



Advanced Perfusion System 1

Operators Manual

This page intentionally left blank.



Advanced Perfusion System 1

Operators Manual (synonymous with Instructions for Use)

REF 801763 100V - 120V, 15A (circuit breaker),
or 50/60 Hz (20A power source required)

REF 801763J 100 - 120V, 15A (circuit breaker),
50/60 Hz (15A power source required)

or

REF 801764 220V - 240V, 7A (circuit breaker),
50/60 Hz (10A power source required)

Cautions

Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

Proper surgical procedures and techniques are the responsibility of the medical professional.

It is the operator's responsibility to use, check, and maintain this device according to the labels of the product, accompanying instruction manuals, and any revisions of the labeling or instructions that may be subsequently issued.

Service Policy

Only Terumo Cardiovascular Systems Corporation certified service technicians are authorized to service or repair this device. Only Terumo Cardiovascular Systems Corporation approved replacement parts may be used in this device. Terumo Cardiovascular Systems Corporation approved parts are only available through Terumo Cardiovascular Systems Corporation certified service technicians. Any service or repair by an unauthorized service technician or use of unapproved parts will void your Terumo Cardiovascular Systems Product Warranty and may increase the risk of a product failure.

Contact Terumo Cardiovascular Systems Corporation Service, your local Terumo company or your authorized distributor for technical assistance and to arrange for service.

If the device is to be returned, instructions will be given for returning the device and a Returned Goods (RG) number will be issued. For contaminated devices, request the appropriate Product Return Safety Pack. Returned devices must be packaged with adequate protection against shipping damage. Include a note describing the problem, stating the RG number, and giving the name, address, and telephone number of a person to contact for additional information.

In the United States, contact the Terumo Cardiovascular Systems Corporation Technical Support Department:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road, Ann Arbor, Michigan 48103 U.S.A.
Telephone: (800) 441-3220 Fax: (734) 741-6449

Outside the United States, please contact your local Terumo company, your authorized distributor or the Technical Support Department at Terumo Cardiovascular Systems Corporation.

Telephone: (734) 663-4145 Fax: (734) 741-6449

Europe: Technical Support - Medical Electronics - Call Free Number from:

AT 0800-293711	BE 0800-94410	DK 808-80701
FI 0800-115226	IE 1800-553224	CH 0800-563694
FR 0800-908793	IT 800-785891	GB 0800-9179659
DE 0800-1808183	NL 0800-0222810	NO 800-12270
GR 00800-3212721	ES 900-963251	SE 020-791373

Other countries call +32 16 381204 at international rates

E-mail: meservice@terumo-europe.com Fax: +3216381420

Table of Contents

About Advanced Perfusion System 1

Introduction	1-2
Using this manual	1-3
Indications and Warnings	1-4
Indications.....	1-4
Contraindications	1-4
User Qualifications.....	1-4
System Warnings	1-4
System Equipment Precautions	1-5
Copyright.....	1-6
Classification.....	1-6
Patents	1-6
Training Overview	1-7

System Overview

System Philosophy	2-1
Institutional Controls	2-2
System Base.....	2-3
Features.....	2-3
Central Control Monitor.....	2-4
Features	2-4
Display Areas	2-4
Roller Pumps	2-8
Features	2-8
Centrifugal Control Unit	2-9
Features	2-9
Modules	2-11
Features	2-11
Air Bubble Detect Module	2-12
Level Detect Module	2-12
Pressure Module	2-13
Temperature Module	2-14
Flowmeter Module	2-15
Occluder Module.....	2-16
Interface Modules	2-17
Electronic Gas Blender.....	2-18

Table of Contents

System Base

Base Components	3-2
Mains Power Cord.....	3-2
Circuit Breakers.....	3-2
Auxiliary Outlet.....	3-3
Mains Power On and Off	3-3
System Power	3-4
Battery System.....	3-4
System Network	3-11
Casters and Wheel Lock System	3-12
Poles, Shelf, and Brackets	3-12
Module Bracket System	3-17
Pump Platform	3-17
Lamp.....	3-19
Hand Cranks.....	3-19
Cable Management	3-20
Module Covers.....	3-21
Cable Cover	3-21

Central Control Monitor

Features.....	4-1
Connect CCM	4-2
Start-Up Messages.....	4-3
PC Card Compartment	4-4
USB Drive Storage Compartment	4-4
Functional Areas	4-5
Displays and Controls.....	4-7
Device Icons and Displays	4-7
Buttons.....	4-8
Security.....	4-10
Perfusion Screen	4-11
Perfusion Screen.....	4-11
Primary Pump	4-13
Pump Controls and Displays	4-14
Slide Bars.....	4-15
Displays	4-17
Perfusion Screen Tabs	4-18
Perfusion Screen Tabs.....	4-18
Setup Tab	4-19
Safety Tab	4-26
CPG Tab	4-26
Aux Tab	4-31
System Tab.....	4-32
Post Case Tab	4-36
Pump Tab	4-36
Servo Subtab	4-36

Table of Contents

Pulse Subtab.....	4-37
Master and Follower Status Subtab	4-38
Central Control Monitor Messages	4-39
Configuration	4-49
Configuration.....	4-49
System Settings	4-50
Perfusion Screens.....	4-55
Configure Pumps	4-59
Add Primary Pump	4-59
Configure Perfusion Screen	4-61
Configure Other Pumps	4-61
Configure Other Devices	4-69
Add Air Detectors	4-70
Add a Level Detector.....	4-72
Add an Occluder	4-73
Add Pressure Sensors (Transducers).....	4-75
Add Flow Sensors.....	4-77
Add Temperature Sensors.....	4-79
Add CDI™ Devices	4-80
Add a CDI™ 100/101	4-80
Add a CDI™ 500/550.....	4-82
Add Timers	4-85
Edit Safety Connections	4-87
Connection Matrix.....	4-95
Assign Devices to Modules.....	4-97
Assign Air Detectors, Level Detectors, Occluder, Flow Sensors, CDI.....	4-98
Assign Pressure and Temperature Sensors	4-99
Assign Roller Pumps, Centrifugal Control Units.....	4-101
Save a Perfusion Screen.....	4-102
Edit a Perfusion Screen	4-103
View Summary, Rename, Set Password and Delete	4-104
Return to Main Screen	4-105

Roller Pumps

Features.....	5-1
Installation and Connection	5-3
Pump Cable	5-3
Base Mounting	5-3
Sliding Back Cover Panel Kit.....	5-4
Pole Mounting	5-5
Rotating the Raceway	5-5
System Connection	5-6
Installing Tubing	5-7
Setting Occlusion	5-10
During Perfusion	5-13
Manual Operation of Pump	5-13
Controls and Displays	5-14
Check the Start-up Test	5-16
Pump Menu.....	5-17

Table of Contents

Continuous Mode	5-20
Pulse Mode	5-21
Servo Mode	5-23
Master/Follower Mode.....	5-25
Roller Pump Messages	5-27

Centrifugal Pumps

Sarns™ Centrifugal Control Pumps	6-1
Features	6-1
Installation and Connection.....	6-2
Control Unit Cable.....	6-2
Pole Mounting	6-2
Drive Motor	6-3
Flexible Mounting Arm	6-3
Centrifugal Motor Mount Arm	6-3
System Connection	6-4
Manual Drive Unit	6-4
Set Up and Prime.....	6-5
Controls and Displays	6-6
Check the Start-up Test	6-7
Continuous Mode.....	6-8
Coast™ Response	6-9
Pulse Mode	6-11
Servo Mode	6-13
Using Standby Equipment	6-15
Centrifugal Control Unit Messages	6-15

Capiox™ Centrifugal Control Pumps	6-21
Features	6-21
Installation and Connection.....	6-22
Control Unit Cable.....	6-22
Pole Mounting	6-22
Drive Motor	6-23
Flexible Mounting Arm	6-23
Centrifugal Motor Mount Arm	6-23
System Connection	6-24
CAPIOX Hand Crank	6-24
Set Up and Prime.....	6-25
Controls and Displays	6-26
Check the Start-up Test	6-27
Continuous Mode.....	6-28
Coast™ Response	6-29
Pulse Mode	6-31
Servo Mode	6-33
Using Standby Equipment	6-35
Centrifugal Control Unit Messages	6-35

Table of Contents

Modules

Features.....	7-1
Air Bubble Detection (ABD)	7-3
Connect ABD Module.....	7-4
Connect ABD Sensor	7-4
Enabling and Disabling Air Detection Alarms.....	7-5
Test Before Use.....	7-6
Air Bubble Detection Messages	7-6
In the Event of an Air Alarm	7-7
In the Event of an ABD Module Malfunction	7-8
Level Monitoring	7-9
Connect Level Sensor System	7-9
Attach Sensors to Reservoir	7-10
Selecting the Level Detection Mode.....	7-11
Enabling and Disabling Level Detection System	7-11
Test Before Use.....	7-13
Level Monitoring Messages	7-14
Pressure Monitoring.....	7-17
Label and Connect Pressure System	7-17
Setting Pressure Limits	7-18
Calibrating the Pressure Transducer	7-19
Pre-Case Check	7-21
Test Before Use.....	7-21
Pressure Monitoring Messages.....	7-21
Temperature Monitoring.....	7-23
Label Probe.....	7-23
Connect Probe and Module	7-23
Setting Alarm Limits	7-24
Test Before Use.....	7-25
Temperature Monitoring Messages.....	7-25
Flow Monitoring	7-27
Flow Monitoring.....	7-27
Connect Flowmeter Module	7-28
Attach Flow Sensor	7-28
Test Before Use.....	7-30
Flow Monitoring Messages	7-30
Occluder Module	7-31
Connect Occluder Head.....	7-31
Connect Occluder Module	7-32
Occluder Module	7-33
Insert Tubing	7-33
Calibration.....	7-34

Table of Contents

Test Before Use.....	7-34
Control and Display.....	7-34
Occluder Module Messages	7-35
In the Event of an Occluder Module malfunction	7-35
Interface Module for CDI™ 100/101 and CDI™ 500/550	7-37
CDI™ 100 and CDI™ 101	7-37
CDI™ 500/550	7-39
CDI™ Messages.....	7-41
Interface Module RS-232.....	7-41
Data Transfer Interface Module	7-41

Electronic Gas Blender

Features.....	8-1
Installation and Connection	8-2
Setup	8-3
Choosing the Blending Gas.....	8-4
Setting the FiO2 Alarm.....	8-4
Calibrating the Oxygen Analyzer and Gas Flow Sensor	8-5
Control and Monitor Flow.....	8-8
Operating the Electronic Gas Blender from the CCM	8-9
Local Control of the Electronic Gas Blender	8-10
Electronic Gas Blender Messages.....	8-12

Run a Case

Check the System 1	9-1
Power On.....	9-1
Set Up	9-1
Perfuse the Patient	9-3

Emergency Procedures

Perfusion Situations.....	10-1
Equipment Situations.....	10-5

Technical Support

Using this Section.....	11-1
Communication Protocol.....	11-2
EMC Tables	11-12
Nominal Mains Power Consumption.....	11-15

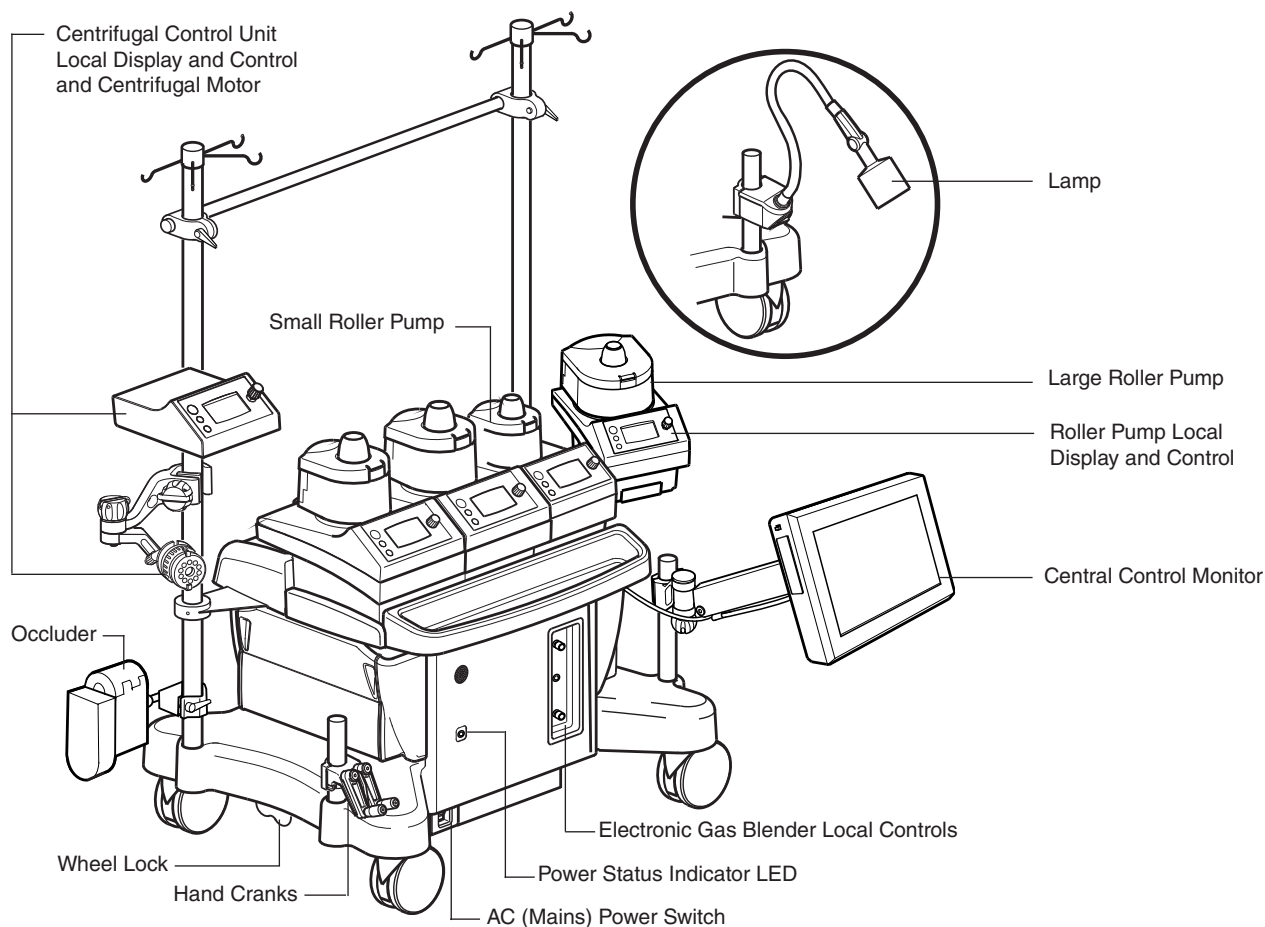
Additional Information

Summary of Warnings and Precautions	12-1
System Warnings	12-1
System Equipment Precautions	12-1
Warnings	12-3
Equipment Precautions	12-6
Equipment Care.....	12-8
Clean and Check the System After Each Use.....	12-8
Test the Alarms, and Alerts Every Three Months	12-11
Electronic Gas Blender Maintenance.....	12-13
The “Service O2 Sensor” Message.....	12-13
Oxygen Sensor Maintenance.....	12-13
Water Trap Maintenance	12-13
Removal and Cleaning of Tube Clamps	12-14
Removal and Cleaning of the Instrument Tray	12-14
Replacing Air Filters and Lamp Bulbs	12-15
Service	12-17
System Components	12-19
Accessory Kit	12-21
Recommended Spare Parts	12-22
Symbol Glossary	12-23
Glossary	12-29

Index	Index-1
-------------	---------

Limited Warranty

About Advanced Perfusion System 1



With this system, you may...

- Use Central Control from the Central Control Monitor
- Integrate Pump Responses with Safety and Monitoring Systems
- Choose Direction of Flow
- Choose Continuous or Pulse Mode
- Choose Servo Control to Pressure or Flow
- Choose Master/Follower Functionality
- Choose Remote Mounting of Pumps to Reduce Tube Length
- Blend Gases and Monitor Gas Flow
- Detect Air Bubbles and Select Pump Responses
- Detect Low Blood Level and Select Pump Responses
- Monitor Pressures and Select Pump Responses
- Monitor Temperatures
- Monitor Flow and Select Pump Responses
- Monitor Cardioplegia Fluid Delivery Times and Volumes
- Occlude the Venous Line
- Capture Data and Events for a Perfusion Record
- Display Blood Chemistry Data from CDI Devices
- Operate on Battery Backup

About Advanced Perfusion System 1

Introduction

The Terumo® Advanced Perfusion System 1 allows users to choose system components and mounting configurations to meet current clinical needs, while providing adaptability to reconfigure the system as their needs change. The Advanced Perfusion System 1 may also be referred to as the System 1 throughout this Operators Manual.

The System Base uses a distributed network to provide power and communications to all system components. This design allows users to select the number and types of devices needed to control and monitor patient perfusion during cardiopulmonary bypass. These devices include any combination of the following components up to the system maximum of 24:

Device	Maximum	
Electronic Gas Blender	1	
Large Roller Pump	8	} 8 in use at any given time, 6 can be controlled from Central Control Monitor (CCM)
Small Roller Pump	8	
Centrifugal Pump	2	
Occluder Module	1	
Air Bubble Detect Module	4	
Level Detect Module	1	
Pressure Module	4	} 2 sensors per Module
Temperature Module	4	
Flowmeter Module	4	
CDI 100/101 Module	1	} 1 in use at any given time
CDI 500/550 Module	1	
Data Transfer Module	1	

Pumps can be mounted side by side on the system base or they can be pole mounted to reduce the lengths of tubing in the perfusion circuit. Roller pumps can be mounted on the system base or on a pole with an appropriate mounting bracket. The distributed network design allows modules to be plugged into any of the System Base module receptacles. This design allows users to connect modules to any connection point on the system base.

A Central Control Monitor (CCM) allows users to configure up to 12 different Perfusion Screens for different equipment and protocol setups. When setting up a Perfusion Screen, the user can define not only the system components that will be used, but also the pump responses to safety system alerts and alarms.

In addition to monitoring system and perfusion data during a procedure, the CCM allows touch screen control of pump speeds, gas flow and FiO2 settings (if an electronic gas blender is installed), and occluder position. Additional advanced functions of System 1 include Pulse Mode, Servo Control to pressure or flow, Master/Follower functionality, and Automatic Cardioplegia Delivery.

About Advanced Perfusion System 1

Using this manual

This Operators Manual provides directions for operating the Terumo® Advanced Perfusion System 1.

This manual is organized to be a training tool; simply begin with this section and proceed through the manual.

- Understand this fully integrated, adaptable perfusion system and how various features function together and independently.
- Study the **Indications and Warnings** section to ascertain the system's uses and functional boundaries.
- Learn to start, test and customize the system.
- Learn how the pumps function.
- Learn about the safety systems.
- Learn about using the gas flow system.
- Monitor and capture perfusion data.
- Prepare for potential emergencies by studying the **Emergency Procedures** section.
- Maintain the system as directed in the **Equipment Care** section.
- Refer to the **Additional Information** section to find information on components available for the system.
- Refer to the **Technical Support** section for performance information.

Note: Only trained technicians should use the Technical Support information to make installation adjustments and replace equipment.

- Locate specific aspects of the system by using the Index.

After you have read the manual, simulate a case for practice. Simulate the emergency situations you may encounter during perfusion and practice responding to system messages, alarms and alerts, especially those associated with the safety systems for air and level detection.

Note: Store product updates and instructions for system components in the inside pocket of the manual.

About Advanced Perfusion System 1

Indications and Warnings

Indications

The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

Contraindications

This device is not designed, sold or intended for use except as indicated.

The centrifugal pump is contraindicated for use as a cardiectomy suction device.

Intended Patient Population

The System 1 is used in extracorporeal circulation of blood in patient populations ranging from neonates to adults.

User Qualifications

Proper perfusion procedures and techniques are the responsibility of the medical professional.

User must read and understand all information in the Operators Manual for the Terumo® perfusion system being used.

System Warnings

The System 1 is indicated for use for up to 6 hours duration. The safety and effectiveness of System 1 for long-term use (longer than 6 hours duration) has not been established.

Use the system and any attached equipment according to the manufacturer's instructions and good medical practice.

This device is qualified only for durations appropriate to cardiopulmonary bypass procedures. It has not been qualified, through *in vitro*, *in vivo*, or clinical studies, for long-term use in bridge to transplant or pending recovery of the natural heart.

Do not use an apparently malfunctioning device in an operation.

Do not modify the Advanced Perfusion System 1 or any attached equipment or accessories. Only use spare parts provided by Terumo Cardiovascular Systems. Modifying the system, using unapproved spare parts, or using the system in ways not indicated by this manual could lead to injury, compromised performance, and/or damage.

This device must not be allowed to run unattended. Patient safety requires that operation be properly and continuously monitored by a qualified medical professional.

This device must be configured with clinically relevant alarm and alert limits. Setting alarm and alert limits to extreme values can render the alarm system useless. A potential hazard can exist if different alarm or alert limits are used for similar equipment operating in the area of the System 1.

About Advanced Perfusion System 1

System 1 is a configurable system allowing users to create perfusion screens utilizing different combinations of equipment with different responses to events. Because of this high degree of configurability, it is important that user institutions establish appropriate controls to assure that users are properly trained and qualified to run Perfusion Screens. **Failure to establish such controls may result in operator error that could result in patient injury or death.**

System Equipment Precautions

Grounding reliability can only be achieved when this equipment is connected to an appropriate receptacle which has been inspected for proper grounding.

This device requires a dedicated 15 or 20 Amp AC (Mains) power source for the 100V – 120V model or a dedicated 10 Amp AC (Mains) power source for the 220V - 240V model.

Complete any external equipment connections before turning the system on as connecting equipment during use may cause system malfunction.

Do not use this device in the presence of explosive or flammable gases.

To avoid electrical shock hazard, do not remove panels; refer servicing to qualified service personnel.

Do not operate the system without the module covers secured in place as spilled liquids may damage the connections.

Connect only hospital equipment of appropriate voltage and current rating to the auxiliary outlet. Electrical equipment connected to the auxiliary outlet leads to creating an medical electrical system that can result in a reduced level of safety.

The auxiliary outlet is not backed up by battery power. During loss of AC (Mains) power any equipment connected to the auxiliary outlet will lose power and remain unpowered until AC (Mains) power is restored.

Do not use extension cords to connect the system to AC (Mains) power nor to connect modules or accessories to the system. Use of extension cords may compromise performance.

In the event that an AC (Mains) circuit breaker trips immediately after a reset, DO NOT attempt to reset again. The system will only operate from battery power until it has been repaired. Call for service.

Use only the cables provided to connect pumps and flowmeter modules to the system.

Do not touch the electrical contacts of any connectors at the same time as touching a patient.

The use of accessory equipment not complying with the equivalent safety requirements of this system may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity;
- evidence that safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized international standards.

Equipment used to heat and cool the water used to regulate the temperature of the blood supplied to a heat exchanger should be rated Type CF. If the equipment is not Type CF and a malfunction occurs, the possibility exists that electrical current may pass through the heat exchanger and into the patient perfusion circuit.

About Advanced Perfusion System 1

The system can be stored in a ventilated area with a temperature range of 0°C to 40°C (32°F to 104°F) and a relative humidity range of 10% to 95%, non-condensing. The system can be operated at a temperature range of 10°C to 40°C (50°F to 104°F) at 30% to 75% relative humidity, non-condensing and an atmospheric pressure of 106 kPa to 70 kPa.

Do not use chemical solvents such as ether, acetone, etc., in or on any part of the system as such solvents may be destructive to the device. Do not disinfect with Virex® Tb*. Do not spill anesthetics on the system or components as chemicals such as Forane (isoflurane) may be destructive. Follow the cleaning procedure in the **Equipment Care** section.

Following standard practices for electronic devices, monitor this equipment closely when it is exposed to intense electrical noise or fluctuating line voltage. Strong electromagnetic fields radiated from equipment elsewhere in the operating room (particularly defibrillators and electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.

This device needs special precautions regarding electro-magnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the **Technical Support** section.

Read the additional Warnings and Precautions located in the appropriate sections throughout the manual. A summary list of all the Warnings and Precautions in this manual can be found in the **Additional Information** section. Use only recommended components and meet all specifications to ensure the system will operate properly.

Copyright

Copyright © 2024 Terumo Cardiovascular Systems Corporation

This manual and the software described in this manual, are copyrighted. No part of this manual or the described software may be copied, reproduced, translated or reduced to any electronic medium or machine readable form without the prior written consent of Terumo Cardiovascular Systems Corporation.

Classification

This device is classified as follows: Mobile, Continuous Operation, Class 1 and Internally Powered, Type CF, Not suitable for use in the presence of a flammable anesthetic.



MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/ AAMI ES60601-1 (2005) + AMD 1 (2012) and CAN/CSA-C22.2 No. 60601-1:14. E360151

Patents

This device or components of this device are protected by U.S. Patents 5,752,931; 5,813,972; 6,164,920; 6,607,363; 6,609,900; 6,722,865; 6,736,617; 6,783,328; 6,971,143; 7,006,005; 7,148,786 and foreign equivalents. Other U.S. and foreign patents pending.

* Virex® Tb is a registered trademark of JohnsonDiversy™.

About Advanced Perfusion System 1

Training Overview

System Base

- ☐ System power (external and battery)
- ☐ Power Cord
- ☐ Power Indicator
- ☐ Powering Down
- ☐ Battery life
- ☐ Casters, wheel locks
- ☐ Poles
- ☐ Modules
 - ☐ LEDs
 - ☐ Channels
 - ☐ Sensors
 - ☐ Dedicated connections
- ☐ Pump connections
- ☐ Dedicated connections for CCM
- ☐ Dedicated connections for a lamp
- ☐ Isolated AC outlet for ancillary equipment
- ☐ Air Filters
- ☐ Covers
- ☐ Cable Management
- ☐ Cable Cover
 - ☐ Install Cover
 - ☐ Remove Cover

Central Control Monitor

- ☐ Connection to System Base
- ☐ Start up test
- ☐ Main screen
- ☐ Configuring a perfusion screen
 - ☐ Adding pumps
 - ☐ Adding devices
 - ☐ Safety connections
 - ☐ Assigning devices
- ☐ Saving a perfusion screen
- ☐ Institutional Controls
- ☐ Password Protection
- ☐ PC Cards/USB Drives
- ☐ Running a case
 - ☐ Message area
 - ☐ Alarm
 - ☐ Alert
 - ☐ Status
 - ☐ Error
 - ☐ Mute All button
 - ☐ Slide Bar Controls
 - ☐ Primary Pump
 - ☐ Gas System/Occluder
 - ☐ Other Pumps
 - ☐ Perfusion Screen Tabs
 - ☐ Setup Tab
 - ☐ Patient Subtab
 - ☐ Gas Subtab
 - ☐ Pump Subtab

- ☐ Occluder Subtab
- ☐ Timer Subtab
- ☐ Time/Date Subtab
- ☐ Safety Tab
 - ☐ Mute Button
 - ☐ Air Subtab
 - ☐ Level Subtab
 - ☐ Pressure Subtab
 - ☐ Temperature Subtab
 - ☐ Flow Subtab
- ☐ CPG Tab
 - ☐ Delivery Subtab
 - ☐ Auto Dose Setup Subtab
- ☐ Auxiliary Tab
 - ☐ Timers Subtab
 - ☐ Messages Subtab
- ☐ System Tab
 - ☐ Settings Subtab
 - ☐ Power Subtab
 - ☐ Reassign Module Subtab
 - ☐ Module Info Subtab
- ☐ Post Case Tab
- ☐ Service Area
- ☐ Shut down

Roller Pumps

- ☐ Maximum number
 - ☐ Connected – 8
 - ☐ Configured on perfusion screen – 6
- ☐ Large and Small
 - ☐ Raceway size
 - ☐ Large 6 inch (15 cm)
 - ☐ Small 4 inch (10 cm)
 - ☐ Flow ranges
 - ☐ Tubing sizes
- ☐ Mounting and positioning (raceway orientation)
- ☐ Accessing power
- ☐ Air Filters
- ☐ Self diagnostics
- ☐ Control
 - ☐ Local
 - ☐ CCM
- ☐ Local Control
 - ☐ Graphic Display
 - ☐ Pump Name/Module ID
 - ☐ Direction icon
 - ☐ Speed control knob
 - ☐ Pump speed
 - ☐ Flow rate display
 - ☐ Alarm, alert, status, and error messages
 - ☐ Speed indicator/Bar graph

About Advanced Perfusion System 1

- ☐ Three buttons
 - ☐ Start/Stop
 - ☐ Select
 - ☐ Direction
 - ☐ Flow Constant
 - ☐ Tube Size
 - ☐ Exit
 - ☐ Manual
- ☐ Central Control
 - ☐ Pump Icon
 - ☐ Slide Bar
 - ☐ Pump Tab
 - ☐ Summary Subtab
 - ☐ Servo Subtab
 - ☐ Pressure
 - ☐ Flow
 - ☐ Pulse Subtab
 - ☐ Master/Follower Subtab
- ☐ Tube clamp mechanism
- ☐ Setting occlusions
- ☐ Hand cranking
- ☐ Pump replacement
 - ☐ Verify direction of rotation
- ☐ Operating modes
 - ☐ Start
 - ☐ Stop
 - ☐ Continuous
 - ☐ Pulse
 - ☐ Master/follower
 - ☐ Servo
- ☐ Roller Pump Events
 - ☐ Pump Stopped
 - ☐ Pump Started
 - ☐ Pump Paused
- ☐ Roller Pump Responses to Alerts/Alarms/Other Pumps
 - ☐ Stop
 - ☐ Pause
 - ☐ Reduce speed
 - ☐ Message only
 - ☐ No response
- ☐ Safety Cover open, pause response
- ☐ Alarm Messages
- ☐ Alert Messages
- ☐ Status Messages
- ☐ Error messages

Centrifugal Pump (Optional)

- ☐ Maximum number - 2
- ☐ Mounting and Positioning
- ☐ Accessing Power
- ☐ Self Diagnostics
- ☐ Control
 - ☐ Local
 - ☐ CCM

- ☐ Local Control
 - ☐ Graphic Display
 - ☐ Pump Name
 - ☐ Centrifugal Icon
 - ☐ Speed control knob
 - ☐ Pump speed
 - ☐ Flow rate display
 - ☐ Alarm, alert, status, and error messages
 - ☐ Speed indicator/Bar graph
- ☐ Three buttons
 - ☐ Start/Stop
 - ☐ Select
 - ☐ Manual
- ☐ Central Control
 - ☐ Pump Icon
 - ☐ Slide Bar
 - ☐ Pump Tab
 - ☐ Summary Subtab
 - ☐ Servo Subtab
 - ☐ Pressure
 - ☐ Flow
 - ☐ Pulse Subtab
- ☐ Min RPMs
- ☐ Setting minimum flow alarm
- ☐ Hand cranking
- ☐ Pump replacement
- ☐ Operating Modes
 - ☐ Start
 - ☐ Stop
 - ☐ Continuous
 - ☐ Pulse
 - ☐ Servo
- ☐ Centrifugal Pump Events
 - ☐ Pump Stopped
 - ☐ Pump Started
 - ☐ Minimum Flow
 - ☐ Pump goes to Coast speed
- ☐ Centrifugal Pump Responses to Alerts/Alarms/Other Pumps
 - ☐ Stop
 - ☐ Coast™ Response
 - ☐ Message only
 - ☐ No response
- ☐ Alarm Messages
- ☐ Status Messages
- ☐ Alert Messages
- ☐ Error Messages

Air Bubble Detect Modules and Sensors

- ☐ Maximum number – 4
- ☐ Proper positioning
- ☐ Control with CCM
 - ☐ On, Off, Reset
- ☐ Connection to Devices

About Advanced Perfusion System 1

- ☐ Roller pumps
- ☐ Centrifugal pumps
- ☐ Reset button
- ☐ Testing the ABD
- ☐ Alarm Messages
- ☐ Status Messages
- ☐ Error Messages

Level Detect Modules and Sensors

- ☐ Maximum number – 1
- ☐ Use with Hardshell reservoirs only
 - ☐ Dimensions
- ☐ Pad, sensor attachment
- ☐ Alarm/Alert Mode
- ☐ Control with CCM
 - ☐ On, Off
- ☐ Connection to Devices
 - ☐ Roller pumps
 - ☐ Centrifugal pumps
- ☐ Testing the Level Detection System
- ☐ Alarm Messages
- ☐ Alert Messages
- ☐ Status Messages
- ☐ Error Messages

Pressure Modules and Transducers (Optional)

- ☐ Maximum number – 8 transducers
- ☐ Placement of transducers
- ☐ Calibration of transducers
- ☐ Pressure Display
- ☐ Setting limits
 - ☐ Positive
 - ☐ Negative
- ☐ Connection to Devices
 - ☐ Roller pumps
 - ☐ Centrifugal pumps
- ☐ Testing the Pressure System
- ☐ Servo control
- ☐ Alarm Messages
- ☐ Alert Messages
- ☐ Status Messages
- ☐ Error Messages

Temperature Modules and Probes (Optional)

- ☐ Maximum number – 8 probes
- ☐ Probes used
- ☐ Setting alarms
- ☐ Testing the Temperature probes

- ☐ Alarm Messages
- ☐ Status Messages
- ☐ Error Conditions

Flowmeter Modules and Sensors (Optional)

- ☐ Maximum number – 4
- ☐ Connection to Devices
 - ☐ Roller pumps
 - ☐ Centrifugal pumps
- ☐ Connection to centrifugal pump for local display and min flow alarm capability
- ☐ Placement of Flowmeter Module
- ☐ Placement of Flow Sensors
- ☐ Testing the Flow Sensor
- ☐ Servo Control
- ☐ Alarm Messages
- ☐ Status Messages
- ☐ Error Conditions

Occluder Module and Head (Optional)

- ☐ Maximum number – 1
- ☐ Proper insertion of tubing
- ☐ Setting up and controlling
- ☐ Tubing sizes
- ☐ Calibration
- ☐ Percent Open
- ☐ Occluder Responses to primary pump
 - ☐ No Response
 - ☐ Full Open
 - ☐ Full Close
 - ☐ Go To Flow 0% (up to 100%)
- ☐ Testing the Occluder
- ☐ Status Messages
- ☐ Error Conditions

Connecting to CDI (Optional)

- ☐ Maximum number of CDI 500/550 monitors – 1
- ☐ Maximum number of CDI 100 monitors – 1
- ☐ Maximum number of CDI 101 monitors – 1
- ☐ Selecting and displaying data values

About Advanced Perfusion System 1

Electronic Gas Blender Module (Optional)

- ☐ Connections
- ☐ Blending gases
 - ☐ 95/5
 - ☐ Air
- ☐ Control
 - ☐ Manual
 - ☐ CCM
- ☐ Flow Rate Range
- ☐ Oxygen Analyzer
- ☐ Calibrating the Oxygen Analyzer
- ☐ FiO2 alarm
- ☐ External Flowmeter
- ☐ Water Trap Care
- ☐ Alarm Messages
- ☐ Alert Messages
- ☐ Status Messages
- ☐ Error Messages

Primary and Backup Pumps

- ☐ Assigning Primary Pump
 - ☐ Dedicated Slide Bar
 - ☐ Flow Display Choices
 - ☐ Pulse Mode
- ☐ Assigning Backup Pump
 - ☐ Primary Pump functionality can be reassigned
 - ☐ Different pump type
 - ☐ Centrifugal Coast™ responses

Cardioplegia Delivery

- ☐ Assigning cardioplegia pump
- ☐ Volume tracking
- ☐ Timers
 - ☐ Time since last delivery
- ☐ Adjusting total volume delivered
- ☐ Servo Control
- ☐ Varying CPG ratios
- ☐ Delivering a fixed dose
 - ☐ By Volume
 - ☐ By Time

Timers

- ☐ Maximum number – 4
- ☐ Two timers preassigned
 - ☐ Pump
 - ☐ Clamp
- ☐ Auxiliary timers
- ☐ Timer Modes

Emergency Procedures

- ☐ Emergency situations (wet run)
 - ☐ Air detected
 - ☐ Low level
 - ☐ High pressure
 - ☐ Unexpected return to CPB
 - ☐ Loss of (Hospital) gas supply
 - ☐ Loss of power
 - ☐ System circuit breaker
 - ☐ Hospital supply
 - ☐ Intermittent AC and DC power supply
 - ☐ Power failure – safety system functions
 - ☐ Local pump controls
 - ☐ Local gas flow controls
 - ☐ Air deprimes centrifugal pump
- ☐ Equipment situations
 - ☐ Arterial pump failure
 - ☐ Replacing Pumps
 - ☐ Verify direction of rotation
 - ☐ ABD, level failure
 - ☐ Operating the system without the CCM
 - ☐ Operating the system in case of network failure
 - ☐ Centrifugal pump decouples
 - ☐ Servo Loss

Equipment Care

- ☐ Cleaning and lubrication
- ☐ Preventive maintenance
- ☐ Batteries
- ☐ Power off

System Overview

System Philosophy

The System 1 uses a software-based design and a user interface to provide an adaptable perfusion system.

Each system device and sensor module contains software that allows it to transmit and receive messages via a Controller Area Network (CAN). This design allows users to:

- Connect modules to any connection point on the system base
- Enable communications links between sensors and devices
- Select how they want pumps and an occluder to respond to alert and alarm conditions

An additional advantage of this design is the ability to use advanced functions without requiring specialized hardware. All pumps can be configured to deliver advanced functions such as:

Roller and Centrifugal Pumps

- Pulse mode
- Servo regulation to pressure or flow

Roller Pumps only

- Master/Follower operation
- Cardioplegia volume tracking
- Automatic cardioplegia dose delivery

The System 1 uses an intuitive patient graphic interface to organize the system information. This centralized monitoring helps the user to view current perfusion parameters without having to look at multiple displays.

The System 1 Central Control Monitor (CCM) also serves as the central area for controlling pumps, an occluder, and the gas flow system. Pumps and the gas flow system also have local controls and displays that can be used interchangeably with the central monitor controls. This allows the user to:

- Remotely mount pumps and sensors
- Reduce tube lengths
- Reduce the prime volume of the extracorporeal circuit

System Overview

Institutional Controls

WARNING: System 1 is a configurable system allowing users to create perfusion screens utilizing different combinations of equipment with different responses to events. Because of this high degree of configurability, it is important that user institutions establish appropriate controls to assure that users are properly trained and qualified to run Perfusion Screens. **Failure to establish such controls may result in operator error that could result in patient injury or death.**

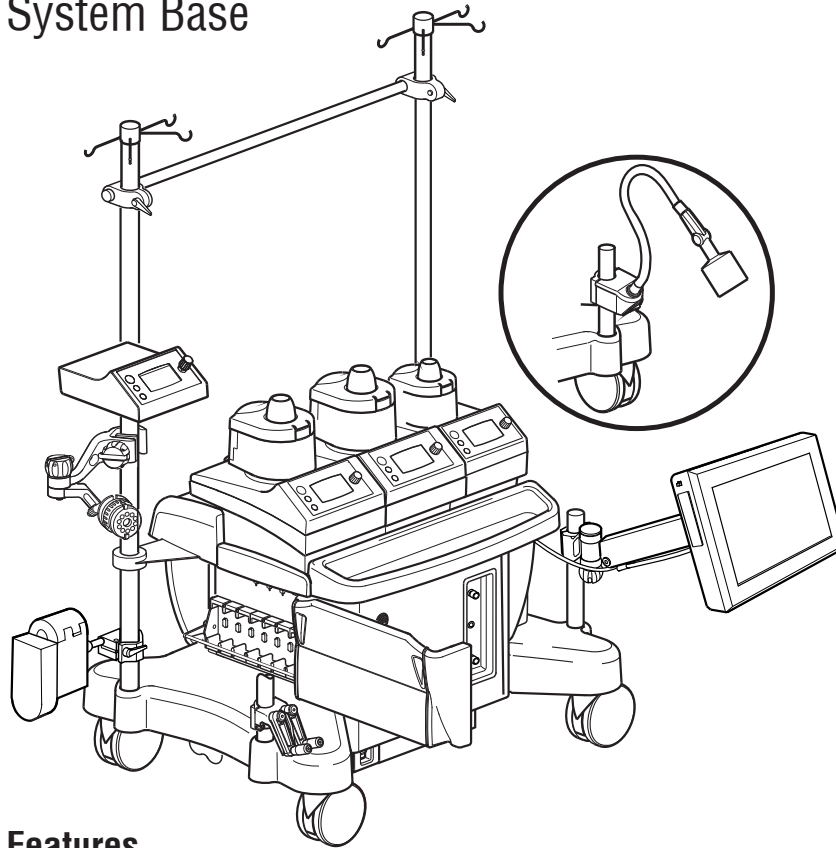
To reduce the likelihood of such errors, user institutions should establish policies or procedures for developing, qualifying, controlling, maintaining and securing perfusion screen configurations. The following list includes suggested actions to be covered by such procedures. This is not intended as an all-inclusive list of actions, but is merely a guide to illustrate examples of what an institution should consider when using System 1. Additional or different actions may be necessary depending on particular use and/or institutional policies and procedures.

Suggested policies and/or procedures to be established:

- Authorization of appropriately qualified individuals to create, revise and approve Perfusion Screens.
- Use of passwords to prevent unauthorized changes to Perfusion Screens.
- Testing methods to assure all system responses are completely understood and meet expectations.
- Establishment of protocols or methods for responding to situations that may occur during use.
- Establishment of a standard system direction for roller pump forward flow.
- Establishment of a policy to re-set the roller pump default direction to the institution's chosen standard system direction. This particularly applies to replacement, loaner or returned pumps.
- Training of users.

System Overview

System Base



Features

The system base houses the internal network architecture, electronics, power supply components, batteries, communications and power connections and circuit breakers.

The base has a pair of casters on each side. Each pair of casters has a 3 position locking lever to control the movement of the casters.

Roller pumps are mounted along a central rail on the top of the base or on the poles with mounting brackets. There are 2 sizes of pump mounting extensions to allow different combinations of large and small pumps to be mounted along the central mounting area. Cable clips are built in to the mounting area to aid in cable management. The centrifugal control unit is mounted on the system with a pole mounting bracket.

Modules are connected to the receptacles on the sides of the base. A locking rail protects the modules from accidental disconnection.

Protective cover panels are attached to the top and sides of the base after components are installed to protect cables and components from liquid spills.

Long mounting poles are installed on the back corners of the base and short mounting poles are installed on the front corners of the base. A crossbar can be mounted between the 2 longest poles.

A pole-mountable halogen lamp is available in 2 sizes, long or short. A pole-mountable LED lamp is available in one size only.

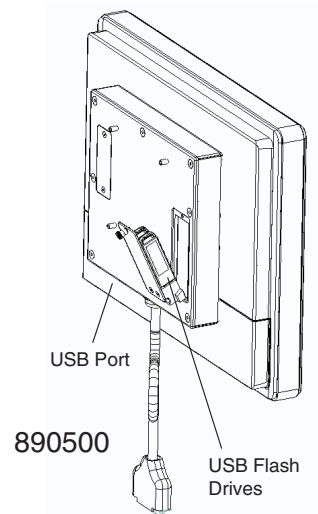
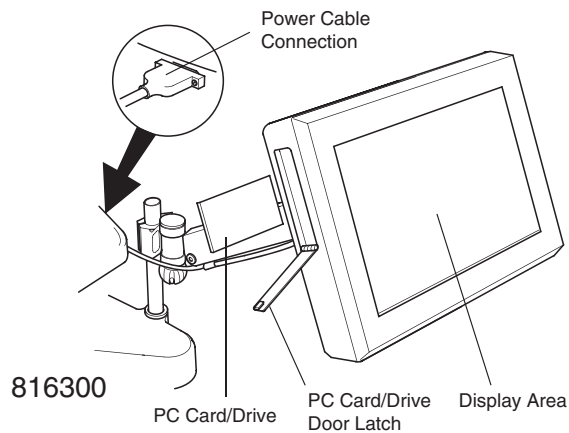
A hand crank bracket, which holds 2 hand cranks, can be mounted on a pole in a convenient location.

There is an auxiliary outlet on the back of the system base for powering additional equipment.

System Overview

Central Control Monitor

Features



The Central Control Monitor (CCM) is the primary control and monitoring center for the Advanced Perfusion System 1. The CCM comprises an embedded computer with an integrated graphical display and a touch screen.

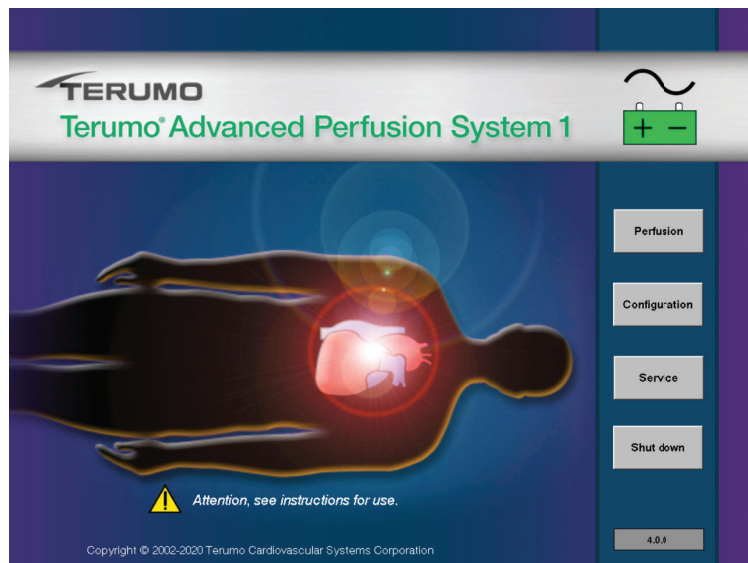
A power cable connects the Central Control Monitor to the system.

The Central Control Monitor holds 2 PC cards or USB drives (depending on model): a system configuration card/drive and a service data card/drive. The system configuration card/drive may be used to transfer perfusion screen configurations between systems. The service card/drive collects and stores data for use by authorized service representatives. The service card/drive should be handled only by qualified service technicians.

Display Areas

Main Screen

The Main Screen is the first screen that is displayed after the system completes initialization and a self test. If any device fails the start up test, a failure message will be displayed at the top of the screen.

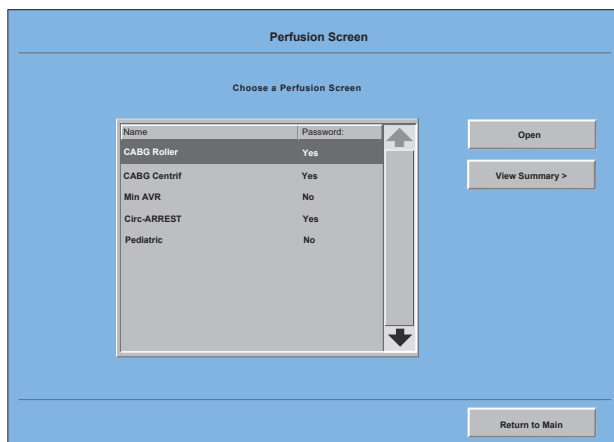


System Overview

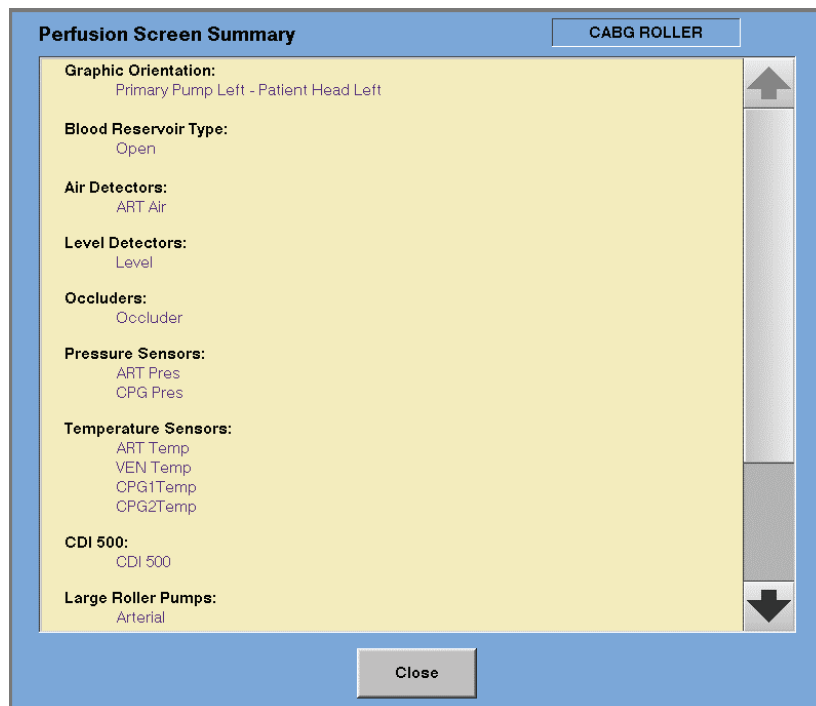
The system software version can be viewed on the lower right side of the Main Screen. Four buttons, **Perfusion**, **Configuration**, **Service**, and **Shut down** allow access to the functional areas or provide a controlled shut down of the system computer before turning the AC (Mains) power off to the entire system.

Perfusion

A Perfusion Screen is a graphical representation of the perfusion circuit on the CCM touch screen that is used to control and monitor perfusion parameters during a case. The Perfusion area allows the user to select a Perfusion Screen for running a case. The initial screen lists all the Perfusion Screen names and their password protection status.



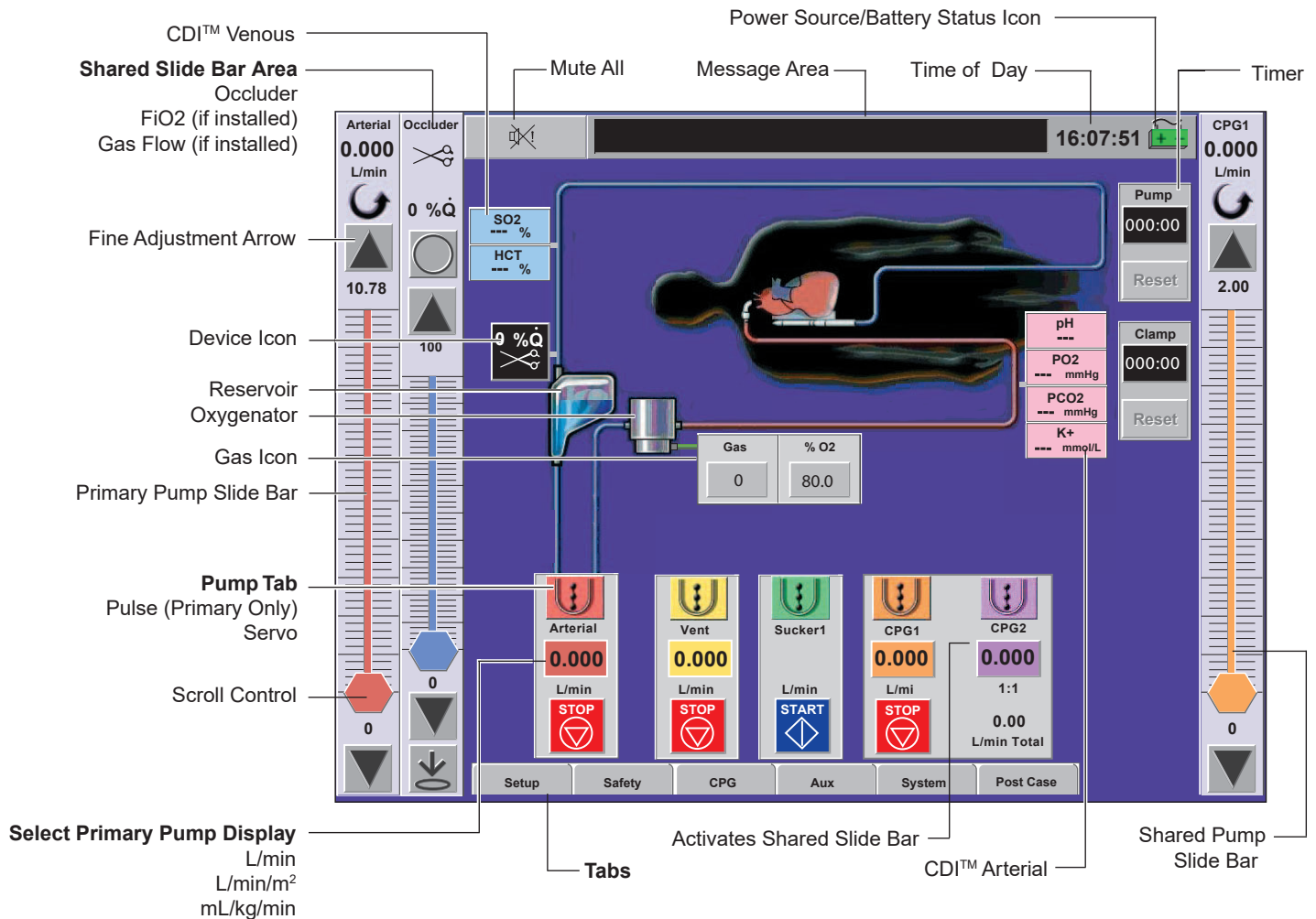
A Configuration Summary can be viewed for each Perfusion Screen or the desired screen can be selected and opened.



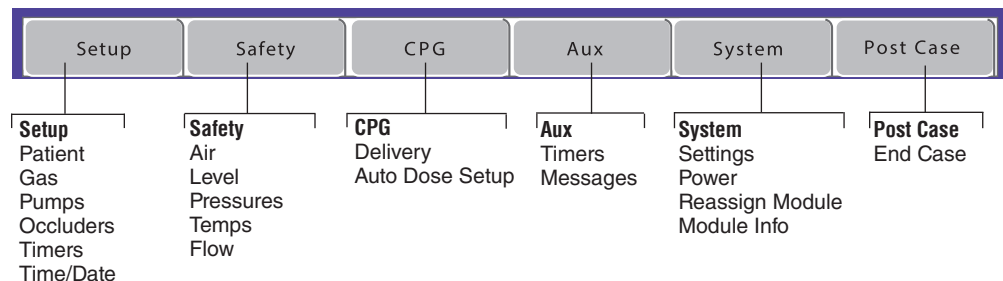
Perfusion Screens are created or modified in the configuration area. If desired, access to a Perfusion Screen can be limited by assigning a password.

System Overview

The illustration below is an example of a Perfusion Screen -the different elements and areas of the Perfusion Screen are labeled. For detailed information about the function of the Perfusion Screen, refer to the **Perfusion Screen** section of the **Central Control Monitor** chapter.



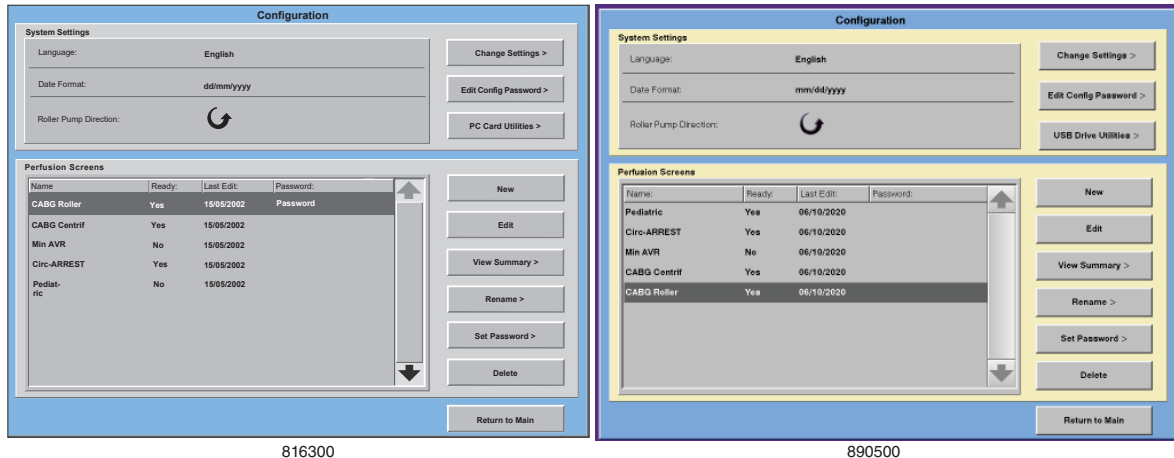
Tabs and Subtabs



System Overview

Configuration

The Configuration area can be password protected and allows authorized users to view and change system settings and Perfusion Screens.



The System Settings area is used to select the display language, the date format, set the default system direction for roller pumps, edit the configuration password, and access the PC Card/USB Drive Utilities.

The PC Card/USB Drive Utilities are used to move or copy Perfusion Screen files between the CCM and a PC card/USB drive, view a Perfusion Screen Summary, and rename or delete a Perfusion Screen.

The Perfusion Screens area is used to create, edit, rename, or delete perfusion screens. A Perfusion Screen Summary can be viewed and a password can be assigned to the screen in order to limit access to authorized users.

When creating a new Perfusion Screen, the user is led through a step by step process:

- Selecting primary pump and patient orientation
- Selecting additional pumps including on-screen names and colors
- Selecting additional modules including names and, if available, colors
- Establishing safety connections
- Setting alert and alarm limits
- Selecting pump responses to external events
- Selecting occluder responses to primary pump events
- Assigning screen representation to physical modules and devices
- Naming the Perfusion Screen and identifying the screen as ready for use

For more details on the operation of the Configuration area, refer to the **Configuration** section of the **CCM** chapter.

Service

Access to the Service area is password protected and limited to authorized personnel. This area is used to view the system log, export the system log to an external computer via the service data card, view module error event data and calibrate the touch screen. It is also used to manage security access control and view the system software version control area.

Shut down

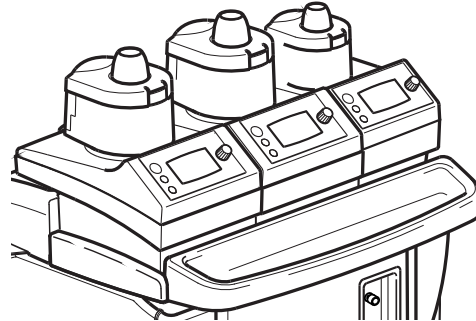
Provides a controlled shut down of the system computer and must be performed before AC (Mains) power to the entire system is turned off. Failure to follow the controlled shut down procedure may result in improper start-up at the next power-on.

System Overview

Roller Pumps

Features

Roller pumps are available in 2 sizes. Large roller pumps have a 6 inch (15 cm) raceway and small roller pumps have a 4 inch (10 cm) raceway.



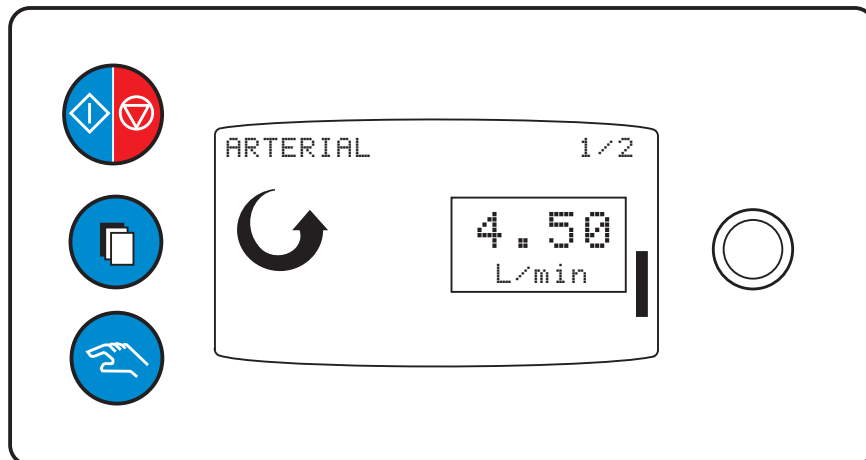
Pumps can be mounted side by side on the system base or they can be pole mounted to reduce the lengths of tubing in the perfusion circuit. Roller pumps can be mounted on the system base or on a pole with an appropriate mounting bracket. Various arrangements of large and small pumps can be mounted on the system base using the mounting extensions provided.

Roller pumps are connected to the system with a cable. There are 6 pump receptacles on the system, 3 on each side. Roller pumps can also be connected to any of the module receptacles. Up to 8 pumps can be connected to the system, but only 6 can be controlled through the Central Control Monitor at any given time.

The roller pump raceway can be rotated in 15° increments and locked into position to allow for options to reduce tubing length. A universal tube clamp mechanism accommodates a variety of tubing sizes, including dual tubing sets, without the need for different size inserts.

The occlusion mechanism allows the position of the rollers to be adjusted at any time, including while the pump is rotating. An audible click can be heard whenever the occlusion is being adjusted.

Roller pumps can be controlled from the Central Control Monitor or from controls on the pump itself. Tubing size, direction of rotation, speed, flow rate or RPMs, and safety, status and error messages are displayed on the pump as well as on the Central Control Monitor. An amber colored bar graph represents pump speed.



System Overview

There are 5 operating modes for a roller pump:

- Continuous: the pump operates at a constant speed set by the user.
- Pulse: available on the primary pump only; the pump speed alternates between a peak speed and a baseline speed. Base, Rate and Width can be adjusted through the Central Control Monitor.
- Master/Follower: set up during configuration; involves two roller pumps in Continuous Mode. The Follower pump demand flow rate or speed is a percentage of the master pump flow rate or speed. The percentage can be adjusted through the Central Control Monitor or from the pump speed control knob on the follower pump. The pump designated as the primary or arterial pump cannot be designated as a master/follower pump.
- Servo Control: pump speed is regulated to maintain a specific pressure or flow rate. The pressure and flow rate setpoints can be adjusted through the Central Control Monitor or from the pump speed control knob on the pump.
- Automatic Delivery: the pump delivers a set fluid volume or delivers fluid for a set amount of time and then stops.

Roller pumps can be connected to safety and monitoring systems and other pumps during configuration, followed by choosing pump responses. Roller pump response choices are No Response, Stop, Pause, Reduce Speed and Message Only. The choices allowed for a pump response vary depending on the type of alert or alarm and the type of device connected to the pump.

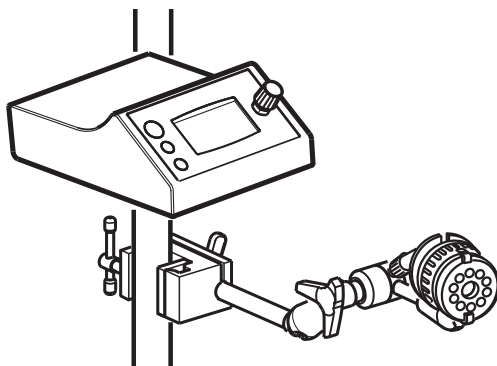
When a connected device is in alert or alarm mode, a message will display on the pump display.

Centrifugal Control Unit

Features

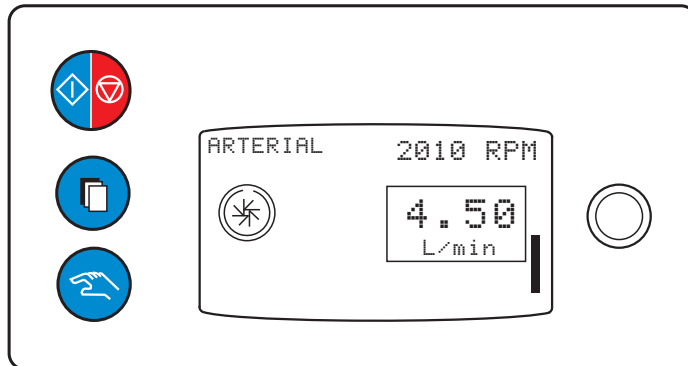
The centrifugal control unit provides an interface between the system and a centrifugal drive motor. A disposable centrifugal pump magnetically couples to the drive motor. The drive motor is mounted on a pole and connects to the centrifugal control unit with a cable. The centrifugal control unit mounts on a pole and connects to the system with a cable. The control unit can be connected to a pump receptacle or to any of the module receptacles.

Up to 2 centrifugal control units can be connected to the system at a time. The centrifugal pump can be controlled from the Central Control Monitor or from controls on the centrifugal control unit.



System Overview

Motor speed, flow rate, as well as safety, status, and error messages are displayed on the centrifugal control unit control panel as well as on the Central Control Monitor. Pump speed is displayed in RPMs on the pump as well as represented as an amber colored bar graph.



There are 3 operating modes for a centrifugal pump:

- Continuous: pump operates at a constant speed set by the user.
- Pulse: available on the primary pump only; the pump speed alternates between a peak speed and a baseline speed. The baseline speed can be adjusted through the Central Control Monitor.
- Servo Control: pump speed is regulated to maintain a specific pressure or flow rate. The pressure and flow rate setpoints can be adjusted through the Central Control Monitor or from the pump speed control knob on the centrifugal control unit.

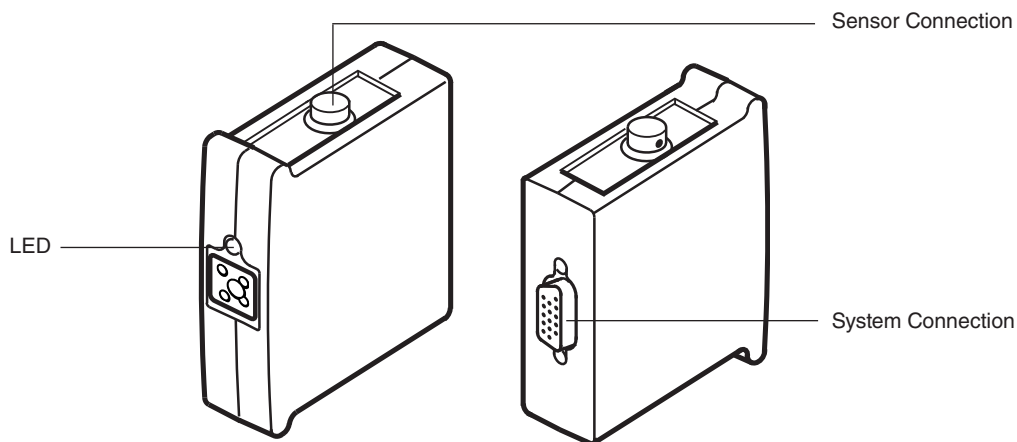
The centrifugal system can be connected to safety and monitoring systems and other pumps during configuration, followed by choosing centrifugal control unit responses. Centrifugal control unit response choices are No Response, Stop, Coast and Message Only. The choices allowed for a pump response vary depending on the type of alert or alarm and the type of device connected to the pump.

When a connected device is in alert or alarm mode, a message will display on the centrifugal control unit display.

System Overview

Modules

Features



The following modules connect to the system: Air Bubble Detect, Level Detect, Occluder, Temperature, Pressure, Flowmeter, Interface Module for CDI 100/101, Interface Module for CDI 500/550, and Interface Module RS-232.

Modules provide an interface between an appropriate type of sensor or device and the system.

Each module has appropriate connections for the type of sensor needed.

Each module has a tricolor LED (light emitting diode) to indicate module status.

Status modes are:

Constant Green – Online Mode

Blinking Green – Assignment Mode

Constant Yellow – Offline Mode

Blinking Yellow – Alert Condition

Constant Red – Broken Mode

Blinking Red – Alarm Condition

Up to 18 modules can be connected to the system; 9 on each side.

Modules are connected directly to the receptacles on either side of the system, with the exception of the flowmeter module, which is mounted on a bracket and connected to the system by a cable from the module.

System Overview

Air Bubble Detect Module

The air bubble detect module (ABD) is used with an air sensor to detect air bubbles in the perfusion circuit. Use only Terumo® Sarns™ Ultrasonic Air Sensors with the system.

Up to 4 air bubble detect modules may be connected to the system at the same time.

The air sensor connects to the module with the air sensor cable. The air sensor can be mounted directly on the tubing or on a bracket.

Select the sensor which is appropriate for the tubing size and flow rate to be used.

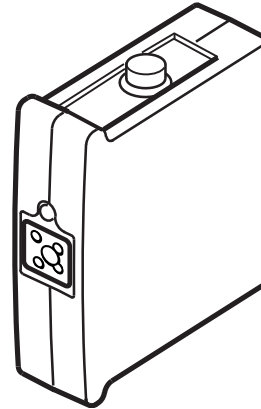
Tubing size can be 3/8 in (9,5 mm) I.D. (Inner Diameter) x 3/32 in (2,4 mm) wall thickness, 1/4 in (6,4 mm) I.D. x 3/32 in (2,4 mm) wall thickness or 1/4 in (6,4 mm) I.D. x 1/16 in (1,6 mm) wall thickness.

The air sensor detects air bubbles within clear, flexible medical grade polyvinyl chloride (PVC) tubing in clear priming solutions or blood with a hematocrit from 15% to 40%.

The air sensor detects air bubbles of 0.3 cc or larger at flow rates up to 3 L/min for 1/4 in (6,4 mm) I.D. tubing, and gas bubbles of 0.5 cc or larger at flow rates up to 6 L/min for 3/8 in (9,5 mm) I.D. tubing.

The air bubble detect module only operates in the alarm mode. Pump responses to an air alarm are selected during configuration.

In the event of an alarm, an audible dual tone alarm sounds, a message appears on the Central Control Monitor, the appropriate air detect icon on the Central Control Monitor flashes red, and the status LED on the appropriate air bubble detect module flashes red. If a safety connection was made to a pump, a message will also appear on the message area on the pump control panel, and the pump will react with the response chosen.

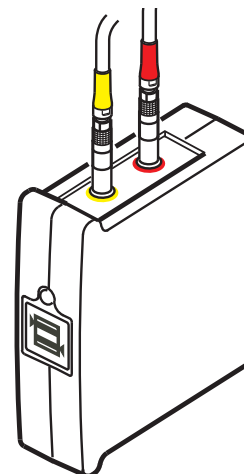


Level Detect Module

Always use a level detect module with level sensors to monitor blood levels in hardshell reservoirs. Use only Terumo® Sarns™ Ultrasonic Level Transducers with the system.

One level detect module may be connected to the system.

Level sensors are attached to the color coded connectors on the module and then to a hardshell reservoir. A yellow alert sensor attaches to the yellow connector and a red alarm sensor attaches to the red connector. Level sensors are attached to the hardshell reservoir with level sensor pads.



System Overview

The hardshell reservoir must be made of polycarbonate material with wall thicknesses of 0.07 inches (1,8 mm) – 0.15 inches (3,8 mm). Level sensors should be placed so that internal structures of the reservoir are more than 1 cm away from the transducer face. The level sensors function normally with clear priming solutions and blood of any hematocrit.

An operating mode for the module of Alert Only or Alert and Alarm is selected during configuration. The operating mode can also be changed during a case.

In the event of an alarm, an audible dual tone alarm sounds, a message appears on the Central Control Monitor, the level detect icon on the Central Control Monitor flashes red and the status LED on the level module flashes red.

In the event of an alert, an audible single tone alert sounds, a message appears on the Central Control Monitor, the level detect icon on the Central Control Monitor flashes yellow and the status LED on the level module flashes yellow.

In the event of an alert or alarm, if a safety connection was made to a pump, a message will also appear in the message area on the pump control panel, and the pump will react with the response chosen.

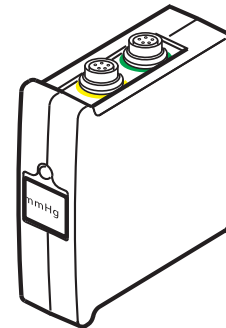
Pressure Module

The pressure module provides the interface between pressure transducers and the system. Each pressure module has 2 channels. Two pressure transducers can connect to each pressure module.

Up to 4 pressure modules can be connected to the system at a time.

Terumo offers pressure transducers known to be compatible for use with the pressure module.

Pressure transducers interface directly with the patient's blood, which is in contact with the patient. As such, they are considered to be CF applied parts.



Pressure transducers must be calibrated before use.

Pressure alarm limits, alert limits, safety connections and pump responses are set up during configuration. Pressure information can be viewed and changed through the Safety tab on the case screen.

The System 1 is capable of displaying pressure values between –250 mmHg and +900 mmHg. Information is displayed on the Central Control Monitor in the perfusion screen, in a square icon labeled mmHg.

“CAL” will be displayed if the pressure transducer requires calibration, “– – –” is displayed at pressures less than –250 mmHg or if no pressure transducer is connected, “999” is displayed at pressures greater than +900 mmHg. The display is blank in the event of a module malfunction.

CAUTION: The accuracy of the pressure information is dependent on the specification of the pressure transducer. Always ensure the pressure transducers used are appropriately specified for the application. Refer to instructions for use provided with the pressure transducer for the transducer's specifications.

System Overview

If a pressure module has been configured to operate with a pump in servo mode, pressure information will also be displayed on the pump control panel display during servo operation.

In the event of a pressure alarm, a dual tone audible alarm sounds, a message is displayed on the Central Control Monitor, the appropriate icon turns red and flashes, and the status LED on the appropriate pressure module flashes red.

In the event of a pressure alert, a single tone audible alert sounds, a message is displayed on the Central Control Monitor, the appropriate icon turns yellow and flashes, and the status LED on the appropriate pressure module flashes yellow.

In the event of an alert or alarm, if a safety connection was made to a pump, a message will also appear in the message area on the pump control panel, and the pump will react with the response chosen.

In the event of overrange/underrange readings or pressure system malfunction, physiological alerts or alarms are cleared automatically. If a safety connection from a pressure event had paused or stopped a pump, that pump can then resume or be restarted (if no other pause or stop responses are in effect). If the pressure reading returns into range between -250 mmHg and +900 mmHg inclusive, the physiological alerts or alarms will reoccur as appropriate.

Temperature Module

The temperature module provides the interface between temperature sensors and the system. In order to maintain electrical isolation in accordance with applicable standards, insulated temperature probes must be used.

YSI Series 400 compatible probes, with the exception of Model 416, must be used in order to monitor temperature properly with System 1.

Temperature probes interface directly with the patient's blood, which is in contact with the patient. As such, they are considered to be CF applied parts.

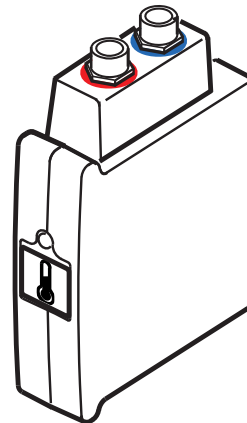
Each temperature module has 2 channels. Two temperature sensors can connect to each temperature module.

Up to 4 temperature modules can be connected to the system at a time.

Temperature information is displayed on the Central Control Monitor in the perfusion screen, in a rectangular icon labeled °C. The display will show — — if no sensor is attached.

A high temperature alarm can be set for each temperature sensor.

In the event of a temperature alarm, a dual tone audible alarm sounds, a message is displayed on the Central Control Monitor, the appropriate icon flashes red, and the status LED on the temperature module flashes red.



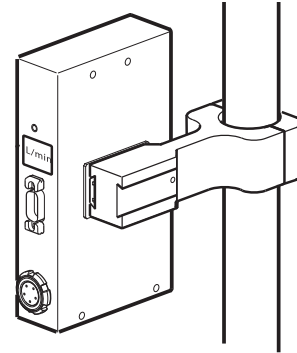
System Overview

Flowmeter Module

The flowmeter module provides the interface between an ultrasonic flow sensor and the system. Up to 2 flowmeter modules can be mounted on each flowmeter mounting bracket. Up to 4 flowmeter modules can be connected to the system at a time.

It is recommended that a flowmeter module always be used when a centrifugal pump is used.

Flow information is displayed in a rectangular icon, in L/min, on the Perfusion Screen. Placement of the icon is chosen during configuration. If the flowmeter has been placed on a centrifugal pump, flow data will also be displayed on the centrifugal control unit display and the minimum flow alarm will be functional.



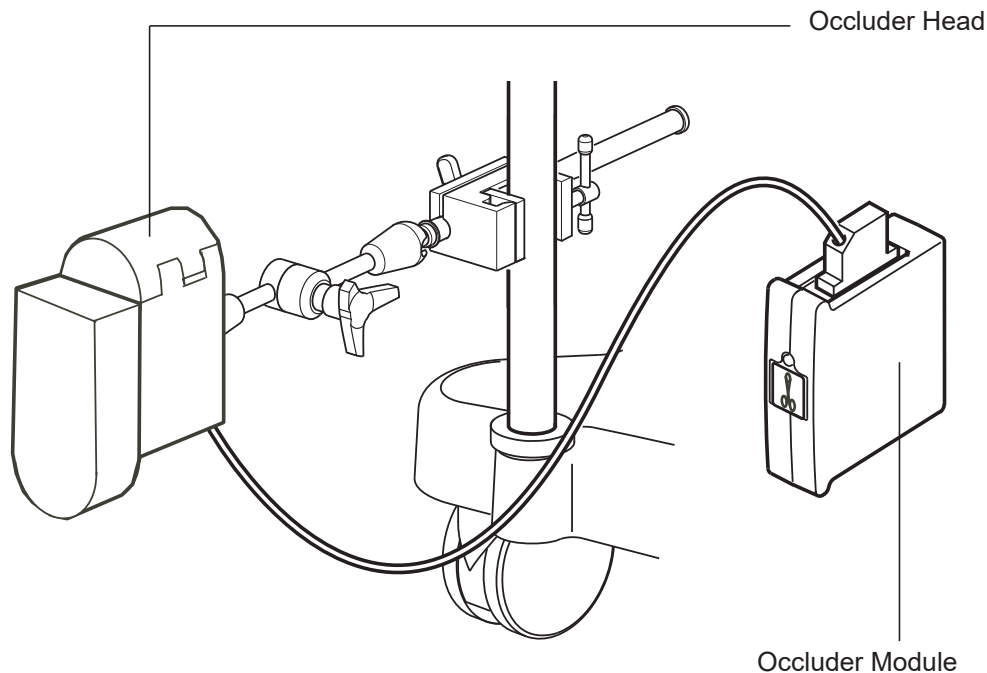
For centrifugal pumping, a minimum flow alarm can be set to warn of reduced flow. In the event of a minimum flow alarm, a dual tone audible alarm sounds, a message is displayed on the Central Control Monitor and on the control panel of the centrifugal control unit.

The flowmeter module generates an alarm when backflow is detected. In the event of a backflow alarm, a dual tone audible alarm sounds, a message is displayed on the Central Control Monitor, the appropriate icon turns red and flashes (unless the icon was placed on a centrifugal pump), and the status LED on the appropriate flow meter module flashes red. If a safety connection was made to a pump, a message will also appear on the pump control panel and the pump will react with the response chosen.

System Overview

Occluder Module

The occluder module is used with the occluder head to provide a computer-controlled tube clamping mechanism to regulate the flow in the venous line. The occluder head is attached to the module with the occluder head power cable.



Only 1 occluder may be connected to the system.

Tubing is positioned in the occluder head and is compressed by a plunger. Tubing can range in size from 1/4 in (6,4 mm) I.D. x 1/16 in (1,6 mm) wall thickness to 1/2 in (12,7 mm) I.D. x 3/32 in (2,4 mm) wall thickness with a recommended nominal durometer range of 65-70 Shore A.

The occluder is controlled through the occluder slide bar on the Central Control Monitor. Use the Open and Close buttons on the slide bar or choose a percentage open by using the scroll control. There are no local controls on the occluder head.

The occluder must be calibrated prior to use. The occluder icon on the Central Control Monitor will display "CAL" to indicate that the occluder needs calibration.

System Overview

Interface Modules

Interface Module for CDI™ 100/101

The Interface Module for CDI™ 100/101 provides an interface between the system and a CDI™ 100 or 101 Extracorporeal Hematocrit/Oxygen Saturation Monitor*. The module is connected to the CDI™ 100 or CDI™ 101 monitor with a serial cable.

Data from the CDI™ 100 or CDI™ 101 monitor can be configured to be displayed on the Central Control Monitor. Parameters that can be displayed are oxygen saturation, hematocrit and hemoglobin.

Interface Module for CDI™ 500/550

The Interface Module for CDI™ 500/550 provides an interface between the system and a CDI™ 500/550 Blood Parameter Monitoring System. The module is connected to the CDI™ 500/550 monitor with a serial cable.

Data from the CDI™ 500 monitor can be configured to be displayed on the Central Control Monitor. Parameters that can be displayed are arterial PO₂, arterial PCO₂, arterial pH, arterial temperature, arterial oxygen saturation, bicarbonate, base excess, venous PO₂, venous PCO₂, venous pH, venous temperature, venous oxygen saturation, potassium concentration, oxygen consumption, hemoglobin, and hematocrit.

The CDI™ 500 monitor receives flow data from System 1. The flow data is displayed on the front of the CDI™ 500 monitor and is used to calculate and display the O₂ consumption.

Interface Module RS-232

Data Transfer

The Interface Module RS-232 provides an interface between the system and a data management system. The module is connected with a serial cable to the serial port on the computer on which the perfusion software has been installed.

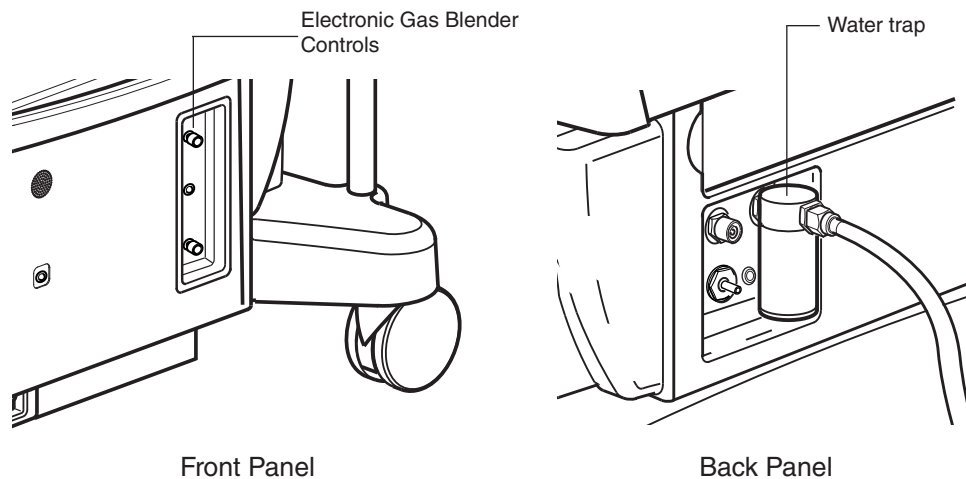
During a case, perfusion data and events from System 1 are sent through the Interface Module to be captured by the perfusion software.

* The Terumo CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System is not cleared for marketing in the United States by the US Food and Drug Administration (FDA).

System Overview

Electronic Gas Blender

The electronic gas blender is a module that is internally installed in the system base. The gas blender provides control and monitoring of the gas output to an oxygenator. An integrated oxygen analyzer measures the oxygen content of the gas blend.



The oxygen analyzer requires, at a minimum, daily calibration and can be calibrated from the Central Control Monitor.

An air or 95% oxygen/5% carbon dioxide (95/5) inlet, an oxygen inlet, a gas outlet, and an exhaust port are on the back of the system base. Use only medical grade gases supplied at an inlet pressure of 50 psi \pm 20 psi with the difference between the two inlet gas pressures being no more than 18 psi.

The gas blender can be controlled from the Central Control Monitor by using the Gas and FiO₂ slide bars or locally by using the control knobs on the front of the base. Gas flow information is displayed on icons labeled Gas, %O₂ and FiCO₂, if appropriate, on the Perfusion Screen. An external, mechanical flowmeter, provided in the accessory kit, should be connected to the gas outlet and be positioned between the vaporizer and the oxygenator to monitor the gas flow in the event Central Control Monitor capability is lost.

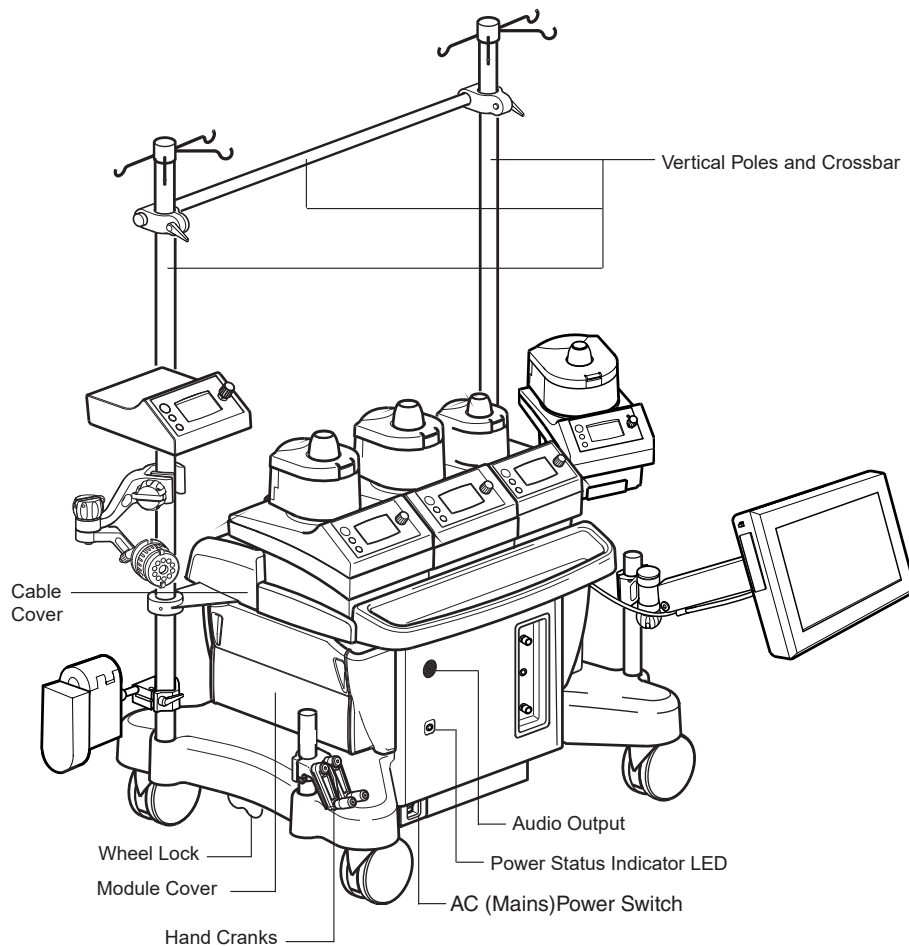
An alarm limit for Low FiO₂ can be chosen during case setup.

High and low pressure alarms are generated by the system if the inlet pressure of a source gas exceeds 70 psi or falls below 30 psi. In the event of a pressure alarm, a dual tone audible alarm sounds and an alarm message is displayed on the Central Control Monitor.

System Base

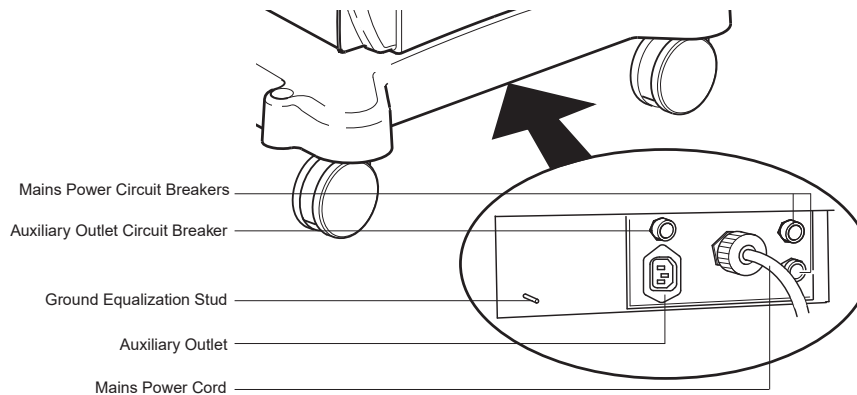
The system base is a moveable platform designed for the flexible mounting of system components on poles and on a central rail. The base houses the network infrastructure that provides power and communications to all system components. Each component connects to the system network via receptacles on the base. There are 6 pump connections, 2 receptacles for the Central Control Monitor (CCM), 18 receptacles for modules, and 2 receptacles for a lamp. The base also provides 1 AC outlet to supply power to auxiliary equipment.

Note that the system base P/N 801763J is only available in the Japanese market, and is not currently marketed, sold, or used in the United States of America.



System Base

Base Components



Mains Power Cord

The AC (Mains) power cord connects the system to the wall electrical supply. When the system is operating from the AC (Mains) power supply, the AC (Mains) power status indicator LED located on the front panel is illuminated and steady.

Attach the system AC (Mains) power cord to an appropriate wall electrical supply as indicated on the name plate label.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with a protective earth ground.

WARNING: Check the AC (Mains) power cord and plug for damage prior to use. Do not use the system if damage to the power cord or plug is found. Damage may include worn or twisted cord insulation and loose, bent, or missing plug pins. Additionally, damage may result from tightly wrapping the power cord around any HLM fixture or pole.

CAUTION: Do not use extension cords to connect the system to AC (Mains) power or to connect modules or accessories to the system. Use of extension cords may compromise performance.

In some countries, regulations require potential compensation; in this case, connect the cable from the potential compensation network to the ground equalization stud.

Circuit Breakers

There are 3 resettable circuit breakers on the system base.

Two resettable circuit breakers located near the AC (Mains) power cord protect the system from excessive power consumption. The breakers are protected from liquid by a clear plastic cover.

The system will switch from AC (Mains) to Battery Power in the event that one or both circuit breakers protecting the system trips. To reset the circuit breakers, depress the push button(s) until it clicks into place. Verify that the system returns to AC (Mains) power.

CAUTION: In the event that the breaker trips immediately after a reset, **DO NOT attempt to reset again.** The system will only operate from battery power until it has been repaired. Call for service.

One resettable circuit breaker protects the auxiliary outlet from excessive AC (Mains) power draw.

System Base

If the auxiliary outlet circuit breaker is tripped, devices plugged into this outlet will not power ON. To reset the circuit breaker, depress the button until it clicks into place.

Auxiliary Outlet

The auxiliary outlet is an AC outlet protected with a 1.5 amp resettable circuit breaker for the 100-120V system or a 0.7 amp resettable circuit breaker for the 220V-240V system.

Do not use this outlet to power devices or equipment which require voltage or current above the specified limit.



WARNING: Electrical equipment connected to the auxiliary outlet leads to creating an medical electrical system that can result in a reduced level of safety.

CAUTION: The auxiliary outlet is not backed up by battery power. During loss of AC (Mains) power, any equipment connected to the auxiliary outlet will lose power and will remain unpowered until AC (Mains) power is restored.

Mains Power On and Off

The AC (Mains) power switch turns power to the system On or Off and enables or disables the automatic battery backup. Do not block the AC (Mains) power switch with objects (box, etc.) during operation.



AC (Mains) Power Switch (Switch Guard not shown)

When the system is operating from AC (Mains) power, the power status indicator LED on the front panel is illuminated and steady.

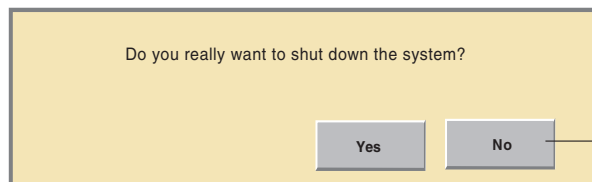
To Turn the System On:

1. Press the top of the AC (Mains) power switch. The system start-up tone sounds and indicates the audio system is working properly. If you do not hear the start-up tone, call for service.

To Turn the System Off:

Note: Failure to follow the controlled shut down procedure may result in improper start-up at the next power-on.

1. Touch the **Shut down** button on the main screen.
A screen prompts the user to shut down the system.



User returns to main screen

2. Select **Yes** to shut down.

The shut down process takes approximately 10 seconds. A message will display when it is safe to power down the system.

Please wait for the system to shut down. 10

It is safe to power down the system.

3. Turn the AC (Mains) power off by pressing the bottom of the AC (Mains) power switch.

System Base

System Power

The power system is located within the base and includes two internal DC power supplies, integrated batteries, and an internal power manager. The power supplies transform AC (Mains) power into the DC levels required by the system components. The integrated batteries provide backup power in the event of AC (Mains) power loss during use or when power needed exceeds power available.

The internal power manager monitors the power needed to run the system and compares the power needed (load) with the power available (AC (Mains) power capacity). If the power needed exceeds the power available, the system will switch to battery power. The auxiliary outlet will remain powered as long as AC (Mains) power is still available. To decrease the load, noncritical modules or pumps may be turned off by the user. When the system power need falls below the available power limit for at least 10 seconds, the system will automatically switch back to using AC (Mains) power.

If the system switches to battery power, the battery alert tone will sound and the power status indicator LED will flash. If a Perfusion Screen is open, a message will be displayed on the CCM and posted in the Aux tab, the Power Source/Battery Status icon will flash and display a color indicating approximate battery time available and the approximate battery run time in minutes will be displayed above the Power Source/Battery Status icon.

If the system switches to battery power, the battery alert tone will sound and the power status indicator LED will flash. If the Main Screen is open, the Power Source/Battery Status icon will flash and display a color indicating the approximate battery time available and the approximate battery run time in minutes will be displayed above the Power Source/Battery Status icon.

Note: If the system is started by battery power, the auxiliary outlet will not be available. When AC (Mains) power is connected, the auxiliary outlet is immediately powered and, after a short delay, the system will automatically switch to AC (Mains) power.

Battery System

Integrated batteries provide uninterruptible battery backup power in the event AC (Mains) power is lost or when power needed exceeds power available.

During power loss, fully charged batteries will power a fully loaded System 1 for at least 60 minutes. A fully loaded System 1 is defined as:

A combination of 6 blood pumps, from the list below:

- 2 roller pumps, speed set to 120 RPM while using 1/2 in (12,7 mm) I.D. x 3/32 in (2,4 mm) wall tubing and/or speed set to 190 RPM while using 3/8 in (9,5 mm) I.D. x 3/32 in (2,4 mm) wall tubing, properly occluded and fluid temperature of 25°C;

- 2 roller pumps, speed set to 100 RPM while using 1/4 in (6,4 mm) I.D. x 3/32 in (2,4 mm) wall tubing, properly occluded and fluid temperature of 25°C;

- 1 roller pump, speed set to 50 RPM while using 1/4 in (6,4 mm) I.D. x 3/32 in (2,4 mm) wall tubing, properly occluded and fluid temperature of 25°C;

- 1 roller pump, speed set to 30 RPM while using 8:1 dual tubing set, properly occluded and fluid temperature of 5°C;

- 1 centrifugal pump, flow set to 5.0 L/min, a backpressure of 400 mmHg and fluid temperature of 25°C;

System Base

18 monitoring modules; any combination of flow, temperature, pressure, level, occluder, air bubble detect, and serial interface modules; all modules assigned and activated;

1 Electronic Gas Blender module, connected and activated;

1 lamp; connected and activated;

1 Central Control Monitor; connected and activated.

WARNING: If a partially charged battery system is used, there may be less than 60 minutes of battery power available for a fully loaded system.

WARNING: Turn the system power off at the AC (Mains) power switch on the system before inspection, cleaning, preparation for use, or storage in order to turn off both the battery power and the AC (Mains) power.

WARNING: Charge the batteries monthly. Storage of a System 1 without charging the batteries monthly may damage the batteries and lead to overstated battery life. This damage, caused by a gradual discharge of the batteries, may cause loss of battery backup without warning.

Battery charge level should be checked before each case.

The batteries must be fully recharged after storage, prior to use on a case. During storage there is a gradual discharge of the batteries which may reduce the available battery backup time. A power status indicator LED on the front panel of the base indicates the status of the battery charge. When starting a system that has been in storage, allow at least 1 minute to elapse after the CCM displays the Main Screen, before checking the power status indicator LED.

On the Main Screen, the Power Source/Battery Status icon will display a color indicating the approximate battery time available. In addition, charge level information can be found within a Perfusion Screen. The Power Source/Battery Status icon will display a color indicating the approximate battery time available. More information is available in the Power subtab when a Perfusion Screen is open.

The batteries will charge, as needed, while the system is operating from AC (Mains) power.

To recharge the batteries, the system must be plugged into the AC (Mains) power supply with the AC (Mains) power switch turned on. It takes up to 13 hours to fully recharge the batteries.

As the batteries recharge, the color of the power status indicator LED and Power Source/Battery Status icon will change to indicate the condition of the batteries:

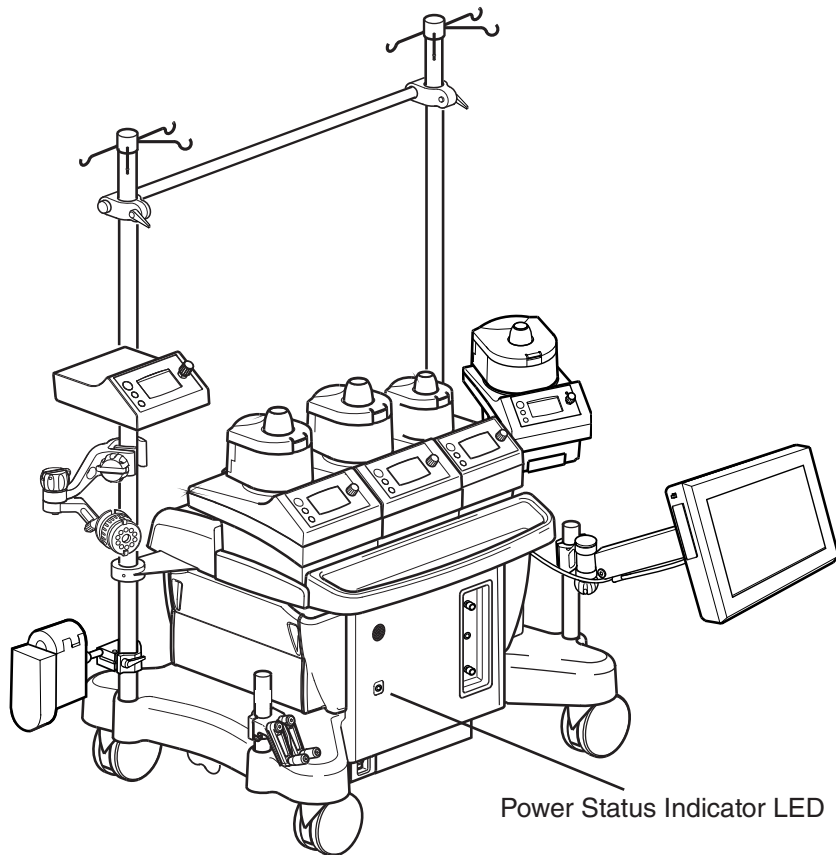
- Steady green indicates a battery system with one hour or more run time for a fully loaded system;
- Steady red indicates a battery system with less than one hour run time for a fully loaded system.

System Base

When the system is operating from battery power, an audible battery alert tone sounds and repeats every 3 minutes. The battery alert tone is a unique, single tone pattern used only to indicate that the system is operating on battery power. The battery alert tone cannot be muted. In addition, the Power Source/Battery Status icon flashes and the power status indicator LED on the front panel flashes. If a Perfusion Screen is opened, a message is displayed in the message area of the CCM and in the Messages subtab in the Aux tab.

There are three different indicators that provide information regarding battery status: the Power Status Indicator LED, the Central Control Monitor Power Source/Battery Status Icon, and the Power subtab within the System tab.

Power Status Indicator LED – Provides a status as the batteries charge or the battery capacity if the battery system is actively providing backup power. When starting a system that has been in storage, allow at least 1 minute to elapse after the CCM displays the Main Screen, before checking the power status indicator LED.



The Power Status LED provides information about battery life as follows:

When operating from AC (Mains) power:

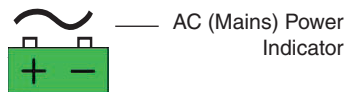
- Steady green indicates a battery system with greater than one hour run time with a fully loaded system.
- Steady red indicates a battery system with less than one hour run time with a fully loaded system.

When operating from the battery system:

- Flashing green indicates 30 minutes or more battery life at present discharge rate
- Flashing yellow indicates 15 minutes or more, but less than 30 minutes battery life at present discharge rate
- Flashing red indicates less than 15 minutes battery life at present discharge rate.

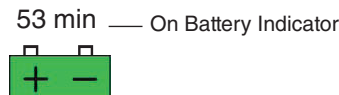
System Base

Central Control Monitor Power Source/Battery Status Icon (only displayed on the Main and Perfusion Screens) – Provides information about battery life as follows:



When operating from AC (Mains) Power:

- Steady green indicates a battery system with greater than one hour run time with a fully loaded system
- Steady red indicates a battery system with less than one hour run time with a fully loaded system

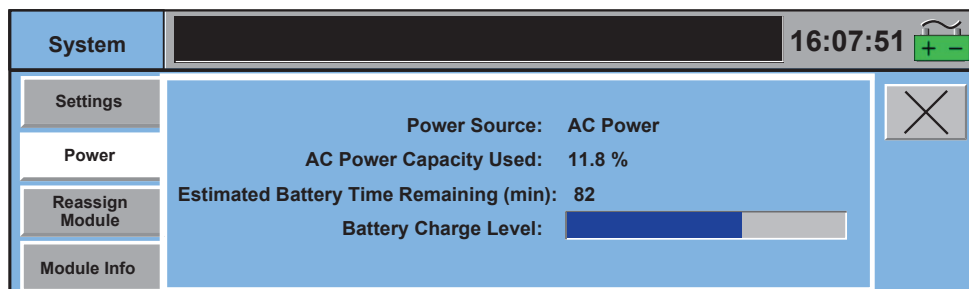


When operating from the battery system:

- The approximate battery life in minutes is displayed above the Power Source/Battery Status icon
- The color of the Power Source/Battery Status icon will change as the estimated remaining capacity in minutes decreases:
- Flashing green indicates 30 minutes or more battery life at present discharge rate
- Flashing yellow indicates 15 minutes or more, but less than 30 minutes battery life at present discharge rate
- Flashing red indicates less than 15 minutes battery life at present discharge rate.

The time displayed above the Power Source/Battery Status icon, the color of the icon, and the available capacity in minutes in the Power subtab within the System tab should only be used as *approximations* of the amount of time remaining.

Power subtab within the System tab (only displayed on the Perfusion Screen) - Contains a summary of the power information for the system. See the **Central Control Monitor** section, **Power Subtab** for further details.



The Battery Charge Level found in the Power subtab within the System tab provides a bar graph indicating the approximate charge status of the battery.

- Power Source - AC power or battery.
- AC Power Capacity Used - Indicator of power consumption when using AC power.
- Estimated Battery Time Remaining - Provides an estimated remaining battery backup time, regardless of current Power Source.
Note: This will be the same time estimate as shown over the Power Source/Battery Status icon when on battery backup.
- Battery Charge Level - Provides a bar graph indicating the charge status of the battery.

