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CTS™ Compleo™ Fill and Finish System

USER GUIDE

Catalog Number A57164

Publication Number MAN1000687

Revision A

For Research Use or Manufacturing of Cell, Gene, or Tissue-Based Products.

ThermoFisher SCIENTIFIC

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For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

Revision history: MAN1000687 A (English)

Revision	Date	Description
A	8 January 2026	Initial release.

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

The CTS™ Compleo™ Fill and Finish System is for use in further manufacturing applications. Drug manufacturers are responsible for ensuring the purity, potency, safety, and identity of finished drug products and for obtaining the appropriate regulatory approvals.

Contents

1 Product information

IMPORTANT! Before using this product, read and understand the information in the “Safety” appendix in this document.

Product description

The CTS™ Compleo™ Fill and Finish System is an automated, closed-flow benchtop instrument with the flexibility to perform a broad range of formulation, fill and finish workflows.

The CTS™ Compleo™ Single-Use Kit is specifically designed to allow protocol flexibility with 11 user-configurable input/output tubes connectable via sterile welding or luer connection, an air inlet filter, and Carrier Frame for ease of loading and error-free tube management.

The CTS™ Compleo™ Protocol Builder Application allows users to create, modify and save protocols for subsequent operation on the instrument.

Features

Compleo easily fits into existing workflows, from research to commercial manufacturing.

- Up to 4 inputs (media) and 10 outputs (doses) can be defined with either common or unique specifications (that is, volume, cell concentration, and formulation)
- The Protocol Builder App automatically minimises the time that cells are exposed to cryoprotectant with the actual exposure time displayed on the GUI throughout the run
- Patented fluid handling technology that provides accurate and reproducible output volumes down to 0.5 mL with self-verification
- Protocol Builder App that enables Users to create and optimize protocols to suit their specific workflow and save them for subsequent use
- Intuitive Graphical User Interface (GUI) that enables cell concentration and Input volumes to be updated as they become available during the protocol
- Patented software algorithm to optimize the volume, cell concentration, number of doses dispensed and destination for residual based on the cell count and volume for the specific batch
- Automated mixing of formulated media
- Ability to collect up to 10 in-process samples
- Automated "burping" of Dose bags to remove air
- Manual burping mode to optimize air removal of individual dose bags
- Automatic and manual purge modes to enable Kits to be reset to a known starting condition before implementing a recovery protocol

- Users can transition from process development to GMP manufacturing on the same system
- Integration with additional modules via CAN bus
- OPC-UA interface for integration with external laboratory information systems (LIS) or manufacturing execution systems (MES)

Contents

Table 1 Contents of CTS™ Compleo™ Fill and Finish System (Cat. No. A57164)

Contents	Amount
CTS™ Compleo™ Instrument	1 each
CTS™ Ovation™ Mixer Module	1 each
Bag Hanger Post	1 each
CTS™ Compleo™ Single-Use Kits	Available separately
CTS™ Compleo™ Protocol Builder Application	Downloadable
Dell™ laptop for operation/programming	1 each
USB-C cable to supply power and comms between the Instrument and laptop	1 each

System overview

IMPORTANT! The Compleo™ system shall be used exclusively with Compleo™ kits which are for single use only and should be used within their stated expiration date. The user is responsible for appropriate storage, handling, and disposal of CTS™ Compleo™ Single-Use Kits. Thermo Fisher Scientific shall not be held responsible for any consequences resulting from use of kits other than as specified in the user guide. Contact an approved Thermo Fisher Scientific representative if there is any doubt as to the use of the Compleo™ system.

Instrument views

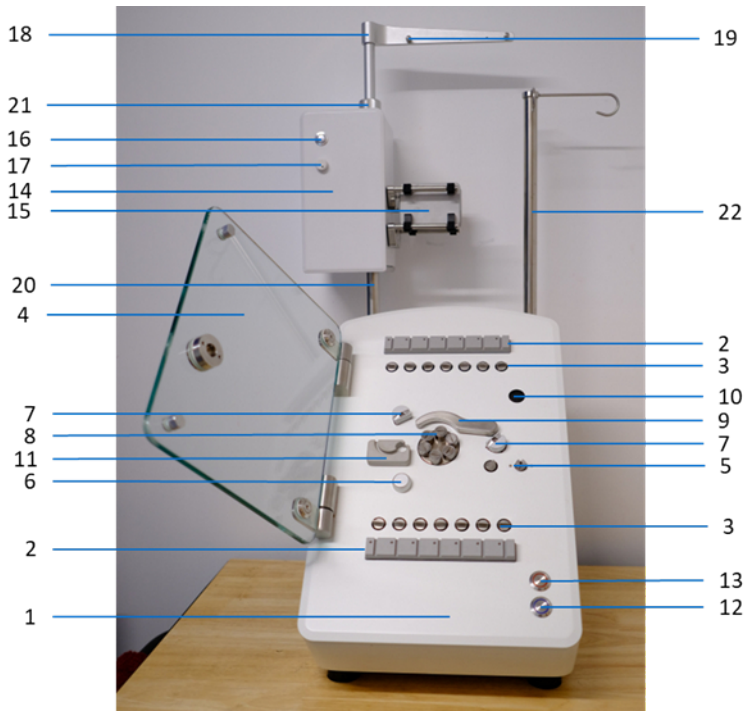
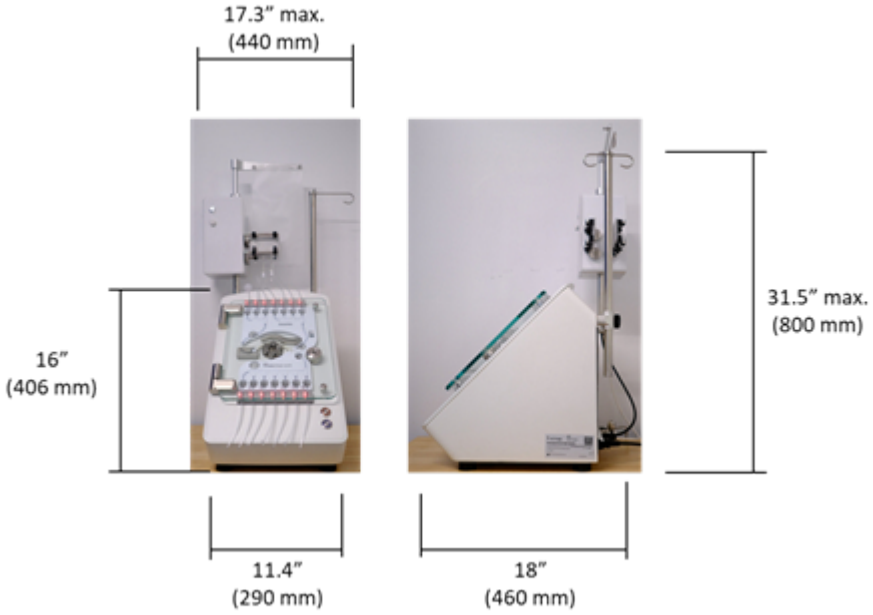


Figure 1 Instrument front and rear views

① Compleo™ instrument
② Bubble Sensor Array
③ Pinch valves
④ Glass door
⑤ Door latch
⑥ Locating Pin
⑦ Locating Pin and Pressure Sensor
⑧ Pump Head
⑨ Pump Arm
⑩ Barcode Scanner
⑪ Pump Tube Retainer Block
⑫ Start button
⑬ Stop/Pause button
⑭ Mixer Module
⑮ Mixer Paddle
⑯ Mixer button

⑰ Mixer Speed Control
⑱ Mixer Hanger Arm
⑲ Mixer Bag Pin
⑳ Mixer Lower Post
㉑ Arm Adjustment Clamp
㉒ Bag Hanger Post
㉓ Bag Hanger Post Clamp
㉔ Bag Hook
㉕ Mixer Post Clamp
㉖ Power switch
㉗ Mains IEC Connector
㉘ Mixer power cable
㉙ CAN bus cable for Mixer
㉚ CAN bus connector (x2)
㉛ Ethernet connector
㉜ USB-C cable

Instrument Dimensions



Working Space

The Compleo™ instrument is designed for benchtop use and requires a working space of approximately Height: 31.5" (800 mm), Width: 31.5" (800 mm), and Depth: 23.5" (600 mm) (assuming the door is open and the laptop is positioned on the right side of the instrument).

Note: The laptop is connected via a USB-C cable providing flexibility as to its location relative to the instrument.

Instrument Weight

Component	Weight
Instrument	43.6 lb (19.8 kg)
Mixer Module including Mixer Hanger Arm	10.8 lb (4.9 kg)
Bag Hanger Post	0.6 lb (0.3 kg)
Total weight	**55.0 lb (25.0 kg)**

Instrument properties

Property	Value
Electrical	
Supply voltage	100–240 V AC +/- 10%, 50/60 Hz
Phases	Single
Maximum rated input current	5 A
Fuses	2 x 5 A
Sound level	
Maximum sound level	70 dBA (measured 1 m from instrument)
Typical sound level	65 dBA (measured 1 m from instrument)
Environmental ranges	
Ambient temperature	15°C to 30°C
Transport temperature	0°C to 45°C
Storage temperature	15°C to 30°C
Maximum relative humidity	80% (non-condensing)
Altitude (max.)	2,000 m
Indoor use only	—
Not intended for use in a wet location	—
Intended for use in Pollution Degree 2 environments	—
Operating limits	

(continued)

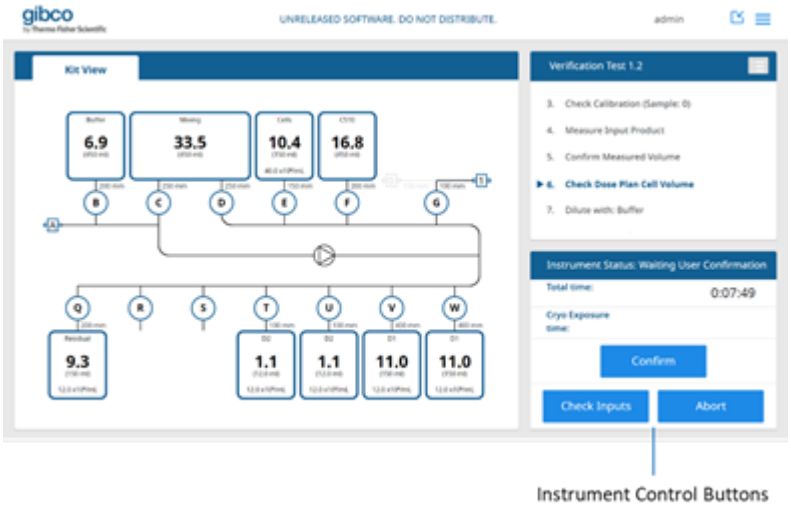
Property	Value
Media bag volume	0.3 mL to 750 mL
Input Cells Volume	7 mL to 750 mL
Output bag/vial volume	0.3 mL to 750 mL
Mixing bag volume	Up to 750 mL
Maximum bag weight per bag hanger post	2.2 lb (1 kg)
Number of Input bags	1 to 4 (including Mixing bag and depending on in-process sample allocation)
Number of Output bags/vials	1 to 10 (depending on number of Input bags and in-process sample allocation)
Number of in-process samples	0 to 10 (all in-process samples are dispensed through line G and manually directed to the sample vessel)
In-process sample volume	0.2 mL to 750 mL (Protocol Builder limit)
Flow rate	5 mL/min to 50 mL/min (Auto speed ramping and user-adjustable for specific steps. The flow rate used depends on the protocol step being performed and the volume being dispensed)
Mixing parameters	Initial Mix: 5–200 cycles at 1–80 cycles/min Continuous Mix: 0 to 80 cycles/min until all outputs have been dispensed
Maximum pressure	120 kPa (based on Firmware limit for ΔP)
Blockage detection pressure	80 kPa (based on Firmware limit for ΔP)
Media temperature	4°C to 38°C
Media density	1.0 g/mL to 1.1 g/mL (DMSO)
Media viscosity	1.0 kg/ms x 10^{-3} to 2.0 kg/ms x 10^{-3} (DMSO)
CAN bus connections	
Purpose	Connection and control of external devices including Mixer Module
Connector	TE connectivity T4111402051-000 M12 Plug
Connections	Pin 1: VCC CAN — +5V out
	Pin 2: CAN-H — Dominant High
	Pin 3: CAN-L — Dominant Low

(continued)

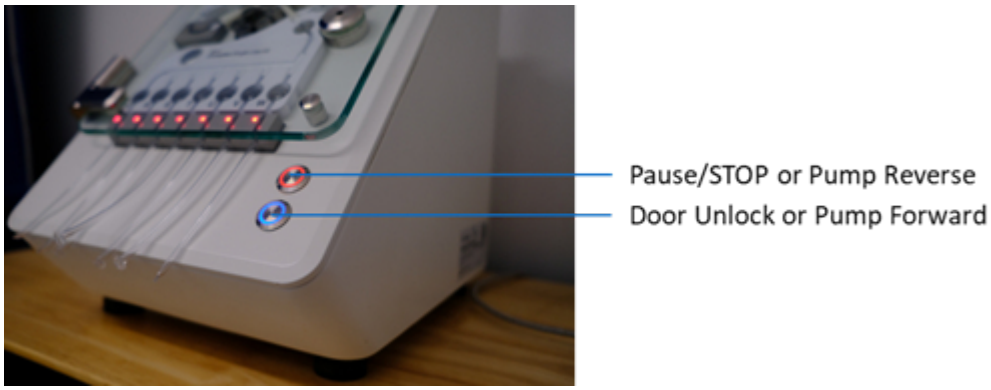
Property	Value
Connections	Pin 4: GND — Ground
	Pin 5: GND — Shield (optional)

Push button controls

Operation of the Compleo™ system is primarily via the Compleo™ Application on the laptop.



Two mechanical push buttons are also provided on the front panel of the instrument to pause and restart the instrument during a protocol and to open the instrument door.



The two buttons can also be used to manually operate the pump in the forward and reverse direction when purging fluid lines or burping output bags.

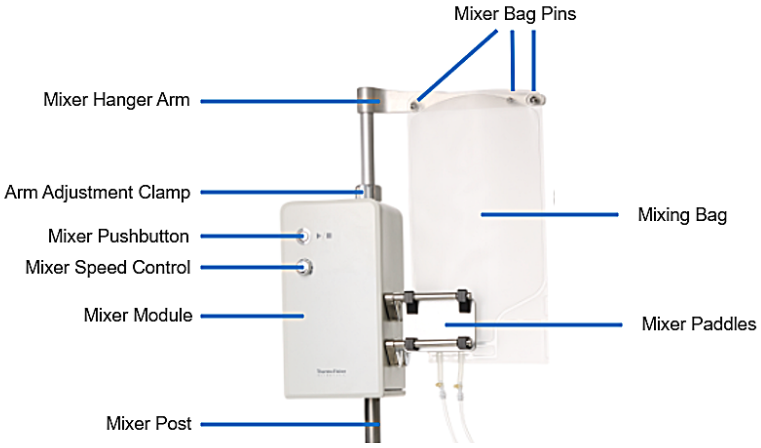
Pushbutton	Symbol	Function	Colour	Indication prior to button press
Pause/STOP OR	⏸/■	• If the instrument is running, stops rotation of the Peristaltic Pump and places the instrument into Pause mode. Pinch valves remain in the current state. • If an alarm is present, resets alarms	Red	**Continuous** – Instrument on and no alarms **Flashing** – Instrument has an alarm
Pump Reverse		Rotates pump slowly in the forward direction whilst depressed		Only available when manually purging or burping outputs
Door Unlock OR		Unlocks the door if the protocol has been aborted and the instrument stopped	Blue	**Continuous** – Instrument is stopped, and the door can be unlocked
Pump Forward		Rotates pump slowly in the reverse direction whilst depressed		Only available when manually purging or burping outputs

Figure 2 Instrument push button controls

CTS™ Ovation™ Mixer Module

The CTS™ Ovation™ Mixer Module is controlled by the Compleo™ instrument via CAN bus. A mechanical push button on the face of the Mixer Module also enables the user to turn the Mixer Module off and on.

Note: The speed of the Mixer Module during manual operation will be whatever is currently stored on its embedded controller.



The position of the Mixer Module is set by the collar on the Mixer Lower Post.

The Mixing Bag height is adjusted by loosening the Arm Adjustment Clamp, raising or lowering the Mixer Hanger Arm and then re-tightening the Arm Adjustment Clamp.

Bubble Sensors

Bubble Sensors are available on all lines (A to G and Q to W) to detect whether fluid or air is present in that section of the tube.

Only Bubble Sensors being used as a trigger (i.e., change in state from "wet to dry" or "dry to wet") for the protocol step being performed will be illuminated.

Note: When being used as a trigger, the volume of fluid or air required to trigger the next step is 0.06 mL (~10 mm of tube).

Bubble Sensor states

The state and color of a Bubble Sensor has the following meanings:

State	Color	Meaning
OFF	OFF	Sensor not active for the protocol step
Flashing	Red	Sensor is on and fluid is NOT being detected by the Bubble Sensor
Solid	Green	Sensor is on and fluid is being detected by the Bubble Sensor

Volume measurement

Bubble Sensors are also used to measure the volume transferred based on the volume pumped whilst the Bubble Sensor is wet. Unless the Bubble Sensor is also being used as a trigger, it will NOT be illuminated.

Pressure Sensors

The system uses the pressure difference (ΔP) between Pressure Sensor (fwd.) and Pressure Sensor (rev.) to detect kit blockages during priming (ΔP > 80 kPa) and to provide protection from over-pressure events (ΔP > 120 kPa).

Volume control and verification

The Compleo™ system dispenses volumes based on the number of pump revolutions required required per the Pump Calibration Factor (mL / rev). Refer to the Calibration section (see “Pump calibration” on page 36) for more information.

CAUTION! The Compleo™ system has been demonstrated to deliver an accurate and reproducible volume, *provided* that the fluid being pumped does not contain a significant volume of air.

To provide verification of the dispensed volumes, the Compleo™ system includes an independent volume-checking feature that measures the volume dispensed **while liquid is present** at the Bubble Sensors ("Wet volume") on the Input and/or Output line.

CTS™ Compleo™ Single-Use Kit

The Compleo™ Single-Use Kit enables users to configure kits to match pre-prepared protocols by attaching input and output vessels to the various tubes using a Tube Welder or luer lock fittings. Unused fluid lines are simply left sealed off.

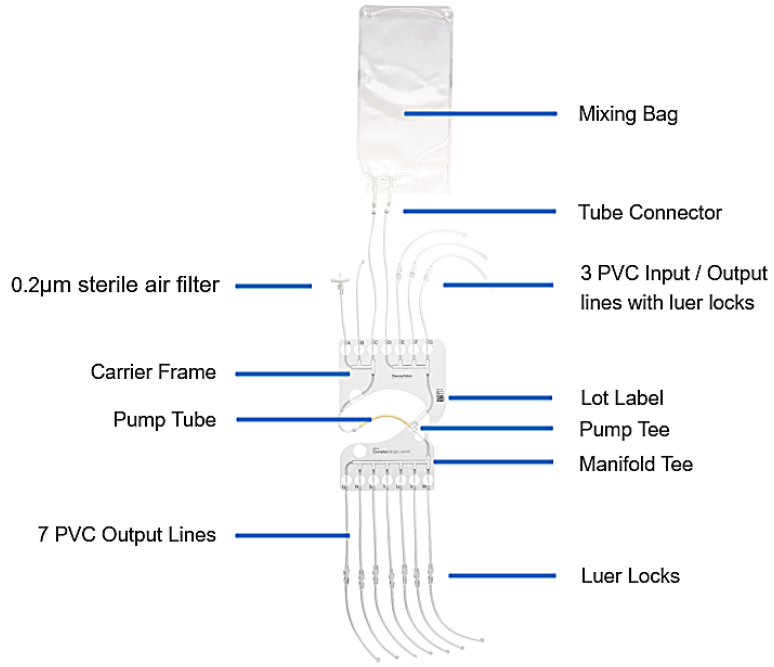


Figure 3 Compleo™ Single-Use Kit assembly

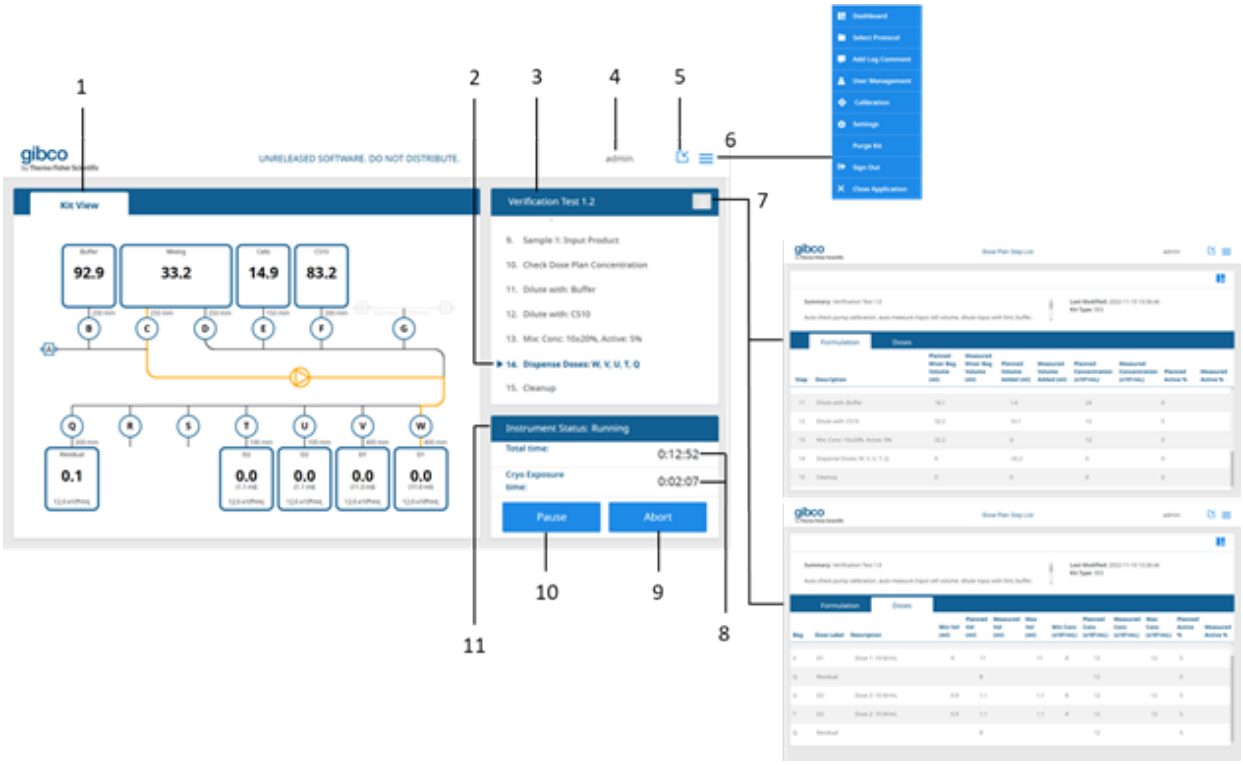
Wetted components

The materials used in the manufacturing of the Compleo™ Single-Use Kit have been chosen for their biological and chemical compatibility.

Description	Material
Manifold Tee	Tritan™ MX711 Copolyester, White
Tube Connector	Tritan™ MX711 Copolyester, White
Pump Tee	Tritan™ MX711 Copolyester, White
PVC Tube	DEHP-FREE PVC, 2.4 mm ID, 4 mm OD
Pump Tube	PharmaPure™ TPE (thermoplastic elastomer) tubing
Luer Connector	MABS
0.2 micron Sterile Air Filter	Housing Material - Polypropylene (PP) Membrane Material - Polyethersulfone, Hydrophobic (PES)
Mixing Bag	FP-FLEX1000A 1 Liter cryobag

Compleo™ application

The Compleo™ Application graphical user interface is the primary means of navigation and operation of the Compleo instrument. It can be operated using the laptop touchscreen or with the attached keyboard.



① Kit view showing schematic of current kit status including current volume in each bag, fluid path and pump direction, Target Volume, and Target Cell Concentration
② Protocol step summary with current active step highlighted
③ Protocol name
④ Username
⑤ Minimize screen
⑥ Navigation menu
⑦ Shortcut to Dose Plan Step list
⑧ Total Run Time and Active Ingredient (Cryobuffer) Exposure Time
⑨ Abort button (to stop run and exit out of protocol)
⑩ Pause/Resume button
⑪ Instrument status
⑫ Kit schematic (current path highlighted)

2 Installation and setup

This section provides information about the installation and setup procedures.

Packaging contents

The Compleo™ instrument package includes the following items:

- Compleo™ instrument
- Mixer Module including Mixer Hanger Arm
- Hanger post
- Mains plug IEC cables (USA/EUROPE/AUSTRALIA)
- Dell™ laptop (this will be in a separate carton)
- USB-C cable
- CAN bus connector

Instrument installation

Gather the following materials:

- Compleo™ instrument unit
- Mixer Module
- Bag Hanger Post
- CAN bus cable
- Mixer power cable
- Mains cable
- USB-C cable
- Spare CAN bus connector

Remove the outer packaging before beginning the installation procedure.

1. Prepare the bench space to receive the Compleo™ instrument unit (see “Working Space” on page 10).

   Ensure that there is easy access to the On/Off switch and mains IEC connector at the rear of the instrument.

CAUTION! The Compleo instrument should be installed on a stable bench. If a mobile set up is used, it is the user's responsibility to ensure all safety hazards and functional risks are addressed including adequately supporting the weight of the instrument and having sufficient wheel span so that both the trolley and instrument are stable.

2. Ensure that the bench is stable and level to within ±0.4 inches (10 mm).

3. Position the instrument on the bench with a minimum of 4 inches (100 mm) between the rubber feet and the edges of the bench.

CAUTION! The Compleo™ instrument weighs 43.6 lbs (19.8 kg) and the Mixer Module weighs 10.8 lbs (4.9 kg). Use appropriate care and seek assistance, if necessary, when installing the Mixer Module or lifting and moving the instrument.

CAUTION! Do not lift the instrument using the Bag Hanger Posts, Mixer Module, cables or connectors.

CAUTION! Position the instrument such that it is easy to disconnect the power cord from the power inlet.

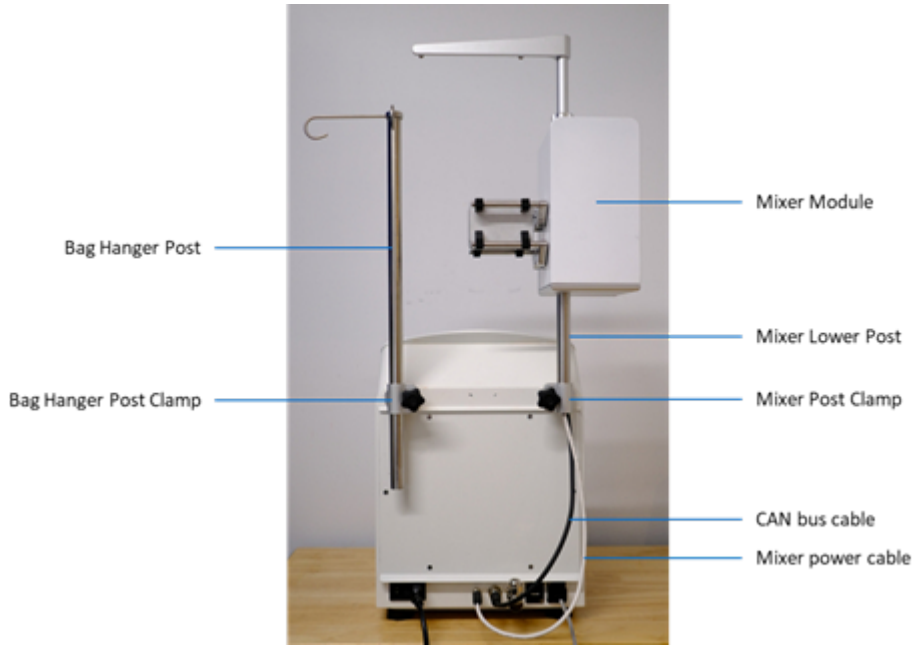
4. Feed the CAN bus cable followed by the Mixer Power Cable through the Mixer Post Clamp.

