliding the toggle to the 'ON' position.



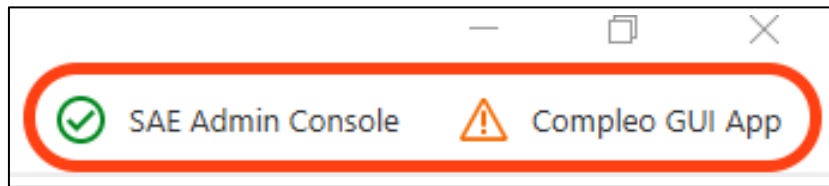


5. After verifying successful communication between the Compleo™ instrument and Compleo™ GUI software (Instrument name, version numbers and serial number will get updated), minimize the Compleo™ GUI software window. Do not close the Compleo™ GUI software.

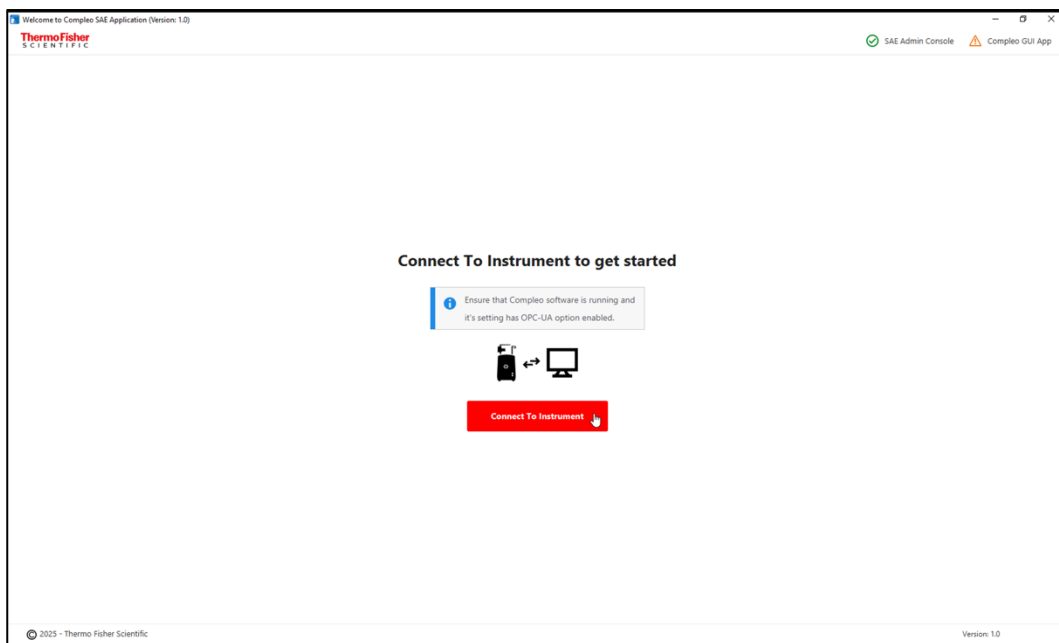


Important: To run the Compleo™ instrument with SAE, the GUI software must continue to run in the background. However, in order to capture accurate traceability records, users should utilize the Compleo™ SAE software interface.

6. Launch the Compleo™ SAE software and verify the green circle with a checkmark (The green checkmark typically indicates a successful connection) before the SAE Admin Console at the upper right corner.



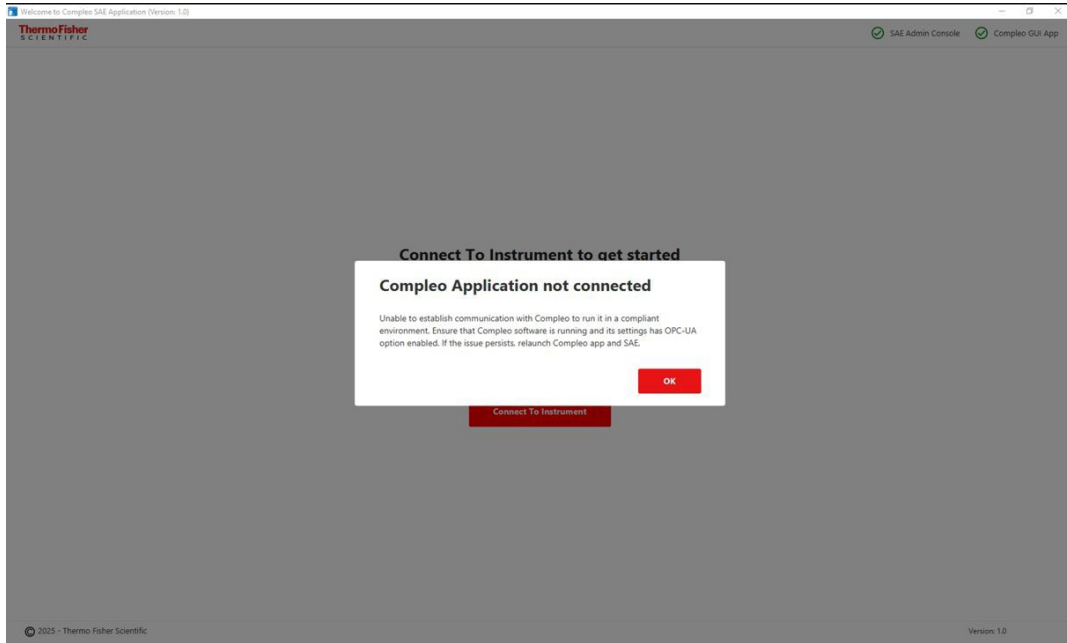
7. Click **Connect to Instrument**. Once the connection is established, the user login page will be displayed. Upon a successful connection, the orange triangle with an exclamation mark icon before the Compleo™ GUI App will change to a green checkmark.



This step will fail and display an error message if any of the following conditions are met:

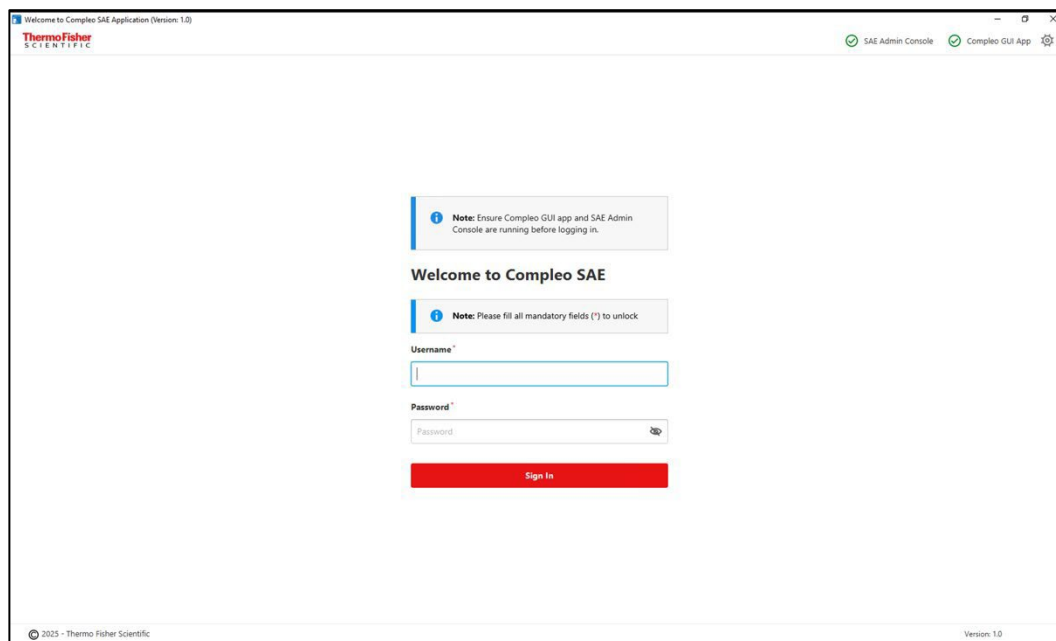
- A protocol run has already been initiated in Compleo™ GUI.
- A protocol is currently running in Compleo™ GUI.
- A protocol from an earlier session of Compleo™ SAE is still active.

If this issue occurs repeatedly, log into the Compleo™ GUI software and ensure that no protocol is currently running before retrying.



Important: Your username and password must be created by the SAE Admin Console Administrator within the SAE Admin Console software. Roles and permissions need to be configured prior to logging into the Compleo™ SAE software.

8. Log in to run the instrument in SAE mode.



Note: The default “Administrator” role for the SAE Admin Console software has permissions for all actions in the SAE Admin Console software as well as in the Compleo™ SAE software. Permissions for “Administrator” role are by default. Other user roles have permissions defined between the SAE Admin Console software and the Compleo™ SAE software. See the example below (screenshot) which shows the Create Role screen and a role named Compleo™ SAE Only. The permissions defined for this role are only for the Compleo™ SAE software. This role does not have any permissions in the SAE Admin Console software. This example shows the ability to set permissions as needed for each role for both the SAE Admin Console and Compleo™ SAE software.

Create Role

*** Name**

Description

Permissions

- ▶ Rotea SAE
- ▲ SAE Administrator Console
 - ▶ Security Configuration
 - ▶ Audit History
- ▲ Compleo SAE
 - ▶ Protocol
 - ▶ Protocol Run
 - ▶ Run Settings
 - ▶ Security Configuration

Important: Please keep the SAE Admin Console Administrator’s login information stored somewhere safe. Password recovery is not available through Thermo Fisher Scientific.

