gibco

CTS™ Rotea™ Counterflow Centrifugation System

USER GUIDE

Catalog Number A44769

Publication Number MAN0018908

Revision C.0

For Research Use or Manufacturing of Cell, Gene, or Tissue- Based Products. CAUTION: Not intended for direct administration into humans or animals.

ThermoFisher SCIENTIFIC

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Revision	Date	Description
C.0	18 August 2022	Added Caution to Kit configuration; Warning to User maintenance shedule; Caution to Warnings and precautions; updated Caution in Instrument safety, General; added Caution to Cleaning and decontamination.
B.0	2 December 2020	MInor change to CTS™ Rotea™ Counterflow Centrifugation System specific disclaimer statement.
A.0	2 October 2020	New document. User guide for new workflow.

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

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1 Product information

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

Product description

The CTS™ Rotea™ Counterflow Centrifugation System is an automated, closed-flow benchtop instrument that can perform a wide variety of cell processing steps across different cell types.

The CTS™ Rotea™ Single-Use Kit is specifically designed for a range of cell processing applications such as separation, isolation, buffer exchange, wash and concentrate. Each kit has 8 input/output sterile weldable tubes, counterflow centrifuge and Carrier Frame for unparalleled setup flexibility.

The CTS™ Rotea™ Software is user-programmable and allows users to save, create, and modify protocols depending on the application. The system's open design and integrated camera allows users to visualize cells in real-time to more easily optimize protocols.

Features

CTS™ Rotea™ Counterflow Centrifugation System easily fits into existing workflows, from research to commercial manufacturing.

- Integrated camera provides real-time sample visualization
- Patented technology that can process up to 20 L of starting volume to as little as 5 mL of output volume
- Gentle fluidized bed results in unmatched cell recovery and viability
- Seamlessly transition from process development to GMP manufacturing on the same system.

Contents

Table 1 CTS™ Rotea™ Counterflow Centrifugation System (Cat. No. A44769)

Contents	Amount
CTS™ Rotea™ Centrifuge	1 ea
CTS™ Rotea™ Single-Use Kit	Available separately
Protocol Development Application	1 ea
Dell™ 2-in-1 laptop for operation/programming	1 ea

System overview

Instrument description

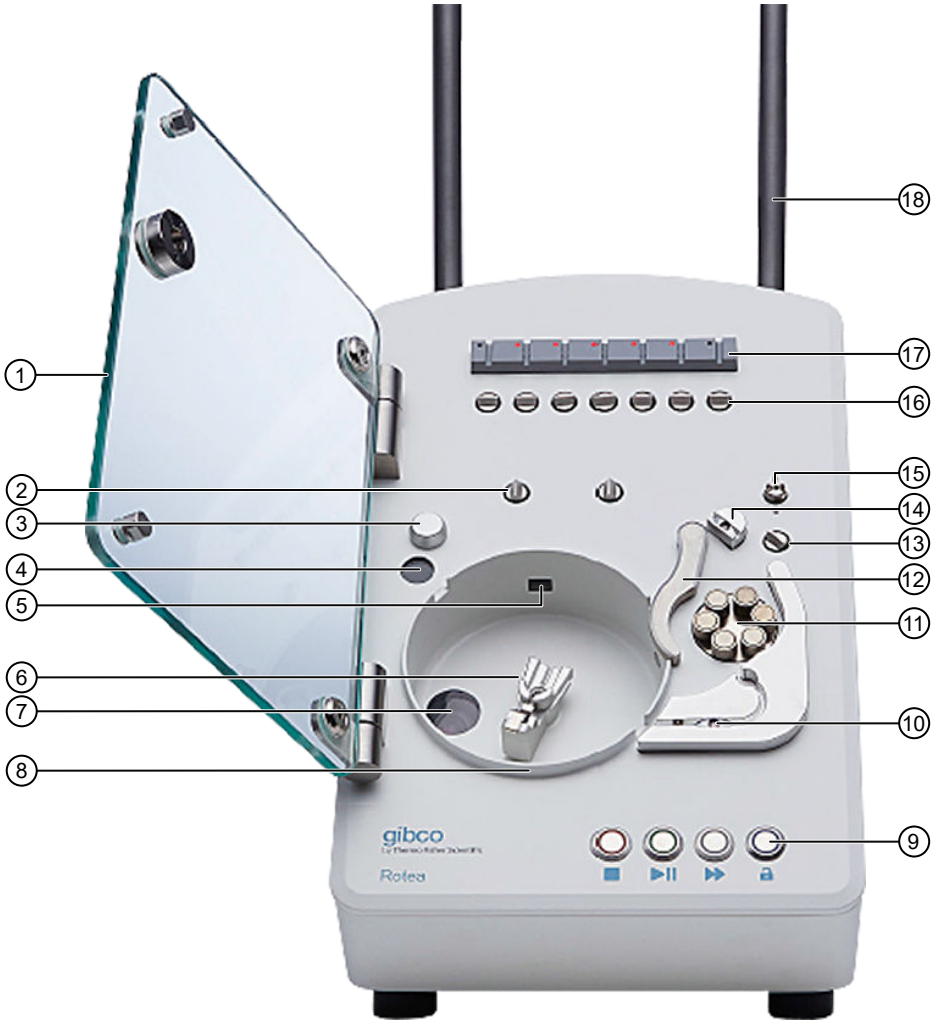


Figure 1 Instrument – Front View

1. Instrument Door
2. Pinch Valves (J & K)
3. Kit Location Button
4. 2D Barcode Reader
5. CFC Chamber Detector
6. CFC Chamber Carrier
7. Camera
8. Moisture Sensor
9. Pushbutton Controls
10. Optical Density Sensor & Pressure Sensor (P1)
11. Peristaltic Pump
12. Pump Clamp Arm
13. Pinch Valve (H)
14. Kit Location Button & Pressure Sensor (P2)
15. Door Latch
16. Pinch Valves (A, B, C, D, E, F, & G)
17. Bubble Sensors
18. Hanger Posts

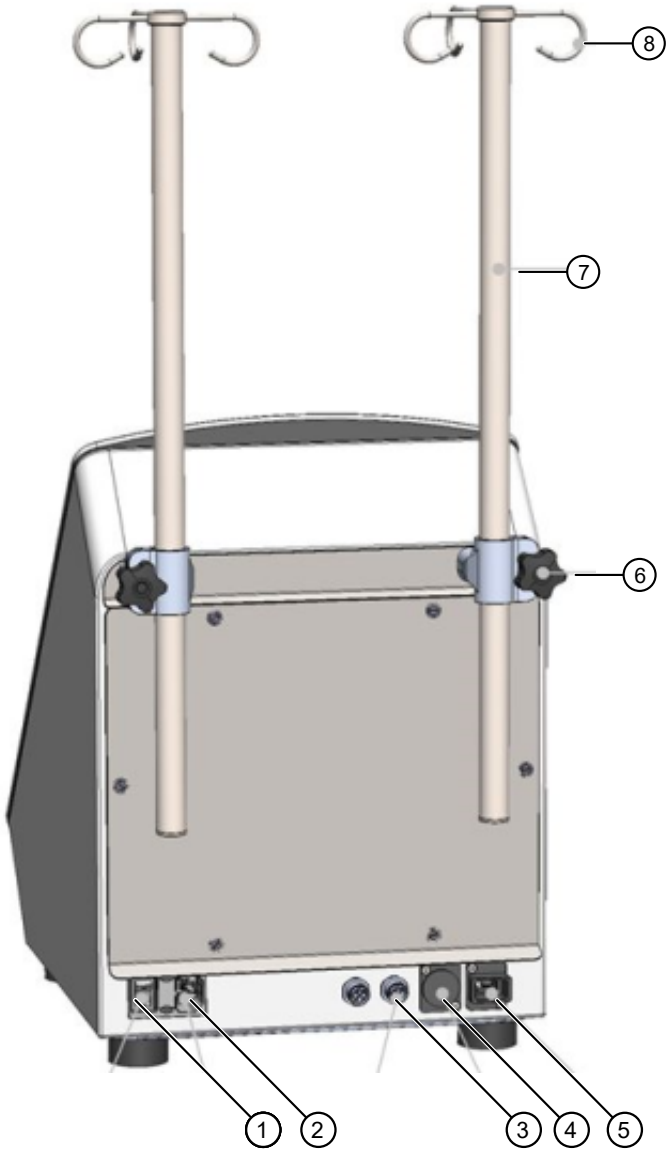
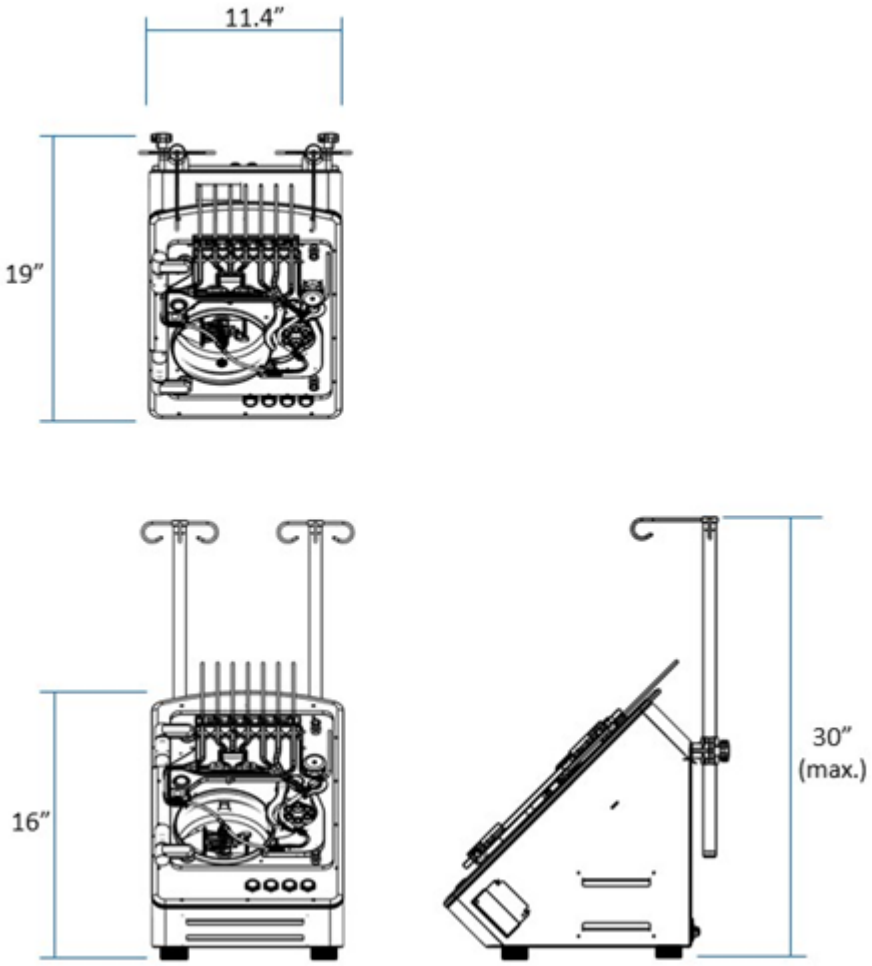


Figure 2 Instrument – Rear View

1. Power Switch
2. Mains Connector
3. CAN bus (2 off)
4. Ethernet (RJ-45)
5. USB-C
6. Bag Hooks
7. Hanger Post
8. Hanger Post Adjustment

Instrument dimensions



Working space

The Rotea™ instrument is designed for bench top use and requires a working space of approximately Height: 30” (76 cm), Width: 25” (63.5 cm), Depth: 20” (50.8 cm).

Note: The 2-in-1 laptop is connected via a USB-C cable and hence can be located in a range of positions. The width dimension of 25” assumes that the laptop is located on the bench beside the instrument.

Instrument weight

The Rotea™ instrument weighs 44 lbs (20 kg) with hanger posts installed.

Instrument properties

Category	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.)	2000 m
	Indoor use only	—
	Not intended for use in a wet location	—
	Intended for use in Pollution degree 2 environment	—
Operating limits		
	Centrifuge speed	0 to 3000 × *g* (7000 rpm)
	Flow rate	Standard: 5 to 110 mL/min (LS19) Hi-Flow: 30 to 160 mL/min (LS16 tube)
	System pressure	100 kPa
	Liquid temperature	4°C to 38°C
	Fluid density	1.0 to 1.1 g/mL
	Minimum working volume	Approx. 50 mL **Note:** Smaller volumes of input material can be diluted to enable processing

(continued)

Category	Property	Value
	Minimum concentrate recovery volume	5 mL (subject to protocol optimization)
	Centrifuge chamber volume	10 mL chamber containing up to 5×10^9 cells (cell type and operating parameters dependent). **Note:** Centrifuge chamber can be filled multiple times to process larger batches.
	Maximum bag weight per pole	4.4 lb (2 kg)
	Output concentration	Up to 300×10^6 cells/mL (cell type and operating parameters dependent)
CAN bus connection		
	Purpose	For connection and control of external devices
	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 Pin 4 - GND - Ground Pin 5 - GND - Shield, optional

Push button controls

Once a protocol has been loaded and confirmed, the Rotea™ instrument can be operated almost entirely from the push buttons on the front of the instrument.

Figure 3 Instrument push button controls

Light	STOP	START/PAUSE	ADVANCE	DOOR UNLOCK
Push button operation				
Solid	Push button to stop the instrument and the current protocol	Push button to start the Protocol, pause the current step in the protocol or re-start a paused step	Push button to advance to the next step in the protocol	Push button to unlock the door
Flashing	Instrument has stopped due to an alarm condition. User intervention is required.	Instrument is in a paused condition. Pressing allows the instrument to continue the current step of the protocol.	Button can be pushed, advancing to the next step of the protocol	N/A

CTS™ Rotea™ Single-Use Kit schematic

The CTS™ Rotea™ Single-Use Kit enables users to configure kits to suit different protocols by adding input and output vessels. Unused fluid lines are simply left sealed off.

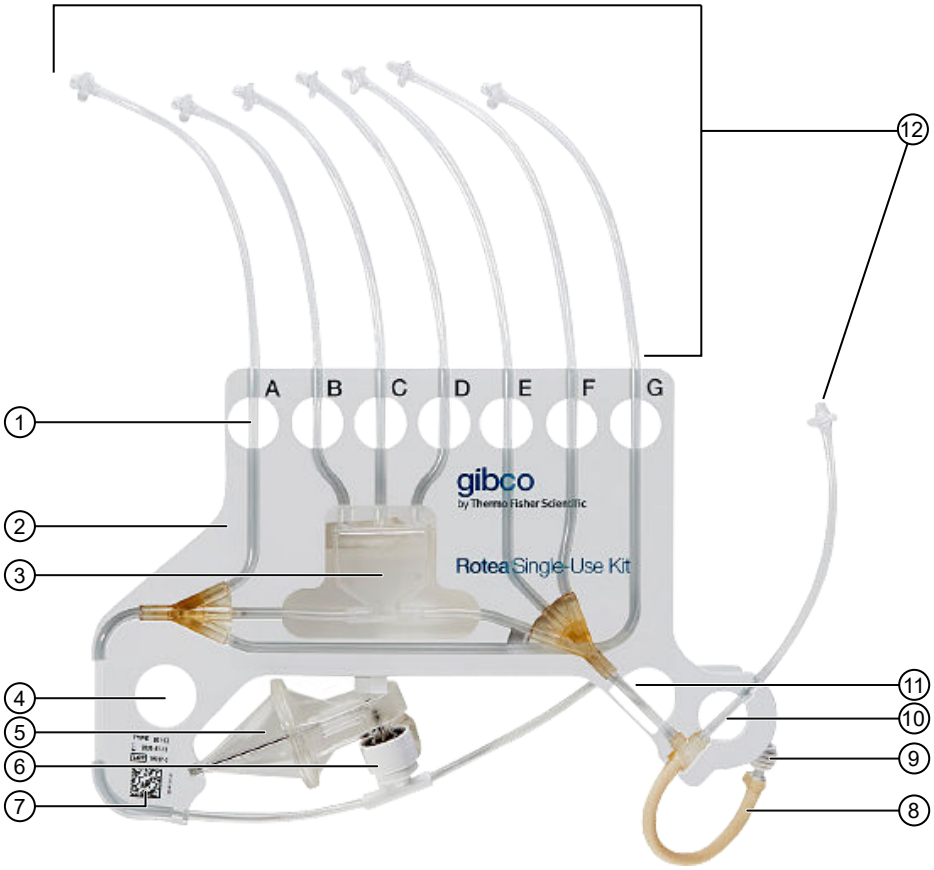


Figure 4 CTS™ Rotea™ Single-Use Kit

1. Valve Hole & Tube ID
2. Carrier Frame
3. Bubble Trap
4. Location Hole
5. CFC Chamber
6. Rotary Coupling
7. 2D Barcode
8. Pump Tubing
9. Tube Retainer
10. Valve H Hole
11. Location Hole
12. Kit Tubing (Input and Output)

Wetted components

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

Component	Description	Material
Pump tubing		
	Pump tube	Bioprene
Kit tubing		
	0.160” OD, 0.116” ID (4 mm OD, 3 mm ID)	DEHP-FREE PVC
CFC ChamberC		
	Base	Tritan MX711
	Cone	Tritan MX711
Rotary Coupling		
	O-Rings	EPDM, 70 DURO, FDA compliant
	Cannular	316 SS
	Cap	Tritan MX711
	Body	Tritan MX711
	Bush & Collar	Ketron LSG Peek Classix, USP Class VI
Bubble Trap		
	Base	Tritan MX711
	Cap	Tritan MX711
Fittings		
	Triple Y Connector	PVC
	Barbed T-Connector	Polyproylene

Allowed chemicals for wetted surfaces

Chemical	Concentration	Maximum exposure time
WFI	100%	5 minutes
Ethanol in water	50%	5 minutes
Culture media	100%	5 minutes

2 Installation and setup

Packaging contents

- Rotea™ instrument
- Hanger posts (2 off)
- Mains plug IEC cables (USA/EUROPE/AUSTRALIA)
- Pre-fitted mains fuses (2 x 5A)
- USB-C (male) to USB-C (female)
- Dell™ 2-in-1 laptop tablet (this will be in a separate carton)

Instrument installation

- Remove outer packaging
- Prepare bench space to receive Rotea™ instrument unit (see “Working space” on page 10) ensuring that there is easy access to the “On/Off” switch and mains IEC connector at the rear of the instrument

CAUTION! The Rotea™ 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.

- Ensure that the bench is stable and level to within ±0.4" (10 mm)
- Position the instrument on the bench with a minimum of 4" (10 m) between the rubber feet and the edges of the bench

CAUTION! The Rotea™ instrument weighs 40 lbs (18 kg) excluding hanger bag posts. Use appropriate care and seek assistance if necessary when lifting or moving the instrument. Lift the instrument, holding between the rubber feet on the bottom of the instrument.

CAUTION! Do not position the instrument is such a way that it would make it difficult to disconnect the power cord from the power inlet.

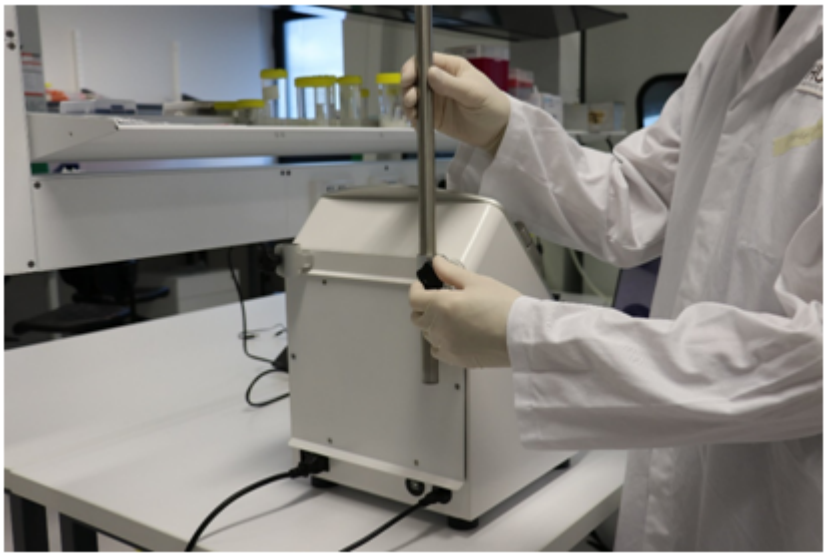
CAUTION! If using an alternate mains cable, ensure it is rated for at least 10A.

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

Figure 5 Back view of instrument

① Mains IEC connector
② USB-C port

1. Connect mains IEC connector.
2. Plug mains into power GPO
3. Connect the laptop to USB-C port on the instrument using the USB-C cable.
4. Insert 2 off bag hanger posts, adjust height to suit Kit and turn nut clockwise to secure in place.



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

Power instrument "On"

1. Switch on using the mains IEC switch at the rear of the instrument.

2. The instrument button lights will sequence as the instrument powers up. If the door is closed, the instrument will automatically check if a Single-Use Kit is installed.

Power instrument "Off"

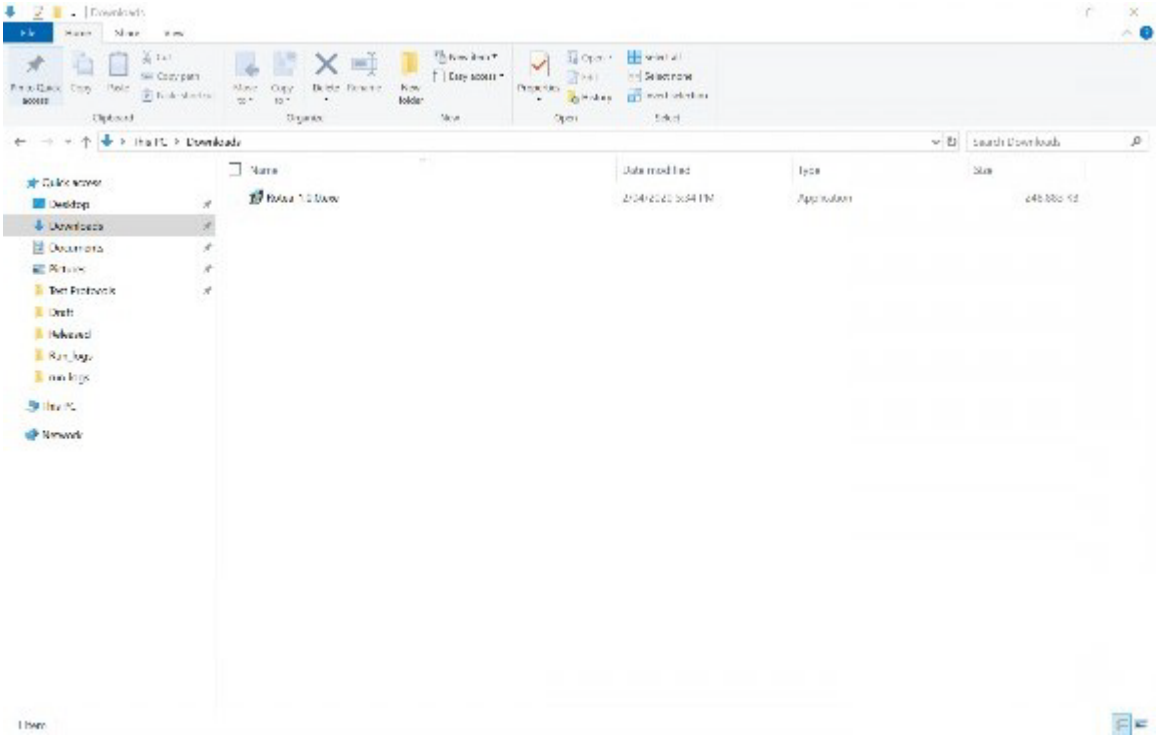
Switch off the instrument using the mains IEC switch or mains power.

CAUTION! There is no automatic recovery procedure. If a loss of power event has occurred see “Restart after shut down” on page 117.

Installation

The Dell™ 2-in-1 laptop will be pre-installed with Windows™ OS. The latest CTS™ Rotea™ Graphical User Interface (GUI) software will need to be installed onto the Dell™ 2-in-1 laptop provided. New releases of the Rotea™ GUI software will be available for download from **thermofisher.com**.

1. Download the `Rotea-X.X.X.exe` installer.

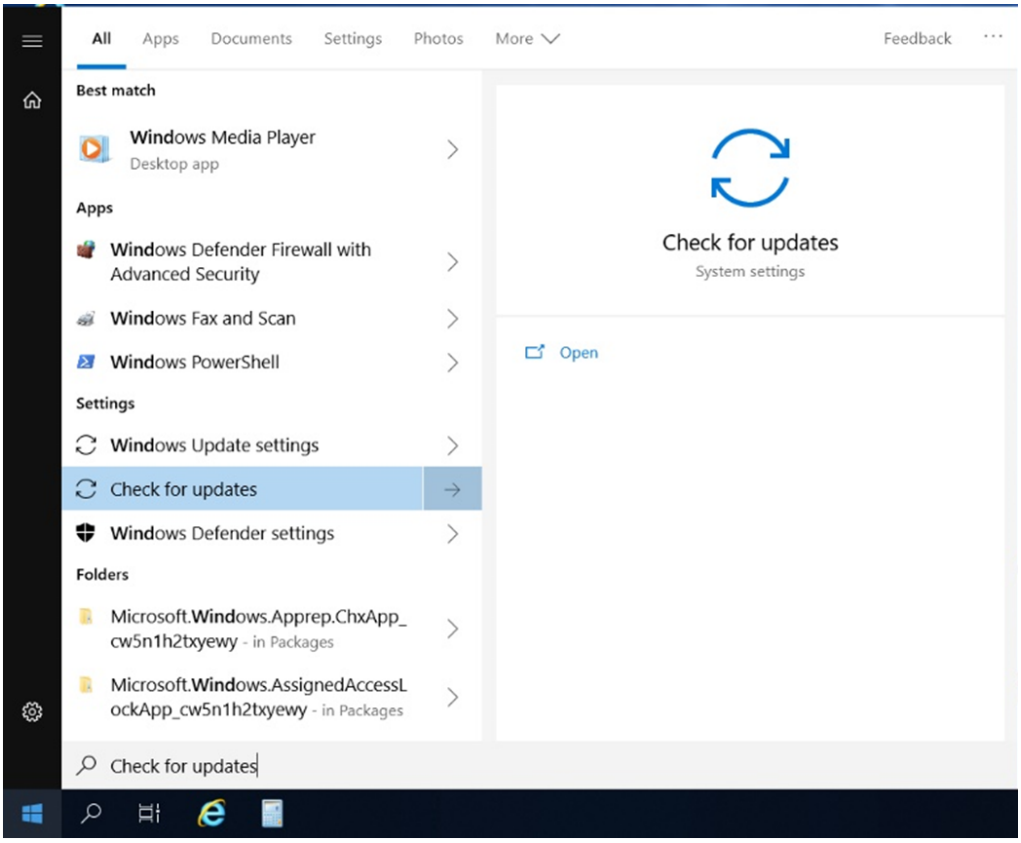


2. Run the `Rotea-X.X.X.exe` installer. Click **Install**. The application will be installed in `C:\Program Files (x86)\Rotea\`.

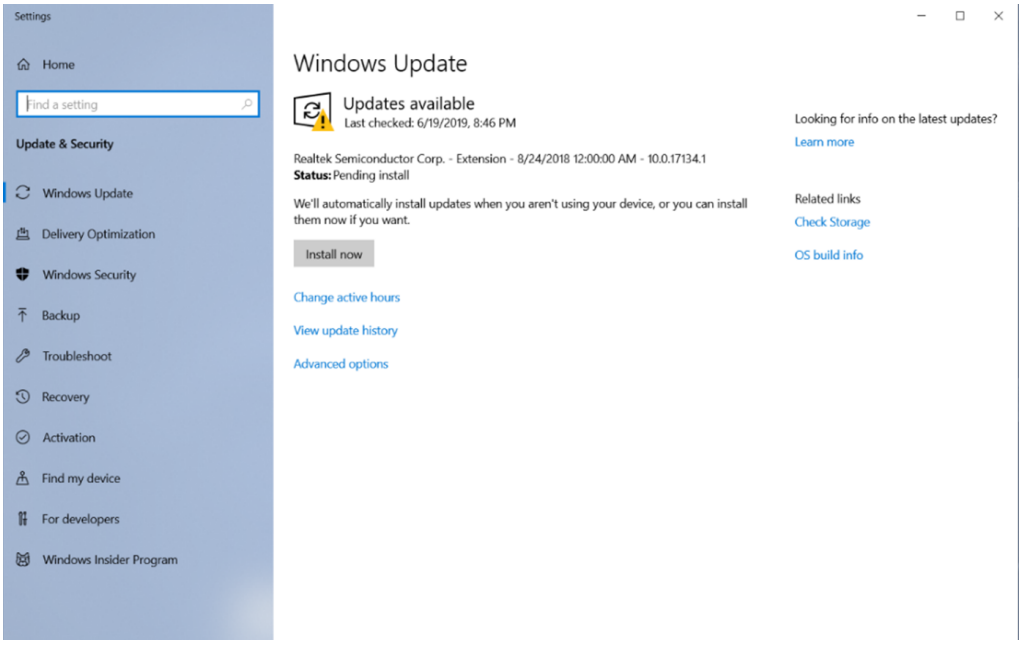
3. Click **Close** to finish the app installation.

4. Power on the Rotea™ instrument (with the switch on the back) and plug it into the laptop.

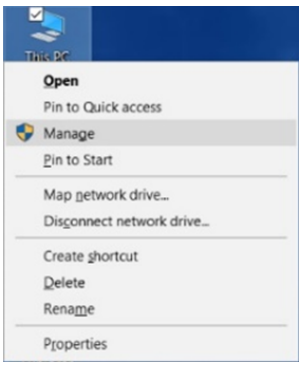
5. The next step is to update Windows™ software. Make sure the laptop is connected to the local wifi network. This can be done by opening the start menu and searching for **Check for updates**.



6. Click **Check for updates**, **Install now** and restart the laptop as required. This process may need to be repeated multiple times until Windows™ software is completely up to date.

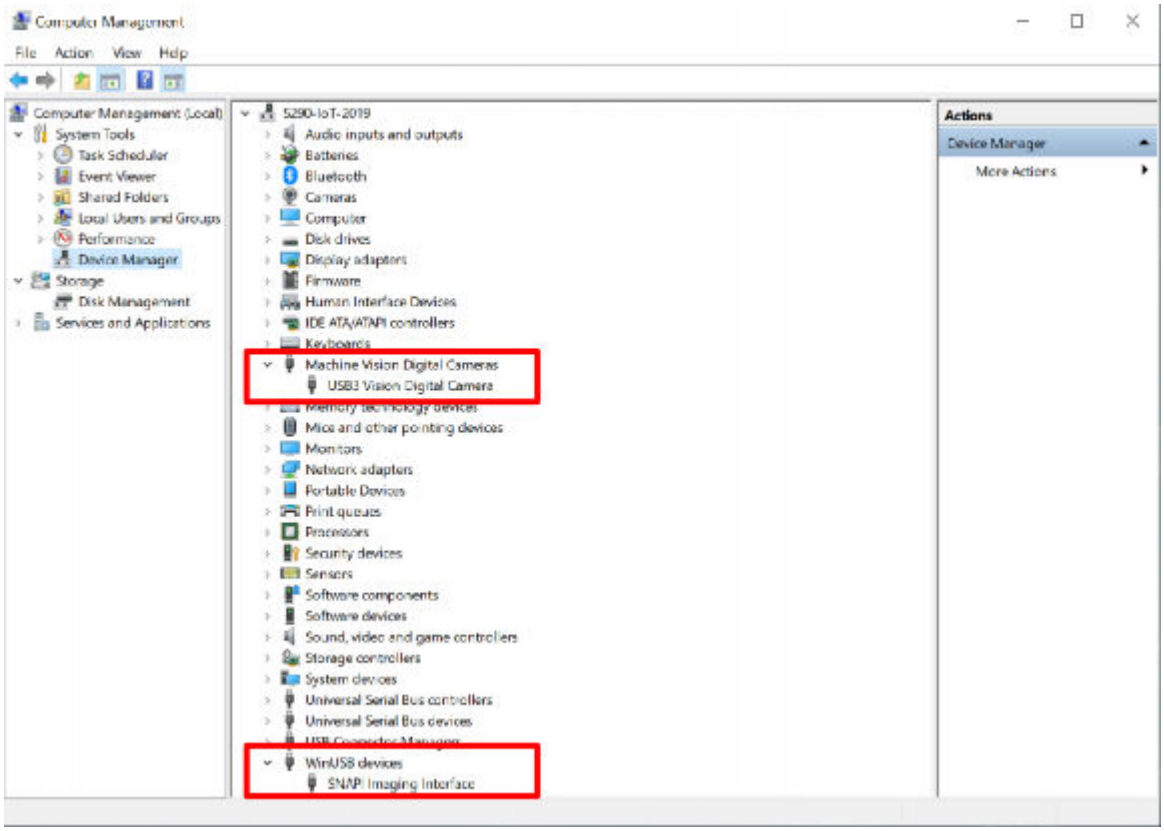


7. Check if **Windows Update** installed the required USB device drivers. Right click on **This PC** on the desktop and open **Manage**.