5. Insert the Lower Post of the Mixer Module in the Mixer Post clamp until it rests on the collar.

   Rotate the Mixer Module so that the Mixer Paddles are facing inwards and tighten the knob.

6. Install the Bag Hanger Post in the clamp and tighten the knob.

Note: The Bag Hanger Post can be rotated and adjusted in height to best suit the size and type of Input bags connected to the Kit.



7. Connect the cables and ports on the back of the instrument as shown in the following figure.

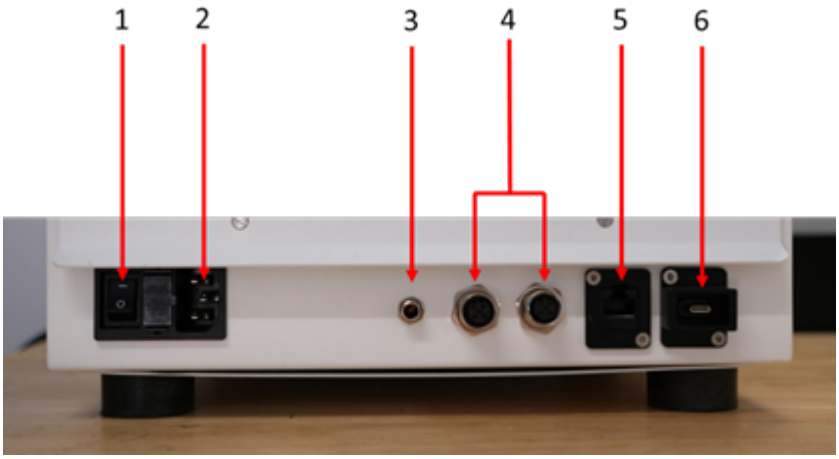


Figure 4 Back view of instrument

① Mains Switch
② Mains IEC connector
③ Bag Mixer Power Connector
④ CAN bus sockets
⑤ Ethernet port
⑥ USB-C port

a. Connect the Mixer Power Cable to the Mixer Power connector (3).

b. Connect the CAN bus cable to the CAN bus socket (4).

c. Screw the spare CAN bus connector into the CAN bus socket (4).

d. Connect the mains IEC connector (2).

CAUTION! If using an alternate mains cable, ensure it is rated for a minimum current of 10A.

Note: Suitable means of protective earthing are provided for this device.

e. Plug the mains cable into the power outlet.

f. Connect the laptop to the USB-C port (6) on the instrument using the USB-C cable.

8. Adjust the instrument position on the bench where it is required.

Power instrument On

Switch on using the mains IEC switch at the rear of the instrument.
The instrument lights will sequence as the instrument powers up.

Figure 5 Assembled Compleo System

Power instrument Off

Switch off the instrument using the mains IEC or mains Power on the rear of the instrument.

CAUTION! If a loss of power event has occurred, restart the instrument and take the appropriate steps to complete the run, which may involve initiating a recovery protocol. Contact Technical Support for further assistance as needed.

Software Installation

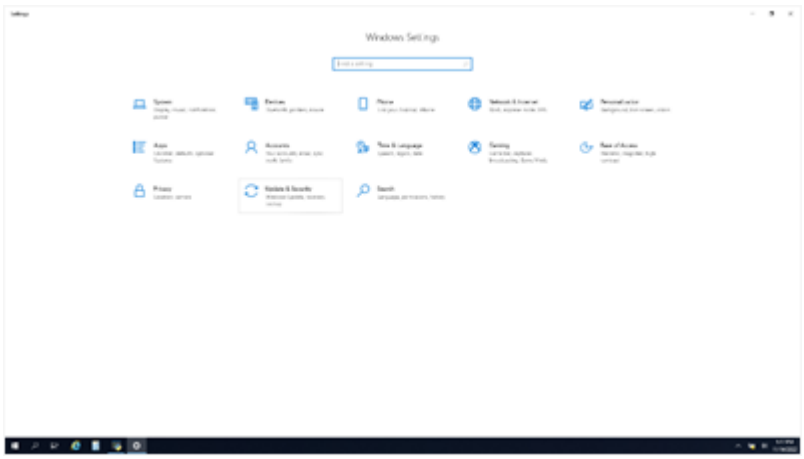
This section provides information about installing the software on the system.

Laptop

The laptop will be pre-installed with Windows™ software that should be updated periodically as follows:

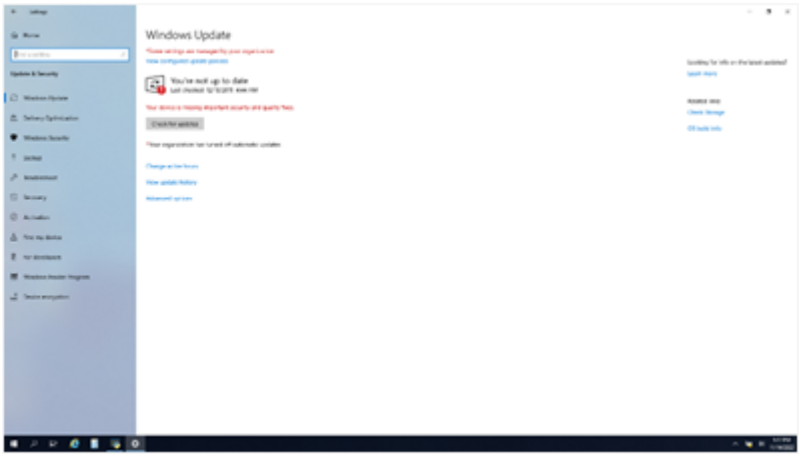
Ensure that the laptop is connected to the local WiFi network.

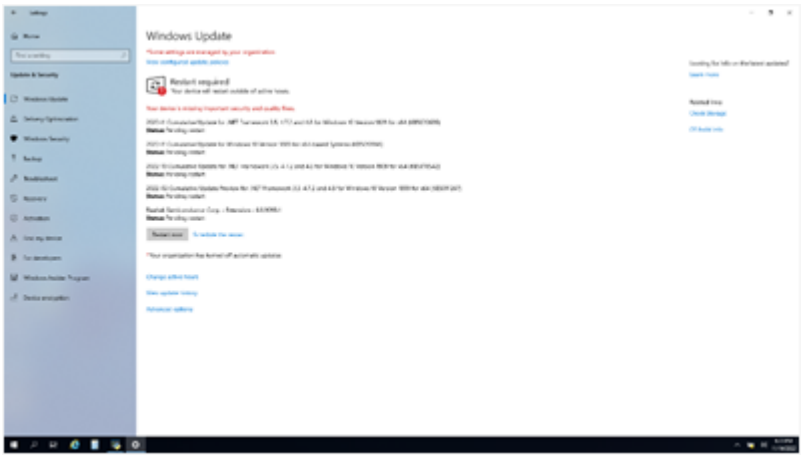
1. Right click on the Windows™ icon and open the **Windows Settings** page.



2. Open the **Update & Security** page and click **Check for updates**, **Install now**, and **Restart now** as required.

Note: This process may need to be repeated multiple times until Windows™ software is completely up to date.





Compleo™ Application

The Compleo™ Application will be pre-installed on the Laptop and provides a Graphical User Interface (GUI) for operation of the instrument including:

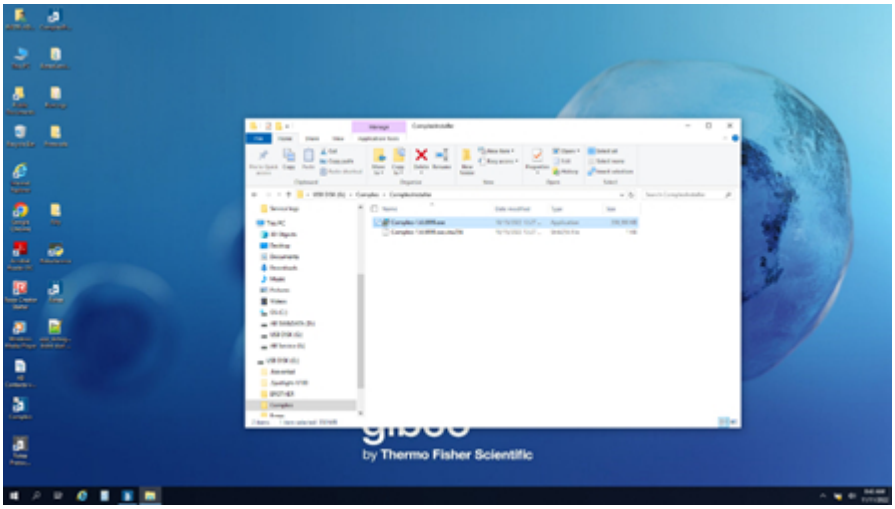
- User Management
- Instrument configuration
- Automatic generation of run_log files
- Selection of protocols
- Data entry
- Start/Stop
- Pause/Un-pause

- Abort
- Retry

Released versions of the Compleo™ Application are available for download from **thermofisher.com**.

The Compleo™ Application can be updated as follows:

1. Uninstall existing Compleo™ Application (refer to “Uninstall Compleo and Protocol Builder Applications” on page 50).
2. Download the required Compleo-X.X.X.exe installer from thermofisher.com and save to an accessible network folder or portable storage device.



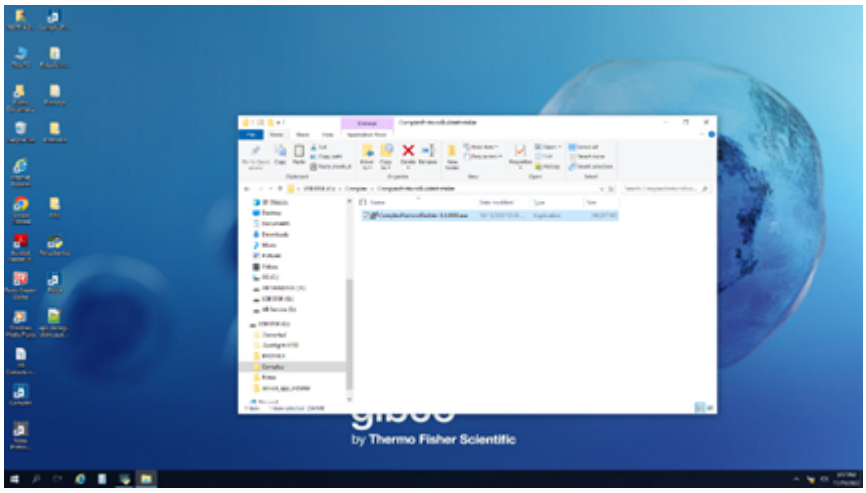
3. Run the Compleo-X.X.X.exe installer and click **Install**. The application will be installed in C:\Program Files (x86)\Compleo\.
4. Click **Close** to finish the app installation.

Compleo™ Protocol Builder application

The Compleo™ Protocol Builder application can be installed on any Windows™ 10- or 11-compatible computer including the Laptop. Released versions of the Compleo™ Protocol Builder are available for download from **thermofisher.com**.

1. Uninstall the existing Compleo™ Protocol Builder application (see “Uninstall Compleo and Protocol Builder Applications” on page 50.)

2. Download the required **CompleoProtocolBuilder** installer from **thermofisher.com** and save to an accessible network folder or portable storage device.



3. Run the **CompleoProtocolBuilder** installer and click **Install**.
   The application is installed in C:\Program Files (x86)\Compleo\.

4. Click **Close** to finish the application installation.

First time setup

Logging in

Note: Sign in is not possible until firmware information has finished loading.

1. Power on the Compleo instrument with the switch on the back, then plug it into the laptop using the USB-C cable provided.
2. Push the power button on the laptop to start Windows™ software.

3. Run the Compleo™ application from the desktop shortcut or start menu.

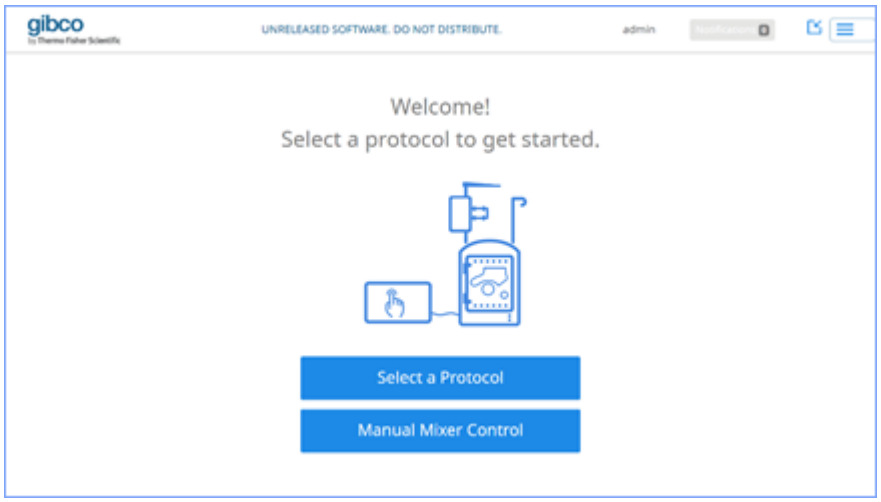
The Compleo™ splash screen is displayed as the application loads.

4. Enter the username and password, then click **Sign In** to access the welcome screen.
   The default credentials are:
   - **Username**: *admin*
   - **Password**: *admin*

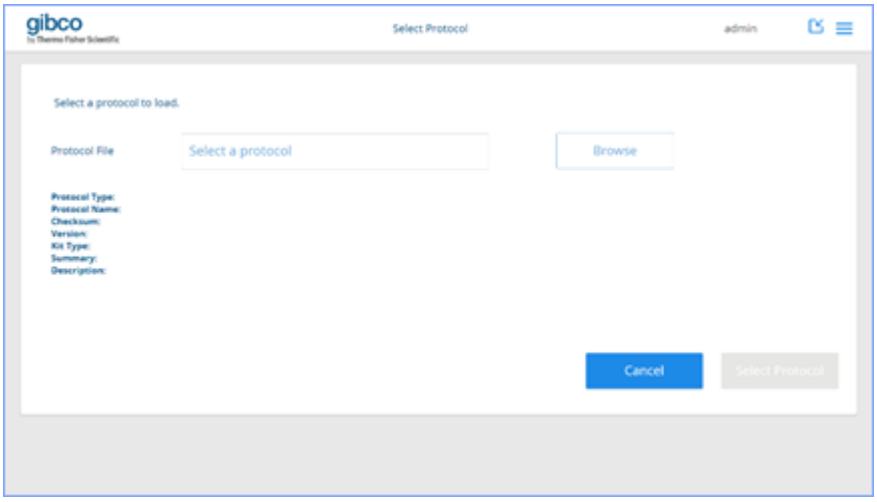
Select a protocol

Select a protocol from the **Welcome** screen or from the **Dashboard** screen.

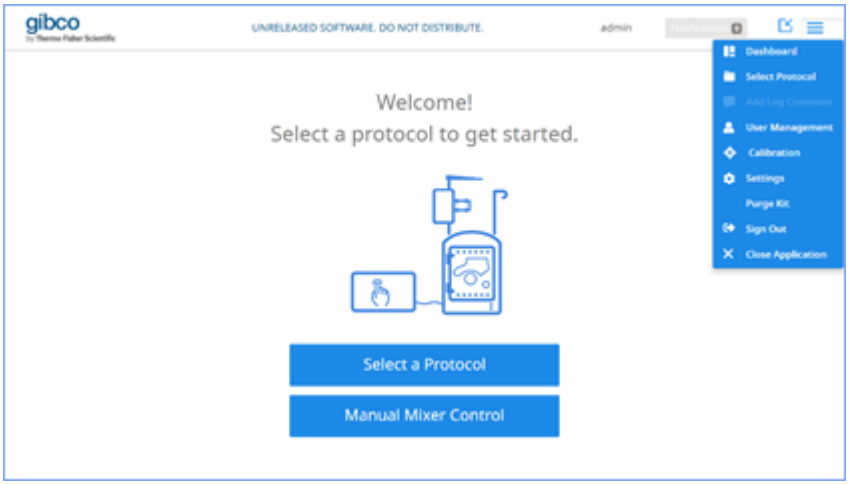
1. In the **Welcome** screen, click **Select a Protocol**.
   The **Select Protocol** screen is displayed.



2. Click **Browse** to open the Windows browser.

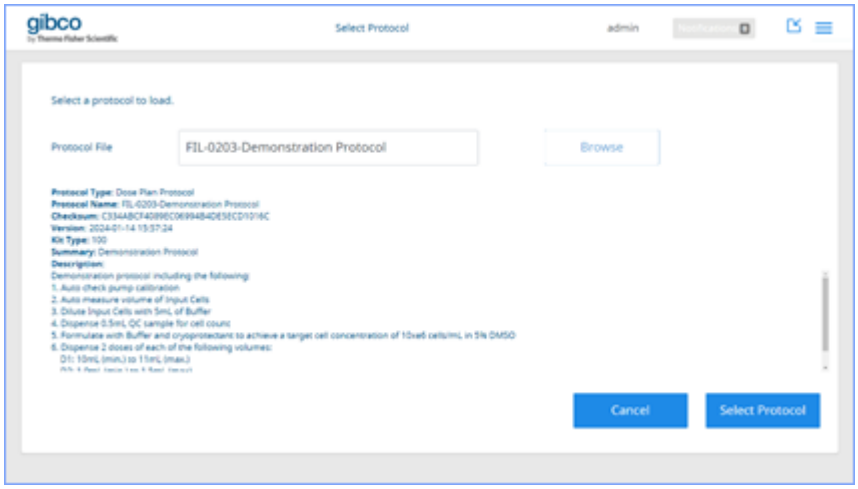


Note: Protocols can also be selected using the drop-down menu.



3. Select a protocol from an accessible directory.
   - Double-click the protocol file, or
   - Select the protocol file, then click **Open**.

   The protocol file name is inserted in the **Select Protocol** screen.



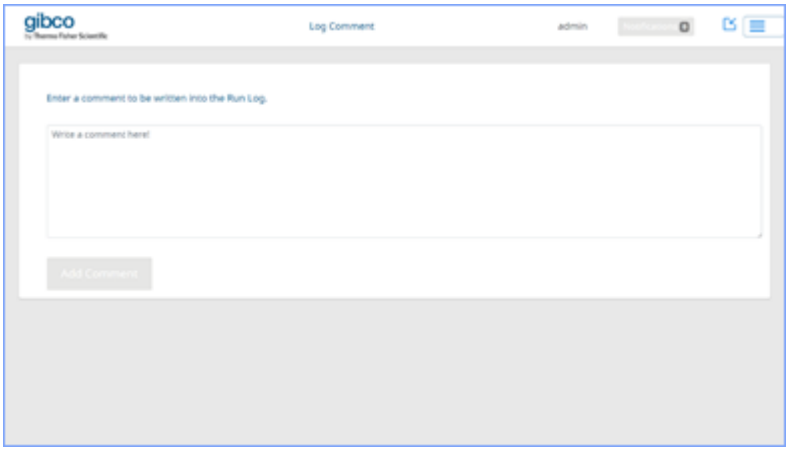
4. Click **Select Protocol** to load the protocol or click **Cancel** to return to the Dashboard screen without loading a protocol.

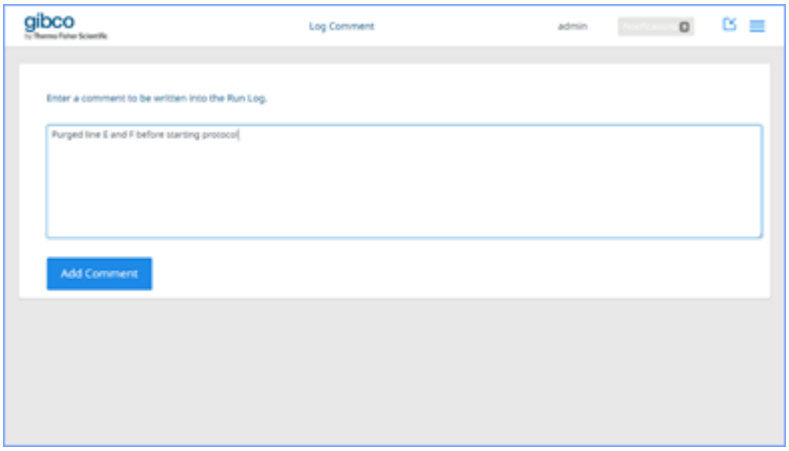
Note: The **Select Protocol** screen can also be accessed from the Dashboard using the drop-down menu.

Add log comment

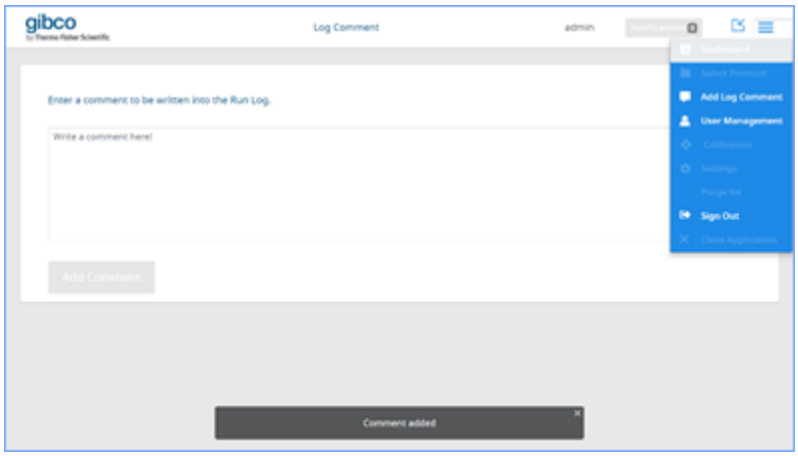
User comments can be added to the run_log whilst the instrument is running.

1. Press the **Pause** button on the GUI or the instrument so that the comment is added to the run_log at a relevant time.
2. Select **Add Log Comment** from the dropdown menu.
3. Click on the text box, type the comment into the text box provided and select **Add Comment** to add it to the run_log.





4. Select **Dashboard** from the dropdown menu to return to the GUI.



Note: The run_log including comments will be saved upon opening of the instrument door.

2024/01/16 07:46:42	14	Blow Air from Bag A to bag F to test if it exists	A to F	Timer	40	4.3
2024/01/16 07:46:43	15	Valve Transition	A	Timer	0	0.8
2024/01/16 07:46:45	User Comment: Purged line E and F before starting protocol					
2024/01/16 07:46:47	16	Blow Air from Bag A to bag E to test if it exists	A to E	Timer	40	4.3
2024/01/16 07:46:48	17	Valve Transition	A	Timer	0	0.8

Figure 6 Extract from corresponding run_log PDF showing user comment and time entered.

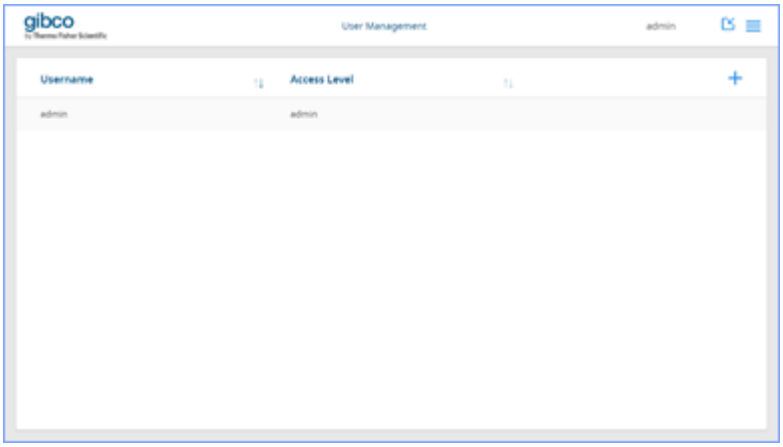
User Management

Administrator

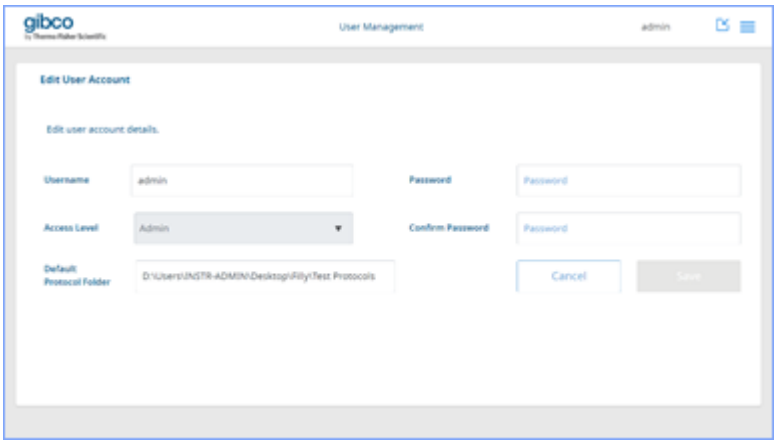
Upon installation, only the default administrator account exists with Username: admin and Access Level: admin.

Note: The default password for "admin" is "admin" and the default protocol folder is D:\Users\INSTR-ADMIN\Desktop\Compleo.

1. Select **User Management** from the dropdown menu to view available users.



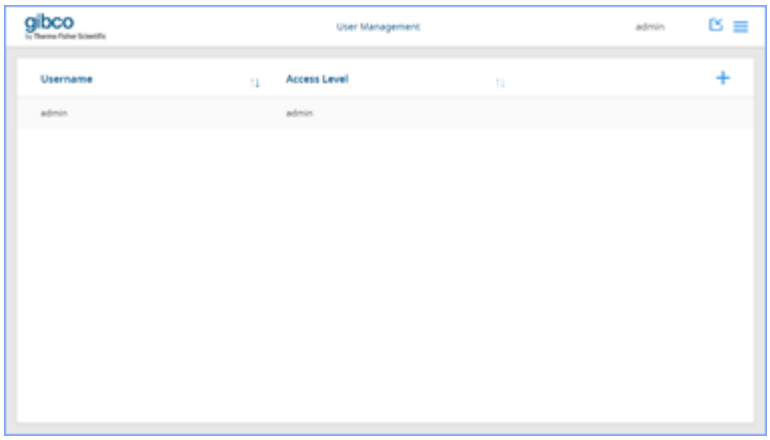
2. Click on the **admin** row to edit the user account details.



