CTS™ DynaCellect™ Magnetic Separation System

USER GUIDE

Catalog Number A55867

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Revision A.0

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

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Revision history: Pub. No. MAN0026480

Revision	Date	Description
A.0	13 October 2022	New document for CTS™ DynaCellect™ Magnetic Separation System.

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

Contents

Product information

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

Product description

The Gibco™ CTS™ DynaCellect™ Magnetic Separation System is an instrument for automated, magnetic cell separation and bead removal. The instrument is accommodated by single-use fit-for-purpose kits for cell isolation and bead removal. The key feature of the instrument is an automated magnet. The magnet is situated on a rocker, which enables mixing of cells and beads during cell-bead incubation. Automated fluid management is achieved by a peristaltic pump and pinch valves allowing transfer of fluid between bags. Fluid movement and pressure is monitored by bubble sensors and pressure occlusion sensors, respectively. Customizable software enables flexibility from process development to commercial manufacturing. The closed and automated configuration minimize failures in manufacturing, offering operator independent results and reduced contamination, while providing increased precision and scalability.

Single-Use Kits

The CTS™ DynaCellect™ Cell Isolation Kit and the CTS™ DynaCellect™ Bead Removal Kit are specifically designed Single-Use Kits for a range of cell processing applications such as isolation, depletion and bead removal. Each kit has input/output sterile weldable tubes for flexible setup configurations. See "CTS™ DynaCellect™ Single-Use Kit schematic" on page 17.

Storage

Store at ambient temperature. Storage at this temperature does not lead to decrease in magnetism. Protect the CTS™ DynaCellect™ Magnetic Separation System from vibration and keep out of direct sunlight.

Instrument features

- Automated magnet
- Rocker
- Embedded Graphical User Interface (eGUI) with 8" touch screen display (800 px × 600 px)
- 8 GB storage capacity for protocols
- Fluidics panel:
  - 11 pinch valves, 2 pressure occlusion sensors, 2 bubble sensors, peristaltic pump, peristaltic pump cover
- Overfill detector
- Leakage sensor
- Lid sensor
- HEPA filter
- 2 Bag hangers
- 2 Pole extensions
- 2 Pole adaptors
- 3 USB ports
  - USB port ready for barcode scanner
- Ethernet port
- Power inlet
- Power switch

Contents

Table 1   CTS™ DynaCellect™ Magnetic Separation System (Cat. No. A55867)

Component	Quantity
CTS™ DynaCellect™ Magnetic Separation System	1
Power cord	1
Ethernet cable	1
Pole extension	2
Bag hanger	2
Pole adaptor	2
Quick reference guide	1
Installation guide	1

Required materials not supplied

Unless otherwise indicated, all materials are available through **thermofisher.com**.

Catalog numbers that appear as links open the web pages for those products.

Item	Source
CTS™ DynaCellect™ Cell Isolation Kit	A52300
CTS™ DynaCellect™ Bead Removal Kit	A52301

Embedded Graphical User Interface (eGUI) features

The embedded graphical user interface (eGUI) is where you control the instrument and user access. See Chapter 3, "Embedded graphical user interface (eGUI) user instructions".

Process development mode

- Parameters
    - Magnet: engaged/disengaged
    - Pinch valves: open/closed
    - Pump speed: 10–150 mL/min
    - Pump: specified volume or duration

– Rocker angle: -30° to 30°

– Rocker speed: 1–30 CPM (cycles per minute)

• Export summary reports (sample ID, run ID, Single-Use Kit lot, bead lot, operator, date)

• DeltaV™ system communication via OPC UA (under development)

Clinical manufacturing mode

• Locked, standardized cell processing protocols

– Cell isolation

– Cell depletion

– Bead removal

• eBatch Records

– Enable 21 CFR part 11 compliance with SAE Administrator Console Software 2.1

System overview

CAUTION! This device contains extremely powerful permanent magnets. Keep ferromagnetic and ferromagnetically-sensitive material away from the magnetic surfaces and associated fields. Do not bring tools, equipment or personal items containing steel, iron or other magnetic materials close to the magnets. The strong magnetic field can erase magnetic media such as hard disc drive (HDD) memory devices, disable ATM and credit cards, and can damage some watches. Strong magnetic fields can also cause serious injury to persons with implanted or attached medical devices, such as pacemakers and prosthetic parts.

The Health and Safety Officer should take all necessary steps and full responsibility to ensure that the precautions and statements are followed and adhered to. IN NO EVENT SHALL Thermo Fisher Scientific BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.
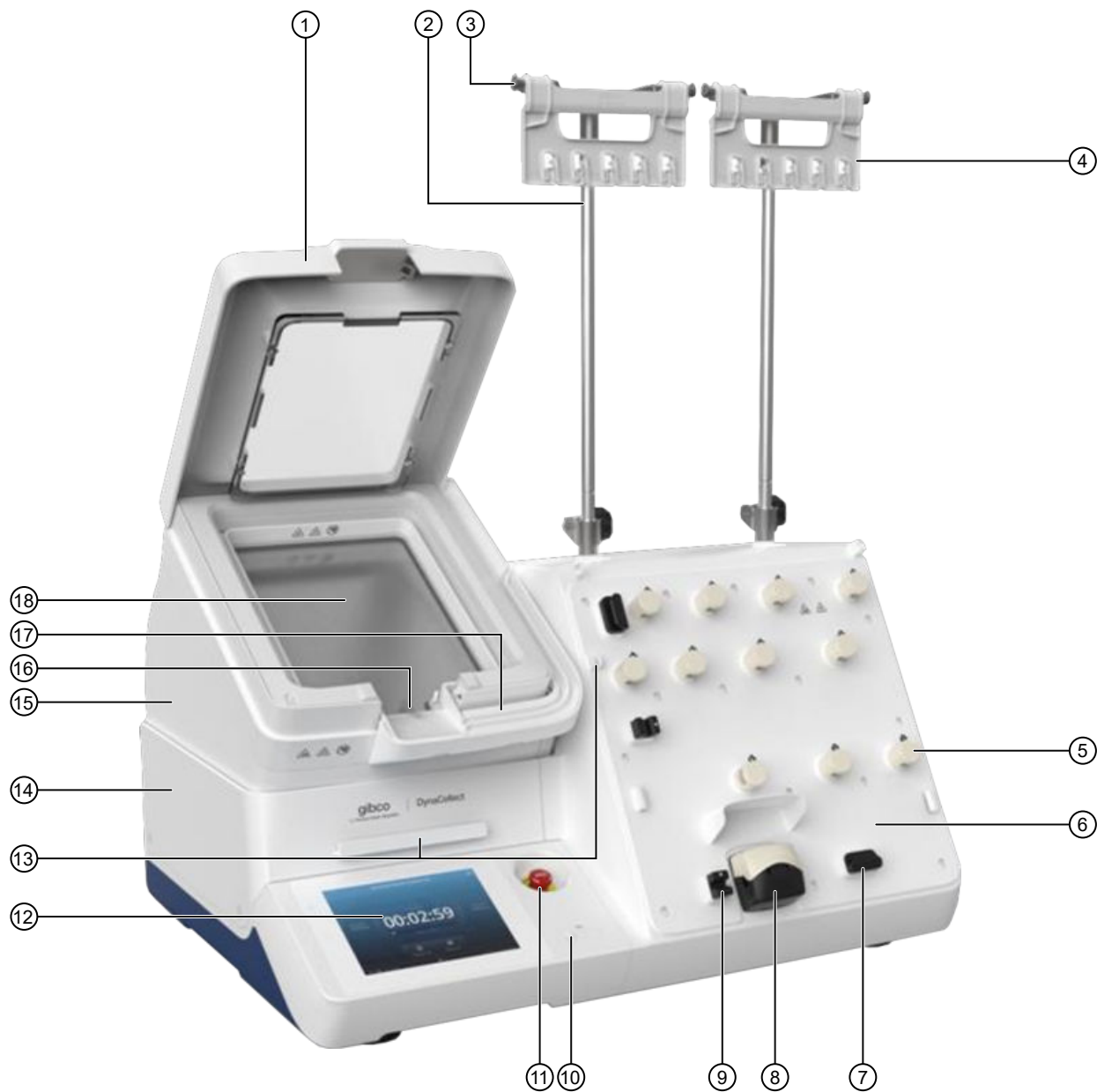
Figure 1   Front view

①	Lid	⑩	USB port
②	Pole extension	⑪	Emergency stop button
③	Pole adaptor	⑫	Embedded Graphical User Interface (eGUI)
④	Bag hanger	⑬	Tube guide for upstream or downstream connection
⑤	Pinch valve	⑭	Rocker guard
⑥	Fluidic panel	⑮	Rocker with integrated magnet
⑦	Pressure occlusion sensor	⑯	Leakage detection sensor and overfill detector
⑧	Peristaltic pump	⑰	Tube guide
⑨	Bubble sensor	⑱	Nest

Figure 2   Rear view

① Exhaust filter
② USB 2.0 port
③ USB wireless adaptor port
④ Ethernet
⑤ Power switch
⑥ Power cable inlet

Instrument dimensions

The dimensions for the CTS™ DynaCellect™ Magnetic Separation System are:

- **Height**: 19" (495 mm with pole base), 17" (434 mm without pole base)
- **Width**: 29.5" (749.5 mm)
- **Depth**: 22.12" (562 mm)

Working space

The CTS™ DynaCellect™ Magnetic Separation System is designed for benchtop use and requires a working space of approximately height 495 mm (19") with pole base and 434 mm (17") without pole base, width 749.5 mm (29.5"), depth 562 mm (22.12"). The system can also be placed on a cart.
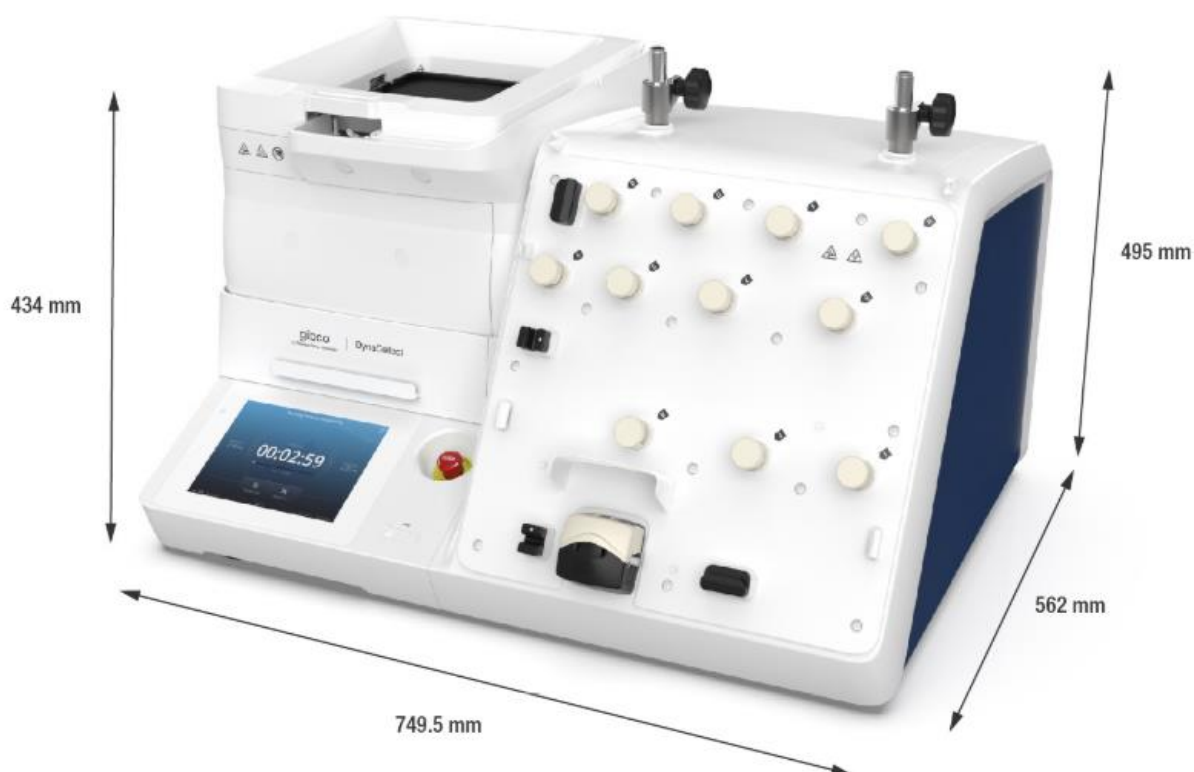
Instrument weight

The CTS™ DynaCellect™ Magnetic Separation System weighs 49.75 kg (109.7 lbs) (50.6 kg/111.6 lbs with poles and bag hangers).

Product specifications

Category	Property	Value
Electrical		
	Supply voltage	100–240 VAC ±10%, 50/60 Hz, 600 W
	Phases	Single
	Maximum rated input current	6 A
	Fuses	2 × 10 A
Instrument		
	Regulatory requirements	HEPA filter meets ISO 14644-14
	Installation category	II
	Instrument type	Benchtop/cart unit
	Instrument dimensions	495 mm (19") with pole base/ 434 mm (17") without pole base (H) × 749.5 mm (29.5") (W) × 562 mm (22.12") (D)
	Instrument weight	49.75 kg (109.7 lbs) (50.6 kg/111.6 lbs with poles and bag hangers)
	Built-in features	8" touch screen display (800 × 600 px)
Sound level		
	Operating sound level	73 dBA (measured 1 m from instrument)
	Non-operating sound level	63 dBA (measured 1 m from instrument)
Environmental ranges		
	Ambient temp	15°C to 30°C
	Transport temperature	-30°C to 60°C (extreme end temperatures at maxium 72 hours)
	Storage temperature	15°C to 30°C
	Relative humidity	15%–80% (non-condensing)
Operating limits		
	Magnet	Engaged/Disengaged

(continued)

Category	Property	Value
	Pinch valves	Open/Closed
	Pump speed	10–150 mL/min
	Rocker angle	-30° to 30°
	Rocker speed	1-30 CPM (cycles per minute)
	Pressure occlusion sensor	Max 2 Bar. Only detect liquid pressure (not pressure build up by air). Following lines are not covered: • CTS™ DynaCellect™ Cell Isolation Kit – Ports B and K • CTS™ DynaCellect™ Bead Removal Kit – Ports B, D and E
	Height rocker lid (isolation)	35 mm (1.4")
	Height rocker lid (bead removal)	5 mm (0.2")
	Overfilled detection	1120 mL (static and rocking)
Magnet		
	Magnet dimensions	265 × 205 mm (10.4" × 8.07")
	Magnetic strength	≥ 6000 G
Pole		
	Max height	1070 mm (42.13") from the bottom of the rubber foot of the instrument to the tip of the bag hanger hook point
Pole adaptor		
	Max weight	3 kg (6.6 lbs) per hook on bag hanger. Total 15 kg (33 lbs) per bag hanger
Use		
	Indoor use only	
	Not intended for use in a wet environment	
	Intended for use in Pollution degree 2 environment	

CTS™ DynaCellect™ Single-Use Kit schematic

1. PVC tubing
2. Tube holder
3. Silicone tubing
4. Sterile air filter
5. Oetiker clamps
6. Cassette
7. Bioprene tubing
8. Isolation bag
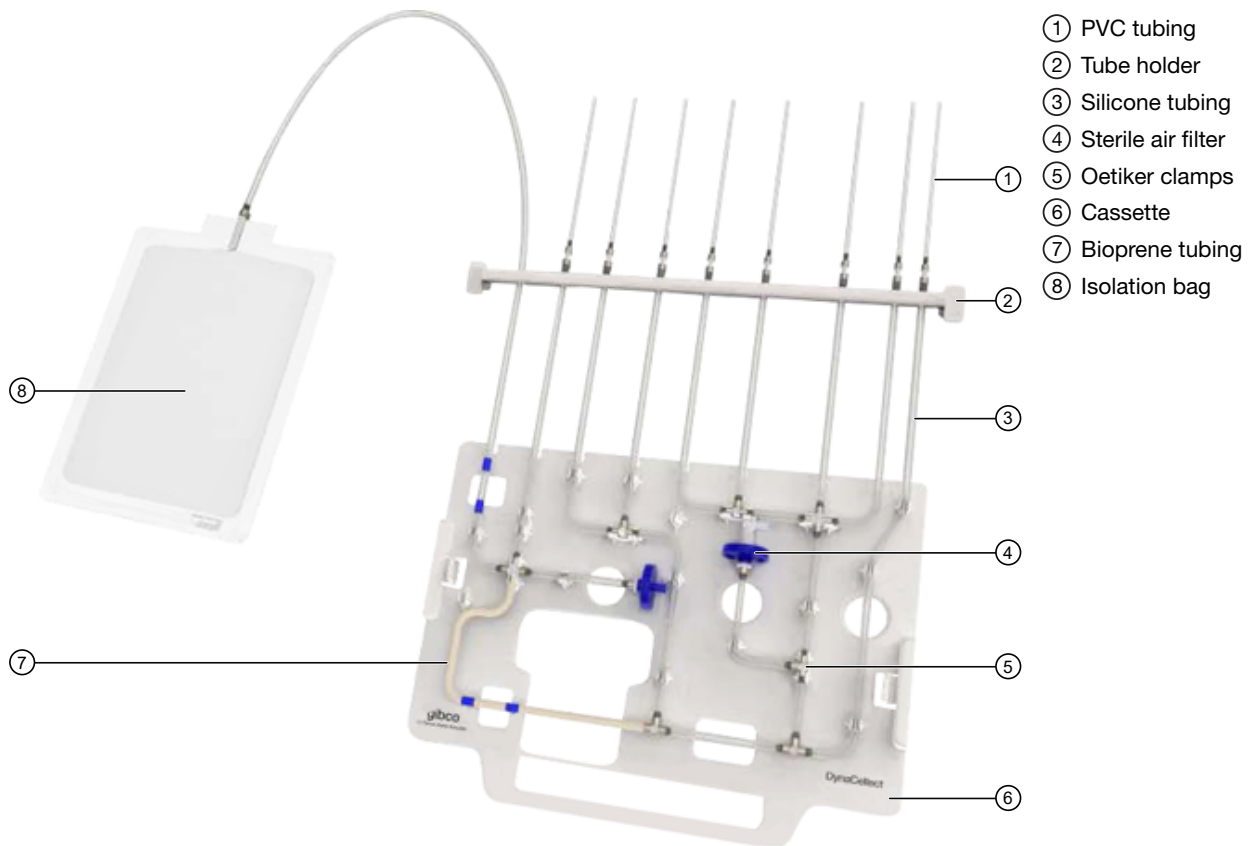
Figure 3 CTS™ DynaCellect™ Cell Isolation Kit (Cat. No. A52300)

- 8 weldable PVC lines [150 mm (5.91") (length), 2.4 mm (0.094") ID, 4.0 mm (0.157") OD]
- Sterile air filter: 0.20 micron
- Max capacity of isolation bag: 1000 mL
- Ease of use cassette and tube holder for loading of tubing set

① PVC tubing
② Tube holder
③ Silicone tubing
④ Sterile air filter
⑤ Oetiker clamps
⑥ Cassette
⑦ Bioprene tubing
⑧ Bead removal bag
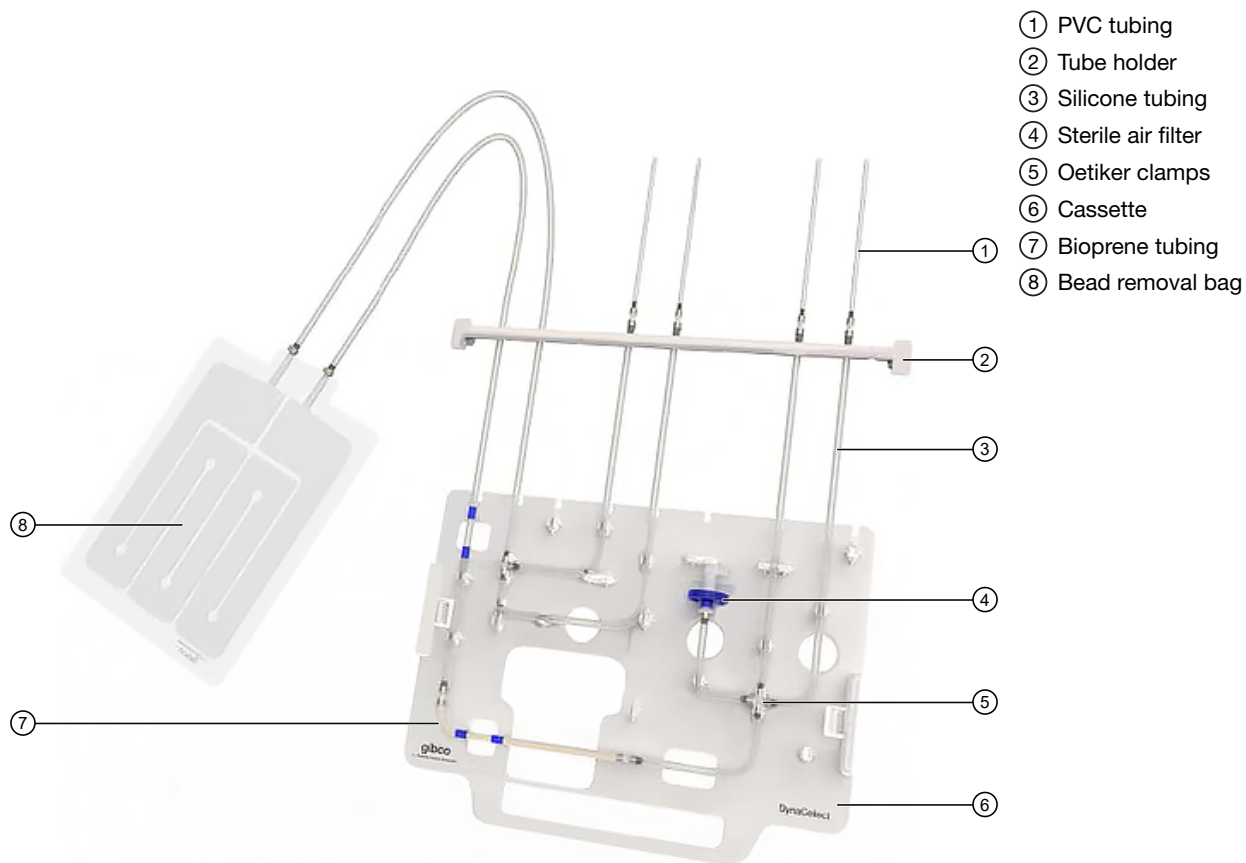
Figure 4 CTS™ DynaCellect™ Bead Removal Kit (Cat. No. A52301)

- 4 weldable PVC lines [150 mm (5.91") (length), 2.4 mm (0.094") ID, 4.0 mm (0.157") OD]
- Sterile air filter: 0.20 micron
- Continuous processing
- Ease of use cassette and tube holder of tubing set

IMPORTANT! Store the CTS™ DynaCellect™ Single-Use Kit at 15–30°C.

⚠️ **CAUTION!** The CTS™ DynaCellect™ Single-Use Kit (Cat. Nos. A52300 and A52301) 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.

Tube sets volume overview

The Single-Use Kits consist of three different tubing: silicone, bioprene, and PVC. The tube types and dimensions are indicated, see Figure 5. In Figure 6, the "dead volume" for the different tube lines is indicated.
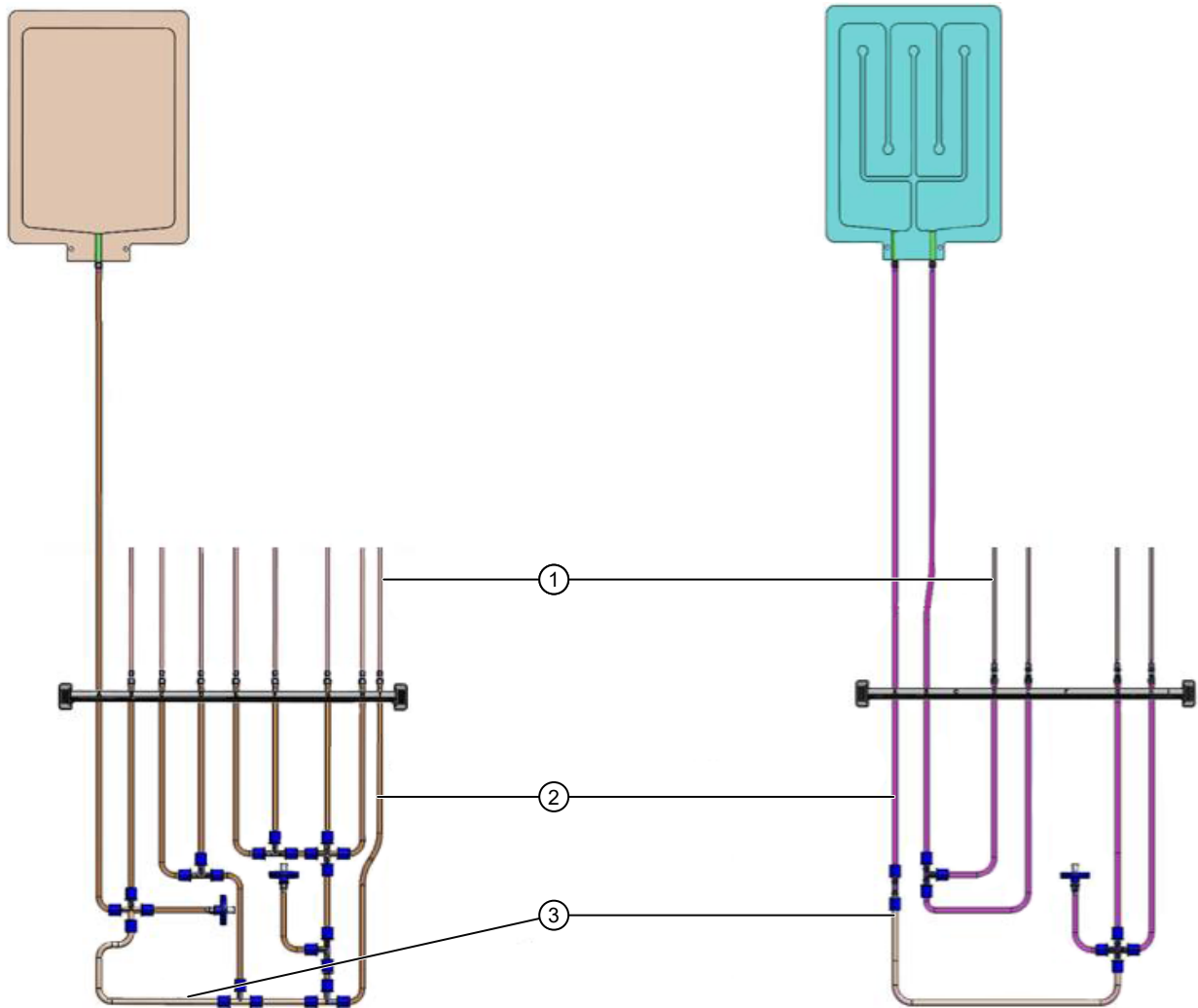
Figure 5   Tube types and thickness
Cell isolation kit (left) and Bead removal kit (right)

(1) PVC: 0.094 in ID 0.157 in OD; 2.4 mm ID 4.0 mm OD

(2) Silicone: 0.125 in ID 0.25 in OD; 3.2 mm ID 6.4 mm OD

(3) Bioprene: 0.125 in ID 0.25 in OD; 3.2 mm ID 6.4 mm OD

The dead volume is calculated based on tube diameter and length, using the following formula:

$V = A\,h$

Since the area of a circle = $\pi\,r^2$, then the formula for the volume of a cylinder is:

$V = \pi\,r^2\,h$

Note: The volume in mL for each tube is indicated in Figure 6. This enables you to adjust for modifications to the input/output line, by e.g. welding particularly short or long tube lines. While it is recommended to keep the welding distance from the Single-Use Kits to cell/bead/buffer bags consistent between runs using the same protocol, note that the dead volume per inch/cm is relatively low. Millimeter precision is therefore not necessary when welding bags onto the Single-Use Kits from run to run.
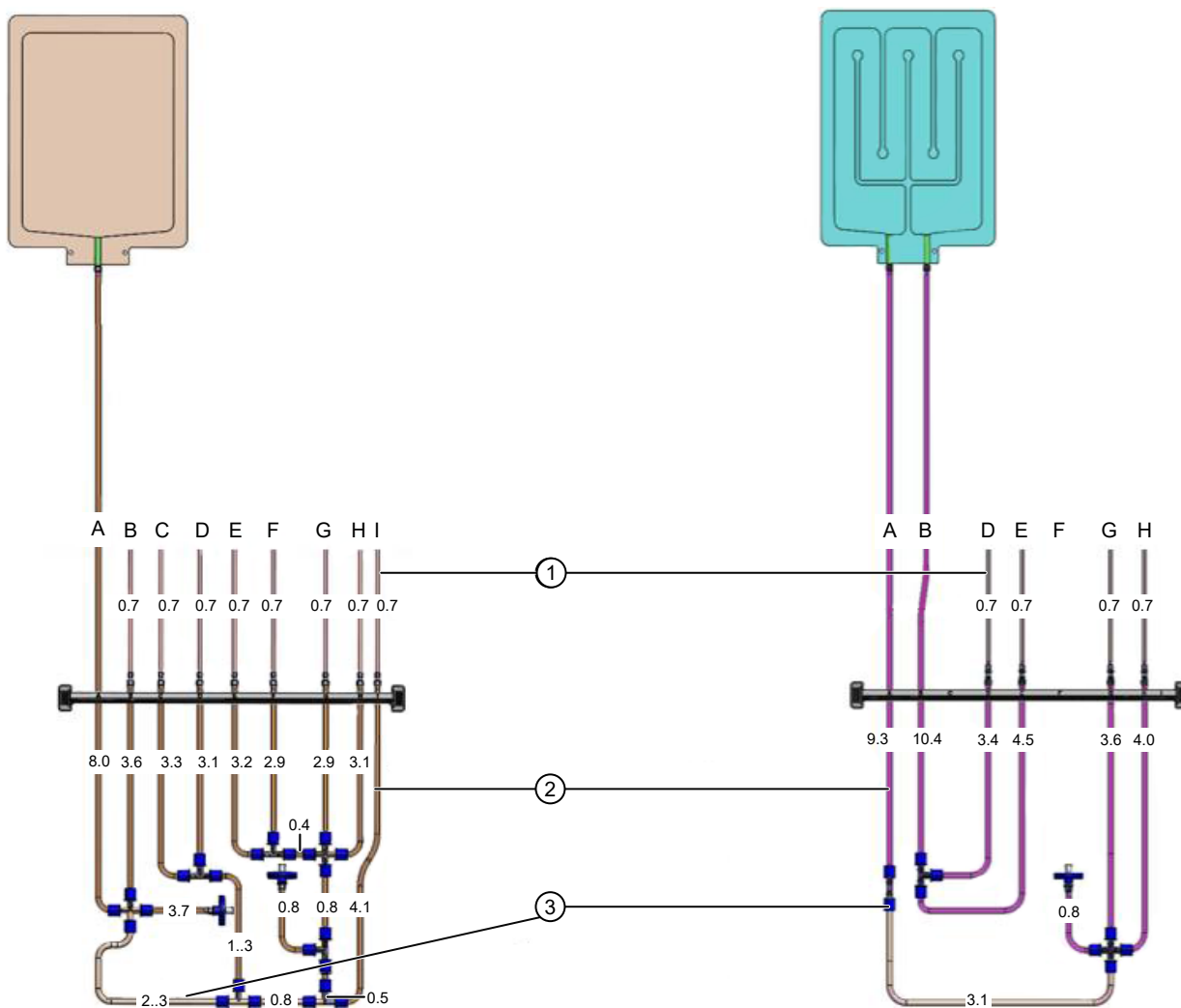
Figure 6   Dead volume in Single-Use Kits
Cell isolation kit (left) and Bead removal kit (right). The numbers show the volume (mL) for each tube.

① PVC: mL per in: 0.11; mL per cm: 0.05

② Silicone: mL per in: 0.2; mL per cm: 0.08

③ Bioprene: mL per in: 0.2; mL per cm: 0.08

Single-Use Kit packaging

① PE foam (top)
② Corrugated, partition set
③ PE foam (cut sheet)
④ Die cut box
⑤ PE foam (bottom)
⑥ Shipper box
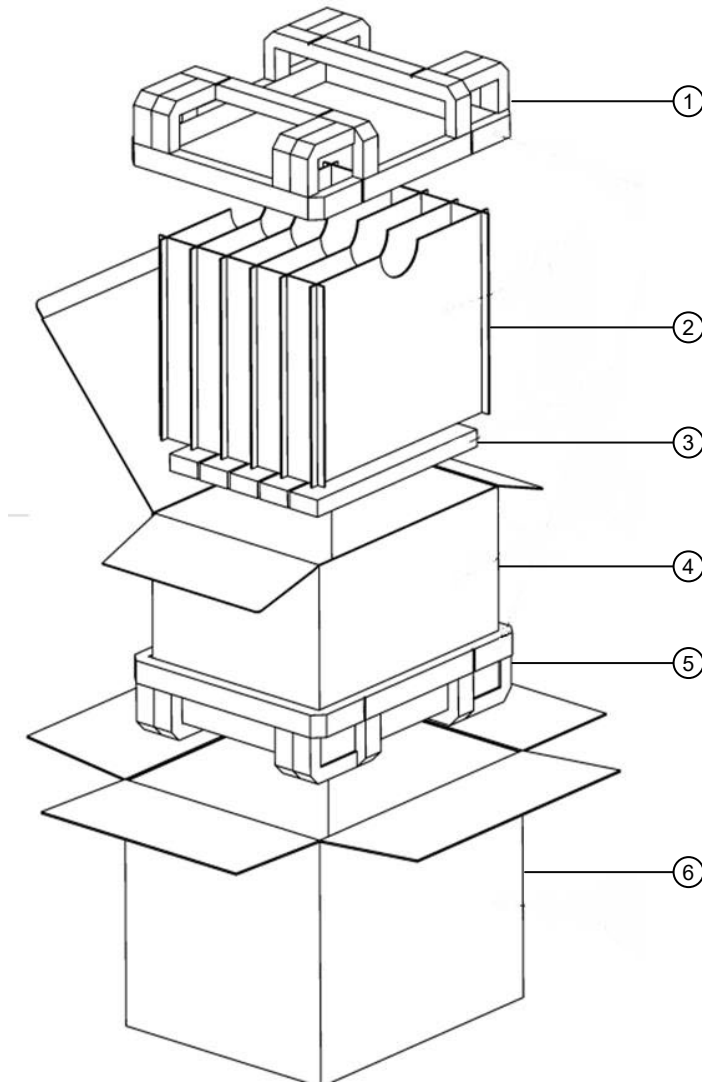
Figure 7   Single-Use Kit packaging

Carton box:

- Quantity: 5 Single-Use Kits
- 460 mm (18.11") (L) × 300 mm (11.81") (W) × 350 mm (13.78") (H)

Wetted components

Component	Description	Material
Pumping tubing		
	Bioprene tubing 3.2 mm ID, 6.4 mm OD (0.125 in ID, 0.25 in OD)	Bioprene
Kit tubing		
	Tygon ND-100-65 Non DEHP tubing 2.4 mm ID, 4.0 mm OD (0.094 in ID, 0.157 in OD)	PVC
	Sanitech STHT-C Platinum Cured Tubing 3.2 mm ID, 6.4 mm OD (0.125 in ID, 0.25 in OD)	Silicone
Fittings		
	Barbed straight connector	Polypropylene
	Barbed tee connector	Polypropylene
	Barbed cross connector	Polypropylene
	Check valve, Female luer lock inlet, Barbed outlet	SAN, MABS, Silicone
	Sterile filter syringe filter, Minisart Polyesthersulfone	MABS
	Barbed straight reducer	EVA
	Barbed bag output port	EVA
Bags		
	Isolation Bag	EVA
	Bead removal Bag	EVA

Installation and setup

Packaging contents

- CTS™ DynaCellect™ Magnetic Separation System instrument
- Power cord
- Ethernet cable
- 2 Pole extensions
- 2 Bag hangers
- 2 Pole adapters
- Quick reference quide
- Installation guide

Upon receiving the instrument

- Check the enclosed packing list against the order.
- Visually inspect the transport package, the instrument and the accessories for any damage.
- If the carton has been damaged in transit, it is particularly important that you retain it for inspection by the carrier in case there has also been damage to the instrument.
- Any damage claims must be filed with the carrier. Neither the manufacturer nor its agents can be held responsible for any damage incurred in transit. Upon receipt of the carrier's inspection report, arrangements will be made for repair or replacement.
- To register the instrument, activate the warranty, and be notified of important updates, see **thermofisher.com**.

Unpack the instrument

To prevent condensation, the instrument should be left in its protective, antistatic plastic wrapping until the ambient temperature has been reached.

- The instrument weighs 49.75 kg (109.7 lbs) (50.6 kg/111.6 lbs with poles and bag hangers) and requires at least two people to lift. Use the proper precautions when lifting the instrument to avoid injury.

- Retain the original packaging and packing material for future transportation. The packaging is designed to assure safe transport and minimize transit damage. Use of alternative packaging materials may invalidate the warranty. Also retain all instrument-related documentation provided by the manufacturer for future use.

- During instrument installation and maintenance, it is necessary to access the back of the instrument. If the back of the instrument faces a wall, ensure that there is sufficient clearance on the bench to rotate the instrument for access.

> **WARNING!**
> - Do not place the instrument adjacent to, or stack with other equipment to avoid improper operation. If this type of placement is necessary, all the instruments and equipment should be observed to ensure that they operate normally.
> - Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the equipment can result in increased electromagnetic emissions, or decreased electromagnetic immunity of this equipment, and result in improper operation.
> - Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) within 30 cm (12 inches) of any part of the instrument (including cables specified by the manufacturer) to avoid degradation of equipment performance.

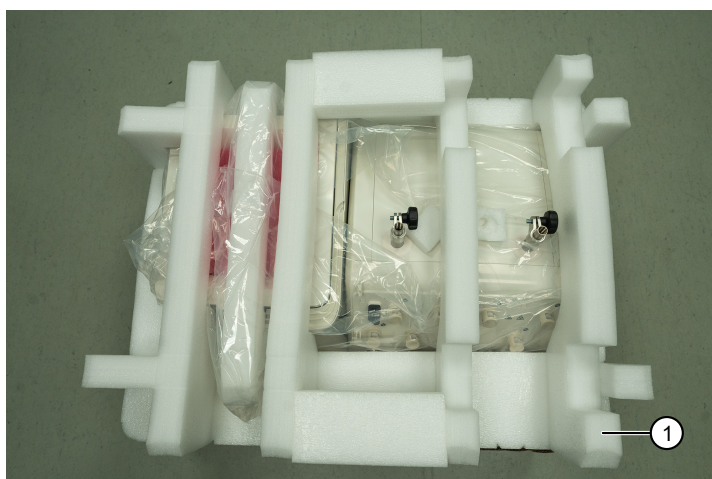1. Lift the cardboard box off the pallet.