In summary, if the system is operating from batteries, the Power Status Indicator LED will flash. If the system is operating from batteries and if a Perfusion Screen is opened, a message is displayed in the message area of the CCM and in the Messages

System Base

subtab within the Aux tab, and an estimated battery time available appears above the Power Source/Battery Status icon.

WARNING: Failure to properly charge and maintain the System 1 Base Batteries can cause the unexpected loss of battery backup function.

WARNING: The Battery Charge Level bar graph and power status indicators depend on the proper charging and maintenance of the battery system. Failure to properly charge and maintain the System 1 battery system can cause battery failures.

CAUTION: Replace the batteries every 2 years, OR whenever the batteries cannot be fully recharged within 13 hours, OR whenever fully charged batteries will not power a fully loaded system for 60 minutes. Only Terumo Cardiovascular Systems Corporation certified service technicians are authorized to perform battery replacement.

CAUTION: Do not store batteries in a discharged state as this will damage them.

Decreasing the power consumption of the system while operating on battery power can enable the batteries to power the system for more than 1 hour. Turning off non-critical devices will decrease the power needs of the system.

If the system shuts down due to depletion of battery power, make sure to plug the system into available wall power and that the system power switch is ON.

Battery System Testing

The batteries are tested at different times during use of the system.

Automatic Testing of Switching to Battery System

Each time the system is powered on, a switching test of the battery system is performed. If the system detects an issue with battery system circuitry at start-up, the following message will be displayed: "Battery Cannot be Charged - Full Backup May Not be Available"

If this message is posted, contact Terumo Customer Service. Do not attempt to operate the system until it has been serviced.

In addition, battery circuit components are monitored constantly during operation. If a problem is detected, the following message will be displayed: "Battery Cannot be Charged - Full Backup May Not be Available."

If this message is posted, contact Terumo Customer Service. Do not attempt to operate the system until it has been serviced.

Manual Testing of Switching to Battery System

To test the battery switching function, unplug the system when it is turned on. If the system does not immediately switch to battery power, contact Terumo Customer Service. Do not attempt to operate the system until it has been serviced.

System Base

WARNING: The following behavior while operating on Battery power indicates discharged or damaged batteries:

- Battery Time Remaining decreases faster than elapsed time on battery
- Power Source/Battery Status Icon changes color faster than elapsed time on battery
- Red Power Source/Battery Status Icon after the system is returned to AC (Mains) Power.

Battery Capacity Updates (Battery Test)

Whenever the system is operating on battery power, it will update its estimate of battery capacity.

Watch for battery capacity updates whenever the system is operating on battery power.

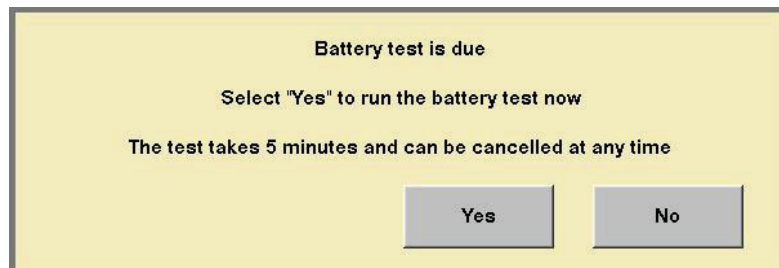
If the Battery Test indicates a damaged or discharged battery AND the system may not be fully charged, recharge the batteries and then repeat Battery Capacity Test. To fully recharge the batteries, the system must be plugged into the AC power supply with the AC (Mains) Power switch turned On. It takes up to 13 hours to fully recharge the batteries. If the Battery Test indicates a damaged or discharged batteries AND the System should be fully charged, call Terumo Customer Service. Do not use the system until the battery system has been serviced.

WARNING: If the Battery Capacity Updates indicate less than 60 minutes battery power AND the battery system should be fully charged, call Terumo Customer Service. Do not use the system until the battery system has been serviced.

Battery Test Reminder

Every 60 days, if the system has not been run on battery for at least 5 minutes, the system will post a reminder at the Main Screen to perform a Battery Test. The most accurate estimate is achieved after 5 minutes operation without AC (Mains) Power. The Battery Test may be skipped or canceled at any time, but the reminder will return whenever the Main Screen is entered until the Battery Test is completed.

The Battery Test reminder appears in a message box as follows:



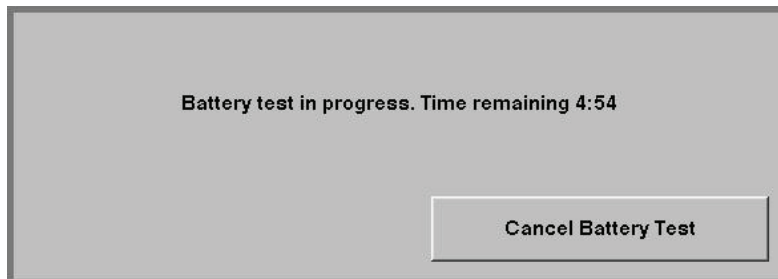
Select "No" to return to the Main Screen

Selecting "Yes" will display the following message box:

System Base



To return to the Main Screen, select "Cancel Battery Test"
Unplugging the system will display the following message box:

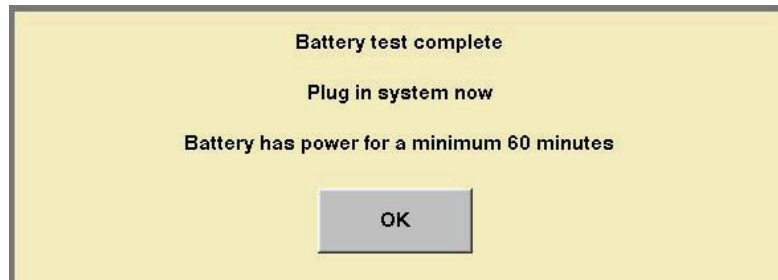


The system will count down to zero from five minutes to complete the Battery Test. To cancel the test, select "Cancel Battery Test" (or plug the system back in). If the Battery Test is canceled without plugging the system back in to AC (Mains) Power, the following message box will be displayed:



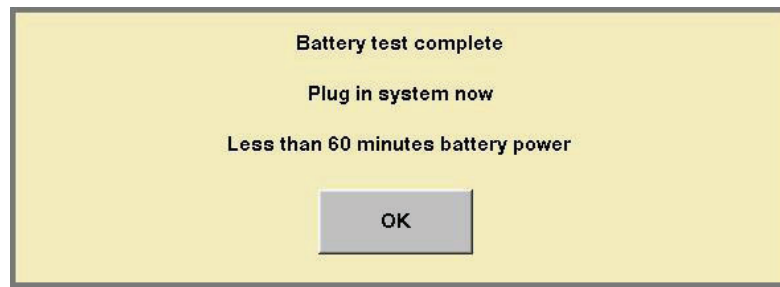
Plugging in the system will remove the message box, canceling the Battery Test. Selecting "OK" will remove the message box canceling the Battery Test.

One of the following message boxes will display upon completion of the Battery Test:



The above message box will be displayed if the battery system has one hour or more capacity for a fully loaded system

System Base



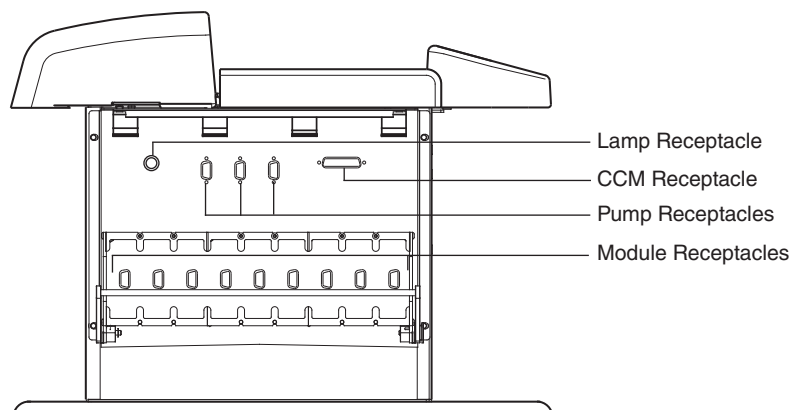
The above message box will be displayed if the battery system has less than one hour capacity for a fully loaded system

If the Battery Test indicates the batteries have less than one hour capacity AND the system may not be fully charged, recharge the battery and then repeat the Battery Test. To fully recharge the battery, the system must be plugged into the AC (Mains) Power with the AC (Mains) Power Switch turned on. It takes up to 13 hours to fully recharge the batteries, if battery charge is very low.

WARNING: If the Battery Capacity Updates indicate less than 60 minutes battery power AND the system should be fully charged, call Terumo Customer Service. Do not use the system until the battery system has been serviced.

System Network

The network design allows the different types of system modules and pumps to be connected to any dedicated receptacle on the base. It also allows multiple types of modules to be connected to the system. The user can define how these modules interact with the system and each other and can set alert and alarm responses and monitoring limits via the Central Control Monitor.



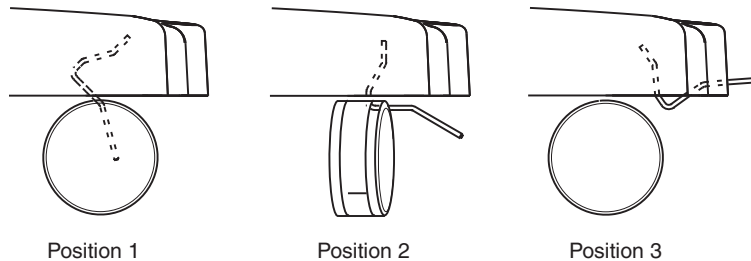
There are 9 module receptacles, 3 pump receptacles, a Central Control Monitor receptacle and a lamp receptacle on each side. If necessary, a pump can be plugged into a module receptacle.

System Base

Standoffs are provided in the accessories kit. Two standoffs should be installed on a module receptacle to securely fasten a pump cable or flowmeter cable to the module receptacle. Modules cannot be inserted into a module receptacle when standoffs are installed.

Casters and Wheel Lock System

The base is mounted on four casters. Each side of the base has a pair of casters and a locking lever that can be set in three positions to either lock the wheels of the casters to prevent unintended movement of the base, allow free movement of the casters and wheels, or lock the casters to allow the base to roll while maintaining a fixed position of the wheels.



Apply upward or downward pressure on the locking lever to change the position.

Position 1

The casters are locked in place and will not move. When the system is in use, the wheel lock should be set in the locked position.

Position 2

The casters are unlocked and move in all directions.

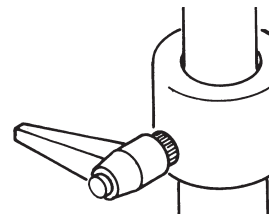
Position 3

The casters align parallel to the base and allow side-to-side movement only.

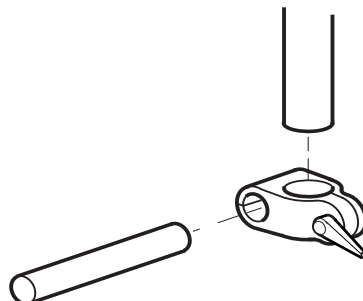
Poles, Shelf, and Brackets

There are two 1.30 in. (3,3 cm) diameter, stainless steel vertical telescoping poles attached to the base platform for mounting devices to the system.

Extend the inner section of the telescoping pole by adjusting the handle screw on the collar of the pole. Do not extend beyond a maximum of 18 in. (45,7 cm) from the retracted position.

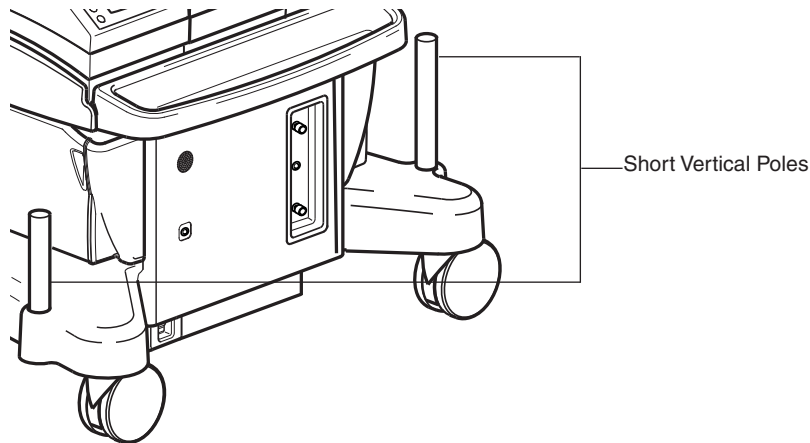


Special fittings connect a horizontal cross bar to the two vertical poles.



System Base

There are two additional shorter vertical poles, one on either side of the front of the base.



The optional System 1 Shelf mounts between the 2 vertical telescoping poles. The shelf provides storage space for items up to a maximum of 50 pounds (22,6 kg).

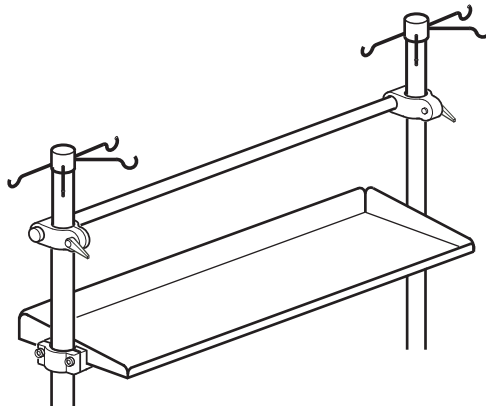
Make sure that the shelf is positioned such that it does not interfere with access to the pumps or other devices. Ensure that all pumps can be hand-cranked without interference from the shelf.

Do not mount, or otherwise attach, any devices or accessories to the shelf. The shelf is for storage of lightweight items only.

Do not allow stored items to extend beyond the edge of the shelf.

To mount the shelf to the base:

Loosen the handle screws on the collars of both of the poles. Remove the inner section of the telescoping pole. Remove both of the collars. If the desired position of the shelf is below the horizontal crossbar, loosen the handle screws on both of the crossbar fittings. Remove the crossbar and fitting by sliding up off the poles. Use a 3/16 in. ball driver (provided with Accessory Kit) to loosen the end caps of the shelf. Position the shelf between the poles by lowering it from the top of the poles to the desired height. Make sure the shelf is level. Tighten the shelf end caps using the 3/16 in. ball driver. Reinstall crossbar (if removed) and tighten handle screws. Reinstall the collars taking care that the handle screws extend through the holes at the top of the vertical poles. Reinsert the inner section of the telescoping pole using the collar handle screws to adjust the desired height. Make sure all fittings are tight and secure.



System Base

The instrument tray in front of the pump platform provides storage space for items up to a maximum of 10 pounds (4,5 kg).

There are dedicated brackets for many of the components used with the Terumo® Advanced Perfusion System 1. Refer to specific chapters for instructions on how to attach pole mount brackets for: roller pumps, centrifugal control units, flowmeter modules, occluder head, and the Central Control Monitor (CCM).

Loading Zones

To prevent tipping, only transport the system in the lengthwise direction. Do not transport the system up or down an incline greater than 10 degrees. Do not hang more than 10 lbs. (4,5 kg) total from the hooks on each telescoping pole. A minimum of two roller pumps must be placed on the system base pump platform. Distribute the weight of additional system components and accessories according to the following figures and instructions. When transporting the system the centrifugal controller and motor must be in or be moved to Zone A, B, or C.

The System 1 Base includes four poles for mounting equipment and a pole-mounted shelf for holding loose items. When mounting equipment, it is important not to overload the system or to concentrate the weight where it could cause the system to tip. The mounting area is divided into six zones, with limits on the amount of that weight can be mounted in each zone. The table below shows the limits for each zone.

The drawings below show the location of each zone. Some of the zones overlap (e.g., zones A and E). If you mount equipment in the overlap area, its weight counts against the limits for both zones (i.e., it is double counted). To help you calculate the loads, the table after the drawings shows the weight of various pieces of equipment.

Some points to keep in mind:

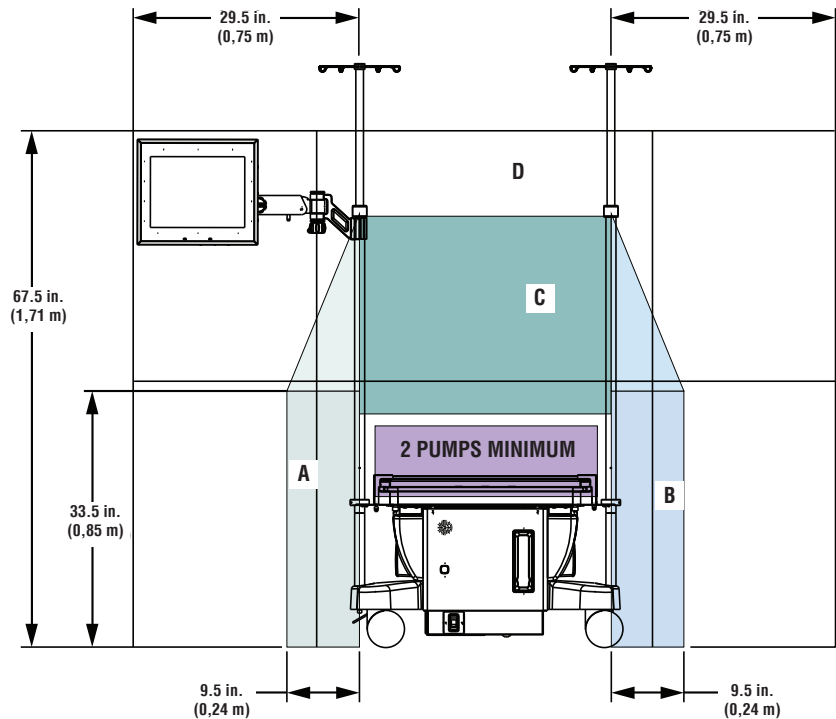
- For stability, place at least two roller pumps on the base
- For calculating load, the center of the weight of the equipment determines which zone it is in, regardless of which pole the equipment is mounted on
- Area D is for the CCM only
- The load in Area C includes both equipment mounted in the area and the weight of anything placed on the shelf. The weight of the shelf is not included.
- The weight of fluids contained in the equipment (e.g., a reservoir) must be included in the load calculations

Zone	Weight
A	90 lbs. 40,8 kg
B	90 lbs. 40,8 kg
C	50 lbs. 22,7 kg
D	CCM and Mounting Arm
E	90 lbs. 40,8 kg
F	90 lbs. 40,8 kg

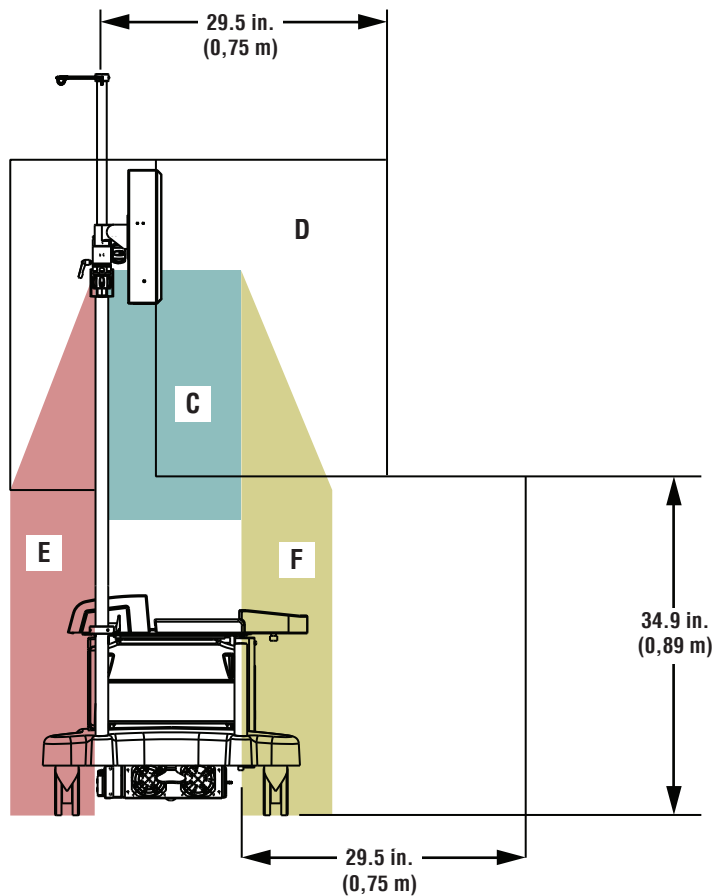
Note: The maximum safe working load of the system is 661 lbs. (300 kg.), including the weight of the Base at 287 lbs. (120,2 kg.).

Note: The dimensions noted in the following graphics refer to inches and (meters).

System Base

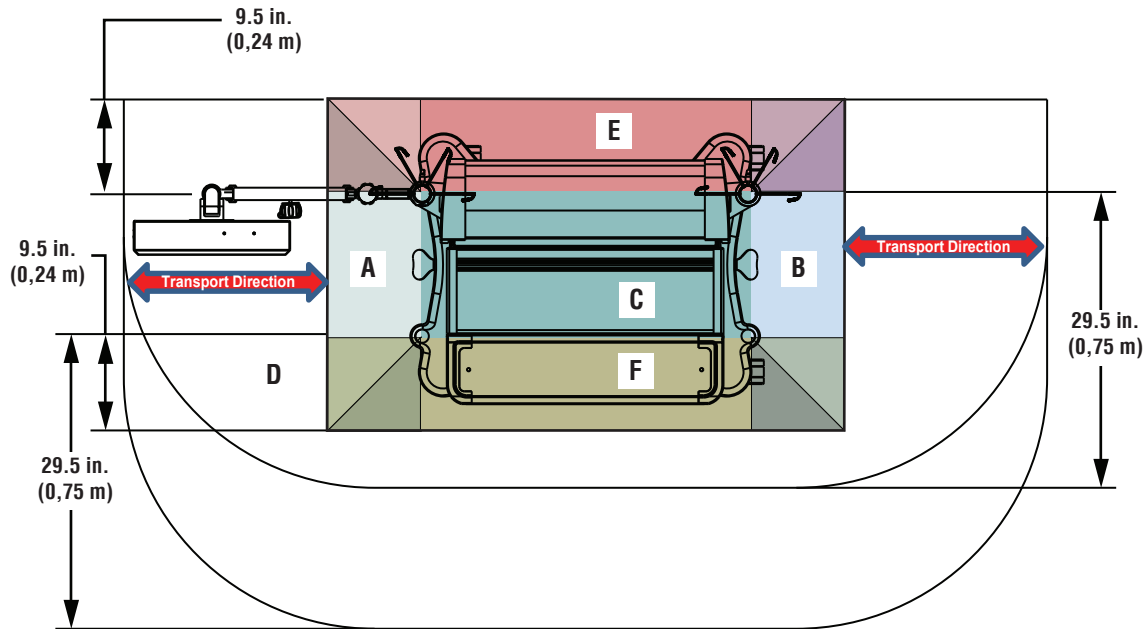


Front View of System Showing Loading Zones



Side View of System Showing Loading Zone

System Base



Top View of System Showing Loading Zones

Weights of various system components are given in the table below.

Component	Weight
Central Control Monitor and mounting arm	26 lbs. (11,8 kg) [P/N 816300] 21.7 lbs. (9,8 kg)[P/N 890500]
Roller Pump, 4 in.	23.5 lbs. (10,7 kg)
Roller Pump, 6 in.	28.5 lbs. (12,9 kg)
Centrifugal Control Unit	2.4 lbs. (1,1 kg)
Centrifugal Drive Motor	3.2 lbs. (1,5 kg)
Manual Drive Unit	5.1 lbs. (2,3 kg)
Lamp, 33 inch (83,8 cm)	3.1 lbs. (1,4 kg)
Lamp, 15 inch (38,1 cm)	2.2 lbs. (1 kg)
Lamp, LED 25 inch (63,5 cm)	3.5 lbs. (1.6 kg)
Occluder head	4.2 lbs. (1,9 kg)
Air Sensor	0.48 lbs. (0,22 kg)
Flowmeter Module	1 lb. (0,5 kg)
Roller Pump Pole Mount	3.6 lbs. (1,6 kg)
Dual Pumps Pole Mount	5.7 lbs. (2,6 kg)
Descending Pump Bracket	5.5 lbs. (2,5 kg)
Centrifugal Unit Pole Mount	1.4 lbs. (0,6 kg)
Shelf	7 lbs. (3,2 kg)
Flexible Mounting Arm	3.5 lbs. (1,6 kg)
Flowmeter Mounting Bracket	0.6 lbs. (0,27 kg)
Hand Crank Bracket and two Hand Cranks	1.7 lbs. (0,8 kg)

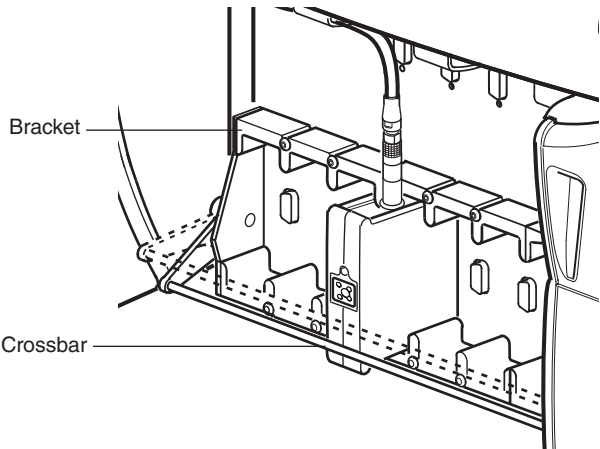
System Base

Module Bracket System

Each module receptacle is surrounded by a rectangular shaped bracket that is mounted on the side of the base. This bracket, along with a crossbar, holds the modules in place.

To Insert or Remove Module:

1. Pull crossbar down.
2. Insert or remove module from receptacle.
3. Release crossbar



Pump Platform

The pump platform is designed to provide adaptable mounting combinations of roller pumps onto the system base. The platform consists of a rail, adjustable endcaps, and extensions that are used in conjunction with the endcaps.

The chart below represents the placement of roller pumps on the platform. L indicates a large roller pump, S indicates a small roller pump. Other roller pump combinations require the use of a pole mount bracket.

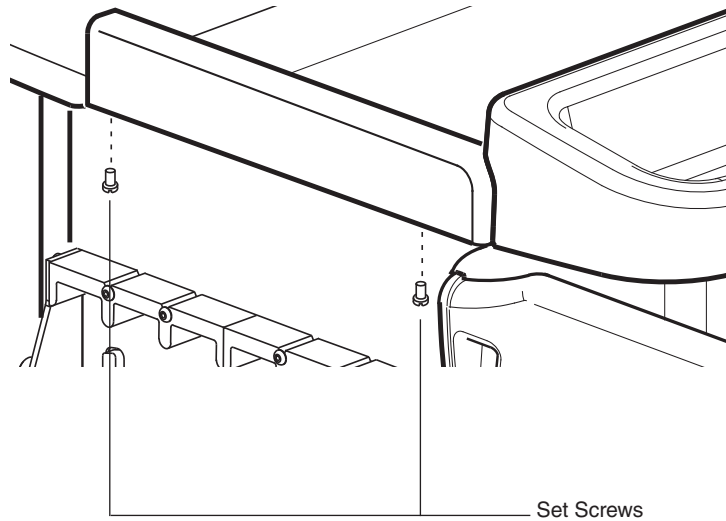
Based on the chart, determine the size extension that is required for the pump combination to be used. Extensions are located in the accessories kit.

No Extension	Small Extension	Large Extension
L S S	S S S L	S S L L
S S L	L S S S	S L S L
L S L	L S S L	L S L S
S L S	S S L S	L L S S
S L L	S L S S	L S L L
L L S	S S S S	L L S L
L L L		S L L S
S S S		

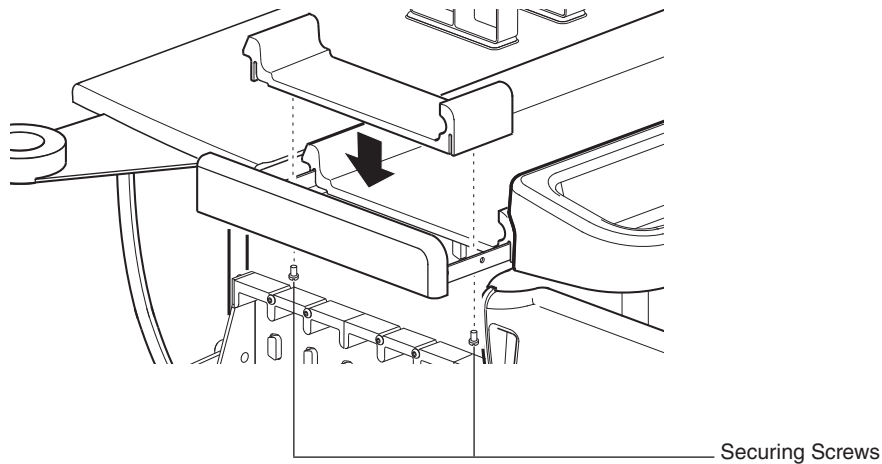
System Base

To Install or Remove Extensions:

1. Remove cable cover.
2. Remove pumps.
3. Remove module cover.
4. Loosen set screws on each side of the base. Some modules may need to be removed to access the set screws.
5. Slide endcaps out.



6. Insert or remove the extension.
 - If removing extensions, remove securing screws and remove extension.
 - If adding extension, insert extension and install securing screws.



7. Push the end caps in until they stop.
8. Tighten set screws. Set screws must be securely tightened to ensure pump stability during operation.
9. Install pumps according to the instructions in **Roller Pump** chapter.
10. Install module covers and cable cover according to the instructions at the end of this chapter.

System Base

Halogen Lamp

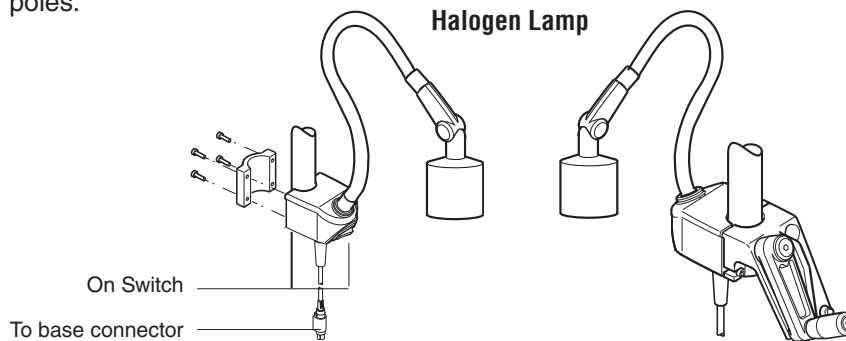
The system halogen lamp is an optional item. The lamp mounts to any of the system poles. It connects to the system base for power and uses a 20 watt, 24 volt halogen bulb. The lamp has a flexible shaft for easy positioning.

CAUTION: The lamp may get hot when powered on for extended durations. Do not allow the lamp housing to touch the patient, user, perfusion circuit or other equipment

To Mount a Lamp to the System Base:

1. Mount lamp bracket to pole.
2. Plug lamp into base receptacle.
3. Turn lamp On.
4. Position as needed.

The front portion of the lamp bracket and the front portion of the hand crank bracket can be coupled into one system to reduce the number of brackets attached to the poles.

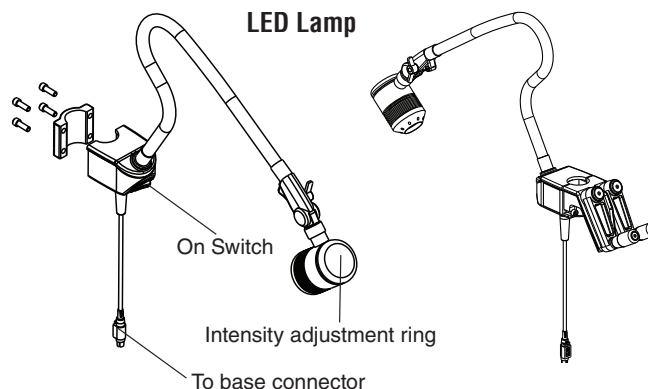


LED Lamp

The system LED lamp is an optional item. The lamp mounts to any of the system poles. It connects to the system base for power and uses a LED bulb. The lamp has a flexible shaft for easy positioning. It has an intensity adjustment ring that allows for different light intensities. Rotating the ring clockwise will increase the intensity of the light and rotating the ring counterclockwise will decrease the intensity of the light.

To Mount a Lamp to the System Base:

1. Mount lamp bracket to pole.
2. Plug lamp into base receptacle.
3. Turn lamp On.
4. Adjust Intensity as needed.
5. Position as needed.



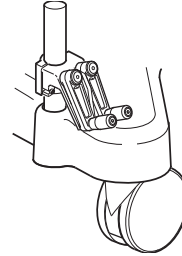
System Base

Hand Cranks

Hand cranks should be positioned for easy access during emergency conditions.

To Mount the Hand Cranks to a Pole:

1. Mount hand crank bracket to pole.
2. Place hand cranks in the bracket slots.

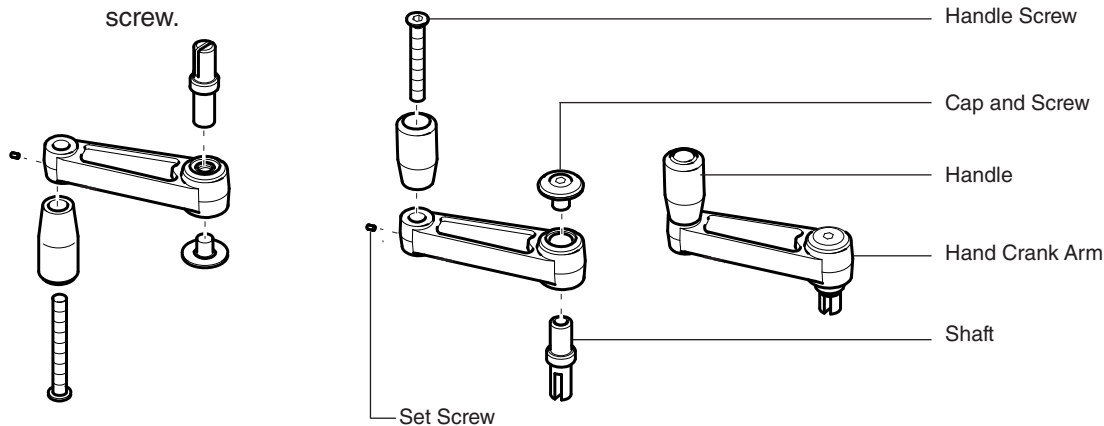


WARNING: Hand cranks must be properly setup to allow hand cranking in the same direction as that selected for forward flow for the roller pump.

WARNING: All roller pumps used in a hospital must be set to run in the same default direction for forward flow to prevent unintended retrograde pumping. RETROGRADE PUMPING MAY CAUSE SEVERE PATIENT INJURY OR DEATH.

To Change Hand Crank Direction:

1. Remove screw and cap from the hand crank arm.
2. Remove shaft from the hand crank arm by sliding the shaft out of the bearing.
3. Insert the shaft into the bearing on the opposite side of the hand crank arm.
4. Reinstall the cap and screw and tighten screw.
5. Loosen the setscrew and remove the handle screw and remove the handle.
6. Insert handle into opposite side of hand crank and tighten setscrew and handle screw.



Test Before Use

Test hand crank to ensure it rotates the pump rollers in the direction of forward flow. If the pump is difficult to turn, unplug the pump cable either at the system connection or at the pump. Reconnect the cable after test. Verify that the hand crank turns freely without moving the pump rollers when it is rotated in the opposite direction of forward flow.

Ensure that the hand crank can be used properly without interference from pole mounted pumps.

Cable Management

The base provides a cable management system that uses a series of cable clips attached to the pump platform and cable management tray.

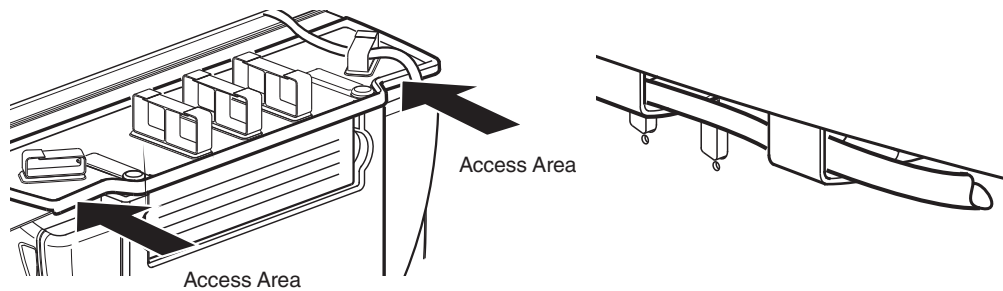
There are 3 clips on each side of the base and 5 clips on the back of the system.

To Arrange Cables:

1. Push the cable into individual clips and route cable toward the cable access area of the module cover.

System Base

2. For pump cables, route cable through the clips and attach to the pump.
3. For modules, the cable exits at the access area. Route to the appropriate location.
4. Install module and cable covers.



Module Covers

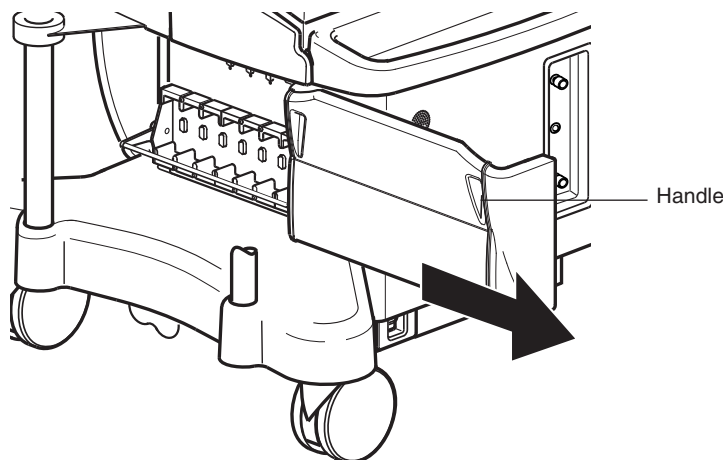
The module covers are located on each side of the base and provide protection from liquid spills. Users may view modules through the cover if required.

To Remove Module Cover:

1. Grasp the module cover handle.
2. Pull toward the front of the base.

To Replace Module Cover:

1. Align the cover on the slide rail.
2. Push into place.



Cable Cover

The cable cover is mounted on the back of the system base and provides protection from spills.

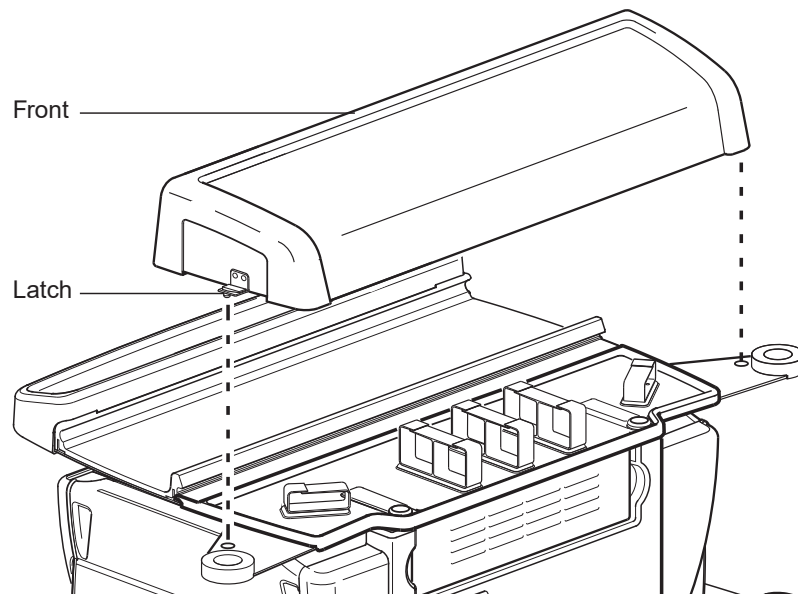
To Install Cover:

1. Slide front part of cover under roller pumps on the base.
2. Align the latches with the holes in the pole retaining brackets and insert the latches through the holes.
3. Push the latch lever down to close each latch and secure the cable cover to the base.

System Base

To Remove Cover:

1. Pull up the latch lever to open each latch.
2. Lift the cover off the base and out from under the roller pumps.



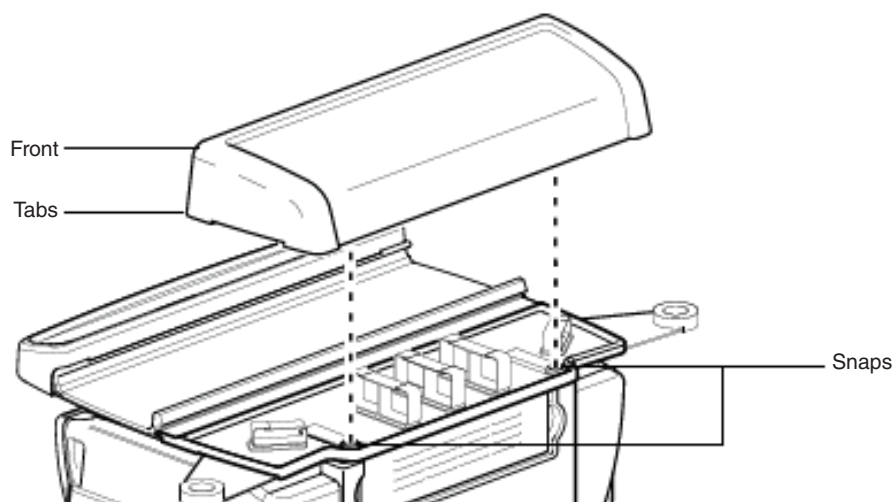
Cable Cover (for the Terumo® Advanced Perfusion System 1, 801763 and 801764, with serial numbers less than 1000)

To Install Cover:

1. Slide front part of cover under roller pumps on the base.
2. Place cover over rear cable management tray.
3. Apply pressure to the outer edges of the front of the tray until tabs snap into place over the cable management tray.
4. Apply pressure to the rear of the tray to lock the cable cover into the snaps.

To Remove Cover:

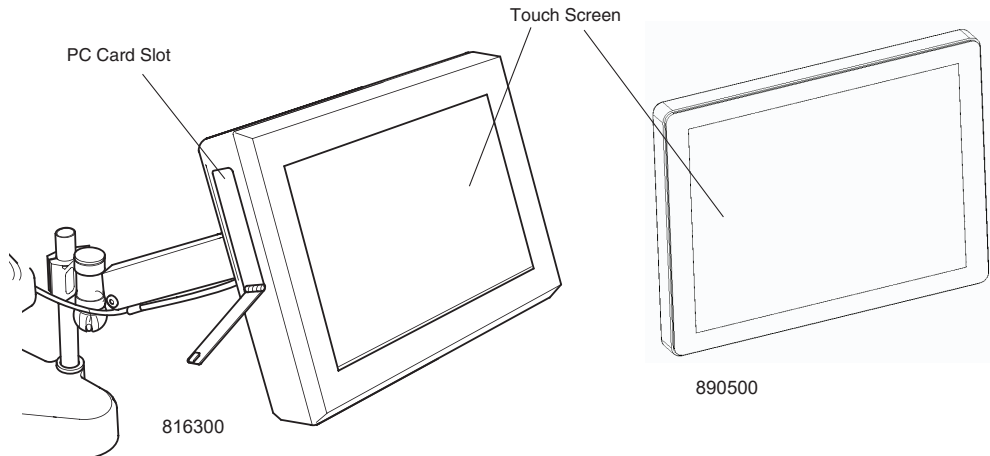
1. Grasp the outer edges of the side of the cover firmly and lift.



Central Control Monitor

Features

The Central Control Monitor (CCM) combines an embedded computer, a touch screen, and a graphical user interface (GUI) to provide a centralized display of system information and on-screen control of all system devices. The CCM is used to create perfusion screens including selecting the number and types of devices and sensors, selecting device names and colors, assigning Perfusion Screen representations to physical modules, connecting devices to safety systems, and selecting alert and alarm limits and device responses. During use, the CCM monitors the system for alert, alarm, error, or status messages and displays the highest priority message in a dedicated message area. The CCM also allows the user to initiate automatic control functionality such as Pulse mode flow, servo regulation to pressure and flow, and automatic cardioplegia time or volume delivery.



CAUTION: The computer touch screen is designed to be a single point control system. Use only one finger when operating the screen. Ensure that there is no additional contact with the touch screen during operation as unintended input may result.

Some versions of the CCM incorporate a screensaver on the touch screen's liquid crystal display if the system is powered on without any touch screen activity for a prolonged amount of time. The screensaver, notably colorful balls bouncing around on the screen, will activate if the CCM's touch screen has not been touched for 6 hours. The screensaver can be deactivated instantly at any time by simply touching the touch screen. Any alert or alarm generated by System 1 or the use of any controls such as buttons or knobs on any roller pump or any centrifugal control unit does not deactivate the screensaver.

Central Control Monitor

Connect CCM

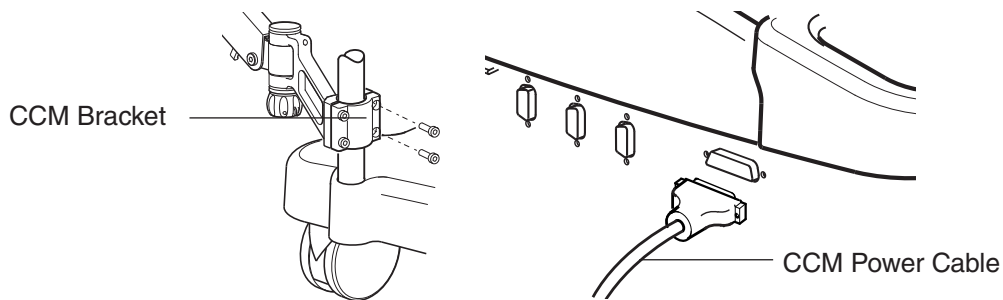
CAUTION: Use care when handling the Central Control Monitor as the controls, displays, or circuitry may be damaged if the display is dropped, struck, or immersed in liquid.

CAUTION: Pump control panels and Central Control Monitor are intended for hand and gloved hand operation only. Do not use any instruments on the pump control panels or Central Control Monitor as this may damage the device.

Attach the CCM bracket to a system pole that will provide easy viewing and access to the CCM while running a perfusion case.

Make sure AC (Mains) power is OFF before connecting or disconnecting the CCM.

Attach the CCM power cable to one of the receptacles located on the left or right side of the base, being careful not to damage the connector pins.



Before use, check that the CCM is within reach and positioned for maximum visibility. The display should be positioned within a viewing angle of $\pm 45^\circ$ horizontal and $\pm 30^\circ$ vertical; exceeding these viewing angles will decrease the contrast of various colors.

When power to System 1 is turned on, the CCM, the entire system, and attached modules perform self tests.

Central Control Monitor

Start-Up Messages

If the Power On Self Test fails, the results are displayed continuously at the top of the Main Screen as long as the Main Screen is displayed or the condition exists. The failure message is displayed in the following format:

<Module Type Name>: X “Fail,”

where X is the number of modules of this type that failed their Power-On Self-Test.

A maximum of 8 failure messages can be displayed simultaneously. Possible messages are as follows:

“System Power”	“Temperature Sensors”
“System Computer”	“Gas System”
“System Network”	“CDI 100”
“Air Detectors”	“CDI 500”
“Level Detectors”	“Large Roller Pumps”
“Occluders”	“Small Roller Pumps”
“Pressure Sensors”	“Centrifugal Pumps”
“Flow Sensors”	“Data Transfer”

The roller pump default direction is set to the system direction during start-up. For more information on setting system direction, see **Configuration, System Settings** in this chapter.

In the event of a System Power, System Computer, System Network, or Gas System start-up failure, cycle power by turning the Mains Power off and then back on. If the message is still displayed, contact Terumo Customer Service.

For a roller pump, centrifugal pump, or flow module start-up failure, disconnect and then reconnect the cable from the back of the pump or module. If the message appears again, follow the module reassign procedure in this chapter, **System tab, Reassign Module subtab**, and contact Terumo Customer Service.

For all other start-up failure messages, disconnect and then reconnect the module to the module receptacle. If the message appears again, follow the module reassign procedure in this chapter, **System tab, Reassign Module subtab**, and contact Terumo Customer Service.

In the event of a CCM start-up failure, the CCM may lose communication capability with the system. The message “No System Computer” will be displayed on the control panels of the roller pumps and centrifugal control unit and the message “System Computer Needs Service” may appear on the CCM.

Central Control Monitor

PC Card Compartment (P/N 816300)

The PC Card model of the CCM holds two PC cards: a system configuration card and a service data card.

The system configuration card is used to backup Perfusion Screens and can also be used to transfer Perfusion Screens between systems and upgrade the CCM and module software.

The service data card collects and stores data for use by authorized service representatives.

The system configuration card and service data card are not interchangeable and must be used in the appropriate slot.

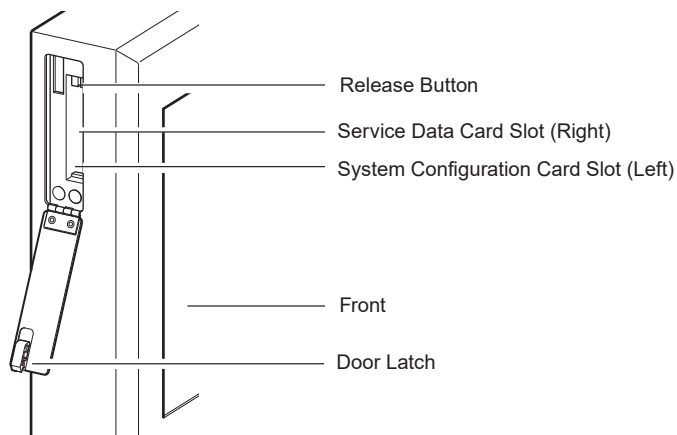
To Install a PC Card:

1. Slide the door latch down to open the compartment door.
2. Insert the PC card into the appropriate slot. The release button above the card protrudes when the card is fully seated in the slot.
3. Close the compartment door.

To Remove a PC Card:

Ensure the CCM is not accessing the card before removal.

1. Slide the door latch down to open the compartment door.
2. Depress the release button.
3. Remove the card.
4. Close the compartment door.



Central Control Monitor

USB Drive Storage Compartment (P/N 890500)

The USB drive model of the CCM stores two USB drives in the USB Drive Storage Compartment: a system configuration drive and a service data drive. The appropriate drive must be removed from the storage compartment and plugged into the USB port on the bottom of the unit in order to transfer files to/from the drive (see figure below).

The system configuration drive (also referred to as the perfusion drive) is used to backup Perfusion Screens and can also be used to transfer Perfusion Screens between systems.

The service data drive collects and stores data for use by authorized service representatives.

The system configuration drive and service data drive are not interchangeable and must be used for the appropriate action.

Note: The USB port is not enabled at times other than during file transfer to/from the USB drive.

WARNING: Do not insert non-Terumo supplied flash drives or other USB devices into the USB port.

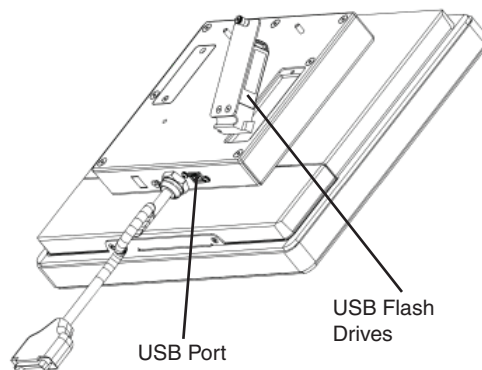
To Install a USB Drive:

1. Loosen the thumb screw on the storage compartment door and pull open to expose the USB drives.
2. Remove the system configuration or the service data drive from the storage compartment and plug it into the USB port.
3. Close the storage compartment door and tighten the thumb screw.

To Remove a USB Drive:

Ensure the CCM is not accessing the drive before removal.

1. Unplug the USB drive from the USB port.
2. Loosen the thumb screw on the storage compartment door and pull open to expose the USB drives.
3. Place the drive into the USB drive storage compartment.
4. Close the storage compartment door and tighten the thumb screw.



Central Control Monitor

Functional Areas

The CCM has 3 functional areas: Perfusion, Configuration, and Service.

The main screen allows access to these functional areas and provides access to initiate a controlled system shut down.

The Perfusion area allows the user to select a Perfusion Screen and run a case. In preparation to run a case, patient information can be entered, calibrations can be performed, and safety system limits can be checked, modified if needed, and activated. During use, the CCM can be used to control and monitor all system modules and devices. The CCM monitors the system for any alert, alarm, error, or status messages and displays the highest priority message in a dedicated message area. The user can also initiate advanced functionality such as primary pump Pulse mode, flow and pressure servo regulation, cardioplegia volume tracking, and automatic cardioplegia time or volume delivery.

The Configuration area of the CCM is used to define Perfusion Screens including number and names of modules and devices, assignment of screen icons to physical devices, safety system connections, and selection of alert and alarm limits. The displays are organized around a patient graphic representation for identification of system data.

The Service area is password protected and allows an authorized user to:

- View system log
 - Logs are maintained through all power down events
 - Power down time is available in the logs
 - The oldest log events are overwritten when log capacity is reached
- Export system logs, module logs, and Perfusion Screens to an external computer via the service data card/USB drive
- View module error event data
- Manage security access controls
- View system software version control area
- Upgrade CCM and/or module software
- Calibrate the touch screen.

The **Shut down** button provides a controlled system shut down and must be used before turning power off to the system base. Failure to follow the controlled shut down procedure may result in improper start-up at the next power-on.









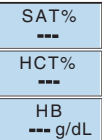

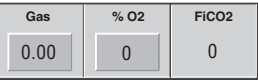


Central Control Monitor

Displays and Controls

The Graphical User Interface has features and functions common to both of the Perfusion and Configuration functional areas. The action of the button or icon on the CCM is initiated when the user lifts the finger from the touch screen.

Ensure that the touch screen cursor arrow is within the perimeter of the button when using the touch screen. If the cursor arrow is outside the perimeter of the button, the control or icon will not be activated.

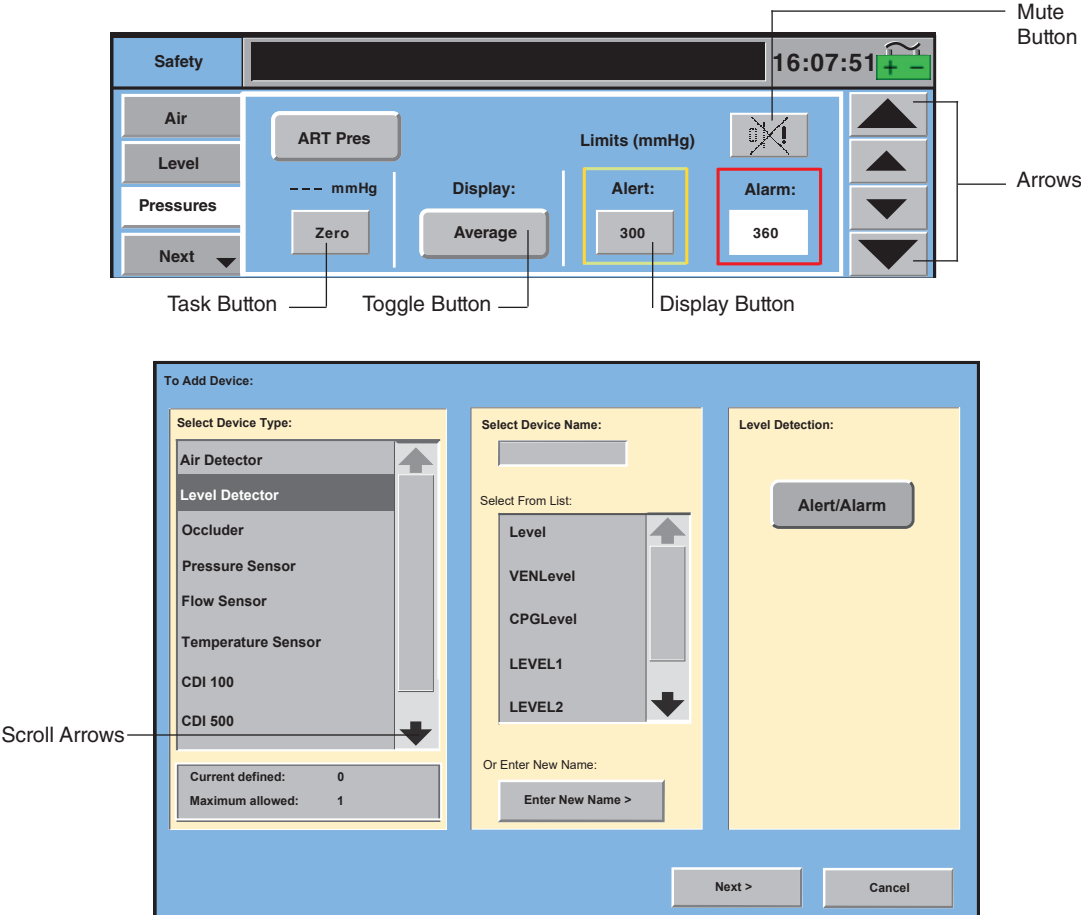
Device Icons and Displays


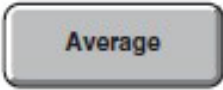

Icon/Display	Device	Action when Pressed
	Air Detector	Opens Air subtab in perfusion screen or selects the device in configuration.
	Level Detector	Opens Level subtab in perfusion screen or selects the device in configuration.
	Pressure Sensor	Opens Pressures subtab in perfusion screen or selects the device in configuration.
	Temperature Sensor	Opens Temp subtab in perfusion screen or selects the device in configuration.
	Flowmeter	Opens Flow subtab in perfusion screen or selects the device in configuration.
	Occluder	Occluder slide bar appears if hidden, disappears if displayed in perfusion screen, or selects the device in configuration.
	CDI 100/101 display	No action - display only.
	CDI 500/550 display	No action - display only.
	Electronic Gas Blender	When %O ₂ button pressed, FiO ₂ slide bar appears if hidden, disappears if displayed. When Gas button pressed, Gas slide bar appears if hidden, disappears if displayed. FiCO ₂ display, no action, displays only if using 95/5.
	Broken Module	Opens Reassign Module subtab. (Refer to Emergency Procedures chapter, Network Malfunction for further information.)
	Noncommunicating or missing module	Opens Reassign Module subtab. (Refer to Emergency Procedures chapter, Network Malfunction for further information.)

Central Control Monitor

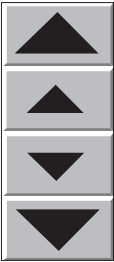



Buttons

There are several types of buttons used throughout the Graphical User Interface screens to select and display information or to accomplish specific tasks. The Safety tab and To Add Device Screens shown below illustrate examples for a Task button, Toggle button, Display button, arrows, Mute button, and Scroll arrows.



Button/Display	Description	Action when Pressed
	Task Button	Action displayed on the button will be taken.
	Toggle Button	Each time the button is pressed, the next value from a selection list is displayed. The label that is displayed is the enabled selection.
	Display Button	The button background turns white and value can be adjusted using control arrows that appear on the right side of the subtab. The button should be pressed again to confirm the new value. The control arrows disappear and other buttons may be activated when the new value is confirmed.

Central Control Monitor

Button/Display	Description	Action when Pressed
	Arrows	Appear when a display button is pressed to adjust the displayed value and disappear when the new value is stored. Touching the small arrows adjusts the selected parameter in small increments; touching the large arrows adjusts the selected parameter in large increments.
	Mute Button	This button appears on all safety subtabs and is activated by an alert or alarm. Pressing this button while active silences the audible alert or alarm tone for that specific alert or alarm.
	Scroll Arrows	Enabled when all the items in a list cannot be viewed within the display area. Touching the arrows will allow additional list items to be viewed.
	Close Button	Use this button to close subtab screen.

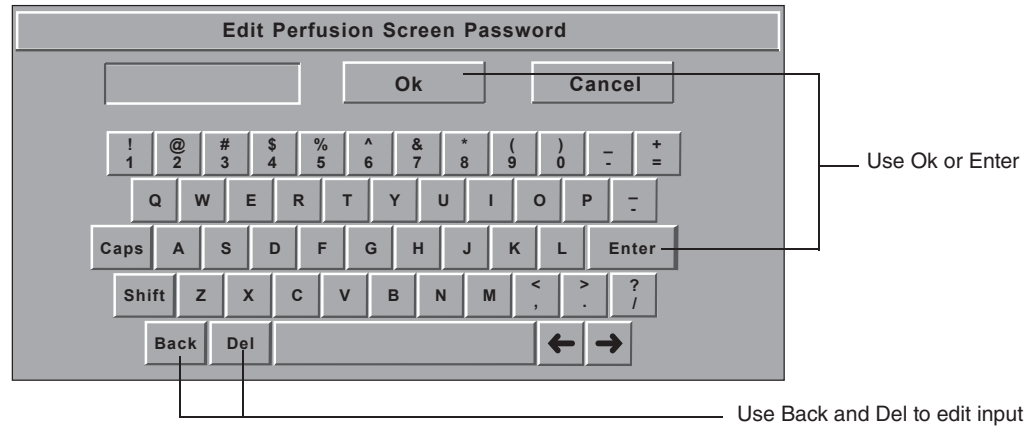
Keyboard

The keyboard is used to create and edit passwords and assign names. Please note the “shift + number” characters are not active.

Passwords are used to limit access to Perfusion Screens and the Configuration area. A password may contain up to 12 characters, consisting of both upper and lower case letters, numbers, and the space key.

Perfusion Screen names are used to identify specific screens and may contain up to 12 characters, consisting of both upper and lower case letters, numbers, and the space key. Perfusion Screen names must be unique.

Device names are used to identify specific devices and may contain up to 8 characters, consisting of letters both upper and lower case, numbers, and the space key. Device names must be unique within each Perfusion Screen.



Central Control Monitor

Security

Password protection can be used to limit access to the Perfusion Screens and the Configuration area only to authorized users. If no passwords are created, any user will be able to select any Perfusion Screen or create and modify Perfusion Screen configurations using the Configuration area.

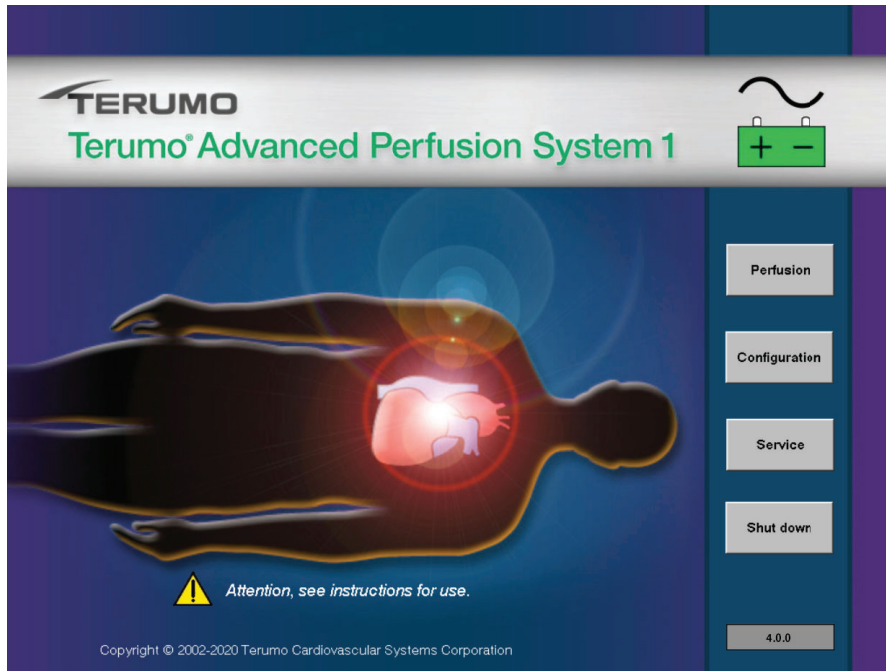
If the password security feature of the System 1 is used, Terumo Cardiovascular Systems Corporation recommends including the following elements in any current security policies and procedures:

- Definition of user levels:
 - Who will have access to Perfusion Screens.
 - Who will have access to Configuration area.
- Definition of password characteristics:
 - Length (e.g., passwords shall contain a combination of at least 6 but no more than 8 alphanumeric characters).
 - Characters (e.g., at least one character shall be a number).
 - Unique (e.g., each Perfusion Screen shall have a unique password, all of which shall be different from the Configuration password).
- Description of whether passwords will be changed on a regular basis.
- Identification of the title or name of the person responsible for the creation and/or modification of passwords.
- Description of how passwords will be communicated to defined users.
- Description of any documentation that will be maintained to demonstrate that the security procedures are being followed.
- In multilingual settings, only use characters that are common to all keyboards.

Central Control Monitor

Perfusion Screen

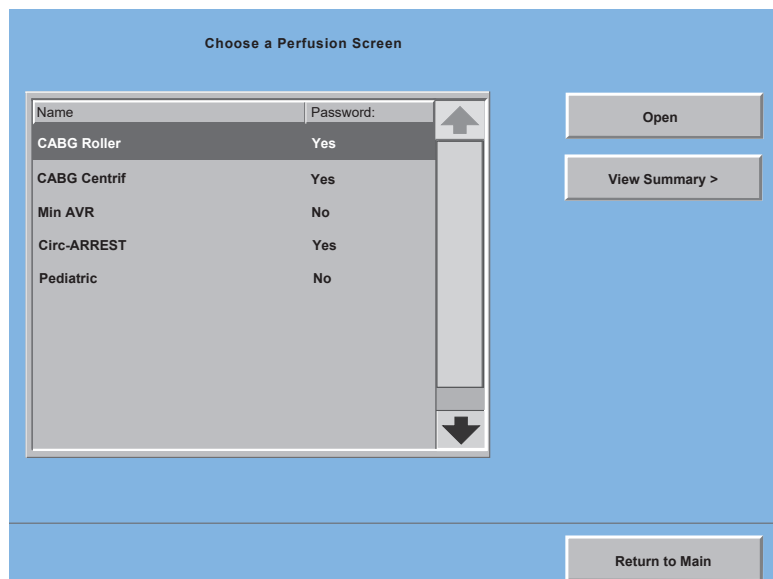
The Perfusion functional area is used to select and run a perfusion case. Touch the **Perfusion** button to go to Choose a Perfusion Screen.



The screen lists all Perfusion Screens by name and indicates whether the screen is password protected. All screens that are password protected require the password to be entered before the screen will display graphically on the CCM.

The user has three options from this screen:

1. View a summary of a Perfusion Screen.
2. Return to the Main Screen.
3. Open a Perfusion Screen.



Central Control Monitor

View Summary

The summary screen displays information about the defined configuration for that Perfusion Screen. The name of the Perfusion Screen, graphic orientation, type of venous reservoir, devices included in the Perfusion Screen, and the assigned names of the devices are displayed. Also included is information about the pumps, such as type, name, and any safety connections between the pumps and the other configured devices.

To view a Perfusion Screen Summary:

1. Touch the Perfusion Screen name. The selected screen will be highlighted.
2. Touch the **View Summary** button to view a summary of the screen.
3. Select the **Close** button to return to the previous screen.

Screen Name

The image shows a screenshot of the 'Perfusion Screen Summary' interface. At the top, the title 'Perfusion Screen Summary' is on the left, and 'CABG ROLLER' is on the right. The main content area is a yellow rectangle with a vertical scrollbar on the right. It lists several categories and their values: 'Graphic Orientation: Primary Pump Left - Patient Head Left', 'Blood Reservoir Type: Open', 'Air Detectors: ART Air', 'Level Detectors: Level', 'Occluders: Occluder', 'Pressure Sensors: ART Pres, CPG Pres', 'Temperature Sensors: ART Temp, VEN Temp, CPG1Temp, CPG2Temp', 'CDI 500: CDI 500', and 'Large Roller Pumps: Arterial'. At the bottom center is a 'Close' button. A line from the 'Screen Name' label points to the 'CABG ROLLER' text.

Category	Value
Graphic Orientation:	Primary Pump Left - Patient Head Left
Blood Reservoir Type:	Open
Air Detectors:	ART Air
Level Detectors:	Level
Occluders:	Occluder
Pressure Sensors:	ART Pres CPG Pres
Temperature Sensors:	ART Temp VEN Temp CPG1Temp CPG2Temp
CDI 500:	CDI 500
Large Roller Pumps:	Arterial

To Return to Main:

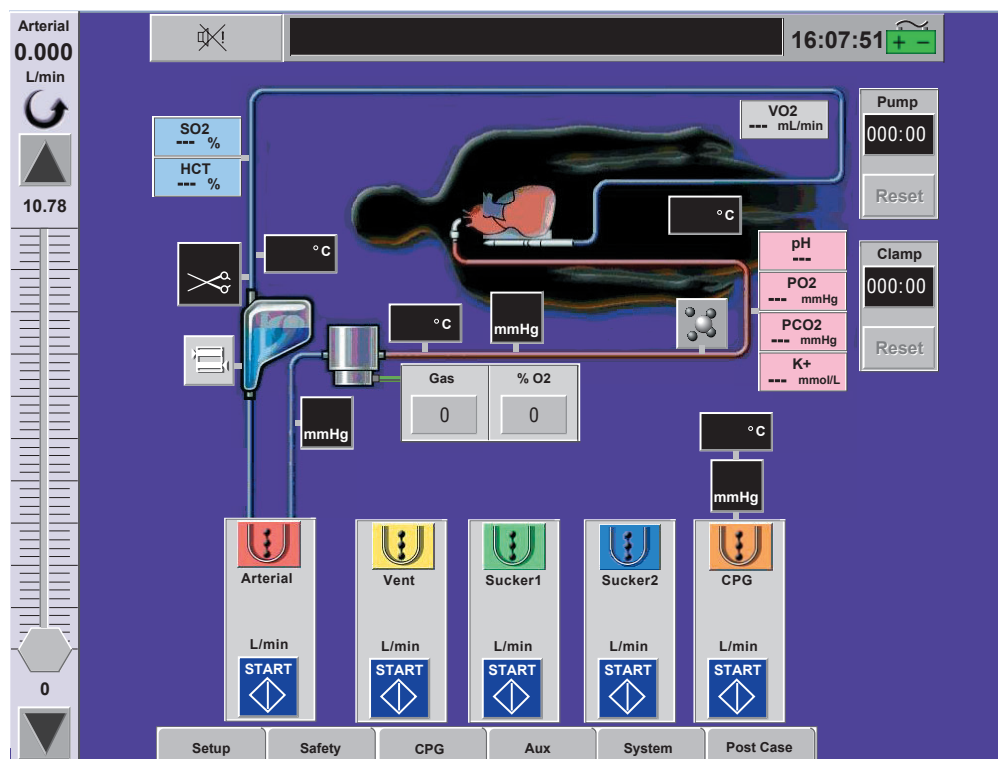
Touch the **Return to Main** button to return to the Main Screen.

Central Control Monitor

To Open a Perfusion Screen:

1. Touch the Perfusion Screen name. The selected screen will be highlighted.
2. Touch the **Open** button.
3. Enter password if the screen is password protected. The CCM will open and display the Perfusion Screen. When a Perfusion Screen is opened, the status of all devices that are a part of the Perfusion Screen will change from offline to online. Online pumps display the pump name and LED of online modules is constant green.

Note: In the event that any visual elements of the Perfusion Screen do not load completely while using the CCM P/N 890500, exit the Perfusion Screen by touching the Post Case tab and following the prompts, then reopen the screen as described above.



Perfusion Screen

Although a Perfusion Screen can be customized to accommodate many different perfusion setups, all Perfusion Screens share some common characteristics including the patient and perfusion circuit graphics, message area, system time, power source/battery status icon, primary pump, pump and clamp timers, pump control area, tabs, control slide bars, and device icons.

Primary Pump

A Perfusion Screen must have a primary pump, usually the arterial pump, designated in the Configuration area. The controls and displays for this pump are always displayed on the right or left side of the Perfusion Screen.

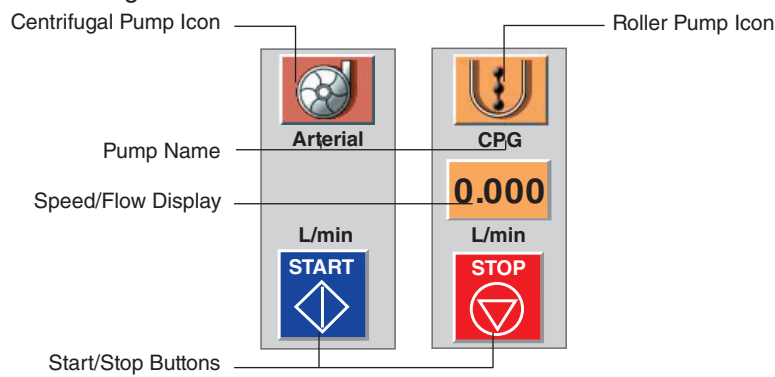
Central Control Monitor

Pump Controls and Displays

Pump control boxes displayed on the lower third of the CCM can be used to start and stop pumps and to monitor current pump speed or flow values. Each pump has a corresponding slide bar located either on the right or left side of the Perfusion Screen which can be used to adjust the pump speed on the CCM. Pumps can also be controlled from their front panel controls.

Pump Control Box

All pump control boxes consist of three elements: a Start/Stop button, a speed/flow display button, and a pump icon button. The only exception is a master/follower pump control box (see **Roller Pumps** chapter for details of a master/follower pump control box). The pump type, name, color, display units, and position are all defined in the CCM Configuration area.



Start Button or Stop Button

The Start button activates and starts the pump at a speed of 0 RPM or a flow of 0.000 L/min. The Stop button stops the pump if it is running and also deactivates it. If the pump is stopped and deactivated using the Stop button, it must be reactivated using the Start button for the pump to be used again.

To start a pump:

1. Touch the **Start** button.
 - The button color changes to red and the label changes to Stop.
 - The pump speed/flow display button appears.
 - The pump slide bar appears on one side of the CCM (the primary pump slide bar is always displayed).

To stop a pump:

1. Touch the **Stop** button.
 - The button color changes to blue and the label changes to Start.
 - If the pump is not the primary pump, the speed/flow button and the pump slide bar disappear.

Pump Speed/Flow Display

The current value of the pump speed or flow rate is displayed in the units selected during Configuration.

Touching the button on a primary pump will scroll through three possible display selections: L/min, L/min/m², or mL/kg/min.

Note: If a centrifugal pump is not configured to display flow through the use of a flowmeter, the button will display dashes.

For all other pumps, the pump speed/flow display button appears when the pump is started and disappears when the pump is stopped. Touching the speed/flow display button will open the slide bar for that pump and close any open slide bar in the shared location.

Central Control Monitor

Pump Icon

The symbol on the pump icon button indicates whether a pump is a roller or centrifugal pump. When the pump is running, the icon will spin in relation to the pump speed. The roller pump icon also reflects the direction of rotation. Touching the pump icon button opens the Pump tab. See the **Perfusion Screen Tabs, Pumps subtab** section for more details.

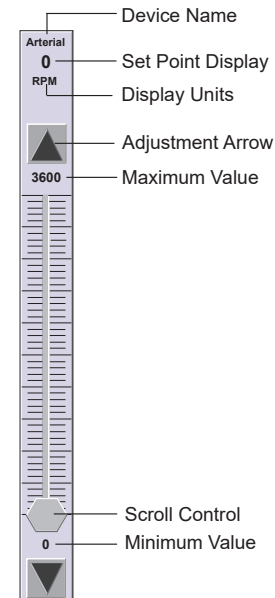
Slide Bars

Slide bars are vertical bars located on either side of the Perfusion Screen that are used to control roller and centrifugal pump speeds, occluder position, total gas flow rate, and the FiO₂ setting. All slide bars include a device name, set point display, display units, adjustment arrows, maximum and minimum value labels, and a scroll control. The central strip and scroll control are color coded to match the device color. When operating a slide bar from a shared location, ensure that the slide bar displayed is for the device you intend to operate.

To adjust an active slide bar:

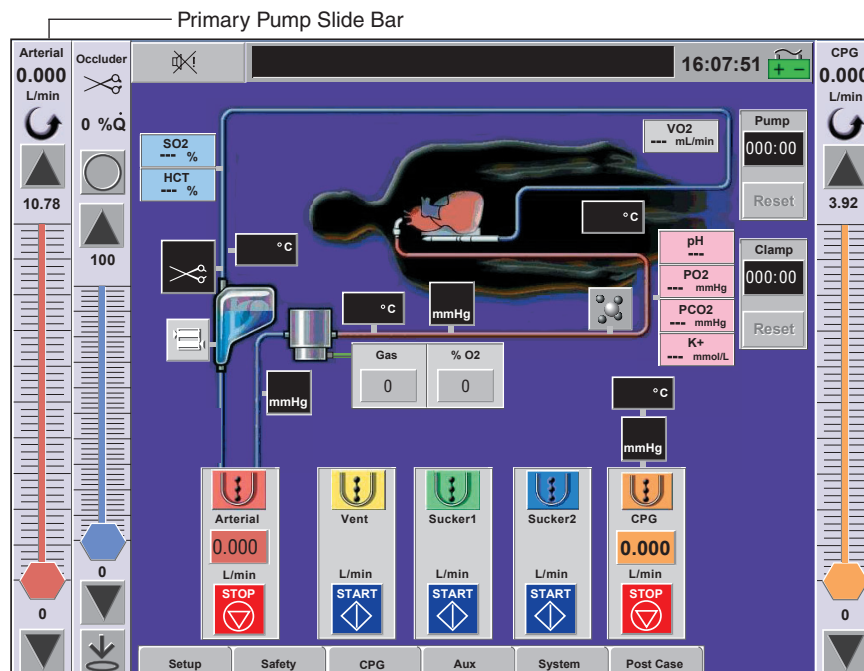
1. Touch and hold the slide bar scroll control.
2. Slide the scroll control to the desired slide bar position. The set point display should display the new setting.
3. Use the adjustment arrows to make fine adjustments.

Each pump has a corresponding slide bar which is used to adjust its speed on the CCM. While in a Perfusion Screen, the primary pump slide bar is always displayed and is configured to appear on the right or left side of the Perfusion Screen. All other pumps share a slide bar location on the side opposite the primary pump slide bar.



Primary Pump Slide Bar

While in a Perfusion Screen, the primary pump slide bar is always displayed on the same side as the primary pump. All other pump slide bars appear one at a time in a single location on the side opposite the primary pump slide bar when the pump speed/flow display button is pressed.



Central Control Monitor

Roller Pump Slide Bar

A roller pump slide bar includes the roller pump name, current speed or flow rate, a flow direction icon, a minimum value of 0 and a maximum value determined by the pump size and selected tube size. The adjustment arrows can be used to adjust the pump speed by 1 RPM. The corresponding change in flow rate will depend on the pump size and selected tube size.

Centrifugal Pump Slide Bar

A centrifugal pump slide bar will include the centrifugal pump name, motor speed in RPM, minimum value of 0 and maximum of 3600 RPM for Sarns centrifugal pumps and 3000 RPM for Capiox centrifugal pumps. The adjustment arrows can be used to adjust the motor speed by 10 RPM.

The bold black horizontal line on the slide bar indicates the Coast position of either 1500 RPM for the Sarns centrifugal pump or 1250 RPM for the Capiox centrifugal pump. At the onset of a Coast response, the centrifugal slide bar is disabled and grayed out for 2 seconds. This occurs even if the Coast response does not include a speed change.

Note: Using the centrifugal pump slide bar to reduce the pump speed to 0 RPM will stop and deactivate the pump. Restarting the pump will require touching start. This is different than the roller pump behavior which does not stop and deactivate at 0 RPM.

Electronic Gas Blender Slide Bars

Two slide bars are associated with the electronic gas blender: gas flow and FiO₂. The slide bars share one location with the occluder slide bar. They appear one at a time, adjacent to the primary pump slide bar when either the gas flow or the FiO₂ icons are pressed.

The gas flow slide bar displays the name Gas and the set point flow rate in L/min. The minimum value is 0 and the maximum is 10 L/min. The adjustment arrows can be used to adjust the flow rate by 0.1 L/min.

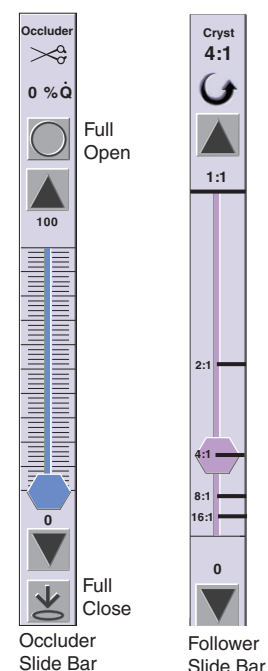
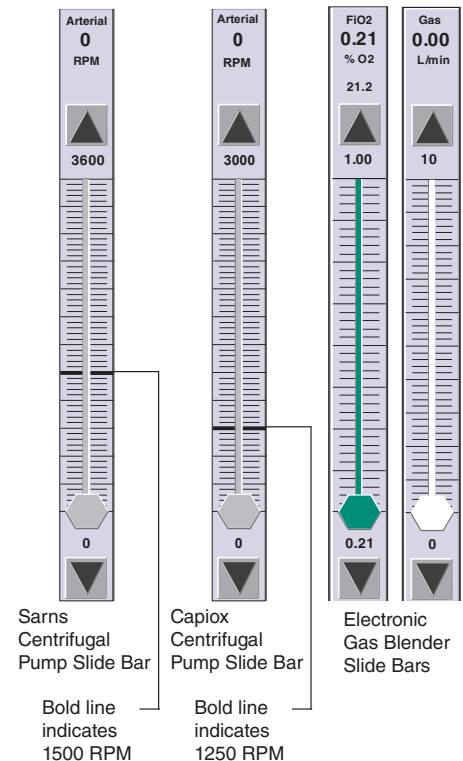
The FiO₂ slide bar displays the name FiO₂, the FiO₂ setpoint and the %O₂ value from the oxygen analyzer, and the current FiO₂ setting. When the blending gas is air, the minimum value is 0.21 and the maximum value is 1.00. When the blending gas is 95-5, the minimum value is 0.95 and the maximum is 1.00.

Occluder Slide Bar

The occluder slide bar appears adjacent to the primary pump slide bar and shares its location with the gas flow and FiO₂ slide bars. The occluder slide bar will appear when the occluder icon is pressed.

The occluder requires an initial calibration. If the calibration has not been performed, "CAL" will be displayed at the top of the slide bar and on the button at the bottom of the slide bar. To calibrate the occluder, touch the **CAL** button.

The calibrated occluder slide bar includes the occluder name, occluder symbol, current value in % open, a full close button, and a full open button. The minimum value is 0 and the maximum value is 100% open. The adjustment arrows can be used to change the % open by 1%.



Central Control Monitor

Follower Slide Bar

The follower slide bar includes the pump name, the current % of master flow, and adjustment arrows. The minimum value is 0% and maximum value is 1:1 or 100%.

Displays

The information displayed in the top portion of the Perfusion Screen appears in all Perfusion Screens. This includes the Mute All button, Message area, Time Display, and the Power Source/Battery Status icon.

Mute All

All active alert and alarm tones are silenced when the Mute All button is touched with the exception of the battery alert tone.

Note: The unique, repeating, audible battery alert tone which indicates that the system is operating from battery power, cannot be muted.

Message Area and Priorities

The message area in the top part of the Perfusion Screen displays the highest priority alarm, alert, status, or error message. If two conditions of equal priority exist at the same time, the condition that was detected first will be displayed on the screen. All messages will post in the Messages subtab within the Aux tab.

In general, the order in which messages are displayed in the Perfusion Screen message area is determined first by the type of message, then by the order in which the Central Control Monitor receives the message. Messages are prioritized in order of importance as:

- Alarms = High Priority / Flash red
- Alerts = Medium Priority / Flash yellow
- Error messages = Low Priority / Flash white
- Status messages = Information signal / Solid white

If two conditions of equal priority exist at the same time, the message for the condition that occurred first will be displayed in the message area until it clears. If the second condition still exists after the first has been cleared, then that message will be displayed.

For example, if a pressure alert condition is detected and no alarm or other alert conditions exist, the pressure icon flashes yellow, an audible alert tone sounds, the Pressures subtab within the Safety tab opens, and the message "<Pressure Name>: CHECK PRESSURE" is displayed in the message area. If a level alert condition now occurs, the level icon will flash yellow, the alert tone will sound, but the level alert message is not displayed in the message area until the pressure alert condition clears.

Status messages post only once. If the message area has a higher priority message, the status message will post only in the Messages subtab within the Aux tab.

At any time during the case, the user can view all messages by pressing the Aux tab and opening the Messages subtab. This subtab displays all system messages along with the time the message was generated. See the **CCM Aux Tab** section for further details.

System Time

The time of day is displayed on the upper right side of the Perfusion Screen. See the **Setup Tab, Time/Date subtab** section in this chapter for details on modifying the time of day.

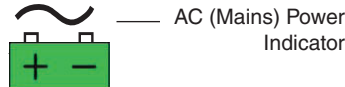
Power Source/Battery Status Icon

The Power Source/Battery Status icon on the upper right of the Perfusion Screen provides the user with:

- Power Source – AC or On Battery

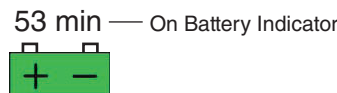
Central Control Monitor

- Estimated battery time remaining in minutes displayed above the Power Source/Battery Status icon when on battery. An AC (Mains) Power Indicator is shown over the Battery Status icon when on AC (Mains) Power.
- Estimated battery time remaining as indicated by icon color:
 - When on AC (Mains) Power:
 - Steady green indicates a battery system with greater than one hour run time with a fully loaded system
 - Steady red indicates a battery system with less than one hour run time with a fully loaded system.



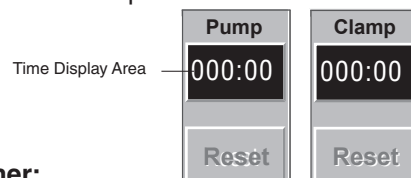
WARNING: If the Battery Capacity is indicated at less than 60 minutes battery power, do not start a case. If the system should be fully charged, but the Battery Capacity indicates less than 60 minutes, call Terumo Customer Service. Do not use the system until it has been serviced.

- When on Battery Power:
 - Flashing green indicates 30 minutes or more battery life at present discharge rate
 - Flashing yellow indicates 15 minutes or more, but less than 30 minutes battery life at present discharge rate
 - Flashing red indicates less than 15 minutes battery life at present discharge rate



Pump and Clamp Timers

A pump and clamp timer are always available on the Perfusion Screen. A Perfusion Screen can be configured to include up to 2 additional timers, for a maximum of 4 timers. The additional timers can be configured to count up from zero or to count down from a chosen value. Count up timers have a range from 00:00 to 99:59; count down timers have a range from 99:59 to 00:00. The pump and clamp timer can only be used in count up mode.



To operate a timer:

- Start the timer by touching the Time Display area. The timer starts counting in minutes and seconds. The start time appears below the Time Display area.
- To stop the timer, touch the Time Display area again. The stop time appears to the right of the start time. The Reset button is activated.
- To restart the timer, touch the Time Display area again. The timer continues counting from the current value. The stop time disappears.
- To reset a count up timer to 0 or a count down timer to its initial value, touch the **Reset** button. The start and stop times disappear.

Perfusion Screen Tabs

The area of the Perfusion Screen below the pump control boxes displays the 6 Perfusion Screen tabs: Setup, Safety, CPG, Aux, System, and Post Case. An additional tab, the Pump tab, is accessed by touching the pump icon. Pressing any one of these opens a screen. Each screen may contain a number of subtabs, which open additional screens that allow access to more information and functions for individual sensors and devices.



Central Control Monitor

Perfusion Screen Tabs

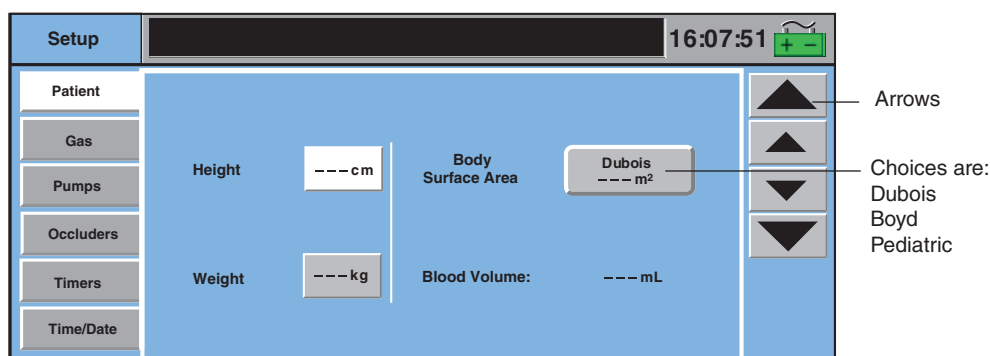
Setup Tab

The Setup tab contains six subtabs, which allow the user to enter patient data, control various functions of the gas system, pumps, occluders, and timers, as well as setting the system time and date.



Patient Subtab

Patient height and weight are entered during the case setup and the patient's body surface area and blood volumes are calculated automatically. The patient data is retained for the current case only and is reset each time a Perfusion Screen is opened.



To Adjust the Height:

1. Touch the **Height** button. The Height button changes to white.
2. Use the arrows to enter patient height in cm. The large and small arrows initially adjust the value to 30 cm. Subsequent adjustments are 20 cm for the large arrows and 1 cm for the small arrows. The maximum height is 250 cm.
3. Touch the **Height** button again to store the new value.

To Adjust the Weight:

1. Touch the **Weight** button. The Height button changes to white.
2. Use the arrows to enter patient weight in kg. The large arrows adjust the value by 2 kg up to 20 kg, then adjust the value by 20 kg increments. The small arrows adjust the value by 0.1 kg or 1 kg and correspond to the large arrow increment value. The maximum weight is 300 kg.
3. Touch the **Weight** button again to store the new value.

Central Control Monitor

Body Surface Area (BSA)

The BSA is calculated automatically when the height and weight data are entered.

Touch the **Body Surface Area** button to toggle through the selection for the formula used to calculate the BSA. BSA can be calculated using the Dubois, Boyd, or Pediatric formulas.

The Dubois formula is $BSA = (Height)^{.725} \times (Weight)^{.425} \times 0.007184$.

The Boyd formula is $BSA = \frac{3.207 (Height)^{0.3} \times (Weight \times 1000)^{(0.7285 - 0.0188 \log (Weight \times 1000))}}{10000}$

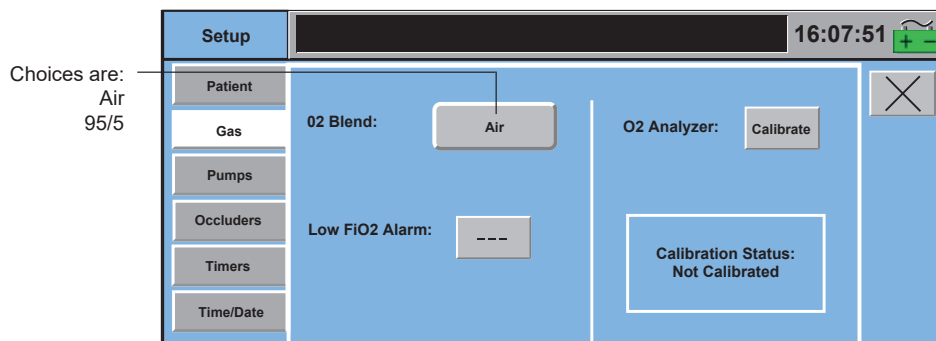
The Pediatric formula is $BSA = (Wt^{.5378} \times Ht^{.3964}) \times 0.024265$.

Blood Volume

The Blood Volume is automatically calculated using the patient weight information and is displayed in milliliters. If the patient weight is greater than or equal to 20 kg, the formula used is 70 mL x Wt (kg). If patient weight is greater than or equal to 10 kg and less than 20 kg, the formula is 75 mL x Wt (kg). If the patient weight is less than 10 kg, the formula is 80 mL x Wt (kg).

Gas Subtab

From the Gas subtab, the user selects the type of gas to blend with O₂, sets the low FiO₂ alarm and calibrates the oxygen analyzer. See the **Electronic Gas Blender** chapter for detailed information about connecting and operating the gas blender.



To Select O₂ Blend:

Touch the **O₂ Blend** button to toggle between Air and 95/5. The O₂ blend selected (95/5 or Air) will be displayed within the button.

To Set Low FiO₂ Alarm:

1. Touch the **Low FiO₂ Alarm** button. The button changes to white.
2. Use the arrows to change the alarm limit. The large arrows adjust the FiO₂ limit by increments of 0.5 and small arrows adjust the limit by increments of 0.1.
3. Touch the **Low FiO₂ Alarm** button again to store the new value.

Note: The low FiO₂ Alarm is retained for the current case only and is reset each time a Perfusion Screen is loaded.

With air selected as the O₂ blend, the Low FiO₂ Alarm defaults to "---" and has a range of 0.21 - 0.99. With 95-5 selected as the O₂ blend, the Low FiO₂ Alarm defaults to "---" and has a range of 0.95 - 0.99. Asterisks are displayed and the alarm is disabled if the alarm limit is set lower than the default value.

Central Control Monitor

To Calibrate O₂ Analyzer:

Touch the **Calibrate** button.

- Calibration takes approximately 2 minutes.
- “Calibrating O₂ analyzer” is displayed during calibration.

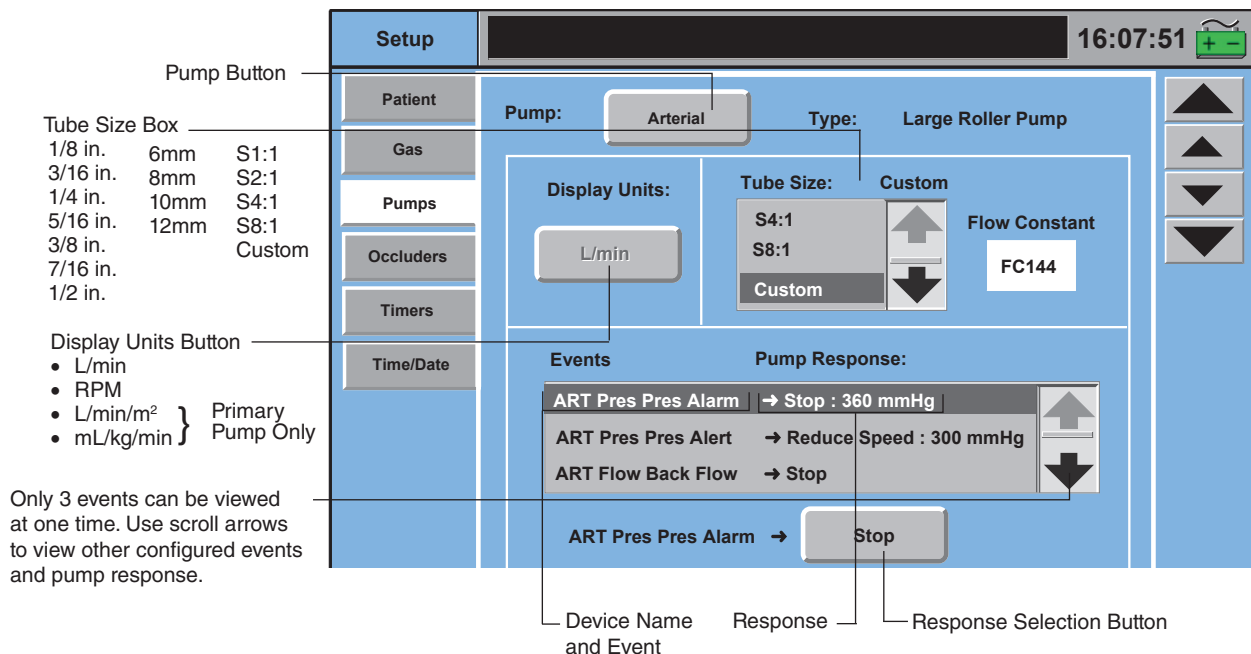
When the calibration is complete, the message “O₂ Analyzer Calibration Complete” will display in the Messages subtab within the Aux tab and in the message area of the CCM if there are no higher priority messages.

Pumps Subtab

The Pumps subtab allows the user to change the roller pump display units, tube size, and pump response to a safety event. The Pumps subtab also allows the user to change centrifugal pump display units, pump response to a safety event, and set the minimum flow alarm. See the **Roller Pumps, Sarns Centrifugal Pumps, or Capioc Centrifugal Pumps** chapter for detailed information about connecting and operating pumps.

For Roller Pumps

Touch the **Pump** button until the correct name is displayed on the button. The roller pump must be in Stop mode to change the display units and the tube size.



To Change Display Units:

Touch the **Display Units** button to toggle through the selections. Stop when the desired selection is displayed. Changes are only retained for the current case.

To Change Tube Size:

1. Use the scroll arrows to view the list of available sizes.
2. Touch the correct tube size from the list. The tube size selection is highlighted and the tube size will display above the selection box and on the roller pump local display.

To enter a custom tube size:

1. Select Custom from the list.
2. Touch the **Flow Constant** button.
3. Use arrows to adjust value.
4. Touch button again to retain the value.

The system will retain this selection until a new selection is made from this screen or from the pump local display.

Central Control Monitor

To Change Pump Response:

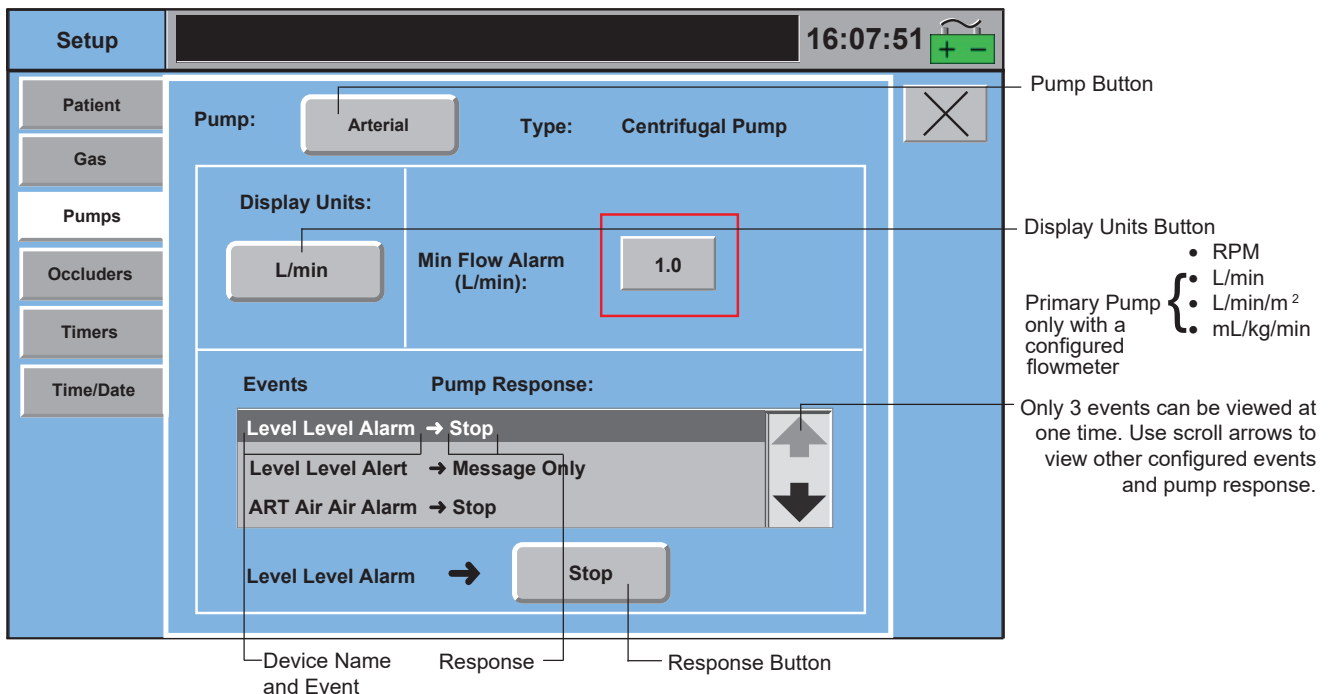
The bottom portion of the screen displays the configured safety connections and gives the user the ability to edit them for the current case only.

1. Select the event/pump response to be changed. The Response button at the bottom of the screen displays the current pump response.
2. Touch the **Response** button to toggle through the list of available response choices. The response that is displayed on the button is the response of the pump for the specified event.

Changes made to pump response from the Perfusion Screen are only retained for the current case. The response will revert to the response set in Configuration when the case is exited.

For Centrifugal Pumps

Touch the **Pump** button until the correct name is displayed on the button. Changes can be made while the pump is operating.



Change Display Units:

Touch the **Display Units** button to toggle through the choices. Stop when the desired selection is displayed. Changes are retained for the current case only.

Set Min Flow Alarm:

The Min Flow Alarm button is only available when a flowmeter has been placed on the centrifugal pump icon. The range for the Min flow alarm is 0.0 to 8.0 L/min.

1. Touch the **Min Flow Alarm** button.
2. Use the arrows to adjust the minimum flow value. The large arrows adjust the value by 1 L/min and the small arrows adjust the value by 0.1 L/min.
3. Touch the **Min Flow Alarm** button again to store the new value.

Central Control Monitor

To Change Pump Response:

The bottom portion of the screen displays the configured safety connections and gives the user the ability to change them for the current case.

1. Select the event/pump response to be changed. The Response button at the bottom of the screen displays the current pump response.
2. Touch the **Response** button to toggle through the list of available response choices. The response that is displayed on the button is the response of the pump for the specified event.

Changes made to pump responses from the Perfusion Screen are only retained for the current case. The response will revert to the response set in Configuration when the case is exited.

