2nd Generation
CentriMag® Primary Console

Operating Manual

For use with
CentriMag® and PediMag®
Blood Pumping Systems

CAUTION
Read the CentriMag and PediMag Pump Instructions For Use (IFU) and the entire contents of this manual before using this device.

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Section 4: **Warnings & Precautions** describes warnings and cautions to be considered when using the Primary Console.

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Section 7: **Setting up** describes the procedure for unpacking the Primary Console and configuring it for use.

Section 8: **Operating** describes how to operate the Primary Console.

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Appendix I: **Alarm/Alert Table** lists the Primary 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 Primary Console.

Appendix III: **Similarities & Differences between the Primary & CentriMag Back-Up Consoles** compares key functions and attributes of the Primary Console to the CentriMag Back-Up Console.

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2 INDICATIONS & CONTRAINDICATIONS

2.1 Indications for Use

As there are four different CentriMag System and one PediMag System Indications For Use, please refer to the table below for exact Indications For Use:

Indications for Use Chart		
Indications For Use	**Refer to Document No.**	**Associated Caution Statement**
PediMag System for Cardiopulmonary Support	**PL-0112**, PediMag Blood Pump IFU (CPB)	**Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.**
CentriMag System for Cardiopulmonary Support	**PL-0006-04**, CentriMag Blood Pump IFU (CPB)	**Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.**
CentriMag VAS Pivotal Trial (G030052)	**PL-0006-01**, CentriMag Blood Pump IFU (Pivotal Trial)	**Investigational Device. Limited by Federal (USA) law to investigational use.**
CentriMag VAS for Pediatric Use Trial (G070087)	**PL-0089**, CentriMag Blood Pump IFU (Pediatric Trial)	**Investigational Device. Limited by Federal (USA) law to investigational use.**
CentriMag RVAS HDE (H070004)	**PL-0085**, CentriMag Blood Pump IFU (RVAS HDE)	**Humanitarian Device: The CentriMag RVAS is 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.** **Distribution of this device is restricted to use by or on the order of a physician.**

2.2 Contraindications for Use

This CentriMag and PediMag Systems are contraindicated for use as a cardiotomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with appropriate anticoagulation such as Heparin or comparable alternative.

3 GENERAL CONVENTIONS AND LIMITED WARRANTY

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 Primary Console.

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 U.S. patents, including U.S. Patent Number 6,100,618, cover this product and its use.

Trademarks: CentriMag® and PediMag® are registered trademarks of Thoratec Corporation.

3.3 Conventions Used in This Manual

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

The Console and Mag 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., Blood Pump, Motor, Console and Mag Monitor).

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

3.4 Limited Warranty

A. Thoratec warrants the CentriMag Primary Console (the "Console") to be free from defects in materials and workmanship for one (1) year following delivery of the Console to the original purchaser. Thoratec will repair or replace at its factory any part or parts of the Primary Console which it finds have become defective within the warranty period or Thoratec may elect to supply a replacement Console, or issue a credit to the purchaser of the Primary Console equal to the Purchase Price, in lieu of repairing any defective part or parts in such Console.

B. To qualify for the repair, replacement, or credit set forth in **Section A**, the defective Primary Console must be returned to Thoratec thirty (30) days after discovery of the defect. Such repair, replacement, or credit, obligation does not apply to any Primary Console: 1) which has been repaired, or altered outside of Thoratec' factory in any way which, in the judgment of Thoratec, affects its stability and reliability; or 2) which has been subjected to alterations, misuse, abuse, or accident.

C. As used herein, the Purchase price shall mean the lesser of the original, or a functionally equivalent, or replacement Primary Console.

D. This Limited Warranty is limited to its express terms. In particular:

   1. Except as expressly provided by this Limited Warranty, **THORATEC IS NOT RESPONSIBLE FOR ANY MATERIAL EXPENSES OR ANY INDIRECT, SPECIAL, EXEMPLARY, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUCTION OF THE PRIMARY CONSOLE, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.**

   2. This Limited Warranty is made only to the original purchaser of the Primary Console. **AS TO OTHERS, THORATEC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN SECTION A ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.**

   3. **NO PERSON HAS ANY AUTHORITY TO BIND THORATEC TO ANY REPRESENTATION, CONDITION, OR WARRANTY EXCEPT THIS LIMITED WARRANTY**. (This Limited Warranty is not applicable to cables or other accessories used with this Primary Console).

4 WARNINGS & PRECAUTIONS

WARNING

Read this Manual as well as the CentriMag Back-Up Console Manual before using the Console with the CentriMag and PediMag Blood Pumps ("Blood Pump"). Thoratec requires users to undergo training prior to use of the Thoratec System.

WARNING

The Primary and CentriMag Back-Up Consoles are designed to be operated only with the CentriMag and PediMag Blood Pumps. There are no safety or performance data that establish compatibility with any other manufacturer's device or components.

WARNING

One CentriMag Back-Up Console and Motor are required in the immediate vicinity of each patient whenever the CentriMag or PediMag Blood Pump is used. The CentriMag Back-Up Console must be connected to the Back-Up Motor, 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 Primary Console or Primary Motor experience a malfunction.

WARNING

The CentriMag Back-Up Console is not designed to replace the Primary Console but to serve as an emergency Back-Up unit for temporary support if the Primary Console has malfunctioned or is suspected to have malfunctioned. The patient must be returned to the Primary Console as soon as the malfunction has been resolved or a new Primary Console becomes available.

5 DESCRIPTION

5.1.1 General Overview

The 2nd Generation CentriMag System is comprised of the following fundamental components: a) a single-use centrifugal Pump, b) a Primary Motor, c) a Primary Console, d) a Monitor e) a Back-Up Motor, f) a CentriMag Back-Up Console, g) a Flow Probe.

Figure 1: a) CentriMag blood pump b) Motor c) Primary Console and d) Monitor

The Primary Console is a fully functional Drive Console, equipped with flow monitoring, pressure sensing, and display capability. The patient is to be supported with the Primary Console at all times unless there is a malfunction necessitating exchanging the Primary Console for a CentriMag Back-Up Console (**Figure 2**).

Figure 2: CentriMag Back-Up Console

The System may be used with either the CentriMag Pump as seen in **Figure 1(a)** or with the PediMag Pump as shown in **Figure 3** below. For each pump, the Primary Console is operated in an identical manner and has the same Console display, alarms and alerts. However, the maximum flow range for the PediMag Pump is 1.5 lpm compared to the maximum flow of the CentriMag Pump of 10.0 lpm.

Figure 3: PediMag Blood Pump

5.1.1.1 CentriMag and PediMag System Components

The components listed in **Table 1** comprise the System. When a patient is supported on the Primary System, the Back-Up System must be available in the immediate vicinity of the patient. A Back-Up System must also accompany a patient during transport.

Table 1: Primary & Back-Up Elements of the System

System Component	Primary System	Back-Up System
CentriMag or PediMag Blood pump or CentriMag VAD Kit	✓	✓
Primary Console	✓	
Motor	✓	✓
Mag Monitor	✓	
Flow Probe (em-tec Adult flow probe for CentriMag Blood Pump and em-tec Pediatric flow probe for PediMag Pump)	✓	
CentriMag Back-Up Console		✓
CentriMag Back-Up Console Battery Module		✓

5.1.1.2 Optional CentriMag and PediMag System Components

The following components are available as optional accessories to the CentriMag and PediMag Systems (**Table 2**):

Table 2: Optional Elements of the System

System Component	Available for the Primary System	Available for the Back-Up System
System Cart	✓	✓
Motor Bracket	✓	✓
Monitor Arm	✓	
Pressure Transducer Cables	✓	
Pressure Transducers	✓	

5.1.2 Technology Overview

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 4**. 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.

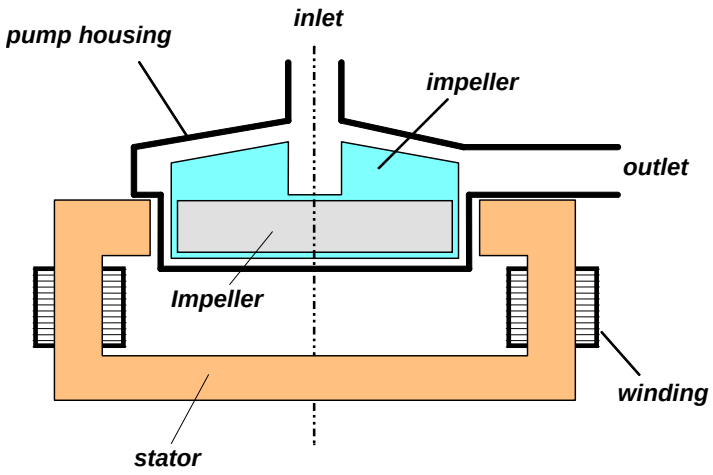


Figure 4: Schematic depicting the basic principle of the bearingless centrifugal Pump and Motor

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 5**). The non-contacting

impeller is levitated by magnetic fields through the walls of the Blood Pump, and floats in the center of the Pump.

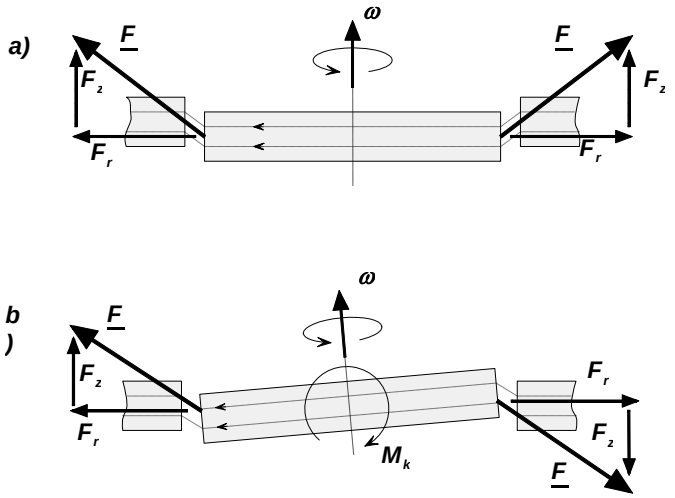


Figure 5: Axial support (a) and stabilization against tilting (b) of the impeller by passive magnetic forces in the Blood Pump

5.1.3 Mag Monitor

The Primary Console is designed to be used with a Mag Monitor (**Figure 1(d)**). The Mag Monitor may be used with one or two Primary Consoles when a patient is supported in either a univentricular or biventricular support mode. The Mag Monitor permits the user to redundantly display data pertaining to system performance and status along with the Primary Console display. When activated, the user is able to view system data directly on the Primary Console or the Mag Monitor. A second function of the Mag Monitor is to provide a redundant user interface to control Motor and Pump function. For detailed information regarding the Mag Monitor, refer to the appropriate section in this manual entitled “Mag Monitor Description and Connections” (**Section 7.22**).

The Mag Monitor is designed for use only with the 2nd Generation CentriMag Primary Console when the System is stationary and powered on AC. **The Mag Monitor is not intended for use when the Primary Console is operating on battery power. The rationale for not having the Monitor used when on battery power is to extend the life of the batteries. The Mag Monitor is also not intended for use with the 1st Generation CentriMag Primary Console or the CentriMag Back-Up Console.**

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

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

If a Mag Monitor is unavailable, the Pump and Motor can be controlled via the Primary Console. When operated in this manner, a number of features that can only be accessed via the Mag Monitor will not be available. These include; stopwatch function (**Section 7.13**), graphical displays of the pressure, as well as flow and alarm limits (**Sections 7.10 through 7.12**).

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

Table 3 summarizes the differences between the system with and without the Mag Monitor.

Table 3: The System with and without the Mag Monitor

System Component	Mag Monitor Display & Functions	Primary 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	✓	

5.1.3.1 Mag Monitor Front Panel

The role of the Mag Monitor (**Figure 1d**) is to display data from the Primary Console and to provide an alternative means of controlling the Primary Console via the soft touch keys on the Mag Monitor. An LCD screen on the Mag 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 Primary Consoles can be displayed simultaneously on one Mag Monitor.

5.1.3.2 Mag Monitor Back Panel

The Mag Monitor back panel (**Figure 6**) provides the required electrical inputs and outputs needed to connect the Mag Monitor to one or two Primary Consoles. Each connector provides the input from, and output to, one Primary Console. As shown in **Figure 6**, 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.

Figure 6: Mag Monitor Back Panel

CAUTION

The Mag Monitor is intended for use only with the 2nd Generation CentriMag Primary Console. The Mag Monitor will not function with the 1ST Generation Primary Console, the CentriMag Back-Up Console, or any other console.

WARNING

The Mag Monitor can only be operated when it is connected to the Primary Console and the Primary Console is operational on AC power. The Mag Monitor is not intended for use when the Primary Console is operating on battery power. Refer to the individual RVAD or LVAD Primary Console display for all operational data and audio/visual alarm messages when operational on Battery Power.

WARNING

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

5.1.4 Primary Console

The Primary Console uses single phase AC power, when used with the CentriMag Blood Pump. The CentriMag System 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 Blood Pump and circuit. In addition, each Primary Console contains a rechargeable internal battery that is capable of maintaining Console functionality in the event of a loss of AC power.

5.1.4.1 Primary Console Front Panel

The Primary Console (**Figure 7 and Figure 8**) is a microprocessor-based device. The microprocessors generate the primary Motor control signal, monitor system 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 7: Front Panel – Primary Console

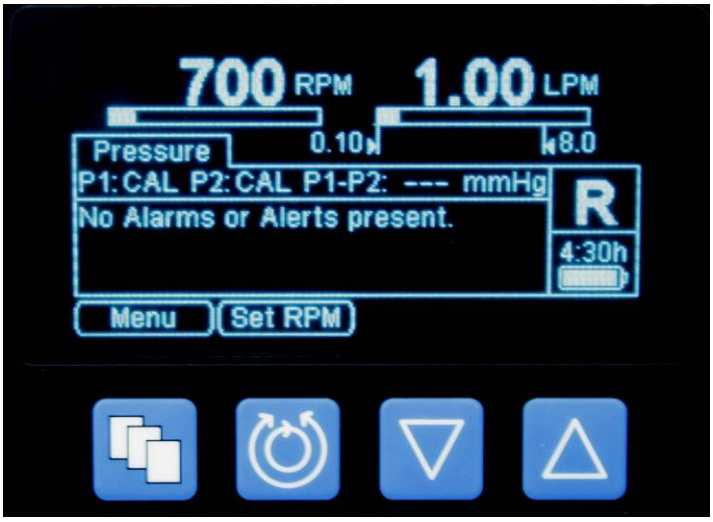


Figure 8: Digital Display – Primary Console

Flow Probes in two sizes are available for use with the 2nd Generation Primary 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 provided with the 1st Generation Primary Console are not interchangeable with and will not work when connected to the 2nd Generation Primary Console.

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.

5.1.4.2 Primary Console Back Panel

The Primary Console back panel (**Figure 8**) provides the required mechanical inputs and outputs needed to operate a CentriMag or PediMag Blood Pump.

