Quantum®
Cell Expansion System

TERUMOBCT

SOFTWARE VERSION 2.1

Operator's Manual

TERUMOBCT

Quantum® Cell Expansion System Operator's Manual for Software Version 2.1

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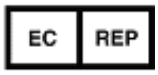

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Preface

About this Manual

This manual is written for personnel who are responsible for operating the Quantum® Cell Expansion System. It includes information and instructions on how to operate, troubleshoot, and maintain the system. You should read and understand the information in this manual before operating the system.

Document Conventions

This document uses certain conventions to help you identify information. This section describes these conventions.

Numbered Steps

All sequential, multiple-step instructions are numbered, as shown in the following example:

1. Attach the media bag to the cell line.
2. Hang the bag on the bag pole.

Bold Text

Certain steps instruct you to touch a button on the screen. Buttons appear in bold, as shown in the following example:

1. Touch **Task**.

Bullets

Bullets (•) indicate list items that are not sequential.

Warning, Caution, and Note Definitions

The following examples show how warnings, cautions, and notes appear in this document:

Warning: Warnings alert the operator of serious hazards, consequences, or conditions that are likely to result in a harmful reaction, trauma, or death to the operator.

Caution: Cautions alert the operator to the possibility of a problem with the system associated with its use or misuse. This includes system malfunction, failure, and damage to the system or other property.

Note: Notes emphasize important details.

Intended Use

Warning: It is the responsibility of the user to validate the safety and efficacy of the expanded cells for their intended application. Expanded cell products for use in human subjects or patients must comply with all applicable country-specific regulatory requirements.

The Quantum Cell Expansion System, a functionally closed cell expansion system, may be used to grow adherent and suspension cells in laboratory, clinical, and manufacturing environments.

Warnings for Use

The following section includes a complete list of the warnings that apply to the use of the Quantum system. Although the information may also appear in the other sections of this manual, operators should read and understand the information in this list before using the system. For specific warnings about a tubing set, refer to the instructions for use that ship with the tubing set.

System Warnings

1. Do not use the Quantum system under any of the following conditions:
   - Any power cords, plugs, or receptacles are damaged or worn.
   - Any switches on the device are loose.
   - The device has received a physical shock, or liquid has spilled on the electronics.
   - Anyone has received an electrical shock while using the system.
   - The device appears to be overheating.
2. Only trained and qualified personnel should move the Quantum device.
3. To avoid the risk of an explosion, the oxygen concentration in the gas supplied to the system must not exceed 20%.
4. The Quantum system includes an external pressure relief valve rated to 75 psi that is located on the back of the device. Do not block the valve discharge area. When gas pressures exceed 75 psi, the relief valve opens and releases high pressure gas. Protect the area from possible contact with personnel.
5. Do not block the external gas connection located on the back of the device on the bottom-left corner. This connection also functions as a safety disconnect for the device.
6. Individuals who operate the Quantum system must be appropriately qualified and trained.
7. Avoid pinching your fingers when opening and closing the incubator door.
8. Always place the device on a sturdy, even surface so that the device is completely supported, which reduces the risk of the device falling or slipping off the supporting surface.
9. Use caution when interacting with the Quantum device, because it has moving parts that could injure fingers and entangle hair, clothing, or other personal articles.
10. Do not lean on or place heavy objects on the incubator door when it is open. Doing so could cause the device to tip and fall.
11. It is the responsibility of the user to validate the safety and efficacy of the expanded cells for their intended application. Expanded cell products for use in human subjects or patients must comply with all applicable country-specific regulatory requirements.
12. If the Quantum system is used in a manner not specified by the manufacturer, the operator protection systems may not be effective in preventing injury to the operator.
13. It is the responsibility of the user to determine any effect residual EtO may have on cells that are cultured in the Quantum system.
14. Use only power cords specified by Terumo BCT. The use of inadequately rated cords could possibly cause property damage or bodily harm.

Service Warnings

1. Only a qualified service representative should service or modify the device. Any modifications must be approved in writing by Terumo BCT.
2. Turn off the primary power switch and unplug the device before cleaning.
3. Use a cleaning technique that does not place your finger in a vulnerable position. For example, you can clean the area around the valve with a cotton swab or by using a flossing technique.
4. Take adequate precautions when cleaning any surfaces of the device that might have been exposed to blood to prevent possible exposure to and transmission of infectious diseases.

Electrical Warnings

1. All electrical installations must comply with all applicable local electrical codes and the Quantum system electrical specifications.
2. To avoid a serious shock, do not install the system on a workstation where fluid may accumulate.
3. Do not place open containers of fluid on the device. Fluid spills can contribute to electrical and mechanical hazards.
4. If a spill occurs on the primary power switch or on the auxiliary power switch, unplug the device and call your service representative. Do not touch the switch to turn off the power.
5. To reduce the risk of electrical shock, do not use an adapter that breaks the protective ground.

Cell Expansion Process Warnings

1. Follow your institution's standard operating procedures for wearing personal protective equipment when using the Quantum system.
2. Always use protective eyewear when operating the Quantum system.
3. Do not clamp the lines to control the flow of fluid through the cell expansion set. Clamping the lines can cause excessive pressure, resulting in possible injury to the operator and damage to the cell expansion set. Allow the system to control the flow of fluid.
4. All used cell expansion set materials should be considered biohazardous and should be handled and disposed of in accordance with applicable regulations.
5. Do not use excessive force when loading or unloading the cell expansion set, because this could lead to operator injury.

Cautions for Use

The following section includes a complete list of the cautions that apply to the use of the Quantum system. Although the information may also appear in the other sections of this manual, operators should read and understand the information in this list before using the system. For specific cautions about a tubing set, refer to the instructions for use that ship with the tubing set.

System Cautions

1. Each operator should be thoroughly familiar with the operating instructions for the Quantum system before using the device.
2. Do not adjust the gas flow control knob, or you may disrupt the pressure in the system. Only a qualified service representative should adjust the gas flow.
3. The system does not produce an alarm when the gas supply is depleted; therefore, you must monitor the gas supply throughout operation of the system.
4. Keep the network ports located on the front of the device covered to prevent fluid from entering.
5. The Quantum system is meant for indoor use only.
6. Do not use a stylus with the Quantum system touch screen.
7. The temperature of the operating environment for the Quantum system should be maintained between 16 °C and 27 °C (60.8 °F and 80.6 °F).
8. The rotor cover on each pump must be closed and the rotor latch must be locked before you turn on and operate the system.
9. At least two people are needed to lift the Quantum system. Use proper lifting techniques when lifting the Quantum system.
10. Use only the cell expansion sets and the accessory sets that Terumo BCT manufactures for the Quantum system.
11. Use only the accessory bags that Terumo BCT manufactures for the Quantum system. Using bags of inappropriate size may cause excess pressure to accumulate in the system.

Service Cautions

1. To disinfect the device, use only a 0.25% sodium hypochlorite (bleach) solution. Using a stronger bleach solution may damage or discolor the device.
2. Do not lubricate the pumps or the pump rotors for any reason.
3. Do not block access to the primary power switch, which is located on the back of the device, during installation.

Cell Expansion Process Cautions

1. Use aseptic technique during cell expansion processes to ensure product quality.
2. When priming the cell expansion set, do not connect the fluids to the cell expansion set before you are instructed to do so.

3. It is very important that the operator address any leaks that arise when a cell expansion set is in use because a set may occasionally fail. If a cell expansion set fails, it could result in the loss of cell products or the introduction of air into the set.
4. Periodically inspect the EC (extracapillary) inlet port and the EC outlet port for air, and if either port contains visible air, remove the air by performing the Remove EC Air task.
5. Periodically inspect the IC (intracapillary) inlet header and the IC outlet header for air, and if either header contains visible air, remove the air by performing the Remove IC Air task.
6. Do not use chilled fluid to prime the cell expansion set.
7. Use only your fingers to load the cell expansion set. Do not use a sharp object, or you may puncture the tubing.
8. When loading the cell expansion set, do not turn the internal mounting clips more than a quarter turn, or you could pinch the tubing.
9. If you have loaded a cell expansion set but you do not plan to prime the set until the following day, turn off the external gas supply to avoid excess gas buildup in the waste bag.
10. When you seal each line loop, seal it in a location that ensures that each resulting line has a name tag. For example, the EC media tag should be located on one line and the reagent tag on the other line; the IC media tag should be located on one line and the wash tag on the other line.
11. When you attach a bag to the cell expansion set, ensure that the bag is attached to the proper line and that the sterile weld is completely open before starting any tasks.
12. When using the In-line Filter 200 Micron Accessory Set, sterile weld to the blue luer end first or you may lose the cell product.

Service Information

Warning: Only a qualified service representative should service or modify the device. Any modifications must be approved in writing by Terumo BCT.

Return of Used Product

If for any reason this product must be returned to Terumo BCT, Inc., a returned goods authorization (an RGA number) is required from Terumo BCT prior to shipping.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained from the Terumo BCT Quality Assurance Department.

IT IS THE RESPONSIBILITY OF THE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT.

Please contact your local representative for information regarding returned goods and product complaints.

Use of Additional Devices and Supplies During Cell Expansion

You need some or all of the following devices and supplies when using the Quantum system:

- A tubing pump
- A tubing sealer
- A sterile tubing welder with the appropriate replacement wafers
- A glucose and lactate analyzer (optional)
- Mixed gas tanks with pressure regulators
- A hose with the connector specified in Table 17-3 of this manual to connect to the external gas supply
- Cell culture fluids

For instructions on how to safely use these items with the Quantum system, refer to the guidelines provided by each of the device or supply manufacturers.

Disposal of Infectious and Non-Infectious Waste

Follow your local regulations for disposing of material that may be contaminated with biohazardous products.

2

Introduction

Quantum System Overview

The Quantum Cell Expansion System is an automated system for growing adherent and suspension cells in a functionally closed environment. The term “functionally closed” is often used in the FDA-regulated blood and blood component industry to describe systems that are closed at the point of manufacture except for tubing with pre-connected sterile barrier filters on spike and port connections, and/or openings that only allow flow out of the system. Under this definition, the Quantum system is functionally closed, as it contains a sterile barrier between the Cell Expansion Set and any external openings. The system also has mechanisms in place for adding media, loading cells, harvesting cells, and taking samples without opening the system.

The Quantum system includes an incubator and a cell expansion set used for expanding different cell types. The cell expansion set has a hollow-fiber bioreactor, an intracapillary (IC) circulation loop, an extracapillary (EC) circulation loop, bags, and other components necessary for the cell expansion process. The system also includes a touch screen that enables the operator to communicate with the system. The operator follows the instructions on the touch screen to perform the following:

- Load, prime, and unload the cell expansion set.
- Select and perform tasks during the cell expansion process, such as feeding and waste removal.
- Troubleshoot alarms.

Quantum System Components

This section describes the components of the Quantum system. Operators should become familiar with the location and function of the components before using the system.

Device Front

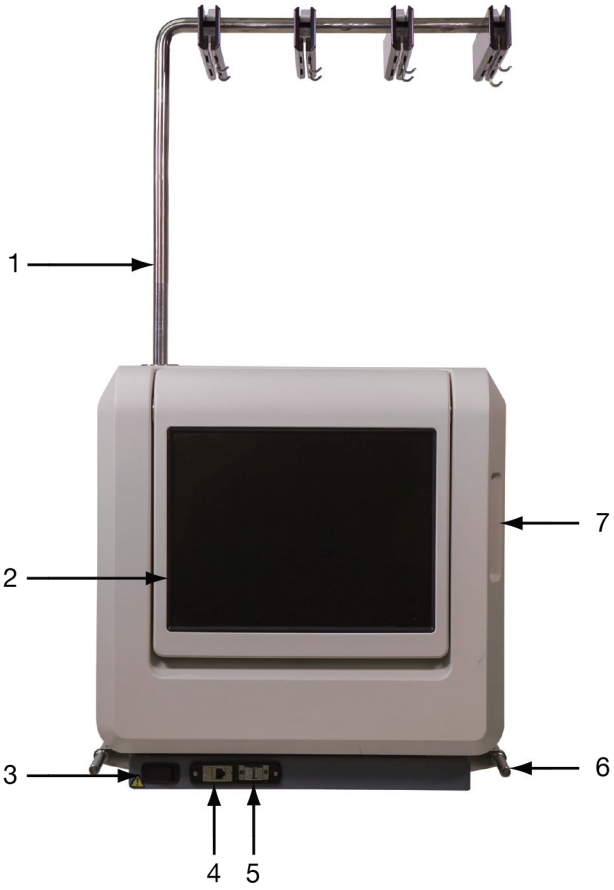


Figure 2-1: Device (external front view)

Table 2-1: Components on the front of the device

Location	Component	Function
1	Bag pole	Allows you to hang bags during the cell expansion process. When you are facing the device, the bag pole is located directly above the device. You can manually swivel the bag pole to the side for easier access when hanging bags.
2	Touch screen	Allows communication between the operator and the device.

Table 2-1: Components on the front of the device (continued)

Location	Component	Function
3	Auxiliary power switch	Allows you to turn on and turn off the pumps, valves, heater, computer, and touch screen, but does not affect the internal power.
4	Ethernet port	Allows service personnel to connect the Quantum system to an external device for the purpose of transferring data.
5	USB port	Allows service personnel to connect the Quantum system to an external device for the purpose of transferring data.
6	Carrying handles	Allows you to grasp the Quantum system when moving the device.
7	Incubator door	Provides access to the incubator. The outside of the door contains the touch screen. The inside of the door contains the heater and the heater fan, which are used to warm the air in the incubator.

Device Back

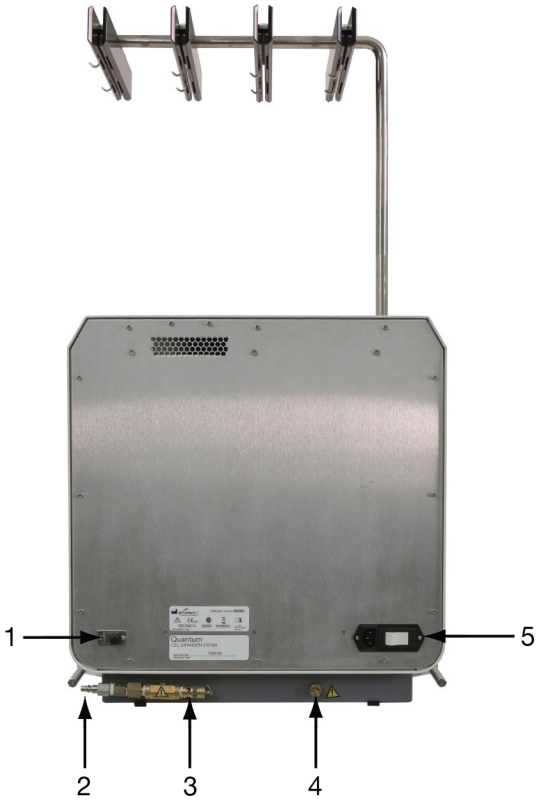


Figure 2-2: Device (external back view)

Table 2-2: Components on the back of the device

Location	Component	Function
1	Rear Ethernet port	Allows you to connect the Quantum system to an external device or a local network for the purpose of transferring data.
2	External gas connector	Connects the external gas supply to the system.
3	External pressure relief valve	Expels excess gas pressure.
4	Gas flow control knob	Allows service personnel to adjust the gas flow rate from the external gas source into the system.
5	Primary power switch	Protects the device from damage caused by an electrical overload or a short circuit. Located on the bottom-left corner on the back of the device as you face the front of the device. The switch must be in the on position to operate the device.

Incubator

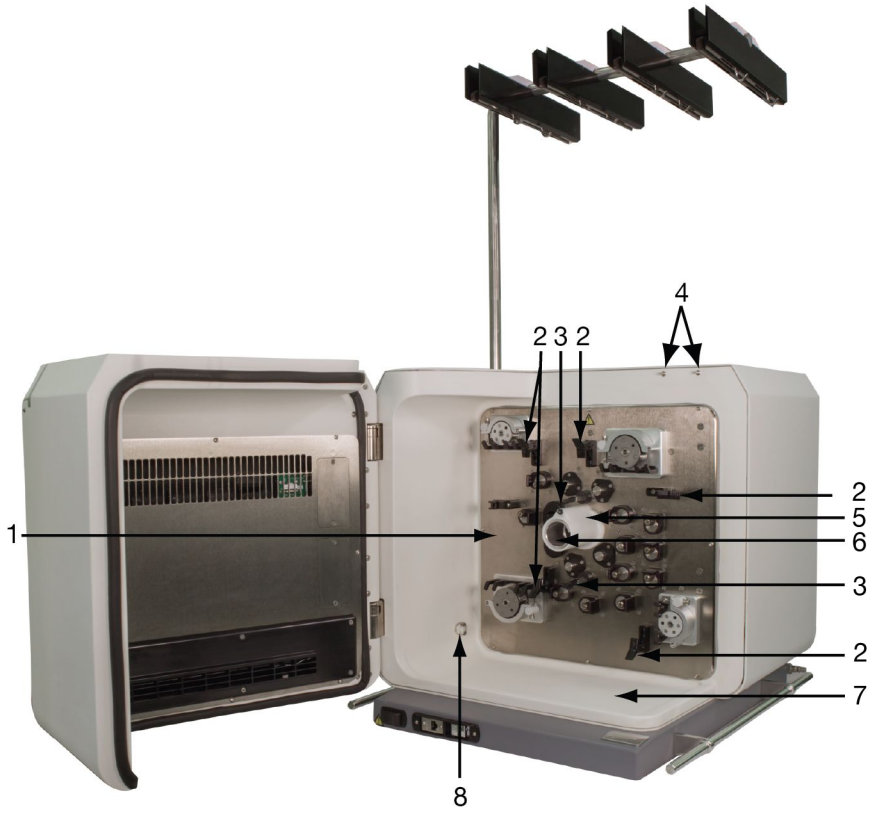


Figure 2-3: Inside the incubator

Table 2-3: Components inside the incubator

Location	Component	Function
1	Mounting plate	Contains the pumps, the valves, the rocker and rocker arm, the external mounting clips, the internal mounting clips, and all the fluid detectors.
2	External mounting clips	Hold the tubing organizer in place. The external mounting clips are located along the perimeter of the mounting plate.
3	Internal mounting clips	Hold the tubing organizer in place. The internal mounting clips are located in the center of the mounting plate.
4	Pegs	Hold the tubing line guide in place.
5	Rocker arm	Holds the bioreactor in place in the incubator.
6	Rocker	Rotates the bioreactor to facilitate priming and to keep cells from settling in the IC inlet and IC outlet headers. The rocker is located on the device and not on the cell expansion set.
7	Spill tray (containing the leak detector)	Captures fluid from leaks that occur inside the incubator and contains the leak detector, which detects the presence of a fluid leak inside the incubator.
8	Gas quick disconnect	Allows the gas supply to flow into the cell expansion set via the gas inlet line.

Pumps

There are four pumps located on the mounting plate, as shown in Figure 2-4. Table 2-4 describes the function of each pump.

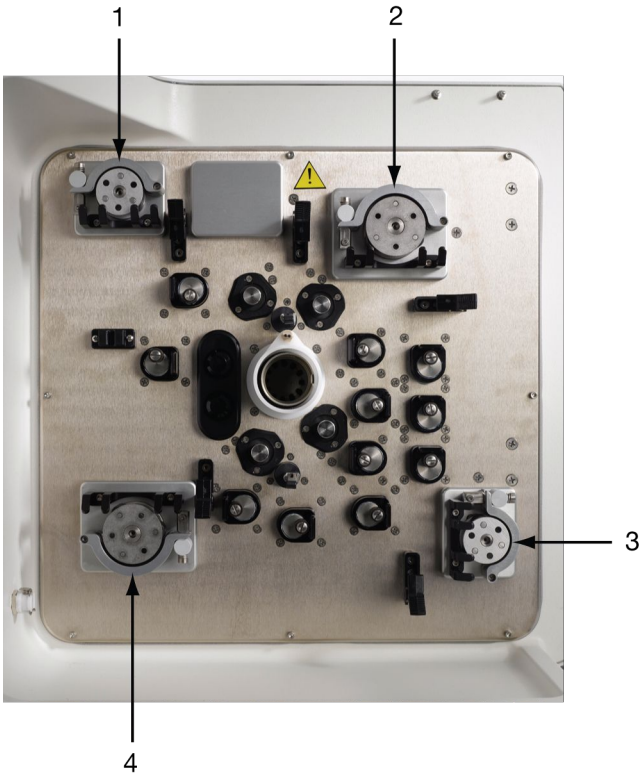


Figure 2-4: Location of the pumps

Table 2-4: Function of the pumps

Location	Component	Function
1	EC inlet pump	Pumps fluid from an inlet bag to the EC circulation loop.
2	IC inlet pump	Pumps fluid from an inlet bag to the IC circulation loop via the air removal chamber (ARC).
3	IC circulation pump	Pumps fluid in the IC circulation loop.
4	EC circulation pump	Pumps fluid in the EC circulation loop.

Parts of a Pump

Figure 2-5 shows the parts of a pump, and Table 2-5 describes each part.

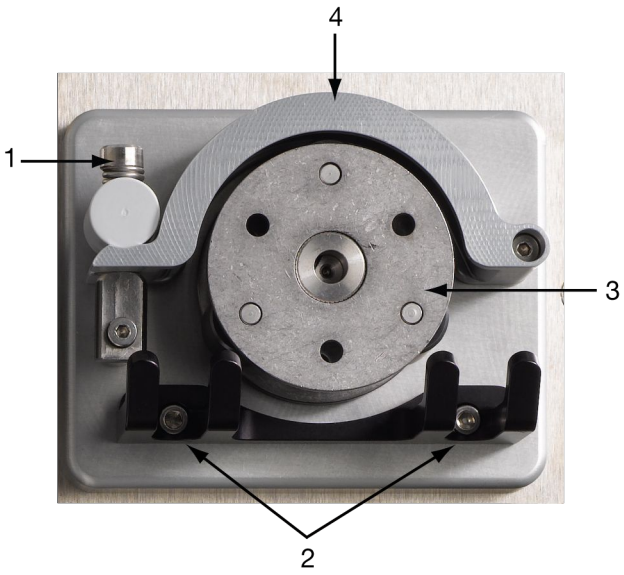


Figure 2-5: Parts of a pump

Table 2-5: Parts of a pump

Location	Component	Function
1	Rotor latch	Contains a locking mechanism that holds the rotor cover in place over the pump rotor.
2	Prongs	Hold the tubing in place around the pump rotor.
3	Pump rotor	Rotates the pump.
4	Rotor cover	Protects the pump rotor and enables the pump to function properly. **Caution:** The rotor cover on each pump must be closed and the rotor latch must be locked before you turn on and operate the system.

Valves

There are 11 valves located on the mounting plate, as shown in Figure 2-6. Table 2-6 describes the function of each valve.

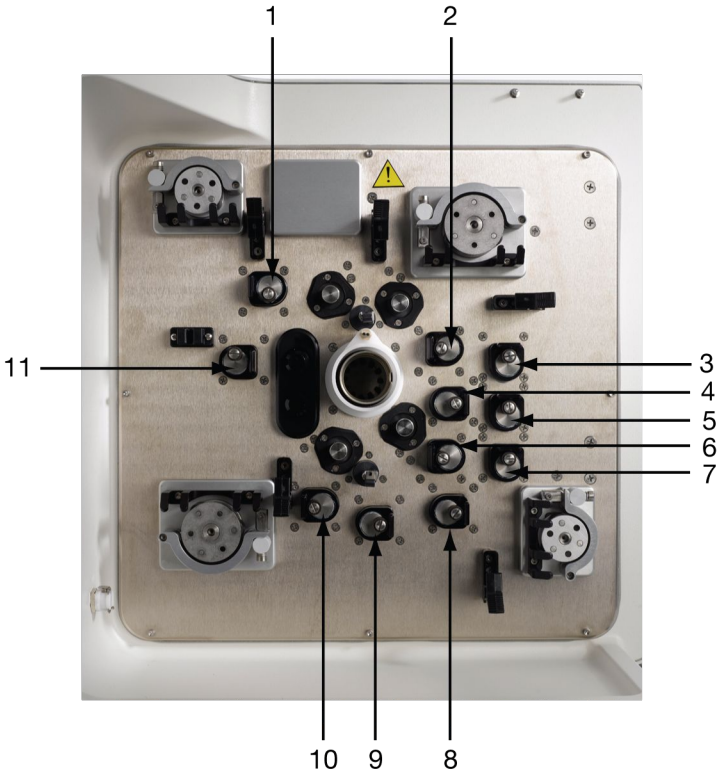


Figure 2-6: Location of the valves

Table 2-6: Function of the valves

Location	Component	Function
1	Air removal valve	Allows air into the ARC.
2	EC media valve	Controls the flow of fluid from the EC media line into the system.
3	IC media valve	Controls the flow of fluid from the IC media line into the system.
4	Cell valve	Controls the flow of fluid from the cell line into the IC inlet line and subsequently into the IC circulation loop via the ARC.
5	Wash valve	Controls the flow of fluid from the wash line into the system.
6	Distribution valve	Controls the flow of fluid between the IC inlet line and the EC inlet line. Does not allow the flow of fluid from the cell line to the EC inlet line.
7	Reagent valve	Controls the flow of fluid from the reagent line into the system.

Table 2-6: Function of the valves (continued)

Location	Component	Function
8	Harvest valve	Controls the flow of fluid from the IC circulation loop into the harvest line and subsequently into the harvest bag.
9	IC circulation valve	Controls the flow of fluid through the IC circulation loop.
10	IC outlet valve	Controls the flow of fluid into the IC outlet line.
11	EC outlet valve	Controls the flow of fluid between the EC circulation loop and the EC outlet line.

Sensors and Fluid Detectors

There are four sensors and three fluid detectors located on the mounting plate, as shown in Figure 2-7. Table 2-7 describes the function of each sensor and each fluid detector.

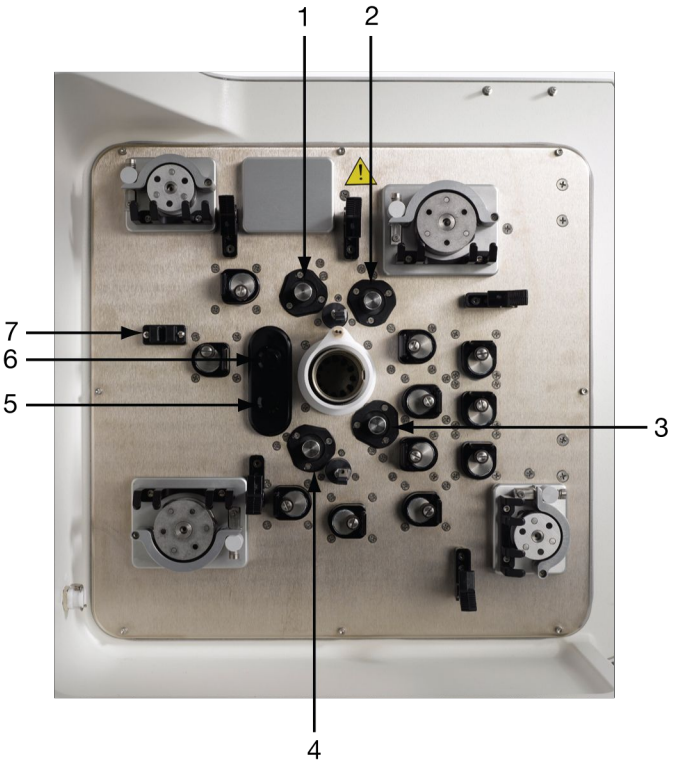


Figure 2-7: Location of the sensors and the fluid detectors

Table 2-7: Function of the sensors and the fluid detectors

Location	Component	Function
1	EC outlet pressure sensor	Measures the fluid pressure in the EC circulation loop.
2	EC inlet pressure sensor	Measures the fluid pressure in the EC circulation loop.
3	IC inlet pressure sensor	Measures the fluid pressure in the IC circulation loop.
4	IC outlet pressure sensor	Measures the fluid pressure in the IC circulation loop.
5	IC low-level fluid detector	Detects the fluid level in the ARC at the low-level limit.
6	IC high-level fluid detector	Detects the fluid level in the ARC at the high-level limit.
7	EC fluid detector	Detects the presence of fluid in the EC inlet line.

Hydraulic Layout

This section contains a diagram of the Quantum system hydraulic layout. Figure 2-8 shows the hydraulic layout after the cell expansion set has been primed.