Occluders Subtab

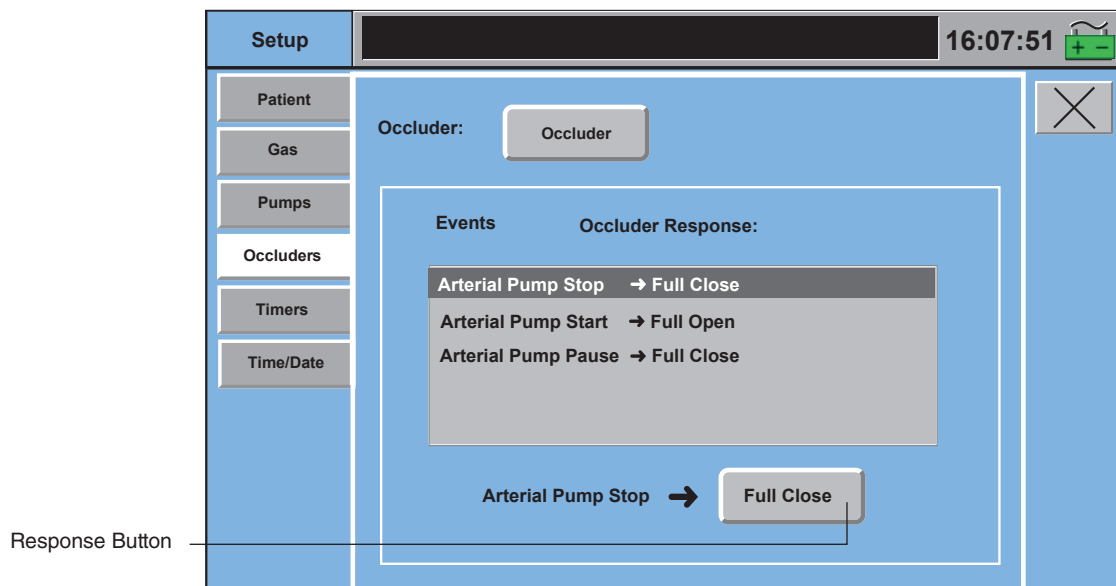
From this subtab, the user can change an occluder response to an external event generated by the primary pump. The name of the occluder will be displayed on the Occluder button.

Occluder responses to the following centrifugal pump events must be the same: pump stop, pump Coast, and minimum flow. The system will automatically assign the response chosen for stop, Coast, or minimum flow to the other two events.

To Change Occluder Response:

1. Select the event/response to be changed. The Response button at the bottom of the screen displays the current occluder response.
2. Touch the **Response** button to toggle through the list of available response choices. Occluder response choices include No Response, Full Open, Full Close, or Go to % Flow. The response that is displayed on the button is the response of the occluder for the specified event. If Go to % Flow is a response that is selected, touch the **0%** button. Use the arrows to adjust the value. Large arrows adjust the value by 10% and small arrows adjust the value by 1%.

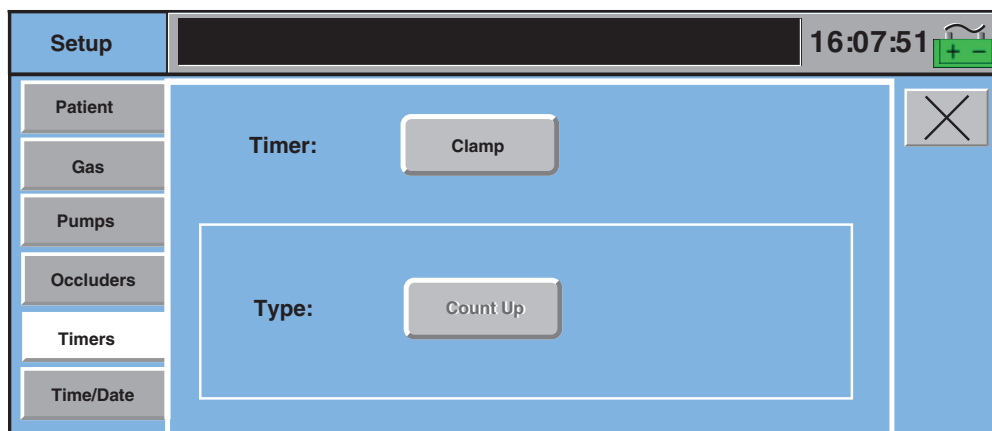
Changes made to a safety response from the Perfusion Screen are only retained for the current case. The response will revert to the response set in Configuration when the case is exited.



Central Control Monitor

Timers Subtab

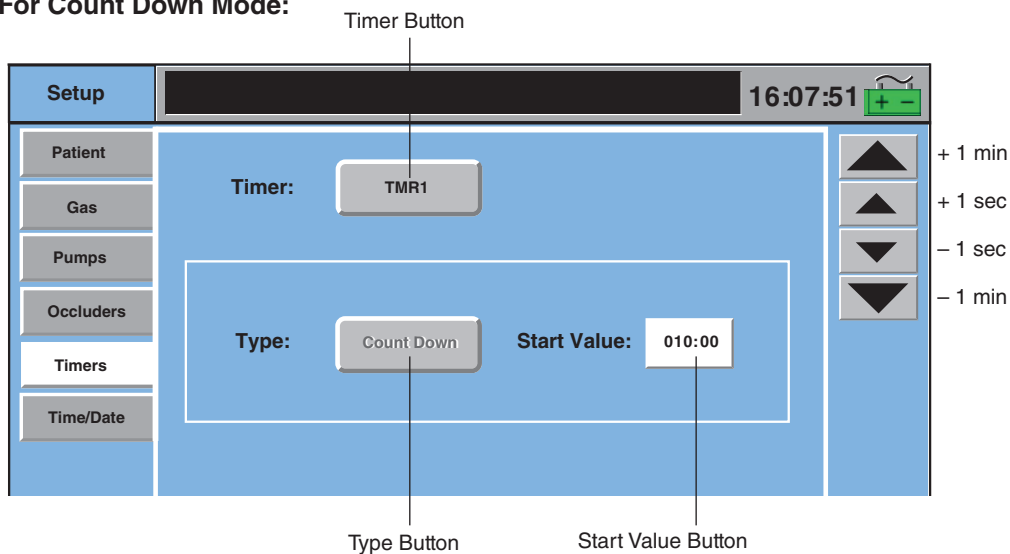
From this subtab, the user can check the mode of a timer. The Pump and Clamp timers are controlled from the Perfusion Screen. Other timers are controlled from the Timers subtab within the Aux tab.



For Count Up Mode:

The timer is ready for use.

For Count Down Mode:



1. Touch the **Start Value** button.
2. Use the arrows to set the start value. The large arrows adjust the value by 1 minute, the small arrows adjust the value by 1 second. The maximum value that can be entered is 990:59.
3. Touch the **Start Value** button to store the value.

Central Control Monitor

Time/Date Subtab

The time is displayed in the upper right corner of the Perfusion Screen. The date appears in various locations throughout the Perfusion, Configuration, and Service functional areas. Both the time and date are set from the Time/Date subtab. Please note that all pumps and timers must be stopped in order to change the time and/or date.

The screenshot shows the 'Time/Date' subtab selected in the left-hand menu. The main display area is blue and contains the following elements:

- Top Bar:** A black bar with the word 'Setup' on the left, a large black rectangular area in the center, and the time '16:07:51' on the right next to a green '+' and '-' button.
- Left Menu:** A vertical list of buttons: 'Patient', 'Gas', 'Pumps', 'Occluders', 'Timers', and 'Time/Date' (which is highlighted in white).
- Main Display:**
 - Time:** A label 'Time:' followed by a white box containing '09:58'.
 - Date:** A label 'Date:' followed by three white boxes: '01' (Month), '29' (Day), and '2002' (Year).
- Right Controls:** A vertical stack of four arrow buttons: a large upward arrow, a small upward arrow, a small downward arrow, and a large downward arrow.

To Change the Time:

1. Touch the **Time** button. The button will turn white.
2. Use the large arrows to adjust the hour and the small arrows to adjust the minutes.
3. Touch the button again to store the new value.

To Change the Date:

1. Touch the **Month** button. The button will turn white.
2. Use the arrows to adjust the value. The large arrows adjust the value by 3 and the small arrows adjust the value by 1.
3. Touch the button again to store the new value.
4. Touch the **Day** button. The button will turn white.
5. Use the arrows to adjust the value. The large arrows adjust the value by 5 and the small arrows adjust the value by 1.
6. Touch the button again to store the new value.
7. Touch the **Year** button. The button will turn white.
8. Use the arrows to adjust the value. The large arrows adjust the value by 5 and the small arrows adjust the value by 1.
9. Touch the button again to store the new value.

Central Control Monitor

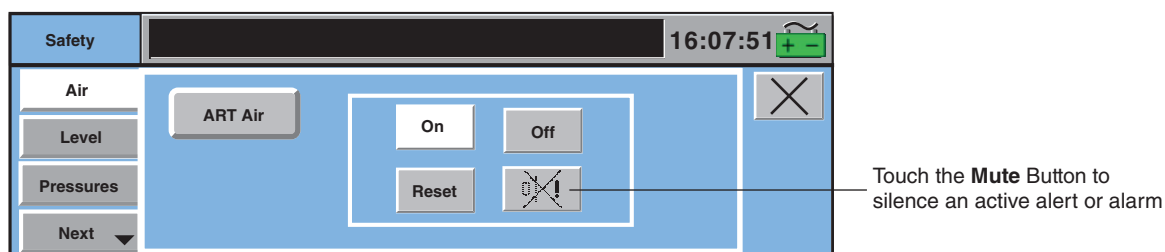
Safety Tab

There are 5 subtabs within the Safety tab: Air, Level, Pressure, Temperature, and Flow. If a device type was not configured for the Perfusion Screen, the name on the subtab for that type of module cannot be selected. Use the **Previous** or **Next** buttons to scroll through the subtabs.

Access an area by touching the subtab or by touching the device icon on the Perfusion Screen.

If more than one sensor for a device type is assigned to a Perfusion Screen, toggle through the sensor names by touching the button.

A Mute button appears in all the Safety subtabs. The Mute button becomes available when the selected safety device has an active alarm or alert and will silence the audible tone when pressed. If there is no active alarm or alert, the Mute button is unavailable.



For detailed information about operating safety systems from the CCM, see the module chapters:

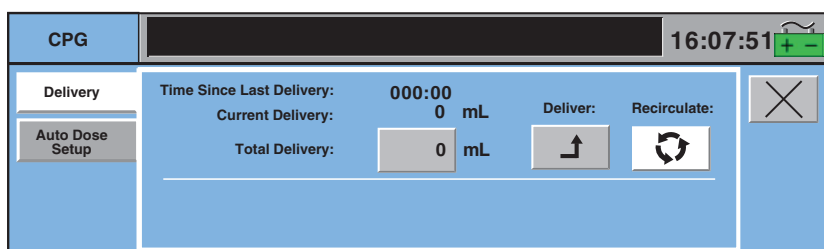
- **Air Bubble Detection**
- **Level Monitoring**
- **Pressure Monitoring**
- **Temperature Monitoring**
- **Flow Monitoring**

CPG Tab

If a pump was identified as the cardioplegia pump during perfusion screen configuration, this tab can be used to track cardioplegia volume delivery and can be set up to deliver up to three separate cardioplegia doses based on delivery volume or delivery time.

Delivery Subtab

The Delivery subtab calculates the current and total accumulated volume delivered by the cardioplegia pump, based on the pump speed and tube size. A timer displays the time since last delivery between cardioplegia doses. The Deliver and Recirculate mode buttons enable and disable the cardioplegia volume tracking.

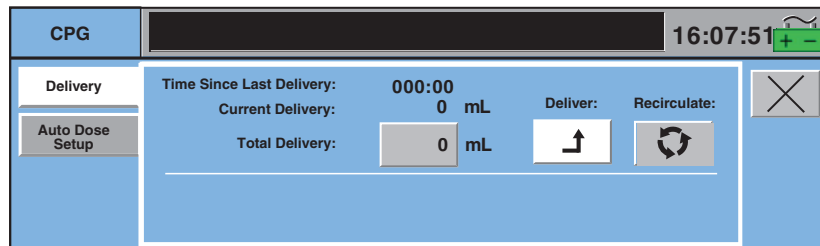


Central Control Monitor

Deliver Mode

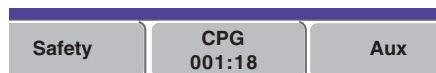
To start tracking cardioplegia delivery:

1. Select Deliver mode by pressing the **Deliver** button.
 2. Start the cardioplegia pump. The cardioplegia pump must be in L/min mode for total flow rate to be displayed on the CCM and pump local display.
- The system tracks and displays the volume for Current Delivery and Total Delivery.
 - The Total Delivery value is grayed out indicating that it cannot be modified.

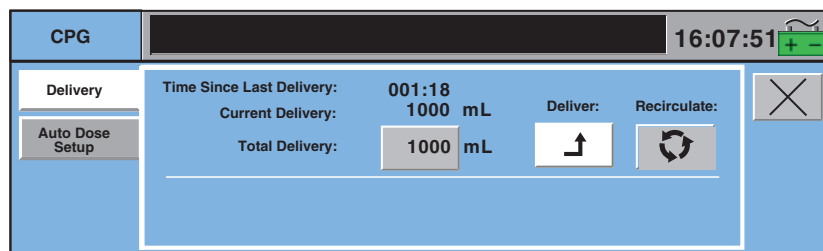


To stop cardioplegia delivery:

1. Touch the cardioplegia pump **Stop** button.
- Volume tracking stops.
 - Time Since Last Delivery is set to 0 and the timer starts counting the time since last delivery.
 - If the subtab is closed while the timer is active, the time since last delivery is displayed on the CPG tab on the CCM.

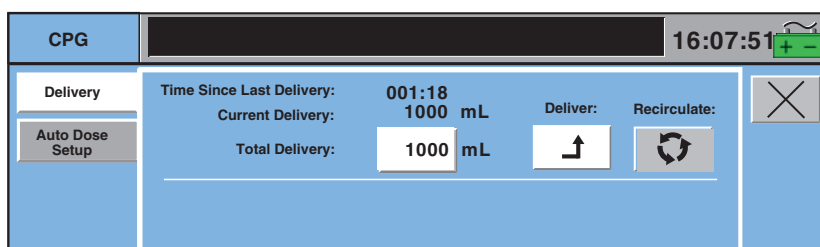


- The Total Delivery value is displayed in black indicating that it can be modified.



To modify the Total Delivery volume:

1. Touch the **Total Delivery** button. The button background turns white.
 2. Use the arrows to adjust the total volume. The small arrows change the volume by 10 mL, the large arrows change the volume by 100 mL.
 3. Touch the **Total Delivery** button again to store the new Total Delivery value.
- The adjustment arrows disappear and the Total Delivery button background turns gray.



Central Control Monitor

Resume cardioplegia delivery:

1. Restart the cardioplegia pump.
 - The Time Since Last Delivery timer stops.
 - The Current Delivery value is set to 0 and the system tracks the volume for Current Delivery and the accumulated volume for Total Delivery.
 - The Total Delivery value is grayed out indicating that it cannot be modified.

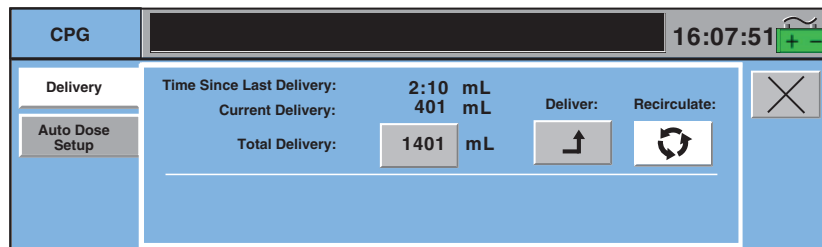
Recirculate Mode



In Recirculate mode, cardioplegia volume tracking is disabled to allow the cardioplegia pump to run without tracking the volume. This may occur when the volume is being recirculated, but not delivered to the patient.

To use Recirculate Mode:

1. Select Recirculate mode by pressing the **Recirculate** button.
2. Start the cardioplegia pump.
 - Volume is not tracked.
 - Time Since Last Delivery timer continues counting.
 - Total Delivery value is displayed in black indicating that it can be modified.



To Switch from Recirculate to Deliver Mode:

1. Select the Deliver mode by pressing the **Deliver** button.
 - If the cardioplegia pump is running:
 - Time Since Last Delivery timer stops.
 - The Current Delivery value is set to 0 and the system tracks the volume for Current Delivery and the accumulated volume for Total Delivery.
 - The Total Delivery value is grayed out indicating that it cannot be modified.
 - If the cardioplegia pump is in Stop mode:
 - The Current Delivery value is set to 0.

To Switch from Deliver to Recirculate Mode:

1. Select Recirculate mode by pressing the **Recirculate** button.
 - If the cardioplegia pump is running:
 - Volume tracking stops.
 - Time Since Last Delivery is set to 0 and the timer starts counting the time since last delivery.
 - If the subtab is closed while the timer is active, the time since last delivery is displayed on the CPG tab button on the CCM.
 - The Total Delivery value is displayed in black indicating that it can be modified.
 - If the cardioplegia pump is in Stop mode:
 - No changes occur.

Central Control Monitor

Automatic Dose Delivery

The Automatic Dose Delivery feature is used to select one of three cardioplegia doses that automatically stop the pump once the dose has been delivered. This feature is set up and enabled using the Auto Dose Setup subtab.

Refer to the **Roller Pumps** chapter, **Roller Pump Messages** section for details on messages which will display in the display area on the front panel of the cardioplegia pump.

Auto Dose Setup Subtab

View and Hide Buttons

Enable the Auto Dose Delivery feature:

1. Touch the **View** button (default is Hide).
- View button background turns white. The Hide button background turns gray.
- Auto Dose Screen appears on the lower half of the Delivery subtab.

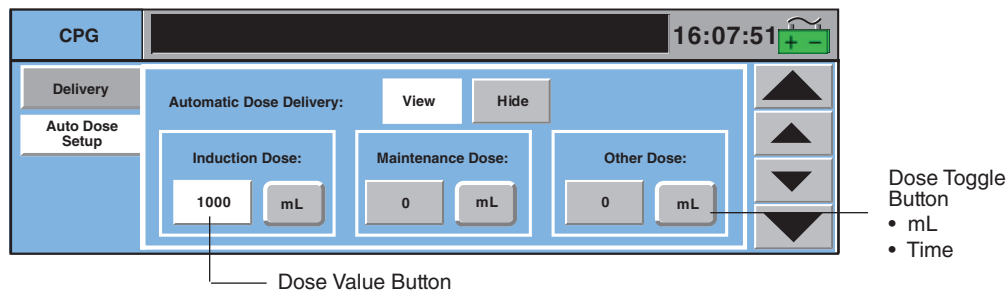
Disable the Auto Dose delivery feature:

1. Touch the **Hide** button (default is Hide).
- Hide button background turns white. The View button background turns gray.
- Lower half of the Delivery subtab is blank.

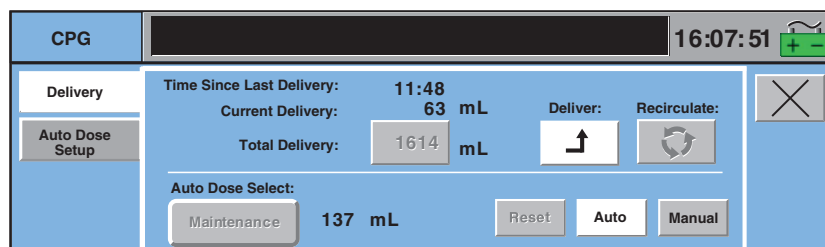
Dose Setup

For each selection, Induction Dose, Maintenance Dose, and Other Dose:

1. Touch the **Dose** toggle button to display the desired units – mL or time (minutes and seconds).
2. Touch the **Dose Value** button.
- The Dose Value button turns white. Adjustment arrows appear.
3. Use the arrows to modify the Dose Value. For mL, the small arrows change the volume by 10 mL and the large arrows by 100 mL. For time, the small arrows change the time by 1 sec and the large arrows change the value by 1 min.
4. Touch the **Dose Value** button again to confirm the value.
- The adjustment arrows disappear. The Dose Value button background turns gray.
- If the View button has been pressed, the value corresponding to the Auto Dose selection appears on the Delivery subtab.



When Automatic Dose Delivery is enabled, the lower half of the Delivery subtab displays a toggle button for selecting the auto dose, a Reset button to reset the dose value after the automatic dose has been delivered, and two mode buttons - Auto and Manual - used to initiate and stop auto dose delivery. The dose value cannot be changed while the dose is being delivered.



Central Control Monitor

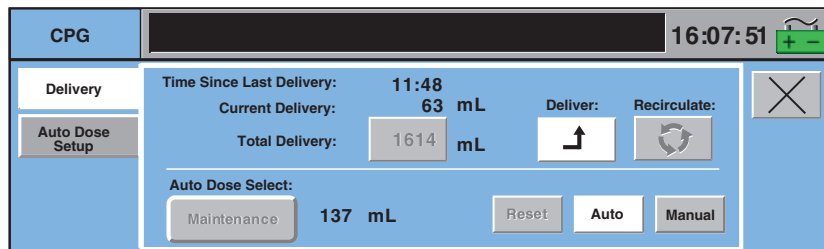
To select Auto Dose:

Make sure the cardioplegia pump is stopped or that the Manual button is selected. Otherwise, the **Auto Dose Select** button text will be gray indicating that the Auto Dose selection cannot be changed.

1. Touch the **Auto Dose Select** button to display the desired Auto Dose. Options are Induction Dose, Maintenance Dose, and Other Dose.
- The value displayed to the right of the Auto Dose Select button is its current value set up in the Auto Dose Setup subtab.

To initiate Auto Dose delivery:

1. Make sure the delivery mode is Deliver.
2. Touch **Auto** button (default is Manual). Start the cardioplegia pump.
- The auto dose value starts counting down.
- The Auto Dose Select and Reset button text turn gray indicating that the auto dose type cannot be changed and the auto dose value cannot be reset.
- Volume tracking operates as described in the **Deliver mode** and **Recirculate mode** sections.
- The volume delivered or time remaining is displayed on the cardioplegia pump control panel display.



To Interrupt Auto Dose Delivery:

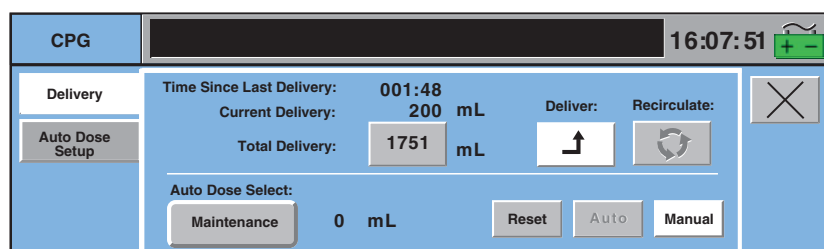
- Stop the cardioplegia pump or change delivery mode from Auto to Manual.
- Auto Dose value stops decreasing and the current value is displayed.
- If the cardioplegia pump is running and Manual mode was selected, Current and Total Delivery continue to increase.

To Resume Auto Dose Delivery:

- Restart the cardioplegia pump or change delivery mode from Manual to Auto.
- Auto Dose continues to decrease.
- The Current Delivery resets to zero and counts up. Total Delivery continues to increase.

Auto Dose Delivery Completion:

- Auto Dose decreases to zero.
- Pump stops automatically when the auto dose delivery is finished.
- The Auto button turns gray and the Manual button background turns white indicating that the auto dose delivery is no longer active.
- A message indicating that the dose is finished is displayed on the cardioplegia pump control panel display.



Central Control Monitor

To Reset Auto Dose Selection:

Make sure the cardioplegia pump is stopped or that the Manual button is selected. Otherwise, the button text will be gray indicating that the Auto Dose value cannot be reset.

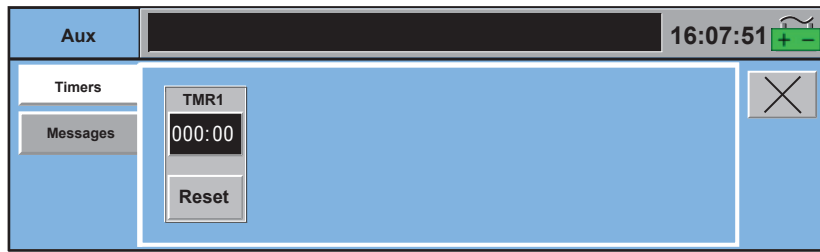
1. Touch the **Reset** button.
 - The value set in the Auto Dose Setup subtab for the selected Auto Dose appears to the left of the Reset button.
 - An additional dose can now be delivered and automatically stop the pump.

Aux Tab

The Aux tab has two subtabs: Timers and Messages.

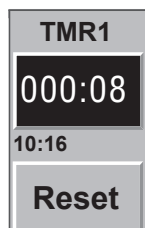
Timers Subtab

Timers, other than Pump and Clamp, are controlled through the Timers subtab. To change the start value of a count down timer, use the Timers subtab within the Setup tab.



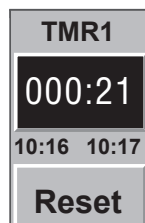
To start the timer:

1. Touch the black box.
 - The start time appears on the left side of the button.



To stop the timer:

1. Touch the black box again.
 - The stop time appears on the right side of the timer display.



To resume the timer:

1. Touch the black box again.
 - The timer continues counting.
 - The resume time appears on the left side of the button.

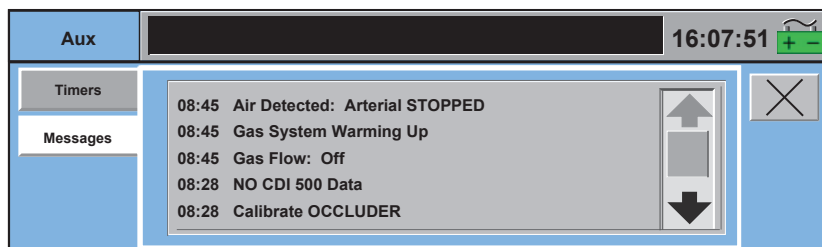
Central Control Monitor

To reset the timer:

1. Stop the Timer.
2. Touch the **Reset** button.
 - The timer resets to 0.

Messages Subtab

The Messages subtab allows the user to access a list of the system messages that have occurred during a case, along with the time that they occurred. The messages are sorted by order of occurrence, with the most recent messages listed first. All system messages including alarm, alert, error, and status messages appear in this list. The list is accessible for the duration of the case and is capable of logging up to 3000 messages. Once the 3000 message limit in the log has been exceeded, the oldest messages in the log will be replaced by the newest messages. Once a Perfusion Screen is exited, this list will be cleared.



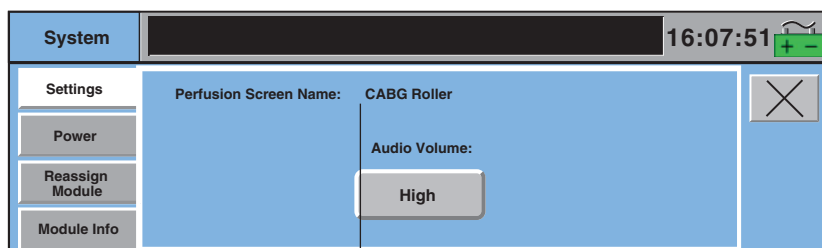
Use the scroll bar to view messages that are beyond the viewing area.

System Tab

The System tab has four subtabs: Settings, Power, Reassign Module, and Module Info.

Settings Subtab

This subtab allows the user to view the current Perfusion Screen name and adjust the volume of the audio tone.



Perfusion Screen Name

To Adjust Volume:

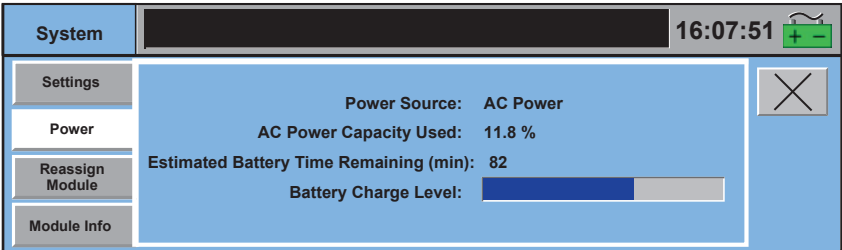
Touch the **Audio Volume** button to toggle through the choices: High, Medium, Low. Default is High and is reset to High when a Perfusion Screen is opened. The alarm volume level is between 80 dB (High) and 69 dB (Low).

WARNING: Alarm and Alert volume levels that are set less than ambient levels can impede the recognition of alarm and alert conditions.

Central Control Monitor

Power Subtab

This subtab indicates the power sources currently in use, the % of AC power in use, an estimate of remaining battery time, and a graphical display of battery charge level.



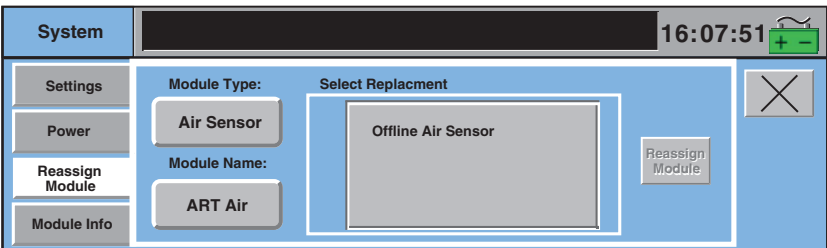
The Power Source is displayed as AC Power¹, Battery, or SYSTEM POWER SHUTDOWN if the batteries are depleted and the system is about to shutdown completely. The AC Power Capacity Used is displayed in % if on AC and dashed out if on battery. This is an indicator of the power consumption. If the system power need approaches the limit of available power, the message, “Power System at 80% Capacity” is displayed on the CCM to alert the user.

The Battery Charge Level is displayed as a bar graph to indicate charge status of the battery.

Reassign Module Subtab

If a pump or module is broken, missing, or not communicating, use the Reassign Module function to replace the device. A reassigned device takes on the role of the broken device including icon control from the Perfusion Screen, all alert and alarm limits, and all safety connections.

Note: When a module/pump has been reassigned, it replaces the original module only for the duration of the case. If this reassigned module is a permanent replacement for the original module, it should be assigned to the system from the Configuration area. If it is not assigned to the screen through the Configuration area, the device icon will display a “?” each time the Perfusion Screen is opened and the module will need to be reassigned before it can be used.

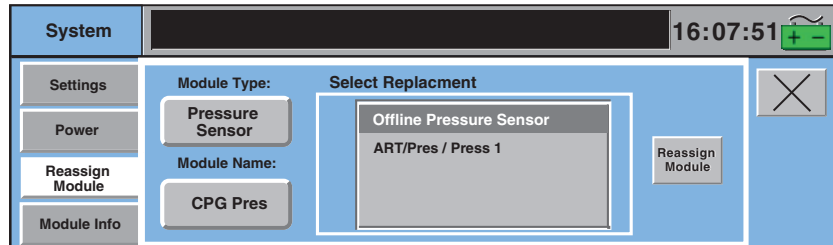


¹ AC power refers to AC (Mains) power.

Central Control Monitor

To Reassign a Module:

1. Select the module type by touching the **Module Type** button to toggle through the choices until the appropriate device is displayed.
2. Select the module name by touching the **Module Name** button to toggle through the choices.

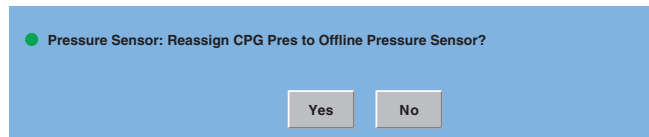


3. Select the replacement module from the list of devices. Offline devices are on the top of the list followed by online devices which are identified by device name.
 - When reassigning temperature and pressure modules, both channels will be assigned to the replacement module.
 - When reassigning the primary pump, if a backup pump was designated during configuration, it will automatically be highlighted.
 - The primary pump appears on the bottom of the list when reassigning pumps of that same type.

Note: If an online device is selected as the replacement, confirm that it is appropriate for reassignment.

- If a primary centrifugal pump is reassigned to a backup roller pump and if flow has been placed on the centrifugal pump, flow module data will no longer be displayed, and the backflow alarm and minimum flow alarm are no longer available. In addition, the centrifugal Coast response becomes a roller pump Stop response for alarm events and a roller pump Message Only response for alert events.
4. Verify that the correct module LED, pump module Identification (ID), or pump name is flashing. When the correct module is flashing, touch the **Reassign Module** button. This button is enabled when a selection has been made from the list.

The system prompts the user to confirm the reassign process. Pump default direction will change to match the system direction except when the pump is running. If the pump is running during the reassign process, the pump direction will only change to match the system direction upon entering a Perfusion Screen or when the system is restarted.



5. Select **Yes** to complete the reassignment.
 - Do not use the local control panel during reassignment.
 - After reassigning modules, ensure that the LED on the reassigned module is constant green or that the reassigned pump displays the new name.
 - If reassigning a Master or Follower pump, re-establish the communications link between the pumps. Use the Master or Follower Status subtab within the Pump tab to reconnect the pumps. See **Central Control Monitor** chapter, **Pump tab, Master and Follower Status subtab** section.

Central Control Monitor

Note: When reassigning pumps, verify all operating parameters after reassignment, including tube size or flow constant, direction, and display units.

Select **No** to return to the previous screen.

Module Info Subtab

Information about each module that is online can be displayed using the Module Info subtab. This information can assist in determining whether operating parameters for the module or pump are within operating range.

For each online module the following information will be displayed:

Module ID:

Software Revision:

Self Test Result: Pass/Fail

Operation Status: Pass/Fail

V5 Voltage (mV): and Pass/Fail Status

V5 Current (mA): and Pass/Fail Status

Vmot Voltage (mV): if applicable and Pass/Fail Status

Vmot Current (mA): if applicable and Pass/Fail Status

Temperature (degrees C): and Pass/Fail Status

Total Volume (mL): total volume delivered for selected roller pump

System		16:07:51	
Settings	Module Type:	Module ID: 00012	Software Revision: 1.00
Power	Air Sensor	Self Test Result: PASS	Operation Status: PASS
Reassign Module	Module Name:	V5 Voltage (mV): 5084	PASS
Module Info	ART Air	V5 Current (mA): 110	PASS
		Vmot Voltage (mV): 22915	PASS
		Vmot Current (mA): 80	PASS
		Temperature (°C): 37.2	PASS

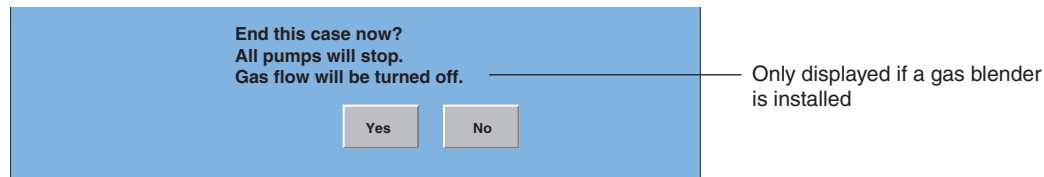
System		16:07:51	
Settings	Module Type:	Module ID: 00019	Software Revision: 1.03
Power	Large Roller Pump	Self Test Result: PASS	Operation Status: PASS
Reassign Module	Module Name:	V5 Voltage (mV): 5020	PASS
Module Info	Arterial	V5 Current (mA): 293	PASS
		Vmot Voltage (mV): 23871	PASS
		Vmot Current (mA): 176	PASS
		Temperature (°C): 30.0	PASS
		Total Volume (mL): 6710	

A failure of the self test or operational status indicates the module or pump is not functioning properly and should be replaced. Values not applicable to a specific device will post an N/A in the Pass/Fail column.

Central Control Monitor

Post Case Tab

This tab allows the user to end the case.



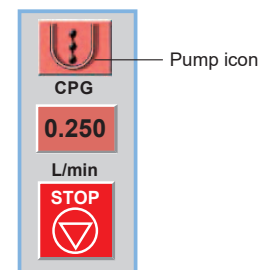
To end the case:

Touch the **Yes** button.

Touch the **No** button to continue the current case.

Pump Tab

The Pump tab is accessed through the pump icon and is used to view a summary of pump parameters or initiate Servo mode and Pulse mode if applicable. For a primary pump, the Pump tab has three subtabs: Summary, Servo, and Pulse. A master or follower pump has three subtabs: Summary, Servo, and Master Status or Follower Status. For all other pumps, the Pump tab has two subtabs: Summary and Servo.

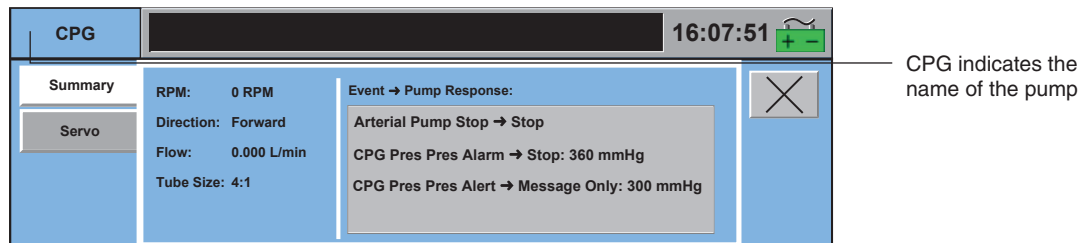


Touch the pump icon to access the Pump tab.

- The pump control box will highlight with a blue perimeter.

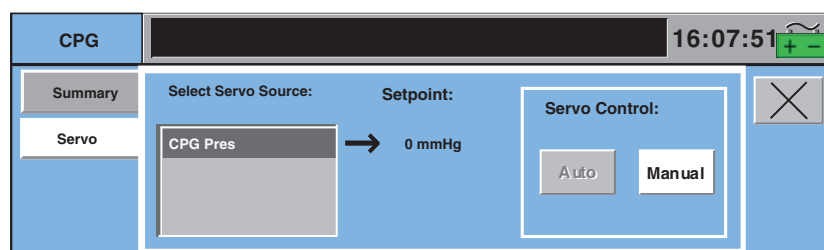
Summary Subtab

The Summary subtab displays the pump name, the current RPM, direction of flow, flow in L/min, and the tube size for roller pumps or the minimum flow alarm value for centrifugal pumps. The configured safety connections are also displayed.



Servo Subtab

In Servo mode, the pump speed is automatically regulated to maintain a specific user selected pressure or flow. During Configuration, a pressure or flow module is designated as a servo data source. If the servo control source designation is not enabled, a pump cannot be placed in Servo mode. See **Edit Safety Connections** section in this chapter for details on setting the servo source.



The Auto button enables Servo mode. The Manual button in the Servo subtab or on the pump local control panel disables Servo mode. See the **Roller Pumps, Sarns Centrifugal Pumps, or Capiox Centrifugal Pumps** chapters for details of servo operation.

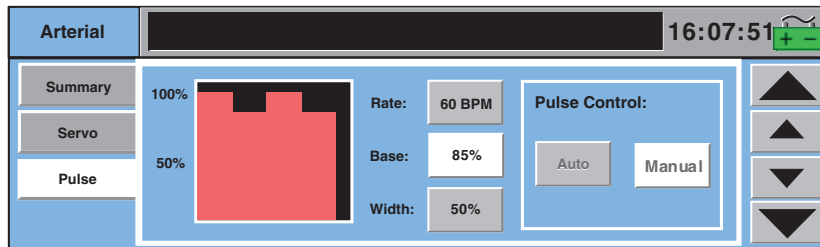
Central Control Monitor

Pulse Subtab

The Pulse subtab can be used to adjust pulse parameters and initiate Pulse mode for a roller pump or centrifugal pump designated as the primary pump.¹

Roller Pump Pulse Parameters

The Rate, Width, and Base are set up using the Pulse subtab.



To Set the Rate:

1. Touch the **Rate** button.
2. Use the large arrows to change the Rate in increments of 10 beats per minute.
3. Use the small arrows to change the Rate in increments of 1 beat per minute.
4. Touch the **Rate** button again to store the new value.

To Set the Base:

1. Touch the **Base** button.
2. Use the large arrows to change the Base in increments of 10%.
3. Use the small arrows to change the Base in increments of 5%.
4. Touch the **Base** button again to store the new value. The recommended minimum Base is 30%.

To Set the Width:

1. Touch the **Width** button.
2. Use the large arrows to change the Width in increments of 10%.
3. Use the small arrows to change the Width in increments of 5%.
4. Touch the **Width** button again to store the new value. The recommended minimum Width is 30%.

See the **Roller Pumps** chapter for details of Pulse mode operation.

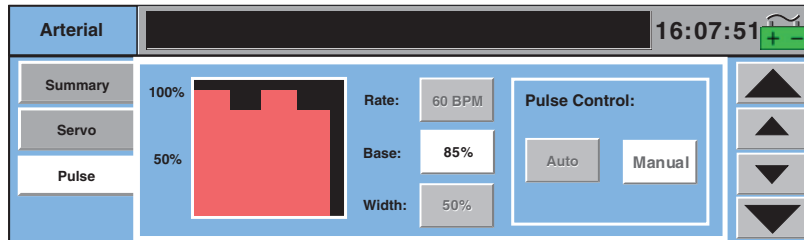
¹ The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

Central Control Monitor

Centrifugal Pulse Parameters

Rate and Width are fixed and only Base must be set up.

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.



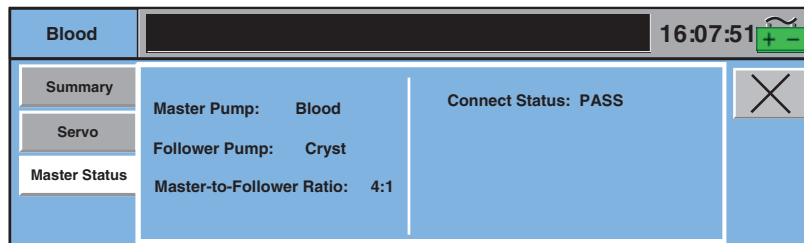
To Set the Base

1. Touch the **Base** button.
2. Use the large arrows to change the Base in increments of 10%.
3. Use the small arrows to change the Base in increments of 5%.
4. Touch the **Base** button again to store the new value. The recommended minimum Base is 50%.

See the **Sarns Centrifugal Pumps or Capiiox Centrifugal Pumps** chapter for details of Pulse mode operation.

Master and Follower Status Subtab

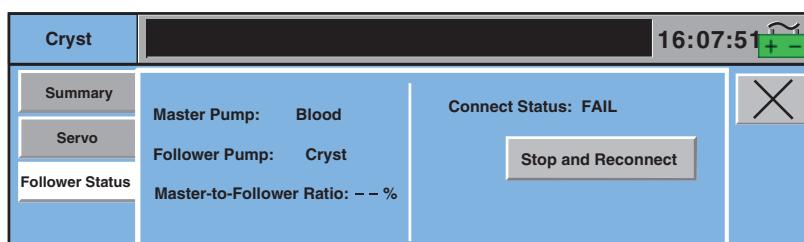
The Master and Follower Status subtab is a summary of the master and follower pump names, the speed or flow ratio setting when the tab was opened, and the connect status of the pumps.



If the master and follower pumps lose their connection to each other, these pumps will stop automatically. The connection between these pumps must be reestablished to continue operation in Master/Follower mode.

To reestablish pump connection:

1. Ensure both pumps are stopped.
2. Touch the **Stop and Reconnect** button.
- If reconnect is successful, the screen will display "Connect Status: PASS". The display on each roller pump will indicate "M" or "F".



Central Control Monitor

Central Control Monitor Messages

The following table includes all the messages that can appear on the CCM display and corresponding operator responses.

Priority	Condition	CCM Display Message	Operator Response
Alarm	Battery is depleted and system is shutting down.	SYSTEM POWER SHUTDOWN	Use manual backup equipment to finish case. Fully recharge battery before using the system again.
	Pump goes to 0 flow as a result of a Reduce Speed response to an alert or alarm.	< Pump Name >: STOPPED	Correct condition. Start pump if stopped.
	Pump goes to 0 flow as a result of receiving a Pause and a Reduce Speed response.	< Pump Name >: STOPPED	Correct the conditions that caused the Reduce Speed/Pause responses. Restart the pump.
	Air detected.	< ABD Name > : AIR DETECTED	Correct air condition, reset air sensor, restart pump if stopped.
	Air detected.	AIR DETECTED: < Pump Name > < Pump Response >	Correct air condition, reset air sensor, restart pump if stopped.
	Air sensor on, and disconnected.	< ABD Name > : AIR DETECTED	Reconnect air sensor, reset air sensor, restart pump if stopped.
	Pressure has risen above alarm limit.	< Pressure Name > : OVER PRESSURE	Correct over pressure condition. Start pump if stopped.
	Pressure has risen above alarm limit.	OVER PRESSURE: < Pump Name > < Pump Response >	Correct over pressure condition. Start pump if stopped.
	Reservoir level below alarm level.	< Level Detector Name > : LOW LEVEL	Fill reservoir to above alarm level. Alarm clears automatically. Restart pump if stopped.
	Reservoir level below alarm level.	LOW LEVEL: < Pump Name > < Pump Response >	Fill reservoir to above alarm level. Alarm clears automatically. Restart pump if stopped.
	Backflow has been detected.	< Flow Sensor Name > : BACKFLOW	Correct backflow condition. Alarm clears automatically. Restart pump if stopped.
	Backflow has been detected.	BACKFLOW: < Pump Name > < Pump Response >	Correct backflow condition. Alarm clears automatically. Restart pump if stopped.
	Flow for flow sensor placed on a centrifugal pump has gone below minimum limit.	< Pump Name > : MINIMUM FLOW	Correct low flow condition. Alarm clears automatically.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Alarm	Flow for flow sensor placed on a centrifugal pump has gone below minimum limit.	MINIMUM FLOW < Pump Name > < Pump Response >	Correct low flow condition. Alarm clears automatically. Restart pump if stopped.
	FiO ₂ has dropped below minimum limit.	LOW FiO ₂	Increase FiO ₂ setting to above minimum limit to clear alarm.
	O ₂ source pressure < 30 psi or more than 18 psi below the air pressure.	LOW OXYGEN SUPPLY PRESSURE	Check O ₂ hose connections. Check O ₂ supply and switch source if necessary.
	O ₂ source pressure > 70 psi.	HIGH OXYGEN SUPPLY PRESSURE	Check O ₂ supply pressure, switch source if necessary.
	Air source pressure < 30 psi or more than 18 psi below the O ₂ pressure.	LOW AIR SUPPLY PRESSURE	Check air hose connections. Check air supply and switch source if necessary.
	Air source pressure > 70 psi.	HIGH AIR SUPPLY PRESSURE	Check air supply pressure and switch source if necessary.
	95/5 source pressure < 30 psi or more than 18 psi below the O ₂ pressure.	LOW 95-5 SUPPLY PRESSURE	Check 95/5 hose connections. Check 95/5 supply and switch source if necessary.
	95/5 source pressure > 70 psi.	HIGH 95-5 SUPPLY PRESSURE	Check 95/5 supply pressure and switch source if necessary.
	Over temperature condition.	< Temperature Name > : OVER TEMPERATURE	Correct over temperature condition. Alarm clears automatically.
	Primary pump internal error detected.	< Primary Pump Name > : SERVICE PUMP	Reassign pump, use standby equipment or use hand crank. Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems.
Alert	Primary pump low level motor faults cause the pump to stop.	< Primary Pump Name > : CHECK MOTOR	Try to restart motor. If message reappears, either reassign pump or use standby equipment. Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems Service.
	Pressure has risen above alert limit, but below alarm limit.	< Pressure Name > : CHECK PRESSURE	Monitor pressure. Check for condition that could lead to pressure alarm.
	Pressure has risen above alert limit, but below alarm limit.	CHECK PRESSURE: < Pump Name > < Pump Response >	Monitor pressure. Check for condition that could lead to pressure alarm.
	Level sensor alert sensor detects low level.	< Level Detector Name > : CHECK LEVEL	Fill reservoir above alert level. Start pump if stopped. Alert clears automatically.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Alert	Level sensor alert sensor detects low level.	CHECK LEVEL: < Pump Name > < Pump Response >	Fill reservoir above alert level. Start pump if stopped. Alert clears automatically.
	Roller/Centrifugal pump loss of servo source.	< Pump Name >: MONITOR FLOW	Check operation and placement of servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Follower pump cannot maintain M/F ratio.	< Follower Pump Name >: CANNOT MEET RATIO < Master Pump Name >: CANNOT MEET RATIO	Check ratio. Adjust speed of master pump. If message appears again, discontinue use of master/follower operation.
	Roller/Centrifugal cannot maintain servo setpoint.	< Pump Name >: MONITOR FLOW	Check the operation and placement of the servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Primary roller/centrifugal pump has detected overcurrent condition.	< Primary Pump Name >: OVERCURRENT	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment or use hand crank.
	Primary roller pump has detected pump jam condition.	< Primary Pump Name >: PUMP JAM	Clear the pump raceway or back off the occlusion and try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump or use standby equipment.
	Primary roller pump has detected overspeed condition.	< Primary Pump Name >: OVERSPEED	Try to restart pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment or use hand crank.
	Roller pump has detected underspeed condition.	< Primary Pump Name > : UNDERSPEED	Stop and start the pump. If the message reappears, discontinue use of the pump and contact Terumo Customer Service. Reassign pump, use standby equipment or use hand crank.
	Roller pump has detected belt slip condition.	< Primary Pump Name > : BELT SLIP	Stop and start the pump. If the message reappears, discontinue use of the pump and contact Terumo Customer Service. Reassign pump, use standby equipment or use hand crank.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Alert	No data from Follower pump.	< Follower Pump Name > : NO RESPONSE	Check the follower pump cable connections. Stop the master pump, open the Master Status subtab within the master pump tab, and touch Reconnect button. Start the Master pump. If Follower pump cannot be reconnected, do not use the Follower pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump or use standby equipment.
	No data from Master pump.	< Master Pump Name > : NO RESPONSE	Check the Master Pump cable connections. Stop the follower pump, open the Master Status subtab within the master pump tab, and touch the Reconnect button. Start the Master pump. If Master pump cannot be reconnected, do not use the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump or use standby equipment.
	Centrifugal pump has detected underspeed condition.	<Centrifugal Pump Name>: UNDERSPEED	Clamp the lines. Stop and start the pump. If the message reappears, discontinue use of the pump and contact Terumo Customer Service. Reassign pump, use standby equipment, or manual drive unit.
	Pump speed is out of servo range limit.	< Pump Name > : MONITOR FLOW	Check the operation and placement of the servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Pump servo range has exceeded maximum limit.	< Roller Pump Name > : MAXIMUM LIMIT	Check the operation and placement of the servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Centrifugal pump servo range has exceeded maximum servo limit.	<Centrifugal Pump Name>: SERVO LIMIT	Check the operation and placement of the servo source. Alert will clear when speed slows to within operating range.
	Centrifugal pump servo range has gone below minimum servo limit.	<Centrifugal Pump Name>: SERVO LIMIT	Check operation and placement of the servo source. Alert will clear when speed increases to within operating range.
	Air sensor malfunction.	< ABD Name > : CHECK SENSOR	Check connection to air sensor, reset air sensor, replace if necessary.
	Calibrated pressure probe disconnected	< Pressure Name > : CONNECT PROBE	Reconnect and recalibrate pressure probe.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Alert	Calibrated pressure probe malfunction detected	< Pressure Name > : CHECK PROBE	Reconnect and recalibrate pressure probe. If message does not clear, replace and recalibrate probe.
	Loss of data for calibrated pressure probe.	< Pressure Name > : NO PRESSURE DATA	Check probe connections. Disconnect then reconnect and recalibrate probe. If message does not clear, replace and recalibrate probe.
	Level system is on, alarm level sensor or alert level sensor not mounted to venous reservoir.	< Level Detector Name > : NOT ATTACHED	Mount the alarm or alert level sensor to venous reservoir. Alert message clears automatically.
	Level system is on, alarm level sensor cable or alert level sensor cable has become disconnected from module.	< Level Detector Name > : DISCONNECTED	Check the alarm or alert level sensor cable connections. If message does not clear, replace and reassign module.
	Level system is on, module hardware malfunction.	< Level Detector Name > : CHECK MODULE	Disconnect and reconnect module to system base. If message does not clear, replace and reassign module.
	Alarm level sensor or alert level sensor self test failure.	< Level Detector Name > : CHECK PROBE	Check alert alarm or level sensor connections. If message does not clear, replace alarm or alert level sensor.
	Occluder head not moving or not responding	< Occluder Name > : NOT RESPONDING	Try disconnecting/reconnecting occluder head. If message does not clear, replace occluder head.
	Internal malfunction detected.	< Module Name > : SERVICE MODULE	Try disconnecting/reconnecting module. If message does not clear reassign module.
	Internal malfunction	SERVICE GAS SYSTEM	If not on bypass, calibrate O ₂ analyzer. If message does not clear, or if on bypass, adjust the FiO ₂ and gas flow using the knobs on the front of the system. If the knobs cannot be turned, use standby gas blender. Do not use gas system until it has been serviced by Terumo Cardiovascular Systems Service. See the Messages subtab within the Aux tab for any additional error or status messages. May be accompanied by additional faults if error is due to gas mixer not meeting demand.
	Oxygen Analyzer Expired.	SERVICE GAS SYSTEM	The Oxygen Analyzer has expired and needs to be replaced. "Service O ₂ Sensor" will appear in the Messages subtab within the Aux tab. Do not use gas system until it has been serviced by Terumo Cardiovascular Systems.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Error	Roller pump has detected overspeed condition.	< Pump Name > : Overspeed	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment or use hand crank.
	Roller pump has detected overcurrent condition.	< Pump Name > : Overcurrent	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Roller pump has detected pump jam condition.	< Pump Name > : Pump Jam	Clear the pump raceway or back off the occlusion and try to restart the pump. If the message reappears, discontinue use of the pump until it can be serviced by Terumo Cardiovascular Systems. Reassign pump or use standby equipment.
	Roller pump power-on Self Test fails or other internal malfunction.	< Pump Name > : Service Pump	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Centrifugal pump Power-On Self Test fails or other internal malfunction.	< Pump Name > : Service Pump	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use manual drive unit.
	Centrifugal pump has detected overspeed condition.	<Centrifugal Pump Name>: Overspeed	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use manual drive unit.
	Centrifugal pump has detected overcurrent condition.	<Centrifugal Pump Name>: Overcurrent	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use manual drive unit.
	Centrifugal pump low level motor faults cause the pump to stop.	<Centrifugal Pump Name>: Check Motor	Try to restart motor. If message reappears, either reassign pump, use standby equipment or manual drive unit. Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems Service.
	Centrifugal motor has become disconnected	<Centrifugal Pump Name>: Connect Motor	Message should clear when the motor is reconnected.
	Pressure probe calibration failed.	< Pressure Name > : Calibrate Failed	Try to recalibrate probe. If message does not clear, replace probe.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Error	Level system is off, module hardware malfunction.	<Level Detector Name > : Check Module	Disconnect and reconnect module to base. If message does not clear, replace and reassign module.
	Occluder has become disconnected after calibration.	<Occluder Name > : Connect Occluder	Reconnect and recalibrate occluder head.
	Calibrated occluder loses calibration.	Calibrate <Occluder Name>	Recalibrate occluder.
	Gas mixer is not meeting demand and has disabled automatic control from the CCM.	Gas System : Knob Adjust Only	If not on bypass, calibrate O ₂ analyzer. If message does not clear or if on bypass, adjust the FiO ₂ and gas flow using the knobs located on the front of the system. If the knobs cannot be turned, use standby gas blender. Do not use gas system until it has been serviced by Terumo Cardiovascular Systems. See the Messages subtab within the Aux tab for any additional error or status messages. May be accompanied by additional faults if error is due to an internal malfunction.
	Flow sensor malfunction detected.	<Flow Sensor Name > : Check Sensor	Disconnect and reconnect flow sensor. If message does not clear, replace flow sensor.
	Flow sensor disconnected from tubing.	<Flow Sensor Name > : Check Sensor	Reconnect flow sensor. If message does not clear, replace flow sensor.
	Temperature probe has become disconnected.	<Temp Channel Name > : Check Probe	Reconnect temperature probe. Error message clears automatically.
Status	Temperature out of range.	<Temp Channel Name > : Check Probe	Correct out of range condition. Message clears automatically.
	AC (Mains) power to system is lost - switch to battery power.	On Battery - Monitor Time	Monitor remaining battery charge level by observing the power status indicator LED and the charge level bar graph in the Power subtab. Prepare to use manual backup equipment if AC (Mains) power is not restored within 60 minutes.
	Battery is not being recharged, or switch to battery not detected at start-up. Battery time available may be less than 60 minutes.	Battery Cannot Be Fully Charged, Full Backup May Not Be Available.	If case has not started, do not start case. If case has started, finish the case. Contact Terumo Customer Service.
	Battery cannot hold maximum charge level. Battery time available may be less than 60 minutes	Battery Needs Service, Full Back Up May Not Be Available.	Finish the case, then contact Terumo Customer Service.
	Cover is open.	<Pump Name > : Cover Open	Message should clear when cover is closed.
	Pump has been set to run in reverse direction.	<Pump Name > : Pumping in Reverse	Message should clear when default direction is resumed. Default direction is resumed when the pump stops.

Central Control Monitor

Priority	Condition	CCM Display Message	Operator Response
Status	Centrifugal pump speed reduced to 1550 RPM	<Centrifugal Pump Name>: Coasting	Verify forward flow. Check connected devices. Increase pump speed when appropriate.
	Reconnecting Master and Follower	Reconnecting <Master Pump Name> to <Follower Pump Name>	Message will clear when connection is completed.
	Enabling Pulse mode	<Pump Name > : Pump Baseline xx%	Pump enters Pulse mode.
	Pump is ramping to baseline setting	<Pump Name > : Ramp Baseline xx%	Ensure pump reaches desired baseline setting.
	Exiting Pulse mode	<Pump Name > : Leaving Pulse	Message clears after approximately 3 seconds.
	Power system detects power usage at 80%.	Power System at 80% Capacity	If possible, reduce power consumption by turning off lamp/s, and slowing or stopping pumps.
	Level system is off, level sensor not mounted to the venous reservoir.	<Level Detector Name > : Not Attached	Mount the level sensor to reservoir. Message clears automatically.
	Level system is off, level sensor becomes disconnected from module.	<Level Detector Name > : Disconnected	Reconnect level sensor. Message clears automatically.
	Level selection is changed from Alert to Alert/Alarm in a Perfusion Screen	<Level Detector Name > : Initializing alarm probe	Allow approximately 10 seconds for probe to initialize.
	Level detection is turned OFF during perfusion	<Level Detector Name > : Off	Message will clear after approximately 3 seconds.
	Pressure alarm set out of range	<Pressure Sensor Name > : Alarm Disabled	Message will clear when pressure alarm is set within range or message is replaced by a higher priority message.
	Occluder responds to an event.	<Occluder Name > : is <open, closed, or % flow>	Note occluder value, change if desired.
	Uncalibrated occluder detected.	Calibrate <Occluder Name>	Calibrate occluder.
	Occluder is disconnected.	<Occluder Name > : Connect Occluder	Reconnect and calibrate occluder.
	Gas system flow is < 0.2 L/min.	Gas Flow : Off	Turn gas flow to ≥ 0.2 L/min to clear message.
	O ₂ calibration in process.	Calibrating O ₂ Analyzer	Message clears when calibration is complete.

Central Control Monitor

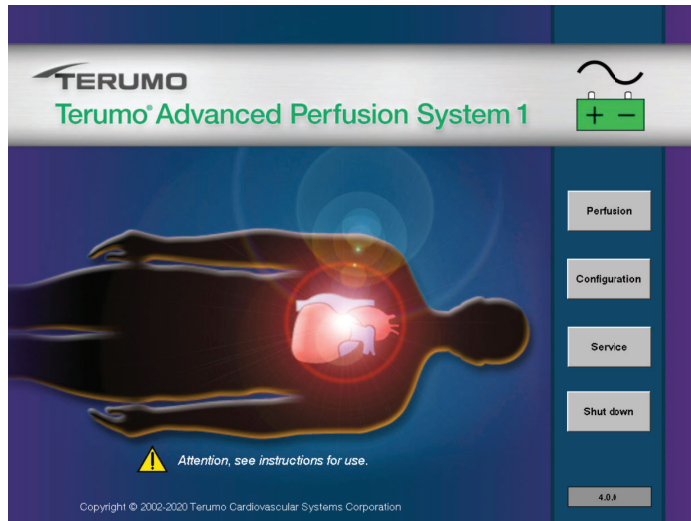
Priority	Condition	CCM Display Message	Operator Response
Status	O ₂ calibration finished.	O ₂ Analyzer Calibration Complete	Message displays for 10 seconds.
	Warm up in progress.	Gas System Warming Up	Message clears when warm up is complete.
	O ₂ sensor exposure limit reached.	Service O ₂ Sensor	Backup analyzer should be used until O ₂ sensor is replaced by Terumo Cardiovascular Systems Service.
	System just powered up and is expecting a calibration.	Calibrate O ₂ Analyzer	Perform O ₂ Analyzer calibration.
	The %O ₂ and the FiO ₂ readings do not agree.	Calibrate O ₂ Analyzer	Inspect gas circuit for kinks, blockages, or leaks. If necessary, use a backup O ₂ analyzer.
	O ₂ Analyzer calibration failed.	Cannot Calibrate O ₂ Analyzer XX (may only appear in Aux tab) 12 User pressed cancel button. 13 Flow or FiO ₂ knob turned during calibration 16 O ₂ Sensor is expired 17, 19 Blender mechanical problem 18 Flow mechanical problem 20, 21, 22 Flow meter fault 23 O ₂ sensor fault	Check status code. Retry calibration. If calibration does not pass, use backup until unit can be serviced.
	Flow sensor has become disconnected from the module.	<Flow Sensor Name > : Check Sensor	Reconnect flow sensor. Message clears automatically.
	CDI 100/101 disconnected or not all data being detected.	No CDI 100 Data	Check CDI 100/101 settings and cable connections. If message still appears, contact Terumo Customer Service.
	CDI 500/550 disconnected or not all data being detected.	No CDI 500 Data	Check CDI 500/550 settings and cable connections. If message still appears, contact Terumo Customer Service.

This page intentionally left blank.

Central Control Monitor

Configuration

The Configuration functional area is used to design, configure, and edit a graphical representation of the devices and pumps used in a perfusion case. Up to 12 Perfusion Screens may be stored in the Central Control Monitor. Options, including language, date format, default roller pump direction, and security passwords, are set through Configuration. Configured Perfusion Screens can be copied to and from the Central Control Monitor by using the system PC card/USB drive.

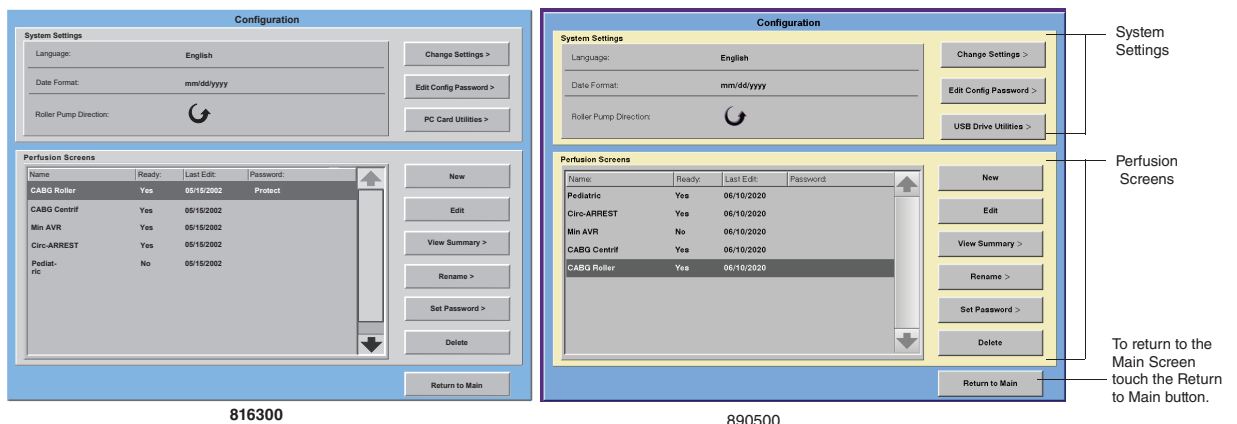


Touch the **Configuration** button on the main screen to access the Configuration functional area.

Use the keyboard to enter password, if necessary.

Configuration

The Configuration area has two sections: System Settings and Perfusion Screens.



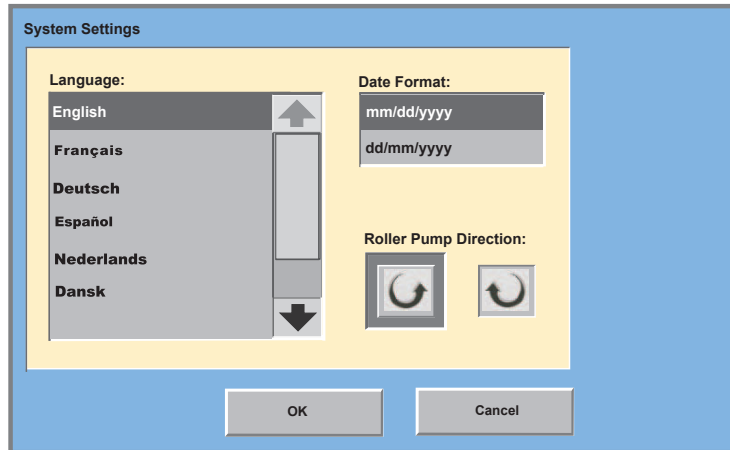
Central Control Monitor

System Settings

System settings are language, date format, and roller pump direction. The user can change the settings, edit configuration passwords, or copy and back up Perfusion Screens using PC cards/USB drives.

To Change Settings:

1. Touch the **Change Settings** button to choose or change language, date format, or default roller pump direction.

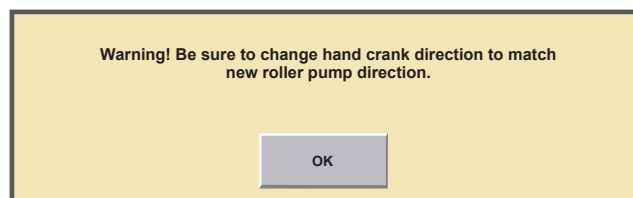


2. Touch the selection on the screen, and verify that the new selection is highlighted.
3. Touch the **OK** button to exit the screen and save the changes.
4. Touch **Cancel** to exit and keep the previous settings.

Note: Pumps connected to the base will have their direction changed to match the new system direction just selected, unless the pump is activated. If the pump is activated when the new system direction is selected, the pump will continue running in its original direction until the system is restarted or the pump is turned off and a Perfusion Screen is opened.

CAUTION: Pumps will be activated at 0 RPM. Check the pump display or CCM to ensure the pumps are stopped before changing the system direction.

When the roller pump direction is changed, a warning appears on the screen prompting the user to change the direction on the hand cranks to match the changed roller pump direction. Refer to the **System Base** chapter for instructions on changing the hand crank direction.



WARNING: Hand cranks must be properly setup to allow hand cranking in same direction as that selected for forward flow for the roller pump.

WARNING: All roller pumps used in a hospital must be set to run in the same default direction for forward flow to prevent unintended retrograde pumping.
RETROGRADE PUMPING MAY CAUSE SEVERE PATIENT INJURY OR DEATH.

Central Control Monitor

Configuration Password

Assigning a configuration password restricts user access to the Configuration area.

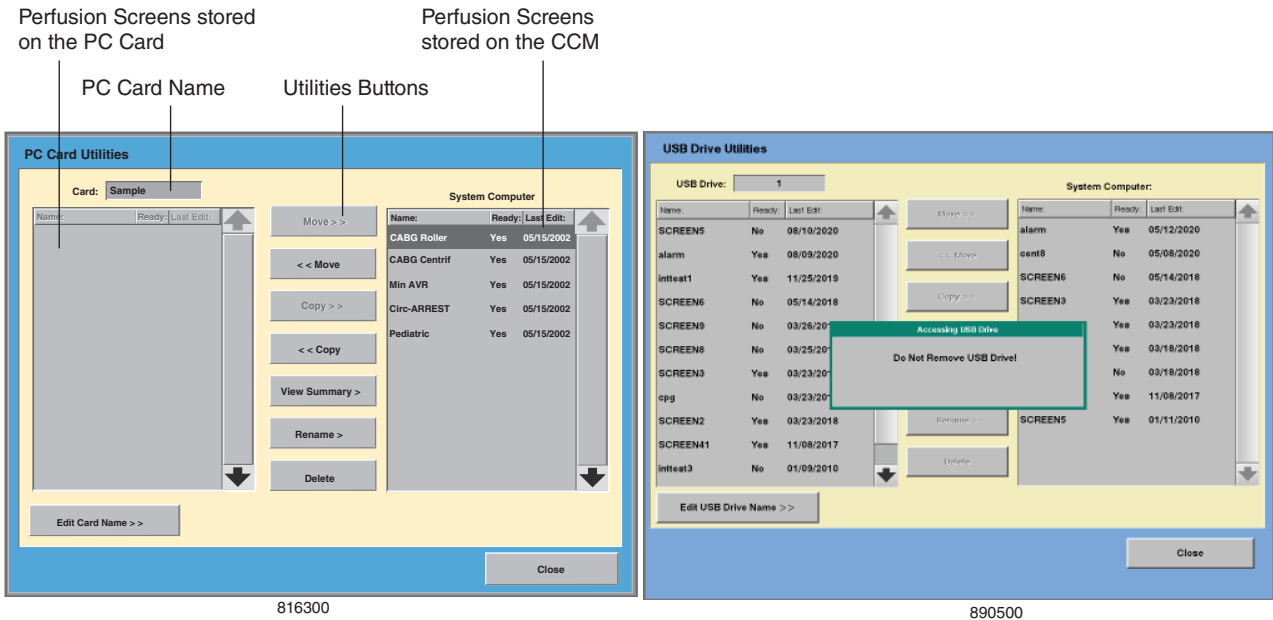
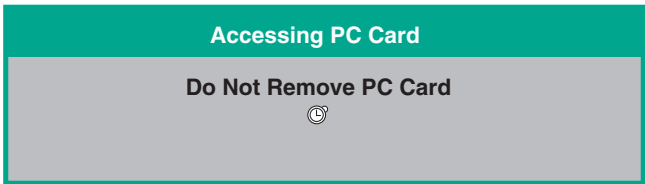
1. Touch the **Edit Config Password** button to set a password.
2. Use the keyboard to enter a password.
3. Touch **OK** or **Enter** to save password.

PC Card/USB Drive Utilities

To save a copy of a Perfusion Screen to a PC card/USB drive, touch the PC Card/USB Drive Utilities button. This enables the user to back up Perfusion Screens and transfer Perfusion Screens from one System 1 to another. It is recommended that Perfusion Screens be backed up when they are first configured, when changes are made, and prior to having the System 1 serviced. The user can also view Perfusion Screen summaries, rename or delete Perfusion Screens, and rename PC cards/USB drives.

To access the PC Card/USB Drive Utilities screen, touch the **PC Card/USB Drive Utilities** button.

- If a PC card/USB drive is installed, the Accessing PC Card/USB Drive and Building PC Card/USB Drive List windows will be displayed. Do not remove card/drive when the Accessing PC Card/USB Drive or Building PC Card/USB Drive List windows are displayed.



The PC Card/USB Drive Utilities Screen will be displayed. The card/drive name is displayed. A list of all Perfusion Screens that are stored on the PC card/USB drive is displayed on the left under Card/USB Drive while all Perfusion Screens that are stored on the CCM is displayed on the right under System Computer. A Yes or No in the Ready column of the list indicates whether that particular Perfusion Screen is ready for use or not. The date in the Last Edit column shows the last time the Perfusion Screen was edited.

Central Control Monitor

In the center are the utilities buttons. These buttons are used to move, copy, view summaries, rename, or delete the Perfusion Screens that appear on either list. The utilities buttons are activated by selecting a Perfusion Screen.

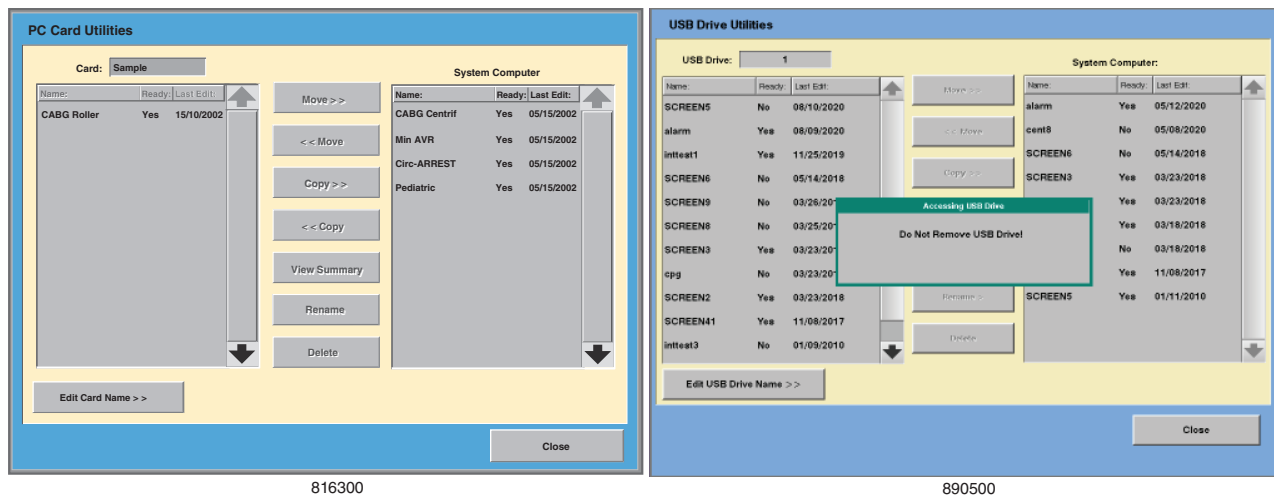
There must be a System PC card/USB drive installed in the Central Control Monitor for the move and copy utilities to activate. Refer to the **Central Control Monitor** chapter **PC Card Compartment/USB Drive Storage Compartment** sections for instructions on inserting a PC card/USB drive.

Move and Copy

Perfusion Screens can be copied and moved between the CCM and PC card/USB drive or vice versa. The Copy function is used to back up Perfusion Screens and for placing the same Perfusion Screen on multiple systems. The Move function removes a Perfusion Screen from its current location, either system computer or PC card/USB drive, and moves it to the other location.

To move a Perfusion Screen

1. Select the Perfusion Screen.
2. Touch the appropriate **Move** button.



- The Accessing PC Card/USB Drive and Building PC Card/USB Drive List windows are displayed in succession.
- The chosen Perfusion Screen no longer appears on the original list and appears on the list on the opposite side.

To copy a Perfusion Screen:

1. Select the Perfusion Screen.
 2. Touch the appropriate **Copy** button.
- The Accessing PC Card/USB Drive List and Building PC Card/USB Drive List windows are temporarily displayed in succession.
 - The Perfusion Screen is copied and the name appears on the appropriate list.

Perfusion Screen names must be unique. If the user tries to move or copy Perfusion Screens to locations where a screen of the same name already exists, the user will be prompted to either overwrite the existing screen or cancel the move or copy action.

Central Control Monitor

Transfer Perfusion Screen

A PC card/USB drive can be used to transfer Perfusion Screens from one System 1 to another. Insert a PC card/USB drive into the System Card slot or USB port of the CCM. Use the Move or Copy function of the PC Card/USB Drive Utilities to copy the desired screen or screens onto the PC card/USB drive. Remove the PC card/USB drive from the CCM and insert into the System Card slot or USB port on the CCM of another System 1. Use the Move or Copy function of the PC Card/USB Drive Utilities to copy the desired screen or screens onto the CCM of the other System 1.

If the pumps and devices in a transferred Perfusion Screen were assigned to the corresponding physical components of the preceding System 1, they must first be unassigned from those devices and then assigned to the corresponding physical components on the System 1 the Perfusion Screen was transferred to.

To unassign pumps and devices, access the Configuration functional area, select the name of the transferred Perfusion Screen, choose “Edit,” choose “Assign Devices to Modules.” The device types appear in the list under Devices - select a device type, choose Assign devices, in the top portion of the Assign Configuration Device to Physical Module window the Assigned Device field will be blank, the device type appears under the Assigned section in the lower right hand portion of the window—select the device type from this window and select Unassign – the device type moves from Assigned to Unassigned. Select OK to return to the Configure Perfusion Screen-Assign Devices window. Choose each device type in the Devices list in turn and unassign the remaining pumps and devices. Once all pumps and devices have been unassigned, follow the instructions in this chapter, **Assign Devices to Modules** section, to assign the pumps and devices to the physical components of the current System 1. Any safety connections set up for the pumps and devices in a configured Perfusion Screen, will transfer with that screen when copied to another System 1. Be sure to check all the safety connections and modify if necessary.

To more easily transfer Perfusion Screens, do not assign the pumps and devices to the physical components of a particular System 1 when creating the Perfusion Screen. Transfer the Perfusion Screen to the desired systems and assign the pumps and devices of each system to the Perfusion Screen.

Central Control Monitor

View Summary

A summary is a text version of a Perfusion Screen. It contains information about the screen name, graphic orientation, reservoir type, assigned devices, assigned pumps, and enabled safety connections.

To view the summary of a Perfusion Screen

1. Touch the Perfusion Screen name.
2. Touch the **View Summary** button.
3. Select the **Close** button to return to the previous screen.

Rename

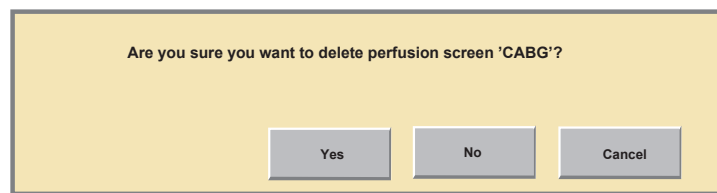
To rename a Perfusion Screen

1. Select the screen to be renamed.
2. Touch the **Rename** button.
3. Use the keyboard to enter the new name.
4. Touch **OK** or **Enter** to save the new name.

Delete

To delete a Perfusion Screen

1. Touch the Perfusion Screen name.
 2. Touch the **Delete** button.
- A confirmation window will be displayed to allow the user to confirm or cancel the deletion.



3. Choose **Yes** to delete the Perfusion Screen.
4. Touch **No** or **Cancel** to keep the Perfusion Screen in the system computer or on the PC card/USB drive.

Edit Card/Drive Name

To edit the name of a PC card/USB drive:

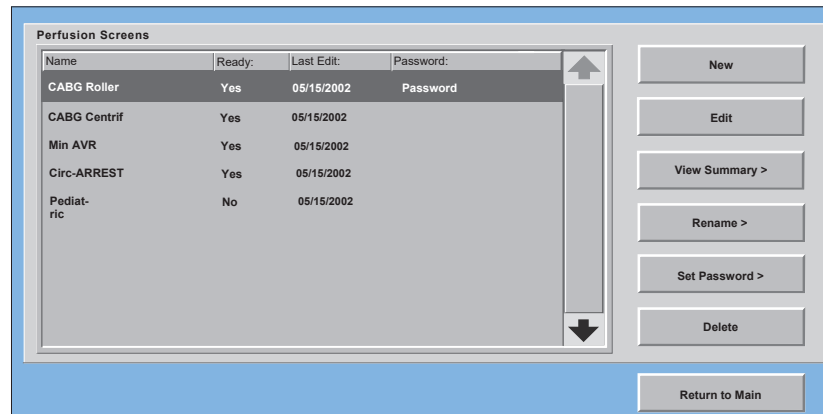
1. Touch the **Edit Card/Drive Name** button.
2. Use the keyboard to edit the name.
3. Touch **OK** or **Enter** to save the new name.

To close the PC Card/USB Drive Utilities Screen and return to the Configuration Screen, touch the **Close** button.

Central Control Monitor

Perfusion Screens

Perfusion Screens are graphical representations of the pumps and other devices that are to be used in a case. The pumps and other devices are controlled through the graphical representation displayed on the touch screen of the Central Control Monitor, known as central control. Devices that are controlled only through the CCM are air bubble detectors, the occluder, level detector, and pressure and temperature modules. Roller pumps, centrifugal control units and the electronic gas blender may be controlled through the CCM or by controls on the devices themselves, known as local controls.



Touch the **Return to Main** button to return to the main screen.

Under Perfusion Screens, a list of the Perfusion Screens that are stored in the Central Control Monitor (CCM) and status information about each Perfusion Screen appears. The CCM can store up to 12 different Perfusion Screens.

A Perfusion Screen can contain a total of 7 pumps, 2 of which can be centrifugal pumps. A maximum of 6 pumps can be displayed and controlled on the touch screen. The seventh pump must be designated as the backup pump. A Perfusion Screen can also contain:

- Up to 4 Air Detectors
- One Level Detector
- One Occluder
- Up to 8 Pressure Sensors (through the use of 4 modules)
- Up to 4 Flowmeters
- Up to 8 Temperature Sensors (through the use of 4 modules)
- One CDI™ 100/101 or one CDI™ 500/550
- One Electronic Gas Blender
- Up to 4 Timers

The name of the Perfusion Screen appears in the Name column. A Yes or No in the Ready column indicates whether that Perfusion Screen is ready for use. The date in the Last Edit column shows the last time the Perfusion Screen was edited. If the Perfusion Screen is password protected, the password appears in the Password column.

Use the buttons to create new Perfusion Screens, edit or make changes to existing Perfusion Screens, view Perfusion Screen summaries, rename existing Perfusion Screens, set passwords for Perfusion Screens, or delete Perfusion Screens from the system computer.

Central Control Monitor

The process of creating a Perfusion Screen involves adding and placing pumps and devices, then creating and/or editing safety connections, and, finally, assigning the physical pumps and devices to their graphical icons.

To Create a New Perfusion Screen Configuration

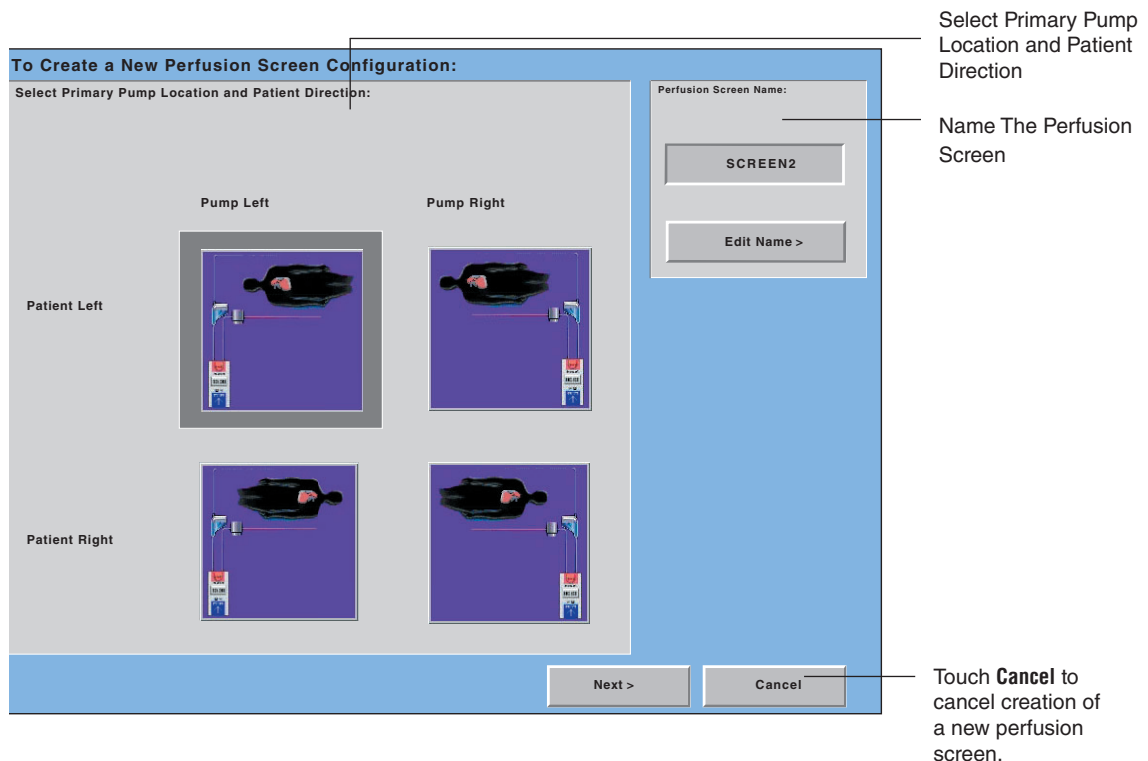
1. Touch the **New** button.
 - From this first screen, choose a unique name for the Perfusion Screen, Select Primary Pump Location and Patient Direction, or cancel the creation of a new screen.
 - This is the first of a series of screens the user must complete in order to configure a Perfusion Screen.
2. Use the **Next** and **Previous** buttons to go back and forth between screens.

To Change Perfusion Screen Name:

The name of the Perfusion Screen appears in the upper right corner. A default name is assigned to all new Perfusion Screens.

To change the default name:

1. Touch the **Edit Name** button.
2. Use the keyboard to enter a new name.
3. Touch Enter or **OK**.

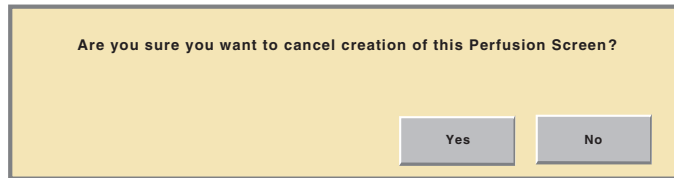


Central Control Monitor

Select Primary Pump Location and Patient Direction

Select a location for the primary or arterial pump and a patient orientation. The default orientation is Patient Left and Pump Left.

1. Touch the patient and pump icon that corresponds to the preferred orientation or make no selection and accept the default.
2. Touch **Next** to continue or touch **Cancel** to cancel the creation of a new screen.
 - If Cancel is chosen, a confirmation window will appear prompting the confirmation of the cancel request.



This page intentionally left blank.

Central Control Monitor

Configure Pumps

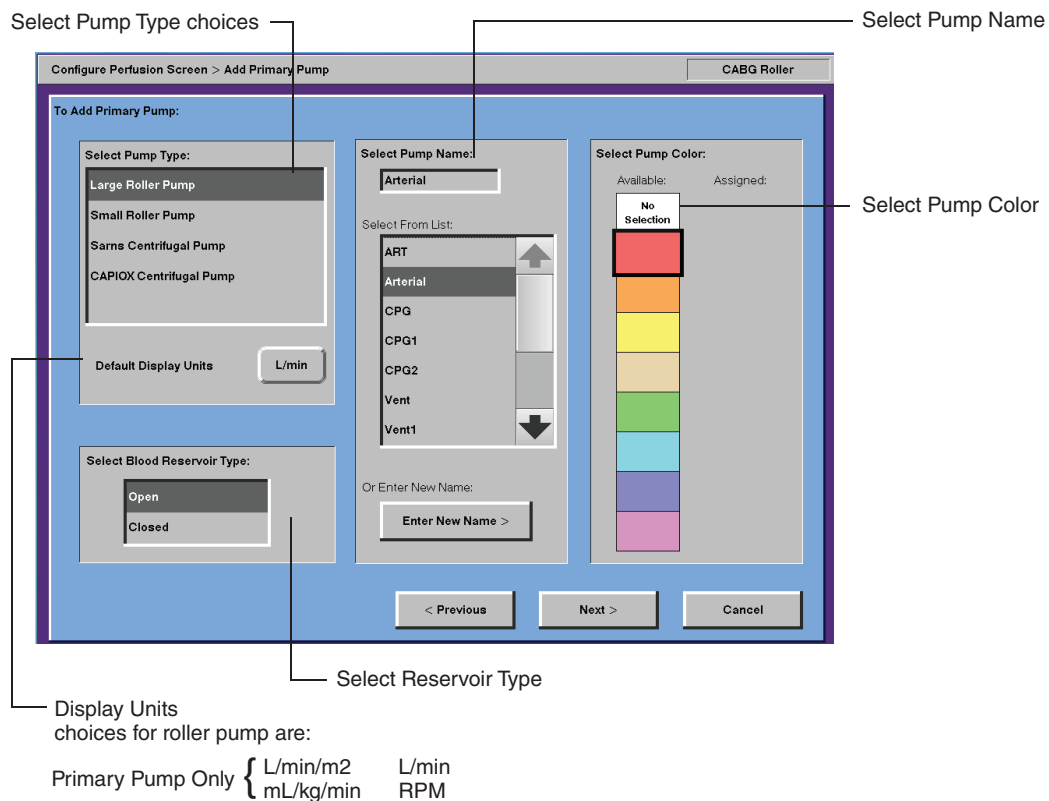
Add Primary Pump

After selecting patient and pump orientation, the next step in creating a Perfusion Screen is to add the primary pump.

The primary pump is the arterial pump.

Pump type, display units, reservoir type, pump name, and pump color are selected from this screen.

All the selections must be made, or the defaults accepted, before continuing.



Select Pump Type

Select the pump type by touching the appropriate name. The default selection is Large Roller Pump.

Display Units

If roller pump is selected as the pump type, a unit of measure related to flow rate can be chosen.

1. Touch the **Default Display Units** button until the desired unit of measure is displayed.
- These units will be displayed on both the CCM and the roller pump display. The default selection is L/min.

If a centrifugal pump is selected as the pump type, the display units default to RPM. A centrifugal pump can be configured to display flow rates in L/min if a flowmeter is added to the configuration and placed on the centrifugal pump icon. (See **Add Flow Sensor** section for further details.)

Central Control Monitor

Select Blood Reservoir Type

Open designates a hardshell venous reservoir or open system. Closed designates a softshell venous reservoir, venous reservoir bag, or a closed system. The reservoir icon is a visual representation only and doesn't have functionality on the touch screen.

To select the reservoir type, touch **Open** or **Closed**.

Select Pump Name

Each pump and device is assigned a unique name so that the pumps and devices are easily identified. The assigned names are used in the alarm, alert, status, and error messages displayed by the system.

Select a name from the list:

1. Use the up and down arrows to scroll through the list.
2. Choose the desired name under Select Pump Name. (The default selection is Arterial.)

To assign a name that is not on the list:

1. Touch **Enter New Name**.
2. Use the keyboard to create a pump name. The names must be unique.
3. Touch **OK** or **Enter** to save new name.

Select Pump Color

Each pump is assigned a unique color to help the user identify the different pumps on the touch screen. There are eight colors available with matching colored pump occlusion knob caps included. The Select Pump Color area shows which colors are available and which colors have already been assigned. If the No Selection box is highlighted, a color has not yet been selected.

To select a color:

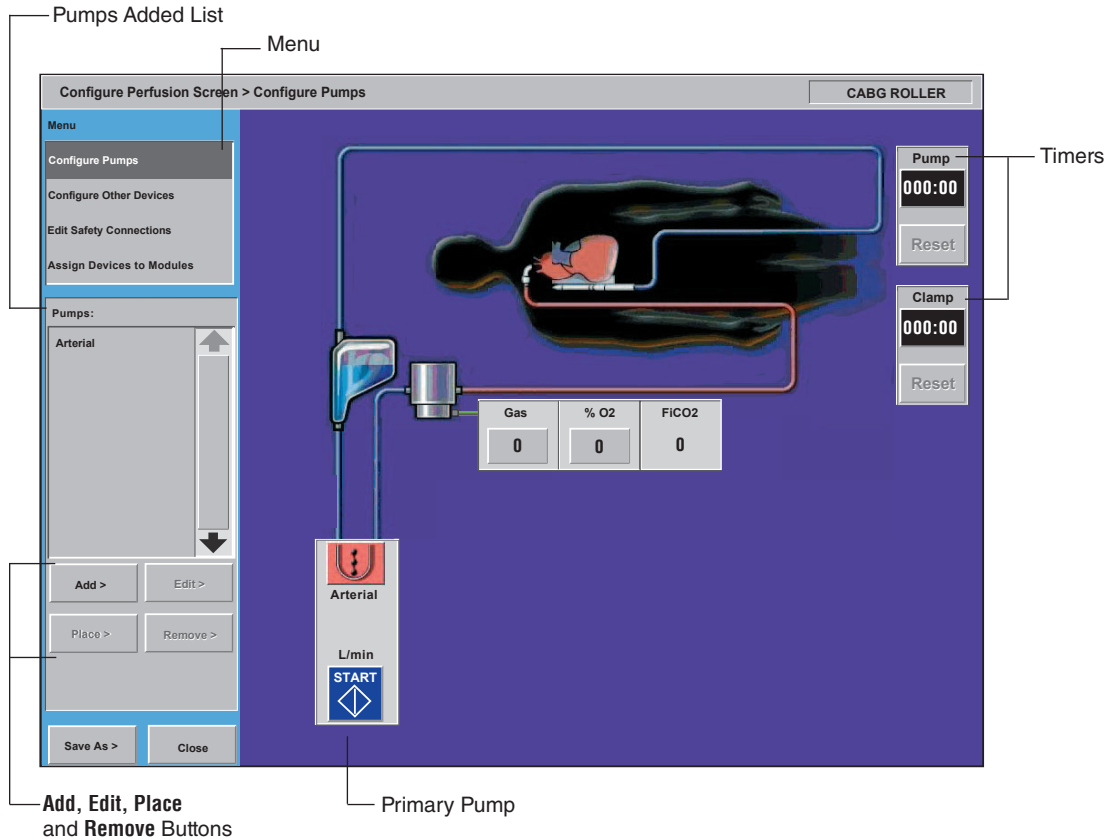
1. Touch a color to select it. The selected color is highlighted with a black outline. The default color for the primary pump is red.
2. Touch the **Next** button to proceed to the next screen.

The image shows a screenshot of the 'Select Pump Color' screen. It has a light gray background. At the top, the title 'Select Pump Color' is centered. Below the title, there are two columns: 'Available:' on the left and 'Assigned:' on the right. Under 'Available:', there is a vertical stack of eight colored squares. The top square is red and has a black border, indicating it is the selected color. Below it are orange, yellow, light brown, green, cyan, blue, and purple squares. Above the red square is a white box with the text 'No Selection'. The 'Assigned:' column is currently empty.

Central Control Monitor

Configure Perfusion Screen

This screen shows a graphical depiction of the patient and primary pump orientation, as well as the primary pump type and reservoir type selected.



Two timers, labeled Pump and Clamp, the oxygenator, and the icon for the electronic gas blender, if installed, appear on the screen. The locations of these devices and controls are fixed and cannot be changed. The primary pump displays the type, color, and flow units selected.

The Configure Perfusion Screen is used to add other pumps and devices to the perfusion circuit. Select an option from the menu.

Configure Other Pumps

Select Configure Pumps to add other pumps and designate a cardioplegia pump and a backup pump. A total of six pumps can be displayed and controlled on a Perfusion Screen.

A list of pumps that have been added appears below the menu. The primary pump name should appear in the list.

Use the **Add** button to add additional pumps.

The Add button is available until the maximum number of pumps have been added to the Perfusion Screen. Use the **Edit**, **Place**, and **Remove** buttons to make changes to pumps that have been added to the Perfusion Screen. Touch the pump name on the list to activate the appropriate buttons.

Central Control Monitor

Select Pump Type

1. Select the pump type. The default selection is Large Roller Pump. The number of pumps currently defined and the maximum number of pumps allowed is displayed. Select pump type before making other selections on this screen.

Select Display Units

If the pump type selected is a roller pump, choose a display unit related to flow rate.

1. Touch the **Default Display Units** button until the desired unit of measure is displayed. The default selection is L/min.

If the pump type selected is a centrifugal pump, the display units default to RPM. A centrifugal pump can be configured to display flow rates in L/min if a flowmeter is added to the configuration and placed on the centrifugal pump icon. (See **Add Flow Sensors** section for further details.)

Select Pump Type Menu

Select Pump Name

To Add Pump:

Select Pump Type:

- Large Roller Pump
- Small Roller Pump
- Large Master Roller Pump
- Small Master Roller Pump
- Sarns Centrifugal Pump
- CAPIOX Centrifugal Pump

Default Display Units

L/min

Current defined: 1

Maximum allowed: 6

Cardioplegia Pump

No

Backup Pump

No

Select Pump Name:

Select From List:

- ART
- CPG
- CPG1
- CPG2
- Vent
- Vent1
- Vent2
- Sucker1

Or Enter New Name:

Enter New Name >

Select Pump Color:

Available:

No Selection

Assigned:

Arterial

Next >

Cancel

Pump Designation

Select Display Units Button choices are:
L/min
RPM

Central Control Monitor

Select Pump Name

Each pump and device is assigned a unique name for identification. The assigned names are used in the alarm, alert, status, and error messages displayed by the system.

To select a name from the list, touch the name. Use the up and down arrows to scroll through the list. Names that have already been chosen no longer appear on the list. The selected name appears under Select Pump Name.

To assign a name that is not on the list, touch **Enter New Name** and use the keyboard to enter a pump name.

Select Pump Color

Select a pump color from the list by touching the desired color. If No Selection is highlighted, a color selection has not yet been made. The color in the control slide bar will match the color chosen for the pump. Colors already assigned appear in the "Assigned" column.

Pump Designation: Cardioplegia Pump or Backup Pump

Choose a pump designation, if desired.

Cardioplegia Pump	<input type="button" value="No"/>
Backup Pump	<input type="button" value="No"/>

Cardioplegia Pump

Designate whether the pump being added is to be used as a cardioplegia pump. The cardioplegia pump features include volume tracking, time between doses, and automatic cardioplegia dose delivery.

Only one pump can be designated as a cardioplegia pump. Choices for cardioplegia pump type are Large Roller Pump, Small Roller Pump, Large Master Roller Pump, or Small Master Roller Pump. Centrifugal pumps cannot be designated as cardioplegia pumps.

Touch the **Yes/No** button to choose the desired designation.

Note: If the pump type is changed after the cardioplegia pump designation is made, the Cardioplegia Pump button will change to No.

Central Control Monitor

Backup Pump

Designate whether the pump being added is to be used as a backup pump. The functionality of the primary pump can be reassigned to the backup pump in the event of primary pump failure, including Pulse mode capability, expanded flow display choices, and the automatic assignment of safety connections that were made to the primary pump. See **CCM System Tab** section for further details.

Designating a pump as a backup pump allows reassignment of primary pump functionality to a pump of a different type.

Note: When reassigning pumps, verify all operating parameters after reassignment, including tube size or flow constant, direction, and display units.

The following chart lists the valid choices for backup pumps:

Primary Pump	Valid Backup Pump Choices
Large and Small Roller Pump	Large Roller Pump
	Small Roller Pump
	Large Master Roller Pump
	Small Master Roller Pump
Centrifugal Pump	Large Roller Pump
	Small Roller Pump
	Large Master Roller Pump
	Small Master Roller Pump
	Centrifugal Pump

If a primary centrifugal pump is reassigned to a backup roller pump and if flow has been placed on the centrifugal pump, flow module data will no longer be displayed and the backflow alarm and minimum flow alarm are no longer available. In addition, the centrifugal Coast™ response becomes a roller pump stop response for alarm events and a roller pump message only response for alert events.

It is recommended, when possible, that the user select a backup pump that is of the same type as the primary pump.

Note: Do not select a small roller pump as a backup for either a large roller pump or a centrifugal pump if the calculated flow rates are expected to exceed 4 L/min. The maximum flow rate for a small roller pump is 4 L/min. Do not select a small roller pump as a backup for a large roller pump if the tube size is greater than 3/8 inch or 10 mm. The maximum tube size for selection of a small roller pump is 3/8 inch or 10 mm.

Touch the **Yes/No** button to choose the appropriate designation. Only one pump can be designated as a backup pump.

Central Control Monitor

Master Roller Pump

If the pump type selected for the pump being added was a master roller pump, a follower roller pump must be selected. The master/follower operation always involves two roller pumps operating in tandem. The follower pump demand flow rate is defined as a percentage of the master pump flow rate. If the master pump is operating in RPM mode, control is an RPM ratio, instead of flow.

Select Pump Type:

- Large Roller Pump
- Small Roller Pump
- Large Master Roller Pump**
- Small Master Roller Pump
- Centrifugal Pump

Select a pump type, name, and color for the follower pump.

To Specify Follower Pump:

Select Follower Pump Type:

- Large Follower Roller Pump**
- Small Follower Roller Pump

Select Pump Name:

Cryst

Select From List:

- ART
- CPG
- CPG1
- CPG2
- Vent
- Vent1
- Vent2

Or Enter New Name:


Enter New Name >

Select Pump Color


Available:	Assigned:
No Selection	Arterial
	Blood
	Vent
	Sucker1
	Sucker2

< Previous Next > Cancel

The master/follower pumps will appear linked together in one box in the graphical display.




Blood



Cryst

L/min

START



0

L/min Total

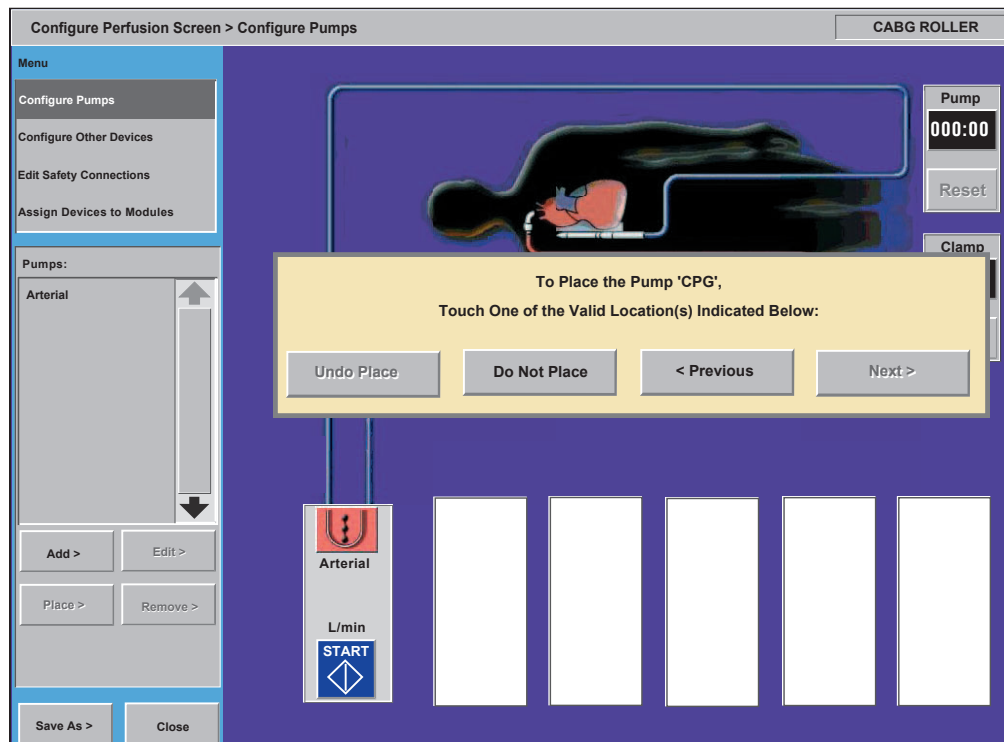
Central Control Monitor

Place the Pump

Select a place on the screen for the pump to appear.

