QUEST MPS® 3

Smarter Myocardial Protection™

Operations Manual

QUEST Medical, Inc.

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Quest Medical - MPS® 3 System

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Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Read this Operations Manual prior to operating the MPS 3 System. The attending clinician is solely responsible for the setup and use of this System.

Only genuine Quest Medical Disposable components, including MPS 3 Delivery Sets and optional accessories, can be used with the MPS 3 System to ensure the intended system performance and reliability.

Accompanying documents shall be consulted before use of equipment or accessories.

This device is not designed, sold, or intended for use except as indicated. All Operations Manual instructions must be followed. In no event shall Quest be responsible for failures, errors, or other liabilities resulting from customer's noncompliance with the procedures and precautions outlined herein.

The MPS 3 System and MPS 3 sterile disposables are covered under one or more of the following U.S. Patents: 7,842,003 and 8,475,138. Also covered by pending U.S. and International Patents and Patent applications.

Operations Manual
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1 Introduction

Quest Medical, Inc. recognizes the need for increased flexibility in cardioplegia delivery. The Quest Medical MPS 3 System enables a variety of intraoperative myocardial protection protocols using Microplegia™ exclusively available through the MPS 3 System technology. The MPS 3 System provides complete control over several elements of myocardial protection, including composition, distribution, temperature, and safety.

The MPS 3 System is the latest addition to the MPS line of Quest Myocardial Protection Systems, which have been the market leader for over 20 years and completed over 1 million cases worldwide.

The MPS 3 System sets the standard for state-of-the-art cardioplegia delivery and myocardial protection. The system allows operators to customize cardioplegia solutions by varying blood/crystalloid ratios, drug delivery, flow and pressure regulation, and temperature control. The new touchscreen controller delivers all critical information to the perfusionist and allows for full control of cardioplegia delivery. Increased functionality and flexibility will allow operators to improve patient care with individualized protocols with specific drug compositions and concentrations to provide optimum myocardial protection.

The MPS 3 System has also been updated to a smaller, modular design to better fit the diverse landscape of heart-lung machine setups. This allows the MPS 3 System to be fully integrated with the heart-lung machine and allow for ideal cardioplegia circuit setup, while keeping the controls easily within reach for convenience. The same pumping technology that has been a staple for the Quest Medical MPS Systems has been dramatically enhanced to increase performance, advance safety, and improve quality. Case setup and delivery set installation have been simplified to allow for quick and easy setup. The MPS 3 System sets a standard in cardioplegia delivery systems.

The Operations Manual is to be used for the installation, operation, and maintenance of the MPS 3 System. While the system has been designed to be intuitive in operation, the Operations Manual is an essential aid for the safe and effective use of the MPS 3 System.

Prior to operation, please carefully read these instructions in detail.

Thank you for investing in Quest Medical, Inc.

1.1 About This Operations Manual

This Operations Manual describes the MPS 3, Myocardial Protection System. It details the MPS 3 System overview, installation, basic operating principles, setting case parameters, navigating the graphical user interface, and system maintenance. This manual is intended for use by perfusionists trained in delivering cardioplegia solution to the myocardium during cardiopulmonary bypass surgery. It is also intended for biomedical technicians and staff trained to install, service, and troubleshoot this equipment. Please read the Operations Manual prior to operating the MPS 3 System.

1.2 Indication for Use

The Quest Medical MPS 3 Myocardial Protection System, consisting of the MPS 3 Console, the MPS 3 Controller, and the MPS 3 Disposables (MPS 3 Delivery Set and optional accessories) together is intended for use by perfusionists and physicians to deliver whole blood (from any arterial source) and/or cardioplegia solutions to the heart during open-heart surgery on either an arrested or beating heart for use up to six hours in duration.

1.3 Contraindications

The MPS 3 System should not be used on patients unable to tolerate extracorporeal circulation.

1.4 Symbols Used in this Operations Manual

The symbols used in these instructions are intended to help the operator find specific information and provide attention to critical information. Understanding the meaning and use of these symbols is important to avoid injury to the patient / operator or unintended damage to the MPS 3 System.

Symbol	Description
	Accompanying documents shall be consulted before use of equipment or accessories.
	Please read before using this device, symbol is used to alert you to potential **Personal Injuries Hazards & Cautions**, understand all safety messages that follow this symbol to avoid injury to the operator and/or patient.
	Consult instructions for use.
	Electronic instructions for use.
	Additional notes for information, suggestions and comments.
	**Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.**
	Catalog Number

1.5 Terminology / Abbreviations

This Operations Manual may contain terminology and abbreviations relevant to the indication for use and use environment. Please refer to the table below for definitions and/or descriptions of those terms.

Term	Definition / Description
Normal Use	Expected normal use pattern for device.
Cardioplegia	The fluid solution, typically comprised of blood mixed with drugs, delivered to the myocardium with the intention to arrest or revive the heart.
Simulgrade	The ability to deliver Antegrade and Retrograde cardioplegia simultaneously.
Perfusionist	A medical professional responsible for extracorporeal oxygenation of the blood during open-heart surgery and for the operation and maintenance of equipment often including a heart-lung machine.
Priming Volume	The minimum volume of priming solution remaining after air is purged from an initially sterile set prior to use.
System Pressure	The pressure sensed in the bubble trap of the heat exchanger.
Delivery Pressure	The pressure sensed at the delivery site using an external pressure sensor. When an external sensor is not used, delivery pressure is the same as System Pressure.
Flow Rate	The rate of delivery of the cardioplegia solution expressed in units of ml/min.
Chamber Pressure	The pressure sensed in the left and right chambers of the pump.
Delivery Temperature	The temperature of the delivery fluid sensed in the bubble trap of the heat exchanger.
B/C Pump	Blood / Crystalloid pumping mechanism (does not include arrest or additive pumps).
CCW	Counterclockwise
CPB	Cardiopulmonary Bypass
ECG	Electrocardiogram
EDMS	Electronic Data Management System
EMC	Electromagnetic Compatibility
GUI	Graphical User Interface
HCU	Heater Cooler Unit
Hgb	Hemoglobin
HLM	Heart-Lung Machine
MPS	Myocardial Protection System
VTBD	Volume to be Delivered
TTBD	Time to be Delivered

2 System Overview

The MPS 3 System consists of the **MPS 3 Console**, **MPS 3 Controller**, and the **MPS 3 Disposables** (MPS 3 Delivery Set and optional accessories). The primary function of the MPS 3 System is to aid the perfusionist in cardioplegia delivery to the patient during Cardiopulmonary Bypass Surgery.

The MPS 3 Console, in conjunction with the MPS 3 Disposables, combines blood from the heart-lung machine and crystalloid from the IV-bag in a specified ratio and then adds in the drug (Arrest Agent or Additive). The electro-mechanical MPS 3 Console incorporates a blood/crystalloid pump, temperature controllable water circulation system, pressure and temperature monitors, a sensor interface with the MPS 3 Delivery Set, an Arrest Agent pump, an Additive pump, and ultra-sonic air detection sensors. The system monitors and controls the blood-crystalloid ratio, drug concentration, flow rate, pressure, temperature, and delivery route of the cardioplegia solution delivered to the patient.

The MPS 3 System is a software-controlled system with a touchscreen, graphical user interface MPS 3 Controller. The MPS 3 Controller can be positioned remotely from the MPS 3 Console on any vertical pole of the Heart Lung Machine via the mounting arm, affording flexibility in equipment setup to achieve the most desirable circuit setup. The MPS 3 Controller is utilized by the operator to select all parameters, initiate/stop cardioplegia delivery, monitor delivery parameters, and view/save relevant case information and data.

2.1 MPS 3 Console

The MPS 3 Console combines the Blood and Crystalloid solution to a proportion set by the operator and adds the arrest agent or additive drug to the solution. This delivery solution is then passed through the heat exchanger, where the temperature of the delivery fluid is set by the operator and regulated by the MPS 3 Console water circulation system. The delivery fluid is monitored for delivery pressure, temperature, and air bubbles before it is delivered to a patient, at the desired flow rate.

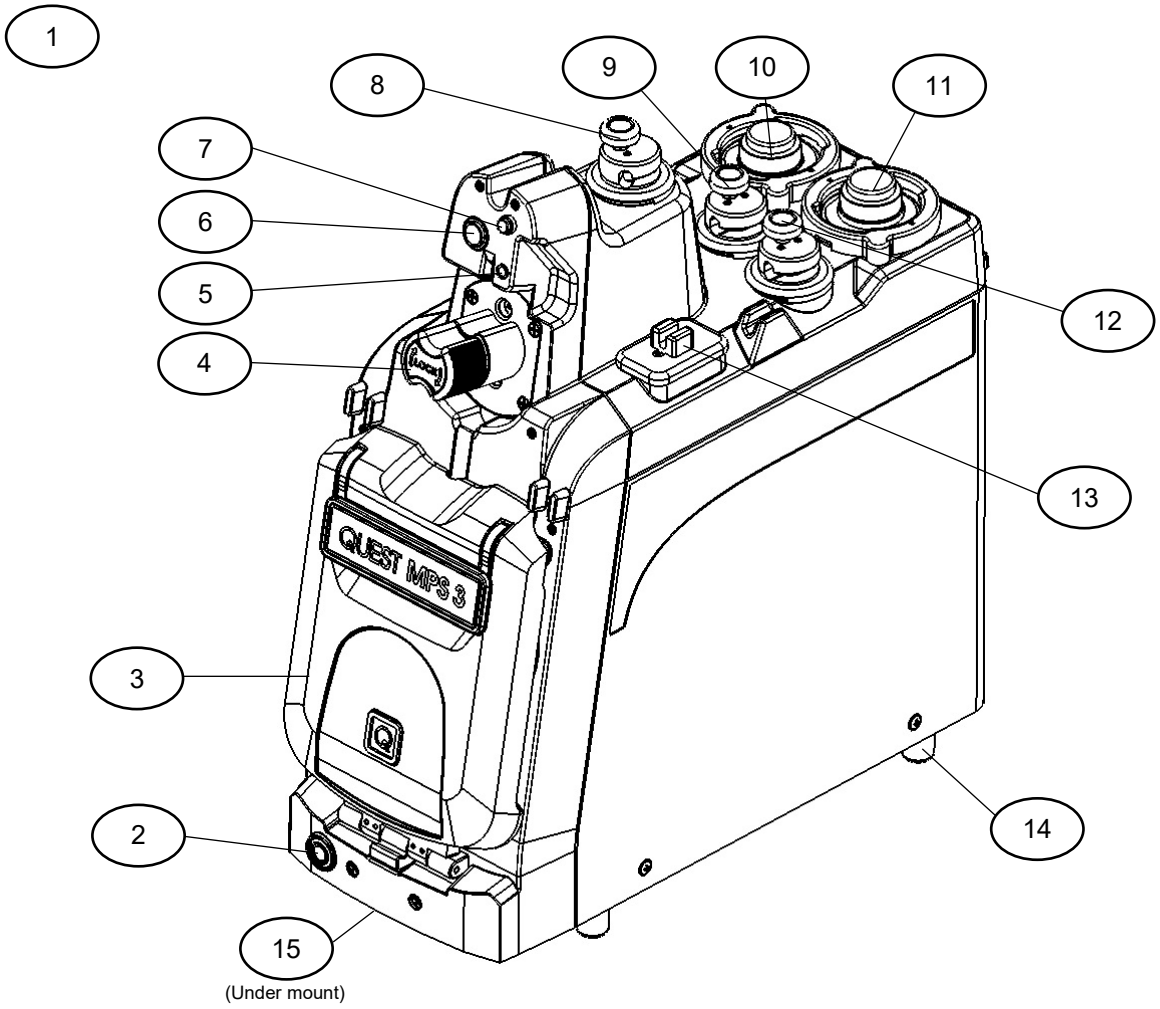


Figure 1: MPS 3 Console Overview

Item	Name	Function
1	MPS 3 Console	
2	Push Button Switch	Sleep (OFF) / Wake (ON)
3	MPS 3 Door	Contain Blood/Crystalloid Cassette
4	Heat Exchanger (HEX) Locking Knob	Secure Heat Exchanger
5	Temperature Sensors	Monitor Delivery Temperature
6	Pressure Transducer	Monitor System Pressure
7	Fluid Level Sensor	Monitor Air in Heat Exchanger
8	Vent Valve	Control Vent Delivery / Expel Air from HEX
9	Retrograde Valve	Control Retrograde Delivery
10	Additive Pump (Green)	Control Additive Delivery
11	Arrest Agent Pump (Yellow)	Control Arrest Agent Delivery
12	Antegrade Valve	Control Antegrade Delivery
13	Air In Line Sensor	Detect Air in Delivery Line
14	Mounting Feet (4X)	Facilitate Mounting
15	Front Handle (under mount)	Facilitate Transport

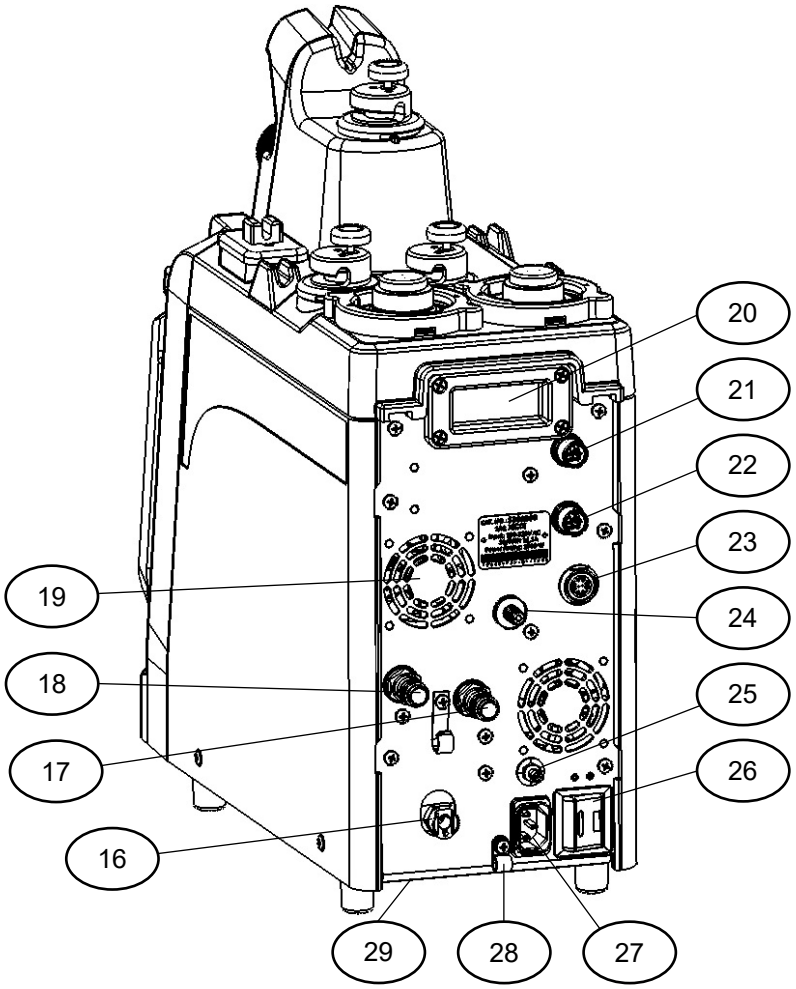


Figure 2: MPS 3 Console Rear Panel

Item	Name	Function
16	Circulation System Drain Port	Drain Circulation System
17	Water Outlet Port	Water Outlet to Cold Water Source
18	Water Inlet Port	Water Inlet from Cold Water Source
19	Cooling Fans (2X)	Maintain Internal Temperature
20	Rear Handle	Facilitate Transport
21	Antegrade Ext. Pressure Connector	Monitor External Antegrade Pressure Transducer
22	Retrograde Ext. Pressure Connector	Monitor External Retrograde Pressure Transducer
23	Console to Controller Comm Port	Connect Console to Controller Cable
24	Medical Air Inlet	Connect Medical Air to Console
25	Ground Equalization Plug	Ground Console
26	Main Power Switch	AC Mains Power Switch
27	Power Plug Socket	Connect AC Mains Power Plug
28	Power Cable Strain Relief	Secure Power Cable
29	Drip Pan Drain Port (under mount)	Drain Drip Pan

2.2 MPS 3 Controller

The MPS 3 Controller is used to select and set cardioplegia parameters including blood/crystalloid ratio, drug concentrations, flow rate, pressure limits, and delivery temperature among others. The MPS 3 Controller is controlled by the operator to start and stop cardioplegia delivery via the touchscreen interface or the flow knob on the front of the MPS 3 Controller. The MPS 3 Controller interfaces with the MPS 3 Console through the Console to Controller Communicable Cable attached on the back of both modules. Power is supplied to the MPS 3 Controller through the Console to Controller Communication Cable.

The MPS 3 Controller allows the operator to perform the following functions:

- Start / Stop Cardioplegia Delivery
- Set, View, and Control System Parameters (Pressure, Volume, Flow Rate, and Temperature)
- View / Address Alarm Notifications
- Toggle System Settings
- View Case Logs / Dose Data
- View ECG Trace
- Protocol Management
- Monitor System Status / Diagnostics

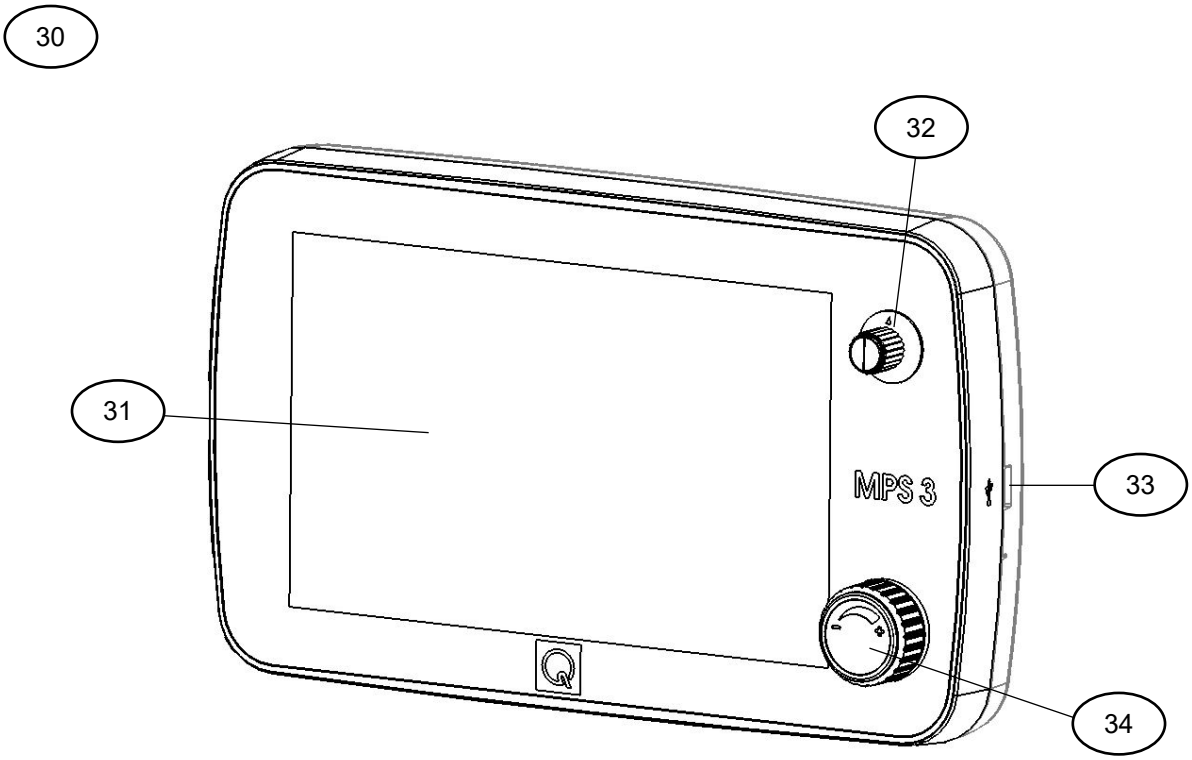


Figure 3: MPS 3 Controller Overview

Item	Name	Function
30	MPS 3 Controller	
31	Touchscreen Display	Monitor / Select / Set Parameters
32	Set Knob	Scroll Through Parameters
33	USB Port	Connect USB Drive
34	Flow Control Knob	Start / Stop Cardioplegia Delivery

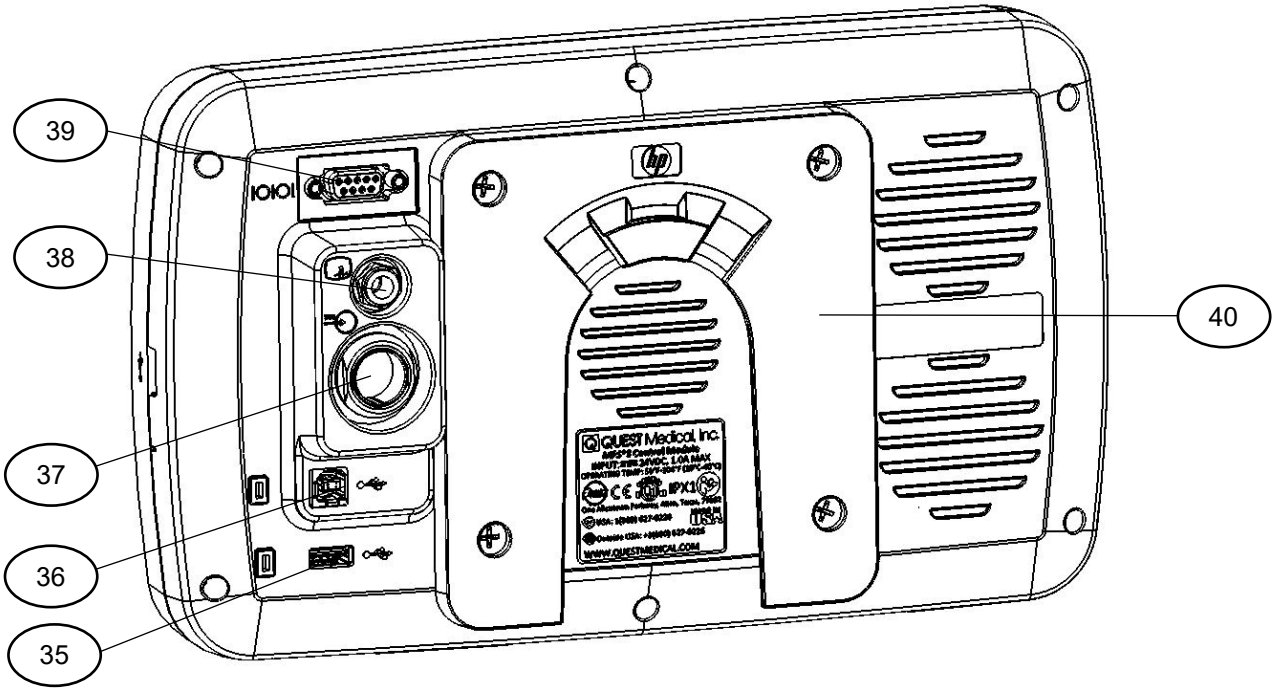


Figure 4: MPS 3 Controller Rear Panel

Item	Name	Function
35	Type A USB Port	Expansion Port
36	Type B USB Port	Service Connection or Electronic Data Management System
37	Communication Cable Port	Connect Console to Controller Communication Cable
38	Analog ECG Port	Connect Analog ECG Cable
39	RS-232 Port	Connect Electronic Data Management System
40	Controller Mounting Bracket	Connect to Controller Mounting Arm

2.3 MPS 3 Disposables

The MPS 3 Disposables (MPS 3 Delivery Sets and optional accessories) are designed to work in conjunction with the MPS 3 Console. The MPS 3 Delivery Sets are sterile, single use disposables which consist of a blood/crystalloid cassette, heat exchanger, blood/crystalloid source lines, delivery extension line, and appropriate tubing and luer fittings to complete the cardioplegia circuit. Arrest Agent and Additive Cartridges may be included with the Delivery Set or may be purchased separately to allow for pharmacy filling. A full list of MPS 3 Delivery Sets and optional accessories can be found in Section 14.2.

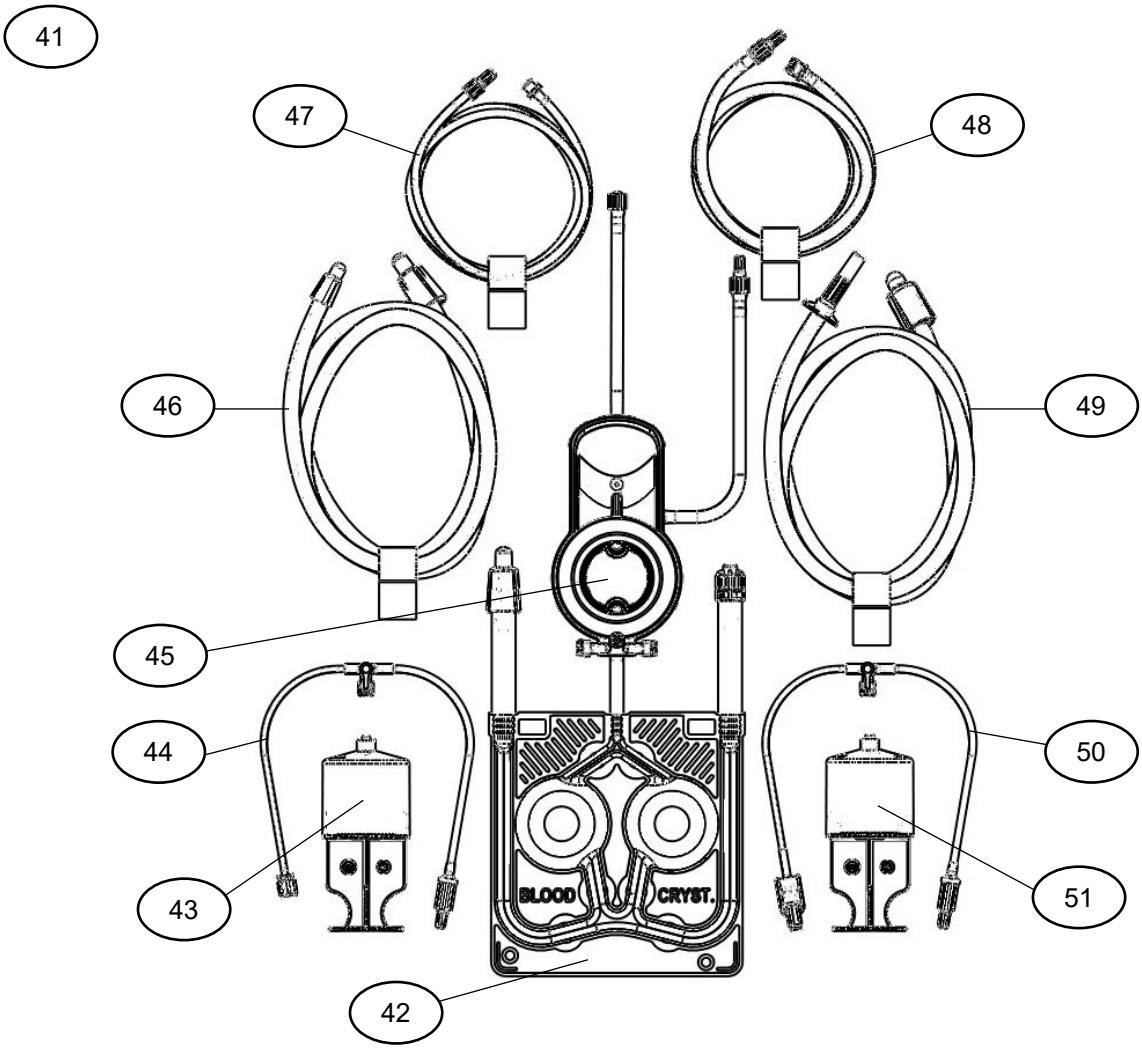


Figure 5: MPS 3 Delivery Set

Item	Name	Function
41	MPS 3 Delivery Set	
42	Blood / Crystalloid Cassette	Ratio Blood / Crystalloid and pump to HEX
43	Additive Cartridge	Deliver Additive
44	Additive Delivery Line	Fill / Refill / Deliver Additive to HEX
45	Heat Exchanger (HEX)	Regulate Temperature of Cardioplegia
46	Blood Source Line	Connect Blood Source to MPS 3 Circuit
47	Vent Line Extension	Connect Vent Line to Reservoir
48	Blood Delivery Extension Line	Line to Table
49	Crystalloid Source Line	Connect Crystalloid Source to MPS 3 Circuit
50	Arrest Agent Delivery Line	Fill / Refill / Deliver Arrest Agent to HEX
51	Arrest Agent Cartridge	Deliver Arrest Agent

3 System Specifications and Performance

3.1 Console Specifications

MPS 3 Console	
Classification of Installation	Stationary
Mode of Operation	Continuous
Ingress Protection Marking	IPX1
AC Mains Supply Voltage	100-120 V 200-240 V
Frequency	50/60 HZ
Nominal System Power Consumption	1320 W (100-120V) 1320 W (200-240V)
Lithium Iron Phosphate Battery Capacity	3200 mAh
Battery Performance	30 minutes of battery time (AC heaters will be disabled)
Battery Overcurrent Protection	Yes
Protection from Electric Shock	 Type CF (Cardiac Floating) Applied Part
Console Physical Dimensions	Length: 16 1/2" Width: 7" Height: 18 1/2"
Console Weight	37.25 lbs.
Operating Environment	Temperature: 10°C to 40°C Humidity: 30 to 75 % ± 3% (non-condensing) Pressure: 700 to 1060 hPa Altitude: < 2000 m
Storage Environment	Temperature: -20°C to 70°C Humidity: 10 to 93 % Pressure: 500 to 1060 hPa Altitude: < 2000 m
Shipping Environment	Temperature: -20°C to 70°C Humidity: 10 to 93 % Pressure: 500 to 1060 hPa
Flow Rate	5 ml/min to 1000 ml/min
Blood to Crystalloid Ratios	All Blood; 66:1; 49:1; 39:1; 32:1; 27:1; 24:1; 21:1 to 1:1; 1:2 to 1:9 and All Crystalloid
Arrest Delivery Concentration	0 mEq/L to 40 mEq/L
Additive Delivery Concentration	0 ml/L to 50 ml/L
System Pressure	0 mmHg to 750 mmHg
Delivery Temperature Control Range	Cold, 15°C to 39°C

MPS 3 Console	
Accuracy	**Flow Rate:** 5% or 5 ml/min (whichever is greater) **Cardioplegia Delivered:** 5% or 10 ml (whichever is greater) **Drug Volume Delivered:** ±1 ml or 5% (whichever is greater) **System Pressure:** 5% or 10mmHg (whichever is greater) **Displayed Delivery Temperatures:** ±1°C
Hospital Air Pressure Range	Max 55 PSI Inlet
System Safety Compliance	IEC 60601-1 Ed 3.1
System EMI Compliance	IEC 60601-1-2 Ed 4th
Battery Safety Compliance (Maintenance Free Battery) Only Quest Medical replaceable battery	Battery complies to the following safety standards: • IEC62133-2, Ed. 1.0 • IEC62281, Ed. 4.0 • UN/DOT 38.3

3.2 Controller Specifications

MPS 3 Controller	
Dimensions	Width: 12.5" Depth: 4.5" Height: 7.5"
Weight	10 lbs.
DC Supply Voltage	24 VDC
Communication ports	• Isolated USB Host port – 2 Ports (USB memory device access) • Isolated Device USB port – 1 Port (PC or Hospital EDMS connectivity) • Isolated RS 232 port – 1 Port (Legacy EDMS connectivity) • Isolated ECG Port – 1 Port (Analog)
Display Panel	Viewing Angle: 85~85° (H), -85~85° (V) Luminance: 640 cd/m2 Resolution: 1280 x 768 pixels Display Size: 9.0"
Ingress Protection Marking	IPX1
Mounting	Pole Mountable

3.3 MPS 3 Disposables Specifications

Part Number REF	Blood Source Line ID	Blood Source Line Length	Extension Line Length	Normal Mode Priming Volume[1]	Low Volume Mode Priming Volume[1]
Delivery Sets with 10 Core Heat Exchangers					
5003103	1/4” (6.35 mm)	42” (106 cm)	72” (183 cm)	<220 ml	<190 ml
Delivery Sets with 16 Core Heat Exchangers					
5163100	1/4” (6.35mm)	72” (183 cm)	120” (305 cm)	<240 ml	<210 ml
5163102	1/4” (6.35 mm)	72” (183 cm)	120” (305 cm)	<260 ml	<230 ml
5163102-AS	1/4” (6.35 mm)	72” (183 cm)	72” (183 cm)	<250 ml	<220 ml
5163103	1/4” (6.35 mm)	42” (106 cm)	72” (183 cm)	<230 ml	<200 ml
7003101	3/16” (4.76 mm)	72” (183 cm)	N/A	N/A	<180mL

[1]Priming volume is the blood diluting priming volume which includes the BC Cassette, Heat Exchanger, and Blood Source Line volumes.

Other Specifications	
Heat Exchanger Filter Size	160 Microns
Additive Cartridge Volume	75 ml
Arrest Agent Cartridge Volume	75 ml
Cartridge Lubrication Application	Manufactured per ISO 7886-1
Delivery Set Packaging Dimensions	22” x 10” x 3.5”
Delivery Set Packaging Weight	< 910 g
Sterilization Method	Ethylene Oxide per ISO 11135
Blood Side Biocompatibility	ISO 10993-1: Cytotoxicity,Sensitization, Irritation, Acute Systemic Toxicity, Pyrogenicity, Subacute/Subchronic Toxicity, Hemocompatibility
Bioburden	Manufactured to ISO 11737 Requirements
Packaging	Tested per ASTM D4169 and Meets Requirements per ISO 11607-1

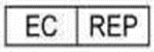
3.4 Glossary of Symbols and Labels

3.4.1 Console and Controller Symbols and Markings

Symbol	Description
ANTEGRADE	Antegrade External Pressure Transducer Cable Connection Port
RETROGRADE	Retrograde External Pressure Transducer Cable Connection Port
Medical Air Max 55 PSI 380 kPa	External Medical Air Access Port
	Stand-by
	Two-way Data Connection
	Console to Controller Communication & Power Cable Port
	Potential Equalization Terminal Connection
	Console Circulation System Drain
	Console Water Inlet
	Console Water Outlet
IPX1	Ingress Protection Marking
	"ON" (Power)
	"OFF" (Power)
	USB Port
	Serial Data Connection Port

Symbol	Description
	Controller Electrocardiogram Cable Port
	Type CF (“Cardiac Floating”) applied parts that may come in direct contact with the heart.
	The Minimum Temperature Limit.
	The Maximum Temperature Limit.
	The acceptable Upper and Lower Limits of relative humidity for transport and storage.
	The acceptable Upper and Lower Limits of atmospheric pressure for transport and storage.
	Dispose all electrical and electronic equipment to a safe and responsible collection, recycling and recovery agency.
	All electrical and electronic components are RoHS II compliant.
	Keep away from rain and dry condition during transport.
	Fragile, Handle with care
	Country of manufacturer
	Non sterile
	Authorized representative in the European Community.
	Product meets the requirements of the applicable EC directives 93/42/EEC.
	Controlled Batch Code/Number
	Serial Number

3.4.2 Delivery Set and Optional Accessories Symbols and Markings

Symbol	Description
	Accompanying documents shall be consulted before use of equipment or accessories
	Do not use if package is damaged
	Do not resterilize
	Single use only
	Non-pyrogenic
	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Sterilized by Ethylene Oxide
	Manufacturer
	Use-by date
	Authorized representative in the European Community.
	Product meets the requirements of the applicable EC directives 93/42/EEC.
	Controlled Batch Code/Number
N/A	Not made with natural rubber latex

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4 Warnings and Cautions

Prior to installation and activation of the MPS 3 System, the operator shall consult the instructions for use for the equipment and accessories carefully to avoid injury. The operator shall comply with the following safety procedures as well as the safety comments and recommendations presented throughout these instructions for use. The manufacturer accepts no liability for any damage resulting from the improper use of this equipment and/or for any purpose other than those covered by these instructions.

4.1 General Warnings and Precautions

Please read all warnings and precautions before using the MPS 3 System. It is important to understand all safety messages that follow in this section to avoid potential injury or harm to the operator and/or patient and avoid unintended damage to the MPS 3 System.

The MPS 3 System has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standard. However, the possibility of electromagnetic or other interference may still exist. When experiencing interference, relocating the system may help to eliminate any interference.

- For Professional Use Only.
- The MPS 3 System must be attended at all times during the procedure.
- It is important to observe the following precautions with the standard safety procedures as well the specific safety recommendations presented in this Operations Manual.
- **USE ONLY QUEST MEDICAL AUTHORIZED SERVICE TECHNICIANS**. Quest Medical, Inc. cannot assure safe operation of the MPS 3 System if it is serviced by anyone other than an authorized service technician. Unauthorized service voids all warranties.
- Use of the device is restricted to professionally trained personnel in accordance with the instructions below.
- The battery should only be serviced or replaced by Quest Medical authorized service technicians.
- **DO NOT** operate the unit in the proximity of flammable mixtures; the MPS 3 system is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide. Use in well-ventilated area.
- Keep solvents, flammable liquids, and sources of intense heat away from the MPS 3 System as they may damage internal and external parts and compromise the integrity of the device.
- Before use, inspect the MPS 3 System for signs of physical damage or deterioration. Specific areas to inspect include the inner door latches for proper locking, Controller display panel surface and control knobs, the mechanism boot (surface where cassettes are

installed) for tears and separation, and the power cabling for deterioration of insulation or bare wires. If a problem is identified, **DO NOT USE** the MPS 3 System. Call an authorized service representative from Quest Medical for correction.

- **DO NOT USE** an MPS 3 System exhibiting electrical malfunctions such as intermittent power failure or circuit breaker shut off. Call a Quest Medical authorized service technician if the MPS 3 System is exhibiting electrical malfunctions.

- **Attend to all** alarms. Read and acknowledge all alarm messages.

- **DO NOT USE** if air is not purged from the delivery circuit. Proceeding with air in the delivery circuit may cause a patient injury (air embolism).

- One (1) ml of arrest agent and/or additive is delivered into the heat exchanger each time the PURGE button is pressed. Repeatedly using the PURGE button will deliver excess arrest or additive into the cardioplegia solution.

- During MPS 3 System use, always clamp all cardioplegia input and delivery lines **BEFORE OPENING** the MPS 3 System door. The MPS 3 System provides protection against free flow if the door is closed. This protection is maintained during any console failure and is not affected by power outages. Failure to clamp the lines before opening the door will result in unrestricted flow (FREE FLOW) of solutions, including drainage from the arterial line of the extracorporeal circuit and possible patient injury.

- Avoid **OPERATOR INJURY**; ensure that all fingers are clear from the door edges before closing the MPS 3 System.

- The surgeon is responsible for monitoring the patient's physical condition: observing the heart, aorta, and coronary sinus for indications of an overpressure condition, inaccurate arrest agent, or additive delivery. Failure to maintain adequate arrest during periods of ischemia may result in myocardial injury.

- **DO NOT USE** the MPS 3 System under any of the following conditions:

    - **DO NOT USE** the MPS 3 System if it repeatedly fails internal diagnostics, is visibly damaged, or has loose or missing components.

- Ensure use of MPS 3 System only with proper functioning equipment in the OR. Use of malfunctioning equipment could be a potential fire hazard.

- The MPS 3 System is able to interface with a heater cooler unit to warm or cool cardioplegia and/or blood. The heater cooler's water quality must be maintained per manufacturer recommendation. **DO NOT** connect the MPS 3 Console to a heater cooler unit that has not been properly disinfected per the manufacturer recommendations.

- The long-term effectiveness of the MPS 3 circulation system disinfection procedures, the supplemental use of hydrogen peroxide to inhibit bacterial growth in between disinfection cycles, and the recommended interval for disinfection were evaluated in the MPS 2 for up to 6 months. The disinfection and water maintenance procedures mitigate but do not prevent biofilm formation.

- Water quality in the MPS 3 must be maintained per the recommendations in Section 12.1. **DO NOT** connect a heater cooler unit to the MPS 3 Console that has not been properly disinfected per the recommendations in Section 12.1.3.

- The MPS 3 System has water circuits, air water interface, and circulating pumps. Devices with these design features may have the potential to aerosolize. To minimize the risk of patient infection from contaminated aerosols, please utilize 0.22 micron filtered tap water, follow the cleaning and disinfection instructions located in Section 12, and ensure that the hypothermic reservoir lid is closed at all times.

4.2 Installation and Setup Cautions

Please read all warnings and precautions before using the MPS 3 System. It is important to understand all safety messages that follow in this section to avoid potential injury or harm to the operator and/or patient and avoid unintended damage to the MPS 3 System.

The MPS 3 System needs to be installed and put into service according to the EMC information provided in appendix section 15.1 of this manual.

Extra precaution is required when the MPS 3 System is used in close proximity of high frequency surgical instruments which are intentional emitters of electromagnetic energy, such devices known for emitting are diathermy, electrocautery, and any other devices that are known for causing electromagnetic disturbance such as RIFD devices.

The MPS 3 System should not be used adjacent to or stacked with other unapproved electrical equipment. In cases in which adjacent or stacked use is necessary, the MPS 3 System should be observed to verify normal operation in the configuration in which it will be used.

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 MPS 3 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- The operator should ensure that the MPS 3 Controller is securely attached and positioned in optimum viewing angle.

- Avoid **OPERATOR INJURY**. If the MPS 3 Controller is mounted to a vertical pole on the HLM via a mounting arm, ensure that the Controller is secure on its arm and all arm tensioners are tight enough to prevent movement. Failure to do so could cause the MPS 3 Controller to fall resulting in possible operator injury.

- Use the proper electrical connections. The MPS 3 System must be plugged into a hospital-grade electrical outlet on an isolated circuit. The hospital Biomedical Engineering department should periodically measure the MPS 3 System ground leakage current to verify acceptable limits. Use only Quest Medical supplied power cords.

- Electromagnetic Interference: The MPS 3 System meets the requirements of the International EMI standard IEC 60601-1-2 for Medical Equipment. If other instruments near the MPS 3 System are having problems possibly associated with electromagnetic emissions from the MPS 3 System, turn the MPS 3 System OFF and ON. If the interference stopped when the MPS 3 System was off, try one or more of the following remedies:
  - Reorient or relocate the receiving device.
  - Increase the separation distance between the receiving device and the MPS 3 System.
  - Connect the MPS 3 System into an outlet on a separate circuit from the receiving instrument(s).
  - If the above actions do not correct the problem, call the Quest Medical Service Department for advice on additional remedies.

- Use only water to prime the water circulation system (except during the cleaning process – Refer to Section 12.1 for more information).
  - During warm delivery, small amounts of cold water are used to regulate temperature. Therefore, the MPS 3 System must always be used with a cold water source.
  - Transportation of the MPS 3 System is restricted. The MPS 3 console should be drained prior to transport outside the operator facility. This prevents damage to electronic components and protects the unit from damage due to freezing.
  - When using a heater cooler unit, ensure water quality is maintained per heater cooler manufacturer recommendations. **DO NOT** connect the MPS 3 Console to a heater cooler unit that has not been properly disinfected per the manufacturer recommendations.
  - The long-term effectiveness of the MPS 3 circulation system disinfection procedures, the supplemental use of hydrogen peroxide to inhibit bacterial growth in between disinfection cycles, and the recommended interval for disinfection were evaluated in the MPS 2 for up to 6 months. The disinfection and water maintenance procedures mitigate but do not prevent biofilm formation.
  - Water quality in the MPS 3 must be maintained per the recommendations in Section 12.1. DO NOT connect a heater cooler unit to the MPS 3 Console that has not been properly disinfected per the recommendations in Section 12.1.3.

4.3 System Warnings and Cautions

Please read all warnings and precautions before using the MPS 3 System. It is important to understand all safety messages that follow in this section to avoid potential injury or harm to the operator and/or patient and avoid unintended damage to the MPS 3 System.

- The MPS 3 System operator is responsible for monitoring and controlling the performance of the system during the surgery. The operator should monitor the delivery parameters displayed on the MPS 3 System and other information presented on the operating room monitors to assess the adequacy and safety of the cardioplegia delivery.

- The analog input port ECG connection on the MPS 3 System Controller is only a signal display and is not a monitoring or diagnostic device. Do not use this information to make decisions on patient care.

- **DO NOT USE** if there are any leaking components or connections (fluid or air). Failure to do so may cause air embolism, patient injury, or death. Throughout the surgery, observe all delivery lines for signs of air or fluid leaks.

- The MPS 3 System provides protection against free flow as long as the door is closed. This protection is maintained during any System failure and is not affected by power outages.

- **DO NOT USE** an MPS 3 System exhibiting electrical malfunctions such as intermittent power failure or circuit breaker shut off. Call a Quest authorized service technician if the MPS 3 System is exhibiting electrical malfunctions.

- Observe all alarm codes and messages. Do not use the MPS 3 System in the event of a non-recoverable (fatal) error message. Contact Quest Medical Customer Service.

- **DO NOT USE** if all the air is not purged from the delivery circuit. Proceeding with air in the delivery circuit may cause a patient injury (air embolism).

- Observe aseptic technique with all tubing connections. Do not over-tighten rigid connections. Use proper sterile technique when passing lines into the sterile field

- **USE ONLY WATER** with no additives to fill the Hypothermic Reservoir with clean 0.22 micron filtered water / ice solutions. Addition of salts, alcohols, or other antifreeze agents may result in super cooling and freezing of cardioplegia solutions and may cause damage to the MPS 3 System.

- The disinfection procedure contained in this Manual has been validated. To reduce the risk of microbiological contamination, operators should clean and disinfect the device according to the instructions contained in this Manual.

- The long-term effectiveness of the MPS 3 circulation system disinfection procedures, the supplemental use of hydrogen peroxide to inhibit bacterial growth in between disinfection cycles, and the recommended interval for disinfection were evaluated in the MPS 2 for up to 6 months, and although biofilm formation is mitigated, it is not prevented.

- **DO NOT USE** any sharp edged or hard objects on the display panel. Touch the screen with your finger to ensure normal operation.

- Operate the panel in a steady environment. Abrupt variation in temperature and humidity may cause malfunction of the panel.

- Avoid high voltage and/or static charge on MPS 3 Controller.

- If the buttons on the controller do not respond to operator's input, it needs to be cleaned. Clean the MPS 3 Controller screen as indicated in MPS 3 cleaning instructions. If the problem persists, contact Quest Medical customer support.

- Ensure that external port covers are closed when not in use.

- **DO NOT CONNECT** anything to the MPS 3 USB port that is not approved by Quest Medical.

- Use the Quest provided USB memory device solely for the MPS 3. **DO NOT USE** this USB memory in other devices or computers not approved for use with the MPS 3 System. Add the Quest supplied USB memory device to your organization's IT security program.

- **DO NOT CHANGE** the file format or directory structure in USB storage device. MPS 3 ONLY recognizes pre-defined formats.

- A Flow rate number that is flashing is indicative of conditions that are less than ideal to attain the desired flow rate. Ensure that the inlet lines are unobstructed and that the device is being filled at a rate greater than the delivery rate. If the flow rate display continues to flash, turn down the flow rate until the flashing stops.

4.4 Disposable Circuit Priming and Delivery Cautions

Please read all warnings and precautions before using the MPS 3 System. It is important to understand all safety messages that follow in this section to avoid potential injury or harm to the operator and/or patient and avoid unintended damage to the MPS 3 System.

- Examine **ALL** sterile packages carefully before opening to confirm the packages' integrity and verify that the expiration date has not passed. The devices are supplied in a sterile, single use package and are non-pyrogenic. **DO NOT USE** a damaged or opened package or if the expiration date has passed.

- Observe aseptic technique with all tubing connections. Do not overtighten rigid connections. Use proper sterile technique when passing lines into the sterile field.

- Dispose of this device according to hospital procedure for contaminated materials.

- **DO NOT LOAD** cassette/cartridges if the pistons are in the forward position. Cycle the power to reset the pistons. If the pistons do not retract, STOP THE MPS 3 System and call Quest Medical Technical Support. If the pump piston is not fully retracted, there may be an unintentional bolus delivery during the onset flow.

- **FULLY INSERT** the tubing through the air-in-line detector for proper MPS 3 System operation.

- Confirm proper installation of the delivery set and accessories disposables. Observe tubing paths and check for kinks, twists, and proper placement and routing. Fill the arrest agent and additive cartridges before priming.

- **DO NOT OVERFILL OR OVERPRESSURIZE** arrest agent or additive cartridges. The maximum allowed cartridge capacity is 75 ml. Overfilling the arrest agent or additive cartridges before or after installation in the console can cause unintentional bolus delivery and possible system malfunction.

- **DO NOT REMOVE** arrest agent or additive cartridges while delivering Cardioplegia. Removing the arrest agent or additive cartridges while delivering cardioplegia can cause inaccurate delivery calculations.

4.4.1 Priming

- **DO NOT PRIME** the delivery set more than 12 hours prior to surgery. Biological contamination is a risk after more than 12 hours.

- Close the door before using the MPS 3 System. The door must be closed to operate the MPS 3 System. However, **DO NOT USE** force to open or close the doors. Forcing a door closed may indicate an improperly installed or overfilled disposable.

- Visually examine all tubing connections for leaks. A leak may cause reduced volumetric accuracy or air entrainment as well as delivery fluid volume loss. If a leak is observed, DO NOT USE the delivery set. Promptly return the delivery set to Quest Medical, Inc. Never open any connection while flow is established.

- The operator should ensure that speaker volume is set to an adequate level before starting a new case.

- **USE ONLY WATER** with no additives to fill the Hypothermic Reservoir with 0.22 micron filtered water / ice solutions. Addition of salts, alcohols, or other antifreeze agents may result in super cooling and freezing of cardioplegia solutions and may cause damage to the MPS 3 System or Delivery Set and cause potential risk to the patient.

- During the water priming process, visually examine the heat exchanger and water lines for leaks. A leak in the heat exchanger may cause biological contamination of the cardioplegia delivery fluid and blood hemolysis. DO NOT USE the delivery set if there is a leak. Promptly return the delivery set to Quest Medical, Inc. See warranty section for instructions

4.4.2 Cardioplegia Delivery

- The MPS 3 essential performance states the device shall perform within the pressure, flow rate, and temperature accuracies specified in the operations manual. If you suspect that the pressure, flow rate, or temperature accuracy is affected by EMC interference, remove power and relocate the device to another area. It should be noted that volume accuracy is directly dependent on flow rate accuracy. If performance continues to be affected discontinue use and contact Quest Medical Field Service.

- When venting, the operator should be aware that system pressures greater than 750 mmHg will cause flow to stop.

- During the venting operation, the arrest and additive pumps are inactive and delivery stops; however, the delivery ratio is maintained at the setting displayed and temperature control is active. This may unnecessarily heat, cool or medicate the volume in the reservoir.

- **DO NOT OPEN** the door while the MPS 3 System is delivering cardioplegia. All valves will close, flow will stop and the pistons will retract to their home positions (safe state).

- The operator is responsible for maintaining safe operating flow rates.

- The ECG connection on the MPS 3 System is only an activity monitor and is NOT A MAIN MONITORING DEVICE. Any decisions in care should be made by a main monitor and not the MPS 3 System display.

- **DO NOT USE** the ports on the MPS 3 Controller during a procedure. This is only for historical data gathering and other file operations.

4.5 System Cleaning

Please read all warnings and precautions before using the MPS 3 System. It is important to understand all safety messages that follow in this section to avoid potential injury or harm to the operator and/or patient and avoid unintended damage to the MPS 3 System.

- **DO NOT** immerse unit in any kind of ultrasonic bath, disinfectant, cleaning solution, or any kind of liquid. Do not spray liquids directly onto the MPS 3 System and prevent liquids from entering the Console and Controller as this may short-circuit the internal electronics and can cause potential hazard for operator and/or patient.

- **DO NOT USE** bleach or any chlorine based cleaning solutions in the MPS 3 circulation system. Chlorine may compromise heat exchanger integrity resulting in water to blood leakage and possibly patient injury.

- **DO NOT USE** any kind of chemical solvent, acidic, or alkali solution. Use neutral detergent or isopropyl alcohol on a clean soft cloth to clean the MPS 3 Controller display panel surface.

- If the buttons on the Controller do not respond to input, the display panel may need to be cleaned. Clean the MPS 3 display panel as indicated in the cleaning section of this manual. If the problem persists, contact Quest Medical customer support.

4.6 System Alarms

Alarms indicate failure or malfunction of a component in the MPS 3 System and notify the operator to take the proper action to resolve the alarm condition. Alarm messages are displayed in the message window and proper action is required from the operator.

The MPS 3 System alarms are classified as follows:

- High priority alarm
- Medium priority alarm
- Informational signal

For more information about Alarms and their corrective actions, refer to Section 10: Alarm overview and Section 11.3: Error Code List and Solutions.

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5 System Installation

This section contains the steps to install the MPS 3 System. The following steps explain how to unpack the components, verify the components list, install the system, and perform the initial setup of the MPS 3 System.

5.1 Installation Introduction

Each MPS 3 System goes through a rigorous final inspection program prior to its shipment to the customer. Upon the arrival of the MPS 3 System, please visually inspect the outside of the shipping container for any damage. If damage is detected, please notify Quest Medical customer service and file a damage claim with the carrier.

The MPS 3 System must be assembled and tested by authorized Quest Medical personnel, an authorized representative of Quest Medical, or a trained technician prior to placing the device into service for the first time.

Tools required for assembling the MPS 3 System:

- Phillips Screwdriver
- Scissors or Box Knife
- ¼" Nut Driver
- $^{3}/_{16}$" Hex Driver
- ¼" Hex Driver
- M3 Hex Driver

5.2 Unpacking the MPS 3 System

Prior to use, inspect the MPS 3 System for signs of physical damage or deterioration. Specific areas to inspect include the door latches for proper locking, the blood/crystalloid pump mechanism, delivery / vent valves, drug pumps and all electrical connection ports / cables. If a problem is identified, DO NOT USE the console. Contact Quest Medical Technical Support at 1-888-510-7623, prior to using the MPS 3 System.

Avoid OPERATOR INJURY; ensure that all fingers are clear from pinch / crush hazards when unpacking and inspecting the equipment.

Safety of Personnel: Shipping containers shall only be moved by personnel with appropriate training, and in adherence with local regulations. It is the responsibility of the customer to guarantee the safety of personnel while working with the system.

Carefully inspect each item prior to installation. If any component is missing or not compatible with your HLM, contact Quest Medical Technical Support at 1-888-510-7623, prior to using the MPS 3 System.

