

CentriMag™ Blood Pump Instructions For Use (IFU)

READ ALL INDIVIDUAL CENTRIMAG CIRCULATORY SUPPORT SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM OPERATION MANUAL, AND THE CENTRIMAG CLINICAL REFERENCE MANUAL BEFORE USE.

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SUPPLIED STERILE AND READY FOR USE – DO NOT USE IF PACKAGING IS DAMAGED OR ANY STERILE SEALS ARE BROKEN.

This product is not made with natural rubber latex.

For U.S. – California Only:

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

WARNING (Definition)

Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

CAUTION (Definition)

Cautions are used to alert the user to exercise special care for the safe use of the device.

DESCRIPTION

The CentriMag™ Blood Pump (Pump) is designed to allow improved blood handling and to decrease trauma by magnetically levitating and rotating the impeller and by eliminating seals and bearings. The Pump has a spinning impeller that imparts rotary motion to the incoming blood, directing it through the outlet port.

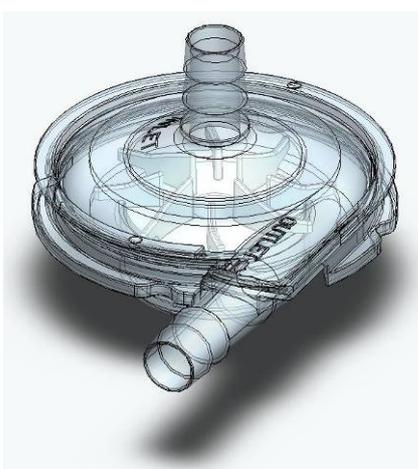


Figure 1 – CentriMag™ Blood Pump

The Pump couples to a magnetic drive motor which is connected to a console. The CentriMag Pump, Motor, Console, Mag Monitor, Flow Probe, and cannulas

comprise the core components of the CentriMag Circulatory Support System (System).

INDICATIONS FOR USE

The CentriMag Blood Pump is indicated for use as:

- Part of a cardiopulmonary or other extracorporeal bypass circuit for periods up to 6 hours [**510k-cleared Device**].
- Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy [**PMA Approved Device**].
- Right ventricular assist device [**Humanitarian Device**]. The CentriMag Circulatory Support System, when used as a right ventricular assist device, is also authorized by Federal law to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

The Pump is indicated for use only with the CentriMag System. This device is not designed, sold, or intended for use except as indicated.

CONTRAINDICATIONS

The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with Heparin or an appropriate alternative anticoagulant.

ADVERSE EVENTS

Adverse events are a known risk of mechanical circulatory support. The adverse events that may be associated with the CentriMag Circulatory Support System are listed below. Adverse events are listed in decreasing order of frequency, except for death, because it is a non-reversible complication. For complete information on all adverse events observed during these studies, please refer to the CentriMag Circulatory Support System Clinical Reference Manual.

- Death
- Bleeding
- Respiratory Failure
- Infection
- Cardiac Arrhythmias
- Right Heart Failure
- Renal Failure/Dysfunction
- Neurologic Dysfunction
- Hemolysis
- Hepatic Dysfunction
- Hypotension
- Hypertension
- Venous Thromboembolism

- Cardiac Tamponade
- Pericardial Fluid Collection
- Wound Dehiscence
- Psychiatric Episode
- Device Malfunction
- Arterial Non-CNS Thromboembolism
- Limb Ischemia
- Aneurysm
- Myocardial Infarction

WARNINGS

1. Read all individual Centrimag Circulatory Support System component Instructions For Use, the CentriMag Circulatory Support System Operation Manual, and the Clinical Reference Manual before use. Failure to read and follow all instruction, or failure to observe all stated warnings, could cause serious injury or death to the patient.
2. Ensure that the Pump and circuit have been debubbled and primed properly prior to use to minimize the risk of air entry to the patient.
3. Massive air entry into the Pump will cause the Pump to deprime and blood flow to stop. Clamp the outlet tubing, stop the Pump, and remove air prior to resuming circulation.
4. Do not expose the Pump to chemical agents as they may affect the integrity of this device. Anesthesia solutions such as forane are known to degrade polycarbonate plastics.
5. To prevent backflow of the patient's blood when the Pump outlet tubing is open, establish and maintain a minimum pump speed that overcomes line and patient resistance. Failure to do this could allow retrograde flow and limit arterial pressure.
6. A Pump stoppage will create a reverse flow shunt through the Pump, as well as limit the body's ability to maintain adequate arterial pressure. If the Pump is stopped, clamp the outlet tubing from the Pump to prevent a low flow, low pressure, and reverse flow condition. The tubing clamp must be removed before returning to normal pumping activity.
7. It is intended that systemic anticoagulation be utilized while this device is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient.
8. The Pump is designed to be operated only with the Console. There are no safety or performance data known to Abbott Medical which establishes compatibility of any other manufacturer's devices or components to the CentriMag Circulatory Support System.
9. Potential risk to the patient should be evaluated prior to changing a Pump.
10. Frequent patient and device monitoring is recommended.
11. Do not use the Pump if the "Use Before" Date on the package has expired.
12. Do not operate the Pump in the absence of forward flow. The temperature within the Pump will rise and increased cellular damage and clotting may result.
13. The Pump must be handled in an aseptic manner until primed and connected to a closed tubing circuit.
14. Do not operate the Pump with its inlet tubing clamped as a negative pressure will be generated in the Pump and air bubbles may be formed in the priming fluid or blood.
15. Monitor the patient's hemodynamics and the Console Flow display to ensure adequate blood volume for the inlet cannula position, Pump RPM, and desired flow. Increase the Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing inlet cannula obstruction, suction, outgassing, and/or cavitation.
16. As with all continuous flow pumps, operating at too high a speed can result in negative pressure at the inlet which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, inspiration of air, outgassing, cavitation and increased risk of embolism. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped and clinically acceptable circulatory support.
17. The Pump contains a magnet. To avoid injury, keep all sharp metal objects and instruments at least six inches away from the Pump. Do not remove the Pump from its inner tray until ready to assemble within the circuit and insert pump into the motor receptacle.
18. If the Pump's operation is ever halted or flow reduced, consideration should be given to monitoring and adjustment of the patient's anticoagulation status.
19. Do not restart the Pump if the Pump has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Pump, extracorporeal circuit, connectors, and cannulae.
20. Monitor the Pump and tubing for air because the Pump, similar to other centrifugal pumps, will pump air immediately. Clamp the Pump outlet tubing if air enters the Pump as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury. A massive air embolus will deprime the Pump, halting blood flow.

21. Use of the Pump for periods longer than 30 days may result in Pump failure, reduced pumping capacity, excessive blood trauma, and/or degradation of blood contact materials (with possible particles passing through the cannulae to the patient), leaks, and increased potential for gaseous emboli.
22. The safety and effectiveness of use of the CentriMag System in an ECMO circuit (i.e. cardiopulmonary support > 6 hours) has not been demonstrated.
23. The safety and effectiveness of use of the CentriMag System for use > 30 days has not been demonstrated.
10. Do not operate the Pump when unprimed as it may damage the Pump impeller.
11. Run the Pump only on a properly maintained Console and Motor.
12. Do not use the Pump if it has been dropped. Dropping or other severe shock may cause damage which could lead to device malfunction.
13. Do not use excessive force to install tubing on the Pump as damage to the Pump and 3/8" pump ports may occur.
14. Take care to prevent damage to Pump connectors when setting up and de-airing the Pump.

CAUTIONS

1. Use of this device should only be by or on the order of a physician.
2. This device should only be used by persons thoroughly trained in extracorporeal circulation procedures.
3. Do not hit or strike the Pump with hands, objects, or instruments. Do not strike the Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.
4. The Pump is provided sterile in an unopened and undamaged unit package. Inspect the device and package carefully prior to use. Do not use if the unit package or the product has been dropped, damaged or soiled.
5. Each Pump is intended for single use only. Safely dispose of the Pump after single use to avoid risk of infection.
6. Attach tubing to the Pump in such a manner as to prevent kinks or restrictions that may alter flow or cause regions of stasis or turbulence. Attach in a manner that does not bend or fracture the tubing connectors or ports. Advance the tubing beyond the second barb point of the Pump connectors.
7. The inlet and outlet tubing and cannulae connections must be secured with two small (approximately 3.94 in (10 cm length)) cable-ties or tie bands on each connector. The locking mechanisms of the two ties should be oriented 180 degrees from each other to insure a tight seal of the tubing to the connector.
8. Ensure the Pump is properly locked into the Motor per the Instructions for Use supplied with the Motor.
9. Monitor carefully for any signs of occlusion throughout the circuit.
15. Always have a backup CentriMag Pump, Console, Motor, and accessories available for use.
16. Do not place the Pump near items adversely affected by magnetic fields.
17. Only use flow probes supplied by Abbott Medical with the CentriMag Circulatory Support System.

PACKAGE CONTENTS

The sterile Pump package contains:

- One CentriMag Blood Pump
- Product documentation

INSPECTION PRIOR TO USE

1. The package containing the Pump should be inspected prior to use for any damage to the sterile barrier. The package seals should be intact to ensure sterility. Do not use the Pump if the associated package is damaged. Contact Abbott Medical regarding return of any damaged product.
2. The Pump should be inspected prior to use for any damage or particulate matter contamination. Do not use the Pump if damaged or if any particulate matter is found on or inside the Pump. Contact Abbott Medical regarding return of any suspect Pump.

ACCESSORIES

The following accessories are required to use the Pump:

- One drainage cannula
- One return cannula
- Tubing (drainage and return sections)

Abbott Medical recommends use of the CentriMag Drainage and Return Cannula Kits, but equivalent commercially available venous and arterial cannula can be used at the preference of the clinician. Any commercially available medical grade 3/8 inch (9.5 mm)

inner diameter PVC tubing and barbed tubing connectors can be used.

PRE-PUMPING CHECKLIST

1. Connect the Motor to the Console.
2. Check that all electrical connections are secure including the flow probe and AC power cord.
3. Test the Console by powering it up; verify that there are no self-test errors upon boot-up.
4. Check the date and integrity of the sterile Pump package, sterile cannulae, sterile tubing and connectors.
5. Check that a flow probe is included with the Console and is clean and ready for use.

PUMP SETUP AND OPERATION

The CentriMag™ Circulatory Support System is designed to be operated safely during use of ESU's (electrosurgery or electrocautery units). An ESU, a frequently used RF technology, is used to cut, cauterize, fulgurate or desiccate tissue. Note: ESUs have the potential for interfering with other medical devices found in the operating and ICU room environment.

If the Console is used concurrently with an Electrosurgery unit, Abbott Medical recommends the user to read and follow the electrocautery manufacturer's instructions for prevention of interference with other electronic devices.

Follow the system preparation directions in the CentriMag Circulatory Support System Operation Manual. Inspect the complete system; do not use a malfunctioning or damaged system.

1. To mount the Pump on the Motor, remove the Pump from the inner tray and insert the Pump into the motor receptacle. Place the bottom of the Pump into the motor receptacle with the outlet port positioned in the large groove. Match the grooves on the periphery of the Pump with the fittings on the motor receptacle. Rotate the Pump counterclockwise until the Pump locks securely into place. Thread the retaining screw clockwise to secure in place. The Pump must be fully seated into the receptacle to function properly.

Note: If the Pump is not properly seated, a "Pump Not Inserted" alarm will be displayed on the Console display.

2. To remove the Pump from the Motor, unthread the retaining screw counterclockwise, and then rotate the Pump clockwise until the grooves are matched. Lift and remove the Pump.

3. Fill a sterile basin with sterile heparinized saline. Use 10,000 units of Heparin per liter saline. Remove from packaging and submerge into the heparinized saline the following four components:

- Two 3/8 X 3/32 inch (9.5 X 2.4 mm) (4') sterile tubing sets,
- One inlet drainage (venous) cannula,
- One outlet return (arterial) cannula, and
- One tubing interconnector 3/8 X 3/8 inch (9.5 X 9.5 mm) Sterile Straight Barbed Connector without Luer Lock .

4. Insert the outlet cannula into a systemic (LVAD) or pulmonary (RVAD) artery by standard technique with the supplied introducer and Trocar from the outlet cannula kit. Clamp the outlet cannula approximately 25 mm (1 inch) from the 3/8" connector as the Trocar is removed to prevent blood loss. Secure the outlet cannula in place with double purse string suture. Carefully bleed the outlet cannula by gently unclamping restriction and letting any air bubbles out.

WARNING

Do not over tighten sutures when securing cannulae to tissues and vessels. Over tightened sutures may result in obstruction and interruption of blood flow through the cannulae. Suturing used to secure cannula must be made with sufficient tension to hold the cannula in place over the full range of patient activity. Failure to effectively secure cannulae in place poses risk of decannulation, bleeding, or air embolus.

5. After the outlet cannula has been surgically inserted and externalized, connect one of the pre-wetted, filled and debubbled extension tubes to the barbed connector of the outlet cannula. Debubble and clamp the tubing at a length beyond the anticipated final tubing length.
6. Fill the inlet cannula with sterile heparinized saline. Clamp at approximately 25 mm from the distal end of the inlet cannula where there is no reinforcing spring. Place the inlet cannula directly into the left (LVAD) or right (RVAD) ventricle (or respective atrium) by means of a surgical incision, and then secure it in place with a pledgeted purse-string suture to the ventricular apex. Ensure that the cannula tip does not compromise the valves of the Ventricle.
7. Allow blood to displace any air within the inlet cannula by holding the distal end vertically, and partially unclamp to gently let any air escape.
8. After the inlet cannula has been surgically inserted and externalized, take the pre-wetted 3/8 X 3/8 inch

(9.5 X 9.5 mm) barbed connector and insert into the inlet cannula.

9. Take the remaining pre-wetted, filled and debubbled extension tubing set and connect to the barbed connector on the inlet cannula. Debubble and clamp at a length beyond the expected final tubing length.
10. Prime and debubble the Pump by flushing through the outlet port while debubbling through the inlet port. Eliminate air from the device by "walking" the air out of the inlet.
11. Cut the outlet extension tubing to a length based on the desired final location of the Pump.
12. Connect the outlet tubing to the outlet port of the Pump taking care to clear the flow path of bubbles. This can be accomplished by continuously irrigating the connection with sterile heparinized saline solution while mating.
13. Position the inlet tubing immediately adjacent to the inlet of the Pump and determine the correct length for the extension tubing. Clamp the extension tubing between the cannula and the Pump inlet port. Cut the extension tubing to length. Fully fill both the inlet tubing and Pump with the sterile heparinized saline solution. While continuously irrigating, make the connection.
14. With the inlet tubing unclamped, and the outlet tubing clamped, turn the Console ON.
15. Connect the flow probe to the outlet tubing according to the instructions provided in the CentriMag Circulatory Support System Operation Manual.

WARNING

Do not reverse the inlet and outlet cannulae connections. Reversal of inlet and outlet cannulae will limit circulatory support. Always use care in determining the direction of flow when connecting the CentriMag Pump to the cannulae to avoid physical harm to the patient.

CAUTION

Do not hit or strike the CentriMag™ Pump with hands, objects, or instruments. Do not strike the CentriMag Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.

WARNING

Ensure that the CentriMag Pump and circuit have been debubbled and primed properly to minimize the risk of air reaching the patient.

WARNING

Massive air entry into the Pump will cause the Pump to deprime and blood flow to stop. Clamp the outlet tubing, stop the Pump, and remove air prior to resuming circulation.

WARNING

Do not operate the Pump in the absence of forward flow. The temperature within the Pump may rise and increased cellular damage may result.

WARNING

Do not operate the Pump with the inlet tubing or cannula clamped as a negative pressure will be generated in the Pump and bubbles may form in the Pump.

16. Remove all remaining tubing clamps, bring the Pump's RPM up to a sufficient speed to achieve a positive flow, inspect the integrity of the Pump, the tubing, and the connections. If any anomalies are noted, immediately stop the Pump, clamp the outlet tubing and correct the anomaly before unclamping and restarting.

CAUTION

Placing a tubing clamp on the tubing near a tubing connection point can damage the connector, resulting in thrombus formation at the area of the damage.

WARNING

If leaks or other anomalies are found in the circuit, remove the Pump and replace with a new, sterile Pump, repeating the above steps to prime.

17. Increase RPM to produce desired flow.
18. Set the Console's low flow alarm to the desired minimum flow point.
19. Secure the motor in order to maintain its location in relation to the patient.

WARNING

The Motor must be immobilized near the patient. Failure to immobilize the Motor could lead to unanticipated movement of the Motor resulting in stress on the cannulae.

WARNING

As with any continuous flow pump, operating at too high a speed can result in negative pressure at the inlet which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, inspiration of air, out gassing, cavitation and increased risk of embolism. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped, cannulae placement, and clinically acceptable circulatory support.

CAUTION

Any time the Pump is stopped, the pump outlet should be clamped to prevent retrograde flow. The clamp used should be a smooth jawed tubing clamp.

EMERGENCY BACKUP EQUIPMENT

1. A backup Console must be plugged in with the motor and flow probe connected (if designed to accommodate a flow probe), and kept near the patient ready for use.
2. A backup sterile Pump and supplies to prime must be available.
3. Backup power must be available.
4. Two smooth jawed tubing clamps.

CLEANUP AFTER USE

1. Turn OFF power to the main and backup Consoles.
2. Properly discard disposable components according to hospital procedure for contaminated materials.
3. Clean the Console and Motor according to established hospital procedure.
4. Clean the flow probe according to established hospital procedure.
5. Reconnect the Consoles to AC power to maintain charge on batteries.

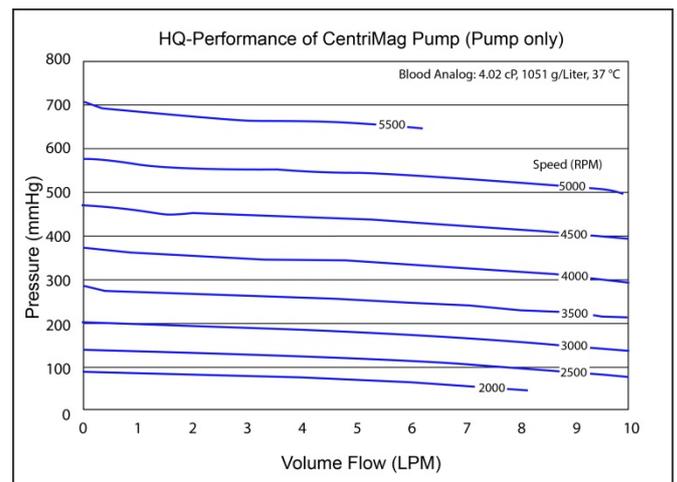
EMERGENCY PUMP REPLACEMENT

In some instances when the Pump has been OFF for more than five minutes, or if there has been a Motor overheating condition, it will be necessary to either terminate pumping or replace the Pump.

To replace the Pump, disconnect the Pump from the Motor and any affected tubing. Attach the replacement Pump per the standard procedures described above, prime and debubble. Operate the Console as described in the CentriMag Circulatory Support System Operation Manual.

PRESSURE VS FLOW GRAPH

The Pump output is pressure responsive. In the graph below, the Pump flow rate (LPM) versus the outlet pressure (mmHg) is plotted at a variety of pump speeds. This graph is for informational purposes only and does not necessarily reflect the rates to be achieved under clinical conditions.



Note: Actual obtainable flow is dependent on the difference between the preload and afterload of the Pump (pump pressure differential), the resistance to flow through the extracorporeal circuit components (cannulas, tubing, etc.) and the patient hemodynamics (intravascular pressures, cardiac output, and available volume).

PUMP SPECIFICATIONS

Blood contact materials: Polycarbonate
 Pump priming volume: 31 ml
 Pump rotational range: 0-5,500 RPM
 Outflow capacity: (see graph) 0-10.0 LPM
 Outflow pressure: (see graph) 0-600 mmHg
 Connects to 3/8 inch (9.5 mm) I.D. tubing

STORAGE CONDITIONS

Temperature: 0 – 40°C (32 – 104°F)

OPERATING CONDITIONS

Temperature: 15 – 40°C (59 – 104°F)

PRODUCT RETURNS

Prior to returning any product, contact your Abbott Medical Customer Service Representative for a return authorization and instructions.

SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols used on the Pump package:

Symbol	Description
	Manufacture Date
	Temperature limitation
	Contents of Package
Rx Only	Caution: Federal U.S. law restricts this device to sale by or on the order of a physician.

Symbol	Description
	Catalog Number
	Lot Number
	Use By Date
	See Instructions for Use
	Single Use Only
	Sterilized By Ethylene Oxide
	Pyrogen free
	Manufacturer

CentriMag™ Circulatory Support System Operation Manual

READ ALL INDIVIDUAL CENTRIMAG CIRCULATORY SUPPORT SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CLINICAL REFERENCE MANUAL, AND THE ENTIRE CONTENTS OF THIS MANUAL BEFORE USE.

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1 MANUAL OVERVIEW

This manual provides technical information and use instructions for the CentriMag™ Circulatory Support System (System). The Clinical Reference Manual contains clinical use information on the System to help guide healthcare professionals. The user must understand and follow both manuals. The following summarizes the content of each section of this manual.

- Section 1:** **Manual Overview** describes the organization of this Manual.
- Section 2:** **Indications & Contraindications** describes the intended use of the System.
- Section 3:** **General Conventions** describes warnings, cautions, and conventions of expression used in this Manual. Also, this section describes the Patents and Trademarks involved.
- Section 4:** **Warnings & Precautions** describes warnings and cautions to be considered when using the System.
- Section 5:** **Device Description** describes the System and each element within the System.
- Section 6:** **Specifications and General Description** describes the product specifications and physical attributes of the System.
- Section 7:** **Setting up the System** describes the procedure for unpacking the System and configuring it for use.
- Section 8:** **System Operation** describes how to operate the Console.
- Section 9:** **Maintenance** describes procedures for maintaining and cleaning the System.
- Section 10:** **Emergency** describes procedures for managing the Console during defibrillation and in the event of equipment malfunction.
- Section 11:** **Disposal of Equipment** describes the procedure for proper disposal of used Console batteries and Consoles that have reached end of useful service life.
- Section 12:** **Appendices**
- Appendix I:** **Alarm/Alert Table** lists the Console's audio/visual alarms and alerts and the expected System and operator response to each alarm or alert condition.
- Appendix II:** **Technical Specification** lists the product specifications and physical attributes of the Console.
- Appendix III:** **Electromagnetic Emissions** describes the electromagnetic environmental conditions under which the System may be operated.
- Appendix IV:** **Electromagnetic Immunity** describes the electromagnetic environmental conditions under which the System may be operated.

2 INDICATIONS AND CONTRAINDICATIONS

2.1 Indications for Use

The CentriMag™ Circulatory Support System and its components may be used only for their intended purpose. The indications for use for the individual system components vary within the United States. Refer to the table below for specific Indications For Use by device product name.

Indications for Use Chart			
Product Name and Market Application Number	Refer to Label Part No.	Required US Caution Statement(s)	Indications for Use
CentriMag Circulatory Support System PMA P170038	PL-0047, CentriMag Circulatory Support System Operation Manual	Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.	The CentriMag Circulatory Support System is indicated for use as temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy [PMA Approved Device] .
CentriMag Right Ventricular Assist System (RVAS) HDE H070004	PL-0085, CentriMag RVAS (Pump) IFU	Right ventricular assist device [Humanitarian Device] . The CentriMag Circulatory Support System, when used as a right ventricular assist device is also authorized by Federal law to provide temporary circulatory support	Right ventricular assist device [Humanitarian Device] . The CentriMag Circulatory Support System, when used as a right ventricular assist device is also authorized by Federal law to provide temporary circulatory support

Indications for Use Chart			
Product Name and Market Application Number	Refer to Label Part No.	Required US Caution Statement(s)	Indications for Use
		for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.	for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.
CentriMag Extracorporeal Blood Pumping System K020271 K051209 K053630 K081221 K083340 K090004 K102129 K131179	PL-0070, CentriMag Blood Pump IFU	Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.	The CentriMag Blood Pump is indicated for use with the 2 nd Generation CentriMag Primary Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (CPB) for up to six hours. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete CPB (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.) This device is not designed, sold, or intended for use except as indicated.
PediMag Blood Pump	PL-0112, PediMag Blood Pump IFU	Federal (U.S.A.) law restricts this device to sale, distribution	The PediMag Blood Pump is indicated for use only with the

Indications for Use Chart			
Product Name and Market Application Number	Refer to Label Part No.	Required US Caution Statement(s)	Indications for Use
K090051		and use by or on the order of a physician.	2 nd Generation CentriMag Primary Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (CPB) for up to six hours. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete CPB (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.) This device is not designed, sold, or intended for use except as indicated.
CentriMag Drainage (Venous) Cannula Kit K110983 K152190	PL-0220, CentriMag Drainage (Venous) Cannula Kit IFU	Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.	The CentriMag Drainage (Venous) Cannula is indicated for use with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.
CentriMag Return (Arterial) Cannula Kit K110980 K152161	PL-0221, CentriMag Return (Arterial) Cannula Kit IFU	Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.	The CentriMag Return (Arterial) Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal

Indications for Use Chart			
Product Name and Market Application Number	Refer to Label Part No.	Required US Caution Statement(s)	Indications for Use
			circulatory support for periods up to six hours.

2.2 Contraindications for Use

The CentriMag™ Circulatory Support System is contraindicated for use as a cardiomy suction device. The System is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

3 GENERAL CONVENTIONS

3.1 Warnings and Cautions

Read and observe all **WARNINGS** and **CAUTIONS** listed in this Manual and observe relevant instructions and safety precautions throughout operation of the System.

WARNING (Definition)

Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

CAUTION (Definition)

Cautions are used to alert the user to exercise special care for the safe and effective use of the device.

Warnings are located within the text of the subject matter to which the warning relates. For this reason, some of the warnings are included in more than one section.

3.2 Patents and Trademarks

Patents: One or more patents or published applications cover this product and its use.

Trademarks: TM Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

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3.3 Conventions Used in This Manual

Switches, keypads and connections on the Console and Monitor are indicated in **NORMAL FACE TYPE IN UPPER CASE** (e.g., POWER, STOP).

The Console and Monitor displays are indicated in **BOLD FACE TYPE IN UPPER CASE** (e.g., **SET SPEED, INCREASE, DECREASE, ON BATTERY**).

The first letter in the name of each System component is capitalized (e.g., Pump, Motor, Console and Monitor).

The headers for warnings are in red and the headers for cautions are in yellow.

4 WARNINGS AND PRECAUTIONS

WARNING

Read this entire manual before you use the CentriMag System. As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. The physician must be trained on the use of the System before using it. The professional staff at Abbott Medical regularly provide laboratory training and on-site, in-service programs. For information, please contact your local Abbott Medical Clinical Field representative.

WARNING

The System is designed to be operated only with the CentriMag and PediMag Pumps. There are no safety or performance data that establish compatibility with any other manufacturer's device or components.

WARNING

One additional CentriMag Console, Motor and Flow Probe are required as backup components in the immediate vicinity of each patient whenever the CentriMag or PediMag Pump is used. The backup Console must be connected to the backup Motor and to the backup Flow Probe, have a battery charge sufficient for at least one hour of operation, be connected to AC power (except during transport) and be immediately available should the main Console, Motor or Flow Probe experience a malfunction.

WARNING

The safety and effectiveness of use of the System in an ECMO circuit (i.e. cardiopulmonary support > 6 hours) has not been demonstrated.

WARNING

The safety and effectiveness of use of the System for use > 30 days has not been demonstrated.

WARNING

Only use parts supplied by Abbott Medical. Do not modify the System in any way as there are no safety or performance data that establish compatibility with any other manufacturer's device or components. Use of any other component may result in a sudden Motor stop.

WARNING

Before use of the CentriMag System, always ensure that all components of the System are properly mounted with Abbott Medical elements. Improper mounting can cause malfunction of the System.

CAUTION

The System is intended for use in all establishments, such as hospitals and medical centers, but not in domestic/residential buildings and environments.

5 DESCRIPTION

5.1 General Overview

The CentriMag™ Circulatory Support System is designed to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support.

The core components of the System consist of a CentriMag™ or PediMag™ Blood Pump, CentriMag Console, Motor, Mag Monitor, Flow Probe, cannulas, and a second system as a backup. Standard medical grade use tubing is not provided.

You can use the Console and Monitor with both of the Pumps. For each Pump, the Console is operated in an identical manner and has the same Console display, alarms, and alerts.

Additional information regarding the individual components of the system, including optional accessories, can be found in the sections below.



Figure 1: CentriMag™ Blood Pump



Figure 2: PediMag™ Blood Pump



Figure 3: CentriMag Motor



Figure 4: 2nd Generation CentriMag Primary Console



Figure 5: Mag Monitor



Figure 6: Flow Probe

5.1.1 CentriMag™ Circulatory Support System Components

The components listed in **Table 1** comprise the main and backup Systems. When a patient is supported on the main System, the backup System must be available in the immediate vicinity of the patient. A backup System must also accompany a patient during transport.

Table 1: Main & Backup System Elements		
System Component	Main System	Backup System
2 nd Generation CentriMag Primary Console	✓	✓
Motor	✓	✓
Mag Monitor	✓	
Flow Probe (em-tec Adult Flow Probe and em-tec Pediatric Flow Probe)	✓	✓

5.1.2 Optional CentriMag™ Circulatory Support System Components

The following components are available as optional accessories for the System (**Table 2**):

Table 2: Optional Elements for the CentriMag and PediMag Systems	
System Component	Image
System Cart	
Motor Bracket	

Table 2: Optional Elements for the CentriMag and PediMag Systems

System Component	Image
Monitor Arm	
Monitor Clamp	
Console Standoff	
CM Distance Holder	
Pressure Transducer Cables	

Table 2: Optional Elements for the CentriMag and PediMag Systems

System Component	Image
	(picture for reference only)
Pressure Transducers	 <p data-bbox="852 757 1235 790">(picture for reference only)</p>

5.1.3 CentriMag and PediMag Blood Pumps

The CentriMag and PediMag Blood Pumps are electronically-driven, centrifugal Pumps based on bearingless motor technology. The centrifugal Pump allows pumping without mechanical bearings and seals. The basic bearingless centrifugal principle is shown in **Figure 7**. An impeller is floating and rotating in the magnetic fields of a stator without mechanical contact. A compact digital signal processor system with a servo amplifier allows precise regulation of the impeller location and speed.

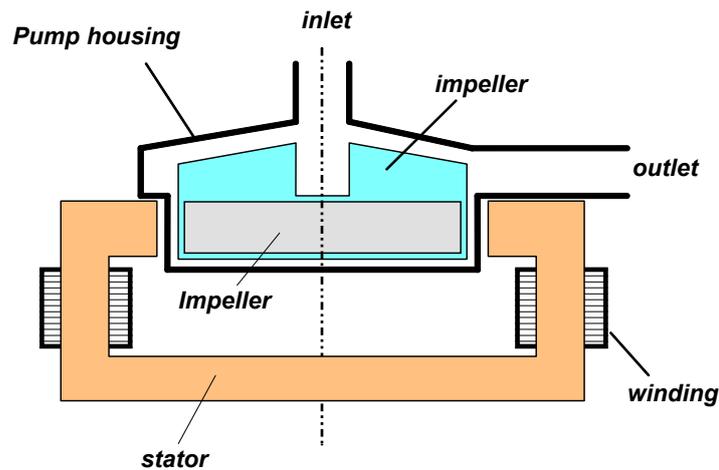


Figure 7: Schematic depicting the basic principle of the bearingless centrifugal Pump and Motor

External position sensors actively control the radial impeller position. Processor-controlled electronics regulate the magnetic fields so that the impeller is always centered. The electronics control precise regulation of the radial impeller position and the speed. Axial position and tilting of the impeller are passively stabilized (**Figure 8**). The non-contacting impeller is levitated by magnetic fields through the walls of the Pump, and floats in the center of the Pump.

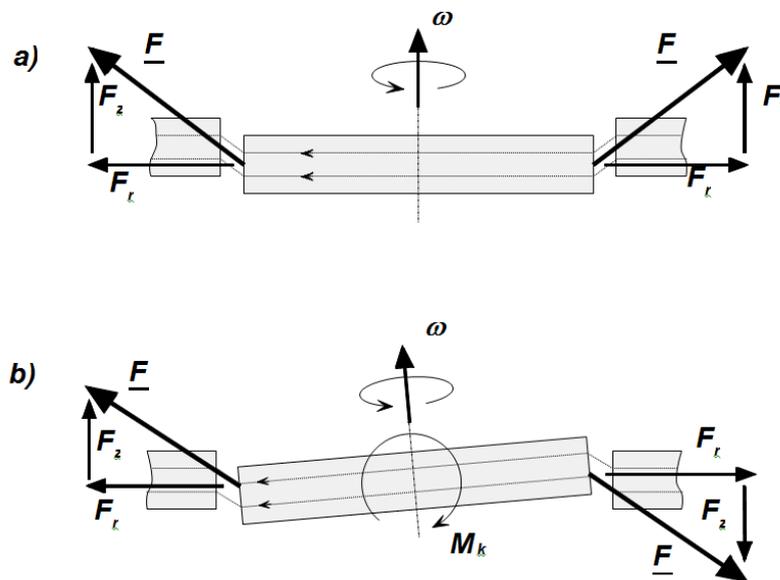


Figure 8: Axial support (a) and stabilization against tilting (b) of the impeller by passive magnetic forces in the Pump

5.1.4 Mag Monitor

The Console is designed to be used with a Mag Monitor. The Monitor may be used with one or two Consoles when a patient is supported in either a univentricular or biventricular support mode, respectively. The Monitor permits the user to redundantly display data pertaining to System performance and status along with the Console display. When activated, the user is able to view System data directly on the Console display or the Monitor. A second function of the Monitor is to provide a redundant user interface to control Motor and Pump function. For detailed information regarding the Monitor, refer to the Monitor Connection section (**Section 7.24**).

The Monitor is designed for use only with the Console when the System is stationary and powered on AC. In combination with the Console Version 2, the Monitor can be powered on battery as well. The runtime of the battery will shorten if the Monitor is used when the System is operated on battery.

In the univentricular mode, one Monitor is connected to one Console. In the biventricular mode, one Monitor is connected to two Consoles. The display on the Monitor then displays data from both of the Consoles. The data from the Console used to support the left side of the heart are displayed in red, whereas the data from the Console used to support the right side of the heart are displayed in blue.

Should the Monitor be disconnected or fail, the Console may be operated independently with the relevant operational data displayed on the Console display. When the Monitor is active, control of Motor and Pump function may be accomplished using either the Monitor or the Console.

If a Monitor is unavailable, the Pump and Motor can be controlled via the Console. When operated in this manner, a number of interactive features that can only be accessed via the Monitor will not be available. These include the stopwatch function (**Section 7.15**), graphical displays of the pressure, as well as flow and alarm limits (**Sections 7.12 through 7.14**).

In the absence of the Monitor, the data log function is not accessible. In addition, data recording will be limited to the previous 16 hours of data. If a Monitor is connected to the Console, it will be able to display the previous 16 hours of data collected by the System.

Table 3: The System with and without the Monitor summarizes the differences between the System with and without the Monitor.

Table 3: The System with and without the Monitor

System Component	Monitor Display & Functions	Console Display & Functions
Display of flow and RPM	✓	✓
Control of flow, RPM and auxiliary settings	✓	✓
Alarm limits for flow and pressure	✓	✓
Stopwatches	✓	
Multicolor display including flow and visual representation of flow, pressure and alarm limits	✓	
Use of the data log and display System	✓	

5.1.4.1 Front Panel

The role of the Monitor (**Figure 5 and Figure 6**) is to display data from the Console and to provide an alternative means of controlling the Console via the soft touch keys on the Monitor. An LCD screen on the Monitor is used to display operational data, System options, and menus. Operator settable alarms and parameters are accessible via the System menus. Data from up to two Consoles can be displayed simultaneously on one Monitor.

5.1.4.2 Back Panel

5.1.4.2.1 Console Connection

The Monitor back panel (**Figure 9**) provides the required electrical inputs and outputs needed to connect the Monitor to one or two Consoles. Each connector provides the input from, and output to, one Console.

5.1.4.2.2 USB port – Logger Data

As shown in **Figure 9**, a USB port is provided on the rear panel of the Monitor between the two round connectors. The USB port provides access by a USB Memory Stick to download logger data stored in the Monitor.

5.1.4.2.3 Ethernet – Disabled

The Monitor provides an Ethernet port on the back panel as shown in **Figure 9**. The Ethernet port is disabled and intended for future use in the US.

5.1.4.2.4 RS232 – Live Data

The Monitor provides an additional RS232 port on the back panel as shown in **Figure 9**. The RS232 port provides a live data stream. For additional information, contact your local Abbott Medical representative. Do not use the RS232 port without contacting your local Abbott Medical representative.

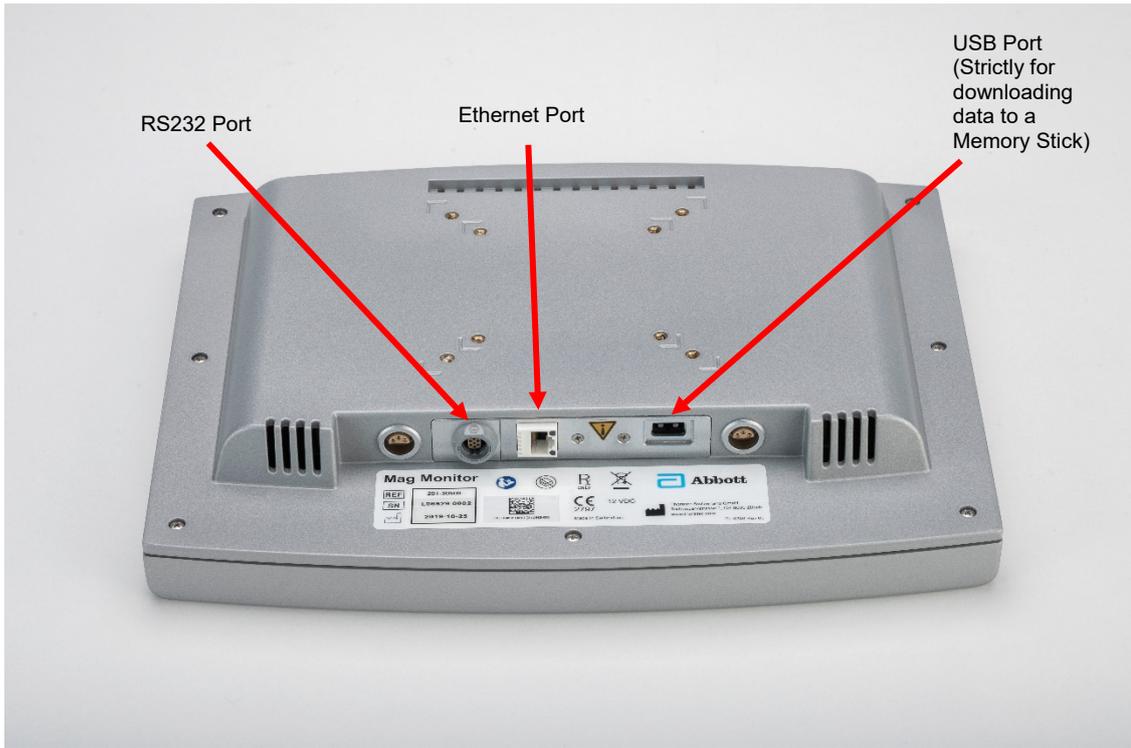


Figure 9: Monitor Back Panel

CAUTION

The Monitor is intended for use only with the 2nd Generation CentriMag Console.

WARNING

The Monitor can only be operated when it is connected to the 2nd Generation CentriMag Console. The Monitor may be operational on AC power or, in combination with the Console Version 2, on battery. Operating the Monitor while the Console runs on battery shortens the battery runtime. Refer to the individual RVAD or LVAD Console display for all operational data and audio/visual alarm messages.

WARNING

Only USB-compatible Memory Sticks may be used to connect to the USB Port of the Monitor. No other USB device may be used with the USB port (e.g. printer).

5.1.5 2nd Generation CentriMag Primary Console

The Console uses single-phase AC power when used with the CentriMag Pump. The Pump is capable of a flow rate of up to 10.0 LPM or maximum pressure head of 600 mmHg. Flows up to 1.5 LPM or a maximum pressure head of 540 mmHg may be generated with the PediMag Pump and circuit. In addition, each Console contains a rechargeable internal battery that is capable of maintaining Console functionality in the event of a loss of AC power.

5.1.5.1 Front Panel

The Console (**Figure 10** and **Figure 11**) is a microprocessor-based device. The microprocessors generate the primary Motor control signal. The Monitor sensors generate front display outputs and provide alarm functions. The microprocessors acquire the sensor data for use in generating operator displays and alarms. A graphical screen is used to display monitored data, System options, and menus. Operator settable alarms and parameters are accessible via the System menus.



Figure 10: Front Panel

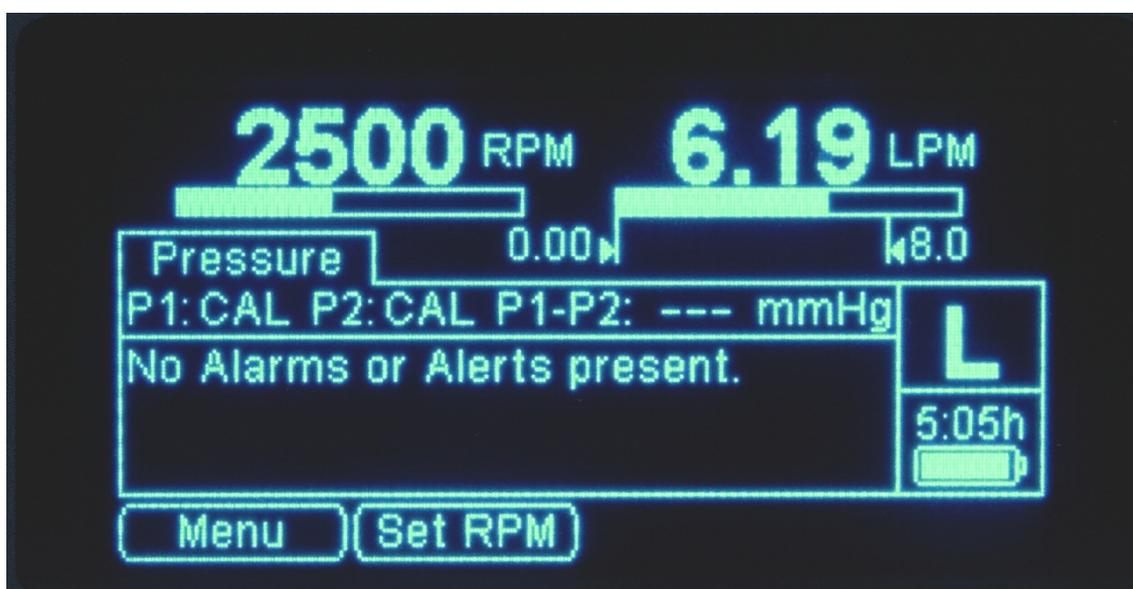


Figure 11: Digital Display

Flow Probes in two sizes are available for use with the Console. Each Flow Probe is a reusable, non-patient contacting ultrasonic Flow Probe which is optimized to detect flows from 0-10.0 LPM or 0 – 3.0 LPM depending on probe size.

The Flow Probes can detect retrograde flow. Retrograde flow of up to 2.0 LPM is displayed as a negative number such as “-0.65 LPM”. Retrograde flow greater than 2.0 LPM is displayed as downward arrows “vv.vv LPM”. A disconnected or malfunctioning probe will display dashes “--.--”. If the probe detects forward flow of more than 10 LPM then it will display as “^^.^^ LPM”.

The Flow Probe used with the CentriMag™ Pump is an em-tec Adult Flow Probe that is compatible with 3/8” ID PVC tubing with a 3/32” wall thickness. The Flow Probe used with the PediMag™ Pump is an em-tec Pediatric Flow Probe that is compatible with 1/4” ID PVC tubing with 3/32” wall thickness. Both probes incorporate a molded clip-on design for easy care and handling.

5.1.5.2 Back Panel

The Console back panel (**Figure 12**) provides the required mechanical inputs and outputs needed to operate a CentriMag or PediMag Pump.