Touch the white rectangle that corresponds to the desired location of the pump. Change the placement position by touching any other blank rectangle. Choose the **Undo Place** button to remove the pump from its place on the screen.

Choose **Do Not Place** and the pump will not be placed on the screen. Up to 6 pumps can be placed on the screen. A seventh pump can be added and not placed if designated as the backup pump. A pump that has not been placed on the graphical display has the label, Not Placed, next to its name in the Pumps list.

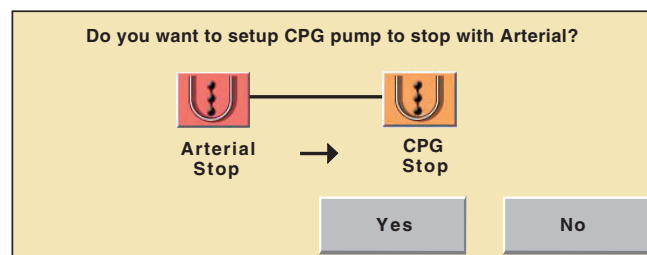


Select the **Next** button to proceed to the next screen.

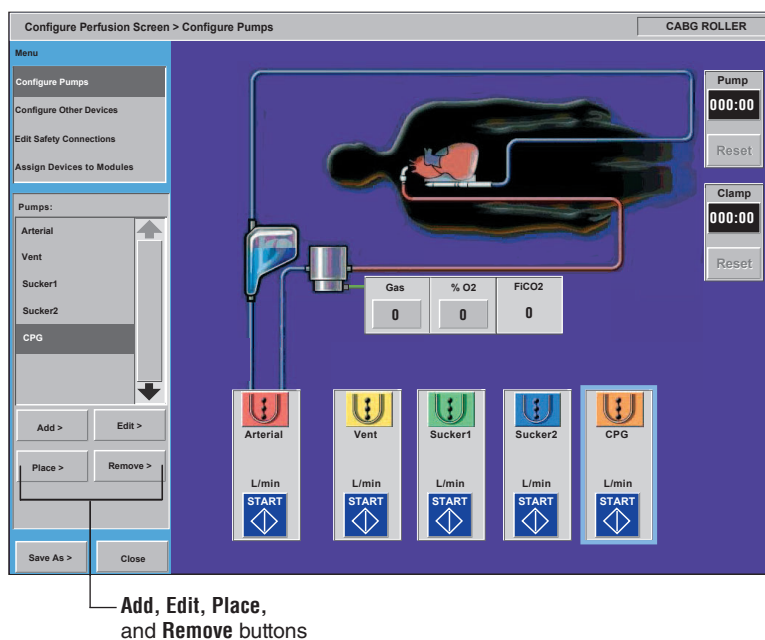
Note: When initially placing a designated cardioplegia pump, a window appears asking if a safety connection between the primary pump and the cardioplegia pump is desired. If the designation is edited, the window does not reappear.

Choose **Yes** and follow the steps to set up the safety connection. For more information, see the section **Edit Safety Connections** in this chapter.

Choose **No** and no safety connection will be made at this time. A safety connection between the arterial and cardioplegia pump may be set up at a later time.



Central Control Monitor



Edit, Place, and Remove

Use the **Edit**, **Place** and **Remove** buttons to change or revise the placement and configuration of the pumps. Select the pump by touching its name on the list or its icon on the screen.

Note: The primary pump may not be removed or relocated, nor can the pump type be changed. The display units, name, and color chosen for the primary pump may be edited.

Use the **Edit** button to change the designation, name, or color of a pump.

If the pump designation is edited, make sure to edit and then verify any safety connections that may have been made to the pump. The safety connections must be set up for the newly designated cardioplegia pump and removed from the previously designated cardioplegia pump.

Use the **Place** button to change the location of the pump on the graphic display.

Use the **Remove** button to remove a pump from the graphic display.

This page intentionally left blank.

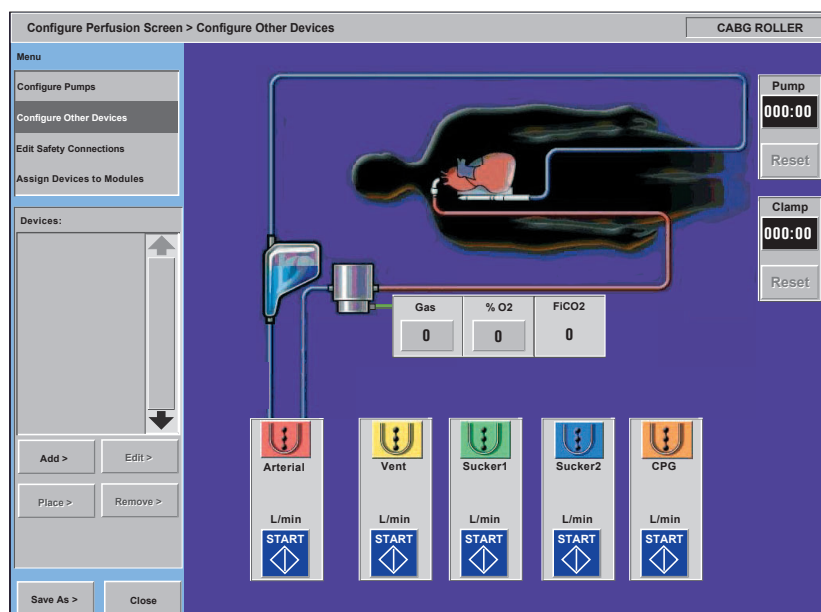
Central Control Monitor

Configure Other Devices

Configure and add other devices to the Perfusion Screen through the Configure Other Devices menu selection.

	Maximum allowed
Air Detector	4
Level Detector	1
Occluder	1
Pressure Sensor	8
Flow Sensor	4
Temperature Sensor	8
CDI™ 100/101 or CDI™ 500/550	1
Timers	4

Note: Two of the 4 timers are designated as Pump and Clamp timers.



When placing devices, consider the appropriate location for the device currently being placed, and also appropriate locations for devices yet to be placed as devices cannot share locations. The Do Not Place button can be used to move devices on the graphic display. All devices except timers and the backup pump will be removed from the Perfusion Screen if they are not placed before the screen is closed.

If using a CDI monitor, it is recommended to add the CDI device before adding other devices. The CDI icons have fixed locations on the screen. Placement of the pressure, flow, and temperature icons in certain areas can interfere with the CDI icon placement.

Central Control Monitor

Add a Device

To add a device to the graphic display, touch the **Add** button.

To Add Device:

Select Device Type:

- Air Detector
- Level Detector
- Occluder
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100
- CDI 500

Current defined: 0
Maximum allowed: 0

Select Device Name:

Select From List:

Or Enter New Name:

Enter New Name >

Next > Cancel

Select Device Type

Choose Device Type by touching the type name. Use the arrows to scroll through the list of device types.

The number of currently defined devices of that type and the maximum number of devices of that type are displayed in the box below the list.

Touch **Cancel** to cancel the addition of a device.

Add Air Detectors

Up to 4 Air Detectors can appear on a Perfusion Screen.

It is highly recommended that an Air Bubble Detection system is used on the arterial line for every case.

To add an Air Detector:

1. Choose **Add**.
2. Choose Air Detector as device type.
3. Name the air detector.
4. Touch the **Next** button.

To Add Device:

Select Device Type:

- Air Detector
- Level Detector
- Occluder
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100
- CDI 500

Current defined: 0
Maximum allowed: 4

Select Device Name:

Select From List:

- ART Air
- VEN Air
- CPG Air
- CPG1 Air
- CPG2 Air

Or Enter New Name:

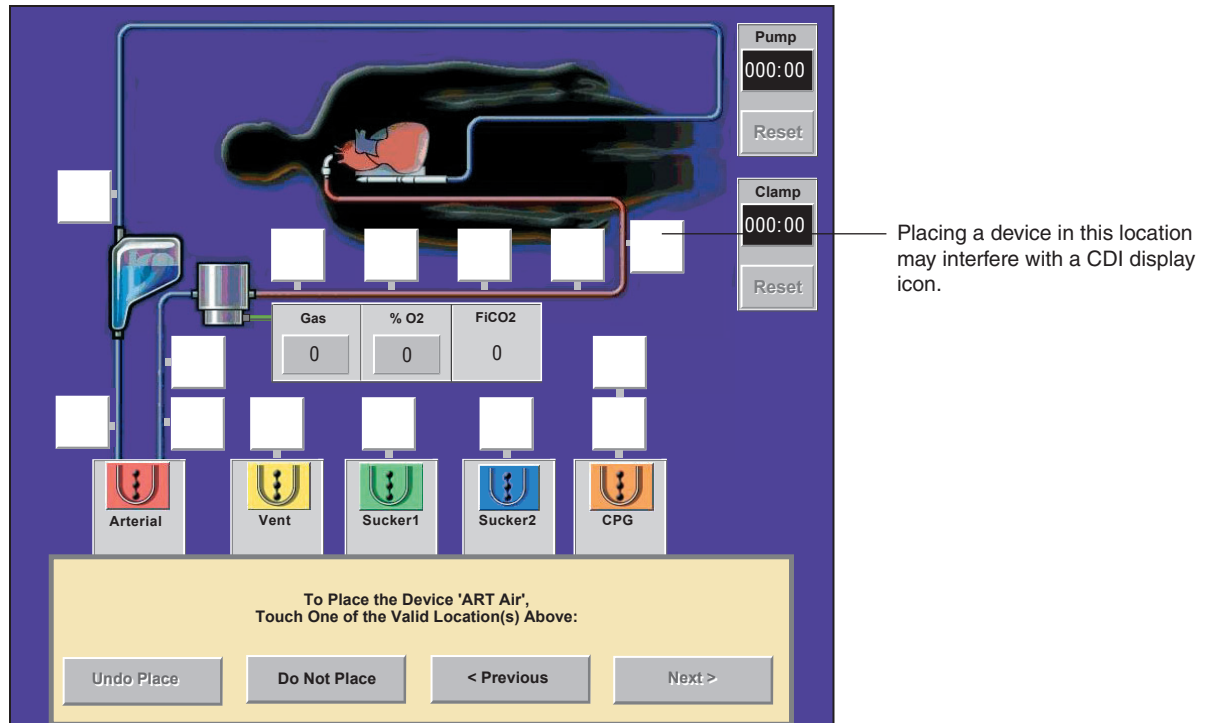
Enter New Name >

Next > Cancel

Central Control Monitor

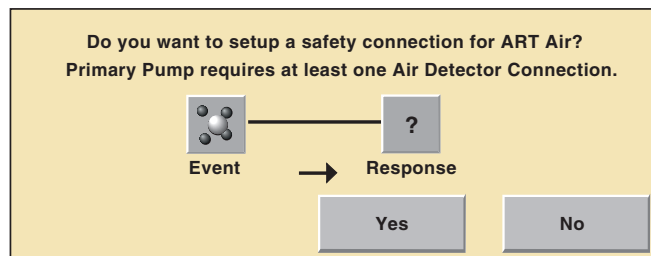
Place the Air Sensor

Available locations for the air sensor appear as white squares on the screen. Place the air sensor in the location that most closely matches the actual location of the air sensor in the circuit by touching the appropriate white square.



Change the location by touching any white square. Choose the **Undo Place** button to remove the air sensor from its place on the screen.

Safety Connections



After an air sensor is placed, the system automatically prompts the user to set a safety connection for the air detector.

At least one safety connection is required between an Air Bubble Detect module and the primary pump. It is highly recommended that an Air Bubble Detection system be used on the arterial line with a safety connection to the primary pump for every case.

Choose **Yes** to set up the safety connection; choose **No** to defer setting a safety connection.

Central Control Monitor

Add a Level Detector

To Add Device:

Select Device Type:

- Air Detector
- Level Detector**
- Occluder
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100
- CDI 500

Current defined: 0
Maximum allowed: 1

Select Device Name:

Select From List:

- Level
- VENLevel
- CPGLevel
- LEVEL1
- LEVEL2

Or Enter New Name:

Enter New Name >

Level Detection:

Alert/Alarm

Alert Only
Alert/Alarm

Next > Cancel

Alert Only and Alert/Alarm

A maximum of 1 level detector can appear on a Perfusion Screen, and it can be configured for either Alert/Alarm requiring two sensors or Alert Only requiring one sensor.

To add a Level Detector

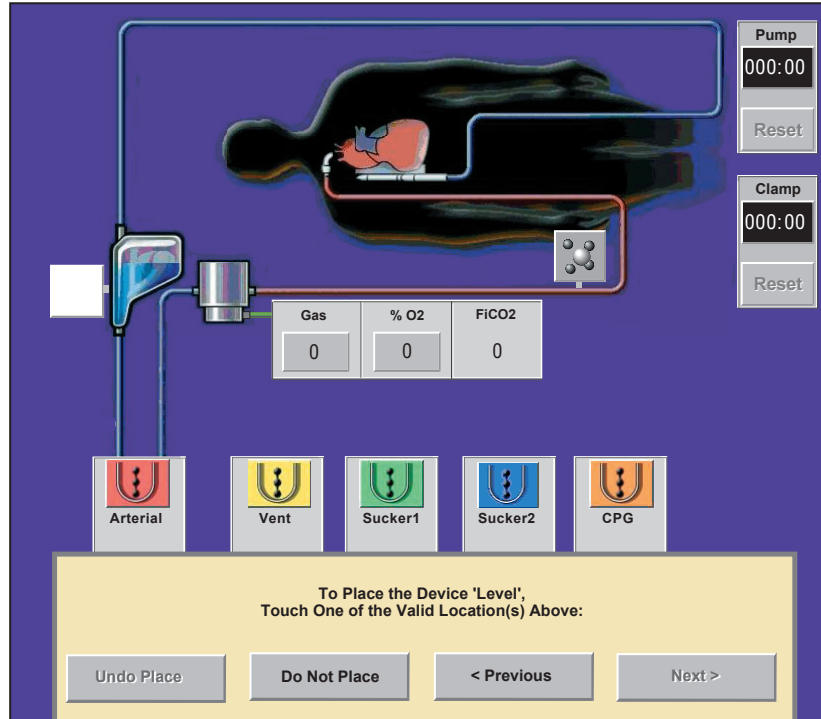
1. Select **Add**.
2. Select Level Detector as device type.
3. Name the Level Detector.
4. Select an operating mode for the Level Detector. The default selection is Alert/Alarm mode.
 - **Alert Only** allows the user to set up one level sensor on a reservoir. Alert sensors cannot be used to stop pumps.
 - **Alert/Alarm** allows the user to set up two level sensors on a reservoir. Alarm sensors can be used to stop any type of pump or Coast the centrifugal pump.

Touch **Next** to continue.

Central Control Monitor

Place the Level Detector

The available location for the level detector appears as a white square. Touch the white square to place the level detector.

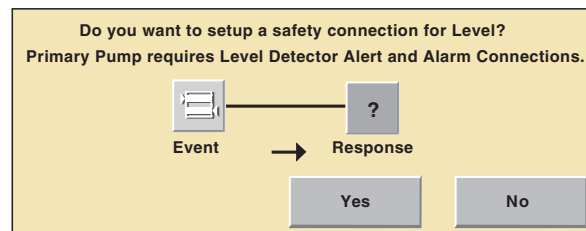


Set Safety Connections

After a level detector is placed, the system automatically prompts the user to set a safety connection for the level detector.

Connections are required between a level detector and the primary pump.

Choose **Yes** to set a safety connection. Choose **No** to defer setting a safety connection.



Add an Occluder

A maximum of 1 occluder is allowed on a Perfusion Screen.

1. Select **Add**.
2. Select Occluder as device type.
3. Name the occluder.

Central Control Monitor

Select a Color

The color chosen for the occluder appears in the control slide bar for the occluder. There are two color choices.

1. Touch the desired color. The default color selection is blue.
2. Touch **Next** to continue.

To Add Device:

Select Device Type:

- Air Detector
- Level Detector
- Occluder**
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100
- CDI 500

Current defined: 0
Maximum allowed: 1

Select Device Name:

Select From List:

- Occluder
- VEN Occl
- ART Occl
- CPG Occl
- OCCL1

Or Enter New Name:

Enter New Name >

Select Occluder Color:

Available: No Selection

Assigned:

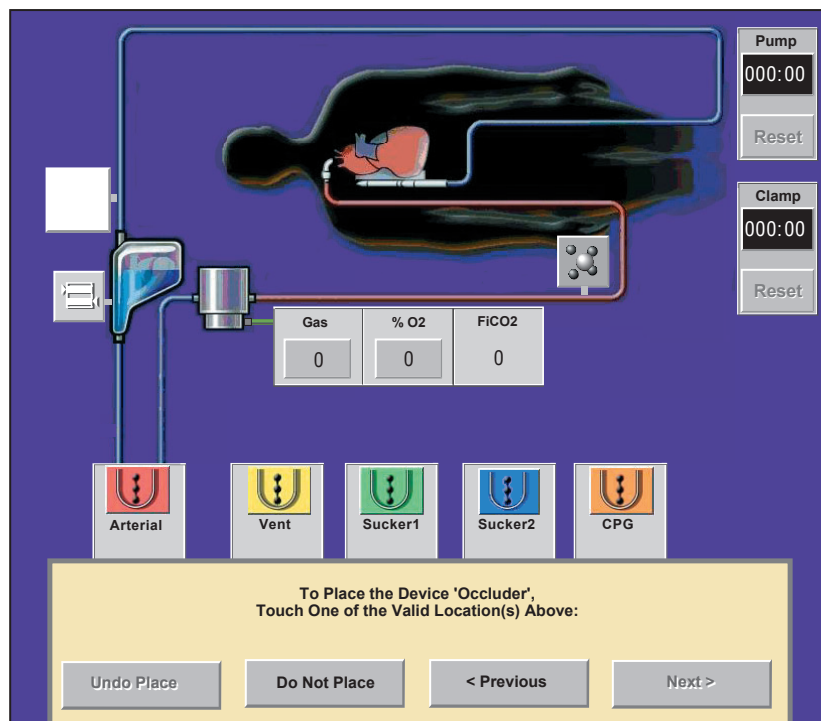
- Red
- Blue

Next > Cancel

Place the Occluder

The available location for the occluder appears as a white square.

Touch the white square to place the occluder.

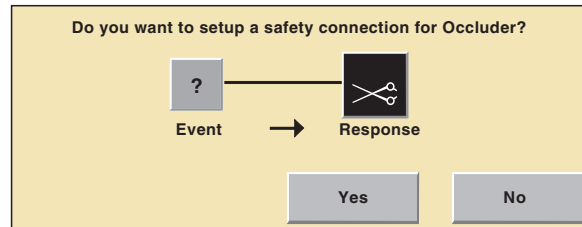


Central Control Monitor

Set Safety Connections

After the occluder is placed, the system automatically prompts the user to set a safety connection for the occluder.

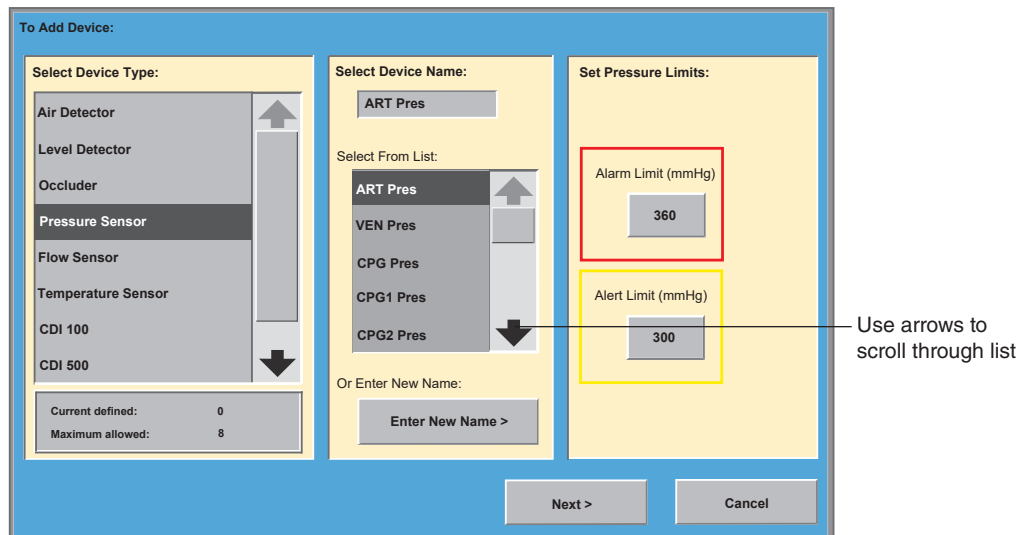
Choose **Yes** to set a safety connection for the occluder. Choose **No** to defer setting a safety connection.



Add Pressure Sensors (Transducers)

A maximum of 8 pressure sensors is allowed on a Perfusion Screen.

1. Select Add.
2. Select Pressure Sensor as device type.
3. Name the Pressure Sensor.



Set Pressure Limits

Alarm and alert limits for each pressure sensor can be set from this screen. Pumps can be configured to respond to these limits. Default values are 360 mmHg for the alarm limit and 300 mmHg for the alert limit. The acceptable range for pressure alarms and alerts is between -250 mmHg and 900 mmHg. If the alert limit chosen is in the positive range, then the alarm limit must also be in the positive range. If the alert limit chosen is in the negative range, then the alarm limit must also be in the negative range.

Central Control Monitor

Alarm limits must always be higher than alert limits. The system maintains a 10 mmHg pressure difference between the alert and alarm limit to ensure that the alert is always less than the alarm.

To change the alarm or alert limit, touch the **Alarm Limit** or **Alert Limit** button and use the arrows to set a new limit. Touch the **Alarm Limit** or **Alert Limit** button again to store the new value.

The 'Set Pressure Limits' screen has a yellow background. It contains two sections: 'Alarm Limit (mmHg)' with a red border and a grey box showing '360', and 'Alert Limit (mmHg)' with a yellow border and a white box showing '300'. To the right of these boxes are four arrow buttons: two pointing up (labeled '+ 50 mmHg' and '+ 10 mmHg') and two pointing down (labeled '- 10 mmHg' and '- 50 mmHg').

Choose **Next** to continue.

Place the Pressure Sensor

Place the pressure sensor in the location that most closely matches the actual location of the pressure sensor in the circuit by touching the appropriate white square.

Choose **Do Not Place** to allow placing the sensor at a later time.

The main monitor screen has a dark blue background. At the top is a patient silhouette with a circuit diagram. Below it are three vital sign displays: 'Gas' (0), '% O2' (0), and 'FICO2' (0). To the right are 'Pump' and 'Clamp' sections, each with a '000:00' timer and a 'Reset' button. At the bottom are five sensor placement icons: 'Arterial' (red), 'Vent' (yellow), 'Sucker1' (green), 'Sucker2' (blue), and 'CPG' (orange). A text box at the bottom says 'To Place the Device 'ART Pres', Touch One of the Valid Location(s) Above:'. Below this are four buttons: 'Undo Place', 'Do Not Place', '< Previous', and 'Next >'. A callout line points to a white square in the circuit diagram with the text: 'Placing a device icon in this location may interfere with a CDI display icon.'

Change placement of the sensor by choosing any other white square.

Central Control Monitor

Choose **Undo Place** to remove the pressure sensor from the Perfusion Screen.

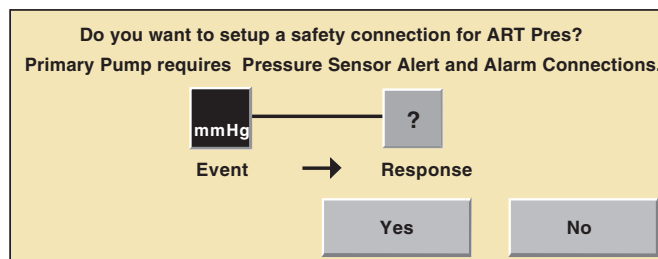
Choose **Next** to continue.

Set Safety Connections

After a pressure sensor is placed, the system automatically prompts the user to set a safety connection. Alert and alarm safety connections are required between a pressure sensor and the primary pump.

Choose **Yes** to set a safety connection.

Choose **No** to defer setting a safety connection.



Do you want to setup a safety connection for ART Pres?
Primary Pump requires Pressure Sensor Alert and Alarm Connections.

mmHg — ?

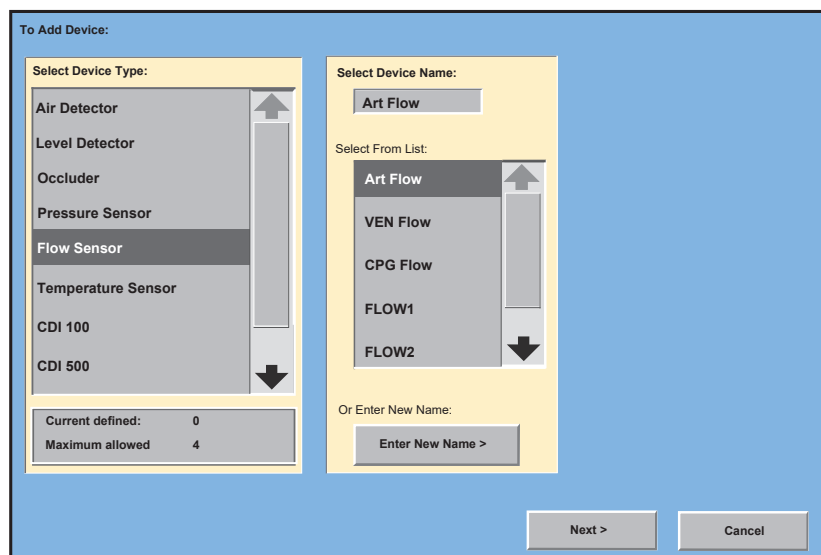
Event → Response

Yes No

Add Flow Sensors

A maximum of 4 flow sensors is allowed in a Perfusion Screen.

1. **Select Add.**
2. Select Flow Sensor as device type.
3. Choose name from the list or choose **Enter New Name** and use the keyboard to enter a device name.



To Add Device:

Select Device Type:

- Air Detector
- Level Detector
- Occluder
- Pressure Sensor
- Flow Sensor**
- Temperature Sensor
- CDI 100
- CDI 500

Current defined: 0
Maximum allowed: 4

Select Device Name:

Art Flow

Select From List:

- Art Flow**
- VEN Flow
- CPG Flow
- FLOW1
- FLOW2

Or Enter New Name:

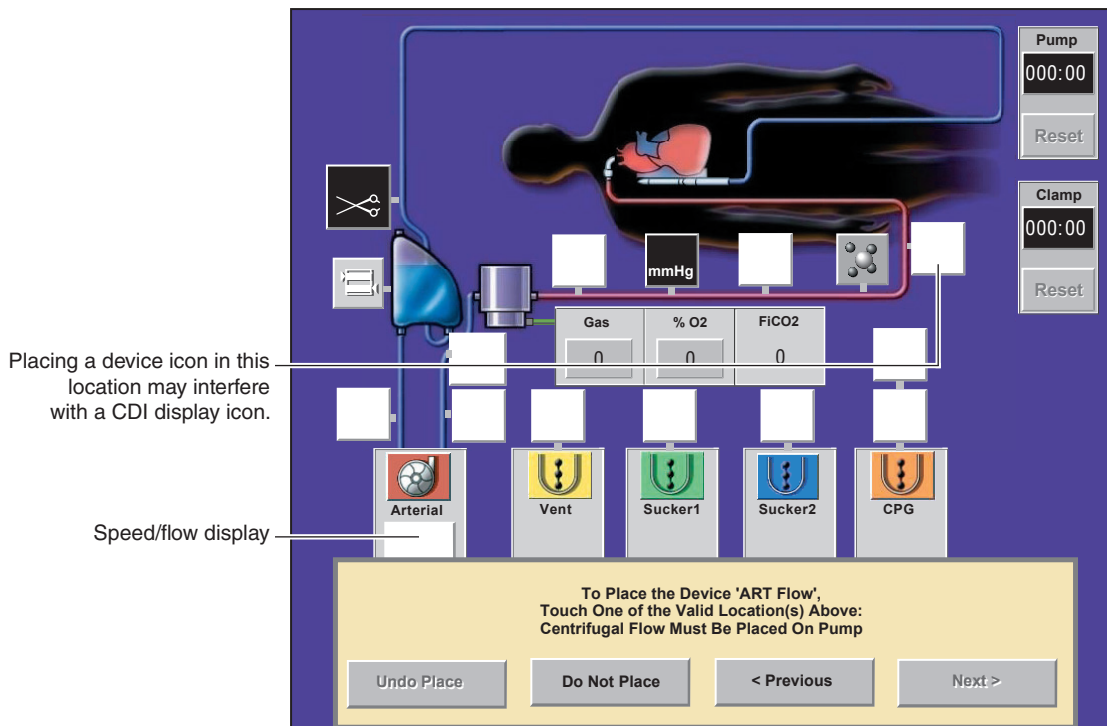
Enter New Name >

Next > Cancel

Central Control Monitor

Place the Flow Sensor

Place the flow sensor by touching a white square. In order for flow information to be displayed on a centrifugal control unit, a flow sensor must be placed on the centrifugal pump speed/flow display area. Change the placement of the flow sensor by touching any other white square.



WARNING: Always place a flow sensor on a centrifugal pump speed/flow display area to enable the minimum flow alarm and any safety connections that have been set for a minimum flow alarm.

Choose **Next** to continue.

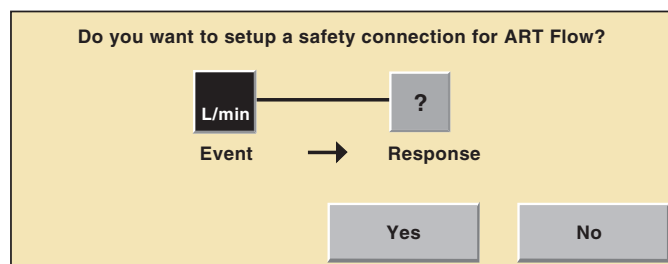
Set Safety Connections

After a flow sensor is placed, the system automatically prompts the user to set a safety connection.

Choose **Yes** to set a safety connection.

Note: If a centrifugal pump is placed in a position other than in the number 1 or number 6 position on the CCM, the Speed/Flow Display area will be hidden from view when in the Edit Safety Connections menu. To avoid moving the pump or flow sensor in order to make safety connections, make the safety connections at this time.

Choose **No** to defer setting a safety connection.



Central Control Monitor

Add Temperature Sensors

A maximum of 8 temperature sensors is allowed in a Perfusion Screen.

1. Select Add.
2. Select Temperature Sensor as device type.
3. Name the temperature sensor. Choose name from the list or choose **Enter New Name** and use the keyboard to enter a device name.

To Add Device:

Select Device Type:

- Air Detector
- Level Detector
- Occluder
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100/101
- CDI 500

Current defined: 0
Maximum allowed: 8

Select Device Name:

Select From List:

- ART Temp
- VEN Temp
- CPG1Temp
- CPG2Temp
- Main H2O

Or Enter New Name:
Enter New Name >

Set Temperature Limit:

Alarm Limit (°C)
42.5

Next > Cancel

Set the Temperature Limit

A temperature limit for each temperature sensor can be set. An alarm condition will be generated if the temperature exceeds the limit. The default value is 42.5 °C. The available range for temperature limit is between 1.0 °C and 42.5 °C.

To change the alarm limit, touch the **Alarm Limit** button and use the arrows to set the new limit. Touch the **Alarm Limit** button again to store the new value.

Set Temperature Limit:

Alarm Limit (°C)
42.5

+ 1.0 °C
+ 0.1 °C
- 0.1 °C
- 1.0 °C

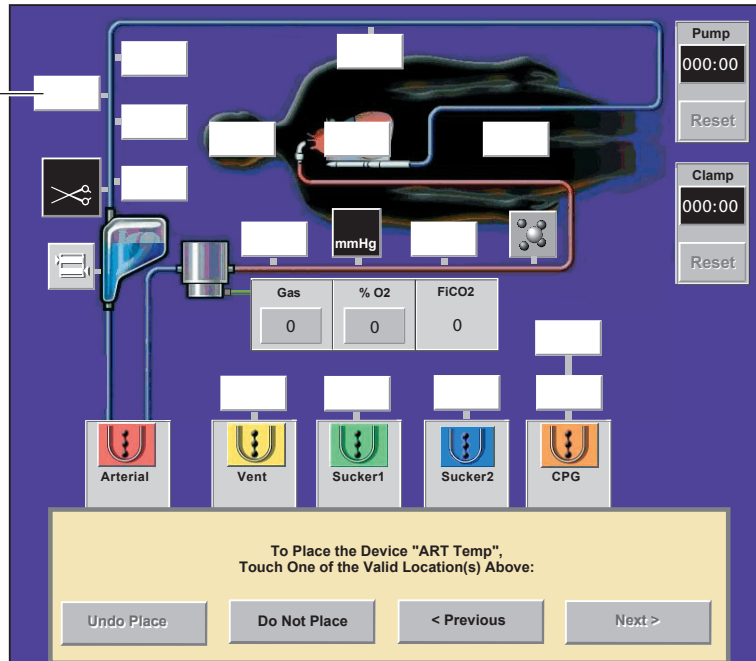
Choose **Next** to continue.

Central Control Monitor

Place the Temperature Sensor

Place the temperature sensor by touching a white square. Change the placement of the temperature sensor by touching any other white square.

Placing a device icon in this location may interfere with a CDI display icon.



Add CDI™ Devices

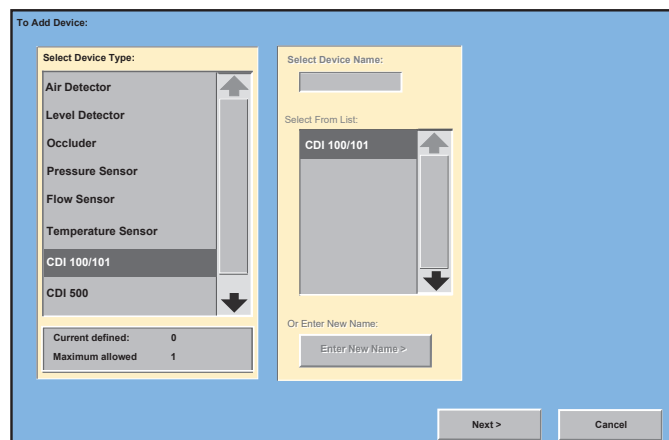
A CDI™ 100, CDI™ 101, or a CDI™ 500/550 monitor can be added to a Perfusion Screen. If a CDI device is added, information from the CDI monitor will be displayed on the CCM.

Add a CDI™ 100/101

Choose CDI™ 100/101 from the Select Device Type list.

Select Device Name

The device name CDI™ 100/101 is automatically chosen as only one monitor of this type is allowed in a Perfusion Screen. This name is used in status and error messages displayed by the system.

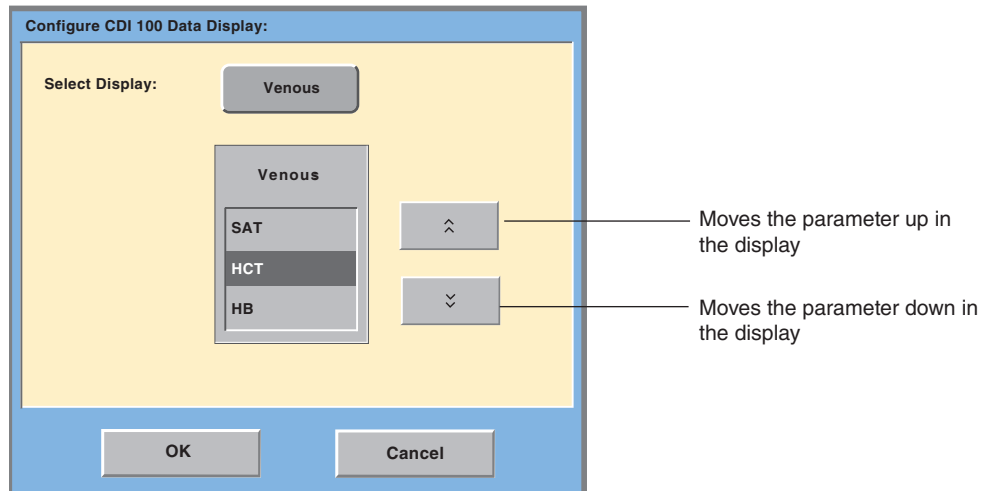


Central Control Monitor

Choose **Next** button to continue.

Configure CDI™ 100/101 Data Display

Three parameters from the CDI™ 100 or CDI™ 101 monitor are displayed on the screen: oxygen saturation (SAT), hematocrit (HCT), and hemoglobin (HB).



Select Display

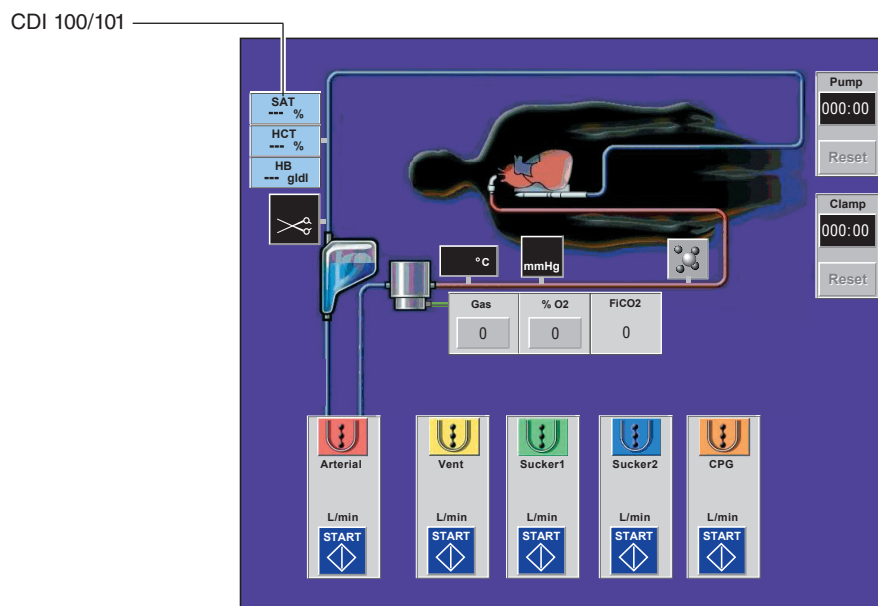
Choose Venous or Arterial as the source for the parameter values.

Touch the **Venous** button to change the selection to Arterial. Touch the button again to revert to Venous.

Arrange Data Values

The data values for the parameters are displayed on the screen in a stack display box. The position of data values in the stack can be changed by selecting the parameter and using the arrows to choose the desired position.

Touch the **OK** button to place the display on the Perfusion Screen or choose cancel to cancel the addition of the display.



Central Control Monitor

Add a CDI™ 500/550

Choose CDI™ 500 from the Select Device Type list.

Select Device Name

The name CDI™ 500 is automatically chosen as only one monitor of this type is allowed in a Perfusion Screen. This name is used in status and error messages displayed by the system.

Choose **Next** button to continue.

Configure CDI 500 Data Display

Configure CDI 500 Data Display

Venous	Arterial:	Other:
pH	pH	VO2
PO2	PO2	
PCO2	PCO2	
SO2	K+	
Modify >	Modify >	Modify >

< Previous OK Cancel

Data Display

Up to 4 venous and 4 arterial parameters from the CDI™ 500/550 monitor can be displayed on the Perfusion Screen at any one time.

Additional Venous parameters are °C, HCT, and HGB.

Additional Arterial parameters are °C, SO2, HCO3, and BE.

Additional Other parameters are K+.

Choose **OK** to accept the defaults and proceed.

Choose **Cancel** to cancel the addition of a CDI™ 500/550.

Choose **Modify** to make changes to a list.

Central Control Monitor

Modify Data Values

Only 4 values can be displayed at once. If there are 4 values in the list, 1 must be removed before another can be added.

To Remove Value:

1. Touch the value to be removed from the list on the right hand side.
2. Touch the **Remove** button to remove the value from the display. That value will be transferred to the Possible Data Values box.

The screenshot shows the 'Configure CDI 500 Venous Data Display' window. On the left, under 'Possible Data Values for Venous:', are °C, HCT, and HGB. In the center are 'Add >>' and '<< Remove' buttons. On the right, under 'Venous:', are pH, PO2, PCO2, and SO2. Below this list are up and down arrow buttons. At the bottom are '< Previous', 'OK', and 'Cancel' buttons.

To Add a Value:

1. Select the value to be added to the display.
2. Touch the **Add** button to add the value to the display.

This screenshot is similar to the previous one, but now pH is in the 'Possible Data Values for Venous:' list and PO2 is in the 'Venous:' list. The 'Add >>' and '<< Remove' buttons are still present. Below the 'Venous:' list are up and down arrow buttons. Callout lines point to these arrows with the text: 'Moves the parameter up in the display' and 'Moves the parameter down in the display'. The bottom buttons are '< Previous', 'OK', and 'Cancel'.

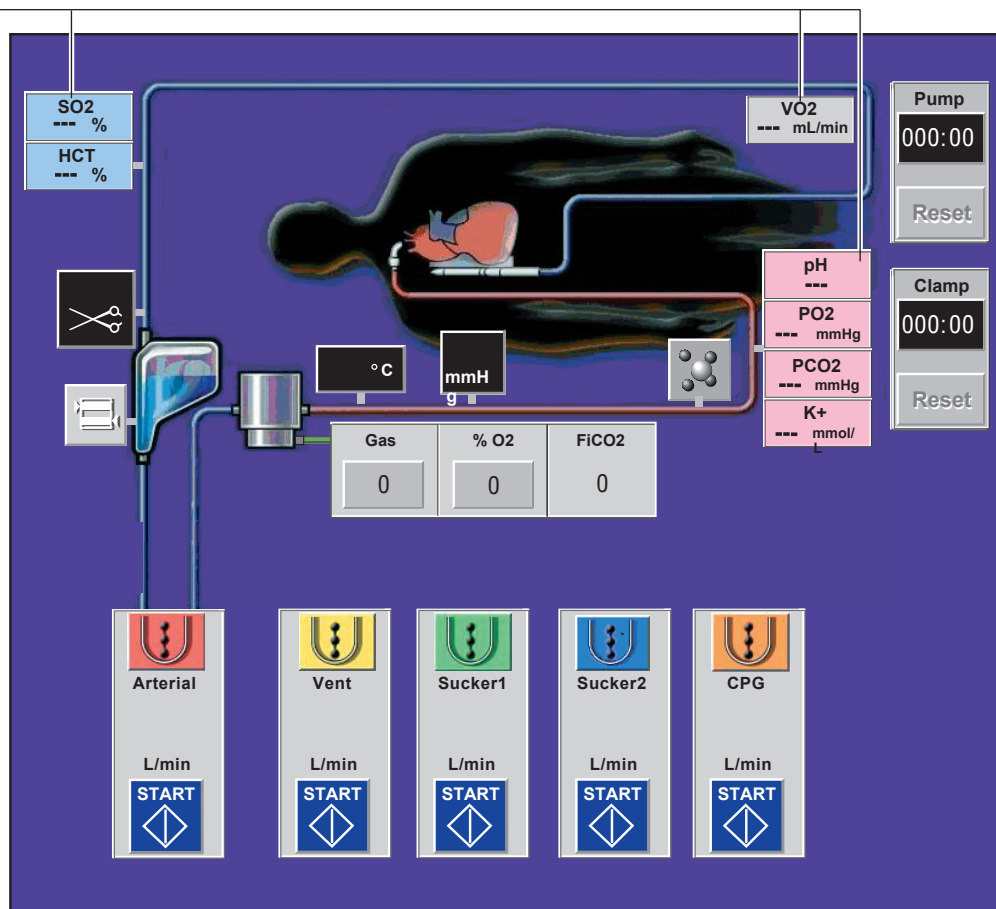
Central Control Monitor

Arrange Data Values

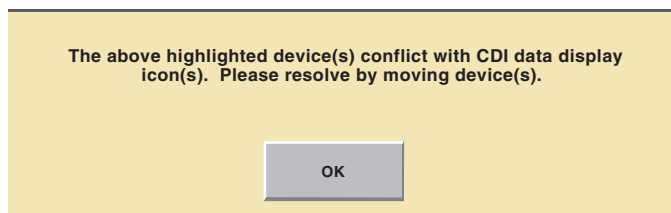
Arrange the order in which the data values appear by using the arrows to position a particular data value in the display.

Touch **OK** to accept the modified data display.

CDI 500/550



Note: CDI™ 100/101 and CDI™ 500/550 display icons have specific fixed locations on the graphic display. If a device location conflicts with the CDI display, a window appears and indicates that the device must be moved. The device will be highlighted with a blue perimeter.



Central Control Monitor

Add Timers

A maximum of 4 timers is allowed in a Perfusion Screen including the Pump timer and Clamp timer. Up to 2 additional timers can be added to a Perfusion Screen configuration.

1. Select Add.
2. Select Timer as device type.
3. Name the Timer. Choose name from the list or choose **Enter New Name** and use the keyboard to enter a device name.

To Add Device:

Select Device Type:

- Level Detector
- Occluder
- Pressure Sensor
- Flow Sensor
- Temperature Sensor
- CDI 100
- CDI 500
- Timer**

Current defined: 2
Maximum allowed: 4

Select Device Name:

Select From List:

- CPG Tmr
- CPG1 Tmr
- CPG2 Tmr
- TMR1
- TMR2

Or Enter New Name:

Enter New Name >

Set Timer Properties:

Timer Mode:

Count Up

Initial Value (Minutes: Seconds)

000:00

Choices are:
Count Up
Count Down

Next > Cancel

Set Timer Properties

Timers can be configured to count up or count down. The default selection is count up.

Touch the **Timer Mode** button to select a mode.

Count Down

To set up a Count Down timer, select the Initial Value to count down from. The default value is 20 minutes.

To change the initial value, touch the **Initial Value** button and use the arrows to set the new initial value.

Touch the **Initial Value** button again to select the new value.

Choose **Next** to continue.

Set Timer Properties:

Timer Mode:

Count Down

Initial Value (Minutes: Seconds)

020:00

+ 1 min
+ 1 sec
- 1 sec
- 1 min

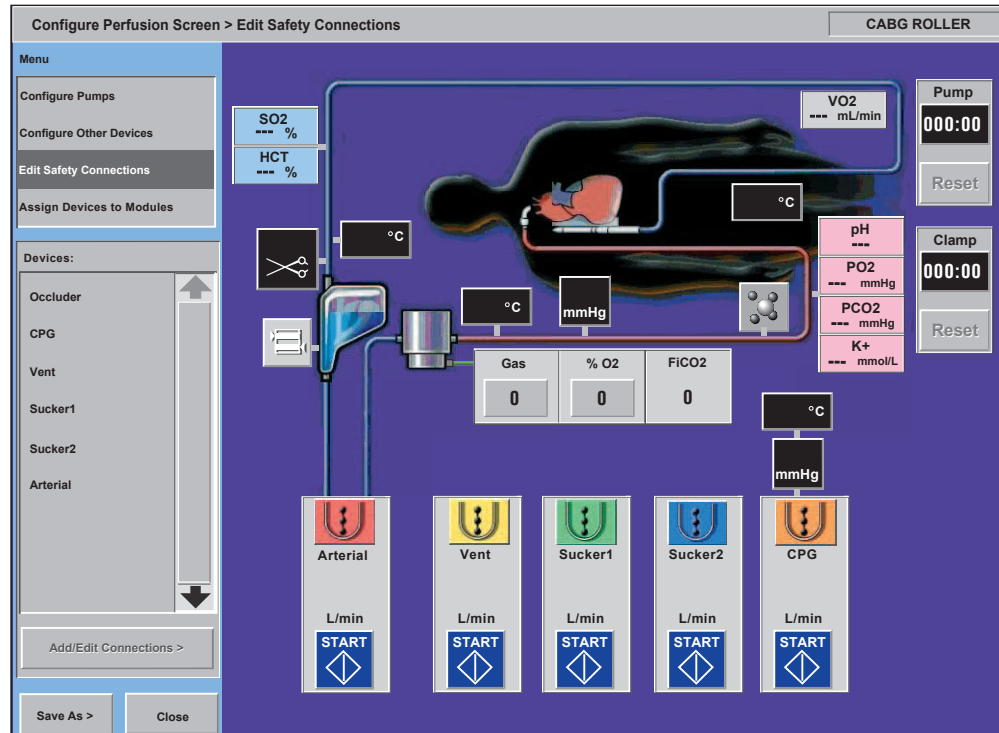
Pump and Clamp timers are always included in a Perfusion Screen and are located in fixed positions on the graphic display. No other timers can be placed on the graphic display. Other timers appear in the device list with a designation of (Not Placed). The additional timers are accessible during a case by touching the Timers subtab within the Aux tab on the Perfusion Screen.

This page intentionally left blank.

Central Control Monitor

Typical Perfusion Screen

A typical Perfusion Screen with pumps and devices in place may look something like this:



The following sections, **Edit Safety Connections** and **Assigning Devices to Modules**, will refer to this Perfusion Screen.

Edit Safety Connections

A safety connection is a communications link set up between two system components that allows a device to receive information from another device or module. Safety connections allow the user to set up pump responses to events generated by air sensors, level sensors, pressure sensors, flow sensors, roller pumps, and centrifugal pumps. Safety connections allow the user to set up occluder responses to primary pump events. Safety connections cannot be set up for follower roller pumps.

For example, a safety connection between an air detector and a roller pump allows the user to set the roller pump to stop in the case of an air detected alarm. It also allows the event message to display on the pump or centrifugal control unit local display.

Servo mode capability is also set up in the safety connections area. A pump can use data from a pressure or flow sensor to regulate its speed to maintain pressure or flow. The events generated by the various devices and response choices that can be made for the occluder, roller pumps, and centrifugal control units are outlined in the Connection Matrix, found at the end of this section. Note that some pump responses are also events.

Prior to setting up safety connections, study the Connection Matrix and prepare a list of the responding devices in the circuit and the events the user would like these devices to respond to.

Central Control Monitor

Roller pumps and centrifugal pumps can respond to events from the following devices, up to a maximum of 7 devices and 16 responses.

	Maximum number of connections to one pump
Level Detectors	1
Air Detectors	4
Pressure Sensors	4
Flow Sensors	1
Roller Pumps	5
Centrifugal Pumps	1

It is recommended that safety connections be established directly between individual devices and pumps to achieve the desired system response.

If using air detection, a safety connection to the primary pump is required. The pump response for the safety connection must not be No response.

If using level and/or pressure detection, Alarm and Alert safety connections from each to the primary pump is required. The pump response for the safety connections must not be No response.

A second pump can be designated as the backup pump. All the primary pump settings can be reassigned to the backup pump if needed. See **Perfusion Screen System tab, Reassign Module subtab** section for more details.

WARNING: When configuring a screen with multiple safety connections, the user must consider the risks and benefits of the additional complexity introduced to the operation of the system. It is possible to configure the system to have events that trigger responses, with the response being events that trigger more responses. The system response in these situations may be confusing to the user and could lead to delays in the user response or possibly errors.

Primary pump functionality and safety connections can be reassigned to other equipment in the event of a primary pump failure. Use the Reassign Module subtab within the System tab to reassign the primary pump to another pump of the same type. It is recommended that the user's fully test the screen configuration to assure that all responses in all situations are completely understood and proper training has taken place for users. The user's institution may find it helpful to establish protocols for handling specific situations that can occur with the screen configurations used. Refer to **System Overview** chapter, **Institutional Controls** section for additional guidance on establishing policies and procedures to control use of screen configurations.

WARNING: In the event the CCM is lost, only those sensors that have a safety connection to at least 1 roller pump or centrifugal control unit will be able to display messages on a local control panel. If no safety connection was established, no audible tone will sound and no messages will display on any local control panel. The only indication that an event has occurred will be the flashing LED on the affected module.

Events

Events that cause pump or occluder responses are communicated by the device generating the event to a connected roller pump, centrifugal control unit, or occluder. User actions may also generate some events such as decreasing the speed of a centrifugal pump to less than or equal to 1550 RPM which will generate a Coast event and initiate a response in a connected device. The communication may be sent only once, as in the case of a pump start or a pump stop, or sent multiple times, as is the case with alarm and alert, pump pause, min flow, and pump Coast events. Events that are sent multiple times must be cleared in order for the connected device to return to normal operational mode.

Central Control Monitor

Roller Pump Responses

Roller pump responses to events are Stop, Pause, Reduce Speed, Message Only, and No Response. In the situation that a pump response clears an event so that the event and the message are no longer present, check the Messages subtab within the Aux tab for additional information, if needed. If a safety tab opens, check the Aux tab for additional information, if needed.

A Stop response causes the pump speed to go to zero and the pump to enter stop mode. The pump must be restarted manually after the event is cleared or the safety system is disabled. If a Stop response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

Note: If a primary centrifugal pump and a cardioplegia roller pump are safety connected for the cardioplegia pump to stop when the centrifugal pump goes to Coast, the cardioplegia pump can be started during, for example, priming when the speed of the Sarns centrifugal pump remains below 1560 RPM (Capiox: 1310 RPM).

Once the Sarns centrifugal pump speed is increased to 1560 RPM (Capiox: 1310 RPM) or above, the safety connection between the two pumps is enabled and active at all centrifugal pump speeds. Thus, the cardioplegia pump cannot be started even if the Sarns centrifugal pump speed is then decreased to 1550 RPM (Capiox: 1300 RPM) or less since the safety connection is active.

To start the cardioplegia pump at a Sarns centrifugal pump speed less than 1560 RPM (Capiox: 1310 RPM) after the safety connection is enabled, the centrifugal pump must be temporarily stopped then restarted to disable the safety connection and then the cardioplegia pump can be started at any centrifugal pump speed.

A Pause response causes the pump speed to be temporarily reduced to zero. The speed remains at zero until the event is cleared or the safety system is disabled. The pump will then automatically start and return to the previous/original speed. If a Pause response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

A Reduce Speed causes the pump to reduce its speed by 10% every half second until the event is cleared and then the pump remains at this reduced speed. If the event persists and is not cleared, the pump will stop within 2 seconds once its speed is reduced to less than 4 RPM. Carefully monitor the pump speed whenever a Reduce Speed response has been executed.

A Message Only response causes a message about the event to be displayed on the pump control panel. There is no change in the pump speed.

If No Response is selected, then no safety connection is established between the device and the pump.

Sarns Centrifugal Pump Responses

Centrifugal Pump responses to events include Stop, Coast, Message Only, and No Response. In the situation that a pump response clears an event so that the event and the message are no longer present, check the Messages subtab within the Aux tab for additional information, if needed. If a safety tab opens, check the Aux tab for additional information, if needed.

A Stop response causes the pump speed to go to zero and the pump to enter stop mode. The pump must be restarted manually after the event is cleared or the safety system is disabled. If a Stop response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

A coast response causes the pump speed to go to 1500 RPM. If a Coast response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

<p>CAUTION: When a Stop response is employed with a centrifugal pump, it is highly recommended that a one-way valve to prevent retrograde flow in the arterial line be used in the cardiopulmonary bypass circuit.</p>

Central Control Monitor

If the Sarns centrifugal pump speed is 1560 RPM or above, a Coast response causes the pump speed to reduce to 1500 RPM. The Coast speed of 1500 RPM may be high enough to allow some forward flow or, in rare instances, may not be sufficient to prevent backflow based on the resistance and back pressure in the perfusion circuit. In addition, a Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds. After this brief lockout, the centrifugal pump speed can be adjusted even though the condition that initiated the Coast response still exists.

If the Sarns centrifugal pump speed is less than 1560 RPM, a Coast response does not cause the pump speed to change, however the lockout still occurs.

Adjust the RPMs by using the pump speed control knob on the centrifugal control unit or the control slide bar on the CCM to achieve a static or no-flow state. Monitor the speed closely whenever a Coast response has been executed. Return the pump to its previous setting when appropriate.

If a Coast response occurs before or after a Stop response, the triggers for both must be cleared before the pump can be restarted.

A Message Only response causes a message about the event to be displayed on the control unit front panel. There is no change in the pump speed.

If No Response is selected, then no safety connection is established between the device and the pump.

Capiox Centrifugal Pump Responses

Capiox centrifugal pump responses to events include Stop, Coast, Message Only, and No Response. In the situation that a pump response clears an event so that the event and the message are no longer present, check the Messages subtab within the Aux tab for additional information, if needed. If a safety tab opens, check the Aux tab for additional information, if needed.

A Stop response causes the pump speed to go to zero and the pump to enter stop mode. The pump must be restarted manually after the event is cleared or the safety system is disabled. If a Stop response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

CAUTION: When a Stop response is employed with a centrifugal pump, it is highly recommended that a one-way valve to prevent retrograde flow in the arterial line be used in the cardiopulmonary bypass circuit.

A Coast response causes the pump speed to go to 1250 RPM. If a Coast response is executed while the pump is in Servo mode or Pulse mode, the pump will switch to Continuous mode after it is restarted.

If the Capiox centrifugal pump speed is 1310 RPM or above, a Coast response causes the pump speed to reduce to 1250 RPM. The Coast speed of 1250 RPM may be high enough to allow some forward flow or, in rare instances, may not be sufficient to prevent backflow based on the resistance and back pressure in the perfusion circuit. In addition, a Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds. After this brief lockout, the centrifugal pump speed can be adjusted even though the condition that initiated the Coast response still exists.

If the centrifugal pump speed is less than 1310 RPM, a Coast response does not cause the pump speed to change, however the lockout still occurs.

Adjust the RPMs by using the pump speed control knob on the centrifugal control unit or the control slide bar on the CCM to achieve a static or no-flow state. Monitor the speed closely whenever a Coast response has been executed. Return the pump to its previous setting when appropriate.

If a Coast response occurs before or after a Stop response, the triggers for both must be cleared before the pump can be restarted.

Central Control Monitor

A Message Only response causes a message about the event to be displayed on the control unit front panel. There is no change in the pump speed. If No Response is selected, then no safety connection is established between the device and the pump.

Occluder Responses

An Occluder responds only to events from the primary pump.

The same occluder response must be selected for these centrifugal pump events: pump stop, pump Coast, and minimum flow. The system automatically assigns the response chosen for stop, Coast, or minimum flow to the remaining two events.

Occluder responses are Full Close, Full Open, Go to % Flow, and No Response.

A Full Close response causes the occluder to fully occlude the venous line. The occluder will remain fully closed until the event is cleared, unless the event is a pump start or pump stop. If the event is a pump start or pump stop, the occluder can still be adjusted through the control slide bar on the CCM.

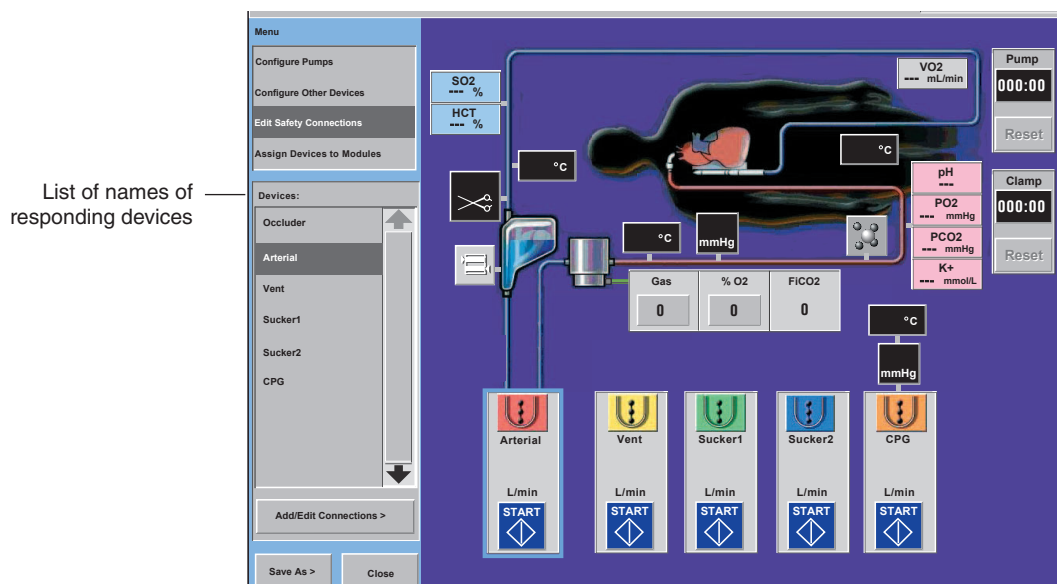
A Full Open response causes the occluder to fully unocclude the venous line. The occluder will remain fully open until the event is cleared, unless the event is a pump start or pump stop. If the event is a pump start or pump stop, the occluder can still be adjusted through the control slide bar on the CCM.

A Go to % Flow response causes the occluder to move to a position to provide the percentage of tube opening selected by the user. The occluder will remain in this position until the event is cleared, unless the event is a pump start or pump stop. If the event is a pump start or pump stop, the occluder can still be adjusted through the control slide bar on the CCM.

If No Response is selected, then no safety connection is established between the primary pump and the occluder.

Add/Edit Safety Connections

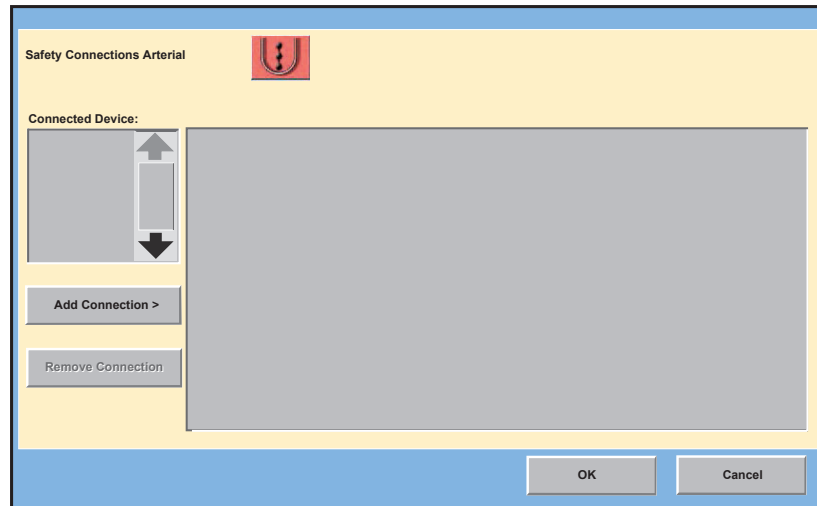
When Edit Safety Connections is selected, a list of the names of devices that can be set up to respond to an event through a safety connection appear.



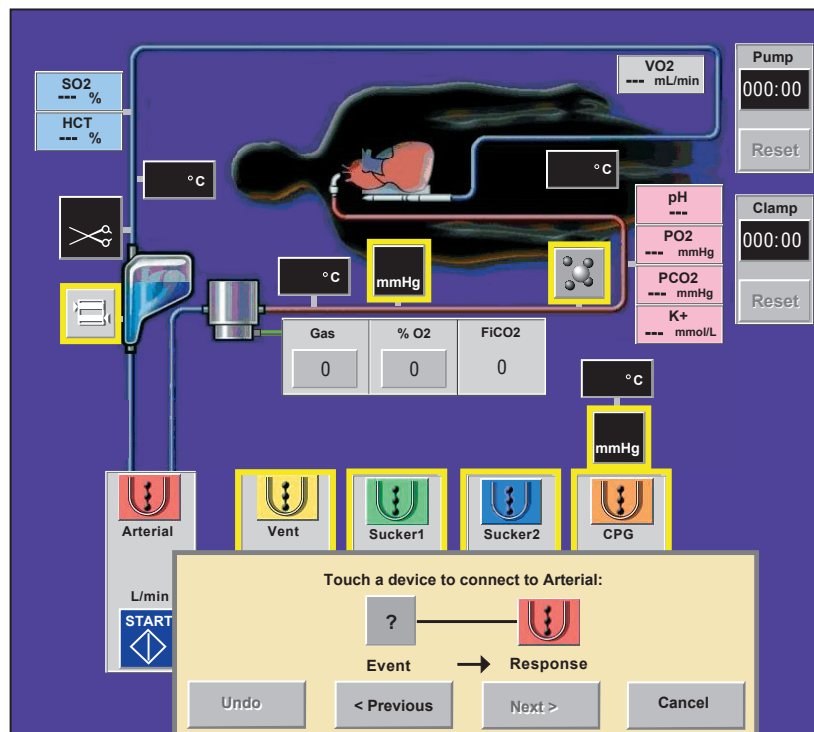
1. Touch the name of the device on the list, or the device icon on the graphic display to add or edit safety connections for that device.
- The name will be highlighted. The device chosen and any existing safety connected devices will be highlighted with a blue border.

Central Control Monitor

2. Touch the **Add/Edit Connections** button to add or edit the safety connections to the device selected.



- A screen appears which shows the safety connections for the selected device. A blank screen indicates that no safety connections are currently set.
3. Touch the **Add Connection** button to add a safety connection.



4. Select a device to connect to the responding device. The devices that can be connected to the responding device are highlighted by a yellow border.

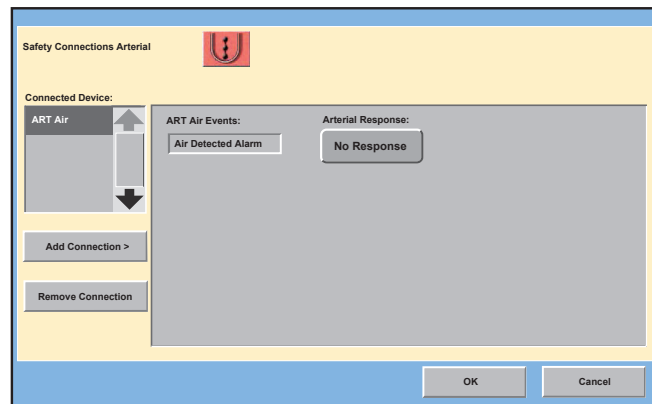
Note: Flow sensors placed on centrifugal pumps that are in the middle of the display will be covered by the screen above. The flow icon may need to be temporarily moved to another location on the graphic display in order to add or edit safety connections to the flow sensor.

Central Control Monitor

5. Select the device by touching the device icon. The border color will change to blue.
 - Touch **Undo** to release the current device and select a different device.
 - Touch **Previous** to view the preceding screen.
 - Touch **Cancel** to cancel the creation of the safety connection.
6. Touch **Next** to continue.

A screen appears showing the possible safety connections. The events associated with the chosen connected device are listed. Connected devices may be associated with more than one event. Select a response by touching the **Response** button to toggle through the choices. The response that is displayed on the button is the response of the pump or occluder for the specified event.

Note: If the response selected is No Response, then no safety connection will be made.



See the Connection Matrix at the end of this section for a list of events and responses.

Edit Safety Connections

Edit, Remove, or Cancel safety connections by selecting the device in the Connected Device list and then select the appropriate action button.

Touch the **Remove Connection** button to remove the selected connected device.

There is no confirmation of the connection being removed. Make sure that the device highlighted dark gray is actually the connection to be removed before touching the Remove Connection button. The device name will no longer appear in the Connected Device list.

Edit the connection by changing the response.

Cancel removes all the new safety connections made to the responding device.

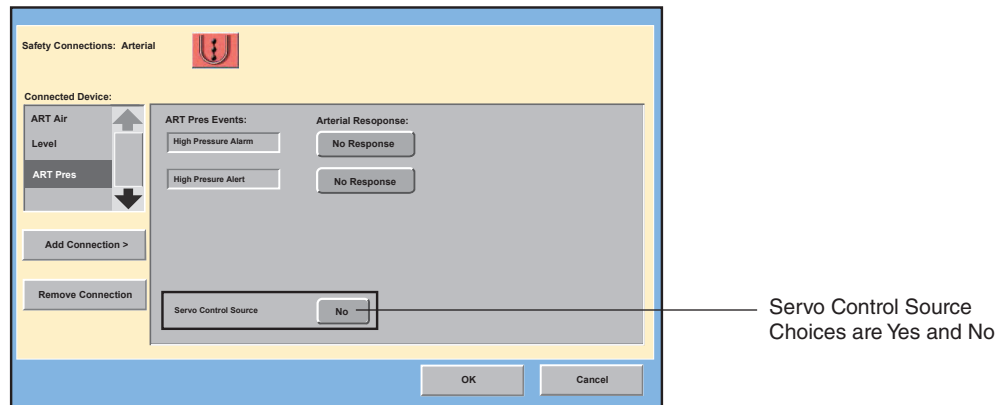
Touch the **OK** button to accept the safety connections that are listed.

Central Control Monitor

Set Servo Mode Connections

Roller pumps and centrifugal pumps can be configured to operate in Servo mode. In Servo mode, the pump speed is automatically regulated to maintain a selected pressure or flow setpoint.

To operate in Servo mode, the desired pressure or flow must be designated as a servo control source. Safety connections may also be established between the pump and the source pressure or flow.



To establish a pressure or flow as a Servo Control Source:

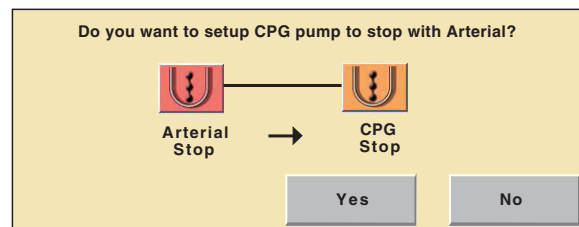
1. Create a safety connection between the pump and the desired pressure or flow source.
2. Touch the **Servo Control Source** button until the button displays Yes.
3. Select pump responses to pressure or flow events, if desired.
4. Touch the **OK** button when all servo control sources have been designated.

Setting a cardioplegia pump to stop with the primary pump

There are instances, such as using blood cardioplegia, when it is desirable to have the cardioplegia pump stop when the primary pump stops. After the cardioplegia pump is placed, the user will be asked if they want to setup the cardioplegia pump to stop with the primary pump.

If using a centrifugal primary pump the cardioplegia pump safety connection will not be active until the centrifugal pump speed has been raised above Coast. This supports priming the perfusion circuit at lower centrifugal pump speeds.

Choosing **Yes** will set the following safety connections:



Primary Pump	Primary Pump Event	Cardioplegia Pump Response
Roller	Stopped	Stop
	Started	No Response
	Paused	Stop
Centrifugal	Stopped	Stop
	Started	No Response
	Minimum Flow	No Response
	Coasting	Stop

Touch the **OK** button to accept the safety connections listed.

Central Control Monitor

Note: If the cardioplegia pump is configured to stop when the primary roller pump stops or pauses, a message that this has occurred will appear on local display of the cardioplegia pump. This message will remain on the local display for a short period of time after the event occurs.

CAUTION: The cardioplegia pump does not stop if the speed or flow of the primary roller pump is only decreased to 0 L/min or 0 RPM since the roller pump will not stop and deactivate at 0 L/min or 0 RPM.

Note: If the cardioplegia pump is configured to stop when the primary centrifugal pump stops or goes to Coast, a message that this has occurred will appear on local display of the cardioplegia pump. This message will remain on the local display for a short period of time after event occurs.

CAUTION: The cardioplegia pump does stop if the speed or flow of the primary centrifugal pump is decreased to 0 L/min or 0 RPM since the centrifugal pump will stop and deactivate at 0 L/min or 0 RPM.

Connection Matrix

Events	Occluder Response	Roller Pump Response	Centrifugal Response
Low Level Alarm	Not Applicable	No Response Stop Pause Reduce Speed Message Only	No Response Stop Coast Message Only
Low Level Alert	Not Applicable	No Response Pause Reduce Speed Message Only	No Response Coast Message Only
Air Detected Alarm	Not Applicable	No Response Stop Pause Message Only	No Response Stop Coast Message Only
High Pressure Alarm	Not Applicable	No Response Stop Pause Reduce Speed Message Only	No Response Stop Coast Message Only
High Pressure Alert	Not Applicable	No Response Pause Reduce Speed Message Only	No Response Coast Message Only
Back Flow Detected Alarm	Not Applicable	No Response Stop Pause Message Only	No Response Message Only
Primary Roller Pump Stopped	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Primary Roller Pump Started	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only

Central Control Monitor

Events	Occluder Response	Roller Pump Response	Centrifugal Response
Primary Roller Pump Paused	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Message Only	No Response
Roller Pump Stopped	Not Applicable	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Roller Pump Started	Not Applicable	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Roller Pump Paused	Not Applicable	No Response Stop Message Only	No Response
Primary Centrifugal Stopped	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Primary Centrifugal Started	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Primary Centrifugal Minimum Flow	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Primary Centrifugal Pump Coasting	No Response Full Open Full Close Go to Flow 0%-100%	No Response Stop Message Only	No Response
Centrifugal Pump Stopped	Not Applicable	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Centrifugal Pump Started	Not Applicable	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Centrifugal Mimimum Flow	Not Applicable	No Response Stop Reduce Speed Message Only	No Response Stop Coast Message Only
Centrifugal Pump Coasting	Not Applicable	No Response Stop Message Only	No Response

Central Control Monitor

Assign Devices to Modules

The pumps and devices configured in the Perfusion Screen must be assigned to the corresponding physical components on the system base.

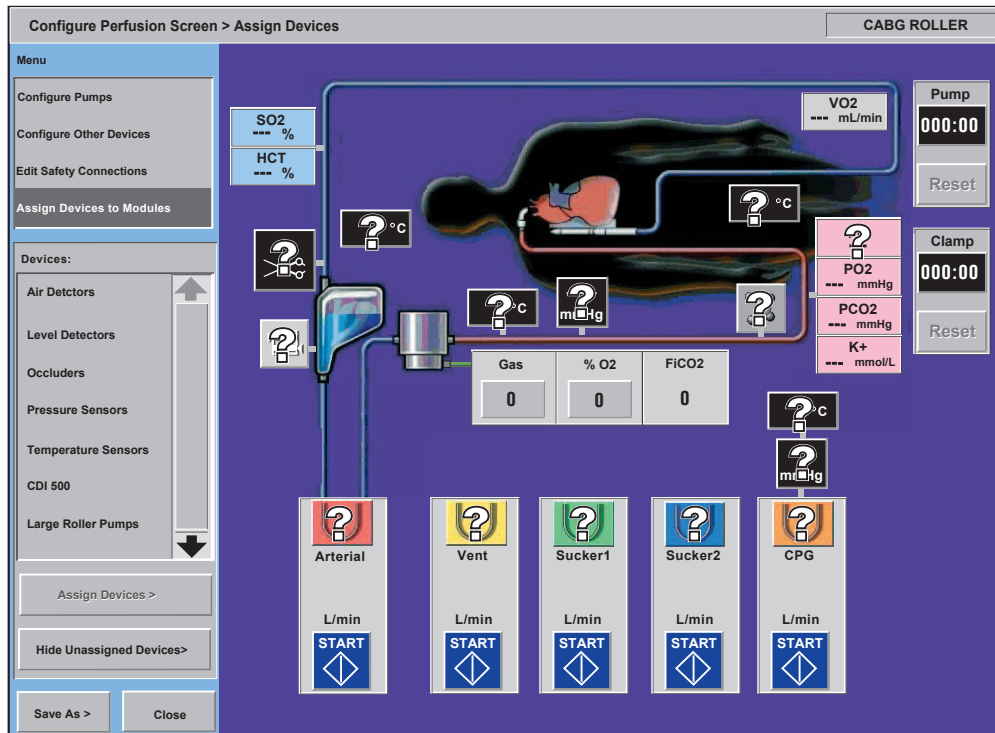
All components must be connected to the system base before they can be assigned.

Select **Assign Devices to Modules** button and the configured pumps and devices appear in the Devices list.

Touch the **Show Unassigned Devices** button to mark each unassigned device and pump in the graphic display with a question mark.

Touch the **Hide Unassigned Devices** button to make the question marks disappear.

Assign Devices by selecting the device type from the list and then touch the **Assign Devices** button.



Central Control Monitor

Assign Air Detectors, Level Detectors, Occluders, Flow Sensors, and CDI

Select device type.

Touch the **Assign Devices** button.

Assign Configuration Device to Physical Module: Air Detectors

1. On the base, locate the module with the green flashing light.

Assigned Device:

Go to Next Module

2. To assign a configuration device to a physical module:
Touch the device in the unassigned list, then touch the 'Assign' button.

Unassigned:

ART Air

Assign >

< Unassign

Assigned:

3. To assign another Air Detector device:
Touch the 'Go to Next Module' button and repeat from step 1.

OK Cancel

- 1. On the base, locate the module with the green flashing light.**
If there is only one device of the type selected on the system base, there will only be one module with a flashing light. If there is more than one device of the type selected on the system base, touch the **Go To Next Module** button until the desired module is flashing.
- 2. To assign a configuration device to a physical module, touch the device in the unassigned list, then touch the 'Assign' button.**
The device name will move from the Unassigned list to the Assigned list. The device name also appears in the Assigned Device box in the top section of the screen.

Devices that appear in the Assigned list may be unassigned by touching the name of the device and then touching the **Unassign** button. The device name moves from the Assigned list to the Unassigned list and disappears from the Assigned Device box. In order to assign a device that has been previously assigned to a different module, it must first be unassigned, and then reassigned.
- 3. To assign another device of the same type, touch the 'Go To Next Module' button and repeat from step 1.**
Continue until all devices of the same type on the graphic display have been assigned to physical modules on the system base. Once the assignments are complete, touch the **OK** button.

Central Control Monitor



Assign Pressure and Temperature Sensors


Select device type.

Touch the **Assign Devices** button.



Assign Configuration Device to Physical Module: Pressure Sensors



1. On the base, locate the module with the green flashing light. Select 'Channel 1' or 'Channel 2'.

Channel 1  Assigned: 

Channel 2  Assigned:

2. To assign a configuration device to the selected channel: Touch the device in the unassigned list, then touch the 'Assign' button. Repeat the process for the other channel.

Unassigned: ART Pres, CPG Pres   Assign > < Unassign

Assigned:  

3. To assign another Pressure Sensor device: Touch the 'Go to Next Module' button and repeat from step 1.

OK Cancel

1. **On the base, locate the module with the green flashing light. Select 'Channel 1' or 'Channel 2'.**

If there is only one device of the type selected on the system base, there will only be one module with a flashing light. If there is more than one device of the type selected on the system base, touch the **Go To Next Module** button until the desired module is flashing. Select the appropriate channel. Channel 1 on a pressure module is marked with the green label and Channel 2 is marked with the yellow label. Channel 1 on a temperature module is marked with a blue label and Channel 2 is marked with a red label. Make sure that the sensor cable for the sensor being assigned is connected to the channel selected.

2. **To assign a configuration device to the selected channel, touch the device in the unassigned list, then touch the 'Assign' button. Repeat the process for the other channel.**

The device name will move from the Unassigned list to the Assigned list. The device name appears in the box labeled Channel 1 or Channel 2 in the top section of the screen.


Devices that appear in the Assigned list may be unassigned by touching the name of the device and then touching the **Unassign** button.


Central Control Monitor

The device name moves from the Assigned list to the Unassigned list and disappear from the Assigned box in the top of the screen. In order to assign a device that has been previously assigned to a different module, it must first be unassigned, and then reassigned.

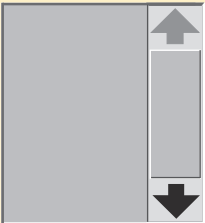
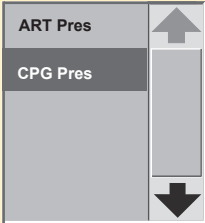
Assign Configuration Device to Physical Module: Pressure Sensors

1. On the base, locate the module with the green flashing light. Select 'Channel 1' or 'Channel 2'.

Channel 1  Assigned: ART Pres Go to Next Module

Channel 2  Assigned: CPG Pres

2. To assign a configuration device to the selected channel:
Touch the device in the unassigned list, then touch the 'Assign' button.
Repeat the process for the other channel.

Unassigned:  Assign >  Assigned:

3. To assign another Pressure Sensor device:
Touch the 'Go to Next Module' button and repeat from step 1.

OK Cancel

3. To assign another device of the same type, touch the 'Go To Next Module' button and repeat from step 1.

Continue until all devices of the same type on the graphic display have been assigned to physical modules on the system base. Once the assignments are complete, touch the **OK** button.

Central Control Monitor

Assign Roller Pumps and Centrifugal Control Units

Select device type.

Touch the **Assign Devices** button. Assignment screen will appear.

Assign Configuration Device to Physical Module: Large Roller Pumps

1. On the base, locate the pump display with the flashing label.

Assigned Device:

2. To assign a configuration pump to a physical module:
Touch the device in the unassigned list, then touch the 'Assign' button.

Unassigned:

Assigned:

2. To assign another Large Roller Pump:
Touch the 'Go to Next Module' button and repeat from step 1.

- 1. On the base, locate the pump display with the flashing label.**
The label is the module ID number in the upper left corner of the pump display. If there is only one pump of the type selected on the system base, there will only be one pump with a flashing label. If there is more than one device of the type selected on the system base, touch the **Go To Next Module** button until the desired pump label is flashing.
- 2. To assign a configuration pump to a physical module, touch the device in the unassigned list, then touch the 'Assign' button.**
The device name will move from the Unassigned list to the Assigned list and appears in the Assigned Device box in the top section of the screen.

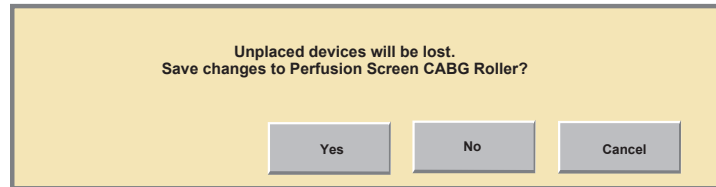
Pumps that appear in the Assigned list may be unassigned by touching the name of the pump and then touching the **Unassign** button. The pump name will move from the Assigned list to the Unassigned list and disappear from the Assigned Device box in the top section of the screen. In order to assign a pump that has been previously assigned, it must first be unassigned, and then reassigned.
- 3. To assign another device of the same type, touch the 'Go To Next Module' button and repeat from step 1.**
Continue until all pumps on the graphic display have been assigned. Once the assignments are complete, touch the **OK** button.

Central Control Monitor

Save a Perfusion Screen

To save an existing Perfusion Screen under a different name, touch the **Save As** button. Enter the new name of the Perfusion Screen using the keyboard.

To save a Perfusion Screen under the current name, touch the **Yes** button.

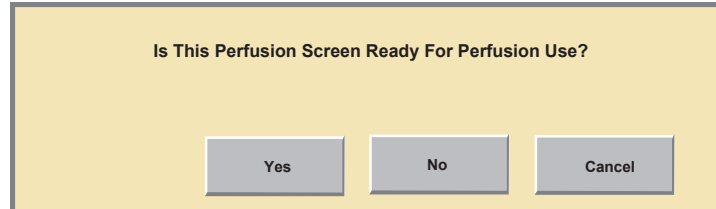


Touch **No** to keep the Perfusion Screen the same as it was before changes were made. Touch **Cancel** to keep the screen open.

All configured devices must be assigned and required safety connections must be made in order for a Perfusion Screen to be designated Ready for Use. If all devices are not assigned or required safety connections are not made, a message window will be displayed. The window will contain messages describing the conditions that have not been met.

Once all devices have been assigned and required safety connections have been made, the configuration may be designated ready for use.

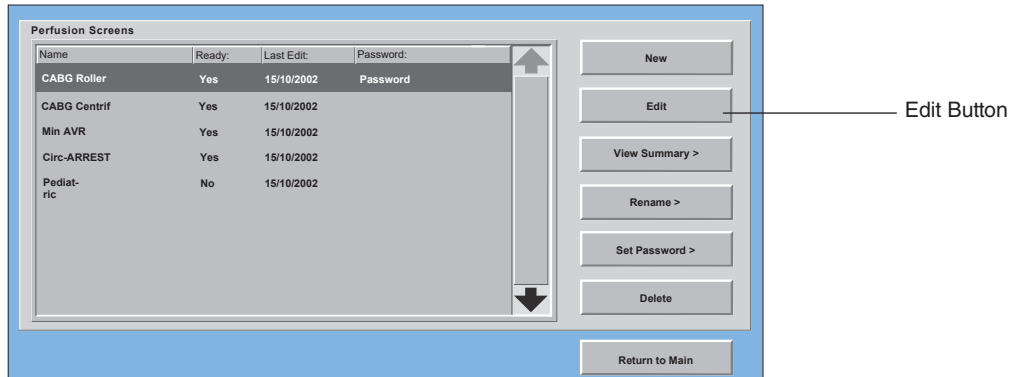
Choose **Yes** and the name of the Perfusion Screen will appear on the list of Perfusion Screens available for use.



Central Control Monitor

Edit a Perfusion Screen

To change an existing Perfusion Screen, select the Perfusion Screen from the list and touch the **Edit** button.



Add, Edit, Place, and Remove

Use the **Add**, **Edit**, **Place**, and **Remove** buttons to make changes to the pumps and devices. Select the component by touching its name on the list. Primary pumps may only be edited; they may not be removed and their position in the graphic display cannot be changed. Devices may be added up to a maximum of 24 components, including 6 pumps in each Perfusion Screen.

Edit is used to change the cardioplegia or backup designation of a pump, the name of the pump, and the color of the pump. If the pump type must be changed, remove the existing pump, and add a new pump of the correct type to the configuration. Edit is also used to change the name of the device, the color of the device, and properties of the devices such as pressure and temperature limits.

Place is used to change the location of the pump or device on the graphic display. Locations for the primary pump, the CDI devices, and Pump and Clamp timers are fixed and cannot be changed.

Remove is used to remove a pump or device from the graphic display. The primary pump cannot be removed.

Central Control Monitor

View Summary, Rename, Set Password, and Delete

View Summary

The summary screen displays information about the selected Perfusion Screen. The name of the Perfusion Screen, graphic orientation, type of venous reservoir, devices included in the Perfusion Screen, and the assigned names of the devices are displayed. Also included is information about the pumps, such as type, name, and any safety connections between the pumps and the other configured devices.

To view a Perfusion Screen Summary:

1. Touch the Perfusion Screen name.
2. Touch the **View Summary** button.
3. To exit the summary screen, touch the **Close** button.

The image shows a screenshot of the 'Perfusion Screen Summary' interface. At the top, there is a title bar with 'Perfusion Screen Summary' on the left and 'CABG ROLLER' in a button on the right. The main content area has a yellow background and lists several categories of settings: 'Graphic Orientation' (Primary Pump Left - Patient Head Left), 'Blood Reservoir Type' (Open), 'Air Detectors' (ART Air), 'Level Detectors' (Level), 'Occluders' (Occluder), 'Pressure Sensors' (ART Pres, CPG Pres), 'Temperature Sensors' (ART Temp, VEN Temp, CPG1Temp, CPG2Temp), 'CDI 500' (CDI 500), and 'Large Roller Pumps' (Arterial). A vertical scrollbar is on the right side of the list. At the bottom center, there is a 'Close' button.

Rename

To rename a Perfusion Screen, touch the Perfusion Screen name and then touch the Rename button. Use the keyboard to enter the new name.

Set Password

To password protect a Perfusion Screen, touch the Perfusion Screen name and then touch the **Set Password** button. Use the keyboard to enter the password.

Central Control Monitor

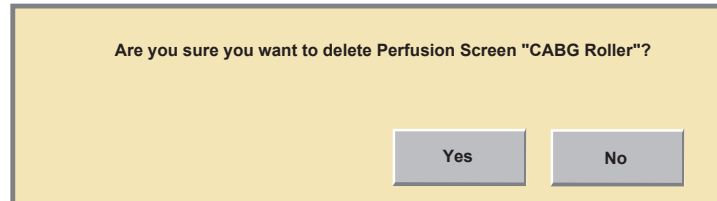
Delete

To delete a Perfusion Screen from the CCM, touch the Perfusion Screen name and then touch the **Delete** button.

A confirmation window will be displayed to allow the user to confirm or cancel the deletion.

Choose **Yes** to delete the Perfusion Screen.

Touch **No** to keep the Perfusion Screen in the CCM.



Return to Main Screen

Touch the **Return to Main** screen button to return to the Main Screen.

This page intentionally left blank.

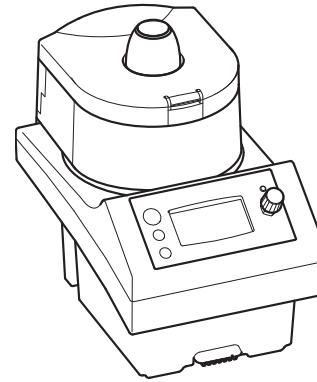
Roller Pumps

Features

The roller pump is used to move fluids through the cardiopulmonary bypass circuit and can be used for a number of applications including arterial blood pumping, cardioplegia delivery, suction, and venting.

The Advanced Perfusion System 1 offers two roller pump sizes - a large pump and a small pump.

- The large roller pump is a peristaltic pump with a 6 inch (15 cm) diameter raceway. It can accommodate applications requiring flow rates up to 10 L/min including arterial, cardioplegia, vent, and suction pumping. Because of the 6 inch diameter raceway, the large roller pump is appropriate for high flow and large single tubing applications. See the **Select Tubing** section in this chapter for allowable tubing sizes.
- The small roller pump is a peristaltic pump with a 4 inch (10 cm) diameter raceway. It can accommodate applications requiring flow rates up to 4 L/min including arterial, cardioplegia, vent, and suction pumping. Because of the 4 inch diameter raceway, the small roller pump is appropriate for low flow and dual-sized tubing applications. See the **Select Tubing** section in this chapter for allowable tubing sizes.



All pumps can be mounted on the system base or on a pole. The pump can be plugged into one of the 6 pump connections on the base or into any of the base module connections.

A variable, insertless tube clamp mechanism accommodates a variety of tubing sizes, including dual tube sets. The pump raceway can be repositioned and locked in 15 degree increments for placement of tubing to reduce its length. The occlusion mechanism allows the user to adjust the position of the rollers at any time, including when the pump is rotating. An audible feedback mechanism provides a series of clicks whenever the occlusion is being adjusted.

Pumps have a front panel display which indicates the selected tube size or RPM, direction of pump rotation, pump speed, flow rate, and safety, status, and error messages.

The pump can be controlled from the pump speed control knob or from the pump control slide bar on the Central Control Monitor (CCM).

Roller Pumps

In the Configuration area of the Central Control Monitor, a roller pump can be designated as primary, backup, cardioplegia, master, follower, or none. Each of these has unique functionality as described in the table below.

Function	CCM Features	Unique Functionality
Primary	<ul style="list-style-type: none">• Dedicated pump slide bar• Choice of RPM or L/min, L/min/m² or mL/kg/min display	<ul style="list-style-type: none">• Pulse mode* operation• Initiate a response in a connected occluder
Backup		<ul style="list-style-type: none">• Primary pump functionality can be reassigned to a pump of the same or different type.
Cardioplegia	<ul style="list-style-type: none">• Shared slide bar• CPG tab tracks time and volume of cardioplegia delivery	<ul style="list-style-type: none">• Automatic cardioplegia dose delivery
Master	<ul style="list-style-type: none">• Master and follower controls and data displayed in one control box	<ul style="list-style-type: none">• Master slide bar controls follower pump speed• Display total volume from master and follower pumps
Follower	<ul style="list-style-type: none">• Master and follower controls and data displayed in one control box	<ul style="list-style-type: none">• Follower slide bar controls master/follower pump ratio• Tracks master

*The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

When operating a device that shares a slide bar location, make sure that the slide bar displayed is for the device you intend to operate. The device name should appear at the top of the slide bar and the corresponding color should appear on the central strip and scroll control.

When a roller pump is designated as the primary pump, the system provides the capability to operate the pump in Pulse mode. In this mode, the user can select the pulse parameters for the Base, Width, and Rate and initiate pulse operation from the Central Control Monitor.

The system provides the capability to automatically regulate the roller pump speed to maintain a selected pressure or flow setpoint. This is known as Servo mode. In this mode, the user selects a pressure or flow source and initiates servo operation on the Central Control Monitor. Once in Servo mode, the servo setpoint can be changed by adjusting the pump speed control knob or using the pump control slide bar on the Central Control Monitor.

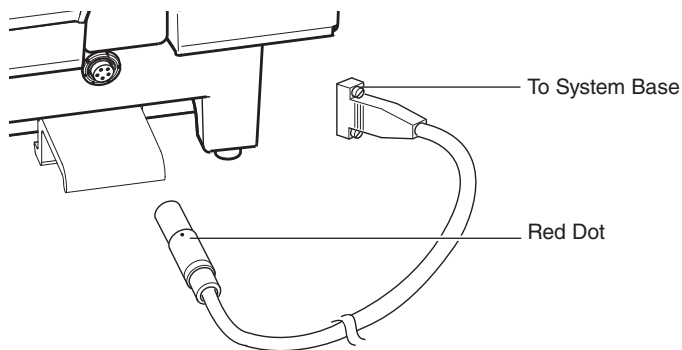
Safety connections such as air detection, level detection, and pressure monitoring are configured using the Configuration area on the Central Control Monitor. Pump responses to alerts and alarms are user selectable. Valid responses for roller pumps are Stop, Pause, Reduce Speed, Message Only, or No Response. The local display will display a message indicating the event from a connected device.

Roller Pumps

Installation and Connection

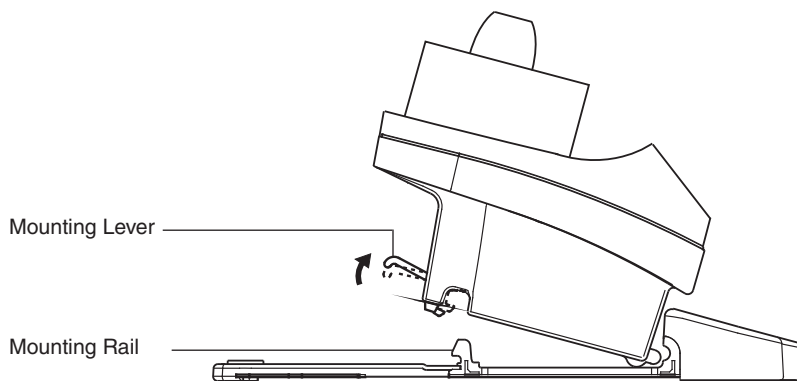
Pump Cable

Connect the pump cable to the receptacle located on the back of the roller pump. Align the red dot on the pump cable connector with the red dot on the pump receptacle. Insert the connector into the receptacle; an audible click indicates that the connector is fully seated in the receptacle. Pull gently on the cable to verify a secure connection.



Base Mounting

Ensure the mounting lever is in the up position. Grasp roller pump firmly with two hands. Tilt pump forward and insert the mounting tab into the front mounting base. Lower the rear of the pump onto the mounting rail. Ensure the mounting lever clicks into place and the pump is secure on the rail.



Roller Pumps

Sliding Back Cover Panel Kit

If a full complement of pumps is not installed across the width of the base, the opening to the cable management area is exposed in each vacant pump space. To cover this opening, protect the area from dust and spills, and hide the wiring and cabling from view, use the appropriate sized cover from the Sliding Back Cover Panel Kit.

To install a sliding back cover panel:

1. Remove the cable cover.
2. Remove the module cover from the side of the base closest to the empty pump space.
3. Loosen the set screws on the endcap. Some modules may need to be removed to access the set screws.
4. Slide the endcap out.
5. Slide the 2 rail slides onto the mounting rail.
6. Position the appropriate sized cover panel on the rail slides. Secure the cover panel to the rail slides with the 2 screws.
7. Install the set screw through the cover panel and rail slide to secure the cover panel to the mounting rail.
8. Slide the endcap back into position and tighten the set screws. Install any removed modules.
9. Install the module cover and the cable cover.

If the empty space occurs between pumps, the pumps may need to be removed in order to install a cover panel into the appropriate place.

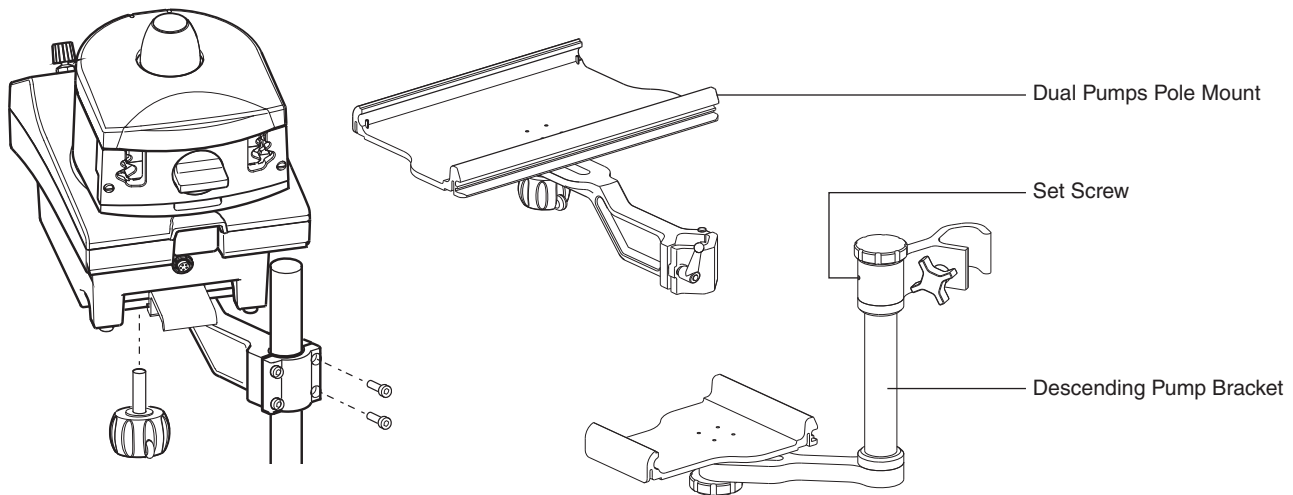
Roller Pumps

Pole Mounting

Select the desired pole position and secure the mounting arm to the pole. Select the desired plate position and secure plate. Ensure the pump mounting lever is in the up position. Grasp roller pump firmly with two hands. Tilt pump forward and insert the mounting tab into the front of the mounting plate. Lower the rear of the pump onto the plate ensuring that the mounting lever clicks into place.

If using the Descending Pump Bracket, make sure to tighten the set screw to lock the bracket securely in position.

Note: Ensure pole mounted pump can be hand cranked without interference from poles or other devices. Ensure pole mounted pumps do not interfere with hand cranking other pumps. Ensure that the Descending Pump Bracket does not impede movement around the base.

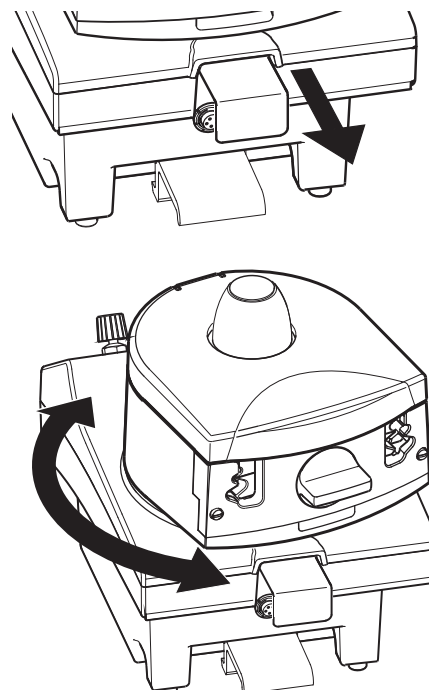


Rotating the Raceway

The roller pump raceway can be rotated for placement of tubing to reduce tubing length. The raceway can be positioned $\pm 90^\circ$ from the center position in 15° increments. To change the raceway position, locate the spring-loaded lever on the rear of the pump. Pull the lever away from the pump housing.

Keeping the lever pulled, rotate the pump raceway to the desired position. Release the lever and rotate the pump raceway until the lever locks into place. The raceway should now be fixed.

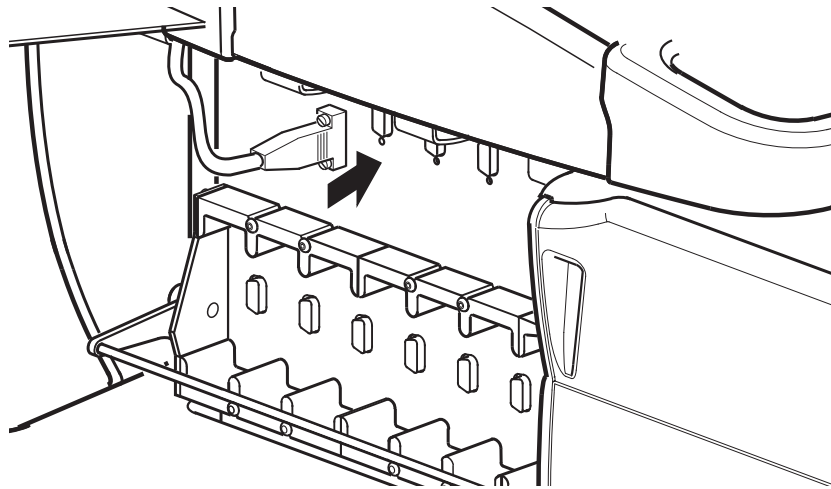
Ensure the raceway is locked in place before operating the roller pump.



Roller Pumps

System Connection

Route and arrange the pump cable to minimize exposure to spills. With a clear view of the desired pump or module connection, carefully connect the pump cable to one of the system pump connections on either side of the system base or, if necessary, to any of the system module connections. Do not use excessive force to seat the connector and make sure not to bend the connector pins. Tighten screws to secure the connection.



Standoffs are included in the accessories kit. Two standoffs must be installed on a module receptacle to securely fasten a pump cable or a flowmeter cable to the module receptacle. Only a pump power cable or flowmeter power cable can be inserted into a receptacle which has the standoffs installed. Modules cannot be inserted into a module receptacle when standoffs are installed.

Roller Pumps

Installing Tubing

WARNING: Tubing must not be reversed in the pump head as air embolism may occur.

WARNING: Make sure tubing is properly aligned before closing tube clamp.

WARNING: The pump must be in Stop mode during tubing installation as accidental starting of the pump could injure the operator and may damage the tubing or the pump.

WARNING: Use only medical grade PVC or medical grade silicone tubing specified for this system with a minimum pressure rating of 45 psi.