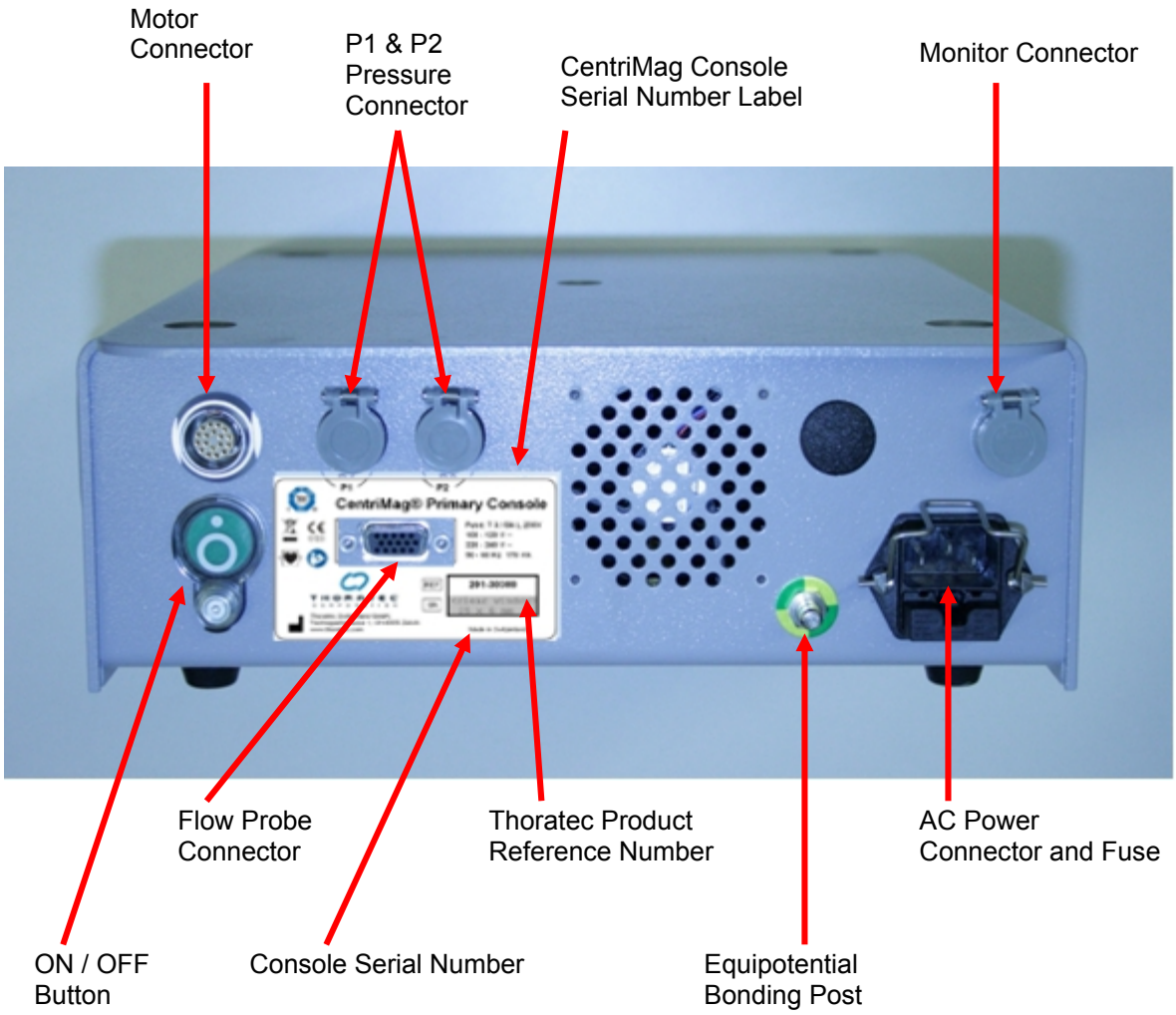


Figure 9: Back Panel – Primary Console

5.1.5 CentriMag and PediMag Blood Pumps

The System uses a sterile, single-use, disposable, polycarbonate, CentriMag or PediMag Centrifugal Blood Pump (**Figure 10a 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 Blood Pumps are designed to move blood by centrifugal force created by the magnetically suspended rotating impeller.

Figure 10: a) CentriMag Blood Pump b) PediMag Blood 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 11** for the CentriMag Blood Pump as an isolated component.

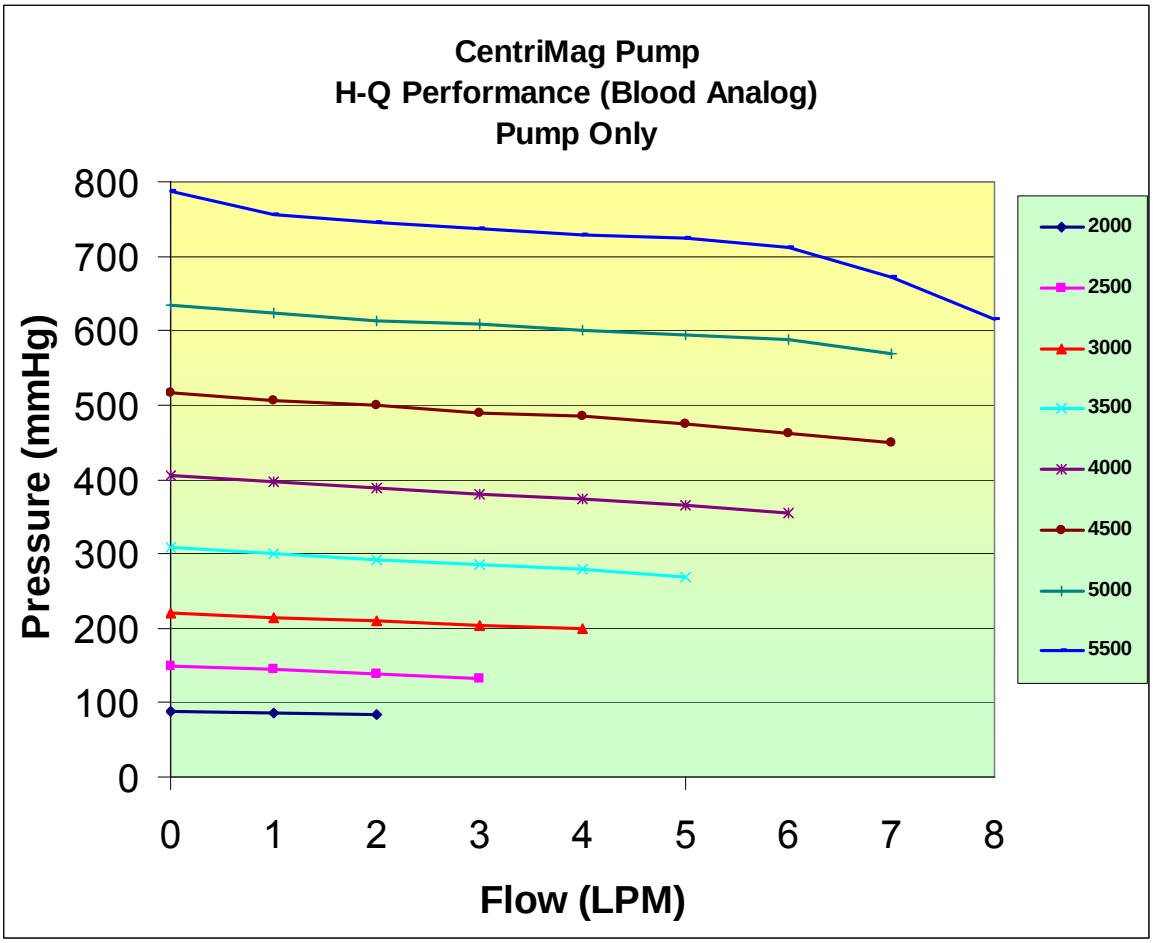


Figure 11: CentriMag Blood Pump Differential Pressure/Flow (H-Q) Curve

The relationship between pressure and flow rate as a function of RPM can also be seen in **Figure 12** for a complete CentriMag VAS Circuit (including the Pump, tubing and one set of cannulae that is provided in the VAD Kit[1]).

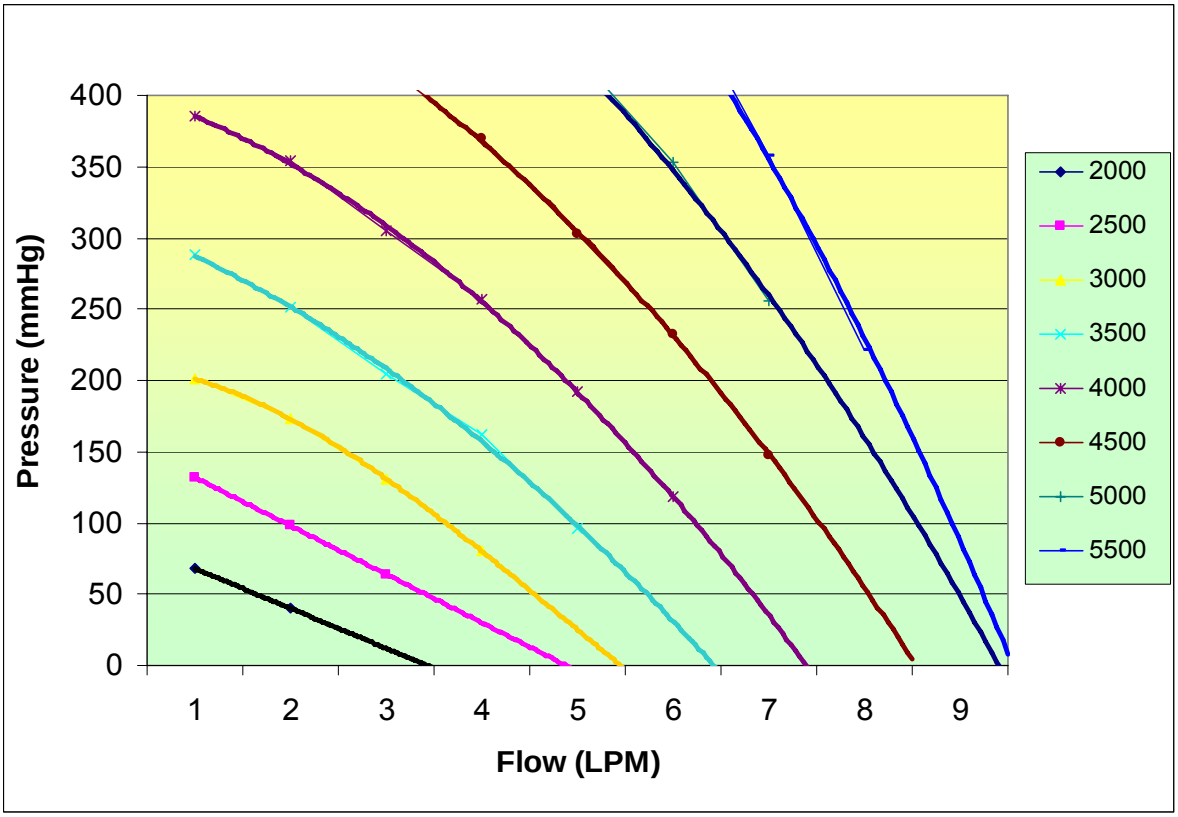


Figure 12: Representative H-Q Curves for the CentriMag VAS Circuit (Blood Analog) (Edwards Lifesciences TFM032L, Medtronic 77722, and 2' of 3/8" ID Tubing)

[1] Specific cannulae are provided in the VAD Kit for the CentriMag RVAS HDE, CentriMag VAS Pivotal Trial, and CentriMag VAS for Pediatric Use Trial). The VAD Kit is only available for IDE and HDE indications for use.

5.1.6 CentriMag VAD Kit

The CentriMag VAD Kit contains the following sterile components (**Table 4**):

Table 4: Contents of the CentriMag VAD Kit	
DESCRIPTION	**QUANTITY**
CentriMag VAD	1
CentriMag Drainage Cannula	1
CentriMag Return Cannula	1
Tubing Set	2
3/8” Straight Connector	2

5.1.7 PediMag Blood Pump

Unlike the CentriMag Blood Pump which is packaged either individually or as a kit with additional components, the PediMag Blood Pump is individually packaged without other components.

This manual describes only the functions, setup, and operation of the Primary Console. A more comprehensive description of the setup and priming of the Blood Pump can be found in the CentriMag and PediMag Blood Pump Instructions for Use.

5.1.8 Motor

The CentriMag Motor (**Figure 13**) holds the CentriMag or PediMag disposable Blood Pump and drives the impeller inside the Blood Pump.

Figure 13: CentriMag Motor

5.1.9 CentriMag Back-Up Console

The CentriMag Back-Up Console (**Figure 2**) uses single phase AC power and is capable of a flow rate of up to 10.0 LPM or maximum pressure head of 600 mmHg. When used with the PediMag Pump, a flow rate up to 1.5 LPM or a maximum pressure head of 540 mmHg may be achieved. Each CentriMag Back-Up Console contains a non-rechargeable, field replaceable internal battery that is capable of maintaining CentriMag Back-Up Console functionality in the event of a loss of AC Power.

The intended function of the CentriMag Back-Up Console is to provide basic life-support in the event of a Primary Console malfunction.

This manual describes only the functions, setup, and operation of the Primary Console. A more comprehensive description of the CentriMag Back-Up Console can be found in the CentriMag Back-Up Console Operating Manual.

5.1.10 System Cart

The Primary and CentriMag Back-Up Consoles and the Mag Monitor are designed to be used with a custom designed System Cart. The System Cart along with the recommended placement of the components may be seen in **Figure 14**.

Figure 14: System Cart, Primary & CentriMag Back-Up Consoles and Mag Monitor. Also shown are two water filled training loops connected to CentriMag pumps.

5.1.11 Application Software

This Operating Manual is written for Primary Consoles with Application Software Version CPC1.01 on board.

This Operating Manual is written for the Mag Monitor with Application Software Version MCM2.00 on board. The Application Software Version is shown on the Mag Monitor's digital display during power up.

For information on displaying the Console Application software see **Section 7.6** and for information on the Mag Monitor Management Software see **Section 7.23**.

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

5.2 Required User Supplied Items

The following item, required for use with the CentriMag and PediMag Systems when used in the VAS configuration, is not provided by Thoratec:

- Smooth jawed tubing clamps

6 SPECIFICATIONS AND GENERAL DESCRIPTION

This section includes the product specifications and physical attributes of the Primary Console.

6.1 Classification

Table 5: Primary Console 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	IPX 0 enclosure.	Not splash proof. Do not spray cleaning agents directly on Console or Monitor enclosure.
None	Not for oxygen rich environment	Not suitable for use in an oxygen rich environment.

6.2 Specifications

Table 6: Primary Console Specifications

PARAMETER	SPECIFICATIONS
AC Power	100 – 120 VAC, 200 – 240 VAC at 50/60 Hz, 170 VA
Battery Power	14.8 VDC Li-Ion, internal rechargeable battery *Discharge time*: approx. 120 minutes @3,500 RPM, 5.5 LPM *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	5.9 kg / 13 pounds
Pump Speed Range	0 – 5,500 revolutions per minute (RPM)
Pump Flow Range	0.0 – 10.0 liters per minute (LPM)

Table 6: Primary Console Specifications	
PARAMETER	**SPECIFICATIONS**
Flow Range Display	-2.0 – 10.0[2] liters per minute (LPM)
Electrical Safety	Earth leakage current: < 500 µA Touch current: < 100 µA Patient leakage current: < 10 µA

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 – 1013 hPa (157 mmHg – 760 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: 793 hPa – 1013 hPa (595 mmHg – 760 mmHg).

6.4 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 Primary Console may interfere with the operation of other equipment in close proximity. Do not place other equipment, other than a 2nd Primary or a CentriMag Back-Up Console, near the Primary Console or Motor.

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

6.5 Permanent Magnet Considerations

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

[2] Note: If the probe detects forward flow of more than 10 LPM then it will display as "^^.^^ LPM".

6.6 Operator Controls

6.6.1 Controls on the Primary Console

The Primary Console Control Panel (**Figure 15**) contains three rows of displays. **Row 1** includes indicators (bars and digital) for the Blood 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 Blood Pump. The other four keypads from left to right are: menu options (**MENU**) Blood Pump speed adjustment (**SET RPM**) and menu item adjustment (**DECREASE) (INCREASE)**.

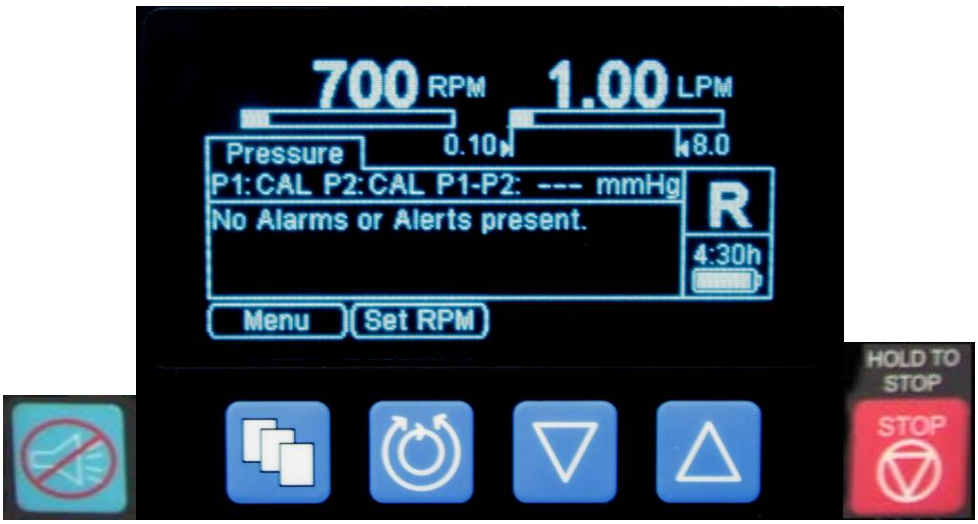


Figure 15: Operator Control Panel

6.6.2 Controls on the Mag Monitor

The Mag Monitor (**Figure 16**) replicates the information found on the Primary Console Control Panel (**Figure 15**). It will display pump speed, flow and alarm limit data, battery status, and pressure information. The Mag Monitor can display the information for up to two Primary Consoles simultaneously. For more information about the Mag Monitor see **Section 7.22**.

The Mag Monitor incorporates the same six soft keypads found on the Primary 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 Blood Pump. The other four keypads from top to bottom are: menu options (**MENU**) Blood Pump speed adjustment (**SET RPM**) and menu item adjustment (**DECREASE) (INCREASE)**.

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

Figure 16: Mag Monitor

6.6.3 Symbols on the Console and the Mag Monitor

The symbols used on the Console and Monitor, and their meanings are listed in **Table 7**.