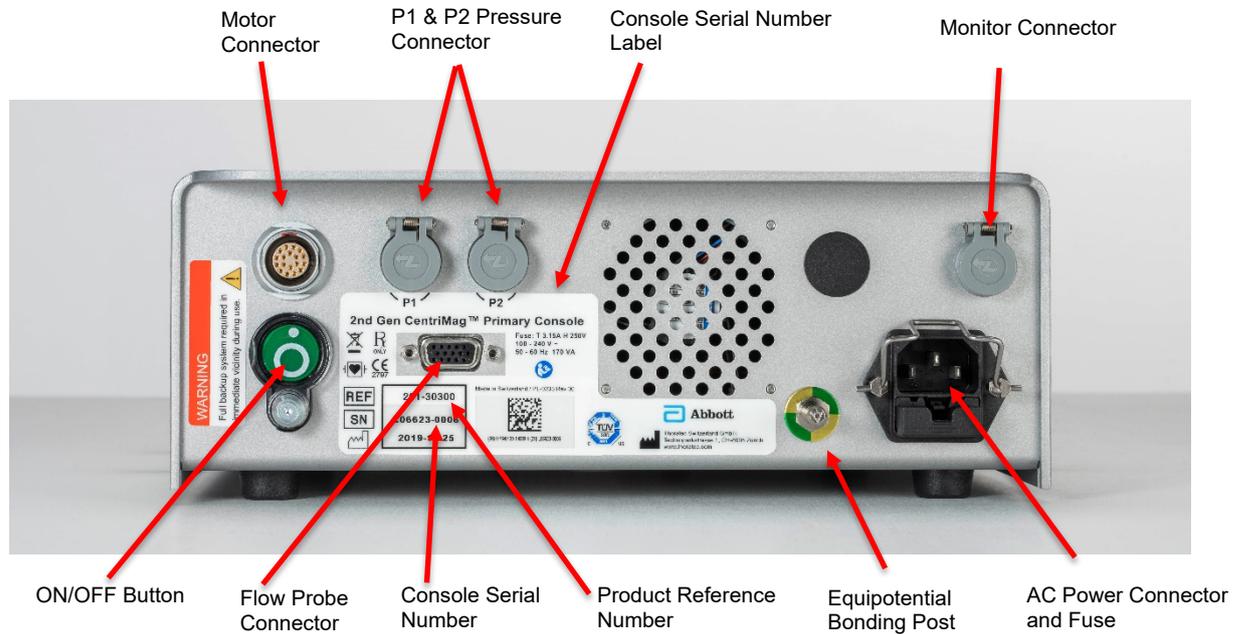


Figure 12: Back Panel

5.1.6 CentriMag™ and PediMag™ Blood Pumps

The System uses a sterile, single-use, disposable, polycarbonate, CentriMag™ or PediMag™ Pump (Figure 13 a and b). The use of magnetic levitation eliminates the need for bearings and seals in the blood pathway. Elimination of these components is designed to minimize blood trauma and the potential for hemolysis and thrombus formation. The Pumps are designed to move blood by centrifugal force created by the magnetically-suspended rotating impeller.



Figure 13: a) CentriMag Pump

b) PediMag Pump

The blood flow is dependent upon the amount of blood entering the Pump, the Pump speed (RPM), the extracorporeal circuit resistance, and drainage and return blood pressures. The relationship between pressure and flow rate as a function of RPM can be seen in Figure 14 for the CentriMag Pump as an isolated component.

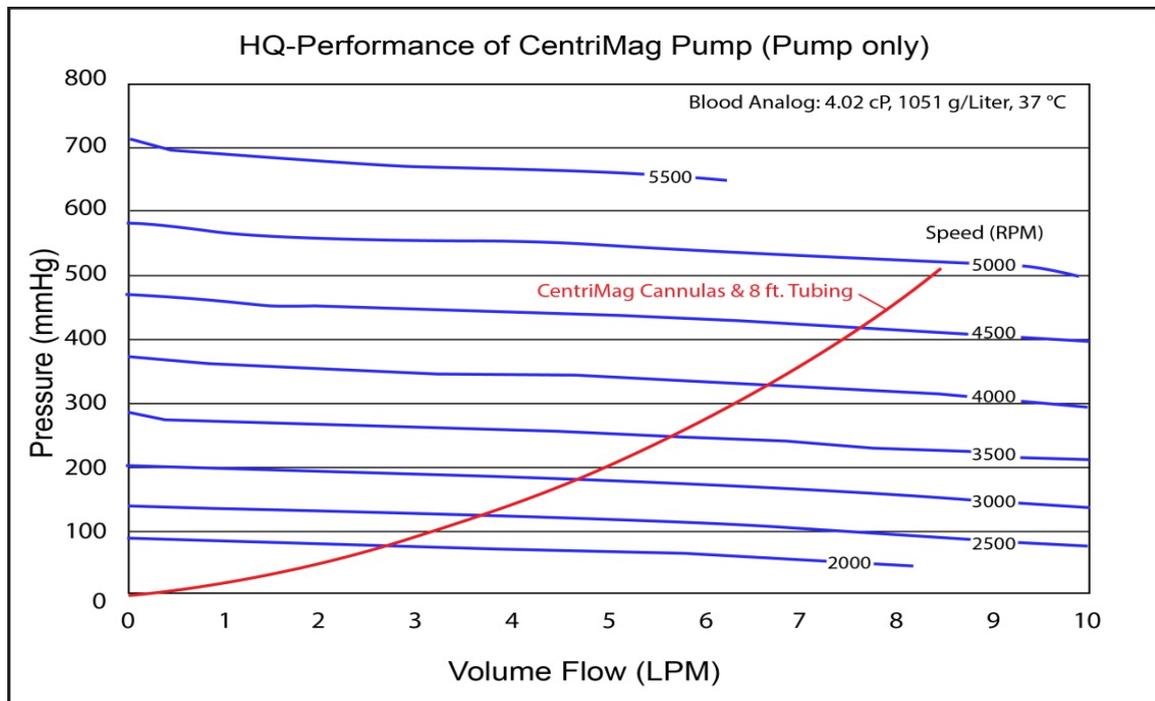


Figure 14: CentriMag™ Pump Differential Pressure/Flow (H-Q) Curve

Refer to the CentriMag and PediMag pump IFUs for additional information.

5.1.7 Motor

The CentriMag™ Motor (**Figure 15**) holds the disposable CentriMag or PediMag Pump and drives the impeller inside the Pump.



Figure 15: CentriMag™ Motor

5.1.8 Backup Console

The 2nd Generation CentriMag Console is also designed for use as a backup Console. The intended function of the backup Console is to provide basic life-support in the event of a main Console malfunction.

5.1.9 System Cart

The Console and the Monitor are designed to be used with a custom designed CentriMag System Cart. The System Cart and an example of placement of components are shown in **Figure 16**.



Figure 16: System Cart, main and backup Consoles, Monitor, and Motors.

5.1.10 Application Software

Compatible software versions for the System components are the following:

- Console: CPC1.02
- Monitor: MCM3.01

For information on displaying the Console Application Software, see **Section 7.8**. For information on the Monitor Management Software, see **Section 7.25**.

More detailed information regarding the software version can be found in **Section 12.2**.

5.2 Required User Supplied Items

The following items, required for use with the CentriMag System, are not provided by Abbott Medical:

- Smooth jawed tubing clamps
- Medical grade 3/8 inch PVC tubing

6 SPECIFICATIONS AND GENERAL DESCRIPTION

This section includes the product specifications and physical attributes of the System.

6.1 Classification

Table 4: System Classification		
SYMBOL	CLASSIFICATION	DESCRIPTION
	Type CF – Defibrillator Proof	Equipment Type for protection against electric shock.
None	Class 1 and internally powered	Equipment Classification for protection against electric shock.
None	Continuous	Mode of Operation.
None	Not for AP or APG	Not suitable for use in the presence of a flammable anesthetic mixture.
None	EtO for Pump	Method of Sterilization.
None	IPX0 enclosure	Not splash proof. Do not spray cleaning agents directly on Console or Monitor enclosure.
None	IPX4 enclosure (Motor)	Splash proof. Do not spray cleaning agents directly on Motor enclosure.
None	Not for oxygen rich environment	Not suitable for use in an oxygen rich environment.

6.2 Specifications

Table 5: Console Specifications	
PARAMETER	SPECIFICATIONS
AC Power	100 – 240 VAC at 50/60 Hz, 170 VA
Battery Power	14.8 VDC Li-Ion, internal rechargeable battery <i>Discharge time:</i> approx. 120 minutes @3,500 RPM, 5.5 LPM <i>Recharge time:</i> 4 hrs to 90% charge, 5 hrs to 100% charge
Dimensions	Height: 10.0 cm / 3.9 in Width: 26.6 cm / 10.5 in Depth: 33.0 cm / 13.0 in
Weight	5.8 kg / 12.8 lbs
Pump Speed Range	0 – 5,500 revolutions per minute (RPM)
Pump Flow Range	0.0 – 10.0 liters per minute (LPM)
Flow Range Display	-2.0 – 10.0 liters per minute (LPM) ¹
Electrical Safety	Earth leakage current: < 500 μ A Touch current: < 100 μ A Patient leakage current: < 10 μ A

6.3 Environmental Conditions

6.3.1 Shipping Conditions

The following are the acceptable environmental conditions during shipping:

- Temperature: -29°C to 60°C (one week maximum)
- Relative humidity: 0% to 85%
- Atmospheric pressure: 210 hPa – 1100 hPa (157 mmHg – 825 mmHg)

6.3.2 Operational and Storage Conditions

The following are the acceptable environmental conditions during operation and storage:

- Temperature: 10°C to 30°C
- Relative humidity: 30% to 75%
- Atmospheric pressure: 702 hPa – 1100 hPa (527 mmHg – 825 mmHg)

¹ Note: If the probe detects forward flow of more than 10 LPM then it will display as “^^.^^ LPM”.

6.4 Essential Performance

The essential performance of the System includes the following:

- The System shall maintain Pump functionality within flow limits and defined speed set by the operator.
- If the flow limits are underrun/exceeded or the speed is out of range, the System shall generate an alarm.
- In any other case where the Pump functionality cannot be achieved anymore, the System shall generate an alarm.

WARNING

Other equipment may interfere with the operation of the System, even if the other equipment complies with CISPR emission requirements. Refer to the Electromagnetic Emissions and Electromagnetic Immunity sections for guidance.

6.5 EMI Considerations

Electromagnetic interference (EMI) sources in the vicinity of the System may interfere with Console performance. If changes occur in the operating parameters of the Console due to EMI sources, immediately remove the source of EMI or move the Console away from the source of the EMI.

The Console may interfere with the operation of other equipment in proximity. Do not place equipment, other than an additional Console, near the main Console or Motor.

For information about potential interference from Electrosurgery Units (ESU), see **Section 10.4** for more details.

WARNING

The System is a Class A product and may cause radio interference in residential environments.

WARNING

The System should not be used in Magnetic Resonance (MR) environments, or in conjunction or association with computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), electronic article surveillance, and electromagnetic security systems such as metal detectors.

6.6 Permanent Magnet Considerations

Permanent magnets can interfere with proper pumping operation when in proximity with the Pump and Motor. These sources of magnetism include items such as, but not limited to, spare Pumps and permanent magnet DC (Direct Current) Motors.

6.7 Operator Controls

6.7.1 Controls on the Console

The Console Control Panel (**Figure 17**) contains three rows of displays. **Row 1** includes indicators (bars and digital) for the Pump's speed (RPM), flow rate (LPM), flow limits (LPM), and pressure measurements (mmHg). The top two lines of **Row 2** on the display are used to display System status. The bottom line displays the four soft keypad

descriptions for the active screen. The remaining Battery Time is also provided in Row 2 with both digital and bar indicators. **Row 3** consists of six keypads. The first keypad (furthest to the left) silences the alarm audio and also serves as the keypad to be depressed to acknowledge the alarm condition, and the last on the right stops the Pump. The other four keypads from left to right are: menu options (**MENU**), Pump speed adjustment (**SET RPM**), and menu item adjustment (**DECREASE**) (**INCREASE**).



Figure 17: Operator Control Panel

6.7.2 Controls on the Monitor

The Monitor (**Figure 18**) replicates the information found on the Console Control Panel (**Figure 17**). It will display Pump speed, flow and alarm limit data, battery status, and pressure information. The Monitor can display the information for up to two Consoles simultaneously. For more information about the Monitor, see **Section 7.24**.

The Monitor incorporates the same six soft keypads found on the Console control panel. The first keypad (at the top) silences the alarm audio and also serves as the keypad to be depressed to acknowledge the alarm condition, and the last (at the bottom) stops the Pump. The other four keypads from top to bottom are: menu options (**MENU**), Pump speed adjustment (**SET RPM**), and menu item adjustment (**DECREASE**) (**INCREASE**).

Any change made to the System parameters on the Monitor will also be shown on the Console, and vice versa. It is possible to control the System using the Console front panel or the Monitor soft keypads when the Monitor is connected to the Console.



Figure 18: Monitor

6.7.3 Features of the Console, Monitor, and Flow Probes

Features of the Console, Monitor, and Flow Probes, and their meanings are listed in Table 6.

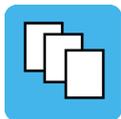
Table 6: Features of the Console, Monitor, and Flow Probes			
FEATURE	NAME	DESCRIPTION	LOCATION
Controls Buttons			
	Alarm Acknowledge	Depressing this keypad performs two functions: 1) silences the alarm audio tone if the alarm is silenceable, and 2) acknowledges the alarm condition. Depressing the keypad signals the Console that the user is aware that an alarm/alert condition(s) has occurred. If the alarm condition is unresolved, the Console will silence the audio alarm/alert for a period of time, if the alarm is silenceable, and will continue to display the visual indication of the Alarm/Alert condition and the audio paused symbol. The audio paused symbol and visual indication of the alarm/alert condition will only be removed provided: a) the condition was acknowledged by depressing the Alarm Acknowledge keypad, and b) the condition has resolved.	On the Console's Front Panel On the Monitor's Front Panel
	Menu	Depressing this keypad will allow the user to select System settings to view or modify (e.g., minimum flow alarm levels, language, etc.).	On the Console's Front Panel On the Monitor's Front Panel
	Set Pump Speed (RPM)	When SET RPM is displayed above this keypad, on the alphanumeric display screen, depressing this keypad will allow adjustment of the Pump speed. When EXIT is displayed above this keypad on the alphanumeric display, depressing this keypad will disable the ability to adjust Pump speed and maintain the Pump speed at the displayed rate.	On the Console's Front Panel On the Monitor's Front Panel
	Decrease	This keypad is used to select/modify the value for the displayed item to be adjusted.	On the Console's Front Panel On the Monitor's Front Panel

Table 6: Features of the Console, Monitor, and Flow Probes

FEATURE	NAME	DESCRIPTION	LOCATION
	<p>Increase</p>	<p>This keypad is used to select/modify the value for the displayed item to be adjusted.</p>	<p>On the Console's Front Panel On the Monitor's Front Panel</p>
	<p>Emergency Pump Stop</p>	<p>When depressed for at least 5 seconds, this keypad will cause the Pump RPM to immediately be set to zero causing the Pump to stop. While the Pump is running, an audio alarm will sound while the keypad is depressed, indicating that the Pump will be stopped soon.</p>	<p>On the Console's Front Panel On the Monitor's Front Panel</p>
	<p>ON/OFF Button</p>	<p>The power switch is recessed and covered to prevent inadvertent actuation. Switching to OFF disables all functions and displays except for the battery charging function. This power switch should not be used to stop the Pump. To stop the Pump use either RPM Decrease or Emergency Pump Stop buttons.</p>	<p>On the Console's Back Panel</p>
Indicators			
	<p>Pump Speed</p>	<p>Pump speed (RPM) Display: The Top portion of the Console's display is the Pump Speed; below the digital speed indication, a bar graph provides a representation of the Pump speed in RPM.</p>	<p>On the front panel of the Console and on the Monitor screen</p>
	<p>Flow Rate</p>	<p>Flow rate (LPM): The top portion of the Flow Display is a 3-digit numeric display that provides a digital representation of the Pump Flow in LPM. Below the digital flow indication, a bar graph provides a representation of the blood flow in LPM. Markers show the current settings of the Maximum and Minimum flow limits.</p>	<p>On the front panel of the Console and on the Monitor screen</p>

Table 6: Features of the Console, Monitor, and Flow Probes

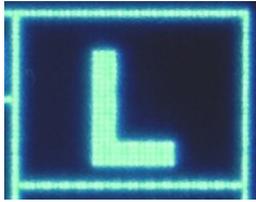
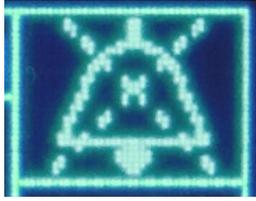
FEATURE	NAME	DESCRIPTION	LOCATION
	<p>Power Source and Battery Time Remaining</p>	<p>A green LED located next to the AC plug icon illuminates when the Console is operating on AC power.</p> <p>A green LED located next to the battery icon illuminates when the Console is operating on battery power.</p> <p>If the battery light is flashing, this indicates that the battery is charging. A flashing AC plug icon indicates the System is plugged in, and is turned off. A flashing light next to the plug icon indicates that the System is plugged in and is turned off.</p> <p>The estimated remaining battery time, in minutes, is indicated by a three-digit numeric display. The Battery charge status is displayed via a battery icon.</p>	<p>On the Console's Front Panel</p> <p>Battery time is also shown on the Monitor's screen</p>
	<p>Support side</p>	<p>The letter "L" or "R" displayed on the right side of the digital display denotes "Left Ventricular Support" or "Right Ventricular Support".</p>	<p>On the Console's Front Panel</p> <p>Colors are used to show the support type on the Monitor's screen: red for left-sided support and blue for right-sided support</p>
	<p>Audio Paused</p>	<p>The Audio Paused Symbol appears when an alarm/alert is acknowledged by depressing the Alarm Acknowledge keypad.</p>	<p>On the Console's Front Panel and on the Monitor's screen.</p>
Connections			
	<p>Motor Power Connector</p>	<p>Connection for power to Motor: A red dot located on top of the connector facilitates alignment of the Motor LEMO connector.</p>	<p>On the Console's Back Panel</p>

Table 6: Features of the Console, Monitor, and Flow Probes

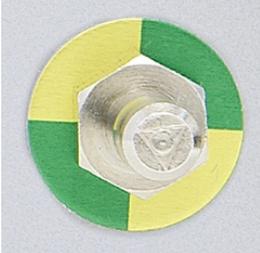
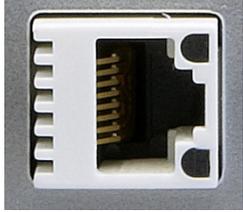
FEATURE	NAME	DESCRIPTION	LOCATION
	Power Entry Module (AC Power and Fuses)	Connection for Console to AC power and fuse box. Use only “5 x 20 mm, T 3.15A L 250V” fuses.	On the Console Back Panel Version 1
		Connection for Console to AC power and fuse box. Use only “5 x 20 mm, T 3.15A H 250V” fuses.	On the Console Back Panel Version 2
	Flow Probe connector	15-Pin connection for the Flow Probe	On the Console's Back Panel
	Equipotentiality Symbol (IEC 60417-5021)	The Equipotential Bonding Post (EBP) provides a low impedance electrical safety common connection point.	On the Console's Back Panel
	Pressure Probe Connectors	Connections for 2 pressure probes	On the Console's Back Panel
	Monitor (CAN/12V) Connector	Connection for the Monitor	On the Console's Back Panel and Monitor's Back Panel (2 sockets)

Table 6: Features of the Console, Monitor, and Flow Probes

FEATURE	NAME	DESCRIPTION	LOCATION
	<p>USB Port</p>	<p>Connection for USB Memory Stick</p>	<p>On Monitor's Back Panel</p>
	<p>RS232 Port²</p>	<p>Connection for RS232</p>	<p>On Monitor's Back Panel</p>
	<p>Ethernet Port³</p>	<p>Connection for Ethernet</p>	<p>On Monitor's Back Panel</p>

² The RS232 port is disabled and intended for future use in the US.

³ The Ethernet port is disabled and intended for future use in the US.

Table 6: Features of the Console, Monitor, and Flow Probes

FEATURE	NAME	DESCRIPTION	LOCATION
2nd Generation CentriMag Primary Console Serial Number Label			
	Abbott Medical Product Reference Number	Identifies the Abbott Medical Reference (reorder) Number	On the serial number label
	Serial Number	Identifies the serial number of the Console	On the serial number label
	Defibrillation-proof Type CF Equipment	Equipment type	On the serial number label
	Read Manual	Consult the CentriMag Circulatory Support System Operation Manual before operating the device.	On the serial number label

Table 6: Features of the Console, Monitor, and Flow Probes

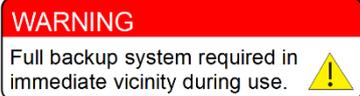
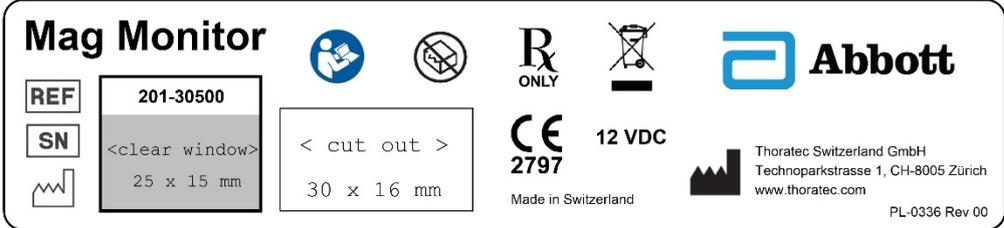
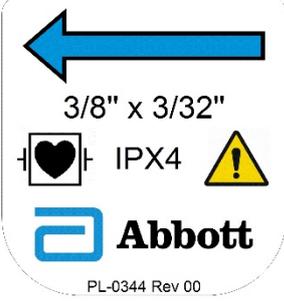
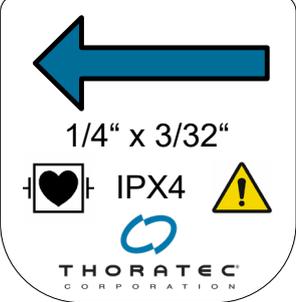
FEATURE	NAME	DESCRIPTION	LOCATION
	CE Mark with Notified Body ID	CE (Conformity European) Mark with Notified Body designation	On the serial number label
	TUV Mark	The TUV Mark is an NRTL (Nationally Recognized Test Laboratory) mark, which signifies that the 2 nd Generation CentriMag Console was tested and meets the minimum requirements of prescribed product safety standards. Moreover, the mark indicates that the production site conforms to a range of compliance measures and is subject to periodic follow-up inspections to verify continued conformance.	On the serial number label
	Manufacturer	Indicates the Manufacturer of the Console	On the serial number label
	Waste Electrical and Electronic Equipment	Waste Electrical and Electrical Equipment (WEEE) Mark	On the serial number label
Console Warning Label			
	Backup System Warning	Indicates that a full backup System must be available in the immediate vicinity of the patient during use of the main System.	On the Console's Back Panel
Monitor Serial Number Label			
			On the Monitor's Back Panel

Table 6: Features of the Console, Monitor, and Flow Probes

FEATURE	NAME	DESCRIPTION	LOCATION
	Abbott Medical Product Reference Number	Identifies the Abbott Medical Reference (reorder) Number	On the serial number label
	Serial Number	Identifies the serial number of the Monitor	On the serial number label
	Read Manual	Consult the CentriMag Circulatory Support System Operation Manual before operating the device.	On the serial number label
	CE Mark with Notified Body ID	CE (Conformity European) Mark with Notified Body designation	On the serial number label
	Manufacturer	Indicates the Manufacturer of the Console	On the serial number label
	Waste Electrical and Electronic Equipment	Waste Electrical and Electronic Equipment (WEEE) Mark	On the serial number label
Monitor USB Warning Label			
	General Warning Sign	Only USB-compatible Memory Sticks may be connected to the USB Port. No other USB device may be used (e.g. printer).	Near the USB Port on the back panel of Monitor
	Warning Hand Crush	Moving parts of the Monitor Arm can crush and cut. Do not place hand on or into joint area.	Near the top joint of the Monitor Arm

Table 6: Features of the Console, Monitor, and Flow Probes

FEATURE	NAME	DESCRIPTION	LOCATION
Flow Probes Labels			
			On the cover of the Flow Probes
	Defibrillation-proof Type CF Equipment	Equipment type	On the label of the Flow Probe's cover
	General Warning Sign	Connect this external flow sensor to the back panel of the Console only.	On the label of the Flow Probe's cover
IPX4	Ingress Protection Rating	Protection against splashing water	On the label of the Flow Probe's cover

6.7.4 Alarm and Alert Conditions

Audible and visual alarm/alert conditions warn the operator to conditions that may interrupt patient support or damage the Pump or the Console. If an alarm/alert condition occurs, the audible alarm/alert sounds, and an alarm/alert message indicating the cause(s) of the alarm/alert appears on the display. Depressing the ALARM ACKNOWLEDGE keypad mutes the audible alarm. The alarm/alert message will be continuously displayed on the top two lines of **Row 2** of the Console's display as long as the alarm/alert condition exists.

In the event of an alert or alarm condition (see **Table 13** or **Table 16** for the full list of alarms and alerts), visual message and audio indicators activate. The Console continues Pump operation during an alert or **MOTOR ALARM** condition, and stops the Pump during an alarm or **MOTOR STOPPED** condition. Both the visual and audio alert indicators are active, even if the problem has resolved, until the alert/alarm condition is acknowledged by pressing the ALARM ACKNOWLEDGE keypad. The user must acknowledge the alert/alarm to silence the audio indicator and to determine if the alert/alarm condition has resolved or is unresolved.

- If the alert/alarm condition has not been resolved, pressing the ALARM ACKNOWLEDGE keypad temporarily mutes the audio alert indication if the alarm/alert condition is silenceable. The alarm/alert message will still be displayed on the screen.
- If the alert/alarm condition has been resolved, pressing the ALARM ACKNOWLEDGE keypad mutes the audio alert indication and removes the visual alarm/alert message.

- If the alarm/alert condition cannot be resolved the user should refer to Table 13 or Table 16 to determine the appropriate Operator Response for the specific Alert/Alarm which has occurred.

A **MOTOR ALARM** condition is not silenceable, unless the condition has resolved.

- If a **MOTOR ALARM** condition occurs and has not been resolved, pressing the ALARM ACKNOWLEDGE keypad will not mute the audio alert indication and will not remove the visual message alert indication.
- If a **MOTOR ALARM** condition occurs and the alert/alarm condition has been resolved, pressing the ALARM ACKNOWLEDGE keypad mutes the audio alert indication and will remove the visual alert indication.

After an alert/alarm condition has been acknowledged by pressing the ALARM ACKNOWLEDGE keypad, a visual indicator message will continue to be displayed under the following conditions:

- If the alert condition is unresolved and the alert/alarm condition persists.
- If the alert/alarm condition reoccurs. (E.g. transient **FLOW BELOW MINIMUM** condition reoccurs). If the alert/alarm condition reoccurs then both the audio and visual indicators will reactivate.
- An additional alert or alarm condition occurs. The new alert/alarm visual indicator will be displayed and an audio alert will sound.

After an alert/alarm condition has been acknowledged and the audio alarm muted, an audio alert/alarm may reactivate under the following conditions, and may require subsequent acknowledgment:

- If the alert condition is unresolved and persists for more than 60 seconds after the alert/alarm has been acknowledged, the audio alert will reactivate.
- If the alert/alarm condition is resolved and then reoccurs. (E.g. transient **FLOW BELOW MINIMUM** condition resolves and then reoccurs). The original text message will continue to be displayed and the audio alert/alarm will sound when the condition reoccurs.
- An additional alert or alarm condition occurs. The new alert/alarm condition will be displayed and the audio alert will sound.

There are four exceptions to the acknowledgement display and audible alert rules described above. These are:

- **BATTERY MAINTENANCE REQUIRED** – this alert only requires one acknowledgment. The visual alert continues to be displayed but the audible alert will not reactivate.
- **ON BATTERY** – acknowledgement mutes the audio indicator, the visual indicator continues, and audio reactivate every 15 minutes or until a **LOW BATTERY** alert occurs or until reconnected to AC power.
- **LOW BATTERY** – acknowledgement mutes the audio indicator, the visual indicator continues, and audio reactivates every 10 minutes or until a **BATTERY BELOW MINIMUM** alarm occurs or the battery is recharged.
- **MOTOR ALARM** – this alarm cannot be muted as long the alarm condition persists.

WARNING

Alarms, with the exception of the **MOTOR ALARM**, are associated with conditions that result in stoppage of the Pump. Alerts are associated with conditions in which the Pump will continue to operate, but additional attention and/or corrective action may be necessary to resolve the alert condition.

WARNING

DO NOT attempt to restart the Pump after it has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Pump, extracorporeal circuit, and Cannulas.

WARNING

DO NOT restart the Pump if it has stopped due to Motor overheating. Overheating is confirmed by a **MOTOR OVER TEMP** alert message and temperature sufficient to prevent the user from placing and holding a hand on the Motor housing. Clamp the return tubing and switch to the backup System according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.

WARNING

A Pump stoppage will create a reverse flow shunt through the Pump, as well as limit the body's ability to maintain adequate arterial pressure. If the Pump is off or stopped, clamping the return tubing from the Pump is necessary to prevent a low flow, low pressure, and reverse flow condition. The tubing clamp must be removed before returning to normal pumping activity.

CAUTION

Accessory equipment connected to the System must be certified to their respective IEC standards (e.g. IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, the user is reminded that any person who connects additional equipment to the System is creating a medical electrical system and is, therefore, responsible for ensuring that the system complies with the system standard IEC 60601-1. If in doubt, consult your local Abbott Medical representative prior to connecting any accessory to the System.

6.8 Digital Display Information

The Console's digital display provides messages and information on System settings, Console configuration and alarms/alerts. **Table 7** shows System alarm and alerts in the order of priority:

Table 7: Front Panel Display – Alarm/Alert Messages in Order of Priority	
ALARMS	ALERTS
<p>POWER ON TEST FAIL SYSTEM FAULT MOTOR STOPPED MOTOR DISCONNECTED PUMP NOT INSERTED MOTOR ALARM</p>	<p>SET PUMP SPEED NOT REACHED BATTERY MODULE FAIL BATTERY BELOW MINIMUM FLOW PROBE DISCONNECTED SYSTEM ALERT FLOW SIGNAL INTERRUPTED FLOW BELOW MINIMUM FLOW ABOVE MAXIMUM PRESSURE 1 DISCONNECTED PRESSURE 2 DISCONNECTED PRESSURE SYSTEM FAIL PRESSURE 1 BELOW MINIMUM PRESSURE 2 BELOW MINIMUM PRESSURE 1 ABOVE MAXIMUM PRESSURE 2 ABOVE MAXIMUM MOTOR OVER TEMP BATTERY CHARGER FAIL BATTERY MAINTENANCE REQUIRED LOW BATTERY ON BATTERY</p>

6.9 Power Assembly

The Power Assembly is located on the Console's back panel and contains the AC Power Connection, Monitor Connection and LEMO Motor Connection.

6.10 Requirements for Connecting Additional Equipment

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Anyone connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

7 SETTING UP THE SYSTEM

This section describes how to unpack the Console, connect the power cord, the Motor, and the Flow Probe and how to mount, power up and operate the System including using the optional elements listed in **Table 2**. The Console carries the following Factory⁴ and Power-Up⁵ defaults for each specified operating parameter:

Table 8: Console Factory & Power-Up Default Values		
OPERATING PARAMETER	FACTORY DEFAULT ⁴	POWER-UP DEFAULT ⁵
Minimum Flow Alert	0.0 LPM	0.0 LPM
Maximum Flow Alert	8.0 LPM	8.0 LPM
Flow Display range	-2.0 – 10.0 LPM ⁶	-2.0 – 10.0 LPM
Pressure Subsystem	Inactive	Last state ⁷
Pressure limits	-30mmHg / +200mmHg	-30mmHg / +200mmHg
Language	English	Last state ⁷
RPM Increment	100	Last state ⁷
Flow Limit Sensitivity	Normal	Last state ⁷
Recorder Speed	2 minutes	2 minutes

7.1 Unpacking

1. Remove the Console, AC Power Cord, and Flow Probe from the Console's shipping container.
2. Remove the Motor from its shipping box.
3. Remove the Monitor from its shipping box

⁴ Factory Default: pre-selected operating parameter of a 2nd Generation CentriMag Console as it is shipped from the manufacturer.

⁵ Power-Up Default: 2nd Generation CentriMag Console operating parameter after the 1st use. These values are stored in the Console's permanent memory and recalled each time the Console is powered up.

⁶ Note: If the probe detects forward flow of more than 10 LPM then it will display as “^^.^^ LPM”.

⁷ Last state: the value/state carried from the last operational use of the 2nd Generation CentriMag Console.

4. Retain all packaging materials in the event that the Console or any other component needs to be returned to Abbott Medical for repair or maintenance.

WARNING

Never put containers of liquids on top of or in the immediate vicinity of the Console. Always prevent liquids from entering the device, since this can cause permanent damage to the Console.

WARNING

Never operate the System in presence of flammable gases (e.g. flammable anesthetic mixture), since this could lead to fire and explosions.

CAUTION

Make sure that the System cables (Motor cable, Flow Probe cable, etc.) are organized properly in order to avoid accidents and reduce the likelihood of EMI. EMI may interfere with the System and potentially may stop the Motor. Prevent cable loops on the floor and avoid cables hanging over other equipment or furniture.

CAUTION

Before each use, verify that the cable connecting the Motor to the Console is not kinked, which can occur with improper handling such as wrapping the cable tightly around the Motor. If the cable is kinked, replace the Motor.

WARNING

Make sure that tubing and Cannulas between the System and patient are secured properly.

WARNING

To avoid the risk of electric shock, do not touch any signal input/output part (SIP/SOP) like pins and contacts of any electrical connector or socket of this equipment and the patient simultaneously.

7.2 Console Mounting

If the Console is desired to be secured to the System Cart, then it is required to use the CM Distance Holder and Console Standoff.

When mounting a single Console onto the System Cart, use the CM Distance Holder to securely fix the Console in place.



Figure 19: Mounting of Single Console onto System Cart

When mounting two stacked Consoles onto the System Cart, use the CM Distance Holder in combination with Console Standoff to securely fix both Consoles in place.



Figure 20: Combination of Distance Holder and Console Standoff



Figure 21: Mounting of Two Consoles onto System Cart

WARNING

Only use the Standoff Distance Holder and the Standoff provided by the supplier. Use of any other component may result in a sudden Motor stop.

7.3 Monitor Mounting

7.3.1 If the Console is intended to be used with the Monitor, the Monitor must be securely fixed to a solid object. This can be achieved with the Monitor Arm provided by Abbott Medical and Ergotron. The Monitor Arm can be mounted either on the edge of a horizontal or vertical solid surface or on a vertical pole. For instructions on how to set-up the Monitor Arm refer also to the manual provided by Ergotron. Steps required to set-up the Monitor Arm:

1. Mount the Monitor Arm Clamp on the adapter plate: **Figure 22** illustrates the two possibilities for mounting the clamp on the adapter plate. If the Monitor Arm is to be mounted on the edge of a vertical surface or a vertical pole, the clamp has to be mounted as shown in part A of **Figure 22**. If the Monitor Arm is to be mounted on the edge of a horizontal surface, the clamp has to be mounted as shown in part B of **Figure 22**. Make sure that the oval end of the adapter plate is on the screw side of the clamp in the latter case.

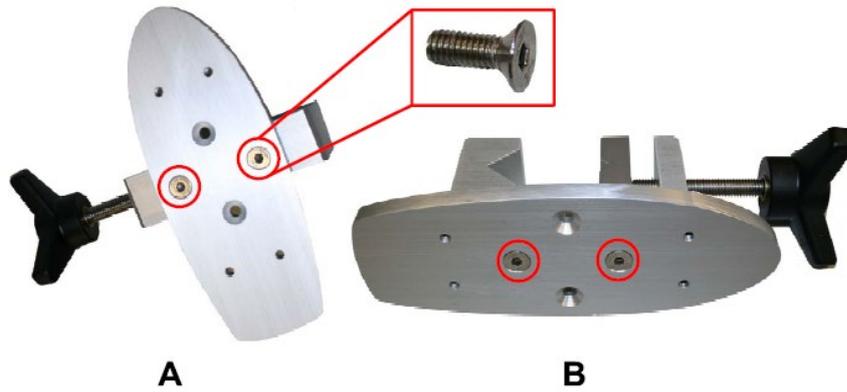


Figure 22: Clamp mounting possibilities on adapter plate

2. Mount the Monitor Arm root joint plate on the adapter plate: Use four screws to mount the root joint plate of the Monitor Arm to the adapter plate. Make sure the orientation of the adapter plate is identical to the orientation of the root joint plate. **Figure 23** shows the assembly for vertical mounting.



Figure 23: Mounting of the Monitor Arm root joint plate on the adaptor plate

3. To mount the Monitor on the Monitor Arm, use the four black screws that can be screwed by hand to allow for easy removal of the Monitor, see **Figure 24**. Make sure the screws are sufficiently tightened.

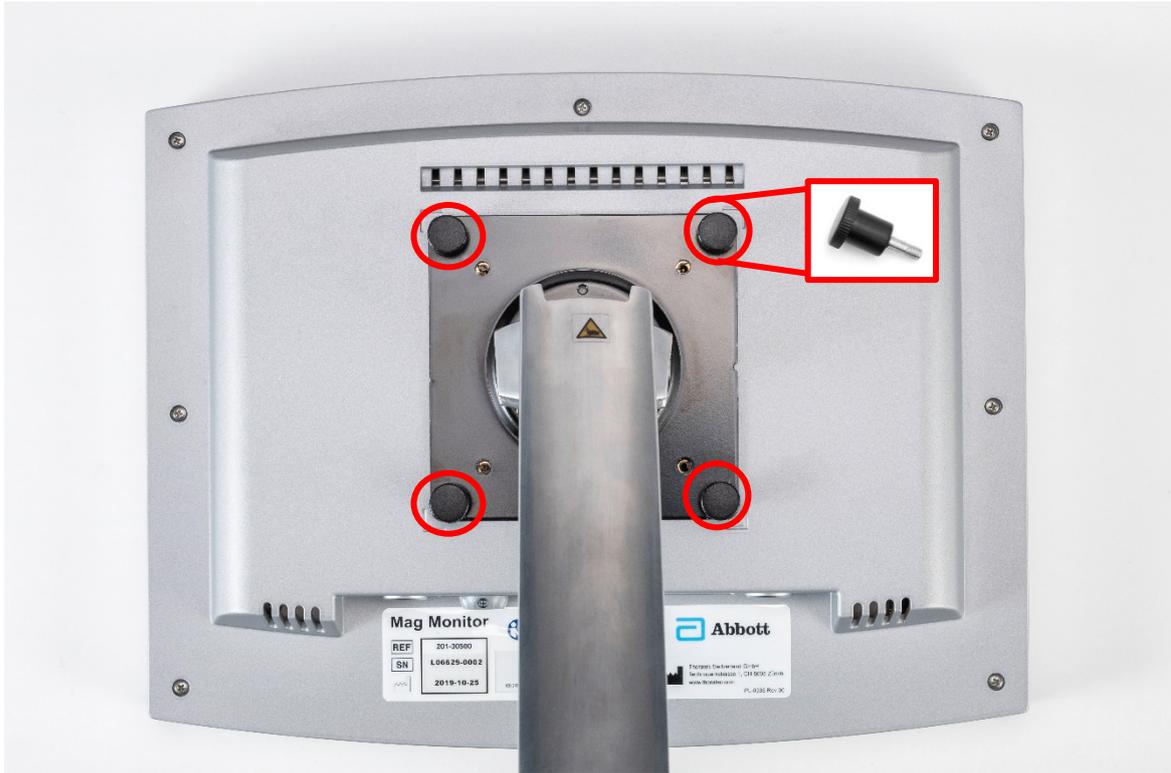


Figure 24: Mounting of the Monitor on the Monitor Arm

4. Mount the Monitor Arm Clamp on the object where the Monitor is to be fixed (a solid surface or a solid pole). The two clamping possibilities are shown in **Figure 25**.



Figure 25: Horizontal or vertical mounting of the Monitor Arm

5. Assemble the Monitor Arm by following the instructions provided in the Ergotron manual (LX Wall Mount LCD ARM) which is included in the Monitor Arm packaging. **Figure 26** shows the complete Monitor assembly.



Figure 26: Completely assembled Monitor Arm with Monitor

WARNING

Moving parts of the Monitor Arm can crush and cut causing severe injury. Do not place hand on or into joint area.



Figure 27: Hand Crush Warning on Monitor Arm

CAUTION

The vertical pole or the edge of the solid surface used to mount the Monitor has to be stable. Mounting the Monitor to unstable objects may lead to personal injury and/or property damage.

CAUTION

Do not mount the Monitor Arm on a horizontal pole to avoid injury or damage to the equipment. Mount the Monitor Arm only on vertical poles or on the edge of solid surfaces.



Figure 28: Do not mount the Monitor Arm on a horizontal pole

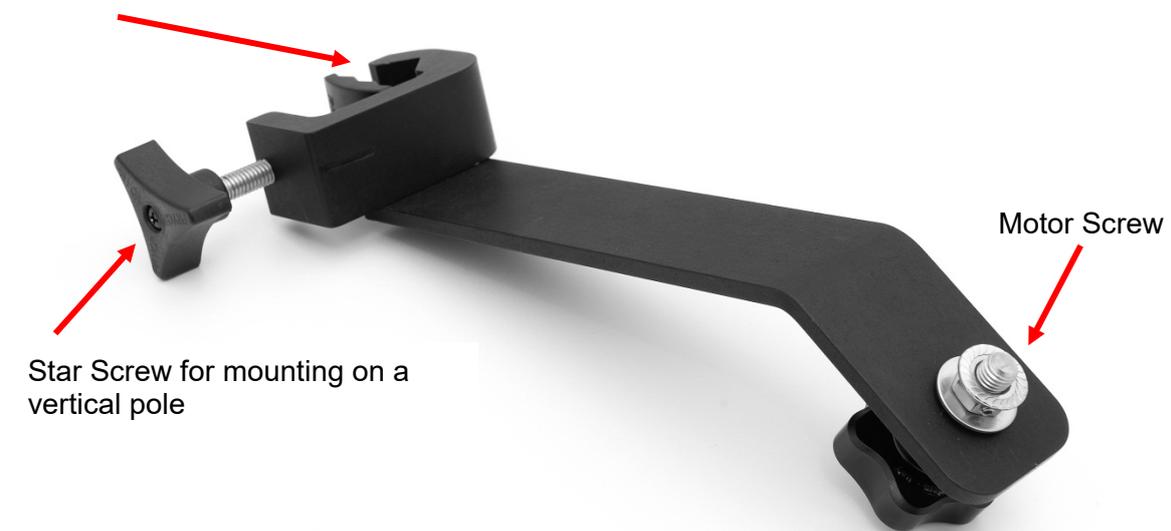
7.4 Motor Mounting

It is crucial that the Motor is securely fixed to a solid object. This can be achieved with the Motor Bracket provided by Abbott Medical. The Motor Bracket can be mounted on a vertical pole.

7.4.1 Steps required to setup the Motor Bracket and the Motor:

1. To mount the Motor Bracket on a vertical pole, use the star screw attached to the clamp of the Motor Bracket. The star screw can be screwed by hand to allow for easy removal of the Motor Bracket. Make sure the screws are sufficiently tightened.

Clamp for mounting on a vertical pole



Star Screw for mounting on a vertical pole

Motor Screw

Figure 29: Motor Bracket with Star Screw and Motor Screw

To mount the Motor onto the Motor Bracket, use the Motor Screw attached to the Motor Bracket and use the threaded hole at the bottom of the Motor. The Motor Screw can be screwed by hand to allow for easy removal of the Motor. Make sure the screws are sufficiently tightened.



Figure 30: Completely assembled Monitor Bracket with Motor

CAUTION

The vertical pole used to mount the Motor has to be stable. Mounting the Motor to unstable objects may lead to personal injury and/or property damage.

CAUTION

Do not mount the Motor Bracket on a horizontal pole to avoid injury or damage to the equipment. Mount the Motor Bracket only on vertical poles.

7.5 Powering Up the Console

To power up the main or backup console:

1. Insert the Power Cord into the AC Power Connection located on the back of the Console. Flip and press the connector latching mechanism over the base of the power connector in order to fully secure the power cord to the Console.
2. Insert the cord into the AC wall outlet.