3. Select **Save** to save the settings or **Cancel** to return to the **User Management** screen.

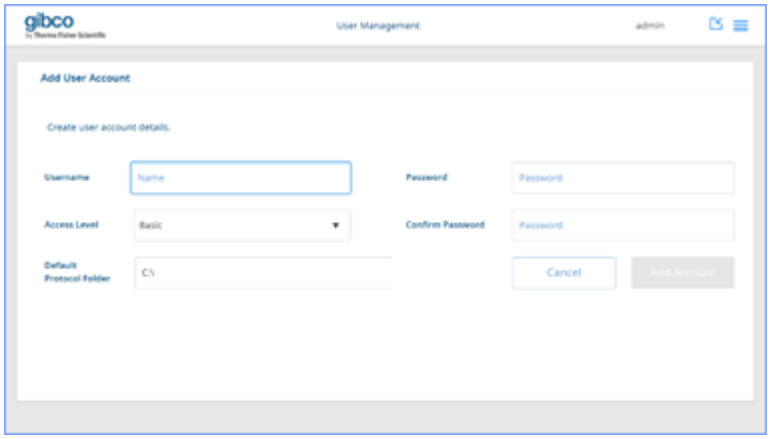
Adding users

1. Select **User Management** from the dropdown menu to view available users.



2. Click **+** to open a new User screen.

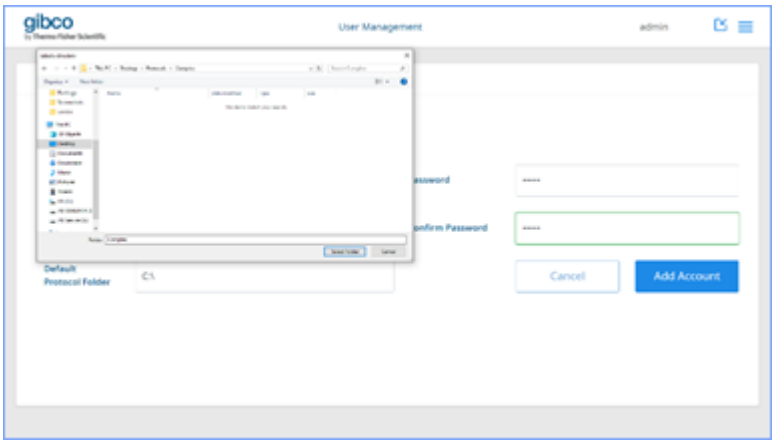
3. Type in a new username (lowercase only) and select an access level from the dropdown list.



4. Add a password and confirm the password.

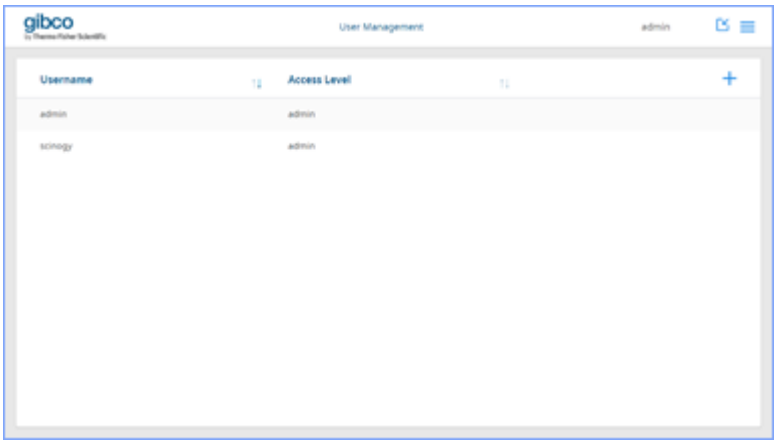
5. Click on the **Default Protocol Folder** box and browse for available folders.

6. Click **Select Folder** or **Cancel** to return to the **Add User Account** screen.



7. Click **Add Account** or **Cancel**.

   You are returned to the User Management screen.



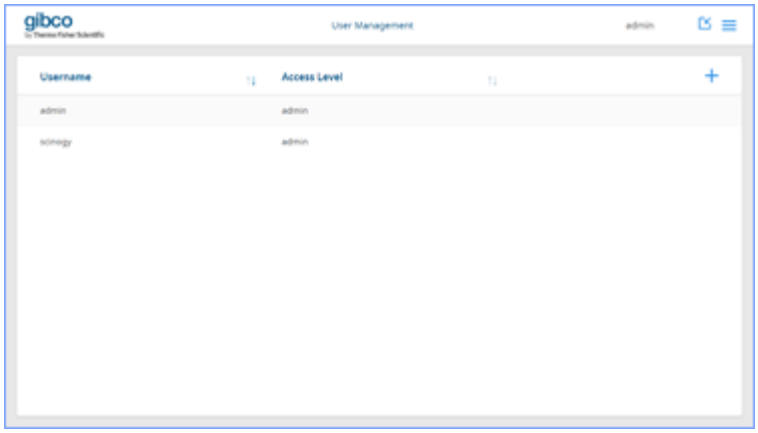
Editing users

Users can change their password and the default protocol folder.

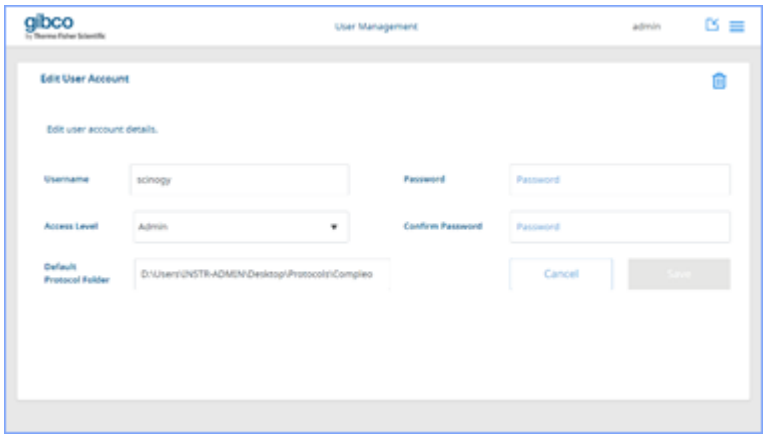
Note: Edits to **Access Level** can only be performed by a user with admin rights.

1. Select **User Management** from the dropdown menu to view available users.

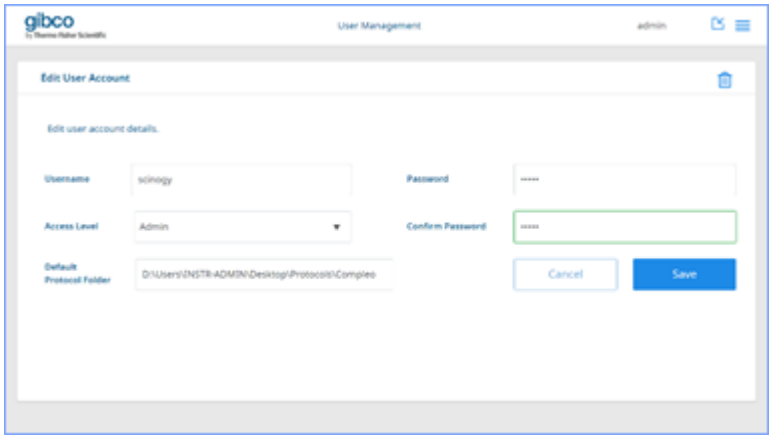
   Note: Usernames and access level can be arranged in ascending or descending order by clicking on the up/down arrows.



2. Click on the user details to be edited (for example, "scinogy") to open the user account details.



3. Edit the user account details and select **Save** or **Cancel**.

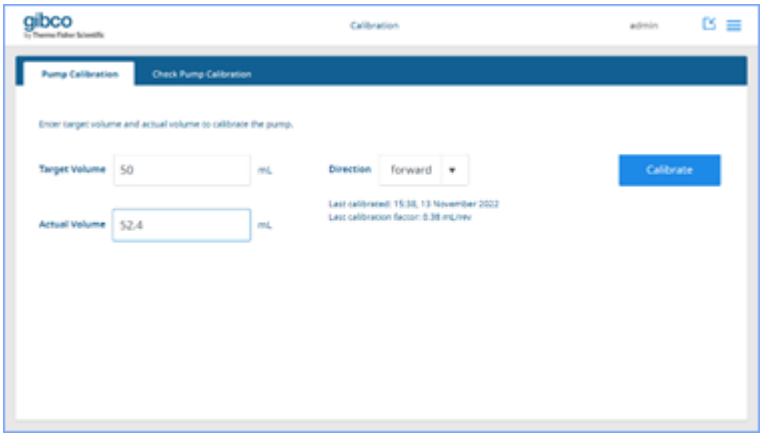


Pump calibration

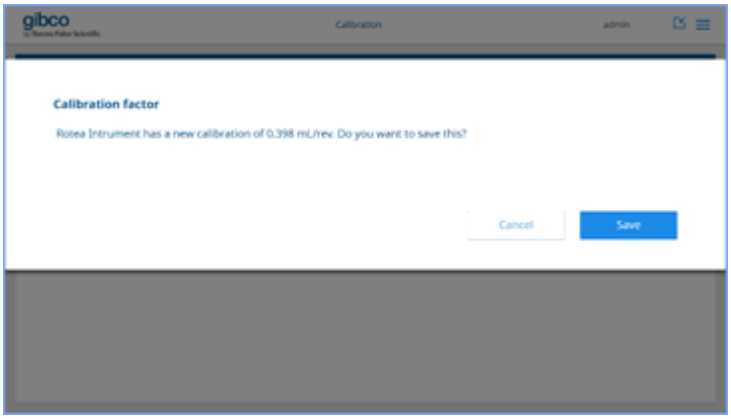
The user is responsible for calibrating the pump and maintaining it in a calibrated state.

Note: The default pump calibration factor for the forward and reverse directions was determined based upon the average (mean) test results from a significant sample size of single-use kits. The user should consider the impact of kit-to-kit variation on volume accuracy before making adjustments to the pump calibration factor.

1. Select **Calibration** from the dropdown menu in the dashboard.
2. Select the forward or reverse direction to be calibrated from the dropdown list.
3. Using the results from the Calibration protocol (refer FIL-0153-##-Pump Calibration), input the **Target Volume** and **Actual Volume**, then click **Calibrate**.

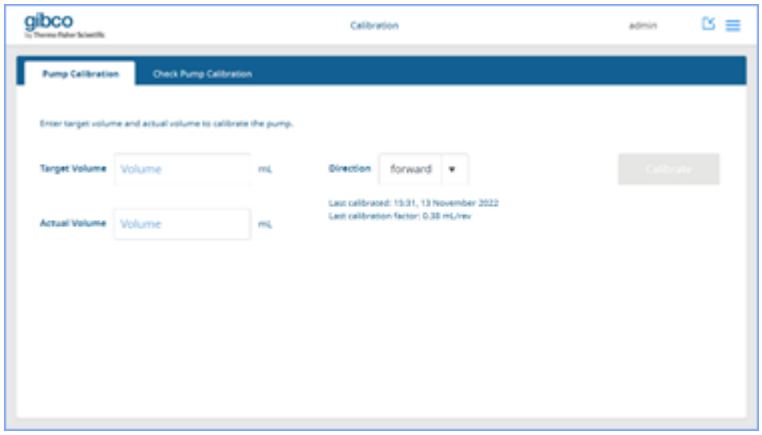


4. Select **Save** to save the new calibration factor or **Cancel** to return to the **Pump Calibration** screen.



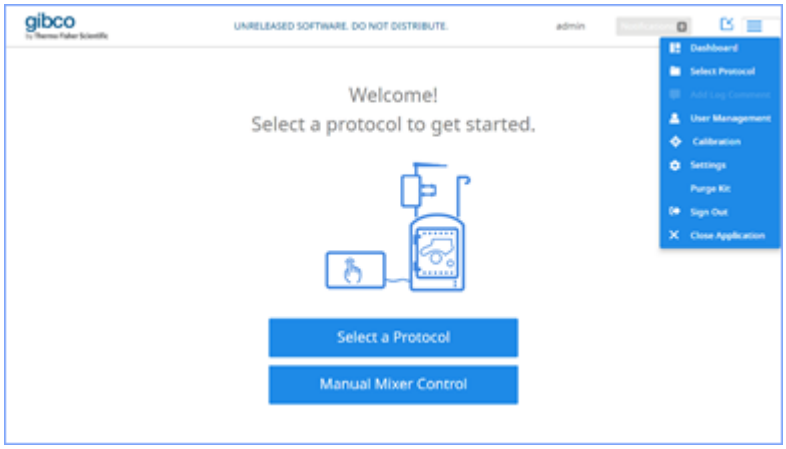
The **Calibration** screen displays the following:

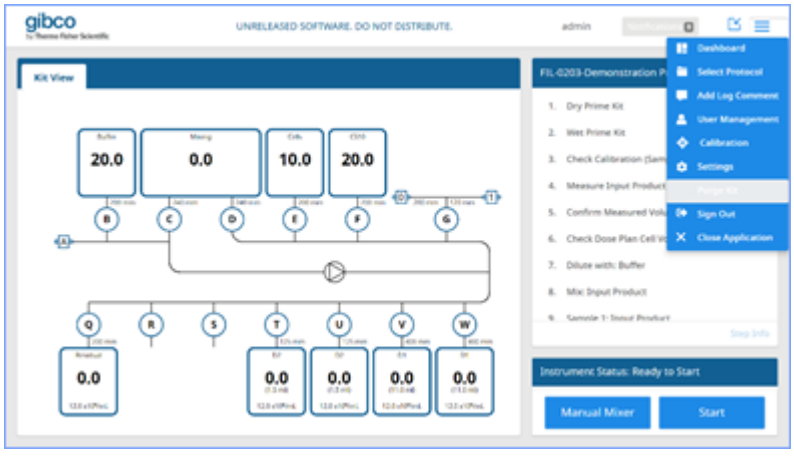
- **Last Calibrated**: Time and date
- **Last Calibration Factor**: 0.XX mL/rev



System settings – ADMIN user access only

Admin users can access system Settings from the dropdown list in the top right corner of the GUI.

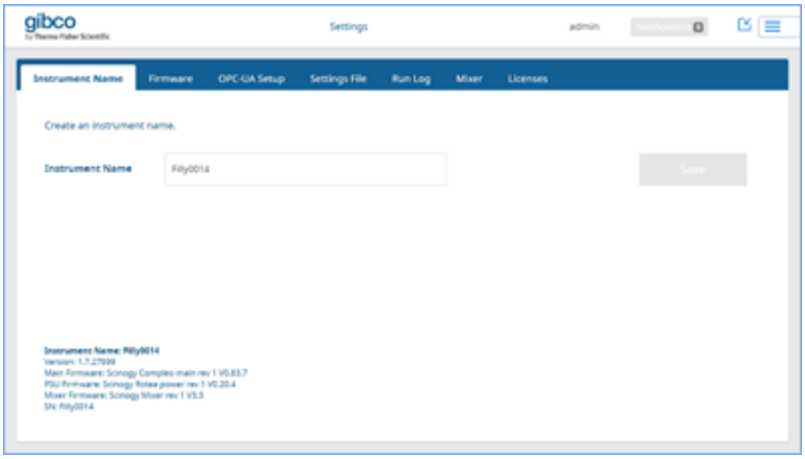




Instrument name

The instrument name can be customized in **Settings**.

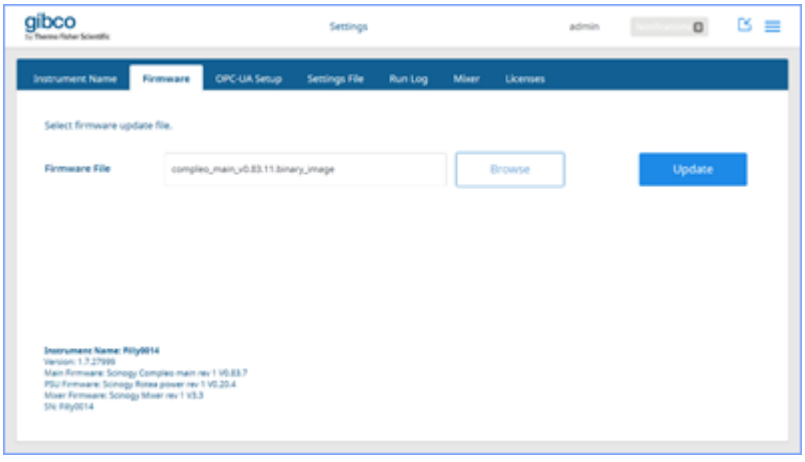
1. Select **Settings** from the dropdown menu.
2. Click the **Instrument Name** tab.
3. Enter a custom name for the instrument.
4. Click **Save**.



Firmware

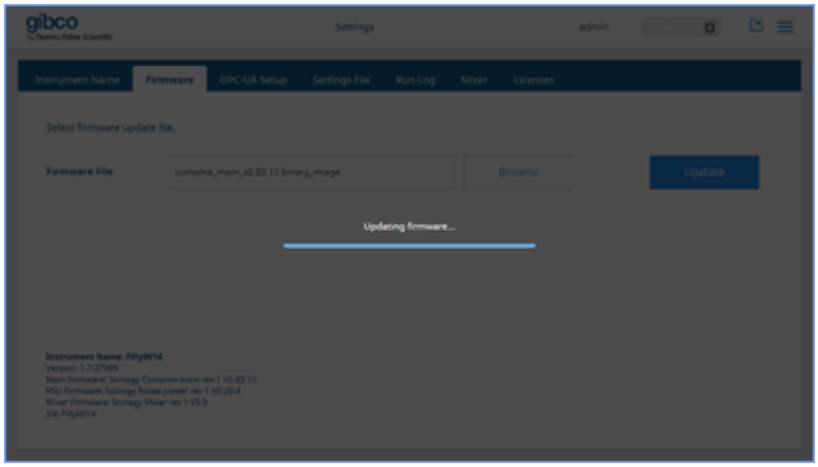
Use the Firmware tab to update the instrument firmware. The instrument automatically reboots after the firmware update is complete.

1. Select **Settings** from the dropdown menu.
2. Click the **Firmware** tab.



3. Click **Browse** to locate the desired firmware file.

4. Select **Update** to automatically update the firmware.
   The firmware is automatically updated and the instrument reboots.

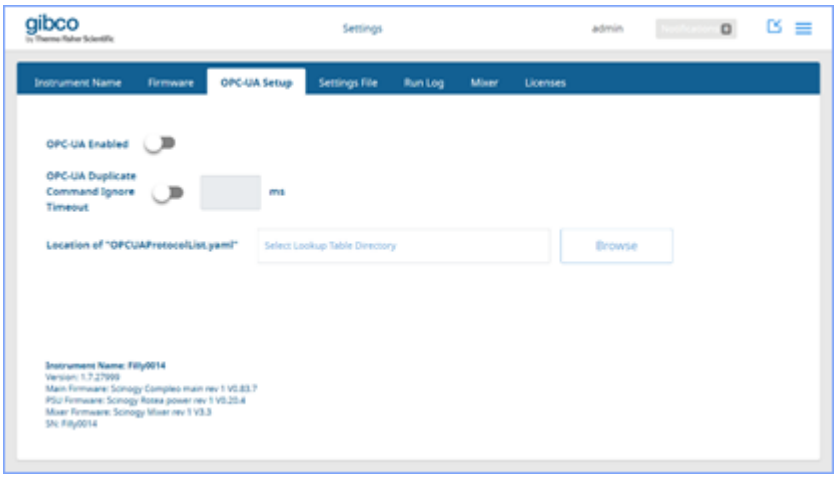


5. After the update is complete, click **Done** to return to the Settings screen.

OPC-UA setup

For information about the OPC-UA interface, see the CTS Compleo™ OPC-UA Connectivity User Guide (MAN1000686).

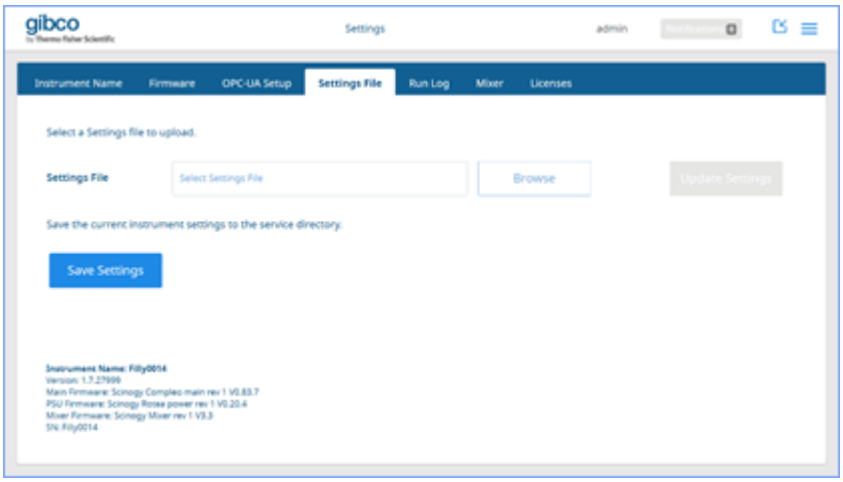
1. From the dropdown menu, select **Settings**.
2. Click the **OPC-UA Setup** tab.



3. Browse and select the appropriate Lookup Table Directory.

Settings file

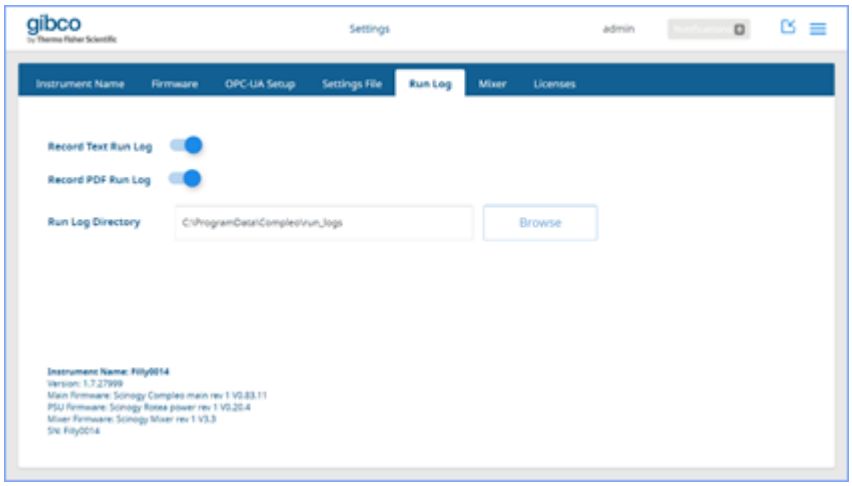
1. Select **Settings** from the dropdown menu.
2. Click the **Settings File** tab, then use the **Browse** button to find the desired file.
3. Click **Update Settings** to update the instrument settings.
4. Select **Save Settings**.



Run log

Text and/or PDF run logs are automatically generated and saved to the laptop when the instrument door is opened.

1. From the main menu, select **Settings ▸ Run Log**.



2. Enable or disable the run log options by clicking on the relevant switches.
   - **Record Text Run Log**
   - **Record PDF Run Log**

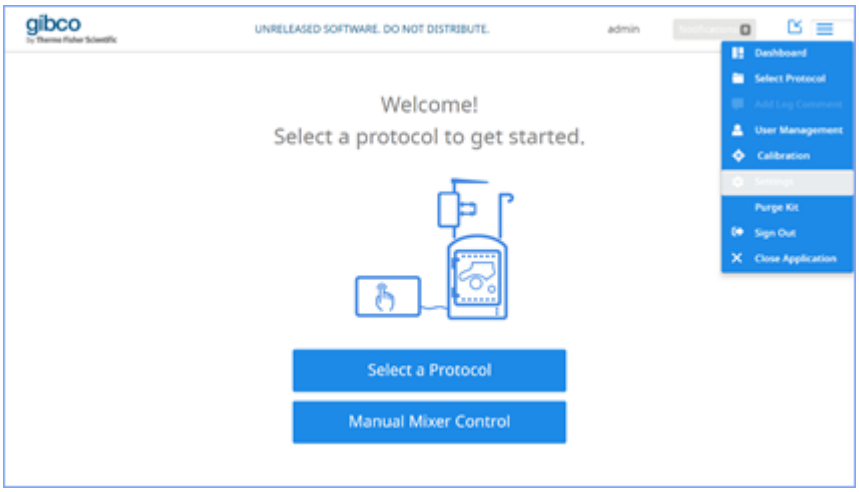
3. (*Optional*) To change the save location, click **Browse** to access available folders, then click **Select Folder** to insert the new folder.

Note: The default directory for run logs is C:\ProgramData\Compleo\run_logs.

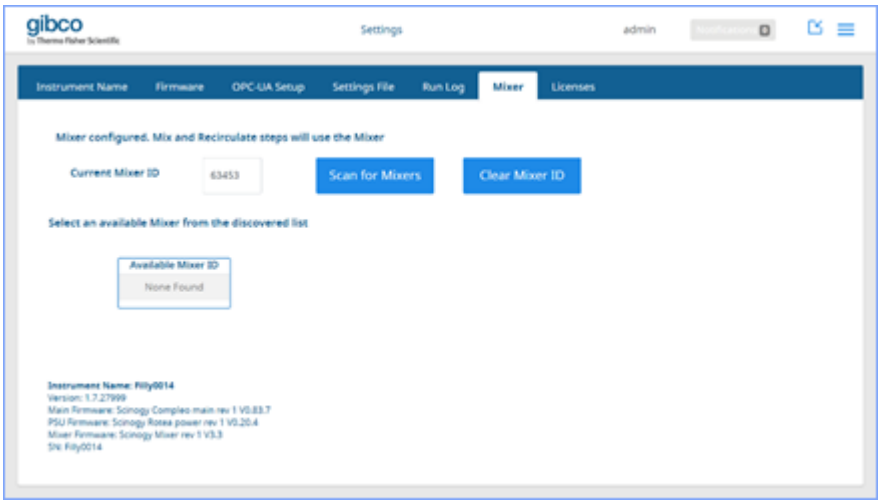
Mixer

The **Mixer** tab allows the user to connect and scan for an attached mixer.

1. From the main menu, select **Settings**.



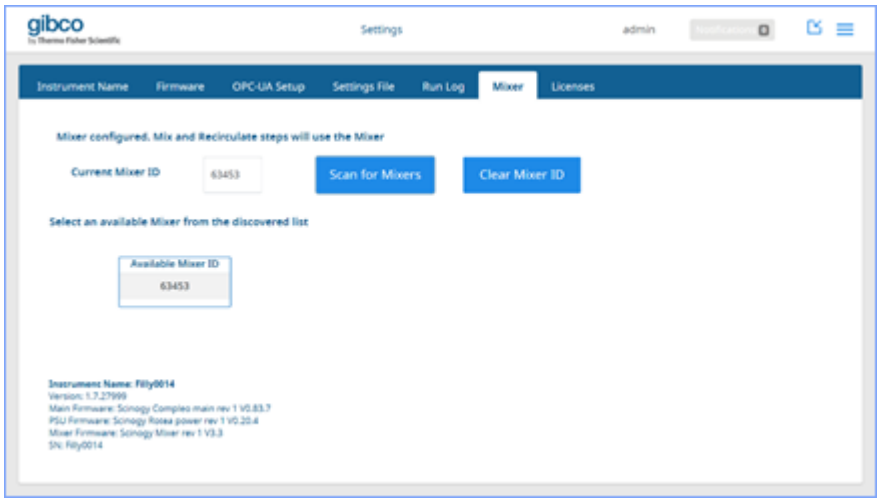
2. Click the **Mixer** tab.