WARNING: Improperly installing tubing can cause Pump Jam errors. See **Insert Tubing in the Pump** section.

Note: It is recommended that an arterial line filter or similar air barrier device be used in the extracorporeal circuit.

Select Tubing

Use flexible medical grade polyvinyl chloride (PVC) or medical grade silicone tubing that is appropriately indicated by the tubing manufacturer for use in roller pumps. Note that silicone tubing has been tested only as a roller pump boot (the tubing placed within the roller pump).

For a large roller pump, select tubing with a maximum outer diameter of 11/16 in. (17,5 mm) and wall thickness range of 1/16-3/32 in. (1,6-2,4 mm). For a small roller pump, select tubing with a maximum outer diameter of 9/16 in (14,3 mm) and wall thickness range of 1/16-3/32 in. (1,6-2,4 mm). A nominal durometer range of 65-70 Shore A is recommended.

Verify that the tubing meets any additional specifications listed for specific features, such as checking that the tube size is appropriate for the air sensor being used.

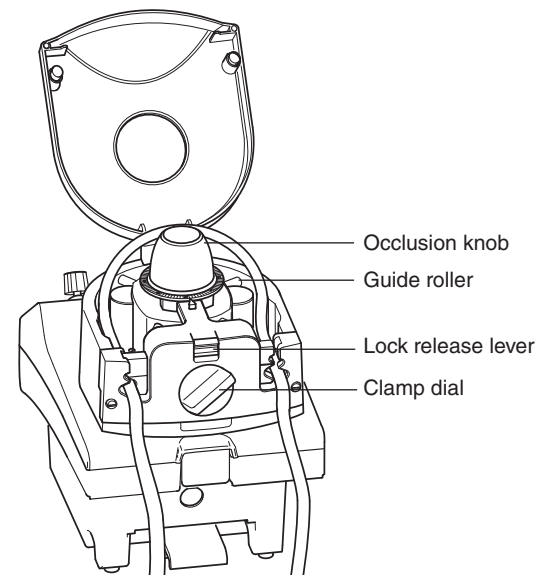
Insert Tubing in the Pump

Determine whether the pump will be used for suction or perfusion. Verify that the default forward direction for each pump matches the system direction by checking the circular arrow on the pump control panel. To change the roller pump default forward direction, see the **Change Pump Default Direction** section.

- For perfusion, install the tubing with the cannula on the outlet side of the pump head when the pump operates in FORWARD.
- For suction, install the tubing with the suction tip on the inlet side of the pump head when the pump operates in FORWARD.

To insert tubing:

1. With the pump in Stop mode, lift the pump safety cover.
2. Turn the occlusion knob clockwise until the space between the pump raceway and the rollers will accommodate the tubing.
3. Position the pump section of the tubing above the pump head so that it follows the curve of the raceway.
4. Turn the universal tube clamp dial until the inlet side mechanism locks open.



Roller Pumps

5. Insert the tubing and lift the lock release lever to release the dial. Make sure the tubing is secured in the grooves of the universal tube clamp mechanism.
6. Feed the tubing between the guide rollers while rotating the pump by hand or with the hand crank and position the tubing in the outlet side of the universal tube clamp mechanism.
7. Adjust the tubing in the pump head so that there is little to no gap between the tubing and the pump raceway. A gap exceeding 1/16 in. (1,6 mm) should be avoided.
8. Repeat Steps 4 and 5 for the outlet side mechanism.
9. Check that the tubing is held securely by pulling it lightly. See that the tubing is not twisted within the pump head and that it fits smoothly along the raceway.
10. Close the pump safety cover.

Tube Clamp Minimum and Maximum Chart

The following chart shows both the minimum and maximum size tubes that will fit into the slides of the universal tube clamp.

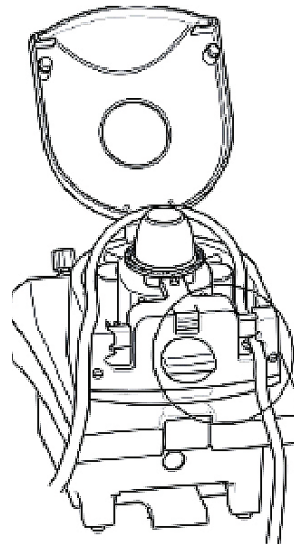
Large Clamp	Minimum	Maximum
Upper	0.089 in. (2,3 mm) I.D. x 1/16 in. (1,6 mm) wall	1/4 in. (6,4 mm) I.D. x 1/16 in. (1,6 mm) wall
Lower	1/4 in. (6,4 mm) I.D. x 1/16 in. (1,6 mm) wall	1/2 in. (12,7 mm) I.D. x 3/32 in. (2,4 mm) wall
Small Clamp	Minimum	Maximum
Upper	0.089 in. (2,3 mm) I.D. x 1/16 in. (1,6 mm) wall	1/4 in. (6,4 mm) I.D. x 1/16 in. (1,6 mm) wall
Lower	1/4 in. (6,4 mm) I.D. x 1/16 in. (1,6 mm) wall	3/8 in. (9,5 mm) I.D. x 3/32 in. (2,4 mm) wall

Confirm the Tube Clamp Functionality

Confirm the proper operation of the tube clamp mechanism by turning the tube clamp dial half the distance of its travel and observe the sliding movement of the upper and lower tube clamp slides on each side of the tube clamp mechanism. If the tube clamp slides retract, the tube clamp is functioning properly.

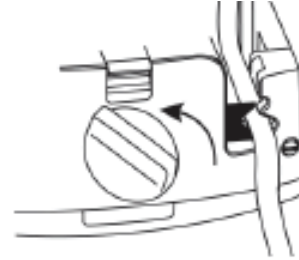
Removing Tubing In Case of Tube Clamp Functionality Issue

1. If the lower tube clamp slide mechanism does not retract, change out the roller pump.
2. To change out the roller pump:
 - a) Remove the tubing from the unaffected side of the tube clamp mechanism.



Roller Pumps

- b) Retract the upper tube clamp slide into the housing on the affected side by turning the tube clamp dial to open.



- c) Grasp the tubing on both sides of the broken tube clamp slide and force the tube clamp slide open toward the center of the tube clamp.



- d) Hold the slide open and apply an upward, twisting force to the tubing in the failed lower tube clamp slide mechanism. Remove the tubing.



3. Replace and reassign the roller pump. See **Emergency Procedures** chapter, **Equipment Situations/Pump Failure** section for instructions. Assure proper operation of all safety connections assigned to the roller pump.
4. Follow the same instructions if the tube clamp failure is observed during unexpected return to bypass that requires the urgent replacement of the perfusion circuit.
5. If a broken tube clamp mechanism is detected, contact Terumo Customer Service.

Roller Pumps

Setting Occlusion

The roller pump occlusion mechanism is used to adjust the position of the rollers with respect to the pump raceway. The occlusion knob can be adjusted while the roller mechanism is rotating. Turning the occlusion knob in a clockwise direction draws the roller assembly away from the pump raceway; turning the occlusion knob counterclockwise pushes the roller mechanism out toward the pump raceway. An audible clicking mechanism indicates adjustment of the occlusion setting. On average, every ten clicks indicates a change of approximately 0.0035 in. (0.0889 mm) to the occlusion setting.

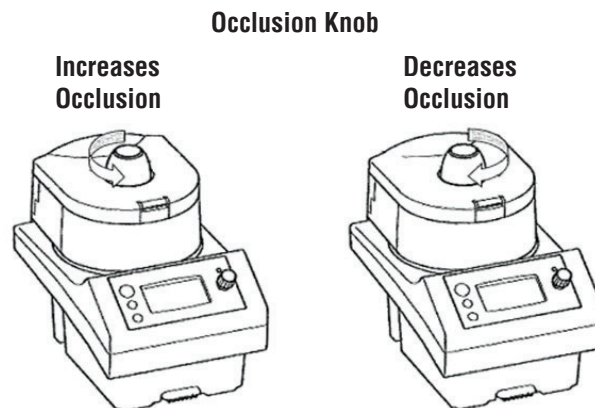
Make sure the occlusion knob caps are in place during use. The cap protects the occlusion knob mechanism against entry of liquid or other foreign objects which may damage the mechanism. The cap can be removed in the event a hand crank needs to be installed.

WARNING: Occlusion must be set by moving the rollers toward the pump raceway in order to take up any free play in the mechanism. Do not adjust occlusion by moving the rollers away from the raceway as under-occlusion may result.

Set the occlusion before each use with the actual tubing to be used. Proper occlusion will vary with each tubing section, due to variations in the wall thickness of the tubing. Rotate the rollers around the raceway several times as tubing will occlude differently after being compressed. Improper occlusion settings can affect the tube life and flow rate and cause blood trauma.

CAUTION: Avoid over-occluding the tubing as over-occlusion may result in a Pump Jam or Belt Slip condition. This is especially important when using dual tubing sets where different inside diameters and variations in wall thickness of the tubes may result in a tendency to over-occlude. Correct the Pump Jam or Belt Slip condition to clear any error or alert message and then continue setting proper occlusion.

CAUTION: Before using the Roller Pump, familiarize yourself with the occlusion mechanism. Counterclockwise rotation increases occlusion and clockwise rotation decreases occlusion.



WARNING: If tubing is improperly installed or over-occluded when using a roller pump for arterial delivery, a Pump Jam condition may occur. A Pump Jam condition causes the pump to stop.

Roller Pumps

See the **Resolving Pump Jam** section for instructions regarding Pump Jam errors.

If an unexpected pump stop occurs when the pump is used for arterial flow, a temporary interruption in arterial blood flow will occur. A number of variables influence patient risk including the duration of the pump stop, the patient's status, and the patient's temperature.

WARNING: If tubing is improperly installed or over-occluded when using a roller pump for cardioplegia delivery, a Pump Jam condition may occur. A Pump Jam condition causes the pump to stop.

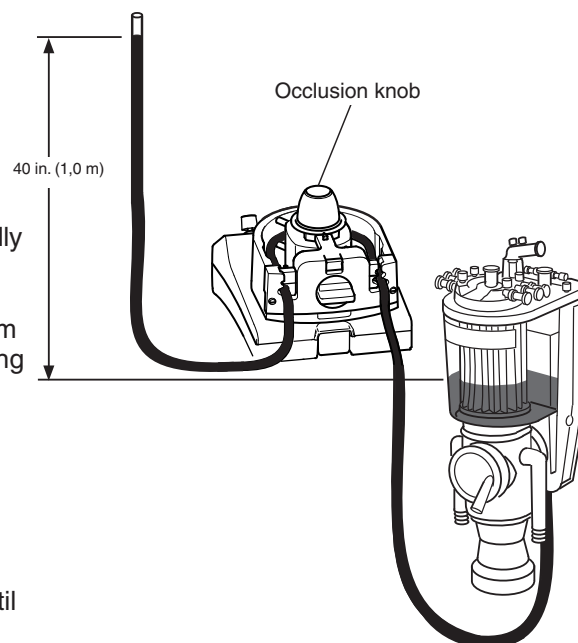
See the **Resolving Pump Jam** section for instructions regarding Pump Jam errors.

If an unexpected pump stop occurs when the pump is used for cardioplegia delivery, the delivery of a dose of cardioplegia may be delayed. The risk to patient is difficult to determine because of the number of variables attendant during cardioplegia delivery, including, but not limited to, surgeon technique, type of procedure, time since last dose, type and temperature of cardioplegia solution, condition of the myocardium, and other patient co-morbidities. Inadequate myocardial protection may result in various levels of myocardial dysfunction.

CAUTION: Do not adjust the rollers of the occlusion mechanism past the limits of its travel (which, when reached, is indicated by increased resistance on the occlusion knob) as this may over-tighten the occlusion mechanism and prevent its release. If the occlusion mechanism is over-tightened (in either direction) and cannot be released by turning the occlusion knob in the opposite direction, then use another pump and call for service.

To set the pump occlusion:

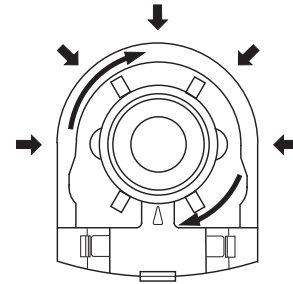
1. Turn the occlusion knob counterclockwise until the tube is compressed against the pump raceway.
2. Place the inlet of the tubing into a container of crystalloid priming solution. Hold the outlet end vertically above the pump head. Using the hand crank, pump a column of solution up the tubing until the bottom of the column's meniscus in the tubing is 40 in. (1,0 m) above the top of the pump's roller head.
3. With one roller occluding the tubing, turn the occlusion knob clockwise allowing the solution level to drop.
4. While the level drops, turn the occlusion knob counterclockwise until the rate of fall is approximately 1 in. (2,5 cm) per minute.
5. If the rate of fall is slower than approximately 1 in. (2,5 cm) per minute, turn the occlusion knob one revolution clockwise to back the rollers away from the raceway and start again.



Roller Pumps

To check the occlusion along the raceway:

1. Move the roller to several positions along the pump raceway, stopping at 45° increments.
2. Check the rate of fall within the tube at each position.
3. Repeat for both rollers. The roller position which allows the slowest rate of fall should be used for setting occlusion.



If the rate of fall is significantly different for one roller than for another at the same position along the pump raceway, the roller assembly may need adjustment. Check this by comparing the rate of fall for both rollers at several positions along the pump raceway. If one roller consistently allows a rate of fall of 7 inches (17,5 cm) per minute or more while the other roller, at the same position, holds the rate of fall to 1 inch (2,5 cm) per minute, contact Terumo Customer Service. Using a pump in this condition may compromise tube life and increase blood trauma.

Resolving Pump Jam

WARNING: In the event of a pump jam you will receive one of the following messages: pump jam within 3 seconds or underspeed within 3 seconds followed by a pump jam within 15 seconds of the occurrence.

CAUTION: Pump Jam is more likely to occur when using the large roller pump for low RPM cardioplegia delivery than when using the small roller pump for low RPM cardioplegia delivery. This is because of the geometric advantages of the small roller pump at low speeds.

The following actions should be taken if you receive Pump Jam error.

During Prime or Setup:

- Check the raceway for obstructions. Check the tubing for too much slack, too little slack, overlapping tubing, or shifting vertically causing interference from the guide rollers. If necessary, clear the obstruction or adjust the tubing and restart the pump.
- When tubing is set up and fully occluded several hours prior to the start of a case, the tubing may take a “set” causing Pump Jam errors to occur during initial start-up. Tubing “set” is defined as temporary conformance of the tubing to the shape of the roller in the pump roller. Manually moving rollers off of the “set” may resolve Pump Jam errors.
- Dual-sized tubing kits are more likely to need occlusion adjustments. Dual-sized tubing kits are more prone to variation in the tubing wall thickness and may require adjusting occlusion to compensate for this variability.
- If you require low volumetric flow and are attempting to start the roller pump at 2 RPM or less with tubing temperatures approaching 10°C (50°F) under heavy occlusion (10 clicks beyond the limits of travel), you may experience a pump jam error. If a pump jam occurs increase the initial motor speed to 3 RPM, start the system, and then reduce to the desired speed after the roller pump begins to rotate. Please refer to the CCM to calculate the corresponding flow rate at 3 RPM using the selected tubing size.
- If a Pump Jam error reappears after the above steps are taken, use a hand crank until you are able to reassign to an alternative pump or use standby equipment. See **Roller Pumps, Manual Operation of Pump** section for instructions on operating the hand crank. Following the case, contact Terumo Customer Service.

Roller Pumps

During Perfusion:

- Check the tubing and raceway for obstructions. If necessary, clear the obstruction and restart the pump.
- Adjust the pump's occlusion to back off of the occlusion slightly. Attempt to restart the pump.
- If a Pump Jam error reappears after the above steps are taken, use a hand crank until able to reassign to an alternative pump or use standby equipment. Following the case, contact Terumo Customer Service.

Manual Operation of Pump

WARNING: When turning the roller assembly by hand, always turn the roller assembly in the direction of forward flow. Reverse rotation of the roller assembly could draw air into the blood line which might then be pumped into the patient, with attendant risk of death or severe bodily injury.

WARNING: Hand cranks must be properly set up to allow hand cranking in the same direction as that chosen for forward flow for the roller pumps.

WARNING: When hand cranking due to loss of AC (Mains) and battery power, the safety systems will not operate; monitor closely for air and reservoir level.

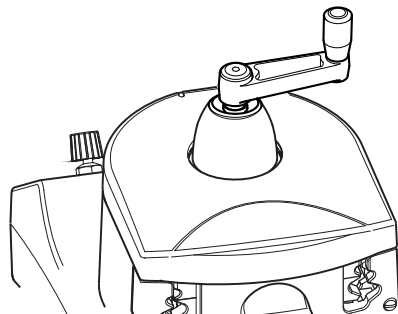
Operating the Hand Crank

Use a hand crank should it be necessary to turn the roller assembly by hand. Cranks should be located on the hand crank mounting bracket on the lower right or lower left side of the base.

To use the hand crank:

1. Remove the plastic cap from the center of the occlusion knob.
2. Insert and seat the hand crank in the opening.
3. Turn the pump in the system FORWARD direction as necessary.
4. If the pump is difficult to turn, unplug the pump cable at the pump. Reconnect the cable before attempting to restart the pump.

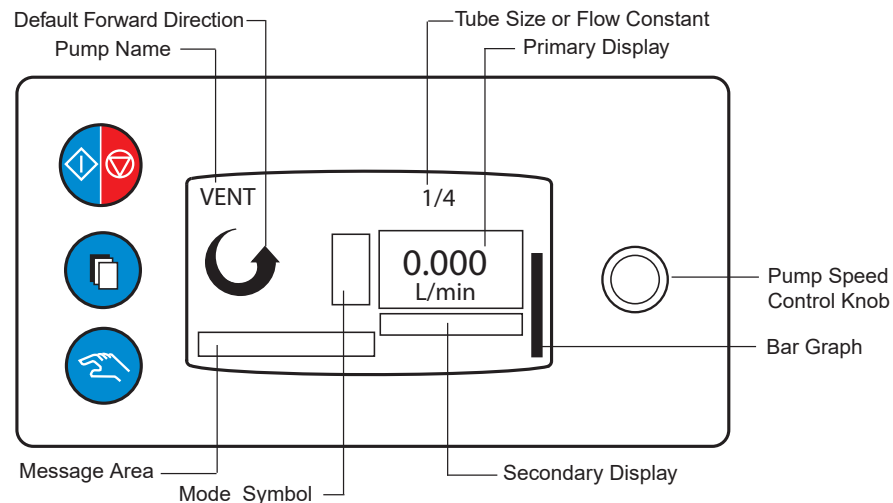
Note: Be aware that you will have to stop hand cranking in order to restart the pump. Hand cranking simulates an overspeed condition.



Roller Pumps

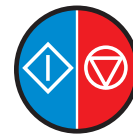
Controls and Displays

CAUTION: Pump control panels and Central Control Monitor are intended for hand and gloved hand operation only. Do not use any instruments on the pump control panels or Central Control Monitor as this may damage the device.



Start/Stop Button

Press the **Start/Stop** button to activate and start the pump at a speed of 0 RPM or a flow of 0.000 L/min in Continuous mode. Pressing the **Start/Stop** button again stops the pump if it is running and also deactivates it. If the pump is stopped and deactivated using the **Start/Stop** button, it must be reactivated using the **Start/Stop** button for the pump to be used again.



Select Button

Pressing the **Select** button will result in the following responses depending on the pump state:

- No response if pump is running or paused with no alerts or alarms.
- Reset an active air alarm on a connected air bubble detection system.
- Display pump menu if pump is stopped.



Manual Button

Pressing the **Manual** button will result in the following responses depending on the pump state:

- No response if pump is stopped or paused.
- No response if pump is in Continuous mode.
- Return to Continuous mode if in Pulse mode.
- Return to Continuous mode if in Servo mode.
- No response if in Master/Follower mode.



Roller Pumps

Pump Speed Control Knob

Use the pump speed control knob to set the pump speed. Turning the knob clockwise increases the speed, counterclockwise decreases the speed. Always use the **Start/Stop** button to stop the pump.



Note: The roller pump does not deactivate at 0 RPM or a flow of 0.000 L/min. This is different than the centrifugal pump behavior which does stop and deactivate at 0 RPM.

Primary Display

This area displays the pump speed in RPMs or the flow rate in L/min according to the following operating parameters:

- Liters/min
Small Pump Range: 0-4.0 L/min
Resolution: 0.001 at 0-1 L/min
0.01 at 1-4 L/min

Large Pump Range: 0-10.0 L/min
Resolution: 0.001 at 0-1 L/min
0.01 at 1-10 L/min
- RPM
Pump Range: 0-250 RPM
Resolution: 1 RPM

Secondary Display

This area displays various information depending on the pump mode.

- Servo Source setpoint in Servo mode
- Total flow in Master Mode
- Master/Follower percentage or ratio in Follower mode

Pump Direction

Circular arrow symbol indicates the pump default forward direction.

Message Area

- Internal alert, alarm, status, and error messages are displayed here.
- External messages related to safety connection alerts and alarms, including the external event, are also displayed.

Mode Symbol

Appears to the left of the primary display to indicate current operating mode: Pulse, Master, Follower, and Servo.

Bar Graph

Indicates the demand from the pump speed control knob relative to the maximum speed or flow or, if the pump is configured as a follower, the percentage of the master pump flow.

Tube Size

Displays tube size or flow constant selected to calculate pump flow.

Pump Name

This area displays the pump name. During the start-up self-test, the pump's Module ID is displayed.

Roller Pumps

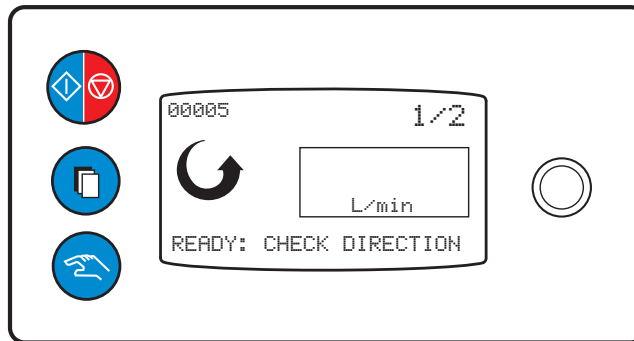
Check the Start-up Test

When the system power is first turned on, a self-test is conducted. If the self-test fails, a message is displayed on the pump display and the CCM. Try turning the system off then on to repeat the start up check. If the message appears again and remains on the display, do not use the pump. Contact Terumo Customer Service.

The pump display will be determined by the pump state. Offline indicates the pump is not assigned to the current Perfusion Screen or a Perfusion Screen has not been opened. Online indicates the pump is assigned to the current Perfusion Screen.

Offline Display

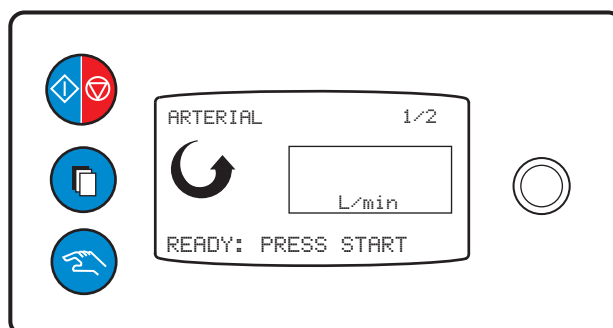
- Module ID
- Pump default direction arrow
- Last tube size or flow constant entered
- “READY: CHECK DIRECTION” is displayed when the pump cannot verify that its default forward direction matches the system direction.
- No message is displayed if the pump has verified that its default forward direction matches the system direction.



WARNING: Always check the direction of rotation before starting a backup or standby roller pump to make sure that the roller pump default direction matches the system direction. Retrograde pumping MAY CAUSE SEVERE PATIENT INJURY OR DEATH by drawing air into the bloodline which might then be pumped into the patient.

Online Display

- Pump Name
- Last tube size or flow constant entered
- Pump default direction arrow
- “READY: PRESS START” displayed until user activates controls from pump control panel or the CCM.



Roller Pumps

Change Pump Default Direction:

Use one of the methods below to change pump default direction.

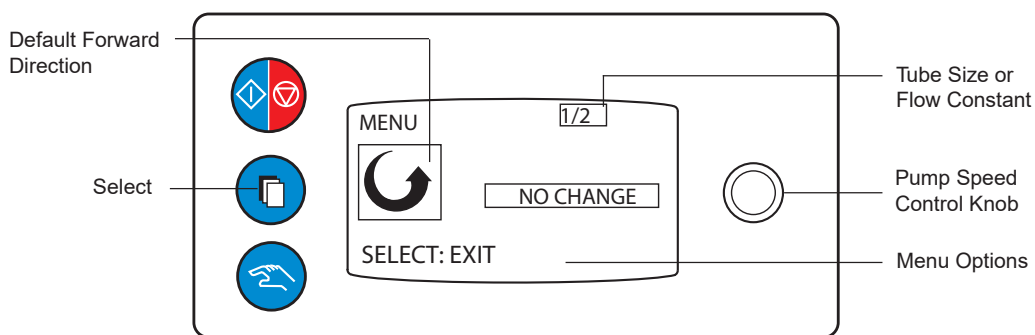
- Plug the pump into the system, power the system on and allow the start-up sequence to complete. Verify that the pump default direction arrow now matches the system direction.
- Pump default direction is also changed to match the system direction during the reassignment process, except when the pump is running at the initiation of reassignment. After reassignment, verify that the pump default direction arrow now matches the system direction.
- The pump direction can be changed by entering Configuration, assigning the stopped pump to a Perfusion Screen and then opening that screen from the Perfusion functional area. Verify that the pump default direction arrow now matches the system direction.

Pump Menu

The pump menu can be used to temporarily reverse the forward direction, enter a flow constant, or change the tube size setting.

To access the pump menu:

1. Place the pump in Stop mode. The primary display should be blank.
2. Ensure that there are no active alarms.
3. Press **Select** button to access the main Pump Menu.
4. Turning the pump speed control knob will successively highlight the different menu options:
 - SELECT: DIRECTION
 - SELECT: FLOW CONSTANT
 - SELECT: TUBE SIZE
 - SELECT: EXIT
5. Press the **Select** button to edit the highlighted parameter.



Roller Pumps

Select: Direction

The pump direction can be temporarily reversed from the default forward setting. The pump direction will revert to its default forward direction when the Stop button is pressed or when the pump is stopped in response to any alert or alarm messages or another pump event.

WARNING: Use caution when roller pumping in the opposite direction of forward flow as air may be drawn into the blood line.

To temporarily reverse the pump direction:

1. Press the **Select** button when “SELECT: DIRECTION” is highlighted.
2. Turn the pump speed control knob until the message “SELECT: REVERSE” appears highlighted in reverse video in the message area.



3. Press **Select** button again, “SELECT: VERIFY REVERSE” is displayed in the message area.
4. To confirm the temporary reversal, press the **Select** button again. Press **Select** again to exit. The direction arrow on the pump display is shown in reverse video if reverse was confirmed and the message “PUMPING REVERSE” is displayed.

To cancel the temporary reversal of pump direction, turn the knob until No Change is highlighted and the menu displays “SELECT: EXIT”. Press **Select** to cancel. Press **Select** once more to exit.

Roller Pumps

Select: Tube Size

The correct flow constant must be entered in order for the flow rate to be properly calculated. For PVC medical grade tubing, a number of predefined flow constants for standard tubing sizes can be selected using the “SELECT: TUBE SIZE” menu (see the following tables for flow constants for large and small tube sizes). When using silicone tubing, flow constants may vary slightly from the default values tabulated. If required, precise flow constants may be determined using “Select: Flow Constant” as detailed below.

To change the pump tube size:

1. Press the **Select** button when “SELECT: TUBE SIZE” is highlighted.
2. Turning the knob will successively display the options for standard tube sizes.
3. Press the **Select** button to save a new tube size.
4. When the selection is made, the main pump menu is displayed.

The system will retain this selection until a new selection is made from the CCM or from the pump control panel.

Tube Sizes and Flow Constants

Large Roller Pump			Small Roller Pump		
Tube Size	mL/revolution	Flow Constant FC Value	Tube Size	mL/revolution	Flow Constant FC Value
1/8 in.	3.25	033	1/8 in.	2.21	022
3/16 in.	7.38	074	3/16 in.	4.68	047
1/4 in.	12.69	127	1/4 in.	8.03	080
5/16 in.	18.17	182	5/16 in.	11.41	114
3/8 in.	27.20	272	3/8 in.	15.97	160
7/16 in.	36.39	364	6mm	7.40	074
1/2 in.	43.19	432	8mm	12.10	121
6mm	11.70	117	10mm	16.90	169
8mm	19.00	190	S1:1(1/4 in. & 1/4 in.)	16.00	160
10mm	27.90	279	S2:1(1/4 in. & 3/16 in.)	12.04	120
12mm	45.00	450	S4:1(1/4 in. & 1/8 in.)	10.11	101
S1:1 (1/4 in. & 1/4 in.)	25.38	254	S8:1 (17/64 in. & 3/32 in.)	9.24	092
S2:1 (1/4 in. & 3/16 in.)	19.23	192			
S4:1 (1/4 in. & 1/8 in.)	15.75	158			
S8:1 (17/64 in. & 3/32 in.)	14.47	145			

For nonstandard tube sizes, the large and small roller pumps both support user-defined flow constants in the range from 1 to 650.

Roller Pumps

Select: Flow Constant

To determine the flow constant (FC) for a nonstandard PVC or silicone tubing size, set the flow rate display to show speed in RPM and stabilize flow through a water circuit with the pump speed above 30 RPM and the water near the intended delivery temperature.

1. Measure the output for a set period of time and then divide the volume collected (milliliters) by the elapsed time (minutes) to determine the flow rate.
2. Divide this flow rate by the speed (RPMs) to get the volume pumped per revolution.
3. Repeat these steps several times, averaging the results.
4. Multiply the volume pumped per revolution by 10 to get the flow constant (FC).

To enter a nonstandard tubing size:

1. Press the **Select** button when “SELECT: FLOW CONSTANT” is highlighted.
2. “KNOB: CHANGE FC” is displayed in the message area.
3. Use the knob to adjust the flow constant to the desired value.
4. Press the **Select** button to save the new flow constant.
5. When selection is made, the main pump menu is displayed.



Select: Exit

To exit Pump Configuration Menu and return to Stop state:

1. Press **Select** button when “SELECT: EXIT” is highlighted.

Continuous Mode

This is the basic functional mode of the roller pump. Exiting any other operating mode will put the roller pump into the Continuous mode.

Initiate Continuous Mode

Pressing the **Start/Stop** button on the front panel or the **Start** button in the Pump Control Box on the CCM will activate Continuous mode. Within this mode, the pump may be configured via the CCM to display the RPM or flow rate as the primary display.

Continuous Operation

During use, the pump flow or speed can be adjusted by using the pump speed control knob or the pump control slide bar on the CCM.

Roller Pumps

Ending Continuous Mode

Pressing the Stop button on the CCM or the Start/Stop button on the front panel will stop the pump.

WARNING: Always check the pump for proper operational mode after a Pause or Reduce Speed response has been executed. A pump may go to Stop mode and need to be started manually if the pump has received multiple high priority messages.

Pulse Mode

When using Pulse mode during a case, monitor the patient waveform on the operating room monitor. The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

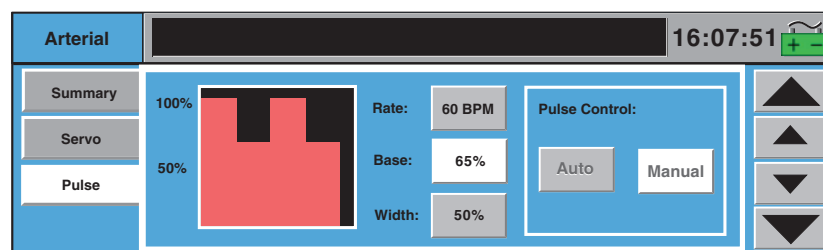
A pulse cycle consists of one high speed period (Peak) and one low speed period (Base). The high speed is controlled by the pump speed control knob or the pump control slide bar CCM and the low speed is determined by the Base setting. The high speed is displayed on the slide bar and the average speed is displayed in the pump control box and the pump local display. The amount of time the pulse cycle is at the high speed is determined by the Width setting. The Rate defines how many pulse cycles will occur per minute.

Pulse Parameters

The Rate, Base, and Width must be set up using the CCM:

Note: Changes to the Width and Rate are initiated after the new value is stored. Changes to the Base are sent as the value is changed.

1. Touch the **Primary Pump** icon to access the Primary Pump tab
2. Select the **Pulse** subtab



To Set the Rate

1. Touch the **Rate** button.
2. Use the large arrows to change the Rate in increments of 10 beats per minute.
3. Use the small arrows to change the Rate in increments of 1 beat per minute.
4. Touch the **Rate** button again to store the new value.

To Set the Base

1. Touch the **Base** button.
2. Use the large arrows to change the Base in increments of 10%.
3. Use the small arrows to change the Base in increments of 5%.
4. Touch the **Base** button again to store the new value. The recommended minimum Base is 30%.

Roller Pumps

To Set the Width

1. Touch the **Width** button.
2. Use the large arrows to change the Width in increments of 10%.
3. Use the small arrows to change the Width in increments of 5%.
4. Touch the **Width** button again to store the new value. The recommended minimum Width is 30%.

To Initiate Pulse Mode:

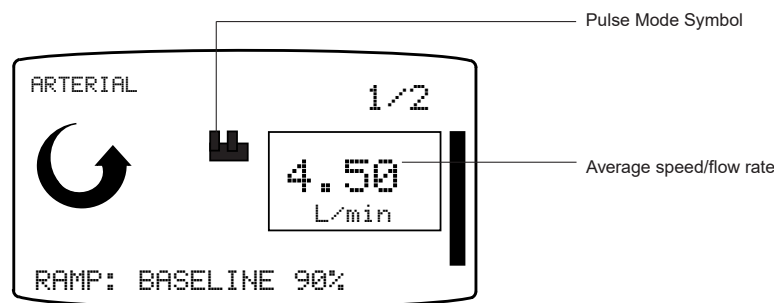
Do not initiate Pulse mode until perfusion has stabilized using continuous flow and a mean flow has been determined.

While running in Continuous mode, start Pulse mode operation via the CCM:

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.
3. Touch the **Auto** button.

The Baseline speed decreases from 100% to the selected percent at a rate of 5% every 2 seconds. The pump message area displays the message “RAMP: BASELINE XX%” (where XX is the current Base setting) until the desired setting is reached.

The Primary Pump display shows the Pulse mode symbol next to the average RPM or L/min.



Pulse Operation

Adjust the average flow by adjusting the peak speed using the pump speed control knob or the pump control slide bar. The average speed/flow rate is calculated from the Peak, Base, and Width. The Pulse mode parameters can be adjusted during use.

Note: When monitoring the arterial pulse peak from the patient, the maximum peak pressure is achieved at the pump outlet; this pressure pulse will be dampened by perfusion components such as a long arterial line, a constrictive arterial cannula, and the positioning and compliance of membrane oxygenators and filters in the arterial line.

To End Pulse Mode

Use one of the following three options:

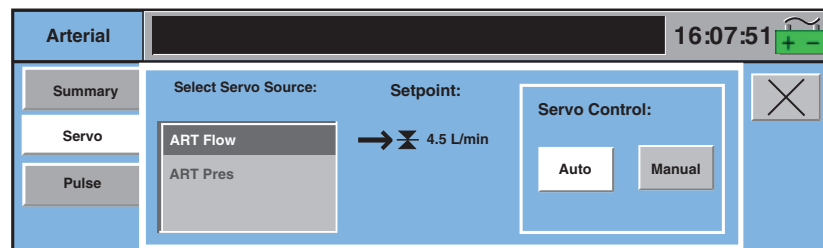
- Press the **Manual** button on the pump control panel and the pump transitions to Continuous mode. The new Continuous mode speed/flow rate is calculated to match the Pulse mode average speed/flow rate.
- Open the **Pulse** subtab within the **Primary Pump** tab on the CCM, touch the **Manual** button, and the pump transitions to Continuous mode. The new Continuous mode speed/flow rate is calculated to match the Pulse mode average speed/flow rate.
- Open the **Pulse** subtab within the **Primary Pump** tab on the CCM. Slowly increase the Base setting to 100%. Note that although the flow will be continuous, the pump still operates in Pulse mode.

Roller Pumps

Servo Mode

In Servo mode, the pump speed is automatically regulated to maintain a specific user selected pressure or flow setpoint. Pressure or flow servo sources are chosen using the Configuration area on the CCM. The servo source should be located at least 24 inches (61 cm) downstream of the pump operating in Servo mode. The location of the servo source sensor in the perfusion circuit can affect servo performance. Proper placement of the sensor is ultimately up to the medical professional. The setpoint must be in the correct operating range before Servo mode can be initiated.

While operating in Servo mode, the pump speed can vary within certain limits to maintain the servo setpoint. The servo speed has a lower speed limit of 0 RPM and an upper speed limit not to exceed the greater of 110% of the speed at which servo mode was entered or 3 RPM over the speed at which servo mode was entered. If the servo reaches either limit, the speed remains at the limit unless required to change by the servo source or user input. Monitor the pump speed closely while in Servo mode as reduced pump speed may result in hypoperfusion of the patient. If the servo source is a flowmeter, the flow displayed on the pump control panel is the measured value from the flow sensor.



Operating Parameters

Flow Servo

Pump Type	Recommended Setpoint		Servo Operating Range	
	Min L/min	Max L/min	Min L/min	Max L/min
Small	2	3	1	4
Large	2	5.5	1	7

Pressure Servo (3/8 in. (9,5 mm) and 1/4 in. (6,4 mm) tube sizes)*

	Recommended Setpoint		Recommended Flow		Servo Operating Range	
	Min mmHg	Max mmHg	Min L/min	Max L/min	Min mmHg	Max mmHg
Small	150	200	2	3	10	400
Large	150	200	4	6	10	400

*Pressure servo is not recommended for use with 1/2 inch (12,7 mm) tube size.

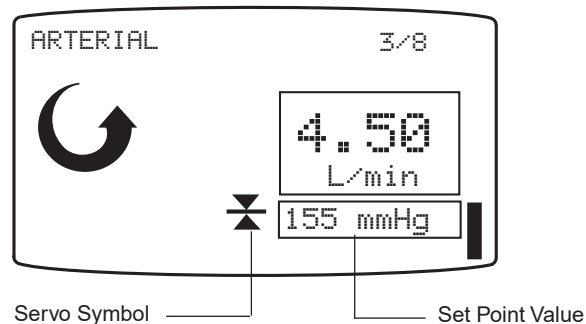
Circuit and clinical parameters, including setpoint value and pump flow rate, should be stabilized in Continuous mode and be within normal operating ranges before initiating Servo mode.

Roller Pumps

To Initiate Servo Mode:

1. Touch the **Pump** icon to open the Pump tab.
2. Open the **Servo** subtab.
3. Select the source pressure or flow.
4. Touch the **Auto** button.

The pump control panel shows the Servo mode symbol next to the current servo setpoint value. The pump secondary display shows the current setpoint value.



The pump will respond to all safety connections, including alerts or alarms that have been established for the servo control source while operating in Servo mode.

To change setpoint:

To change the servo setpoint, turn the pump speed control knob or adjust the pump control slide bar. Increase/decrease the pump speed. When the knob or slide bar adjustment stops, the pump locks onto the current average value of the servo source as the new servo setpoint.

To End Servo Mode:

Use one of the following two options:

- Press the **Manual** button on the pump front panel and the pump transitions to Continuous mode at its current speed.
- Open the **Servo** subtab on the **Pump** tab on the CCM, touch the **Manual** button, and the pump transitions to Continuous mode at its current speed.

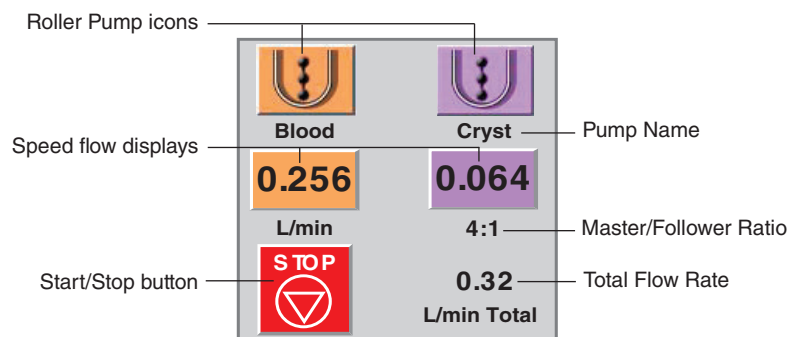
Roller Pumps

Master/Follower Mode

Pumps are designated as master and follower in the CCM Configuration area. Master/follower mode involves two pumps operating in tandem, where the follower pump demand flow rate or speed is a percentage of the master pump flow rate or speed. The follower pump flow rate or speed is always equal to or less than the master pump flow rate or speed. The master pump can be used in Continuous or Servo modes. The follower pump can only be used in Continuous mode.

High delivery ratios (low follower pump percentages) in combination with low master pump speed may cause the follower pump to stop rotating, but not deactivate, if the follower pump speed is not equal to or above 1 RPM. To reduce, but not eliminate, the probability of the follower pump stopping its rotation at low follower pump percentages combined with low master pump speed, two small roller pumps should be employed for master/follower mode.

Master/Follower Pump Control Box

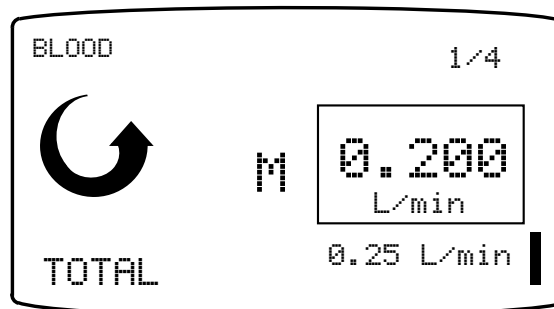


Master and follower controls and data are displayed in one control box. The single **Start/Stop** button is used to start or stop both pumps. The master/follower ratio is displayed on the follower pump below the speed/flow display. If L/min was chosen as the display units, then the total flow rate for both pumps will be displayed.

Master Operation

Press the **Start/Stop** button on the control panel of either the master or follower pump or touch the **Start** button on the CCM to start both pumps. Use the master pump speed control knob or the pump control slide bar to adjust the master pump speed. The master pump control panel display shows an "M" to the left of the current RPM or L/min value. The secondary display shows the total flow rate for both pumps in L/min.

Follower Operation



Roller Pumps

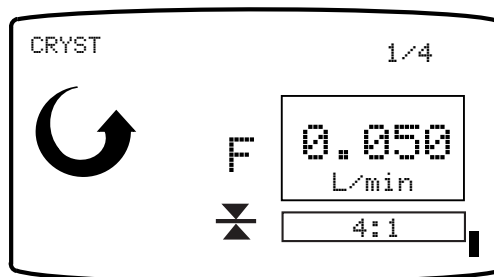
The follower pump speed adjusts automatically to maintain the currently set percentage or, for select percentages, ratio according to the following formula:

$$\text{Desired Follower Speed} = \frac{\text{Master Flow Rate} \times \text{Ratio (\%)} \times 10}{\text{Master Flow Constant}}$$

Use the follower pump speed control knob or pump control slide bar to adjust the percentage (%) of the master pump flow rate or speed, but not the percentage of the follower pump flow rate or speed in the total cardioplegia delivery. For the following % values, the setting is displayed as a ratio rather than a %:

% of Master Flow	Ratio Displayed
100%	1:1
50%	2:1
25%	4:1
12%	8:1
6%	16:1

The follower pump display shows an “F” next to the primary display. Below the “F,” the servo control symbol is displayed indicating that the follower pump speed is being automatically controlled. The secondary display shows the current master/follower pump percentage or ratio. The bar graph indicates the percentage of master pump flow or speed.



Communications Link

Both the master and follower pump must be in Stop mode with pump safety covers closed until the Perfusion Screen opens to permit connection between the pumps which will be indicated by the M and F on the pump control panels. The servo control symbol only appears on the follower pump control panel as it is the servo regulated pump. The servo control symbol alone does not indicate connection between master and follower pumps. If the master and follower pumps lose their connection with each other, these pumps will automatically stop. The connection between the pumps must be reestablished to continue operation in Master/Follower mode. Use the Master or Follower Status subtab to reconnect the pumps. See **Central Control Monitor** chapter, **Pump tab, Master or Follower Status subtab** section.

Roller Pumps

Roller Pump Messages

Roller pump messages are displayed in the message area on the pump display. There are five categories of pump messages.

Response to Messages Table

Message Type	Display
<u>External Alarm</u> - A device or sensor that is connected to the roller pump has reported an alarm condition.	Reverse video, blinking, <Response>: <Message> Possible displays: • STOPPED: < Message > • PAUSED: < Message > • SLOWED: < Message > • < Message > for Message Only
<u>External Alert</u> - A device or sensor that is connected to the roller pump has reported an alert condition.	Reverse video, <Response>: <Message> Possible displays: • STOPPED: < Message > • PAUSED: < Message > • SLOWED: < Message > • < Message > for Message Only
<u>Internal Alert</u> – an alert condition related to the roller pump has been detected.	Reverse video, < Message >
<u>Internal Error</u> – a roller pump error condition has been detected.	Normal video, Blinking < Message >
<u>Internal Status</u> – the status of a pump condition has changed.	Normal video, < Message >

The following table includes the messages that can appear on the roller pump display and corresponding operator responses.

	Priority Condition	Pump Display Message	Operator Response
Alarm	Air detected for connected air bubble detector.	< Response >: AIR DETECTED	Correct air condition, reset alarm, restart pump if stopped.
	Low level detected for connected alarm level sensor.	< Response >: LOW LEVEL	Correct low level condition, restart pump if stopped.
	Alarm over pressure detected for connected pressure sensor	< Response >: OVER PRESSURE	Correct over pressure condition, restart pump if stopped.
Alert	Connected pump has stopped.	< Response >: PUMP STOP	Restart connected pump, restart pump if stopped.
	Connected pump has started.	< Response >: PUMP START	Restart pump if stopped.
	Connected roller pump has paused.	< Response >: PUMP PAUSE	Restart pump if stopped.
	Connected centrifugal pump detects min flow.	< Response >: MINIMUM FLOW	Restart pump if stopped.

Roller Pumps

	Priority Condition	Pump Display Message	Operator Response
Alert	Connected centrifugal pump has gone to Coast speed.	< Response >: PUMP COAST	Restart pump if stopped.
	Connected flow meter backflow detected.	< Response >: BACKFLOW	Clamp the lines. Correct backflow condition. Check for air; clear if present. Restart pump if stopped.
	Alert over pressure detected for connected pressure sensor.	< Response >: OVER PRESSURE	Correct over pressure condition.
	Low Level detected for connected alert level sensor.	< Response >: LOW LEVEL	Correct low level condition.
	Follower Pump unable to maintain Master ratio setting.	CANNOT MAINTAIN RATIO	Reduce the follower ratio setting or adjust the master pump speed. Stop then start master pump. If message appears again, discontinue M/F operation.
	Follower stops due to loss of data from Master pump.	STOPPED: NO MASTER	Check master pump cable connections then stop and start master pump. If message appears again, reassign the master pump. Do not use the master pump until it has been serviced by Terumo Cardiovascular Systems.
	Master stops due to loss of data from Follower pump.	STOPPED: NO FOLLOWER	Check the follower pump cable connections. Stop and start the master pump. If message appears again, reassign the follower pump. Do not use the follower pump until it has been serviced by Terumo Cardiovascular Systems.
	Loss of servo source data.	MANUAL: MONITOR FLOW	Check the operation and placement of servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Cannot maintain servo setpoint.	MANUAL: MONITOR FLOW	Check the operation and placement of servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Motor speed < demand speed for more than 2 seconds.	UNDERSPEED	At start-up, if you are operating under cold temperatures and heavy occlusion (see Resolving Pump Jam Section) an underspeed warning may occur. The underspeed message will clear as the pump rotates and the tubing is warmed. If the message does not clear within 5 minutes, stop and start the pump. If the message reappears, contact Terumo Customer Service. Reassign, use standby equipment, or use hand crank.

Roller Pumps

	Priority Condition	Pump Display Message	Operator Response
Alert	Pump head speed < motor speed for more than 2 seconds.	BELT SLIP	Stop and start the pump. Check the occlusion. If the message reappears, contact Terumo Customer Service. Reassign, use standby equipment, or use hand crank.
	Pump has reached maximum speed trying to attain setpoint.	AUTO: MAX RANGE	Check servo source. Check perfusion circuit. Alert will clear when speed slows to within operating range.
Error	CCM missing.	NO SYSTEM COMPUTER	Continue use of roller pump from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Network communication failure.	NO COMMUNICATION	Continue use of roller pump from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Loss of communication from connected roller or centrifugal pump.	CHECK LINKED PUMP	Check for proper operation of the linked pump. If message does not clear, be aware that the pump may not respond to messages or operations requiring information from the connected pump.
	Loss of connected air bubble detector module.	CHECK AIR SENSOR	Check for proper operation and connection of module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of flow meter module.	CHECK FLOWMETER	Check for proper operation and connection of module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of connected level module.	CHECK LEVEL	Check for proper operation and connection of module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.

Roller Pumps

Priority	Condition	Pump Display Message	Operator Response
Error	Loss of connected pressure module.	CHECK PRESSURE	Check for proper operation and connection of module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Pump stops because <ul style="list-style-type: none"> • Pump head or motor speed is greater than the maximum pump speed OR • Motor speed greater than the demand speed for more than 2 seconds. 	STOPPED: OVERSPEED	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Overocclusion or obstruction in pump raceway stops pump.	STOPPED: PUMP JAM	Clear the pump raceway or back off the occlusion and try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Pump board temperature > 80 °C for more than 2 seconds.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Low level motor fault.	STOPPED: MOTOR ERROR	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Overcurrent condition detected.	STOPPED: OVERCURRENT	Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.
	Self test failure.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign pump, use standby equipment, or use hand crank.

Roller Pumps

	Priority Condition	Pump Display Message	Operator Response
Status	Follower pump has stopped in response to master pump event.	STOPPED: MASTER	Message should clear when Master pump is restarted.
	Follower pump has paused in response to master pump event.	PAUSED: MASTER	Message should clear when master pump resumes.
	Master pump has stopped in response to follower pump event.	STOPPED: FOLLOWER	Message should clear when master pump is restarted.
	Master Pump has paused in response to follower pump event.	PAUSED: FOLLOWER	Message should clear when follower pump resumes.
	Pump pauses because cover has been opened.	PAUSED: COVER OPEN	Message should clear when cover is closed.
	Pump direction has been changed to reverse.	PUMPING: REVERSE	Message should clear when default direction is resumed. Default direction is resumed when the pump stops.
	Pulse mode has been activated - base is ramping down to target value.	RAMP BASELINE: XX%	Monitor the speed change. The base is reduced by 5% every 2 seconds. Message clears when the target Base setting is reached.
	Manual button is pressed when the pump is in Pulse mode or Servo mode.	MANUAL: MONITOR FLOW	Message should clear when speed is changed or pump is stopped.
	Stop button is pressed in Pulse mode or Servo mode.	MANUAL: MONITOR FLOW	Message clears when pump is started.
	Pump is paused during volume auto dose delivery.	PAUSED: <current volume> mL	Message clears when pump resumes or stops.
	Pump is paused during time auto dose delivery.	PAUSED: <current time remaining>	Message clears when pump resumes or stops; time continues to count down.
	Volume auto dose delivery finished.	DONE: <current volume> mL	Message clears when auto dose delivery is restarted.
	Time auto dose delivery finished.	DONE: 00:00	Message clears when auto dose delivery is restarted.
	Pump stops during volume auto dose delivery.	STOPPED: <current volume> mL	Message clears when pump is restarted; volume is reset to zero.
	Pump stops during time auto dose delivery.	STOPPED: <current time remaining>	Message clears when pump is restarted; time resumes counting down.

Roller Pumps

	Priority Condition	Pump Display Message	Operator Response
Status	Time auto dose has been reset to zero.	RESET TO: <new time value>	Message clears when auto dose delivery restarts.
	Volume auto dose delivery has been cancelled.	CANCELLED: <current volume> mL	Message clears when auto dose delivery is resumed; volume is reset to zero.
	Time auto dose delivery has been cancelled.	CANCELLED: <current time remaining>	Message clears when auto dose delivery is resumed; time resumes counting down.

Sarns Centrifugal Pumps

Features

The primary function of a centrifugal pump is to move fluids through a cardiopulmonary bypass circuit. Centrifugal pumps are used primarily for arterial pumping applications and as augmented venous return pumps.

The System 1 Sarns centrifugal pump consists of the control unit for control and display functions and a Sarns drive motor which couples magnetically to a Sarns disposable centrifugal pump head or disposable Capiox iCP centrifugal pump head. The Sarns centrifugal pump head and Capiox iCP centrifugal pump head are not interchangeable with the Capiox (1CX*SP45) centrifugal pump head. For Capiox (1CX*SP45) disposable centrifugal pump heads, see Capiox Centrifugal Pumps chapter. The non-occlusive pump head moves fluid as a result of the pressure gradient created by the rotation of the pump. The centrifugal control unit mounts on a pole with a mounting bracket. The centrifugal control unit may be plugged into one of the 6 pump connections on the base or into any of the base module connections. The drive motor is pole-mountable and connects directly to a receptacle on the centrifugal control unit.

The centrifugal control unit front panel display indicates the pump speed, flow rate (if assigned from a flow meter), and alert, alarm, status, and error messages.

The motor speed may be controlled from either the Central Control Monitor (CCM) or from the pump speed control knob on the front panel of the control unit itself.

In the Configuration area of the Central Control Monitor, a centrifugal pump can be designated as primary, backup, or have no designation. A Sarns centrifugal pump can be designated as a backup pump only for a Sarns primary centrifugal pump. Each of these has unique functionality as described in the table below.

Function	CCM Features	Unique Functionality
Primary	<ul style="list-style-type: none">• Dedicated Pump Slide Bar• Choice of RPM or L/min, L/min/m² or mL/kg/min display (Note: L/min, L/min/m² or mL/kg/min will only be available when a flow meter is included in the configuration)	<ul style="list-style-type: none">• Pulse mode[*] operation• Initiate a response in a connected occluder
Backup		<ul style="list-style-type: none">• Primary centrifugal pump functionality can be reassigned to this pump.

^{*}The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

When operating a device that shares a slide bar location, make sure the slide bar displayed is for the device you intend to operate. The device name appears at the top of the slide bar and the corresponding color appears on the central strip and the scroll control.

When a centrifugal pump is designated as the primary pump, the system provides the capability to operate the pump in Pulse mode. In this mode, the user can select the Base setting and initiate Pulse mode operation from the Central Control Monitor. Pulse flow operation can be discontinued from the control unit front panel or the CCM.

Sarns Centrifugal Pumps

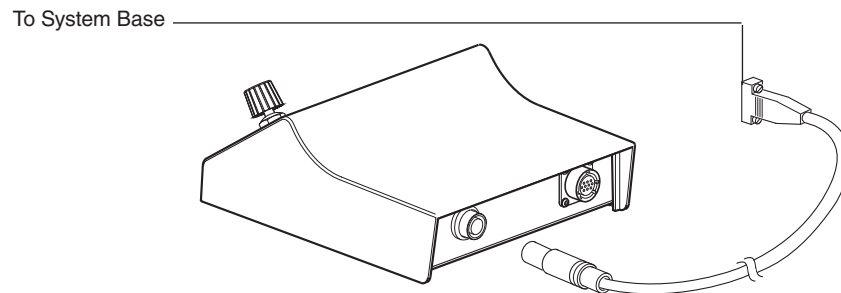
The system provides the capability to automatically regulate the centrifugal pump speed to maintain a desired pressure or flow set point. This is known as Servo mode. In this mode, the user selects a pressure or flow source and initiates servo operation on the Central Control Monitor. Once in Servo mode, the servo setpoint can be changed by adjusting the pump speed control knob or using the pump slide bar on the Central Control Monitor.

Safety connections such as air detection, level detection, and pressure monitoring are configured through the Configuration area on the Central Control Monitor. Pump responses to alerts and alarms are user selectable. Valid responses for centrifugal pumps are Stop, Coast, Message Only, or No Response. The control unit front panel will display a message indicating the event from a connected device.

Installation and Connection

Control Unit Cable

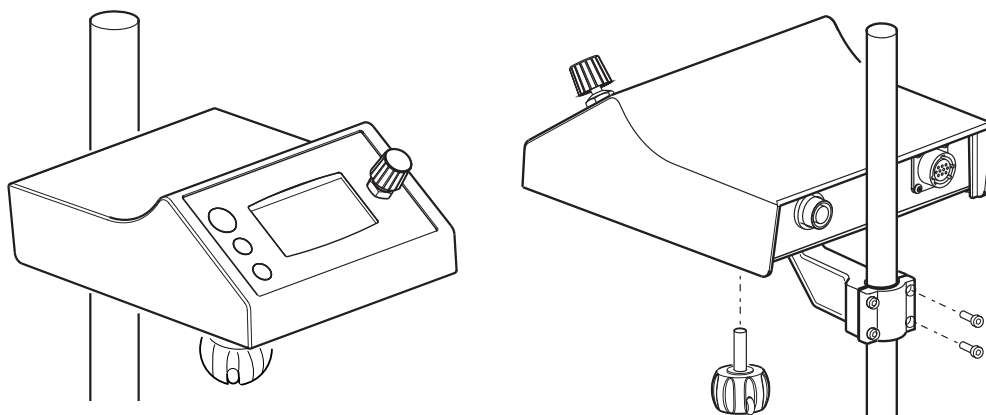
Connect the centrifugal control unit cable to the receptacle located on the back of the control unit. Align the red dot on the control unit cable with the red dot on the control unit receptacle. Insert the connector into the receptacle; an audible click indicates that the connector is fully seated in the receptacle. Pull gently on the cable to verify a secure connection



Pole Mounting

Place the control unit on the mounting arm. Insert the threaded part of the knob through the arm and into the control unit. Select the desired pole position and secure the mounting arm to the pole. Tighten the knob to secure the pump in place.

Adjust the mounting arm to reposition the control unit to the desired location.



Sarns Centrifugal Pumps

Drive Motor

Select the desired pole position and secure the flexible mounting arm to the pole.

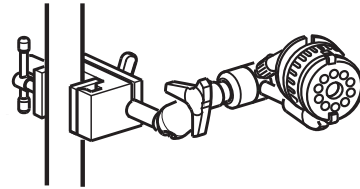
Note: To reduce the potential for an air embolism, the drive motor is typically positioned so that the pump will be near and just below the outlet of the reservoir from which the blood is being pumped.

Flexible Mounting Arm

Select the desired pole position and secure the flexible mounting arm to the pole.

Set the mounting arm to the desired position:

- Turn the tension control knob counterclockwise to loosen the joints of the mount arm. Manually support the flexible arm when adjusting the tension control knob. Do not loosen the knob beyond the stop.



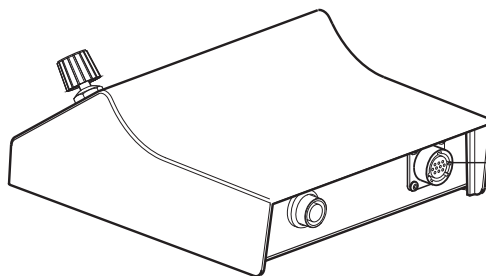
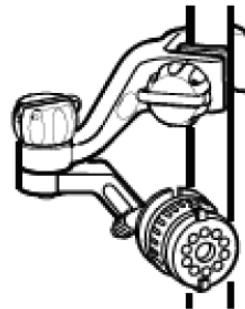
- Position the arm as desired and tighten the tension control knob.

Screw the drive motor onto the threaded stud. Make sure the drive motor is fully installed on the threaded stud. Make sure the drive motor is securely mounted on the mounting arm.

Note: Always manually support the flexible arm when adjusting the tension control knob.

Centrifugal Motor Mount Arm

To mount the drive motor, secure the bracket on a pole or other vertical support and secure the drive motor to the bracket by adding the washer and tightening the bracket knob.



Motor Receptacle

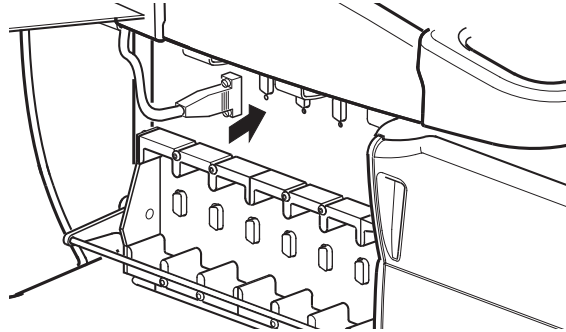
Insert and tightly secure the drive motor cable into the receptacle on the centrifugal drive unit. Remove the safety cover from the drive motor.

CAUTION: Do not sterilize the centrifugal drive motor as sterilization may damage the motor.

Sarns Centrifugal Pumps

System Connection

Route and arrange the pump cable to minimize exposure to spills. Connect the cable to one of the pump connections on either side of the system base or, if necessary, to any of the module connections. With a clear view of the desired pump or module connection, carefully connect the pump cable to one of the system pump connections on either side of the system base or, if necessary, to any of the system module connections. Do not use excessive force to seat the connector and make sure not to bend the connector pins. Tighten screws to secure the connection.



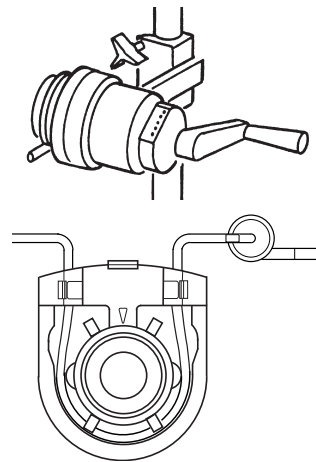
Standoffs are provided in the accessories kit. Two standoffs should be installed on a module receptacle to securely fasten a pump cable or flowmeter cable to the module receptacle. Only a pump power cable or flowmeter power cable can be inserted into a receptacle which has the standoffs installed. Modules cannot be inserted into a module receptacle when standoffs are installed.

Sarns Manual Drive Unit

Terumo Cardiovascular Systems Corporation recommends that either the manual drive unit or a roller pump be prepared for use as standby equipment. Ensure that the tubing length is sufficient.

If using the manual drive unit, mount the manual drive unit securely to a vertical pole, tightening both bracket knobs. Be sure there is sufficient space around the handle to turn it easily.

If using a roller pump, position it on either the inlet or the outlet side of the centrifugal pump. Then adjust the pump so that the tubing is totally unoccluded.



Sarns Centrifugal Pumps

Set Up and Prime

CAUTION: Failure to have a backup pumping method, either a standby roller pump or a manual drive unit, may lead to severe patient injury or death. It is highly recommended that a backup pumping method and protocol are prepared. It is recommended that a one-way valve to prevent retrograde flow in the arterial line be used in the cardiopulmonary bypass circuit.

CAUTION: Do not operate the centrifugal pump when unprimed as operating the pump in a “dry” state may damage the pump.

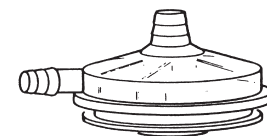
CAUTION: Monitor the centrifugal pump and replace it if there are fluid leaks, noisy operation, or blood in the rear chamber. Blood in the rear chamber will damage the pump bearings and cause the pump to eventually fail (only applicable to the Sarns centrifugal pump).

CAUTION: When located on the inlet side of the centrifugal pump, automatic ball-type shutoff valves (used to prevent gas emboli from entering the arterial line) may seat inadvertently and stop flow.* Follow manufacturer’s instructions for placement of valves.

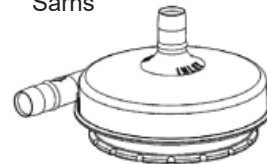
* For additional information, see “Automatic Shutoffs on Centrifugal Heart-Lung Bypass Pumps,” Technology for Perfusion, published by ECRI, September 1988, 1(2):6-7.

Consult the disposable centrifugal pump instructions for directions, warnings, etc., regarding the pump. Use only the Terumo® Sarns™ Centrifugal Pump or Capiox iCP Centrifugal Pump. Install the pump but do not start the drive motor until ready to prime the circuit.

Note: It is recommended that an arterial line filter or similar air barrier device be used in the extracorporeal circuit. Beginning the priming procedure with a crystalloid solution will improve visibility and facilitate bubble removal.



Sarns



Capiox iCP

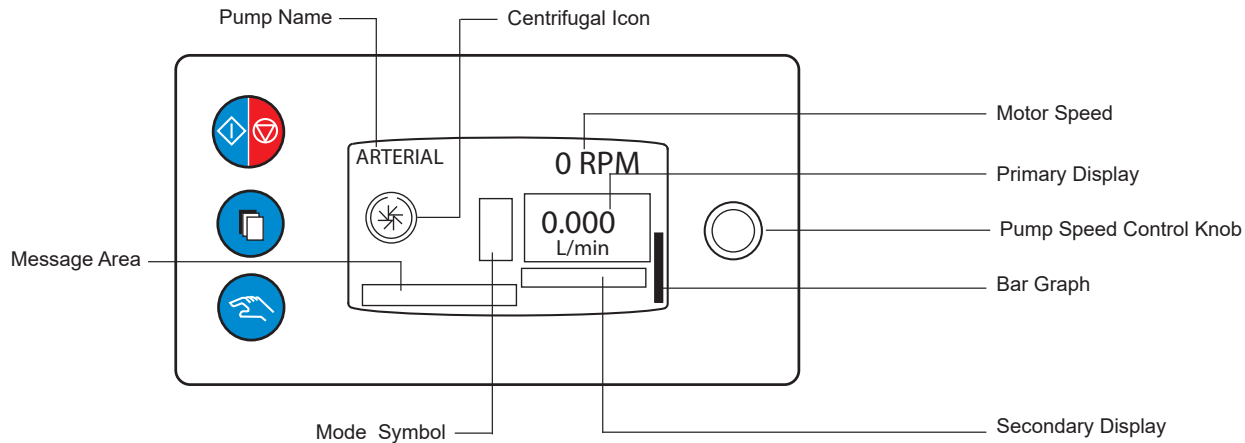
To prime the centrifugal pump:

1. Clamp the pump inlet while priming the reservoir.
2. Unclamp the inlet line slowly and gravity prime the centrifugal pump so that air exits upward through the pump outlet line. The pump may be removed from the drive motor for debubbling. Clamp the pump outlet line after the pump is completely primed. The primed pump may now be used in priming the rest of the circuit.
3. Prime the rest of the circuit, unclamping the pump outlet line as necessary. When stopping flow, clamp the appropriate lines (particularly the pump outlet line and the patient venous line) to prevent depriming this pump.
4. Remove any air from the pump prior to perfusion. Stop the pump, clamp the lines (particularly the pump outlet line), and purge the air back to the reservoir by tipping and tapping. Debubble the circuit by recirculation as necessary.
5. If a roller pump is used instead of the manual drive unit as standby equipment, use tubing specified for roller pumps. Insert the centrifugal pump inlet or outlet tubing into the roller pump, check that the pump operates properly, and verify the proper flow direction through the roller pump. Then adjust the pump so that the tubing is totally unoccluded or remove the tubing from the pump.

Sarns Centrifugal Pumps

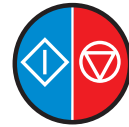
Controls and Displays

CAUTION: Pump control panels and Central Control Monitor are intended for hand and gloved hand operation only. Do not use any instruments on the pump control panels or Central Control Monitor as this may damage the device.



Start/Stop Button

Press the **Start/Stop** button to activate and start the pump. The pump speed will always begin at 0 RPM when the pump is started. The presence of a 0 before RPM indicates that the centrifugal pump is activated. If 0 does not appear before RPM, the centrifugal pump is deactivated. If the Start/Stop button is pressed while the pump is running and the speed is greater than 1550 RPM, the message “TURN SPEED TO ZERO” will be displayed in the message area. Pressing the Start/Stop button again within four seconds will stop the pump. If the speed is less than 1550 RPM, pressing the Start/Stop button once will stop and deactivate the pump. If the pump is stopped and deactivated using the Start/Stop button, it must be reactivated using the Start/Stop button for the pump to be used again.



Select Button

Pressing the **Select** button will reset an active air alarm on a connected Air Bubble Detection system.



Manual Button

Pressing the **Manual** button will result in the following responses depending on the pump state:

- No response if pump is stopped.
- No response if pump is running in Continuous mode.
- Return to Continuous mode if in Pulse mode.
- Return to Continuous mode if in Servo mode.



Pump Speed Control Knob

Use the pump speed control knob to set the pump speed. Turning the knob clockwise increases the speed, counterclockwise decreases the speed.



Note: Unlike a roller pump, turning the centrifugal pump speed control knob to a speed of 0 RPM will stop and deactivate the centrifugal pump.

Sarns Centrifugal Pumps

Primary Display

L/min if a flowmeter module has been placed on the centrifugal pump speed/flow display area. The primary display will show “-.-” otherwise.

Secondary Display

Servo Source setpoint in Servo mode is displayed below the primary display.

Pump Speed

The pump speed in RPM is displayed above the primary display.

Centrifugal Icon

The centrifugal graphic symbol indicates that the controller is a centrifugal control unit.

Message Area

Displays alert, alarm, status, and error messages.

Mode Symbol

Appears to the left of the primary display to indicate current operating mode: Pulse or Servo.

Bar Graph

Indicates the pump speed control knob demand position relative to the maximum speed.

For 2 seconds from the onset of a Coast response, the bar graph blinks to signify the brief lockout period during which speed cannot be adjusted. This occurs even if the Coast response does not include a speed change.

Pump Name

This area displays the pump name. During the start-up self-test, the pump’s Module ID is displayed.

Check the Start-up Test

When the system power is first turned on, a self-test is conducted. If the self-test fails, a message is displayed on the control unit display and the CCM. Try turning the system off then on to repeat the start up check. If the message appears again and remains on the display, do not use the pump. Contact Terumo Customer Service.

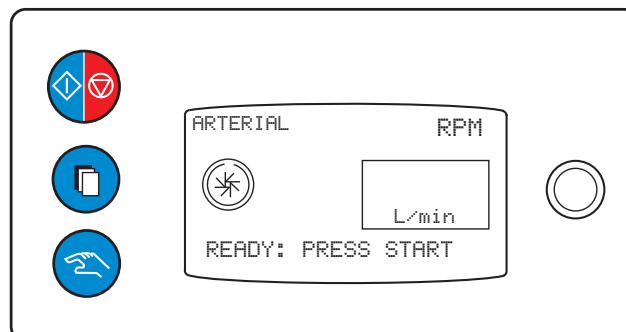
The control unit display will be determined by the pump state. Offline indicates the pump is not assigned to the current Perfusion Screen or a Perfusion Screen has not been opened. Online indicates the pump is assigned to the current Perfusion Screen.

Offline Display

- Module ID
- Centrifugal Icon

Online Display

- Pump Name
- Centrifugal Icon
- “READY: PRESS START” displayed until user activates controls from control unit front panel or the CCM.



Sarns Centrifugal Pumps

WARNING: With a centrifugal pump, maintain a minimum pump speed or clamp the pump outlet line and patient's venous line in order to prevent backflow and drainage of the patient's blood. Minimum pump speed is the speed which overcomes line and patient resistance.

WARNING: If a centrifugal pump stops, clamp the arterial and venous lines and check for air in the arterial line due to retrograde flow; remove air, attain a pump speed adequate to overcome the circuit resistance, and then unclamp the lines.

WARNING: When using a centrifugal pump as the arterial pump, closely monitor the arterial line for air as a centrifugal pump will pump air. Stop infusion if air enters the pump as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury.

WARNING: Avoid prolonged operation of the centrifugal pump with the outlet fully occluded to prevent warming the fluid in the pump chamber and to minimize blood trauma.

WARNING: Use of a centrifugal pump for periods longer than durations appropriate to cardiopulmonary bypass procedures may result in pump failure, reduced pumping capacity, excessive blood trauma, degradation or corrosion of blood contact materials with possibility of particles passing through the blood circuit to the patient, leaks, and increased potential for gaseous emboli.

Continuous Mode

Initiate RPM Mode

Pressing the **Start/Stop** button on the control panel of the centrifugal control unit or the **Start** button on the CCM Pump Control Box will activate and start Continuous mode. This is the basic functional mode of the centrifugal control unit. The pump uses internal RPM data for the motor control.

On the CCM, the centrifugal **Stop** button will be hidden when the pump speed exceeds 1500 RPM. This is intended to prevent the user from stopping the pump suddenly and potentially causing a backflow situation.

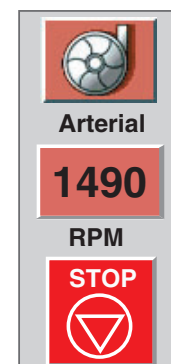
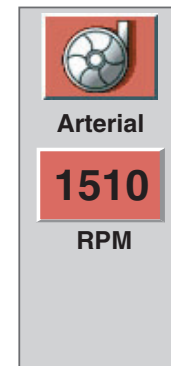
Continuous Operation

During use, the pump speed can be adjusted by using the pump speed control knob or the pump control slide bar on the CCM.

To End Continuous Mode:

On the control panel of the centrifugal control unit, pressing the **Start/Stop** button when the RPMs are greater than 1550 will cause the message "TURN SPEED TO ZERO" to appear in the message area prompting the user to manually reduce the speed. Pressing the **Start/Stop** button again within 4 seconds will stop the pump. If the speed is less than 1560 RPMs, pressing the **Start/Stop** button once will stop the pump. Decreasing the speed to zero using the control knob will stop the pump.

On the CCM, the centrifugal **Stop** button will reappear when the pump



Sarns Centrifugal Pumps

speed is reduced to 1500 RPM. Pressing the **Stop** button will stop and deactivate the pump. Decreasing the speed to zero using the control slide bar will stop the pump. If the pump is stopped and deactivated using the **Start/Stop** button, it must be reactivated using the **Start/Stop** button for the pump to be used again.

Minimum Flow Alarm

Minimum flow alarm is an alarm generated by a centrifugal pump when the flow rate decreases below the user defined limit.

The Min flow alarm is only active at speeds above 1550 RPM.

WARNING: Always place a flow sensor on a centrifugal pump speed/flow display area to enable the minimum flow alarm and any safety connections that have been set for a minimum flow alarm.

1. Set the Min Flow alarm. See **Central Control Monitor** chapter, **Setup tab, Pumps subtab**.
2. Monitor centrifugal pump speed and flow.

Note: Increasing the speed of a centrifugal pump beyond 1550 RPM when the flow is below alarm setpoint after the minflow threshold has been crossed once, can cause an alarm. Devices with established safety connections will respond.

When Pulse mode pumping with a centrifugal control unit, because of variations in flow, the minimum flow alarm is disabled.

Coast™ Response

Coast Response

If the centrifugal pump speed is 1560 RPM or above, a Coast response causes the pump speed to reduce to 1500 RPM. The Coast speed of 1500 RPM may be high enough to allow some forward flow or, in rare instances, may not be sufficient to prevent backflow based on the resistance and back pressure in the perfusion circuit. In addition, a Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds. After this brief lockout, the centrifugal pump speed can be adjusted even though the condition that initiated the Coast response still exists.

If the centrifugal pump speed is less than 1560 RPM, a Coast response does not cause the pump speed to change, however the lockout still occurs.

Adjust the RPMs by using the pump speed control knob on the centrifugal control unit or the control slide bar on the CCM to achieve a static or no-flow state. Monitor the speed closely whenever a Coast response has been executed. Return the pump to its previous setting when appropriate.

Sarns Centrifugal Pumps

CAUTION: A pump may drop to a speed below 1500 RPM if the pump was previously in pulsatile mode with an average speed lower than 1500 RPM when a Coast response occurs.

Coast Lockout

When a safety event with a configured Coast response occurs, a centrifugal pump will lock out manual adjustments to the pump speed for 2 seconds. This brief lockout response guarantees that the safety response occurs.

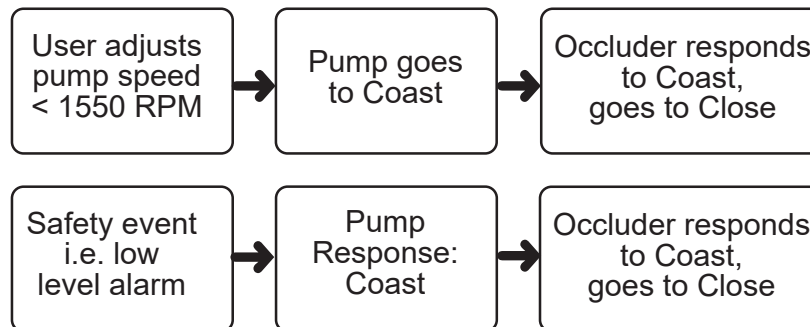
The Coast lockout is signified in two ways during the brief lockout period:

- The centrifugal pump slide bar on the CCM grays out and is disabled.
- The Bar Graph on the Centrifugal Control Unit blinks.

User control is returned after the lockout period.

Coast Event

A Coast event is an event generated by a centrifugal control unit that can initiate a response in other pumps and the occluder. The Coast event message is sent when the centrifugal control unit goes to Coast speed (1500 RPM) as a response to another event or when the user decreases the speed of the centrifugal control unit to 1550 RPMs. Devices configured to respond to a Coast event will do so regardless of how the event was generated. For examples, see the illustration below.



Sarns Centrifugal Pumps

Pulse Mode

The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies

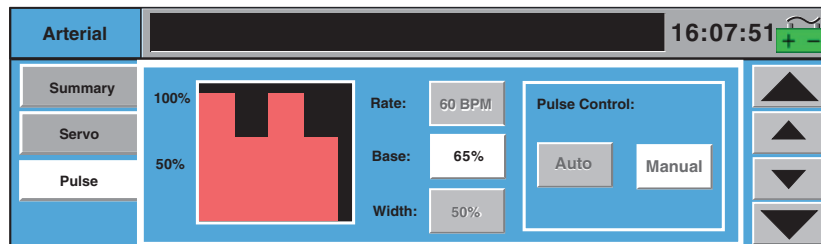
When using Pulse mode during a case, monitor the patient waveform on the operating room monitor.

A pulse cycle consists of one high speed period (Peak) and one low speed period (Base). The high speed is controlled by the pump speed control knob or the pump control slide bar on the CCM and the low speed is determined by the Base setting. The high speed is displayed on the slide bar and the average speed is displayed in the pump control box and on the control unit local display. For the centrifugal control unit, the Width – the amount of time the pulse cycle is at the high speed – is fixed at 50%. The Rate – the number of pulse cycles that occur per minute – is fixed at 60 beats per minute.

Pulse Parameters

The Base must be set up using the CCM:

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.



Sarns Centrifugal Pumps

To Set the Base:

1. Touch the **Base** button.
2. Use the large arrows to change the Base in increments of 10%.
3. Use the small arrows to change the Base in increments of 5%.
4. Touch the **Base** button again to store the new value. The recommended minimum Base is 50%.

To Initiate Pulse Mode:

Initiate Pulse mode only when a stable continuous flow at a speed >1550 RPM has been established.

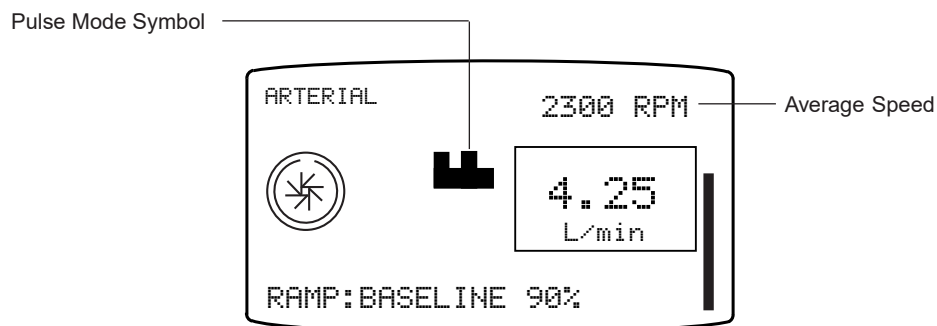
Start Pulse mode operation via the CCM:

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.
3. Touch the **Auto** button.

The Baseline speed decreases from 100% to the selected percent at a rate of 5% every 2 seconds. The pump message area displays the message "RAMP: BASELINE XX%" (where XX is the current Base setting) until the desired setting is reached.

Always adjust the centrifugal pump speed when changing to Pulse mode as the average flow rate will decrease and the speed may be too low, resulting in retrograde flow.

The primary pump display shows the Pulse mode symbol next to the primary display.



Pulse Operation

Adjust the average flow by adjusting the pump speed control knob or the pump control slide bar on the CCM.

CAUTION: During Pulse mode pumping, because of variations in flow, the flow rate displayed is an approximate value.

Note: When monitoring the arterial pulse peak from the patient, the maximum peak pressure is achieved at the pump outlet; this pressure pulse will be dampened by perfusion components such as a long arterial line, a constrictive arterial cannula, and the positioning and compliance of membrane oxygenators and filters in the arterial line.

To End Pulse Mode:

Sarns Centrifugal Pumps

Use **one** of the following options:

- Press the **Manual** button on the control panel and the pump will transition to Continuous mode at the midpoint between the Peak and Base speeds. The message “MANUAL: MONITOR FLOW” appears in the front panel message area.
- Open the Pulse subtab within the Primary Pump tab on the CCM, touch the **Manual** button, and the pump will transition to Continuous mode at the midpoint between the Peak and Base speeds.
- Open the Pulse subtab within the Primary Pump tab on the CCM. Slowly increase the Base setting to 100%. Note that although the flow will be continuous, the pump still operates in Pulse mode.

Note: If the centrifugal pump stops or goes to Coast speed, this will also end Pulse mode.

Servo Mode

In Servo mode, the pump speed is automatically regulated to maintain a specific user selected pressure or flow setpoint. Pressure or flow servo sources are chosen using the Configuration area on the CCM. The servo source should be located at least 12 inches (30,5 cm) downstream of the pump operating in Servo mode. The location of the servo source sensor in the perfusion circuit can affect servo performance. Proper placement of the sensor is ultimately up to the medical professional. The setpoint must be in the correct operating range before Servo mode can be initiated. The centrifugal pump must be above 1550 RPM to initiate Servo mode.

While operating in Servo mode, the pump speed can vary within certain limits to maintain the servo setpoint. The servo speed has a lower speed limit of 1500 RPM and an upper speed limit not to exceed the greater of 125% of the speed at which servo mode was entered or 500 RPM over the speed at which servo mode was entered. If the servo reaches either limit, the speed remains at the limit unless required to change by the servo source or user input. The automatic slowing to 1500 RPM to maintain the servo setpoint will not generate a Coast event nor a Coast response.

Monitor the pump speed closely while in Servo mode, as reduced pump speed may result in hypoperfusion of the patient.

Operating Parameters

The centrifugal pump must be above 1550 RPM to initiate Servo mode.

Flow Servo

Pump Type	Recommended Setpoint		Servo Operating Range	
	Min L/min	Max L/min	Min L/min	Max L/min
Centrifugal	4	6	1	7

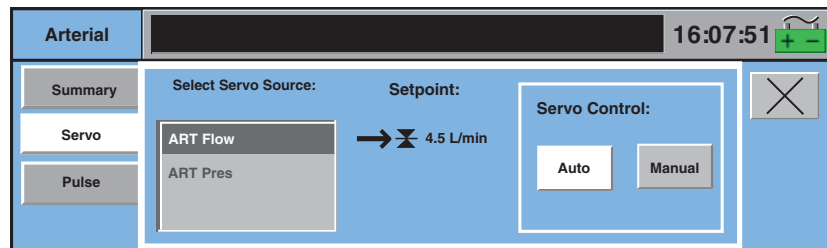
Pressure Servo – Positive

Pump Type	Recommended Setpoint		Recommended Flow		Servo Operating Range	
	Min mmHg	Max mmHg	Min L/min	Max L/min	Min mmHg	Max mmHg
Centrifugal	150	200	4	6	10	400

Pressure Servo – Negative

Pump Type	Recommended Setpoint		Recommended Flow		Servo Operating Range	
	Min mmHg	Max mmHg	Min L/min	Max L/min	Min mmHg	Max mmHg
Centrifugal	-100	-50	4	6	-200	-10

Sarns Centrifugal Pumps



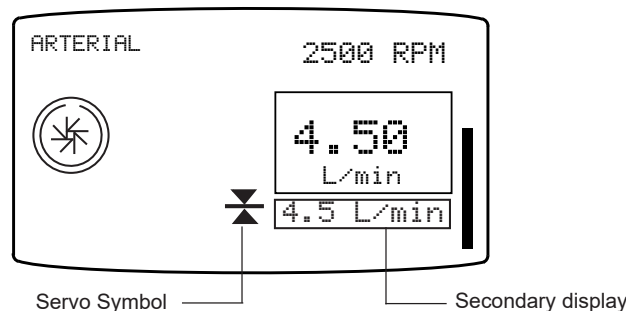
Circuit and clinical parameters, including setpoint value and pump flow rate, should be stabilized in Continuous mode and be within normal operating ranges before initiating Servo mode.

To Initiate Servo Mode:

1. Touch the **Pump** icon to open the Pump tab.
2. Open the **Servo** subtab.
3. Select the source pressure or flow.
4. Touch the **Auto** button.

The pump control panel displays the Servo mode symbol next to the current Servo setpoint value. The control unit secondary display shows the current setpoint value.

The pump will respond to all safety connections including alerts or alarms that have been established for the servo control source while operating in Servo mode.



To change setpoint:

To change the servo setpoint, turn the centrifugal control unit pump speed control knob or adjust the pump control slide bar to increase/decrease the pump speed. When the knob or slide bar adjustment stops, the pump locks onto the current average value of the servo source as the new servo setpoint.

To End Servo Mode:

Use one of the following options:

- Press the **Manual** button on the control panel and the pump will transition to Continuous mode at its current speed. The message “MANUAL: MONITOR FLOW” appears in the control panel message area.
- Open the **Servo** subtab within the **Pump** tab on the CCM, touch the **Manual** button, and the pump will transition to Continuous mode at its current speed.

Note: If the centrifugal pump stops or goes to Coast speed, this will also end Servo mode.

Sarns Centrifugal Pumps

Using Standby Equipment

If the centrifugal control unit fails or the pump will not couple to the drive motor, use the Sarns manual drive or a roller pump to provide arterial flow.

Sarns Manual Drive Unit

Temporarily clamp the patient venous line and the pump outlet line, remove the pump from the drive motor and mount it in the manual drive unit.

- Turn the handle in the direction of the arrows.
- Monitor the speed on the indicators: 1000, 1500, 2000, 2500, 3000 RPM. As the speed increases, each indicator will light and stay lighted once that speed is attained. The lighted indicator with the highest numerical value indicates the speed to the nearest 500 RPM.

Standby Roller Pump

If a standby roller pump is needed, temporarily clamp the patient venous line and the pump outlet line. Reocclude the tubing or insert the tubing from the centrifugal pump into the roller pump and rotate the roller arm by hand to re-engage and occlude the tubing. Verify the proper flow direction. Unclamp the lines and use the roller pump with the centrifugal pump still in the circuit.

Note: If the standby roller pump has been designated as a backup pump, use the Reassign Module subtab within the System tab to assign primary pump functionality and safety connections to the backup roller pump.

Centrifugal Control Unit Messages

Centrifugal control unit messages are displayed in the message area on the control unit display. There are five categories of pump messages.

Response to Messages Table

Message Type	Display
<u>External Alarm</u> - A device or sensor that is connected to the centrifugal control unit has reported an alarm condition.	Reverse video, blinking <Response>: <Message> Possible displays: <ul style="list-style-type: none">• STOPPED: <Message>• COASTING: <Message>• <Message> for Message Only
<u>External Alert</u> - A device or sensor that is connected to the centrifugal control unit has reported an alert condition.	Reverse video <Response>: <Message> Possible displays: <ul style="list-style-type: none">• STOPPED: <Message>• COASTING: <Message>• <Message> for Message Only
<u>Internal Alert</u> - A alert condition related to the centrifugal control unit has been detected.	Reverse video, <Message>
<u>Internal Error</u> - A centrifugal control unit error condition has been detected.	Normal video, blinking <Message>
<u>Internal Status</u> - The status of a centrifugal control unit has changed.	Normal video, <Message>

Sarns Centrifugal Pumps

The following table includes the messages that can appear on the centrifugal control unit display and corresponding operator responses.

Priority	Condition	CCU Display Message	Operator Response
Alarm	Air detected for connected air bubble detector.	<Response>: AIR DETECTED	Clamp lines, when necessary. Correct air condition, reset alarm. Restart pump if stopped.
	Low level detected for connected alarm level sensor.	<Response>: LOW LEVEL	Clamp lines, when necessary. Correct low level condition, restart pump if stopped.
	Alarm over pressure detected for connected pressure sensor.	<Response>: OVER PRESSURE	Clamp lines, when necessary. Correct over pressure condition, restart pump if stopped.
	Connected flow meter minimum flow.	MINIMUM FLOW	Correct minimum flow condition. Message will clear when the condition is corrected.
	Connected flow meter backflow detected.	BACKFLOW	Clamp the lines. Correct backflow condition. Check for air; clear if present. Restart the pump if stopped.
Alert	Connected pump has stopped.	<Response>: PUMP STOP	Restart connected pump, restart pump if stopped.
	Connected pump has started.	<Response>: PUMP START	Restart pump if stopped.
	Connected centrifugal pump detects min flow.	<Response>: MINIMUM FLOW	Restart pump if stopped.
	Low level detected for connected alert level sensor.	<Response>: LOW LEVEL	Correct low level condition.
	Over pressure alert detected for connected pressure sensor.	<Response>: OVER PRESSURE	Correct over pressure condition.
	Motor speed < demand speed for more than 2 seconds.	UNDERSPEED	Clamp the lines. Stop and start the pump. If the message reappears, contact Terumo Cardiovascular Service. Reassign pump, use standby equipment, or manual drive unit.
	Pump cannot maintain servo set point.	MANUAL: MONITOR FLOW	Check that the servo source pressure or flow value is stable. Try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Loss of servo source data.	MANUAL: MONITOR FLOW	Check operation and placement of servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.

Sarns Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Alert	Pump has reached maximum speed trying to attain setpoint.	AUTO: MAX RANGE	Check servo source. Check perfusion circuit. Alert will clear when speed slows to within operating range.
	Pump has reached minimum speed trying to attain setpoint.	AUTO: MIN RANGE	Check servo source. Check perfusion circuit. Alert will clear when speed increases to operating range.
Error	CCM missing.	NO SYSTEM COMPUTER	Continue use of centrifugal control unit from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Network communication failure.	NO COMMUNICATION	Continue use of centrifugal control unit from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Loss of communication from connected roller or centrifugal pump.	CHECK LINKED PUMP	Check for proper operation of the connected pump. If message does not clear, be aware that the pump may not respond to messages or operations requiring information from the connected pump.
	Loss of connected air bubble detector module.	CHECK AIR SENSOR	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of flowmeter module.	CHECK FLOWMETER	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of connected level module.	CHECK LEVEL	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of connected pressure module.	CHECK PRESSURE	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.

Sarns Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Error	Pump stops because: <ul style="list-style-type: none"> • Motor speed is greater than the maximum pump speed OR • Motor speed greater for more than 2 seconds. 	STOPPED: OVERSPEED	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use equipment to maintain perfusion.
	Pump board temperature > 80 °C for more than 2 seconds.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment.
	Low level motor fault	STOPPED: MOTOR ERROR	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Overcurrent condition detected.	STOPPED: OVERCURRENT	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Motor draws too much current	STOPPED: PUMP JAM	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Self test failure.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems.
Status	Drive Motor has become disconnected.	CONNECT MOTOR	Message should clear when the motor is reconnected.
	Manual button is pressed when the pump is in Pulse mode.	MANUAL: MONITOR FLOW	Message should clear when speed is changed or pump is stopped.
	Manual button is pressed when the pump is in Servo mode.	MANUAL: MONITOR FLOW	Message should clear when speed is changed or pump is stopped.
	Stop button pressed in Continuous mode with speed > 1550 RPM.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.
	Stop button pressed in Pulse mode with average RPM > 1550.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.

Sarns Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Status	Stop button is pressed in Servo mode with average RPM > 1550.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.
	Pulse mode has been activated – base is ramping down to target value.	RAMP BASELINE: XX%	Monitor the speed change. The base is reduced by 5% every 2 seconds. Message clears when the target Base setting is reached.

This page intentionally left blank.

Capiox Centrifugal Pumps

Features

The primary function of a centrifugal pump is to move fluids through a cardiopulmonary bypass circuit. Centrifugal pumps are used primarily for arterial pumping applications and as augmented venous return pumps.

The System 1 Capiox centrifugal pump consists of the control unit for control and display functions and a Capiox drive motor which couples magnetically to a disposable Capiox centrifugal pump head. The Capiox (1CX*SP45) centrifugal pump head is not interchangeable with the Sarns centrifugal pump head or the Capiox iCP centrifugal pump head. For Sarns disposable centrifugal pump heads or disposable Capiox iCP centrifugal pump heads, see Sarns Centrifugal Pumps chapter. The non-occlusive pump head moves fluid as a result of the pressure gradient created by the rotation of the pump. The centrifugal control unit mounts on a pole with a mounting bracket. The Capiox centrifugal control unit may be plugged into one of the 6 pump connections on the base or into any of the base module connections. The drive motor is pole-mountable and connects directly to a receptacle on the centrifugal control unit.

Note that the Capiox Drive Motor (P/N 893632) and Capiox Centrifugal Control Unit (P/N 816573) are only available in the Japanese market, and are not currently marketed, sold, or used in the United States of America.

The centrifugal control unit front panel display indicates the pump speed, flow rate (if assigned from a flow meter), and alert, alarm, status, and error messages.

The motor speed may be controlled from either the Central Control Monitor (CCM) or from the pump speed control knob on the front panel of the control unit itself.

In the Configuration area of the Central Control Monitor, a Capiox centrifugal pump can be designated as primary, backup, or have no designation. A Capiox centrifugal pump can be designated as a backup pump only for a primary Capiox centrifugal pump. Each of these has unique functionality as described in the table below.

Function	CCM Features	Unique Functionality
Primary	<ul style="list-style-type: none">• Dedicated Pump Slide Bar• Choice of RPM or L/min, L/min/m² or mL/kg/min display (Note: L/min, L/min/m² or mL/kg/min will only be available when a flow meter is included in the configuration)	<ul style="list-style-type: none">• Pulse mode* operation• Initiate a response in a connected occluder
Backup		<ul style="list-style-type: none">• Primary centrifugal pump functionality can be reassigned to this pump.

*The use of the term "Pulse mode" refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

When operating a device that shares a slide bar location, make sure the slide bar displayed is for the device you intend to operate. The device name appears at the top of the slide bar and the corresponding color appears on the central strip and the scroll control.

Capiox Centrifugal Pumps

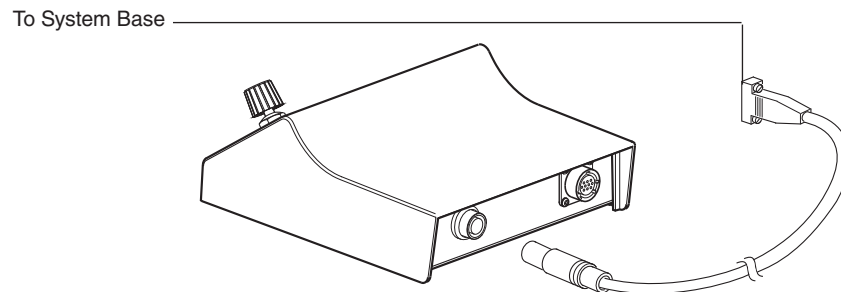
When a centrifugal pump is designated as the primary pump, the system provides the capability to operate the pump in Pulse mode. In this mode, the user can select the Base setting and initiate Pulse mode operation from the Central Control Monitor. Pulse flow operation can be discontinued from the control unit front panel or the CCM.

The system provides the capability to automatically regulate the centrifugal pump speed to maintain a desired pressure or flow set point. This is known as Servo mode. In this mode, the user selects a pressure or flow source and initiates servo operation on the Central Control Monitor. Once in Servo mode, the servo setpoint can be changed by adjusting the pump speed control knob or using the pump slide bar on the Central Control Monitor. Safety connections such as air detection, level detection, and pressure monitoring are configured through the Configuration area on the Central Control Monitor. Pump responses to alerts and alarms are user selectable. Valid responses for centrifugal pumps are Stop, Coast, Message Only, or No Response. The control unit front panel will display a message indicating the event from a connected device.

Installation and Connection

Control Unit Cable

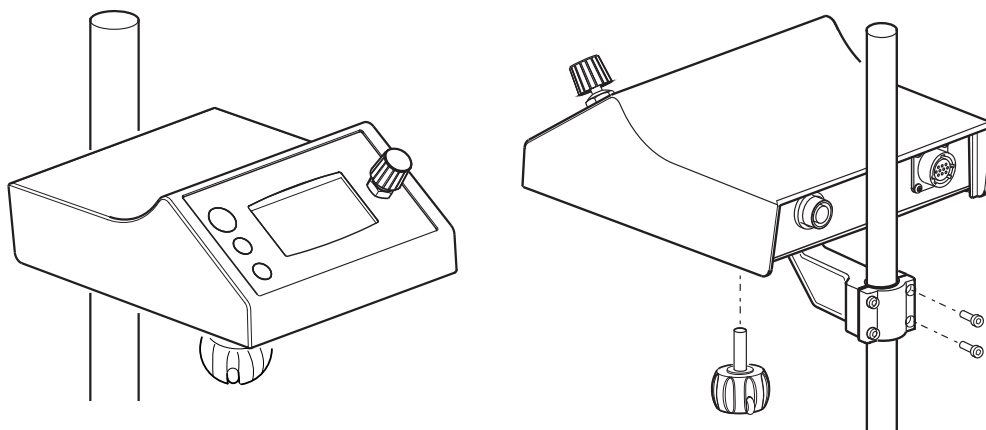
Connect the centrifugal control unit cable to the receptacle located on the back of the control unit. Align the red dot on the control unit cable with the red dot on the control unit receptacle. Insert the connector into the receptacle; an audible click indicates that the connector is fully seated in the receptacle. Pull gently on the cable to verify a secure connection



Pole Mounting

Place the control unit on the mounting arm. Insert the threaded part of the knob through the arm and into the control unit. Select the desired pole position and secure the mounting arm to the pole. Tighten the knob to secure the pump in place.

Adjust the mounting arm to reposition the control unit to the desired location.



Capiox Centrifugal Pumps

Drive Motor

Select the desired pole position and secure the flexible mounting arm to the pole.

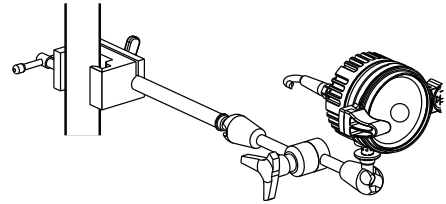
Note: To reduce the potential for an air embolism, the drive motor is typically positioned so that the pump will be near and just below the outlet of the reservoir from which the blood is being pumped.

Flexible Mounting Arm

Select the desired pole position and secure the flexible mounting arm to the pole.

Set the mounting arm to the desired position:

- Turn the tension control knob counterclockwise to loosen the joints of the mount arm. Manually support the flexible arm when adjusting the tension control knob. Do not loosen the knob beyond the stop.
- Position the arm as desired and tighten the tension control knob.

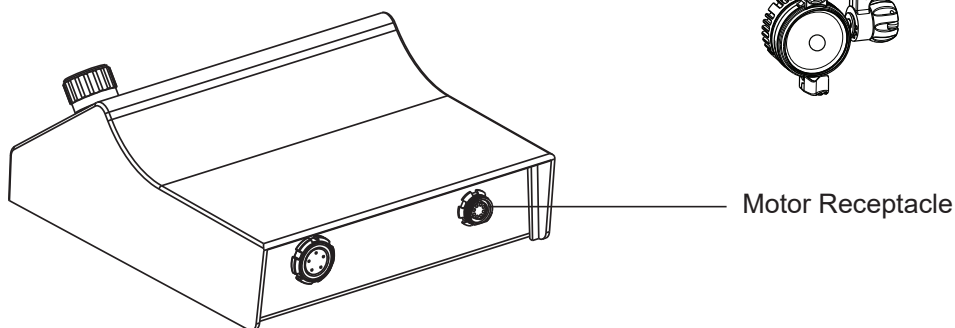
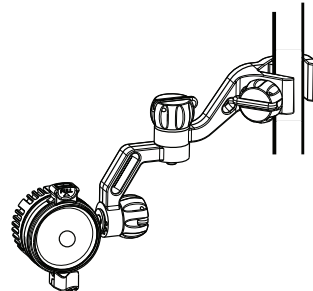


Screw the drive motor onto the threaded stud. Make sure the drive motor is fully installed on the threaded stud. Make sure the drive motor is securely mounted on the mounting arm.

Note: Always manually support the flexible arm when adjusting the tension control knob.

Centrifugal Motor Mount Arm

To mount the drive motor, secure the bracket on a pole or other vertical support and secure the drive motor to the bracket by adding the washer and tightening the bracket knob.



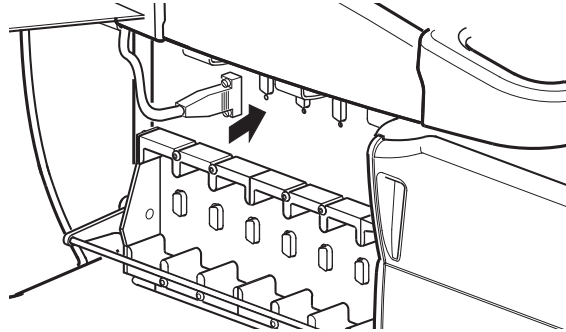
Insert the drive motor cable into the receptacle on the centrifugal drive unit. Pull gently to check the connection. Remove the safety cover from the drive motor.

CAUTION: Do not sterilize the centrifugal drive motor as sterilization may damage the motor.

Capiox Centrifugal Pumps

System Connection

Route and arrange the pump cable to minimize exposure to spills. Connect the cable to one of the pump connections on either side of the system base or, if necessary, to any of the module connections. With a clear view of the desired pump or module connection, carefully connect the pump cable to one of the system pump connections on either side of the system base or, if necessary, to any of the system module connections. Do not use excessive force to seat the connector and make sure not to bend the connector pins. Tighten screws to secure the connection.



