HeartMate III™

Left Ventricular Assist System

Instructions for Use

THORATEC®
CORPORATION

Thoratec Corporation

HEARTMATE III™ LEFT VENTRICULAR ASSIST SYSTEM

Instructions for Use

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INTRODUCTION

This section provides an introduction to the HeartMate III Left Ventricular Assist System.

1 Introduction

Preface

This manual contains information needed to properly and safely operate the HeartMate III™ Left Ventricular Assist System. Users of the HeartMate III Left Ventricular Assist System should have a practical knowledge of the principles of mechanical circulatory support, and should be aware of the physiological and psychological needs of a patient undergoing mechanical ventricular support. New users should read this document in its entirety before system operation. For experienced practitioners, this manual may serve as a reference.

As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. The professional staff at Thoratec® Corporation regularly provides laboratory training and on-site, in-service programs.

Understanding Warnings and Cautions

In this manual, warnings and cautions that are relevant to a specific procedure or piece of equipment appear at the start of each applicable section.

Warnings refer to actions or hazardous conditions that could cause serious injury or death if not avoided. Ignoring a warning can cause sudden and serious injury, life-threatening harm, or death for the user or patient.

WARNING !

Warnings appear in the manual in this format.

Cautions refer to actions or potentially unsafe conditions that may cause injury to a patient or user, damage the equipment, or affect how the system works. Ignoring a caution can cause the patient or user injury, or result in equipment failure or sub-optimal system operation. Although important for maximum safety and optimal system function, usually cautions do not refer to life-threatening risks.

CAUTION !

Cautions appear in the manual in this format.

1 Introduction

Overview

The HeartMate III Left Ventricular Assist System (LVAS) includes equipment and materials that together comprise a medical device designed to provide therapeutic benefit to those affected with advanced heart failure. In service, the LVAS assumes some or all of the workload of the left ventricle, thereby restoring the patient's systemic perfusion while palliating the underlying pathology.

The LVAS features a Left Ventricular Assist Device (a blood pump intended for long-term implantation) and an extracorporeal System Controller. Additionally, it includes all of the features, controls, attachments, interfaces, power sources, supporting equipment, labeling, and tools required to achieve therapeutic benefit.

The LVAS may be used in any of two configurations:

- Line power may be utilized through the Power Module or the Mobile Power Unit™ to run the LVAD indefinitely. This is convenient for sedentary or sleeping periods.

  Whenever the Power Module is used, a System Monitor may also be used as a means of viewing operating conditions, changing operating parameters, and manipulating stored data.

- Portable Battery power may be utilized for limited periods. This is convenient for active periods.

The bifurcation of the Patient Cable allows for switching among these configurations, or from a set of depleted batteries to a set of fully-charged batteries, without interrupting LVAS function.

A set of user manuals provides instructions at various levels appropriate for users to explain how to use the equipment, and how to interpret and respond to alarms. The LVAS is packaged for safe transport and effective use in an operating room under sterile conditions.

The HeartMate III LVAD is part of the LVAS (**Figure 1.1**).

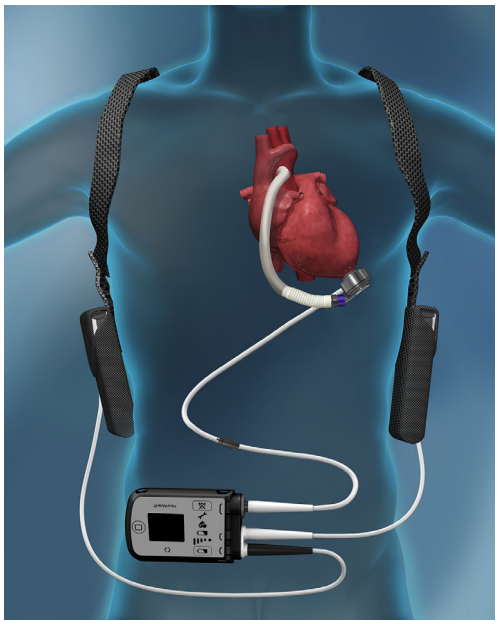


Figure 1.1 HeartMate III LVAS During Battery-Powered Operation

The LVAD is a blood pump intended for long-term implantation in the thorax of patients affected with advanced heart failure. The LVAD contains the Inflow Cannula, a Motor, a Pump Chamber, a Rotor, an Outflow Graft, and a Pump Cable (**Figure 1.2**).

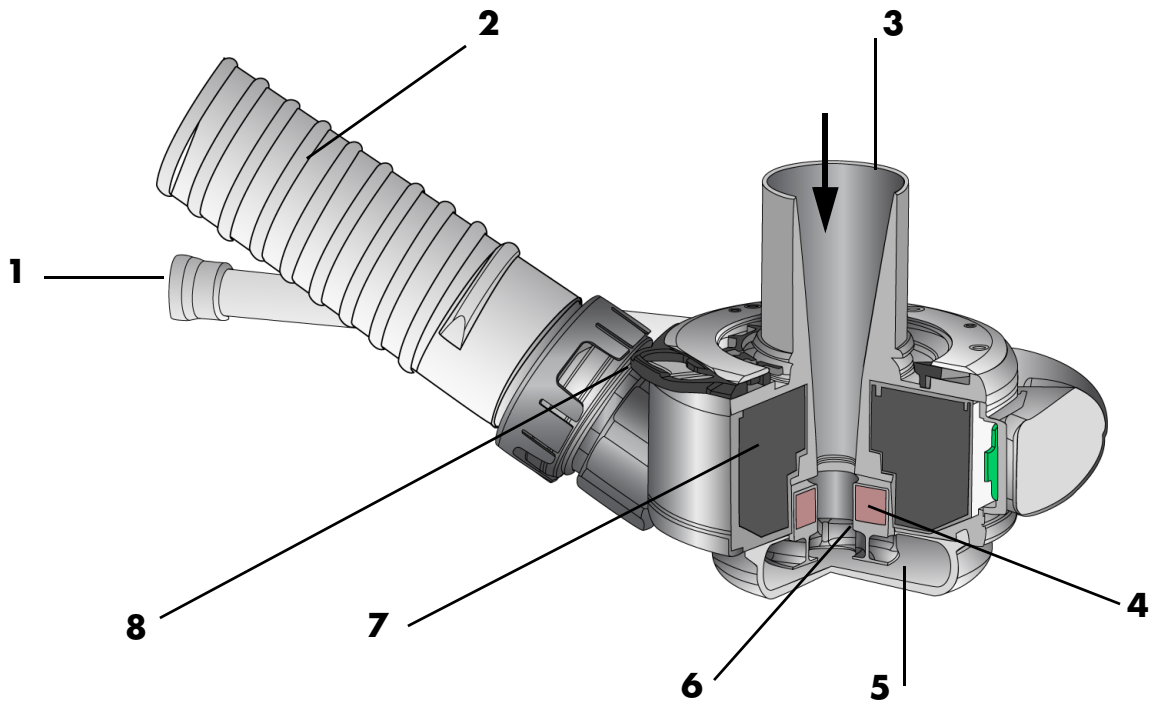


Figure 1.2 Left Ventricular Assist Device Components

1	**Pump Cable**
2	**Outflow Graft with Bend Relief**
3	**Inflow Cannula**
4	**Rotor Magnet**
5	**Pump Chamber**
6	**Rotor**
7	**Motor**
8	**Slide Lock**

1 Introduction

The LVAD is surgically connected to the patient's circulatory system via an Inflow Cannula. It is placed into the left ventricular apex, and an Outflow Graft anastomosed to the ascending aorta.

The LVAD is a centrifugal pump. Ventricular blood is drawn into the Inflow Cannula along a central axis and is expelled at right angles by, and between, the impeller blades of a Rotor that is rotating around the central axis. The fluid, thus angularly accelerated, collects and travels around a volute before it is diffused to the preferred pressure and flow rate by being directed tangentially into the Outflow Graft.

The Rotor is fully supported by magnetic levitation, obviating mechanical or fluid bearings, and essentially eliminating Rotor mechanical wear as a reliability factor. Both drive (that is, rotation) and levitation of the Rotor is accomplished using a single Stator comprising iron pole pieces, a back-iron, copper coils, and position sensors. By measuring the position of a permanent magnet in the Rotor, and appropriately controlling the current in the drive and levitation coils, the radial position and rotational speed of the Rotor is actively controlled. Because of the permanent magnet's attraction to the iron pole pieces, the rotor passively resists excursion in the axial direction, whether such excursion is translation or tilting.

The electronics and software necessary to control motor drive and levitation are integrated into the Pump with the Stator. All of these components, along with the Rotor, comprise the Motor.

The Inflow Cannula is a cylindrical conduit with external size and features similar to those of the HeartMate II® LVAD. It is rigidly affixed to the Pump Cover. During the implantation procedure, a Coring Tool is used to resect a plug of myocardium at the left ventricular apex. This allows insertion of the Inflow Cannula into the left ventricle. An Apical Cuff is sewn to the epicardium, and a Slide Lock is used to secure the Inflow Cannula and establish hemostasis.

The Outflow Graft assembly consists of a sealed woven polyester graft and the hardware necessary to attach the graft to the Pump Cover. This hardware is similar to that of the HeartMate II LVAD, and can be swiveled to correct any twist that may develop during Pump placement. This type of connection allows the clinician to attach the outflow to the Pump at any time during the implantation procedure and assists with de-airing of the system. The distal end of the graft is designed to be cut to the preferred length, and sutured to the ascending aorta by an end-to-side anastomosis. Only the graft should be cut, not the bend relief. A reinforced tube serves as a bend relief around the Outflow Graft to prevent kinking and abrasion. The bend relief can be attached or removed, and reattached during the implantation procedure. If necessary, the Outflow Graft may be detached from the Pump, permitting Pump replacement without re-anastomosis.

A Pump Cable is permanently attached to the Pump to establish electrical connection with the enclosed Motor via a hermetically sealed feed-through. This Pump Cable is tunneled through subdermal abdominal tissue via a Tunneling Tool. It is then exteriorized through a skin wound, prepared with a Skin Punch, at a location deemed optimal for the patient and his or her equipment. The Pump Cable extends only a few inches through this site. It is extended with a Modular Cable, which connects the Pump (through the Pump Cable) to a System Controller. If necessary, the Modular Cable is readily replaceable without surgery.

When connected, the Pump Cable and Modular Cable comprise the Driveline. The Driveline contains duplicate sets of three conductors: two for power and ground, and a third for communication.

The HeartMate III System Controller is also part of the Left Ventricular Assist System (LVAS). The System Controller is an extracorporeal interface device that receives power from the Power Module, the Mobile Power Unit, or portable batteries. It appropriately delivers power to the LVAD. It is the primary user interface and has several important functions:

- Operating condition display
- Source of audible and visible alarms
- Communication link for transferring event/period log and alarm information
- Battery backup in the case of full power disconnection

WARNING !

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using the HeartMate III Left Ventricular Assist System. Read this entire manual before attempting implantation of the Left Ventricular Assist Device or before caring for HeartMate III patients. Completion of the Thoratec Corporation HeartMate III Surgical Training Program is also required prior to use.
- Understanding the operating and safety aspects of the HeartMate III Left Ventricular Assist System is critical for safe and successful use.
- All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use.
- All users, including clinicians, patients, and caregivers, must be trained on any HeartMate III power accessories (Power Module, Mobile Power Unit, Battery Charger, or HeartMate® 14 Volt Lithium-Ion batteries) before use.
- Do not use the HeartMate III Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the Pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Do not modify this equipment without authorization from Thoratec Corporation. The use of unauthorized replacement parts may affect the electromagnetic compatibility of the Mobile Power Unit with other devices. Potential interference may occur between the Mobile Power Unit and other devices.
- Certain parts of the HeartMate III Left Ventricular Assist System are not compatible with other HeartMate systems. Only use HeartMate III parts with the HeartMate III system.
- The HeartMate III Pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.

CAUTION !

- Clinical procedures (including LVAS settings) should be conducted under the direction of the prescribing physician (Authorized Personnel) only.
- Do not try to repair any of the HeartMate III system components. If components need service, contact the appropriate personnel.
- Notify the appropriate personnel if there is a change in how the Pump works, sounds, or feels.
- Counsel the patient to avoid contact sports and jumping activities while implanted with the Pump. Contact sports or jumping can cause bleeding or damage the Pump.
- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.
- If HeartMate III patients are approved for showering, they must always use the Shower Bag. When installed properly, the Shower Bag protects external system components from water or moisture. If external system components have contact with water or moisture, the Pump may stop.

Indications

The HeartMate III Left Ventricular Assist System is intended to provide long term hemodynamic support in patients with advanced, refractory left ventricular heart failure. It is intended either for temporary support, such as a bridge to cardiac transplantation (BTT), or as permanent destination therapy (DT). The HeartMate III is intended for use inside or outside the hospital.

Contraindications

The HeartMate III Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

Adverse Events

The following adverse events may be associated with the use of the HeartMate III Left Ventricular Assist System. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first as it is a non-reversible complication:

- Death
- Bleeding (perioperative or late)
- Local infection
- Cardiac arrhythmia
- Respiratory failure
- Sepsis
- Driveline or Pump pocket infection
- Right heart failure
- Renal failure
- Psychiatric episode
- Stroke
- Peripheral thromboembolic event
- Hepatic dysfunction
- Neurologic dysfunction
- Hemolysis

Pre-Use Requirements

A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is required before using the HeartMate III Left Ventricular Assist System.

It is suggested that patients possess a minimum 5th grade educational level and shall be versed in basic computer literacy (that is, Microsoft® Windows® and Office software).

This manual contains important warnings, cautions, and instructions for use. Read this entire manual before implanting a HeartMate III Left Ventricular Assist Device or before caring for HeartMate III patients. Completion of the Thoratec Corporation HeartMate III Surgical Training Program is also required.

Contact Thoratec Corporation with any questions regarding this manual. Refer to page iii for Thoratec Corporation contact information.

Equipment Overview

Table 1.1 introduces the main parts of the system. For more information regarding descriptions and use of additional accessories, refer to *Patient Care and Management* on page 6-1.

Table 1.1 HeartMate III System Components

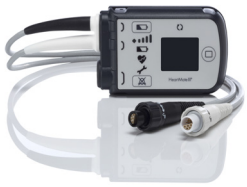
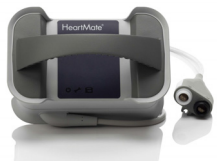
Left Ventricular Assist Device 	The HeartMate III Left Ventricular Assist Device (also called the Pump) is implanted in the chest below the heart. One end is inserted into the apex of the left ventricle. The other end connects to the ascending aorta. The Pump diverts blood from the weakened left ventricle and pumps it to the aorta.
System Controller 	The System Controller is a small computer that controls and monitors system operation. A Driveline connects the implanted Pump to the System Controller. The System Controller uses lights, sounds, and on-screen messages to communicate with users about operating status and alarm conditions.
14 Volt Lithium-Ion Batteries and 14 Volt Battery Clips  	Two HeartMate 14 Volt Lithium-Ion batteries power the system during battery-powered operation, such as when AC electricity is not wanted or unavailable. The batteries are used in pairs, and are inserted into a 14 Volt battery clip. Both batteries are discharged together: not one, then the other. Two power cables are required to transfer battery power to the System Controller. When fully charged, a pair of HeartMate 14 Volt Lithium Ion batteries can power the system for up to 10–12 hours, depending on the activity level of the patient.
Modular Cable 	The Driveline consists of two cables: the Pump Cable and the Modular Cable. One end of the Pump Cable connects to the Pump implanted in the patient's abdomen. The other end of that cable exits the patient's body. One end of the Modular Cable is connected to the Pump Cable and the other end connects to the System Controller.

Table 1.1 HeartMate III System Components (Continued)

Power Module 	The Power Module is for clinical use. It provides power to the HeartMate III system. The Power Module is used when the patient is indoors, stationary, or sleeping. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller.
Power Module Patient Cable 	The Power Module patient cable connects the Power Module to the System Controller.
Mobile Power Unit 	The Mobile Power Unit is for home or clinical use when the patient does not require monitoring using the System Monitor. The Mobile Power Unit is used when the patient is indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.
System Monitor 	The use of the System Monitor during Left Ventricular Assist Device implantation is required. The System Monitor provides clinicians with the ability to monitor a patient's HeartMate system, program system parameters (such as pump speed), assess and track alarm conditions, and view and save performance data.
Battery Charger 	The Battery Charger calibrates, charges, and tests the HeartMate 14 Volt Lithium-Ion batteries that are used to power the system during battery-powered operation.

Components and Equipment for Implant

The HeartMate III LVAS is designed for use both inside and outside of the hospital. Specific system components and equipment may be required for each setting. For a complete list of HeartMate III products and catalog numbers, refer to the *HeartMate III™ Product List* at www.thoratec.com.

Table 1.2 lists the components and equipment that are required for implant and ICU transfer.

Table 1.2 Components and Equipment for Implant

Components Required for Implantation and ICU Transfer	Primary	Backup
HeartMate III Implant Kit*	Required	Required
System Controller with 11 Volt Lithium-Ion Backup Battery	Required	Required
Power Module with patient cable	Required	Required
System Monitor	Required	Required
One set of 4 rechargeable HeartMate 14 Volt Lithium-Ion batteries	Required	Not required
One set of 2 HeartMate 14 Volt battery clips	Required	Not required
Battery Charger	Required	Not required
HeartMate III Tunneling Lance and Handle**	Required	
Apical coring knife**	Optional	
Skin coring punch (6 mm)*	Optional	
Apical cuff**	Optional	
Outflow Graft Thread protectors**	Optional	
Modular Cable Cap	Optional	

* Some optional items are included in the HeartMate III Implant Kit.

** Also available separately.

Components and Equipment for Discharged Patients

Table 1.3 lists components and equipment that are required for a discharged patient. Patients discharged to a lower care facility or to their homes must be trained in device use, maintenance, and troubleshooting. In addition, device malfunction may necessitate emergency treatment. Therefore, patients should not be more than two hours from a healthcare facility that has trained personnel who are capable of treating a HeartMate III patient.

Table 1.3 Components and Equipment for Discharged Patients

Components for a Discharged Patient	Primary	Backup
Implanted HeartMate III Left Ventricular Assist Device	Required	n/a
System Controller with 11 Volt Lithium-Ion backup battery	Required	Required
Mobile Power Unit	Required	Not Required
One set of 4 rechargeable HeartMate 14 Volt Lithium-Ion batteries	Required	Required
One set of 2 HeartMate 14 Volt battery clips	Required	Not Required
Battery Charger	Required	Not Required
One set of wear and carry accessories, including: Shower Bag, Protection Bag for backup System Controller, Holster Vest, Belt Attachment, and System Controller Neck Strap	Required	Not Required
HeartMate III Patient Handbook	Required	Not Required

CAUTION !

- Confirm that the patient's backup System Controller has had the Backup Battery installed, and the time and date have been set.
- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial need.

Principles of Operation

The HeartMate III LVAD is a centrifugal pump that produces flow in the patient's circulatory system by angularly accelerating and expelling blood that enters it. From a clinical viewpoint, this mechanical pump works in concert with the native heart to which it is attached. It is a parallel arrangement: Ventricular blood may flow either through the LVAD or the aortic valve to reach the aorta, the proportion of which depends greatly on the degree of the patient's cardiac function and the set-speed of the LVAD.

As with any continuous flow pump (axial, centrifugal, or mixed), the volume flow rate through the Pump is directly related to the pressure across the Pump and inversely related to the resistance. Clinically, the volume flow rate through the Pump is the difference between aortic and left ventricular pressure, and systemic vascular resistance.

This relationship can be characterized at any Rotor speed, and the family of curves derived in steady-state at different speeds is commonly termed **H-Q curves**, or the pressure head (H) - volume flow rate (Q) relationship. **Figure 1.3** shows HeartMate III H-Q curves.

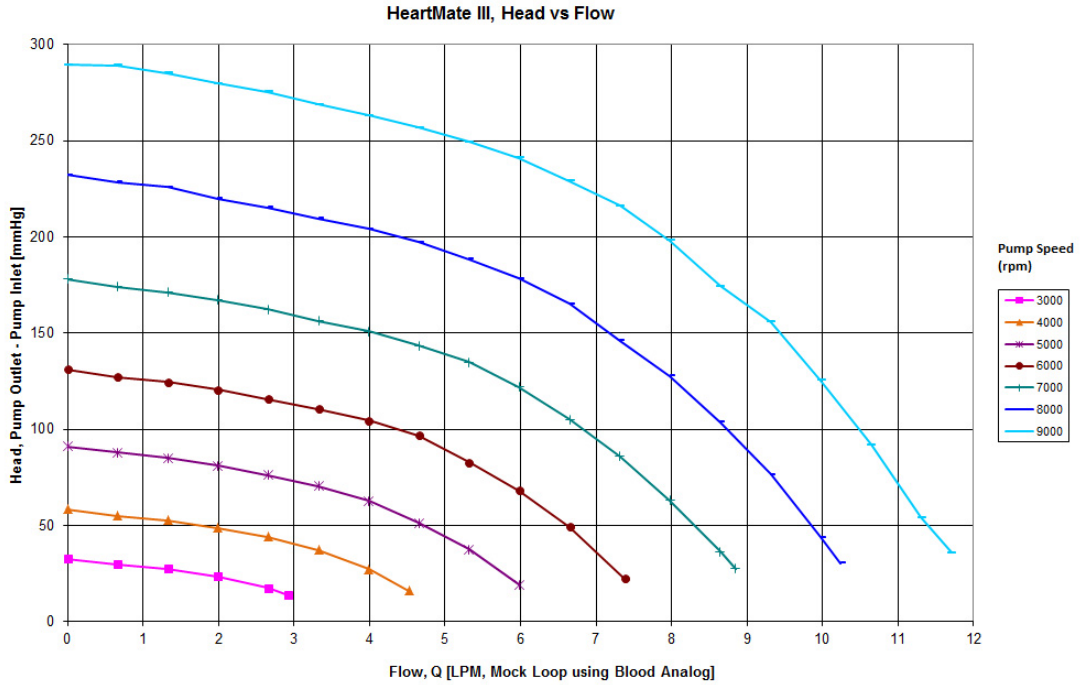


Figure 1.3 Pressure Head-Flow (H-Q) Relationship

Similarly, there is a characteristic relationship between pump power and volume flow rate. Total power consumption includes hydraulic power (useful blood pressure and flow), viscous losses, electrical resistance losses, and others. The relationship between hydraulic power and volume flow rate is always direct, but the various losses have a multitude of dependencies that make inflections in the relationship possible.

In general, if the speed is set optimally, LVAD flow will be unidirectional towards the aorta and much greater than cardiac output. Cardiac output may be minimal or zero if the presence of the LVAD keeps the aortic pressure above the ventricular pressure even during systole.

If the LVAD speed is set *too h*igh, the inflow pressure may fall to the extent that it attempts to recruit blood from the left ventricle, left atrium, and pulmonary vasculature that is not there. This will result in the collapse of the left ventricle and potential arrhythmia. The HeartMate III LVAS employs a feature called Suction Detection to recognize and avert this condition.

When the degree of pulsatility measured in the electrical current waveform has fallen below a preset value, the system regards this as a risk of ventricular suction and quickly lowers the Rotor speed to a preset, programmable Low Speed Limit. It then immediately, but gradually, returns the Rotor to its original speed.

The HeartMate III has an intrinsic limit somewhat above 9000rpm. The system accordingly precludes setting the speed above 9000rpm. Conversely, if the LVAD speed is set too low, support for the failing heart may be insufficient. The HeartMate III LVAS uses the same Low Speed Limit mentioned previously to limit how low the speed may be set. This is to avoid profound retrograde flow (aorto-ventricular shunt). The Low Speed Limit can be set within a range to accommodate customization for a variety of patients.

The HeartMate III employs a feature called Artificial Pulse that adds an element to the discussion about Rotor speed (**Figure 1.4**). Although the clinician will set only a single speed, ω_c in **Figure 1.4**, the Rotor speed will periodically depart from this value to contribute a flow disruption that in some ways mimics native cardiac contractility. This artificial pulse "beats" 30 times per minute, asynchronously with the heart. The Artificial Pulse mode is indicated on the System Controller by the use of a (▲) symbol.

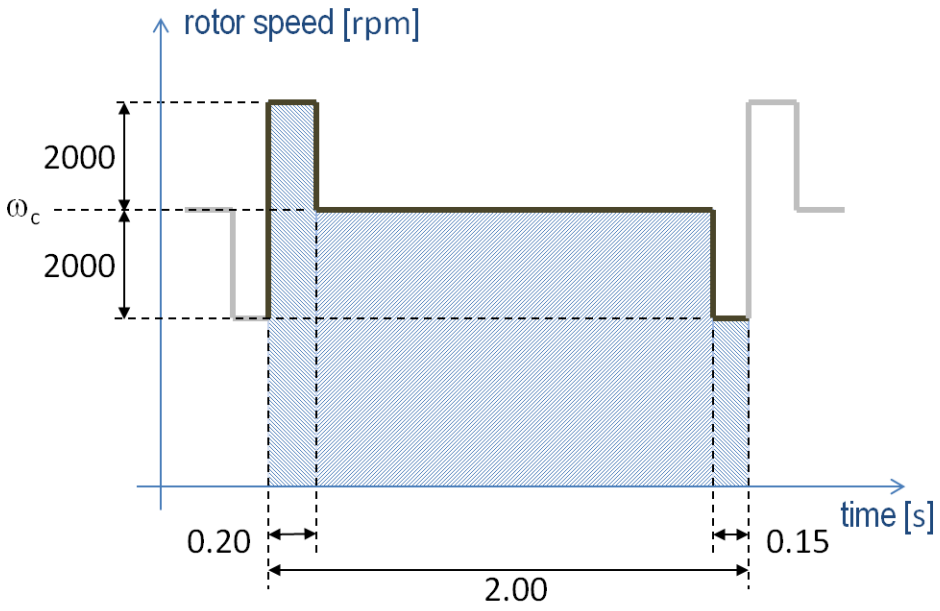


Figure 1.4 Artificial Pulse

Explanation of Parameters

Speed

The HeartMate III Left Ventricular Assist Device operates at a Fixed Speed determined by the physician during a speed ramp study. Refer to *Optimal Fixed Speed* on page 4-19.

Note: The term *Fixed Speed* is a speed that is fixed (or set) by the clinician (that is, ω_c in **Figure 1.4**). This should not be confused with the concept of a **constant speed mode**, as opposed to an **artificial pulse mode**. Either mode requires a Fixed Speed, set by the clinician.

A pre-programmed artificially induced pulse is intermittently generated, changing the Pump speed. The Low Speed Limit for the device is the lowest speed at which it is allowed to operate.

During a suction event, device speed drops to the Low Speed Limit, and then ramps up to the Fixed Speed unless another pulsatility index (PI) event is detected. If another PI event is detected, the device drops to the Low Speed Limit again, and then ramps back up. This cycle repeats as long as PI events are detected. Large changes in speed may indicate an abnormal condition that should be evaluated for cause.

Power

Device power is a direct measurement of Pump motor voltage and current. Changes in Pump speed, flow, or physiological demand can affect Pump power. Gradual power increases, over hours or days, may signal thrombus deposits inside the Pump, or aortic insufficiency. Gradual power decreases may indicate an obstruction of flow and should be evaluated. Depending on the speed of the Pump, power values greater than 10 to 12 watts (W) also can indicate the presence of a thrombus. Abrupt changes in power should be evaluated for cause.