Table 7: Symbols on the Primary Console and Monitor

SYMBOL	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 Primary Console that the user is aware that an alarm/alert condition(s) has occurred. If the alarm condition is unresolved, the Primary 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. **The visual indication of the alarm/alert condition will only be removed providing: 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 Mag 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 Mag 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 Blood Pump speed. When **EXIT** is displayed above this keypad on the alphanumeric display, depressing this keypad will disable the ability to adjust Blood Pump speed and maintain the Blood Pump speed at the displayed rate.	On the Console's Front Panel On the Mag 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 Mag Monitor's Front Panel

Table 7: Symbols on the Primary Console and Monitor			
SYMBOL	**NAME**	**DESCRIPTION**	**LOCATION**
	**Increase**	This keypad is used to select/modify the value for the displayed item to be adjusted.	On the Console's Front Panel On the Mag Monitor's Front Panel
	**Emergency Pump Stop**	When depressed for at least 5 seconds, this keypad will cause the Pump RPM to immediately be set to zero causing the Blood Pump to stop. While the pump is running, an audio will sound, while the keypad is depressed indicating that the pump will be stopped soon.	On the Console's Front Panel On the Mag Monitor's Front Panel
	**ON/OFF Button**	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.	On the Console's Back Panel
Indicators			
	**Pump Speed**	Blood Pump speed (**RPM**) Display: The Top portion of the Console's display is the Blood Pump Speed; below the digital speed indication a bar graph provides a representation of the Blood Pump speed in RPM.	On the front panel of the Primary Console and on the Mag Monitor screen
	**Flow Rate**	Flow rate (**LPM**): The top portion of the Flow Display is a 3-digit numeric display that provides a digital representation of the Blood 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.	On the front panel of the Primary Console and on the Mag Monitor screen

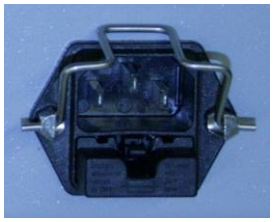
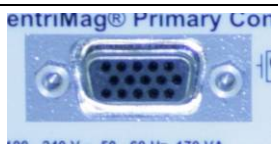
Table 7: Symbols on the Primary Console and Monitor			
SYMBOL	**NAME**	**DESCRIPTION**	**LOCATION**
 	**Power Source**	An AC plug icon indicator (GREEN DOT) illuminates when operating under AC power. Battery icon (GREEN DOT) illuminates when the Primary Console is operating under battery power. If the 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. Estimated remaining battery time, in minutes, is indicated by a three-digit numeric display. The Battery charge status is displayed via a battery icon.	On the Console's Front Panel Battery time is also shown on the Mag Monitor's screen
	**Support side**	The letter "L" or "R" displayed on the right side of the digital display denotes "Left Ventricular Support" or "Right Ventricular Support".	On the Console's Front Panel Colors are used to show the support type on the Mag Monitor's screen – red for left-sided support and blue for right-sided support.
Connections			
	**Motor Power Connector**	Connection for power to Motor. Red dot located on top of connector facilitates alignment of Motor LEMO connector.	On the Console's Back Panel
	**Power Entry Module (AC Power and Fuses)**	Connection for Primary Console to AC power and fuse box. Use only "5 x 20 mm, T 3.15A L 250V" fuses.	On the Console's Back Panel
	**Flow Probe connector**	15-Pin connection for the Flow Probe.	On the Console's Back Panel

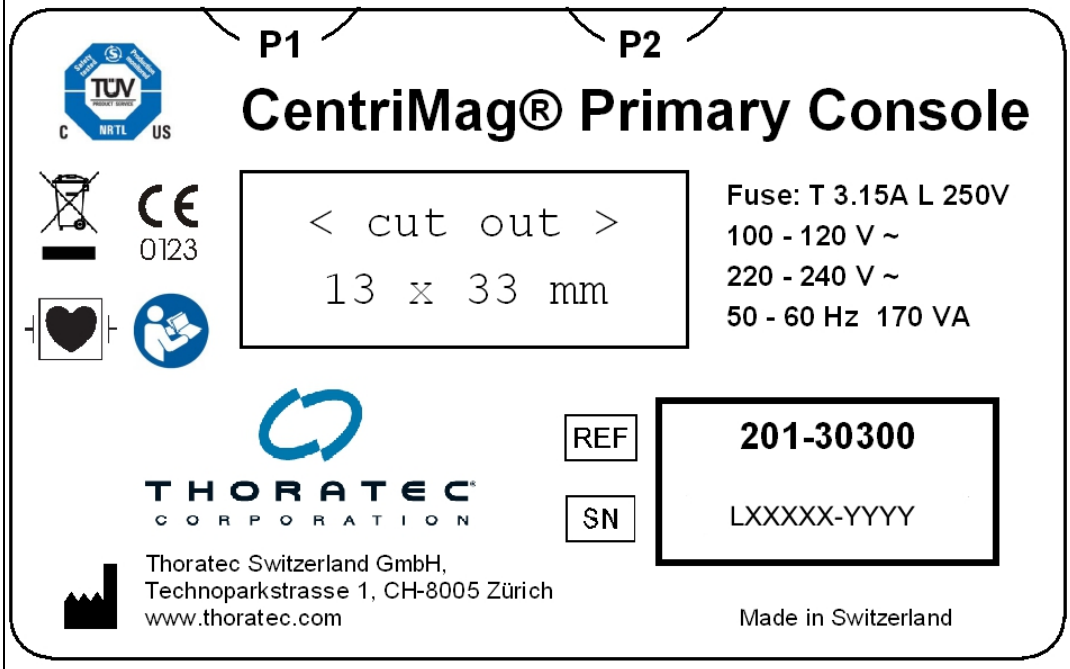
Table 7: Symbols on the Primary Console and Monitor			
SYMBOL	**NAME**	**DESCRIPTION**	**LOCATION**
	**Equipotential Bonding Post accompanied by its applicable international Symbol (IEC 417-5021)**	The Equipotential Bonding Post (EBP) provides a low impedance electrical safety common connection point.	On the Console's Back Panel
	**Pressure Probe Connectors**	Connections for 2 pressure probes	On the Console's Back Panel
	**Monitor (CAN) Connector**	Connection for the Mag Monitor.	On the Console's Back Panel (2) and Mag Monitor's Back Panel (2)
Primary Console Serial Number Label			
			On the Primary Console Back Panel.
REF	Thoratec Product Reference Number	Identifies the Thoratec Reference (reorder) Number.	On the serial number label.
SN	Serial Number	Identifies the serial number of the Primary Console.	On the serial number label.

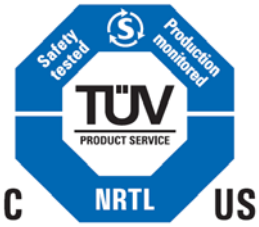
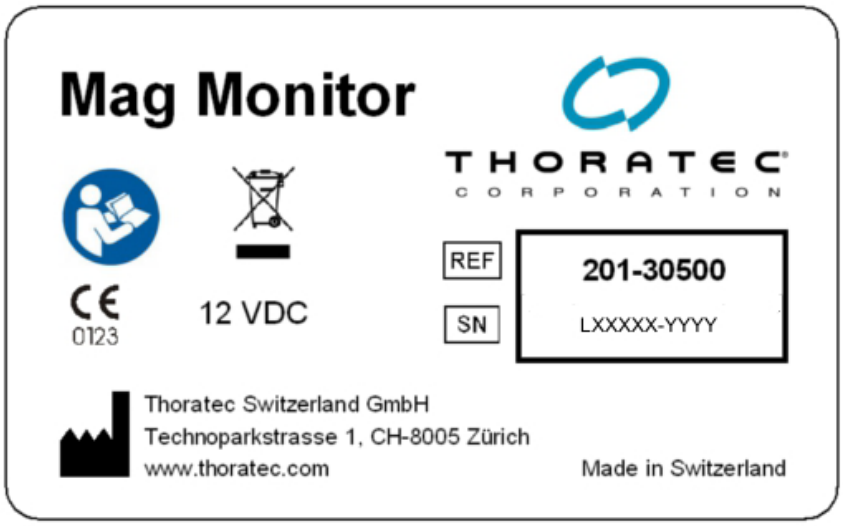
Table 7: Symbols on the Primary Console and Monitor			
SYMBOL	**NAME**	**DESCRIPTION**	**LOCATION**
	Defibrillation-proof Type CF Equipment	Equipment type.	On the serial number label.
	Read Manual	Consult Primary Console Operating Manual before operating the device.	On the serial number label.
	CE Mark with Notified Body ID	CE (Conformity European) Mark with Notified Body designation	On the serial number label.
	**TUV Mark**	The TUV Mark is an NRTL (Nationally Recognized Test Laboratory) mark, which signifies that the CentriMag Console was tested and meets the minimum requirements of prescribed product safety standards. Moreover, the mark indicates that Thoratec' 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.
Monitor Serial Number Label			
			On the Monitor Back Panel.
REF	Thoratec Product Reference Number	Identifies the Thoratec Reference (reorder) Number.	On the serial number label.

Table 7: Symbols on the Primary Console and Monitor			
SYMBOL	**NAME**	**DESCRIPTION**	**LOCATION**
SN	Serial Number	Identifies the serial number of the Monitor.	On the serial number label.
	Read Manual	Consult Primary Console Operating Manual before operating the device.	On the serial number label.
CE 0123	CE Mark with Notified Body ID	CE (Conformity European) Mark with Notified Body designation	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 Mag Monitor.

Audible and visual alarm/alert conditions warn the operator to conditions that may interrupt patient support or damage the Blood Pump or the Primary 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 Primary Console's display as long as the alarm/alert condition exists.

In the event of an alert or alarm condition (see **Table 14** or **Table 16** for the full list of alarms and alerts) visual message and audio indicators activate. The Primary Console continues Blood Pump operation during an alert or **MOTOR ALARM** condition, and stops the Blood 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/alarm condition cannot be resolved the user should refer to Table 14 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:

1) If the alert condition is unresolved and the alert/alarm condition persists.
2) 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.
3) 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:

1) 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.
2) 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.
3) 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:

1) **BATTERY MAINTENANCE REQUIRED –** this alert only requires one acknowledgment. The visual alert continues to be displayed but the audible alert will not reactivate.
2) **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.
3) **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.
4) **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 Blood Pump. Alerts are associated with conditions in which the Blood 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 Blood 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 Blood Pump, extracorporeal circuit, and Cannulae.

WARNING

DO NOT restart the Blood 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 Thoratec representative.

WARNING

A Blood Pump stoppage will create a reverse flow shunt through the Blood Pump, as well as limit the body's ability to maintain adequate arterial pressure. If the Blood Pump is off or stopped, clamping the return tubing from the Blood 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 analog and digital interfaces must be certified to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the systems standard IEC 60601-1-1. Any person, who connects additional equipment to the signal input or signal output interface is creating a medical system, and is therefore, responsible for ensuring that the system complies with the system standard IEC 60601-1-1. If in doubt, consult the Thoratec service department prior to connecting any accessory to the analog and digital interfaces.

6.7 Digital Display Information

The Primary Console's digital display provides messages and information on system settings, Console configuration and alarms/alerts. Table 8 shows system alarm and alerts in the order of priority:

Table 8: Front Panel Display – Alarm/Alert Messages in Order of Priority

ALARMS	ALERTS
POWER ON TEST FAIL	SET PUMP SPEED NOT REACHED
SYSTEM FAULT	BATTERY MODULE FAIL
MOTOR STOPPED	BATTERY BELOW MINIMUM
MOTOR DISCONNECTED	FLOW PROBE DISCONNECTED
PUMP NOT INSERTED	SYSTEM ALERT
MOTOR ALARM	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

6.8 Power Assembly

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

6.9 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 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical

systems (reference IEC 60601-1-1 or clause 16 of the 3rd Ed. of IEC 60601-1, respectively). 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

This section describes how to unpack the Primary Console, connect the power cord, the Motor, and the Flow Probe and how to power up and operate the Primary Console. The Primary Console carries the following Factory[3] and Power-Up[4] defaults for each specified operating parameter:

Table 9: Primary Console Factory & Power-Up Default Values

OPERATING PARAMETER	FACTORY[1] DEFAULT	POWER-UP[2] DEFAULT
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[5] LPM	-2.0 – 10.0 LPM
Pressure Subsystem	Inactive	Last state[6]
Pressure limits	-30mmHg / +200mmHg	-30mmHg / +200mmHg
Language	English	Last state[3]
RPM Increment	100	Last state[3]
Flow Limit Sensitivity	Normal	Last state[3]
Recorder Speed	2 minutes	2 minutes

7.1 Unpacking

1. Remove the Primary Console, AC Power Cord, and Flow Probe from the Console's shipping container.
2. Remove the Motor from its shipping box.
3. Remove the Mag Monitor from its shipping box
4. Retain all packaging materials in the event that the Primary Console or any other component needs to be returned to Thoratec for repair or maintenance.

WARNING

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

[3] Factory Default: pre-selected operating parameter of a Primary Console as it is shipped from Thoratec.
[4] Power-Up Default: Primary 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.
[5] Note: If the probe detects forward flow of more than 10 LPM then it will display as "^^.^^ LPM".
[6] Last state: the value/state carried from the last operational use of the Primary 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. Prevent cable loops on the floor and avoid cables hanging over other equipment or furniture.

WARNING

Make sure that tubing and cannulae between the system and patient are secured properly.

7.2 Mag Monitor Mounting

If the Console is intended to be used with the Monitor it is crucial that the Monitor is securely fixed to a solid object. This can be achieved with the monitor arm provided by Thoratec 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.

7.2.1 Steps required to set-up the Monitor Arm:

1. Mount the clamp on the adapter plate: **Figure 18** 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 17**. 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 17**. Make sure that the oval end of the adapter plate is on the screw side of the clamp in the latter case.

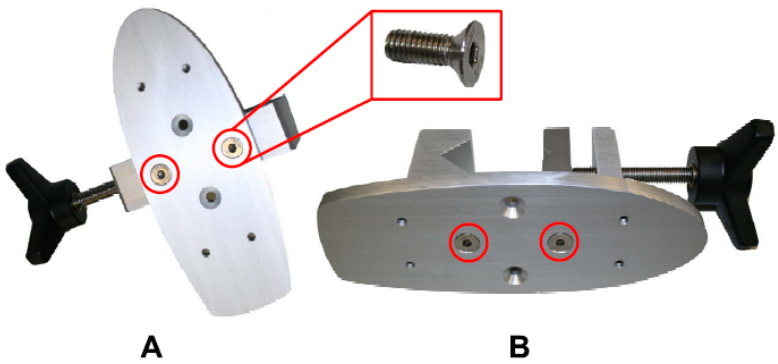


Figure 17: Clamp mounting possibilities on adapter plate

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 18** shows the assembly for vertical mounting.

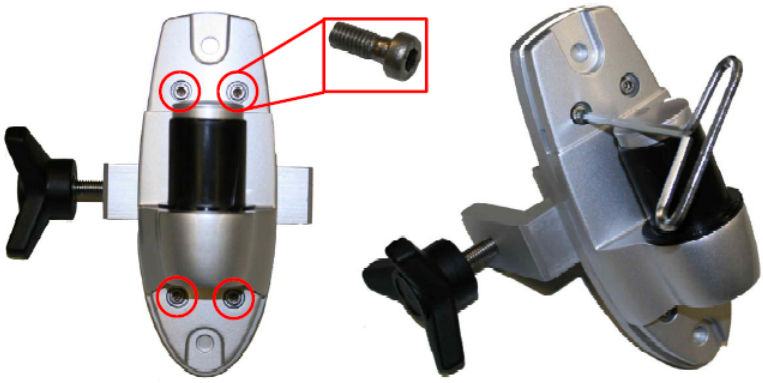


Figure 18: Mounting of the monitor arm root joint plate on the adaptor plate

3. 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 19**. Make sure the screws are sufficiently tightened.

Figure 19: Mounting of the Monitor on the monitor arm

4. Mount the 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 20**.

Figure 20: 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 packaging. **Figure 21** shows the complete Monitor assembly clamped to a table.

Figure 21: Completely assembled monitor arm with Monitor

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 22: Do not mount the monitor arm on a horizontal pole

7.3 Powering Up

1. Insert the Power Cord into the AC Power Connection located on the back of the Primary 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 Primary 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.

