CentriMag® Primary Console

OPERATING MANUAL

Distributed By:

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Manufactured By: Levitronix, Zurich, Switzerland

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1 MANUAL OVERVIEW

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Section 2: **General Conventions** describes warnings, cautions, and conventions of expression used in this Manual.

Section 3: **About the CentriMag Primary Console** describes the general use of the Primary Console.

Section 4: **Specifications and General Description** describes the product specifications and physical attributes of the Primary Console.

Section 5: **Setting up** describes the procedure for unpacking the Primary Console and configuring it for use.

Section 6: **Operating** describes how to operate the Primary Console.

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Section 9: **Disposal of Equipment** describes the procedure for proper disposal of used Console batteries and Primary Consoles that have reached end of useful service life.

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 for the CentriMag Primary Console.

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

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2 GENERAL CONVENTIONS

2.1 Warnings and Cautions

Read and observe all **WARNINGS** listed in this Manual and observe relevant instructions and safety precautions throughout operation of the CentriMag Primary Console.

WARNING

Warnings are used to prevent misuse of the device, ensure patient safety, or when special care should be exercised to prevent improper operation of the device which may potentially harm the patient or the device.

CAUTION

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.

2.2 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: Thoratec® is a registered trademark and HeartLine™ is a trademark of Thoratec Corporation. Levitronix® and CentriMag® are registered trademarks of Levitronix LLC.

2.3 Conventions Used in This Manual

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

Console 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, and Console).

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3 ABOUT THE PRIMARY CONSOLE

WARNING

Read this Manual before using the CentriMag Console with the CentriMag Blood Pump. Thoratec requires users to undergo training prior to use of the Thoratec CentriMag System.

WARNING

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

WARNING

A CentriMag Back-Up Console and Motor are required in the immediate vicinity of the patient whenever the CentriMag System is used. The Back-Up Console must be plugged in and available should the primary Console 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.

3.1 Description

3.1.1 General Overview

As shown in Figure 1, the CentriMag System is comprised of five fundamental components: a) a single-use centrifugal Pump, b) a Motor, c) a Primary Console, d) a Back-Up Console, and e) a flow probe.

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Figure 1: a) CentriMag Blood Pump, b) Motor and c) Primary Console

Figure 1d: CentriMag Back-Up Console

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

3.1.2 Technology Overview

The Thoratec CentriMag Blood Pump is an electronically driven, centrifugal Pump based on bearingless electric motor technology. The bearingless centrifugal Pump allows pumping without mechanical bearings and seals. The basic principle is shown in Figure 2. A rotor 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 rotor speed.

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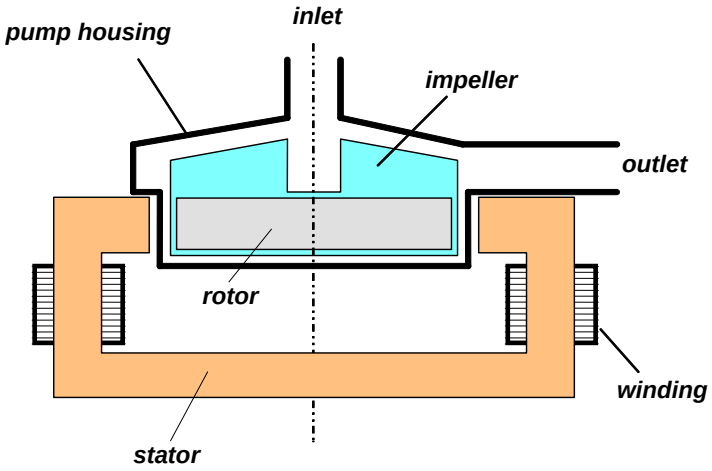

Figure 2: Schematic with the basic principle of the bearingless centrifugal Pump

External position sensors actively control the radial rotor position. Processor-controlled electronics regulate the magnetic fields so that the rotor is always centered. The electronics also allow precise regulation of the radial rotor position and the speed. Axial position and tilting of the rotor are passively stabilized (Figure 3). Only the non-contact rotor floats in the Blood Pump and is levitated by magnetic fields through its walls.

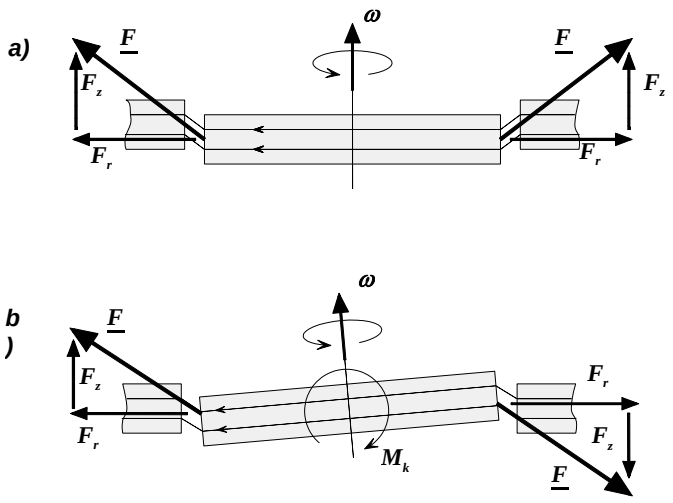

Figure 3: Axial support (a) and stabilization against tilting (b) of the rotor by passive magnetic forces in the CentriMag Blood Pump

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3.1.3 System

3.1.3.1 CentriMag System Components

The components listed in Table 1 comprise the CentriMag System. When a patient is supported on the Primary System, the Back-Up System must be available in the immediate vicinity of the patient.

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

System Component	Primary System	Back-Up System
CentriMag Blood Pump	✓	✓
CentriMag Primary Console	✓	
CentriMag Motor	✓	✓
CentriMag Flow Probe	✓	
CentriMag Back-Up Console		✓
CentriMag Back-Up Console Battery Module		✓

3.1.3.2 Optional CentriMag System Components

The following components are available as accessories to the CentriMag System (Table 2):

Table 2: Optional Elements of the CentriMag System

System Component	Available for the Primary System	Available for the Back-Up System
CentriMag Console Cart	✓	✓[1]
CentriMag Portable Stand	✓	✓
CentriMag Motor Bracket	✓	✓
CentriMag Pressure Transducer Cables	✓	
CentriMag Pressure Transducers	✓	

3.1.4 CentriMag Primary Console

The CentriMag Console uses single phase AC power and is capable of a flow rate of up to 9.9 LPM or maximum pressure head of 600 mmHg. 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.

[1] A cart is available for the Back-Up console only when used together with a Primary Console.

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3.1.4.1 CentriMag Primary Console Front Panel

The CentriMag Primary Console (Figure 4) is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data, system options, and menus. Operator adjustable alarms and parameters are accessible via the system menus.