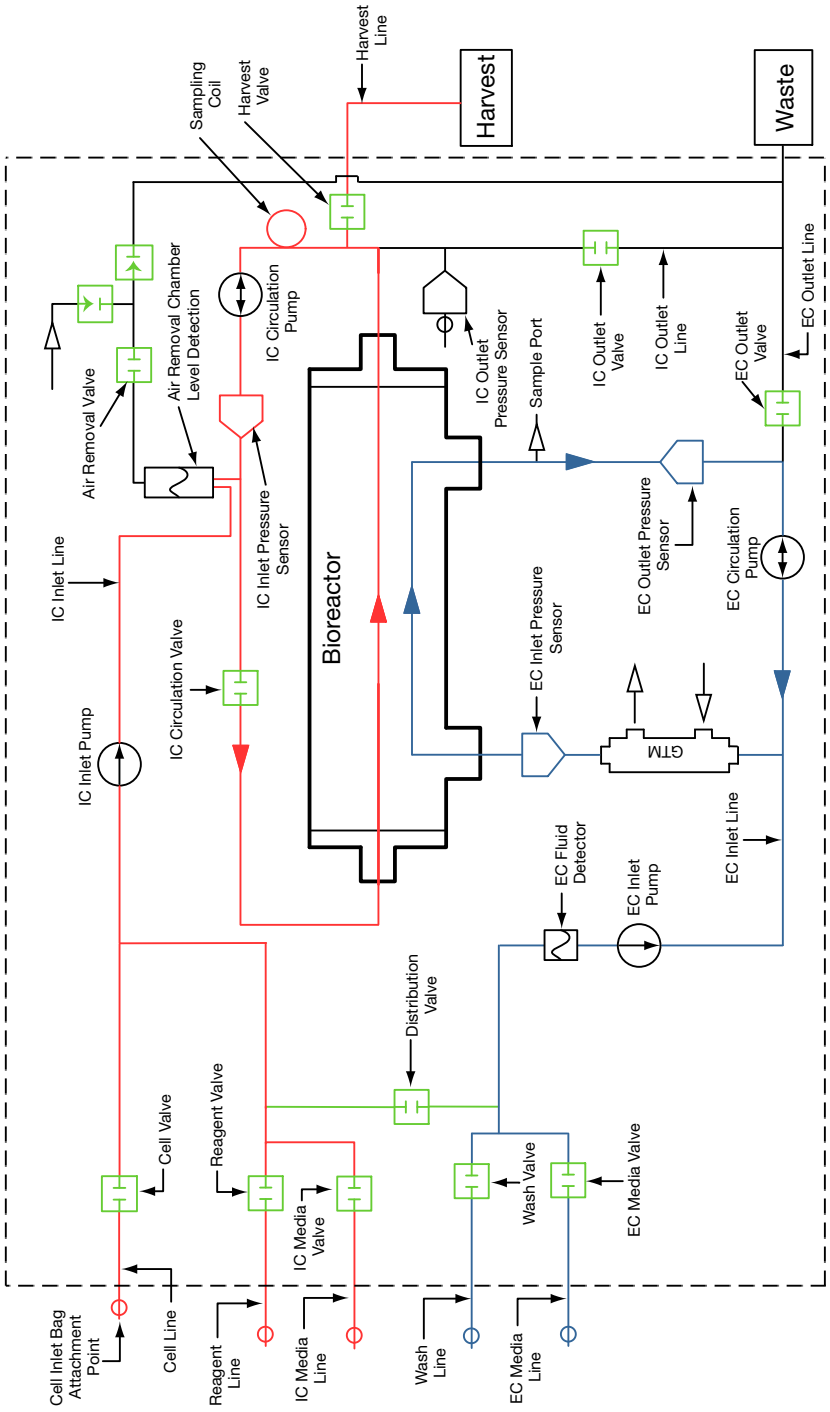


Figure 2-8: Diagram of the Quantum system hydraulic layout after prime

Quantum System Cell Expansion Sets

Cell expansion sets are functionally closed tubing sets for use with the Quantum Cell Expansion System. Figure 2-9 shows an example of a cell expansion set; the cell expansion set you use may look slightly different.

Note: For specific information about a tubing set, such as sterility, warnings, cautions, and definitions for symbols that appear on the kit and case labels of the set, refer to the instructions for use that ship with the tubing set.

Each cell expansion set includes the following main components:

- A hollow-fiber bioreactor
- A gas transfer module
- An intracapillary (IC) circulation loop
- An extracapillary (EC) circulation loop
- A sample coil
- A sample port with a 0.2 micron filter
- Four pressure pods
- Five inlet lines
- A harvest line with a 1 L harvest bag connected
- An outlet line with a 4 L waste bag connected

Figure 2-9: Example of a cell expansion set

Accessory Sets

The Quantum system includes the following types of accessory sets:

- **Cell inlet bags:** Bags that are used to add an amount of fluid less than 0.5 L to the system. The bags include a sample bulb. The operator manually attaches these bags to the inlet line of the cell expansion set using a sterile tubing welder.
- **Media bags:** Bags that are used to add sterile, filtered media to the system. The bags include a 0.2 micron filter. The operator manually attaches these bags to the inlet line of the cell expansion set using a sterile tubing welder.
- **Waste bags:** Bags that collect fluid exiting the cell expansion set. The operator manually attaches these bags to the outlet line of the cell expansion set using a sterile tubing welder.
- **Sampling coil:** A coil of tubing used for sampling cells and fluid in the IC circulation loop. The operator manually attaches the coil of tubing to the cell expansion set, using a sterile tubing welder, when the original sampling coil on the cell expansion set has been used.
- **200 Micron in-line filter:** A filter used to remove large particulates from the inlet fluid before loading the fluid into the system. The operator manually attaches the filter to the inlet line of the cell expansion set using a sterile tubing welder.

About User Authentication

User authentication allows an administrator to manage the level of access for each user of the Quantum system. When user authentication is enabled:

- An administrator assigns a User Role to each user that determines the user's level of access. The system has two User Roles: Operator and Administrator. See “User Role” on page 2-15 for more information.
- At least one user is assigned the User Role of Administrator. This user has access to all functions of the Quantum system, including configuration, and acts as the administrator for the system.
- All users must sign in and out of the system using a user ID and password.
- Only users who are assigned the User Role of Administrator can add a user to or remove a user from the system.
- Run reports record when a user signs in or out of the system, as well as any tasks that a user performed or alarms that occurred while that user was signed in to the system.

For instructions on configuring user authentication, see the Quantum Cell Expansion System Administrator’s Guide.

User Role

The system has two levels of access for users that are called User Roles.

Administrator

This User Role allows a user to:

- Configure the system, including:
  - Display settings
  - System settings
  - Default settings for tasks
  - Report settings
  - Network settings
  - Remote alarm settings
- Add or remove users from the system
- Change the User Role assigned to a user
- View reports
- Send reports
- Delete stored run reports
- Perform all tasks
- Clear alarms
- Change his or her own password
- Change the password assigned to another user

Operator

This User Role allows a user to:

- View reports
- Send reports
- Perform all tasks
- Clear alarms
- Change his or her own password

Signing In to the System

Complete the following steps to sign in to the system:

1. Touch **Sign In**.
   The Sign In window appears.
2. Touch the User ID field.
   A data entry pad appears.
3. Use the data entry pad to enter your user ID, and touch **Enter**.
   The data entry pad closes.
4. Touch the Password field.
   A data entry pad appears.
5. Use the data entry pad to enter your password, and touch **Enter**.
   The data entry pad closes.
6. Touch **Sign In**.
   The system signs you in and displays your user ID on the status bar.

Signing Out of the System

Complete the following steps to sign out of the system.

From the home screen:

1. Touch **Sign Out**.
   The system prompts you to confirm that you want to sign out of the system.
2. Touch **Yes**.
   The system signs you out.

Changing Your Password

If user authentication is enabled, your system administrator assigns you a user ID and password that you use to access the system. You can change your password at any time when you are signed in to the system.

Complete the following steps to change your password:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Change Password**.
   The Change Password window appears, as shown in Figure 2-10.

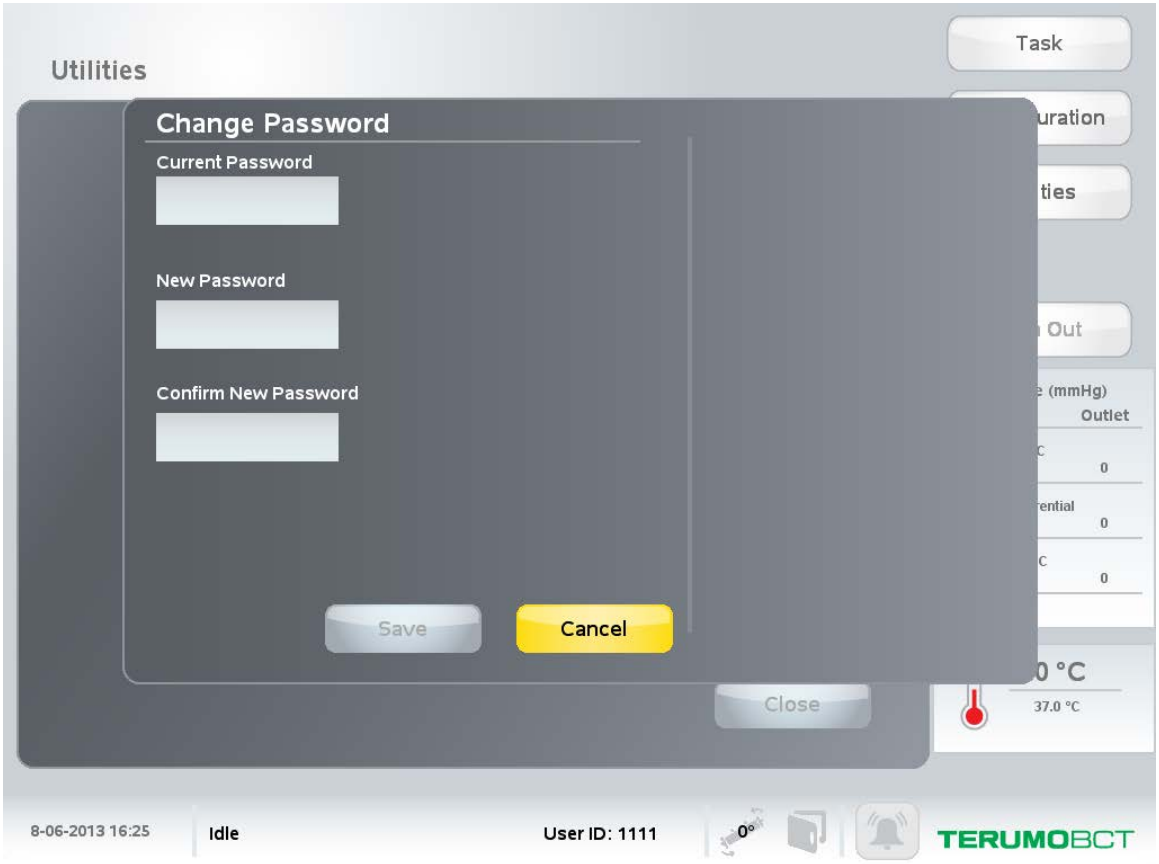


Figure 2-10: Change Password window

3. Touch the Current Password field.
   A data entry pad appears.
4. Use the data entry pad to enter your current password, and touch **Enter**.
   The data entry pad closes.
5. Touch the New Password field.
   A data entry pad appears.
6. Use the data entry pad to enter your new password, and touch **Enter**. The password must be at least 4 characters long, but no more than 10 characters.
   The data entry pad closes.
7. Touch the Confirm New Password field.
   A data entry pad appears.
8. Use the data entry pad to re-enter your new password, and touch **Enter**.
   The data entry pad closes.
9. Touch **Save**.
   The Change Password window closes, and the system saves your new password.

Turning On the Quantum System

Perform the following steps to turn on the Quantum system.

1. Open the incubator door.
2. Confirm that the rotor covers are closed and that the rotor latches are locked on the four pumps on the mounting plate. The rotor covers must be closed and the rotor latches must be locked before you turn on the system.
3. Close the incubator door.
4. Confirm that the external gas supply is attached to the external gas connector. Table 17-3 includes information about the gas supply requirements for the Quantum system.
5. Turn the primary power switch on the back of the device to the on position.
6. Turn the auxiliary power switch on the front of the device to the on position.
   The home screen appears when the system is ready for use.

Turning Off the Quantum System

Perform the following steps to turn off the Quantum system.

1. Close the incubator door.
2. Turn the auxiliary power switch on the front of the device to the off position.
3. Turn the primary power switch on the back of the device to the off position.
4. Disconnect the external gas supply from the external gas connector.

3

Touch Screen

About the Touch Screen

Caution: Do not use a stylus with the Quantum system touch screen.

The touch screen contains buttons that you touch to enter data or to command the system to perform a specific action. The touch screen also displays information about the condition of the system that you can use to monitor and troubleshoot the system. The touch screen works with both gloved and un-gloved hands.

Home Screen

When you turn on the Quantum system, the home screen appears. Figure 3-1 shows the home screen when the system is idle, and Figure 3-2 shows the home screen when the system is performing a task. The home screen allows you to monitor a task because it displays what the system is doing during a task, including the pump rates, pressures, temperature, and the fluid source selections. Table 3-1 describes the sections of the home screen.

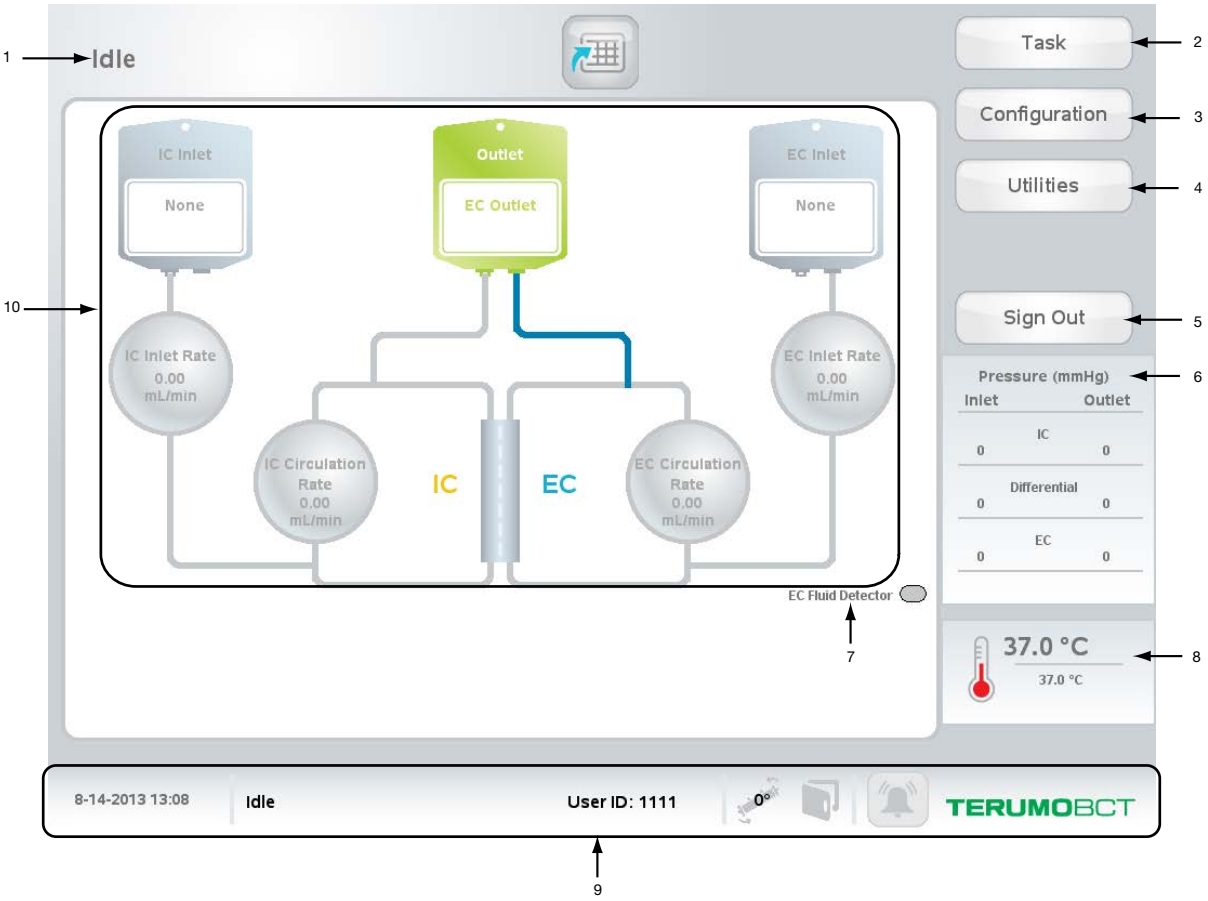


Figure 3-1: Home screen when the system is idle

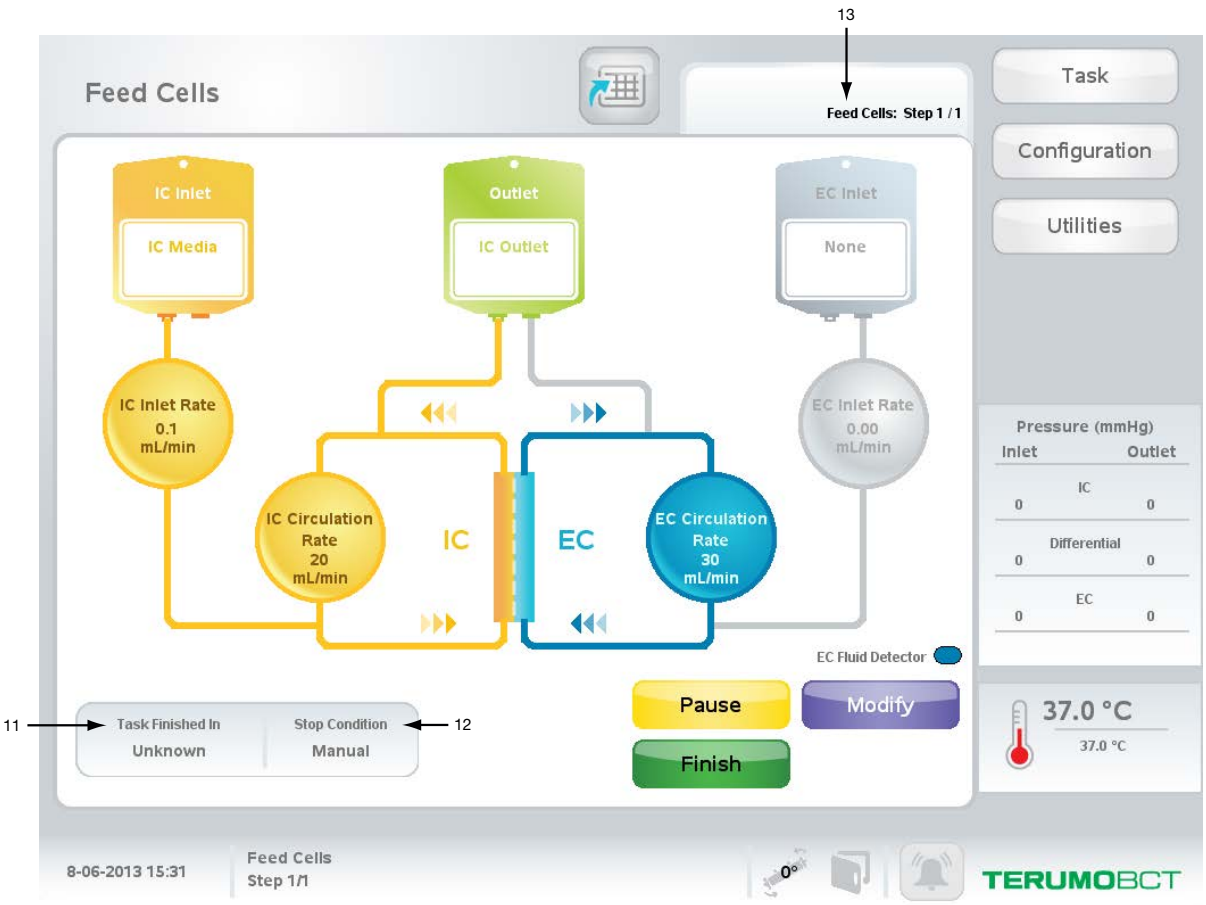


Figure 3-2: Home screen when the system is performing a task

Table 3-1: Home screen buttons, icons, and sections

	Name	Function
1	Screen name	Shows the name of the screen that the system is currently displaying. When the home screen is displayed, the screen name is either Idle (when the system is idle) or the name of the task that the system is currently performing.
2	**Task**	When touched, the Task Selection screen is displayed.
3	**Configuration**	When touched, the Configuration Selection screen is displayed.
4	**Utilities**	When touched, the Utilities screen is displayed.
5	**Sign Out**	When touched, allows you to sign out of the system. This button appears on the home screen only if user authentication is enabled.

Table 3-1: Home screen buttons, icons, and sections (continued)

	Name	Function
6	Pressure window	Displays the following information: • The current pressure readings at the IC inlet, the IC outlet, the EC inlet, and the EC outlet. These pressure readings are measured values. • The inlet differential pressure, which the system calculates by subtracting the EC inlet pressure from the IC inlet pressure. • The outlet differential pressure, which the system calculates by subtracting the EC outlet pressure from the IC outlet pressure.
7	EC Fluid Detector	Turns blue when the EC inlet line contains fluid and the line is properly loaded into the EC fluid detector.
8	Temperature window	Displays two values: the actual temperature of the air inside the incubator and the temperature set point. The actual temperature is listed above the temperature set point. When the incubator is turned off, this window displays Incubator OFF instead of the temperature set point.
9	Status bar	Displays the current status of the device.
10	System window	Visually depicts the current state of the device. The parts of the system involved in the current state are depicted in their normal colors (i.e., the IC side of the bioreactor is yellow and the EC side of the bioreactor is blue), and the parts of the system not involved in the current state are gray. When the system is idle, the illustration on this window changes to gray, except for Outlet. Outlet changes to green and shows the selection EC Outlet. The line from Outlet to the EC circulation loop is depicted in blue.
11	Task Finished In/Next Step In window	During single-step tasks, this window displays the time remaining for the current task, but during multi-step tasks it displays the time remaining for the current step. This window displays the time remaining in minutes and seconds. It does not display the time remaining if the Manual or Empty Bag stop conditions are selected for the current task or step of a task.
12	Stop Condition window	Displays the stop condition selected for the current task or step of a task. If the system is performing an internal process that is required to complete a task, this window displays System.
13	Current step display	Displays the name and number of the current step and the total number of steps in the task.

Status Bar

The status bar, located at the bottom of the touch screen, displays the current status of the device, as well as the buttons and icons that allow you to monitor basic functions. The status bar appears continuously on the touch screen. Figure 3-3 shows the status bar, and Table 3-2 describes the sections, buttons, and icons that appear on it.

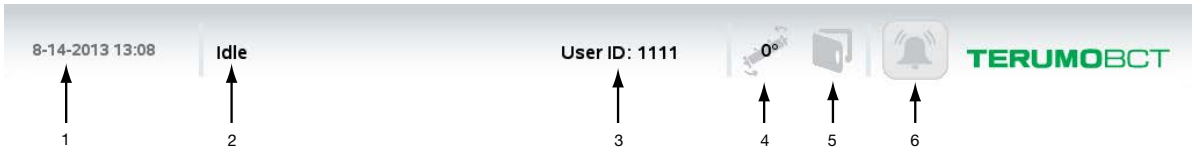


Figure 3-3: Status bar

Table 3-2: Status bar sections, buttons, and icons

	Name	Function
1	Date and time display	Displays the current date and the current time. For information about how to configure the format of the date and time display, see the Quantum Cell Expansion System Administrator's Guide.
2	Status line	Indicates the current status of the system. When the system performs a task, this section displays the task name, which step of the task the system is currently performing, and the total number of steps in the task. When the system is not performing a task, this section displays Idle.
3	User ID display	Displays the user ID of the user who is currently signed in to the system. This appears on the home screen only if user authentication is enabled.
4	Rocker icon	• When the system is idle and the bioreactor is in the home position, this icon is gray and displays 0°. • When the rocker is set to In Motion and the bioreactor is moving, this icon is blue. • When the rocker is set to Stationary and the bioreactor is in a fixed position, this icon is gray and displays a value (in degrees) that indicates the fixed position of the bioreactor.
5	Door icon	Turns blue when the incubator door is open.

Table 3-2: Status bar sections, buttons, and icons (continued)

	Name	Function
6	Alarm button	When there are no alarms, this button is gray, and when an alarm occurs, this button changes to orange. If you clear an alarm by touching **Continue**, the alarm button changes back to gray. However, if you choose to hide the Alarm window by touching the minimize button, the alarm button stays orange to remind you that there are unresolved system alarms. If you touch the button when it is orange, the system displays the Alarm window, which lists all of the current, unresolved alarms. For more information about alarms, see “Troubleshooting Alarms” on page 4-2.

General Navigation Buttons

This section describes the general navigation buttons that appear on the Quantum system touch screen. These buttons help you navigate the system and execute basic functions within the system, such as entering data or confirming a menu selection.

Table 3-3: Description of the general navigation buttons

Name	Function
Cancel	When touched, allows you to exit the current screen without saving any information.
Close	When touched, allows you to close a screen or a window.
Configure	When touched, allows you to configure the settings for a step of a task.
Confirm	When touched, allows you to confirm a selection or entry.
Finish	When touched, allows you to manually end a task. This button only appears when you select Manual as the stop condition.
Modify	When touched, allows you to modify a task. This button appears on the Setup Confirmation screen, and it appears on the home screen when the system is performing certain tasks.
Next	When touched, allows you to confirm that the system should move to the next step in a task. When a Set Management task, such as Prime Cell Expansion Set, is in progress, this button may appear on the system window, but it appears only during a step of a multi-step task that is not the last step and that includes on-screen instructions.
No	When touched, allows you to cancel an action. This button appears on all confirmation dialog boxes.
Pause	When touched, allows you to pause a task.
Resume	When touched, allows you to resume the current task or step of a task that you paused.
Save	When touched, allows you to save and apply changes that have been made to the system configuration.
Start	When touched, allows you to begin a task.
Stop	When touched, allows you to stop a task. Once you touch **Stop**, the system stops all the pumps, closes all the valves except for the EC outlet valve and the air removal valve, and ends the current task.

Table 3-3: Description of the general navigation buttons (continued)

Name	Function
Yes	When touched, allows you to confirm an action. This button appears on all confirmation dialog boxes.
Sign In	When touched, allows you to sign in to the system. This button appears on the home screen only if user authentication is enabled and the touch screen has locked after a period of inactivity.
Sign Out	When touched, allows you to sign out of the system. This button appears on the home screen only if user authentication is enabled.

Touch Screen Views

The touch screen has two views: a diagram view and a tabular view. The system defaults to the diagram view. You can switch from the diagram view to the tabular view by touching the select tabular view button, shown in Figure 3-4. Likewise, you can switch from the tabular view to the diagram view, as needed, by touching the select diagram view button, shown in Figure 3-5.

Diagram View

In the diagram view, the Quantum system is shown as a colored illustration with the intracapillary (IC) side of the bioreactor in yellow and the extracapillary (EC) side of the bioreactor in blue. The illustration also includes arrows that show the bi-directional flow within the IC and EC circulation loops. The Outlet selection is depicted in green when the IC outlet line and/or the EC outlet line are being used. However, when Harvest is the Outlet selection, the color of Outlet changes to purple to emphasize that selection.

Figure 3-4 shows an example of the home screen set to the diagram view when the system is performing a task. When the system is idle, the illustration on the system window changes to gray, except for Outlet, which changes to green and shows the selection EC Outlet; the line from Outlet to the EC circulation loop is depicted in blue. Figure 3-1 shows an example of the home screen set to the diagram view when the system is idle.

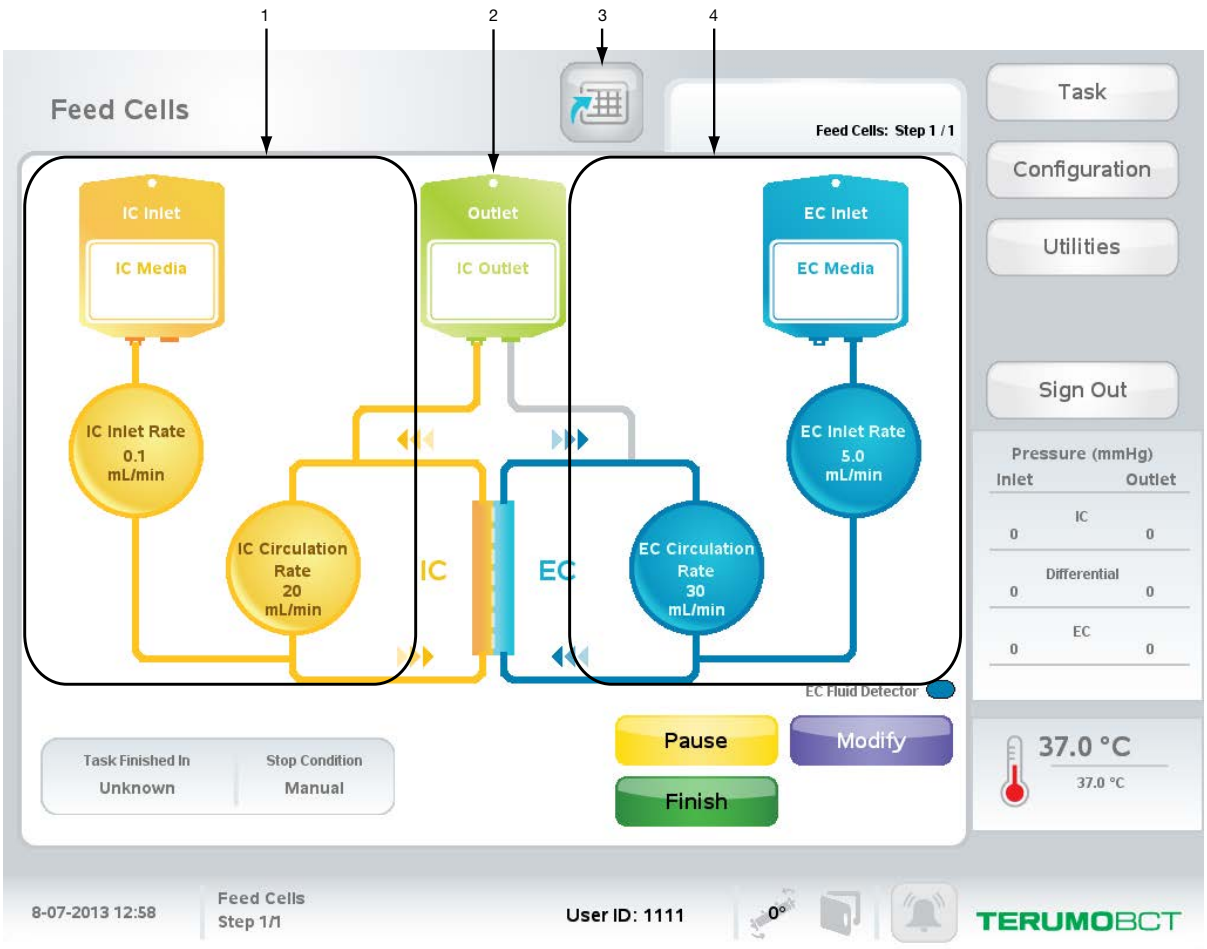


Figure 3-4: Home screen set to the diagram view

1 IC side shown in yellow
2 Outlet shown in green
3 Select tabular view button
4 EC side shown in blue

Tabular View

The tabular view displays the same system information as the diagram view, but it does not include a diagram of the Quantum system. The tabular view provides an alternative way to input and view the settings for a task.