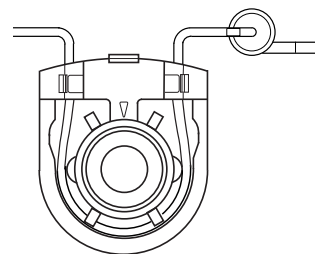
Standoffs are provided in the accessories kit. Two standoffs should be installed on a module receptacle to securely fasten a pump cable or flowmeter cable to the module receptacle. Only a pump power cable or flowmeter power cable can be inserted into a receptacle which has the standoffs installed. Modules cannot be inserted into a module receptacle when standoffs are installed.

Capiox Hand Crank

Terumo Cardiovascular Systems Corporation recommends that either the Capiox Hand Crank or a roller pump be prepared for use as standby equipment. Ensure that the tubing length is sufficient.

If using the Capiox Hand Crank follow the Instructions provided with the Capiox Hand Crank. Be sure there is sufficient space around the handle to turn it easily.

If using a roller pump, position it on either the inlet or the outlet side of the centrifugal pump. Then adjust the pump so that the tubing is totally unoccluded.



Capiox Centrifugal Pumps

Set Up and Prime

CAUTION: Failure to have a backup pumping method, either a standby roller pump or a manual drive unit, may lead to severe patient injury or death. It is highly recommended that a backup pumping method and protocol are prepared. It is recommended that a one-way valve to prevent retrograde flow in the arterial line be used in the cardiopulmonary bypass circuit.

CAUTION: Do not operate the centrifugal pump when unprimed as operating the pump in a “dry” state may damage the internal seal.

CAUTION: Monitor the centrifugal pump and replace it if there are fluid leaks, noisy operation, or blood in the rear chamber. Blood in the rear chamber will damage the pump bearings and cause the pump to eventually fail.

CAUTION: When located on the inlet side of the centrifugal pump, automatic ball-type shutoff valves (used to prevent gas emboli from entering the arterial line) may seat inadvertently and stop flow.* Follow manufacturer’s instructions for placement of valves.

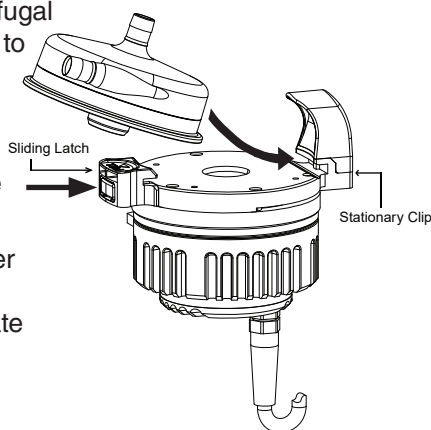
CAUTION: When attaching the disposable centrifugal pump to the drive motor, confirm that the bottom surface of the centrifugal pump is fully engaged with the drive motor and that the slide latch is securely in position. If the flange of the centrifugal pump is not inserted into the notch of the stationary clip decoupling and pump stop may occur.

CAUTION: If the drive motor is started while the slide latch is not secured due to residue of blood and/or drug solutions, the centrifugal pump may detach from the Drive Motor.

* For additional information, see “Automatic Shutoffs on Centrifugal Heart-Lung Bypass Pumps,” Technology for Perfusion, published by ECRI, September 1988, 1(2):6-7.

Consult the disposable centrifugal pump instructions for directions, warnings, etc., regarding the pump. Use only Terumo Capiox Centrifugal Pump. Install the pump but do not start the drive motor until ready to prime the circuit.

Install the Terumo Capiox Centrifugal Pump into the motor by sliding the Pump into the notch of the curved Stationary Clip. Engage the pump into the spring loaded latch and press the pump down into the motor, then release and fully close the sliding latch.



Note: It is recommended that an arterial line filter or similar air barrier device be used in the extracorporeal circuit. Beginning the priming procedure with a crystalloid solution will improve visibility and facilitate bubble removal.

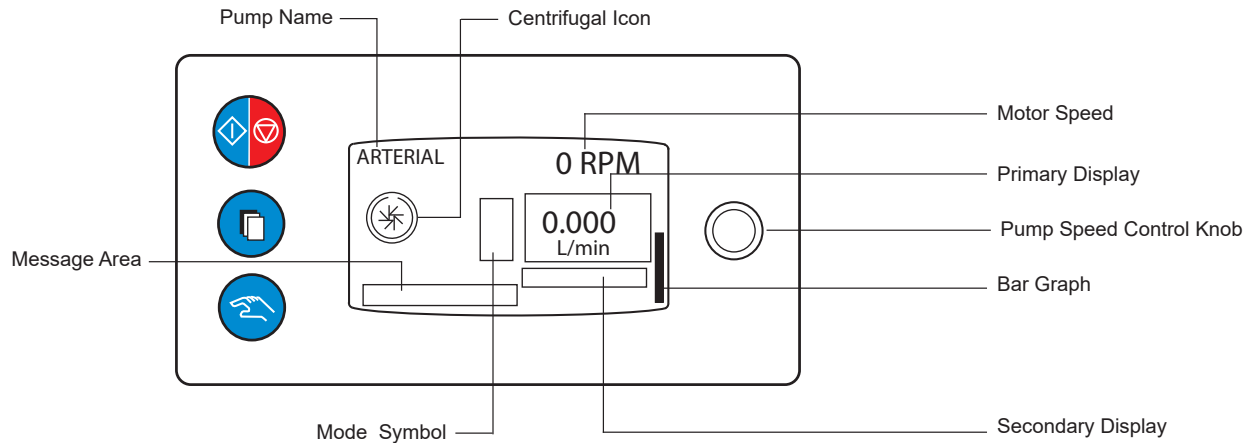
To prime the centrifugal pump:

1. Clamp the pump inlet while priming the reservoir.
2. Unclamp the inlet line slowly and gravity prime the centrifugal pump so that air exits upward through the pump outlet line. The pump may be removed from the drive motor for debubbling. Clamp the pump outlet line after the pump is completely primed. The primed pump may now be use in priming the rest of the circuit.
3. Prime the rest of the circuit, unclamping the pump outlet line as necessary. When stopping flow, clamp the appropriate lines (particularly the pump outlet line and the patient venous line) to prevent depriming this pump.
4. Remove any air from the pump prior to perfusion. Stop the pump, clamp the lines (particularly the pump outlet line), and purge the air back to the reservoir by tipping and tapping. Debubble the circuit by recirculation as necessary.
5. If a roller pump is used instead of the manual drive unit as standbyequipment, use tubing specified for roller pumps. Insert the centrifugal pump inlet or outlet tubing into the roller pump, check that the pump operates properly, and verify the proper flow direction through the roller pump. Then adjust the pump so that the tubing is totally unoccluded or Remove the tubing from the pump.

Capiox Centrifugal Pumps

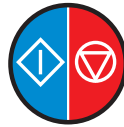
Controls and Displays

CAUTION: Pump control panels and Central Control Monitor are intended for hand and gloved hand operation only. Do not use any instruments on the pump control panels or Central Control Monitor as this may damage the device.



Start/Stop Button

Press the **Start/Stop** button to activate and start the pump. The pump speed will always begin at 0 RPM when the pump is started. The presence of a 0 before RPM indicates that the centrifugal pump is activated. If 0 does not appear before RPM, the centrifugal pump is deactivated. If the Start/Stop button is pressed while the pump is running and the speed is greater than 1300 RPM, the message "TURN SPEED TO ZERO" will be displayed in the message area. Pressing the Start/Stop button again within four seconds will stop the pump. If the speed is less than 1300 RPM, pressing the Start/Stop button once will stop and deactivate the pump. If the pump is stopped and deactivated using the Start/Stop button, it must be reactivated using the Start/Stop button for the pump to be used again.



Select Button

Pressing the **Select** button will reset an active air alarm on a connected Air Bubble Detection system.



Manual Button

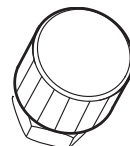
Pressing the **Manual** button will result in the following responses depending on the pump state:

- No response if pump is stopped.
- No response if pump is running in Continuous mode.
- Return to Continuous mode if in Pulse mode.
- Return to Continuous mode if in Servo mode.



Pump Speed Control Knob

Use the pump speed control knob to set the pump speed. Turning the knob clockwise increases the speed, counterclockwise decreases the speed.



Note: Unlike a roller pump, turning the centrifugal pump speed control knob to a speed of 0 RPM will stop and deactivate the centrifugal pump.

Capiox Centrifugal Pumps

Primary Display

L/min if a flowmeter module has been placed on the centrifugal pump speed/flow display area. The primary display will show “-.-” otherwise.

Secondary Display

Servo Source setpoint in Servo mode is displayed below the primary display.

Pump Speed

The pump speed in RPM is displayed above the primary display.

Centrifugal Icon

The centrifugal graphic symbol indicates that the controller is a centrifugal control unit.

Message Area

Displays alert, alarm, status, and error messages.

Mode Symbol

Appears to the left of the primary display to indicate current operating mode: Pulse or Servo.

Bar Graph

Indicates the pump speed control knob demand position relative to the maximum speed.

For 2 seconds from the onset of a Coast response, the bar graph blinks to signify the brief lockout period during which speed cannot be adjusted. This occurs even if the Coast response does not include a speed change.

Pump Name

This area displays the pump name. During the start-up self-test, the pump’s Module ID is displayed.

Check the Start-up Test

When the system power is first turned on, a self-test is conducted. If the self-test fails, a message is displayed on the control unit display and the CCM. Try turning the system off then on to repeat the start up check. If the message appears again and remains on the display, do not use the pump. Contact Terumo Customer Service.

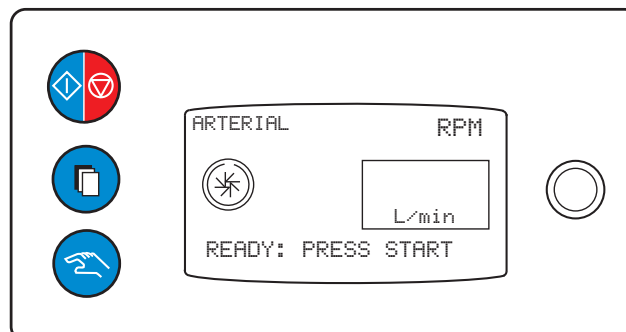
The control unit display will be determined by the pump state. Offline indicates the pump is not assigned to the current Perfusion Screen or a Perfusion Screen has not been opened. Online indicates the pump is assigned to the current Perfusion Screen.

Offline Display

- Module ID
- Centrifugal Icon

Online Display

- Pump Name
- Centrifugal Icon
- “READY: PRESS START” displayed until user activates controls from control unit front panel or the CCM.



Capiox Centrifugal Pumps

WARNING: With a centrifugal pump, maintain a minimum pump speed or clamp the pump outlet line and patient's venous line in order to prevent backflow and drainage of the patient's blood. Minimum pump speed is the speed which overcomes line and patient resistance.

WARNING: If a centrifugal pump stops, clamp the arterial and venous lines and check for air in the arterial line due to retrograde flow; remove air, attain a pump speed adequate to overcome the circuit resistance, and then unclamp the lines.

WARNING: When using a centrifugal pump as the arterial pump, closely monitor the arterial line for air as a centrifugal pump will pump air. Stop infusion if air enters the pump as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury.

WARNING: Avoid prolonged operation of the centrifugal pump with the outlet fully occluded to prevent warming the fluid in the pump chamber and to minimize blood trauma.

WARNING: Use of a centrifugal pump for periods longer than durations appropriate to cardiopulmonary bypass procedures may result in pump failure, reduced pumping capacity, excessive blood trauma, degradation or corrosion of blood contact materials with possibility of particles passing through the blood circuit to the patient, leaks, and increased potential for gaseous emboli.

Continuous Mode

Initiate RPM Mode

Pressing the **Start/Stop** button on the control panel of the centrifugal control unit or the **Start** button on the CCM Pump Control Box will activate and start Continuous mode. This is the basic functional mode of the centrifugal control unit. The pump uses internal RPM data for the motor control.

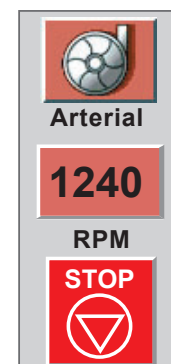
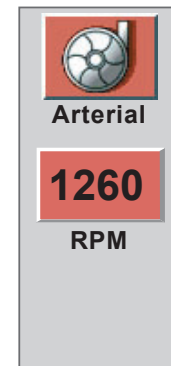
On the CCM, the centrifugal **Stop** button will be hidden when the pump speed exceeds 1250 RPM. This is intended to prevent the user from stopping the pump suddenly and potentially causing a backflow situation.

Continuous Operation

During use, the pump speed can be adjusted by using the pump speed control knob or the pump control slide bar on the CCM.

To End Continuous Mode:

On the control panel of the centrifugal control unit, pressing the **Start/Stop** button when the RPMs are greater than 1300 will cause the message "TURN SPEED TO ZERO" to appear in the message area prompting the user to manually reduce the speed. Pressing the **Start/Stop** button again within 4 seconds will stop the pump. If the speed is less than 1310 RPMs, pressing the **Start/Stop** button once will stop the pump. Decreasing the speed to zero using the control knob will stop the pump.



Capiox Centrifugal Pumps

On the CCM, the centrifugal **Stop** button will reappear when the pump speed is reduced to 1250 RPM. Pressing the **Stop** button will stop and deactivate the pump. Decreasing the speed to zero using the control slide bar will stop the pump. If the pump is stopped and deactivated using the **Start/Stop** button, it must be reactivated using the **Start/Stop** button for the pump to be used again.

Minimum Flow Alarm

Minimum flow alarm is an alarm generated by a centrifugal pump when the flow rate decreases below the user defined limit.

The Min flow alarm is only active at speeds above 1300 RPM.

WARNING: Always place a flow sensor on a centrifugal pump speed/flow display area to enable the minimum flow alarm and any safety connections that have been set for a minimum flow alarm.

1. Set the Min Flow alarm. See **Central Control Monitor** chapter, **Setup tab, Pumps subtab**.
2. Monitor centrifugal pump speed and flow.

Note: Increasing the speed of a centrifugal pump beyond 1300 RPM when the flow is below alarm setpoint after the minflow threshold has been crossed once, can cause an alarm. Devices with established safety connections will respond.

When Pulse mode pumping with a centrifugal control unit, because of variations in flow, the minimum flow alarm is disabled.

Coast™ Response

Coast Response

If the centrifugal pump speed is 1310 RPM or above, a Coast response causes the pump speed to reduce to 1250 RPM. The Coast speed of 1250 RPM may be high enough to allow some forward flow or, in rare instances, may not be sufficient to prevent backflow based on the resistance and back pressure in the perfusion circuit. In addition, a Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds. After this brief lockout, the centrifugal pump speed can be adjusted even though the condition that initiated the Coast response still exists.

If the centrifugal pump speed is less than 1310 RPM, a Coast response does not cause the pump speed to change, however the lockout still occurs.

Adjust the RPMs by using the pump speed control knob on the centrifugal control unit or the control slide bar on the CCM to achieve a static or no-flow state. Monitor the speed closely whenever a Coast response has been executed. Return the pump to its previous setting when appropriate.

Capiox Centrifugal Pumps

CAUTION: A pump may drop to a speed below 1250 RPM if the pump was previously in pulsatile mode with an average speed lower than 1250 RPM when a Coast response occurs.

Coast Lockout

When a safety event with a configured Coast response occurs, a centrifugal pump will lock out manual adjustments to the pump speed for 2 seconds. This brief lockout response guarantees that the safety response occurs.

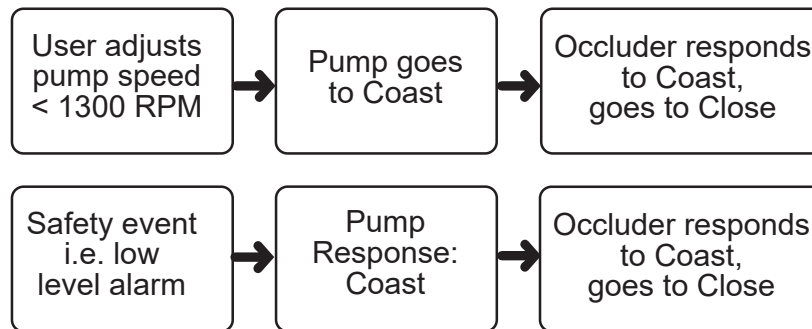
The Coast lockout is signified in two ways during the brief lockout period:

- The centrifugal pump slide bar on the CCM grays out and is disabled.
- The Bar Graph on the Centrifugal Control Unit blinks.

User control is returned after the lockout period.

Coast Event

A Coast event is an event generated by a centrifugal control unit that can initiate a response in other pumps and the occluder. The Coast event message is sent when the centrifugal control unit goes to Coast speed (1250 RPM) as a response to another event or when the user decreases the speed of the centrifugal control unit to 1300 RPMs. Devices configured to respond to a Coast event will do so regardless of how the event was generated. For examples, see the illustration below.



Capiox Centrifugal Pumps

Pulse Mode

The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies

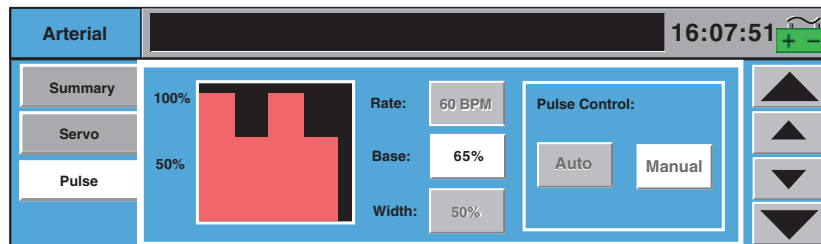
When using Pulse mode during a case, monitor the patient waveform on the operating room monitor.

A pulse cycle consists of one high speed period (Peak) and one low speed period (Base). The high speed is controlled by the pump speed control knob or the pump control slide bar on the CCM and the low speed is determined by the Base setting. The high speed is displayed on the slide bar and the average speed is displayed in the pump control box and on the control unit local display. For the centrifugal control unit, the Width – the amount of time the pulse cycle is at the high speed – is fixed at 50%. The Rate – the number of pulse cycles that occur per minute – is fixed at 60 beats per minute.

Pulse Parameters

The Base must be set up using the CCM:

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.



Capiox Centrifugal Pumps

To Set the Base:

1. Touch the **Base** button.
2. Use the large arrows to change the Base in increments of 10%.
3. Use the small arrows to change the Base in increments of 5%.
4. Touch the **Base** button again to store the new value. The recommended minimum Base is 50%.

To Initiate Pulse Mode:

Initiate Pulse mode only when a stable continuous flow at a speed >1300 RPM has been established.

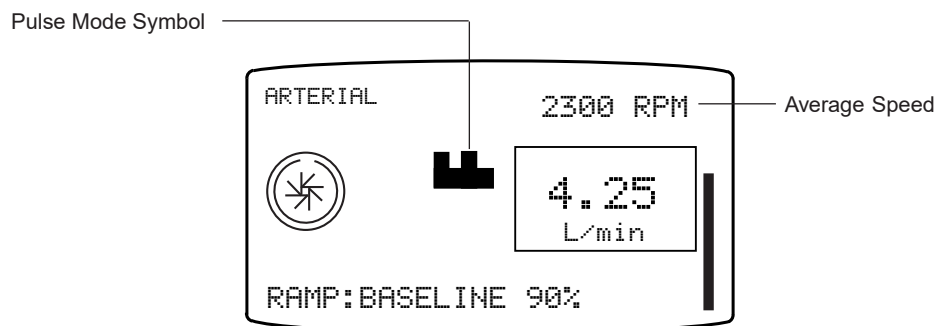
Start Pulse mode operation via the CCM:

1. Touch the **Primary Pump** icon to access the Primary Pump tab.
2. Select the **Pulse** subtab.
3. Touch the **Auto** button.

The Baseline speed decreases from 100% to the selected percent at a rate of 5% every 2 seconds. The pump message area displays the message “RAMP: BASELINE XX%” (where XX is the current Base setting) until the desired setting is reached.

Always adjust the centrifugal pump speed when changing to Pulse mode as the average flow rate will decrease and the speed may be too low, resulting in retrograde flow.

The primary pump display shows the Pulse mode symbol next to the primary display.



Pulse Operation

Adjust the average flow by adjusting the pump speed control knob or the pump control slide bar on the CCM.

CAUTION: During Pulse mode pumping, because of variations in flow, the flow rate displayed is an approximate value.

Note: When monitoring the arterial pulse peak from the patient, the maximum peak pressure is achieved at the pump outlet; this pressure pulse will be dampened by perfusion components such as a long arterial line, a constrictive arterial cannula, and the positioning and compliance of membrane oxygenators and filters in the arterial line.

Capiox Centrifugal Pumps

To End Pulse Mode:

Use **one** of the following options:

- Press the **Manual** button on the control panel and the pump will transition to Continuous mode at the midpoint between the Peak and Base speeds. The message “MANUAL: MONITOR FLOW” appears in the front panel message area.
- Open the Pulse subtab within the Primary Pump tab on the CCM, touch the **Manual** button, and the pump will transition to Continuous mode at the midpoint between the Peak and Base speeds.
- Open the Pulse subtab within the Primary Pump tab on the CCM. Slowly increase the Base setting to 100%. Note that although the flow will be continuous, the pump still operates in Pulse mode.

Note: If the centrifugal pump stops or goes to Coast speed, this will also end Pulse mode.

Servo Mode

In Servo mode, the pump speed is automatically regulated to maintain a specific user selected pressure or flow setpoint. Pressure or flow servo sources are chosen using the Configuration area on the CCM. The servo source should be located at least 12 inches (30,5 cm) downstream of the pump operating in Servo mode. The location of the servo source sensor in the perfusion circuit can affect servo performance. Proper placement of the sensor is ultimately up to the medical professional. The setpoint must be in the correct operating range before Servo mode can be initiated. The centrifugal pump must be above 1300 RPM to initiate Servo mode.

While operating in Servo mode, the pump speed can vary within certain limits to maintain the servo setpoint. The servo speed has a lower speed limit of 1250 RPM and an upper speed limit not to exceed the greater of 125% of the speed at which servo mode was entered or 500 RPM over the speed at which servo mode was entered. If the servo reaches either limit, the speed remains at the limit unless required to change by the servo source or user input. The automatic slowing to 1250 RPM to maintain the servo setpoint will not generate a Coast event nor a Coast response.

Monitor the pump speed closely while in Servo mode, as reduced pump speed may result in hypoperfusion of the patient.

Operating Parameters

The centrifugal pump must be above 1300 RPM to initiate Servo mode.

Flow Servo

Pump Type	Recommended Setpoint		Servo Operating Range	
	Min L/min	Max L/min	Min L/min	Max L/min
Centrifugal	4	6	1	7

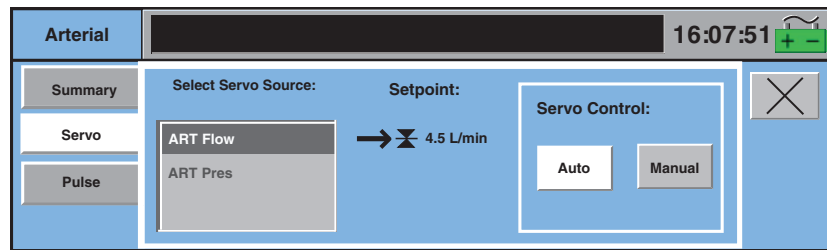
Pressure Servo – Positive

Pump Type	Recommended Setpoint		Recommended Flow		Servo Operating Range	
	Min mmHg	Max mmHg	Min L/min	Max L/min	Min mmHg	Max mmHg
Centrifugal	150	200	4	6	10	400

Pressure Servo – Negative

Pump Type	Recommended Setpoint		Recommended Flow		Servo Operating Range	
	Min mmHg	Max mmHg	Min L/min	Max L/min	Min mmHg	Max mmHg
Centrifugal	-100	-50	4	6	-200	-10

Capiox Centrifugal Pumps



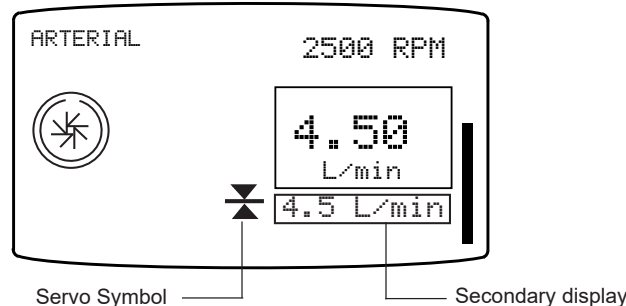
Circuit and clinical parameters, including setpoint value and pump flow rate, should be stabilized in Continuous mode and be within normal operating ranges before initiating Servo mode.

To Initiate Servo Mode:

1. Touch the **Pump** icon to open the Pump tab.
2. Open the **Servo** subtab.
3. Select the source pressure or flow.
4. Touch the **Auto** button.

The pump control panel displays the Servo mode symbol next to the current Servo setpoint value. The control unit secondary display shows the current setpoint value.

The pump will respond to all safety connections including alerts or alarms that have been established for the servo control source while operating in Servo mode.



To change setpoint:

To change the servo setpoint, turn the centrifugal control unit pump speed control knob or adjust the pump control slide bar to increase/decrease the pump speed. When the knob or slide bar adjustment stops, the pump locks onto the current average value of the servo source as the new servo setpoint.

To End Servo Mode:

Use one of the following options:

- Press the **Manual** button on the control panel and the pump will transition to Continuous mode at its current speed. The message “MANUAL: MONITOR FLOW” appears in the control panel message area.
- Open the **Servo** subtab within the **Pump** tab on the CCM, touch the **Manual** button, and the pump will transition to Continuous mode at its current speed.

Note: If the centrifugal pump stops or goes to Coast speed, this will also end Servo mode.

Capiox Centrifugal Pumps

Using Standby Equipment

If the centrifugal control unit fails or the pump will not couple to the drive motor, use the manual drive or a roller pump to provide arterial flow.

Capiox Hand Crank

Temporarily clamp the patient venous line and the pump outlet line, remove the pump from the drive motor and mount it in the Capiox Hand Crank. Follow the Instructions provided with the Capiox Hand Crank.

Standby Roller Pump

If a standby roller pump is needed, temporarily clamp the patient venous line and the pump outlet line. Reocclude the tubing or insert the tubing from the centrifugal pump into the roller pump and rotate the roller arm by hand to re-engage and occlude the tubing. Verify the proper flow direction. Unclamp the lines and use the roller pump with the centrifugal pump still in the circuit.

Note: If the standby roller pump has been designated as a backup pump, use the Reassign Module subtab within the System tab to assign primary pump functionality and safety connections to the backup roller pump.

Centrifugal Control Unit Messages

Centrifugal control unit messages are displayed in the message area on the control unit display. There are five categories of pump messages.

Response to Messages Table

Message Type	Display
<u>External Alarm</u> - A device or sensor that is connected to the centrifugal control unit has reported an alarm condition.	Reverse video, blinking <Response>: <Message> Possible displays: <ul style="list-style-type: none">• STOPPED: <Message>• COASTING: <Message>• <Message> for Message Only
<u>External Alert</u> - A device or sensor that is connected to the centrifugal control unit has reported an alert condition.	Reverse video <Response>: <Message> Possible displays: <ul style="list-style-type: none">• STOPPED: <Message>• COASTING: <Message>• <Message> for Message Only
<u>Internal Alert</u> - A alert condition related to the centrifugal control unit has been detected.	Reverse video, <Message>
<u>Internal Error</u> - A centrifugal control unit error condition has been detected.	Normal video, blinking <Message>
<u>Internal Status</u> - The status of a centrifugal control unit has changed.	Normal video, <Message>

Capiox Centrifugal Pumps

The following table includes the messages that can appear on the centrifugal control unit display and corresponding operator responses.

Priority	Condition	CCU Display Message	Operator Response
Alarm	Air detected for connected air bubble detector.	<Response>: AIR DETECTED	Clamp lines, when necessary. Correct air condition, reset alarm. Restart pump if stopped.
	Low level detected for connected alarm level sensor.	<Response>: LOW LEVEL	Clamp lines, when necessary. Correct low level condition, restart pump if stopped.
	Alarm over pressure detected for connected pressure sensor.	<Response>: OVER PRESSURE	Clamp lines, when necessary. Correct over pressure condition, restart pump if stopped.
	Connected flow meter minimum flow.	MINIMUM FLOW	Correct minimum flow condition. Message will clear when the condition is corrected.
	Connected flow meter backflow detected.	BACKFLOW	Clamp the lines. Correct backflow condition. Check for air; clear if present. Restart the pump if stopped.
Alert	Connected pump has stopped.	<Response>: PUMP STOP	Restart connected pump, restart pump if stopped.
	Connected pump has started.	<Response>: PUMP START	Restart pump if stopped.
	Connected centrifugal pump detects min flow.	<Response>: MINIMUM FLOW	Restart pump if stopped.
	Low level detected for connected alert level sensor.	<Response>: LOW LEVEL	Correct low level condition.
	Over pressure alert detected for connected pressure sensor.	<Response>: OVER PRESSURE	Correct over pressure condition.
	Motor speed < demand speed for more than 2 seconds.	UNDERSPEED	Clamp the lines. Stop and start the pump. If the message reappears, contact Terumo Cardiovascular Service. Reassign pump, use standby equipment, or manual drive unit.
	Pump cannot maintain servo set point.	MANUAL: MONITOR FLOW	Check that the servo source pressure or flow value is stable. Try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.
	Loss of servo source data.	MANUAL: MONITOR FLOW	Check operation and placement of servo source. If source is operating properly, try to initiate servo operation via the CCM. If message appears again, discontinue use of servo operation.

Capiox Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Alert	Pump has reached maximum speed trying to attain setpoint.	AUTO: MAX RANGE	Check servo source. Check perfusion circuit. Alert will clear when speed slows to within operating range.
	Pump has reached minimum speed trying to attain setpoint.	AUTO: MIN RANGE	Check servo source. Check perfusion circuit. Alert will clear when speed increases to operating range.
Error	CCM missing.	NO SYSTEM COMPUTER	Continue use of centrifugal control unit from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Network communication failure.	NO COMMUNICATION	Continue use of centrifugal control unit from front panel controls and displays. Be aware that the pump may not respond to events from connected devices. Do not use the system again until it is serviced by Terumo Cardiovascular Systems Service.
	Loss of communication from connected roller or centrifugal pump.	CHECK LINKED PUMP	Check for proper operation of the connected pump. If message does not clear, be aware that the pump may not respond to messages or operations requiring information from the connected pump.
	Loss of connected air bubble detector module.	CHECK AIR SENSOR	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of flowmeter module.	CHECK FLOWMETER	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of connected level module.	CHECK LEVEL	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.
	Loss of connected pressure module.	CHECK PRESSURE	Check for proper operation and connection of the module or try connecting module to another base receptacle. If message does not clear, be aware that the pump may not respond to messages from the module. Replace module and reassign.

Capiox Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Error	Pump stops because: <ul style="list-style-type: none"> • Motor speed is greater than the maximum pump speed OR • Motor speed greater for more than 2 seconds. 	STOPPED: OVERSPEED	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use equipment to maintain perfusion.
	Pump board temperature > 80 °C for more than 2 seconds.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment.
	Low level motor fault	STOPPED: MOTOR ERROR	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Overcurrent condition detected.	STOPPED: OVERCURRENT	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Motor draws too much current	STOPPED: PUMP JAM	Clamp the lines. Try to restart the pump. If the message reappears, discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems. Reassign or use standby equipment to maintain perfusion.
	Self test failure.	SERVICE PUMP	Discontinue use of the pump until it has been serviced by Terumo Cardiovascular Systems.
Status	Drive Motor has become disconnected.	CONNECT MOTOR	Message should clear when the motor is reconnected.
	Manual button is pressed when the pump is in Pulse mode.	MANUAL: MONITOR FLOW	Message should clear when speed is changed or pump is stopped.
	Manual button is pressed when the pump is in Servo mode.	MANUAL: MONITOR FLOW	Message should clear when speed is changed or pump is stopped.
	Stop button pressed in Continuous mode with speed > 1300 RPM.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.
	Stop button pressed in Pulse mode with average RPM > 1300.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.

Capiox Centrifugal Pumps

	Priority Condition	CCU Display Message	Operator Response
Status	Stop button is pressed in Servo mode with average RPM > 1300.	TURN SPEED TO ZERO	Message clears in 4 seconds if no action is taken. Press Stop button again to stop the pump.
	Pulse mode has been activated – base is ramping down to target value.	RAMP BASELINE: XX%	Monitor the speed change. The base is reduced by 5% every 2 seconds. Message clears when the target Base setting is reached.

This page intentionally left blank.

Modules

Features

Modules are the physical devices that connect safety and monitoring systems to the Terumo® Advanced Perfusion System 1. There are 9 types of modules that connect to the system base and they are held in place with the module bracket system. Module types and the maximum number of modules that can be used in a Perfusion Screen are:

Module Types	Maximum
Air Bubble Detection	4
Level Monitoring	1
Pressure Monitoring	4
Temperature Monitoring	4
Flow Monitoring	4
Occluder	1
CDI 100/101 or 500/550	1
Data Transfer RS-232	1

Although modules look similar (except the flow module) and have identical connectors for attaching to the base, each module has specific software and unique connectors which enables it to communicate with and attach to its intended device or sensor.

Each module is labeled so it can be identified while it is attached to the system base and has a tricolor LED above the label that indicates its operational status.

The LED will display green, red, or yellow indications as follows:

- Constant Green – Online Mode
- Blinking Green – Assignment Mode
- Constant Yellow – Offline Mode
- Blinking Yellow – Alert Condition
- Constant Red – Broken Mode
- Blinking Red – Alarm condition

Before opening a Perfusion Screen, the module LED will cycle green, yellow, red, then will remain constant yellow in Offline Mode. When a Perfusion Screen is opened and the module is recognized as part of the case, the module enters Online mode and the LED displays constant green.

If the Power-On Self-Test fails, a message is displayed at the top of the Main Screen and the LED will either display constant red or will continuously cycle through the colors. To verify a module is broken, connect the module to another base receptacle and allow the Power-On Self-test to run again. If the module fails again, replace the module. A broken module will display a red X on the device icon when a Perfusion Screen is opened on the Central Control Monitor (CCM).

CAUTION: Do not touch the module connector pins as static electricity and moisture may damage the module circuitry and pins.

CAUTION: Check the connectors for damage before use. Do not use a module if damaged or bent connector pins are found.

CAUTION: Do not use extension cords to connect the modules to the system. Use of extension cords may compromise performance.

CAUTION: Use only the cables provided to connect flowmeter modules to the system.

This page intentionally left blank.

Modules

Air Bubble Detection (ABD)

A Perfusion Screen can contain up to 4 air sensors.

To detect air before its introduction to the patient, it is highly recommended that an ABD system be used on the tubing between the outlet of the venous reservoir and the arterial pump, the arterial line after the oxygenator, or in both locations in the extracorporeal circuit for every case.

There are three air sensor sizes. The 3/8 in. (9,5 mm) x 3/32 in. (2,4 mm) sensor (red) will detect air bubbles of 0.5 cc or larger at flow rates up to 6 L/min for 3/8 in. (9,5 mm) tubing. The 1/4 in. (6,4 mm) x 3/32 in. (2,4 mm) sensor (gold) and 1/4 in. (6,4 mm) x 1/16 in. (1,6 mm) sensor (black) will detect air bubbles of 0.3 cc or larger at flow rates up to 3 L/min for 1/4 in. (6,4 mm) tubing.

The ABD detects air bubbles within clear, flexible medical grade PVC tubing in clear priming solutions or blood with hematocrit from 15% to 40%.

WARNING: The level detection and air bubble detection systems must be properly set up and turned ON as UNDETECTED AIR in the line may cause gaseous emboli to be pumped into the patient, with attendant risk of DEATH OR SEVERE INJURY. The performance of the level and air detection must be verified before each use.

WARNING: If an air or level detection system is turned OFF or is configured not to stop a pump, then constant monitoring is required to reduce the risk of air embolism in the line.

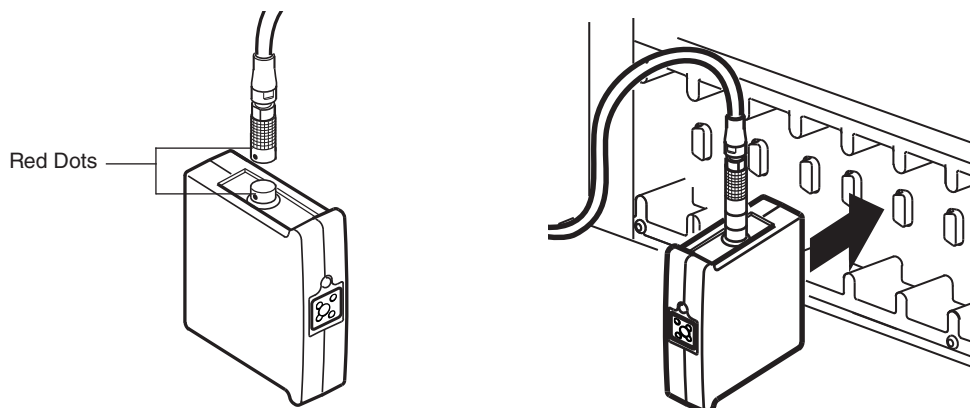
WARNING: If the cardioplegia pump is drawing blood from the arterial line, stop the cardioplegia pump whenever the arterial pump is stopped to avoid infusion of air.

Connect ABD Module

1. Select the sensor which is appropriate for the tubing size to be used.

WARNING: The air sensor may not detect air bubbles smaller than the minimum size specified for the air sensor used. The air sensor must be used with the appropriate tubing size and within the flow rate limitations specified for the air sensor or the air sensor may not detect air bubbles.

2. Ensure the sensor is clean, free of debris, and undamaged.
3. Align red dots on the sensor cable and module receptacle and insert cable into module. Pull gently to check the connection.
4. Insert ABD module into base receptacle as close as possible to the location where the sensor will be used. Arrange cables to minimize exposure to spills.



Modules

Air Bubble Detection (ABD)

Connect Air Sensor

The air sensor size and weight allow it to mount directly on the tubing. However, the sensor can be mounted on a bracket to provide stability and is recommended for 1/4 in. tubing.

CAUTION: Do not drop air, level, or flow sensors as shock may damage the sensor.

CAUTION: Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.

Attach mounting bracket to pole, if desired.

Determine proper position within perfusion circuit.

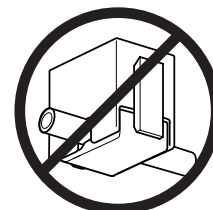
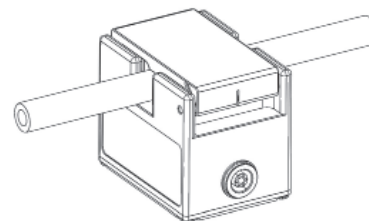
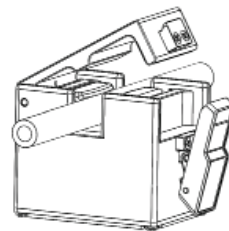
WARNING: The air sensor must be positioned a minimum of 4 ft. (1,2 m) from the patient to allow the air bubble detection system sufficient time to respond before air can reach the patient.

WARNING: The air sensor latch must be completely closed to secure the sensor to the tubing.

WARNING: The air sensor may falsely alarm with intense electrical noise.

- Proper positioning of the air sensor is the choice of the medical professional.
- The air sensor must be positioned so there will be sufficient time to stop the pump and vent air bubbles before reaching the patient.
- High flow rate, differences in circuit configuration, and changing conditions of operation can cause air bubbles to travel 4 ft. (1,2 m) when the pump stops. Air bubbles may then move to a higher point in the circuit.

1. If necessary, use reducing connectors to adapt the tubing section so that the appropriate size of tubing can be placed into the air sensor.
2. Open the sensor by pushing up on the bottom of the latch and slide latch off the door bracket.
3. Insert tubing.
4. Close and latch the sensor door to secure the sensor around the tube. Do not apply gel, as acoustical couplant is not required nor recommended for the sensor.
5. If desired, connect the sensor to the bracket. The air sensor may be mounted directly on the tubing, provided the weight of the sensor does not kink or stress the tube.
 - Do not position the sensor upside down (cover toward floor) as bubbles may go undetected.



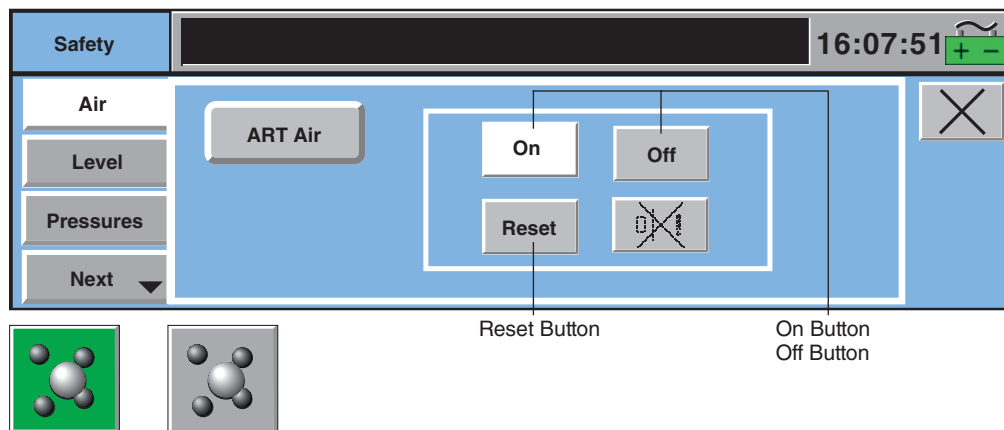
Modules

Air Bubble Detection (ABD)

Enabling, Resetting, or Disabling Air Bubble Detection Alarms

Select the **Air** subtab within the Safety tab on the Perfusion Screen or touch the **Air** icon on the CCM.

1. Touch the air detection **On** button to enable the alarm capability for the air detection system and the icon on the CCM turns green.
2. Touch the air detection **Off** button to disable the alarm capability for the air detection system and the icon on the CCM turns gray.



3. When air is detected, correct the condition, and then touch the **Reset** button on the CCM to clear an air alarm and leave the air bubble detector enabled. If an air detector has a safety connection to a pump, the alarm can also be reset by touching the **Select** button on the pump control panel after the air has been cleared. The ABD is the only safety device that requires a reset by the user to confirm that the issue has been addressed. All other safety devices automatically reset when the issue is resolved.

System Response to Air Bubble Detection Alarm

Air Icon	Air Module	Message	Connected Device(s)	Audible Tone
Flashes red	LED flashes red	Message with sensor name in the CCM message area and on the local display of any pumps with an air safety connection. Safety tab opens.	Respond as configured	Dual-tone alarm

The alarm state will clear when the condition is corrected and the air bubble detection system is Reset or turned Off.

Note: The ABD system will alarm when the air sensor is disconnected from the module.

Modules

Air Bubble Detection (ABD)

Test Before Use

The performance of every air bubble detection system must be verified before each use.

Action	Results
Make necessary safety connections. This is done in the Configuration Screen. Refer to CCM chapter Configuration section for details.	
Air bubble detection system is off; sensor does not contain tubing.	Air icon is gray. Module LED is green.
Start pump(s). Adjust speed.	Pumps start because air detection system is off.
Turn air bubble detection system on.	Pumps should respond as they were configured and message will display on the pump display. Air icon flashes red. Air detect message appears in the message area of the CCM and the air module LED flashes red. Dual-tone alarm sounds.
Insert tubing containing clear liquid or blood into sensor, touch reset on the CCM or press Select on the pump control panel.	Air message clears from pump display and CCM. Air icon and module LED turn green.
Start pump(s) if stopped. Adjust speed.	Pump(s) start.

Air Bubble Detection Messages

Priority	Condition	CCM Message	Operator Response
Alarm	Air detected	<ABD name>: AIR DETECTED	Correct air condition, reset air sensor, restart pump if stopped.
	Air detected	AIR DETECTED: <Pump Name> <Pump Response>	Correct air condition, reset air sensor, restart pump if stopped.
	Air sensor on and disconnected	<ABD name>: AIR DETECTED	Reconnect air sensor, reset air sensor, restart pump if stopped.
Alert	Air sensor malfunction	<ABD name>: CHECK SENSOR	Check air sensor cable connections. Reset air sensor. If message does not clear, replace air sensor.

Modules

Air Bubble Detection (ABD)

In the Event of an Air Alarm

The following actions should be taken if you receive an Air Alarm.

During Prime or Setup:

- Ensure there is no air in the circuit.
 - Reset air alarm and restart pump(s), if required.
- If alarm persists or repeats with no air present, check for the following setup issues.
 - Check to ensure the tubing is properly placed inside the sensor and the latch is fully and securely closed.
 - Check to ensure the air sensor cable is properly attached to both the sensor and the ABD Module.
- If no setup issues were found, consider backup air detection equipment.
 - Contact Terumo Customer Service.

During Cardiopulmonary Bypass:

- If necessary, stop the arterial and/or cardioplegia pump.

CAUTION: Failure to stop the cardioplegia pump when stopping the arterial pump may cause infusion of air into the circuit depending on the circuit setup.

- Clamp the line, if appropriate.
- Inspect for air and remove air, if needed.
- Reset the alarm and restart the pump.
- If alarm will not reset:
 - Disable the air sensor by turning it **OFF** on the CCM in the Air subtab within the Safety tab. It will be necessary to use an alternate air monitoring method.
 - Use a backup Air Sensor and Cable, if possible.
 - Contact Terumo Customer Service after the case is completed.

Modules

Air Bubble Detection (ABD)

In the Event of an ABD Module Malfunction:

Symptoms	How to respond
<p>The following symptoms will occur in the event the ABD system fails because of a faulty component:</p> <ul style="list-style-type: none"> The “CHECK AIR SENSOR” message appears on the local pump display. <div data-bbox="418 701 708 741" data-label="Text"> <p>CHECK AIR SENSOR</p> </div> The ABD icon on the Central Control Monitor (CCM) remains “green;” a question mark superimposes itself intermittently over the icon. <div data-bbox="363 898 737 1014" data-label="Image"> </div> The LED light on the module cycles between green, yellow, red, and Off. 	<ul style="list-style-type: none"> Replace the ABD Module and reassign a backup module. Refer to Central Control Monitor chapter, Reassign Module Subtab section. If you do not have a backup ABD module, use increased vigilance throughout the remainder of the case. <u>If you are using a reservoir-optional circuit:</u> Any malfunction of a safety system requires consideration for converting to a circuit with a venous reservoir. Contact Terumo Customer Service at the end of the case.
<p>The following symptoms <u>may</u> or <u>may not</u> occur with this failure:</p> <ul style="list-style-type: none"> The pump may stop/coast/pause with or without any audible or visual alarms. The ABD system may activate its audible alarm. The ABD system may activate its visual alarm. 	<ul style="list-style-type: none"> Restart the pump after determining that there is no air in the circuit. Replace the ABD Module and reassign a backup module. Refer to Central Control Monitor chapter Reassign Module Subtab section. If you do not have a backup ABD module, use increased vigilance throughout the remainder of the case. <u>If you are using a reservoir-optional circuit:</u> Any malfunction of a safety system requires consideration for converting to a circuit with a venous reservoir. Contact Terumo Customer Service at the end of the case.

Modules

Level Monitoring

A Perfusion Screen can be configured to monitor one alert and one alarm level location through the use of one module. The system detects blood/prime solution level in polycarbonate venous hard shell reservoirs.

WARNING: The level detection and air bubble detection systems must be properly set up and turned ON as UNDETECTED AIR in the line may cause gaseous emboli to be pumped into the patient, with attendant risk of DEATH OR SEVERE INJURY. The performance of the level and air detection must be verified before each use.

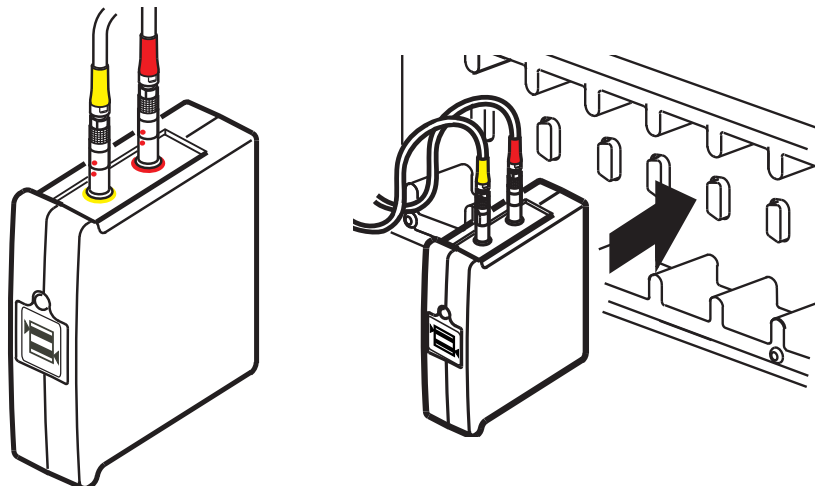
WARNING: If an air or level detection system is turned OFF or is configured not to stop a pump, then constant monitoring is required to reduce the risk of air embolism in the line.

WARNING: Conduct a wet run and test that the level detection system will function properly with the particular reservoir to be used.

WARNING: To prevent the level sensor from detaching and causing a false alarm, do not place the level sensor over labels, decals, or painted markings.

Connect Level Sensor System

1. Connect the yellow alert and the red alarm sensor to the color coded connectors on the level module. Align the red dot on the sensor cable with the red dot on the module receptacle.
2. Insert level module into base receptacle as close as possible to the location where the sensor will be used. Arrange cables to minimize exposure to spills.



Modules

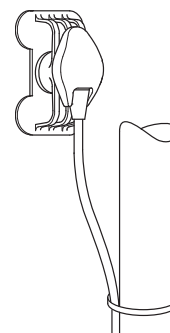
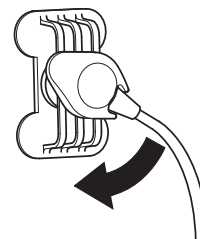
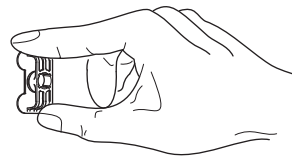
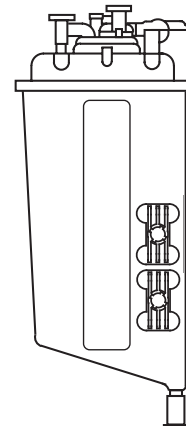
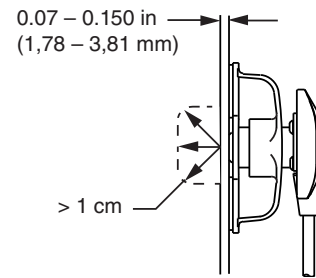
Level Monitoring

Attach Sensors to Reservoir

- Do not position sensors within 1 cm of internal reservoir structures.
 - Verify that the reservoir wall thickness is within 0.07 – 0.150 in (1,78 – 3,81 mm). Thin walls may cause false alarms while thick walls prevent alarms from activating.
 - Do not place sensors over surface irregularities.
 - Do not place sensors below the minimum level recommended by the reservoir manufacturer.
1. Attach the level sensor pads to the sides of the rigid reservoir only.
 2. Determine the appropriate detection positions for the low level alert and alarm. Detection positions must be slightly offset and above the minimum level for the reservoir.
 3. Be sure the surface is flat and clean.
 4. Hold the pad vertically and align the center of the sensor pad at the level to be detected. Press firmly on the tabs to secure the mounting pad to the reservoir.
 5. Allow the adhesive to set five minutes to get maximum adhesion prior to connecting the sensor.
 6. Lightly press the sensor lens against the sponge saturated with Sarns™ Level Sensor II Gel.
 7. Align the tabs of the sensor with the slots in the pad. Rotate the sensor clockwise to lock in place.
 8. Do not twist the sensor too hard as this may weaken the adhesive bond to the reservoir and dislodge the pad.
 9. The cable must hang straight down. Secure each cable, as illustrated, to an adjacent pole to prevent accidentally dislodging a sensor. (Mounting straps are provided in the Accessories kit.)

CAUTION: Do not drop air, level, or flow sensors as shock may damage the sensor.

CAUTION: Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.



Modules

Level Monitoring

Selecting the Level Detection Mode

Touch the **Level Detection** button to select the desired mode: Alert Only when using only the alert sensor or select Alert/Alarm when using both the alert and alarm sensors.



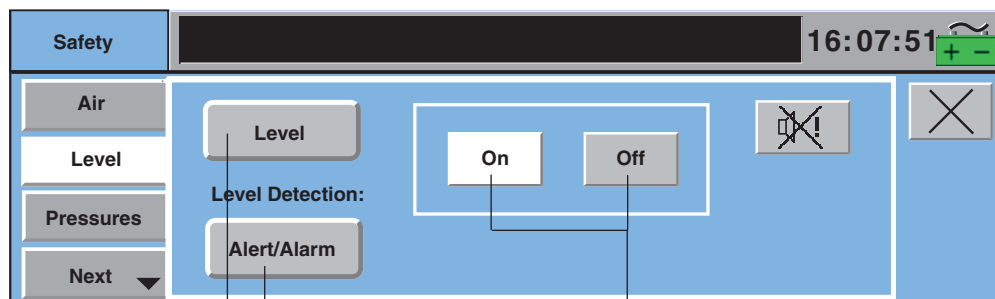
- When switching to **Alert/Alarm** from **Alert Only**, the level alarm probe will take approximately 10 seconds to initialize.

The operating mode is established during configuration of the Perfusion Screen.

Changes to the configured mode made during a perfusion case are retained only for the current case. The mode will revert to the mode chosen during configuration when the case is exited.

Enabling and Disabling Level Detection System

Use the alert/alarm warnings to warn of changing level conditions that may allow the blood or prime solution level to fall below optimum conditions.



Device Name Button — Level Detection Button — On and Off Buttons

Select the **Level** subtab within the Safety tab on the Perfusion Screen or touch the **Level** icon on the CCM.

1. Touch the level detection **On** button to enable the alert and alarm capability for level detection and the icon on the CCM turns green.
2. Level detection **Off** button disables the alert and alarm capability for the level detection and the icon on the CCM turns gray.



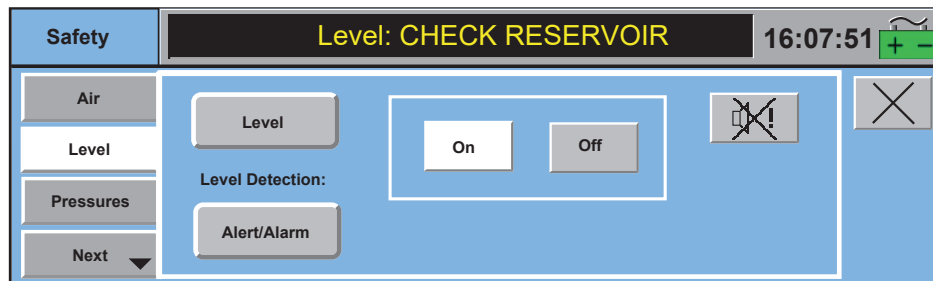
Modules

Level Monitoring

System Response to Alert Condition

When no blood or prime solution is present at the alert level sensor, the system will respond as indicated in the following table.

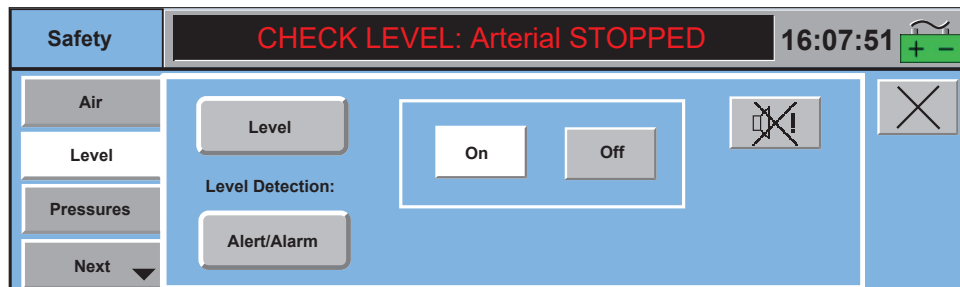
Level Icon	Level Module	Message	Connected Device(s)	Audible Tone
Flashes yellow	LED flashes yellow	Message with sensor name in the CCM message area and on the local display of any pumps with a level safety connection. Safety tab opens.	Respond as configured. Message displays on the local pump display.	Single-tone alert



System Response to Alarm Condition

When no blood/prime solution is present at the alarm level sensor, the system will respond as indicated in the following table.

Level Icon	Level Module	Message	Connected Device(s)	Audible Tone
Flashes red	LED flashes red	Message with sensor name in the CCM message area and on the local display of any pumps with a level safety connection. Safety tab opens.	Respond as configured. Message displays on the local pump display.	Dual-tone alarm



Modules

Level Monitoring

Test Before Use

The performance of the level detection system must be verified before each use.

Action	Results
Make necessary safety connections. This is done in the Configuration Screen. Refer to CCM chapter Configuration section for details.	
Turn level detection on.	Level icon is green. Module LED is green.
Start pump. Lower the blood or prime solution level in the reservoir below the level of the alert sensor.	Level icon flashes yellow, level module LED flashes yellow, message on CCM and local display of connected pumps. Connected devices respond as configured. Single-tone alert sounds.
Lower the blood or prime solution level in the reservoir below the level of the alarm sensor.	Level icon flashes red, level module LED flashes red, message on CCM and local display of connected pumps. Connected devices respond as configured. Dual-tone alarm sounds. (Unless in “Alert Only” mode.)
Raise blood or prime solution level above alarm sensor	Alarm responses clear. System returns to alert state.
Raise blood or prime solution level above alert sensor	Alert responses clear. Level icon turns green.

Should the level detection alert/alarm falsely or fail to alert/alarm, correct any problems. Test until assured that the level detection system is functioning properly.

Place the primary pump in the STOP mode until needed but leave level detection on.

Modules

Level Monitoring

Level Monitoring Messages

Priority	Condition	CCM Display Message	Operator Response
Alarm	Reservoir level below alarm level.	< Level detector name > : LOW LEVEL	Fill reservoir to above alarm level. Alarm clears automatically. Restart pump if stopped.
	Reservoir level below alarm level.	LOW LEVEL: < Pump Name > < Pump Response >	Fill reservoir to above alarm level. Alarm clears automatically. Restart pump if stopped.
	Pump goes to 0 flow as a result of a Reduce Speed response to a level alert/alarm.	< Pump name > : STOPPED	Fill reservoir above alert level. Restart pump.
Alert	Reservoir level below alert level.	< Level detector name > : CHECK LEVEL	Fill reservoir above alert level. Start pump if stopped. Alert clears automatically.
	Level sensor alert sensor detects low level.	CHECK LEVEL: < Pump Name > < Pump Respose >	Fill reservoir above alert level. Start pump if stopped. Alert clears automatically.
	Level system is on, alarm level sensor or alert level sensor not mounted to venous reservoir.	< Level detector name > : NOT ATTACHED	Mount the alarm or alert level sensor to venous reservoir. Alert message clears automatically.
	Level system is on, alarm level sensor cable or alert level sensor cable has become disconnected from module.	< Level detector name > : DISCONNECTED	Check alarm or alert level sensor cable connections. If message does not clear, replace and reassign module.
	Level system is on, level hardware malfunction.	< Level detector name > : CHECK MODULE	Disconnect and reconnect module to system base. If message does not clear, replace and reassign module.
	Alarm level sensor or alert level sensor self test failure.	< Level detector name > : CHECK PROBE	Check alarm or alert level sensor connections. If message does not clear, replace the alarm or alert level sensor.
Error	Level system is off, module hardware malfunction.	< Level detector name > : Check Module	Disconnect and reconnect module to base. If message does not clear, replace and reassign module.

Modules

Level Monitoring

Priority	Condition	CCM Display Message	Operator Response
Status	Level system is off, level sensor is not mounted to the venous reservoir.	< Level detector name > : Not Attached	Mount level sensor to reservoir. Message clears automatically.
	Level system is off, level sensor becomes disconnected from module.	< Level detector name > : Disconnected	Reconnect level sensor. Message clears automatically.
	Level selection is changed from Alert to Alert/Alarm in a Perfusion Screen	<Level Detector Name > : Initializing alarm probe	Allow approximately 10 seconds for sensor to initialize.
	Level detection is turned OFF during perfusion	<Level Detector Name > : Off	Message will clear after approximately 3 seconds.

This page intentionally left blank.

Modules

Pressure Monitoring

A Perfusion Screen can be configured to monitor up to 8 pressure locations through the use of 4 modules with each module having 2 channels. Pressure transducers used with System 1 must meet the ANSI/AAMI BP22:1994 standard for physiologic pressure transducers. Independent of the transducer, the system will perform over a range of -30 to 300 mmHg with an accuracy of +/- 10 mmHg.

The pressure monitoring system meets IEC 60601-1 when used with Terumo-tested pressure transducers. See “Terumo-Tested Pressure Sensors” in chapter 12 for a list of Terumo-tested pressure transducers.

CAUTION: The accuracy of the pressure information is dependent on the specification of the pressure transducer. Always ensure that the pressure transducers used are appropriately specified for the application.

CAUTION: Although the System 1 is capable of displaying values from the pressure transducer between -250 mmHg and +900 mmHg, no claim of accuracy beyond the range of -30 to 300 mmHg has been determined.

For values below -250 mmHg or in the condition of a disconnected transducer, the pressure icon on the CCM will display “— —”. For values above +900 mmHg, the icon will display “999”.

In the event of overrange/underrange readings or pressure system malfunction, physiological alerts or alarms are cleared automatically. If a safety connection from a pressure event had paused or stopped a pump, that pump can then resume or be restarted (if no other pause or stop responses are in effect). If the pressure reading returns into range between -250 mmHg and +900 mmHg, inclusive, the physiological alerts or alarms will reoccur as appropriate.

The pressure system has only been tested with pressure transducers provided by Terumo Cardiovascular Systems.

Pressure data can be used as a servo setpoint to regulate roller and centrifugal pump speeds. See the **Roller Pumps**, **Sarns Centrifugal Pumps**, and **Capiiox Centrifugal Pumps** chapters, **Servo mode** sections for instructions on using pressure data as a servo setpoint.

When changing disposable transducers during use, disconnect the pressure transducer cable from the module.

WARNING: Pressure transducer cables without transducers attached must be disconnected from the system. Cables without transducers act as an antenna which may cause the pressure module to generate an alarm that then will stop a safety configured pump due to electromagnetic interference.

WARNING: Use only the specified temperature probes and pressure transducers to ensure that the temperature and pressure monitoring function properly.

Label and Connect Pressure System

1. Mark both ends of pressure cable with identical codes, using the correct size of marker from the accessories kit.
2. Connect the pressure cable to the correct channel on the pressure module. Properly align the pressure cable with the module receptacle.
 - Each channel is assigned separately during configuration. Each pressure cable must be attached to the proper channel for the pressure reading to display in the correct location on the Perfusion Screen.
3. Insert pressure module into base receptacle as close as possible to the location where the transducer will be used. Arrange cables to minimize exposure to spills.

Modules

Pressure Monitoring

Setting Pressure Display

1. Touch the **Display** button until the desired selection is displayed. Average is an average pressure reading; Systolic is the high pressure reading; Diastolic is the low pressure reading.

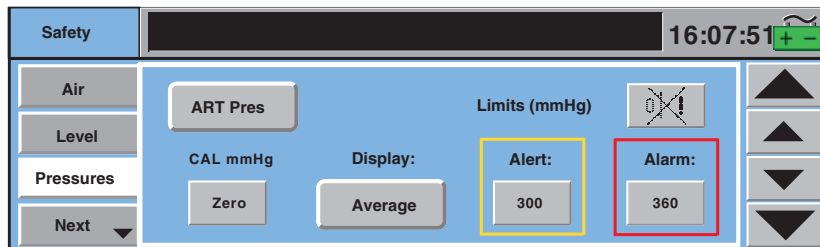
Calibrating the Pressure Transducer

The pressure monitoring system requires each transducer to be calibrated to establish a zero reference. When a pressure transducer requires zeroing, the icon will display “CAL mmHg.”



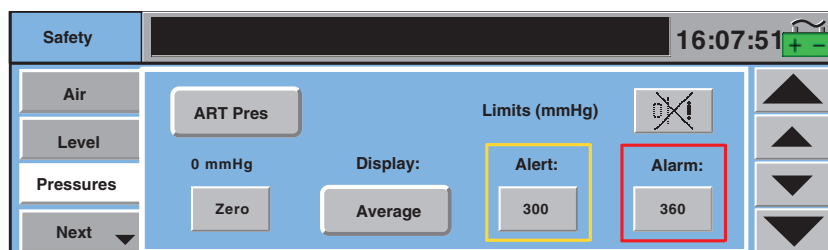
To calibrate the pressure transducer:

1. Open pressure transducer to atmospheric pressure.
2. Select the **Pressure** subtab within the Safety tab or touch the pressure icon.
3. Ensure the correct device name is displayed.



Device Name _____ Zero Button _____

4. Touch the **Zero** button to calibrate pressure system. Calibration takes a few seconds. The button turns dark gray during calibration.
- The Pressure subtab and the pressure icon on the CCM will display “0 mmHg” when the pressure system has been zeroed.



5. Close the pressure transducer to atmospheric pressure.

Modules

Pressure Monitoring

6. Close the Safety Screen by touching the **Close** button.

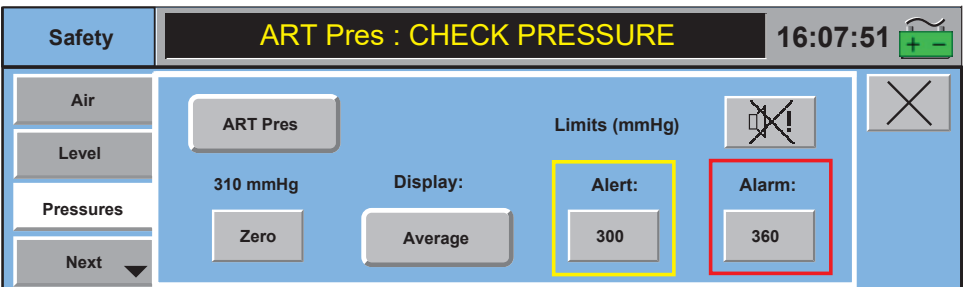


7. Repeat steps 1-6 for each transducer assigned to the system. Once a pressure transducer is calibrated, closed to atmospheric pressure, and open to the circuit, it does not need to be turned on to enable pressure monitoring.

System Response to Alert Conditions

Pressure Icon	Pressure Module	Message	Connected Device(s)	Audible Tone
Flashes yellow	LED flashes yellow	Message with transducer name in the CCM message area and on the local display of any pumps with a pressure safety connection. Safety tab opens.	Respond as configured	Single-tone alert

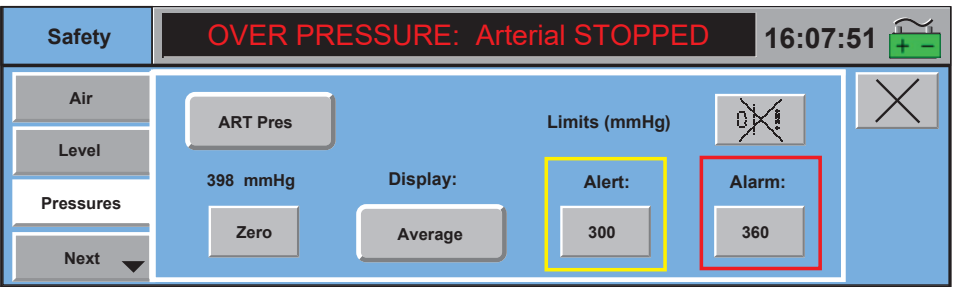
The alert limit should be set to warn of slowly changing conditions which may raise the average pressure significantly, such as a cannula misalignment, increased systemic resistance, etc.



System Response to Alarm Condition

Pressure Icon	Pressure Module	Message	Connected Device(s)	Audible Tone
Flashes red	LED flashes red	Message with transducer name in the CCM message area and on the local display of any pumps with a pressure safety connection. Safety tab opens.	Respond as configured	Dual-tone alarm

The alarm limit should be set to warn of instantaneous high pressure situations which may rupture the tubing circuit, such as a clamped or kinked line.



Modules

Pressure Monitoring

Pre-Case Check

Once the alert and alarm limits have been set, a pre-case check should be performed to ensure the pressure monitoring system is operating as the user intends.

Test Before Use

Ensure every pressure monitoring system is functioning properly prior to use.

Action	Results
Make necessary safety connections. This is done in the Configuration Screen. Refer to CCM chapter, Configuration section for details.	
Set alert and alarm limits.	
Calibrate pressure transducer.	Pressure icon displays "0", module LED is green.
Generate sufficient pressure to exceed the alert limit, but remain below the alarm limit.	Connected devices respond as configured. A message displays on the local displays of connected pumps and on the CCM. The pressure icon flashes yellow. The LED on the module flashes yellow and a single tone alert sounds.
Generate sufficient pressure to exceed the alarm limit.	Connected devices respond as configured. A message displays on the local displays of connected pumps and on the CCM. The pressure icon flashes red. The LED on the module flashes red and a dual tone alarm sounds.

Pressure Monitoring Messages

Priority	Condition	CCM Message	Operator Response
Alarm	Pressure has risen above alarm limit.	<Pressure name>: OVER PRESSURE	Correct over pressure condition. Start pump if stopped.
	Pressure has risen above alarm limit.	OVER PRESSURE: <Pump Name> <Pump Response>	Correct over pressure condition. Start pump if stopped.
	Pump goes to 0 flow as a result of a Reduce Speed response to a pressure alert.	<Pressure name>: STOPPED	Correct high pressure condition. Restart pump.
Alert	Pressure has risen above alert limit, but below alarm limit.	<Pressure name>: CHECK PRESSURE	Monitor pressure. Check for condition that could lead to pressure alarm.
	Pressure has risen above alert limit, but below alarm limit.	CHECK PRESSURE: <Pump Name> <Pump Response>	Monitor pressure. Check for condition that could lead to pressure alarm.
	Calibrated pressure transducer malfunction detected.	<Pressure name>: CHECK PROBE	Reconnect and recalibrate transducer. If message does not clear, replace and recalibrate transducer.
	Calibrated pressure transducer has become disconnected.	<Pressure name>: CONNECT PROBE	Reconnect and recalibrate pressure transducer.

Modules

Pressure Monitoring

Priority	Condition	CCM Message	Operator Response
Alert	Loss of data for calibrated pressure transducer.	<Pressure name>: NO PRESSURE DATA	Check transducer connections. Disconnect/reconnect and recalibrate transducer. If message does not clear, replace and recalibrate transducer.
Error	Pressure transducer calibration failed.	<Pressure name>: Calibrate Failed	Retry pressure transducer calibration. If message does not clear, replace and recalibrate transducer.
Status	Pressure alarm set out of range	<Pressure Transducer Name > : Alarm Disabled	Message will clear when pressure alarm is set within range or message is replaced by a higher priority message.

Modules

Temperature Monitoring

A Perfusion Screen can be configured to monitor up to 8 temperature locations through the use of 4 modules with each module having 2 channels. The temperature monitoring system provides high temperature alarm monitoring for each temperature channel. The system measures temperature in the range of 0.0 to 50.0°C with an accuracy of $\pm 0.3^{\circ}\text{C}$ and display resolution of 0.1°C. The system refresh rate for temperature updating is 0.5 seconds and has no additional required time between measurements.

For temperatures below this range or if a probe is disconnected, the temperature icon will display “— — °C”.

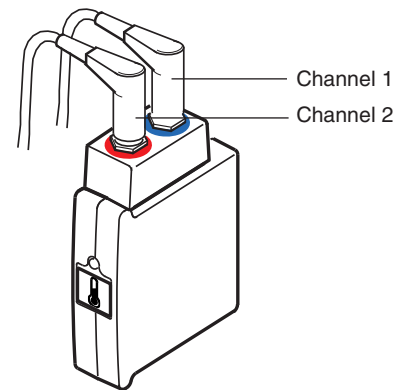
For temperatures above this range or if a probe is partially connected, the temperature icon will display “999 °C”.

The temperature icon is blank if the temperature system malfunctions. Once a temperature probe is connected to the circuit, it does not need to be calibrated or turned on to enable temperature monitoring.

Capiox Luer Thermistor or YSI Series 400 compatible probes, with the exception of Model 416, must be used in order to monitor temperature properly with System1. Probes must have a minimum insulation resistance of 20Mohms and withstand a test voltage of 500V.

Reference the temperature probes Manufacturer's Instructions for Use regarding environmental conditions requirements and risks, appropriate measuring site, rated output range, minimum measuring time, and time between measurements.

The temperature monitoring system meets IEC 60601-1 when used with Terumo-tested temperature sensors. See “Terumo-Tested Pressure and Temperature Sensors” in chapter 12 for a list of Terumo-tested temperature sensors.



WARNING: Use only the specified temperature probes and pressure transducers to ensure that the temperature and pressure monitoring function properly.

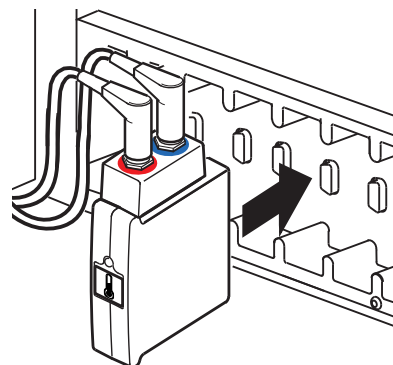
WARNING: Measurement of body site locations to determine true body temperature is not recommended.

Label Probe

Mark both ends of each temperature probe cable with identical codes, using the correct size of marker from the accessories kit.

Connect Probe and Module

1. Connect the temperature probe to the correct channel on the temperature module.
- Each temperature channel is assigned separately during configuration. Temperature cables must be attached to the proper channel for the temperature reading to display in the correct location on the Perfusion Screen.
2. Insert temperature module into any base receptacle as close as possible to the location where the probe will be used. Arrange cables to minimize exposure to spills.



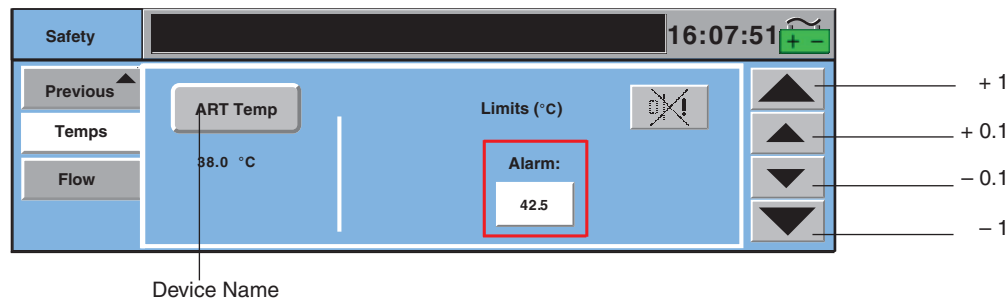
Modules

Temperature Monitoring

Setting Alarm Limits

The default alarm limit is set when a Perfusion Screen is configured.

To change the default value for the current case only:



1. Select the **Temps** subtab within the Safety tab at the bottom of the CCM or touch the **Temperature** icon on the CCM.
2. Ensure the correct device name is displayed on the Safety Screen.
3. To change the alarm value, touch the **Alarm** button. The background of the button will turn white.
4. Use the arrows to adjust the limit.
5. Touch the **Alarm** button again to store the new limit.

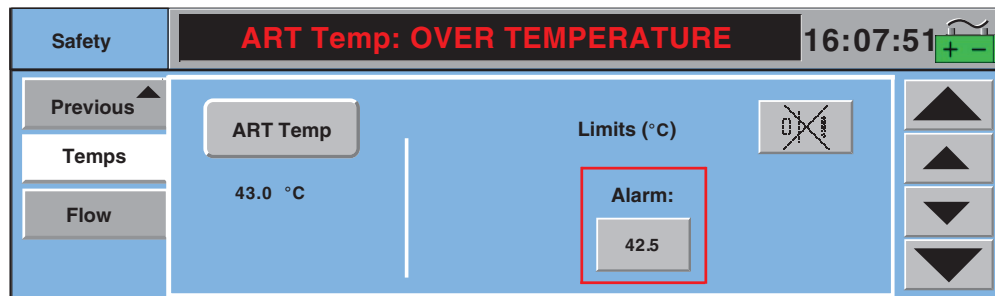
System Response to Alarm Condition

Temp Icon	Temp Module	Message	Audible Tone
Flashes red	LED flashes red	Message with sensor name in the CCM message area. Safety tab opens.	Dual-tone alarm

Modules

Temperature Monitoring

The alarm will clear when the condition has been corrected.



Test Before Use

The performance of the temperature probes must be verified before each use.

Action	Results
Cool probe below room temperature.	Temperature decreases
Warm probe above alarm level.	Temperature icon flashes red. Temp alarm displays on the CCM and the temp module LED flashes red.

Temperature Monitoring Messages

Priority	Condition	CCM Message	Operator Response
Alarm	Temperature has risen above alarm limit.	<Temperature name>: OVER TEMPERATURE	Correct over temperature condition. Alarm clears automatically.
Error	Temperature probe has become disconnected.	<Temp channel name>: Check Probe	Reconnect temperature probe. Error message clears automatically.
	Temperature out of range.	<Temp channel name>: Check Probe	Correct out of range condition. Error message clears automatically.

This page intentionally left blank.

Modules

Flow Monitoring

The Perfusion Screen can be configured to monitor up to 4 flow locations. A flow sensor can be used to monitor flow generated by a roller pump or centrifugal pump. Flow is measured in the range of -9.99 to +9.99 L/min.

The flowmeter system is compatible with medical grade PVC tubing 3/8 in. (9,5 mm) I.D. x 3/32 in. (2,4 mm) wall thickness.

Display Accuracy *	$\pm 10\%$ of actual flow for -7.0 L/min to -1.0 L/min ± 0.10 L/min of actual flow for -1.0 L/min to -0.1 L/min ± 0.10 L/min of actual flow for 1.0 L/min to 0.1 L/min $\pm 10\%$ of actual flow for 1.0 L/min to 7.0 L/min
Display Resolution	(flowmeter placed within centrifugal pump icon on CCM) 0.01 L/min between -9.99 to -1.00 L/min and between 1.00 to 9.99 L/min 0.001 L/min between -0.091 to -0.999 L/min and between 0.091 to 0.999 L/min Between -0.090 and +0.090 L/min inclusive, the display shows 0.000 L/min (flowmeter placed outside centrifugal pump icon on CCM) 0.01 L/min between -0.09 to -1.99 L/min and between 0.09 to 1.99 L/min 0.1 L/min between -2.0 to -9.9 L/min and between 2.0 to 9.9 L/min Between -0.09 and +0.09 L/min inclusive, the display shows 0.00 L/min
Pulse Mode	Reading fluctuations are limited to less than +/- 0.50 L/min. For flow outside of this range, the flow icon will display “— —” L/min. If no data is received, the flow icon will display “— —” L/min.

Flow data can be used as a servo setpoint to regulate roller and centrifugal pump speed. See the **Roller Pumps**, **Sarns Centrifugal Pumps**, and **Capiiox Centrifugal Pumps** chapters, **Servo Mode** sections for instructions on using a flow value as the servo setpoint.

* **Note:** For displayed flow rates of -0.1 L/min to 0.1 L/min, actual flow considered to be zero.

Modules

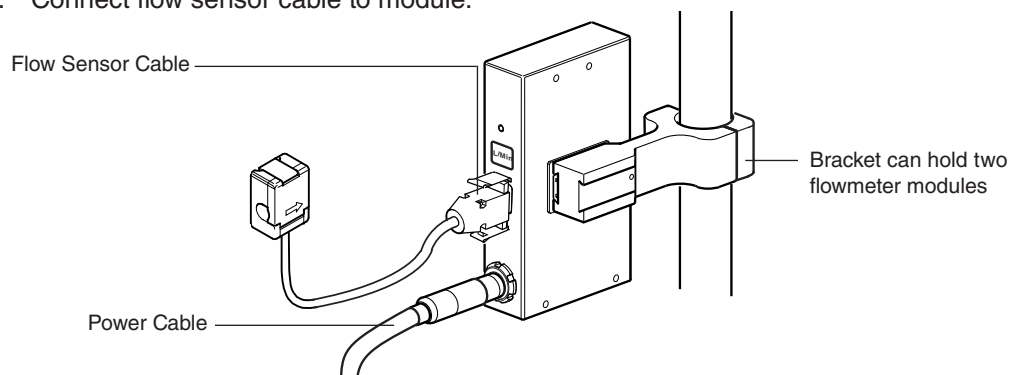
Flow Monitoring

Connect Flowmeter Module

1. Mount the flowmeter module bracket to the desired pole location.
2. Mount flowmeter module to the bracket. Note that two flowmeter modules can be mounted on each bracket.
3. Install 2 standoffs on the desired base module receptacle to securely fasten a power cable to the module receptacle. With a clear view of the module receptacle, carefully connect the flowmeter cable to the module receptacle. Do not use excessive force and make sure not to bend the connector pins. Arrange cables to minimize exposure to spills.

Note: Only a flowmeter power cable or pump power cable can be inserted into a receptacle which has the standoffs installed.

4. Connect power cable to module. Align the red dot on the power cable with the red dot on the flowmeter module. Insert the connector into the receptacle. An audible click indicates that the connector is fully seated in the receptacle. Pull gently on the cable to verify a secure connection.
5. Connect flow sensor cable to module.



Attach Flow Sensor

1. Position the flow sensor distal to the pump. For best accuracy, position the flow sensor at least 12 in. (30,5 cm) from any in-line component in the extracorporeal circuit.

CAUTION: Do not drop air, level, or flow sensors as shock may damage the sensor.

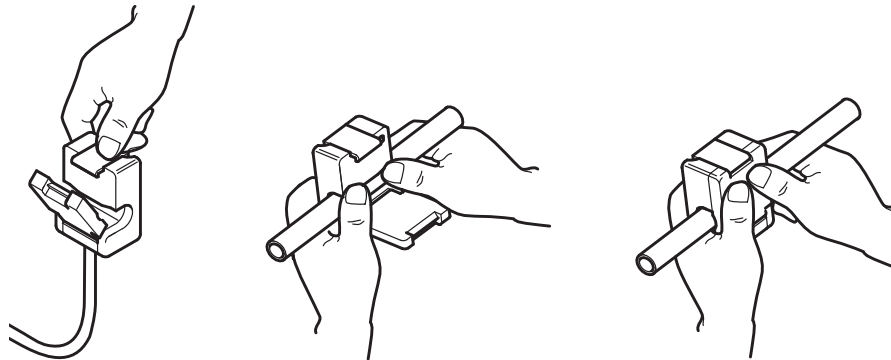
CAUTION: Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.

2. Open the flow sensor latch.
3. Seat the tubing in the sensor. Ensure the arrow on the sensor points in the direction of the circuit flow.

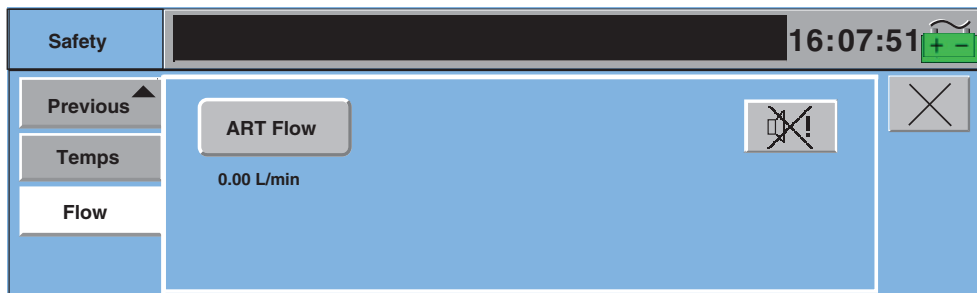
Modules

Flow Monitoring

4. Close the sensor latch. Ensure the latch closes securely.



The flow system is operational when Perfusion Screen has initialized and the flow icon displays “0.00” L/min.



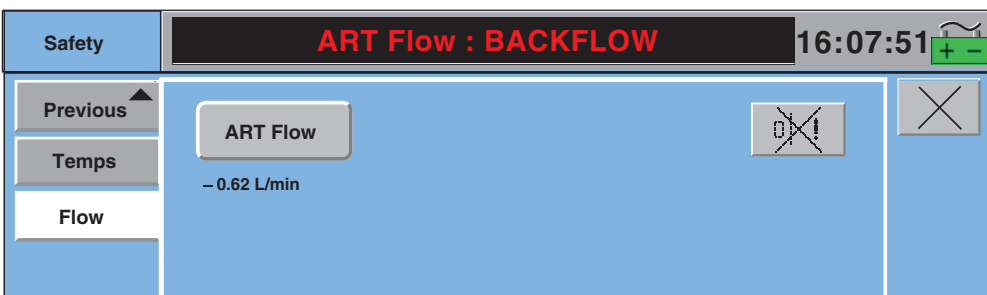
0.00
L/min

Once a flow sensor is connected to the circuit, it does not need to be calibrated or turned on to enable flow monitoring. Once there is blood or prime solution circulating in the system, verify the flowrate display by varying the speed and seeing that the display changes accordingly.

System Response to Alarm Condition

The flow system will alarm in a backflow condition.

Flow Icon	Flow Module	Message	Connected Device(s)	Audible Tone
Flashes red	LED flashes red	Message with sensor name in the CCM message area and on the local display of any pumps with a flow safety connection.	Respond as configured	Dual-tone alarm



Modules

Flow Monitoring

The alarm will clear when the backflow condition has been corrected.

Note: When the flow icon has been placed on a centrifugal pump icon, the flow icon will not flash red during an alarm and touching the flow icon will not open the Safety tab. To open the Safety tab, select the **Safety** tab at the bottom of the screen.

Test Before Use

The performance of the flow system must be verified before each use.

Action	Results
Set necessary Safety connection. This is done in the Configuration Screen. Refer to CCM chapter Configuration section for details.	
Place sensor on the tubing opposite the normal direction of flow.	Flow icon flashes red. Connected pumps respond as configured. LED flashes red. Dual tone alarm sounds.
Place sensor on the tubing in the direction of forward flow so the arrow on the sensor points in the same direction of flow.	System stops alarming.

Flow Monitoring Messages

Priority	Condition	CCM Message	Operator Response
Alarm	Backflow has been detected.	<Flow sensor name>: BACKFLOW	Correct backflow condition. Alarm clears automatically. Restart pump if stopped.
	Backflow has been detected.	BACKFLOW: <Pump Name> <Pump Response>	Correct backflow condition. Alarm clears automatically. Restart pump if stopped.
	Flow for flow sensor connected to a centrifugal pump has gone below minimum limit.	<Pump name>: MINIMUM FLOW	Correct low flow condition. Alarm clears automatically.
	Flow for flow sensor connected to a centrifugal pump has gone below minimum limit.	MINIMUM FLOW: <Pump Name> <Pump Response>	Correct low flow condition. Alarm clears automatically. Restart pump if stopped.
Error	Flow sensor malfunction detected.	<Flow sensor name>: Check Sensor	Disconnect and reconnect flow sensor. If message does not clear, replace flow sensor.
	Flow sensor disconnected from tubing.	<Flow sensor name>: Check Sensor	Reconnect flow sensor. If message does not clear, replace flow sensor.
Status	Flow sensor has become disconnected from the module.	<Flow sensor name>: Check Sensor	Reconnect flow sensor. Message clears automatically.

Modules

Occluder Module

A Perfusion Screen can be configured to operate 1 occluder. The occluder system provides a computer-controlled tube clamping mechanism used to control flow in the venous line.

The occluder display on the CCM displays % open from 0-100% in 1% increments.

The occluder display shows the approximate % that the venous tube is open over the range from 0% or fully closed to 100% or fully opened in only 1/2 in. (12,7 mm) or 3/8 in. (9,5 mm) I.D. tubing with blood or prime solution. A decrease in the occluder % will result in a decrease of flow through the venous tube. The display shows a reference number only for other tubing sizes. Accuracy requires proper calibration and no backpressure.

The occluder supports tubing sizes in the range of 1/4 in. (6,4 mm) I.D. x 1/16 in. (1,6 mm) wall thickness to 1/2 in. (12,7 mm) I.D. x 3/32 in. (2,4 mm) wall thickness and fluid temperatures of 20°–40°C. A nominal durometer range of 65-70 Shore A is recommended.

The occluder can be configured to respond to primary pump events using the Configuration Screen on the Central Control Monitor. Occluder responses are user selectable. Valid responses for the occluder are Full Close, Full Open, Go to % Flow, or No Response.

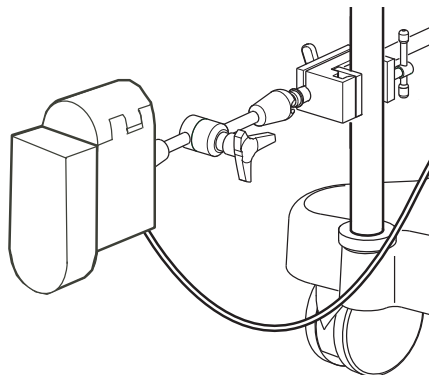
The occluder slide bar shares a location on the CCM with the gas slide bars. When operating a device that shares a slide bar location, make sure that the slide bar displayed is for the device you intend to operate.

Connect Occluder Head

Flexible Mounting Arm

1. Select the desired pole position and secure the flexible mounting arm to the pole.
2. Set the mounting arm to the desired position:
 - Turn the tension control knob counterclockwise to loosen the joints of the mount arm. Manually support the flexible arm when adjusting the tension control knob. Do not loosen the knob beyond the stop.
 - Position the arm as desired and tighten the tension control knob.
3. Screw the occluder head onto the threaded stud. Make sure the occluder head is fully installed on the threaded stud. Make sure the occluder head is securely mounted on the mounting arm.

Note: Always manually support the flexible arm when adjusting the tension control knob.

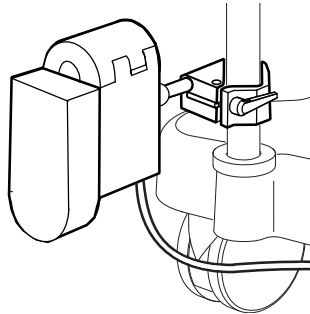


Modules

Occluder Assembly

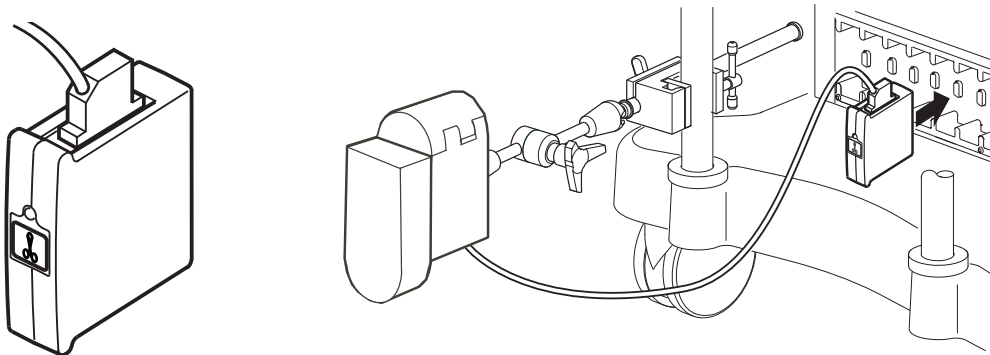
Mount the occluder head on a pole according to these installation instructions.

1. Attach the occluder mounting bracket to the desired pole location.
2. Place the ball end of the mounting rod into the occluder head socket.
3. Insert the rod into the mounting bracket and tighten the mounting screws as needed.



Connect Occluder Module

1. Attach the occluder cable to the occluder module.
2. Insert the occluder module into any base receptacle as close as possible to the location where the occluder will be used. Arrange cables to minimize exposure to spills.



Modules

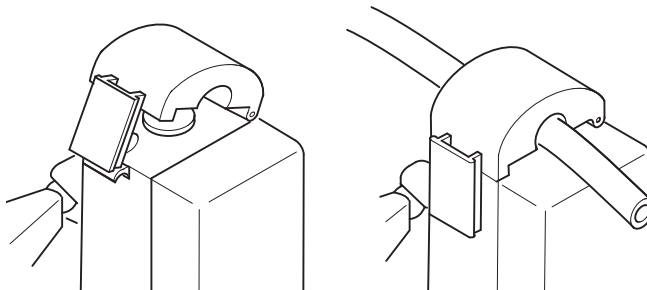
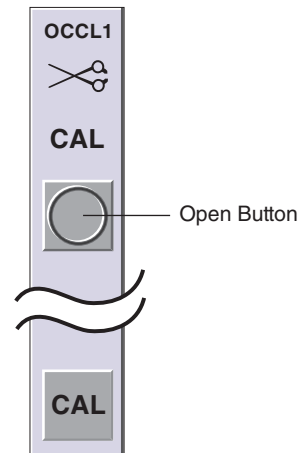
Occluder Module

Insert Tubing

1. From the Perfusion Screen, touch the **Occluder** icon on the CCM. This will activate the occluder control slide bar.



2. On the occluder control slide bar, touch the **Open** button to retract the plunger sufficiently to insert tubing.
3. Unlatch and open the occluder cover.
4. Insert tube into the tubing channel of the cover.
5. Close the cover, keeping the tubing properly aligned in the channel, and secure latch.



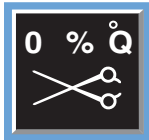
Note: If the cover does not close easily, touch the **Open** button again to retract the plunger another step. The **Open** button can be pressed up to 3 times.

Modules

Occluder Module

Calibration

1. On the occluder control slide bar, touch the **CAL** button. When calibrated, the occluder icon displays 0% Q and the control slide bar changes to the operational control slide bar.



2. After calibration, ensure the tube is properly positioned in occluder head.

Test Before Use

1. Using the control arrows and the scroll control, adjust the occluder position to ensure it increments properly.
2. On the occluder slide bar, touch the **Open** button to ensure the occluder opens fully.
3. Touch the **Close** button to ensure the occluder closes fully.
4. Use the scroll control to adjust the percentage of tube opening. Verify that the occluder adjusts properly.

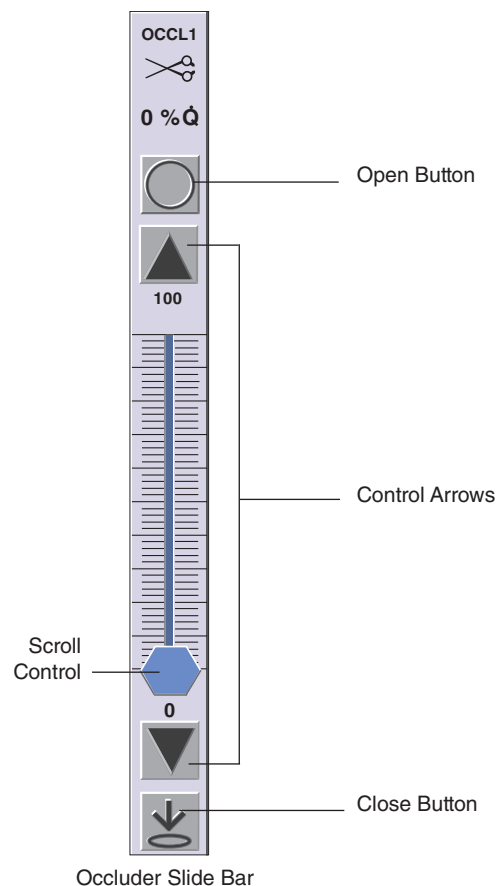
Control and Display

Note: To reposition the tubing (without recalibrating), touch the **Open** button twice to free the tubing. Reposition tubing, without opening the occluder cover, and adjust occluder to appropriate tube opening setting. If you inadvertently open the cover, always recalibrate by pushing the **Close** button after the cover is closed.

The icon and the occluder slide bar display an approximate percent of tube opening.

Use the scroll control, the control arrows, or the open and close buttons to adjust the occluder position. Avoid continuous or constant activation of the occluder as an overcurrent condition may result which will cause the occluder to be unresponsive.

If the occluder will not operate, unlatch and open the cover, remove the tubing, and use a tubing clamp to control flow to the venous reservoir.




Modules

Occluder Module

Occluder Module Messages

Priority	Condition	CCM Message	Operator Response
Alert	Occluder head not moving or not responding.	<Occluder name>: NOT RESPONDING	Try disconnecting/reconnecting occluder head. If message does not clear, replace occluder head.
	Internal malfunction detected.	<Occluder name>: SERVICE MODULE	Try disconnecting/reconnecting module. If message does not clear, reassign module.
Error	Occluder becomes disconnected after calibration.	<Occluder name>: Connect Occluder	Reconnect and recalibrate occluder head.
	Calibrated occluder loses calibration.	Calibrate <Occluder Name>	Recalibrate occluder.
Status	Uncalibrated occluder detected.	Calibrate <Occluder Name>	Calibrate occluder.
	Occluder responds to an event.	<Occluder name>: is <open, closed, or % flow>	Note occluder value, change if desired.
	Occluder is disconnected	<Occluder name>: Connect Occluder	Reconnect and calibrate occluder.

In the Event of an Occluder Module malfunction:

Symptoms	How to respond
<p>The system responds with indications to the user that the occluder is non-functional.</p> <ul style="list-style-type: none"> A 'connect occluder' message appears on the CCM in white text and the occluder maintains its current position. Audible tone accompanies 'Service Occluder' message in flashing yellow text and the occluder maintains its current position. 	<p>Unlatch and open the occluder cover, remove the tubing, and use a tubing clamp to control flow.</p> <ul style="list-style-type: none"> Replace the occluder module and reassign a backup module. Refer to Reassign Module Subtab in the Central Control Monitor chapter. If you do not have a backup occluder module, use increased vigilance throughout the remainder of the case. <u>If you are using a reservoir-optional circuit:</u> Any malfunction of a safety system requires consideration for converting to a circuit with a venous reservoir. If a venous reservoir is not available, use extra diligence and be prepared to manually clamp the line immediately in response to a pump stop/coast event triggered by an air alarm. Contact Terumo Customer Service at the end of the case.

This page intentionally left blank.

Modules

Interface Module for CDI™ 100/101 and CDI™ 500/550

The System 1 can be configured to display blood gas data on the Central Control Monitor from one CDI™ 100, CDI™ 101*, or CDI™ 500/550 blood gas monitor. Additionally, the primary pump flow data is displayed on the CDI™ 500 monitor and is used to calculate oxygen consumption (VO₂).

The serial cable provided with the Interface Module for CDI™ 100/101 and the Interface Module for CDI™ 500/550 are RS-232 protocol, with DB9 connector, male to female, with all pins wired in a straight through configuration.

Note: The CDI™ 100/101 or CDI™ 500/550 cables are NOT interchangeable with the serial cable used with the RS-232 Data Transfer Interface Module.

WARNING: The CDI 100/101 and CDI 500/550 DB9 connector may only be connected to CDI 100/101 or CDI 500/550, which are IEC 60601-1 compliant medical devices.

CDI™ 100 and CDI™ 101

The CDI™ 100 monitor and CDI™ 101 monitor are inline monitors that measure and output hematocrit, hemoglobin, and oxygen saturation values. The Interface Module for CDI™ 100/101 Module collects blood parameter data and displays it on the CCM. Values displayed on the CCM are for information only.

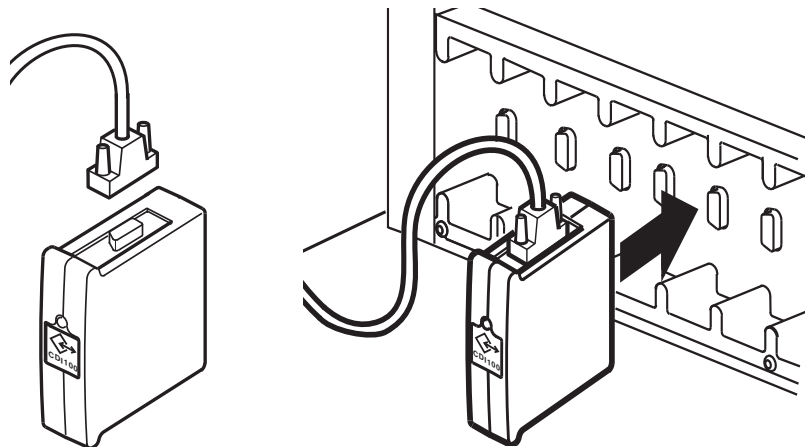
CAUTION: Always refer to the CDI™ 100 or CDI™ 101 monitor as the primary source for the blood parameter information prior to taking any action during the case.

Data Values:

<u>Parameter</u>	<u>Range of displayed values on the CCM</u>
Hematocrit	15 to 45%
Hemoglobin	5 to 15 g/dL
O2 Saturation	60 to 99%

To Connect CDI™100 or CDI™101 System:

1. Attach the serial cable to the CDI™ 100/101 module.
2. Insert module into base receptacle as close as possible to the location where the monitor is located.

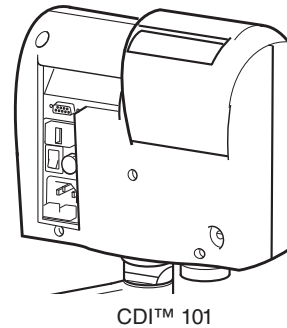
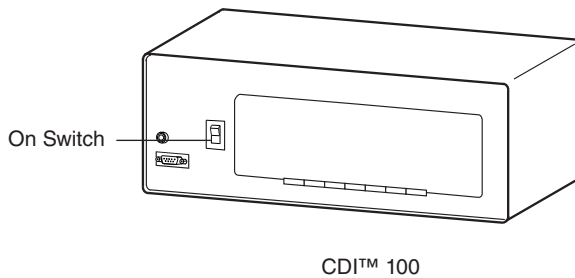


* The Terumo CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System is not cleared for marketing in the United States by the US Food and Drug Administration (FDA).