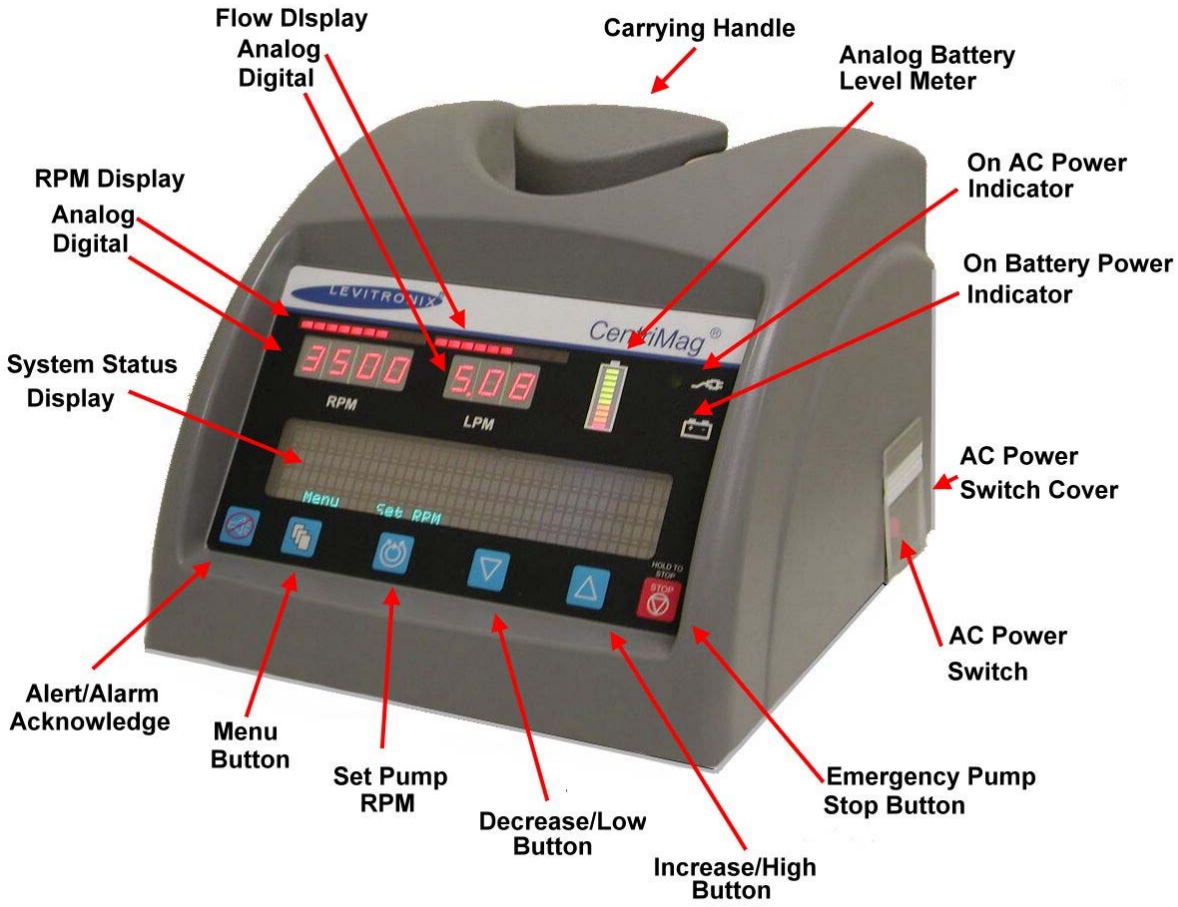

Figure 4: Thoratec CentriMag Primary Console

A Flow Probe is provided with each Primary Console. The Flow Probe is a reusable, non-patient contacting ultrasonic Flow Probe which can detect flows from 0-9.9 LPM when used in conjunction with the CentriMag Primary Console. The probe can detect retrograde flow of ≥40 cc/min. Retrograde flow ≥40 cc/min is always displayed as dashes "-.--". A disconnected or malfunctioning probe will display blank spaces " ".

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This sensor is compatible with 3/8” ID by 3/32” wall tubing and is a molded clip-on design for easy care and handling.

3.1.4.2 CentriMag Primary Console Back Panel

The CentriMag Primary Console back panel (Figure 5) provides the required mechanical inputs and outputs needed to operate a CentriMag Blood Pump.

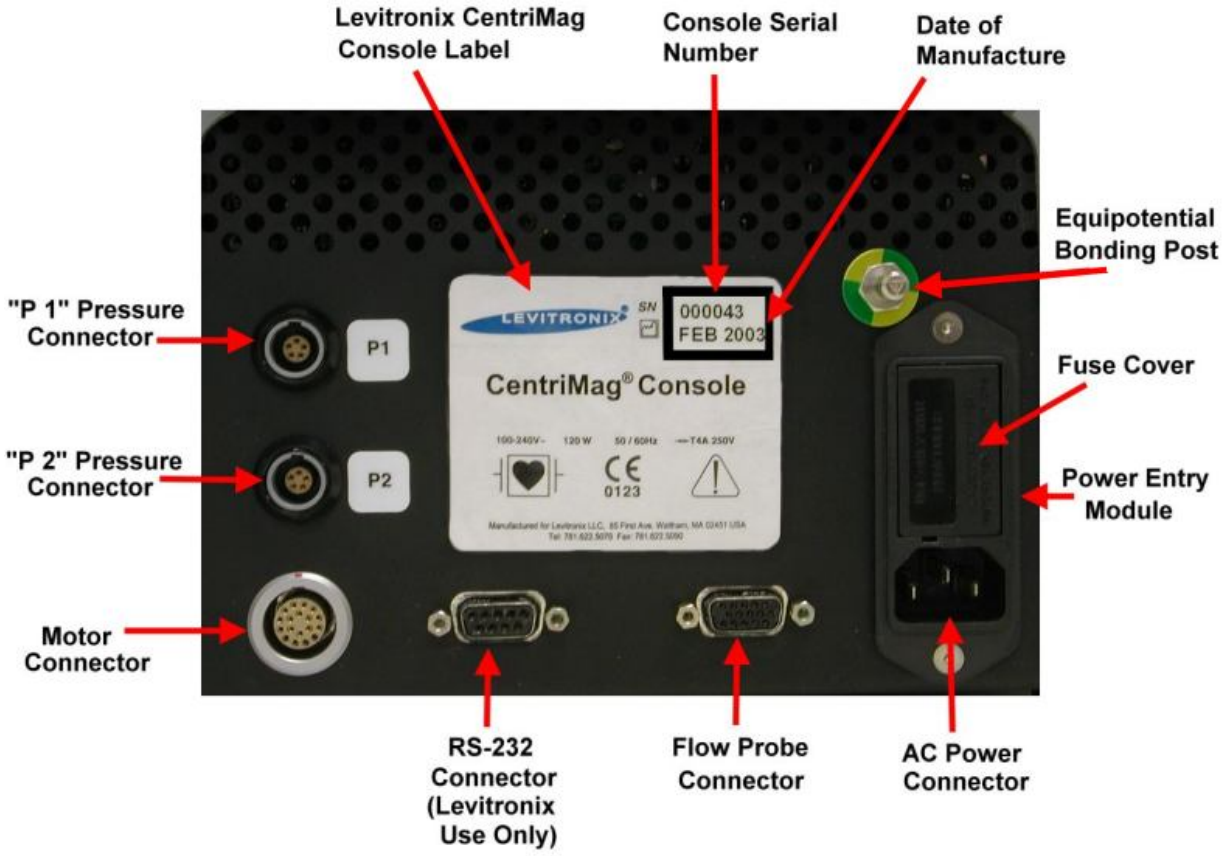

Figure 5: Back panel - Thoratec CentriMag Primary Console

3.1.5 CentriMag Blood Pump

The CentriMag System contains a sterile, single-use, disposable, Centrifugal Blood Pump (Figure 6).. The use of magnetic levitation eliminates the need for bearings and seals in the blood pathway, therefore, minimizing blood trauma, and the potential for hemolysis and thrombus formation. The Pump is designed to move blood by centrifugal force created by the magnetically suspended rotating impeller.

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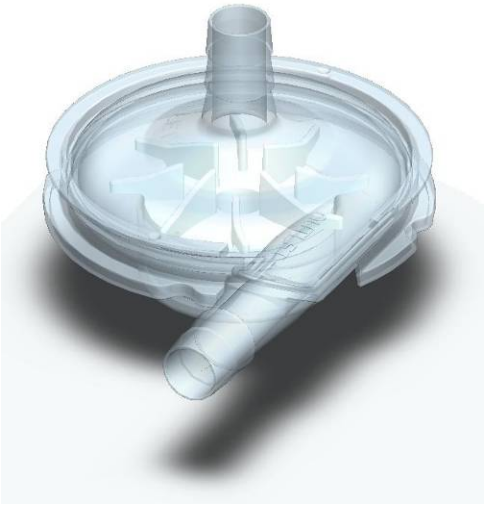

Figure 6: CentriMag Blood Pump

The flow rate is dependant on the available amount of blood to be pumped, the Pump speed (RPM), and the blood pressure at the pump outlet. The relationship between pressure and flow rate as a function of RPM can be seen in Figure 7 for the CentriMag Blood Pump as an isolated component of the Circuit.

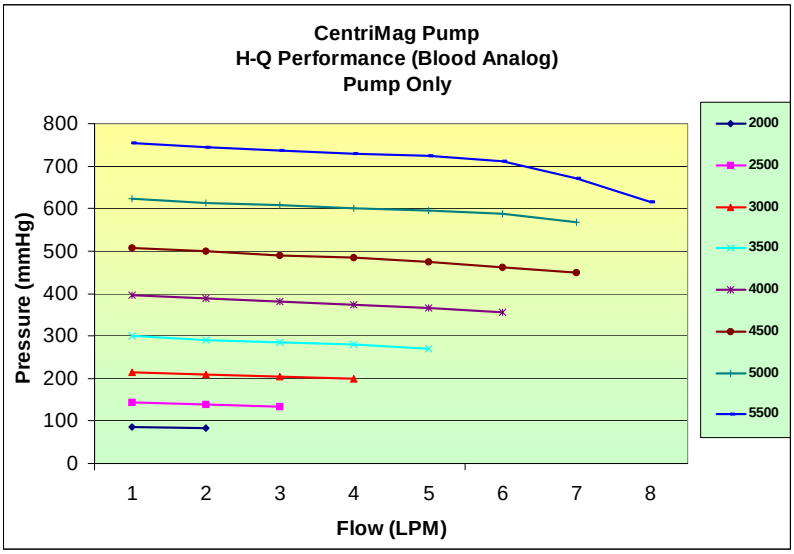

Figure 7: CentriMag Blood Pump Differential Pressure/Flow Curve

Note: Actual obtainable flow is dependent on the afterload of the Blood Pump, which results from the extracorporeal circuit (e.g. oxygenator, tubing, etc.) as well as patient arterial resistance.