Follow these steps to unpack the MPS 3 Console:

1. Prior to opening the outer shipping box, please verify the packing slip matches your sales invoice. Items may ship separately.
2. Orient the box so THIS SIDE UP arrow is facing up. Carefully open the outer box making sure not to insert the knife or scissors too deep into the packaging.
3. Before removing the contents, inspect the accessory components, layer by layer for damage. If the accessories are visibly damaged, **DO NOT** unpack the components. Contact Quest Medical Customer Service.
4. Remove the top layers of foam packaging to uncover the MPS 3 inner box.
5. With the help of an assistant, remove the inner box from the shipping box by lifting it from the handles on the side of the inner box.

5.2.1 Unpacking the MPS 3 Controller

Follow these steps to unpack the MPS 3 Controller:

1. Orient the box so THIS SIDE UP arrow is facing up. Carefully open the box making sure not to insert the knife or scissors too deep into the packaging.
2. Before removing the contents, inspect the device components for damage. If the device is visibly damaged, **DO NOT** unpack the device. Contact Quest Medical Technical Support.
3. Remove the top layer of foam packaging to uncover the MPS 3 Controller.

4. Remove the Controller from the shipping box by lifting it from the underside of the module. Discard the two foam pieces. **DO NOT** lift the Controller using the Set / Flow Control Knobs.
5. Carefully place the Controller on a clean, dry, flat surface with the touchscreen facing up.
6. Inspect the Controller closely for damage. Specifically, carefully inspect the Set / Flow Knobs, display glass, and all electrical connection ports. **DO NOT** install the device if damage is observed. Contact Quest Medical Technical Support.
7. Inspect the communication cable and inspect it for damage. **DO NOT** use the communication cable if it is damaged or frayed. Contact Quest Medical Technical Support.
8. Use care when transporting your MPS 3 System to its point of use.

5.2.2 Unpacking the MPS 3 Console

Follow these steps to unpack the MPS 3 Console:

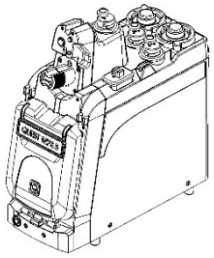
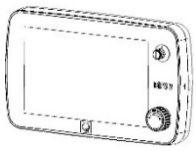
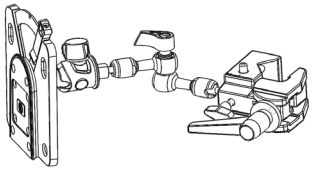
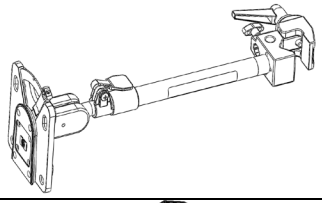
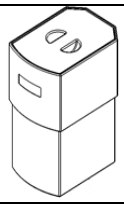
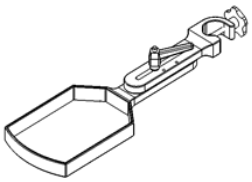
1. If the Controller is unpacked, proceed to step 3.
2. Orient the box so THIS SIDE UP arrow is facing up. Carefully open the box making sure not to insert the knife or scissors too deep into the packaging.
3. Before removing the contents, inspect the device for damage. If the device is visibly damaged, **DO NOT** unpack the device. Contact Quest Medical Technical Support.
4. Remove the top layers of foam packaging to uncover the MPS 3 Console.
5. With the help of an assistant, remove the Console from the shipping box by lifting it from the underside of the module. **DO NOT** lift the Console using the water ports or delivery / vent valves, or heat exchanger locking knob.
6. Use scissors or a box knife to carefully cut away the moisture barrier bag surrounding the Console. Use care to avoid scratching the equipment.
7. Carefully place the Console on a clean, dry, flat surface with the mounting feet facing down.
8. Inspect the Console closely for damage. Specifically, carefully inspect the door and latching mechanism, the blood/crystalloid pump, drug pumps, delivery/vent valves, and all electrical and water connection ports. **DO NOT** install the device if damage is observed. Contact Quest Medical Technical Support.
9. Remove the power cord and inspect it for damage. **DO NOT** use the power cord if it is damaged or frayed. Contact Quest Medical Customer Service. Remove the USB memory stick and set aside.
10. Use care when transporting your MPS 3 System to its point of use.

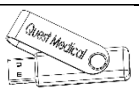
5.2.3 Unpacking the MPS 3 Disposables

The MPS 3 Delivery Sets and optional accessories are packaged and shipped separately from the MPS 3 System. The MPS 3 Disposables are not required for initial System installation and setup. Please refer to Section 8 for complete installation instructions for the MPS 3 Delivery Sets.

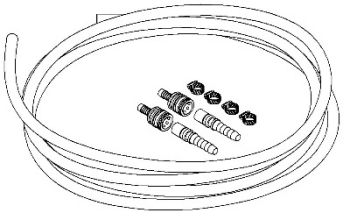
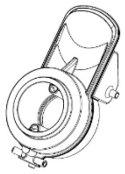
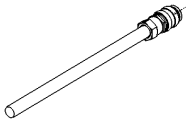
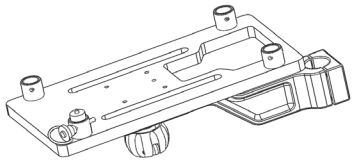
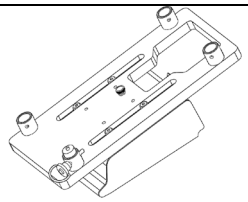
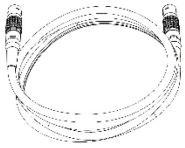
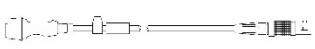
5.3 System Components

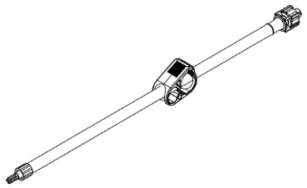
The following components are required for installation and initial system setup.

Component P/N	Description	Reference Image
5301000 OR 5302000	MPS 3 Console 100 – 120V, 50/60 Hz MPS 3 Console 200 – 240V, 50/60 Hz	
5303000	MPS 3 Controller	
	MPS 3 Console to Controller Communication Cable	
5303007 OR	MPS 3 Articulating Controller Mounting Arm	
5303008	MPS 3 Telescoping Controller Mounting Arm	
5001001G	MPS Hypothermic Reservoir	
5001002	MPS Hypothermic Reservoir Holder	

Component P/N	Description	Reference Image
530XX15	MPS 3 Power Cord	
5301010	MPS 3 Operator's Manual	N/A
5301035	MPS 3 and MPS 3 ND Troubleshooting Manual	N/A
801285	MPS 3 USB Memory Stick with Operator's Manual	

5.4 System Accessories

Component P/N	Description	Reference Image
801221	MPS Heater Cooler Hose Kit	
5001110	MPS Water Circuit Adapter	
5303010-(XX)	MPS 3 Medical Air Hose Kit	
5301023	MPS 3 Console Pole Mount	
5301025	MPS 3 Console Adapter	
513PWCC10	MPS 3 Console to Controller Communication Cable	
513UDMS	MPS 3 USB UDMS Cable	
513USCC	MPS 3 RS232 EDMS Cable	
513UECG	MPS 3 Controller In to ECG Out	
511800A	MPS 3 Antegrade (Aortic Root) Transducer Interface Cable	

Component P/N	Description	Reference Image
511800R	MPS 3 Retrograde (Coronary Sinus) Transducer Interface Cable	
5301016	MPS 3 Blood Bypass Tubing	

5.5 Installing the MPS 3 System

5.5.1 Installing the MPS 3 Console

The MPS 3 System should be integrated with the Heart-Lung Machine (HLM) for delivery of cardioplegia solution to the patient. This can be accomplished by mounting the MPS 3 Console on the base of the HLM or on a Quest Medical supplied MPS 3 Console Pole Mount. The MPS 3 Console should be placed in a location that is convenient for safe and effective operation.

Before installing the MPS 3 Console, consult the HLM Operations Manual / User Manual to verify the MPS 3 Console can safely be installed on the HLM according to recommended load restrictions. The HLM should be configured to best fit the MPS 3 Console. Prior to installation of the MPS 3 Console, clean and tidy the area / surface in which the Console will be placed. Ensure the area is clean, dry, stable and level prior to attempting to place the MPS 3 Console. Never install an MPS 3 Console on a surface that is not suitable to support the Console.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to install the MPS 3 Console. Use proper lifting techniques. Ensure that all fingers are free from pinch / crush hazards while installing the MPS 3 Console.

Use the proper electrical connections. The MPS 3 console power cord must be plugged into a dedicated hospital-grade electrical outlet. The hospital biomedical engineering department should periodically measure console ground leakage current to verify acceptable limits. Use only Quest Medical power cords.

In the event of AC Power loss or failure, the MPS 3 System Battery Backup will be activated. When this occurs, the console heaters will be disabled.

A Heart Lung Machine Adapter may be required to ensure safe and effective installation of the MPS 3 Console. Consult Quest Medical Customer Service or Sales Representative to determine if an adapter is required for installation.

For installation of the MPS 3 Console on the HLM Base, follow these steps:

1. Consult the HLM Operation Instructions prior to attempting to install the MPS 3 Console to ensure the console can be safely installed.
2. Once a placement location has been identified, clean and tidy the area. Ensure the surface is **DRY, STABLE, and LEVEL**, prior to placing the MPS 3 Console.

3. If a Heart Lung Machine Adapter is required, consult the installation instructions for the adapter and install the adapter.
4. Lift the MPS 3 Console using the handles located under the front of the Console and at the top of the back panel. If necessary, seek assistance when lifting the MPS 3 Console.

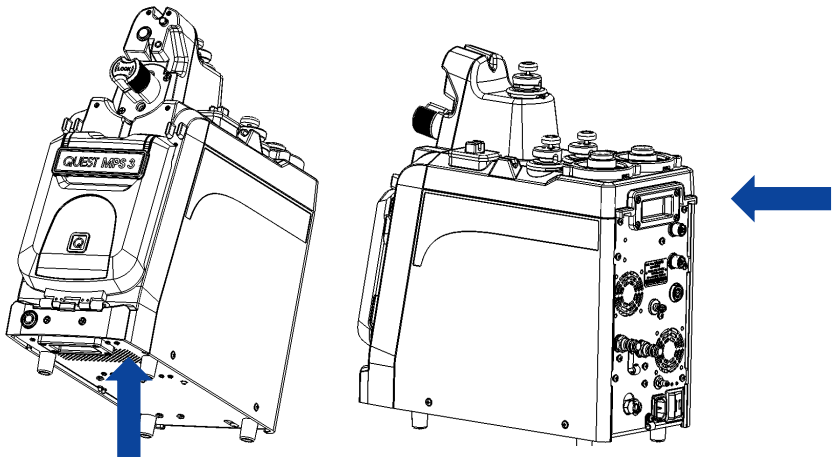


Figure 6: Lift Console with Handles

5. Carefully lower the MPS 3 Console on to the HLM base. Verify that the console is secure in the installation location.
6. Connect the Power Cord to the AC Connector on the back of the MPS 3 Console. The Power Cord should be inserted through the Strain Relief Clamp by unscrewing the clamp and running the power cord through the clamp. This will help prevent accidentally unplugging the power cord.

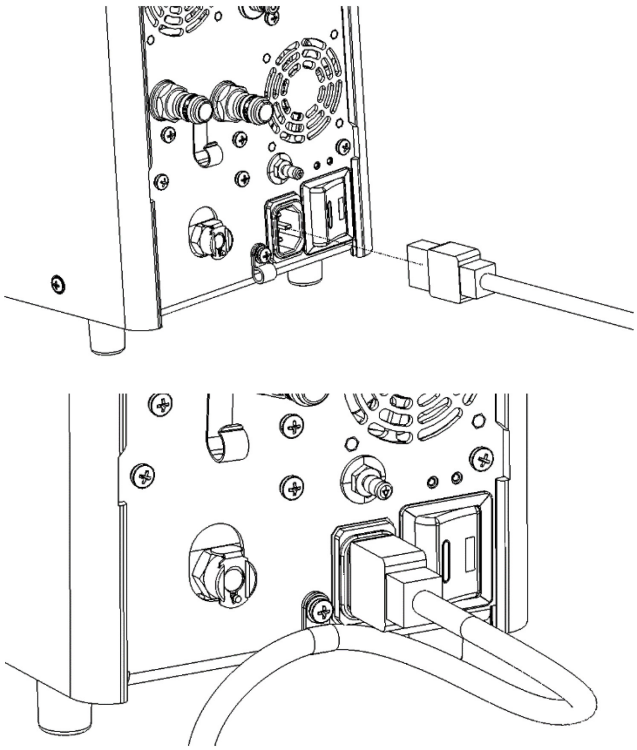


Figure 7: Install Power Cord

For installation of the MPS 3 Console on the HLM Pole, follow these steps:

1. Consult the HLM Operation Instructions prior to attempting to install the MPS 3 Console to ensure the console can be safely installed.
2. Once a placement location has been identified, clean and tidy the area and install the MPS 3 Console Pole Mount Adapter per the instructions provided with the accessory.
3. Using a Philips screwdriver, remove one of the feet on the MPS 3 Console and replace it with the locking foot provided with the MPS 3 Pole Mount Adapter. Choose a foot that will be in a convenient position for easy access once the Console is installed. Remove the locking pin prior to attempting to place the Console on the Pole Mount Adapter.

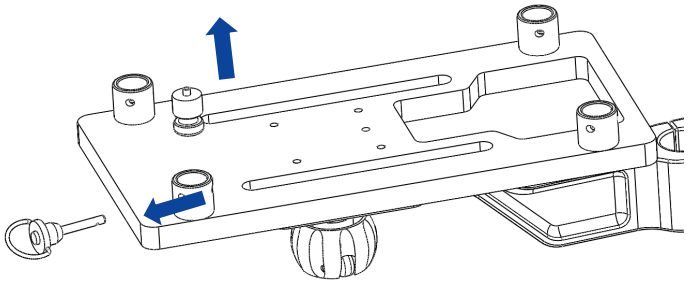


Figure 8: Remove Locking Foot from Pole Mount Adapter

4. Using ¼ inch Hex Driver, loosen the pole clamp screws (1/4 - 20) and place the pole clamp over pole in the desired location. Reinsert the screws to secure the pole clamp.

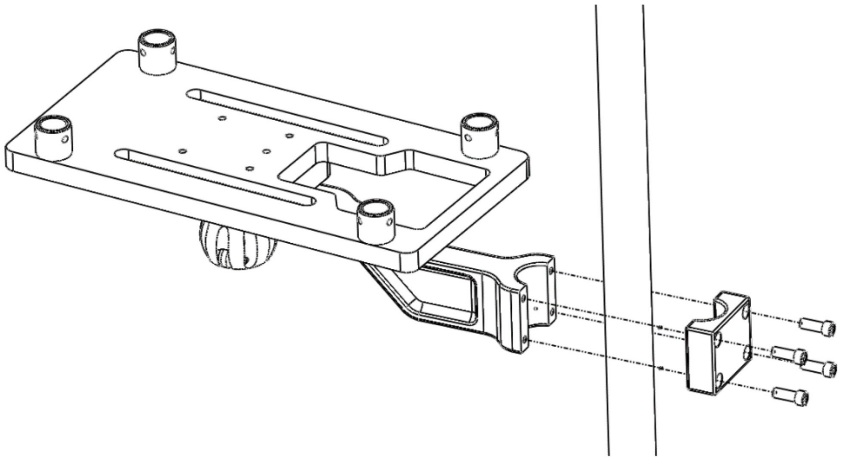


Figure 9: Secure Console Pole Mount

5. Ensure the MPS 3 Console Pole Mount Adapter is secure and the surface is **DRY, STABLE, AND LEVEL**, prior to placing the MPS 3 Console.

6. Lift the MPS 3 Console using the handles located under the front of the Console and at the top of the back panel. If necessary, seek assistance when lifting the MPS 3 Console.

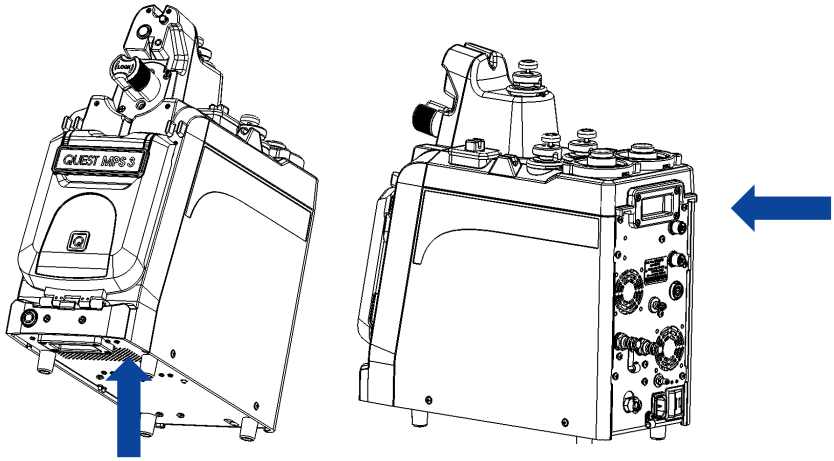


Figure 10: Lift Console with Handles

7. Carefully lower the MPS 3 Console on to the Pole Mount Adapter. Ensure the rubber feet align with the cups on the Pole Mount Adapter and all four feet are securely in the cups. Use the Locking Pin on the Pole Mount Adapter to secure the locking foot on the MPS 3 Console. Verify that the console is secure in the installation location.

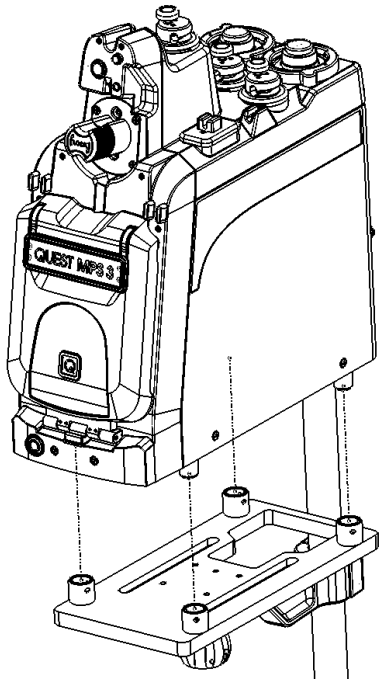


Figure 11: Install Console to Pole Mount Adapter

8. The Pole Mount may be adjusted by loosening the knob underneath the mount, adjusting to the desired position, and then tightening to secure.

9. Connect the Power Cord to the AC Connector on the back of the MPS 3 Console. The Power Cord should be inserted through the Strain Relief clamp by unscrewing the clamp and running the power cord through the clamp. This will help prevent accidentally unplugging the power cord.

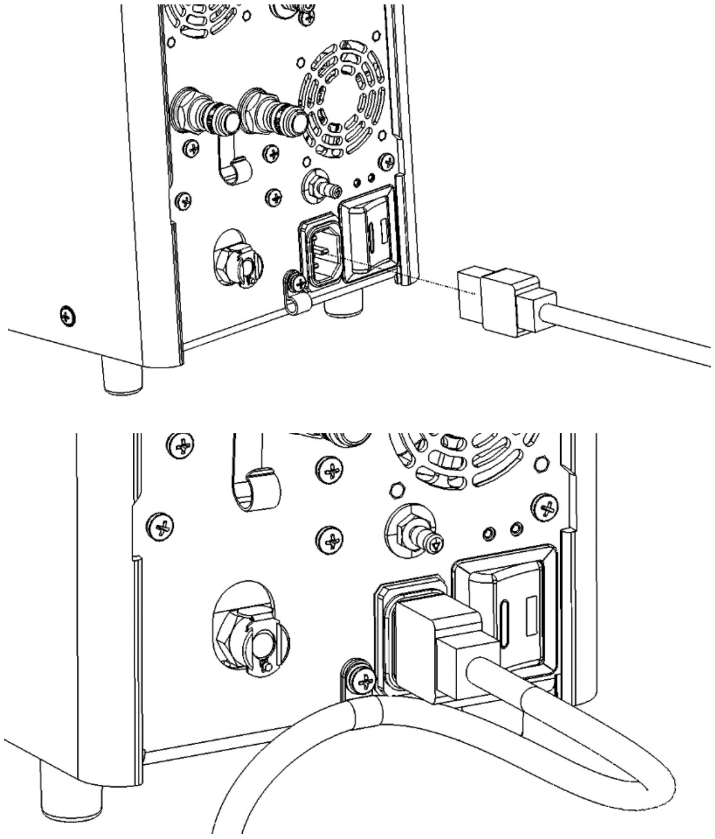


Figure 12: Insert Power Cord

5.5.2 Installing the MPS 3 Hypothermic Reservoir

If the cold water source to be used with the MPS 3 System is the Quest Medical Hypothermic Reservoir, the reservoir should be placed in a location that is easily accessible for the operator to fill, refill, and add ice and drain, as required. The MPS 3 Hypothermic Reservoir must be used with the Hypothermic Reservoir Bracket and must be installed on a vertical pole of the Heart Lung Machine for proper operation.

Before installing the MPS 3 Hypothermic Reservoir, consult the HLM Operations Manual / User Manual to verify the Reservoir can safely be installed on the HLM Pole according to recommended load restrictions. Ensure the pole is clean, dry, and stable prior to attempting to install the Reservoir. Never install a Reservoir on a pole / mast that is not suitable to support the Reservoir.

Do not install the MPS 3 Hypothermic Reservoir so that it may obstruct viewing angles for other equipment. Do not install the Reservoir so that it may obstruct tubing routing for the cardiopulmonary bypass circuit. The Reservoir should be positioned to be convenient and accessible, but not intrusive.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to install the MPS 3 Hypothermic Reservoir. Ensure that all fingers are free from pinch / crush hazards while installing the Reservoir and tubing connections.

To ensure proper operation, the MPS 3 Hypothermic Reservoir shall be placed so that the Outlet Port at the bottom of the Reservoir is, at a minimum, above the heat exchanger level of the MPS 3 Console. Failure to follow these instructions may result in improper water prime, water flow and ultimately, loss of temperature control.

During warm delivery, small amounts of cold water are used to regulate temperature. Therefore, the MPS 3 System must be connected to a cold water source.

After disinfecting the MPS 3 Console every 28 days per instructions in section 12.1.3, replace the MPS Water Hose Kit (REF 801221).

If the cold water source to be used with the MPS 3 System is the Quest Medical Hypothermic Reservoir, please follow these steps to install the Hypothermic Reservoir.

1. Consult the HLM Operation Instructions prior to attempting to install the MPS 3 Hypothermic Reservoir to ensure the Reservoir can be safely installed.
2. Once a placement location has been identified, clean and tidy the area and install the MPS 3 Hypothermic Reservoir Bracket. **Please note that the Reservoir must be positioned with the Reservoir outlet above the heat exchanger on the Console, at a minimum, to ensure proper priming and flow.**
3. To install the Reservoir Bracket, loosen the pole clamp by turning the handle counterclockwise so that it fit over the pole / mast intended to be used for installation.

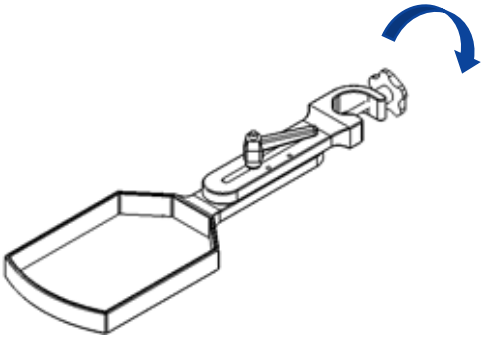


Figure 13: Loosen Pole Clamp on Reservoir Bracket

4. Position the pole clamp over the pole and tighten the pole clamp by turning the handle clockwise. Tighten the pole clamp hand tight so that it is secure, but not overtightened. Test the securement of the pole clamp to the pole prior to installing the MPS 3 Hypothermic Reservoir.

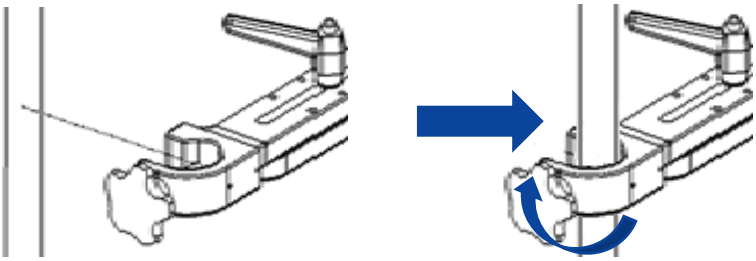


Figure 14: Secure Reservoir Bracket to Pole

5. Insert the Reservoir into the Bracket so that the water ports face the opening on the Bracket to allow for tubes be installed.

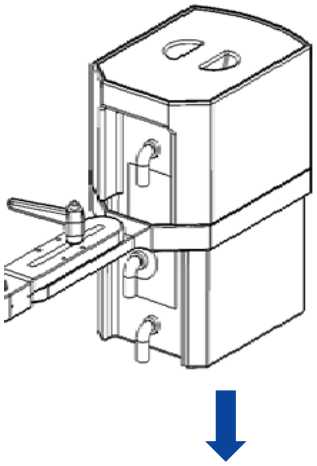


Figure 15: Insert Reservoir into Bracket

6. The position of the Reservoir may be adjusted using the lever handle on the top of the bracket. Loosen the handle, set the Reservoir to the proper position and tighten the handle to secure the Reservoir. Set the Reservoir in a position close to the pole so that when full, the weight of the Reservoir does not cause the pole to lean.

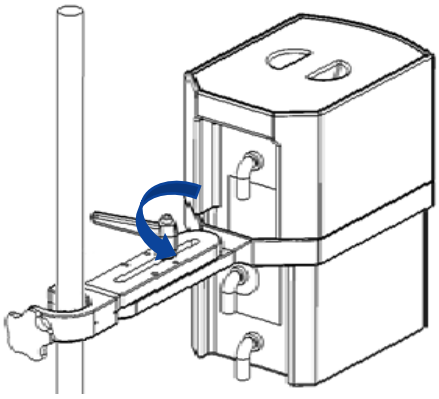


Figure 16: Set Position of Reservoir Bracket

7. Install the ½” Tubing supplied with the Hose Kit to the Reservoir Inlet and Outlet and secure the tubing with a hose clamp. Route the tubing of the Reservoir Inlet up through the bracket.

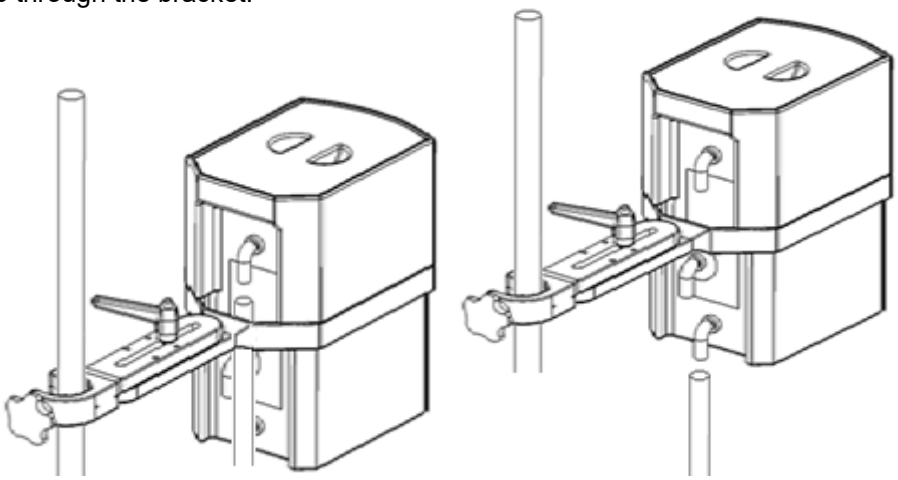


Figure 17: Install Tubing to Reservoir

8. Install the 3/8” Tubing supplied with the Hose Kit to the Reservoir port labeled “Drain” and secure the tubing with a zip ties.
9. Measure and cut the drain tubing to the desired length and insert the drain valve into the end of the tubing and secure with a zip tie. Ensure the drain valve is closed by pressing the button on the top of the drain valve.
10. Measure and cut the inlet and outlet tubing to the desired length. Ensure the tubing length is long enough to reach the console, but not too short to cause kinks or stress the connectors or too long to create a trip hazard.
11. Install one female Hansen fitting into the Reservoir Outlet – Console Inlet tubing and secure with a hose clamp. Insert the other female Hansen fitting into the Reservoir Inlet – Console Outlet tubing and secure with a hose clamp. Flow directional arrows may be applied to the tubing to help prevent accidental misconnections.

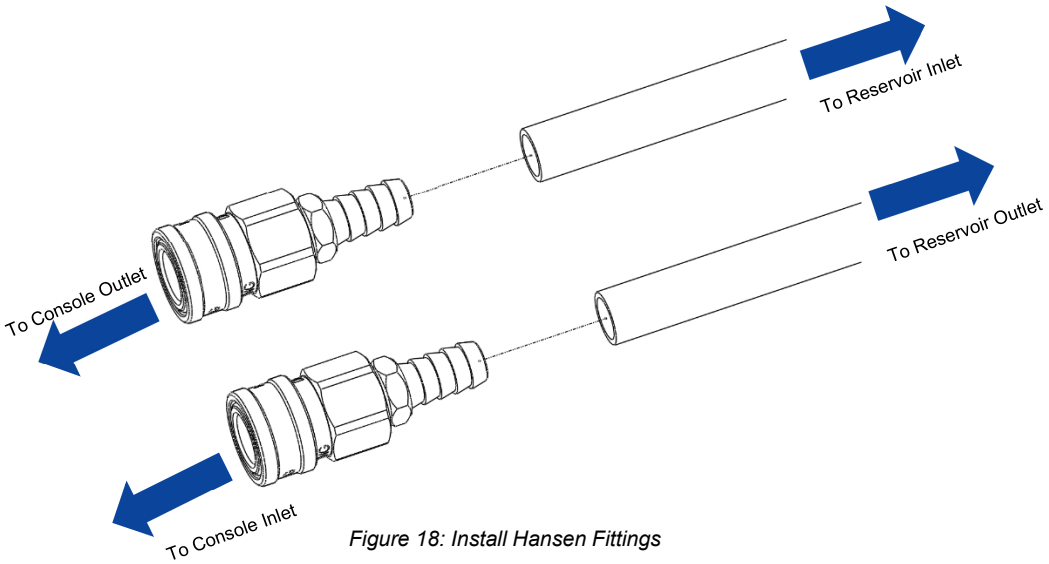


Figure 18: Install Hansen Fittings

12. Connect the Hansen fittings to the Console Inlet and Outlet ports. Connect the Reservoir Outlet tubing to the Console Inlet. Connect the Reservoir Inlet tubing to the Console Outlet.

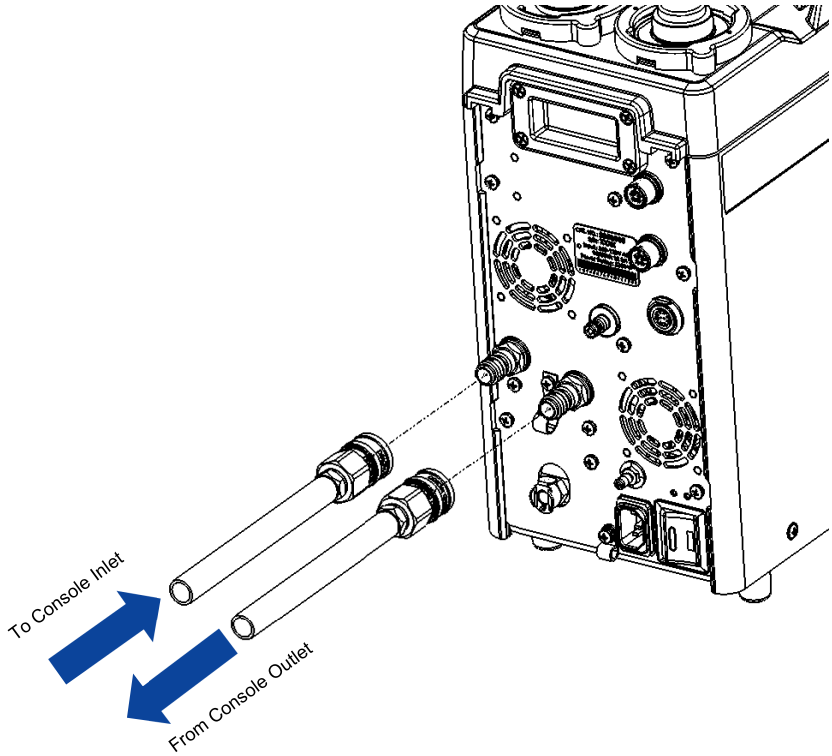


Figure 19: Connect Reservoir Tubing to Console

5.5.3 Installing the MPS 3 Controller

The MPS 3 Controller should be placed in a location that is easily accessible and visible for the operator. The location should also allow for minor adjustments to the Controller position to accommodate viewing angles and reach for all operators who may operate the device. The MPS 3 Controller must be installed on a vertical pole of the Heart Lung Machine for proper operation.

Before installing the MPS 3 Controller, consult the HLM Operations Manual / User Manual to verify the MPS 3 Controller can safely be installed on the HLM Pole according to recommended load restrictions. The HLM should be configured to best fit the MPS 3 Controller. Prior to installation of the MPS 3 Controller, clean and tidy the pole / mast in which the Controller will be placed. Ensure the pole is clean, dry, and stable prior to attempting to install the MPS 3 Controller. Never install an MPS 3 Controller on a pole / mast that is not suitable to support the Controller.

Do not install the MPS 3 Controller so that it may obstruct viewing angles for other equipment. Do not install the MPS 3 Controller so that it may obstruct tubing routing for the cardiopulmonary bypass circuit. The MPS 3 Controller should be positioned to be convenient and accessible, but not intrusive.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to install the MPS 3 Controller. Ensure that all fingers are free from pinch / crush hazards while installing the MPS 3 Controller.

5.5.3.1 To install the MPS 3 Controller using the Telescoping Mounting Arm (P/N 5303008) on the HLM Pole, follow these steps:

1. Consult the HLM Operation Instructions prior to attempting to install the MPS 3 Controller to ensure the Controller can be safely installed.
2. Once a placement location has been identified, clean and tidy the area and install the MPS 3 Controller Telescoping Mounting Arm.
3. To install the Telescoping Mounting Arm, loosen the pole clamp by turning the handle counterclockwise so that it fits over the pole / mast intended to be used for installation.

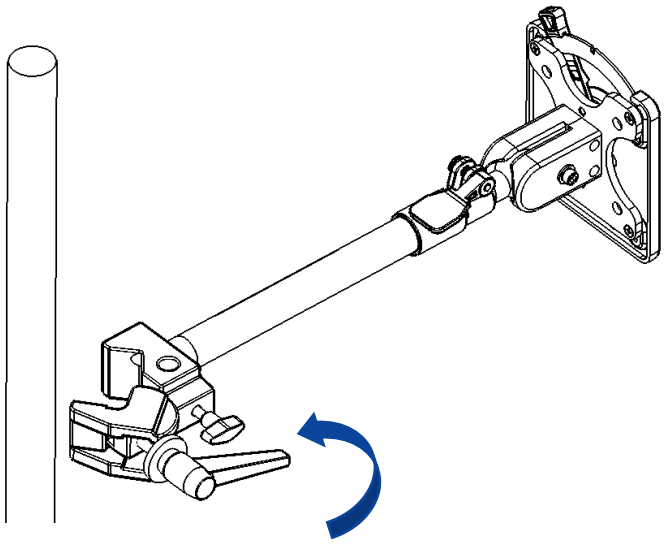


Figure 20: Loosen Pole Clamp and Position Clamp over Pole

4. Position the pole clamp over the pole and tighten the pole clamp by turning the handle clockwise. Tighten the pole clamp hand tight so that it is secure, but not overtightened. Test the securement of the pole clamp to the pole prior to installing the MPS 3 Controller. Ensure the quick release mounting adapter is oriented upwards.

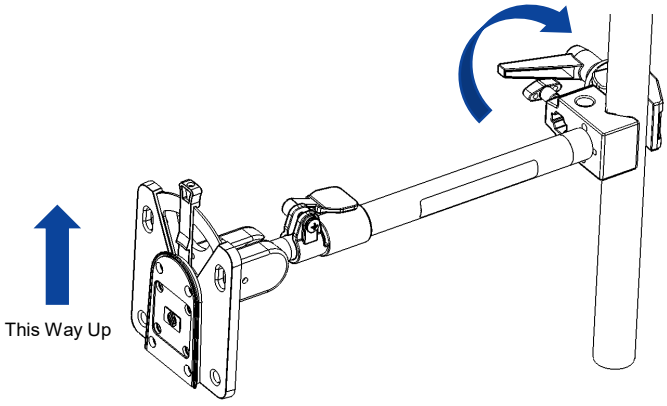


Figure 21: Tighten Pole Clamp to Secure Mounting Arm

5. To install the MPS 3 Controller, align the quick disconnect mounting adapter on the back of the Controller with the mating connector on the Telescoping Mounting Arm. Carefully slide the Controller onto the Pole Mounting Arm. The quick release adapter should click into place when properly secure. The quick release lever should be positioned vertically after the Controller is secured to Telescoping Mounting Arm.

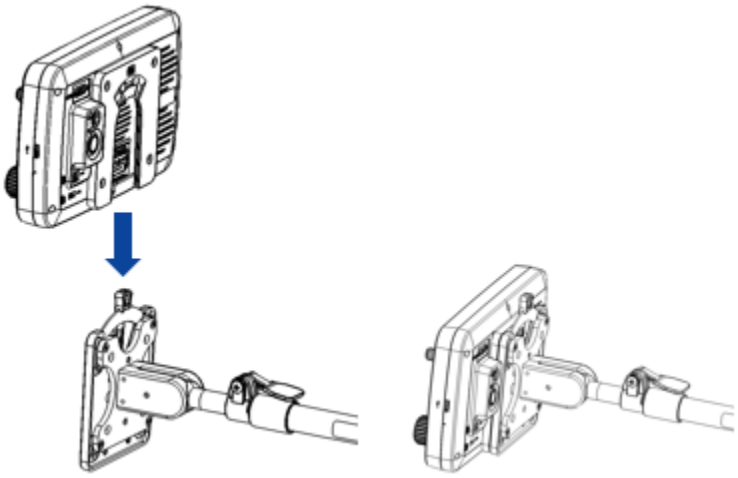


Figure 22: Connect Controller to Arm using Quick Release Adapter

6. Once installed, the MPS 3 Controller viewing angle can be adjusted simply by grabbing both sides of the Controller and adjusting. If the viewing angle adjustment mechanisms needs to be tightened or loosened, simply adjust the hex nut on the mechanism with a 3/16” hex driver to the desired setting.

7. The Pole Mounting Arm length can be adjusted by lifting the telescoping clamp and extending the arm to the desired length. If the telescoping clamp needs to be tightened or loosed, simply adjust the hex nut on the mechanism with a 3/16” hex driver to the desired setting. **Note that the screw is left hand threaded so turning the screw counterclockwise will tighten the mechanism.**

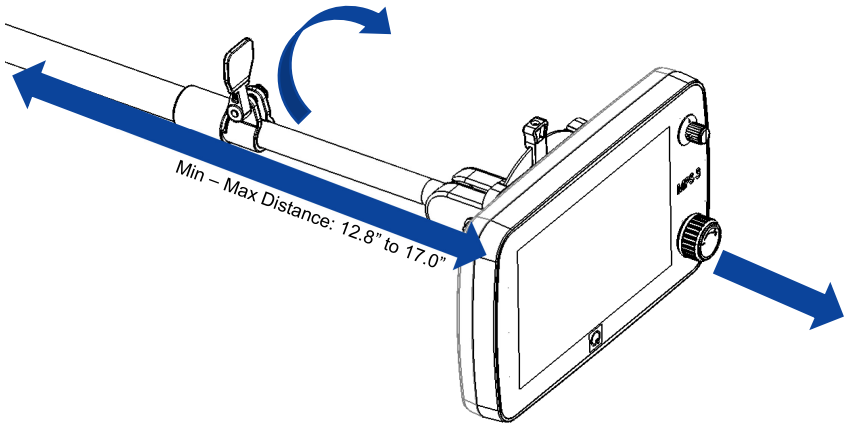


Figure 23: Loosen Telescoping Clamp to Extend Arm

8. Connect the Console to Controller Communication Cable to the port on the back of the Controller and Console. Be sure to align the connector tabs. The connector should click into place to ensure it is secure and will not accidentally be unplugged.

5.5.3.2 To install the MPS 3 Controller using the Articulating Mounting Arm (P/N 5303007) on the HLM Pole, follow these steps:

1. Consult the HLM Operation Instructions prior to attempting to install the MPS 3 Controller to ensure the Controller can be safely installed.
2. Once a placement location has been identified, clean and tidy the area and install the MPS 3 Controller Articulating Mounting Arm.
3. To install the Articulating Mounting Arm, loosen the pole clamp by turning the handle counterclockwise so that it fits over the pole / mast intended to be used for installation.

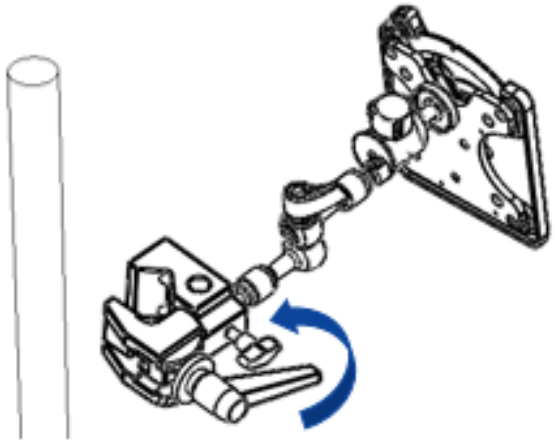


Figure 24: Loosen Pole Clamp and Position Clamp over Pole

The Controller can be damaged and/or become unusable if it collides with another piece of equipment or the ground when the Operator loosens the lock knob without holding onto the Controller or if the arm starts to droop after the configuration is locked into place.

4. Position the pole clamp over the vertical pole and tighten the pole clamp by turning the handle clockwise. Tighten the pole clamp hand tight so that it is secure, but not overtightened. Test the securement of the pole clamp to the pole prior to installing the MPS 3 Controller. Ensure the quick release mounting adapter is oriented upwards.

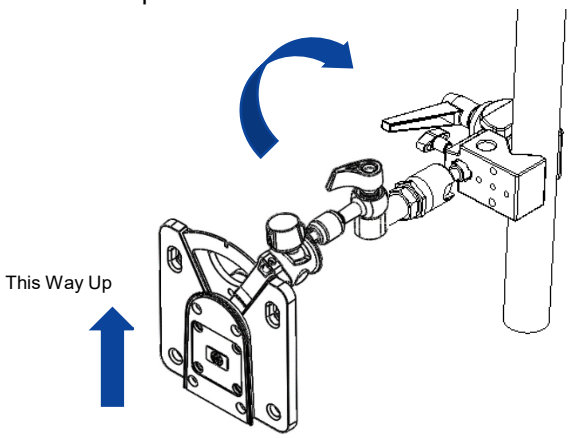


Figure 25: Tighten Pole Clamp to Secure Mounting Arm

5. Connect the Console to Controller Communication Cable to the port on the back of the Controller and Console. Be sure to align the connector tabs. The connector should click into place to ensure it is secure and will not accidentally be unplugged.

6. To install the MPS 3 Controller, align the quick disconnect mounting adapter on the back of the Controller with the mating connector on the Articulating Mounting Arm. Carefully slide the Controller onto the Articulating Mounting Arm. The quick release adapter should click into place when properly secure. The quick release lever should be positioned vertically after the Controller is secured to Articulating Mounting Arm.

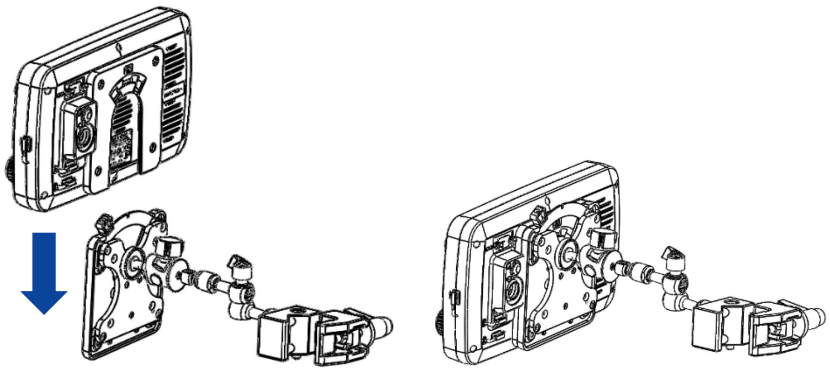


Figure 26: Connect Controller to Arm using Quick Release Adapter

7. Once installed, the MPS 3 Controller viewing angle can be adjusted by first unscrewing the “lock” on the controller tilt head closest to the mounting plate until just loose enough. Once loose, grab both sides of the Controller and adjust. Once in the desired location, rescrew the “lock” which tightens and keeps the Controller in the same place.

8. The Articulating Mounting Arm configuration can be changed by **holding onto the Controller**, loosening the locking knob and adjusting the mounting arm to the desired configuration. Lock the configuration into place by tightening the quick release knob. Cautiously let go of the Controller and ensure the mounting arm is secured and does not droop in the desired configuration. If the mounting arm does droop, loosen the locking knob once again and try adjusting the arm to a new configuration. If the viewing angle adjustment mechanisms needs to be tightened or loosened, simply unscrew and/or rescrew the tilt head attachment..

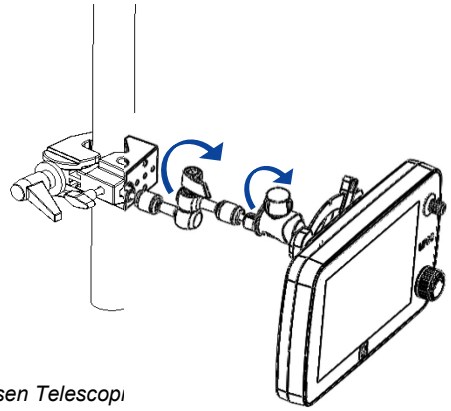


Figure 27: Loosen Telescopi

9. Connect the Console to Controller Communication Cable to the port on the back of the Controller and Console. Be sure to align the connector tabs. The connector should click into place to ensure it is secure and will not accidentally be unplugged.

5.5.4 Connecting a Heater Cooler Unit to the MPS 3 System

If the cold/warm water source to be used with the MPS 3 System is a third party Heater Cooler Unit (HCU), the HCU must supply an adequate water flow rate (greater than 1.25 gpm) and water temperatures (0 – 41°C) for the MPS 3 System to operate properly.

Before connecting the Heater Cooler Unit (HCU), consult the HCU Operations Manual / User Manual to verify the HCU can safely be connected to the MPS 3 System. The HCU needs to supply adequate water flow (greater than 1.25 gpm) and water temperatures (0 – 41°C) for the MPS 3 System to perform optimally. Do not connect a third party HCU to the MPS 3 System if the maximum HCU water pressure exceeds 25psi.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to connect a Heater-Cooler Unit to the MPS 3 System. Ensure that all fingers are free from pinch / crush hazards while connecting the HCU and tubing connections.

Water quality must be maintained per heater cooler manufacturer recommendations. DO NOT connect the MPS 3 Console to a heater cooler unit that has not been properly disinfected per the manufacturer recommendations.

The long-term effectiveness of the MPS 3 circulation system disinfection procedures, the supplemental use of hydrogen peroxide to inhibit bacterial growth in between disinfection cycles, and the recommended interval for disinfection were evaluated in the MPS 2 for up to 6 months. The disinfection and water maintenance procedures mitigate but do not prevent biofilm formation.

Water quality in the MPS 3 must be maintained per the recommendations in this manual. DO NOT connect a heater cooler unit to the MPS 3 Console that has not been properly disinfected.

During warm delivery, small amounts of cold water are used to regulate temperature. Therefore, the MPS 3 System must be connected to a cold water source.

After disinfecting the MPS 3 Console every 28 days per instructions in section 12.1.3, replace the MPS Water Hose Kit (REF 801221).

If the cold water source to be used with the MPS 3 System is a third party Heater Cooler Unit (HCU), please follow these steps to connect the HCU to the MPS 3 System.

1. Consult the HCU Operation Instructions / User Manual prior to attempting to connect the HCU to the MPS 3 System the HCU will supply adequate water flow and water temperatures. **DO NOT** connect a third party HCU to the MPS 3 System if the maximum HCU water pressure exceeds 25psi.
2. Identify the Inlet and Outlet ports on the HCU cardioplegia water circuit. Connect ½" tubing from the Hose Kit to the Inlet and Outlet connectors on the HCU.
3. Measure and cut the tubing to the desired length so that it can easily attach to the MPS 3 Console. Ensure the tubing length is long enough to reach the console, but not too short to cause kinks or stress the connector or too long to create a trip hazard.
4. Install hose clamps on the tubing ends. Install one female Hansen fitting supplied with the Hose Kit into the HCU Outlet – Console Inlet tubing and secure hose clamp using ¼" nut driver. Insert the other female Hansen fitting supplied with the hose kit into the HCU Inlet – Console Outlet tubing and secure hose clamp using ¼" nut driver. Flow directional arrows may be applied to the tubing to help prevent accidental misconnections.

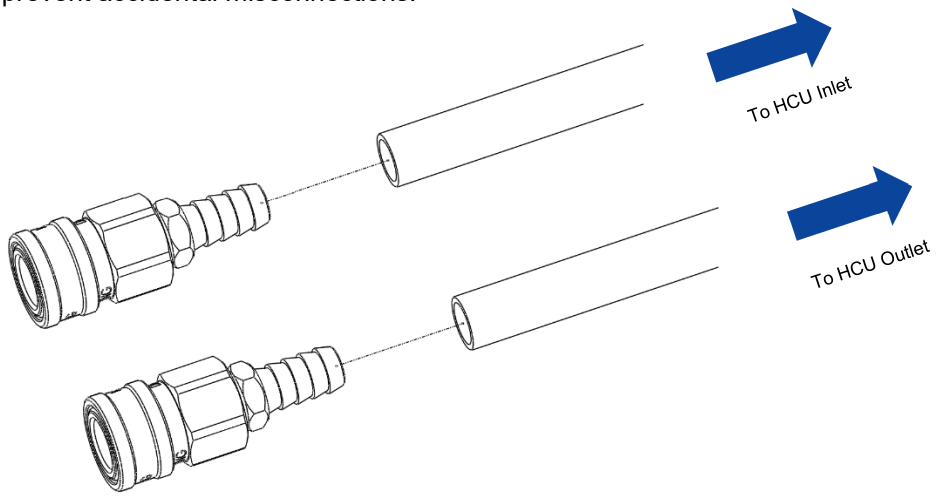


Figure 28: Install Hansen Fittings

5. Connect the Hansen fittings to the Console Inlet and Outlet ports. Connect the HCU Outlet tubing to the Console Inlet. Connect the HCU Inlet tubing to the Console Outlet.

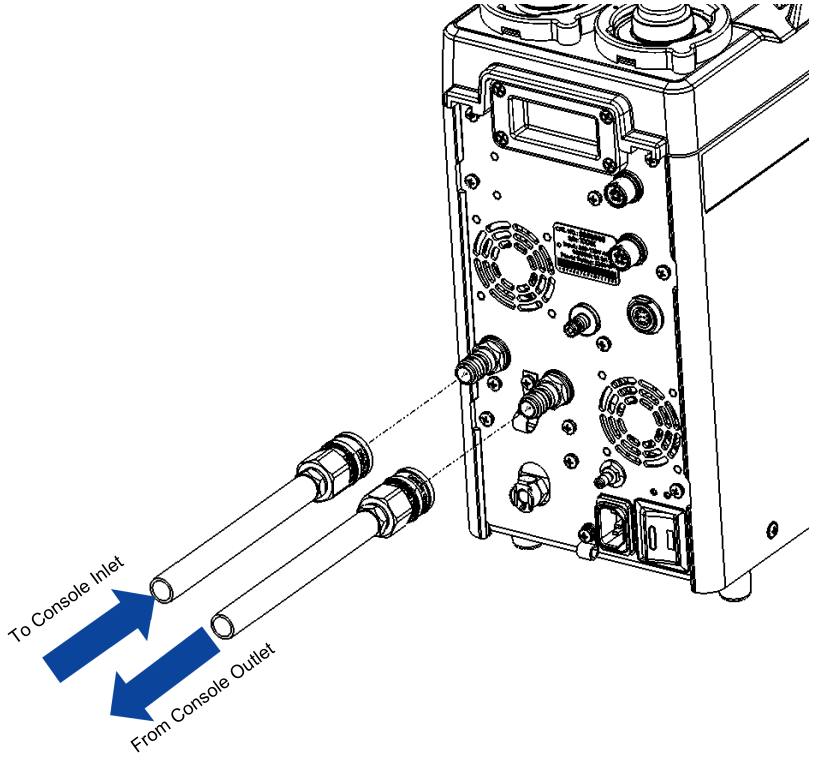


Figure 29: Connect Reservoir Tubing to Console

5.5.5 Priming the Circulation System

Prior to first use of the MPS 3 System, follow the disinfection procedure outlined in Section 12.1.3.

The MPS 3 water circulation system must be fully primed and purged of all air prior to use to ensure full functionality of the system. Failure to do may result in loss of temperature control, inadequate cooling, and inability to perform leak tests during priming and may result in premature wear or damage to the equipment.

The MPS 3 System may be used with the Quest Medical Hypothermic Reservoir or a heater-cooler unit. The MPS 3 System requires an adequate supply of cold water from the water source to properly regulate cardioplegia delivery temperature.

Use with a Hypothermic Reservoir

To prime the system using a hypothermic reservoir, follow these steps.

1. Connect the hypothermic reservoir to the MPS 3 Console following the steps outlined in Section 5.5.2.
2. Verify that the hypothermic reservoir is positioned so that the Outlet of the hypothermic reservoir is located ABOVE the heat exchanger to ensure proper priming.
3. Ensure the locking knob is in the 10 convolution position and install the water circuit adapter (**REF** 5001110) to the console using the locking knob. To put the knob in the 10 convolution position, push in on the knob and rotate clockwise until the knob will no longer turn.