2. Remove the two small cardboard boxes.
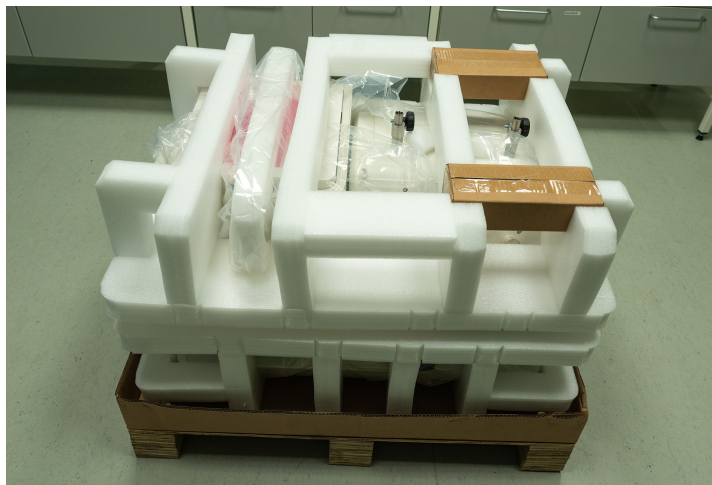
3. Remove the top foam.

① Top foam

4. Unwrap the packaging bag and remove the ethernet cable and power cord.

5. Lift the instrument to the bench or cart. The operation require two persons. Use the four holding recesses (front left side, back right side, and on both sides) to lift in diagonal position.

6. Remove the rocker homing position foam from the side. Once the rocker has been permitted to fall to its extreme (±30°) resting position, users should not attempt to force it out of position. There is risk to damage bearings and the motor if excessive force is applied after the rocker has moved to its resting position.

① Rocker homing position foam

7. Unpack the two small cardboard boxes; 2 bag hangers, 2 pole extensions, and 2 pole adaptors.
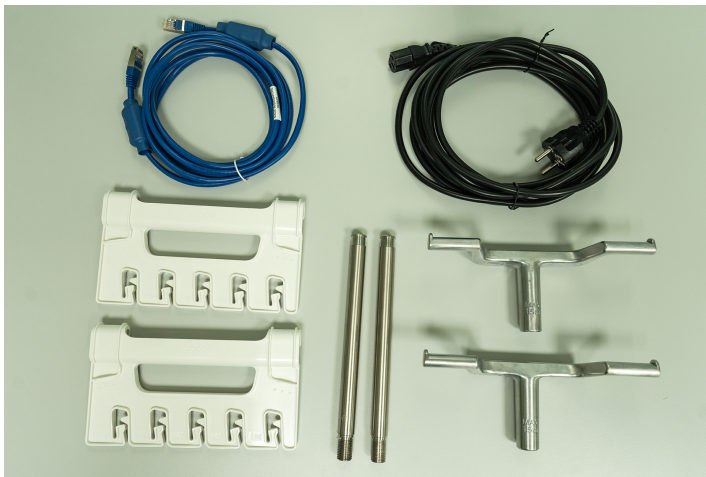
A summary of the unpacking and installation instructions are also provided in the *CTS™ DynaCellect™ Magnetic Separation System Installation Guide* (Pub. No. 1100117621).

Installing the instrument

Prepare bench space to receive the DynaCellect™ instrument unit (see "Instrument dimensions" on page 14) ensuring that there is easy access to the "On/Off" switch and mains IEC connector at the rear of the instrument.

⚠️ **CAUTION!** The DynaCellect™ instrument should be installed on a stable bench. If a mobile set up is used, it is the user's responsibility to ensure that 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 cm) between the rubber feet and the edges of the bench.

⚠️ **CAUTION!**
- The DynaCellect™ instrument weighs 49.75 kg (109.7 lbs) (50.6 kg/111.6 lbs with poles and bag hangers). Use appropriate care and seek assistance if necessary when lifting or moving the instrument. Use the holding recess to lift the instrument.
- Do not position the instrument is such a way that it would make it difficult to disconnect the power cord from the power inlet.

Installation

1. Find the 2 pole extensions and 2 pole adaptors.

① Pole adaptor
② Pole extension

2. Loosen the screw on the pole adaptor.

3. Place the pole adaptor on top of the pole extension and tighten with a 2 mm allen key. Repeat with the second pole extension and pole adaptor.

4. Install both pole extensions with the pole adaptor to the 2 pole bases on the instrument. Turn to tighten.
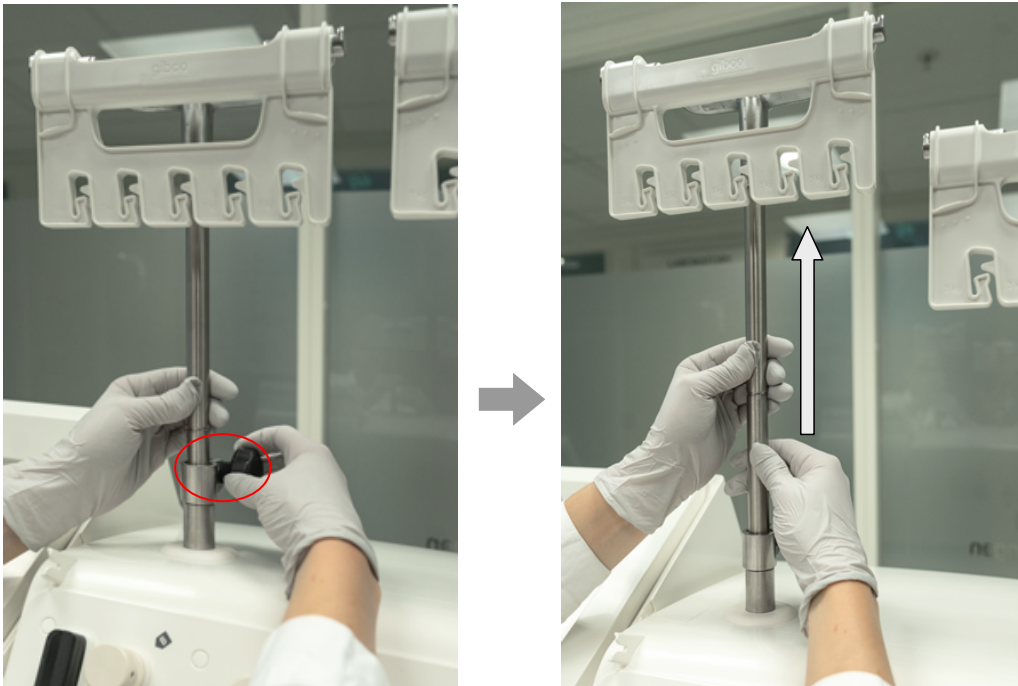

① Pole adaptor
② Pole extension
③ Pole base

5. Place the bag hangers on the pole adaptors.

6. To extend the poles, loosen the nut (shown in red circle), pull the pole upwards and tighten the nut.

7. The instrument is installed.

Power instrument "On"

1. Insert the power cord to instrument and a 100-240V outlet.

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

① Power button

3. The instrument will be initialized by itself, which will take ~90 seconds

Power instrument "Off"

Switch off using the mains IEC switch at the rear, right side of the instrument.

① Power button

⚠ **CAUTION!** There is no automatic recovery procedure. If a loss of power event has occurred, see "Restart after shut down" on page 156.
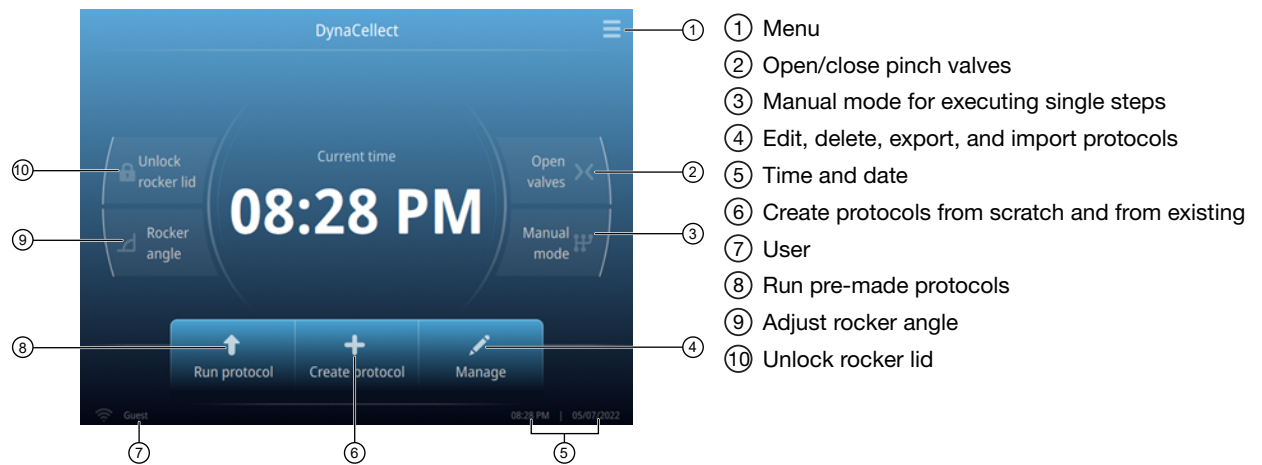
Embedded graphical user interface (eGUI) user instructions

The embedded graphical user interface (eGUI) is where you control the instrument and user access. Besides installing the Single-Use Kit by hand and adjusting pole height, all instrument actions are managed from the eGUI.

Home screen

On the home screen the main user interaction points are shown in the following figure. How to create and run protocols is described in the next sections.

① Menu
② Open/close pinch valves
③ Manual mode for executing single steps
④ Edit, delete, export, and import protocols
⑤ Time and date
⑥ Create protocols from scratch and from existing
⑦ User
⑧ Run pre-made protocols
⑨ Adjust rocker angle
⑩ Unlock rocker lid

User interface overview

Symbol	Function
Run Protocol	
	Open and run protocol
Create Protocol	
	• Create a new protocol • Create a new protocol from existing protocols
Manage protocol	
	• Edit existing protocols • Import protocols • Export protocols • Delete protocols
Unlock rocker lid	
	Unlock rocker lid
Rocker angle	
	Adjust the rocker angle
Open/close pinch valves	
	Open and close pinch valves
Manual mode	
	Manual mode for executing single steps. For more details on how to create a step, see page 54.

Touch screen controls

Button	Function
〈	Returns to the previous screen
✕	Close the current window
☰	Go to menu screen

Status indicators

Button	Function
🔲	Indicates whether a USB device is inserted into the instrument
🖧	Indicates whether the instrument is connected to wired network
Guest	Indicates user

Enter text

When you press a field that requires the input of text, the text editor, as seen in the following figure, opens.

① Enter a letter
② Change letter case
③ Close and save
④ Delete
⑤ Close without saving

Enter numbers

When you press a field that requires a numerical input, the numeric editor, as seen in the following figure, opens.
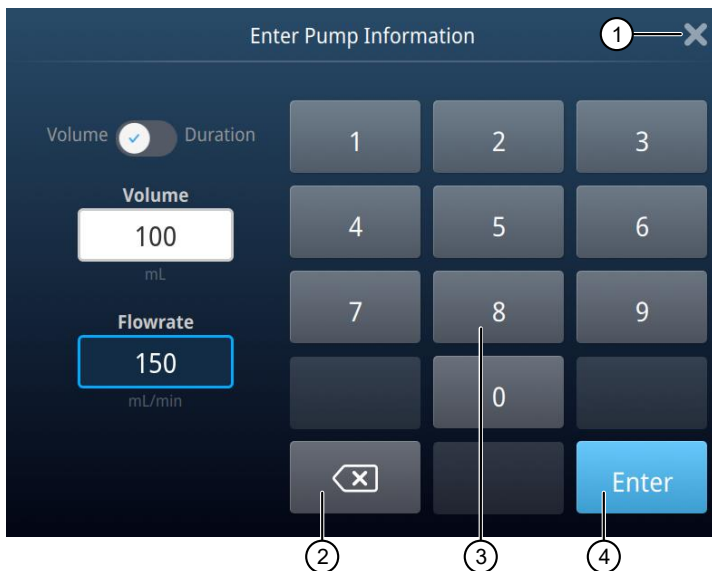
① Close without saving
② Delete
③ Enter a number
④ Close and save

Connect the instrument to the internet

The instrument can connect to the internet with the Ethernet cable.

Set up a wired connection

Connect one end of an Ethernet cable to the instrument Ethernet port, and the other end to an Ethernet port wall plug (for port location, see "System overview" on page 11).

1. On the **Home** screen, select ☰ (**Menu**).
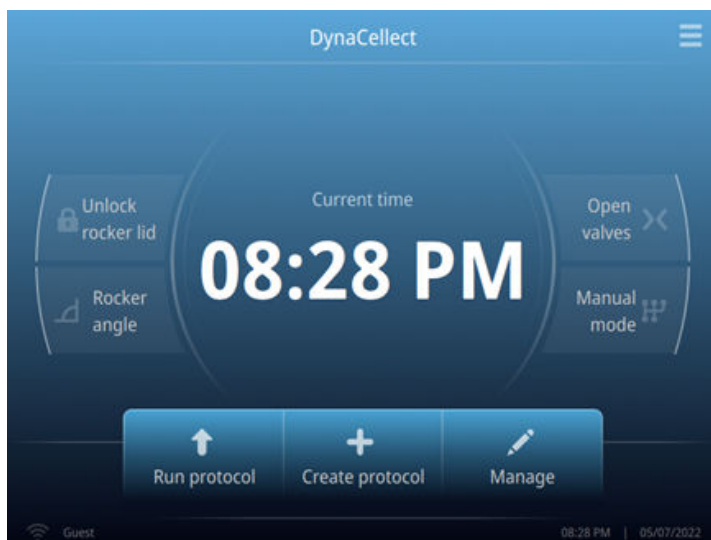
2. In the **Menu** screen, select ⚙ (**Settings**).
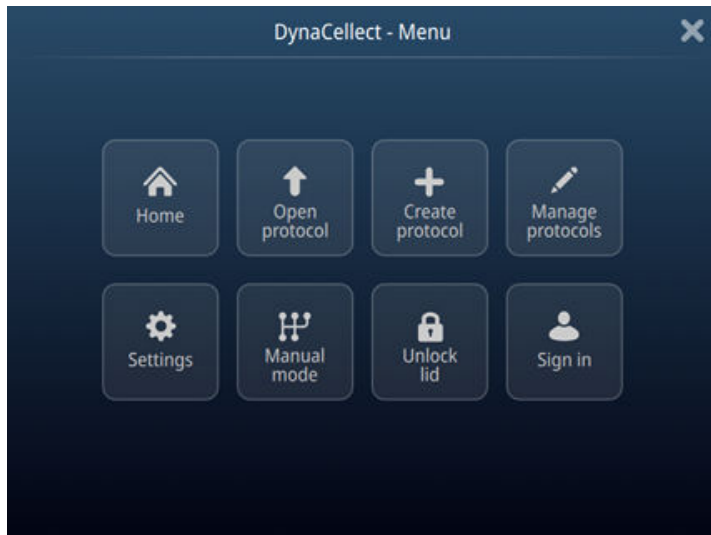
3. In the **System Settings** screen, select **Instrument settings**.
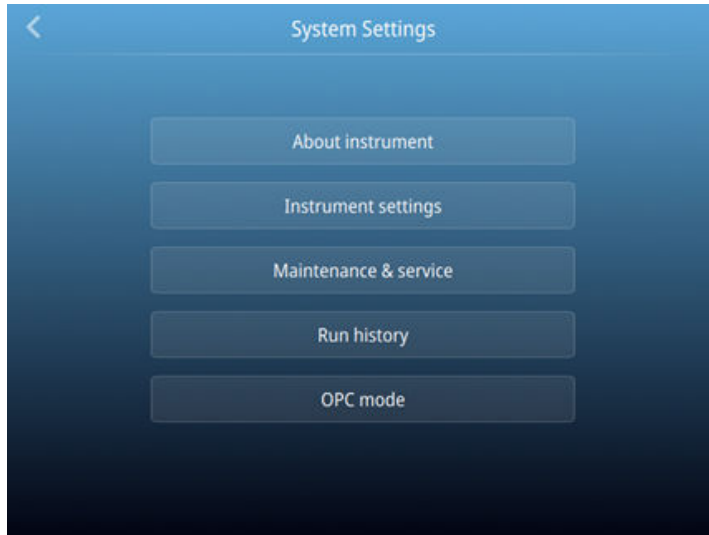
4. In the **Instrument Settings** screen, select **Network configuration**.

3
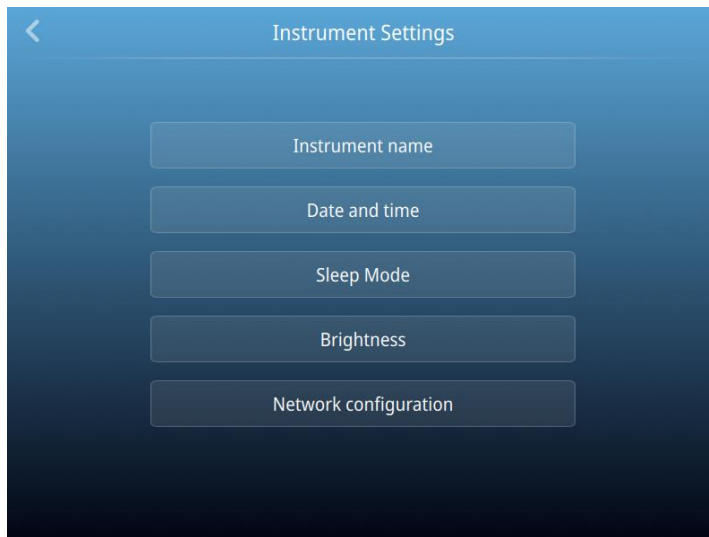
5. In the **Network Configuration** screen, select **Edit**.
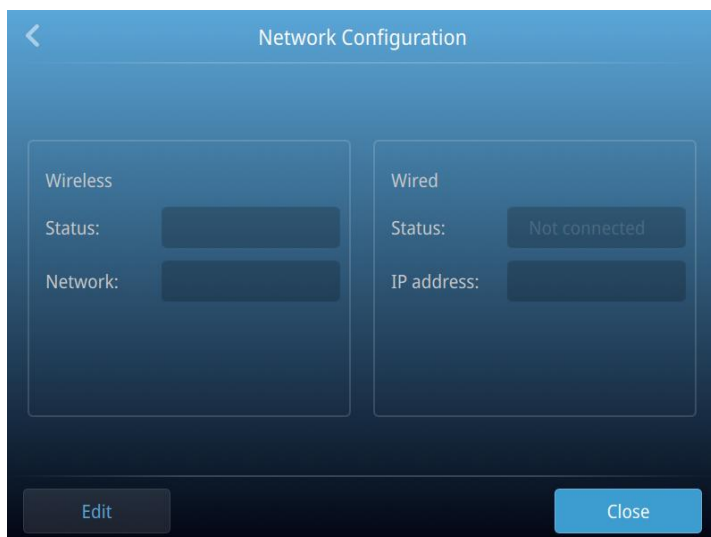
6. In the **Network Configuration** screen, select a field in the **Wired** panel.
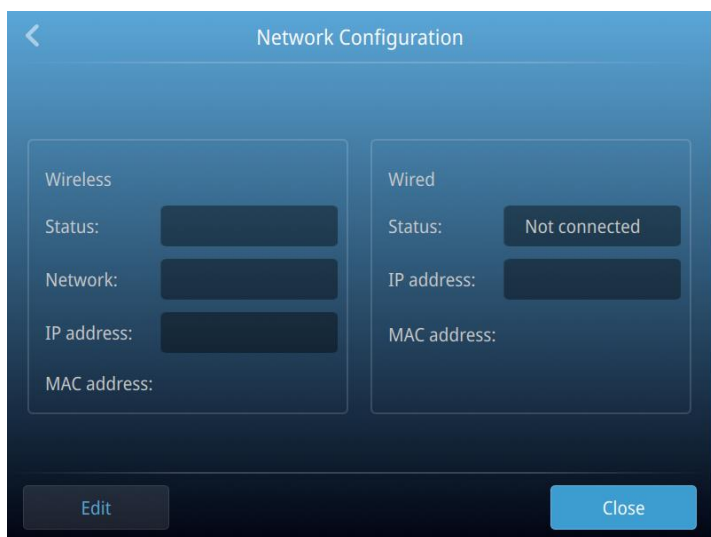
7. Select a method to enter an IP address.
   - Select **DHCP** to obtain an IP address automatically. A check mark appears when **DHCP** is selected.
   - Select **Static** to enter an IP address manually, then enter the appropriate IP addresses for the instrument, the Subnet Mask, and, optionally, the Default Gateway, the Primary DNS Server, and the Secondary DNS Server using the numeric editor. Addresses are in the form of X.X.X.X, where each X is a number, from 001 to 255.

Note: If your instrument is not on a network, you do not need to set the IP address. Ask your system administrator if the IP address is assigned statically or dynamically. For static addresses, you need to know the IP address for the instrument, the subnet mask, and the default gateway.

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8. Select **Done** to save the changes and go back to the **Instrument Settings** screen or select **Cancel** to exit the screen without saving the changes.

Create a user profile on the instrument

Users can create their own password-protected profile. Access can also be granted without password via the **Guest user**. Protocols made with the **Guest user** is only available to the **Guest user**, whereas the password protected-generated protocols are limited to the respective users.

1. Select ≡ **(Menu)**.

2. Select 👤 **(Sign In)** > **Get started** > **Create profile**.

3. Fill in the required text fields and enter a four-digit PIN to create your user profile.

   Note: The first profile created is automatically given an Administrator profile (indicated by an asterisk after the Username).

   ---

4. Select **Create**.

Manage user profiles

All users can manage their profiles to edit personal folder names, and change PINs by selecting their 👤 **(Profile)** to enter their **My Profile** page.

Users with Administrator profiles (as indicated by an asterisk after their username) also have the ability to manage all user accounts by selecting **All profiles** after entering their **My Profile** page.

The following actions are available from the user profile screen:

- Reset a PIN
- Create a new user profile
- Grant administrator rights to selected user profile (Administrator only)
- Delete a user profile (Administrator only)
- Delete a PIN (Administrator only)

Change a user PIN

1. Select 👤 **(Profile)**.

2. Select **Reset PIN**.

3. Enter old PIN.

4. Enter a new four-digit PIN.

5. Confirm new PIN by re-entering the new PIN.

6. Select **Reset PIN.**

Delete a user PIN

If a password is forgotten, an administrator can delete the existing password to allow a new one to be created. This function resets a PIN, so the user with a deleted PIN is prompted to create a new PIN the next time they log in.

1. Select **All profiles**.

2. Select the profile with the forgotten password.

3. Select **Delete PIN**.

Add a user profile

1. Select **All profiles**.

2. Select **Add profile**.

Delete a user profile

1. Select **All profiles**.

2. Select the account to be deleted.

3. Select **Delete account**.

Assign or remove administrator privileges

An asterisk appears next to user profiles with administrator privileges.

1. Select **All profiles**.

2. Select the account to be modified.

3. Switch the toggle to **Yes** to grant privileges, or **No** to remove privileges.

Manual mode

Manual mode can be used to execute single steps without creating a protocol.

1. From the home screen select **Manual mode**.

2. Select **Cell isolation protocol** or **Bead removal protocol**.
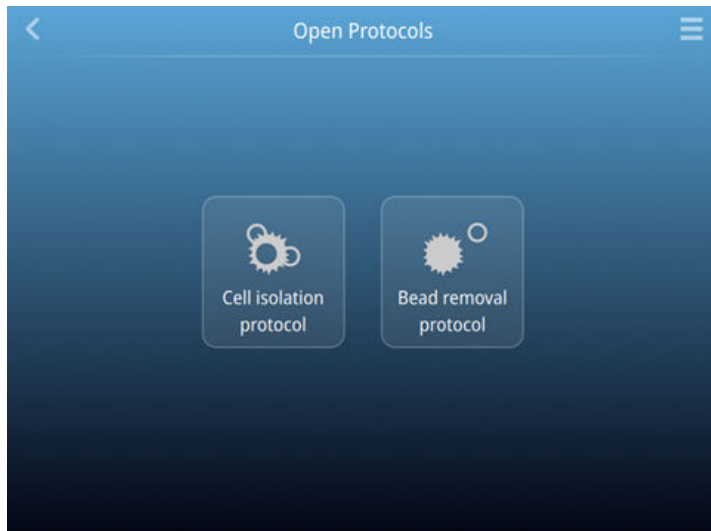
3. Create a desired step (see "Create protocol steps" on page 54) and select **Run** to initate the step.
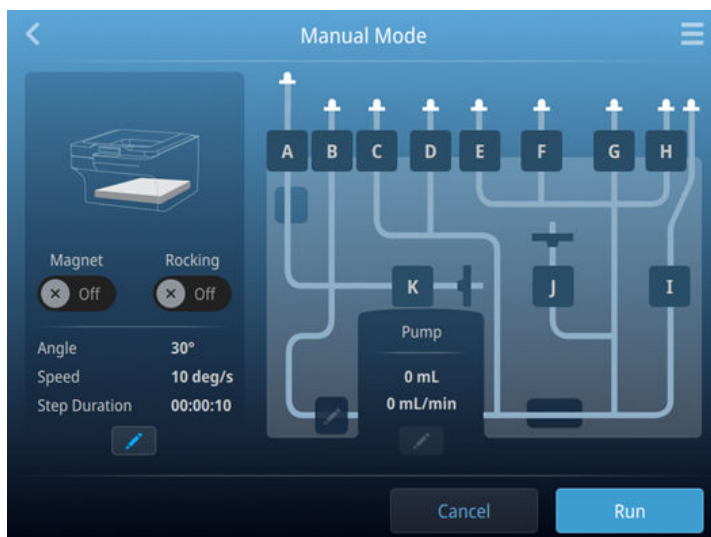
Manage protocols

There are different options available for selecting a protocol:

- If a protocol with the necessary parameters already exists, the protocol can be chosen from a list of User created or Template protocols by selecting **Run Protocol** on the **Home** screen.

If a new protocol is required, there are two methods for creating a new protocol:

- Use **Create protocol** and select **Create new** to create a new protocol, see "Create protocols" on page 45.
- Use **Create protocol** and select **Create from Existing** to created a protocol from an existing protocol, see "Create from existing protocol" on page 48.

Select **Manage** to edit an existing protocol, import a protocol, or export a protocol or review protocol details:

1. Select **Manage**.

2. Choose either **Cell isolation protocol** or **Bead removal protocol**.

3. Select **Edit**, **Import** or **Export**.

Protocol parameters

The CTS™ DynaCellect™ Magnetic Separation System is designed to operate within specific parameters. The values and limits for each parameter are listed below. If your input value exceeds the maximum value, an error is displayed.

Parameters that can be modified include:

- Magnet (engaged/disengaged)
- Pinch valves (open/closed)
- Pump speed (range 10–150 mL/min)
- Pump (specified volume or duration)
- Rocker angle (-30°–30°)
- Rocker speed (range 1–30 CPM)
- Bubble sensor (stop when dry/ stop when wet/ inactive)
- Fluid path

Create protocols

Protocols comprise a series of individual steps that are to be performed by the instrument.

Note: At a high level, there are three parameters that can be set in a step, which are: magnet, rocker, and pump. The setting of these should be considered for each step.

An isolation and bead removal protocol comprises numerous steps, and the system allows users to create protocols exactly like they want to. Keep in mind that what may appear as a single step at the high level may need to be broken down into substeps. For example, "drain isolation bag" can be broken down into the following steps:

1. Tilt rocker to positive 30 degrees to move liquid towards the sample port,
2. Pump liquid for a certain duration at a certain flow rate to the output bag.

Another example of how a high-level step must be broken down into multiple steps is "fill isolation bag". It is advised to keep the isolation bag at a negative angle when filling to avoid foam. Thus, the step must be broken down into:

1. Move the rocker to negative 30 degrees.
2. Transfer a certain volume from the input bag at a certain flow rate/for a certain duration to the isolation bag.

Study the template protocols from Thermo Fisher Scientific to get a better understanding of how to best design protocols.

When creating a protocol from scratch, there are zero pre-made steps, and every single step in the protocol must be programmed. If you have an existing protocol that roughly resembles the new protocol that you want to create, it is recommended to use the **Create from existing** feature, where you can edit, add, and remove steps to existing protocols. Alternatively, you can edit the existing protocols directly without creating a new one using the **Manage** function in the home screen.

Users can create new protocols using the eGUI. From the **Home** screen, select **Create Protocol**.
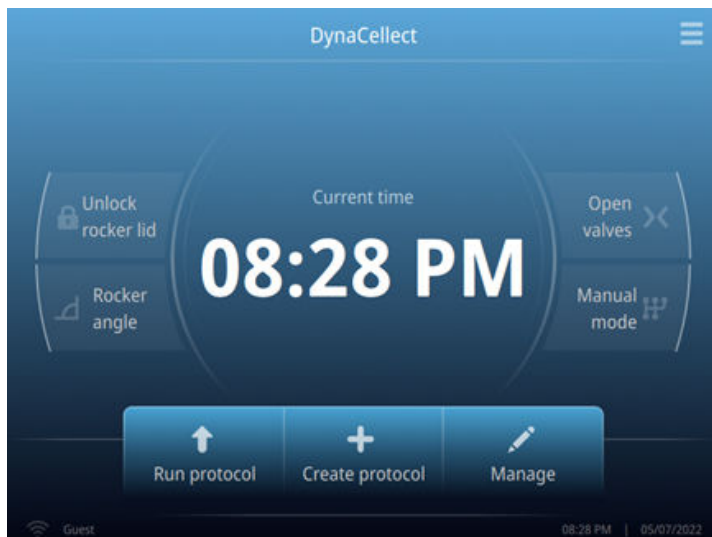
Create new

Create new is for creating protocols from scratch, without any pre-existing steps.

1. In the **Create New Protocol** screen, select **Create new**.
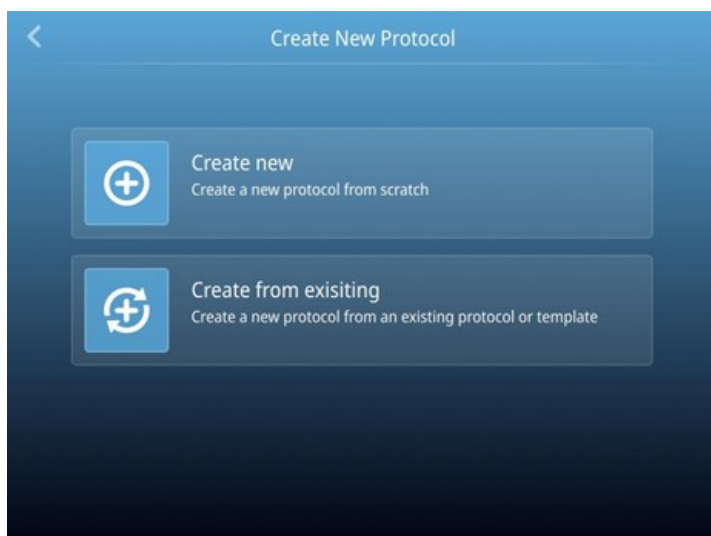
2. In the **Create New Protocol** screen, enter **Protocol name** (white spaces are not allowed), select **Select kit** (**Cell Isolation** or **Bead Removal**). The kit selected will determine whether you get access to the isolation- or bead removal-specific workflow). In the **Notes** section information about the protocol can be included for you or other users as reference or instruction. Select **See kit details** to proceed.
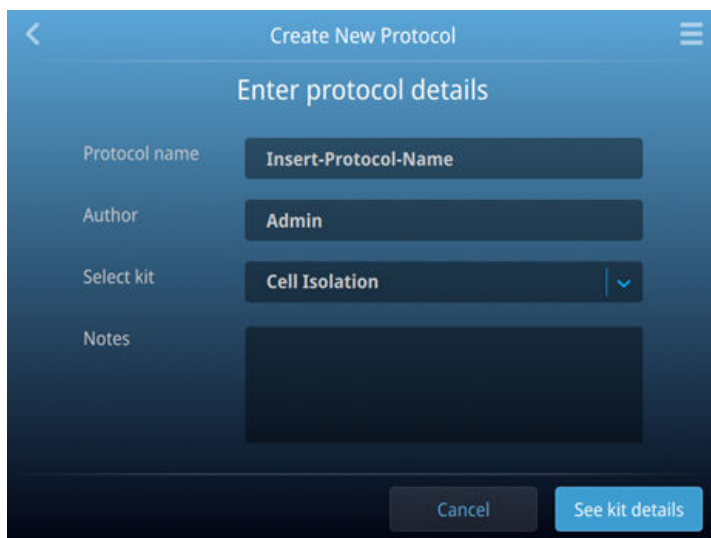
3. In the **Isolation Protocol Kit: Details** screen, the sites can be labelled (the site label does not influence the instrument behavior; it only informs users what content should be on the specific lines for the protocol in question. Site A **Isolation Bag** is default when the isolation kit is chosen). Select **Bead location** to proceed.
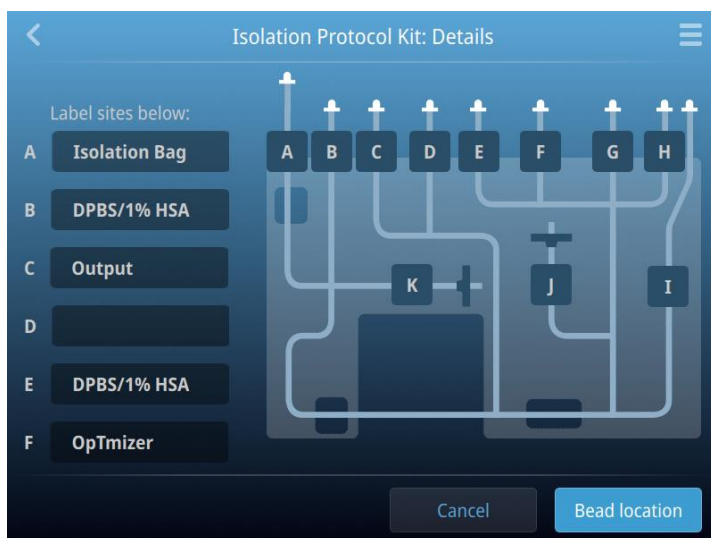
4. In the **Select All Bead Site Locations** screen, select site location of your beads (the identification of the bead site is needed to update the batch-specific bead volume in **Run Protocol** mode as output from the bead calculator). Select **Edit volumes** to proceed.
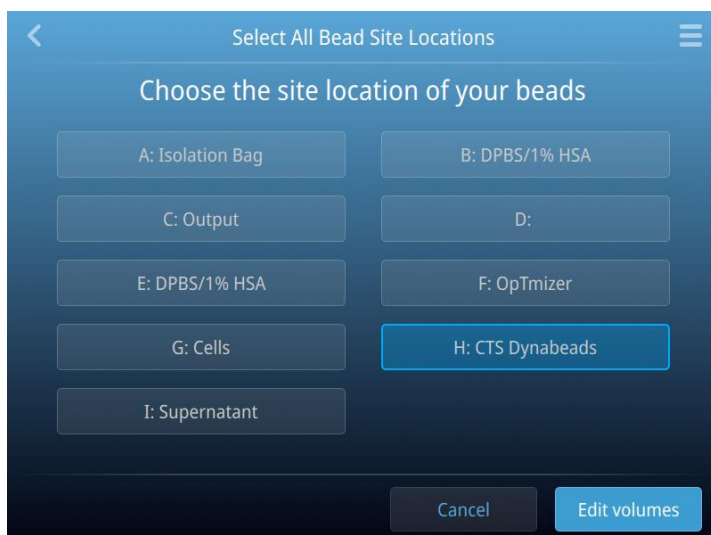
5. In the **Edit Volumes** screen insert volumes in the different sites (this information is for instructional purposes when running the specific protocol and does not influence the instrument behavior itself). It is recommended to add some "dead volume" to the minimum volume requirement, to account for user-dependent preparations of solutions and consumables. Select **Create steps** to proceed. For instruction on how to make steps, see "Create protocol steps" on page 54.

Note: Swipe the screen to scroll up or down.

Create from existing protocol

Create from existing is for creating protocols from an existing protocol, either templates provided by Thermo Fisher Scientific or protocols made by others.

1. In the **Create New Protocol** screen, select **Create from existing**.
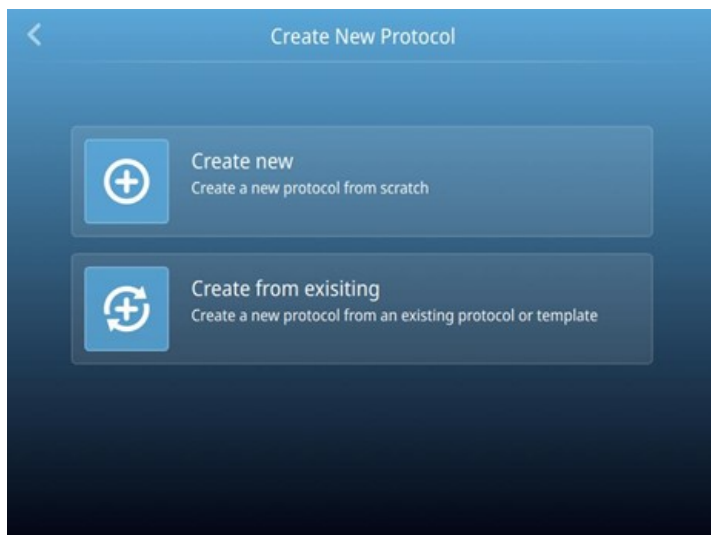
2. Select **Cell isolation protocol** or **Bead removal protocol**.
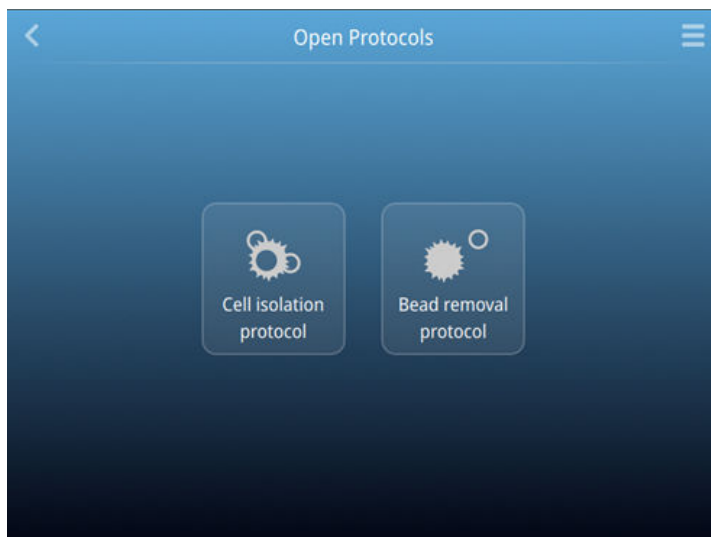
3. In the **Isolation Protocol** screen, select a protocol under **User created** or **Template**. Select **Open** to proceed.