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3.1.7 CentriMag Motor

The Thoratec CentriMag Motor (Figure 8) holds the CentriMag disposable Blood Pump and drives the rotor inside the Blood Pump.

Figure 8: CentriMag Motor

This Manual describes the functions, setup and operation of the CentriMag Primary Console. A more complete description of the setup and priming of the Blood Pump can be found in the Thoratec CentriMag Blood Pump Instructions for Use.

3.1.8 CentriMag Back-Up Console

The CentriMag Back-Up Console (Figure 1d) uses single phase AC power and is capable of a flow rate of up to 9.9 LPM or maximum pressure head of 600 mmHg. In addition each Back-Up Console contains a non-rechargeable, field replaceable internal battery that is capable of maintaining 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 during a Primary Console malfunction until the Primary Console can be replaced with another Primary Console.

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

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3.2 Application Software Version

This Operating Manual is written for CentriMag Primary Consoles with Application Software Version 2.01 on board. The Application Software Version flashes on the Primary Console's digital display during power up.

3.3 Indications for Use

The CentriMag® Blood Pump is indicated for use only with the Thoratec CentriMag® Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

3.4 Contraindications for Use

This CentriMag System is 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.

3.5 Required User Supplied Items

The following items, required for use with the CentriMag® Blood pump, are or may be necessary but not provided by Thoratec:

- Hemostats or vascular clamps
- Connecting tubing and adapters
- Oxygenator
- Circuit prime
- Circuit Filter
- Tubing Adapters with Luer Lock ports

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4 SPECIFICATIONS AND GENERAL DESCRIPTION

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

4.1 Classification

Table 3: Primary Console Classification		
SYMBOL	**CLASSIFICATION**	**DESCRIPTION**
	Type CF – Defibrillator Proof	Equipment Type.
None	Class 1	Equipment Classification.
None	Continuous, internally powered	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 enclosure.

4.2 Specifications

Table 4: Primary Console Specifications	
PARAMETER	**SPECIFICATIONS**
AC Power	100 – 240 VAC at 50/60 Hz, 120 W
Battery Power	20.4 VDC NiMH (17 cells), internal rechargeable battery *Discharge time*: 60 minutes at 5.5 LPM and 3,500 RPM *Recharge time*: 4 hrs to 90% charge, 5 hrs to 100% charge
Dimensions	Height: 21.2 cm / 8.4 inches Width: 26.0 cm / 10.2 inches Depth: 32.0 cm / 12.6 inches
Weight	6.6 kg / 15 pounds
Pump Speed Range	0 – 5,500 revolutions per minute (RPM)

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Table 4: Primary Console Specifications	
PARAMETER	**SPECIFICATIONS**
Pump Flow	0.0 – 9.9 liters per minute (LPM)
Serial Output	For Thoratec use only.
Electrical Safety	Earth leakage current: < 500 µA Enclosure leakage current: < 100 µA Patient leakage current: < 10 µA

4.3 Environmental Conditions

4.3.1 Shipping Conditions

The following are the acceptable environmental conditions during shipping:

- Temperature: -35^{o} C to 65^{o} C. (one week maximum)
- Relative humidity: 0% to 95%.
- Atmospheric pressure: 157 – 760 mmHg.

4.3.2 Operational and Storage Conditions

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

- Temperature: 10^{o}C to 30^{o}C.
- Relative humidity: 30% to 75%.
- Atmospheric pressure: 595 – 760 mmHg.

4.4 EMI Considerations

Electro-magnetic interference (EMI) sources in the vicinity of the CentriMag 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 CentriMag 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 Back-Up Console, near the Primary Console.

4.5 Permanent Magnet Considerations

Permanent magnets can interfere with proper pumping operation when in close proximity with the CentriMag blood Pump and CentriMag Motor. These sources of

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magnetism include items such as, but not limited to, spare CentriMag Pumps and permanent DC (Direct Current) Motors.

4.6 Console Control Panel

The CentriMag Primary Console Control Panel (Figure 9) contains three rows of information/functions. **Row 1** includes indicators (bars and LED's) for the Blood Pump's speed (RPM), flow rate (LPM), and power source (battery gauge and battery icon for battery power and plug icon for AC power). **Row 2** consists of a four-line alphanumeric vacuum fluorescent display. The top two lines on the display are used to display system status. The third line is used to display the selected system parameter, and the bottom line displays the four soft keypad descriptions for the active screen. **Row 3** consists of six keypads. The first keypad (furthest to the left) silences the alarm audio, 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)**.

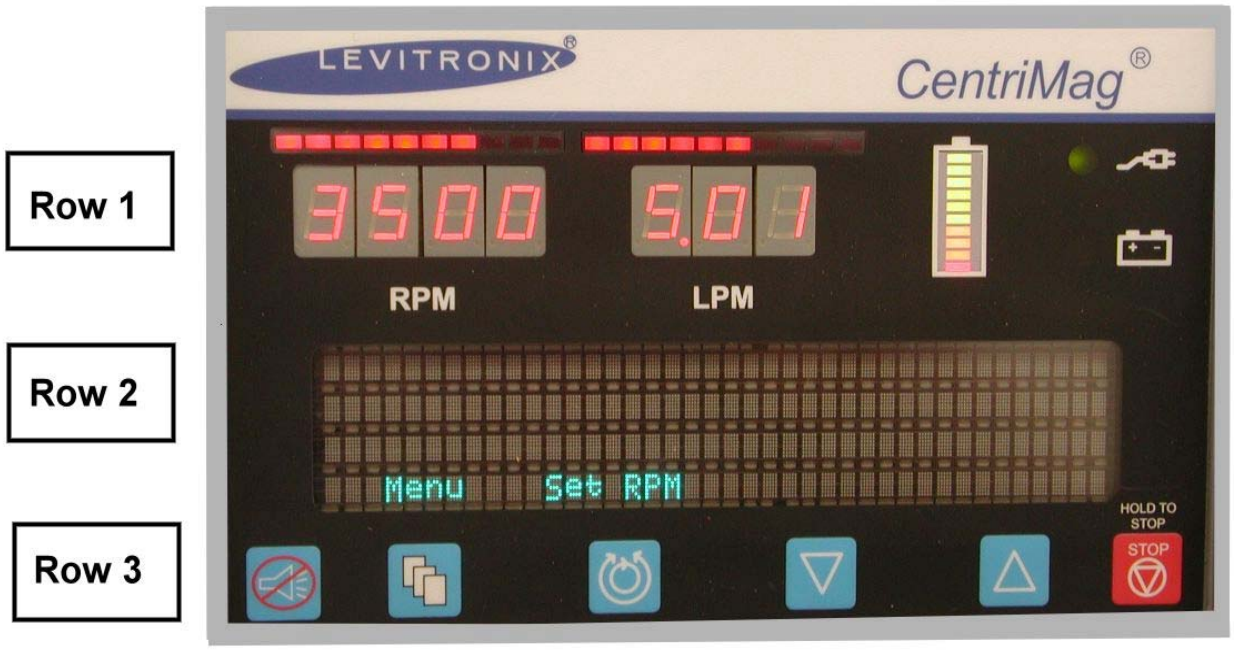

Figure 9: Console Control Panel

The symbols used on the Console and their meanings are listed in Table 5.

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Table 5: Symbols on the Primary Console		
SYMBOL	**NAME**	**DESCRIPTION**
Controls – Front Panel		
	Alarm Acknowledge	Depressing this keypad signals the Primary Console that the user is aware of an alarm/alert condition(s). The Primary Console will silence the audio alarm/alert indicator for a fixed period depending upon the nature of the alert/alarm.
	Menu	Depressing this keypad will allow the user to select system settings to view or modify (e.g., flow alarm levels, audio volume, language, etc.).
	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.
	Decrease	This keypad is used to select/modify the value for the displayed item to be adjusted.
	Increase	This keypad is used to select/modify the value for the displayed item to be adjusted.

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Table 5: Symbols on the Primary Console		
SYMBOL	**NAME**	**DESCRIPTION**
	Emergency Pump Stop	When depressed for at least 2 seconds, this keypad will cause the Pump RPM to immediately be set to zero causing the Blood Pump to stop.
	ON/OFF Switch	Power switch located on the lower the right side panel of the Primary Console. The power switch is recessed, and covered with hinged plastic cover to prevent inadvertent actuation. Switching to off disables all functions and displays except for battery charging function.
Indicators – Front Panel		
	Pump Speed	Blood Pump speed (**RPM**) Display: The Top portion of the Blood Pump Speed display is an analog representation of the Blood Pump Speed (shown as dashes); one LED (one dash) is equivalent to 550 RPM. The bottom portion of the Blood Pump Speed display is a 4-digit display that provides a numeric representation of the Blood Pump speed in RPM.
	Flow Rate	Flow rate (**LPM**): The Top portion of the Flow Rate Display is an analog representation of the Blood Pump Flow (shown as dashes); one LED (one dash) is equivalent to 1.0 LPM. Note that an additional dash is displayed when entering the next “liter” of flow. The bottom portion of the Flow Rate Display is a 3-digit numeric display that provides a digital representation of the Blood Pump Flow in LPM.