Figure 3-5 shows an example of the home screen set to the tabular view.

Figure 3-5: Home screen set to the tabular view showing the select diagram view button

Utilities Screen

Access the Utilities screen by touching **Utilities** on the home screen. The Utilities screen displays a list of buttons. Table 3-4 describes the buttons that appear on the Utilities screen.

Table 3-4: Utilities screen buttons

Name	Function
Reports	When touched, displays the Reports window.
Change Password	When touched, displays the Change Password window.
About	When touched, displays the Quantum System Information dialog box, which lists the following information: • The serial number for the device • The software version installed on the device • The revision number for Control 1 • The revision number for Control 2 • The netmask for the device • The gateway address of the device

Task Selection Screen

Access the Task Selection screen by touching **Task** on the home screen. The Task Selection screen displays a list of buttons that allow you to view the available tasks by type, as shown in Figure 3-6.

Figure 3-6: Task Selection screen

For example, to view a list of the Set Management tasks, touch **Set Management**. **Set Management** changes to black to indicate that it is selected, and another list of buttons appears. Each button indicates an available Set Management task, as shown in Figure 3-7. Table 3-5 describes the buttons that appear on the Task Selection screen.

Figure 3-7: Task Selection screen displaying the available Set Management tasks

Table 3-5: Task Selection screen buttons

Name	Function
Set Management	When touched, allows you to access the Set Management tasks.
System Management	When touched, allows you to access the System Management tasks.
Washout	When touched, allows you to access the Washout tasks.
Load and Attach	When touched, allows you to access the Load and Attach tasks.
Feed and Add	When touched, allows you to access the Feed and Add tasks.
Release and Harvest	When touched, allows you to access the Release and Harvest tasks.
Custom	When touched, allows you to access the Custom tasks.

Setup Confirmation Screen

When you select a task, the Setup Confirmation screen appears and lists the settings for each step of the task. The name and number of a step is listed at the top of each column of settings, as shown in Figure 3-8. Table 3-6 describes the buttons that appear on the Setup Confirmation screen. You can perform a task using the default values, which the system pre-selects for you. If you choose to perform a task using the default values, you do not need to enter any settings manually; therefore, you can immediately start the task by touching **Start**.

If you choose to use different settings than the default values, you must enter those settings manually. Touch **Modify** at the top of the column for the step you want to modify, as shown in Figure 3-8. The Setup screen appears for that step, as shown in Figure 3-9.

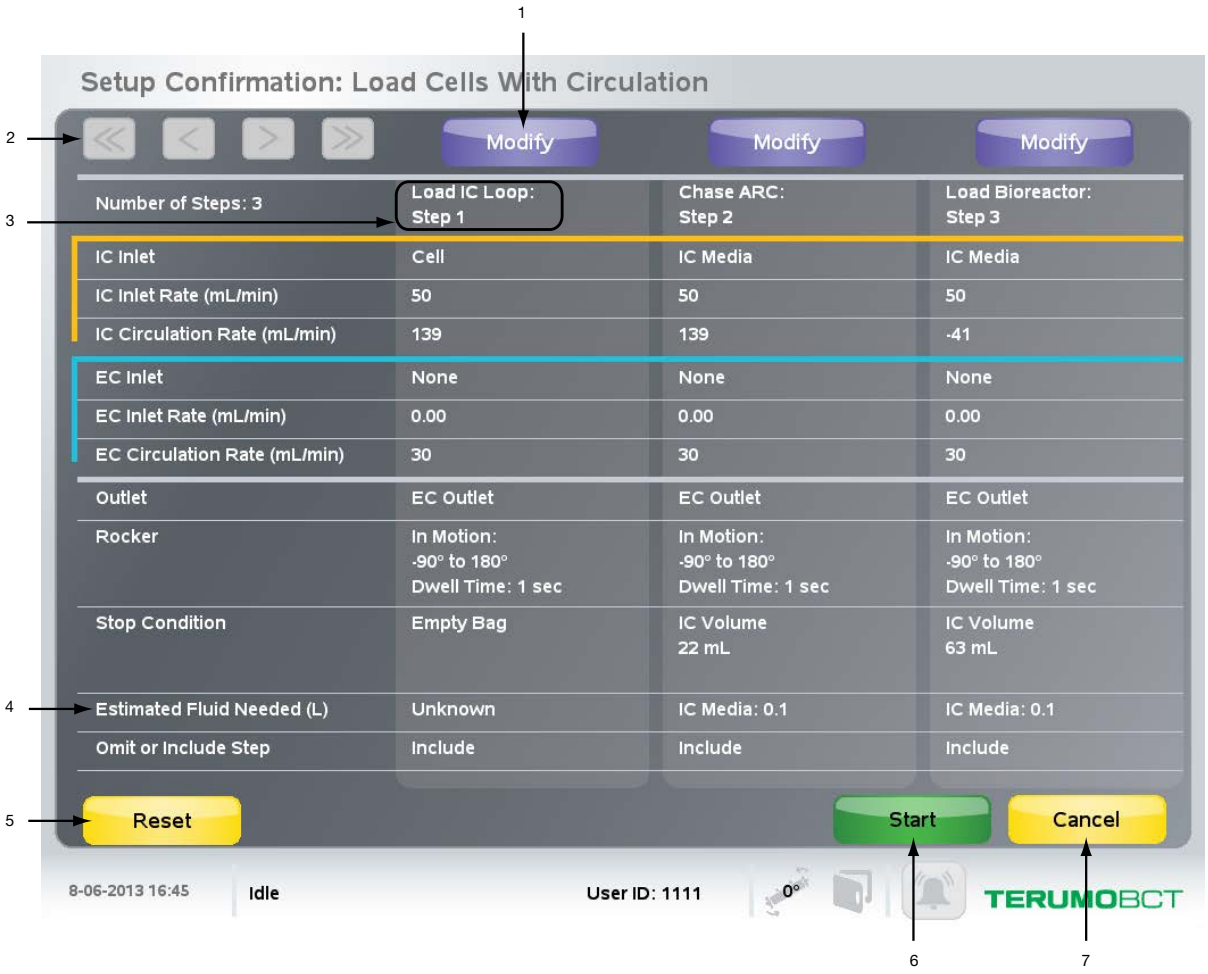


Figure 3-8: Setup Confirmation screen

Table 3-6: Setup Confirmation screen buttons and sections

	Name	Function
1	**Modify**	When touched, allows you to modify a task.
2	Scroll buttons	When touched, allow you to scroll through the setup information for all of the steps of a task. The Setup Confirmation screen automatically displays the setup information for the first three steps of a multi-step task.
3	Step information	Displays the name and number of the step.
4	Estimated fluid needed	Displays the estimated volume of fluid needed to complete that step of the task.
5	**Reset**	When touched, allows you to reset all the settings for all the steps of the task to the configured default values.
6	**Start**	When touched, allows you to begin a task.
7	**Cancel**	When touched, allows you to exit the current screen without saving any information.
Not shown	**Help**	When touched, allows you to display the Help window, which provides information about one or more task setting issues that you must resolve before you can start a task. This button appears only on the Setup Confirmation screen when a settings issue needs to be resolved.

Setup Screen

The Setup screen allows you to manually enter task settings either for a single-step task or for one step in a multi-step task. The buttons that are enabled on the Setup screen vary depending on the task you are performing. Figure 3-9 shows the Setup screen for a single-step task. Table 3-7 describes all the buttons that can appear on the Setup screen.

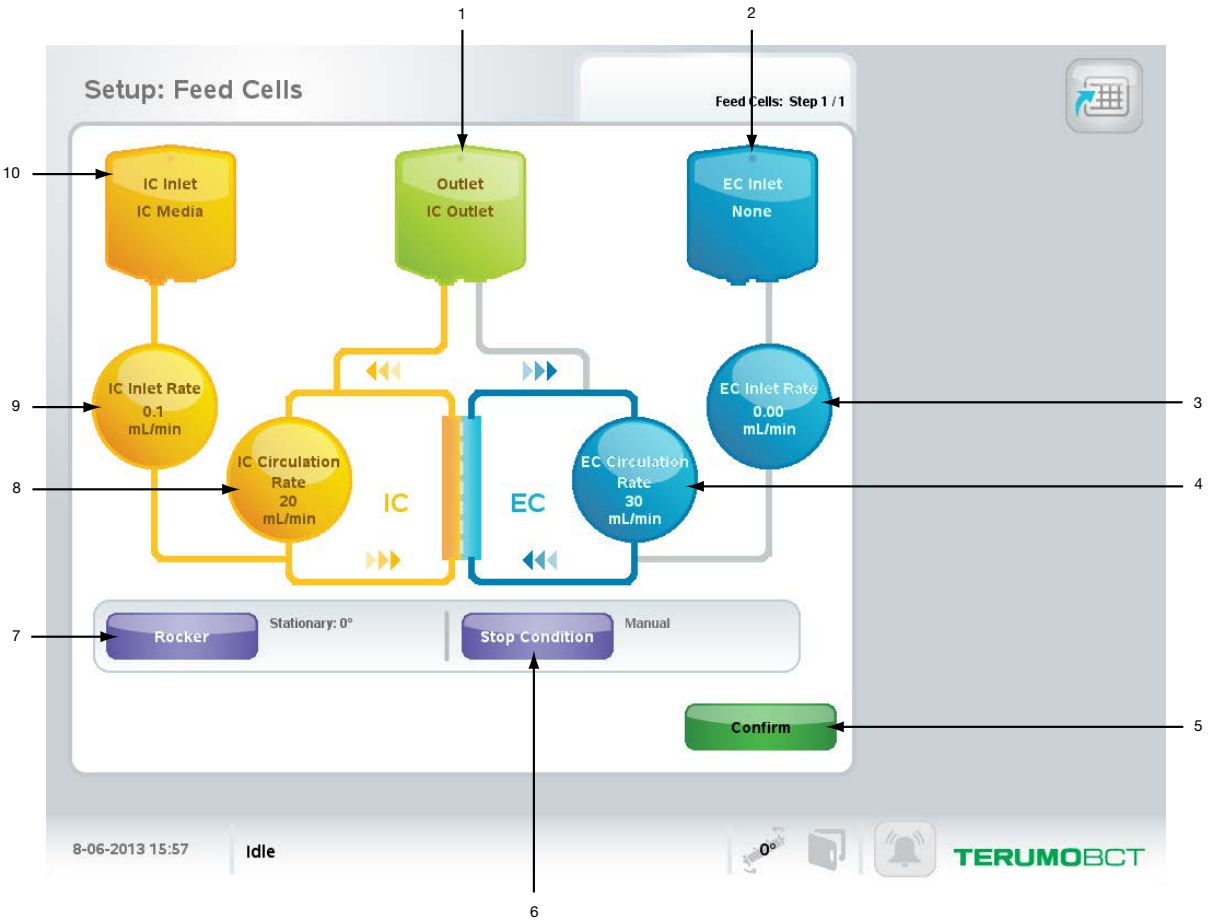


Figure 3-9: Setup screen

Table 3-7: Setup screen buttons

	Name	Function
1	**Outlet**	When touched, allows you to designate the pathway from the bioreactor to an outlet. This selection controls the outlet valve positions.
2	**EC Inlet**	When touched, allows you to select the fluid source (line) for the EC inlet. This selection controls the inlet valve positions.

Table 3-7: Setup screen buttons (continued)

	Name	Function
3	**EC Inlet Rate**	When touched, allows you to enter the flow rate for the EC inlet pump.
4	**EC Circulation Rate**	When touched, allows you to enter the flow rate for the EC circulation pump.
5	**Confirm**	When touched, allows you to confirm a selection or an entry and to save that information.
6	**Stop Condition**	When touched, allows you to select the stop condition.
7	**Rocker**	When touched, allows you to select the rocker setting.
8	**IC Circulation Rate**	When touched, allows you to enter the flow rate for the IC circulation pump.
9	**IC Inlet Rate**	When touched, allows you to enter the flow rate for the IC inlet pump.
10	**IC Inlet**	When touched, allows you to select the fluid source (line) for the IC inlet. This selection controls the inlet valve positions.
Not shown	**Next Step**	When touched, allows you to display the Setup screen for the next step in the task. This button appears only when you are setting up a multi-step task.
Not shown	**Previous Step**	When touched, allows you to display the Setup screen for the previous step in the task. This button appears only when you are setting up a multi-step task.
Not shown	**Include Step**	When touched, allows you to include the step in the task. This button appears only when you are setting up a multi-step task.
Not shown	**Omit Step**	When touched, allows you to omit the step from the task. This button appears only when you are setting up a multi-step task.

Table 3-7: Setup screen buttons (continued)

	Name	Function
Not shown	**Maximum IC Inlet Rate**	When touched, allows you to enter a value for the Maximum IC Inlet Rate up to a specified limit. This button appears only on the Setup screen when High Density Washout is selected.

Help Window

When setting up a task, you must resolve any settings issues before the system can start that task. For example, if you have set the IC Inlet Rate higher than 0 mL/min but have not selected an IC Inlet, you must resolve the issue by either setting the IC Inlet Rate to 0 mL/min or selecting an IC Inlet. If there are any settings issues with a task, the system disables **Start** on the Setup Confirmation screen and enables **Help**.

If you touch **Help**, the Help window appears and provides information about any settings issues that you must resolve before you can start the task. The information on the Help window includes the step in which the settings issue occurs, an explanation of the issue, and the options for resolving the issue. Figure 3-10 shows an example of the Help window.

Figure 3-10: Help window

Using the Data Entry Pad

When you touch a data entry field that requires you to enter a numeric value, the system displays a data entry pad, as shown in Figure 3-11. The data entry pad shows an initial value of 0.0. The acceptable numeric range for the setting you are entering is listed beneath the data display window.

To enter a numeric value on the data entry pad:

- Touch the appropriate number button on the data entry pad. The value you enter appears on the data display window located on the data entry pad.
- Touch **Enter** to save the value and close the data entry pad, or touch the clear button to clear the value from the data display window.
- Touch **Cancel** to close the data entry pad without saving any data.

The following rules apply to entering numeric values using the data entry pad:

- Any integer is acceptable as long as it falls within the numeric range specified on the data entry pad. The system will not allow you to enter a value that falls outside the acceptable numeric range.
- You can input decimals only for rates less than 10 mL/min, and the rate must be within the range of 0.1 to 9.9 mL/min.

Decimal Separator

The decimal separator automatically appears in the data display window located on the data entry pad. If you need to enter a value that is a fraction of one, such as 0.2, first touch the decimal button, and then touch the number that follows the decimal separator. You do not need to enter the zero that precedes the decimal, because the system automatically accounts for the zero and displays the value as 0.2.

Negative Numbers

To enter a negative number on the data entry pad, either enter the value first, and then touch the plus/minus button, or touch the plus/minus button first, and then enter the value.

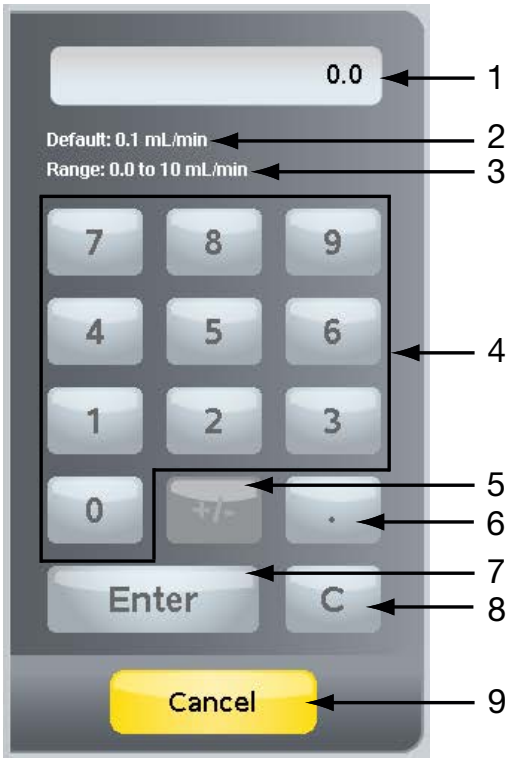


Figure 3-11: Data entry pad

1 Data display window
2 Default value (dependent on the setting you are entering)
3 Acceptable numeric range
4 Number buttons
5 Plus/minus button
6 Decimal button
7 **Enter**
8 Clear button
9 **Cancel**

4

Troubleshooting

Troubleshooting Alarms

Warning: Use caution when interacting with the Quantum device, because it has moving parts that could injure fingers and entangle hair, clothing, or other personal articles.

Warning: Avoid pinching your fingers when opening and closing the incubator door.

The Quantum system monitors itself throughout a task, and if the system detects a condition that requires attention, it sounds a critical alarm or a non-critical alarm, depending on the level of severity. Critical alarms and non-critical alarms are defined as follows:

- Critical alarm: occurs when a condition exists that interferes with the cell expansion process. The system responds to a critical alarm by taking an action to prevent interference with the cell expansion process. For example, the system might pause or stop a task, turn off the incubator, or turn off the IC inlet and EC inlet pumps. Critical alarms are displayed in a red Alarm window.

  If the **Continue** button is disabled, you must resolve the condition that caused the critical alarm before you can clear the alarm. If the **Continue** button is enabled, you should resolve the condition that caused the alarm before moving forward. If user authentication is enabled, you must be signed in to the system to access the **Continue** button on a critical alarm. If you are not signed in, minimize the alarm and sign in to the system. For more information, see “Signing In to the System” on page 2-16.

- Non-critical alarm: warns you about a condition that could potentially interfere with the cell expansion process. The system does not take any action when a non-critical alarm occurs. Non-critical alarms are displayed in an orange Alarm window.

When an alarm occurs, the system displays information about the alarm and troubleshooting instructions on the screen. Figure 4-1 shows an example of the Alarm window, which appears when an alarm occurs. Table 4-1 describes the different sections of the Alarm window.

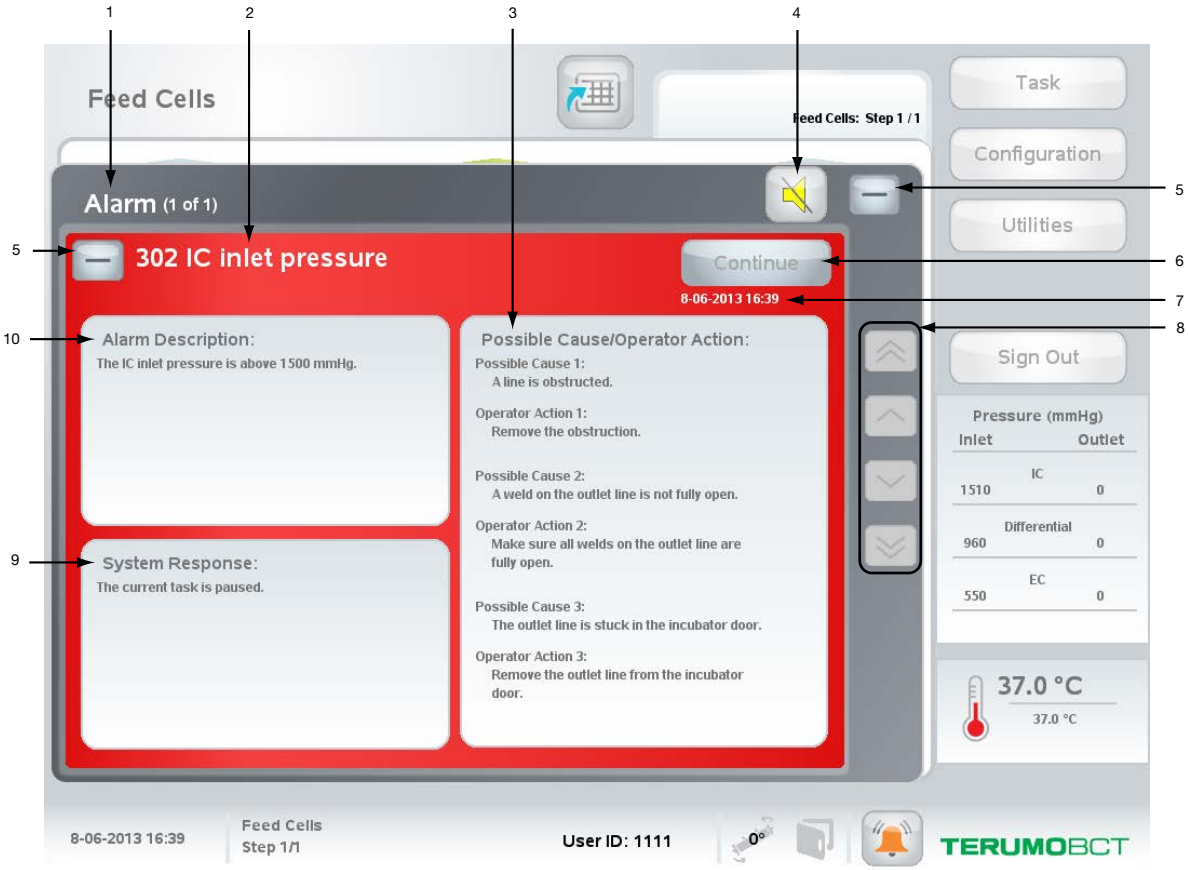


Figure 4-1: Alarm window displaying a critical alarm

Table 4-1: Alarm window buttons and sections

	Name	Function
1	Alarm header	Displays how many alarms are occurring at one time and which alarm you are currently viewing.
2	Alarm name	Displays the alarm identification number and the alarm name.
3	Possible Cause/Operator Action	Lists the possible causes of the alarm. Each possible cause includes an action you should perform to resolve the condition that is causing the alarm.
4	Mute button	When touched, allows you to mute the sound of any current alarms.
5	Minimize button	When touched, allows you to hide the Alarm window. This button also allows you to view less detail about an individual alarm.
6	**Continue**	When touched, allows you to clear the alarm.
7	Date and time stamp	Displays the date and time when the alarm occurred.

Table 4-1: Alarm window buttons and sections (continued)

	Name	Function
8	Scroll buttons	When touched, allows you to scroll through the list of alarms.
9	System Response	Explains what the system did when the alarm occurred. For example, the system might pause a task in response to an alarm.
10	Alarm Description	Provides a brief explanation of the condition that caused the alarm.
11 (shown in Figure 4-2)	Maximize button	When touched, allows you to view additional detail about an individual alarm, including the Alarm Description, the System Response, and the Possible Cause/Operator Action list.

When multiple alarms occur at the same time, the Alarm window displays a list of all the alarms. Figure 4-2 shows an example of the Alarm window when multiple alarms occur.

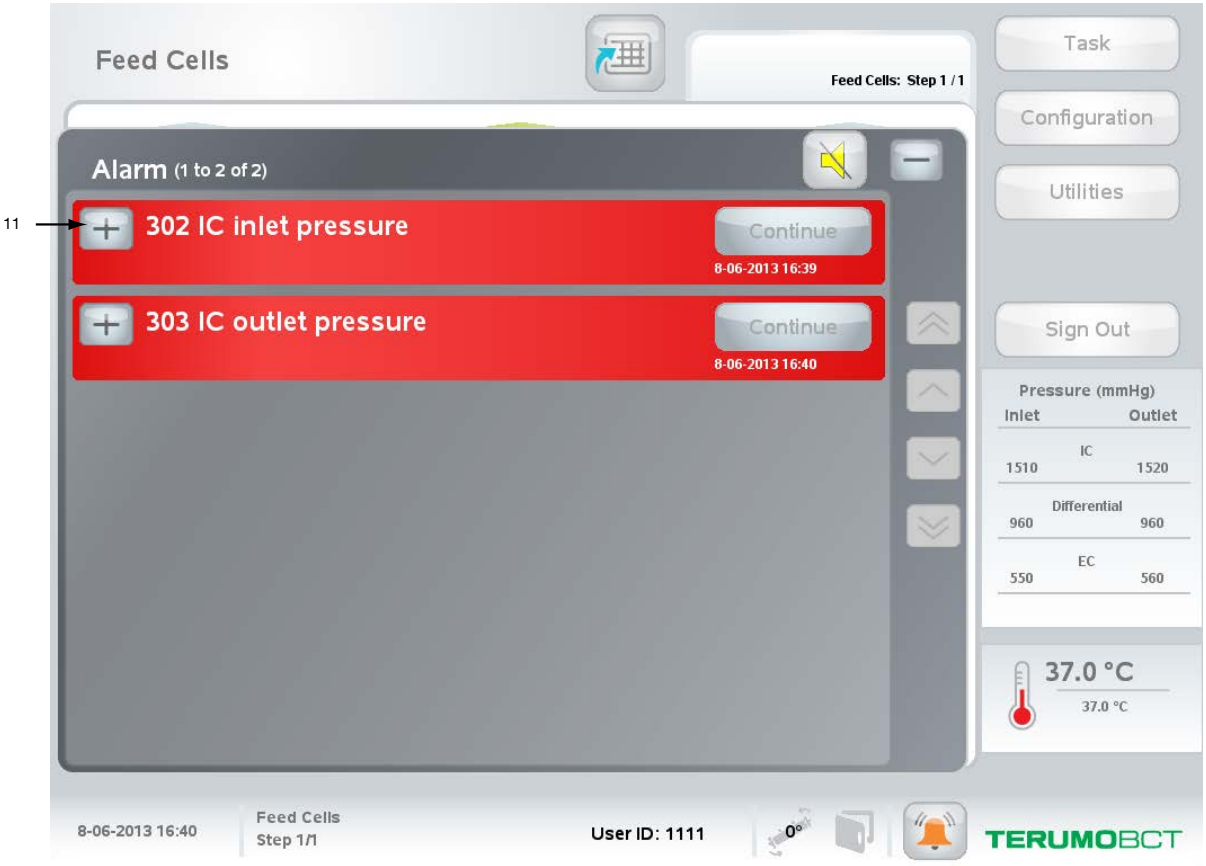


Figure 4-2: Alarm window displaying multiple alarms

Clearing An Alarm

If an alarm occurs, perform the following steps:

1. Read the alarm identification number and name, the Alarm Description, and the System Response.
2. Read all of the possible causes and the operator actions for the alarm.
3. Perform the operator actions to resolve the condition causing the alarm.
4. Once you have resolved the condition causing the alarm, touch **Continue**.

About Remote Alarm Notification

Remote alarm notification allows you to connect your Quantum system to an existing alarm notification system at your facility so that you can receive notification of alarms that occur on the Quantum system when an operator is not present at the device.

If remote alarm notification is enabled and an alarm occurs on the Quantum system, it sends a copy of the alarm message to a server that is set up to receive and process the messages. The alarm message is sent using port control protocol (PCP) and is saved as an Extensible Markup Language (XML) file. For more information about remote alarm notification and how to configure it, see the Quantum Cell Expansion System Administrator's Guide.

Power Fail Recovery

If a power failure occurs during operation, the Quantum system restarts and undergoes a system recovery. During recovery, the system is restored to the state it was in at the time the power failure occurred.

- If the system was idle when the power failure occurred, it restarts and displays the home screen in the idle state.
- If the system was performing a task when the power failure occurred, it restarts and then restores the task that was in progress. If the incubator door was open when the power failure occurred, the system restores the task that was in progress, but it pauses the task so that no parts are moving on the device during recovery. Once the system restores the task that was in progress, it produces an alarm that provides the following information about the power failure:
  - The name of the task that was in progress at the time the power failure occurred
  - The time at which the power failure occurred
  - The time at which the system was restored
  - The duration of the power failure

5

Operator Procedures

Preparing the System

This section contains instructions for filling the media bags and the cell inlet bags. You should have the following supplies:

- A media bag
  - Fluid
  - A tubing pump
- A cell inlet bag
  - Fluid
  - A syringe or a similar device that has a male luer connector
- A tubing sealer

Filling the Media Bags

Complete the steps in this section to fill the media bags.