WARNING

Insert the cord into the AC wall outlet only. Do not use power strips and socket extensions. In the BVAD configuration, both Console power cords must be inserted directly into an AC wall outlet.



Figure 31: Correct Biventricular Assist Power Connection



Figure 32: Incorrect Biventricular Assist Power Connection

WARNING

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

3. Insert the LEMO connector on the Motor cable into the Motor connection on the rear of the Console. Make sure the connector is fully inserted. Check that the connector is fully seated by attempting to retract the connector and verifying that it remains within the receptacle.
4. Connect the Flow Probe cable to the Console by tightening the two thumb screws to the mating threaded receptacles found on either side of the 15-Pin connector on the rear of the Console.

WARNING

Use of Flow Probes from sources other than Abbott Medical is not recommended. Flow probes that are not obtained from Abbott Medical may not function, may cause the Console to malfunction, or may lead to missing or inaccurate flow information.

WARNING

Make certain the arrow on the Flow Probe clamp is facing in the direction of the flow. If the arrow on the Flow Probe faces in the wrong direction, the flow will be displayed negative. Flows which are lower than – 2 LPM are shown as “∞.∞” on the display.

5. Check the Power Status on the Console front panel to verify that the green AC power ON indicator is illuminated. The Console should be connected to AC power for at least twelve hours prior to use to recharge the internal battery and to ensure battery power availability, when needed.
6. Connect the Monitor if the Console is to be used with the Monitor.
7. Turn ON the power to the Console using the power switch located on the back panel of the Console.

7.6 Self-Test Initiation

When the power is turned ON, a sequence of self-tests will immediately be performed. All operating parameters will be verified. If any test fails, an appropriate message will be displayed and an alarm will occur.

WARNING

Always verify two audio beepers sound during the self-test. If the audio beepers fail to operate, the System will not be able to alarm or alert the user with audio signals while the System is operated.

WARNING

If the Console fails the self-test, turn OFF the Console, check all of the power and cable connections for the Console, and attempt to re-boot the Console by turning the power ON. If the Console does not boot correctly after a second attempt, do not use the Console and replace the Console with another 2nd Generation CentriMag Console.

When all power-up self-tests are completed successfully, the System will require the user to choose a support type. The available options are **L (left sided support)** or **R (right sided support)**. For VAD support, the user must select one of these options for each Console. Once the selection is made, the System is ready for use. The MENU and SET RPM options will appear, and the Monitor will activate (if connected).

7.7 Configuring the Console

The ability to set the Pump speed, flow alert thresholds, flow alert sensitivity, language, set speed resolution, enable and disable the pressure measurement capability, and calibrate the pressure transducers is accessed through the **MENU** keypad. **Figure 35** outlines the basic **MENU** scheme which is available after the support type has been selected

When the System is driven by the Console and is connected to the Monitor, the main user interface is the Monitor (**Figure 33**); however, most of the selections described below are accessible through the Monitor as well as on the Console's user interface (**Figure 34**).



Figure 33: Monitor – Front Panel

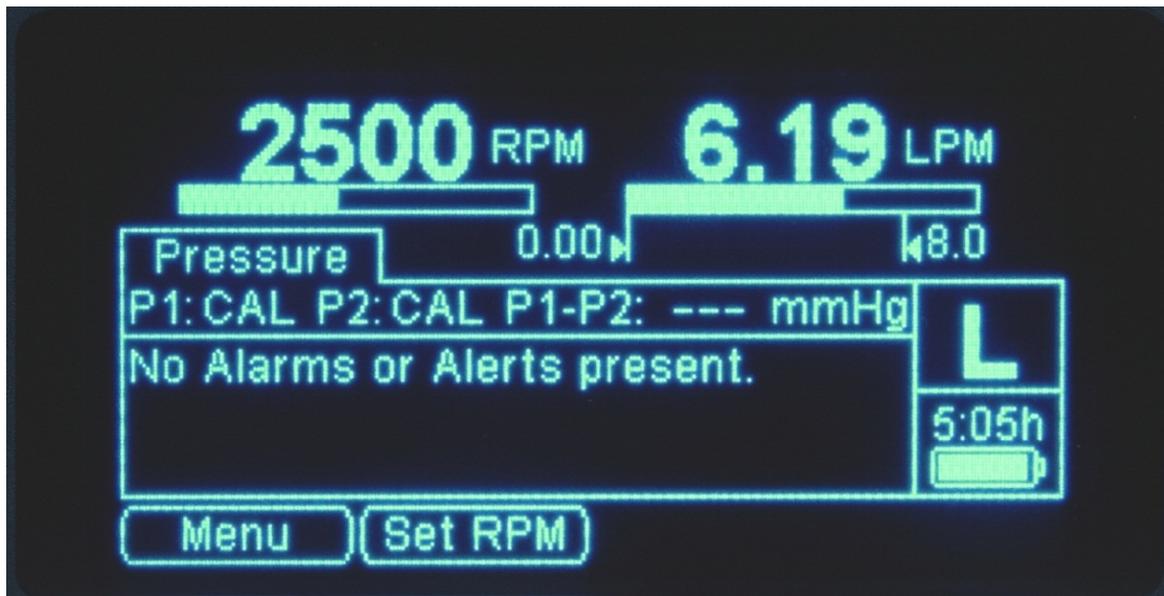


Figure 34: Console – Close up of the Display

Depressing the **SET RPM** keypad allows the user to increase or decrease the speed of the Pump using the **UP** and **DOWN ARROWS**.

Depressing the **MENU** keypad leads to different user options that can be accessed by scrolling through the options:

- **MINIMUM FLOW ALERT SETTING**
- **MAXIMUM FLOW ALERT SETTING**
- **PRESSURE MENU**
 - **PRESSURE CALIBRATION**
 - **MINIMUM PRESSURE (P1) ALERT SETTING**
 - **MAXIMUM PRESSURE (P1) ALERT SETTING**
 - **MINIMUM PRESSURE (P2) ALERT SETTING**
 - **MAXIMUM PRESSURE (P2) ALERT SETTING**
- **STOPWATCH (Monitor only)**
- **EXTENDED MENU**
 - **PRESSURE DISPLAY** (for one or two pressure probes)
 - **SPEED STEP RESOLUTION**
 - **FLOW RANGE SELECTION**
 - **FLOW LIMIT SENSITIVITY**
 - **FLOW RECORDER SPEED (Monitor only)**
 - **SUPPORT TYPE**
 - **LANGUAGE SELECTION**
 - **DATA LOGGER (Monitor only)**
 - **COPY DATA (Monitor only)**
 - **MANAGEMENT (Monitor only)**

The procedure for how to navigate the **MENU** options, as well as an explanation for the purpose of each option, is shown below. In general, the **MENU** scheme allows the user to scroll through a series of options. Messages associated with each **MENU** option are displayed on the Console display to assist the user in making selections. As the user scrolls through the **MENU**, the current setting for each option is displayed in the mid region of the screen. The **UP** and **DOWN** arrows are used to change a value or option. The resultant change in the value or option is updated and displayed in the mid region of the screen.

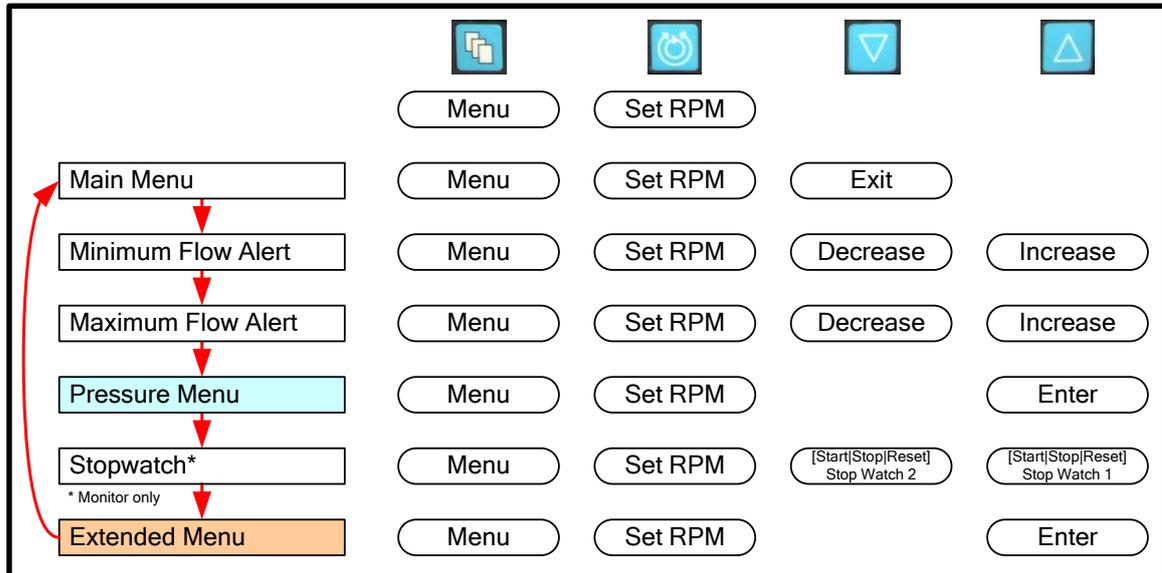


Figure 35: Monitor's Top level MENU Structure

7.8 Console BIOS

Note: The System cannot be used while the Console BIOS is being accessed. If the Monitor is attached, it will only display the company logo while the BIOS is being accessed.

The Console BIOS contains engineering information about the Console. For additional information on the Monitor Management, see **Section 7.25**.

To access the Console BIOS, hold the **MENU** button on the Console during power on self-test (not on the Monitor). The start-up screen will display the word BIOS in the top right hand corner. Once the power on self-test has completed the BIOS information will be displayed.

The BIOS contains four pages of information. Access each page by pressing the **UP** key. These four information pages are described below:

1) BATTERY MAINTAINANCE

This page contains information about the battery charge and displays information relating to ongoing battery maintenance, if applicable.

The battery maintenance procedure is accessed by pressing the **DOWN ARROW** key. For full information about the battery maintenance procedure, see **Section 9.4**.

2) FACTORY DEFAULT SETTINGS

This page contains the user option of returning the Console to the factory default settings which are also listed on this page of the BIOS.

3) SERIAL NUMBER / SOFTWARE VERSION (FOR SERVICE PURPOSE ONLY)

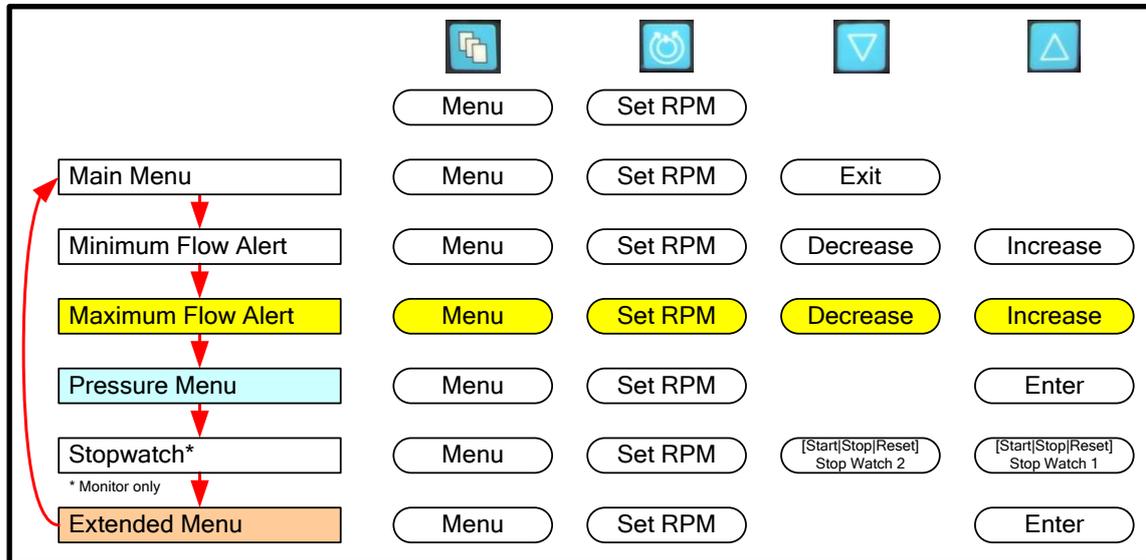
This page contains information about the software installed on the Console.

4) CHARACTER SET (FOR SERVICE PURPOSE ONLY)

This page displays all the possible characters that the Console display can produce.

To exit from the Console BIOS, turn the System OFF using the main power switch on the rear panel of the Console.

7.9 Setting the Console Max Flow Alert

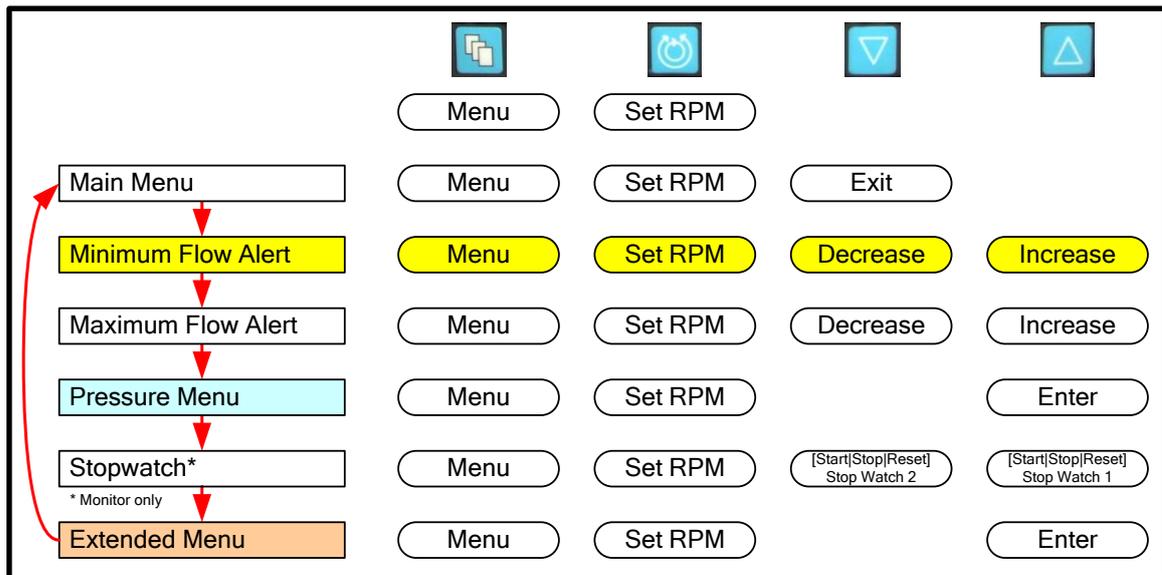


**Figure 36: Monitor MENU Structure
Setting Maximum Flow Alert**

To change the **MAXIMUM FLOW ALERT** setting, depress the **MENU** keypad until the **MAX FLOW ALERT** option is displayed. Use the **DECREASE** or **INCREASE** arrow keys to decrease or increase the alert setting. The default **MAX FLOW ALERT** value is set to 8.0 LPM at startup. The **MAX FLOW ALERT** threshold setting is continuously displayed in the upper part of the display.

If the System detects flow in excess of 10 LPM, the digital flow display will not display a numerical flow, but will display upwards pointing arrows: “^^.^^ LPM”

7.10 Setting the Console Min Flow Alert



**Figure 37: Monitor MENU Structure
Setting Minimum Flow Alert**

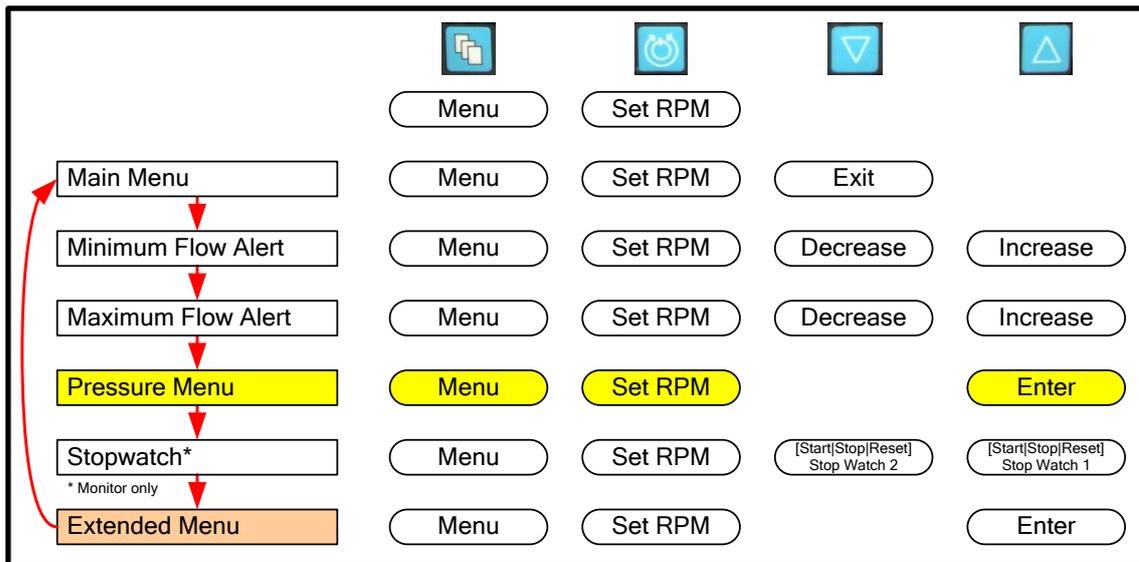
The **MINIMUM FLOW ALERT** should not be set until after the Pump is started. If the value of the **MINIMUM FLOW ALERT** is set before the Pump is started, a continuous alert will sound indicating **FLOW BELOW MINIMUM**. The default value for the **MINIMUM FLOW ALERT** is factory set to 0.00 LPM. As soon as practical after initiation of support the **MINIMUM FLOW ALERT** must be set to the minimal acceptable flow appropriate for the patient's size, clinical condition, and physiologic needs. To change the **MINIMUM FLOW ALERT** value, depress the **MENU** keypad until the **MINIMUM FLOW ALERT** option is displayed. Use the **DECREASE** or **INCREASE** arrow keys to decrease or increase the alert setting. The actual **MINIMUM FLOW ALERT** threshold is continuously displayed in the upper part of the display.

Retrograde flow of up to 2.0 LPM will be displayed as a negative number such as "-0.65 LPM". Retrograde flow greater than 2.0 LPM is displayed as downward arrows "vv.vv LPM". A disconnected or malfunctioning probe will result in display of dashes "--.--".

WARNING

Minimum flow levels must be chosen carefully with respect to anticoagulation status of the patient, the patient's hemodynamic status, and clinical condition. During weaning and periods of sustained low flow it may be necessary to reevaluate and consider increasing the level of anticoagulation. Refer to the Clinical Reference Manual for details.

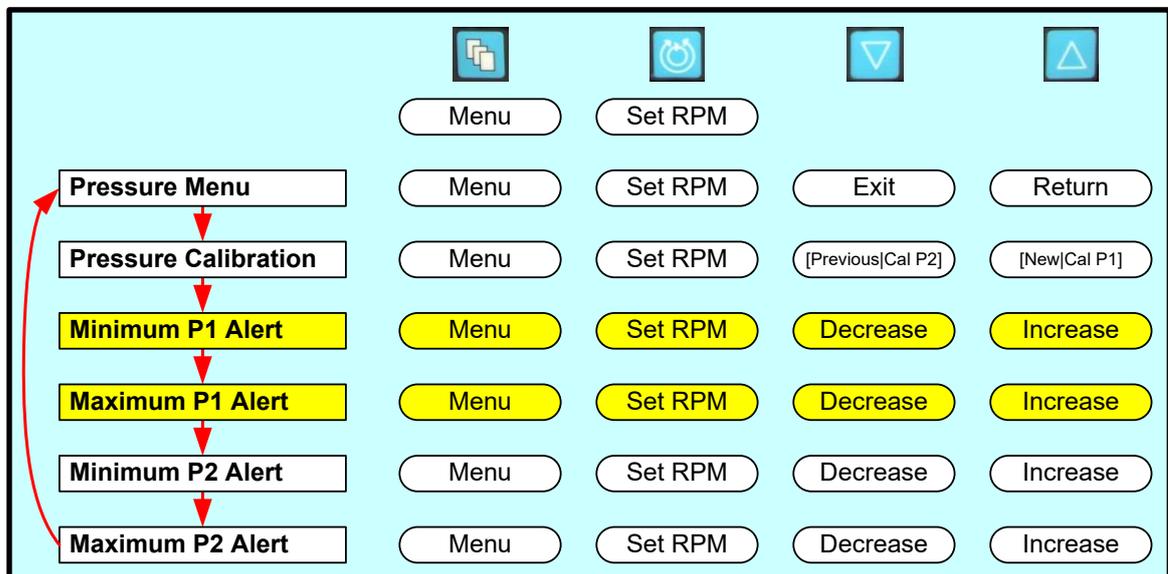
7.11 Entering the Pressure Menu



**Figure 38: Monitor MENU Structure
Entering Pressure Menu**

If the pressure subsystem is active, the pressure menu can be accessed by pressing **ENTER**, while the **PRESSURE MENU** option is highlighted. Activation and deactivation of the pressure subsystem is explained in **Section 7.14**.

7.12 Setting the Max or Min Pressure Alert Settings for the P1 Transducer



**Figure 39: Monitor MENU Structure
Setting the Max or Min Pressure Alert Settings for the P1 Transducer**

To change the **MAXIMUM** or **MINIMUM PRESSURE ALERT** settings for the P1 pressure transducer, depress the **MENU** keypad to display PRESSURE MENU followed by ENTER. Select either the **MAX** or **MIN P1 ALERT** options. Use the **DECREASE** or **INCREASE** arrow keys to decrease or increase the alert setting.

7.13 Setting the Max or Min Pressure Alert Settings for the P2 Transducer

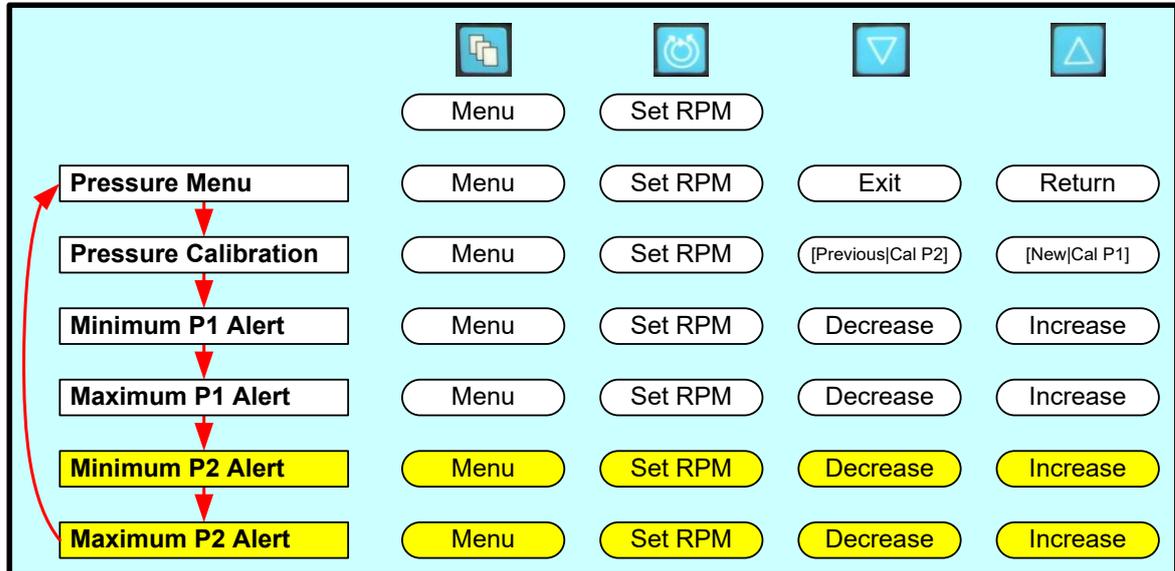


Figure 40: Monitor MENU Structure
Setting the Max or Min Pressure Alert Settings for the P2 Transducer

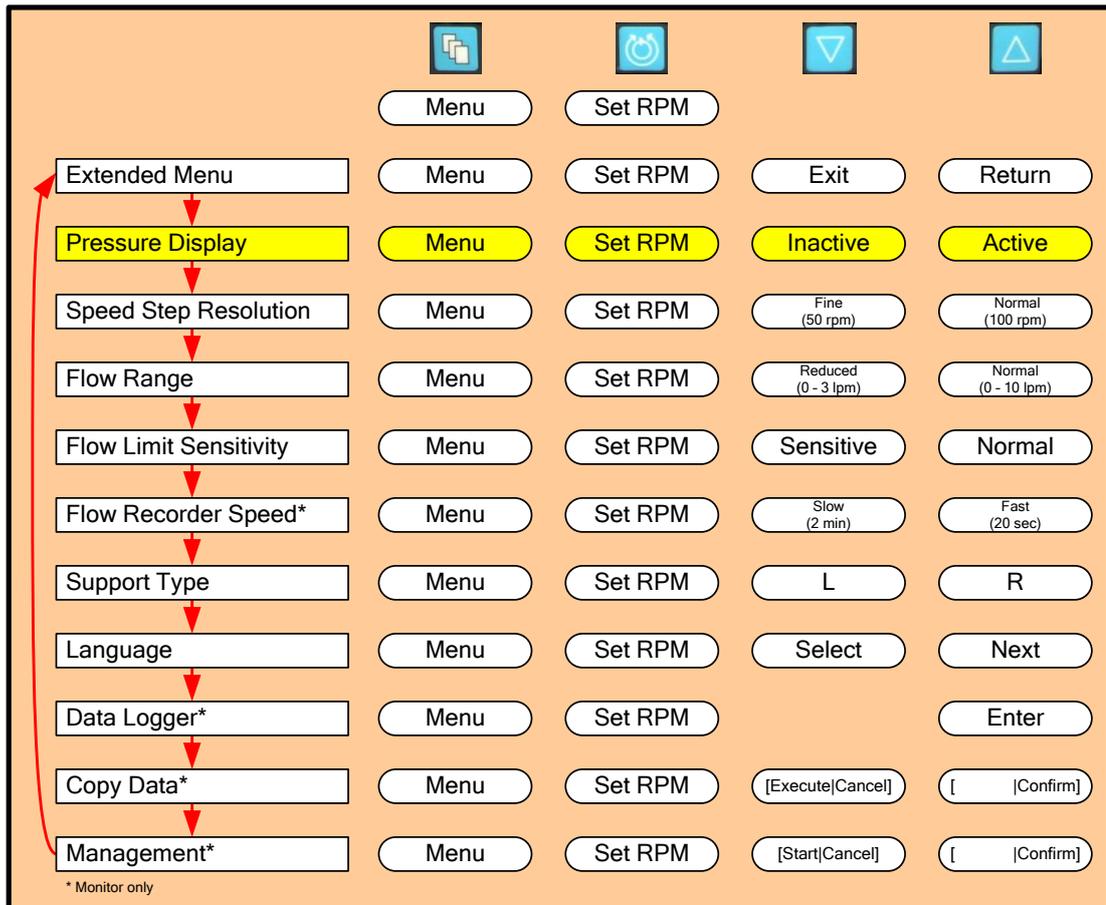
To change the **MAXIMUM** or **MINIMUM PRESSURE ALERT** settings for the P2 pressure transducer, depress the **MENU** keypad to display PRESSURE MENU followed by ENTER. Select either the **MAX** or **MIN P2 ALERT** options. Use the **DECREASE** or **INCREASE** arrow keys to decrease or increase the alert setting.

7.14 Activating the Pressure Monitoring System (Pressure Display)

1. Install the Pressure Probes into the Pressure Probe Cables and connect the Cables into the mating connectors P1 and P2 on the back of the Console. For operation of a single pressure probe, connect the cable into the P1 connector on the back of the Console.

WARNING

If there is a failure to obtain pressure data confirm that the pressure transducer and cable connection are fully seated. Additional troubleshooting may include recalibrating, or disconnecting and reconnecting the connections.



**Figure 41: Monitor MENU Structure
Activating the Pressure Subsystem**

- To activate the pressure subsystem from the Monitor, depress the **MENU** keypad to display EXTENDED MENU and ENTER. Press MENU to display the **PRESSURE DISPLAY** option and press the **UP** arrow to select **ACTIVE**. The default setting is with the pressure subsystem **INACTIVE**.
- Depress the **MENU** keypad to display **PRESSURE MENU**, and then select **PRESSURE CALIBRATION** in order to calibrate the Pressure Probe(s) using the following method.

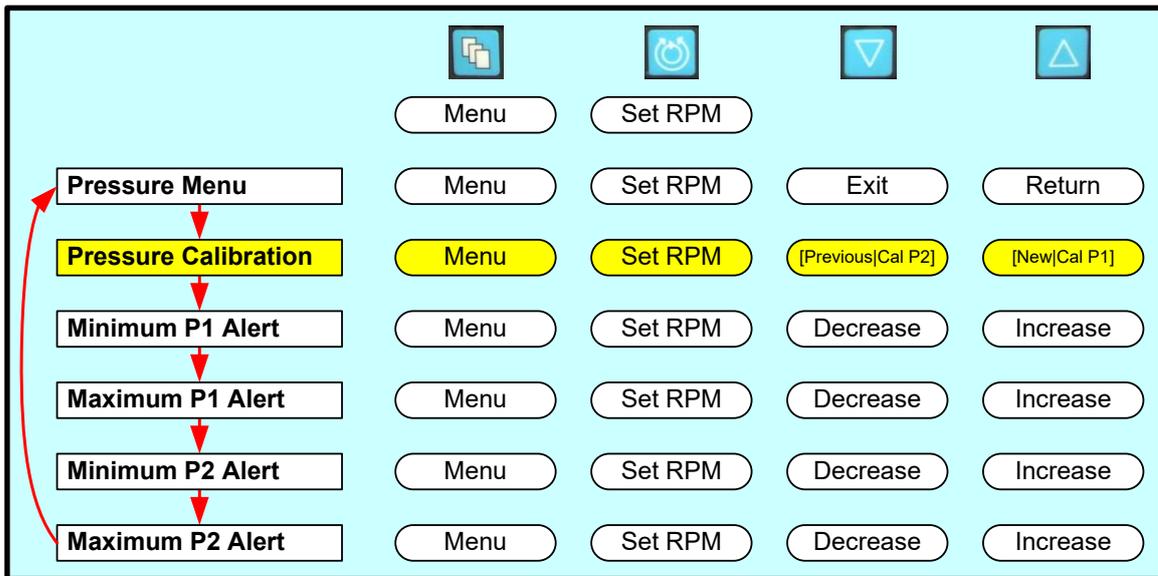


Figure 42: Monitor MENU Structure Performing Pressure Calibration

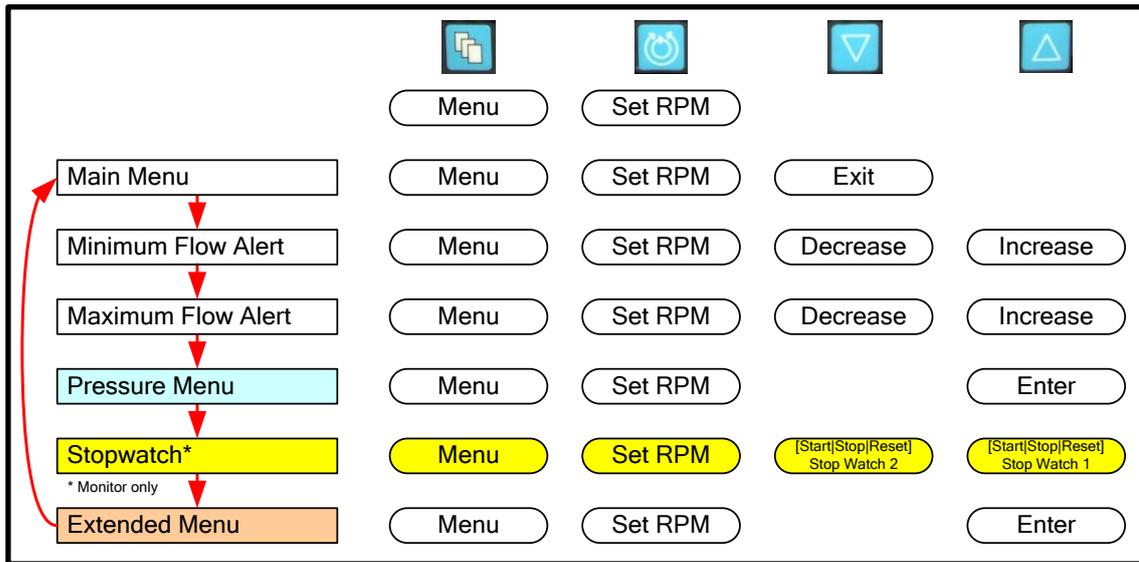
Note: The following calibration procedure assumes that two cables and two pressure transducers or probes will be used. When two pressure transducers are in use, three pressures will be displayed: one for each probe and the difference between the two pressures. The Console will support use of a single pressure probe. However, when only one pressure probe is used, no differential pressure reading will be displayed.

Note: The pressure monitoring system has a functional range of (-) 150 mmHg to (+) 900 mmHg with a display resolution of 1 mmHg. If one channel exceeds either limit, the values displayed on the specific channel as well as the difference will be invalid, which is indicated by either “vvvv” for values below -150 mmHg and “^^^^” for values above 900 mmHg. If one channel is invalid, then the difference will be displayed as dashes: “----”.

- Assuming the pressure monitoring system has been activated and calibrated, a measured value can range from (-)150 to (+)900 mmHg. If the System has been activated or the Console is powered or rebooted, the sensors are no longer considered to be calibrated. This is indicated with the three letters **CAL** instead of the numbers. The probes may be calibrated/recalibrated at this time.
- Select either **NEW** or **PREVIOUS**. By electing to use the previous calibration constant (**PREVIOUS**), you are acknowledging that the last calibration value stored was within acceptable limits. By selecting **NEW**, you are prompted to vent the transducer to atmospheric pressure to establish the transducer offset point. By pressing **CAL P1** and/or **CAL P2**, the specific channels are calibrated. Always close the transducer vent before returning transducer into service.
- The pressure monitoring system is now ready for use.

7.15 Stopwatches

The Stopwatch function is only available via the Monitor.

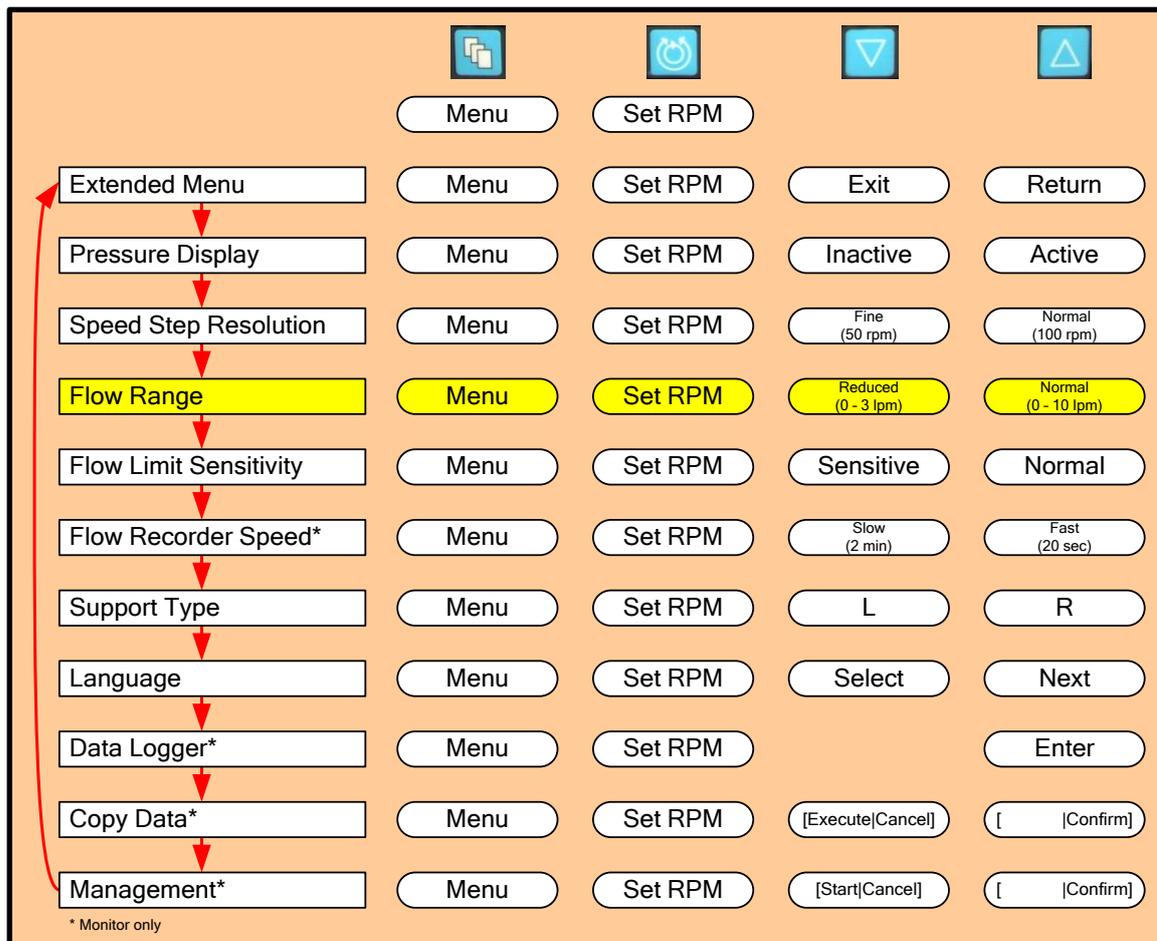


**Figure 43: Monitor MENU Structure
Stopwatches**

The stopwatches are provided for measuring times associated with the System. They measure to the nearest second.

To start the timer, depress the **MENU** button until the **STOPWATCH** option is displayed. To start the stopwatch, depress the **START** button. To stop the stopwatch, press the **STOP** button. Once the timer has been stopped, the System will offer the option to **RESET**, which will clear the timer.

7.16 Flow range



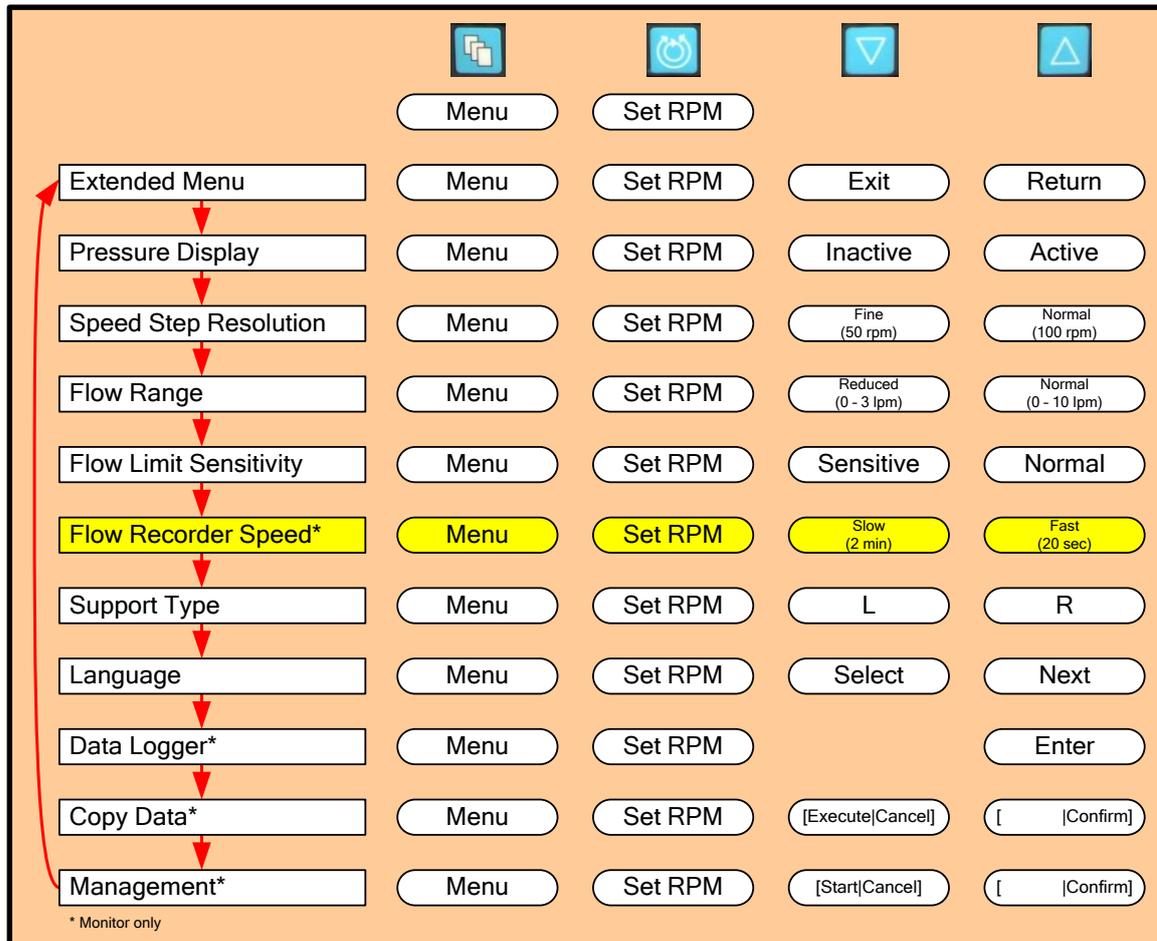
**Figure 44: Monitor MENU Structure
Flow Range**

The System may be used to treat a variety of conditions to accommodate different ranges of flow. Under different conditions, the System may be operated in one of two flow ranges 0 – 10 LPM and 0 – 3 LPM. Changing the flow range will adjust the range of the flow display bar, as well as the default limit for the maximum flow alarm if the high limit is more than 3.0 LPM. The most common use of the low flow range is for display of flow during use of the smaller flow transducer designed to be placed on ¼” ID tubing.

To change between the two ranges, depress the **MENU** button until the **EXTENDED MENU** option is displayed, then use the **MENU** key to scroll through the menu options until the **FLOW RANGE** option is displayed. Select between the two options using the arrow keys.

7.17 Changing the flow recorder speed

The flow recorder function is only available via the Monitor.

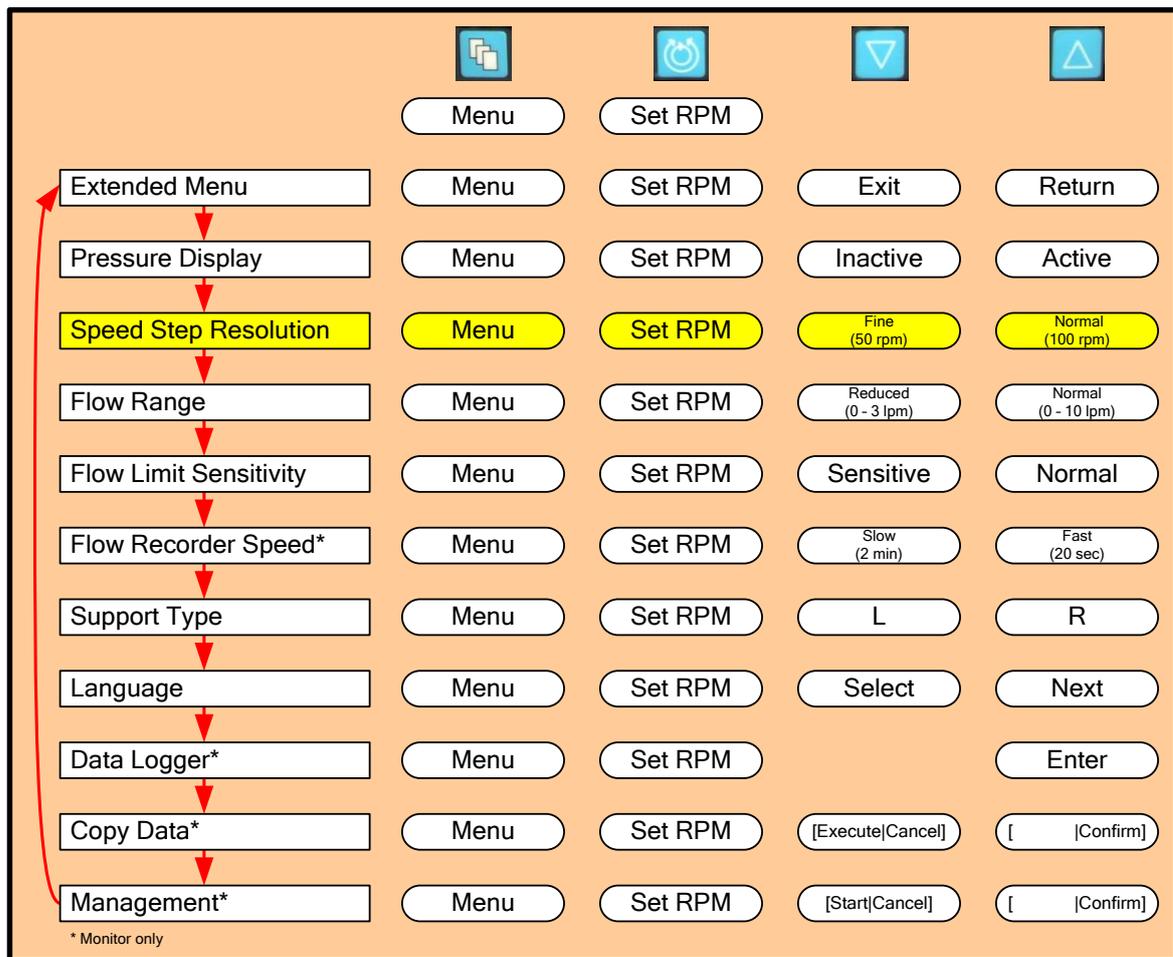


**Figure 45: Monitor MENU Structure
Changing the flow recorder speed**

The System allows the user to alter the speed of the moving flow graph displayed on the bottom of the Monitor screen. The available speeds are 2 minutes and 20 seconds. The speed changes the amount of time taken to fill one screen with flow data; changing this parameter allows the user to see flow trends over different time periods.