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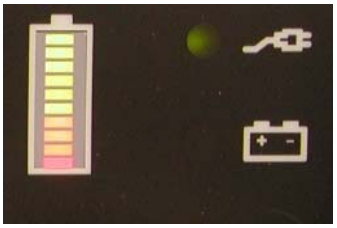
Table 5: Symbols on the Primary Console		
SYMBOL	**NAME**	**DESCRIPTION**
	Power Source	AC plug icon indicator (GREEN DOT) illuminates when operating under AC power. Battery icon (GREEN DOT) illuminates when the Primary Console is operating under battery power. Battery charge LED indicates charge remaining in the Primary Console's internal battery. Full battery charge is indicated until nominal battery charge falls below 80%.
Connections – Back Panel		
	Motor Power	Connection for power to Motor. Red dot located on top of connector facilitates alignment of Motor LEMO connector.
	Power Entry Module (AC Power and Fuses)	Connection for Primary Console to AC power and fuse box. Use only T4A 250V fuses only.
	Flow Probe connector	15-Pin connection for the Flow Probe.
	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.
	RS-232 Connector	The RS-232 Connector is reserved exclusively for Thoratec use.

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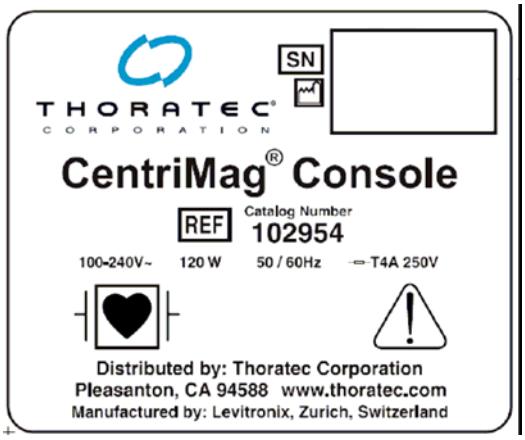
Table 5: Symbols on the Primary Console		
SYMBOL	**NAME**	**DESCRIPTION**
Serial Number Label		
		
SN	Serial Number	Identifies the serial number of the CentriMag Primary Console.
	Date of Manufacture	Specifies the date of manufacture of the CentriMag Primary Console.
REF Catalog Number	Catalog Number	Thoratec Catalog Number.
	Defibrillation-proof Type CF Equipment	Equipment type.
Attention, See Instructions For Use	Caution	Consult Thoratec CentriMag Primary Console Operating Manual before operating the device.

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 alphanumeric display. Depressing the ALARM ACKNOWLEDGE keypad mutes the audible alarm. The alarm/alert message will be continuously displayed on the top two lines of the Primary Console's alphanumeric display as long as the alarm/alert condition exists. If no alarm/alert message is active, the first row of the Primary Console's display shows the actual min/max flow alert thresholds and the flow sensitivity filter setting.

In the event of an alert condition (see Appendix I for the full list of alarms and alerts), the Primary Console continues Pumping operation. The Primary Console allows the

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user to acknowledge the alert, which silences the audio alert indication, but will not remove the visual alert indication. If the alert condition persists for more than 60 seconds after the alert has been acknowledged, the audio alert reactivates and continues until acknowledgement except for **BATTERY MAINTENANCE REQUIRED** (only requires acknowledgment one time) and **ON BATTERY / LOW BATTERY** (audio reactivates every 10 minutes or until reconnected to AC power).

In the event of an alarm condition (see Appendix I for the full list of alarms and alerts), the Primary Console stops the Blood Pump. The Primary Console allows the user to acknowledge the alarm, which silences the audio alarm indication, but will not remove the visual alarm indication and will not allow Pumping to continue until the alarm condition no longer exists. If the alarm condition remains for more than 60 seconds after the alarm has been acknowledged, the audio alarm indication reactivates and continues until acknowledged except for any run time diagnostic (only requires acknowledgement one time).

WARNING

Alarms are associated with conditions that require the Blood Pump to stop.

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. In addition, do not restart the Blood Pump if it has stopped due to Motor overheating.

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 outlet tubing from the Blood Pump is necessary to prevent a low flow, pressure, or reverse flow condition. The tubing clamp must be removed before returning to normal Pumping activity.

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4.7 Digital Display Information

The Primary Console's alphanumeric digital display provides messages and information on system settings, Console configuration, and alarms/alerts. Table 6 shows system alarm and alerts in the order of priority:

Table 6: Front Panel Display – Alarm/Alert Messages in Order of Priority

ALARMS	ALERTS
POWER ON TEST FAIL SYSTEM FAULT BATTERY BELOW MINIMUM MOTOR DRIVE FAIL MOTOR DISCONNECTED PUMP NOT INSERTED MOTOR FAIL	SET PUMP SPEED NOT REACHED FLOW PROBE DISCONNECTED SELF TEST FAIL FLOW SIGNAL FAIL FLOW BELOW MINIMUM FLOW ABOVE MAXIMUM MOTOR OVER TEMP BATTERY CHARGER FAIL BATTERY MAINTENANCE REQUIRED LOW BATTERY ON BATTERY

4.8 Power Assembly

The Power Assembly is located at the rear of the Console Base and contains the AC Power Connection, RS232 Computer I/O port, and LEMO Motor Connection.

CAUTION

The RS232 Computer I/O port is for Thoratec use only.

Accessory equipment connected to the analog and digital interfaces must be certified according 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.

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5 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 CentriMag Primary Console carries the following Factory[2] and Power-Up[3] defaults for each specified operating parameter:

Table 7: Primary Console Factory & Power-Up Default Values

OPERATING PARAMETER	FACTORY DEFAULT	POWER-UP DEFAULT
Minimum Flow Alert	0.0 LPM	0.0 LPM
Maximum Flow Alert	8.0 LPM	8.0 LPM
Pressure Monitoring System	Inactive	Last state[4]
Language	English	Last state[4]
RPM Increment	100	Last state[4]
Flow Limit Sensitivity	Normal	Last state[4]

5.1 Unpacking

1. Remove the Primary Console, AC Power Cord, and Flow Probe from the Console's shipping container.

2. Remove the CentriMag Motor from its shipping box.

3. 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 around the Primary Console. Always prevent liquids from entering the device.

[2] Factory Default: pre-selected operating parameter of a Primary Console as it is shipped from Thoratec.
[3] 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.
[4] Last state: the value/state carried from the last operational use of the Primary Console.

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5.2 Powering Up

1. Insert the Power Cord into the Console's AC Power port, flip and press the connector latching mechanism over base of the power connector in order to fully secure the power cord to the Primary Console.

2. Insert the LEMO connector on the Motor cable into the Motor Connection on the rear of the Primary Console. **Make sure that the connector is fully seated and locked in place. Verify the correct seating of the connector by slightly pulling the cable; the connector must remain securely locked.**

3. 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.

4. Insert the cord into the AC wall outlet after all connections are made on the Console's back-panel.

5. Turn ON the power to the Primary Console (the power switch is located on the lower rear side panel of the Primary Console).

6. 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 six hours prior to use to recharge the internal battery and to ensure battery power availability, when needed.

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.

5.3 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

If the Console fails self test, immediately turn OFF the Console, and attempt to re-boot. If Console does not boot correctly, replace with another Console.

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When all power-up self-tests are completed successfully, the **INITIALIZATION COMPLETE** message along with the software version number (**X.XX**) will flash briefly on the Console display. This verifies proper Control Unit operation. Alarm/alert monitoring is active. **MENU** and **SET RPM** are displayed indicating the Console is ready for use.

5.4 Configuring the Console

The ability to set Pump speed, set flow alert thresholds, select the flow alert sensitivity, select the language, select the set speed resolution, enable and disable the pressure measurement capability, and calibrate the pressure transducers is accessed through the **MENU** keypad. Figure 10 outlines the basic menu scheme after powering ON the Console. The first message displayed upon power-up is the **SET RPM** message. 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 seven different user options that can be accessed by scrolling through the options:

- **MINIMUM FLOW ALERT**
- **MAXIMUM FLOW ALERT**
- **FLOW LIMIT SENSITIVITY**
- **PRESSURE DISPLAY** (for one or two pressure probes)
- **SELECT PRESSURE CAL** (to calibrate the pressure probes)
- **SPEED STEP RESOLUTION**
- **LANGUAGE**

The procedure for how to navigate the MENU scheme to access each of these options and their purpose is described in detail below.