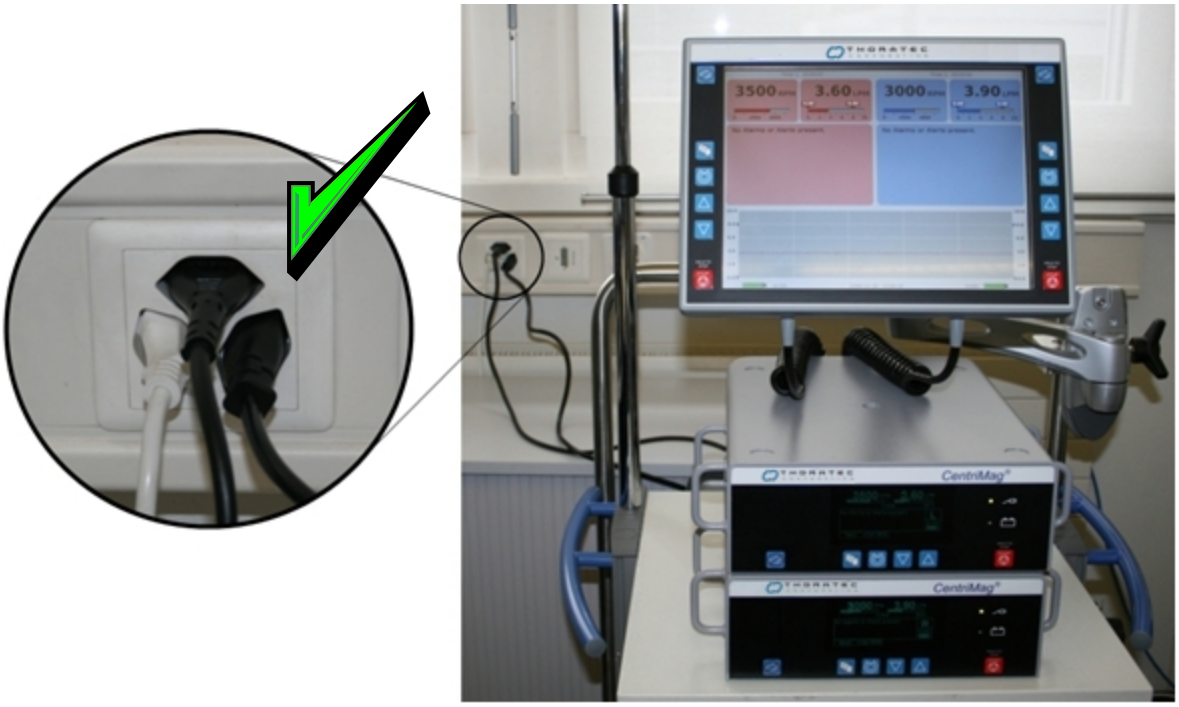


Figure 23: BVAD Configuration - both Console power cords must be inserted directly into the AC wall outlet.

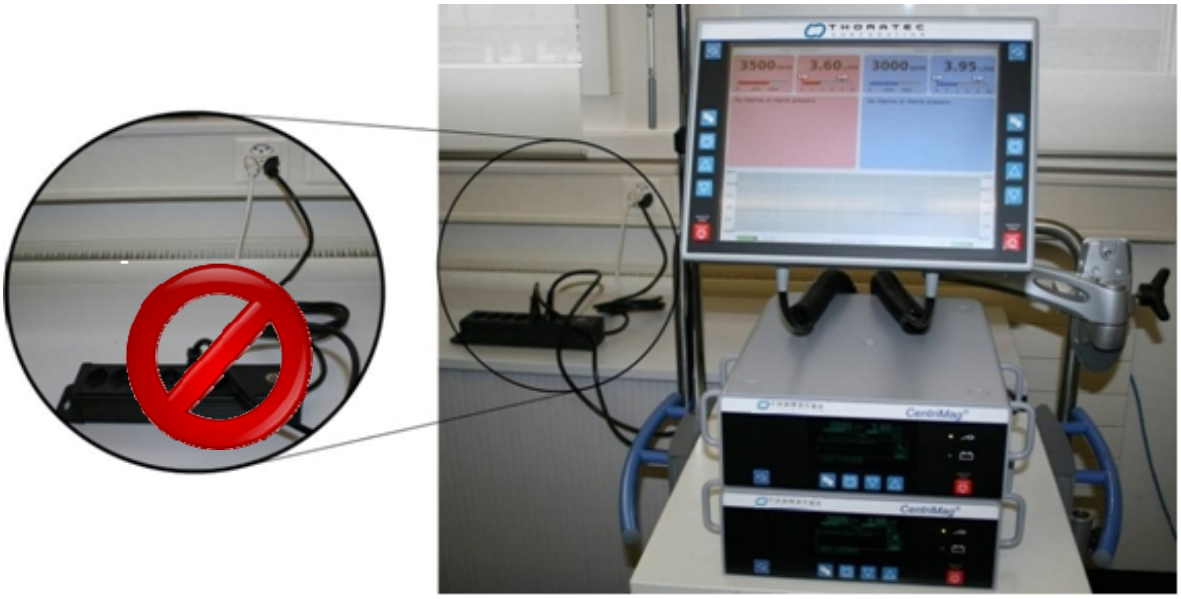


Figure 24: BVAD Configuration - both Console power cords must be inserted directly into the AC wall outlet – DO NOT connect via a power strip.

3. Insert the LEMO connector on the Motor cable into the Motor connection on the rear of the Primary 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 Primary 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 Primary Console.

WARNING

Use of flow probes from sources other than Thoratec is not recommended. Flow probes that are not obtained from Thoratec 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 "vv.vv" on the display.

5. Check the Power Status on the Primary Console front panel to verify that the green AC power ON indicator is illuminated. The Primary 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 Mag Monitor if the Console is to be used with the Monitor.

7. Turn ON the power to the Primary Console using the power switch located on the back panel of the Primary Console.

7.4 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 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 PRM options will appear, and the Mag Monitor will activate (if connected).

7.5 Configuring the Console

The ability to set 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 27 outlines the basic MENU scheme which is available after the support type has been selected

When the CentriMag System is driven by the 2nd Generation Console and is connected to the Mag Monitor, the main user interface is the Mag Monitor (**Figure 25**); however, most of the selections described below are accessible through the Mag Monitor as well as on the Primary Console's user interface (**Figure 26**).

Figure 25: Mag Monitor – Front Panel

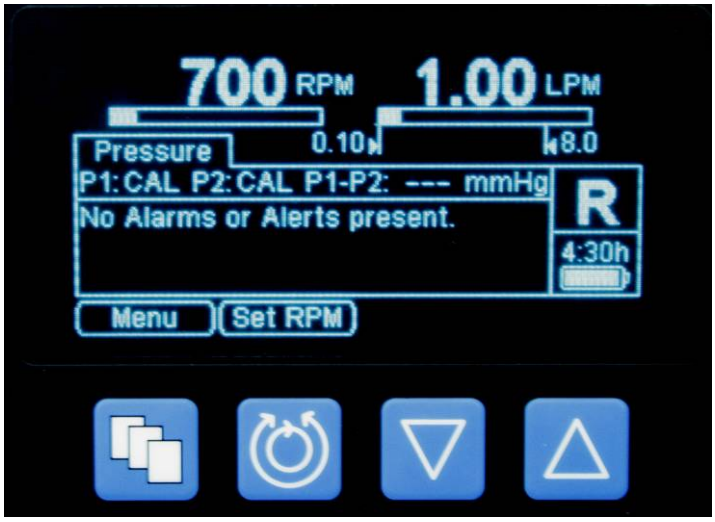


Figure 26: Primary Console – Close up of the Display

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**
  - **MAXIMIUM PRESSURE (P2) ALERT**
- **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 Primary 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.

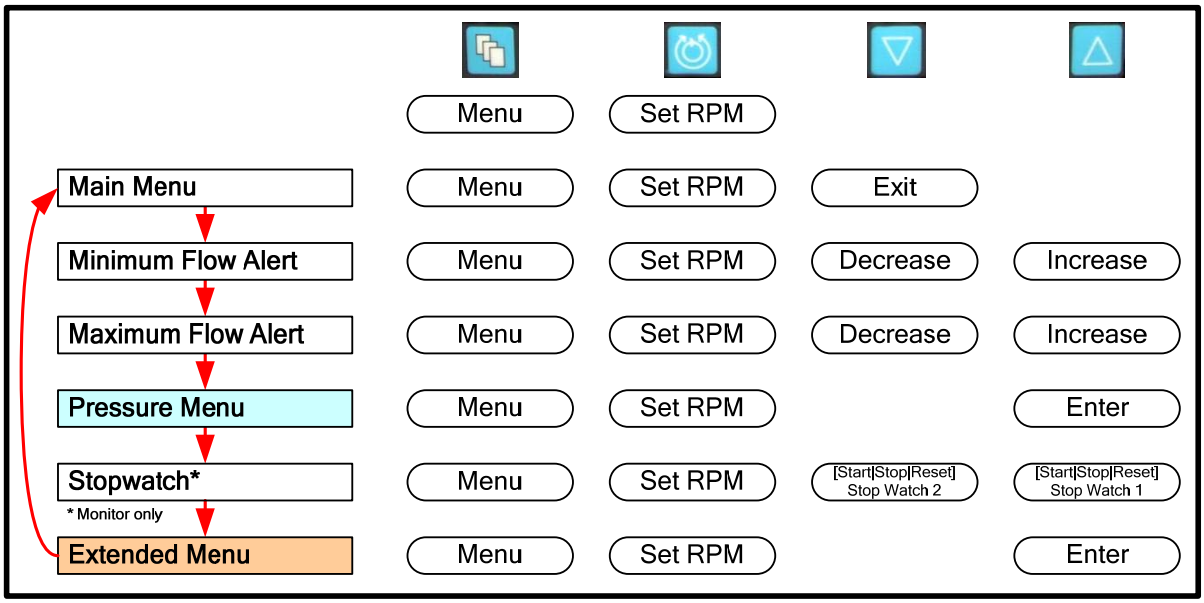


Figure 27: Mag Monitor's Top level MENU Structure

7.6 Console BIOS

Note: The system cannot be used while the console BIOS is being accessed. If a Mag Monitor is attached it will display only the Thoratec logo while the BIOS is being accessed.

The Console BIOS contains engineering information about the console. For additional information on the Mag Monitor Management, see **Section 7.23**.

To access the Console BIOS, hold the **MENU** button on the Primary Console during power on self test (not on the Mag 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 Primary Console.

7.7 Setting the Console Max Flow Alert

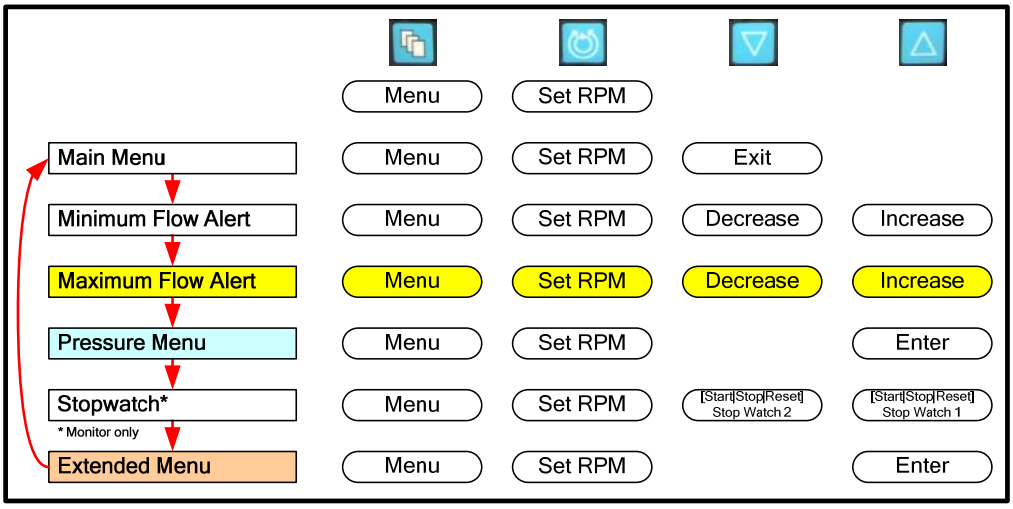


Figure 28: Mag Monitor MENU Structure
Setting Maximum Flow Alert

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”

7.8 Setting the Console Min Flow Alert

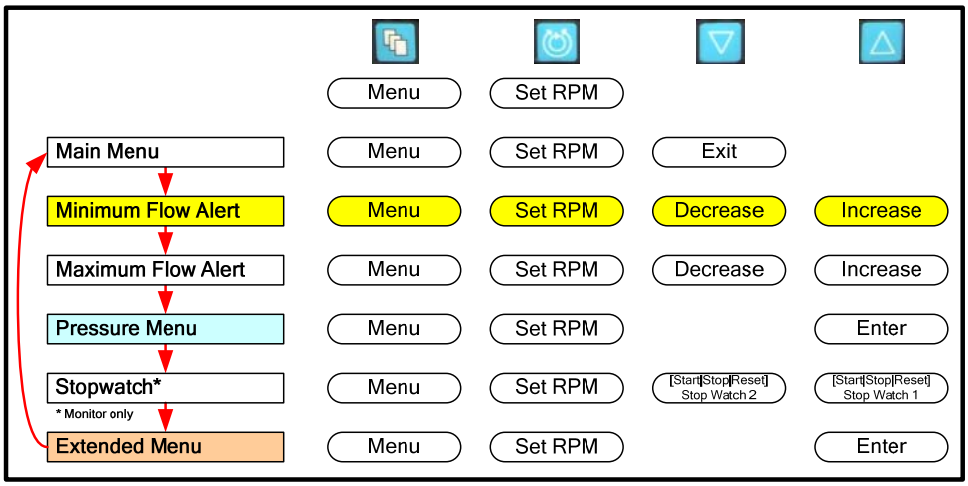


Figure 29: Mag Monitor MENU Structure
Setting Minimum Flow Alert

The **MINIMUM FLOW ALERT** should not be set until after the Blood Pump is started. If the value of the **MINIMUM FLOW ALERT** is set before the Blood 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 should 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.

7.9 Entering the Pressure Menu

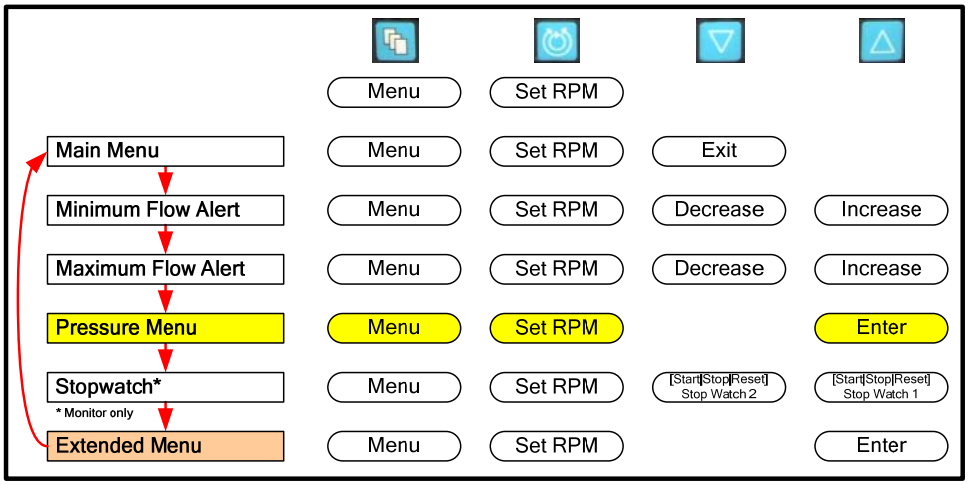


Figure 30: Mag Monitor MENU Structure
Entering Pressure Menu

If the pressure subsystem is active, the pressure menu is can be accessed by pressing **ENTER**, while the **PRESSURE MENU** option is highlighted. Activation and deactivation of the pressure subsystem is explained in **Section 7.12**.

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

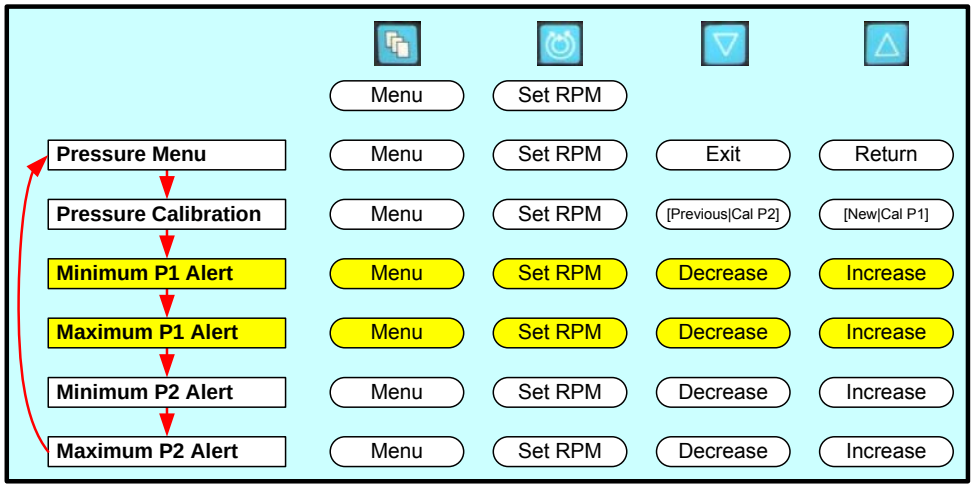


Figure 31: Mag Monitor MENU Structure
Setting the Max or Min Pressure Alert Settings for the P1 Transducer

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.