3. Ensure that the glass door of the instrument is closed and the instrument is powered on.

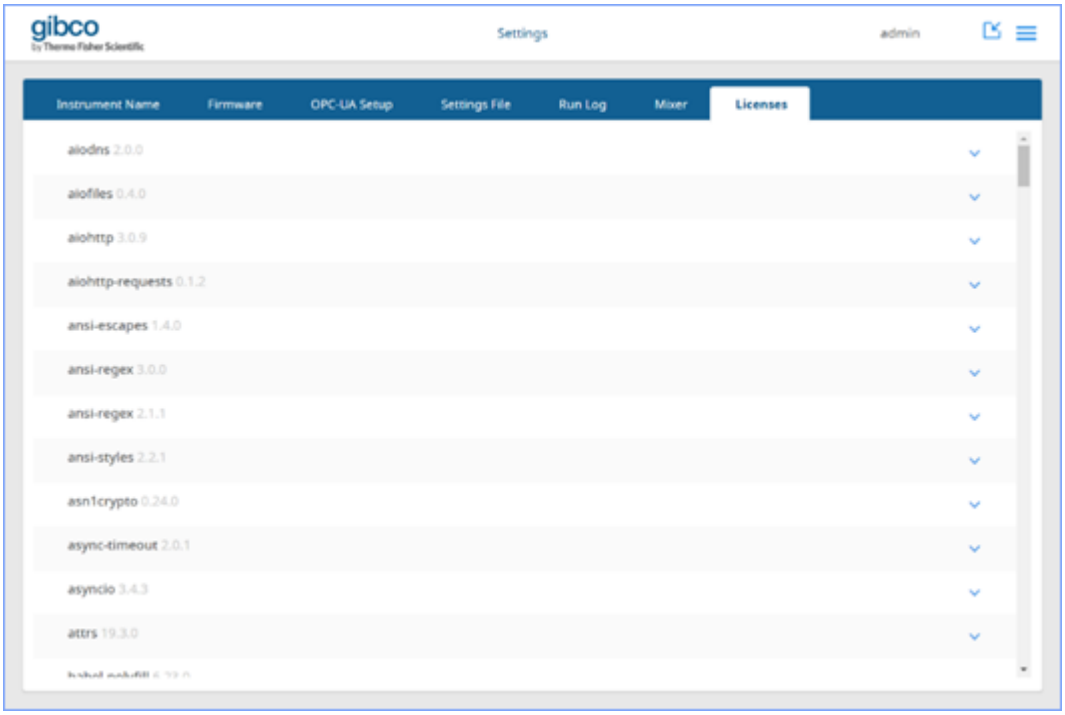
4. Click **Scan for Mixers**.
   The system automatically scans for available devices and displays them in the **Available Mixer ID** box.

5. Click the **Available Mixer ID** to set it as the **Current Mixer ID**.



Licenses

This tab lists the available licenses for this software.

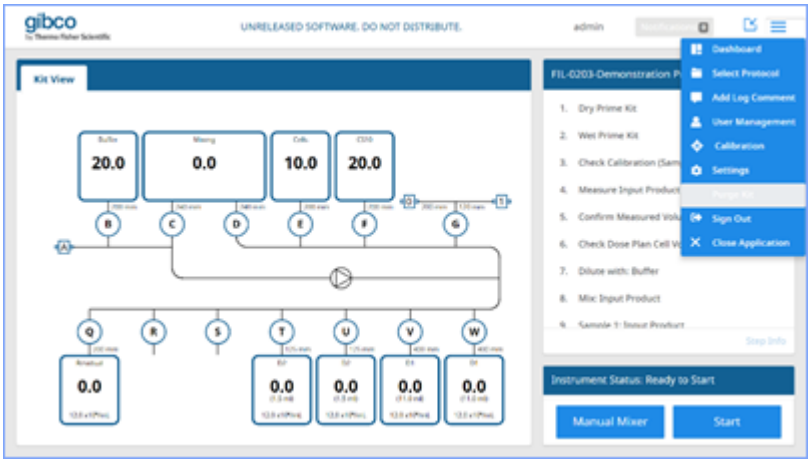


Purge kit

The purge function is primarily for recovery purposes and uses air to push residual fluid trapped within kit tubing to a selected bag.

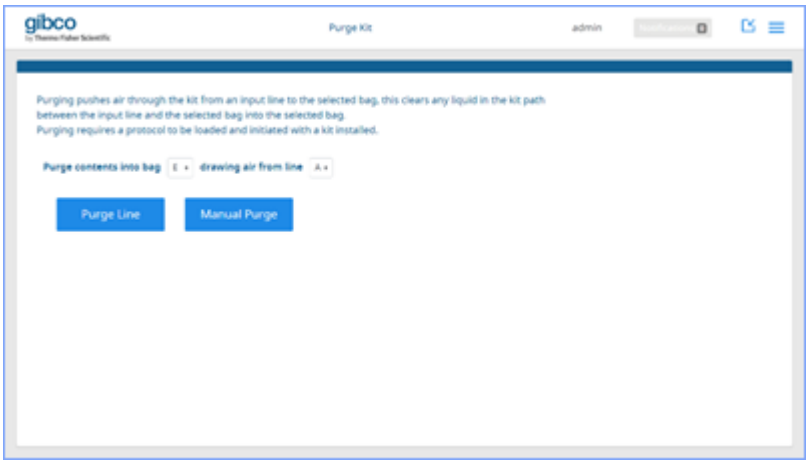
Note: The **Purge Kit** function is only available when a valid protocol has been initiated.

1. Select **Purge Kit** from the dropdown menu in the dashboard.



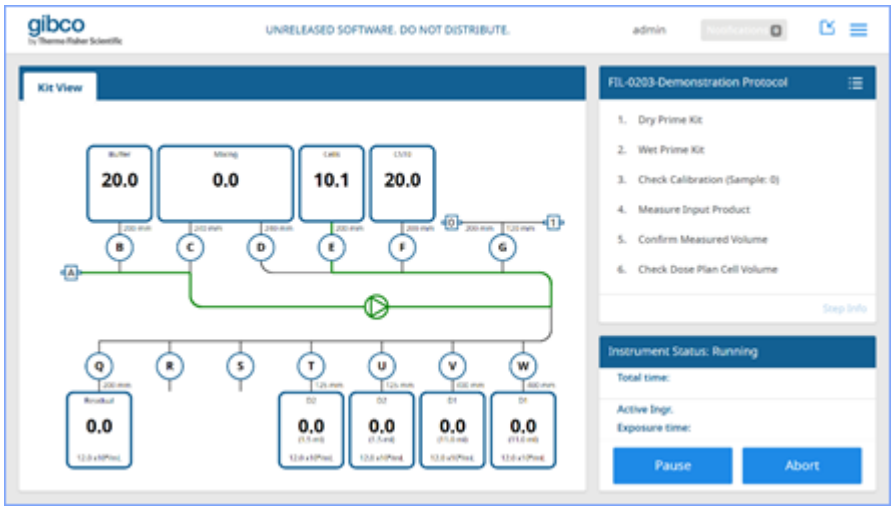
2. From the dropdown lists, select the bag that residual fluid is to be purged into and the line that will be the air source.

   To purge tube lines in the Forward pump direction, the air source will always be via the sterile filter attached to line A.

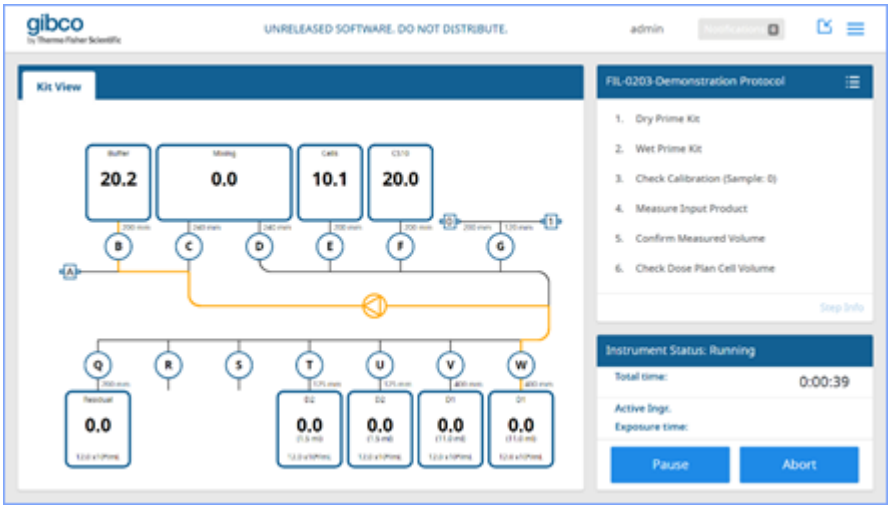


3. Select **Purge Line** ▸ **Yes** to automatically purge fluid from the tube line between the 2 selected bags.

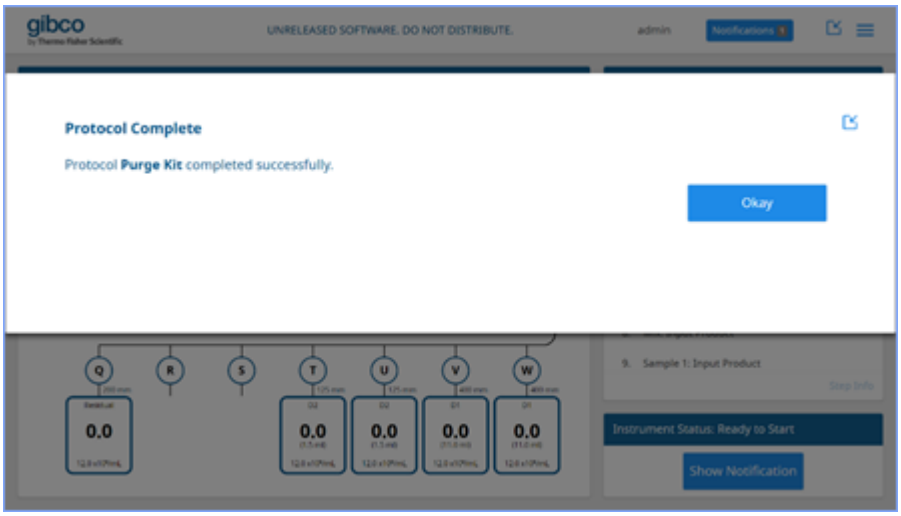
Below, **Kit View** shows an example of the fluid path being purged with air drawn in through line A and fluid purged into bag E.



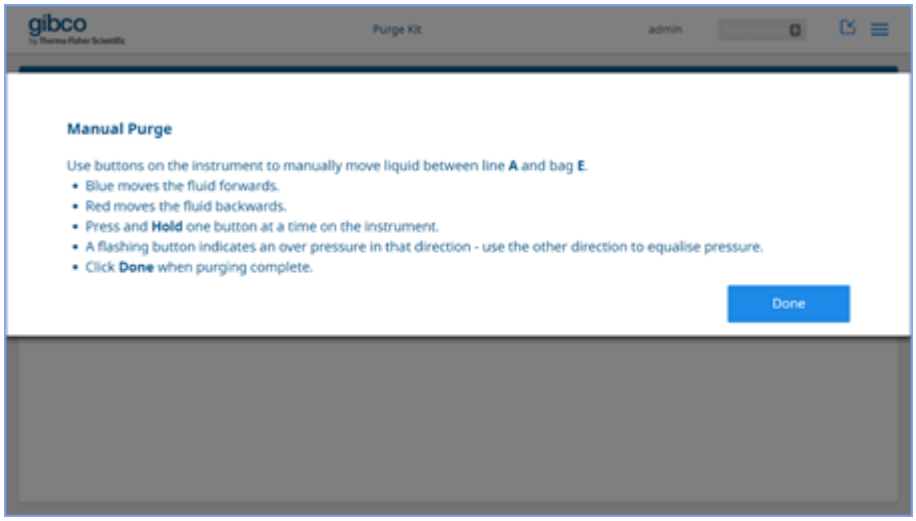
To purge tube lines B and C, the source of air needs to be from a bag that does **not** contain media (for example, typically bags Q to W). The image below shows an example of the fluid path being purged with air drawn in through line W and fluid purged into bag B.

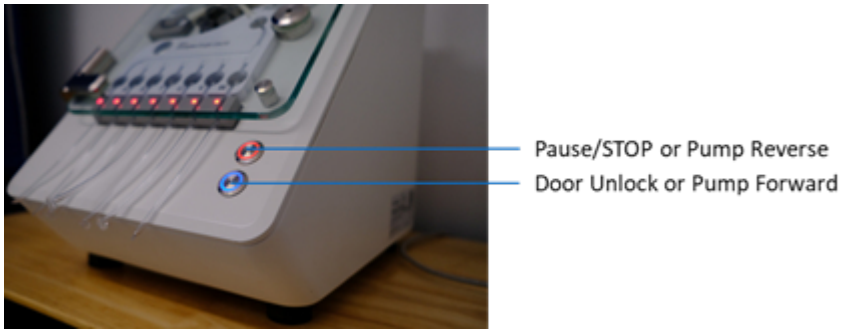


4. Once the purge protocol is complete, select **Okay** to return to the main screen.



5. Select **Manual Purge** to purge the selected fluid path manually using the **Pump Forward** (blue) and **Pump Reverse** (red) buttons on the face of the instrument. Follow the instructions on the screen for the full Manual Purge procedure.





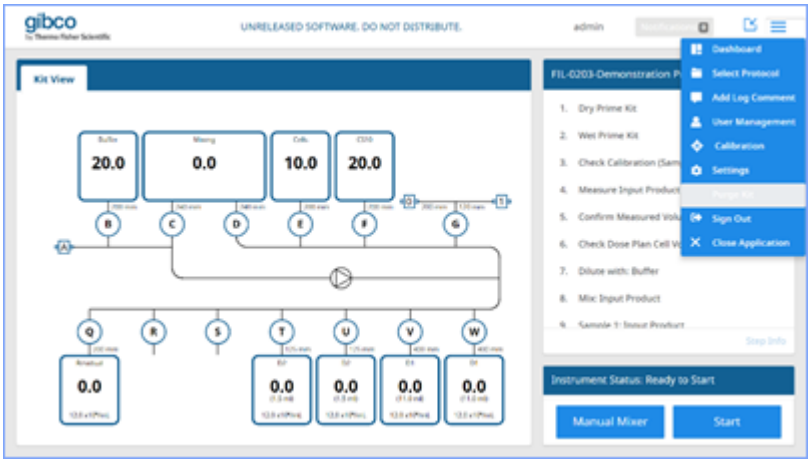
CAUTION! Do not manually operate the pump using the push buttons until the Manual Purge pop-up is displayed and the push button lights are off. Pressing the Door Unlock button when buttons are illuminated will open the door, allowing media to flow if manual clamps have not been fitted.

6. Once the selected fluid path has been manually purged, click **Done** to return to the purge screen.
7. Purge additional lines by selecting different destination bags and repeating the purge process.

Sign out

You can sign out and return to the log in screen without impacting the current protocol.

1. In the Dashboard, select **Sign Out** from the dropdown list.



The log in screen is displayed.

2. Enter the username and password for the user who is signing in.

The GUI returns to displaying the current protocol. The user change is recorded in the run_log.

Close the application

Ensure that the protocol has ended before closing the application.

After the protocol has ended, select **Close Application** from the dropdown list in the Dashboard.

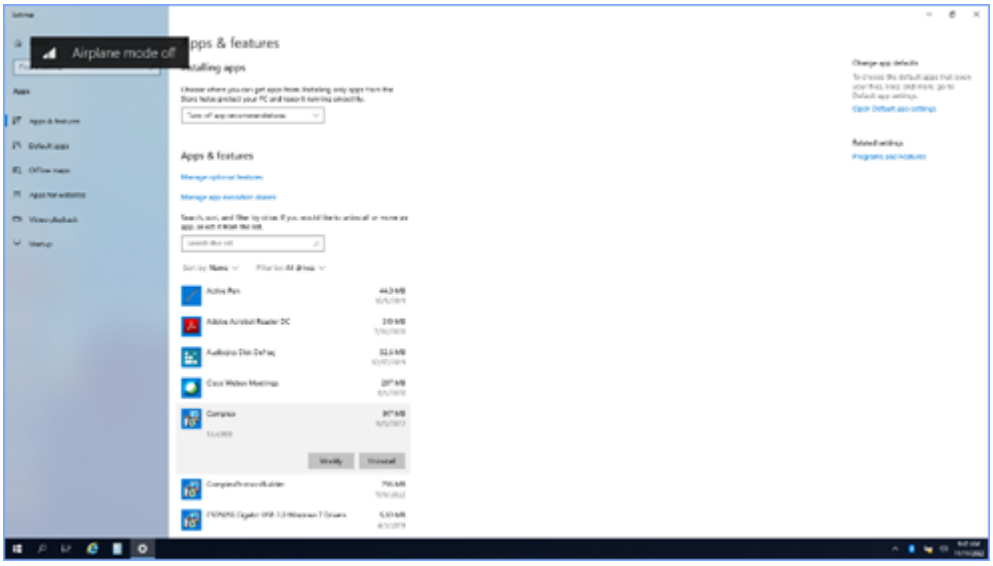
The application closes and the desktop screen is displayed.

Uninstall Compleo and Protocol Builder Applications

CAUTION! Prior to installing a new release of either the Compleo or Compleo Protocol Builder Application, it is important to uninstall the existing application.

1. Right click on the Windows icon in the bottom left corner of the laptop screen and select **Apps and Features**.

2. Left click on the **Compleo** or **CompleoProtocolBuilder** application and select **Uninstall**.



3. Press **Close** once Uninstall is complete.

3 Basic Instrument Operation

Open the door

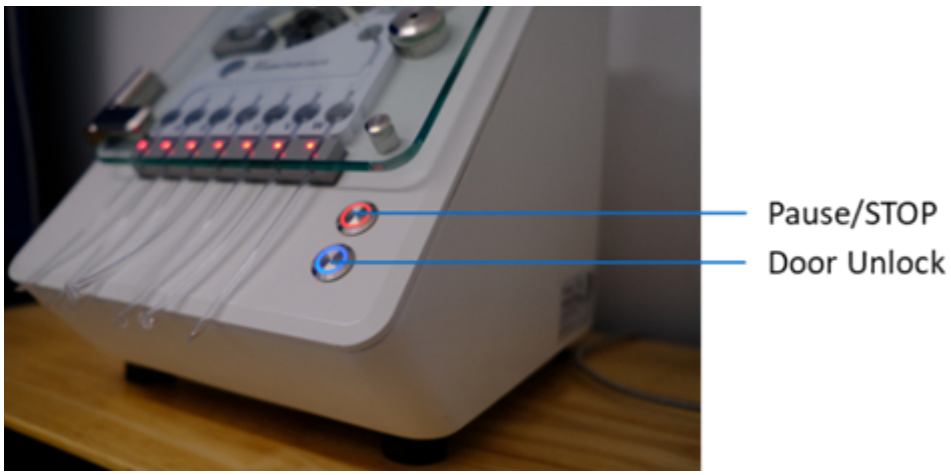
The instrument door is automatically locked when the door is closed and can only be opened when the:

- Instrument is powered up
- Blue **Door Unlock** button is illuminated
- Instrument is not currently running a protocol
- Peristaltic pump is stationary

1. Close all manual tube clamps on the Compleo™ Single-Use Kit **before** opening the door.

   Note: If there is a kit installed on the instrument, unlocking the door will release the valves that are clamping the tubes of the kit closed. Any fluids in bags or vessels attached to the kit will be free to flow.

2. Press the blue **Door Unlock** button when illuminated to unlock the door.



3. Open the door and raise until past vertical.

   Soft close hinges prevent the door from abruptly opening or closing.

Note: An emergency maintenance access method can be used to open the door should this be required (for example, after power loss).

When the **Door Unlock** button is pressed, the safety circuit is disabled to prevent the pump from operating and triggers the following:

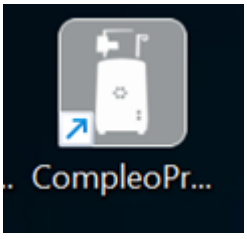
- Pinch valves retract
- Pump clamp is released
- Door is unlocked and partially opens

Kit preparation, loading and removal

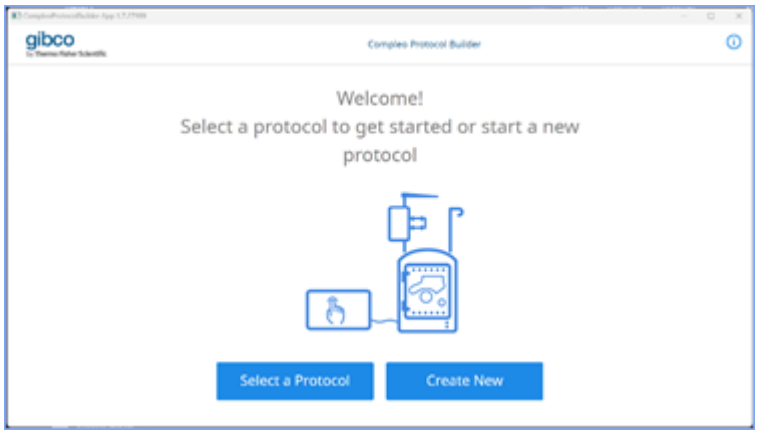
Kit Configuration

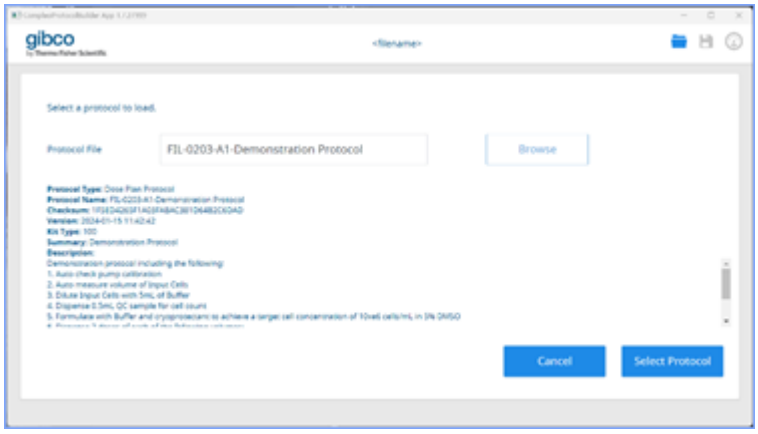
Prior to preparing a kit, the protocol simulator in the Protocol Builder should be run using the anticipated data for the run.

1. Run the Compleo Protocol Builder application from the desktop shortcut or start menu.

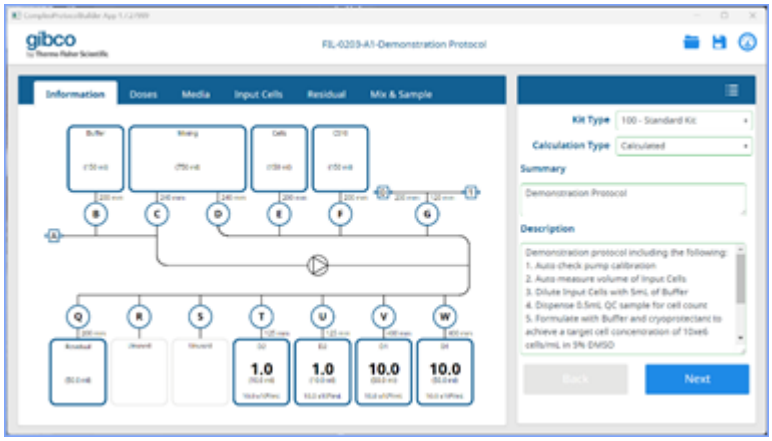


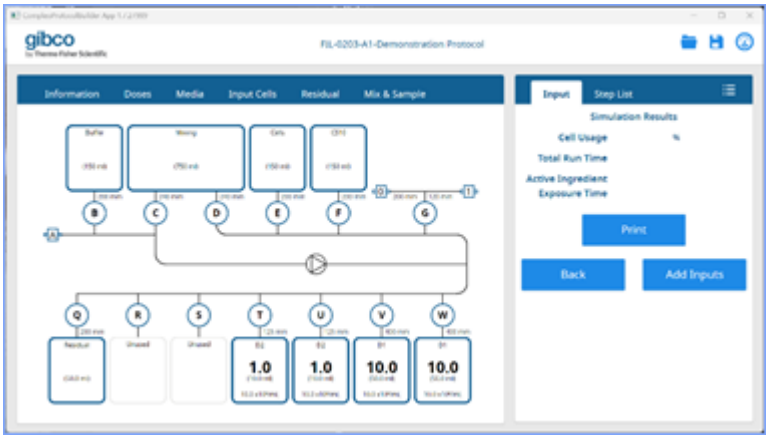
2. Click **Select a Protocol** to open the protocol being run.





3. Click on the simulator icon in the top right of the screen, then click **Add Inputs**.

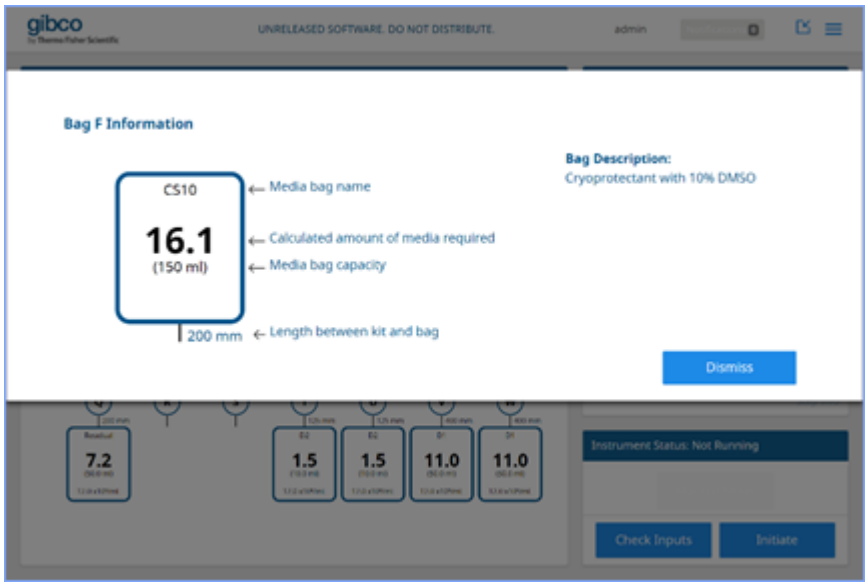




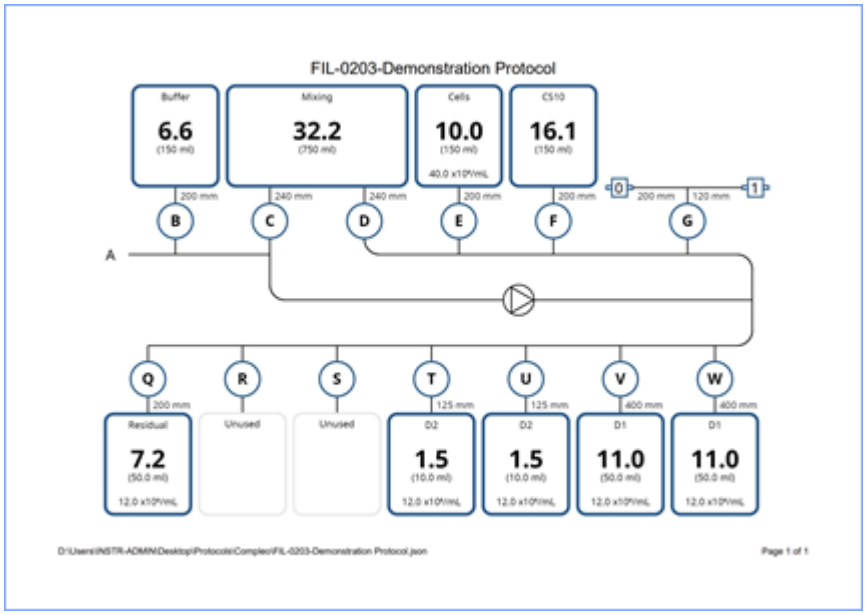
4. Enter the estimated data for the run, then select **Confirm** to simulate the run.
   For example, Volume = 10 mL and Cell Concentration = 40 × 10^6 cells/mL.