Flow

Device flow and power generally retain a linear relationship at a given speed. However, while power is directly measured by the System Controller, the reported flow is estimated, based on power. Since the flow displayed on the System Controller is a calculated value, it somewhat underestimates actual flow at high flows.

Any increase in power not related to increased flow (such as thrombus) causes erroneously high flow readings. Conversely, an occlusion of the flow path decreases flow and causes a corresponding decrease in power. In either situation, Pump output should be assessed.

Pulsatility Index (PI)

When the left ventricle contracts, the increase in ventricular pressure causes an increase in Pump flow during cardiac systole. The magnitude of these flow pulses are measured and averaged over 15-second intervals to produce a Pulsatility Index (occasionally shortened to "PI" for on-screen messages).

The PI calculation represents cardiac pulsatility. PI values typically range from 1 to 10. In general, the magnitude of the PI value is related to the amount of assistance provided by the Pump. Higher values indicate more ventricular filling and higher pulsatility (that is, the Pump is providing less support to the left ventricle). Lower values indicate less ventricular filling and lower pulsatility (that is, the Pump is providing greater support and further unloading the ventricle).

PI values should be routinely monitored and should not vary significantly during resting conditions. Under otherwise stable conditions, a significant drop in value may indicate a decrease in circulating blood volume. Pulsatility Index values near or above 10 may indicate potential problems. For PI values near 10 or above, contact Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information.

IMPORTANT! One single Pump parameter is not a surrogate for monitoring the overall clinical status of the patient. Any change in parameters should be evaluated with all clinical considerations taken into account.

SYSTEM OPERATIONS

This section describes the primary system operations of the HeartMate III Left Ventricular Assist System.

2 System Operations

HeartMate III Left Ventricular Assist Device Overview

The HeartMate III Left Ventricular Assist Device (LVAD) is a centrifugal flow rotary heart pump that is connected in parallel to the native circulation (**Figure 2.1)**. The Inflow Cannula of the LVAD attaches to the apex of the left ventricle. Its sealed Outflow Graft connects to the ascending aorta. Frequently, the HeartMate III Left Ventricular Assist Device is referred to as the Pump.

Figure 2.1 HeartMate III Left Ventricular Assist Device

Function

The LVAD uses a rotary blood pump to generate flow and assist the left ventricle. It is a centrifugally-configured device so that the paths of the entering and exiting flow stream are perpendicular to the Pump's axis. The device has only one moving part, the Rotor assembly. The Rotor assembly is fully (that is, actively) magnetically levitated within the flow stream. The Pump is driven by an external power source via a Driveline.

The Pump operates in parallel with the heart, such that either can supply blood to the aorta. The LVAD can generate a blood flow up to 10 liters per minute (lpm). Blood enters the Pump from the left ventricle through an Inflow Cannula. Blades on the spinning Rotor move the blood through the Pump to an Outflow Cannula, and ultimately to the native circulation.

Implant Location

The HeartMate III Left Ventricular Assist Device is implanted in the chest (**Figure 2.2**). For more information, refer to *Implant Procedures* on page 5-30.

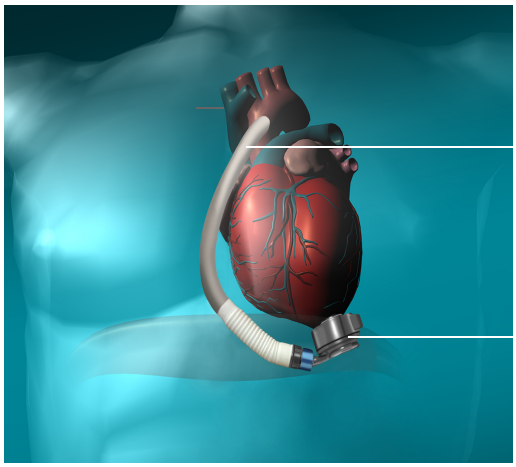


Figure 2.2 HeartMate III Implant Configuration

1	**Outflow Graft**
2	**Inflow Cannula**

The HeartMate III LVAD is part of the Left Ventricular Assist System (**Figure 2.3**).

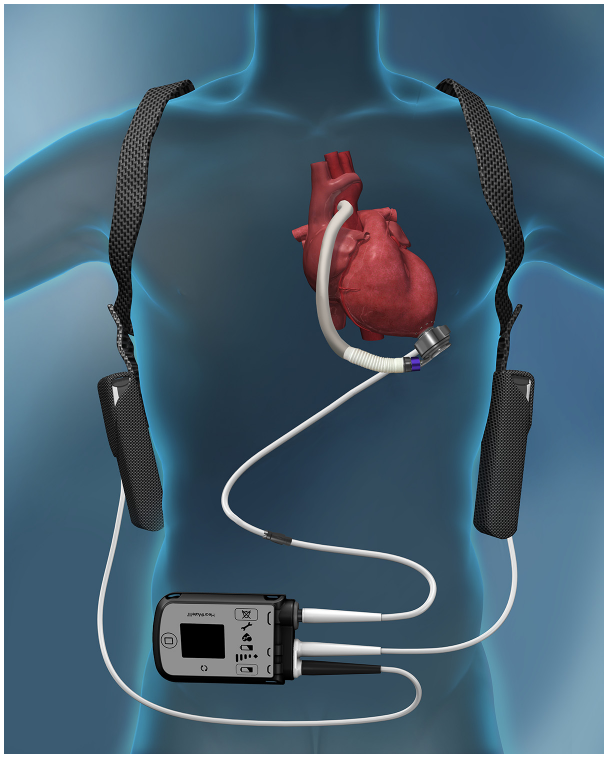


Figure 2.3 HeartMate III LVAS During Battery-Powered Operation

Driveline

The Driveline consists of two cables:

- The Pump Cable, which extends from the LVAD through the skin
- The Modular Cable, which connects the Pump Cable to the System Controller

The Driveline contains six wires: three primary wires and three backup wires. These wires power the Pump Motor and facilitate communication with the System Controller.

To reduce infection, the Driveline is covered with woven polyester, which encourages tissue ingrowth. Over time, tissue bonds to the textured material and anchors the external surface of the Driveline to the surrounding tissue. After emerging from the body, the Driveline has a Modular Connector that joins the Pump Cable to the Modular Cable. The Modular Cable then has an electric connector that attaches to the System Controller.

Experience with other left ventricular assist devices has shown that wear and fatigue of the Driveline may result in damage that can interrupt device function. Such damage may require another operation to replace the Pump, or may result in death. For information about caring for the Driveline, refer to *Care of the Driveline* on page 8-5.

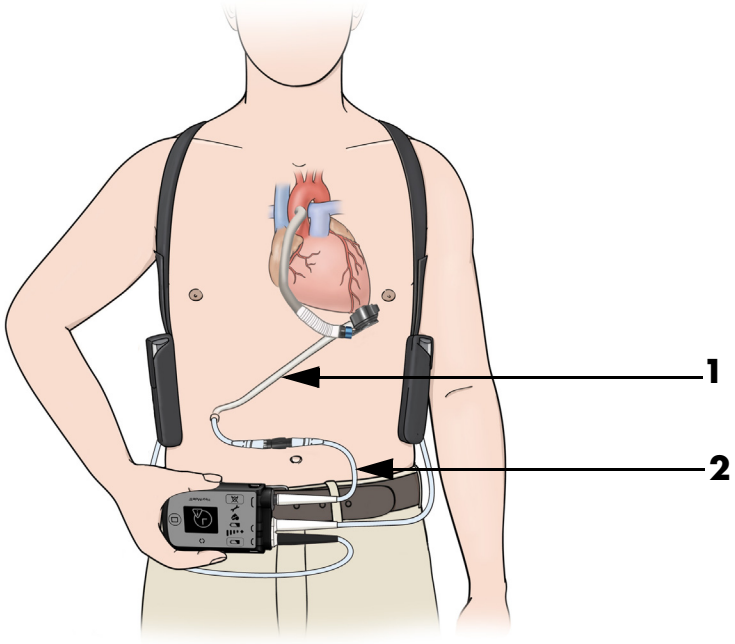


Figure 2.4 Driveline

1	**Pump Cable**
2	**Modular Cable (Referred to as the Driveline when both cables are connected.)**

Driveline damage due to wear and fatigue may occur in both the externalized (Modular Cable) and implanted (Pump Cable) portions of the lead. Damage to the conductors within the Driveline may or may not be preceded by visible damage to the outer layer of the Driveline.

Driveline damage may be evidenced by the following:

- A Driveline Power Fault, Driveline Comm Fault, or Communication Fault alarm on the System Controller
- Transient alarms due to short or open circuits, often associated with movement of the patient or the lead
- Fluid leakage from the external portion of the Pump Cable
- Cessation of pumping

WARNING !

If the Driveline or Driveline connector appears damaged, contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

X-ray images and System Controller log files are useful to assess the extent and location of the damage. If the Driveline or Driveline conductors are damaged internal to the patient's body, the Pump should be replaced as soon as possible. If It has been determined that the damage has been detected in the Modular Cable, it can be replaced. Refer to *Replacing the Modular Cable* on page 2-51 for the procedure for exchanging the Modular Cable.

Pump Motor Power

The Left Ventricular Assist Device Motor is powered through the System Controller by one of three sources:

- Power Module
- Mobile Power Unit
- 2 HeartMate 14 Volt Lithium-Ion Direct Current (DC) Batteries

Note: The Backup System Controller is charged every six months.

Acceptable Operating Conditions

For safe and optimal use of HeartMate system components, follow the operating guidelines listed in **Table 2.1** page 2-7.

CAUTION !

Operating system components outside of the environmental parameters listed in **Table 2.1** may affect device operation or result in equipment failure.

Table 2.1 Operating Conditions

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Power Module	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
Mobile Power Unit	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
System Monitor	50°F to 104°F (10°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
Battery Charger	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
System Controller, Backup System Controller[a,b]	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
11 Volt Lithium-Ion Backup Battery	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)

[a] Standby components (extra 14 Volt Lithium-Ion batteries, backup System Controller) should be maintained at conditions within the acceptable ranges so that they are available for immediate use.

[b] Every six months, the "sleeping" backup System Controller must be connected to a power source to charge the 11 Volt Lithium-Ion backup battery inside. If the 11 Volt Lithium-Ion backup battery inside the backup System Controller is not charged every six months, its charge level will diminish and there may not be sufficient power to support the Pump if the backup System Controller is in use during a power emergency (refer to *Maintaining Backup System Controller Readiness* on page 2-44).

System Controller Overview

The HeartMate III System Controller acts as the central power and communication hub for the HeartMate III LVAS. It passes power from the Power Module, the Mobile Power Unit, Lithium-Ion Batteries, or its own integrated emergency backup supply, down to the LVAD via the Driveline. The System Controller constantly monitors system performance through communication with the implanted LVAD and System Controller internal measurements. It alerts the user to any alarm conditions by activating membrane panel LEDs and integrated audio annunciators. Further

information on alarm conditions, as well as system status, can be attained from the front panel LCD on the System Controller. When connected to a System Monitor, the System Controller sends information regarding the System Controller and Pump Status once per second to provide additional information to the user. This link also allows the clinician to set new patient operating parameters (for example, Pump speed) and provides a link for downloading trend and/or event recorder data.

The System Controller has been designed with redundant power and communication lines to the Driveline. This not only provides for a robust continuous operation of the implanted Pump in the event of a fault situation, but also alerts the user to possible Driveline degradation.

The System Controller is the chief decision-making component of the system. It instructs the Pump at which speed to operate in any of the following ways:

- By passing a command sent by the System Monitor
- When it is in Power Saver mode
- At a Pulsatility Index (PI) event detection

The System Controller connects to the LVAD via a Driveline that passes through the patient's abdomen. The Driveline carries power to the Pump. The Driveline also supplies information from the Pump to the System Controller.

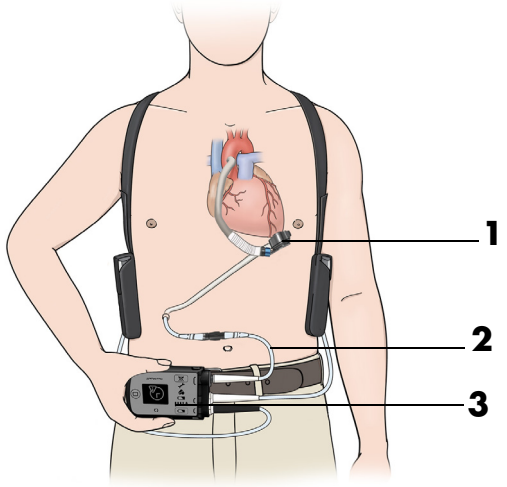


Figure 2.5 HeartMate III Left Ventricular Assist System

1	**HeartMate III LVAD**
2	**Driveline**
3	**System Controller**

The System Controller uses sounds, lights, symbols, and on-screen messages to communicate with users (**Figure 2.6**).

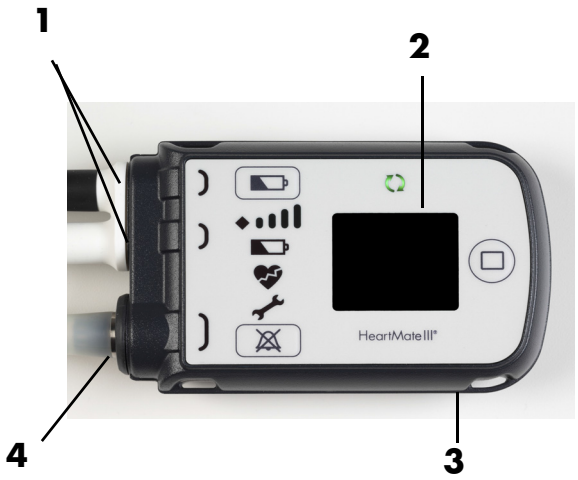


Figure 2.6 System Controller Major Components

1	**Power Cable Connectors**	Two Power Cable Connectors: link external power source (Power Module, Mobile Power Unit, or 2 HeartMate 14 Volt Lithium-Ion Batteries) to the System Controller.
2	**User Interface**	User Interface provides buttons, lights, and a screen where system data, alarms, and user instructions appear.
3	**Backup Battery (not shown)**	Backup battery located inside the System Controller, powers the Pump for at least 15 minutes during a power-loss emergency.
4	**System Controller Driveline Connector**	The System Controller Driveline Connector links the Modular Cable portion of the Driveline to the System Controller.

2 System Operations

The System Controller is described in the following sections:

System Controller Warnings and Cautions
This section provides important information regarding the use and care of the System Controller and its components.

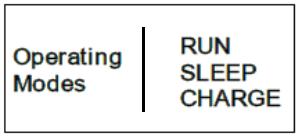
System Controller User Interface Overview
This section provides information about the sounds, lights, symbols, and messages used by the user interface to communicate how the system is working.

System Controller Driveline Connector
This section provides a description of the Driveline Connector, and instructions on connecting and disconnecting the Driveline.

System Controller Power Cable Connectors
This section provides a description of the two power cables on the System Controller (one white and one black) that connect the System Controller to the Power Module, the Mobile Power Unit, or two 14 Volt Lithium-Ion batteries.

Performing a System Controller Self Test
This section provides instructions for the self test.

System Controller Battery Power Gauge
This section provides a description of how to read the Battery Power Gauge, which shows the approximate charge status of the power source that is connected to the System Controller's power cables.



System Controller Operating Modes
This section provides an overview with instructions on how to switch between the operating modes: Run, Sleep, and Charge.

System Controller Backup Battery Power
This section provides a functional overview with instructions on how to replace the 11 Volt Lithium-Ion backup battery that is inside the System Controller.

System Controller Warnings and Cautions

WARNING !

- Check the System Controller Driveline connector to confirm that the Driveline is securely inserted in the socket. If the Driveline disconnects from the System Controller, the Pump stops. If the Driveline disconnects from the System Controller, promptly reconnect it to resume Pump operation.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- Keep the System Controller power cables dry and away from water or liquid. If the System Controller power cables come into contact with water or liquid, the system may fail to operate properly or cause a serious electrical shock.
- Do not allow patients to swim or take tub baths while implanted with the Left Ventricular Assist Device. Patient immersion in water may cause the device to stop.
- Do not allow patients to shower without a doctor's permission. HeartMate III patients may be allowed to shower, but only after sufficient post-operative healing and with a doctor's permission.
- If external system components have contact with water or moisture, the Pump may stop. If a HeartMate III patient is approved for showering, he or she must always use the Shower Bag during every shower. The Shower Bag protects external system components from water or moisture.
- The 11 Volt Lithium-Ion backup battery should be used only for temporary support during a power-loss emergency. The 11 Volt Lithium-Ion backup battery inside the HeartMate III System Controller provides enough power to run the implanted HeartMate III Pump for at least 15 minutes if the main power source (either the Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) is disconnected or fails. Inappropriate use of the 11 Volt Lithium-Ion backup battery may result in diminished run time during a power-loss emergency.
- Do not use damaged, defective, or expired 11 Volt Lithium-Ion backup batteries in the System Controller. Using a damaged, defective, or expired System Controller backup battery may cut operating time during an emergency or cause the Pump to stop.
- Use only a Thoratec Corporation HeartMate III 11 Volt Lithium-ion battery with the HeartMate III System Controller. Using another battery may cause the Pump to stop.
- Do not open, crush, heat above 104°F (40°C), or incinerate batteries because of the risk of fire and burns. Follow manufacturer's instructions.
- Malfunction of the 11 Volt Lithium-Ion backup battery may cause the System Controller to become excessively hot. If this occurs, switch to the backup System Controller.

CAUTION !

- Do not drop the System Controller or subject it to extreme physical shock.
- Instruct the patient to advise hospital personnel immediately if they drop the System Controller. Emphasize to users the importance of not waiting to report a dropped System Controller, even if everything seems fine. Dropping the System Controller can cause trauma or tissue damage at the Driveline exit site, which can increase the patient's risk of serious infection.
- Instruct the patient to stabilize their Driveline at all times to avoid pulling on or moving the Driveline at the exit site. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, Power Module patient cable, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be charged at least once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in diminished or no support during a power-loss emergency when the backup System Controller is in use.
- Damage to the redundant electrical wires inside the Driveline can occur that is not visible to the user. Signs of Driveline damage include (but are not limited to):
  - The System Controller alarming when the Driveline is moved or when the patient changes position.
  - Driveline Power Fault or Driveline Communication Fault yellow wrench and audio alarm.
  - Fluid leaking from the external portion of the Pump Cable.
  - Pump stoppage.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Never use tools to tighten power cable connectors; securely hand tighten only. Using tools may damage the connectors.
- Confirm that the patient's backup System Controller has had the Backup Battery installed, and the time and date have been set.

CAUTION ! (Continued)

- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial requirement.
- The System Controller uses lights, sounds, and on-screen messages to communicate with users about system operation. HeartMate III patients with sight or hearing impairment may need extra help using the System Controller.
- Do not place the System Controller on bare skin for an extended time.
  The System Controller surface temperature can become uncomfortably warm, especially when the room temperature is above 104°F (40°C).

System Controller User Interface Overview

The user interface on the System Controller is the primary interface for users during routine system operation. It uses sounds, lights, symbols, and on-screen messages to communicate about how the system is working. The user interface provides a visual display of system operation and on-screen messages that instruct how to respond to alarms and other situations (**Figure 2.7**).

HeartMate III patients (and their family members and caregivers) must be thoroughly trained on how to interpret and use the user interface prior to discharge. Refer to *Educating and Training Patients, Families, and Caregivers* on page 6-12.

For situations that require attention, and depending on the urgency, the System Controller provides one of two types of alarms: hazard and advisory. Hazard alarms occur for conditions that are potentially life threatening for the patient and require immediate attention. Advisory alarms are important, but not life threatening. For more information on System Controller alarms and how to resolve them, refer to *System Controller Alarms* on page 7-3.

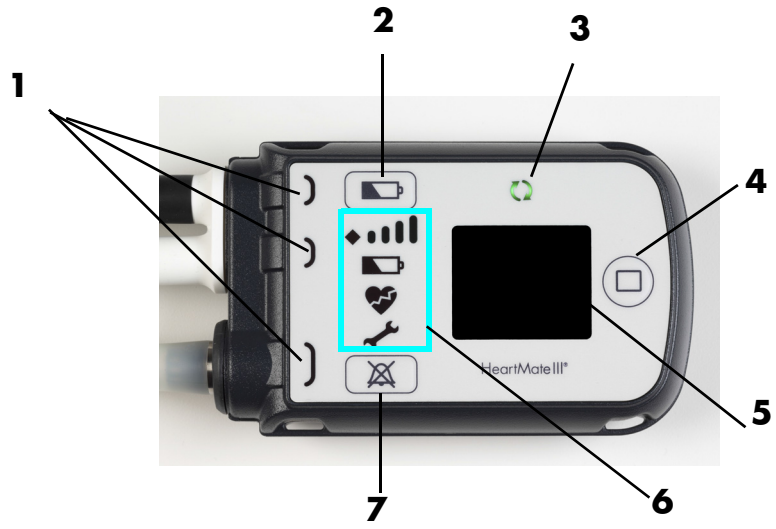


Figure 2.7 System Controller User Interface

1	**Cable Disconnect Symbols**
2	**Battery Button**
3	**Pump Running Symbol**
4	**Display Button**
5	**User Interface Screen**
6	**Status Symbols**
7	**Silence Alarm Button**

System Controller User Interface Components

Table 2.2 describes the symbols and alarms, and when each illuminates.

Table 2.2 System Controller User Interface Symbols and Alarms

Pump Running Symbol 	The Pump Running symbol illuminates green when the Left Ventricular Assist Device is running.
Low Battery Alarm 	The red low battery symbol illuminates when less than 5 minutes of battery power remain. This is applicable only during 14 Volt Lithium-Ion battery-powered operation. This is a **Hazard** alarm. When the red battery symbol illuminates, immediately replace the depleted batteries with a fully-charged pair, or switch to the Power Module or the Mobile Power Unit.
Yellow Wrench Alarm 	The yellow wrench symbol illuminates when the System Controller detects a mechanical, electrical, or software issue with the system. This is an **Advisory** alarm. When the yellow wrench illuminates, check the screen for troubleshooting instructions.
Red Heart Alarm 	The red heart symbol illuminates when the System Controller detects a problem that could cause serious injury or death. This is a **Hazard** alarm. When the red heart illuminates, check the screen for instructions and take immediate action to resolve the problem.
Black Power Cable Alarm 	The yellow light near the *black* power cable connector illuminates when the black power cable becomes loose or disconnects from the System Controller. This is an **Advisory** alarm. If the black power cable disconnects or becomes loose, promptly restore the connection.
White Power Cable Alarm 	The yellow light near the *white* power cable connector illuminates when the white power cable becomes loose or disconnects from the System Controller. This is an **Advisory** alarm. If the white power cable disconnects or becomes loose, promptly restore the connection.

Table 2.2 System Controller User Interface Symbols and Alarms (Continued)

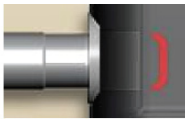
Driveline Connector Alarm 	The red light near the Driveline connector illuminates when the Driveline becomes loose or disconnects from the System Controller. This is a **Hazard** alarm. If the Driveline loosens or disconnects from the System Controller, promptly restore the connection. If the Driveline is not reconnected immediately, the Pump stops.
Battery Power Gauge 	The battery power gauge illuminates to show the approximate charge status of the power source that is connected to the System Controller's white and black power cables: the 14 Volt Lithium-Ion batteries or the Power Module. The number of green bars indicates power remaining. The more green bars that are illuminated, the more power remaining. **Yellow diamond** = less than 15 minutes of battery power remain. Appearance of this symbol indicates an **Advisory** alarm. If the yellow diamond comes on, promptly replace the low batteries with two fully-charged batteries, or switch to the Power Module or the Mobile Power Unit. Do this as soon as possible. ***IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller). To check the status of the System Controller's backup battery, refer to Table 2.3 on page 2-17.***
Pulse Mode 	The presence of the black triangle indicates that the HeartMate III system is operating in Pulse Mode. Once every 2 seconds, the HeartMate III Pump will automatically modify its speed to create an artificial pulse.

Table 2.3 describes using the buttons on the user interface.

Table 2.3 System Controller User Interface Buttons and Corresponding Actions

Battery Button 	The battery button is used for the following: • **Operating the battery power gauge:** Press and release the **Battery** button. • **Starting a System Controller self test:** Press and hold the **Battery** button for 5 seconds, and then release it. Perform a self test daily on the running System Controller, and monthly on the backup System Controller (when it is in Charge Mode). • **Putting a running System Controller into Sleep Mode:** When a System Controller is no longer in use, it can be put to sleep. 1. Disconnect the Driveline and power source. 2. Press and hold the **Battery** button for 5 seconds, and then release it.
Silence Alarm Button 	The silence alarm button is used for the following: • **Silencing an active alarm:** Press and release the **Silence Alarm** button to silence an active alarm on the System Controller. How long it is silenced depends on the alarm. Refer to *System Controller Alarms* on page 7-3. The LCD screen on the System Controller displays the audio alarm silence symbol. ***IMPORTANT!*** Using the **Silence Alarm** button only silences the alarm. It does not fix the alarm condition. • **Viewing the last six System Controller alarms on the screen:** Press and release the **Silence Alarm** button () and the **Display** button () at the same time to display the last six System Controller alarms on the screen.
Display Button 	The **Display** button activates the information display screen. Press and release the **Display** button one or more times repeatedly to display information about Pump speed, power, flow, pulsatility index, and the charge status of the System Controller's 11 Volt Lithium-Ion backup battery. The **Display** button is functional only when a System Controller is in use.

Viewing Pump and System Information

Viewing information about the Pump is useful when recording daily values or trying to resolve system problems on the telephone. When the System Controller is running, the user interface can display the following information about current system operations:

- Speed
- Mode (indicated as Pulse Mode by ▲ symbol)
- Flow
- Pulsatility Index (abbreviated as "PI" on the screen)
- Power
- Charge status of the System Controller's backup battery (11 Volt Lithium-Ion)

To view information on the user interface screen, press and release the **Display** button (□). Each push of the **Display** button brings up a new screen. Each screen illuminates for 15 seconds before it goes black, unless another button is pushed. The screens are always displayed in the same order, starting with the first (Speed) screen. A dot at the bottom of each screen provides navigational information about which of the five screens is in view.

Table 2.4 shows the display sequence.

Table 2.4 System Controller Display Screen Sequence

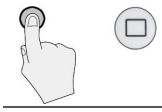
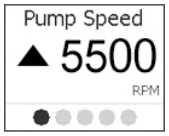
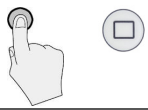
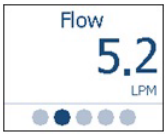
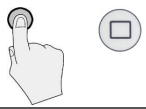
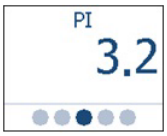
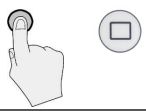
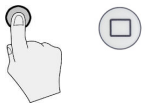
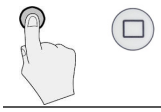
Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press **Display** button **ONCE**		Pump speed in revolutions per minute (RPM) ▲ Triangle indicates that the Pump is in Pulse Mode.
Press 	Press **Display** button **TWO** times		Pump flow in liters per minute (LPM)
Press 	Press **Display** button **THREE** times		Pulsatility Index (PI)
Press 	Press **Display** button **FOUR** times		Power in watts (W)

Table 2.4 System Controller Display Screen Sequence (Continued)

Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press display button **FIVE** times		The System Controller's backup battery is located inside the System Controller and used to temporarily run the Pump during a power emergency. The System Controller's backup battery has three charge status states: • Charged (ready for use). • Charging (actively charging). • Fault (there is a fault or problem with the backup battery that could affect its reliability).
Press 	Press display button **SIX** times		A blank screen indicates the screen is off. This is normal.