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

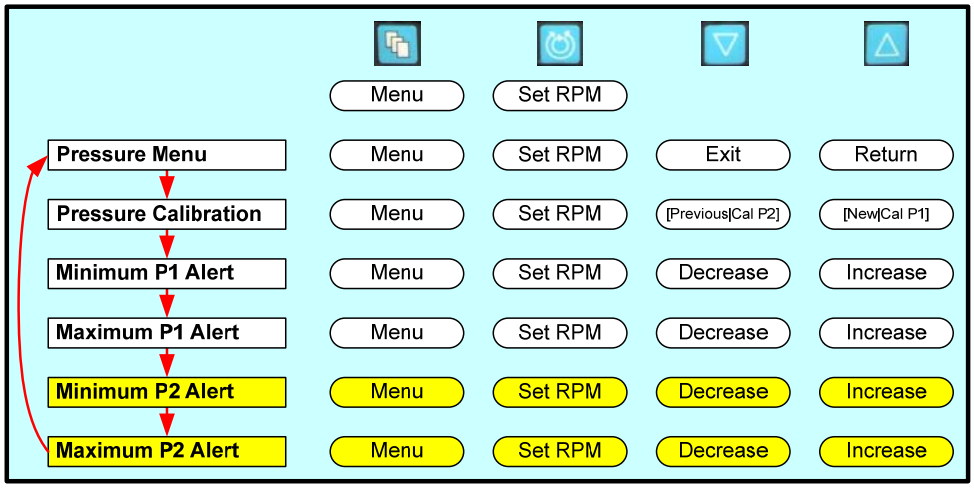


Figure 32: Mag Monitor MENU Structure
Setting the Max or Min Pressure Alert Settings for the P2 Transducer

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.

7.12 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 Primary 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 included recalibrating, or disconnecting and reconnecting the connections.

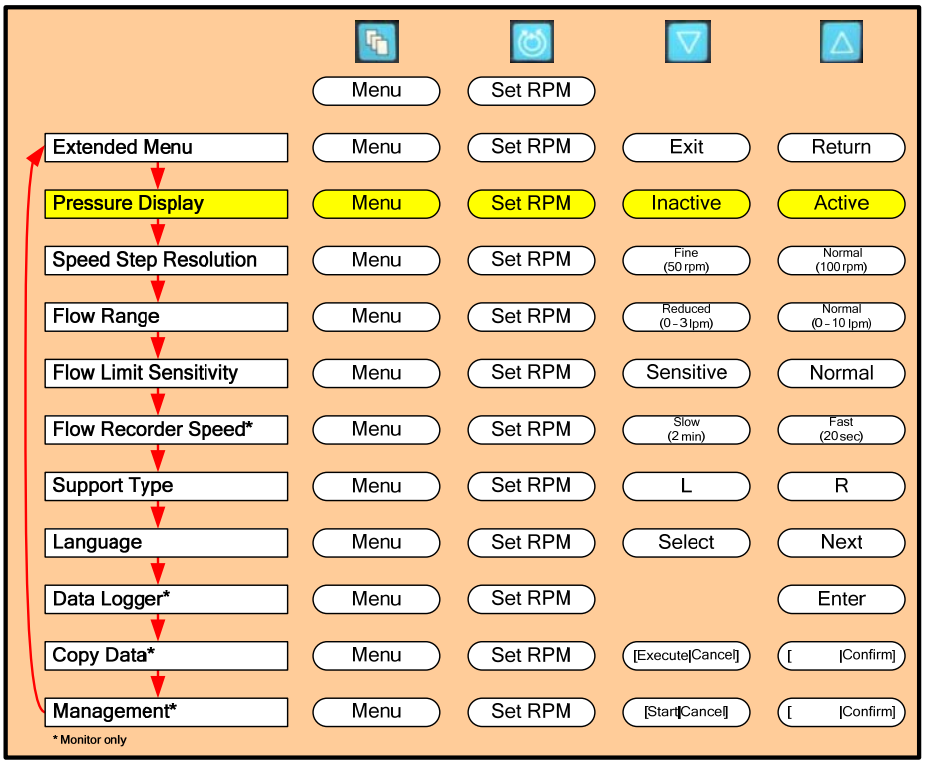


Figure 33: Mag Monitor MENU Structure
Activating the Pressure Subsystem

2. To activate the pressure subsystem from the Mag 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**.
3. 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.

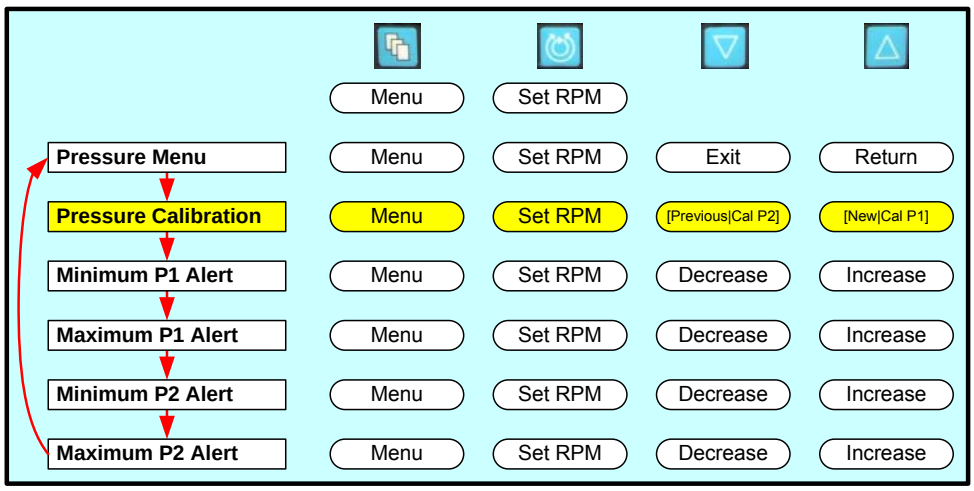


Figure 34: Mag Monitor MENU Structure
Performing Pressure Calibration

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 Primary 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 (-) 100 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 -100 mmHg respectively "^^^^" for values above 900 mmHg. If one channel is invalid then difference will be displayed as dashes: "----".

A. Assuming the pressure monitoring system has been activated and calibrated, a measured value can range from (-)100 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.

B. 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.

C. The pressure monitoring system is now ready for use.

7.13 Stopwatches

The Stopwatch function is only available via the Monitor.

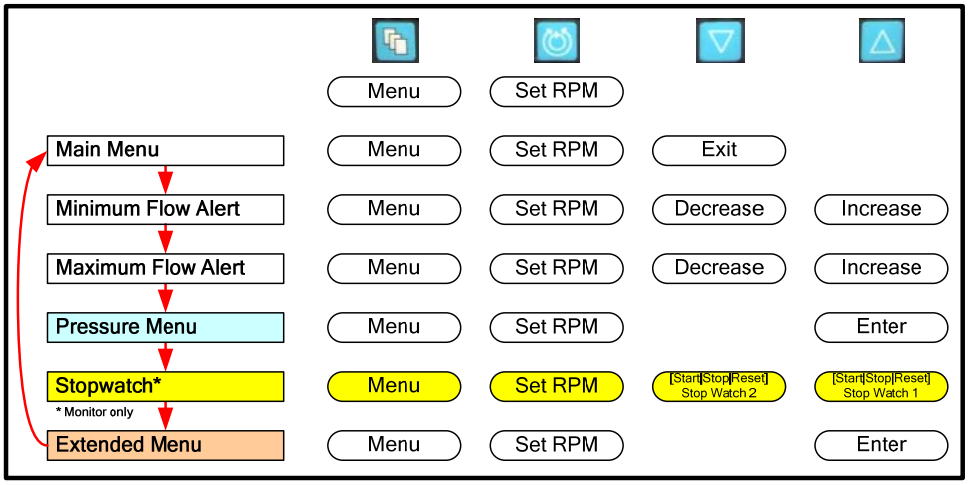


Figure 35: Mag Monitor MENU Structure Stopwatches

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.

7.14 Flow range

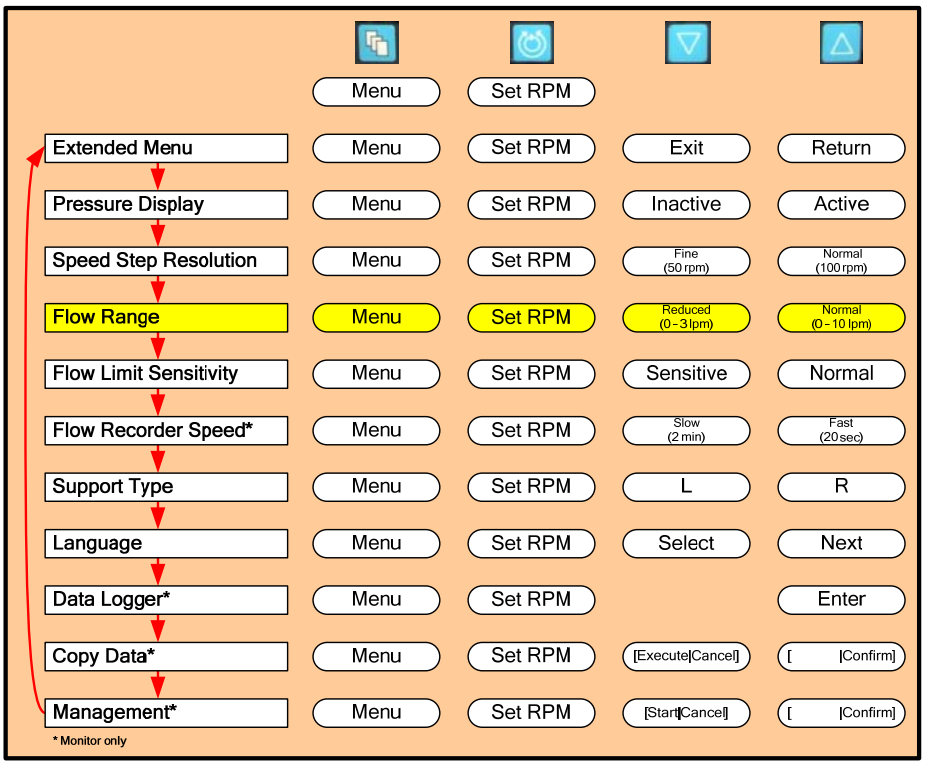


Figure 36: Mag Monitor MENU Structure
Flow Range

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.

7.15 Changing the flow recorder speed

The flow recorder function is only available via the Monitor.

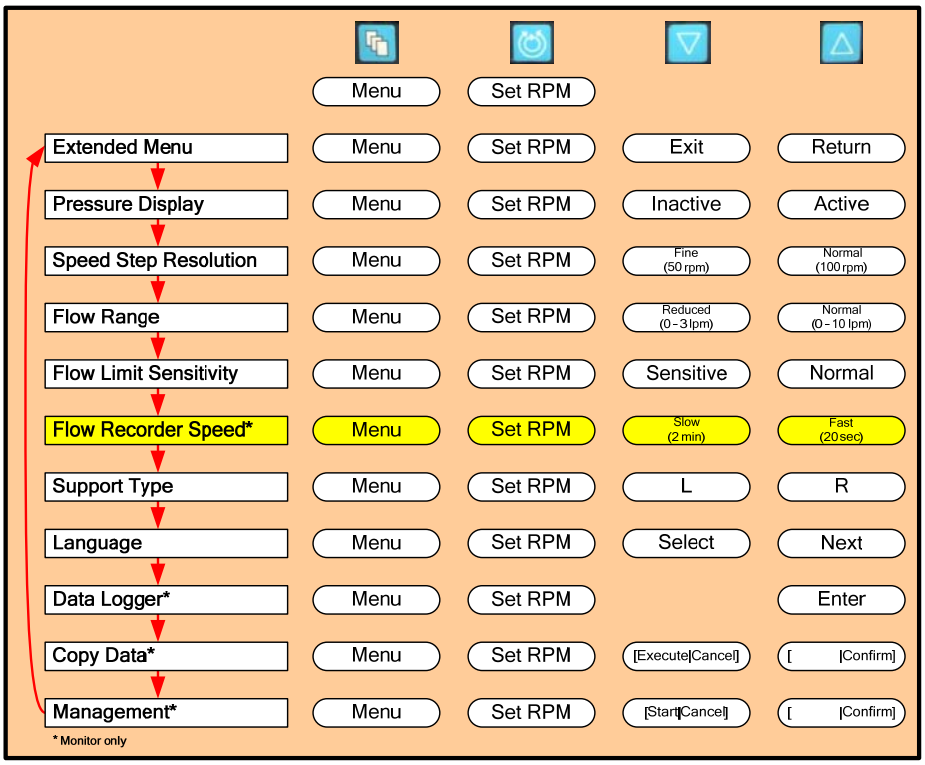


Figure 37: Mag Monitor MENU Structure
Changing the flow recorder speed

The system allows the user to alter the speed of the moving flow graph displayed on the bottom of the Mag 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.

7.16 Setting the Console Speed Step Resolution

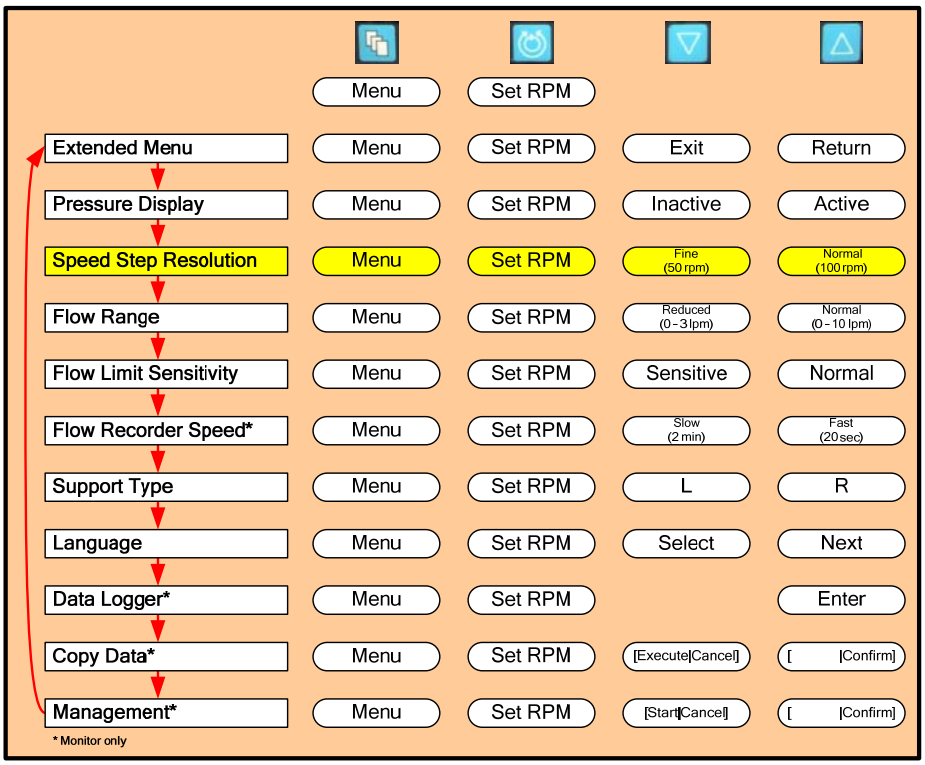


Figure 38: Mag Monitor MENU Structure
Speed Step Resolution

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.