1. Open the pouch that contains the media bag, and remove the contents.
2. Remove the protective cover from the end of the tubing.
3. Connect the end of the tubing to the fluid source; for example, place the tubing into the fluid container. Use an appropriate method to avoid contamination of the fluid.
4. Load the white tube into the tubing pump.
5. Ensure that the cap on the pressure relief valve on the filter is tight.
6. Set the tubing pump to a low flow rate, such as 150 mL/min, to prime the filter. When priming the filter, hold it upright.

   After the filter cartridge is full and the fluid begins to flow into the bag, you can slowly increase the flow rate of the tubing pump.

   Note: Ensure that the opening to the white tube remains below the level of the fluid in the fluid source.

7. When the last of the fluid has been pumped from the fluid source:
   a. Set the tubing pump to a low flow rate.
   b. Slowly pump the fluid from the white tubing into the inlet of the filter.
   c. Stop the pump.

   Note: This filter has not been validated for maintaining sterility if air is forced through the membrane.

8. Use a tubing sealer to double-seal the clear tubing. To ensure that you will have enough tubing to attach the bag to the cell expansion set using a sterile tubing welder, leave as much of the clear tubing as possible connected to the bag.
9. Separate the media bag from the filter at the double seal.

Filling the Cell Inlet Bags

The cell inlet bag has a female luer, which allows you to connect a syringe or a similar device that has a male luer. Use this port to add a product to the bag in an aseptic manner.

Replacing a Bag

The following instructions describe how to replace a bag, such as an inlet bag or an outlet bag, while the system is performing a task.

Caution: When you attach a bag to the cell expansion set, ensure that the bag is attached to the proper line and that the sterile weld is completely open before starting any tasks.

1. Touch **Pause**.
2. Touch **Yes**.
   The system pauses the current task.
3. Use the sterile tubing welder to attach the new bag to the appropriate line.
4. Hang the new bag on the bag pole.
5. Touch **Resume**.
6. Touch **Yes**.
   The system resumes the current task.

Using the In-line Filter 200 Micron Accessory Set

Caution: When you attach a bag to the cell expansion set, ensure that the bag is attached to the proper line and that the sterile weld is completely open before starting any tasks.

Caution: When using the In-line Filter 200 Micron Accessory Set, sterile weld to the blue luer end first or you may lose the cell product.

1. Use the sterile tubing welder to attach the in-line filter line that has a blue luer to the cell line of the cell expansion set.

Note: The in-line filter has two lines coming out of the top that are meant for attaching the cell inlet bag. These lines are each a different size and are made of different materials to accommodate various sizes and types of tubing. Choose the appropriate tubing size and type before you attach the cell product, or a sterile weld failure could occur.

2. Use the sterile tubing welder to attach the in-line filter line to the cell inlet bag that contains the inlet fluid that needs to be filtered.
3. Hang the bag on the bag pole.
4. Prime the in-line filter by squeezing it until the bottom of the filter contains fluid, as shown in Figure 5-1. Figure 5-2 shows the in-line filter in use.

Note: You do not need to fill the entire filter with fluid for it to function properly.

Figure 5-1: Priming the in-line filter

Figure 5-2: In-line filter in use

Taking a Sample from the Sample Coil

1. Touch **Pause**.
2. Open the incubator door.
3. Remove the sample coil strain relief from the rocker assembly by lifting one tab.

   Figure 5-3 shows the sample coil and the sample coil strain relief located on the cell expansion set.

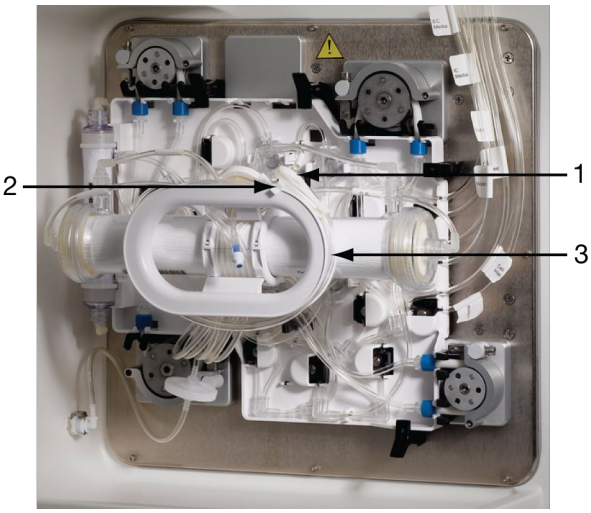


Figure 5-3: Cell expansion set

1 Sample coil strain relief
2 Tab on the sample coil strain relief
3 Sample coil

4. Uncoil the sample coil from the rocker assembly.

5. Remove the sample coil strain relief from the sample coil line, as shown in Figure 5-4.

Figure 5-4: Removing the sample coil strain relief

6. Load the sample coil line 1 to 2 inches from the midpoint into the sterile tubing welder, as shown in Figure 5-5, and complete the sterile weld with the sterile tubing welder.

   Creating a sterile weld at the midpoint of the sample coil may hinder fluid flow when the sample coil is loaded into the sample coil strain relief.

Figure 5-5: Sample coil loaded into the sterile tubing welder

Note: Sterile welding near the midpoint of the sample coil allows you to simultaneously take a sample and reconnect the sample coil.

7. Set aside the sample you took from the sample coil.
8. Open the sterile weld on the sample coil.
9. Connect the sample coil strain relief to the sample coil line.
10. Recoil the sample coil around the rocker assembly.
11. Connect the sample coil strain relief to the rocker assembly.
12. Close the incubator door.
13. Touch **Resume**.

Taking a Sample from the Sample Port

1. Open the incubator door.
2. Use a cleansing wipe that contains an appropriate laboratory disinfectant to clean the sample port surface that will interface with the syringe.
3. Connect the syringe to the sample port, as shown in Figure 5-6.

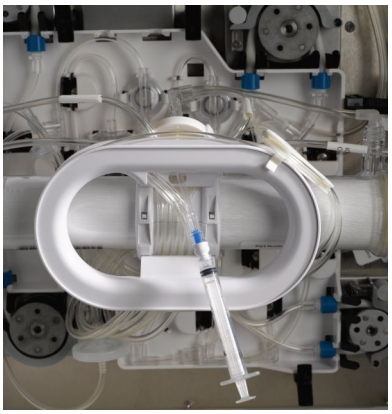


Figure 5-6: Sample port with the syringe connected

Note: Performing step 4 removes any residual media from the filter, which ensures that you are testing media that is currently circulating in the EC circulation loop.

4. Draw 3 mL of media through the filter and the sample port, and then discard the media.
5. Repeat step 2 to clean the sample port.

Note: To avoid drawing waste into the EC circulation loop, draw the minimum volume from the sample port that is appropriate for the desired analysis, such as measuring the glucose or lactate levels. This sampling method is not appropriate for measuring gas concentrations.

6. Draw the volume of sample needed.
7. Repeat step 2 to clean the sample port.
8. Close the incubator door.

6

Performing Tasks

About Tasks

Warning: Do not clamp the lines to control the flow of fluid through the cell expansion set. Clamping the lines can cause excessive pressure, resulting in possible injury to the operator and damage to the cell expansion set. Allow the system to control the flow of fluid.

A task consists of one or more steps, and each step includes a set of valve and pump states that achieves a specific result, such as loading the cells from the cell inlet bag into the bioreactor. The Quantum system includes seven types of tasks: Set Management tasks, System Management tasks, Washout tasks, Load and Attach tasks, Feed and Add tasks, Release and Harvest tasks, and Custom tasks.

On the touch screen, you can modify the settings for some tasks. When you modify a task, the system performs the task using the modified settings, but the system does not save any modified settings for future use. However, you can configure the default settings for a task so that each time you select a task, it uses the default settings you have configured instead of the factory default settings. For more information about configuring the default settings for tasks, see the Quantum Cell Expansion System Administrator's Guide.

Task Finished Window

When the system successfully completes a task, the Task Finished window appears and the system emits a short sound. The Task Finished window displays the name of the task and the date and time when the system completed the task, as shown in Figure 6-1. The window does not appear if the system prematurely ends a task because of an alarm or if you stop a task manually by touching **Stop** or by using the Manual stop condition.

Figure 6-1: Task Finished window

How Tasks Appear in this Operator's Manual

In this operator's manual, each task includes instructions for completing that task. Some tasks include a table of settings for each step of the task, and each table includes the factory default and any additional options for each setting. A task may also include a table that describes the solutions needed to perform the task, such as the types of fluids to use, the line to which you should attach each type of fluid, and the approximate volume of each fluid required to complete that task. This information is based on performing a task using the factory default settings for that task.

The instructions for a task may also include one or more preconditions that you need to satisfy before you begin that task. Most tasks also include a pathway, which is a shorthand reminder for how to select that task. The following example shows the actual instructions for selecting Load Cells With Circulation and the corresponding pathway:

1. Touch **Task**.
2. Touch **Load and Attach**.
3. Touch **Load Cells With Circulation**.

Load Cells With Circulation pathway: **Task** > **Load and Attach** > **Load Cells With Circulation**

About Settings

Each task has multiple settings for each step of the task, including IC Inlet, IC Inlet Rate, IC Circulation Rate, EC Inlet, EC Inlet Rate, EC Circulation Rate, Outlet, Rocker, and Stop Condition. These settings determine what happens during each step of a task. You can modify the settings for some tasks. For those tasks, the instructions in this operator's manual include a table of settings for each step that lists the factory default for each setting and the additional options for each setting.

For some tasks that have multiple steps, a setting in a step is dependent on the value entered for the same setting in a previous step. For example, if you enter an IC Inlet Rate of 10 mL/min for step 1 of a task, and the IC Inlet Rate setting for step 2 is dependent, the system automatically populates an IC Inlet Rate of 10 mL/min for step 2. This operator's manual denotes dependent settings by listing one of the following phrases in the settings table for the affected step:

- Same as step 1
- Same as step 2

The highlighted row in Table 6-1 is an example of how this appears in a table of settings in this operator's manual.

Table 6-1: Example of a dependent setting

Setting	Factory Default	Setting Options
IC Inlet	Cell	N/A
IC Inlet Rate	50 mL/min	Same as step 1
IC Circulation Rate	0 mL/min	N/A
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, –180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (0°)
Stop Condition	Empty Bag	N/A

The following sections explain each setting and describe how to select those settings, which appear on the Setup screen, shown in Figure 6-2.

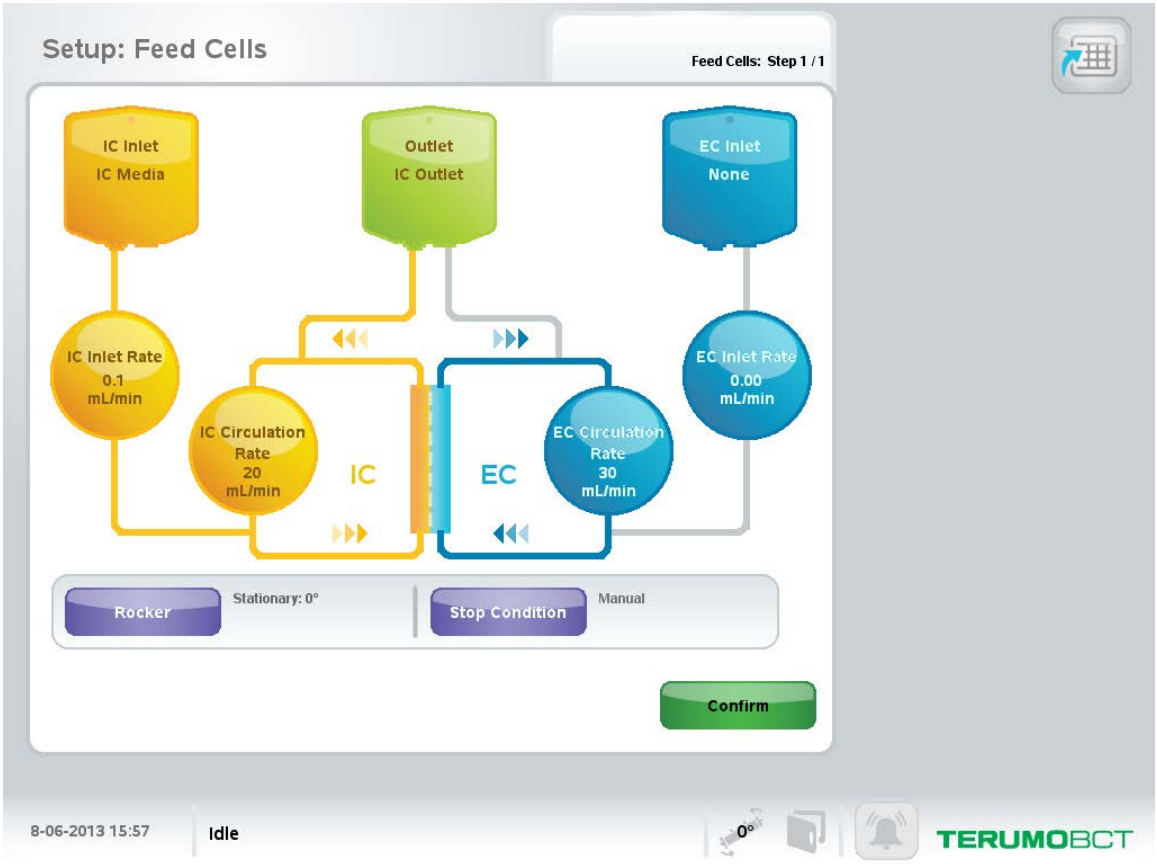


Figure 6-2: Setup screen

Selecting the IC Inlet or EC Inlet

The following instructions explain how to select the IC Inlet or the EC Inlet.
From the Setup screen:

1. Touch the button for the inlet that you wish to select, such as **IC Inlet**.

   A menu of inlet settings appears, and the button that you touched, **IC Inlet** in this example, changes to black.

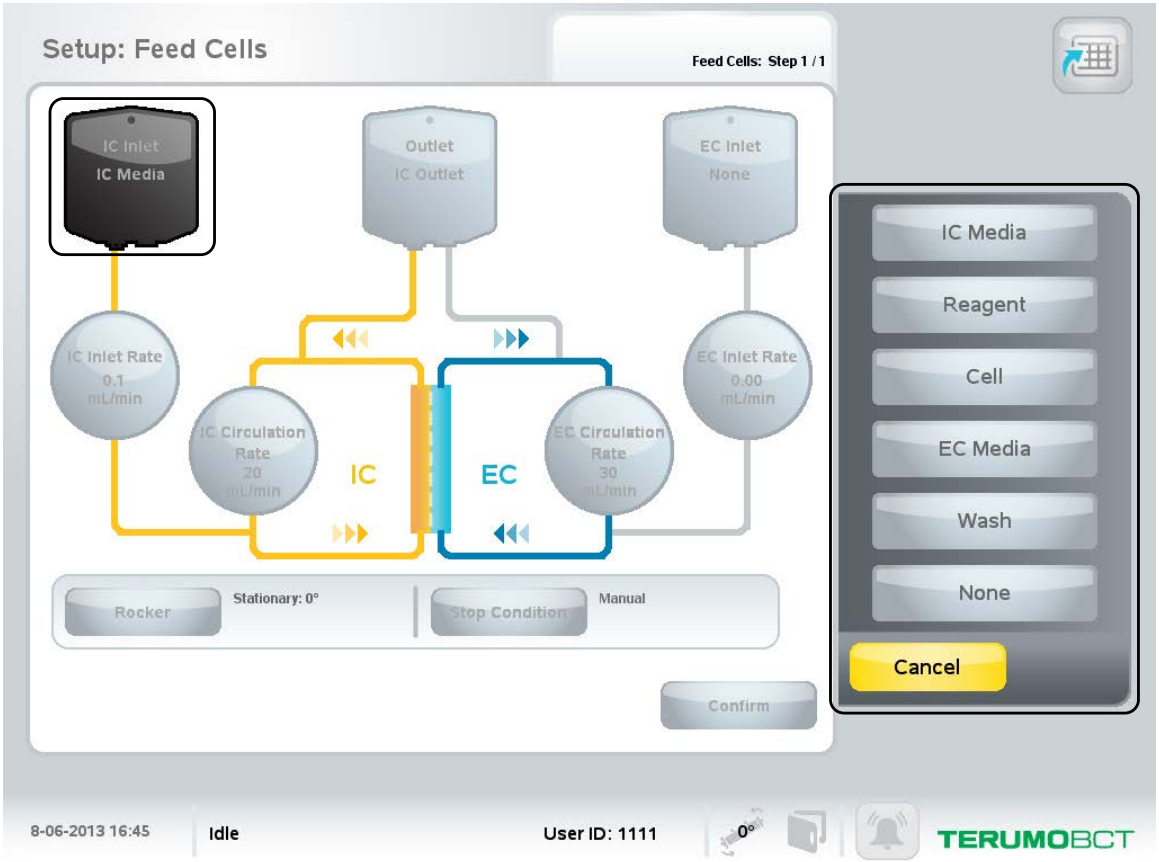


Figure 6-3: Menu of IC Inlet setting options

2. Touch the desired setting in the menu.
   The button now displays the setting you selected, and it changes from black to the appropriate color (yellow for IC Inlet or blue for EC Inlet). In this example, **IC Inlet** changes to yellow and displays the setting you selected.

Entering Pump Rates

There are four task settings that require you to enter a pump rate: the IC Inlet Rate, the IC Circulation Rate, the EC Inlet Rate, and the EC Circulation Rate. Each setting corresponds to a button that appears on the Setup screen. For a description of all the buttons that appear on the Setup screen, see "Setup Screen" on page 3-17. For information about using the data entry pad, see "Using the Data Entry Pad" on page 3-21.

The following example describes how to enter a pump rate.

From the Setup screen:

1. Touch the button for the pump rate that you wish to change, such as **IC Inlet Rate**.
   A data entry pad appears, and the button that you touched, **IC Inlet Rate** in this example, changes to black.
2. Enter the rate using the data entry pad.
   The data entry pad displays the rate you entered.
3. Touch **Enter** on the data entry pad.
   The button now displays the rate you entered, and it changes from black to its designated color. In this example, **IC Inlet Rate** displays the rate that you entered and changes from black to yellow.

Automatically Calculated Pump Rates

A task may include a pump rate, such as the IC Circulation Rate, that the system automatically calculates based on another pump rate for that task, such as the IC Inlet Rate. When a pump rate is automatically calculated, an explanatory note is included in the table of settings.

You can override an automatically calculated pump rate by entering a different rate, as long as it is within the available options for that setting. However, you cannot override an automatically calculated rate if there are no other available options for that setting. The highlighted row in Table 6-2 is an example of how an automatically calculated pump rate that you can override appears in a table of settings in this operator's manual.

Table 6-2: Example of an automatically calculated pump rate (override available)

Setting	Factory Default	Setting Options
IC Inlet Rate	10 mL/min	0.1 to 100 mL/min
IC Circulation Rate	100 mL/min	–300 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.

The highlighted row in Table 6-3 is an example of how an automatically calculated pump rate that you cannot override appears in a table of settings in this operator's manual.

Table 6-3: Example of an automatically calculated pump rate (override not available)

Setting	Factory Default	Setting Options
IC Inlet Rate	260 mL/min	50 to 500 mL/min
IC Circulation Rate	–45 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this step.

Outlet

Outlet designates a pathway from the bioreactor to an outlet destination during a task or a step of a task. The outlet destination is either the bag attached to the outlet line or the harvest bag. The following list describes all the possible setting options for Outlet:

- EC Outlet: allows fluid to flow from the EC side of the bioreactor into the bag that is attached to the outlet line.
- IC Outlet: allows fluid to flow from the IC side of the bioreactor into the bag that is attached to the outlet line.
- IC and EC Outlet: allows fluid to flow from both the IC side and the EC side of the bioreactor into the bag that is attached to the outlet line.
- Harvest: allows fluid to flow from the IC side of the bioreactor into the harvest bag.
- Synchronization: The system synchronizes the IC and EC inlet pumps with the IC and EC outlet valves and alternates between the following two states every five minutes:
  1. The IC inlet pump turns on and the IC outlet valve opens while the EC outlet valve closes and the EC inlet pump turns off. (In order to achieve an average flow rate equal to the entered value, the actual IC inlet rate is double the value that has been set.)
  2. The EC inlet pump turns on and the EC outlet valve opens while the IC outlet valve closes and the IC inlet pump turns off. (In order to achieve an average flow rate equal to the entered value, the actual EC inlet rate is double the value that has been set.)

Table 6-4 describes the positions of the valves for each Outlet setting.

Table 6-4: Valve positions for each Outlet setting

Outlet setting	IC outlet valve position	EC outlet valve position	Harvest valve position
EC Outlet	closed	open	closed
IC Outlet	open	closed	closed
IC and EC Outlet	open	open	closed
Harvest	closed	closed	open
Synchronization	alternates between open and closed	alternates between open and closed	closed

Selecting an Outlet

The following instructions explain how to select an Outlet setting.
From the Setup screen:

1. Touch **Outlet**.

   A menu of Outlet settings appears, and **Outlet** changes to black, as shown in Figure 6-4.

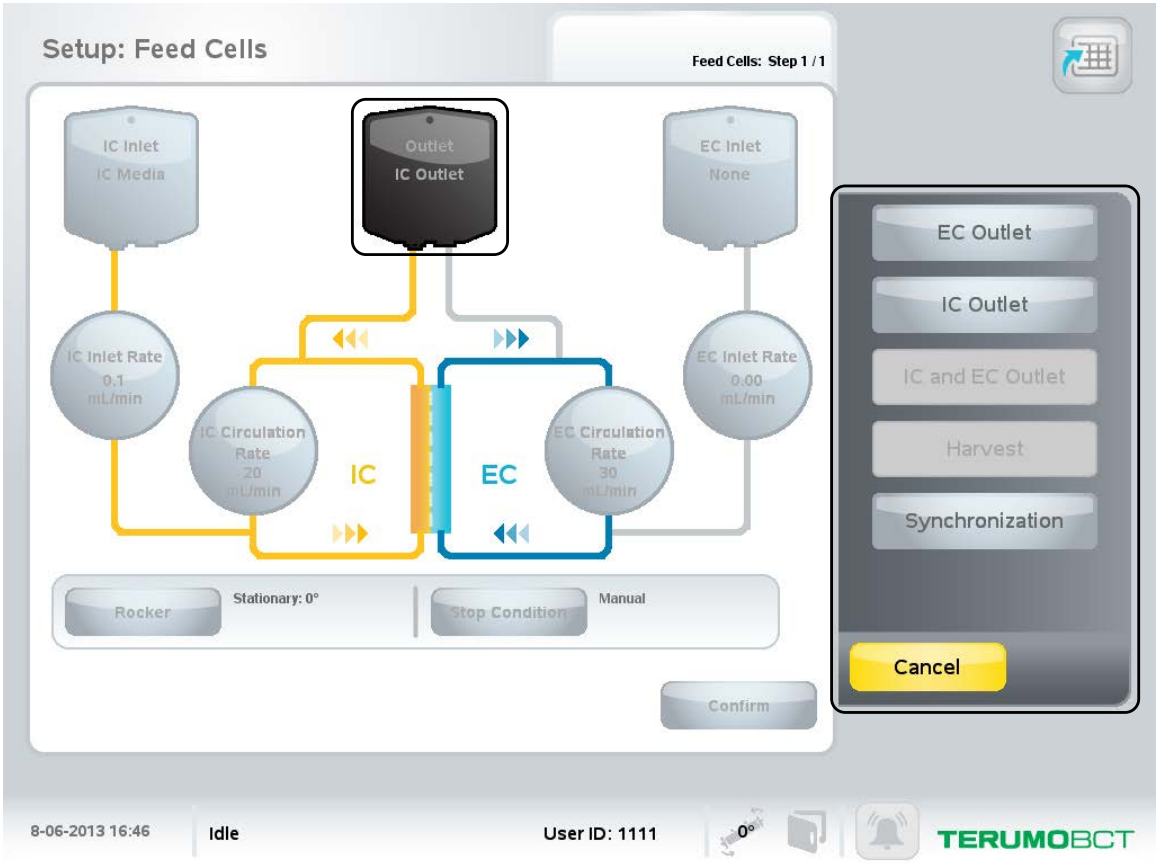


Figure 6-4: Menu of Outlet setting options

2. Touch the desired setting in the menu.

Outlet changes to green and displays the setting you selected.

Note: If you select Harvest, **Outlet** changes to purple, not green.

Rocker

The rocker determines the position and movement of the bioreactor throughout a task. When the system is in an idle state, the bioreactor is in the home position of 0°, as shown in Figure 6-5.

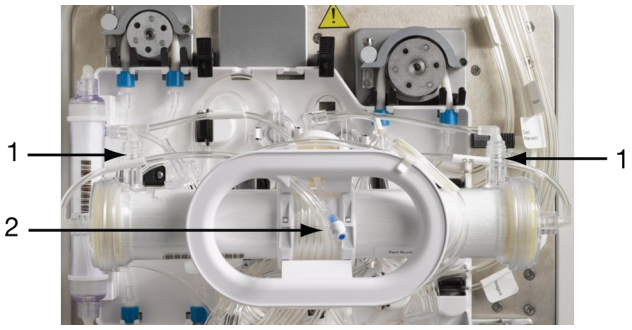


Figure 6-5: Bioreactor in the home position

1 EC inlet and EC outlet ports facing upward

2 Sample port facing downward

The rocker has two settings: In Motion or Stationary. The bioreactor range of motion is from −180° to 270°. A negative value, such as −10°, means that the bioreactor moves clockwise, whereas a positive value, such as 20°, means that the bioreactor moves counter-clockwise.

In Motion

The In Motion rocker setting includes three values: the start position of the bioreactor, the end position of the bioreactor, and the dwell time. The start and end positions indicate the number of degrees from the home position of 0°, and both positions must fall within the range of −180° to 270°. The bioreactor moves back and forth between the start and end positions for the duration of the task or a step of a task.

The dwell time indicates how long the system rests at the start and end positions. The dwell time range is 0 to 3600 sec. The following example shows how this operator's manual denotes In Motion as the rocker setting:

In Motion (−90°, 180°, 1 sec)

Selecting In Motion as the Rocker Setting

The following instructions explain how to select In Motion as the rocker setting for a task or a step of a task. For information about using the data entry pad, see “Using the Data Entry Pad” on page 3-21.

From the Setup screen:

1. Touch **Rocker**.

   The Setup: Rocker window opens, as shown in Figure 6-6.

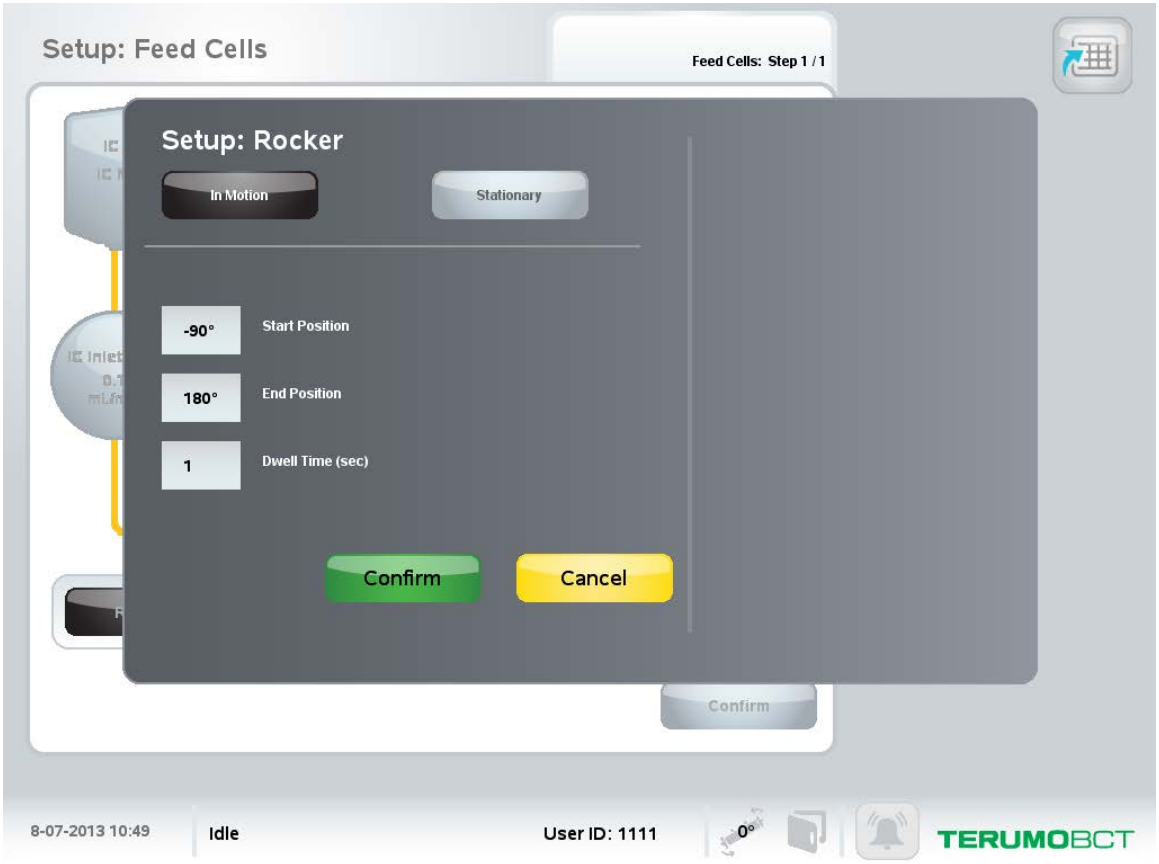


Figure 6-6: Setup: Rocker window

2. Touch **In Motion**.
   Three data entry fields appear, and **In Motion** changes to black.
3. Touch the Start Position field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired number of degrees from the home position of 0°.
5. Touch **Enter** on the data entry pad.
   The Start Position field displays the position you entered.
6. Touch the End Position field.
   A data entry pad appears.
7. Use the data entry pad to enter the desired number of degrees from the home position of 0°.
8. Touch **Enter** on the data entry pad.
   The End Position field displays the position you entered.
9. Touch the Dwell Time field.
   A data entry pad appears.
10. Enter the desired dwell time using the data entry pad.
11. Touch **Enter** on the data entry pad.
    The Dwell Time field displays the number of seconds you entered.
12. Touch **Confirm**.
    The Setup: Rocker window closes.

