Quantum Pump Console

User Manual

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1 Introduction

The Quantum Pump Console has been designed to be used by experienced and trained clinicians as part of a cardiopulmonary bypass procedures.

The device is not intended to be used by the patient or any untrained personnel.

! Danger

The content of this manual must be read and understood before you begin using the Quantum Pump Console.

1.1 Warning Instructions in this Guide

The following warning instructions are used in this user guide.

! Danger

A warning notice at this level indicates an impending dangerous situation.
If this dangerous situation is not avoided it can lead to serious injury or even death.
Follow the instructions in this notice to prevent death or serious injury.

! Warning

A warning notice at this level indicates a potentially dangerous situation.
If this dangerous situation is not avoided it can lead to serious injury.
Follow the instructions in this notice to prevent serious injury.

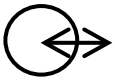
! Caution

A warning notice at this level indicates a potentially dangerous situation.
If this dangerous situation is not avoided it can lead to moderate or minor injury.
Follow the instructions in this notice to prevent serious injury.

A warning notice at this level indicates a potential for material damage.
If this dangerous situation is not avoided it can lead to material damage.
Follow the instructions in this notice to prevent material damage.
A warning notice at this level indicates a potentially dangerous situation.

1.2 Symbols

The following is an explanation of symbols found on the Quantum Pump Console or packaging:

	Stand-by		Follow instructions for use
	Suitable for Direct Current (DC) only		Warning: Do not open
	Alternating current		
	Input / Output Network Connector		Defibrillation proof Type BF Applied part
	Waste Electrical and Electronic Equipment directive 2012/19/EU		The Ventilation Grilles should not be covered, to avoid over-heating
	Manufacturer	SN	Serial Number
YYYY-MM-DD	Date of Manufacture		Warning, Electricity
	No Step	"RX Only"	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
	MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment	REF	Model Reference

1.3 Environmental Conditions

Operating Temperature	10 – 40 °C
Operating Humidity	35 – 75 %
Storage Temperature	0 – 60 °C
Storage Humidity	0 – 90 %
Atmospheric Pressure	80 – 106 kPa
Altitude	2000m Max

1.4 Electromagnetic Compatibility (EMC)

Medical electrical equipment requires precautions regarding electromagnetic compatibility and must be installed and put into service according to the EMC information provided in the following guidance and the manufacturer's declaration.

- Do not connect the Quantum Pump Console to any other equipment other than those approved by Spectrum Medical. Connection to unapproved equipment may result in electromagnetic compatibility issues and improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to the equipment, including cables specified by Spectrum Medical. Otherwise, degradation of the performance of this equipment could occur.
- RFID readers operating on low frequencies (e.g. 133kHz and 13.56kHz) must not be placed within 2.5cm (1 inch) of the Quantum system when it is in use.
- RFID readers operating on higher frequencies (e.g. 868kHz and 2.45GHz) must not be placed within 20cm 98 inches) of the Quantum system when it is in use.
- Do not use the Quantum Pump Console system in close proximity to equipment that generates high levels of electromagnetic or magnetic fields (e.g. MRI scanners), sources of ionizing radiation.
- Centrifugal pumps use magnetic coupling between the Motor drive and Pump head. Magnetic couplings may be affected by other devices that use permanent magnets. (e.g Speakers) Do not bring devices that use permanent magnets close to the Motor drive and Pump head.
- Using the equipment near or stacked on other equipment could result in improper operation.
- Under certain electromagnetic environmental conditions EMC interference may occur on the product for the following reasons:
    - Badly connected cables.
    - Electrostatic discharge.
    - Fast burst transients.
    - The system being located too close to equipment that generates or uses high power electromagnetic fields e.g. RFID Readers, MRI Scanners, diathermy or electro-cautery equipment.
- If EMC interference is encountered, readings on the Quantum Workstation would be very unstable, intermittent, replaced with the warning indicator (!!!) or show a false alarm.
- EMC interference may be solved by the following methods:
    - Ensure each device has been mounted correctly on the frame, this should include:
    - Clean and secure metal to metal mounting on the frame plates.
    - Clean interconnection connectors on the cables and frame connections.
- If EMC issues remain, relocate the individual devices to a different location on the cart, move the interconnection cables to a different port on the cart, move the cart to a different location away from other equipment that may be causing EMC interference.
- The equipment requires no special precautions to be taken to protect the patient or operator during defibrillation or HF Surgery. If the equipment encounters interference from these procedures, normal operation will resume within 15 seconds after interference stops.
- All staff that use this equipment should be giving training in reducing Electrostatic discharge risks.

- The product uses various legacy sensitive electronic medical sensors, these types of devices can be damaged when exposed to high levels of Electrostatic Discharge; the following precautions must be taken to ensure damage does not occur.
    - Ensure the equipment is connected to a suitable electrical ground connection.
    - Before touching any part of the Quantum System, touch the building frame or the metal chassis of the cart to dissipate any electrostatic charge that may have built up.
    - Do not touch the pins of the electrical connections or conductors.
    - All staff that use this equipment should be giving training in reducing Electrostatic discharge risks.

1.4.1 Guidance & Manufacturer's Declaration – Electromagnetic Emission

The Spectrum Medical Quantum Pump Console is intended for use in Professional Health Care Environments according to the electromagnetic environmental specifications detailed below.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Spectrum Medical Quantum Pump Console uses RF energy only for its internal function. The RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Spectrum Medical Quantum Pump Console satisfies emission requirements for any type of product, system or installation intended for use in either industrial, scientific or medical applications in residential (Class B) or industrial (Class A) environments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 1 - Electromagnetic Emission

1.4.2 Guidance & Manufacturer's Declaration – Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
IEC/EN 61000-4-2 Electrostatic Discharge Immunity	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air ± 12.5 kV air (Hb/SO2 Sensor only)	The relative humidity should be at least 20%.
IEC/EN 61000-4-3 Radiated RF Immunity	3 V/m, 80MHz to 2.7GHz 3 V/m, 80MHz to 6GHz	3 V/m, 80MHz to 2.7GHz 3 V/m, 80MHz to 6GHz	Professional healthcare facility environment
IEC/EN 61000-4-3 Radiated RF Immunity – Intentional Transmitters	As per IEC 60601-1-2 table:-Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	As per IEC 60601-1-2 table:-Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	Professional healthcare facility environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
	communications equipment	communications equipment	
IEC/EN 61000-4-4 Electrical Fast Transient/Burst Immunity	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC/EN 61000-4-5 Surge Immunity	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
ICE/EN 61000-4-6 Conducted RF Immunity	3V 0.15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3V 0.15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Professional healthcare facility environment
IEC/EN 61000-4-8 Power Frequency Magnetic Field Immunity	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC/EN 61000-4-11 [1]Voltage Dips, Short Interruptions and Voltage Variations Immunity	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.

Table 2 – Electromagnetic Immunity

1.5 Class B Device Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. There is no guarantee, however, that such interference will not occur in a particular installation. If the equipment does cause harmful interference (which can be determined by turning the equipment off and on), the user is encouraged to try to correct the interference by taking one or more of the following measures:

[1] U_T is the AC mains voltage prior to application of the test level.

- Reorient or relocate the equipment experiencing the interference.
- Increase the distance between this equipment and the equipment experiencing the interference.
- Connect this equipment to an outlet on a circuit different from that to which the equipment experiencing the interference is connected.
- Consult the Spectrum Medical service department for assistance.

NOTE:
"Harmful interference" is defined by the FCC as follows:
Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with FCC rules.

1.6 Essential Performance

The Quantum Pump Console system meets the following Essential Performance requirements:

Following exposure to the defibrillation voltage, the equipment will resume normal operation after a recovery time not exceeding 15 seconds without any OPERATOR interactions.

When the equipment is used together with HF Surgical equipment for electrosurgery, it will return to previous operating mode within 10 seconds after exposure to the field produced by the HF Surgical equipment, without loss of any stored data.

The equipment will resume normal operation in the previous operating mode, without loss of any operator settings or stored data, and shall continue to provide basic safety and essential performance.

1.7 Regulatory Notice

CE 1434

Markings with the CE symbol and Notified Body number indicate the compliance of this system with the provision of the Medical Devices Directive (MDD) 93/42/EEC. The Harmonized European Standard EN60601 has been applied to the device's design and the device has been tested for compliance to applicable parts of the standard.

1.8 Independent Underwriters Laboratories Approval

The following models QWS, QDM1, QDM2, QSOR and QSOL have been independently tested and approved by Underwriters Laboratories and authorised to display the following UL marking.

MEDICAL - PATIENT-MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012, IEC 60601-2-49:2011, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015, CAN/CSA-C22.2 No. 60601-1-8:2008 + A1:2014, CAN/CSA-C22.2 No. 60601-2-49:2011

The following models QCM, QPF1, QPF2, QRP4, QRP6, QRP8, QCD22, QCD37, QCM and QPS have been independently tested and approved by Underwriters Laboratories and is authorised to display the following UL markings.

MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005 + C1:2009 +A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2: No. 60601-1-6:2011 + A1:2015

2 Overview of Quantum Pump Console

The Quantum Perfusion System is a uniquely modular and expandable range of extracorporeal technologies that has been developed by Spectrum Medical to maximize patient safety during cardiopulmonary bypass therapy.

The Quantum Pump Console is a Quantum sub-system that provides speed control pumps on the extracorporeal circulation circuit for cardiopulmonary bypass procedures.

The Quantum Pump Console is an accessory to the Quantum Workstation which controls and displays the measurements provided by the Quantum Pump Console. The User Interface of the Quantum Workstation self-detects the Quantum Pump Console or any accessories when they are connected.

The Quantum Pump Console space frame design offers internal cabling and a flexible pump mounting system which is fully customizable to meet the individual needs of the end user.

The Quantum Pump Console includes, or is compatible with, the following products:

Quantum Pump Frame 2 - Cheltenham	QPF2	Quantum Pump Frame 4 – New York	QPF4
Quantum Workstation 12 inch	QWS12E/QWS12S	Quantum Workstation 15 inch	QWS15S
Quantum Diagnostics Module	QDM1	Quantum Diagnostics Module (No Gas)	QDM2
Quantum Ventilation Module	QVM	Quantum Console Module	QCM
Quantum Smart Occluder – Righthand	QSOR	Quantum Smart Occluder – Lefthand	QSOL
Quantum Roller Pump – 4 in	QRP4	Quantum Roller Pump – 6 in	QRP6
Quantum Roller Pump – 8 in	QRP8	Quantum Power Supply	QPS
Quantum Centrifugal Drive High Pressure	QCD37	Quantum Centrifugal Drive Medium Pressure	QCD22
Quantum PureFlow Centrifugal Blood Pump	CP37	Quantum PureFlow Centrifugal Blood Pump	CP22
CP5 Centrifugal Drive Kit	52-000001-00	560A Centrifugal Drive Kit	52-000002-00

2.1 Notice

The Quantum Pump Console is a system of Quantum products: The Quantum Workstation, the Quantum Diagnostics module and the Quantum Console module. The user must study the User Manual of each individual component before using the Quantum Pump Console as each user manual contains relevant information to configure the specifics of your set-up including the display of data and to set alarm limits.

The User Manual gives instructions for the operation and use of the Pump Console to ensure the safety of the patients and all users.

The Quantum Pump Console is only intended to be used in conjunction with the Quantum Workstation and the Quantum Diagnostics Module. Only connect one of each variants of Quantum Diagnostics Module and one Quantum Workstation to the Quantum Pump Console.

The Quantum Pump Console has been designed to be used by experienced and trained clinicians. The device is not intended to be used by the patient or other untrained personnel.

The Quantum Workstation is also referred to as the "QWS" or "Workstation" in this User Manual. The Quantum Pump Console is also referred to as the "Pump Console" in this User Manual.

The term Quantum Centrifugal Pump is used to identify the combination of a Quantum Centrifugal Drive fitted with a Quantum PureFlow Blood Pump. Quantum Centrifugal Drives may also be referred to as QCD or QCD*nn* (when identifying a model). Quantum PureFlow Blood Pumps may also be referred to as centrifugal blood pumps.

2.2 Indications for Use

The Quantum Pump Console is indicated for use for up to 6 hours in cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

2.3 Contraindications

There are no known contraindications to the Quantum Pump Console.

2.4 Warnings and Safety Notices

! Warning

Federal (U.S.) law restricts this device to sale by or on the order of a physician.
Operate the Quantum Pump Console only in accordance with the procedures described in this Instruction for Use.
Read all manuals before operating the Quantum Pump Console.
- Quantum Workstation (QWS) User Manual.
- Quantum Diagnostics Module User Manual.
- Quantum Ventilation Module User Manual.
- Quantum Smart Occluder User Manual
- Quantum PureFlow Centrifugal Blood Pump User Manual.
- Quantum Centrifugal Pumps Supplementary User Manual.
- Medtronic 560A Centrifugal Pump Supplement
- LivaNova CP5 Centrifugal Pump Supplement

The correct operation of this system is dependent upon the following:
- Proper set-up of the Quantum Pump Console and associated accessories.
- Use of all available system features.

Do not use the Quantum Pump Console in the presence of flammable or explosive gases.
Failure to provide continuous surveillance of the Quantum Pump Console and associated devices constitutes a misuse of the Quantum Pump Console.
The device should not be in direct contact with the patient.

The use of the system is restricted to one patient at a time.
The device is not intended to be sterile.
To prevent electric shock, use only the Spectrum Medical supplied mains cable and ensure it is plugged into a properly ground power supply. Make sure the cable is located where it cannot be tripped over and nothing rests on it.
The Quantum Pump Console can connect to an IT network via the Quantum Workstation; all IT Network connections should be considered secure.
Do not load the IV / Drip Stand or the tray when transporting the equipment.

2.5 Technical Specification

There are no user serviceable parts or fuses in the Quantum Pump Console. Do not attempt to disassemble the Quantum Pump Console.

Physical Properties	
Cheltenham Frame Dimensions	Height 1762mm, Width 842mm, Depth 490mm (H 69.37in, W33.14, D19.29)
Mass	203 kg (447 lbs)
New York Frame	Height 1397mm, Width 762mm, Depth 490mm (H 55in, W30, D19.29)
Mass	202 kg (445 lbs)
Operating conditions	
Temperature	10 – 40 °C (50-104°F)
Humidity	35 – 75 %
Atmospheric pressure	80 – 106 kPa
Altitude	2000m max. (6562ft)
Transport & storage conditions	
Temperature	0 – 60 °C (32 – 140 °F)
Humidity	0 – 90 %
Atmospheric pressure	76 – 106 kPa
Electrical Installation (see note *)	
Input Voltage	100 – 240V AC
Frequency	50 – 60Hz
Input Current	15A max.
Safety ratings	
Earth Leakage (current)	< 5 mA
Patient Leakage (current)	< 100 µA
Electric shock protection	Class 1
Defibrillation proof type BF applied part	
Mode of Operation	Continuous
Degree of ingress protection	IPX0 (Not Protected)
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not Protected

Notes: * Performance of the unit is not affected by supply voltage variations as long as they are within the specifications shown under 'Electrical Installation' above.

2.6 Components

The Quantum Pump Console is a radical breakthrough in the design of the Heart Lung Machine. Use of a stainless-steel space frame construction has allowed for a solution that offers significant savings in weight and footprint when compared to conventional technologies and allows for flexibility in use.

The Quantum Pump Console consists of the Space Frame, Pumps, Pump Controller Module, and Power Supply Pack.

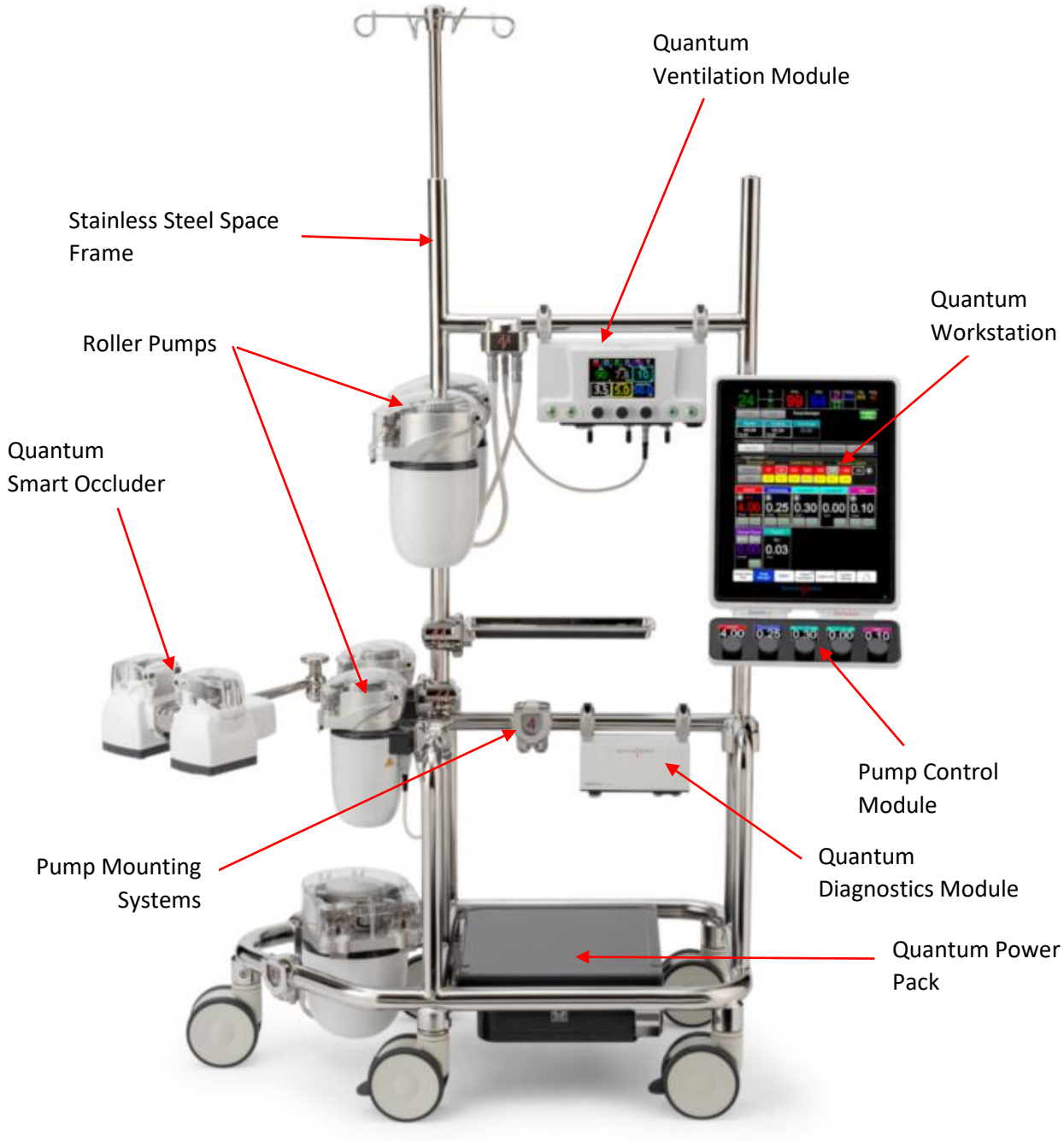


Figure 1: Quantum Pump Console

2.6.1 Stainless Steel Space Frame

The Quantum Pump Console stainless-steel space frame design offers internal cabling and a flexible pump mounting system, which allows positioning of pumps closer to the patient, to reduce tubing length and prime volume. The Pump Console also accommodates and protects the uninterruptible power supply. Power points for pumps are installed per end user specifications and provided by way of 'hub' system and/or integrated within the pump mount.

With a smaller foot-print than a traditional heart lung machine, the Quantum Pump Console supports use in the standard operating theatre, as well as hybrid settings where space can be limited. Once positioned, four of the five castor wheels can be locked to provide stability.

Vertical masts can be used for mounting the Quantum Workstation. Horizontal masts provide additional stability and mounting options for Quantum optional accessories such as drip stands and movable clamps.

2.6.2 Pump Mounting System

The pump mounting solution affords quick and easy pump exchange.

Each Quantum Pump Frame includes one customized moveable hinge, as well as Integrated hinge mounts. The Integrated hinge mounts include electrical power connections to which the pumps are attached.

2.6.3 Pump Control Module

The Pump Control Module is attached to the bottom of the QWS, uses rotational controls to provide instantaneous access to pump RPM control, designed for emergent initiation of CPB and manual pump control functionality. Large digital displays of flow rate provide a quick overview of current pump functions. The displays are colour coded to the individual pumps.

Figure 2 – Pump Control Module

The Pump Control Module can be powered from the Quantum Workstation; however, to provide contingency for any issues with the QWS it is recommended that the Pump Control Module is powered from the frame.

2.6.4 Quantum Power Pack

The Quantum Power Pack has two power supplies: a mains supply that provides power during normal operation and a battery backup supply.

Figure 3 – Quantum Power Pack

2.7 Quantum Pump Console Accessories

The Quantum Pump Console can be fitted with the following accessories:

Description	Part N°.
Medium Tray 15mm	43-000914-00
Drip Stand	43-000916-01
Single Plate Vertical Mount Clamp	43-000653-02
Double Pole Mount Clamp	43-000654-01
Triple Pole Mount Assembly	43-000656-01
Hand Crank – 4 inch	43-000954-00
Hand Crank – 6 inch	43-000955-00
Hand Crank – 8 inch	43-000956-00
Quantum Centrifugal Emergency Hand Crank High Pressure	52-000028-00
Quantum Centrifugal Emergency Hand Crank Medium Pressure	52-000027-00
Tray 300 x 200 x 15mm Assembly	52-000004-00
Tray 600 x 130 x 15mm Assembly	52-000005-00
Blank Mounting Plate (SM Logo)	43-000639-01
Pole Mount Clamp Assembly 1 1/2 Inch with 1 1/4 Inch Tube Attached	43-000623-01
Oxygenator Mounting Arm Assembly	52-000007-00
Hook Plate Pole Mount	52-000024-00
Cable Clip - 1.25 In 6.5mm SAP T1 Single (Qty 10)	52-000019-00
Cable Clip - 1.25 In 6.5 & 9.5mm SAP T1 & T3 Double (Qty 10)	52-000020-00
Cable Clip - 1.25 In 9.5mm SAP T3 Single (Qty 10)	52-000021-00
Gas Bottle Mounting Kit	52-000040-00

Table 3 - Accessories

2.8 Applied Parts

The Quantum Pump Console does not contain any Applied parts, other than those defined in the Quantum Workstation User Manual (SUM-32000001), Quantum Smart Occluder User Manual (SUM-30011002), Quantum Ventilation Module (SUM-30010030 or SUM-30011010) and the Quantum Diagnostics Module User Manual (SUM-30010031).

3 Pumps

This section provides information about Quantum Roller Pumps, Quantum Centrifugal Pumps and third-party centrifugal pumps.

3.1 Quantum Roller Pumps

Quantum Roller Pumps use peristaltic action to push blood through the venous and arterial circuits. Roller pumps can be used for cardiopulmonary bypass surgery procedures of not more than 6 hours.