To change between the available options, depress the **MENU** button until the **EXTENDED MENU** option is displayed and then use the **MENU** key to scroll through the menu options until the **RECORDER SPEED** option is displayed. Select between the two available options using the arrow keys.

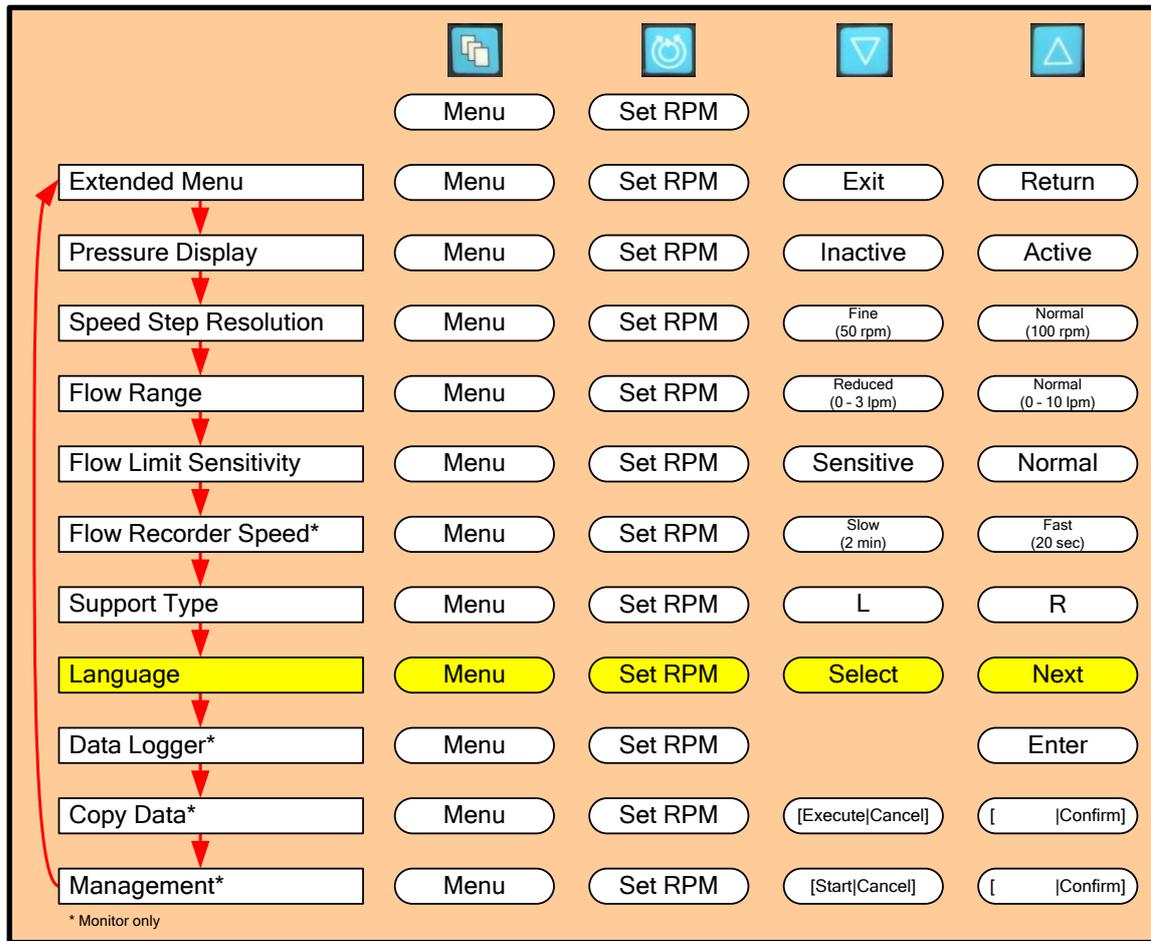
7.18 Setting the Console Speed Step Resolution



**Figure 46: Monitor MENU Structure
Speed Step Resolution**

The System may be used to treat patients with a wide range of body sizes and conditions. The **SPEED STEP RESOLUTION** function is provided to allow the user to select smaller incremental changes in speed (50 RPM increments) for small individuals, and larger (100 RPM) changes for the larger patients. The default setting is the 100 RPM option. To access the **SPEED STEP RESOLUTION** function, depress the **MENU** keypad and scroll down to the **EXTENDED MENU** option, then depress the Menu key until the **SPEED STEP RESOLUTION** option appears. Choose between the **STEP 50** (50 RPM) and **STEP 100** (100 RPM) options using the **UP** and **DOWN** arrows. Once selected, this will dictate the speed that the Pump will increase with each depression of the **UP** or **DOWN** ARROW keypads when using the **SET RPM** option.

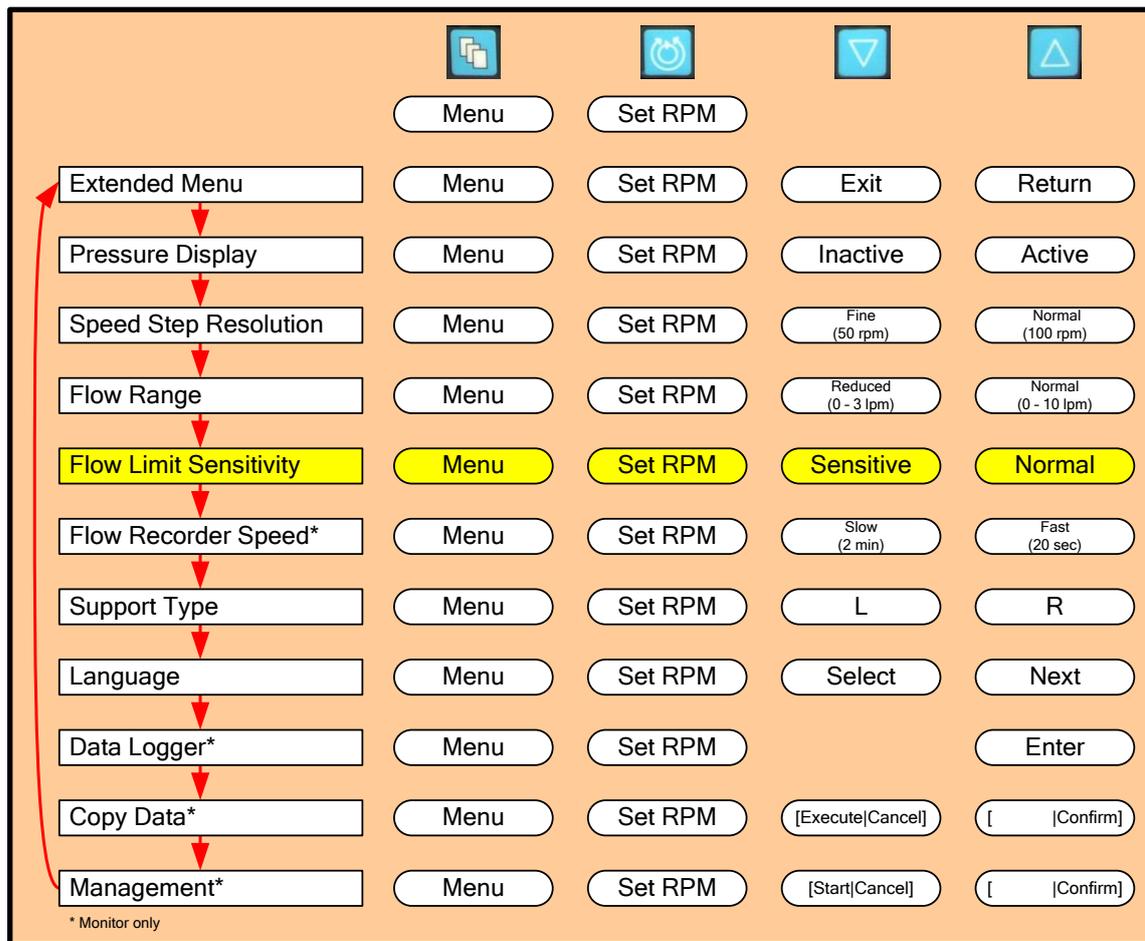
7.19 Selecting Displayed Language



**Figure 47: Monitor MENU Structure
Language Selection**

Language selection is a standard menu option. The default language is English. To change the language, depress the **MENU** keypad and scroll down to the **EXTENDED MENU** option, then use the **MENU** key to scroll through the menu options until the **LANGUAGE** option appears. The available language options will be displayed using the **DOWN** arrow for the **NEXT** language option. The **LANGUAGE** options include: **ENGLISH, FRENCH, GERMAN, SPANISH, DUTCH, and ITALIAN**. Press the **SELECT** keypad to lock in the language selection. The language selected will be stored in permanent memory by the Console and recalled each time the Console is powered up.

7.20 Setting the Console flow limit sensitivity



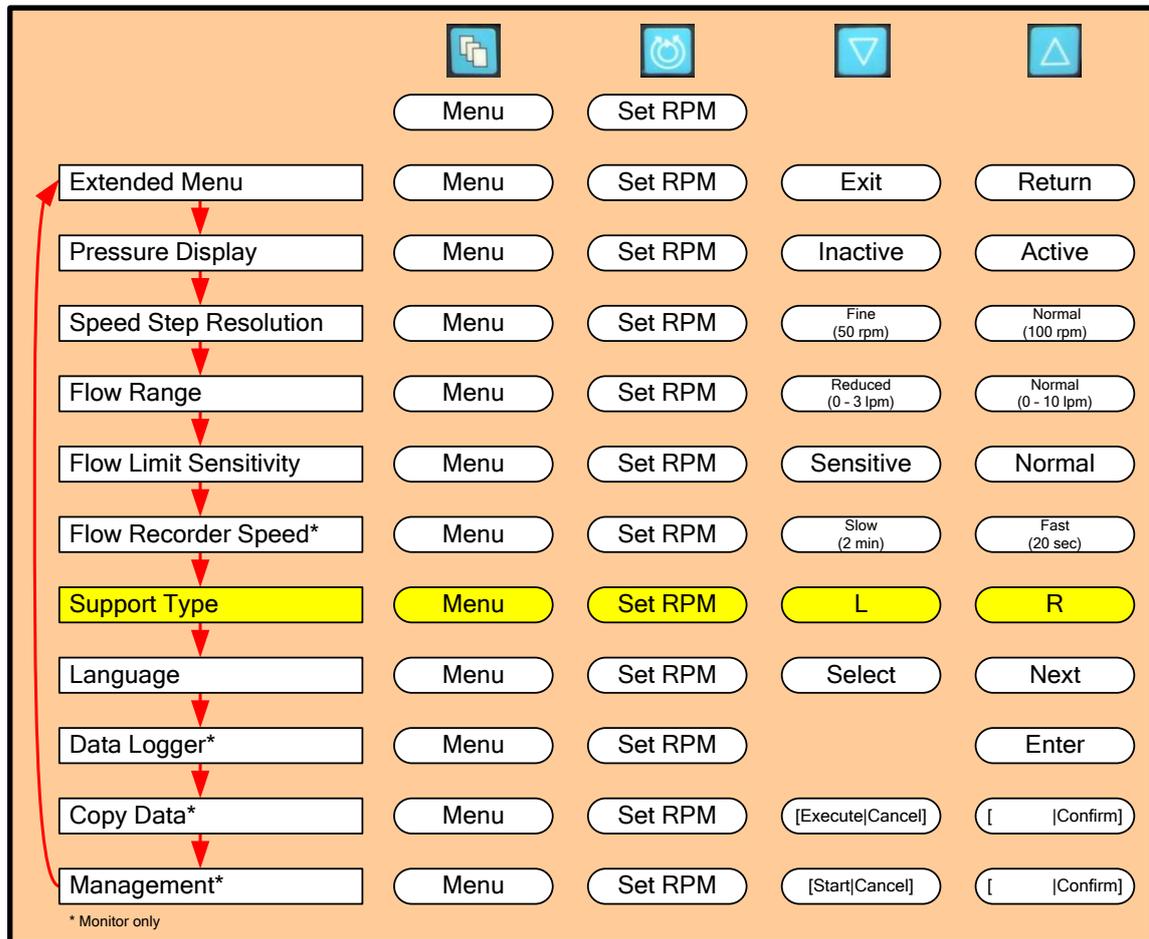
**Figure 48: Monitor MENU Structure
Flow Limit Sensitivity**

A sudden decrease in flow below the **MINIMUM FLOW ALERT** setting could indicate a potentially hazardous condition. The Console incorporates sensing technology to alert the user of such transient events. Should the System alert the user that the flow has dropped below the **MINIMUM FLOW ALERT** setting, the user is instructed to carefully reduce the speed (RPM) of the Pump until the hazardous condition is resolved. Naturally, care must be taken to provide sufficient flow for the patient while investigating the root cause of the event.

The Console may be operated with the **FLOW LIMIT SENSITIVITY** set in one of two modes: **NORMAL** or **SENSITIVE**. Under routine use, the System is designed to be operated in the **NORMAL** mode which is the factory default setting. The **NORMAL** mode is capable of detecting reductions in flow below the minimum flow setting under routine conditions. There are circumstances, however, especially with small patients or during the early postoperative period, where the operator may wish to run the System in the **SENSITIVE** mode. The **SENSITIVE** mode increases the flow data sampling frequency in order to detect shorter duration low flow events compared to the **NORMAL** mode. As a result, a sudden, brief reduction in flow below the **MINIMUM FLOW ALERT** setting that may occur with patient movement is more likely to be detected in the **SENSITIVE** mode than the **NORMAL** mode.

To choose between the **NORMAL** and **SENSITIVE** options, depress the **MENU** keypad and scroll down to the **EXTENDED MENU** option, then use the **MENU** key to scroll through the menu options until the **FLOW LIMIT SENSITIVITY** option is displayed. Depress either the **NORMAL** or **SENSITIVE** keypads to select the option. The sensitivity chosen affects both **FLOW BELOW MINIMUM** alert and **FLOW ABOVE MAXIMUM** alert.

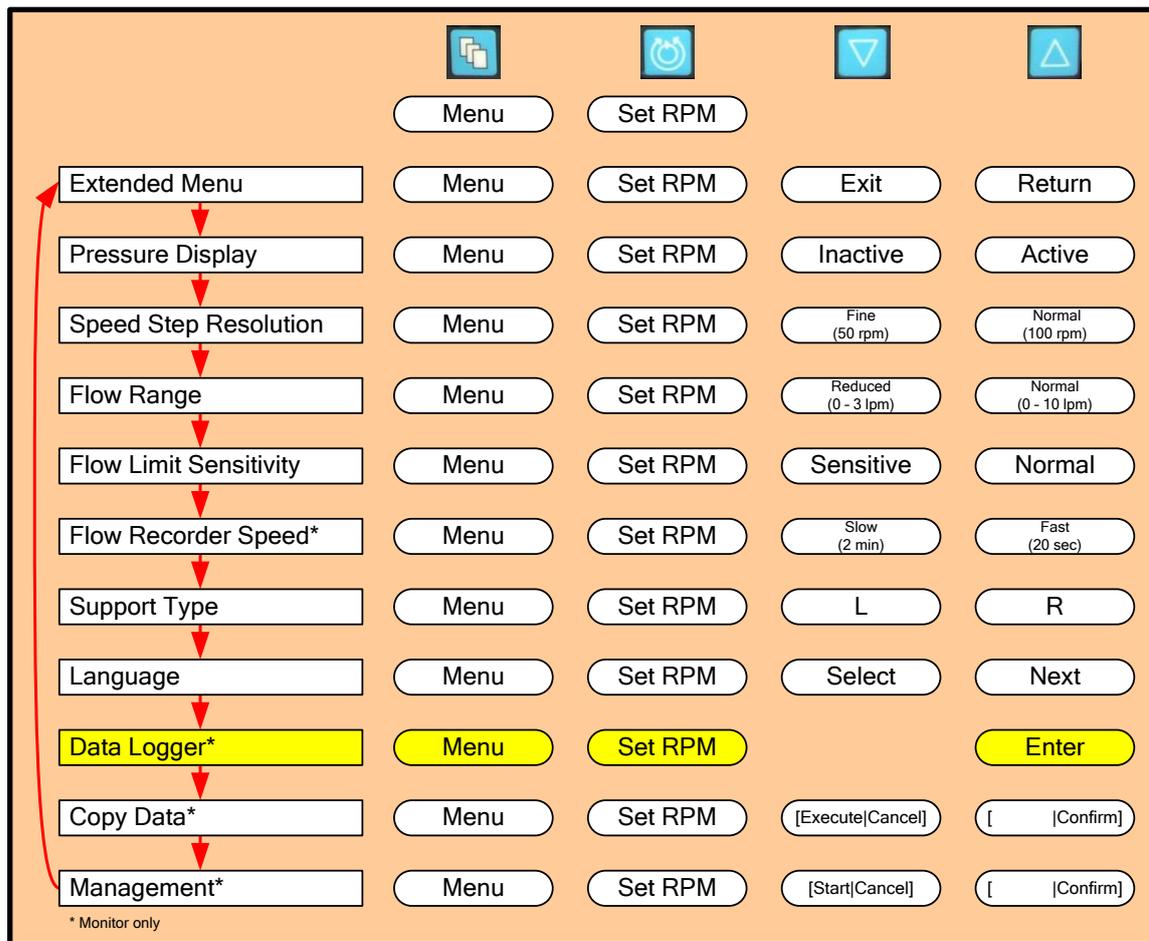
7.21 Setting the Application Mode



**Figure 49: Monitor MENU Structure
Setting Application Mode**

The Console can be used for a variety of conditions. The display for each Console can be set to identify the Console as the L or R Console identifying use of an LVAD (L) or as an RVAD (R). The specific mode must be selected during startup, and can be altered through the user menu. To access the **APPLICATION MODE** setting, depress the Menu keypad and scroll down to the **APPLICATION MODE** setting. Choose between the **L** or **R** using the **UP** and **DOWN** arrows. Please note that this selection only affects the background color of the Monitor and does not affect function or options available on the Consoles. Identification of each Console allows an easy differentiation in case the System is used in a bilateral configuration.

7.22 The System Data Logger



**Figure 50: Monitor MENU Structure
System Data Logger**

The Console has the ability to record significant events. To access the **DATA LOGGER** setting, depress the **MENU** keypad and scroll down to the **EXTENDED MENU** option, then use the **MENU** key to scroll through the menu options until the **DATA LOGGER** option appears.

The Console can record approximately 16 hours of data. When a Console is connected to the Monitor, it uploads the data stored in the Console to the Monitor. The Monitor can store several consecutive days of data. The number of days is dependent on the number of events for a given period. If a Monitor is not connected to a Console within 16 hours, the oldest recorded data on the Console will be overwritten with new data as it is generated. When the Console is used with the Monitor, the data are recorded directly into the Monitor.

The Monitor must be attached to the Console to allow viewing of the stored data. If a Console is powered off or rebooted then all recorded data will be lost.

The System data logger allows users to view a log of significant events that have occurred since the System was powered up. Each logged event follows the format shown in the figure below.



Figure 51: Monitor – Sample Data Logger Event

The System records a number of parameters for each event.

a) There are 9 different types of events and each has its own associated icon. The icons and the associated events are shown in the table below (**Table 9**).

Table 9: Event Types for the System data logger		
Name	Symbol	Event
Uptime		This event is generated every 15 min to give the total amount of time that the Console has been powered up.
Info		This event is generated when the System is started, stopped, turned off and for System time changes.
Alarm		This event is generated when a System alarm is activated. See Table 13 for a list of alarms.
Alarm acknowledged		This event is generated when the “Alarm Acknowledge” button is pressed and an alarm is still active.
Alarm Deactivated		This event is generated when an alarm is no longer active (i.e. the condition is resolved).
Alert		This event is generated when an alert is activated. See Table 13 for a list of alerts.
Alert acknowledged		This event is generated when the “Alarm Acknowledge” button is pressed and an alert is still active.

Table 9: Event Types for the System data logger		
Name	Symbol	Event
Alert Deactivated		This event is generated when an alert is no longer active (i.e. the condition is resolved).
Setting Change		This event is generated whenever a setting is changed e.g. Pump speed, pressure alarms, etc.

b) Timestamp

The System records the time that the event was logged. The time used is the System clock. For information on setting the System clock, see **Section 7.25**.

c) Date stamp

The System records the date the event took place. For information on setting the System clock, see **Section 7.25**.

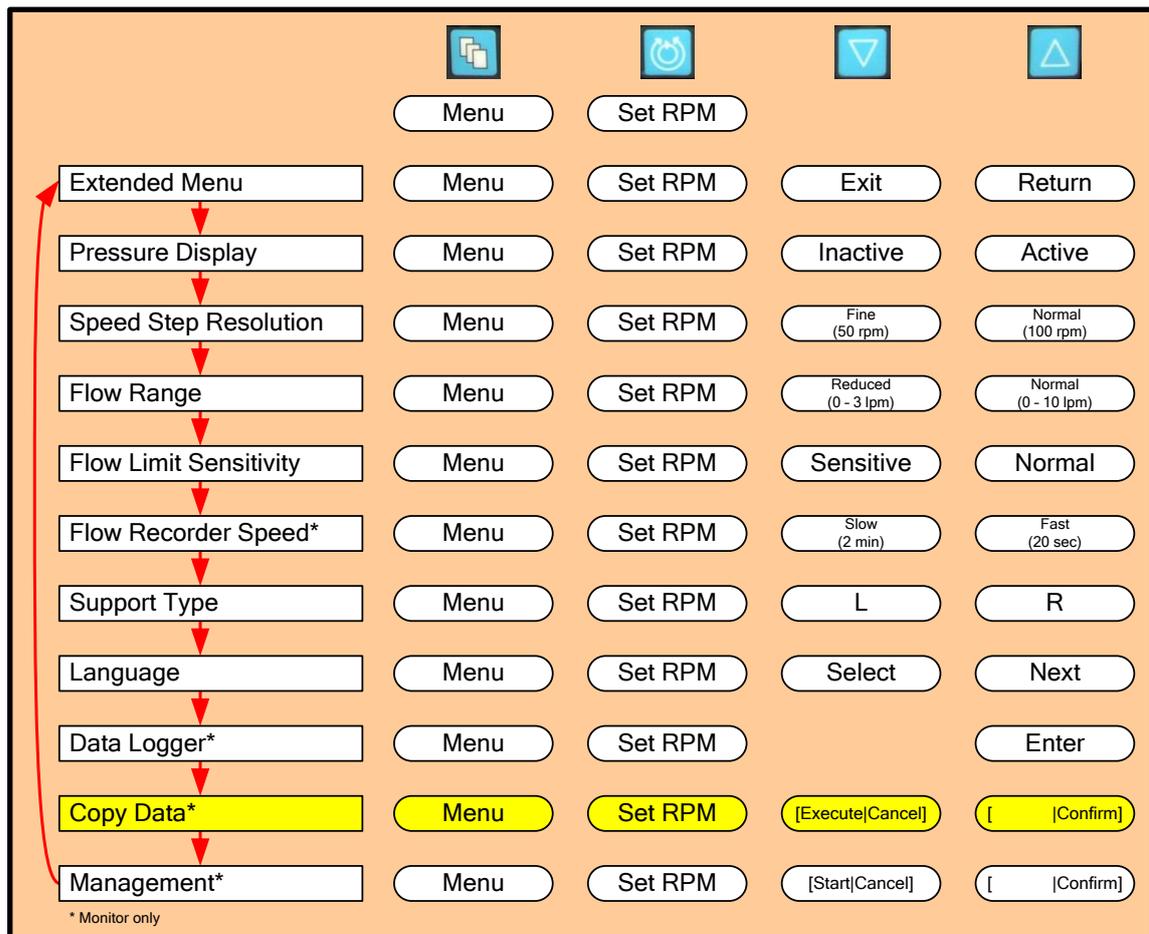
d) Details on the event.

The System records details about the event. This includes such detail as the alarm name and the exact parameter changes that have been made.

To navigate through the list of logged events, use the **UP ARROW** and **DOWN ARROW** on the right of the Monitor to move up and down through the list of logged events and the **UP ARROW** and **DOWN ARROW** on the left of the Monitor to move between pages of data.

In addition to events, the System also records flow every 5 seconds and displays this on a graph. The graph will display one hour of flow data. The graph will center on the event that is highlighted; to display older flow data scroll down through the list of events until the required epoch of flow is displayed.

7.23 Copy Logger Data to a USB Memory Stick



**Figure 52: Monitor MENU Structure
Copy Data**

The logger data may be copied to a USB Memory Stick. A new session is started every time the Console is switched ON.

Connect a USB Memory Stick to the USB Port of the Monitor. A connected Memory Stick is indicated with a USB Stick Icon in the status bar on the Monitor (left of the date/time indication).

WARNING

Only USB-compatible Memory Sticks may be used with the Monitor. No other USB devices may be used (e.g. printer) with the Monitor.

To access the **COPY DATA** command from the Monitor menu, depress the Menu keypad and scroll down to the **COPY DATA** entry. Select **EXECUTE** and **CONFIRM** using the **UP** and **DOWN** arrows. The logger data copy process will be initiated. This is indicated with a blinking USB Memory Stick Icon in the status bar on the Monitor (left of the date/time indication). Wait until the Icon stops blinking. The USB Stick can now be disconnected, and the data are ready for further processing (e.g. Mag Log Converter).

The Logger Data is stored on the USB Memory Stick in the “**log**” folder.

The sub-folders are labeled “xx-xx-xx-xx-xx-xx_JJJJ-MM-DD_hh-mm-ss” where “xx-xx-xx-xx-xx-xx” represents the Monitor hardware ID and “JJJJ-MM-DD_hh-mm-ss” indicates the copy date and time (e.g. 00-00-10-74-61-3f_2010-01-25_14-25-36).

The logger data files are stored within these subfolders. The logger data file names are labeled “yy-yy-yy-yy-yy-yy_zzzz-zzzz-zzzz_aaaa.log” where “yy-yy-yy-yy-yy-yy” represents the Console hardware ID, “zzzz-zzzz-zzzz” represents the Console firmware ID and “aaaa” indicates the logger session (e.g. 00-00-10-61-2f-9f_0021-0000-003a_001e.log).

7.24 Monitor Connection

The Console may be used with or without the Monitor. It is recommended that the Monitor be used whenever the patient is not being transported and is in a stationary mode. To use the Monitor, connect the cable from the Monitor to the rear panel of the Console, and mount the Monitor to the mounting bracket on the Cart. The Monitor is automatically powered ON as soon as it is connected to the Console. The Monitor displays basic operational data and System status updates when the System is operated in either the biventricular or univentricular mode of operation.

The Monitor is designed to display information derived from one or two Consoles. It is possible, therefore, to view data when the System is operated in the univentricular configuration (LVA or RVA) or when the System is used in the BiVA configuration (LVA + RVA). To do so, the user must provide input to the Console, either during set-up or at any time thereafter, by designating whether the Console is being used as an LVA or an RVA. This is accomplished by accessing the **MENU** Options on the Console and selecting **Application Mode**. Use the **UP** and **DOWN** arrows to select either LVA or RVA. The information on the Monitor will be displayed in **Red** when a Console is designated for use as an **LVA**, in **Blue** if designated for use as an **RVA**.

CAUTION

The Monitor may be operated when the 2nd Generation CentriMag Console is running on AC power or in combination with the Console Version 2 on battery. Operating the Monitor while the Console runs on battery shortens the battery runtime. Refer to the individual RVA or LVA Console display when the Monitor is not in use.

7.25 Accessing the Monitor Management Application

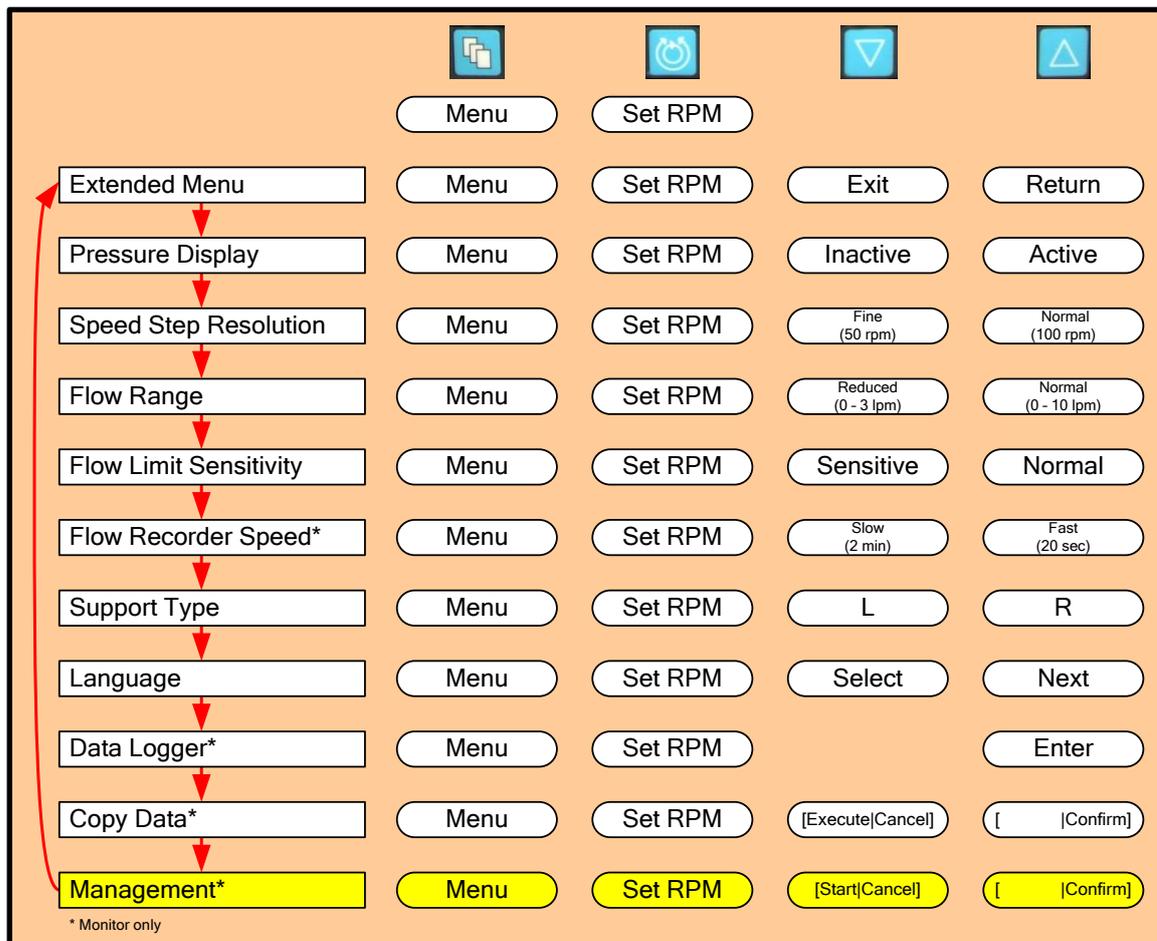


Figure 53: Monitor MENU Structure Starting Management Application

The Monitor has a Management Application which allows users to change options, including time and date, as well as retrieve information about the software version installed on the Monitor.

To access the **MANAGEMENT** Application, depress the Menu keypad and scroll down to the **MANAGEMENT** entry. Select **START** and **CONFIRM** using the **UP** and **DOWN** arrows. The Monitor will reboot and display the words "**MANAGEMENT. LOADING APPLICATION...**". Note: The rebooting sequence will only restart the Monitor, and not the Console.

One other option to access the Management Application is to hold down the **MENU** key while the Monitor is being connected to the Console. The system will display the words "**MANAGEMENT. LOADING APPLICATION...**".

The Management Application has a menu on the left side and an Information Panel on the right side. Menu items are accessible with the **MENU** key.

1) Time & Date Menu:

This menu item allows users to set the System time and date. This is essential for ensuring that the System data logger is recording data with the correct timestamps.

On the "Time & Date Menu" press the **UP** key to enter the sub menu. In the sub menu, time/date can be changed by using the **MENU** key (selection) and **UP** key (increase) or **DOWN** key (decrease).

2) Reboot:

This menu item allows users to exit the Management Application and return to normal operation, Note: This will restart the Monitor only and not the Console.

Once “Reboot” is selected, press the **UP** key and then the **DOWN** key (confirm) to reboot the Monitor.

The Information Panel on the right displays the following information:

- 1) Actual Time/Date Setting
- 2) Application Selection Setting: Always “CentriMag”
- 3) Debug Mode Setting: Always “Off”
- 4) Data Logger View Mode Setting: Always “Normal”
- 5) Application Software Version

7.26 Pump Set-up

Refer to the CentriMag and PediMag Pump Instructions for Use for proper setup and operation of the Pumps.

WARNING

Always fully unscrew the Pump retaining screw built into the Motor before inserting and locking the Pump in the Motor receptacle. This requires five complete counter-clockwise rotations of the screw. Failure to do so may inhibit the ability to fully seat and lock the Pump in the Motor receptacle resulting in loss of function and a MOTOR ALARM or PUMP NOT INSERTED alarm. Should this condition occur, unscrew the retaining screw, remove the Pump, reinsert the Pump, tighten the retaining screw, turn the Console power OFF and ON, ensure no alerts/alarms are displayed, and set the Console to initiate pumping.

8 SYSTEM OPERATION

This section describes the operation of the Console including starting and stopping the Pump and adjusting the Pump speed. This section also contains information on the System parameters, alarms and battery operation for patient transport.

Prior to starting the Pump, the Flow Probe cable must be connected to the Console and the Flow Probe attached to the return tubing. Clamp the Pump outlet or return tubing to prevent retrograde flow before connecting the extracorporeal circuit to the Cannulas and prior to turning the Pump ON.

8.1 Operation of the Pump

WARNING

Monitor the patient's hemodynamics and the Console flow display to ensure the patient has adequate blood volume that the drainage cannula is properly positioned, the Pump RPM is appropriate, and the desired flow is achieved. Increase Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing drainage cannula obstruction.

CAUTION

The Console, Monitor, Mag Motor, and Flow Probe are not sterile and cannot be sterilized. Do not use the Console, Monitor, Motor, and Flow Probe inside of the sterile field or in a location where they may come into contact with items that must remain sterile.

8.1.1 Starting the Pump

To start the Pump, perform the following steps:

1. Place the Pump into the Motor receptacle and secure in place per the Instructions for Use supplied with the Pump.
2. Start the Pump by first depressing the **SET RPM** keypad. **SET PUMP SPEED = 0000 RPM** will be displayed. Depress the **INCREASE** keypad and increase the RPM to a level sufficient to overcome the Pump afterload (>1000 RPM for large return cannula or low arterial pressure and >1600 RPM with small return cannula or high arterial pressure) while slowly unclamping the return tubing. Higher RPM's (>1800 RPM) may be required with very small Cannulas.
3. Slowly increase the RPM until the flow rate is at the desired level.

The **RPM** and **LPM** will be displayed on the Console display.

Note: Always set the **MINIMUM FLOW ALERT** to the desired minimum flow level as soon as possible after initiation of support by following the instructions provided in **Section 7.10**.

WARNING

Depressing opposing inputs to the Monitor and Console at the same time, such as depressing the **UP** arrow on the Monitor and the **DOWN** arrow on the Console, will result in no change in the Console, consistent with no input.

WARNING

Switch to a backup Console, Motor and Flow Probe if any of the buttons malfunction, if the display goes blank, and/or the main Console ceases to operate.

WARNING

Switch to another Monitor if any of the buttons on the Monitor malfunction, if the display goes blank, or if the Monitor ceases to operate.

8.1.2 Adjusting Pump Speed

Pump speed can be adjusted by first depressing the **SET RPM** keypad and then depressing the **INCREASE** or **DECREASE** keypads. The available speed range is between 500 and 5,500 RPM. The flow at a given RPM is dependent upon the position of the drainage and return Cannulas, intravascular blood volume, patient's hemodynamic status, and resistance of the extracorporeal blood circuit components.

8.1.3 Manually Stopping the Pump

Depressing and holding the **STOP** keypad on the Console's front panel for five seconds manually stops the Pump if the Pump is running. While depressing the **STOP** keypad, the message **TO STOP PUMP HOLD DOWN STOP KEY** will be displayed. The **FLOW BELOW MINIMUM** alert message is then displayed (if a Minimum Flow Alarm Level is set) and the audible alarm sounds.

WARNING

Only depress the Main AC Power Button to OFF when the System is no longer in clinical use. To stop the Pump during patient support, depress and hold the **STOP** keypad on the Console's front panel for five seconds.

8.1.4 Restarting the Pump

If the Pump has been stopped, either manually or from an alarm condition, the user should follow the Pump restart sequence described below.

WARNING

DO NOT attempt to restart the Pump after it has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Pump, circuit, and Cannulas.

WARNING

DO NOT restart the Pump if it has stopped due to Motor overheating. Overheating is confirmed by a **MOTOR OVER TEMP** alert message and temperature sufficient to prevent the user from placing and holding a hand on the Motor housing. Clamp the return tubing and switch to the backup System according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.

WARNING

A Pump stoppage will create a reverse flow shunt, as well as limit the body's ability to maintain adequate arterial pressure. Clamping the Pump outlet tubing is necessary to prevent a low flow or low pressure incident in a Pump-off scenario. The tubing clamp must be removed before returning to normal Pumping activity.

WARNING

DO NOT clamp, partially clamp, or restrict the tubing during normal Pump activity. Clamping the tubing may cause increased risk of thromboembolic events.

WARNING

Monitor patient's hemodynamics and the Console flow display to ensure the patient has adequate blood volume, that the drainage cannula is properly positioned, the Pump RPM is appropriate, and desired flow is achieved. Increase Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing drainage cannula obstruction.

To restart the Pump, perform the following steps:

1. Ensure that the Pump is securely located in the Motor per the Instructions for Use supplied with the Pump.
2. Ensure that any alarm condition has been corrected.
3. Start the Pump by first depressing the **SET RPM** keypad. **SET PUMP SPEED = 0000 RPM** will be displayed. Depress the **INCREASE** keypad and increase the RPM to a level sufficient to overcome the Pump afterload (>1000 RPM for large return cannula or low arterial pressure and >1600 RPM with small return cannula or high arterial pressure) while slowly unclamping the return tubing. Higher RPM's (>1800 RPM) may be required with very small cannulas.
4. Slowly increase the RPM until the flow rate is at the desired level.

The **RPM** and **LPM** will be displayed on the Console.

8.2 Console Alarm/Alert Strategy

A normal operating condition is free of any alerts or alarms and is classified as a green state of operation. The Console alarm/alert strategy is based on the following philosophy. Audio and visual advisories are divided into two groups, System **Alerts** and System **Alarms**, to warn the operator of conditions that may interrupt patient support or damage the Pump, Motor, or Console. **Alert Advisories** activate when the System is about to, or has entered, an unsafe but resolvable operating state (yellow state). In the event of an **Alert condition (medium priority)**, the Console continues pumping operation. **Alarm Advisories** activate when the System is about to, or has entered, an unsafe state of operation which may be hazardous to the patient, operator, or device (red state). Except for the **MOTOR ALARM** condition, in the event of an **Alarm condition (high priority)**, the Console stops the Pump. **Table 10** illustrates the fundamental strategy.

Table 10: Main Console Alarm/Alert Advisory Strategy		
Operating State	Advisory Level	Anticipated Operator Response
Green	None	None
Yellow	Alert	Resolve Fault Condition
Red	Alarm	Resolve Alarm Condition or Switch to backup Console/Motor/Flow Probe

If an alarm or alert condition occurs, the audible advisory sounds along with a visual message indicating the cause(s) of the alarm/alert condition on the alphanumeric display. Depressing the ALARM ACKNOWLEDGE keypad temporarily mutes the audible alarm for most alarms and the audio paused symbol is displayed on the Console and the Monitor. There are three high priority alarms which may not be muted (**Table 11**). For all alarms/alerts, the alarm/alert message is continuously displayed on the Console display as long as the alarm/alert condition exists. The visual display of the alarm/alert condition and the audio paused symbol will be automatically removed provided: a) the condition was acknowledged by depressing the Alarm Acknowledge button, and b) the condition was resolved. If the visual indication of the alarm/alert condition remains, the user either failed to acknowledge the condition by depressing the Alarm Acknowledge button, the alarm/alert condition has resolved and reoccurred, or the condition has not been successfully resolved.

Note: Should the alarm/alert condition be successfully resolved but the visual indication persists, the user may clear the visual display by depressing the Alarm Acknowledge button. Persistence of the visual display after depressing the Alarm Acknowledge button indicates the alarm/alert condition has not been resolved or has reoccurred. If the alarm/alarm condition cannot be resolved, the user should refer to Table 13 or Table 16 to determine the appropriate operator response for the specific Alert/Alarm which has occurred.

In the case of multiple alarms/alerts, each time a new alarm/alert condition occurs, a new audible alarm and a new message will be displayed on the Console and Monitor. The alarm/alert messages will be listed in order of priority from most severe to less severe. Alarms always take higher priority than alerts. If more than three alarm/alert conditions occur simultaneously, the Console will offer the DOWN option. Depressing the **DOWN** keypad will scroll down one alarm/alert message. Refer to **Table 7** for a listing of alarm and alert messages in their order of priority.

The Console features 6 alarms and 20 alerts as shown in **Table 11**.

Table 11: Console Alarms & Alerts In Order Of Priority			
ID	Alarm/ Alert	Description	Ability to Silence Audio (Yes/No) (Silence Interval⁸)
S1	Alarm	POWER ON TEST FAIL	No
S2	Alarm	SYSTEM FAULT (Run-Time System Failure)	No
M1	Alarm	MOTOR STOPPED	Yes (60 Sec.)
M2	Alarm	MOTOR DISCONNECTED	Yes (60 Sec.)
M3	Alarm	PUMP NOT INSERTED	Yes (60 Sec.)
M4	Alarm	MOTOR ALARM	No
M5	Alert	SET PUMP SPEED NOT REACHED	Yes (60 Sec.)
B1	Alert	BATTERY MODULE FAIL	Yes (60 Sec.)
B2	Alert	BATTERY BELOW MINIMUM	Not while running on batteries – can be silenced when reconnected to AC
F1	Alert	FLOW PROBE DISCONNECTED	Yes (60 Sec.)
S3	Alert	SYSTEM ALERT	Yes (60 Sec.)
F2	Alert	FLOW SIGNAL INTERRUPTED	Yes (60 Sec.)
F3	Alert	FLOW BELOW MINIMUM	Yes (60 Sec.)
F4	Alert	FLOW ABOVE MAXIMUM	Yes (60 Sec.)
P1	Alert	PRESSURE 1 DISCONNECTED	Yes (Permanent – visual message remains)
P2	Alert	PRESSURE 2 DISCONNECTED	Yes (Permanent – visual message remains)

⁸ When applicable, audio tone will reactivate if the condition persists during time lapse.