Changes made in SAE Admin Console configuration will be applied in Compleo™ SAE, and audits from Compleo™ SAE will be seen in the SAE Admin Console within a minute or two from the time the change is made.

If the communication is not established with the Compleo™ GUI software, then Compleo™ SAE Software would display an error message to indicate that it is unable to link to the instrument.

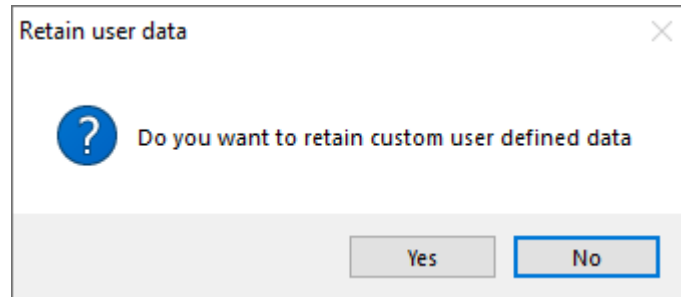
An offline sign-in option is available, which can be configured in SAE Admin Console. This option would allow user login even if the connection between Compleo™ SAE and SAE Admin Console is lost. Audit data for actions taken on Compleo™ SAE in offline mode would be logged internally and updated in the Audit history the next time communication is established with the SAE Admin Console.

Important: All users should log in to Compleo™ SAE at least once with their latest password while Compleo™ SAE and SAE Admin Console are connected (online mode), so that they can access Compleo™ SAE later in offline mode when the connection is lost.

1.7 Uninstalling the Compleo™ SAE Software

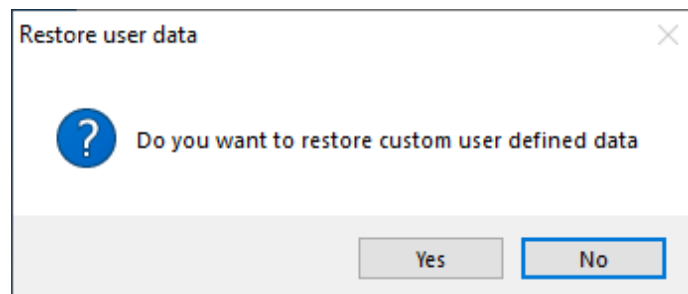
Steps to Uninstall Compleo™ Software:

1. Open Windows™ Add or Remove Programs.
2. Locate and select Compleo™ SAE from the list.
3. Click the Uninstall button. The uninstallation wizard will open.
4. As soon as the uninstallation begins, a prompt “Retain user data” will appear.
5. Click “Yes” to back up essential properties and license files.
6. These files will be stored unless removed from the Windows™ TEMP folder.
7. Follow the on-screen instructions to complete the uninstallation.



Reinstallation Note:

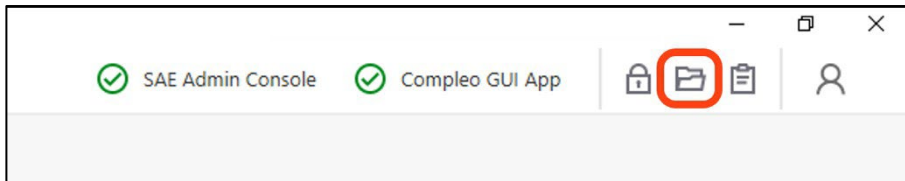
1. During reinstallation, a similar prompt “Restore user data” will appear.
2. If the backup files are still available, clicking “Yes” will restore them.



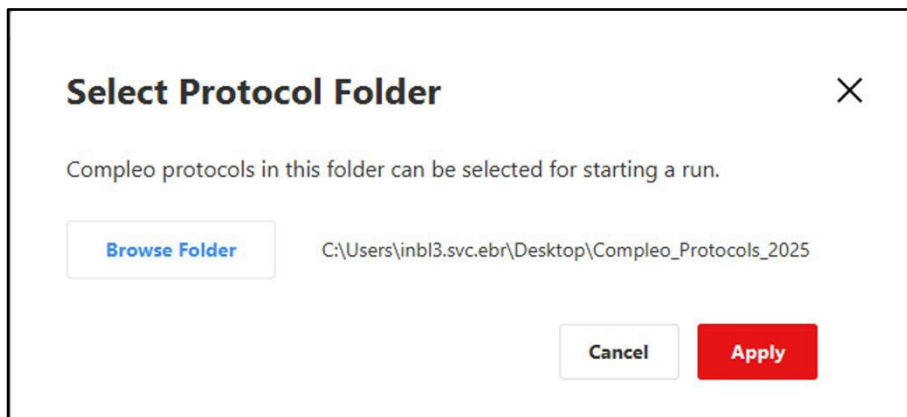
Chapter 2 Configuration

2.1 Set Protocol Folder

- This option is available on the Header Bar in the Compleo™ SAE Software.



- Any user who has access to Select Protocol Folder (via the SAE Admin Console) can set the protocol source folder in Compleo™ SAE software. The Compleo™ SAE software will look for protocol files within this designated folder location. Loading protocols from a different directory is not allowed.



- If the user does not have access to this option in Compleo™ SAE software, they can contact their SAE Admin Console Administrator for assistance, as their role may not have the appropriate permissions. (Role tab of SAE Admin Console requires permission for Compleo SAE > Protocol > select the “Select Protocol Folder”).



- The user must select a reason and enter comments to change the protocol folder if the audit pop-up is displayed (and if this was configured to do so). This is because the SAE Admin Console Administrator role has configured this setting in the SAE Admin Console software. The folder selection will be successful only after submitting the reason and comments.
- If an Electronic Signature window is displayed, then an authorized user will have to approve this action by entering their username and password. The e-signature will be requested as configured in the SAE Admin Console software. The folder selection would be successful only if the approval is successful.

Note: Once the Compleo™ protocol is initiated, the option for changing the default folder is disabled.

2.2 Audit Settings

The "Audit" tab configures audit logging for various steps and processes. An authorized user can check or uncheck the "Include" box for each audit type in the Audit Settings section (Protocol Folder, Pause Run, and Protocol Run) and select the audit modes: Optional, Silent, or Required, for different types of audits. The Audit Reason Settings section provides a list of predefined reasons for the audits, which will be displayed to the user if the corresponding checkbox at the bottom is selected.

2.3 E-Signature Configuration

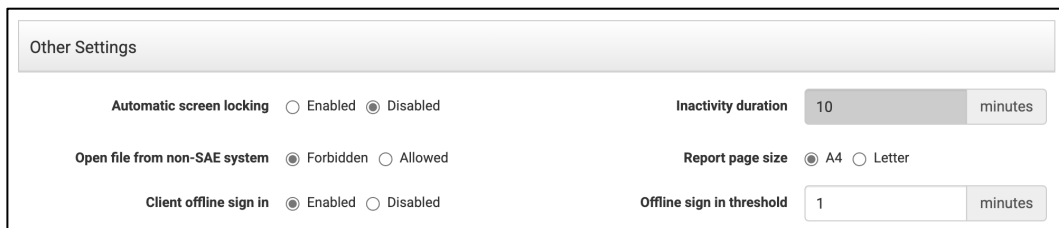
The "Enable Audits" checkbox in the e-Signature tab indicates that electronic signatures are required for specific actions. The e-Signature Meanings section outlines predefined approval meanings, such as "Approve New Protocol Folder," "Approve Start Protocol Run," "Approve Deviation," "Confirm Expired Kit," and "Approve Kit Reuse." Authorized users can enable or disable the e-signature for each action. If the e-signature is enabled, it is also necessary to specify the required number of signatures from each user group for each action separately.

- Set Protocol Folder: For configuring the default folder for browsing the protocols (Meaning: Approve New Protocol Folder).
- Start Protocol Run: For starting a protocol (Meaning: Approve Start Protocol Run).
- Select Cell Volume: For selecting the volume measurements that are falling outside the tolerance range defined inside the protocols (Meaning: Approve Deviation).
- Confirm Kit Reuse: If the protocol is run in a row with the same kit without opening the door (Meaning: Approve Kit Reuse).
- Confirm Expired Kit: If the expired kit is loaded for executing the protocol run (Meaning: Approve Expired Kit).

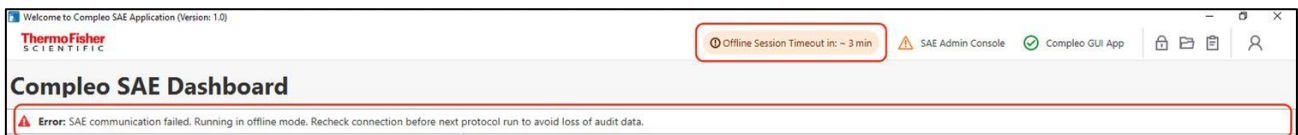
2.4 Offline Session Configuration

The Compleo™ SAE allows users to log in and run protocols even when the SAE Admin Console is offline. To enable this feature, an authorized user must log in to the SAE Admin Console and navigate to the System tab. Here, the "Client Offline Sign-in" option needs to be enabled, and the "Offline Sign-in Threshold" must be defined in minutes. These options can be found under the "Other Settings" section. A few prerequisites must be met for a user to log in during an offline session. Specifically, the user's status must be active, and the user must have logged into the Compleo™ SAE at least once before attempting to log in during an offline session.