Quantum Roller pumps are available in three sizes: 4 inch (51-000011), 6 inch (51-000013) and 8 inch (51-000008).

Figure 4 – Quantum Roller Pump

3.1.1 Pump Performance Specifications (All Sizes)

	Range
Speed Range	**0 to 250 RPM**
Deviation in speed accuracy (when the pump speed is not limited to the actions of safety features).	+/- 1% max set point

Table 4 – Roller Pump Speed Range

3.1.2 Tubing Specifications & Capacity

The operation of the pump console requires tubing provided by the user.

Spectrum Medical Pump Console must be used with TYGON S-50-HL Medical grade tubing.
The tubing has the following specification:

- Maximum operating temperature of 74°C / 165°F.
- Dielectric strength of 620v/mil 24.4 kV/mm.
- Durometer value is 65 Shore A Hardness, ±4.
- Clear in colour.

! Caution

Silicone tubing under 60 Shore A must not be used with Quantum Roller Pumps.

Tubing is designed for single use only, it must not be re sterilized or reused.

Roller Pump Size (inches)			ID (inches)	Wall (inches)	ID (mm)	OD (mm)
4			1/8	1/32	3.175	4.7625
4				1/16	3.175	6.35
4			3/16	1/32	4.7625	6.35
4	6			1/16	4.7625	7.9375
4	6	8		3/32	4.7625	9.525
4	6	8		1/8	4.7625	11.1125
4	6	8	1/4	1/32	6.35	7.9375
4	6	8		1/16	6.35	9.525
4	6	8		3/32	6.35	11.1125
4	6	8		1/8	6.35	12.70
4	6	8	5/16	1/16	7.9375	11.1125
4	6	8		3/32	7.9375	12.70
4	6	8		1/8	7.9375	14.2875
4	6	8	3/8	1/16	9.525	12.70
	6	8		3/32	9.525	14.2875
	6	8		1/8	9.525	15.875
	6	8	1/2	1/16	12.70	15.875
	6	8		3/32	12.70	17.4625
		8		1/8	12.70	19.05

Table 5 - Tube Capacity

3.1.3 State & Errors

The LEDs built into the pump indicate the status of the unit, using colour and flashing sequences to indicate operating modes and errors. The LEDs are also used to associate the pump to the pump console and workstation channels, where the colours are coordinated.

State	Indicator Colour		Indicator State
Active Mode	Configured Colour	(example colour)	Solid
Idle Mode	No Colour		None
Unrecoverable Error	Red/Yellow		Alternating
Recoverable Error	Configured Colour	(example colour)	Flashing
Bootloading	Magenta		Solid
Software Update	Magenta		Flashing

Table 6 - LED Indicators

If the system displays a recoverable error, identifying and removing the issue may resolve the error. Unrecoverable errors must be referred to Spectrum Medical.

📖 Refer to section 19.2 System Alarms on page 96 for information on alarms generated by the pump console.

The active mode colour is used to create an association between the pump and information channels and controls pertaining to it on the Quantum Pump Console and Quantum Workstation.

📖 Refer to section 5.2 Configuration Options on page 43 for information on configuring colour associations for pumps.

3.2 Quantum Centrifugal Pumps

The Quantum Pump Console is compatible with Quantum Centrifugal Pumps.

📖 Refer to the Quantum Centrifugal Pumps Supplementary User Guide (SUM-30011014) for information pertaining to the specification and use of Quantum Centrifugal Pumps.

3.3 Third-Party Centrifugal Pumps

The Quantum Pump Console is compatible with third-party centrifugal pump drives from LivaNova (Sorin CP5) and Medtronic (560A) when the correct boards and connection ports are fitted to the Quantum Power Pack.

Refer to the following documentation for details:

📖 SUM-30011003 – 560A Centrifugal Pump Drive Operation Guide.

📖 SUM-30011004 – CP5 Centrifugal Pump Drive Operation Guide.

3.3.1 Configuration of Third-Party Centrifugal Pumps

Available configurations limited to the following (REF)	Hardware similarities / differences)
QPS	QPS with two SAP ports (without any additional driver kits)
QPS + 1 - CP5 centrifuge drive kit. Part No: 52-000001-00	QPS employing one additional CP5 Centrifuge Drive Kit. One SAP port unchanged, the other SAP port replaced by the connector specific for the CP5 pump.
QPS + 2 - CP5 centrifuge drive kits. Part No: 52-000001-00	QPS employing two additional CP5 Centrifuge Drive Kits. Both SAP ports replaced by the connectors specific for the CP5 pump.
QPS + 1 - 560A centrifuge drive kit. Part No: 52-000002-00	QPS employing one additional 560A Centrifuge Drive Kit. One SAP port unchanged, the other SAP port replaced by the connector specific for the 560A pump.
QPS + 2 - 560A centrifuge drive kits. Part No: 52-000002-00	QPS employing two additional 560A Centrifuge Drive Kits.

Available configurations limited to the following (REF)	Hardware similarities / differences)
	Both SAP port replaced by the connector specific for the 560A pump.
QPS + 1 - CP5 centrifuge drive kit. Part No: 52-000001-00 and 1 - 560A centrifuge drive kit. Part No: 52-000002-00	QPS employing both CP5 and 560A additional Centrifuge Drive Kits. Both SAP ports replaced by the connector specific for the CP5 pump and the connector specific for the 560A pump.

Table 7 - Centrifugal Pump Configuration

3.4 Powering Pumps

Roller and Centrifugal pumps can be powered either from the Quantum Frame or from the Quantum Workstation using the supplied SAP cables.

Pump Type	Size	Power Source	SAP Type
Quantum Roller Pumps	4-inch	Frame or Workstation	SAP Type 1
	6-inch	Frame	SAP Type 3
	8-inch	Frame	SAP Type 3
Quantum Centrifugal Pumps	High Pressure	Frame	SAP Type 2
	Medium Pressure	Frame or Workstation	SAP Type 1
Third-Party Centrifugal	n/a	Quantum Power Supply	Third-party supplied

Table 8 - Pump Power Sources & Connectors

4 Getting Started

This section provides details of how your Spectrum Medical Quantum Pump Console is connected, assembled and powered.

4.1 Preparing the Installation

The Quantum Pump Console must only be unpacked, installed and tested by a Spectrum Medical Authorised technician. After the installation has been performed, a Spectrum Medical Authorised technician will train the perfusionist(s) responsible for the operating, maintaining and carrying out the emergency procedures on the system.

As part of the training, all staff will be trained to take the proper precautions in identifying the Electrostatic Discharge risks. This will include how to reduce damaging Electrostatic Discharge events, correct grounding of the equipment, the risks from synthetic materials, the increased Electrostatic discharge risk when humidity is low (less than 50%), reduction of discharge from the users and identifying parts sensitive to electrostatic discharge.

The Quantum Pump Console must only be operated by personnel who are trained and instructed to do so.

The participation in training is mandatory and must be countersigned by the perfusionist.

4.2 Post installation assembly

Only authorised Spectrum Medical representatives can carry out the initial installation of the Quantum Pump Console. The system has been designed to allow the perfusionist to mount the Quantum Pumps into different locations.

4.3 Mounting Pumps or Devices to Fixed Locations

The Quantum Pump console has a number of fixed locations to which pumps or devices can be mounted. See Figure 5 for various orientations for one such fixed location.

Figure 5 – Pump Locations

All pumps and devices are fitted with a standard bracket that allows for fitting onto any fixed pump location on the console.

Figure 6 – Pump Mounting Bracket

To mount a pump or device:

1. Hook the mounting bracket, at an angle, onto the fixed mounting point.
2. Gently move the device into a vertical position.
   When transporting, the pump or device can be secured from the underside, (using the supplied ball nose screwdriver (Part No. BE-8705), turning anti-clockwise until hand tight). However, securing the pump is **not** recommended for clinical use, as this would lengthen the changeover time should the pump need replacing.
3. The pump or device can then be connected to the console using the appropriately sized SAP lead (provided).

Figure 7 – Positioning Pump

4.4 Mounting Pumps or Devices to a Movable Clamp

The Quantum Pump console can be fitted with vertical movable clamps that can hold multiple devices. The movable mount must be hinged shut and locked in place onto the console using the supplied ball nose screwdriver, turning clockwise until firmly hand tight.

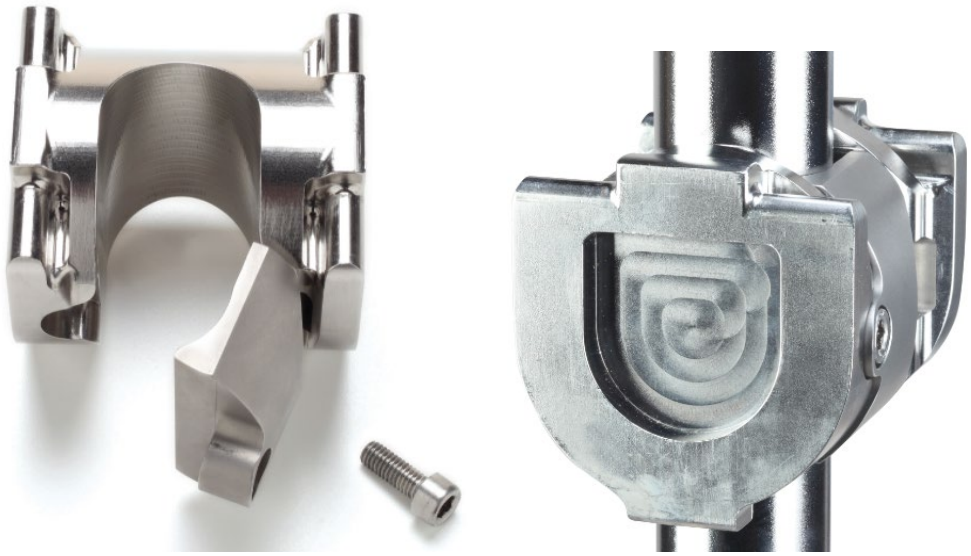


Figure 8 - Movable Clamp

Once locked, follow the same method described to attach a device and SAP lead.

📖 Refer to section 4.3 Mounting Pumps or Devices to Fixed Location on page 31.

! Caution

Use the proper length SAP cable to ensure the SAP cable is not strained in any way.

To raise or lower a movable clamp:

1. Loosen the Allen bolt sufficiently, so that clamp can slide freely, to prevent scratching the console frame.
2. Position the clamp.
3. Secure the using the supplied ball nose screwdriver, turning clockwise until firmly hand tight.

! Warning

Movable clamps should not be mounted more than 1.1m (3.6 ft) above the floor.

4.5 Fitting Tubing into a Roller Pump

Tubing can be fitted once pumps are mounted on the Quantum Pump Console. Quantum Roller Pumps can be fitted with any specified tube size.

📖 Refer to section 3.1.1 Pump Performance Specifications (All Sizes) on page 27.

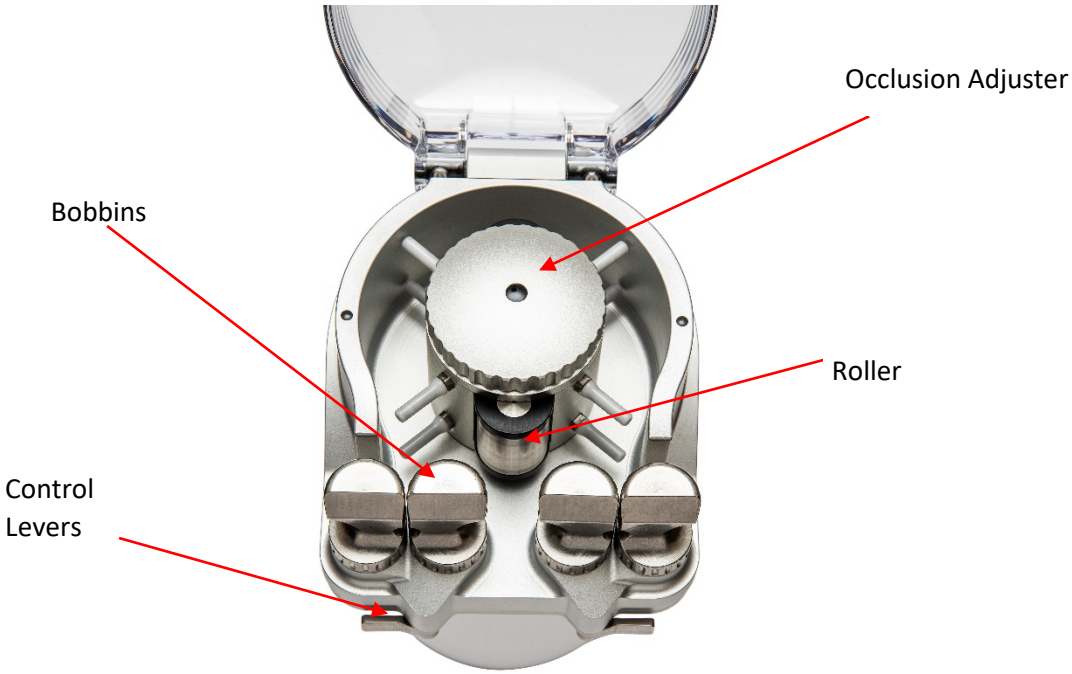


Figure 9 - Pump (without tubing)

To fit tubing:

1. Position the two ratchet control levers perpendicular to the roller pump.
2. Rotate the bobbins so that they are fully open.

Figure 10 - Bobbins Fully Open

Each half of a bobbin pair are interconnected internally, so rotating one half will automatically turn the other half of the pair. When the left-hand outer bobbin is rotated clockwise, the right-hand outer bobbin will rotate anticlockwise.

3. Looking directly down onto the pump with the bobbins at the bottom, ensure that the two black rollers are in the vertical position. Their positions can be adjusted by holding the top tubing guides and turning in either direction.
4. Determine the length of tubing needed for the roller pump.
5. Taking the natural curve of the tubing into consideration, feed the tubing onto the pump under the front right tubing guide and above the back-right hand tubing guide.

Figure 11 - Fitting Tubing (1)

6. Pull through the required amount of tubing.

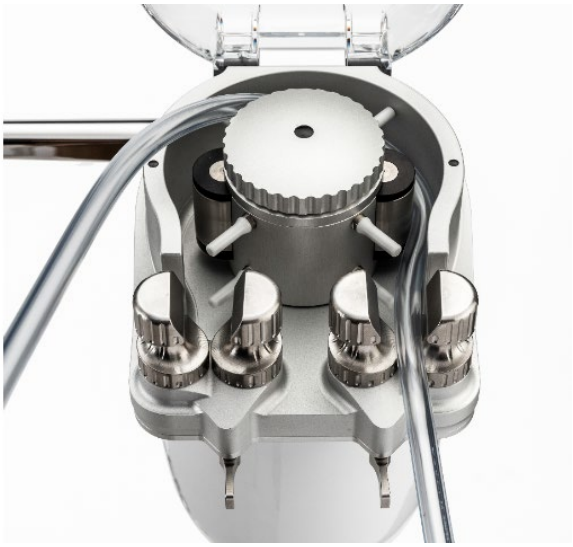


Figure 12 - Fitting Tubing (2)

7. While holding the tubing guides only, being careful not to move the occlusion adjuster knob, rotate the roller in an anticlockwise direction to load the tubing in the raceway of the roller pump.

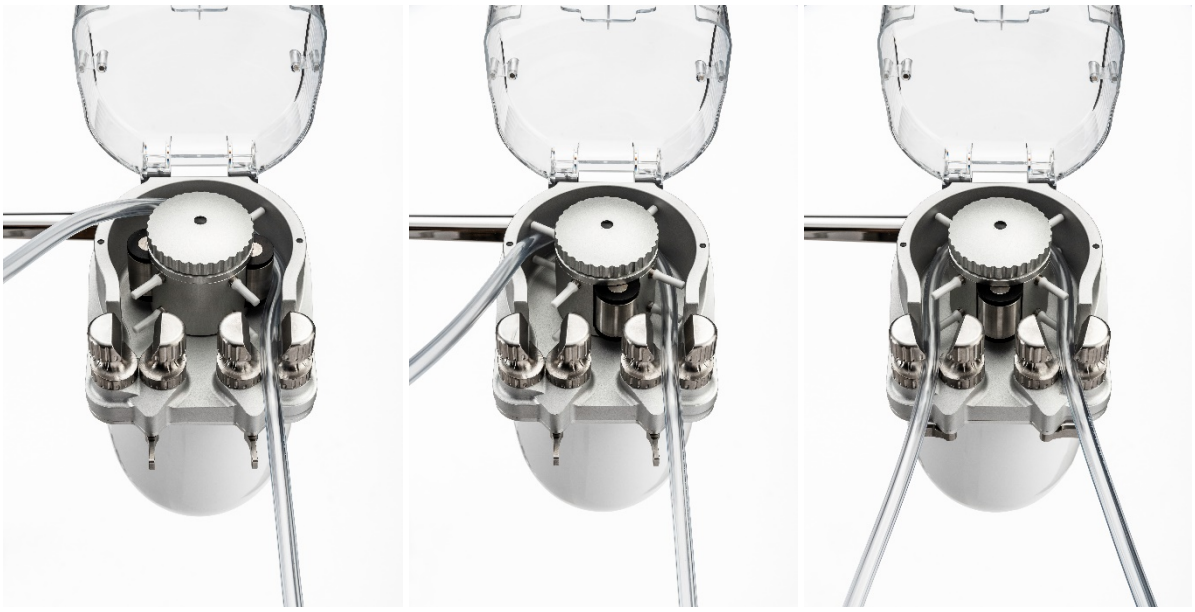


Figure 13 - Fitting Tubing (3)

8. Continue turning the pump roller by utilizing the tubing guides, until the two black rollers are again in the vertical position when looking down onto the pump. If looking from the front, any one of the two rollers should be exactly in the middle of the two bobbins.

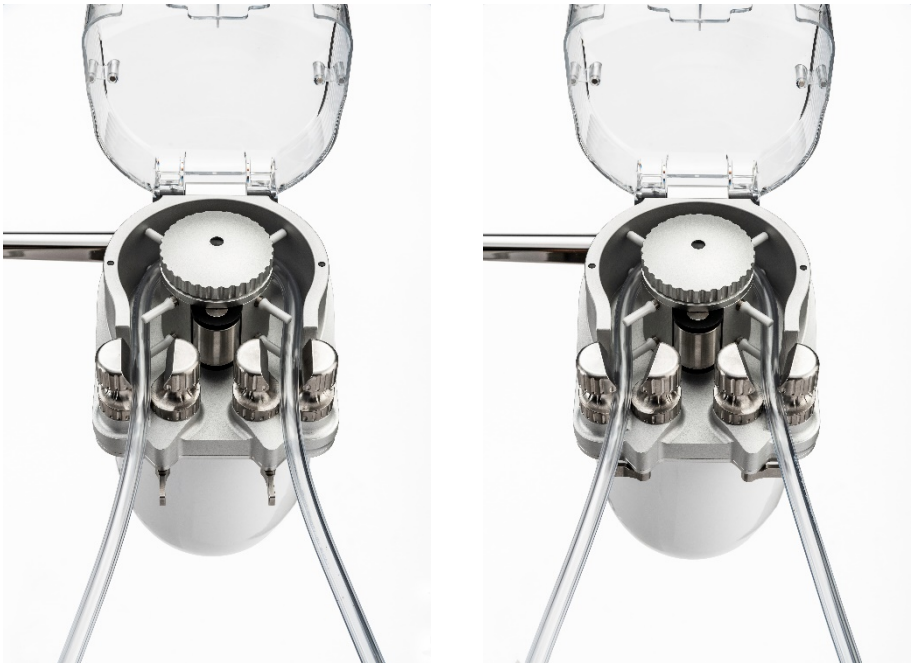


Figure 14 - Fitted Tubing with unlocked (left) & locked ratchets (right)

9. When the tube is fully fitted, the universal bobbins can be locked in place to secure the tubing. Before clamping, a small amount of tension needs to be applied to the tubing to slightly straighten it, which will in turn pull it away from the wall of the pump. The two arrows in Figure 15 shows the gap that has now been created.

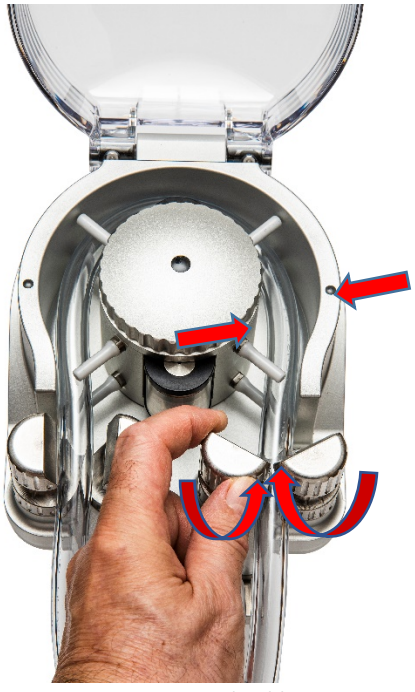


Figure 15 – Rotated Bobbins

10. While maintaining the tension, start turning the bobbins in the direction shown. The clamps grip the tubing and start to push it slightly back into the pump and up against the wall.
11. Continue to turn the bobbins by hand until no more bobbin travel is possible.

Figure 16 – Clamping

12. Repeat this clamping process for the left-hand tubing and bobbins.
    The result is shown in Figure 17, where the tubing is just in contact with the pump wall as indicated by the two sets of arrows and is clamped by the bobbins at either side of the pump.

Figure 17 – Positioned tubing

13. Close the lid.

4.6 Powering the Pump Console

The Quantum Power Pack connects to the mains and supplies a backup battery power supply. The battery backup supply powers the pump console in the event of mains power failure; run time is dependent on load the system is placing on the battery so must be closely monitored.

4.6.1 Connecting to Mains Power

The power cord connects the Quantum Pump Console to the mains power supply.

Figure 18 – Mains Power Supply (1)

Figure 19 - Mains Power Supply (2)

4.6.2 Power Status Indicator

The Power Status indicator LED is located on the power supply switch next to the mains power connector. The LED displays the following different conditions:

Unit State	Mains Power	Battery State	Indicator Colour	Indicator State	
Off	Connected	Fully Charged	Blue	Solid	
Off	Connected	Charging	Blue	Pulsing	
Off	Disconnected	Fully Charged	Off	-	
On	Connected	Charging	Green	Pulsing	
On	Connected	Fully Charged	Green	Solid	
On	Disconnected	Battery Discharging	Blue	Flashing	
On	Connected	Bootloader	Magenta	Solid	

Table 9 - Power Status Indicators

The Power Status indicator LED also indicates error states. These are split in to two main error types, recoverable and unrecoverable.

Error Type	Indicator Colour	Indicator State		Action
Unrecoverable failure with error code	Red	Flashing		Contact Spectrum Medical
Unrecoverable error without error code	Red	Solid		
Recoverable issue with error code	Amber/Yellow	Flashing		Reboot the complete system
Recoverable issue without error code	Amber/Yellow	Solid		

Table 10 - Error States

If a unit displays a recoverable error, reboot the complete system and the unit may recover after a short period of time.