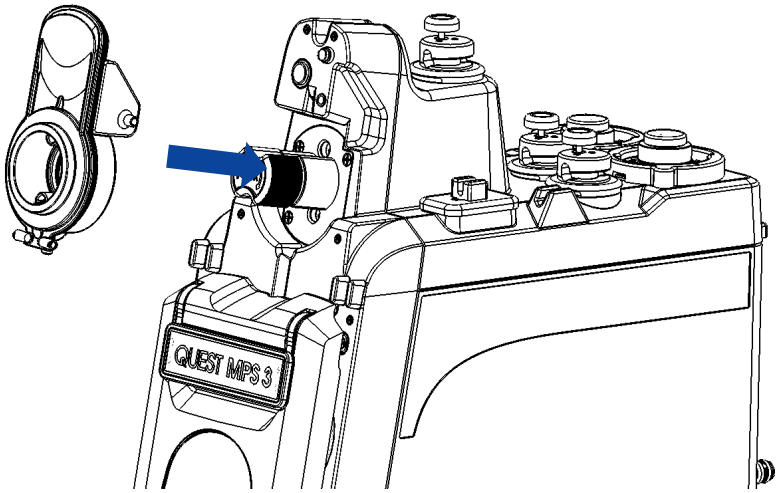


Figure 30: Installing Water Circuit Adapter

4. Remove the lid and fill the hypothermic reservoir with at least 3 liters of sterile water or tap water filtered with a 0.22 micron filter. Verify the water level is covering the drain port, at a minimum. Replace hypothermic reservoir lid on the reservoir. Squeeze the tubing connected to the MPS 3 inlet to remove all air before attempting to prime the system.
5. Power on the MPS 3 System. Select MENU → H2O Circ
6. The Start button may be used to prime the H2O Circulation system. This is needed to eliminate any air that might be trapped in the circulation system.
7. It takes approximately 24 seconds to complete the H2O Prime. A countdown timer is displayed during the process. The process can be stopped and resumed.

8. Verify that water flow is established by checking the inlet of the hypothermic reservoir during the priming sequence.
9. Once flow rate has been established, add 25 ml of 3% Hydrogen Peroxide to the hypothermic reservoir to inhibit microbial growth in the system.
10. If water flow is not established, there may be an airlock present in the circulation pump. To **MANUALLY PURGE** the system of air, remove the water circuit adapter. Place a towel below the heat exchanger knob to collect water that may drip out. Using hemostats, depress the top water port puck seal valve until water begins to come out of the valve. Release the valve, reinstall the water circuit adapter, and repeat the prime sequence.

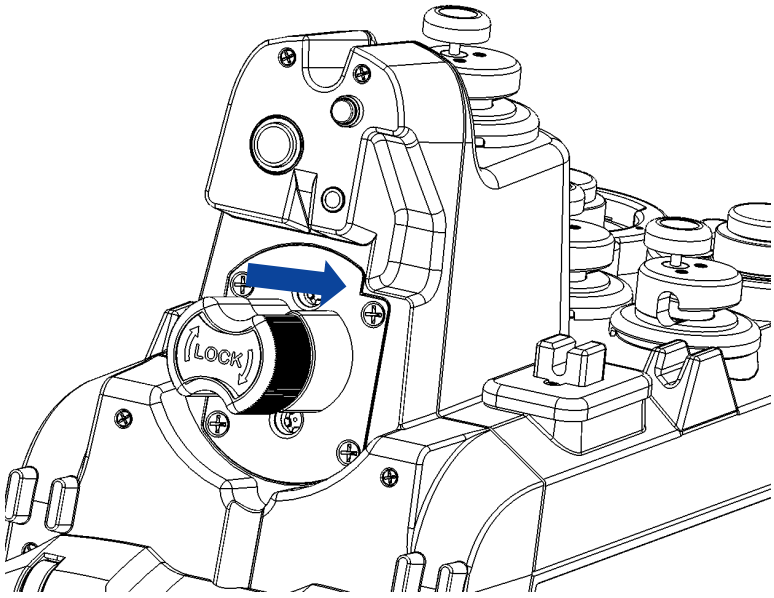


Figure 31: Manual Purge of Circulation System

Use with a Heater Cooler Device

If using a heater cooler unit (HCU), follow the procedure outlined below to prime the MPS 3 System.

1. Ensure the device is connected properly to the MPS 3 System (Section 5.5.4) and the HCU is compatible for use with the MPS 3 System.
2. Ensure the locking knob is in the 10 convolution position and install the water circuit adapter (**REF** 5001110) to the console using the locking knob. Note: a normal delivery set with heat exchanger can also be used to prime the system.

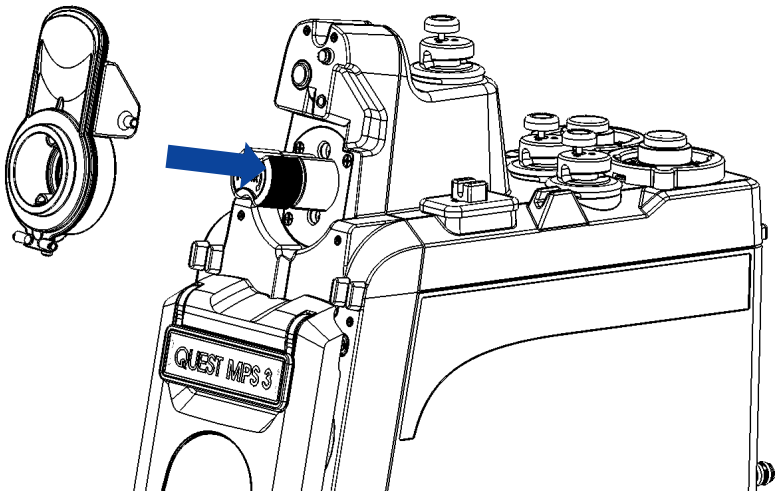


Figure 32: Console and Hypothermic Reservoir Drain Ports

3. Once the water lines are connected, the HCU flow may be started. If the HCU has variable speed settings, ensure it is set to tis maximum flow mode. The pressure and flow from the HCU should automatically purge the air from the MPS 3 System. If a bypass loop is being used in conjunction with the HCU, clamp the loop during the H2O Circulation System prime to maximize water pressure into the MPS 3 System.
4. Power on the MPS 3 System. Select MENU → H2O Circ → Start to eliminate any additional air that might be trapped in the H2O Circulation System.
5. Verify water flow is established between the MPS 3 System and HCU. If water flow is not observed, verify the settings on the heater cooler device are correct, water lines are properly connected, the MPS 3 System is in cold mode, and there are not kinks or obstructions in the tubing lines.

5.6 Installing the Optional Accessories

The following accessories are considered optional for use with the MPS 3 System and are not required for initial installation and setup. These accessories are provided to enhance the experience with the MPS 3 System and accommodate a variety of needs for various operators.

5.6.1 Connecting Medical Air

The MPS 3 System utilizes pneumatics to drive many key components within the system. The MPS 3 System has pneumatic compressors to drive the pneumatic power, but the MPS 3 Console is equipped with a Medical Air Inlet. This can be used to attach a Medical Air Supply to the inlet to bypass the internal compressors for quieter operation or in the event of compressor failure.

Before connecting the Medical Air Supply to the MPS 3 System, please ensure the maximum pressure does not exceed 55psi. While the MPS 3 System will regulate the pressure down to the necessary operating levels, connecting high pressure may damage internal components.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to connect a Medical Air Supply to the MPS 3 System. Ensure that all fingers are free from pinch / crush hazards while connecting the Medical Air Supply and tubing connections.

Please ensure that the Medical Air Supply is free from oil, water, and residue to prevent unintended damage to the MPS 3 System.

To connect the Medical Air Supply to the MPS 3 System, please follow the following steps.

1. Verify that the Medical Air Supply has a pressure not exceeding 55psi. High pressures may damage the MPS 3 System.
2. Verify that the Medical Air Hose Kit provided has the correct connections for your Medical Air Supply. Refer to 5303010 IFU for a full list of Medical Air Hose adapters.
3. Connect the Medical Air Supply Outlet fitting to the Medical Air Supply.
4. Connect the Medical Air Supply Inlet fitting to the Medical Air Inlet on the rear panel on the MPS 3 Console. The inlet fitting has a locking mechanism which will click when the fitting is properly secured.

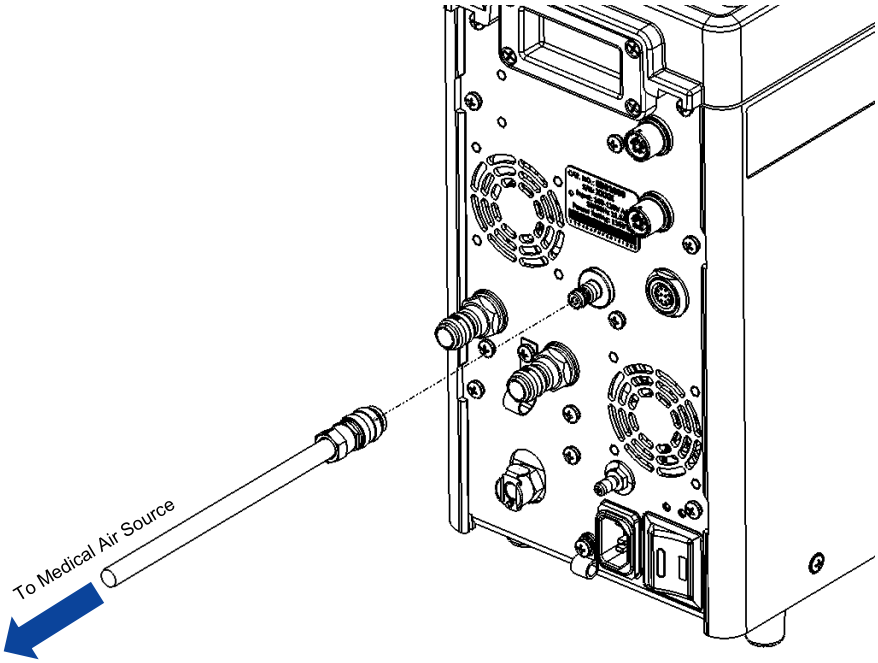


Figure 33: Install Medical Air Fitting

5.6.2 Connecting to the Electronic Data Management System (EDMS)

The MPS 3 System may be connected to a third party Electronic Data Management System to export Case Log and Dose History data. Because there are a variety of EDMS systems, please consult your sales representative to determine which EDMS Cable is needed for your setup.

Before connecting the MPS 3 System to the Electronic Data Management System (EDMS), consult the EDMS service provider to understand the data interface requirements and compatibility.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to connect the EDMS Cable to the MPS 3 System. Ensure that all fingers are free from pinch / crush hazards while connecting the EDMS Cable.

To connect the EDMS Cable to the MPS 3 System, please follow the following steps.

1. Verify that the EDMS is compatible with the MPS 3 System.
2. Verify that the EDMS Cable provided has the correct connections for your EDMS system.
3. Connect the EDMS Cable to the appropriate port on the EDMS system.
4. Remove the supplied cover from the USB or RS-232 port (depending on the cable required). Retain the cover for use if the cable is to be removed.
5. Connect the EDMS Cable to the USB or RS-232 port (depending on the cable required) on the rear panel of the MPS 3 Controller.

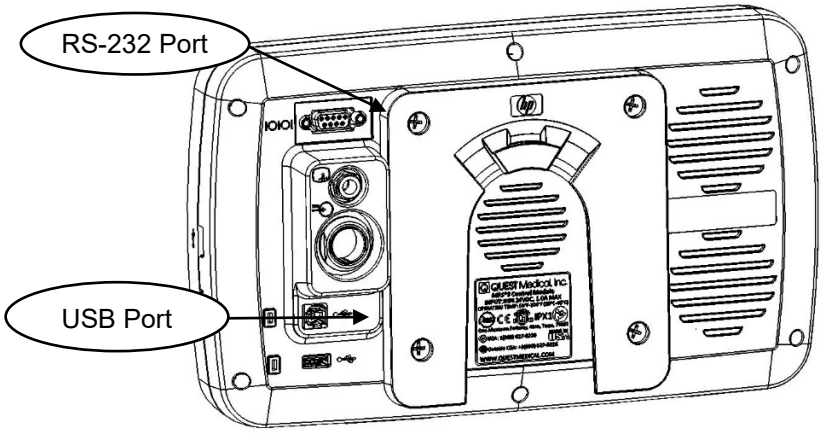


Figure 34: EDMS Ports on MPS 3 Controller

5.6.3 Connecting the Electrocardiogram (ECG) Cable

The MPS 3 System can be connected to a third party Electrocardiogram (ECG) to display the ECG signal on the MPS 3 Controller. Because there are a variety of ECG systems, please consult your sales representative to determine which ECG Cable is needed for your setup.

Before connecting the MPS 3 System to the Electrocardiogram (ECG), consult the ECG Operations Manual / User Manual to ensure the MPS 3 System is compatible and can be safely connected.

Avoid OPERATOR INJURY. Only qualified technicians should connect the ECG Cable to the MPS 3 System. Ensure that all fingers are free from pinch / crush hazards while connecting the ECG Cable.

The MPS 3 System does not measure, detect, or interpret the ECG Signal from the patient leads. The MPS 3 System only displays the analog ECG output signal from the ECG equipment.

To connect the ECG Cable to the MPS 3 System, please follow the following steps.

1. Verify that the ECG is compatible with the MPS 3 System. The ECG port of the MPS 3 System is designed to be used with a ¼" Phono ECG cable.
2. Verify that the ECG Cable provided has the correct connections for your ECG system.
3. Connect the ECG Cable to the appropriate port on the ECG system.
4. Remove the supplied cover from the ECG port. Retain the cover for use if the cable is to be removed.
5. Connect the ECG Cable to the analog ECG port on the rear panel of the MPS 3 Controller.

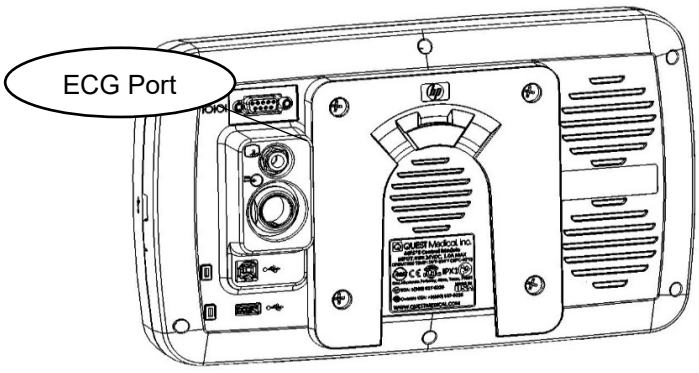


Figure 35: ECG Port on MPS 3 Controller

5.6.4 Connecting the External Antegrade and Retrograde Pressure Cables

The MPS 3 System may be connected to external Antegrade or Retrograde Pressure Transducers, if desired. These pressure transducers can be used to measure the pressure in the Aortic Root or Coronary Sinus to be displayed on the MPS 3 Controller display. The sterile, single use Pressure Transducers can be purchased as optional disposable accessories. This section will detail how to connect the reusable Pressure Cables to the MPS 3 System for use with the disposable Pressure Transducers.

Avoid OPERATOR INJURY. Ensure that all fingers are free from pinch / crush hazards while connecting the Antegrade and Retrograde Pressure Cables.

To connect the External Antegrade or Retrograde Pressure Cables to the MPS 3 System, please follow the following steps.

1. Connect the External Antegrade Pressure Cable to the rear panel of the MPS 3 Console in the Antegrade Pressure Connector. The Antegrade Pressure Cable and Pressure Connector are color coded red to help guide proper connections. Be sure to align the guide tabs on the Cable connector and Console connector to ensure a secure connection.
2. Connect the External Retrograde Pressure Cable to the rear panel of the MPS 3 Console in the Retrograde Pressure Connector. The Retrograde Pressure Cable and Pressure Connector are color coded blue to help guide proper connections. Be sure to align the guide tabs on the Cable connector and Console connector to ensure a secure connection.
3. The figure below shows the Antegrade and Retrograde Pressure Ports on the rear panel of the MPS 3 Console.

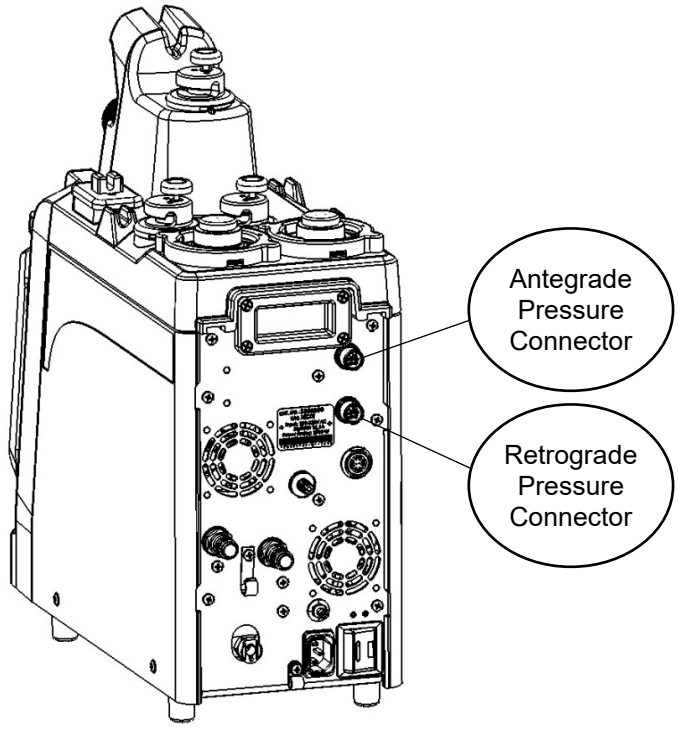


Figure 36: External Antegrade and Retrograde Pressure Connectors

4. The Antegrade and Retrograde Pressure Transducers may be purchased separately as optional disposable accessories.

For information on connecting the Pressure Transducers to the Pressure Cables, please refer to the Transducer Interface Cable IFU or Section 15.2. of this Operations Manual.

6 MPS 3 Startup

This section contains the steps to power on the MPS 3 System. Prior to attempting to power on the MPS 3 System for the first time, please ensure all steps outlined in Section 5 were followed closely and with the help of authorized Quest Medical personnel, an authorized representative of Quest Medical, or a trained technician. This section describes the steps to power on the MPS 3 System and configure the system settings. The system settings are saved in the system software and may be changed at any time if the operator chooses to do so. The system settings may be customized to each operator's preference. It is recommended to keep the MPS 3 Console and MPS 3 Controller paired as a System by matching Serial Numbers (located on the Console and Controller rear labels). Please refer to section 11.3 for instructions on how to start up the MPS 3 System in a Console or Controller emergency change out scenario.

6.1 System Power On

DO NOT USE the MPS 3 System if it is exhibiting electrical malfunctions such as intermittent power failures or circuit breaker shut off. Call Quest Medical Customer Service for Technical Support for information or Refer to Section 11: Troubleshooting.

DO NOT USE the MPS 3 System if it fails internal diagnostics, is visibly damaged, or has loose connections or missing components.

If the main power switch is turned off, the MPS 3 Battery will not charge.

DO NOT connect or disconnect the MPS 3 Controller while the MPS 3 System is on (i.e. while the push button switch indicator light is blue).

When the MPS 3 System is powered on, the system will emit an audible beep and begin to execute internal System Diagnostics. System Diagnostics will test various electro-mechanical components to ensure the system is functioning properly prior to use. Refer to Section 11: Troubleshooting if any alarms or error messages are experienced during system startup.

To power on the MPS 3 System, follow the steps outlined below:

1. Turn main power switch on the rear panel of the MPS 3 Console to the ON position. The push button switch on the front of the MPS 3 Console will be illuminated in orange to verify the main power switch is in the ON position. The main power switch may be left in the ON position between uses. To charge the MPS 3 Battery, the main power switch must be in the ON position.

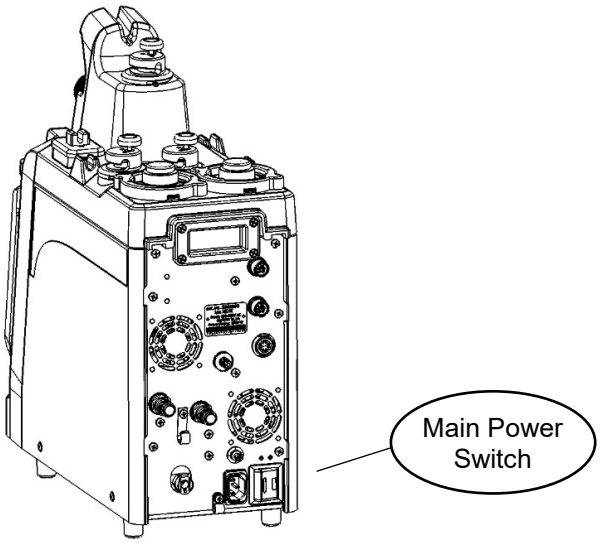


Figure 37: Main Power Switch

2. Press and hold the push button switch on the front of the MPS 3 Console until the indicator light turns blue. At this point, the MPS 3 System will power on and begin the startup diagnostics sequence. The MPS 3 System may be powered ON / OFF using the push button switch between uses. The main power switch must be left in the ON position to do this.

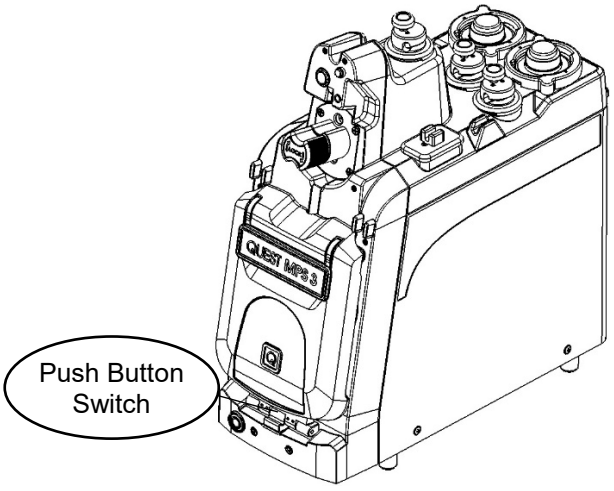


Figure 38: Push Button Switch

3. After the system is powered on, the MPS 3 Controller will display the startup screen. The startup screen will indicate the MPS 3 System is powered on and System Diagnostics is being performed. Alarm messages will be displayed on the startup screen should an error be encountered during System Diagnostics. Only the Protocol Manager is accessible during system startup and the other 3 startup options (Resume Case, New Case, and Menu) will be inaccessible until System Diagnostics is complete.

Figure 39: Startup Screen

4. Once System Diagnostics has completed successfully, the selection screen will illuminate the following options:

    - RESUME CASE (Section 9.2)
    - NEW CASE (Section 9.1)
    - PROTOCOL MANAGER (Section 9.3)
    - MENU (Section 9.4)

Figure 40: Selection Screen

6.2 System Settings

When the MPS 3 System is powered on for the first time, it is recommended that the operator adjust the System Settings to the desired preference.

The following parameters may be changed in the Settings menu.

- Delivery Line Type
- Audio Level
- Key Clicks (Audible Button Presses)
- Flow Knob Sensitivity (%)
- Language
- Arrest Agent Unit
- LCD Brightness (%)
- Date
- Time

Settings can be changed at any time by following the steps outlined below.

1. Select MENU → Settings to enter the Settings menu.

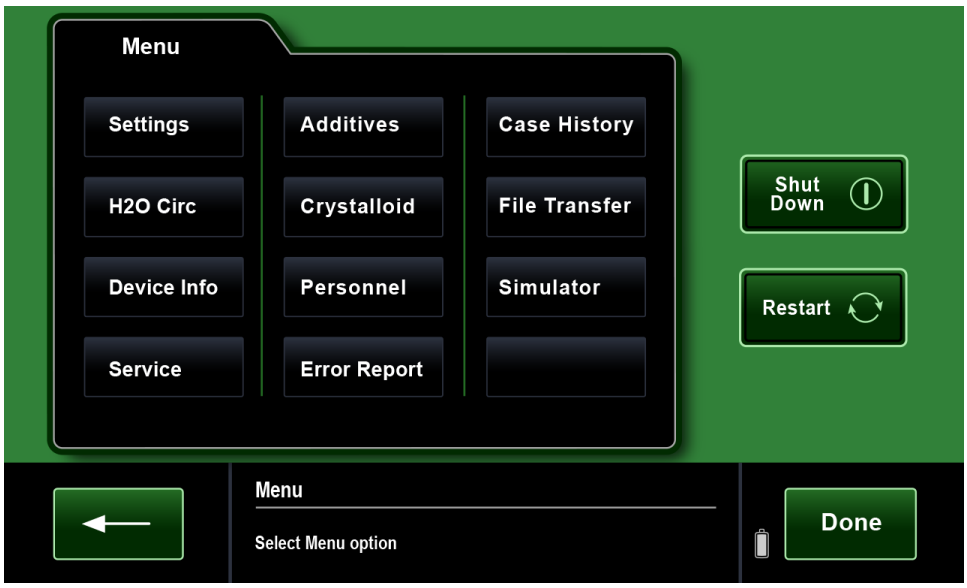


Figure 41: Menu Screen

2. The settings menu is displayed on 3 pages. To cycle through pages, use the arrow buttons near the page numbers.

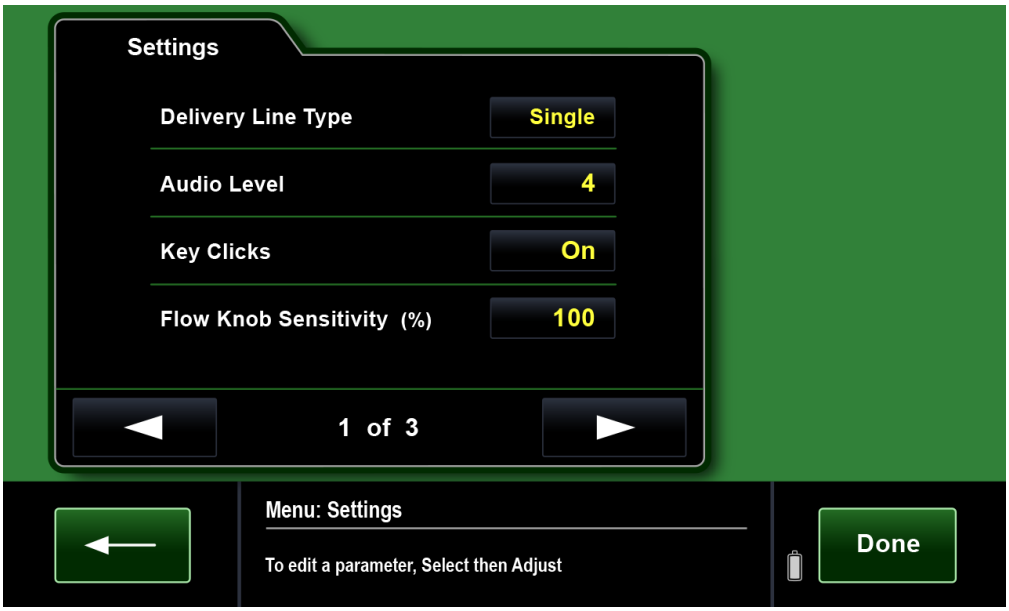


Figure 42: Settings Menu, Page 1

3. To change Delivery Line Type, select the selection button and choose single or double.
4. To change Audio Level, select the Audio Level selection button and set the desired level 1-5 (5 = Loudest).
5. To change Key Clicks (Audible Button Presses), select the selection button and choose On / OFF.
6. To set the Flow Knob Sensitivity %, select the selection button and set the desired level 10 – 100% (100% = Most Sensitive).
7. Once the settings on page 1 are configured, select the right arrow to move to page 2 of the Settings menu.

Figure 43: Settings Menu, Page 2

8. To select Language, select the selection button and choose the desired language.
9. To set the Arrest Source Limit, select the selection button and choose the desired units.
10. To select the LCD Brightness level, select the selection button and set the desired level 30 -100% (100% = Brightest).
11. Once the settings on page 2 are configured, select the right arrow to move to page 3 of the Settings menu.

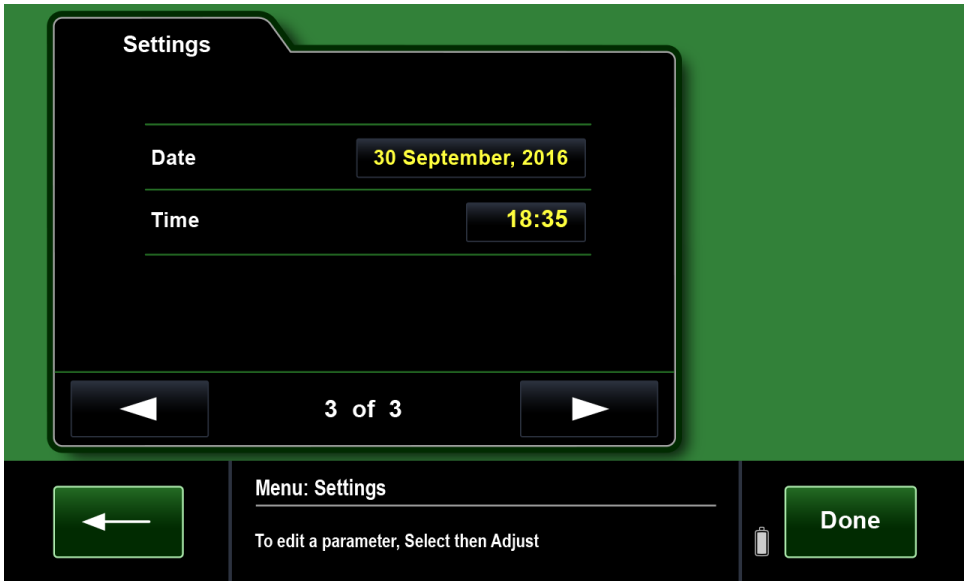


Figure 44: Settings Menu, Page 3

12. To set the Date, select the selection button and enter the date using the arrow keys.
13. To set the Time, select the selection button and enter the time using the arrow keys.
14. Once the desired settings are configured, select DONE to return to the Selection Screen.
15. Select the back arrow in the lower left corner to exit the settings menu at any time.

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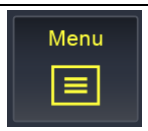
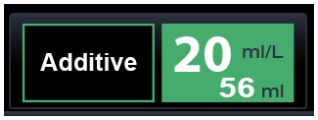
7 Graphical User Interface (GUI) Overview

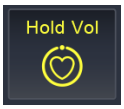
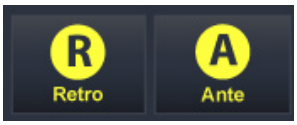
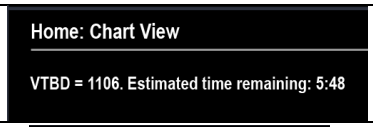
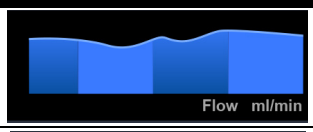
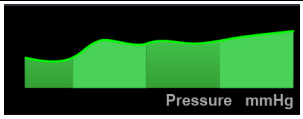
The MPS 3 Controller utilizes a Graphical User Interface (GUI) to allow the operator to set parameters, start / stop cardioplegia delivery and monitor delivery parameters. The interface is intuitive in operation, but this section will detail the layout of the interface for further clarification.

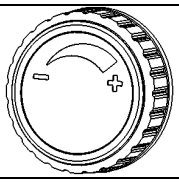
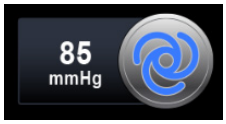
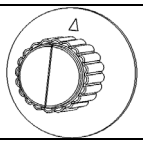
7.1 Home Screen Overview

The figure below shows the Home Screen and the interactive icons that can be used to select and change parameters during use.

Figure 45: Home Screen Icons

#	Icon	Name	Description
1		Flow Rate and Range	The Flow Rate (1) displays the current flow rate. A dynamic vertical flow bar displays the flow range and dynamically represents the current flow rate value with respect to the flow limits.
2		System and Delivery Pressure and Limits	The System Pressure (2) is always displayed. If the pressure source is selected as external, the corresponding Antegrade or Retrograde delivery pressure is also displayed. A dynamic vertical pressure bar displays the pressure limits and dynamically represents the current delivery pressure value with respect to the pressure limits
3		Delivery Time (On/Off)	The Time (3) displays delivery On/Off time, in the format H:MM:SS
4		Incremental Delivery Volume	The Incremental Volume (4) displays the total cardioplegia volume (blood + crystalloid + arrest + additive) delivered during the current 'On' Time.
5		Target Pressure Adjust (during Auto-Mode)	Target Pressure (5) increment and decrement buttons can be used to raise or lower the target pressure during auto-mode.
6		Protocol	The Protocol (6) button displays the protocol name, if selected. Operator can modify the protocol parameters by selecting the protocol name or can select a new protocol from the existing protocol list.
7		Menu	The Menu (7) displays the menu options, where operator can select Settings, H2O Circ, Service, File Transfer, Case History or Additive / Crystalloid / Personnel Lists.
8		Arrest Agent Volume Remaining Delivery Concentration Value and High or Low K+ Selection Button	The Arrest (8) displays the concentration setting of the arrest agent in mEq/L. The volume remaining bar displays the volume of fluid remaining in the Arrest cartridge. High or Low K+ indicates which selection is active and is used to toggle the setting.
9		Additive Volume Remaining, Additive Name, Delivery Concentration Value	The Additive (9) displays the concentration setting of the additive solution in ml/L and the Additive Name. The volume remaining displays the volume of fluid remaining in the Additive cartridge.
10		Blood-to-Crystalloid Ratio and Crystalloid Volume Remaining Bar	The B:C (10) displays the Blood-to-Crystalloid Ratio setting and the Crystalloid Name. The volume remaining displays the volume of fluid remaining in the crystalloid bag.

#	Icon	Name	Description
11		Delivery Temperature and Water Temperature.	The Delivery Temperature (11) displays the delivery temperature in °C. The Water Temperature (11) displays the water temperature in °C.
12		ECG	The ECG (12) button displays the waveform of the ECG signal received from the analog ECG port.
13		Hold Volume	The Hold Vol (13) button indicates and toggles the Hold Volume mode as Active /Inactive.
14		Vent	The Vent (14) button indicates and toggles the vent mode as Active / Inactive. The Vent (14) button is active only when Flow is set to zero.
15		Graft	The Graft (15) button indicates and toggles the Graft mode as Active / Inactive.
16		Delivery Route Options: Antegrade or Retrograde or Simulgrade	Antegrade or Retrograde (16) button indicates and selects the delivery direction. Simulgrade shall be selected by holding down (long press) the Antegrade or Retrograde (16) button. The delivery route button is disabled when the VENT mode is activated.
17		Auto	The Auto button (17) indicates and toggles the Auto mode as Active / Inactive
18		Home	The Home button (18) displays the Home Screen and also toggles between Home view or Chart view.
19		Message Window	The Message Window (19) is an area of the screen reserved for displaying messages
20		Flow Rate Chart	The Flow Rate Chart (20) is a real-time chart showing 16 second dynamic flow rate history. Only displayed in Chart view.
21		Delivery Pressure Chart	The Delivery Pressure Chart (21) is a real-time chart showing 16 second dynamic delivery pressure history. Only displayed in Chart view
22		Stopwatch Timer	The Stopwatch Timer (22) counts up every second when the timer is started and halts when the timer is stopped

#	Icon	Name	Description
23		VTBD / TTBD Counter	The VTBD and TTBD (23) counters count down the volume or time during delivery. Flow is automatically stopped when the counter reaches 0.
24		Flow Knob	The Flow Knob (24) is used to adjust the flow rate.
25	 	Stop Flow Auto-Start	The Stop Flow (25) button, displayed only when flow is greater than zero, may be used to immediately stop flow. The Auto-Start button, displayed only when flow is zero, may be used to ramp to the target pressure and then activate Auto Mode by holding down Auto-Start button for 3 seconds.
26		Set Knob	The Set Knob (26) is used to set parameters.
27		Flow Increment & Decrement Buttons	The Flow Increment and Decrement (27) button may be used to adjust the flow rate. Tap the button for slow adjustments or hold down the button for rapid adjustments.

7.2 Home Screen Views

The Home Screen provides the operator with the buttons and views that allows the operator the flexibility to view and modify the parameters while delivering Cardioplegia to the patient. These parameters can be set and monitored by the operator at any time during the case. The screens listed below are available through the Home Screen selection options:

- **Chart View** – Flow, Pressure, Time, and Volume are displayed in a smaller view. Additionally displays the real time pressure and flow in a graphical representation.

Figure 46: Chart View

- **Home View** – Flow, Pressure, Time, and Volume are displayed in an enlarged view

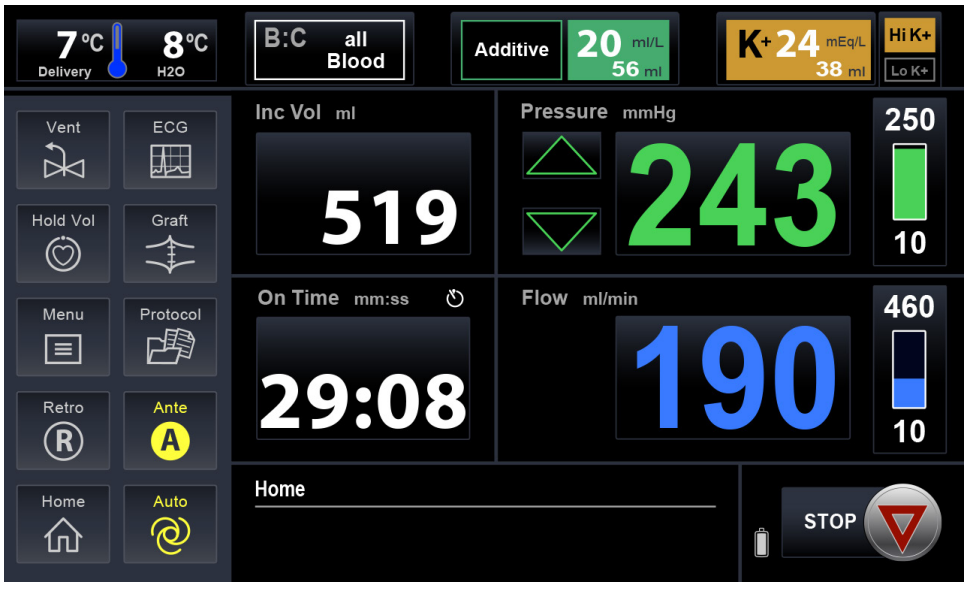


Figure 47: Home View

7.3 Changing Case Parameters During Delivery

Case parameters can be set and monitored by the operator at any time during the case. Additionally, the MPS 3 System can store and recall up to 64 delivery protocols.

7.3.1 Flow Settings

1. Select the flow display on the Home Screen. Flow setting screen is displayed.

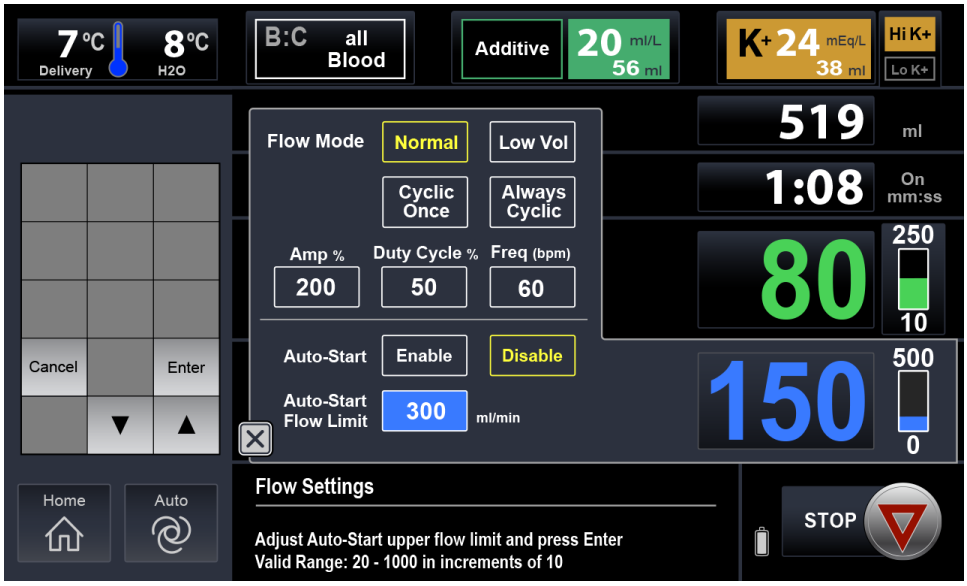


Figure 48: Flow Settings

2. The Low Vol button is only active if the current flow rate is 0 ml/min. Selecting the Low Vol button will put the MPS 3 System in a flow mode where it pumps with a reduced stroke volume. The maximum flow rate is limited to 200 ml/min. The Low Vol icon shall be displayed in the Flow display.
3. When flowing in Normal Flow mode, the Cyclic once and Always Cyclic buttons are enabled. When selected, the MPS 3 System pumps in a cyclic (pulsatile) profile. The Amplitude, Duty Cycle, and Frequency parameters can be adjusted to obtain the desired profile. The Cyclic mode icon and the calculated pulsatile pressure are displayed in Cyclic Mode. If Cyclic Once is selected, cyclic mode is exited after one use. If Always Cyclic is selected, the MPS 3 pumps in cyclic mode until Normal flow mode is selected.
4. The operator can adjust the flow rate by using the flow increment/decrement buttons or the flow knob.
5. Auto-Start Enable button is used to enable Auto-Start Mode.
6. Auto-Start Flow Limit is the maximum flow rate that will not be crossed when ramping up the flow to achieve the desired Target pressure. The Auto Start Flow Limit setting can be adjusted while flowing until the target pressure is reached. Any adjustments made during this time are not remembered permanently.
7. When flow is Zero and delivery route is Ante, the operator has the option to select the Auto-Start button which causes the flow to ramp up until the Target pressure is reached. Auto-Start is disabled for Ante-External Pressure, Retro, Simulgrade, and Graft mode.

7.3.2 Delivery Pressure Settings

The System pressure is always displayed. If the pressure source is selected as external, the corresponding external Antegrade or Retrograde pressure is displayed, and the System pressure is displayed with the 'Sys' label.

Figure 49: Delivery Pressure

The upper and lower pressure limits are always displayed. To adjust either pressure limit, select the limit and edit the value.

To set the pressure limits:

1. Select the Pressure display on the Home Screen. The Pressure Settings screen is displayed.
2. Select the Antegrade, Retrograde, or Graft Only tabs to select the respective pressure limits.

- **Only one pressure source (System or External) can be selected at a given time.**
- **The Zero button is used to Zero the Antegrade or Retrograde External Pressure sensor.**

Figure 50: Ante Pressure Settings

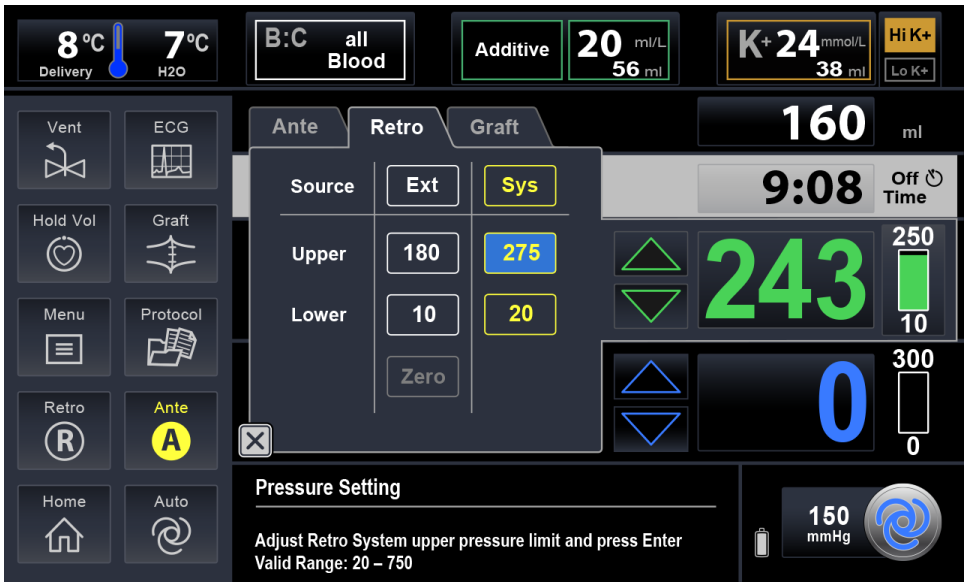


Figure 51: Retro Pressure Settings

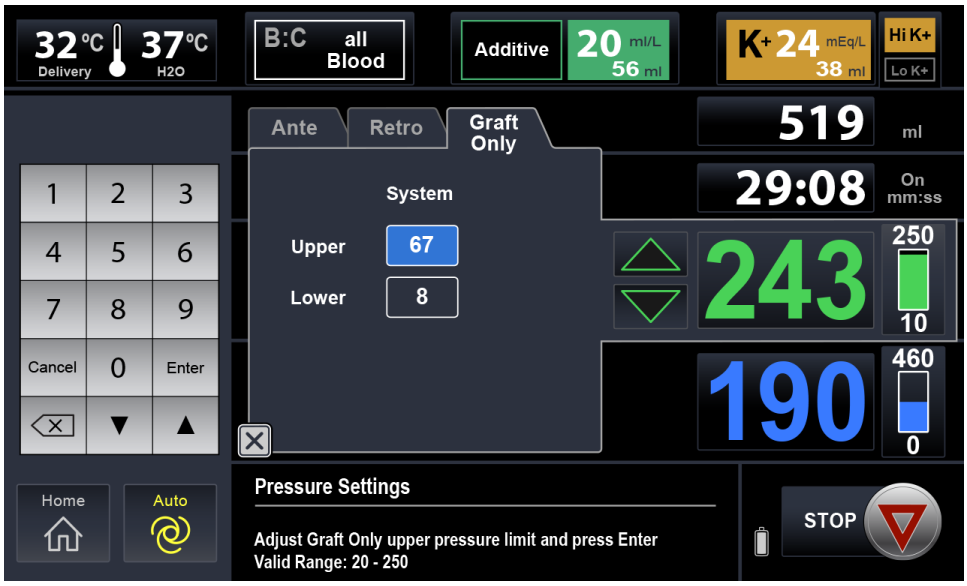


Figure 52: Graft Only Pressure Settings

3. The following table summarizes the pressure limits for Antegrade, Retrograde, and Graft Only modes. All are settable in increments of 1. The lower pressure limit maximum will be limited to 20mmHg less than the current upper pressure limit setting. The target pressure maximum will be limited to 20mmHg less than the current upper pressure limit.

	Antegrade		**Retrograde**		**Graft Only**
Source	**System (mmHg)**	**External (mmHg)**	**System (mmHg)**	**External (mmHg)**	**(mmHg)**
Upper	20 – 750	20 – 250	20 – 750	20 – 250	20 – 200
Lower	0 – 500	0-200	0 – 500	0 – 200	0 – 180
Target	20 – 700	–	–	–	–

7.3.3 Time

The Time displays the On / Off time for the pump. The ‘On Time’ displays when the dose is delivering and ‘Off Time’ is displayed when not delivering. The Stopwatch Timer will be displayed in the ‘On Time’ display, if it is activated.

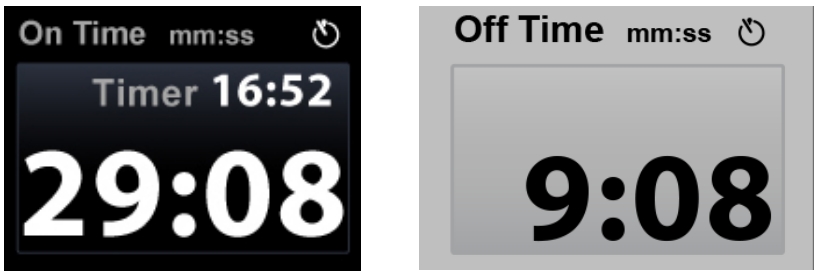


Figure 53: Time display

Select the ‘Off Time’ Time. It displays an Add? button as shown below

Figure 54: Add Button

If the Add? button is selected, the previous ‘On’ Time and the previous ‘Off’ time is added to the current ‘Off’ Time and the total ‘Off’ Time is displayed. This allows combining 2 doses that are separated by an unintentional pause.

7.3.3.1 Ischemic Timer

The Ischemic Timer gives the operator the ability to be notified when a set period of non-delivery has elapsed. This notification is provided by an audible tone and by flashing the timer display. There are two different timers that can be set: The Initial Timer and the Repeat Timer.

To set the Ischemic Timer:

1. Select the Time display on the Home Screen and a delivery time setting screen displays

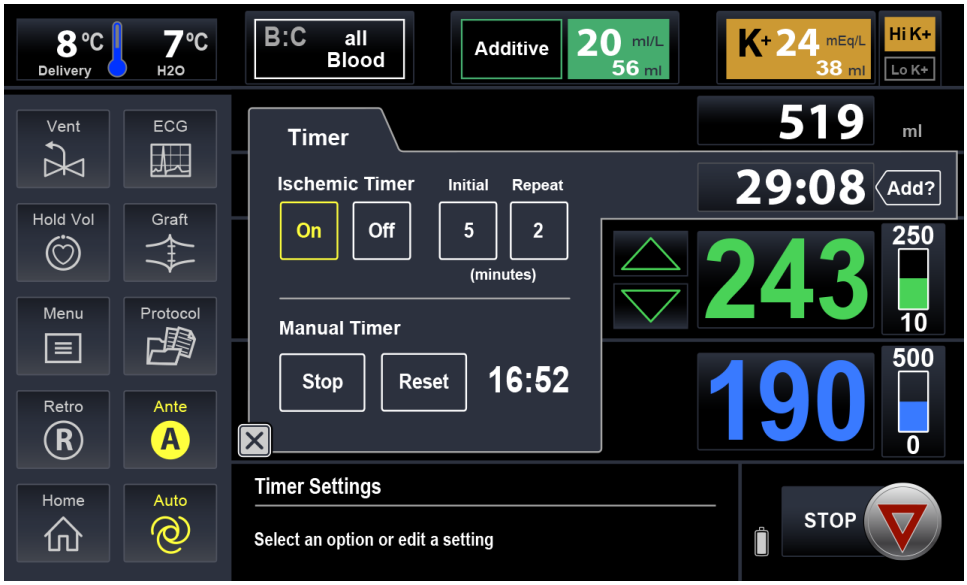


Figure 55: Timer Settings

2. Use the Numeric keypad to set the Initial and Repeat timer values in minutes. Use the On and Off buttons to turn the Ischemic Timer On or Off.
3. The Initial and Repeat Timers shall have a range of 1 to 120 minutes in 1 minute intervals.

7.3.3.2 Manual Timer

1. Select the Start button and the stopwatch timer starts counting every second from the current timer value to a maximum of 99 minutes and 59 seconds. Select the Stop button to stop the timer.
2. Select the Reset button to reset the timer to 00:00. If the timer is counting when during the reset, timer continues counting after resetting to 00:00.

7.3.4 Volume

The Incremental Volume displays the total Cardioplegia volume (blood + crystalloid + arrest + additive) delivered during the current 'On' Time. When flow is stopped, the Incremental Volume display shall continue showing the incremental volume. If flow is resumed before Off Time displays, the Incremental Volume continues counting from the previous value. If flow is resumed after Off Time displays the counter resets to zero and starts counting.

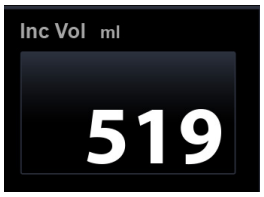


Figure 56: Incremental Volume

7.3.4.1 Set VTBD / TTBD

The VTBD button is used to set a specific volume to be delivered and the TTBD button is used to set a specific duration to deliver the cardioplegia to the patient. When the total specified volume / duration is delivered, the MPS 3 automatically stops the flow and sounds a double beep to notify the operator of completion of the delivery. If VTBD / TTBD is turned on while flowing the target Volume and Time will be added to the current Incremental Volume or Duration.

To set the VTBD / TTBD values:

1. Select the Incremental Volume button on the Home Screen.
2. Select the VTBD / TTBD tab.
3. The VTBD / TTBD settings screen is displayed.

Figure 57: VTBD/TTBD Settings

4. Set the VTBD and TTBD values.

Button	VTBD	TTBD
One Time	Delivers the set volume for a single dose	Delivers for the set duration for a single dose
Always	Delivers the set volume for every dose until the operator cancels the VTBD mode.	Delivers for the set duration for every dose until the operator cancels the TTBD mode.
Off	Turns Off VTBD	Turns Off TTBD

7.3.4.2 Volume Summary / Delivery Summary

The Total, Blood, Crystalloid, Arrest, Additive, Antegrade, Retrograde, Simulgrade, and Graft Only volume counters shall be tracked and dynamically displayed to the operator. Use the Reset Volumes button to reset all the counters to zero. When Flow = 0, the Dose History button transitions to the Dose History screen for the current Dose.

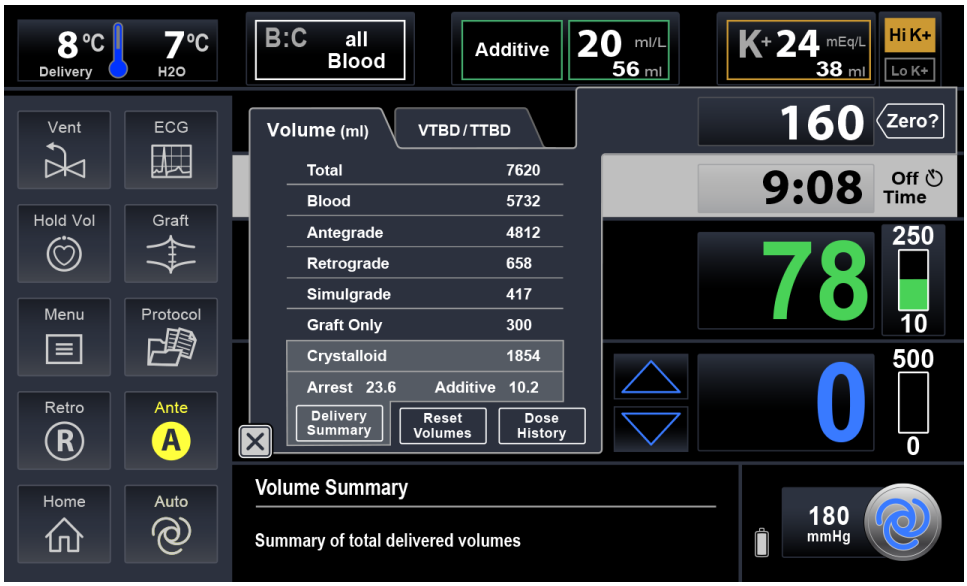


Figure 58: Volume Summary

The Delivery Summary button is used to display the summary of all delivered components to the patient. First the total non-blood volume is displayed. This is the sum of Crystalloid + Arrest Agent + Additive Volume delivered. Next, the total Potassium delivered to the patient is displayed. This includes the Potassium delivered by the Arrest pump as well as the Potassium delivered from Additive and Crystalloid solutions. Finally all other volumes of delivered components in the Additive and Crystalloid solutions are displayed alphabetically.