8. Ensure the USB devices are detected correctly. Check that the devices highlighted in figure can be seen:
   - USB Vision Digital Camera
   - USB Serial Port (COM X)
   - SNAPI Imaging Interface

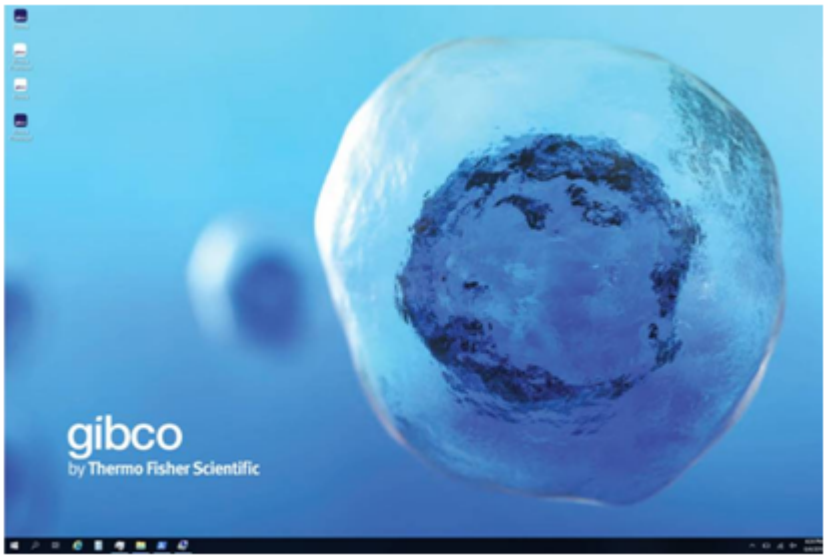
Note: If these devices are missing ensure the USB cable is plugged in, the Rotea™ instrument is powered and on, that there are no more Windows™ software updates to complete.



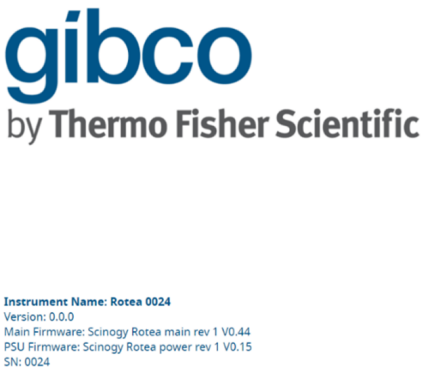
9. The installation is now complete. Move onto setting up the application for the first time.

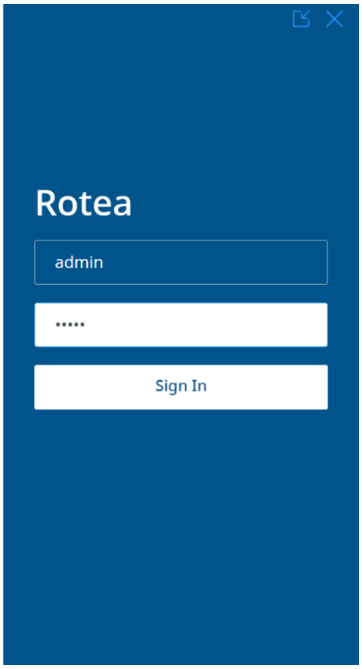
First time setup

1. Push the power button on the laptop to start Windows™ software.

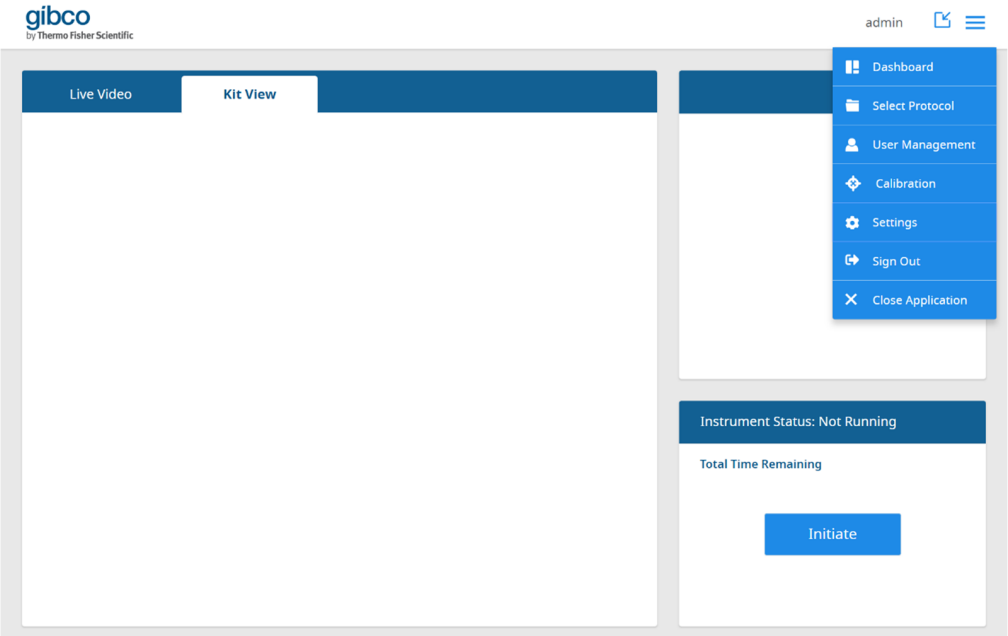


2. Run the Rotea™ application from the desktop or start menu. The application has a single admin user with **Username**: *admin*, **Password**: *admin* on a fresh installation.

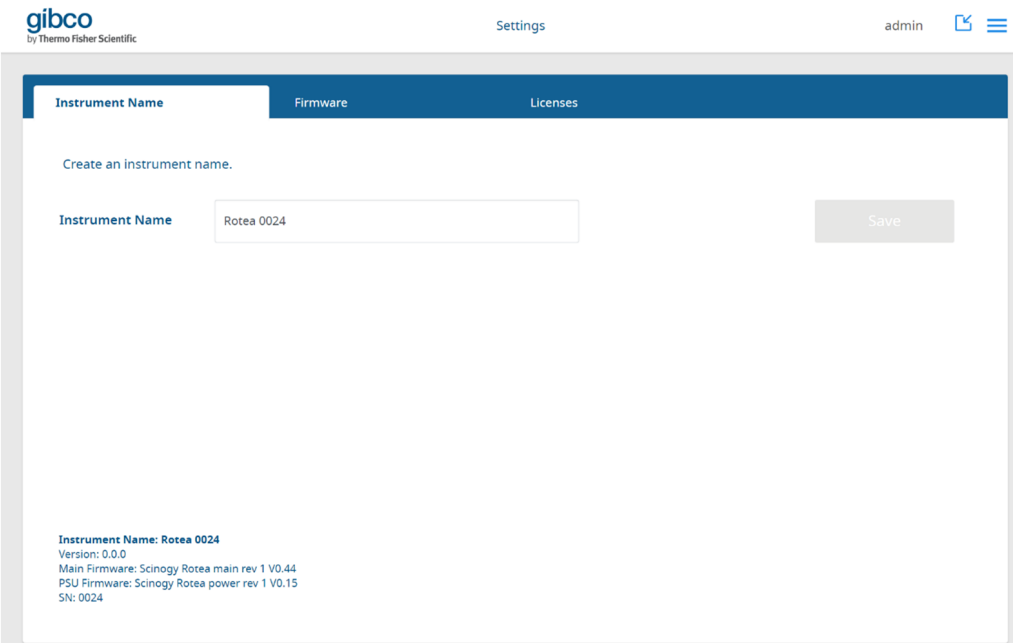




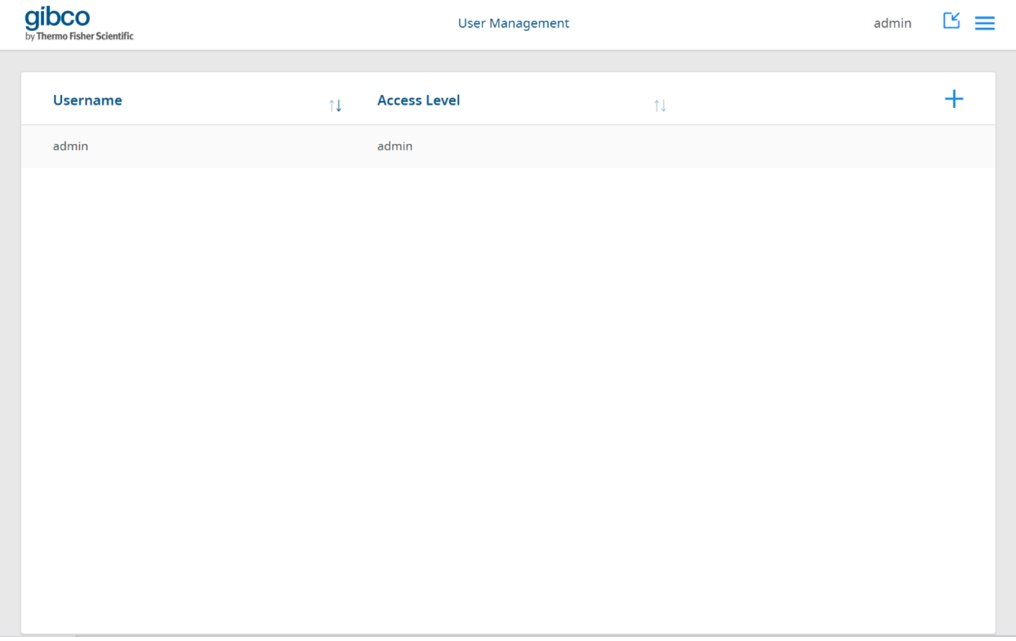
3. The main navigation menu in the top right corner is used to get to all areas of the applications.



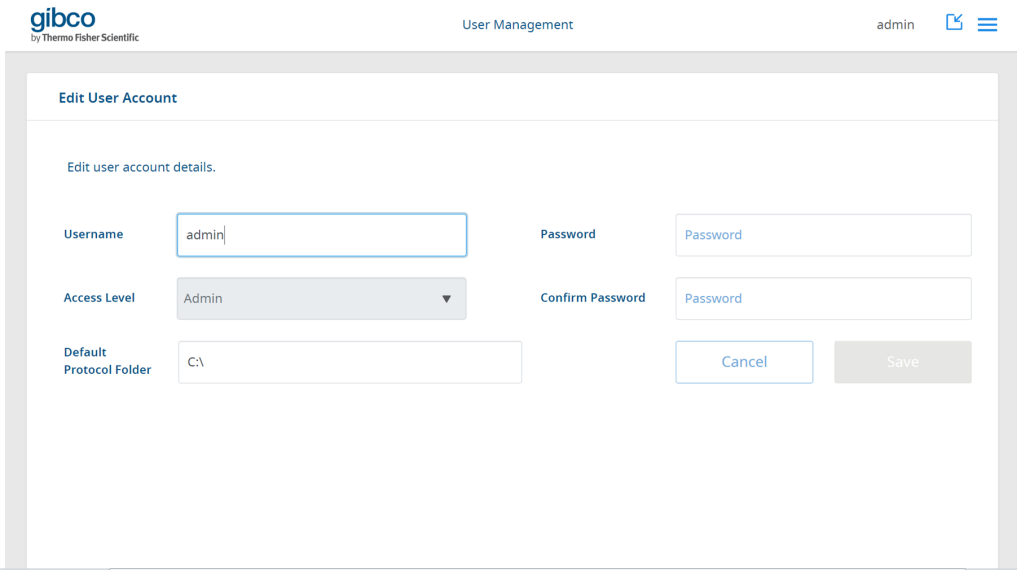
4. Click the **Settings** in the navigation menu to set the instrument name. Edit the instrument name if required.



5. Click **User Management** in the navigation menu to change the admin username/password. This page shows all the users configured for in the application. Click the **admin** user to change the account details. New users can be added with the **+** button.



6. Change the admin user account username, password and the default directory for this user to find protocols. Click **Save** for any changes.



7. The configuration is now complete.

Download protocols

Create protocols

Protocols comprise a series of individual steps that are to be perfomed by the instrument. Triggers are used to define when the instrument will move to the next step. A range of existing protocols can be downloaded from the Thermo Fisher Scientific portal.

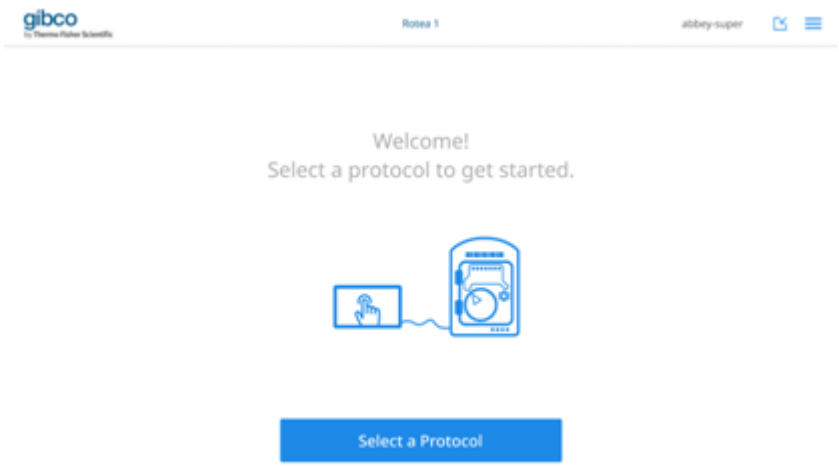
Users can also modify existing protocols or create entirely new protocols using the **Rotea Protocol App** that can be installed on any Windows™ PC, laptop or tablet.

Protocols can be saved for future retrieval using the GUI.

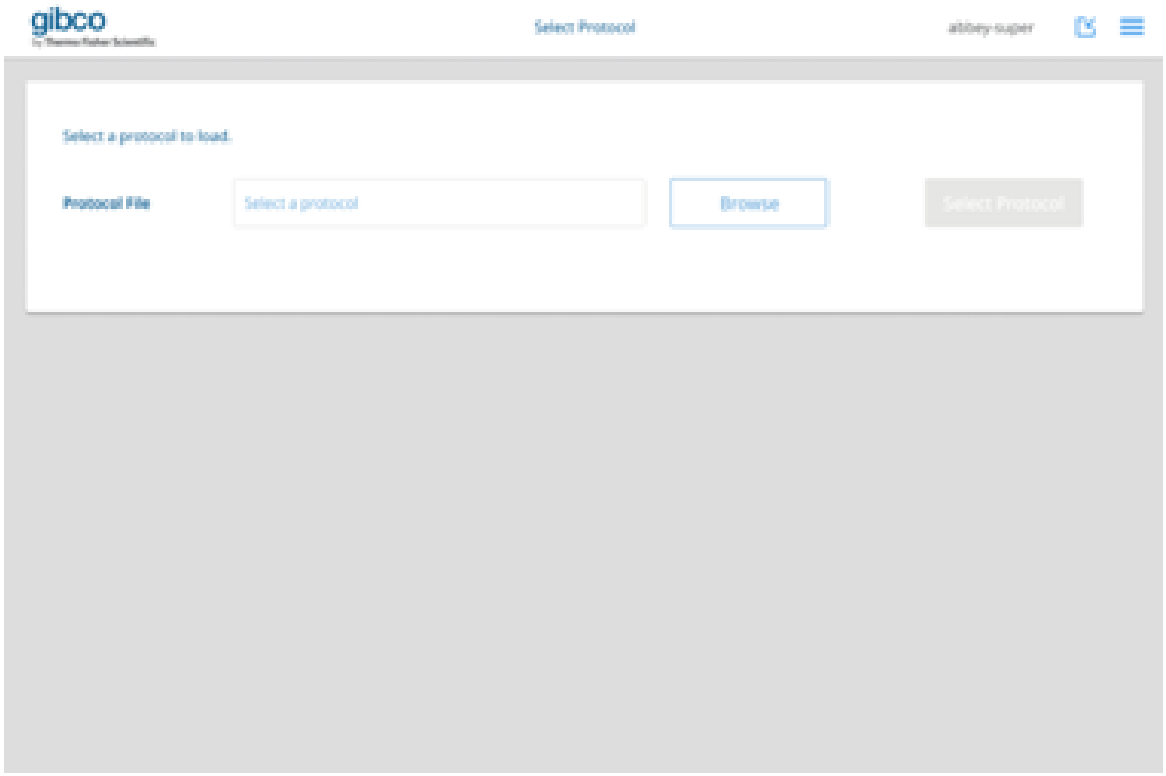
The **Rotea Protocol App** can be accessed at any time by clicking on the icon on the desktop.

Load a protocol

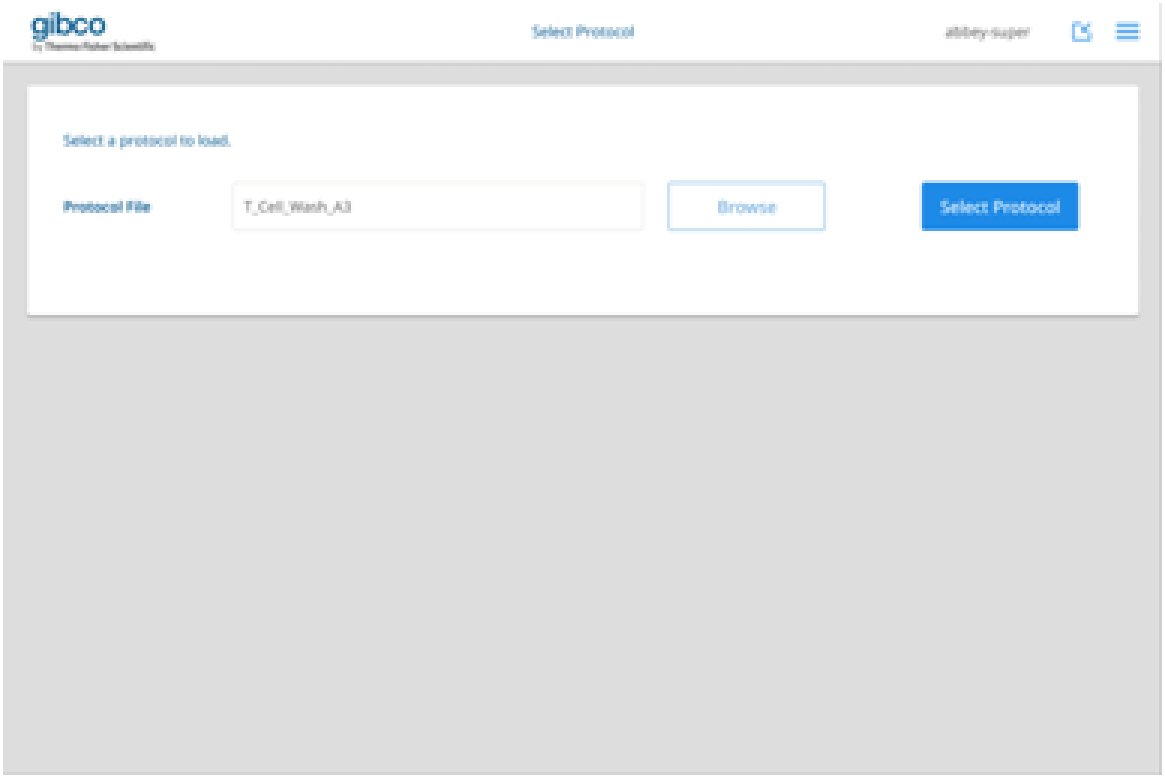
1. Click on the **Select a Protocol** button



2. Click **Browse** or **Select a Protocol** to browse for a protocol stored locally or on any connected devices.

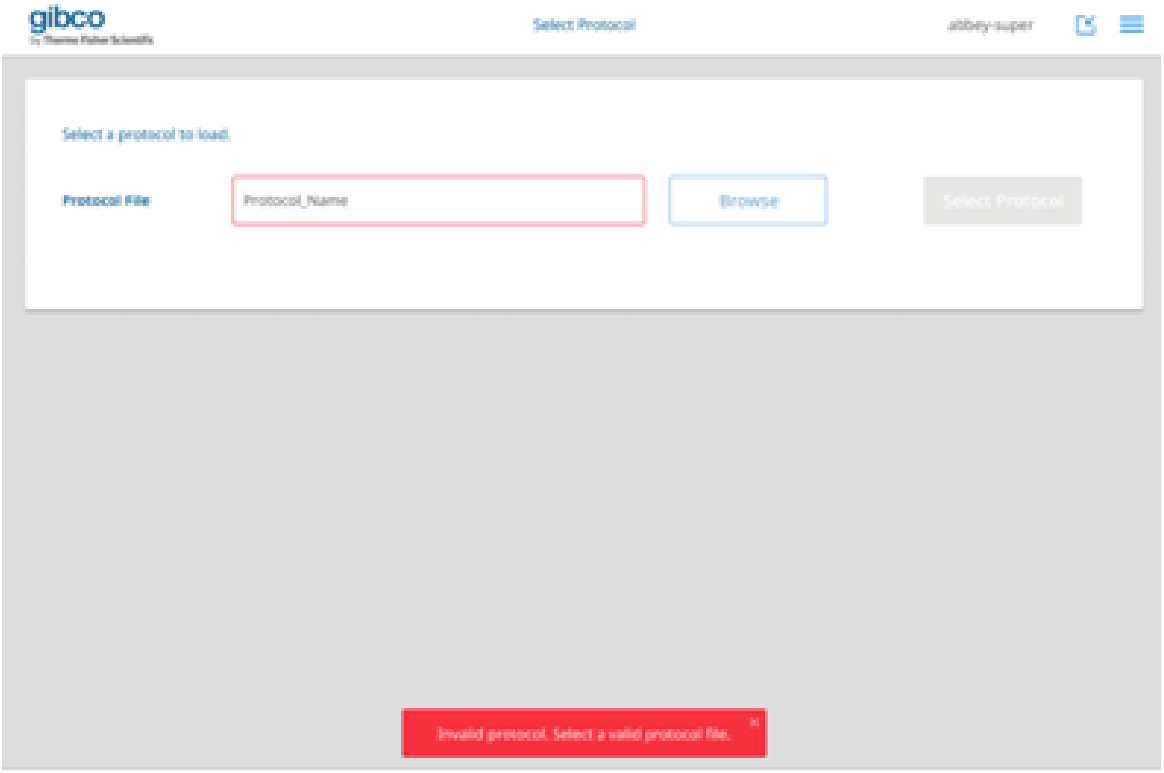


3. Double click the required protocol to display the filename in the **Protocol File** text box.



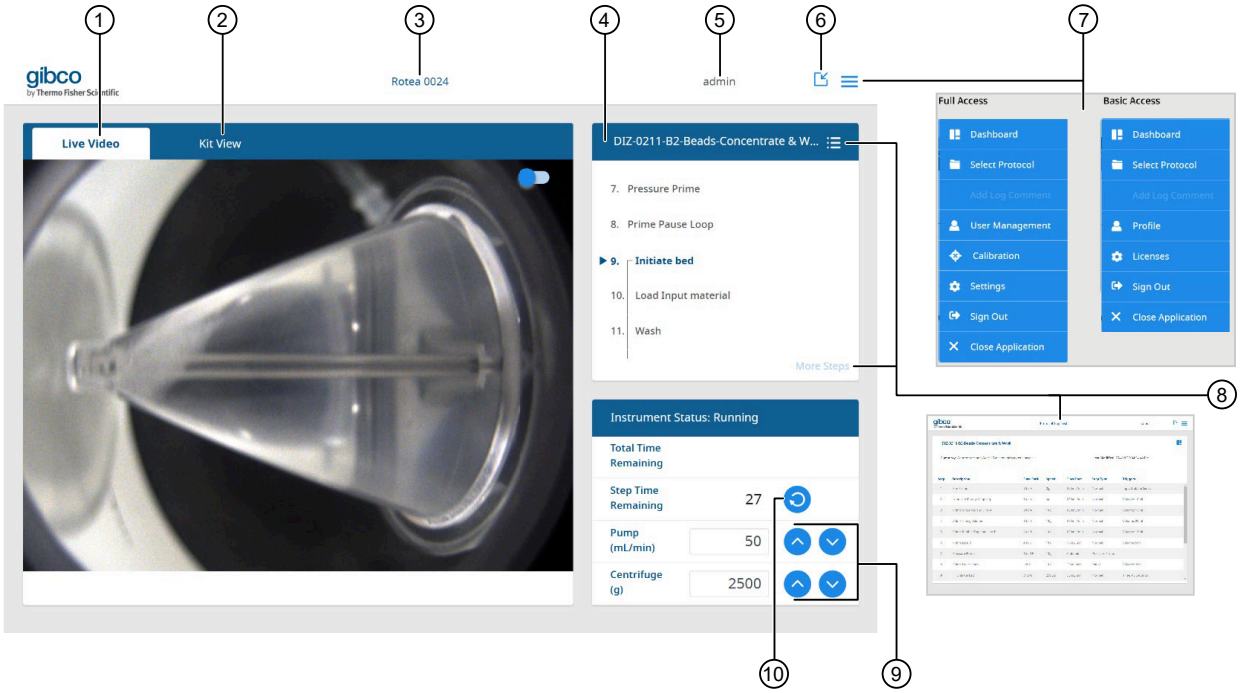
4. Click on **Select Protocol**.

Note: If an invalid protocol is selected, a warning box will be displayed.


gibco
Select Protocol
Select a protocol to load.
Protocol File
Protocol_Name
Browse
Select Protocol
Invalid protocol. Select a valid protocol file.

Rotea™ GUI dashboard

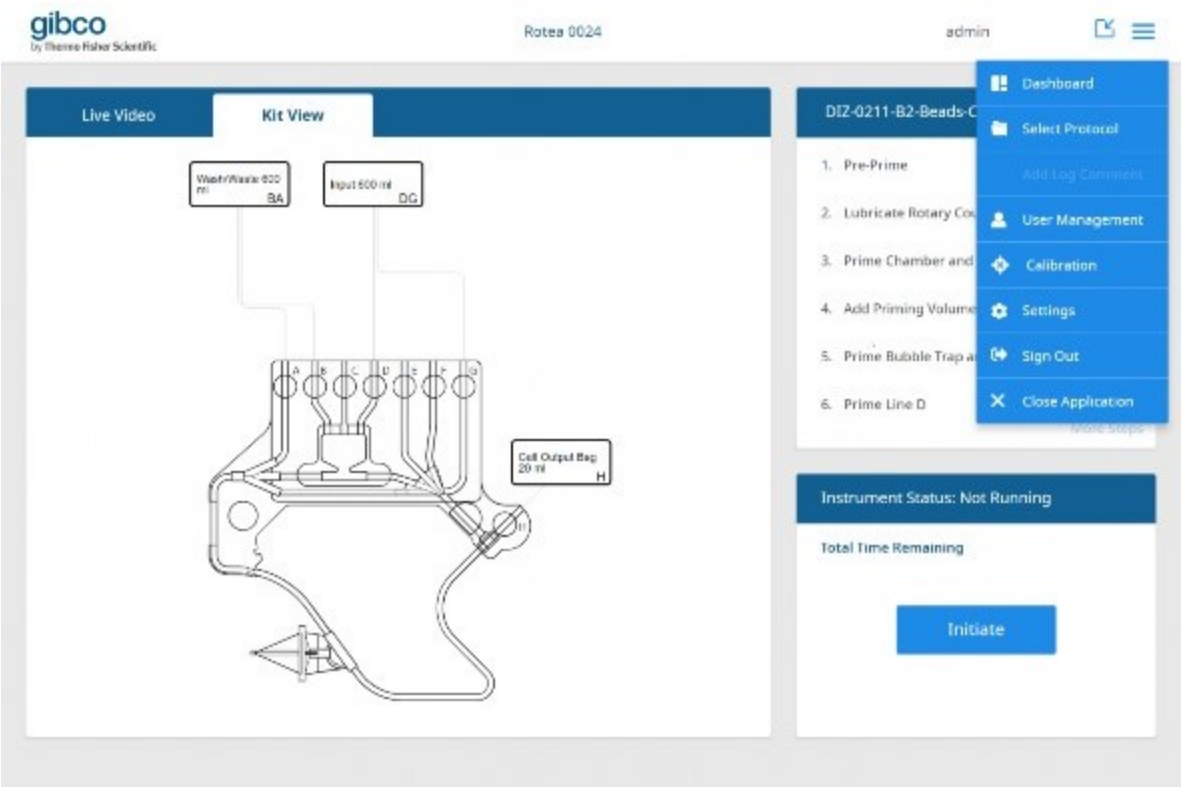
The Rotea™ GUI dashboard is the primary means of navigation around the Rotea™ GUI and operation of the Rotea™ instrument. It can be operated using the laptop touch screen only or with the keyboard attached.