The simulator displays a schematic of the Compleo™ Single-Use Kit including bag/vial connections, tube lengths, bag capacity, input and output volumes, target cell concentration, cell usage, Total Run Time and Active Ingredient Exposure Time.

5. (*Optional*) Click on an individual bag to display the Bag Information.



6. (*Optional*) To print the kit configuration required for the run, click **Print**, then select an available printer.



Note: The Compleo™ App uses the same Protocol Simulator. Once a protocol has been selected to run on the instrument, and the relevant input data provided, the Compleo™ App will display the same schematic in the Kit View panel on the Dashboard. Bag Information is also available throughout the run by clicking on the Bag of interest.

Pre-assemble the Compleo™ Single-Use Kit

The Compleo™ Single-Use Kit uses DEHP-Free PVC 4 mm OD tubing and pre-attached luer locks, enabling sterile attachment to compatible bags, vials, and other accessories.

Cryogenic freezing bags and some cryogenic vials will often have a length of PVC tube for tube welding and/or Luer lock fittings that can be connected to the Compleo™ kit in a sterile environment (for example, a biosafety cabinet).

The tube length on the kit schematic is the distance (mm) between the edge of the Carrier Frame and where the tube enters or exits the corresponding bag/vial. The Compleo™ application uses the user-defined Push Volume when priming, clearing lines, and "burping" output bags. The tube length on the kit schematic is not used by the Compleo™ application. However, it is advised to keep the tube length between the edge of the Carrier Frame and the top of the output container consistent across kits, since the appropriate push volume varies based on tubing length and dimensions.

IMPORTANT! It is recommended that the tubing line length between the edge of the Carrier Frame and the top of the output container be slightly less than the tube length specified in the protocol. This ensures that the defined Push Volume is enough to push all fluid into the output container.

---

1. Open the cardboard carton and remove bagged kits.

   Remove the cable tie and outer bag prior to transferring the single kits to the cell processing area (for example, clean room or BSC).

2. Remove the cable tie and inner bag containing 5 single-use kits.

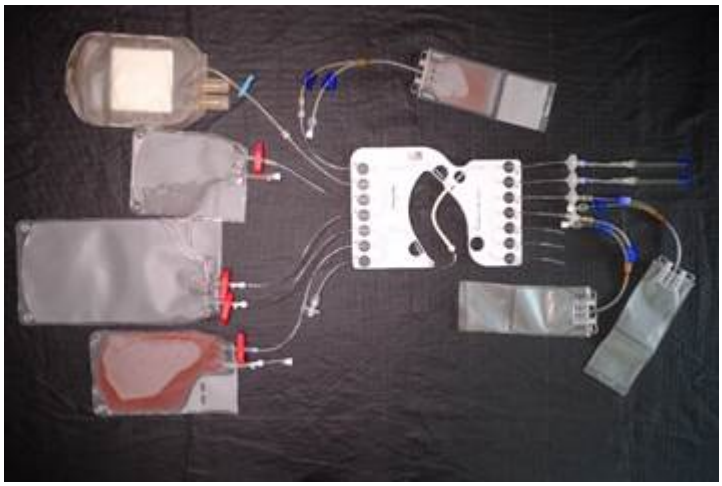
3. Open the pouch containing a single-use kit using the easy-peel feature and remove from the pouch.

CAUTION! The single-use kit has been designed exclusively for use with the Compleo instrument and includes several features to enable fast, error-free loading by the user. It is the responsibility of the user to ensure correct assembly and loading of the single-use kit prior to initiating an instrument protocol.

CAUTION! Only use kits supplied by Thermo Fisher Scientific or its agents.

CAUTION! Inspect each single-use kit for any damage or imperfections that may result in incorrect operation. Do not use kit if any such defect is found.

4. Attach bags and/or vials to the single-use kit, closely adhering to the tube lengths specified in the protocol.

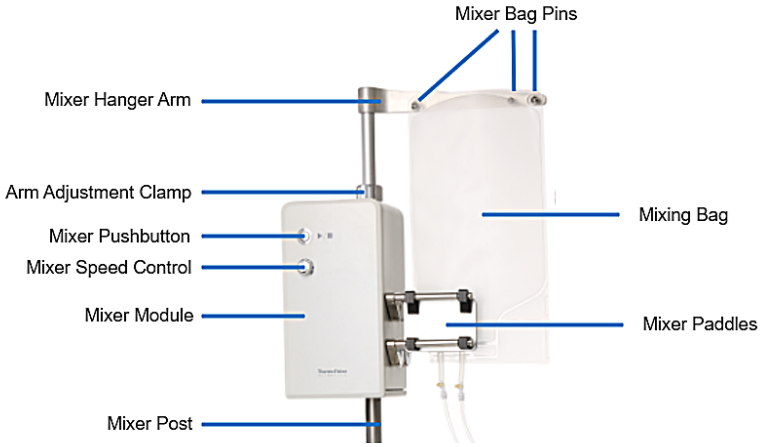


Example of fully assembled kit

Kit installation

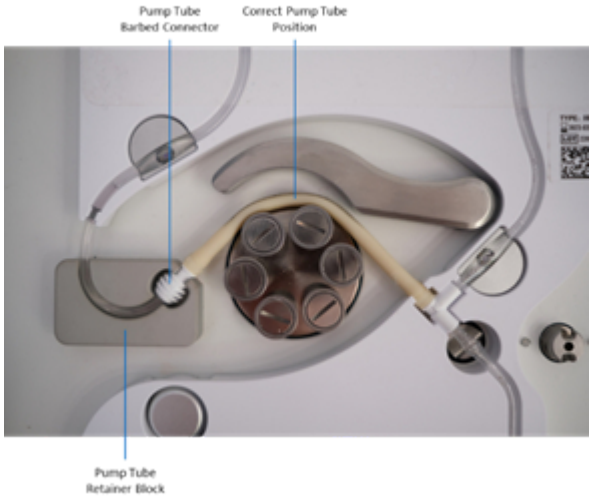
Ensure the Compleo™ instrument door is open and any previous single-use kit has been removed.

1. Hang the Mixing Bag on the Mixing Bag Pins, ensuring that the bag is positioned between the two Mixing Paddles.
2. Adjust the height of the Mixer Hanger Arm so that the Mixing Bag is hanging freely without tension or kinking of the output tubes. After the position is set, tighten the Arm Adjustment Clamp.



3. Hang Buffer bags on the Mixer Module Pin and Bag Hanger Post.
4. Hang the Cell Input Bag on the Bag Hanger Post.
5. Position QC Sample outputs (for example, bags and vials) as appropriate.
6. Place the Carrier Frame over the Locating Pins.

7. Stretch the pump tubing around the Peristaltic Pump rollers and insert the Pump Tube Barbed Connector into the Pump Tube Retainer Block to hold it in place.



8. Insert tubes A, B, C, D, E, F, and G into the corresponding slot in the Bubble Sensor Array and push downwards with fingers to fully engage each tube.

CAUTION! Do not stretch the PVC tubing when inserting into the Bubble Sensor slots as this can affect Bubble Sensor performance.

9. Insert tubes Q, R, S, T, U, V, and W into the corresponding slot in the Bubble Sensor Array and push downwards with fingers to fully engage each tube.

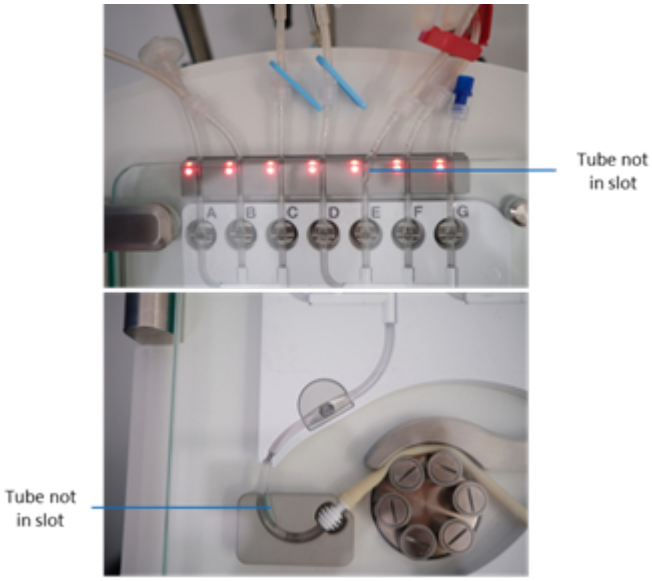
10. Check that Input Bags, Output Bags and their respective tubes are free from kinks.

11. Check that the kit tubing is properly seated in the two Locating Pins with Pressure Sensors, slots in Bubble Sensor Arrays and Pump Tube Retainer Block.

Note: The tube will sit slightly proud of the channel in the region of the Pressure Sensors so that the tube is compressed into the required shape when the door is closed.

12. Close the door, pressing down until the Door Latch engages.

13. Check that tubing is still correctly positioned in the Bubble Sensor Array, Pump Tube Retainer Block and Locating Pins.



Examples of incorrect tube loading

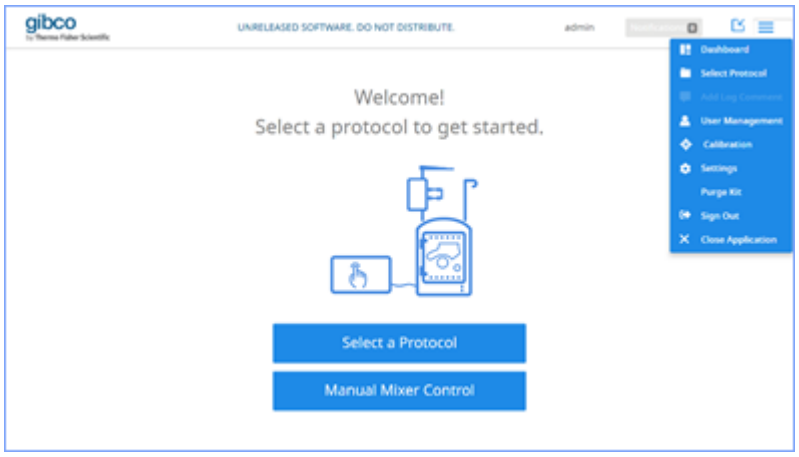
14. Check that all pinch valves have closed against the glass door.

Note: The pinch valves will not close unless the Laptop is turned on, the Compleo Application is running and a Protocol selected.

15. Remove manual Clamps from all Input and Output bags.

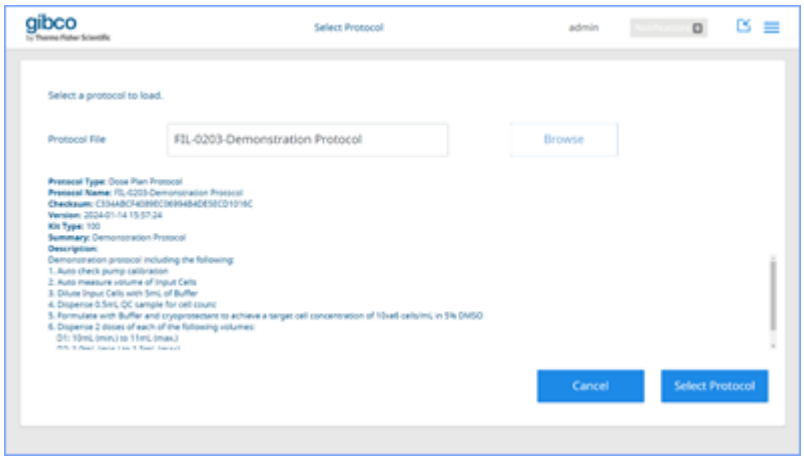
Select protocol

1. Select a protocol by clicking on the button or using the dropdown menu.



2. Click **Browse**, search and select the desired protocol.

3. Click **Select Protocol**.



Initiate a protocol

Once a protocol has been selected, the User will be directed to the dashboard. A schematic of the protocol and instrument will be presented on the left-hand side as well as the step list on the right-hand side of the window.

1. Select **Add inputs**.

2. Input data estimates for the run/batch and select **Confirm** to continue or **Cancel** to exit.

Input Data Definitions

- **Volume:** Estimated volume (mL) of Input cells
- **Cell Concentration:** Estimated cell concentration (x 10^6 cells/mL) of Input Cells
- **Media 1** (for example, Buffer): Estimated volume required (mL) *plus contingency volume*
- **Media 2** (for example, CS10): Estimated volume required (mL) *plus contingency volume*

Note: It is important to include contingency volume for Media to accommodate variability in the Volume or Cell Concentration of Input Cells.

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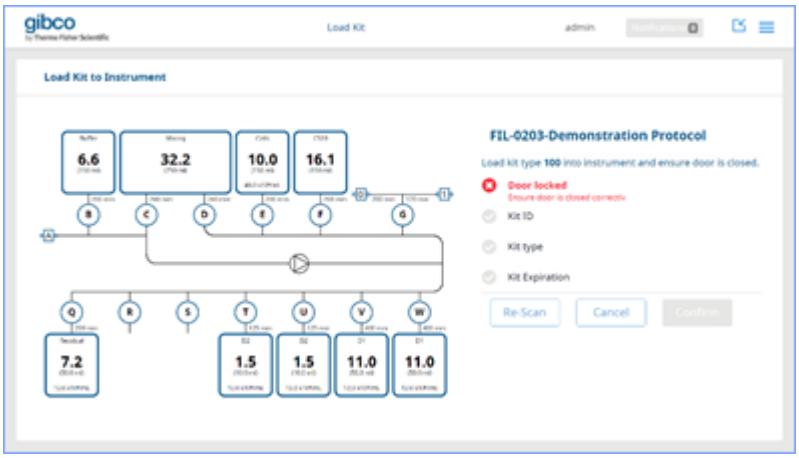
3. Select **Initiate** to run the Instrument or **Check Inputs** to return to the **Input Data Estimates** screen.

4. (*Optional*) Select **Manual Mixer** if you wish to mix cells pre-loaded to the Mixing Bag. Input the desired Mixer Speed and select **Set Mixer Speed** followed by **Done** to exit.

5. Select **Confirm** if the various automatic system checks are ticked, bags are connected as shown in the schematic, and manual clamps are open.

6. Correct any identified system errors:
   a. **Door Locked:** Ensure the door is properly latched. A **Door Locked** system error can indicate an incorrectly loaded kit.



   b. **Kit ID:** If the system fails to successfully read the single-use kit barcode, select **Re-scan** to try again.

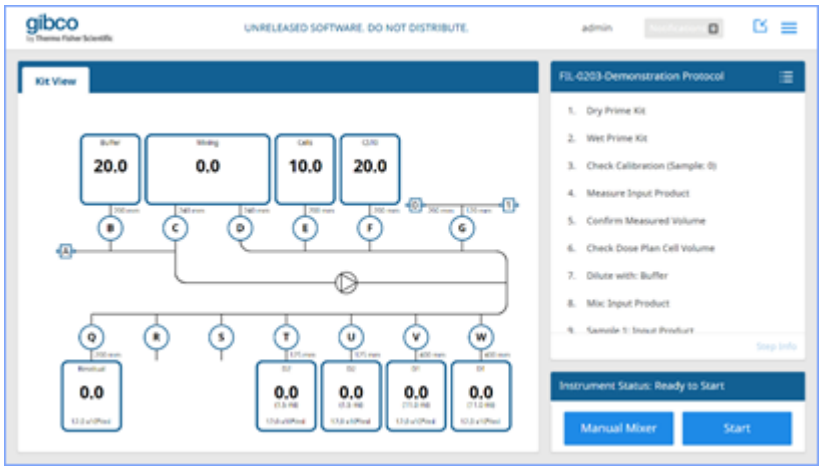
   c. **Kit Type:** Check that the kit type matches the Protocol.

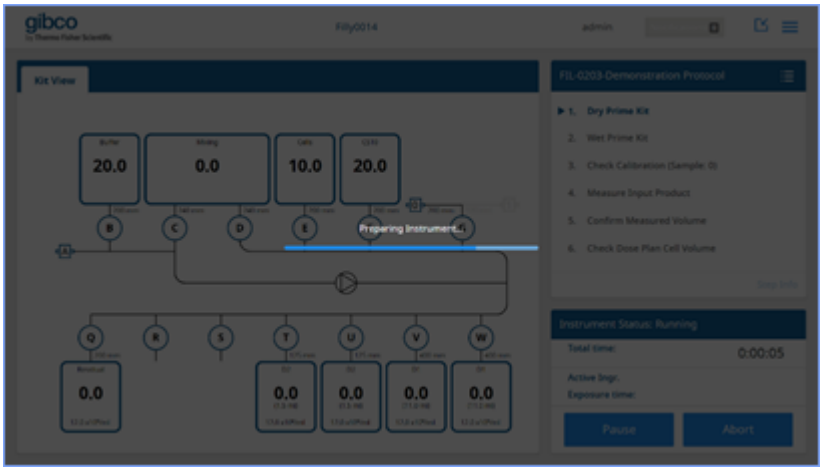
   d. **Kit Expiration:** Check that the kit expiry date has not been exceeded.

7. Once the instrument is ready, select **Confirm** to continue or **Cancel** to abort the run.

Start protocol

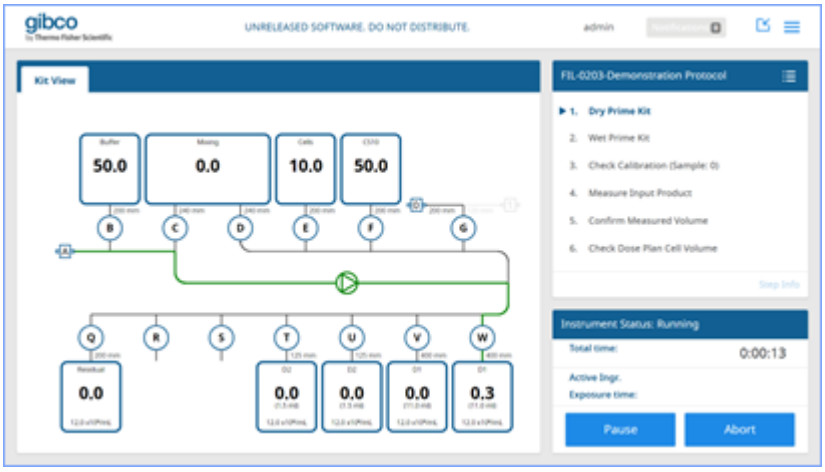
Review the starting condition of the kit based on the entered data, then tap **Start** to download the selected protocol to the instrument.





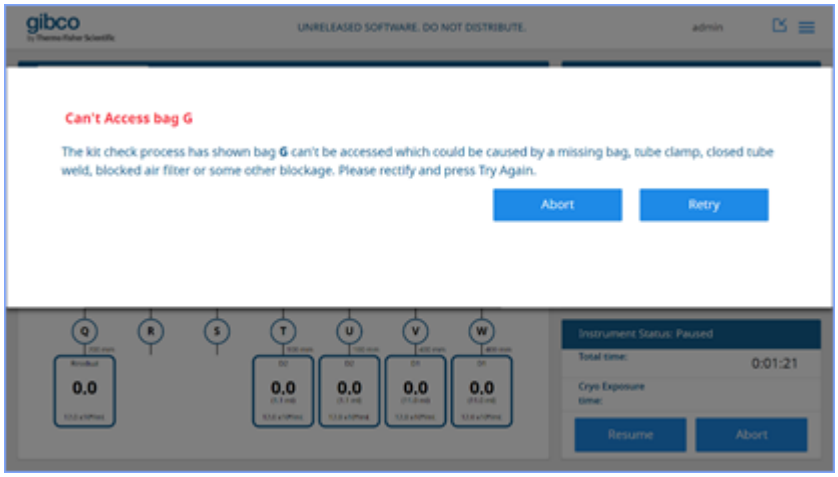
Dry Prime kit

The protocol will start with a dry priming sequence of all connected lines using air to ensure that there are no blockages in the kit. Typical examples include manual clamps left on tube lines, tube welds not "popped", or a kit being left in the instrument for an extended period with the door and pinch valves closed. The green path on the schematic shows an example of the instrument dry priming valve W. The direction of the pump is forward, hence the green highlighted path.



Prior to priming Line G, a modal will be displayed requesting the User to Open the sample line **0**, that is remove the manual clamp on the first QC sample line. Once done, select **Continue**.

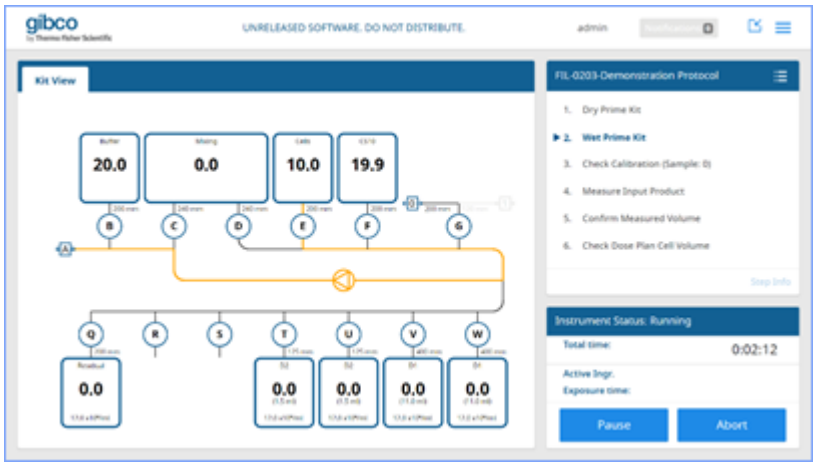
If a blockage is detected during Dry Priming, a modal will be displayed highlighting which line has the blockage. In this example there is an issue with Line G. Once rectified, select **Retry** to continue the dry priming sequence or **Abort**.



Note: The direction of the pump will be reversed when dry priming valves B and C, with the path highlighted in orange and the pump icon reversed. This requires a small volume of air to be pumped from line A to the last bag in the filling sequence, before reversing the pump and priming the lines using this air.

Wet Prime kit

Wet Prime draws in liquid from the Input Cells bag and any Input bag containing fluid until the Bubble Sensor on the associated line is triggered or the estimated priming volume exceeded. The Wet Prime volume is defined in the protocol.

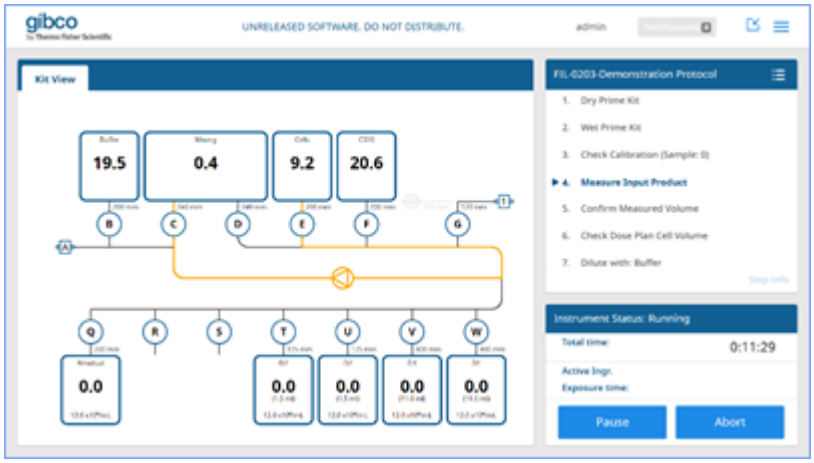


If a line does not fully prime within the calculated priming volume, the instrument will pause, and a modal displayed highlighting which line has failed to prime. Check for restrictions and the presence of fluid in the line. If fluid is present but has not yet reached the Bubble Sensor, a pop-up message will allow the user to perform a manual wet priming by clicking on **Retry** to cancel the priming.

Measure input product

Compleo will automatically measure the volume transferred from the Cells bag to the Mixing bag. The measured volume is then compared to the Volume entered by the User when initiating the protocol.

Note: If the user has defined that the Input cells are pre-loaded in the Mixing bag, then this feature will not be available.



In the above example, Bubble Sensor E detects when the Cells bag has emptied. A pop-up will then be displayed to enable the User to check the Cells bag and tubing and select Continue if empty, Retry if not, or Abort if there is an issue that cannot be resolved in-situ.

After selecting Continue, the fluid remaining in the line will be pumped to the Mixing bag until Bubble Sensor C is triggered, allowing the total volume of Cells to be calculated.

Confirm measured volume

After the volume measurement sequence completes, the user selects a **Cell Volume** to use for the dose plan calculations.

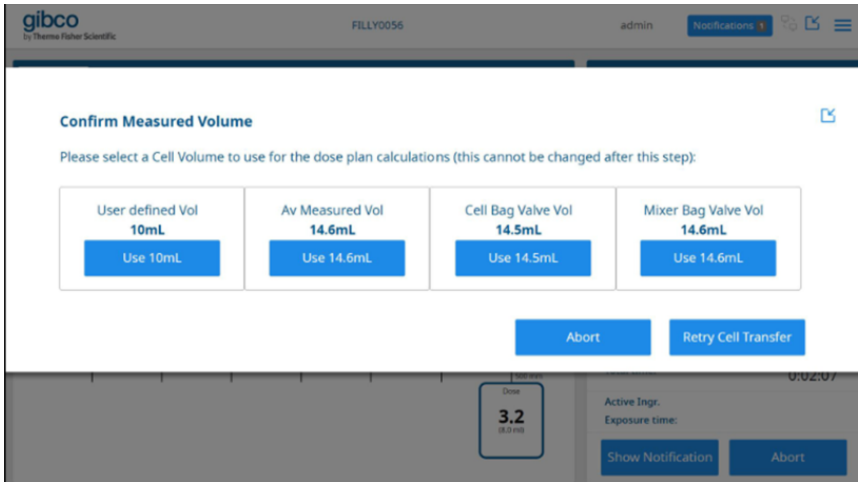
CAUTION! Accuracy of the formulation is dependent on the accuracy of the **Input Cell Volume**. After an **Input Cell Volume** is selected and confirmed, it cannot be changed.

The user has 4 options to choose from:

- **User defined Vol** – The **Input Cell Volume** the user defined at the start of the protocol. The user should only select this option if they have high confidence in the initial volume measurement and should consider residual volume lost to the bag and tubing during the transfer to the mixing bag. Otherwise, the **User defined Vol** may be inaccurate leading to an inaccurate formulation.
- **Av Measured Vol** – Average of the volumes measured by the bubble sensors located on the Cell Bag line and Mixer Bag line.
- **Cell Bag Valve Vol** – Volume measured by the Bubble Sensor located on the Cell Bag line.
- **Mixer Bag Valve Vol** – Volume measured by the Bubble Sensor located on the Mixing Bag input line.