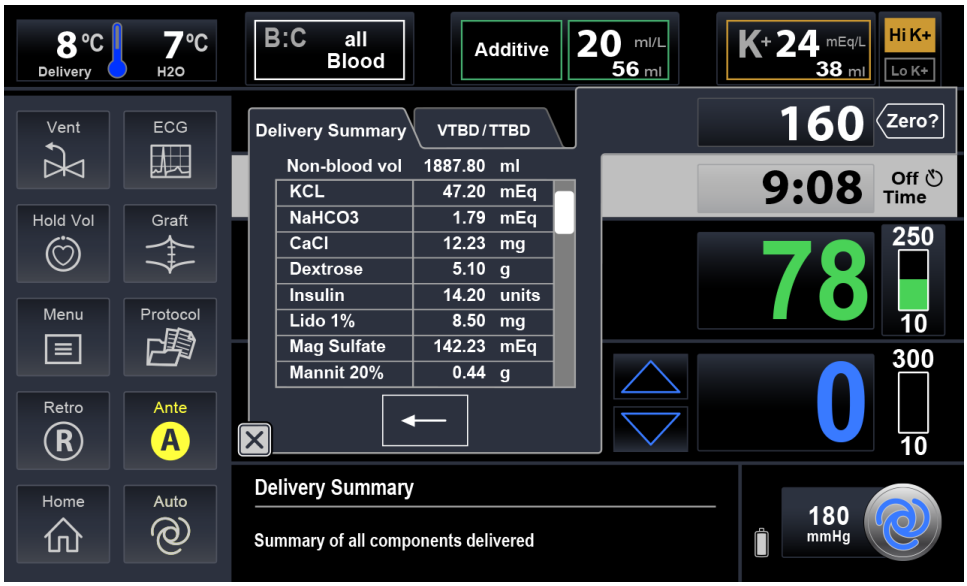


Figure 59: Delivery Summary

7.3.5 Arrest Agent (K+)

The MPS 3 System offers the capability to set two arrest agent delivery concentrations as High K+ and Low K+. The High/Low K+ button allows the operator to change between the two concentrations and also, when highlighted, indicates which concentration is displayed. The arrest agent concentration range is between 0 mEq/L to 40 mEq/L.

The surgeon is responsible for monitoring the patient's physical condition: observing the heart, aorta, and coronary sinus for indications of an overpressure condition, inaccurate arrest agent, or additive delivery. Failure to maintain adequate arrest during periods of ischemia may result in myocardial injury.

1. To set Arrest Agent settings, select 

on the Home Screen. The Arrest Agent Setting screen is displayed. The display has the solid-yellow look and the yellow LED on the Arrest pump is turned on to indicate to the operator that the Arrest Agent is being delivered.

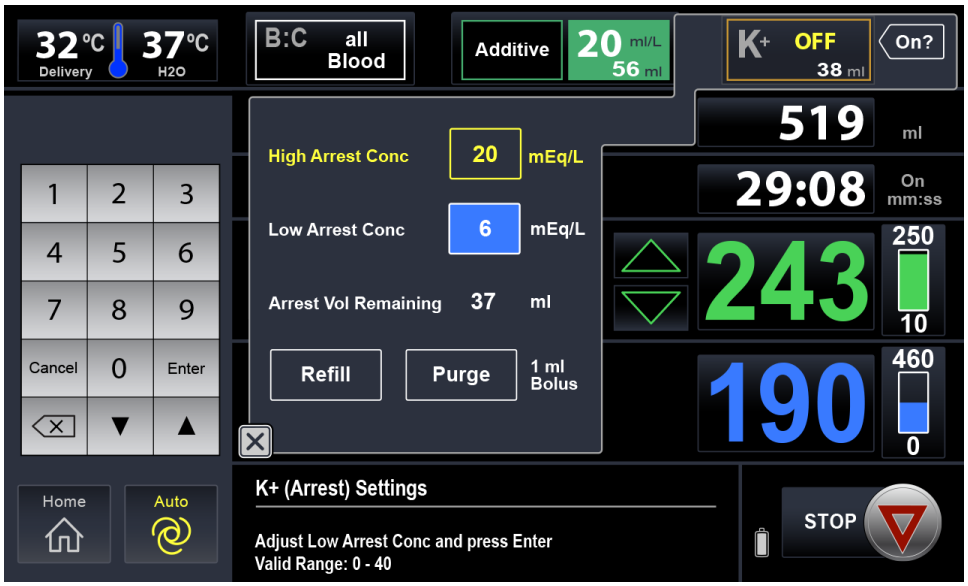


Figure 60: Arrest Agent Setting screen

2. Select the High Arrest Conc and Low Arrest Conc fields to modify the values. A numeric keypad is displayed to modify the values.
3. The Arrest Volume Remaining displays the remaining arrest volume present in the Arrest cartridge. The volume is measured, and the value cannot be changed by the operator. When the volume remaining is < 10 ml, it is highlighted in yellow.

To refill or purge the Arrest agent, select the Refill or Purge button. For more information about Refill and Purge, Refer to Section 8.3.

7.3.6 Additive

The MPS 3 System offers the capability to select the name of the Additive and to set the delivery concentration. The Additive concentration range is between 0 ml/L to 50 ml/L.

1. To set Additive settings, select 

on the Home Screen. The Additive Setting screen is displayed. The display has the solid-green look and the green LED on the Additive pump is turned on to indicate to the operator that the Additive drug is being delivered.

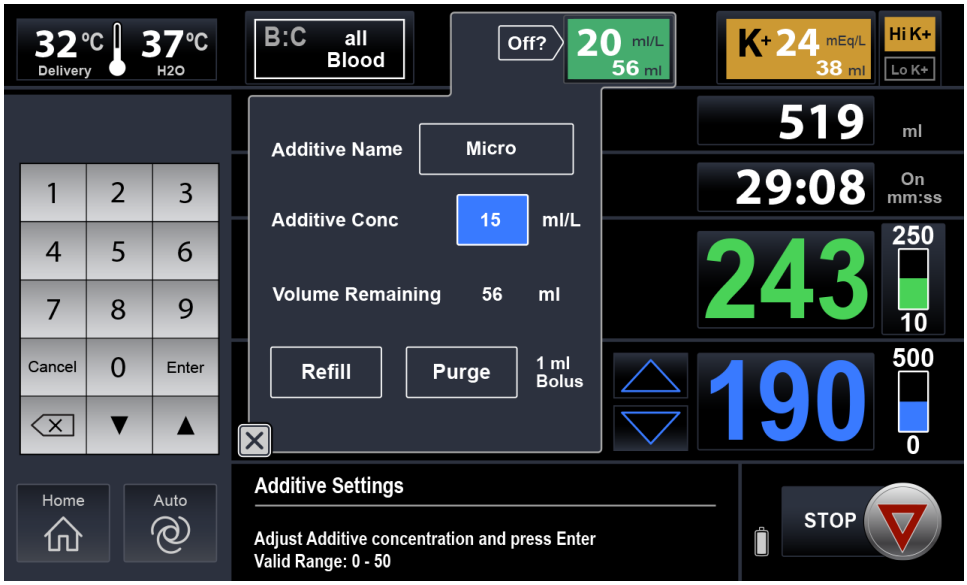


Figure 61: Additive Settings

2. Select the Additive Name. A list of previously created Additive names is displayed. Select the desired Additive drug/solution.
3. Select the Additive concentration value. A numeric keypad is displayed to modify the value.
4. The Volume Remaining displays the remaining Additive volume present in the cartridge. The volume is measured and cannot be changed by the operator. When the volume remaining is < 10 ml, it is highlighted in yellow.

To refill or purge the Additive, select the Refill or Purge button. For more information about Refill and Purge, refer to Section: 8.4.

7.3.7 Blood : Crystalloid

The MPS 3 System offers the capability to deliver blood and crystalloid in various ratios. The available options are:

- All crystalloid (Cryst)
- Blood : Crystalloid Ratios of 1:9 to 1:1 and 2:1 to 66:1
- All blood (Blood)

Blood : Crystalloid Ratio	Percentage of Crystalloid
20:1	4.8%
21:1	4.5%
24:1	4.0%
27:1	3.5%
32:1	3.0%
39:1	2.5%
49:1	2.0%
66:1	1.5%

When the remaining crystalloid volume reaches zero, flow is stopped and the ratio is changed to ‘all blood’ after getting operator confirmation.

1. To set Blood : Crystalloid settings, select 

on the Home Screen. The B:C Settings screen is displayed.

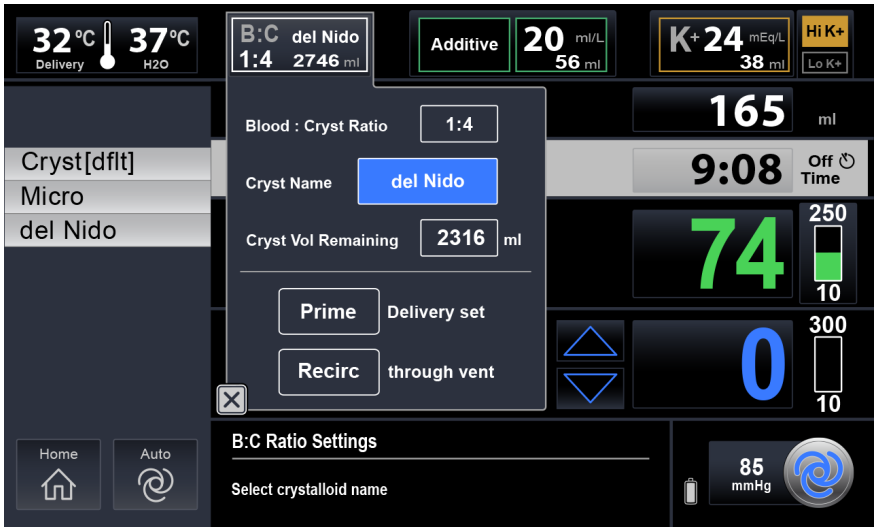


Figure 62: B:C Settings Screen

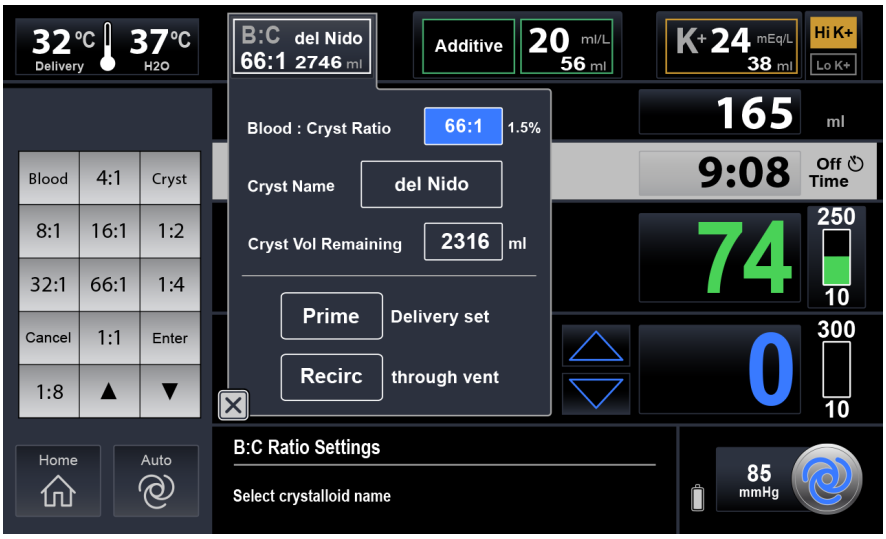


Figure 63: Blood : Cryst Ratio Selection

2. Select the Blood : Cryst Ratio value. A numeric keypad with commonly used ratios is displayed to set the ratio. Use the set knob for access to the full range of blood : crystalloid ratio settings.
3. Select the Cryst Name. A list of previously created Crystalloid names is displayed. Select the desired Crystalloid solution. The B:C ratio is automatically changed to the ratio that was saved when the Crystalloid solution was created.
4. The Cryst Volume Remaining displays the remaining Crystalloid volume present in the crystalloid bag. The volume is calculated and can be changed by the operator at any time. When the volume remaining is < 150 ml, it is highlighted in yellow.
5. Prime and Recirc are allowed when flow is zero. Select the Prime or Recirc button to initiate the Prime or Recirc processes.

7.3.8 Temperature

The MPS 3 System offers the capability to set the temperature of the cardioplegia solution delivered to the patient. The delivery temperature as measured in the heat exchanger and the H2O temperature as measured in the water circuit path are displayed. The display shows the various circulation system conditions such as circulation system off, priming, heater diagnostics, heater disabled, and temperature sensor error.

1. To set Temperature settings, select 

on the Home Screen. The Temperature setting screen is displayed.

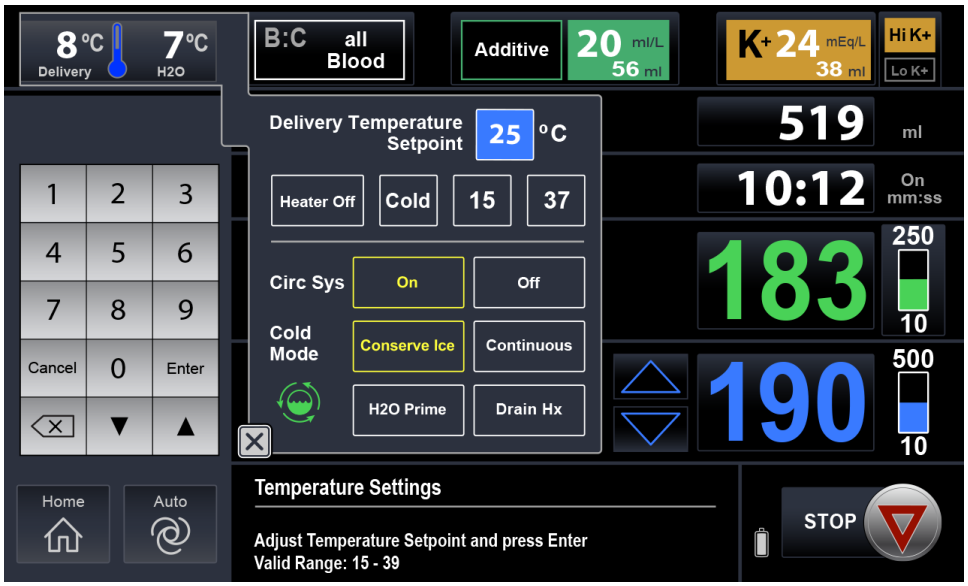


Figure 64: Temperature Settings

2. Select the temperature value. A numeric keypad is displayed to set the delivery temperature between 15°C and 39°C. The Heater Off, Cold, Preset 1 and Preset 2 buttons may be used as shortcuts to set the desired value.
3. The circulation system may be turned On or Off by using the Circ On and Off buttons.
4. The Cold Mode may be set to Conserve Ice or Continuous. In Conserve Ice mode, water is not circulated through the external reservoir when cardioplegia flow is stopped. In Continuous mode, water is always circulated through the external reservoir.
5. The Drain Hex button may be used at the end of the case to drain the water in the heat exchanger to prevent dripping during removal. H2O Circ has to be turned off to enable the Drain Hex button.
6. The H2O Prime button may be used to prime the H2O Circulation system. This is needed to eliminate any air that might be trapped in the circulation system.
7. The Circ flow icon  conveys the health of the water circulation flow. The green icon is displayed when the water flow is healthy. A flashing gray icon is displayed if the water flow is suboptimal.

7.4 Function Buttons

The Operator can select the following function buttons from the Home Screen.

- Vent
- ECG
- Hold Volume
- Graft
- Menu
- Protocol
- Retro
- Ante
- Home
- Auto

- **A dose may also be referred to as a delivery period.**
- **A dose starts when the flow is initiated and dose ends when the flow is stopped for more than programmable 'off time delay.'**
- **If the flow is resumed before 'off time delay' the current dose resumes.**
- **A new dose starts when a delivery route is changed, a new protocol is launched, Graft mode is activated or deactivated, a Graft is labeled, or when an ECG event is recorded.**
- **A dose always ends when Vent, Recirc, or Hold Vol mode is activated.**

7.4.1 Vent

The operator can purge air from the bubble trap by selecting the Vent button. The MPS 3 System opens the vent valve instead of the delivery valve. Any air that is trapped in the heat exchanger bubble trap can now be purged via the vent line. The MPS 3 controls ratios and temperature but does not deliver Arrest or Additive drugs in Vent mode.

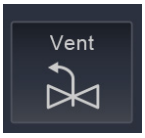


Figure 65: Vent Button

During normal delivery, the vent valve will automatically open when air is detected in the bubble trap. The vent valve will stay open as long as air is sensed. If the vent valve stays open for an extended period of time, the message "Vent valve is open. Check for Air in the bubble trap. Ensure the heat exchanger is locked" displays. Select Confirm if there is air in the heat exchanger bubble trap. The console continues to flow with the vent valve open.

7.4.2 ECG

To view the ECG trace, connect the Controller to the ECG Monitor using the MPS 3 ECG cable. Follow your ECG monitor manufacturer's instructions for connection and configuration. Refer to Section 5.6.3 for connection instructions to the MPS 3 Controller. This option allows the operator to view the ECG strip chart. To view the ECG chart, select the ECG button in the Home Screen. The ECG icon turns yellow and the ECG strip chart is displayed. The DC baseline Shift increment and decrement buttons can be used to shift the baseline of the ECG trace in the strip chart.

Figure 66: ECG View

7.4.2.1 ECG Events

Selecting the ECG chart displays the ECG Event screen. An ECG cable does not have to be connected to the Controller to enter the ECG Event screen or to record events.

- ***XClamp Time:*** The time elapsed between selecting XC-ON button and selecting XC-OFF button.
- ***Time to Arrest:*** The value of On Time when the Arrested button is selected.
- ***Arrest Time:*** The time elapsed from when selecting Arrested button to selecting Rhythm button.
- ***Ischemic Time:*** The Arrest Time minus the Delivery Time.
- ***Time to Rhythm:*** The time elapsed between selecting XC-OFF button or confirming Hotshot and selecting Rhythm button.

The XClamp Time can be started by selecting the XC-ON button. Select the Arrested button to freeze and record the Time to Arrest value. The Arrest Time counter then starts counting and the Ischemic counter starts to display the accumulated 'Off Time.' When the Rhythm button is selected the operator can select confirm to then record whether the heart was defibrillated, paced, temporarily paced or spontaneously restarted. To enable the Rhythm button, the operator must first select XC-OFF or confirm the Hotshot Detection when Delivery Temperature reaches 35°C. After the Rhythm button has been confirmed, the Time to Arrest timer resets and the operator has the option to record all of the ECG Event timers for four additional arrest events. After the Rhythm button has been confirmed for a fifth time, all of the buttons on the ECG Event screen become disabled.

Figure 67: ECG Event View

Figure 68: Hot Shot Detection Confirmation Screen

Figure 69: Heart Restart Method Selection Screen

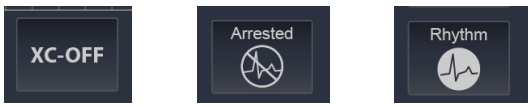


Figure 70: Cross Clamp (left), Arrested (center) and Rhythm (right) Buttons

7.4.3 Hold Volume

The Hold Vol button indicates the Hold Volume mode is active / inactive. When activated the Hold Vol icon flashes yellow. The incremental volume stops counting and the Off timer starts counting (even if flow > 0). The Air inline sensor is deactivated. This mode is recommended when priming the extension line or when purging air bubbles down the delivery line.

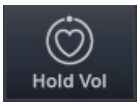


Figure 71: Hold Volume

7.4.4 Graft

Select the Graft icon button to activate Graft mode and to display the Graft settings screen. The Route label for the dose will change to 'Ante+Graft,' 'Retro+Graft,' or 'Simul+Graft.'

Figure 72: Graft Selection Screen

Select a Conduit and/or Distal label(s) and then select the Label button to record the conduit and distal(s) for the next dose. If flowing, selecting Label will create a new dose with the selected labels shown in the label field. When the Graft Only button is selected, the 'Graft Only' pressure limits are activated and the route for the dose is recorded as 'Graft Only'. It is recommended to setup labels and the route prior to starting the graft dose.

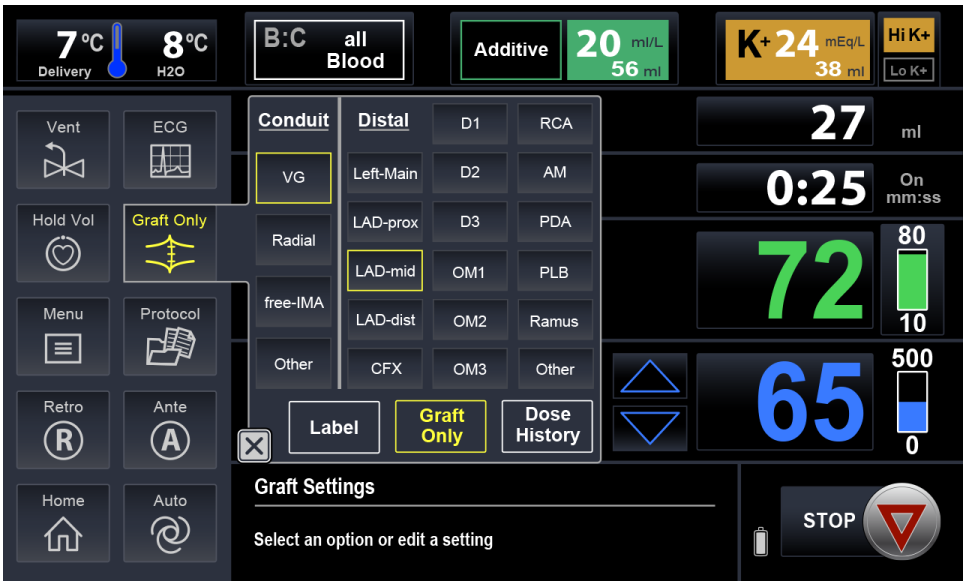


Figure 73: Graft Only Screen

Select the Graft Only button to exit Graft Only Mode and to change the route label and pressure limits to 'Ante+Graft,' 'Retro+Graft,' or 'Simul+Graft.' Select the Graft icon button to exit 'Ante+Graft,' 'Retro+Graft,' 'Simul+Graft,' or 'Graft Only' modes.

7.4.5 Menu

The Menu displays the menu options, where operator can select and adjust the parameters in Settings, H2O Circ, Device Info, Additive, Crystalloid, Personnel, Error Report, Case History, or File Transfer sub-menu options. Long press the Menu button to directly enter page 2 of the Case Report screen.

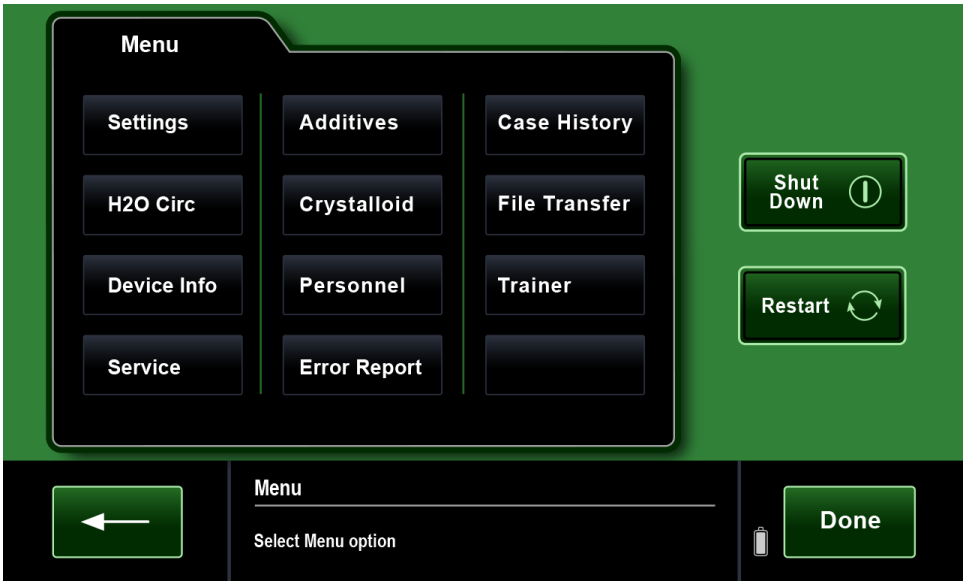


Figure 74: Menu Screen

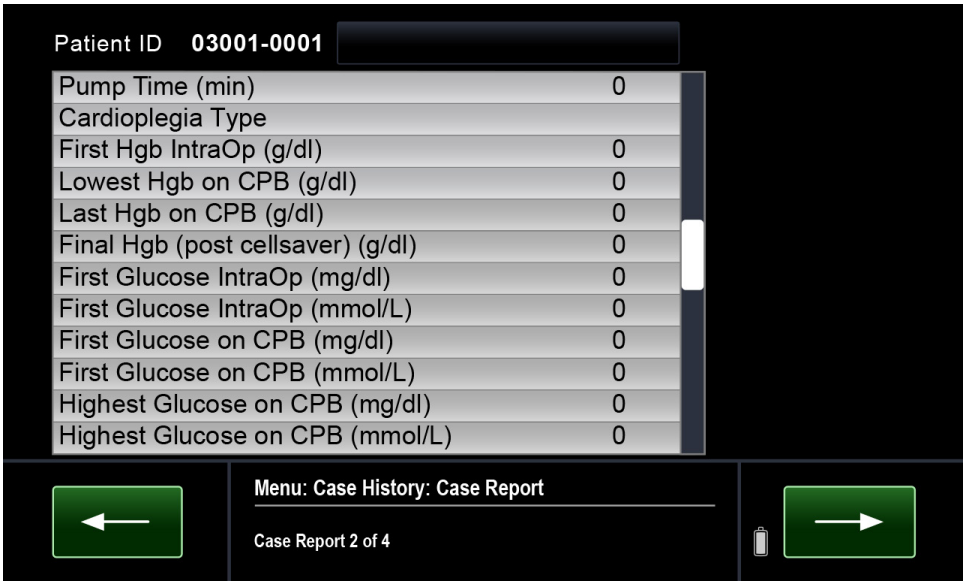


Figure 75: Page 2 of 4 of Case Report

7.4.6 Protocol

The Protocol icon button displays the protocol name, if a protocol asides from Defaults is launched. An asterisk '*' next to the name indicates that one or more parameters have been modified from the original saved Protocol when launched. Operator can modify the protocol parameters by selecting the protocol name or they can select a new protocol from the existing protocol list. Selecting the Launch button, when flow rate = 0, launches the Protocol. To manage saved protocols go to the Protocol Manager, select the Protocol Mgr button (when flow rate = 0) to enter the Protocol Manager module.

Figure 76: Protocol Screen

7.4.7 Delivery Routes

Cardioplegia can be delivered in the following three delivery valve modes:

- Antegrade
- Retrograde
- Simulgrade

The currently active delivery route is shown in yellow:

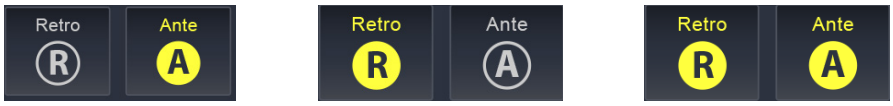


Figure 77: Antegrade (left), Retrograde (center), and Simulgrade (right) Delivery Routes

To change delivery routes, pressure limits, and dose route labels from Antegrade to Retrograde, or vice versa, short press the route in grey. To change the route to Simulgrade delivery, use one finger to hold down (long press) either delivery route buttons and Confirm the warning. When in Simulgrade mode both the Ante and Retro buttons are highlighted and the Retrograde pressure limits are activated. To exit Simulgrade delivery short press either the Ante or Retro buttons.

When flow is initiated in Single Line mode, the console only opens the Antegrade valve regardless of which route is selected. If the system is in Double Line mode, the console opens the Antegrade valve when Antegrade is selected or the retrograde valve when Retrograde is selected or both the Antegrade and the Retrograde valves when Simulgrade is selected. Single and Double Line mode can be changed via the Settings screen.

7.4.8 Home

The Home button exits various setting screens and also toggles between Home view and Chart view.

Figure 78: Home Button

7.4.9 Auto Mode and Auto-Start Mode

The auto mode feature provides constant pressure cardioplegia delivery. To activate Auto mode, the operator first adjusts the flow rate to achieve the desired delivery pressure and then select the Auto button. Auto button is disabled for flow rates below 25 ml/min. The MPS 3 System calculates the flow rate limits and automatically increases / decreases the cardioplegia flow within these limits to maintain the selected delivery pressure.

Auto-Start mode is also a constant pressure delivery mode where the flow is automatically ramped up from zero until the target pressure is reached and then the MPS 3 System automatically increases / decreases the flow rate to maintain the Target pressure.

To activate the Auto-Start mode, first ensure that the mode is enabled in the Flow Settings screen. Press and hold the Auto-Start button on the Home Screen when flow is zero to activate Auto-Start mode. This is a safety factor to prevent accidental activation. Auto-Start is only allowed in Antegrade delivery mode.

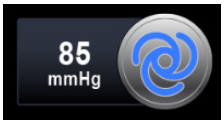


Figure 79: Auto-Start

The target pressure value is displayed in the Auto-Start button and in the message window while in Auto Mode. The Auto-Start button is disabled when VENT mode is activated.

The Target pressure can be adjusted by using the increment and decrement buttons. During Auto or Auto-Start mode, the upper and lower flow limits are displayed. The upper flow limit is twice the flow rate value when Auto mode is selected or when target pressure is reached.
The MPS 3 System exits auto mode when the Auto or Stop button is pressed or the flow is adjusted using the flow knob.

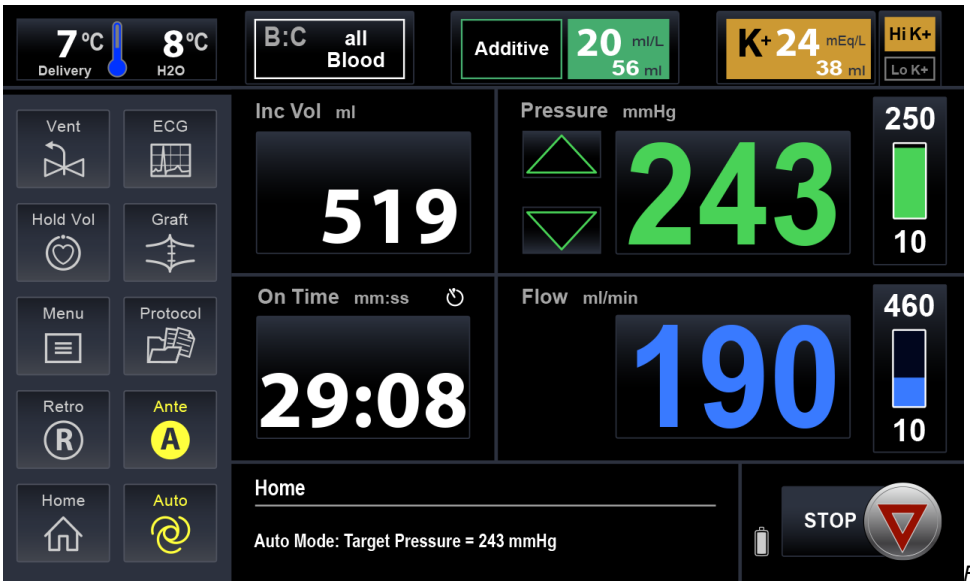


Figure 80: Auto Mode Screen

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8 MPS 3 Disposable Installation

This section details the instructions for installing the MPS 3 Delivery Set and optional accessories for use with the MPS 3 System.

Only genuine Quest disposable components, including delivery sets and extension lines, can be used with the MPS System to ensure the intended system performance and reliability.

Read this Operating Instruction prior to operating the MPS 3 System. The attending clinician is solely responsible for the setup and use of the MPS 3 Delivery Sets and accessories for use with the MPS 3 System.

Avoid OPERATOR INJURY. Only qualified technicians should attempt to install the MPS 3 Delivery Sets and optional accessories. EnsureEnsure that all fingers are free from pinch / crush hazards while installing the MPS 3 Delivery Sets and accessories.

The MPS 3 System water circulation system must be properly primed and purged of air in order to receive efficient heat transfer in the delivery set.

8.1 Installing the MPS 3 Delivery Set

The setup sequence prepares the MPS 3 System to deliver cardioplegia to the patient. During setup, the operator will install the system, fill the disposable components, set the delivery parameters, and prime the system.

The standard MPS 3 Delivery Set consists of the following: (See Section 2.3)

- Heat Exchanger
- Blood : Crystalloid Cassette
- Blood Source Line
- Crystalloid Source Line with I.V. Spike
- Vent Line
- Extension Line
- Arrest Agent Cartridge
- Additive Cartridge

8.1.1 Installing the Heat Exchanger

1. Turn the MPS 3 Console power switch off and then on to ensure the pump pistons are retracted. Open the door to reveal the pumping chambers.

DO NOT LOAD cassette if the pistons are in the forward position (convex). Cycle the power to reset the pistons. If the pistons do not retract, STOP THE MPS 3 CONSOLE and call for service. If the pump pistons are not fully retracted, there may be unintentional delivery when the door is closed.

2. Verify the heat exchanger locking knob is in the proper position to secure either the 10 or 16 convolution heat exchanger. To put the knob in the 10 convolution position, push in on the knob and rotate clockwise until the knob will no longer turn. To put the knob in the 16 convolution position, push in on the knob and turn counterclockwise until the knob will no longer turn.
3. Verify the knob is unlocked (rotate Counterclockwise).
4. Using proper technique, open the outer tray, remove the extension line, source lines, drug cartridges and drug lines and set aside.
5. With one hand, grasp the heat exchanger and remove the heat exchanger and blood/crystalloid cassette from the tray.
6. To ensure proper installation when installing the heat exchanger, allow the blood/crystalloid cassette to lay inside the door over the pump chambers. The words “Blood” and “Cryst” should be in the correct orientation facing the operator.
7. With cassette oriented properly in the door, place the vent line from the heat exchanger through the vent line channel on the top of the MPS 3 Console so the vent line tubing may pass through the vent valve.

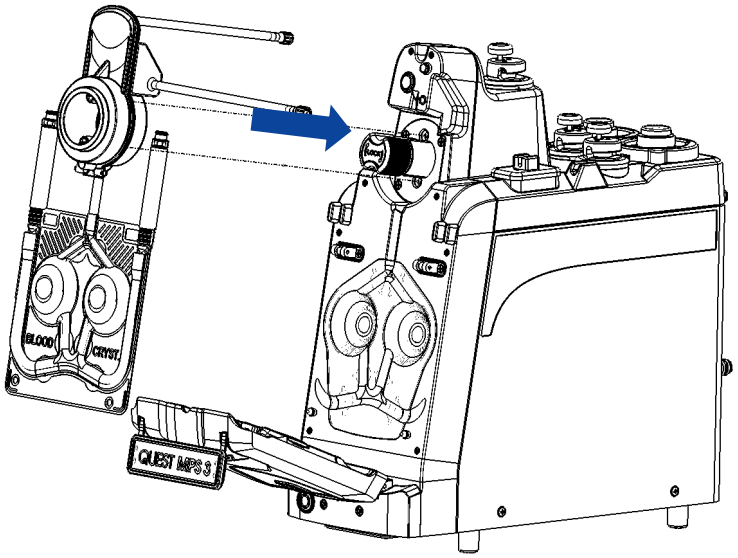

Figure 81: MPS 3 Heat Exchanger Installation

8. With the bubble trap oriented upwards, insert the two water ports of the heat exchanger into the two water ports on the MPS 3 Console. While applying pressure to the heat exchanger, turn the knob clockwise to lock the heat exchanger in position. Once the knob is locked, the water port seals and bubble trap sensor interface will automatically engage with the MPS 3 Console.

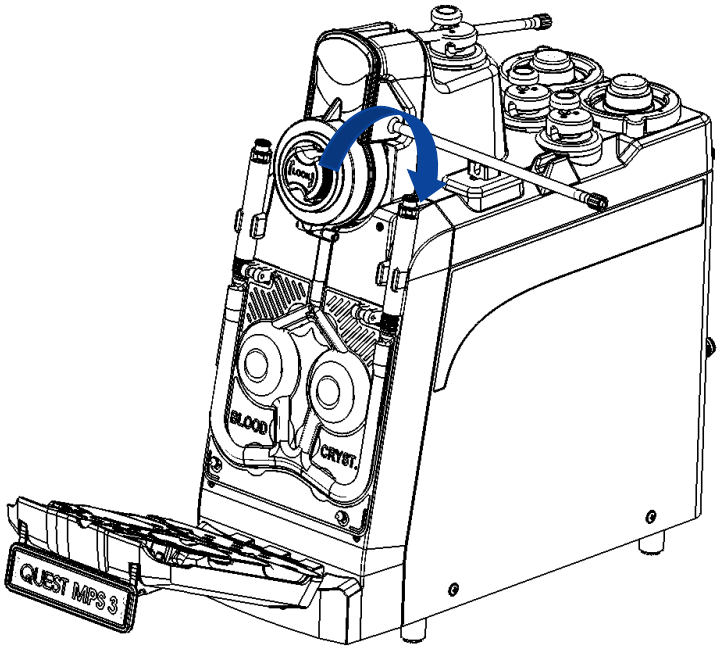

Figure 82: MPS 3 Locking Knob Engagement

9. Route the vent line through the vent valve on the MPS 3 Console by pressing down on the vent valve manual operation button. Ensure tubing is not overstressed or kinked upon installation.

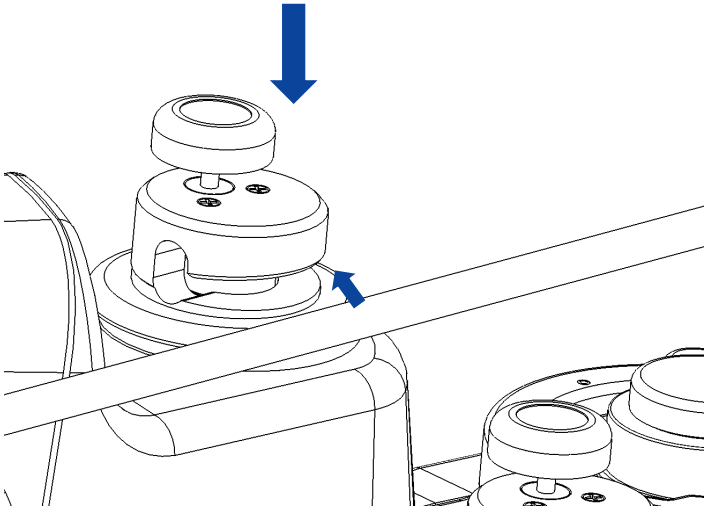

Figure 83: MPS 3 Vent Valve Loading

8.1.2 Installing the Blood / Crystalloid Cassette

1. Secure the blood/crystalloid cassette by firmly seating the cassette over the two bottom pins and door latches.

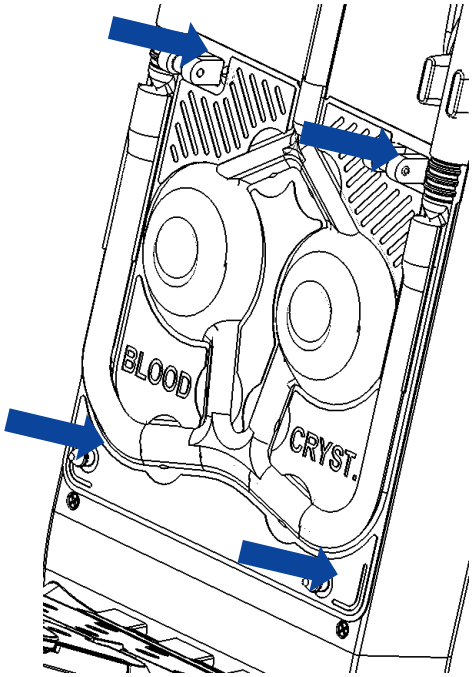

Figure 84: MPS 3 B / C Cassette Loading

2. Route the blood and crystalloid inlet tubes through the tubing clamps located on the MPS 3 Console and carefully close the door.

DO NOT LOAD cassette if the pistons are in the forward position (convex). Cycle the power to reset the pistons. If the pistons do not retract, STOP THE MPS 3 CONSOLE and call for service. If the pump pistons are not fully retracted, there may be unintentional delivery when the door is closed.

Avoid OPERATOR INJURY by ensuring all fingers are clear from the door edges before attempting to close the door.

Close the door before using the MPS 3 Console. The door must be fully closed with the handle engaged prior to operation of the MPS 3 Console. DO NOT USE excessive force to open or close the door. Forcing a door closed may indicate an improperly installed or overfilled cassette.

3. The blood source line is connected to the blood inlet tubing. Route the tubing along the top of the MPS 3 Console using the tubing clamps on the Console.

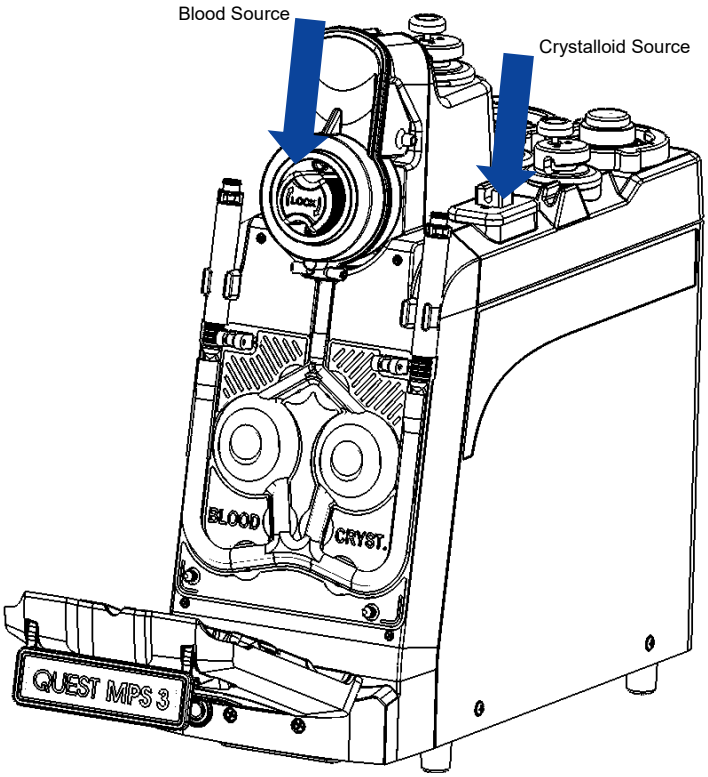

Figure 85: MPS 3 B / C Cassette Source Lines

4. If necessary, remove the cap and connect the crystalloid source line to the crystalloid inlet tubing and route the tubing along the top of the MPS 3 Console using the tubing clamps on the Console.

8.1.3 Connecting the Delivery Set to the Extracorporeal Circuit

1. Connect the blood source to the cardioplegia outlet on the oxygenator
2. If necessary, insert the spike on the crystalloid line into the crystalloid bag and hang the bag.

The crystalloid bag must hang at least 3 feet (1 m) above the pumping chamber to ensure adequate pressure is supplied to fill the pump.

3. Route the delivery line from the heat exchanger through the air in line detector and antegrade delivery valve (A). To open the valve, press down firmly on the manual button and hold while inserting the tubing. (see step 8 from section 8.1.1)

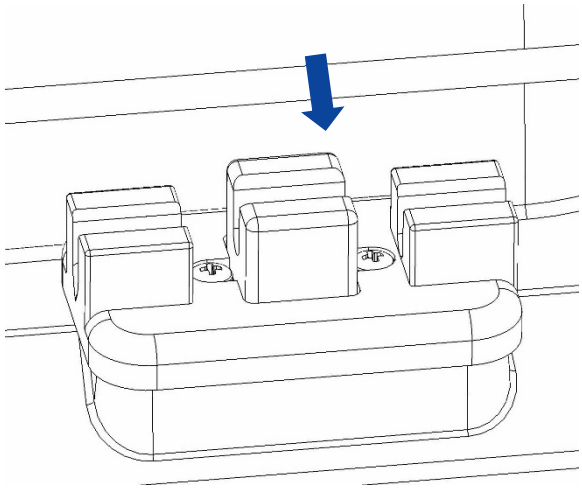

Figure 86: MPS 3 Air in Line Sensor Engagement

FULLY INSERT the tubing through the air in line detector for proper MPS 3 Console operation.

4. Uncoil the vent line and attach the luer connector to the non-pressurized luer port of the cardiotomy reservoir.
5. Following catheterization, connect the extension line to the delivery catheter.

8.1.4 Installing and Filling the Arrest Agent Cartridge

DO NOT USE an arrest agent (potassium chloride) concentration other than 2 mEq/ml. The MPS 3 System is designed to operate with an arrest agent concentration of 2 mEq/ml. Using an arrest agent concentration other than 2 mEq/ml will result in inaccurate delivery concentrations and may cause patient injury.

DO NOT OVERFILL arrest agent or additive cartridges. The normal maximum cartridge capacity is 75 ml. Overfilling the arrest agent or additive cartridges before or after installation in the console can cause unintentional bolus delivery and possible system malfunction.

DO NOT REMOVE arrest agent or additive cartridges while delivering cardioplegia. Removing the arrest agent or additive cartridges while delivering cardioplegia can cause inaccurate delivery calculations.

1. Ensure the plunger tip is fully inserted to the end of the Arrest Agent Cartridge barrel by pushing the plunger into the cartridge.

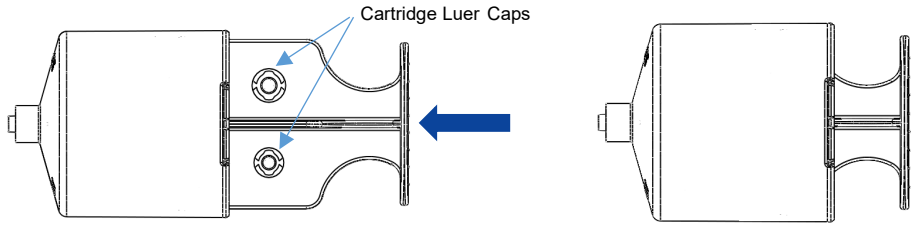

Figure 87: Fully Insert Plunger in Cartridge

2. **Exercise the plunger a few times** and remove the plunger handle by squeezing cartridge and unscrewing handle in a counterclockwise motion. **Plunger tip should remain in cartridge.**

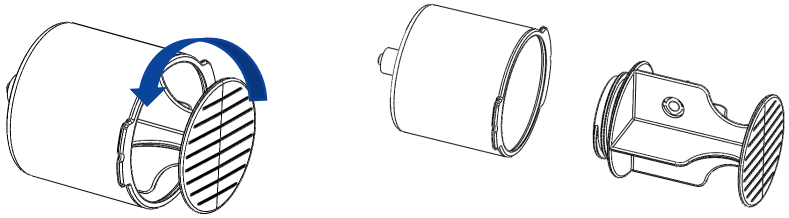

Figure 88: Plunger Removal

3. With printing facing to the right, align the two flanges on the Arrest Cartridge with the matching features on the Arrest Pump on the MPS 3 Console.

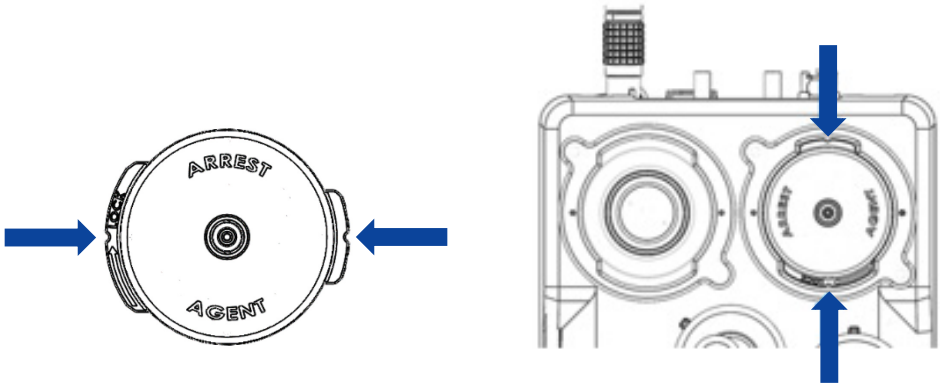

Figure 89: Align the Cartridge

4. Insert the Arrest Cartridge into the Arrest Pump and turn clockwise 90° to lock into the pump.

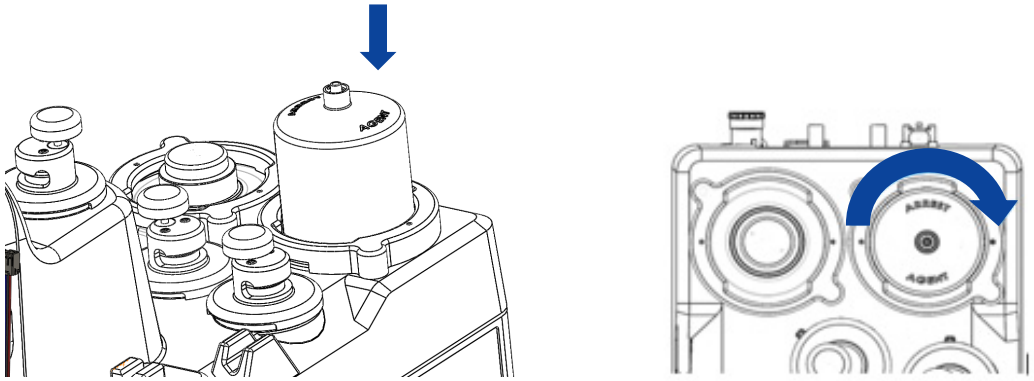

Figure 90: Secure Cartridge to Console

5. Connect the Yellow stopcock Arrest Cartridge Delivery Line with the non-standard luer fitting to the Arrest cartridge and the check valve fitting to the heat exchanger.

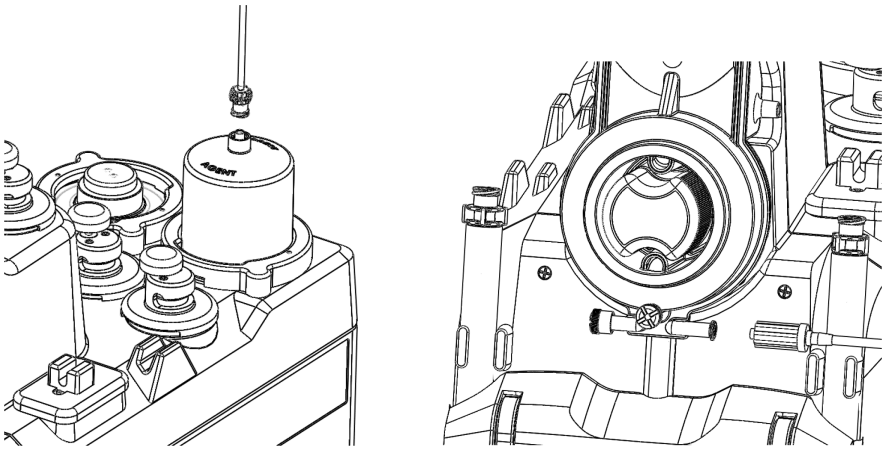

Figure 91: Arrest Delivery Line Connections

6. Connect the filling syringe to the fill port of the yellow stopcock and turn the handle to the fill position.

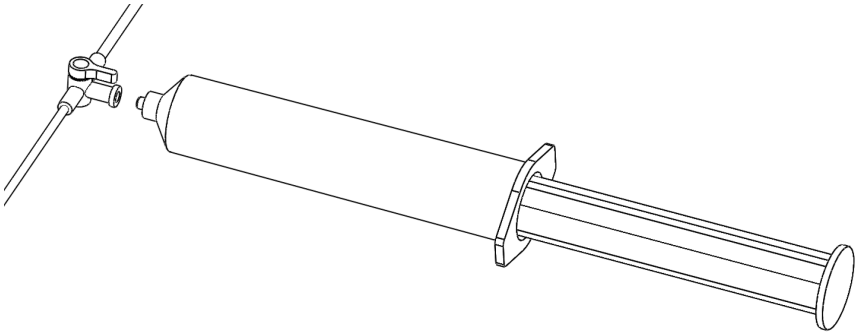

Figure 92: Syringe Connection

7. Carefully fill the Arrest Cartridge by moving the solution from the filling syringe to the Arrest Cartridge.

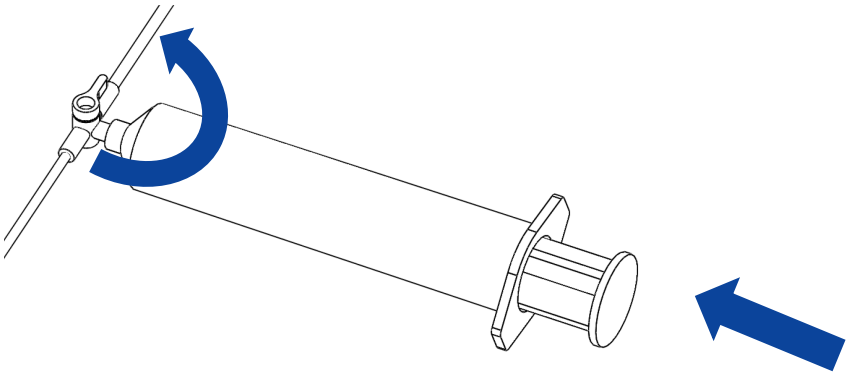

Figure 93: Cartridge filling

8. For best results, ensure that the Arrest Cartridge is free of air by aspirating with the filling syringe.
9. Disconnect the filling syringe from the stopcock and turn the stopcock handle to the delivery position.
10. During the console setup procedure, set the desired high and low arrest agent delivery concentrations between 0 and 40 mEq/L of cardioplegia solution.

8.1.5 Installing and Filling the Additive Cartridge

DO NOT OVERFILL arrest agent or additive cartridges. The normal maximum cartridge capacity is 75 ml. Overfilling the arrest agent or additive cartridges before or after installation in the console can cause unintentional bolus delivery and possible system malfunction.