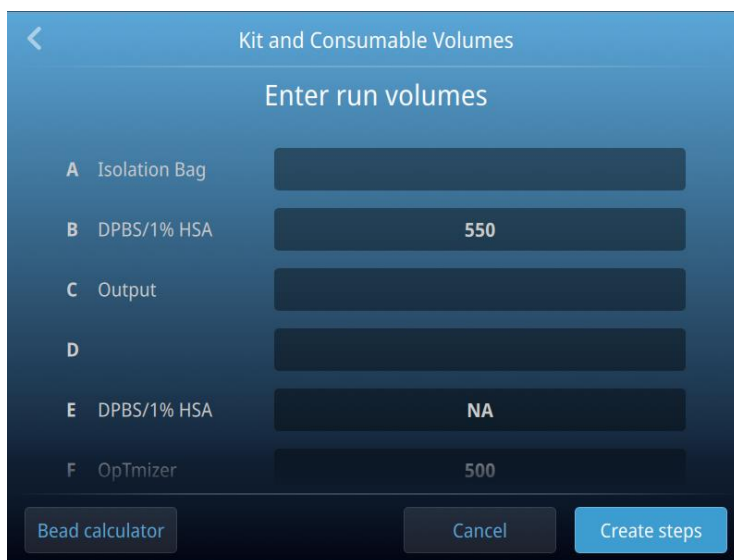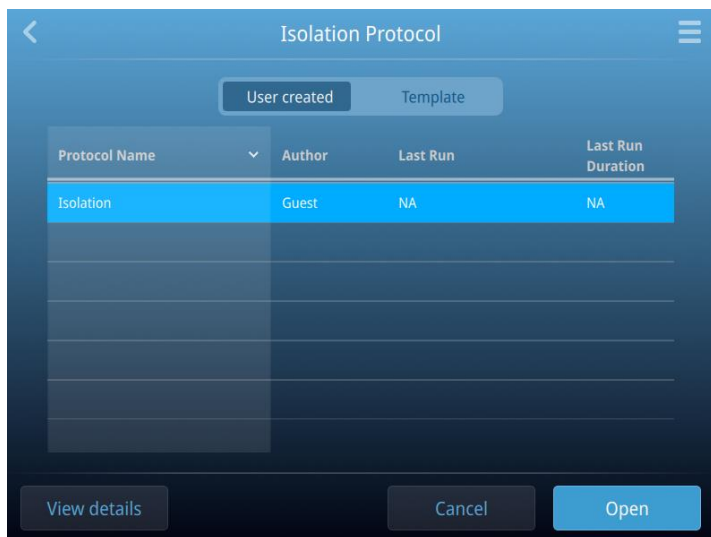4. In **Protocol name** field enter a name for the new protocol. Select **Edit sites**.
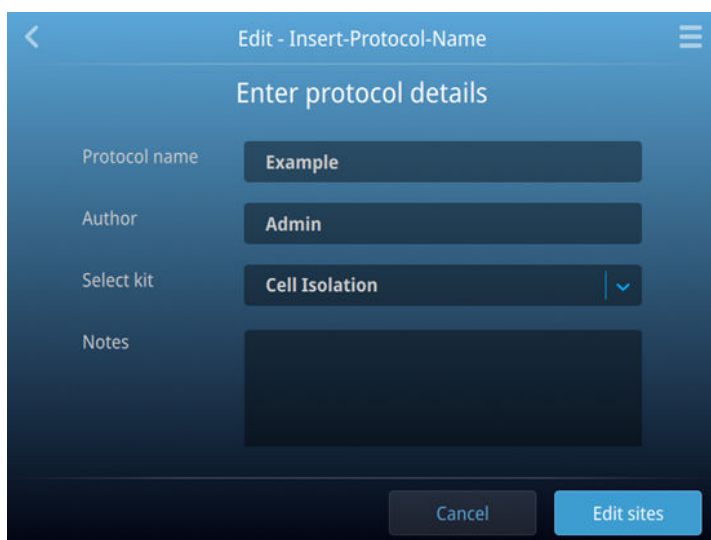
5. In the **Isolation Protocol Kit: Details** screen, the sites can be labelled (the site label does not influence the instrument behavior; it only informs users what content should be on the specific lines for the protocol in question. Site A Isolation Bag is default when the isolation kit is chosen). Select **Bead location** to proceed.
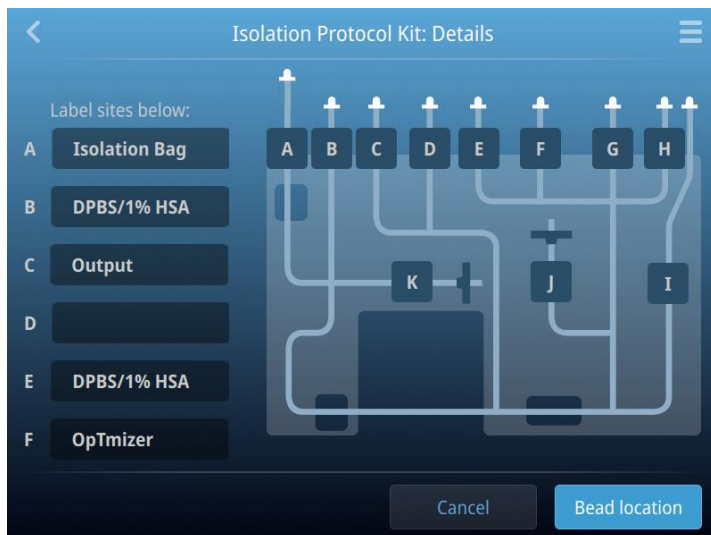
6. In the **Select All Bead Site Locations** screen, select site location of your beads (the identification of the bead site is needed to update the batch-specific bead volume in **Run Protocol** mode as output from the bead calculator). Select **Edit volumes** to proceed.

7. In the **Kit and Consumables Volumes** screen insert volumes in the different sites (this information is for instructional purposes when running the specific protocol and does not influence the instrument behavior itself). It is recommended to add some "dead volume" to the minimum volume requirement, to account for user-dependent preparations of solutions and consumables. Select **Review Steps** to proceed. See , for instruction on how to make steps.

Bead calculator

The bead calculator is a tool to help users easily calculate the volume of beads to use in a workflow, given a specific number of target cells, bead-to-target cell ratio, and bead stock concentration. The calculator only provides the volume of beads the user needs to add to the bead bag, it does not influence the protocol itself. The standard bead stock concentration of CTS™ Dynabeads™ CD3/CD28 is 4×10^8 beads/mL but may vary ± 10% from batch to batch. The batch-specific concentration can be found in the Certificate of Analysis (CoA) for the beads.

① Number of target cells for isolation. Target cells refers to CD3+ for CTS™ Dynabeads™ CD3/CD28

② Bead to target cell ratio. 3:1 is recommended for isolation using CTS™ Dynabeads™ CD3/CD28

③ Standard bead concentration of CTS™ Dynabeads™ CD3/CD28 is 4×10^8 beads/mL

Since the same protocol may be used repeatedly with different bead batches, the bead calculator is also used in **Run Protocol**, so that the bead volumes can be updated for each single run. If this level of precision (controlling for ± 10% deviation in bead stock concentration) is not necessary, assume the bead stock concentration (4×10^8 beads/mL), and thus bead volume, is the same for every run, regardless of batch.

Note: Take note of the resulting volume of beads from the bead calculator to enter into the bead site in the **Kit and Consumable Volumes** screen.

Create protocol steps

This is the Create step view, which is where the actual protocol is programmed in a stepwise manner. More details about the different functionalities are shown, see Table 2.

Note: At a high-level, there are three parameters that can be set in a step, which are: magnet, rocker, and pump. The setting of these should be considered for each step.

---
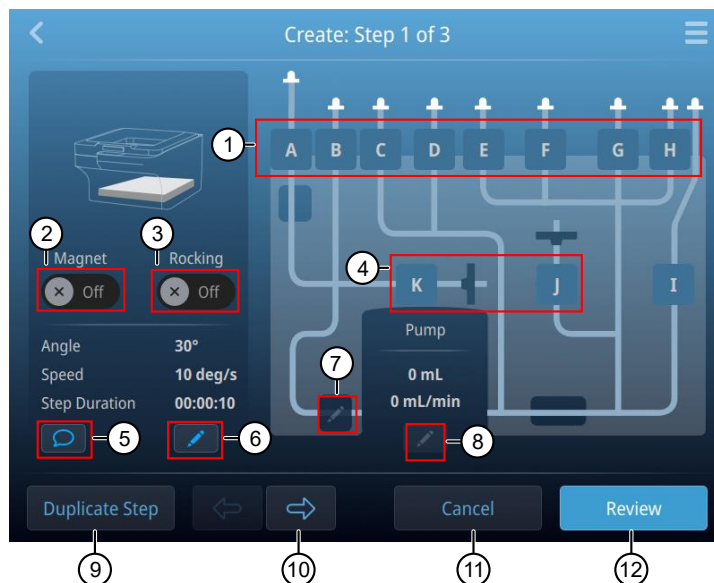
1. Start/end point of fluid lines
2. Engage/disengage magnet
3. Engage/disengage continous rocking
4. Start point of air
5. Add prompts
6. Rocker settings
7. Bubble sensor settings
8. Pump settings
9. Create next step by duplicating current
10. Navigate steps
11. Cancel protocol writing
12. Review all steps

Table 2   Features of the Create step view

Feature	Details
Magnet	Can be on or off.
	When a duration is set for the magnet, it determines how long the rocker will be in the specified position before moving to the next step.
Rocker	When off, a static angle can be set, when on, continuous rocking is specified.
	Angle range: -30° to +30°
	Speed range (cycles per minute): 1–30 CPM
	The rocking can be symmetric (e.g. -10° to 10°) or "asymmetric" (e.g. -5° to 30°).

Table 2   Features of the Create step view *(continued)*

Feature	Details
A–K	A–K reflect the various liquid and air lines. To make a valid path, one start destination and one end destination must be chosen. Valid fluid paths go via the pump.
Pump	Flow rates: 1–150 mL/min. Duration: Up to several hours.
Bubble sensor	When active, it is outlined by a blue ring on the screen. Choose between two modes, 1) stop when wet, or 2) stop when dry. When triggered, the bubble sensor will override the pump and stop it, regardless of what initial pump volume was set for that step.
Prompt	A prompt can be added as a "gatekeeper" for the step in question, such as "harvest sample from A for cell count analysis". The prompt needs to be acknowledged before allowing the subsequent step to be initiated.
Duplicate step	This button creates the next step in protocol. It does so by duplicating the current step, with the assumption that the next step will build on the current.
Forward/backward (arrows)	When >1 step has been created, the steps can be navigated through using the forward/backward buttons.
Cancel	When this is selected, the protocol and protocol setup will be deleted without saving.
Review	The **Review** screens brings you to the protocol overview where all steps are shown in sequence at a high level. Individual steps can be re-accessed via the **Edit** and **Back to create** buttons.

When the protocol has been completed, select **Review**. This will bring you to the **Protocol Summary** where the protocol steps are shown with key parameters.
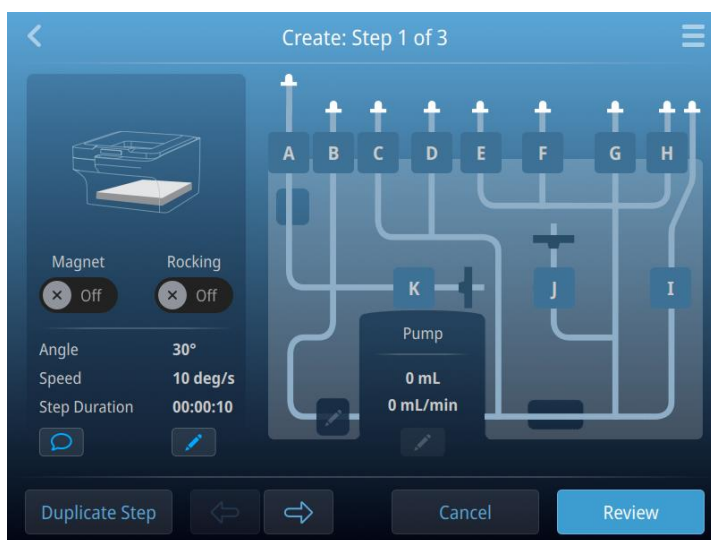
Below is the **Review** screen which shows all steps created in a protocol. The **Review** screen enables the user to delete, edit, and rename individual steps, duplicate steps and move them in relation to each other (drag and drop), go back to the **Create** screen, **Cancel** or **Save** protocol.

Note: **Back to Create** is used for editing multiple steps, whereas **Edit** is for editing the selected single step only.
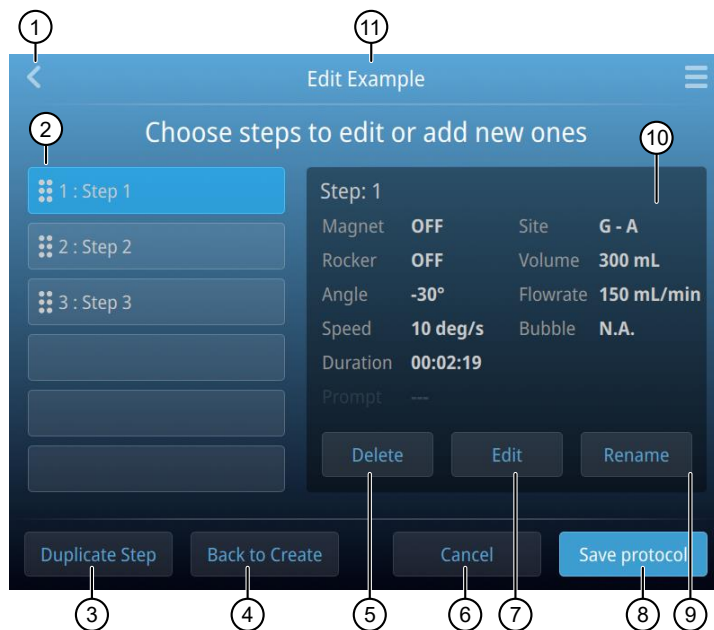
① Back to Enter run volumes screen

② All steps are shown here. Drag and drop to change sequence of steps

③ Duplicate current step

④ For editing multiple steps

⑤ Delete selected step

⑥ Cancel protocol writing

⑦ Edit selected step

⑧ Save protocol

⑨ Rename selected step

⑩ Details of step

⑪ Protocol name

When a protocol has been saved, it will be accessible in **Run protocol**, which is used for running premade protocols. It will also be visible in **Create from existing** and **Manage**, where it can be used as template for new protocols or edited.

Save Protocol

Protocol saved successfully

Home
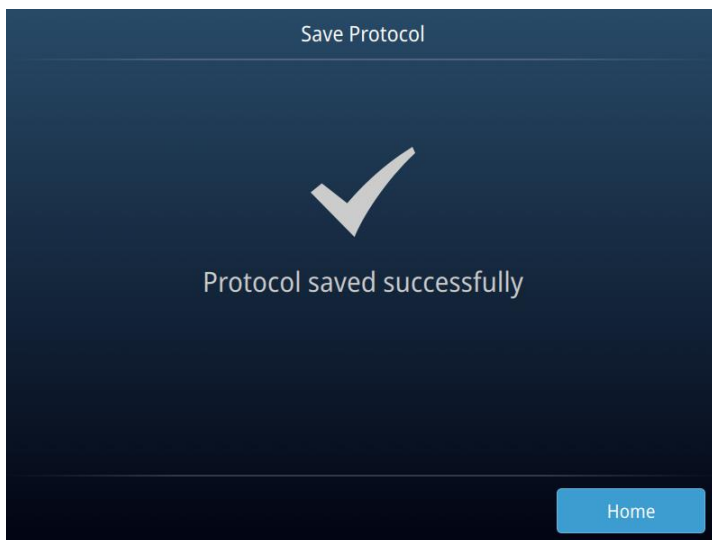
Fluid and air movement

1. Go to the **Create** screen.

Create: Step 1 of 3

A B C D E F G H

K

J

I

Magnet   Rocking

× Off   × Off

Pump

Angle   30°
Speed   10 deg/s   0 mL
Step Duration 00:00:10   0 mL/min

Duplicate Step   Cancel   Review
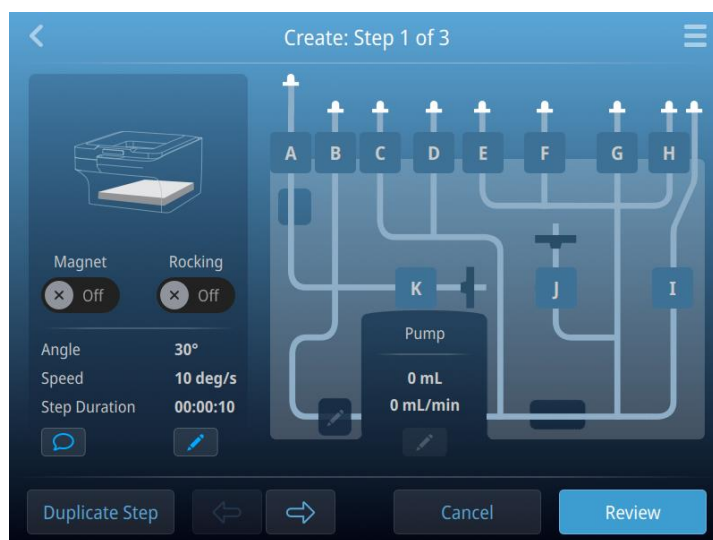
2. First select the line you want to transfer fluid (A–I) or air (J–K) from. After selecting the line the fluid is transferred from, the fluid path will be highlighted with the different options fluid can be transferred to.
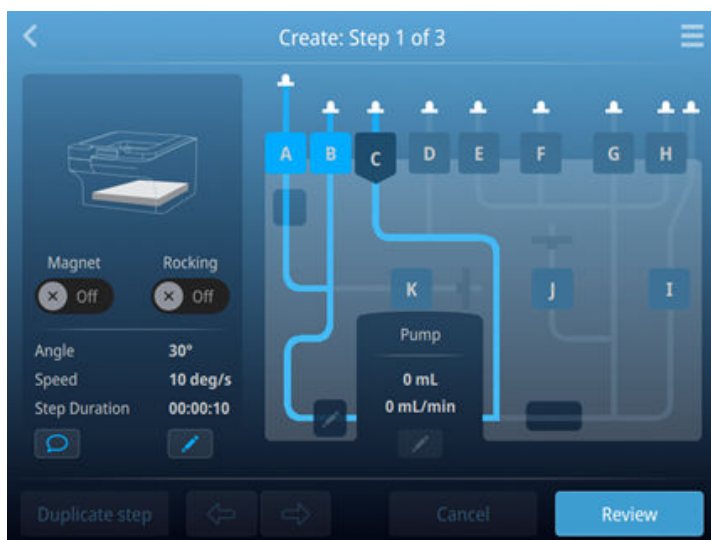
3. Select the line you want to transfer the fluid to. Only liquid movement through the pump is valid (e.g. you cannot transfer liquid from D to H). The selected fluid line becomes highlighted.
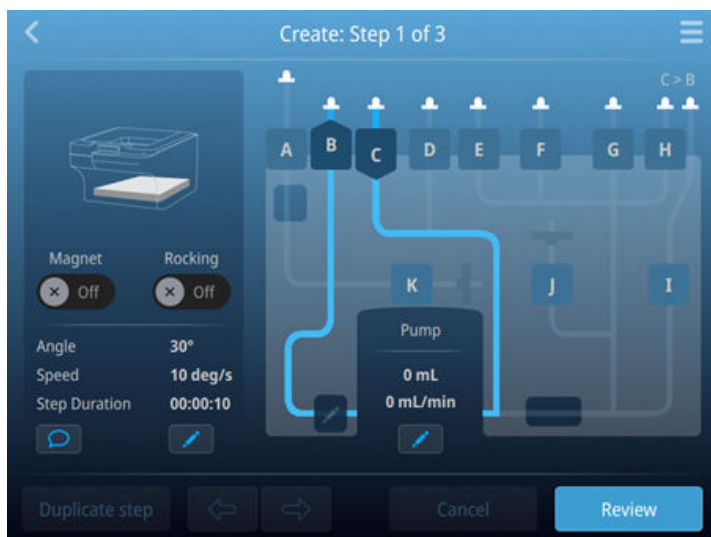
4. Select ✏️ under the pump to edit the pump settings. This is done either based on volume or duration. Select **Volume** and insert a desired volume (mL) and flow rate (mL/min). The duration is a result of the volume and flow rate.
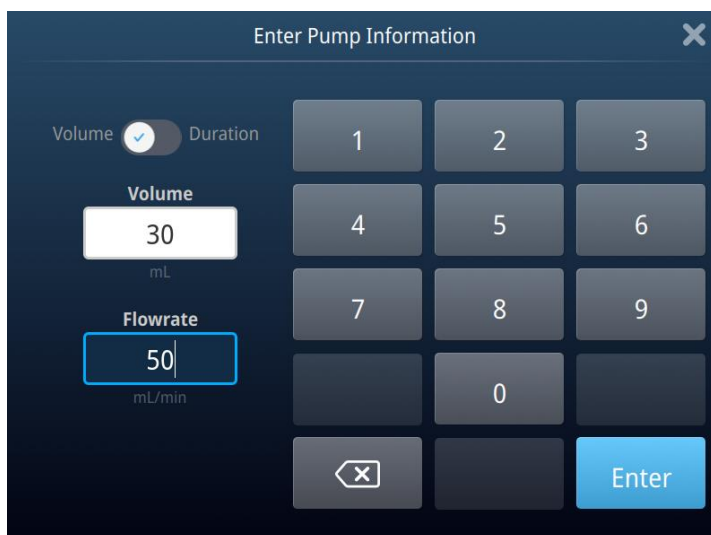
5. When **Duration** is selected, the volume is a result of the duration and flow rate setting. Press **Enter** to confirm.
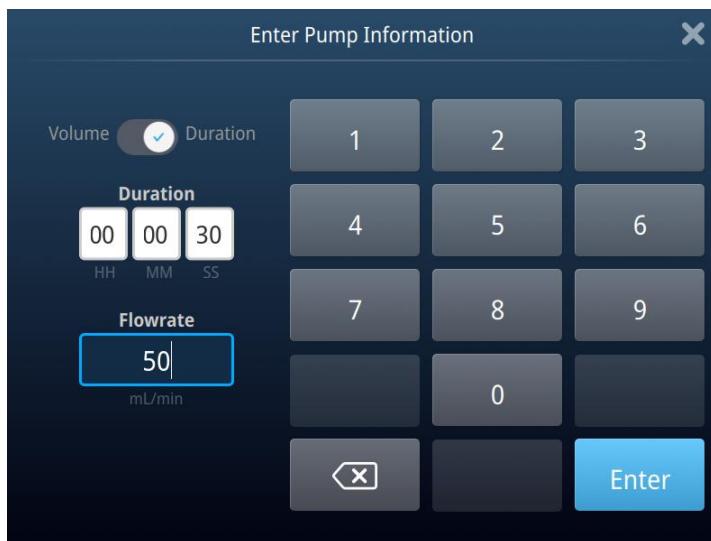
Bubble sensor

The bubble sensor, located to the left of the pump, can be enabled to stop the pump when the bubble sensor is wet or dry. When the bubble sensor is triggered, the pump will stop pumping, even if the intended pump volume has not been transferred. As such, the bubble sensor is a way of overriding the pump once a parameter has been met (the bubble sensor detects liquid or air).

1. Select [✎] to activate the bubble sensor.
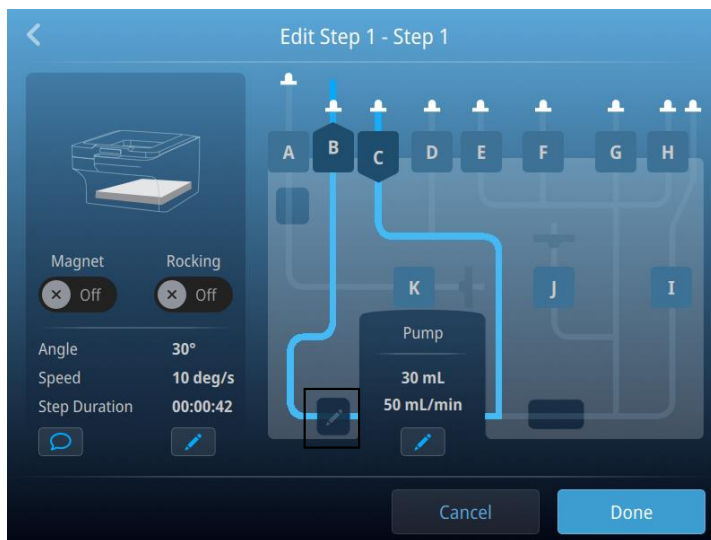
2. In the state where the bubble sensor is inactive, it will not interfere with pumping.

3. When the bubble sensor is active, the bubble sensor can stop the pump either when it detects absence of liquid, **Stop when dry**, or when it detects liquid, **Stop when wet**.
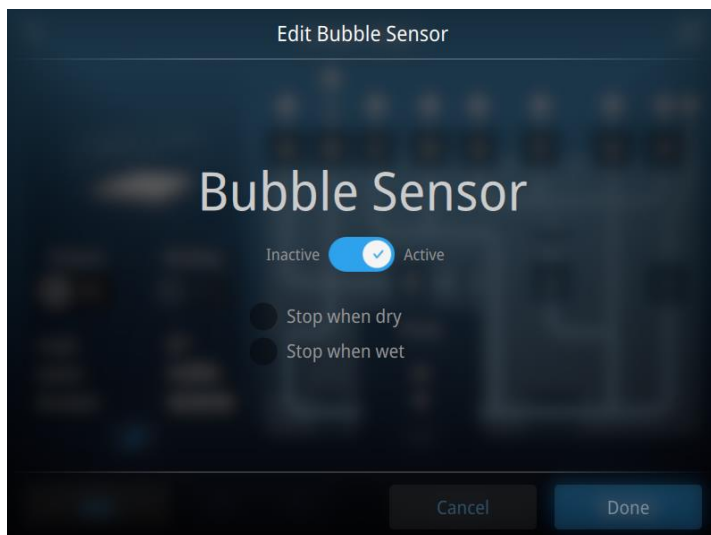
4. When the bubble sensor is active, it is highlighted in blue on the screen .
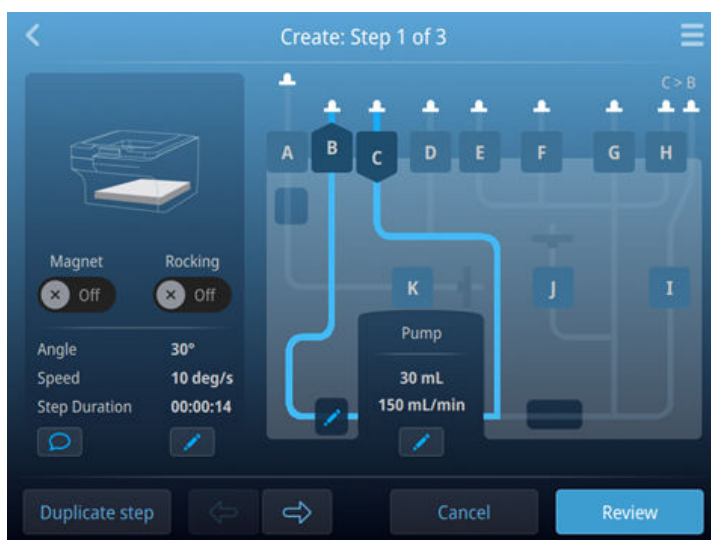
Note: The bubble sensor detects air gaps of a duration of 500 milliseconds.

Note: When activating the bubble sensor it is recommended to add a prompt (see "Prompts" on page 66) to act as a gatekeeper before the protocol moves to the next step.

Rocker

Pump active

When the rocker has been activated (**On**), it can be programmed as shown in the following image.

Note: When the pump is active the pump duration dictates the duration of the step and the magnet/rocker activity will continue for the entire step duration.
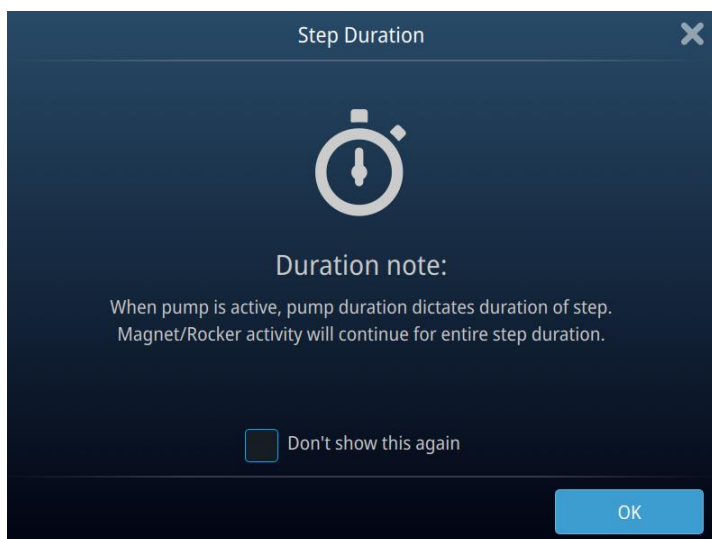
The duration windows are grey, reflecting that the duration cannot currently be altered. This is because the duration of the pump determines the step duration (42 seconds, as shown in the following image), which means the rocker cannot have a different duration within the same step.
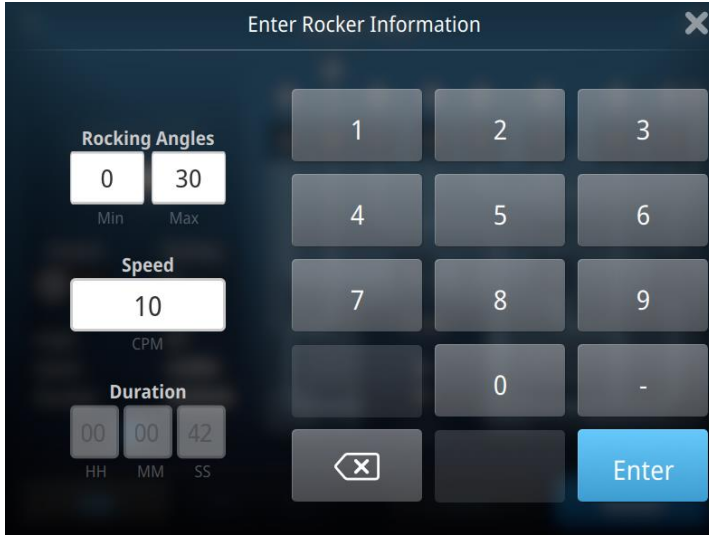
If the rocker is **Off**, the angle of the rocker can still be changed. This is a static movement (if the rocker stays the same as in the previous step) or it will be a single-step rocker movement, not continuous. The duration windows are grey, reflecting that the duration cannot currently be altered. This is because the duration of the pump determines the step duration (42 seconds, as shown in the previous image), which means the rocker cannot have a different duration within the same step.
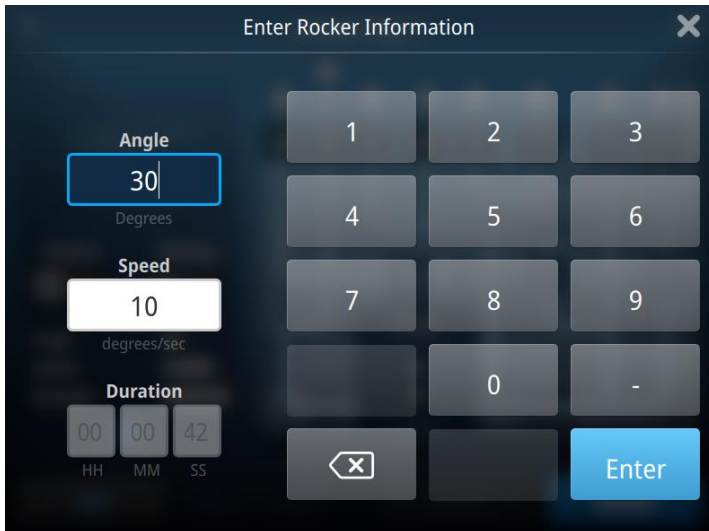
Pump inactive

When the rocker has been activated (**On**), it can be programmed as shown in the following image. Now, as the pump is inactive, a duration for the rocker can be set.

If the rocker is **Off**, the angle of the rocker can still be changed. This is a static movement (if the rocker stays the same as in the previous step) or it will be a single-step rocker movement, not continuous. Now, as the pump is inactive, a duration for the rocker can be set. The duration starts counting down when the rocker has reached the target angle.

Magnet

Without step duration

When the magnet is set to **On** without step duration, the instrument will move to next step after the magnet has been engaged and the rocker has reached the target angle.
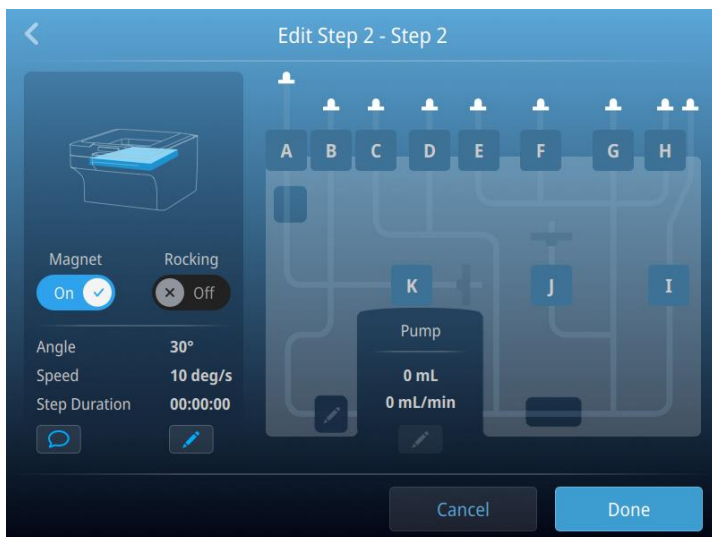
When the magnet is **On**, it is engaged, reflected by the magnet upward position.

With step duration

When the magnet is set to **On** with step duration, first the magnet will be engaged and then the rocker will move to the target angle. After the rocker has moved to the target angle, then the step timer will start counting down.
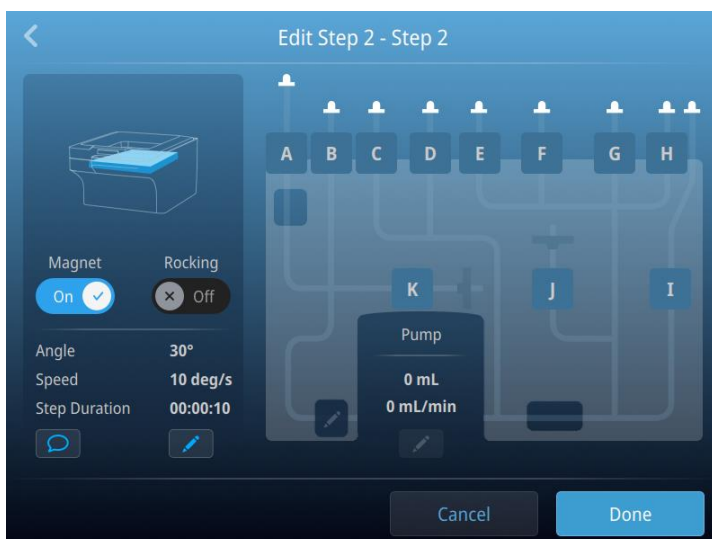
Prompts

A prompt can be added as a gatekeeper for the step in question, such as "harvest sample from A for cell count analysis" or "Is bag G empty?". The prompt needs to be acknowledged before allowing the subsequent step to be initiated.

1. Select prompt 💬.
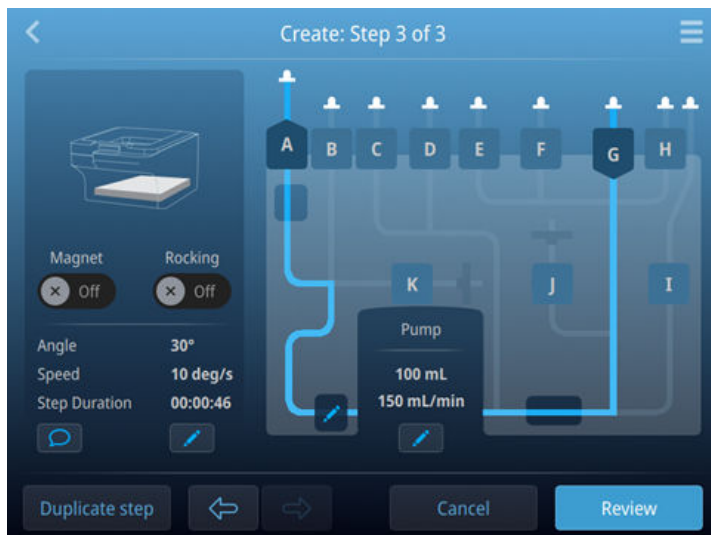
2. Insert desired text into the **Prompt** field and select **Enter**.
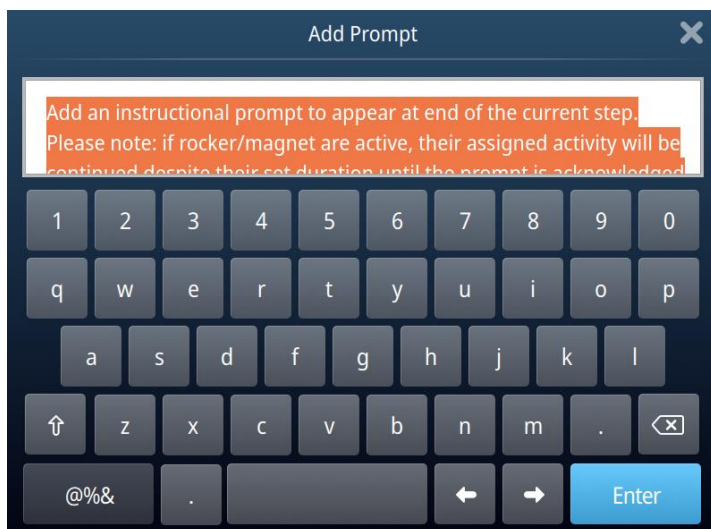
Note: If the rocker/magnet is active, the assigned activity will be continued despite the set duration until the prompt is acknowledged and the run is resumed.