Table 11: Console Alarms & Alerts In Order Of Priority			
ID	Alarm/Alert	Description	Ability to Silence Audio (Yes/No) (Silence Interval⁸)
P3	Alert	PRESSURE SYSTEM FAIL	Yes (60 Sec.)
P4	Alert	PRESSURE 1 BELOW MINIMUM	Yes (60 Sec.)
P5	Alert	PRESSURE 2 BELOW MINIMUM	Yes (60 Sec.)
P6	Alert	PRESSURE 1 ABOVE MAXIMUM	Yes (60 Sec.)
P7	Alert	PRESSURE 2 ABOVE MAXIMUM	Yes (60 Sec.)
M6	Alert	MOTOR OVER TEMP	Yes (60 Sec.)
B3	Alert	BATTERY CHARGER FAIL	Yes (60 Sec.)
B4	Alert	BATTERY MAINTAINANCE REQUIRED	Yes (Permanent – visual message remains)
B5	Alert	LOW BATTERY	Yes (10 Min. while running on batteries – permanent when reconnected to AC, visual message remains)
B6	Alert	ON BATTERY	Yes (15 Min.)

A complete list of all Alarms and Alerts may be found in **Table 13**. This list includes a description of each advisory, the System response, and the anticipated response of the operator. Also shown is the trigger for each alarm/alert condition.

8.3 Alarms

In the event of an Alarm condition (see **Table 13**, for alarm condition listing), the Console stops the Pump. The Console allows the user to acknowledge the Alarm, which for all but two high priority alarms silences the audio alarm advisory, but will not remove the visual message, and will usually not allow pumping to continue until the alarm condition no longer exists. The audio advisory reactivates and continues until acknowledged. Run time diagnostic messages/alarms only need to be acknowledged once and will not reactivate until the next occurrence after the “Alarm Acknowledge” button has been pressed.

The recommended action by the operator during an Alarm Condition is to rapidly assess and respond to the cause of the alarm condition. If equipment change is necessary, clamp the return tubing before switching the Pump to backup equipment. Always unclamp the tubing prior to resumption of pumping.

WARNING

Alarms are associated with conditions during which the Pump usually stops. To prevent retrograde flow through the Pump during an alarm condition during which the Pump has stopped, the Pump outlet tubing must be clamped.

WARNING

DO NOT attempt to restart the Pump after it has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Pump, extracorporeal circuit, and Cannulas.

WARNING

DO NOT restart the Pump if it has stopped due to Motor overheating. Overheating is confirmed by a MOTOR OVER TEMP alert message and temperature sufficient to prevent the user from placing and holding a hand on the Motor housing. Clamp the return tubing and switch to the backup System according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.

8.3.1 Alarm Conditions Requiring Powering Off Before Restarting

If during set-up, the Console produces an alarm condition listed in **Table 12**, turn the power switch to OFF, check all cable connections, and turn the power switch back to ON. If the alarm reoccurs, use another Console and Motor. Do not use the suspect Console and Motor either as a main or a backup unit.

In the event of a Console alarm when a Pump has been running, consult **Table 13** for the appropriate action.

Table 12: Alarm Conditions Requiring Powering Off Before Restarting

POWER ON TEST FAIL
SYSTEM FAULT

WARNING

It is intended that systemic anticoagulation be utilized while the System is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient.

8.3.2 Alerts

In the event of an Alert condition (see **Table 11** or **Table 13** for complete list of all alert and alarm conditions), the 2nd Generation CentriMag Console continues pumping operation. An alert is an advisory that a System operating parameter is approaching or has produced an undesirable operating condition. An alert is sounded, and the alert

message is displayed, but the Pump does NOT stop. The operator can mute the audible alert by depressing the ACKNOWLEDGE keypad, which silences the audio advisory, but will not remove the visual message.

The exception to audio alarm silencing is the **BATTERY BELOW MINIMUM** alert while running on battery. This alert cannot be silenced until the Console is plugged into AC power. The **BATTERY BELOW MINIMUM** alert will not stop the Pump until the battery is fully discharged at which point the Console will power off. If this alert occurs, the user must immediately plug the System into AC power, or change to a backup System.

If an alert condition persists for more than 60 seconds after the alert has been acknowledged, the audio advisory reactivates and continues until acknowledgement except for **BATTERY MAINTENANCE REQUIRED** (only requires acknowledgment once) and **ON BATTERY / LOW BATTERY** (audio reactivates every 15 / 10 minutes or until reconnected to AC power). The recommended action by the operator during an Alert Condition is to take action to resolve the specific fault condition.

The visual display of the alert condition will be automatically removed provided: a) the condition was acknowledged by depressing the Alarm Acknowledge button, and b) the condition was resolved. If the visual indication of the alert condition remains, the user either failed to acknowledge the condition by depressing the Alarm Acknowledge button, the alert condition has resolved and reoccurred, or the condition has not been successfully resolved.

Note: Should the alert condition be successfully resolved but the visual indication persists, the user may clear the visual display by depressing the Alarm Acknowledge button. Persistence of the visual display after depressing the Alarm Acknowledge button indicates the alert condition has not been resolved or has reoccurred. If the alert condition cannot be resolved the user should refer to **Table 11** or **Table 13** to determine the appropriate operator response for the specific alert which has occurred.

8.3.3 Response to System Alarms or Alerts

When a System alarm or alert condition exists, an alarm tone sounds and a text message appears on the display of the Console. Most alarms and alerts require some action on the user's part to correct the cause. The following table can be used to determine how to correct an alarm or alert condition.

Table 13: Console Alarms & Alerts			
ID	Alarm/Alert	Text Message	System Status & Operator Response
S1	Alarm	POWER ON TEST FAIL	The Pump will not start. An audible alarm will sound, which cannot be muted. Switch the Console OFF and ON again. If the alarm reappears, switch to the backup Console, Motor and Flow Probe, record the alarm message and contact your local Abbott Medical representative.
S2	Alarm	SYSTEM FAULT (Run-Time System Failure)	The Pump will stop. An audible alarm will sound, which cannot be muted. Clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.
M1	Alarm	MOTOR STOPPED	The Pump will stop. An audible alarm will sound, which can be muted for 60 seconds.

Table 13: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
			Clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.
M2	Alarm	MOTOR DISCONNECTED	<p>The Pump will stop.</p> <p>An audible alarm will sound, which can be muted for 60 seconds.</p> <p><u>During setup of the System:</u></p> <p>Press the alarm acknowledge button and check that the Motor connector is fully inserted into the back of the Console.</p> <p><u>During support:</u></p> <p>Press the alarm acknowledge button and check that the connector of the Motor is fully inserted into the back of the Console. Resume support. If the visual alarm message does not disappear, clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M3	Alarm	PUMP NOT INSERTED	<p>System will not start.</p> <p>An audible alarm will sound, which can be muted for 60 seconds.</p> <p>Press the alarm acknowledge button. Insert or re-insert the Pump and secure it with the locking screw.</p> <p>If the alarm repeats, switch to backup Console, Motor and Flow Probe according the procedure described in Section 10.1.</p>
M4	Alarm	MOTOR ALARM	<p>An audible alarm will sound and the System will continue to operate.</p> <p>Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M5	Alert	SET PUMP SPEED NOT REACHED	<p>Check the Pump flow: If Pump flow is satisfactory; reduce set speed while insuring that flow is maintained.</p> <p>Press the alarm acknowledge button. If the alert repeats, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alert message and contact your Abbott Medical representative.</p> <p>If the Pump flow is not satisfactory, clamp the return tubing and switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support.</p> <p>Record the alert message and contact Abbott Medical representative.</p>
B1	Alert	BATTERY MODULE FAIL	The Console battery will not function. An audible alarm will sound.

Table 13: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
			Switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative.
B2	Alert	BATTERY BELOW MINIMUM	The Pump will stop after a very short time. Plug the Console into a AC power outlet to charge the battery. If no AC outlet is available, switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support.
F1	Alert	FLOW PROBE DISCONNECTED	Check the Flow Probe connection on back of the Console. If necessary, reconnect the Flow Probe connector to the back of the Console. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.
S3	Alert	SYSTEM ALERT	Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.
F2	Alert	FLOW SIGNAL INTERRUPTED (Flow rate sensor error)	Manually disconnect, reposition and reconnect the Flow Probe transducer to the tubing. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats. If problem still persists after switching to the backup Flow Probe, stop the Pump and switch to a backup Primary Console. Follow the instructions described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative.
F3	Alert	FLOW BELOW MINIMUM (Low Flow)	Check for physiologic cause or circuit obstruction. Check minimum flow set point. Do not increase RPM without confirming adequate blood volume is available. Common cause of this alert is inadequate blood volume at the drainage cannula site for the desired Pump flow.
F4	Alert	FLOW ABOVE MAXIMUM	Reduce Pump speed and check for cause.
P1	Alert	PRESSURE 1 DISCONNECTED	Check the electrical connections on the pressure 1 transducer and recalibrate. If the problem persists disconnect, reconnect, and recalibrate the transducer. Consider changing the transducer and cable if the problem persists.
P2	Alert	PRESSURE 2 DISCONNECTED	Check the electrical connections on the pressure 2 transducer and recalibrate. If the problem persists disconnect, reconnect, and recalibrate the transducer. Consider changing the transducer and cable if the problem persists.
P3	Alert	PRESSURE SYSTEM FAIL	The pressure monitoring system will not function. If pressure monitoring is needed then change to the backup Console, Motor and Flow Probe.

Table 13: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
			Switch to the backup System according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative
P4	Alert	PRESSURE 1 BELOW MINIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P5	Alert	PRESSURE 2 BELOW MINIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P6	Alert	PRESSURE 1 ABOVE MAXIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
P7	Alert	PRESSURE 2 ABOVE MAXIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
M6	Alert	MOTOR OVER TEMP	Switch to backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Verify that the backup Motor stands free and is not covered (e.g. blankets).
B3	Alert	BATTERY CHARGER FAIL	Press the alarm acknowledge button. If the alert message repeats, switch to backup System as described in Section 10.1. If this alarm is associated with BATTERY MODULE FAIL then carry out the procedure associated with that alarm.
B4	Alert	BATTERY MAINTENANCE REQUIRED	Do not use the Console. Perform battery maintenance according to the instructions provided in Section 9.4.
B5	Alert	LOW BATTERY	Plug the Console into a AC power outlet to charge the battery. If no AC outlet is available, switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support.
B6	Alert	ON BATTERY	Verify that the user wants the Console to be on battery. If so, carefully monitor the status of the battery charge indicator, while using the System on battery. Re-connect to AC-outlet, as soon as possible.

WARNING

Increase Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing drainage cannula obstruction.

8.4 Battery Operation

The Console is designed for operation on AC power; however, it also contains an internal rechargeable battery and charger. If a power failure causes loss of AC power or patient transport is necessary, a new fully charged internal battery will operate the Console for approximately 120 minutes at 5.5 LPM and 3,500 RPM when used with the CentriMag Pump and approximately 180 minutes at 1.0 LPM and 3,000 RPM when used with the PediMag Pump.

The switch from AC power to battery power is automatic and is accomplished without interruption of patient support as long as the battery has sufficient charge. If the System runs in combination with the Console Version 2 on battery, the Monitor will shorten the battery runtime. The reduced runtime depends on the working point of the Pump. With a high load, there is approximately 20% less runtime with the Monitor at nominal speed.

WARNING

If a **LOW BATTERY** alert message is displayed, **AC power must be restored as quickly as possible.**

If the Console is operating on batteries and a **BATTERY BELOW MINIMUM** alarm message is displayed, the Pump is likely to stop at any time without further warning. **AC power must be restored and the alarm acknowledged to prevent the Pump from stopping.**

Alternatively, the Motor and Pump may be switched to the backup Console, Motor and Flow Probe to resume pumping operation.

CAUTION

Always operate the System at the lowest acceptable clinical flows when operating on Console batteries to conserve remaining battery time. Administer appropriate anticoagulation at all times and assess adequacy of anticoagulation when reducing blood flow.

CAUTION

Confirm that the System is operating on AC or battery power by viewing the lit LED for the appropriate power source on the indicator to the right of the display.

AC power loss or disconnection for transport will cause a visual and audio alert to be activated. The Console display shows **ON BATTERY**. The green AC indicator is no longer illuminated and the green battery indicator is illuminated.

When transporting a patient on Console battery power and then returning to AC power, the **ON BATTERY** message is cleared, the green AC indicator is illuminated and the green battery indicator is no longer illuminated.

CAUTION

Whenever the unit is not attached to AC power, regardless of whether the Console is ON or OFF, the internal battery will discharge. The rate of battery discharge will be greater if the Console is ON. In order to prevent unintentional discharge of the battery, always leave the unit plugged into AC Power. The Console must be connected to AC Power to charge or maintain the battery charge, but does not need to be powered ON.

8.5 Operation of the CentriMag™ Circulatory Support System On Internal Console Battery Power

If there is a need to operate the System for a longer period than the Console's internal battery will allow, a backup Console must be used. Refer to Table 14 for appropriate times.

The following System components are required for the operation of the System on Console Battery Power:

- 1) 1 main Console
- 2) 1 backup Console
- 3) Two Motors (one Motor will be connected to the main Console and the other connected to the backup Console)
- 4) 1 main and 1 backup Flow Probe.
- 5) Mag Monitor (optional)

8.5.1 Planning for Battery Support

The duration the System can be operated without mains power is limited by the available battery charge. Careful planning should be taken before extended duration battery support is initiated, and the duration of battery support should be kept to a minimum. The total duration should be planned so that only the internal battery of the main Console is used. The battery in the backup Console should only serve as a reserve for emergency situations or in instances where exact battery support time cannot be estimated beforehand.

The Console should never be connected to ambulance-derived AC mains power. All Consoles need to have fully charged internal batteries before mains power is disconnected from the System. In the event the duration of the patient transit is longer than expected, operate the CentriMag Motor and Pump with the backup Console.

8.5.2 Changing from the Main to the backup Console

When the charge level of the main Console's internal battery reaches a pre-set minimum level, the LOW BATTERY alert is activated, accompanied by an audio tone. In this instance, the main Console must be replaced with a backup Console. In the latter case, follow the steps in the Switching to Backup Hardware section.

8.5.3 Battery Support Time at Various Operating Levels

Estimated battery runtimes of the System at various operating levels while on internal Console battery support are listed in the table below.

Table 14. Console with Monitor when running on Internal Battery (estimated total runtime, minutes)	
System Operating Point	Battery Support Time
2000 RPM, 2 LPM	210
3500 RPM, 5.5 LPM	120
5000 RPM, 9 LPM	80

CAUTION

The estimated battery runtimes reported above are only valid if all batteries are new, fully charged prior to use and have been maintained properly.

8.6 Patient Transport

The System is designed to be transportable as shown in **Figure 54**. A backup Console must be available near the main Console. The 2nd Generation CentriMag Console may be connected to the CentriMag System Transporter (**Figure 54**) for ground vehicle or aircraft transport, or placed on a Cart (**Figure 16**) for intra-hospital transport.



Figure 54: CentriMag™ System Transporter

In some instances, a patient on System support may need to be transported to another medical center. If a patient needs to be transported to another medical center, the following information should be considered.

8.6.1 Transport Vehicle Qualification

- 1) Planning adequate space is important. Review the physical hardware specifications provided in Appendix II – 2nd Generation CentriMag Primary Console Technical Specification.

8.6.2 Console Considerations

- 1) Ensure that the Console's internal battery is fully charged prior to transport.
- 2) A backup System should be fully assembled (power cord, backup Motor, Flow Probe, etc.), tested, and transported with the patient for emergency backup availability.
- 3) Ensure that the backup Console's internal battery is fully charged prior to transport.
- 4) Ensure that the backup Console is kept dry and in a place within the emergency vehicle that minimizes the chance that liquid will fall on it.
- 5) Load all backup equipment (monitors, ventilators, etc.) and supplies into the transport vehicle before bringing patient from the hospital Intensive Care Unit (ICU) or Operating Room.
- 6) Position the Console in a location where the display is visible.

- 7) Monitor the Console's internal battery runtime. Refer to the tables in **Section 8.5.3** for additional information.
- 8) Fasten the Console to the transporter and ensure that the transporter is securely fastened inside the vehicle to prevent movement.

8.6.3 Examples of Additional Equipment to Consider

- 1) Portable vital signs monitor, ventilator, and intra-aortic balloon pump console.
- 2) Oxygen tank(s), if applicable.
- 3) Straps to secure Console.
- 4) Supplies (sterile Pump, tubing, prime solution, etc.) and instruments (sterile tubing clamps and scissors) necessary to replace a Pump, connector, or other component of the System that may be damaged during transport.

8.6.4 FAA Recognized and Other Standards for Transport

The CentriMag Circulatory Support System, including the 2nd Generation CentriMag Console and Monitor, has been successfully tested against applicable international standards for air and ground transport. The System met all applicable requirements for the following standards:

- IEC 60068-2-27: Basic Environmental Testing Procedures: Shock
- IEC 60068-2-6: Environmental Testing: Vibration
- RTCA/DO-160G: Environmental Conditions and Test Procedures for Airborne Equipment; Test Levels
 - Section 20.5, Radiated Susceptibility (RS) Test, **Category R**
 - Section 21.5, Radiated RF Emissions Test, **Category M**

WARNING

The Monitor should not be used in aircraft environments.

8.7 Shut Down by Operator

If the System is no longer needed to provide circulatory support, then the System shut down can be executed as follows:

- 1) Stop the Pump (see **Section 8.1.3** "Manually Stopping the Pump").
- 2) Push the power button at the back of the Console to shut down the System.
- 3) Store the Console plugged into AC power.

CAUTION

If the Console is turned OFF but left connected to the Mains (AC power source), components inside the Console remain powered. Turn the Console OFF and unplug the Console from the Mains to completely turn OFF power to the Console.

WARNING

The Console's internal battery must be fully charged prior to use. The Console must be connected to AC power during storage to charge the battery. If the Console is not charged prior its use, the battery may not have sufficient power to operate the System and the support time will be shorter than if it had been charged.

9 MAINTENANCE

Instructions on how to change the fuses, maintain the Console, and visually inspect the Motor cable for damage are provided below.

WARNING

The Console is serviceable (e.g. opening of the housing) only by a Abbott Medical service representative or Abbott Medical authorized representative.

9.1 Changing Fuses

CAUTION

The Console must be unplugged from AC power source while replacing fuses.

Main System fuses are located just above the receptacle for the AC power cord on the rear panel of the Console.

To change a fuse, follow the steps below:

- 1) Unplug the Console.

NOTE: Fuses can be replaced while the Console is operational on battery power, but the Console MUST be unplugged from AC power source while replacing fuses.

- 2) Locate the Fuse Cartridge Release Tab and gently press up on the Tab with a small flathead screwdriver inserted into the Release Tab Slot. The Fuse Cartridge will partially eject.
- 3) Gently remove the Fuse. The fuses are secured in the end of the cartridge.
- 4) Remove a blown fuse by pulling the fuse out from the cartridge, and replace it only with an identical "5 x 20 mm, T 3.15A L 250V" fuse for **Version 1** or T 3.15A H 250V" fuse for **Version 2**. (Consult Abbott Medical for recommended replacements.)
- 5) After blown fuses have been replaced, secure the Fuse Cartridge in place by pushing the cartridge into its receptacle until the Release Tab clicks into place.
- 6) Reconnect the Console to AC power.

9.2 Maintenance Following Each Patient Use

CAUTION

DO NOT spray bactericidal solution directly on the Console. Spray bactericidal or cleaning solutions on a cloth, and then wipe surfaces with the cloth. Spraying fluids into the air holes of the Console may create permanent damage

Immediately after removing a patient from Pump support, the Console should be thoroughly cleaned using the following procedure:

- 1) Disconnect AC power before cleaning the exterior of the main Console.
- 2) Clean the exterior of the Console with bactericidal solution by spraying the solution on a cloth and wiping off the unit.

3) Reconnect AC power when cleaning is completed.

WARNING

The Console should not be covered with plastic or insulating material during use or AC powered storage as it may overheat and malfunction.

9.3 Recommended Preventive Maintenance

The services listed in **Table 15** are applicable to the main and backup Consoles and should be performed by qualified personnel trained by Abbott Medical. These maintenance processes are only to be performed off-patient.

WARNING

Perform routine battery maintenance by following the preventive maintenance schedule in order to confirm proper calibration of the “battery charge remaining” indicator.

WARNING

During routine maintenance, verify that the fan is not blocked. A faulty or blocked fan within the Console may cause overheating, System malfunction, or trigger an alarm.

Table 15: Console Maintenance Schedule

Required Action	After Each Use	Every 6 Months	Every 12 Months	Every 2 Years
Perform Battery Maintenance provided in Section 9.4 .		X		
Clean all external surfaces and verify the general condition of the Console. If any damage is present return the Console back to Abbott Medical for service.	X	X		
Verify that all labels on the Console are present and legible.	X	X		
Verify that the leakage currents comply with the requirements of IEC 60601-1. Refer to Appendix II – Technical Specification for specific electrical safety requirements for the Console.			X	
Verify that the ground resistance complies with the requirements of IEC 60601-1.			X	
Replace Internal Rechargeable Battery Pack.				X

To ensure proper operation and patient safety, only Abbott Medical-approved spare parts must be used to maintain this device.

The user may NOT replace the internal battery without proper training by Abbott Medical or its distributor. Please request assistance by calling Abbott Medical Customer Service if the internal battery requires replacement.

To avoid shipping damage, the hardware (Console and Motor) packaging is designed for safe transport to and from the end user. Always use the original packaging for all shipping.

9.4 Battery Maintenance

The battery maintenance procedure needs to be performed every 6 months. If the System requires the battery maintenance procedure to be performed, it will display the alert **BATTERY MAINTENANCE REQUIRED**.

The aim of the battery maintenance procedure is to fully charge the battery, then to discharge it against a load (an internal resistor). During the discharge, the total energy stored in the battery is recorded and compared to System specifications.

9.4.1 Battery Maintenance Procedure

- 1) Plug the Console into AC power. The peripherals (Motor, Monitor, Flow Probe etc.) should be disconnected.

NOTE: Do not unplug the Console at any point during this procedure.

- 2) First enter the Console BIOS by holding down the **MENU** key during System startup. For more information on the Console BIOS, see **Section 7.8**.
- 3) Select **START BATTERY MAINTAINANCE**. The System will begin to discharge the battery, and will estimate the amount of time until the procedure is complete. The procedure may take up to 24 hours to complete. At some points, the System may appear to be idle, but the user should allow the full time to elapse for the battery maintenance to take place.

WARNING

During routine battery maintenance, the System may become warmer than usual. Ensure that the Console is not covered, and that air is free to flow around the Console to prevent overheating.

- 4) When the System has finished the battery maintenance procedure, it will display the message **BATTERY MAINTENANCE: PASSED** and ask the user to **CONFIRM** using the **DOWN ARROW**. The Console will then return to the BIOS and will need to be turned OFF and ON again before it can be clinically used.
- 5) If the message displayed on completion of the procedure is **BATTERY MAINTENANCE: FAILED**, or if the System still displays **BATTERY MAINTAINANCE REQUIRED** once the procedure has been completed, then repeat the procedure. If the message is still displayed, then contact your local Abbott Medical representative, and do not use the Console.
- 6) If the System displays the message **BATTERY CHARGER FAIL** or **BATTERY MODULE FAIL**, then do not use the System. Contact your local Abbott Medical representative for assistance.

- 7) If the System is needed during battery maintenance, then the procedure can be stopped. In this case, the amount of charge in the battery will not be known, and the accuracy of the battery meter cannot be guaranteed. Any patient on the Console should be transferred to another Console as soon as possible.

9.5 Motor Visual Inspection

The cable that connects the CentriMag Motor to the CentriMag Console has been designed for and tested to withstand five years use, however as any cable can be damaged during use or storage, it should be visually inspected for damage prior to each use.

Complete the steps outlined below. If any damage is found, remove the Motor from service.



Figure 55: CentriMag Motor

- 1) Visually inspect the CentriMag Motor connector for bent or broken pins. Check for burn marks or melted plastic.

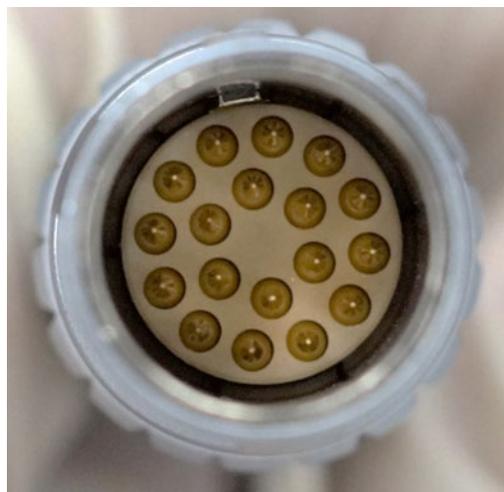


Figure 56: Motor Connector Pin View

Note: If there are any issues while connecting the CentriMag Motor to the CentriMag Console, inspect the Motor port on the rear of the Console for damage, particularly for any broken pins that may be lodged inside.

2) Visually inspect the entire length of the CentriMag Motor cable, including both bend reliefs (see Figures 57 and 58), for any damage such as separations of the bend reliefs, deformations, kinks, or cuts. These types of damage indicate wear and tear or previous rough handling of the cable, which has the potential to result in internal wire damage. Cable thickness and shape should be uniform throughout the length of the cable.

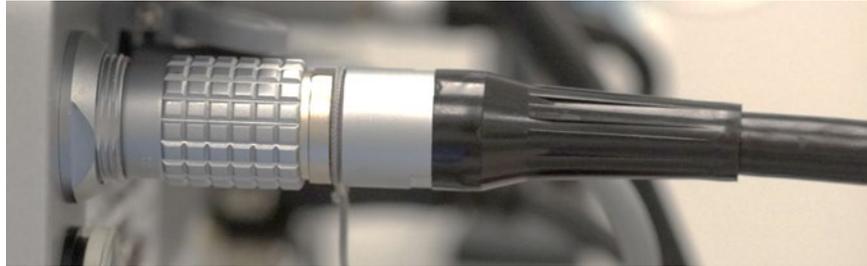


Figure 57: Cable Bend Relief at the Console Connector



Figure 58: Cable Bend Relief at the Motor



Figure 59: Cable Damage at the Motor Bend Relief



Figure 60: Undamaged and Intact Motor Cable



Figure 61: Damaged Motor Cable



Figure 62: Damaged Motor Cable

10 EMERGENCY / TROUBLESHOOTING

This section contains instructions for operation of the Pump during external defibrillation, and under circumstances where there is a need to exchange the main Console or Motor with a backup Console or Motor.

The recommended practice whenever there is a Console or Motor malfunction is to replace the Console and Motor as a set. Remove the Pump from the malfunctioning Motor and Console and place the Pump in the backup Motor and Console to continue patient support. DO NOT exchange individual Motors or individual Consoles during patient support.

WARNING

A Pump stoppage will create a reverse flow shunt, as well as limit the body's ability to maintain adequate arterial pressure. If the Pump is off, clamping the Pump outlet cannula or tubing is necessary to prevent a low flow, low pressure, or reverse flow condition. The tubing clamp must be removed before returning to normal pumping activity.

10.1 Switching to Backup Hardware

A backup Console, Motor and Flow Probe should be transported with the patient and immediately available for use at all times. Should the main Console or Motor cease to function, it will be necessary to replace the hardware by disconnecting the Pump from the main Motor and Console and switching to a backup Motor and backup Console. Switching to a backup Console and Motor is performed in accordance with the steps shown in **Figure 63**. Switch all components (Console, Motor, Flow Probe and cables) simultaneously and then perform troubleshooting on the non-functioning System when it is no longer being used for patient support.

To switch to a backup Console and Motor set:

- 1) Clamp the return tubing (outlet side).
- 2) Continue clamping the tubing while lowering the RPM to zero. Turn the main Console's power switch off. Turn on the backup System, and make sure that it is properly assembled with the backup Motor.
- 3) Unthread the Pump retaining screw on the Motor by turning the screw counterclockwise several revolutions until the screw tip is clear of the locking groove on the Pump.
- 4) Rotate the Pump body clockwise until the grooves in the Pump match the Motor. Lift the Pump from the receptacle.
- 5) Place the Pump in the backup Motor receptacle (the Pump will drop into place in one of 3 orientations).
- 6) Rotate the Pump counterclockwise until it stops.
- 7) Thread the Pump retaining screw to secure the Pump in place by turning the screw clockwise until it stops. Confirm that the retaining screw is visible in one of the notches on the side of the pump. If the retaining screw is not visible in a notch, loosen the retaining screw, remove the pump, remount, rotate the Pump counterclockwise, and secure by advancing the retaining screw.

- 8) Pumping operation may now be re-established via the backup Console by increasing the RPM to about 1000 RPM. Gradually increase RPM while unclamping the Pump outflow tubing. Continue to gradually increase the RPM to achieve the desired flow. Pumping operation should be returned to the last operating condition of the Pump. Be sure to reset options and alarms to match those selected before hardware exchange.

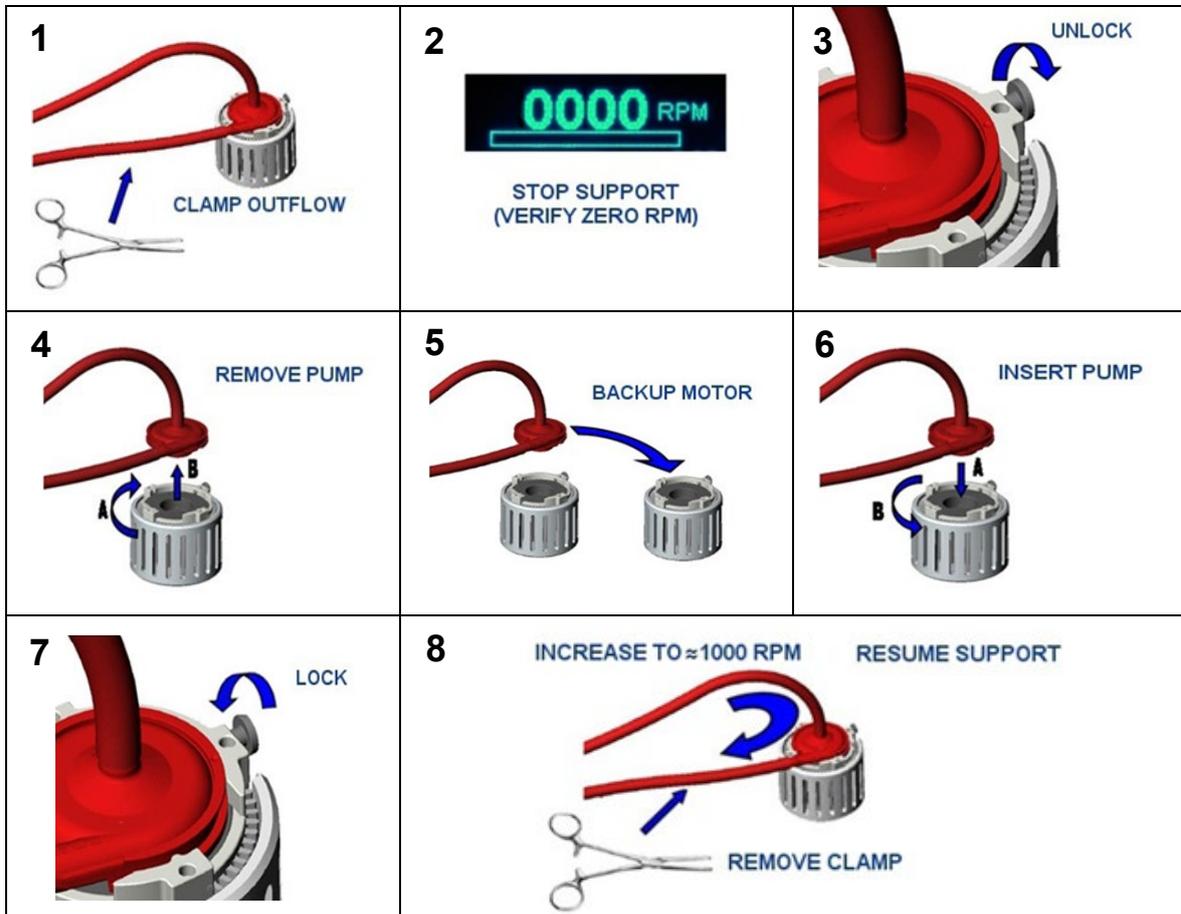


Figure 63: Emergency Switch to Backup System

If the Pump has been OFF for more than five minutes without adequate anticoagulation, or if there has been a Motor Overheating condition, it will be necessary to replace the Pump and circuit, including Cannulas.

NOTE: To be available for emergency use, the backup Console, Motor and Flow Probe must be transported with and in proximity of the main Console and Motor with the main power switch OFF. The battery for the backup Console must be periodically assessed according to **section 9.3 and 9.4**.

10.2 Switching to another Pump

WARNING

DO NOT restart the Pump if it has stopped due to Motor overheating. Overheating is confirmed by a **MOTOR OVER TEMP** alert message and temperature sufficient to prevent the user from placing and holding a hand on the Motor housing. Clamp the return tubing and switch to the backup System according to the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.

WARNING

Always fully unscrew the Pump retaining screw built into the Motor before inserting and locking the Pump in the Motor receptacle. This requires five complete counter-clockwise rotations of the screw. Failure to do so may inhibit the ability to fully seat and lock the Pump in the Motor receptacle resulting in loss of function and a **MOTOR ALARM** or **PUMP NOT INSERTED** alarm. Should this condition occur, unscrew the retaining screw, remove the Pump, reinsert the Pump, tighten the retaining screw, turn the Console power **OFF** and **ON**, ensure no alerts are displayed, and set the Console to begin pumping.

In instances other than Motor overheating, when the Pump has been OFF for more than five minutes without adequate anticoagulation, it will be necessary to replace the Pump and other circuit components.

10.3 Defibrillation/ Cardioversion

Defibrillation or cardioversion may be necessary during severe arrhythmias. Cardioversion may be performed without stopping the Pump. Ensure that a backup Console is available, powered and in the immediate vicinity.

If cardioversion is attempted without discontinuing support, consideration should be given to reducing the RPM of the Pump (or Pumps for BVAD support) to reduce the likelihood of Right-Left imbalance and Pump inlet obstruction. Following cardioversion, slowly increase the VAD RPM (or resume BVAD support) while monitoring the patient's hemodynamics to ensure adequate volume available for the desired flow.

WARNING

During cardioversion, ensure the backup Console, Motor and Flow Probe is on and prepared for use in the event of main Console malfunction. After defibrillation or cardioversion is performed, ensure that the main Console is working correctly and return the backup Console to the AC Off condition.

10.4 Electrosurgical Units

The System is designed to be operated safely during use of ESU's (electrosurgery or electrocautery units).

Under rare conditions, this might cause Console and/or Monitor display flickers while the ESU is activated.

If the System is used concurrently with an Electrosurgery unit, Abbott Medical recommends that the user should read and follow the electrocautery manufacturer's instructions for prevention of interference with other electronic devices.

WARNING

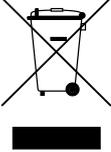
ESUs have the potential to interfere with other medical devices found in the operating and ICU room environment.

Ensure that the backup System is on and prepared for use in the event of a malfunction of the main Console during use of the ESU.

Survey the display of the main Console and/or Monitor during use of the ESU. If there is a malfunction other than the known potential flicker while the ESU is activated, change to the backup System.

After the ESU is used, ensure that the main Console is working correctly and return the backup Console to the AC Off condition.

11 DISPOSAL OF EQUIPMENT

Symbol	Description
	Do not dispose with normal waste. Disposal of this device is governed by the European Union (EU) WEEE Directive (2002/96/EC) and local electronic waste disposal legislation.

This device is designed and manufactured with materials and components that can be recycled and reused and therefore, it must be treated differently from normal household waste. The above symbol is affixed to the rear of the Console to remind the user of this requirement.

In the European Union (EU), when a 2nd Generation CentriMag Console has reached end of life, it must be treated as an electronic waste and disposed of in accordance with the European Directive 2002/96/EC, "Waste Electrical and Electronic Equipment (WEEE)", and also in accordance with applicable local legislation.

Please comply with local waste collection system for electrical and electronic products. For more information and further assistance about where you can drop off electronic waste for recycling, please contact your local distributor.

Please act according to your local rules and do not treat electronic waste as normal household waste. Proper disposal of electronic waste helps prevent potential negative consequences for the environment and human health.

12 APPENDICES

12.1 Appendix I – Console Alarms and Alerts

Table 16: Console Alarms & Alerts			
ID	Alarm/Alert	Text Message	System Status & Operator Response
S1	Alarm	POWER ON TEST FAIL	<p>The Pump will not start.</p> <p>An audible alarm will sound, which cannot be muted.</p> <p>Switch the Console OFF and ON again. If the alarm reappears, switch to the backup Console, Motor and Flow Probe, record the alarm message and contact your local Abbott Medical representative.</p>
S2	Alarm	SYSTEM FAULT (Run-Time System Failure)	<p>The Pump will stop.</p> <p>An audible alarm will sound, which cannot be muted.</p> <p>Clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M1	Alarm	MOTOR STOPPED	<p>The Pump will stop.</p> <p>An audible alarm will sound, which can be muted for 60 seconds.</p> <p>Clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M2	Alarm	MOTOR DISCONNECTED	<p>The Pump will stop.</p> <p>An audible alarm will sound, which can be muted for 60 seconds.</p> <p><u>During setup of the System:</u></p> <p>Press the alarm acknowledge button and check that the Motor connector is fully inserted into the back of the Console.</p> <p><u>During support:</u></p> <p>Press the alarm acknowledge button and check that the connector of the Motor is fully inserted into the back of the Console. Resume support. If the visual alarm message does not disappear, clamp the return tubing and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M3	Alarm	PUMP NOT INSERTED	<p>System will not start.</p> <p>An audible alarm will sound, which can be muted for 60 seconds.</p> <p>Press the alarm acknowledge button. Insert or re-insert the Pump and secure it with the locking screw.</p> <p>If the alarm repeats, switch to backup Console, Motor and Flow Probe according the procedure described in Section 10.1.</p>

Table 16: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
M4	Alarm	MOTOR ALARM	<p>An audible alarm will sound and the System will continue to operate.</p> <p>Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Abbott Medical representative.</p>
M5	Alert	SET PUMP SPEED NOT REACHED	<p>Check the Pump flow: If Pump flow is satisfactory; reduce set speed while insuring that flow is maintained.</p> <p>Press the alarm acknowledge button. If the alert repeats, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alert message and contact your Abbott Medical representative.</p> <p>If the Pump flow is not satisfactory, clamp the return tubing and switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support.</p> <p>Record the alert message and contact Abbott Medical representative.</p>
B1	Alert	BATTERY MODULE FAIL	<p>The Console battery will not function. An audible alarm will sound.</p> <p>Switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative.</p>
B2	Alert	BATTERY BELOW MINIMUM	<p>The Pump will stop after a very short time.</p> <p>Plug the Console into a AC power outlet to charge the battery.</p> <p>If no AC outlet is available, switch to the backup Console, Motor and Flow Probe according to the procedure described in Section 10.1.</p> <p>Resume support.</p>
F1	Alert	FLOW PROBE DISCONNECTED	<p>Check the Flow Probe connection on back of Console.</p> <p>If necessary, reconnect the Flow Probe connector to the back of the Console. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.</p>
S3	Alert	SYSTEM ALERT	<p>Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flow Probe according the procedure described in Section 10.1. Resume support.</p> <p>Record the alarm message and contact your local Abbott Medical representative.</p>

Table 16: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
F2	Alert	FLOW SIGNAL INTERRUPTED (Flow rate sensor error)	Manually disconnect, reposition and reconnect the Flow Probe transducer to the tubing. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats. If problem still persists after switching to the backup Flow Probe, stop the Pump and switch to a backup Console. Follow the instructions described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative.
F3	Alert	FLOW BELOW MINIMUM (Low Flow)	Check for physiologic cause or circuit obstruction. Check minimum flow set point. Do not increase RPM without confirming adequate blood volume is available. Common cause of this alert is inadequate blood volume at the drainage cannula site for the desired Pump flow.
F4	Alert	FLOW ABOVE MAXIMUM	Reduce Pump speed and check for cause.
P1	Alert	PRESSURE 1 DISCONNECTED	Check the electrical connections on the pressure 1 transducer and recalibrate. If the problem persists disconnect, reconnect, and recalibrate the transducer. Consider changing the transducer and cable if the problem persists.
P2	Alert	PRESSURE 2 DISCONNECTED	Check the electrical connections on the pressure 2 transducer and recalibrate. If the problem persists disconnect, reconnect, and recalibrate the transducer. Consider changing the transducer and cable if the problem persists.
P3	Alert	PRESSURE SYSTEM FAIL	The pressure monitoring System will not function. If pressure monitoring is needed then change to the backup Console, Motor and Flow Probe. Switch to the backup System according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Abbott Medical representative
P4	Alert	PRESSURE 1 BELOW MINIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P5	Alert	PRESSURE 2 BELOW MINIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P6	Alert	PRESSURE 1 ABOVE MAXIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
P7	Alert	PRESSURE 2 ABOVE MAXIMUM	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.

Table 16: Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
M6	Alert	MOTOR OVER TEMP	Switch to backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Verify that the backup Motor stands free and is not covered (e.g. blankets).
B3	Alert	BATTERY CHARGER FAIL	Press the alarm acknowledge button. If the alert message repeats, switch to backup System as described in Section 10.1. If this alarm is associated with BATTERY MODULE FAIL then carry out the procedure associated with that alarm.
B4	Alert	BATTERY MAINTENANCE REQUIRED	Do not use the Console. Perform battery maintenance according to the instructions provided in Section 9.4.
B5	Alert	LOW BATTERY	Plug the Console into AC power outlet to charge battery. If no AC outlet is available, switch to backup Console, Motor and Flow Probe according to the procedure described in Section 10.1. Resume support.
B6	Alert	ON BATTERY	Verify that the user wants the Console to be on battery. If so, carefully monitor the status of the battery charge indicator, while using the System on battery. Re-connect to AC-outlet, as soon as possible.