Modules

Interface Module for CDI™ 100/101 and CDI™ 500/550

3. To connect a CDI™ 100 monitor, connect the serial cable to the serial communications connector of the monitor.



4. Route cable to minimize exposure to spills.
5. Configure the CDI™100 monitor:
 - Turn the monitor on.
 - Enter the setup mode from the main menu.
 - Select RS-232 from the Select Function menu.
 - Set the desired data output interval. Choices are 0, 30, 60 or 120 seconds. Selecting 0 results in no data being transferred.
 - Select Enter to store a new choice into memory.
 - Select Return to return to the main menu and make no change to the output interval.
6. To connect a CDI™ 101 monitor, install the gender changer on the serial communications port of the monitor. Connect serial cable to the gender changer.
7. Route cable to minimize exposure to spills.
8. Configure the CDI™101 monitor:
 - Turn the monitor on.
 - Use setup screen 6 on the monitor to enter these settings:
 - o Output type: S100
 - o Data Bits: 8 data bits, 1 stop bit
 - o Parity: None
 - o Baud Rate: 4,800
 - o Output Interval: 1 second

Data Transfer

Data is available when a Perfusion Screen is opened on the CCM.

The icon will display “— — —” when no data is received or the data is below range.

The icon will display “999” when the data is above range.

SAT % 75
HCT % 24
HB 8.0 g/dL

Modules

Interface Module for CDI™ 100/101 and CDI™ 500/550

CDI™ 500/550

The CDI™ 500/500 Monitor is an inline blood parameter monitoring system that is used during cardiopulmonary bypass procedures. It monitors the blood in the extracorporeal circuit and provides information about the blood parameters.

The Interface Module for CDI™ 500/550 module is the interface between the CDI™ 500/550 monitor and the system. The module performs the following functions:

- Communicates primary pump flow data to the CDI™ 500/550;
- Receives blood parameter data from the CDI™ 500/550 and displays it on the CCM.

Values displayed on the CCM are for information only.

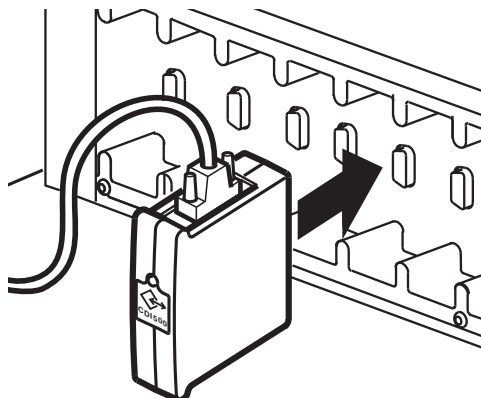
CAUTION: Always refer to the CDI™ 500 monitor as the primary source for the blood parameter information prior to taking any action during the case.

This module is used with CDI™ 500 software versions 1.4 through 1.6 while operating in standard mode and versions 1.65 and above while operating in either standard or graphical mode.

Data Values Parameter	Range of displayed values on the CCM
Arterial and Venous PO ₂	10 to 500 mmHg
Arterial and Venous PCO ₂	10 to 80 mmHg
Arterial and Venous pH	6.8 to 8.0
Arterial and Venous Temperature	10 to 45°C
Arterial and Venous Oxygen saturation (SO ₂)	60 to 100%
Potassium concentration (K ⁺)	1.0 to 8.0 mmol/L
Arterial Bicarbonate (HCO ₃)	0 to 50 meq/L
Arterial Base Excess (BE)	-25 to 25 meq/L
Venous Hemoglobin (Hb)	5 to 15 g/dL
Venous Hematocrit (Hct)	15 to 45 %
O ₂ Consumption (VO ₂)	10 to 400 mL/min

To Connect CDI™ 500/550 System:

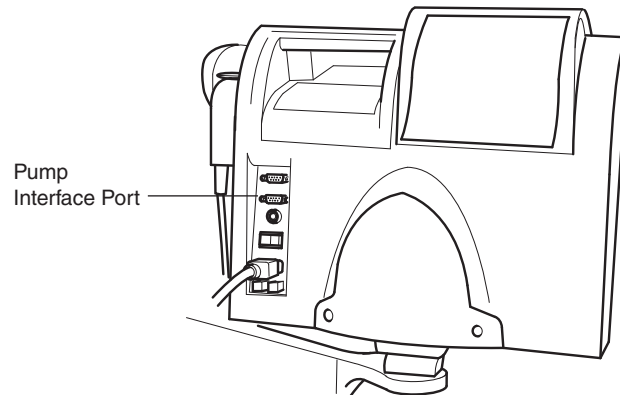
1. Attach the serial cable to the Interface Module for CDI™ 500/550.
2. Insert module into base receptacle as close as possible to the location where the monitor is located.



Modules

Interface Module for CDI™ 100/101 and CDI™ 500/550

3. Connect the serial cable to the CDI™ 500/550 monitor at the pump interface port. The serial cable must be connected to the pump interface port on the monitor to input blood flow data from the System 1 primary pump.



4. Arrange cables to minimize exposure to spills.

To Configure Monitor:

1. Turn CDI™ 500/550 monitor On.
2. Using the setup screens on the monitor, set only the following parameters:
 Q Source: Pump
 Pump type: CDI pump interface

Note: Refer to CDI™ 500/550 Operators Manual for instructions on setting up calculations data.

Data Transfer

Four venous, four arterial and one “other” data values can be displayed on the CCM. These values are selected during case configuration. Refer to **Central Control Monitor** chapter, **Configuring Other Devices** section for information about configuring the CDI™ 500/550 data display.

Data is available when a Perfusion Screen is opened on the CCM.

The flow data from the primary pump is sent to the CDI module. If a centrifugal pump is used as the primary pump, it must have a flow module configured as its flow source for the flow data to be displayed on the CDI monitor. The CDI monitor uses the flow data to compute the oxygen consumption value.

Data values display on the CCM as they appear on the CDI monitor.

When no data is received the icon will display “— —”.

When data values are higher than the range, the icon will display “999”.

When data values are below the range the icon will display “— — —”.

pH 7.40
PO2 157 mmHg
PCO2 40 mmHg
K+ 4.0 mmol/L

Modules

Interface Module for CDI™ 100/101 and CDI™ 500/550

CDI™ Messages

Interface Module for CDI™ 100/101

Priority	Condition	CCM Message	Operator Response
Status	CDI™ 100/101 disconnected or not all data is being detected.	No CDI 100/101 Data	Check CDI™ 100/101 settings and cable connections. If message still appears, contact Terumo Cardiovascular Systems Service.

Interface Module for CDI™ 500/550

Priority	Condition	CCM Message	Operator Response
Status	CDI™ 500/550 disconnected or not all data is being detected.	No CDI 500 Data	Check CDI™ 500/550 settings and cable connections. If message still appears, contact Terumo Cardiovascular Systems Service.

Interface Module RS-232

Data Transfer Interface Module

The System 1 provides perfusion case data transfer through the use of the data transfer module. This module is a general purpose serial interface and is the interface between a data management system and the system.

The data collected and exported by the data transfer module includes physiological data and device events to record the progress and events during a procedure.

The cable provided with the Interface Module RS-232 has a DB9 connector, male to female, with pins wired in offset-null configuration. This cable is NOT interchangeable with the serial cables used with the CDI Interface Modules.

Note: Customers are able to interface and use the data transfer module output by referring to the **Communication Protocol** in the **Technical Support** chapter.

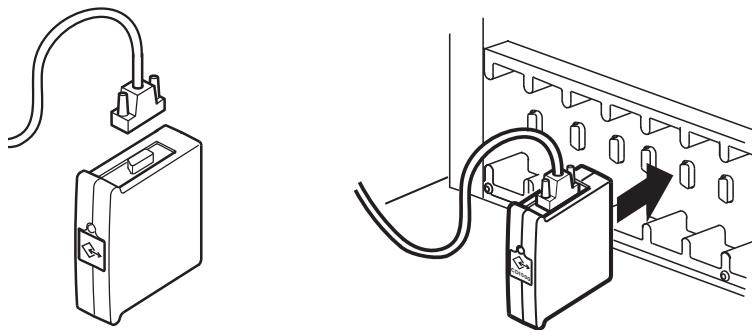
WARNING: The Data Interface Transfer DB9 connector may only be connected to IEC 60950-1, IEC 62368-1, or IEC 60601-1 compliant devices.

Modules

Interface Module RS-232

Connect Data Transfer Module

1. Attach the serial cable to the appropriate data transfer module.
2. Insert module into base receptacle as close as possible to the location where the data collection system will be used.
3. Connect the serial cable to the data collection system.
4. Route the cable to minimize exposure to spills.



Data Transfer

Data transfer takes place after a Perfusion Screen is opened on the CCM. Only devices and/or modules that are online will transmit data.

Perfusion data is exported from the module at least every 30 seconds. In addition, events are also exported when they occur. The data includes a System 1 time stamp and is identified by its system assigned label.

Electronic Gas Blender

Features

The electronic gas blender provides control and monitoring of the gas flow rate and oxygen content of the gas input to the oxygenator in the perfusion circuit. It also provides monitoring of the carbon dioxide if 95% oxygen / 5% carbon dioxide (95/5) is used as the blending gas instead of air.

The electronic gas blender is an optional component of the Terumo® Advanced Perfusion System 1 and it is integrated into the system base. A multicolored LED on the electronic gas blender provides status indications to the user. The electronic gas blender contains an integrated oxygen analyzer to measure the oxygen content of the blended gas.

If the electronic gas blender is included with the System 1, it will automatically appear in the Perfusion Screens that are used with that system. No additional configuration is required by the user. When a gas blender is installed after Perfusion Screens have been created, check to ensure the Gas Blender icon does not obscure other device icons that are on the Perfusion Screen. Some device icons may need to be moved.

The electronic gas blender can be controlled from the Central Control Monitor (CCM) or from the FiO_2 and flow control knobs located on the front panel of the system base. These two control systems are linked such that if a change is made to the FiO_2 or the flow rate using one set of controls, that change is reflected on the other set of controls.

The values for the gas flow rate setpoint, the measured gas flow rate, the FiO_2 setpoint, the $\%\text{O}_2$ reading from the oxygen analyzer, and the FiCO_2 (if using 95/5) are displayed on the CCM.

WARNING: When using a microporous membrane oxygenator, negative pressure pulses (which can result from abrupt decreases in arterial flow) may introduce gaseous emboli into the blood by creating blood pressures lower than the gas path pressure. Monitor arterial line pressure and adjust the pump so that pressure in the blood compartment of the oxygenator is always greater than the gas path pressure.

WARNING: Use clean, dry, medical grade gases and keep the water trap empty as liquid water or other contaminants in the gas supplies will cause malfunction of this system.

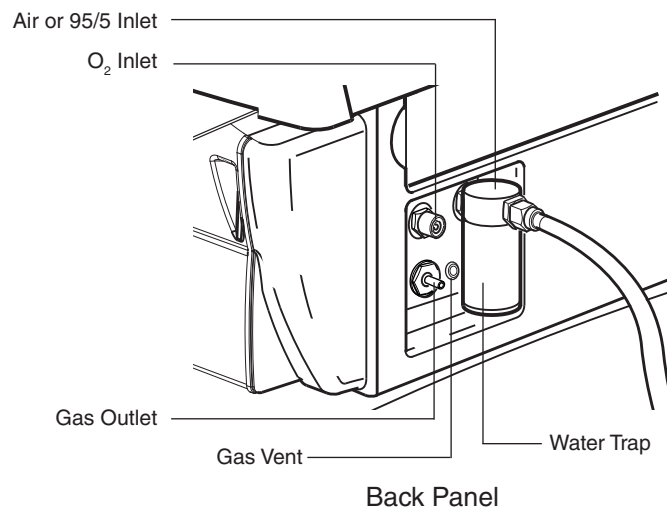
Electronic Gas Blender

Installation and Connection

Gas inlet connections are located on the back panel of the system base. The air inlet connector incorporates an externally mounted water trap. Depress the valve on the bottom of the water trap to empty any water.

Note: See Additional Information, System Components for selections of color-coded hoses and wall supply adapters.

CAUTION: The oxygen and air supplies must both be connected (or disconnected) to prevent unequal pressure from damaging the gas blender.



To connect gas hoses:

1. Connect oxygen gas line from the oxygen source to the oxygen inlet.
2. Connect medical grade air line from the air source to the air inlet.
 - An optional 95/5 supply hose allows this mixture to replace the medical grade air. The hose with the 6 inch (15.2 cm) adaptor section must be properly connected to the water trap and to the 95/5 gas source.
3. Turn source gases on.

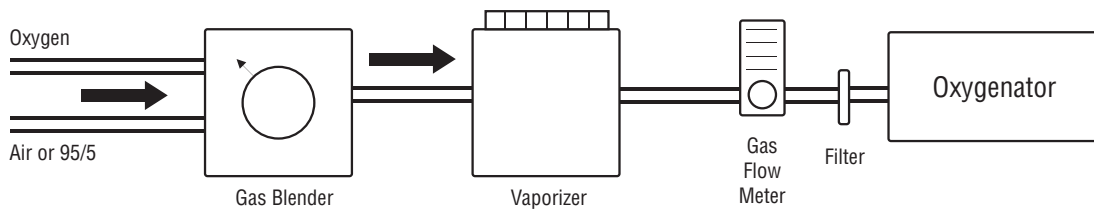
WARNING: Provide inlet gases at a pressure of 50 ± 20 psi with the difference between the two pressures being no more than 18 psi. Observe the CCM for messages indicating variations in inlet pressures or an inadequate gas supply.

4. Gather the necessary components and 1/4 inch (6,4 mm) I.D. medical grade tubing to make the connections to the oxygenator.

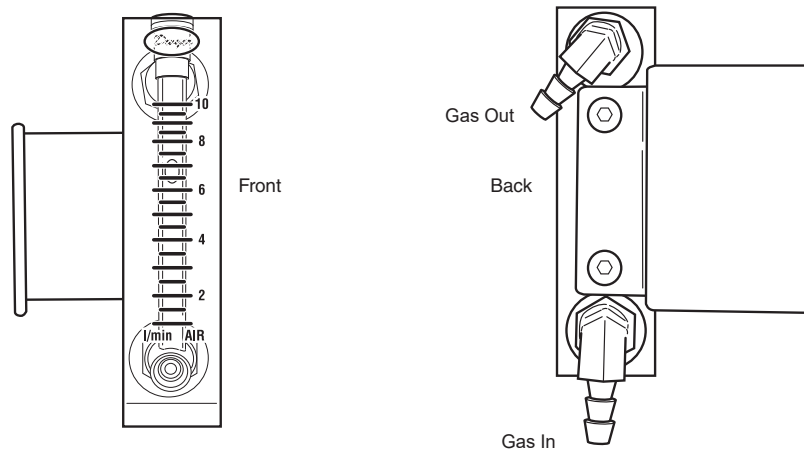
WARNING: Always use a 0.2 micron medical gas filter on the gas outlet line to prevent contaminating the extracorporeal circuit.

Electronic Gas Blender

- Refer to the figure below for a typical setup of the inline components used in this connection.



- Use of the backup external mechanical flowmeter (supplied in the Terumo APS1 Accessory Kit) is strongly recommended. Position the backup flowmeter just before the oxygenator to detect any possible gas leak between the gas outlet and the oxygenator, and as a backup to monitor gas flow in the event CCM capability is lost.
- To determine gas flow with the backup flowmeter, view the float from eye level and use the center of the float to determine the rate. Refer to the figure below.

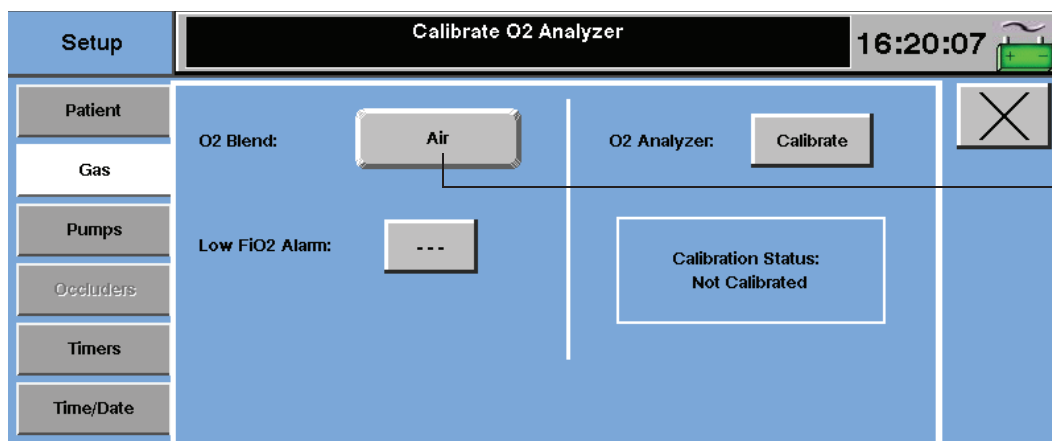


- Securely mount all components and verify that gas flows freely through the tubing and inline components (e.g. no kinked tubing).

Note: Always disconnect or turn off the gas supply when not in use as the system will vent several liters of gas per minute even when the flow is set to zero using the CCM slider.

Note: The lifespan of the oxygen sensor will continue to decline even if gas is not flowing through the system.

Setup



Choices are:
Air
95/5

Electronic Gas Blender

Choosing the Blending Gas

The user has the option to blend the oxygen with either medical grade air or 95/5. The default O₂ Blend is Air.

To change the O₂ Blend:

1. Touch the **Setup** tab in the Perfusion Screen and then touch the **Gas** subtab.
2. Touch the button labeled **O2 Blend** to toggle through the choices for blending gas.
3. Select the desired blending gas. The text displayed on the **O2 Blend** button indicates the current blending gas selection.

Changes made to the blending gas are retained only for the duration of the case. The system will revert back to Air when the case is exited.

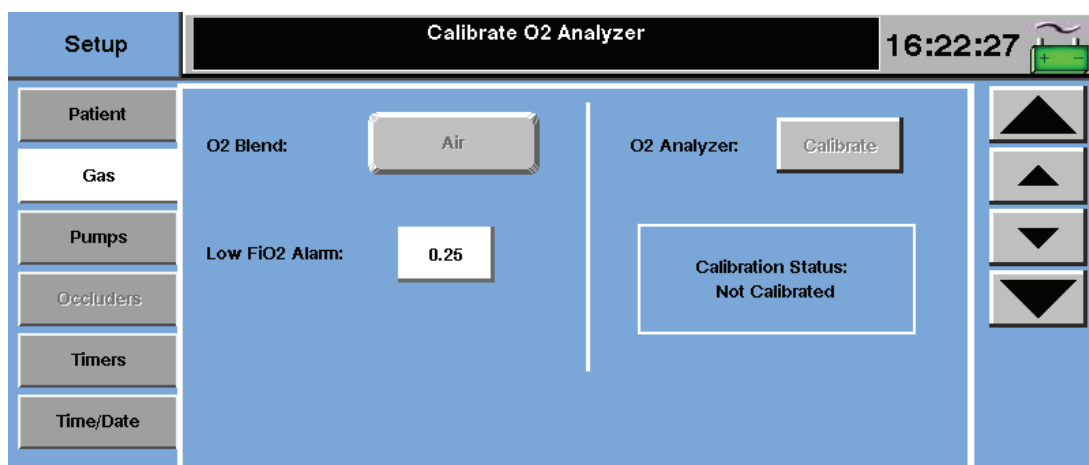
Setting the FiO₂ Alarm

This alarm will notify the user when the FiO₂ falls below the user selected alarm limit. The FiO₂ alarm reacts to the %O₂ reading from the integrated oxygen analyzer. The lowest setting is 0.21 for air. The lowest setting is 0.95 for 95/5.

The FiO₂ Alarm is enabled when the alarm value is set and the gas flow rate is set to any flow rate greater than or equal to 0.2 L/min.

To set or change the FiO₂ alarm limit:

1. Touch the **Setup** tab in the Perfusion Screen and then touch the **Gas** subtab.
2. Touch the button labeled **Low FiO2 Alarm**. The background of the button will turn white.
3. Use the up and down arrows that appear on the right side of the CCM to adjust the limit.
4. Touch the **Low FiO2 Alarm** button again to store the new value.



To disable the alarm, set the limit below 0.21 when using air as the blending gas, or below 0.95 when using 95/5 as the blending gas. The button will read “***” when the alarm has been disabled by the user.

FiO₂ alarm values are retained only for the duration of the case. The system will revert back to not set (— — —) when the case is exited. The system will also revert back to not set (— — —) if the blending gas selection is changed.

Electronic Gas Blender

Calibrating the Oxygen Analyzer and Gas Flow Sensor

Calibration of the oxygen analyzer and flow sensor should be performed prior to each case.

Note: In an emergency situation, the user may proceed to go on bypass without performing calibration. The gas system will still operate using the most recent calibration data.

CAUTION: It is not recommended to calibrate while on bypass, due to wide changes in gas flow rate and FiO₂ settings during the calibration process.

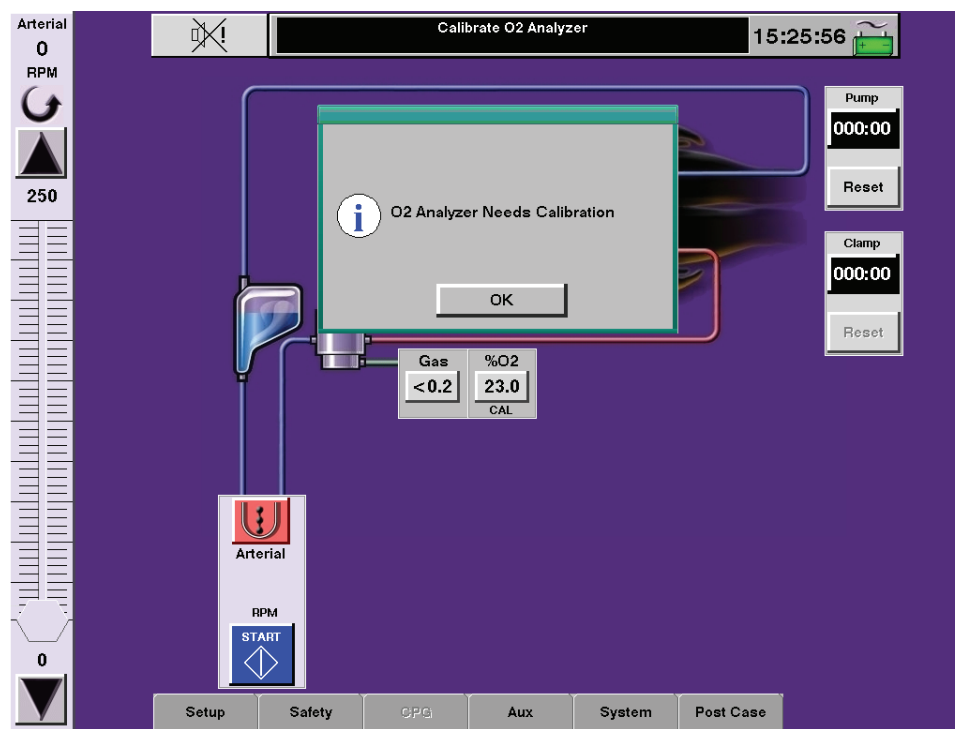
Before calibration can be performed, the O₂ analyzer requires a warm-up period after system power on. The minimum warm-up period is 2 minutes, with maximum warm-up period being 15 minutes. The source gases must also be connected and turned on.

A dialog box stating “O₂ Analyzer Needs Calibration” will appear automatically after the warm-up period completes to notify the user of the need for calibration.

This dialog box will also appear the first time the user makes an adjustment to the FiO₂ or gas flow setpoints in either of the following conditions:

- Before warmup is complete.
- After warmup is complete but before initiating calibration.

While the dialog box is on screen, access to the CCM controls will be disabled, but local controls such as knobs will still function and displays will continue to update. Pressing the **OK** button will clear the dialog box and restore access to the CCM controls. The dialogs will not appear for repeats of the same event. For example, adjusting the FiO₂ before the warmup is complete will create a dialog box. After clearing the dialog box, adjusting the gas flow or FiO₂ again will not create another dialog box before the warmup is complete.



To initiate a calibration of the oxygen analyzer:

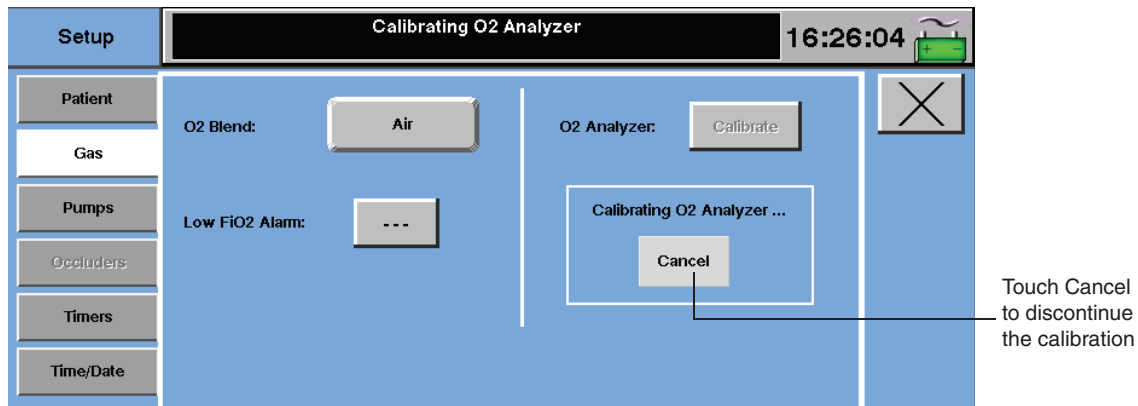
1. **Important:** Verify that the entire gas circuit is connected to the oxygenator prior to initiating the calibration.
2. Touch the **Setup** tab in the Perfusion Screen and then touch the **Gas** subtab.
3. Touch the **Calibrate** button.

Electronic Gas Blender

Calibration takes approximately 1 minute and 50 seconds. During the calibration process, gas flow is temporarily shut off. Following the gas flow shut off:

- If the O₂ blending gas is air, the FiO₂ knob automatically adjusts to 21% and then to 100%.
- If the O₂ blending gas is 95% oxygen / 5% carbon dioxide, the FiO₂ knob automatically adjusts to 95% and then to 100%.

Then the flow rate is set to 5 L/min and then 2 L/min. The Gas subtab screen will change as indicated in the following picture. The Gas icon on the screen will display CAL, and control of the gas system will be disabled from the CCM for the duration of the calibration. After calibration, the gas flow and FiO₂ setpoints are returned to the values set prior to calibration.



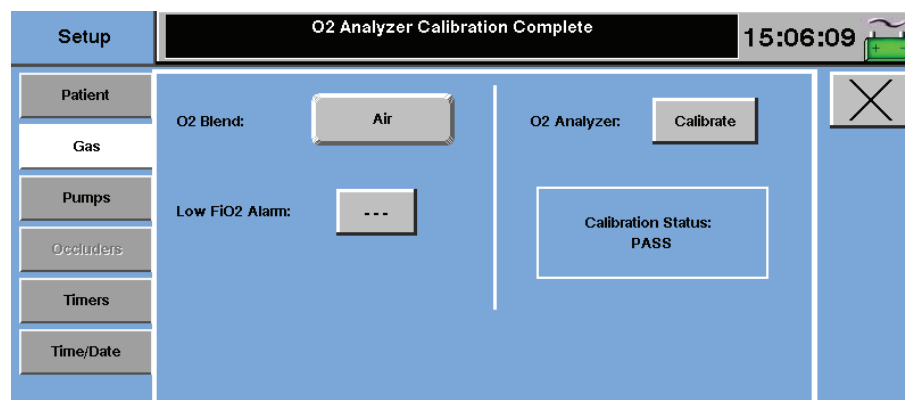
Note: Do not obstruct the gas flow outlet during calibration as this may affect the accuracy of the calibration.

Note: Do not attempt to change the gas flow rate or the FiO₂ via the local control knobs during calibration as this will cause the calibration to fail.

After a Successful Calibration:

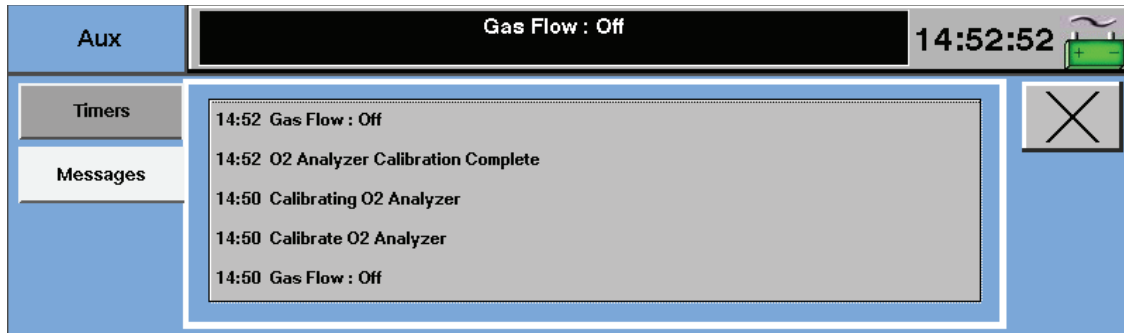
A successful calibration is indicated by the following items:

- The label for **Calibration Status** in the Gas subtab within the Setup tab is "PASS".
- **CAL** is removed from the %O₂ icon.
- "O₂ Analyzer Calibration is Complete" is displayed in the message area at the top of the CCM window. Note that this message may not be displayed in the message area if a higher priority message is present.



Check the Messages subtab within the **Aux** tab to verify that a successful calibration has been performed. The "O₂ Analyzer Calibration Complete" message will be present.

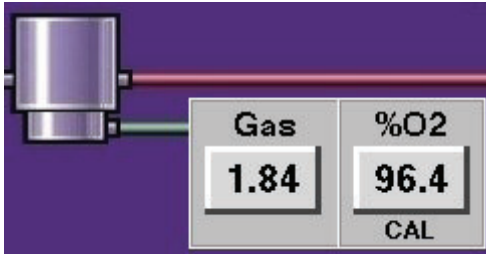
Electronic Gas Blender



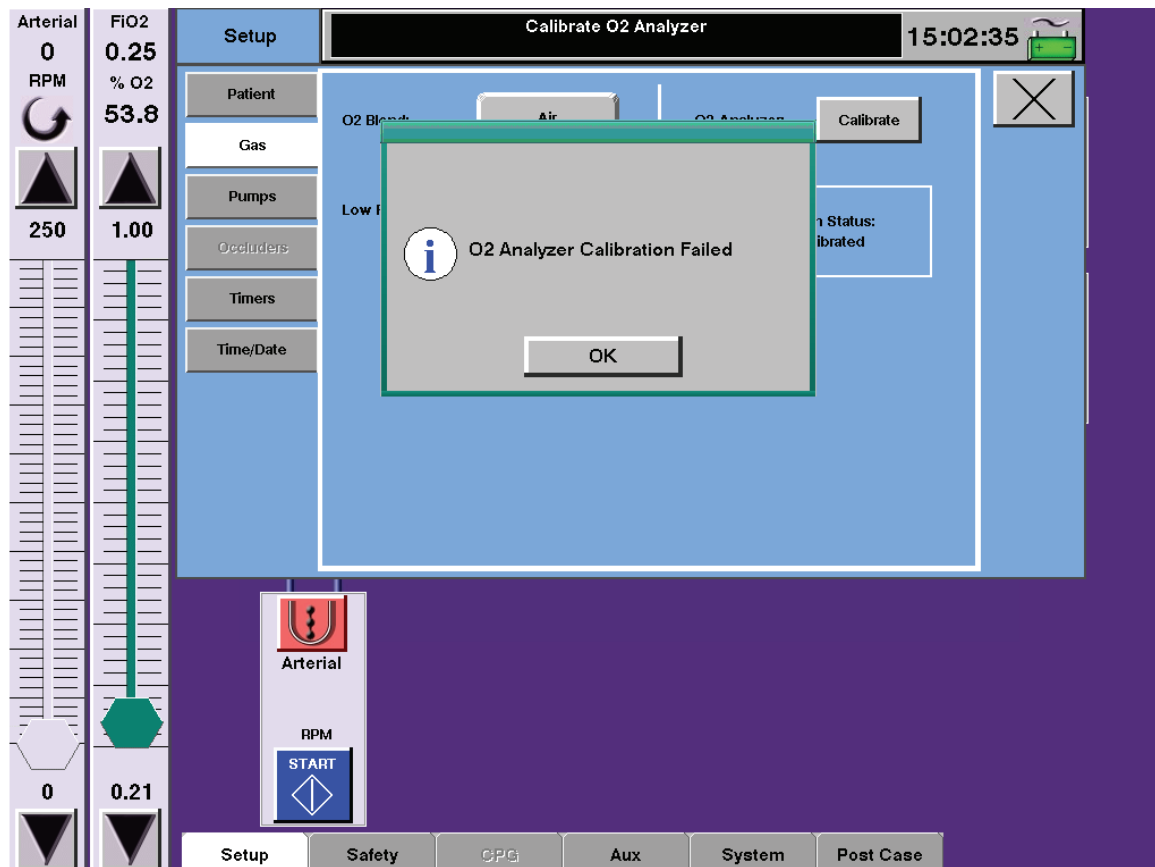
If Calibration is Not Successful:

An unsuccessful calibration is indicated by the following items:

- The label for **Calibration Status** in the **Gas** subtab within the **Setup** tab remains "Not Calibrated".
- **CAL** remains on the %O2 icon.

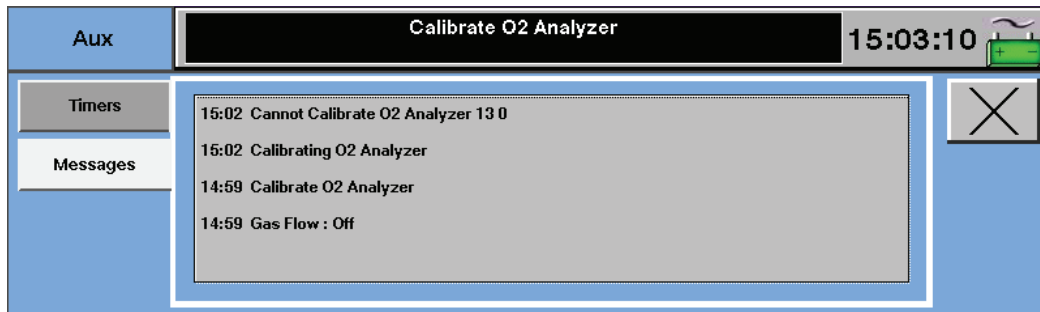


- A dialog box stating "O2 Analyzer Calibration Failed" will appear.



Electronic Gas Blender

- “Calibrate O2 Analyzer” message will be displayed in the message area at the top of the CCM window. Note that this message may not be displayed if a higher priority message is present.
- The message “Cannot Calibrate O2 Analyzer” will be displayed under the **Messages** subtab within the **Aux** tab. Note that the message contains a status code and value that provides further detail about the specific failure. Refer to the **Electronic Gas Blender Messages** section of this manual for further details.



If calibration is not successful during setup, take the following actions:

- Check for flow restrictions (e.g. kinked or blocked tubing) in the inlet and outlet lines of all components connected between the gas outlet and the oxygenator.
- Use the backup flowmeter to verify that no gas leaks are present.
- Retry calibration.

If calibration is unsuccessful again during setup, then:

- Use the local knob controls for FiO_2 and gas flow rate adjustment.
- Use the external backup flowmeter to measure flow.
- If available, use an external O_2 analyzer to measure oxygen content.
- Contact Terumo Cardiovascular Systems Customer service for assistance.

Note: During a case, if the oxygen sensor and gas blender readings do not agree, the % O_2 icon will display **CAL** and a CCM message “Calibrate O2 Analyzer” will appear. This condition can be caused by changes in the gas circuit since calibration, such as kinked or blocked tubing. The calibration data has not been lost and all controls remain functional. Once the cause of this condition is cleared, **CAL** on the % O_2 icon and the CCM message will disappear. It is not recommended to calibrate while on bypass.

Control and Monitor Flow

The electronic gas blender can be controlled from the CCM or controlled locally from the FiO_2 and flow control knobs located on the front of the system base. Flow and FiO_2 adjustments made from either the CCM or by the control knobs are simultaneously updated at each control location.

The gas slide bars share a location on the CCM with the occluder slide bar. When operating a device that shares a slide bar location, make sure that the slide bar displayed is for the device you intend to operate.

The gas system values are displayed on the CCM.

Note: After adjusting the flow rate or FiO_2 , there may be a short delay before the displayed oxygen content settles to the correct value.

Electronic Gas Blender

Operating the Electronic Gas Blender from the CCM

Controlling the Gas Flow

1. Touch the **Gas** icon.
2. Use the gas slide bar to increase and decrease the gas flow rate within the range of 0 to 10 L/min. The gas flow setpoint is displayed at the top of the gas slide bar. The measured gas flow rate is displayed on the gas icon.

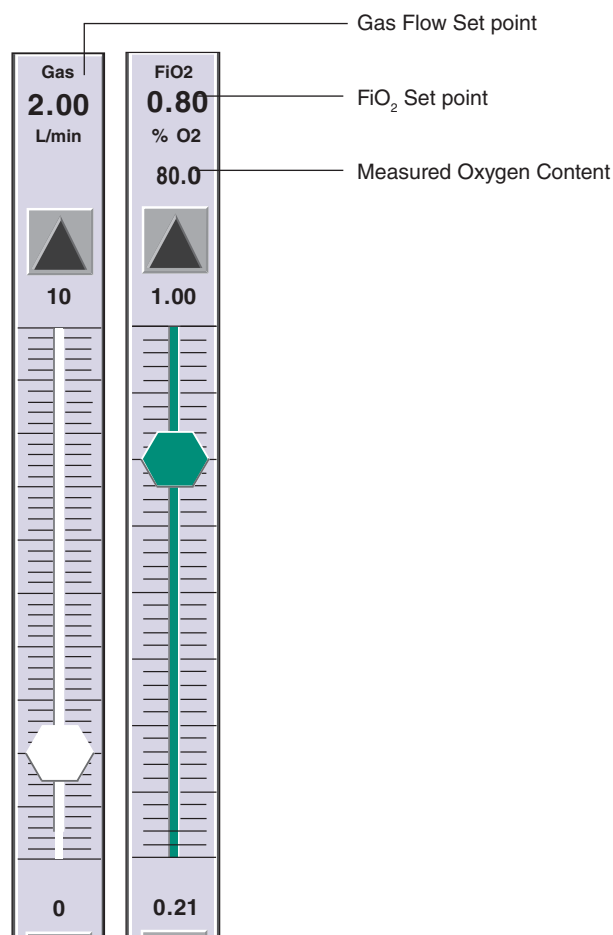
Note: When operating the system at flow rates below 0.2 L/min, finer control of the gas flow setpoint can be achieved using the local gas flow control knob.

Note: Measured flow rates less than 0.2 L/min, including 0 L/min, are displayed as "< 0.2" on the gas icon. Measured flow rates between 0.2 and 10 L/min are displayed with a resolution of 0.01.

Note: When using the gas flow slide bar on the CCM to shut off the gas flow or when ending a case, the gas flow knob may not return to its full off position and a small amount of gas may still be flowing. Manually turn the gas flow knob clockwise until it stops to completely stop the flow of gas.

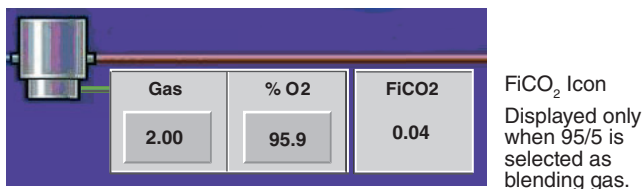
Controlling the FiO₂

1. Touch the **%O₂** icon.
2. Use the FiO₂ slide bar to increase and decrease the percentage of oxygen in the blended gas. The FiO₂ setpoint is displayed at the top of the FiO₂ slide bar. The measured oxygen content from the oxygen analyzer is displayed beneath the FiO₂ setpoint on the slide bar and on the %O₂ icon.



FiCO₂ Display

When 95/5 is used as the blending gas, the calculated value for FiCO₂ is displayed in the FiCO₂ icon. FiCO₂ is calculated using the %O₂ reading from the oxygen analyzer.

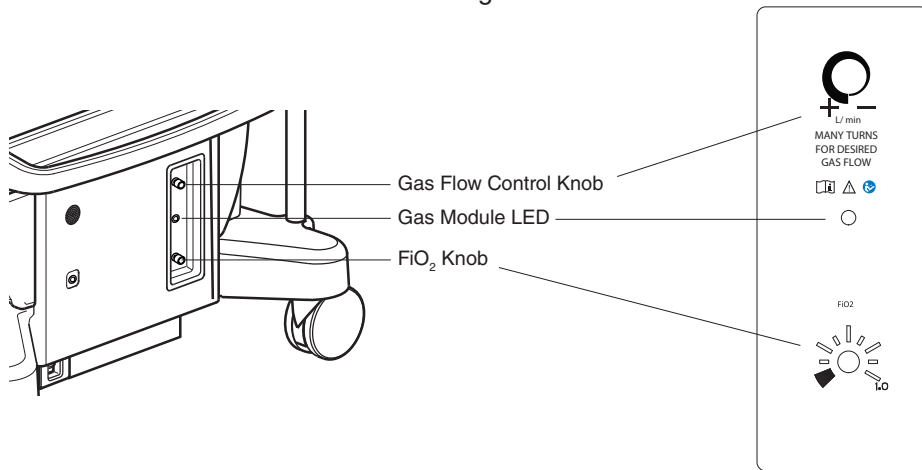


Electronic Gas Blender

Local Control of the Electronic Gas Blender

Controlling the Gas Flow

The gas flow control knob has a graphic indicating the direction to turn the knob to increase or decrease gas flow. Turn the knob counterclockwise to increase the gas flow rate and clockwise to decrease the gas flow rate.



Note: When necessary, the gas flow control knob can be used to set the gas flow rate > 10 L/min. The setpoint will be displayed at the top of the gas flow slide bar on the Central Control Monitor as an approximate reading. The gas flow icon will read > 10. Monitor the patient status closely and use either the gas flow control knob or the gas flow slide bar to adjust the flow rate as required.

Note: The gas flow knob of the electronic gas system has hard stops at both ends of its travel. Turn the gas flow knob clockwise until it reaches the hard stop to shut off gas flow. Turn the gas flow knob counter-clockwise until it reaches the hard stop to achieve maximum gas flow.

Note: When using the gas flow control knob of the electronic gas system to increase gas flow from 0 L/min, the gas flow will increase slowly until one full counter-clockwise revolution of the gas flow knob has been reached. Multiple turns of the gas flow knob, as indicated by the label on the control panel, may be required to reach the desired gas flow rate.

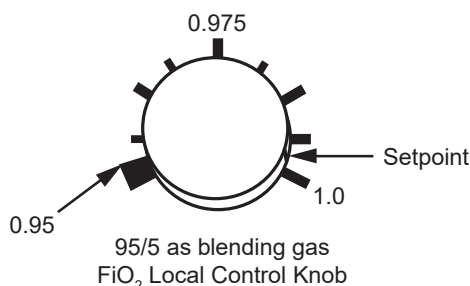
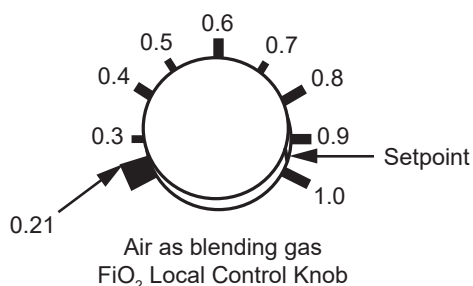


Use the external, mechanical flowmeter (supplied in the Accessory Kit) just before the oxygenator to detect any possible gas leak between the gas outlet and the oxygenator and as a backup to monitor gas flow in the event Central Control Monitor display capability is lost.

Electronic Gas Blender

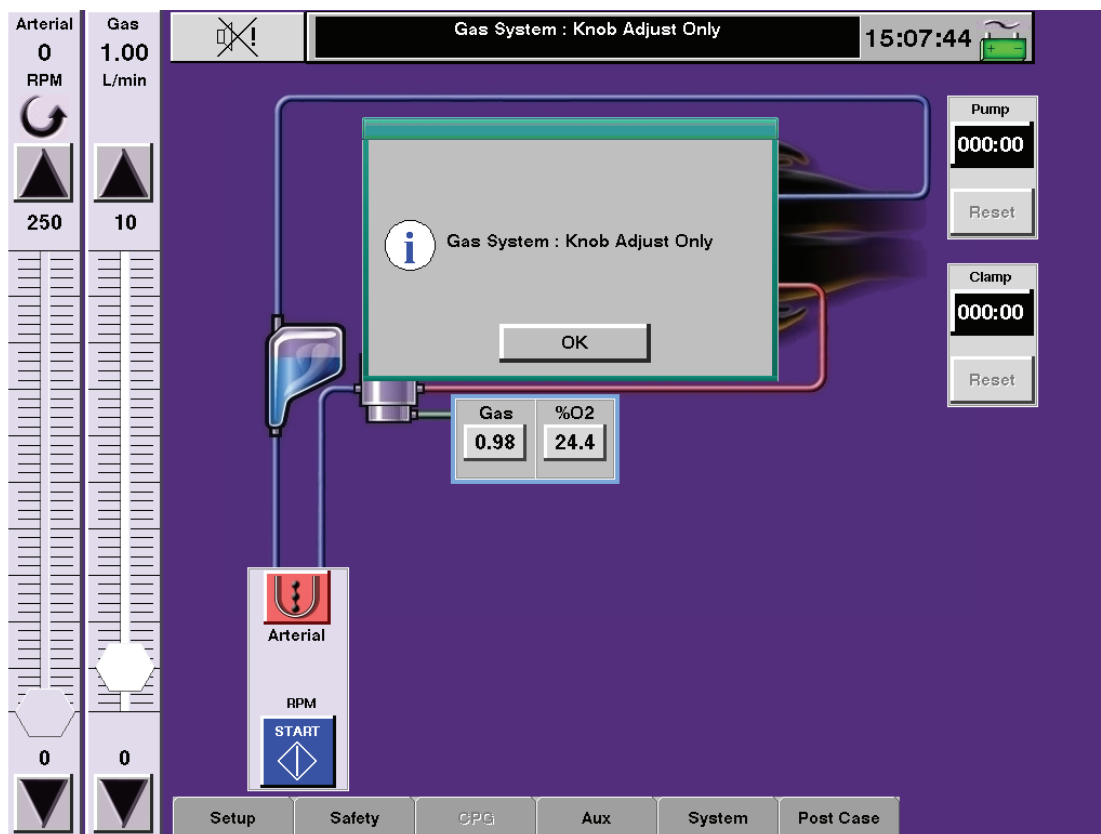
Controlling the FiO₂

The FiO₂ knob has a reference mark and tic marks on the front panel approximately indicating 0.1 increments in FiO₂ from 0.21 to 1.00 when using air as the blending gas. When using 95/5 (95% oxygen/5% carbon dioxide) as the blending gas, the tic marks approximately indicate 0.00625 increments from 0.95 to 1.00. Turn the FiO₂ knob clockwise to increase the percentage of oxygen in the blended gas and counterclockwise to decrease.



Knob Adjust Only Mode

If the system detects certain internal faults, it will enter Knob Adjust Only Mode. Flow and FiO₂ adjustments using the CCM sliders will be disabled, and the gas system will have to be controlled by using the knobs. A dialog box will appear to notify the user if this condition occurs. While the dialog box is on screen, access to the CCM controls will be disabled. Pressing the **OK** button will clear the dialog box. See the **Electronic Gas Blender Messages** section for instructions on how to respond to this error condition.



Electronic Gas Blender

System Response to Alarm Conditions

% O ₂ Icon	Gas Module	Message	Audible Tone
Flashes red	LED flashes red	Message in the CCM message area	Dual-tone alarm

System Response to Alert Conditions

Gas Icon	Gas Module	Message	Audible Tone
Flashes yellow	LED flashes yellow	Message in the CCM message area	Single-tone alert

Electronic Gas Blender Messages

Priority	Condition	CCM Message	Operator Response
Alarm	FiO ₂ has dropped below minimum limit.	LOW FiO ₂	Increase FiO ₂ setting to above minimum limit to clear alarm.
	O ₂ source pressure < 30 psi or more than 18 psi below the air pressure.	LOW OXYGEN SUPPLY PRESSURE	Check O ₂ hose connections. Check O ₂ supply and switch source if necessary.
	O ₂ source pressure > 70 psi.	HIGH OXYGEN SUPPLY PRESSURE	Check O ₂ supply pressure, switch source if necessary.
	Air source pressure < 30 psi or more than 18 psi below the O ₂ pressure.	LOW AIR SUPPLY PRESSURE	Check air hose connections. Check air supply and switch source if necessary.
	Air source pressure > 70 psi.	HIGH AIR SUPPLY PRESSURE	Check air supply pressure and switch source if necessary.
	95/5 source pressure < 30 psi or more than 18 psi below the O ₂ pressure	LOW 95-5 SUPPLY PRESSURE	Check 95/5 hose connections. Check 95/5 supply and switch source if necessary.
	95/5 source pressure > 70 psi	HIGH 95-5 SUPPLY PRESSURE	Check 95/5 supply pressure and switch source if necessary.
Alert	Oxygen Analyzer Expired.	SERVICE GAS SYSTEM	The Oxygen Analyzer has expired and needs to be replaced. "Service O ₂ Sensor" will appear in the Messages subtab within the Aux tab. Do not use gas system until it has been serviced by Terumo Customer Service.

Electronic Gas Blender

Alert	Gas mixer has detected an internal malfunction	SERVICE GAS SYSTEM	If not on bypass, calibrate O ₂ analyzer. If message does not clear or if on bypass, adjust the FiO ₂ and gas flow using the knobs located on the front of the system. If the knobs cannot be turned, use standby gas blender. Do not use gas system until it has been serviced by Terumo Cardiovascular Systems. See the Messages subtab within the Aux tab for any additional error or status messages. May be accompanied by additional faults if error is due to gas mixer not meeting demand.
-------	--	--------------------	--

Error	Gas mixer is not meeting demand and has disabled control from the CCM.	Gas System : Knob Adjust Only	If not on bypass, calibrate O ₂ analyzer. If message does not clear or if on bypass, adjust the FiO ₂ and gas flow using the knobs located on the front of the system. If the knobs cannot be turned, use standby gas blender. Do not use gas system until it has been serviced by Terumo Cardiovascular Systems. See the Messages subtab within the Aux tab for any additional error or status messages. May be accompanied by additional faults if error is due to an internal malfunction.
-------	--	-------------------------------	---

Priority	Condition	CCM Message	Operator Response
Status	Gas flow is < 0.2 L/min.	Gas Flow : Off	Turn gas flow to > 0.2 L/min to clear message.
	O ₂ analyzer calibration in progress.	Calibrating O2 Analyzer	Message clears when calibration is complete.
	O ₂ analyzer calibration finished	O2 Analyzer Calibration Complete	Message displays for 10 seconds.
	Warm up in progress.	Gas System Warming Up	Message clears when warm up is complete.
	O ₂ sensor exposure limit reached.	Service O2 Sensor	Backup analyzer should be used until O ₂ sensor is replaced by Terumo Cardiovascular Systems Service.
	System just powered up and is expecting a calibration.	Calibrate O2 Analyzer	Calibrate O ₂ analyzer
	The %O ₂ and the FiO ₂ readings do not agree	Calibrate O2 Analyzer	Inspect gas circuit for kinks, blockages, or leaks. If necessary, use a backup O ₂ analyzer.
	O ₂ Analyzer calibration failed.	Cannot Calibrate O2 Analyzer XX (may only appear in Message tab) 12 User pressed cancel button. 13 Flow or FiO ₂ knob turned during calibration 16 O ₂ Sensor is expired 17, 19 Blender mechanical problem 18 Flow mechanical problem 20, 21, 22 Flow meter fault 23 O ₂ sensor fault	Check status code. Retry calibration. If calibration does not pass, use backup O ₂ analyzer until unit can be serviced.

This page intentionally left blank.

Run a Case

These are condensed directions on how to check, start-up, set up, and use the System 1. When necessary, refer to other sections of the manual for specific information.

Check the System 1

Hand Cranks/Standby Pumps

Verify that the hand cranks and any standby pumps are present, set to direction of forward flow, and are accessible.

Cables

See that all cables are properly connected and not visibly damaged, including roller pump, centrifugal pump, CCM, occluder, and all other cables. Verify that the Interface Module cables for a CDI device and data management are in place. Make sure that all necessary air, level, pressure, temperature, and flow sensors are in place and ready to be connected to the circuit.

Gas Lines

Check that gas supply lines are properly connected with the necessary source pressure. Attach a 0.2 micron filter to the gas outlet line to the oxygenator. Use a wall pressure regulator if the gas supply pressure varies beyond ± 5 psi. Ensure that backup gas sources, especially oxygen, are available.

Circuit Breakers

Verify that the three circuit breakers on the back of the system base are properly set.

AC (Mains) Power Cord

Verify that the AC (Mains) power cord is securely connected to the AC (Mains) power source.

Power on the System

Power on the system.

Alarm

Verify that the audio alarm sounds when the power is turned on.

Power On Self Test

Verify that the main screen comes up on the Central Control Monitor with no continuous failure messages. Roller pump displays should display no failure messages. The roller pump module ID should be displayed and the tube size should display the last tube size selected.

Centrifugal control unit displays should display no failure messages. The centrifugal pump module ID should be displayed.

Power

Verify that the System 1 is operating from AC (Mains) power and that the backup battery system is fully charged.

When starting a system that has been in storage, allow at least 1 minute to elapse after the CCM displays the Main Screen before checking the power status indicator LED.

Modules

Verify that the module LEDs are constant yellow.

External Devices

Power on and check any external devices, such as a CDI™ 500/550.

Set Up the System 1

Open the Perfusion Screen.

Run a Case

Online Pumps

Access the Pumps subtab within the Setup tab and verify pump labels, display units, and tube size. Verify safety connections and pump responses. Adjust tube sizes, display units, and pump responses if necessary. Verify pump labels, pump direction, and tube size on the pump local display. Verify the assignment of the primary pump by checking the pump display for the proper names, such as “Arterial.” For Pulse mode flow on the primary pump, use the Pulse subtab within the Pump tab to set Rate, Width, and Base (Base only for centrifugal).

Roller Pumps

Install the tubing and set occlusion. Pumps used for venting or suction should be fully occluded. Verify that the default direction for offline pumps matches the system direction.

Sarns or Capiiox Centrifugal Pumps

Set the minimum flow alarm by using the Pumps subtab within the Setup tab. Install the disposable pump(s) but do not start the drive motor until ready to prime the circuit.

Power

Check the power source and battery charge level by accessing the Power subtab within the System tab. Test the battery switching function by temporarily disconnecting the AC (Mains) power supply. Check that the audible battery alert tone sounds, the power status indicator LED on the front panel flashes, a message is displayed on the CCM and is posted in the Messages subtab within the Aux tab, an estimated available battery time is displayed above the Power Source/Battery Status icon, and the entire system is functional. Reconnect the system to the AC (Mains) power supply.

Modules

Verify that the module LEDs change to green for each module in the Perfusion Screen. Check the Module Info subtab within the System tab to verify critical information regarding the modules in the Perfusion Screen.

Gas System (if used)

Access the Gas subtab within the Setup tab and verify the gas blend and set the FiO₂ alarm limit. Wait for the 15 minute warm up period to complete. Secure gas outlet line to oxygenator inlet. Calibrate the oxygen analyzer after the warm up period is complete and source gases are connected.

Occluder (if used)

Verify that the occluder icon reads CAL. Calibrate the occluder, after placing the tubing in the occluder head. Verify the occluder label and any safety connections to the primary pump via the Occluder subtab within the Setup tab.

Temperature Sensors

See that the room temperature appears on each temperature sensor. Using the Temperature subtab within the Safety tab or by touching the icon, verify temperature labels and the temperature alarm limits for each sensor. Adjust the limits, if necessary.

CCM

Verify that there are no question marks or red Xs on any of the device icons in the Perfusion Screen. Verify that the correct time is displayed. Check the Message Area and Messages subtab within the Aux tab for any potential error or status messages. Check the Settings subtab within the System tab to verify the Perfusion Screen and to adjust the audio tone volume.

Run a Case

Pressure Transducers

Verify that all pressure icons read CAL. Check that each transducer is at the correct elevation. Calibrate the pressure sensors while the transducers are open to atmospheric pressure. Verify pressure labels and the alarm and alert limits via the Pressure subtab within the Safety tab or by touching the icon(s). Adjust the limits if necessary.

Patient Data

Enter the patient height and weight using the Patient subtab within the Setup tab. Verify that the correct BSA formula is being used.

Circuit

Set up and prime the extracorporeal circuit according to protocol.

Flow Sensors

Check that the flow sensor arrow points in the direction of circuit flow. Verify flow sensor labels in the Flow subtab within the Safety tab or by touching the flow icon(s). If the flow sensor was placed on the centrifugal pump, touching the flow icon will not open the Safety tab.

Air Detection

Verify the labels of all air sensors in the Perfusion Screen by checking the Air subtab within the Safety tab or by touching the air icon(s). Set up the air sensor(s). Verify the performance of all air sensors as part of the priming procedure and leave the sensors on.

Level Detection

Verify the selection of alert and alarm and the level detection label in the Level subtab within the Safety tab or by touching the level icon. Set up the level detection. Verify its performance as part of the priming procedure and leave it on.

Automatic CPG Delivery

Using the Auto Dose Setup subtab within the CPG tab, set up the required doses, either by volume or time. Enable the Auto Dose feature in the Delivery subtab.

Servo Mode

Verify through the pump tabs that Servo mode is accessible for the desired parameter(s).

Perfuse the Patient

Pumps

Start the pumps and adjust the pump speed. With a centrifugal pump, wait until above minimum pump speed to unclamp arterial and venous lines. Always adjust the centrifugal pump speed when changing to Pulse mode as the average flow rate will decrease and the speed may be too low resulting in retrograde flow. Start arterial pumping in Continuous mode and initiate Pulse mode when appropriate. Adjust speeds when changing between Pulse mode and Continuous flow mode.

Gas System

Initiate gas flow when appropriate and adjust FiO₂ as necessary.

Timers

Start the pump, clamp, and other timers when appropriate.

Occluder

Use the Open and Close buttons on the CCM for rapid changes in flow. Use the Control Arrows for slow changes.

Run a Case

Monitor

Monitor the patient and system controls and displays, adjusting the controls as necessary.

Servo Control

Initiate servo control when appropriate and when pump flow rates and servo setpoints have stabilized.

CPG Delivery

Utilize the Delivery subtab within the CPG tab to track cardioplegia delivery, employ cardioplegia timers, and to deliver auto doses, if desired.

Messages

Respond to any message immediately. Should a centrifugal pump stop or go to Coast speed, clamp lines. Always check the pump display and the CCM for messages related to pressure, air bubble, and level detection. Determine the cause of the alarm and take appropriate action (see the **CCM** and **Modules** chapters, messages section, and the messages sections at the end of the **Roller Pump**, **Sarns Centrifugal Pumps**, and **Capiiox Centrifugal Pumps** chapters).

The message area at the top of the Perfusion Screen displays the highest priority alarm, alert, status, or error message. If two conditions of equal priority exist at the same time, the condition that was detected first will be displayed on the CCM until it clears. If the second condition still exists after the first has been cleared, then that message will be displayed.

Status messages post only once. If the message area has a higher priority message, the status message will post only in the Messages subtab within the Aux tab.

All messages post in the Messages subtab within the Aux tab. The messages can be viewed at any time during the case by pressing the Aux tab and opening the Messages subtab. The subtab displays the messages and the time the message was generated.

Battery

Monitor battery supply, when in use. Observe the power status indicator LED and the battery charge level bar graph in the Power subtab within the System tab.

Ending a Case

When the case is finished, exit the case by touching the Post Case tab and following the prompts. When the case is exited, the pumps will stop and the gas flow rate will be set to zero. Any modifications to the Perfusion Screen will revert to default settings or configured settings after the perfusion screen is exited. Modifications could include patient data, gas blend, FiO2 alarm value, pump display units, pump(s) and occluder responses to safety connections, minimum flow alarm value(s), level detect mode, pressure display, pressure alert and alarm limit(s), temperature alarm limit(s), cardioplegia volume tracking and autodoses setup, messages in the Messages subtab within the Aux tab, volume of the audio alarm, reassigned modules, and timer value(s).

Note: When using the gas flow slide bar on the CCM to shut off the gas flow or when ending a case, the gas flow knob may not return to its full off position and a small amount of gas may still be flowing. Manually turn the gas flow knob clockwise until it stops to completely stop the flow of gas.

Powering Down

Use the Shut down button on the main screen to perform a controlled shut down of the system computer. Then power down the entire system using the AC (Mains) power switch on the front of the system base.

Emergency Procedures

The situations in this section will help you use this system proficiently should an actual emergency occur. Practice operating the system during a wet run, simulate the emergency condition, and follow the suggested operator responses.

Perfusion Situations

Conditions such as Air Detected, Low Blood Level, High Pressure, Backflow, and Minimum Flow

Provided you have configured your System 1 to include air, level, pressure, flow and/or centrifugal control units, and they have been enabled, the first indication of an emergency situation should be the flashing of a message and icon and the sounding of the audio tone.

- Check the message area and the flashing icon on the Central Control Monitor (CCM) to identify the problem. The message area at the top of the Perfusion Screen displays the highest priority alarm, alert, status, or error message. If two conditions of equal priority exist at the same time, the condition that was detected first will be displayed on the CCM until it clears. If the second condition still exists after the first has been cleared, then that message will be displayed.

All messages post in the Messages subtab within the Aux tab. The messages can be viewed at any time during a case by pressing the Aux tab and opening the Messages subtab. The subtab displays the messages and the time the message was generated.

Follow the instructions provided under the “Messages” section in each of these chapters:

- **Central Control Monitor**
- **Roller Pumps**
- **Sarns Centrifugal Pumps**
- **Capiiox Centrifugal Pumps**
- **Modules**
- **Electronic Gas Blender**
- Resolve the emergency as directed. Clamp lines, when necessary, to prevent air from entering the patient. Stop the cardioplegia pump if it is drawing blood from the arterial line and the arterial pump has been configured to stop or pause.
Note: You may configure your system so that the cardioplegia pump will stop whenever an event stops or pauses the arterial (or primary) pump.
- Reset the air detection system after clearing any air if there is an air bubble alarm.
- Restart the pump(s), if they have been configured to stop. Increase the pump speed if they have been configured to reduce speed or go to Coast speed. With a roller pump, unclamp the venous line and increase the speed to attain the desired flow rate. With a centrifugal pump, attain the minimum pump speed before unclamping the venous and arterial lines.

Air Deprimes a Centrifugal Pump

Air may deprime the centrifugal pump, stopping or greatly reducing flow. Small amounts of air may be detected by a thin, pink line of foam at the top of the arterial line. Clamp both the arterial and venous lines, then unclamp the arterial line and let backflow purge air to the reservoir. If necessary, reclamp the arterial line, remove the pump from the motor, and tip and tap the pump to remove the air.

Note: Letting backflow purge air to the reservoir will cause any pumps with a safety connection to a backflow alarm to respond. Check connected pumps and restart if stopped. Check the arterial cannula and arterial line for air that may have entered as a result of the backflow condition.

Emergency Procedures

Air Detection Stops a Centrifugal Pump

When an Air Bubble Detector stops the centrifugal pump, clamp both the arterial and venous lines. Remove any air from the arterial line before resetting the air detection and restarting the pump.

Air Detection Causes a Centrifugal Pump to Coast

When an Air Bubble Detector causes the centrifugal pump to go to Coast speed, clamp both the arterial and venous lines. Remove any air from the arterial line before resetting the air detection and increasing the pump speed.

Pressure display of '999' or '---'

In the event of a pressure transducer failure and a pressure display of 999 or --- the following should be considered in order to re-engage pressure measurement.

If 999 or --- is displayed prior to cardiopulmonary bypass:

- Verify the circuit pressure is not actually elevated or dropped to out of range levels.
- Check transducer connections.
- Attempt to re-zero the pressure transducer by opening to atmospheric pressure and recalibrating.
- Connect a backup pressure transducer.
- If a backup pressure transducer is not available, consider use of a stand-alone pressure device. Keep in mind, this will not allow for pressure-related safety connections.

If 999 or --- is displayed during cardiopulmonary bypass:

- Verify the circuit pressure is not actually elevated or dropped to out of range levels.
- Check transducer connections.
- If troubleshooting is delayed, consider hand cranking any stopped pumps.
- Attempt to re-zero the pressure transducer by opening to atmospheric pressure and recalibrating.
- The physiological alerts or alarms will be cleared automatically. If a safety connection from a pressure event paused or stopped a pump, that pump can resume or be restarted (if no other pause or stop responses are in effect).

CAUTION: The pressure safety connection response described above is applicable even in a loss of Central Control Monitor situation. With pressure monitoring capability lost, safety connections may still be functional and may cause responses if pressure readings are in range and the pressure related safety messages may also appear in the message area on the pump control panel. If the behavior of the pressure transducer appears erratic or as a preventive measure, discontinue use of integrated pressure monitoring by disconnecting pressure transducers from the module. Consider use of a stand-alone pressure monitoring device. Keep in mind that this will not allow for pressure-related safety connections.

- After pump restart, consider the use of a backup pressure transducer.
- If a backup pressure transducer is not available, consider use of a stand-alone

Emergency Procedures

pressure device. Keep in mind, pressure measurement will be available but pressure-related safety connections will not exist and pumps will not be able to respond to high pressure events.

- If disconnecting the pressure transducer is not possible, change the Pump Response to “Message Only.” This should prevent potentially erratic pressure readings from stopping/pausing the pump, if the pressure system malfunction manifests intermittently.
- Contact Terumo Customer Service after the case is completed.

Unexpected Return to Bypass

- Power up the system.
- Recalibrate the pressure values to quickly resume bypass.
- Set up and prime the circuit per your hospital protocol.
- Calibrate the venous occluder, if used.
- Connect the air and level detection sensors. Resolve any air or level conditions, reset the air detection system, and turn all air and level systems ON as soon as possible.
- If using a flow display that is indexed to patient BSA or weight, reenter the patient height and weight.
- Use the electronic gas blender, recalibration of the oxygen analyzer should not be necessary, if it has been calibrated within the last 24 hours. The FiO₂ alarm needs to be reset.
- Verify that the tube size selection is correct.
- Start the arterial pump and attach any other monitoring equipment.

Loss of Gas Supply

Ensure that backup gas sources are available. If tanks are being used, they must be used with a pressure regulator. The electronic gas blender requires that the source gases be within a specified range of 50 psi \pm 20 psi and that there be no more than 18 psi difference between the inlet pressures of the 2 source gases.

Loss of AC (Mains) Power Supply

Monitor the battery power indicators, such as the power status indicator LED and the battery charge level bar graph in the Power subtab within the System tab, to determine the battery charge level status.

Decreasing the power consumption of the system while operating on battery power can enable the batteries to power the system for more than 1 hour.

Turning off noncritical devices, such as the lamp, will decrease the power needs of the system.

Loss of Battery Power, Total Power Loss

In the event that the AC (Mains) power supply is lost and the duration of the case exceeds that of the battery power supply, System 1 pumps and Electronic Gas Blender may be operated manually to continue perfusion and oxygenation. Safety devices and their safety connections to pumps will not function after a total loss of power until power is restored and safety connections are enabled. Instructions for manual operation of roller pumps are in the **Roller Pump** chapter, **Manual Operation of Pump** section. Instructions for manual operation of centrifugal pumps are in the **Sarns Centrifugal Pumps and Capiox Centrifugal Pumps** chapter, **Using Standby Equipment** section. The electronic gas blender can be manually operated from the local controls as described in the **Electronic Gas Blender** chapter, **Local Control of the Electronic Gas Blender** section.

Emergency Procedures

Loss of Power Without Automatic Switch To Battery Backup System

WARNING: Confirm that the entire system has lost power before continuing with these instructions. Check the central control monitor (CCM), the local pump displays, the LED indicators on the modules, and the power status indicator on the front of the system to confirm that power has been lost.

After confirming that the entire system has lost power, switch the AC (Mains) power switch on the front panel to the “**OFF**” position then to the “**ON**” position.

If toggling the AC (Mains) power switch is successful in restarting the system:

- Power will be available to the pumps prior to the CCM screen restarting.
- Pumps can be restarted using local controls.
- After the system has restarted, select a perfusion screen, and enable all safety systems.

WARNING: If using a centrifugal pump, be sure to follow these emergency procedures to prevent backflow:

- Clamp the arterial and venous lines.
- Discontinue vacuum-assisted venous drainage, if applicable.

If toggling the AC (Mains) power switch is NOT successful in restarting the system:

- Initiate or continue manual hand cranking of the arterial pump.
- Prepare to transition to backup equipment.

Circuit Breaker Trips

If one or both of the system AC (Mains) power circuit breakers trip, the system will automatically switch to battery power. To reset the circuit breakers, depress the push button(s) until it clicks into place. Verify that the system returns to AC (Mains) power.

If the auxiliary outlet circuit breaker trips, devices plugged into the outlet will lose power. To reset the circuit breaker, depress the button until it clicks into place.

CAUTION: In the event that the breaker trips immediately after a reset, **DO NOT attempt to reset again**. The system will only operate from battery power until it has been repaired. Call for service.

CAUTION: The auxiliary outlet is not backed up by battery power. During loss of AC (Mains) power, any equipment connected to the auxiliary outlet will lose power and will remain unpowered until AC (Mains) power is restored.

Emergency Procedures

Equipment Situations

Pump Failure

An audible alert or alarm and message or only a message will be generated to indicate a pump failure involving a roller pump overspeed condition, a roller pump jam, or centrifugal pump overcurrent condition. Check the message area on the CCM to identify whether there is an overspeed condition, roller pump jam, or centrifugal pump overcurrent condition. Follow the specific operator response for these messages.



WARNING: Always check the direction of rotation before starting a backup or standby roller pump to make sure that the roller pump default direction matches the system direction. Retrograde pumping MAY CAUSE SEVERE PATIENT INJURY OR DEATH by drawing air into the bloodline which might then be pumped into the patient.

If you must switch to another pump, consider the tubing length available and select the appropriate method below.

- If there is sufficient tubing length to reach another pump, clamp the lines, switch the tubing to a new pump, verify default direction, and check tubing size flow constants.
- If the tubing is not long enough, clamp the lines and remove the tubing from the current pump. Replace current pump with new pump and place the tubing into the new pump. Verify default direction and check tubing size flow constants.

If the new pump was designated as the backup pump or is a pump of the same type, do not deactivate the safety systems during this switch. Use the Reassign Module subtab within the Systems tab to assign pump functionality and safety connections to the backup pump or another pump of the same type. After reassignment, verify all operating parameters, including tube size or flow constant, direction, and display units on the pump display, before starting pump.

If a primary centrifugal pump is reassigned to a backup roller pump and if flow has been placed on the centrifugal pump, flow module data will no longer be displayed and the backflow alarm and minimum flow alarm are no longer available. In addition, the centrifugal Coast response becomes a roller pump Stop response for alarm events and a roller pump Message Only response for alert events. The table indicates how pump responses change when a primary centrifugal pump is reassigned to a backup roller pump.

Primary Centrifugal Pump Response:

Stop
Coast

Message Only
No Response

Backup Roller Pump Response:

Stop
Stop - for alarm events
Message Only - for alert events
Message Only
No Response

If manual operation of a roller pump is necessary, use a properly set up hand crank to turn the pump in the direction of forward flow. If the pump is difficult to turn, unplug the pump cable at the pump. See the **Roller Pump** chapter, **Manual Operation of the Pump** section for additional details regarding the use of the hand crank.

If manual operation of a centrifugal pump is necessary, temporarily clamp the arterial and venous lines, remove the pump from the drive motor, and mount it in a manual drive unit that has been secured to a vertical pole. Turn the handle in the direction of the arrows and monitor the speed using the indicators. See the **Sarns Centrifugal Pumps and Capiiox Centrifugal Pumps** chapter, **Manual Drive Unit** section, and **Using Standby Equipment** section, for additional details regarding the use of the centrifugal manual drive.

Emergency Procedures

Centrifugal Pump Decouples from the Drive Motor

Decoupling of the pump from the motor is noted by a drop in flow and may be accompanied by a loud “whirring” or “buzzing” noise. Clamp the arterial and venous lines and stop the pump. After a complete stop, remove any air that may have resulted from retrograde flow and restart the drive motor at a reduced speed. If the coupling cannot be accomplished or the desired flow cannot be achieved, use standby equipment. Contact Terumo Cardiovascular Systems and do not use the drive motor until it is serviced.

Stopped Drive Motor with the Centrifugal Control Unit

In the event of a stopped drive motor with the Centrifugal Control Unit, the user should:

Clamp the arterial and venous lines

- Discontinue vacuum-assisted venous drainage, if applicable.
- Close all purge and recirculation lines to minimize the potential for air entrainment and backflow in the CPB circuit.
- If necessary, stop the cardioplegia pump to minimize the potential for air entrainment.
- Resume arterial flow using backup equipment, either a manual drive unit or roller pump, according to hospital protocol.
 - For additional information regarding Centrifugal Control Unit issues, see **Sarns Centrifugal Pumps and Capiox Centrifugal Pumps** chapter.

Loss of Local Display (roller pump, Sarns Centrifugal control unit, or Capiox Centrifugal control unit)

A failure of the local display may exhibit any or all of these symptoms: blank display, distorted display, flickering display, vertical line through display, or spot on display.

- If this occurs while not on bypass, replace and re-assign the pump with backup equipment.
- If this occurs while on bypass, attempt to finish the case referring to the pump status information on the CCM.

WARNING: If the local display fails, the pump information can be viewed from the CCM. For any configured pump, the pump control box and associated slide bar display pump name, pump direction (for roller pumps), speed/flow or set point display, and display units. Safety messages are displayed on the CCM.

WARNING: If the local display fails, the pump may still be operational and the local controls may still function. Confirm the pump status using other indicators before attempting to start/stop the pump or adjust speed. Pressing the Start/Stop button could result in the unintentional stopping of a running pump.

Emergency Procedures

Loss of Local Control (roller pump or centrifugal control unit)

A failure of the local controls may result in the pump failing to respond to a user command from these local control points: Start/Stop button, pump speed control knob, Select button, or Manual button. Specific user commands that may be affected include: starting/stopping of the pump, speed adjustment, return to continuous mode from Pulse mode or Servo mode, or reset of an active air bubble detection alarm.

- If this occurs while not on bypass, replace and re-assign the pump with backup equipment
- If this occurs while on bypass, the pump controls on the CCM may still be completely functional. Attempt to finish the case with the controls on the CCM.

WARNING: If the local controls fail, the pump can be controlled through the controls on the CCM. The CCM controls provide all necessary commands including: starting, stopping, or adjusting the speed of the pump, returning to continuous mode from pulse mode or servo mode, and resetting an active air bubble detection alarm.

WARNING: If any of the local controls fail, the pump may still be operational and other local controls may still function. Confirm the pump status using other indicators before attempting to start/stop the pump or adjust speed. Pressing the Start/Stop button could result in the unintentional stopping of a running pump.

Module Failure

If a module fails and/or loses communication with the network, all safety connections related to that module will become inactive. For example, an occluder which has a safety connection response to close when the arterial pump stops, will not respond if the occluder module or pump fails and/or loses communication with the network.

Check the LED on the module itself to determine if there has been a module failure. The LED will display constant or flashing red in the event of a broken module. A module failure may also be accompanied by a message in the message area of the CCM. A question mark or a red X may appear over the broken module icon (see **Network Malfunction** subsection). Operating parameters for each module can be viewed using the Module Info subtab within the System tab.

To verify a module is broken, connect the module to another base receptacle and allow the Power-On Self-Test to run again. If the module fails again, replace the module.

Broken modules can be replaced with the same type module. Plug the sensors into the new module and plug the new module into the system base. Use the Reassign Module subtab within the System tab to reassign the new module. Enable safety systems and calibrate pressure transducers and, if necessary, the occluder.

Emergency Procedures

Electronic Gas Blender Failure

Use backup gas blender and oxygen analyzer to mix and monitor the gases.

Sensor Failure

In the event of a sensor failure, the appropriate message will be displayed in the message area of the CCM. Check the sensor connections and, if the message does not clear, replace the sensor with the appropriate back up sensor.

Loss of Servo Control

Servo control will be lost if either the flow module, pressure module, or the flow sensor or pressure transducer providing the data setpoint fails. Servo control will be lost if the pump cannot maintain the servo setpoint. Loss of servo control will be accompanied by a message (“MANUAL: monitor flow”) on the pump display. The message “<Pump Name>: MONITOR FLOW” will appear in the message area of the CCM. Check the servo source. Once the source is operating properly, try again to establish servo control via the CCM. If the message appears again, discontinue the use of servo control.

Remember that there are operating parameters that the user must remain within in order to establish servo control. See the **Roller Pumps** chapter, **Servo Mode** section and the **Sarns Centrifugal Pumps or Capiox Centrifugal Pumps** chapter, **Servo Mode** section for more information regarding operating parameters.

Central Control Monitor Malfunctions

Pumps and connected safety devices will function even if the Central Control Monitor fails. If there is a failure, contact Terumo Cardiovascular Systems Service before using the system again.

A failure of the Central Control Monitor may be expressed as: a frozen touch screen, portions of the screen may appear blank, or there may be a message “System Computer Needs Service” displayed on the screen. If you are not on bypass, cycle power to reset the computer. If you are on bypass, finish the case with the local controls on the pumps, centrifugal control unit, and electronic gas blender.

WARNING: If the Central Control Monitor fails, the system can be controlled through the local controls on the roller pump, centrifugal control unit, and electronic gas blender, if installed.

WARNING: In the event the Central Control Monitor fails, only those sensors that have a safety connection to at least 1 roller pump or centrifugal control unit will be able to display messages on a local control panel. If no safety connection was established, no audible tone will sound and no messages will display on any local control panel. The only indication that an event has occurred will be the flashing LED on the affected module.

WARNING: Do not turn the system power off in the event of a Central Control Monitor failure during use as this will cause all settings and device assignments to be lost.

During a case, do not attempt to re-enter the Perfusion Screen. Finish the case through local control.

Emergency Procedures

If the system computer is lost, it will not be possible to follow the recommended shut down procedure. The system power should be turned off when the case is finished by depressing the bottom of the AC (Mains) power switch.

Using Local Control upon a Central Control Monitor Failure

If the Central Control Monitor Fails During Bypass

Failures of the CCM include frozen touch screen, portions of the screen may appear blank, the entire screen may go blank, or there may be a message “System Computer Needs Service” displayed on the screen and/or local pump display.

CAUTION: If the Central Control Monitor fails and does not reboot itself, do NOT touch the CCM touch screen. Touching the CCM touch screen may cause unexpected system responses. Only use local controls.

WARNING: Carefully follow these instructions to safely complete the case through use of local controls. A failure to understand how to use the manual controls in the case of a CCM failure may lead to patient harm.

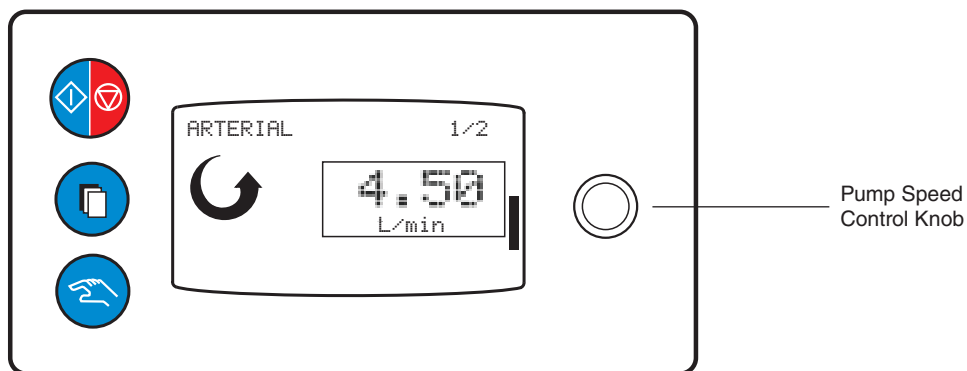
WARNING: Do not turn the system power off if the CCM fails as this will cause all settings, device assignments, and safety connections to be lost.

WARNING: If the CCM reboots itself during bypass, it is recommended that caution be used when reentering the Perfusion Screen as this will cause safety devices to turn off. If you choose to re-enter the Perfusion Screen, you must reactivate safety devices.

WARNING: Failure to understand how to clear safety alarms through the manual controls may lead to patient harm.

Use the local controls for roller pumps, centrifugal control unit, and electronic gas blender. All safety systems that were active when the CCM was lost will still be functional.

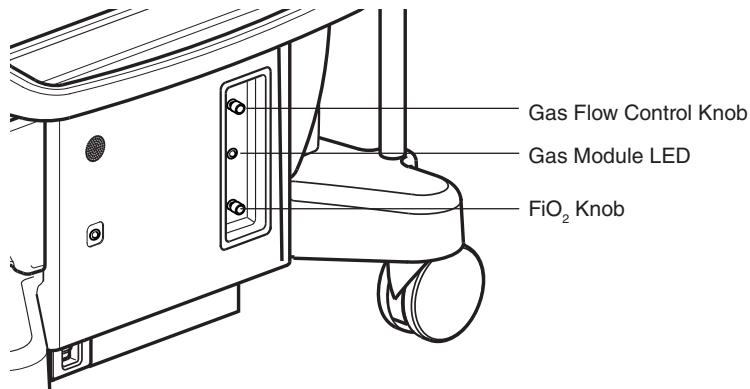
- The roller pump and centrifugal pump speeds are controlled with the pump speed control knob (see below) on the front of the pump.



Pump Display and Pump Speed Control Knob

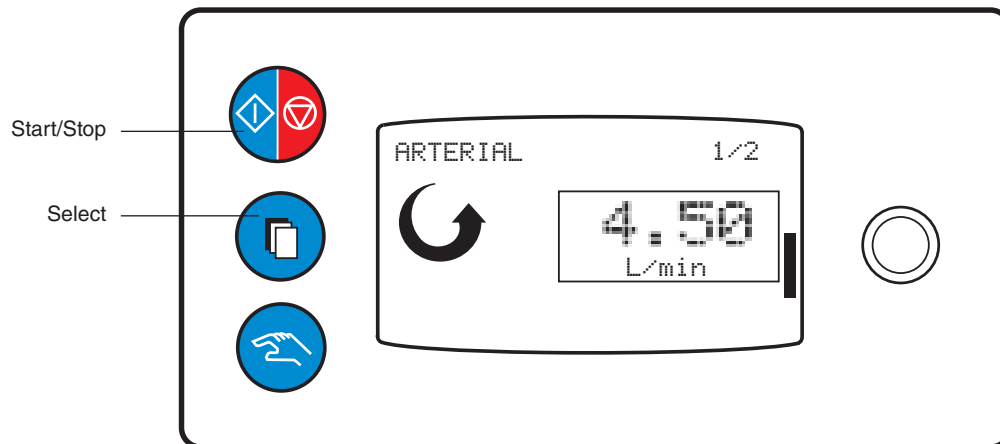
Emergency Procedures

- The electronic gas blender manual controls for output gas flow and FiO_2 are located on the front of the system base under the front tray. An external gas flow meter should always be connected to the output for confirmation of the output gas flow. Use the external flowmeter to set the desired gas flow and the tic marks on the FiO_2 knob to set the desired FiO_2 output.



Manual Controls for Gas Blender

- For established safety connections, alarm messages will be displayed on the pump display. Upon hearing an alarm the user should check the pump display message area (see below) for the alarm type.
- To reset an active Air Bubble Detection alarm, press the Select button (see below) on the pump stopped by the alarm. To restart a stopped pump, press the Start/Stop button (see below).



Pump Display Buttons and Message Area

- For a low reservoir level or over pressure alarm conditions that result in a pump stop, the operator should respond by correcting the low reservoir level or over pressure condition. Then restart the pump using the Start/Stop button.

Emergency Procedures

- If an occluder was in use, the occluder latch can be opened at any time to release the tubing. Utilize tubing clamps to occlude the line for the remainder of the case.
 - **Note:** Occluder safety connection configurations active prior to loss of the CCM will still be active, but the occluder will not be controllable through the CCM.
- Safety connections for backflow and over pressure will continue to function as configured, but specific pressure readings will not be available. Temperature alarms will continue to function as configured, but specific temperature readings will not be available. A flow meter configured with a centrifugal pump will have the flow rate displayed on the local pump control.
 - Use backup devices for pressure and/or temperature monitoring.
 - Use backup devices for all patient physiological monitoring.
- If a dual-tone alarm is sounding and no related message is displayed on the pump, the alarm can be identified by looking at the attached modules for a flashing LED. Identify the module with a flashing red LED to determine what type of alarm has occurred (for example, an over pressure alarm condition will cause the pressure module to have a flashing red LED).
- If a single-tone alert is sounding and no related message is displayed on the pump, the alert can be identified by looking at the attached modules for a flashing yellow LED. Identify the module with a flashing yellow LED to determine what type of alert has occurred (for example, an over pressure alert condition will cause the pressure module to have a flashing yellow LED).
- For information on power, refer to the LED located on the front panel of the base. If the system is on AC (Mains) power, this will be indicated through a steady LED.
 - Steady green indicates one hour or more battery capacity with a fully loaded system.
 - Steady red indicates less than one hour battery capacity with a fully loaded system.
- If the system switches to the backup battery system, a unique alarm tone will sound every three minutes and the LED on the front panel will flash with the following indications:
 - Flashing green indicates 30 minutes or more battery life at present discharge rate.
 - Flashing yellow indicates 15 minutes or more, but less than 30 minutes battery life at present discharge rate.
 - Flashing red indicates less than 15 minutes battery life at present discharge rate.
- All servo control setpoints including Pulse mode that were set prior to the CCM failure will remain active and be displayed on the local pump display. The Servo setpoints can be adjusted with the pump speed control knob. These can be disabled using the manual button on the pump control panel.

CAUTION: If these setpoints are disabled during a CCM failure, they cannot be re-enabled.

- If a Master/Follower setup was in use, the local master speed control can be used to adjust the speed of both pumps while the follower pump speed control knob can be used to adjust the master/follower ratio or percentage.

CAUTION: If the Master/Follower pumps lose their connection with each other during a CCM failure, they cannot be re-connected.

Emergency Procedures

If the Central Control Monitor Fails During Prime or Setup

- Based on patient risks, switch to backup equipment if possible.
- If backup equipment is not available, try to reset the CCM by turning the system off and then back on.

CAUTION: Prior to using a CCM that has recovered from a failure, review the “**If the Central Control Monitor Fails During Bypass**” section.

- If the CCM resets properly, proceed with caution. Although unlikely, the malfunction may recur during use.

For details on how to manage each component during a CCM failure during bypass, refer to the appropriate section of the **Emergency Procedures** chapter.

Network Malfunction

In the event of a system network failure, the Central Control Monitor, roller pumps, centrifugal control units, and modules may lose communication capability with each other, and, therefore, original safety connections may not be active although the system will still have AC (Mains) and backup power. Multiple question marks (?) may appear on the Central Control Monitor. The messages “Check Sensor” or “Check Linked Pump” may appear on the control panels of roller pumps and centrifugal control units linked to those sensors or pumps. The message “No Communication” may appear on the control panels of roller pumps and centrifugal control units. The message “System Computer Needs Service” may appear on the Central Control Monitor.

If not on bypass, cycle power to reset the system. If on bypass, do not reset the system since all settings, safety devices, and safety connections will be lost. Finish the case with local controls on the roller pumps, centrifugal control units, and electronic gas blender. Be aware that pumps may not communicate with or respond to events from connected devices. There may be no alarm or alert audible tones or messages. No data transfer will occur if CCM is unavailable. Contact Terumo Cardiovascular Systems for service.

Each module and pump for Advanced Perfusion System 1 has self-monitoring capabilities. If a single pump or module detects an internal error on a single base receptacle, it will display the Broken Module icon.

If a single Pump or Module icon has a superimposed red X during Bypass

- Only that pump or module is affected.
- If necessary, reassign a backup pump or module plugged into a different receptacle.
- If necessary, use backup equipment to complete the case.
- Contact Terumo Customer Service.

If multiple Pump or Module icons have a superimposed red X and/or “?” during Bypass

- If multiple pumps or modules display the broken module icon simultaneously or sequentially within a short period of time, a System Base component failure may have occurred. It is possible that all pumps or modules may be affected.
- Use a backup heart-lung machine, if needed, to complete the case.
- Contact Terumo Customer Service.

In the event of a CCM failure, consult the following chart for more detailed information regarding display and control of the devices. This chart does not apply to a network failure.

Emergency Procedures

Roller Pump

Mode	Status	Display	Control
Start Stop Pause Continuous	Remains as set	Flow rate or speed on pump display	Complete control from knobs and buttons on pump control panel.
Servo Control	Remains as set	Setpoints and status displayed on pump display	Control from pump speed control knob. Pump speed control knob can be used to adjust setpoint. Disable servo control using manual button on pump control panel. Cannot enable if disabled.
Pulse Mode	Remains as set	Pulse mode status displayed on pump display	Disable Pulse mode control using the manual button on pump control panel. Cannot enable if disabled.
Master/Follower	Remains as set	Master/Follower status, ratio, and total flow displayed on pump	Control from pump speed control knob on pump control panel. Master pump speed control knob can be used to change total flow rate. Follower pump speed control knob can be used to change the ratio or percentage.

Centrifugal Control Unit

Mode/Alarm	Status	Display	Control
Start Stop Coast Continuous	Remains as set	Flow rate or speed on pump display	Complete control from knobs and buttons on centrifugal control unit.
Servo Control	Remains as set	Setpoints and status displayed	Control from pump speed control knob on centrifugal pump display control unit. Pump speed control knob can be used to adjust setpoint. Disable servo control using manual button on centrifugal control unit. Cannot enable if disabled.
Pulse Mode	Remains as set	Pulse mode status displayed on control unit display	Disable Pulse mode control using manual button on centrifugal control unit. Cannot enable if disabled.
Min Flow Alarm	Remains as set	Message on pump display of centrifugal control unit and connected pump(s)	No control, message clears when condition clears.

Emergency Procedures

Air Bubble Detect Module

Condition	Status	Display	Control
On/Off	Remains as set	LED on module displays status	Cannot enable if disabled.
Air Detect Alarm	Functional	LED flashes red Dual tone alarm sounds if connected to a pump. Message on pump display of connected pump(s)	Reset Air Bubble Detect module via Select button on pump control panel of connected pump when condition is cleared.

Level Detect Module

Condition	Status	Display	Control
On/Off	Remains as set	LED on module displays status	Cannot enable/disable.
Low Level Alarm	Functional	LED flashes red Dual tone alarm sounds if connected to a pump. Message on pump display of connected pump(s)	No control, alarm clears when condition clears.
Low Level Alert	Functional	LED flashes yellow Single tone alarm sounds if connected to a pump. Message on pump display of connected pump(s)	No control, alert clears when condition clears.

Pressure Monitoring

Condition	Status	Display	Control
Monitoring	Monitoring capability is lost	LED on module displays status. Setpoint displayed on pump display if in Servo mode.	Unable to calibrate.
High Pressure Alarm	Functional	LED flashes red Dual tone alarm sounds if connected to a pump. Message on pump display of connected pump(s)	No control, alarm clears when condition clears. Cannot change limits.
High Pressure Alert	Functional	LED flashes yellow Single tone alarm sounds if connected to a pump. Message on pump display of connected pump(s)	No control, alert clears when condition clears. Cannot change limits.

Temperature Monitoring

Condition	Status	Display	Control
Monitoring	Monitoring capability is lost	LED on module displays status Connect sensors to portable monitor to display temperatures.	None
Over Temp. Alarm	Functional	LED flashes red	No control, alarm clears when condition clears. Cannot change limits.

Emergency Procedures

Flowmeter Module

Condition	Status	Display	Control
Monitoring	Monitoring capability is lost unless flow was placed on Centrifugal Pump icon	LED on module displays status. Flow displayed on the centrifugal pump display if flowmeter was placed on the Centrifugal Pump icon. Setpoint displayed on pump display if in Servo mode	None.
Backflow Alarm	Functional	LED flashes red Dual tone alarm sounds if connected to a pump. Message on pump display of connected pump(s).	No control, alarm clears when condition clears.

Occluder Module

Condition	Status	Display	Control
Any	Remains as set, will still respond to primary pump safety connections.	LED on module displays status; % of max flow display lost.	No control; Remove tubing from occluder head and control flow manually with a tubing clamp.

Interface Module for CDI 100/101 or CDI 500/550

Condition	Status	Display	Control
Monitoring	Monitoring capability is lost	LED on module displays status	Monitor data from the CDI 100/101 or CDI 500/550 monitor.

Interface Module RS-232

Condition	Status	Display	Control
Data Transfer	Data Transfer capability is lost	N/A	N/A

Timers

Condition	Status	Display	Control
Monitoring	Monitoring capability is lost	No display	Use clocks in room or backup stopwatch to monitor times.

Electronic Gas Blender

Condition	Status	Display	Control
Any	Remains as set	LED on module displays status. Use tic marks on FiO_2 control knob for approximate FiO_2 . Use external flowmeter to monitor gas flow rate.	Control from knobs on front of the system base.
FiO_2 Alarm	Functional	LED flashes red	No control, alarm clears when condition clears.

This page intentionally left blank.

Technical Support

Using this Section

This section includes technical information about the Terumo® Advanced Perfusion System 1.

Only Terumo Cardiovascular Systems Corporation certified service technicians are authorized to service or repair this device. Only Terumo Cardiovascular Systems Corporation approved replacement parts may be used in this device. Terumo Cardiovascular Systems Corporation approved parts are only available through Terumo Cardiovascular Systems Corporation certified service technicians. Any service or repair by an unauthorized service technician or use of unapproved parts will void your Terumo Cardiovascular Systems Product Warranty and may increase the risk of a product failure.

Technical Support

Communication Protocol

Functional Description

The data transfer module of the System 1 collects and sends formatted ASCII information through an RS-232 port.

Two types of case information are output from the data transfer module: periodic and event data. Periodic data is sent every 30 seconds. Event data is sent when the event occurs.

There are 2 types of event data – Safety events and Cardioplegia events. When an event occurs, a snapshot of the relevant periodic data is taken and is output at the same time the event is output. In effect, periodic data is sent at least once every 30 seconds and some periodic data is also output with specific events.

The case information is transferred in data records. The data record content is determined by the configuration of System 1 and is described in detail in the **Data Record Description** section.

Interface Description

Communication Hardware

The data transfer module provides one-way communication from the System 1 to an external data collection system. The interface on the module is a DTE female DB-9 connector. Connect to an external data collection system using a shielded, null modem cable with 9-pin D-type male to female connectors (DB-9). The connection between these systems should be made before turning on either device.

Any connected device must be battery operated or on its own isolation transformer to avoid compromising the leakage current of the data transfer module.

Characters are sent at 38,400 baud using 8 data bits, no parity, and 1 stop bit.

Data Record Description

Data Record Framing

Data records are framed, or packaged, and then transferred from the data transfer module. The primary function of this communication layer is to detect data corruption between the data transfer module and the receiving system.

There is no provision for requesting a retransmission if a failure is detected. The receiving system must ignore the transmission in this case. Only one data record is transmitted in a frame. The frame has the following format:

STX	FN	RECORD CONTENT	ETX	C1	C2	CR	LF
-----	----	----------------	-----	----	----	----	----

Technical Support

Frame Definitions

STX	ASCII Start of text transmission control character, decimal value 2.
FN	Single ASCII numeric character 0 through 7, decimal values 48 through 55, representing the frame number, modulo 8. In this application, FN is always 0.
RECORD CONTENT	Variable length record content. This field contains the specific periodic or event data information.
ETX	ASCII end of text transmission control character, decimal value 3.
C1 C2	Most and least significant hex characters of the message checksum, ASCII characters, 0 – 9 and A – F, decimal value of 48 – 57 and 65 – 70. Adding the binary values of the FN, DATA, and ETB or ETX and keeping the least significant 16 bits of the result, compute the checksum.
CR	ASCII carriage return character, decimal value 13.
LF	ASCII line feed character, decimal value 10.

Data Record Content

The content for each periodic data variable and event is sent in the RECORD CONTENT field of the data record. The format of a RECORD CONTENT field is represented below:

DATE/TIME	DATA LABEL	VALUE	UNITS
-----------	------------	-------	-------

The caret (^) is used to delimit the fields in the RECORD CONTENT field. The caret must be escaped if used in any device type, data label, or data value in the data stream. The escape delimiter is the backslash (\) character. To include the escape delimiter, it must be escaped (i.e., \). The components of the RECORD CONTENT field are described below.

Date/Time Field (14 bytes)

The date/time field is an ASCII string of the form: YYYYMMDDHHMMSS where YYYY is the year, MM is the month (01 – 12), DD is the day of the month, HH is hours (00 – 23), MM is minutes, and SS is seconds. The date/time uses the date and time set in the System 1 Central Control Monitor (CCM).

Data Label Field (37 bytes maximum)

The data label field is a UTF-8 encoded string that represents the data label. Data labels are formatted as follows:

<Device Name>:<Variable Mnemonic>

where <Device Name> and <Variable Mnemonic> are listed in the **Device Names and Variable Names** sections, to follow. Device names are limited to 32 bytes and variable mnemonics are limited to five bytes.

Value Field (15 bytes maximum – not enforced)

The value field is an ASCII string that represents the value of the data. If data is invalid, it is output with a dash ('-') in the value field. Note that some devices, the CDI 500/550 in particular, transmit values with dashes when the data is unavailable.

Technical Support

Units Field (9 bytes maximum)

The units field is an ASCII string that represents the units of the data value.

Device Names

Device names are defined in the CCM Configuration area. The following tables show the standard, provided device names. Custom names are allowed but not recommended. Variables that are not associated with a device (e.g., Patient Information) have “-” as the device name. The following device names are fixed.

Device	Device Name
Gas Mixer	GASMIXER
CDI 100	CDI 100
CDI 500/550	CDI 500

English

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	ART Air	Level	Pump	Occluder	ART Pres	ART Flow	ART Temp
Arterial	VEN Air	VENLevel	Clamp	VEN Occl	VEN Pres	VEN Flow	VEN Temp
CPG	CPG Air	CPGLevel	CPG Tmr	ART Occl	CPG Pres	CPG Flow	CPG1Temp
CPG1	CPG1 Air	LEVEL1	CPG1Tmr	CPG Occl	CPG1Pres	FLOW1	CPG2Temp
CPG2	CPG2 Air	LEVEL2	CPG2Tmr	OCCL1	CPG2Pres	FLOW2	Main H2O
Vent	AIR1		TMR1	OCCL2	CS Pres	FLOW3	TEMP1
Vent1	AIR2		TMR2		BALLPres	FLOW4	TEMP2
Vent2	AIR3		TMR3		PRES1		TEMP3
Sucker1	AIR4		TMR4		PRES2		TEMP4
Sucker2			ARR Tmr		PRES3		
Venous			ISC Tmr		PRES4		
VEN							

Technical Support

Danish

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	ART luft	Niveau	Pumpe	Klemme	ART tryk	ART flow	ART temp
Arteriel	VEN luft	VEN niv	Klem tim	VENklemm	VEN tryk	VEN flow	VEN temp
CPG	CPG luft	CPG niv	CPG tim	ARTklemm	CPG tryk	CPG flow	CPG1temp
CPG1	CPG1luft	NIVEAU1	CPG1 tim	CPGklemm	CPG1tryk	FLOW1	CPG2temp
CPG2	CPG2luft	NIVEAU2	CPG2 tim	KLEMME1	CPG2tryk	FLOW2	HovedH2O
Vent	LUFT1		TIM1	KLEMME2	SC tryk	FLOW3	TEMP1
Vent1	LUFT2		TIM2		BAL tryk	FLOW4	TEMP2
Vent2	LUFT3		TIM3		TRYK1		TEMP3
Suger1	LUFT4		TIM4		TRYK2		TEMP4
Suger2			STANDtim		TRYK3		
Venøs			ISK tim		TRYK4		
VEN							

Dutch

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	ARTlucht	Niveau	Pomp	Klem	ARTdruk	ARTflow	ARTtemp
Art	VENlucht	VENniv	KLEMr	VENklem	VENdruk	VENflow	VENTemp
CPG	CPGlucht	CPGniv	CPGtimer	ARTklem	CPGdruk	CPGflow	CPG1temp
CPG1	CPG1luch	NIVEAU1	CPG1timr	CPGklem	CPG1druk	FLOW1	CPG2temp
CPG2	CPG2luch	NIVEAU2	CPG2timr	KLEM1	CPG2druk	FLOW2	HoofdH2O
Ventila	LUCHT1		TMR1	KLEM2	CorSiDrk	FLOW3	TEMP1
Ventila1	LUCHT2		TMR2		Bal druk	FLOW4	TEMP2
Ventila2	LUCHT3		TMR3		DRUK1		TEMP3
Zuiger1	LUCHT4		TMR4		DRUK2		TEMP4
Zuiger2			STOPtimr		DRUK3		
Veneus			ISCr		DRUK4		
VENEUS							

Technical Support

French

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	AirART	Niveau	Pompe	Clamp	PressART	DébitART	TempART
Art	AirVEIN	NivVEIN	Clampage	ClmpVEIN	PresVEIN	DébVEIN	TempVEIN
CPG	AirCPG	NivCPG	ChronCPG	ClampART	PressCPG	DébitCPG	TempCPG1
CPG1	AirCPG1	Niveau1	ChroCPG1	ClampCPG	PresCPG1	DÉBIT1	TempCPG2
CPG2	AirCPG2	Niveau2	ChroCPG2	CLAMP1	PresCPG2	DÉBIT2	H2O Oxy
Ventil	AIR1		Chrono1	CLAMP2	PressSC	DÉBIT3	TEMP1
Ventil1	AIR2		Chrono2		BALLPres	DÉBIT4	TEMP2
Ventil2	AIR3		Chrono3		PRESS1		TEMP3
Aspir1	AIR4		Chrono4		PRESS2		TEMP4
Aspir2			Chr CEC		PRESS3		
Veineuse			ChroISCH		PRESS4		
VEIN							

German

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	ART Luft	Niveau	PerfZeit	Klemme	ARTDruck	ARTFluß	ART Temp
Art	VEN Luft	VENNiv	Aorta zu	VENKlemm	VENDruck	VENFluß	VEN Temp
KPG	KPG Luft	KPGNiv	KPGZtg	ARTKlemm	KPGDruck	KPGFluß	KPG1Temp
KPG1	KPG1Luft	Niveau1	KPG1Ztg	KPGKlemm	KPG1Druc	FLUß1	KPG2Temp
KPG2	KPG2Luft	Niveau2	KPG2Ztg	KLEMME1	KPG2Druc	FLUß2	HauptH2O
Ventil	LUFT1		ZTG1	KLEMME2	KS Druck	FLUß3	TEMP1
Ventil1	LUFT2		ZTG2		BALLDruc	FLUß4	TEMP2
Ventil2	LUFT3		ZTG3		DRUCK1		TEMP3
Sauger1	LUFT4		ZTG4		DRUCK2		TEMP4
Sauger2			EKZ Ztg		DRUCK3		
Venös			ISCH Ztg		DRUCK4		
VEN							

Technical Support

Italian

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	BolleART	Livello	Pompa	Occl	PressART	FlussART	TempART
Art	BolleVEN	LivVEN	Clamp	OcclVEN	PressVEN	FlussVEN	TempVEN
CPG	BolleCPG	LivCPG	CronoCPG	OcclART	PressCPG	FlussCPG	TempCPG1
CPG1	BolIcPG1	LIVELLO1	CronCPG1	OcclCPG	PresCPG1	FLUSS01	TempCPG2
CPG2	BolIcPG2	LIVELLO2	CronCPG2	OCCL1	PresCPG2	FLUSS02	H2O prin
Vent	BOLLE 1		Cronom1	OCCL2	PresSENO	FLUSS03	TEMP1
Vent1	BOLLE 2		Cronom2		BALLPres	FLUSS04	TEMP2
Vent2	BOLLE 3		Cronom3		PRESS1		TEMP3
Aspirat1	BOLLE 4		Cronom4		PRESS2		TEMP4
Aspirat2			Cron ARR		PRESS3		
Ven			Cron Isc		PRESS4		
VEN							

Spanish

Pumps	ABD	Level	Timer	Occluder	Pressure	Flow	Temperature
ART	Burb ART	Nivel	Bomba	Oclusor	Pres ART	FlujoART	Temp ART
Arterial	Burb VEN	Niv VEN	Pinza	Ocl VEN	Pres VEN	FlujoVEN	Temp VEN
CPG	Burb CPG	Niv CPG	CronCPG	Ocl ART	Pres CPG	FlujoCPG	TempCPG1
CPG1	BurbCPG1	NIVEL1	CronCPG1	Ocl CPG	PresCPG1	Flujo 1	TempCPG2
CPG2	BurbCPG2	NIVEL2	CronCPG2	OCL 1	PresCPG2	Flujo 2	H2O Prin
Vent	BURB1		Cronóm1	OCL 2	PresSnCr	Flujo 3	TEMP1
Vent1	BURB2		Cronóm2		PresBaln	Flujo 4	TEMP2
Vent2	BURB3		Cronóm3		PRES 1		TEMP3
Aspir1	BURB4		Cronóm4		PRES 2		TEMP4
Aspir2			CronPARO		PRES 3		
Ven			CronISQM		PRES 4		
VEN							

Technical Support

Variable Names

Each configured device in System 1 has a set of periodic data or events that it provides to the data transfer module. Each of the System 1 devices is listed in the following sections with the specific periodic data and event information that is transmitted from the data transfer module.