7.17 Selecting Displayed Language

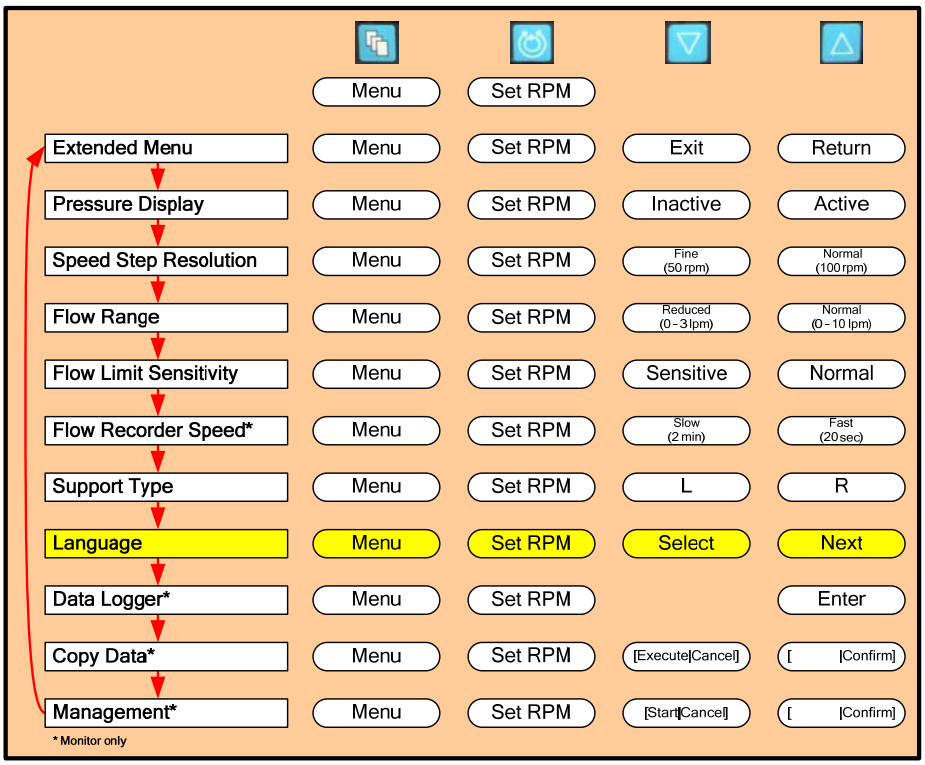


Figure 39: Mag Monitor MENU Structure
Language Selection

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.

7.18 Setting the Console flow limit sensitivity

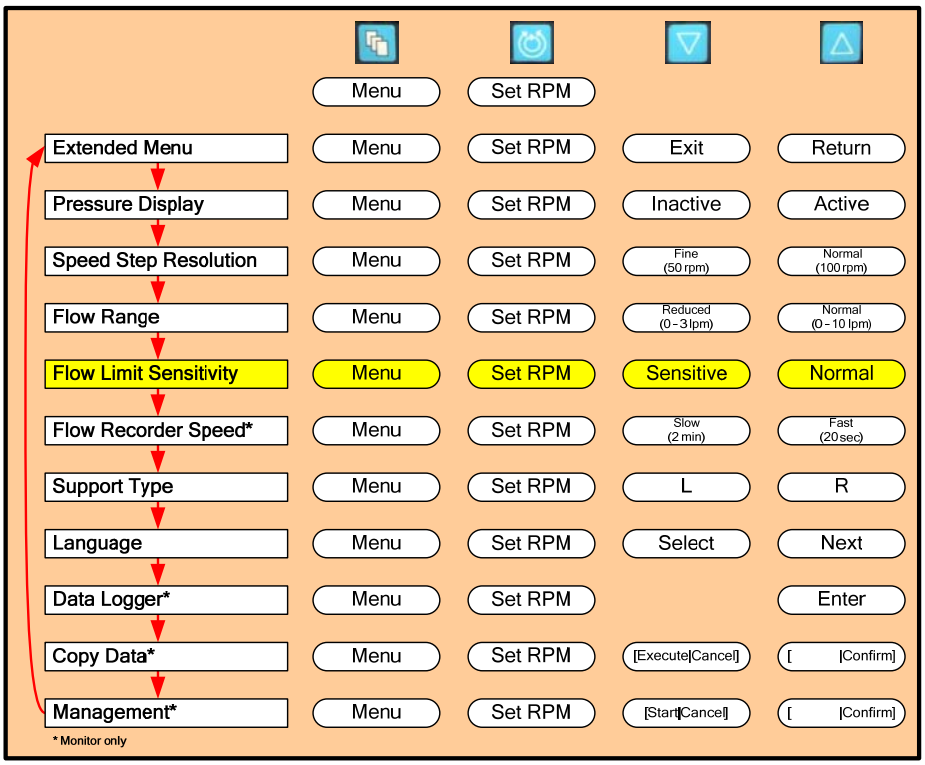


Figure 40: Mag Monitor MENU Structure
Flow Limit Sensitivity

A sudden decrease in flow below the **MINIMUM FLOW ALERT** setting could indicate a potentially hazardous condition. The Primary 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.

7.19 Setting the Application Mode

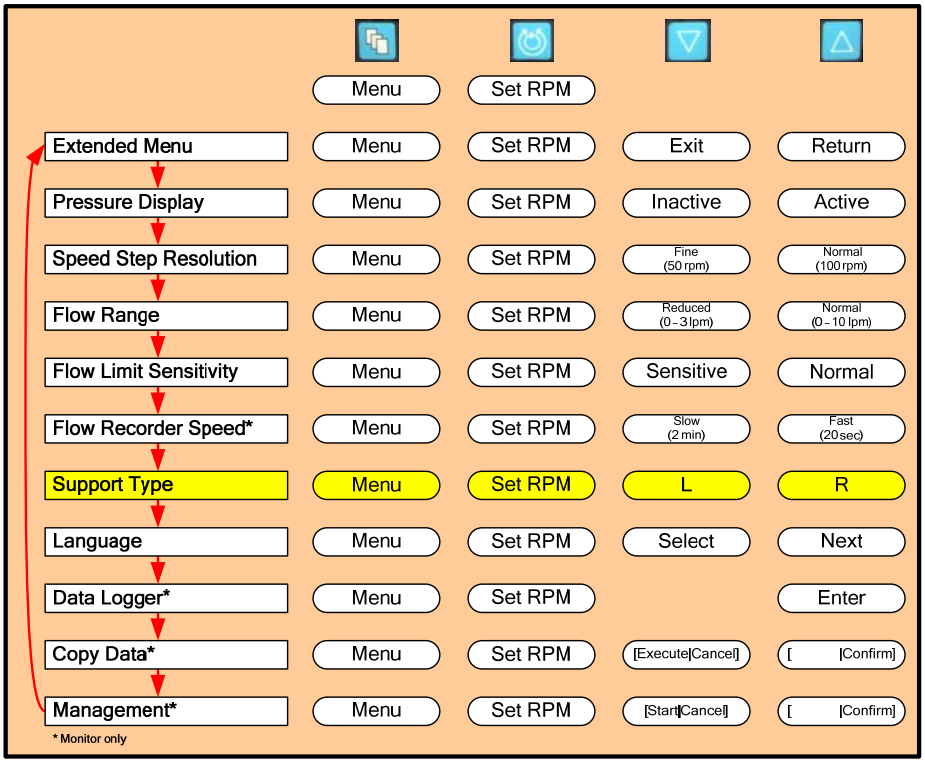


Figure 41: Mag Monitor MENU Structure
Setting Application Mode

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 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.

7.20 The System Data Logger

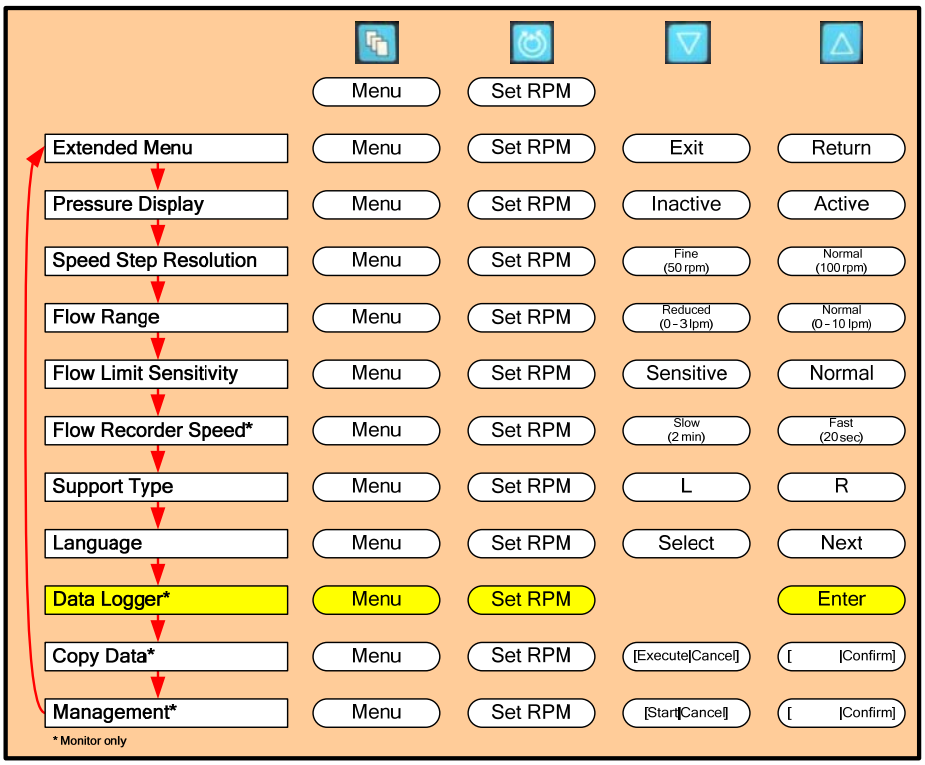


Figure 42: Mag Monitor MENU Structure
System Data Logger

The Primary 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 primary console can record approximately 16 hours of data. When a primary console is connected to the Mag Monitor it uploads the data stored in the Console to the Mag Monitor. The Mag 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 Mag Monitor is not connected to a Primary console within 16 hours, the oldest recorded data on the Primary console will be overwritten with new data as it is generated. When the Primary console is used with the Mag Monitor, the data are recorded directly into the monitor.

The Mag Monitor must be attached to the Primary 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.

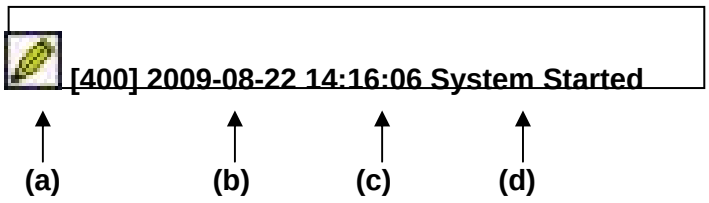


Figure 43: Mag Monitor – Sample Data Logger Event

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 10** below.

Table 10: Mag Monitor – 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 14 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 14 for a list of alerts.**
Alert acknowledged		**This event is generated when the "Alarm Acknowledge" button is pressed and an alert is still active.**
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 7.23** on the Monitor Management Software.

c) Date stamp

The system records the date the event took place. For information on setting the system clock see section 7.23 on the monitor Management Software.

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 Mag Monitor to move up and down through the list of logged events and the **UP ARROW** and **DOWN ARROW** on the left of the Mag 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.

7.21 Copy Logger Data to a USB Memory Stick

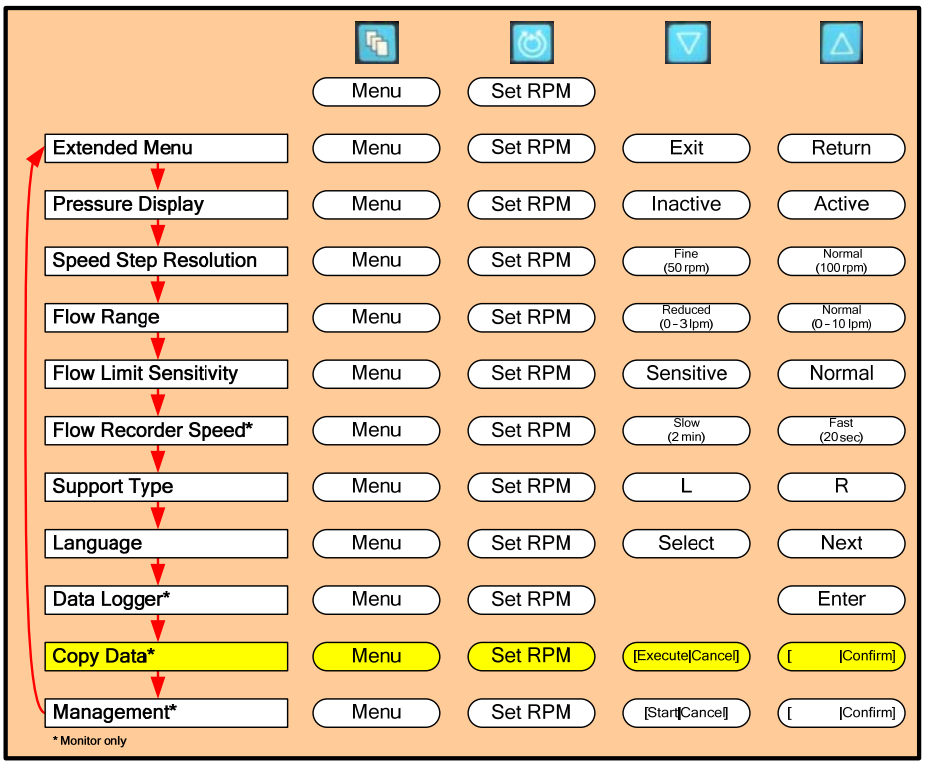


Figure 44: Mag Monitor MENU Structure
Copy Data

The logger data may be copied to a USB Memory Stick. A new session is started every time the Primary 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. Now the USB Stick can 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 folder "**log**".

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).

7.22 Mag Monitor Description and Connections

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

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

CAUTION

The Mag Monitor is only powered when one or both of the Primary Consoles is/are connected to AC Power. Refer to the individual RVAD or LVAD Console display when operating on Battery Power, when the Monitor is not in use, or and when the Monitor is not powered on.

7.23 Accessing the Mag Monitor Management Application

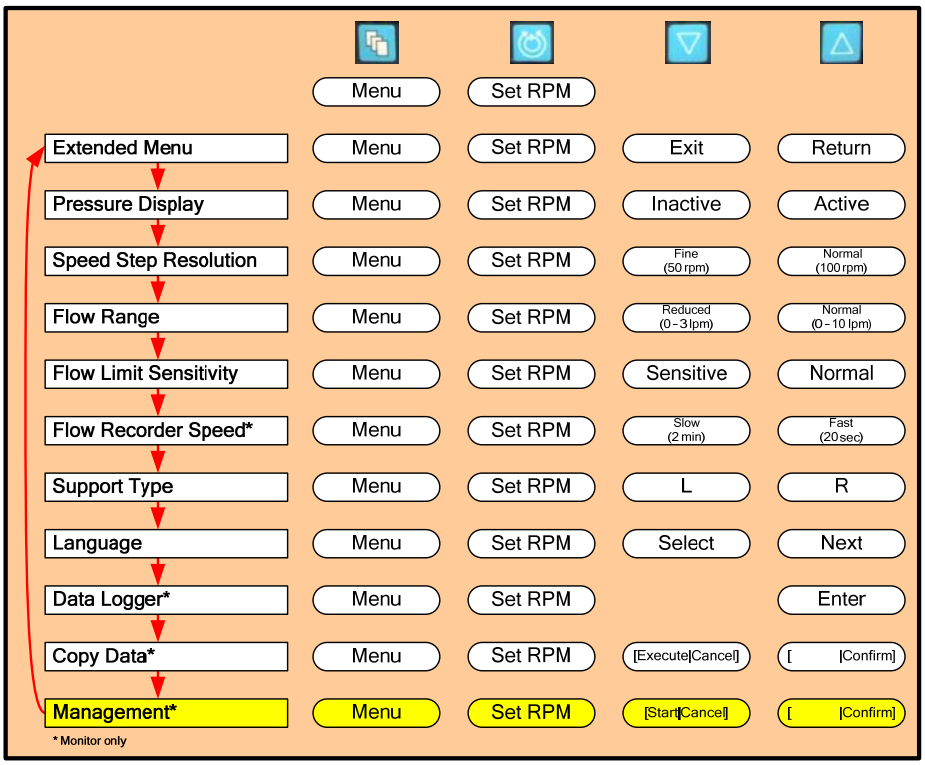


Figure 45: Mag Monitor MENU Structure
Starting Management Application

The Mag Monitor has a Management Application which allows users to change options, including time and date, as well as getting information about the software version installed on the Mag 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 Mag Monitor, and not the console.

One other option to access the Management Application is to hold down the **MENU** key while the Mag 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 **MENU** key (selection) and **UP** (increase) or **DOWN** (decrease) key.

2) Reboot:

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

On “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) Ethernet Settings (Used only for Debug Mode “On”)
3) Application Selection Setting: Always “CentriMag”
4) Debug Mode Setting: Always “Off”
5) Data Logger View Mode Setting: Always “Normal”
6) Application Software Version

7.24 Blood Pump Set-up

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

WARNING

Always fully unscrew the Pump retaining screw built into the Motor before inserting and locking the Blood 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 Blood 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 Blood Pump, reinsert the Pump, tighten the retaining screw, turn the Primary Console power OFF and ON, ensure no alerts/alarms are displayed, and set the Primary Console to initiate pumping.

8 OPERATING

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

Prior to starting the Blood 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 cannulae and prior to turning the Pump ON.

8.1 Operation of the Blood Pump

WARNING

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

CAUTION

The Primary Console, Monitor, 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 Blood Pump

To start the Blood Pump, perform the following steps:

1. Place the Blood Pump into the Motor receptacle and secure in place per the Instructions for Use supplied with the Blood Pump.
2. Start the Blood Pump by first depressing the **SET RPM** keypad. **SET PUMP SPEED = 0000 RPM** will be displayed. Depress the **INCREASE** keypad, increase 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 cannula.
3. Slowly increase the RPM until the flow rate is at the desired level.