If a unit displays an unrecoverable error the user must contact spectrum Medical for assistance.

! Caution

Do not use extension cords to connect the system to mains power or to connect the modules or accessories to the Quantum Pump Console. Do not position the equipment so that it is difficult to disconnect the power cord from the mains.
Do not stand on any part of the Pump Console or Frame.
Check the power cord and plug for damage before each use. Do not use the system if the power cord is damaged.

4.6.3 Power On / Off

The Quantum Pump Console can be powered On and Off via the Quantum Workstation or the stand-by button on the Quantum Power Supply.

It is recommended that the system is rebooted between cases.

Powering on:

1. Press and release the power button on the lower right side of the Quantum Workstation or the stand-by button on the Quantum Power Pack.

Powering off:

1. Press and release the power button on the lower right side of the Workstation or the stand-by button Quantum Power Pack.
   A Shut-down System dialog is displayed.

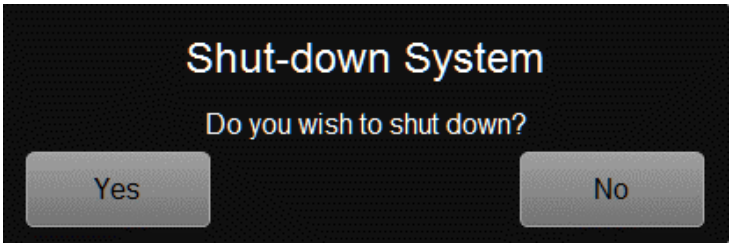


Figure 20 - Confirm Shut-down dialog

2. To power down the system, select Yes.
   Select No to cancel the dialog and return to the previous screen. Pressing in the shadow also cancels the dialog.
   Once shut-down is confirmed pumps will not run.

If the Quantum Pump Console is being powered up while disconnected from the mains supply, it must be powered up using the stand-by button on the Quantum Power Pack.

5 Configuring Pumps

Pumps are configured from the Quantum Workstation.

You must be in Administrator mode to configure and manage a pump.

📖 Refer to the Quantum Workstation User Guide (SUM-32000001) for details on accessing Administrator mode and other admin functions.

When the Quantum Pump Console is connected to the Quantum Workstation, additional functionality includes:

- **Gauge Bar**-displays physiologic/diagnostic parameters, measured/calculated values.
- **Command Bar**-allows selection of other screens/functions.
- **Pump Manager** – Central display for control of pumps, timers, circuit selection, cardioplegia delivery selection and Manual functionality.
    - **Circuit** – Circuit information. The selection of tubing dimensions specific to each pump, zero of flow and pressure sensors.
    - **Manual** – Allows the end user to control each pump independently without interlock, pressure, level or bubble protections and reverse roller pump rotation.
    - **Timers** – Bypass, Cross Clamp, Circ Arrest plus two custom timers.
    - **Extracorporeal Circuit** – Select mode of operation. This includes Circulatory Arrest and Cerebral Perfusion Selections as well as Main Cardioplegia Delivery Function (Crystalloid, Master/Follower, Dual line Blood:Crystalloid sets, or Single pump with Syringe pump).
    - **Cardioplegia Delivery Mode Selection** – Select delivery mode, volume, blood:crystalloid ratios for Cardioplegia.

5.1 Screen Overview

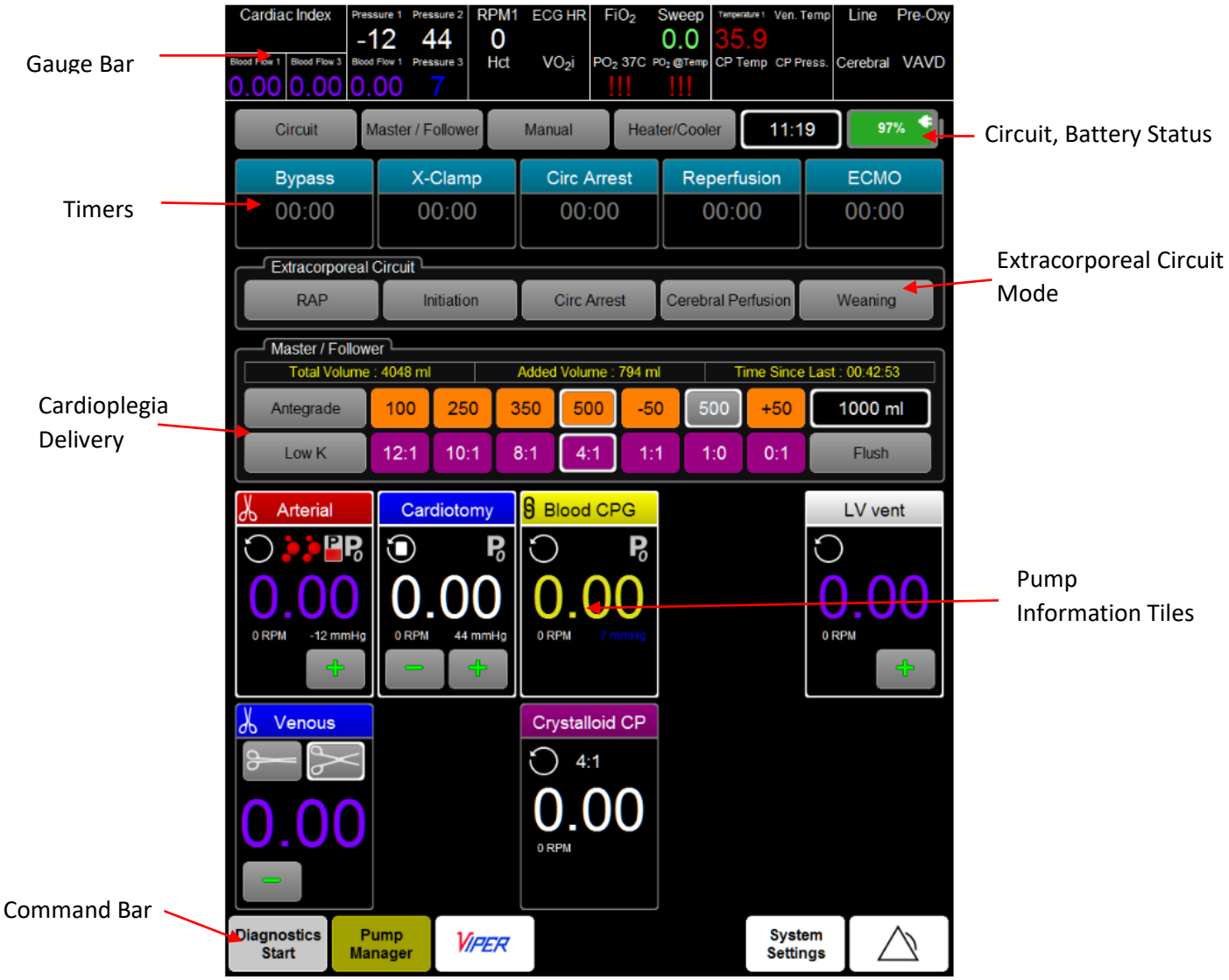


Figure 21 - Main Screen

5.2 Configuration Options

Each pump must be configured before use.

When configuring a pump on the Workstation selecting an option will display a list, numeric or alphanumeric keypad or a colour palette. Click an entry to select and use OK, where available, to confirm a selection or setting.

To configure a pump:

1. Select the Settings icon ( ).
   The Panel Location tile is displayed.
   The Pump Tiles are located sequentially left-to-right, numbered 1-5 on each row.

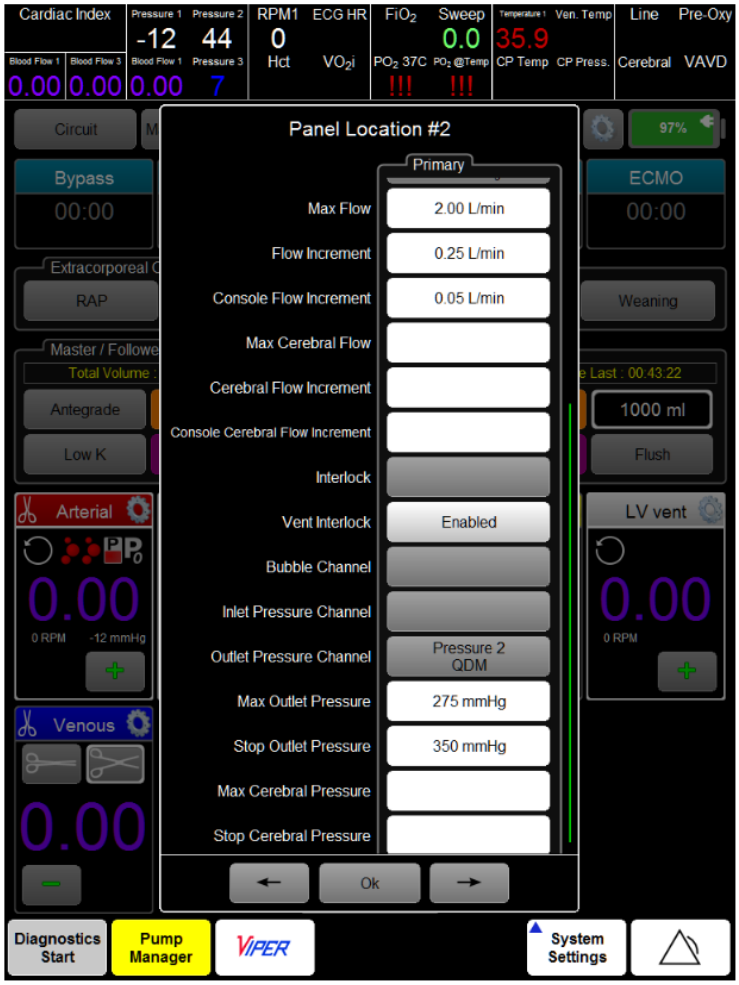


Figure 22 - Pump Configuration

2. Select Type
   The Pump Type Dialog is displayed.

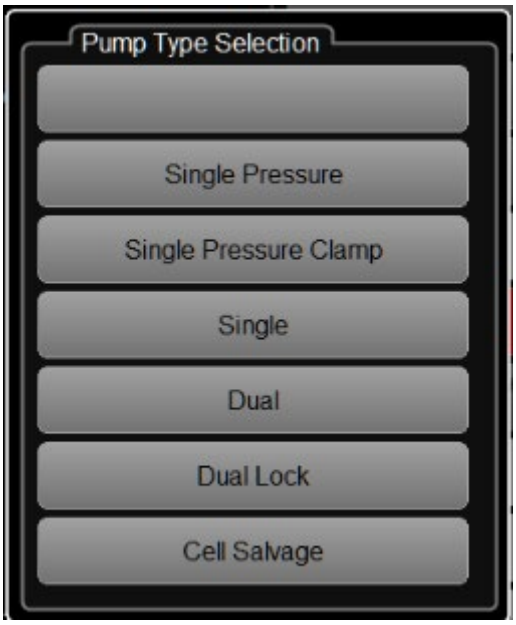


Figure 23 - Set Pump Type

The purpose of the Single Pressure pump is to provide the main systemic arterial blood flow. These pumps support an arterial Smart Occluder, reservoir level sensor and bubble detectors. It provides support for Circulatory Arrest, Initiation, Weaning and optional Cerebral Perfusion System. The Single Pressure Clamp is identical to the Single Pressure type except that it supports a venous and arterial Smart Occluder in the secondary pump panel position.

Pump Manager supports only one Single Pressure or Single Pressure Clamp pump type in a circuit.

The Single Pressure and Single Pressure Clamp pump types do not support an input minimum circuit pressure as these pumps provide the pressure for the rest of the system, although these pump types do support modulation of the pump speed due to monitored inlet pressures.

To set the Pump Type, click the required pump type.

3. Set the identity of the pump.

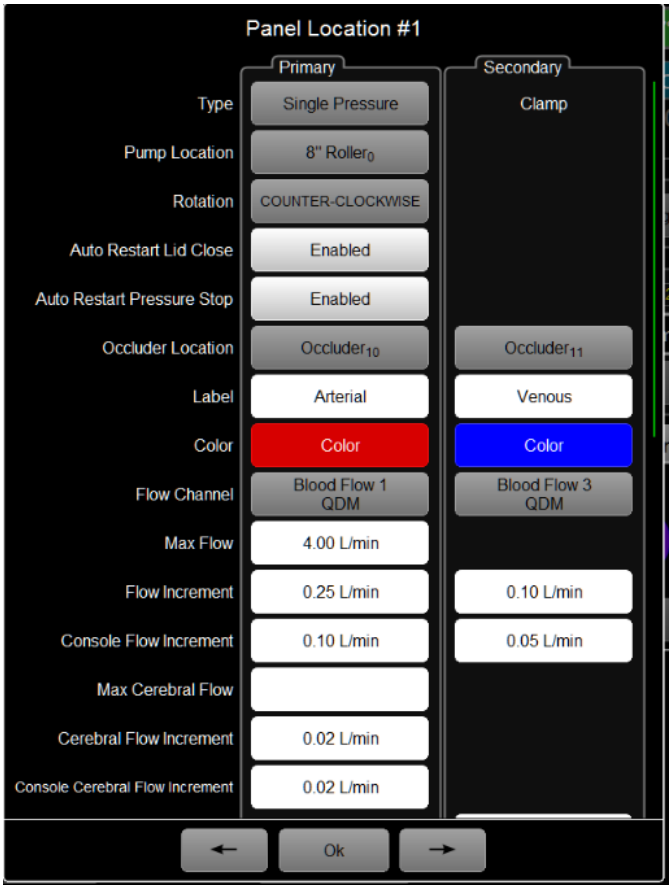
   Label – sets the name of the pump as displayed on the Workstation.

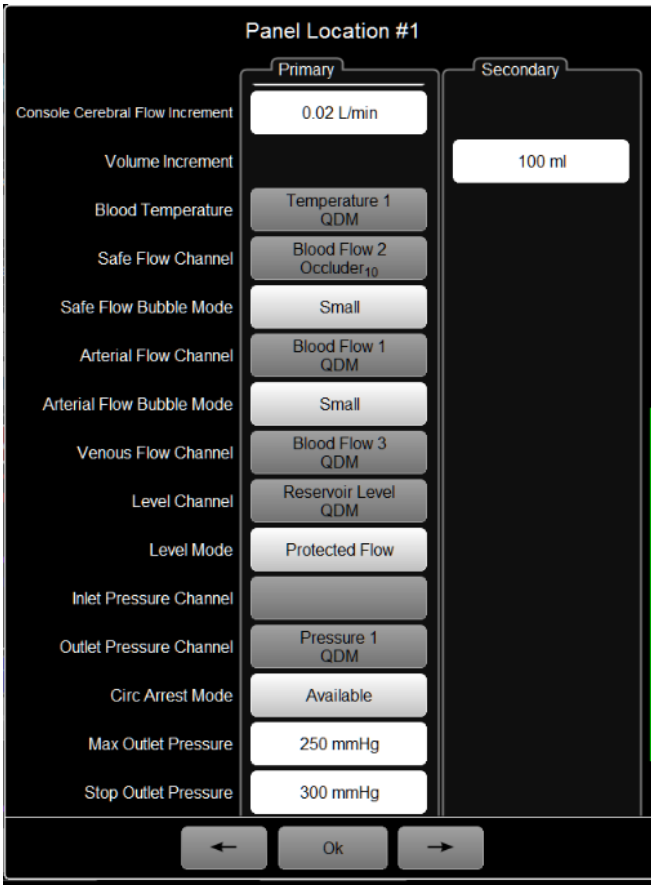
   Colour – sets the colour of the pump tile on the Workstation and the operational LEDs.

   Location – displays a select list of the available pumps including the currently selected pump.

4. Configure the pump's operational settings. Selections are managed in the pump configuration screen.

   Configuration options are dynamic and reflect the pump type. Information on each option can be found in section 5.3 Definitions of Configuration Settings on page 46.





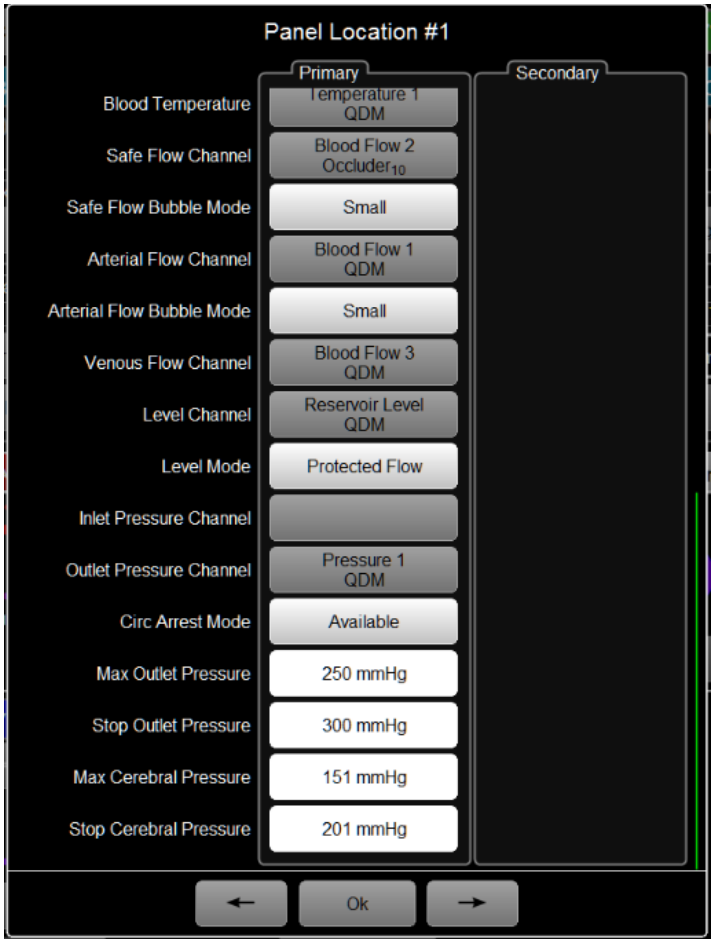


Figure 24 – Selections (top)

5. If required, the tile position can be changed using the ← and → arrows.
6. To save the pump configuration, click Ok.

! Warning

If a configured pump goes off-line an audible alert is generated and the pump tile will display !!!.

5.3 Definitions of Configuration Settings

The configuration settings, maintained in the Config menu, are used as default settings on start-up and are determined by the type of pump.

Type
Lists all available pump types for the installation.

Location
displays a select list of the available pumps including the currently selected pump.

Rotation
The default direction of pumps rotation.

Auto-Restart Lid Closed
When enabled, allows the pump to return to the demanded set point when the lid is closed. Only applicable to roller pumps.

Auto-Restart on Stop Pressure
When enabled, allows the pump to return to the demanded set point after recovering from a pressure stop caused by user interruption. If not enabled, when stopped restarting is from zero rpm. Where max pressure is configured the measured pressure must drop to the max pressure to permit a restart. Where max pressure is not configured, to permit a restart the measured pressure must drop to 50% of the configured stop pressure. In Circ Arrest Mode the measured pressure must drop to the target pressure to permit a restart.

Bubble Delay
For centrifugal pumps, the time, in seconds, for which retrograde arterial flow is allowed following a bubble stop. When the delay is disabled (set to zero) the pump will go directly to zero flow.

Occluder Location
Occluder location displays a select list of the available arterial occluders including the currently selected occluder.

Label
The display name for the pump.

Colour
The display colour for the pump. This colour is displayed (approximately) by the LEDs on the pump.

Flow Channel
The flow measurement displayed by the pump panel. This may be the calculated flow measurement on a rotary pump or an external flow measurement.

Max Flow/RPM
The maximum flow/RPM allowed by the pump during normal operation. When in Circ Arrest mode, this value represents the stop point (as opposed to adopting the unlimited setting).

Flow/RPM Increment
The step value associated with the -/+ buttons on the pump panel. This value is added to the current demanded set-point for the pump.

Console Flow/RPM Increment
The step value associated with the rotary control on the console. This value is added to the current demanded set-point for the pump.

Interlock
Setting a Min Inlet Pressure prevents a roller pump from running faster than appropriate for the current arterial line pressure. There is no offsetting by a centrifugal arterial pump. Interlocks can be enabled/disabled during operation. Cannot be enabled when Vent Interlock is enabled for a non-pressure pump.

Vent Interlock
Safely and automatically maintains the relationship between blood entering and leaving the Venous Reservoir, minimizing the constant intervention that would otherwise be required to maintain this balance during the Weaning process. Only displayed for Non-pressure pump types. Can be enabled/disabled during operation. Disabled by default. Cannot be enabled when Interlock is enabled for a non-pressure pump.

Max Cerebral Flow/RPM
The maximum flow allowed by the pump during cerebral perfusion operation.

Cerebral Flow/RPM Increment
The step value associated with the -/+ buttons on the pump panel during cerebral perfusion operation. This value is added to the current demanded set-point for the pump. Cannot be set to zero (0).

Cerebral Console Increment
The step value associated with the rotary control on the console during cerebral perfusion operation. This value is added to the current demanded set-point for the pump.

Volume Increment
Sets the volume to be translocated by touching the + or – buttons on the venous tile during Initiation or weaning.

Blood Temperature
Defines the temperature to be used by occluders to estimate the tubing stiffness due to blood temperature.

Safe Flow Channel
The safe flow channel is an external flow measurement used for bubble detection and for level protection when in Safe Flow mode.

Safe Flow Bubble Mode
The safe flow bubble mode allows the pump to be stopped if a bubble of the configured size OR larger is detected.

Arterial Flow Channel
The arterial flow channel is an external flow measurement used for bubble detection and for flow control during initiation and weaning operations. Where a centrifugal pump is being used this channel is used to maintain zero flow.

Arterial Flow Bubble Mode
The arterial flow bubble mode allows the pump to be stopped if a bubble of the configured size OR larger is detected.

Venous Flow Channel
The venous flow channel is an external flow measurement used for level protection when in Safe Flow mode and during initiation and weaning operations.

Bubble Channel
The flow channel is an external flow measurement used for bubble detection.

Bubble Mode
The bubble mode allows the pump to be stopped if a bubble of the configured size OR larger is detected.

Level Channel
The level sensor is an external measurement used for sensing the blood level in the venous reservoir.

Level Sensor Mode
The level sensor mode is used during safe or protected Level Protection to determine what the pump should do in low blood situations. In Safe Flow Mode, if the level drops below the upper sensor (Yellow), the pump shall modulate its demand until the level returns to this sensor position. In Safe Flow OR Protected Flow modes, if the level drops below the lower sensor (Red), the pump will stop.

Inlet Pressure Channel
The inlet pressure channel is an external pressure measurement used for circuit / patient protection.

Min Inlet Pressure
The minimum inlet pressure is a pressure threshold preventing a pump from starting or stops a running pump if the detected pressure falls below this value. When used for a positive flow pump, the pump will only run when a positive pressure is detected at the pump inlet. Cannot be configured if Max Inlet Pressure is configured.

Max Inlet Pressure
Use Max Inlet Pressure to modulate venous flow or to modulate the vacuum being generated by sucker and/or vent pumps.