Stationary

The Stationary rocker setting includes a single value, which denotes the fixed position the bioreactor holds for the duration of a step of a task. The position is a certain number of degrees from the home position of 0°, and it must fall within the range of –180° to 270°. The following example shows how this operator's manual denotes Stationary as the rocker setting:

Stationary (45°)

Selecting Stationary as the Rocker Setting

The following instructions explain how to select Stationary as the rocker setting for a step of a task. For information about using the data entry pad, see “Using the Data Entry Pad” on page 3-21.
From the Setup screen:

1. Touch **Rocker**.
   The Setup: Rocker window opens.
2. Touch **Stationary**.
   The Position field appears, and **Stationary** changes to black.
3. Touch the Position field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired number of degrees from the home position of 0°.
5. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the Position field displays the position you entered.
6. Touch **Confirm**.
   The Setup: Rocker window closes.

Stop Condition

The stop condition determines how and when the system stops performing the current task or step of a task. There are eight stop conditions: Manual, Time, IC Volume, EC Volume, Exchange, Empty Bag, Inlet Volume, and System. You must select a stop condition for each task or step of a task. Each stop condition is based on specific criteria that the system must meet before the system stops and ends a task or a step of a task.

Manual

The Manual stop condition requires the operator to stop the system manually by touching **Finish** or starting another task. The following example shows how this operator's manual denotes the Manual stop condition:

Manual

Selecting the Manual Stop Condition

The following instructions explain how to select Manual as the stop condition for a task or a step of a task.
From the Setup screen:

1. Touch **Stop Condition**.

   The Setup: Stop Condition window opens, as shown in Figure 6-7.

Figure 6-7: Setup: Stop Condition window

2. Touch **Manual**.
   Manual changes to black.
3. Touch **Confirm**.
   The Setup: Stop Condition window closes, and the stop condition you selected appears to the right of **Stop Condition**.

Time

The Time stop condition allows you to specify the total number of minutes that must elapse before the system ends the step. The following example shows how this operator's manual denotes the Time stop condition:

Time (4 min)

Selecting the Time Stop Condition

The following instructions explain how to select Time as the stop condition for a task or a step of a task. For information about using the data entry pad, see “Using the Data Entry Pad” on page 3-21.
From the Setup screen:

1. Touch **Stop Condition**.
   The Setup: Stop Condition window opens.
2. Touch **Time**.
   A data entry field appears, and **Time** changes to black.
3. Touch the data entry field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired number of minutes.
5. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the data entry field displays the number of minutes you entered.
6. Touch **Confirm**.
   The Setup: Stop Condition window closes.

Exchange

The Exchange stop condition includes two values: the IC Volumes value and the EC Volumes value. The IC Volumes and EC Volumes values are units of measure unique to the Quantum system. IC Volumes reflects the IC circulation loop volume plus an approximated inlet line volume. EC Volumes reflects the EC circulation loop volume plus an approximated inlet line volume.

1 IC Volume = the volume of fluid in the IC circulation loop + an approximated inlet line volume (approximately 200 mL of fluid)

1 EC Volume = the volume of fluid in the EC circulation loop + an approximated inlet line volume (approximately 300 mL of fluid)

For example, if you enter 1.5 IC Volumes, the system calculates, based on the IC circulation loop volume, the amount of fluid needed to exchange the volume of fluid in the IC circulation loop 1 ½ times. The system then adds fluid until it reaches the calculated amount and the task ends. The system also determines the pump rates based on the values that you enter for both IC Volumes and EC Volumes, so it always reaches the specified IC Volumes and EC Volumes at the same time. The following example shows how this operator's manual denotes the Exchange stop condition:

Exchange (2.5 IC Volumes) (2.5 EC Volumes)

Selecting the Exchange Stop Condition

The following instructions explain how to select Exchange as the stop condition for a task or a step of a task. For information about using the data entry pad, see "Using the Data Entry Pad" on page 3-21. From the Setup screen:

1. Touch **Stop Condition**.
   The Setup: Stop Condition window opens.
2. Touch **Exchange**.
   Two data entry fields appear, and **Exchange** changes to black.
3. Touch the first data entry field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired number of IC Volumes.
5. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the data entry field displays the number of IC Volumes you entered.
6. Touch the second data entry field.
   A data entry pad appears.
7. Use the data entry pad to enter the desired number of EC Volumes.
8. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the data entry field displays the number of EC Volumes you entered.
9. Touch **Confirm**.
   The Setup: Stop Condition window closes.

IC Volume

The IC Volume stop condition allows you to specify the total IC inlet volume that must be added before the system ends the step. The following example shows how this operator's manual denotes the IC Volume stop condition:

IC Volume (50 mL)

Selecting the IC Volume Stop Condition

The following instructions explain how to select IC Volume as the stop condition for a task or a step of a task. For information about using the data entry pad, see "Using the Data Entry Pad" on page 3-21. From the Setup screen:

1. Touch **Stop Condition**.
   The Setup: Stop Condition window opens.
2. Touch **IC Volume**.
   A data entry field appears, and **IC Volume** changes to black.
3. Touch the data entry field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired volume.
5. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the data entry field displays the volume you entered.
6. Touch **Confirm**.
   The Setup: Stop Condition window closes.

EC Volume

The EC Volume stop condition allows you to specify the total EC inlet volume that must be added before the system ends the step. The following example shows how this operator's manual denotes the EC Volume stop condition:

EC Volume (50 mL)

Selecting the EC Volume Stop Condition

The following instructions explain how to select EC Volume as the stop condition for a task or a step of a task. For information about using the data entry pad, see “Using the Data Entry Pad” on page 3-21.
From the Setup screen:

1. Touch **Stop Condition**.
   The Setup: Stop Condition window opens.
2. Touch **EC Volume**.
   A data entry field appears, and **EC Volume** changes to black.
3. Touch the data entry field.
   A data entry pad appears.
4. Use the data entry pad to enter the desired volume.
5. Touch **Enter** on the data entry pad.
   The data entry pad closes, and the data entry field displays the volume you entered.
6. Touch **Confirm**.
   The Setup: Stop Condition window closes.

Empty Bag

The Empty Bag stop condition allows you to empty a bag into the system completely. The following example shows how this operator's manual denotes the Empty Bag stop condition:

Empty Bag

Selecting the Empty Bag Stop Condition

The following instructions explain how to select Empty Bag as the stop condition for a task or a step of a task.
From the Setup screen:

1. Touch **Stop Condition**.
   The Setup: Stop Condition window opens.
2. Touch **Empty Bag**.
   Empty Bag changes to black.
3. Touch **Confirm**.
   The Setup: Stop Condition window closes.

Inlet Volume

The Inlet Volume stop condition is available only on High Density Washout. The Inlet Volume stop condition indicates the total inlet volume (based on both the IC inlet and the EC inlet volumes) that must be added before the system ends the step. When you select High Density Washout, the system

pre-selects the Inlet Volume stop condition, and you cannot modify the task to use any of the other stop conditions. The following example shows how this operator's manual denotes the Inlet Volume stop condition:

Inlet Volume (1000 mL)

System

The System stop condition is used when the system performs an internal process that is required to complete a task. The operator cannot select the System stop condition; however, when the system is performing an internal process, the Stop Condition window displays System.

Table of Tasks

Table 6-5 contains a list of all the tasks, except for the Custom tasks, that are available on the Quantum system. This table is meant as a reference for you in determining which tasks to perform and for what purpose.

Table 6-5: Tasks available on the Quantum system

	Task Name	Adherent Cells	Suspension Cells	Purpose	Page
Set Management Tasks	Load Cell Expansion Set	Yes	Yes	Allows you to load the cell expansion set onto the Quantum device.	page 7-2
	Prime Cell Expansion Set	Yes	Yes	Allows you to remove air from the cell expansion set.	page 7-10
	Unload Cell Expansion Set	Yes	Yes	Allows you to remove the cell expansion set from the Quantum device.	page 7-12
	Connect Sampling Coil	Yes	Yes	Allows you to attach a sampling coil accessory set to the cell expansion set.	page 7-13
System Management Tasks	Remove IC Air	Yes	Yes	Allows you to remove any visible air from the inlet port and the outlet port of the IC side of the bioreactor.	page 8-2
	Remove EC Air	Yes	Yes	Allows you to remove any visible air from the inlet port and the outlet port of the EC side of the bioreactor.	page 8-4
	Condition Media	Yes	Yes	Allows the media to reach equilibrium with the provided gas supply.	page 8-6
	Coat Bioreactor	Yes	Yes	Allows you to coat the bioreactor membrane.	page 8-8
Washout Tasks	High Density Washout	Yes	No	Allows you to remove any non-adhered cells from the bioreactor after loading 25 mL to 62 mL of bone marrow.	page 9-2
	Rapid IC Washout	Yes	No	Allows you to remove non-adherent cells from the bioreactor.	page 9-3
	IC EC Washout	Yes	No	Allows you to replace the fluid in both the IC circulation loop and the EC circulation loop.	page 9-5
	IC EC Washout Through Membrane	Yes	Yes	Allows you to replace small molecule components on the IC side of the bioreactor and all the components on the EC side.	page 9-7
	Inlet Line Washout	Yes	Yes	Allows you to wash a line or add fluid to a bag using fluid from another bag.	page 9-9

Table 6-5: Tasks available on the Quantum system (continued)

	Task Name	Adherent Cells	Suspension Cells	Purpose	Page
Load and Attach Tasks	Load Cells With Circulation	Yes	Yes	Allows you to load the cells from the cell inlet bag into the IC circulation loop until the bag is empty, and uses IC circulation to distribute the cells.	page 10-2
	Load Cells Without Circulation	Yes	Yes	Allows you to load the cells from the cell inlet bag into the bioreactor via the IC circulation loop until the bag is empty.	page 10-5
	Attach Cells	Yes	No	Allows adherent cells to attach to the bioreactor membrane while allowing flow in the EC circulation loop.	page 10-7
	Load Cells With Uniform Suspension	Yes	Yes	Allows you to load the cells into the bioreactor from the cell inlet bag until the bag is empty and to use IC circulation to create uniform cell suspension.	page 10-9
Feed and Add Tasks	Feed Cells With Ultrafiltration	Yes	Yes	Allows you to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. This task uses ultrafiltration to remove excess IC fluid.	page 11-2
	Feed Cells	Yes	No	Allows you to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. There are several outlet settings that you can use to remove the fluid that is added to the system during this task.	page 11-4
	Add Bolus	Yes	Yes	Allows you to quickly add a selected volume of reagent into the IC circulation loop; you can also add a bolus into the EC circulation loop at the same time.	page 11-6
	Add Bag Contents	Yes	Yes	Allows you to load a fluid, such as a reagent, into the IC circulation loop until the bag that contains the fluid is empty.	page 11-8
	Add Fluid Continuously	Yes	No	Allows you to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. There are several outlet settings that you can use to remove the fluid that is added to the system during this task.	page 11-10
	Add Fluid Continuously With Ultrafiltration	Yes	Yes	Allows you to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. This task uses ultrafiltration to remove excess IC fluid.	page 11-12

Table 6-5: Tasks available on the Quantum system (continued)

	Task Name	Adherent Cells	Suspension Cells	Purpose	Page
Release and Harvest Tasks	Release Adherent Cells	Yes	No	Allows you to release cells from the membrane, leaving the cells in the IC circulation loop.	page 12-2
	Release Adherent Cells And Harvest	Yes	No	Allows you to release and harvest cells.	page 12-5
	Harvest Cells	Yes*	Yes	Transfers cells in suspension from the IC circulation loop, including cells in the bioreactor, to the harvest bag. *When using adherent cells you must always perform the Release Adherent Cells task before performing this task so that the cells are suspended and ready for harvesting.	page 12-9

7

Set Management Tasks

Load Cell Expansion Set

Warning: Use caution when interacting with the Quantum device, because it has moving parts that could injure fingers and entangle hair, clothing, or other personal articles.

Warning: Do not use excessive force when loading or unloading the cell expansion set, because this could lead to operator injury.

Warning: Follow your institution's standard operating procedures for wearing personal protective equipment when using the Quantum system.

Warning: Always use protective eyewear when operating the Quantum system.

Caution: Use only your fingers to load the cell expansion set. Do not use a sharp object, or you may puncture the tubing.

The purpose of this task is for the system to open all the valves, which allows you to load the cell expansion set.

1. Touch **Task**.
2. Touch **Set Management**.
3. Touch **Load Cell Expansion Set**.
   The Setup: Load Cell Expansion Set screen appears. You can edit the name of the current run report at this time by touching the Report Name field. For more information, see "Editing the Name of the Current Run Report at the Start of Load Cell Expansion Set" on page 15-9.
4. Touch **Start**.
   The Load Cell Expansion Set Status screen appears and includes a progress bar. The system opens all the valves, and you can proceed with the remaining steps of loading the cell expansion set.
5. Open the incubator door.

6. Unlock the rotor latches, and open the rotor covers on the pumps, as shown in Figure 7-1.

Note: The rotor cover on the EC inlet pump cannot remain open because of hindrance from the incubator wall.

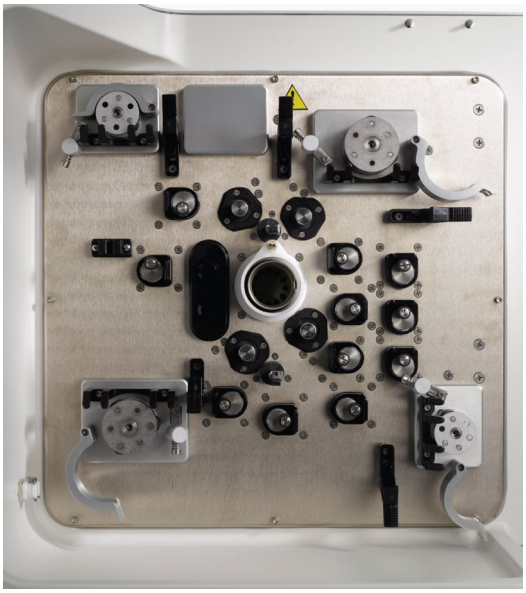


Figure 7-1: Rotor covers open

7. Open the five external mounting clips.
8. Confirm that the internal mounting clips are in the correct horizontal position, as shown in Figure 7-2, and if they are not, perform the following steps:
   a. Grasp the top internal mounting clip, bend it to the side, and pull and rotate it one-quarter turn clockwise to open the clip.
   b. Grasp the bottom internal mounting clip, bend it to the side, and pull and rotate it one-quarter turn clockwise to open the clip.

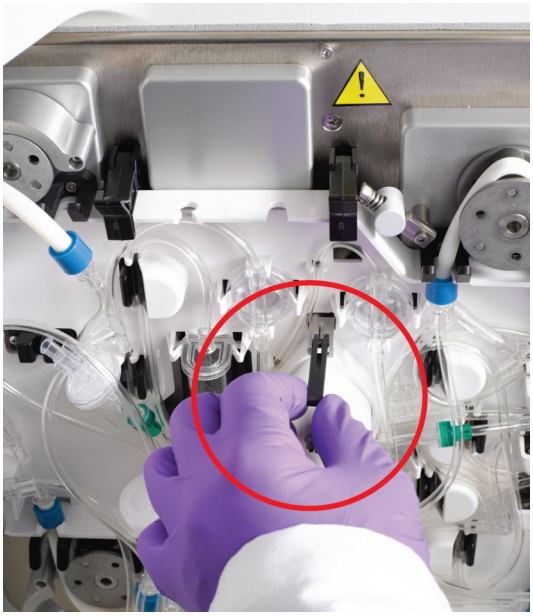


Figure 7-2: An internal mounting clip in the correct horizontal position

9. Peel back the tray cover from the cell expansion set package.
10. Place the tubing organizer on the mounting plate:
    - Grasp the sides of the tubing organizer with both hands, lift the tubing organizer up to the mounting plate, align the hole in the center of the tubing organizer with the rocker arm on the mounting plate, and partially slide the tubing organizer onto the rocker arm.
    - Rest the bioreactor with the attached rocker assembly on the spill tray of the Quantum device, as shown in Figure 7-3.
    - Take out the coils and the bags, and set them aside.
11. Press on the sides of the tubing organizer to snap it onto the mounting plate, and ensure that all five external mounting clips lock over the edges of the tubing organizer. Figure 7-3 shows the tubing organizer attached to the mounting plate.

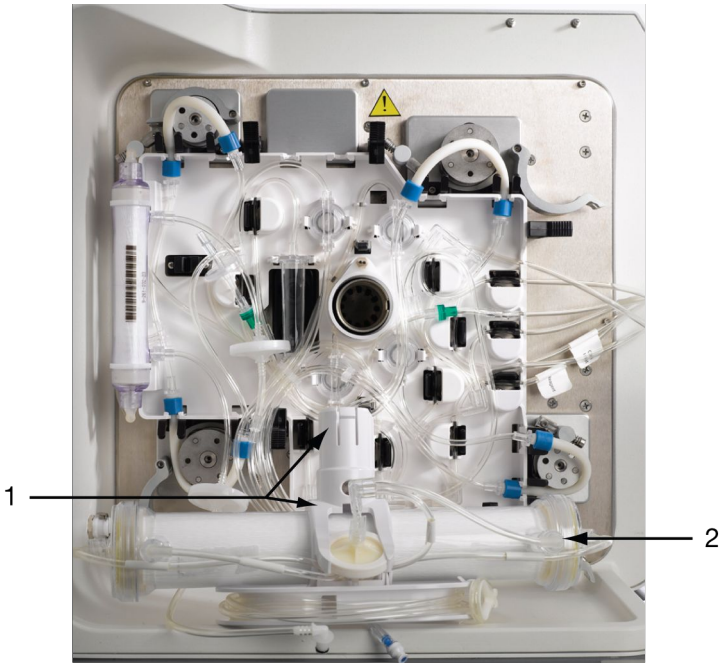


Figure 7-3: Tubing organizer attached to the mounting plate

1 Rocker assembly

2 Bioreactor (with the rocker assembly attached) resting on the spill tray

Caution: When loading the cell expansion set, do not turn the internal mounting clips more than a quarter turn, or you could pinch the tubing.

12. Grasp the top internal mounting clip, bend it up, and rotate the base of the mounting clip one-quarter turn counter-clockwise to secure the tubing organizer to the mounting plate, as shown in Figure 7-4.

Figure 7-4: Securing the tubing organizer with an internal mounting clip

13. Repeat step 12 with the bottom internal mounting clip.
14. Ensure that the rotor latches are unlocked and that the rotor covers on the pumps are open.

Note: The rotor cover on the EC inlet pump cannot remain open because of hindrance from the incubator wall.

15. Grasp the blue collar at the base of the tubing that is not attached to the tubing organizer, as shown in Figure 7-5.

Figure 7-5: Grasping the blue collar

16. Pull the tubing over the center of the pump rotor, through the prong, and in behind the notch, as shown in Figure 7-6.

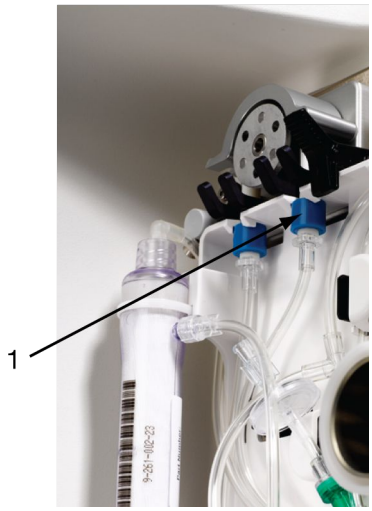


Figure 7-6: Loading the tubing into the pump

1 **Blue collar correctly loaded behind the notch**

17. Ensure that the tubing is centered on the pump rotor, as shown in Figure 7-7.

Figure 7-7: Tubing centered on the pump rotor

18. Close the rotor cover and lock the rotor latch. Figure 7-8 shows tubing properly loaded onto a pump.

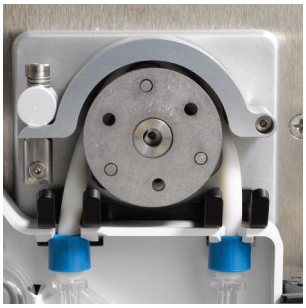


Figure 7-8: Tubing properly loaded onto a pump

19. Repeat steps 15 through 18 to load all four pumps.
20. Use a flossing technique to load the EC inlet line located on the right side of the EC inlet pump into the EC fluid detector. Figure 7-9 shows the EC inlet line properly loaded into the EC fluid detector.

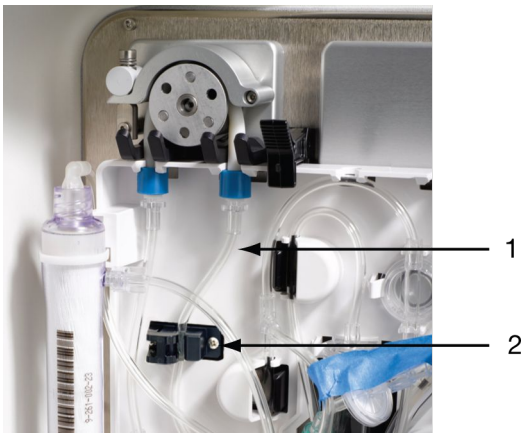


Figure 7-9: EC inlet line properly loaded

1 **EC inlet line on the right side of the EC inlet pump**

2 **EC inlet line loaded into the EC fluid detector**

21. Align the notch on the rocker arm to the groove on the rocker assembly.

22. Push the rocker assembly into the rocker arm until it is completely inserted. The bioreactor will be in the home position with the EC inlet and EC outlet ports facing upward and the sample port facing downward, as shown in Figure 7-10.

Note: The lines going into the rocker assembly should not wrap around the rocker arm; they should hang below the bioreactor.

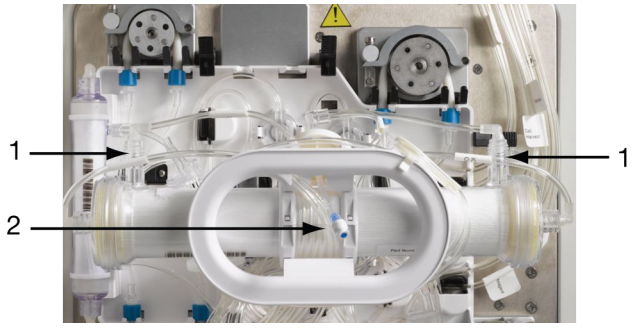


Figure 7-10: Bioreactor in the home position

1 EC inlet and EC outlet ports facing upward

2 Sample port facing downward

23. Verify that the lines are inserted into the valves correctly.
24. Hang the waste bag on the bag pole.
25. Hang the harvest bag on the bag pole.
26. Check for kinked lines.
27. Press the tubing line guide onto the pegs located on the top-right side of the incubator door frame (as you face the mounting plate). Figure 7-11 shows the tubing line guide properly attached.

Figure 7-11: Tubing line guide properly attached

28. Remove the two blue end caps and the one red end cap from the cell expansion set.
29. Connect the gas inlet line to the gas quick disconnect located inside the incubator on the bottom-left side, as shown in Figure 7-12. Rotate the gas inlet line towards the back of the incubator so it does not hinder the rocker motion.
You should hear a click when you properly connect the gas inlet line.

Figure 7-12: Connecting the gas inlet line

30. Ensure that all lines are clear of the incubator door.
31. Close the incubator door.

Caution: If you have loaded a cell expansion set but you do not plan to prime the set until the following day, turn off the external gas supply to avoid excess gas buildup in the waste bag.

32. Touch **Finish**.
33. Touch **Yes**.
    The home screen appears, the system changes to an idle state, and the status line displays Idle.
34. Properly dispose of the cell expansion set packaging.

Prime Cell Expansion Set

The purpose of this task is to remove air from the set. Before you begin this task, you should have a media bag available that contains at least 2 L of desired electrolyte solution, such as PBS (phosphate buffered saline) or HBSS (Hank's Buffered Salt Solution), to use for priming the cell expansion set.

Caution: When priming the cell expansion set, do not connect the fluids to the cell expansion set before you are instructed to do so.

Caution: Do not use chilled fluid to prime the cell expansion set.

1. Turn on the external gas supply.
2. Attach the media bag to the cell line, and hang the bag on the bag pole.
3. Touch **Task**.
4. Touch **Set Management**.
5. Touch **Prime Cell Expansion Set**.
   The Setup: Prime Cell Expansion Set screen appears.
6. Touch **Start**.

   Priming begins, and the system updates the Prime Cell Expansion Set status screen and the status message at each step throughout the prime process.

Note: During the final step of prime, the bioreactor is oriented at 180°.

7. Take a sample from the sample port to prime the filter. See “Taking a Sample from the Sample Port” on page 5-7 for sampling instructions.
8. Touch **Finish** when you are finished sampling.
9. Touch **Yes**.
   The home screen appears, the system changes to an idle state, the status line displays Idle, and the bioreactor moves to the home position of 0°.
10. Seal and remove the waste bag on the outlet line. Then use a sterile tubing welder to attach a replacement bag to the outlet line, and hang the bag on the bag pole.
11. Separate the tubing lines, as described in “Separating the Tubing Lines” on page 7-11.

Separating the Tubing Lines

Note: Each line has two white tags that state the name of that line.

After the system primes the cell expansion set, you must manually separate the lines of the EC media/reagent loop and the IC media/wash loop, as outlined in the following instructions. Before you begin, remove the tape from the coils of lines if you have not already done so.

Caution: When you seal each line loop, seal it in a location that ensures that each resulting line has a name tag. For example, the EC media tag should be located on one line and the reagent tag on the other line; the IC media tag should be located on one line and the wash tag on the other line.

Note: All seals should be double seals.

1. Find the midpoint between the EC media tag and the reagent tag, and seal the line at that point with a tubing sealer.
2. Find the midpoint between the IC media tag and the wash tag, and seal the line at that point with a tubing sealer.
3. Separate each loop at the seal to divide each loop into two lines.

Unload Cell Expansion Set

The purpose of this task is for the system to open all the valves, which allows you to unload the cell expansion set.

Note: All seals should be double seals.

When the task is completed:

1. Seal and disconnect the lines on all the bags.
2. Touch **Task**.
3. Touch **Set Management**.
4. Touch **Unload Cell Expansion Set**.
   The Setup: Unload Cell Expansion Set screen appears.
5. Touch **Start**.
   The Unload Cell Expansion Set status screen appears and includes a progress bar. The system opens all the valves.
6. Open the incubator door.
7. Unlock the rotor latches, and open the rotor covers on the pumps.
8. Remove the tubing from the pumps.
9. Disconnect the gas inlet line from the gas quick disconnect by pressing down on the silver button on the top of the gas inlet line.
10. Turn off the external gas supply.
11. Remove the bioreactor from the rocker arm.
12. Remove the tubing line guide from the pegs.
13. Grasp the top internal mounting clip, bend it to the left, and rotate it a quarter turn clockwise to unlatch the clip from the tubing organizer.
14. Grasp the bottom internal mounting clip, bend it to the left, and rotate it a quarter turn clockwise to unlatch the clip from the tubing organizer.
15. Unlock the five external mounting clips, and wiggle the tubing organizer in and out while pulling it towards yourself to pull it off the mounting plate.
16. Dispose of the cell expansion set properly.
17. Close the rotor covers, and lock the rotor latches on all the pumps.
18. Touch **Finish** when you are ready to complete the task.
19. Touch **Yes**.
    The home screen appears, the system changes to an idle state, and the status line displays Idle.

Connect Sampling Coil

The purpose of this task is to attach a sampling coil accessory set to the cell expansion set after the existing sample coil on the cell expansion set has been used.

1. Touch **Task**.
2. Touch **Set Management**.
3. Touch **Connect Sampling Coil**.
   The Setup: Connect Sampling Coil screen appears, as shown in Figure 7-13, which prompts you to select the IC Inlet Source and enter the chase volume.