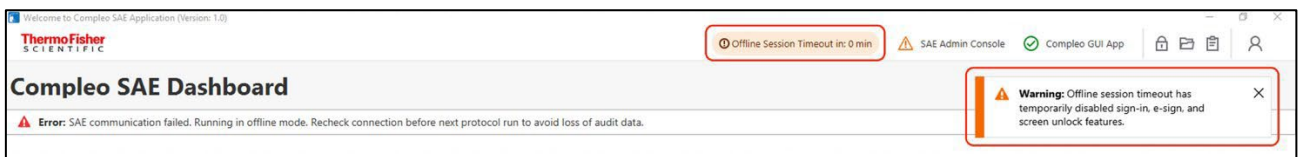
This feature is intended for use only during critical situations. We strongly advise running experiments only when connected to the SAE Admin Console.



Other Settings	
Automatic screen locking	<input type="radio"/> Enabled <input checked="" type="radio"/> Disabled
Open file from non-SAE system	<input checked="" type="radio"/> Forbidden <input type="radio"/> Allowed
Client offline sign in	<input checked="" type="radio"/> Enabled <input type="radio"/> Disabled
Inactivity duration	10 minutes
Report page size	<input checked="" type="radio"/> A4 <input type="radio"/> Letter
Offline sign in threshold	1 minutes



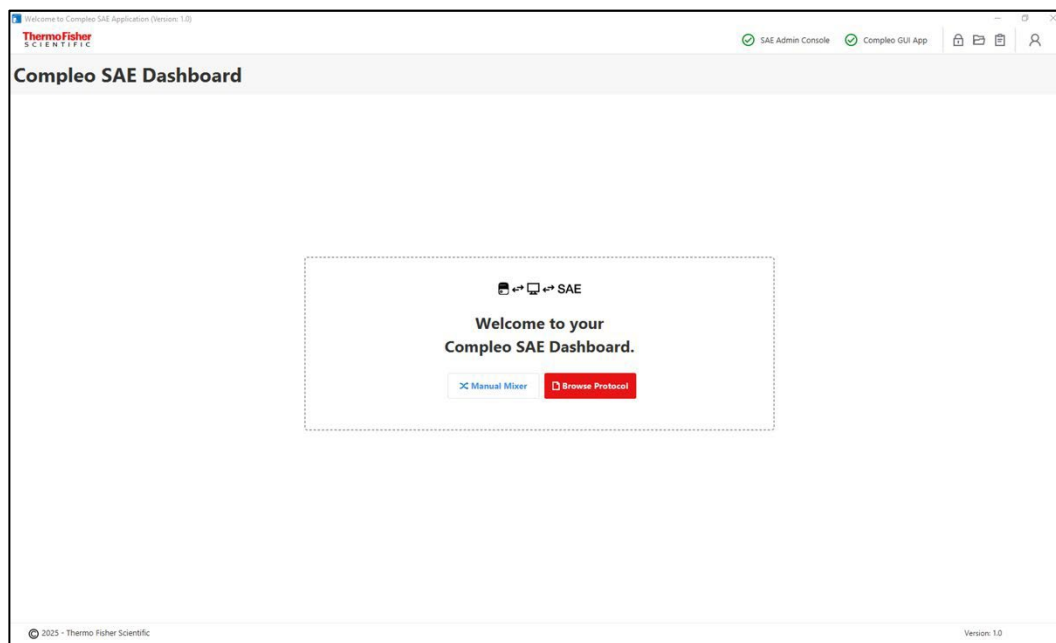
When a user logs into the Compleo™ SAE when the SAE Admin server is offline or there is a connectivity interruption during the active session, a message will be displayed in the banner along with a timeout counter in the header bar (above image). This message will disappear as soon as connectivity is restored. If a timeout occurs, a toaster message will indicate that the offline session has timed out (image below), temporarily disabling the sign-in, e-sign, and screen unlock features.



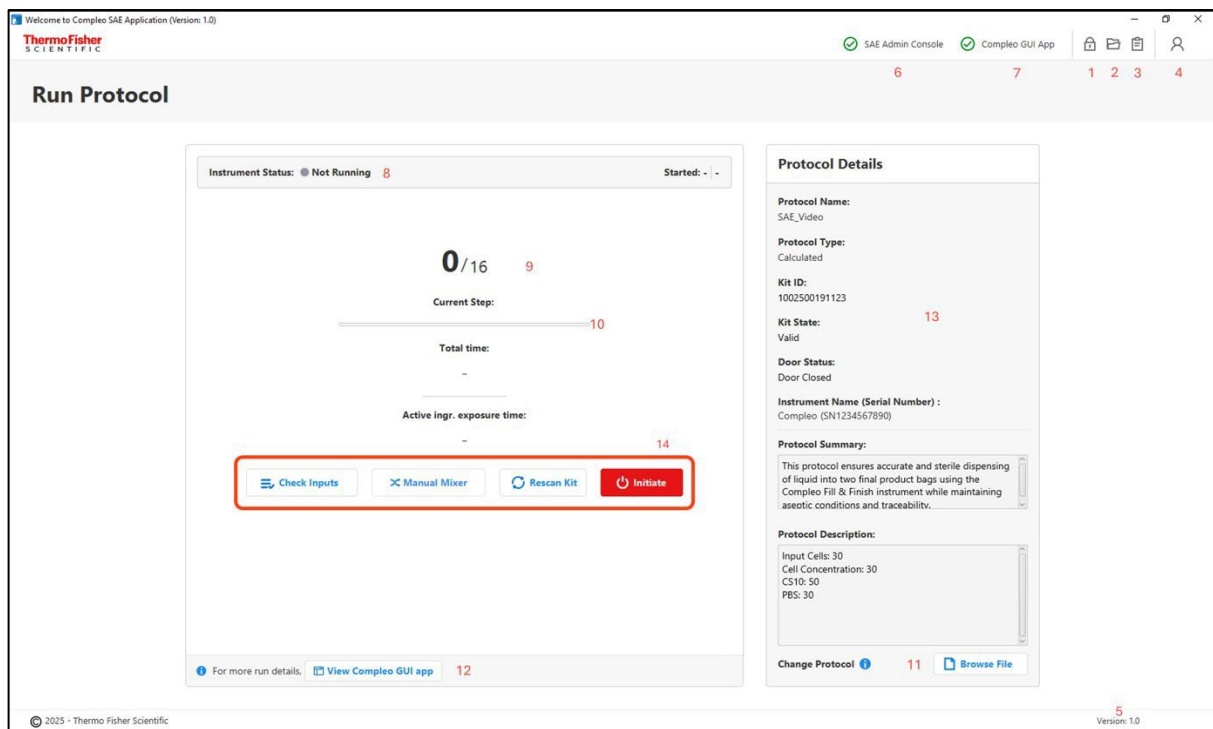
Chapter 3 Instrument operation

3.1 Compleo™ SAE

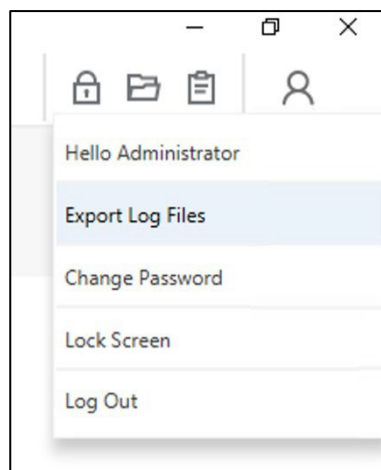
After successful login, the user will land on the main screen, known as the Protocol Dashboard (see image below). This screen allows users to browse and select protocols and use the Manual Mixer functionalities. Additionally, it hosts several control options in the header bar above.



Note: If a protocol file has already been loaded via the Compleo™ GUI or a previous session of Compleo™ SAE, the user will be taken directly to the next screen upon successful login, called the Run Details Dashboard. This screen is where the actual execution of the protocol run occurs. Important parts of this screen are numbered and explained below.



1. Lock Screen: A manual lock screen can be activated by clicking this button.
2. Select Default Protocol Folder: You can configure a default folder for browsing protocols by clicking this icon. Only an authorized user can perform this configuration, and it may require filling out an audit pop-up and providing an e-signature if Audit and e-Signatures are configured for this action.
3. SAE Settings Overview: Clicking this icon opens a pop-up window that displays the SAE settings. Each time the user clicks this icon, the settings are fetched from the SAE Admin Console. Once the protocol is initiated, only the user's confirmed settings will be displayed (as discussed in section 3.2(7)). These confirmed settings will be used throughout the run.
4. Profile Menu: This menu provides several options, including exporting log files, changing the password, locking the app screen, and logging out.