The **RPM** and **LPM** will be displayed on the Primary 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 7.8.**

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 another Primary Console and Motor or switch to a CentriMag Back-Up Console and Motor if any of the buttons malfunction, if the display goes blank and/or the Primary Console ceases to operate.

WARNING

Switch to another Mag 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 Blood Pump Speed

Blood 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. Flow at a given RPM is dependent upon position of the drainage and return cannulae, intravascular blood volume, patient's hemodynamic status, cannulae, and resistance of the extracorporeal blood circuit components.

8.1.3 Manually Stopping the Blood Pump

Depressing and holding the **STOP** keypad on the Primary Console's front panel for five seconds manually stops the Blood Pump if the Blood 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 Primary Console's front panel for five seconds.

8.1.4 Restarting the Blood Pump

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

WARNING

DO NOT attempt to restart the Blood 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 Blood Pump, circuit and cannulae.

WARNING

DO NOT restart the Blood 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 Thoratec representative.

WARNING

A Blood 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

Don't clamp, partially clamp or restrict the line during normal pump activity. Clamping the line may cause increased risk of thromboembolic events.

WARNING

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

To restart the Blood Pump, perform the following steps:

1. Ensure that the Blood Pump is securely located in the Motor per the Instructions for Use supplied with the Blood Pump.
2. Ensure that any alarm condition has been corrected.
3. Start the Blood Pump by first depressing the **SET RPM** keypad. **SET PUMP SPEED = 0000 RPM** will be displayed. Depress the **INCREASE** keypad, increase 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 cannula.

4. Slowly increase the RPM until the flow rate is at the desired level.

The **RPM** and **LPM** will be displayed on the Primary 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 Primary 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 Blood 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**, the Primary 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**, the Primary Console stops the Blood Pump. The **Table 11** below illustrates the fundamental strategy:

Table 11: Primary 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 CentriMag Back-Up Console/Motor

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. There are three high priority alarms which may not be muted (**Table 12**). For all alarms 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 will be automatically removed providing: 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 14 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 Primary Console and Mag 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 8** for a listing of alarm and alert messages in their order of priority.

As shown in **Table 12**, the Primary Console features 6 alarms and 21 alerts:

Table 12: Primary Console Alarms & Alerts In Order Of Priority

ID	Alarm/ Alert	Description	Ability to Silence Audio (Yes/No) (Silence Interval[7])
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)

[7] When applicable, audio tone will reactivate if the condition persists during time lapse.

Table 12: Primary Console Alarms & Alerts In Order Of Priority			
ID	**Alarm/ Alert**	**Description**	**Ability to Silence Audio (Yes/No) (Silence Interval[7])**
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 14**. 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 14**, for alarm condition listing), the Primary Console stop the Blood Pump. The Primary 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 Blood Pump to back-up equipment. Always unclamp the tubing prior to resumption of pumping.

WARNING

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

WARNING

DO NOT attempt to restart the Blood 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 Blood Pump, extracorporeal circuit, and cannulae.

WARNING

DO NOT restart the Blood 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 Thoratec representative.

8.3.1 Alarm Conditions Requiring Powering Off Before Restarting

If during set-up a Console produces an alarm condition listed in **Table 13** turn the power switch to OFF, check all cable connections, and turn the power switch back to ON. If the alarm re-occurs, use another Console and Motor. Do not use the suspect Console and Motor either as a primary or a backup unit.

In the event of a Console alarm when a blood pump has been running, consult **Table 14** for the appropriate action.

Table 13: 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 12** or **Table 14** for complete list of all alert and alarm conditions), the Primary 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 Blood 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 **BATTERY BELOW MINIMUM**, while running on battery. This alert cannot be silenced until the console is plugged into AC power. The **BATTERY BELOW MINIMUM** alarm 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 providing: 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 12** or **Table 14** 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 text message appears on the display of the Primary Console. Most alarms and alerts require some action on the users' part to correct the cause. The following table can be used to determine how to correct an alarm or alert condition.

Table 14: Primary Console Alarms & Alerts

ID	Alarm/ Alert	Text Message	System Status & Operator Response
S1	Alarm	POWER ON TEST FAIL	The blood pump will not start. An audible alarm will sound, which cannot be muted. Switch the console OFF and ON again. If the alarm re-appears, switch to the backup Console and Motor, record the alarm message and contact your local Thoratec representative.

Table 14: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
S2	Alarm	SYSTEM FAULT (Run-Time System Failure)	The blood pump will stop. An audible alarm will sound, which cannot be muted. Clamp the return tubing and switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec representative.
M1	Alarm	MOTOR STOPPED	The blood pump will stop. An audible alarm will sound, which can be muted for 60 seconds. Clamp the return tubing and switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec representative.
M2	Alarm	MOTOR DISCONNECTED	The blood pump will stop. An audible alarm will sound, which can be muted for 60 seconds. During setup of the system: Press the alarm acknowledge button and check that the motor connector is fully inserted into the back of the console. During support: 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 and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec representative.
M3	Alarm	PUMP NOT INSERTED	System will not start. An audible alarm will sound, which can be muted for 60 seconds. Press the alarm acknowledge button. Insert or re-insert the pump and secure it with the locking screw. If the alarm repeats, switch to backup Console and Motor according the procedure described in Section 10.1.
M4	Alarm	MOTOR ALARM	An audible alarm will sound and the system will continue to operate. 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 and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec representative.
M5	Alert	SET PUMP SPEED NOT REACHED	Check the pump flow: If pump flow is satisfactory; reduce set speed while insuring that flow is

Table 14: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
			maintained. Press the alarm acknowledge button. If the alert repeats, clamp the return tubing, stop the pump and switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alert message and contact your Thoratec representative. If the pump flow is not satisfactory, clamp the return tubing and switch to the backup Console and Motor according to the procedure described in Section 10.1. Resume support. Record the alert message and contact Thoratec representative.
B1	Alert	BATTERY MODULE FAIL	The console battery will not function. An audible alarm will sound. Switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec representative.
B2	Alert	BATTERY BELOW MINIMUM	The blood pump will stop after a very short time. Plug the console into AC power outlet to charge battery. If no AC outlet is available, switch to CentriMag Back-Up Console and Motor according to the procedure described in Section 10.1. Resume support.
F1	Alert	FLOW PROBE DISCONNECTED	Check the flow probed connection on back of console. If necessary, reconnect the flow probe connector to the back of the console. Press the alarm acknowledge button. Switch to the back-up 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 and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec 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 back-up flow probe, if the alert message repeats. If problem still persists after switching to the back-up flow probe, stop the pump and switch to a back-up Primary Console. Follow the instructions described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec 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

Table 14: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
			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 CentriMag Back-Up Console and Motor. Switch to the backup system according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec 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 CentriMag Back-Up Console and Motor 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.

Table 14: Primary Console Alarms & Alerts			
ID	Alarm/ Alert	Text Message	System Status & Operator Response
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 CentriMag Back-Up Console and Motor 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 Blood 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 Primary 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 Primary Console for approximately 120 minutes at 5.5 LPM and 3,500 RPM when used with the CentriMag Blood Pump and approximately 180 minutes at 1.0 LPM and 3,000 RPM when used with the PediMag Blood 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 a charge. If the system is run on battery, the monitor will be switched off in order to increase the battery run time.

WARNING

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

If the Primary Console is operating on batteries and a BATTERY BELOW MINIMUM alarm message is displayed, the Blood 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 pump may be switched to the backup Console and Motor to resume pumping operation.

CAUTION

Always operate the system at the lowest acceptable clinical flows when operating on 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 Primary 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 Primary 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 <u>not</u> attached to AC power, regardless of whether the Console is ON or OFF, the 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 in to 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 Patient Transport

As shown in **Figure 46** the Primary Console is designed to function in combination with the CentriMag Back-Up Console. Both units have been designed to be transportable. **The Primary Console should always be the default Console used to support and transport the patient**. The CentriMag Back-Up Console is only provided to function as an emergency back-up unit should the Primary Console malfunction. The CentriMag Back-Up Console should be mounted beneath the Primary Console. The Primary and CentriMag Back-Up Consoles may be connected to a portable stand (**Figure 46**), or placed on a Cart (**Figure 14**) so that the units can be moved together during transport.

WARNING

The CentriMag Back-Up Console and Motor are not designed to replace the Primary Console and Motor but to serve as an emergency back-up unit for temporary support if the Primary Console and Motor have malfunctioned or are suspected to have malfunctioned.

The patient must be returned to the Primary Console and Motor as soon as the malfunction has been resolved or a replacement Primary Console and Motor become available.

Figure 46: Primary & CentriMag Back-Up Consoles Mounted on Portable Stand Illustrating the Univentricular Support Configuration

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.

8.5.1 Transport Vehicle Qualification

1. Planning adequate space is crucial. Review physical hardware specifications provided in Appendix II – Primary Console Technical Specification.

2. Satisfactory operation should be expected from a nominal 120 Vac. 60 Hz sine wave source with at least 500 watt capacity or from a 120 Vac. 60 Hz quasi-sine wave source. A square-wave source should not be used. The Primary and, if necessary, the CentriMag Back-Up Console can be operated on its internal battery for short periods of time.

8.5.2 Console Considerations

1) Ensure that the Primary Console's internal batteries are fully charged prior to transport.
2) Ensure that a CentriMag Back-Up Console with extra sets of Battery Modules or a 2nd Primary Console with a fully charged battery is available for back-up support.
3) The CentriMag Back-Up Console or a 2nd Primary Console should be fully assembled (power cord, Back-Up Motor, Flow Probe, etc.), tested, and transported with the patient for emergency backup availability.
4) 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.
5) Position the Primary Console in a location where the display is visible.
6) A Primary Console requires up to 170 watts of power for each console. Ensure that the transport vehicle is able to provide the necessary power for all of the primary and backup equipment.
7) Unplug the Primary Console's power cord prior to transport vehicle shutdown and confirm operation on battery power.
8) Monitor battery runtime. The Primary Console, when operating the CentriMag Blood Pump, has an approximate battery runtime of 120 minutes at 5.5 LPM and 3,500 RPM and approximate 180 minutes at 1.0 LPM and 3,000 RPM when used with the PediMag Blood Pump. Much, if not all, of this runtime can be consumed during transport. A CentriMag Back-Up Console and Motor must be available during transport.

   NOTE: To be available for emergency use, the CentriMag Back-Up Console and Motor must be in close proximity to the Blood Pump and the Primary Console at all times.
9) Fasten the Primary Console to the transport vehicle with appropriate straps or fixture to prevent movement.

8.5.3 Examples of Additional Equipment to Consider

1) Power strips for extra outlets (for use with equipment other than the system).
2) Portable vital signs monitor, ventilator, and intra-aortic balloon pump console.
3) Oxygen tank(s), if applicable.
4) Straps to secure Primary Console.
5) Supplies (sterile Blood Pump, tubing, prime solution, etc.) and instruments (sterile tubing clamps and scissors) necessary to replace a Blood Pump, connector, or other component of the system that may be damaged during transport.
6) Uninterruptible Power Supply (UPS). Thoratec has qualified commercially-available UPS for this purpose. This information is contained in document PL-0051,

"Operation of the System with an UPS". To obtain additional information or a copy of PL-0051 please contact your local distributor or Thoratec Technical Service.

Since the CentriMag Back-Up Console power consumption is identical to the Primary Console, the Thoratec qualified UPS are suitable as off-the-shelf power sources for the Back-Up System as well.

8.5.4 FAA Recognized and Other Standards for Transport

The CentriMag System has been successfully tested against applicable international standards for air and ground transport. The System met all applicable requirements for the following standards:

- IEC 68-2-27: Basic Environmental Testing Procedures: Shock
- IEC 68-2-6: Environmental Testing: Vibration
- RTCA/DO-160F: Environmental Conditions and Test Procedures for Airborne Equipment; Test Levels
    - Section 20.4, Conducted Susceptibility (CS) Test, **Category R**
    - Section 20.5, Radiated Susceptibility (RS) Test, **Category R**
    - Section 21.4, Conducted RF Emissions Test, **Category M**
    - Section 21.5, Radiated RF Emissions Test, **Category M**

Note: When transporting a patient on AC power in an aircraft, the CentriMag Console must be plugged into a CentriMag Power Conditioning Unit (PCU) and not directly into the airplanes power bus for the CentriMag system to meet the above standards.

8.6 Shut Down by Operator

If the CentriMag system is no longer used, then the system shut down can be executed as follows:

1) Stop the pump (see **Section 8.1.3** "Manually Stopping the Blood Pump").

2) Push the power button at the back of the Primary Console to shut down the system.

3) Store the Primary 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 Primary Console's internal battery must be fully charged prior to use. The Primary 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 and maintain the Console are provided below.

WARNING

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

9.1 Changing Fuses

CAUTION

The Primary 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 Primary Console.

To change a fuse, follow the steps below:

1. Unplug the Primary Console.

   NOTE: Fuses can be replaced while the Primary Console is operational on battery power but the Primary 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. (Consult Thoratec 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 Primary Console to AC power.

9.2 Maintenance Following Each Patient Use

WARNING

DO NOT spray bactericidal solution directly on the Primary 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 CentriMag/PediMag support, the Primary Console should be thoroughly cleaned using the following procedure:

Disconnect AC power before cleaning the exterior of the Primary Console.

Clean the exterior of the Primary Console with bactericidal solution, by spraying the solution on a cloth and wiping off the unit.

Reconnect AC power when cleaning is completed.

WARNING

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

9.3 Recommended Preventive Maintenance

The services listed in Table 15 are to be performed by qualified personnel trained by Thoratec. 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 Primary Console may cause overheating system malfunction, or trigger an alarm.

Table 15: Primary 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 Primary Console. If any damage is present return the Primary Console back to Thoratec for service.	X	X		
Verify that all labels on the Primary Console are present and legible.	X	X		
Verify that the leakage currents comply with the requirements of IEC 60601-1. Refer to **Section 6.2** for specific electrical safety requirements for the Primary 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 Thoratec-approved spare parts must be used to maintain this device.

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

To avoid shipping damage, the hardware (Primary Console, CentriMag Back-Up 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, Mag Monitor, flow probe etc.) shall 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 7.6**.

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 Primary Console is not covered, and that air is free to flow around the Primary Console to prevent overheating.

5) 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 Primary Console will then return to the BIOS, and will need to be turned OFF and ON again before it can be clinically used.

6) 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 Thoratec representative, and do not use the console.

7) If the system displays the message **BATTERY CHARGER FAIL** or **BATTERY MODULE FAIL** then do not use the system. Contact your local Thoratec representative for assistance.

8) 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.

10 EMERGENCY / TROUBLESHOOTING

This section contains instructions for operation of the Blood Pump during external defibrillation, and under circumstances where there is a need to exchange the Primary Console or Motor with a CentriMag Back-Up 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 Blood Pump from the malfunctioning Motor and Console and place the Blood Pump in the Back-Up Motor and Console to continue patient support. DO NOT exchange individual Motors or individual Consoles during patient support.

WARNING

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

10.1 Switching to Back-Up Hardware

A CentriMag Back-Up Console and Motor should be transported with the patient and immediately available for use at all times. Should the Primary Console or Motor cease to function, it will be necessary to replace the hardware by disconnecting the Blood Pump from the Primary Motor and Console and switching to a Back-Up Motor and CentriMag Back-Up Console. Switching to a CentriMag Back-Up Console and Motor is performed in accordance with the steps shown in **Figure 47**. Switch all components (Console, Motor, and cables) simultaneously and then perform troubleshooting on the non-functioning system when it is no longer being used for patient support.

The steps to switch to a CentriMag Back-Up Console and Motor set are as follows:

As shown in **Figure 47**, clamp the return tubing while lowering the RPM to zero prior to turning the Primary Console's main power switch to OFF. Unthread the Blood 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 Blood Pump. Rotate the Blood Pump body clockwise until the grooves in the Blood Pump match the Motor. Lift the Blood Pump from the receptacle. Place the Blood Pump in the back-up Motor receptacle (the Blood Pump will drop into place in one of 3 orientations). Rotate the Blood Pump **counterclockwise** until it stops, then thread the Blood Pump retaining screw to secure the Blood 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 Blood Pump **counterclockwise**, and secure by advancing the retaining screw.

If the Motor's round LEMO connector is not already connected, connect to the mating receptacle on the back-panel of the CentriMag Back-Up Console. Pumping operation may now be re-established via the CentriMag Back-Up Console by increasing the RPM to >800-1600 RPM. Gradually increase RPM while unclamping the Blood 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 Blood Pump. Be sure to reset options and alarms to match those selected before hardware exchange.