Stop Inlet Pressure
The stop inlet pressure is the pressure value during normal operation below which the pump will stop.

Outlet Pressure Channel
The outlet pressure channel is an external pressure measurement used for circuit / patient protection.

Circ Arrest Mode
The circulatory arrest mode is an enable for circuit arrest availability on the Pump Manager interface.

Circ Arrest Target Pressure
The circulatory arrest target pressure is the target pressure during circulatory arrest operation. The pump will modulate to maintain this pressure until the user intervenes.

Max Outlet Pressure
The maximum outlet pressure is the maximum pressure value during normal operation above which the pump will modulate demand until pressure has been reduced. Disabling while engaged causes pumps to run at the current speed. Disable is unavailable for Initiation and Weaning modes.

Stop Outlet Pressure
The stop outlet pressure is the pressure value during normal operation above which the pump will stop.

Max Cerebral Pressure
The maximum cerebral pressure is the maximum pressure value during cerebral operation above which the pump will modulate demand until pressure has been reduced.

Stop Cerebral Pressure
The stop cerebral pressure is the pressure value during cerebral operation above which the pump will stop.

Max Antegrade Pressure
The maximum antegrade pressure is the maximum pressure value during antegrade cardioplegia operation above which the pump will modulate demand until pressure has been reduced.

Stop Antegrade Pressure
The stop antegrade pressure is the pressure value during antegrade cardioplegia operation above which the pump will stop.

Max Retrograde Pressure
The maximum retrograde pressure is the maximum pressure value during retrograde cardioplegia operation above which the pump will modulate demand until pressure has been reduced.

Stop Retrograde Pressure
The stop retrograde pressure is the pressure value during retrograde cardioplegia operation above which the pump will stop.

5.4 Cardioplegia Pump Types

The Cardioplegia Single (Figure 25) and Cardioplegia Master/Follower (**Error! Reference source not found.**) pump type selection depends upon the expected cardioplegia mode.

Crystalloid, 4:1 Crystalloid and 1:4 Crystalloid modes would typically be practiced using a Cardioplegia Single.

Master/Follower mode requires a Cardioplegia Master/Follower pump type. The Follower pump type is not user selectable.

Cardioplegia pumps support route-specific output pressure configuration.

The Cardioplegia Master/Follower pump type imposes a ratio-metric relationship between the primary (blood) and the secondary (crystalloid) pumps that always requires a ratio selection. This allows control of both pumps using the primary pump control system. Selecting the appropriate ratio allows for multiple various delivered volume scenarios.

Figure 25 – Single

Figure 26 – Master/Follower

When cardioplegia pumps are accessing blood from a pressurized line source, an Inlet Pressure Channel Option can be selected to ensure a minimum blood line pressure is present.

1. Enter Admin Mode.
2. Select the Inlet Pressure Channel box
3. Select the appropriate Pressure Sensor which is attached to that line source.
   Interlock is an option that ties pump flow to the Main Arterial Roller Pump for the purpose of a Flow Offset Function.
   A Single Pump type is a general-purpose pump used for vents, suckers or a dedicated function such as cerebral perfusion**.**
   A Dual Pump type is a general-purpose pump used for vents, suckers or a dedicated function such as cerebral perfusion. The Dual Pump type supports two pumps in the pump panel. The user may switch between the two pumps regardless of flow. See Figure 27.

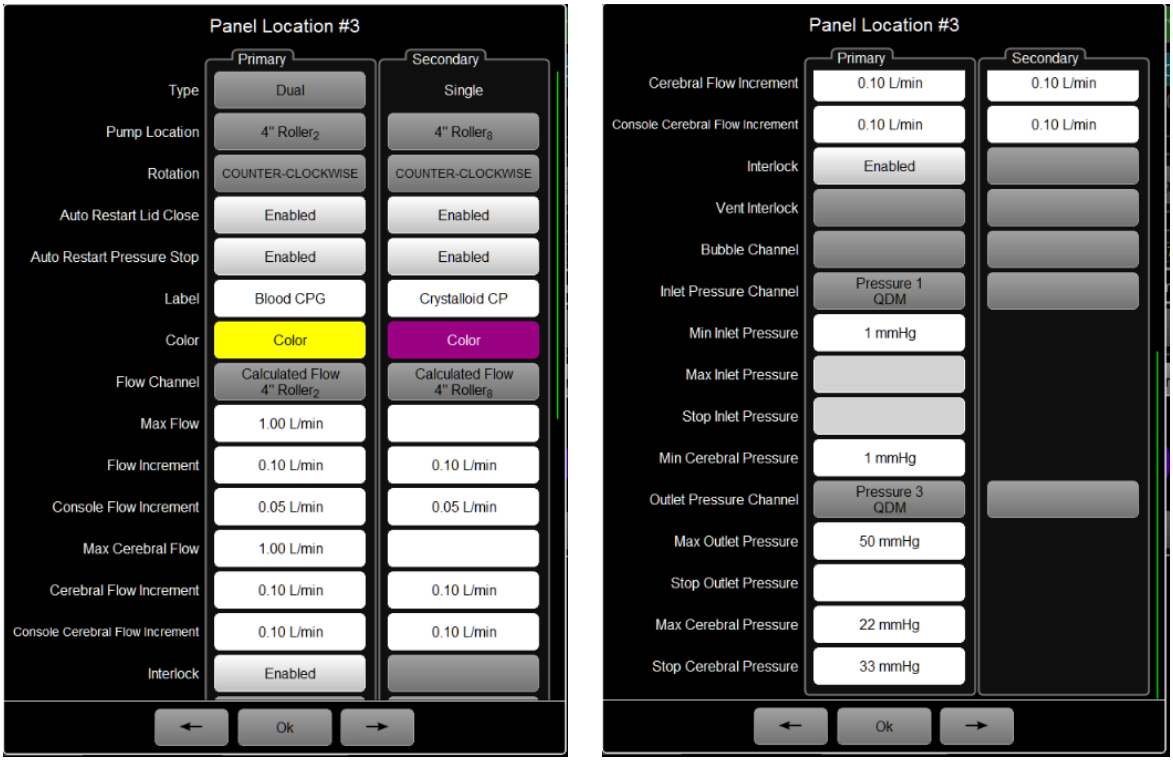


Figure 27 - Switch Pumps

A Dual Lock pump type is a general-purpose pump used for vents, suckers or a dedicated function such as cerebral perfusion. The Dual Lock pump type supports two pumps in the pump panel. You CANNOT switch between the two pumps unless the both flows are ZERO.

4. Exit Admin Mode to return to the Pump Console Main Screen.

5.4.1 Pump Manager Settings

1. Enter Admin Mode.
2. Select the Settings Icon ( ) adjacent to the Battery Status Indicator.
   The Pump Manager Settings dialog is displayed.

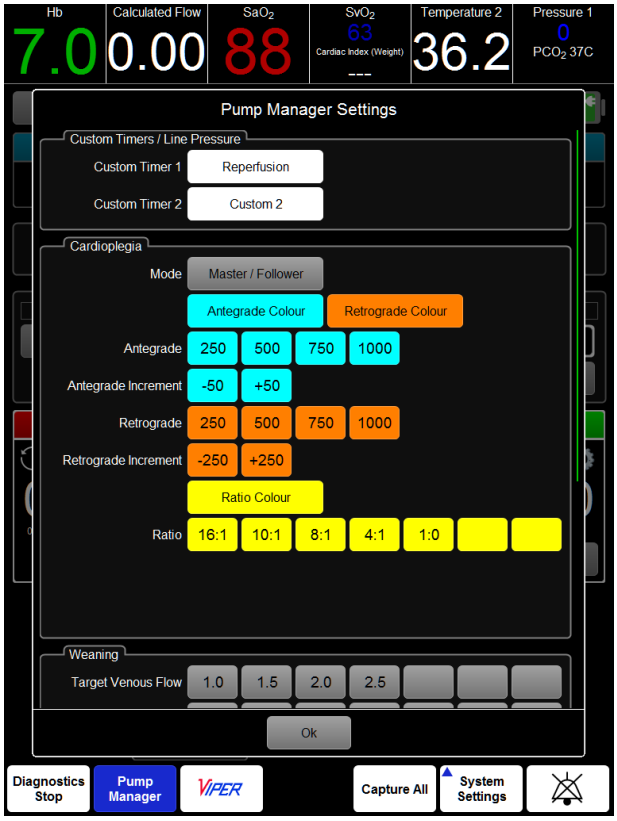


Figure 28 - Pump Manager Settings

3. If required, set Custom timers by selecting the white field and entering text using the pop-up Keyboard
4. Select Ok.
5. Select the Cardioplegia Mode by clicking a Mode option.
   The Cardioplegia Mode Selection dialog is displayed.

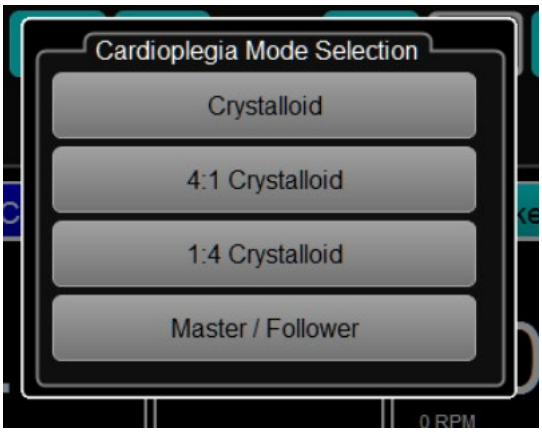


Figure 29 - Mode Selection

6. Select the required mode.
   A second dialog box is displayed, with appropriate choices for that Mode.

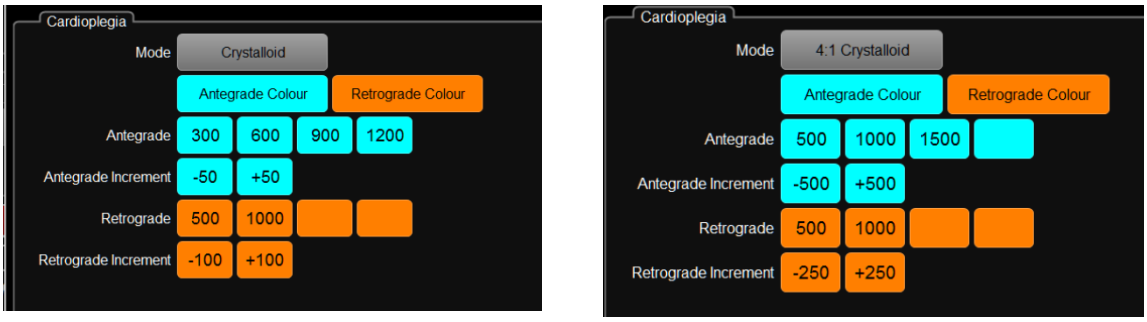


Figure 30 - Cardioplegia Mode Settings

7. To change the display colour, select any Colour button to bring up the Colour Palette. Choose a colour, which is adopted by associated buttons.
8. Select any button in the Antegrade, Antegrade Increment, Retrograde, or Retrograde Increment fields to display the numeric keypad. The title of the dialog box shows the selection.
9. Enter the required value.
10. To save the settings, click Ok.
11. Exit Admin Mode to return to normal Pump Manager Screen.

5.4.2 Extracorporeal Circuit Buttons

Cardioplegia Type**:** toggles between the settings previously made in the Cardioplegia Mode Selection selected in Pump Manager Settings above.

Circ Arrest**:** toggles between Circ Arrest function On or Off. Selecting No cancels the mode; selecting Yes confirms entering into Circulatory Arrest Function.

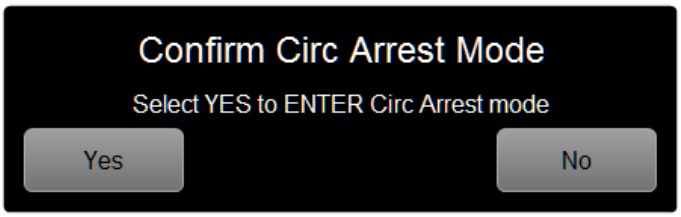


Figure 31 – Confirmation Required

When Circ Arrest Mode is selected the display is as in Figure 32.

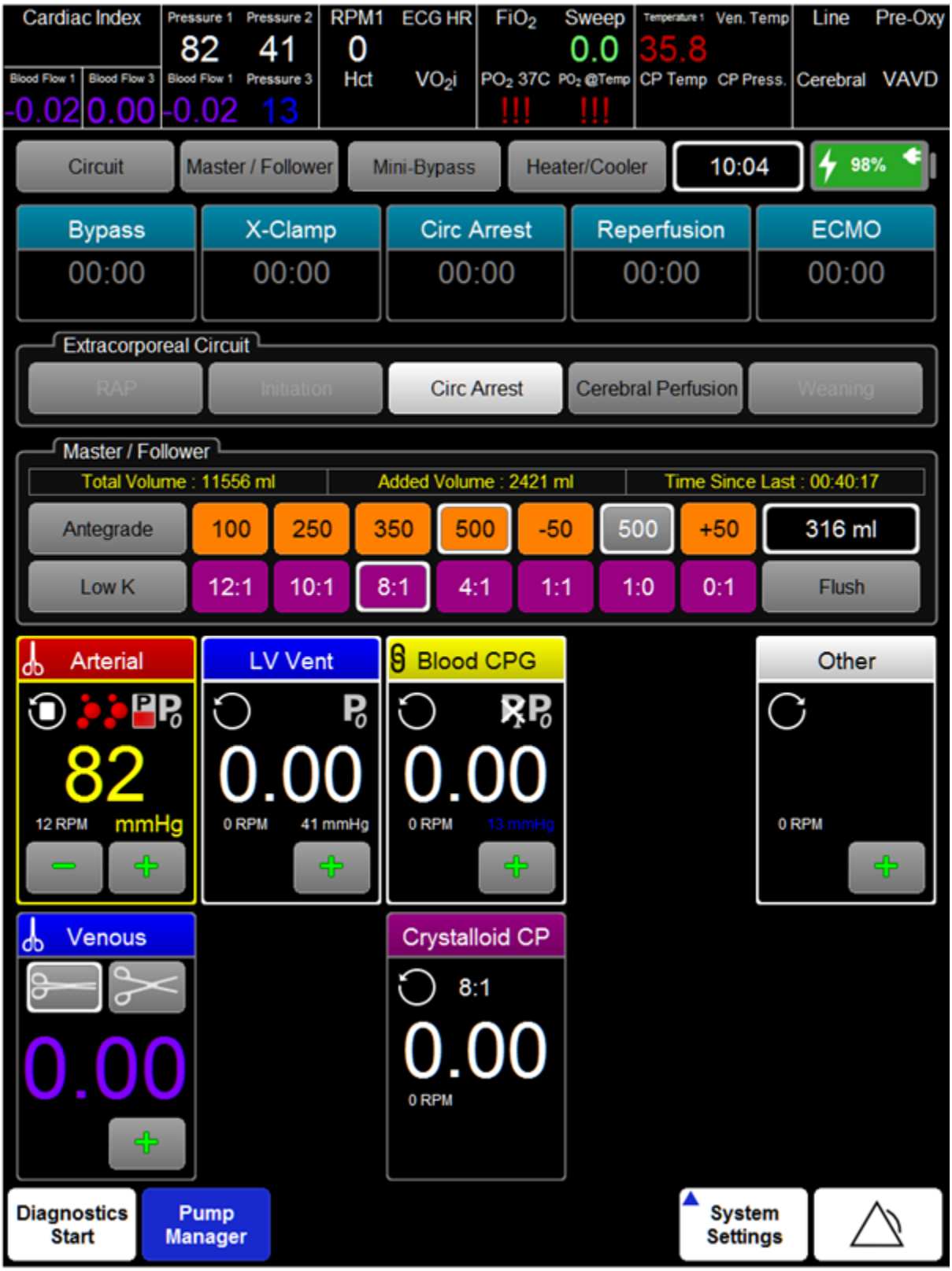


Figure 32 – Main Screen – Circ Arrest Mode

The Circ Arrest Button is highlighted, the Art Flow Pump border is yellow, the Value in the Art Flow Pump is yellow and displays a Pressure Value.

📖 The setup process is described in section 5.2 Configuration Options on page 43, and is available for Single Pressure or Single Pressure Clamp Pump Types only.

To exit Circ Arrest Mode, select the Circ Arrest button. The Main Arterial pump will stop (roller pump) or go to zero flow (centrifugal pump), and normal operation of that pump is resumed.

Cerebral Perfusion**:** toggles between Pump Types set up with Cerebral Perfusion options. Selecting Cerebral Perfusion displays the available options. A selected option installs the cerebral settings onto that pump type.

To exit from Cerebral Perfusion, touch the illuminated Cerebral Perfusion button. The Pump Type settings for non-Cerebral Perfusion operation are resumed for that pump.

When Cerebral pumps are accessing blood from a pressurized line source, an Inlet Pressure Channel Option can be selected to ensure a minimum blood line pressure is present. Selecting the Inlet Pressure Channel box allows the appropriate Pressure Sensor to be selected.

5.5 Circuit Configuration

Tube sizes and flow and pressure sensors need to be set for each circuit.

📖 Refer to the Quantum Diagnostics Module User Manual (SUM-30010031) and proprietary sensor user manuals for information of attaching and configuring sensors.

5.5.1 Setting Tube Sizes

Pumps must be stopped before tube size can be set.

1. From the Pump Manager main screen, select Circuit.
   The Circuit Setting dialog is displayed.

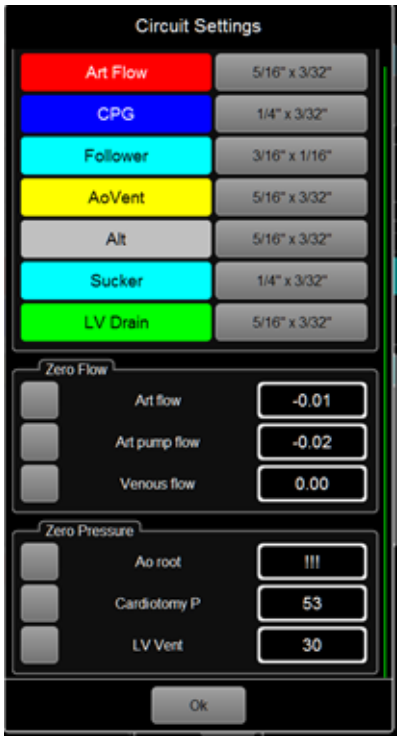


Figure 33 - Circuit Settings

2. To set a tube size, select the field to the right of a pump name.
   The Tube Selection dialog is displayed.

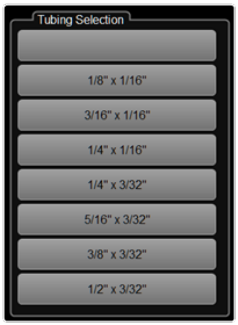


Figure 34 – Tubing Selection

3. Select the required tube size.
4. Click Ok.

5.5.2 Zeroing Sensors

📖 Refer to the Quantum Diagnostics Module User Manual (SUM-30010031) and proprietary sensor user manuals for information of attaching and configuring sensors.

1. Select Circuit Settings.
2. Select the check box beside the flow sensor.
   A checkmark will appear in the box.

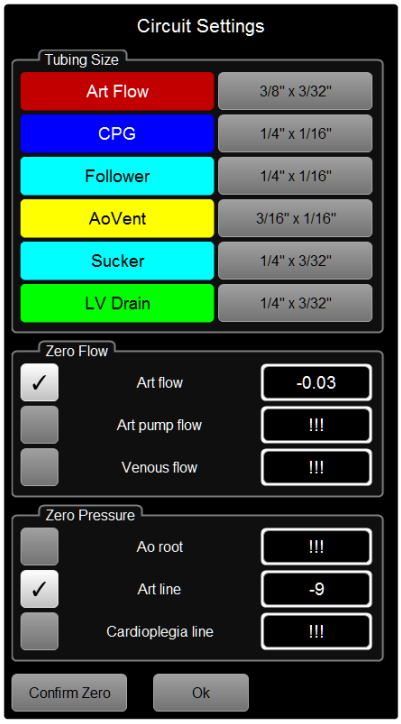


Figure 35 – Circuit Settings

3. Select all flow sensors to be zeroed.
4. Click Confirm Zero.

6 Controlling Pump Speed

Quantum Roller Pumps and centrifugal pumps are controlled from the Quantum Workstation screen or Pump Control Module, if fitted.

When setting the speed for centrifugal pumps it is important to maintain a pump RPM level high enough to prevent backflow, based on the sum of the pressures that are experienced by the centrifugal pump. To allow zero flow and prevent backflow, centrifugal pumps have a pre-set idle speed, determined by the model. Where the idle speed is not sufficient to maintain zero flow the RPM is constantly adjusted, based on flow sensor information, to ensure there is no retrograde arterial flow. However, there is a maximum RPM limit of 2000 during zero flow modulation.

! Warning

Centrifugal pumps drives operate at high temperatures – **DO NOT TOUCH** the pump drive unnecessarily during operation or after use until it has had time to cool.

Figure 36 - QWS with Pump Control Module

To adjust pump speed from the QWS:

1. Open Pump Manager.

Figure 37 - Pump Manager Screen

2. Use the + and − to adjust pump speed in accordance with the increments set in Flow Increment of the Settings screen.
3. To decrease a centrifugal pump to idle RPMs/zero flow modulation, use − to decrease the RPM value, or click the white square at the top left of the pump panel to enter Zero Flow Modulation.
4. Top stop the pump, click the white square at the top left of the pump panel again, for a total of two clicks.

To adjust pump speed from the Pump Control Module:

1. Use the appropriate control knob to increase (clockwise) or decrease (counter-clockwise) in accordance with the increments set in Console Increment of the Settings screen.

6.1 Manually Reversing Pump Direction

The direction of pumps can be reserved from the pump tile, when the pump is stopped.

1. On the pump tile, select  .
   A confirmation message is displayed.

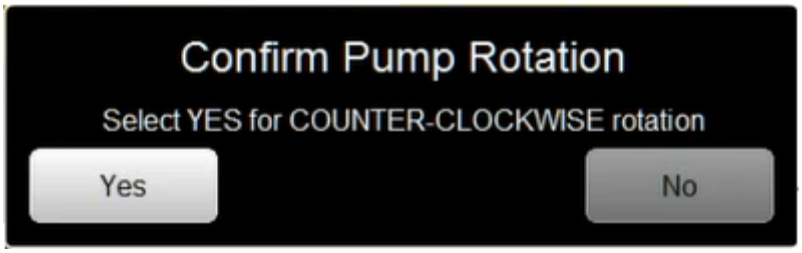


Figure 38 - Confirm Pump Rotation

2. Select Yes to confirm the direction change.

   The directional arrow will reorient to show the direction of flow ().
   The tile border will flash if the current direction is different to the default direction in the Settings dialog.

7 Mini-Bypass Mode

Mini-Bypass Mode allows cardiopulmonary bypass procedures to be performed in a closed-volume system. In a closed-volume system the patients' body forms the reservoir and the venous return indicates the cardiac output.