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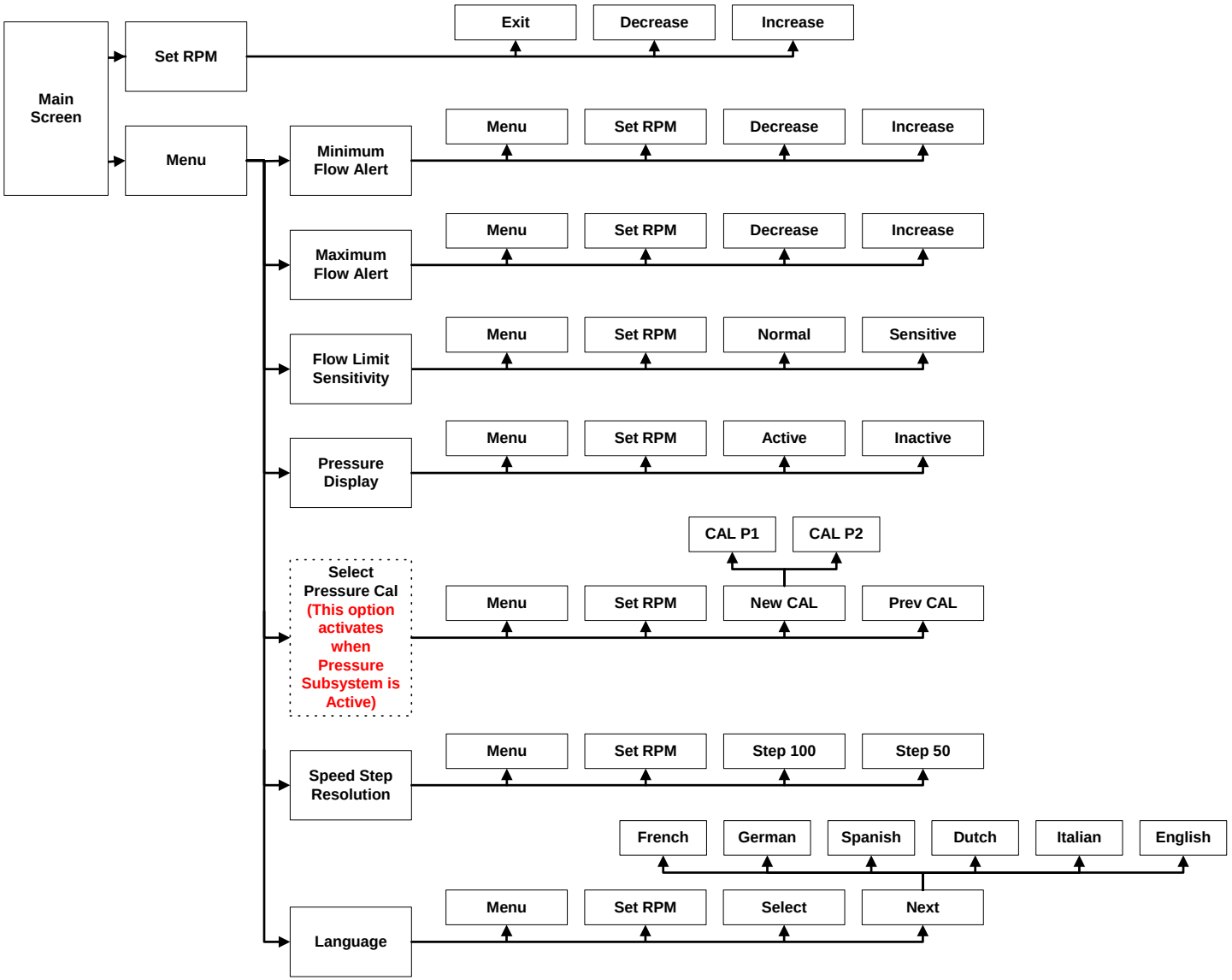

Figure 10: CentriMag Primary Console Menu Structure

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5.5 Setting the Console MINIMUM FLOW ALERT

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 minimum flow alert is factory set to 0.00 LPM. To change the minimum flow alert value, depress the **MENU** keypad to display the **MINIMUM FLOW ALERT** option. Use the **DECREASE** or **INCREASE** arrow keys to increase or decrease the alert setting. The actual **Min Flow** alert threshold is continuously shown on the first line of the display, as long as no alarm/alert is active.

The probe can detect retrograde flow of ≥40 cc/min. Retrograde flow ≥40 cc/min is always displayed as dashes "-.--". A disconnected or malfunctioning probe will display blank spaces " ".

WARNING

Minimum flow levels should be chosen carefully with respect to anticoagulation status of the patient and the patient's hemodynamic status. Thoratec does not recommend a sustained flow below 2.0 LPM.

5.6 Setting the Console MAXIMUM FLOW ALERT

To change the **MAXIMUM FLOW ALERT** setting, depress the **MENU** keypad to display **MAXIMUM FLOW ALERT** option. Use the **DECREASE** or **INCREASE** arrow keys to increase or decrease the alert setting. The **MAX FLOW Alert** default after power up is set to 8 LPM. The actual max flow alert threshold is continuously shown on the first line of the display, as long no alarm/alert is active.

5.7 Setting the Console FLOW LIMIT SENSITIVITY

A sudden decrease in flow below the **MINIMUM FLOW ALERT** setting could indicate a potentially hazardous condition. The CentriMag 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 alert is resolved. Naturally, care must be taken to maintain 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, where the operator may wish to run the system in the **SENSITIVE** mode. The

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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 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 the **MENU** until the **FLOW LIMIT SENSITIVITY** message is displayed. Depress either the **NORMAL** or **SENSITIVE** keypads to select the option. The sensitivity chosen affects both **MIN FLOW alert** and **MAX FLOW alert.** The actual setting is continuously shown on the first line of the display, as long no alarm/alert is active.

5.8 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.

2. To activate the pressure monitoring system of the CentriMag Primary Console, depress the **MENU** keypad to display **PRESSURE DISPLAY** option and press the **ACTIVE** button to activate the pressure monitoring system. The default setting is with the pressure monitoring system INACTIVE. If no pressure probes are to be used, skip to section 5.9.

3. Set option to **ACTIVE** by toggling the “Next” button. Depress the **SELECT** keypad button to choose the **ACTIVE** option.

4. Depress the **MENU** keypad to display **SELECT PRESSURE CAL** in order to calibrate the Pressure Probe(s) using the following method.

   Note: The following Calibration procedure assumes that 2 cables and 2 pressure probes will be used, which provides for monitoring pressure differential within the blood pumping circuit. 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 (-) 50 mmHg to (+) 900 mmHg, with a display resolution of 1 mmHg. If one channel exceeds either limit, the values displayed on both channels will be invalid.

   A. Assuming the pressure monitoring system has been activated, the previous calibration values may be displayed on the screen. A correct calibration value should range from (-) 1 to (+) 1. Otherwise, Pressure (mmHg) P1 = _ _. _, P2 = _ _ . _ P1-P2 = _ _ . _ is displayed. The probes may be calibrated at this time.

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B. Either select **NEW CAL** or **PREV CAL**. By electing to use the previous calibration constant (**PREV CAL**), you are acknowledging that the calibration value was within acceptable limits. By selecting **NEW CAL**, you will prompted to vent the transducer to atmospheric pressure to establish the transducer offset point. Always close the transducer valve before returning transducer into service.

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

Note: To de-activate the pressure monitoring system, the **INACTIVE** option must be chosen within the menu system.

5.9 Setting the Console SPEED STEP RESOLUTION

The CentriMag System may be used to treat patients with a wide range of body size. 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 **SPEED STEP RESOLUTION** option. Choose between the **STEP 50** (50 RPM) and **STEP 100** (100 RPM) options. 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.

5.10 Selecting Displayed LANGUAGE

Language selection is a standard menu option. The default language is English. To change the language, depress the **MENU** keypad button and scroll through the menu options until the **LANGUAGE** option appears. The available language options will be displayed when the **NEXT** keypad is pressed, which include: **ENGLISH, FRENCH, GERMAN, SPANISH, DUTCH, and ITALIAN.** Press the **SELECT** keypad to lock in the language selection. Note: If the **SELECT** keypad is not depressed, twenty seconds after the last keystroke the language displayed on the screen will be chosen. Once selected, the language will be stored in permanent memory by the Console and recalled each time the Console is powered up.

5.11 Blood Pump Set-up

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

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CAUTION

Always fully unscrew the pump retaining screw before inserting the pump. Failure to do so may inhibit the ability to fully insert the pump resulting in loss of function and a MOTOR FAIL alarm. Should this condition occur, remove the pump, unscrew the retaining screw, reinsert the pump, tighten the retaining screw, turn the Console power OFF and ON, and begin pumping.