3. The prompt is active 💬 .
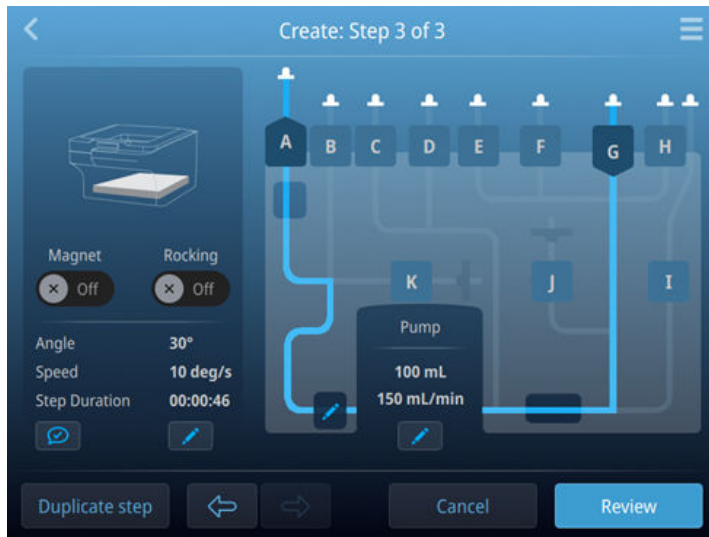
4. When running the protocol the prompt will appear in the end of the step where the prompt was added. The user is then prompted to acknowledge completion of the step and choose **Next Step**, **Repeat Step**, or **Abort Run**.
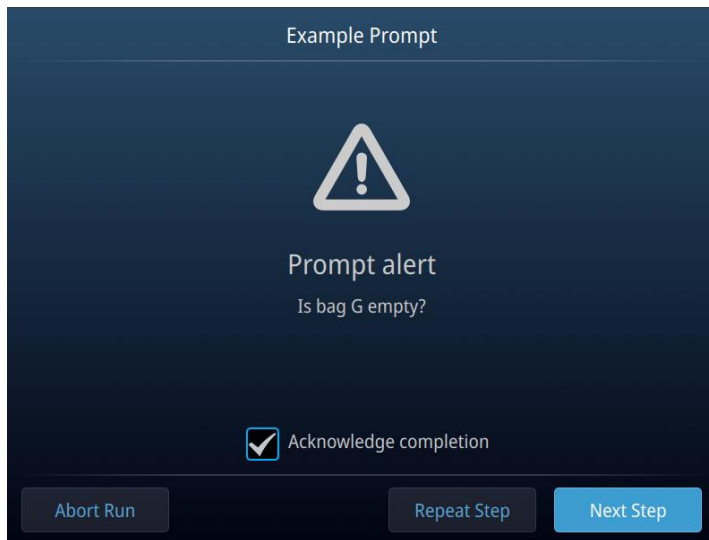
Run protocol

1. From the **Home** screen, select **Run protocol**.
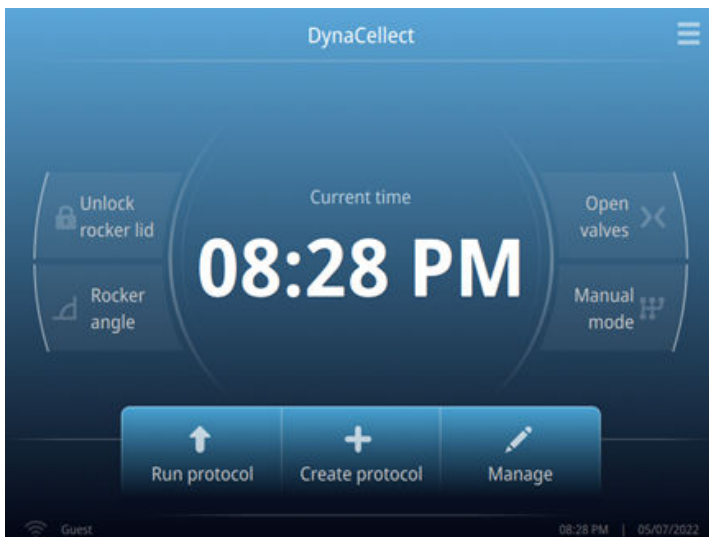
2. In the **Open Protocols** screen, select **Cell isolation protocol** or **Bead removal protocol**.
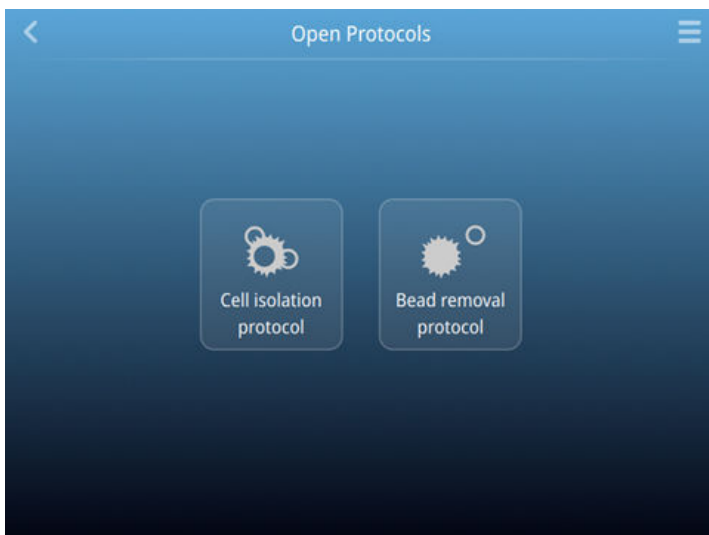
3. Select a protocol from **User created** or **Template**.
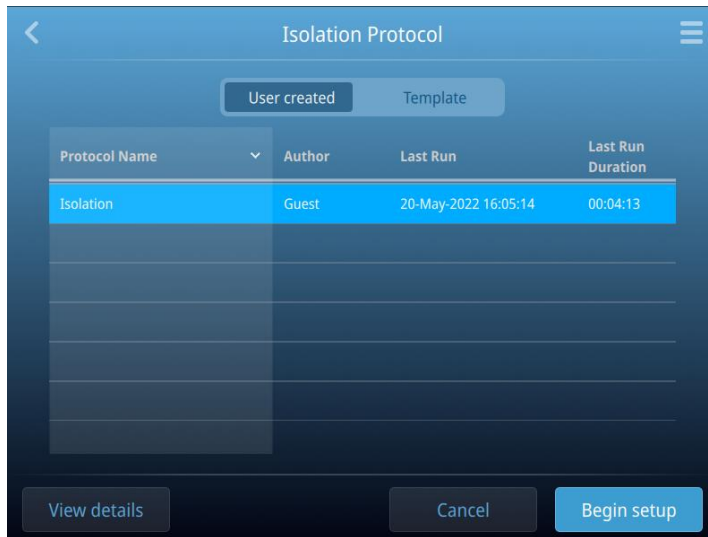
4. Select the protocol you want to run, either a user-created protocol or a template protocol. Select **View details** to see the details provided for the respective protocols during **Create** or **Manage**, if that is necessary to ensure the correct protocol has been selected.
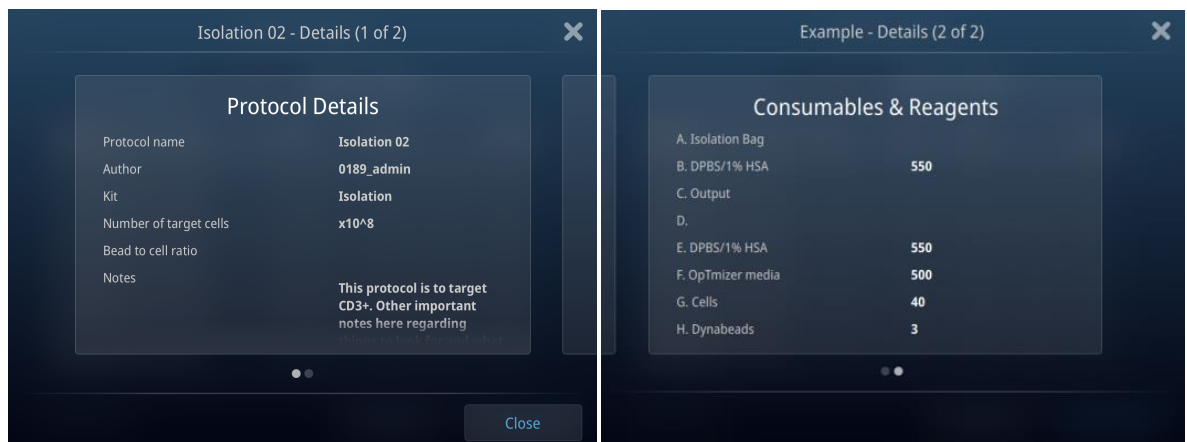
Examples of protocol details submitted during **Create** or **Manage**, which helps ensure that the correct protocol is selected for running. Navigate between the two screens by swiping.

5. To start the run setup, select a protocol and then **Begin setup**.
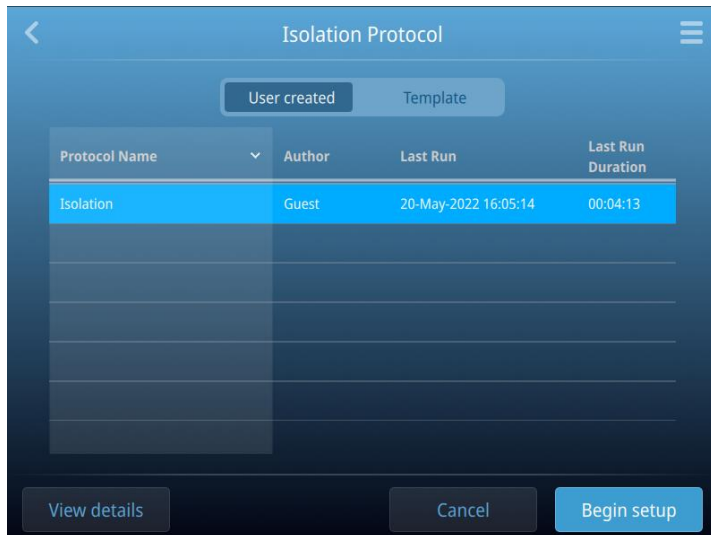
6. In the **Setup** screen it is informed that an Cell Isolation Kit is required.

7. In the following screens you can enter information that is unique for every run. This information will be captured in the **Summary Report**, which can be exported and included as part of an eBatch-record. Select **Edit volumes** to proceed.

8. To get bead volume for the specific bead lot, enter the number of target cells and bead to target cell ratio (same as used in **Create**) and the bead stock concentration from the CoA. If 100% accurate bead stock is not necessary, assume bead stock is 4×10^8/mL. Select **Enter** to proceed.

9. The resulting bead volume is then updated to the pre-defined bead site, and will be captured in the **Summary report**.
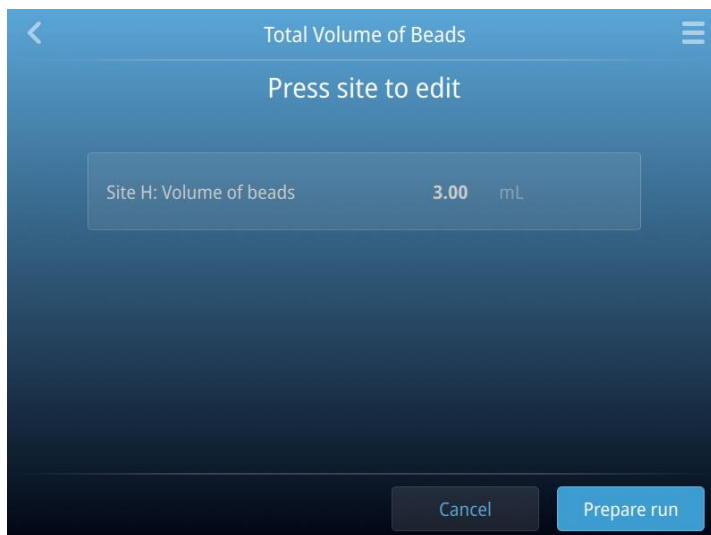
10. The **Prepare** screen shows how the consumables should be prepared (which bags contain what and how much of the various solutions), and is intended to help get the system ready for the actual run. Select **Add notes** to add pre-run notes to the summary report. Use the **How to install** function to get instructions for installing the kit. Select **Confirm**, when all bags have been prepared, connected to the kit, and kit installed on the instrument.
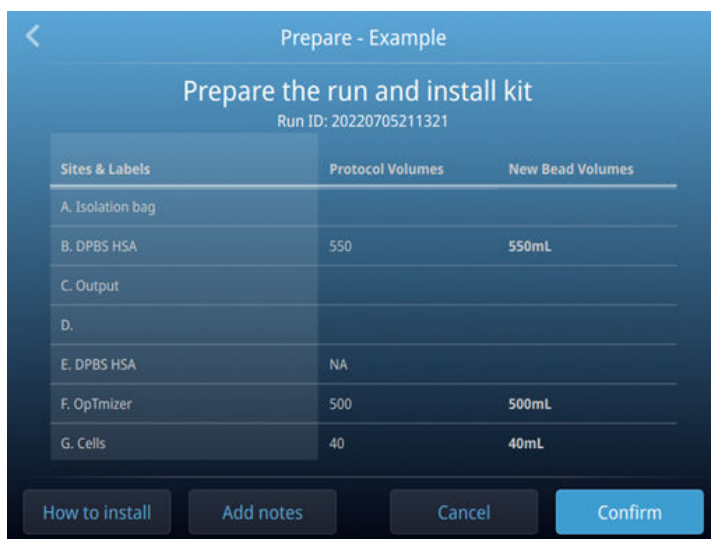
11. **Confirm Installation** is the final screen before the run is initiated and includes important check points to go through before starting the run.

Note: The most common error is to start the run without having opened clamps on the buffer/cell/bead bags, which are not controlled by the instrument. It is therefore important to check those before initiating the run.

---

12. Select **Start run** to initiate the run.
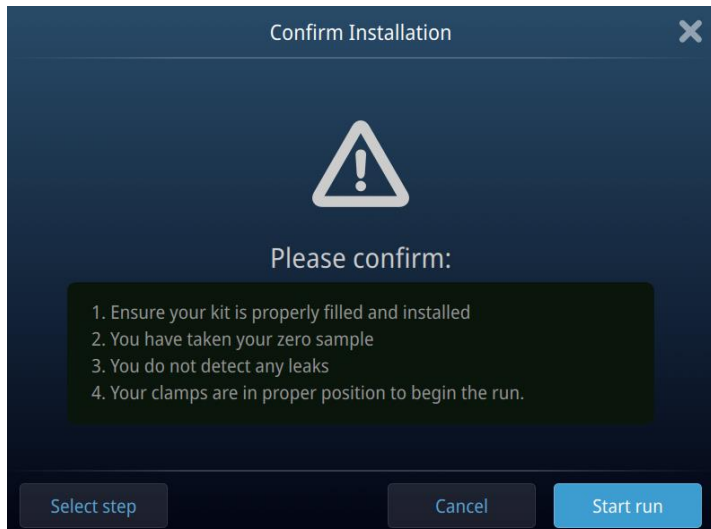
It is also possible to start the protocol from a chosen step. Press **Select step**, then choose the step you want to start from and select **Jump start**.
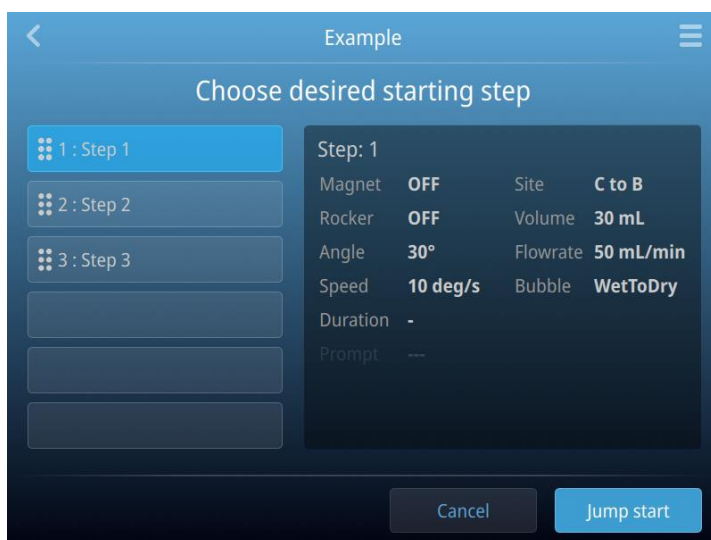
13. Run view 1 of 3, displaying run information. This view is the one with the least amount of details. Swipe to the right to get the alternative view screens, all acting as run "monitors" with differing levels of detail.
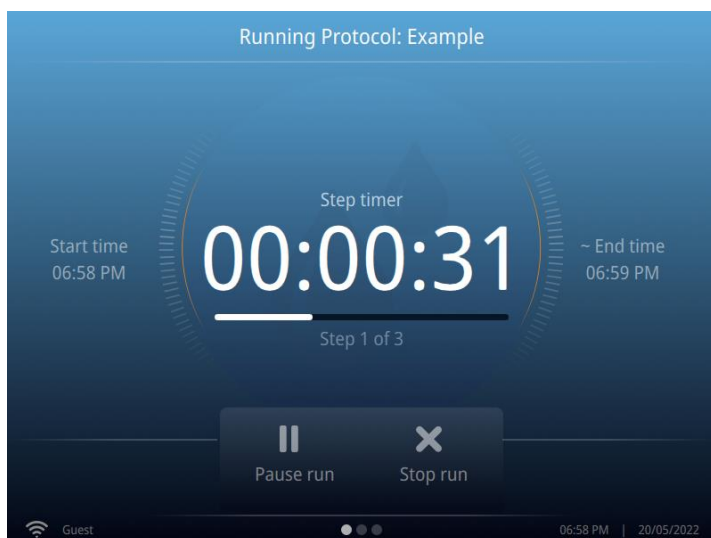
14. The second view style, with high-level details for the rocker, magnet, and pump.
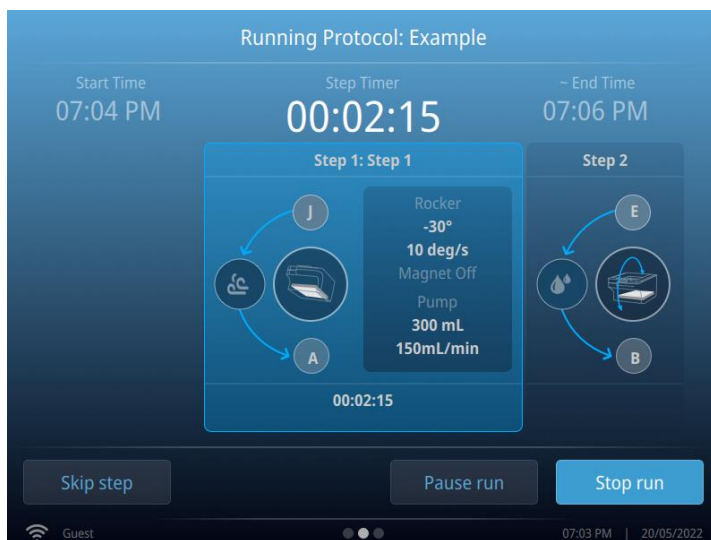
Table 3   Symbols second view screen

Symbol	Description
	Air flow
	Liquid flow

Table 3   Symbols second view screen *(continued)*

Symbol	Description
	Active bubble sensor
	Rocker activated
	Single rocker movement
	Magnet engaged
	Magnet disengaged

15. The third view style, with all step details included.
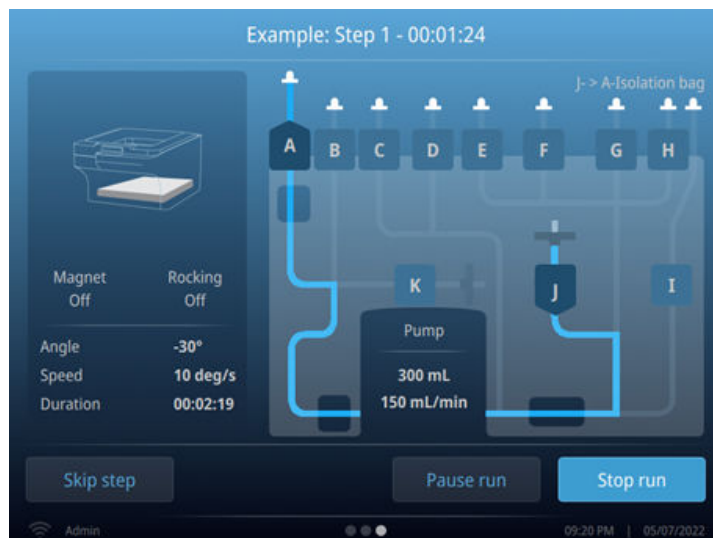
When the run has completed, it is possible to see the summary report by swiping to the left. Select **Add notes** to add notes to the **Summary Report**. The **Summary Report** can be exported by selecting **Export**.
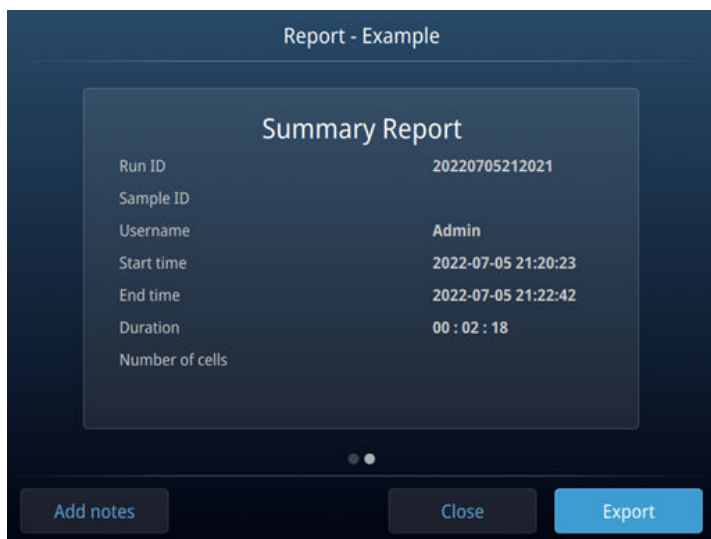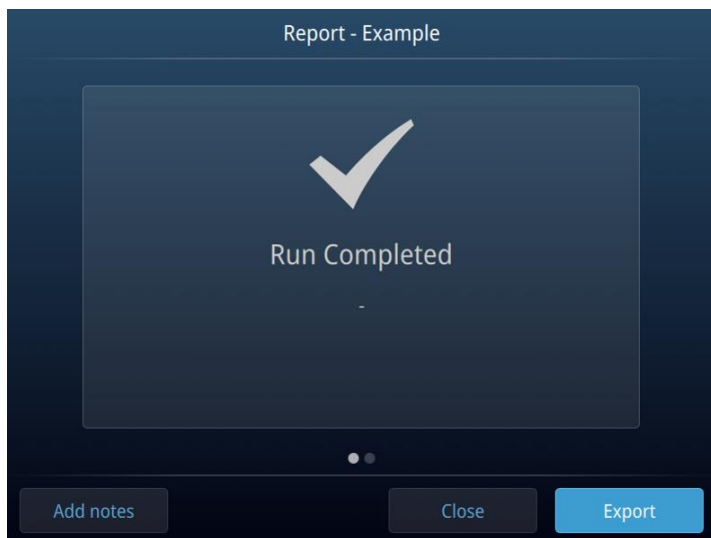
16. Then, choose the **Role of exporter** (Administrator, Scientist or Guest), select **Export** and select to export to USB drive or network drive.
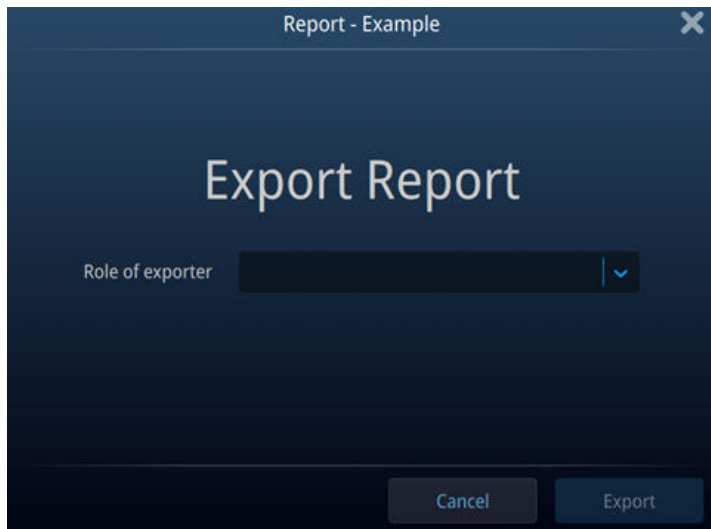
17. In the **Report** screen, Select **Close** to get instructions on how to remove the kit from the instrument. Select **Next** in the **Disconnect** screen to follow the instructions.
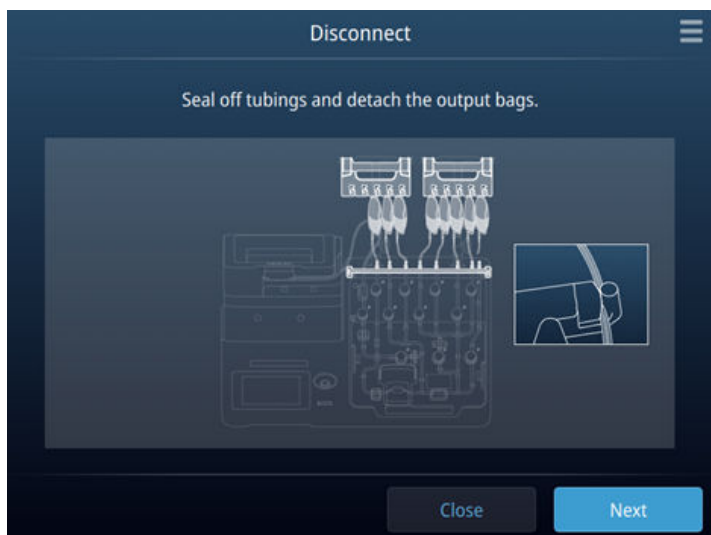
Pause protocol

1. The protocol can be paused by selecting **Pause run** on all the three run view screens. The following screen will pop up. Confirm pausing run by selecting **Yes**.
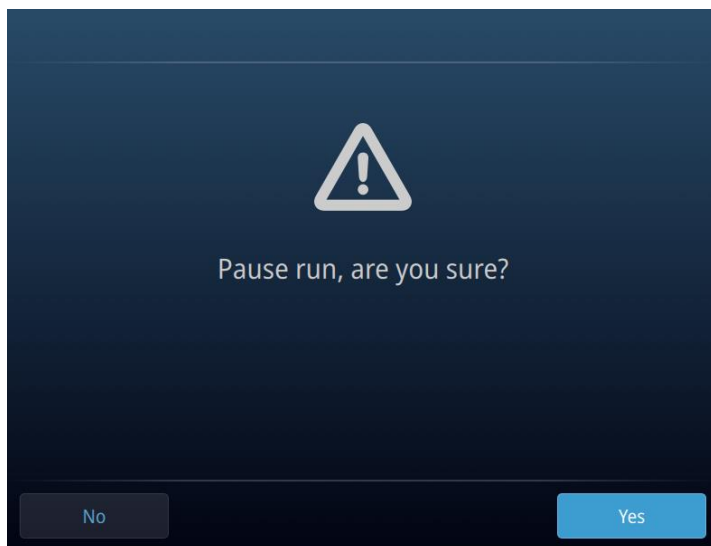
The protocol is now paused, and the timer shows how long the protocol has been paused.

Note: If the rocker/magnet is active, their assigned activity will be continued until the run is resumed.

2. To resume the run, select **Resume run**.
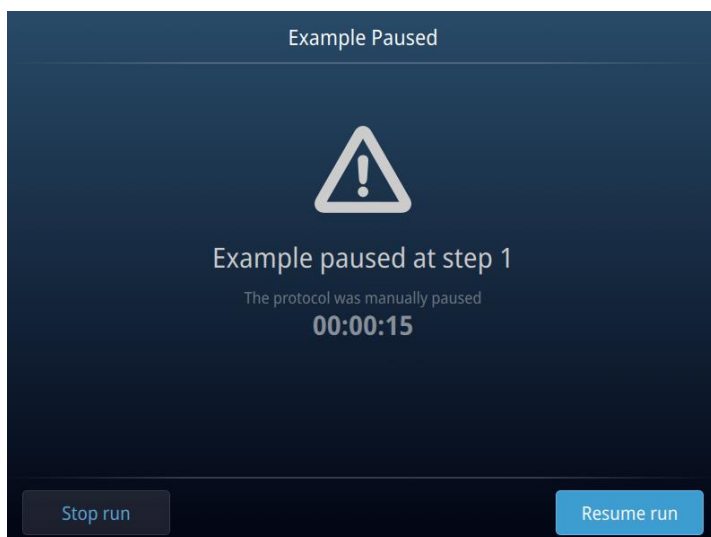
It is also possible to add prompts during **Create Protocol** or **Manage** to force the user to acknowledge that certain actions are performed during the run. See "Prompts" on page 66.

Skip step

It is possible to skip steps when a protocol is running.

1. Select **Skip step** on screen number two or three.
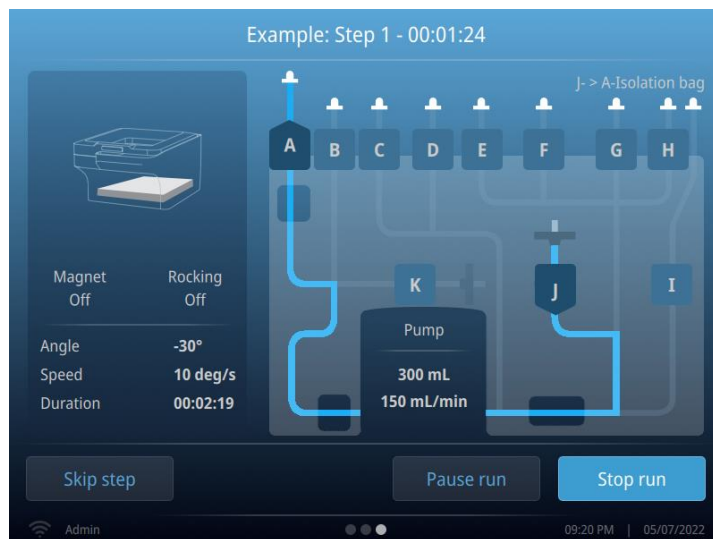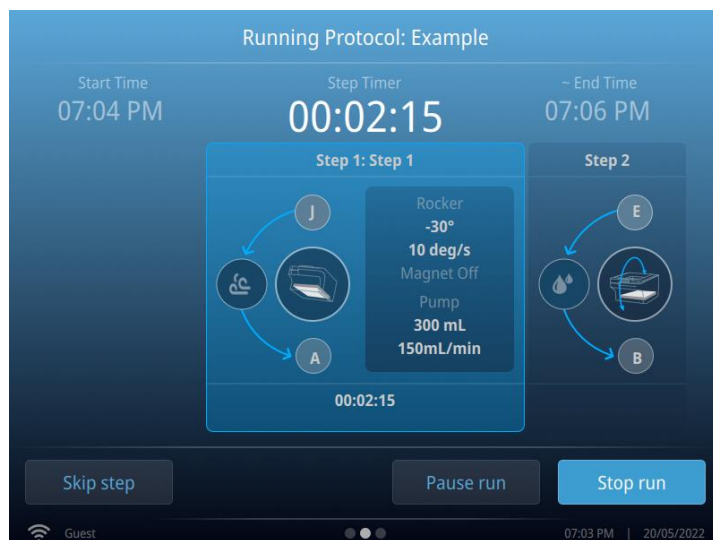
2. The following screen will appear. Select **Yes** to skip the current step.
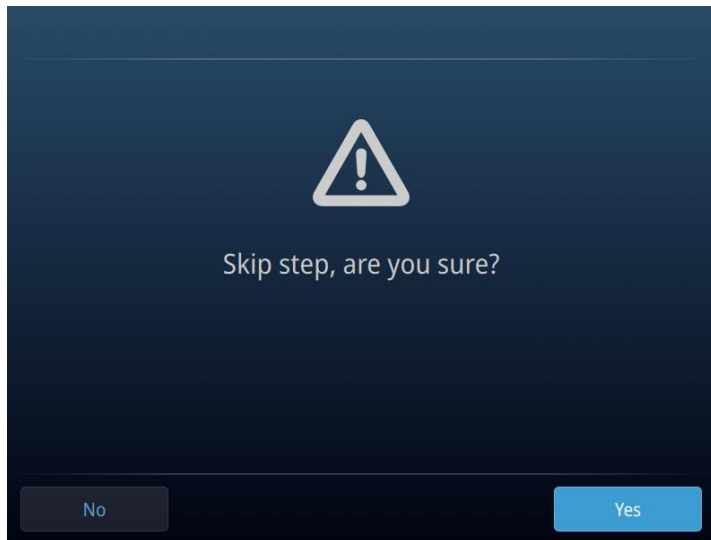
Stop protocol

The protocol can be stopped by selecting **Stop run** on all the three run view screens.