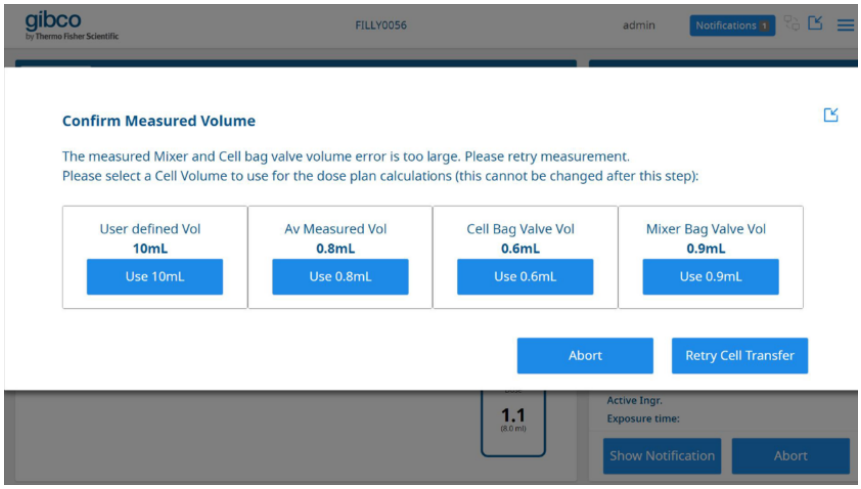
Note: It is generally appropriate to select the **Av Measured Vol** value. A user may opt to use either the **Cell Bag Valve Vol** or **Mixer Bag Valve Vol** if there is an issue with the measurement on one of the lines that affects the average. For example, if an air bubble is stuck at one of the bubble sensors, the volume measurement will be reduced for that line. Therefore, the user would select the other valve measurement.

The user can also select **Retry Cell Transfer** to repeat the volume measurement sequence, or **Abort** if there is an issue that cannot be resolved in-situ.



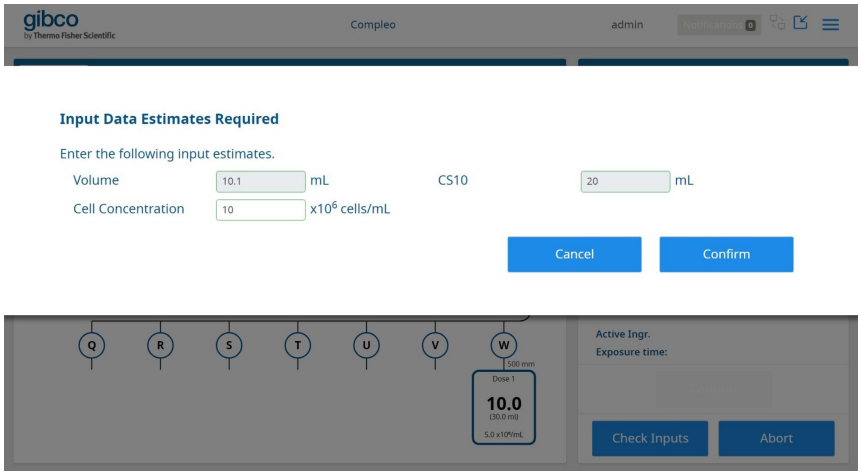
If the difference in the volume measured by the Bubble Sensors on the Mixing Bag and Cell bag is outside the expected tolerance, the user will be prompted to retry measurement as shown below.

Note: Some pop-up features may vary between user access and administrator levels.

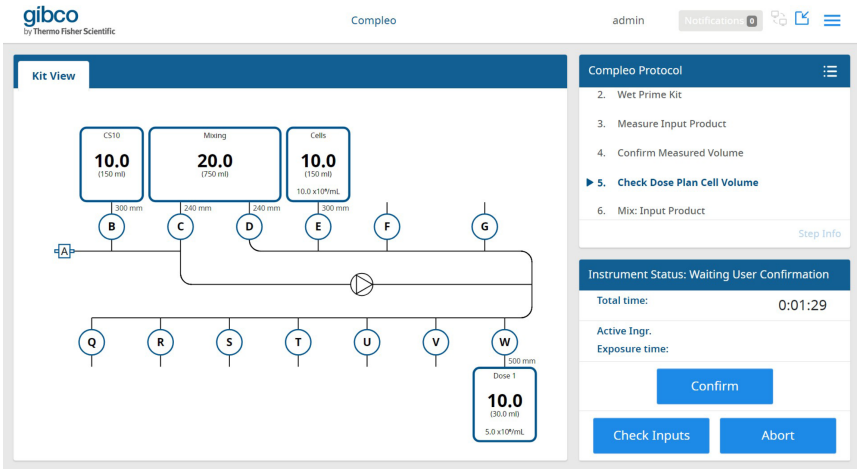


Once the user has selected an **Input Cell Volume**, the **Volume** in the **Input Data** screen will be automatically updated and no longer editable.

After the **Input Cell Volume** is selected by the user, the **Cell Concentration** remains editable until the user selects **Confirm** twice in the menu windows shown below, after which the protocol advances to the next step.

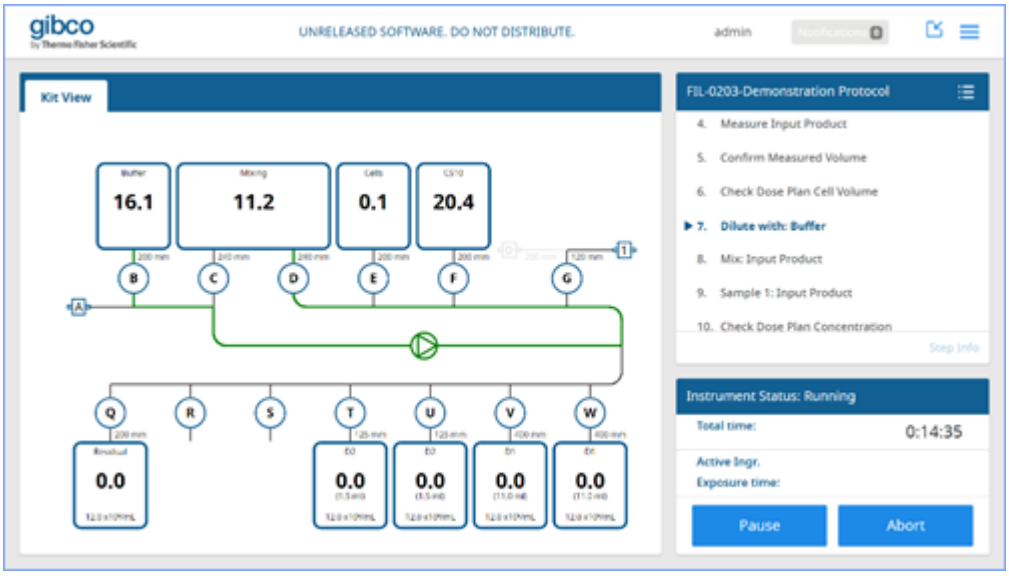


The dose plan will be automatically updated based on the measured **Cell Input Volume** and the current **Cell Concentration**. Check that bag sizes and Buffer Volumes are sufficient to complete the Protocol. Select **Confirm** to continue the protocol, **Check Inputs** to return to the **Input Data Estimates Required** screen (only **Cell Concentration** will be editable), or **Abort** to cancel the protocol.



Dilute with: Buffer

This optional sequence dilutes the input cells with buffer prior to performing an initial cell count (for example, when processing a small volume of highly concentrated cells).



Mix: Input Product

Mixing is automatically initiated after the input product is transferred to the Mixing Bag and a new formulation is created, based on the user-defined parameters. A user can also choose to perform mixing during priming, diluting, and/or dispensing a QC sample or dose. For this step in the protocol, the description has been automatically labelled *Mix: Input Product*.

Once the cells and Buffer have been transferred to the Mixing bag, the Bag Mixer Module will start automatically. The two Bag Mixer Paddles open and close across the bottom corner of the Mixing bag based on the number of cycles and frequency (cycles/min) defined in the protocol. The mixing motion displaces the contents of the Mixing Bag vertically and horizontally to ensure comprehensive and efficient mixing.

Media in the Mixing bag will also be recirculated from C to D during mixing to improve mixing efficiency, avoid concentration of cells at the inlet and outlet port ports and ensure homogeneity of media regardless of where it is within the fluid path.

Recirculation requires a minimum of 7 mL of media to fill the recirculation line and bridge between ports C and D of the Mixing bag. This reduces the likelihood of air entering the fluid path during recirculation and impacting subsequent volume transfers. The protocol will not be able to continue if the Input Data does not meet the minimum Mixing Bag volume requirement.

CAUTION! To ensure proper mixing, it is important that the Mixing Bag has sufficient excess capacity to accommodate the fluid displaced when the Mixing Paddles close. The user will also need to determine appropriate mixing parameters to suit the media, cell concentration, formulation and volume used in the protocol.

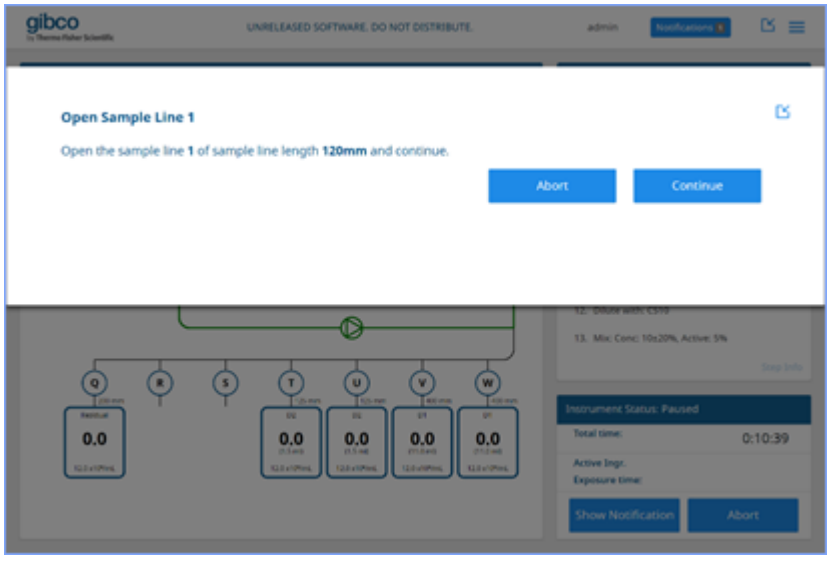
Sample 1: Input Product

The Compleo™ system can automatically dispense up to 100 unique in-process QC samples into suitable sample vessels connected to line G for subsequent removal by the user (for example, to determine the cell concentration and cell viability, or for further testing).

Note: While the software allows the user to dispense up to 100 samples, Thermo Fisher has only validated the collection of up to 10 samples from Line G.

QC sample collection

1. Open and close manual clamps for the specific sample and select **Continue**.



2. In this example, the QC sample has been automatically labelled *Sample 1: Input Product*, indicating that the QC sample is "Input Product".

Input data estimates

The **Input Data Estimates Required** screen will be displayed, with the Volume and Cell Concentration automatically recalculated to include any Buffer added prior to QC sampling.

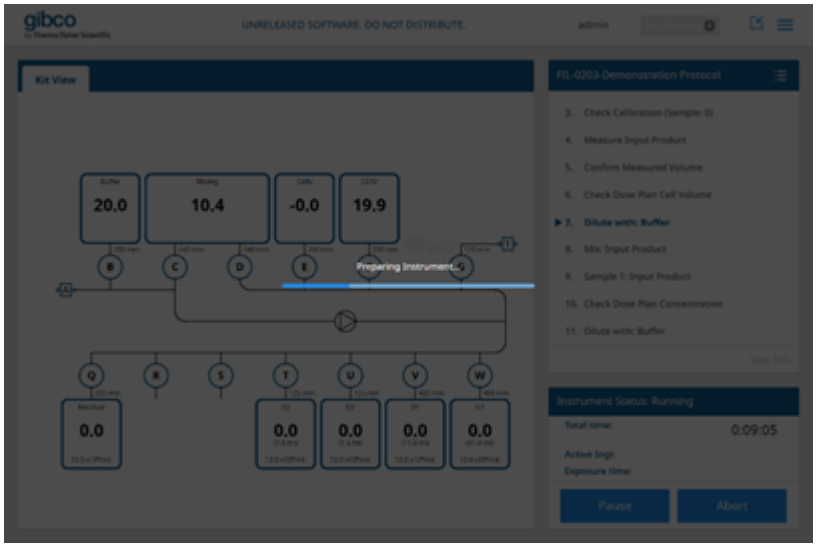
1. Manually compare the Cell Concentration of the QC Sample with the theoretical estimate displayed in the Input Data Estimates page.
2. Manually enter the new Cell Concentration and select **Confirm** to continue.

Note: If the Cell Concentration obtained from the QC Sample is not within the expected range for the target dose concentration, the User can select **Redispense Sample** to provide additional samples for measurement or **Cancel**. Adjustments to the user-defined Cell Concentration can only be made after sampling the Input Product in the Mixing Bag. No further changes to the Cell Concentration are allowed after formulation has begun.

Check Dose Plan Concentration

The Kit View will be updated based on the updated Input Data Estimates to create the Dose plan for the protocol/batch. Click **Confirm** if the values depicted in the Kit View are as expected, **Check Inputs** to review and adjust the Input Data, or **Abort** to cancel the protocol.

The new protocol parameters will be automatically downloaded to the instrument.



Formulation

This sequence dilutes the contents of the Mixing bag with each Buffer to achieve the specified formulation. In the example shown, there are two Buffers:

- Buffer – PBS+3%HSA
- CS10 – CS10 containing 10% active (DMSO)

Note: The "Active Ingr. Exposure Time" displayed in the bottom-right corner of the GUI will start accumulating as soon as Buffer containing "active" (for example, DMSO) starts to enter the Mixing Bag.

Mix: Conc: 10 ± 20%, Active: 5%

The instrument automatically mixes the contents of the Mixing Bag and assigns a label to the step to describe the unique formulation, (for example, the formulation being mixed has a cell concentration of 10×10^6 Cells/mL with a tolerance of ±20% and contains 5% Active (DMSO).

Dispense Doses: W, V, U, T, Q

The instrument automatically dispenses the specified doses to the allocated output bags/vials starting from bottom right (line W). In this example, doses W and V have a Planned Volume of 11.0 mL, doses U and T have a Planned Volume of 1.5 mL, and residual cells will be dispensed into bag Q. All doses and the residual will have the same formulation (12.0×10^6 cells/mL).

Bubbles entering the Kit during dispensing of Doses will trigger the Bubble Sensor on line C. This could be due to stray bubbles or because the Mixing Bag is empty.

Note: Where the Protocol is intentionally designed to empty the Mixing Bag (for example, "Residual" is dispensed into a separate Dose Bag Q), the Bubble Sensor on line C will always be triggered at the end of the dispense cycle.

Select **Retry** if the Mixing Bag is not empty, **Continue** if the Mixing Bag is empty, or **Abort** to end the protocol.

On completion of the Dispense Doses step, the Wet Volume will be displayed in **bold** for all Bags including the Dose bags. The Wet Volumes can be then compared against the Planned Volumes using the Kit View. The same data is also captured in the run_log.

The pump will then clear any fluid remaining in the tube between the Mixing bag and the white manifold and pump air to push fluid remaining in the line to the output bag.

The protocol will then run through the final protocol steps including burping of output bags where required and Kit clean up before ending.

If the Mixing bag still contains fluid, click **Retry** to draw down remaining fluid or **Abort** to end the protocol if there is an issue that cannot be resolved.

Burping

Automatic burping is an optional sequence that removes air from specified Dose Bags before, after, or before and after filling (for example, in preparation for cryogenic freezing). Burping of designated bags is performed after all doses have been dispensed, with extracted air pumped to the Mixing Bag.

Note: Rigid vessels such as cryovials CANNOT be burped.

Burping process

The burping process uses the peristaltic pump to extract air from an Output bag until liquid is detected at its corresponding Bubble Sensor. Once a bag has been burped, the pump reverses, drawing air from line A to push the fluid in the line back into the Output Bag based on the user-defined push volume for that line.

Note: The push volume required is based on the tubing-line length from the edge of the Carrier Frame on the kit to the top of the output bag. It is recommended to make the tubing-line length consistent across runs so the push volume remains appropriate as defined in the protocol.

Automatic burping sequence

If a Bubble Sensor fails to detect media when dispensing to an Output bag that is to be burped (that is, the output volume displayed on the GUI is negligible), the system automatically skips this bag during automatic burping. On completion of the automatic burping sequence, the user is prompted to manually burp skipped Output bags prior to ending the protocol.

Bubble Sensor C on the Mixing Bag is active during automatic burping. If the Bubble Sensor on an Output bag fails to detect fluid, Bubble Sensor C is triggered when fluid is detected. This reverses the pump and transfers the cells back to the Output bag being burped.

Important considerations

CAUTION! Output bags must be hanging such that the outlet tubes are at the TOP so that the air is removed prior to drawing in fluid. This is particularly important when using lines E, F, or G for Doses.

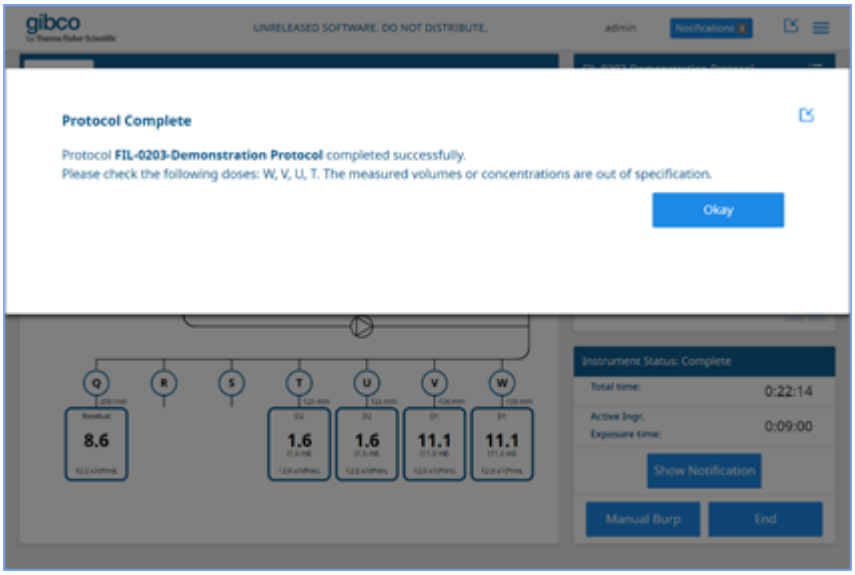
CAUTION! Fresh Output bags do not typically contain a significant volume of air and Compleo only adds a relatively small volume of sterile filtered air to bags during processing. After dispensing doses, including residual, the Mixing Bag should be essentially empty and hence capable of accommodating a significant volume of air. However, it is the user's responsibility to ensure that the combined volume of air in Dose bags does not exceed the capacity of the Mixing Bag.

Cleanup

Cleanup uses a small volume of air to push fluid remaining in the input lines back to the various input bags.

Completion

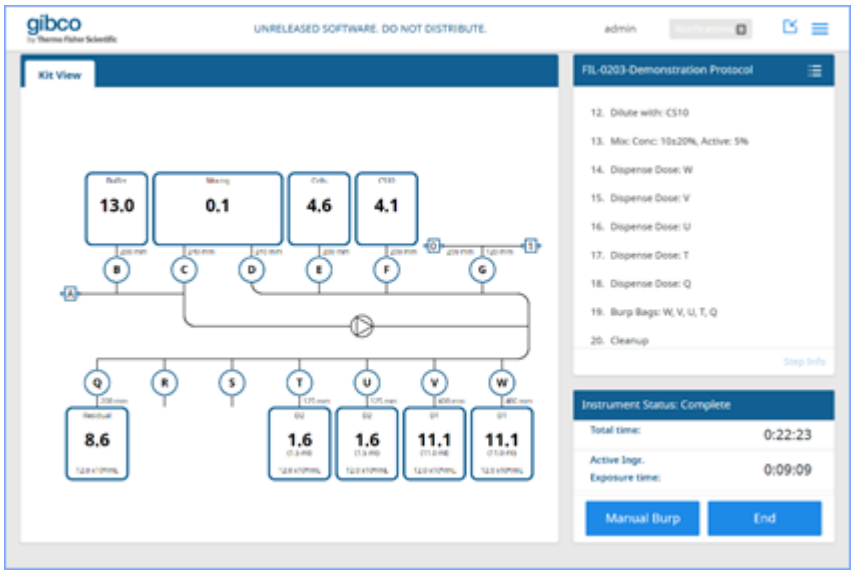
Select **Okay** to complete the automated protocol.



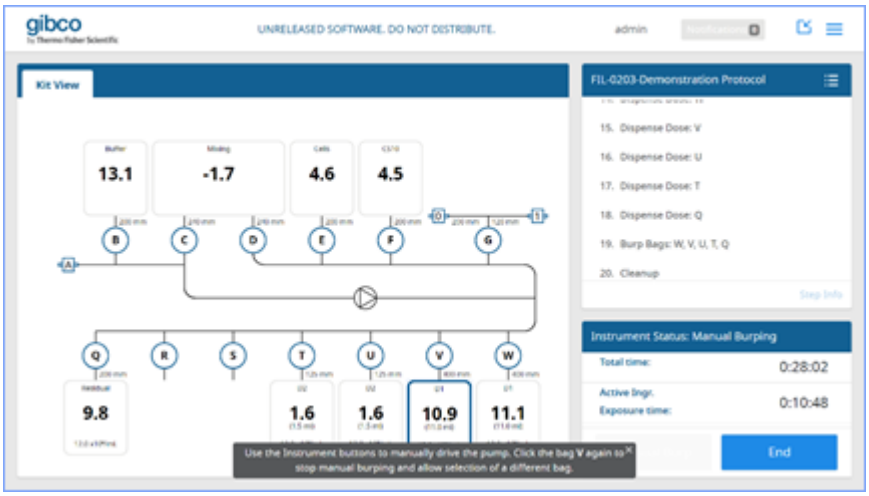
Manual burping

After completion of the automated protocol, the user has the option to manually burp any of the dose bags where automated burping was previously defined.

1. Select **Manual Burp**.



2. Select the output bag to be manually burped by clicking on the letter for the line in the Kit View. For example, to select the bag on line V for manual burping, click the "V" in the circle above the bag.



3. Orientate the bag being burped so that the tube connecting to the bag is positioned at the top where the air will accumulate and be extracted by the pump.

Note: When manually burping bags connected to lines E, F or G, it will be necessary to invert the bag.

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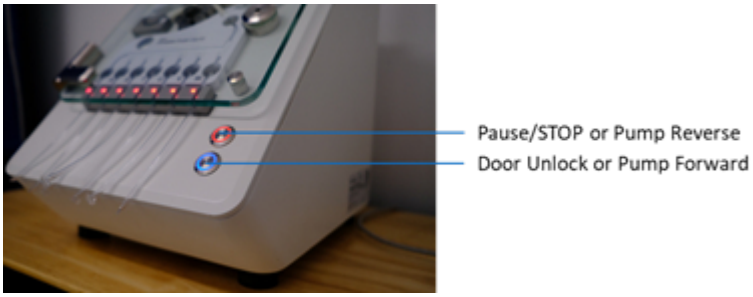
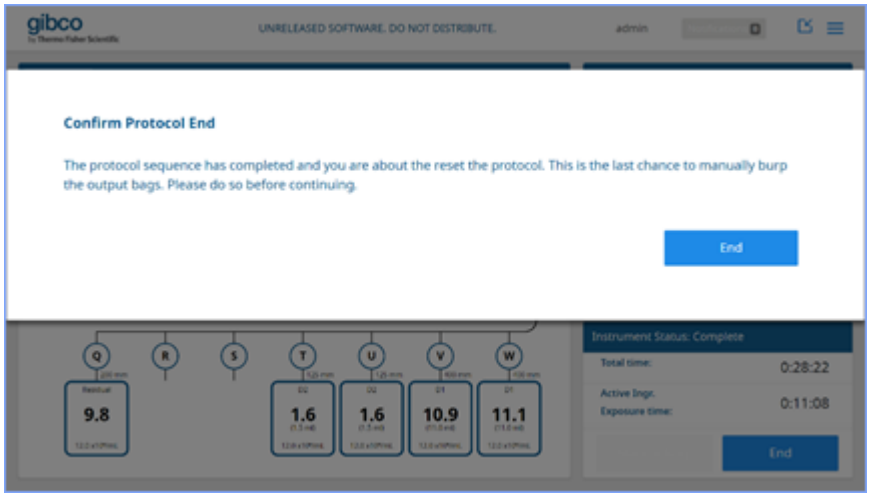
4. Use the instrument buttons to manually drive the pump in the forward and reverse direction.



5. Manually burp additional bags by deselecting the current active bag and selecting the next bag.

6. Once manual burping is complete, select **End**.

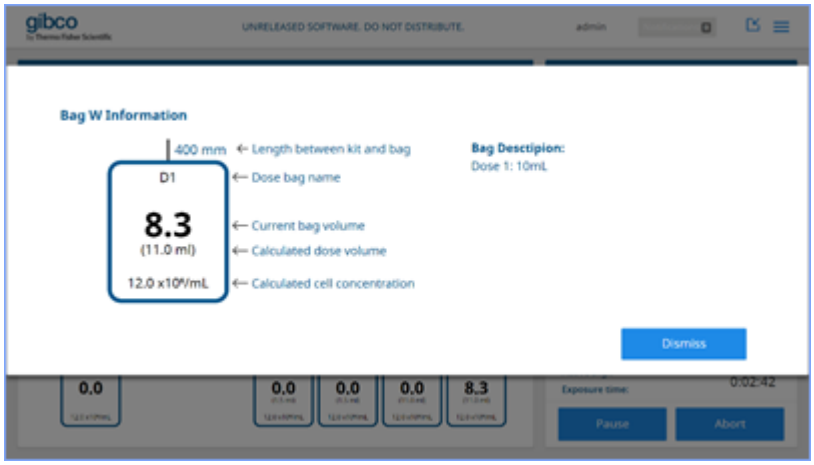
7. Press **End** to end the protocol.



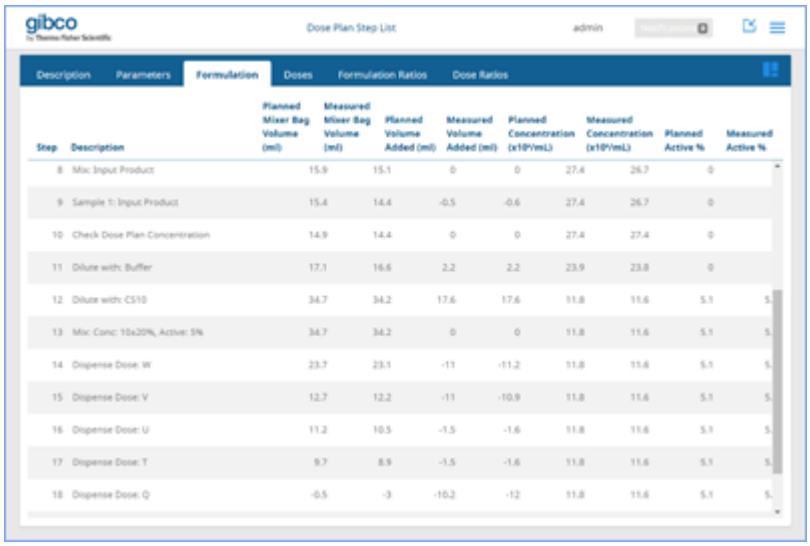
Volume measurements

The Current bag volume (Measured Volume) is displayed in bold in each of the Input and Output Bags/Vials. This is the current cumulative volume based on the starting volume for each bag and the Wet Volume added or removed as each step in the protocol progresses.