ABD

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
ABAM	Air bubble detected alarm			Safety Event	
ABMC	Air bubble alarm cleared			Safety Event	

CDI 100 (device name is “CDI 100”)

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
SAT	Oxygen Saturation	0 to 100	%	Periodic	Yes
HCT	Hematocrit	0 to 100	%	Periodic	Yes
HB	Hemoglobin	0.0 to 100.0	g/dL	Periodic	Yes

CDI 500/550 (device name is “CDI 500”)

Mnemonic	Description	Value ¹	Units	Type	Part of Snapshot?
A_PH	Arterial pH	6.8 -8.0		Periodic	Yes
A_CO	Arterial PCO2	10 - 80, 1 - 11	mmHg, kPa	Periodic	Yes
A_O2	Arterial PO2	10 - 500, 1 - 67	mmHg, kPa	Periodic	Yes
A_TM	Arterial Temperature	10 - 45	C	Periodic	Yes
A_SO	Arterial Oxygen Saturation	60 - 100	%	Periodic	Yes
A_HC	Arterial Bicarbonate	0 - 50	mEq/L	Periodic	Yes
A_BE	Arterial Base Excess	-25.0 to +25.0	mEq/L	Periodic	Yes
K+	Potassium	1.0 - 8.0	mmol/L	Periodic	Yes
VO2	Oxygen Consumption	10 - 400	mL/min	Periodic	Yes
V_PH	Venous pH	6.8 - 8.0		Periodic	Yes
V_CO	Venous PCO2	10 - 80, 1 - 11	mmHg, kPa	Periodic	Yes
V_O2	Venous PO2	10 - 500, 1 - 67	mmHg, kPa	Periodic	Yes
V_TM	Venous Temperature	10 - 45	C	Periodic	Yes
V_SO	Venous Oxygen Saturation	60 - 100	%	Periodic	Yes
HCT	Hematocrit	15 - 45	%	Periodic	Yes
HGB	Hemoglobin	5-15	g/dL	Periodic	Yes
V_HC	Venous Bicarbonate	0-50	mEq/L	Periodic	Yes
V_BE	Venous Base Excess	-25.0 to +25.0	mEq/L	Periodic	Yes

¹ These values are all left justified within a 4-character field. The fifth character of the value has a space, “L”, “H”, or “A” character. The space indicates normal analyte status; the “L” indicates a Low alarm status; and the “H” indicates a High alarm status. The “A” indicates actual value.

Technical Support

Flow

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
BFAM	Back flow alarm			Safety Event	
BFMC	Back flow alarm cleared			Safety Event	
FLOW	Flow	-10000 to 10000	mL/min	Periodic	Yes

Gas (device name is "GASMIXER")

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
BGPO	Blending gas pressure over range			Safety Event	
BGPU	Blending gas pressure under range			Safety Event	
BGPI	Blending gas pressure in range			Safety Event	
CFIC	Calculated FiO2	0.000 to 0.050		Periodic	Yes
OGPO	O2 gas pressure over range			Safety Event	
OGPU	O2 gas pressure under range			Safety Event	
OGPI	O2 gas pressure in range			Safety Event	
LFAM	Low FiO2 alarm			Safety Event	
LFMC	Low FiO2 alarm cleared			Safety Event	
MFIO	Measured FiO2	0.000 to 1.000		Periodic	Yes
TGOF	Total Gas Output Flow	0 to 20000	mL/min	Periodic	Yes

Level

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
LLAL	Low level alert			Safety Event	
LLLC	Low level alert cleared			Safety Event	
LLAM	Low level alarm			Safety Event	
LLMC	Low level alarm cleared			Safety Event	

Occluder

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
OCFC	Full close			Safety Event	
OCFO	Full open			Safety Event	
OPFL	Percent flow	0 to 100	%	Periodic	Yes

Technical Support

Pressure

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
OPAL	Over pressure alert			Safety Event	
OPLC	Over pressure alert cleared			Safety Event	
OPAM	Over pressure alarm			Safety Event	
OPMC	Over pressure alarm cleared			Safety Event	
PRES	Average pressure	-250 to 900	mmHg	Periodic	Yes

Pumps

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
MLPM	Flow	-10000 to 10000	mL/min	Periodic	Yes
CIF	Cardiac index flow	0.0 to 10.0	L/min/m2	Periodic	Yes
KGF	Kilogram flow	0.0 to 10000	mL/kg/min	Periodic	Yes
PDIR	Direction	CW or CCW		Event	
POCU	Overcurrent			Safety Event	
POCC	Overcurrent cleared			Safety Event	
POSP	Overspeed			Safety Event	
POSC	Overspeed cleared			Safety Event	
PPAU	Pump paused (only for roller pumps)			Safety Event	
PRAT	Ratio (when follower)	1:1, 2:1, 4:1, 8:1, 16:1 0 to 99	M:F %	Periodic	Yes
PSTA	Pump started			Safety Event	
PSTO	Pump stopped			Safety Event	
PUSP	Underspeed			Safety Event	
PUSC	Underspeed cleared			Safety Event	
RPM	RPM	0 to 250 0 to 4000	RPM	Periodic	Yes
TMLP	Total flow	0 to 20000	mL/min	Periodic	Yes

System

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
SOFB	Off battery (on AC)			Safety Event	No
SONB	On battery			Safety Event	No
TROB	Time remaining on battery	0 to 1440	Min	Periodic	Yes

Technical Support

Temperature

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
OTAM	Over temperature alarm			Safety Event	
OTMC	Over temperature alarm cleared			Safety Event	
TEMP	Temperature	0.0 to 50.0	C	Periodic	Yes

Timer

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
TRST	Timer Reset			Event	
TSTA	Timer Started			Event	
TSTO	Timer Stopped			Event	

Patient Information (device name is "-")

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
PBSA	Patient body surface area	0.0 to 4.7	Dubois, Boyd, Pediatric	Periodic	No
PBV	Patient blood volume	0 to 21000	mL	Periodic	No
PHGT	Patient height	30 to 250	cm	Periodic	No
PWGT	Patient weight	1.0 to 300.0	kg	Periodic	No

Cardioplegia (device name is "-")

Mnemonic	Description	Value	Units	Type	Part of Snapshot?
CPGD	Cardioplegia delivery state	Deliver or Recirculate		CPG Event	
CURD	Cardioplegia current delivery	0 to 9990	mL	CPG Periodic	CPG Yes
DSTA	Dose Started			CPG Event	
DSTO	Dose Completed			CPG Event	
TOTD	Cardioplegia total delivery	0 to 9990	mL	CPG Periodic	CPG Yes
PSTA	Cardioplegia pump started			Safety Event CPG Event	
PSTO	Cardioplegia pump stopped			Safety Event	
ADR	Cardioplegia auto dose remaining	0 to 9990 or 00:00 to 59:59	mL MM:SS	CPG Periodic	
TBD	Cardioplegia time between last delivery	0 to 59400	seconds	CPG Periodic	

Technical Support

EMC Tables

Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3))


Guidance and manufacturer's declaration – electromagnetic emissions		
The Terumo® Advanced Perfusion System 1 is intended for use in the electromagnetic environment specified below. The user of the Terumo® Advanced Perfusion System 1 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Terumo® Advanced Perfusion System 1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [A]	NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class [A]	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6))

Guidance and manufacturer's declaration – electromagnetic immunity			
The Terumo® Advanced Perfusion System 1 is intended for use in the electromagnetic environment specified below. The user of the Terumo® Advanced Perfusion System 1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2,4,6,8 kV contact ±2,4,8,15 kV air	±2,4,6,8 kV contact ±2,4,8,15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on mains power supply lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5,1 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	0 % U_T (100 % dip in U_T) for 0.5,1 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Terumo® Advanced Perfusion System 1 requires continued operation during power mains interruptions, it is recommended that the Terumo® Advanced Perfusion System 1 be powered from an uninterruptible power supply or a battery.
Mains power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Technical Support

Table 203 – Guidance and manufacturer's declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS (see 6.8.3.201 b))

Guidance and manufacturer's declaration – electromagnetic immunity			
The Terumo® Advanced Perfusion System 1 is intended for use in the electromagnetic environment specified below. The user of the Terumo® Advanced Perfusion System 1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80 MHz outside ISM bands ^a	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Terumo® Advanced Perfusion System1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 Vrms 150 kHz to 80 MHz in ISM bands ^a 10 V/m 80 MHz to 2.5 GHz 80% AM Modulation at 2 Hz 3 V/m 80 MHz to 2.7 GHz 80% AM Modulation at 1 kHz	10 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 29,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. ^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. ^c 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 Terumo® Advanced Perfusion System 1 is used exceeds the applicable RF compliance level above, the Terumo® Advanced Perfusion System 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Terumo® Advanced Perfusion System 1. ^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Technical Support

Table 205 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS (see 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the Terumo® Advanced Perfusion System 1				
The Terumo® Advanced Perfusion System 1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Terumo® Advanced Perfusion System 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Terumo® Advanced Perfusion System 1 as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1,2 \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,12	0,23
0,1	0,38	0,38	0,38	0,73
1	1,2	1,2	1,2	2,3
10	3,8	3,8	3,8	7,3
100	12	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.				
NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 29,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.				
NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.				
NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Additional RF Proximity Test Data:

Frequency (MHz)	Modulation	Field Level (V/m)
385	PM 18Hz	27
450	PM 18Hz	28
710	PM 217Hz	9
745	PM 217Hz	9
780	PM 217Hz	9
810	PM 18Hz	28
870	PM 18Hz	28
930	PM 18Hz	28
1720	PM 217Hz	28
1845	PM 217Hz	28
1970	PM 217Hz	28
2450	PM 217Hz	28
5240	PM 217Hz	9
5500	PM 217Hz	9
5785	PM 217Hz	9

Technical Support

This device is suitable for use in hospitals and is compatible with high frequency surgical equipment.

This device's essential performance is 1) to circulate blood and deliver cardioplegia solution, 2) to monitor line pressure, 3) to deliver gas. To carry this out, 1) the pumps circulating blood and delivering cardioplegia solution must maintain user speed settings, with allowance for a momentary reduction in pump flow rate as low as 0 LPM with recovery to normal operation within four seconds, 2) the line pressure in the extracorporeal circuit must be monitored, with allowance of a blank display, display of a non-number, or a value above the stated accuracy, with recovery to normal operation within four seconds, 3) the gas system must deliver gas at the user specified flow rate. If this essential performance is lost or degraded due to electromagnetic disturbances the circulation of blood, delivery of cardioplegia solution, reporting of pressure, and/or delivery of gas may become erratic or stopped.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Advanced Perfusion System 1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Nominal AC (Mains) Power Consumption

System Configuration*	100 VAC	115 VAC	120 VAC	220 VAC	240 VAC
4-Pump System	9.5A – 11.5A	8.5A – 10A	8A – 10A	4.5A – 5A	4A – 5A
5-Pump System	10.5A – 13A	9.5A – 11.5A	9A – 11A	5A – 6A	4.5A – 5.5A
6-Pump System	11.5A – 14A	10.5A – 12.5A	10A – 12A	5.5A – 6.5A	5A – 6A
7-Pump System	13A – 15.5A	11.5A – 14A	11A – 13.5A	6A – 7A	5.5A – 6.5A
8-Pump System	14A – 17A	12A – 15A	12A – 15A	6.5A – 8A	6A – 7A

*Each System Configuration is defined as:

All large roller pumps, speed set to 250 RPM while using 1/2 inch (12.7mm) I.D. x 3/32 inch (2.4mm) wall tubing, properly occluded and fluid temperature of 25°C;

All available module connections used with any combination of Flow, Temperature, Pressure, Level, Occluder, Air Bubble Detector, and Serial Interface Modules with all assigned and activated;

1 Electronic Gas Blender Module, connected and activated;

1 Lamp connected and powered "ON";

1 Central Control Monitor, connected and activated;

Peripheral equipment connected to the auxiliary outlet and activated.

This device requires a dedicated 15 or 20 Amp mains power source for the 100V - 120V model or a dedicated 10 Amp mains power source for the 220V - 240V model.

This page intentionally left blank.

Additional Information

Summary of Warnings and Precautions

System Warnings

Use the system and any attached equipment according to the manufacturer's instructions and good medical practice.

The Terumo Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

Do not use an apparently malfunctioning device in an operation.

This device must not be allowed to run unattended. Patient safety requires that operation be properly and continuously monitored by a qualified medical professional.

System 1 is a configurable system allowing users to create Perfusion Screens utilizing different combinations of equipment with different responses to events. Because of this high degree of configurability, it is important that user institutions establish appropriate controls to assure that users are properly trained and qualified to run Perfusion Screens. **Failure to establish such controls may result in operator error that could result in patient injury or death.**

System Equipment Precautions

Grounding reliability can only be achieved when this equipment is connected to an appropriate receptacle which has been inspected for proper grounding.

This device requires a dedicated 15 or 20 Amp AC (Mains) power source for the 100V – 120V model or a dedicated 10 Amp mains power source for the 220V - 240V model.

Complete any external equipment connections before turning the system on as connecting equipment during use may cause system malfunction.

Do not use this device in the presence of explosive or flammable gases.

To avoid electrical shock hazard, do not remove panels. Refer servicing to qualified service personnel.

Do not operate the system without the module covers secured in place as spilled liquids may damage the connections.

Connect only hospital equipment of appropriate voltage and current rating to the auxiliary outlet.

The auxiliary outlet is not backed up by battery power. During loss of AC (Mains) power, any equipment connected to the auxiliary outlet will lose power and remain unpowered until AC (Mains) power is restored.

Do not use extension cords to connect the system to AC (Mains) power nor to connect modules or accessories to the system. Use of extension cords may compromise performance.

Additional Information

In the event that the circuit breaker trips immediately after a reset **DO NOT attempt to reset again**. The system will only operate from battery power until it has been repaired. Call for service.

Use only the cables provided to connect pumps and flowmeter modules to the system.

The use of accessory equipment not complying with the equivalent safety requirements of this system may lead to a reduced level of safety of the resulting system. Consideration relating to the choice of auxiliary equipment shall include:

- use of the accessory in the patient vicinity;
- evidence that safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

Equipment used to heat and cool the water used to regulate the temperature of the blood supplied to an heat exchanger should be rated Type CF. If the equipment is not Type CF and a malfunction occurs, the possibility exists that electrical current may pass through the heat exchanger and into the patient perfusion circuit.

Do not use chemical solvents such as ether, acetone, etc., in or on any part of the system as such solvents may be destructive to the device. Do not disinfect with Virex® Tb*. Do not spill anesthetics on the system or components as chemicals such as Forane (isofluorane) may be destructive. Follow the cleaning procedure in the **Equipment Care** section using only recommended cleaning agents.

This device's essential performance is 1) to circulate blood and deliver cardioplegia solution, 2) to monitor line pressure, 3) to deliver gas. To carry this out, 1) the pumps circulating blood and delivering cardioplegia solution must maintain user speed settings, with allowance for a momentary reduction in pump flow rate as low as 0 LPM with recovery to normal operation within four seconds, 2) the line pressure in the extracorporeal circuit must be monitored, with allowance of a blank display, display of a non-number, or a value above the stated accuracy, with recovery to normal operation within four seconds, 3) the gas system must deliver gas at the user specified flow rate. If this essential performance is lost or degraded due to electromagnetic disturbances the circulation of blood, delivery of cardioplegia solution, reporting of pressure, and/or delivery of gas may become erratic or stopped.

This device is suitable for use in hospitals and is compatible with high frequency surgical equipment.

Following standard practices for electronic devices, monitor this equipment closely when it is exposed to intense electrical noise or fluctuating line voltage. Strong electromagnetic fields radiated from equipment elsewhere in the operating room (particularly defibrillators and electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.

This device needs special precautions regarding electro-magnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the **Technical Support** section

Warnings

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Advanced Perfusion System 1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

* Virex® Tb is a registered trademark of JohnsonDiversity™

Additional Information

Warnings

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The Data Interface Transfer Module DB9 connector may only be connected to IEC60950-1 or IEC 60601-1 compliant devices.

Central Control Monitor

- If the Central Control Monitor fails, the system can be controlled through the local controls on the roller pumps, centrifugal control unit, and electronic gas blender, if installed.
- In the event the Central Control Monitor fails, only those sensors that have a safety connection to at least 1 roller pump or centrifugal control unit will be able to display messages on a local control panel. If no safety connection was established, no audible tone will sound and no messages will display on any local control panel. The only indication that an event has occurred will be the flashing LED on the affected module.
- Do not turn system power off in the event of a Central Control Monitor failure during use, as this will cause all settings and device assignments to be lost.

Level and Air Detection

- The level detection and air bubble detection systems must be properly set up and turned ON as UNDETECTED AIR in the line may cause gaseous emboli to be pumped into the patient, with attendant risk of DEATH OR SEVERE INJURY. The performance of the level and air detection systems must be verified before each use.
- If an air or level detection system is turned OFF or is configured not to stop a pump, then constant monitoring is required to reduce the risk of air in the line.
- The air sensor must be positioned a minimum of 4 ft (1,2 m) from the patient to allow the user and the air detection system sufficient time to respond before air can reach the patient.
- The air sensor may not detect air bubbles smaller than the minimum size specified for the air sensor used. The air sensor must be used with the appropriate tubing size and within the flow rate limitations specified for the air sensor or the air sensor may not detect air bubbles.
- The air sensor latch must be completely closed to secure the sensor to the tubing.
- The air sensor may falsely alarm with intense electrical noise.
- If the cardioplegia pump is drawing blood from the arterial line, stop the cardioplegia pump whenever the arterial pump is stopped to avoid infusion of air.
- Conduct a wet run and test that the level detection system will function properly with the particular reservoir to be used.
- To prevent the level sensor from detaching and causing a false alarm, do not place the level sensor over labels, decals, or painted markings.

Additional Information

Roller Pumping

- Use caution when roller pumping in the opposite direction of forward flow as air may be drawn into the blood line.

WARNING: Always check the pump for proper operational mode after a Pause or Reduce Speed response has been executed. A pump may go to Stop mode and need to be started manually if the pump has received more than one high priority safety messages such as low level alarm and air alarm.

- Tubing must not be reversed in the pump head as air embolism may occur.
- When turning the roller assembly by hand, always turn the roller assembly in the direction of forward flow. Reverse cranking could draw air into the blood line which might then be pumped into the patient with attendant risk of death or severe bodily injury.
- All roller pumps used in a hospital must be set to run in the same default direction for forward flow to prevent unintended retrograde pumping. RETROGRADE PUMPING MAY CAUSE SEVERE PATIENT INJURY OR DEATH.
- Always check the direction of rotation before starting a backup or standby roller pump to make sure that the roller pump default direction matches the system direction. Retrograde pumping MAY CAUSE SEVERE PATIENT INJURY OR DEATH by drawing air into the blood line which might then be pumped into the patient.
- Hand cranks must be properly set up to allow hand cranking in the same direction as that chosen for forward flow for the roller pumps.
- When hand cranking because of the loss of AC (Mains) and battery power, the safety systems will not operate. Monitor closely for air and reservoir level.
- Make sure tubing is properly aligned before closing tube clamp.
- Set the pump in Stop mode during tubing installation as accidental starting of the pump could injure the operator and may damage the tubing or the pump.
- Use only tubing specified for this system.
- Occlusion must be set by moving the rollers toward the pump raceway in order to take up any free play in the mechanism. Do not adjust occlusion by moving the rollers away from the raceway as under-occlusion may result.
- Avoid over-occluding the tubing as over-occlusion may result in a Pump Jam or Belt Slip condition. This is especially important when using dual tubing sets where different inside diameters and variations in wall thickness of the tubes may result in a tendency to over-occlude. Correct the Pump Jam or Belt Slip condition to clear any error or alert message and then continue setting proper occlusion.
- Do not adjust the rollers of the occlusion mechanism past the limits of its travel (which, when reached, is indicated by increased resistance on the occlusion knob) as this may over-tighten the occlusion mechanism and prevent its release. If the occlusion mechanism is over-tightened (in either direction) and cannot be released by turning the occlusion knob in the opposite direction, then use another pump and call for service.

Additional Information

Centrifugal Pumping

- With a centrifugal pump, maintain a minimum pump speed or clamp the pump outlet line and patient's venous line in order to prevent backflow and drainage of the patient's blood. Minimum pump speed is the speed which overcomes line and patient resistance.
- If a centrifugal pump stops, clamp the arterial and venous lines and check for air in the arterial line due to retrograde flow. Remove air, attain a pump speed adequate to overcome the circuit resistance, and then unclamp the lines.
- When using a centrifugal pump as the arterial pump, closely monitor the arterial line for air as a centrifugal pump will pump air. Stop infusion if air enters the pump as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury.
- Always place a flow sensor on a centrifugal pump speed flow display area to enable the minimum flow alarm and any safety connections that have been set for a minimum flow alarm.
- Avoid prolonged operation of the centrifugal pump with the outlet fully occluded to prevent warming the fluid in the pump chamber and to minimize blood trauma.
- Use of a centrifugal pump for periods longer than durations appropriate to cardiopulmonary bypass procedures may result in pump failure, reduced pumping capacity, excessive blood trauma, degradation or corrosion of blood contact materials with possibility of particles passing through the blood circuit to the patient, leaks, and increased potential for gaseous emboli.

Gas System

- When using a microporous membrane oxygenator, negative pressure pulses (which can result from abrupt decreases in arterial flow) may introduce gaseous emboli into the blood by creating blood pressures lower than the gas path pressure. Monitor arterial line pressure and adjust the pump so that pressure in the blood compartment of the oxygenator is always greater than the gas path pressure.
- Use clean, dry, medical-grade gases and keep the water trap empty as liquid water or other contaminants in the gas supplies will cause malfunction of this system.
- Always use a 0.2 micron filter on the gas outlet to prevent contaminating the extracorporeal circuit.
- Provide inlet gases at a pressure of 50 ± 20 psi, with the difference between the two being no more than 18 psi. Observe the CCM for messages indicating variations in the inlet pressure or an inadequate gas supply.

Pressure and Temperature Monitoring

- Pressure transducer cables without transducers attached must be disconnected from the system. Cables without transducers act as an antenna which may cause the pressure module to generate an alarm that then will stop a safety configured pump due to electromagnetic interference.
- Use only the specified temperature probes and pressure transducers to ensure that temperature and pressure monitoring functions properly.

Additional Information

Battery Power

- If a partially charged battery is used, there may be less than 60 minutes of battery power available for a fully loaded system.
- Turn the system power off at the AC (Mains) power switch on the system before inspection, cleaning, preparation for use, or storage in order to turn off both the battery power and the AC (Mains) power.
- The battery discharges slowly over time if the system is not plugged into the wall power supply with the AC (Mains) power switch turned ON.

Equipment Precautions

Battery Power

- Replace the batteries every two years OR whenever the batteries cannot be fully recharged within 13 hours OR whenever fully charged batteries will not power the entire system for at least 60 minutes.
- Do not store batteries in a discharged state as this will damage them.
- Do the monthly maintenance of the battery backup system. For more details on the monthly maintenance procedure see **Equipment Care** section of **Additional Information** chapter. Failure to do so may damage the batteries. This damage may cause loss of battery backup without warning.

Modules

- Do not touch the module connector pins as static electricity and moisture may damage the module circuitry and pins.
- Check the connectors for damage before use. Do not use a module if damaged or bent connector pins are found.
- Do not use extension cords to connect the modules to the system. Use of extension cords may compromise performance.
- Use only the cables provided to connect flowmeter modules to the system.

Central Control Monitor and Control Panels

- When configuring a screen with multiple safety connections, the user must consider the risks and benefits of the additional complexity introduced to the operation of the system. It is possible to configure the system to have events that trigger responses, with the response being events that trigger more responses. The system response in these situations may be confusing to the user and could lead to delays in the user response or possibly errors.
- Use care when handling the Central Control Monitor as the controls, displays, or circuitry may be damaged if the display is dropped, struck, or immersed in liquid.
- The computer touch screen is designed to be a single point control system. Use only one finger when operating the screen. Insure that there is no additional contact with the touch screen during operation as unintended input may result.
- Pump control panels and Central Control Monitor are intended for hand and gloved hand operation only. Do not use any instruments on the pump control panels or Central Control Monitor as this may damage the device.

Additional Information

Air Sensors

- Do not drop air, level, or flow sensors as shock may damage the sensor.
- Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.

Level Sensors

- Do not drop air, level, or flow sensors as shock may damage the sensor.
- Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.
- Use only Sarns™ Level Sensor II Gel. The use of any other gel, couplant, or lubricant may cause damage to the level sensor lens.

Flow Sensors

- Do not drop air, level, or flow sensors as shock may damage the sensor.
- Do not sterilize air, level, or flow sensors as sterilization may damage the sensor.

Gas System

- The oxygen and air supplies must both be connected (or disconnected) to prevent unequal pressure from damaging the gas blender.

Centrifugal Pumping

- Do not operate the centrifugal pump when unprimed as operating the pump in a “dry” state may damage the internal seal.
- Monitor the centrifugal pump and replace it if there are fluid leaks, noisy operation, or blood in the rear chamber. Blood in the rear chamber will damage the pump bearings and cause the pump to eventually fail.
- During Pulse mode pumping, because of variations in flow, the flow rate displayed is a mean value.
- When located on the inlet side of the centrifugal pump, automatic ball-type shutoff valves (used to prevent gas emboli from entering the arterial line), may seat inadvertently and stop flow.* Follow manufacturer’s instructions for placement of valves.
- Do not sterilize the centrifugal drive motor, as sterilization may damage the motor.

* See “Automatic Shutoffs on Centrifugal Heart-Lung Bypass Pumps” Technology for Perfusion, published by ECRI, September 1988, 1 (2): 6-7.

Additional Information

Equipment Care

Clean and Check the System After Each Use

WARNING: Turn the system power off before inspection, cleaning, preparation for use, or storage.

CAUTION: Do not disinfect with Virex® Tb*. Do not use chemical solvents such as ether, acetone, etc. in or on any part of the system as such solvents may be destructive to the device. Do not spill anesthetics on the system or components as chemicals such as Forane (isofluorane) may be destructive.

CAUTION: Do not immerse the hand cranks.

CAUTION: Do not use any alcohol-based or ammonia-based cleaning products to clean the Acrylic lens LED Lamp Assembly, as this may cause damage. A mild solution of soap/detergent and water can be used to safely clean the lens.

Follow your institution's infection control policies and procedures when cleaning this equipment. Contact your institution's Infection Control or Safety Coordinator if assistance is needed. Follow manufacturer's instructions for use of disinfectants and heed all manufacturer's warnings concerning their handling. Work in a well ventilated area when using disinfectants. Disinfectants should be applied after cleaning with a cloth dampened with warm, soapy water as organic materials may inactivate chemical germicides and protect microorganisms from the disinfecting process. Disinfecting solutions should be wiped dry after approximately 10 minutes of contact time.

After Each Use . . .	Clean and Check your Components
Check the water trap.	Check the water trap, located on the air or 95/5 inlet of the gas blender, and drain, if necessary.
Clean air, level, and flow sensors.	<p>Clean with mild soap and water solution. Do not use any sharp instruments or abrasive materials.</p> <p>Do not drop the sensors as shock may damage them.</p> <p>Wipe transducer of air sensor. Do not immerse air sensor. Between cases store the air sensor on the bracket.</p> <p>Do not sterilize the air, level, or flow sensors as this will damage the sensor.</p> <p>Wipe the level sensor transducer lens to remove gel.</p> <p>If a sensor is damaged, contact Terumo Customer Service.</p>
Clean the CCM.	Use a cloth dampened with glass cleaner to clean the Central Control Monitor display screen.
Clean all system surfaces, including pump heads, occlusion rollers, tube clamp assemblies, and centrifugal drive motor.	<p>Working in a well ventilated area, remove spilled liquids, blood, etc.</p> <p>Use a disinfecting solution recommended by your institution.</p> <p>Wipe all surfaces - except the air, level, and flow sensors. See sensor cleaning instructions above. Check tube clamp assembly for spills. If contaminated, follow the cleaning instruction in Removal and Cleaning of Tube Clamps in this section.</p> <p>If necessary, use appropriate cleaning pads and polish to remove residue from stainless steel and aluminum surfaces.</p>

* Virex® Tb is a registered trademark of JohnsonDiversy™

Additional Information

After Each Use. . .	Clean and Check your Components
Check roller pumps.	<p>See that in Stop mode the roller assembly does not move and the flow or speed display is blank.</p> <p>See that in Forward mode, the roller assembly turns in the direction of forward flow and the display speed increases accordingly up to approximately 250 RPM.</p> <p>See that the pump pauses when the Pump Safety Cover is opened and restarts when the cover is closed.</p> <p>Check that the tube guide rollers are free of chips, cracks, or breaks.</p> <p>See that the tube guide rollers and the occlusion rollers rotate freely.</p> <p>Check that the occlusion knob turns freely and with no significant change in resistance. If the occlusion knob does not turn freely or the resistance changes, contact your Terumo Customer Service.</p>
Check the centrifugal pump.	<p>See that in Stop mode the drive motor is stopped and the speed is at 0 RPM.</p> <p>See that in Start mode the motor starts and the speed display increases accordingly up to 3600 RPM.</p> <p>Place the protective cover over the drive motor receptacle when storing centrifugal pump components.</p>
Inspect all components.	<p>Inspect all components for worn, cracked, or frayed cables, loose connector parts, or malfunctioning parts.</p> <p>If a malfunctioning part is found, contact Terumo Customer Service and do not use a damaged or malfunctioning device.</p>
Monthly. . .	Clean Base, Check Air Filters, and Check Gas Flow
Clean under pumps and check air filter.	<p>Remove all of the pumps and clean the mounting area. Clean the bottom and the sides of the pumps and chassis thoroughly.</p> <p>Check and replace the air filters on the base and pumps whenever dirt and dust will impede air flow.</p>
Check the Gas Flow.	<p>Connect the air or 95/5 and oxygen to the proper gas supplies.</p> <p>Turn the FiO_2 to 100% using either the control knob or CCM control. Set the gas flow rate to maximum by turning knob fully counterclockwise multiple times. The gas flow display on the CCM should read >10, indicating that the gas flow rate is greater than 10 L/min, and there is an unrestricted flow from the oxygen inlet through the system. The FiO_2 and $\%\text{O}_2$ display on the CCM should read 1.00 and 100%, respectively. The $\%\text{O}_2$ reading should be within 90% of the FiO_2 setpoint within 20 seconds.</p> <p>Turn the FiO_2 to 21% if using air or 95% if using 95/5 using either the control knob or CCM control. The gas flow display on the CCM should read >10, indicating that the gas flow rate is greater than 10 L/min, and there is an unrestricted flow from the air inlet through the system. If using air, the FiO_2 and $\%\text{O}_2$ display on the CCM should read 0.21 and 21%, respectively. If using 95/5, the FiO_2 and $\%\text{O}_2$ will display 0.95 and 95%, respectively. The $\%\text{O}_2$ reading should be within 90% of the FiO_2 setpoint within 20 seconds.</p>

Additional Information

Monthly...

Battery backup system

The battery system requires monthly maintenance to ensure the condition of the batteries. If the system is not charged monthly, see the **Long Term Storage** section below.

Plug the system into AC (Mains) power and turn it on using the AC (Mains) power switch.

CAUTION: If AC (Mains) power switch is not turned on, the battery system will not charge.

Ensure the system is connected to AC (Mains) power and powered on until the power status indicator LED turns green. If the power status indicator LED does not turn green after 13 hours, contact Terumo Customer Service.

After fully charging the battery system, remove the system from AC (Mains) power and confirm the system properly goes onto backup battery power. Run the Battery Test by running system on battery for at least 5 minutes.

CAUTION: If the Battery Test results in an indication of less than one hour battery life for a fully loaded system, call Terumo Cardiovascular Systems service.

WARNING: Do not start a case with less than one hour battery life. If the battery should be charged, then contact Terumo Customer Service. Do not operate the system until the battery system has been serviced.

Note that if more than 60 days elapses without running the Battery Test, a reminder will be posted each time the Main Screen is entered until the test is performed.

CAUTION: Replace the batteries every two years OR whenever the batteries cannot be fully recharged within 13 hours OR whenever fully charged batteries will not power the entire system for at least 60 minutes.

Disposal

Prior to disposal follow the cleaning and disinfecting procedure above. For end-of-life product return and disposal contact Terumo Customer Service.

Additional Information

Test the Alarms and Alerts Every Three Months

The following checks and tests should be performed periodically.

Every Three Months. . .	Test Your Alarms and Alerts
Pressure Limit Alerts and Alarms	<p>Set an alert and alarm. Apply a pressure (slightly above alert value) to the pressure transducer. Check that the audible alert sounds, a message is displayed on CCM, the appropriate icon on the CCM flashes yellow, and the status LED on the appropriate module flashes yellow. Check that a message is displayed on all pumps with a safety connection to the pressure transducer.</p> <p>Increase the pressure as necessary. Check that the audible alarm sounds, a message is displayed on CCM, the appropriate icon on the CCM flashes red, and the status LED on the appropriate module flashes red. Check that a message is displayed on all pumps with a safety connection to the pressure transducer.</p>
Roller Pump Overspeed and Pump Jam	<p>Start the pump, insert the hand crank, and set the speed to 15 RPMs.</p> <p>Begin hand cranking rapidly for at least 5 revolutions. Check that the pump changes to Stop mode and "< Pump Name >: Overspeed" appears on the Central Control Monitor message display and "STOP: OVERSPEED" appears on the pump control panel.</p> <p>Insert tubing in the pump raceway and start the pump heads rotating. Turn the occlusion knob counterclockwise to overocclude. Check that the pump switches to Stop mode and "< Pump Name >: Pump Jam" appears on the Central Control Monitor message display and "STOP: PUMP JAM" appears on the pump control panel.</p>
Temperature Alarm	<p>Check that the audible alarm sounds and that the alarm message appears on the CCM when the temperature probes are inserted in water warmer than the alarm limit. Check each probe.</p>
Flow alarm and alerts for Centrifugal Pump.	<p>Test the flow alarms associated with centrifugal pumps and flowmeter modules. Set up an unrestricted test circuit using priming solution. Set the minimum flow alarm setting at 0.1 L/min. Verify the alarms as follows:</p> <p>To check the backflow alarm, adjust the flow to 1.0 L/min. Reposition the flow sensor so that the arrow is pointing in the opposite direction of circuit flow. The backflow alarm should activate, displaying "<Flow Name>: BACKFLOW" on the CCM and sounding a dual tone audible alarm. Any pumps with a safety connection to the flow sensor should display "<Response>: BACKFLOW" on the pump display. Reposition the flow sensor so that the arrow is pointing in the direction of flow.</p> <p>Ensure that the speed is above 1550 RPM and the flow is above the minimum flow alarm setpoint. Clamp the outlet line. The minimum flow alarm should activate, displaying "<Pump Name>: MINIMUM FLOW" on the CCM, sounding the dual tone alarm, and displaying "MINIMUM FLOW" on the control unit display.</p> <p>Note: The minimum flow alarm is only enabled when the flowmeter module is linked to the centrifugal pump by placing the flow sensor on the primary display area of the Centrifugal Pump icon during configuration.</p>

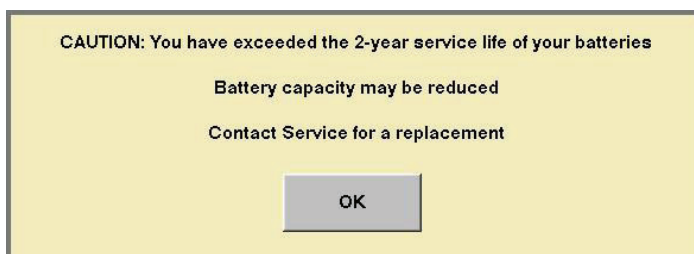
Additional Information

Every Two Years. . .

Replace Your Batteries

CAUTION: Replace the batteries every two years OR whenever the batteries cannot be fully recharged within 13 hours OR whenever fully charged batteries will not power the entire system for at least 60 minutes.

The batteries must be replaced every two years. If the batteries are not replaced, the system will post a reminder each time the Main Screen is entered. The following message box will be posted:



When OK is selected, the system will return to the Main Screen.

WARNING: Do not operate the System with Batteries that have exceeded their 2-year Service life. Less than specified battery life may result. Contact Terumo Customer Service for replacement batteries.

Additional Information

Electronic Gas Blender Maintenance

Replace the Oxygen Sensor

Replace the oxygen sensor whenever prompted by the system.

The “Service O2 Sensor” Message

If the oxygen sensor exposure limit is reached, the message ‘Service Gas System’ will be displayed in the message area of the CCM and ‘Service O2 Sensor’ will be displayed in the Aux tab. A backup analyzer should be used until the oxygen sensor is replaced by an authorized Terumo Cardiovascular Systems service provider.

Oxygen Sensor Maintenance

To maximize the life of the oxygen sensor, always disconnect or turn off the gas supply to the electronic gas blender when the system is not in use as the system will vent several liters of gas per minute, even when the flow is set to zero using the slider bar on the CCM or using the local gas flow knob on the front panel.

Flow Meter

Replace or recalibrate the flow meter every 24 months. The flowmeter must be recalibrated or replaced by an authorized Terumo Cardiovascular Systems service provider.

Recondition the Gas System

The Electronic Gas Blender must be reconditioned every 24 months. The Electronic Gas Blender must be returned to an authorized Terumo Cardiovascular Systems service provider for reconditioning.

Water Trap Maintenance

Drain the water trap (located on the air or 95/5 inlet) after each use if necessary. Depress the valve on the bottom of the water trap to empty any water.

Replace the water trap filter at least every six months.

1. Depress the valve on the bottom of the water trap and empty any water.
2. Loosen the large center nut and rotate the trap 180°.
3. Pinch clip and remove the metal guard.
4. Unscrew and remove the clear plastic bowl.
5. Unscrew and remove the center core.
6. Remove the filter and covering. Replace the cylindrical filter with a new water trap filter.
7. Reassemble the water trap, rotate it 180°, and tighten the center nut. Take care not to use any grease or oil on parts which are exposed to oxygen content gases. Do not use solvents or cleaning solutions on the polycarbonate bowl. If cracks or abrasions are found on the bowl, replace it with a new bowl.

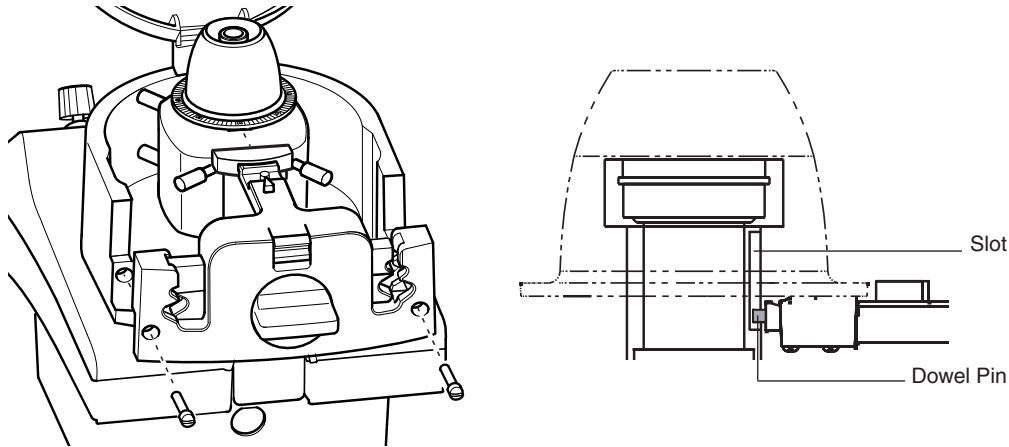
Additional Information

Removal and Cleaning of Tube Clamps

The tube clamp mechanism can be removed from the roller pump for cleaning.

To clean the tube clamp assembly:

1. Use a flat head screwdriver (provided with Accessory Kit) to loosen the two screws that hold the tube clamp to the pump head.
2. Remove the tube clamp assembly from the pump.
3. Immerse the tube clamp in warm soapy water and cycle the knob back and forth several times.
4. Rinse the tube clamp and allow the tube clamp to drain in the upright position.
5. Position the tube clamp so that the black rubber button in front of the occlusion indicator arrow slides under the occlusion indicator ring.
6. Rotate the occlusion knob until the metal dowel pin at the end of the tube clamp slides into the slot of the adjustment screw.



Note: Failure to position the metal dowel pin into the slot of the adjustment screw will result in the inability to set occlusion.

7. Seat and fasten the tube clamp onto the raceway using the two screws.

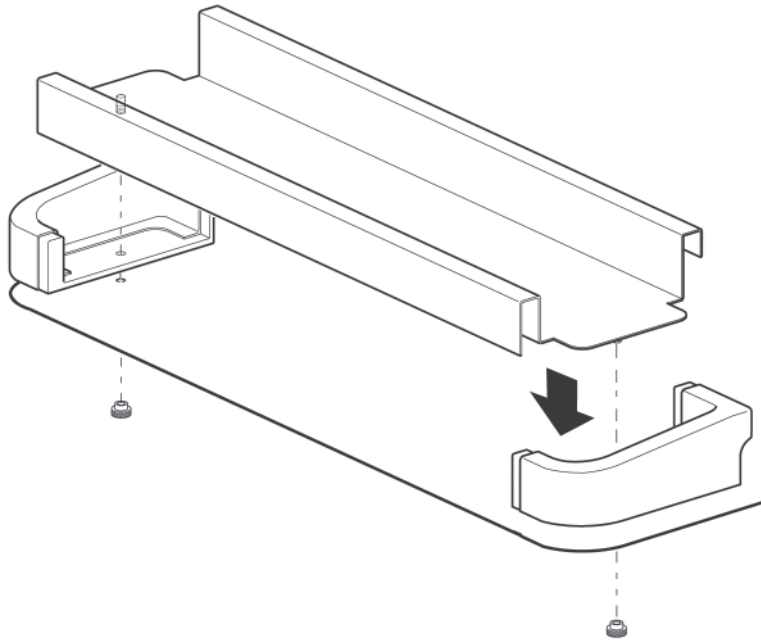
Removal and Cleaning of the Instrument Tray

The instrument tray can be removed to clean underneath the tray.

1. Remove the 2 thumbnuts from under the tray, 1 under each end.
2. Lift the tray off of the base.
3. Separate the end caps from the tray.
4. Clean and dry the 3 tray pieces and the tray mounting surface on the base.
5. Put the end caps onto the tray.

Additional Information

6. Align the studs on the bottom of the tray with the holes in the tray mounting surface of the base and position the tray against the mounting surface.
7. Install the thumbnuts onto the studs. Make sure the nuts are tight and secure.

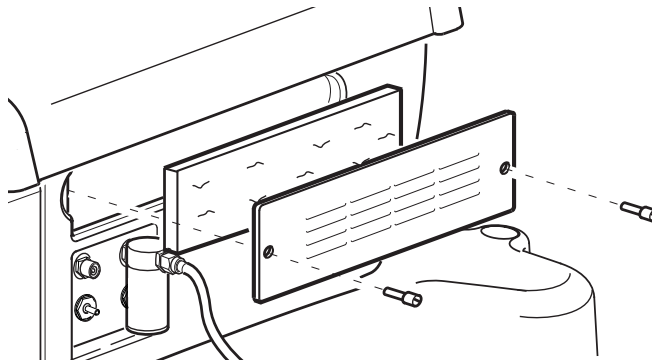


Replacing Air Filters and Lamp Bulbs

Air Filters

Base

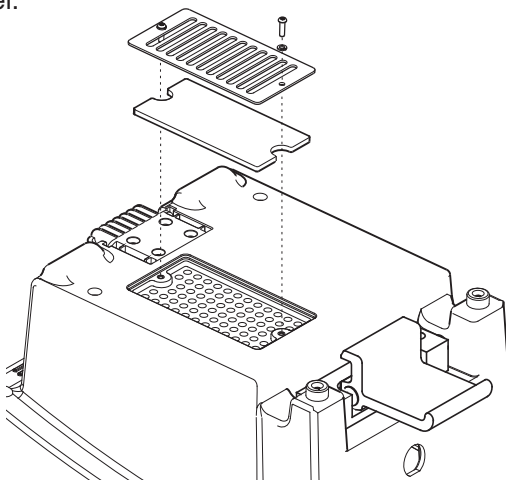
The fan filter, located on the back panel of the base, should be replaced every 6 months or more often if necessary. Use a flat head screwdriver (provided with Accessory Kit) to loosen the 2 screws and remove the back panel. Remove the used filter and insert a new air filter with the blue side of the filter facing base and the white side facing out. Replace back panel.



Additional Information

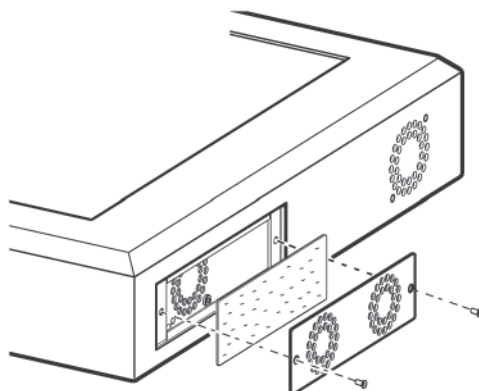
Roller Pump

The fan filter, located on the bottom of the pump, should be replaced every 6 months or more often if necessary. Use a 1/16 in. ball driver (provided with Accessory Kit) to loosen the 2 screws and remove the panel. Remove the used filter and insert a new air filter. Replace panel.



CCM (816300 Only)

The CCM filter, located on the bottom of the CCM, should be replaced every 6 months or more often if necessary. Use a Phillips head screwdriver (provided with Accessory Kit) to loosen the 2 screws and remove the panel. Remove the used filter and insert a new filter. Replace the panel.



Lamp Bulb

When replacing the 24 VDC lamp bulb, hold the bulb with a cloth or tissue during installation to prevent skin oils from shortening the life of the bulb. LED Lamp bulbs are not replaceable.

Long Term Storage

Long term storage is defined as greater than one month without charging the backup battery system by connecting the Advanced Perfusion System 1 to AC (Mains) power and turning the System 1 on.

WARNING: Charge the batteries monthly. Storage of a System 1 without charging the batteries monthly may damage the batteries and lead to overstated battery life. This damage, caused by a gradual discharge of the batteries, may cause loss of battery backup without warning.

If long term storage (beyond a month without a full charging cycle) of the System 1 is desired, the batteries must be replaced before clinical use.

Additional Information

Service

It is recommended that the Terumo® Advanced Perfusion System 1 have a maintenance inspection every 6 months to ensure proper operation. Periodic inspection and maintenance by an authorized service technician, including replacement of any necessary components as described in the System 1 Field Service Handbook, must be conducted in order to assure continued, proper performance of the system.

Only Terumo Cardiovascular Systems Corporation certified service technicians are authorized to service or repair this device. Only Terumo Cardiovascular Systems Corporation approved replacement parts may be used in this device. Terumo Cardiovascular Systems Corporation approved parts are only available through Terumo Cardiovascular Systems Corporation certified service technicians. Any service or repair by an unauthorized service technician or use of unapproved parts will void your Terumo Cardiovascular Systems Product Warranty and may increase the risk of a product failure.

Contact Terumo Cardiovascular Systems Corporation Service, your local Terumo company or your authorized distributor for technical assistance and to arrange for service.

In the United States, contact the Terumo Cardiovascular Systems Corporation Technical Support Department:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103 U.S.A.
Telephone: (800) 441-3220
Fax: (734) 741-6449

Outside the United States, please contact your local Terumo company, your authorized distributor, or the Technical Support Department at Terumo Cardiovascular Systems Corporation.

Telephone: (734) 663-4145
Fax: (734) 741-6449

Europe: Technical Support - Medical Electronics -
Call Free Number from:

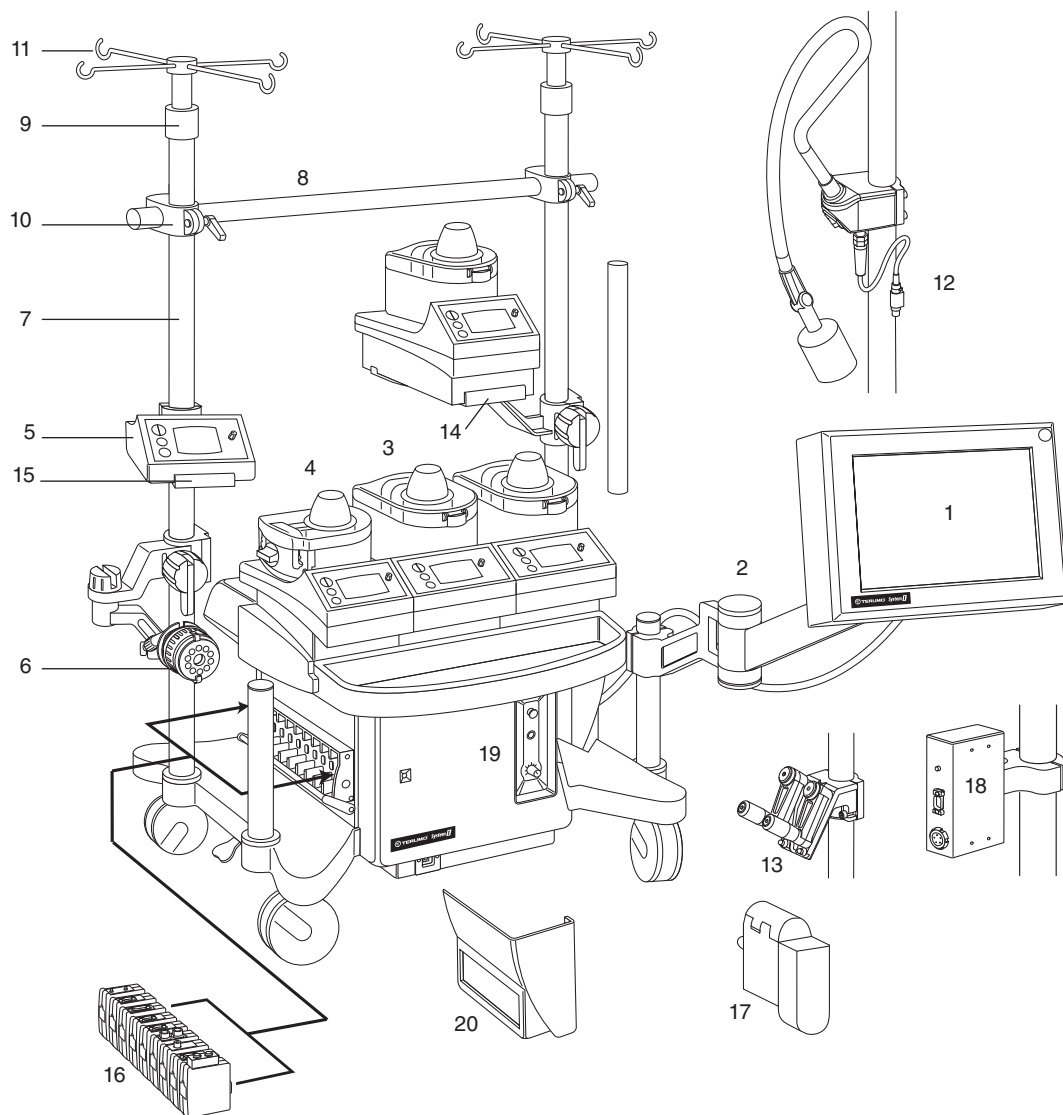
AT 0800-293711	BE 0800-94410	DK 808-80701
FI 0800-115226	IE 1800-553224	CH 0800-563694
FR 0800-908793	IT 800-785891	GB 0800-9179659
DE 0800-1808183	NL 0800-0222810	NO 800-12270
GR 00800-3212721	ES 900-963251	SE 020-791373

Other countries call +32 16 381204 at international rates

E-mail: meservice@terumo-europe.com

Fax: +3216381420

Additional Information



Additional Information

System Components

	Description	REF /Catalog No.
1	Central Control Monitor	816300
		816300J
	System Configuration PC Card	803739
	Service Data PC Card	803740
2	Monitor Mounting Arm (for 816300 CCM)	801441
1	Central Control Monitor	890500
	System Configuration Drive	90000143
	Service Data Drive	90000160
2	Monitor Mounting Arm (for 890500 CCM)	90000746
3	Roller Pump, 6 inch	801041
	Roller Pump, 6 inch, Gray	816571
	Cover-Hinge Assembly, 6 inch	871928
4	Roller Pump, 4 inch	801040
	Roller Pump, 4 inch, Gray	816570
	Cover-Hinge Assembly, 4 inch	871929
5	Centrifugal Control Unit (Sarns)	801046
	Centrifugal Control Unit, Gray (Sarns)	816572
	Centrifugal Control Unit, Gray (Capirox)	816573
6	Centrifugal Drive Motor (Sarns)	164267
	Centrifugal Drive Motor (Capirox)	893632
	Flexible Mounting Arm	816620
	Manual Drive Unit	164268
	Capirox Hand Crank	XX-SP05
7	Telescoping Pole	16431701
	(1.3 inch (3,3 cm) diameter; 6 –7.5 feet (1,8 – 2,3 m) in length)	
	Mounting Pole (4 feet (1,2 m) in length)	16553401
	Mounting Pole (3 feet (0,9 m) in length)	131115
	Mounting Pole (2 feet (0,6 m) in length)	16553301
	Short Pole	801407
8	Crossbar	16426
9	Pole Collar	150826
10	Crossbar Fitting	145980
11	Solution Rack	146819
	Shelf (not shown)	816489
12	Lamp, 33 inch (83,8 cm)	801238
	Lamp, 15 inch (38,1 cm)	801558
	LED Lamp, 25" ((63,5 cm) in length)	893479
13	Hand Crank Bracket	802089
	(includes 2 each hand cranks)	801016
14	Roller Pump Pole Mount	801093
	Dual Pumps Pole Mount	816477
	Descending Pump Bracket	816483
15	Centrifugal Unit Pole Mount	804372
	Roller Pump Mounting Extension, large	802523
	Roller Pump Mounting Extension, small	802524
	Sliding Back Cover Panel Kit	816370
16	Modules	
	Air Bubble Detect Module	802110
	Air Sensor, 3/8 in. x 3/32 in.	5773
	Air Sensor, 1/4 in. x 1/16 in.	5785

Additional Information

System Components

Description		REF /Catalog No.
Modules (Continued)		
Air Sensor, 1/4 in. x 3/32 in.		5791
Cable Assembly		883796
Sensor Holder		149876
Air Sensor Bracket		5793
Level Detect Module		802111
Alarm Sensor, Red		195274
Alert Sensor, Yellow		195215
Level Detect Module		
Level Sensor Pads		195240
Temperature Module		802114
		884660
Pressure Module		802112
		893607
Occluder Module		803480
17 Occluder Head		806455
18 Flowmeter Module		802018
Flow Sensor		6382
Flowmeter Mounting Bracket		801550
19 Electronic Gas Blender Module		801188
Oxygen Sensor		801074
Galvanic Oxygen Sensor		889773
Gas Supply Hose Kit (US)		814475
Oxygen Hose – green; Air Hose – yellow		
Hoses do not include adapters for hospital gas outlets		
Gas Supply Hose Adapter sets (US)		
NCG Hose Adapter Set		144207
DISS Hand Tight Hose Adapter Set		144215
Ohio Diamond Hose Adapter Set		144223
Gas Supply Hose Kit (Outside the US)		814474
Oxygen Hose – white; Air Hose – white/black		
Hoses do not include adapters for hospital gas outlets		
Gas Supply Hose Adapter Sets (Outside the US)		
DISS Hose Adapter Set		815457
NCG Hose Adapter Set		815459
Ohio Diamond Hose Adapter Set		815461
95-5 Supply Hose (%O2/%CO2)		164595
Interface Module for CDI 500/550		803479
Serial Cable		804981
Interface Module RS-232		802113
Serial Cable		804982
20 Module Cover		
Right Side		804405
Left Side		804404
Wire Cover		816622

Additional Information

Accessory Kit

Description	Qty.	REF /Catalog No.
Colored Magnetic caps for pump occlusion knobs:		
Red	1	837760
Yellow	1	837763
Blue	1	837761
Green	1	837762
Purple	1	837765
Tan	1	837764
Light Blue	1	837767
Orange	1	837766
Cable Retainer, 1/2 inch	6	806441 / 896789
Cable Retainer, 1 inch	2	806459 / 896790
Halogen Bulb, 24 V 20 W	1	132265
Intake Air Filter, Base	1	802094
Intake Air Filter, Pump	1	802280
Flowmeter	1	147361
Ball Driver, 3/8 inch	1	804686
Ball Driver, 5/64 inch	1	809258
Ball Driver, 3/16 inch	1	132361
Ball Driver, 1/4 inch	1	808152
Ball Driver, 1/8 inch	1	803743
Ball Driver, 1/16 inch	1	803744
Nut Driver, 3/8 inch	1	235571
Screwdriver	1	133612
Screwdriver, Slotted	1	802650
Threaded Handle, 1/4-20 x 7/8	6	132530
Shaft Collar, 1.312 I.D., 2.125 O.D.	1	134068
Set Screw, 1/4-20 X 3/16	4	805281
Thumbscrew, 1/4 -20 x 2.0	2	150957
Cap screw, socket-head, 1/4-20 x 0.75	4	203369
Standoff, 4-40 x 0.25, Hex	8	804459
Cinchstrap	10	147125
Wire Marker Tape with number "0"	1	807897
Wire Marker Tape with number "1"	1	807879
Wire Marker Tape with number "2"	1	807884
Wire Marker Tape with number "3"	1	807880
Wire Marker Tape with number "4"	1	807881
Wire Marker Tape with number "5"	1	805647
Wire Marker Tape with number "6"	1	805648
Wire Marker Tape with number "7"	1	805649
Wire Marker Tape with number "8"	1	805650
Wire Marker Tape with number "9"	1	805651
Wire Marker Tape with letter "A"	1	807899
Wire Marker Tape with letter "C"	1	807900
Wire Marker Tape with letter "E"	1	807901
Wire Marker Tape with letter "G"	1	807902
Wire Marker Tape with letter "H"	1	807903
Wire Marker Tape with letter "I"	1	807904
Wire Marker Tape with letter "L"	1	807905
Wire Marker Tape with letter "M"	1	807906
Wire Marker Tape with letter "N"	1	807907
Wire Marker Tape with letter "O"	1	807908
Wire Marker Tape with letter "P"	1	807909
Wire Marker Tape with letter "R"	1	807910
Wire Marker Tape with letter "T"	1	807911
Wire Marker Tape with letter "V"	1	807912
Divided Box, Small	2	807350
Tool Box	1	807103

Additional Information

Recommended Spare Parts

It is recommended these replacement parts be kept in stock.

Pump Safety cover, small	1	803720
Pump Safety cover, large	1	803719
Halogen Bulb, 24 V 20 W	1	132265
Intake Air Filter, Base	1	802094
Intake Air Filter, Pump	1	802280
Intake Air Filter, CCM [for CCM P/N 816300]	1	804517
Water Trap Filter	1	132257
Occluder Cover Asby	1	147141
Occluder Hinge Pin	1	133217
Water Trap Bowl Asby	1	132935

Terumo-Tested Temperature and Pressure Sensors

Pressure

<u>Description</u>	<u>REF Part Number</u>	<u>Manufacturer Contact Information</u>
Meritrans DTXPlus®	688694 (kit)	Merit Medical Systems, Inc.
Disposable Transducer	682000 (transducer only)	1600 West Merit Parkway South Jordan UT 84095 USA

DTXPlus® is a registered trademark of Merit Medical Systems, Inc.












Temperature

<u>Description</u>	<u>REF Part Number</u>	<u>Manufacturer</u>
Capiox Luer Thermistor	1CX*TL	Terumo Cardiovascular Systems
Thermistor wire, blue	1CX*BP021	
Thermistor wire, red	1CX*BP022	












Additional Information

Symbols Glossary
















The following symbols may appear in the labeling, marking, or display of the Terumo Cardiovascular Systems (TCVS) Advanced Perfusion System 1. These symbols are in accordance with the internationally harmonized standards.

Symbol	Title	Description	Source
	Consult instructions for use.	Indicates the need for the user to consult the instructions for use.	ISO 15223-1-5.4.3
	Refer to Instruction Manual	Indicated that the instruction manual must be read prior to use of the product.	ISO 7010-M002
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1-5.4.4
	General Warning Sign	Indicates the need for the user to consult instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 7010-W001
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1-5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1-5.1.4
	Protective earth ground.	Protective earth ground.	IEC 60417-5019
	Type CF equipment.	Type CF equipment.	IEC 60417-5335
	Direct current.	Direct current.	IEC 60417-5031
	Equipotentiality	Equipotentiality	IEC 60417-5021
	WEEE	This standard applies to Electronic equipment in accordance with article 11(12) of Directive 2002/96/EC.	Directive 2002/96/EC

















Additional Information

Symbol	Title	Description	Source
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1-5.1.4
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15223-1-5.1.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1-5.3.4
	This way up.	This way up	ISO 7000-0623
	Date of manufacture.	Indicates the date when the medical device was manufactured.	ISO 15223-1-5.1.3
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1-5.3.7
	CE Mark	Indicates conformity of the product to Council Directive 93/42/ EEC	Council Directive 93/42/ EEC
	Battery recycling (European).	Battery recycling (European).	WEEE 2012/19/EU
	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1-5.3.8
	Number of contents in carton.	Identifies the number of contents	Terumo Cardiovascular Systems
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community	ISO 15223-1-5.1.2
Rx ONLY	Prescription only	Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician	21 CFR 801.109















Additional Information

Symbol	Title	Description	Source
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1-5.1.6
	ON, circuit closed.	ON, circuit closed.	Terumo Cardiovascular Systems
	OFF, circuit open.	OFF, circuit open.	Terumo Cardiovascular Systems
	Do not turn upside down	Indicates not to turn the Ultrasonic Air Sensor upside down	Terumo Cardiovascular Systems
	START/STOP	START/STOP	Terumo Cardiovascular Systems
	Select	Select	Terumo Cardiovascular Systems
	Manual	Manual	Terumo Cardiovascular Systems
	Servo Mode	Servo Mode	Terumo Cardiovascular Systems
	Pulse Mode	Pulse Mode	Terumo Cardiovascular Systems
	Master Pump	Master Pump	Terumo Cardiovascular Systems
	Follower Pump	Follower Pump	Terumo Cardiovascular Systems
	Centrifugal Pump	Centrifugal Pump	Terumo Cardiovascular Systems
	Air Bubble Detector, air bubble detection.	Air Bubble Detector, air bubble detection.	Terumo Cardiovascular Systems
	Level Detector, level detection.	Level Detector, level detection.	Terumo Cardiovascular Systems
	Pressure Module	Pressure Module	Terumo Cardiovascular Systems






Additional Information

Symbol	Title	Description	Source
	Temperature Module	Temperature Module	Terumo Cardiovascular Systems
	Flowmeter Module	Flowmeter Module	Terumo Cardiovascular Systems
	Data transfer, RS-232 protocol, output only	Data transfer, RS-232 protocol, output only	Terumo Cardiovascular Systems
	Data transfer, CDI™ 500/550 Monitor, input and output.	Data transfer, CDI™ 500/550 Monitor, input and output.	Terumo Cardiovascular Systems
	Data transfer, CDI™ 100/101 Monitor, input only.	Data transfer, CDI™ 100/101 Monitor, input only.	Terumo Cardiovascular Systems
	Occluder Module	Occluder Module	Terumo Cardiovascular Systems
	STOP	STOP	Terumo Cardiovascular Systems
	START	START	Terumo Cardiovascular Systems
	Direction of rotation, counterclockwise	Direction of rotation, counterclockwise	Terumo Cardiovascular Systems
	Direction of rotation, clockwise	Direction of rotation, clockwise	Terumo Cardiovascular Systems
	Gas inlet	Gas inlet	Terumo Cardiovascular Systems
	Maximum Input Gas Pressure	Designates the maximum rated inlet gas pressure for the electronic gas blender	Terumo Cardiovascular Systems
	Gas outlet	Gas outlet	Terumo Cardiovascular Systems
	CPG delivery mode	CPG delivery mode	Terumo Cardiovascular Systems
	CPG recirculate mode	CPG recirculate mode	Terumo Cardiovascular Systems
	Roller Pump	Roller Pump	Terumo Cardiovascular Systems

Additional Information

Symbol	Title	Description	Source
	Centrifugal Pump	Centrifugal Pump	Terumo Cardiovascular Systems
	Open reservoir	Open reservoir	Terumo Cardiovascular Systems
	Close reservoir	Close reservoir	Terumo Cardiovascular Systems
	Oxygenator	Oxygenator	Terumo Cardiovascular Systems
	Battery	Battery	Terumo Cardiovascular Systems
	Occluder fully open, on occluder slide bar.	Occluder fully open, on occluder slide bar.	Terumo Cardiovascular Systems
	Occluder fully closed, on occluder slide bar.	Occluder fully closed, on occluder slide bar.	Terumo Cardiovascular Systems
	Mute, silence an audible alert or alarm.	Mute, silence an audible alert or alarm.	Terumo Cardiovascular Systems
	Mute all, silence multiple audible alerts or alarms.	Mute all, silence multiple audible alerts or alarms.	Terumo Cardiovascular Systems
	Non-communicating or missing module	Non-communicating or missing module	Terumo Cardiovascular Systems
	Broken Module	Broken Module	Terumo Cardiovascular Systems
	Occluder	Occluder	Terumo Cardiovascular Systems
	Approximate percent open of venous line from 0% Open (fully closed) to 100% Open.	Approximate percent open of venous line from 0% Open (fully closed) to 100% Open.	Terumo Cardiovascular Systems
	Close Window	Close Window	Terumo Cardiovascular Systems
CAL	Calibrate	Calibrate	Terumo Cardiovascular Systems

Additional Information

Symbol	Title	Description	Source
	Turn counterclockwise to increase gas flow and clockwise to decrease gas flow	Turn counterclockwise to increase gas flow and clockwise to decrease gas flow	Terumo Cardiovascular Systems
	Recyclable	Recyclable	Terumo Cardiovascular Systems
	Caution, hot surface	Caution, hot surface	Terumo Cardiovascular Systems
	Occlusion Knob Cover	Describing direction to turn the occlusion knob to reduce or increase occlusion of tubing within the pump raceway	Terumo Cardiovascular Systems
	Alternating current.	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals	IEC 60417-5032

Standards:

ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements

IEC 60417: Graphical symbols for use on equipment

ISO 7000: Graphical symbols for use on equipment

IEC 60529: Degrees of protection provided by enclosures (IP Code)

Additional Information

Glossary

Air Bubble Detect Module

The air bubble detect (ABD) module is the interface between an air sensor and the system. The ABD module monitors the air sensor and communicates any alarms to the system.

Air Sensor

The air sensor is a non-invasive, ultrasonic sensor which can detect air bubbles in the perfusion circuit. The air sensor is detachable from the ABD module.

Alarm

An event that requires immediate attention and correction, e.g., an air alarm. An alarm message is displayed in the CCM message area in large flashing red letters. A dual tone sounds and repeats at one minute intervals to warn the user that an alarm event has occurred. Pumps and the occluder can be set up to respond to certain alarm events.

Alert

An event that may lead to an alarm situation if it is not corrected, e.g., a low level alert. An alert message is displayed in the CCM message area in large flashing yellow letters. A single tone sounds and repeats at one minute intervals to warn the user that an alert event has occurred. Pumps can be set up to respond to certain alert events.

Applied Part

A part of medical electrical equipment that in NORMAL USE necessarily comes into physical contact with the PATIENT for medical electrical equipment or a medical electrical system to perform its function

Assigning Devices

Takes place in the Configuration Screen when devices and sensors configured on a Perfusion Screen are assigned to actual physical components.

Automatic Event

An event that is not generated directly by a device or sensor, for example, the completion of an automatic cardioplegia dose.

Auxiliary Tab

A Perfusion Screen tab that allows the user to view and control auxiliary timers and view system messages.

Backup Pump

A designation that can be assigned to one pump in a Perfusion Screen. This feature allows all the settings of the Primary Pump to be reassigned to the backup pump with the exception of the tube size or roller pump flow constant. Backup pump designation also allows the reassignment of primary pump functionality to a pump of a different type.

Battery Alert Tone

A unique single tone pattern, repeated at 3 minute intervals, which indicates that the system is operating on battery power. This alert tone cannot be muted.

BPM

Beats per minute

Additional Information

BSA

Body Surface Area

Cardioplegia Pump

A designation that can be assigned to either one roller pump or two roller pumps operating in a master/follower arrangement in a Perfusion Screen. The CCM will use data from this pump to calculate cardioplegia delivery information and when using the automatic cardioplegia dose feature.

CCM

Central Control Monitor

CDI™ 100/101 Monitor*

A stand alone venous saturation, hemoglobin, and hematocrit monitor capable of providing saturation, hemoglobin, and hematocrit parameters on its external serial port. This device interfaces with the System 1 using an Interface Module for CDI 100/101.

CDI™ 100/101 Interface Module

The Interface Module for CDI 100/101 provides the interface between a CDI™ 100 or CDI™ 101 Saturation/Hematocrit Monitor and the system. The module communicates the CDI monitor values to the system for display on the CCM.

CDI™ 500/550 Monitor

A standalone blood gas monitor capable of outputting blood gas parameters from its external serial port. This device interfaces with the System 1 using an Interface Module for CDI 500/550.

CDI™ 500/550 Interface Module

The Interface Module for CDI 500/550 Module provides the interface between the CDI™ 500/550 Blood Parameter Monitoring System and the system. The module communicates the CDI 500/550 monitor values to the system for display on the CCM.

Central Control Monitor

The Central Control Monitor (CCM) combines an embedded computer, a touch screen, and a Graphical User Interface (GUI) to provide a centralized display of system information and on-screen control of all system devices. During use, the CCM monitors the system for any alert, alarm, error, or status messages and displays the highest priority message in a dedicated message area. The CCM also allows the user to initiate automatic control functionality such as: Pulse mode, servo regulation to pressure and flow, and automatic cardioplegia time or volume delivery.

Central Control

The ability to control a device from the Central Control Monitor (CCM). All devices can be controlled from the CCM.

Centrifugal Control Unit

The centrifugal control unit provides the local display and control mechanism for the centrifugal motor with its disposable pump and serves as the interface between the centrifugal motor and the rest of the system. The local display indicates the motor speed, flow rate, and safety, status, and error messages. The pump can be controlled from either the CCM or from the pump speed control knob on the control unit. The CCM can be used to configure the centrifugal control unit safety connections and pump responses to alert and alarm events.

* The Terumo CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System is not cleared for marketing in the United States by the US Food and Drug Administration (FDA)."

Additional Information

Centrifugal Motor

The centrifugal motor is the drive mechanism necessary to pump fluid through a disposable centrifugal pump which is magnetically coupled to the motor. The motor is detachable from the centrifugal control unit.

Centrifugal Pump

A disposable centrifugal pump head coupled to the centrifugal motor, which spins the impeller of the pump head in response to control signals from the centrifugal control unit.

Channel

One of two receptacles for connecting a sensor on a pressure or temperature module.

CI

Cardiac Index

Coast Event (Sarns Centrifugal Pumps)

A Coast event is an event generated by a centrifugal control unit that can initiate a response in other pumps and the occluder. The Coast event message is sent when the centrifugal control unit briefly locks out manual speed changes as a configured Coast response to another event, or when the user decreases the speed of the centrifugal control unit to 1550 RPM.

Coast Event (Capiox Centrifugal Pumps)

A Coast event is an event generated by a centrifugal control unit that can initiate a response in other pumps and the occluder. The Coast event message is sent when the centrifugal control unit briefly locks out manual speed changes as a configured Coast response to another event, or when the user decreases the speed of the centrifugal control unit to 1300 RPM.

Coast™ Response (Sarns Centrifugal Pumps)

A centrifugal pump response to an event. If the centrifugal pump speed is 1560 RPM or above, the centrifugal pump will slow down to a speed of 1500 RPM. Regardless of the pump speed, a safety event with a configured Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds.

Coast™ Response (Capiox Centrifugal Pumps)

A centrifugal pump response to an event. If the centrifugal pump speed is 1310 RPM or above, the centrifugal pump will slow down to a speed of 1250 RPM. Regardless of the pump speed, a safety event with a configured Coast response triggers a brief lockout of speed adjustments to guarantee that the safety response occurs. The result is that the speed of the pump is fixed after a Coast response for a period of 2 seconds.

Component

Any device or sensor that can be configured on a Perfusion Screen and assigned to a pump, occluder, or module.

Configuration

Configuration is a functional area of the Central Control Monitor that is used to define a Perfusion Screen including number and types of modules and devices, on-screen names and colors, assignment of screen representations to physical devices and modules, safety system connections, and selection of alert and alarm limits and device responses.

Additional Information

CPG

Cardioplegia

CPG Auto Dose

A user selectable delivery of cardioplegia by volume or by time that will stop the pump after delivery is finished.

CPG Delivery

A section of the CPG tab that is used to select the Delivery mode (Deliver or Recirculation), view the time since last delivery, current delivery, and total delivery, and, if needed, to adjust the total delivery volume.

CPG Tab

The section of the Perfusion Screen used to track cardioplegia delivery and to set up and deliver automatic cardioplegia doses.

Device

A device is any component of the System 1 which can be actively controlled from the CCM including roller pumps, centrifugal pumps, occluders, the gas blender, and timers.

Display Units

A user selection for pump speed or flow rate displays. Display unit options include liters per minute (L/min) and revolutions per minute (RPM). Display unit options for the primary pump include L/min/m² and mL/kg/min.

Electronic Gas Blender

The electronic gas blender is an optional module that integrates into the system base. It accepts inputs of medical grade oxygen and air, or oxygen and 95/5 (a blend of 95% oxygen and 5% carbon dioxide), and allows the user to control and regulate the gas output to an oxygenator. The electronic gas blender module can be controlled from either the CCM or from control knobs located on the module itself. A built-in oxygen analyzer measures the oxygen content of the blended gas and provides the information to the system for display on the CCM.

Event

The detection of an alert or alarm or a change in pump state. Pumps and an occluder can be set up to respond to events in the Configuration area.

External Event

An alert or alarm generated by an external device or sensor. For example, for the primary pump, an air alarm would be defined as an external event.

Flowmeter Module

The flowmeter module provides the interface between the flow sensor and the system. The module processes the signals necessary to compute fluid flow values. Those flow values are then communicated to the system. Flowmeter values are displayed on the CCM and, if assigned, on a centrifugal pump's local display.

Flow Sensor

The flow sensor is a non-invasive, ultrasonic transducer used to measure fluid velocity. The signals are used by the flowmeter module to compute fluid flow. The sensor is detachable from the flowmeter module.

Flow Servo

The regulation of pump speed using flow data as the feedback source to maintain a constant flow rate.

Additional Information

Follower Pump

A roller pump used in tandem with a master pump. The follower pump regulates its speed to maintain a constant master/follower ratio using the master pump speed or flow rate as the feedback source. Adjusting the pump speed control knob on the pump control panel or CCM control slide bar changes the follower pump ratio.

Go to Flow Response

An occluder response to an event. The occluder position will be set to a % Flow value set up by the user. For example, “Go to Flow = 50%” repositions the occluder to the 50% open position in response to a primary pump event.

Graphical User Interface

The touch screen area of the CCM that allows the user to interact with the system. It is divided into three functional areas – Configuration, Perfusion, and Service.

GUI

Graphical User Interface

High Frequency Surgical Equipment

Medical electrical equipment, including its associated accessories, intended for the performance of surgical operations such as the cutting and coagulation of biological tissue by means of high frequency (HF) currents.

Interface Module RS-232

The RS-232 module provides the interface between RS-232 protocol data acquisition software and the system. The module outputs system data to the data acquisition software.

Internal Event

An alert, alarm, or error generated internally by a device. For example, for the primary pump, a pump jam error would be defined as an internal event.

LED

Light Emitting Diode

Lamp

Up to two pole mounted lamps can be plugged into dedicated receptacles, one on either side of the base.

Large Roller Pump

The large roller pump is a peristaltic pump with a 6 inch (15 cm) raceway that can be used for arterial, cardioplegia, vent, and suction applications. The pump can be mounted on the base or on a pole with a mounting bracket. The pump can be plugged into one of the 6 pump connections on the base or into any of the base module connections. A universal tube clamp mechanism accommodates a variety of tubing sizes, including dual tube sets. The pump raceway can be positioned and locked in 15 degree increments for positioning of the tubing. The occlusion mechanism allows the user to adjust the position of the rollers at any time, including when the pump is rotating.

The large roller pump has a local display for indicating tube size, direction of pump rotation, flow rate or RPM, and safety, status, and error messages. The pump can be controlled from either the CCM or from the pump speed control knob on the pump itself. The CCM can be used to configure which safety sensors interact with the roller pump and how the pump responds to the sensor alerts and alarms.

Additional Information

Level Detect Module

The level detect module serves as the interface between a level sensor and the system. This module monitors level sensors mounted on a hardshell blood reservoir and communicates any alerts or alarms to the system.

Level Sensor

The level sensor is an ultrasonic transducer that is mounted on a hardshell blood reservoir and detects the presence or absence of blood or prime solution at the point of detection. This sensor is detachable from the level detector module and is compatible with hardshell reservoirs only.

Local Control

The ability to control a device from controls on the device itself. Devices with local control are roller pumps, centrifugal control units, and electronic gas blender.

Local Display

A display area located on the device itself. Devices with local displays are roller pumps and centrifugal control units.

Main Screen

The first screen displayed when the system is started up. From this screen, the user can access the Perfusion, Configuration, and Service areas, and perform a controlled shut down of the system computer.

Master/Follower Mode

Master/Follower operation involves two roller pumps operating in tandem. The follower pump demand flow rate or speed is defined as a ratio or percentage of the master pump flow rate or speed. The ratio or percentage is user adjustable by changing the pump speed via the follower pump speed control knob or its control slide bar on the CCM.

Master Pump

A roller pump used in tandem with a follower pump. The master pump provides speed and flow information to the follower pump so it can regulate its speed to maintain a constant master/follower ratio or percentage. Adjusting the master pump speed will increase or decrease the total flow rate.

Message Area

A message box that is located on the top portion of the Perfusion Screen. This message area displays the highest priority alarm, alert, status, or error message.

Message Only Response

There is no active response by the pump to an event, but a message is displayed on the CCM and the pump local display.

Minimum Flow Alarm

Alarm generated by centrifugal pump when the flow rate decreases below the user defined limit.

Module

The interface between a sensor and the rest of the system.

Module ID

A unique label that allows the network to recognize individual devices.

Additional Information

Mute

A button located on subtabs in the Safety tab used to silence an audible alert or alarm tone with the exception of the battery alert tone.

Mute All

A button located on all Perfusion Screens. Used to silence multiple audible alerts and alarms with the exception of the battery alert tone.

No Response

A choice of No Response causes the system to respond as if no safety connection has been made.

Occluder Head

The occluder head provides a computer-controlled tube occlusion mechanism. The occluder head is controlled via signals received from the occluder module. The occluder head can be detached from the occluder module.

Occluder Module

The occluder module serves as the interface between the occluder head and the system. The occluder system is controlled from the CCM and can be configured to respond to primary pump events.

Offline Device

A device that has not been configured as part of the current Perfusion Screen.

Online Device

A device that has been configured as part of the current Perfusion Screen.

Password

A code that protects access to the Configuration and Service areas of the CCM. Passwords can be set up for individual Perfusion Screens.

Pause Response

The temporary reduction of the roller pump speed to zero in response to an event. The pump speed will automatically ramp back up to its previous setting when the condition is cleared. A roller pump will pause when the safety cover is opened. A pause response can also act as an event and initiate a response in another connected device.

PC Card

A PCMCIA data storage and transfer card.

Perfusion

Perfusion is a functional area of the Central Control Monitor that is used to select a Perfusion Screen and run a case. In preparation to run a case, patient information can be entered, calibrations can be performed, and safety system limits can be checked, modified for that case only if needed, and activated. During use, the CCM can be used to control and monitor all system modules and devices.

Perfusion Screen

A representation of the perfusion circuit on the CCM touch screen that is used to control and monitor perfusion parameters during a case. Perfusion Screens can be created or modified in the Configuration area.

Post Case Tab

The section of the Perfusion Screen used to exit a case and return to the Main Screen.

Additional Information

Pressure Alert/Alarm Limit

User settable limits for negative and positive pressure values. When these limits are exceeded, an event is reported to the system. Pumps can be set up to respond to pressure events.

Pressure Module

The pressure module serves as the interface between up to two pressure transducers and the system. This module monitors signals from the pressure transducers and communicates pressure values, alerts, and alarms to the system.

Pressure Servo

The regulation of pump speed using pressure data as the feedback source to maintain a constant pressure.

Pressure Transducer

The pressure transducer converts pressure into electrical signals detected by the pressure module.

Primary Pump

A designation that is assigned to one pump in a Perfusion Screen, usually the arterial pump.

Pulse Mode

The use of the term “Pulse mode” refers to the variable pressure and flow waveforms that result from the cyclic operation of the primary pump. Replication of a physiologic pulse from a natural heart is not obtained with a pump speed controller. No claim of clinical benefit from the use of the Pulse mode has been reviewed by global Regulatory Agencies.

Primary pump function used to deliver Pulse mode flow for a roller or centrifugal pump.

Pump Icon

Button with a roller or centrifugal pump symbol that, when pressed, opens or closes the Pump tab.

Pump Summary

The area of the Pump tab used to view the pump flow, pump RPM, tube size or flow constant (roller pump only), minimum flow alarm limit (centrifugal pump only), default forward direction, and event-response list.

Pump Tab

The section of the Perfusion Screen used to view the pump summary, initiate Pulse mode for the primary pump, initiate Servo mode, and view master or follower pump status.

Reassign Module Subtab

The area in the System tab used to reassign the settings from one system component to another.

Reduce Speed Response

A roller pump response to an event. The pump speed will decrease by 10% every half second until the event is cleared and then the pump remains at this reduced speed. If the event persists and is not cleared, the pump will stop within 2 seconds once its speed is reduced to less than 4 RPM.

Additional Information

Response

A pump or occluder action initiated by an event. Possible roller pump responses are Stop, Pause, Reduce Speed, and Message Only. Possible centrifugal pump responses are Stop, Coast, and Message Only. Possible occluder responses are Open, Close, and Go to % Flow.

Safety Connection

A communication link set up between two system components allowing a device to receive information from another device or module. Safety connections must be set up in the Configuration area to enable devices to respond to events from other devices or modules.

Safety Tab

The area of the Perfusion Screen used to operate safety systems including: air, level, pressure, temperature, and flowmeter.

Scroll Button

A button or arrow used to scroll through the views for components of the same type, one at a time.

Service Data Card/Drive

A PC card or USB drive that stores system logs, module logs, and Perfusion Screens and is used by authorized service personnel.

Service Screen

Service is a functional area of the Central Control Monitor that is used by Terumo authorized service personnel to perform service functions. It is password protected. Examples of functions that can be performed are: viewing the logs; exportation of the system logs, module logs, and Perfusion Screens to an external computer via the service data card, and viewing module error event data. It can also be used to manage security access controls and view the system software version control area.

Servo Mode

Roller or centrifugal pump function that uses the feedback from a pressure transducer or flowmeter to regulate the pump speed to maintain a constant pressure or flow rate.

Servo Setpoint

The target pressure or flow value to be maintained by a roller or centrifugal pump operating in Servo mode.

Servo Source

A pressure transducer or flowmeter that is used to provide feedback information to a roller or centrifugal pump. The pump speed is then regulated to maintain the servo source set point constant.

Setup Tab

The area of the Perfusion Screen used to input patient information, view and modify blending gas and low FiO₂ alarm, view and modify pump and occluder responses, view and modify timer types, and view and modify the time and date.

Slide Bar

A representation on the Perfusion Screen that allows the user to adjust pump speed, FiO₂, total gas flow, and occluder % flow. The slide bar provides a method to make large and small adjustments and displays the minimum, maximum, and current value of the parameter being adjusted.

Additional Information

Small Roller Pump

The small roller pump has all the characteristics described for the large roller pump, except it has a 4 inch (10 cm) raceway. It can be used for arterial, cardioplegia, vent, or suction applications.

Stop Response

The reduction of the pump speed to zero and transition to Stop mode in response to an event. The user must restart the pump.

Subtab

A view contained within a tab.

Summary

A description of the components, connections, and responses for a Perfusion Screen that can be viewed in the Perfusion Screen selection area.

System Base

The system base is a moveable platform designed for the adaptable mounting of system components on poles and on a central rail. The base houses the network infrastructure that provides power and communications to all system modules.

System Configuration Card/Drive

A PC card/drive that stores CCM settings and Perfusion Screens. This card/drive can be used to transfer Perfusion Screens from one CCM to another.

System Network

A design that distributes power and communications to all system components. This design allows all the different types of system modules to be connected to any module receptacle on the base. It also allows multiple types of modules to be connected to the system.

System Power

The power system located within the base transforms AC (Mains) power into the DC levels required by the system modules. Integrated batteries provide uninterruptible backup power in the event of AC (Mains) power loss during use.

System Tab

The area of the Perfusion Screen used to reassign modules and to view system settings, power, and module information.

Tab

Tabs are located on the bottom part of a Perfusion Screen. They allow access to the following sections of the Perfusion Screen: Setup, Safety, CPG, Aux, System, and Post Case. An additional tab, the Pump tab, is accessed by touching the Pump icon.

Temperature Module

The interface between a temperature probe and the rest of the system.

Temperature Probe

The temperature probe converts temperature into electrical signals detected by the temperature module.

USB Drive

A USB data storage and transfer drive.

Index

A

- Accessory Kit 12-21
- Air Bubble Detect Module (ABD)
 - adding air detectors in CCM 7-3
 - air bubble detection 7-3
 - connecting ABD sensor 7-4
 - connecting module 7-3
 - enabling and disabling alarms 7-5
 - messages 7-6
 - overview 2-12
 - test before use 7-6
 - warnings 12-3
- Assign Devices to Modules
 - Air Detectors, Level Detectors, Occluders, Flow Sensors, CDI 4-97
 - editing a perfusion screen 4-103
 - Pressure and Temperature Sensors 4-99
 - Roller Pumps, Centrifugal Units 4-101
 - saving a perfusion screen 4-102
 - View Summary, Rename, Set Password and Delete 4-104
- Aux Tab
 - Messages Subtab 4-32
 - Timers Subtab 4-31

B

- Backup Pump 4-64, 12-29
- Base. *See System Base*
- Battery
 - precautions summary 12-6
 - status 4-17
 - test every 3 months 12-11
 - warnings 12-8
- Buttons 4-8. *See also Controls and Displays*

C

- Cables
 - arranging 3-20
 - cable management 3-20
 - centrifugal control unit 6-2
 - check the system 9-1
 - installing and removing cable cover 3-21
 - power cord 9-1
 - roller pump 5-3
 - Capiox Centrifugal Pump
 - (same subsections as Sarns)
- Central Control Monitor (CCM)
 - Assign Devices to Modules 4-97
 - Configure Other Devices 4-69
 - Configure Pumps 4-59
 - connecting 4-2
 - connection matrix 4-95
 - displays 4-17, 4-18

- Edit Safety Connections 4-87
- electronic gas blender 8-9
- features 2-4, 4-1
- functional areas 4-6
- malfunctions 10-7
- messages 4-39
- PC card compartment 4-4
 - installing and removing 4-4
- precautions summary 12-6
- pump controls and displays 4-14
- slide bars 4-15
- start-up messages 4-3
- symbols 12-23
- warnings 12-3
- Sarns Centrifugal Pumps
 - cables 6-2,
 - check start-up test 6-7, 9-1
 - continuous mode 2-10, 6-8
 - controls and displays 6-6
 - drive motor 6-3
 - features 2-9, 6-1
 - installation and connection 6-2
 - manual drive unit 6-4, 6-15
 - messages 6-15
 - mounting 6-2
 - Pulse mode 6-12
 - pumping precautions summary 12-7
 - pumping warnings 12-5
- Responses
 - Coast™ response 4-89
 - message only response 4-89
 - no response 4-88
 - stop response 4-89
 - servo 2-10, 6-13
 - set up and prime 6-5
 - standby equipment 6-15
 - symbols 12-23
- Circuit Breakers 9-1
- Coast 6-9
 - event 6-10
 - response 6-9
- Configuration
 - PC card 4-51
 - pump designation 4-63
 - selecting patient direction 4-57
 - selecting primary pump location 4-57
 - system settings 4-50
- Configure Other Devices
 - adding a device 4-67
 - adding air detectors 4-66
 - adding a level detector 4-72
 - adding an occluder 4-73
 - adding CDI™ devices 4-80
 - adding flow sensors 4-77

Index

- adding pressure transducers 4-75
- adding temperature sensors 4-75
- adding timers 4-85
- selecting device type 4-70
- Configure Perfusion Screen
 - configuring pumps 4-59, 6-61
- Configure Pumps
 - adding primary pump 4-59
 - adding pump color 4-60
 - backup pump 4-64
 - cardioplegia pump 4-63
 - edit, place, remove 4-67
 - master roller pump 4-65
 - placing pump 4-66
 - selecting display units 4-56, 4-59
 - selecting pump name 4-57, 4-60
 - selecting pump type 4-59
- Continuous Mode
 - centrifugal control unit 6-8
 - roller pump 5-20
- Controls and Displays
 - buttons 4-8
 - Central Control Monitor (CCM) 4-17
 - centrifugal control unit 6-6
 - device icons and displays 4-7
 - keyboard 4-9
 - perfusion screen 4-13, 4-17
 - precautions summary 12-6
 - roller pump 5-14
 - slide bars 4-15
- CPG Tab
 - Auto Dose Setup Subtab 4-29
 - Delivery Subtab 4-26
- D**
- Device Icons and Displays 4-7
 - keyboard 4-9
- Display Areas
 - main screen 2-4
- E**
- Electronic Gas Blender
 - calibration 8-5
 - check gas lines 9-1
 - choosing the blending gas 8-4
 - control and monitor flow 8-8
 - features 8-1
 - gas system precautions summary 12-7
 - gas system warning 12-5
 - installation and connection 8-2
 - local operation 8-10
 - maintenance 12-12
 - messages 8-12
 - operating from CCM 8-9

- overview 2-18
- setting FiO2 alarm 8-4
- setup 8-3
- EMC Tables 11-12
- Emergency Procedures
 - centrifugal pump decouples from drive motor 10-6
 - equipment situations 10-5
 - perfusion situations 10-1
- Equipment Care
 - after each use 12-8
 - instrument tray 12-14
 - monthly 12-9
 - test alarms, alerts and batteries 12-10
 - tube clamps 12-14
- Equipment Precautions 1-5, 12-6
- Equipment Situations
 - CCM malfunctions 10-8
 - loss of servo control 10-8
 - module failure 10-7
 - sensor failure 10-8
- Events 4-88

F

- Filter replacement 12-15
- Flowmeter Module
 - adding flow sensors in CCM 4-77
 - attaching flow sensor 7-28
 - connecting flow module 7-28
 - flow monitoring 7-27
 - messages 7-30
 - overview 2-15
 - system response to alarms 7-29
 - test before use 7-25
- Flow Sensors
 - precautions summary 12-7

G

- Gas Flow
 - check monthly 12-9

H

- Hand Cranks
 - changing direction 3-20
 - directional warning 3-20
 - mounting and positioning 3-20
 - operation 5-13
 - warnings 5-13
- Hand Cranks/Standby Pumps
 - check the system 9-1

Index

I

- Indications and Warnings 1-4
- Institutional Controls 2-2
- Interface Modules
 - CDI™ 100/101 7-37
 - CDI™ 500/550 7-39
 - Data Transfer Module RS-232 7-38
 - overview 2-17

K

- Keyboard 4-9

L

- Lamp
 - bulb replacement 12-15, 12-16
 - mounting 3-19
- Level Detect Module
 - adding a level detector in CCM 4-72
 - attaching sensors to reservoir 7-10
 - connecting level sensor system 7-9
 - enabling and disabling level detector system 7-11
 - level monitoring 7-9
 - messages 7-14
 - overview 2-12
 - selecting level detection mode 7-11
 - system response to alarms 7-12
 - system response to alerts 7-12
 - test before use 7-13
 - warnings 12-3
- Level Sensors
 - precaution summary 12-7

M

- Messages
 - Air Bubble Detect Module 7-6
 - CDI™ 7-37
 - Central Control Monitor (CCM) 4-38
 - Electronic Gas Blender 8-10
 - Flowmeter Module 7-28
 - Level Detect Module 7-9
 - Occluder Module 7-32
 - perfuse the patient 9-3
 - perfusion situations 10-1
 - Pressure Module 7-18
 - Temperature Module 7-23
- Min Flow Alarm 4-22
- Modules
 - Air Bubble Detect Module (ABD) 7-3
 - bracket system 3-17
 - features 2-11, 7-1
 - Flowmeter Module 7-27

Interface

- CDI™ 100/101 4-81, 7-37
- CDI™ 500/550 4-82, 7-39
- Data Transfer Module RS-232 7-38
- Level Detect Module 7-9
- module failure 10-7
- Occluder Module 7-31
- precautions summary 12-6
- Pressure Module 7-17
- symbols 12-23
- Temperature Module 7-23

O

- Occluder
 - Responses
 - full close response 4-91
 - full open response 4-91
 - go to % flow response 4-91
 - no response 4-91
- Occluder Module 7-31
 - adding an occluder in CCM 4-69
 - calibration of 7-34
 - during use 7-34
 - inserting tubing 7-33
 - messages 7-35
 - overview 2-16
 - test before use 7-34

P

- Password
 - configuration 4-51
 - set 4-51
- Perfusion Screen 4-11
 - creating a new perfusion screen 4-56
 - displays 4-17
 - editing 4-103
 - message area and priorities 4-17
 - mute all 4-17
 - options 4-11
 - primary pump 4-13
 - pump and clamp timers 4-18
 - pump controls and displays 4-14
 - return to main 4-12
 - saving 4-97
 - Setup Tab 4-19
 - tabs 4-15, 4-18
 - to open 4-13
 - view summary 4-11

Index

Power

- auxiliary outlet 3-3
- battery 3-4
- circuit breakers 3-2
- equipment precautions 12-1
- nominal power consumption 11-15
- power cord 3-2
- verify on 9-1

Power Cord 9-1

Pressure Module

- adding pressure transducers in CCM 4-75
- calibrating pressure transducer 7-19
- label and connect pressure system 7-17
- messages 7-21
- overview 2-13
- pressure monitoring 7-17
- pressure monitoring warnings 12-5
- setting pressure limits 7-18
- system response to alarms 7-20
- system response to alerts 7-20
- test before use 7-21

Pulse Mode

- centrifugal control unit 6-12
- roller pump 5-21

Pump Tab

- Pulse Subtab 4-37
- Summary Subtab 4-36

R

Reassign Module Subtab 4-33

Roller Pump

- auto delivery 2-9
- cables 5-3, 5-6
- check start-up test 5-16, 9-1
- cleaning of tube clamps 12-14
- continuous mode 2-9, 5-20
- controls and displays 5-14
- features 2-8, 5-1
- flow constants 5-20
- installation and connection 5-3
- installing tubing 5-7
- manual operation 5-13
- master/follower 2-9, 5-25
- menu 5-17
- messages 5-27
- mounting 5-3
- occlusion warnings 5-10
- operating hand crank 5-13
- Pulse mode 2-9, 5-21
- pumping warnings 12-4

Responses

- no response 4-88
- pause response 4-89
- reduce speed response 4-85
- stop response 4-89
- rotating raceway 5-5
- servo control 2-9
- setting occlusion 5-10
- symbols 12-23
- test overspeed and pump jam 12-11
- tube sizes 5-19

Run a Case

- check the system 9-1
- perfuse the patient 9-3
- power on 9-1
- set up 9-1

S

Security 4-10

Service

- maintenance inspections 12-17
- service policy iii, 12-17

Servo

- loss of control 10-6
- roller pump 2-9, 5-23, 5-24

Setup Tab

- Gas Subtab 4-20
- Occluders Subtab 4-23
- Patient Subtab 4-19
- Pumps Subtab 4-21
- Time/Date Subtab 4-25
- Timers Subtab 4-24

Slide Bars

- adjusting 4-15
- centrifugal pump 4-17
- electronic gas blender 4-17
- primary pump 4-15
- roller pump 4-17

Spare Parts 12-21

Symbol Key

- base 12-23
- central control monitor 12-25
- modules 12-24
- pump control 12-24

System Base

- auxiliary outlet 3-3
- battery 3-4
- castors and wheel locking system 3-12
- circuit breakers 3-2
- components 3-2
- features 2-3
- module bracket system 3-17
- module covers 3-21

Index

- poles, shelf, brackets 3-12
- power cord 3-2
- pump platform 3-17
 - extensions 3-18
- system network 3-11
- System Components 12-18
- System Network 3-11
- System Philosophy 2-1
- System Tab
 - Module Info Subtab 4-35
 - Power Subtab 4-33
 - Reassign Module Subtab 4-33
 - Settings Subtab 4-32
- System Time 4-17

T

Tabs

- Aux Tab 4-31
- CPG Tab 4-26
- Pump Tab 4-36
- Safety Tab 4-26
- Setup Tab 4-19
- System Tab 4-32

Temperature Module

- adding temperature sensors in CCM 4-79
- connecting probe and module 7-23
- labeling probe 7-23
- messages 7-25
- overview 2-14
- setting alarm limits 7-24
- system response to alarms 7-24
- temperature monitoring 7-23
- temperature monitoring warnings 12-5
- test before use 7-25

Training Overview 1-7

V

View Summary 2-5, 4-12, 4-104

W

Warnings and Precautions

- battery power 12-6
- centrifugal pumping 12-5
- equipment precautions 12-1, 12-6
- gas system 12-5
- institutional controls 2-2
- level and air detection 12-3
- pressure monitoring 12-5
- roller pumping 12-4
- summary 12-1
- temperature monitoring 12-5
- warnings 12-3

Water Trap Maintenance 12-13

Limited Warranty

Terumo Cardiovascular Systems Corporation warrants that this product will be free from defects in workmanship or material for one year from the date of shipment. This warranty does not apply to filters, light bulbs, fuses, or other expendable items, or to those parts damaged by improper use, accident, improper maintenance or unauthorized repair.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Limitation of Remedies

As your exclusive remedy under this warranty, Terumo Cardiovascular Systems Corporation will repair or replace free of charge, or at Terumo Cardiovascular Systems Corporation's option, return the purchase price of, any part or unit found to be defective in workmanship or material during one full year from the date of shipment.

Terumo Cardiovascular Systems Corporation shall not be liable under any circumstances for any consequential, incidental or indirect damages or expenses associated with this product or its use. This exclusion does not apply to claims for personal injury by a third party.

Customers

If a warranty condition develops, contact Terumo Cardiovascular Systems Corporation Service, or your authorized distributor. This warranty gives you specific legal rights; you may have other rights as well, which vary from state to state in the U.S.A.

In the United States, contact the Customer Service Department:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103 U.S.A.
Telephone: (734) 663-4145 (800) 521-2818
Fax: (734) 741-6449

Outside the United States, please contact your authorized Terumo Cardiovascular Systems Corporation distributor regarding local warranty conditions or contact the Technical Support Department at Terumo Cardiovascular Systems Corporation:

Telephone: (734) 663-4145
Fax: (734) 741-6449

Note: All returned goods must have a Returned Goods (RG) number prior to return.



TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
6200 Jackson Road, Ann Arbor, Michigan 48103, USA
(734) 663-4145 (800) 521-2818



TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium



TERUMO AUSTRALIA PTY LTD,
Macquarie Park NSW 2113, Australia

TERUMO CORPORATION
44-1, 2-Chome, Hatagaya, Shibuya-ku,
Tokyo 151-0072, Japan