1. The following screen will pop up. Confirm stopping the run by selecting **Yes**.
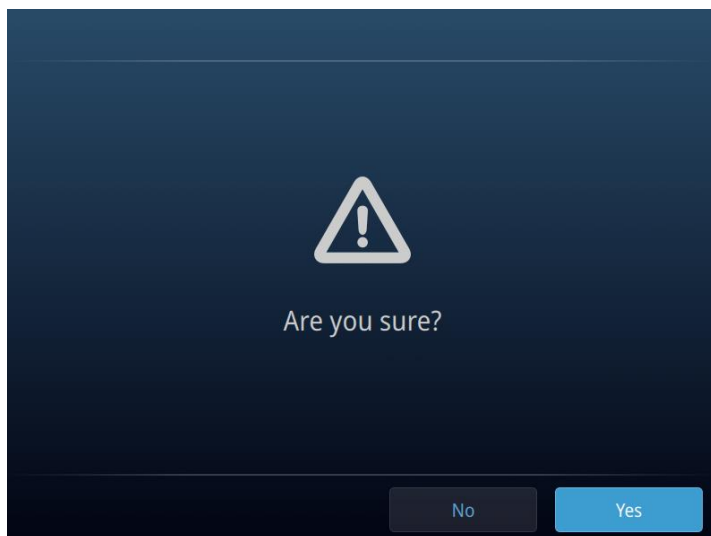
2. The protocol has stopped and it is possible to see the summary report by swiping to the left. Select **Add notes** to add notes to the Summary Report. The summary report can be exported by selecting **Export**.
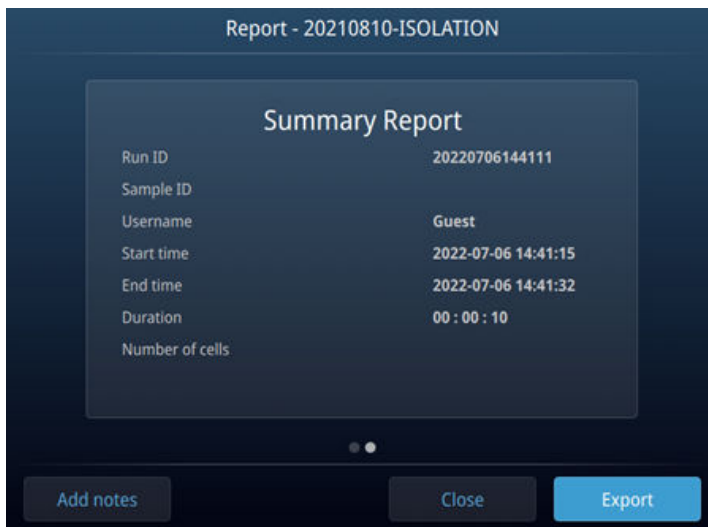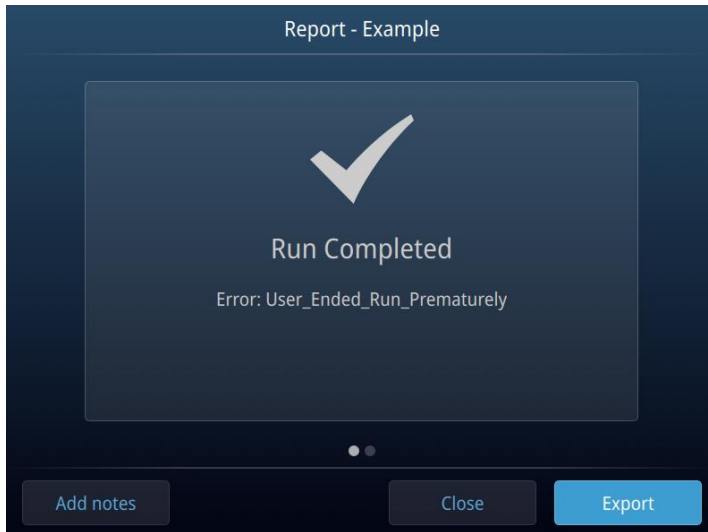
Import a protocol

Protocols can be imported from the following locations:

- USB memory device
- Network drive

3

1. From the **Home** screen, select **Manage**.

2. Select **Cell isolation protocol** or **Bead removal protocol**, depending on which protocol that is going to be imported.
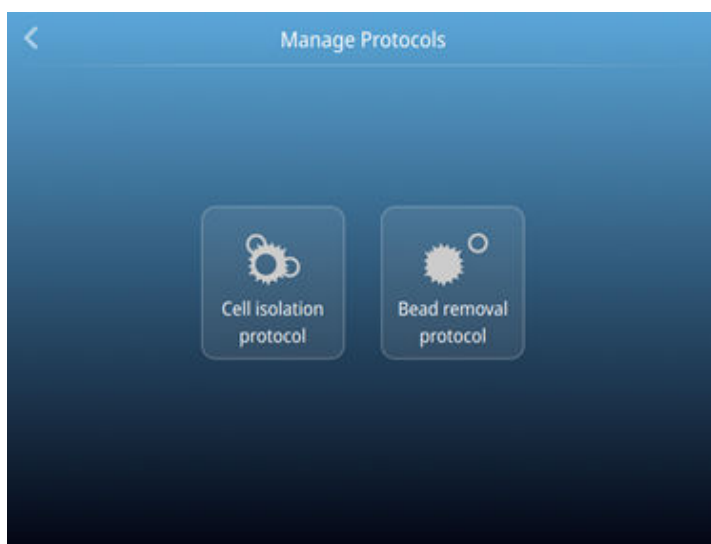
3. In the **Manage Isolation Protocols** screen, select **Import**.
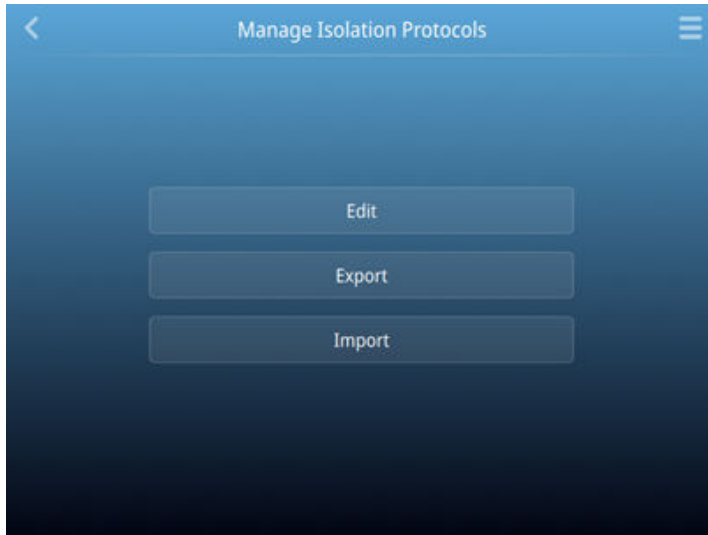
4. In the **Import** screen, select the platform to import the protocol from.
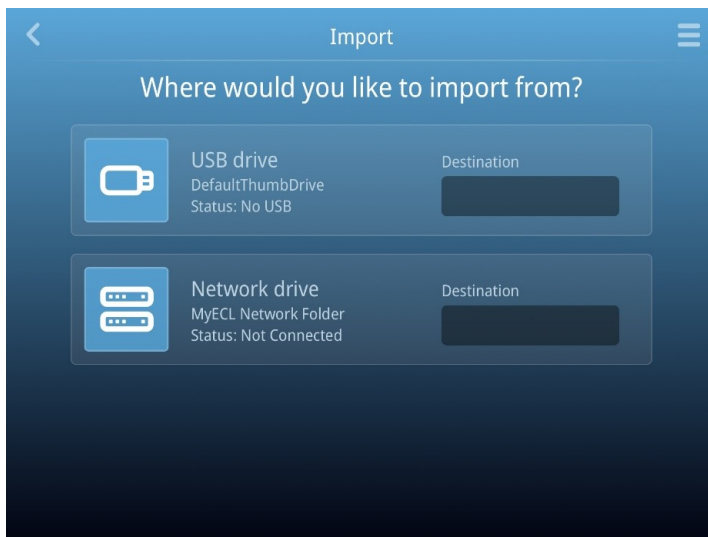
Export a protocol

Protocols can be exported to the following locations:

- USB memory drive
- Network drive

1. From the **Home** screen, select **Manage**.
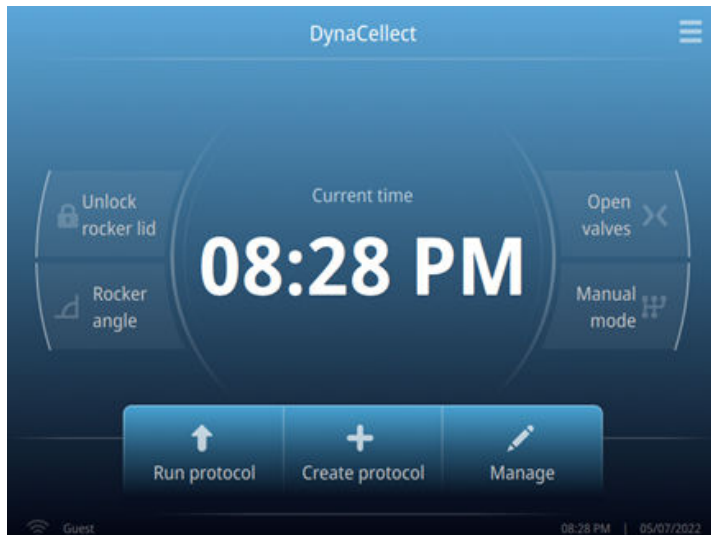
2. Select **Cell isolation protocol** or **Bead removal protocol**, depending on which protocol that is going to be exported.
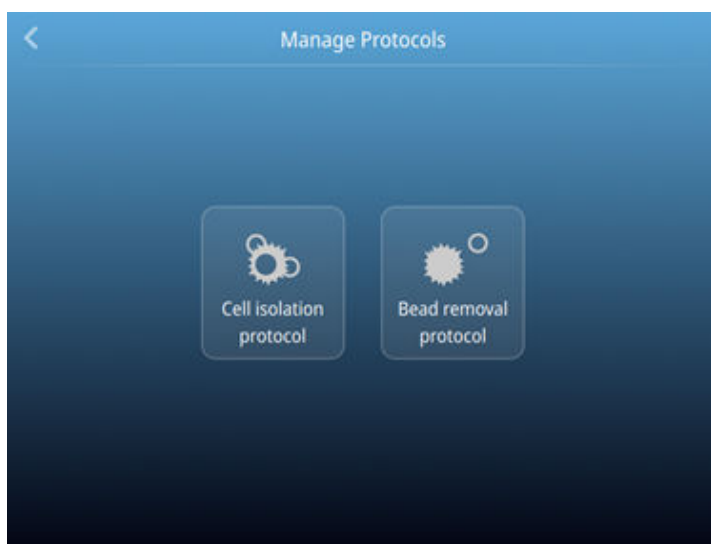
3. In the **Manage Isolation Protocols** screen, select **Export**.
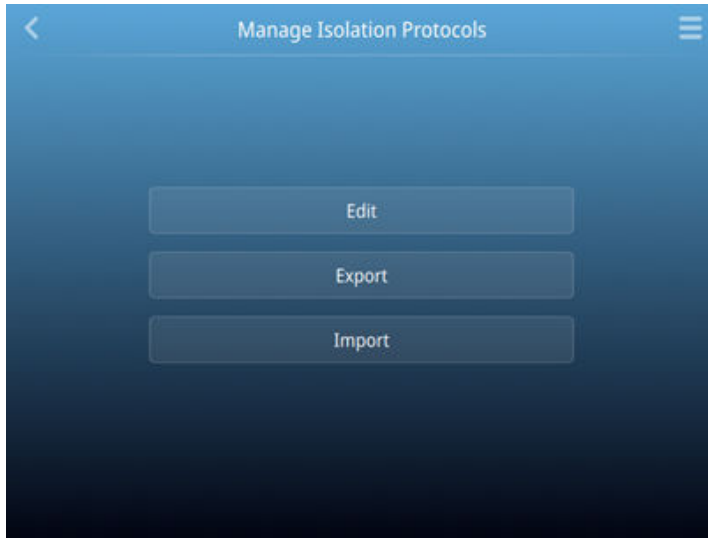
4. In the **Export** screen, select the protocols to export.
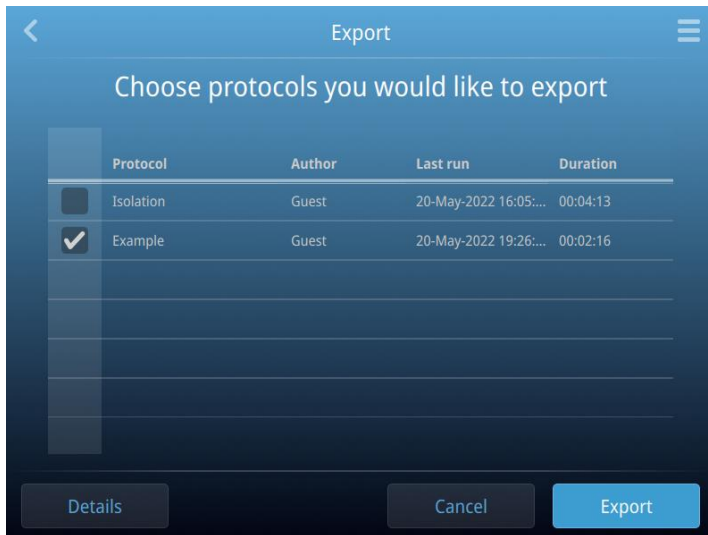
5. In the **Export** screen, select the location you want to export to (USB drive or network drive).
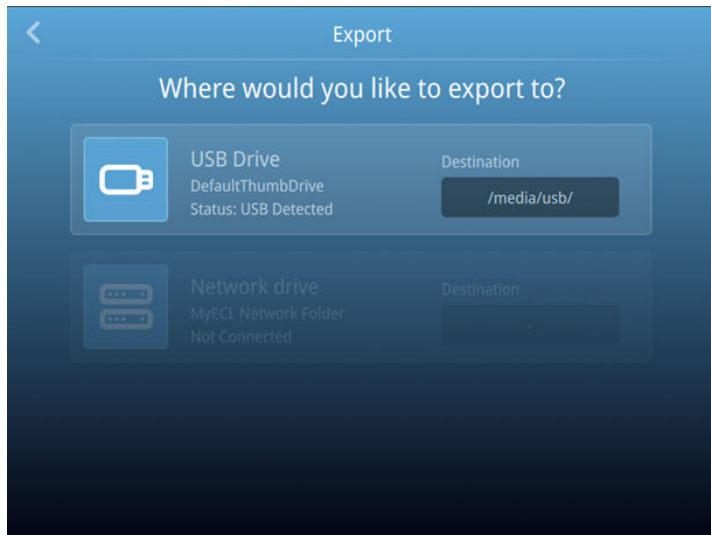
6. When the export is complete, the following screen will show.
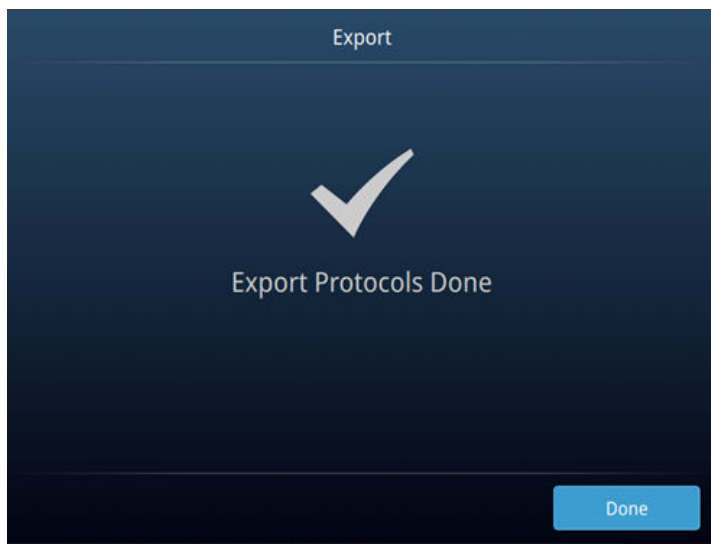
Edit protocols

1. To edit an existing protocol, from the **Home** screen, select **Manage**.
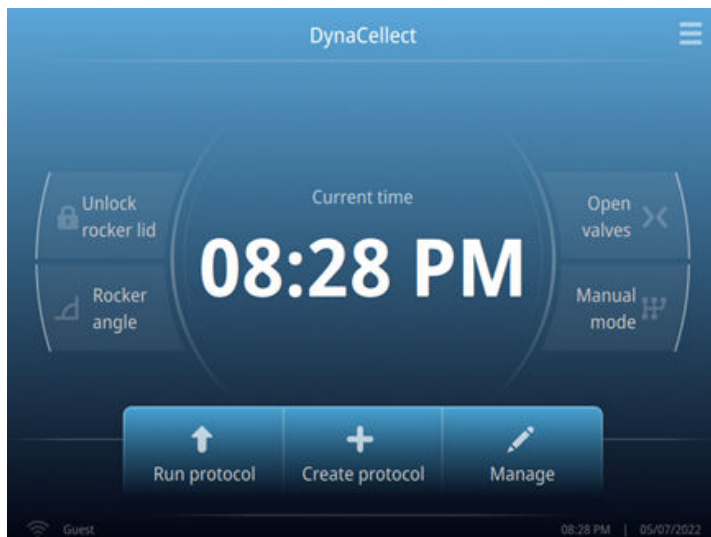
2. Choose to edit an **Cell isolation protocol** or **Bead removal protocol**.
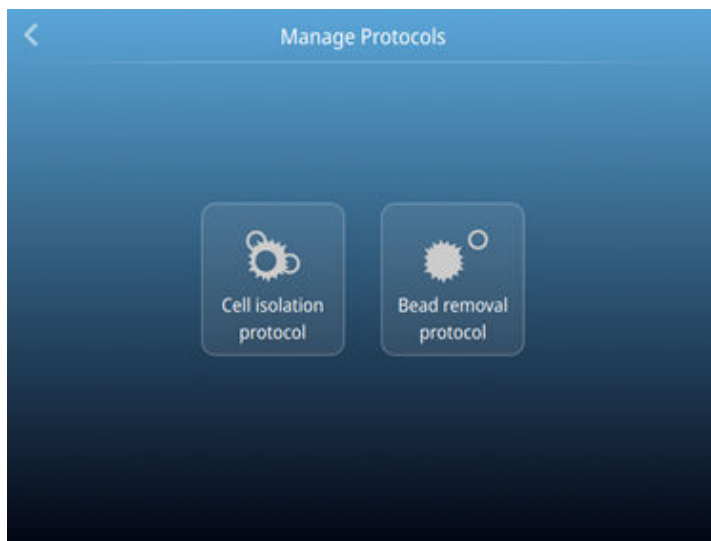
3. In the **Manage Isolation Protocols** screen, select **Edit**.
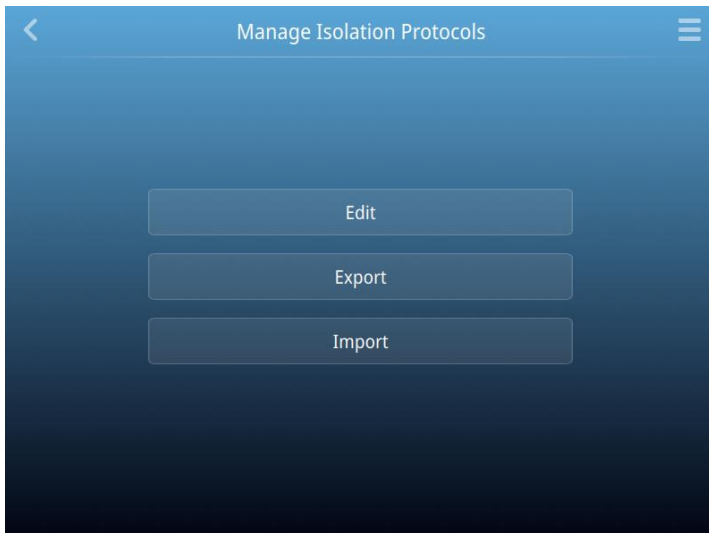
4. Select a protocol and select **Edit** to proceed.
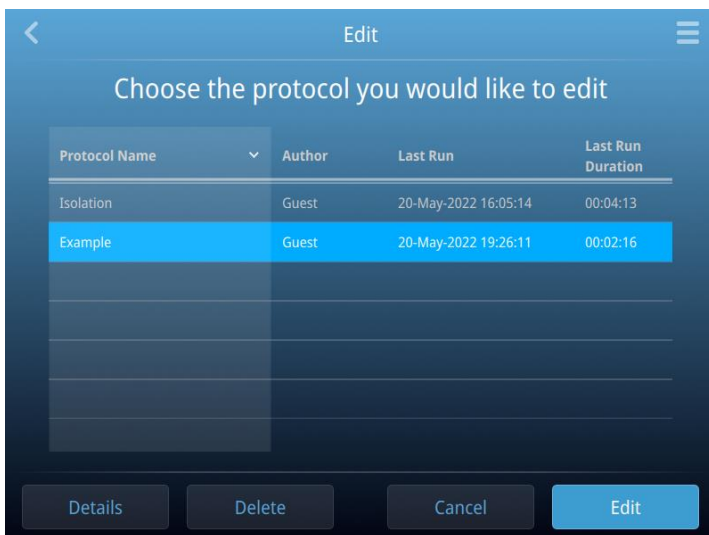
5. The details of the protocol are shown. The name and type of kit cannot be altered when editing a protocol. (If it is desired to change the protocol name, you must create a new protocol from an existing protocol. See "Create from existing protocol" on page 48). Select **Edit sites** to proceed.
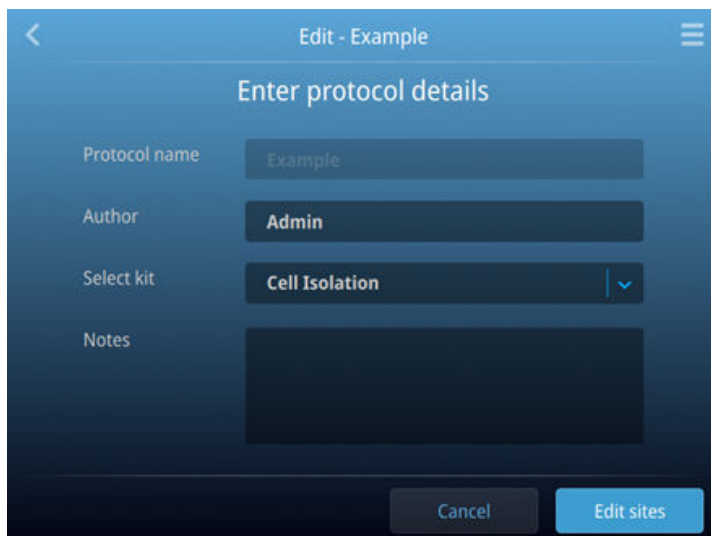
6. In the **Edit sites** screen, the sites can be labelled (the site label does not influence the instrument behavior, it only informs users what content should be on the specific lines for the protocol in question. Site A Isolation Bag is default when the isolation kit is chosen). Select **Bead location** to proceed.

7. In the **Bead location** screen, select site location of your beads (the identification of the bead site is needed to update the batch-specific bead volume in **Run Protocol** mode as output from the bead calculator). Select **Edit volumes** to proceed.
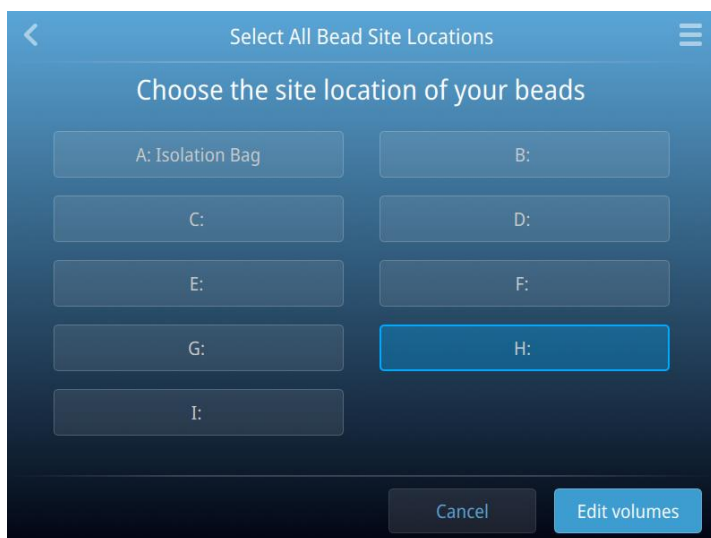
8. In the **Kit and Consumables Volumes** screen insert volumes in the different sites (this information is for instructional purposes when running the specific protocol and does not influence the instrument behavior itself). It is recommended to add some "dead volume" to the minimum volume requirement, to account for user-dependent preparations of solutions and consumables. Select **Review steps** to proceed. For instruction on how to make steps, see "Create protocol steps" on page 54.
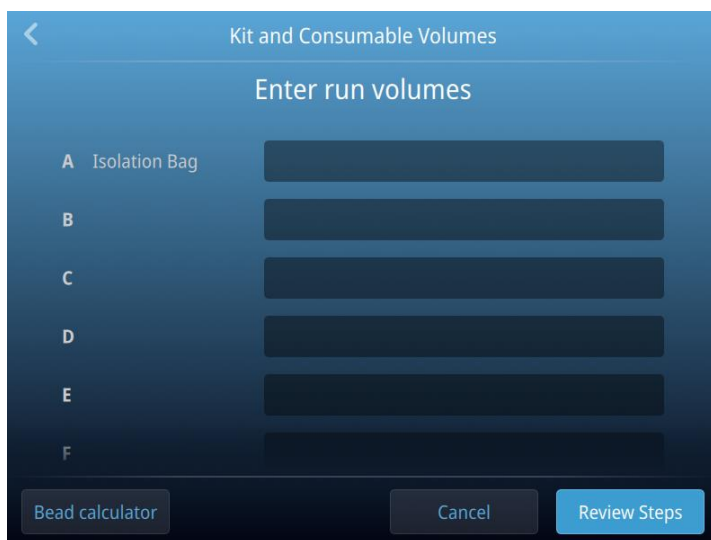
9. Steps can now be edited/duplicated/deleted/added in the review mode. Or select **Back to Create** to edit/duplicate steps in create mode.
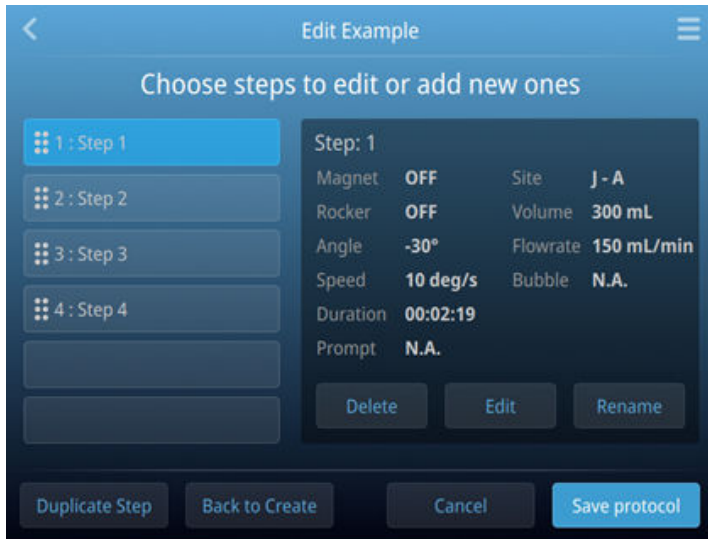
10. In the **Create** screen, select **Review** to get back to the review mode.
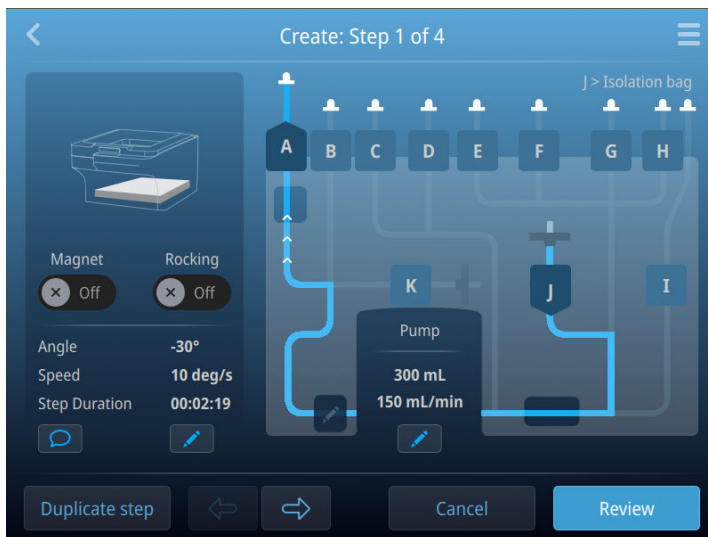
11. Select **Save Protocol**.
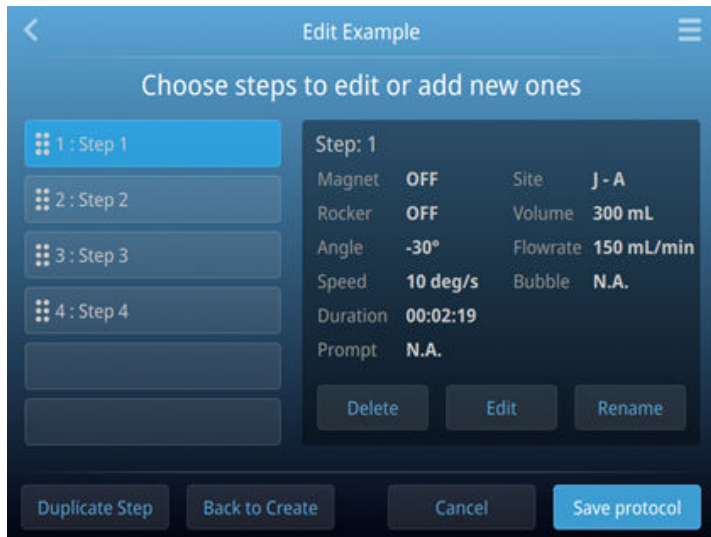
12. As you have edited a protocol the following message will show. Select **Yes** to save the new changes to the protocol.
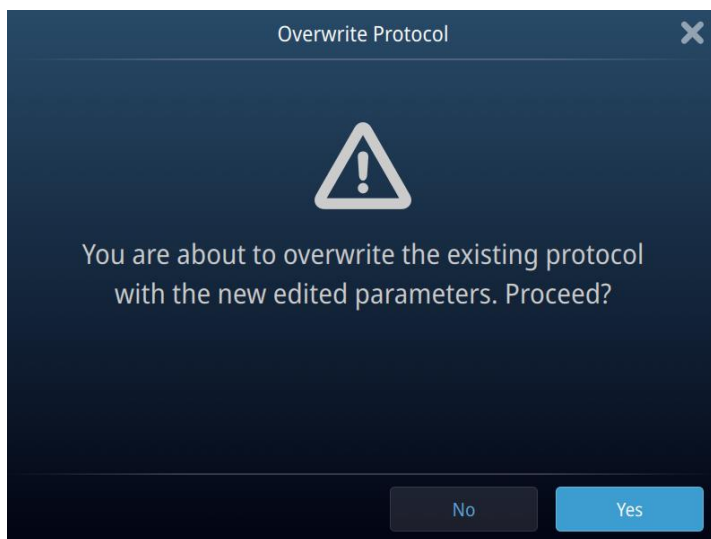
System settings

Software updates

Perform software updates via the USB port, located to the right of the eGUI and below the emergency stop button.

1. On the **Home** screen, select ≡ **(Menu)**
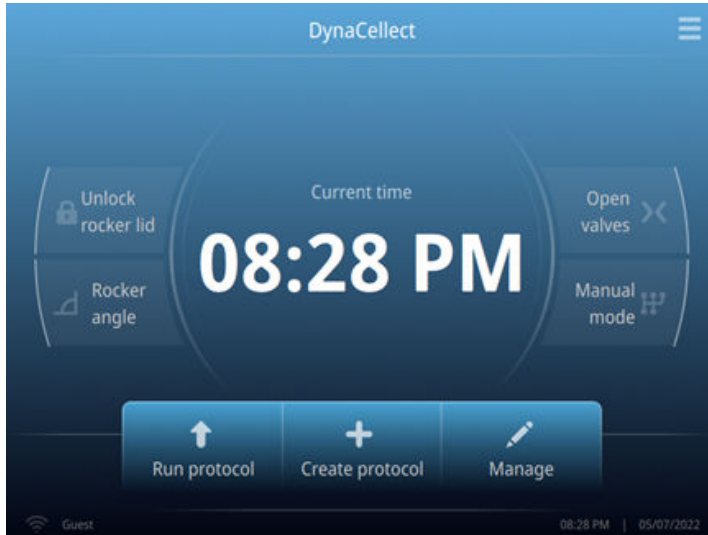
2. In the **Menu** screen, select ⚙ (**Settings**).
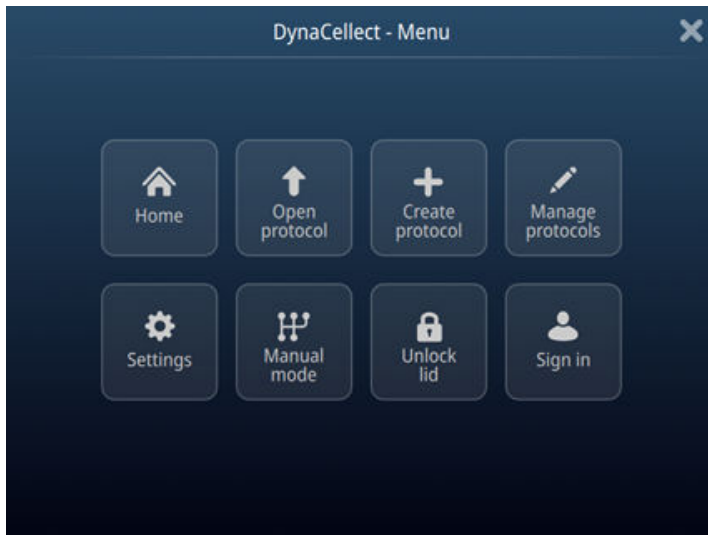
3. In the **System Settings** screen, select **Maintenance & service**.

System Settings

About instrument

Instrument settings

Maintenance & service

Run history

OPC mode
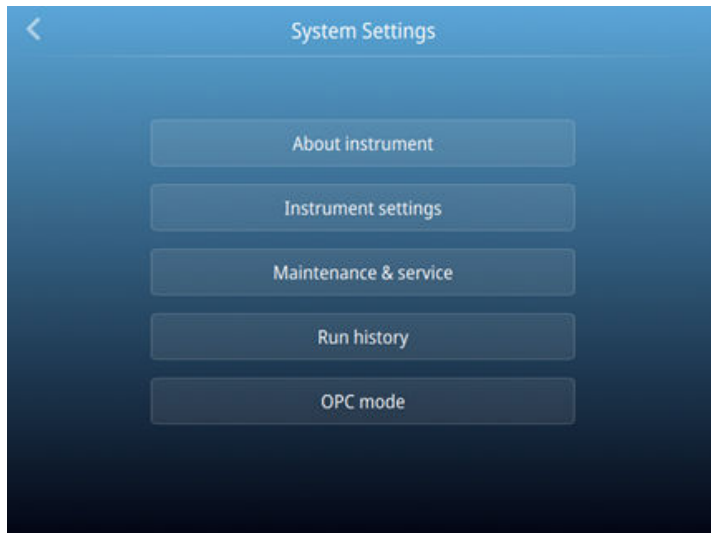
4. In the **Maintenance & Service** screen, select **Software update**.

Maintenance & Services

Software update

Pump calibration

Export service logs

Run diagnostic tests

Restore factory settings
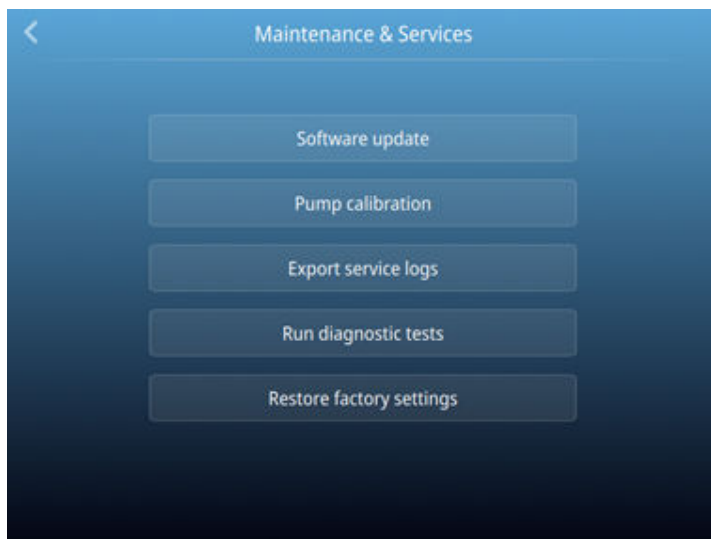
5. Insert the USB drive and select the software update file.

IMPORTANT! Remember to backup the data before updating the software.
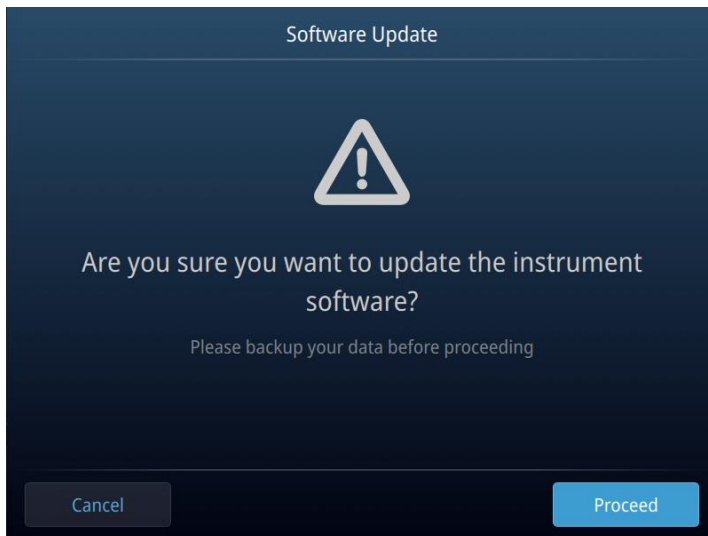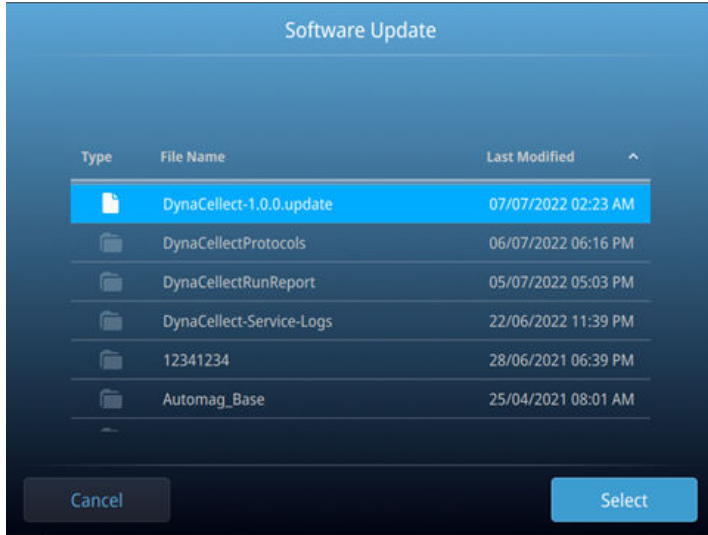
6. Wait for the software update process to complete (3 to 5 minutes).
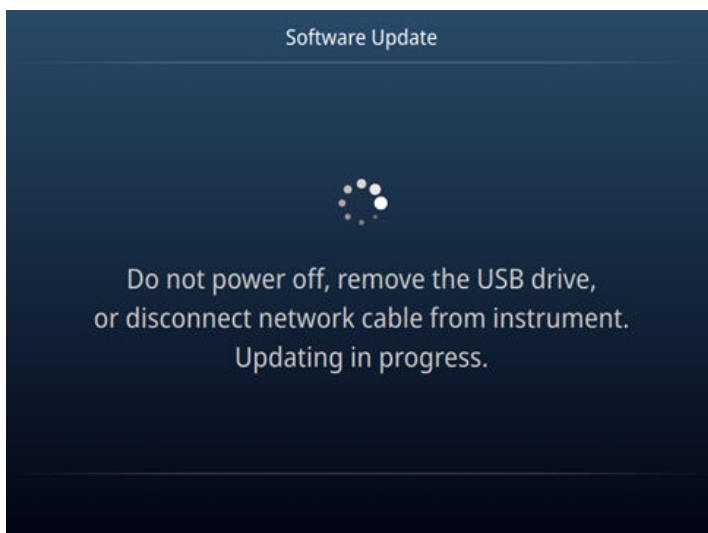
OPC-UA

An Open Platform Communications - United Architecture (OPC-UA) interface is provided that enables admin users to connect the CTS™ DynaCellect™ Magnetic Separation System 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".
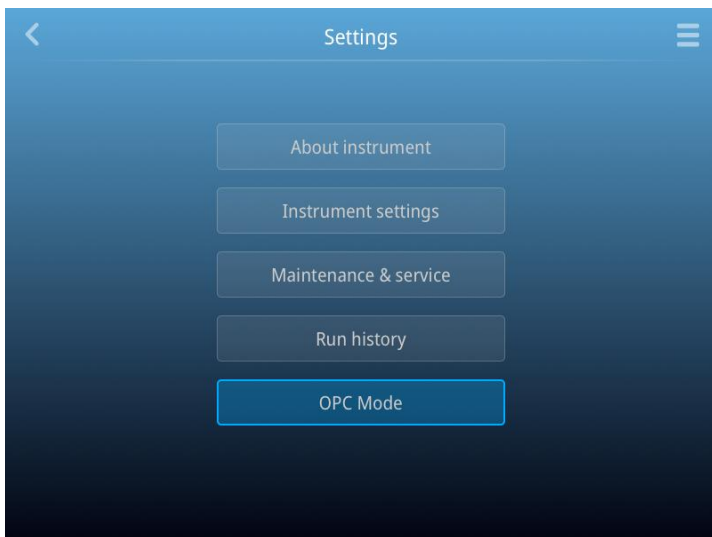
OPC-UA interface

Introduction

There are requirements where the CTS™ DynaCellect™ Magnetic Separation System instrument will need to be monitored and controlled by a Distributed Control System (DCS). The Emerson DeltaV™ system is one of the DCS systems which will be used here to perform these operations targeted for clinical and commercial manufacturing.

These monitoring and controls will include the following:

- Monitoring
  - Run status
  - Instrument status
  - Protocol details
- Controls
  - Select the protocol index
  - Load and unload a protocol
  - Start a protocol run
  - Pause and resume run
  - Abort a run

Each DynaCellect™ instrument will have an OPC-UA server installed together in the package for a client server based communication to perform data exchange with the DeltaV™ System.

OPC Unified Architecture (OPC-UA) is a machine to machine protocol communication for industrial automation developed by the OPC Foundation.

Definitions

Abbreviations	Definition
eGUI	Embedded 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

(continued)

Abbreviations	Definition
Protocol	A series of equipment instructions
Run	The execution (running) of a protocol, from beginning to end
DCS	Distributed Control System
OPC-UA	Open Platform Communications - United Architecture, a machine to machine communication protocol for industrial automation

MES Interface

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

Background

The CTS™ DynaCellect™ Magnetic Separation 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™ DynaCellect™ Magnetic Separation 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.