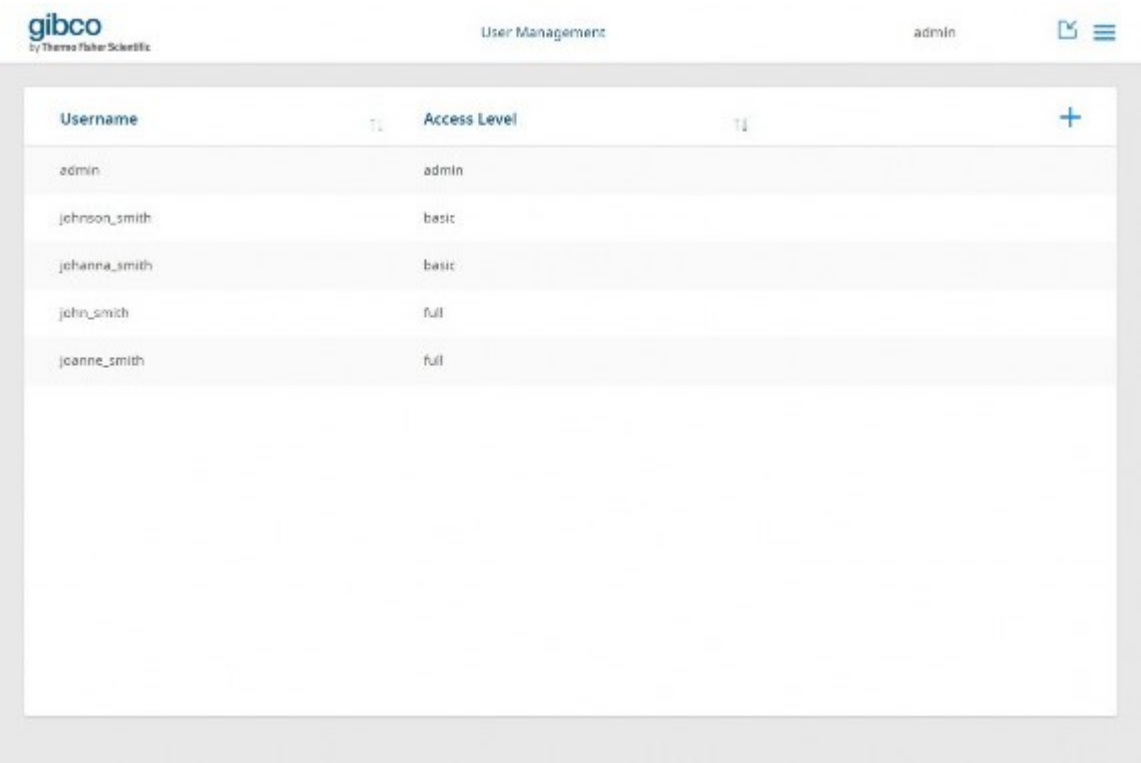
1. Live video of the spinning centrifuge chamber
2. **Kit View** for the current step
3. Instrument name
4. Protocol name and list of adjacent steps (current step in bold)
5. Username
6. Minimize screen
7. Dropdown menu
8. Shortcut to **Step List**
9. Manual speed adjustment (buttons or keyed values)
10. Resettable timer

User Management

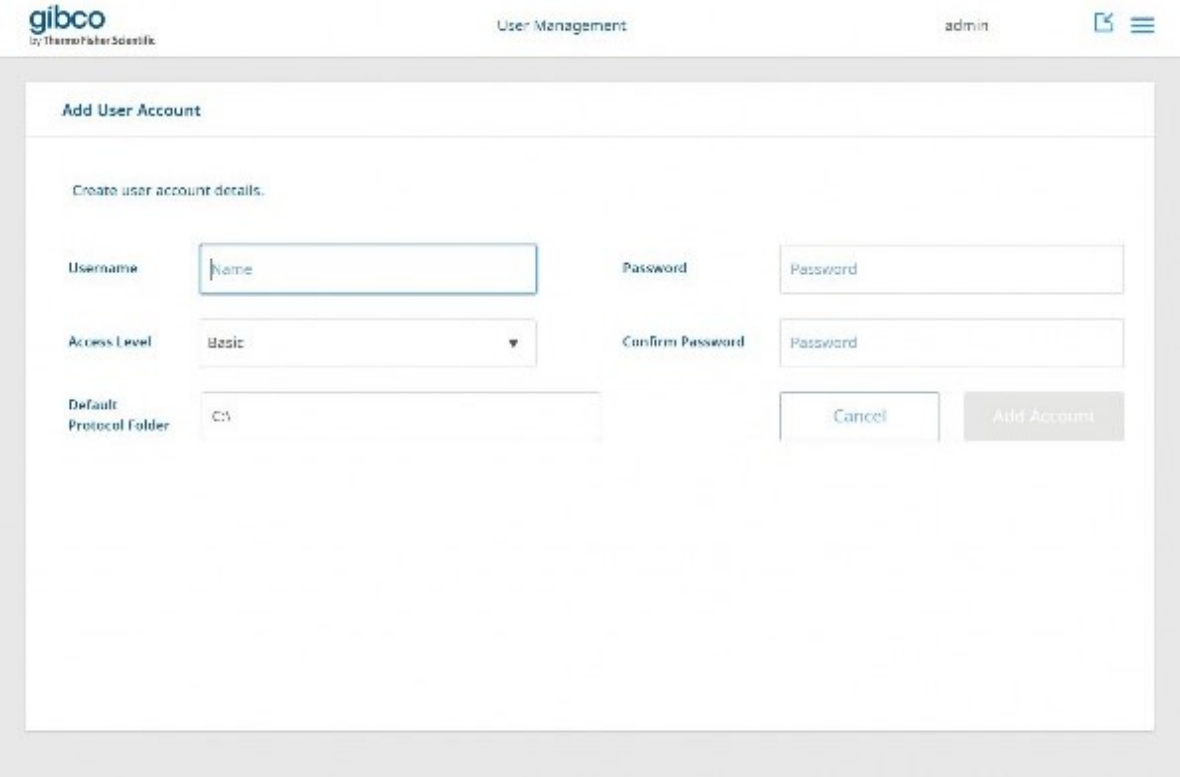
1. Select **User Management** from the dropdown menu.



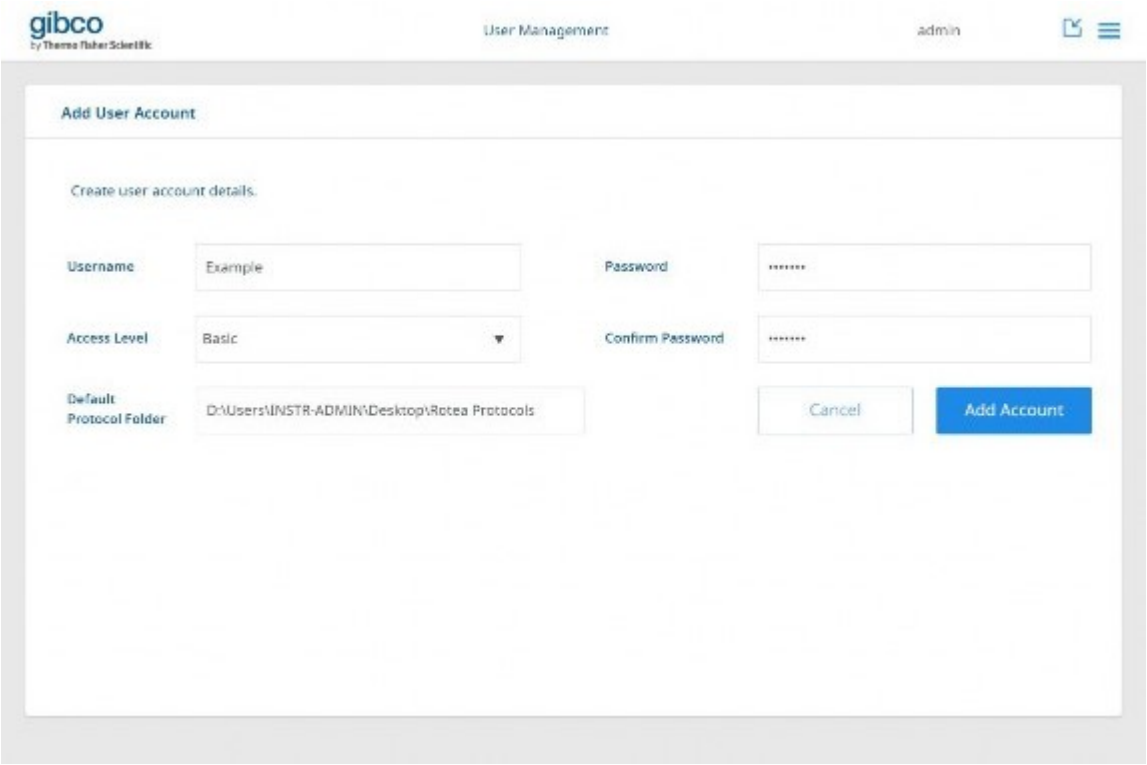
2. Click on the **+** icon to add a new user.



3. Type in new **Username** and **Password**.



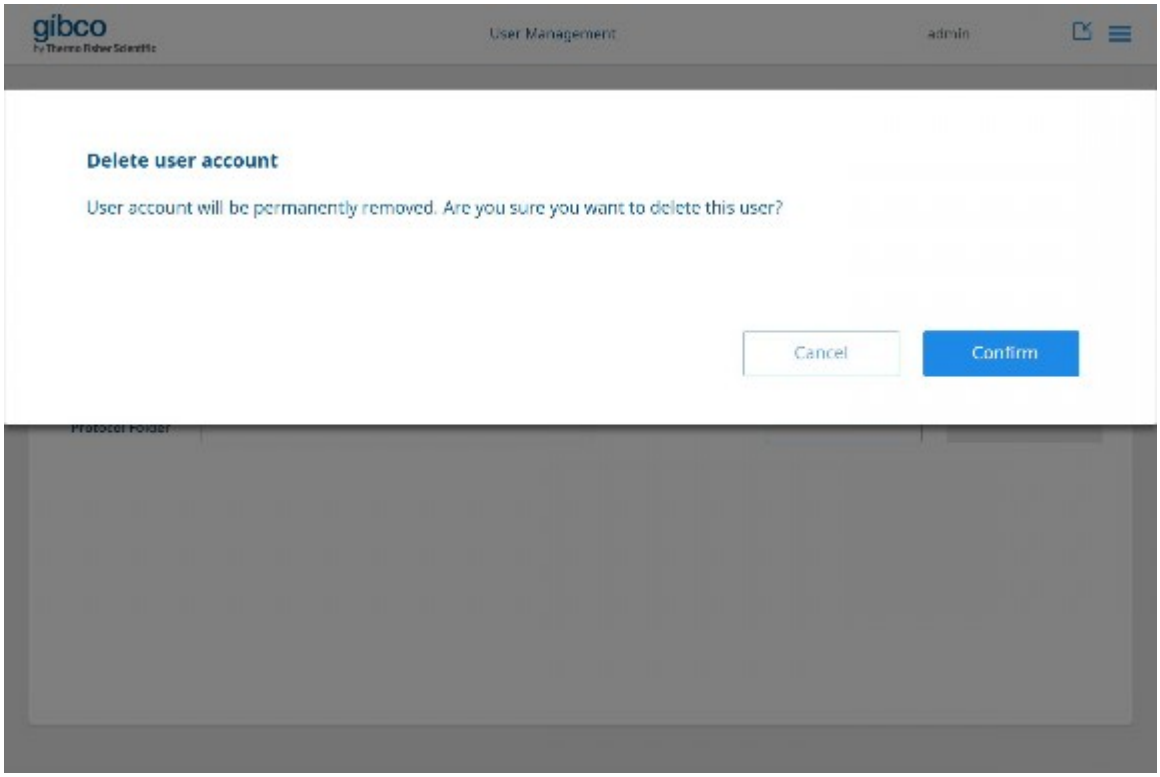
4. Confirm new password.
5. Select **Access Level** from dropdown list.
6. Select default folder for saving protocols.
7. Click **Add Account** to save new user settings.
8. Edit user account details including setting **Access Level**.



9. Click **Save** or **Cancel**.

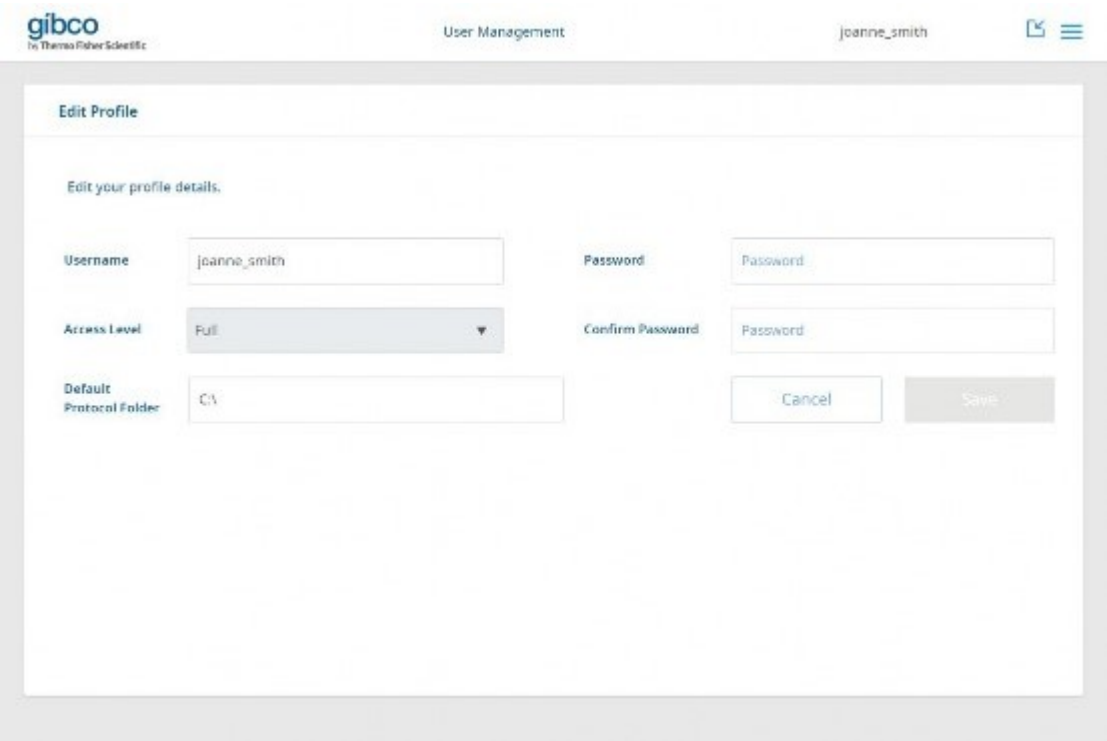
Note: Edits to **Access Level** can only be performed by a user with admin rights.

10. Select to delete a user.



11. Click **Confirm** or **Cancel**.

12. Users without admin rights can edit their profile by selecting **Profile** from the dropdown menu.

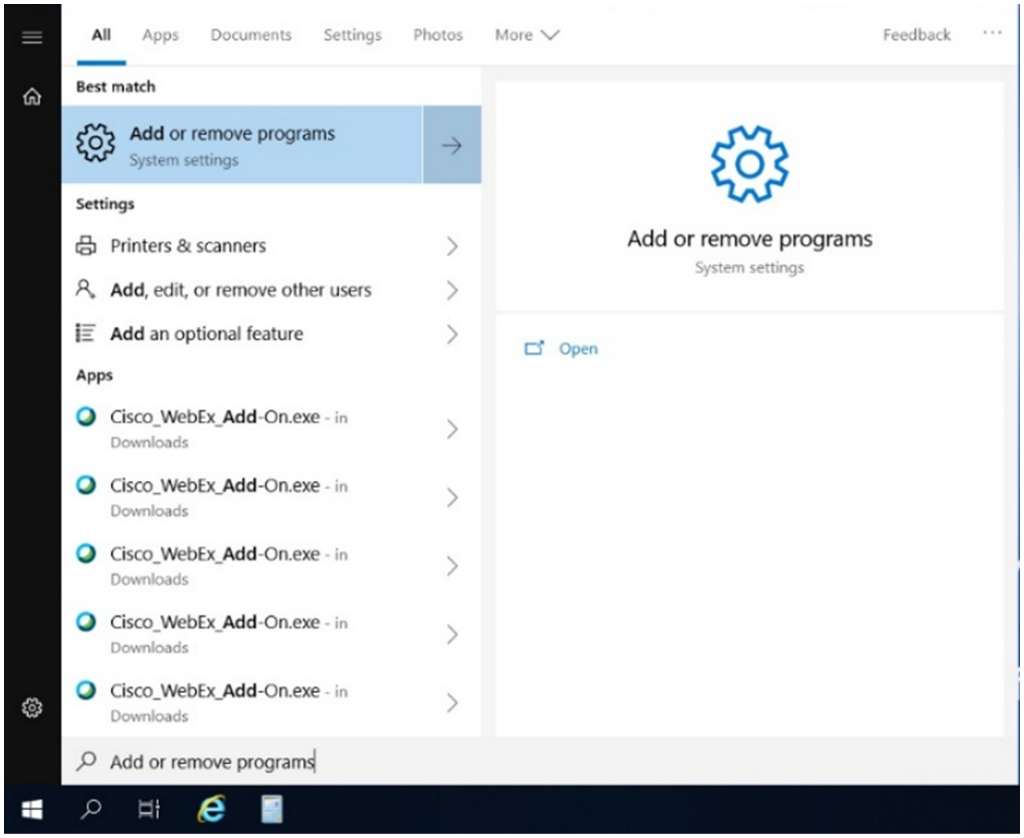


13. Edit user profile fields.

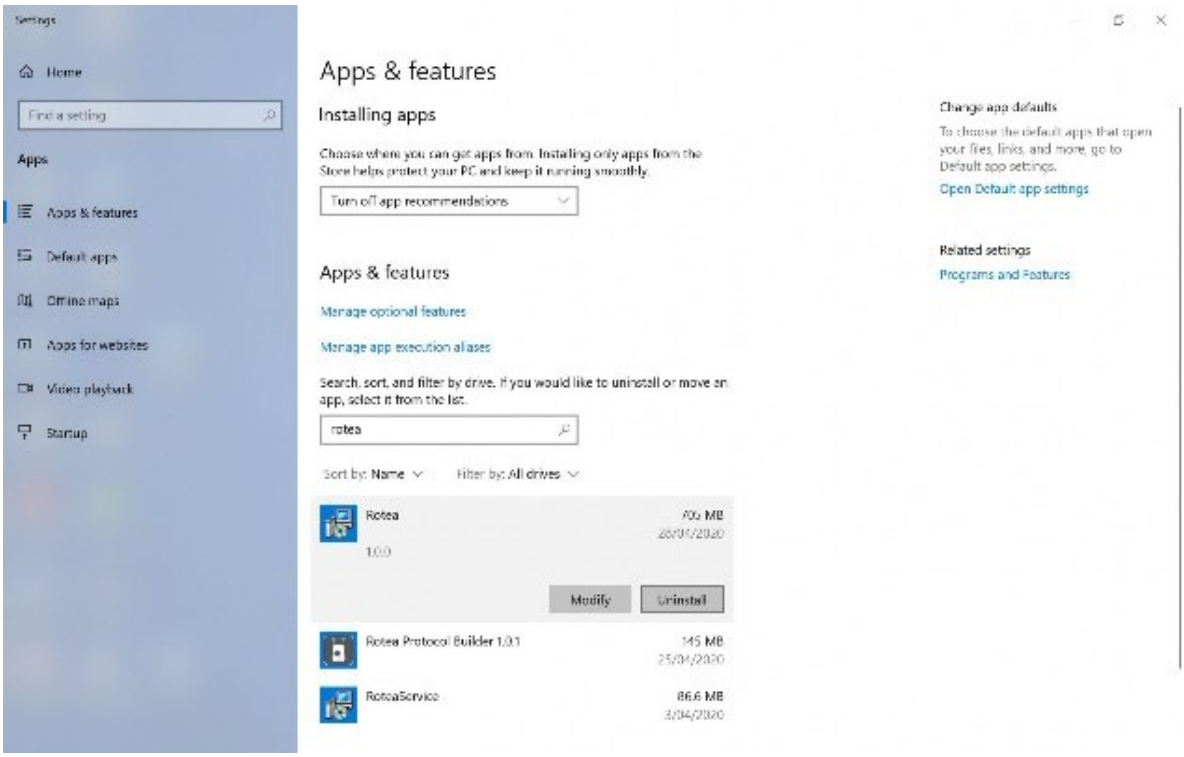
14. Click **Save** or **Cancel**.

Uninstall

1. Open the **Add or remove programs** utility by searching for it in the start menu.



2. Search and remove the Rotea™ application.



3. Wait for the uninstall to complete and the Rotea™ application will be removed. The user database and log files will not be deleted when the application is uninstalled. If the user wants to permanently delete them, they need to be deleted manually by removing the `C:\ProgramData\Rotea` directory.

Logging

The application saves several logs. The main logs of interest to the user are the run logs which contain a run history of each run performed by the laptop.

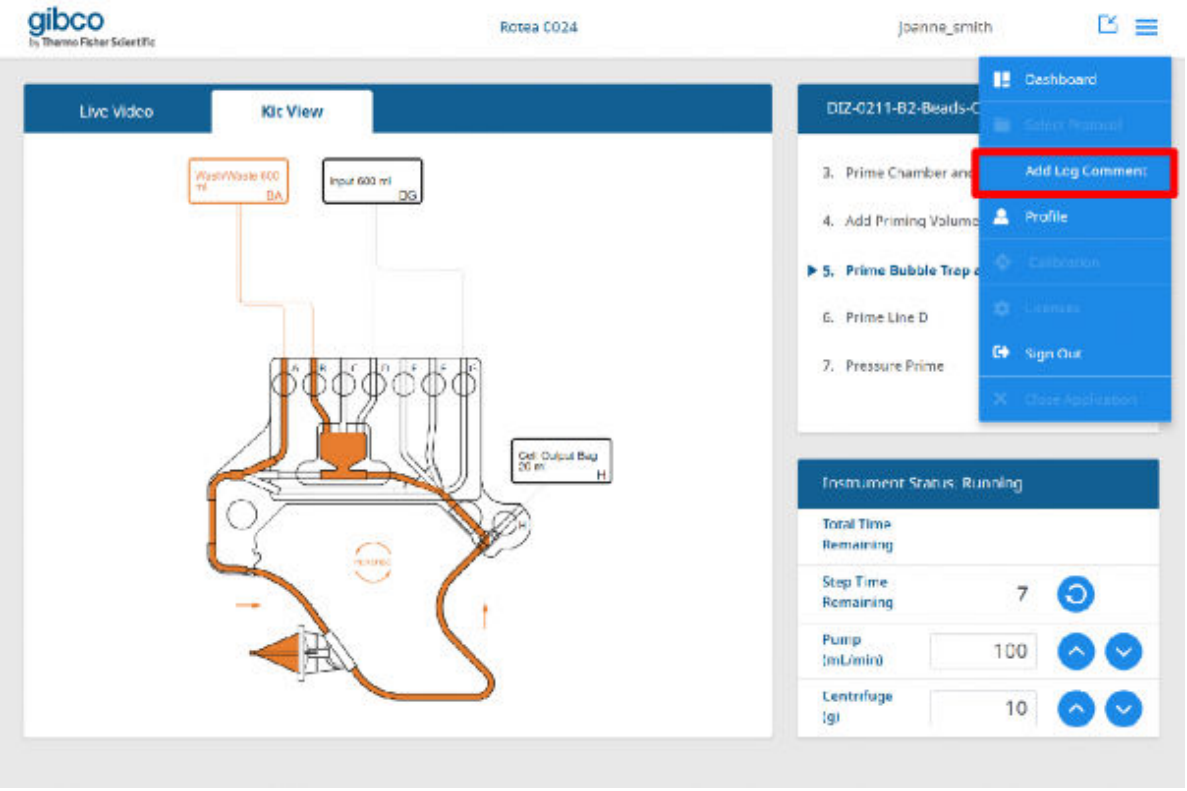
The run log files are saved in: `C:\ProgramData\Rotea\logs\run_logs`.

The service logs are saved in: `C:\ProgramData\Rotea\logs\service` and may be required for warranty claims and to help resolve application issues.

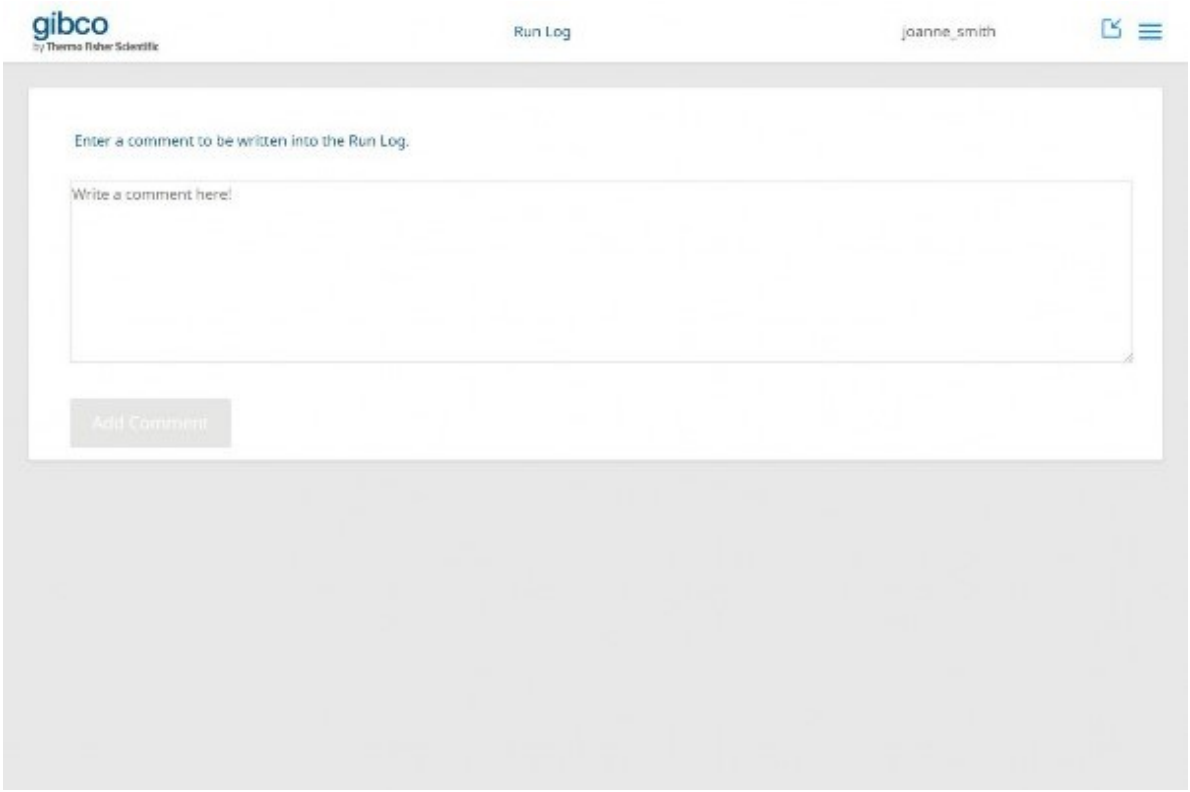
Note: The **ProgramData** directory is a hidden directory, typing `C:\ProgramData\Rotea` in the address bar will take you to the directory.

You can also add notes to the run log.

- Click **Add Log Comment** in the dropdown menu during a protocol run.



- Write comment in the comment box and click **Add Comment**.



3 Basic instrument operation

Open the door

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

- Instrument is powered up
- Blue door unlock button is illuminated
- Instrument is not currently running a protocol
- Centrifuge carrier and peristaltic pump are stationary

1. Press pushbutton when it is illuminated to unlock the door.

2. Open the door and raise until past vertical.

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

Note: An emergency maintenance access method can be used to open the door should this be required e.g. in the case of power loss – (See “Open the door without power” on page 111).

When the unlock button is pressed, the safety circuit is disabled to prevent the pump or centrifuge from operating and triggers the following:

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

Note: If there is a Single-Use 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. Close all manual tube clamps before opening the door.

Kit preparation, loading and removal

Kit configuration

Once a protocol has been selected to run on the instrument, the **Kit View** on the Rotea™ GUI dashboard will display a schematic of the CTS™ Rotea™ Single-Use Kit with bag connections.

Figure 6 Instrument with CTS™ Rotea™ Single-Use Kit

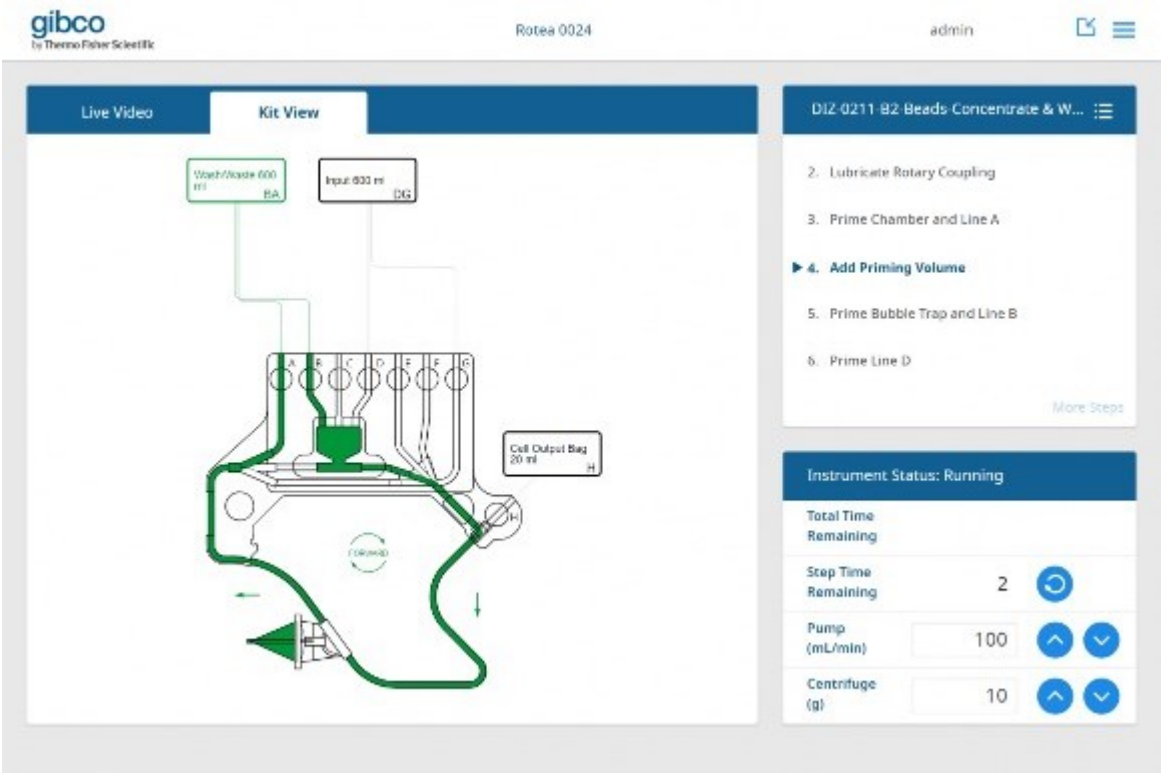


Figure 7 Rotea™ GUI showing Kit View

CAUTION! The Single-Use Kit has been designed exclusively for use with the Rotea™ 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.

CAUTION! The Gibco™ CTS™ Rotea™ Single-Use Kit (Cat. Nos. A49585, A49313) and CTS™ Rotea™ Hi-Flow Single-Use Kit (Cat. Nos. A46575, A49239) have been validated for one-time use by customers. Single-Use Kits are not recommended to be washed, re-sterilized, or reused as sterility and quality of these kits have not been validated for multiple uses.

Pre-assembly of processing kit

1. Peel open the sealed pouch and remove the Single-Use Kit.

2. Release the CFC Chamber from the Carrier Frame if still retained.

Connecting vessels, bags and reagents

The instrument has been specifically designed for single use, functionally closed processing. The CTS™ Rotea™ Single-Use Kit uses DEHP-Free PVC 0.160” OD tubing to enable sterile welding to compatible bags using devices that service the blood banking industry such as the TSCD II Sterile Tubing Welder (TerumoBCT). See the instructions provided by instrument providers for completion of sterile welding.

Figure 8 TSCD II Sterile Tubing Welder (TerumoBCT)

Bubble Trap

To manage air in the system, the CTS™ Rotea™ Single-Use Kit includes a small bubble trap with a capacity of approximately 5 mL.

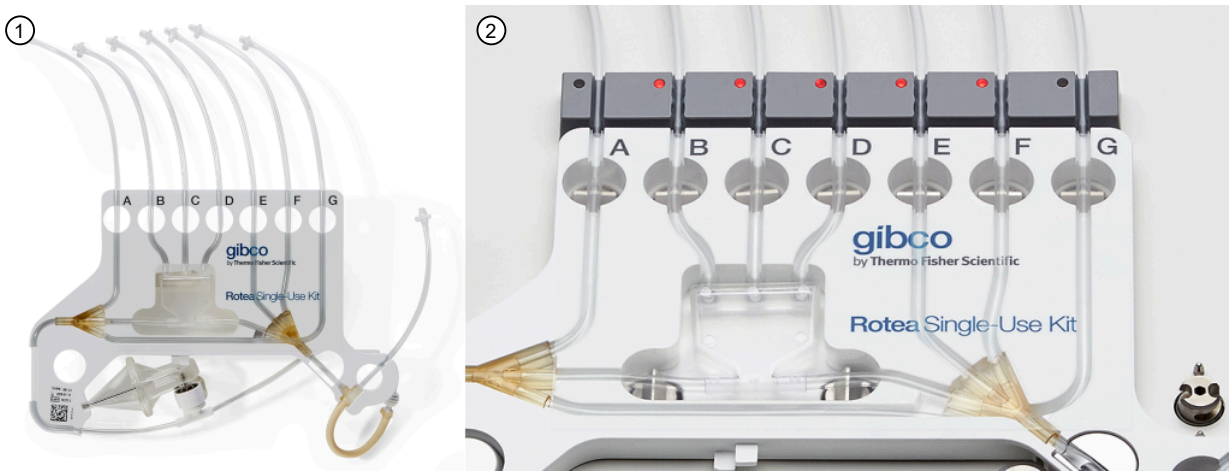


Figure 9 CTS™ Rotea™ Single-Use Kit and close-up of Bubble Trap

① CTS™ Rotea™ Single-Use Kit
② Close-up of Bubble Trap

CAUTION! Once the Bubble Trap volume is consumed, any additional air in the system will now be able to enter the CFC Chamber and ultimately cause an over-pressure fault, shutting down the instrument.