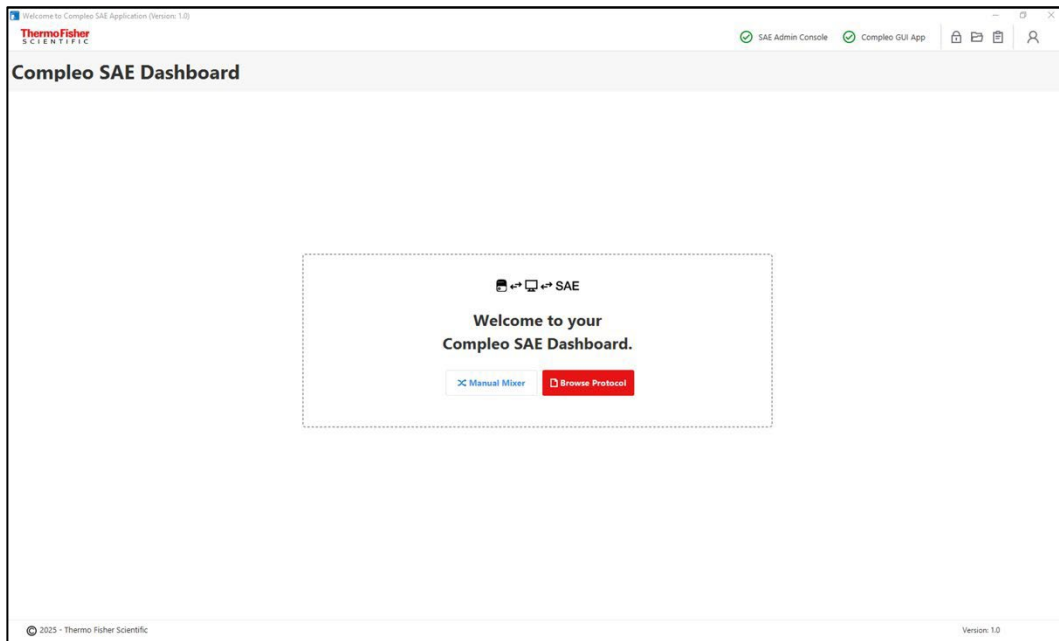


5. Version Number: Displays the Compleo™ SAE version number.
6. Status Indication – SAE Admin Console: This label appears in green if the connection to the SAE Admin Console server is successful. It is orange if it has failed.
7. Status Indication – Compleo™ GUI: This label appears in green if the connection between the OPC-UA server and the Compleo™ SAE client is successful. It is orange if it has failed.
8. Instrument Status: An indicator & label that represents the current state of the Compleo™ instrument.
9. Steps Indicator: This label shows the current progress of the protocol run.
10. Progress Bar: A visual representation of the current progress of the protocol run.
11. Browse Protocol: This button takes you back to the Protocol Dashboard for browsing protocols. It remains enabled until the protocol is started.
12. View Compleo™ GUI App: Clicking this button brings the Compleo™ GUI to the forefront of the screen for quick reference to the Kit View.
13. Protocol Details Section: Displays the protocol name, type, kit ID, kit state, door status, instrument name (serial number), protocol summary, and protocol description. Any errors with respect to kit ID, type, state, and door are highlighted in red colour in this block.
14. Control Buttons: Various buttons are displayed here to manage different options. The buttons shown in this section may vary based on the state or progress of the protocol run.

3.2 Run a protocol using Compleo™ SAE software

Important: Security, Auditing, and E-signature functionality applies to actions performed within the Compleo™ SAE Software interface. Ensure that Compleo™ GUI software is minimized, and all run operations are performed within the Compleo™ SAE software interface.

1. After logging into the Compleo™ SAE software, select the protocol file by clicking on **Browse Protocol**.



2. Select the relevant protocol file and click Open.
3. Click **Apply**. A pop-up window will display the Protocol Name, Type, Summary, and Description. User can verify the information and click on **Continue** to proceed further. The user will be taken to another page called **Protocol Run Dashboard**, where the protocol name and kit lot number, etc., are displayed. This page will display the details of a run, such as the run status, current step name, and step number.

Protocol Name :
SAE_Video

Protocol Type :
Calculated

Protocol Summary :
This protocol ensures accurate and sterile dispensing of liquid into two final product bags using the Compleo Fill & Finish instrument while maintaining aseptic conditions and traceability.

Protocol Description :
Input Cells: 30
Cell Concentration: 30
CS10: 50
PBS: 30

Cancel Continue

Note: The control buttons displayed on the Protocol Run Dashboard change based on the current step of the execution.

4. If the kit ID is not displayed on this user interface, the user can click on the Rescan Kit button to scan the kit and read its ID. If the kit ID continues not to be displayed, please inspect the barcode for smudges and wipe the barcode window to ensure it is clear. If the kit ID is still not read, please request a repair service visit to verify the barcode scanner alignment.
5. User must click the Add Inputs button to open the Input Data Estimates Form, where they need to enter the appropriate values according to the protocol configuration and click on the Confirm button.

Input Data Estimates [Close]

Enter the following input estimates

Volume * mL Range: 1.2 - 150.0

Cell Concentration * x10⁶ cells/mL Range: 0 - 10000000

Active Ingredient * %

PBS * mL Range: 0.3 - 150

CS10 * mL Range: 0.3 - 150

Media Volume 3 * mL

Media Volume 4 * mL

[Cancel] [Confirm]

Figure 1: Calculated Protocol - Input Data Estimate Form

Input Data Estimates [Close]

Enter the following input estimates

Cell Volume * mL Range: 0 OR 1.2 - 750.0

Initial Media Volumes

CS10: * mL Range: 0.3 - 150.0

PBS: * mL Range: 0.3 - 150.0

Media Volume 3 * mL

Media Volume 4 * mL

Volume Media added for DA

CS10: * mL Range: 0 OR 0.3 - 150.0

PBS: * mL Range: 0 OR 0.3 - 150.0

Media 3 * mL

Media 4 * mL

Volume Media added for BagB

[Cancel] [Confirm]

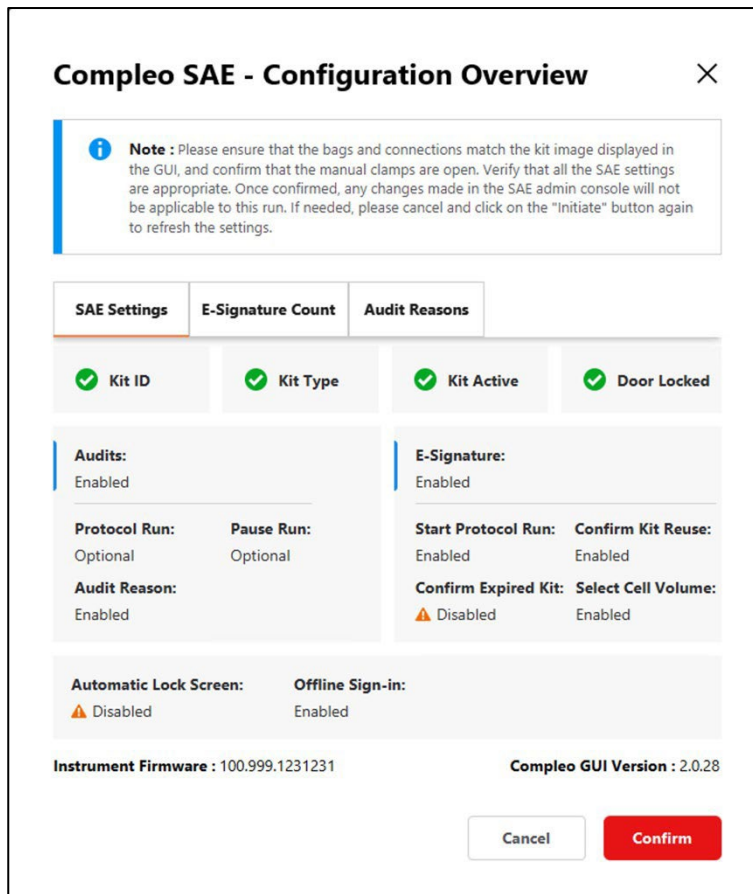
Figure 2: Manual Protocol - Input Data Estimate Form

Important: Decimal points are restricted to four digits in the input data estimate form for both manual and calculated protocols.

- If the user's input is acceptable, the Check Input and Initiate buttons will be displayed. If there is an error, an appropriate error message will appear in the Protocol Run Dashboard. The user cannot proceed until the provided values are accepted.



- When the user clicks on the Initiate button, a pop-up titled SAE Configuration Overview appears. This pop-up displays the status of the Kit ID, Kit Type, and Door, and retrieves the configuration from the SAE Admin Console for the user to review. The user can verify settings for the Audit, E-Signature, Automatic Lock Screen, and Offline Session by navigating to different tabs. If the settings are satisfactory, the user can click "Confirm" to accept them. Once confirmed, any changes made in the SAE Admin Console thereafter will not apply to the upcoming run.



Compleo SAE - Configuration Overview



Note : Please ensure that the bags and connections match the kit image displayed in the GUI, and confirm that the manual clamps are open. Verify that all the SAE settings are appropriate. Once confirmed, any changes made in the SAE admin console will not be applicable to this run. If needed, please cancel and click on the "Initiate" button again to refresh the settings.

SAE Settings

E-Signature Count

Audit Reasons

SN	Action	Roles & Count
1	Set Protocol Folder	
2	Start Protocol Run	Administrator : 1
3	Select Cell Volume	test : 1
4	Confirm Expired Kit	

Cancel

Confirm

Compleo SAE - Configuration Overview



Note : Please ensure that the bags and connections match the kit image displayed in the GUI, and confirm that the manual clamps are open. Verify that all the SAE settings are appropriate. Once confirmed, any changes made in the SAE admin console will not be applicable to this run. If needed, please cancel and click on the "Initiate" button again to refresh the settings.