Note: On-screen messages come in many different languages and can be changed from the System Monitor to support the patient's needs. Refer to *System Controller Language* on page 4-42.

System Controller Driveline Connector

The System Controller Driveline Connector attaches the Driveline (comprised of the Pump Cable and the Modular Cable) to the System Controller (**Figure 2.8**). The System Controller Driveline Connector uses a double-lock feature that lowers the risk of accidentally disconnecting the Driveline.

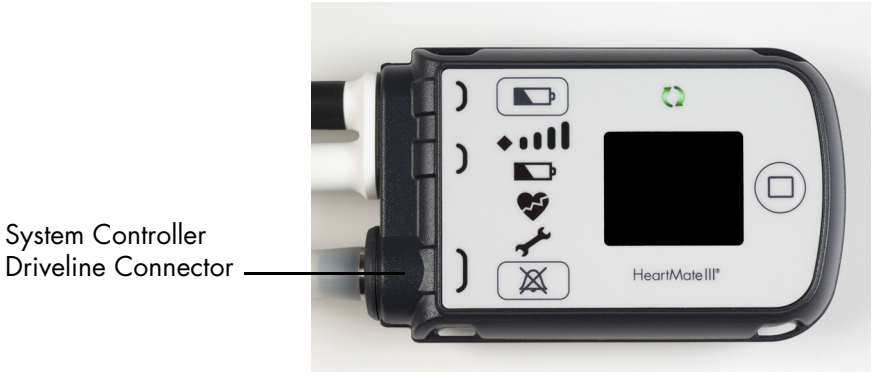


Figure 2.8 System Controller Driveline Connector Attached to the System Controller

The System Controller continually monitors the connection status of the System Controller Driveline Connector. If the System Controller detects a problem, it immediately alarms.

The Driveline is initially connected to the patient's System Controller during the procedure to implant the LVAD. The same System Controller remains in use unless it requires replacement for clinical or technical reasons. Refer to *Backup System Controller Overview* on page 2-41.

It is impossible to connect (or disconnect) the Driveline without first rotating the Safety Lock on the back of the System Controller into the unlocked position. When the Driveline is properly and fully inserted into the Controller Driveline Connector port, the Driveline cannot be removed without firmly pressing the red button under the raised Safety Lock (**Figure 2.9**).

If there is a problem with the Driveline connection, the System Controller alarms immediately.

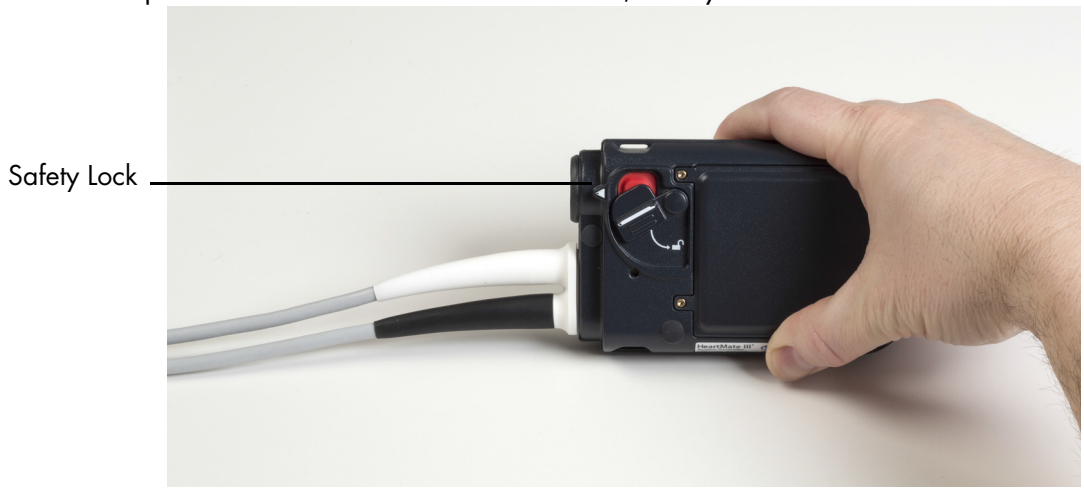


Figure 2.9 Moving the Safety Lock to the Unlocked Position

Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

A programmed System Controller

TO CONNECT THE DRIVELINE TO THE SYSTEM CONTROLLER:

1. Orient the System Controller so the display is facing down.
2. Rotate the Safety Lock to the unlocked position (**Figure 2.10**).

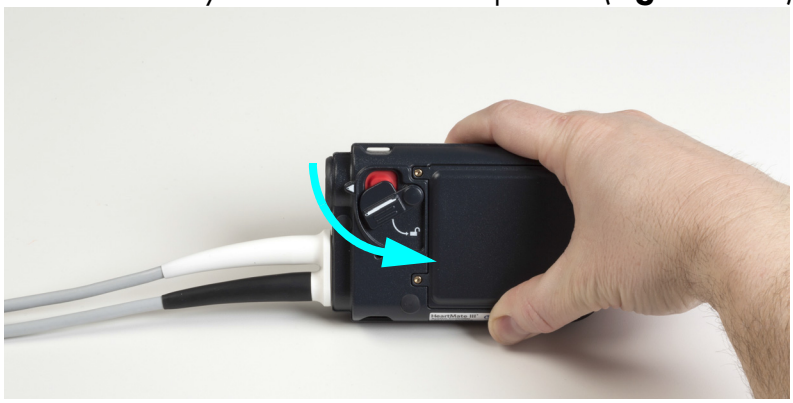


Figure 2.10 Unlocking the Safety Lock

3. Align the BLACK arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.11**).

Figure 2.11 Aligning the Arrows

4. Insert the Driveline Cable Connector into the socket.
5. Press firmly until it snaps into place (**Figure 2.12**).

   The Left Ventricular Assist Device may take up to 10 seconds to start running when the cable is fully and properly inserted in the socket (if the Pump Set Speed is set above 4000 rpm).

   IMPORTANT! The arrow/alignment mark on the driveline is no longer visible when properly connected.

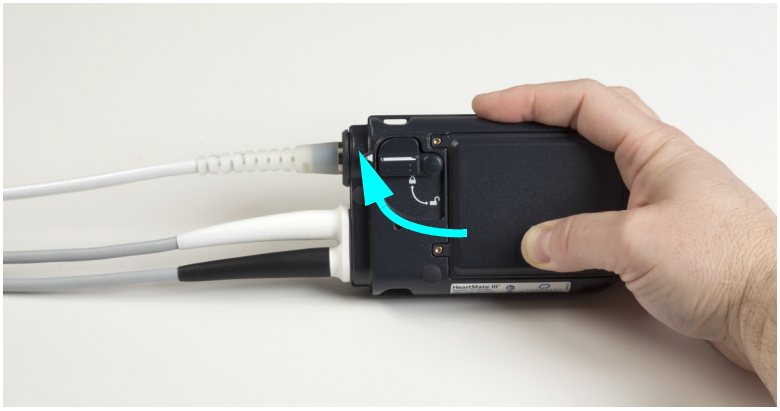


Figure 2.12 Inserting and Locking the Driveline Into the Socket

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

6. Move the Safety Lock to the locked position, so that it covers the red button.

   IMPORTANT! If the safety tab does not fully cover the red button, the Driveline is not connected. Disconnect and reconnect the Driveline.

7. Gently tug on the Modular Cable to check the connection.

   Do not pull on or bend the Driveline.

   If there is a problem with the connection, the System Controller immediately alarms with a Driveline Disconnected alarm. This is a Hazard alarm.

CAUTION !

Do not pull on or bend the Driveline that connects the Pump to the System Controller. Pulling on or bending the Driveline may damage wires inside, even if external Driveline damage is not visible.

Disconnecting the Driveline from the System Controller

WARNING !

- Failure to connect to a running System Controller may result in serious injury or death.
- Failure to adhere to the following instructions may result in serious injury or death.

FOR THIS TASK YOU NEED:

A running System Controller

TO DISCONNECT THE DRIVELINE FROM THE SYSTEM CONTROLLER:

1. Orient the System Controller so the display is facing down.
2. Rotate the Safety Lock to the unlocked position (**Figure 2.13**).

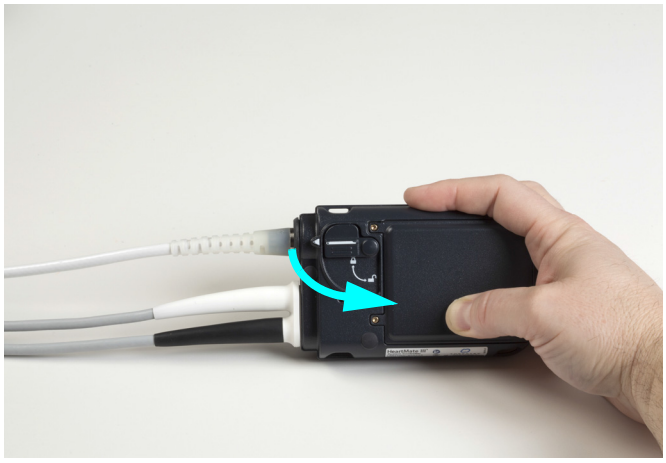


Figure 2.13 Unlocking the Safety Lock

3. Complete the following steps:
   a. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket.
   b. Grasp the bend relief of the Modular Cable while removing it.

      Do not pull on or bend the System Controller Driveline Connector (**Figure 2.14**).

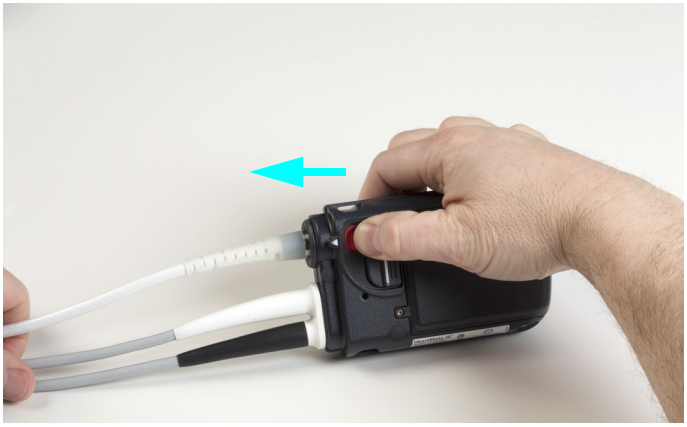


Figure 2.14 Removing the Driveline

WARNING !

The Left Ventricular Assist Device stops if the Driveline is disconnected from the System Controller. If the Driveline is disconnected, reconnect it as quickly as possible to restart the Pump. If the System Controller does not work, replace with a backup System Controller.

System Controller Power Cable Connectors

Two power cables on the System Controller (a black connector and a white connector) connect the System Controller to the Power Module, the Mobile Power Unit, or two 14 Volt Lithium-Ion batteries (**Figure 2.15**).

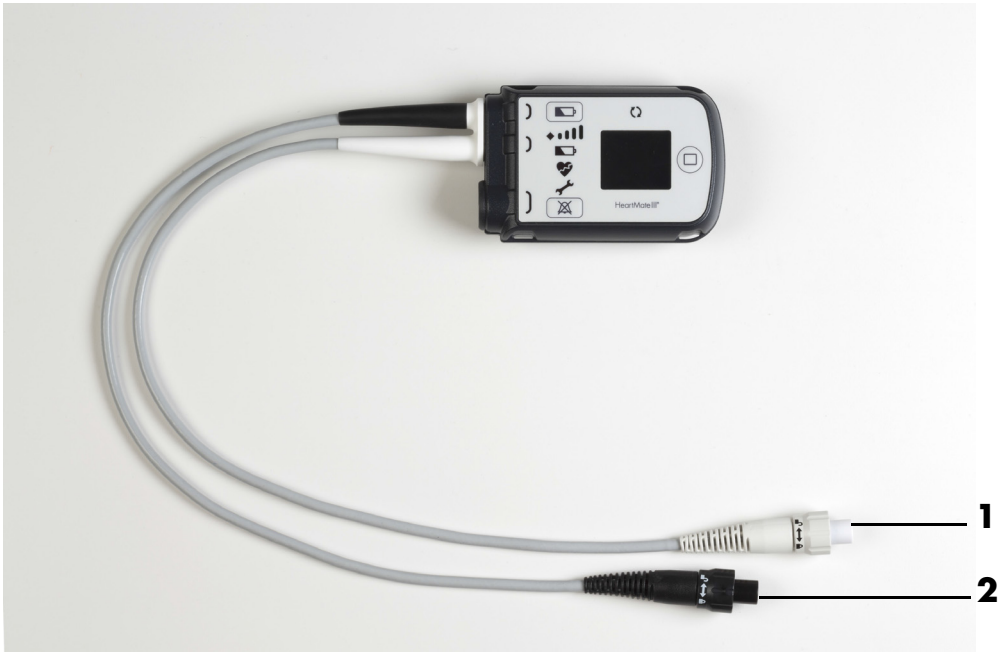


Figure 2.15 Black and White Power Cable Connectors on the System Controller

1	**White Connector**
2	**Black Connector**

The System Controller power cable connectors (and the corresponding connectors for the Power Module patient cable and the Mobile Power Unit patient cable connectors) are color coded. Always connect black-to-black and white-to-white. Both System Controller power cables provide equal power. However, the cable with the white connector transmits signals between the System Controller and System Monitor. Refer to *System Monitor Setup* on page 4-5. The data link does not work without a white-to-white connection.

During routine operation, the HeartMate III LVAS is powered by one of the following power sources:

- **Power Module**: The Power Module is used when the patient is indoors, stationary, or sleeping. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller. Refer to *Using the Power Module* on page 3-5 for details.
- **Mobile Power Unit**: The Mobile Power Unit can be used when the patient is indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller. Refer to *Using the Mobile Power Unit* on page 3-34 for details.
- **Two HeartMate 14 Volt Lithium-Ion batteries**: HeartMate batteries are used to power the system during battery-powered operation when AC electricity is not wanted or is unavailable. Batteries are used in pairs. Each battery is inserted into a 14 Volt battery clip. The clips transfer battery power to the System Controller with two power cables, one for each clip. Without battery clips, the batteries cannot transfer power to the system. When fully charged, a pair of new HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 10–17 hours, depending on the activity level of the patient. Refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46 for details.

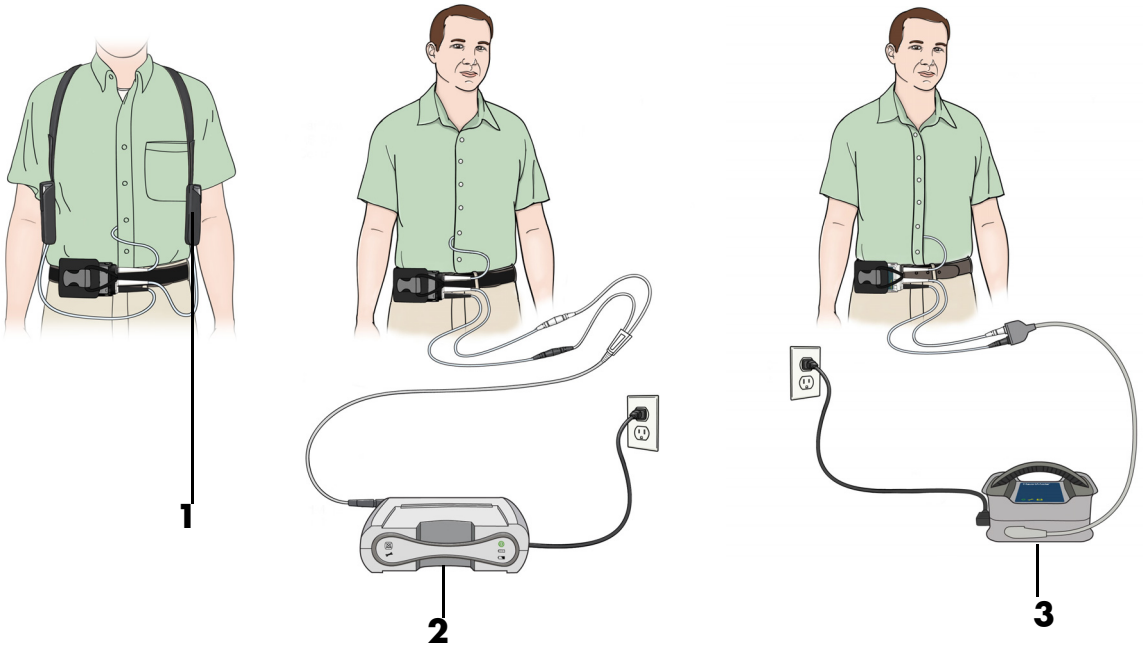


Figure 2.16 HeartMate III LVAD on Battery Power (1), Power Module Power (2), and Mobile Power Unit Power (3)

1	**Battery**	Refer to page 3-46
2	**Power Module**	Refer to page 3-5
3	**Mobile Power Unit**	Refer to page 3-34

The System Controller continually monitors the connection status of the power cable connectors. If the System Controller detects a problem, it immediately alarms. For more information about the alarm, refer to *Power Cable Disconnect Alarm* on page 7-16.

WARNING !

The System Controller must be connected to the Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries at all times when connected to a patient.

Performing a System Controller Self Test

Use a daily System Controller self test to check the audible and visual alarm indicators on the user interface, as well as the status of the backup battery for the System Controller. During the self test, the Pump Set Speed will not be changed.

The System Controller self test is a loud and bright function. All of the audible and visual indicators should come on, and the words *Self Test* should appear on the screen (**Figure 2.17**).

Figure 2.17 User Interface During System Controller Self Test

Perform the self test at least once a day on the running System Controller. A backup System Controller in Charge Mode can be tested as well, if needed.

Consider testing the System Controller at the same time daily to establish a routine.

TO PERFORM A SYSTEM CONTROLLER SELF TEST:

1. Press and hold the **Battery** button ( ) for five seconds.
2. Check that:

   - ☐ The words Self Test (first briefly white, then black) appear on the screen.
   - ☐ All symbols and indicators on the user interface illuminate at the same time.
   - ☐ The System Controller is making a loud, steady, audio alarm tone.

3. Release the **Battery** button ( ).

   All the audible indicators/lights should remain on for 15 seconds. After 15 seconds, the audible indicators/lights stop, the screen goes black, and the self test is complete.

   If all of the alarms and lights come on together as previously described, the System Controller passed the self test. If any of the lights remain off, or if the audible indicators do not sound or they produce sounds other than a loud steady tone, there is a problem with the System Controller.

   Do not use a System Controller that fails its self test.

4. If the System Controller fails the self test, complete the following steps:
   a. Replace the System Controller with the backup System Controller.
   b. Contact Thoratec for a new backup System Controller.

IMPORTANT! If an alarm occurs during a self test, the self test terminates and the alarm's on-screen indicator remains active. A System Controller self test cannot be initiated during the following alarms: any Hazard alarm, Power Cable Disconnected Advisory alarm, Low Battery Power Advisory alarm.

System Controller Battery Power Gauge

The battery power gauge shows the approximate charge status of the power source that is connected to the System Controller's white and black power cables. The power source will be the 14 Volt Lithium-Ion batteries, the Power Module, or the Mobile Power Unit. The number of green bars indicates the power remaining. The more green bars that are illuminated, the more power remaining.

To activate the battery power gauge, press and release the **Battery** button ( ) on the user interface (**Figure 2.18**).

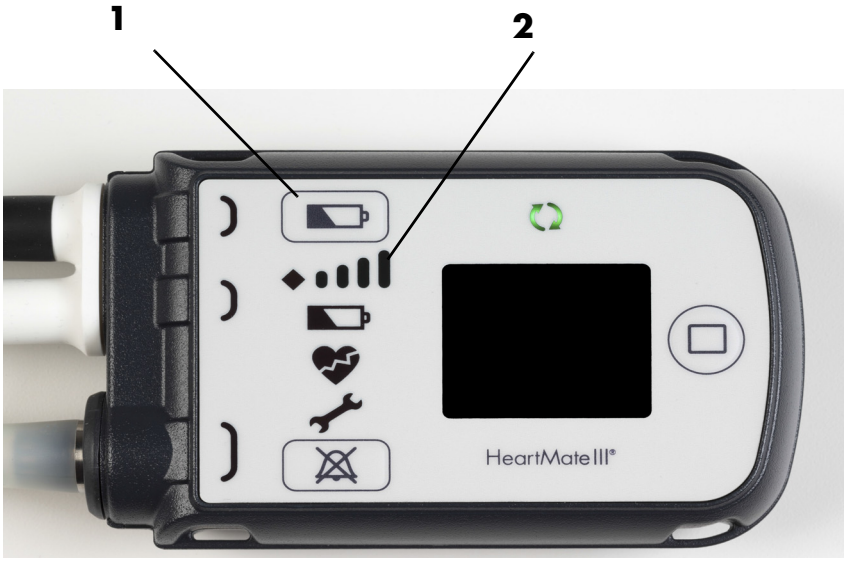


Figure 2.18 Battery Power Gauge Showing Full Charge

1	**Battery Button**
2	**Battery Power Gauge**

IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller). To check the status of the System Controller's backup battery, refer to *Viewing Pump and System Information* on page 2-18.

14 Volt Lithium-Ion Battery Power

4 green bars =
75–100% of battery power remains.

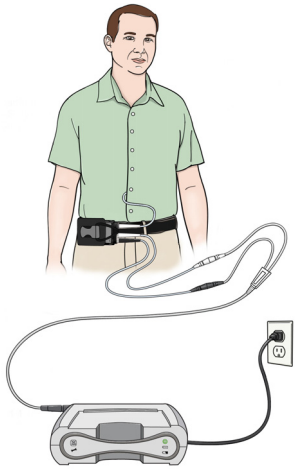
3 green bars =
50–75% of battery power remains.

2 green bars =
25–50% of battery power remains.

1 green bar =
less than 25% of battery power remains.

IMPORTANT! Every HeartMate 14 Volt Lithium-Ion battery also has its own on-battery gauge. It shows the power level for that battery. The on-battery readout communicates information about a single source using five green bars. The System Controller battery power gauge communicates information about a combined source of power using four green bars. For more information, refer to *Checking Battery Charge Status* on page 3-50.

Power Module Power



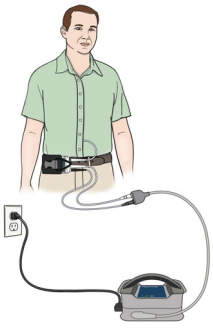
4 green bars =
Normal Power Module operation.

3 green bars =
Running on the Power Module backup battery and 50–75% of battery power remains.

2 green bars =
Running on the Power Module backup battery and 25–50% of battery power remains.

1 green bar =
Running on the Power Module backup battery and less than 25% of battery power remains.

Mobile Power Unit Power



4 green bars = Normal Mobile Power Unit operation.

Recognizing Low Battery Alarms

If the yellow diamond or the red battery illuminate, the system's power level is dangerously low. This condition prompts a Low Battery Power alarm.

Yellow diamond: Less than 15 minutes of combined battery power remain. This is an **Advisory** alarm.

Red battery: Less than 5 minutes of combined battery power remain. This is a **Hazard** alarm.

If either the yellow diamond or the red battery illuminate, immediately replace the depleted batteries with a fully-charged pair of batteries, or switch to the Power Module or Mobile Power Unit.

Refer to *Switching from Battery Power to the Power Module* on page 3-61 or *Connecting to the Mobile Power Unit* on page 3-42.

System Controller Operating Modes

The System Controller has three modes, each with a distinct function:

- Run Mode: The system is operating and is in use.
- Sleep Mode: The system is not in use, but is ready to function.

  The backup System Controller is predominantly in Sleep Mode.

- Charge Mode: The system is not connected to a Driveline, but is connected to a power source.

  This is to charge and maintain the readiness of its internal 11 Volt Lithium-Ion backup battery.

IMPORTANT! The backup System Controller must be put into Charge Mode every six months to ensure backup battery readiness.

Run Mode

Run Mode is the usual state for the operating System Controller (**Figure 2.19**).

Figure 2.19 System Controller in Run Mode While on Battery Power (left) and the Power Module (right)

In Run Mode, the Pump Running symbol is illuminated green (🔄) and the System Controller:

- Connects to a power source (the Power Module, the Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries)
- Connects to the Left Ventricular Assist Device via the Driveline
- Sends power to the Pump via the Driveline
- Controls and monitors physiological and operating conditions
- Displays data about physiological and operating conditions
- Accesses user interface indicators to reflect System Controller and Pump conditions
- Responds to user interface button pushes
- Charges the 11 Volt Lithium-Ion backup battery inside the System Controller
- Communicates with the System Monitor, if connected
- Performs a System Controller self test, when needed

For instructions on switching from Run Mode to Sleep Mode, refer to *Switching Operating Modes* on page 2-34.

Sleep Mode

Sleep Mode is the usual state for a backup System Controller (**Figure 2.20**).

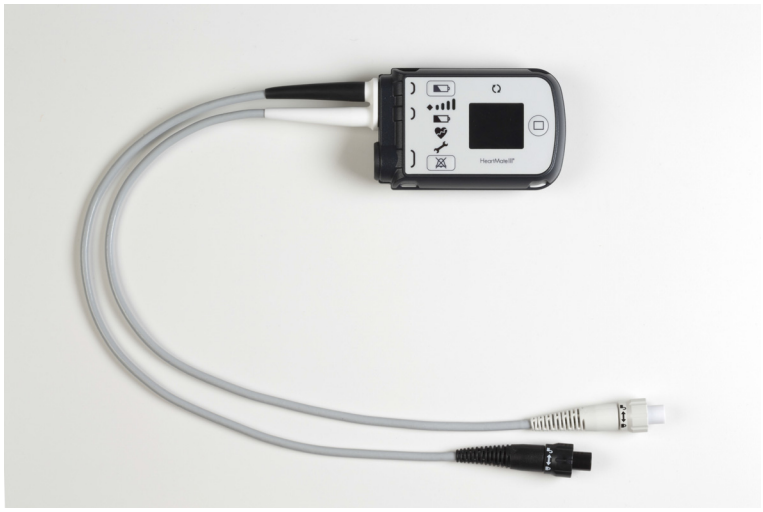


Figure 2.20 System Controller in Sleep Mode

The backup System Controller remains in Sleep Mode until one of the following occurs:

- It is put into Charge Mode (connected to power)
- It is used in Run Mode (used to replace the running System Controller)

In Sleep Mode, the Pump Running symbol (🔄) is off (black), and the backup System Controller is:

- Disconnected from an external power source and powered off
- Disconnected from the Driveline
- Not displaying operating/alarm data on the information display screen
- Not responding to user interface button pushes
- Not charging the 11 Volt Lithium-Ion backup battery inside the System Controller
- Disconnected from, and not communicating with, the System Monitor

For instructions on switching from Sleep Mode to Run Mode or Charge Mode, refer to *Switching Operating Modes* on page 2-34.

Charge Mode

The backup System Controller must be connected to power for the 11 Volt Lithium-Ion backup battery to charge (**Figure 2.21**).