The Calculated Dose Volume (Planned Volume) is the calculated volume of fluid to satisfy the requirements of the protocol, and is the volume that the pump will deliver.

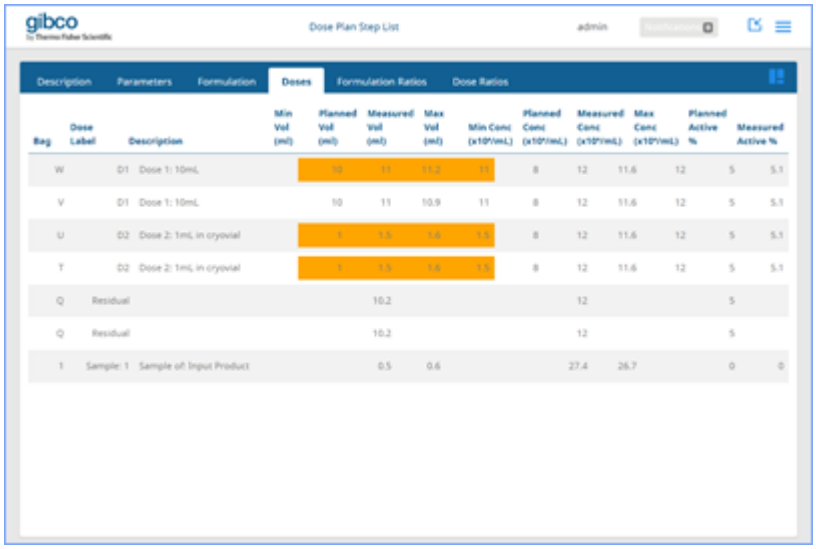


The Dose Plan Step List shows a live update of the "Planned Volume" and "Measured volume" for the Formulations and Doses as the protocol progresses.

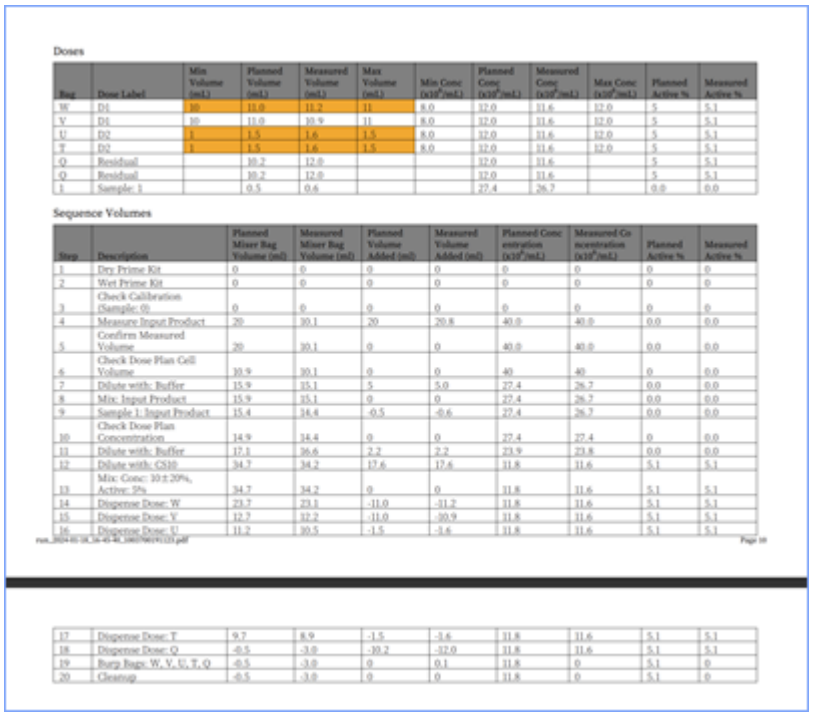


Values that are outside the specified range will be highlighted for subsequent review by the User.

Note: The Volume Alert reflects the user-defined tolerance range set in the Protocol Builder. A value outside this range does not necessarily indicate that the transferred volume is inaccurate. Instead, it serves as an alert that the volume measurement from a specific bubble sensor (for example, Bubble Sensor W for Output W) may have been affected by an event—such as a small bubble—during the transfer. This alert indicates a potential bubble-sensor measurement irregularity during the run and should not be interpreted as a failure of the volume transfer.



The Planned Volumes and Measured Volumes at the end of each step are also recorded in the run_log for review and verification by the User.



Doses

Bag	Dose Label	Min Volume (mL)	Planned Volume (mL)	Measured Volume (mL)	Max Volume (mL)	Min Conc ($x10^6$/mL)	Planned Conc ($x10^6$/mL)	Measured Conc ($x10^6$/mL)	Max Conc ($x10^6$/mL)	Planned Active %	Measured Active %
W	D1	10	11.0	11.2	11	8.0	12.0	11.6	12.0	5	5.1
V	D1	10	11.0	10.9	11	8.0	12.0	11.6	12.0	5	5.1
U	D2	1	1.5	1.6	1.5	8.0	12.0	11.6	12.0	5	5.1
T	D2	1	1.5	1.6	1.5	8.0	12.0	11.6	12.0	5	5.1
Q	Residual		10.2	12.0			12.0	11.6		5	5.1
Q	Residual		10.2	12.0			12.0	11.6		5	5.1
I	Sample: 1		0.5	0.6			27.4	26.7		0.0	0.0

Sequence Volumes

Step	Description	Planned Mixer Bag Volume (ml)	Measured Mixer Bag Volume (ml)	Planned Volume Added (ml)	Measured Volume Added (ml)	Planned Concentration ($x10^6$/mL)	Measured Concentration ($x10^6$/mL)	Planned Active %	Measured Active %
1	Dry Prime Kit	0	0	0	0	0	0	0	0
2	Wet Prime Kit	0	0	0	0	0	0	0	0
3	Check Calibration (Sample: 0)	0	0	0	0	0	0	0	0
4	Measure Input Product	20	20.1	20	20.8	40.0	40.0	0.0	0.0
5	Confirm Measured Volume	20	20.1	0	0	40.0	40.0	0.0	0.0
6	Check Dose Plan Cell Volume	10.9	10.1	0	0	40	40	0	0.0
7	Dilute with: Buffer	15.9	15.1	5	5.0	27.4	26.7	0.0	0.0
8	Mix: Input Product	15.9	15.1	0	0	27.4	26.7	0.0	0.0
9	Sample 1: Input Product	15.4	14.4	-0.5	-0.6	27.4	26.7	0.0	0.0
10	Check Dose Plan Concentration	14.9	14.4	0	0	27.4	27.4	0	0.0
11	Dilute with: Buffer	17.1	16.6	2.2	2.2	23.9	23.8	0.0	0.0
12	Dilute with: CS10	34.7	34.2	17.6	17.6	11.8	11.6	5.1	5.1
13	Mix: Conc: 10±20%, Active: 5%	34.7	34.2	0	0	11.8	11.6	5.1	5.1
14	Dispense Dose: W	23.7	23.1	-11.0	-11.2	11.8	11.6	5.1	5.1
15	Dispense Dose: V	12.7	12.2	-11.0	-10.9	11.8	11.6	5.1	5.1
16	Dispense Dose: U	11.2	10.5	-1.5	-1.6	11.8	11.6	5.1	5.1
17	Dispense Dose: T	9.7	8.9	-1.5	-1.6	11.8	11.6	5.1	5.1
18	Dispense Dose: Q	-0.5	-3.0	-10.2	-12.0	11.8	11.6	5.1	5.1
19	Purge Bags: W, V, U, T, Q	-0.5	-3.0	0	0.1	11.8	0	5.1	0
20	Cleanup	-0.5	-3.0	0	0	11.8	0	5.1	0

Figure 7 Extracts from sample run_log

Perform pump calibration

The CTS Compleo™ instrument is shipped with default calibration settings that are checked during commissioning prior to shipment.

The User is responsible for qualifying the instrument performance including pump calibration and maintaining the system in a qualified state.

Note: The default pump calibration factor for the forward and reverse directions was determined based upon the average (mean) test results from a significant sample size of single-use kits. The user should consider the impact of kit-to-kit variation on volume accuracy before making adjustments to the pump calibration factor.

A recommended pump calibration protocol, FIL-0153-##-Pump Calibration, is available for download from the Thermo Fisher Scientific website. This protocol enables calibration of the peristaltic pump in forward and reverse directions.

Calibration should ideally be performed using conditions that replicate the expected operating conditions for the protocol including:

- Fresh single use Kit
- Same media temperature and density
- Typical volumes to transfer Input Cells or Buffer from lines E or F to the Mixing Bag (Reverse) and dispense Doses (Forward)

Note: To obtain multiple calibration volumes for the Forward pump direction, the protocol can be modified to deliver multiple, smaller doses into lines Q to W.

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1. Prepare the single-use kit for calibration protocol based on the schematic contained in FIL-0153-##-Pump Calibration protocol.

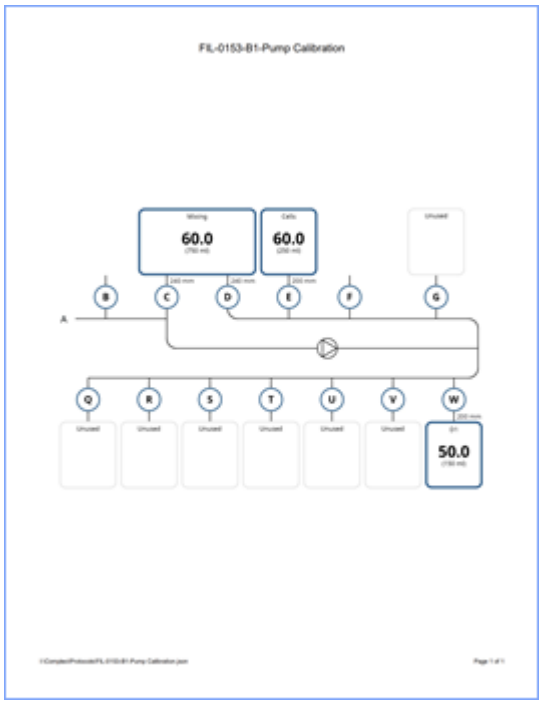


Figure 8 Pump Calibration Kit

Bag E: Cells (150 mL capacity)

- Attach luer lock fittings and manual clamp on output line.
- Fill bag with >60 mL of media (for example, 100 mL).
- Record the **Initial Weight** including manual clamp.
- Attach Bag to line E of the Kit using the luer lock connectors.

Bag W: D1 (150 mL capacity)

- Attach luer lock fittings and manual clamp on output line.
- Record the **Initial Weight**.
- Attach Bag to line W of the Kit using luer lock connectors.

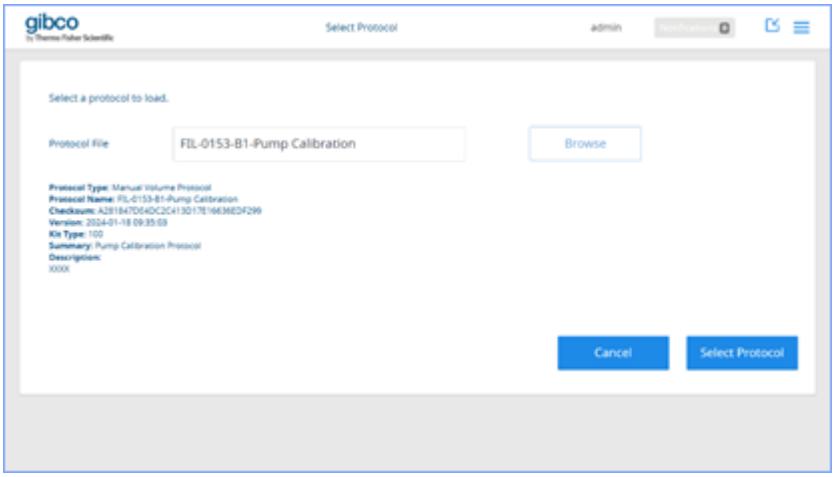
Note: The bag does not have to be empty.

Table 2 Example Calculation Table

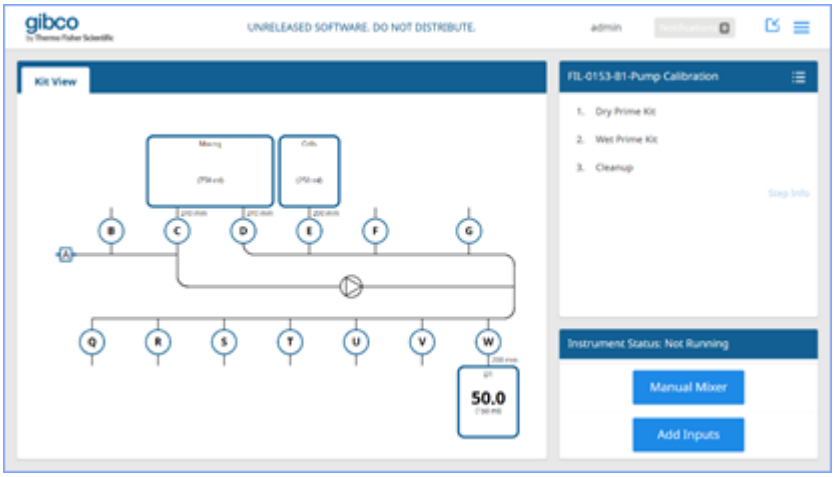
Pump Direction	Bag	Target Volume (mL)	Initial Weight (g)	Final Weight (g)	Actual Volume (mL)
Reverse	E	60	**102.3**		
Forward	W	50	**36.1**		

2. Load the single use Kit to the Instrument and close the door.

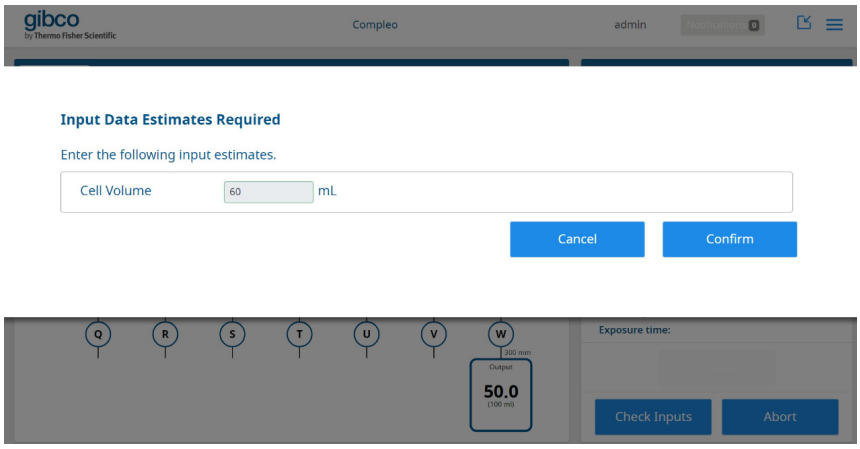
3. Select the FIL-0153-##-Pump Calibration protocol using the Compleo App.

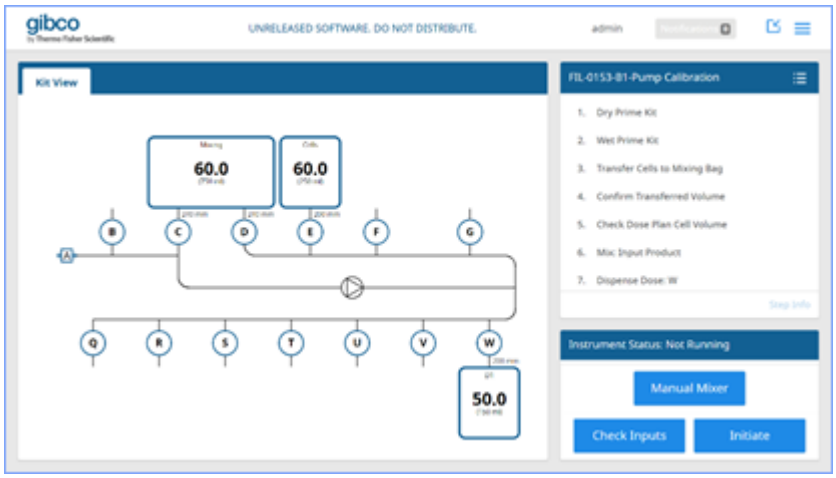


4. Select **Add Inputs**.

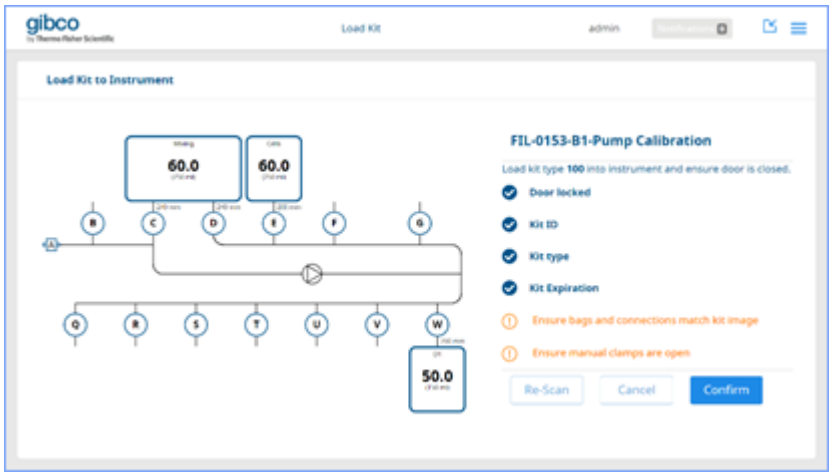


5. Enter Cell Volume: **60 mL** and select **Confirm** to display the Kit View based on the Input Data Estimates.

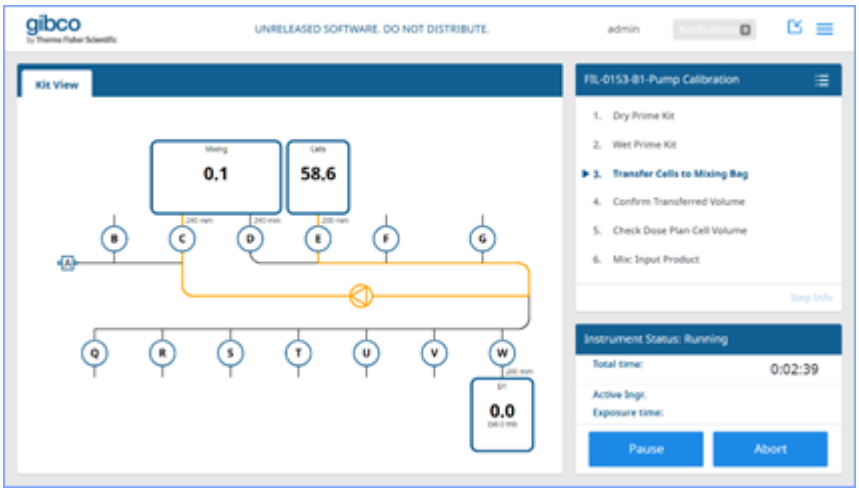




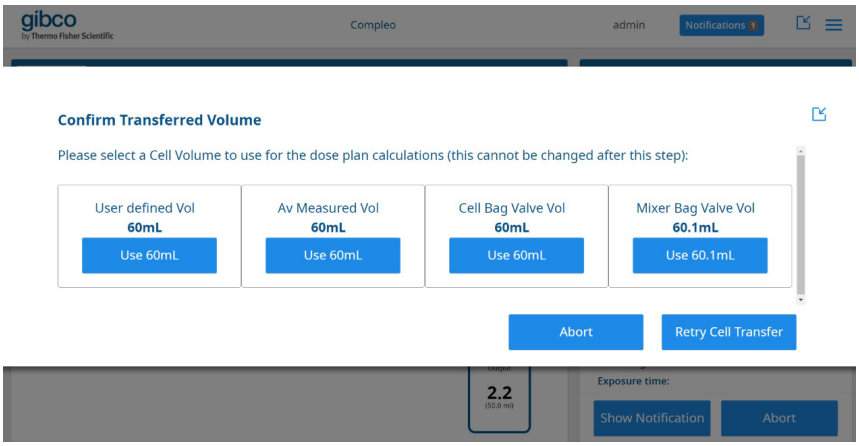
6. Select **Initiate** to perform the system checks and then **Confirm** followed by **Start** to commence the protocol.



7. Allow the system to automatically **Dry prime**, **Wet prime**, and then transfer 60 mL from the Cells Bag to the Mixing Bag using the **reverse** pump direction.



8. When the **Confirm Measured Volume** screen is displayed, select the appropriate option.



- Select **User defined Vol** if the transfer of fluid completed without user intervention and the Measured Volumes are within tolerance.
- If there was an obvious issue during transfer of water from Bag E to the Mixing Bag, select **Retry Cell Transfer** to return the water and repeat the transfer sequence or **Abort** to start the protocol again.
- Do **NOT** select **Av Measured Vol**, **Cell Bag Valve Vol**, or **Mixer Bag Valve Vol**, as this is not required for calibration purposes.

Note: The actual volume of fluid transferred will be reduced by the volume of air that enters line E or C during the fluid transfer steps. This will be evident as a discrepancy between the User defined volume and the Measured Volumes.

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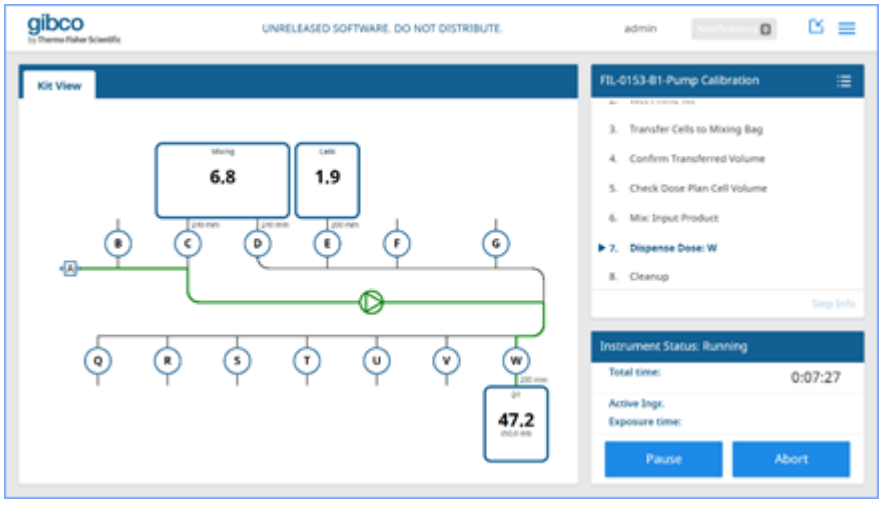
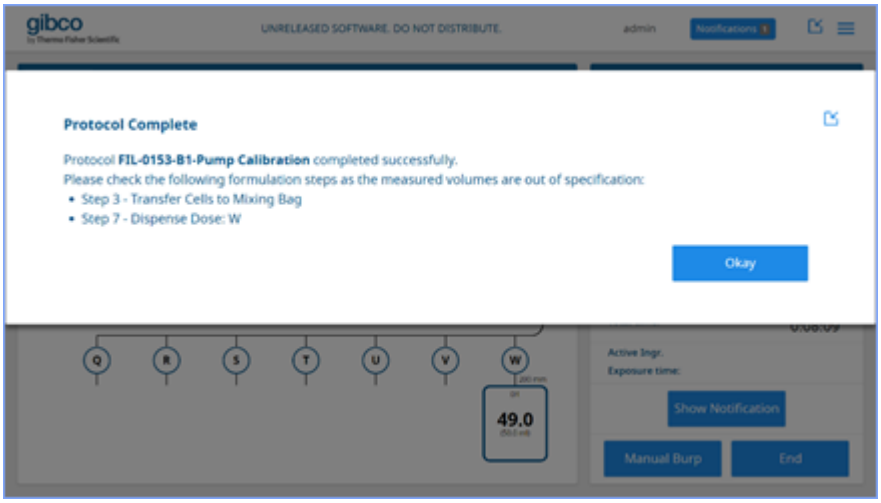
9. Select **Confirm**. On the next screen, select **Confirm** to continue.

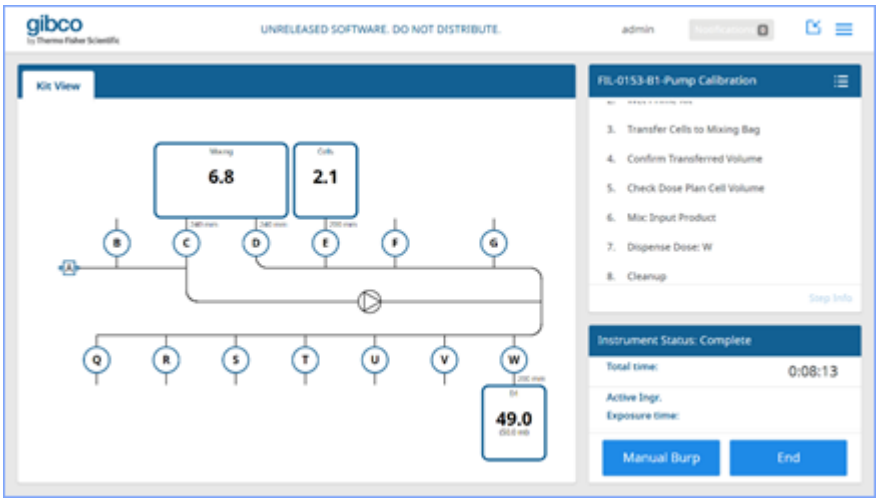
10. After a brief mixing cycle, allow 50 mL to be dispensed from the Mixing Bag to Bag W using the **forward** pump direction.

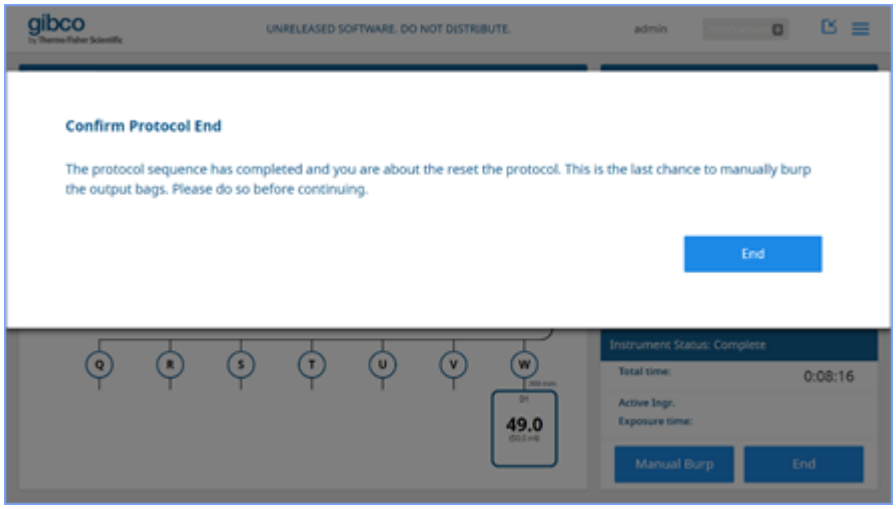


11. Allow the automatic **Cleanup** sequence to purge fluid from within the Tube Carrier towards each of the attached bags.