SAE Settings

E-Signature Count

Audit Reasons

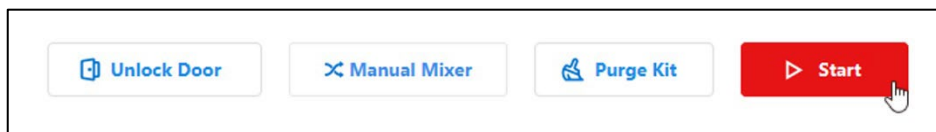
SN	Reason
1	Manually edited.
2	Entry error.
3	Well anomaly.
4	Calculation error.
5	Need to change threshold.
6	Need to reanalyze.
7	Starting a new experiment

Cancel

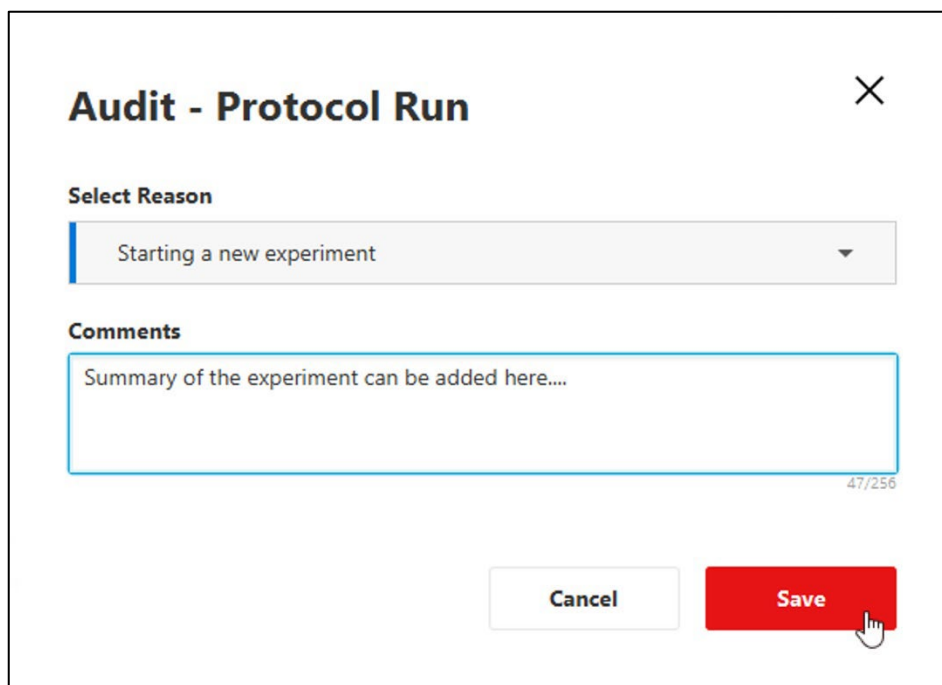
Confirm

Note: Once the user clicks the Confirm button, all SAE settings, such as Audit, E-Signature, Lock Screen, and offline thresholds, are locked in place. Any changes made in the SAE Admin Console after this point will not apply to the run that is about to start. However, if the user clicks the Cancel button, they can consult the SAE Administrator for the necessary configuration adjustments. It is important to note that each time the user clicks the Initiate button, Compleo™ SAE reloads the settings from the SAE Admin Console.

8. If the loaded protocol has expired, a message will be displayed to the user giving them the option to confirm and continue using the expired kit.
9. The user can then click the Start button to begin executing the Protocol Run.



10. Depending on the SAE Configuration that the user has confirmed, the user will have to select a reason from the drop-down and enter comments to start the Protocol Run if the Audit pop-up is displayed. The protocol will be started after submitting the reason and comments. If the audit field is configured as Optional in the SAE Admin Console, then the user may skip without providing the inputs. If it is configured as Silent, then no pop-up will be displayed to the user for this input.

A pop-up window titled 'Audit - Protocol Run' with a close button (X) in the top right corner. It contains a 'Select Reason' dropdown menu with 'Starting a new experiment' selected. Below it is a 'Comments' text area with the placeholder text 'Summary of the experiment can be added here...' and a character count '47/256'. At the bottom are 'Cancel' and 'Save' buttons. A mouse cursor is pointing at the 'Save' button.

This pop-up is shown to the user because the SAE Admin Console Administrator role has configured this setting in the SAE Admin Console software.

11. If an Electronic Signature window is displayed for this action, then an authorized user will need to approve this action. Approval would occur by providing their username and password. This window is displayed because the SAE Admin Console Administrator role has configured this setting in the SAE Admin Console software. The protocol will start if the approval is given successfully.
12. Once the protocol is started, the status will change from Not Running to Running.
13. Once the protocol is completed, a pop-up message will display the calculated versus measured volumes, along with any warnings related to the protocol completion. The pop-up can be dismissed by clicking Done.
14. After this, the user will have the option to perform a manual burp or to end the protocol run. Clicking End will return control to the Protocol Run Dashboard.

3.3 Pause Protocol Execution

The status of the instrument can be changed from Running to Pause through the following actions:

1. Case #1 - Clicking the Pause Button in the user interface: In the Protocol Run dashboard, clicking the Pause button will instantly change the instrument status from Running to Pause. If audit settings were configured in the SAE Admin console, the user must provide the required information before resuming the protocol.
2. Case #2 - Pressing the Pause Button on the Instrument: Pressing the pause button on the instrument also immediately pauses its operation and prompts for an audit reason if configured. **NOTE: See Release Notes for a known Issue.**
3. Case #3 - User Acknowledgments: User acknowledgments are prompt messages that request an action from the user. When these acknowledgments are raised, the instrument state changes from Running to Pause. The messages and available action buttons may vary depending on the current step and state of the experiment.
4. Case #4 - Mixer State Changes: Errors related to the mixer, such as Mixer Lost, Mixer Fault, or User Stopped the Mixer, can also change the instrument status from Running to Pause.

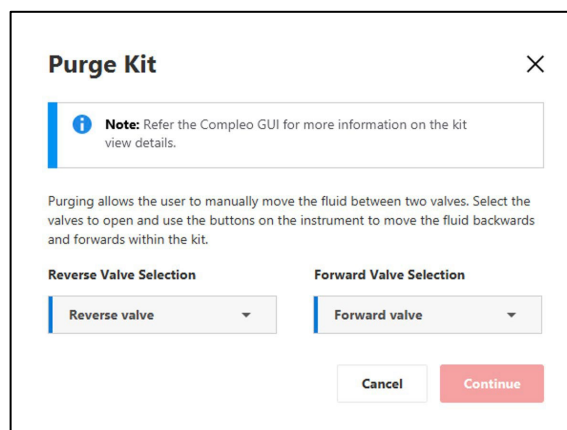
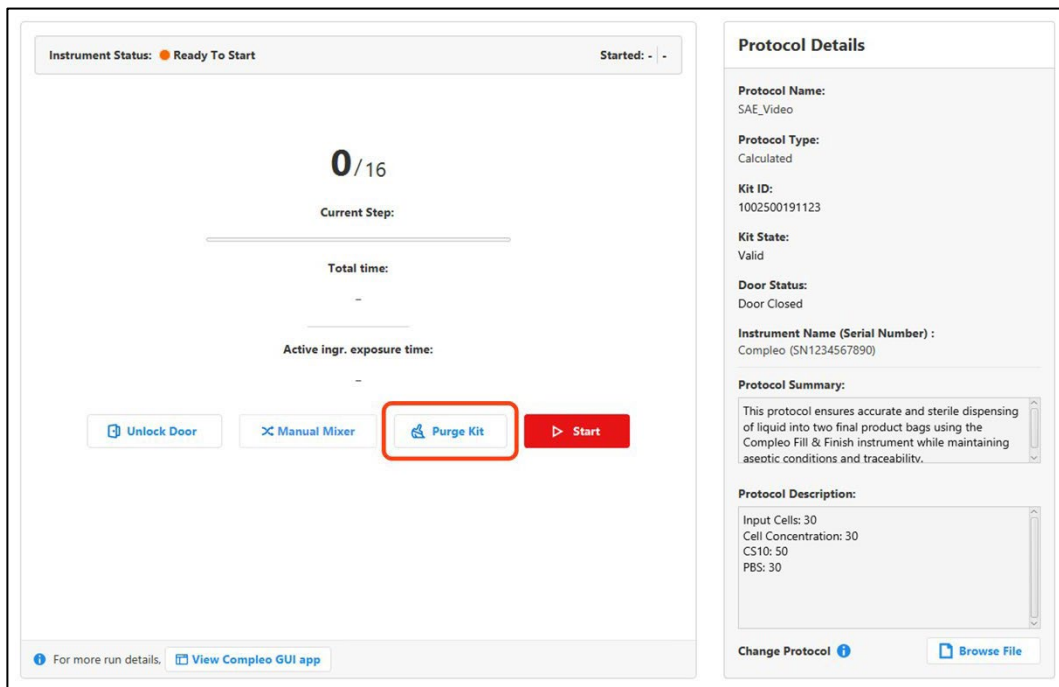
For resuming protocol execution:

- In cases #1 and #2, the user can click the "Resume" button available in the Protocol Run dashboard.
- In cases #3 and #4, the user must take action to acknowledge the message before resuming.

Important: Physical buttons on the instrument will be disabled when running the Compleo™ SAE software, except for the Pause button. Commands must be submitted through the Compleo™ SAE software interface for security, audit, and e-signature functionality. The physical buttons will be enabled during wet prime, manual burp, and the purge kit process.