Architecture

The following component diagram describes the communication within subcomponents of DynaCellect™ instrument and to the external OPC-UA Client (DeltaV™ system).
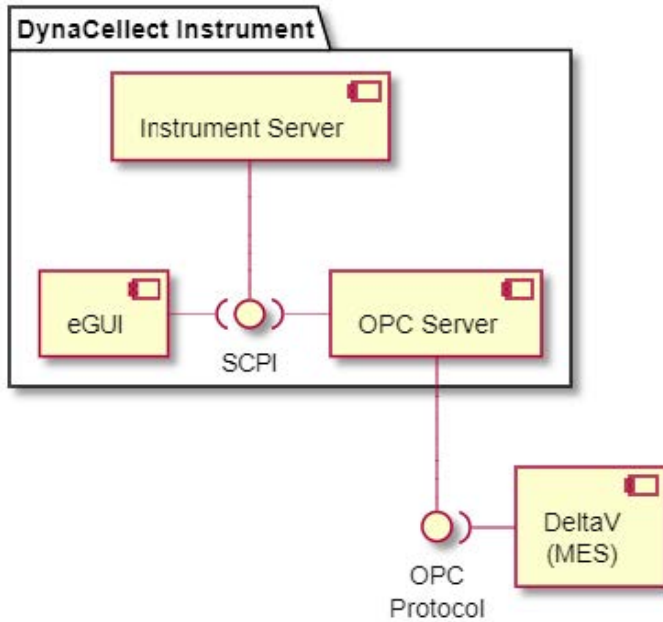
The Instrument Server will be the main interface performing back end logic to support both eGUI and OPC-UA Server interactions. The DeltaV™ system will establish login authentication and communication exchange with the OPC server that is a part of DynaCellect™ system.

The communication between DynaCellect™ system and the DeltaV™ system will be as follows:

1. The DeltaV™ system will send the commands (Controls) to OPC-UA Server and OPC-UA Server will in turn relay these commands to the Instrument Server.

2. Instrument Server will send status updates (Monitoring) to OPC-UA Server and the OPC-UA Server will in turn relay these data to the DeltaV™ system.
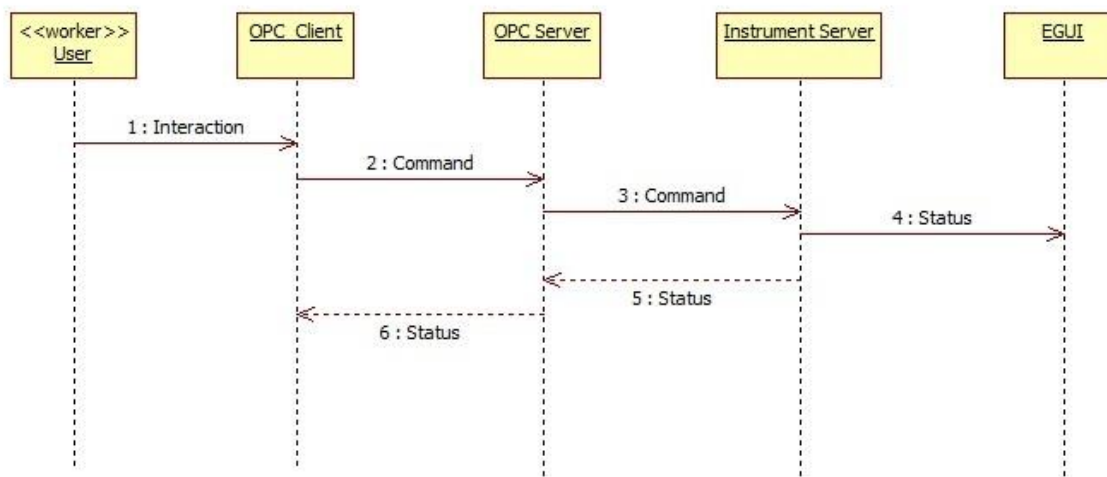
It is assumed the MES applications will be located externally to the CTS™ DynaCellect™ Magnetic Separation System.

Communications by any MES system to the instrument will be through the CTS™ DynaCellect™ Magnetic Separation System embedded OPC-UA software installed in the instrument.

Initial OPC-UA Setup

User will have to configure OPC initial settings if it is a first-time user. In the following screen, the user will have the option to enable/disable OPC server and allow/disallow control functions from OPC server.

1. From the **Home** screen, navigate to **Settings** and press **OPC Mode**.
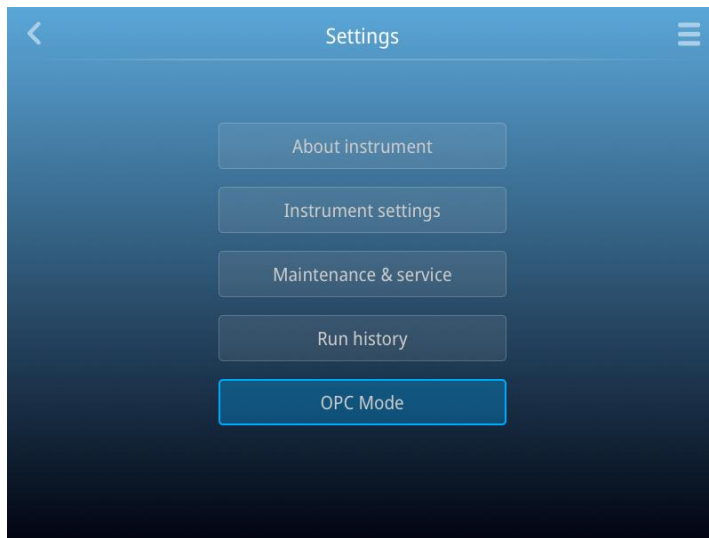
2. Enable **OPC Mode**, allow control via OPC server, then select **Next**.
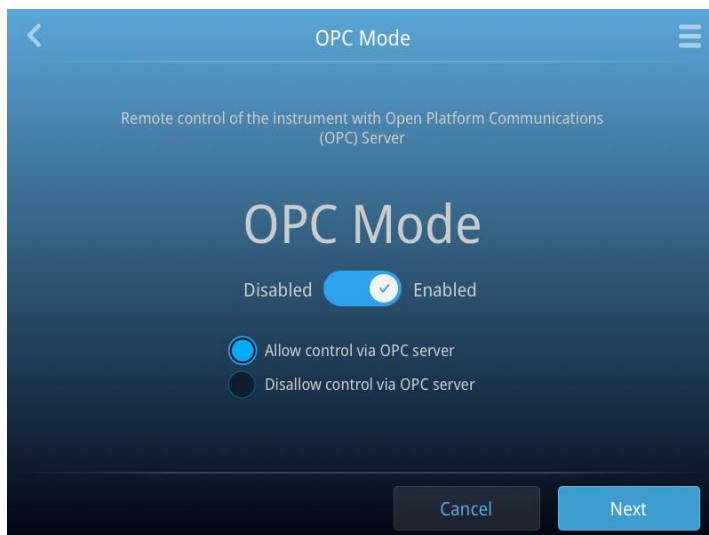
Disallow control via OPC server option prevents the OPC server from accepting control functions while still allows sending status information.

Access Methods

There are 2 available option for OPC client authentication. The user can either select authentication via SSL certificate or username and password. A copy of the certificate from the OPC-UA client (DeltaV) must be saved on a USB disk before proceeding with the instructions below. Also, the OPC endpoint URL port number, i.e. "opc.tcp://<ip-address>:<port>/ThermoFisher" can be edited here.

1. Select **Edit port**.
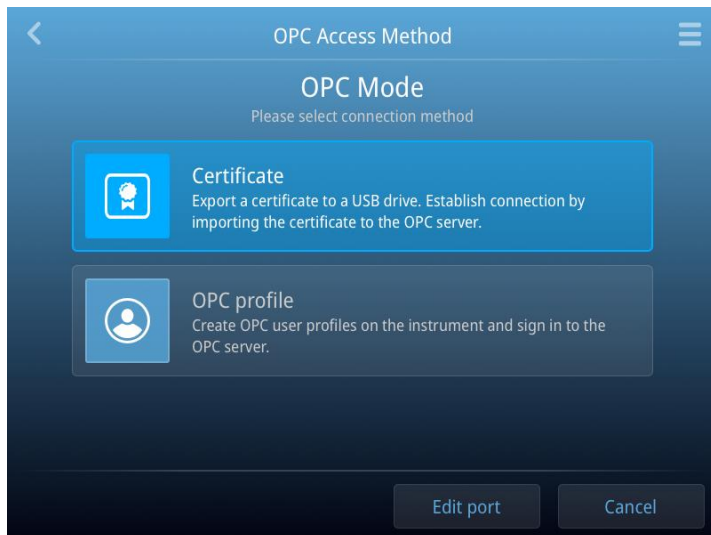
2. Key in the port number (default: **4880**) and press **Enter**.

Certificate

The user will have to perform the following to setup the login credential via SSL certificate.

- Import the certificate from the OPC-UA client's (DeltaV™ system) trust store
- Export DynaCellect™ OPC-UA server certificate for import to client side

The sequence diagram below describes the flow for user to retrieve the SSL certificate from the instrument.

1. The instrument server will generate client SSL certificate and add it into OPC server's trust store.
2. The user then exports the OPC-UA client application certification and import it into the OPC server's trust store.
3. The user then exports the public certificate to a USB disk from the eGUI.
4. The user then imports the public certificate for OPC Client authentication to establish connection with OPC server.
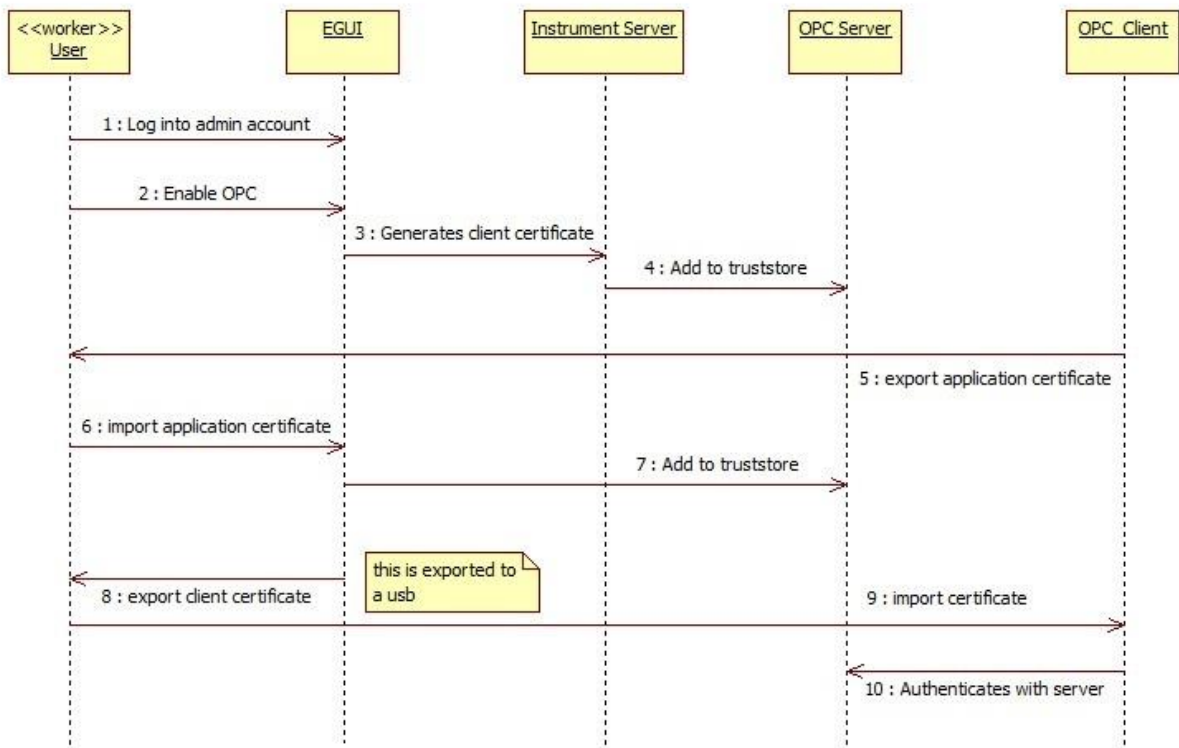
The certificates must be exchanged between the server and client to each others trusted store for authentication
For client to server authentication, the application and client user certificate need to be added into the server truststore
For server to client authentication, the server certificate need to be added into the client truststore

The following steps will put the OPC-UA client's certificate into the OPC-UA server trust store (Import) and vice versa (Export) using the DynaCellect™ instrument's embedded Graphical User Interface (eGUI).

1. From the **OPC Access Method** dialog, select **Certificate**.
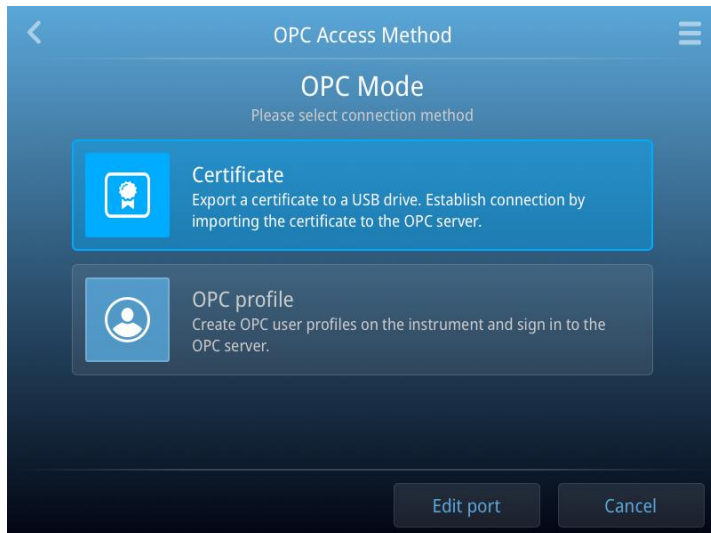
2. Plug in the USB disk with the OPC-UA client certificate into the DynaCellect™ instrument.

3. Select **Import certificate**.
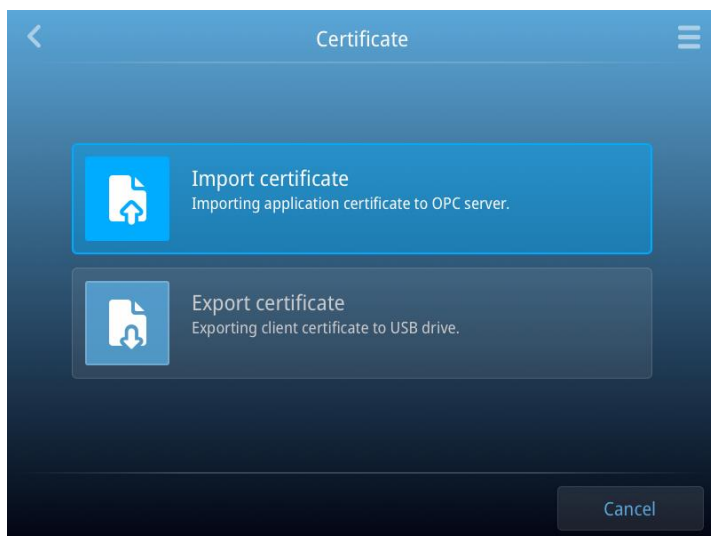
4. Select the OPC-UA certificate from the USB drive dialog screen shown in the following image, press **Select** and wait for the import process to complete.
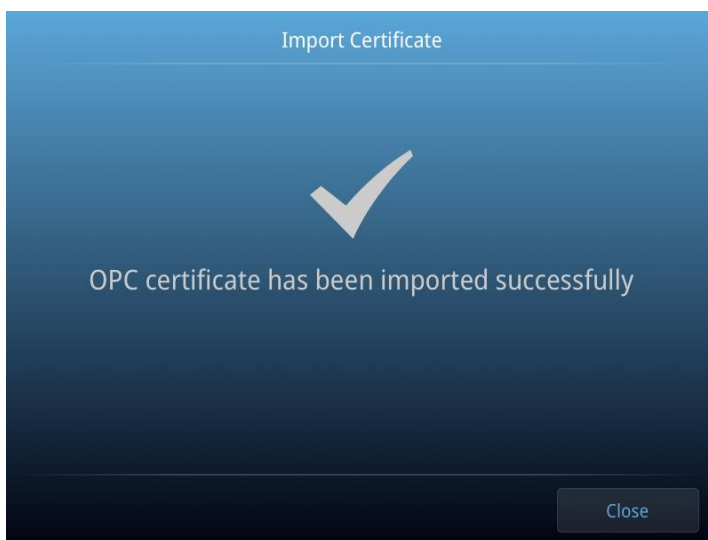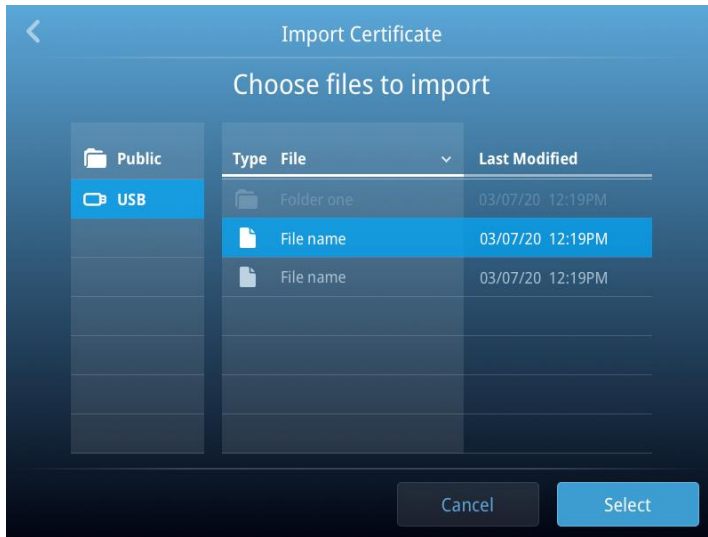
5. Select **Export certificate**. This will generate a client certificate into the USB drive. The user will then be able to import this into the OPC client's trust store.

6. Copy the password shown after generating the certificate. This password will be used to authenticate the certificate at the OPC-UA client side.
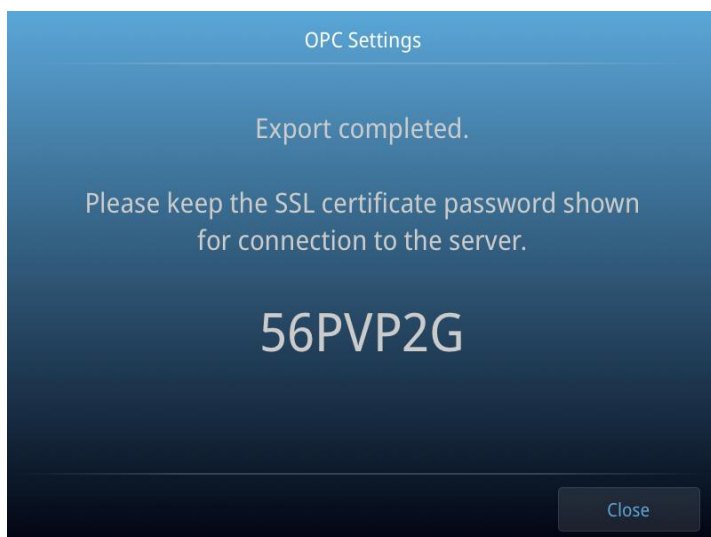
Username and Password

The sequence diagram below describes the flow for user to generate username and password for OPC-UA client authentication to the server.

1. The user exports the OPC-UA client application certificate and import it into the OPC server's trust store.
2. The user will input the desired username and password for the first time in the eGUI.
3. These credentials will be sent to instrument server and then to OPC server for storage.
4. The user then uses these log in credentials from the OPC-UA client application (MES) for authentication to establish connection with DynaCellect™ instrument's OPC-UA server.
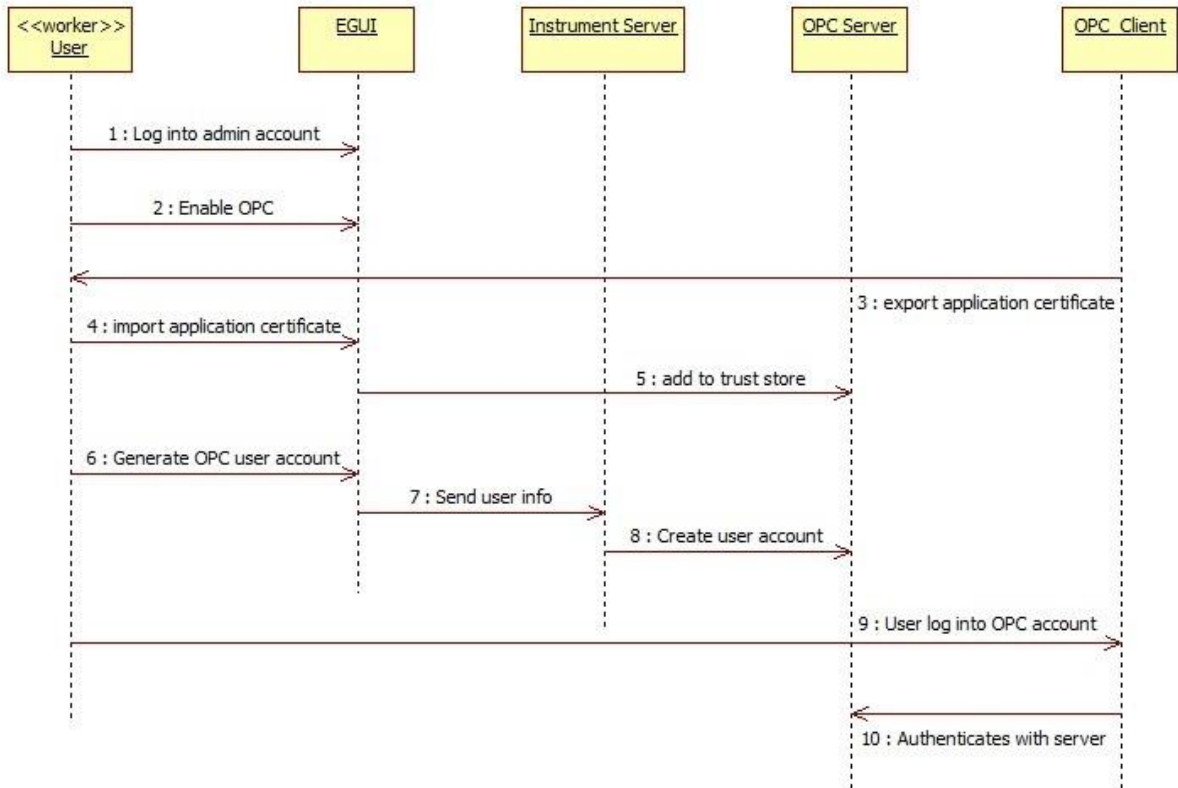
The user will have to perform the following steps to setup a username and password credential through DynaCellect™ instrument's eGUI.

1. From the **OPC Mode** dialog, select **Username & Password**.
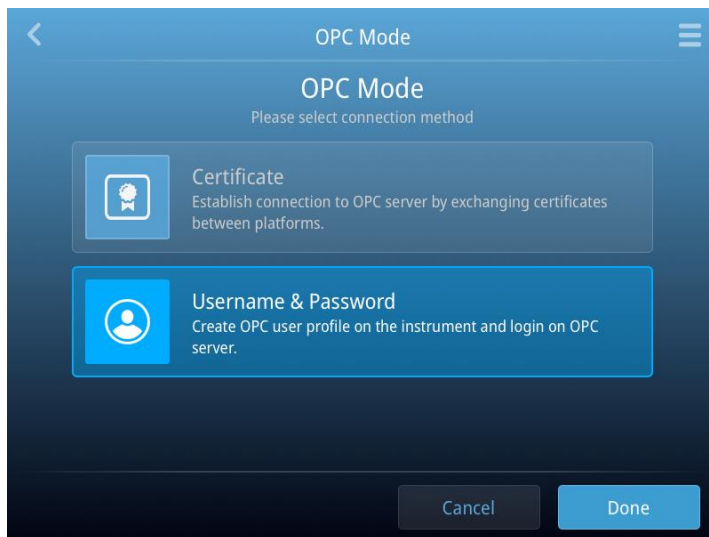
2. Plug in the USB disk with the OPC-UA client certificate into the DynaCellect™ instrument.

3. Import OPC-UA client application certificate from USB drive.
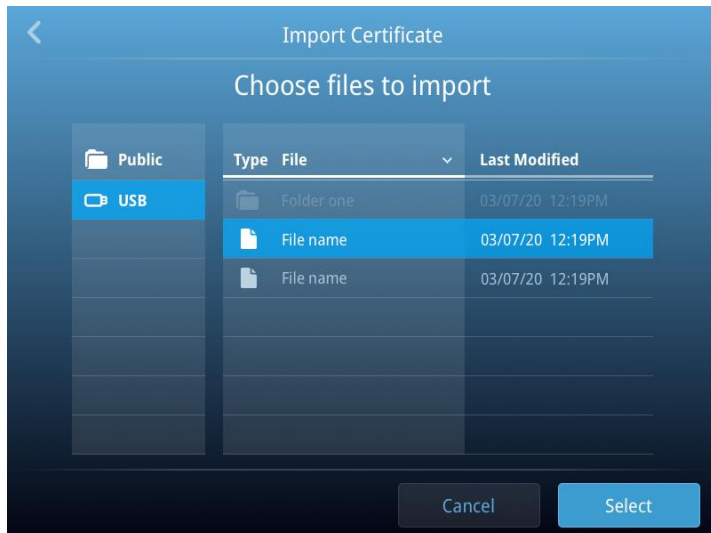
4. Import OPC-UA client application certificate from USB drive.

5. Enter username and password to be used for authentication using the OPC-UA client application.
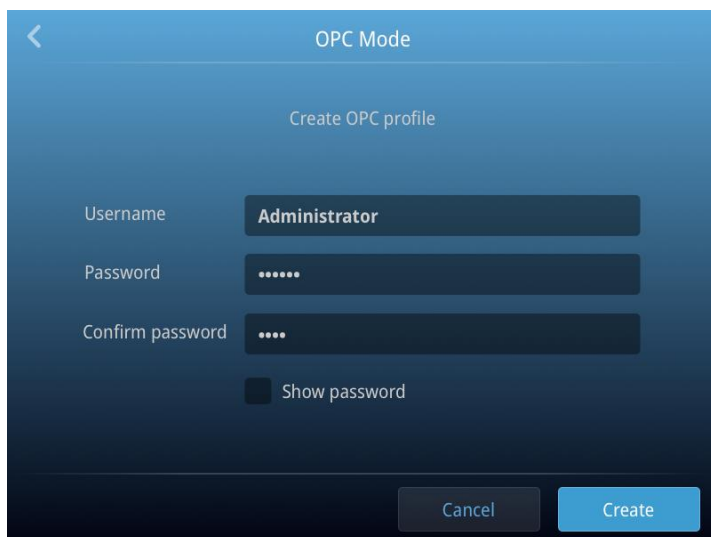
Enable OPC-UA

The OPC-UA interface is enabled using DynaCellect™ instrument's embedded Graphical User Interface (eGUI) following the instructions

1. From **Setting** menu, press **OPC Mode** and select **Done**.

2. OPC mode is enabled and the following dialog is displayed.

Import protocol for OPC-UA

The sequence diagram below describes the process of importing a protocol to DynaCellect™ instrument's OPC-UA server application.
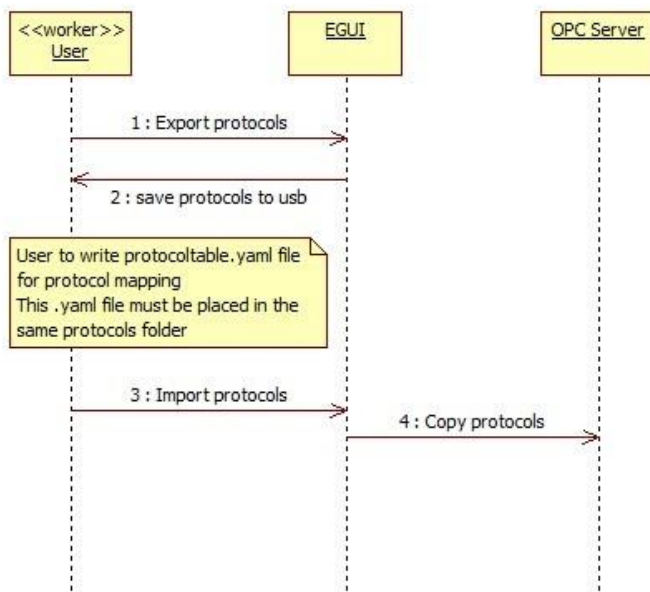
1. Using the instrument's eGUI, the user creates and exports the protocol to USB. This will create \DynaCellectProtocols folder in the root directory of the USB disk.

2. User must create a protocoltable.yaml file which must be in the same folder as the exported protocols in the root directory \DynaCellectProtocols of the USB disk.

3. User can then import protocol via the import/export settings from the OPC Mode dialog in the instrument's eGUI.

4. The eGUI application will then copy the protocols files and protocol table YAML file into the OPC server's protocol directory.

The protocoltable.yaml file must be created manually by the user and then copied in the same directory where the exported instrument protocols are located i.e \DynaCellectProtocols. The format for the protocol table YAML file is shown below:

```
version: 1
mapid:
  - id: 1
    filename: protocol1.json
  - id: 2
    filename: protocol2.json
```

After the table file is generated and copied in the same folder as the protocol files, the user can proceed to import the protocols using the DynaCellect™ instrument's eGUI application.

1. Press **Import/Export** from the **OPC Mode** screen.

2. This step requires an admin user account. Enter admin username and password, then press **Next**.
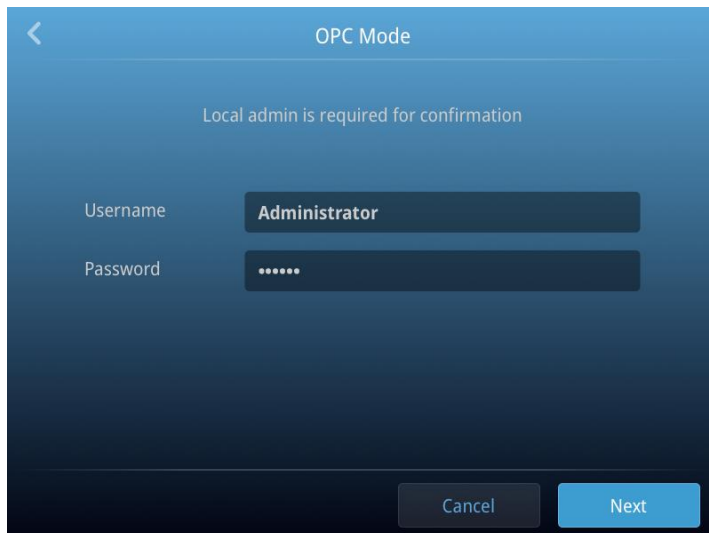
3. Press **Import** and then press **Next** in the following screens.
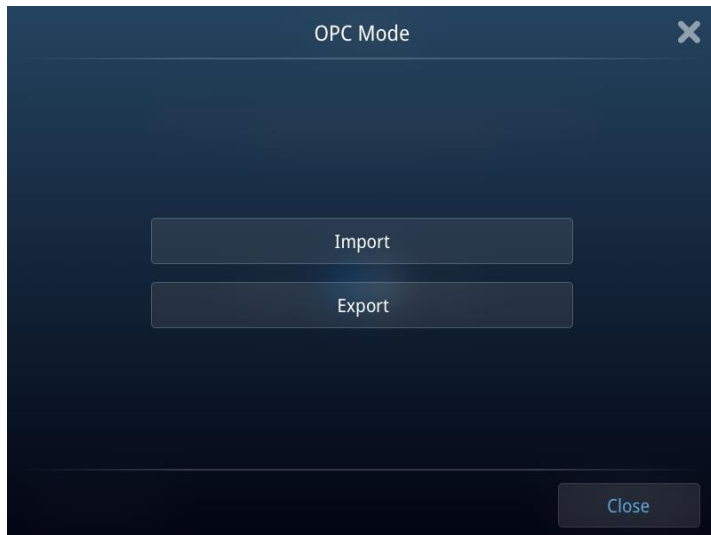
4. Wait for the import process to complete, press **Close**.
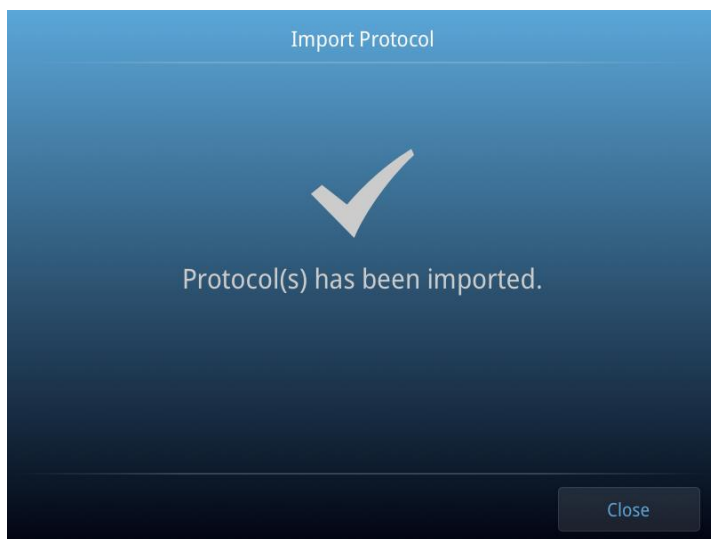
OPC-UA interface

Information model
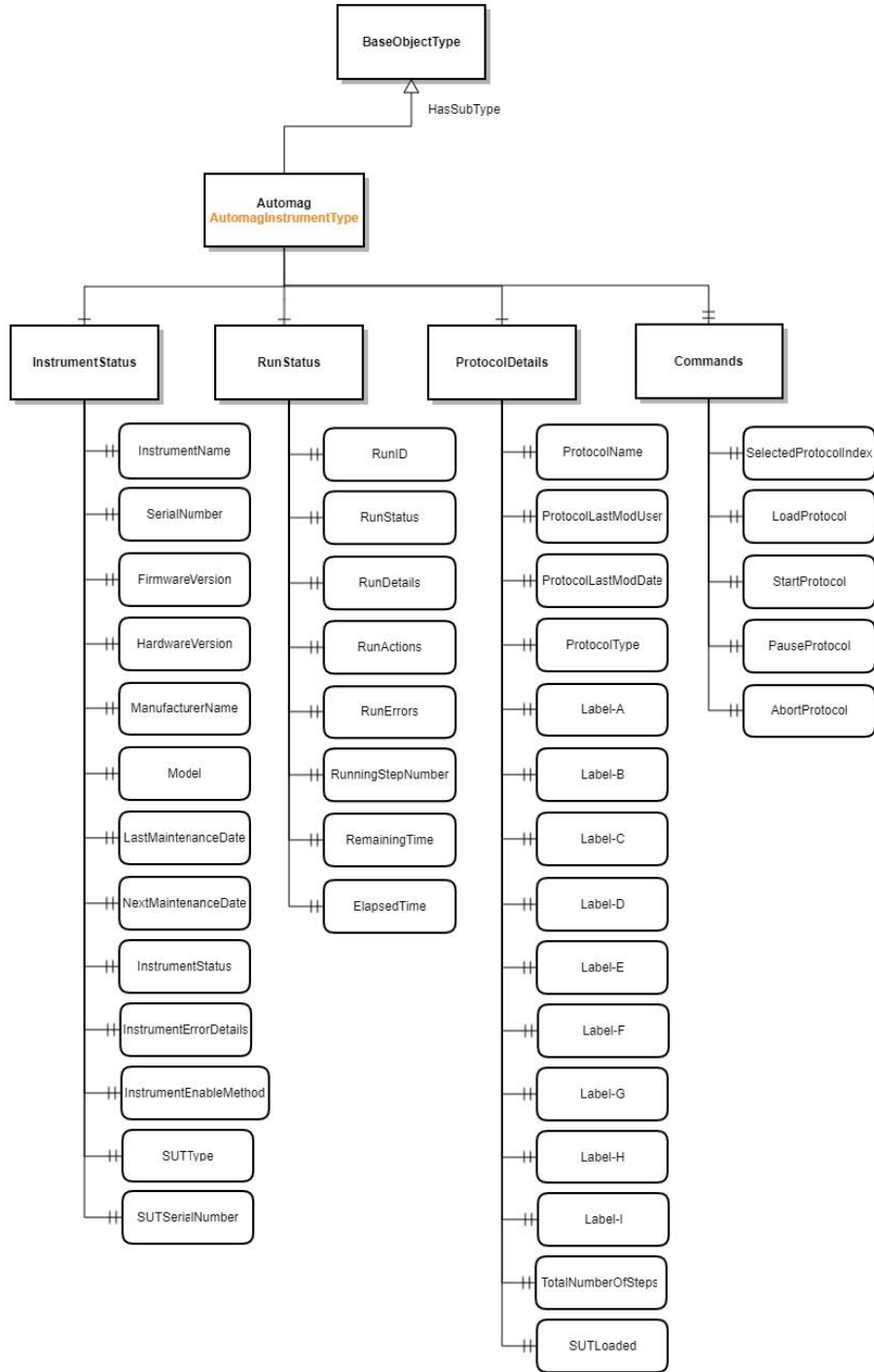
Monitoring

Instrument properties

Variable	Type	Access	Value/Description
InstrumentName	String	Read	The name of the instrument
SerialNumber	String	Read	The serial number of the instrument
FirmwareVersion	String	Read	The firmware version of the instrument
HardwareVersion	String	Read	The hardware version of the instrument
ManufacturerName	String	Read	Static value – Thermo Fisher Scientific
Model	String	Read	The product name of the instrument
LastMaintenanceDate	String	Read	The last maintenance date for the instrument
NextMaintenanceDate	String	Read	The next maintenance date for the instrument
InstrumentStatus	String	Read	The instrument status
InstrumentErrorDetails	String	Read	The instrument error details
InstrumentEnableMethod	Boolean	Read	To determine if OPC control function is enabled or disabled False = Disabled True = Enabled
SUTType	String	Read	—
SUTSerialNumber	String	Read	Supply by egui from barcode scanner

Protocol properties

Variable	Type	Access	Value/Description
ProtocolName	String	Read	The name of the loaded protocol
ProtocolLastModUser	String	Read	The last user who modified the protocol
ProtocolLastModDate	String	Read	The last modification date of the protocol
ProtocolType	String	Read	The protocol type
Label-A	String	Read	The protocol bag A label name
Label-B	String	Read	The protocol bag B label name
Label-C	String	Read	The protocol bag C label name
Label-D	String	Read	The protocol bag D label name
Label-E	String	Read	The protocol bag E label name
Label-F	String	Read	The protocol bag F label name
Label-G	String	Read	The protocol bag G label name
Label-H	String	Read	The protocol bag H label name
Label-I	String	Read	The protocol bag I label name
Volume-A	UInt32	Read	The protocol bag A volume number
Volume-B	UInt32	Read	The protocol bag B volume number
Volume-C	UInt32	Read	The protocol bag C volume number
Volume-D	UInt32	Read	The protocol bag D volume number

(continued)

Variable	Type	Access	Value/Description
Volume-E	UInt32	Read	The protocol bag E volume number
Volume-F	UInt32	Read	The protocol bag F volume number
Volume-G	UInt32	Read	The protocol bag G volume number
Volume-H	UInt32	Read	The protocol bag H volume number
Volume-I	UInt32	Read	The protocol bag I volume number
TotalNumberOfSteps	UInt32	Read	The total number of steps for the loaded protocol
SUTLoaded	UInt32	Read	

Run status

Variable	Type	Access	Values / Description
ElapsedTime	UInt32	Read	The total elapsed time of the run
RemainingTime	UInt32	Read	The time remaining for current step run to complete
RunActions	String	Read	The latest instrument command
RunDetails	String	Read	The latest run information
RunErrors	String	Read	The latest run error
RunID	String	Read	The current run unique identifier which will be using the UNIX time in seconds
RunningStepNumber	UInt32	Read	The current running step number

(continued)

Variable	Type	Access	Values / Description
RunStatus	String	Read	The current run status • Running • Pausing • Paused • Resuming • Aborting • Stopped • End

Controlling

Method	Type	Range	Access	Value/Description
SelectedProtocolIndex	UInt32	1–99	Read/write	The selected protocol index. This will find the protocol file from the map file (protocoltable.yaml) that is imported into the instrument. This is a required step before the user is able to load or perform a run.
LoadProtocol	UInt16	0–1	Read/write	0 = unload 1 = load This is a required step before the user can perform a run. Prior to this, the user will have to select the protocol index first.
StartProtocol	UInt16	1	Read/write	start run
PauseProtocol	UInt16	0–1	Read/write	0 = resume 1 = pause
AbortProtocol	UInt16	1	Read/write	1 = abort run

Maintenance

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

Cleaning and maintenance

> ⚠️ **CAUTION!** Cleaning and decontamination. Use only the cleaning and decontamination methods specified in the user documentation. It is the responsibility of the operator (or other responsible person) to ensure the following requirements are met:
> - No decontamination or cleaning agents are used that can cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in the equipment.
> - The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) prior to having the instrument serviced at your facility or sending the instrument for repair, maintenance, trade-in, disposal, or termination of a loan (decontamination forms may be required from customer service). ·
> - Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.