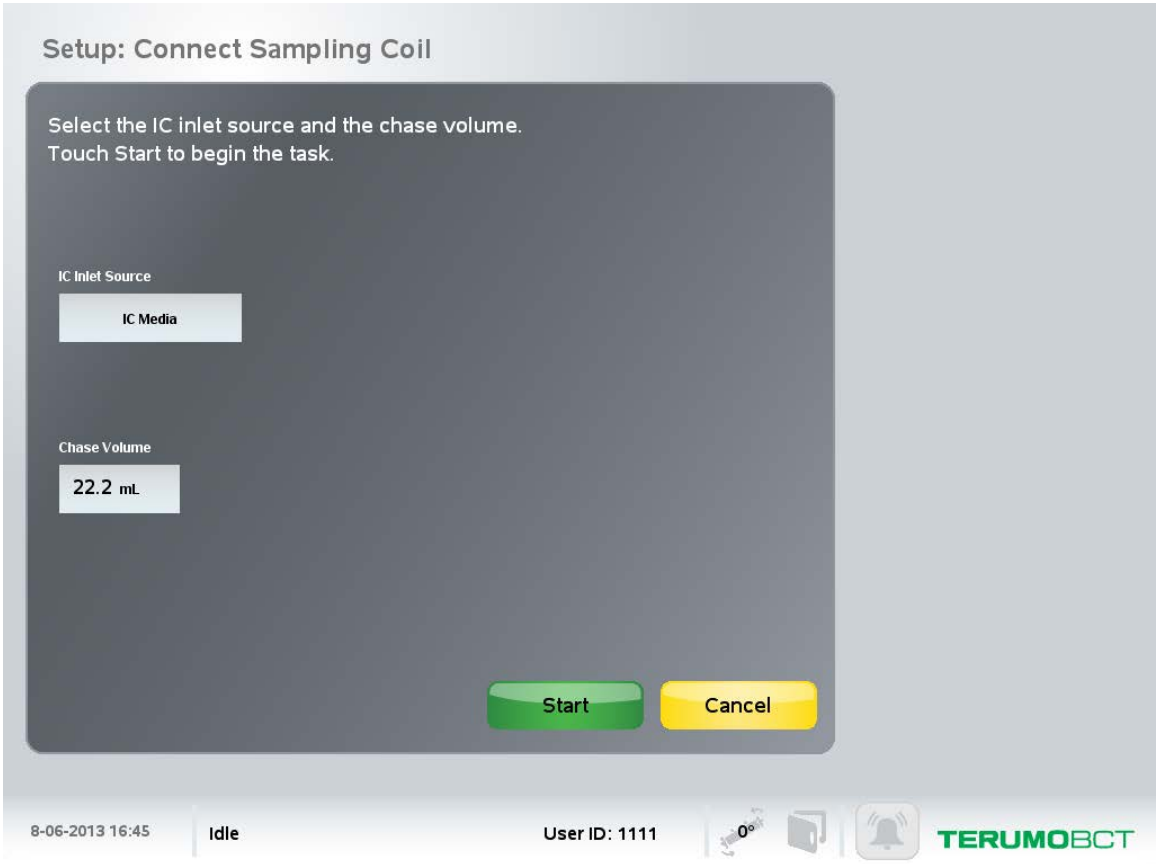


Figure 7-13: Setup: Connect Sampling Coil screen

4. Touch the IC Inlet Source field.
   A menu of IC inlet source options appears, and the IC Inlet Source field changes to black. The available IC inlet source options for this task include IC Media, Reagent, EC Media, and Wash.
5. Select the desired IC Inlet Source from the menu.
   The IC Inlet Source field displays the option you selected and changes to gray.
6. Touch the Chase Volume field.
   A data entry pad appears.
7. Enter the desired chase volume using the data entry pad.
   The data entry pad displays the chase volume you entered.
8. Touch **Start**.
   The Connect Sampling Coil status screen appears and includes a progress bar.

9. When the screen prompts you to connect the sampling coil, open the incubator door, remove the sample coil strain relief from the rocker assembly by lifting one tab, and uncoil the existing sample coil from the rocker assembly.
10. Remove the sample coil strain relief from the line.
11. Use a sterile tubing welder to attach the end of the sampling coil accessory set that has a filter to one end of the existing sample coil.
12. Use a sterile tubing welder to attach the remaining end of the sampling coil accessory set to the remaining end of the existing sample coil.
13. Open the sterile welds.
14. Connect the sample coil strain relief to the sample coil line.
15. Recoil the sample coil around the rocker assembly.
16. Connect the sample coil strain relief to the rocker assembly.
17. Close the incubator door.
18. Touch **Next**.
    The system continues the task, and the system updates the Connect Sampling Coil status screen and the status message at each step throughout the task. When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

8

System Management Tasks

Remove IC Air

Caution: Periodically inspect the IC (intracapillary) inlet header and the IC outlet header for air, and if either header contains visible air, remove the air by performing the Remove IC Air task.

The purpose of this task is to remove any visible air from the inlet port and the outlet port of the IC side of the bioreactor. Figure 8-1 shows the IC inlet and IC outlet headers located on the bioreactor.

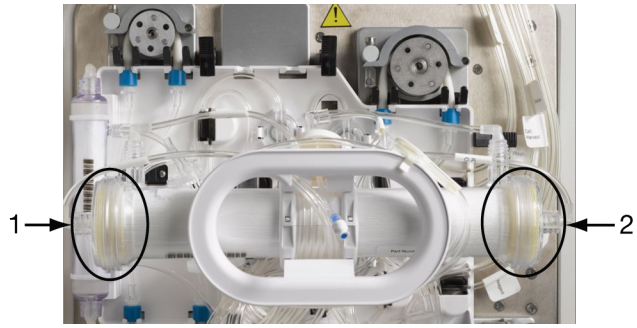


Figure 8-1: IC headers

1 IC inlet header
2 IC outlet header

To perform Remove IC Air:

1. Touch **Task**.
2. Touch **System Management**.
3. Touch **Remove IC Air**.

   The Setup: Remove IC Air screen appears, which prompts you to select the inlet source, as shown in Figure 8-2.

Figure 8-2: Setup: Remove IC Air screen

4. Touch the Inlet Source field.
   A menu of inlet source options appears, and the Inlet Source field changes to black. The available inlet source options for this task include IC Media, Reagent, EC Media, and Wash.
5. Select the desired inlet source from the menu.
   The Inlet Source field displays the option you selected and changes to gray.
6. Touch **Start**.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Remove EC Air

Caution: Periodically inspect the EC (extracapillary) inlet port and the EC outlet port for air, and if either port contains visible air, remove the air by performing the Remove EC Air task.

The purpose of this task is to remove any visible air from the inlet port and outlet port of the EC side of the bioreactor. The system starts this task by removing air from the EC outlet, then it removes air from the EC inlet, and then it removes any residual air left in the EC outlet. Figure 8-3 shows the EC inlet and EC outlet ports located on the bioreactor.

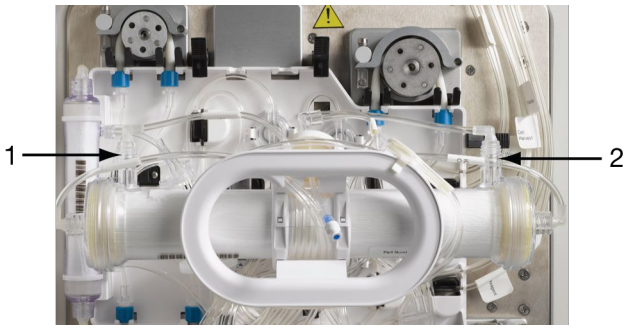


Figure 8-3: EC ports

1 EC inlet port

2 EC outlet port

To perform Remove EC Air:

1. Touch **Task**.
2. Touch **System Management**.
3. Touch **Remove EC Air**.

   The Setup: Remove EC Air screen appears, which prompts you to select the inlet source, as shown in Figure 8-4.

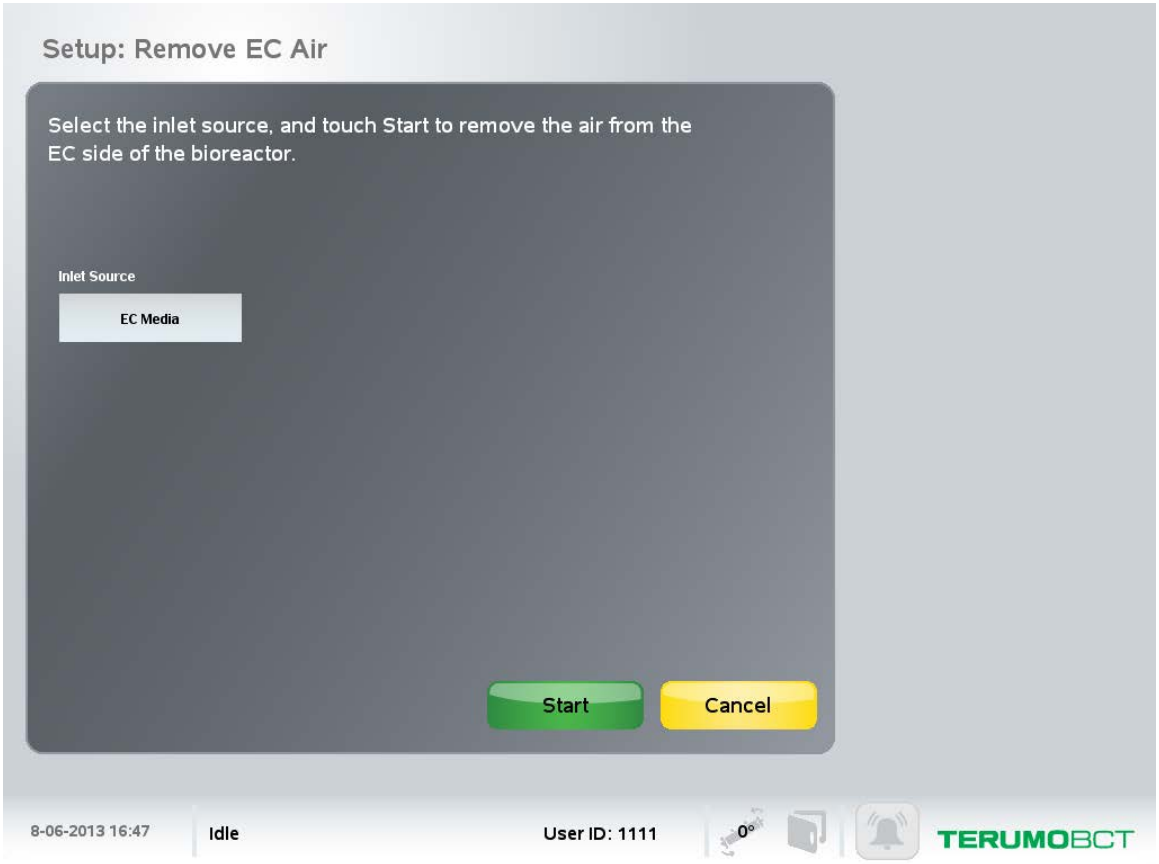


Figure 8-4: Setup: Remove EC Air screen

4. Touch the Inlet Source field.
   A menu of inlet source options appears, and the Inlet Source field changes to black. The available inlet source options for this task include IC Media, Reagent, EC Media, and Wash.
5. Select the desired inlet source from the menu.
   The Inlet Source field displays the option you selected and changes to gray.
6. Touch **Start**.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Condition Media

Note: Use the information in “Performing Tasks” to complete this task.

The purpose of this task is to allow the media to reach equilibrium with the provided gas supply before loading the cells. This task includes two separate steps:

- Step 1: provides rapid contact between the media and the gas supply by using a high EC circulation rate.
- Step 2: maintains the system in a proper state until the operator is ready to load the cells.

Table 8-1 describes the types of solution that are needed to attach to each line when performing Condition Media. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 8-1: Solutions for Condition Media

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	None	N/A
Wash	None	N/A
EC Media	Media without protein	0.1 L plus 6 mL/hour

Condition Media pathway: **Task** > **System Management** > **Condition Media**

1. Confirm the settings for step 1 shown in Table 8-2.

Table 8-2: Step 1 Settings for Condition Media

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	100 mL/min	N/A
EC Inlet	EC Media	Reagent, IC Media, EC Media, Wash
EC Inlet Rate	0.1 mL/min	N/A
EC Circulation Rate	250 mL/min	N/A

Table 8-2: Step 1 Settings for Condition Media (continued)

Setting	Factory Default	Setting Options
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	Stationary (–180° to 270°)
Stop Condition	Time (10 min)	Time (6 to 15 min)

2. Confirm the settings for step 2 shown in Table 8-3.

Table 8-3: Step 2 Settings for Condition Media

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	100 mL/min	Same as step 1
EC Inlet	EC Media	Same as step 1
EC Inlet Rate	0.1 mL/min	Same as step 1
EC Circulation Rate	30 mL/min	0 to 100 mL/min
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	Stationary (–180° to 270°)
Stop Condition	Manual	N/A

3. Touch **Start**.
4. Check the status line to confirm that the task has started.
5. Touch **Finish** when you are ready to complete the task.
6. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

Coat Bioreactor

The purpose of this task is to coat the bioreactor membrane with a reagent.

- Step 1: loads a reagent into the IC circulation loop until the bag is empty.
- Step 2: chases the reagent from the ARC into the IC circulation loop.
- Step 3: circulates the reagent in the IC circulation loop.

Table 8-4 describes the types of solution that are needed to attach to each line when performing Coat Bioreactor. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Table 8-4: Solutions for Coat Bioreactor

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	Reagent	As desired
IC Media	None	N/A
Wash	Wash solution	0.1 L plus 6 mL/hr
EC Media	None	N/A

Coat Bioreactor pathway: **Task** > **System Management** > **Coat Bioreactor**

1. Confirm the settings for step 1 shown in Table 8-5.

Table 8-5: Step 1 Settings for Coat Bioreactor

Setting	Factory Default	Setting Options
IC Inlet	Reagent	Cell, Reagent
IC Inlet Rate	10 mL/min	0.1 to 100 mL/min
IC Circulation Rate	100 mL/min	–300 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	0 to 100 mL/min

Table 8-5: Step 1 Settings for Coat Bioreactor (continued)

Setting	Factory Default	Setting Options
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Empty Bag	N/A

2. Confirm the settings for step 2 shown in Table 8-6.

Table 8-6: Step 2 Settings for Coat Bioreactor

Setting	Factory Default	Setting Options
IC Inlet	Wash	IC Media, Wash, EC Media
IC Inlet Rate	10 mL/min	Same as step 1
IC Circulation Rate	100 mL/min	Same as step 1
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	Same as step 1
Stop Condition	IC Volume (22 mL)	IC Volume (1 to 100 mL)

3. Confirm the settings for step 3 shown in Table 8-7.

Table 8-7: Step 3 Settings for Coat Bioreactor

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	20 mL/min	N/A
EC Inlet	Wash	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	0.1 mL/min	N/A
EC Circulation Rate	30 mL/min	N/A

Table 8-7: Step 3 Settings for Coat Bioreactor (continued)

Setting	Factory Default	Setting Options
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	Same as step 1
Stop Condition	Manual	Manual, Time (0.1 to 2880 min)

4. Touch **Start**.
5. Check the status line to confirm that the task has started.
6. Touch **Finish** when you are ready to complete the task.
7. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

9

Washout Tasks

High Density Washout

The purpose of this task is to remove any non-adhered cells from the bioreactor after loading 25 mL to 62 mL of bone marrow. The types of cells removed include red blood cells, platelets, and non-adherent mononuclear cells.

This task is also a useful washout task for any occasion when the bioreactor is packed with a large number of cells. When loading 10 mL or less of bone marrow, the Rapid IC Washout task is recommended. When loading between 10 mL and 25 mL of bone marrow, no specific guidelines exist; using this task in such cases should not cause problems but may not be necessary.

Table 9-1 describes the types of solution that are needed to attach to each line when performing High Density Washout. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 9-1: Solutions for High Density Washout

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	Approximately 0.5 L
Wash	None	N/A
EC Media	Media without protein	Approximately 0.5 L

High Density Washout pathway: **Task** > **Washout** > **High Density Washout**

1. Confirm the settings for High Density Washout shown in Table 9-2.

Table 9-2: Settings for High Density Washout

Setting	Factory Default	Setting Options
IC Inlet	IC Media	IC Media, Wash, EC Media
Maximum IC Inlet Rate	100 mL/min	80 to 200 mL/min
EC Inlet	EC Media	IC Media, Wash, EC Media
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Stop Condition	Inlet Volume (1000 mL)	Inlet Volume (400 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Rapid IC Washout

The purpose of this task is to remove non-adherent cells from the bioreactor. This task imposes ultrafiltration onto the fiber across the entire fiber length.

Table 9-3 describes the types of solution that are needed to attach to each line when performing Rapid IC Washout. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 9-3: Solutions for Rapid IC Washout

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	0.6 L
Wash	None	N/A
EC Media	Media without protein	0.1 L

Rapid IC Washout pathway: **Task** > **Washout** > **Rapid IC Washout**

1. Confirm the settings for Rapid IC Washout shown in Table 9-4.

Table 9-4: Settings for Rapid IC Washout

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	260 mL/min	50 to 500 mL/min
IC Circulation Rate	–45 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	40 mL/min	0 to 100 mL/min
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	IC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)

Table 9-4: Settings for Rapid IC Washout (continued)

Setting	Factory Default	Setting Options
Stop Condition	Exchange (2.5 IC Volumes) (N/A for EC Volumes)	Time (0.1 to 60 min), IC Volume (1 to 4000 mL), Exchange (0.5 to 5.0 IC Volumes) (N/A for EC Volumes)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

IC EC Washout

The purpose of this task is to replace the fluid in both the IC circulation loop and the EC circulation loop. The replacement volume is specified by the number of IC Volumes and EC Volumes exchanged.

Table 9-5 describes the types of solution that are needed to attach to each line when performing IC EC Washout. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 9-5: Solutions for IC EC Washout

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	0.6 L
Wash	None	N/A
EC Media	Media without protein	0.9 L

IC EC Washout pathway: **Task** > **Washout** > **IC EC Washout**

1. Confirm the settings for IC EC Washout shown in Table 9-6.

Table 9-6: Settings for IC EC Washout

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	100 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate and the number of IC Volumes and EC Volumes used for the Exchange stop condition for this task.
IC Circulation Rate	–17 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	148 mL/min	N/A The system automatically calculates this rate based on the number of IC Volumes and EC Volumes used for the Exchange stop condition for this task.

Table 9-6: Settings for IC EC Washout (continued)

Setting	Factory Default	Setting Options
EC Circulation Rate	–1.7 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate for this task.
Outlet	IC and EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Exchange (2.5 IC Volumes) (2.5 EC Volumes)	Exchange (0.5 to 5.0 IC Volumes) (0.5 to 5.0 EC Volumes)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

IC EC Washout Through Membrane

The purpose of this task is to replace small molecule components on the IC side that pass through the membrane either by diffusion or by ultrafiltration. IC components retained by the membrane are not removed from the IC circulation loop. Components on the EC side are washed out by fluid replacement. The replacement volume is specified by the number of IC Volumes and EC Volumes exchanged.

Table 9-7 describes the types of solution that are needed to attach to each line when performing IC EC Washout Through Membrane. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 9-7: Solutions for IC EC Washout Through Membrane

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	0.3 L
Wash	None	N/A
EC Media	Media without protein	0.4 L

IC EC Washout Through Membrane pathway: **Task** > **Washout** > **IC EC Washout Through Membrane**

1. Confirm the settings for IC EC Washout Through Membrane shown in Table 9-8.

Table 9-8: Settings for IC EC Washout Through Membrane

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	100 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate and the number of IC Volumes and EC Volumes used for the Exchange stop condition for this task.
IC Circulation Rate	–59 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media

Table 9-8: Settings for IC EC Washout Through Membrane (continued)

Setting	Factory Default	Setting Options
EC Inlet Rate	148 mL/min	N/A The system automatically calculates this rate based on the number of IC Volumes and EC Volumes used for the Exchange stop condition for this task.
EC Circulation Rate	–1.7 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate for this task.
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Exchange (1.0 IC Volumes) (1.0 EC Volumes)	Exchange (0.5 to 5.0 IC Volumes) (0.5 to 5.0 EC Volumes)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Inlet Line Washout

The purpose of this task is to wash a line or to add fluid to a bag using fluid from another bag. For example, following a bone marrow load, you could wash the droplets left in the cell line back into the cell inlet bag, which would leave a clean line for future use.

Note: During this task, the system opens the appropriate valves to provide flow between the selected bags. You must determine both the direction and the force of the fluid flow by adjusting the relative height of the source and destination bags.

1. Touch **Task**.
2. Touch **Washout**.
3. Touch **Inlet Line Washout**.

   The Setup: Inlet Line Washout screen appears, which prompts you to select the inlet source and the inlet destination, as shown in Figure 9-1.

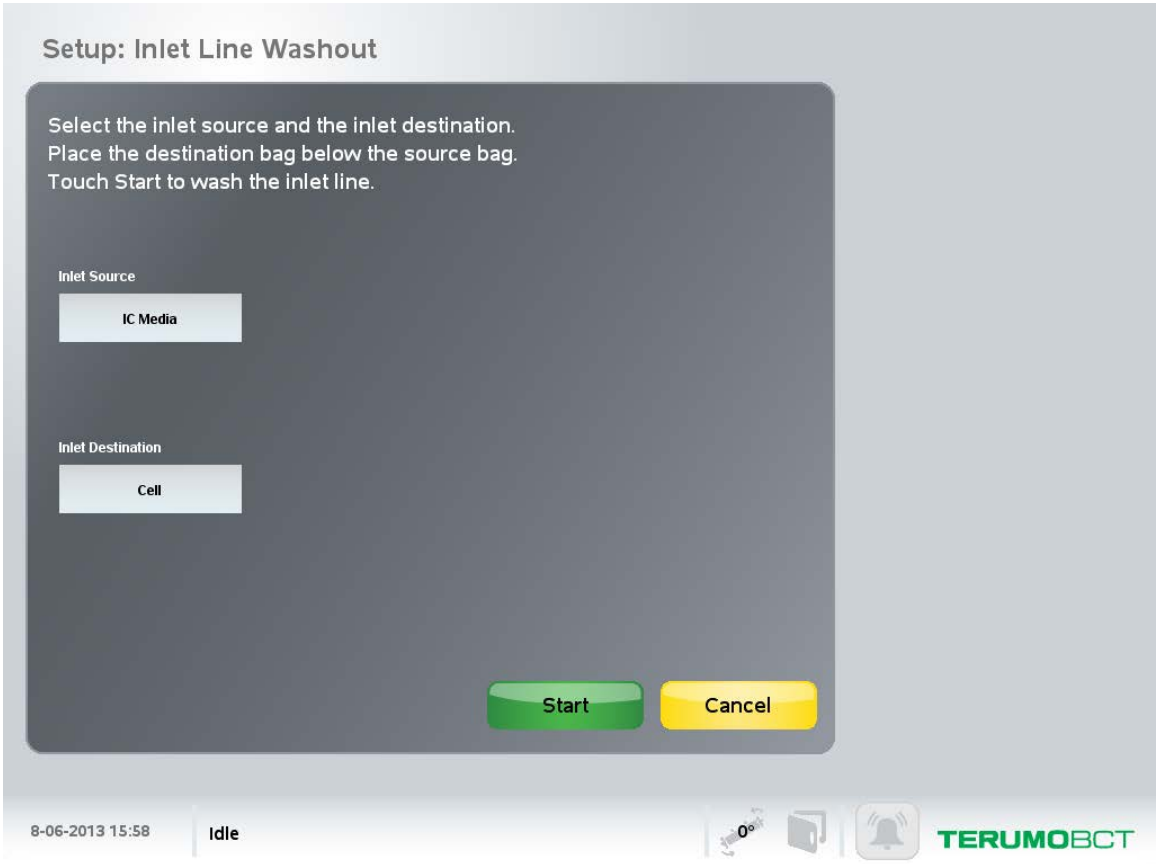


Figure 9-1: Setup: Inlet Line Washout screen

4. Touch the Inlet Source field.
   A menu of inlet source options appears, and the Inlet Source field changes to black. The available inlet source options for this task include Cell, IC Media, Reagent, EC Media, and Wash.
5. Select the desired inlet source from the menu.
   The Inlet Source field displays the option you selected, and the Inlet Source field changes to gray.

6. Touch the Inlet Destination field.
   A menu of inlet destination options appears, and the Inlet Destination field changes to black. The available destination options for this task include Cell, IC Media, Reagent, EC Media, and Wash.
7. Select the desired inlet destination from the menu.
   The Inlet Destination field displays the option you selected, and the Inlet Destination field changes to gray.
8. Follow the on-screen instructions, and lower the destination bag so that it hangs below the source bag.
9. Touch **Start**.
   The Inlet Line Washout status screen appears and includes a progress bar.
10. Follow the on-screen instructions, and touch the **Finish** button when you see the desired volume in the destination bag.
11. Touch **Yes**.
    The valves close, the home screen appears, the system changes to an idle state, and the status line displays Idle. You can remove or hang the source and destination bags.

10

Load and Attach Tasks

Load Cells With Circulation

The purpose of this task is to load the cells into the bioreactor from the cell inlet bag until the bag is empty and to use IC circulation to distribute the cells. This task includes three separate steps:

- Step 1: loads the cells into the bioreactor.

Note: One method for determining the volume in the cell inlet bag (step 1) is to use a volume that is an integer multiple of the IC Inlet Rate.

- Step 2: chases the cells from the ARC into the IC circulation loop.
- Step 3: chases the cells from the IC circulation loop into the bioreactor.

Table 10-1 describes the types of solution that are needed to attach to each line when performing Load Cells With Circulation. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Table 10-1: Solutions for Load Cells With Circulation

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	Cells	As desired
Reagent	None	N/A
IC Media	Media with protein	0.2 L
Wash	None	N/A
EC Media	None	N/A

Load Cells With Circulation pathway: **Task** > **Load and Attach** > **Load Cells With Circulation**

1. Confirm the settings for step 1 shown in Table 10-2.

Table 10-2: Step 1 Settings for Load Cells With Circulation

Setting	Factory Default	Setting Options
IC Inlet	Cell	N/A
IC Inlet Rate	50 mL/min	20 to 100 mL/min
IC Circulation Rate	139 mL/min	20 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	None	N/A

Table 10-2: Step 1 Settings for Load Cells With Circulation (continued)

Setting	Factory Default	Setting Options
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Empty Bag	N/A

2. Confirm the settings for step 2 shown in Table 10-3.

Table 10-3: Step 2 Settings for Load Cells With Circulation

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	50 mL/min	Same as step 1
IC Circulation Rate	139 mL/min	Same as step 1
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 1
Stop Condition	IC Volume (22 mL)	IC Volume (1 to 100 mL)

3. Confirm the settings for step 3 shown in Table 10-4.

Table 10-4: Step 3 Settings for Load Cells With Circulation

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	50 mL/min	Same as step 1
IC Circulation Rate	–41 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this step.

Table 10-4: Step 3 Settings for Load Cells With Circulation (continued)

Setting	Factory Default	Setting Options
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 1
Stop Condition	IC Volume (63 mL)	IC Volume (22 to 84 mL)

4. Touch **Start**.
5. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Load Cells Without Circulation

The purpose of this task is to load the cells into the bioreactor from the cell inlet bag until the bag is empty. This task does not use IC circulation to distribute the cells. This task includes two separate steps:

- Step 1: loads the cells from the cell inlet bag into the bioreactor.
- Step 2: chases the cells from the ARC to the bioreactor. Larger chase volumes spread the cells and move them towards the IC outlet.

Table 10-5 describes the types of solution that are needed to attach to each line when performing Load Cells Without Circulation. These solutions and corresponding volumes are based on the factory default settings for this task.

As preconditions before starting this task:

- Fill the cell inlet bag with a minimum of approximately 40 mL of air.
- Follow the instructions in "Using the In-Line Filter 200 Micron Accessory Set" on page 5-4 to add the in-line filter to the cell line of the cell expansion set, if desired.

Table 10-5: Solutions for Load Cells Without Circulation

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	Cells	As desired
Reagent	None	N/A
IC Media	Media with protein	0.1 L
Wash	None	N/A
EC Media	None	N/A

Load Cells Without Circulation pathway: **Task** > **Load and Attach** > **Load Cells Without Circulation**

1. Confirm the settings for step 1 shown in Table 10-6.

Table 10-6: Step 1 Settings for Load Cells Without Circulation

Setting	Factory Default	Setting Options
IC Inlet	Cell	N/A
IC Inlet Rate	50 mL/min	20 to 100 mL/min
IC Circulation Rate	0 mL/min	N/A
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	10 to 300 mL/min

Table 10-6: Step 1 Settings for Load Cells Without Circulation (continued)

Setting	Factory Default	Setting Options
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Empty Bag	N/A

2. Confirm the settings for step 2 shown in Table 10-7.

Table 10-7: Step 2 Settings for Load Cells Without Circulation

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	50 mL/min	Same as step 1
IC Circulation Rate	0 mL/min	Same as step 1
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 1
Stop Condition	IC Volume (47 mL)	IC Volume (1 to 200 mL)

3. Touch **Start**.
4. Check the status line to confirm that the task has started.
5. Verify that there are no contents left in the bag.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Attach Cells

The purpose of this task is to allow adherent cells to attach to the bioreactor membrane while allowing flow in the EC circulation loop. The pump flow rate to the IC circulation loop is set to zero.