Figure 2.21 System Controller in Charge Mode While on Battery Power (left) and the Power Module (right)

Once every six months, the backup System Controller must be connected to an external power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Connecting the System Controller to power and putting it into Charge Mode allows its 11 Volt Lithium-Ion backup battery to charge. A fully-depleted 11 Volt Lithium-Ion backup battery takes up to three hours to charge.

In Charge Mode, the Pump Running symbol ( ) is off (black), and the backup System Controller is:

- Charging the 11 Volt Lithium-Ion backup battery inside the System Controller
- Able to perform a System Controller self test
- Disconnected from the Driveline
- Displaying charging status or any active alarms
- Not responding to silence alarm ( ) or display ( ) buttons

Switching Operating Modes

Figure 2.22 shows how to transition between operating modes.

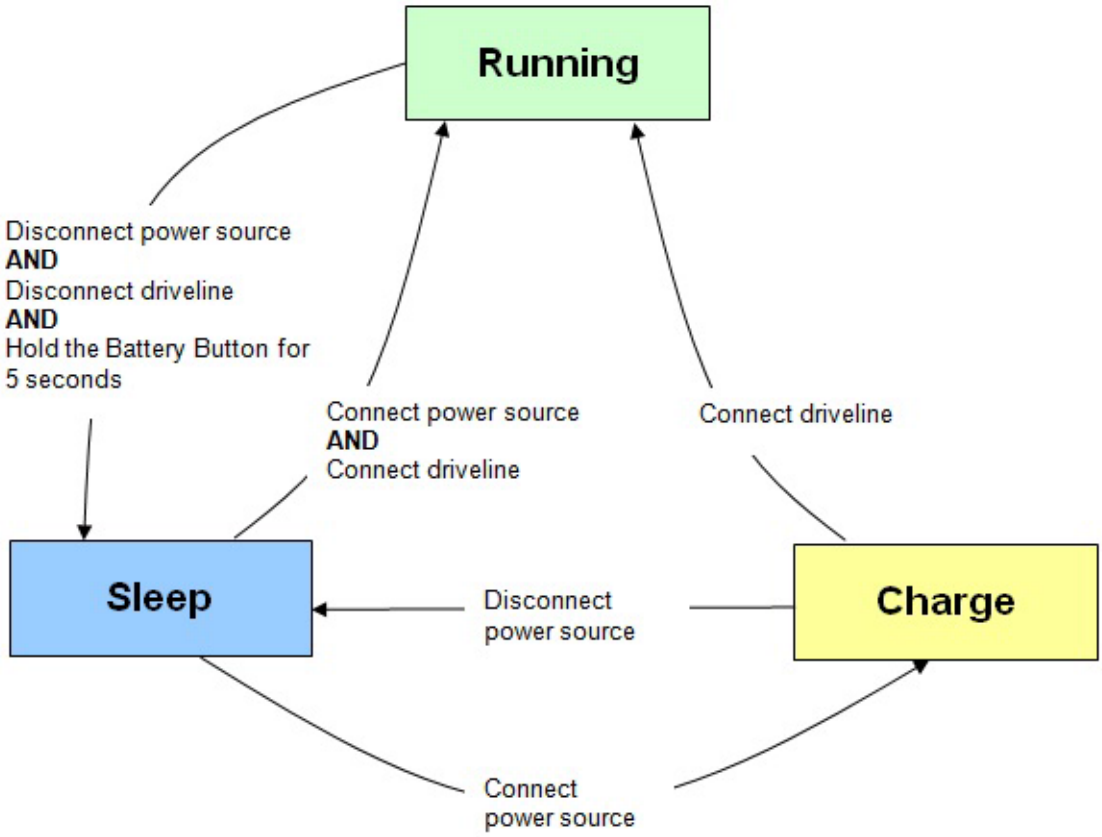


Figure 2.22 System Controller Operating Modes

TO SWITCH FROM SLEEP MODE TO RUN MODE:

1. Connect the System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
2. Connect the Driveline to the System Controller. Refer to *Connecting the Driveline to the System Controller* on page 2-21.

   The Pump Running symbol is illuminated green( ) and the System Controller is in Run Mode.

TO SWITCH FROM CHARGE MODE TO RUN MODE:

This procedure assumes that the System Controller is not in use, but is connected to a power source and is in Charge Mode.

Connect the Driveline to the System Controller. Refer to *Connecting the Driveline to the System Controller* on page 2-21.

The Pump Running symbol is illuminated green ( ) and the System Controller is in Run Mode.

TO SWITCH FROM CHARGE MODE TO SLEEP MODE:

Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).

Note: The Driveline must be disconnected to put in Sleep Mode.

TO SWITCH FROM SLEEP MODE TO CHARGE MODE:

IMPORTANT! Do not permit patients to perform this task without approval and proper training.

Connect the System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).

It can take up to 3 hours to charge the 11 Volt Lithium-Ion backup battery. During this time, the word *Charging* and five dashes scroll across the bottom of the screen. This indicates that the 11 Volt Lithium-Ion backup battery is actively charging.

The words *Charging Complete* appear on the screen when the battery has finished charging. After the backup battery is charged, the System Controller can either be put into Run Mode for immediate use or into Sleep Mode to await future use.

TO SWITCH FROM RUN MODE TO SLEEP MODE:

1. Disconnect the Driveline from the System Controller.
2. Press and release the **Silence Alarm** button ( ) to silence the Driveline Disconnected Alarm.
3. Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
4. Press and release the **Silence Alarm** button ( ) to silence the Power Cable Disconnect Alarm.
5. Press and hold the **Battery** button ( ) for five seconds.

   The word *Hold* accompanied by a reverse countdown from five dots to one dot (5 dots, 4 dots, 3 dots, 2 dots, 1 dot) appears on the screen.

   When the countdown ends, the screen goes black, the Pump Running symbol is black ( ), and the System Controller is in Sleep Mode. If this sequence is not fully completed, the System Controller will not enter Sleep Mode.

System Controller Backup Battery Power

An 11 Volt Lithium-Ion backup battery is installed post-implant inside the System Controller. It provides at least 15 minutes of backup power to the LVAD if the in-use power source is disconnected or fails. To provide backup power, the 11 Volt Lithium-Ion backup battery must be properly installed and fully charged.

The 11 Volt Lithium-Ion backup battery is intended only for backup power during a power emergency. Emphasize to patients that inappropriate use during non-emergencies may reduce the power available to them in a true emergency. Backup battery use is automatically recorded by the System Controller. This allows for follow-up training with patients, if needed, to reinforce that usage should be limited to power emergencies. Refer to *System Controller Information* on page 4-43 for instructions on accessing 11 Volt Lithium-Ion backup battery usage records.

After proper installation, the rechargeable 11 Volt Lithium-Ion backup battery recharges automatically any time the running System Controller is connected to a power source. It takes up to three hours to charge a fully-depleted 11 Volt Lithium-Ion backup battery. Although rechargeable, the backup battery has a limited lifespan. The lifespan of a backup battery is 36 months from manufacture date. Therefore, it may be necessary to install a replacement backup battery if the current one expires, or if prompted by a Backup Battery Fault alarm.

Figure 2.23 Backup Battery Fault Alarm

The backup System Controller also has an 11 Volt Lithium-Ion backup battery. The sleeping backup System Controller must be connected to power (put into Charge Mode) at least every six months to charge the backup battery inside the backup System Controller. Refer to *Maintaining Backup System Controller Readiness* on page 2-44.

WARNING !

The 11 Volt Lithium-Ion back up battery inside the System Controller will not by itself start a HeartMate III LVAD if both of the System Controller's power cables are disconnected from a power source. Always ensure that the power cables are connected to a power source to ensure that the HeartMate III Pump will restart during a System Controller exchange.

Replacing a Backup Battery

The 11 Volt Lithium-Ion backup battery is first installed in a running System Controller after implantation, and after the sterile field has been broken. Refer to *Installing the Backup Battery* on page 5-52. The System Controller can remain attached to the patient while replacing the 11 Volt Lithium-Ion backup battery.

If the original 11 Volt Lithium-Ion backup battery exceeds its expiration date, or if a Backup Battery Fault alarm appears on the information display screen, the battery must be replaced. Refer to *Installing the Backup Battery* on page 5-52 for a complete list of warnings and cautions related to the 11 Volt Lithium-Ion backup battery.

The System Monitor displays information about the System Controller 11 Volt Lithium-Ion backup battery charge level, and the time remaining before its replacement is mandatory. Depending on an outpatient's clinic schedule, replacement of the 11 Volt Lithium-Ion backup battery should be considered when less than 6 months remain before the mandatory replacement date.

FOR THIS TASK YOU NEED:

- 1 replacement 11 Volt Lithium-Ion backup battery (obtained from Thoratec Corporation)
- 1 lever to remove the screw cover of the battery compartment (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 screwdriver to loosen the four battery cover screws (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 spare screw cover (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 running System Controller that is connected to a power source (Power Module, Mobile Power Unit, or 2 14 Volt Lithium-Ion batteries)

TO REPLACE THE BACKUP BATTERY IN THE SYSTEM CONTROLLER:

1. Before replacing the backup battery, confirm that the date and time on the running System Controller are correct and complete one of the following steps:
   - If the date and time are correct, go to Step 2.
   - If the date or time is incorrect, the System Controller's Backup Battery Alarm may occur. For more information about the alarm, refer to *System Controller Alarms* on page 7-3.
2. Gather the equipment (**Figure 2.24**) and place it within reach.

Figure 2.24 11 Volt Backup Battery Replacement Kit

3. Use the lever to remove the screw cover of the battery compartment on the System Controller (**Figure 2.25**).

Figure 2.25 Using the Lever to Remove the Screw Cover

4. Use the screwdriver to loosen the four screws on the battery compartment (**Figure 2.26**).

Figure 2.26 Using the Screwdriver to Loosen the Screws

5. Remove the battery compartment cover.
6. Remove the current 11 Volt Lithium-Ion battery from the battery compartment as follows:
   a. Grasp the end of the ribbon cable that is attached to the current battery.
   b. Gently remove the ribbon cable from the battery socket (**Figure 2.27**).

Figure 2.27 Removing the Ribbon Cable From the Battery Socket

   c. Discard the used battery. For more information, refer to *Product Disposal* on page 8-8.

7. Retrieve the replacement 11 Volt Lithium-Ion backup battery.
8. Align the arrow on the end of the ribbon cable with the arrow on the end of the replacement backup battery.
9. Insert the end of the ribbon cable into the battery socket.
10. Confirm that the backup battery is properly connected by verifying both of the following:
    - Either a green or amber indicator light appears on the battery.

      A green light indicates that the backup battery is fully charged. An amber light indicates that the battery is charging.

      AND
    - The backup battery installation graphic no longer appears on the information display screen.
11. Place the backup battery and attached ribbon cable inside the battery compartment.
12. Place the cover over the battery compartment.
13. Use the provided screwdriver to tighten the four screws on the cover (**Figure 2.28**).

Figure 2.28 Tightening the Screws

14. Replace the screw cover.

IMPORTANT! A newly inserted battery needs to finish charging before it can reliably provide backup power. It takes approximately 3 hours for a fully-depleted 11 Volt Lithium-Ion backup battery to become fully charged. The words "Charging Complete" appear on the information display screen when the newly-installed 11 Volt Lithium-Ion backup battery has finished charging. Refer to *Charge Mode* on page 2-33.

Setting the System Controller Clock

The System Controller has an internal clock. The clock tracks the timing of system events and monitors the expiration date of the System Controller's 11 Volt Lithium-Ion backup battery.

IMPORTANT! Be aware that installing an 11 Volt Lithium-Ion backup battery may prompt a System Controller Clock Not Set advisory alarm on the System Monitor.

Complete the following steps to resolve a System Controller Clock Not Set advisory alarm:

1. Use the System Monitor to reset the System Controller clock.
   Refer to *Date and Time* on page 4-40.
2. Ensure that the System Monitor clock is correct before relying on it.

Backup System Controller Overview

HeartMate III patients receive two System Controllers: one to actively use (running), and a reserve (backup) in case the running System Controller experiences a failure.

Every HeartMate III patient receives a backup System Controller, which is identical to the running System Controller. If a failure occurs on the running System Controller, it may need to be replaced with the backup System Controller. For this reason, and in case of an emergency, the backup System Controller must remain with the patient at all times (**Figure 2.29**).

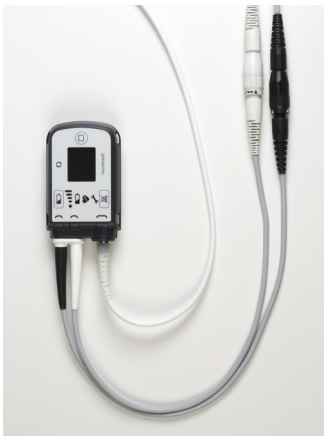
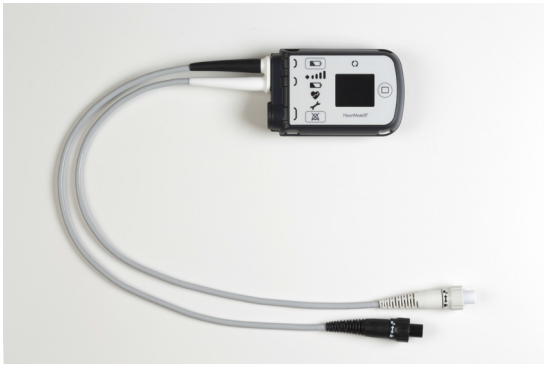
Running System Controller	Backup System Controller
 **On Power Module or Mobile Power Unit**	**If needed, ready to use**  **Backup is not connected to:** • **Power** • **Driveline**
 **On Batteries**	

Figure 2.29 System Controller States

IMPORTANT! To replace the running System Controller with the backup System Controller, refer to *Replacing the Current System Controller* on page 2-46.

Configuring the Backup System Controller

The backup System Controller's internal backup battery must be installed and the clock set. This way, the backup System Controller is ready if the running System Controller needs to be replaced.

IMPORTANT! After system operating parameters have been entered (Pump Speed and Low Speed Limit), the Pump stores these values. Therefore, the backup System Controller does not need to have the patient's parameters programed. After the backup System Controller is connected to the Pump, the operating parameters are transferred from the Pump to the System Controller.

FOR THIS TASK YOU NEED:

- 1 new and packaged System Controller complete with 11 Volt Lithium-Ion backup battery and *Patient Handbook*
- 1 working Power Module with patient cable and AC power cord connected
- 1 System Monitor installed on Power Module
- 1 System Monitor data cable
- 1 functioning and grounded (3-prong) AC electrical outlet

TO CONFIGURE THE BACKUP SYSTEM CONTROLLER

1. Remove the System Controller, the 11 Volt Lithium-Ion backup battery, and the *Patient Handbook* from the System Controller packaging.
2. Connect the backup System Controller to the Power Module (**Figure 2.30**).

   The System Controller will alarm. This is normal.

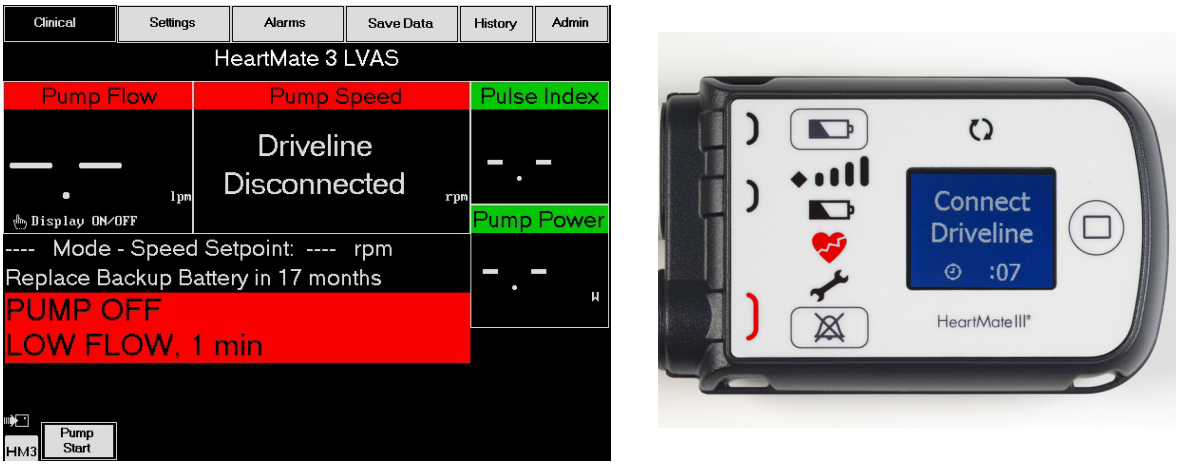


Figure 2.30 System Monitor (left) and System Controller (right)

3. Set the System Controller clock via the Admin screen (**Figure 2.31**).

   For more information, refer to *Admin Screen* on page 4-40.

Figure 2.31 Admin Screen

4. Set the System Controller's language, if needed, via the Admin screen (**Figure 2.31**).

   For more information, refer to *System Controller Language* on page 4-42.

5. Install the 11 Volt backup battery into the System Controller (**Figure 2.32**).

   For more information, refer to *Installing the Backup Battery* on page 5-52.

Figure 2.32 Installing the Backup Battery

6. Disconnect power from the System Controller.

   Note: The System Monitor will have the PUMP OFF, LOW FLOW, and Driveline Disconnected alarms active. The System Controller will show a red heart alarm ( ) and display a *Connect Driveline* message. This is normal.

7. Press and hold the **Battery** button ( ) for five seconds to put the System Controller to sleep.

   Note: The following "Hold" screen appears accompanied by a reverse countdown from five dots to one dot (**Figure 2.33**). When the countdown ends, the System Controller is in Sleep Mode.

Figure 2.33 Holding the Battery Button

Maintaining Backup System Controller Readiness

Over time, the backup battery inside the System Controller loses power and must be recharged every six months. The backup battery must be awakened, connected to power, and put into Charge Mode. Connecting the backup System Controller to power charges its internal 11 Volt Lithium-Ion backup battery. While the backup System Controller is in Charge Mode, a self test should be performed.

FOR THIS TASK YOU NEED:

- 1 backup System Controller
- 1 power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries)

TO PERFORM BACKUP SYSTEM CONTROLLER SIX MONTH CHARGING AND SELF TEST:

1. Connect the backup System Controller to a power source: Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries (**Figure 2.34**).

Figure 2.34 System Controller on Power Module Power (left) and Battery Power (right)

When the System Controller is connected to power, the user display screen shows *Charging* or *Charging Complete* (**Figure 2.35**).

Figure 2.35 System Controller Charging or Charging Complete

IMPORTANT! Do not remove power until the words *Charging Complete* appear. It can take up to three hours to charge the System Controller's backup battery.

2. Perform a self test on the backup System Controller.
3. Press and hold the **Battery** button ( ) for five seconds (**Figure 2.36**).

For more information, refer to *Backup System Controller Overview* on page 2-41.

Note: A self test can only be performed when power is connected to the System Controller.

Figure 2.36 System Controller Self Test

4. Disconnect power from the backup System Controller.

This will put the backup System Controller back into Sleep Mode. No further action is needed for six months.

5. Put the backup System Controller into its Protection Bag (**Figure 2.37**). For more information, refer to *Using the Protection Bag* on page 6-62.

Figure 2.37 Backup System Controller in Protection Bag

Replacing the Current System Controller

There are two ways in which the System Controller can be exchanged. The first method assumes that only the System Controller is exchanged and that a second power source is not available. The second exchange method involves exchanging the System Controller using a second power source.

The Pump Cable is the cable that is implanted inside the patient. One end connects directly to the Pump and the other end exits the body. One end of the Modular Cable connects to the end of the Pump Cable that exits the body. The other end of the Modular Cable connects directly to the System Controller. Collectively, the cables are referred to as the Driveline.

IMPORTANT! Ensure that the patient understands the need for having a caregiver present during System Controller exchange and that all labeling instructions are followed. This includes calling the hospital contact if instructed.

IMPORTANT! The ability to successfully replace a System Controller may be affected by several factors such as native cardiac output, cognitive function, and so on. Any of these may change over the course of LVAD support, and therefore should be periodically assessed.

Replacing the Current System Controller with One Power Source

To replace the current System Controller with the replacement System Controller:

1. If the current System Controller is alarming, press the **Silence Alarm** button ().

   This will silence the audio alarms for 2 minutes.
2. Locate the replacement HeartMate III System Controller.
3. Complete the following steps:
   a. Disconnect the White Power connection from the current System Controller.
   b. Connect the White Power connection to the replacement System Controller.
   c. Fully secure the white nut until tight.

4. Complete the following steps to disconnect the Driveline from the current System Controller:
   a. Orient the System Controller so the display is facing down.
   b. Rotate the Safety Lock to the unlocked position (**Figure 2.38**).

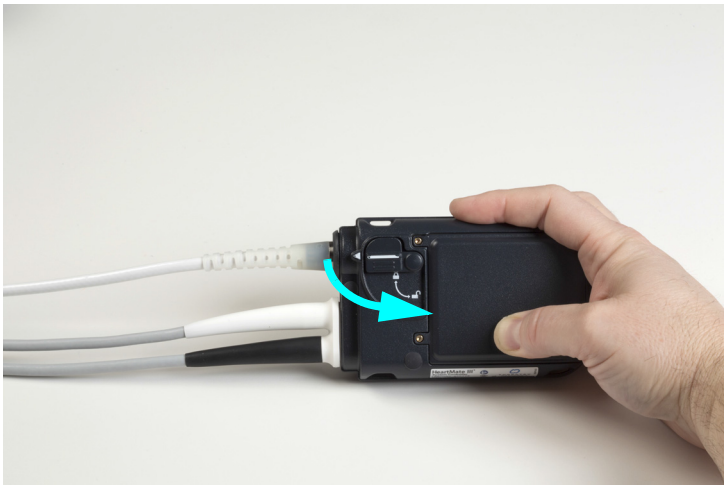


Figure 2.38 Unlocking the Safety Lock

   c. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket.
   d. Grasp the bend relief of the Driveline while removing it.

      Do not pull on or bend the Controller Driveline Connector (**Figure 2.39**).

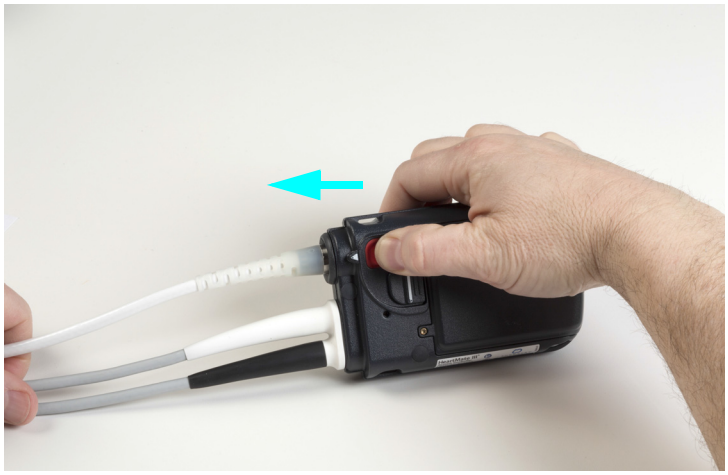


Figure 2.39 Removing the Driveline

5. Complete the following steps to connect the Driveline to the replacement System Controller:
   a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.40**).

Figure 2.40 Aligning the Arrows

   b. Insert the Driveline Cable Connector into the socket pressing firmly until it snaps into place.

      The Left Ventricular Assist Device may take up to 10 seconds to start running when the cable is fully and properly inserted in the socket (if Pump Set Speed is set above 4000 rpm).

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

6. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.41**).

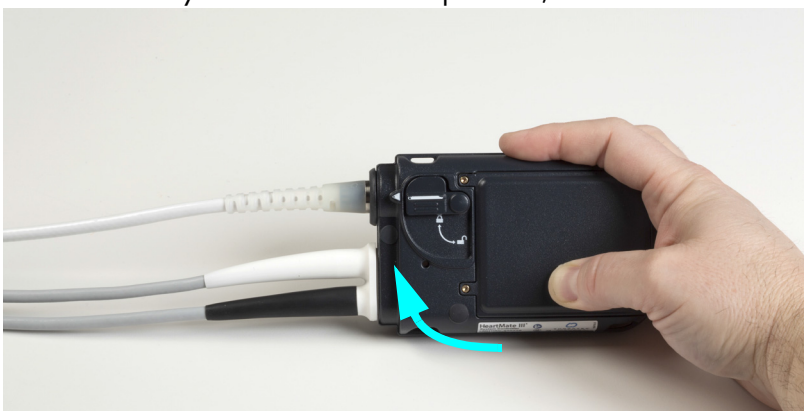


Figure 2.41 Closing the Safety Lock

7. Complete the following steps:
   a. Disconnect the Black Power connection from the previously running System Controller.
   b. Connect the Black Power connection to the replacement System Controller, which is now supporting the patient.
   c. Fully secure the black nut until tight.
8. Put the previously running System Controller into Sleep Mode.

For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 2-51.

Replacing the Current System Controller with Multiple Power Sources

To replace the current System Controller with the replacement System Controller using multiple power sources:

1. If the current System Controller is alarming, press the **Silence Alarm** button ( ).

   This will silence the audio alarms for 2 minutes.

2. Locate the replacement HeartMate III System Controller and second power source.
3. Complete the following steps to power the replacement System Controller:
   a. Connect both the White and Black Power connections.
   b. Fully secure both the white and black nuts until tight.
4. Complete the following steps to disconnect the Driveline from the current System Controller:
   a. Orient the System Controller so the display is facing down.
   b. Rotate the Safety Lock to the unlocked position (**Figure 2.42**).

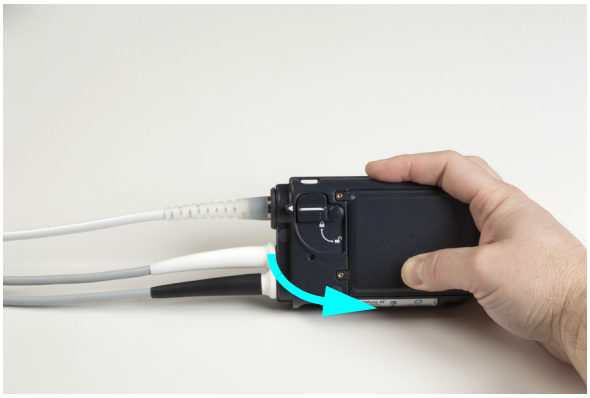


Figure 2.42 Unlocking the Safety Lock

   c. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket.
   d. Grasp the bend relief of the Driveline while removing it.

      Do not pull on or bend the Controller Driveline Connector (**Figure 2.43**).

Figure 2.43 Removing the Driveline

5. Complete the following steps to connect the Driveline to the replacement System Controller:
   a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.44**).

Figure 2.44 Aligning the Arrows

   b. Insert the Driveline Cable Connector into the socket pressing firmly until it snaps into place.

      The Left Ventricular Assist Device may take up to 10 seconds to start running when the cable is fully and properly inserted in the socket (if Pump Set Speed is set above 4,000 rpm).

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

6. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.45**).