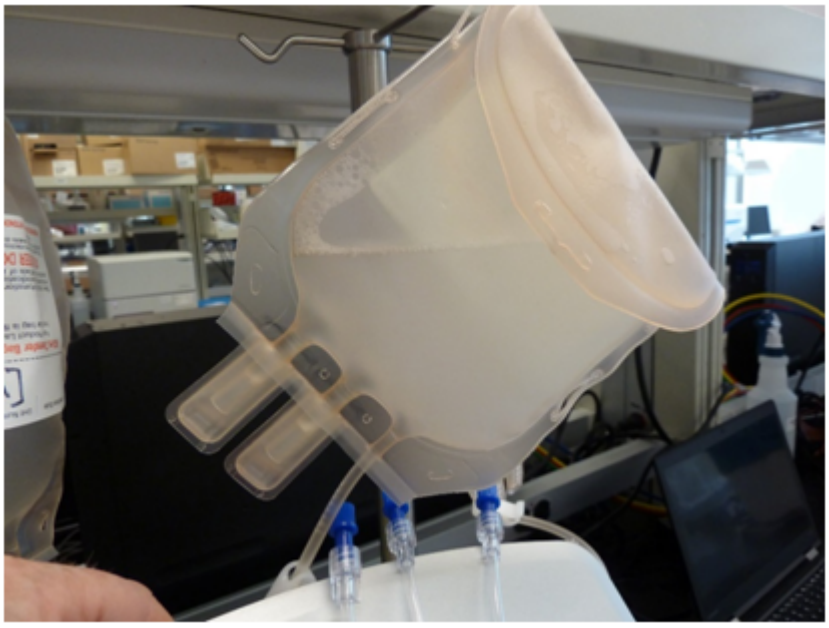
CAUTION! Protocols created for the Rotea™ instrument must include a suitable priming sequence to ensure air in fluid supply lines and the Bubble Trap is replaced with fluid prior to commencing processing.

Note: If the length of tubing from the product supply bag has a volume greater than the Bubble Trap, then air can enter the circuit. It is therefore preferred that the length of tubing for each connection (1/8" ID assumed) is less than 12" (or 300 mm). In some cases where the supply vessel is large, e.g. remote bioreactor, additional process strategies can be included to re-fill the supply tube when needed.

Kit installation

1. Ensure door is open and any previous Single-Use Kit has been removed.

2. Hang input / output bags on hanger hooks.

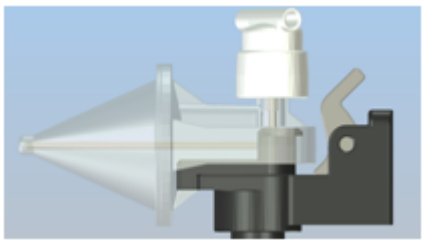


Note: The product input bag can be suspended using one of the side cut-outs on the bag to help ensure that all product drains from the bag.

3. Place the Carrier Frame over the two Single-Use Kit location buttons on the instrument.

4. Install the CFC Chamber into the CFC Chamber Carrier.
   a. Load CFC Chamber into the CFC Chamber Carrier.

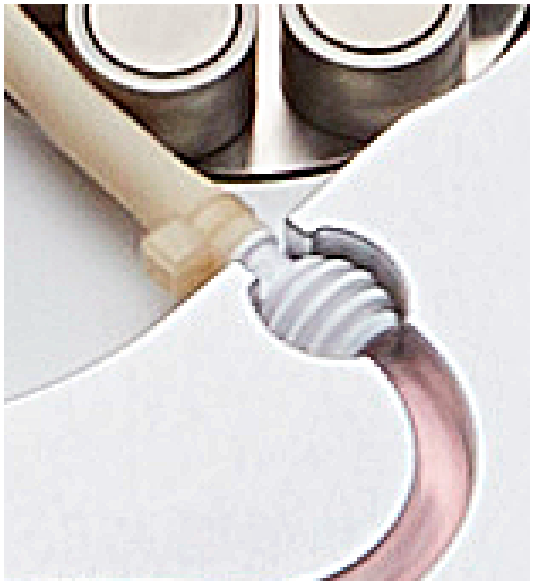
   b. Push CFC Chamber down into CFC Chamber Carrier to depress latch.



c. Slide CFC Chamber away from axis of rotation until the latch clicks.

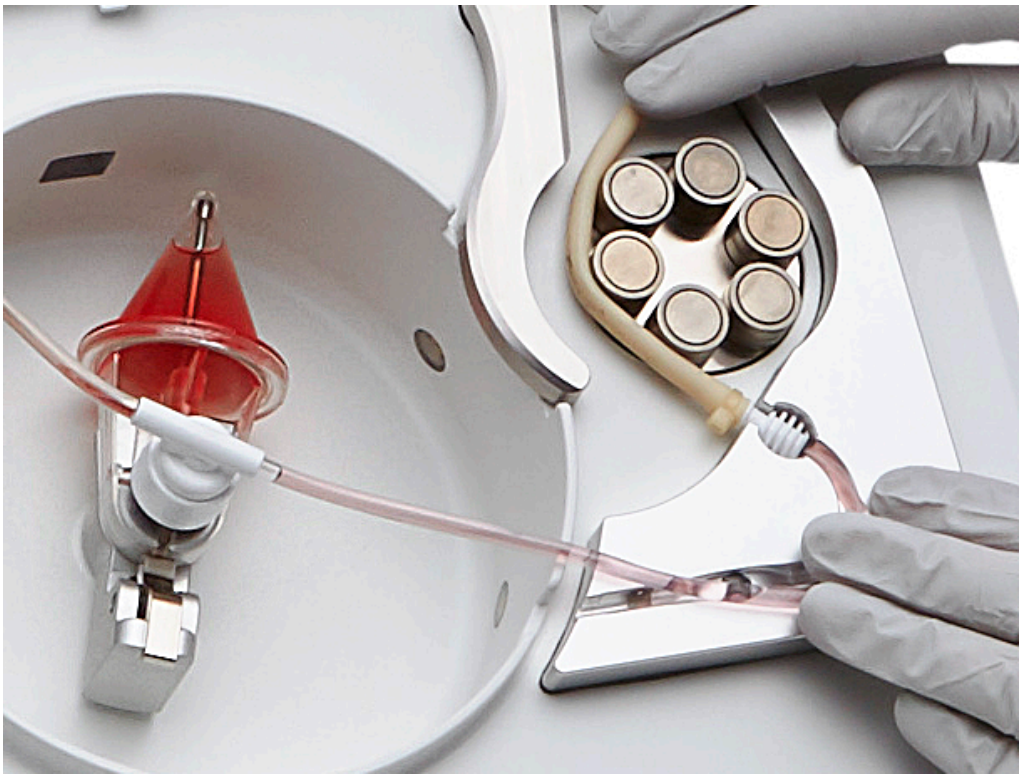
5. Insert tubes A, B, C, D, E, F & G into the corresponding slot in the Bubble Detector Strip and push downwards with fingers to fully engage each tube in the slot.

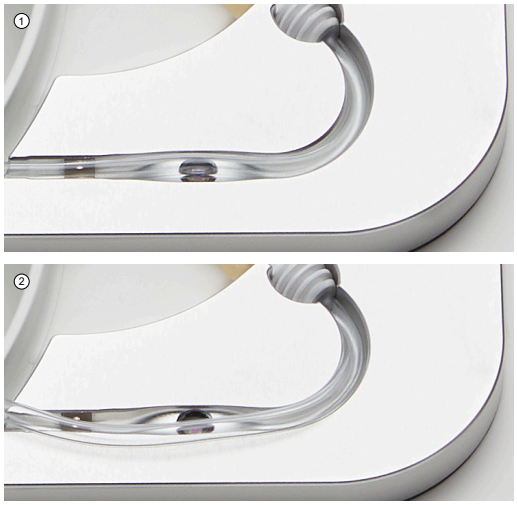
6. Stretch the pump tubing around the Peristaltic Pump rollers and insert the Tube Retainer into the Sensor Block to hold it in place.



Pump tube barbed connector correctly placed in the Sensor Block.

7. Insert tubing in Sensor Block channel.





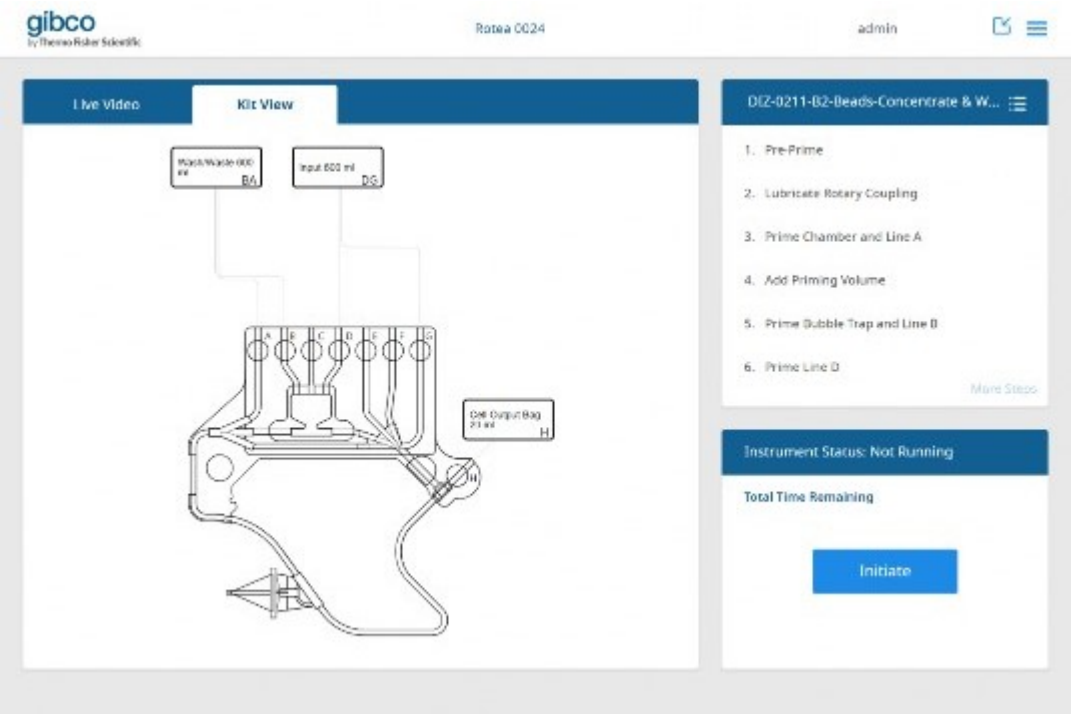
① **Correct**: Pressure Sensor tubing in
② **Incorrect**: Pressure Sensor tubing out

CAUTION! The instrument cannot detect if the pump tubing or Tube Retainer have been correctly positioned. Check prior to closing the door.

CAUTION! The tube will sit slightly proud of the channel in the region of the Pressure Sensor so that the tube is compressed into the required shape when the door is closed. If not correctly located in the channel, the tubing may be crushed when the door is closed.

Initiate a protocol

1. Click **Initiate** to commence running the protocol.

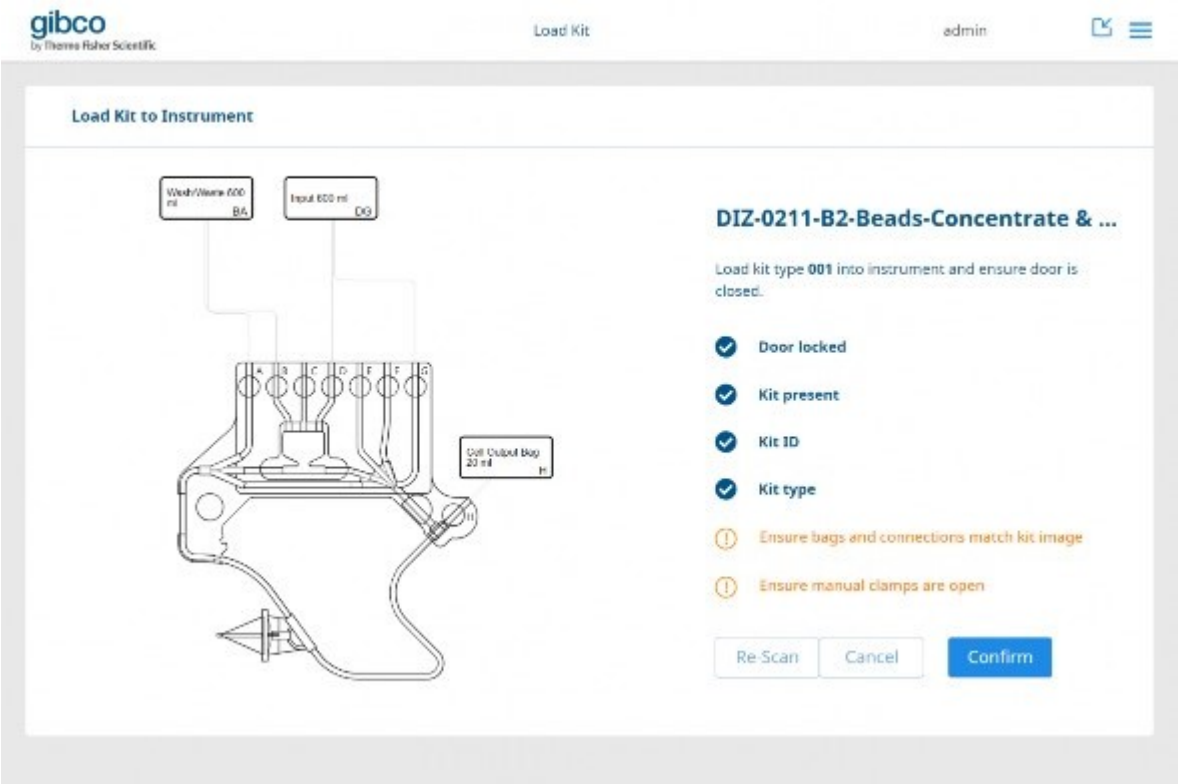


2. Close the door.

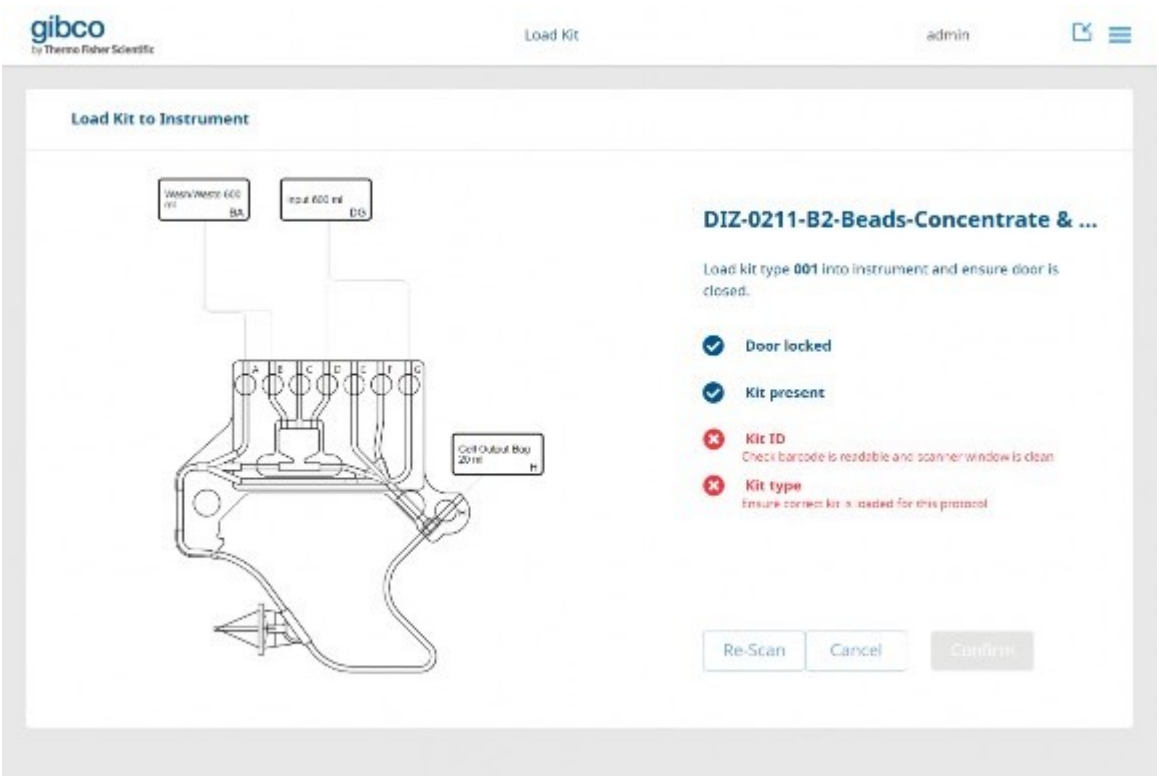
Note: Soft close hinges prevent the door from dropping suddenly.

3. Push the door downwards to compress the Single-Use Kit tubing onto Pressor Sensors and other control features.

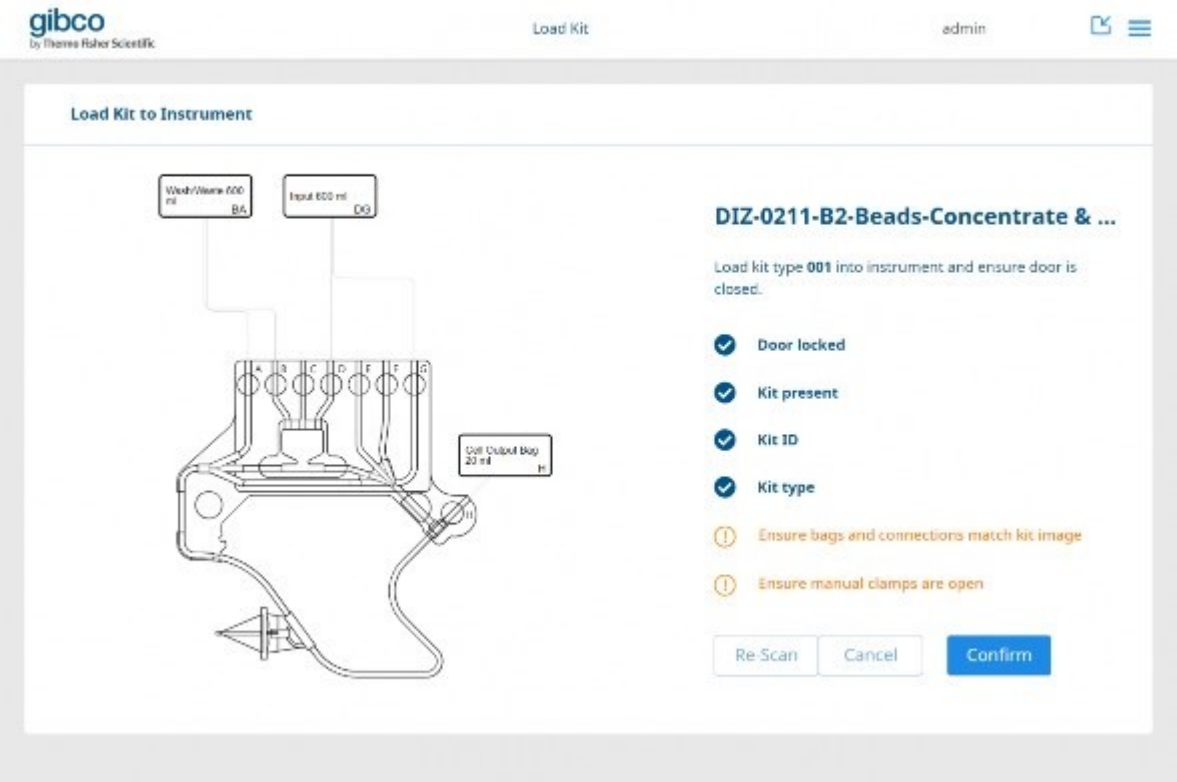
4. (auto): Closing the door initiates the following automatic system checks. The status of each system check is displayed on the Rotea™ GUI with ✔ indicating correct installation of the Single-Use Kit.



5. Errors detected during the automatic system check are identified with a ⊗ and will require the user to identify and rectify the source of the error.



6. Manually confirm that the Single-Use Kit configuration matches the image and that manual clamps have been opened.



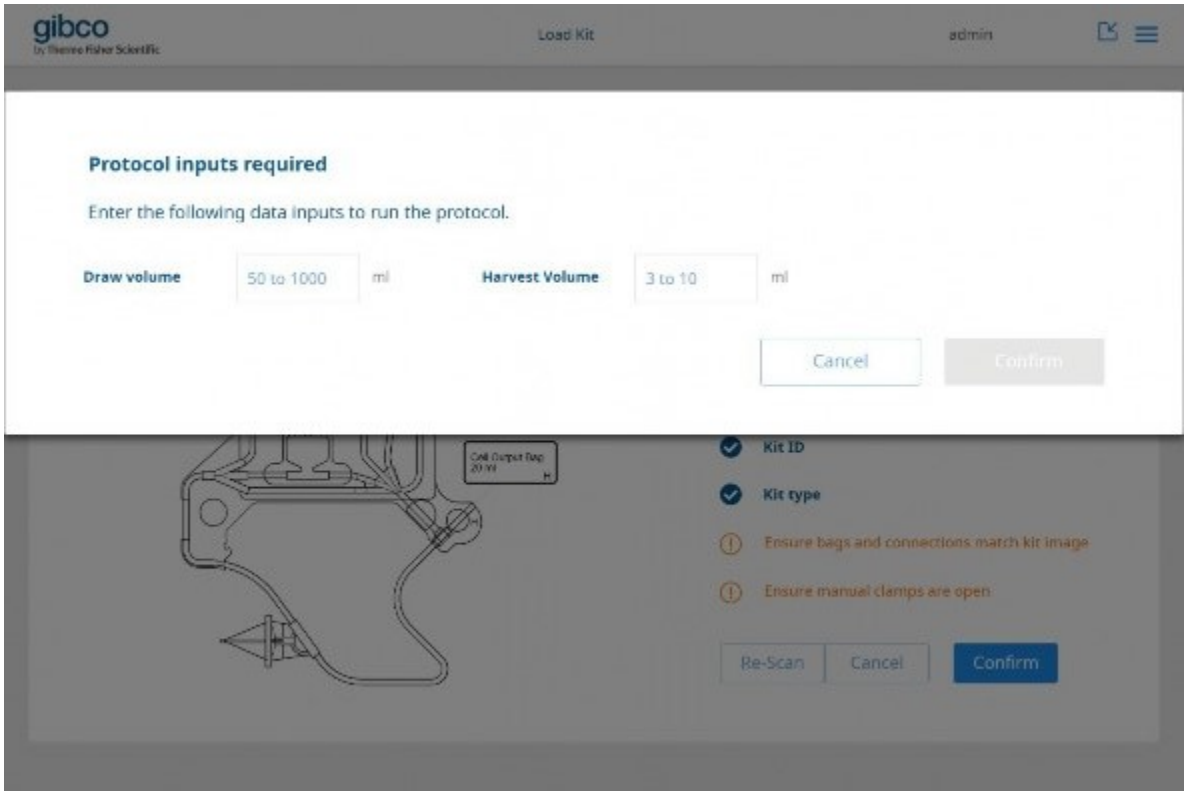
7. Click **Confirm** to continue.

CAUTION! Manual clamps are provided for use on input and output lines on the Single-Use Kit to prevent fluid movement until the instrument Pinch Valves are engaged. However, manual clamps also represent a significant process hazard if left in the closed state. Whilst the instrument should detect this failure mode as an over-pressure fault, it will stop the process potentially compromising the batch. **Release all manual clamps prior to starting the automatic sequence**.

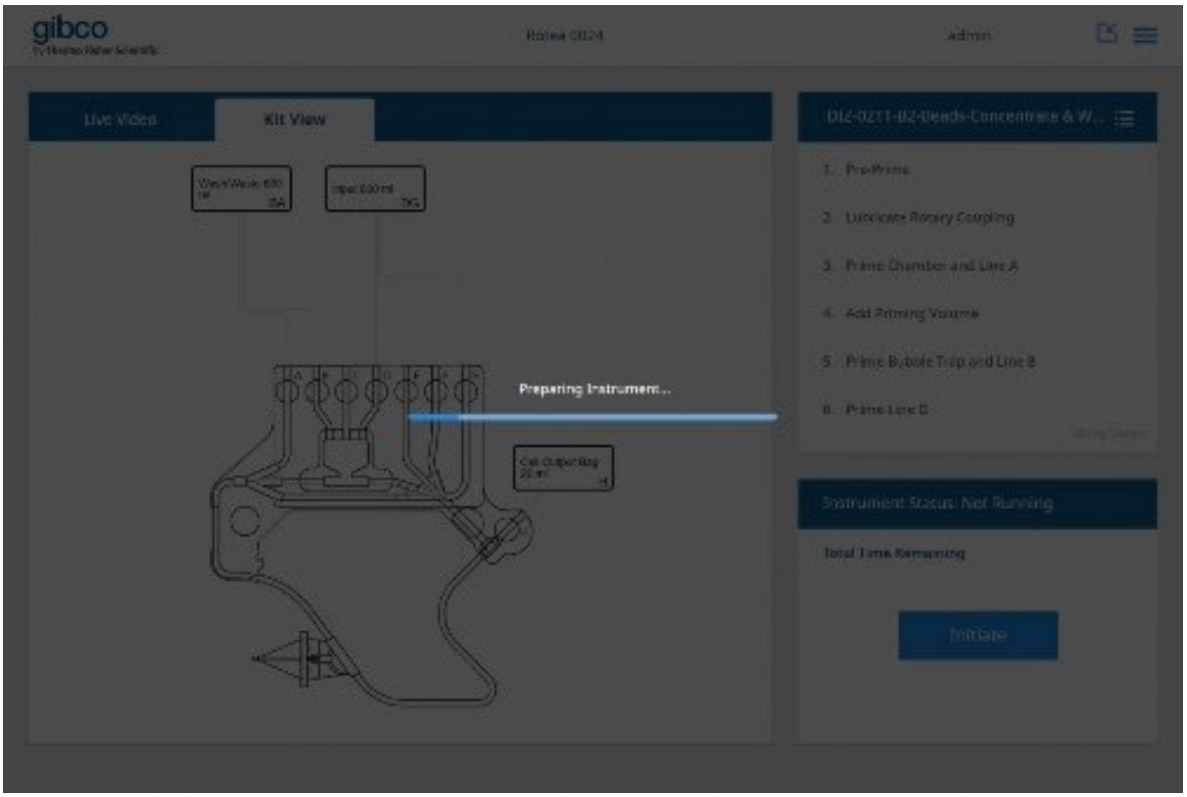
If required by the selected protocol:

8. Enter data inputs.

9. Click **Confirm** or **Cancel**.



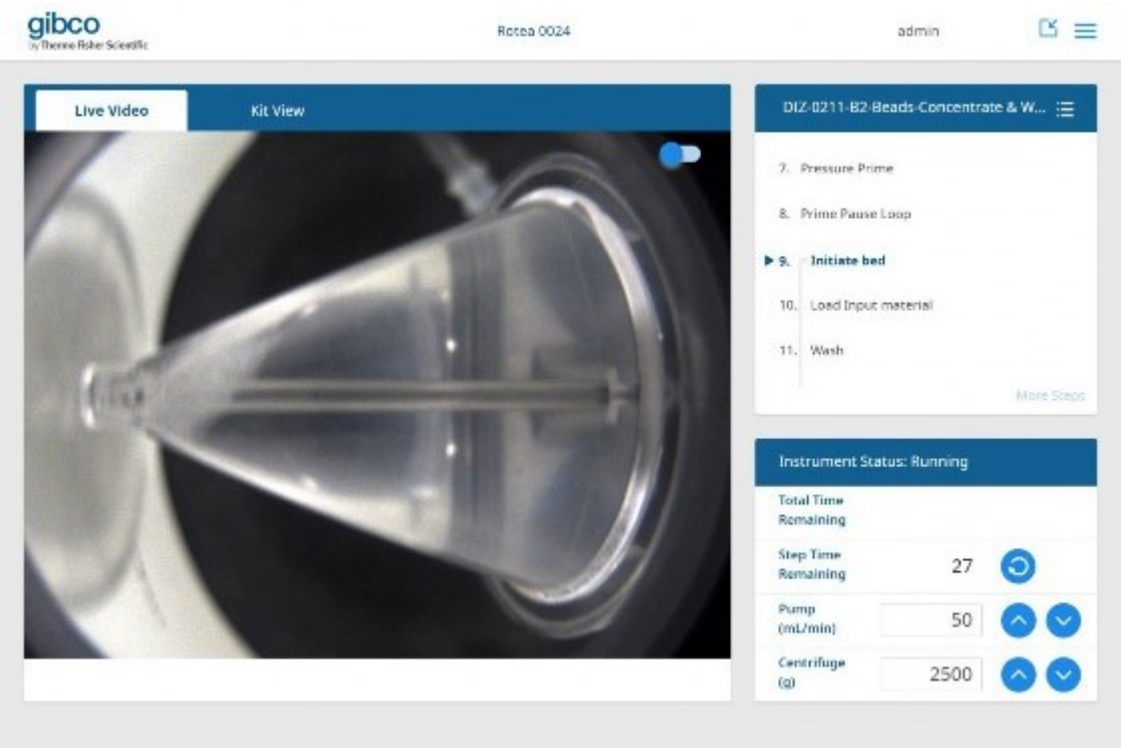
10. The protocol is automatically sent to the instrument and the Rotea™ GUI dashboard is displayed for the new protocol.