DO NOT REMOVE additive cartridge while delivering cardioplegia. Removing the additive cartridge while delivering cardioplegia can cause inaccurate delivery calculations.

1. Ensure the plunger tip is fully inserted to the end of the Additive Cartridge barrel by pushing the plunger into the cartridge.

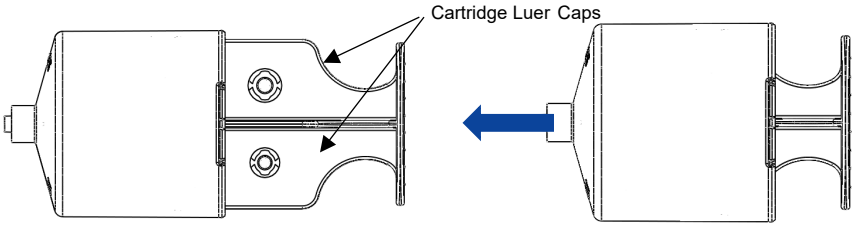

Figure 94: Fully Insert Plunger in Cartridge

2. **Exercise the plunger a few times** and remove the plunger handle by squeezing cartridge and unscrewing handle in a counterclockwise motion. **Plunger tip should remain in cartridge.**

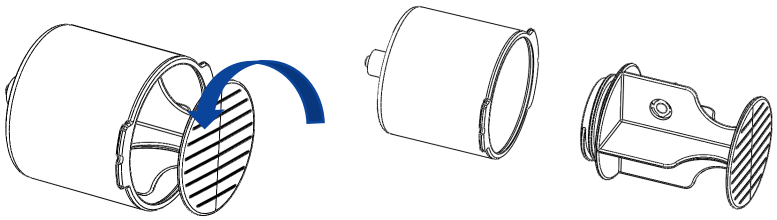

Figure 95: Plunger Removal

3. With printing facing to the right, align the two flanges on the Additive Cartridge with the matching features on the Additive Pump on the MPS 3 Console.

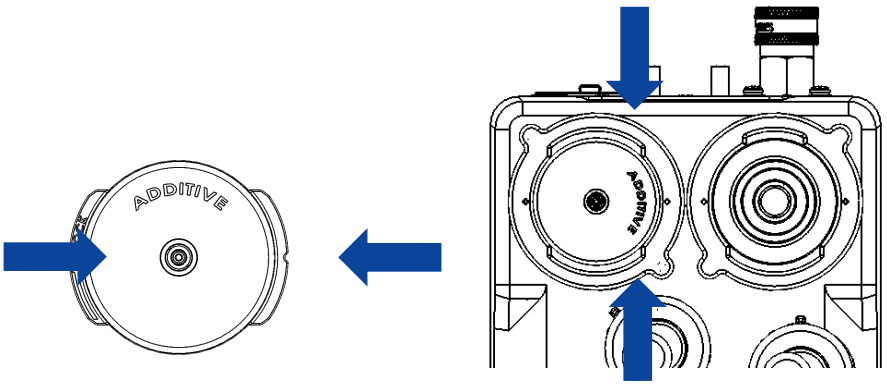

Figure 96: Align the Additive Cartridge

4. Insert the additive Cartridge into the Additive Pump and turn clockwise 90° to lock into the pump.

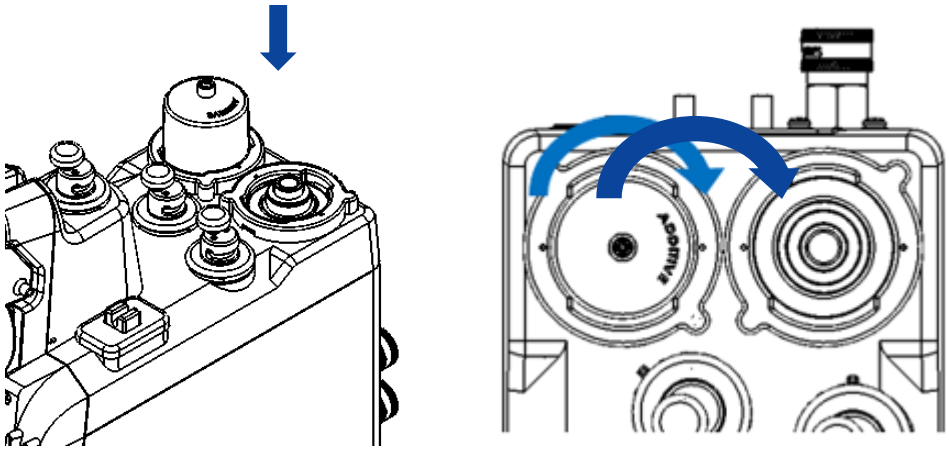

Figure 97: Secure Additive Cartridge to Console

5. Connect the green stopcock Additive Cartridge Delivery Line with the standard luer fitting attaching to the Additive cartridge and the check valve fitting to the heat exchanger.

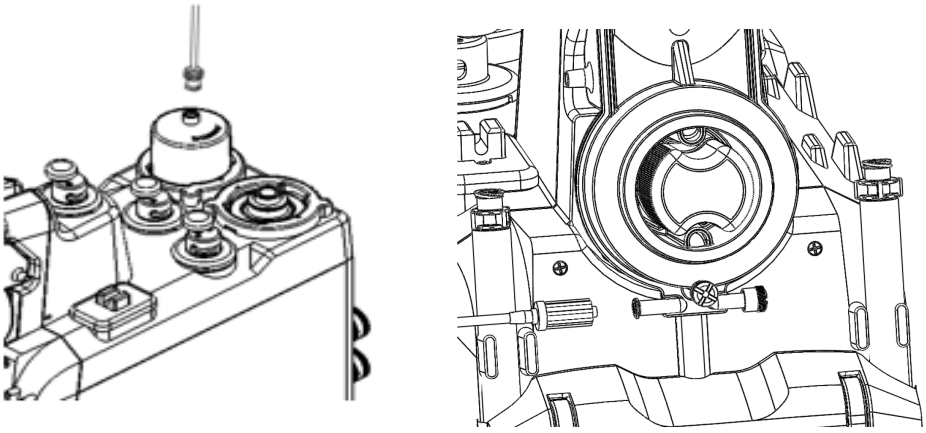

Figure 98: Connect check valve to heat exchanger

6. Connect the filling syringe to the fill port of the green stopcock and turn the handle to the fill position.
7. Carefully fill the Additive Cartridge by moving the solution from the filling syringe to the Cartridge.

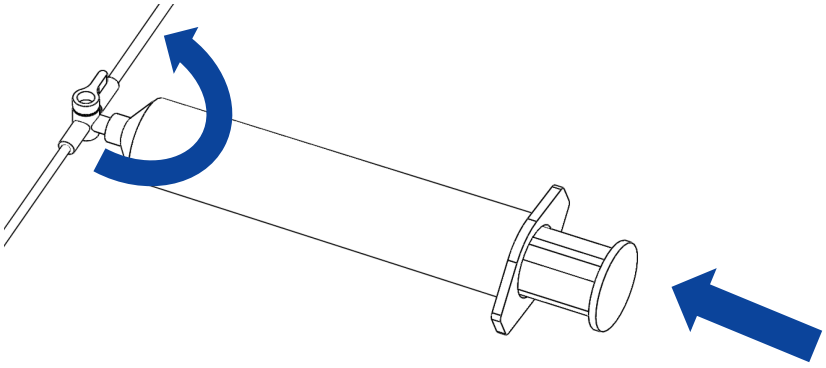

Figure 99: Cartridge filling

8. For best results, ensure that the Additive Cartridge is free of air by aspirating with the filling syringe.
9. Disconnect the filling syringe from the stopcock and turn the stopcock handle to the delivery position.
10. The coupler for the additive pump allows either the Arrest or Additive Cartridge to be loaded.
11. During the Console setup procedure, set the desired additive delivery concentration between 0 and 50 ml/L of cardioplegia solution.

8.2 Priming and Recirculation

DO NOT PRIME the delivery set more than 12 hours prior to surgery. Biological contamination is a risk after more than 12 hours.

When recirculating in Recirc mode or Vent mode, the operator must ensure that the system has sufficient flow and positive pressure. If not, the delivery set pouch may drain into the reservoir which could cause a delay in the next dose of delivery.

Prior to delivering cardioplegia, the delivery set must be primed to remove all air in the delivery set and the drug cartridges.

After the disposable is loaded, the MPS 3 System is powered on, and case parameters have been entered, the MPS 3 System is ready to perform the priming sequence. On completion of prime, the operator has the option to recirculate fluid through the Vent Valve.

When an operator presses the Prime button, the MPS 3 System initiates the priming sequence. During the automatic priming sequence, the MPS 3 System circulates just enough cardioplegia solution to clear air bubbles in the delivery line. At the completion of the auto priming sequence, the manual recirculation mode screen displays.

Prior to starting the priming process, the Arrest Agent and Additive cartridges must be filled. If a cartridge is not filled a message is displayed giving the operator an option to disable the specific pump or retest.

To start the Auto Prime sequence, follow the steps outlined below:

1. Select the Prime button on the New Case Setup screen and the start prime screen displays.

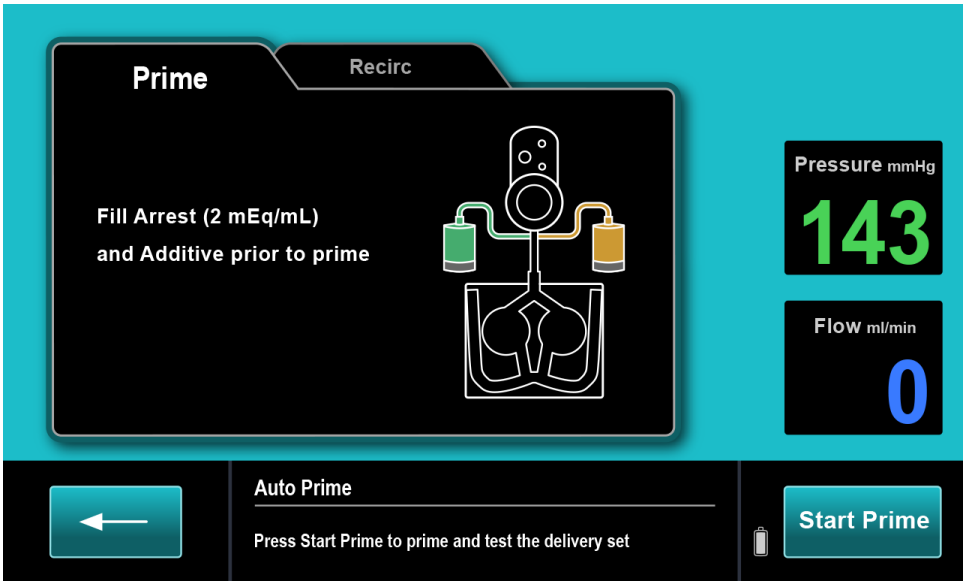

Figure 100: Prime Screen

2. Select the Start Prime button on the Prime screen, and the Auto Prime sequence will initiate.

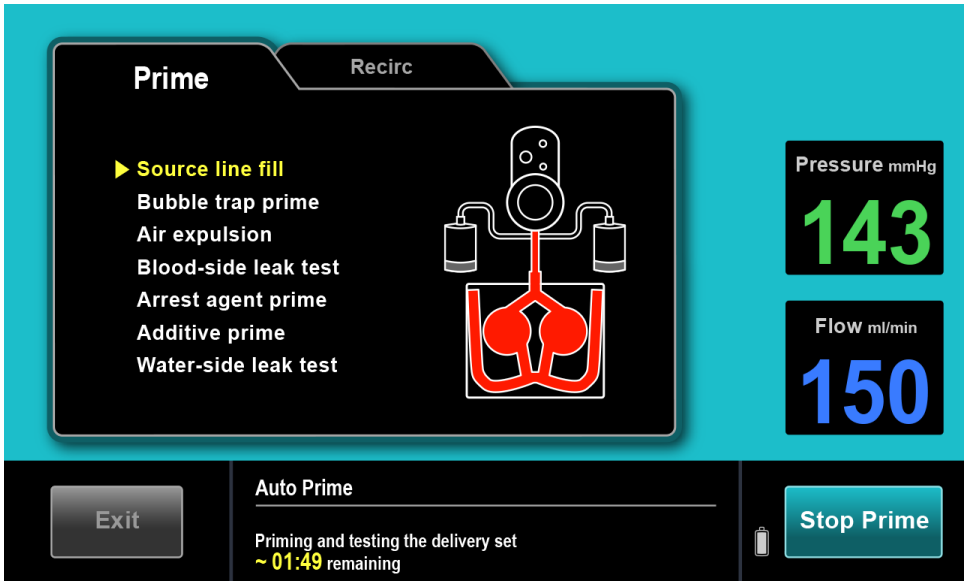

Figure 101: Auto Prime Sequence Initiated

During the Auto Prime process, the following operations are performed:

- Source line fill
- Bubble trap prime
- Air expulsion
- Blood-side leak test
- Arrest agent prime
- Additive prime
- Water-side leak test

The approximate time to complete the priming operation is 1:50 minutes and the remaining time is displayed in the screen.

When the Auto Prime sequence is complete, the operator has the option to recirculate through the delivery set by adjusting the flow knob. During recirculation mode (Recirc) the MPS 3 System switches to all blood mode and recirculates the solution through the vent valve to the cardiotomy reservoir. To perform Recirc, set the flow rate by adjusting the flow knob. When finished, adjust the flow knob to zero and select the Done button to go to the Home Screen.

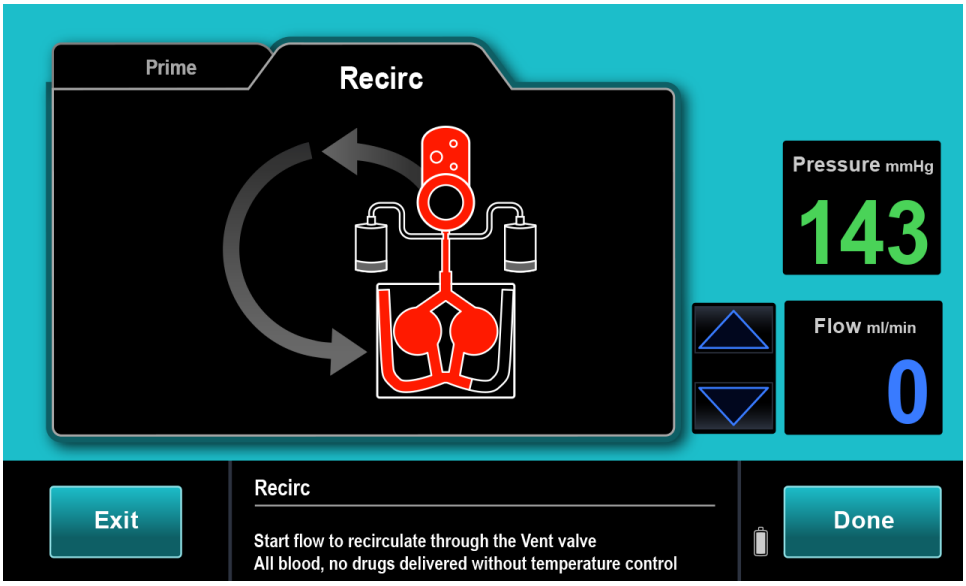

Figure 102: Recirc Screen

Visually examine the heat exchanger and water lines for leaks. A leak in the heat exchanger may cause biological contamination of the cardioplegia delivery fluid and blood hemolysis. If a leak is observed, DO NOT USE the delivery set. Promptly return the delivery set to Quest Medical, Inc.

During Recirculation Mode, the temperature system is OFF, neither heating nor cooling. To recirculate with the temperature system being operational, use the Vent Mode. Also, no arrest agent or additive is delivered during Recirculation Mode

In Vent mode, the MPS 3 System will recirculate by delivering via the Vent valve the selected blood/crystalloid value. (i.e., if 4:1 is selected, 4 parts Blood and 1 part Crystalloid will be delivered). No arrest agent or additive is delivered in Vent Mode. Temperature system is ON and delivery solution will be regulated to the temperature setting. The VENT icon flashes during Vent Mode.

8.3 Refill Arrest Agent

DO NOT OVERFILL arrest agent or additive cartridges. The normal maximum cartridge capacity is 75 ml. Overfilling the arrest agent or additive cartridges before or after installation in the console can cause unintentional bolus delivery and possible system malfunction.

The purge button will be disabled while refilling the arrest agent.

The MPS 3 System allows the operator to refill the arrest agent cartridge at any time. To refill the arrest agent:

1. Select 

icon on the Home Screen.
2. Select the Refill button.
3. The Refill button toggles to DONE and starts blinking.
4. Attach a syringe filled with Arrest Agent to the yellow stopcock fill port and rotate the cartridge stopcock to the fill position. Inject no more than 75 ml of arrest agent.
5. Hold the syringe in an upright position and withdraw sufficient fluid to ensure the cartridge is free of air. Fill the cartridge and turn the stopcock to the delivery position. Refer to Section 8.1.4: Installing and Filling the Arrest Agent.
6. Select Done button and the MPS 3 System determines and updates the arrest agent cartridge volume.

The Arrest pump is automatically turned off when the cartridge is empty and the following alarm is displayed:
"Arrest cartridge is empty
Arrest pump is Off"
When the cartridge is refilled, the pump is automatically turned on.

8.3.1 Purging the Arrest Agent Cartridge Line

One (1) ml of arrest agent is delivered into the heat exchanger each time the Purge button is selected. Repeatedly using the Purge button will DELIVER excess arrest agent into the cardioplegia solution.

Do not use Purge button if air is not present in the arrest agent cartridge or drug line.

Follow these steps to purge excess air from the drug delivery lines:

1. Select 

icon on the Home Screen.
2. Select the Purge button to initiate the purging process. 1 ml bolus of Arrest agent is delivered.

8.4 Refill Additive

DO NOT OVERFILL OR OVERPRESSURIZE arrest agent or additive cartridges. The normal maximum cartridge capacity is 75 ml. Overfilling the arrest agent or additive cartridges before or after installation in the console can cause unintentional bolus delivery and possible system malfunction.

The purge button will be disabled while refilling the arrest agent.

The MPS 3 System allows the operator to refill the additive cartridge at any time. To refill the additive cartridge:

1. Select 

icon on the Home Screen.
2. Select the Refill button.
3. The Refill button toggles to done and starts blinking.
4. Attach a syringe filled with additive solution to the green stopcock fill port and rotate the cartridge stopcock to the fill position. Inject no more than 75 ml of desired additive.
5. Hold the syringe in an upright position and withdraw sufficient fluid to ensure the cartridge is free of air. Fill the cartridge and turn the stopcock to the delivery position. Refer to Section 8.1.5: Installing and Filling the Additive Cartridge
6. Select the Done button and the MPS 3 System determines and updates the additive cartridge volume.

The additive pump is automatically turned Off when the cartridge is empty and the following alarm is displayed:
"Additive cartridge is empty
Additive pump is Off"
When the cartridge is refilled, the pump is automatically turned on.

8.4.1 Purging the Additive Cartridge Line

One (1) ml of additive is delivered into the heat exchanger each time the Purge button is selected. Repeatedly using the Purge button will DELIVER excess additive into the cardioplegia solution.

Do not use Purge button if air is not present in the additive cartridge or drug line.

Follow these steps to purge excess air from the drug delivery lines:

1. Select 

icon on the Home Screen.
2. Select the Purge button to initiate the purging process. 1 ml bolus of Additive solution is delivered.

8.5 Auto Prime for Disabled Arrest and Additive Pumps

The Arrest Agent and Additive pumps must be primed prior to operation to ensure patient safety and drug delivery accuracy. When the Arrest Agent or Additive pump is disabled, the K+ or Additive buttons display "Disabled" on the Home Screen. To prime the Arrest Agent or Additive drug pumps from the Home Screen, follow the steps outlined below.

1. Set the flow rate to zero.
2. Select the Disable button on the corresponding K+ or Additive button on the Home Screen depending on which pump is disabled. A message window to enable the pump will be displayed.

Figure 103: Arrest Agent and Additive Disabled

3. Fill the cartridge and then select the ENABLE button on the message window. System initiates the Auto Priming sequence and Home Screen will be displayed when the priming process is completed.

8.6 Replacing the Crystalloid Bag

If crystalloid is being used for cardioplegia delivery, a Crystalloid Volume Remaining must be entered. The MPS 3 System uses this value to calculate the volume remaining in the crystalloid bag and reminds the operator of a low volume condition.

To replace the crystalloid bag:

1. Set the flow rate to zero and then select 

icon in the Home Screen.
2. After spiking a new crystalloid bag, select Cryst. Vol Remaining button and set the Cryst Vol Remaining to new volume available.
3. Adjust the flow rate knob to resume delivery.

8.7 Removing the Delivery Set

Always clamp all input and delivery lines BEFORE OPENING the MPS 3 System door. Failure to clamp the lines will result in unrestricted flow (FREE FLOW) of solutions, including drainage from the arterial line of the extracorporeal circuit and possible patient injury.

Avoid OPERATOR INJURY. Only qualified operators should attempt to install the MPS 3 Delivery Sets and optional accessories. Ensure that all fingers are free from pinch / crush hazards while installing the MPS 3 Delivery Sets and accessories.

Before removing the delivery set, use the Drain Hx option provided in the Temperature Setting menu. For more information, refer to Section 7.3.8.

Prior to closing the door, be sure to clean or wipe away any fluid spills anywhere on the MPS 3 System, particularly the Delivery Temperature Sensor and the Flow Control Valves.

To remove the disposable from the MPS 3 Console:

1. Adjust the flow rate knob to zero.
2. Clamp the blood, crystalloid, and delivery lines.
3. Turn the H2O Circ Off and use the Drain Hx button to drain water from the heat exchanger water ports. If using a heater cooler, turn the heater cooler unit off and drain all water from the MPS 3 Console. If the heater cooler has a water removal feature, perform this function prior to shutting off the heater cooler.
4. Open the MPS 3 Console door.
5. Remove the additive and arrest agent cartridges.
6. Power off the MPS 3 System.
7. Remove the blood : crystalloid cassette from the mounting pins, and the tubing from the valves and air in line detector.
8. Rotate the heat exchanger knob counterclockwise. Remove the heat exchanger.
9. Remove the delivery set from the MPS 3 System.

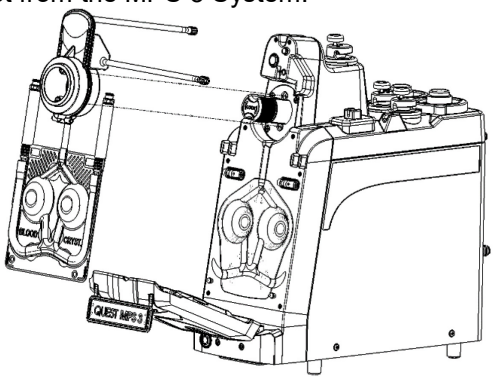

Figure 104: Delivery Set Removed from the MPS 3 Console

10. Close the console outer door.

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9 MPS 3 System Functional Use

This section details higher level functionality of the MPS 3 System. To power on the MPS 3 System refer to Section 6.1.

Figure 105: Selection Screen

9.1 New Case Setup

The New Case Setup screen allows the operator to select case parameters to be used in setting up the new case. To enter the New Case Setup menu, select the New Case button on the Selection Screen. Once a protocol in New Case Setup is confirmed, the Resume Case button becomes disabled if navigated back to the Selection Screen from New Case Setup. Two options are available to set up New Case parameters:

- Defaults
- An Existing Protocol

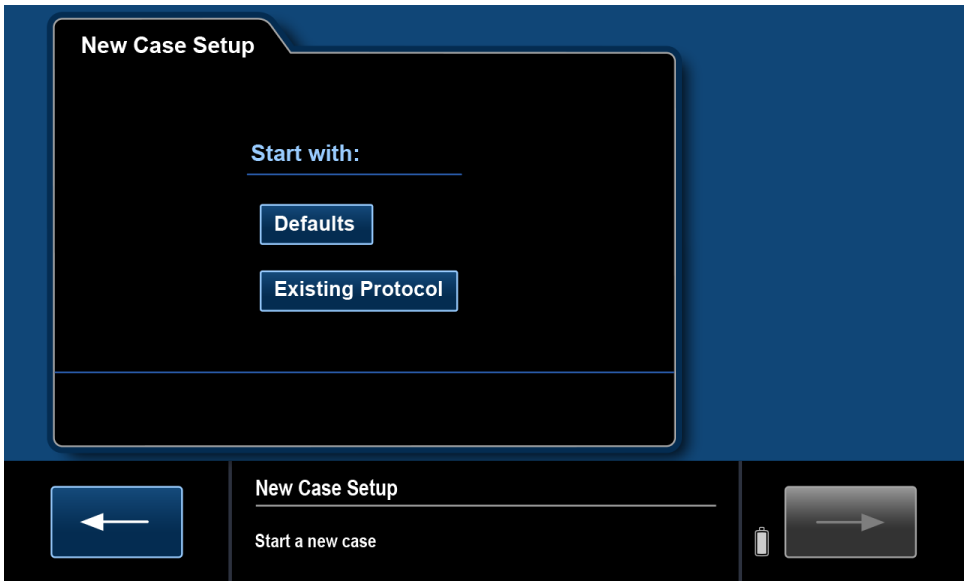

Figure 106: New Case Setup

9.1.1 Defaults

Defaults allows the operator to setup the new case parameter using the default values set in the Protocol Manager. The default values are saved in memory and displayed for editing or conformation during the setup sequence.

In the New Case Setup screen select Defaults to select default values. The operator can then customize the parameters in setting up the current case. Use the Confirm button to confirm the displayed case parameters. Use Confirm All button to accept all the parameters and go directly to the Auto Prime screen.

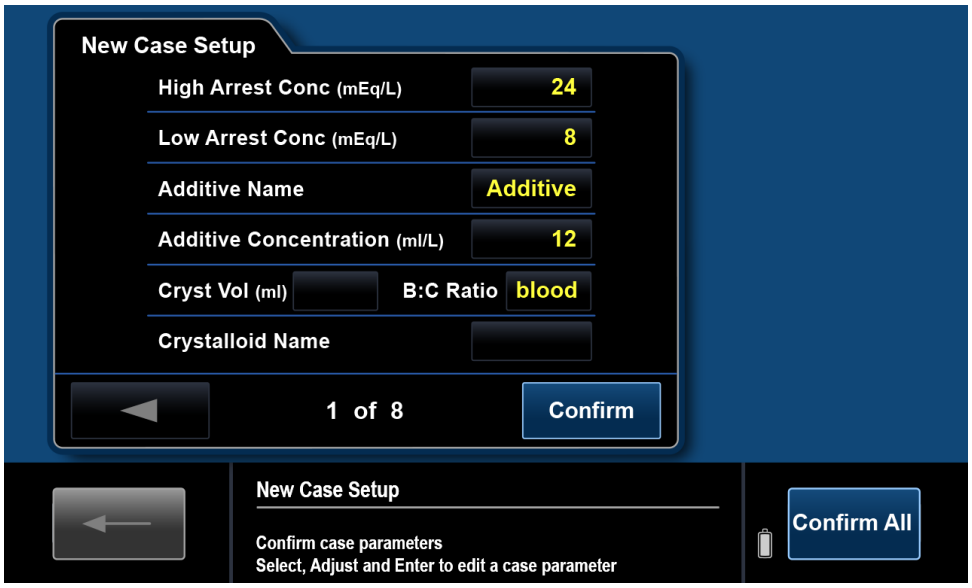

Figure 107: New Case Parameters, Page 1

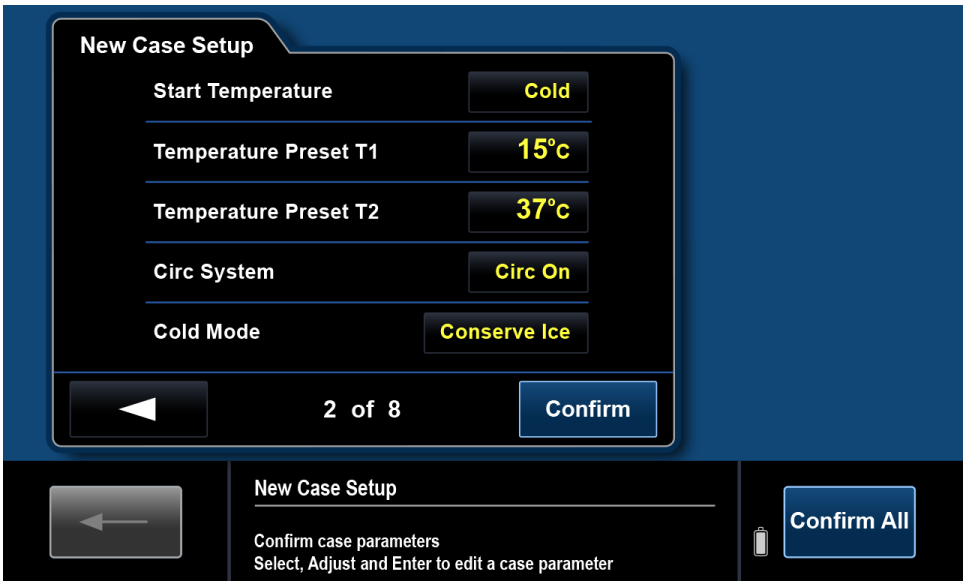

Figure 108: New Case Parameters, Page 2

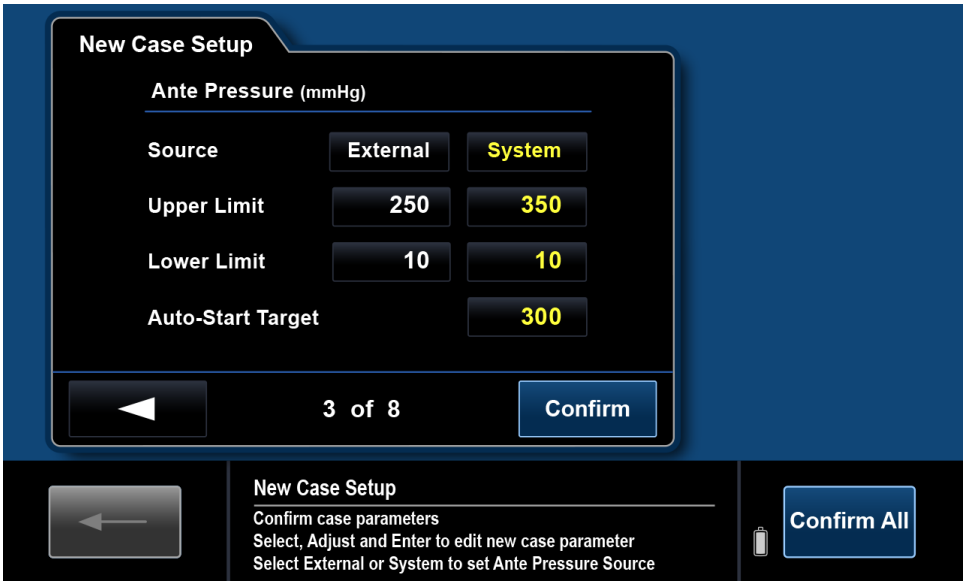

Figure 109: New Case Parameters, Page 3

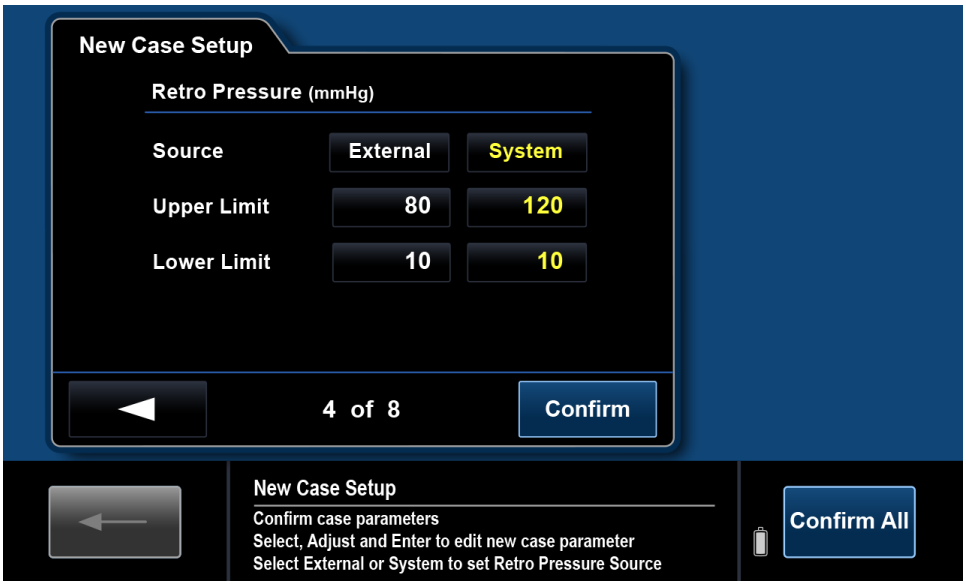

Figure 110: New Case Parameters, Page 4

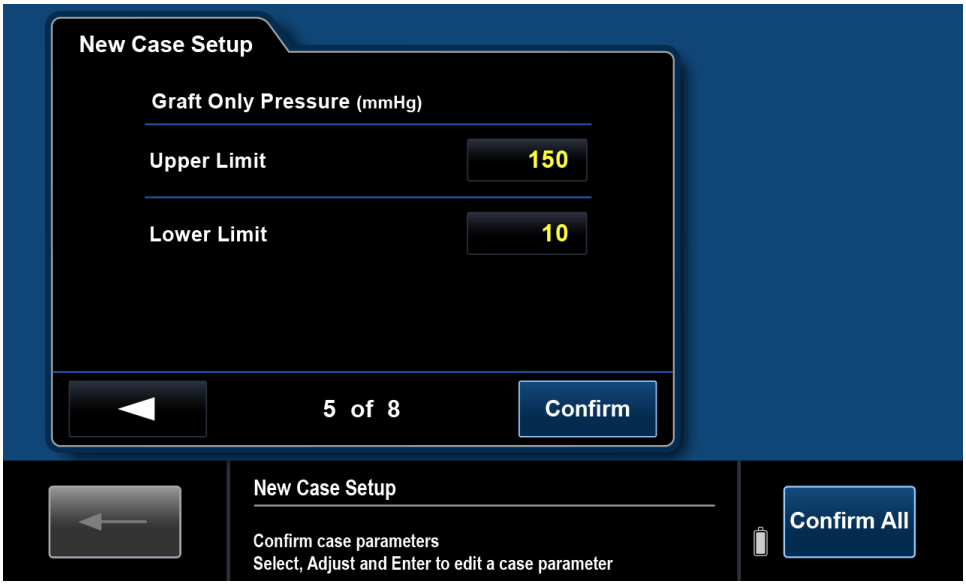

Figure 111: New Case Parameters, Page 5

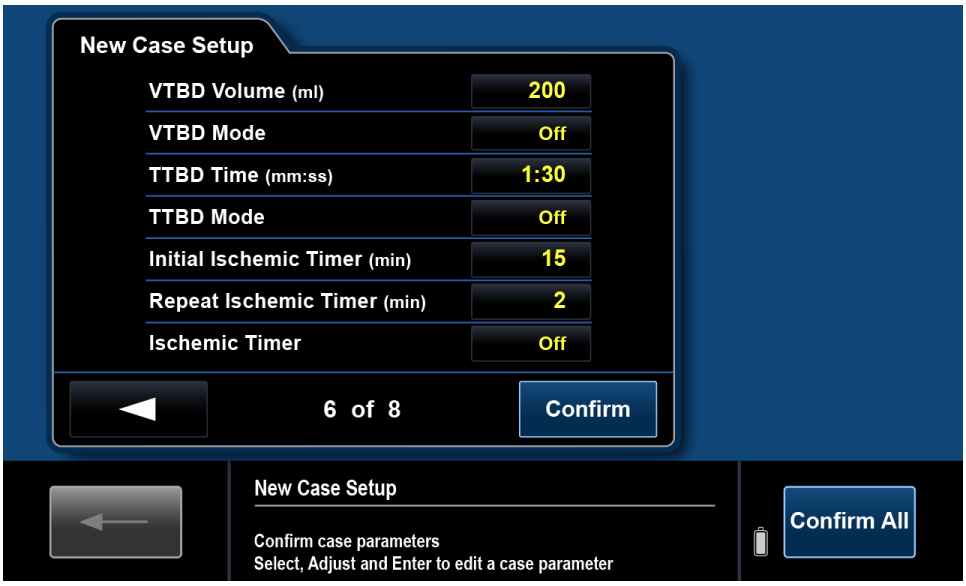

Figure 112: New Case Parameters, Page 6

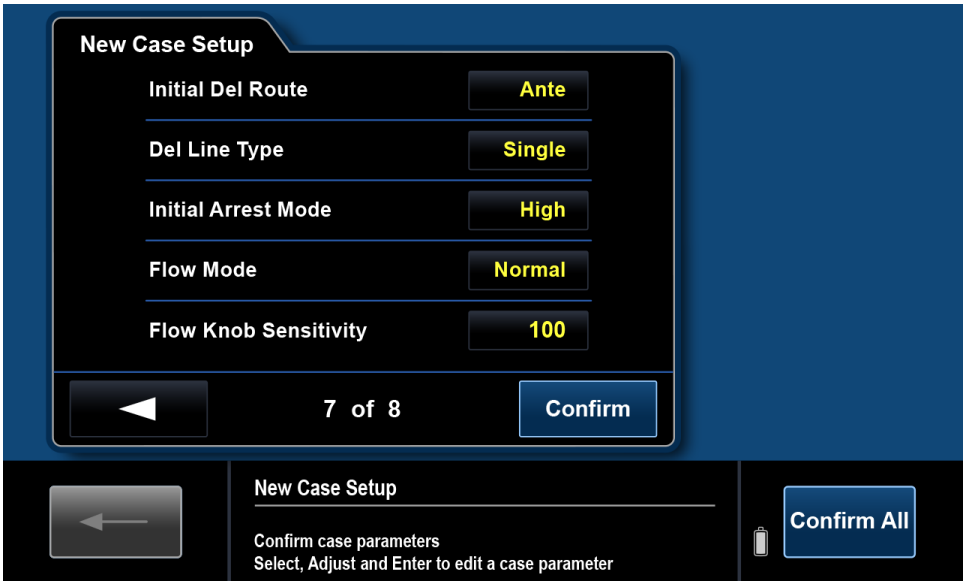

Figure 113: New Case Parameters, Page 7

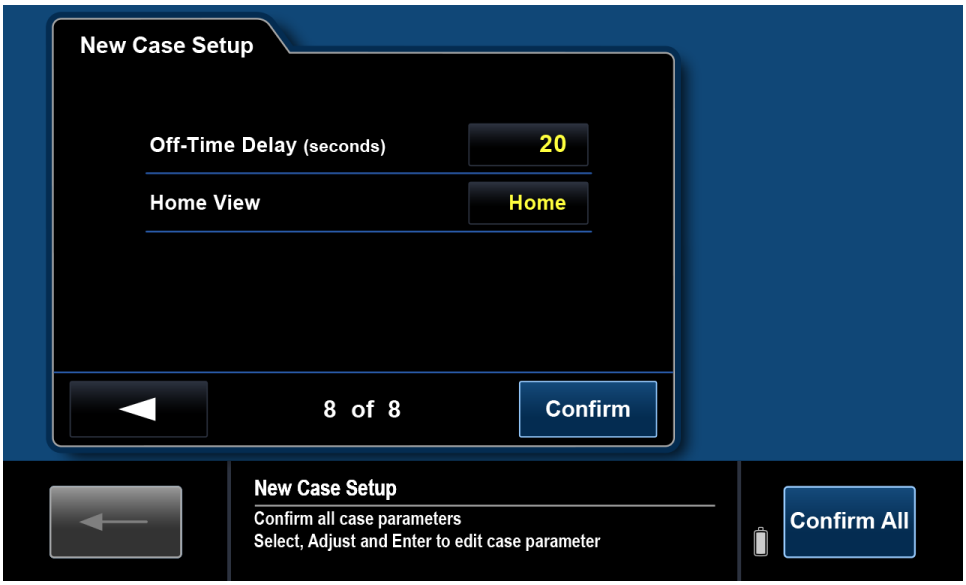

Figure 114: New Case Setup Parameters, Page 8

The following table summarizes the New Case parameters that can be set by the operator during each new case setup.

Item	Parameter Name	Description	Range		Factory Default Value
			Minimum Value	Maximum Value	
1	High Arrest Conc (mEq/L)	High arrest agent delivery concentration	0	40	24
2	Low Arrest Conc (mEq/L)	Low arrest agent delivery concentration	0	40	10
3	Additive Name	Name of Additive solution	NA	NA	Additive
4	Additive Concentration (ml/L)	Additive Concentration	0	50	8
5	Blood : Cryst Ratio	Blood to crystalloid ratio	Blood, 66:1, 49:1, 39:1, 32:1, 27:1, 24:1, 21-2:1, 1:1, 1:2-9, Cryst		Blood
6	Cryst Bag Volume (ml)	Crystalloid bag volume	0	3000	1000
7	Start Temperature	Start Temperature	Cold, T1, T2		Cold
8	Temperature Preset T1	Temperature Preset T1	Off, 15-39		15
9	Temperature Preset T2	Temperature Preset T2	Off, 15-39		37
10	Circ System	Water circulation	On, Off		On
11	Cold Mode	Cold mode	Conserve Ice, Continuous		Conserve Ice
12	Ante Source	Pressure source for Antegrade	External, System		System

Item	Parameter Name	Description	Range		Factory Default Value
			Minimum Value	Maximum Value	
13	Ante Ext Upper Limit	Ante Ext Pressure upper limit	20	250	100
	Ante Sys Upper Limit	Ante Sys Pressure upper limit	20	750	350
14	Ante Ext Lower Limit	Ante Ext Pressure lower limit	0	200	10
	Ante Sys Lower Limit	Ante Sys Pressure lower limit	0	500	25
15	Ante Sys Auto Target	Ante Sys Target Pressure for Auto Start mode	20	700	175
16	Retro Source	Pressure source for Retro	External, System		System
17	Retro Ext Upper Limit	Retro Ext Pressure upper limit	20	250	50
	Retro Sys Upper Limit	Retro Sys Pressure upper limit	20	750	200
18	Retro Ext Lower Limit	Retro Ext Pressure lower limit	0	200	10
	Retro Sys Lower Limit	Retro Sys Pressure lower limit	0	500	25
19	Graft Upper Limit	Vein Graft Pressure upper limit	20	250	100
20	Graft Lower Limit	Vein Graft Pressure lower limit	0	80	10

Item	Parameter Name	Description	Range		Factory Default Value
			Minimum Value	Maximum Value	
21	VTBD Volume (ml)	VTBD volume	10	4000	1000
22	VTBD Mode	VTBD mode	Once, Always, Off		Off
23	TTBT Time (min)	TTBD time	1:00	15:00	4:00
24	TTBD Mode	TTBD mode	Once, Always, Off		Off
25	Initial Ischemic Timer (min)	Initial Ischemic Time	1	120	20
26	Repeat Ischemic Timer (min)	Repeat Time for Ischemic Time	1	120	5
27	Ischemic Timer	Ischemic Timer Mode	On, Off		Off
28	Initial Del Route	Initial Delivery Route Setting After Prime	Antegrade, Retrograde, Simulgrade		Antegrade
29	Del Line Type	Delivery Line Type	Single, Double		Single
30	Initial Arrest Mode	Initial Arrest Mode Setting After Prime.	High, Low		High
31	Flow Mode	Flow Mode	Normal, Low Vol, Always Cyclic		Normal
32	Flow Knob Sensitivity	sensitivity setting of flow knob	10,20,30,40,50,60,70,80,90,100		70
33	Off-Time Delay (Seconds)	Off time delay setting used to define a dose	1	60	20
34	Home View	Set the view of Home Screen	Chart, Home		Home

9.1.2 Using an Existing Protocol

New Case Setup Using an Existing Protocol allows the operator to select an existing protocol from a list of previously saved protocols. The saved protocol feature can standardize cardioplegia delivery parameters and shorten set-up time. The operator can customize the protocol in setting up the current case. To create a new protocol refer to Section 9.3 of this operations manual.

To utilize an existing protocol, select the Existing Protocol option from the New Case Setup screen and select any of the existing protocols.

The saved protocol values are displayed, and the operator can change the values.

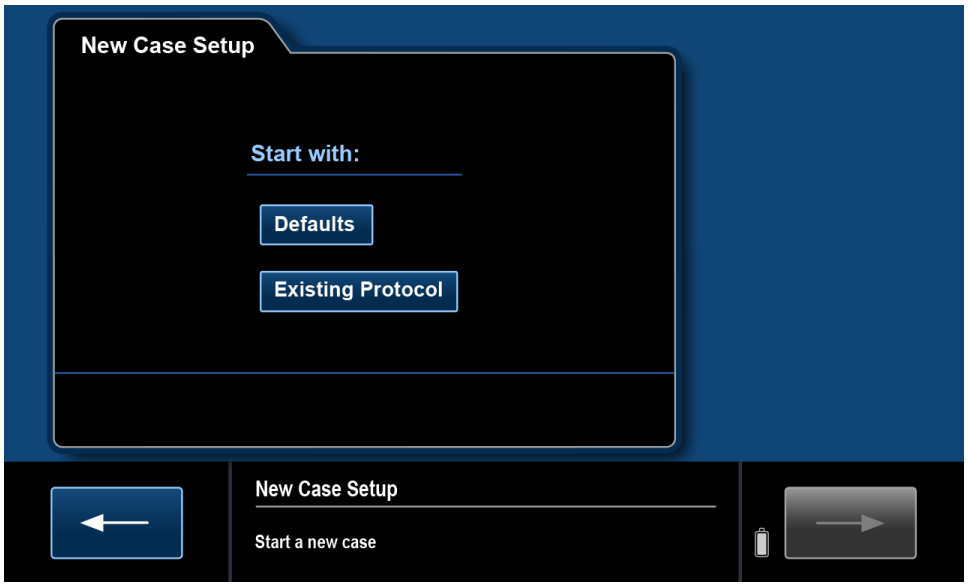

Figure 115: New Case Setup Using an Existing Protocol

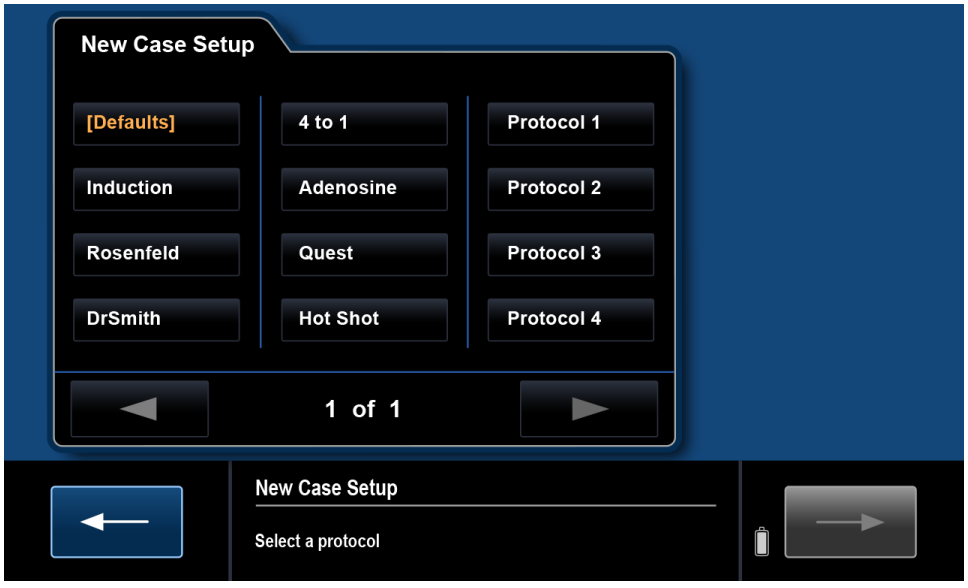

Figure 116: Selecting the Existing Protocol

9.2 Resuming an Existing Case

When a previous case is resumed, the MPS 3 System displays the Home Screen using the parameters set in the previous case. The Resume Case button becomes disabled if the operator returns to the Selection Screen after confirming a protocol in New Case Setup or if the different controller option is selected on Alarm 315. To resume the previous case:

1. Select the Resume Case from the Selection Screen. The Home Screen is displayed with the previous case parameters from the last time the MPS 3 System was used.
2. The operator may change the parameters from the Home Screen if the last parameters used are not desirable.

9.3 Using MPS 3 Protocol Manager

MPS 3 System allows a maximum of 64 protocols. When the limit is reached, the Create New button is disabled and the operator may not add new protocols without deleting another protocol.

The Protocol Manager allows the operator to recall and edit an existing protocol or to create a new protocol and store it on the MPS 3 System for future use.

1. To create a new protocol. Select the Protocol Manager Button in the Selection screen. A Protocol list screen is displayed with an existing protocol list.

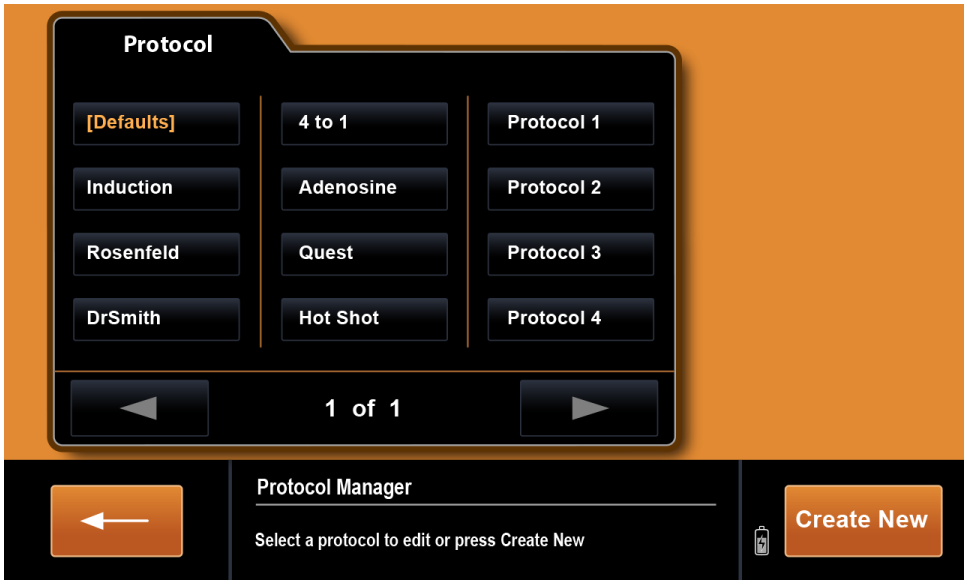

Figure 117: Protocol Manager Screen

2. To create a new protocol, select the Create New button on the Protocol list screen. The Create From screen displays as shown below:

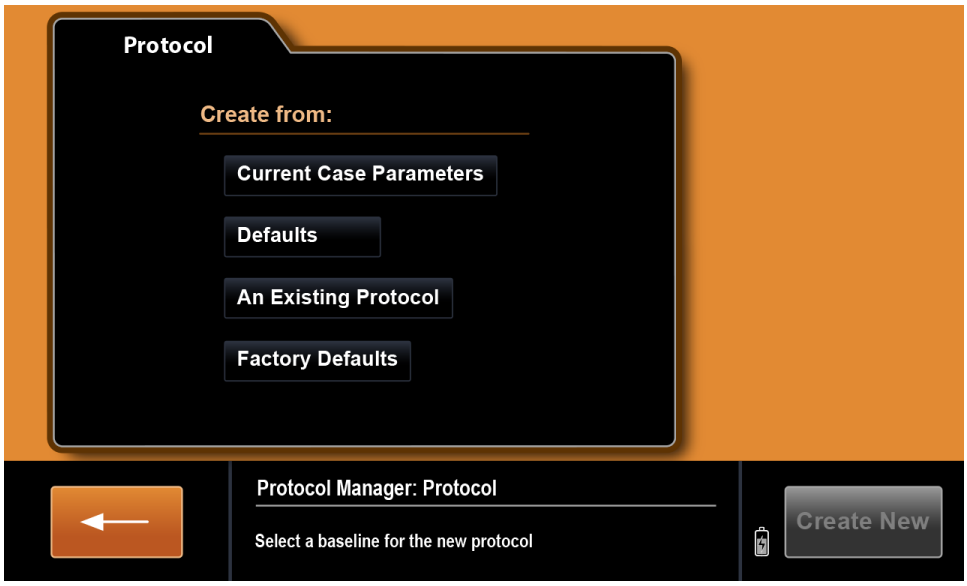

Figure 118: Create Protocol Screen

3. Select an option and the Protocol Name screen displays where the new protocol name may be entered.

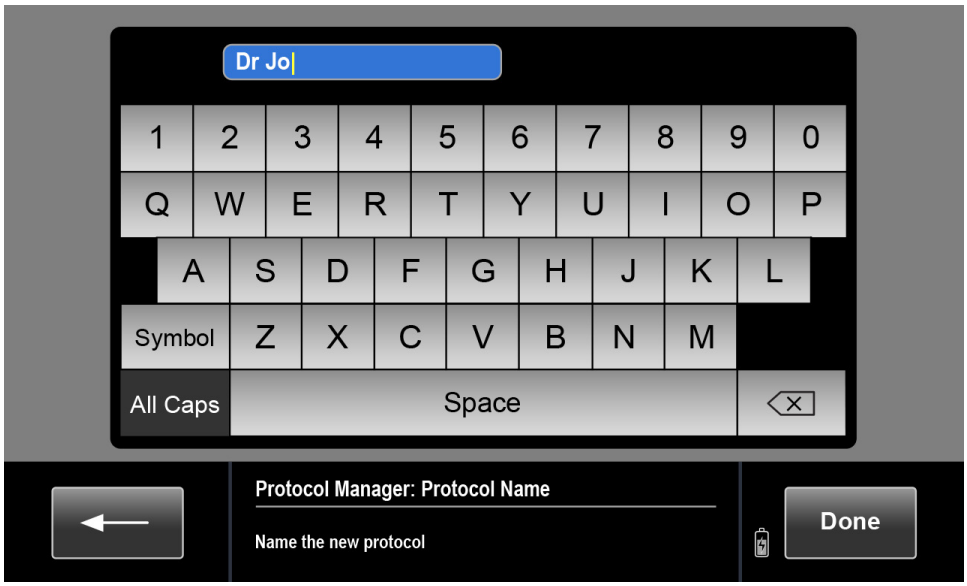

Figure 119: Protocol Naming Screen

4. Enter the protocol name and select the Done button to save the protocol name. The maximum character length for the protocol name is 14 alpha-numeric characters. All parameters can be reviewed and edited.