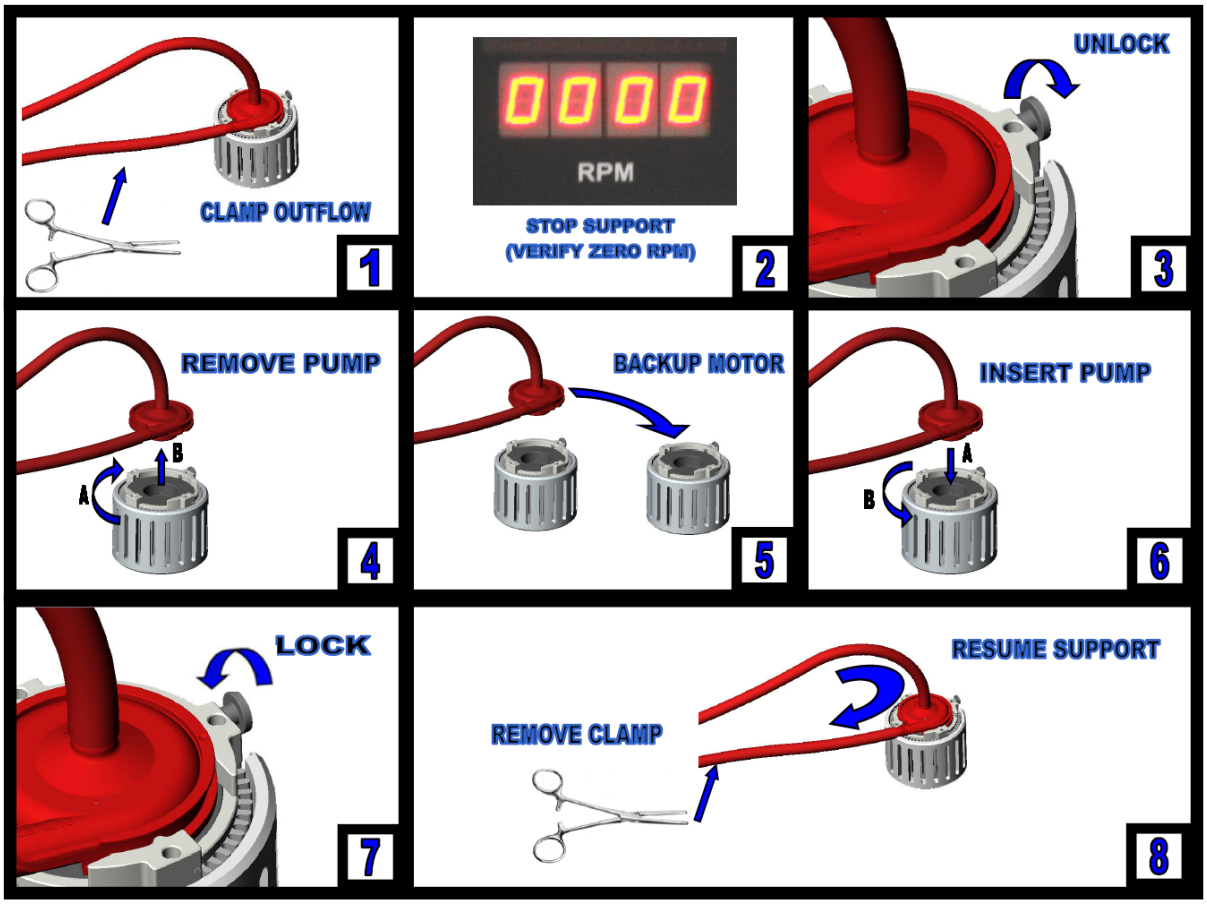


Figure 47: Emergency Switch to Backup System

If the Blood 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 Blood Pump and circuit, including cannulae.

NOTE: To be available for emergency use, the CentriMag Back-Up Console and Motor must be in the close proximity of, and transported with, the Primary Console and Motor, and plugged into AC power, with the main power switch OFF. The battery power for the CentriMag Back-Up Console must be periodically assessed by turning the main power switch ON, checking the status of the battery, and then turning the main power switch OFF. In addition the expiration date of the CentriMag Back-Up Console's Battery Module must be checked on a periodical basis. Operate the CentriMag Back-Up Console as described in the CentriMag Back-Up Console's Operating Manual.

10.2 Switching to another Blood Pump

WARNING

DO NOT restart the Blood 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 Thoratec representative.

WARNING

Always fully unscrew the Pump retaining screw built into the Motor before inserting and locking the Blood 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 Blood 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 Blood 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 Blood Pump has been OFF for more than five minutes without adequate anticoagulation, it will be necessary to replace the Blood 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 Back-Up System 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 and Motor is on and prepared for use in the event of Primary Console malfunction. After defibrillation or cardioversion is performed, ensure that the Primary 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). 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.

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

If the CentriMag Primary or CentriMag Back-Up Consoles are used concurrently with an Electrosurgery unit, Thoratec recommends that the user should read and follow the electrocautery manufacturer's instructions for prevention of interference with other electronic devices.

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 Primary 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 – Primary Console Alarms and Alerts

Table 16: Primary Console Alarms & Alerts

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

Table 16: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
			Motor according the procedure described in Section 10.1.
M4	**Alarm**	**MOTOR ALARM**	**An audible alarm will sound and the system will continue to operate.** **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 and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your local Thoratec representative.**
M5	**Alert**	**SET PUMP SPEED NOT REACHED**	**Check the pump flow: If pump flow is satisfactory; reduce set speed while insuring that flow is maintained.** **Press the alarm acknowledge button. If the alert repeats, clamp the return tubing, stop the pump and switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alert message and contact your Thoratec representative.** **If the pump flow is not satisfactory, clamp the return tubing and switch to the backup Console and Motor according to the procedure described in Section 10.1. Resume support.** **Record the alert message and contact Thoratec representative.**
B1	**Alert**	**BATTERY MODULE FAIL**	**The console battery will not function. An audible alarm will sound.** **Switch to the backup Console and Motor according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec representative.**
B2	**Alert**	**BATTERY BELOW MINIMUM**	**The blood pump will stop after a very short time.** **Plug the console into AC power outlet to charge battery.** **If no AC outlet is available, switch to CentriMag Back-Up Console and Motor according to the procedure described in Section 10.1.** **Resume support.**
F1	**Alert**	**FLOW PROBE DISCONNECTED**	**Check the flow probed connection on back of console.** **If necessary, reconnect the flow probe connector to the back of the console. Press the alarm acknowledge button. Switch to the back-up 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 and Motor according the procedure described in Section 10.1. Resume support.** **Record the alarm message and contact your local**

Table 16: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
			Thoratec 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 back-up flow probe, if the alert message repeats. If problem still persists after switching to the back-up flow probe, stop the pump and switch to a back-up Primary Console. Follow the instructions described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec 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 CentriMag Back-Up Console and Motor. Switch to the backup system according the procedure described in Section 10.1. Resume support. Record the alarm message and contact your Thoratec 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	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.

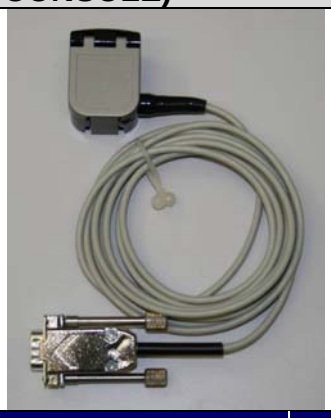
Table 16: Primary Console Alarms & Alerts			
ID	**Alarm/ Alert**	**Text Message**	**System Status & Operator Response**
		MAXIMUM	Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
M6	Alert	MOTOR OVER TEMP	Switch to CentriMag Back-Up Console and Motor 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 CentriMag Back-Up Console and Motor 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

PRIMARY 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 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	5.9 kg / 13 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	-0.2 – 10.0 liters per minute (LPM)		
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 L 250V”		
Shipping Condition	Temperature: -29°C to 60°C / -20°F to 140°F Relative humidity: 0% to 85%		
Operational & Storage Conditions	Temperature: 10°C to 30°C / 50°F to 86°F Relative humidity: 30% to 75%		
Primary Console Application Software	Version CPC1.01		
	LMCEBPX:	SW-0032-01	Rev 00
	IFD:	SW-0033-01	Rev 01
	SPS-MSP:	SW-0034-01	Rev 01
	SPS-PIC:	SW-0043-01	Rev 00
Max. Product Life	5 years		

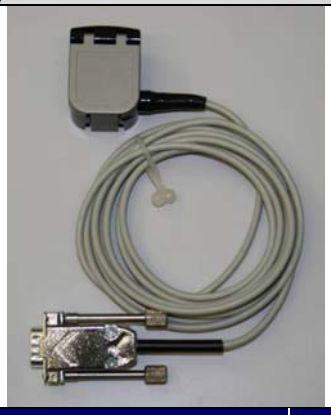
MAG MONITOR			
PARAMETER	**SPECIFICATIONS**		
DC Power	12 VDC, 12 W (from Console)		
Dimensions	Height: 23.2 cm / 9.1 in Width: 31.8 cm / 12.5 in Depth: 6.2 cm / 2.4 in		
Weight	1.9 kg / 4.2 lbs		
Screen Size	12.1''		
Screen Resolution	800(H) x 600(V) pixels		
Language Options	English, Dutch, French, German, Italian and Spanish		
Electrical Safety	Earth leakage current: < 500 µA Touch current: < 100 µA Patient leakage current: < 10 µA		
Shipping Condition	Temperature: -29°C to 60°C / -20°F to 140°F Relative humidity: 0% to 85%		
Operational & Storage Conditions	Temperature: 10°C to 30°C / 50°F to 86°F Relative humidity: 30% to 75%		
Monitor Application Software	Version MCM2.00		
	IPL:	SW-0038-01	Rev 01
	Application:	SW-0040-01	Rev 01
	CPLD:	SW-0041-01	Rev 00
Max. Product Life	5 years		
USB Port	Use only USB-compatible Memory Sticks (FAT/FAT32 formatted)		

EM-TEC ADULT FLOW PROBE FOR CENTRIMAG (SUPPLIED WITH PRIMARY CONSOLE)



PARAMETER		SPECIFICATIONS
Brand Name & Model Number		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	3/8” (9.5 mm)
	Wall Thickness	3/32” (2.4 mm)
	Tubing OD	9/16” (14.3 mm)
	Material	Polyvinyl Chloride
Probe Calibration	Calibrated for Fluid Temperature (ºC)	Blood at 37 ºC
	Tubing Type	Tygon S-50-HL

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



PARAMETER		SPECIFICATIONS
Brand Name and Model Number		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	1/4” (6.4 mm)
	Wall Thickness	3/32” (2.4 mm)
	Tubing OD	7/16” (11.1 mm)
	Material	Polyvinyl Chloride
Probe Calibration	Calibrated for Fluid Temperature (ºC)	Blood at 37 ºC
	Tubing Type	Tygon S-50-HL

12.3 Appendix III – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The 2nd Generation CentriMag System is intended for use in the electromagnetic environment specified below. The customer or the user of the 2nd Generation CentriMag System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The 2nd Generation CentriMag System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The 2nd Generation CentriMag 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.
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 2nd Generation CentriMag System is intended for use in the electromagnetic environment specified below. The customer or the user of the 2nd Generation CentriMag 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	Pulse amplitude – AC Power Port: 2.0 kV Pulse amplitude – Signal/Data Non Control Port: 1.0 kV Burst frequency: 5.0 kHz	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	Pulse amplitude – AC Power Port: 1.0 kV for differential mode 2.0 kV for 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 % V_{NOM} (>95 % dip in V_{NOM}) for 0,5 cycle 40 % V_{NOM} (60 % dip in V_{NOM}) for 5 cycles 70 % V_{NOM} (30 % dip in V_{NOM}) for 25 cycles <5 % V_{NOM} (>95 % dip in V_{NOM}) for 5 s	Nominal Mains Voltage (V_{NOM}): 110/230 Vac Voltage Dips: 30% of V_{NOM} for 25 Line Cycles 60% of V_{NOM} for 5 Line Cycles Interruptions: >95% V_{NOM} for ½ Line Cycle >95% V_{NOM} for 5 Sec	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: V_{NOM} 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 2nd Generation CentriMag System is intended for use in the electromagnetic environment specified below. The customer or the user of the 2nd Generation CentriMag 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]	outside ISM bands: 3 V	Portable and mobile RF communications equipment should be used no closer to any part of the 2nd Generation CentriMag System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	inside ISM bands: 10 V	$d = 1.2\sqrt{P}$
Radiated RF **IEC 61000-4-3**	10 V/m 80 MHz to 2,5 GHz	Frequency range: 150 kHz – 2.5 GHz Field strength: 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 2nd Generation CentriMag System is used exceeds the applicable RF compliance level above, the 2nd Generation CentriMag 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 2nd Generation CentriMag 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 2nd Generation CentriMag System

The 2nd Generation CentriMag System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 2nd Generation CentriMag System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 2nd Generation CentriMag 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 $d = 1.17 \sqrt{P}$	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	0.37	0.38	0.38	0.73
1	1.17	1.2	1.2	2.3
10	3.69	3.8	3.8	7.3
100	11.70	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 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.

12.5 Appendix V – Similarities & Differences Between Primary & CentriMag Back-Up Console

Function	Primary Console	CentriMag Back-Up Console
Pump Speed (RPM) Range	0 – 5,500 RPM	0 – 5,500 RPM
Pump Flow Range	0 – 10.0 LPM	0 – 9.9 LPM
Flow Range Display	-2.0 – 10.0 LPM	No
Flow Sensing Capability	Yes	No
Pressure Sensing Capability	Yes	No
Display	Graphical Display	Alphanumeric Digital Display
Mag Monitor	Available	No
RPM Bar graph	Yes	No
LPM Bar graph	Yes	No
Battery Bar graph	Yes	Digital display of remaining battery time only
Audio/Visual Alarm Capability	Yes	Yes
Power Mode(s)	AC or Battery Power	AC or Battery Power
Power Mode Indicator(s)	Yes	Yes
AC Power	100 – 120VAC, 200 – 240 VAC at 50/60 Hz, 170 VA	100 – 240 VAC at 50/60 Hz, 150 W
Battery Power	Yes	Yes
Battery Type	Rechargeable	Non-Rechargeable
Battery Chemistry	Lithium Ion	Alkaline Manganese
Battery Voltage	14.8 Volts	31.5 Volts
Available Battery Time	120 min @ 3,500 RPM, 5.5 LPM	2 hours @ 5,500 RPM, 3 LPM
Weight	5.9 kg / 13 lbs	6.0 kg / 13.2 lbs (With Battery Module)
Dimensions	Height: 10.0 cm / 3.9 in Width: 26.6 cm / 10.5 in Depth: 33.0 cm / 13.0 in	Height: 10.0 cm / 3.9 in Width: 26.6 cm / 10.5 in Depth: 33.0 cm / 13.0 in

12.6 Appendix VI – Similarities & Differences Between 1ST Generation & 2ND Generation Primary Consoles

Function	2nd Generation Console	1ST Generation Console
Pump Speed (RPM) Range	0 – 5,500 RPM	0 – 5,500 RPM
Pump Flow Range	0 – 10.0 LPM	0 – 9.9 LPM
Flow Range Display	-0.2 – 10.0 LPM	0 – 9.9 LPM
Flow Sensor type	Ultrasonic (em-tec)	Ultrasonic (Transonic)
Pressure Sensing Capability	Yes	Yes
Pressure Alarms	Yes	No
Display	Graphical Display	Alphanumeric Digital Display
Mag Monitor Available	Yes	No
Data logging	Yes	No
Stopwatch	Yes	No
RPM Bar graph	Yes	Yes
LPM Bar graph	Yes	Yes
Battery Bar graph	Yes, and digital display of remaining battery time	Yes
Audio/Visual Alarm Capability	Yes	Yes
Power Mode(s)	AC or Battery Power	AC or Battery Power
Power Mode Indicator(s)	Yes	Yes
AC Power	100 – 120VAC, 200 – 240 VAC at 50/60 Hz, 170 VA	100 – 240 VAC at 50/60 Hz, 120 W
Battery Power	Yes	Yes
Battery Type	Rechargeable	Rechargeable
Battery Chemistry	Lithium Ion	Nickel Metal Hydride (NiMH)
Battery Voltage	14.8 Volts	20.4 Volts
Available Battery Time	CentriMag Blood Pump: Approx. 120 min @ 3,500 RPM, 5.5 LPM	CentriMag Blood Pump: Approx. 60 min @ 3,500 RPM, 5.5 LPM
Weight	5.9 kg / 13 lbs	6.6 kg / 15 lbs
Dimensions	Height: 10.0 cm / 3.9 in Width: 26.6 cm / 10.5 in Depth: 33.0 cm / 13.0 in	Height: 21.2 cm / 8.4 in Width: 26.0 cm / 10.2 in Depth: 32.0 cm / 12.6 in