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6 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.

NOTE: If there is any doubt regarding the integrity of the protective earth connection of the AC circuit or power cord, the Primary Console should be operated on battery power until safe AC power can be applied to the unit.

Prior to starting the Blood Pump, the Flow Probe must be set-up and connected to the Blood Pump outlet tubing.

6.1 Operation of the Blood Pump

WARNING

Increase Blood Pump RPM in small increments to minimize the risk of causing ventricular suction and cavitation.

WARNING

Pump may stop and display MOTOR FAIL alarm during use of a Valley Lab Model SSE2L electrocautery device. Should this occur, clamp the Pump outflow line, switch to bipolar mode on the electrocautery device then reboot the CentriMag Console and reinitiate support. Go to a Back-Up system if the device fails to operate following rebooting. Once the system is operational, unclamp the outlet tubing and resume support.

6.1.1 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 while slowly unclamping the outlet tubing until the flow rate is at the desired level.

3. Remove the tubing clamp from the circuit.

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

Note: Always set the Low Flow Alarm to the desired minimum flow point.

6.1.2 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 the patient's hemodynamic status and the resistance of the extracorporeal blood circuit.

6.1.3 Manually Stopping the Blood Pump

Depressing and holding the **STOP** keypad on the Primary Console's front panel for two 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.

Alternatively, in an emergency, the Blood Pump may be stopped by switching the AC Power Switch to OFF and clamping the Blood Pump outlet with a smooth jawed tubing clamp to prevent retrograde flow.

WARNING

Only switch Main Power Switch OFF in an emergency. Make certain to switch Main Power Switch to ON when the problem is resolved.

6.1.4 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. In addition, do not restart the Blood Pump if it has stopped due to Motor overheating.

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WARNING

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

WARNING

Increase Blood Pump RPM in small increments to minimize the risk of causing ventricular suction and cavitation.

To restart the Blood Pump, perform the following steps:

1. Insure that the Blood Pump is securely located in the Motor per the Instructions for Use supplied with the Blood Pump.

2. Insure that any alarm condition has been corrected.

3. Start the Blood Pump by first depressing the **SET RPM** keypad and then depressing the **INCREASE** keypad while slowly unclamping the outlet tubing until the flow rate is at the desired level.

4. Remove the tubing clamp from the circuit.

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

6.2 Console Alarm/Alert Strategy

The CentriMag 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. A normal operating condition is free of any alerts or alarms and is classified as a green state of operation. **Alert Advisories** activate when the system is about to, or has entered, an unsafe but resolvable operating state (yellow state). **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). The table 8 below illustrates the fundamental strategy:

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Table 8: CentriMag Primary Console Alarm/Alert Strategy		
Operating State	**Advisory Level**	**Anticipated Operator Response**
Green	**None**	**None**
Yellow	**Alert**	**Resolve Fault Condition**
Red	**Alarm**	**Resolve Alarm Condition or Switch to Back-Up hardware**

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 mutes the audible alarm. The alarm/alert message is continuously displayed on the top two lines of the alphanumeric display as long as the alarm/alert condition exists.

In the case of multiple alarms/alerts, each time a new alarm/alert condition occurs, a new audible alarm and a new message will be displayed on the Console. The alarm/alert messages will be listed in order of priority from highest to lowest. Alarms always take higher priority than alerts. If more than two alarm/alert conditions occur simultaneously the message **PRESS MORE FOR ADDITIONAL ALARMS/ALERTS** will be displayed. Depressing the **MORE** keypad allows scrolling through the alarm/alert messages. Refer to Table 6 for a listing of alarm and alert messages in their order of priority.

As shown in Table 9, the Primary Console features seven alarms and eleven alerts:

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Table 9: CentriMag Primary Console Alarms & Alerts			
No.	**Alarm/ Alert**	**Description**	**Ability to Silence Audio (Yes/No) (Silence Interval[5])**
1	Alarm	POWER ON TEST FAIL	No
2	Alarm	SYSTEM FAULT (Run-Time System Failure)	No
3	Alarm	BATTERY BELOW MINIMUM	Yes (60 Sec.)
4	Alarm	MOTOR DRIVE FAIL	Yes (60 Sec.)
5	Alarm	MOTOR FAIL	Yes (60 Sec.)
6	Alarm	MOTOR DISCONNECTED	Yes (60 Sec.)
7	Alarm	PUMP NOT INSERTED	Yes (60 Sec.)
8	Alert	SET PUMP SPEED NOT REACHED	Yes (60 Sec.)
9	Alert	FLOW PROBE DISCONNECTED	Yes (60 Sec.)
10	Alert	SELF TEST FAIL (Run-Time Diagnostics)	Yes (60 Sec.)
11	Alert	FLOW SIGNAL FAIL (Flow rate sensor error)	Yes (60 Sec.)
12	Alert	FLOW BELOW MINIMUM (Low Flow)	Yes (60 Sec.)
13	Alert	FLOW ABOVE MAXIMUM	Yes (60 Sec.)
14	Alert	MOTOR OVER TEMP	Yes (60 Sec.)
15	Alert	BATTERY CHARGE FAIL	Yes (60 Sec.)
16	Alert	BATTERY MAINTENANCE REQUIRED	Yes (60 Sec.)
17	Alert	LOW BATTERY	Yes (10 Min.)
18	Alert	ON BATTERY	Yes (10 Min.)

A complete list of all Alarms and Alerts may be found in Appendix 1. This list includes a description of each advisory, the system response and the anticipated response of the operator. Also shown is what triggers each alarm/alert condition.

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

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6.3 Alarms

In the event of an **Alarm condition**, the Console stops the Blood Pump. The Console allows the user to acknowledge the Alarm, which silences the audio alarm advisory, but will not remove the visual message and will 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 silence 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 Blood Pump outlet tubing before moving to back-up equipment. Always unclamp the tubing prior to resumption of pumping.

WARNING

Alarms are associated with conditions that require the Blood Pump to stop. To prevent retrograde flow through the Blood Pump during an alarm condition the 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.

WARNING

DO NOT restart the Blood Pump if it has stopped due to Motor overheating. Immediately clamp the outlet tubing, confirm overheating has occurred by checking the temperature of the Motor, and take emergency steps to either terminate support and remove all circuit components or replace the entire circuit (tubing, Pump, Motor and Console).

6.3.1 Alarm Conditions Requiring Powering Off Before Restarting

If the Blood Pump was stopped because of one of the alarm conditions listed in Table 10, correct the alarm condition, turn the Console POWER SWITCH to OFF and then

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back to ON. Once **MENU** and **SET RPM** are displayed, depress the **SET RPM** keypad and then depress the **INCREASE** keypad until the flow rate is at the desired level.

Table 10: Alarm Conditions Requiring Powering Off Before Restarting
POWER ON TEST FAIL **SYSTEM FAULT** **MOTOR FAIL** **MOTOR DRIVE FAIL**

If the Blood Pump does not restart, turn the Console OFF and disconnect it from AC power and use another Console.

If the Blood Pump has not been restarted within five minutes of stoppage with anticoagulation suitable for cardiopulmonary bypass, fully anti-coagulate the patient and prepare for removal of device and fluid path connections.

6.4 Alerts

An alert is a warning 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. If the 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 one time) and **ON BATTERY** / **LOW BATTERY** (audio reactivates every 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.

6.5 Battery Operation

The Console is designed for operation on AC power; however, it also contains an internal rechargeable battery and charger. If a power failure causes loss of AC power or patient transport is necessary, a new fully charged internal battery will operate the Console and Pump for a minimum of 60 minutes at 3,500 rpm, 5.5 LPM. The switch from AC power to battery power is automatic and is accomplished without interruption of patient support.

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WARNING

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

If the Console is operating on batteries and a BATTERY BELOW MINIMUM alarm message is displayed, the Blood Pump will stop. AC power must be restored or another Console must be connected to the Blood Pump in order to resume Pump operation.

CAUTION

Always operate the system at the lowest acceptable clinical flows when operating ON Batteries to conserve remaining Battery time. Keep flows above 2.0 LPM and administer appropriate anticoagulation at all times.

CAUTION

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

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

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

6.6 Patient Transport

As shown in Figure 11, The CentriMag 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 Back-Up Console is only provided to function as an emergency back-up unit should the Primary Console malfunction. The Back-Up Console should be mounted beneath the Primary Console. In this configuration, the handle on the Primary Console may be used to carry and lift both units. The Primary and Back-Up Consoles may be connected to a portable stand (Figure 11), or placed on a CentriMag Cart (Figure 12) so that the units can be moved together during transport.

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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 replacement Primary Console becomes available.