12.2 Appendix II – Technical Specification

2 nd GENERATION CENTRIMAG CONSOLE			
PARAMETER	SPECIFICATIONS		
AC Power	100 – 240 VAC at 50/60 Hz, 170 VA		
Battery Type & Chemistry	Rechargeable internal battery, Lithium Ion		
Battery Voltage	14.8 Volts		
Available Battery Run Time	approx. 120 min @ 3,500 RPM, 5.5 LPM		
Battery Recharge Time	4 hrs to 90% charge, 5 hrs to 100% charge		
Dimensions	Height: 10.0 cm / 3.9 in Width: 26.6 cm / 10.5 in Depth: 33.0 cm / 13.0 in		
Weight	5.8 kg / 12.8 lbs		
Pump Speed Range	0 – 5,500 revolutions per minute (RPM)		
Pump Flow Range	0.0 – 10.0 liters per minute (LPM)		
Flow Range Display	-2.0 – 10.0 liters per minute (LPM)		
Flow Resolution	10 mLPM		
Pressure Range Display	-150 – 900 mmHg		
Alarm/Alert Audio Volume	70 dB		
Language Options	English, Dutch, French, German, Italian and Spanish		
Electrical Safety	Earth leakage current: < 500 µA Touch current: < 100 µA Patient leakage current: < 10 µA		
Fuse	"5 x 20 mm, T 3.15A H 250V"		
Shipping Condition	Temperature: -29°C to 60°C / -20°F to 140°F Relative humidity: 0% to 85% Atmospheric pressure: 210 hPa – 1100 hPa (157 mmHg – 825 mmHg)		
Operational & Storage Conditions	Temperature: 10°C to 30°C / 50°F to 86°F Relative humidity: 30% to 75% Atmospheric pressure: 702 hPa – 1100 hPa (527 mmHg – 825 mmHg)		
2 nd Generation CentriMag Console Application Software	Version CPC1.02		
	LMCEBPX:	SW-0032-01	Rev 00
	IFD:	SW-0033-01	Rev 02
	SPS-MSP:	SW-0034-01	Rev 02
	SPS-PIC:	SW-0043-01	Rev 00

2nd GENERATION CENTRIMAG CONSOLE

PARAMETER	SPECIFICATIONS
Max. Product Life	5 years

MAG MONITOR

PARAMETER	SPECIFICATIONS		
DC Power	12 VDC, 12 W (from Console)		
Dimensions	Height: 26.2 cm / 10.3 in Width: 33.8 cm / 13.3 in Depth: 5.4 cm / 2.1 in		
Weight	2.0 kg / 4.4 lbs		
Screen Size	12.1"		
Screen Resolution	800(H) x 600(V) pixels		
Language Options	English, Dutch, French, German, Italian and Spanish		
Electrical Safety	Earth leakage current: < 500 μ A Touch current: < 100 μ A Patient leakage current: < 10 μ A		
Shipping Condition	Temperature: -29°C to 60°C / -20°F to 140°F Relative humidity: 0% to 85% Atmospheric pressure: 210 hPa – 1100 hPa (157 mmHg – 825 mmHg)		
Operational & Storage Conditions	Temperature: 10°C to 30°C / 50°F to 86°F Relative humidity: 30% to 75% Atmospheric pressure: 702 hPa – 1100 hPa (527 mmHg – 825 mmHg)		
Monitor Application Software	Version MCM3.01		
	IPL:	SW-0058-01	Rev 01
	Application:	SW-0060-01	Rev 01
	CPLD:	SW-0061-01	Rev 01
Max. Product Life	5 years		
USB Port	Use only USB-compatible Memory Sticks (FAT/FAT32 formatted)		

**EM-TEC ADULT FLOW PROBE
(SUPPLIED WITH CONSOLE)**



PARAMETER		SPECIFICATIONS
Product Name		em-tec Adult Flow Probe
Design		Ultrasonic transit time technology
Physical Specification	Width (L1)	33mm (1.29")
	Length (L2)	45mm (1.77")
	Thickness (L3)	25mm (0.98")
Accuracy	0.0 to 1.0 LPM	± 0.1 LPM + Offset Drift
	1.0 to 10.0 LPM	±7 % of the value + Offset Drift
	Flow Offset Drift	max. 0.03 LPM within 2 hours
Ultrasound Frequency		15 kHz to 18 MHz, different patterns possible, resolution 8 bit
Resolution		1 mLPM
Retrograde Flow Detection		Measured to -2.0 LPM
Tubing Specification	Tubing ID	9.5 mm (3/8")
	Wall Thickness	2.4 mm (3/32")
	Tubing OD	14.3 mm (9/16")
	Material	Polyvinyl Chloride
Probe Calibration	Calibrated for Fluid Temperature (°C)	Blood at 37 °C
	Tubing Type	Tygon S-50-HL

**EM-TEC PEDIATRIC FLOW PROBE FOR PEDIMAG™ PUMP
(AVAILABLE SEPARATELY)**



PARAMETER		SPECIFICATIONS
Product Name		em-tec Pediatric Flow Probe
Design		Ultrasonic transit time technology
Physical Specification	Width (L1)	33mm (1.29")
	Length (L2)	45mm (1.77")
	Thickness (L3)	25mm (0.98")
Accuracy	0.0 to 1.0 LPM	± 0.1 LPM + Offset Drift
	1.0 to 8.0 LPM	±7 % of the value + Offset Drift
	Maximum Slope Error	max. 0.03 LPM within 2 hours
Ultrasound Frequency		15 kHz to 18 MHz, different patterns possible, resolution 8 bit
Resolution		1 mLPM
Retrograde Flow Detection		Measured to -2.0 LPM
Tubing Specification	Tubing ID	6.4 mm (1/4")
	Wall Thickness	2.4 mm (3/32")
	Tubing OD	11.1 mm (7/16")
	Material	Polyvinyl Chloride
Probe Calibration	Calibrated for Fluid Temperature (°C)	Blood at 37 °C
	Tubing Type	Tygon S-50-HL

12.3 Appendix III – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
<p>The CentriMag Circulatory Support System with 2nd Generation CentriMag Console and Mag Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the CentriMag Circulatory Support System should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	<p>The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> <p>The System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
RF emissions CISPR11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

12.4 Appendix IV – Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The CentriMag Circulatory Support System with 2 nd Generation CentriMag Console and Mag Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment-guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The CentriMag Circulatory Support System with 2nd Generation CentriMag Console and Mag Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, outside ISM bands ^a	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of equipment marked with the <div style="text-align: center;">  </div> following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The CentriMag Circulatory Support System with 2nd Generation CentriMag Console and Mag Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment-guidance
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^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the CentriMag Circulatory Support System

The CentriMag Circulatory Support System with 2nd Generation CentriMag Console and Mag Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter			
	m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2 \sqrt{P}$	150 kHz to 80 MHz inside ISM bands $d = 1.2 \sqrt{P}$	80MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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

Recommended separation distances between portable and mobile RF communications equipment and the CentriMag Circulatory Support System

The CentriMag Circulatory Support System with 2nd Generation CentriMag Console and Mag Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2 \sqrt{P}$	150 kHz to 80 MHz inside ISM bands $d = 1.2 \sqrt{P}$	80MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$

manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CentriMag™ Motor

INSTRUCTIONS FOR USE (IFU)

READ ALL INDIVIDUAL CENTRIMAG CIRCULATORY SUPPORT SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM OPERATION MANUAL, AND THE CENTRIMAG CLINICAL REFERENCE MANUAL BEFORE USE.

Abbott Medical Clinical & Technical Support Phone number(s)		
United States	Emergency HeartLine™ Support USA: Abbott Medical Main Switchboard:	Tel: +1-800-456-1477 Tel: +1-925-847-8600 Fax: +1-925-847-8574
Outside United States	Emergencies outside USA: Urgent/24-Hour Europe: Thoratec Switzerland Main Switchboard:	Tel: +1-925-847-8600 Tel: +44 (0) 7659 877901 Tel: +41 (0) 44 275 7171 Fax +41 (0) 44 275 7172



R_x Only

Manufacturer:
Thoratec Switzerland GmbH
Technoparkstrasse 1
CH-8005 Zürich
Switzerland

US Headquarters:
Abbott Medical
6035 Stoneridge Dr.
Pleasanton, CA 94588
USA
www.abbott.com



PL-0069 Rev. 06
November 2019
DCO No. 19-038

DESCRIPTION

The CentriMag™ Motor contains a receptacle for insertion of the CentriMag or PediMag™ Blood Pump. The Motor induces rotation of a magnet within the rotor of the Pump at a speed that is set by the CentriMag Console. Three bayonet sockets on top of the Motor allow mounting of the Pump in three directions (every 90 degrees) to allow flexibility in the orientation of the Pump outlet.

The CentriMag Pump, Motor, Console, Mag Monitor, Flow Probe, and cannulas comprise the core elements of the CentriMag Circulatory Support System.

INDICATIONS FOR USE

The CentriMag Motor is indicated for use as:

- Part of a cardiopulmonary or other extracorporeal bypass circuit for periods up to 6 hours [**510k-cleared Device**].
- Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy [**PMA Approved Device**].
- Right ventricular assist device [**Humanitarian Device**]. The CentriMag Circulatory Support System, when used as a right ventricular assist device, is also authorized by Federal law to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

CONTRAINDICATIONS

This CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with Heparin.

ADVERSE EVENTS

Adverse events are a known risk of mechanical circulatory support. The adverse events that may be associated with the CentriMag Circulatory Support System are listed below. Adverse events are listed in decreasing order of frequency, except for death, because it is a non-reversible complication. For complete information on all adverse events observed during these studies, please refer to the

CentriMag Circulatory Support System Clinical Reference Manual.

- Death
- Bleeding
- Respiratory Failure
- Infection
- Cardiac Arrhythmias
- Right Heart Failure
- Renal Failure/Dysfunction
- Neurologic Dysfunction
- Hemolysis
- Hepatic Dysfunction
- Hypotension
- Hypertension
- Venous Thromboembolism
- Cardiac Tamponade
- Pericardial Fluid Collection
- Wound Dehiscence
- Psychiatric Episode
- Device Malfunction
- Arterial Non-CNS Thromboembolism
- Limb Ischemia
- Aneurysm
- Myocardial Infarction

WARNINGS

1. Read the Clinical Reference Manual and Operation Manual for the CentriMag Circulatory Support System prior to use.
2. The Motor is designed to be operated only with the CentriMag Console. There are no safety or performance data known to Abbott Medical which establishes compatibility of any other manufacturer's pump motor with the CentriMag Circulatory Support System.
3. Potential risk to the patient should be evaluated prior to changing the Motor.
4. Do not operate the Motor in the absence of flow. The temperature within the Pump may rise and increased cellular damage may result.

CAUTIONS

1. Caution: Federal law restricts this device to sale by or on the order of a physician.
2. This device should only be used by trained personnel.
3. The Motor is a non-sterile device. Inspect the device and package carefully prior to use. Do not use if the unit package or the product has been damaged or soiled.
4. The Motor is reusable. Do not sterilize. Sterilization by any means may cause

severe damage to the Motor or its components. Use standard hospital cleaning procedures for a device of this type. A wipe down with non-caustic cleaning detergents followed by a wipe down with a damp cloth is recommended. The cleaning procedure must not submerge or otherwise saturate the internal components of the Motor.

5. The Motor is not sealed or moisture proofed and is subject to short-circuiting if handled improperly. Patient or operator injury may result from improper cleaning of the unit.
6. Do not use the Motor if dropped. Dropping or other severe shock may cause damage which could lead to device malfunction.
7. Inspect the Motor, cable, Console connector, and locking mechanism for damage prior to use. If any component is damaged, do not use the Motor.
8. There is no recommended maintenance or consumer repairable components internal to the Motor. If the unit fails to operate according to the Motor specifications or a Console diagnostic error indicates a Motor malfunction (refer to the CentriMag Circulatory Support System Operation Manual), it should be returned to Abbott Medical.
9. A backup system consists of a Console, Flow Probe, and Motor. Ensure that a complete backup system is always available.
10. This product is not made with natural rubber latex.
11. The CentriMag Motor should be handled with care at all times during use, after use, and prior to storage. Do not tightly wrap the cable around the Motor as this may cause kinking and damage to the cable.
12. Before each use, verify that the cable connecting the Motor to the Console is not kinked, which can occur with improper handling such as wrapping the cable tightly around the Motor. If the cable is kinked, replace the Motor.



Figure 1: CentriMag Motor with a Kinked Cable

MOTOR VISUAL INSPECTION

The cable that connects the CentriMag Motor to the CentriMag Console has been designed for and tested to withstand five years use, however as any cable can be damaged during use or storage, it should be visually inspected for damage prior to each use.

Complete the steps outlined below. If any damage is found, remove the Motor from service.



Figure 2. CentriMag Motor

1. Visually inspect the CentriMag Motor connector for bent or broken pins. Check for burn marks or melted plastic.

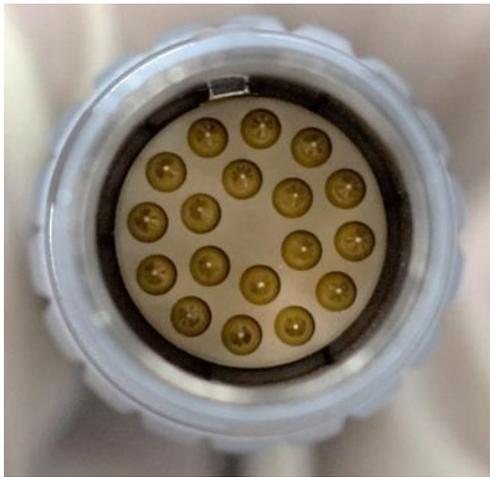


Figure 3. Motor Connector Pin View

Note: If there are any issues while connecting the CentriMag Motor to the CentriMag Console, inspect the Motor port on the rear of the Console for damage, particularly for any broken pins that may be lodged inside.

2. Visually inspect the entire length of the CentriMag Motor cable, including both bend reliefs (see Figures 4 and 5), for any damage such as separations of the bend reliefs, deformations, kinks, or cuts. These types of damage indicate wear and tear or previous rough handling of the cable, which has the potential to result in internal wire damage. Cable thickness and shape should be uniform throughout the length of the cable.



Figure 4. Cable Bend Relief at the Console Connector



Figure 5. Cable Bend Relief at the Motor



Figure 6. Cable Damage at the Motor Bend Relief



Figure 7. Undamaged and Intact Motor Cable



Figure 8: Damaged Motor Cable



Figure 9: Damaged Motor Cable

INSTALLATION

Follow the system preparation directions in the CentriMag™ Circulatory Support System Operation Manual. Inspect the complete system. Do not use a malfunctioning or damaged system.



Figure 10: CentriMag Motor with CentriMag Blood Pump Installed

1. Remove the Motor from its packaging and examine for any sign of damage.
2. Insert the LEMO connector on the Motor cable into the Motor connection on the rear of the Console.
3. After the Pump has been primed and is connected to the extracorporeal circuit, mount it on the Motor. This is accomplished by unscrewing the locking screw and matching the grooves on the circumference of the Pump with the fittings on the CentriMag receptacle. Rotate the Pump counterclockwise until the matching groove on the Pump body is located in front of the locking screw. Turn the locking screw clockwise until it is completely seated into the groove and the Pump is secured in place. The Pump must be fully seated into the receptacle to function properly.
4. Follow the instructions in the CentriMag Circulatory Support System Operation Manual to operate the Motor and System.
5. To remove the Pump from the Motor, locate the locking screw on the topside of the Motor; unscrew it counterclockwise until it clears the Pump groove completely. Rotate the Pump clockwise until it can be lifted from the receptacle by grasping the body and lifting it straight up and away from the Motor.

SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols used on the Motor package:

Symbol	Description
	Catalog Number
	Serial Number
IPX4	Protection against splashing water
	Manufacture Date
R_x Only	Caution: Federal U.S. law restricts this device to sale by or on the order of a physician.
	See Instructions for Use.
	Manufacturer
	Do not dispose with normal waste. Disposal of this device is governed by the European Union (EU) WEEE Directive (2002/96/EC) and local electronic waste disposal legislation.
	Contents of Package
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation

PRODUCT RETURNS

Prior to returning any product, contact your Abbott Medical Customer Service Representative for a return authorization number and instructions.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

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CentriMag™ 34Fr Drainage (Venous) Cannula Kit Instructions For Use (IFU)

Abbott Medical Clinical & Technical Support Phone number(s)

United States	Emergency HeartLine™ Support USA: Abbott Medical Main Switchboard:	Tel: +1-800-456-1477 Tel: +1-925-847-8600 Fax: +1-925-847-8574
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READ ALL INDIVIDUAL CENTRIMAG CIRCULATORY SUPPORT SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM OPERATION MANUAL, AND THE CENTRIMAG CLINICAL REFERENCE MANUAL BEFORE USE.



R_x Only

Manufacturer:
Thoratec Switzerland GmbH
Technoparkstrasse 1
CH-8005 Zürich
Switzerland

US Headquarters:
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA
www.abbott.com



PL-0220USEN.11

PL-0220,Rev.11
DCO No. 19-038
November 2019

SUPPLIED STERILE AND READY FOR USE. DO NOT USE IF PACKAGING IS DAMAGED, IF STERILE SEALS ARE BROKEN, OR IF CANNULA IS BEYOND ITS EXPIRATION DATE.

This product is not made with natural rubber latex.

For U.S. – California Only:

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

WARNING (Definition)

Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

CAUTION (Definition)

Cautions are used to alert the user to exercise special care for the safe use of the device.

DESCRIPTION

The CentriMag™ 34Fr Drainage (Venous) Cannula Kit (Figure 1) is designed for use with the CentriMag Circulatory Support System. It is marked with a large **BLUE** arrow at the proximal end.

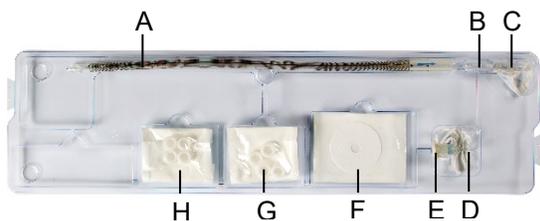


Figure 1: CentriMag Drainage (Venous) Cannula Kit

KIT CONTENTS

Each CentriMag Drainage (Venous) Cannula Kit contains the following components:

- A) One Drainage (Venous) Cannula
- B) One 3/8-inch Barbed Connector
- C) One Cap with Umbilical Tape
- D) One Apical Sewing Ring Handle
- E) One Apical Sewing Ring
- F) One Apical Support Cuff
- G) Four Suture Rings – Large
- H) Four Suture Rings – Medium

KEY FEATURES OF THE CANNULA

- Radiopaque indicator near the distal tip for X-ray visualization (Figure 2).

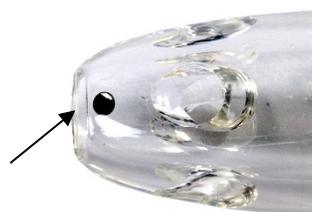


Figure 2: Radiopaque Indicator

- Graduation marks on the tip at 1 cm (0.4 inch) increments, beginning 3 cm (1.2 inch) from the distal end and continuing to 10 cm (4 inch), for visualization of the insertion depth.
- Malleable wire in the Cannula wall to allow bending and enable atrial cannulation.
- Spiral wire-reinforced wall for minimized possibility of kinking.

KEY FEATURES OF THE BARBED CONNECTOR (Figure 3)

- Two-sided 3/8 inch (9.5 mm) non-integrated barb connector for use with the proximal end of the Cannula.
- Threaded on one side for screwing into the Cap.



Figure 3: 3/8-inch Barbed Connector

KEY FEATURES OF THE CAP (Figure 4)

- Threaded for screwing onto the threaded end of the 3/8 inch (9.5 mm) barbed connector to maintain cleanliness of the connector barbs and Cannula lumen while tunneling.



Figure 4: The Cap

KEY FEATURES OF THE APICAL SUPPORT CUFF (Figure 6)

- Comprised of a PTFE material approximately 3 inches (7 cm) in diameter.
- May be used to support fragile heart tissue, help reduce bleeding and stabilize the Cannula entry site.

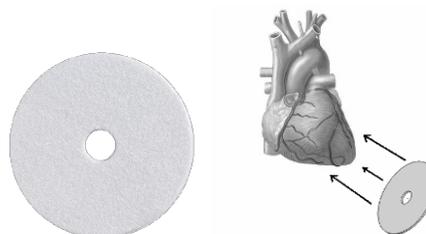


Figure 6: Apical Support Cuff

KEY FEATURES OF THE APICAL SEWING RING WITH HANDLE (Figure 5)

- Provided for use in ventricular cannulation.
- Designed to help maintain the geometry and placement of the sewing ring during surgical placement.
- Pledged sutures (not included) may be used to secure the sewing ring to the apex of the heart.
- The pre-attached white tape (umbilical tape) allows the Cannula to be secured within the Apical Sewing Ring.



Figure 5: Apical sewing ring with umbilical tape and sewing ring handle

KEY FEATURES OF THE SUTURE RINGS – MEDIUM AND LARGE (Figure 7)

- Provided in two sizes (medium and large), which match the diameter profiles of the Cannula along its length. Spare rings are provided in the event that more than one is needed.
- Designed to be positioned along the length of the Cannula at strategic locations to promote Cannula fixation in the patient, and to prevent Cannula crimping or damage due to excessive force applied by sutures.



Figure 7: Suture Ring

INDICATIONS FOR USE

The CentriMag™ Drainage (Venous) Cannula is indicated for use as:

- Part of a cardiopulmonary or other extracorporeal bypass circuit for periods up to 6 hours [**510k-cleared Device**].
- Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy [**PMA Approved Device**].

CONTRAINDICATIONS

The CentriMag Drainage (Venous) Cannula is contraindicated for patients who are unable or unwilling to be treated with Heparin.

The Cannula is not intended for peripheral cannulation.

CAUTION

This device contains phthalates that have been determined to be toxic for reproduction. For children, pregnant and nursing women, alternative devices may be appropriate.

ADVERSE EVENTS

Adverse events are a known risk of mechanical circulatory support. The adverse events that may be associated with the CentriMag Circulatory Support System are listed below. Adverse events are listed in decreasing order of frequency, except for death, because it is a non-reversible complication. For complete information on all adverse events observed during these studies, please refer to the CentriMag Circulatory Support System Clinical Reference Manual.

- Death
- Bleeding
- Respiratory Failure
- Infection
- Cardiac Arrhythmias
- Right Heart Failure
- Renal Failure/Dysfunction
- Neurologic Dysfunction

- Hemolysis
- Hepatic Dysfunction
- Hypotension
- Hypertension
- Venous Thromboembolism
- Cardiac Tamponade
- Pericardial Fluid Collection
- Wound Dehiscence
- Psychiatric Episode
- Device Malfunction
- Arterial Non-CNS Thromboembolism
- Limb Ischemia
- Aneurysm
- Myocardial Infarction

INSPECTION PRIOR TO USE

Inspect the outer packaging for any damage, and check the expiration date. Do not use the Cannula or any accessories if the package / sterile barrier appear to be compromised, if the Cannula has passed its expiration date, or if there is any damage or manufacturing defect.

WARNINGS

1. Read these Instructions for Use, the Clinical Reference Manual, and the CentriMag Circulatory Support System Operation Manual prior to use.
2. Thoroughly inspect the Cannula prior to use to verify that the lumen and side holes are patent and that the Cannula has not been damaged or kinked.
3. Systemic anticoagulation should be utilized while this device is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient. Initiate appropriate anticoagulation therapy **prior** to patient cannulation.
4. Possible side effects include, but are not limited to: infection, hemolysis and thromboembolic phenomena. These possible side effects are consistent with all extracorporeal blood pumping systems.
5. Ensure that the Cannula and circuit have been primed and debubbled properly prior to beginning pumping to minimize the risk of air reaching the patient.

6. Do not expose the Cannula or other components of the kit to chemical agents as they may affect the integrity of the Cannula and/or the components.
7. The Cannula must be handled and used in an aseptic manner.
8. Do not clamp the wire-reinforced section or the area immediately preceding the portion of the barbed connector inserted in the Cannula. An area is designated on the Cannula body (Figure 8) where a clamp may be applied. Clamping on the wire-reinforced section may cause damage to the Cannula including permanent wall distortion and/or lumen collapse. Clamping too close to the barbed connector may reduce the integrity of the connector/Cannula interface.



Figure 8: Acceptable Clamp Area

9. During insertion or manipulation of the Cannula, care should be taken to ensure that the Cannula is not kinked and blood flow is not restricted.
10. The safety and effectiveness of use of the CentriMag System in an ECMO circuit (i.e. cardiopulmonary support > 6 hours) has not been demonstrated.
11. The safety and effectiveness of use of the CentriMag System for use > 30 days has not been demonstrated.

CAUTIONS

1. Use of this device should only be by or on the order of a physician.
2. This device contains phthalates that have been determined to be toxic for reproduction. For children, pregnant and nursing women, alternative devices may be appropriate.
3. The Cannula is supplied sterile. Inspect the device and package carefully prior to

- use. Do not use if the package or the product has been damaged or soiled.
4. The Cannula and kit components are intended for single use only. Safely dispose of the Cannula after single use to avoid risk of infection.
5. If one or more of the kit components are not used, they should be disposed of and not stored for future use.
6. Cannula and tubing connections must be secured with standard straps or tie wraps to ensure connection integrity. Do not use excessive force to connect the Cannula or tubing as damage to the Cannula or tubing may occur.
7. Care must be taken to avoid over insertion of the Cannula and possible impingement of the Cannula tip against the ventricular/atrial walls.
8. Always have a spare CentriMag Drainage (Venous) Cannula available for exchange.
9. During movement of the patient (from bed to stretcher, or any type of physical therapy), great care must be taken to avoid dislodgment of the Cannula and disconnection of the Cannula, connectors, tubing and Pump.
10. It is recommended to thoroughly inspect each connection in the circuit. Reinforce as necessary with tie bands or other means.

CANNULA SETUP

1. Remove the CentriMag Drainage (Venous) Cannula Kit from the outer box. Ensure that the product sterility has not expired. Inspect the sterile packaging for damage.
2. Using aseptic technique, open the protective packaging containing the Cannula and accessories. Remove the tray lid and discard.

NOTE: The Cannula, barbed connector, and Cap are located in the same package well. Exercise caution and avoid dropping the components.

3. Carefully lift the Cannula, barbed connector, and Cap from the tray and inspect the components for damage. Ensure that the lumen and side holes of the Cannula are patent and that the Cannula is not damaged or kinked.
4. Insert the barbed connector into the proximal end of the Cannula. Pre-wetting of the barbed connector can assist with insertion. Verify that the barbs are fully inside the Cannula lumen before proceeding.

NOTE: Ensure that the non-threaded side of the barbed connector is inserted into the proximal end of the Cannula. It is recommended that the Cap remain on the barbed connector during insertion into the Cannula.

5. Verify that the Cap is secured to the barbed connector. If it is not, secure it with a ¼ turn clockwise twist. Be careful not to cross-thread. If cross-threading occurs, unscrew the Cap and re-attach.
6. Determine the desired Cannula placement site: atrial or apical.

CANNULA SURGICAL PLACEMENT

1. Verify that the level of anticoagulation is sufficient to safely allow the Cannula to be inserted into the vessel without an increased risk of thrombus formation. If required, give the patient a bolus of intra-venous Heparin.
2. To enable atrial cannulation, the Cannula contains a malleable wire that permits the Cannula to maintain a desired bend angle to conform to the anatomy of the patient. At the point where the Cannula is bent, the malleable wire should be oriented on the side of the Cannula at the 3 or 9 o'clock position. This should help to prevent kinking and to maintain the desired bend shape.

NOTE: To enable apical cannulation, two accessories, an Apical Sewing Ring (Figure 5) and an Apical Support Cuff (Figure 6), are provided to facilitate placement.

3. Suture rings should be placed on the Cannula **before** inserting the Cannula into

the atrium or apical placement site. Alternatively, Suture Rings may be cut and wrapped about the Cannula should additional rings be required. Cannula fixation is accomplished by securing sutures around a Suture Ring, then securing the assembly to adjacent tissue.

4. Place a clamp on the marked portion of the Cannula (Figure 8).
5. Prepare the Cannula insertion site and surgically insert the Cannula.
6. Slowly release the clamp to allow back-filling of the Cannula and re-clamp. Secure the Cannula in place with sutures.
7. Slowly fill the remainder of the Cannula with sterile priming fluid to displace any air out through the tube connector before connecting the fluid filled tubing.
8. Connect a primed 3/8 inch (9.5 mm) Inner Diameter (ID) x minimum 3/32 inch (2.4 mm) wall tubing to the Drainage (Venous) Cannula. Secure the connection with a tie band.
9. Follow the instructions provided in the Blood Pump IFU to initiate patient support.
10. When it is determined that circulatory support is no longer required, the Cannula may be carefully removed and its placement site repaired according to standard surgical practice.

TUNNELING

1. Avoid undue stress on the Cap and connector during the tunneling process.
2. Choose Cannula exit sites, keeping in mind chest tube location.
3. Make a stab incision with a surgical blade.
4. Pass the large clamp through the incision and dilate the tract.
5. Grasp the umbilical tape on the end of the Cap and pull the Cannula from the inside of the chest to the outside.

NOTE: There should be minimal resistance during the tunneling process.

WARNING

Ensure that the circuit and circuit components have been debubbled and primed properly prior to beginning support, to minimize the risk of air reaching the patient.

WARNING

If leaks or other anomalies are found, replace with a new Cannula, repeating the steps to prime.

DISPOSAL

Properly discard the used Cannula and accessories according to hospital procedure for contaminated materials.

SPECIFICATIONS

- Blood/tissue contacting materials:
 - Cannula: medical-grade PVC.
 - Barbed connector: medical-grade polycarbonate.
 - Cap: medical-grade polycarbonate, cotton (lanyard).
 - Apical Sewing Ring: medical-grade PTFE felt, medical-grade silicone, cotton (umbilical tape).
 - Apical Sewing Ring Handle: medical-grade PVC.
 - Apical Support Cuff: medical-grade PTFE felt.
 - Suture Rings: medical-grade silicone
- Barbed connector: Connects to 3/8 inch (9.5 mm) Inner Diameter (ID) x 3/32 inch (2.4 mm) wall perfusion tubing
- 34 Fr (11.33 mm) diameter
- Approximately 22 inch (56 cm) length with barbed connector inserted

PRODUCT RETURNS

Prior to returning any product, contact your Abbott Medical Customer Service Representative for a return authorization number and instructions.

PRESSURE-FLOW CURVE

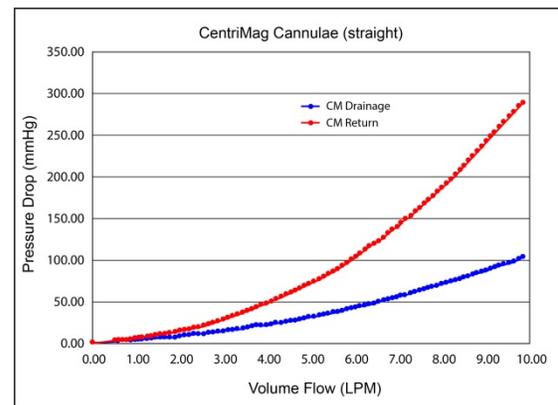


Figure 9: Pressure-Flow Curve

SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols that are used on the CentriMag 34Fr Drainage (Venous) Cannula Kit package:

Symbol	Description
	Catalog Number
	Lot Number
	Use By Date
R _x Only	Caution: Federal U.S. law restricts this device to sale by or on the order of a physician.
	See Instructions for Use.
	For Single Use Only.
	Sterilized By Ethylene Oxide.
	Do Not Use if Package is Damaged.
	Pyrogen free
	Contains or Presence of Phthalate
	Contents of Package
	Temperature Limitation
	Humidity Limitation
	Manufacturer

CentriMag™ 24Fr Return (Arterial) Cannula Kit Instructions For Use (IFU)

Abbott Medical Clinical & Technical Support Phone number(s)

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READ ALL INDIVIDUAL CENTRIMAG CIRCULATORY SUPPORT SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM OPERATION MANUAL, AND THE CENTRIMAG CLINICAL REFERENCE MANUAL BEFORE USE.



Rx Only

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SUPPLIED STERILE AND READY FOR USE. DO NOT USE IF PACKAGING IS DAMAGED, IF STERILE SEALS ARE BROKEN, OR IF CANNULA IS BEYOND ITS EXPIRATION DATE.

This product is not made with natural rubber latex.

For U.S. – California Only:
Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

WARNING (Definition)

Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

CAUTION (Definition)

Cautions are used to alert the user to exercise special care for the safe use of the device.

DESCRIPTION

The CentriMag™ 24Fr Return (Arterial) Cannula Kit (Figure 1) is designed for use with the CentriMag Circulatory Support System. The Cannula is designated with a large **RED** arrow at the proximal end.

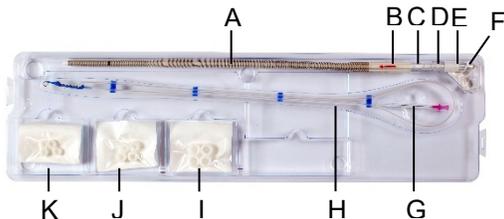


Figure 1: CentriMag Return (Arterial) Cannula Kit

KIT CONTENTS

Each CentriMag Return (Arterial) Cannula Kit contains the following components:

- A) One Return (Arterial) Cannula
- B) One Introducer
- C) One 3/8-inch Barbed Connector
- D) One Hemostasis Seal
- E) One Cap with Umbilical Tape
- F) One Porous Plug
- G) One Introducer Needle with Sheath
- H) One J-Tip Guidewire Assembly
- I) Four Suture Rings – Medium
- J) Four Suture Rings – Small
- K) Four Tip Rings

KEY FEATURES OF THE CANNULA

- Graduation marks at 1 cm (0.4 inch) increments up to 10 cm (4 inch), beginning 1 cm (0.4 inch) from the distal end, for visualization of insertion depth.
- Spiral wire-reinforced wall for minimized possibility of kinking.

KEY FEATURES OF THE BARBED CONNECTOR (Figure 2)

- Two-sided 3/8 inch (9.5 mm) non-integrated barb connector for use with the proximal end of the Cannula.
- Threaded on one side for screwing into Cap.



Figure 2: 3/8-inch Barbed Connector

KEY FEATURES OF THE CAP (Figure 3)

- Threaded for screwing onto the threaded end of the 3/8 inch (9.5 mm) barbed connector to maintain cleanliness of the connector barbs and Cannula lumen while tunneling.



Figure 3: The Cap

KEY FEATURES OF THE INTRODUCER

- Designed to facilitate passage of the Cannula into the target vessel.
- Fabricated from medical-grade polyurethane.
- Formed tip to minimize trauma to the vessel.
- Hollow to accommodate the guidewire.
- Integrally bonded Introducer Hub that acts as a handle as well as the insertion site for the guidewire and Porous Plug.

KEY FEATURES OF THE NEEDLE & GUIDEWIRE

- The needle is designed to allow passage of the Guidewire into the target vessel.
- The Guidewire provides a path for the Cannula and Introducer assembly into the target vessel.

KEY FEATURES OF THE HEMOSTASIS SEAL

- Creates a leak-proof barrier between the Introducer and the Cannula during insertion of the Cannula into the target vessel.
- Prevents leakage of blood between the Introducer and Cannula connector during removal of the Introducer.

KEY FEATURES OF THE POROUS PLUG

- Allows passage of the guidewire through the lumen of the Introducer when removed.

- Reinsertion of the Porous Plug prevents leakage of blood through the center of the Introducer after insertion into the target vessel.

KEY FEATURES OF THE SUTURE RINGS – SMALL AND MEDIUM (Figure 4)

- Provided in two sizes (small and medium), which match the diameter profiles of the Cannula along its length. Spare rings are provided in the event that more than one is needed.
- Designed to be positioned along the length of the Cannula at strategic locations to promote Cannula fixation and to prevent Cannula crimping or damage due to excessive force applied by sutures.



Figure 4: Suture Ring

KEY FEATURES OF THE TIP RING (Figure 5)

- Designed to help secure the Cannula tip at the target vessel and help prevent Cannula crimping or damage due to excessive force applied by sutures.



Figure 5: Tip Ring

INDICATIONS FOR USE

The CentriMag™ Return (Arterial) Cannula is indicated for use as:

- Part of a cardiopulmonary or other extracorporeal bypass circuit for periods up to 6 hours [**510k-cleared Device**].
- Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy [**PMA Approved Device**].

CONTRAINDICATIONS

The CentriMag Return (Arterial) Cannula is contraindicated for patients who are unable or unwilling to be treated with Heparin. The Cannula is not intended for peripheral cannulation.

CAUTION

This device contains phthalates that have been determined to be toxic for reproduction. For children, pregnant and nursing women, alternative devices may be appropriate.

ADVERSE EVENTS

Adverse events are a known risk of mechanical circulatory support. The adverse events that may be associated with the CentriMag Circulatory Support System are listed below. Adverse events are listed in decreasing order of frequency, except for death, because it is a non-reversible complication. For complete information on all adverse events observed during these studies, please refer to the CentriMag Circulatory Support System Clinical Reference Manual.

- Death
- Bleeding
- Respiratory Failure
- Infection
- Cardiac Arrhythmias
- Right Heart Failure
- Renal Failure/Dysfunction

- Neurologic Dysfunction
- Hemolysis
- Hepatic Dysfunction
- Hypotension
- Hypertension
- Venous Thromboembolism
- Cardiac Tamponade
- Pericardial Fluid Collection
- Wound Dehiscence
- Psychiatric Episode
- Device Malfunction
- Arterial Non-CNS Thromboembolism
- Limb Ischemia
- Aneurysm
- Myocardial Infarction

INSPECTION PRIOR TO USE

Inspect the outer packaging for any damage, and check the expiration date. Do not use the Cannula or any accessories if the package / sterile barrier appear to be compromised, if the Cannula has passed its expiration date, or if there is any damage or manufacturing defect.

WARNINGS

1. Read these Instructions for Use, the Clinical Reference Manual and the CentriMag Circulatory Support System Operation Manual prior to use.
2. Thoroughly inspect the Cannula prior to use to verify that the lumen is patent and that the Cannula has not been damaged or kinked.
3. Systemic anticoagulation should be utilized while this device is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient. Initiate appropriate anticoagulation therapy **prior** to patient cannulation.
4. Possible side effects include, but are not limited to infection, hemolysis and thromboembolic phenomena. These possible side effects are consistent with all extracorporeal blood pumping systems.
5. Ensure that the Cannula and circuit have been primed and debubbled

properly prior to beginning pumping to minimize the risk of air reaching the patient.

6. Do not expose the Cannula or other components of the kit to chemical agents as they may affect the integrity of the Cannula and/or the components.
7. The Cannula must be handled and used in an aseptic manner.
8. Do not clamp the wire-reinforced section or the area immediately preceding the portion of the barbed connector inserted in the Cannula. An area is designated on the Cannula body (Figure 6) where a clamp may be applied. Clamping on the wire-reinforced section may cause damage to the Cannula including permanent wall distortion and/or lumen collapse. Clamping too close to the inserted portion of the barbed connector may reduce the integrity of the connector/Cannula interface.



Figure 6: Acceptable Clamp Area

9. During insertion or manipulation of the Cannula, care should be taken to ensure that the Cannula is not kinked and blood flow is not restricted.
10. Do not cross-clamp the Cannula with the introducer within the Cannula. Cross clamping the introducer may prevent removal of the introducer from the Cannula and prevent the formation of an effective seal.
11. Forcing the Introducer Hub or Hemostasis Seal into the connector could result in stress cracking of the connector.
12. Gently guide the Cannula tip into the target vessel. Exerting excessive pressure while the Cannula is introduced into the aortic or pulmonary arteries can cause vessel damage.

13. The safety and effectiveness of use of the CentriMag System in an ECMO circuit (i.e. cardiopulmonary support > 6 hours) has not been demonstrated.
14. The safety and effectiveness of use of the CentriMag System for use > 30 days has not been demonstrated.

CAUTIONS

1. The use of this device should only be by or on the order of a physician.
2. This device contains phthalates that have been determined to be toxic for reproduction. For children, pregnant and nursing women, alternative devices may be appropriate.
3. The Cannula is supplied sterile. Inspect the device and package carefully prior to use. Do not use if the package or the product has been damaged or soiled.
4. The Cannula and kit components are intended for single use only. Dispose of safely after single use to avoid risk of infection.
5. If one or more of the kit components are not used, they should be disposed of and not stored for future use.
6. Care must be taken to avoid over insertion of the Cannula and possible impingement of the Cannula tip against the vessel walls.
7. Always have a spare CentriMag Return (Arterial) Cannula available for exchange.
8. During movement of the patient (from bed to stretcher, or any type of physical therapy), great care must be taken to avoid dislodgment of the Cannula and disconnection of the Cannula, connectors, tubing and Pump
9. It is recommended to thoroughly inspect each connection in the circuit. Reinforce as necessary with tie bands or other means.

CANNULA SETUP

1. Remove the CentriMag Return (Arterial) Cannula Kit from the outer box. Ensure that the product sterility has not expired. Inspect the sterile packaging for damage.
2. Using aseptic technique, open the protective packaging containing the Cannula and accessories. Remove the tray lid and discard.

NOTE: Exercise caution and avoid dropping the components.

3. Carefully lift the Cannula, barbed connector, and Cap from the tray and inspect the components. Ensure that the Cannula lumen is patent and that the Cannula is not damaged or kinked.
4. Remove the Cap and verify that the Porous Plug is secure in the Introducer Hub. Re-attach the Cap.
5. With the Introducer still inside the Cannula and the Cap screwed onto the Barbed Connector, insert the barbed connector into the proximal end of the Cannula. Pre-wetting of the barbed connector can assist with insertion. Verify that the barbs are fully inside the Cannula lumen before proceeding.

NOTE: Ensure that the non-threaded side of the barbed connector is inserted into the proximal end of the Cannula. It is recommended that the Cap remain on the barbed connector during insertion into the Cannula.

6. Verify that the Cap is secured to the barbed connector. If it is not, secure it with a ¼ turn clockwise twist. Be careful not to cross-thread. If cross-threading occurs, unscrew the Cap and re-attach.

TUNNELING

1. Avoid undue stress on the Cap and connector during the tunneling process.
2. Choose Cannula exit sites, keeping in mind chest tube location.

3. Make a stab incision with a surgical blade.
4. Pass the large clamp through the incision and dilate the tract.
5. Grasp the umbilical tape on the end of the Cap and pull the Cannula from the inside of the chest to the outside.

NOTE: There should be minimal resistance during the tunneling process.

CANNULA SURGICAL PLACEMENT

1. Verify that the level of anticoagulation is sufficient to safely allow the Cannula to be inserted into vessels without an increased risk of clot formation. If required, give the patient a bolus of intravenous Heparin.
2. Determine the desired Cannula placement site: Aortic or Pulmonary Artery.
3. Suture Rings should be placed on the Cannula **before** inserting the Cannula into the vessel. Alternatively, Suture Rings may be cut and wrapped about the Cannula should additional stabilizers be required. Cannula fixation is accomplished by securing sutures around a Suture Ring, then securing the assembly to adjacent tissue.
4. For Insertion using a guidewire:
 - a. Insert the needle into the intended Cannula insertion site (standard Seldinger technique).
 - b. Slide the guidewire into the needle and into the artery the desired distance.
 - c. Remove the guidewire from the sheath, and then remove the needle by following the guidewire away from the insertion site keeping the guidewire in the intended insertion site.
 - d. Remove the Cap from the proximal end of the Cannula along with the small white Porous Plug in the Introducer Hub.

- e. Verify that the Introducer is fully inserted through the Cannula tip. Insert the Cannula/Introducer onto the proximal end of the guidewire and slowly advance it up the guidewire and into the vessel to the desired distance. Gentle pressure at the tip of the Cannula will maintain the orientation of the Introducer to the Cannula tip during insertion.
 - f. Secure the Cannula in place by standard surgical technique including purse string sutures.

NOTE: Excessive tightening at the tip of the Cannula may make it difficult to remove the Introducer.
 - g. Remove the guidewire and replace the small white Porous Plug into the proximal end of the Introducer. The plug will allow blood to advance up the center of the Introducer without leaking.
 - h. To remove the Introducer, grasp the two raised rings on the Hemostasis Seal. This is important as it will maintain the position of the Hemostasis Seal over the barbed connector during Introducer retraction and prevent rapid filling and leakage of blood from the Cannula.
 - i. Re-check hemostasis and placement of the Cannula tip in the vessel as the Introducer may have partially supported the Cannula wall during placement in the vessel.
 - j. When the Introducer is approximately 2.5 inches (64 mm) from being fully retracted, a black ring will appear outside of the Hemostasis Seal. This is an indication that the Cannula may be safely clamped at the clamp area located on the proximal end of the Cannula between the connector and the wire reinforcement. Clamp the Cannula to prevent blood loss and remove the Introducer and Hemostasis Seal. Rinse the Cannula connector with sterile irrigation solution to prepare it for connection.
 - k. Slowly fill the remainder of the Cannula with sterile priming fluid displacing any air out through the tube connector before connecting fluid filled tubing.
5. For insertion without using the guidewire:
 - a. Determine the Cannula entry site and make two purse string suture lines at this entry site.
 - b. Place a side biting clamp on the vessel.
 - c. Make a small incision in the vessel, taking care not to damage the purse string suture lines.
 - d. Slowly release the side biting clamp and gently insert the Cannula into the vessel. The Hemostasis Seal is used to prevent blood leakage between the Introducer and Cannula connector during removal of the Introducer.
 - e. Place a clamp on the marked portion of the Cannula. Gently release the clamp to allow the Cannula to fill and then re-clamp once the Cannula is full of blood.
 - f. Secure the Cannula with the purse string sutures and Suture Rings.
 6. Connect a section of primed 3/8 inch (9.5mm) Inner Diameter (ID) x minimum 3/32 inch (2.4 mm) tubing to the Cannula. Secure the connection with a tie band.
 7. Follow the instructions provided in the Blood Pump IFU to initiate patient support.
 8. When it is determined that circulatory support is no longer required, the Cannula may be carefully removed and its placement site repaired according to standard surgical practice.

WARNING

Ensure that the circuit and circuit components have been debubbled and primed properly prior to beginning support, to minimize the risk of air reaching the patient.

WARNING

If leaks or other anomalies are found, replace with a new Cannula, repeating the steps to prime.