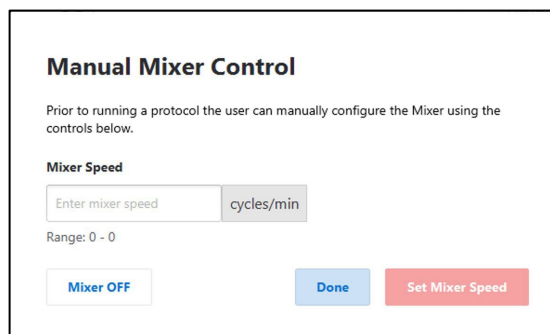
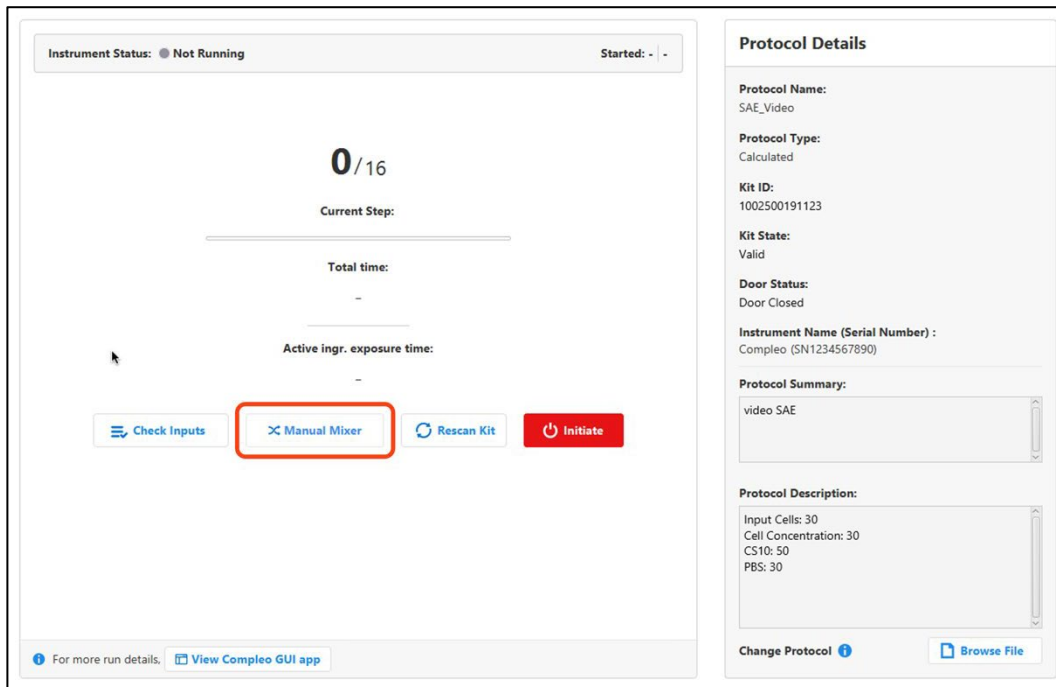
3.4 Manual Purging

Compleo™ SAE also provides an option for the user to Purge the kit. The "Purge Kit" button becomes available once the protocol is initiated (when the instrument status shows: Ready to Start). Like the Compleo™ GUI, the user must select the Reverse Valve and the Forward Valve, then click "Continue" to begin the process. A new pop-up will appear with instructions for starting the purging process.



3.5 Manual Mixer

The Compleo™ SAE enables users to operate the mixer as a standalone device prior to starting the protocol run. There is a button available on both the Protocol Dashboard and the Run Details Dashboard to control the mixer. Users can access manual mode until the protocol run begins. When this button is clicked, a pop-up window opens, allowing users to set the mixer speed and turn the mixer on or off.



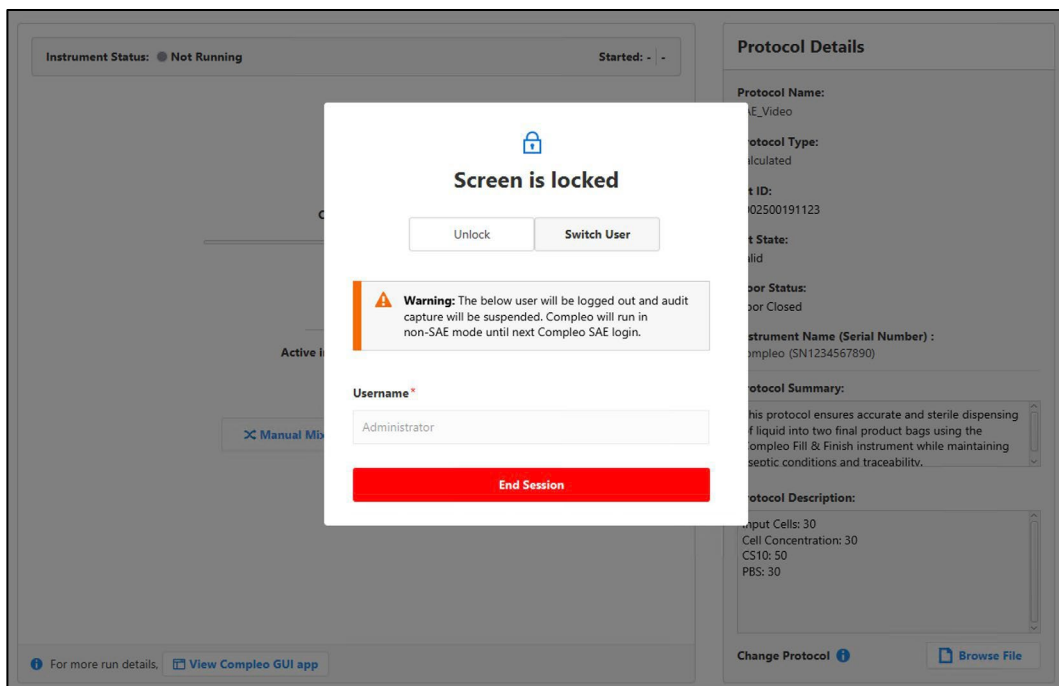
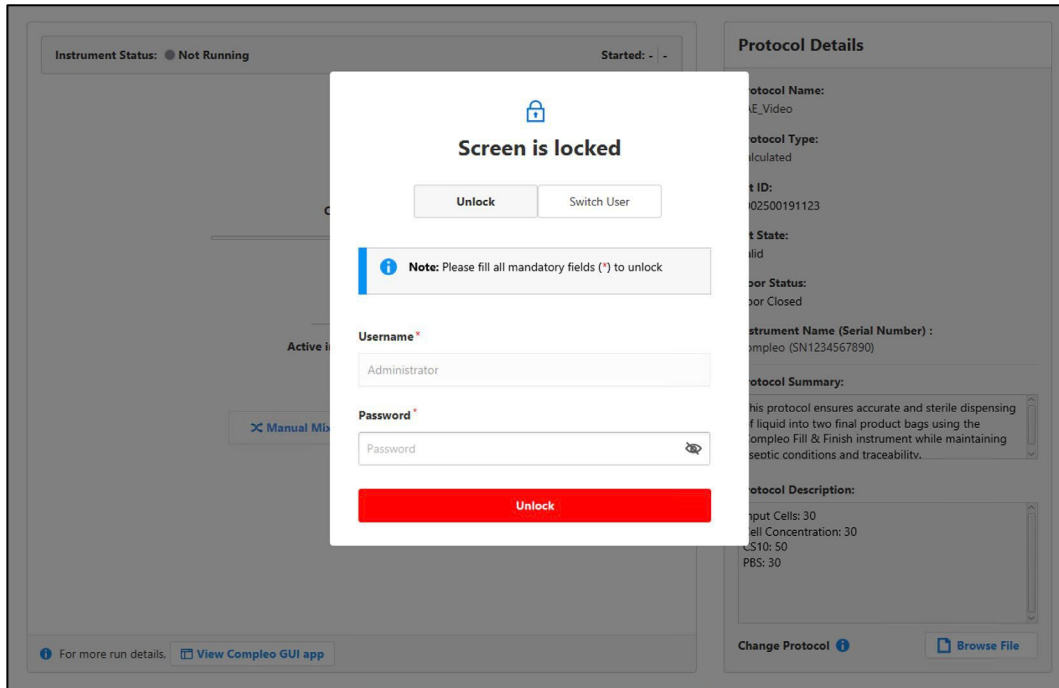
Note: Setting the mixer speed to zero turns off the mixer.

3.6 Lock the Compleo™ SAE software

- A lock the screen option is available in Compleo™ SAE software to prevent unauthorized users from accessing their session while it is in progress. The screen can be unlocked using their account password.
- Both manual and automatic lock screen options are available.
- The Manual screen lock button is available from the header bar present at the top of the software.