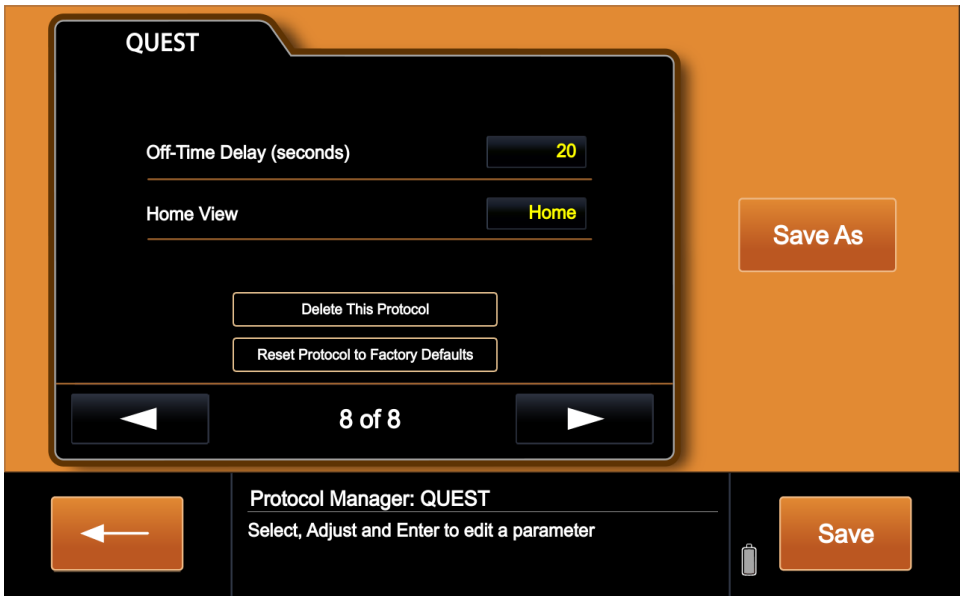

Figure 120: Save Protocol Screen

5. The operator can restore Factory Defaults by pressing the Reset to Factory Defaults button on the save screen. Pressing the Save button will save the protocol. Pressing the Save As button will allow the user to save any edits under a different protocol name.

9.4 Interfacing with Menu

The following options can be accessed within the Menu.

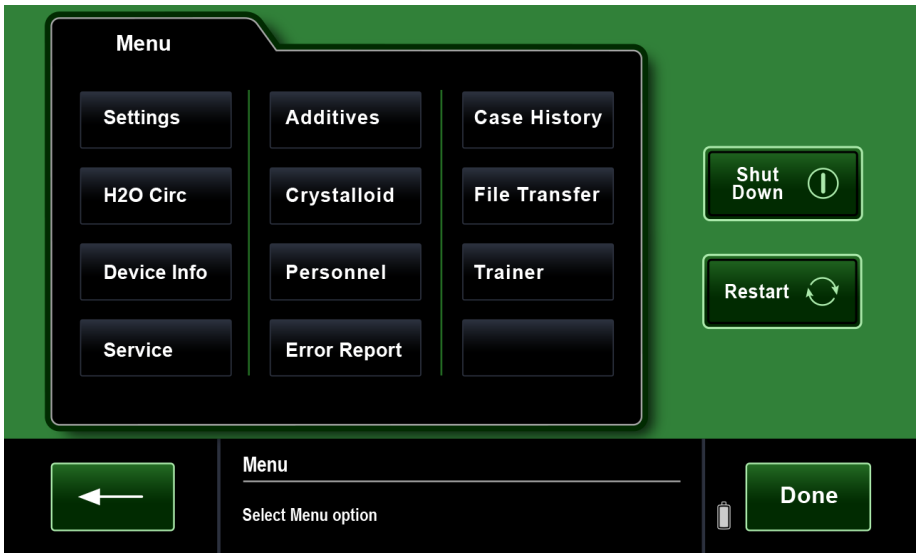

Figure 121: Menu Screen

9.4.1 Settings

For details regarding the Settings menu, refer to Section 6.2.

9.4.2 H2O Circ

The H2O Prime and H2O Clean options are available within the: Menu → H2O Circ Menu option.

The Start button may be used to prime the H2O Circulation system. This is needed to eliminate any air that might be trapped in the circulation system.

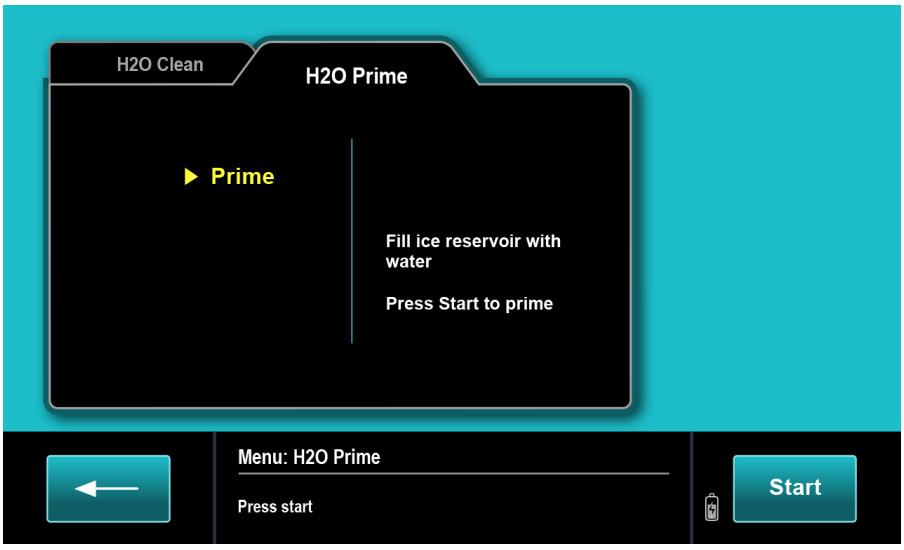

Figure 122: H2O Prime Screen

It takes approximately 24 seconds to complete the H2O Prime. A countdown timer is displayed during the process. The process can be stopped and resumed.

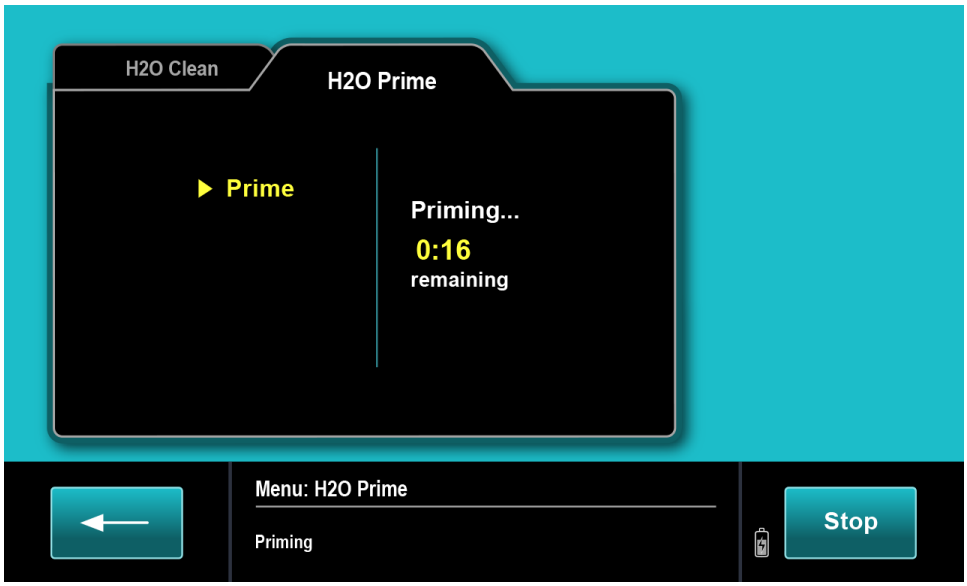

Figure 123: H2O Prime Sequence

To run the H2O Cleaning Cycle, select the H2O Clean tab and select Start. See Section 12.5 for details on how to clean the MPS 3 System circulation system.

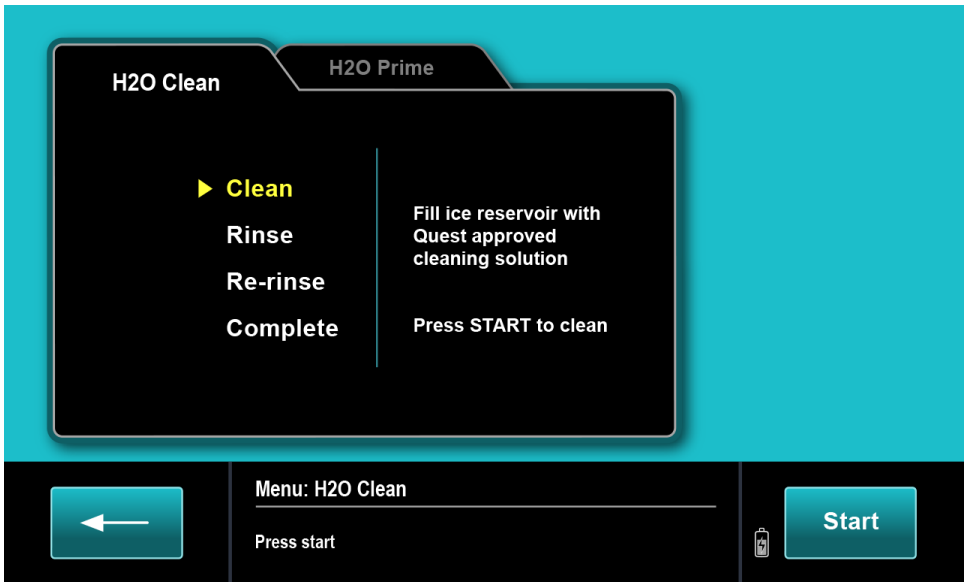

Figure 124: H2O Clean Menu

9.4.3 Device Info

Device Info contains MPS 3 System information required for service personnel.

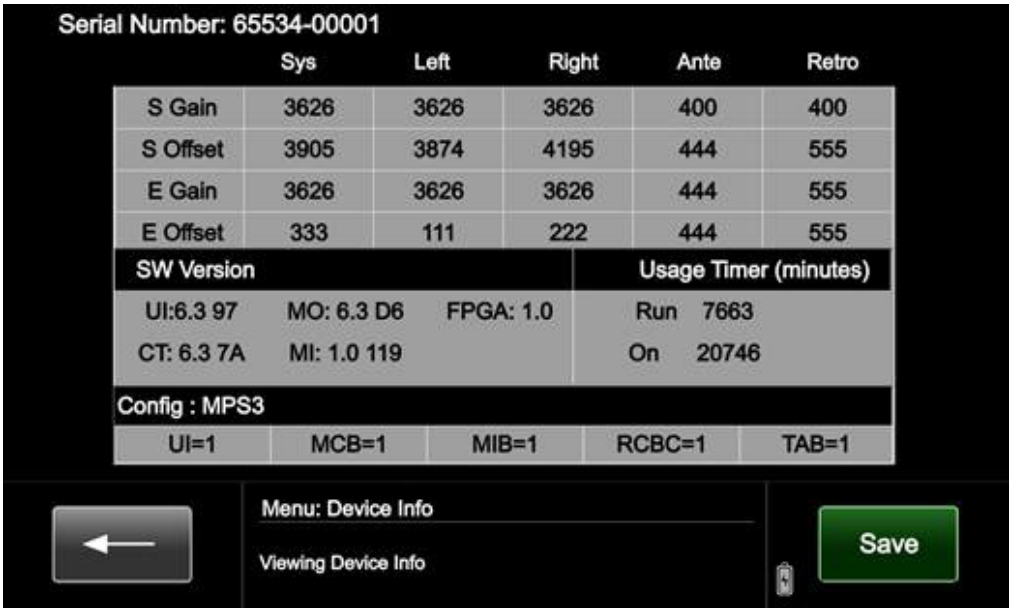

Figure 125: Device Info Screen

Pressing the Save button will save the device information to an external USB memory when connected.

9.4.4 File Transfer

The Operator is able to transfer the Master files and Case History from/to an external USB memory device.

Operators are encouraged to use the Master Copy feature to standardize all MPS 3 Systems in their account to have identical operator customizable data.

Select Menu → File Transfer→ Create Master after inserting a USB memory device. A master copy of Protocols, Additive, Crystalloid and Personnel is created on the USB memory.

Select Menu → File Transfer → Copy from Master to replace all the Protocols, Additive, Crystalloid, and Personnel data on the MPS 3 System with that from the Master File on the inserted USB memory device.

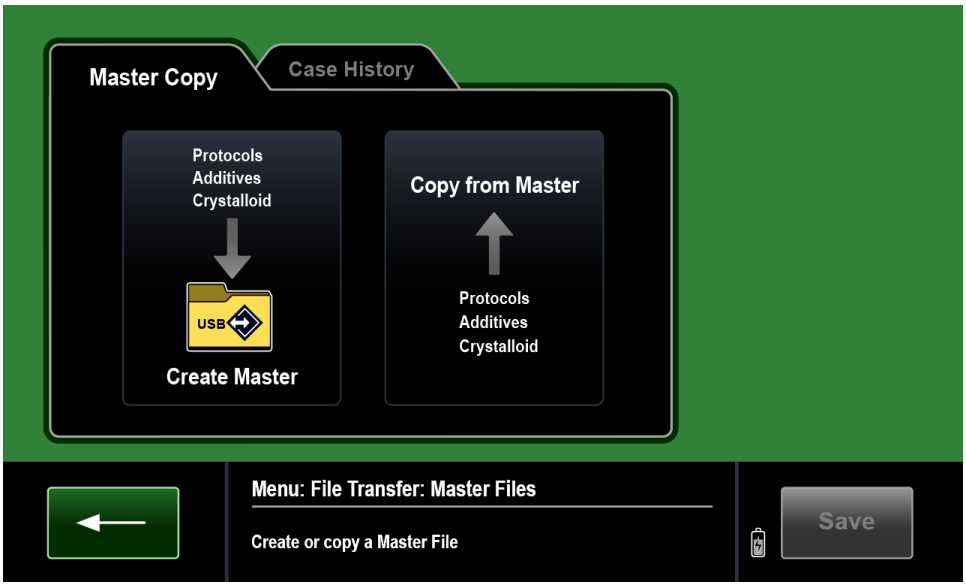

Figure 126: File Transfer Menu

Select Menu → File Transfer→ Case History → Quest Internal Memory to view the list of all Case Records available on the MPS 3 System up to a max of 225 cases. Select cases and use the delete button to delete them. Select 1 case and use the View button to view the Case details. Select cases and use the Copy to USB button to save the cases to USB memory.

Figure 127: File Transfer – Case History – Internal Memory

Select Menu → File Transfer→ Case History → USB to view the list of all Case Records available on the USB memory. Select cases and use the delete button to delete them. Select 1 case and use the View button to view the Case details. Copying cases from the external USB memory to the Quest Internal memory is not allowed. Selecting the Delete Patient Data button will delete the Age, BSA, Weight, Patient ID and Gender data stored for all cases in internal device memory.

Figure 128: File Transfer – Case History – USB Memory

9.4.5 Case History

The Case History function allows the operator to view the list of 225 most recent case records. These records are identified by the case start date and time, for example [21 JUN 2020 13:15]. When an external storage device is plugged in, a case record can be copied to the memory. The Dose records, all Pressure, Flow & Temperature data and Case Report data associated with that case are saved as part of Case Data.

To view the Case History details:

1. In Selection Screen, select Menu → Case History. The Case History screen is displayed.
2. Select the desired case record to view the Dose History details of that case file.

Figure 129: File Transfer: Case History

The dose history displays in a table where each row or record corresponds to a dose. If while flowing during a case the operator changes Delivery Route (Ante/Retro/Simul), selects Arrested/ Rhythm/Hotshot, Graft On/Off, Graft Only, or Graft Label a New Dose is created. If while flow is stopped the operator allows the off-time delay to expire, changes Delivery Route (Ante/Retro/Simul), selects Arrested/Rhythm/Hotshot, Graft On/Off, Graft Only, Graft Labels, changes Additive Name or Crystalloid Name, or launches a new Protocol, then a new dose is created. The column headings for Dose History Screen are explained below.

- ***Time****:* Shows the time corresponding to the start of the record and the duration. If a note was previously entered for this record, the Note icon is displayed.
- ***Avg Flow****:* Shows the average flow rate during the dose. If the Auto-Start feature was used, the field is tagged with an 'AS' label.
- ***Avg Pressure****:* Shows the average system pressure (and average external pressure, if applicable) during the dose.
- ***Arr****:* Shows the volume of Arrest Agent delivered in ml.
- ***Additive/Crystalloid:*** Shows the Additive/Crystalloid Name and the volume delivered. If no volume was delivered, show '- -'.
- ***Avg Temp:*** Shows the average delivery temperature for the dose in °C.
- ***Volume****:* Shows the total delivered volume for the dose in ml.
- ***Route****:* Shows the route selected in the dose (A-Antegrade, R-Retrograde, S-Simulgrade, or G-Graft Only).
- ***Graft Label****:* Shows the Graft Label if it was named previously.

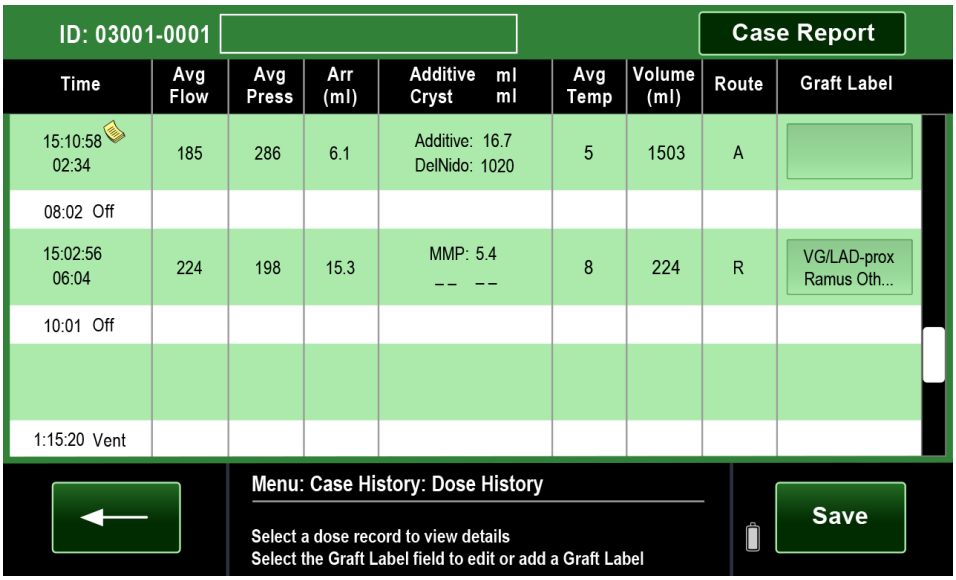

Figure 130: Dose History Screen

9.4.5.1 Editing Graft Label

To edit the Graft label:

1. Select the Graft Label cell and a Graft label screen displays as shown below:

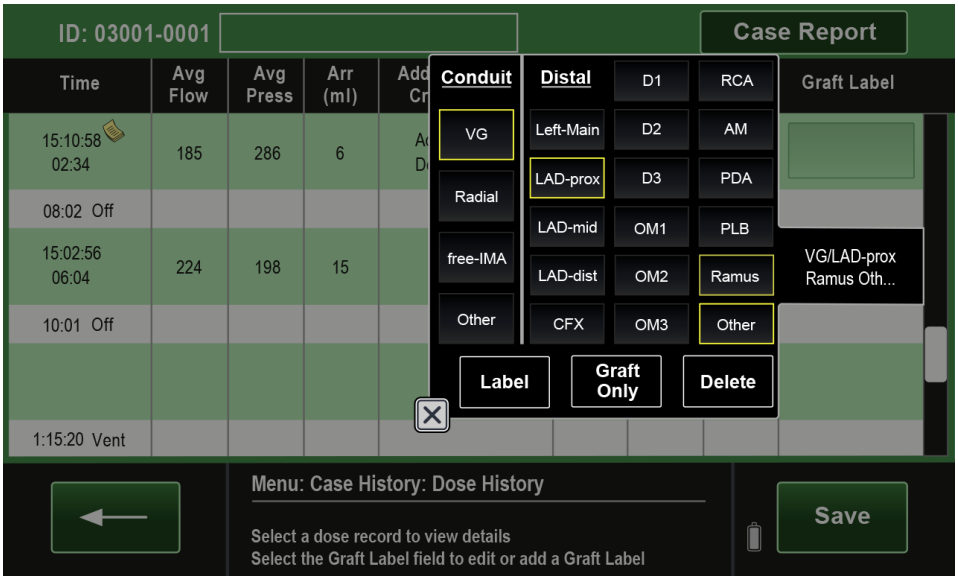

Figure 131: Graft Label Screen

2. The operator may label or re-label a Dose by selecting from two different lists to label the Graft; one selection from the Conduit list and one or more selections from the Distal list and then pressing Label. If the Graft has already been labeled these labels are shown highlighted in yellow. Selecting Delete, deletes the label without changing the Route entry. Selecting Graft Only changes the Route entry to 'G'.

9.4.5.2 Dose Record View

When a dose is selected, the corresponding pressure, flow and external pressure data is displayed on three separate graphs. A single dose is limited to a maximum of four hours (looped data). The data corresponding to the dose is displayed

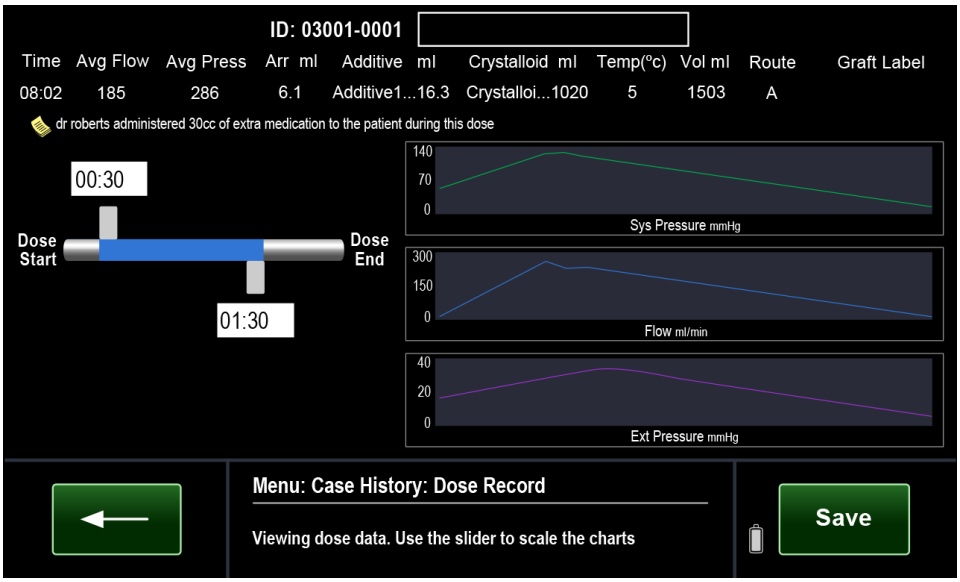

Figure 132: Dose Record View

Operator can zoom in or out using the slider bars. The Save button can be used to save a screenshot of the dose record to the external memory when connected. The ID displays the Controller serial number followed by the case number.

9.4.5.3 Case Report

The Case Report contains all Patient and Procedure details in one place. To view the Case Report:

1. Select Menu → Case History → Case → Case Report. The Case Report screen 1 of 4 is displayed.

   The fields in Case Report screen 1 of 4 are explained below.

   - ***ID****:* This field is used to enter the Patient ID with range 6 – 20 alphanumeric characters. This field is not shown on the Case Report screen once saved.
   - ***Age****:* This field is used to enter the patient age with range 0 – 120 years.
   - ***Weight:*** This field is used to enter the patient weight with range 1 – 200 Kg.
   - ***Gender:*** This field is used to enter the patient gender.
   - ***BSA:*** This field displays the BSA with range 0.5 to 3.0 in 0.1 increments.
   - ***Procedure:*** This field displays the selected Procedure if a single Procedure was previously selected or 'Combo' if multiple procedures are selected. The procedure screen has 2 levels to allow you to select any combination of all available Procedure options.
   - ***Surgeon:*** This field displays the Surgeon Name that is selected from the Surgeon List. The Surgeon List is customizable using the Personnel Menu option.
   - ***Perfusionist:*** This field displays the Perfusionist Name that is selected from the Perfusionist List. The Perfusionist List is customizable using the Personnel Menu option.
   - ***Anesthesiologist:*** This field displays the Anesthesiologist Name that is selected from the Anesthesiologist List. The Anesthesiologist List is customizable using the Personnel Menu option.

Patient ID, Age, Weight, and Gender are encrypted for previous cases and hidden for privacy after transitioning to the next screen.

Figure 133: Case Report 1 of 4

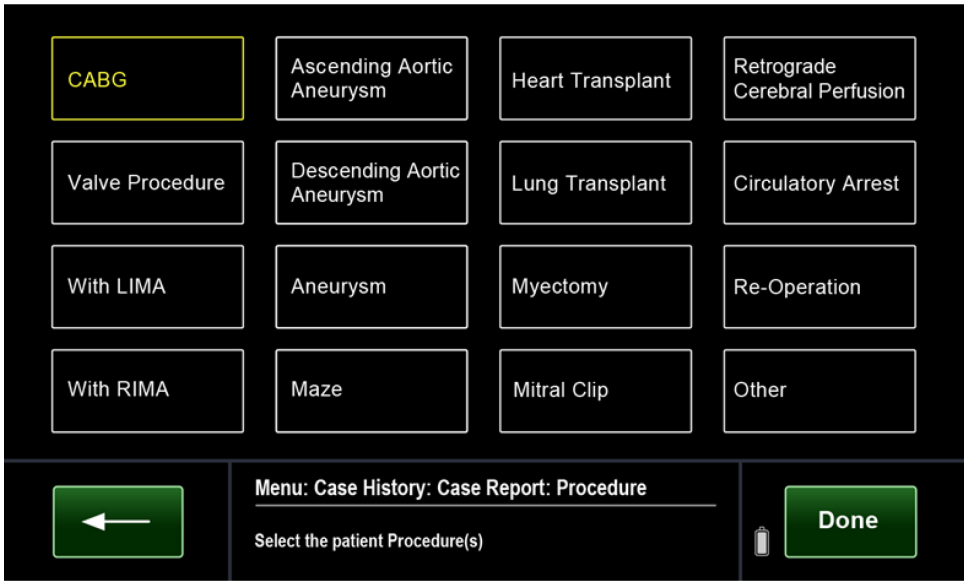

Figure 134: Case Report: Procedure View

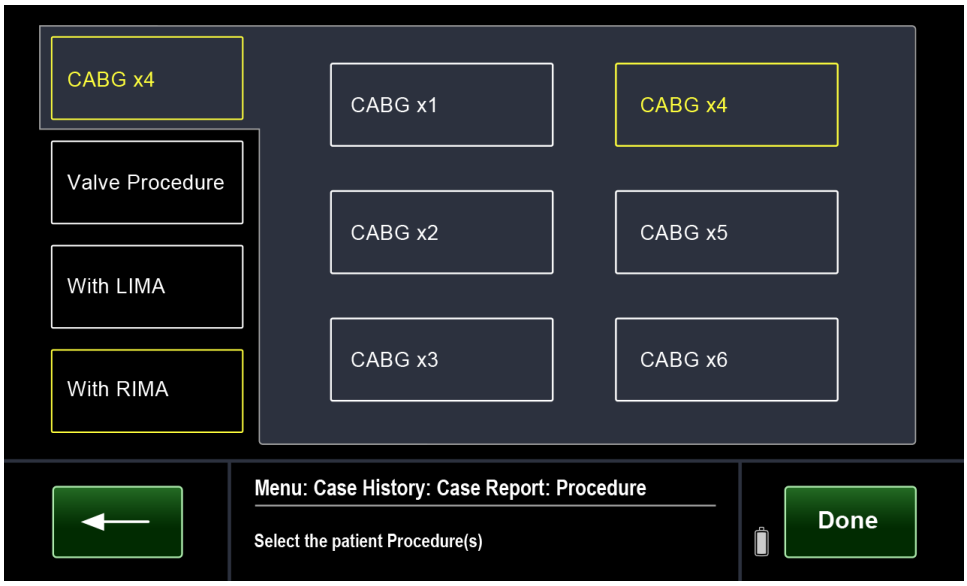

Figure 135: Case Report: Procedure: CABG View

The fields in Case Report screen 2 of 4 are explained below. Glucose values in the alternate units are auto populated in the corresponding fields.

Cross-Clamp Time (min): This field displays the XClamp Time as recorded in the ECG Setting screen. Subsequent XClamp Times are displayed if recorded in the ECG Event screen.

Arrest Time (min): This field displays the total Arrest Time. It is the time elapsed between the Arrested and Rhythm events. It will match the value displayed in the ECG Event screen. Subsequent Arrest Times are displayed if recorded in the ECG Event screen.

Ischemic Time (min): This non-editable field displays the Total Ischemic Time.

Delivery Time (min): This field displays the sum of all delivery times for the case from all delivery routes.

Time to Arrest (mm:ss): This field displays the Time to Arrest. It is the time elapsed between the start of the dose and when the Arrested button is selected. It will match the value displayed in the ECG Event screen. Subsequent Time to Arrest are displayed if recorded in the ECG Event screen.

Volume to Arrest (ml): This field displays the Arrest Volume delivered during the dose the Arrest button was selected on the ECG Setting screen. Subsequent Volume to Arrest are displayed if recorded in the ECG Event screen.

Arrest Dose Route: This field displays the dose route during the dose the Arrest button was selected on the ECG Setting screen. Subsequent Arrest Dose Routes are displayed if multiple Arrest Doses are recorded in the ECG Event Screen.

Arrest Dose Flow (ml/min): This field displays the average cardioplegia flow during the dose the Arrest button was selected on the ECG Setting screen. Subsequent Arrest Dose Flows are displayed if multiple Arrest Doses are recorded in the ECG Event Screen.

Arrest Dose Pressure (mmHg): This field displays the average system pressure during the dose the Arrest button was selected on the ECG Setting screen. Subsequent Arrest Dose Pressures are displayed if multiple Arrest Doses are recorded in the ECG Event Screen.

Time to Rhythm (mm:ss): This field displays the Time to Rhythm as recorded in ECG Setting screen. Subsequent Time to Rhythms are displayed if recorded in the ECG Event screen.

HotShot Dose Route: This field displays the dose route during the Hotshot dose.

HotShot Dose Flow (ml/min): This field displays the average cardioplegia flow during the Hotshot dose.

HotShot Dose Pressure (mmHg): This field displays the average system pressure during the Hotshot dose.

Spontaneous Rhythm: This field reflects the Rhythm selection made in the ECG Event screen when the Rhythm button was selected.

Defib (Count): This field reflects the Rhythm selection made in the ECG Event screen when the Rhythm button was selected. Edit this field to record the number of times the heart needed to be defibrillated to restart.

Paced Rhythm: This field reflects the Rhythm selection made in the ECG Settings screen when the Rhythm button was selected.

Pump Time (min): Use this field to record the Pump Time in minutes.

Cardioplegia Type: Use this field to select the Cardioplegia Type from the list.

First Hgb IntraOp (g/dl): Use this field to record the Hemoglobin concentration prior to going on CPB.

Highest Hgb on CPB (g/dl): Use this field to record the highest Hemoglobin concentration while on CPB.

Lowest Hgb on CPB (g/dl): Use this field to record the lowest Hemoglobin concentration while on CPB.

Last Hgb on CPB (g/dl): Use this field to record the last Hemoglobin concentration while on CPB.

Final Hgb (post Cell Saver) (g/dl): Use this field to record the Hemoglobin concentration post Cell Saver.

First Glucose IntraOp (mg/dl): Use this field to record the Glucose concentration in mg/dl prior to going on CPB.

First Glucose IntroOp (mmol/L): Use this field to record the Glucose concentration in mmol/L prior to going on CPB.

First Glucose on CPB (mg/dl): Use this field to record the first Glucose concentration in mg/dl while on CPB.

First Glucose on CPB (mmol/L): Use this field to record the first Glucose concentration in mmol/L while on CPB.

Highest Glucose on CPB (mg/dl): Use this field to record the highest Glucose concentration in mg/dl while on CPB.

Highest Glucose on CPB (mmol/L): Use this field to record the highest Glucose concentration in mmol/L while on CPB.

Last Glucose CPB (mg/dl): Use this field to record the last Glucose concentration in mg/dl while on CPB.

Last Glucose on CPB (mmol/L): Use this field to record the last Glucose concentration in mmol/L while on CPB.

Final Glucose Post CPB IntraOp (mg/dl): Use this field to record the final Glucose concentration in mg/dl after CPB.

Final Glucose Post CPB IntraOp (mmol/L): Use this field to record the final Glucose concentration in mmol/L after CPB.

First K+ IntraOp (mmol/L): Use this field to record the first K+ concentration prior to going on CPB.

First K+ on CPB (mmol/L): Use this field to record the first K+ concentration while on CPB.

Highest K+ on CPB (mmol/L): Use this field to record the highest K+ concentration while on CPB.

Last K+ on CPB (mmol/L): Use this field to record the last K+ concentration while on CPB.

Final K+ post CPB IntraOp (mmol/L): Use this field to record the final K+ concentration after CPB.

Assist Device Pre-Op: Use this field to record whether an Assist Device was used Pre-Op.

Assist Devices Intra-Op: Use this field to record whether an Assist Device was used Intra-Op.

On CPB Ultrafiltrate?: Use this field to record whether ultrafiltrates were used while on CPB.

Required Insulin drip on CPB?: Use this field to record whether an insulin drip was used while on CPB.

On Insulin drip prior to CVOR?: Use this field to record whether an insulin drip was used prior to CVOR.

Cell Saver Return Volume (ml): Use this field to record Cell Saver Return Volume.

Hemo Concentrator used?: Use this field to record whether a Hemo concentrator was used.

Hemo Concentrator Volume (ml): Use this field to record the volume of Hemo concentration.

Non-Cpg (HLM) volume (ml): Use this field to record the volume of Non-Cardioplegia Volume delivered.

ERAS: Use this field to record whether ERAS were used.

Urine Output (ml): Use this field to record Urine Output volume.

Maintenance Dose Routes: Use this field to record the route used during maintenance doses.

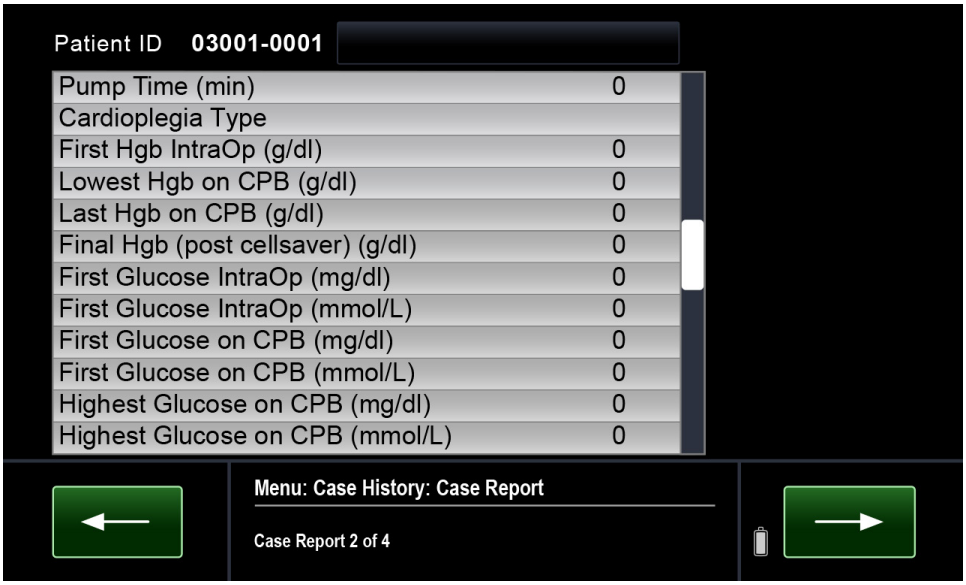

Figure 136: Case Report 2 of 4

The fields in Case Report screen 3 of 4 are explained below.

TEE Score: Enter the TEE (Transesophageal Echocardiogram) score with range 0 - 9.

PRBC: Enter PRBC (Packed Red Blood Cells) given with range 0 – 9 Units.

FFP: Enter FFP (Fresh Frozen Plasma) given with range 0 – 9 Units.

Cryoprecipitate: Enter Cryoprecipitate given with range 0 – 9 Units.

Platelets: Enter Platelets given with range 0 – 9 Units.

Figure 137: Case Report 3 of 4

Case Report screen 4 of 4 shows the Volume summary for the case.

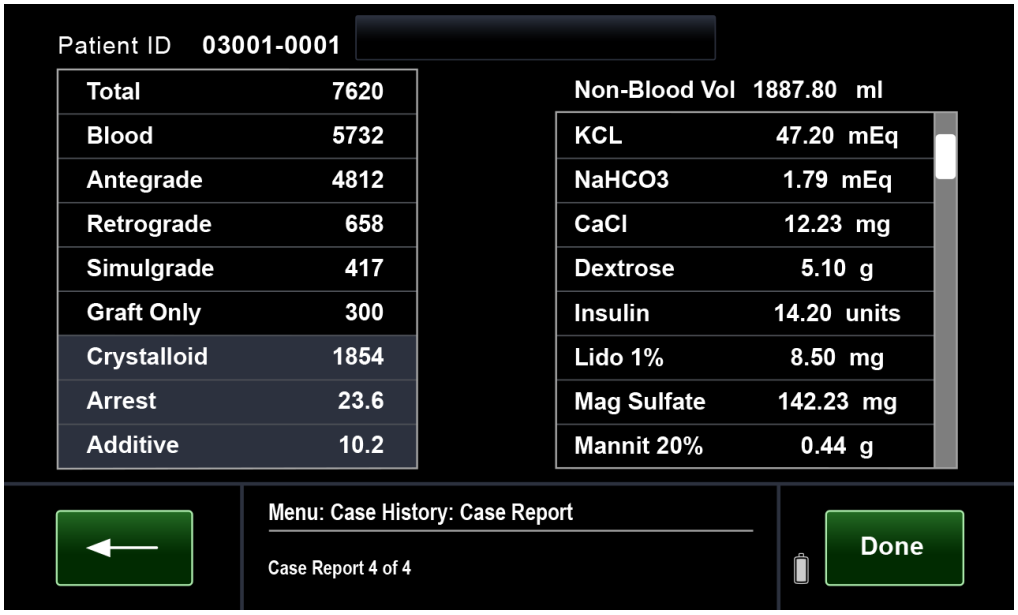

Figure 138: Case Report 4 of 4

9.4.6 Additive List

The Additive List contains a list of Additives created by the operator. Items in the list can be added, deleted, or edited.

To add an item to the Additive list:

1. In Selection Screen, select Menu → Additives. The Additive List screen is displayed.

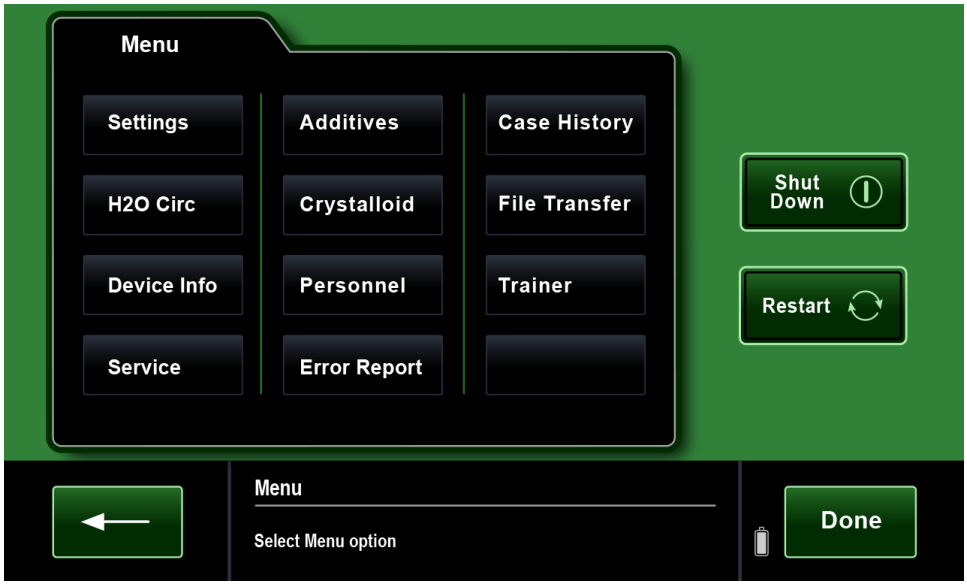

Figure 139: Menu

Figure 140: Additive List

2. Select an Additive name to edit an existing Additive or select Create New to add a new Additive to the List. The Operator is able to use a Blank Template or Existing Additive as a baseline for the New Additive and then naming it using a maximum of up to 8 characters.

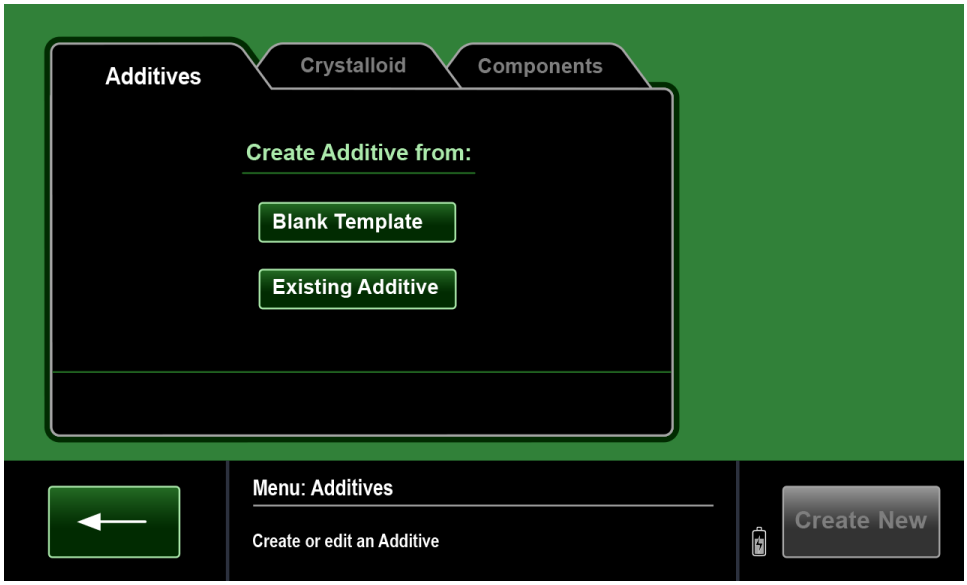

Figure 141: Additive Template Selection

3. All the fields in the Additive Template have to be filled to match the Additive solution being used. The 'per L cdpg' (quantity of component delivered per liter of cardioplegia) and 'Total Volume' fields are calculated by the MPS 3 based on the provided information. A component can be deleted by selecting the component's name and then selecting Delete Row.

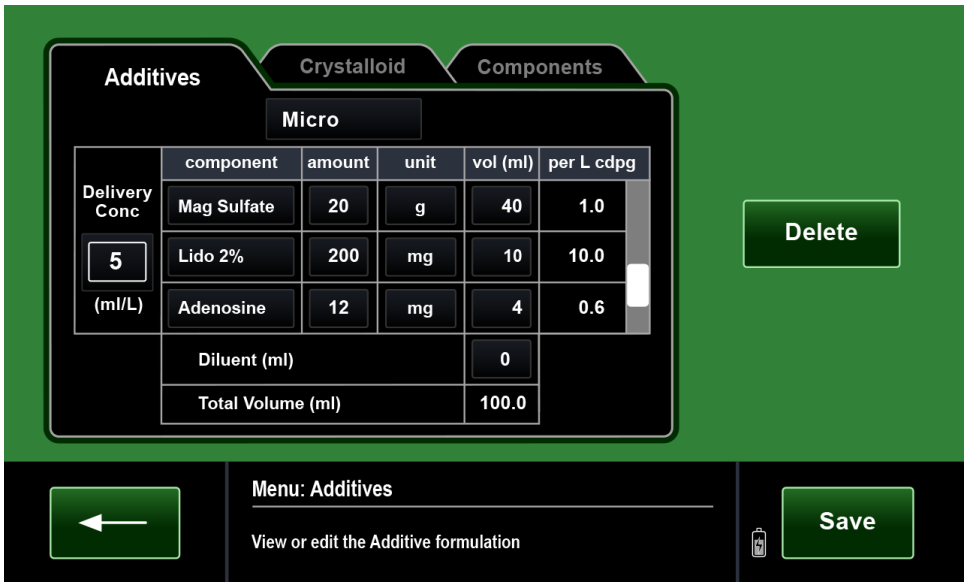

Figure 142: Additive Input Parameters

9.4.7 Crystalloid List

The Crystalloid List contains a list of Crystalloid solutions created by the operator. Items in the list can be added, deleted or edited.

To add an item to the Crystalloid list:

1. In Selection Screen, select Menu -> Crystalloid. The Crystalloid List screen is displayed.

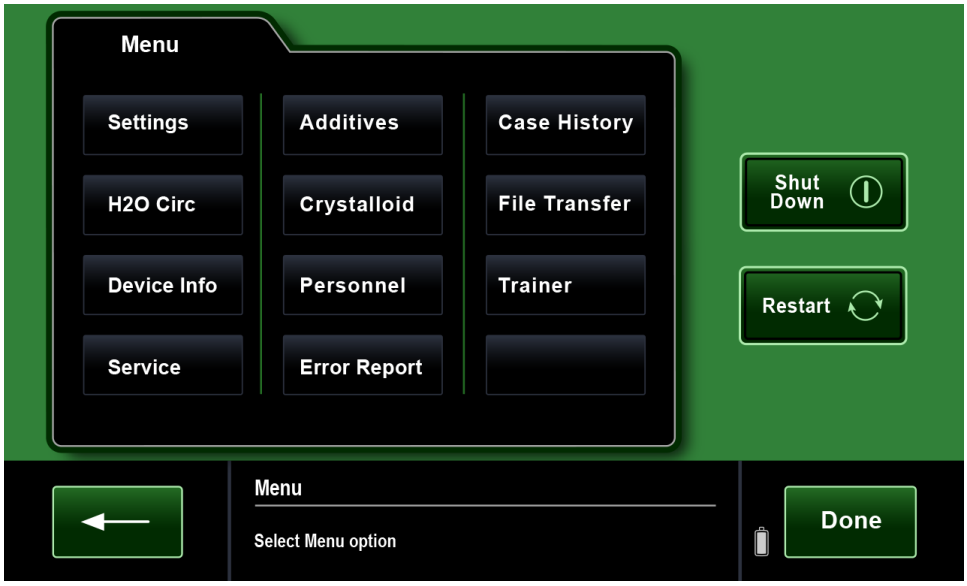

Figure 143: Menu

2. Select a Crystalloid name to edit an existing Crystalloid or select Create New to add a new Crystalloid to the List. Operator is able to use a Blank Template or an existing Crystalloid as a baseline for the New Crystalloid and then naming it using a maximum of up to 8 characters.

3. All the fields in the Crystalloid Template have to be filled to match the Crystalloid solution being used. The ‘per L cdpg’ and ‘Crystalloid Volume’ fields are calculated by the MPS 3 based on the provided information. A component can be deleted by selecting the component’s name and then selecting Delete Row.

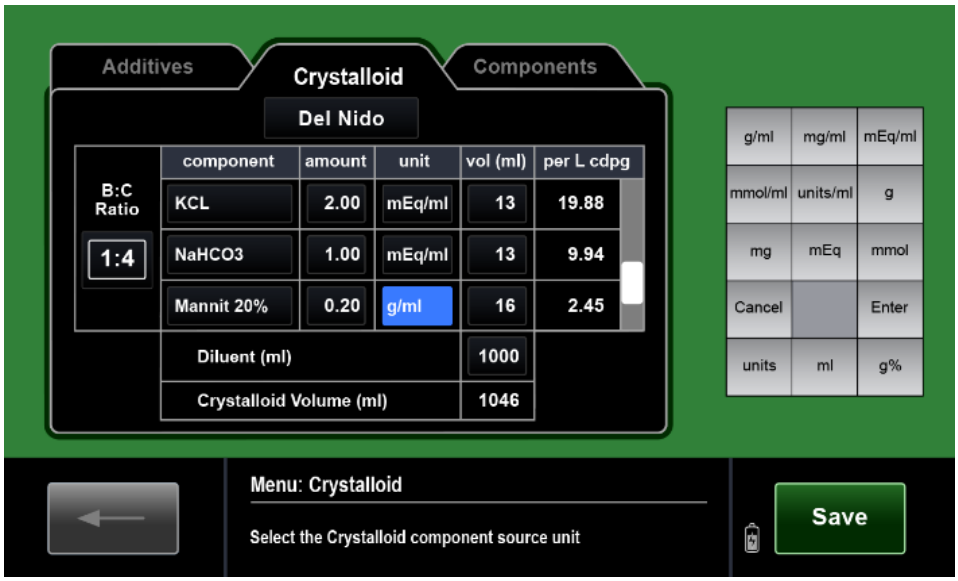

Figure 144: Crystalloid Input Parameters

9.4.8 Component List

The Component List contains a list of up to 6 custom Components created by the operator. The Component List already has 9 reserved Component names (KCL, Mag Sulfate, Lido 1%, Lido 2%, Mannit 20%, Adenosine, $NaHCO_3$, Mannit 25% and Insulin).

To add or delete a custom component to the Component list:

1. In Additive or Crystalloid screen, select the Components tab. The Component List screen is displayed.
2. Select Create New to add a new Component to the List. Operator is able to name it using a maximum of up to 8 characters.
3. Select an existing Component from the list and select Delete to delete the custom component from the list.

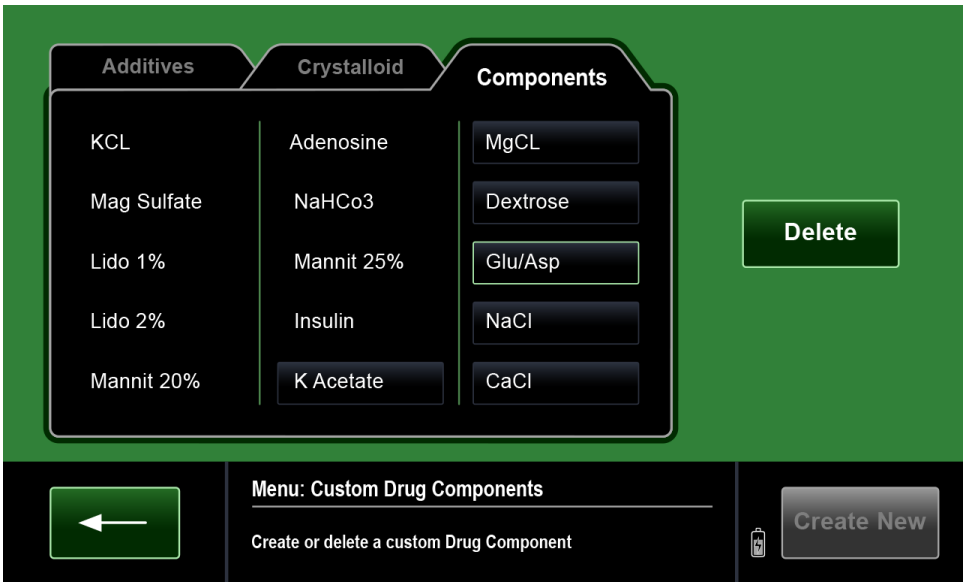

Figure 145: Component List

9.4.9 Personnel

The Personnel List allows the customization of personnel in the account. This includes the Surgeon, Anesthesiologist and Perfusionist Lists. All Personnel entries (Surgeon, Anesthesiologist & Perfusionist) are automatically sorted alphabetically based on the first letter of the name as entered. This list is accessible from the Case report screen and is used to keep track of personnel involved in each case.

To add or delete a custom member to the Personnel list:

1. Select Create New to add a new member to the List. Operator is able to name it using a maximum of up to 25 characters.
2. Select an existing name from the list and select Delete to delete the member name from the list.

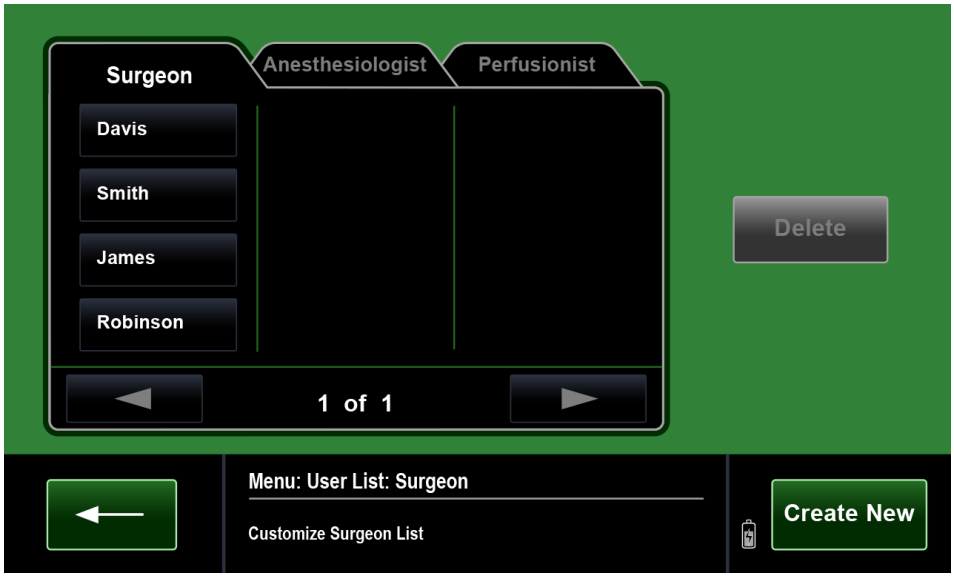

Figure 146: Surgeon List

Figure 147: Anesthesiologist List

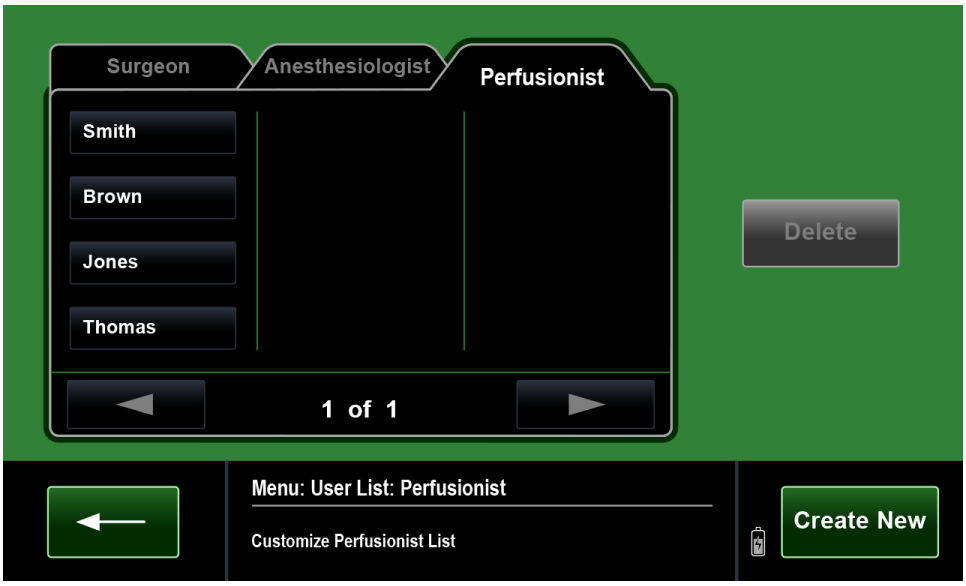

Figure 148: Perfusionist List

9.4.10 Error Report

The Error Report menu option lists all the Errors on the device in Chronological order along with time stamp and Error code. This list helps Service personnel to identify and troubleshoot an error condition on your device. Select Save to save the report to the USB memory device.