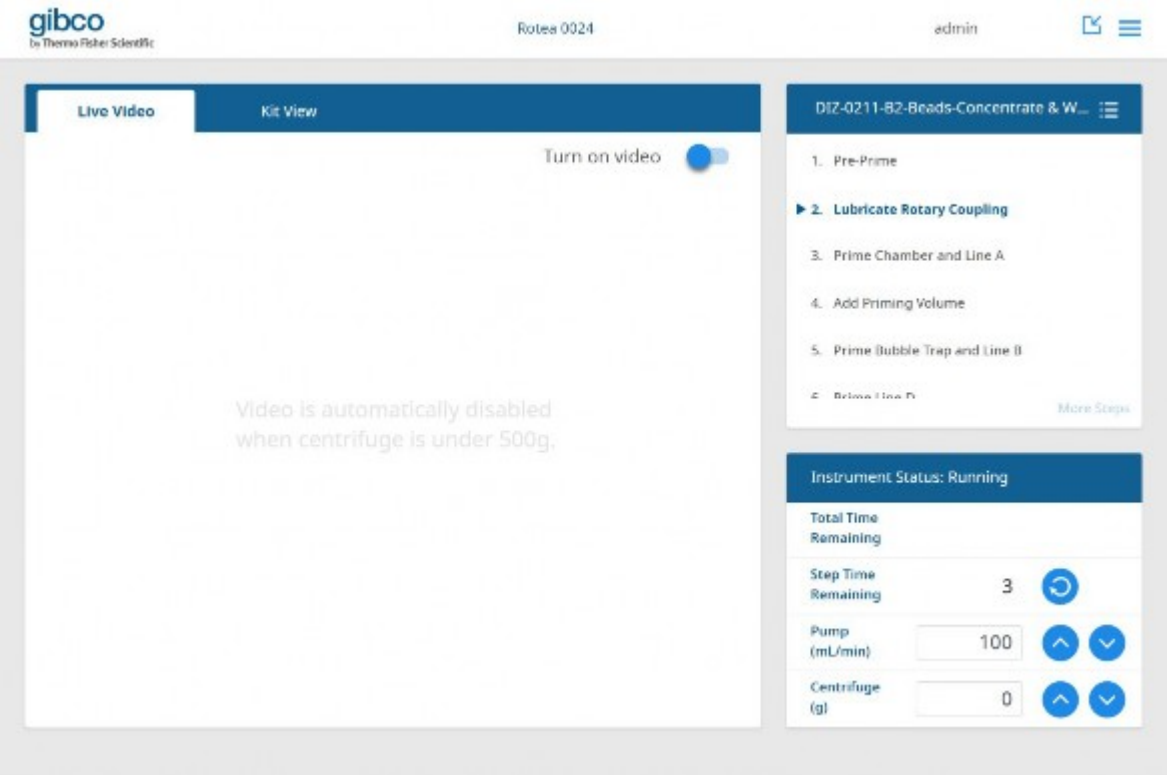
Run a protocol

Rotea™ GUI navigation and instrument operation

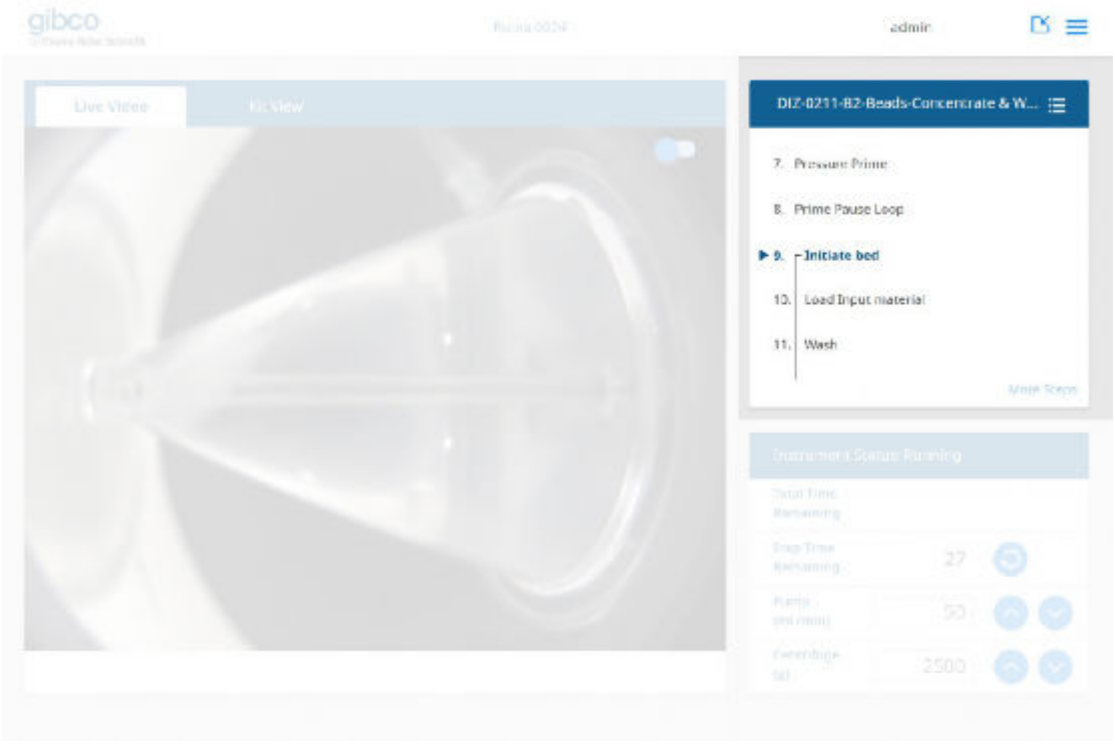
1. Press the **Start** button on the instrument to start the protocol.
2. Change the Rotea™ GUI dashboard view as required by clicking on the tabs.



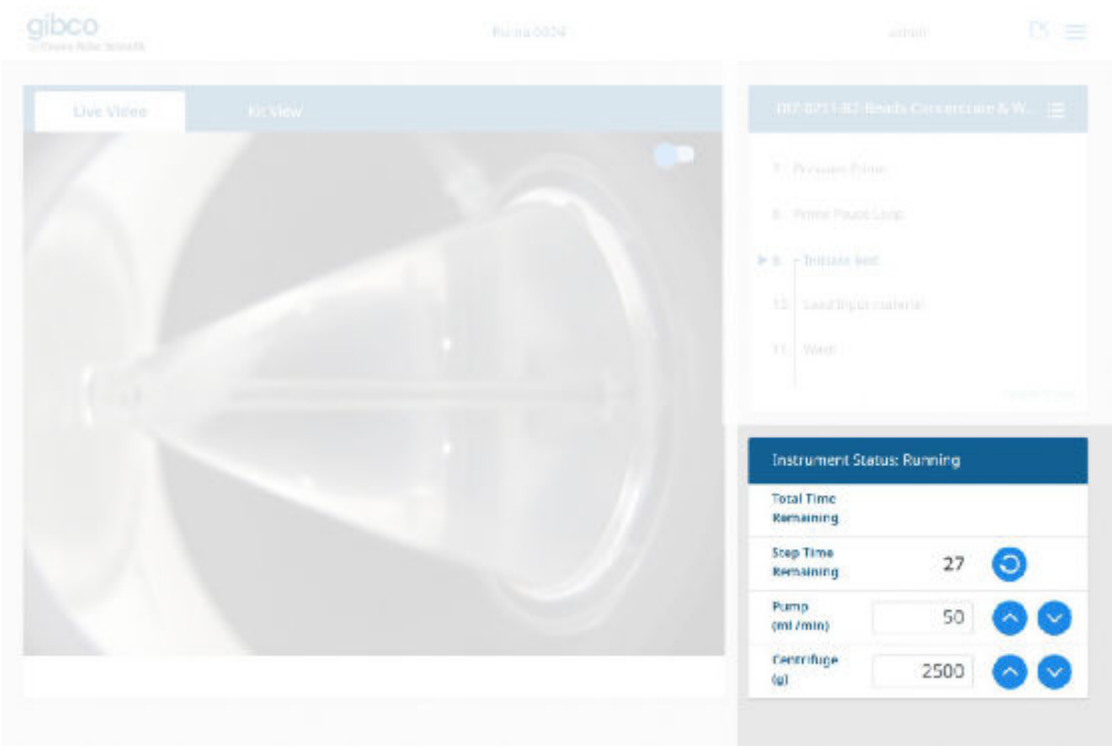
3. The live video will automatically turn on when the centrifuge speed exceeds 500 × *g*. The live video can be manually turned on at any operating speed by clicking on the **Turn on video** toggle.



4. The instrument will automatically progress through each step in the protocol until the protocol is complete, pre-defined user intervention is required or an error occurs.

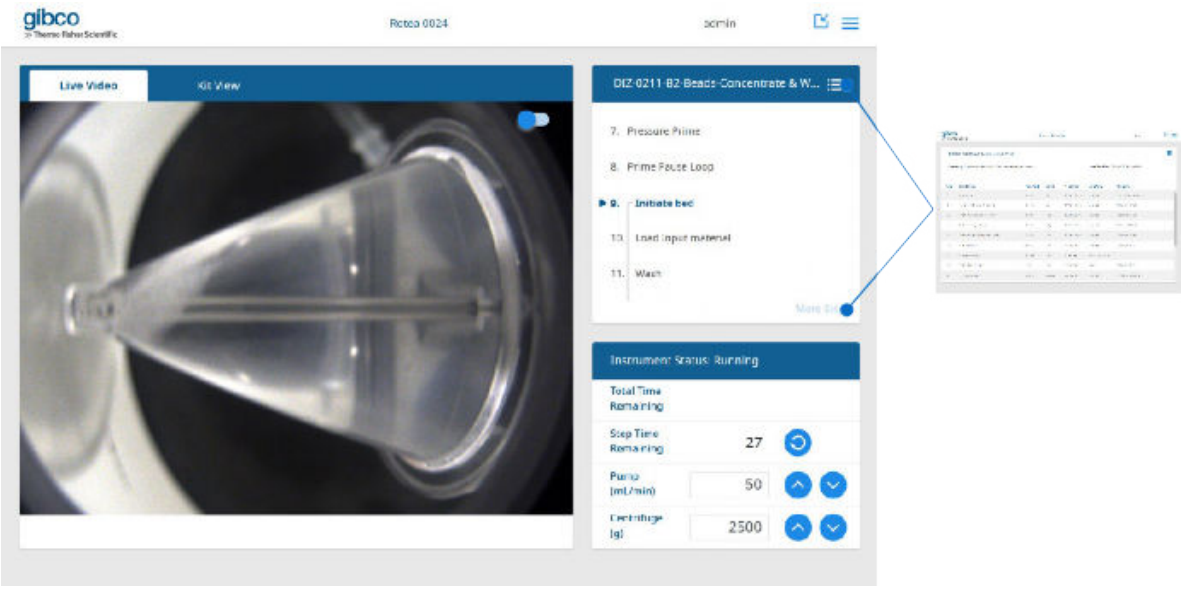


5. Depending on user access rights, the user can make in-process adjustments to the following parameters using the control buttons:

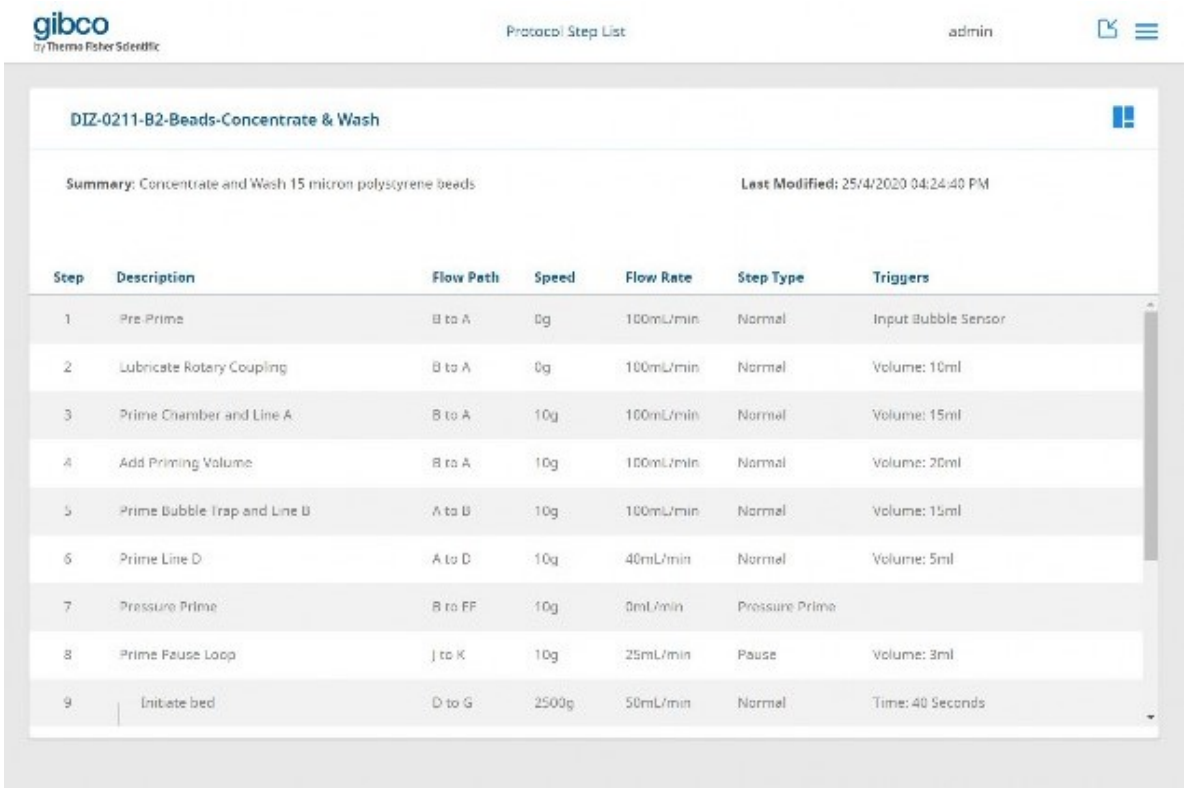


- Reset **Step Time Remaining**
- Increase/reduce **Pump** flow rate
- Increase/reduce **Centrifuge** g-force

6. Switch to the **Step List** to see a summary of all steps in the protocol.

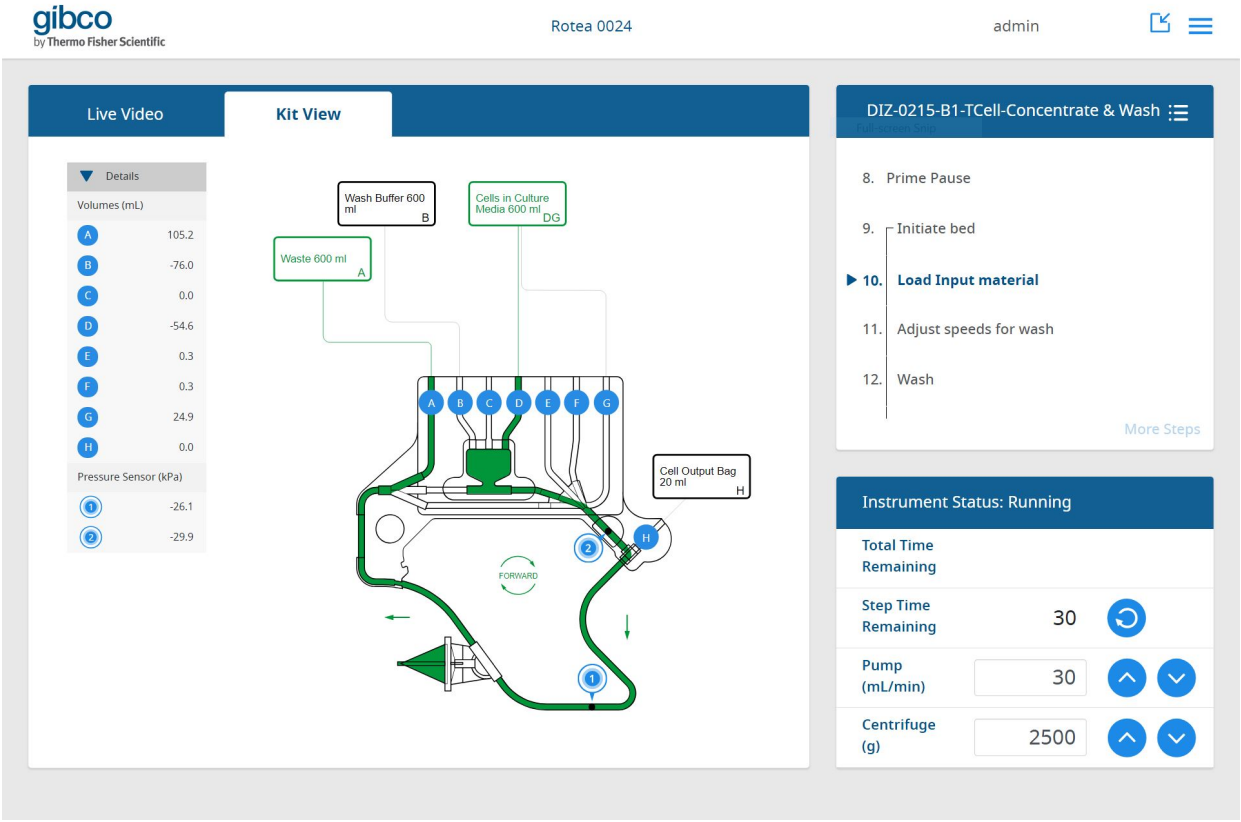


7. Return to the dashboard by clicking on or using the dropdown menu.



Valve volumes and pressure sensor values

When in **Kit View**, click on the **Details** to display the current net volume that has passed through each valve and the current pressure of P1 and P2.



When the valve volume is positive, more liquid has been pumped out through a valve than has been pumped in, increasing the volume in the attached bag. A negative value means more liquid has been pumped in through a valve than has been pumped out, reducing the bag volume.

The example, shows that the net valve volumes are as follows:

1. + 105.2 mL has been pumped out through valve A
2. - 76.0 mL has been pumped in through valve B
3. - 54.6 mL has been pumped in through valve D
4. + 24.9 mL has been pumped out through valve G
5. A small volume of + 0.3 mL has been pumped out through valves E & F which occurred during the **Prime Pressure** step.

Note:

- The valve volumes are not the same as the volume that has entered or left a bag. In the example shown, the input bag (cells in culture) is a dual port bag connected to both valve D and G. To calculate the volume change in or out of the input bag, add the valve volumes for valves D and G e.g. - 54.6 + 24.9 = - 29.7mL (out of the input bag)
- The valve volume is the volume displaced by the pump and hence does not account for volume retained in the Single-Use Kit during priming. For example, the net volume for valve A would over-estimate the volume that has been delivered to the waste bag by the volume of the CFC Chamber plus the kit tubing.

Note: The Pressor Sensors, P1 and P2, are at a low negative pressure meaning there is a slight vacuum in the system. These will fluctuate during processing depending on the flow rate and pump direction. A rapidly increasing Pressure Sensor value would indicate a flow restriction or blockage.

Error messages

Alarm or message	Critical alarm	Warning	Instrument response	GUI message
Safety system error	Yes	—	Cut power to pump and centrifuge, trigger instrument stop state	**Safety system error** **Protocol run has stopped. Press the stop button on the instrument, close manual clamps and open and close the instrument door to reset. Restart the protocol or select a protocol step to start from. If error persists, abort the run.**
Protocol is Malformed	Yes	—	GUI error message after loading protocol will appear	**Protocol is Malformed error** **Note:** Check pump calibration number to ensure protocol flow rates are within range.
Door lock error	Yes	—	Trigger instrument stop state	**Door lock error** **Protocol run has stopped. Open and close the door, then restart the protocol. If error persists, abort the run.**
Pump error	Yes	—	Trigger instrument stop state	**Pump error** **Protocol run has stopped. Press the stop button to clear the error, then restart the protocol or select a step to start from. If error persists, abort the run.**

(continued)

Alarm or message	Critical alarm	Warning	Instrument response	GUI message
Centrifuge error	Yes	—	Trigger instrument stop state	**Centrifuge error** **Protocol run has stopped. Press the stop button on the insturment, close manual clamps and open and close the instrument door to reset. Restart the protocol or select a protocol step to start from. If error persists, abort the run.**
Valve error	Yes	—	Trigger instrument stop state	**Valve error** **Protocol run has stopped. Press the stop button on the instrument, close manual clamps and open and close the instrument door to reset. Restart the protocol or select a protocol step to start from. If error persists, abort the run.**
Out of balance condition	Yes	—	Trigger instrument stop state	**Instrument out of balance** **Protocol run has stopped. Press the stop button to clear the error, then restart the protocol or select a step to start from. If error persists, abort the run.**
Moisture in bowl	Yes	—	Trigger instrument stop state	**Centrifuge leak detected** **Protocol run has stopped. Press the stop button to clear the error or temporarily override the moisture sensor if safe to do so. If error persists, abort the run.**

(continued)

Alarm or message	Critical alarm	Warning	Instrument response	GUI message
Over-pressure condition	Yes	—	Trigger instrument stop state	**Blockage detected** **Protocol run has stopped. Ensure manual clamps are open and bags are connected correctly. Press the stop button to relieve pressure to Bag X. Restart the protocol or select a protocol step to start from.**
Communication error	—	Yes	Instrument continues running protocol, GUI indicates error until communications are restored	**Communication error** **Ensure that the cable between the laptop interface and instrument is connected.**

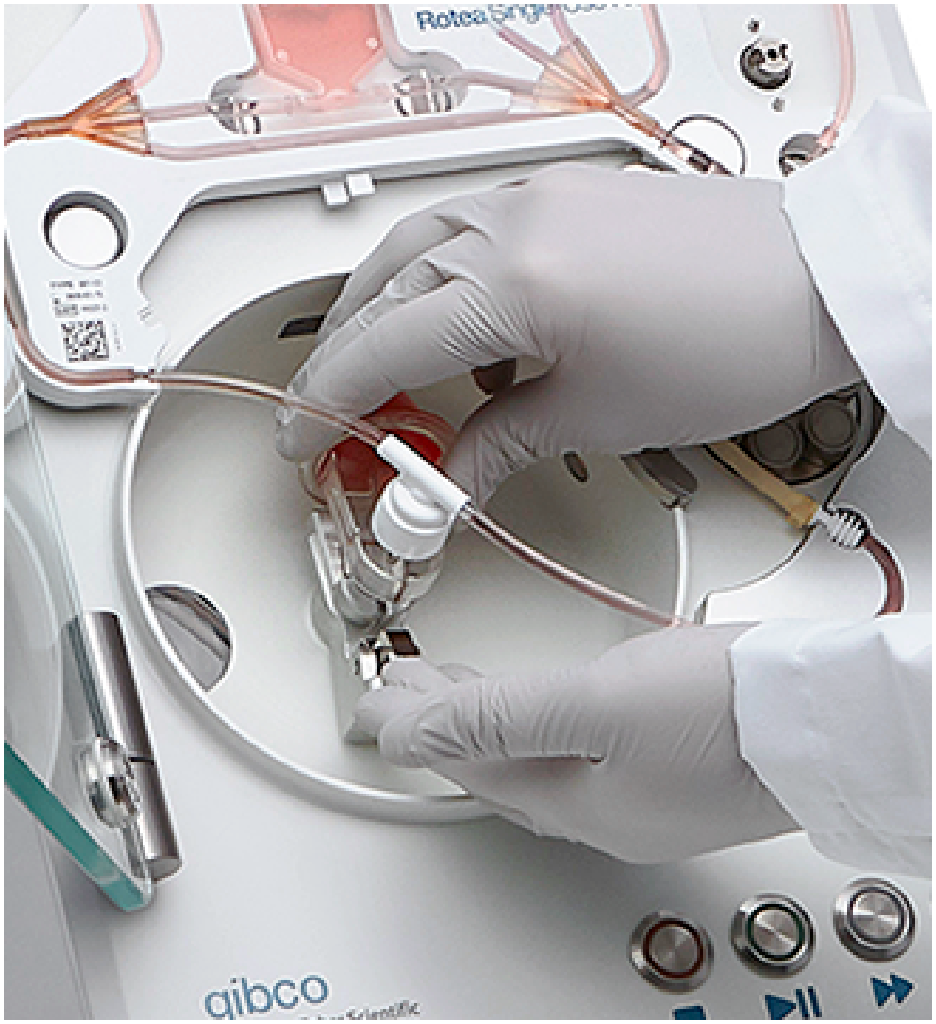
Kit removal

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

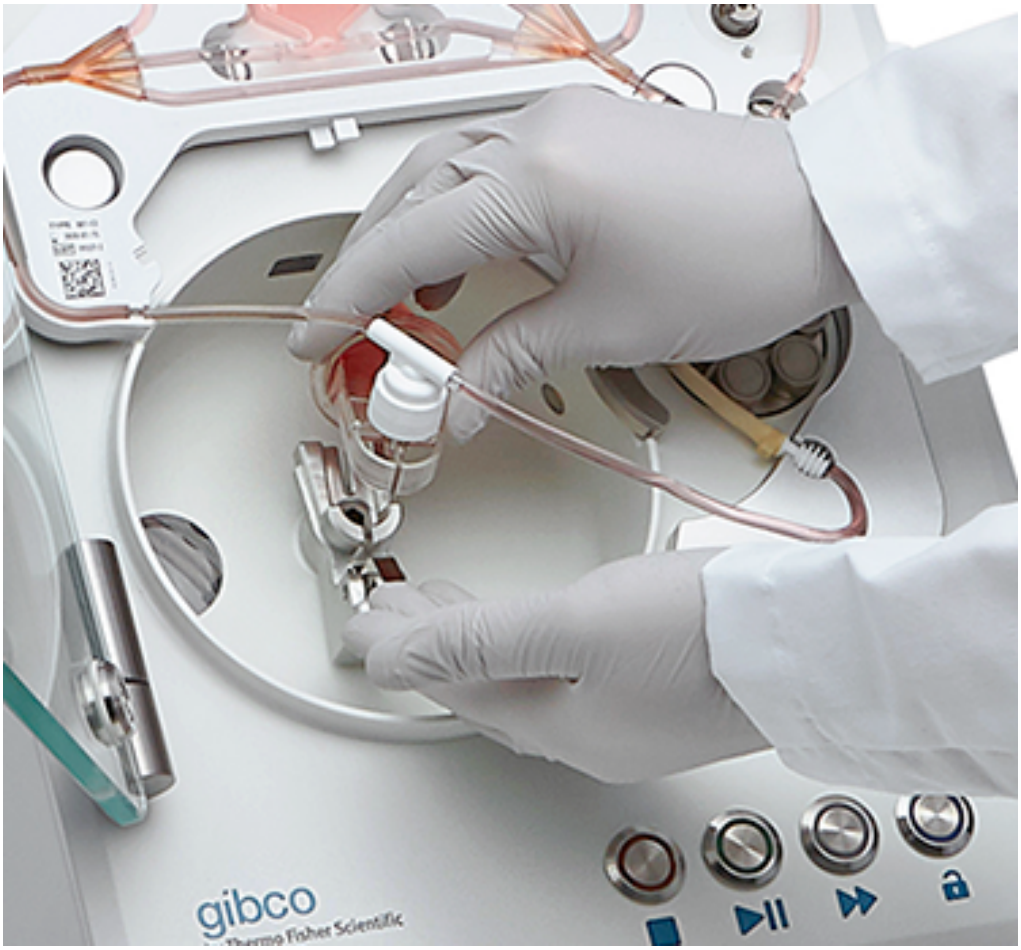
1. Press pushbutton when it is illuminated to unlock the door.

2. Open the door and raise until past vertical.

3. Remove the CFC Chamber from the CFC Chamber Carrier by lifting the lever and rotating the CFC Chamber back towards the latch.

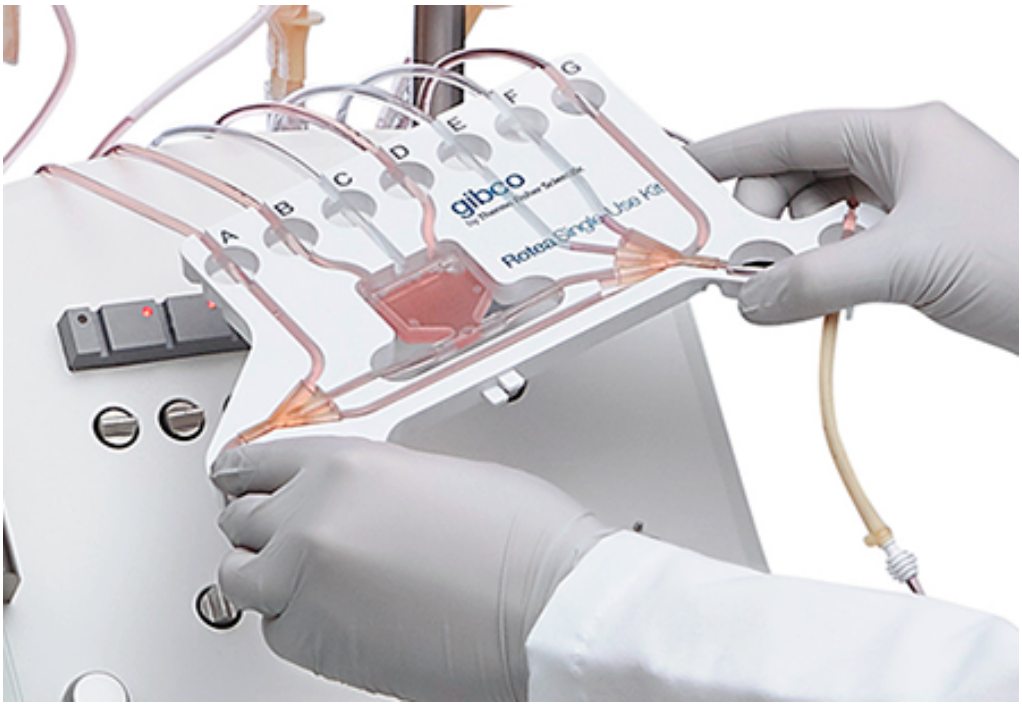


4. Lift CFC Chamber clear of the Centrifuge Carrier.



5. Remove the tubing from the Sensor Block and Peristaltic Pump.

6. Gently raise the Carrier Frame drawing out the tubes from the Bubble Sensor.



Aseptic disconnection of the kit components

If not done prior to Single-Use Kit removal from the instrument:

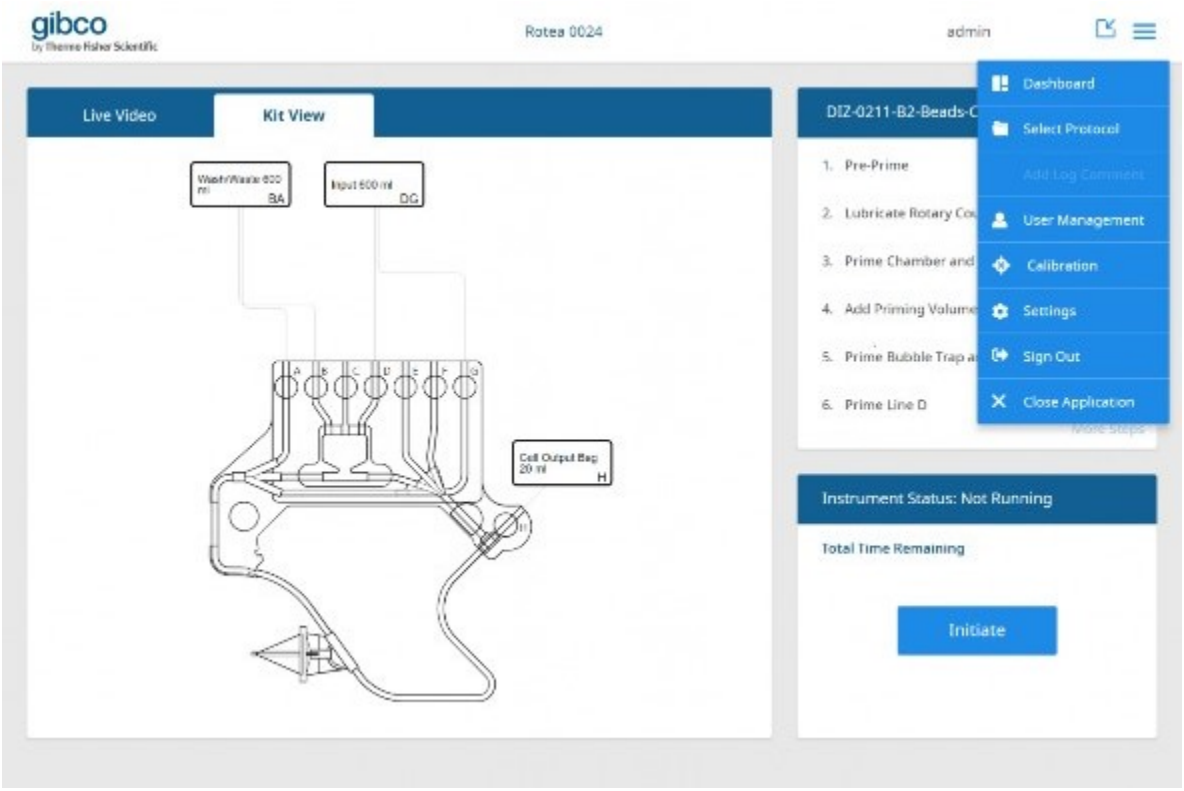
- Create sterile seal and disconnect finished product from the Single-Use Kit.
- Create sterile seal and disconnect any bags or subassemblies to be disposed of separately or manually clamp tube connections to bags if preferred.
- Dispose of used Single-Use Kit in accordance with approved procedures.