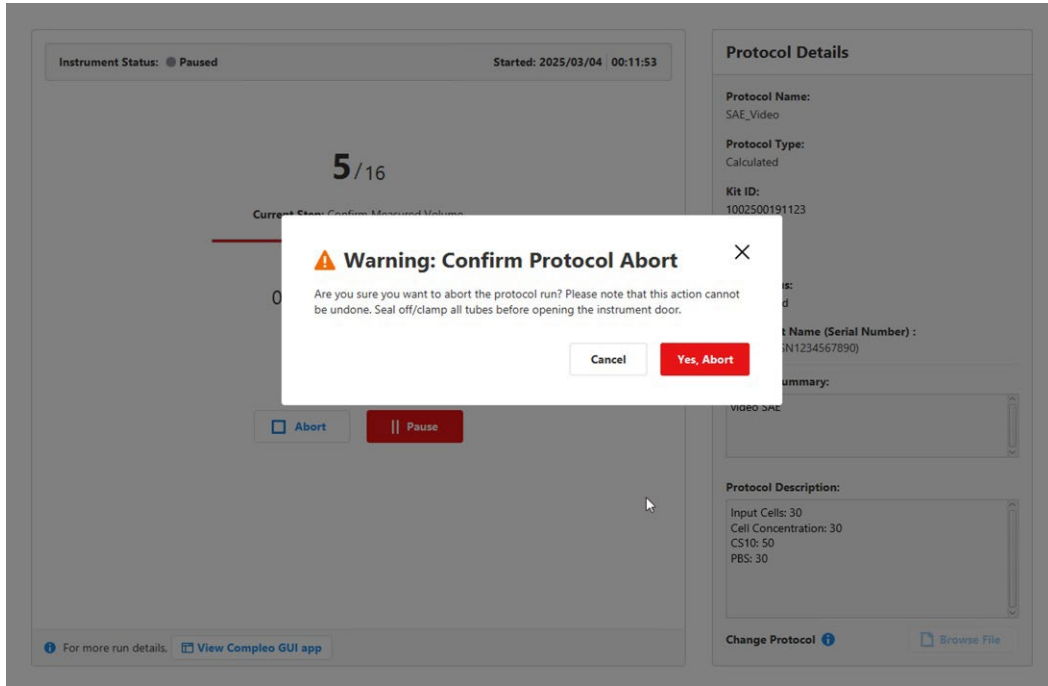
- Automatic lock screen can be configured in SAE Admin Console by setting an inactivity duration. The Compleo™ SAE will read this duration and lock the screen if it is left idle for longer than the set duration.



A Switch User option is available if the locked user is unavailable for unlocking the Compleo™ SAE. Any user would be able to end the current login session by using this option if the protocol is not in the running state.

3.7 Stopping a protocol

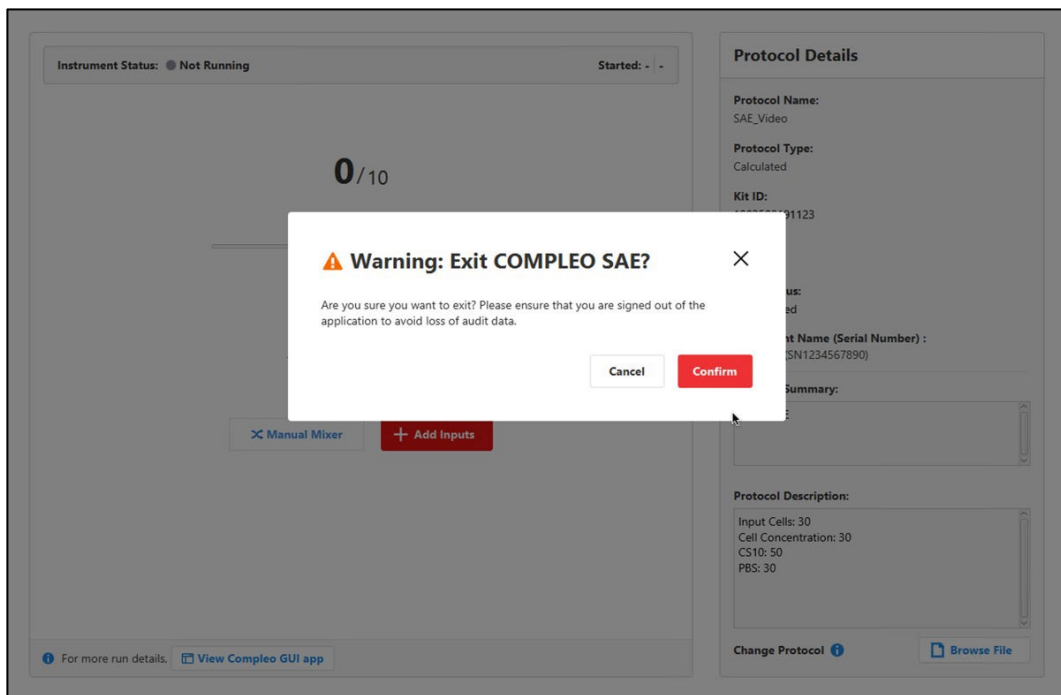
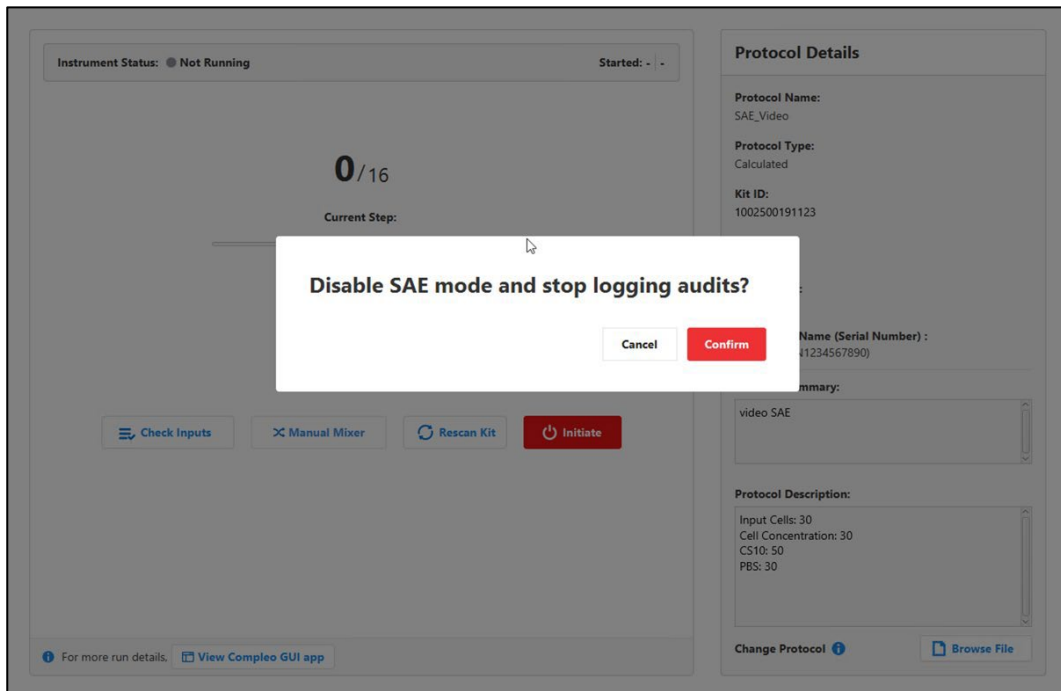
If a run is stopped by clicking the “Abort” button, then the user must enter a reason for stopping the run. Specifying this reason is mandatory for the user to move on.



3.8 Closing Compleo™ SAE software

Log out of the Compleo™ SAE software to disable SAE mode.

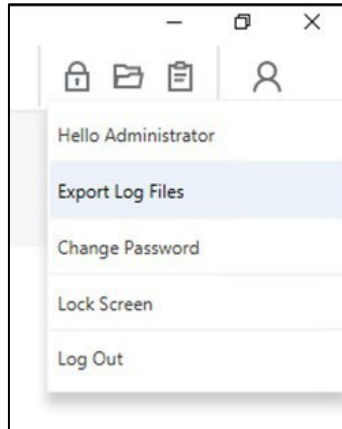
Note: Log Out will be disabled if a protocol is running. The close icon “X” will be available at the top-right corner of the screen when the protocol run is in progress. If this is chosen, the SAE functions will be disabled.



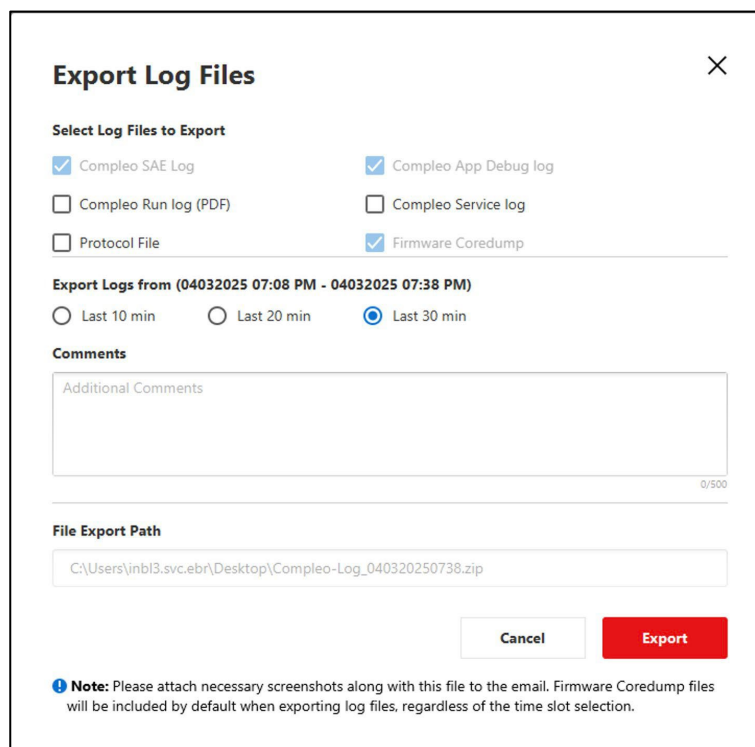
- For optimal performance, it is recommended that the Compleo™ GUI app, Compleo™ SAE software, and the SAE Admin Console software are closed after use or relaunched periodically between protocol runs.
- If the Compleo™ SAE software loses connectivity to the SAE Admin Console during a run, a temporary audit file is stored and updated to the SAE Admin Console once the connection is re-established.