Mini-Bypass Mode uses bubble detectors to start pumps and does not utilize level detectors.

To use Mini-Bypass mode the following setup requirements **must** be met:

- Centrifugal main arterial pump.
- Bubble-trap venting roller pump dedicated to mini-bypass venting only.
- Bubble detectors on venous line, venting roller pump line and arterial line. Additionally, it is recommended between the centrifugal pump and bubble trap.
- Quantum Smart occluders – if only one, on the arterial line. A bubble detector, if activated, will automatically close the arterial line. Any venous occluder must be manually closed.

To initiate Mini-bypass mode:

1. From the Pump Manager App, select Mini-Bypass.
   A confirmation dialog box is displayed.
2. Select Yes to continue or No to cancel.

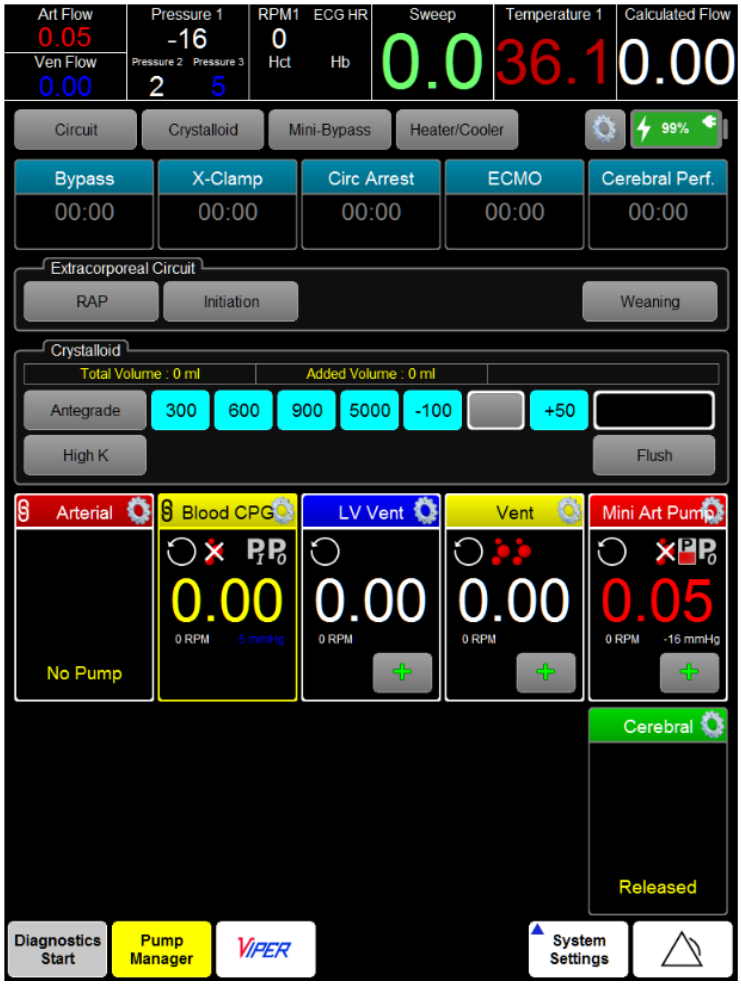


Figure 39 - Mini-Bypass Mode

When selected, mini by-pass mode will:

- Disable level protection
- Disable safe flow regulation
- Flash pump panels yellow during pump modulation
- Removes default flow control from system reset.

8 Manual Mode

In Manual Mode, the User has independent manual control of all pumps.

! Warning

In Manual Mode all interlocks, flow and pressure limits, level protection and bubble detection are disabled. Extreme care should be exercised when the system is in manual mode.
When entering or leaving Manual Mode, all running pumps will be stopped.

1. From the Pump Manager App, select Circuit.
   The Circuit Settings dialog is displayed.

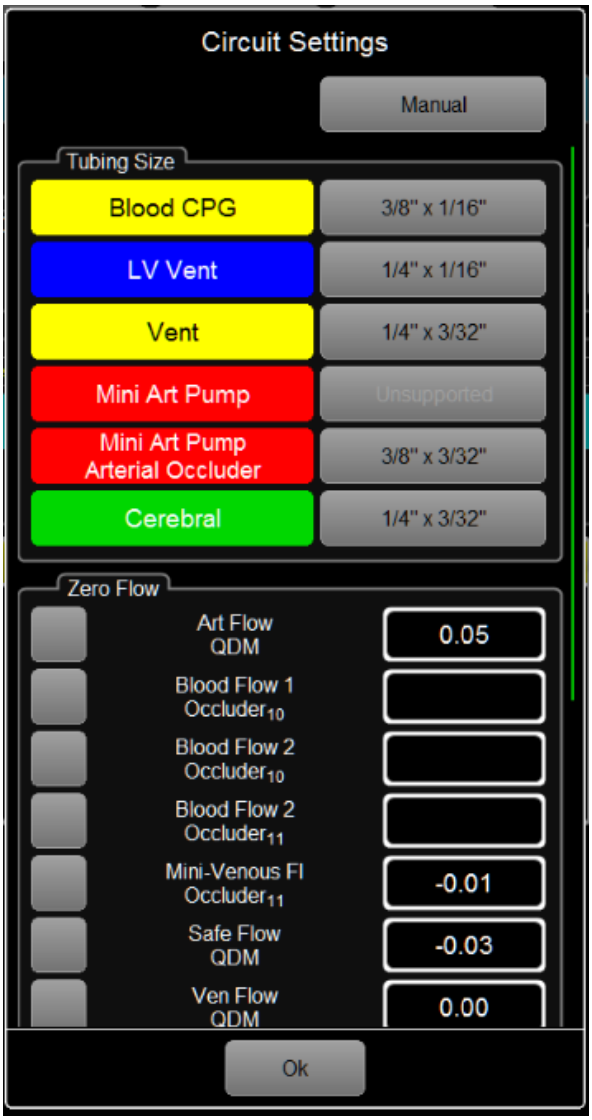


Figure 40 - Circuit Settings

2. Select Manual.
   A confirmation dialog box is displayed.

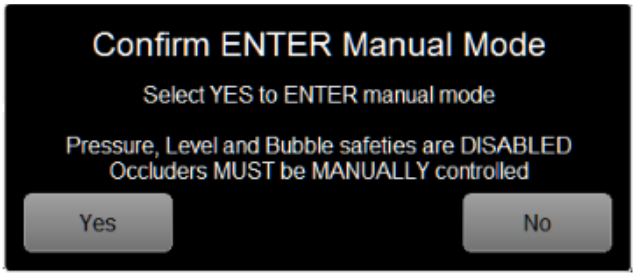


Figure 41 - Confirm Manual Mode

3. Select Yes to continue or No to cancel.

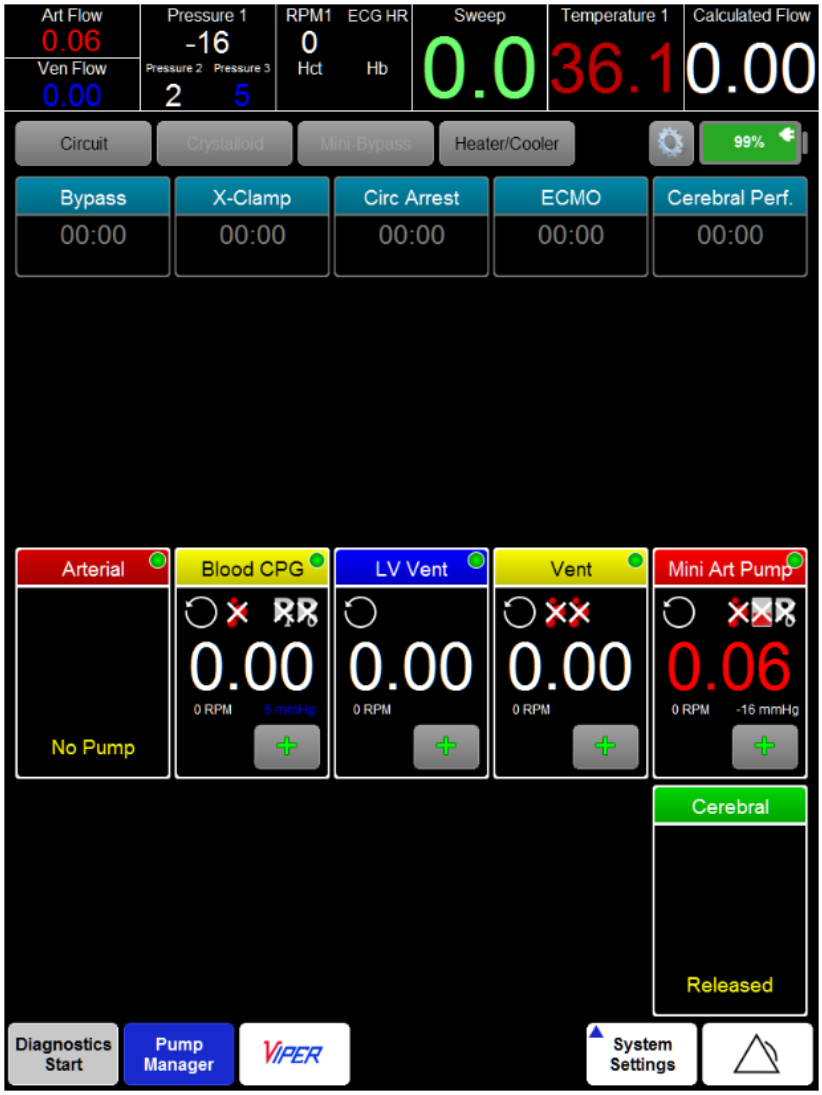


Figure 42 – Manual Mode

When in Manual Mode, the white border of each pump tile will flash.

4. Press and hold  to increase flow or RPM or tap for incremental increases in flow or RPM.

   Press and hold  to decrease flow or RPM, or tap for incremental decreases in flow or RPM, or, use the control knob assigned to that pump.

5. To select a pump tile located on the lower pump tile positions, press the control knob associated with the pump tile immediately above to toggle to that lower pump tile. Pressing the Control Knob again returns control to the pump tile on the upper level.
6. Select the Manual tab again to exit Manual Mode.
7. To adjust pump speed, select  and  or, use the Control Knob assigned to that pump.

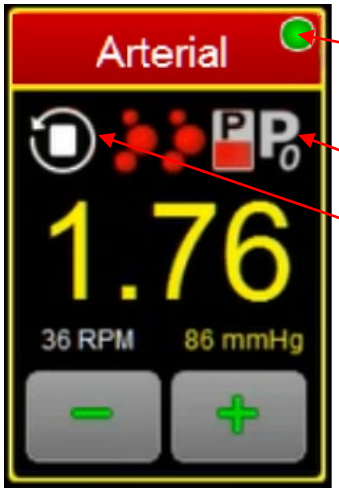


Figure 43 - Pump Status

The Green icon indicates all pump functions are satisfactory. Any other colour indicates a malfunction, and appropriate steps should be taken.

Selected safety functions that are applied when not operating in Manual Mode.

To reverse the rotation of a roller pump, select the tile corresponding to the desired pump and press the  icon. A confirmation dialog is displayed, requesting confirmation to reverse pump rotation.

8. To exit Manual Mode, select the Manual button.

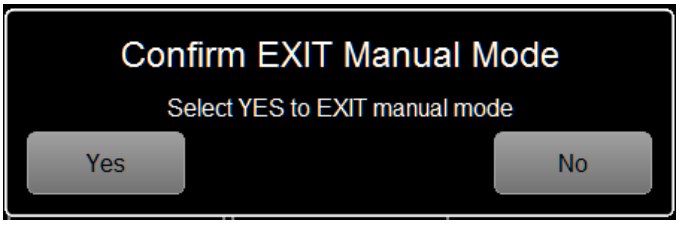


Figure 44 – Confirm Manual Mode Exit

9. To confirm exit of Manual Mode, click Yes or cancel exit by clicking No.

! Warning

When entering or leaving Manual mode, all running pumps will be stopped.

9 Bubble Mode Sensitivity Adjustment

Bubbles are detected by the Ultra-sonic Flow/Emboli Sensors. Adjusting the sensitivity can be done by Spectrum Service Team. The differences in Sensitivity are expressed as Bubble Size.

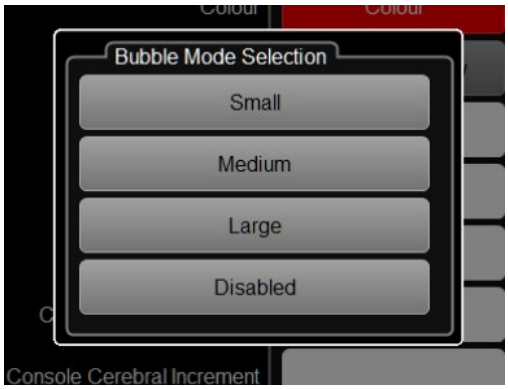


Figure 45 – Bubble Mode Selection

The Small bubble setting is configured to be set as the most sensitive, large the least sensitive. Disabled cancels the Bubble Mode Selection process.

Consider each Flow/Emboli Sensor function when selecting a Bubble Setting. For example, the more sensitive settings may be chosen for the site in the line closest to the Patient, referred to as the Arterial or Actual Flow site. The less sensitive settings may be chosen for the site between the Venous Reservoir and the Main Arterial Pump, as it would not be unusual for this site to contain some level of gaseous emboli. The Venous Line Flow/Emboli Sensor site could have very large air bubbles.

Care should be taken when setting up the sensitivity levels, as well as the selection made for each respective Flow/Emboli Sensor site, because choosing the relative sensitivity affects the pump Stop functions.

Selecting Disabled will disable the feature in the pump.

10 Circulatory Arrest Information

Quantum Pump Console supports a circulatory arrest mode where the main systemic arterial pump will be controlled by a target pressure. Utilizing a contained pressure system, this may increase safety when used in conjunction with peristaltic pumps such as Cerebral and/or Cardioplegia pumps.

Circulatory arrest is supported by the Single Pressure and Single Pressure Clamp pump types only. Where roller pumps are used Max Flow is supported.

This mode requires an automated occluder or a tubing clamp to clamp the arterial main line. A pressure sensor on the arterial line monitoring the section between the pump and occluder provides the sensor input for monitoring pressure. The pump will ramp to the desired circulatory arrest target pressure. This target pressure must be less than the selected maximum or stop circuit pressures.

! Warning

If a bubble is detected and an alert posted, set points will be lost and must be reset.

As the cerebral or cardioplegia (or other peristaltic flow) pumps demand blood, the main systemic pump control senses decreasing line pressure and increases pump RPM or flow to meet the demand. When the cerebral or cardioplegia pumps are stopped, the main systemic pump control senses increasing line pressure and reduces pump RPM or flow.

In Circulatory Arrest mode, interlocked operation works by maintaining the target pressure. In the event of a bubble alarm target pressure will be cleared and any occluders reset to their ‘Ready’ position.

If maximum pressure is disabled during operation a pump will continue to run at its current speed.

11 Cerebral Perfusion Selection

Cerebral perfusion is the process of using the Extracorporeal Circuit to provide blood flow usually specifically to the brain, most commonly used during circulatory arrest.

Pump Manager supports cerebral perfusion on the following pump types: Single Pressure, Single Pressure Clamp, Cardioplegia Master/Follower, Single, Dual and Dual Lock.

To support cerebral perfusion, a pump must be configured with maximum cerebral flow or maximum and stop cerebral pressures.

Selecting the cerebral perfusion button updates the flow and pressure limits in the cerebral pump control to match those settings made in the respective Pump Tile during setup.

If more than one pump has been configured for cerebral perfusion, selecting the cerebral perfusion button displays a selection dialog for selecting the appropriate pump(s).

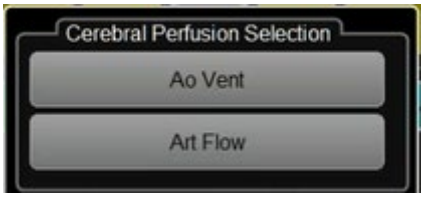


Figure 46 - Pump Selection

The pump remains in cerebral mode until cerebral perfusion is de-selected. When de-selected the flow and pressure limits of the cerebral pump are returned to their non-cerebral set limits as selected in Pump Type.

12 RAP Mode

Retrograde Autologous Priming (RAP), when used, occurs before initiation. The technique removes any priming solution from the arterial line and helps conserve the blood through the restriction of hemodilution to reduce the need for transfusion during surgery.

RAP configures the arterial smart occluder to operate in flow mode, with the clinician slowly opening the occluder to allow the patient's blood and gravity to replace the priming solution.

When RAP mode is selected, a confirmation message is displayed.

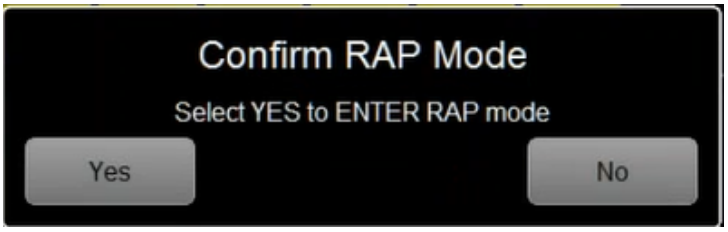


Figure 47 - Confirm RAP Mode

On confirmation, the Venous Occluder tile is replaced by a RAP tile; which is the active Arterial occluder.

Figure 48 - RAP Mode

The RAP arterial occluder is closed when RAP mode is initiated. Any engaged safety features are disabled.

Use the  buttons or use the console knob to set the drain rate.

Once the desired volume has been drained set the rate to zero then exit RAP mode. At this point any safety features that were applied before entering RAP mode are re-applied.

RAP mode may be exited at any time by pressing two buttons on the pump control module simultaneously. On exit the system returns to the default mode; closed occluders remain closed, occluders that are not closed will move to the ‘Ready’ position.

13 Initiation Mode

The initiation process operates by controlling the venous flow demand and adjusting arterial flow in order to provide structure to the commencement of circulatory report.

! Caution

Initiation Mode depends upon the venous flow demand set point to be achievable. If there is a venous drainage problem due to cannula position, kinking of the venous line, inadequate volume status of the patient, etc., the Initiation Mode goal of balancing the arterial flow to the venous flow may not be achieved.
If you wish to run the reservoir level to zero before initiation the Level Sensor System must be disabled; invoking initiation automatically activates Protected Level.

The initiation process uses venous flow demand to define the flow provided to the arterial pump circuit and operates in conjunction with the reservoir level protection system to ensure the arterial and venous flows are matched, by using a Quantum Smart Occluder on the venous circuit.

When the initiation option is selected a confirmation dialog box is displayed.

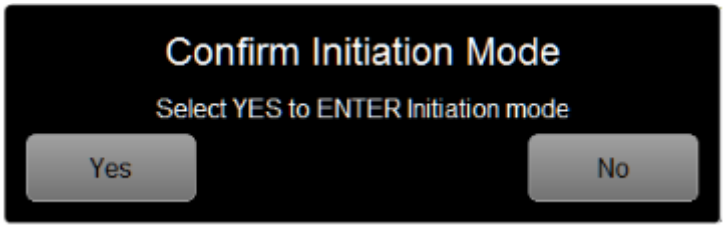


Figure 49 - Confirm Initiation Dialog

On confirmation, the system will change to Protected Flow mode. Operation focus moves to the Venous Tile, as indicated by the white border. When initiation commences pump rpm is limited (limit is pump model dependent) to prevent accidental reservoir draining. Limits are sufficient to provide a pressure level that prevents backflow; as soon as demand is given to the system the rpm limit is removed and the clinician is able to control demand. The current position of the occluder is shown in the tile title bar.

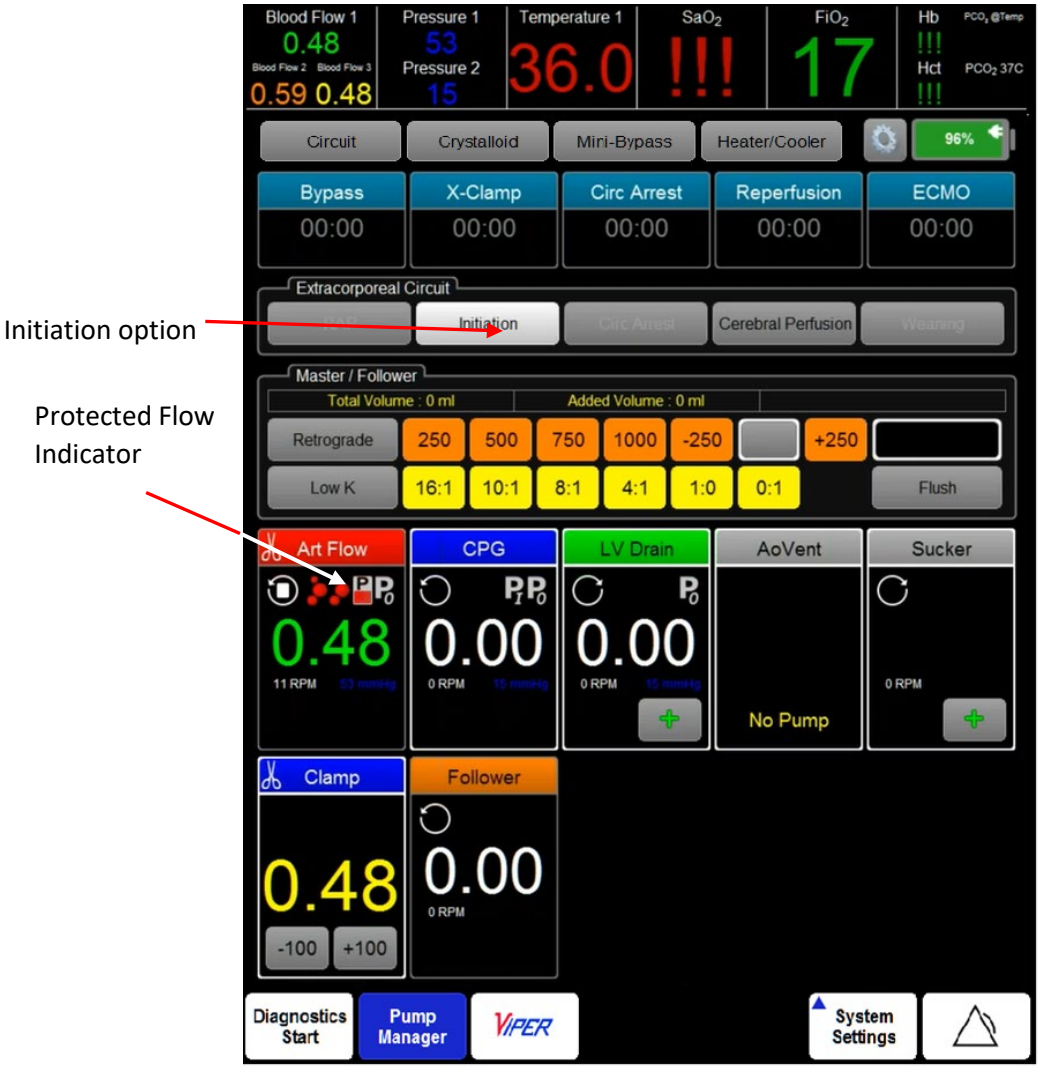
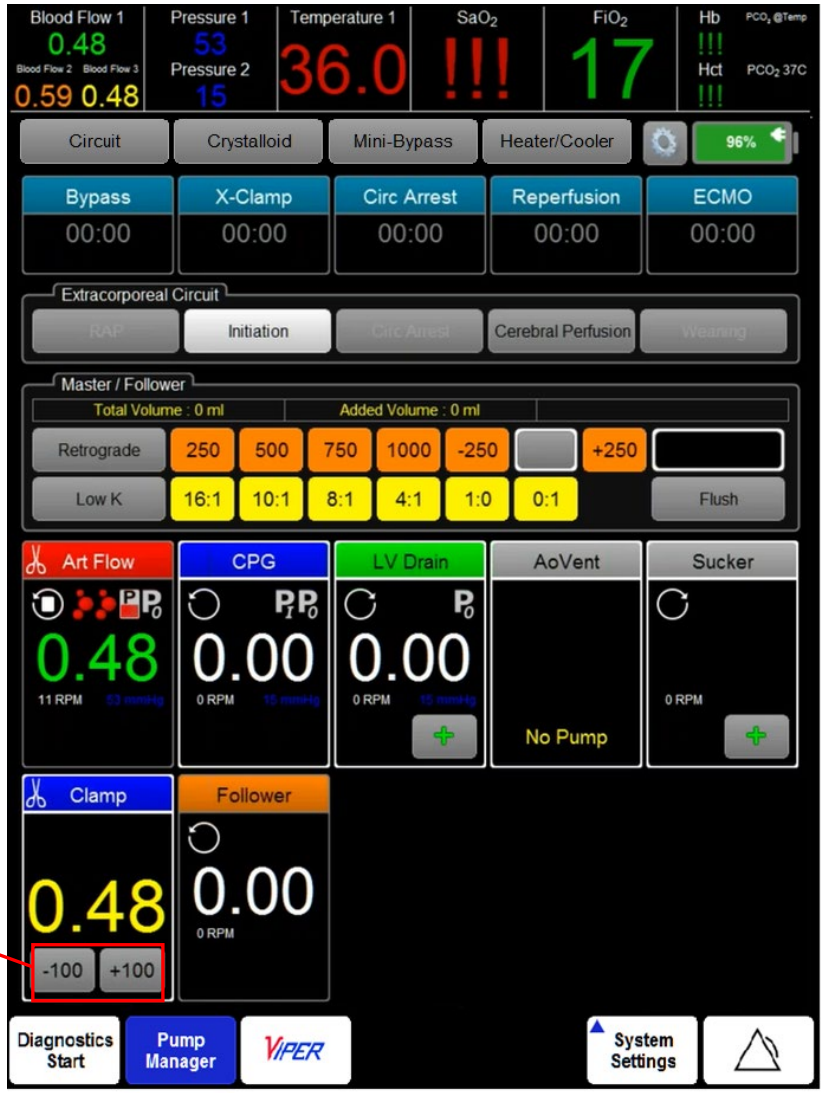


Figure 50 – Initiation

When venous flow is increased the venous occluder opens to the demanded flow but the arterial occluder remains closed. The arterial occluder only opens to allow flow towards the patient when the protected level is reached. Once the arterial occluder has opened the pump will become operational so that venous and arterial flows are maintained at the level set for the venous circuit.