Note: *The Single-Use Kit tube materials are suitable for RF sealing using a SEBRA or Terumo Tube Sealer or equivalent. Please consult the tube sealer supplier's manual for instructions on creating a sterile disconnection.*

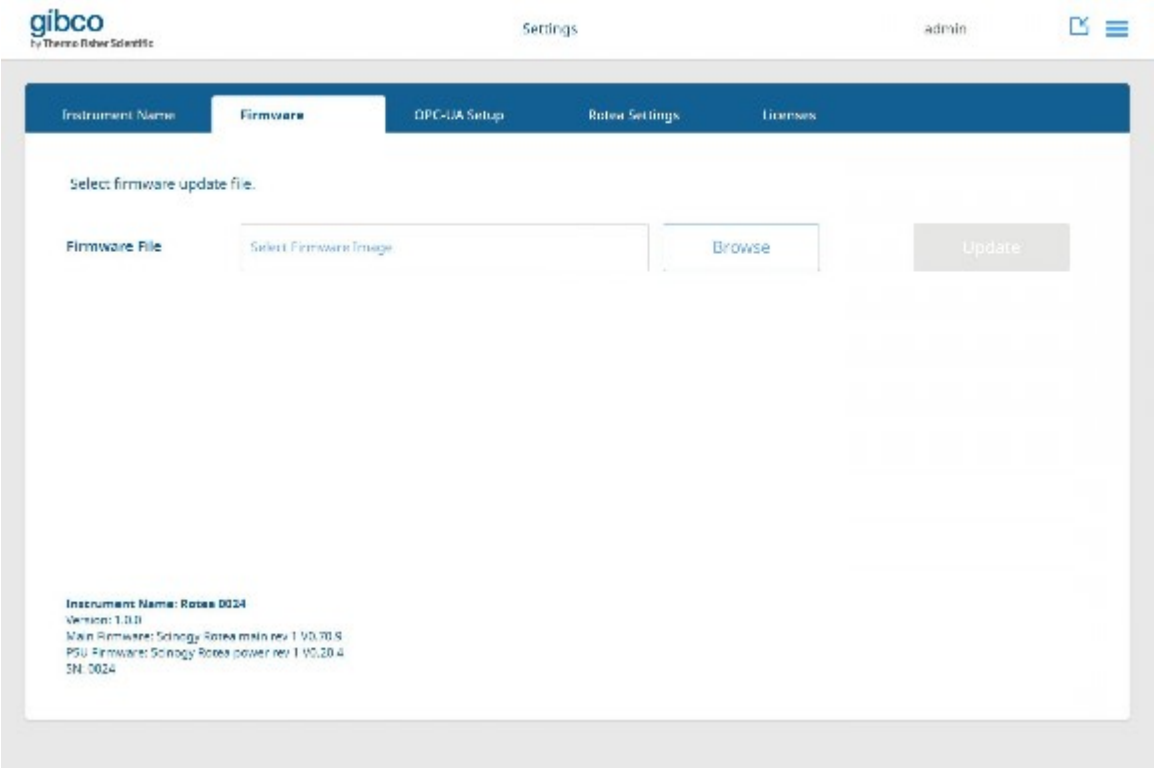
System settings

Instrument firmware

1. Select **Settings** from the drop down menu.



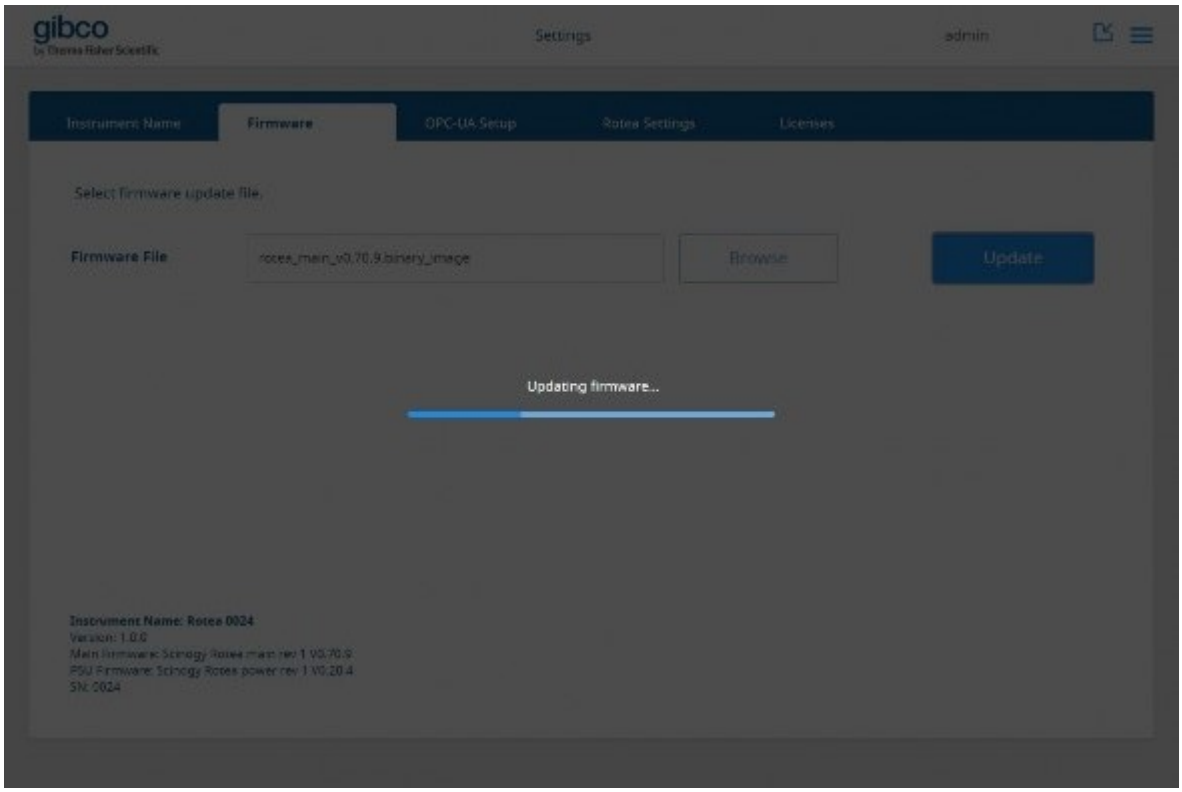
2. Click on the **Firmware** tab.



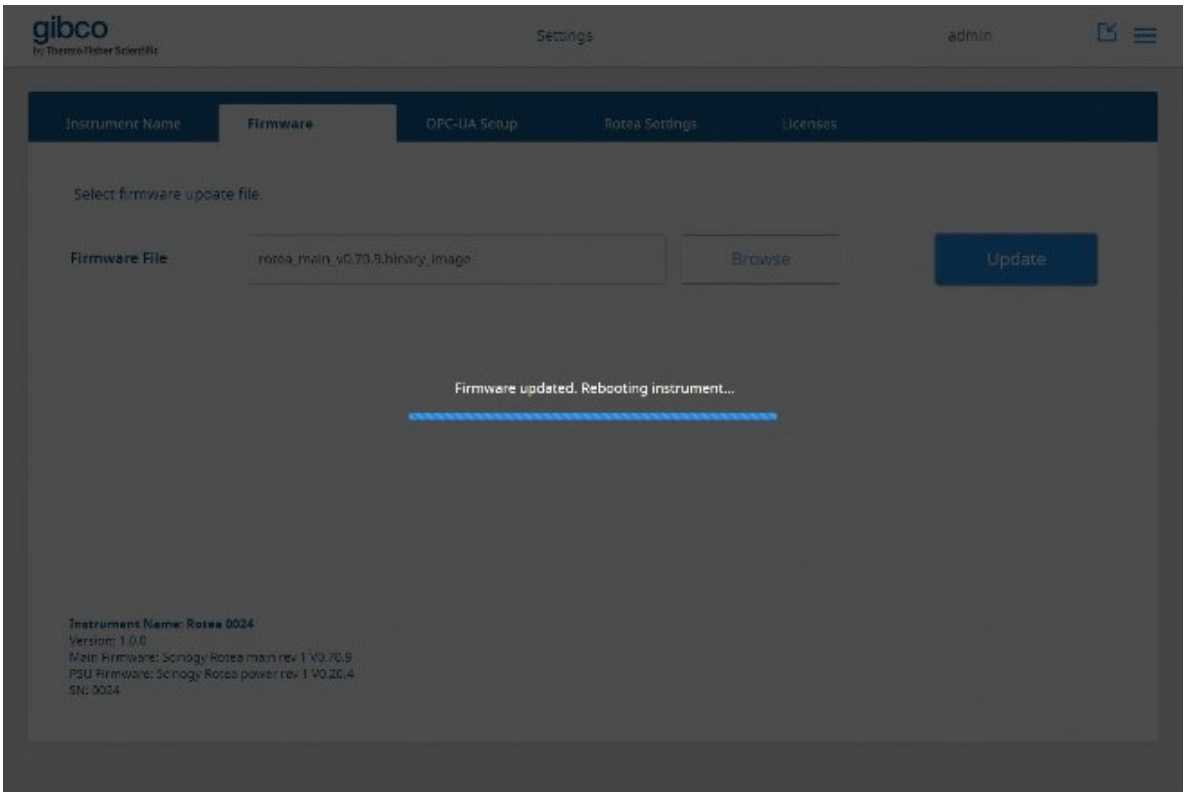
3. Select the latest firmware.

4. Click **Update**.

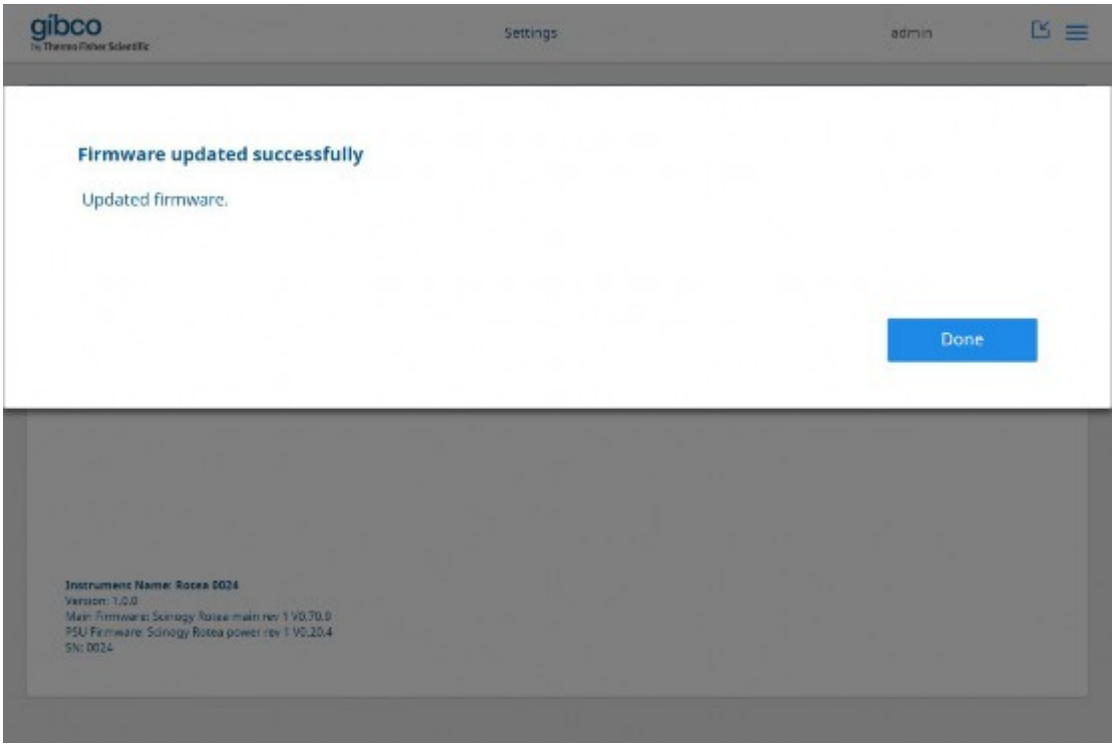
5. The selected firmware will be automatically updated.



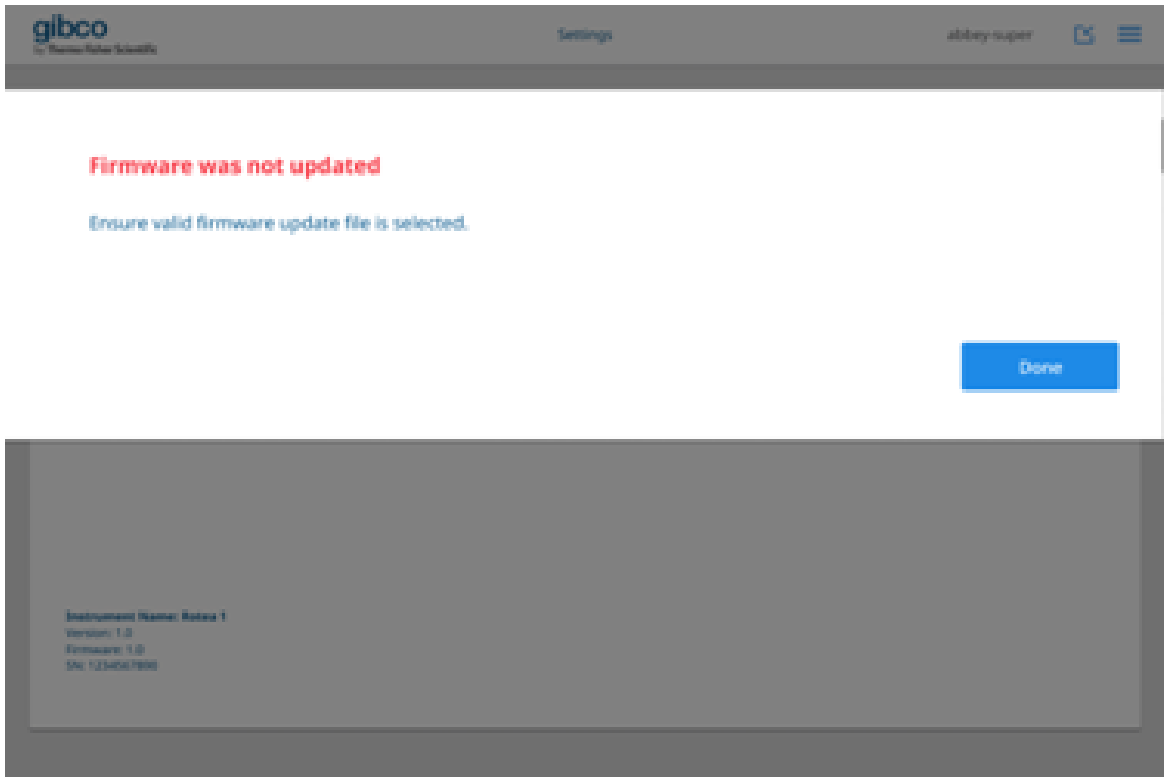
6. The system will automatically reboot.



7. Once firmware has updated successfully, click **Done**.

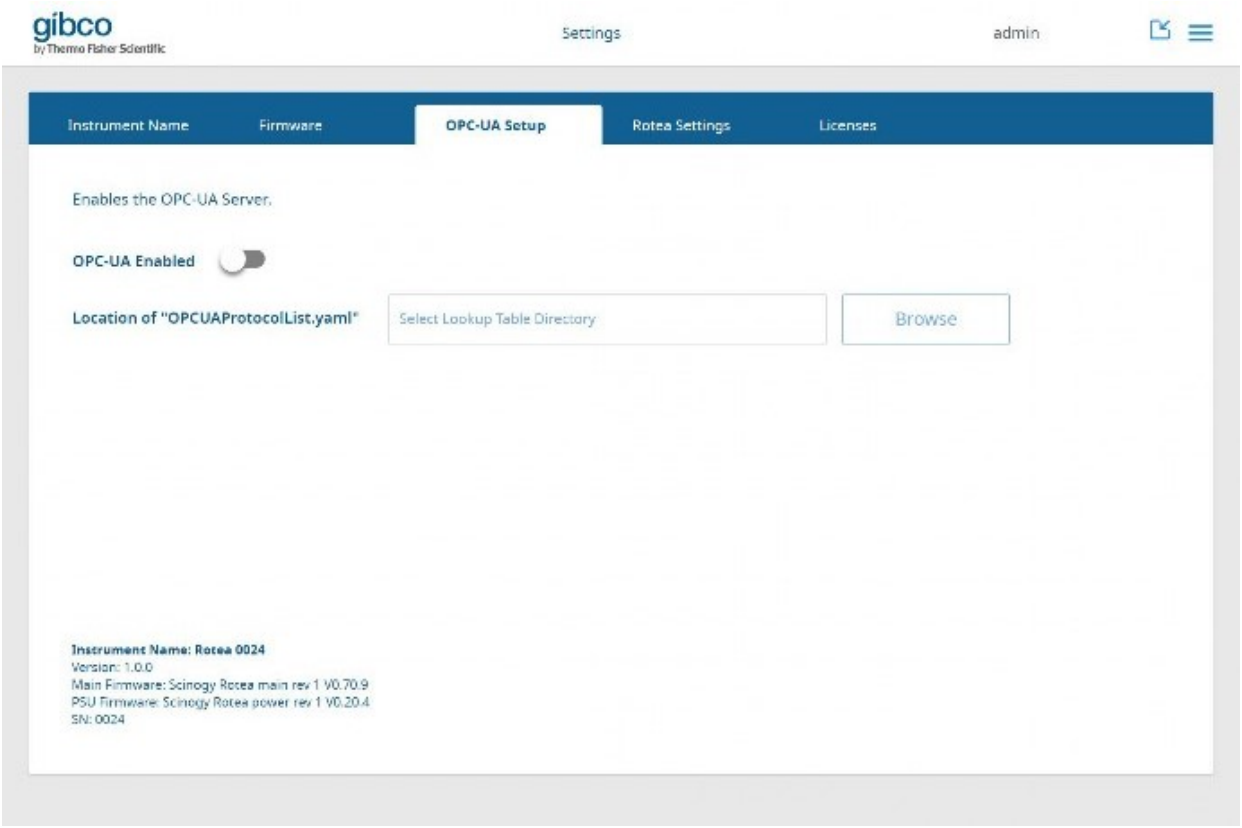


8. If firmware has not been updated click **Done** and restart the firmware update.



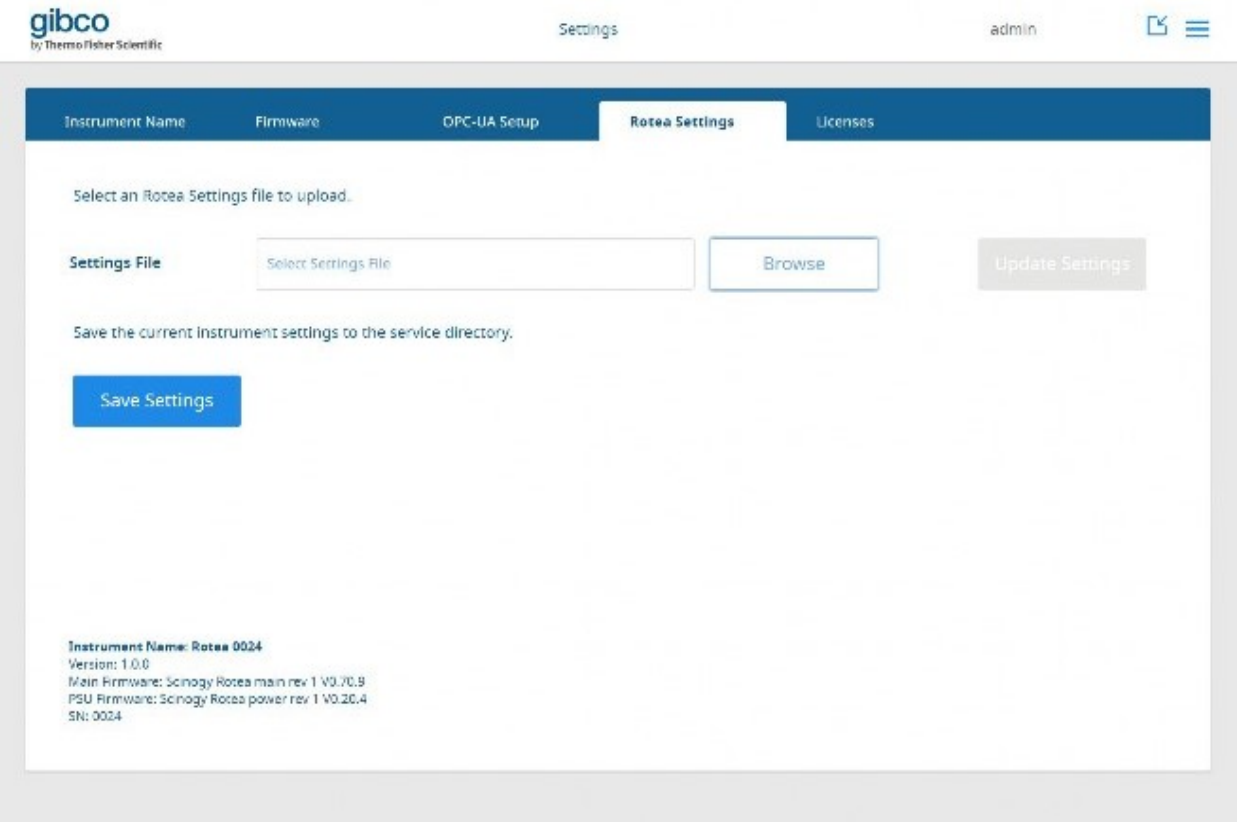
OPC-UA

An Open Platform Communications - United Architecture (OPC-UA) interface is provided that enables admin users to connect Rotea™ instrument to a Supervisory Control and Data Acquisition (SCADA) system to send protocols, start a protocol and monitor run progress, see Chapter 4, “OPC-UA interface”.



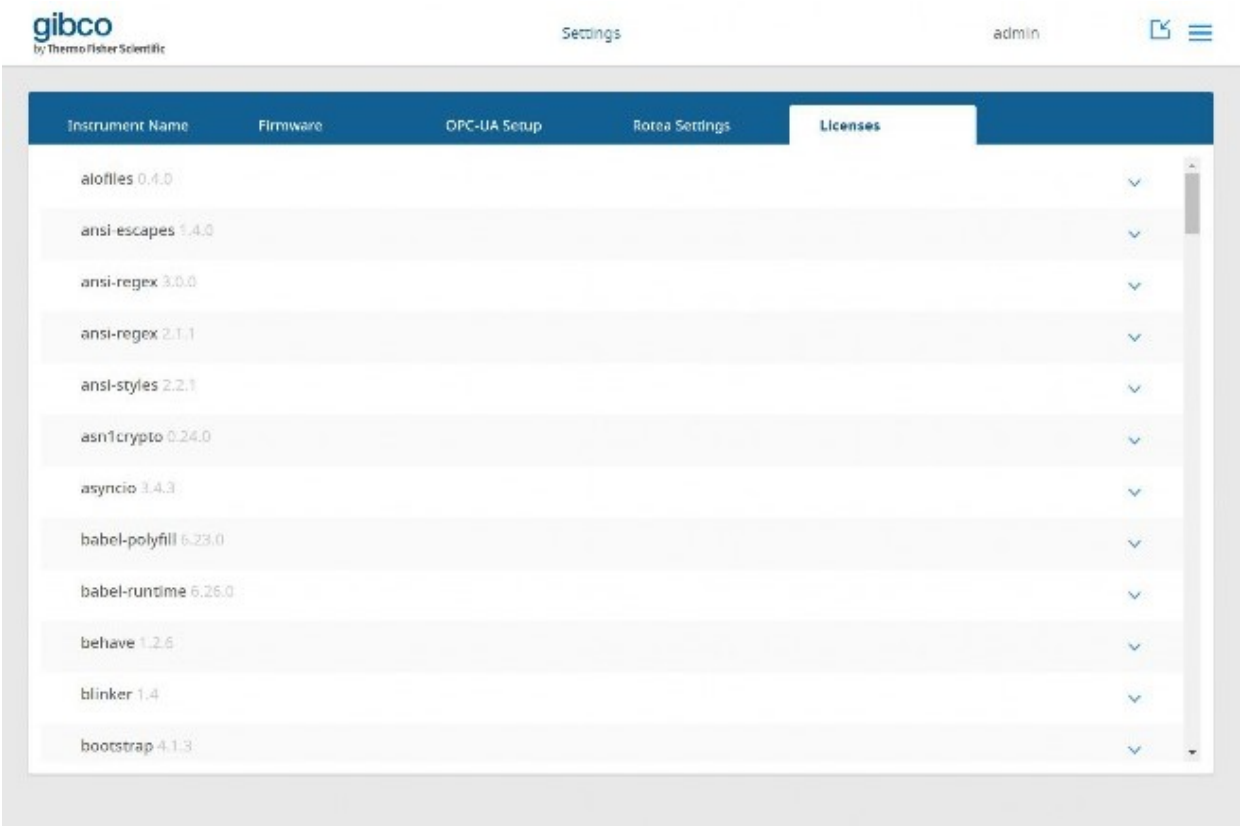
Settings

Admin users have the ability to update the instrument settings via the **Rotea Settings** tab.



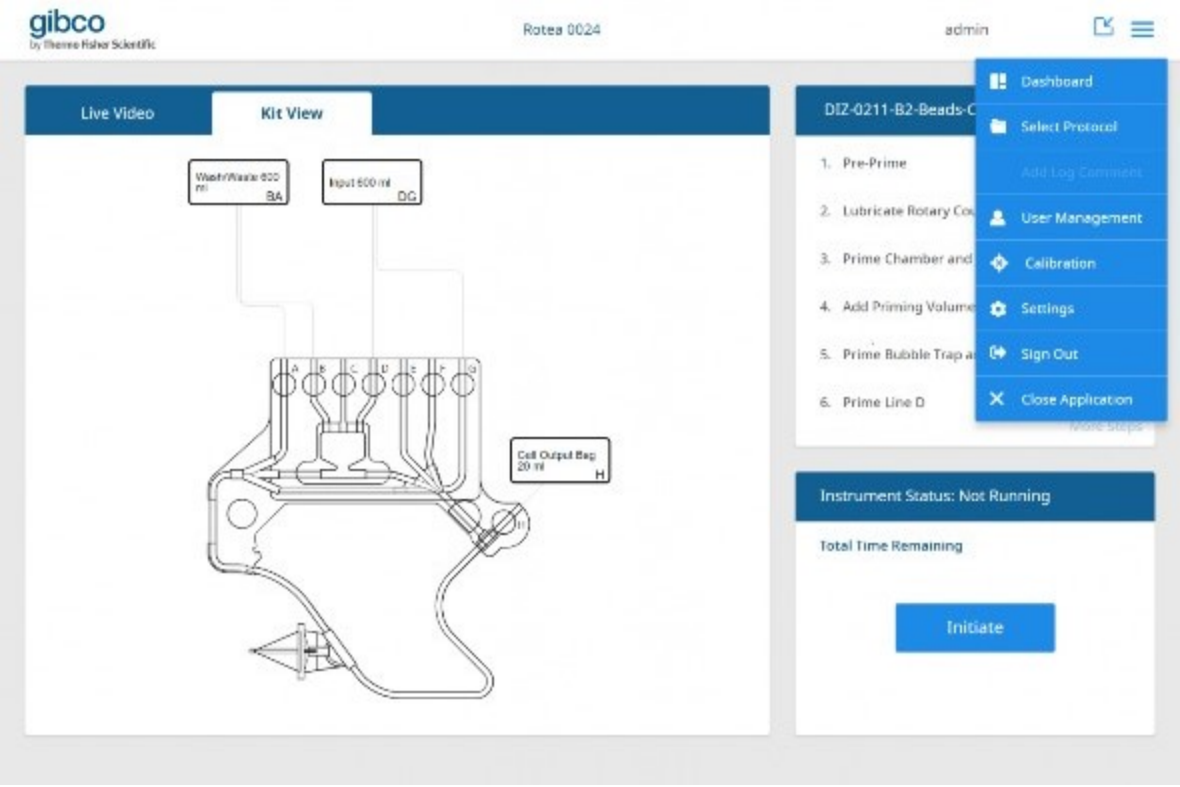
Licenses

All relevant software licenses are listed in the **Licenses** tab. The detail for each license can be displayed by clicking on the **v** arrows.

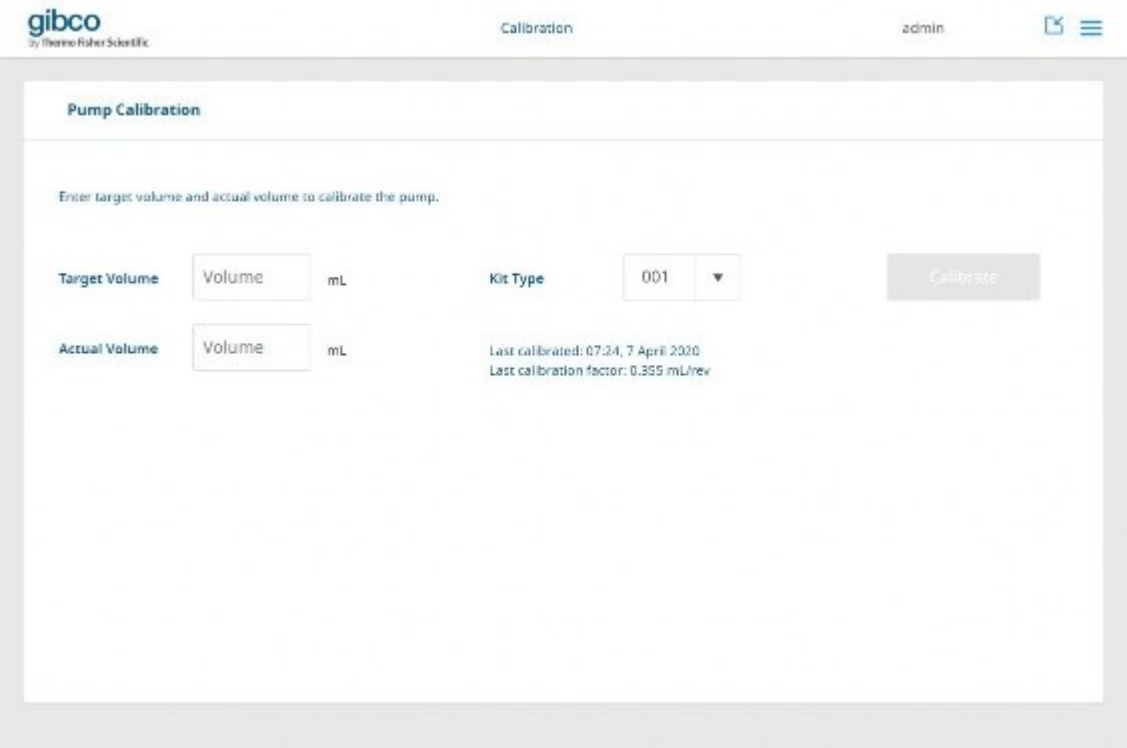


Calibration

1. Select **Calibration** (Calibration) from the drop down menu.

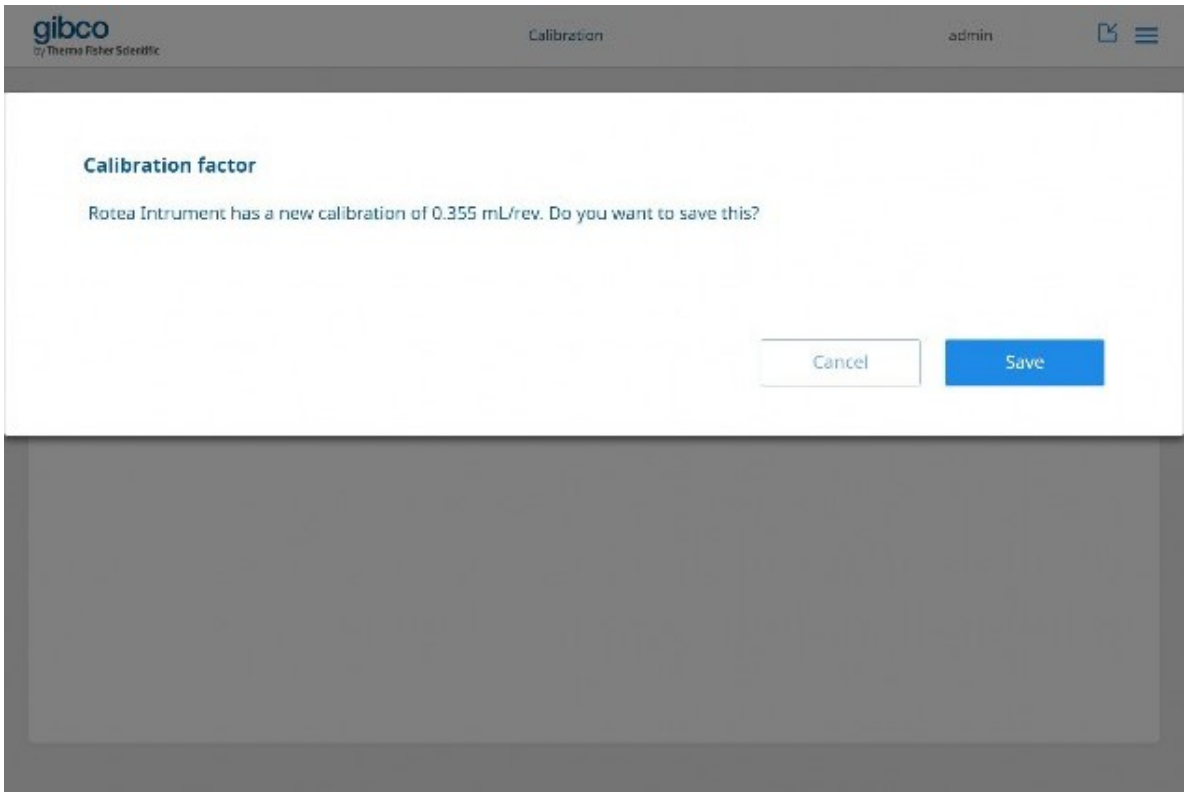


2. Input **Target Volume**.

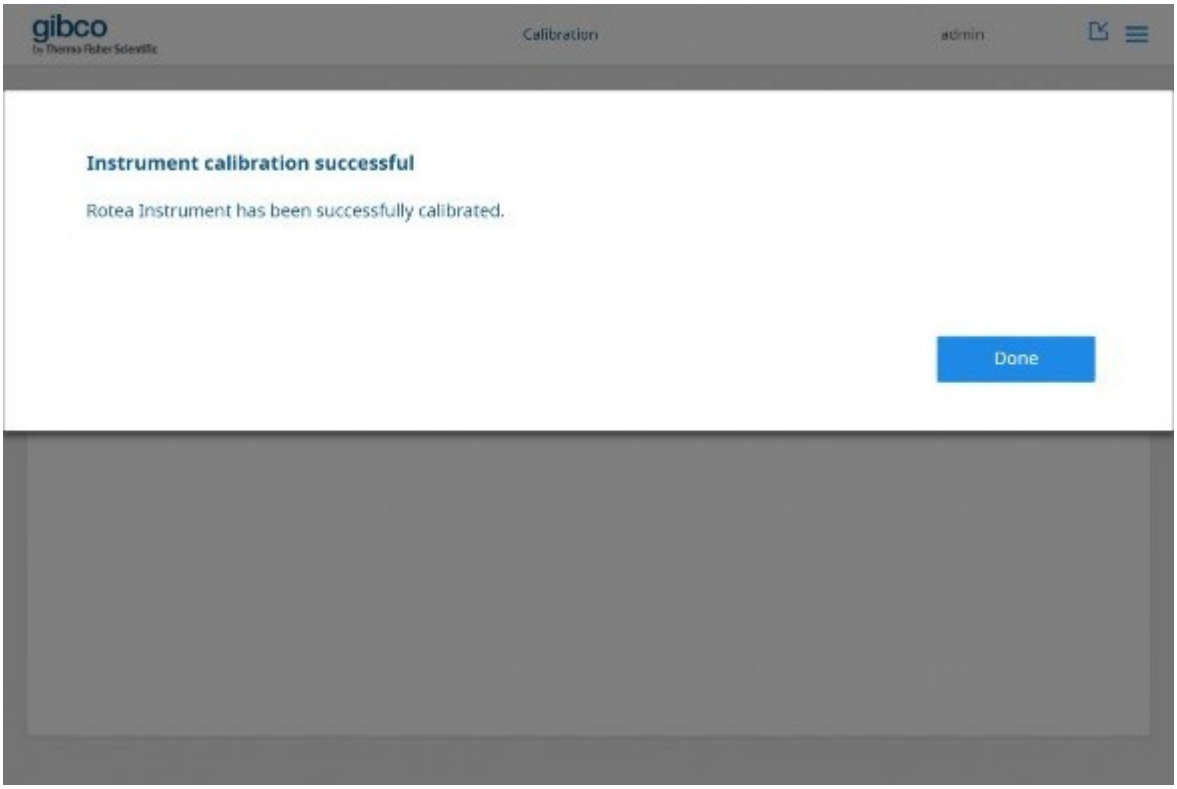


3. Input **Actual Volume** from calibration test run.
4. Select **Kit Type** from the drop down list.
5. Click **Calibrate**.