Table 10-8 describes the types of solution that are needed to attach to each line when performing Attach Cells. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 10-8: Solutions for Attach Cells

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	None	N/A
Wash	None	N/A
EC Media	Media without protein	6 mL/hour

Attach Cells pathway: **Task** > **Load and Attach** > **Attach Cells**

1. Confirm the settings for Attach Cells shown in Table 10-9.

Table 10-9: Settings for Attach Cells

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	0 mL/min	N/A
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	0.1 mL/min	0.1 to 10 mL/min
EC Circulation Rate	30 mL/min	0 to 100 mL/min
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	Stationary (0° to 180°)
Stop Condition	Manual	Time (0.1 to 2880 min), Manual, EC Volume (1 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
4. Touch **Finish** when you are ready to complete the task.

5. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

Load Cells With Uniform Suspension

The purpose of this task is to load the cells into the bioreactor from the cell inlet bag until the bag is empty and to use IC circulation to create uniform cell suspension. This task includes three separate steps:

- Step 1: loads the cells into the bioreactor.

Note: One method for determining the volume in the cell inlet bag (step 1) is to use a volume that is an integer multiple of the IC Inlet Rate.

- Step 2: chases the cells from the ARC into the IC circulation loop.
- Step 3: circulates the cells to create uniform cell suspension.

Table 10-10 describes the types of solution that are needed to attach to each line when performing Load Cells With Uniform Suspension. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Table 10-10: Solutions for Load Cells With Uniform Suspension

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	Cells	As desired
Reagent	None	N/A
IC Media	Media with protein	0.2 L
Wash	None	N/A
EC Media	None	N/A

Load Cells With Uniform Suspension pathway: **Task** > **Load and Attach** > **Load Cells With Uniform Suspension**

1. Confirm the settings for step 1 shown in Table 10-11.

Table 10-11: Step 1 Settings for Load Cells With Uniform Suspension

Setting	Factory Default	Setting Options
IC Inlet	Cell	N/A
IC Inlet Rate	25 mL/min	20 to 100 mL/min
IC Circulation Rate	150 mL/min	30 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.

Table 10-11: Step 1 Settings for Load Cells With Uniform Suspension (continued)

Setting	Factory Default	Setting Options
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Empty Bag	N/A

2. Confirm the settings for step 2 shown in Table 10-12.

Table 10-12: Step 2 Settings for Load Cells With Uniform Suspension

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	25 mL/min	Same as step 1
IC Circulation Rate	150 mL/min	Same as step 1
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 1
Stop Condition	IC Volume (47 mL)	IC Volume (1 to 100 mL)

3. Confirm the settings for step 3 shown in Table 10-13.

Table 10-13: Step 3 Settings for Load Cells With Uniform Suspension

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	200 mL/min	Same as step 1

Table 10-13: Step 3 Settings for Load Cells With Uniform Suspension (continued)

Setting	Factory Default	Setting Options
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 1
Stop Condition	Time (2 min)	Time (0.1 to 20 min)

4. Touch **Start**.
5. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

11

Feed and Add Tasks

Feed Cells With Ultrafiltration

The purpose of this task is to add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. If you use the factory default settings for this task and the solution volumes based on those defaults, large molecules could become concentrated in the IC circulation loop. In this instance, the task would use ultrafiltration to remove excess fluid from the IC side of the bioreactor.

Table 11-1 describes the types of solution that are needed to attach to each line when performing Feed Cells With Ultrafiltration. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 11-1: Solutions for Feed Cells With Ultrafiltration

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	6 mL/hour
Wash	None	N/A
EC Media	None	N/A

Feed Cells With Ultrafiltration pathway: **Task** > **Feed and Add** > **Feed Cells With Ultrafiltration**

1. Confirm the settings for Feed Cells With Ultrafiltration shown in Table 11-2.

Table 11-2: Settings for Feed Cells With Ultrafiltration

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Cell, Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	0.1 mL/min	0 to 10 mL/min
IC Circulation Rate	20 mL/min	–100 to 100 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 10 mL/min
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)

Table 11-2: Settings for Feed Cells With Ultrafiltration (continued)

Setting	Factory Default	Setting Options
Stop Condition	Manual	Time (0.1 to 21600 min), Manual, IC Volume (1 to 4000 mL), EC Volume (1 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
4. Touch **Finish** when you are ready to complete the task.
5. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

Feed Cells

The purpose of this task is to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. There are several outlet settings that you can use to remove the fluid added to the system during this task.

Table 11-3 describes the types of solution that are needed to attach to each line when performing Feed Cells. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 11-3: Solutions for Feed Cells

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	6 mL/hour
Wash	None	N/A
EC Media	None	N/A

Feed Cells pathway: **Task** > **Feed and Add** > **Feed Cells**

1. Confirm the values for each setting for Feed Cells shown in Table 11-4.

Table 11-4: Settings for Feed Cells

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Cell, Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	0.1 mL/min	0 to 10 mL/min
IC Circulation Rate	20 mL/min	–100 to 100 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 10 mL/min
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	IC Outlet	EC Outlet, IC Outlet, Synchronization
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)

Table 11-4: Settings for Feed Cells (continued)

Setting	Factory Default	Setting Options
Stop Condition	Manual	Time (0.1 to 21600 min), Manual, IC Volume (1 to 4000 mL), EC Volume (1 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
4. Touch **Finish** when you are ready to complete the task.
5. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

Add Bolus

The purpose of this task is to quickly add a selected volume of reagent into the IC circulation loop; you can also add a bolus into the EC circulation loop at the same time.

Table 11-5 describes the types of solution that are needed to attach to each line when performing Add Bolus. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 11-5: Solutions for Add Bolus

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	Reagent	0.1 L
IC Media	None	N/A
Wash	None	N/A
EC Media	None	N/A

Add Bolus pathway: **Task** > **Feed and Add** > **Add Bolus**

1. Confirm the settings for Add Bolus shown in Table 11-6.

Table 11-6: Settings for Add Bolus

Setting	Factory Default	Setting Options
IC Inlet	Reagent	Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	10 mL/min	0 to 200 mL/min
IC Circulation Rate	100 mL/min	–300 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 300 mL/min
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	EC Outlet	IC Outlet, EC Outlet, Harvest
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)

Table 11-6: Settings for Add Bolus (continued)

Setting	Factory Default	Setting Options
Stop Condition	IC Volume (10 mL)	IC Volume (1 to 200 mL), EC Volume (1 to 300 mL), Time (0.1 to 20 min)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Add Bag Contents

The purpose of this task is to load a fluid, such as a reagent, into the IC circulation loop until the bag that contains the fluid is empty. The IC outlet valve is closed during this task. This task includes two separate steps:

- Step 1: loads a fluid into the system.
- Step 2: chases the fluid from the ARC into the IC circulation loop.

Table 11-7 describes the types of solution that are needed to attach to each line when performing Add Bag Contents. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Table 11-7: Solutions for Add Bag Contents

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	Reagent	As desired
IC Media	Media with protein	0.1 L
Wash	None	N/A
EC Media	None	N/A

Add Bag Contents pathway: **Task** > **Feed and Add** > **Add Bag Contents**

1. Confirm the settings for step 1 shown in Table 11-8.

Table 11-8: Step 1 Settings for Add Bag Contents

Setting	Factory Default	Setting Options
IC Inlet	Reagent	Cell, Reagent
IC Inlet Rate	10 mL/min	0 to 100 mL/min
IC Circulation Rate	100 mL/min	–300 to 300 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A

Table 11-8: Step 1 Settings for Add Bag Contents (continued)

Setting	Factory Default	Setting Options
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	EC Outlet	IC Outlet, EC Outlet
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Empty Bag	N/A

2. Confirm the settings for step 2 shown in Table 11-9.

Table 11-9: Step 2 Settings for Add Bag Contents

Setting	Factory Default	Setting Options
IC Inlet	IC Media	IC Media, Wash, EC Media
IC Inlet Rate	10 mL/min	Same as step 1
IC Circulation Rate	100 mL/min	Same as step 1
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	Same as step 1
EC Circulation Rate	30 mL/min	Same as step 1
Outlet	EC Outlet	Same as step 1
Rocker	Stationary (0°)	Same as step 1
Stop Condition	IC Volume (22 mL)	IC Volume (1 to 100 mL)

3. Touch **Start**.
4. Check the status line to confirm that the task has started.
5. Verify that there are no contents left in the bag.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Add Fluid Continuously

The purpose of this task is to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. There are several outlet settings that you can use to remove the fluid added to the system during this task.

Table 11-10 describes the types of solution that are needed to attach to each line when performing Add Fluid Continuously. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 11-10: Solutions for Add Fluid Continuously

Line	Solution Attached to the Line	Required Volume (estimate based on factory default values)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	6 mL/hour
Wash	None	N/A
EC Media	None	N/A

Add Fluid Continuously pathway: **Task** > **Feed and Add** > **Add Fluid Continuously**

1. Confirm the values for each setting for Add Fluid Continuously shown in Table 11-11.

Table 11-11: Settings for Add Fluid Continuously

Setting	Factory Default Values	Setting Options
IC Inlet	IC Media	Cell, Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	0.1 mL/min	0 to 10 mL/min
IC Circulation Rate	20 mL/min	–100 to 100 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 10 mL/min
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	IC Outlet	EC Outlet, IC Outlet, Synchronization
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)

Table 11-11: Settings for Add Fluid Continuously (continued)

Setting	Factory Default Values	Setting Options
Stop Condition	Manual	Time (0.1 to 1440 min), Manual, IC Volume (1 to 4000 mL), EC Volume (1 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
4. Touch **Finish** when you are ready to complete the task.
5. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

Add Fluid Continuously With Ultrafiltration

The purpose of this task is to continuously add fluid at a low flow rate to the IC circulation loop and/or the EC circulation loop. If you use the factory default settings for this task and the solution volumes based on those defaults, large molecules could become concentrated in the IC circulation loop. In this instance, the task would use ultrafiltration to remove excess fluid from the IC side of the bioreactor.

Table 11-12 describes the types of solution that are needed to attach to each line when performing Add Fluid Continuously With Ultrafiltration. These solutions and corresponding volumes are based on the factory default settings for this task.

Table 11-12: Solutions for Add Fluid Continuously With Ultrafiltration

Line	Solution Attached to the Line	Required Volume (estimate based on factory default values)
Cell	None	N/A
Reagent	None	N/A
IC Media	Media with protein	6 mL/hour
Wash	None	N/A
EC Media	None	N/A

Add Fluid Continuously With Ultrafiltration pathway: **Task** > **Feed and Add** > **Add Fluid Continuously With Ultrafiltration**

1. Confirm the settings for Add Fluid Continuously With Ultrafiltration shown in Table 11-13.

Table 11-13: Settings for Add Fluid Continuously With Ultrafiltration

Setting	Factory Default Values	Setting Options
IC Inlet	IC Media	Cell, Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	0.1 mL/min	0 to 10 mL/min
IC Circulation Rate	20 mL/min	–100 to 100 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 10 mL/min
EC Circulation Rate	30 mL/min	10 to 300 mL/min
Outlet	EC Outlet	N/A

Table 11-13: Settings for Add Fluid Continuously With Ultrafiltration (continued)

Setting	Factory Default Values	Setting Options
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Manual	Time (0.1 to 1440 min), Manual, IC Volume (1 to 4000 mL), EC Volume (1 to 4000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
4. Touch **Finish** when you are ready to complete the task.
5. Touch **Yes**.
   The home screen appears, the system changes to an idle state, and the status line displays Idle.

12

Release and Harvest Tasks

Release Adherent Cells

The purpose of this task is to release cells from the bioreactor membrane, leaving the cells in the IC circulation loop. This task includes four separate steps:

- Step 1: performs the IC EC Washout task in preparation for adding a reagent. For example, the system replaces IC media and EC media with PBS to remove protein, Ca++, and Mg++ in preparation for adding trypsin.
- Step 2: loads a reagent into the system until the bag is empty.
- Step 3: chases the reagent into the IC circulation loop.
- Step 4: mixes the reagent within the IC circulation loop.

Table 12-1 describes the types of solution that are needed to attach to each line when performing Release Adherent Cells. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Table 12-1: Solutions for Release Adherent Cells

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	Trypsin	As desired
IC Media	None	N/A
Wash	PBS	1.5 L
EC Media	None	N/A

Release Adherent Cells pathway: **Task** > **Release and Harvest** > **Release Adherent Cells**

1. Confirm the settings for step 1 shown in Table 12-2.

Table 12-2: Step 1 Settings for Release Adherent Cells

Setting	Factory Default	Setting Options
IC Inlet	Wash	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	100 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate and the number of IC Volumes and EC Volumes used for the Exchange stop condition for this step.

Table 12-2: Step 1 Settings for Release Adherent Cells (continued)

Setting	Factory Default	Setting Options
IC Circulation Rate	–17 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	Wash	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	148 mL/min	N/A The system automatically calculates this rate based on the number of IC Volumes and EC Volumes used for the Exchange stop condition for this step.
EC Circulation Rate	–1.7 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate for this step.
Outlet	IC and EC Outlet	EC Outlet, IC Outlet, IC and EC Outlet
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Exchange (2.5 IC Volumes) (2.5 EC Volumes)	Exchange (0.5 to 5.0 IC Volumes) (0.5 to 5.0 EC Volumes)

2. Confirm the settings for step 2 shown in Table 12-3.

Table 12-3: Step 2 Settings for Release Adherent Cells

Setting	Factory Default	Setting Options
IC Inlet	Reagent	Cell, Reagent
IC Inlet Rate	50 mL/min	20 to 100 mL/min
IC Circulation Rate	300 mL/min	30 to 300 mL/min
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec)
Stop Condition	Empty Bag	N/A

3. Confirm the settings for step 3 shown in Table 12-4.

Table 12-4: Step 3 Settings for Release Adherent Cells

Setting	Factory Default	Setting Options
IC Inlet	Wash	IC Media, Wash, EC Media
IC Inlet Rate	50 mL/min	Same as step 2
IC Circulation Rate	300 mL/min	Same as step 2
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 2
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 2
Stop Condition	IC Volume (22 mL)	IC Volume (1 to 100 mL)

4. Confirm the settings for step 4 shown in Table 12-5.

Table 12-5: Step 4 Settings for Release Adherent Cells

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	300 mL/min	30 to 300 mL/min
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 2
Stop Condition	Time (4.0 min)	Time (0.1 to 20 min)

5. Touch **Start**.
6. Check the status line to confirm that the task has started.
7. Verify that there are no contents left in the bag.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

Release Adherent Cells And Harvest

The purpose of this task is release and harvest cells. This task begins with the Release Adherent Cells task followed by the Harvest Cells task. This task includes five separate steps:

- Step 1: performs the IC EC Washout task in preparation for adding a reagent. For example, the system replaces IC media and EC media with PBS to remove protein, Ca++, and Mg++ in preparation for adding trypsin.
- Step 2: loads a reagent into the system until the bag is empty.
- Step 3: chases the reagent into the IC circulation loop.
- Step 4: mixes the reagent within the IC circulation loop.
- Step 5: transfers the cells in suspension from the IC circulation loop, including cells in the bioreactor, to the harvest bag.

Table 12-6 describes the types of solution that are needed to attach to each line when performing Release Adherent Cells And Harvest. These solutions and corresponding volumes are based on the factory default settings for this task.

As a precondition before starting this task:

Fill the cell inlet bag with a minimum of approximately 40 mL of air.

Note: When harvesting cells, you should adjust the media composition in the harvest bag to ensure that it is appropriate for the way in which you intend to use the cells after harvest.

Table 12-6: Solutions for Release Adherent Cells And Harvest

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	Trypsin	As desired
IC Media	Harvest media	0.4 L
Wash	PBS	1.5 L
EC Media	Media without protein	0.1 L

Release Adherent Cells And Harvest pathway: **Task** > **Release and Harvest** > **Release Adherent Cells And Harvest**

1. Confirm the settings for step 1 shown in Table 12-7.

Table 12-7: Step 1 Settings for Release Adherent Cells And Harvest

Setting	Factory Default	Setting Options
IC Inlet	Wash	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	100 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate and the number of IC Volumes and EC Volumes used for the Exchange stop condition for this step.
IC Circulation Rate	–17 mL/min	N/A The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	Wash	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	148 mL/min	N/A The system automatically calculates this rate based on the number of IC Volumes and EC Volumes used for the Exchange stop condition for this step.
EC Circulation Rate	–1.7 mL/min	N/A The system automatically calculates this rate based on the EC Inlet Rate for this step.
Outlet	IC and EC Outlet	EC Outlet, IC Outlet, IC and EC Outlet
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Exchange (2.5 IC Volumes) (2.5 EC Volumes)	Exchange (0.5 to 5.0 IC Volumes) (0.5 to 5.0 EC Volumes)

2. Confirm the settings for step 2 shown in Table 12-8.

Table 12-8: Step 2 Settings for Release Adherent Cells And Harvest

Setting	Factory Default	Setting Options
IC Inlet	Reagent	Cell, Reagent
IC Inlet Rate	50 mL/min	20 to 100 mL/min
IC Circulation Rate	300 mL/min	30 to 300 mL/min
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A

Table 12-8: Step 2 Settings for Release Adherent Cells And Harvest (continued)

Setting	Factory Default	Setting Options
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec)
Stop Condition	Empty Bag	N/A

3. Confirm the settings for step 3 shown in Table 12-9.

Table 12-9: Step 3 Settings for Release Adherent Cells And Harvest

Setting	Factory Default	Setting Options
IC Inlet	Wash	IC Media, Wash, EC Media
IC Inlet Rate	50 mL/min	Same as step 2
IC Circulation Rate	300 mL/min	Same as step 2
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	Same as step 2
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 2
Stop Condition	IC Volume (22 mL)	IC Volume (1 to 100 mL)

4. Confirm the settings for step 4 shown in Table 12-10.

Table 12-10: Step 4 Settings for Release Adherent Cells And Harvest

Setting	Factory Default	Setting Options
IC Inlet	None	N/A
IC Inlet Rate	0 mL/min	N/A
IC Circulation Rate	300 mL/min	30 to 300 mL/min
EC Inlet	None	N/A
EC Inlet Rate	0 mL/min	N/A
EC Circulation Rate	30 mL/min	0 to 300 mL/min

Table 12-10: Step 4 Settings for Release Adherent Cells And Harvest (continued)

Setting	Factory Default	Setting Options
Outlet	EC Outlet	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	Same as step 2
Stop Condition	Time (4.0 min)	Time (0.1 to 20 min)

5. Confirm the settings for step 5 shown in Table 12-11.

Table 12-11: Step 5 Settings for Release Adherent Cells And Harvest

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	400 mL/min	100 to 500 mL/min
IC Circulation Rate	–70 mL/min	–87 to –18 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this step.
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	60 mL/min	0 to 100 mL/min
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	Harvest	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec)
Stop Condition	IC Volume (378 mL)	IC Volume (50 to 1000 mL)

6. Touch **Start**.
7. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.
8. Seal and remove the harvest bag.

Harvest Cells

The purpose of this task is to transfer cells in suspension from the IC circulation loop, including cells in the bioreactor, to the harvest bag.

Table 12-12 describes the types of solution that are needed to attach to each line when performing Harvest Cells. These solutions and corresponding volumes are based on the factory default settings for this task.

Note: When harvesting cells, you should adjust the media composition in the harvest bag to ensure that it is appropriate for the way in which you intend to use the cells after harvest.

Table 12-12: Solutions for Harvest Cells

Line	Solution Attached to the Line	Required Volume (estimate based on factory default settings)
Cell	None	N/A
Reagent	None	N/A
IC Media	Harvest media*	0.4 L
Wash	None	N/A
EC Media	Media without protein	0.1 L

*When harvesting non-adherent cells, you can use PBS or a similar electrolyte solution as the harvest media; in this situation the harvest media does not have to consist of a media formulation, because there is no trypsin to neutralize.

Harvest Cells pathway: **Task** > **Release and Harvest** > **Harvest Cells**

1. Confirm the settings for Harvest Cells shown in Table 12-13.

Table 12-13: Settings for Harvest Cells

Setting	Factory Default	Setting Options
IC Inlet	IC Media	Reagent, IC Media, Wash, EC Media
IC Inlet Rate	400 mL/min	100 to 500 mL/min
IC Circulation Rate	–70 mL/min	–87 to –18 mL/min The system automatically calculates this rate based on the IC Inlet Rate for this task.
EC Inlet	EC Media	Reagent, IC Media, Wash, EC Media
EC Inlet Rate	60 mL/min	0 to 100 mL/min

Table 12-13: Settings for Harvest Cells (continued)

Setting	Factory Default	Setting Options
EC Circulation Rate	30 mL/min	0 to 300 mL/min
Outlet	Harvest	N/A
Rocker	In Motion (–90°, 180°, 1 sec)	In Motion (–180° to 270°, 0 to 3600 sec)
Stop Condition	IC Volume (378 mL)	IC Volume (50 to 1000 mL)

2. Touch **Start**.
3. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.
4. Seal and remove the harvest bag.

13

Custom Tasks

Custom Tasks

The system includes eight Custom tasks: Custom 1, Custom 2, Custom 3, Custom 4, Custom 5, Custom 6, Custom 7, and Custom 8. You must enter all of the settings for a Custom task manually using **Modify**. The system performs the task using the settings you enter, but the system does not save those settings for future use. However, you can configure the default settings for each Custom task. For more information about configuring the default settings, see the Quantum Cell Expansion System Administrator's Guide. Table 13-1 shows the settings for all the Custom tasks.

Table 13-1: Factory defaults and setting options for all of the Custom tasks

Setting	Factory Default	Setting Options
IC Inlet	None	Cell, Reagent, IC Media, Wash, EC Media, None
IC Inlet Rate	0 mL/min	0 to 500 mL/min
IC Circulation Rate	0 mL/min	–300 to 300 mL/min
EC Inlet	None	Reagent, IC Media, Wash, EC Media, None
EC Inlet Rate	0 mL/min	0 to 300 mL/min
EC Circulation Rate	0 mL/min	–300 to 300 mL/min
Outlet	EC Outlet	EC Outlet, IC Outlet, IC and EC Outlet, Harvest
Rocker	Stationary (0°)	In Motion (–180° to 270°, 0 to 3600 sec), Stationary (–180° to 270°)
Stop Condition	Manual	Manual, Time (0.1 to 21600 min), IC Volume (1 to 4000 mL), EC Volume (1 to 4000 mL), Empty Bag

The following example explains how to select, setup, and start a Custom task:

1. Touch **Task**.
2. Touch **Custom**.
3. Touch **Custom 1**.
   The Setup Confirmation screen appears for Custom 1.
4. Touch **Modify** to select the settings for the task. Table 13-1 shows all the possible setting options for all of the Custom tasks.
5. Touch **Start**.
6. Check the status line to confirm that the task has started.
   When the system completes the task, the home screen appears, the system changes to an idle state, and the status line displays Idle.

14

Quantum System Configuration

Quantum System Configuration

The Quantum system allows you to configure the following types of settings:

- Display settings
- System settings
- Default settings for tasks
- Report settings
- Network settings
- User settings
- Remote alarm settings

If user authentication is enabled, only a user who is assigned the User Role of Administrator can make configuration changes. To make configuration changes, touch **Configuration** to display the Configuration Selection screen, as shown in Figure 14-1. If user authentication is enabled, the system prompts you to enter your user ID and password before it displays the Configuration Selection screen. From the Configuration Selection screen, you can select the type of settings you want to configure. All of the configuration screens in the Quantum system include a purple border and wrench symbol.

For instructions on how to configure specific settings, see the Quantum Cell Expansion System Administrator's Guide.

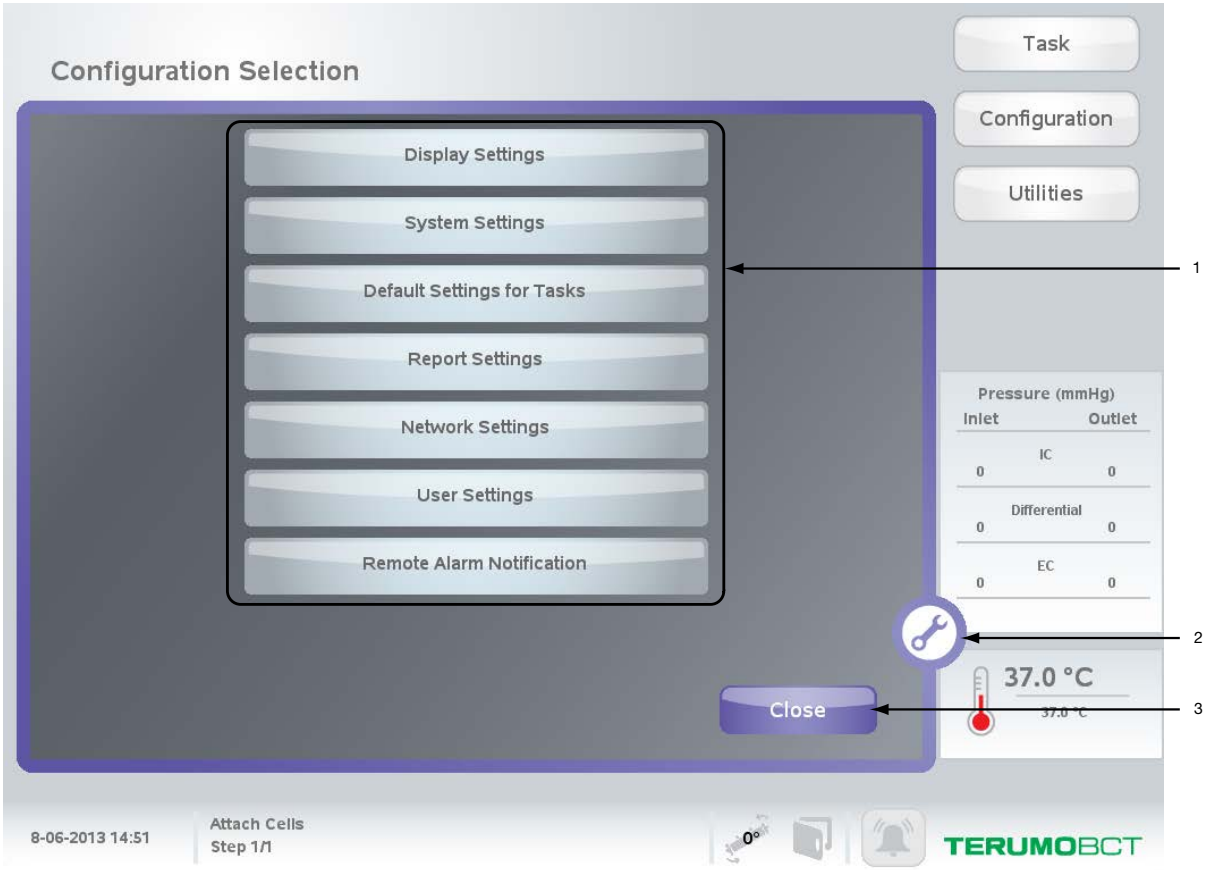


Figure 14-1: Configuration Selection screen

1 Configuration selection buttons

2 Purple border and the wrench symbol that indicate configuration screens

3 **Close**, which allows you to close the Configuration Selection screen

15

Reports

About Reports

The Quantum system allows you to generate three types of reports: run reports, user reports, and configuration reports. For information on configuring the following report settings, see the Quantum Cell Expansion System Administrator's Guide:

- Configure the system to generate run reports.
- Set the system to send run reports automatically to a server.
- Set the frequency to record temperature and pressure on a run report.
- Set the current system configuration as the baseline for the configuration report.
- Configure the connection to an FTP server to receive reports.