The Venous Flow demand can be increased or decreased during initiation, the arterial flow automatically adjusting to match the increment or decrement. When the demand is increased or decreased the level of fluid will stay above the Protected Level.

Fixed volumes can be translocated into or out of the patient. The translocation volume is preset during setup; in the images of this section the volume is 100 mL. The volume can be adjusted by using the +/- buttons in the dynamic dialog.



Translocation Buttons

Figure 51 - Translocation

To translocate from the patient (subtract), click -100; the venous occluder will adjust to allow more venous flow to be leaving the patient than the arterial pump is running toward the patient, until the approximate volume has been translocated.

To translocate to the patient (add), click +100; the venous flow rate will drop to zero because the venous occluder closes. Once the volume has been translocated the venous occluder will open to the set demand, which the arterial held constant during the translocation.

Where translocation is performed with Venous Flow Demand set at zero, translocating from the patient (subtract) the venous occluder opens to allow translocation of the set volume. Where translocation is to the patient (add) the arterial occluder will respond to inputs via the +/- buttons, by opening to permit the arterial pump to translocate the set volume to the patient.

While a translocation is taking place, the +/- buttons are replaced by a flashing yellow stop button ( ); clicking this button during translocation will halt the process, even if the preset volume has not been translocated. To change the volume being translocated from the default while the process

continues, touch the active venous tile to use the dynamic dialog +/- buttons to set a revised translocation volume. When the required volume has been translocated, or manually stopped, both venous and arterial flows are again matched. To minimize the risk of setting an unbalanced state, during translocation the console knobs are disabled.

Initiation is ended by tapping the Initiation button a second time; this will make the arterial pump the controller. At this point the Level Protection and Bubble Detection will return to their pre-initiation setting, or, if the Level Protection has been disabled, Level Protection will go to Protected Level and the venous occluder will fully open.

! Warning

On exiting Initiation, if there is zero venous demand the occluder will remain at zero flow. If there is demanded flow the occluder will fully open. The clinician must intervene and manually set the occluder to the required position if that position is anything other than these default positions.

Initiation mode may be exited at any time by pressing two buttons on the pump control module simultaneously. On exit the system returns to the default mode; closed occluders remain closed, occluders that are not closed will move to the 'Ready' position.

14 Weaning Mode

The weaning process operates by restricting the venous return flow and adjusting arterial flow in order to provide structure to the termination of circulatory report.

! Caution

Weaning Mode depends upon the venous flow demand set point to be achievable. If there is a venous drainage problem due to cannula position, kinking of the venous line, inadequate volume status of the patient, et cetera, the Weaning Mode goal of balancing the arterial flow to the venous flow may not be achieved.

The weaning process uses venous flow control to define the flow provided to the arterial pump circuit and operates in conjunction with the reservoir level protection system to ensure the arterial and venous flows are matched, by using Quantum Smart Occluder on the venous circuit.

The weaning interface is used to set the required venous flow, which is then matched by the arterial pump.

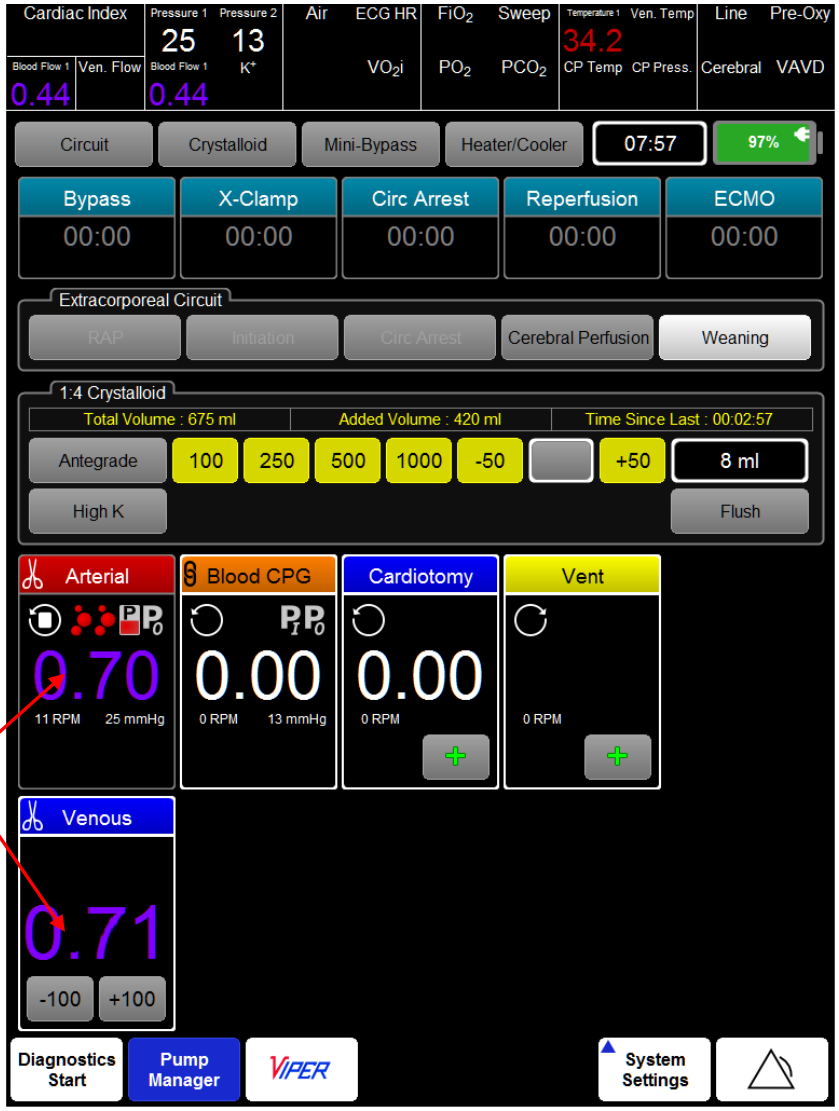
If the Vent Interlock function is selected in the Pump Setup menu, the relationship between blood entering and leaving the venous reservoir is safely and automatically maintained. This minimizes the intervention required by the clinician to maintain the balance. The Arterial Pump Flow rate is controlled to equal the sum of the Venous Return Flow rate plus the Left Ventricular Vent Flow rate. This relationship between the Left Ventricular Vent Flow rate and the Arterial Pump Flow rate continues even if the Venous Blood Flow rate becomes Zero. At a Zero Venous Blood Flow rate, the Arterial Pump will continue to run at precisely the same flow rate as the Left Ventricular Vent, and the Venous and Arterial Occluders will operate appropriately, opening and closing as required.

📖 Refer to section 14.1 Enabling/Disabling Vent Interlock on page 82 for information on using Vent Interlock.

When the weaning option is selected the system will change to Protected Flow mode and set VAVD to zero (0mmHg). Operation focus moves to the Venous Tile, as indicated by the white border. Arterial and venous flows are matched to the lower flow level.

Figure 52 - Weaning Initiation

Once weaning has been initiated, and the required flow set, both venous and arterial flows are matched and maintained as closely as possible by modulating the venous flow rate.



Matched Flows

Figure 53 - Matched Flows

The current position of the occluder is shown in the tile title bar.

Where zero flow is required the venous occluder is closed and an  icon displayed on the arterial pump tile to indicate the closure of the arterial occluder. Both flows are displayed as zero.

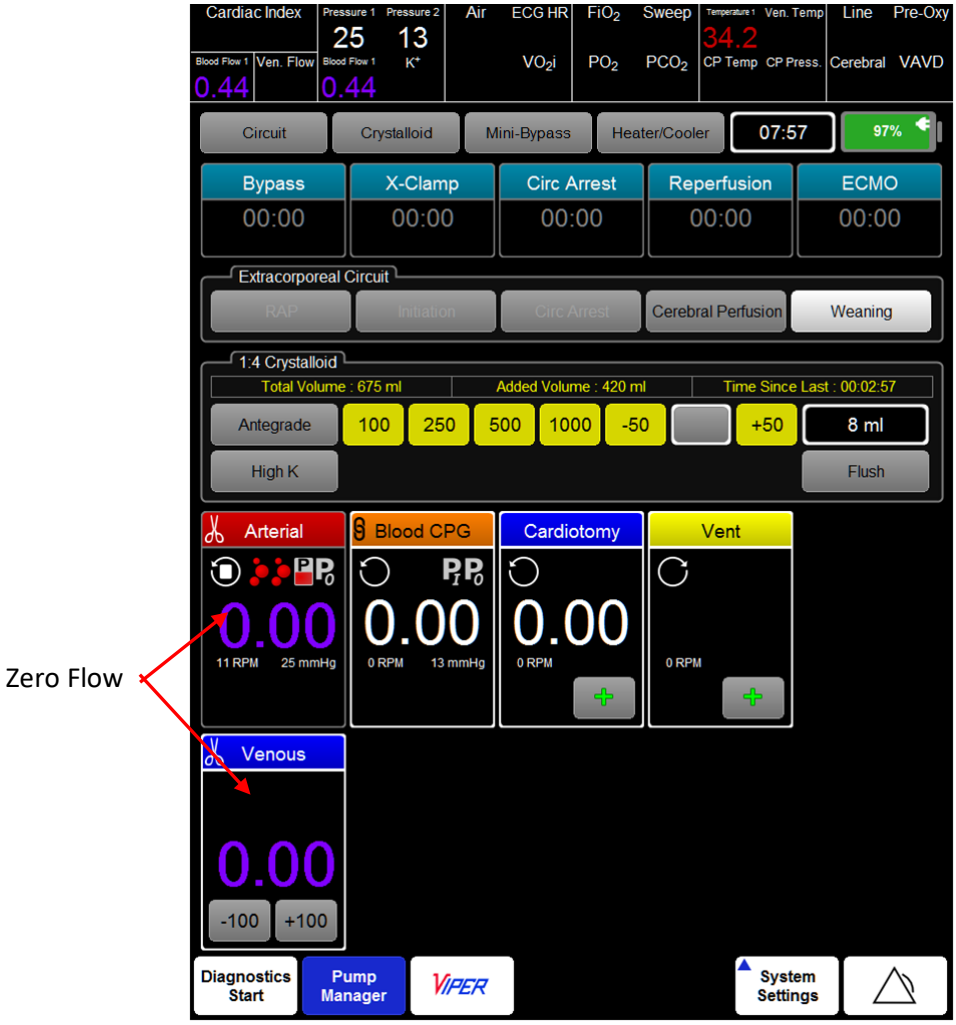


Figure 54 - Zero Flow

! Caution

When the arterial line is fully occluded and the centrifugal pump RPM level is set to maintain Zero Flow, the patient's arterial pressure MUST be monitored. As pressure increases, the RPM required to maintain Zero Flow after the occlusion is removed changes. It may be necessary to adjustment the RPM before removing the occlusion to allow for increases in patient pressure which the system cannot detect.

When parameter limits, such as bubble protection, are breached, alarms sound or are displayed, the venous occluder closes and weaning mode deactivated until user intervention corrects or overrides the cause of the alarm.

When required, the perfusionist can translocate preset volumes into or out of the patient. The translocation volume is preset during setup; in the images of this section the volume is 100 mL. The volume can be adjusted by using the +/- buttons in the dynamic dialog.

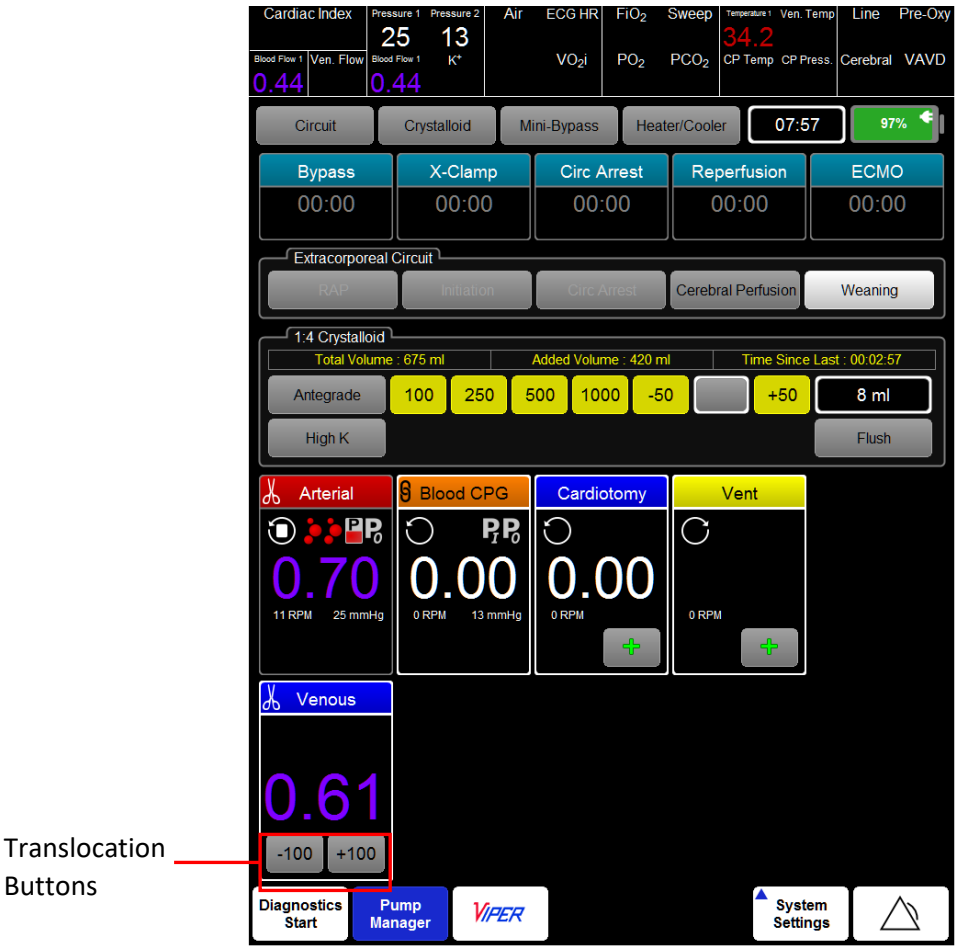


Figure 55 - Translocation

To translocate to the patient (add), click +100 ; the venous flow rate will drop to zero because the venous occluder closes. Once the volume has been translocated the venous occluder will open to the set demand, which the arterial held constant during the translocation.

To translocate from the patient (subtract), click -100; the venous occluder will adjust to allow more venous flow to be leaving the patient than the arterial pump is running toward the patient, until the approximate volume has been translocated.

Where translocation is performed with Venous Flow Demand set at zero, translocating from the patient (subtract) the venous occluder opens to allow translocation of the set volume. Where translocation is to the patient (add) the arterial occluder will respond to inputs via the +/- buttons, by opening to permit the arterial pump to translocate the set volume to the patient.

While a translocation is taking place, the selected +/- buttons are replaced by a flashing yellow stop button ( ); clicking this button during translocation will halt the process, even if the preset volume has not been translocated. To change the volume being translocated from the default while the process continues, touch the active venous tile to use the dynamic dialog +/- buttons to set a revised translocation volume. When the required volume has been translocated, or manually stopped, both venous and arterial flows are again matched.

Weaning mode may be exited at any time by pressing two buttons on the pump control module simultaneously. On exit the system returns to the default mode; closed occluders remain closed, occluders that are not closed will move to the 'Ready' position.

14.1 Enabling/Disabling Vent Interlock

When a Vent pump is configured to run Vent Interlock, Vent Interlock can be enabled or disabled from the Dynamic Configuration dialog. Vent interlocking is disabled by default.

To enable vent interlock:

1. Open the dynamic configuration dialog.

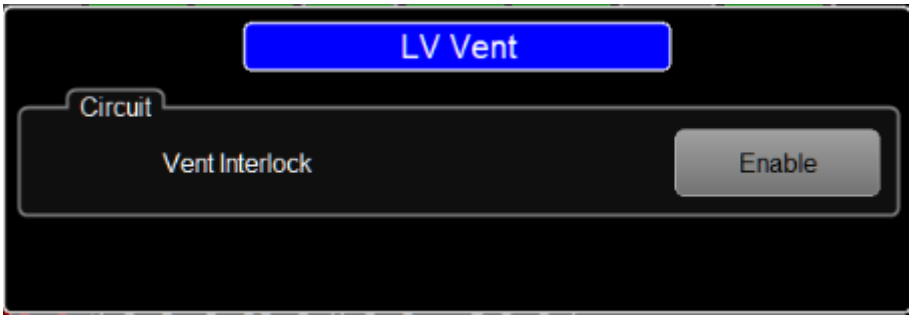


Figure 56 - Dynamic Configuration - Vent Interlock Enable

2. Select Enable.
   The Enable button toggles to Enabled.

Figure 57 - Dynamic Configuration - Vent Interlock Enabled

To disable Vent Interlock:

1. Select Enabled.
   The Enabled button toggles to Enable.

15 Cardioplegia Information

Cardioplegia may be delivered as volume where the pump stops once the desired volume is reached or as an open-ended volume that must be stopped manually.

Cardioplegia is initiated by the perfusionist. It will never start autonomously, except if Auto Pressure Restart is selected in the Pump Tile. When in pressure regulated cardioplegia delivery mode dose accumulation is disabled.

📖 Refer to section 5.4 Cardioplegia Pump Types on page 50 for information on the following cardioplegia modes:

- Crystalloid
- Crystalloid 4:1
- Master/Follower
- Single Syringe

Cardioplegia Master/Follower requires the user to select a ratio before delivery is allowed. The system supports traditional blood-crystalloid ratios, a blood only ratio (1:0), a crystalloid only ratio (0:1) or crystalloid-blood cardioplegia ratios of 1:1 to 1:20.

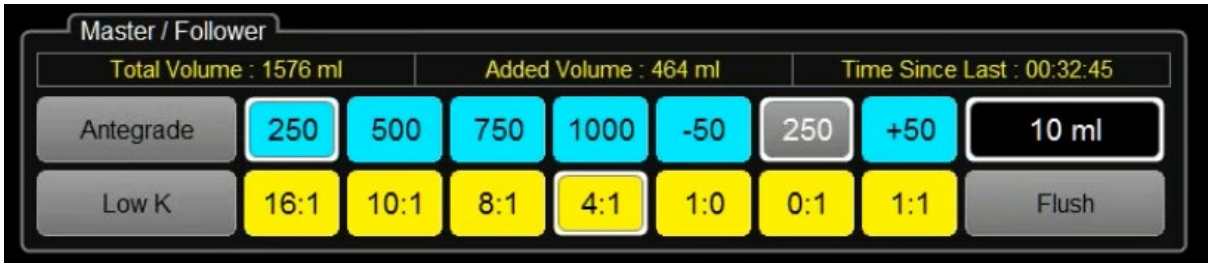


Figure 58 - Cardioplegia Display

The visibility of the cardioplegia and initiation/weaning displays are mutually exclusive and controlled by the selection of cardioplegia mode or initiation/weaning mode.

The cardioplegia display shows only those controls that are supported by the currently selected cardioplegia mode. For example, the ratio selection interface is only visible for Master/Follower mode and the syringe interface is only visible for Single/Syringe mode.

The cardioplegia display includes the delivered totals for blood (where required) and crystalloid, a time for duration of current dose or an elapsed time of the last dose. There is also a running volume total for the current dose.

Cardioplegia may be delivered as a requested volume where the cardioplegia system stops after the desired volume has been delivered or as an unspecified volume where the cardioplegia system must be manually stopped.

The Flush button allows the perfusionist to run the cardioplegia system without recording a dose. Flushing continues until stopped. In flushing mode, it is not possible to change volume or ratio using the console, the workstation must be used.

When controlling Cardioplegia Master/Follower pumps from the Pump Control Module, pushing and holding the control knob for three seconds will enter menu mode. From menu mode it is possible to toggle through and set options for volume and ratio. Press the knob to confirm a selection. To exit menu mode, select a different control knob, or the toggle function will time-out after a few seconds.