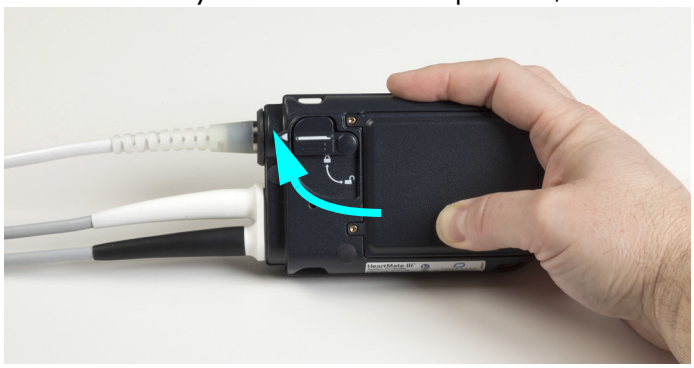


Figure 2.45 Closing the Safety Lock

7. Complete the following steps:
   a. Disconnect the Black Power connection from the previously running System Controller.
   b. Disconnect the White Power connection from the previously running System Controller.
   c. Put the previously running System Controller into Sleep Mode.

      For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 2-51.

Turning Off the System Controller (Sleep Mode)

1. Disconnect the Driveline from the System Controller.
2. Press and release the **Silence Alarm** button ( ) to silence the Driveline Disconnected Alarm.
3. Disconnect the System Controller from its power source: Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries.
4. Press and release the **Silence Alarm** button ( ) to silence the Power Cable Disconnect Alarm.
5. Press and hold the **Battery** button ( ) for five seconds.

   The word *Hold* accompanied by a reverse countdown from five dots to one dot (5 dots, 4 dots, 3 dots, 2 dots, 1 dot) appears on the screen.

   When the countdown ends, the screen goes black, the Pump Running symbol is black ( ), and the System Controller is in Sleep Mode. If this sequence is not fully completed, the System Controller will not enter Sleep Mode.

Replacing the Modular Cable

One segment of the Driveline includes the Modular Cable. If the Modular Cable needs to be replaced due to damage or fatigue, it can be accomplished in two ways.

- Option 1: Replace the current Modular Cable with both a NEW Modular Cable and replacement System Controller.
- Option 2: Replace the current Modular Cable with a NEW Modular Cable only.

Option 1: Replacing the Current Modular Cable with a Replacement Modular Cable and a Replacement System Controller

This method is intended to have the shortest time that the Pump is not running while changing the Modular Cable.

Before beginning this task, check that:

- The replacement Modular Cable is available.
- The replacement System Controller is available.
- There is an additional power source for the replacement System Controller.

PROCEDURE:

1. If the current System Controller is alarming, press the **Silence Alarm** button ( ).

   This will silence the audio alarms for 2 minutes.
2. Gather the replacement Modular Cable and the replacement System Controller.

3. Connect the additional power source to the replacement System Controller.

   The additional power source can be batteries, the Power Module patient cable, or the Mobile Power Unit patient cable.

4. To connect the replacement Modular Cable to the replacement System Controller:

   a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.46**).

Figure 2.46 Aligning the Arrows

   b. Insert the Driveline Cable Connector into the socket and press firmly until it snaps into place.

   Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

5. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.47**).

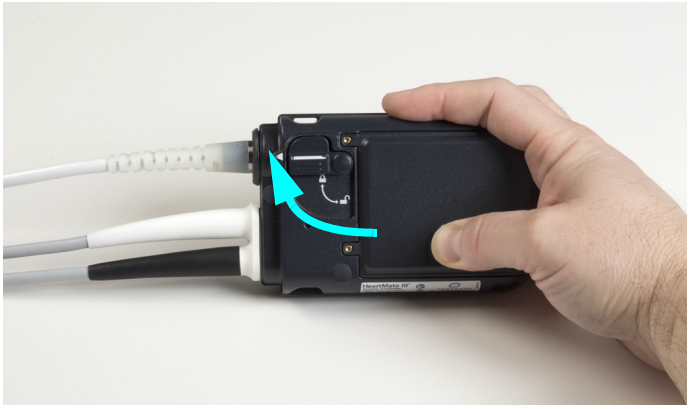


Figure 2.47 Closing the Safety Lock

6. Complete the following steps to disconnect the currently connected Modular Cable from the Pump Cable:
   a. Rotate the locking nut of the in-line connector (**Figure 2.48**).
   b. Listen for a clicking sound as the locking nut is rotated.

      The clicking sound is normal. When the clicking sound has stopped, and the locking nut spins freely, the locking nut has been unlocked.

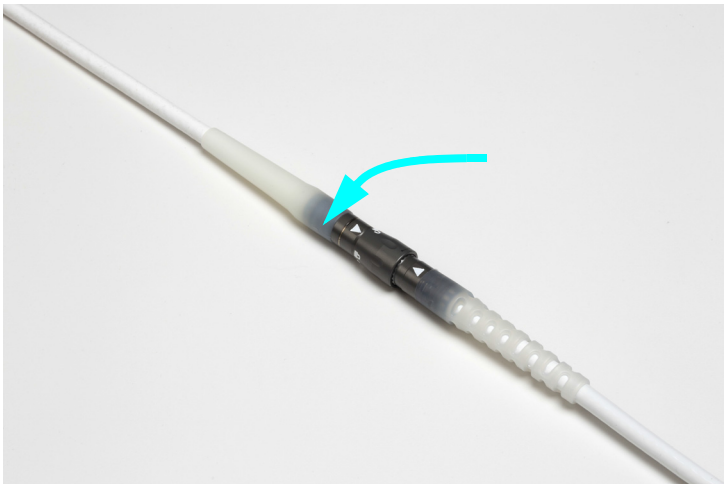


Figure 2.48 Rotating the Locking Nut

   c. Pull the connectors apart (**Figure 2.49**).

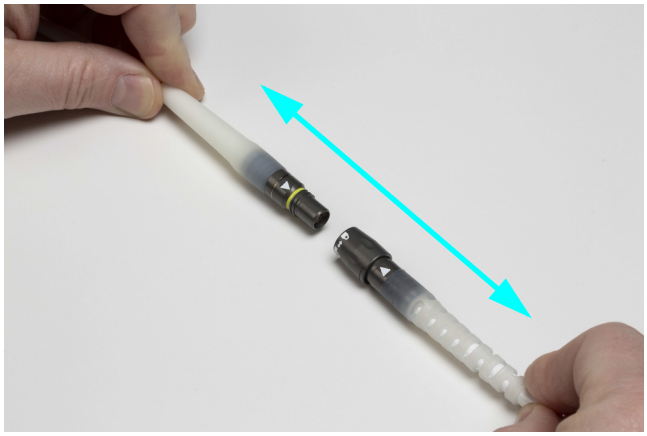


Figure 2.49 Pulling the Connectors Apart

7. Complete the following steps to connect the replacement Modular Cable to the Pump Cable (which has already been connected to the replacement System Controller):
   a. Align the white triangles.
   b. Push the connectors firmly together (**Figure 2.50**).

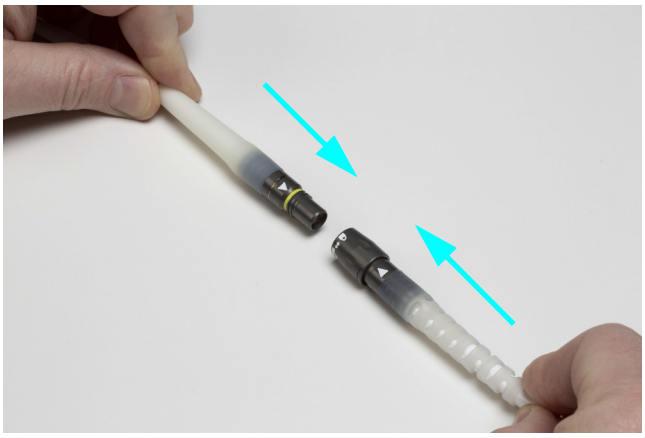


Figure 2.50 Aligning the White Triangles

   c. Rotate the locking nut of the Modular In-Line connector.
   d. Wait for the clicking sound to stop and ensure that the yellow line is hidden by the locking nut (**Figure 2.51**).

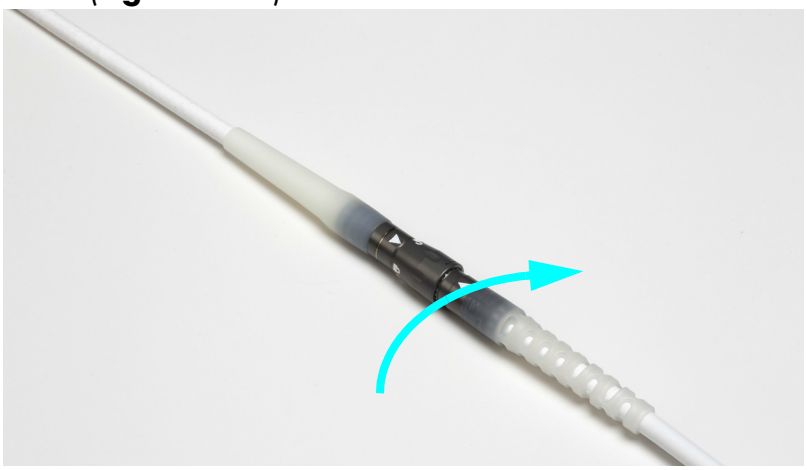


Figure 2.51 Rotating the Locking Nut

8. Disconnect power and the Modular Cable from the original System Controller.
9. Put the System Controller into Sleep Mode or it will continue to alarm.

Option 2: Replacing the Current Modular Cable with a Replacement Modular Cable

PROCEDURE:

1. Ensure that the replacement Modular Cable is available.
2. If the current System Controller is alarming, press the **Silence Alarm** button ( ).

   This will silence the audio alarms for 2 minutes.
3. To disconnect the current Modular Cable from the System Controller:
   a. Orient the System Controller so the display is facing down.
   b. Rotate the Safety Lock to the unlocked position (**Figure 2.52**).

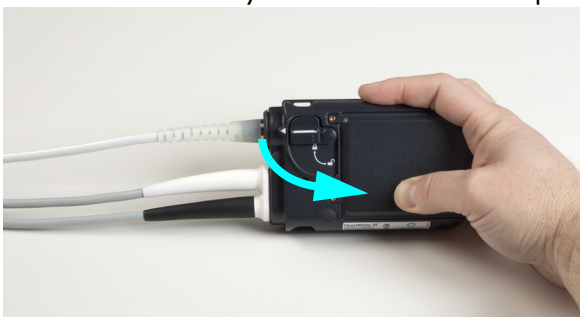


Figure 2.52 Unlocking the Safety Lock

   c. Unlock the Locking Nut on the currently connected Modular Cable from the Pump Cable by rotating the locking nut of the in-line connector (**Figure 2.53**).
   d. Listen for a clicking sound as the locking nut is rotated.

      The clicking sound is normal. When the clicking sound has stopped, and the locking nut spins freely, the locking nut has been unlocked.

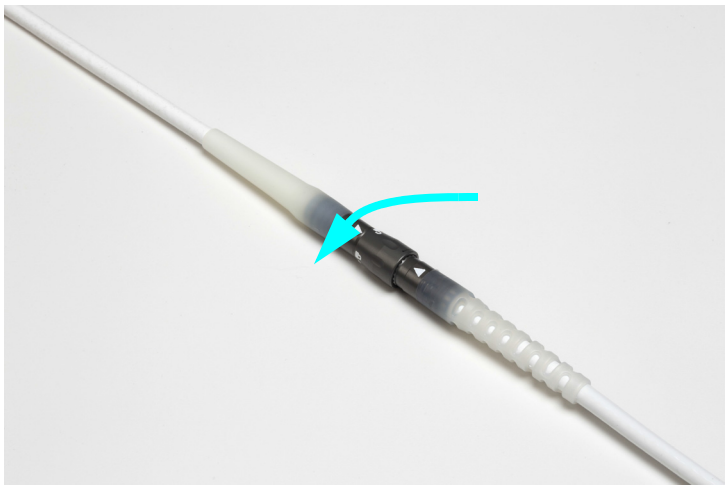


Figure 2.53 Rotating the Locking Nut

e. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket.

f. Grasp the bend relief of the Driveline while removing it.

Do not pull on or bend the Controller Driveline Connector (**Figure 2.54**).

Figure 2.54 Removing the Driveline

4. Complete the following steps to connect the replacement Modular Cable to the System Controller:

a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.55**).

Figure 2.55 Aligning the Arrows

b. Insert the Driveline Cable Connector into the socket and press firmly until it snaps into place.

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

5. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.56**).

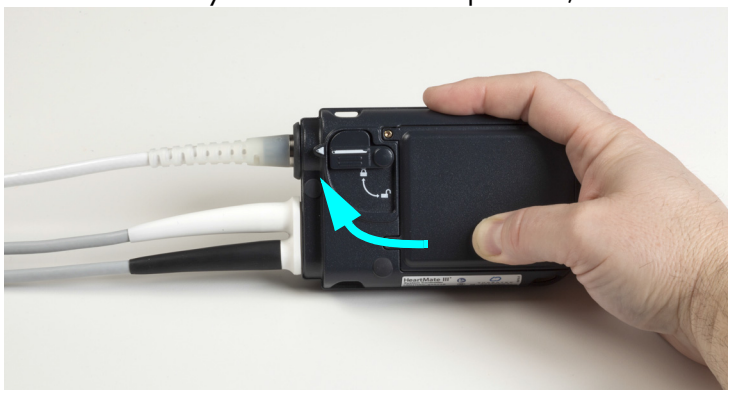


Figure 2.56 Closing the Safety Lock

6. Pull apart the Modular In-line Connector (**Figure 2.57**).

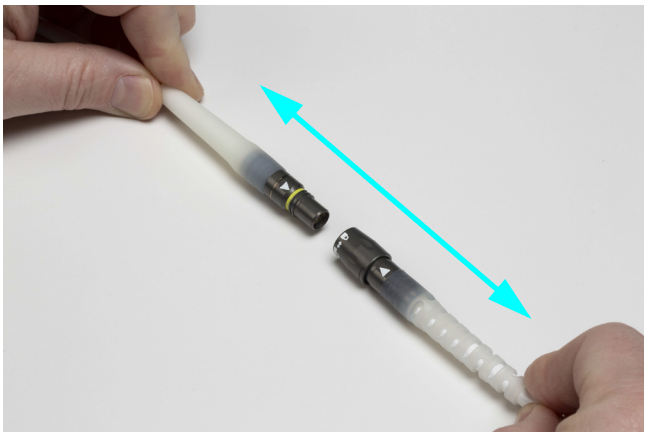


Figure 2.57 Pulling the Connectors Apart

7. Complete the following steps to connect the replacement Modular Cable to the Pump Cable (which has already been connected to the replacement System Controller):
   a. Align the white triangles.
   b. Push the connectors firmly together (**Figure 2.58**).

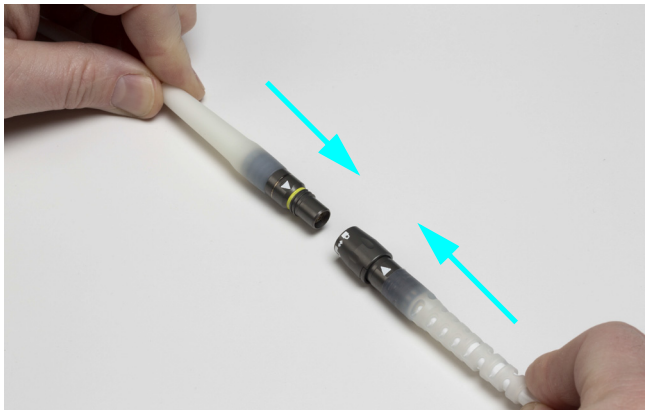


Figure 2.58 Aligning the White Triangles

8. Rotate the locking nut of the Modular In-Line connector (**Figure 2.59**).
9. Wait for the clicking sound to stop and ensure that the yellow line is hidden by the locking nut.

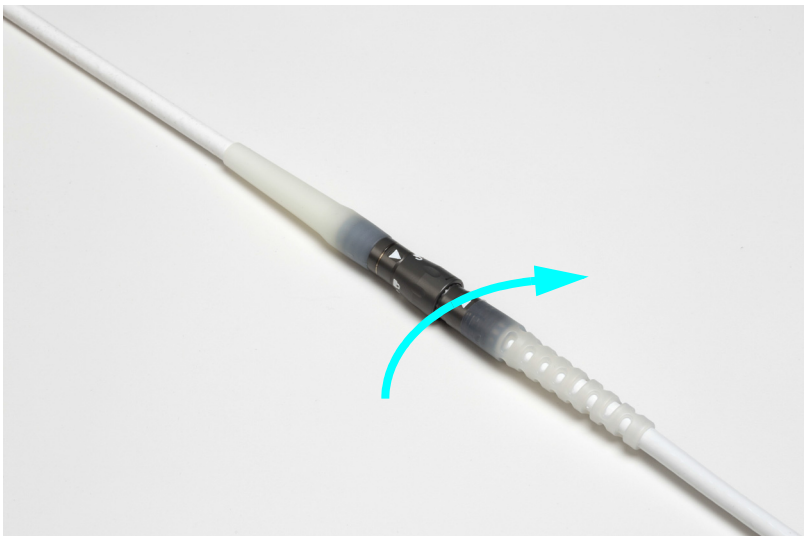


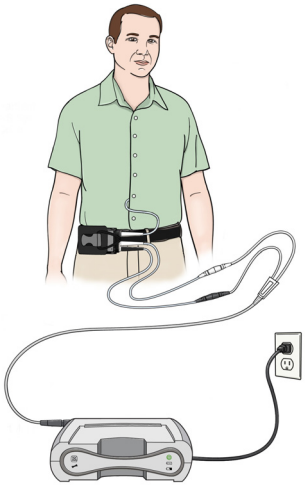
Figure 2.59 Rotating the Locking Nut

POWERING THE SYSTEM

This section describes the various methods that can be used to power the HeartMate III Left Ventricular Assist System.

3 Powering the System

Power Overview



Power Module—The Power Module is intended for use in the clinical setting when the patient requires monitoring using the System Monitor. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller.

Mobile Power Unit—The Mobile Power Unit is for home or clinical use when the patient does not require monitoring using the System Monitor. The Mobile Power Unit is used when the patient is indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.

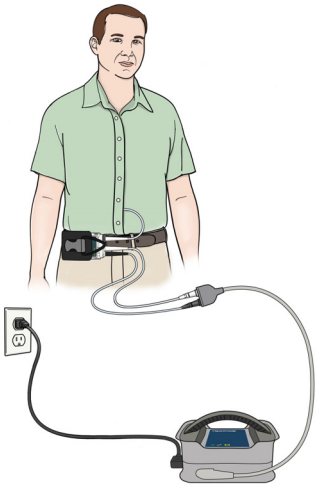


Figure 3.1 Power Module and Mobile Power Unit

Two HeartMate 14 Volt Lithium-Ion Batteries—HeartMate batteries are used to power the system during battery-powered operation when AC electricity is not wanted or is unavailable. Batteries are used in pairs and are discharged at the same time. Each battery is inserted into a 14 Volt battery clip. The clips transfer battery power to the System Controller with two power cables, one for each clip. Without battery clips, the batteries cannot transfer power to the system. When fully charged, a pair of new HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 17 hours, depending on the activity level of the patient.

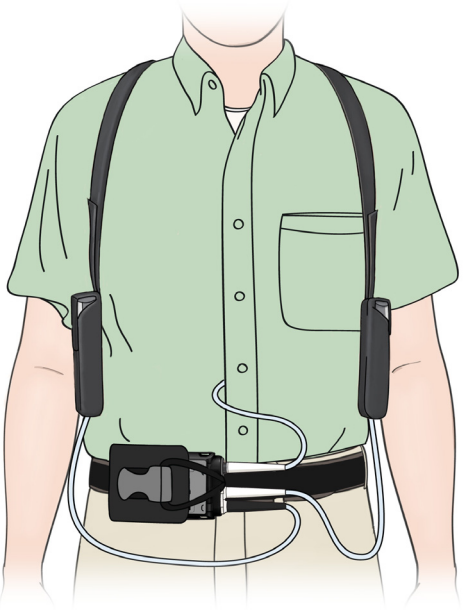


Figure 3.2 HeartMate 14 Volt Lithium-Ion Batteries

The Battery Charger is needed to charge, test, and calibrate the 14 Volt Lithium-Ion batteries. The Battery Charger can accommodate up to four batteries at one time.

Figure 3.3 Battery Charger

Using the Power Module

Overview

The Power Module (**Figure 3.4**):

- Provides power to the System Controller and Pump
- Provides power to the System Monitor when it is connected to the Power Module
- Connects the System Monitor to the System Controller for monitoring purposes
- Echoes System Controller alarms

Figure 3.4 Power Module

Required Components

The following components are required for connecting the Power Module to the System Controller:

- HeartMate Power Module with an installed Power Module backup battery
- Power Module patient cable
- Power Module power cord
- HeartMate III System Controller

WARNING !

- To avoid the risk of electrical shock, plug the Power Module into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use.
  - Do not use an outlet that is controlled by a wall switch.
  - Do not use an adapter plug for an ungrounded wall outlet.
  - Do not use portable, multiple outlet (power strip) adapters.
- When using the Power Module to power the system, make sure that the Power Module patient cable is correctly connected to the Power Module.
- Do not use the Power Module or Mobile Power Unit in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide, otherwise an explosion could occur.
- Keep the Power Module and Mobile Power Unit dry and away from water or liquid. If the Power Module comes into contact with water or liquid, it may fail to operate properly or cause a serious electrical shock.
- Ensure that the backup battery is connected prior to initial use and after the Power Module is shipped for service or maintenance. The Power Module contains an internal backup battery that provides approximately 30 minutes of backup power to the system during a power emergency. The Power Module ships with the backup battery disconnected. The battery must be connected prior to initial use. If the Power Module backup battery is not connected, the backup power source does not work.
- Do not disconnect the Power Module patient cable from the Power Module when troubleshooting for a *Not Receiving Data* message.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- The patient must always connect to the Power Module or Mobile Power Unit for sleeping, or when there is a chance of sleep. A sleeping patient may not hear System Controller alarms.
- Before using the Power Module, a trained individual must install the Power Module backup battery.
- Before using the Mobile Power Unit, the Mobile Power Unit batteries must be installed.
- Keep the Power Module plugged into electrical power at all times. If the Power Module is without electrical power for approximately 18 hours or more, the Power Module backup battery may be damaged.
- Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.

WARNING ! (Continued)

- If the patient travels long distances, such as by aircraft, instruct the patient to ask for a travel safety plan. The travel plan must address steps necessary for safe travel, including the location of the nearest HeartMate implant center.
- The HeartMate Power Module and Mobile Power Unit radiate radio frequency energy. If not used according to instructions, the Power Module and the Mobile Power Unit may cause harmful interference with nearby devices. To confirm interference, unplug the Power Module and/or the Mobile Power Unit, and observe the effect on devices in the area. If interference is detected, switch to battery power and:
  - Re-orient or move the affected device or devices.
  - Increase the distance between the Power Module and/or the Mobile Power Unit, and the affected device or devices.
  - Connect affected device or devices to an electrical outlet different from the outlet used to power the Power Module and/or the Mobile Power Unit.
- Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may affect electromagnetic compatibility of the Power Module with other devices. Potential interference may occur between the Power Module and other devices.
- If traveling by aircraft, the patient should be instructed to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.

CAUTION !

- The Power Module requires preventive maintenance at least once every 12 months. Preventive maintenance includes (but is not limited to): a functional test, replacing the Power Module backup battery (the backup battery is rechargeable but has a limited life), and replacing the Power Module patient cable.
- Power Module service and maintenance should be performed only by service personnel who are trained by Thoratec Corporation.
- Do not clean or service the Power Module while it is providing power to the system.
- If the System Monitor is mounted on top of the Power Module, do not attempt to lift or carry the two components by using the System Monitor handle. Doing so may damage the Power Module and/or System Monitor.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Avoid positioning the Power Module such that the access to the power cord plug into the wall socket is limited and/or where disconnection of the plug from the wall socket is difficult.
- The Power Module has an AC Power Cord and Patient Cable, both of which may be a tripping hazard. Ensure that the patient, caregivers, and all other persons near the Power Module are aware of this potential hazard.

Setting Up the Power Module Before Use

To set up the Power Module, perform these tasks:

- Install the Power Module backup battery
- Connect the power cord
- Connect the Power Module patient cable

Installing the Power Module Backup Battery

After receiving the Power Module, an individual trained by Thoratec Corporation personnel must open the Power Module to install its backup battery. This must be done prior to using the Power Module.

WARNING !

After the Power Module backup battery is installed, the Power Module should be plugged into electrical power at all times. The Power Module may need to be unplugged from electrical power for an extended time, such as for transport for service or maintenance. If so, the Power Module Backup Battery should be disconnected to prevent damage to the battery.

FOR THIS TASK YOU NEED:

- 1 Power Module
- 1 crosshead (Phillips) screwdriver
- 1 Power Module backup battery

TO INSTALL THE POWER MODULE BACKUP BATTERY:

1. Place the Power Module on a flat, stable surface.
2. Transfer the patient to battery power before disconnecting the Power Module.
3. Ensure that the Power Module is unplugged from AC power and disconnected from the patient.
4. Inspect the Power Module for dents, chips, cracks, or other signs of damage:
   - If the Power Module is not damaged, go to Step 5.
   - If the Power Module is damaged, contact Thoratec Corporation for a replacement, if needed. Do not use a Power Module that appears damaged.
5. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure that they are not lost (**Figure 3.5**).

Figure 3.5 Loosening the Screws

6. Open the battery compartment cover on the rear of the Power Module (**Figure 3.6**).

Figure 3.6 Removing the Battery Compartment Cover

7. Use the crosshead (Phillips) screwdriver to remove the metal bracket that will hold the internal battery in place (**Figure 3.7**).

Figure 3.7 Removing the Metal Bracket

8. Remove the Power Module backup battery from the packaging.
9. Place the black battery connector over the metal contact end of the backup battery. The contacts should snap into place.
10. Gently pull on the connection to ensure that it is secure (**Figure 3.8**).

Figure 3.8 Securing the Battery to the Battery Connector

The Power Module alarms (audio and visual) indicating that the unit is disconnected from AC power.

11. Press the **Silence Alarm** button ( ) on the user panel to silence the alarm.
    The alarm clears when AC power is applied to the Power Module.
12. Place the Power Module backup battery in the battery compartment (**Figure 3.9**).

Figure 3.9 Placing the Battery in the Battery Compartment

13. Complete the following steps:
    a. Use the crosshead (Phillips) screwdriver to reattach the metal bracket.
    b. Ensure that the white connectors and wires are not trapped under the metal bracket.
    c. Ensure that the connection is secure (**Figure 3.10**).

Figure 3.10 Reattaching the Metal Bracket

14. Gently fold the wires and white connector along the top of the Power Module backup battery, and over the metal bracket screws (**Figure 3.11**).

Figure 3.11 Folding the Wires and Connector Along the Top

15. Replace the battery compartment cover and complete the following steps:
    a. Use the crosshead (Phillips) screwdriver to tighten the two ¼-turn screws.
    b. Ensure that the screws are tight and the cover is securely closed (**Figure 3.12**).