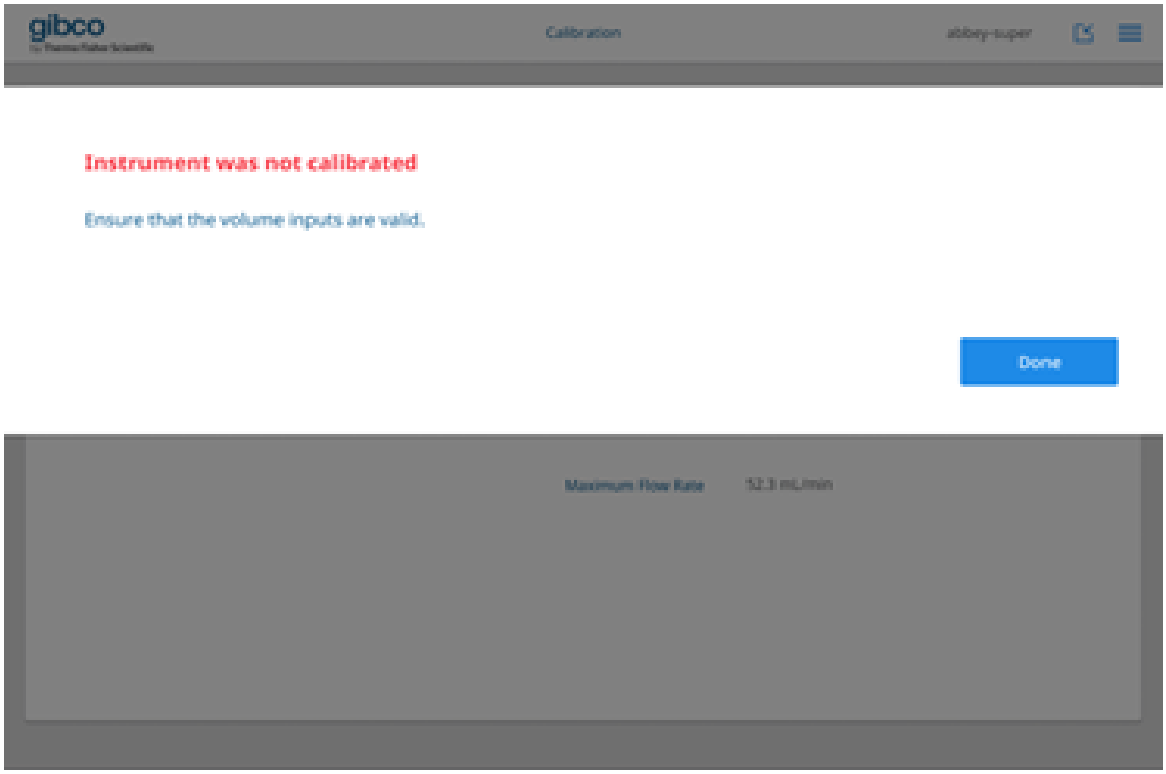
6. Click **Save** or **Cancel**.



7. Click **Done** if calibration is successful.



8. If calibration was not successful, click **Done** and restart the calibration process.



4 OPC-UA interface

Introduction

There are applications for the CTS™ Rotea™ Counterflow Centrifugation System where a Supervisory Control and Data Acquisition (SCADA) system will supervise the operation. This supervision will include items like sending a protocol to the Rotea™ instrument, starting a protocol and monitoring of run progress.

Each CTS™ Rotea™ Counterflow Centrifugation System includes a dedicated Dell™ 2-in-1 laptop with software applications to program and operate the instrument. An open data communication interface is also included to interface with SCADA systems.

One SCADA system is the Emerson DeltaV. DeltaV is technically a Process Control System (PCS), but it incorporates all the functionality of a SCADA system, and those are the functions that will be primarily used with the Rotea™ instrument.

Definitions

Abbreviation	Definition
GUI	Graphical User Interface
DeltaV	A Process Control System (PCS made by Emerson
ERP	Enterprise Resource Planning
MES	Manufacturing Execution System
PCS	Process Control System
PLC	Programmable Logic Controller
Protocol	A series of equipment instructions
Run	The execution (running) of a protocol, from beginning to end
SCADA	Supervisory Control and Data Acquisition
OPC-UA	Open Platform Communications - United Architecture, a machine to machine communication protocol for industrial automation

Scope of system

CTS™ Rotea™ Counterflow Centrifugation System is a stand alone instrument with an operational configuration comprising:

- The instrument hardware
- Firmware and software
- Dell™ 2-in-1 laptop
- The installed CTS™ Rotea™ Single-Use Kit and attached tubing and bags/vessels
- The protocol file
- In-process data that is supplied as protocol metadata before the protocol commences

Instrument hardware configuration

The Rotea™ instrument's embedded control has been designed to enable integration of functional components that are external to the base instrument and hence would vary the configuration from the standard:

- External components may be externally powered
- Communications from the Rotea™ instrument's embedded control to external components is through a CAN-BUS interface
- External devices may be individual devices already defined in the Rotea™ instrument's embedded schema such as a pump, centrifuge, push button, bubble sensor or valve
- External devices may be newly defined with a set of device specific commands and status reports
- External devices may also comprise a series of components managed by a self-contained control that responds to purpose designed messages from the Rotea™ instrument's embedded through the CAN-BUS

Single-Use Kit

The Single-Use Kit defines:

- The fluidic connections between instrument components such as the pump and valves
- The size of the pump tubing for each pump
- Optionally the volume capacity of each attached bag/vessel
- Optionally the priming volume for each valve line
- Optionally the required minimum volume for each reagent supply to be attached

The Single-Use Kit is identified by:

- A barcode read from a label attached to the kit
- The kit identification includes a unique number, batch identification number and kit type specifier. The kit type specifier is used for verification of kit type to the protocol requirements.

The scope of a Single-Use Kit may extend beyond the base instrument to include attached devices such as external mixers and pumps, or simply the tubing or other features that facilitate connection to external systems such as bio-reactors or electroporation systems that are not managed by the Rotea™ instrument's control.

Protocol file

- Protocol files for the Rotea™ instrument will be stored and transmitted in JSON format.
- The JSON format provides an extensible structure to support future devices and software functions.
- The Rotea™ instrument's embedded control supports one only protocol file.
- The protocol file is re-written to the instrument each time the protocol is run.

Protocol metadata

Protocol metadata entries provide the means to adjust fixed, qualified protocols to respond to process conditions.

- Metadata is supplied at the time the protocol is transferred to the instrument
- The metadata populates variables that are needed to complete the protocol definition
- This is managed by the IAL as part of the protocol transfer actions

MES interface

A Manufacturing Execution System (MES) interface is provided to enable processing by the Rotea™ instrument within a qualified clinical cGMP environment.

Background

The CTS™ Rotea™ Counterflow Centrifugation System is for research use or manufacture of cell, gene or tissue-based products.

For use in a qualified manufacturing processes, the instrument, Single-Use Kit and protocol must be qualified and maintained fit for purpose for the application.

When a qualified process is run, a record is required to verify that the process was performed in the formally defined way. If any variation to the process operations occur, then such events need to be documented and formally reviewed before the product can be released.

An MES interface is a communication system that links the CTS™ Rotea™ Counterflow Centrifugation System to a formally qualified electronic batch management system and associated data capture and record management functions.

The MES system is responsible for formal identification of users, their level of training, recording of equipment, consumables and events associated with each processing run.

The CTS™ Rotea™ Graphical User Interface (GUI) does not support this formal data capture activity. If an automated electronic interface is part of the implementation plan for CTS™ Rotea™ Counterflow Centrifugation System, then the MES interface provides that tool.

Electronic communications

It is assumed the MES applications will be located externally to the CTS™ Rotea™ Counterflow Centrifugation System.

Communications by any MES system to the instrument will be through the CTS™ Rotea™ GUI installed on the Dell™ 2-in-1 laptop attached to the instrument. View the structure diagram, see “MES run a protocol” on page 104.

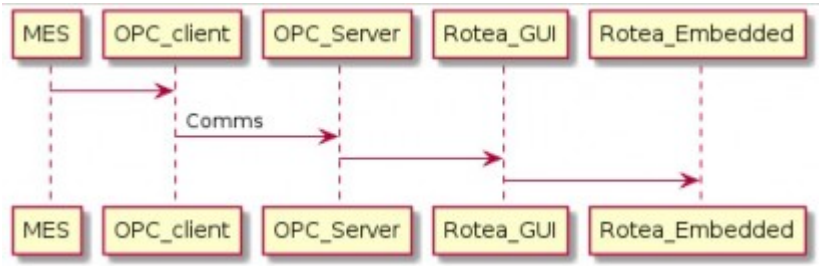


Figure 10 System components

Communications protocol

The MES interface to the Rotea™ instrument application will be through an implementation of OPC-UA. When enabled in the Rotea™ GUI, an OPC-UA server will run on the laptop allowing an MES OPC-UA client to connect to it.

The commands and reports available to OPC-UA client are outlined (see “MES – Commands and reports overview” on page 91) with details (see “OPC-UA interface” on page 96).

MES – Commands and reports overview

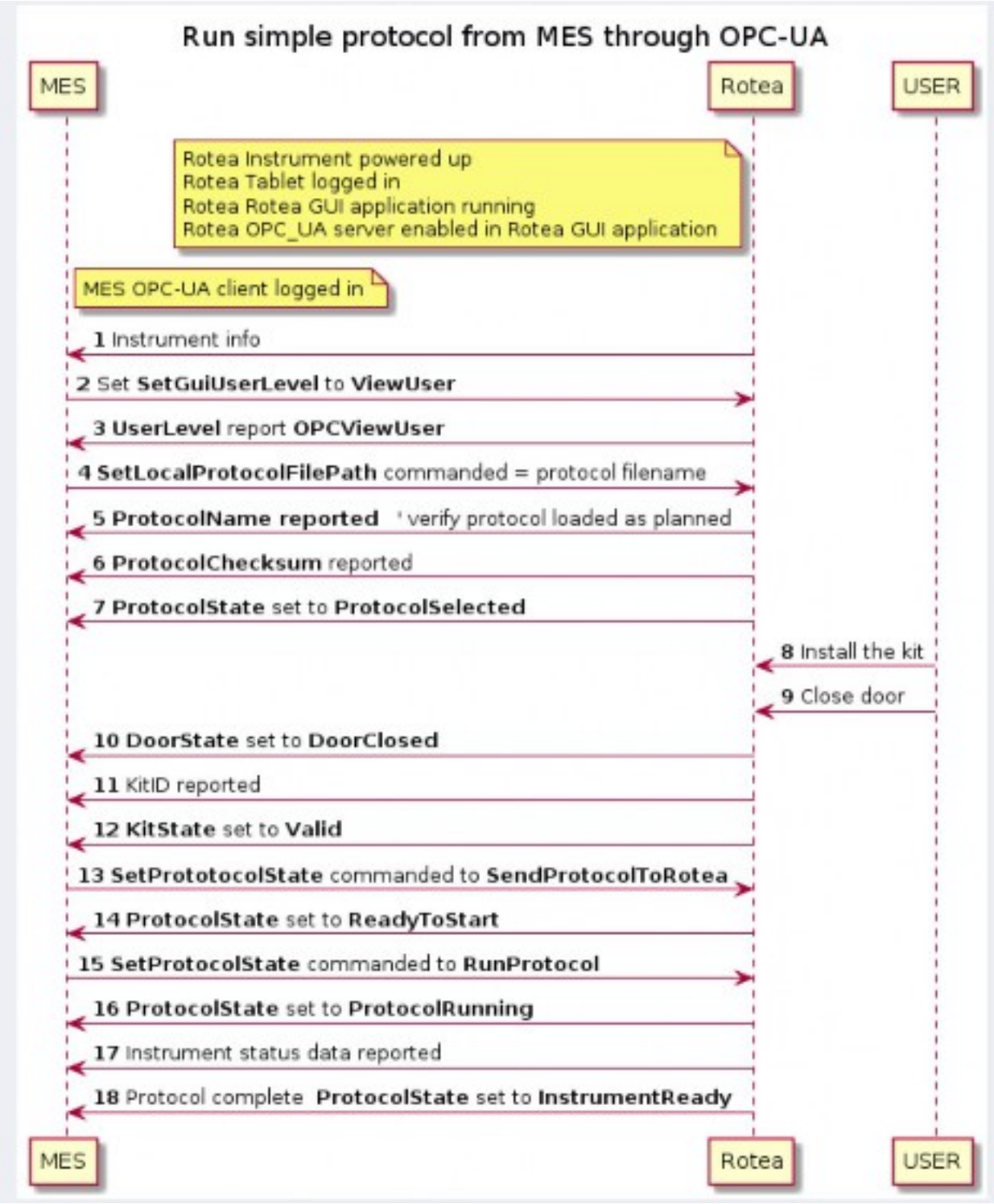


Figure 11 Run protocol workflow

For more use cases, See “Use case sequence diagrams” on page 104.

Enable OPC-UA

The OPC-UA interface is not enabled by default. The enable button is available to an administrator under the **Settings**: **OPC-UA Setup** tab. The OPC-UA server only supports one OPC-UA client connecting to it. The Rotea™ application uses a Unified Automation OPC-UA stack which supports a number of configurable parameters, including: encryption level, security level, certificate configuration, valid certificates, end point addresses, server names, server url, etc. The full list of parameters can be found at the following link. **http://documentation.unified-automation.com/uasdkcpp/1.7.0/html/L2ServerSdkServerConfig.html#server_config_xml_file**

The Rotea™ application configuration file is available on the laptop under:

`C:\Program Files (x86)\Rotea\opcua\opcua_server_config.xml`

The user can modify the configuration file to suit their needs. The configuration file is loaded when the laptop is started if the OPC-UA server is enabled or when the OPC-UA server is enabled under the **OPC-UA Setup** tab.

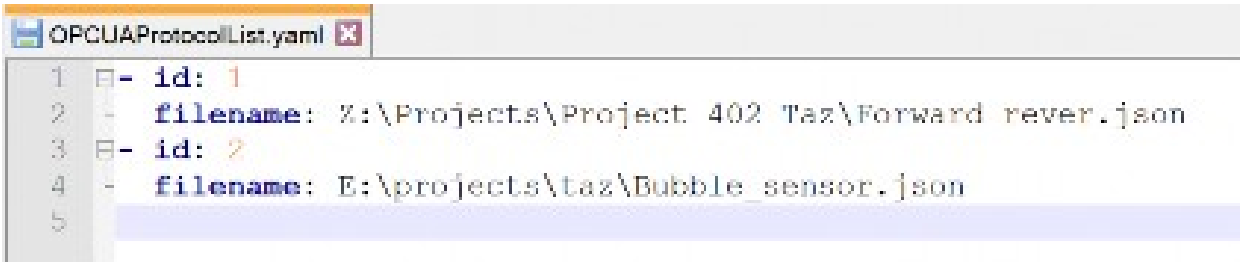
Log in to instrument

The MES can login to the Rotea™ GUI at any time, it does so by changing the **SetGuiUserLevel** node. Full details of the **SetGuiUserLevel** values, see “OPC-UA interface” on page 96.

Load protocol

A protocol can be loaded three ways:

1. **SetLocalProtocolFilePath** – Sets the file path on the laptop of where to load the protocol file.
2. **SetProtocolFileContents** – Supply the protocol file contents to transfer to Rotea™ GUI and the Rotea™ instrument.
3. **SetProtocolFileByLookupTableId** – Select a protocol based on the id in a lookup table. The user must generate a YAML file called `OPCUAProtocolList.yaml` with the ids and filenames in it. This is an example `OPCUAProtocolList.yaml` file with 2 files in it:



The user must set the directory where the `OPCUAProtocolList.yaml` file can be found. This is done on the OPC-UA settings page.

Note: The YAML file can be modified in any text editor. Freeware program NotePad++ is used in the illustration.

Confirmation of protocol loading can be obtained from the **ProtocolName** and **ProtocolChecksum** reports. **ProtocolCheckSum** can be used to verify integrity of protocol file transfer from uncontrolled repositories.

The protocol checksum is an hexidecimal number with 32 characters.

Example: **e152abb59e4949980731c5bbf7194ffb**

It can be saved and compared as a string.

The **ProtocolState** report should now report **ProtocolSelected**.

Load kit

The instrument verification process needs the instrument door to be closed and a valid kit to be detected. The kit ID is read by the instrument when the door is closed.

The **DoorState** is reported **Closed**, and the **KitID** string is supported by **KitState** report that checks the kit type against that required for the protocol. If the kit ID is valid and aligned to the protocol then the **KitState** is reported as valid.

Transfer metadata

Protocols can be defined with metadata or parameters that allow a qualified recipe to respond to changing input materials and output targets.

Refer to the sequence diagram, see “MES drives Rotea in response to external systems” on page 106.

After the protocol information is loaded the instrument will set **ParameterName1** through **ParameterName20** to the names of the variables that need to set in the protocol metadata.

The MES can check **ParameterValid1** to **ParameterValid20** to determine the status of metadata definition for the protocol. This will advise if that parameter is in use, if it has been set, and if the setting is valid.

To set the value, use **SetParameter1** through **SetParameter20** and supply an **Int32** value.

Initialize protocol on to instrument

Once the protocol has been specified, kit loaded and any metadata defined within acceptable ranges, set the **SetProtocolState** to **SendProtocolToRotea**.

The protocol definition is sent to the instrument and **ProtocolState** will report **ProtocolReadyToStart**.

Start/Stop/Pause/Resume protocol

- The MES can **Start**, **Stop** and **Pause/Resume** the instrument with **SetProtocolState** variable.
- The **ProtocolState** will report **ProtocolRunning**.
- These actions are available through the buttons on the instrument when enabled.
- The MES can disable **Start**, **Pause** and **Advance** functions with the **SetSkipButtonEnable** and **SetPlayPauseButtonEnable**. When the buttons are enabled they will follow the configuration in the protocol file, if they are disabled the buttons on the instrument are disabled.

- When the instrument completes the protocol or is stopped for any other reason, the instrument state will be reported as **InstrumentReady**. This provides the option for the protocol to be re-started using **StartatStep** or other administrator actions from the **InstrumentReady** state.
- When a user with administrator authority is logged in via the MES or without MES supervision, the **Pause** and **Advance** instrument buttons become active independent of protocol settings.

Instrument run status

The instrument status can be monitored on the Rotea™ GUIor via the exposed OPC-UA variables.

- The **ProtocolState** will report **ProtocolRunning** or **ProtocolPaused**.
- The **ProtocolStepNumber** reports the current step.
- **WaitingUserAck** reports if the instrument is waiting for verification to proceed to the next step or repeat the current step. The MES uses **SetProtocolState** to **RunProtocol** to repeat the same step, or **SkipToNextStep** in response to this state.

MES batch history data

- The Rotea™ Run Manager captures the run history data into a unique file each time the protocol is run.
- Run history contains details of the process conditions throughout the run.

Alarm recovery tools

- Alarm reset commands; these may include active instrument reactions such as opening valves for a controlled period to release pressure.
- Several options for product recovery are available through MES commands:
  - Re-start the protocol at a specified step. The protocol can contain dedicated blocks of code independent of the main process.
  - Download a new protocol and start it at a specified step
  - Start running the settings of a single step in the existing protocol.
- The MES can also log in a qualified user with administrative privileges to run the instrument from the Rotea™ GUI as a manual intervention.
  - All actions are recorded in the history files and instrument status is reported to the MES
  - To return to MES managed operations, the administrator user logs out of the MES. The MES then logs in as **ViewUser** again. (The instrument can be running the protocol while users/MES log in and log out.)

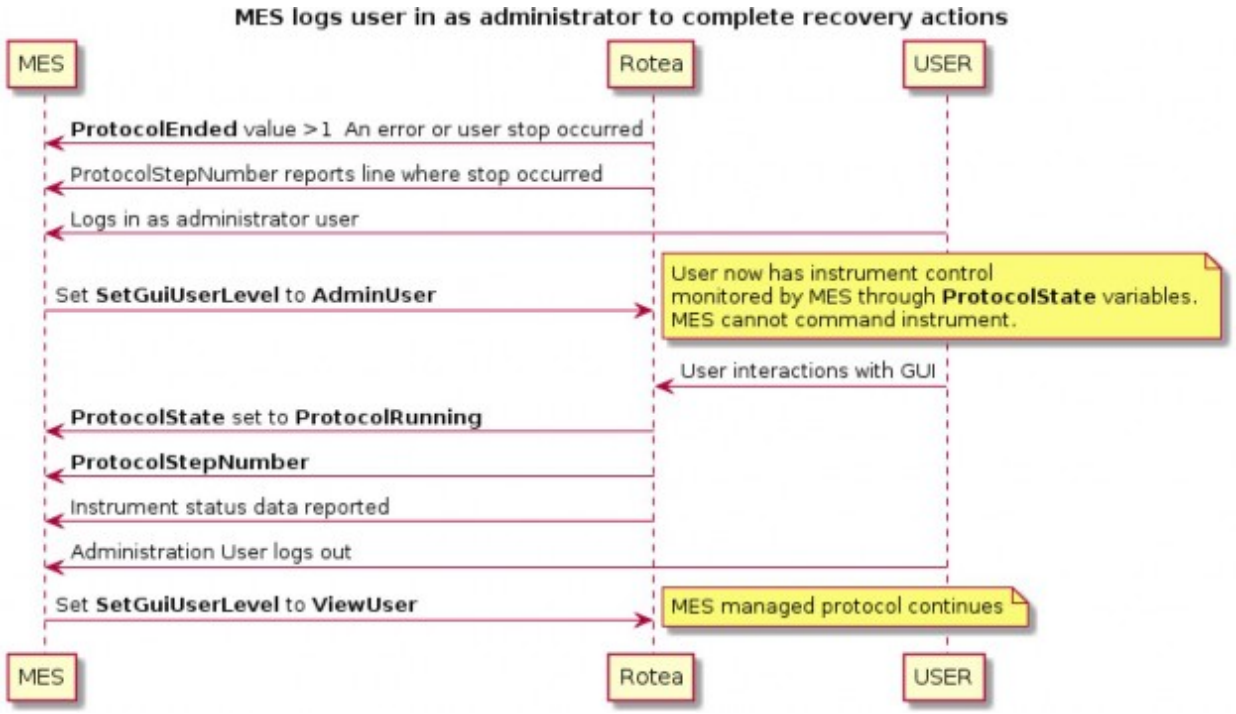


Figure 12 OPC-UA enabled administrator to perform recovery

OPC-UA interface

Commands OPC-UA to Rotea™ application

Table 2 OPC-UA command list

Variable	Type	Values/Description
RescanKit	**Boolean**	Force a kit rescan: • True – The instrument will rescan the kit barcode. • False – No action.
SetGuiUserLevel	**Enum**	• **GUIManagedLogin** – Application login is managed by the GUI, OPC-UA commands are ignored in this mode. • **ViewUser** – The MES has control of the Rotea™ instrument and GUI just displays the instrument status. • **AdminUser** – The GUI is logged in as an administrator and has control the Rotea™ instrument, OPC-UA commands are ignored in this mode. **Note:** When OPC-UA enabled, a SetGuiUserLevel command from the OPC-UA server will over-ride the current instrument log-in state.
SetLocalProtocolFilePath	**String**	Set the file name path of the protocol on the laptop to be loaded to the Rotea™ instrument.
SetPlayPauseButtonEnable	**Enum**	Enable the Play/Pause button on the Rotea™ instrument. • Disabled • AsPerProtocol • Enabled
SetProtocolFileContents	**String**	Send the protocol file contents to the laptop to be loaded to the Rotea™ instrument.
SetProtocolFileByLookupTableId	**UInt32**	Id of the protocol file in the OPC-UA look up table. The lookup table is defined in `OPCUAProtocolList.yaml`
SetParameter1 through **SetParameter20**	**Int32**	The Metadata parameter data for the protocol. The associated name of the parameter can be found in variables **ParameterName1** through **ParameterName20** after the protocol has been loaded.

Table 2 OPC-UA command list *(continued)*

Variable	Type	Values/Description
SetProtocolState	Enum	• **StopProtocol** – Stop the protocol. • **SendProtocolToRotea** – Load the protocol to the Rotea™ instrument. • **RunProtocol** – Start the protocol, same as pressing the **Start** button on the instrument. • **PauseProtocol** – Pause the protocol • **RecoveryRunProtocolFromStep** – Start a protocol from the step specified in **SetRecoveryStepNumber**. • **RecoveryRunProtocolFromStep** – Start a protocol from the step specified in **SetRecoveryStepNumber**. • **RecoveryRunProtocolSingleStep** – Start a protocol and run a single step number SetRecoveryStepNumber. • **SkipToNextStep** - advances the protocol to the next step by ending this step.
SetRecoveryStepNumber	UInt32	The recovery step number to start from. Used by **SetProtocolState**.
SetSkipButtonEnable	Enum	Enable the advance button on the Rotea™ instrument: • **Disabled** • **AsPerProtocol** • **Enabled**

Reports Rotea™ application to OPC-UA

Table 3 Variable set when changed

Variable	Type	Value/Description
CentrifugeSpeed	UInt32	The current centrifuge speed
InstrumentName	String	The name of the instrument, stored on the instrument, set by the GUI
MainFirmwareVersion	String	The main board firmware version on the instrument
ModelNumber	String	The model number of the instrument, set during manufacture

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
PowerFirmwareVersion	**String**	The power board firmware version on the instrument
RoteaAppVersion	**String**	The Rotea™ application version
RoteaLinkUp	**Boolean**	The Rotea™ link state: • True – The Rotea™ application is connected to the instrument and communication is successful. • False – The Rotea™ application cannot communicate with the instrument, all commands will fail and the status is invalid.
SerialNumber	**String**	The serial number of the instrument, set during manufacture
UpTime	**UInt32**	Number of seconds the server has been running, updated every 10 seconds

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
WaitingUserAck	**Enum**	Instrument has entered pause state. This will also cause the **ProtocolState** to transition to **ProtocolPaused**. The initiating event for this pause state is described: • **NotWaiting** - Not waiting for User acknowledge • **WaitingBubbleAck** - Waiting for User acknowledge following pause on a bubble trigger event • **WaitingPressureAck** - Waiting for User acknowledge following pause on pressure trigger event • **UserPausedButton** – The user paused the protocol via the pause button on the instrument • **UserPausedOPCUA** – The user paused the protocol via the OPCUA interface • In order to acknowledge the event; The user can press a play/advance buttons (if enabled) on the instrument. The MES can write the: • **ProtocolState** to **RunProtocol** to continue with the current step or • **ProtocolState** to **SkipToNextStep** to advance

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
ProtocolEnded	**Enum**	The state indicates that the protocol has stopped and the reason that it stopped. Press the stop button or write the **ProtocolState** to **StopProtocol** will clear any Errors. • **NotApplicable** – Not Applicable • **CompletedSuccessfully** – Protocol completed successfully • **UserStoppedRun** – The user or OPC-UA stopped the protocol • **DoorUnlatchedError** – The instrument has raised a door error; the door failed to close or has opened unexpectedly • **PumpMotorError** – The instrument has raised a pump motor fault • **CentrifugeMotorError** -The instrument has raised a centrifuge motor fault • **ValveError** – The instrument has raised a valve error. A valve may have failed to close or open properly • **OutOfBalanceError** – The instrument has raised an out of balance error, the centrifuge may be out of balance • **MoistureInBowlError** – The instrument has raised a moisture in bowl error, the kit may be leaking • **OverPressureConditionError** – The instrument has raised an over pressure error; excessive pressure has been detected in one of the kit tubes • **UnknownError** – The instrument is in an unknown error state
DoorState	**Enum**	• **DoorOpened** – The door is closed • **DoorClosed** – The door is open

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
ErrorRaised	**Enum**	• **NoError** – There are no errors • **InternalError** – An internal application error has occurred • **FileNotFound** – The SetLocalProtocolFilePath file cannot be found • **JsonParsingError** – The protocol file is corrupted • **FileCannotBeOpened** – The protocol file cannot be opened • **CmdFailed** – Generic fail, the last command issued did not succeed • **ParameterNotSet** – A parameter has not been set, protocol not loaded • **ParameterOutOfRange** – A parameter is out of range, protocol not loaded • **KitNotLoaded** – The kit is not loaded, protocol not loaded • **KitNotValid** – The kit is not valid, protocol not loaded • **InstrumentNotReady** – Changing to the specified. **ProtocolState** cannot be performed from the current state • **RecoveryStepOutOfRange** – The **ProtocolStepNumber** is not a valid step in the protocol • **ProtocolListDoesNotExist** - `OPCUAProtocolList.yaml` cannot be found • **ProtocolListCannotBeOpen** – Cannot open `OPCUAProtocolList.yaml` • **ProtocolListParsingError** – `OPCUAProtocolList.yaml` format invalid • **ProtocolListIdDoesNotExist** – The **LookupTableId** cannot be found in **OPCUAProtocolList.yaml**
KitId	**String**	The Kit id of the loaded kit

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
KitState	**Enum**	• **NotLoaded** – Kit not loaded in instrument • **LoadedNotValid** – Kit loaded in instrument but the Kit ID is invalid or kit type cannot be used with this protocol • Valid – Kit is loaded in the instrument and Kit ID is valid. Can now be sent to the instrument
ProtocolChecksum	**String**	The **Checksum** of the loaded protocol
ProtocolName	**String**	The protocol name of the loaded protocol
ParameterName1 through **ParameterName20**	**String**	The Metadata parameter field names for the loaded protocol
ParameterValid1 through **ParameterValid20**	**Enum**	• **NotInUse** – Parameter not used in protocol • **NotSet** – Parameter needs to be set • **OutOfRange** – Parameter not in valid range • **Valid** – Parameter valid
ProtocolState	**Enum**	• **NoProtocolSelected** – No protocol loaded in the application • **ProtocolSelected** – Protocol loaded in the application • **InstrumentReady** – Protocol and kit loaded and valid. User can run recovery operations from this state • **ReadyToStart** – Protocol sent to the instrument and ready to start. The user can start the protocol with the start button (if enabled), set the **ProtocolState** to **RunProtocol** and run recovery operations. • **ProtocolRunning** – Protocol is running • **ProtocolPaused** – Protocol is paused • **InstrumentError** – An error has been raised on the Instrument .