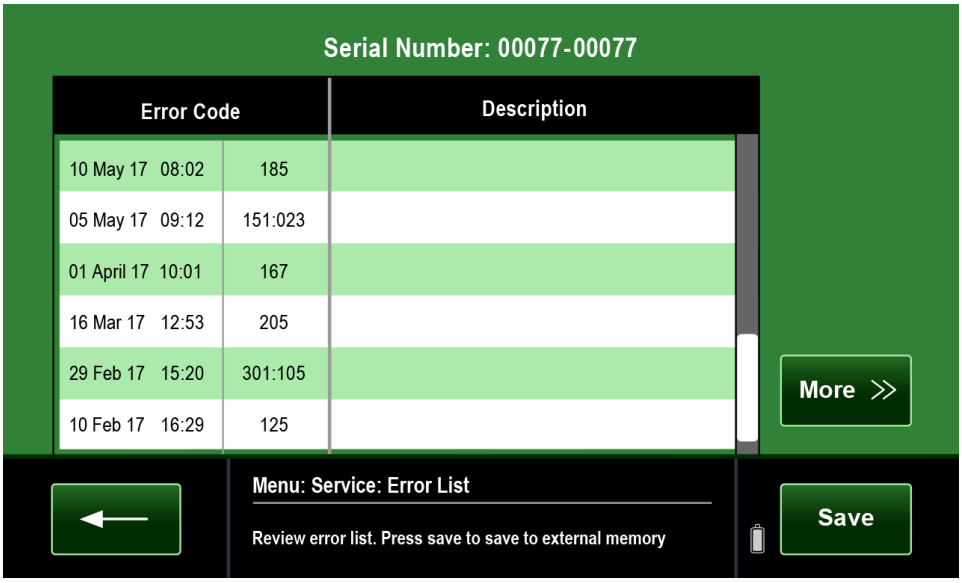

Figure 149: Error Report

9.4.11 Trainer Mode

Trainer Mode is a training feature that allows operators to become familiar with the MPS 3 Controller without having to load a disposable onto the Console. To enter Trainer Mode, select Trainer and confirm Yes on the dialogue box. The MPS 3 System will restart and an orange border will be displayed around the screen to alert operators they are in Trainer Mode and the Console is no longer responding to commands from the Controller. To exit Trainer Mode, restart the System with the push button switch and confirm the orange border is no longer displayed after System Diagnostics is completed.

While in Trainer Mode, the Console is not receiving commands from the Controller and remains in safe state until it is restarted. Trainer mode is for training purposes only.

While in Trainer Mode, changes made to Protocols, Additive & Crystalloid Formulations, Components, and Personnel are maintained separately as Trainer data to protect Patient data.

While in Trainer Mode, Master File Copy and some File transfer operations are disabled to protect Patient data.

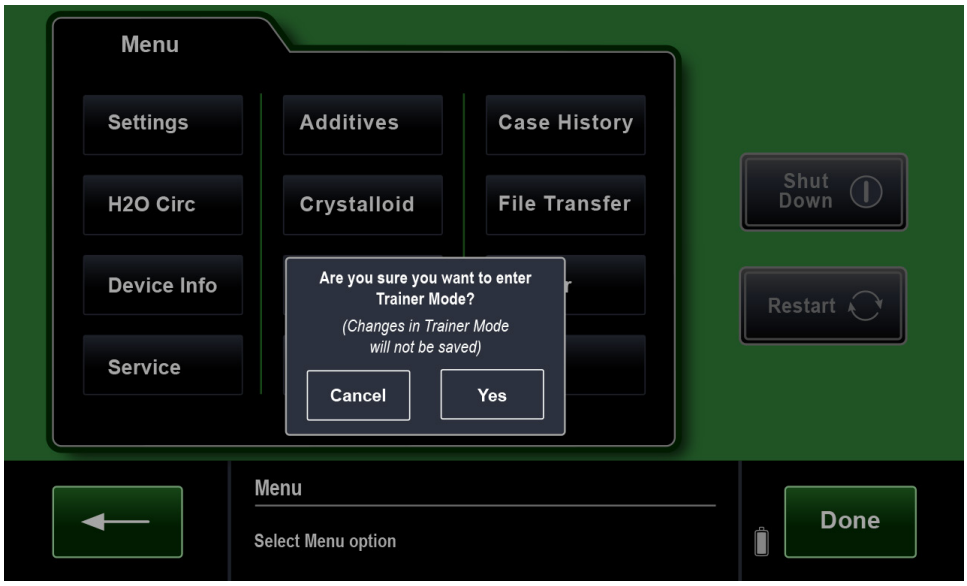

Figure 150: Entering Trainer Mode Warning

Figure 151: Trainer Mode

9.4.12 Shut Down and Restart

To power off the MPS 3 System into Standby mode, select Shut Down and confirm Shut Down on the dialogue box. To completely shut down the MPS 3 System, turn main power switch on the rear panel of the MPS 3 Console to the OFF position. To restart the MPS 3 System from Standby mode, select and hold the push button switch on the front of the MPS 3 Console until the indicator light turns blue. The backup battery only charges while in Standby mode.

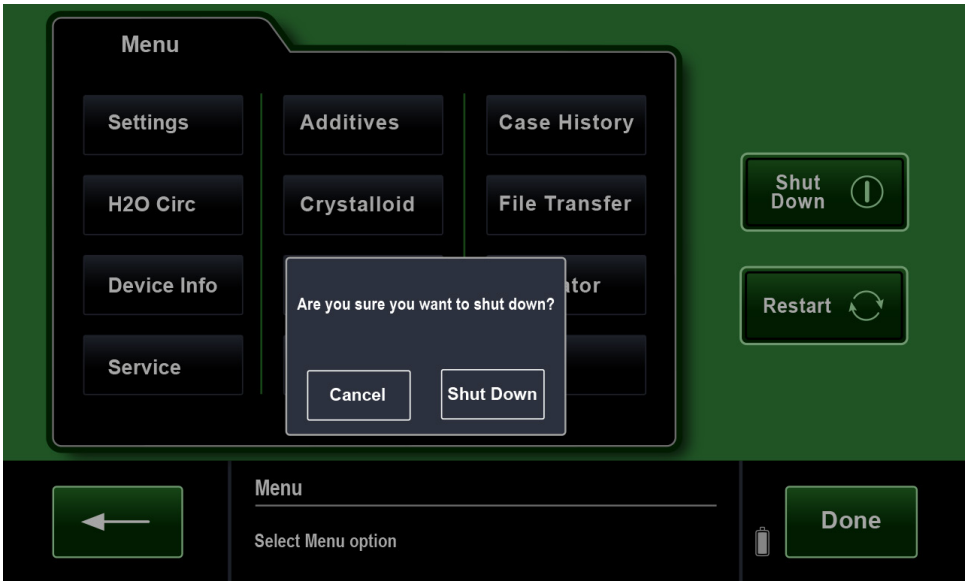

Figure 152: Shutdown Warning

To Restart the MPS 3 System to return to the Selection Screen, select Restart and confirm Restart on the dialogue box.

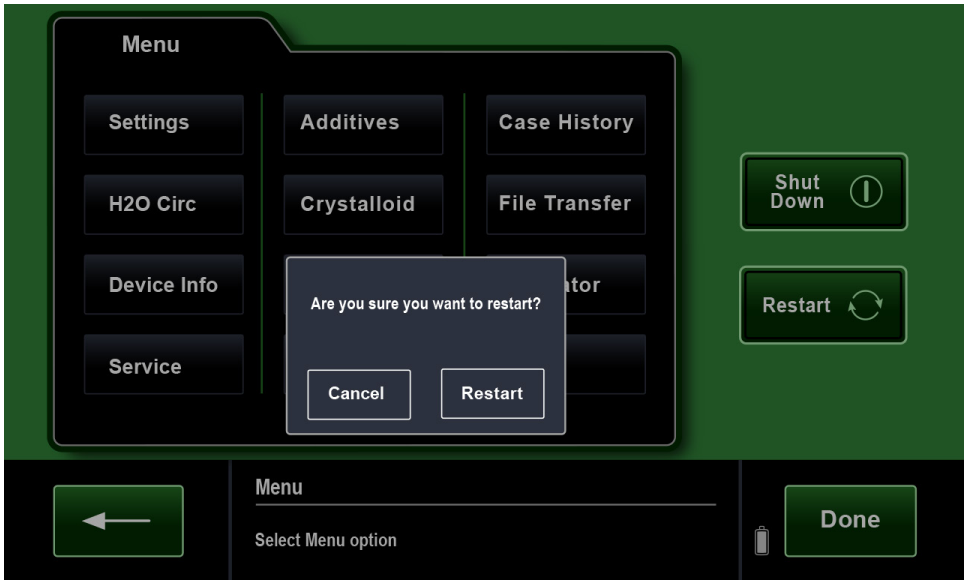

Figure 153: Restart Warning

Refer to Section 6.1 for more information on system startup.

Shut Down and Restart events are remembered in the Data Logs with time stamps.

9.5 Data Transfer

Data transfer allows the operator to copy the information from MPS 3 System to external storage media. The operator is able to copy the information related to:

- Protocols, Additives, Crystalloids, Components, Personnel
- Case History
- Error Report
- Service Reports (authorized Service personnel only)

Storage Media for data transfer must be a Quest Medical approved USB external storage device with a Quest signature file loaded. Contact your customer service representative for instructions on how to add the Quest signature file to your hospital encrypted USB external storage device. Storage media is connected to the MPS 3 System through the USB port available on the side of the Controller.

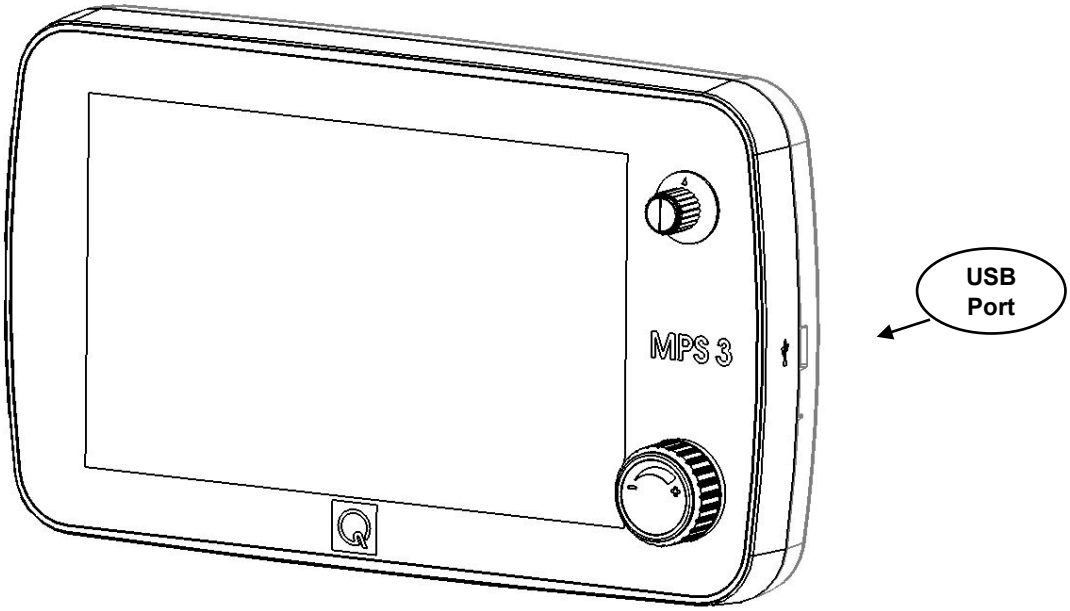

Figure 154: USB Port in the Controller

10 Alarm Overview

Alarms and errors are the notifications to the operator to ensure safe and proper function of the MPS 3 System. The alarm message states the alarm or error code, a brief description of the alarm, and prompts for clearing the alarm. All Alarms are recorded in the Alarm Report and may be accessed from the Menu option. The Alarm Report is retained permanently during System power down and during total loss of power events. The oldest alarms are discarded in the event of the Alarm log memory becoming full.

The AUDIO PAUSE button  is displayed in the High and Medium Priority Alarm screens. When the AUDIO PAUSE button is selected, the audible alarm tone will be silenced for 30 seconds.

10.1 High Priority Alarms

High priority alarms halt fluid delivery and require acknowledgement by the operator. High priority alarms are announced in a red message window with a flashing yellow border and a repeating audible tone. The alarm number is displayed along with the message. When a high priority alarm is displayed, the display outside the message window is dimmed and the flow knob and all buttons outside the high priority message window become inactive until CONFIRM button is pressed.

The operator has the option to pause the audible alarm tone for 30 seconds. The operator has to acknowledge the alarm by selecting an option in the Alarm message window.

Figure 155: Home Screen with High Priority Alarm

The sound pressure level for the High Priority acoustic alarm tones can be adjusted using the Audio Level Menu setting according to the table below

	Audio Level = 1	Audio Level = 5
High Priority Alarms	44 - 48 dB(A)	52 - 56 dB(A)

10.2 Medium Priority Alarms

Medium priority alarms require acknowledgement by the operator without halting fluid delivery. Medium priority alarms are announced in a yellow message window and a repeating audible tone. The alarm number is displayed along with the message When a medium priority alarm is displayed, the flow knob and all buttons remain active. The operator has the option to pause the audible alarm tone for 30 seconds. The operator may acknowledge the alarm by selecting an option in the error message window.

Figure 156: Home Screen with Medium Priority Alarm

The sound pressure level for the Medium Priority acoustic alarm tones can be adjusted using the Audio Level Menu setting according to the table below

	Audio Level = 1	Audio Level = 5
Medium Priority Alarms	43 - 47 dB(A)	50 - 54 dB(A)

10.3 Informational Tones

Informational Tones are used to indicate conditions that do not require any operator acknowledgement. They are announced by a non-repeating audible signal and sometimes visually by flashing a displayed value or symbol such as when pressure or flow limit values exceed the set limit or the Ischemic Timer has expired.

When adjusting the Audio level for the acoustic alarm tones. Be aware that sound pressure levels less than ambient levels can impede the recognition of alarm tones.

The Audio level setting must be adjusted individually according to the expected ambient noise level to ensure proper perception of audible alarms.

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11 Troubleshooting

This section provides a quick reference for responding to alarm conditions and error messages and any subsequent troubleshooting that may be helpful to remedy certain situations.

11.1 General troubleshooting

Each MPS 3 System is rigorously tested prior to shipment to ensure the devices function reliably as intended. It is expected that over the life of the device, some issues may arise as a result of use conditions, environment, handling, and storage. Annual Preventative Maintenance helps ensure that the MPS 3 System will function properly during use. Even so, this troubleshooting guide may be helpful in working through minor issues to get the system functioning properly.

Only Quest Medical Service personnel or trained technicians and operators should attempt to troubleshoot the MPS 3 System. If this troubleshooting guide does not remedy the situation, please call Quest Medical Technical Support at +1 (888) 510-7623.

DO NOT attempt to disassemble or dismantle the MPS 3 System unless trained to do so. Doing so may void the product warranty.

11.2 MPS 3 Blood Bypass Tubing

The MPS 3 Blood Bypass Tubing (**REF** 5301016) is only for use as a back-up with the MPS 3 System to continue fluid delivery in the event of complete battery depletion after AC power failure or if the System becomes unusable even after following the corrective action and troubleshooting suggestions in Sections 11.3 and 11.4. Follow the instructions for install and use in the accompanying IFU with each Bypass Tubing (also found in Section 15.3 of this Operations Manual).

11.3 Alarm Code List and Solutions

The following table lists alarm (error) codes, the displayed message, and recommended corrective action. The alarm code is displayed in the message window. A chronological listing of all alarm codes on the device can be accessed by selecting the Error Report button from the Menu screen.

Alarm Code Priority	Message Display	Corrective Action
1 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
2 **High**	**System Data Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple alarms
3, 4 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
5 **Medium**	**Door is open** **Close door to continue** **SHUTDOWN**	* Close the door * Select shutdown to turn System off
6 **High**	**Door is open** **Close door to continue**	* Close the door
7 **High**	**Door Open still detected** **Press IGNORE only if faulty sensor** **IGNORE** **RETEST**	* Open and Close door * Select ignore if operator feels door is securely closed but the console is not recognizing that. * Contact service following procedure
8 **High**	**Door Open detected** **Open then Close door** **RETEST**	* Open and Close door * Contact service following procedure

Alarm Code Priority	Message Display	Corrective Action
9 High	**Door Open detected** **Close door and press RETEST** **(Press IGNORE only if faulty sensor)** **IGNORE** **RETEST**	* Open and Close door * Select ignore if operator feels door is securely even when alarms is repeating itself * Contact service immediately
10, 11 High	**System Config mismatch Error** **Call Service** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
12 High	**Left Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
13 High	**Right Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
14 High	**Left Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
15 High	**Right Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
16 High	**Pneumatic leak or compressor malfunction** **Consider attaching medical air if available** **Consult Service after this case** **SHUTDOWN** **RESTART**	* Connect medical air * Contact service following procedure
17 High	**Mechanism Valve failed diagnostics** **RESTART** **CONFIRM**	* Open door and manually depress mechanism valves several times. * Restart System * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
18 **High**	**Delivery Valve failed diagnostics** **RESTART** **CONFIRM**	* Manually actuate delivery and vent valves several times * Clean valves if dirty * Restart System * Call service after multiple occurrences
19	**H2O Circ valve error detected** **Proceed with potential heating issues** **RESTART** **CONFIRM**	* Restart System * Call service after multiple alarms
20, 21 **High**	**Pressure sensor zeroing failure** **Check Vent line for clamps** **SHUTDOWN** **RESTART**	* Check line for clamps, kinks, or occlusions * Restart System * Call service after multiple occurrences
22 **High**	**Left Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System *Call service after multiple occurrences
23 **High**	**Right Pump failed diagnostics** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
24 **High**	**Mechanism Valve failed diagnostics** **RESTART** **CONFIRM**	* Open door and manually depress mechanism valves several times * Restart System * Call service after multiple occurrences
25 **High**	**Delivery Valve failed diagnostics** **RESTART** **CONFIRM**	* Manually actuate valves several times * Clean valves if dirty * Restart System * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
26, 27 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
28, 29 **High**	**System Config mismatch Error** **Call Service** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
30 **High**	**Fluid Level sensor test failure** **Manually Vent bubble trap** **Proceed with Caution** **RESTART** **CONFIRM**	* Continue with case while manually venting air accumulations in bubble trap * Contact service following procedure
31 **High**	**Air in line sensor test failure** **Air detection may be compromised** **Proceed with Caution** **RESTART** **CONFIRM**	* Continue with case while manually monitoring for air in delivery line * Contact service immediately following procedure
32 **Medium**	**Is there fluid in the bubble trap?** **RETEST** **YES**	* If fluid is present, select YES OR * If fluid is not present, restart and repeat the priming process & contact service after multiple occurrences
33 **Medium**	**Is there fluid in the delivery line?** **RETEST** **YES**	* If fluid is present, select YES OR * If fluid is not present, restart and repeat the priming process & Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
34 **High**	**Air in bubble trap after Prime** **Check source fluid and circuit** **RETEST**	* If there is NOT air present in heat exchanger, check heat exchanger to ensure it is secured tightly with the locking knob & reprime the circuit OR * If there is air present in heat exchanger, check the lines for clamps and ensure there is adequate blood source pressure & reprime the circuit
35 **High**	**Delivery Set pressure test error** **Check circuit and** **Delivery/Vent valves** **RETEST**	* Check heat exchanger to ensure it is secured tightly with the locking knob * Manually actuate the delivery and vent valves & Reprime the circuit * Check lines for clamps, kinks, or occlusions
36 **High**	**Heat Exchanger pressure test failed** **Replace delivery set** **REPRIME**	* Check heat exchanger to ensure it is secured tightly with the locking knob * If using a heater-cooler unit, turn off the heater-cooler unit and repeat the prime sequence * Replace disposable set after multiple occurrences
37 **High**	**Unable to Prime due to inadequate fill** **Check fluid source pressure and circuit** **RETEST**	* Check the lines for clamps, ensure there is adequate blood source pressure & reprime the circuit
38 **High**	**Unable to Prime** **Check fluid source pressure and circuit** **RETEST**	* Check the lines for clamps, ensure there is adequate blood source pressure & reprime the circuit

Alarm Code Priority	Message Display	Corrective Action
39 **High**	**System pressure sensor error** **RETEST**	* Check the lines for clamps, kinks, or occlusions * Manually actuate delivery and vent valves several times. * Check heat exchanger to ensure it is secured tightly with the locking knob * Restart System * Contact service after multiple occurrences
40 **High**	**External Antegrade sensor not detected** **USE SYSTEM** **RETEST**	* Select USE SYSTEM OR * Retest and if multiple failures are observed, disconnect the cable and try again * Contact service after multiple occurrences
41 **High**	**External Retrograde sensor not detected** **USE SYSTEM** **RETEST**	* Select USE SYSTEM OR * Retest and if multiple failures are observed, disconnect the cable and try again * Contact service after multiple occurrences
42 **High**	**Max System pressure Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Manually actuate delivery and vent valves several times. * Check heat exchanger to ensure it is secured tightly with the locking knob * Restart System * Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
43 **High**	**Max external Antegrade pressure** **Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Check the stopcock position at the sensor * Try to reestablish zero by re-zeroing sensor * If it is believed sensor is faulty, replace sensor and try again. * Contact service after multiple occurrences
44 **High**	**Max external Retrograde pressure** **Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Check the stopcock position at the sensor * Try to reestablish zero by re-zeroing sensor * If it is believed sensor is faulty, replace sensor and try again. * Contact service after multiple occurrences
45 **High**	**Excessive system pressure** **Check lines for clamps** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Manually actuate delivery and vent valves several times. * Check heat exchanger to ensure it is secured tightly with the locking knob * Restart System * Contact service after multiple occurrences
46 **High**	**Excessive Blood source pressure** **Check Blood source** **CONFIRM**	* Check the source line pressure * Restart and resume case, if the problem persists * Contact service after multiple occurrences
47 **High**	**Excessive Cryst source pressure** **Check Cryst source** **CONFIRM**	* Check the crystalloid line pressure * Restart and resume case, if the problem persists * Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
48, 49 **High**	**Excessive chamber pressure** **CONFIRM**	* Continue as normal OR * Restart and resume case * Call service after multiple occurrences
50 **Medium**	**Low delivery line pressure** **Check delivery line connections** **Check Vent pump** **CONFIRM**	* Check heat exchanger to ensure it is secured properly with the locking knob * Check location of delivery line and catheter * Check external pressure sensor * Re-zero external pressure sensor
51 **High**	**Antegrade delivery valve sensor mismatch** **Flow may be resumed** **CONFIRM**	* Manually actuate valve several times. * Clean valves if dirty
52 **High**	**Retrograde delivery valve sensor mismatch** **Flow may be resumed** **CONFIRM**	* Manually actuate valve several times. * Clean valves if dirty
53 **High**	**Vent valve sensor mismatch** **Flow may be resumed** **CONFIRM**	* Manually actuate valve several times. * Clean valves if dirty
54 **High**	**Air detected in delivery Line** **IGNORE** **CONFIRM** **When IGNORE is selected:** **Next Air detection will not stop flow** **Select Confirm only if you agree** **CONFIRM** **CANCEL**	* Check delivery line to ensure it is fully inserted in sensor * If sensor is ignored, manually inspect delivery line for air moving forward

Alarm Code Priority	Message Display	Corrective Action
55 **Medium**	**Air detected in delivery line. Flow continues** **Manually check for air** **CONFIRM**	* Check delivery line to ensure it is fully inserted in sensor * If sensor is ignored, manually inspect delivery line for air moving forward
56 **Medium**	**More Air detected in delivery line** **Continue to Flush** **CONFIRM**	* Check delivery line to ensure it is fully inserted in sensor * If sensor is ignored, manually inspect delivery line for air moving forward
57 **Medium**	**Vent Valve Is Open** **Check for Air in the bubble trap** **Ensure the heat exchanger is locked** **CONFIRM**	* Check heat exchanger to ensure it is secured tightly with the locking knob * Check vent line for clamps, kinks, or occlusions * Attempt to manually actuate valve several times. * Restart System * Contact service after multiple occurrences
58 **Medium**	**Low pressure in heat exchanger** **Check circuit** **CONFIRM**	* Check heat exchanger to ensure it is secured tightly with the locking knob * Check vent and delivery lines to ensure they are properly inserted in delivery and vent valves.
59 **High**	**Delivery occlusion** **Check for clamps** **Check pressure limit setting** **CONFIRM**	* Check delivery line for clamps, kinks, or occlusions * Check the upper pressure limit settings
60 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
61, 62 **Medium**	**Inadequate Crystalloid fill** **Check Source** **CONFIRM**	* Check Crystalloid inlet line for clamps, kinks, or occlusions * Raise the Crystalloid bag or use a pressure cuff
63, 64 **Medium**	**Inadequate Blood fill** **Check Source** **CONFIRM**	* Check Blood inlet line for clamps, kinks, or occlusions * Increase the blood inlet source pressure
65 **Medium**	**Inadequate Fill Check Source** **CONFIRM**	* Check blood/crystalloid source lines and pressures * If problem persists, restart system * Call service after multiple occurrences
66, 67 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
68, 69 **High**	**System FPGA Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple alarms
70 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
71, 72 **High**	**System FPGA Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple alarms
73 **High**	**System Mechanism Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
74 **High**	**Door is open** **Close door to continue** **SHUTDOWN**	* Close the door * Select shutdown to turn System off
75, 76 **High**	**System FPGA Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple alarms
78, 79, 84, 85 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
86, 87, 88, 89 **High**	**Blood Pump Error** **Flow may be resumed** **Shutdown** **Confirm**	* Continue with procedure * If error occurs multiple times over the course of the procedure, contact service immediately following procedure
92, 93 **High**	**Unable to maintain flow rate setting** **Check circuit** **CONFIRM**	* Check blood/crystalloid source lines and pressures * Stop flow and restart flow * If problem persists, restart system * Call service after multiple occurrences
94 **High**	**Mechanism valve error** **Reinitializing. Please wait…**	* Continue with procedure * If error occurs multiple times over the course of the procedure, contact service immediately following procedure
95 **High**	**Delivery valve sensor mismatch** **Flow may be resumed** **CONFIRM**	* Continue with procedure * If error occurs multiple times over the course of the procedure, contact service immediately following procedure

Alarm Code Priority	Message Display	Corrective Action
96, 97, 98 **High**	**Arrest pump failed diagnostics** **Proceed without Arrest pump** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
99 **Medium**	**Arrest cartridge is empty or absent** **Fill Arrest cartridge, press RETEST** **DISABLE** **RETEST**	* Choose DISABLE if Arrest delivery is no longer needed for procedure OR * Refill Arrest Cartridge and select RETEST
101 **Medium**	**Arrest occlusion during prime** **Check Arrest line and stopcock** **CONFIRM** **RETEST**	* Check arrest delivery line for clamps, kinks, or occlusions * Check stopcock position * If problem persists, replace arrest delivery line and try again * If problem still exists after replacing arrest delivery line, restart system and try again * Contact service after multiple occurrences
102 **Medium**	**Arrest cartridge is empty or absent** **Arrest pump is Off** **REFILL** **CONFIRM**	* Choose CONFIRM if Arrest delivery is no longer needed for procedure OR * Select REFILL and refill Arrest Cartridge
103 **Medium**	**Arrest occlusion detected** **Check Arrest line and stopcock** **Arrest pump is Off** **CONFIRM** **RETEST**	* Check arrest delivery line for clamps, kinks, or occlusions * Check stopcock position * If problem persists, replace arrest delivery line and try again * If problem still exists after replacing arrest delivery line, restart system and try again * Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
104 **Medium**	**Arrest over-delivery detected** **Arrest has been turned off** **RETEST** **CONFIRM**	* Select CONFIRM to turn Arrest pump off and continue procedure OR * Select RETEST to turn Arrest pump on and continue procedure
105 **Medium**	**Arrest under-delivery detected** **Check cartridge and circuit** **CONFIRM**	* Check arrest delivery line for clamps, kinks, or occlusions * Check cartridge for occlusions/leaks * Check stopcock position * If problem persists, replace arrest delivery line and try again * If problem still exists after replacing arrest delivery line, restart console and try again * Contact service after multiple occurrences
106, 107, 108 **High**	**Additive pump failed diagnostics** **Proceed without Additive pump** **RESTART** **CONFIRM**	* Restart System * Call service after multiple occurrences
109 **Medium**	**Additive cartridge is empty or absent** **Fill Additive cartridge, press RETEST** **DISABLE** **RETEST**	* Choose DISABLE if Additive delivery is no longer needed for procedure OR * Refill Additive Cartridge and select RETEST

Alarm Code Priority	Message Display	Corrective Action
111 **Medium**	**Additive occlusion during prime** **Check Additive line and stopcock** **CONFIRM** **RETEST**	* Check additive delivery line for clamps, kinks, or occlusions * Check stopcock position * If problem persists, replace additive delivery line and try again * If problem still exists after replacing additive delivery line, restart console and try again * Contact service after multiple alarms
112 **Medium**	**Additive cartridge is empty or absent** **Additive pump is Off** **REFILL** **CONFIRM**	* Choose CONFIRM if Additive delivery is no longer needed for procedure OR * Select REFILL and refill Additive Cartridge
113 **Medium**	**Additive occlusion detected** **Check Additive line and stopcock** **Additive pump is Off** **CONFIRM** **RETEST**	* Check additive delivery line for clamps, kinks, or occlusions * Check stopcock position * If problem persists, replace additive delivery line and try again * If problem still exists after replacing additive delivery line, restart console and try again * Contact service after multiple alarms
114 **Medium**	**Additive over-delivery detected** **Additive has been turned off** **RETEST** **CONFIRM**	* Select CONFIRM to turn Additive pump off and continue procedure OR * Select RETEST to turn Additive pump on and continue procedure

Alarm Code Priority	Message Display	Corrective Action
115 **Medium**	**Additive under-delivery detected** **Check cartridge and circuit** **CONFIRM**	* Check additive delivery line for clamps, kinks, or occlusions * Check cartridge for occlusions/leaks * Check stopcock position * If problem persists, replace additive delivery line and try again * If problem still exists after replacing additive delivery line, restart console and try again * Contact service after multiple alarm errors
117 **Medium**	**Arrest pump error** **Arrest pump is Off** **CONFIRM** **RETEST**	* Select CONFIRM to turn Arrest pump off and continue procedure OR * Select RETEST to turn Arrest pump on and continue procedure
118 **Medium**	**Arrest pump failed** **Proceed without Arrest pump** **CONFIRM**	* Restart System and resume case * Call service after multiple occurrences
119 **Medium**	**Additive pump error** **Additive pump is off** **CONFIRM** **RETEST**	* Select CONFIRM to turn Additive pump off and continue procedure OR * Select RETEST to turn Additive pump on and continue procedure
120 **Medium**	**Additive pump failed** **Proceed without Additive pump** **CONFIRM**	* Restart System and resume case * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
121 **Medium**	**Arrest pump is Disabled** **CONFIRM**	* Prime arrest pump
122 **Medium**	**Additive pump is Disabled** **CONFIRM**	* Prime additive pump
123 **Medium**	**Circulation valve sensor mismatch** **Manually monitor delivery temperature** **H2O Circ is OFF. Heaters are disabled.** **CONFIRM**	* Continue procedure without ability to control temperature using the MPS 3 console * Try connecting medical air * Restart System * Contact service after multiple occurrences
124 **Medium**	**H2O temperature sensor error** **H2O temperature will not be displayed** **Heaters Disabled** **CONFIRM**	* Continue without temperature control OR * Restart and resume case * Call service after multiple occurrences
125 **Medium**	**Delivery temperature sensor error** **Delivery temperature will not be displayed** **Call Service after this Case** **CONFIRM**	* Manually monitor delivery temperature * Restart System * Contact service after multiple occurrences
126 **Medium**	**Temperature exceeded allowed limit** **Ensure that cold water is available** **H2O Circ turned OFF** **CONFIRM**	* Check cold water source temperature * Ensure cold water source has adequate water level and flow rate * Check blood inlet temperature

Alarm Code Priority	Message Display	Corrective Action
127, 128 **Medium**	**Water flow sensor failed** **Continue with heaters disabled** **Start a NEW CASE to retest.** **CONFIRM**	* Continue without temperature control OR * Restart and resume case * Call service after multiple occurrences
129 **Medium**	**Low water flow detected** **Check for air locks. Check external heater/cooler** **Temperature Control may be affected** **CONFIRM**	* Ensure the H2O Circulation System has been fully primed using the steps outlined in Section 5.5.5 * Ensure cold water source has adequate water level and flow rate * Check water lines for clamps, kinks, or occlusions * Check water lines to ensure they are connected properly and not reversed * Increase head height of Hypothermic Reservoir * Increase water pressure and flow mode settings in heater cooler unit if possible * If a bypass loop is being used in conjunction with the heater cooler unit, then partially clamping/reducing the tubing size or installing pressure relief check valve will increase flow into the MPS 3 H2O Circulation System. * Try to prime/re-prime circulation system * If system will still not prime properly, remove heat exchanger and manually burp top puck seal to remove air and then try to prime/reprime system (Section 5.5.5)

Alarm Code Priority	Message Display	Corrective Action
130 **Medium**	**Reverse water flow detected** **Check water connections** **H2O Circ is OFF. Turn Circ ON to retest.** **CONFIRM**	* Ensure the H2O Circulation System has been fully primed using the steps outlined in Section 5.5.5 * Ensure cold water source has adequate water level and flow rate * Check water lines for clamps, kinks, or occlusions * Check water lines to ensure they are connected properly and not reversed * Increase head height of Hypothermic Reservoir * Increase water pressure and flow mode settings in heater cooler unit if possible * If a bypass loop is being used in conjunction with the heater cooler unit, than partially clamping/reducing the tubing size of the bypass loop or installing pressure relief check valve in line will increase flow into the MPS 3 H2O Circulation System. * Try to prime/re-prime circulation system * If system will still not prime properly, remove heat exchanger and manually burp top puck seal to remove air and then try to prime/reprime system (Section 5.5.5)
131 **Medium**	**Low pressure in heat exchanger** **Check Circuit** **CONFIRM**	* Ensure adequate flow rate is set during Recirc and/or Vent modes. * Check head height of cardiotomy reservoir to ensure it is not too far below vent valve on MPS 3 console.

Alarm Code Priority	Message Display	Corrective Action
134, 135, 136 **Medium**	**Heater diagnostics failed** **Continue with heaters disabled** **Start a NEW CASE to retest heaters** **CONFIRM**	* Continue if heating is not required for procedure * Ensure the H2O Circulation System has been fully primed using the steps outlined in Section 5.5.5 * Restart and select New Case to retest heater diagnostics * Contact service after multiple occurrences
137 **Medium**	**Heater diagnostics started** **May take up to 100 seconds** **CONFIRM**	* Wait for heater diagnostics to complete
138 **High**	**Pneumatic pressure sensor error** **Service required** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
139 **Medium**	**Low Pneumatic pressure detected** **CONFIRM**	* Connect to medical air * Contact service following procedure
140 **High**	**Blood/Cryst pump has been stopped** **Pneumatic pressure critical** **Check compressor or connect to medical air** **CONFIRM**	* Connect to medical air * Contact service following procedure
141 **High**	**Pneumatic over pressure (> 55 psi)** **Check medical air source** **SHUTDOWN** **RETRY**	* Disconnect from medical air and retry
142 **Medium**	**Pneumatic leak or internal compressor malfunction** **Consider attaching medical air if available** **Consult Service after this case** **CONFIRM**	* Connect to medical air * Contact service following procedure

Alarm Code Priority	Message Display	Corrective Action
143, 144 **Medium**	**Compressor malfunction detected** **Consult Service after this case** **CONFIRM**	* Connect to medical air * Contact service following procedure
145 **High**	**Pneumatic system failure** **Connect medical air** **Service required** **SHUTDOWN** **CONFIRM**	* Connect to medical air * Contact service following procedure
146 **High**	**System Communication Error** **Manual Restart Required**	* Manually Restart System * Call service after multiple occurrences
147 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
148 **High**	**System Communication Error** **Manual Restart Required**	* Manually Restart System * Call service after multiple occurrences
149 **Medium**	**Temperature sensor Fail** **Call Service after this Case** **CONFIRM**	* Safe to use. Board temperature sensor is not essential for operation. * Call service after multiple occurrences
151 **Medium**	**H2O temperature sensor error** **H2O temperature will not be displayed** **Heaters Disabled** **CONFIRM**	* Continue without temperature control OR * Restart and resume case * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
152 **High**	**Pneumatic pressure sensor error** **Service required** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
153 **Medium**	**Heater controls failed** **Continue with heaters disabled** **Start a NEW CASE to retest** **CONFIRM**	* Continue without temperature control OR * Restart and start New Case * Call service after multiple occurrences
155 **Medium**	**Drug pump LED fail** **Contact Service after this Case** **CONFIRM**	* Safe to use. Drug pump is fully functional. Only the LED may be compromised. * Call service after multiple occurrences
157, 158 **Medium**	**Board Temperature sensor Fail** **Call Service after this Case** **CONFIRM**	* Safe to use. Board temperature sensor is not essential for operation. * Call service after multiple occurrences
160 **Medium**	**Elevated internal temperature detected** **Check for obstructed air flow** **Maintenance required** **CONFIRM**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
161 **High**	**Internal temperature Error detected** **Check for obstructed air flow** **Unable to proceed. Call for Service** **SHUTDOWN**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
162, 163 **High**	**System Communication Error** **Manual Restart Required**	* Manually restart system * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
165 **Medium**	**Elevated internal temperature detected** **Check for obstructed air flow** **Maintenance required** **CONFIRM**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
166 **High**	**Internal temperature Error detected** **Check for obstructed air flow** **Unable to proceed. Call for Service** **SHUTDOWN**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
167 **Medium**	**Elevated internal temperature detected** **Check for obstructed air flow** **Maintenance required** **CONFIRM**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
168 **High**	**Internal temperature Error detected** **Check for obstructed air flow** **Unable to proceed. Call for Service** **SHUTDOWN**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
169 **Medium**	**Elevated internal temperature detected** **Check for obstructed air flow** **Maintenance required** **CONFIRM**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
170 **High**	**Internal temperature Error detected** **Check for obstructed air flow** **Unable to proceed. Call for Service** **SHUTDOWN**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
171, 172 **High**	**Power Supply Voltage Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
173 **Medium**	**Power loss detected. Running on battery** **Heaters disabled.** **Reconnect power when available** **CONFIRM**	* If power loss did not occur, check power cord, outlet, or circuit breaker * Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
174 **Medium**	**AC power detected** **Previous functionality restored** **CONFIRM**	* No action required
175 **Medium**	**Battery capacity at 75%** **Reconnect power when available** **CONFIRM**	* Reconnect AC power. If power loss did not occur, check power cord, outlet, or circuit breaker
176 **Medium**	**Battery capacity at 50%** **LCD has been dimmed to conserve power** **CONFIRM**	* Reconnect AC power. If power loss did not occur, check power cord, outlet, or circuit breaker
177 **Medium**	**Battery capacity at 25%** **Reconnect power immediately** **CONFIRM**	* Reconnect AC power. If power loss did not occur, check power cord, outlet, or circuit breaker
178 **High**	**Battery critically low** **Shutting down**	* Reconnect AC power. If power loss did not occur, check power cord, outlet, or circuit breaker
179 **High**	**Battery temperature elevated** **Turn off switch on the rear panel** **Unable to proceed. Call for Service**	* Check fans and air inlets for obstructions * Restart System * Contact service after multiple occurrences
180, 181 **Medium**	**Battery Charge Error** **Battery backup unavailable** **Consult service after this case** **CONFIRM**	* Call service after multiple occurrences
182 **Medium**	**Battery Charge Error** **Consult service after this case** **CONFIRM**	* Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
183 **Medium**	**Battery Charge Error** **Consult service after this case** **CONFIRM**	* Call service after multiple occurrences
184 **High**	**Air detected in delivery Line** **IGNORE** **CONFIRM**	* Check delivery line to ensure it is fully inserted in sensor * If sensor is ignored, manually inspect delivery line for air moving forward
185 **Medium**	**Air detected in delivery line. Flow continues** **Manually check for air** **CONFIRM**	* Check delivery line to ensure it is fully inserted in sensor * If sensor is ignored, manually inspect delivery line for air moving forward
186 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
187 **High**	**Max System pressure** **Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Manually actuate delivery and vent valves several times. * Check heat exchanger to ensure it is secured tightly with the locking knob * Restart System * Contact service after multiple occurrences
188 **High**	**Max external Antegrade pressure** **Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Check the stopcock position at the sensor * Try to reestablish zero by re-zeroing sensor * If it is believed sensor is faulty, replace sensor and try again. * Contact service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
189 **High**	**Max external Retrograde pressure** **Check circuit** **CONFIRM**	* Check the lines for clamps, kinks, or occlusions * Check the stopcock position at the sensor * Try to reestablish zero by re-zeroing sensor * If it is believed sensor is faulty, replace sensor and try again. * Contact service after multiple occurrences
190 **High**	**Unable to maintain flow rate setting** **Check circuit** **CONFIRM**	* Check blood/crystalloid source lines and pressures * Stop flow and restart flow * If problem persists, restart system * Call service after multiple occurrences
191 **Medium**	**Arrest pump Home Sensor fail** **Arrest pump is disabled** **CONFIRM** **RETEST**	* Select RETEST * If error still persists, restart system and try again * Contact service after multiple occurrences
192 **Medium**	**Additive pump Home Sensor fail** **Additive pump is disabled** **CONFIRM** **RETEST**	* Select RETEST * If error still persists, restart system and try again * Contact service after multiple occurrences
197 **High**	**Arrest pump piston sensor error** **Verify Arrest cartridge installation** **DISABLE**	* Select DISABLE to complete Prime * Check Arrest Cartridge to verify it is properly installed. * Retry drug Prime from the Home screen. * If error still persists, contact Service

Alarm Code Priority	Message Display	Corrective Action
198 **Medium**	**Arrest over-delivery detected** **Arrest has been turned off** **CONFIRM OFF** **TURN ON**	* Select CONFIRM OFF to leave Arrest pump off and continue procedure OR * Select TURN ON to turn Arrest pump back on and continue procedure
199 **Medium**	**Arrest under-delivery detected** **Check cartridge and circuit** **CONFIRM** **RETEST**	* Select CONFIRM to suspend monitoring until next dose OR * Select RETEST to continue monitoring
201 **High**	**Additive pump piston sensor error** **Verify Additive cartridge installation** **DISABLE**	* Select DISABLE to complete Prime * Check Additive Cartridge to verify it is properly installed. * Retry drug Prime from the Home screen. * If error still persists, contact Service
202 **Medium**	**Additive over-delivery detected** **Additive has been turned off** **CONFIRM OFF** **TURN ON**	* Select CONFIRM OFF to leave Additive pump off and continue procedure OR * Select TURN ON to turn Additive pump back on and continue procedure
203 **Medium**	**Additive under-delivery detected** **Check cartridge and circuit** **CONFIRM** **RETEST**	* Select CONFIRM to suspend monitoring until next dose OR * Select RETEST to continue monitoring

Alarm Code Priority	Message Display	Corrective Action
204 **Medium**	**Internal H2O temperature sensor error** **Ensure proper Cold water source** **Call Service after this Case** **CONFIRM**	* Continue as normal OR * Restart and resume case * Call service after multiple occurrences
205 **High**	**Temperature exceeded allowed limit** **Ensure that cold water is available** **H2O Circ turned OFF** **CONFIRM**	* Check cold water source temperature * Ensure cold water source has adequate water level and flow rate * Check blood inlet temperature
207 **High**	**Unsafe temperature detected** **Disconnect main power. Call for Service** **SHUTDOWN**	* Check fans and air inlets for obstructions * Restart * Contact service after multiple alarm errors
208 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220 **Medium**	**Data Logging Error** **Consult Service after this case** **CONFIRM**	* Continue as normal. * Contact service after multiple alarm errors
221, 222, 223 **Medium**	**Data Log File Transfer** **CONFIRM**	* Continue as normal. * Contact service after multiple alarm errors

Alarm Code Priority	Message Display	Corrective Action
226 **Medium**	**Internal H2O temperature sensor error** **Ensure proper Cold water source** **Call Service after this Case** **CONFIRM**	* Continue as normal OR * Restart and resume case * Call service after multiple occurrences
228 **Medium**	**Battery Error** **Consult service after this case** **CONFIRM**	* Continue as normal OR * Restart and resume case * Call service after multiple occurrences
229, 230, 231, 232 **Medium**	**Board Temperature sensor Fail** **Call Service after this Case** **CONFIRM**	* Continue as normal. Board temperature sensor is not essential for operation. * Call service after multiple occurrences
235 **High**	**System Data Error** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
236, 237 **High**	**Memory Access Failure** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
238 **Medium**	**Secondary Comm channel Error** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
244 **Medium**	**System Data Error** **Defaults loaded** **CONFIRM**	* System Settings and Protocols are loaded with default values * Select NEW CASE and verify all case data during setup

Alarm Code Priority	Message Display	Corrective Action
247 **Medium**	**Arrest pump piston sensor error** **Verify Arrest cartridge installation** **CONFIRM**	* Check Arrest Cartridge to verify it is properly installed and fully secured to the Arrest pump * If the cartridge was secure, try selecting Refill then Done again * If error still persists, restart system and try again * Contact service after multiple occurrences
248 **Medium**	**Additive pump piston sensor error** **Verify Additive cartridge installation** **CONFIRM**	* Check Additive Cartridge to verify it is properly installed and fully secured to the Arrest pump * If the cartridge was secure, try selecting Refill then Done again * If error still persists, restart system and try again * Contact service after multiple occurrences
249 **High**	**System FPGA Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple alarms
270 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
271 **High**	**System Communication Error** **Manual Restart Required**	* Manually restart system * Call service after multiple occurrences
272 **High**	**System Data Error** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
273 **High**	**System Config mismatch Error** **Call Service** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
274 **Medium**	**Startup Diagnostics failed** **RESTART** **CONTINUE**	* Restart and resume case * Call service after multiple occurrences
275 **High**	**System Error** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
276 **High**	**UI Internal Error** **Call Service** **SHUTDOWN** **RESTART**	* Restart System * Call service after multiple occurrences
277 **High**	**Elevated internal UI temperature** **Check for obstructed air flow** **Maintenance required** **CONFIRM**	* Ensure the device has sufficient air flow to cool * Call service after multiple occurrences
278 **High**	**Internal UI temperature Error** **Check for obstructed air flow** **Unable to proceed. Call for Service** **SHUTDOWN**	* Restart and resume case * Call service after multiple occurrences
279 **High**	**UI Voltage Critical** **SHUTDOWN** **RESTART**	* Restart and resume case * Call service after multiple occurrences
280 Medium **281, 282, 283** **High**	**Internal ECG Error** **ECG cannot be displayed** **CONFIRM**	* Continue as normal. Internal ECG is not essential to operation. * Call service after multiple occurrences
284 **Medium**	**Copy to Media Failed** **CONFIRM**	* Retry * Try another Flash memory device

Alarm Code Priority	Message Display	Corrective Action
285 **High**	**User default Protocol Error Resetting to Factory Defaults** **CONFIRM**	* Continue as normal. Check Protocols in Protocol Manager *Re-download Master File * Call service after multiple occurrences
286 **High**	**Protocol error. Deleting all Protocols. Copy or re-create the protocols if needed** **CONFIRM**	* Continue as normal. Check Protocols in Protocol Manager * Re-download Master File * Call service after multiple occurrences
287 **Medium**	**File Access Failure** **CONFIRM**	* Continue as normal. * Call service after multiple occurrences
288 **High**	**System Data Error** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
289 **High**	**Memory Access Failure** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
290 **Medium**	**Protocol File Access Failure** **CONFIRM**	* Continue as normal. Check Protocols in Protocol Manager * Call service after multiple occurrences
291 **Medium**	**Memory Access Failure** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
292 **High**	**System Exception Error** **Manual Restart Required**	* Manually restart system * Call service after multiple occurrences

Alarm Code Priority	Message Display	Corrective Action
293 **Medium**	**EEPROM Rest to Defaults. Please Restart** **SHUTDOWN** **RESTART**	* Restart system * Call service after multiple alarms
295 **Medium**	**System settings Data Error** **Settings Reset to Defaults** **CONFIRM**	* Continue as normal. Check Settings in Menu.
296 **Medium**	**Case Data Error** **Reset to Defaults** **CONFIRM**	* Continue as normal. Case Data is not essential to operation. * Call service after multiple occurrences
297 **Medium**	**Delivered volume Data Error** **Reset to Defaults** **CONFIRM**	* Continue as normal. Check delivered volumes for accuracy * Call service after multiple occurrences
298 **Medium**	**Master file Unavailable** **Please insert media with Master File** **CONFIRM**	* Master file may be corrupted * Re-download Master File * Call service after multiple occurrences
299 **Medium**	**Incompatible Master file detected** **Please insert media with compatible file** **CONFIRM**	* Master file may be corrupted * Re-download Master File * Call service after multiple occurrences
300 **Medium**	**Customized data corrupted** **All customized data needs review** **CONFIRM**	* All Personnel, Additive, Crystalloid, and Component data should be reviewed
301 **Medium**	**CaseLog Version** **Mismatch/Recovery Error** **CONFIRM**	* Retry * Try another Flash memory device

Alarm Code Priority	Message Display	Corrective Action
302, 303 **Medium**	**System maintenance due** **Please schedule System Maintenance** **CONFIRM**	* Continue as normal. Contact service to schedule maintenance
304, 305 **Medium**	**Audio module Error** **Check the screen for all Alarms/Notifications** **CONFIRM**	* Audible tones may not be heard. * Call service after multiple occurrences
306 **Medium**	**Unable to set System Audio level** **CONFIRM**	* May not be able to adjust audio volume level. * Call service after multiple occurrences
307 **Medium**	**Low Arrest volume** **< 10 ml** **REFILL** **CONFIRM**	* Refill Arrest
308 **Medium**	**Low Additive volume** **< 10 ml** **REFILL** **CONFIRM**	* Refill Additive
309 **Medium**	**Crystalloid source volume low** **< 150 ml** **REPLACE** **CONFIRM**	* Stop flow to replace Crystalloid bag and enter new volume
310 **Medium**	**Crystalloid Source Volume low** **< 50 ml** **REPLACE** **CONFIRM**	* Stop flow to replace Crystalloid bag and enter new volume
311 **High**	**Flow set to zero** **Crystalloid Source Empty** **REPLACE** **CONFIRM**	* Stop flow to replace Crystalloid bag and enter new volume

Alarm Code Priority	Message Display	Corrective Action
312 **Medium**	**Flow range is limited in Low Vol mode** **Shift to NORMAL flow for full range** **NORMAL** **LOWVOL**	* Select LOWVOL to remain in Low Volume mode and stay below 200 ml/min * Select NORMAL to exit LOWVOL mode and increase the flow range
313 **High**	**EEPROM Version Change Detected.** **EEPROM Reset to Defaults** **CONFIRM**	* Manually restart system * Call service after multiple occurrences
314 **High**	**Different Console-Controller pair detected** **Press SHUTDOWN and reconnect original** **Press SWAP if intended** **SWAP** **SHUTDOWN**	* Select SWAP to continue OR * Select SHUTDOWN to power off system and re-connect original pair
315 **High**	**Resume case allowed ONLY if** **Same Controller is present** **DIFF CNTLR** **SAME CNTLR**	* Select DIFF CNTLR if Controller is swapped *Resume Case is disabled OR * Select SAME CNTLR if Console is swapped *Resume Case is enabled

11.4 Further Troubleshooting

This section describes how to troubleshoot issues that may not be found in the previous table. These tips and guidelines have been developed from operator feedback and experiences.

11.4.1 Delivery Line Occlusion/Max Overpressure Alarms

- Check for any clamps accidentally left on the delivery tubing or kinks present in the delivery tubing at the console or at the table.
- Check for improper settings on stopcocks and any other external devices.
- Check the upper pressure limit settings. Ensure that they are set to the proper levels.

11.4.2 Arrest & Additive Alarms

- If drug occlusion alarms are raised, check the drug and delivery lines for kinks or blockages and ensure the drug line stopcock is in the correct delivery position prior to selecting Retest on the alarm. If Confirm is selected to clear a drug occlusion alarm then turn the drug pump back on by selecting the drug pump and then selecting the On button. See sections 7.3.5 and 7.3.6.
- If either drug pump is listed as disabled, the pumps may be primed by selecting the component and confirming the prompt on the Controller to enable drug pump functionality.
- If one of the drug pumps is behaving abnormally with no specific alarm occurring, try stopping and restarting cardioplegia flow prior to doing a System Restart or Console Swap Out.

11.4.3 Bubble Trap Errors

- If unexpected Venting occurs, check for Micro bubbles around the fluid level detector in the heat exchanger. If present, stop flow and tap on the face of the heat exchanger to release the bubbles.
- If unexpected Venting occurs, ensure the heat exchanger is fully locked onto console.
- If the Vent valve is remaining open and not closing, ensure that Vent mode is not turned on (Vent icon on Controller will be grey if not in Vent mode).
- If the Vent valve is constantly open and the System is not in Vent mode, navigate to the Prime screen and start the auto-prime process with the primed disposable set. If the Controller does not display a yellow message asking if there is fluid in the bubble trap, then power off the System and contact service personnel to replace the Fluid Level Sensor.