12. Once the protocol is complete, select **Okay**.







Note: It is important that all fluid is purged from the Kit beyond the luer lock fittings prior to removal of Bags E and W otherwise it will be excluded from the bag weights. Provided the luer lock fittings are positioned <100 mm from the top of the Tube Carrier, the **Cleanup** sequence should satisfy this requirement. However, if necessary, select the **Purge Kit** option from the dropdown list prior to removal of bags for weighing.

13. Apply manual clamps to the tubes on Bags E and W and then remove the bags from the Kit using the luer locks.

    Weigh Bags E and W and record the **Final Weight** in grams.

    Calculate the **Actual Volume** using the following formula:

$$\text{Actual Volume (mL)} = \frac{\text{Final Weight} - \text{Initial Weight (g)}}{\text{Density (g/mL)}}$$

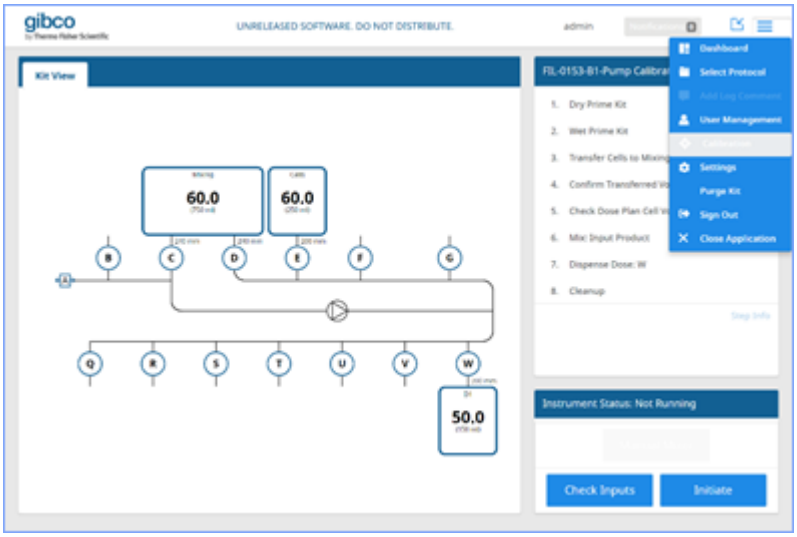
Note: The density of water is 1.0 g/mL.

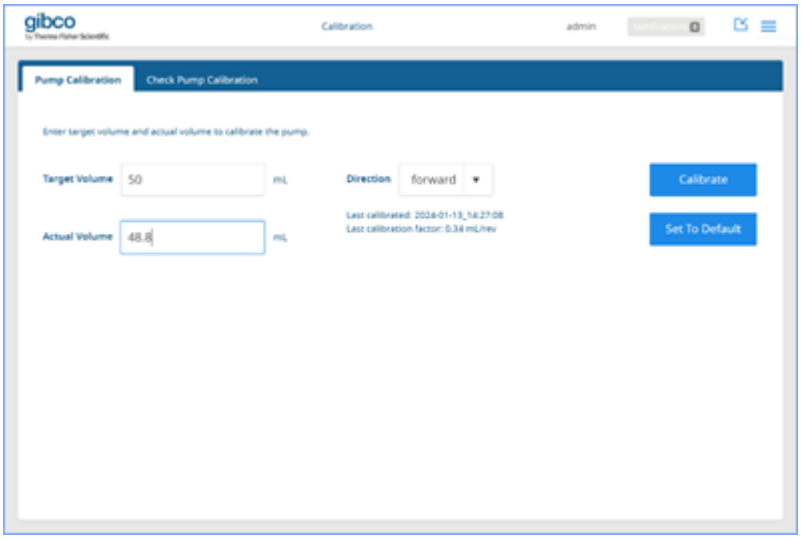
Table 3 Example Calculation Table

Pump Direction	Bag	Target Volume (mL)	Initial Weight (g)	Final Weight (g)	Actual Volume (mL)
Reverse	E	60	102.3	**41.8**	60.5
Forward	W	50	36.1	**84.9**	48.8

14. Select **Calibration** from the dropdown menu and update the Calibration Factor in Forward and Reverse using the Target Volumes and Actual Volumes.

    Refer to Pump Calibration documentation for calculation details.





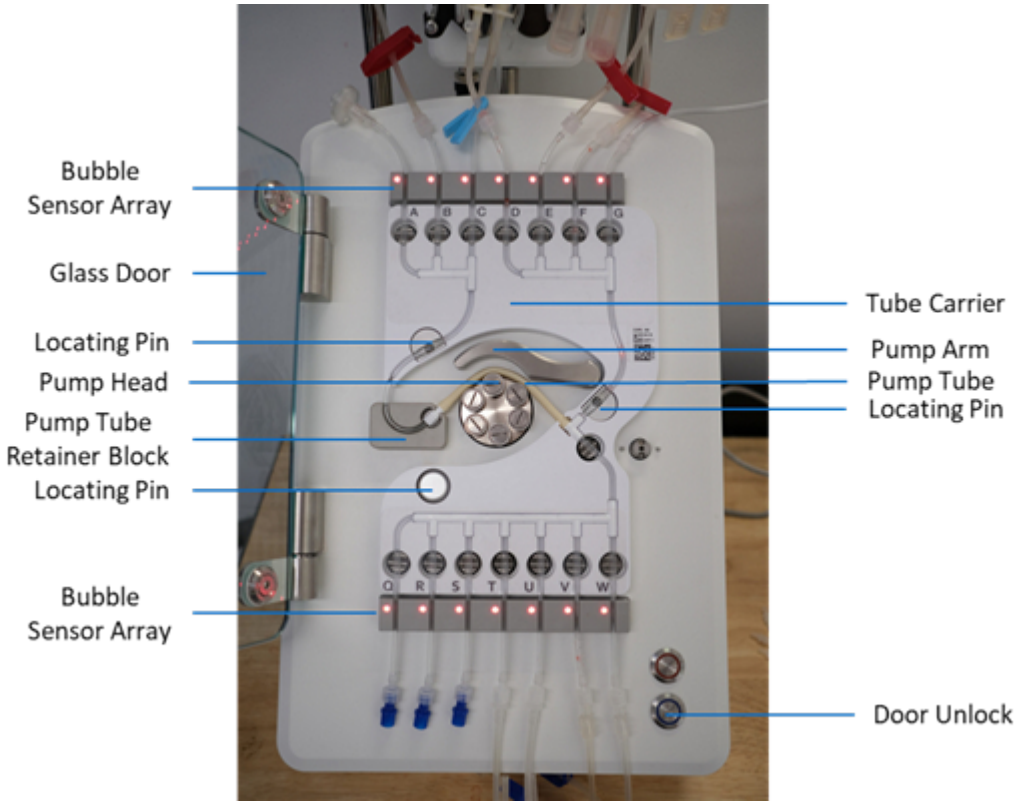
Remove the kit

1. Seal and disconnect the input and output bags from the single-use kit.

Note: The single-use kit tube materials are suitable for RF sealing using a tube-sealer device.

CAUTION! Output bags/vials come in a variety of tube materials. Consult the supplier's manual for instructions on creating a sterile disconnection with your selected bags/vials.

CAUTION! Ensure all fluid lines are sealed using a tube sealer or manual clamps before unlocking the door to prevent fluid movement when the instrument pinch valves are released.



2. Press the blue **Door Unlock** button to release the door.
3. Open the glass door and raise until past vertical.
4. Remove the pump tube from the pump tube retainer block and pump head.
5. Gently raise the tube carrier, drawing out the tubes from the two bubble sensor arrays.
6. Dispose of the used single-use kit in accordance with approved procedures.

4 OPC-UA Interface

The OPC-UA (Open Platform Communications Unified Architecture) Interface provides standardized communication between the instrument and external systems for data exchange and process control.

Overview

OPC-UA is a platform-independent, service-oriented architecture that enables secure and reliable data exchange in industrial automation and laboratory environments. The interface allows for:

- Real-time data monitoring and collection
- Remote instrument control and configuration
- Integration with laboratory information management systems (LIMS)
- Secure communication using industry-standard encryption

Key Features

The OPC-UA Interface supports the following capabilities:

- **Data Access**—Read and write instrument parameters and settings.
- **Event Notification**—Receive notifications about instrument status changes and alarms.
- **Historical Data Access**—Retrieve archived run data and audit logs.
- **Security**—User authentication and encrypted data transmission.

Scope of System

Using the Compleo™ or Rotea™ instruments requires the following items:

- Instrument hardware inventory
- Windows™ 10 or 11 tablet computer interfacing with the installed application
- Single-use kit with connected tubing and bags/vessels
- Protocol file
- Protocol configuration data

Protocol file

A protocol file contains the parameters and settings required to run a specific procedure or experiment. Protocol files ensure consistency and reproducibility across multiple runs by storing predefined configurations.

Protocol files can be created, imported, exported, and managed through the software interface. Users with appropriate permissions can modify protocol parameters to optimize performance for specific applications.

Protocol metadata

Protocol metadata provides essential information about the protocol configuration, settings, and parameters used during experimental procedures.

Overview

Metadata associated with protocols includes details such as protocol name, version, creation date, and specific parameters that define how the protocol operates. This information ensures traceability and reproducibility of experimental results.

Key metadata elements

Protocol metadata typically includes the following information:

- **Protocol identification**—Name, version number, and unique identifier for the protocol.
- **Creation and modification details**—Date created, last modified date, and author information.
- **Protocol parameters**—Specific settings and configurations that define protocol behavior.
- **Compatibility information**—Instrument models, software versions, and reagent kits compatible with the protocol.

Accessing protocol metadata

Protocol metadata can be accessed through the software interface or exported as part of the protocol file. This information is essential for protocol validation, regulatory compliance, and quality control purposes.

5 Maintenance

This section provides information about maintenance procedures for the instrument.

User Maintenance Schedule

The user is responsible for defining and implementing a suitable maintenance schedule based on their specific usage of the Compleo instrument.

WARNING! Regular maintenance should be scheduled with Thermo Fisher Scientific to ensure correct operation of the instrument. Any modifications, revisions, maintenance or repair to the Compleo system shall be performed by Thermo Fisher Scientific approved technicians.

WARNING! Only spare parts and accessories that are approved or supplied by Thermo Fisher Scientific may be used for maintaining or servicing the product.

Instrument cleaning

All biological contaminants are contained within the Compleo™ Single-Use Kit. However, if needed, a sanitization procedure can be used to reduce microbiological levels on the Instrument between product batches or following accidental microbiological contamination.

With the single-use kit removed, the instrument face and features may be decontaminated with:

- Light spraying with 70% isopropanol or ethanol
- 10% bleach solutions followed by a rinse of water or ethanol
- Wipe with a lint-free disposable cloth

CAUTION! All features on the front deck of the instrument are sealed against moisture ingress but the instrument has not been designed for aggressive wash down or vapor sterilization regimes.

Inspect casing

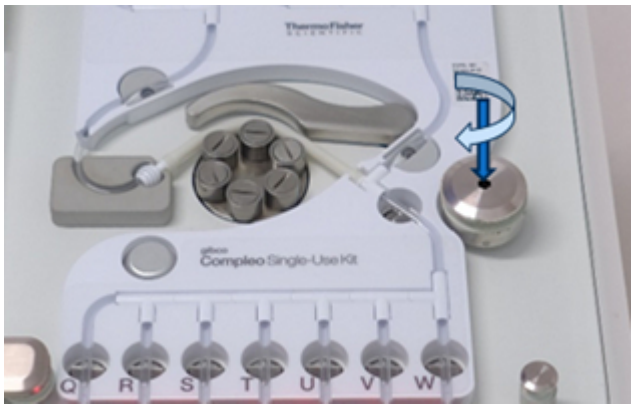
On a monthly basis, check the instrument enclosure, glass door, and chamber carrier for any damage, cracks, corrosion, effects of chemicals, or wear. If any such defects are found, discontinue use of the instrument and contact Thermo Fisher Scientific for repair.

Open the door without power

Gather the following materials:

- 3 mm hex key

1. Disconnect the instrument from power.
2. Insert the 3 mm hex key through the center of the door latch feature and engage the key firmly into the socket.
3. Rotate the hex key clockwise to unlatch the door.
   The total movement is 90 degrees to release the latch.



Power and Fuses

Power supply

The instrument power supply is rated to operate with international standard single-phase power.

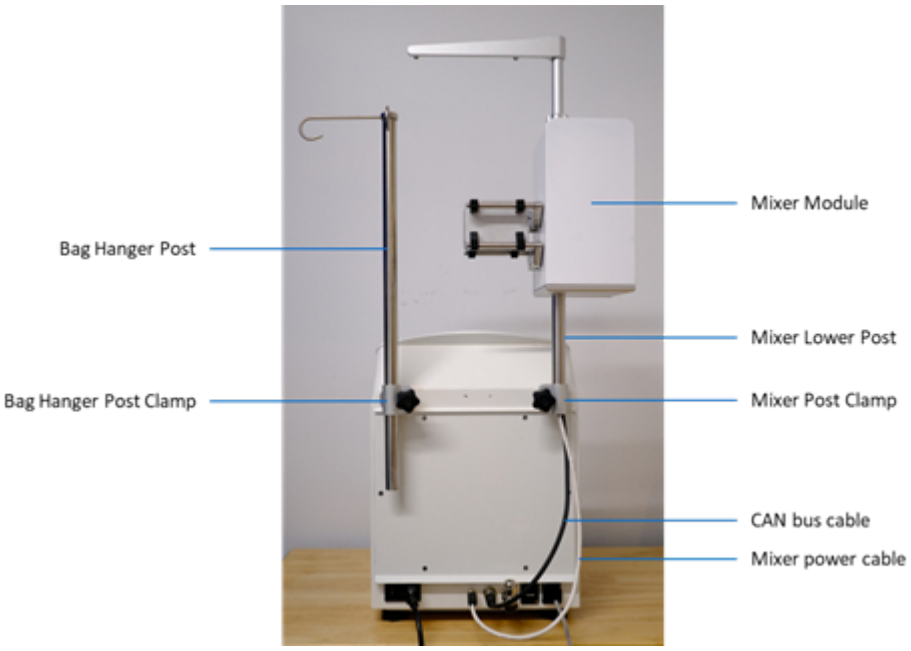
Specification

- Voltage: 90–264 VAC
- Frequency: 47–63 Hz
- Power: 240 Watts

Replace fuses

The power inlet module houses 2 × 5A cartridge fuses, 5 mm diameter × 20 mm long, fast acting, 250 VAC (5 Amp).

1. Turn off mains power and unplug the cable from the IEC connector at the rear of the instrument.



2. Remove fuse cover.
3. Remove faulty fuse.
4. Check that the replacement fuse is the correct rating for the instrument.
5. Insert new fuse and replace fuse cover.

A Troubleshooting

WARNING! Before performing any of the procedures described in this section, you must first read and understand all contents in prior sections of the user guide. Please ensure that you contact an approved Thermo Fisher Scientific representative if there is any doubt as to the use or maintenance of the Compleo™ system.

Component	Error or message	Fault	Corrective action
Power	"Communication Error – Ensure that the cable between the tablet interface and instrument is connected"	Instrument was not turned on	Check mains switch and instrument on/off switch.
		Replaceable fuse had blown	Replace fuse
Peristaltic pump	Reduced flow or over pressure		Check that all manual clamps are open.
			Check that input and output vessels are connected to the correct fluid lines on the single-use kit.
			Check tube connections/welds are open.
			Check pump tubing condition and that it is correctly located on the pump rollers.
			Check viable circuit and that correct pinch valves are open.
	Pump was not rotating		Check instrument status.
			Check mains and instrument on/off switch.
			Contact Thermo Fisher Scientific Service Representative.
Door	Door would not unlock.		Check instrument status and that the door unlock button is illuminated. Note: For instructions on how to open the door manually to retrieve a Single-Use Kit or perform maintenance, refer to "Open the door" on page 51.

(continued)

Component	Error or message	Fault	Corrective action
Door	Door would not unlock.		Depress door fully.
	Door would not unlock.		Check that the single-use kit has been correctly loaded with tubing retained in tube tracks.
			Check for obstructions.
Pinch Valves	Valves were not fully closing.		Perform single-use kit loading and unloading sequence multiple times.
	Valves were slow to close.		Replace single-use kit and check performance.
Dose volume	Incorrect volume or highly variable output volume.		Check that your priming sequence eliminates air from fluid lines in the concentrate output path.
			Check pump calibration. Check that there isn't any flow restriction in the output line. Note: If delivering into a syringe, friction between the syringe barrel and the plunger can affect the output volume.
Mixer	"Mixer not communicating"	Communication error	Check correct mixer ID is selected (Under settings -> Mixer). If the Mixer fails to connect during a protocol, the User can select **Continue** to enable the protocol to be completed. Note: the User will be required to manually mix the Bag and to initiate progression to the next step.
Bubble Sensor	"Confirm empty Bag"		Check if there is still liquid in Bag. If Yes, press retry until bubble has passed sensor. If no, select from either **User Defined Vol** or **Measured Vol**. If either volumes are inaccurate, select abort.

(continued)

Component	Error or message	Fault	Corrective action
Bubble Sensor	"Can't Access Bag _" "The kit check process has shown bag can't be accessed which could be caused by a missing bag, tube clamp, closed tube weld or some other blockage."	Blockage to Bag	Check if clamps are open. Check if bag is connected. Check if tube is blocked or damaged. Press Retry until error disappears.
			Replace single-use kit and check performance.
			Pinch the tubes at the valves (within circular holes) to separate. Tube surface may be stuck together.
	"An air vent Bubble Sensor has gone Wet when it should have stayed Dry. An error has occurred with the bubble sensor or the protocol."	Air Vent Bubble Sensor Wet error	Press **Abort** and restart protocol. Wet volume measurements may not be accurate.
	The User will be prompted to manually burp the bag prior to ending the protocol.	Bubble Sensor on Dose bags fails to record the Wet Volume during dispensing.	If the dose bag was intended to be "burped", the bag will be skipped during automated burping.
	The User will be prompted to manually burp the bag prior to ending the protocol.	Bubble sensor on Dose bag failed to detect fluid during automatic burping.	Bubble Sensor C is also active during automatic burping. If fluid reaches C before fluid is detected by the Dose bag Bubble Sensor, the fluid will be automatically returned to the Dose bag.
	Error message	Bubble Sensor A or Q failed during "Check Calibration"	The instrument will automatically pause if the Bubble Sensors have not been triggered within the expected range.

Note: Some faults may be rectified by rebooting the instrument. To do this, turn the power off using either the mains switch or on/off switch on the rear of the instrument, wait 2 minutes, then turn the power back on (refer to "Power instrument On" on page 21).

B

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words.

- **CAUTION!**—Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!**—Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!**—Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Standard safety symbols

Symbol and description
CAUTION! Risk of danger. Consult the manual for further safety information.
CAUTION! Risk of electrical shock.
CAUTION! Hot surface.

(continued)

Symbol and description
CAUTION! Potential biohazard.
CAUTION! Ultraviolet light.

Symbole et description
MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.
MISE EN GARDE ! Risque de choc électrique.
MISE EN GARDE ! Surface chaude.
MISE EN GARDE ! Danger biologique potentiel.
MISE EN GARDE ! Rayonnement ultraviolet.

Additional safety symbols

Symbol and description
CAUTION! Moving parts.
CAUTION! Moving parts.
CAUTION! Moving parts.
CAUTION! Moving parts.
CAUTION! Moving parts.

(continued)

Symbol and description
CAUTION! Piercing hazard.
CAUTION! Sharp edges.
CAUTION! Potential slipping hazard.

Symbole et description
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Danger de perforation.
MISE EN GARDE ! Bords coupants.
MISE EN GARDE ! Danger de glisser potentiel.
MISE EN GARDE ! Danger en surplomb potentiel.
MISE EN GARDE !
electrostatic

Control and connection symbols

Symbols and descriptions	
	On (Power)
	Off (Power)
	Earth (ground) terminal
	Protective conductor terminal (main ground)
	Direct current
	Alternating current
	Both direct and alternating current

Conformity symbols

Conformity mark	Description
	INDICATES CONFORMITY WITH SAFETY REQUIREMENTS FOR CANANDA AND U.S.A.
	INDICATES CONFORMITY WITH CHINA RoHS REQUIREMENTS.
	INDICATES CONFORMITY WITH AUSTRALIAN STANDARDS FOR ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY.
	INDICATES CONFORMITY WITH THE WEEE DIRECTIVE 2012/19/EU. **CAUTION!** To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Safety information for instruments not manufactured by Thermo Fisher Scientific

Some of the accessories provided as part of the instrument system are not designed or built by Thermo Fisher Scientific. Consult the manufacturer's documentation for the information needed for the safe use of these products.

Instrument safety

General

CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

If covers are removed, do not use the instrument. Contact Technical Support.

CAUTION! Solvents and Pressurized fluids. Wear eye protection when working with any pressurized fluids. Use caution when working with any polymeric tubing that is under pressure:

- Extinguish any nearby flames if you use flammable solvents.
- Do not use polymeric tubing that has been severely stressed or kinked.
- Do not use polymeric tubing with tetrahydrofuran or nitric and sulfuric acids.
- Be aware that methylene chloride and dimethyl sulfoxide cause polymeric tubing to swell and greatly reduce the rupture pressure of the tubing.
- Be aware that high solvent flow rates (~40mL/min) may cause a static charge to build up on the surface of the tubing and electrical sparks may result.

Physical injury

CAUTION! Moving and Lifting Injury. If the instrument needs to be repositioned, proper technique should be used. Improper lifting can cause painful and permanent back injury.

Things to consider before lifting or moving the instrument or accessories:

- Depending on the weight, moving or lifting may require two or more persons.
- If you decide to lift or move the instrument after it has been installed, do not attempt to do so without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques.
- Ensure you have a secure, comfortable grip on the instrument or accessory.
- Make sure that the path from where the object is to where it is being moved is clear of obstructions.
- Do not lift an object and twist your torso at the same time. Keep your spine in a good neutral position while lifting with your legs.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.
- For smaller packages, rather than lifting the object from the packing box, carefully tilt the box on its side and hold it stationary while someone else slides the contents out of the box.

CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical safety

WARNING! Fuse Installation. Before installing the instrument, verify that the fuses are properly installed and the fuse voltage matches the supply voltage. Replace fuses only with the type and rating specified for the unit. Improper fuses can damage the instrument wiring system and cause a fire.

WARNING! Voltage Selector Switch. Before installing the instrument, verify that the voltage selector switch is set for the supply voltage. This will prevent damage to the instrument, reduce risk of fire, and enable proper operation.

WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.

AVERTISSEMENT ! Veiller à utiliser une alimentation électrique appropriée. Pour garantir le fonctionnement de l'instrument en toute sécurité :

- Brancher le système sur une prise électrique correctement mise à la terre et de puissance adéquate.
- S'assurer que la tension électrique est convenable.
- Ne jamais utiliser l'instrument alors que le dispositif de mise à la terre est déconnecté. La continuité de la mise à la terre est impérative pour le fonctionnement de l'instrument en toute sécurité.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility. If the line cord is damaged, contact Technical Support.

AVERTISSEMENT ! Cordons d'alimentation électrique. Utiliser des cordons d'alimentation adaptés et approuvés pour raccorder l'instrument au circuit électrique du site.

WARNING! Disconnecting Power. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

AVERTISSEMENT ! Déconnecter l'alimentation. Pour déconnecter entièrement l'alimentation, détacher ou débrancher le cordon d'alimentation. Placer l'instrument de manière à ce que le cordon d'alimentation soit accessible.

Cleaning and decontamination

CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods that are specified in the manufacturer user documentation. It is the responsibility of the operator (or other responsible person) to ensure that the following requirements are met:

- No decontamination or cleaning agents are used that can react with parts of the equipment or with material that is contained in the equipment. Use of such agents could cause a HAZARD condition.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. Request decontamination forms from customer service.
- Before using any cleaning or decontamination methods (except methods that are recommended by the manufacturer), confirm with the manufacturer that the proposed method will not damage the equipment.

MISE EN GARDE ! Nettoyage et décontamination. Utiliser uniquement les méthodes de nettoyage et de décontamination indiquées dans la documentation du fabricant destinée aux utilisateurs. L'opérateur (ou toute autre personne responsable) est tenu d'assurer le respect des exigences suivantes:

- Ne pas utiliser d'agents de nettoyage ou de décontamination susceptibles de réagir avec certaines parties de l'appareil ou avec les matières qu'il contient et de constituer, de ce fait, un DANGER.
- L'instrument doit être correctement décontaminé a) si des substances dangereuses sont renversées sur ou à l'intérieur de l'équipement, et/ou b) avant de le faire réviser sur site ou de l'envoyer à des fins de réparation, de maintenance, de revente, d'élimination ou à l'expiration d'une période de prêt (des informations sur les formes de décontamination peuvent être demandées auprès du Service clientèle).
- Avant d'utiliser une méthode de nettoyage ou de décontamination (autre que celles recommandées par le fabricant), les utilisateurs doivent vérifier auprès de celui-ci qu'elle ne risque pas d'endommager l'appareil.

Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.

Safety standards

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
IEC 61010-2-051 EN 61010-2-051	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-051: Particular requirements for laboratory equipment for mixing and stirring*
IEC 61010-2-081 EN 61010-2-081	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*

EMC standards

Reference	Description
EU Directive 2014/30/EU	European Union “EMC Directive”
EN 61326-1 IEC 61326-1	*Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements*
ICES-003, Issue 7	*Scientific Information Technology Equipment (including Digital Apparatus)*
FCC Part 15 Subpart B (47 CFR)	*U.S. Standard Radio Frequency Devices* This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union “WEEE Directive”—Waste electrical and electronic equipment
Directive 2011/65/EU & Commission Delegated Directive 2015/863	European Union “RoHS Directive”—Restriction of hazardous substances in electrical and electronic equipment
SJ/T 11364-2014	“China RoHS” Standard—Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products For instrument specific certificates, visit our customer resource page at **www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html**.

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

AVERTISSEMENT ! PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES. Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

WARNING! **HAZARDOUS WASTE (from instruments).** Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.

WARNING! **4L Reagent and Waste Bottle Safety.** Four-liter reagent and waste bottles can crack and leak. Each 4-liter bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position.

Biological hazard safety

WARNING! **Potential Biohazard.** Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

WARNING! **BIOHAZARD.** Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020 **cdc.gov/labs/bmbl**
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs) **who.int/publications/i/item/9789240011311**

Documentation and support

Customer and technical support

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- Product documentation
  - User guides, manuals, and protocols
  - Certificates of Analysis
  - Safety Data Sheets (SDSs; also known as MSDSs)

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

Limited product warranty

Life Technologies Corporation and its affiliates warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have questions, contact Life Technologies at **www.thermofisher.com/support**.