Clean the surface of the CTS™ DynaCellect™ Magnetic Separation System with a damp cloth. Do not use harsh detergents or organic solvents to clean the unit. The instrument is resistant to the following chemicals:

- Cleaning agents containing 70% isopropanol, 5–10% bleach or steriprox (6% H_2O_2).

In case liquids (e.g., buffer, water) are accidentally spilled on the instrument, wipe the spill using dry laboratory paper. For any other repairs and service, contact Technical Support.

IMPORTANT! Do not perform any repairs or service by yourself to avoid damage to the instrument or voiding the warranty.

Power and fuses

Power supply

The instrument power supply is rated to operate with international standard single-phase power. Specification: 85–264 VAC, Frequency 50/60 Hz, 600 Watts.

Fuses

The power inlet module houses 2 × 10 A cartridge fuses, 5 mm diameter × 20 mm long, time-lag.

- 250 VAC (10 Amp)

When required, replacement of fuses is performed as follows:

1. Confirm that the instrument power toggle is in the off position.

2. Unplug the mains cable located at the back of the instrument, near the power toggle.

3. Use tweezers or a small flathead screwdriver, to open the cover to expose the fuse housing.

4. Pull out the fuse housing.

5. Remove the fuses located inside the housing to replace with new ones on both sides of the housing. Check that the replacement fuse is the correct rating for your instrument (see page 15).

Note: The placement inside the housing is as pictured. Incorrect fuse placement will not work.

6. Return the fuse housing back to the instrument.

7. Close the cover over the housing.

8. Re-connect the mains cable and toggle the power to start up the instrument.

Restore factory settings (Administrator profile only)

1. Select ☰ **(Menu)** then ⚙ **(Settings)**.

2. Select **Maintenance and & Services** and select **Restore factory settings** and **Restore** to remove all the data and customized settings and revert to factory settings.

    All data and settings will be erased once factory settings are restored.
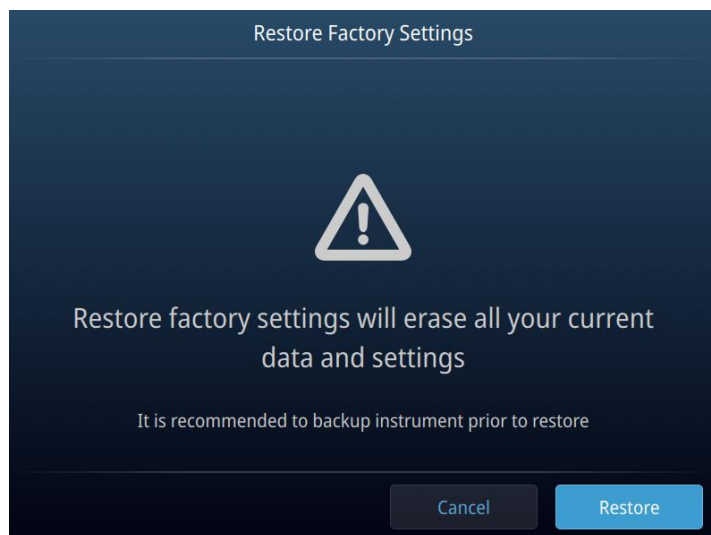
    At the end of the restoration process, the message, "Your instrument has been restored." is displayed and the instrument automatically reboots after 30 seconds.

Repackaging the instrument

If you need to send the instrument to Thermo Fisher Scientific for warranty issues, or you wish to transport the instrument to another location, repackage the unit as follows.

Note: Prior to sending the instrument, ensure the instrument is properly decontaminated if the instrument is exposed to any viable biological agents, radioactive materials, or hazardous chemicals (toxic, carcinogenic, mutagenic, toxic for reproduction, sensitizing, and/or have not been fully tested). Contact Technical Support for a decontamination protocol and to obtain a Returns Goods Authorization (RGA) number and return shipping instructions.

Repackaging and storage instructions

1. Turn off the main power switch at the rear of the instrument and detach the power cord from the rear of instrument.

2. Place the instrument in the original box including the original packing foam.

3. Tape the box securely and place appropriate shipping labels for shipping the instrument to Thermo Fisher Scientific. Always transport the box with the unit in the upright position.

4. If the instrument is not to be used for extended periods of time, store the repackaged instrument in an upright position at 15°C to 30°C

Basic instrument operation

Unpack Single-Use Kits

There are two types of single-use kits:

- CTS™ DynaCellect™ Cell Isolation Kit (Cat. No. A52300)
- CTS™ DynaCellect™ Bead Removal Kit (Cat. No. A52301)

They are packaged in two bags that have both gone through gamma sterilization.

① CTS™ DynaCellect™ Cell Isolation Kit
② CTS™ DynaCellect™ Bead Removal Kit

1. Unfold the Tyvek™ bags and remove the first layer of the bag by peeling off the Tyvek™ bag shown in the following image.

2. Follow the same procedure illustrated in step 1 to remove the second layer of the Tyvek™ bag to clear off the packaging of the Single-Use Kit.

3. Loosen the tube holder from the catch at the back of the cassette.

4. Take all tubes out of the catch on the top of the cassette.
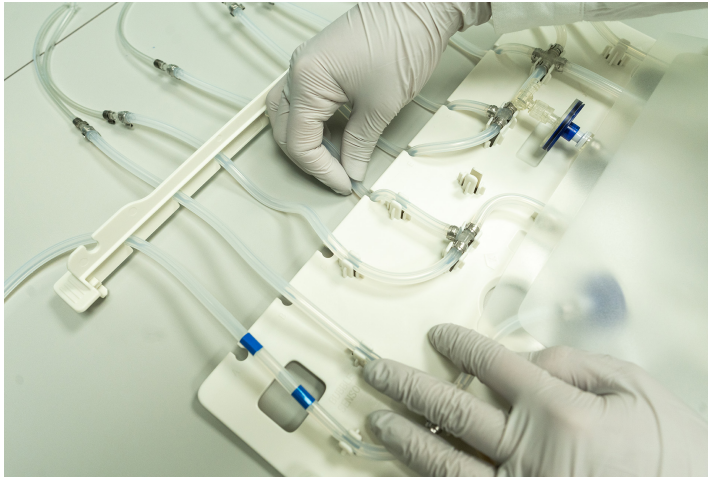
⚠️ **CAUTION!** The CTS™ DynaCellect™ Single-Use Kit (Cat. Nos. A52300 and A52301) have been validated for one-time use by customers. Single-Use Kits are not recommended to be washed, re-sterilized, or reused as sterility and quality of these kits have not been validated for multiple uses.

Connecting vessels, bags and reagents

The instrument has been specifically designed for single-use, functionally closed processing. The CTS™ DynaCellect™ Cell Isolation Kit and CTS™ DynaCellect™ Bead Removal Kit use DEHP-Free PVC, specifically Tygon ND-100-65 size of 3/32" I.D. x 5/32" O.D. x 1/32" Wall to enable sterile welding to compatible bags using devices that service the blood bank industry such as the TSCD II Sterile Tubing Welder (Terumo BCT). See the instructions provided by instrument providers for completion of sterile welding.
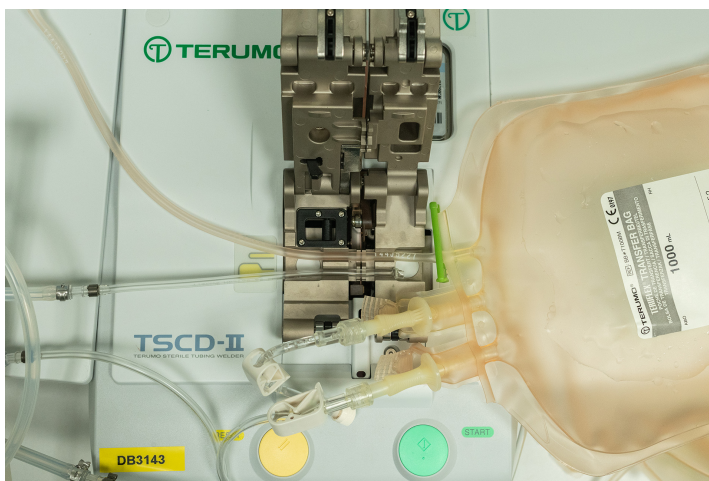
Prepare consumables for a run

Example consumable configuration

Example consumable configuration for isolation of 400 million target cells and bead removal of
1 L culture
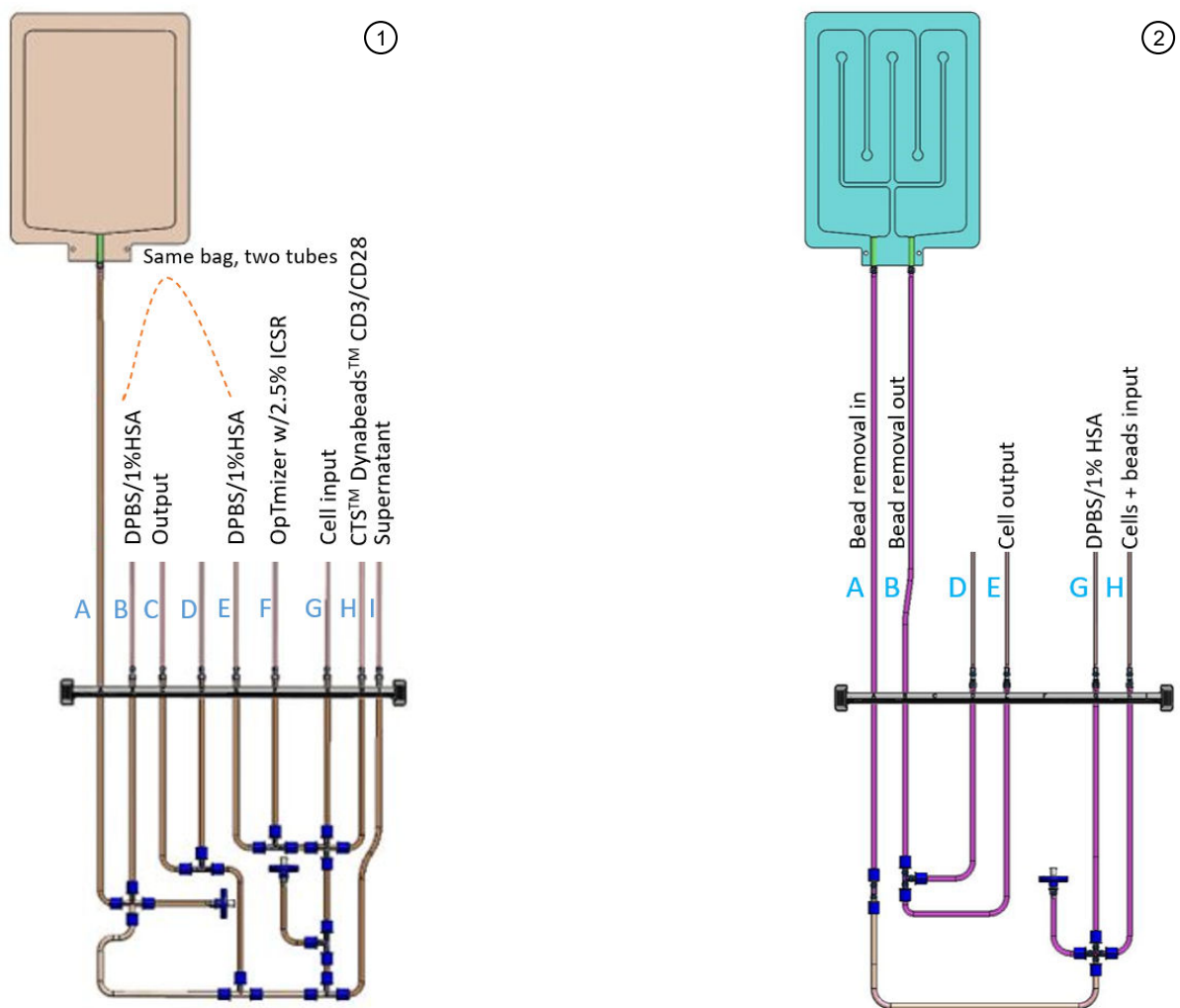
Figure 8   Examples of consumable configurations

① CTS™ DynaCellect™ Cell Isolation Kit
② CTS™ DynaCellect™ Bead Removal Kit

Table 4   Bags used for the cell isolation configuration

Content	Bag type	Connectors	Tube line	Volume
DPBS/1% HSA	1 L Terumo™ bag	Spike to female luer with 10 cm tube and spike to male luer with 50 cm tube	B, E	550 mL
Output	1 L Terumo™ bag	N/A	C	Empty
CTS™ OpTmizer™ T-Cell Expansion SFM w/ 2.5% ICSR	OpTmizer™ bag	Spike to female luer with 50 cm tube	F	500 mL
Cell input	150 mL Terumo™ bag	Spike to female luer with 10 cm tube	G	40 mL
CTS™ Dynabeads™ CD3/CD28	Conical bag	Spike to female luer with 50 cm tube	H	3 mL
Supernatant	1 L Terumo™ bag	N/A	I	Empty

Table 5   Bags used for the bead removal configuration

Content	Bag type	Connectors	Tube line	Volume
Cell output	2 × 1 L Terumo™ bag	N/A	E	Empty
DPBS/1% HSA	1 L Terumo™ bag	Spike to female luer with 10 cm tube	G	350 mL
Cells + beads input	1 L Terumo™ bag	N/A	H	1000 mL

Bags and connectors

Note: All preparations of reagent bags with cells/beads/media etc must be prepared in a laminar flow hood to ensure sterility.

CTS™ OpTmizer™ T-Cell Expansion SFM bag with spike to female luer with 50 cm (19.7") tube.

Conical bag for bead input. Input line welded with spike to female luer with 50 cm (19.7") tube. VueLife® clamp to limit bead movement.

Terumo™ bag for miscellaneous content with spike to female luer with 10 cm (3.94") tube and spike to male luer with 50 cm (19.7") tube.

Prepare bags (for DPBS/1% HSA, waste, output, cells)

Note: All preparations of reagent bags with cells/beads/media etc must be prepared in a laminar flow hood to ensure sterility.

1. Spike the 1 L Terumo™ bag with a spike to female luer with 10 cm (3.94") tube (enables filling via luer-lock syringe).

2. If a bag shall be welded to multiple sites, the bag can be spiked with spike to male luer with 50 cm (19.7") tube to add a weldable tubing. Clamp off integrated tubing to avoid spill.

3. Transfer fluid via luer-lock syringe.

4. Purge with air to transfer all liquid to the bag. Also, air is added to the bag to avoid creating vacuum and ease draining when running a protocol on the DynaCellect™ system.

5. Spike the 150 mL Terumo™ bag with spike to female luer with 10 cm (3.94") tube to enable filling bag with cells via luer-lock syringe.

Prepare conical bag (for bead input)

1. Seal off top left tube to simplify handling.

2. Weld spike to female luer with 50 cm (19.7") tube to the bag input port. The luer-lock replaces the blunt tube end, so that beads can be added via the luer-lock syringe.

3. With the luer-lock, beads can now be added to the bag via luer-lock syringe. The conical shape ensures beads sediment near the bag port, reducing loss of beads.

Transfer the beads to bag with a vial adapter

Note: All preparations of reagent bags with cells/beads/media etc must be prepared in a laminar flow hood to ensure sterility.

1. Clamp the bag to limit the volume of the bead bag.

2. Partially remove the cap.

3. Connect the vial adapter to the bead vial (after rolling beads for 30 minutes at room temperature).

4. Add air to the vial to ease the withdrawal of beads.

5. Resuspend approximately 5 times before collecting beads.

6. Transfer beads to the bag via luer-lock. Purge two times with air to minimize loss.

Welding transfer bags to kit

1. Place the Single-Use Kit on one side of the welder and the transfer bags on the other side of the welder. Place the Single-Use Kit tube in the welder (use tube holder to find correct tube) together with the bag tube and weld the bags to the Single-Use Kit.
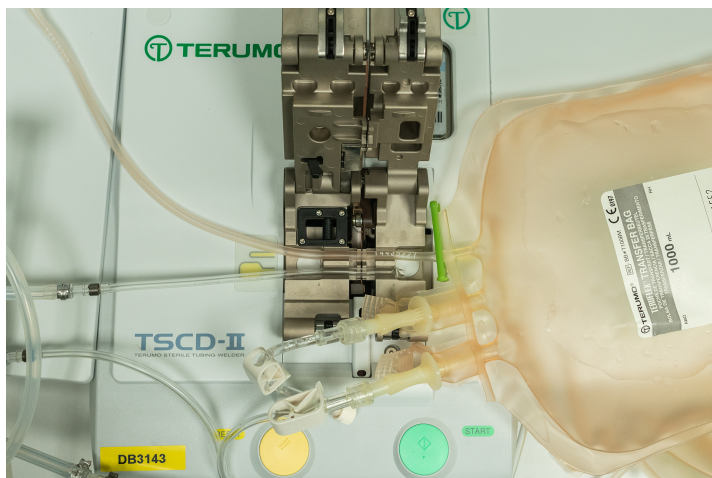
2. Open the weld by pressing on the tube. Ensure that the weld was successful by pulling on the tubes.

3. Keep clamps on bag side of the weld to keep filled bags clamped after welding.
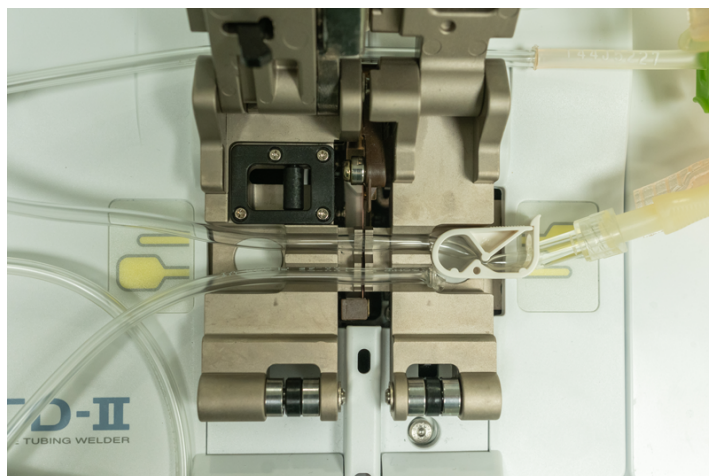
4. To keep track on tubes that are welded to the kit, move them "behind" welder as shown in the previous picture before welding the next tube.

Install CTS™ DynaCellect™ Cell Isolation Kit on the instrument

1. Transport the Single-Use Kit to the instrument using the bag hangers and the cassette handle.

2. Attach the bag hanges onto the pole adaptors.

3. Fit the cassette onto the fluidic panel.

4. Ensure that both sides of the cassette are secured on the instrument.

5. Route the isolation bag and tube behind the left pole. Unlock the rocker lid from eGUI.

6. Place the bag in the nest with the Gibco™ logo facing upwards.
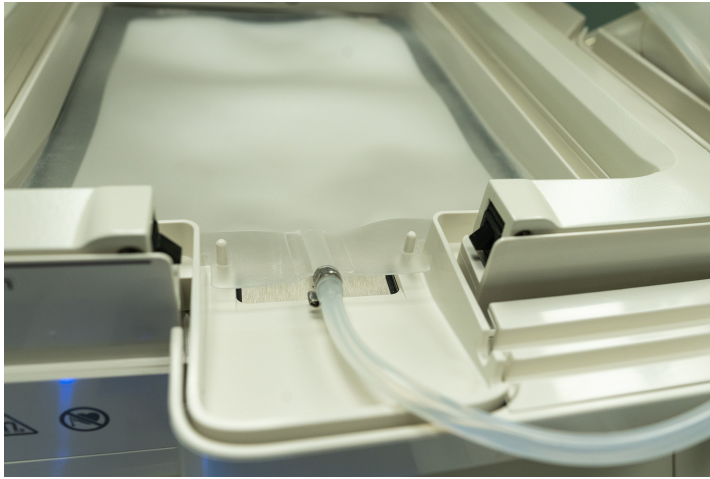
7. Close lid (locks automatically). Check that the lid is locked. Secure tube in the tube guide on the rocker.

8. Click the tube holder into position.
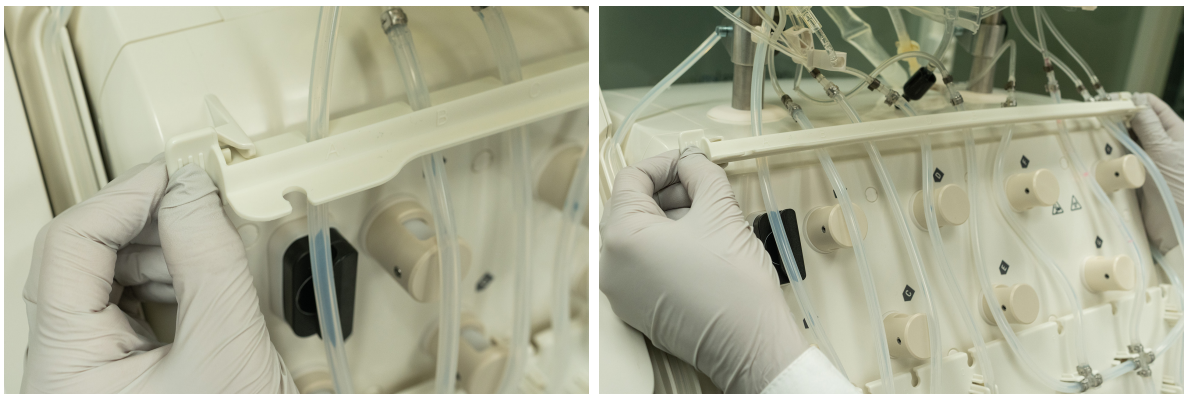
9. Open the pinch valves using the eGUI and manually open the pump lid. Install the tubes into the two pressure sensors, the two bubble sensors, the pump and the pinch valves.
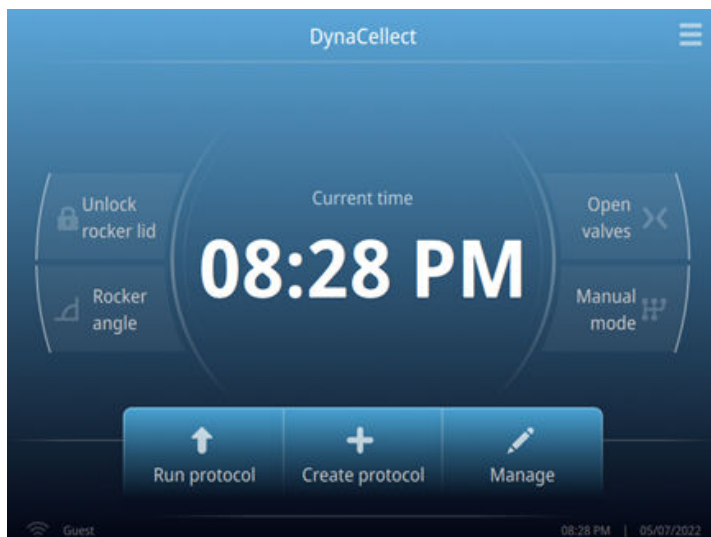
10. Install tubes in pressure sensors (stretch while inserting).

11. Install tubes in bubble sensors.

12. Ensure that tube is seated all the way into the recess of the pressure sensors and the bubble sensors.

13. Insert the tube into the pump and close pump lid.
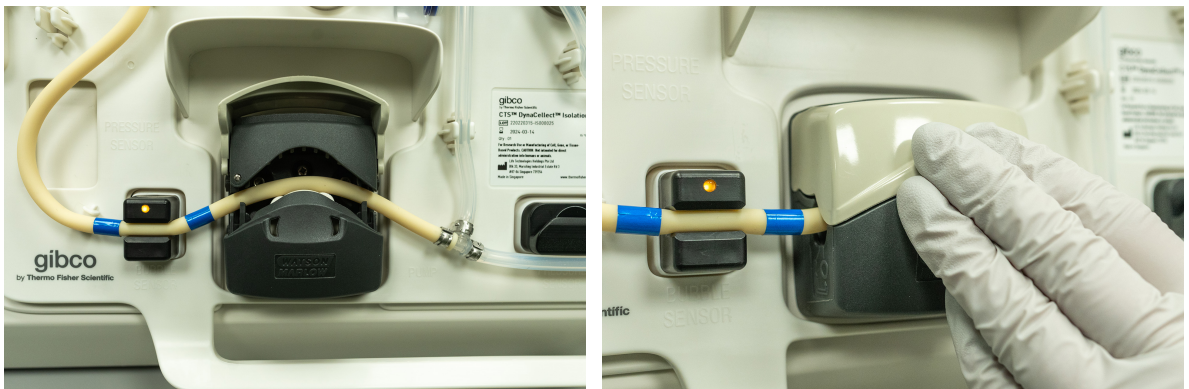
14. Insert the tube into the second pressure sensor (stretch while inserting).
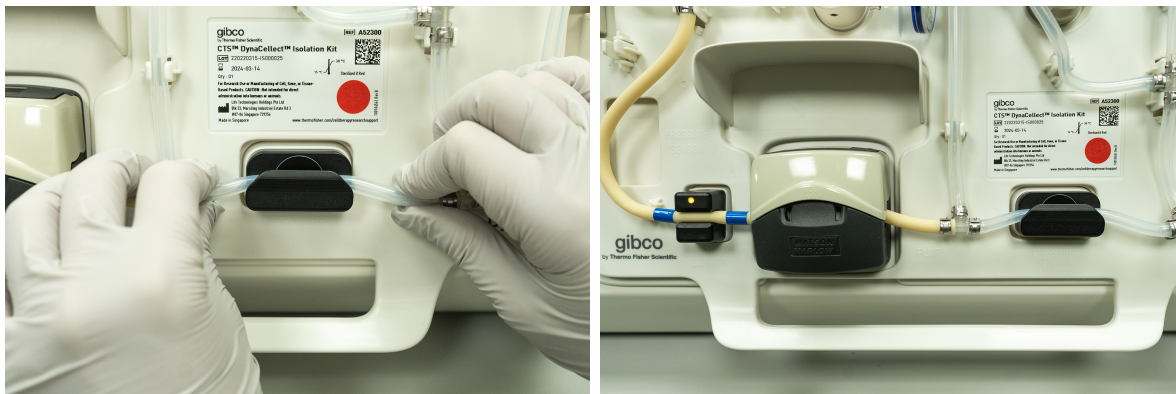
15. Insert the tubes into all pinch valves.

16. The tube holder, the cassette and the pinch valves have letters to ensure correct placing of the tubing.

17. When all tubes are installed, straighten tubes and close pinch valves using eGUI.

18. Correct installation of the fluidic panel.

19. Raise poles to straighten out tubes to ensure no kinks are present on the tubes.

20. Remove/open all clamps on the bags.
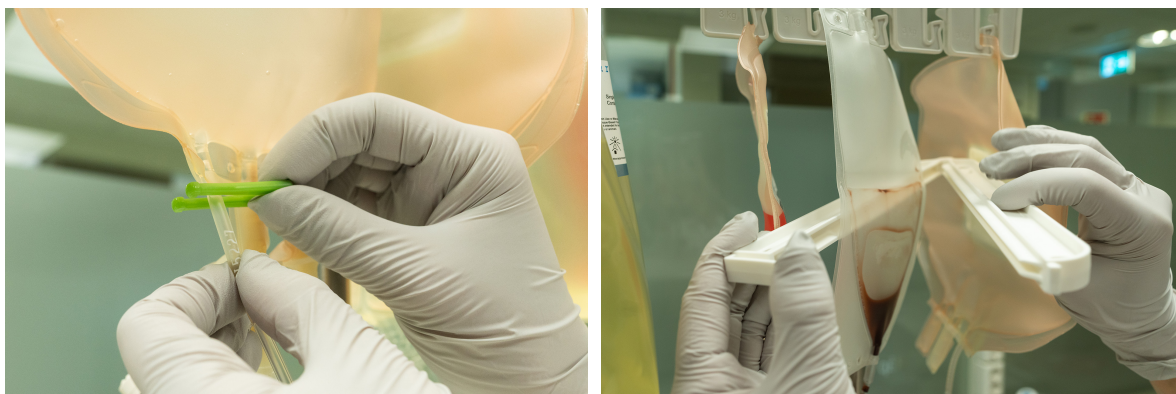
21. Press on the tubing where the clamp was to ensure no kinks on tubes are present.

22. The system is now ready to run.

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

Install CTS™ DynaCellect™ Bead Removal Kit on the instrument

The installation of the CTS™ DynaCellect™ Bead Removal Kit is similar to the CTS™ DynaCellect™ Cell Isolation Kit except for the placement of tubes in the tube guide. As shown in the following figure, there are two tubes to the reaction bag on the bead removal kit (the isolation kit has one tube to the reaction bag).

1. Route bead removal bag and tubes behind the left pole.

2. Unlock the lid from eGUI and place the bead removal bag in the nest.

3. Close the lid and secure the tubes in the tube guide.

4. Additionally, the CTS™ DynaCellect™ Bead Removal Kit has 4 input/output lines (while the isolation kit has 8 input/output lines). The final installation of the CTS™ DynaCellect™ Bead Removal Kit is shown in the following figure.
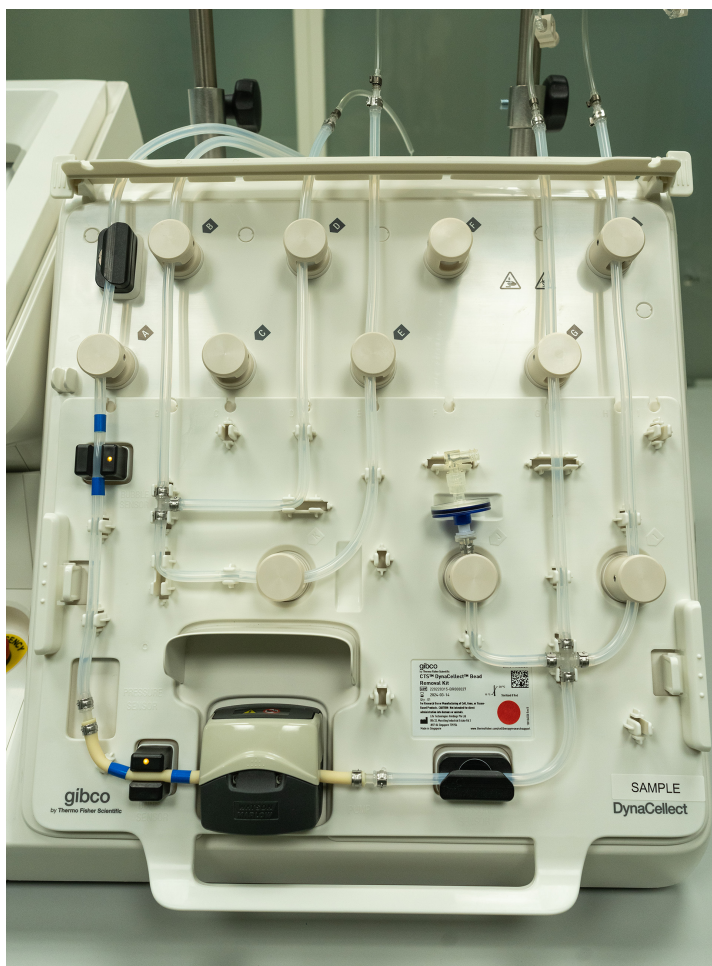
5. The system is ready to run.

Initiate a protocol

⚠️ **CAUTION!** Manual clamps are used on input and output lines on the Single-Use Kits 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. Release all manual clamps prior to starting the automatic sequence.

See "Run protocol" on page 68.

Isolation protocol overview

High-level overview of isolation protocol with CTS™ Dynabeads™ CD3/CD28.

1. Inflate and prime the isolation bag.

   a. Add air to the isolation bag to inflate it and enable mixing.

   b. Prime the isolation bag to avoid cells/beads from sticking to the bag.

2. CTS™ Dynabeads™ bead injection and wash.

   a. Wash CTS™ Dynabeads™ CD3/CD28 out of the bead input bag and transfer to the isolation bag.

   b. Wash the beads, remove the supernatant, and transfer to the supernatant bag.

3. Inject and incubate T cells.

   a. Transfer T cells to the isolation bag.

   b. Incubate for 30 minutes for T cells and beads to bind.

   c. Transfer the supernatant with unbound non-target cells to the supernatant bag.

4. Wash T cells.

   a. Wash 3X to increase the purity of the isolated cells.

   b. Transfer the wash supernatant to the supernatant bag.

5. Elute T cells and beads to output.

   a. Elute bead-bound T cells in CTS™ OpTmizer™ T-Cell Expansion SFM and transfer to the output bag.

Bead removal protocol overview

High-level workflow of bead removal protocol with CTS™ Dynabeads™ CD3/CD28.

1. Prime the bead removal bag with wash buffer.

2. Bead capture

   a. Engage magnet, and transfer cell/bead input through the bead removal bag.

   b. Capture CTS™ Dynabeads™ CD3/CD28 on the magnet while cells are transferred to the output bag.

3. Wash the bead removal bag with wash buffer to transfer the remaining cells in the bead removal bag to the output bag.

4. Add air to the bead removal bag to push the remaining liquid and cells in the bead removal bag to the output bag.

Remove Single-Use Kit

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

1. Seal off finished product from the Single-Use Kit.

2. From the home screen select **Open valves**. Remove the tubes from the pinch valves.
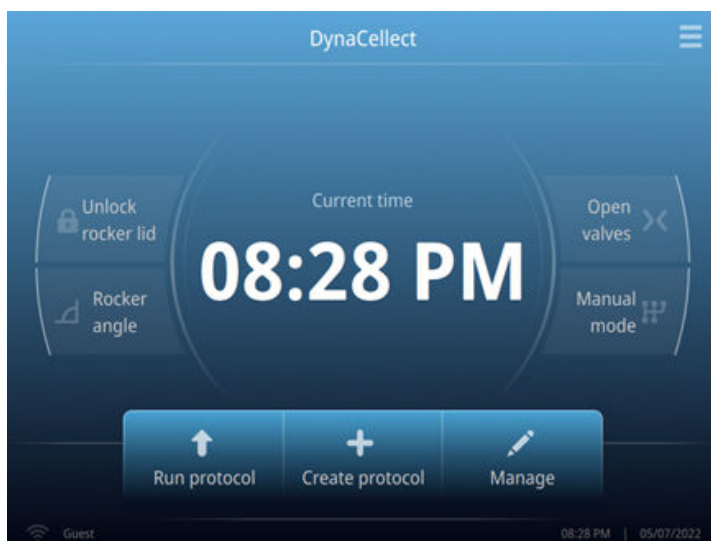
3. Manually open the pump lid and remove the tubing from the pump, the pinch valves, the pressure sensors and the bubble sensors.

4. From the Home screen, select **Unlock rocker lid** while pressing down the lid. Remove reaction bag from the nest.

Note: To relieve pressure from the reaction bag, the pinch valves and the pump lid must be opened before before the rocker lid.

5. Loosen the tube holder and the cassette by pressing the clips on both sides of the cassette. The kit can now be removed from the instrument.
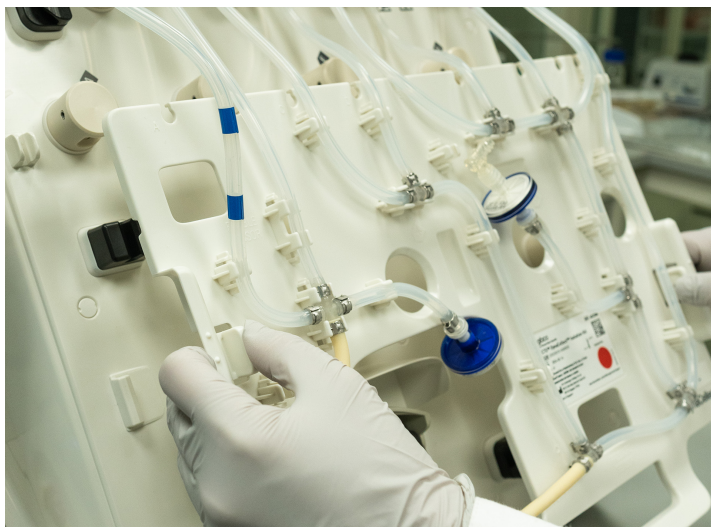
6. Close all pinch valves after the kit is removed.

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.

7 Safety instructions

Labels

Emergency procedures

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

Instrument emergency stop event

The instrument will automatically stop a running protocol if:

- The emergency stop button is activated. Safety relay contacts welded or intermittent
- Power is cut off to the rocker and pump motor
- The leakage sensor detects fluid leaking in the nest
- Overfill detector detects overfilling of the bag in the nest
- One of the pressor sensors detects sustained pressure over the threshold
- An internal error of the pump drive, rocker or valves is detected

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:

- Activating the emergency stop button
- Turn off the instrument using the on/off switch or disconnecting mains power.

Figure 9   Turn off the instrument using the on/off switch or disconnecting mains power.