Figure 3.12 Tightening the Screws

16. If the Power Module was transported or shipped for service, reconnect the Power Module backup battery.

Connecting the Power Module Power Cord

FOR THIS TASK YOU NEED:

- 1 Power Module, with Power Module backup battery installed and connected
- Functioning and grounded (3-prong) AC electrical outlet dedicated to Power Module use and not controlled by a wall switch
- 1 Power Module power cord

TO CONNECT THE POWER MODULE POWER CORD:

1. Place the Power Module on a flat, sturdy surface.
2. Plug the power cord into the Power Module (**Figure 3.13**).

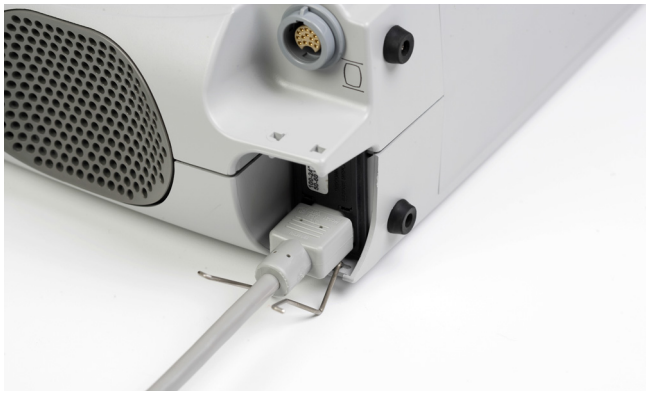


Figure 3.13 Plugging the Power Cord into the Power Module

3. Lift the power cord retention clip into the locked position.
4. Insert the two ends of the clip into the holes and ensure that the clip is securely engaged (**Figure 3.14**).

Figure 3.14 Inserting the Ends of the Clip Into the Holes

5. Plug the Power Module into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use.
   - Do not use an outlet that is controlled by a wall switch.
   - Do not use an adapter plug for an ungrounded wall outlet.
   - Do not use portable, multiple outlet (power strip) adapters.
6. Observe the front panel of the Power Module and complete one of the following steps:
   - If the green Power On light illuminates (**Figure 3.15**), the Power Module power cord is connected.
   - If the light does not illuminate, contact Thoratec Corporation for a replacement, if needed. The device may be defective. Do not use a defective device.

IMPORTANT! Wait for the Power Module backup battery to charge before using the Power Module for the first time, after service transportation, or after prolonged storage. It can take up to 3 hours to charge the backup battery.

Within a few hours, the Power Module backup battery should be charged and ready for use, as indicated by a green battery symbol (**Figure 3.15**).

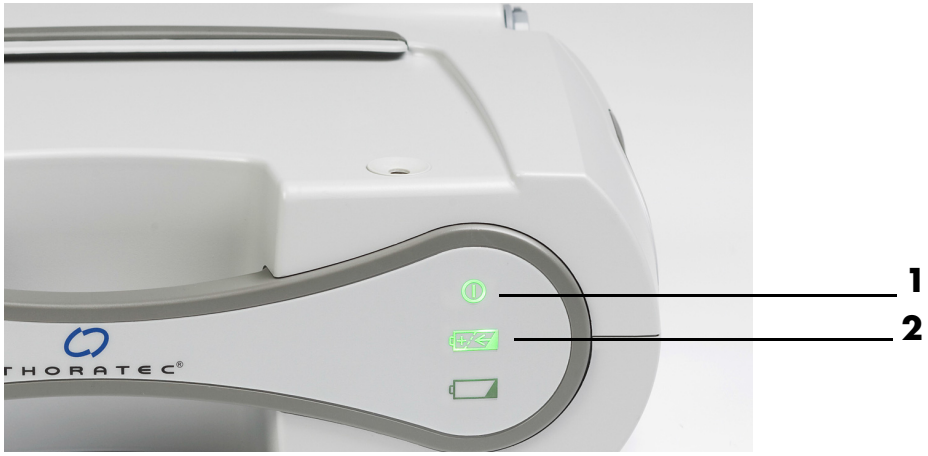


Figure 3.15 Power Module is Ready for Use When the Power On and Charge Lights are Green

1	**Power On Light**
2	**Green Battery Symbol**

Connecting the Power Module Patient Cable

The System Controller cannot connect to the Power Module without the Power Module patient cable. The 20-foot (6.1-meter) Power Module patient cable allows a patient some mobility while tethered to the Power Module.

FOR THIS TASK YOU NEED:

- 1 Power Module with Power Module backup battery installed and connected
- 1 running System Controller
- 1 Power Module patient cable
- 1 Power Module power cord to connect to an AC electrical power outlet

TO CONNECT THE POWER MODULE PATIENT CABLE:

1. Locate the Power Module patient cable (**Figure 3.16**).

Figure 3.16 Power Module Patient Cable

2. Align the red dot on the patient cable with the red dot near the heart socket (♥) on the Power Module, and then insert the patient cable into the socket (**Figure 3.17**).

   The cable clicks into place when fully engaged in the socket.

Figure 3.17 Aligning the Red Dots

3. Tug gently on the black strain relief portion of the connector to confirm that the connection is tight. Do not pull on the cable (**Figure 3.18**).

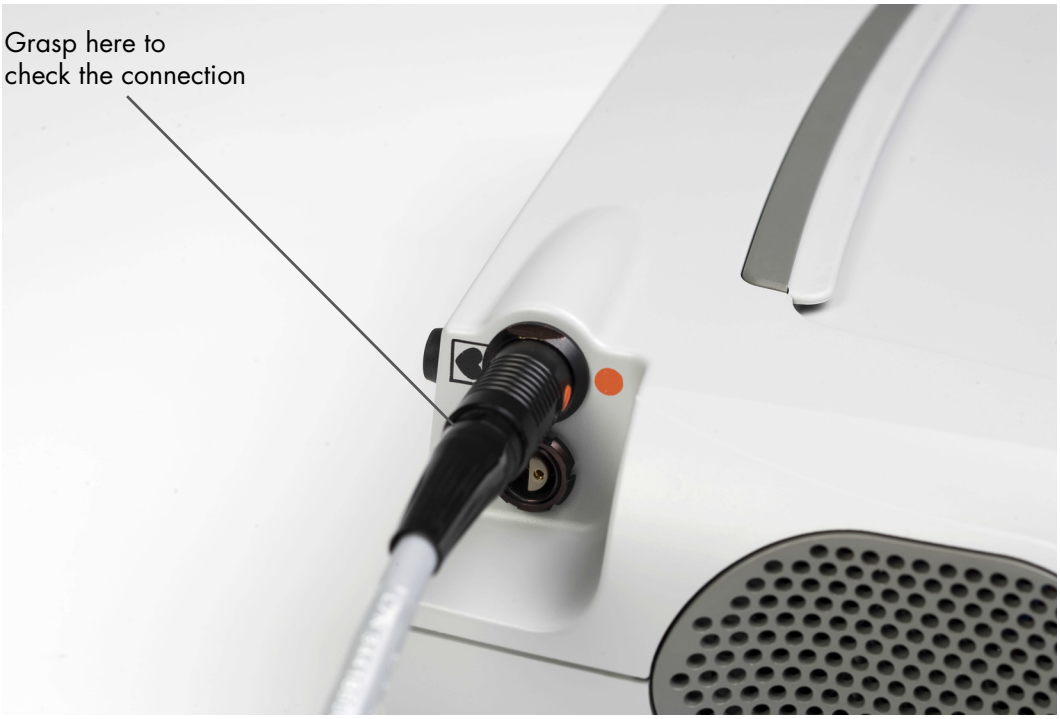


Figure 3.18 Tugging on the Black Strain Relief Portion to Check the Connection

The Power Module should be ready for use after the following actions occur:

- The Power Module internal battery is charged.
- The Power Module is plugged in.
- The Power Module patient cable is connected to the "♥" socket.

4. If the Power Module is being used for the first time, perform a Power Module system self test.

   For more information about performing the self test, refer to *Performing a Power Module Self Test* on page 3-22.

5. If the Power Module patient cable remains connected to the Power Module when not in use, complete the following steps:
   - Ensure that the Power Module patient cable does not become damaged.
   - Ensure that the Power Module patient cable is placed so that the patient does not trip or fall.

Connecting to the Power Module

Connect the System Controller to the Power Module (or Mobile Power Unit) when the patient is stationary or relaxing indoors. The patient must always connect to the Power Module (or Mobile Power Unit) for sleeping or when sleep is likely. A sleeping patient may not awaken to hear low power alarms for batteries. For more information, refer to *System Controller Alarms* on page 7-3.

The Power Module patient cable is used to connect the System Controller to the Power Module (**Figure 3.19**). Care should be used when connecting or disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 7-36.

Figure 3.19 Power Module Patient Cable

FOR THIS TASK YOU NEED:

- A running System Controller
- A working Power Module that is ready for use
- A working Power Module patient cable

TO CONNECT THE SYSTEM CONTROLLER TO THE POWER MODULE:

1. Gather the equipment.
2. Confirm that the Power Module is ready for use.
   Refer to *Setting Up the Power Module Before Use* on page 3-9.
3. Grasp the single-connector end of the Power Module patient cable (**Figure 3.20**).

Figure 3.20 Single-Connector End of the Power Module Patient Cable

4. Locate the red dot on the single-connector end of the Power Module patient cable connector (**Figure 3.21**).

Figure 3.21 Red Dot on the Connector

5. Align the red dot on the connector with the red dot near the heart socket (♥) on the Power Module.
6. Firmly insert the single-connector end into the heart socket (♥) on the Power Module (**Figure 3.22**).

   The connector clicks into place when correctly inserted.

Figure 3.22 Aligning the Red Dot on the Connector with the Red Dot on the Power Module

7. Test the connection by tugging gently on the flexible strain-relief portion of the inserted connector.

CAUTION !

Do not pull on or bend the cable, as this could damage it.

8. Place the black and white System Controller power cable connectors within reach (**Figure 3.23**).

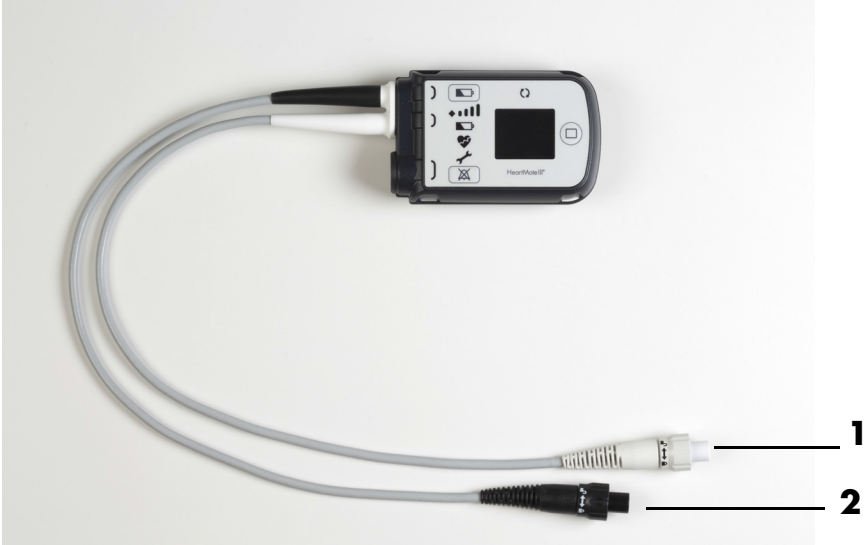


Figure 3.23 Black and White System Controller Power Cable Connectors

1	**White Connector**
2	**Black Connector**

9. Place the black and white Power Module patient cable connectors within reach (**Figure 3.24**).

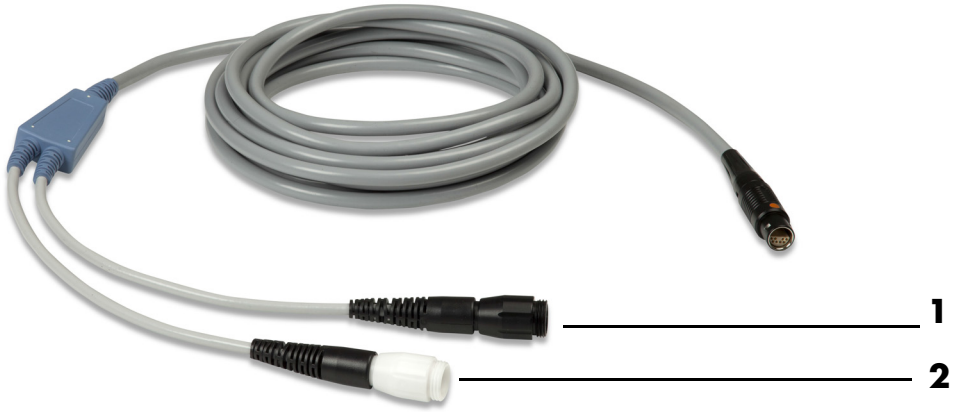


Figure 3.24 Black and White Power Module Patient Cable Connectors

1	**Black Connector**
2	**White Connector**

10. If currently using battery power, complete the following steps:
    a. Refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.
    b. Place the batteries and attached battery clips within reach.
    c. Unscrew and disconnect only the ***white*** System Controller power cable connector from the attached battery clip.

    IMPORTANT! The Power Cable Disconnect alarm comes on when a power cable is removed from power. This is normal. The alarm continues until the connection is restored or the silence alarm button ( ) is pressed.

    d. Promptly align opposite half circles inside the white System Controller power cable connector and the white Power Module patient cable connector (**Figure 3.25**).

CAUTION !

Do not try to join together misaligned connectors. Doing so can damage them.

    e. Firmly push together the two connectors.

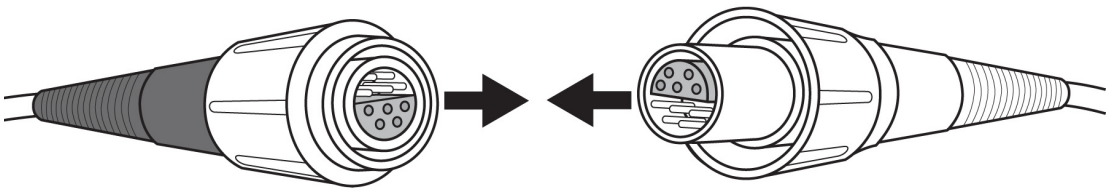


Figure 3.25 Aligning the Half Circles on the Connectors

    f. Securely hand tighten the connector nut.

    Do not use tools.

    g. Unscrew and disconnect only the ***black*** System Controller power cable connector from the attached battery clip.
    h. Promptly align opposite half circles inside the black System Controller power cable connector and the black Power Module patient cable connector.

CAUTION !

Do not try to join together misaligned connectors. Doing so can damage them.

i. Firmly push together the two connectors.

j. Securely hand tighten the connector nut. Do not use tools.

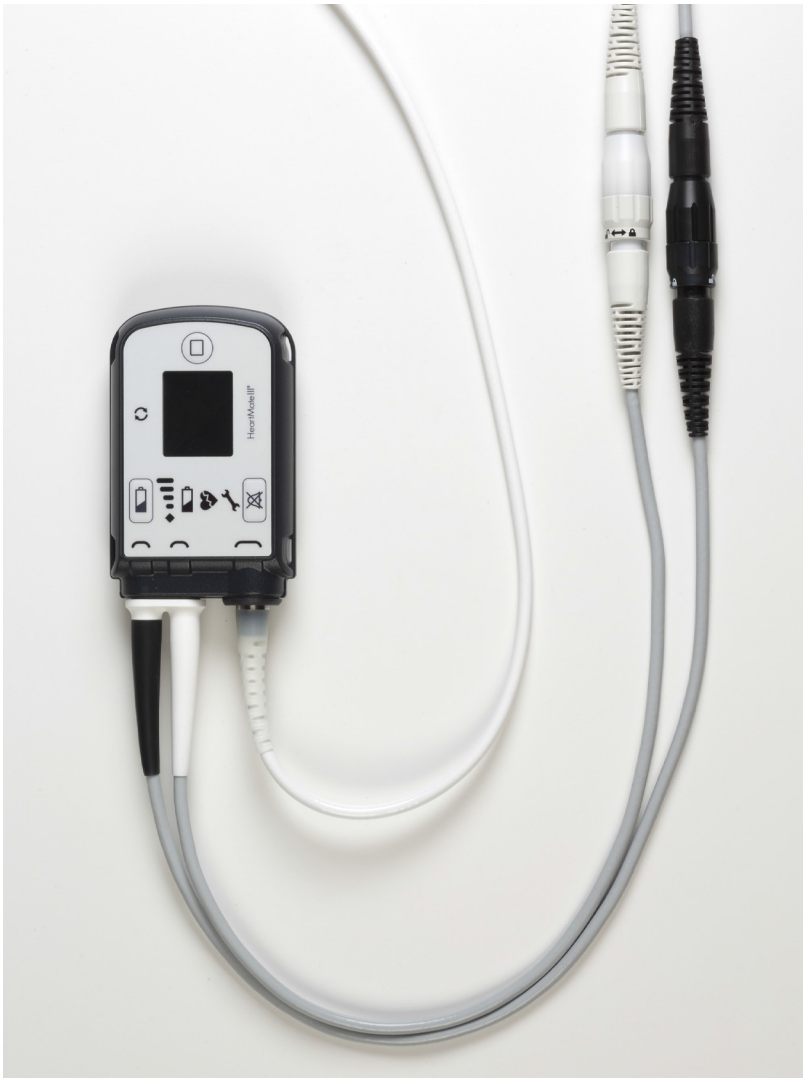


Figure 3.26 System Controller Power Cables Connected to Power Module Patient Cables

Monitoring Power Module Performance

The computer inside the Power Module is continually monitoring Power Module performance. If the Power Module computer detects a problem or malfunction, the yellow wrench symbol appears on the front of the Power Module. The yellow wrench is accompanied by an audio tone. This is a steady or beeping tone, depending on the condition. Refer to *Handling Power Module Alarms* on page 7-29 for guidelines on handling Power Module alarms.

Performing a Power Module Self Test

Perform a Power Module self test before using the Power Module for the first time, and at least once daily to ensure that the Power Module is working properly. A self test may be performed while the Power Module is powering the pump.

FOR THIS TASK YOU NEED:

- 1 Power Module, with Power Module backup battery connected
- Functioning and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use and not controlled by a wall switch

TO PERFORM A POWER MODULE SELF TEST:

1. Press and hold the Power Module's silence alarm button () for five seconds.
2. Listen for 3 beeps and watch the front of the Power Module:
   - If the Power Module passes the self test and is ready for use, the lights will come on in sequence: one at a time, not all at the same time.
   - The Power Module may have a problem if any of the following conditions occur:
     - There is no sound
     - Anything other than 3 beeps (such as continuous beeping or a broken tone)
     - All the lights come on at the same time
     - All the lights remain off
     - One of the lights does not come on
3. If any of the previous unexpected conditions occur, contact Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information.

   For guidelines on responding to Power Module alarms, refer to *Handling Power Module Alarms* on page 7-29.

Power Module Backup Power

The Power Module has an internal backup battery. A new Power Module backup battery provides approximately 30 minutes of backup power to the HeartMate III system if power fails or is disconnected. Over time, the internal battery may provide shorter periods of backup power.

The Power Module backup battery remains charged as long as the Power Module remains connected to AC power. If the Power Module is disconnected from external power, the Power Module backup battery operates the LVAS and the Power Module alarms until the battery is depleted. After AC power is restored, the Power Module backup battery automatically begins to recharge and no longer provides power to the Power Module.

The Power Module backup battery must be charged prior to use. **Table 3.1** provides a description of the charge status indicators for the Power Module backup battery.

The Power Module must be plugged into AC power at all times to ensure that the Power Module backup battery is charged and ready for use in case of power interruption. If the Power Module is without AC power for approximately 18 hours or more, the Power Module backup battery may be damaged. If the Power Module backup battery is damaged, an alarm is generated on the Power Module. Refer to *Power Module Alarms* on page 7-30. Emphasize to the patient that inappropriate use during non-emergencies may reduce the power available to them in a true emergency.

If the Backup Battery Malfunction alarm occurs, replace the backup battery immediately. Only trained individuals should replace the battery. Call Thoratec Corporation for assistance, if needed. Refer to page iii for Thoratec Corporation contact information.

The Power Module internal backup battery is rechargeable. However, the battery has a limited lifespan. The backup battery is replaced during annual planned Power Module maintenance. Refer to *Cleaning and Maintenance* on page 8-4.

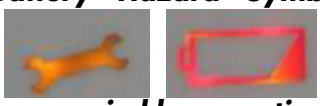
During Power Module power failure, transfer a patient from the Power Module to a Mobile Power Unit or battery-powered operation. Refer to *Switching from the Power Module to Battery-Powered Operation* on page 3-58.

Note: Although the System Monitor may be plugged in to the Power Module, it will not operate without AC power.

Checking the Charge Status of the Power Module Backup Battery

Indicator symbols on the front panel of the Power Module illuminate to indicate the charge status of the Power Module backup battery. **Table 3.1** describes the indicator symbols.

Table 3.1 Charge Status Indicators for the Power Module Backup Battery

Green Charge Lamp 	The Power Module backup battery is charged and ready for use.
Yellow Charge Lamp 	The Power Module backup battery is charging.
Yellow Battery Advisory Symbol  ***accompanied by beeping audio tone***	Less than 15 minutes of Power Module backup battery power remain. Promptly switch to another power source.
Red Battery Hazard Symbol  ***accompanied by beeping audio tone***	Less than 5 minutes of Power Module backup battery power remain. Immediately switch to another power source.
Yellow Wrench with Red Battery "Hazard" Symbol  ***accompanied by a continuous audio tone***	The Power Module Backup battery is not functioning properly or it is not installed.

The Power Module is shipped with the Power Module backup battery not installed. If the Power Module backup battery is not installed or connected when the Power Module is plugged in, the Power Module alarms. This alarm indicates that it cannot provide backup power in the event of a power interruption or failure.

When the Power Module alarms, a continuous audio tone sounds, and the yellow wrench and red battery symbols illuminate. To clear the alarm, the Power Module should be disconnected from AC power, and then the internal backup battery should be connected. To connect the internal backup battery, refer to the instructions in *Installing the Power Module Backup Battery* on page 3-9.

Figure 3.27 Green Charge Symbol (Power Module Backup Battery is Charged)

Figure 3.28 Yellow Charge Symbol (Power Module Backup Battery is Charging)

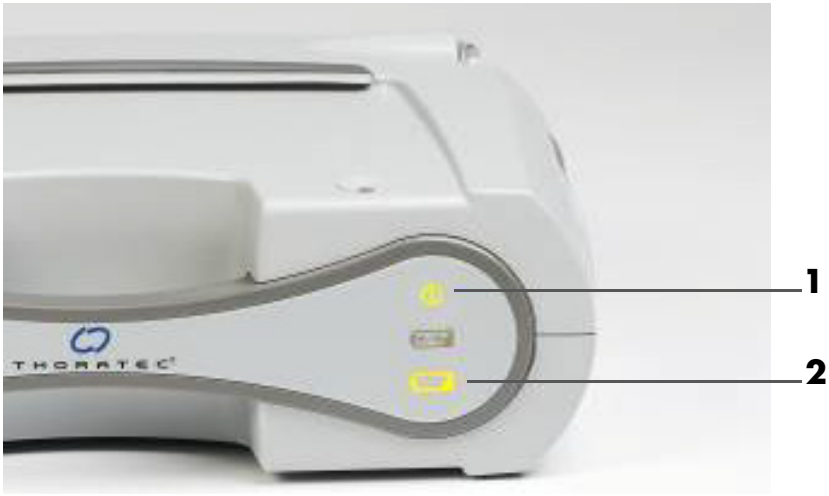


Figure 3.29 Yellow Power On Light and Battery Advisory Symbol (Less than 15 Minutes of Power Module Backup Power)

1	**Power On light is yellow**
2	**Battery Advisory symbol is yellow**

WARNING !

If the Wrench Malfunction symbol illuminates yellow and the Battery Hazard symbol illuminates red (**Figure 3.30**), switch to another Power Source immediately.

Figure 3.30 Yellow Wrench and Red Battery Hazard Symbol (Power Module Backup Battery is Not Working)

1	**Wrench Malfunction symbol is yellow**
2	**Battery Hazard symbol is red**

Storing and Shipping the Power Module

If the Power Module is without electrical power for approximately 18 hours or more, the internal backup battery may be damaged. The Power Module backup battery must be disconnected if the Power Module is not being used and will be unplugged from electrical power for an extended time (such as for travel or for transport for service or maintenance). Disconnecting the Power Module backup battery prevents damage to the battery.

Disconnecting the Power Module Backup Battery

The Power Module backup battery should be disconnected any time the Power Module is unplugged for an extended period, such as when the Power Module is shipped for service or during extended periods of time without AC. In these situations, the battery remains in the battery compartment but is not connected.

FOR THIS TASK YOU NEED:

- 1 Power Module backup battery installed and connected
- 1 crosshead (Phillips) screwdriver

TO DISCONNECT THE POWER MODULE BACKUP BATTERY:

1. Transfer the patient to battery power prior to disconnecting the Power Module backup battery.
2. Place the Power Module on a flat, stable surface.
3. Ensure that the Power Module is unplugged from AC power and disconnected from the patient.
4. Inspect the Power Module for dents, chips, cracks, or other signs of damage, and complete one of the following steps:
   - If the Power Module is undamaged, go to Step 5.
   - If the Power Module is damaged, contact Thoratec Corporation for a replacement if needed. Do not use a Power Module that appears damaged.
5. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure they are not lost (**Figure 3.31**).

Figure 3.31 Loosening the Screws

6. Open the battery compartment cover on the rear of the Power Module (**Figure 3.32**).

Figure 3.32 Removing the Battery Compartment Cover

7. Leave the metal bracket and black clip in place, and use your finger to gently pull the wires and white connectors out away from the battery (**Figure 3.33**).

Figure 3.33 Gently Pulling the Wires and Connectors Away From the Battery

8. Complete the following steps to disconnect:

   a. Gently squeeze the white latch on the connector to free the two halves.

   b. Pull the connector halves away from each other (**Figure 3.34**).

Figure 3.34 Gently Squeezing the Latch

Note: The Power Module has audio and visual alarms that indicate that the unit is disconnected from AC power. The alarm is silenced by pressing the Silence Alarm button (⊠) on the user panel. The alarm clears when AC power is applied to the Power Module.

9. Gently fold the wires and white connector along the top of the battery, and over the metal bracket screws (**Figure 3.35**).

Figure 3.35 Gently Folding the Wires and Connector Along the Top of the Battery

10. Replace the battery compartment cover and complete the following steps:
    a. Use the crosshead (Phillips) screwdriver to tighten the two ¼-turn screws.
    b. Ensure that the screws are tight and the cover is securely closed (**Figure 3.36**).

Figure 3.36 Tightening the Screws

Reconnecting the Power Module Backup Battery

The Power Module backup battery should be reconnected any time it may have been disconnected, such as for annual maintenance.

FOR THIS TASK YOU NEED:

- 1 Power Module backup battery installed but not connected
- 1 crosshead (Phillips) screwdriver

TO RECONNECT THE POWER MODULE BACKUP BATTERY:

1. Place the Power Module on a flat, stable surface.
2. Inspect the Power Module for dents, chips, cracks, or other signs of damage, and complete one of the following steps:
   - If the Power Module is undamaged, go to Step 3.
   - If the Power Module is damaged, contact Thoratec Corporation for a replacement if needed. Do not use a Power Module that appears damaged.
3. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure they are not lost (**Figure 3.37**).

Figure 3.37 Loosening the Screws

4. Open the battery compartment cover on the rear of the Power Module (**Figure 3.38**).

Figure 3.38 Removing the Battery Compartment Cover

5. Leave the metal bracket and black clip in place, and use a finger to gently pull the wires and the two halves of the white connector out of the battery compartment (**Figure 3.39**).