PRESSURE-FLOW CURVE

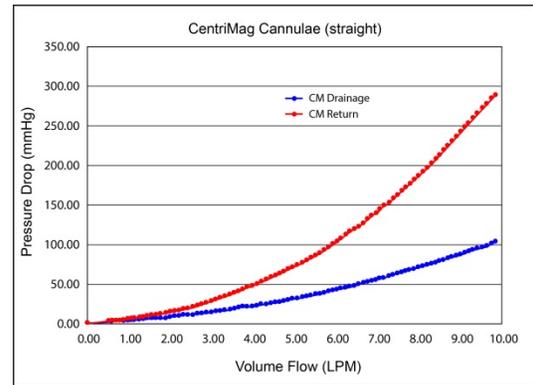


Figure 7: Pressure-Flow Curve

DISPOSAL

Properly discard the used Cannula and accessories according to hospital procedure for contaminated materials.

SPECIFICATIONS

- Blood/tissue contacting materials:
 - Cannula: medical-grade PVC.
 - Barbed Connector: medical-grade polycarbonate.
 - Cap: medical-grade polycarbonate, cotton (lanyard).
 - Suture Ring: medical-grade silicone.
 - Guidewire: medical-grade stainless steel.
 - Needle: medical-grade stainless steel.
 - Introducer: medical-grade plastic.
 - Tip Ring: medical-grade silicone.
- Barbed connector: Connects to 3/8 inch (9.5 mm) Inner Diameter (ID) x 3/32 inch (2.4 mm) wall perfusion tubing.
- 24 Fr (8 mm) diameter.
- Approximately 22 inch (56 cm) length with barbed connector inserted.

PRODUCT RETURNS

Prior to returning any product, contact your Abbott Medical Customer Service Representative for a return authorization number and instructions.

SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols that are used on the CentriMag 24Fr Return (Arterial) Cannula Kit package:

Symbol	Description
	Catalog Number
	Lot Number
	Use By Date
	Caution: Federal U.S. law restricts this device to sale by or on the order of a physician.
	See Instructions for Use
	Single Use Only
	Sterilized By Ethylene Oxide.
	Do Not Use if Package is Damaged.
	Pyrogen free

Symbol	Description
	Contains or Presence of Phthalate
	Contents of Package
	Temperature Limitation
	Humidity Limitation
	Manufacturer

CentriMag™ Circulatory Support System Clinical Reference Manual

READ ALL INDIVIDUAL CENTRIMAG SYSTEM COMPONENT INSTRUCTIONS FOR USE (IFU), THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM OPERATION MANUAL, AND THE ENTIRE CONTENTS OF THIS MANUAL BEFORE USING THE CENTRIMAG CIRCULATORY SUPPORT SYSTEM.

Abbott Medical Clinical & Technical Support Phone number(s)		
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Introduction

This manual is designed for healthcare professionals. It contains clinical and technical information for guidance in the proper and safe use of the CentriMag™ Circulatory Support System when used as intended. The information in this manual supplements the CentriMag Circulatory Support System Operation Manual and each of the individual system component instructions for use.

The CentriMag system performs life-sustaining functions. Users should have a practical knowledge of the principles of mechanical circulatory support and should be aware of the physiological and psychological needs of a patient undergoing mechanical circulatory support. New users should read this manual in its entirety before system operation. For experienced practitioners, this manual may serve as a reference.

As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. The professional staff at Abbott Medical regularly provide laboratory training and on-site, in-service programs. For information, please contact your local Abbott Medical Clinical Field representative.

Indications for Use

The CentriMag system is indicated for use as:

- Part of a cardiopulmonary or other extracorporeal bypass circuit for periods up to 6 hours **[510k-cleared Device]**.
- Temporary circulatory support for up to 30 days for one or both sides of the heart to treat postcardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy **[PMA Approved Device]**.
- Right ventricular assist device **[Humanitarian Device]**. The CentriMag system, when used as a right ventricular assist device, is also authorized by Federal law to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

Contraindications

The CentriMag system is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

Potential Adverse Events

Adverse events (e.g., complications) are a known risk of mechanical circulatory support use. The adverse events observed during four clinical studies of the CentriMag system are listed below. The adverse events are listed in decreasing order of frequency, except for death, because it is a non-reversible complication. There were no unexpected adverse events observed in these studies. For the incidence summary of all the adverse events that were observed, refer to the Summary of Clinical Experience section.

- Death
- Bleeding
- Respiratory Failure
- Infection
- Cardiac Arrhythmias
- Renal Failure/Dysfunction
- Right Heart Failure
- Neurologic Dysfunction
- Hemolysis
- Hepatic Dysfunction
- Hypotension
- Venous Thromboembolism
- Hypertension
- Cardiac Tamponade
- Psychiatric Episode
- Pericardial Fluid Collection
- Device Malfunction
- Wound Dehiscence
- Arterial Non-CNS Thromboembolism
- Limb Ischemia
- Myocardial Infarction
- Aneurysm

Warnings and Cautions

Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

Cautions are used to alert the user to exercise special care for the safe and effective use of the device.

Terminology and Abbreviations

Abbreviations for terms used in this manual include:

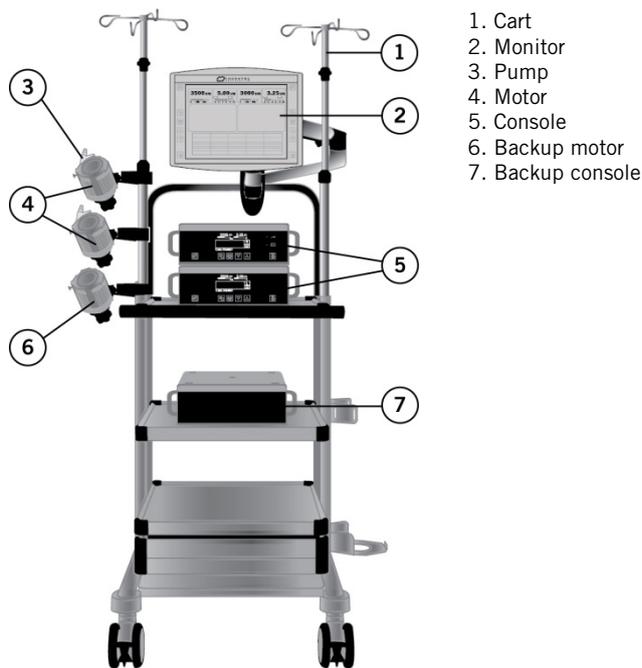
- ABP, arterial blood pressure
- ACT, activated coagulation time
- AMI, acute myocardial infarction
- BiVAD, biventricular assist device
- BUN, Blood Urea Nitrogen
- CI, cardiac index
- CPB, cardiopulmonary bypass
- CVP, central venous pressure
- ECMO, extracorporeal membrane oxygenation
- FTW, Failure to wean
- HIT, Heparin-induced thrombocytopenia
- IABP, intra-aortic balloon pump
- IJ, internal jugular
- LAP, left atrial pressure
- LPM, liters per minute
- LVAD, left ventricular assist device
- MAP, mean arterial pressure
- mmHG, millimeters of Mercury
- PADP, pulmonary artery diastolic pressure
- PCCS, Postcardiotomy cardiogenic shock
- PCWP, pulmonary capillary wedge pressure
- PFO, patent foramen ovale
- PTT, partial thromboplastin time
- PVR, pulmonary vascular resistance
- RAP, right atrial pressure
- RPM, revolutions per minute
- RVAD, right ventricular assist device
- TEE, transesophageal echocardiography
- TEG, thromboelastography

Description

The CentriMag system is designed to provide a versatile and effective means for implementing mechanical circulatory support in a variety of clinical scenarios. The system is intended to treat acute heart failure by decreasing ventricular workload, stabilizing hemodynamic conditions, and facilitating potential myocardial recovery. Patients in acute cardiac failure are at risk of developing multisystem organ failure which can threaten long-term survival. For these patients, the CentriMag system can provide short-term circulatory support pending recovery of ventricular function or provide a means to hemodynamically stabilize the patient until an alternative, longer-term therapy can be implemented.

The core components of the system include a CentriMag Blood Pump, 2nd Generation CentriMag Primary Console, motor, Mag Monitor, flow probe, tubing, and cannulas.

Figure 1. CentriMag system



The primary design features of the system include:

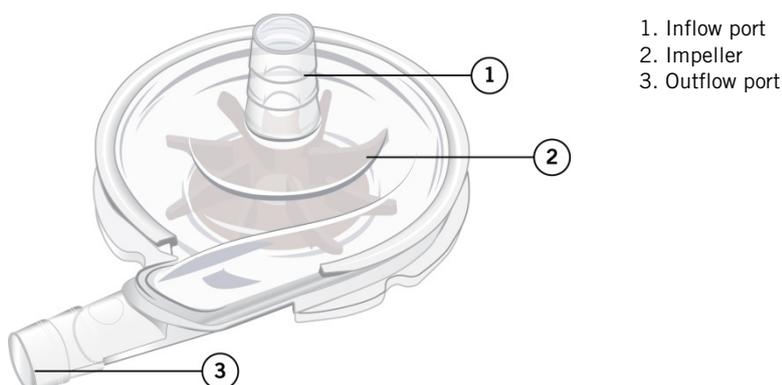
- Fully magnetically levitated impeller
- No bearings, shafts, valves, or seals within pump
- Low priming volume (31 cc) designed to reduce hemodilution
- Disposable (polycarbonate) pump with standard 3/8" connectors
- Reusable motor, console, non-invasive flow probe and accessories
- Configurable as an LVAD, RVAD, or BiVAD

The CentriMag pump is a continuous flow, fully magnetically levitated centrifugal pump. When the pump is inserted into the motor and activated, the internal impeller is electromagnetically levitated and centered, eliminating the need for shafts, seals, and bearings in the pump. Shafts, seals, and bearings are the sites typically responsible for hemolysis, thrombus, and particle formation. Large gaps between the impeller and pump housing are designed to minimize potential shear forces on blood cells, allowing a high blood flow rate with minimal hemolysis and thrombosis. Full MagLev™ technology suspends and rotates the impeller without a physical bearing, reducing friction and shear stress, resulting in minimal heat generation and minimal wear of the pump components.

The pump contains an inflow port on the top and an outflow port on the side that are at right angles to one another, as well as a magnetically levitated impeller. When the impeller is rotated, a pressure gradient develops between the center and outside edge of the pump, causing blood to flow from the inflow to the outflow port of the pump. The rotation of the impeller, as well as the resulting blood flow, is not sensitive to the pump height or position. The amount of flow through the pump depends on the set speed of the impeller, and the difference between the inlet and outlet pressures. Clinical factors affecting the flow include the following:

- Pump speed
- Preload pressure
- Afterload pressure
- Inflow cannula size, resistance and position
- Outflow cannula size, resistance and position
- Tubing length

Figure 2. CentriMag pump



Flow is generated by the rotation of the pump impeller. The blood flow is measured by a clamp-on, non-invasive flow probe and displayed on the console screen and optional monitor.

The speed of the pump must be set high enough to overcome native cardiac pressure in order to prevent retrograde flow. Increasing the RPM will increase the flow of blood through the pump.

CAUTION: If an increase in set speed does not cause an increase in flow, lower the set speed and assess the position of the cannula and the patient's hemodynamic condition.

During patient support, the console is used to control pump speed, the resultant blood flow, and to monitor the safe operation of the system. A cable connects the console to the motor, allowing flexibility in the pump motor and pump positioning. When needed, a battery in the console will power the system for two hours. An additional console and motor should be available at all times for emergency backup.

For system specifications, refer to the CentriMag Circulatory Support System Operation Manual.

Clinical Use of the CentriMag Circulatory Support System

General Principles

The CentriMag system provides circulatory assistance for patients in acute hemodynamic compromise, a population whose treatment options are limited.

WARNING: Read this entire manual before you use the CentriMag System. As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. The physician must be trained on the use of the System before using it. The professional staff at Abbott Medical regularly provide laboratory training and on-site, in-service programs. For information, please contact your local Abbott Medical Clinical Field representative.

Temporary circulatory support with the system can restore hemodynamic stability, reduce the risk of further end-organ damage, and provide conditions under which organ function can recover. By stabilizing the hemodynamics and optimizing the patient's condition, the patient's end-organ function can be assessed to determine the clinical course for the patient. In many cases, myocardial and end-organ recovery will be sufficient to allow weaning the patient from CentriMag system support. Some patients may need long-term support with an implantable LVAD or a heart transplant.

WARNING: The safety and effectiveness of use of the CentriMag system in an ECMO circuit (i.e. cardiopulmonary support > 6 hours) has not been demonstrated.

WARNING: The safety and effectiveness of use of the CentriMag system for use > 30 days has not been demonstrated.

Patients undergoing cardiac surgery who fail to be weaned from cardiopulmonary bypass due to poor cardiac function or high risk of dysrhythmias may benefit from continued circulatory support with a ventricular assist device. In this postcardiotomy scenario, CentriMag system support can be initiated quickly without significant additional resources. Patients can then be transferred to a recovery area or intensive care unit in a hemodynamically stable condition. Further patient assessment and treatment options can then be considered.

Types of Support

The CentriMag system can be used as an LVAD, RVAD, or BiVAD as described in the sections below.

Isolated LVAD Support

When compromised or impaired left ventricular function results in a patient being unable to wean from cardiopulmonary bypass, CentriMag LVAD support may be beneficial. Cannulation options include placement of a drainage cannula in the left atrium or left ventricle with a return cannula placed or attached to the ascending aorta, axillary artery, or a femoral artery.

Isolated RVAD Support

Patients who may require isolated RVAD support include those in cardiogenic shock due to acute right ventricular failure¹ or those whose right ventricular function is too compromised to wean from cardiopulmonary bypass. Patient history and pre-implant assessment of the heart using cardiac echocardiography and a determination of PVR should help to identify patients who will benefit from RVAD support for cardiogenic shock. Cannulation options are placement of a drainage cannula in the right atrium, right ventricle, superior vena cava, or inferior vena cava, with a return cannula in the pulmonary artery.

RVAD Support following LVAD Implantation²

RVAD support may be required following implantation of a durable LVAD. Initiating LVAD support can cause an acute decrease in left ventricular pressure that can change the position of the intra-ventricular septum, lead to distention of the right ventricle, and an increase in right atrial pressure. Under these conditions, right atrial pressures above 15-20 mmHg are suggestive of right ventricular dysfunction. Such a condition is often associated with a decrease in right ventricular contractility and tricuspid insufficiency. If adequate LVAD flow cannot be achieved, and there are signs of right heart failure, it may be necessary to temporarily support the right ventricle with a CentriMag™ RVAD. Diagnostic assessments include cardiac echocardiography, measurement of right heart pressures, and if possible, direct visualization of right ventricular function.

Biventricular Support

Biventricular support may be necessary in instances where the entire heart is functioning too poorly to wean a patient from

¹ Humanitarian Use. The effectiveness of this device for this use has not been demonstrated.

² Humanitarian Use. The effectiveness of this device for this use has not been demonstrated.

cardiopulmonary bypass.

Preparing for CentriMag System Use

The CentriMag system components and supplies are often stored in the operating room area to be immediately available when needed. The consoles must be connected to AC power during storage to ensure that the batteries are always fully charged. A backup system must always be close to the patient in the event it becomes necessary to switch to backup system components.

System Setup

System setup and initiation of support is often performed under emergent conditions. The procedure for setting up the CentriMag system, as described in the CentriMag Circulatory Support System Operation Manual, may be tailored to meet the anatomical and clinical conditions of individual patients. Different methods for priming the pump and circuit are discussed below.

After the setup and priming steps are completed, all of the connections should be secured with bands.

CAUTION: Ensure that the tubing is secured with bands on a portion of the connection where the two components overlap (i.e. where the tubing covers the pump inlet). The tubing should be over the lip of the pump connector.

Alternatives for Pump Priming and De-airing

Priming should be performed using either a priming pack or circuit submersion technique that follows standard surgical protocols. Two alternatives are described below.

Priming Pack Technique

Typical Contents

The following is a suggested list of equipment and supplies that may be used with a pre-assembled circuit or priming pack.³

- CentriMag™ pumps
- Drainage cannulas
- Return cannulas
- 2nd Generation CentriMag™ console with motor and flow probe connected
- Preassembled circuit and priming pack
- Two 3/8" two-sided, straight, barbed connectors (and backups), if not included with the cannula kits
- Sterile tubing clamps and scissors
- One liter of a warm balanced electrolyte solution for priming
- Small nylon bands (~3" in length)

Typical Priming Pack Procedure

The priming pack procedure should be performed using aseptic techniques. To prime the pump:

1. Open the priming pack. Open the pump package. Attach the drainage tubing and return tubing to the appropriate barbed ports of the pump. Suspend the recirculation bag from an IV pole.

CAUTION: The outside of pump packaging is not sterile.

2. When possible, flush the recirculation bag and circuit with CO₂ to remove air. Clamp the outlet lines from the reservoir bag. Fill the reservoir bag with one liter of a balanced electrolyte solution. Open the reservoir bag air vent line.

CAUTION: Maintain an adequate level of priming solution in your reservoir bag at all times to prevent depriming the circuit.

3. Raise the pump up to the level of the bag. Remove the clamps from the reservoir bag outlet lines. Slowly fill the circuit with fluid by "walking" the fluid through the circuit, while venting the air through the vent line.

CAUTION: When the clamps are removed, ensure that you are priming the tubing slowly to minimize the risk of air entrainment.

4. Secure and lock the pump in the motor mount and recirculate the fluid at a low flow of approximately 1500 RPMs.

CAUTION: Ensure that the pump is properly seated, aligned, and locked into the motor.

Submersion Priming Technique

Typical Contents

The following is a suggested list of equipment and supplies that may be used for this technique.⁴

³ For the pumps, you will need one for univentricular support, two for biventricular support, plus a backup. For the console with motor and flow probe connected, you will need one of each for univentricular support, two of each for biventricular support, plus one of each for backup.

⁴ For the pumps, you will need two pumps for univentricular support and three pumps for biventricular support. For the console with motor and flow probe connected, you will need one of each for univentricular support and two of each for biventricular support.

- CentriMag pumps
- Drainage cannulas
- Return cannulas
- 2nd Generation CentriMag console with motor and flow probe connected
- Standard 3/8" ID x 3/32" wall tubing
- Two 3/8" straight barbed connectors per pump, if not included with the cannula kits
- Sterile tubing clamps and scissors
- Three liters of warm balanced electrolyte solution
- Bulb syringe and scissors
- Small nylon bands (~ 3" in length)

Submersion Technique – Dry Connection

The dry connection submersion technique should be performed using aseptic techniques. To prime the pump:

1. Fill a large sterile basin with three liters of a warm balanced electrolyte solution.
2. Open the pump package. Connect the inlet and outlet of the pump to separate segments of the tubing.

CAUTION: The outside of pump packaging is not sterile.

3. Slowly submerge the open side of the drainage tubing segment, then gradually submerge the entire piece, allowing the tubing to fill completely from one end to the other, remaining under the surface at all times. Allow the pump to fill and deair. Continue filling past the pump until the return tubing segment is also filled and deaired.

CAUTION: Avoid striking the pump housing in order to force air through the circuit, as damage to the pump housing may occur.

4. Once the circuit is completely primed and deaired, clamp both open ends of the tubing.
5. Pass the pump off the field (leave the ends of the tubing in the basin and maintain sterility of the tubing above the area which was passed off) and place the pump in the motor.
6. Connect the flow probe to the return segment of the tubing.
7. Turn on the console, and set the speed to approximately 1500 RPMs with the clamps still on the drainage and return tubing in the basin.
8. Remove the clamp from the drainage tubing and then remove the clamps from the return tubing. Allow the priming solution to recirculate until all visible air is removed.

CAUTION: Ensure that the open ends of the tubing segments remain submerged during recirculation to avoid air entrainment.

9. Inspect the circuit to ensure all air has been removed. If there is residual air, continue to run the pump with the open ends of the tubing in the basin to complete the de-airing process.

CAUTION: If air is entrained in the pump head, turn the set speed to zero, and then walk the air bubble out of the pump.

10. Replace the clamps on the inflow and outflow tubing in the basin. The circuit is now ready for use.

Submersion Technique – Wet connection

The wet connection submersion technique should be performed using aseptic techniques. To prime the pump:

1. Fill a large sterile basin with three liters of a warm balanced electrolyte solution.
2. Slowly submerge one end of the drainage tubing segment, then gradually submerge the entire piece, allowing the tubing to fill completely from one end to the other, remaining under the surface at all times. Clamp both ends of the tubing segment once all air has been dispelled and tubing is primed. Repeat for the return tubing segment.

CAUTION: The CentriMag pump may magnetically attract to a metal basin. Use caution if a metal basin is used.

3. Open the pump package. Submerge the pump in the saline, rotating from side to side to ensure complete removal of air.

CAUTION: The outside of the pump packaging is not sterile.

4. Remove the clamp from one end of the drainage tubing segment and then connect it to the inflow of the pump. Remove the clamp from one end of the return tubing segment and then connect it to the outflow of the pump. Ensure that all of the connections are made while the components are fully submerged.

Figure 3. Submersion of tubing

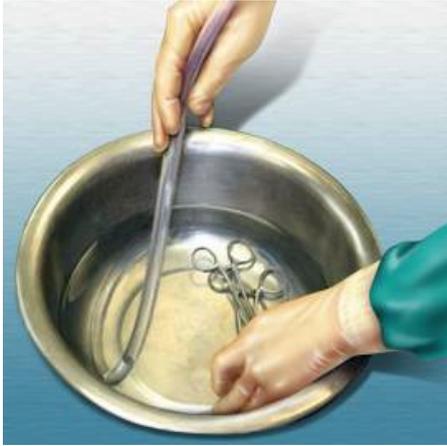


Figure 4. Submersion of pump



Cannulas

For left and/or right sided support for failure to wean, Abbott Medical recommends the CentriMag™ Drainage (Venous) Cannula (34Fr) and Return (Arterial) Cannula (24Fr). Other equivalent commercially available venous and arterial cannula may be used at the preference of the clinician.

For central cannulation, it is advisable to use cannulas that are wire-reinforced to resist kinking. The drainage cannula should be malleable so that it will hold its shape after introducing a bend. For ventricular cannulation, the drainage cannula may not need to be bent. Placing an approximately 90° bend in the cannula may help with atrial cannulation.

Surgical Technique for Implantation

Overview

This section describes the surgical considerations necessary to prepare, implant, and explant the CentriMag system. Standard surgical techniques will be used for implantation of the system. The components of the circuit will be similar for most patients, although the surgical procedures may vary according to the patient's anatomy, circumstances of support initiation and hospital protocols. In general, the procedures are as follows: the cannulas are tunneled and positioned for left, right, or biventricular support. The extracorporeal circuit (or circuits) is prepared, primed, connected to the cannulas, and subjected to a final inspection of the circuit; support is then initiated.

If CentriMag cannulas or other centrally-placed cannulas are used, the surgical approach for implantation will usually include the following general order of process:

1. Sternotomy
2. Tunneling
3. Cannulation

If the condition and stability of the patient permit, all cannulas should be tunneled and brought through the skin of the anterior abdominal wall (the subcostal region) prior to cannulation of the heart and major vessels. For left heart LVAD support, the drainage cannula will be placed in the apex of the left ventricle or left atrium and the return cannula will usually be placed in the ascending aorta. If ambulation is planned, consideration should be given to placement in the axillary artery. If an RVAD for right heart support is needed, the drainage cannula will usually be placed in the right atrium and the return cannula will be placed in the proximal portion of the main pulmonary artery.

CAUTION: The position of the drainage cannula in the left ventricular apex should be positioned pointing toward the mitral valve (the tip should be placed in the direction of the mitral valve) in order to maximize drainage and minimize suction events.

CAUTION: The preferred placement of the return cannula is in the ascending aorta. Confirm that the point of anastomosis is not calcified to avoid the risk of a stroke.

The circuit is primed with a balanced electrolyte solution, deaired, and inspected. Connection of the primed circuit to the cannula connector is made while adding fluid to the connection to exclude air. The cannulas are secured to the skin with sutures. All external connections should be further secured with bands for added security and circuit integrity. The pump is positioned on the motor and the console is powered on and speed set to at least 1000 RPMs with a clamp on the outlet tubing.

CAUTION: If the clamps are removed before the speed is set higher than 1000 RPMs, there is a risk of retrograde flow.

NOTE: If other manufacturers' cannulas are used, follow standard surgical techniques applicable to those cannulas.

The status of the heart is monitored with echocardiography, hemodynamic monitoring, palpation, and direct visualization, to ensure adequate intravascular volume, CPB flow is reduced while VAD support is initiated. After cannulation, the sternum and skin are closed using standard surgical techniques. If unable to close the sternum due to mediastinal bleeding, or if edema causes compromised flow, the chest may be packed, sternum splinted open, and the skin opening covered with an appropriate patch for closure later.

Monitoring

Hemodynamic assessment before and during CentriMag system support should include standard cardiac surgery pressure monitoring such as a central venous catheter, an arterial line, and a pulmonary artery catheter. Before initiating CPB and placement of the CentriMag™ cannulas, transesophageal echocardiogram should be performed to rule out the following:

- A patent foramen ovale or other septal defects
- Intra-atrial and intra-ventricular thrombus
- Aortic valve insufficiency
- Valvular dysfunction
- Any other structural abnormalities that may interfere with the safe operation of the device (i.e. trabeculae or ruptured chordae)

TEE should be used to visualize the heart chambers and to ensure that the heart is completely deaired prior to initiation of support. TEE may also be used to assess cannula tip position, ventricular volume, ventricular size, optimal neutral position of the ventricular septum, and the amount of unloading in the heart chambers.

If CPB is used for the implant, anticoagulation appropriate for CPB must be administered before CPB. If the implant is to be performed without CPB, heparin should be administered to the patient prior to cannulation with a recommended target of an activated coagulation time between 200 and 250 seconds.

Tunneling

The cannulas should be tunneled through the chest wall using a standard surgical technique. It is recommended that tunneling be performed prior to cannulation so that the cannula can be positioned without bends or kinks. Prior to tunneling, cover the tip of the cannula with the included tunneling cap, or if none is included, a glove tip or other material to prevent debris from entering the internal lumen. At the end of the case, the cannulas should be securely sutured to both fascia and skin, with minimal tension. For more information, refer to the instructions for use for the cannulas.

CAUTION: If the cannula kit does not include a tunneling cap, use caution to not tear or damage the glove tip or other material to prevent damaging the cannula connector.

Cannula Site Selection and Cannulation

Common cannulation⁵ locations are shown in the table below.

Table 3. Cannulation locations

Therapy	Access Point	Drainage Vessels	Return Vessels
LVAD support	Central	Left Atrium Left Ventricle	Ascending Aorta Via direct cannulation or with a graft sewn to ascending aorta Axillary Artery
RVAD support	Central Peripheral	Right Atrium Right Ventricle Superior Vena Cava Inferior Vena Cava	Pulmonary Artery Via direct cannulation or with a graft sewn to pulmonary artery
BiVAD support	Central Peripheral	See options above for left and right sided support	See options above for left and right sided support

Two cannulation approaches are shown in the figures below. The left ventricle is drained via the left ventricular apex or the left atrium. In both approaches, blood is returned via the ascending aorta. Left ventricular cannulation may be preferred because the unloading is more complete, the risk of intra-ventricular thrombus is much lower, and collapse of the chamber is less likely, though care should be taken to minimize the risk of suction.

Figure 5. Drainage via the left ventricular apex

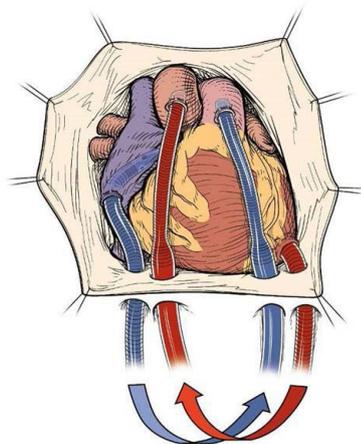
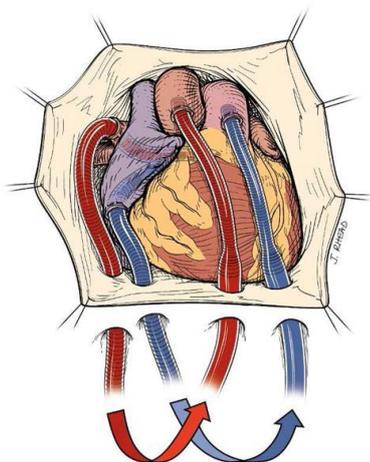


Figure 6. Drainage via the left atrium



⁵ The CentriMag Return (Arterial) Cannula and the CentriMag Drainage (Venous) Cannula are not intended for peripheral cannulation.

Intraoperative Device Management

After all cannula-to-tubing connections are completed, a clamp is placed on the return tubing of each pump, while all other clamps are removed from the circuit. Before the outflow clamp is released, the pump set speed (RPM) is increased to at least 1,000 RPM in order to prevent retrograde flow through the system. The set speed is then gradually increased to reach the desired flow rate. As the set speed is gradually increased, CPB support can be simultaneously decreased to allow filling of the heart, and then terminated. During weaning from CPB and initiation of CentriMag system support, the patient must be carefully monitored with hemodynamic monitoring (usually CVP, PAP and ABP), echocardiography, manual palpation and visual inspection of the heart to ensure that adequate blood volume is available for the desired flow and to reduce the risk of a suction event. For LVAD support, left atrial pressure should be maintained between 10 and 15 mmHg in order to avoid suction within the left ventricle and inflow obstruction, which can lead to air entrainment. For RVAD support, right atrial pressure should also be maintained between 10 and 15 mmHg.

CAUTION: Ensure that air does not enter into the circuit when the tubing is connected to the cannula.

CAUTION: If CPB support is not decreased as the set speed is increased, suction events may occur due to lack of volume.

The desired flow rate can be predetermined by calculating the flow needed to achieve a cardiac index of approximately 2.0-2.2 l/min/m². As the flow is increased, the atria and/or ventricles are monitored for adequate pressure and blood volume. The console operator continuously monitors the pump flow, RPM, and blood pressure for signs of suction within the circuit. Suction is most likely when filling pressures are <10 mmHg and is accompanied by fluctuations in flow. When suction is detected, the speed of the pump must be immediately decreased until the filling pressure and volume are adequate to increase the flow. The system should be monitored frequently in the operating room when the patient's chest is open as this is the period of highest risk for suction and air entrainment.

The central venous pressure, flow rate, total cardiac output, pulmonary capillary wedge pressure, left atrial pressure (valuable, but not essential) and arterial blood pressure should be monitored frequently as hemodynamic conditions change rapidly during surgery. Communication of hemodynamic parameters between the surgeon, perfusionist, anesthesiologist, and console operator is vital to safe support.

Initially, TEE, hemodynamic monitoring, palpation, and direct visualization of the heart will help to determine the volume of blood available for the circuit and the optimal level of flow. After the chest is closed, the patient can be monitored with conventional hemodynamic parameters (CVP, PCWP, MAP, LAP, PADP) and TEE to ensure adequate ventricular unloading, and to permit a gradual increase to a target CI between 2.0 and 2.5 l/min/m², consistent with the patient's physiologic needs.

CAUTION: After closure of the chest, limited space in the inter-thoracic cavity may cause an observable decrease in flow.

TEE should also be used to rule out the presence of a patent foramen ovale after left ventricular decompression. A previously undetected PFO may develop when the pump begins to decompress the left heart. If present, a significant defect should be repaired to prevent right-to-left shunting and the resulting hypoxemia. Unloading of the ventricle(s) during VAD support may also cause atrial or ventricular collapse, which may be able to be observed or assessed with manual palpation by the surgeon.

CAUTION: During closure of the chest, the CentriMag system flow and the patient's hemodynamics must be monitored as cannula position can change, altering flow through the pump.

Guidelines to Prevent Air Entrainment when Initiating Support

Guidelines to prevent air entrainment when initiating support include the following:

1. Fill the chest with warm normal saline or CO₂.
2. Ensure adequate volume in heart chamber when coming off CPB bypass.
3. Watch the circuit, flow, CVP, MAP and LAP (if monitored) continuously and be prepared to immediately clamp the outflow tubing if air is observed.
4. Partially inflate the lungs prior to separation from CPB.
5. Maintain atrial pressures between 10 and 15 mmHg during surgery.
6. Place the patient in Trendelenburg position.
7. Check the heart and aorta for air with TEE.
8. Increase RPM very slowly while initiating support.
9. Under-perfuse circulation while the chest is open or patient is being moved.

CAUTION: If an increase in flow is not observed with an increase in set speed, suction may be occurring.

WARNING: If a suction event occurs and is not addressed promptly, there is potential for air entrainment.

Patient Care and Management

Postoperative care with the CentriMag system is similar to other types of mechanical circulatory support. Key principles of care include hemodynamic stabilization, adequate anticoagulation, and prevention of wound infection. The intravascular volume must be carefully assessed and controlled. Management of bleeding, and prompt blood product replacement, is essential to stabilization and recovery. Frequent laboratory assessment of hematology, coagulation, enzymes, and blood chemistry must be used to evaluate end organ function and to guide therapy.

Guidelines to Prevent Air Entrainment during Support

Guidelines to prevent air entrainment during support include the following:

- Monitor the volume with TEE and pressures.
- Reduce CentriMag flow rate while the chest is open.
- Reduce RPM for any indication of inadequate volume, during manipulation of the heart, or prior to moving the patient.
- Monitor the tubing for chatter and be prepared to respond by decreasing RPMs and giving volume.
- As soon as practical, set the low-flow alarm at 75% of the target flow.
- Train staff that air can be drawn into the vasculature by the flow characteristics of circulatory support:
 - Through any open stopcock or port on central line
 - Through an IV or infusion line
 - During insertion/changing of a central line with an open port. Be sure there are no signs of suction during insertion of a central line.
 - Through any loose connection point on the system circuit
- Avoid conditions that may result in suction, line chatter, or shaking.

CentriMag System Assessment and Adjustments

Pump speed and alarm settings must be assessed frequently and manually adjusted when necessary. Speed changes should be gradual while monitoring the changes in available volume and the resultant hemodynamic effects.

Ensure that you clamp the return tubing prior to turning off the pump or reducing set speed below 1000 RPM to avoid retrograde flow. Pump flow (LPM) and speed (RPM) should be recorded with vital signs on the patient's chart to trend hemodynamic change with the pump parameters.

Table 4. Target pump and clinical conditions

Parameter	Value ⁶
CentriMag pump	3000-4000 RPM
Pump flow	4-5 LPM
RAP and LAP	10-15 mmHg [8-12 mmHg after several stable days of support]
Mean arterial pressure	60-80 mmHg
Target ACT	160-180 seconds (after bleeding has subsided)

For biventricular support, the hemodynamic conditions of the pulmonary and systemic circulations should be balanced. To do this, manage the RVAD flow relative to the LVAD flow. Increase or decrease the RVAD set speed gradually, in 50-100 RPM increments every few seconds, allowing the patient's vascular system to adjust between each RPM change. The pump set speed should be gradually increased to the desired flow. If flow drops or tubing chatter is observed, the set speed should be immediately reduced 100-200 RPM. Once target flows are acquired, if changes are necessary to one of either the LVAD or RVAD flows, ensure that the other is also changed accordingly.

CAUTION: If the RVAD speed is increased but no change in the LVAD flow is observed, a pulmonary edema may be present. Decrease the RVAD set speed, and increase the LVAD set speed as needed to balance appropriately.

CAUTION: If the LVAD speed is increased without adjusting the RVAD speed, risk of LV suction may occur.

Normally the left heart output is slightly greater than the right heart due to natural shunting. When providing maximal support, the right and left pump flows should be nearly equal, but may vary as much as 0.5 LPM to 1.0 LPM, with the left side support usually being greater. The factors that affect this difference are the valvular incompetence, and ventricular ejection through the pulmonic or aortic valves, that is not reflected in the VAD flow. Generally, the right flow should not greatly exceed the left flow.

WARNING: A high RVAD pulmonary flow without a corresponding high LVAD systemic flow may result in pulmonary edema.

The position of the flow probe should be such that it does not cause kinking of the tubing. If positioned close to the pump, the weight of the flow probe may cause a kink in the tubing near the inlet or outlet of the pump. Moving the probe further away from the pump will usually resolve this. Repositioning the flow probe on the tubing line periodically to maintain accuracy and avoid kinking of tubing is recommended.

Periodic checks should be performed to ensure:

- There is no entrained air.
- There are no clots at tubing connections to the cannulas and pump. A flashlight can be used to inspect.
- Cannulas are secured to the patient.
- Tubing is free of sharp bends or kinks.
- The console is on AC power.
- The battery is fully charged.
- An additional console is available to use as a backup console.

⁶ Actual patient values will vary significantly based on individual needs and hemodynamic condition.

- The low flow alarm is set. This should be set at approximately 75% of the desired clinical flow.
- There is air circulation around the motor and console.
- There are two tubing clamps near each pump.

Staff should periodically rehearse switching to the backup motor and console using a spare system and training (mock circulatory) loop. Refer to the CentriMag Circulatory Support System Operation Manual for details.

Hemodynamic Assessment and Support

Hemodynamic monitoring during support with the CentriMag system has some special considerations. During LVAD support, the arterial pressure waveform will normally show a significantly reduced pulse pressure (Systolic-Diastolic) when the left ventricle is completely unloaded. An increase in the pulse pressure will be observed as the ventricle recovers, when the pump flow is decreased, or if the volume status of the patient is increased. A similar change will be seen on the pulmonary artery waveform during RVAD support.

Pulmonary artery catheters may prove useful for monitoring during CentriMag system support, but there are some important considerations during RVAD support. First, because the pulmonary artery catheter is inserted and maintained in position with the aid of blood flow through the right heart, insertion of a catheter during RVAD support is usually not possible. Pulmonary artery catheters that are in place before RVAD implant may be used for pressure monitoring and mixed venous oxygen saturation only, but often can migrate out of the pulmonary artery. Thermodilution or continuous cardiac output determinations are inaccurate during RVAD support. Since the inflow and outflow cannulas are placed in the right atrium and pulmonary artery, the majority of the circulating blood travels through the pump circuit, rendering the pulmonary artery flow measured by the catheter incorrect. The RVAD flow bypasses the thermistors that measure the temperature changes needed for the cardiac output measurement. However, in most cases the mixed venous oxygen saturation may be used to estimate changes in total cardiac output based on the Fick principle.

CAUTION: The usual thermodilution methods for measuring total cardiac output might be inaccurate, and pump flow may not represent total cardiac output. Although the CentriMag system may capture the majority of blood flow, some ventricular output may be through the aortic or pulmonic valve. CentriMag system flow may also be elevated due to shunts or incompetent valves.

Adequate volume is essential for pump operation. Fluid balance should be routinely monitored using patient weight, CVP, LAP, and/or PCWP, with careful attention to intake and output.

If there is significant diuresis, intravascular fluid shifts or bleeding, this will adversely affect the available blood volume needed to operate the system, and the flow may need to be temporarily reduced while these conditions are treated. If a CVP catheter needs to be placed during CentriMag system support, care must be taken to avoid air entrainment during placement. Consider temporarily decreasing the RPMs during insertion. This will make it easier to see the IJ or subclavian. Place the patient in the Trendelenberg position, if tolerated. Be sure there are no signs of negative pressure during insertion (line chatter, ramping of the flows, or flow below the minimum alert). Place a stopcock on the open ports of the central line to avoid air being entrained.

CAUTION: Never leave any ports open to the air, as sudden suction could result in air entrainment and the subsequent air embolus will be delivered to the patient.

Bleeding is a common complication following CentriMag system placement and should be carefully monitored. Excessive bleeding that does not decrease may require a reoperation. Constant attention must be given to maintaining a normal hemoglobin concentration. Excessive diuresis in the post-operative phase should also be carefully monitored, and replacement volume administered as required. Inotropic support is often used to support ventricular function, maintain wall motion, and reduce the risk of intra-ventricular thrombosis, but should be used conservatively during CentriMag system support. High doses or prolonged use of inotropes may deplete myocardial energy stores, making weaning and complete recovery more difficult. Milrinone is the usual drug of choice because of its positive inotropic and vasodilatation effects. Inotropic support should be avoided during the initial weaning and assessments of recovery, but gradually increased during the CentriMag system explant.

The pulmonary vascular resistance should be carefully monitored and treated when necessary. Because the PVR is not continuously monitored, acute changes may not be observed. A sudden decrease in the LVAD flow is often caused by inadequate intra-ventricular volume but may also be an indication of an elevated PVR due to administration of blood products, a response to an infusion, or other cause. Pulmonary vasodilators are commonly used in the immediate postoperative period, with inhaled nitric oxide being the most effective and safe. Patients with significant bleeding that require transfusions may be expected to have an increase in PVR. Many CentriMag system users apply prophylactic nitric oxide and use intravenous vasodilators as a last resort.

Intra-aortic Balloon Pump

An intra-aortic balloon pump may provide pulsatility during CentriMag system support, but its usefulness with the CentriMag system has not been demonstrated. If used with LVAD support, the augmentation or balloon volume should be decreased so that complete occlusion of the aorta does not occur. Consider pulling back the sheath to improve distal perfusion, which should be assessed at least hourly. The IABP may be removed in the critical care unit after coagulation parameters have normalized. If weaning is anticipated within 48 to 72 hours, leaving the IABP in place may be appropriate.

Defibrillation/Cardioversion

Defibrillation or cardioversion may be necessary during severe arrhythmias. Cardioversion may be performed without stopping the pump. Ensure that a backup console and motor are available, powered and in the immediate vicinity.

If cardioversion is attempted without discontinuing support, consideration should be given to reducing the speed of the pump (or pumps for BiVAD support) to reduce the likelihood of Right-Left imbalance and pump inlet obstruction. Following cardioversion, slowly increase the speed (or resume BiVAD support) while monitoring the patient's hemodynamics to ensure adequate volume available for the desired flow.

CAUTION: If you choose to reduce the speed during cardioversion, carefully monitor systemic hemodynamics for adequate

perfusion, and immediately increase the speed to reach target flow when cardioversion is complete.

Anticoagulation

Generally, no anticoagulation therapy is used in the first 6 to 24 hours after initiation of support due to usual postoperative bleeding. Cases where CPB was not used prior to initiation of support, and bleeding is minimal, low dose anticoagulation with heparin should be started sooner. Pump thrombosis may be minimized by maintaining flow of at least 3.0 LPM. Intravenous heparin is usually started after the chest tube drainage is less than 50 ml/hour for at least 2 to 3 hours. The initial target ACT is 160-180 seconds, the target PTT is 1.3-1.6 times the laboratory normal, or the anti-Xa assay shows 0.3-0.7 IU/mL.

As anticoagulation and hemostasis may be affected by end organ function, platelet levels, platelet function, CentriMag system flow, native cardiac output, and other factors, anticoagulation must be individualized for each patient by the attending physicians.

CAUTION: Monitor and administer anticoagulation carefully, as risk of bleeding or thrombosis may occur with inappropriate management.

Heparin-induced thrombocytopenia is a complication of heparin therapy that presents with bleeding and consumption of platelets. Treatment for HIT consists of withholding or reversing heparin. Aspirin, bivalirudin, warfarin, and a variety of other anticoagulants may be considered as alternatives to heparin, depending on clinical objectives, experience at the individual center, and hepatic and/or renal function. Existing institutional protocols for managing HIT should be implemented as appropriate. A hematology consult can also be valuable in the management of these patients.

Thromboelastography is used by some centers for the management of anticoagulation. Its use for VAD patients is not universally accepted, although some centers with TEG equipment, experienced personnel, and well-defined protocols have found it useful and reliable. If TEG is used, teams should be trained to ensure consistent results. The TEG should be initially reviewed carefully every day to assess antiplatelet needs until stable and satisfactory levels are achieved. Anticoagulation needs vary by patient and should be adjusted based on clinical judgment.

Wound Care

If the cannulas are tunneled, postoperative wound care should be consistent with standard surgical protocols. A standard occlusive dressing should be used at the surgical sites to minimize the risk of infection. Cannula exit sites should be under a separate dressing from the chest tube exit sites if possible.

Aseptic technique should be used by all staff when handling the surgical sites during dressing changes and other wound care. The importance of consistent hand washing practices by staff and caretakers cannot be overemphasized. Wound sites should be carefully inspected for signs of tissue breakdown or excessive drainage. Undue pressure or torque to the surgical site should be avoided in order to minimize trauma with special care to secure the wound site taken during patient ambulation or transportation.