Table 3 Variable set when changed *(continued)*

Variable	Type	Value/Description
UserLevel	Enum	• **NoUser** – No user is logged in. OPC-UA has no control • **ServiceUser** – The service user is logged in. OPC-UA has no control • **AdminUser** – A GUI Administration user is logged in. OPC-UA has no control • **FullUser** – A GUI Full user is logged in. OPC-UA has no control • **BasicUser** – A GUI Basic user is logged in. OPC-UA has no control • BasicUser – A GUI Basic user is logged in. OPC-UA has no control • BasicUser – A GUI Basic user is logged in. OPC-UA has no control • **ViewUser** – A GUI View user is logged in. OPC-UA has no control • **OPCViewUser** – An OPC-UA View user is logged in. The GUI is in view only mode, the OPC-UA interface has full control • **OPCViewUser** – An **OPC-UA** View user is logged in. The GUI is in view only mode, the OPC-UA interface has full control. • **OPCAdminUser** – An OPC-UA Administration user is logged in. The GUI has full control of the instrument, OPC-UA has no control.
ProtocolStepNumber	**UInt32**	The protocol step number
ProtocolStepName	**String**	The protocol step name
ProtocolTotalSteps	**UInt32**	Total number of steps in the protocol
PumpDirection	**Enum**	The current pump direction. • **NotApplicable** • **Forward** • **Reverse**
PumpRate	**UInt32**	The current pump speed
RunLogFileName	**String**	The filename of the current run log

Use case sequence diagrams

MES run a protocol

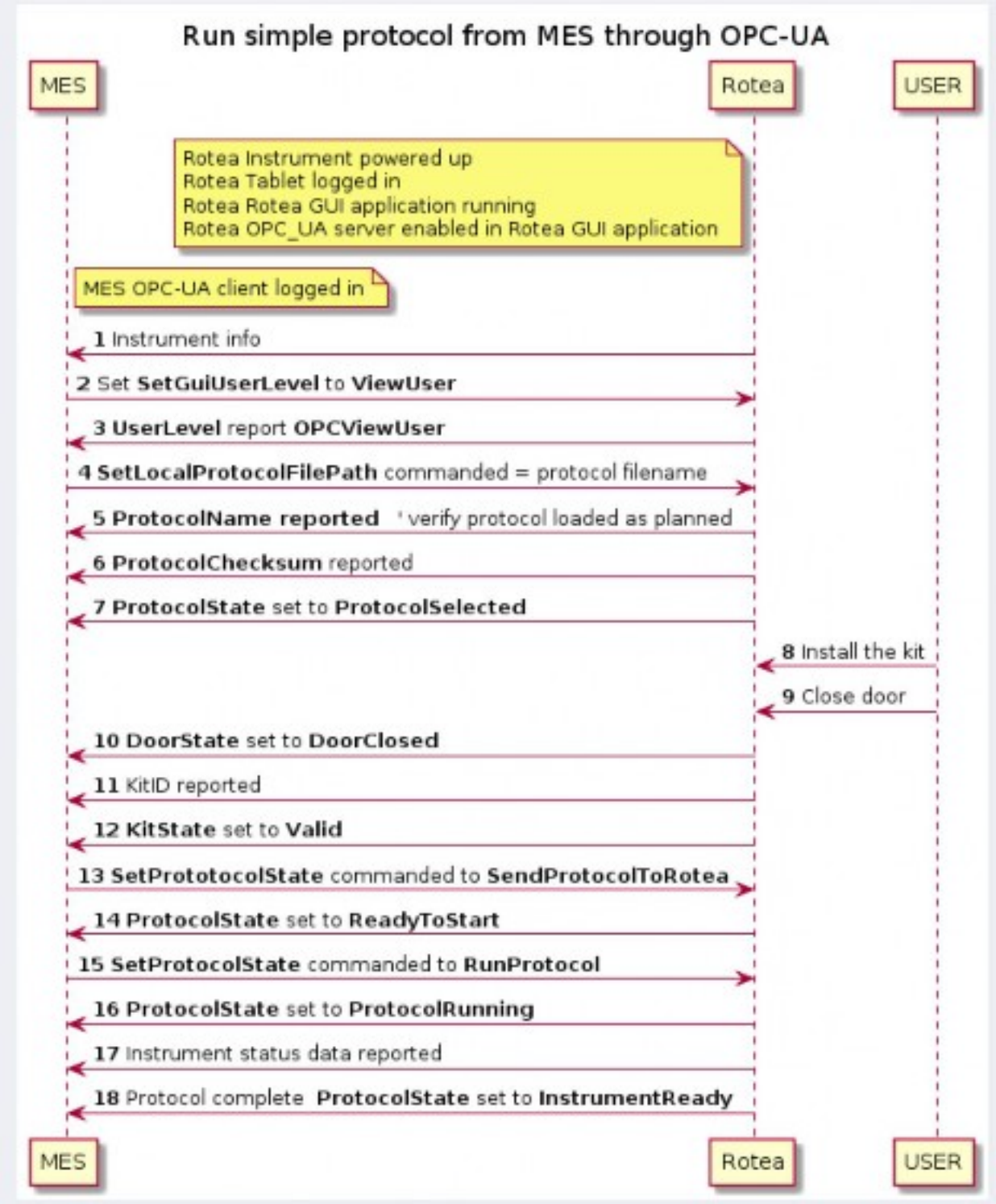


Figure 13 Run a simple protocol

Protocol with parametric data

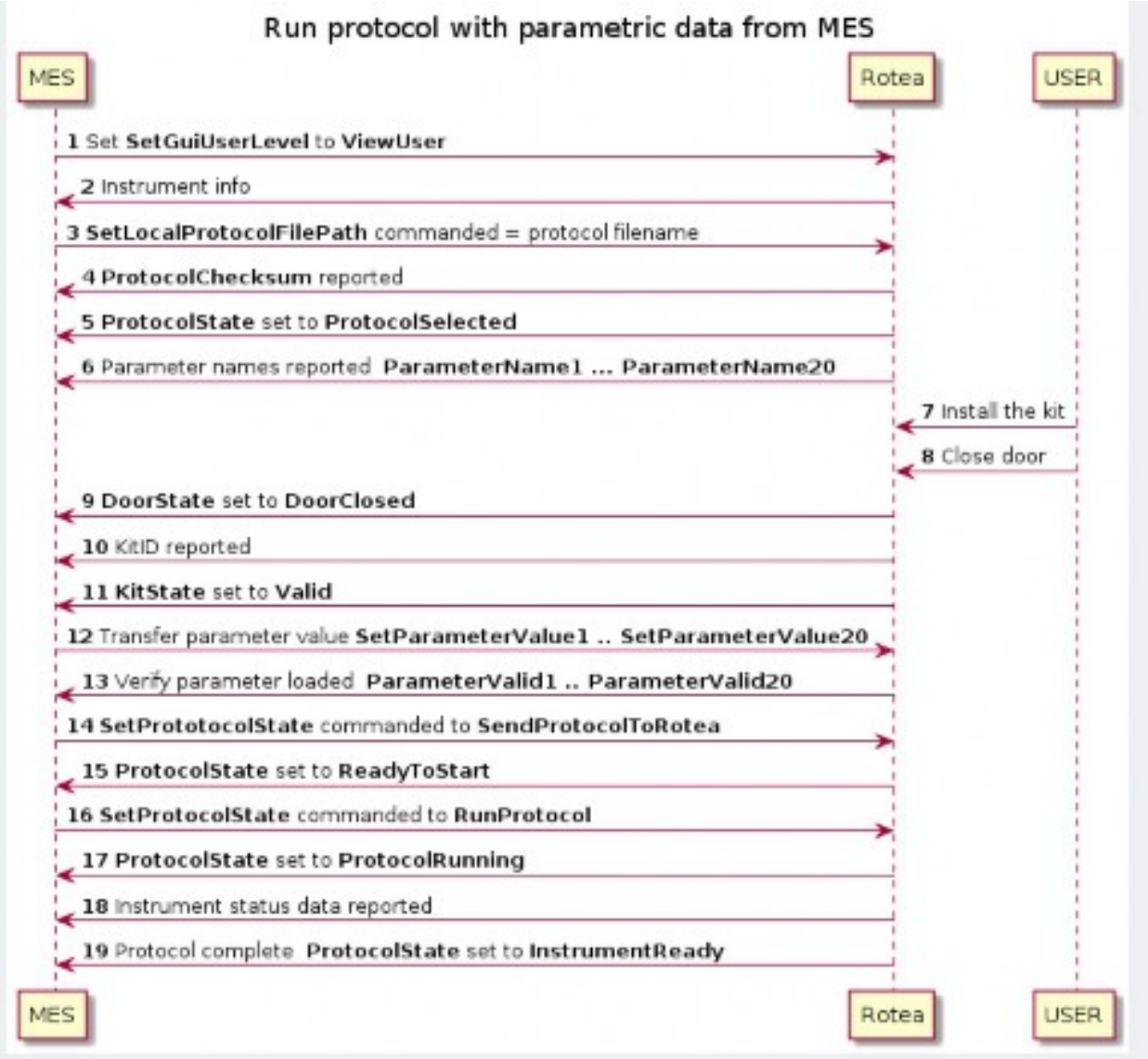


Figure 14 Run a simple protocol with parameters

MES drives Rotea in response to external systems

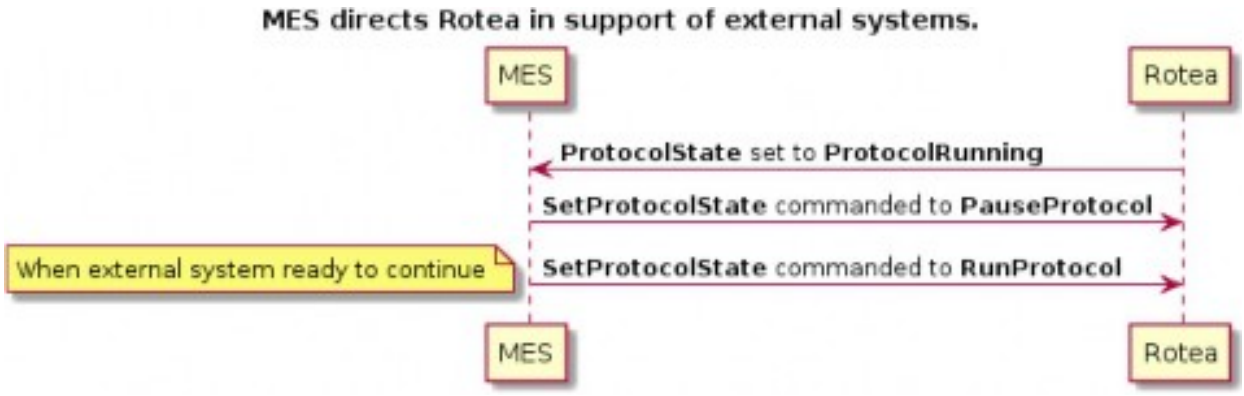


Figure 15 Pause/Play protocol while running

MES drives steps within protocol

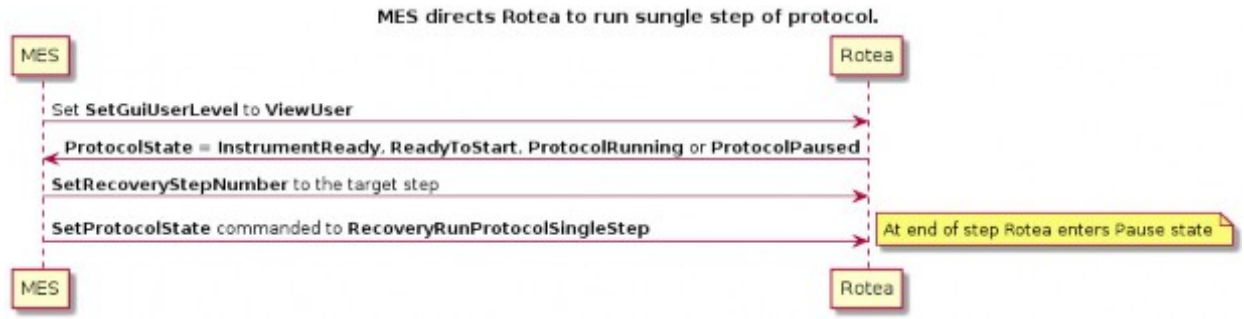


Figure 16 Perform single step recovery operation from OPC-UA while running a protocol

Figure 17 Perform run from step recovery operations from OPC-UA while running a protocol

MES manage error recovery events with admin user

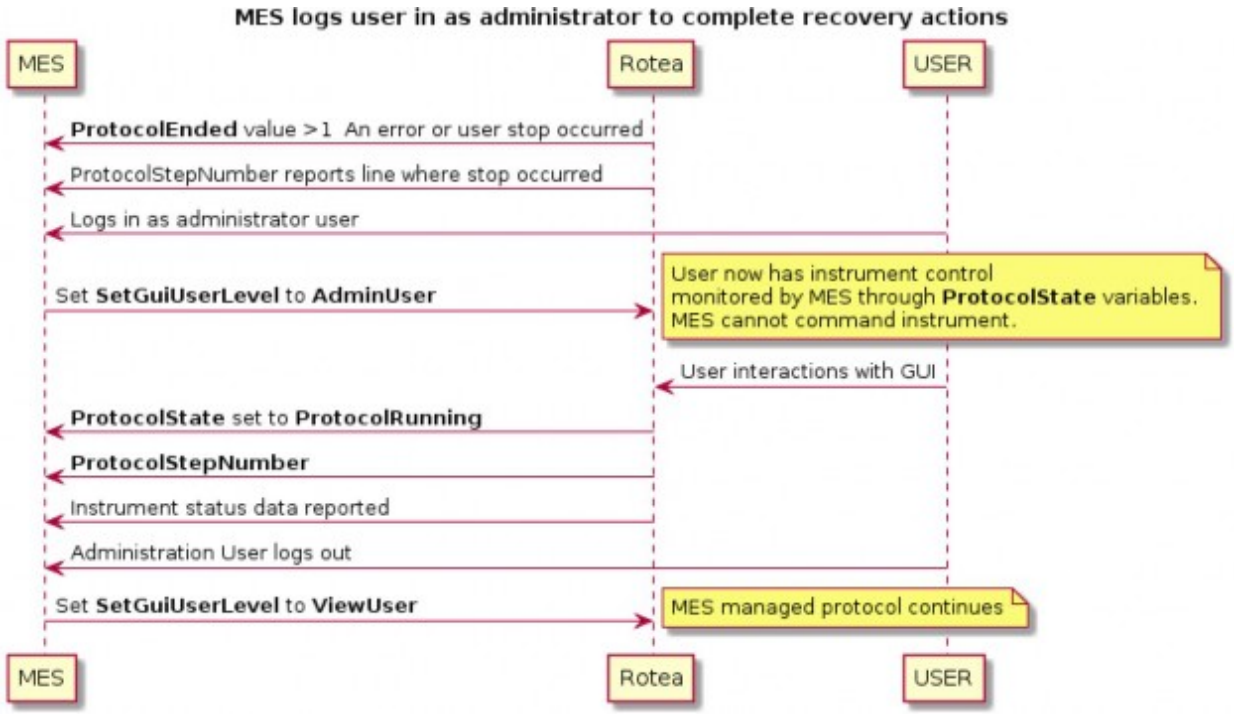


Figure 18 Change user level to perform recovery with the Rotea™ GUI

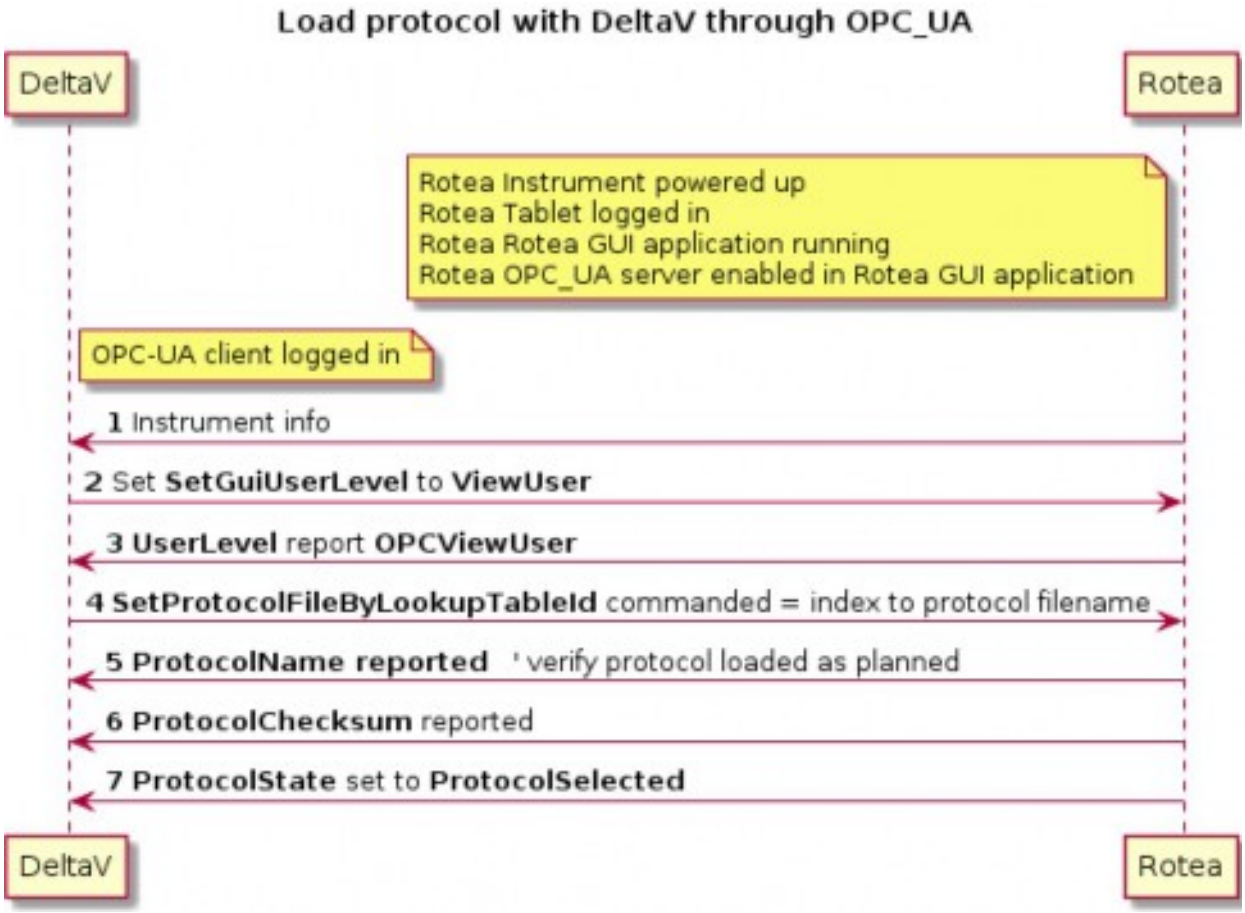
Use list file to load protocol

The look up or list file is always named `OPCUAProtocolList.yaml`. The Rotea™ admin user defines the directory where this file is to be found. That could be a shared directory, or a directory local to the Rotea™ instrument.

OPCUAProtocolList.yaml

```
1 - id: 1
2   filename: X:\Projects\Project 402 Taz\Forward rever.json
3 - id: 2
4   filename: E:\projects\taz\Bubble_sensor.json
5
```

- Each new entry is started with a "-"
- **id**: is an **int32** so potentially a larger number. The entries do not need to be in any order. The first match to the id number is used. There is no check for duplicate id entries.
- **Filename**: included path details



When DeltaV sends the index number, the Rotea™ GUI searches the pre-defined directory for the file `OPCUAProtocolList.yaml`, opens it and searches for the index number. If the index number is found, the protocol is loaded, and the status is reported to the OPC-UA server.

5 Maintenance

User maintenance schedule

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

WARNING! The Gibco™ CTS™ Rotea™ Single-Use Kit (Cat. Nos. A49585, A49313) and CTS™ Rotea™ Hi-Flow Single-Use Kit (Cat. Nos. A46575, A49239) have been validated for one-time use by customers. Single-Use Kits are not recommended to be washed, re-sterilized, or reused as sterility and quality of these kits have not been validated for multiple uses.

Instrument cleaning

All biological contaminants are contained within the 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

1. Disconnect the instrument from power.

2. Insert 3mm 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: 90 - 264 VAC, Frequency 47 – 63 Hz, 240 Watts.

Fuses

The power inlet module houses 2 x 5A cartridge fuses, 5 mm diameter x 20 mm long, fast acting.

- 250 VAC (5 Amp)

When required, replacement of fuses is performed as follows:

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 your instrument (see “Instrument properties” on page 11).
5. Insert new fuse and replace fuse cover.

6 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 Rotea™ system.

Component	Fault	Corrective action
Power	Instrument not turned on	Check mains switch and instrument on/off switch
	Replaceable fuse blown	Replace fuse (see "Fuses" on page 112)
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 such as tube 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 not rotating	Check instrument status
		Check mains switch and instrument on/off switch
		Contact Thermo Fisher Scientific Service Representative
Centrifuge	Centrifuge not rotating	Contact Thermo Fisher Scientific Service Representative
	Centrifuge noisy	Contact Thermo Fisher Scientific Service Representative
	Centrifuge out of balance	Check that CFC Chamber is correctly loaded
		Check that CFC Chamber is full of liquid and not leaking
		Check that the bench is stable

(continued)

Component	Fault	Corrective action
Door	Door won't 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, see "Open the door without power" on page 111.
	Door won't lock	Depress door fully
		Check that the KSingle-Use Kit has been correctly loaded with tubing retained in tube tracks
		Check for obstructions
Pinch valves	Valves not fully closing	Perform Single-Use Kit loading and unloading sequence multiple times, (see "Kit preparation, loading and removal" on page 43).
	Valves slow to close	Replace Single-Use Kit and check performance
	Loud audible noise when valves close	Replace Single-Use Kit and check performance
Moisture detector	Leaking Kit	Replace Single-Use Kit
		Wipe internal surface of centrifuge housing with a soft cloth or dry paper towel and restart Instrument.
	External spill	Wipe internal surface of centrifuge housing with a soft cloth or dry paper towel and restart the instrument.
Concentrate output 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.

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 and then turn power back on as described in "Power instrument "On"" on page 18.

Compliance

The Rotea™ instrument has been designed to comply with the following standards:

1. **UL 61010-1:2012**
2. **UL 61010-2-020: 2017**
3. **UL 61010-2-081: 2015**
4. **CAN/CSA C22.2 No. 61010-1-12**
5. **CAN/CSA C22.2 No. 61010-2-020: 2017**
6. **CAN/CSA C22.2 No. 61010-2-081: 2015**
7. **IEC 61010-1:2010**
8. **IEC 61010-2-020: 2016**
9. **IEC 61010-2-081: 2015**
10. **EN 61010-1:2010**
11. **EN 61010-2-020: 2017**
12. **EN 61010-2-081: 2015**
13. **European Low Voltage Directive 2014/35/EU**
14. **EMC Directive 2014/30/EU**
15. **EN 61326-1:2013 (Class A)**
16. **IEC 61326-1:2012**
17. **FCC 47 CFR Part 15 Subpart B**
18. **ICES-001:Issue 4**
19. **AS/NZS CISPR 11:2011**
20. **RoHS, Directive 2011/65/EU**
21. **China GB/T 26572-2011**, markings comply with **SJ/T 11364-2014**
22. **REACH Regulation (EC) 1907/2006**
23. **WEEE Directive 2012/19/EU**

8 Safety instructions

Labels

Safety label is located on the right side of the instrument.

Emergency procedures

This section describes the process for initiating an emergency shutdown and the consequence of a power failure.

Instrument emergency stop events

The instrument will automatically stop a running protocol if:

- Mains power is lost
- The Moisture Sensor detects fluid leaking in the centrifuge chamber zone
- The Vibration Sensor detects out of balance condition
- One of the Pressor Sensors detects sustained pressure over the threshold
- An internal error of the centrifuge drive, pump drive or valves is detected.
- Safety relay contacts welded or intermittent
- Door closed sensors opening
- Door latched sensor not true.

Instrument stop events are included for the safety of the operator and instrument. Where possible, warnings of problematic settings will be reported by the instrument if they can be identified before a stop is triggered.

Emergency shut down

The instrument can be shut down by the user in the following ways:

Figure 19 Turn off the instrument using the on/off switch or disconnecting mains power.

Figure 20 Immediately stop all instrument functions by pressing the stop ■ button.

Restart after shut down

Prior to restarting the Rotea™ instrument, ensure that the condition that caused the shut down has been rectified. The instrument can now be restarted; see Chapter 3, “Basic instrument operation”.

Protocol recovery process

Once the conditions causing the fault have been addressed it may be possible to restart a protocol from a specific protocol step.

Note: Unless there has been a breach of the closed fluidic system, the cells will have been retained in the system and are potentially recoverable.

For manufacturing situations with external run history monitoring, qualified protocols specific to the point in the program where the triggering event for the shut down occurred, can be initiated.

Where this isn't possible, manual intervention may be required to re-locate the fluid containing cells into a known bag and conduct a custom protocol to recover the cells.

If power is not available or the instrument is not serviceable, *page 111* describes how to manually open the door to enable removal of the Single-Use Kit for manual processing or transfer to a second instrument.

Warnings and precautions

Warnings

WARNING!

- The Rotea™ instrument is capable of producing liquid pressures up to 400 kPa if the flow is restricted. It is the users responsibility to ensure the volume of liquid pumped to any connected vessel does not exceed the rated volume of that vessel. Users should conduct their own hazards analysis based on the configuration of connected vessels or equipment and protocols used.
- The Rotea™ system should only be operated by trained personnel. The user is responsible for ensuring that they have read and understood the user guide.
- If the Rotea™ system is used in a manner not specified by Thermo Fisher Scientific, the protection provided by the equipment may be impaired.
- The user must check that the instruments and kits are in a safe operating condition prior to use.
- Thermo Fisher Scientific shall not be liable for any injury or damage resulting from use of the Rotea™ system that does not conform with the user guide.
- Always use appropriate Personal Protective Equipment (PPE) when operating the instrument or performing maintenance activities.
- Rotea™ instrument is not approved for use with flammable or explosive materials, or materials which could react chemically with sufficient vigour to cause a hazard.
- Rotea™ instrument is not approved for use in a potentially explosive atmosphere.
- Never exceed the operating limits stated in this document and on the system label. Operation outside these limits could damage equipment and cause personal injury or death.
- The kits are intended to be part of the biocontainment system however they are not to be relied on as the only means of safeguarding users and the environment when handling pathogenic micro-organisms.
- Do not use the Rotea™ instrument or kits if they are not working properly or have suffered any damage.
- Handle fluids with care when assembling and loading kits, attaching input vessels, collecting in-process samples, unloading kits, disconnecting and handling output material and disposing of used kits and components. Always use appropriate Personal Protective Equipment when operating or interacting with the Rotea™ system.
- Before maintenance or service is performed by Thermo Fisher Scientific or an approved representative, including return of the instrument, the system owner must first clean and decontaminate the system and provide documentary confirmation.
- Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with Thermo Fisher Scientific that the proposed method will not damage the equipment.

Cautions

CAUTION!

- The Rotea™ system shall be used exclusively with the Single-Use Kit. The kits 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 the Single-Use Kit. Thermo Fisher Scientific shall not be held responsible for any consequences resulting from use of kits other than as specified in the user guide.
- Please ensure that you contact an approved Thermo Fisher Scientific representative if there is any doubt as to the use of the Rotea™ system.

CAUTION! The Gibco™ CTS™ Rotea™ Single-Use Kit (Cat. Nos. A49585, A49313) and CTS™ Rotea™ Hi-Flow Single-Use Kit (Cat. Nos. A46575, A49239) have been validated for one-time use by customers. Single-Use Kits are not recommended to be washed, re-sterilized, or reused as sterility and quality of these kits have not been validated for multiple uses. Customers using Rotea™ Single-Use Kits multiple times are operating outside of Thermo Fisher Scientific guidance and risk voiding terms and conditions of warranty/service contract coverage.

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! Potential biohazard.

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
c UL us	Indicates conformity with safety requirements for Canada and U.S.A.
10	Indicates conformity with China RoHS requirements.

(continued)

Conformity mark	Description
CE	Indicates conformity with European Union requirements.
	Indicates conformity with Australian standards for 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 or crushing.

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, dimethyl sufloxide, and sodium hydroxide cause polymeric tubing to swell and greatly reduce the rupture pressure of the tubing.
- Be aware that high solvent flow rates (~40 mL/min) may cause a static charge to build up on the surface of the tubing and electrical sparks may result.

CAUTION! Do not lean on the operating instrument. Do not stay within 11.8" (300 mm) of the instrument longer than necessary for operational reasons. Do not deposit any potentially hazardous materials within 11.8" (300 mm) of the instrument.

Physical injury

CAUTION! Moving and Lifting Injury. The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. 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.

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! 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.

WARNING! Instrument protective bonding. For safe operation of the instrument regularly check grounding continuity to the instrument chassis, front plate and bag hangers.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.

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

CAUTION! Cleaning methods referenced within the *CTS™ Rotea™ Counterflow Centrifugation System User Guide* refer to the instrument only and do not apply to the Single-Use Kits. The Gibco™ CTS™ Rotea™ Single-Use Kit (Cat. Nos. A49585, A49313) and CTS™ Rotea™ Hi-Flow Single-Use Kit (Cat. Nos. A46575, A49239) have been validated for one-time use by customers. Single-Use Kits are not recommended to be washed, re-sterilized, or reused as sterility and quality of these kits have not been validated for multiple uses. Customers using Rotea™ Single-Use Kits multiple times are operating outside of Thermo Fisher Scientific guidance and risk voiding terms and conditions of warranty/ service contract coverage.

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*

(continued)

Reference	Description
IEC 61010-2-020 EN 61010-2-020	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-020: Particular requirements for laboratory centrifuges*
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*
AS/NZS CISPR 11	*Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment*
ICES-001, Issue 4	*Industrial, Scientific and Medical (ISM) Radio Frequency Generators*
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.

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union "WEEE Directive"—Waste electrical and electronic equipment
Directive 2011/65/EU	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.

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

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)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at:
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at:
  www.who.int/publications/i/item/9789240011311

B

Documentation and support

Customer and technical support

Visit **thermofisher.com/support** for the latest service and support information.

- Worldwide contact telephone numbers
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  - Training for many applications and instruments
- Order and web support
- 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/or its affiliate(s) 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 any questions, please contact Life Technologies at **www.thermofisher.com/support**.