Figure 3.39 Gently Pulling the Wires and Connector Halves Out

6. Line up the two connector halves (**Figure 3.40**).

Figure 3.40 Lining Up the Connector Halves

7. Firmly press the halves together.

   There is an audible click when the connector is fully engaged.

8. Gently fold the wires and white connector along the top of the battery, and over the metal bracket screws (**Figure 3.41**).

Figure 3.41 Gently Folding the Wires and Connector Along the Top of the Battery

9. Replace the battery compartment cover and complete the following steps:

   a. Use the crosshead (Phillips) screwdriver to tighten the two ¼-turn screws.

   b. Ensure that the screws are tight and the cover is securely closed (**Figure 3.42**).

Figure 3.42 Tightening the Screws

Silencing Power Module Alarms

Press the silence alarm button () to silence a Power Module audio alarm.
Table 3.2 lists the alarm types and how long each is silenced. Silence periods vary by alarm type. After the silence period ends, the audio alarm resumes unless the alarm condition has been resolved. If a new alarm condition arises during a silence period, a new audio alarm sounds.

IMPORTANT! Pressing the silence alarm button only silences the alarm. The alarm condition is not resolved, as indicated by persistence of the visual alarm.

Table 3.2 Audio Alarm Silence Periods

Audio Alarm	How Long Alarm is Silenced
Echo System Controller alarm	5 minutes.
AC Fail	Silence lasts until canceled by another alarm, such as yellow battery.
Yellow Battery	8 hours or until canceled by another alarm, such as red battery.
Red Battery	Alarm cannot be silenced if patient is connected to pump.
Yellow Wrench (Advisory)	8 hours.
Yellow Wrench (Hazard/Critical)	8 hours for non-critical faults. Alarm cannot be silenced if patient is connected to pump.

Caring for the Power Module

Refer to *Cleaning and Maintenance* on page 8-4 for warnings, cautions, and instructions on caring for the Power Module.

Using the Mobile Power Unit

The Mobile Power Unit (**Figure 3.43**):

- Provides power to the System Controller and Pump
- Powers the system while the patient is sleeping or relaxing indoors
- Echoes System Controller alarms

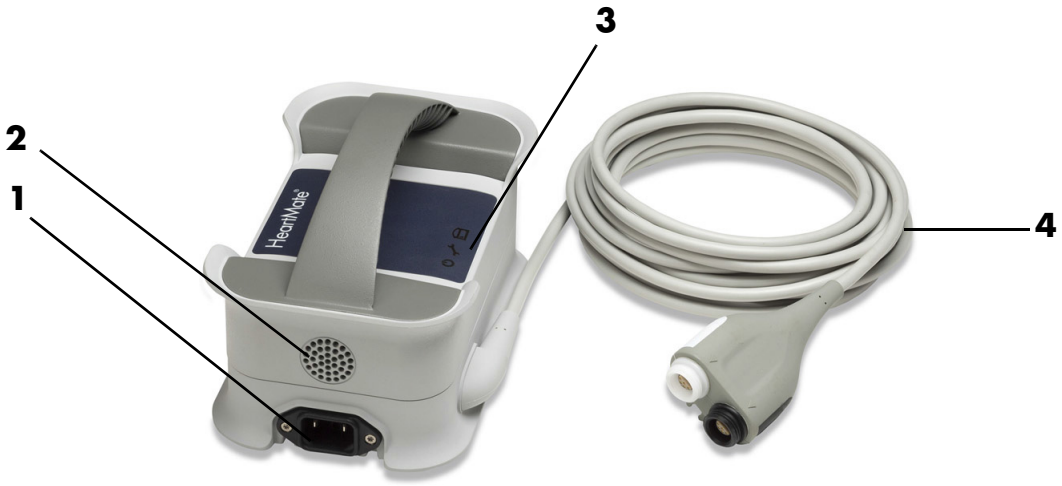


Figure 3.43 Mobile Power Unit

1	**AC Power Receptacle**
2	**Speakers**
3	**Status Symbols**
4	**Patient Cable**

WARNING !

- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.
- The Mobile Power Unit radiates radio frequency energy. If not used according to instructions, the Mobile Power Unit may cause harmful interference with nearby devices. To confirm interference, switch to battery power, and then unplug the Mobile Power Unit and observe the effect on devices in the area. If interference is detected, switch to another power source and then:
  - Re-orient or move the affected devices.
  - Increase the distance between the Mobile Power Unit and the affected devices.
  - Connect the affected devices to an electrical outlet different from the outlet used to power the Mobile Power Unit.

WARNING ! (Continued)

- The patient must always connect to the Mobile Power Unit when sleeping, or when there is a chance of sleep. A sleeping patient may not hear system alarms if not connected to the Mobile Power Unit. The Mobile Power Unit echoes the alarms.
- Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the System Controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.
- If there is a power failure, transfer the patient from the Mobile Power Unit to another power source. The backup battery in the System Controller will temporarily power the Pump while transferring to battery power. Do not rely on the System Controller's backup battery as a power source during AC power failure, as it will only power the Pump for a limited amount of time and the pump will stop.
- Keep the Mobile Power Unit dry and away from water or liquid. If the Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or cause an electrical shock.
- Do not use the Mobile Power Unit in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide, otherwise an explosion could occur.

CAUTION !

- To avoid the risk of electric shock, plug the Mobile Power Unit into a properly-tested AC electrical outlet that is dedicated to Mobile Power Unit use. Do not use portable, multiple outlet (power strip) adapters or extension cords.
- Avoid covering the Mobile Power Unit, such as with a blanket. Covering the Mobile Power Unit may reduce the ability to hear important system alarms or may cause the Mobile Power Unit to fail due to overheating.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- At least one System Controller power cable must be connected to a power source (the Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times. Do not rely on the controller's backup battery, as it will only power the pump for a limited amount of time.
- Do not use the Mobile Power Unit with DC to AC inverters, as they may cause the Mobile Power Unit to fail.
- Do not connect the Mobile Power Unit to electrical outlets that are controlled by a wall switch, as the Mobile Power Unit will fail to supply power.
- Avoid positioning the Mobile Power Unit where access to the power cord plug into the wall socket is limited or where disconnection of the plug from the wall socket is difficult.

CAUTION !

- The Mobile Power Unit has an AC Power Cord and Patient Cable, both of which may be a tripping hazard. Ensure that the patient, caregivers, and all other persons near the Mobile Power Unit are aware of this potential hazard.
- Do not clean or service the Mobile Power Unit while it is plugged into an AC electrical outlet, or electrical shock may occur.
- Do not incinerate, disassemble, crush, puncture, or otherwise damage batteries, as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not mix old and new batteries, or mix battery types (such as rechargeable and non-rechargeable). This can cause battery leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Mobile Power Unit power output may be affected by mobile phones, resulting in low power alarms on the System Controller, or loss of the green power LED on the Mobile Power Unit. If either of these conditions is observed, separate the mobile phone from the Mobile Power Unit by at least .6 meters (24 inches). If the condition persists after separating the devices, switch to two HeartMate 14 Volt Lithium-Ion batteries.
- Keep the Mobile Power Unit free of excessive lint and dust. Also, keep the Mobile Power Unit away from heat or humidity sources, such as a fireplace, radiant heater, nebulizer, or steam kettle. The Mobile Power Unit may fail to operate properly due to excessive lint, dust, heat, or humidity.
- Inspect the Mobile Power Unit patient and power cables for damage. Do not use the Mobile Power Unit if either cable shows signs of damage.
- When moving the Mobile Power Unit to a different location or AC power source, first connect the System Controller to HeartMate 14 Volt batteries.
- Do not change the Mobile Power Unit batteries while the Mobile Power Unit is powering the HeartMate system. Prior to replacing the Mobile Power Unit batteries, switch to another power source. Then disconnect the Mobile Power Unit power cord from the wall socket.
- Do not carry or touch the Mobile Power Unit for an extended time. To avoid the risk of burns, do not touch the top surface of the Mobile Power Unit for longer than one minute. The Mobile Power Unit surface temperature can become uncomfortably warm, especially when the room temperature is above 104°F (40°C). Surface temperatures can approach 131°F (55°C).

Mobile Power Unit User Interface Components

Table 3.3 describes the buttons, lights, symbols, and display screen on the Mobile Power Unit user interface.

Table 3.3 Mobile Power Unit User Interface Components

Power On Symbol 	The power symbol is illuminated green when the Mobile Power Unit is powered and functioning properly.
Yellow Wrench Alarm 	The yellow wrench symbol illuminates when the Mobile Power Unit detects a mechanical, electrical, or software issue with the system. This is an **Advisory** alarm. When the yellow wrench illuminates, switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.
Replace Mobile Power Unit Battery Alarm 	The yellow Replace Mobile Power Unit Battery symbol illuminates when the Alkaline AA batteries are not installed, or are depleted and need to be replaced. This is an **Advisory** alarm. When the Replace Mobile Power Unit Battery symbol illuminates, replace the internal batteries in the Mobile Power Unit.

Setting Up the Mobile Power Unit

To set up the Mobile Power Unit, perform these tasks:

- Install the Mobile Power Unit batteries
- Connect the Mobile Power Unit power cord to the Mobile Power Unit and AC power

Installing or Replacing the Mobile Power Unit Batteries

The Mobile Power Unit uses three Alkaline AA batteries to power its alarms. The Mobile Power Unit batteries must be installed before using the Mobile Power Unit. The batteries power the alarm echo function when an AC power failure occurs or the power cord is disconnected.

The yellow Mobile Power Unit battery symbol () illuminates and a beeping audio tone sounds when the Alkaline AA batteries are not installed, or when the batteries are depleted and need to be replaced.

CAUTION !

Never change the Mobile Power Unit batteries while the Mobile Power Unit is powering the HeartMate system. Switch to another power source, and then disconnect the Mobile Power Unit power cord from the power socket prior to replacing the batteries.

FOR THIS TASK YOU NEED:

- A Mobile Power Unit
- 3 new alkaline AA batteries
- A flathead screwdriver or coin

TO INSTALL OR REPLACE THE MOBILE POWER UNIT BATTERIES:

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Ensure that the power cord is unplugged from the Mobile Power Unit.
3. Inspect the Mobile Power Unit for dents, chips, cracks, or other signs of damage, and complete one of the following steps:
   - If the Mobile Power Unit is undamaged, go to Step 4.
   - If the Mobile Power Unit is damaged, contact Thoratec Corporation for a replacement if needed. Do not use a Mobile Power Unit that appears damaged.
4. Use a flathead screwdriver or coin to loosen the screw from the rear panel.

   The screw remains in the screw hole to ensure it is not lost (**Figure 3.44**).

Figure 3.44 Loosening the Screw

5. Open the battery compartment cover on the rear of the Mobile Power Unit (**Figure 3.45**).
6. Remove and dispose of the battery installation reminder tag, if present.

Figure 3.45 Removing the Battery Compartment Cover

7. If replacing the batteries, gently pull the ribbon to remove the depleted batteries from the case.
8. Complete the following steps to insert the batteries:
   a. Follow the orientation markings on the battery clip.
   b. Place the alkaline AA batteries in the battery compartment (**Figure 3.46**).

Figure 3.46 Installing the AA Batteries

9. Replace the battery compartment cover and complete the following steps:
   a. Use the flathead screwdriver or coin to tighten the screw.
   b. Ensure that the screw is tight and the cover is securely closed (**Figure 3.47**).

Figure 3.47 Tightening the Screw

10. Dispose of, or recycle, the depleted batteries in compliance with all applicable local, state, and federal regulations.

Connecting the Power Cord

FOR THIS TASK YOU NEED:

- A Mobile Power Unit (with 3 AA batteries installed)
- A Mobile Power Unit power cord
- Functioning AC electrical outlet that is dedicated to Mobile Power Unit use and not controlled by a wall switch

TO CONNECT THE POWER CORD:

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Plug the power cord into the Mobile Power Unit (**Figure 3.48**).

Figure 3.48 Plugging the Power Cord into the Mobile Power Unit

3. Plug the Mobile Power Unit into an AC electrical outlet that is dedicated to Mobile Power Unit use.

CAUTION !

- Do not use an outlet that is controlled by a wall switch.
- Do not use an adapter; a portable, multiple outlet power strip; a ground fault interrupter (GFI); or a residual current device (RCD) outlet.

4. Observe the top panel of the Mobile Power Unit.

   When initially connected to power, the Mobile Power Unit automatically performs a self test during which the following should occur:

   - The green Power On light turns on.
   - The yellow wrench and the Replace Mobile Power Unit Battery lights flash.
   - The Mobile Power Unit beeps twice.

   After the self test is completed, the green Power On light remains illuminated (**Figure 3.49**).

Figure 3.49 Mobile Power Unit Ready for Use

5. If any of the behaviors in Step 4 are not observed, contact Thoratec Corporation.

   Refer to page iii for Thoratec Corporation contact information.

   IMPORTANT! The power symbol (⏻) is illuminated green when the Mobile Power Unit is powered and functioning properly.

6. If the green "Power On" light does not come on, plug the power cord into another electrical outlet.

   If the green light still does not come on, the Mobile Power Unit may have a problem. Do not use a defective device. Contact Thoratec Corporation for a replacement, if needed.

WARNING !

For international travel, the patient needs a Thoratec Corporation power cord. The power cord must be compatible with the local voltage, and meet applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Contact Thoratec Corporation for a power cord, if needed. Refer to page iii for Thoratec Corporation contact information.

Connecting to the Mobile Power Unit

Connect the System Controller to the Mobile Power Unit when the patient is stationary or relaxing indoors. Do not use the Mobile Power Unit when the patient may require monitoring using the System Monitor. Patients must always connect to the Mobile Power Unit before sleeping or when sleep is likely. A sleeping patient may not awaken to hear low power alarms for batteries. Refer to *System Controller Alarms* on page 7-3.

The Mobile Power Unit patient cable connects the System Controller to the Mobile Power Unit. Similar to the power cable connectors on the System Controller, the connectors on the Mobile Power Unit patient cable are also color coded (**Figure 3.50**). When connecting the System Controller to the Mobile Power Unit patient cable, always connect white-to-white and black-to-black.

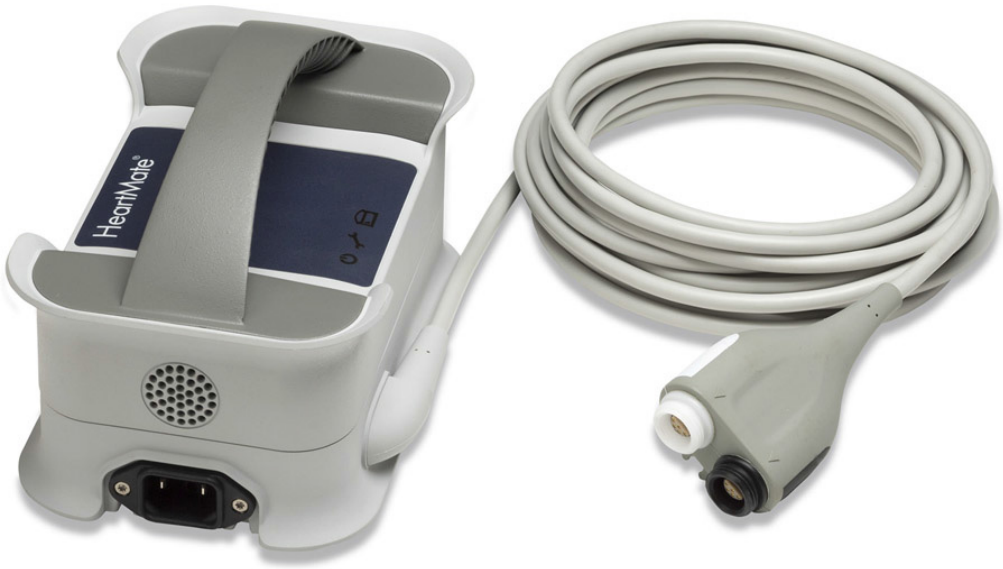


Figure 3.50 Mobile Power Unit Patient Cable

CAUTION !

Do not allow the cable to come into contact with sharp edges, and use care to prevent it from being pinched or bent.

FOR THIS TASK YOU NEED:

- A running System Controller
- A working Mobile Power Unit that is ready for use

TO CONNECT THE SYSTEM CONTROLLER TO THE MOBILE POWER UNIT:

1. Gather equipment.
2. Confirm that the Mobile Power Unit is ready for use.
   Refer to *Setting Up the Mobile Power Unit* on page 3-37.

3. Place the black and white System Controller power cable connectors within reach (**Figure 3.51**).

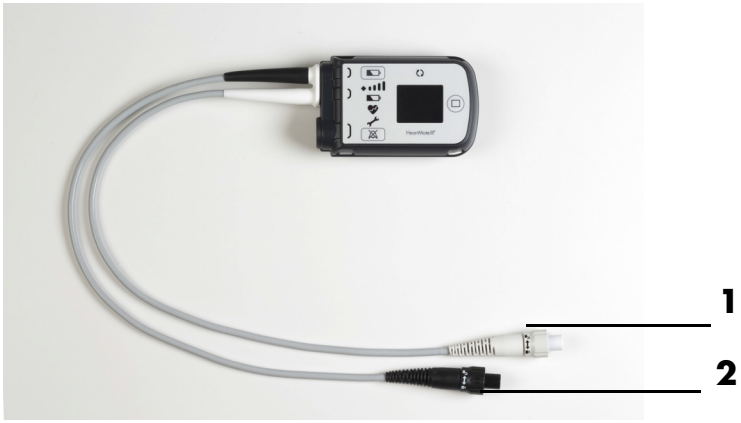


Figure 3.51 System Controller Power Cable Connectors

1	**White Connector**
2	**Black Connector**

4. Place the black and white Mobile Power Unit patient cable within reach.
5. Complete the following steps to connect from battery power:
   a. Place the batteries with their attached battery clips within reach.
   b. Unscrew and disconnect only the ***white*** System Controller power cable connector from the attached battery clip.
   c. Promptly align opposite half circles inside the white System Controller power cable connector and the white Mobile Power Unit patient cable connector (**Figure 3.52**).

CAUTION !

Do not try to join together misaligned connectors. Doing so can damage them.

Figure 3.52 Carefully Aligning the Connectors

d. Firmly push together the two connectors (**Figure 3.53**).

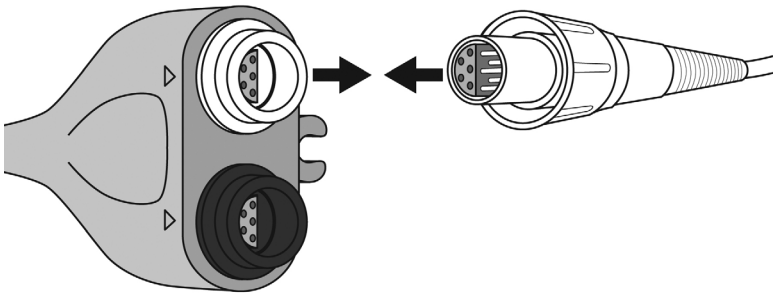


Figure 3.53 Pushing Together the Two Connectors

e. Tighten the connector nut until secure (**Figure 3.54**). Hand tighten only. Do not use tools.

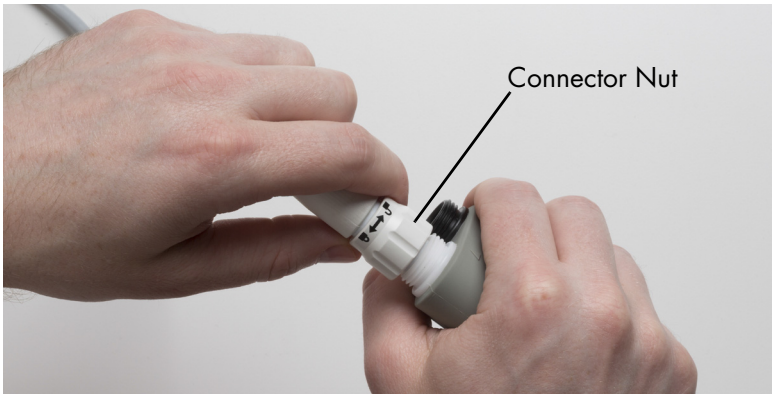


Figure 3.54 Tightening the Connector Nut

f. Unscrew and disconnect only the ***black*** System Controller power cable connector from the attached battery clip.

g. Promptly align opposite half circles inside the black System Controller power cable connector and the black Mobile Power Unit patient cable connector.

CAUTION !

Do not try to join together misaligned connectors. Doing so can damage them.

h. Firmly push together the two connectors.

i. Tighten the connector nut until secure. Hand tighten only. Do not use tools.

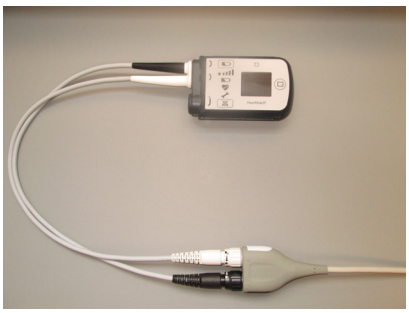


Figure 3.55 System Controller Power Cables Connected to Mobile Power Unit Patient Cable Connectors

Mobile Power Unit Storage

If the Mobile Power Unit will not be used for an extended time, unplug the AC power cord from power and detach the power cord from the device. Wrap the Mobile Power Unit patient cable around the Mobile Power Unit for storage (**Figure 3.56**). This is also a convenient way to prepare the device and patient cable for travel.

Figure 3.56 Storing the Mobile Power Unit

Caring for the Mobile Power Unit

The Mobile Power Unit requires little planned maintenance. However, it should be inspected routinely to ensure the safest and best possible performance. For complete information about caring for the Mobile Power Unit, refer to *Caring for the Power Module and Mobile Power Unit* on page 8-6.

IMPORTANT! Periodically, and as needed, use a clean, damp (not wet) cloth to clean the exterior surfaces of the Mobile Power Unit. A mild detergent may be used, if necessary.

WARNING !

- Unplug all connections before cleaning the Mobile Power Unit.
- Do not put the Mobile Power Unit into water or liquid.
- Never clean the Mobile Power Unit while it is providing power to the Pump. Switch to another power source before cleaning the Mobile Power Unit.

Using HeartMate 14 Volt Lithium-Ion Batteries

Using battery power for the HeartMate III LVAS allows for greater patient mobility than when the patient is connected to the Power Module or Mobile Power Unit. When using battery power, a patient can enjoy activities outdoors or away from home, such as gardening or shopping.

A pair of HeartMate 14 Volt Lithium-Ion batteries (**Figure 3.57**) provides direct current (DC) to the Pump. Both batteries are discharged together (not one, then the other).

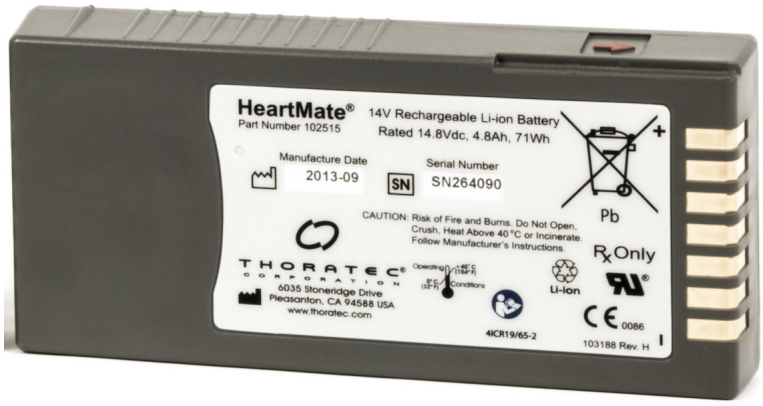


Figure 3.57 HeartMate 14 Volt Lithium-Ion Battery

Each battery is inserted into a 14 Volt battery clip (**Figure 3.58**). The batteries and attached battery clips can be worn in holsters (one under each arm), or across the body (in a bag), or in a pouch around the waist. The battery clips transfer power from the batteries to the System Controller. Using battery clips is required with the batteries.

Figure 3.58 Inserting the Battery into the Battery Clip

During battery-powered operation, the System Controller battery power gauge shows overall power capacity for both batteries. Refer to *Performing a System Controller Self Test* on page 2-26. The System Controller's battery power gauge indicates when the batteries are running low and prompts the user to switch to a different power source: the Power Module, Mobile Power Unit, or a new, fully-charged pair of HeartMate 14 Volt Lithium-Ion batteries. The status of an individual battery can be checked at any time by pressing the on-battery power gauge on the individual battery. Refer to *Checking Battery Charge Status* on page 3-50.

Required Components

Components for operating the HeartMate III system on battery power include the following:

- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 compatible 14 Volt battery clips

In addition, the System Controller must be connected to the LVAD via the Driveline.

IMPORTANT! HeartMate batteries only work in matching pairs with matching compatible clips.

The HeartMate III Left Ventricular Assist System is optimized for operation with two batteries, but the system can run on only one battery for a very short period (minutes). For example, when switching from batteries to the Power Module or Mobile Power Unit (or vice versa), operation will continue on a single battery while connections are made.

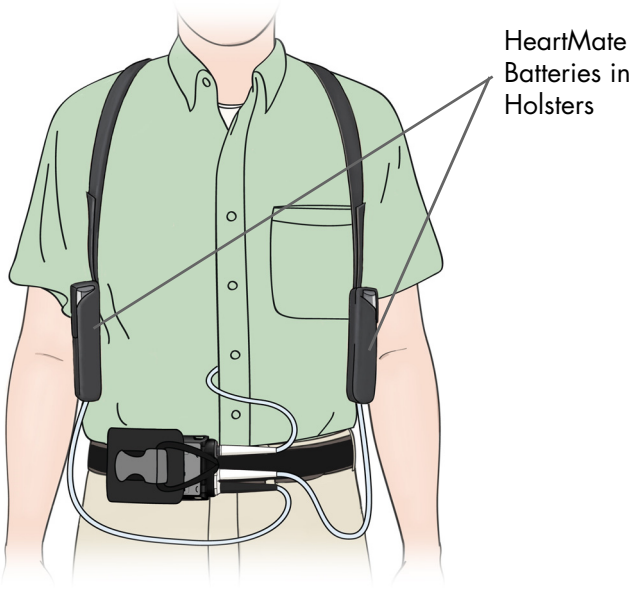


Figure 3.59 HeartMate Batteries Worn in Holsters

WARNING !

- Use only HeartMate 14 Volt Lithium-Ion batteries supplied by Thoratec Corporation with the HeartMate III Left Ventricular Assist System. Using the wrong batteries may cause the Pump to stop.
- HeartMate 14 Volt Lithium-Ion batteries must be charged before use. Before removing a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After removing the battery from the Battery Charger, use the battery power gauge that is on the battery to check the battery's charge level.
- Use only 14 Volt battery clips supplied by Thoratec Corporation with HeartMate 14 Volt Lithium-Ion batteries. Other clips will not transfer electrical power to the LVAS.
- Do not use batteries to power the LVAS when the patient is sleeping. The patient must always connect to the Power Module or Mobile Power Unit for sleeping or when there is a chance of sleep. A sleeping patient may not hear the System Controller alarms.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- Do not use damaged, defective, or expired batteries. Using damaged, defective, or expired batteries may reduce operating time or the pump may stop.

CAUTION !