Nutrition

Enteral or parenteral feeding should be implemented when feasible during support. It is important that patients who achieve explantation receive proper nutritional education from the hospital nutritionist to optimize recovery.

Physical Therapy

When feasible, the patient should receive passive and active range of motion physical therapy as tolerated. Some patients have also been able to ambulate during CentriMag system support.

Should ambulation be considered, care must be taken to protect the cannulas, tubing and pump from any kinks or tension on the circuit. It is advisable to ensure additional securing features (i.e., bands) on all connection sites of the circuit. Furthermore, if ambulation is considered ensure that there is an appropriate number of staff available to monitor and support both patient and circuitry. Before movement of the patient or circuit, inspect all connections of the circuit to be sure they are intact.

CAUTION: Ensure that the length of the tubing is adequate for ambulation to avoid the risk of disconnection, cannula migration, or dislodgement.

Bedside range of motion or other light exercise is possible with extreme care, and useful for patients on support for multiple weeks.

Patient Transport

In some cases, a patient on CentriMag system support may need to be transported to another location within the hospital or to another medical center. The CentriMag system meets international standards for air and ground transport and is designed for ease of use during transport between medical centers. The system has been designed for portability in acute and critical care situations.

When transporting a patient within the hospital, consider the following:

- Care must be taken to avoid dislodgement or disconnection of the cannula and tubing connections.
- The pump and motor unit should be on a stable cart or placed in the bed with the patient and secured, or placed in the CentriMag system transporter which has been attached to the bed.
- If the motor is placed on the patient's bed, the cable length from the console to the motor is usually sufficient to transport the console on its cart alongside of the patient's bed.
- If the motor is placed on the patient's bed, ensure that the pump and tubing are visible at all times. If necessary, the console can be detached from its cart and placed on the bed. Because of the weight of the motor and the console, these items should not be placed on top of the patient.
- The motor, when operating, is warm to the touch. A barrier between the motor and the patient can be used to ensure that heat from the motor does not come in contact with the patient's skin.

CAUTION: Do not cover the motor or console with blankets to prevent them from overheating.

In the event that the patient is being transported to another medical center, the transport process involves three teams: the transferring (spoke) center team; air or ground transport team; and the receiving (hub) center team. Key priorities include pre-transport coordination, maintaining hemodynamic support, and continuous monitoring of the patient's hemodynamics and CentriMag system flow.

Transport Protocols

Existing institutional protocols for IABP, cardiopulmonary support, or ventilator- dependent patient transport may serve as useful templates for institutional CentriMag system transport protocols. Transport protocols should include:

- Equipment and supplies needed
- Individuals and responsibilities
- Primary and backup power sources
- Securing of equipment during transport
- Response to most likely complications

Transporting a patient on CentriMag system support requires a team approach for the best results. Some guidelines to follow include:

- Identify and communicate with the receiving or hub hospital in advance.
- Assign one individual to monitor the circuit, consoles and pumps who will be prepared to make system adjustments as needed during transport.

CAUTION: There is increased risk of air entrainment when the patient is being moved, particularly when the patient's chest has not been fully closed.

- Pre-position equipment and supplies. Load all backup equipment and supplies into the transport vehicle before loading the patient.
- Ensure that the pumps and motors are not covered, and that an additional console, motor and tubing clamps are always with the patient.
- The equipment should be secured to the gurney, stretcher or transport vehicle with appropriate straps or fixtures to prevent movement during transport, for both intra- and inter-hospital transport.
- The console has 2 hours of battery power. Ensure that there is another console fully charged with a motor attached in immediate vicinity of the patient during transport.
- Prior to shutting off the power supply and removal of the patient from the transport vehicle, briefly unplug the console's power cord to confirm adequate battery charge and console operation.

For details on the equipment as well as FAA and other standards for transport, refer to the CentriMag Circulatory Support System Operation Manual.

Prevention and Management of Potential Complications

Potential complications are similar to those seen with other ventricular assist devices. Flow disruption is the most common complication and can result from hypovolemia, obstruction or malposition of the cannulas, right ventricular failure, cardiac tamponade, and/or arrhythmia. In these cases, increasing the RPM may result in an exacerbation of the complication, or accelerated decrease in VAD flow. This should alert the operator to immediately reduce the RPM, diagnose, and address the underlying condition causing the complication. Patients should be carefully and frequently assessed for complications listed in the table below.

Table 5. Prevention and management of potential complications

Complication	Prevention and management
Low flow or inflow obstruction	Decrease RPM. Monitor pressures and flow. Rule out and correct hypovolemia, tamponade, and/or obstruction or malposition of cannula.
Right ventricular dysfunction	Rule out and, if possible, adjust VAD flows, vasodilators, and/or inotropes to correct an intra- ventricular septal shift toward the left ventricle. Consider pulmonary vasodilators or mechanical right ventricular RVAD support.
Increased pulmonary vascular resistance	Minimize fluids and transfusions as feasible. Hyperventilate. Consider pulmonary vasodilators.
Patent foramen ovale with shunting	Repair defect if feasible. If not feasible, reduce or eliminate shunting by adjusting VAD flow and pharmacological support to maintain RAP>LAP.
Bleeding at cannulation and other sites	Use meticulous technique during surgery and cannulation. Secure the cannulas with dual purse-string pledgeted sutures. Minimize postoperative patient movement. Monitor anticoagulation and hemostasis status.

Table 5. Prevention and management of potential complications

Complication	Prevention and management
Thrombus formation within the heart, circuit or system components	Assess thrombi with TEE for stability; and remove during surgery or address with appropriate anticoagulation. Delay weaning, if necessary, until resolved. Avoid conditions which can cause suction or line chatter. Avoid flexing the tubing, particularly near the connectors, which can dislodge fibrin or deposits.
Hemolysis	Troubleshoot to identify cause: cannula position, cannula selection, CVVH, oxygenator, kinked tubing, another device, high RPM/flow. Check that pump is mounted properly. Consider pump change if suspect as a final option.
Pump not inserted correctly	Mount the pump correctly. Change pump if incorrect mount is accompanied by platelet consumption &/or hemolysis.
Console or motor malfunction	Switch pump to backup console and motor. Document, replace, and report.
Decannulation	Prevent by securing the cannulas to the tissue at multiple sites following cannulation. Minimize postoperative patient and circuit movement. Use extreme care when moving the patient.
Air entrainment and embolism	Immediately clamp pump outlet tubing. Stop pump. Depending on circumstances and anticoagulation, consider splicing in a connector, deairing, and/or pump exchange.

Alarms/Alerts and Troubleshooting

For information on alarms and alerts, refer to the CentriMag Circulatory Support System Operation Manual.

Weaning and Explantation

Recovery sufficient for removal from CentriMag system support will depend on specific patient hemodynamic status. Depending on the extent of myocardial injury:

- Patients may recover sufficiently to be weaned within 48 to 72 hours.
- Patients may require support for multiple weeks.
- Patients may not recover sufficiently to be weaned from support and will require long-term support with an implantable LVAD or heart transplant.

Improvement in ventricular function is usually first noted with increased contractility and ventricular ejection apparent on the arterial pressure waveform, decreased flow required to maintain patient hemodynamics, and a decreased dependence on inotropic support. Initial assessments of ventricular function should be made without increasing inotropic support, IABP support, or without volume loading of the ventricles. Echocardiography is useful to assess improvement in ventricular size, wall motion and ejection fraction. When possible, a pulmonary artery catheter provides useful information on recovery. Recovery is based on the patient's ability to maintain hemodynamic status, perfusion, and end organ function during extended period of low CentriMag system flow without additional pharmacological or mechanical support.

CAUTION: There is a risk of thrombosis if the pump flow is reduced without adequate anticoagulation. Before you reduce the pump speed, allow time for adequate anticoagulation circulation.

CAUTION: If the drainage or return cannula is placed directly in the heart (left or right atria or ventricles), then the removal of blood from the heart will unload the heart and reduce the amount of blood flowing through the ventricular outflow (pulmonary or aortic) valves.

A trial period of CentriMag system weaning over at least three hours may be attempted after the following criteria are met:

- Hemodynamic evidence of ventricular function improvement based on increased cardiac output
- Increase in mean arterial blood pressure
- Documented pressure, echocardiographic evidence, or TEE evidence of ventricular ejection with little or no inotropic support

Initial attempts to wean should be short in duration with an appropriate increase in anticoagulation and gradual reduction in pump flow to 1.5 to 2.0 liters per minute. If the ventricles become visibly dilated on TEE, mixed venous oxygen saturation is compromised, or the patient's hemodynamic parameters deteriorate, the weaning attempt should be discontinued.

Once weaning is successful, expect increased pharmacological support to be required.

WARNING: After you wean the patient from support, closely monitor their hemodynamics for deterioration, as this may require emergent re-initiation of support.

Weaning Protocol

The most appropriate timing for weaning CentriMag system support has not been determined and there are no specific criteria. Key parameters to assess for weaning are ventricular contractility and ejection. As the heart recovers function, the pulse pressure on the

arterial pressure tracing will increase. Serial echocardiography to assess contractility and ejection fraction provides a good indication of ventricular recovery. Decreased dependence on inotropic drugs is an important indicator of recovery.

Guidelines for weaning a patient from and termination of CentriMag system support include:

1. Final weaning and termination is preferentially done in an operating room.
2. Transesophageal echocardiography should be used continuously to assess ventricular function. Observe for ventricular dilation, septal shift, ejection fraction, and changes in inotropic drug requirements.
3. Decrease the flow rate by 0.5 LPM every 15-30 minutes until 2.0 LPM is reached.
4. Increase anticoagulation to a target ACT > 300 seconds.
5. Continue weaning as above until flow rate is 0.5 LPM.
6. Clamp the return tubing to terminate support, decrease the set speed to zero, and continue to carefully monitor the patient's hemodynamics and perfusion.
7. If the patient remains stable on low dose inotropic support, decannulate.
8. Consider using an IABP and/or leaving the sternum unwired (skin closure only) for patients with marginal function following decannulation.

Pump Exchange

Pump exchange may be necessary if the duration of support exceeds the indicated duration for use, if hemolysis is believed to be caused by the pump, or if there are indications of thrombosis at the inlet or outlet of the pump or inside the pump. A pump may be exchanged using the following procedure:

1. Using a sterile field and aseptic technique, a new pump or pump and circuit are primed as described in the Preparing for CentriMag System Use section. Tubing connectors are placed at the patient ends of the tubing. It is always advisable to change the pump as well as the tubing, rather than the pump alone.

CAUTION: Ensure that the patient is adequately pharmacologically supported before discontinuing CentriMag system support, as the patient's arterial pressure may drop upon discontinuation of support.

2. Four tubing clamps are used to clamp the patient's existing drainage and return tubing.
3. After the clamps are placed, the pump speed setting on the console is turned to zero.
4. The existing tubing is cut at least 4-5 cm from the cannula-connector end.
5. The new tubing connectors are attached using a wet-wet connection while taking care to eliminate air at the junction as well as in the circuit. Secure these new connections with bands.
6. Ensure that the pump is securely inserted into the motor, and that the pin is screwed in.
7. Turn the CentriMag system set speed to >1000 RPM, and remove clamps. Increase the set speed to achieve target flow.

Explantation

Before device removal, ensure adequate volume and anticoagulation levels, particularly if the pump is going to be run with low flow (under 2 liters per minute) for any length of time. If available, use TEE to check for the presence of thrombi in the atria, ventricles, and at the cannulation sites prior to weaning and device removal.

Explantation generally requires a repeat sternotomy. During decannulation, the surgeon should allow retrograde bleeding from the cannulation site to remove any thrombus that may have formed at the cannula site. During periods when the heart is being manipulated, the CentriMag system set speed should be reduced. If flow is compromised by manipulation of the heart, immediately reduce the set speed or clamp the return tubing as necessary to prevent inflow obstruction and/or air entrainment.

CAUTION: Abrupt changes in the CentriMag system flow due to manipulation of the heart may result in air entrainment.

Summary of Clinical Experience

The clinical study experience for the CentriMag system includes four FDA-approved, prospective, non-randomized, multi-center, unblinded, controlled studies encompassing 95 patients. The clinical studies are:

1. Cardiogenic Shock Pilot Trial [CentriMag VAS Cardiogenic Shock Trial] (IDE G030052)
2. RVAS Pilot Study [CentriMag VAS: Use as an RVAS Following Implantation of a Commercially Approved LVAS] (IDE G040029)
3. Pivotal Study [CentriMag VAS Failure to Wean (FTW) from Cardiopulmonary Bypass Trial] (IDE G030052/S21)
4. HDE PAS Study [CentriMag RVAS U.S. Post Approval Study (PAS)] (H070004)

Data from these clinical studies, together with the results of a comprehensive literature review and an analysis of global post-market surveillance data, are the basis for the CentriMag system clinical experience overview. The pivotal study (IDE G030052/S21) enrolled only patients for the indication for use in this PMA, postcardiotomy failure to wean from cardiopulmonary bypass. Only results from that study were used to assess effectiveness of the device. Data from patients enrolled in all four studies

were used to assess safety of the device. A summary of the clinical studies is presented below.

Study Design

Patients were treated in the four clinical studies between May 2004 and December 2013. There were 14 unique investigational sites across the four studies as shown in the table below. Each patient was followed for 6 months post-device removal in the three pre-market studies and for 30 days post-device removal in the HDE post-approval study.

Table 6. CentriMag Clinical Studies

Study	Cardiogenic Shock Trial	RVAS Trial	Failure to Wean From CPB Pivotal Trial	RVAS HDE Post-Approval Study
FDA IDE No.	G030052	G040029	G030052/S21	H070004/S1
Start Enrollment	May 2004	Oct 2004	Oct 2008	Feb 2010
End Enrollment	Dec 2007	Feb 2008	March 2013	Dec 2013
Investigational Sites ⁷	6	2	8	7
Patients	26	12	32	25

The pivotal trial conducted under IDE G030052/S21 enrolled only postcardiotomy patients who failed to wean from CPB, the primary indication for use in the US, while the other three studies included patients enrolled for other indications as well.

The Failure to Wean from CPB pivotal trial (G030052/S21) utilized a Data Safety Monitoring Board (DSMB) and Clinical Events Committee (CEC). The CEC was responsible for adjudicating all adverse events occurring during the study. The DSMB was responsible for reviewing adverse events, data quality, endpoints, device efficacy data and overall study conduct to evaluate device safety.

The control group was comprised of patients who failed to wean from cardiopulmonary bypass and who required mechanical circulatory support, as reported in peer-reviewed, published scientific literature.

The failure to wean from CPB population was defined as a subset of patients suffering from postcardiotomy cardiogenic shock who were unable to be separated from CPB prior to leaving the operating room.

Clinical Inclusion Criteria

Enrollment in the studies was limited to patients at least 18 years of age for whom informed consent was given either by the patient or their legally authorized representative, and who met the following inclusion criteria.

Inclusion Criteria – Failure to Wean from Cardiopulmonary Bypass Pivotal Trial (G030052/S21)

- Cardiac dysfunction due to failure-to-wean from cardiopulmonary bypass.
- All potential subjects must meet the following hemodynamic criteria at the time of enrollment:
 - Cardiac index ≤ 2.2 L/min/m².
 - For patients being evaluated for left-sided support (LVAD):
 - Pulmonary Capillary Wedge Pressure (PCWP) ≥ 18 mmHg or
 - Pulmonary Artery Diastolic Pressure (PADP) ≥ 18 mmHg or
 - Left Atrial Pressure (LAP) ≥ 18 mmHg.
 - For patients being evaluated for Right or Biventricular support (BVAD):
 - Central Venous Pressure (CVP) ≥ 15 mmHg or
 - Right Atrial Pressure (RAP) ≥ 15 mmHg.
 - Right Ventricular Stroke Work Index (RVSWI) ≤ 4.1 gm-m²/beat.
 - Enrollment without hemodynamic measurements due to frequent or unpredictable dysrhythmias, unacceptable cardiac function, or hemodynamic instability is allowed.
- Placement of an intra-aortic balloon pump has been attempted unless contraindicated.
- All possible measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, dysrhythmias and residual hypothermia.
- Cardiac resuscitation using pharmacologic agents, and epicardial pacing (if appropriate and possible) has been attempted.

Table 7. Inclusion Criteria – Other Premarket CentriMag System Pilot Studies

G030052	G040029
Cardiogenic Shock Trial	CentriMag RVAS
Potentially reversible cardiogenic shock with one of the following diagnoses: Postcardiotomy cardiogenic shock Post-Acute Myocardial Infarction cardiogenic shock	Undergoing treatment with an LVAS as a bridge to transplant or for destination therapy

⁷ Fourteen unique investigational sites; many sites participated in more than one study.

Table 7. Inclusion Criteria – Other Premarket CentriMag System Pilot Studies

G030052	G040029
Cardiogenic Shock Trial	CentriMag RVAS
Potentially reversible cardiogenic shock following myocardial infarction (AMI) subjects must meet two of the following three criteria: History and physical consistent with acute myocardial infarction ECG changes consistent with AMI Serum cardiac protein or enzyme changes consistent with AMI	Not applied to this study
Potentially reversible postcardiotomy cardiogenic shock following a cardiac surgical procedure subjects must be within 6 hours of the surgical procedure.	Potentially reversible postcardiotomy cardiogenic shock following implantation of an FDA cleared, commercially available LVAS. Enrollment must be within 24 hours of the surgical procedure to implant the LVAS
For patients considered for LVAS support: PCWP \leq 18 mmHg or PAD \leq 18 mmHg or LAP \leq 18 mmHg With cardiac index \leq 2.0 l/min/m ²	Not applied to this study
Patients supported with a CentriMag LVAS, with a dilated right ventricle, and being considered for BVAS support must meet two of the following three criteria: CVP or RVP \geq 15 mmHg Right Ventricular Stroke Work Index (RVSWI) \leq 4.1 gm-m ² /beat Decrease in mean PAP \leq 10 mmHg following the initiation of LVAS support	Patients being considered for RVAS support must meet two of the following three criteria:
For patients unweanable from CPB: No hemodynamic inclusion criteria required for either LVAS or BVAS support	For patients unweanable from CPB and being considered for BVAS support: No hemodynamic inclusion criteria required for RVAS support
Patient is unable to maintain adequate hemodynamics due to dysrhythmias: No hemodynamic inclusion criteria required for either LVAS or BVAS support	Not applied to this study
All possible measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, dysrhythmias and residual hypothermia.	
Cardiac resuscitation using pharmacologic agents, and epicardial pacing (if appropriate and possible) has been attempted.	

The only inclusion criterion for the post-approval study of the CentriMag RVAS HDE (H070004/S1) was 25 consecutive patients with acute right ventricular failure from any cause requiring use of the CentriMag RVAS to sustain life.

Clinical Exclusion Criteria

Patients were not permitted to enroll in the three premarket studies if they met any of the following exclusion criteria. No exclusion criteria were specified in the post-approval study protocol for the CentriMag RVAS HDE (H070004/S1).

Table 8. Exclusion Criteria – All CentriMag System Premarket Studies

G030052/S21	G030052	G040029
FTW from CBP Pivotal Trial	Cardiogenic Shock Trial	CentriMag RVAS
BUN > 100 mg/dl. (Based on lab data from the 24 hours prior to enrollment).		
Creatinine > 5 mg/dl (Based on lab data from the 24 hours prior to enrollment).		
Presence of any investigational mechanical circulatory support device.		Presence of any ongoing mechanical circulatory support device, other than a commercially approved LVAS and an intra-aortic balloon pump.
Not applied to this study		On an Abbott Medical PVAD (LVAD) undergoing treatment for failure to wean from CPB.
Not applied to this study	Presence of any mechanical cardiac valve prosthesis	
Known history of liver cirrhosis or portal hypertension.		
Pulmonary infarction. Pulmonary angiograms with evidence of significant embolism within two weeks prior to consideration. A significant embolism is one that causes lung infarction in more than one lung segment proven by a V/Q scan or pulmonary angiogram.		
Not applied to this study	Fixed pulmonary hypertension with a PVR > 8 Wood units, unresponsive to pharmacologic intervention, O ₂ , NO, etc.	
Stroke, TIA or history of either condition within the last six months and/or any confirmed, existing neurologic deficits.		

Table 8. Exclusion Criteria – All CentriMag System Premarket Studies

G030052/S21	G030052	G040029
FTW from CBP Pivotal Trial	Cardiogenic Shock Trial	CentriMag RVAS
Active systemic infection defined as positive blood cultures, core temperature >100.5°F, white blood count > 12,500, and treatment with antimicrobials.		
Not applied to this study	Prolonged (>15 min) or unsuccessful attempts at cardiopulmonary resuscitation prior to initiation of the surgical procedure, or prior to initiation of CPB.	
Participation in a clinical trial with any experimental treatment within 30 days prior to screening or previous participation in the present study.	Not applied to this study	
Not applied to this study		Severe blood dyscrasia as determined by INR >1.5, PT >16.0, PTT >45.0, and Platelet count <50,000 unresponsive to therapy.
Other serious disease(s) limiting life expectancy.	Cancer – unresolved malignancy	

Follow-up Schedule

All patients were followed throughout their course of treatment with the CentriMag system. Patients were also assessed at the time of discharge from the hospital, and at 30 days and 6 months after removal of the device.

Preoperatively, hemodynamic data (e.g. blood pressure, cardiac output, CVP, PAP, PCWP, LAP) and laboratory assessments (blood chemistry, coagulations studies, hematology) were collected for each patient.

Postoperatively, the objective parameters measured during the study included survival, hemodynamic data, laboratory assessments and adverse events.

Hemodynamic data and laboratory assessments were obtained at the following timepoints:

- Baseline (prior to initiation of CentriMag system support)
- 4 hours after initiation of CentriMag system support
- Daily during CentriMag system support (except for invasive hemodynamic monitoring which was only required for the first two days of CentriMag system support)
- Daily during the first two days after CentriMag system removal
- Hospital discharge
- 30 days after CentriMag system removal

Survival was assessed as a percentage of patients discharged alive from the hospital, and at 30 days and 6 months after CentriMag system removal. Adverse events and complications were recorded throughout the duration of CentriMag system support, through device removal and until the patient was discharged from the hospital.

Clinical Endpoints

Patients enrolled in this study included those who failed-to-wean from cardiopulmonary bypass. Failure-to-wean from cardiopulmonary bypass was defined as patients who undergo an operative procedure that are hemodynamically unstable and unable to leave the operating room without mechanical circulatory support. A total cohort of 32 patients was enrolled in the pivotal study.

With regards to safety, the frequency of major adverse events such as neurological dysfunction, bleeding, infection, and device failure was assessed.

Survival was the primary measure of effectiveness. Secondary measures of effectiveness included improvements in hemodynamics and key laboratory values as measures of end organ function.

With regard to success/failure criteria, patients were considered successes if they survived to hospital discharge or 30 days after device removal, whichever was longer. Patients were also considered successes if they survived on CentriMag system support until induction of anesthesia for the purpose of cardiac transplantation or converting the patient to a longer-term mechanical circulatory support device. Overall, the Pivotal FTW study was considered a success if at least 27% of the patients survived to the longer of either hospital discharge or 30 days post device removal, based upon data from the published clinical reports of FTW patient outcomes.

Accountability of the FTW Study Cohorts

Ninety-five (95) patients were enrolled in the four clinical studies supporting this PMA as shown in the following table. One of the studies enrolled only patients for the indication for use in this PMA, postcardiotomy failure to wean from cardiopulmonary bypass, but the other three enrolled patients for other indications as well. Data from patients enrolled for the other indications for use was used to assess safety of the device. All patients enrolled in the studies were evaluated. No patients withdrew from the studies or were lost to follow-up.

Table 9. All CentriMag Clinical Study Enrollment

Clinical Study	Indications for Use		Total Patients Enrolled
	Postcardiotomy Failure to Wean From CPB	Other	
FTW from CPB Pivotal Trial (G030052/S21)	32	0	32

Table 9. All CentriMag Clinical Study Enrollment

Clinical Study	Indications for Use		Total Patients Enrolled
	Postcardiotomy Failure to Wean From CPB	Other	
Cardiogenic Shock Trial (G030052)	10 ⁸	16	26
RVAS Trial (G040029)	11	1	12
RVAS Post-Approval Study (H070004/S1)	0	25	25
Total	53	42	95

Study Population Demographics and Baseline Parameters

The demographics of the study populations are typical for studies of mechanical circulatory support devices performed in the US. Demographic information for the four study populations is summarized in the table below.

Table 10. Demographics -All CentriMag System Clinical Studies

Clinical Study	FTW from CPB Pivotal Trial (G030052/S21) ⁹	Cardiogenic Shock Trial (G030052) ¹⁰	RVAS Trial (G040029) ¹¹	RVAS HDE Post Approval Study (H070004/S1) ¹²
Patients (N)	32	26	12	25
Sex: Male	24 (75%)	15 (58%)	8 (67%)	20 (80%)
Female	8 (25%)	11 (42%)	4 (33%)	5 (20%)
Race: White	24 (75%)	N/A ¹³	N/A ¹³	19 (76%)
African American	4 (13%)			4 (16%)
Other	4 (13%)			2 (8%)
Age: (mean years ± SD)	58 ± 13.8	59 ± 11.6	55 ± 14.3	53 ± 13.9
Hx of diabetes	12 (38%)	10 (39%)	2 (17%)	N/A ¹³
Hx of cardiovascular disease	29 (91%)	24 (92%)	12 (100%)	N/A ¹³

Baseline hemodynamic and laboratory values for only the pivotal study of the postcardiotomy failure to wean from CPB indication are summarized in the following tables.

⁸ Estimated number of FTW subjects (± 2-3) within total enrollment in Cardiogenic Shock trial.

⁹ Pivotal FTW Trial enrolled 100% (32/32) FTW subjects.

¹⁰ The Cardiogenic Shock Trial (G030052) enrolled a mixed cohort of patients in CS, at least 27% FTW subjects.

¹¹ The RVAS Trial (G040029) enrolled patients in post-cardiotomy cardiogenic shock following implantation of an LVAD, over 90% FTW subjects.

¹² The RVAS HDE Post Approval Study enrolled no identified FTW subjects.

¹³ Not collected per study protocol.

Table 11. Baseline Hemodynamic Values – FTW from CPB (G030052/S21)

Variable	N	Mean	SD	Median	Min	Max
Systolic Blood Pressure (mmHg)	30	98.6	23.2	94.0	58.0	153.0
Diastolic Blood Pressure (mmHg)	30	54.2	12.7	52.5	22.0	79.0
Pulmonary Artery Systolic (mmHg)	22	37.3	14.0	36.0	13.0	58.0
Pulmonary Artery Diastolic (mmHg)	22	22.9	8.5	22.0	8.0	39.0
Central Venous Pressure (mmHg)	26	16.3	8.0	14.5	6.0	33.0
Cardiac Output (LPM)	11	3.9	1.3	3.7	2.6	7.2
Cardiac Index (L/min/m ²)	10	1.6	0.4	1.6	1.0	2.0

Table 12. Baseline Laboratory Values – FTW from CPB (G030052/S21)

Variable	N	Mean	SD	Median	Min	Max
Blood Urea Nitrogen (mg/dl)	32	39.1	21.3	32	12	94
Creatinine (mg/dl)	32	1.8	0.8	1.6	0.9	4
Total Bilirubin (mg/dl)	31	1.8	1.8	1.2	0.4	9.7
aPTT (sec)	29	81.4	60.7	49.8	23.4	200
PT (sec)	31	23.8	17.8	16.1	11.6	100
INR	31	2.3	2.3	1.3	0.9	12.8
Activated Clotting Time	21	294	182	174	117	640
Red Blood Cells (x10 ⁶ /ml)	32	4.6	5.2	3.5	2.4	32.6
White Blood Cells (x10 ³ /ml)	32	11.3	5.5	10.7	3	28.2
Platelets (x10 ⁶ /ml)	32	152	79.1	173	21	369
Hematocrit (%)	32	31.7	6.5	29.8	23	43.5
SGOT (U/L)	29	344	1071	48	16	5766
SGPT (U/L)	31	237	586	39	13	3125
LDH (U/L)	19	1203	1479	678	198	5404
Plasma Free Hemoglobin (mg/dl)	20	28.8	28.9	14.5	3.1	89

Safety and Effectiveness and Results

Safety Results

The analysis of safety was based on all 95 patients enrolled in the four clinical studies of the CentriMag system described above, thereby providing a more conservative estimate of the safety profile inclusive of all study (mixed) cohorts, not just FTW subjects. Safety was evaluated on the basis of adverse events and device malfunctions.

Adverse Events that occurred in all CentriMag Clinical Studies

Adverse events observed during the four studies are summarized in the table below. The clinical studies were not powered for a specific analysis of adverse events. The adverse event rates observed during the clinical studies were not unexpected in this critically ill patient population, being typical for patients recovering from open heart surgery and supported by a mechanical circulatory support device, as reported in the literature. The risk of bleeding, infection and respiratory failure is high in this patient population, although the number of these events which were reported as directly attributable to the device was relatively low. There were no unanticipated adverse events reported in any of the four clinical studies. Adverse event definitions were similar but not identical across the studies so direct comparisons are not possible. However, the table shows that general trends in types and incidence of adverse events were similar across all four studies.

Table 13. Summary of Adverse Events, All CentriMag System Clinical Trials¹⁴

Adverse Event Type	IDE G030052 Pivotal FTW ¹⁵ (n=32)		IDE G030052 Pilot Cardiogenic Shock (BVAD) ¹⁶ (n=26)		IDE G040029 Pilot RVAD w/ LVAD ¹⁷ (n=12)		RVAD HDE PAS RVAD w/ HMII LVAD ¹⁸ (n=25)		All CentriMag System Clinical Patients (n=95)		
	Total Number of Events	Number of Subjects With Event	Total Number of Events	Number of Subjects With Event	Total Number of Events	Number of Subjects With Event	Total Number of Events	Number of Subjects With Event	Total Number of Events	Number of Subjects With Event	Number of Subjects With Event
Death [While on device support or < 30 days post explant]	10	10 31%	15	15 58%	5	5 42%	5	5 20%	35	35	37%
Infection	22	13 41%	39	13 50%	17	4 33%	25	15 60%	103	45	47%

¹⁴ Pivotal trial AE's are during device use only, all other studies include adverse events both during device use and during follow-up after explant.

¹⁵ Pivotal FTW Trial enrolled 100% (32/32) FTW subjects.

¹⁶ The Cardiogenic Shock Trial (G030052) enrolled a mixed cohort of patients in CS, at least 27% FTW subjects.

¹⁷ The RVAS Trial (G040029) enrolled patients in post-cardiotomy cardiogenic shock following implantation of an LVAD, over 90% FTW subjects.

¹⁸ The RVAS HDE Post Approval Study enrolled no identified FTW subjects.

Table 13. Summary of Adverse Events, All CentriMag System Clinical Trials¹⁴

	IDE G030052 Pivotal FTW ¹⁵ (n=32)			IDE G030052 Pilot Cardiogenic Shock (BVAD) ¹⁶ (n=26)			IDE G040029 Pilot RVAD w/ LVAD ¹⁷ (n=12)			RVAD HDE PAS RVAD w/ HMII LVAD ¹⁸ (n=25)			All CentriMag System Clinical Patients (n=95)		
Bleeding	74	27	84%	34	20	77%	29	11	92%	51	20	80%	188	78	82%
Respiratory Failure	14	14	44%	20	20	77%	9	8	67%	20	16	64%	63	58	61%
Arrhythmias	14	12	38%	14	9	35%	14	4	33%	17	16	64%	59	41	43%
Hypertension	1	1	3%	0	0	0%	0	0	0%	9	5	20%	10	6	6%
Hypotension	1	1	3%	5	5	19%	2	2	17%	0	0	0%	8	8	8%
Hepatic Dysfunction	1	1	3%	8	7	27%	3	2	17%	0	0	0%	12	10	11%
Renal Failure/ Dysfunction	8	8	25%	3	3	12%	1	1	8%	12	12	48%	24	24	25%
Neurologic Dysfunction	0	0	0%	8	8	31%	2	2	17%	4	4	16%	14	14	15%
Venous Thromboembolism	2	2	6%	0	0	0%	3	3	25%	1	1	4%	6	6	6%
Pericardial Fluid Collection	0	0	0%	0	0	0%	0	0	0%	5	4	16%	5	4	4%
Right Heart Failure	2	2	6%	14	14	54%	1	1	8%	7	6	24%	24	23	24%
Hemolysis	4	4	13%	7	4	15%	1	1	8%	2	2	8%	14	11	12%
Myocardial Infarction	0	0	0%	0	0	0%	0	0	0%	1	1	4%	1	1	1%
Psychiatric Episode	2	2	6%	0	0	0%	0	0	0%	3	3	12%	5	5	5%
Arterial non-CNS Thromboembolism	1	1	3%	0	0	0%	0	0	0%	1	1	4%	2	2	2%
Wound Dehiscence	3	3	9%	0	0	0%	0	0	0%	0	0	0%	3	3	3%
Cardiac Tamponade	0	0	0%	3	3	12%	2	2	17%	0	0	0%	5	5	5%

Table 13. Summary of Adverse Events, All CentriMag System Clinical Trials¹⁴

	IDE G030052 Pivotal FTW ¹⁵ (n=32)			IDE G030052 Pilot Cardiogenic Shock (BVAD) ¹⁶ (n=26)			IDE G040029 Pilot RVAD w/ LVAD ¹⁷ (n=12)			RVAD HDE PAS RVAD w/ HMII LVAD ¹⁸ (n=25)			All CentriMag System Clinical Patients (n=95)		
Limb Ischemia	0	0	0%	0	0	0%	2	2	17%	0	0	0%	2	2	2%
Aneurysm	0	0	0%	0	0	0%	1	1	8%	0	0	0%	1	1	1%
Device Failure	0	0	0%	0	0	0%	0	0	0%	0	0	0%	0	0	0%
Device Malfunction	1	1	3%	2	2	8%	1	1	8%	0	0	0%	4	4	4%
Other ¹⁹	14	11	34%	0	0	0%	0	0	0%	21 ²⁰	10	40%	35	21	22%

¹⁹ Right arm compartment syndrome, bronchorrhea and desaturation, cardiogenic shock with suspected platelet dysfunction, tear in ventricular tissue near durable LVAD sewing ring, bilateral lower extremity ischemia with gangrene, coagulopathy, pressure ulcer, right abdominal wall hematoma, critical illness myopathy, septic shock, pleural effusion (x2)

²⁰ Pressure ulcer; ischemic bowel, mediastinal washout/wound management (x7), device thrombosis, thrombus in tubing RVAD circuit (x2), thrombocytopenia (x2), microcytic hypochromic anemia (x2), thrombus on pump impellar, leukocytosis, pleural effusion, pneumothorax, thrombus

Device Malfunctions and Failures

The CentriMag Circulatory Support System has been in commercial distribution for use up to 30 days in many countries since 2002. Commercial distribution in the US began in 2003 under 510(k) Premarket notification for short term (6-hour) use during cardiopulmonary bypass procedures.

From June 2014 through June 2019, all reports of death or serious injury associated with the device, or device malfunctions that had the potential to cause death or serious injury if they were to recur (Medical Device Reports, MDR), were analyzed and the results are summarized in Table 14. Over 32,000 CentriMag pumps were distributed during that same time period, providing a reasonable estimate of the number of times that the CentriMag system is used, the denominator used to calculate the incidence of these events.

Table 14. MDR Reports: CentriMag Circulatory Support System Adverse Events by Component (June 2014 – June 2019)

CentriMag System Component	No. of Events
Motor	
Motor cable break	60
System stopped	25
Overheating	20
Abnormal sounds	12
Abnormal operation	4
Variable flow	1
Total	122
Console	
System Alarm(s)/Fault (console and/motor)	68
Abnormal operation	10
System stopped	4
Battery	2
Total	84
Pump (Adult and Pediatric)	
Thrombus	20
Variable flow	11
Damage	2
Blood leak	1
Death	1
Unknown/Other	1
Total	36
Cannula	
Blood leak (cannula connector)	8
Detachment (cannula color band)	4
Decannulation	1
Total	13
Multiple/Indeterminate Component(s)	
Stroke	7
Death	5
Unknown/Other	5
Physical Damage	4
Infection	3
Air entrainment	3
Hemolysis	2
Bleeding	1
Total	30
Total Number of MDRs	285

The blood leak events listed in Table 14 associated with the cannula were related to failure of the solvent bond between the body of the cannula and the integral connector that was used to join the cannulas to the circuit tubing. The designs of the arterial and venous cannula were changed in 2015 to use a separate barbed connector to join the cannulas to the circuit tubing.

The motor cable break events listed in Table 14 were the subject of a field action initiated by the applicant in 2018. All previously reported complaints with this failure mode were reanalyzed for reportability, resulting in an increase in reportable events related to motor cable break failure. Labeling updates and a cable redesign were initiated and have been approved for commercial distribution. The overall MDR rate (number of MDR's/number of pumps distributed) observed for the CentriMag Circulatory Support System is consistent with those documented in the published literature for other short-term mechanical circulatory support devices.

Effectiveness Results

The analysis of effectiveness was based on only the 32 evaluable Pivotal FTW Study patients at the 30-day post-device removal time point. Success in meeting the primary study endpoint in the pivotal trial for failure to wean from cardiopulmonary bypass (FTW from CPB) was 63%, far exceeding the pre-specified performance goal of 27%. Key effectiveness outcomes are presented in the tables below.

Table 15. CentriMag Effectiveness in FTW Subjects from CPB Pivotal Study (G030052/S21) – Survival and Primary Endpoint

Clinical Study	N	Survival to 30 Days Post-device	Survival To Discharge	Primary Endpoint Success ²¹
FTW from CPB Pivotal Trial (G030052/S21)	32	22/32 (69%)	20/32 (63%)	20/32 (63%)

The outcomes summarized in the table above were a function of use of the CentriMag system for durations that range from a minimum of 1 day and up to a maximum duration of 110 days. The duration of support observed for the Pivotal Study is summarized below in the table below.

Table 16. Duration of CentriMag Support in FTW Subjects from CPB Pivotal Study (G030052/S21)

Clinical Study	Indication For Use	N	Mean Duration Of Support (days)	Range (days)
FTW from CPB Pivotal Trial (IDE G030052)	FTW	32	12.7	1 - 90

Improvements in hemodynamics were evaluated as a secondary endpoint in the pivotal study for failure to wean from cardiopulmonary bypass. As shown in the table below, MAP increased and CVP decreased during support with the CentriMag system during the pivotal study for FTW from CPB, based on a comparison of paired values. No paired data points were available for analysis of Left Atrial Pressure or Cardiac Index because, given the hemodynamic instability of the patient population at baseline, data for these parameters were collected only at the discretion of the investigator.

Table 17. Hemodynamics - FTW from CPB Pivotal Study (G030052/S21)

Hemodynamic Parameter	Paired Values (n)	Baseline	Mean Value During CentriMag System Support
CVP	5	19.2 mmHg	13.7 mmHg
MAP	23	67.6 mmHg	75.3 mmHg

Key indicators of end organ function (blood urea nitrogen, creatinine and bilirubin) were tracked during the Pivotal FTW Study of the CentriMag system. Mean blood chemistry values during the first 14 days of support with the device during the pivotal study of failure to wean from cardiopulmonary bypass show decreasing trends for BUN and creatinine but increasing levels of bilirubin (Table 18).

Table 18. End Organ Function – FTW from CPB Pivotal Study (G030052/S21)

	Interval	N	Mean	Range
Blood Urea Nitrogen (BUN) (mg/dl)	Baseline	32	39	12 – 94
	Day 1	30	37	15 – 76
	Day 2	29	40	15 – 76
	Day 3	28	41	14 – 86
	Day 7	16	30	14 – 67
	Day 14	10	28	18 – 62
Creatinine (mg/dl)	Baseline	32	1.8	0.9 – 4.0
	Day 1	30	1.8	0.9 – 4.0
	Day 2	29	1.9	0.9 – 3.1
	Day 3	28	1.8	0.7 – 3.3

²¹ Success: Survival to 30 days post-device removal or to hospital discharge, whichever is longer; or survival to induction to anesthesia for surgery for cardiac transplantation or conversion to other long-term mechanical circulatory support system.

Table 18. End Organ Function – FTW from CPB Pivotal Study (G030052/S21)

	Interval	N	Mean	Range
	Day 7	16	1.4	0.7 – 4.8
	Day 14	10	1.2	0.9 – 1.9
Total Bilirubin (mg/dl)	Baseline	31	1.8	0.4 – 9.7
	Day 1	26	3.8	0.7 – 8.7
	Day 2	26	5.0	0.5 – 14.5
	Day 3	27	5.9	0.8 – 13.2
	Day 7	15	5.0	0.5 – 16.0
	Day 14	10	5.7	0.5 – 28.1

Survival at six months after cessation of support with the CentriMag system was also tracked as a secondary effectiveness endpoint in the pivotal study of the failure to wean from CPB indication for use. At six months after device removal survival was 53%, compared to 69% 30 days after device removal, showing that recovery from the initial hemodynamic instability that required use of the CentriMag system for circulatory support was sustained over time.

A supplemental analysis of effectiveness at the 30-day post-device removal time point was conducted for the 38 evaluable patients that participated in the other premarket pilot studies. Each of these studies had mixed cohorts, with some percentage of FTW patients. These supplemental effectiveness outcomes are presented in Table 19 and Table 20.

Table 19. CentriMag Effectiveness in Two Pilot Studies – Survival and Primary Endpoint

Clinical Study	N	Survival to 30 Days Post-device	Survival to Discharge	Primary Endpoint Success
Cardiogenic Shock Trial (G030052) ²²	26	11/26 (42%)	---	Not Defined
RVAS Trial (G040029) ²³	12	7/12 (58%)	---	Not Defined

Table 20. Duration of CentriMag Support in in two Pilot Studies

Clinical Study	Indication For Use	N	Mean Duration of Support (days)	Range (days)
RVAS Trial (IDE G040029)	PCCS after LVAD implantation, 90% FTW	12	15.3	1 - 29
Cardiogenic Shock Trial (IDE G030052)	CS (PCCS and/or post Myocardial Infarction); ≥ 27% FTW	26	12.8	1 - 60

Subgroup Analyses

Due to the small number of patients in the clinical studies, statistically meaningful evaluations of potential associations of preoperative characteristics with outcomes could not be performed.

For the Pivotal FTW Clinical Study, the primary effectiveness endpoint and survival to 6 months after cessation of CentriMag system circulatory support were analyzed with respect to device configuration as shown in the table below. Due to the small number of patients in each group no conclusions can be drawn from the analysis.

Table 21. Six Month Survival Post-Device Removal for FTW from CPB Pivotal Study (G030052/S21)

Device Configuration	Number of Subjects	Primary Endpoint Success	Subjects Surviving to 6 Months
LVAD	7	4 (57%)	3 (43%)
BiVAD ²⁴	5	2 (40%)	0 (0%)
RVAD	3	1 (33%)	1 (33%)
RVAD with HM II ²⁵	17	13 (76%)	13 (76%)
All Configurations	32	20 (63%)	17 (53%)

²² The Cardiogenic Shock Trial (G030052) enrolled a mixed cohort of patients in CS, at least 27% FTW subjects.

²³ The RVAS Trial (G040029) enrolled patients in post-cardiotomy cardiogenic shock following implantation of an LVAD, over 90% FTW subjects.

²⁴ Two CentriMag pumps, one LVAD and one RVAD

²⁵ CentriMag RVAD used in conjunction with HeartMate II LVAD (Thoratec, PMA P060040).

Clinical Study Safety and Effectiveness Conclusions

Four clinical studies have been conducted to evaluate the CentriMag system. Overall, ninety-five (95) patients were studied using the device in a variety of configurations, including 15 as an LVAD only, 11 RVAD only, 23 BVAD and 46 as a hybrid system with the CentriMag system supporting the right ventricle and another device supporting the left ventricle. The device was studied treating cardiogenic shock following acute myocardial infarction or postcardiotomy, failure to wean from cardiopulmonary bypass and in patients with acute right ventricular failure from any cause.

In all studies, the adverse event rates were as expected for this gravely ill patient population. The number of adverse events judged to be caused by the CentriMag system were relatively small. No unexpected adverse events were reported. There were no device failures.

In all studies, patients exceeded the 27% performance goal of survival to 30 days post-support or hospital discharge, whichever is longer, or to induction of anesthesia for the implantation of a long-term device or heart transplant, that was established for the Pivotal Clinical Study.

The totality of the available data demonstrates that the CentriMag system is safe and effective for temporary short-term use for up to 30 days.