11.4.4 System and Internal Error Alarms (Non-Recoverable Alarms)

- Constant System and/or Internal Errors alarms are usually an indication of more serious problems with the instrument.
- System and Internal Errors are designed to be displayed in instances of possible external electrical disturbance such as ESD, EMI, and/or EMC. In addition, the alarm may be presented due to unintentional ESD discharged from the operator when interacting with the disposable set.
- Occasionally an instrument will display a one-time System/Internal error that can be corrected by following the directions on the screen. Restart system and select Resume Case to retest. Contact Quest Medical Technical Support for assistance if the problem persists.

11.4.5 Delivery Temperature Reads More Than 5° Above Water Temperature

- It is likely that the IR temperature sensor behind the heat exchanger has a dirty lens. Clean the lens with water and a soft cloth.

- If wiping the sensor does not fix the issue, ensure that there is not a heat source pointed at the HEX or making contact with it.

11.4.6 Delivery/Vent Valves Errors

- The antegrade, retrograde, or vent valve may have debris or buildup in the mechanism. Rinse the valve with warm water and actuate the valve manually several times to clear the debris.

11.4.7 Low/No Water Flow in Circulation System

- The circulation system may not be primed properly.
    - If using Hypothermic Reservoir:
        - Ensure the Hypothermic Reservoir has water filled to the drain port.
        - Elevate the Hypothermic Reservoir above the MPS 3 System so that the outlet port of the reservoir is above the heat exchanger.
        - Check the water lines to ensure they are properly connected to the correct inlet and outlet ports
        - Check the water lines to ensure they are not kinked or blocked.
        - Try to prime the circulation system using the H2O Prime function.
    - If using Heater Cooler:
        - Ensure the heater cooler unit is properly filled with water and primed per manufacturer recommendations
        - Check the water lines to ensure they are properly connected to the correct inlet and outlet ports
        - Check the water lines to ensure they are not kinked or blocked.
        - Ensure the heater-cooler is in the correct mode and able to flow properly.
- If Circulation system is having trouble priming due to excessive air, unlock heat exchanger and insert one prong of the hemostat into HEX port to remove air locked in Circulation system.

11.4.8 Cannot Close the Door

- If the door is opened while the delivery set is primed, blood will fill the cassette and make it difficult to close the door. To close the door, clamp the source lines, manually open the vent valve and depress both cassette chambers until most of the fluid is evacuated. Release the vent valve and close the door.

11.4.9 Cannot Install Heat Exchanger

- Refer to section 8.1.1 for full details on installation of the heat exchanger.
- Verify that the locking knob is fully unlocked by rotating it counterclockwise (CCW).
- Verify that the locking knob is in the correct orientation to secure the 10 convolution or 16 convolution heat exchanger. Refer to section 8.1.1.1 for full details.

11.4.10 Inadequate Fill Alarms/Delay in Delivery

- If inadequate fill alarms are repeatedly encountered, the source pressures need to be increased. Increase the blood source pressure or increase the head height and/or utilize a pressure cuff for the crystalloid source.
- When delivering in Recirc mode or Vent mode, always ensure there is a positive pressure seen in the heat exchanger. If the cardiotomy reservoir is below the vent, a siphon effect can occur and empty the pump cassette chambers which might cause a delay in delivery as the chambers will need to be refilled before delivery can resume.
- If AutoStart button is disabled, ensure the setting is enabled under the Flow Setting screen, Antegrade delivery route with System Pressure is selected, and not in Graft mode.

11.4.11 Battery Not Charged/Charging While Not in Use

- In order to charge the battery while the device is not in use, ensure the power cord is plugged in and the main power switch is in the ON position. The orange indicator light on the soft switch should be illuminated.

11.4.12 Air in Delivery Line

- If Air in Line alarms are repeatedly encountered, check the delivery line tubing and ensure it is fully inserted into the air in line sensor.
- If alarm is still occurring with the tubing fully inserted in the sensor, put the System in Hold Volume Mode and flow for multiple minutes or until no more air-in-line warnings occur.

11.4.13 Circulation System Not Heating

- If the circulation system is not heating in warm mode, put the circulation system in cold mode momentarily and then return to warm mode to see if the problem is resolved.
- If the system is still not heating, restart, select New Case, re-select all relevant case parameters, and go through auto-prime to rerun heater diagnostics.

11.4.14 Cannot Drain HEX

- In order to use the Drain HEX functionality, the system must be in cold mode and the circulation pump must be turned off.
- If a heater-cooler unit is being used with the MPS 3 System, the heater-cooler unit flow must be turned off prior to using the Drain HEX functionality.

11.5 Console or Controller Swap Out

It is recommended to change out the MPS 3 Console or MPS 3 Controller only if the MPS 3 System becomes unusable after following the corrective actions and troubleshooting suggestions in Sections 11.3 and 11.4.

Follow the following instructions if a MPS 3 Console needs to be replaced during a case:

1. Stop Flow.
2. Select Shutdown with Alarm Button or Rear Switch.
3. Clamp Source and Delivery Line.
4. Remove Disposable Set from Console.
5. Unplug Power Cord, Console to Controller Communication Cable from Console, Circulation Inlet and Outlet Lines, and any additional Accessories connected to the Console Rear.
6. If on Pole Mount, remove Console Pole Mount locking pin from foot.
7. Replace Console.
8. Connect Power Cord, Console to Controller Communication Cable into Console, Circulation Inlet and Outlet Lines (ensure adequate water in Circulation System), and any required Accessories.
9. Turn on Console with Rear Switch and Standby Switch. After System Diagnostics is completed, select SWAP on Alarm 314.
10. Select SAME CNTLR on Alarm 315.
11. Select RESUME CASE for all previous case parameters to be returned.
12. If using a Hypothermic Reservoir, prime the Circulation System by selecting Temp Settings → H2O Prime. If using a Heater-Cooler Unit, resume flow from Heater-Cooler Unit.

Follow the following instructions if a MPS 3 Controller needs to be replaced during a case:

1. Stop Flow.
2. Select Shutdown with Alarm Button or Standby Switch on front of Console (hold for 3 seconds and wait for switch to turn orange).
3. Remove Controller from Mounting Arm.
4. Disconnect Console to Controller Communication Cable from Controller and Accessory cables.
5. Replace Controller.
6. Connect Console to Controller Communication Cable and required Accessories to new Controller.
7. Turn on Console with Standby Switch (hold for 3 seconds and wait for switch to turn blue).
8. After System Diagnostics is completed, select SWAP on Alarm 314.
9. Select DIFF CNTLR on Alarm 315.
10. Select NEW CASE to setup parameters either manually or via a protocol.

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12 System Maintenance

This section details important procedures and practices to maintain the MPS 3 System to ensure proper function.

Only Quest Medical Service personnel or trained technicians and operators should attempt to perform maintenance on the MPS 3 System. Any and all maintenance procedures must be performed as outlined in these instructions.

DO NOT attempt to disassemble or dismantle the MPS 3 System unless trained to do so. Doing so may void the product warranty.

12.1 Cleaning

To ensure proper system functionality and accurate operation, the MPS 3 System requires periodic cleaning of the external surfaces and internal fluid circulation system. Aside from scheduled preventive maintenance service, the MPS 3 System must be maintained on a recommended time interval. The following items should be cleaned based on the Quest recommended time intervals:

- MPS 3 System Surface Cleaning and Decontamination
- MPS 3 System Delivery and Vent Valve Cleaning
- Water Circulation System Disinfection

Time / Interval	Task(s)	Section
Prior to initial operation	Surface Cleaning and Disinfection	12.1.1
	Water Circulation System Disinfection	12.1.3
Prior to every connection	Surface Cleaning and Disinfect Connections and Fittings	12.1.1
After every operation	Surface Cleaning and Disinfection	12.1.1
Daily	Monitor Hydrogen Peroxide Concentration	12.1.3.5
Every 7 days	Change water in circulation system; add 3% hydrogen peroxide to the circulation system	12.1.3
Every 28 days	Water Circulation System Disinfection	12.1.3
	MPS Water Hose Kit Replacement	12.1.3.4
Quarterly or as needed	Clean Delivery and Vent Valves	12.1.2
Once per year	Annual Preventive Maintenance	12.4

12.1.1 MPS 3 Surface Cleaning and Disinfection

As with all equipment in the operating room, the MPS 3 System external surfaces should be cleaned and disinfected periodically. Always wipe off spills (blood, crystalloid, etc.) immediately. Delays may create conditions for microbial growth or damage the device.

12.1.1.1 Surface Cleaning

To clean the exterior surfaces, follow the steps outlined below.

Avoid OPERATOR INJURY. Ensure that all fingers are free from pinch / crush hazards while cleaning the MPS 3 System.

Wipe external surfaces thoroughly using only CaviCide® Wipes or Spray. Do not allow excess solution to enter housing.

Only use cleaning agents and disinfectants in compliance with these instructions.

Wear protective gloves when cleaning and disinfecting the system. Wear protective goggles during the disinfection process, when disconnecting used tubing or removing disposables from the system.

Be careful not to blemish the Delivery Temperature Sensor as this may cause higher than actual Delivery Temperature displays. Reference Figure 1 for Delivery
Temperature Sensor location.

1. Shutdown the system and unplug the power cord to the MPS 3 Console prior to cleaning.
2. Open the door to the console.
3. Prepare cleaning solution by adding a 1 tsp (5 ml) of Dish Liquid to 1 gallon of lukewarm tap water. Mix thoroughly.
4. Wipe the external surfaces of the MPS 3 System with a lint-free cloth moistened with the prepared soapy water to remove visible soil. Clean all exposed surfaces of the console exterior and the surfaces inside the door.
5. Use a soft-bristled brush dipped in the prepared soapy water to aid in the removal of visible soil. Wring any excess solution from the cloth prior to wiping the console.
6. Wring excess solution from CaviWipes® and gently wipe the external surfaces of the MPS 3 System until all surfaces are clean from stains, liquid, and dust.
7. Spray CaviCide® on to the external surfaces of the MPS 3 System. Ensure to pay attention to areas which are difficult to access.
8. Wipe the external surface with CaviWipes® and ensure that the surface remains visibly wet for 3 minutes.

9. Allow the external surfaces to fully air dry.
10. Visually inspect surfaces for visible soil. If soil is seen, repeat the surface cleaning procedure.

12.1.1.2 Surface Disinfection

After the surfaces have been cleaned, the surfaces should be disinfected to prevent the spread of bacteria and microbes that may be present. To effectively disinfect the exterior surfaces of the MPS 3 System, follow the steps outlined below.

Approved disinfectants:

- CaviCide® Spray
- CaviWipes® Wipes

1. Wring excess solution from CaviWipes® and gently wipe the external surfaces of the MPS 3 System until all surfaces are clean.
2. Spray CaviCide® onto the external surfaces of the MPS 3 System. Ensure the device remains visibly wet for 2 minutes and ensure to pay attention to areas which are difficult to access.
3. Wipe the external surfaces of the MPS 3 System with CaviWipes® and ensure the surfaces remain visibly wet for 5 minutes. Ensure to pay attention to areas which are difficult to access.
4. Allow the surfaces to fully air dry.

12.1.2 Delivery and Vent Valve Cleaning

The MPS 3 Console Delivery and Vent Valves consist of a mechanism to open and close the valves during normal operation. This mechanism is designed to last for years, but it must be free from debris and buildup to function properly. The manual override button on top of each valve can be used to test the actuation of each valve. If the valves do not operate smoothly when actuated, cleaning should be performed.

Avoid OPERATOR INJURY. Ensure that all fingers are free from pinch / crush hazards while cleaning the delivery and vent valves.

1. Visually inspect the valve mechanism for debris. If possible, remove large debris prior to cleaning the valve mechanism.
2. Fill 60cc syringe with warm water.
3. Wrap a towel around the valve to collect the spillage and saturate the inside and outside of the valve with warm water. Ensure to blast the area under the manual override button for each valve. Move the valve up and down 5 to 10 times repeatedly. Also, check and ensure that the button rotates easily.
4. Press firmly and hold the manual override button and clean the inside part of the valve above the plunger tip with a lint-free swab.

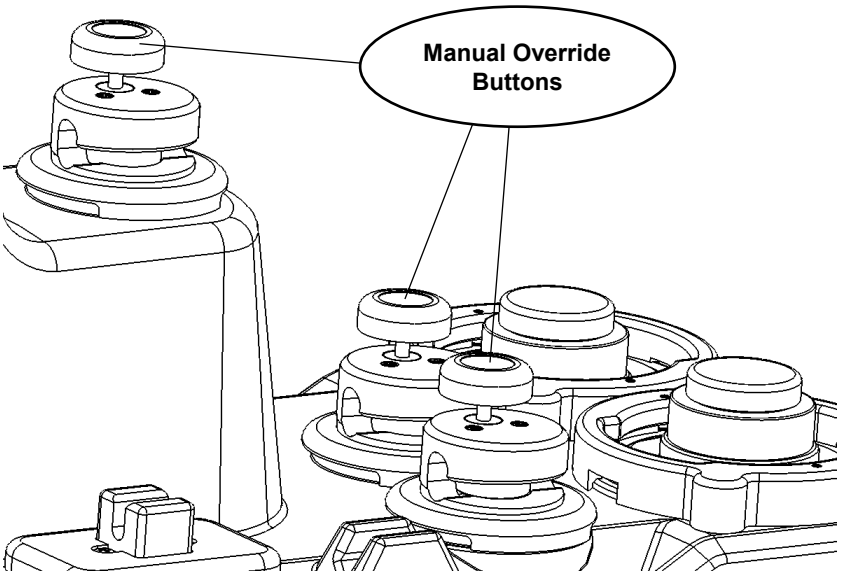

Figure 157: Delivery and Vent Valve Manual Override

12.1.3 Water Circulation System Cleaning

The MPS 3 System water circulation system must be disinfected prior to its first use, while in operation, and while in storage at a frequency of 28 days.

DO NOT use bleach or any chlorine based cleaning solutions in the MPS 3 circulation system. Chlorine may damage the heat exchanger, resulting in water to blood leakage AND possible patient injury.

Other disinfectants with the same active ingredients may contain different additives which can influence the material compatibility. Thus the use of any other disinfectant is explicitly not recommended.

Immediately remove from service any device that show discoloration or cloudiness in the water hoses which may indicate bacterial growth. Consult hospital infection control for further action. Replace hoses that connect to external devices annually at a minimum to minimize biofilm formation.

Do not leave the MPS disposable Heat exchanger primed with water for a prolonged time as this may damage the heat exchanger, resulting in water to blood leakage AND possible patient injury.

Use Minncare HD to clean and disinfect the MPS 3 console water circulation system. Follow all manufacturer's recommendations for preparation, storage, and disposal of disinfection solution. Rinse MPS 3 per this IFU after disinfecting.

The cleaning mode may be accessed by selecting H2O CIRC from the MENU screen.

Prior to cleaning the water circulation system, ensure that the delivery set and accessories have been removed, the hypothermic reservoir has been drained and the water circuit adapter has been installed.

12.1.3.1 Water Circulation System Draining

1. Skip steps 2 and 3 if you are preparing for initial device setup or using a device that has been previously drained (e.g. for storage).
2. Inspect the hoses for discoloration or cloudiness, which may indicate bacterial growth. If the hoses need replacement due to discoloration or bacterial growth, replace them now.
3. Connect the drain/adapter assembly to the drain port on the console's back panel and drain the internal reservoir (Figure 8-1) into a wastewater container.
4. Open the Drain Shutoff valve of the Hypothermic Reservoir and drain.
5. Remove the ice grate from the Hypothermic Reservoir. Remove any debris from the lint screen. Using an approved disinfectant spray and/or wipe, wipe clean the entire Reservoir, ice grate and inside and outside of the Hypothermic Reservoir lid.
6. Ensure proper water flow direction by connecting the Outlet of reservoir to the Inlet of the MPS console. Connect another length of tubing to the Inlet of the reservoir to the Outlet if the MPS console.

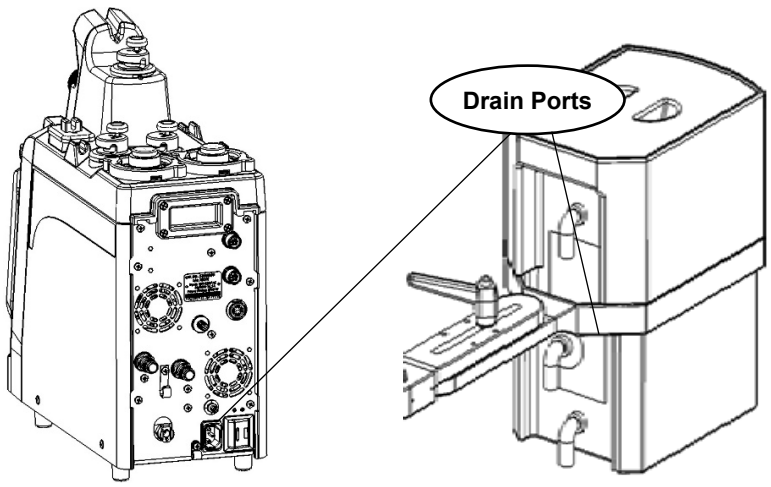

Figure 158: Console and Hypothermic Reservoir Drain Ports

12.1.3.2 Water Circulation System Cleaning

The MPS 3 water circulation system includes the pump, heater, water reservoirs, fittings, warm / cold valve, temperature sensors, and all interconnected tubing.

1. If it is not already, connect the Hypothermic Reservoir to the MPS 3. Connect the hypothermic reservoir outlet tubing to the MPS 3 inlet fitting. Connect the hypothermic reservoir inlet tubing to the MPS 3 outlet fitting.
2. Fill the hypothermic reservoir with 3 liters of sterile water or tap water filtered with a 0.22 micron filter. Place hypothermic reservoir lid on the reservoir.
3. Manually purge the air from the circulation system by depressing the top puck seal until water comes out (Section 5.5.5).
4. Ensure the locking knob is in the 10 convolution position and install the water circuit adapter **REF** 5001110 to the console using the locking knob.

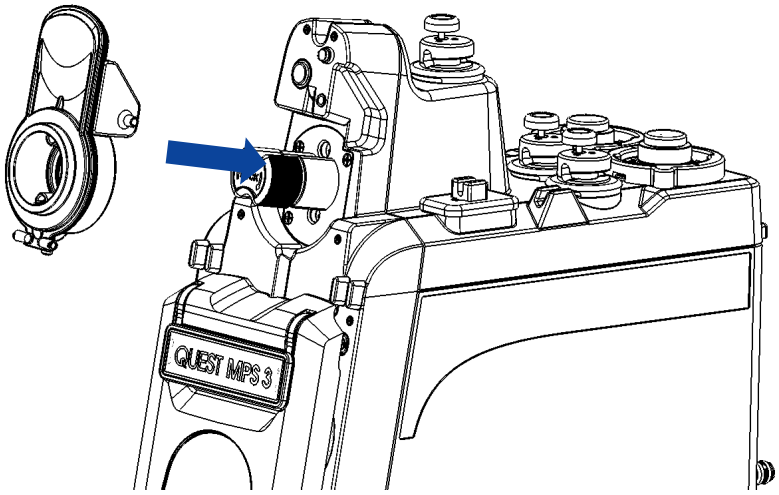

Figure 159: Console and Hypothermic Reservoir Drain Ports

5. Turn on the MPS 3 System.
6. Navigate to MENU → H2O CIRC.
7. Prime the circulation system (Section 9.4.2). Only proceed with cleaning the system after the system is properly primed.
8. Verify there is adequate water flow by visually checking flow in the hypothermic reservoir.
9. Refer to the Minncare instruction for proper Personal Protection Equipment (PPE).
10. Add 90 ml (3 oz.) Minncare HD disinfectant solution to the hypothermic reservoir and replace the lid. Repeat the auto PRIME function to circulate the solution.
11. Select the H2O Clean tab after the solution has been mixed.
12. Select the Start button in the H2O Clean Tab and wait for the cleaning cycle to finish (approx. 15 minutes).

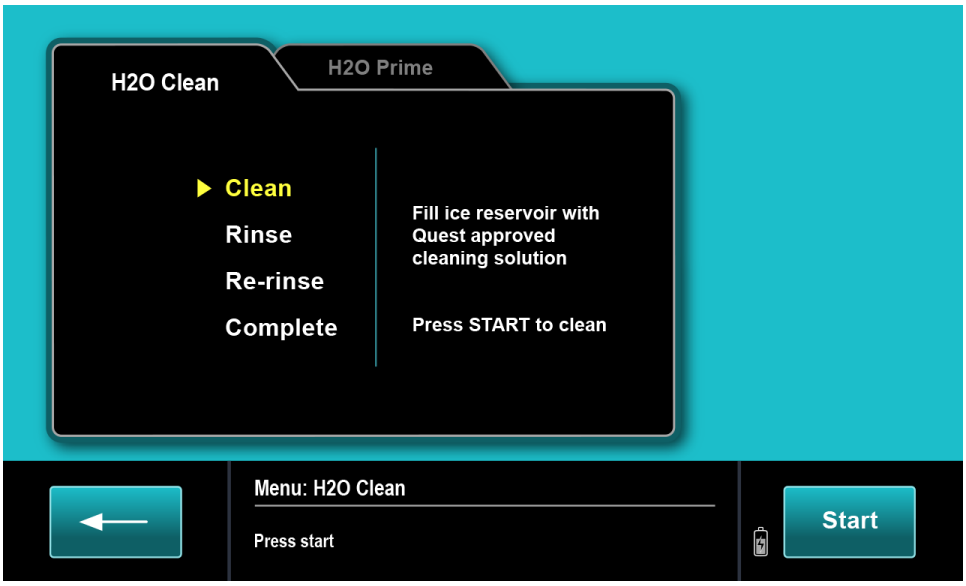

Figure 160: H2O Circ- Clean

When the Start button is selected, the cleaning instructions along with the time remaining shall be shown. The MPS circulates the disinfectant solution through the warm and cold water paths for 15 minutes and indicates when the cleaning process is complete.

The Stop button should be used to stop the clean process and pause the countdown timer. Priming can be resumed by pressing Resume.

12.1.3.3 Rinsing H2O Circulation System

1. After the cleaning cycle has completed in its entirety, drain the system using the procedure outlined in section 12.1.3.1.
2. Fill the hypothermic reservoir with 3 liters of sterile water or tap water filtered with a 0.22 micron filter. Place hypothermic reservoir lid on the reservoir.
3. Manually purge the circulation system of air (Section 5.5.5).
4. Select the Start button in the H2O Clean Tab and wait for the rinse cycle to finish (approx. 5 minutes).
5. Repeat steps 1-4 for the re-rinse cycle.
6. To minimize water spillage the Drain Hx is automatically performed after the final rinse cycle.
7. Drain the system after completion of the re-rinse cycle.

12.1.3.4 Refilling H2O Circulation System after Cleaning

1. Prior to refilling the H2O Circulation System, replace the MPS Water Hose Kit (REF 801221) using the procedure outlined in the sections 5.5.2.
2. Fill the hypothermic reservoir with 3 liters of sterile water or tap water filtered with a 0.22 micron filter. Place hypothermic reservoir lid on the reservoir.
3. Manually purge the circulation system of air (Section 5.5.5).

12.1.3.5 Changing the Water in the System

The water in the circulation system must be changed every 7 days. After changing, add 25 ml of 3% Hydrogen Peroxide to the Hypothermic Reservoir and circulate to inhibit microbial growth. After each use of the MPS 3 System, drain the Hypothermic Reservoir to its drain spout, add an additional 25 ml of 3% hydrogen peroxide, to compensate for dilution of melted ice, and circulate to ensure distribution throughout the water circulation system.

Note: To ensure the hydrogen peroxide concentration is maintained above 100ppm conduct daily monitoring of the concentration follows:

- Drain 100 ml of water from the circulation system drain valve and discard.
- Drain a minimum volume of 5 ml from the drain valve into a sterile sample container for measurement and then discard the drain/adapter assembly.
- Test the concentration of hydrogen peroxide using a peroxide test strip (The MPS 3 disinfection procedure was validated using Indigo Instruments High Level Peroxide Test Strip 33815-P400). Refer to test strip Manufacturer's IFU for instruction on using test strip.
- If the H_2O_2 concentration falls below 100ppm, repeat the Disinfection process.

12.1.4 System Controller Cleaning

The Controller display panel has a special coating that can be ruined by strong cleaners. Do not spray water or other liquids directly on the screen or the case. Protect the Controller from spills and dripping OR solutions. Prevent any kind of adhesive application to the surface of the display panel.

Do not use alcohol wipes or antimicrobial wipes to clean the display panel as it may damage the screen.

If the Controller does not respond to the operator's touch or is visibly soiled, the display panel needs cleaning. Pause the screen to avoid inadvertent parameter changes. Clean the display panel with only a damp soft cloth to prevent scratching. Clean spills immediately after the occurrence of the spill.

Clean the case, Power / Data cable, and mounting arm with antimicrobial wipes.

12.2 Storage Instructions

The MPS 3 console that is not in use should be properly cleaned, drained, and stored in a cool, dry location protected from freezing temperatures, see 3.1 Storage Environment.

12.3 Preventative Maintenance

Quest Medical Inc. uses only authorized Quest Medical trained hospital employed technicians or Quest employed Field Service Engineers for its Preventative Maintenance program.

Preventative Maintenance (PM) is performed annually at a time at the discretion of Quest. MPS 3 Consoles requiring PM that are no longer under warranty are serviced for a cost. Consoles can be returned to Quest for PM or PM serviced in the field. Prior to any PM, a determination of ownership is made to establish if the MPS 3 system is Quest-owned, customer-owned, or under Service contract for billing purposes. A verbal estimate or a not-to-exceed estimate and a schedule of the service is given to the customer. A purchase order will be required from the original purchaser consistent with the verbal estimate. A written estimate of the PM Service is provided upon request.

12.4 System Service

To access the MPS 3 System Service Menu, follow the steps outlined below.

The MPS 3 System Service Menu is only accessible to authorized Quest Medical trained hospital employed technicians and Quest employed Field Service Engineer.

1. In Selection Screen, select Menu → Service. The Service password screen is displayed.
2. The Service Menu is password protected. The technician must enter the correct password to view the Service screen.

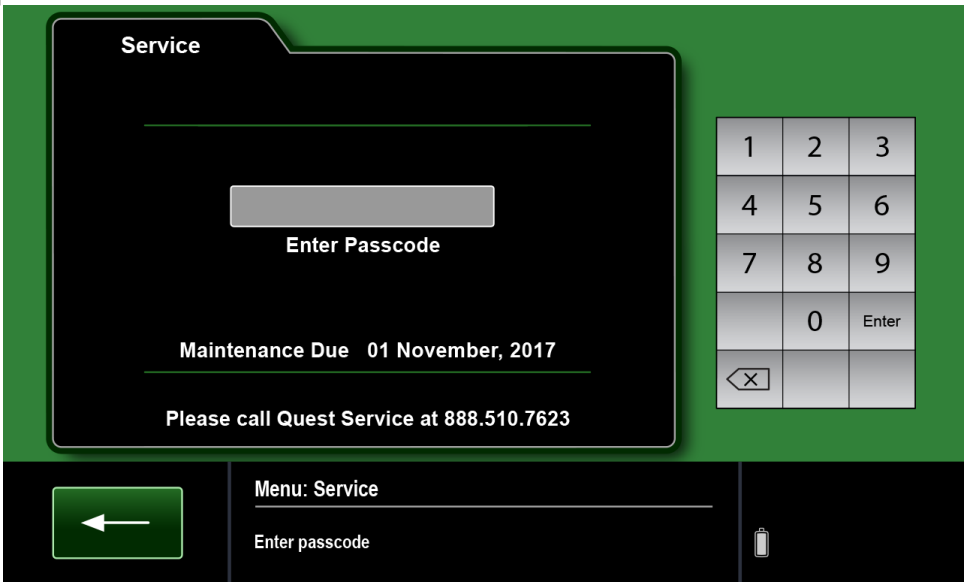

Figure 161: Service - Passcode Screen

3. Select the Data Logs button to view a list of all the log files identified by Case start time, that are available in the system. The operator can select just one or last 10 or last 20 or last 30 or all of the available logs; then select the Copy button to save it to the memory. The Logs contain time-stamped user events, machine events, settings and case data. The Log also contains the identity, time-stamped alarm raise and clear events, and inactivation state of all High and Medium priority alarms. The data is stored in binary format. It requires a utility available to authorized Quest personnel to convert the binary into readable text.

Data Logs are permanently remembered, even after total power loss.

Log capacity is limited to 250 Cases. When capacity is reached, the oldest case log is replaced with the newest.

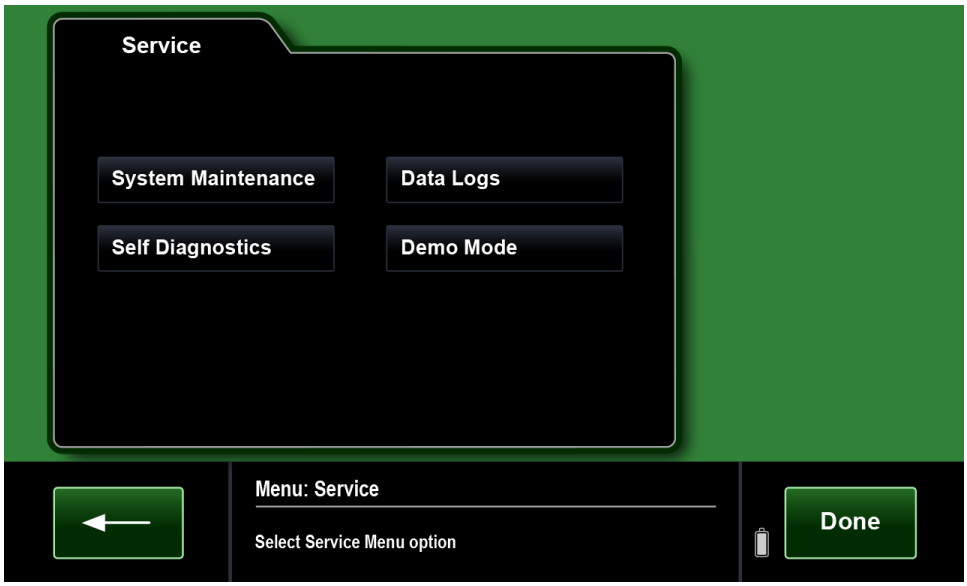

Figure 162: Service Screen

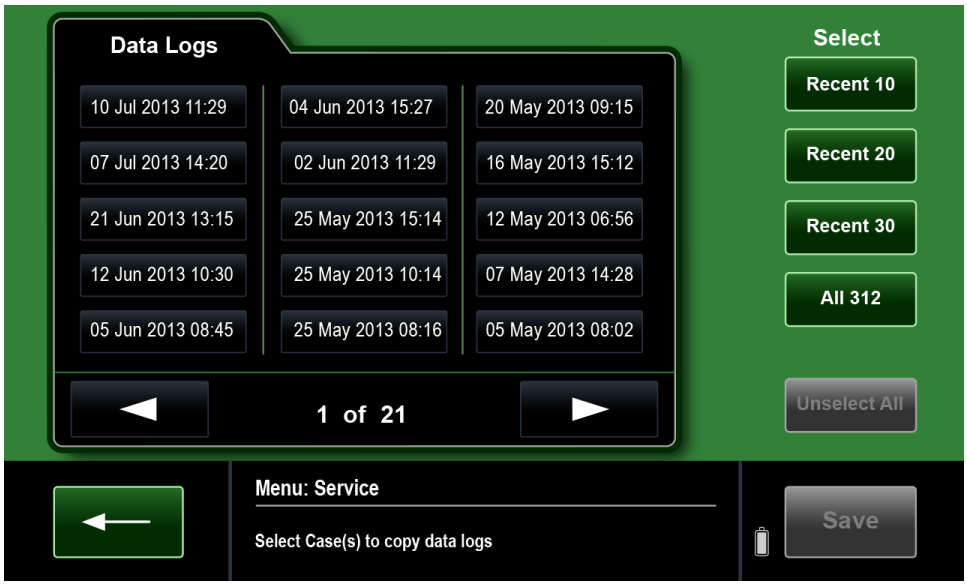

Figure 163: Data Logs Screen

4. Select the Self Diagnostics button to display the Diagnostics screen. After completion of diagnostics the test result can be copied to the memory.

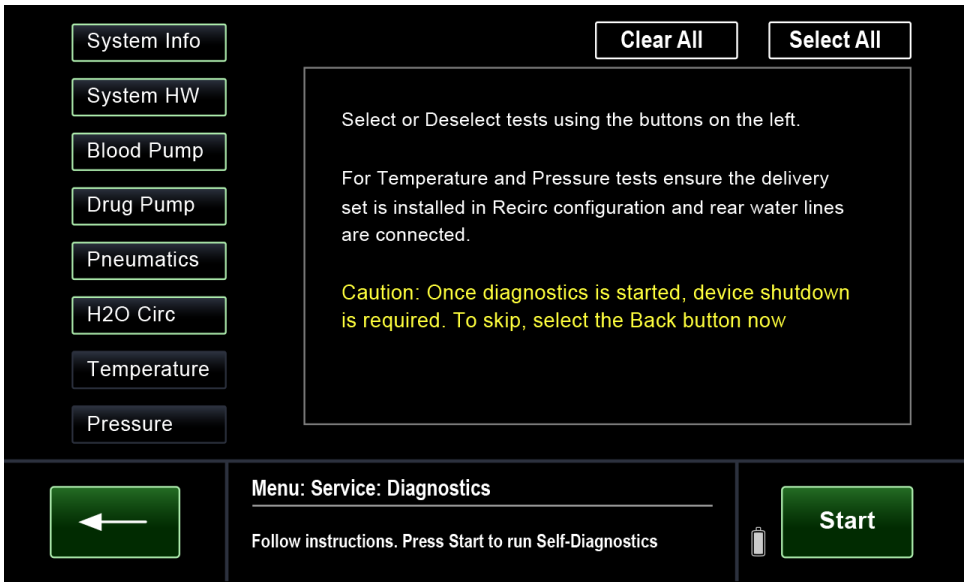

Figure 164: Self Diagnostics Screen

5. Select System Maintenance to view the maintenance screen. The next scheduled Maintenance due date is displayed. Operator is able to change the maintenance due date for the MPS 3 System.

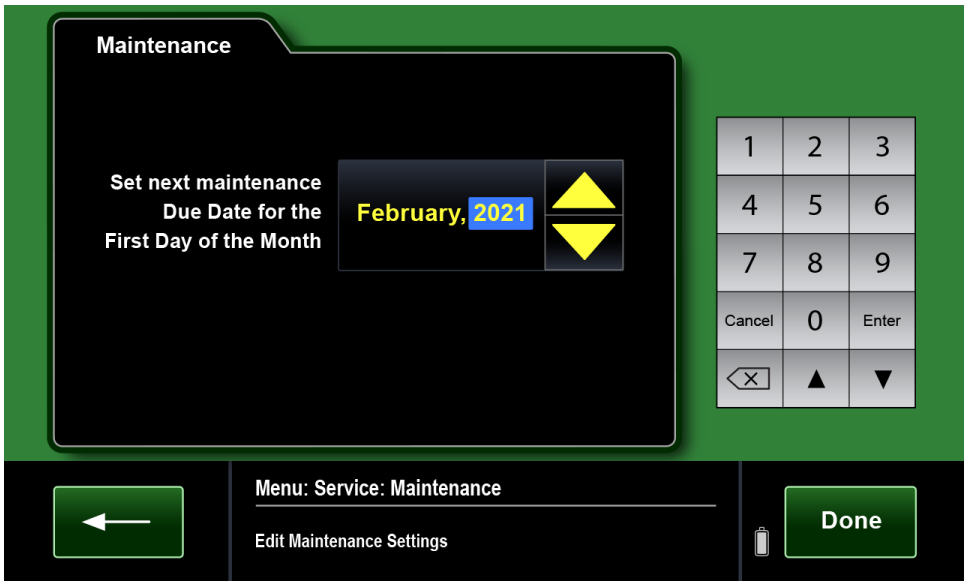

Figure 165: Maintenance Screen

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13 Service

13.1 Warranty Service

Quest Medical, Inc. warrants its MPS 3 system to be free of any defect in material or workmanship for a period of one (1) year from the date of purchase. Any MPS system that, upon receipt and examination by Quest Medical or its authorized agent is found to be defective, will be replaced or repaired at Quest Medical's sole discretion, without charge, as long as this warranty applies. This warranty does not apply to: (i) damage caused by misuse, neglect, accident or improper application; (ii) any damage caused by any repair or attempted repair by one other than an authorized Quest Medical trained technician; or (iii) any product not used in accordance with the Operations Manual furnished by Quest Medical. Any product repaired or replaced under this warranty will, itself, be warranted only for the remainder of the warranty period of the original product being repaired or replaced. This warranty runs to the original purchaser of an MPS 3 console only. If the defect has been caused by those events to which this warranty does not apply, as stated herein above, Quest will repair the defective product, upon receipt of approval of purchaser, at Quest Medical then current charges.

For warranty service, please contact MPS 3 service at (800) 627-0226 ext. 636 to obtain a return material authorization (RMA) number. Return the MPS 3 console freight prepaid, to:

QUEST MEDICAL, INC.
RMA: #
ONE ALLENTOWN PARKWAY
ALLEN, TX 75002-4211 USA
Or a Quest Medical authorized repair facility.

THIS WARRANTY CONTAINS THE SOLE EXPRESSED WARRANTY MADE BY QUEST MEDICAL IN CONNECTION WITH ITS MPS SYSTEM. ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO A PERIOD OF ONE (1) YEAR FROM THE DATE OF PURCHASE.

Some states do not allow limitation on how long an implied warranty lasts, so the above limitation may not apply and depending on location of sale. Please contact Quest Medical for any question reading the warranty of your MPS System.

IF AN MPS SYSTEM IS DETERMINED TO BE DEFECTIVE, YOUR SOLE AND EXCLUSIVE REMEDY, AND QUEST MEDICAL'S SOLE AND EXCLUSIVE LIABILITY, IS REPAIR OR REPLACEMENT AS DESCRIBED IN THIS LIMITED WARRANTY. UNDER NO CIRCUMSTANCES WILL QUEST MEDICAL BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY THE USE OR INABILITY TO USE AN MPS SYSTEM, EVEN IF QUEST MEDICAL HAS BEEN ADVISED OF SUCH LIABILITY OR OTHER CLAIMS.

This written warranty constitutes the final, complete, and exclusive statement of warranty terms and no person is authorized to make any other guarantees, warranties, or representations on behalf of Quest Medical.

The warranty expiration date will be one year from the date of purchase, at which time you will be offered the option to continue with the Quest Medical warranty.

If you have any questions or need additional information concerning this warranty, please call 1 (888) 510 7623 or write to Quest Medical, Inc., One Allentown Parkway, Allen TX 75002-4211, USA.

If an MPS 3 System requires disposal, please contact Quest Medical for return authorization.

13.2 Unscheduled Services

Quest Medical, Inc. uses only authorized Quest Medical trained technician or Quest employed Field Service Engineers. Any repair or attempted repair by one other than an authorized Quest Medical trained technician may incur additional costs.

USE ONLY QUEST MEDICAL AUTHORIZED SERVICE TECHNICIANS. Quest Medical, Inc. cannot assure safe operation of the MPS 3 console if it is serviced by anyone other than an authorized service technician. Unauthorized service voids all warranties.

Quest Medical, Inc. will provide 24 hour technical support to help resolve problems. The technician will be dispatched upon the determination that the problem cannot be resolved over the phone and is field repairable. Should the console or Controller devise not be field repairable, a loaner device, if available, will be sent to allow the return and servicing of the faulty device to the factory.

MPS 3 Systems requiring service that are no longer under warranty are serviced for a cost. Consoles can be returned to Quest for service or serviced in the field. Prior to any service that may be performed a determination of the problem must be provided to Quest Service personnel to determine if the problem is field or factory repairable. Also, a determination of ownership is made to establish if the MPS 3 system is Quest-owned, customer-owned, or under Service contract for billing purposes. A verbal estimate or a not to exceed estimate and a schedule of the service is given to the customer. A purchase order will be required from the original purchaser consistent with the verbal estimate. A written estimate of the service is provided upon request. Loaner devices are available upon request. Rental fees may apply.

For MPS 3 Systems that are out of warranty, a variety of Service Contracts are available. To learn about our Service Contract Options, contact the MPS Service Coordinator line at 1 (888) 510-7623.

Type of service	Description
On Site Service Systems repaired at the customer's facility while not in use with patient.	A qualified Field Service Engineer (FSE) determines the corrective action, performs servicing of console, and provides documentation of the service. If the console can't be repaired on site, it may be returned to the Quest factory at the discretion of the FSE. Travel expenses may apply.
Factory Service Systems repaired or serviced at the Quest Facility.	Consoles returned are promptly inspected and a verbal estimate of the repair cost will be provided. A Qualified Field Service Engineer determines the corrective action, performs servicing of console and provide documentation of the repair. Shipping expenses may apply.

EU (European Union) Customers: Serious incidents resulting from use of a Quest Medical device should be reported to Quest Medical and the Competent Authority in the country where the serious incident occurred. To report serious incidents to Quest Medical, send an email to custserv@questmedical.com or call +1 (800) 627-0226.

14 Part Numbers and Accessories List

14.1 Accessories List SKUs

Part Number REF	Description
5301016	MPS 3 Blood Bypass Tubing
5001001G	MPS 3 Hypothermic Reservoir
5001002	MPS 3 Hypothermic Reservoir Bracket
801221	MPS Water Hose Connection Kit
801260	MPS Water Line Tubing
801259	MPS 3/8” Connector Subassembly
513PWCC10	MPS 3 Console to Controller Communication Cable
5303007	MPS 3 Articulating Controller Mounting Arm
5303008	MPS 3 Telescoping Controller Mounting Arm
5301023	MPS 3 Console Pole Mount Adapter
5301025	MPS 3 Console HLM Adapter
511800A	Cable Antegrade, (Aortic Root Transducer Interface Cable)
511800R	Cable Retrograde, (Coronary Sinus Transducer Interface Cable)
5140004	Transducer Holder
5001110	MPS Water Circuit Adapter
5303010	MPS 3 Medical Air Hose Kit
513UDMS	MPS 3 USB UDMS Cable
513USCC	MPS 3 RS232 EDMS Cable
513UECG	MPS 3 Controller In to ECG Out
5301010	Operations Manual
5301035	MPS 3 and MPS 3 ND Troubleshooting Manual
5303011	Ohmeda Adapter Kit
5303012	Chemetron Adapter Kit
5303013	Purittan Adapter Kit
530NA15	North America
530CE15	Continental Europe
530IT15	Italy

14.2 MPS 3 Delivery Sets

MPS 3 Delivery Sets with 10 Convolution Heat Exchanger

Part Number REF	Blood Source Line ID	Blood Source Line Length	Extension Line Length	Drug Cartridges Included
5003103	1/4” (6.35 mm)	42” (106 cm)	72” (183 cm)	✓
7003101	3/16” (4.76 mm)	72” (183 cm)	N/A	✓

MPS 3 Delivery Sets with 16 Convolution Heat Exchanger

Part Number REF	Blood Source Line ID	Blood Source Line Length	Extension Line Length	Drug Cartridges Included
5163100	1/4” (6.35mm)	72” (183 cm)	120” (305 cm)	
5163102	1/4” (6.35 mm)	72” (183 cm)	120” (305 cm)	✓
5163102-AS	1/4” (6.35 mm)	72” (183 cm)	72” (183 cm)	✓
5163103	1/4” (6.35 mm)	42” (106 cm)	72” (183 cm)	✓

14.3 MPS 3 Disposables Optional Accessories

Part Number REF	Description
5003104	Arrest Agent Cartridge
5003105	Additive Cartridge
5053106	Arrest Agent Delivery Line
5053107	Additive Delivery Line
5001106	3/16” x 10 ft. (120”) Extension Line
5001108	Antegrade/Retrograde Y-Set
5051101	Retrograde Extension Pressure Line with Transducer
5051102	Retrograde Extension Pressure Line with Transducer and Y-Set
5051103	Pressure Line with Transducer
5051107	Dual Lumen Retrograde Extension Line with Y-Set
7001103	3/16” x 6 ft. (72”) Extension Line

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15 Appendix

15.1 Electromagnetic Environment Recommendations

The MPS 3 System complies with all requirements for electromagnetic compatibility according to the IEC 60601-1-2 4th edition, which applies to the basic safety and essential performance of Medical Equipment (ME) equipment and ME systems in the presence of electromagnetic disturbances.

USE ONLY QUEST MEDICAL AUTHORIZED SERVICE TECHNICIANS. Quest Medical, Inc. cannot assure safe operation of the MPS 3 console if it is serviced by anyone other than an authorized service technician. Unauthorized service voids all warranties.

The MPS 3 System should not be used adjacent to or stacked with unapproved electrical equipment. If adjacent or stacked use is necessary, the MPS 3 System should be observed to verify normal operation in the configuration in which it will be used.

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 MPS 3 System, including cables specified by Quest Medical in this Operations Manual, otherwise, degradation of the performance of the MPS 3 System could result.

The MPS 3 System software is designed to inform operators with a System and/or Internal Error Alarm in instances of unexpected and/or abnormal operation such as electrical disturbances. The built in Resume Case feature following a restart allows resumption of device operation within 45 seconds. In addition, IEC compliance testing demonstrated no permanent damage to system and safe use of the product following high levels of disturbances. Refer to Section 11.4.4 for further information on System and Internal Error alarms.

Extra precaution is required when the MPS 3 System is used in close proximity of high frequency surgical instruments which are intentional emitters of electromagnetic energy. Devices known for emitting electromagnetic energy include diathermy, electrocautery devices, and any other devices that are known for causing electromagnetic disturbance such as RIFD devices.

The MPS 3 System is designed to perform within the pressure, flow, and temperature accuracies specified in the operations manual. If you suspect that the essential performance accuracy is affected by EMC interference remove power and relocate the device to another area. If performance continues to be affected consult Quest Medical service representative.

Any electrical device can unintentionally emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified radiation. When the MPS 3 System is used adjacent to or in close proximity to other equipment the operator should be attentive to unexpected device behavior which may be caused by such radiation. The MPS 3 System is intended for use in the electromagnetic environment specified in the tables below.

15.1.1 Electromagnetic Emission

Guidance and Manufacturer's Declaration – Electromagnetic Emissions.		
The MPS 3 is intended for use in the electromagnetic environment specified below. The customer or the operator of the device should assure that the device is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The MPS 3 System 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 B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

15.1.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
These devices are intended for use in the electromagnetic environment specified below. The customer or the operator of the device should assure that the device is used in such an environment.			
Immunity test	**IEC 60601-2, 4th Ed. Test Level**	**Compliance level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical transients / bursts IEC 61000-4-4	±0.5, ±1, ±2 kV - 100kHz repetition frequency	±0.5, ±1, ±2 kV - 100kHz repetition frequency	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode voltage	± 1 kV differential mode ± 2 kV common mode voltage	The quality of the line power supply should be that of a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile radio equipment must not be used within the recommended working clearance from the unit and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. **Recommended separation distance** d= [1.17] √P d= [1.17] √P at 80 MHz to 800 MHz d= [2.33] √P at 800 MHz to 2.7 GHz where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended working clearance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level (b) in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Magnetic field of power frequencies (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m 50 and 60 Hz	The quality of the line power supply should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and variations of the power supply according to IEC 61000-4-11	0% UT; 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0,5 Cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the operator of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery. MPS 3 system is equipped with backup battery.
	0% UT;0°	1Cycle	
	0% UT; 70%	25/30 Cycles (50/60Hz)	
	0% UT; 0%	250/300 Cycles (50/60Hz) (5s)	

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, people, and animals.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 MPS 3 System are used exceeds the applicable RF compliance level above, the MPS 3 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MPS 3 System.
b) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

15.1.3 Recommended Separation Distance

Guidance and Manufacturer's Declaration – Recommended Separation Distance

The MPS 3 System is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 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, people, and animals.

15.2 MPS® 3 Aortic Root and Coronary Sinus Transducer Interface Cable

DESCRIPTION:
Transducer interface cable with red collared (Aortic Root, REF 511800A) and blue collared (Coronary Sinus, REF 511800R) male connector. Cable connects a disposable pressure transducer with the MPS 3 console.

INDICATION FOR USE:
The transducer interface cable is indicated to be used as the electronic interface between the MPS 3 console and a disposable pressure transducer for purpose of monitoring a defined pressure.

CONTRAINDICATION:
This product is designed and warranted for use with the MPS 3 cardioplegia delivery system only. Use with other systems is contraindicated. This product is not designed, sold, or intended for use except as indicated.

WARNINGS:
Read instructions carefully. The attending clinician is solely responsible for the setup and use of this device.
Use cable to interface disposable pressure transducer with the MPS 3 console.
The transducer will not accurately measure pressures above 300 mmHg.

CAUTIONS:
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
Do not immerse electrical connectors. Do not autoclave or kink cables.

INSTRUCTIONS FOR USE:
1. Connect transducer end of MPS 3 interface cable to the disposable transducer cable connector.
2. Plug the MPS 3 Aortic Root and/or Coronary Sinus interface cable connector into the red antegrade or blue retrograde port, respectively, on back of the MPS 3 console.
3. If using a Transducer Holder (REF 5140004), ensure it is securely mounted to a pole (0.5” - 1.5” diameter). Slide pressure transducers until they snap in place.
4. Follow disposable pressure transducer setup procedure to ensure proper priming and zeroing.
5. Adjust the colored tabs to the appropriate configuration to use.
6. To reposition the holder on the pole: unclamp, adjust the position, reclamp, and ensure transducers are properly leveled.

15.3 MPS® 3 Bypass Tubing Instructions for Use

REF 5301016 MPS® 3 Blood Bypass Tubing

Description

The MPS® 3 Blood Bypass Tubing contains the following component:

1. MPS® 3 Blood Bypass Tubing

Indication For Use

The MPS 3 Blood Bypass Tubing is only for use as a back-up with the Quest MPS 3 Console to continue fluid delivery in the event of complete battery depletion or if the MPS 3 Console becomes unusable. The Blood Bypass Tubing, when used in conjunction with the MPS Console and Delivery Set, is intended for use by perfusionists and surgeons trained in the delivery of cardioplegia solutions to the myocardium during open heart surgery. This is a sterile single use product.

Contraindication

This device is designed for use with only the MPS 3 Console. Use with other systems is contraindicated. This device is not designed, sold or intended for use except as indicated.

Warnings and Cautions

1. Read and understand the information in these instructions prior to operating the MPS 3 Console. See MPS 3 Operations Manual for a complete listing of Warnings and Cautions and Storage Conditions. The attending clinician is solely responsible for the setup and use of the MPS 3 Console, Delivery Set, and Blood Bypass Tubing.
2. Observe all additional warnings and cautions contained in this Instruction for Use.
3. Examine sterile package carefully before opening to confirm package integrity and verify that the expiration date has not passed. The device is supplied in a sterile, single use package and is non-pyrogenic.
   DO NOT USE Blood Bypass Tubing with damaged packaging or if the expiration date has passed. DO NOT resterilize or reprocess.
4. Observe aseptic technique with all tubing connections. Do not overtighten rigid connections.
5. The main door must be closed to operate the MPS 3 Console with the Blood Bypass Tubing.
6. Dispose of this device according to hospital procedure for contaminated material.

Installing the Blood Bypass Tubing

1. Using sterile technique, remove the Blood Bypass Tubing from the sterile pouch.
2. Ensure the clamp on the Blood Bypass Tubing is closed prior to installation.
3. Stop flow and ensure both delivery valves are closed.
4. Clamp both Blood and Crystalloid inlet lines leading to main pumping cassette distal to the large bore luer connectors.
5. Vent heat exchanger by manually depressing the vent valve to reduce the system pressure to zero.
6. Disconnect and cap blood source line from disposable cassette using female cap on Blood Bypass Tubing.
7. Attach Blood Bypass Tubing large bore luer connector to blood source line.
8. Connect Blood Bypass Tubing standard male luer connector to the auxiliary luer port of 16 convolution heat exchanger or disconnect additive check valve and connect Blood Bypass Tubing onto left port of 10 convolution heat exchanger.
9. Unclamp Blood Bypass Tubing and blood source line.
10. Manually depress vent valve to prime Blood Bypass Tubing and heat exchanger of air.
11. Once primed, clamp Blood Bypass Tubing and release vent valve
12. As protocols requires, unclamp Blood Bypass Tubing and then initiate flow by manually depressing delivery valve.
13. If Controller is unresponsive, monitor pressure from Arterial Monitor.
14. Monitor heat exchanger and delivery line for air bubbles and vent heat exchanger as needed.

Arrest Agent and Additive Delivery with 16 Convolution Heat Exchanger

1. Ensure delivery valves are closed and Blood Bypass Tubing is clamped.
2. Manually vent heat exchanger to reduce the system pressure to zero.
3. Connect syringes to arrest agent and additive stopcocks.
4. Place arrest agent and additive stopcocks in the refill position and evacuate cartridge content.
5. Turn and break arrest agent and additive stopcocks towards cartridges.
6. As protocol requires, inject arrest agent and/or additive cartridge content into drug delivery lines.
7. Unclamp Blood Bypass Tubing and initiate flow with drug bolus by pressing down on delivery valve.

Arrest Agent and Additive Delivery with 10 Convolution Heat Exchanger

1. Ensure delivery valves are closed and Blood Bypass Tubing is clamped.
2. Manually vent heat exchanger to reduce the system pressure to zero.
3. Connect syringes to arrest agent and additive stopcocks.
4. Place arrest agent and additive stopcocks in the refill position and evacuate cartridge content.
5. Turn and break arrest agent stopcock towards cartridge.
6. Disconnect and connect arrest agent or additive syringe to yellow arrest stopcock as protocol requires.
7. Inject arrest agent or additive cartridge content into drug delivery line as protocol requires.
8. Unclamp Blood Bypass Tubing and initiate flow and drug bolus by pressing down on delivery valve.

Operating Precautions

1. The MPS 3 Delivery Set should not be used if there is any visible damage.
2. User should first clamp both inlet lines before disconnecting from pump cassette.
3. User is responsible for pressure monitoring as indicated by hospital protocol.
4. User is responsible for delivering proper arrest agent and additive concentrations by hospital protocol.
5. User is responsible for purging air from the system as indicated by hospital protocol.

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