Figure 11: Primary & Back-Up Consoles Mounted on Portable Stand

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Figure 12: Primary & Back-Up Consoles Mounted on CentriMag Console Cart

In some instances, a patient on CentriMag System support may need to be transported. If a patient needs to be transported to another medical center, the following information should be considered. Planning ahead and being prepared is important and makes any transport easier.

6.6.1 Transport Vehicle Qualification

1. Planning adequate space is crucial. Review physical hardware specifications provided in Appendix II and consider the total number of devices included in the applicable configuration.

2. Satisfactory operation should be expected from a nominal 100-240 VAC 50-60 Hz sine wave source with at least 500 watt capacity or from a 100-240 VAC 50-60 Hz quasi-sine wave source. A square-wave VAC source should not be used. The Primary Console can be operated on its internal battery for short periods of time. The Back-Up Console may also be operated on batteries.

6.6.2 Console Considerations

1. Make sure Primary Consoles internal batteries are fully charged prior to transport.

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2. Make sure a CentriMag Back-Up Console with extra sets of Battery Modules or a 2nd CentriMag Primary Console with a fully charged battery is available for back-up support.

3. The CentriMag Back-Up Console or a 2nd CentriMag 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 Console in a location where the display is visible.

6. Each CentriMag Primary Console 120 watts power consumption. Make sure that the vehicle is able to provide the necessary power for all of the primary and backup equipment.

7. When you have reached the destination, unplug the Console's power cord prior to transport-vehicle shutdown and confirm operation on battery power.

8. Monitor battery runtime. Primary Console has a maximum battery runtime of 60 minutes at 3,500 rpm and 5.5 LPM when fully charged. Much, if not all, of this runtime can be consumed during the transfer from the ambulance to the ICU and back. Remember that a Back-Up Console is available, if needed.

   NOTE: To be available for emergency use, the Back-Up Console and Motor must be at all times be in close proximity to the Primary Console.

9. Fasten the Console to the ambulance/aircraft with appropriate straps or fixture to prevent movement.

6.6.3 Examples of Additional Equipment and Supplies to Consider during Transport

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. Straps to secure Console.

4. Supplies (sterile blood pump, tubing, prime solution, etc.) and instruments (sterile tubing clamps and scissors) necessary to replace a blood pump,

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connector, oxygenator, or other component of the extracorporeal circuit that may be damaged during transport.

5. Uninterruptible Power Supply (UPS). Thoratec has qualified the “APC Back-UPS RS 1500” (Figure 13) for this purpose. Additional information about this unit and other APC UPS models can be obtained from APC’s website at http://www.apc.com.

   Since the CentriMag Back-Up Console power consumption is identical to the CentriMag Primary Console, the APC Back-UPS RS 1500 Model and the APC Back-UPS RS 1500 with the add-on BR24BP Module are suitable as off-the-shelf power sources for the CentriMag Back-Up System. The APC Back-UPS RS 1500 Model with the add-on BR24BP Module are recommended for patient transport periods greater than 2 hours.

Figure 13: APC RS-1500 Model (Front and Back Panels) next to the Battery add-on module (BR24BP)

Other UPS models may be used after they have been qualified by Thoratec for safe operation of the CentriMag System. Please contact Thoratec Technical Support for system runtime information about the APC BACK-UPS RS 1500 or if you wish to use other brands and models.

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7 MAINTENANCE

Instructions for how to change the fuses and maintain the Console are provided below.

7.1 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 operating 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 T4AL 250V fuse (4 Amp, 5 mm x 20 mm, time delay 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.

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7.2 Maintenance Following Each Patient Use

WARNING

DO NOT spray bactericidal solution directly on the Console. Spray bactericidal or cleaning solutions on a cloth, and then wipe surfaces with the cloth.

Immediately after using the Console for a patient procedure, the Console should be thoroughly cleaned using the following procedure:

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

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

3. Reconnect AC power when cleaning is completed.

WARNING

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

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7.3 Recommended Preventive Maintenance

The services listed in Table 11 are to be performed by qualified personnel trained by Thoratec. These maintenance processes are only to be performed off-patient.

Table 11: Primary Console Maintenance Schedule

Required Action	After Each Use	Every 6 Months	Every 12 Months
Perform Battery Maintenance: Contact Thoratec Technical Support for specific instructions for performing battery maintenance.		X	X
Verify the general condition of the Console. If any damage is present return the Primary Console back to Thoratec for service.	X	X	X
Verify that all labels on the Primary Console are present and legible.	X	X	X
Verify that the leakage currents comply with the requirements of IEC 60601-1. Refer to Appendix II for specific electrical safety requirements for the CentriMag Primary Console.			X
Verify that the ground resistance complies with the requirements of IEC 60601-1.			X

To avoid shipping damage the CentriMag hardware (Primary Console, 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.

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8 EMERGENCY

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 Back-Up Console or Motor.

WARNING

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

8.1 Switching to Back-Up Hardware

Should the CentriMag Primary Console or CentriMag Motor cease to function, it will be necessary to replace the hardware by disconnecting the Blood Pump and Motor assembly and switching to a Back-Up Console and back-up Motor. Switching to a Back-Up Console and Motor is performed in accordance with the steps shown in Figure 14. Whenever possible, 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 Back-Up Console and Motor are as follows.

Clamp the outlet tubing while lowering the RPM to zero prior to turning the Console 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 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. If the Motor's round LEMO connector is not already connected, connect to the mating receptacle on the back-panel of a Back-Up Console. Pumping operation may now be reestablished via the Back-Up Console by increasing the RPM on the Back-up Console to approximately while slowly unclamping the Blood Pump outflow tubing. Pump operation should be returned to the last operating condition of the Blood Pump prior to hardware replacement. Be sure to reset options and alarms to match those selected before hardware exchange.

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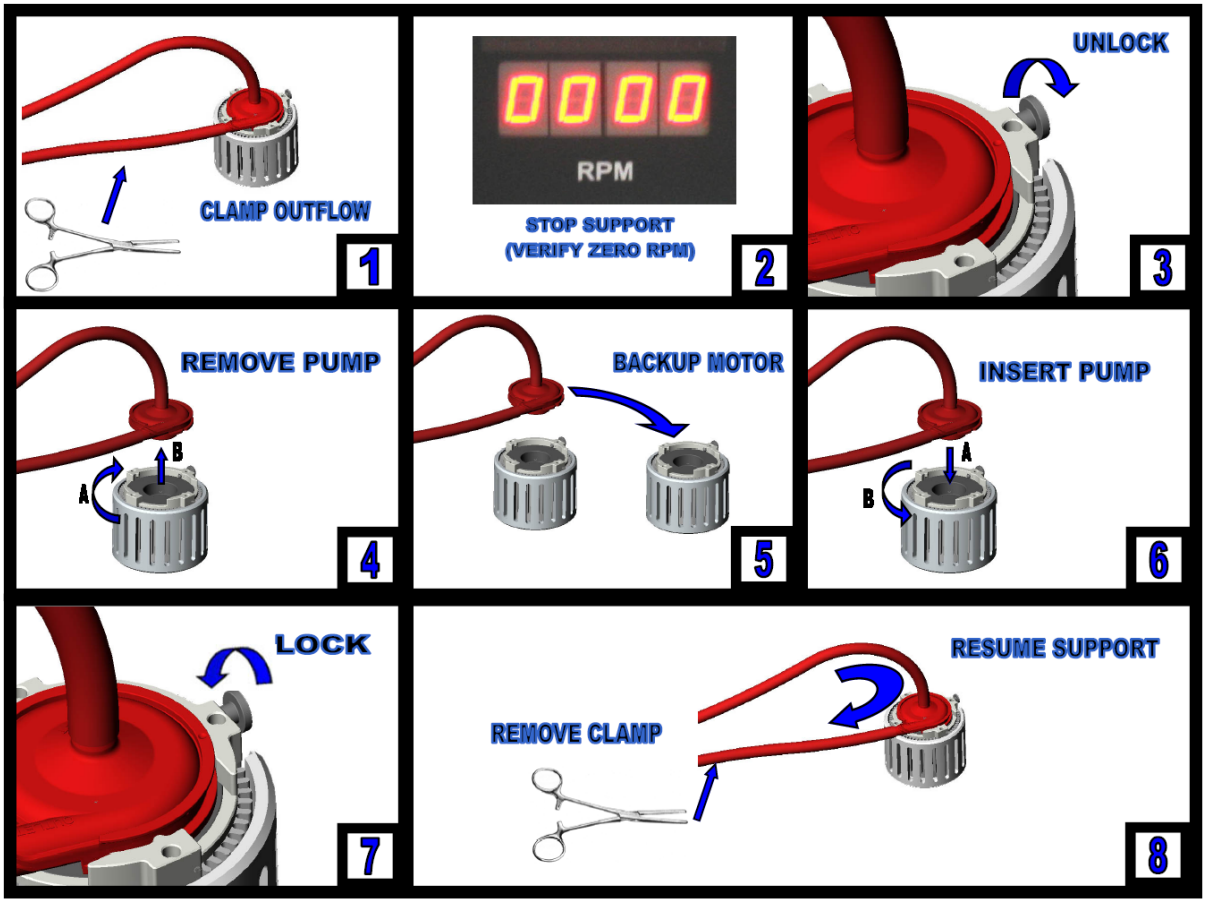

Figure 14: Emergency Switch to Backup System

In some instances when the Blood Pump has been OFF for more than five minutes or if there has been a Motor Overheating condition, it will be necessary to also replace the Blood Pump and circuit. To do so, disconnect the Blood Pump and any affected tubing. Attach the Blood Pump per the standard procedure, prime and debubble. Operate the Console as described in Section 6.