3.9 Exporting Compleo™ SAE Log files

When log files are needed for technical support or troubleshooting, they can be combined into a zip file and exported to the desktop. This option is available in the Profile drop-down menu under "Export Log Files".



Clicking this option opens a pop-up window with several choices. The Compleo™ SAE log, Compleo™, and Firmware coredump files are selected by default and cannot be unchecked, as they are mandatory for troubleshooting. Users can also select additional files, such as Protocol file, Compleo™ Run log (PDF) file, and Service log file, to simplify the troubleshooting process.



Users can choose to combine all log files generated in the last 10, 20, or 30 minutes, with a timestamp displayed to help make the appropriate selection. Additionally, there is a comment box where users can describe the issue, which will be included along with the exported log files. The path of the exported file will also be displayed once the export is

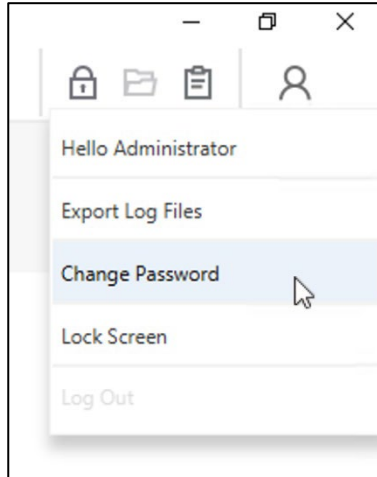
complete. Exported log files can be shared with the respective point of contact or support team.

Note: Firmware coredump files are log files generated by the instrument whenever it crashes during the protocol run. The generation of these files may indicate that the instrument encountered a software issue. The files do not contain any information related to protocols or clients' sensitive or uniquely identifiable information. Instead, they only include generic information about the valves open or close, the running step information and various sensor data. This information will help us to identify the instrument state prior to the firmware crash to help fix the issue.

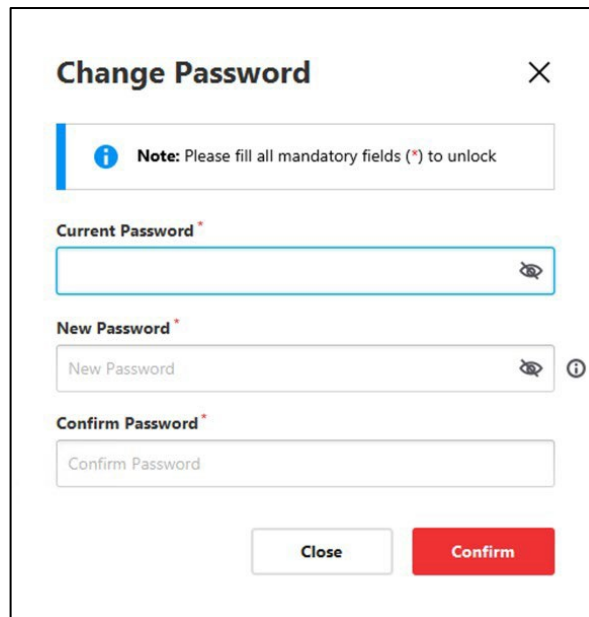
Chapter 4 Security management

4.1 Change your password in Compleo™ SAE

After signing-in, use the Change Password menu item under the Profile menu at the top right corner.



Enter your Current Password, a New Password, and then Confirm the new password.



Note: If the SAE Admin Console Administrator password is lost, it cannot be reset. In such cases, a software reinstall may be required. Please ensure you save this information in a secure location.

- Your new password must meet the complexity requirements set by the SAE Admin Console Administrator.
- If you exceed the maximum number of sign-in attempts, you will be temporarily locked out of your account. (See the SAE Admin Console user guide).
- You may have limited access to Compleo™ instrument functions based on the user role set by the SAE Admin Console Administrator.

4.2 Permissions and default user roles

SAE User Roles	Role Description
Administrator (SAE Admin Console Admin)	A default system role with full access privileges to the SAE Admin Console software. The SAE Admin Console Administrator creates new SAE user accounts, defines which privileges are granted to each SAE user role, and assigns user roles to all other SAE users. The SAE Admin Console Administrator manages all security, auditing, and e-signature setting preferences through the SAE Admin Console software.

To determine the permissions for a role or to edit them, the SAE Admin Console Administrator must Sign-In to the SAE Admin Console software and select the role, then click Edit. The following table shows all user-configurable permissions and the settings for the default user accounts.

Permissions		Available Roles
Category	Function	Administrator
Protocol	Select Protocol Folder	Yes
	Browse Protocol	Yes
Protocol Run	Initiate	Yes
	Start	Yes
	Pause	Yes
	Abort	Yes
	End	Yes
Run Settings	Run Settings	Yes
Security Configuration	Perform E-Signing	Yes

4.3 Disable SAE mode

- Log out of the Compleo™ SAE software to disable SAE mode.
- Within the Compleo™ GUI software settings, users can make the OPC-UA Setting toggle to the Off position.
- When operating runs from the Compleo™ GUI software interface, users are operating without security, auditing, or e-signature functionality.

Chapter 5 Troubleshooting

5.1 Known Issues

1. In rare events, prolonged inactivity truncates the OPC-UA connection without formally displaying the relevant error or warning messages to the user.
2. While operating the Mixer in manual mode, it accepts a leading zero (ex., 01) in the mixer speed field, but only an integer (ex., 1) is recorded in the AR (Action Records).
3. If Audits are not enabled, then 'NA' is captured in the AOR (Application Object Records) rows. However, E-Signatures are captured if configured.
4. Opening the door will stop the mixer. However, this action is not captured as audit data.
5. If the Manual Mixer or Confirm SAE Settings pop-up windows are open when the user opens the door, any open pop-up will automatically close without the need for the user to click any buttons or icons. Additionally, no notifications will be displayed to the user.
6. Error messages or error-raised events will only be captured in AOR after the protocol has started.
7. During a communication error (i.e., unplugging the Type-C cable or a loose contact between the Type-C and the terminal adapter) situation, all the applicable buttons in the Run Details Dashboard Screen are enabled, and clicking them leads to an instrument error.
8. In the manual mixer mode, the Mixer Fault/Lost/User Stopped the Mixer error messages are not displayed.
9. The **Save** button should allow users to proceed without entering a comment when the audit is set to **Optional**, even if they type and delete the input. Validation should only enforce comments when the field is mandatory.

5.2 Helpful information

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 system is not specific to the Compleo™ instrument and should only be used as a general guide.

5.3 Best Practices

1. Restart Compleo™ SAE software and Compleo™ GUI software if protocol data is not reset after a protocol is run.
2. If the 'Change Password at next login' option is enabled for a user, they should log in immediately and update their password to ensure a straightforward experience during e-Signature, screen unlocking, and offline sign-in activities.
3. If a protocol has an error, assess the error message, add clamps to all lines connected to a bag, and open the front door of the instrument to inspect the kit for any pinches or clotting. After reseating the kit and closing the front door, reload the protocol to start the protocol again.
4. Refer to the protocol name in Compleo™ GUI if its full name is not visible in Compleo™ SAE. The correct full name will also be captured in audit logs.
5. Set the maximum allowed inactivity duration equal to the maximum possible protocol step duration. This is found under Other Settings in the System tab of the SAE Admin Console software.
6. Do not alter any of the folders or files in the folder where Compleo™ SAE and SAE Admin Console are installed
7. Restart Compleo™ SAE after a protocol run if audit data for that run is not reflected in the SAE Admin Console.

5.4 Support Topics

Observations	Possible Causes	Recommended Actions
Activation Error	License key did not match the serial and sales order number.	<p>Check if the correct values are entered for:</p> <ul style="list-style-type: none"> • Serial number is correct • Sales order number • Activation key
Connection Error with SAE Admin Console	The connection was lost.	<ul style="list-style-type: none"> • The SAE Admin Console should be up and running, and port 8443 is open for communication. • Access the SAE Admin Console portal to identify the IP address of the SAE Admin Console. Then, update this IP address in the Compleo™ SAE application under the 'Configure SAE Server Settings' section on the login page.

		<ul style="list-style-type: none"> User should be logged out to update the SAE Admin Console configuration.
Connectivity with the instrument (Compleo™ GUI app)	The connection was lost.	<ul style="list-style-type: none"> Ensure that the instrument is running, Compleo™ GUI app is running, and OPC-UA settings are enabled, and retry the connection. If the issue persists, close Compleo™ GUI and Compleo™ SAE, launch 'Task manager,' end the processes Python and OpenJDK Platform binary if they are listed.
Compleo™ SAE	Unable to switch to SAE mode.	Ensure a user is not already logged in to the Compleo™ GUI app, or a protocol is not already in progress
Error while uninstalling Compleo™ SAE	Uninstall	Before uninstalling Compleo™ SAE, ensure that Compleo™ SAE software is closed, and 'OpenJDK Platform Library' is not running in the Task Manager of the Windows™ system
CmdFailed Error	Unable to process the last command.	<p>This could be due to the limited time available for the instrument to process the last command.</p> <ul style="list-style-type: none"> Avoid clicking the Retry button or any other button repeatedly within 1-2 seconds.
InstrumentNotReady	Instrument was not ready for the last command.	<ul style="list-style-type: none"> Ensure the appropriate action is taken based on the instrument status and protocol. Use the export module to combine necessary files to include when reporting issues.



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

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