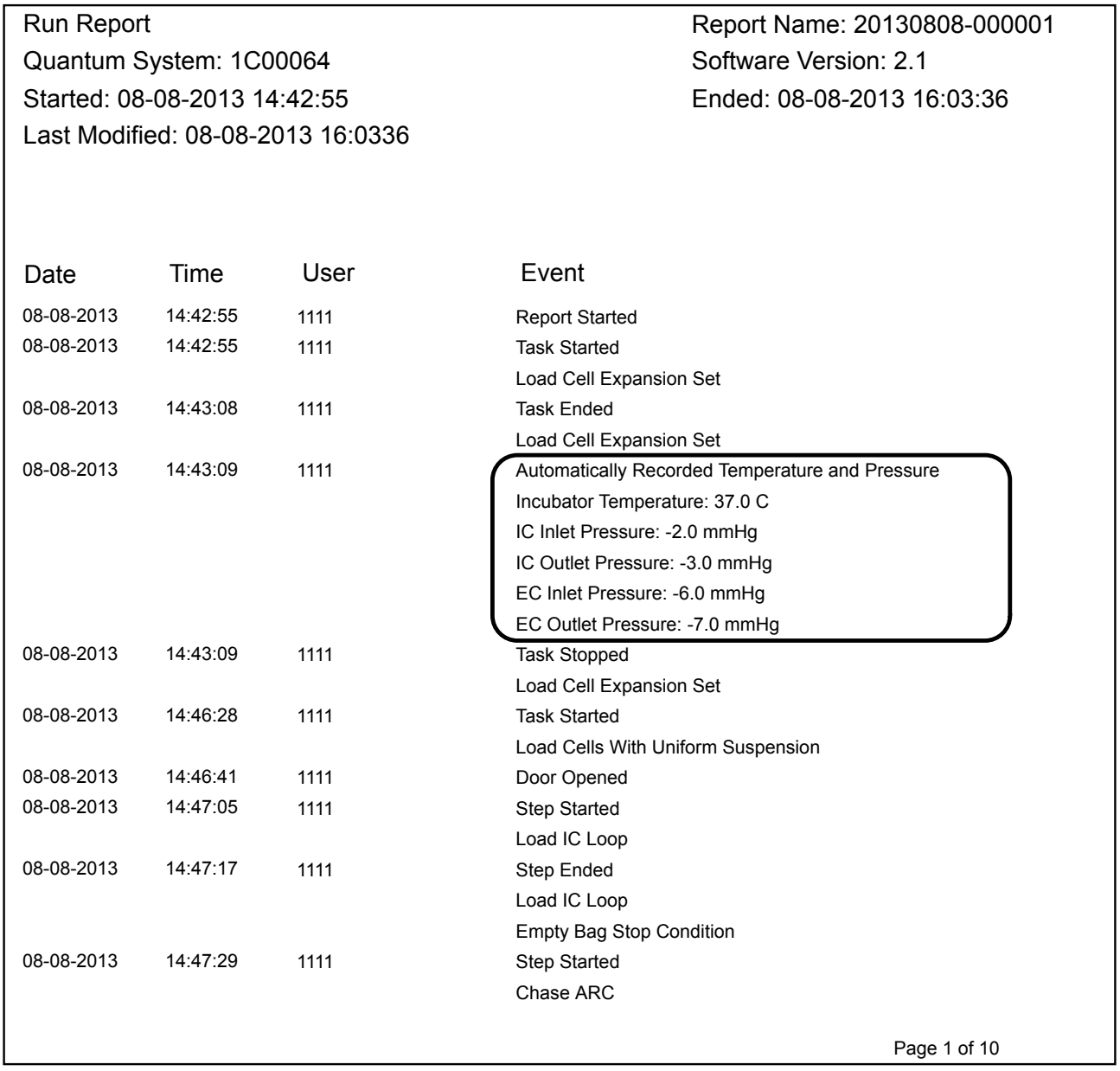
Run Reports

A run report contains information about a single run on the system. A single run includes each task that the system performed from the start of Load Cell Expansion Set through the completion of Unload Cell Expansion Set. The system records the following information in each run report:

- Each task the system performed, including tasks that were stopped prior to completion, and any settings that the user modified during setup
- Temperature and pressure readings at a configured interval throughout the run
- All alarms that occurred during the run
- All sign-in errors that occurred during the run, if the system is configured to record failed sign-in attempts

The Quantum system stores completed run reports.

You can configure the system to generate a new run report each time you start Load Cell Expansion Set. You can also configure the system so it automatically sends the report to an FTP server. For more information about configuring reports, see the Quantum Cell Expansion System Administrator's Guide. Figure 15-1 shows an example run report.



Run Report
Report Name: 20130808-000001
Quantum System: 1C00064
Software Version: 2.1
Started: 08-08-2013 14:42:55
Ended: 08-08-2013 16:03:36
Last Modified: 08-08-2013 16:0336

Date	Time	User	Event
08-08-2013	14:42:55	1111	Report Started
08-08-2013	14:42:55	1111	Task Started
			Load Cell Expansion Set
08-08-2013	14:43:08	1111	Task Ended
			Load Cell Expansion Set
08-08-2013	14:43:09	1111	Automatically Recorded Temperature and Pressure
			Incubator Temperature: 37.0 C
			IC Inlet Pressure: -2.0 mmHg
			IC Outlet Pressure: -3.0 mmHg
			EC Inlet Pressure: -6.0 mmHg
			EC Outlet Pressure: -7.0 mmHg
08-08-2013	14:43:09	1111	Task Stopped
			Load Cell Expansion Set
08-08-2013	14:46:28	1111	Task Started
			Load Cells With Uniform Suspension
08-08-2013	14:46:41	1111	Door Opened
08-08-2013	14:47:05	1111	Step Started
			Load IC Loop
08-08-2013	14:47:17	1111	Step Ended
			Load IC Loop
			Empty Bag Stop Condition
08-08-2013	14:47:29	1111	Step Started
			Chase ARC

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Figure 15-1: Example of a run report that includes a temperature and pressure record

User Reports

The user report contains a list of all the current users in the system, including the User Role that is assigned to each user. The Quantum system does not store user reports, so you can only view the current user report or send it to an FTP server.

Configuration Reports

The configuration report contains information about how a Quantum system is configured. It records the configuration baseline and any changes made to the configuration once the baseline is set. The configuration report also records the date and time when each configuration change was made. If user authentication is enabled, the system also records the user who made the change. The following information is included in a configuration report:

- Display settings
  - Time format, date format, and type of decimal separator
- System settings
  - Alarm sound, incubator status, temperature set point, and low-temperature alarm configuration
- Default settings for all tasks
  - Records if steps were omitted from a task
- Report settings
  - Run report generation, automatic report sending, selected report formats, and IP address for the FTP server that receives reports
- Network settings
  - DHCP status, static IP address, static netmask, and static gateway address
- User settings
  - User authentication status, touch screen lock, and reporting of failed sign-in attempts
- Remote alarm notification settings
  - IP address for the remote alarm server and remote alarm server port

The Quantum system does not store configuration reports, so you can only view the current configuration report or send it to an FTP server.

Viewing Reports

The Quantum system allows you to view the current report for any of the three report types, but only run reports are stored and can be viewed later. The system does not store configuration reports or user reports.

Viewing a Current Report

Complete the following steps to view a current report:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under the type of report that you want to view, touch **View**. For example, if you want to view the current run report, touch **View** under the Run Reports section.
   The system displays the current report.

Viewing the Current Run Report from the Manage Run Reports Screen

You can also view the current run report on the Manage Run Reports screen by completing the following steps:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **Manage**.
   The Manage Run Reports screen appears and shows a list of all the stored run reports, as shown in Figure 15-2 on page 15-6. The list also includes the current run report that is in progress, which is indicated by the green dot.
4. Touch the check box next to the current run report that is indicated by the green dot.
5. Touch **View**.
   The system displays the current run report.

Viewing a Stored Run Report

The system allows you to view stored run reports; however, you can view only one report at a time. Complete the following steps to view a single stored run report:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **Manage**.
   The Manage Run Reports screen appears and shows a list of all the stored run reports, as shown in Figure 15-2. The list also includes the current run report that is in progress, which is indicated by the green dot.

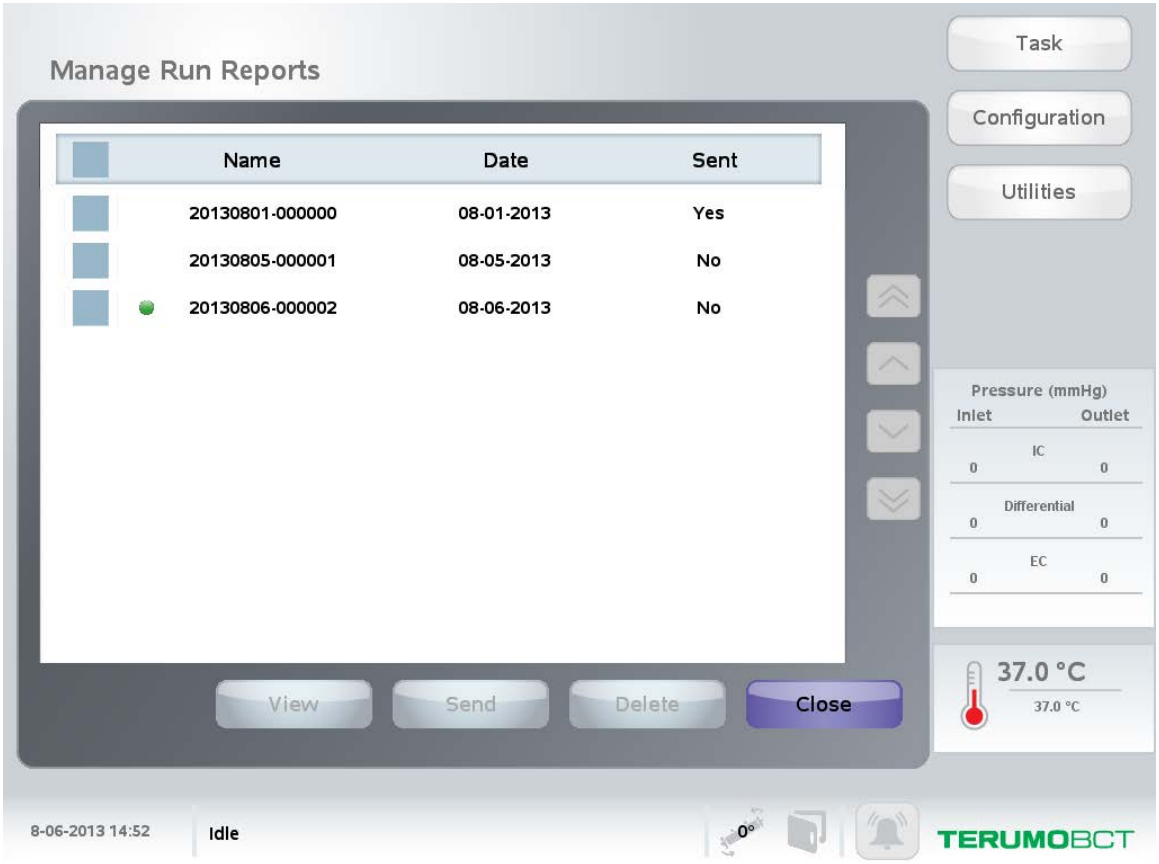

Figure 15-2: Manage Run Reports screen

4. Touch the check box for the report that you want to view.
5. Touch **View**.
   The system displays the report.
6. Touch **Close** to close the report and return to the Manage Run Reports screen.

Sorting Stored Run Reports

On the Manage Run Reports screen, shown in Figure 15-2, you can sort the list of stored run reports by name, by completion date, or by whether or not the reports have been sent to the configured FTP server.

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **Manage**.
   The Manage Run Reports screen appears and shows a list of all the stored run reports, as shown in Figure 15-2.
4. Complete one of the following:
   - To sort by the name of the reports, touch **Name**.
   - To sort by the date the reports were completed, touch **Date**.
   - To sort by whether or not the reports have been sent to the configured FTP server, touch **Sent**.

Deleting Stored Run Reports

The Quantum system allows you to delete stored run reports. You cannot delete the current run report that is in progress. You can delete one or more stored reports at a time. If user authentication is enabled, only an administrator can delete reports. If a user who is assigned the User Role of Operator is signed in to the system, the system disables **Delete** on the Manage Run Reports screen.

Complete the following steps to delete stored run reports:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **Manage**.
   The Manage Run Reports screen appears, as shown in Figure 15-2 on page 15-6.
4. Touch the check boxes for the reports that you want to delete.
5. Touch **Delete**.
6. Touch **Yes**.
   The system permanently deletes the reports, and they no longer appear in the list of reports on the Manage Run Reports screen.

Sending Reports

The Quantum system allows you to send reports to an FTP server. You can send current reports for each of the report types, and you can send stored run reports. You can also configure the system so it automatically sends run reports to a server when they are completed. For more information see the Quantum Cell Expansion System Administrator's Guide.

Sending a Current Report

Complete the following steps to send a current report to an FTP server:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under the report type that you want to send to the FTP server, touch **View**. For example, if you want to send the current configuration report to the server, touch **View** under the Configuration Reports section.
   The system displays the current report.
4. Touch **Send**.
   The system sends the report to the server.

Sending Stored Run Reports

Complete the following steps to send stored run reports to an FTP server:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **Manage**.
   The Manage Run Reports screen appears, as shown in Figure 15-2 on page 15-6.
4. Touch the check boxes for the reports that you want to send.
5. Touch **Send**.
   The system sends the reports to the server.

Editing the Name of the Current Run Report

The system assigns a default name to the new run report that is generated each time you start Load Cell Expansion Set. The default name uses the following format:
<date>-<unique ID for the day>-<machine serial number>

If user authentication is enabled, users who are assigned the User Role of Operator can edit the default name of the current run report only at the start of Load Cell Expansion Set. A user who is assigned the User Role of Administrator can also edit the name of the current run report from the Reports screen. If user authentication is disabled, anyone can edit the name of the current run report either at the start of Load Cell Expansion Set or from the Reports screen. Once the system completes and stores a run report, the name of that report cannot be edited.

Editing the Name of the Current Run Report at the Start of Load Cell Expansion Set

Complete the following steps to edit the name of the current run report at the start of Load Cell Expansion Set.

From the Setup: Load Cell Expansion Set screen:

1. Touch the Report Name field.
   A data entry pad appears.
2. Use the data entry pad to edit the name of the current run report.
3. Touch **Enter**.
   The data entry pad closes, and the Report Name field displays the new name of the current run report.

Editing the Name of the Current Run Report from the Reports Screen

Complete the following steps to edit the name of the current run report from the Reports screen:

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears.
3. Under Run Reports, touch **View**.
   The system displays the Current Run Report screen that shows the current run report.
4. Touch **Rename**.
   The Rename Report window opens.
5. Touch the New Report Name field.
   A data entry pad appears.
6. Use the data entry pad to edit the name of the current run report.
7. Touch **Enter**.
   The data entry pad closes, and the current run report shows the new name.

Recording Temperature and Pressure on a Run Report

The system allows you to record the temperature and pressure on a run report in two ways. You can configure the system to record the temperature and pressure on a run report at a set interval throughout a run. For more information, see the Quantum Cell Expansion System Administrator's Guide. You can also complete the following steps at any time during a run to record temperature and pressure on a run report.

1. Touch **Utilities**.
   The Utilities screen appears.
2. Touch **Reports**.
   The Reports screen appears, as shown in Figure 15-3.
3. Under Run Reports, touch **Record**.
   The circle next to the Record button flashes red as the system records the actual current temperature and pressure.

Figure 15-3: Record button on the Reports screen

For an example of how a temperature and pressure recording appears on a run report, see Figure 15-1 on page 15-3.

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Maintaining the Quantum System

Installing the Quantum System

Warning: Only trained and qualified personnel should move the Quantum device.

Caution: Do not block access to the primary power switch, which is located on the back of the device, during installation.

Installation information is included in the shipping container of each Quantum system. An authorized service representative uses this information to install the system in your facility. The service representative also tests the system to confirm that it is functioning properly before you begin using it.

Electrical Requirements

Warning: To reduce the risk of electrical shock, do not use an adapter that breaks the protective ground.

Connect the Quantum system power cord only to a properly installed, three-wire-grounded, hospital-approved grounding-type electrical receptacle. See, “Electrical Power and Safety Specifications” on page 17-2 for the electrical specifications for the Quantum device.

Maintaining the Quantum System

Caution: Do not lubricate the pumps or the pump rotors for any reason.

Follow the instructions in this chapter to clean and disinfect the Quantum system. Other than to ensure that the system is clean and undamaged before use, you are not required to maintain the system.

Cleaning the System

Warning: Turn off the primary power switch and unplug the device before cleaning.

Warning: Use a cleaning technique that does not place your finger in a vulnerable position. For example, you can clean the area around the valve with a cotton swab or by using a flossing technique.

Warning: Take adequate precautions when cleaning any surfaces of the device that might have been exposed to blood to prevent possible exposure to and transmission of infectious diseases.

When cleaning the Quantum system, remove dirt and fluid using a soft cloth and a solution of water and a mild detergent that is safe for plastic. To avoid scratching the touch screen, do not clean the touch screen with an abrasive brush or scrub material. Do not remove the pump rotors or the mounting plate when cleaning the system. To disinfect the system in the case of a biohazardous spill, follow the instructions in “Disinfecting the System.”

Disinfecting the System

Caution: To disinfect the device, use only a 0.25% sodium hypochlorite (bleach) solution. Using a stronger bleach solution may damage or discolor the device.

Note: The bleach solution may leave streaks on the touch screen. A mild, non-abrasive detergent or water can be used to remove the streaks.

Use a soft cloth and a 0.25% sodium hypochlorite (bleach) solution, consisting of 1 part 5.25% to 6.0% commercial household bleach diluted with 18 parts water, to disinfect any portion of the Quantum system that comes in contact with a biohazardous spill. Allow the surfaces to air-dry. For maximum effectiveness, the solution should be prepared on the day it is used.

Performing Preventive Maintenance

To prolong equipment life and to ensure maximum performance of the Quantum system, a qualified service technician should calibrate the system and perform preventive maintenance every six months.

17

System Specifications

System Specifications

This section describes the specifications for the Quantum system.

Environmental Specifications

Table 17-1: Environmental Specifications

Characteristic	Specification
Ambient operating temperature	16 °C to 27 °C (60.8 °F to 80.6 °F) at a temperature set point of 37 °C (98.6 °F)
Degree of protection provided by enclosure	IPX0
Altitude	Up to 2000 m

Electrical Power and Safety Specifications

Table 17-2: Electrical power and safety specifications

Characteristic	Specification
Classifications	Class 1 Equipment (Grounded type), per EN 61010-1:2001 (Safety requirements for electrical equipment for measurement, control, and laboratory use–Part 1:–General Requirements)
Safety standards	Complies with: • EN 61010-1 (Safety requirements for electrical equipment for measurement, control, and laboratory use–Part 1:–General Requirements) • EN 61326 (Electrical equipment for measurement, control, and laboratory use–EMC requirements)
Input voltage	100 to 240 ± 10% VAC rms, 50/60 Hz The use of an uninterrupted power supply (UPS) is recommended.
Input power	500 W maximum
Installation over-voltage	Category II for transient over-voltages, per EN 61010-1 (Safety requirements for electrical equipment for measurement, control, and laboratory use–Part 1:–General Requirements)
Pollution degree	2
Ethernet port	Allows service personnel to connect the Quantum system to an external device for the purpose of transferring data.

Table 17-2: Electrical power and safety specifications (continued)

Characteristic	Specification
Rear Ethernet port	Allows you to connect the Quantum system to an external device or a local network for the purpose of transferring data.
USB port	Allows service personnel to connect the Quantum system to an external device for the purpose of transferring data.

Physical Specifications

Table 17-3: Physical specifications

Characteristic	Specification
Surface space required	Fits on a 58.4-cm (26-in) deep surface
Physical dimensions	Height: 50 cm (19.65 in) Height with the bag pole: 96.5 cm (38 in) Width: 48.3 cm (19 in) Depth: 58.4 cm (23 in)
Weight	Weight without the bag pole: less than or equal to 56.7 kg (125 lb)
Clearance for air flow and cables	• 7.6 cm (3 in) horizontal clearance from the back of the device • 99 cm (39 in) vertical clearance
Housing clearance	• Front clearance to open the door: – 10.2 cm (4 in) on the left – 7.6 cm (3 in) on the right • Environments with two devices: – A minimum of 10.2 cm (4 in) between the devices • Environments with two or more devices and operators: – A minimum of 35.6 cm (14 in) between the devices

Table 17-3: Physical specifications (continued)

Characteristic	Specification
Gas supply requirements	• Connector location: when facing the back of the device, the connector is located on the back on the bottom-left corner. • Inlet pressure range: regulated between 40 psi and 60 psi. Set point pressure is 45 +15/–5 psi. • Oxygen volume in the gas supplied must not exceed 20%. • Device includes an external pressure relief valve rated to 75 psi. – Discharge area: when facing the back of the device, the discharge area is located on the back on the bottom-left side. • Internal: 40-micron filter installed. • Device has a 303-stainless steel, ARO-shape hose coupling plug.
Gas usage	One gas tank with a volume of 6.26 m^3 (221 cu. ft.) lasts approximately 30 days under normal operating conditions.

Touch Screen Specifications

Table 17-4: Touch Screen Specifications

Characteristic	Specification
Touch screen display	• Width: 30.5 cm (12 in) • Height: 22.9 cm (9 in) • VGA liquid crystal display (LCD)

Electromagnetic Compatibility (EMC) Information

The Quantum Cell Expansion System is intended for use in the electromagnetic environment specified in Table 17-5. The customer or the user of the Quantum system should ensure that it is used in such an environment.

Table 17-5: EMC Emissions Guidance

Emissions Test	Compliance	Electromagnetic Environment —Guidance
RF emissions CISPR 11 EN 55011	Group 1	The Quantum system uses high frequencies only for its internal function (e.g., computer timing signals and internal communication). The RF emissions meet the requirements of CISPR 11. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 EN 55011	Class A	The Quantum system is suitable for use in all establishments other than residential and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.

The Quantum system is intended for use in the electromagnetic environment specified in Table 17-6. The customer or the user of the Quantum system should ensure that it is used in such an environment.

Table 17-6: EMC Electromagnetic Immunity

Immunity Test	IEC 61326 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 4 kV contact ± 8 kV air	± 4 kV contact ± 8 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 0.5 kV for input/output lines ± 1 kV for power supply lines	± 0.5 kV for input/output lines ± 1 kV for power supply lines	Mains power quality should be that of a typical blood center or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV line to line (DM) ± 1 kV line to earth (CM)	± 0.5 kV line to line (DM) ± 1 kV line to earth (CM)	Mains power quality should be that of a typical blood center or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% during half cycle 0% during 1 cycle 70% during 25/30 cycles[1] 0% during 250/300 cycles[2]	0% during half cycle 0% during 1 cycle 70% during 25/30 cycles[1] 0% during 250/300 cycles[2]	Mains power quality should be that of a typical blood center or hospital environment. **If the user of the Quantum system is aware of frequent power interruptions at his or her facility** and requires continued operation during power mains interruptions, it is recommended that the Quantum system be powered from a suitably rated uninterruptible power supply.
Power frequency H-field immunity IEC 61000-4-8	3 A/m 50 to 60 Hz	3 A/m 50 to 60 Hz	

Note: *U*T is the AC mains voltage prior to application of the test level.

[1] 25/30 cycles means 25 cycles for the 50 Hz test and 30 cycles for the 60 Hz test.

[2] 250/300 cycles means 250 cycles for the 50 Hz test and 300 cycles for the 60 Hz test.

The Quantum system is intended for use in the electromagnetic environment specified in Table 17-7. The customer or the user of the Quantum system should ensure that it is used in such an environment.

Table 17-7: Guidance and Manufacturer's Declaration—Electromagnetic Immunity (1 of 2)

Immunity Test	IEC 61326 Test Level	Compliance Level	Electromagnetic Environment —Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Quantum system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
	3 V/m (80 MHz to 1.0 GHz)	3 V/m (80 MHz to 1.0 GHz)	For calculations based on this equation, see Table 17-9.
Radiated RF IEC 61000-4-3	3 V/m (1.4 GHz to 2.0 GHz)	3 V/m (1.4 GHz to 2.0 GHz)	
	1 V/m (2.0 GHz to 2.7 GHz)	1 V/m (2.0 GHz to 2.7 GHz)	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz For calculations based on this equation, see Table 17-9.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The Quantum system is intended for use in the electromagnetic environment specified in Table 17-8. The customer or the user of the Quantum system should ensure that it is used in such an environment.

Table 17-8: Guidance and Manufacturer's Declaration—Electromagnetic Immunity (2 of 2)

Immunity Test	IEC 61326 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz For calculations based on this equation, see Table 17-9. Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[1] Field strengths from fixed transmitters—such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast—cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Quantum system is used exceeds the applicable RF compliance level above, the Quantum system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Quantum system.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The Quantum system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Based on immunity test data, it is unlikely that commonly used communication devices such as cell phones or WiFi or Bluetooth equipped devices meeting 802.11g/n will adversely affect the Quantum system.

However, if interference is noticed or higher powered devices such as two-way radios are to be used in the vicinity of the Quantum system, the customer or the user of the Quantum system can help prevent electromagnetic interference. Electromagnetic interference can be prevented by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Quantum system as recommended in Table 17-9, according to the frequency and maximum output power specified by the manufacturer of the communications equipment.

Table 17-9: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Quantum System

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter *m*		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Symbols

The symbols shown in Table 17-10 may appear on the Quantum system, as applicable.

Table 17-10: Quantum system symbols

Symbol	Description
	Indicates that the machine requires an alternating supply current.
	Indicates a protective earth ground. The symbol is located near the chassis' main grounding location and at other protective ground points.
	Indicates that power is switched on.
	Indicates that power is switched off.
	Indicates that the user must read the accompanying documents to ensure safe operation.
	Indicates the product manufacturer.
	Indicates that the user should consult the instructions for use.
	Indicates that the equipment is subject to directive 2002/96/EC concerning waste electrical and electronic equipment (WEEE) and must be disposed of accordingly.
	Indicates that the product was manufactured in accordance with Annex II of the European Council Directive, 93/42/EEC, as amended.
	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
	Device is certified by CSA International in accordance with applicable U.S. and Canadian standards for conformance with the requirements of CAN/CSA-C22.2.61010.1:2004(R2009) and UL 61010-1: 2008, as well as the applicable respective amendments to these standards.
	Indicates risk of electric shock.

Glossary

A

Air removal chamber (ARC) — A component that prevents air from entering the IC circulation loop.

B

Bioreactor — The container of hollow fibers in the cell expansion set that is used to support and expand cells.

C

Ca++ — The abbreviation for calcium ions.

Cell expansion set — A sterile, functionally closed tubing set for use with the Quantum Cell Expansion System.

Chase — The process of flushing a line of the cell expansion set with fluid to displace the existing contents and to move the contents from one location to another. For example, you could use media to chase cells from the ARC to the IC circulation loop.

CO_2 — The abbreviation for carbon dioxide.

Configuration report — A report that details all configuration settings for the system. The configuration report records the configuration baseline and any changes made to the configuration once the baseline is set.

D

DEHP — The abbreviation for Di(2-ethylhexyl)phthalate.

E

EC — The abbreviation for extracapillary.

Electromechanical (EM) chamber	The compartment that holds the electrical and mechanical components of the device.
Extracapillary (EC) circulation loop	The tubing loop used to circulate fluids on the extracapillary (EC) side of the bioreactor.
Extracapillary (EC) side	The space outside the hollow fibers of the bioreactor.

F

FBS	The abbreviation for fetal bovine serum.

G

Gas transfer module (GTM)	A component of the cell expansion set that is used to exchange gases in the fluid that is in the EC circulation loop.
Grow	To expand cells.

H

Harvest	The process of collecting expanded cells.
HBSS	The abbreviation for Hank's Buffered Salt Solution.

I

IC	The abbreviation for intracapillary.
Incubator	The environmentally controlled chamber in which the cell expansion process takes place.
Intracapillary (IC) circulation loop	The tubing loop used to circulate fluids on the intracapillary (IC) side of the bioreactor.
Intracapillary (IC) side	The space inside the hollow fibers of the bioreactor.

M

Mg++	The abbreviation for magnesium ions.
Mounting plate	The metal plate inside the incubator that contains the pumps, the valves, the rocker arm, the external mounting clips, the internal mounting clips, and all the fluid detectors.

O

O_2	The abbreviation for oxygen.

P

PBS	The abbreviation for phosphate-buffered saline.

R

Remote alarm notification — A feature that allows you to connect your Quantum system to an existing alarm notification system at your facility so that you can receive notification of alarms that occur on the Quantum system when an operator is not present at the device.

Rocker — A component on the device that rotates the bioreactor to facilitate priming and to keep cells from settling in the IC inlet and IC outlet ports.

Run — A single run on the Quantum system. A run includes each task that the system performed from the start of Load Cell Expansion Set through the completion of Unload Cell Expansion Set.

Run report — A report that contains all tasks including any modified settings, sign-in and sign-out events, and alarms that occurred during a single run, which is from the start of Load Cell Expansion Set to the end of Unload Cell Expansion Set.

S

Stop condition — The setting that determines how and when the system stops performing the current task or step of a task.

T

Task — A series of one or more steps. Each step includes a set of valve and pump states that achieve a specific result, such as loading the cells from the cell inlet bag into the bioreactor.

Temperature set point — The point at which the temperature of the Quantum system incubator is set. The operator can configure this value.

U

Ultrafiltration — Filtration through the membrane that allows small molecules, such as water, glucose, or O_2 to pass but holds back larger molecules, such as proteins. Ultrafiltration can take place either from the intracapillary (IC) side to the extracapillary (EC) side of the bioreactor or in the opposite direction.

User authentication — The method that the Quantum system uses to identify a user and verify that a user is allowed to access the Quantum system. When enabled, this feature also allows an administrator to manage the level of access for each user of the Quantum system.

User ID	A unique sequence of numerical characters that the Quantum system uses to identify a user when user authentication is enabled.
User report	A report that contains a list of all the current users in the system, including the User Role that is assigned to each user.
User Role	When user authentication is enabled, this setting determines the level of access a user has on the Quantum system.

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Operator's Manual

Quantum® Cell Expansion System

SOFTWARE VERSION 2.1

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