15.1 Pressure Regulated Delivery from Non-pressure Pumps

Quantum Pump Console supports pressure regulated delivery for non-pressure pumps; for example, cardioplegia, vent and sucker.

To utilise pressure regulated delivery Max Flow must be configured to make the option available.

Pressure regulation can be enabled once the flow has been set on the QWS or the pump console. Use the dynamic configuration dialog (Figure 59) to set the target pressure. Once the desired pressure value is displayed, select the greyed-out Enabled button adjacent to the displayed value. The button will change to white and the display to yellow and begin to pulse.

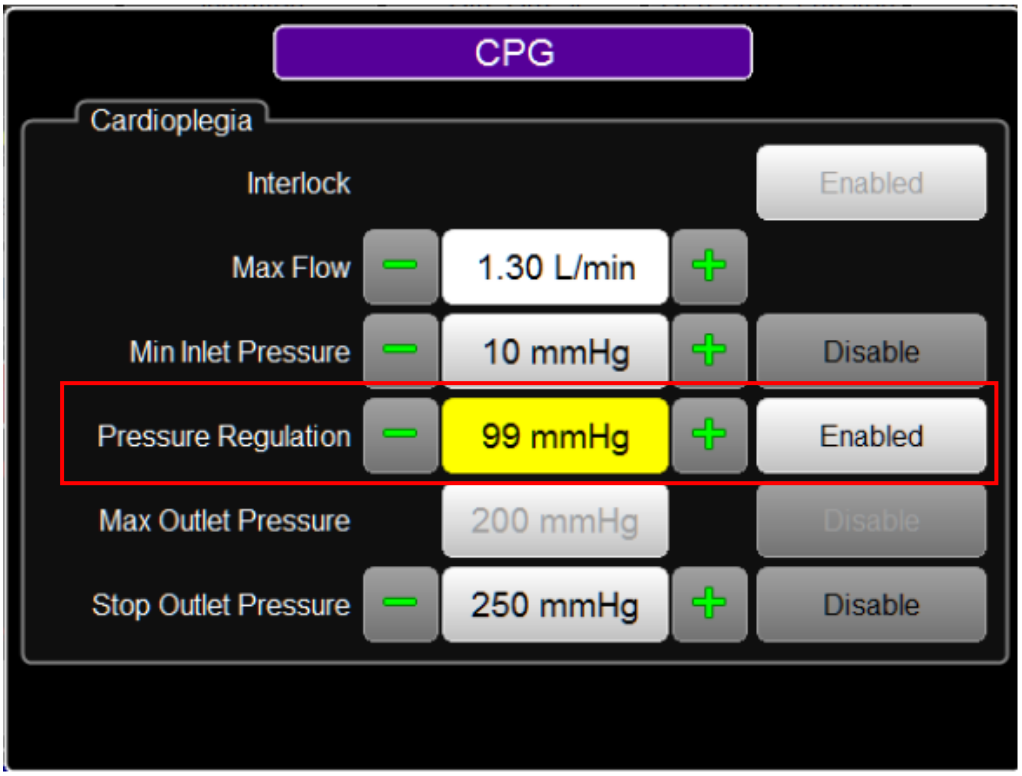


Figure 59 - Pressure Regulation

Pressure can be adjusted using the  buttons. Any change to flow from the QWS or console will cancel pressure regulation.

16 Safe Flow

Sensor placement is important to provide the intended functionality provided by Safe Flow. A Flow Sensor should be placed on the blood line between the Venous Reservoir and the main Arterial Pump. A second Flow Sensor should be placed on the Venous Line prior to the Venous Blood entering the reservoir. Both Flow Sensors are connected to a functioning Diagnostics Module or Ventilation Module, and that Module must be in communication with the Quantum Workstation that is controlling the main Arterial Pump.

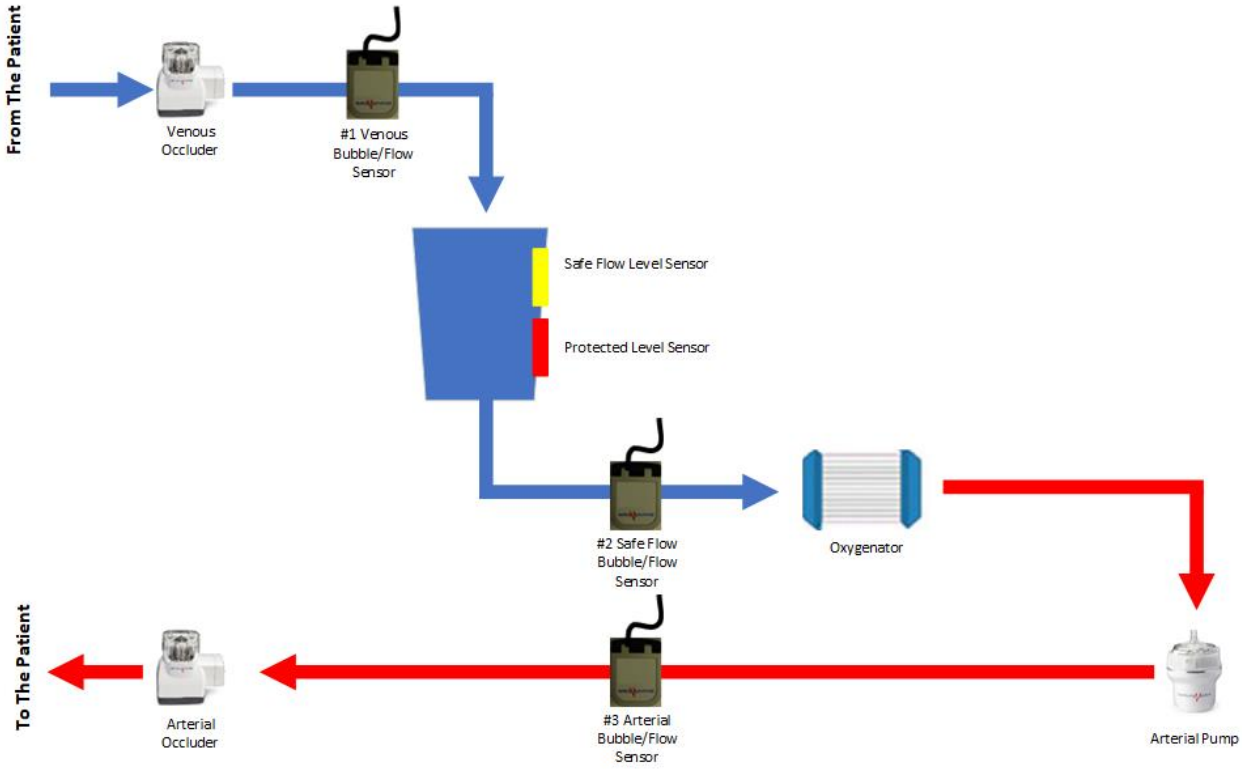


Figure 60 – Safe Flow

📖 Refer to the Quantum Diagnostics Module User Manual (SUM-30010031).

Where a level violation occurs while modulating the setpoint can be changed to a lower value than that at the time of violation. Disabling safe flow while pumps are running will cause pumps to run at the current speed.

16.1 Level Protection

Icon indicating Safe Flow Level Protection Configured and Selected, Level Sensor attached and fluid level sensed to be at least as high as the Sensor attachment point. The Venous Flow Sensor must be functioning and sensing fluid. If not, the Safe Flow icon will change to Protected Flow.

The partially filled reservoir with the white ‘S’ indicates Safe Flow Level protection is configured with two Flow Sensors, Safe Flow is Selected, Upper Level Sensor attached, and fluid level sensed to be at least as high as the Sensor attachment point. In Safe Flow mode, if the reservoir level drops below the

upper (yellow) level sensor, the main Arterial pump slows to match the flow sensed by the Venous Flow Probe, but, not less than 25% of the pre-Safe Flow demand as explained above. If the venous reservoir level returns to the upper (yellow) level sensor, the pump will return to the pre-Safe Flow demand.

Icon indicating Protected Flow Level Protection Configured and Selected, Level Sensor attached and fluid level sensed to be at least as high as the Sensor attachment point.

The partially filled reservoir with the white 'P' indicates Level protection is configured with two Flow Sensors, Safe Flow or Protected Flow is Selected, Lower Level Sensor attached, and fluid level sensed to be at least as high as the Sensor attachment point. In Protected Flow mode, demand for roller pumps may decrease, if the reservoir level drops below the lower (red) level sensor, the pump will STOP. When the reservoir level returns to the lower (red) level sensor, the pump will return to the pre-Protected Flow demand.

If the level drops below the lower (red) Protected Level sensor, the pump will STOP.

When Level protection is selected with a Bubble Sensor on the reservoir outlet and operating as intended, the patient is PROTECTED against air being drawn into the extracorporeal circuit from the Venous Reservoir. Demand can only be reduced, not increased, when level protection is selected.

Icon indicating Level Protection NOT Working

The partially filled reservoir with the white 'X' indicates Level protection is configured and is NOT working as intended. This can be due to either the Level protection being disabled, OR the associated level measurement is offline or in error.

When level protection is NOT operating as intended, the patient is NOT PROTECTED against air being drawn into the extracorporeal circuit.

! Caution

Level Protection Disabled condition is a HAZARDOUS condition, and EXTREME caution should be taken by the clinician.

17 Flow Offset Information

In a standard extracorporeal blood circulation circuit, the Main Arterial pump is located after the Venous Reservoir, and prior to the Oxygenator, if fitted. There is a monitored pressure in the line after the pump in normal operational circumstances when the Main Arterial pump is set up correctly and running with enough speed.

The Calculated Flow rate of a roller pump equals the volume of fluid moved per revolution times the number of revolutions per minute. This volume per rpm is a function of occlusion setting as well as tubing diameter. Centrifugal pumps do not use flow offset.

An Arterial Blood Flow measurement to the patient can be obtained using an external flow probe after all the shunts and sites where blood may be extracted from the pressurized line. The difference between the Calculated Flow rate and the Arterial Flow rate of blood going to the patient is affected whenever blood is shunted out of the pressurized line, or, if blood is pulled out of the Main Arterial line by another pump.

Pumps for Blood Cardioplegia, Cerebral Perfusion, and Hemo-concentrators are sometimes used to pull blood out of the Main Arterial Pump line. When blood is removed from the Main Arterial line by any of these pumps, the Flow Offset function can be activated by choosing Interlock. The Calculated Flow of an Interlocked Pump is used to adjust the Main Arterial Flow rate to increase to match the flow rate of any of these other pumps. Interlocked pumps can restart with zero flow on arterial pumps. It is recommended that inlet pressure protection (Pi) is used for additional safety.

Example: When an Interlocked pump demands a flow from the main arterial line, this value is added to the demand on the master pump. If the main arterial pump is delivering 4 L/min and an interlocked pump goes from 0 L/min to 1 L/min, the master pump would increase RPM to deliver 5 L/min. When the demand of the interlocked pump is reduced back to 0 L/min, the master pump would decrease RPM to deliver 4 L/min. The Arterial Blood Flow measurement will therefore remain at 4 L/min the entire time. If the arterial pump is in an alarm state the cardioplegia pump cannot increase flow because the arterial pump is being modulated.

18 Dynamic Configuration

The Dynamic Configuration/System Alerts dialog allows the user to modify the current operational protections, their associated limits, to be alerted with run-time conditions and create an alertable event (i.e.: pump stoppage, flow or pressure modulation).

During normal operation the user does not have access to the pump configuration dialog. Therefore, while the entire list of configuration settings is not available, the dynamic dialog allows adjustment of some settings. At any time during a case, the user may be permitted to change, enable or disable one or more operational settings in this list; circuit support for maximum flow, inlet or outlet pressure limits, cardioplegia pressures, level detection, bubble selection and vent interlock while weaning.

Dynamic configuration is supported for the following pump parameters:

- Maximum Flow
- Minimum Inlet Pressure
- Maximum Outlet Pressure
- Target Pressure
- Stop Outlet Pressure
- Reservoir Level
- Vent Interlock
- Safe Flow Bubble Detection
- Arterial Flow Bubble Detection
- Interlock
- Maximum RPM for centrifugal pumps
- Smart Occluder information

To access dynamic configuration:

1. Tap the flow display on the pump gauge.

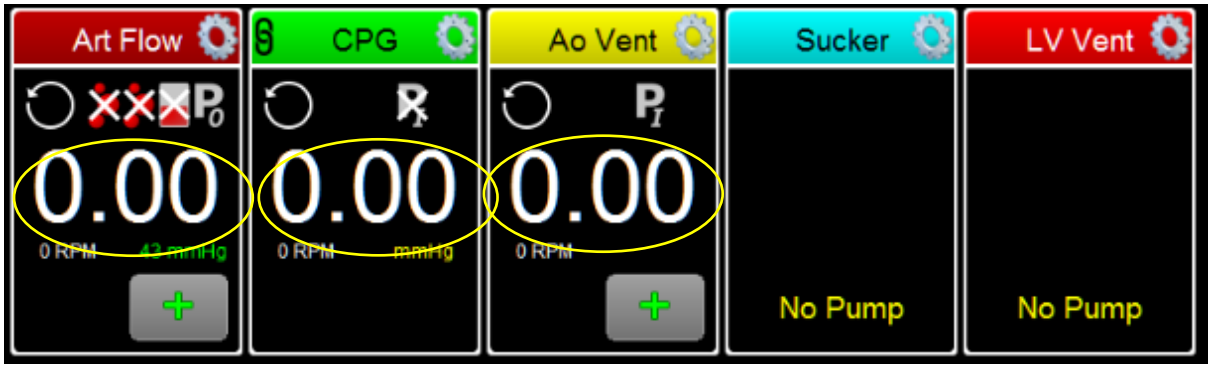


Figure 61 – Dynamic Flow Rate

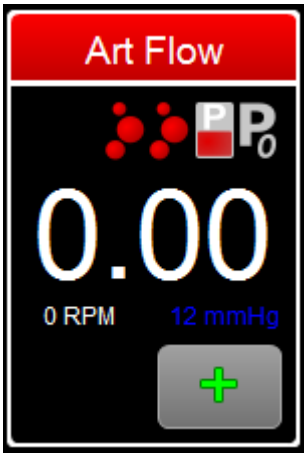
The Dynamic Configuration Dialog is displayed.

Figure 62: - Dynamic Configuration Dialog

2. Set the configuration parameters
   The Dynamic Configuration dialog displays a configuration interface for only those operational features that have been configured in the Pump Configuration dialog.
   In Figure 62, the outlet pressure measurement has been configured for both the maximum and stop circuit pressures. Therefore, both elements are available on the dynamic configuration dialog. If either maximum or stop circuit pressure had not been configured, it would not appear on this interface.

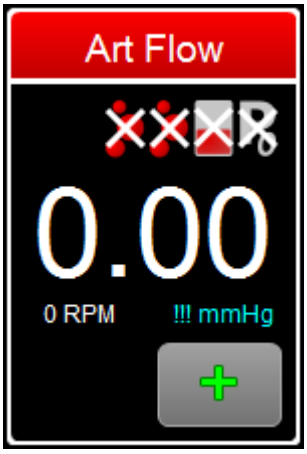
18.1 Pump Panel and Dynamic Configuration

When the pump is configured for an operational protection, a protection image is displayed. This image indicates whether the protection is operational or it is disabled. The system does not differentiate between operational or not working when the user has disabled the protection or if there is a problem (measurement offline or in error).



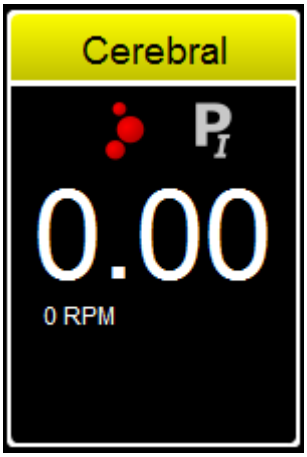
Single-Pressure pump (arterial pump) where bubble detection (2 channels), level and output pressure protections are operational.

Figure 63 - Pressure Pump Panel Display



Single-Pressure pump (arterial pump) where bubble detection (2 channels), level and output pressure protections are disabled. Flashing with no cross means the parameter is in alarm; cross with no flashing means parameter is disabled; a cross with flashing means the parameter is disabled and in an alarm state.

Figure 64 - Pressure Pump Panel Display



Single pump (cerebral pump) where bubble detection and input pressure protections are operational.

Figure 65 - Single Pump Panel Display

Single pump (cerebral pump) where input pressure and output pressure protections are **NOT** working.

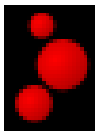
Figure 66 - Single Pump Panel Display

18.2 Description of the Non-Single Pressure Pump Icons

The Non-Single-Pressure pump types support the display of up to 3 safety feature icons: bubble detection, input pressure and output pressure.

The Follower pump type supports two safety feature icons: input pressure and output pressure.

18.2.1 Bubble Detection Protection



When bubble detection is operational, the system protects against circulating significantly large bubbles around the circuit.

Bubble Detection Protection. The red bubbles indicate bubble detection is configured and is operational. If a bubble passes through the flow sensor that is equal in size or larger, it will be detected and trigger the pump to stop.

When bubble detection is disabled, the system does NOT protect against circulating significantly large bubbles around the circuit.

The red bubbles with the white X indicates bubble detection is set to disabled in the Settings dialog for the tile.

! Warning

Bubble detection NOT working is a HAZARD for the patient and EXTREME caution should be taken by the clinician.

18.2.2 Inlet Pressure Protection

When inlet pressure protection is operational, the associated pump operation function is modulated by the inlet pressure value and the pump will stop if the value is lower than the setting.

The grey Pi indicates inlet pressure protection is configured and is operational. If minimum circuit pressure has been configured and the pressure drops below this value, the pump will STOP. Pressure Inlet can be used to modulate or stop the pump in response to an inlet pressure becoming lower than the set value.

When inlet pressure protection is NOT working, the circuit is NOT modulated by the inlet pressure value.

The grey Pi with the white X indicates input pressure protection is configured and is NOT working. This can be due to either the inlet pressure protection being disabled, OR the associated pressure measurement is offline or in error.

! Warning

Inlet pressure protection NOT working is a HAZARD for the patient and EXTREME caution should be taken by the clinician.

18.2.3 Outlet Pressure Protection

When outlet pressure protection is operational, the associated pump operation function is modulated by the outlet pressure value and the pump will stop if the value is lower than the setting.

The grey Po indicates outlet pressure protection is configured and is operational. If maximum outlet pressure has been configured and the pressure reaches this value, the pump will modulate to keep the pressure at this value. If stop outlet pressure has been configured and the pressure reaches this value, the pump will STOP.

When outlet pressure protection is NOT working, the circuit is NOT modulated by the outlet pressure value.

The grey Po with the white X indicates outlet pressure protection is configured and is NOT working. This can be due to either the outlet pressure protection being disabled, OR the associated pressure measurement is offline or in error. If outlet pressure is not configured, inlet pressure (Pi) is displayed.

! Warning

Outlet pressure protection NOT working is a HAZARD for the patient and EXTREME caution should be taken by the clinician.

18.3 Pump Panel Display Messages

Figure 67 - Lid Open

If the pump lid is open, the pump panel displays “Lid Open”.

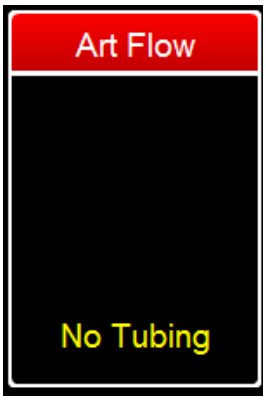


Figure 68 - No Tubing

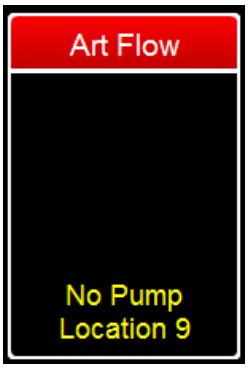
If the pump tubing has not been configured, the pump panel displays “No Tubing”.

Figure 69 - Invalid Tubing

If the pump tubing is incorrectly configured the pump panel displays “Invalid Tubing”.

If a pump has not been configured, the pump panel displays “No Pump”.

Figure 70 - No Pump



If a pump has been configured but is not detected, the pump panel displays “No Pump Location *X*” where *X* is the port location on the HLM frame.

Figure 71 - No Pump at Location

During weaning, when the venous occluder is closed because zero flow is demanded and the arterial clamp is closed.

Figure 72 - Arterial Clamp Closed

Indicates a fault with lid magnets or switches on a roller pump. To permit pumps to continue running the mismatch can be overridden in the Pump Settings dialog.

A lid mismatch is persistent until the pump is replaced.

Figure 73 - Lid Mismatch

18.4 Displaying Status Alerts

During a case, configured operational modes may trigger status alerts. Status alerts are conveyed to the user by the automatic presentation of the dynamic configuration dialog.

If the status alert is a STOP condition, the pump panel border and the dynamic configuration dialog border will flash RED and indicate the stop conditions (bubble, level or pressure) in the tile title bar. The interface element that controls the triggered operational mode will flash RED. The user must then modify the pump setting or disable the operational mode that triggered the pump stop. The user may then re-start the pump.

If the pump stops due to the reservoir sensor dropping below the lower (RED) sensor, the status alert dialog is displayed. This is for notification.

If the status alert is a modulation condition, the pump panel, corresponding console display and Pump Manager button **flash YELLOW**. The user is not required to act as the pump will modulate flow until the operational mode is no longer in alert.

18.5 Stop Conditions

The following conditions either prevent the starting of a pump or will trigger the pump to stop. When stopping the system sounds two beeps.

- Input pressure is below the set minimum circuit pressure.
- Output stop pressure is exceeded.
- If an Interlocked pump cannot detect the single-pressure pump on the system bus.
- Bubble detection has detected a bubble larger than or equal to the configured sensitivity setting. Bubble is displayed in the panel caption and flashes red.
- If the yellow sensor detects volume but the red sensor does not. This is an implausible condition that generates a Sensor Error message in the dynamic menu.

18.6 Modulation Conditions

The following conditions will cause the pump to modulate flow or RPM. When entering a modulation condition the pump sounds a single beep and the gauge bar display goes yellow and flashes for the appropriate display panel.

- Output maximum pressure is exceeded.
- Level sensor detects reservoir level has dropped below the upper (YELLOW) sensor and the system is in Safe Flow mode.
- Level sensor detects reservoir level has dropped below the lower (RED) sensor.
- Maintain Target Pressure
- Maximum Inlet Pressure too high.
- Minimum Inlet Pressure too low.
- Maximum Outlet Pressure too high.
- Circ Arrest.
- Vent Interlock

19 Alarms

This section provides information about alarms.

19.1 Alarm Specifications

Only default alarm limit settings for each measurement are retained when the monitor is powered off. All user set alarm limits are reset to the default limits.