NOTE: To be available for emergency use, the Back-Up Console and Motor must be in close proximity to the Primary Console and plugged into AC power, with the main power switch OFF. The remaining battery power 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 Back-Up Console's Battery Module must be checked on a periodical basis. Operate the Console as described in Section 6.

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8.2 Switching to another Blood Pump

WARNING

DO NOT restart the Blood Pump if it has stopped due to Motor overheating. Immediately clamp the outlet tubing, confirm overheating has occurred by checking the temperature of the motor, and if confirmed, take emergency step to either terminate support and remove all circuit components or replace the entire circuit (tubing, Pump, Motor and Console).

CAUTION

Always fully unscrew the Pump retaining screw before inserting the Pump. Failure to do so may inhibit the ability to fully insert the Pump resulting in loss of function and a MOTOR FAIL alarm. Should this condition occur, remove the Pump, unscrew the retaining screw, reboot the Console by turning the power off and then back on, reinsert the Pump, tighten the retaining screw and resume pumping.

DO NOT restart the Blood Pump if it has stopped due to Motor overheating. Immediately clamp the outlet tubing and take emergency step to either terminate support and remove all circuit components or replace the entire circuit (tubing, pump, motor and console).

8.3 Defibrillation/ Cardioversion

Defibrillation or Cardioversion may be necessary during severe arrhythmia. It is recommended that the Blood Pump be removed from the Motor receptacle before defibrillation. If the patient's condition does not permit the pump to be stopped prior to cardioversion, cardioversion may be performed without stopping the pump. Under this condition insure a Back-Up System is available in the event of a primary system malfunction.

In the event that the Pump is to be removed from the Motor for Cardioversion, always stop the Blood Pump and clamp the outlet line of the circuit prior to removing it from the Motor. Return the Blood Pump to the Motor receptacle after defibrillation and insert per the instructions above. Unclamp the outlet line, and return to the desired operating condition after the Defibrillation or Cardioversion procedure has been completed.

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WARNING

After defibrillation or cardioversion is performed, ensure that the Console is working correctly.

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9 DISPOSAL OF EQUIPMENT

The user may not replace the internal battery. Request assistance by calling Thoratec Customer Service if the internal battery needs to be replaced.

At the end of the Console's useful service life, all parts are to be sent back to Thoratec for proper disposal. Please contact Thoratec for any special return instructions.

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APPENDIX I – CENTRIMAG PRIMARY CONSOLE ALARMS & ALERTS

No.	Alarm/ Alert	Description	System Response	Operator Response
1	Alarm	POWER ON TEST FAIL	Blood Pump will not start	Attempt Console re-boot; switch to Back-Up Console if error repeats.
2	Alarm	SYSTEM FAULT (Run-Time System Failure)	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
3	Alarm	BATTERY BELOW MINIMUM	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor. Recharge primary Console.
4	Alarm	MOTOR DRIVE FAIL	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
5	Alarm	MOTOR FAIL	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
6	Alarm	MOTOR DISCONNECTED	No Blood Pump operation	Reconnect Motor and re-start. Switch to Back-Up Console and back-up Motor if alarm repeats.
7	Alarm	PUMP NOT INSERTED	No Blood Pump operation	Reconnect Blood Pump to Motor and re-start. Switch to Back-Up Console and back-up Motor if alarm repeats.
8	Alert	SET PUMP SPEED NOT REACHED	Pumping operation continues	Reduce Pump speed.
9	Alert	FLOW PROBE DISCONNECTED	Pumping operation continues	Manually connect the flow probe. Switch to back-up flow probe if alert repeats.
10	Alert	SELF TEST FAIL (Run-Time Diagnostics)	Pumping operation continues	Switch to Back-Up Console and back-up Motor.
11	Alert	FLOW SIGNAL FAIL (Flow rate sensor error)	Pumping operation continues	Switch to back-up flow probe.
12	Alert	FLOW BELOW MINIMUM (Low Flow)	Pumping operation continues	Check for physiologic cause or circuit obstruction. Check minimum flow set point. Do not increase RPM without confirming adequate blood volume. *See Warning Below.
13	Alert	FLOW ABOVE MAXIMUM	Pumping operation continues	Reduce Pump speed and check for cause.
14	Alert	MOTOR OVER TEMP	Pumping operation continues	Switch to Back-Up Console and back-up Motor.
15	Alert	BATTERY CHARGE FAIL	Pumping operation continues	Switch to Back-Up Console and back-up Motor. Return Console to Thoratec for service or repair.
16	Alert	BATTERY MAINTENANCE REQUIRED	Pumping operation continues	Console does not need to be changed out. Perform Battery Maintenance as detailed in Table 11 after support has been discontinued.
17	Alert	LOW BATTERY	Pumping operation continues	Plug into AC outlet to charge battery.
18	Alert	ON BATTERY	Pumping operation continues	Verify user wants to be on battery. If not, switch to AC power.

WARNING

Increase Blood Pump RPM in small increments to minimize the risk of causing ventricular suction and cavitation.

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APPENDIX II – TECHNICAL SPECIFICATION

CENTRIMAG PRIMARY CONSOLE	
PARAMETER	**SPECIFICATIONS**
AC Power	100 – 240 VAC at 50/60 Hz, 120 W
Battery Type & Chemistry	Rechargeable internal battery, Nickel Metal Hydride (NiMH)
Battery Voltage	20.4 Volts
Available Battery Time	Approx. 60 min @ 3,500 rpm, 5.5 LPM
Battery Recharge Time	4 hrs to 90% charge, 5 hrs to 100% charge
Dimensions	Height: 21.2 cm / 8.4 in Width: 26.0 cm / 10.2 in Depth: 32.0 cm / 12.6 in
Weight	6.6 kg / 15 lbs
Pump Speed Range	0 – 5,500 revolutions per minute (RPM)
Pump Flow	0.0 – 9.9 liters per minute (LPM)
Language Options	English, Dutch, French, German, Italian and Spanish
Serial Output	For Thoratec use only.
Electrical Safety	Earth leakage current: < 500 µA Enclosure leakage current: < 100 µA Patient leakage current: < 10 µA
Fuse	Two T3.15A, 250V fuses (3.15 Amp, 5 mm x 20 mm, time delay fuse)
Shipping Condition	Temperature: -35°C to 65°C / -31°F to 149°F Relative humidity: 0% to 95%
Operational & Storage Conditions	Temperature: 10°C to 30°C / 50°F to 86°F Relative humidity: 30% to 75%

Primary Console Application Software	**Version 2.01**

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APPENDIX III – SIMILARITIES & DIFFERENCES BETWEEN PRIMARY & BACK-UP CONSOLE

Function	CentriMag Primary Console	CentriMag Back-Up Console
Pump Speed (RPM) Range	0 – 5,500 RPM	0 – 5,500 RPM
Flow Range	0 – 9.9 LPM	0 – 9.9 LPM
Flow Sensing Capability	Yes	No
Pressure Sensing Capability	Yes	No
Display	Alphanumeric Digital Display	Alphanumeric Digital Display
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 – 240 VAC at 50/60 Hz, 120 W	100 – 240 VAC at 50/60 Hz, 150 W
Battery Power	Yes	Yes
Battery Type	Rechargeable	Non-Rechargeable
Battery Chemistry	Nickel Metal Hydride (NiMH)	Alkaline Manganese
Battery Voltage	20.4 Volts	31.5 Volts
Available Battery Time	Approx. 60 min @ 3,500 rpm, 5.5 LPM	Approx. 110 min @ 3,500 rpm, 5.5 LPM
Weight	6.6 kg / 15 lbs	6.0 kg / 13.2 lbs (With Battery Module)
Dimensions	Height: 21.2 cm / 8.4 in Width: 26.0 cm / 10.2 in Depth: 32.0 cm / 12.6 in	Height: 10.2 cm / 4.0 in Width: 32.5 cm / 12.8 in (with Battery Module) Depth: 33.0 cm / 13.0 in

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