- Stop all instrument functions by selecting **Stop run**.
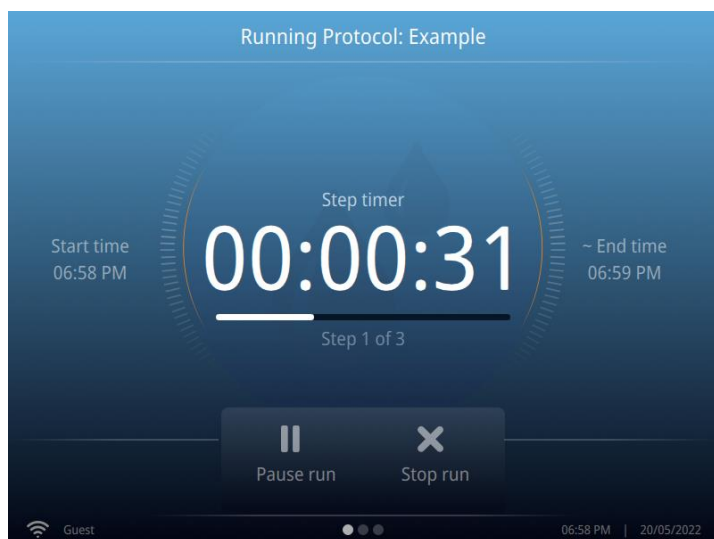
Figure 10   Stop all instrument functions by pressing Stop run.

Restart after shut down

Prior to restarting the DynaCellect™ instrument, ensure that the condition that caused the shut down has been rectified. The instrument can now be restarted; see .

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 reagents 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. Jump start from a selected step is described at page 68.

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

Warnings and precautions

Warnings

⚠️ **WARNING!**
- The DynaCellect™ instrument is capable of producing liquid pressures up to 200 kPa if the flow is restricted. It is the user's 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 DynaCellect™ 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 DynaCellect™ 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 DynaCellect™ system that does not conform with the user guide.
- Always use appropriate Personal Protective Equipment (PPE) when operating the instrument or performing maintenance activities.
- DynaCellect™ instrument is not approved for use with flammable or explosive materials, or materials which could react chemically with sufficient vigour to cause a hazard.
- DynaCellect™ 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 DynaCellect™ 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 DynaCellect™ 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 DynaCellect™ system shall be used exclusively with the Single-Use Kits. 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 Kits. Thermo Fisher Scientific shall not be held responsible for any consequences resulting from use of kits other than as specified in the user guide.
- Please ensure that you contact an approved Thermo Fisher Scientific representative if there is any doubt as to the use of the DynaCellect™ system.

⚠️ **CAUTION!** The CTS™ DynaCellect™ Single-Use Kit (Cat. No. A52300 and A52301) 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 DynaCellect™ Single-Use Kits multiple times are operating outside of Thermo Fisher Scientific guidance and risk voiding terms and conditions of warranty/service contract coverage.

⚠️ **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 CTS™ DynaCellect™ Magnetic Separation System.

Note: Some faults may be rectified by rebooting the instrument. To do this, turn the power off using the on/off switch on the rear of the instrument, wait 2 minutes and then turn power back on. See page 32.

Observation	Possible cause	Recommended action
No power (the display remains blank when the power is turned on)	AC power cord is not connected	Check AC power cord connections at both ends. Use the correct cords.
Instrument does not respond when powered on	Faulty fuses	Replace the fuses
Consumable error (e.g. kit leaking or tubes are occluded)	Consumable has been previously used	Consumables are single use products. Change to a new consumable.
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
Leakage detector	Leaking Single-Use Kit	Replace Single-Use Kit
	External spill	Wipe internal surface of the nest with a soft cloth or dry paper towel and restart the instrument.
Overfill detector	Too much liquid/air in the bag in the nest.	• Replace Single-Use Kit • Reprogram protocol. • Reduce liquid/air transfer to the bag in the nest.
Run ending immediately	Emergency stop button activated	Deactivate emergency stop button

Observation	Possible cause	Recommended action
Pressure sensor	Occluded tubes	Ensure tubes are not occluded by clamps, welds or otherwise pinched tubings
Rocker lid not opening	Too high pressure in reaction bag in the nest	Open pinch valves and pump lid to release pressure. Use manual mode to pump liquid/air out of reaction bag.

B
Error lists

Definitions/Acronyms

Acronyms	Definitions
eGUI	Embedded Graphical User Interface
System	Instrument Server System
MCB	Motion Control Board
BLDC	Brushless DC Motor Control
VCB	Valve Control Board
Code	Error code or id
Message	Error message shown in graphical user interface
Context	State when the error condition may or will occur • Startup: error occurs during startup, system initialization • Recipe: error occurs during recipe or protocol run • Manual: error occurs when system is in manual mode • Idle: erros occurs when system is idle • Upgrade: error occurs during software upgrade
Description	Provides more details on the error
Recovery Action	Provides tips or guidelines in recovering the error if applicable

System error list

Code	Message	Context	Description	Recovery action
0x8855	Unknown initialization error	Startup	Error was detected during instrument startup	Export service logs and send to tech support for further assistance
0x8857	Unable to decrypt upgrade package	Upgrade	Unable to decrypt the software update package	Export service logs and send to tech support for further assistance
0x8860	Package is not suitable for this instrument	Upgrade	Software update file is not compatible with instrument	Export service logs and send to tech support for further assistance
0x8861	Instrument class is not supported by this upgrade package	Upgrade	Software update file is not compatible with instrument	Export service logs and send to tech support for further assistance
0x8865	Unable to power up instrument	Startup	Error was detected during power up sequence	• Power cycle and check if the instrument can self recover • Export service logs and send to tech support for further assistance
0x8867	Unable to recover from upgrade failure	Upgrade	Error was detected when trying to recover from an interrupted software update	• Ensure that power is not turned OFF during software update • Retry software update, contact tech support if error persists
0x8870	Emergency stop activated at startup	Startup	Emergency stop was active at startup	Reset emergency stop switch and perform a power cycle on the instrument

(continued)

Code	Message	Context	Description	Recovery action
0x8871	Emergency stop is activated	Idle Recipe Manual	Emergency stop was activated	Reset emergency stop switch and perform recovery using the reset button in the user interface prompt dialog after releasing the switch
0x8810	Rocker lid is not closed	Recipe	Rocker bag lid is not closed when starting a run	Export service logs and send to tech support for further assistance
0x8811	No kit detected	Recipe	No kit detected when a run when starting a run	Ensure that the tube is stretched before inserting into pressure sensors
0x8812	Pressure sensor is out of range	Recipe	Occlusion pressure sensor is out of detection range	Ensure that the tube is stretched before inserting into pressure sensors
0x8813	Rocker bed leak detected	Recipe	Leak sensor in rocker nest detects a leak	Check for leaks in rocker nest and clean the leak accordingly
0x8814	Pump is not closed	Recipe	Pump cover is not closed when starting a run	Ensure that the pump cover is closed before starting a run
0x8815	Tube occlusion detected	Recipe	• Pressure sensor exceeded threshold and detects a possible tube occlusion event while a recipe run is in progress • Recipe run is aborted	Investigate for tube blockage in fluidics path

(continued)

Code	Message	Context	Description	Recovery action
0x8816	Rocker guard is not closed	Recipe	Rocker motor guard is not installed when starting a run	Export service logs and send to tech support for further assistance
0x8817	Overfill detected	Recipe	• Rocker bag overfill was detected during a recipe run • Run is aborted	• Check protocol integrity • Export service logs and send to tech support for further assistance

BLDC error list

Code	Message	Context	Description	Recovery Action
0x8061	Rocker motion timeout	Recipe Manual	Rocker motion failed to reach its target within the time limit	• Move rocker back to home using manual mode • Check for obstructions during rocker motion
0x8063	Rocker analog sensor threshold exceeded	Idle Recipe Manual	Rocker sensors exceeded operating limits	Export service logs and send to tech support for further assistance
0x8064	Rocker motion error	Recipe Manual	Rocker motor exceeded the operating current limits	• Move rocker back to home using manual mode • Check for obstructions during rocker motion
0x8065	Rocker home sensor error	Startup Manual	Rocker failed to home due to rocker home sensor error	Export service logs and send to tech support for further assistance
0x8066	Rocker home position not valid	Startup Manual	Rocker failed to home due to rocker home sensor error	Export service logs and send to tech support for further assistance

VCB error list

Code	Message	Context	Description	Recovery action
0x801C	Pressure sensor threshold exceeded	Recipe	• Pressure exceeded threshold during recipe run • Run is aborted	• Check Single-Use Kit tube paths for blockage • If it happens before a run, re-insert tube by stretching the tube first before inserting again into pressure sensor slot
0x8020	Rocker bag lid was opened	Idle Recipe Manual	Rocker cover is opened	Information only, no action required
0x8021	Rocker bag lid was closed	Idle Recipe Manual	Rocker cover is closed	Information only, no action required
0x8022	Threshold voltage exceeded	Startup Recipe Manual	System voltage exceeded specification limits	Export service logs and send to tech support for further assistance
0x8023	Leak detected	Startup Recipe Manual	Leak is detected in rocker nest	Check for leaks in rocker nest and clean accordingly before restarting a run
0x8027	Pinch valve overcurrent detected	Startup Recipe Manual	Firmware detected an overcurrent condition when operating the pinch valve driver	Export service logs and send to tech support for further assistance
0x8101	Pinch valve A failed to open	Manual Recipe	Pinch valve A position sensor failed to detect open state	Export service logs and send to tech support for further assistance

(continued)

Code	Message	Context	Description	Recovery action
0x8102	Pinch valve B failed to open	Manual Recipe	Pinch valve B position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8103	Pinch valve C failed to open	Manual Recipe	Pinch valve C position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8104	Pinch valve D failed to open	Manual Recipe	Pinch valve D position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8105	Pinch valve E failed to open	Manual Recipe	Pinch valve E position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8106	Pinch valve F failed to open	Manual Recipe	Pinch valve F position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8107	Pinch valve G failed to open	Manual Recipe	Pinch valve G position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8108	Pinch valve H failed to open	Manual Recipe	Pinch valve H position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x8109	Pinch valve I failed to open	Manual Recipe	Pinch valve I position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x810A	Pinch valve J failed to open	Manual Recipe	Pinch valve J position sensor failed to detect open state	Export service logs and send to tech support for further assistance
0x810B	Pinch valve K failed to open	Manual Recipe	Pinch valve K position sensor failed to detect open state	Export service logs and send to tech support for further assistance

(continued)

Code	Message	Context	Description	Recovery action
0x8201	Pinch valve A failed to close	Manual Recipe	Pinch valve A position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8202	Pinch valve B failed to close	Manual Recipe	Pinch valve B position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8203	Pinch valve C failed to close	Manual Recipe	Pinch valve C position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8204	Pinch valve D failed to close	Manual Recipe	Pinch valve D position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8205	Pinch valve E failed to close	Manual Recipe	Pinch valve E position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8206	Pinch valve F failed to close	Manual Recipe	Pinch valve F position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8207	Pinch valve G failed to close	Manual Recipe	Pinch valve G position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8208	Pinch valve H failed to close	Manual Recipe	Pinch valve H position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8209	Pinch valve I failed to close	Manual Recipe	Pinch valve I position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x820A	Pinch valve J failed to close	Manual Recipe	Pinch valve J position sensor failed to detect close state	Export service logs and send to tech support for further assistance

B

(continued)

Code	Message	Context	Description	Recovery action
0x820B	Pinch valve K failed to close	Manual Recipe	Pinch valve K position sensor failed to detect close state	Export service logs and send to tech support for further assistance
0x8850	Subsystem module is not responding	Startup	Subsystem failed to respond to instrument controller at startup	Export service logs and send to tech support for further assistance

MCB error list

Code	Message	Context	Description	Recovery Action
0x8106	The motor driver encountered a fault condition	Recipe Manual	Motor driver fault error	• Power cycle instrument • If error persists, export service logs and send to tech support for further assistance
0x8124	Home switch not found	Startup	Motor failed to detect home switch	Export service logs and send to tech support for further assistance
0x8125	Could not move out of home switch	Startup	Motor failed to move out of home switch	Export service logs and send to tech support for further assistance
0x8801	Magnet jack failed to move up	Recipe Manual	Magnet jack motor up position sensor failed to activate after move up command	Export service logs and send to tech support for further assistance
0x8802	Magnet jack failed to move down	Recipe Manual	Magnet jack motor down position sensor failed to activate after move down command	Export service logs and send to tech support for further assistance
0x8803	Magnet jack position sensors are both active	Startup Recipe Manual	Both magnet jack up and down position sensors are activated	Export service logs and send to tech support for further assistance
0x8804	Magnet jack motor failed to home	Startup Manual	Magnet jack motor failed to find its home position	Export service logs and send to tech support for further assistance
0x8805	Bag lid height motors failed to extend	Recipe Manual	Bag lid height motor extend position sensor failed to activate after extend command	Export service logs and send to tech support for further assistance

B

(continued)

Code	Message	Context	Description	Recovery Action
0x8806	Bag lid height motors failed to retract	Recipe Manual	Bag lid height motor retract position sensor failed to activate after retract command	Export service logs and send to tech support for further assistance
0x8807	Bag lid height position sensors are both active	Recipe Manual	Both bag lid height retract and extend position sensors are activated	Export service logs and send to tech support for further assistance
0x8808	Bag lid height motors failed to home	Recipe Manual	Bag lid height motors failed to find its home position	Export service logs and send to tech support for further assistance
0x8809	Peristaltic pump stall detected	Startup	Peristaltic pump motor sensors failed to detect rotation at startup	Export service logs and send to tech support for further assistance

C   Recommended instrument settings

About instrument

Select ≡ **(Menu)**, ⚙ **(Settings)**, **About instrument** to find out more information about the instrument. (e.g. software version)
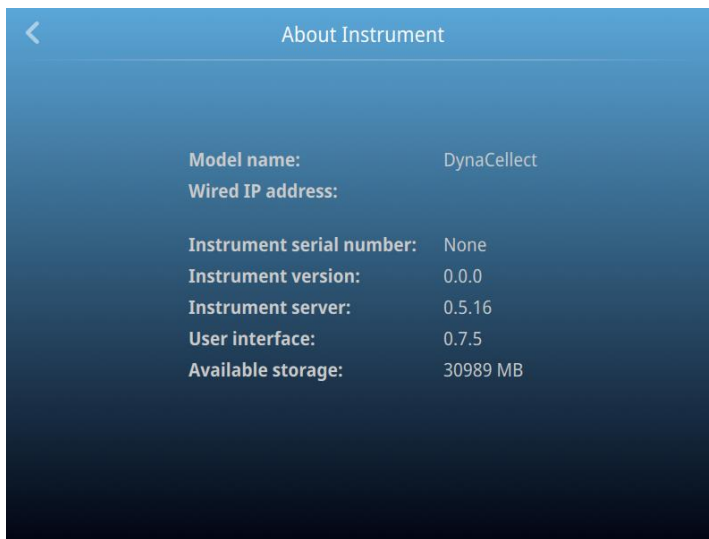
Recommended instrument settings

Select ≡ **(Menu)**, ⚙ **(Settings)** and access the **Settings** screen to configure the instrument.
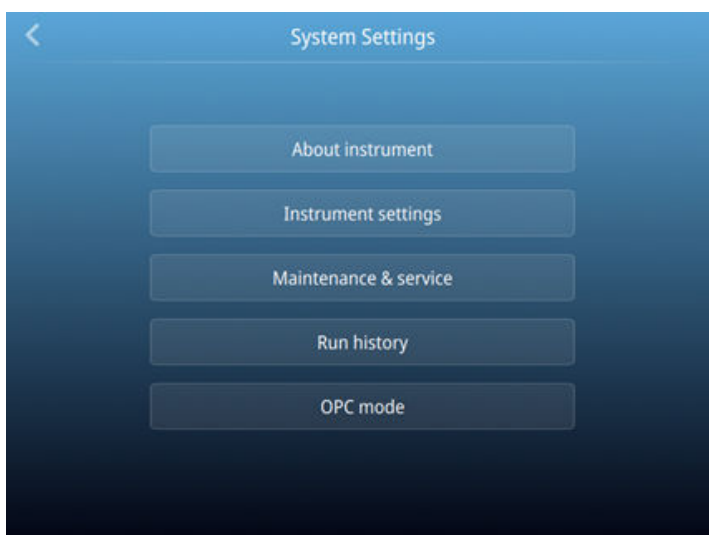
Instrument settings (administrator only)

Select **Instrument Settings** to set the following instrument parameters.
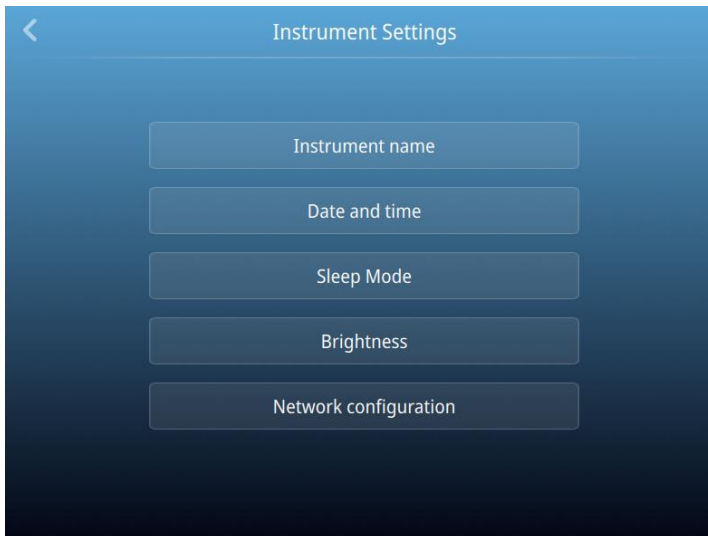
- Instrument name:
  - Select the **Instrument name** field to activate the text editor. Enter up to 32 alphanumeric characters to identify the instrument.

Note: The instrument name cannot have spaces. Separate consecutive characters with a hyphen or underscore; for example, My_Instrument.
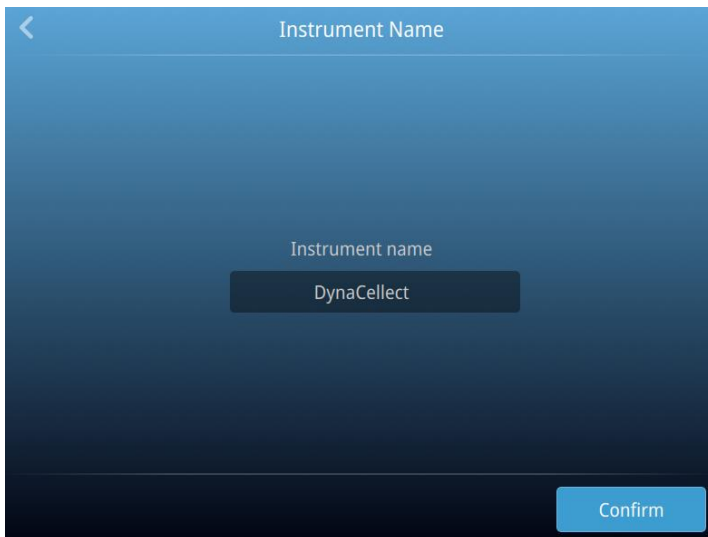
- Date and time
  - Select the **Time zone** field to set the time zone.
  - Select the **Date format** field to choose the date format and set the date.
  - Select the **Time format** field to activate the numeric editor to set the time.
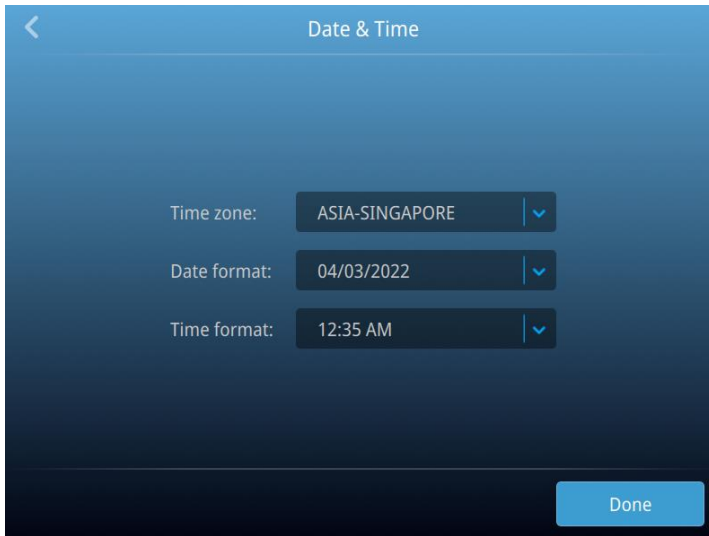
- Sleep mode:
  - Use the Off and On toggle to disable or enable sleep mode. In the 'On' mode, select the **Edit Time** field to activate the numeric editor to set the time after which the instrument will go from idle mode to standby mode.
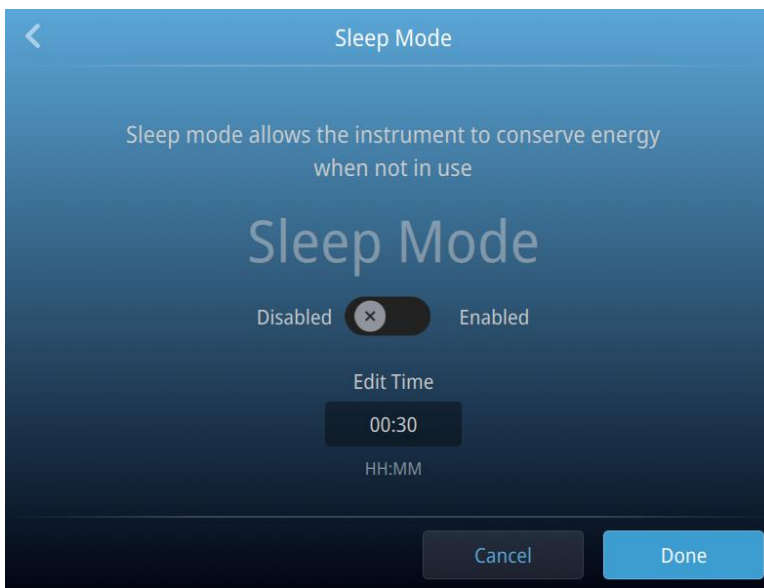
- Brightness
  - Use the slider to adjust the brightness of the touch screen.
- Network confirguration
  - Select the type of network connection that will be used to connect the instrument to the internet. For details on using the Ethernet option, see "Connect the instrument to the internet" on page 37.
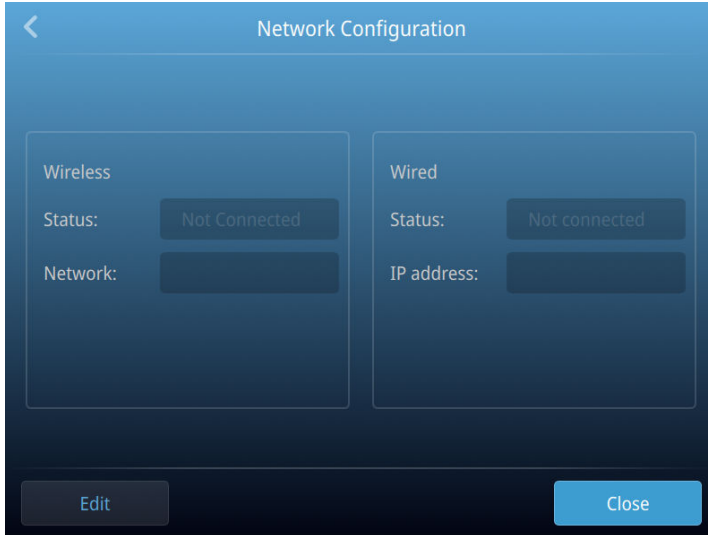
Maintenance and service

Select **Maintenance & Service** to set the following instrument parameters.
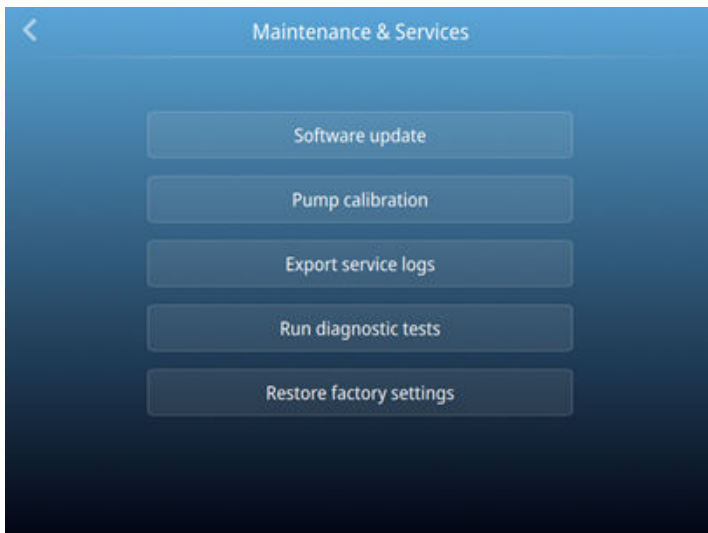
- (Administrator only) Select **Software update** to update the System software. See page 93 for instructions on updating the software.

- Select **Export service logs** to export the instrument service logs to a USB memory device. Insert the USB memory device into the USB port before using this feature.

- Select **Run diagnostic tests** to check the instrument hardware.

- (Administrator only) **Select Restore factory settings** to reset the instrument to the original factory settings See page 123.

Run history

Select **Run History** to display the entire list of runs performed by the instrument.

- Select a particular file to view the details of that run.

D

Related products

Additional products

The following products are for use with the CTS™ DynaCellect™ Magnetic Separation System and are available separately. Unless otherwise indicated, all materials are available through **thermofisher.com**.

	Amount	Cat. No.
Reagents		
CTS™ Dynabeads™ CD3/CD28	10 mL	40203D
CTS™ DPBS without calcium chloride, without magnesium chloride	1 L (bottle)	A1285601
CTS™ DPBS without calcium chloride, without magnesium chloride	2 L (bag)	A1285602
CTS™ OpTmizer™ T-Cell Expansion SFM, no phenol red	1 L (bottle)	A3705001
CTS™ OpTmizer™ T-Cell Expansion SFM, no phenol red	1 L (bag)	A3705003
CTS™ OpTmizer™ T-Cell Expansion SFM	1 L (bottle)	A1048501
CTS™ OpTmizer™ T-Cell Expansion SFM	1 L (bag)	A1048503
CTS™ OpTmizer™ Pro SFM	1 L (bottle)	A4966101
CTS™ OpTmizer™ Pro SFM	1 L (bag)	A4966103
CTS™ IL-2 Recombinant Human	100 µg	CTP0021
	1 mg	CTP0023
CTS™ Immune Cell SR	50 mL	A2596101
	250 mL	A4702901
	500 mL	A2596102
	1 L	A4702902

(continued)

	Amount	Cat. No.
Consumables		
CTS™ DynaCellect™ Cell Isolation Kit	1 kit	A52300
CTS™ DynaCellect™ Bead Removal Kit	1 kit	A52301
Teruflex™ transfer bags	1 L	BB*T100BM (Terumo BCT)
Teruflex™ transfer bags	150 mL	BB*T015CM (Terumo BCT)
V-shaped bags for bead and/or cell input: Cryostore 400 Conical EVA Freezing bag Reagent bag	 60–135 mL 20 mL	 CSD400Y9 (OriGen Biomedical) 170-076-631 (Miltenyi Biotec)
One spike with needle-free valve	—	CBS (OriGen Biomedical)
Vial spike with needle-free valve	—	VSV (OriGen Biomedical)
One spike to one female luer with 10 cm of tubing and pinch clamp	—	S-F10 (OriGen Biomedical)
One spike to one female luer with 50 cm SCD tubing and pinch clamp	—	S-F50 (OriGen Biomedical)
One spike to one male luer with 50 cm SCD tubing and pinch clamp	—	S-M50 (OriGen Biomedical)
Instruments		
CTS™ Rotea™ Counterflow Centrifugation System	1 unit	A50757 (Europe and North America) A47695 (Rest of world)
CTS™ Xenon™ Electroporation System	1 unit	A52727

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.

Safety labels

Symbol	Description
	CAUTION! 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.
	CAUTION! Strong magnetic field.
	CAUTION! High magnetic fields may be present. Pacemakers or other similar implanted devices may be affected.
	CAUTION! Pinch point. Keep hands clear. Can cause severe personal injury

Location of safety labels

Label and location

Figure 11   Front view, lid open

Figure 12   Front view, lid closed

Figure 13   Rear view

Safety compliance

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

Reference	Description
EU Directive 2014/35/EU	European Union "Low Voltage Directive"
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 61010-2-081 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

Informational symbols

Symbol and description
⚠ **CAUTION!** Risk of danger. Consult the manual for further safety information.
⚠ **CAUTION!** Risk of electrical shock.
WEEE (Waste Electrical and Electronic Equipment) symbol indicates that this product should not be disposed of in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of WEEE. This instrument meets European requirement WEEE Directive 2012/19/EU.
ON (power)
OFF (power)
Protective earth (ground)
The CE mark symbolizes that the product conforms to all applicable European Community provisions for which this marking is required. Operation of the CTS™ Xenon™ Electroporation Instrument is subject to the conditions described in this manual. The protection provided by the device may be impaired if the instrument is used in a manner not specified by the manufacturer.

(continued)

Symbol and description
This product conforms to UL 61010-1, CAN/CSA C22.2 No.61010-1 "Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part I: General Requirements." Instruments bearing the UL symbol are certified by Underwriters Laboratories to be in conformance with the applicable safety standard for the US and Canada.
The UKCA mark symbolizes that the product conforms to all applicable provisions in Great Briitain (England, Wales, and Scotland) for which this marking is required. Operation of the CTS™ Xenon™ Electroporation Instrument is subject to the conditions described in this manual. The protection provided by the device may be impaired if the instrument is used in a manner not specified by the manufacturer.
Regulatory Compliance Mark indicates conformity with Australian standards for electromagnetic compatibility.
China RoHS EFUP 25

Symboles d'information

Symbol and description
MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.
MISE EN GARDE ! Risque de choc électrique.
Le symbole **DEEE** (Déchets d'équipements électriques et électroniques) indique que ce produit ne doit pas être mis au rebut avec des déchets ménagers non triés. Suivez la réglementation locale relative à l'élimination des déchets usuels pour réduire l'impact environnemental des DEEE. Rendez-vous sur **www.invitrogen.com/weee** pour prendre connaissance des options de collecte et de recyclage..
ON (MARCHE) (alimentation)
OFF (ARRÊT) (alimentation)
Protection par la mise à la terre (masse)
La marque CE est un symbole indiquant que le produit est conforme à toutes les dispositions applicables de la Communauté européenne pour lesquelles ce marquage est obligatoire. L'utilisation du CTS™ Xenon™ Electroporation Instrument est soumise aux conditions décrites dans ce manuel. Si vous utilisez l'instrument d'une manière non spécifiée par le fabricant, la protection offerte par l'appareil pourrait s'en trouver détériorée.

(continued)

Symbol and description
Ce produit est conforme à UL 61010-1, CAN/CSA C22.2 No.61010-1 «Exigences de sécurité pour l'équipement électrique pour la mesure, le contrôle et l'utilisation en laboratoire, Partie I : Généralité Les exigences.» Les instruments portant le symbole UL sont certifiés par Underwriters Laboratories conforme à la norme de sécurité applicable aux États-Unis et au Canada.
La marque UKCA est un symbole indiquant que le produit est conforme à toutes les dispositions applicables en Grande-Bretagne (Angleterre, Pays de Galles et Écosse) pour lesquelles ce marquage est obligatoire. L'utilisation du CTS™ Xenon™ Electroporation Instrument est soumise aux conditions décrites dans ce manuel. Si vous utilisez l'instrument d'une manière non spécifiée par le fabricant, la protection offerte par l'appareil pourrait s'en trouver détériorée.
La marque de conformité réglementaire indique qu'elle est conforme aux normes australiennes compatibilité électromagnétique
Chine RoHS EFUP 25

Instrument safety

General

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

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

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

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

Physical injury

CAUTION! Moving and Lifting Injury. 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.

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

Electrical safety

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

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

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

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

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

⚠️ **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.

Instrument component and accessory disposal

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

Environmental requirements

⚠️ **WARNING!** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 22 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment may not offer adequate protection to radio-frequency communication services. It may be necessary for the user to take mitigation measures, such as relocating or re-orienting the equipment.

Condition	Acceptable range
Installation site	Indoor use only
Electromagnetic interference	Do not use this instrument in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). Strong electromagnetic radiation may interfere with the proper operation of the instrument.
Pollution degree	The instrument has a Pollution Degree rating of II. The instrument may only be installed in an environment that has non-conductive pollutants such as dust particles or wood chips. Typical environments with a Pollution Degree II rating are laboratories and sales and commercial areas.

Electromagnetic compatibility (EMC) standards

Class A notice

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; and CISPR 11 Class A. 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 or domestic environment is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

EMC compliance

Reference	Description
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
IEC 61326-1	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
IEC 61000-3-2	Harmonic current Emissions
IEC 61000-3-3	Voltage changes, voltage fluctuations and flocker emissions
IEC 61000-4-2	Electrostatic Discharge Immunity
IEC 61000-4-3	Radiated RF Electromagnetic Field Immunity Immunity to proximity fields from RF wireless communications equipment
IEC 61000-4-4	Electrical Fast Transient/Burst Immunity
IEC 61000-4-5	Surge Immunity
IEC 61000-4-6	Immunity to conducted disturbances induced by RF fiedls
IEC 61000-4-8	Power-frequency Magnetic Field Immunity
IEC 61000-4-11	Voltage Dips, short Interruptions and Voltage Variation Immunity
FCC Part 15 Subpart B (47 CFR)	U.S. Standard Radio Frequency Devices
ICES-001	Industrial, Scientific and Medical (ISM) Equipment
AS/NZS CISPR 11	Industrial, scientific and medical equipment - Radiofrequency disturbance characteristics - Limits and methods of measurement

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**.

Electrical safety

The following information on electrical safety must be observed, failing to follow these instructions may result in electric shock, fire and/or serious personal injury or death. In the event of an equipment malfunction, it is the responsibility of the customer to report the need for service to Thermo Fisher Scientific or to one of the authorized agents. For service information, contact Technical Support. See Appendix F, "Documentation and support".

Servicing of this device is to be performed by trained service personnel only.

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Prior to switching on the product, ensure that the nominal voltage setting on the product matches the nominal voltage of the AC supply network.
- This product should be connected to the power mains using a 3-wire (two conductors and ground) power cable and plug. Use this power cable with a properly grounded electrical outlet to avoid electrical shock.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.
- If extension cords or connector strips are implemented, they must be checked on a regular basis to ensure that they are safe to use.
- Never use the product if the power cable is damaged. Check the power cable on a regular basis to ensure that it is in proper operating condition. By taking appropriate safety measures and carefully laying the power cable, you can ensure that the cable will not be damaged and that no one can be hurt by, for example, tripping over the cable or suffering an electric shock.
- Do not insert the plug into sockets that are dusty or dirty. Insert the plug firmly and all the way into the socket. Otherwise, sparks that result in fire and/or injuries may occur.
- Do not overload any sockets, extension cords or connector strips; doing so can cause fire or electric shocks.
- To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.
- Ensure that the connections with information technology equipment, e.g., PCs or other industrial computers, comply with the IEC60950-1/EN60950-1 or IEC61010-1/EN 61010-1 standards that apply in each case.

- Use suitable overvoltage protection to ensure that no overvoltage (such as that caused by a bolt of lightning) can reach the product. Otherwise, the person operating the product will be exposed to the danger of an electric shock.

- The overvoltage protection should limit the magnitude of the overvoltage surge to 1 kV between the any of the power line and ground.

- Unless expressly permitted, never remove the cover or any part of the housing while the product is in operation. Doing so will expose circuits and components and can lead to injuries, fire or damage to the product.

- Any object that is not designed to be placed in the openings of the housing must not be used for this purpose. Doing so can cause short circuits inside the product and/or electric shocks, fire or injuries.

Magnet Safety

The CTS™ DynaCellect™ Magnetic Separation System has very strong permanent magnets for separation of paramagnetic Dynabeads™ magnetic beads with or without bound cells. The magnetic strength of the magnet is up to 8,500 Gauss (0.85 T). Carriers of medical devices or medical implants are strongly advised to not transport the CTS™ DynaCellect™ Magnetic Separation System, assemble or use the device without prior medical consultation in order to avoid possible health hazards. EHS professionals should be consulted to further inspect the entire working area for possible risks and to provide additional safety instructions, if necessary. Optionally, third party providers like workplace safety consultants could be enlisted. Please note, that the magnetic field strength decreases exponentially with distance. However, the actual magnetic field exposure is depending on the position of the magnet inside the instrument (engaged or disengaged) as well as the position of the magnet on the laboratory bench, which is why the actual exposure needs to be assessed for each situation individually. No ferromagnetic materials or materials that are sensitive to magnetic fields should come in close vicinity of the magnets. We recommend including these safety instructions in the training for all users of the CTS™ DynaCellect™ Magnetic Separation System magnet as well as any laboratory or clean room personnel.

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)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  www.who.int/publications/i/item/9789240011311

Service personnel

Service personnel must carefully read all safety precautions that follow:

- If there is a risk that can cause injury or death, a warning tells you about the risk.
- If there is a risk that can cause damage to the instrument, a caution tells you about the risk.

⚠ **WARNING! Injury or death is possible.**

Read carefully the related instructions.

⚠ **CAUTION! Damage to the instrument is possible.**

Read carefully the related instructions.

Safety precautions

Risk of contamination

Symbol	Description
☣	• Wear Personal Protective Equipment (PPE) and do not contact spilled fluids directly. If necessary, do the decontamination procedure before you do servicing. • Biological samples run on the instrument may contain potentially infectious diseases.

Strong magnet

If you have a medical or an electronic device in your body, make sure that the device is not sensitive to magnet. Individuals with magnet-sensitive medical devices or medical implants are strongly advised to not transport or hold the instrument close to the body.

Symbol	Description
⚠	• DynaCellect™ instrument contains very strong permanent magnet. • The strong magnet can cause failure to the medical or electronic device.

Risk of the parts that move

Keep fingers out of parts that move:

Symbol	Description
⚠	• Some parts may move during service diagnostic and testing. • The parts that move can cause injury.

Risk of electrical shock

Symbol	Description
⚠	• Always remove power to the instrument before you opening and replacing parts of the instrument. • Never operate equipment with the grounding conductor disconnected. Grounding circuit continuity is required for the safe operation of equipment.

Electrostatic discharge protection

Symbol	Description
	• Use ESD wrist-straps, shoes, or ESD heel grounder and keep ESD-sensitive parts in their packaging, if not yet installed. • ESD can cause damage to instrument parts that are sensitive to ESD.

Return to use

After service is performed, use the diagnostic software to test, perform qualification services, and confirm instrument performance.

Documentation and support

F

Customer and technical support

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

- Worldwide contact telephone numbers
- Product support information
  - Product FAQs
  - Software, patches, and updates
  - 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**.

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