! Caution

The alarm limit settings for all measurements must be checked before each case to ensure that they are appropriate for the patient.
Caution: Setting the alarm limits for a measurement to extreme values will render the alarm function for that measurement useless.
Caution: Where other monitoring equipment is used to perform the same or similar measurements on the same patient, use of differing alarm limit settings between the different equipment may cause a hazard.

19.2 System Alarms

The Quantum Workstation reports the technical alarms for the Quantum Pump Console.

The technical alarms in the table below are generated by the Quantum Pump Console. These are indicated on the Quantum Workstation by a flashing red gauge with the current measured value displayed.

A numeric code will be shown at the bottom of the gauge according to the following table.

Parameter	Error Code	Cause of Alarm	Alarm generation delay
Roller Pump	1580	ARM ID error	< 2 second
Roller Pump	1581	Hardware ID error	< 2 second
Roller Pump	1582	MCU above maximum temperature	< 2 second
Roller Pump	1583	MCU link protocol error	< 2 second
Roller Pump	1584	Driver PCB error	< 2 second
Roller Pump	1585	Lid interlock switches error	< 2 second
Roller Pump	1586	Motor drive MCU error	< 2 second
Roller Pump	1587	Encoder error	< 2 second
Roller Pump	1588	Hall sensors error	< 2 second
Roller Pump	1589	MCU clock error	< 2 second
Roller Pump	1590	Integrity counter error	< 2 second
Roller Pump	1591	Integrity flags error	< 2 second
Roller Pump	1592	Integrity MCU error	< 2 second
Roller Pump	1593	Ethernet link error	< 2 second
Roller Pump	1594	Digipot directional error	< 2 second

Parameter	Error Code	Cause of Alarm	Alarm generation delay
Roller Pump	1595	LDO 1V8 error	< 2 second
Roller Pump	1596	FETs above maximum temperature	< 2 second
Roller Pump	1597	Motor above maximum temperature	< 2 second
Roller Pump	1598	MCU link – SPI underflow	< 2 second
Roller Pump	1599	MCU link – SPI overflow	< 2 second
Flow Measurement	13610	Minimum inlet pressure deceeded	< 2 second
Flow Measurement	13611	Stop outlet pressure exceeded	< 2 second
Flow Measurement	13612	Level protected mode triggered	< 2 second
Flow Measurement	13613	Bubble detection 1 triggered	< 2 second
Flow Measurement	13614	Bubble detection 2 triggered	< 2 second
Flow Measurement	13615	Link error - pump pool partner primary pump 'Interlocked Primary'	< 2 second
Flow Measurement	13616	Link error - pump pool partner master pump in 'Master/Follower'	< 2 second
Flow Measurement	13617	Link Error - pump pool partner follower pump 'Master/Follower'	< 2 second
Flow Measurement	13618	Stop inlet pressure exceeded	< 2 second
Flow Measurement	13620	Link error – inlet pressure (min/max/stop)	< 2 second
Flow Measurement	13621	Link error – outlet pressure (max/stop)	< 2 second
Flow Measurement	13622	Link error – level	< 2 second
Flow Measurement	13623	Link error – safe flow	< 2 second
Flow Measurement	13624	Link error – venous flow	< 2 second
Flow Measurement	13625	Link error – bubble 1	< 2 second
Flow Measurement	13626	Link error – bubble 2	< 2 second
Flow Measurement	13627	Link error – external flow	< 2 second
Flow Measurement	13628	Link error – arterial occluder	< 2 second
Flow Measurement	13629	Link error – venous occluder	< 2 second
Flow Measurement	13645	Over voltage error	< 2 second
Flow Measurement	13646	Under voltage error	< 2 second
Flow Measurement	13660	System initialization error	< 2 second
Flow Measurement	13661	Encoder - initialization error	< 2 second
Flow Measurement	13662	Hall sensors - initialization error	< 2 second
Flow Measurement	13663	ADC - initialization error	< 2 second
Flow Measurement	13664	MCU link protocol - initialization error	< 2 second
Flow Measurement	13665	System monitor - initialization error	< 2 second
Flow Measurement	13666	DRV8301 - initialization error	< 2 second
Flow Measurement	13667	DRV8301 - configuration error	< 2 second
Flow Measurement	13668	Pump manager - initialization error	< 2 second
Flow Measurement	13669	Encoder direction	< 2 second
Flow Measurement	13675	Internal error	< 2 second
Pump Speed	13710	Minimum Inlet Pressure Deceeded	< 2 second
Pump Speed	13711	Stop Outlet Pressure Exceeded	< 2 second
Pump Speed	13712	Level Protected Mode Triggered	< 2 second
Pump Speed	13713	Bubble Detection 1 Triggered	< 2 second
Pump Speed	13714	Bubble Detection 2 Triggered	< 2 second

Parameter	Error Code	Cause of Alarm	Alarm generation delay
Pump Speed	13715	Link error - pump pool partner primary pump 'Interlocked Primary'	< 2 second
Pump Speed	13716	Link error - pump pool partner master pump in 'Master/Follower'	< 2 second
Pump Speed	13717	Link Error - pump pool partner follower pump 'Master/Follower'	< 2 second
Pump Speed	13718	Stop Inlet Pressure exceeded	< 2 second
Pump Speed	13720	Link Error – Inlet Pressure (min/max/stop)	< 2 second
Pump Speed	13721	Link Error – Outlet Pressure (max/stop)	< 2 second
Pump Speed	13722	Link Error – Level	< 2 second
Pump Speed	13723	Link Error – Safe flow	< 2 second
Pump Speed	13724	Link Error – Venous flow	< 2 second
Pump Speed	13725	Link Error – Bubble 1	< 2 second
Pump Speed	13726	Link Error – Bubble 2	< 2 second
Pump Speed	13727	Link Error – External Flow	< 2 second
Pump Speed	13728	Link Error – Arterial Occluder	< 2 second
Pump Speed	13729	Link Error – Venous Occluder	< 2 second
Pump Speed	13740	System Overvoltage Error	< 2 second
Pump Speed	13741	System Undervoltage Error	< 2 second
Pump Speed	13742	Isolated 24V Overvoltage Error	< 2 second
Pump Speed	13743	Isolated 24V Undervoltage Error	< 2 second
Pump Speed	13744	System Current Error	< 2 second
Pump Speed	13745	System Current Warning	< 2 second
Pump Speed	13761	System monitor – Initialization Error	< 2 second
Pump Speed	13762	Pump manager – Initialization Error	< 2 second

Table 11 - System Alarms

Alarms for bubble, pressure and level and lid open alerts are displayed on the appropriate settings tab and the pump tile.

20 Service & Maintenance

The Quantum Console is supplied with a service contract that is compulsory, this covers damage and warranty to the product.

There are no user serviceable parts in the equipment, all servicing must be performed by Spectrum Medical personnel.

! Warning

Unauthorised dismantling of Spectrum Medical products and the fitting of any non-approved spares will invalidate the warranty.
No modification of this equipment is allowed.

20.1 Daily Routine Inspection

The equipment must be inspected for correct operation or damage before each use.

- Cables should be checked for scuffs, abrasions or other damage.
- Check for physical damage to the Quantum Pump Console and accessories.
- Sockets should be checked for obstruction.
- Ensure the batteries are fully charged before use, especially if the equipment has been in storage.

! Warning

Do not use the Quantum Pump Console if it is found to be defective.

20.2 Cleaning Spectrum Products

After use, clean all surfaces with a cloth dampened with isopropyl alcohol or a mild soap and water solution only. Avoid solutions that contain acetone or abrasives.

After cleaning equipment must be carefully inspected to check for damage and to ensure it is properly clean. If necessary, repeat the cleaning process.

21 Upgrading Software

Software upgrades are provided by Spectrum Medical using a Secure Digital (SD) card. All connected equipment is upgraded from the Quantum Workstation.

To upgrade software:

1. Ensure the workstation is connected to mains power.
2. Power down the workstation.
3. Remove the SD storage card, if one is in place.
4. Insert the Spectrum Medical Upgrade SD card into the SD slot.
5. Power on the workstation.
   The unit will automatically commence the upgrade process.
6. Follow the onscreen instructions.
7. Remove the Spectrum Medical Upgrade SD card
8. Click Finish
   When the upgrade is complete the workstation will automatically restart and update any accessories. During this process the System Settings button and any affected accessory becomes magenta in colour and flashes. Click any magenta screen object to view update progress.

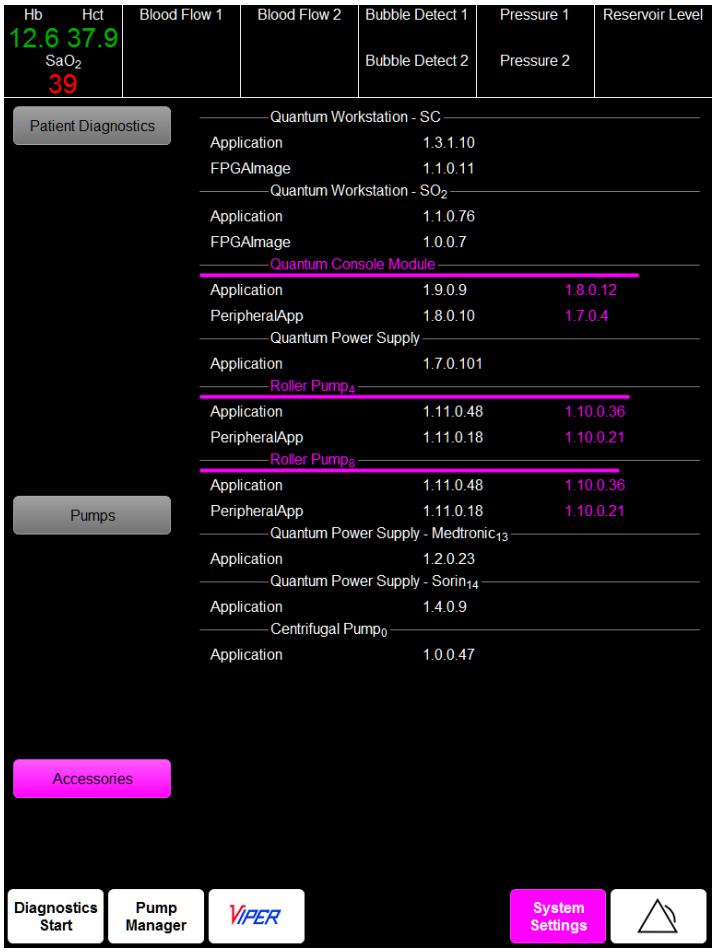


Figure 74 - System Update

If for any reason the update fails, try to perform the process again; this may require the mains power to be disconnected and then reconnected.

22 Transport, Storage and End of Life Disposal

The Quantum Pump Console must be stored and transported in its original packaging.

Waste Electrical and Electronic Equipment Policy Statement

The Waste Electrical and Electronic Equipment Regulations (WEEE), EU Directive 2012/19/EU became operational under UK law in January 2014. These regulations state that, when disposing of electrical and electronic equipment at the end of its useful life, it must be recycled and/or disposed of in accordance with the directive. The manufacturer or importer (the producer) of the goods is responsible for their disposal/recycling in the correct manner.

Spectrum Medical Ltd is the manufacturer and will take back waste electronic equipment which it has sold when it has reached end of life.

The Pump Console System should be returned to Spectrum Medical for disposal.

22.1 Disposal of Consumables

Any single-use items, such as centrifugal pump heads or tubing, must be disposed of in accordance with applicable local environmental laws, regulations and device Instructions for Use. Always observe hospital regulations when disposing of these items.

23 Troubleshooting

This section provides information to help you in the unlikely event that you encounter problems using you Spectrum Medical equipment.

23.1 Resetting the System

In the event of a failure, the system can be reset using the Pump Control Module, by pushing and holding two knobs for 2 seconds. The effect of this reset is determined by the status of the system and workstation:

- If the workstation or pump console are no longer running alarms are cleared and the system switched to default flow mode.
- If the workstation is operational, default mode is enabled and new settings sent to all connected devices.
- If the workstation is disconnected, pumps are set back to default settings and occluders moved to the Ready position.

23.2 Noise and Vibration

If a pump makes grinding noises or vibrates, consider the following:

- Replacing the pump.
- For centrifugal pumps, check pump heads are correctly fitted.
- Reduce pump speed to zero, then restart the pump.

Any faulty or failed pump must be returned to Spectrum Medical.

23.3 Hand Cranking Roller Pumps

In the event of power failure, roller pumps can be hand cranked.

Figure 75 – Hand Crank

To hand crank a pump:

1. Place cap of hand crank over affected roller pump.

Figure 76 – Fitted Hand Crank

2. Lift handle to the vertical position and turn the pump in the required rotation.

23.4 Lid Mismatches

In the event of a lid interlock mismatch for a roller pump, the fault can be over-ridden to permit the pump to continue working.

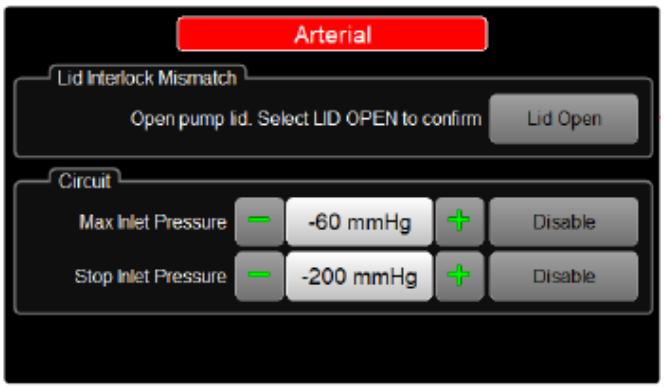


Figure 77 - Lid Interlock Mismatch

To override the mismatch, on the dynamic dialog, select Lid Open.

24 Manufacturers Contacts

24.1 United Kingdom

Telephone	UK +44 (0) 1242 650120
Fax	UK +44 (0) 8452 808127
Email	enquiries@spectrummedical.com
Web	www.spectrummedical.com
Mail	Spectrum Medical Limited Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucester, GL2 9QL United Kingdom

24.2 USA

Telephone	800 265 2331
Fax	803 802 1455
Email	ussales@spectrummedical.com
Web	www.spectrummedical.com
Mail	Spectrum Medical Inc. 481 Munn Road, Suite 180, Fort Mill SC, 29715

25 Warranty

Spectrum Medical, Inc. provides a one-year hardware warranty beginning at the time of hardware installation.

Should the hardware fail during the warranty period due to materials defects or workmanship at the time of installation, Spectrum shall, at its discretion: 1) make all necessary adjustments, repairs and replacements, subject to the terms and conditions of any relevant Agreement; and 2) replace any parts which were installed under any relevant Agreement and were found to be defective at the time of installation.

Spectrum will furnish all parts necessary for repair of the Equipment at no cost to Customer. All replacement parts will be installed on an exchange basis. Consequently, parts replaced will become the property of Spectrum upon their removal from this equipment.

This warranty shall not include the rectification of any fault resulting from:

i. Willful damage of the Equipment;
ii. the failure by the Customer to implement recommendations in respect of or solutions to faults previously advised by Spectrum;
iii. any repair adjustment, alteration or modification of the Equipment by any person other than Spectrum or Spectrum approved personnel using Spectrum Service tools and spares;
iv. the Use of the Equipment either separately or together for a purpose for which they were not designed; and
v. any changes either hardware or software made to devices connected to the Equipment that have not been approved by Spectrum.

Spectrum Medical's hardware warranty is conditional on users complying with the "instructions for use" as detailed in the product I.F.U.s and specifically excludes the failure of the monitor or its accessories due to customer misuse or damage.

A. Frame Models

A.a. Cheltenham Frame

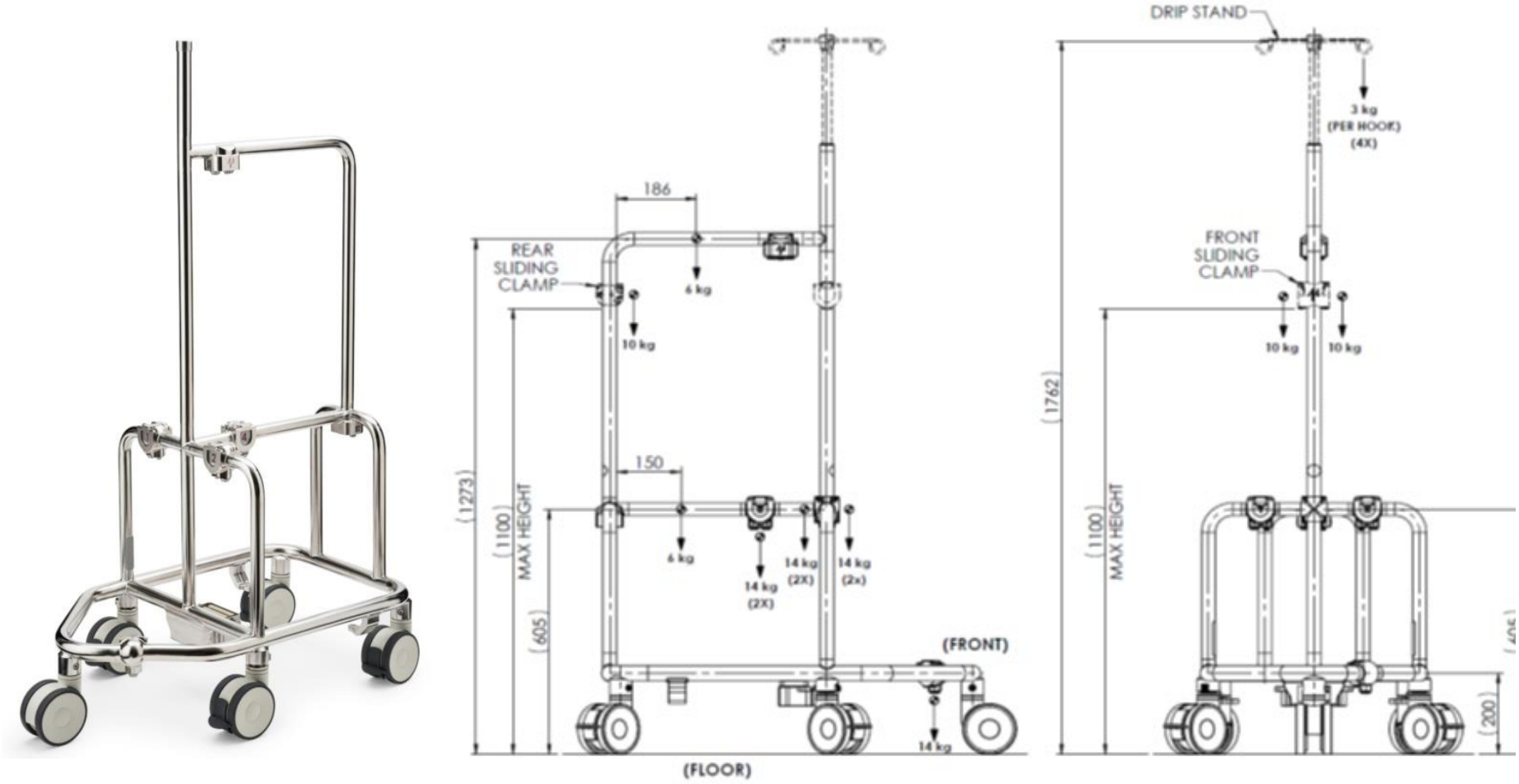


Figure 78 - Cheltenham Frame

A.b. New York Frame

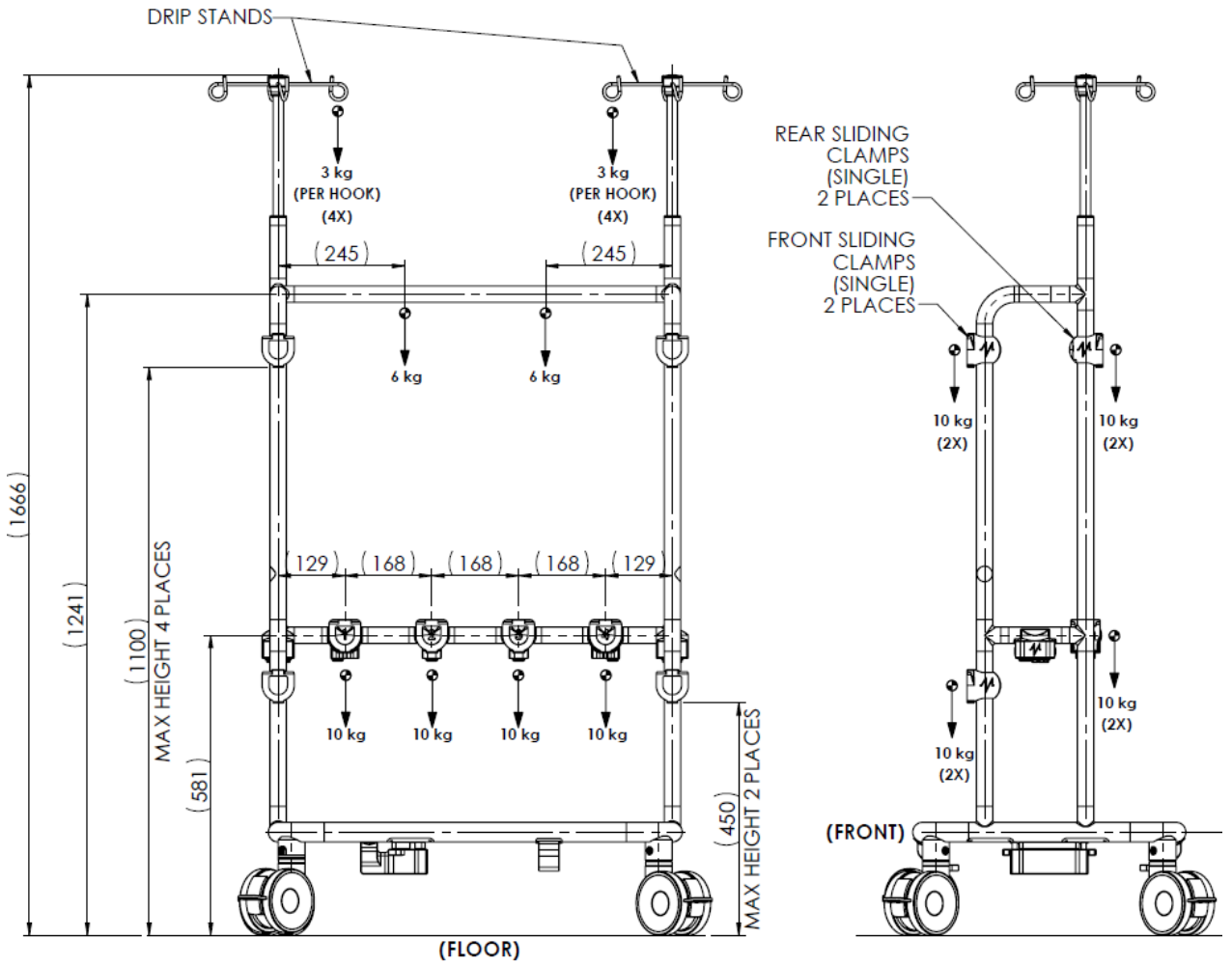


Figure 79 - New York Frame