- Use only the Battery Charger supplied by Thoratec Corporation to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- Calibrate a battery as soon as possible after being prompted, to prevent a backlog of uncalibrated batteries. After approximately 70 uses, HeartMate 14 Volt Lithium-Ion batteries may need to be recalibrated. The Battery Charger indicates when a battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time.
- Leave a calibrating 14 Volt Lithium-Ion battery in the Battery Charger for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery. The on-battery power gauge will reflect this status.
- Clean the metal contacts on the batteries and inside the battery clips at least once a month. Dirty battery contacts on the 14 Volt Lithium-Ion battery may prevent proper charging, which can affect operation. Use a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or battery clips, or before placing batteries into the Battery Charger.
- As 14 Volt Lithium-Ion batteries get older, they support the left ventricular assist system for shorter periods of time. If batteries do not give at least four hours of support, take them out of service.

CAUTION ! (Continued)

- After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. If stored and used within recommended guidelines, HeartMate 14 Volt Lithium-Ion batteries should be usable for approximately 360 use/charge cycles or for 36 months from the date of manufacture, whichever comes first.
- If a 14 Volt Lithium-Ion battery leaks, do not touch the leaking fluid. If the fluid touches skin or eyes, wash the affected area with plenty of water and seek medical advice.
- To prevent deterioration or damage to a 14 Volt Lithium-Ion backup battery:
  - Do not store in direct sunlight.
  - Store within approved temperatures: 14°F to 104°F (-10°C to 40°C). Refer to *Storage and Transport* on page 8-3 for complete storage guidelines, including greater than 30 days.
  - Do not use in temperatures that are below 32°F (0°C) or above 104°F (40°C) or the battery may fail suddenly.
  - Do not dismantle, open, or shred.
  - Do not drop or hit hard objects or each other.
  - Do not leave or store in extremely hot or cold temperatures, such as in automobiles or automobile trunks, or battery life will be shortened.
  - Do not expose to heat or fire.
- Keep batteries out of the reach of children.
- Keep batteries clean and dry.
- Dispose of, or recycle, an expired battery in accordance with local, state, and federal regulations.

Charging a New HeartMate Battery Before Use

Every HeartMate 14 Volt Lithium-Ion battery must be charged before being used for the first time. It takes up to four hours to charge a new battery, depending on the initial charge status of the battery. Batteries are charged in the Battery Charger, which can charge up to four batteries simultaneously. Charging a battery in the Battery Charger is described in more detail in *Charging HeartMate Batteries* on page 3-72.

Checking Battery Charge Status

After a HeartMate Battery is charged, it should be ready for use. After the Battery has finished charging, use the on-battery Power Gauge to confirm that the battery is fully charged (**Figure 3.60**).

Figure 3.60 Battery Symbol on the Battery (On-Battery Power Gauge)

The on-battery power gauge on a HeartMate battery uses five green bars to show available battery power (**Figure 3.61**). Each bar represents approximately 20% of available power. When a battery is fully charged, all five bars light up when the **Power Gauge** button is pressed. This indicates that the battery is 80–100% charged. Fewer bars illuminate as power is depleted. When battery power drops below 10%, only one green blinking bar comes on.

Figure 3.61 On-Battery Power Gauge and Pressing the Battery Symbol to Activate Bars

FOR THIS TASK YOU NEED:

- 1 HeartMate 14 Volt Lithium-Ion battery
- Battery Charger

TO CHECK THE BATTERY CHARGE STATUS USING THE BATTERY POWER GAUGE:

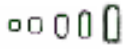
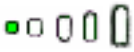
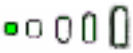
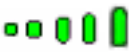
1. Obtain a battery from one of the Battery Charger charging pockets.
2. Look at the lights next to the charging pocket for the battery.
   A green light on the charger means that the battery is charged and ready for use.
3. Remove the battery from the charging pocket.
4. Find the battery symbol on the battery's power gauge.
5. Press and hold the battery symbol for five seconds.
   - If all five green power gauge bars light, the battery is between 80–100% charged.
   - If four or fewer bars light, the battery is not fully charged.

6. If four or fewer bars light, return the battery to the pocket for more charging.

   If the power gauge continues to show four or fewer bars after additional charging, the battery may be defective. Do not use it. Contact Thoratec Corporation for a replacement, if needed. Refer to page iii for Thoratec Corporation contact information.

Table 3.4 describes the on-battery power gauge on a 14 Volt Lithium-Ion battery.

Table 3.4 14 Volt Lithium-Ion Battery On-Battery Power Gauge

No bars 	Battery is in "sleep" mode, due to being in storage for a long period of time. Charge battery immediately.
1 bar (blinking) 	Approximately 10% or less of power remains. Do not use if battery has one blinking bar.
1 bar (steady) 	Approximately 10–20% of power remains.
2 bars 	Approximately 20–40% of power remains.
3 bars 	Approximately 40–60% of power remains.
4 bars 	Approximately 60–80% of power remains.
5 bars 	Approximately 80–100% of power remains.

A battery's power gauge may show five bars illuminated, while the Battery Charger indicates a charging yellow light. This is normal. Five bars on the battery does not indicate that the battery is fully charged, but rather that it is 80–100% charged.

IMPORTANT! A green light next to the Battery Charger pocket is the only assurance that a battery in the charger is 100% charged. If the yellow light next to the pocket is on, the battery is still charging. If the red light next to the pocket is on, the battery has a problem. Do not use it.

If all of the power gauge bars come on except for one in the middle of the sequence, the light emitting diode (LED) for the bar may be broken or burned out. If this happens, contact Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information

IMPORTANT! Depending on how long a battery has been in storage, its power gauge may not work until after the battery undergoes its first charge.

Connecting to Batteries

Connect the System Controller to battery power when the patient is active and mobile, outdoors, or when AC electricity fails or is unavailable. For more information, refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

FOR THIS TASK YOU NEED:

- A running System Controller
- Two charged and working HeartMate 14 Volt Lithium-Ion batteries
  Refer to *Charging HeartMate Batteries* on page 3-72.
- Two HeartMate 14 Volt Lithium-Ion battery clips
- One battery holster or other accessory for holding or carrying in-use batteries

TO CONNECT THE SYSTEM CONTROLLER TO 14 VOLT BATTERIES:

1. Gather the equipment.
2. Insert a charged HeartMate 14 Volt Lithium-Ion battery into each 14 Volt battery clip.
   Refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.
3. Place the batteries with attached battery clips within reach.
4. Place the black and white System Controller power cable connectors within reach (**Figure 3.62**).

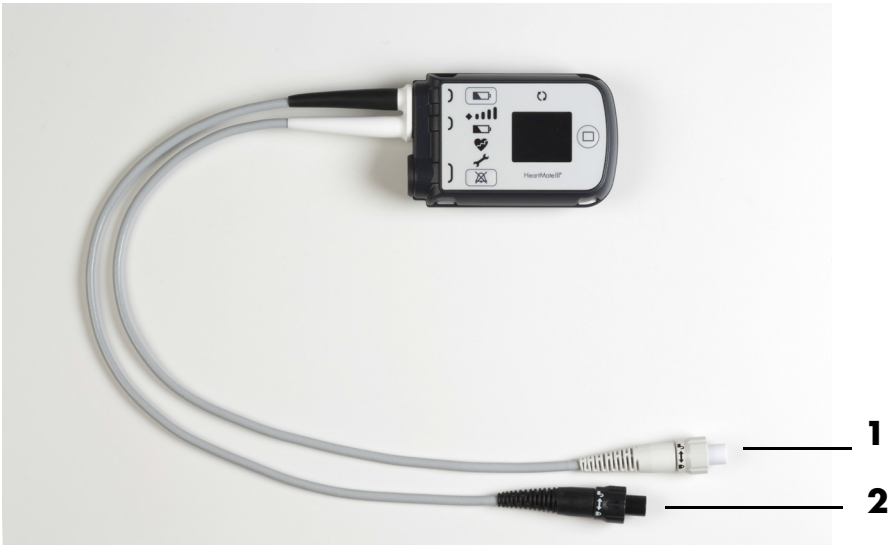


Figure 3.62 Black and White System Controller Power Cable Connectors

1	**White Connector**
2	**Black Connector**

5. Unscrew and disconnect only the ***white*** System Controller power cable connector from its current power source.

WARNING !

Do not disconnect the other connector.

6. Align the opposite half circles inside the white System Controller power cable connector and the power cable connector for one of the battery clips (**Figure 3.63**).

CAUTION !

Do not try to join together misaligned connectors. Doing so can damage them.

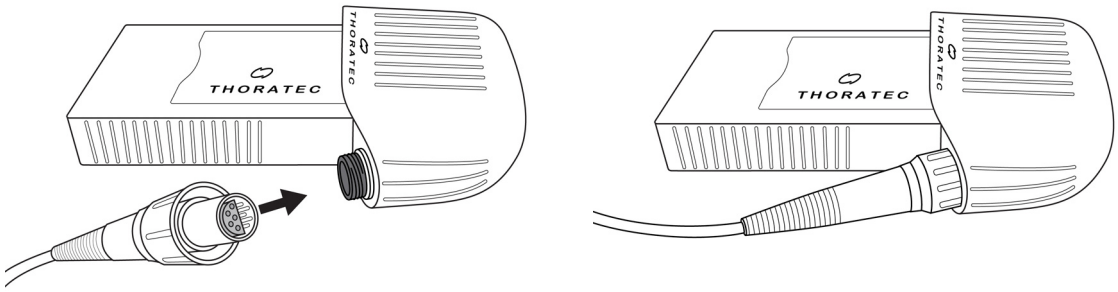


Figure 3.63 Aligning the Half Circles on the Connectors

7. Firmly push together the two connectors.
8. Securely hand tighten the connector nut. Do not use tools.
9. Repeat Steps 5 through 8 for the ***black*** System Controller power cable connector and the second battery clip connector.

Figure 3.64 System Controller Power Cables Connected to Battery Clips

Estimating Remaining Time for In-Use Batteries

When approximately 15 minutes of battery power are left, the System Controller initiates a Low Battery Power **Advisory** alarm, which is indicated by the following:

- Flashing yellow diamond on the System Controller's user interface
- The words *Low Battery* and *Replace Power* alternate on the user interface screen
- Alarm tone: slow beep

When approximately five minutes of operation remain, the System Controller initiates a Low Battery Power **Hazard** alarm, which is indicated by the following:

- Flashing red battery on the System Controller's user interface
- The words *Low Battery* and *Replace Power Immediately* alternate on the user interface screen
- Alarm tone: constant tone

The Low Battery Power Hazard Alarm requires an immediate response. Refer to *System Controller Alarms* on page 7-3 for detailed instructions on responding to System Controller alarms.

During a Low Battery Power Hazard Alarm, the system reverts to power saver mode and gradually ramps down to the Low Speed setting. If the Fixed Speed setting is lower than the Low Speed Limit, the Pump remains at the lower speed setting.

The LVAS remains in power saver mode until a new pair of fully-charged batteries are installed, or until the System Controller is connected to the Power Module, Mobile Power Unit, or until no further power remains.

When adequate power is supplied, the Pump reverts to the previous mode and speed, and the red battery alarm clears.

Replacing Depleted Batteries

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 2 in-use HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO REPLACE DEPLETED BATTERIES WITH CHARGED BATTERIES:

1. Obtain two charged HeartMate batteries and place them within reach.
2. If batteries are removed from the Battery Charger, ensure that the light near the charging pocket for each battery is green.
3. This indicates that the battery is charged. Refer to *Charging HeartMate Batteries* on page 3-72.
4. Ensure that each battery is charged and ready for use by pressing and holding the battery symbol on each battery.
5. Grasp the battery clip and attached battery for one of the batteries that is currently powering the system, and remove the clip and battery from the holster/carrying case.

   Do not remove the battery from its clip at this time.
6. Locate the battery power gauge symbol on the battery that was removed in Step 5 and complete the following steps:

   a. Press and hold the battery symbol for five seconds.

   b. Observe how much battery power remains for this battery by counting the number of bars that light.
7. Repeat Step 5 and Step 6 for the second battery that is currently in use.
8. Determine which battery has the least power.

   If both batteries have the same amount of power, replace either battery. Otherwise, replace the battery that has the least power first.
9. Complete the following steps to replace the battery:

   a. Press the battery release button on the battery clip.

   b. Withdraw the battery from its clip.

   The System Controller's Power Cable Disconnect alarm will come on. This is normal.

   IMPORTANT! Ensure that a charged battery rather than a depleted battery is used in Step c.

   c. Pick up one of the charged batteries and locate the orange arrow on the battery.

d. Align the orange arrow on the charged battery with the orange arrow on the battery clip, so the arrows point toward each other (**Figure 3.65**).

Figure 3.65 Aligning the Arrows and Inserting the Battery in the Clip

e. Slide the charged battery into the battery clip.
The battery should click into place.

f. Gently pull on the battery and try to remove it from the clip.
If the battery is properly and fully inserted, the battery remains in the clip and the System Controller's Power Cable Disconnect alarm will stop.

g. Remove the other depleted battery and repeat Steps a–f.

10. Return the clips and charged batteries to the holsters or carrying case.
11. Ensure that the Battery Charger is plugged in and turned on.
12. Place the depleted batteries in the pockets for recharging.

HeartMate Battery and Battery Clip Accessories

For warnings, cautions, and instructions on wearing and carrying HeartMate batteries, battery clips, and the System Controller, refer to *Wearing and Carrying System Components* on page 6-30.

Removing Batteries from Service

One pair of new HeartMate 14 Volt Lithium-Ion batteries provides up to 17 hours of support under nominal operating conditions (pump flows of 5.4 lpm). Refer to *Cleaning and Maintenance* on page 8-4 for information on cleaning and maintaining HeartMate 14 Volt Lithium-Ion batteries and battery clips.

HeartMate 14 Volt Lithium-Ion batteries last for less time if the patient is active or emotionally stressed. As batteries get older, they power the system for shorter periods of time. If a pair of HeartMate batteries does not give at least four hours of support, take both batteries out of service.

A new battery that is stored and used according to the acceptable environmental conditions should be usable for approximately 360 cycles or 36 months from the date of manufacturer, whichever comes first. After this time, battery performance cannot be guaranteed. Call Thoratec Corporation for a replacement when either of these milestones is reached. Refer to *Storage and Transport* on page 8-3.

The white battery label on each battery contains several safety symbols and the battery's expiration date. The battery may need to be replaced earlier than the expiration date, depending on usage. Batteries should not be used after their expiration date. Dispose of expired batteries according to local, state, and federal regulations. Refer to *Product Disposal* on page 8-8 for information on disposing of HeartMate batteries.

Caring for Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning for the most reliable performance. Refer to *Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 8-6 for detailed information on inspecting and cleaning batteries and battery clips.

Switching Power Sources

Switching from the Power Module to Battery-Powered Operation

Use care when connecting or disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 7-36.

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 Power Module power cord
- 2 14-Volt battery clips
- 1 functioning, in-use Power Module
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 1 battery holster, or other wear and carry accessory

TO SWITCH FROM POWER MODULE TO BATTERIES:

1. Place the following items within reach:
   - Two battery clips
   - Two charged batteries (as indicated by the green light on the Battery Charger)
   - The white and black Power Module patient cable connectors
2. Complete the following steps to place the first charged battery into a battery clip:
   a. Line up the arrows on the battery and battery clip.
   b. Push until the battery clicks into place.
3. Repeat Step 2 for the second battery and battery clip.
4. Unscrew the white System Controller and white Power Module patient cable connectors.
   The Power Cable Disconnect alarm will come on. This is normal.
5. Put aside the white Power Module patient cable connector.
6. Promptly connect the battery clip connector to the white System Controller power cable connector (**Figure 3.66**).
   The alarm will stop when the white System Controller power cable is connected.

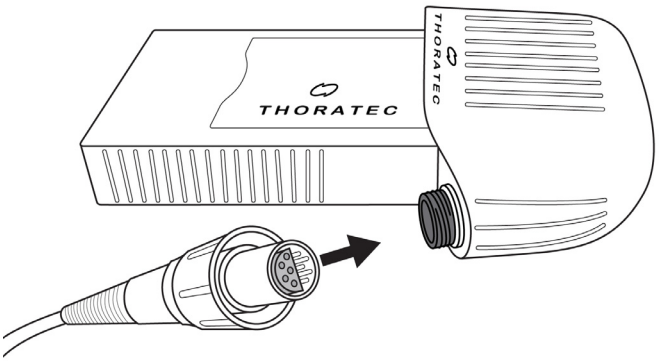


Figure 3.66 Connecting the System Controller Power Cable Connector to the Battery Clip Connector

7. Unscrew the black System Controller connector and black Power Module patient cable connectors.

   The Power Cable Disconnect alarm will come on. This is normal.

8. Put aside the black Power Module patient cable connector.
9. Promptly connect the battery clip connector to the black System Controller power cable connector.

   The alarm will stop when the black System Controller power cable is connected.

10. Place the batteries and battery clips into the holsters or carrying case.
11. Keep the Power Module patient cable connected to or near the Power Module until next use.
12. Place at least two additional charged batteries in the travel case.

IMPORTANT! If the Power Module patient cable remains connected to the Power Module when not in use, ensure that the cable is located where it will not become damaged, dirty, or wet. The cable should be placed so that it will not cause tripping or falling.

Switching from the Mobile Power Unit to Battery-Powered Operation

Use care when connecting or disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 7-36.

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 working, in-use Mobile Power Unit with batteries installed
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 battery clips
- Holster or carrying case

TO SWITCH FROM THE MOBILE POWER UNIT TO BATTERIES:

1. Place the following items within reach:
   - Two battery clips
   - Two charged batteries (as indicated by the green light on the Battery Charger)
   - The white and black Mobile Power Unit patient cable connectors within reach
2. Complete the following steps to place the first charged battery into a battery clip:
   a. Line up the arrows on the battery and battery clip.
   b. Push until the battery clicks into place.
3. Repeat Step 2 for the second battery and battery clip.
4. Unscrew the white System Controller and white Mobile Power Unit patient cable connectors. The Power Cable Disconnect alarm will come on. This is normal.
5. Promptly connect the battery clip connector to the white System Controller power cable connector (**Figure 3.67**).
   The alarm will stop when the white System Controller power cable is connected.

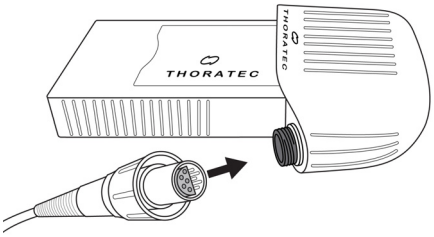


Figure 3.67 Connect the System Controller Power Cable Connector to the Battery Clip Connector

6. Unscrew the black System Controller and black Mobile Power Unit patient cable connectors. The Power Cable Disconnect alarm will come on. This is normal.
7. Promptly connect the battery clip connector to the black System Controller power cable connector. The alarm will stop when the black System Controller power cable is connected.
8. Place the batteries and battery clips into the holsters or carrying case.
9. Place at least two additional charged batteries in the travel case.

IMPORTANT! When not in use, place the Mobile Power Unit where it will not become damaged, dirty, or wet. The cable should be placed so that it will not cause tripping or falling.

Switching from Battery Power to the Power Module

Use care when connecting or disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 7-36.

FOR THIS TASK YOU NEED:

- 1 running System Controller on 14 Volt Lithium-Ion battery power
- 1 functioning Power Module
- Functioning and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use and not controlled by a wall switch
- 1 AC power cord to connect to an AC electrical power outlet
- 1 battery holster or other wear and carry accessory

TO SWITCH FROM BATTERIES TO THE POWER MODULE:

1. Confirm that the Power Module is plugged into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use.

WARNING !

- Do not use an outlet that is controlled by a wall switch.
- Do not use an adapter plug for an ungrounded wall outlet.
- Do not use portable, multiple outlet (power strip) adapters.
- Using adapters or power strips may cause a serious electrical shock or cause the Pump to stop.

2. Perform a Power Module self test and complete one of the following steps:
   - If the Power Module passes the self test, go to Step 3
   - If the Power Module fails the self test, contact Thoratec Corporation

   Refer to *Performing a Power Module Self Test* on page 3-22.
3. Complete one of the following steps:
   - If the Patient Cable is connected to the Power Module, continue to Step 5.
   - If the Patient Cable is not connected to the Power Module, go to Step 4.
4. Complete the following steps to connect the Patient Cable to the Power Module:
   a. Line up the red dot on the Patient Cable with the red dot near the "♥" socket on the Power Module.
   b. Insert the Power Module patient cable into the socket (**Figure 3.68**).

The cable clicks into place when fully engaged in the socket.

Figure 3.68 Aligning the Red Dots

c. Tug gently on the black strain relief portion of the connector to confirm that the connection is tight (**Figure 3.69**).

CAUTION !

Do not pull on the cable.

Figure 3.69 Tugging on the Black Strain Relief Portion to Check the Connection

5. Place the black and white Power Module patient cable connectors and System Controller power cable connectors within reach.
6. Remove the battery clips and attached batteries from the patient's holsters or carrying case.
7. Press the battery power gauge on each battery to determine which battery has the least power.

   Refer to *Checking Battery Charge Status* on page 3-50.
8. Complete one of the following steps:
   - If one battery has less charge, start with that battery and disconnect the connector from the battery.
   - If both batteries are charged equally, disconnect the white connector first.
9. Unscrew the white connector from its battery clip.

   The Power Cable Disconnect alarm will come on. This is normal.
10. Put aside the battery clip and attached battery.

11. Connect the white Power Module power patient cable connector to the white System Controller power cable connector.

    The alarm will stop.

12. Unscrew the black connector from its battery clip.

    The Power Cable Disconnect alarm will come on. This is normal.

13. Put aside the battery clip and attached battery.

14. Connect the black Power Module patient cable connector to the black System Controller power cable connector.

    The alarm will stop.

15. Press the battery release button on one of the battery clips to release its battery.

16. Repeat Step 15 for the second battery.

    The System Controller is now connected to the Power Module, and the Power Module is powering the system. Store the battery clips in a clean, dry location until next use.

17. Place the depleted batteries into the Battery Charger for charging.
    Refer to *Charging HeartMate Batteries* on page 3-72.

Switching from Battery Power to the Mobile Power Unit

Use care when connecting or disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 7-36.

FOR THIS TASK YOU NEED:

- 1 running System Controller on 14 Volt Lithium-Ion battery power
- 1 functioning Mobile Power Unit
- Functioning AC electrical outlet that is dedicated to Mobile Power Unit use and not controlled by a wall switch
- 1 AC power cord to connect to an AC electrical power outlet
- 1 Battery Holster or other wear and carry accessory

TO SWITCH FROM BATTERIES TO THE MOBILE POWER UNIT:

1. Confirm that the Mobile Power Unit is plugged into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Mobile Power Unit use.

WARNING !

- Do not use an outlet that is controlled by a wall switch.
- Do not use portable, multiple outlet (power strip) adapters.

2. Place the black and white Mobile Power Unit patient cable connectors and System Controller power cable connectors within reach.
3. Remove the battery clips and attached batteries from the patient's holsters or carrying case.
4. Press the battery power gauge on each battery to determine which battery has the least power.

   Refer to *Checking Battery Charge Status* on page 3-50.
5. Complete one of the following steps:
   - If one battery has less charge, start with that battery and disconnect the connector from the battery.
   - If both batteries are charged equally, disconnect the white connector first.
6. Unscrew the white connector from its battery clip and disconnect the cable.

   The Power Cable Disconnect alarm will come on. This is normal.
7. Put aside the battery clip and attached battery.
8. Connect the white Mobile Power Unit patient cable connector to the white System Controller power cable connector.

   The alarm will stop.
9. Tighten the nut.
10. Unscrew the black connector from its battery clip and disconnect the cable.

    The Power Cable Disconnect alarm will come on. This is normal.
11. Put aside the battery clip and attached battery.

12. Complete the following steps:
    a. Connect the black Mobile Power Unit patient cable connector to the black System Controller power cable connector.
    b. Tighten the nut.
    The alarm will stop.
13. Press the battery release button on one of the battery clips to release its battery.
14. Repeat Step 13 for the second battery.
    The System Controller is now connected to the Mobile Power Unit, and the Mobile Power Unit is powering the system.
15. Store the battery clips in a clean, dry location until the next use.
16. Place the depleted batteries into the Battery Charger for charging.
    Refer to *Charging HeartMate Batteries* on page 3-72.

Battery Charger Overview

The Battery Charger (**Figure 3.70**) is designed to charge the HeartMate 14 Volt Lithium-Ion batteries that are used to power the HeartMate III Left Ventricular Assist System during battery-powered operation. Specifically, the Battery Charger can:

- Charge up to four batteries in four hours or less. Refer to *Charging HeartMate Batteries* on page 3-72.
- Monitor the need for calibration, and calibrate individual batteries. Refer to *Calibrating HeartMate Batteries* on page 3-75.
- Perform diagnostic testing on up to four batteries at a time. Refer to *Charging HeartMate Batteries* on page 3-72.

Figure 3.70 Battery Charger

WARNING !

- Do not use the Battery Charger next to other equipment. Do not stack the Battery Charger on top of other equipment.
- The Battery Charger radiates radio frequency energy. If the Battery Charger is not used according to instructions, it may cause harmful interference with nearby devices. To confirm if interference is occurring, turn off/on the Battery Charger and observe the effect on devices in the area. If interference is detected:
  - Re-orient or move the affected devices.
  - Increase the distance between the Battery Charger and the affected devices.
  - Connect the affected devices to an electrical outlet different from the outlet used to power the Battery Charger.
- To avoid the risk of electrical shock, plug the Battery Charger into a properly tested and grounded (3-prong) AC electrical power outlet that is dedicated to Battery Charger use.
  - Do not use an outlet that is controlled by a wall switch.
  - Do not use an adapter plug for an ungrounded wall outlet.
  - Do not use portable, multiple outlet (power strip) adapters.
- Keep the Battery Charger dry and away from water or liquid. If the Battery Charger comes in contact with water or liquid, it may fail to operate properly or cause a serious electrical shock.
- Do not use the Battery Charger in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide, otherwise an explosion could occur.
- Be sure to use only equipment and supplies that are authorized by Thoratec Corporation. If unauthorized parts are used, potential interference may occur between the Battery Charger and other devices.

CAUTION !

- Use only the Battery Charger supplied by Thoratec Corporation to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- Do not attempt to test or charge non-HeartMate batteries in the Battery Charger. Doing so may damage the charger or the batteries, or injure the user.
- Before inserting a battery into the Battery Charger for charging or recharging, inspect the battery for signs of damage. Do not use a battery that appears damaged.
- The Battery Charger requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but is not limited to) a functional check of the device and cleaning/inspecting all internal connections. Service and maintenance of the Battery Charger should be performed only by service personnel who are trained by Thoratec Corporation.
- Make sure the Battery Charger is plugged in and turned on ("I") before placing batteries into the pockets for charging.
- Calibrate a battery as soon as possible after being prompted, to prevent a backlog of uncalibrated batteries. After approximately 70 uses, HeartMate batteries may need to be recalibrated. The Battery Charger indicates when a battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time.
- Leave a calibrating battery in the Battery Charger for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery. The on-battery power gauge will reflect this status.
- Do not touch the metal contacts inside the Battery Charger when the charger is connected to AC power and turned on, or it may cause a serious electrical shock.
- Keep the metal contacts inside the Battery Charger pockets clean and dry. Dirty metal contacts inside the Battery Charger pockets may prevent proper battery charging, which can affect battery operation.

Setting Up the Battery Charger Before Use

Before using the Battery Charger to charge HeartMate batteries, the Battery Charger must be plugged in and turned on. The display panel on the front of the Battery Charger displays messages during setup and operation. Refer to *Selecting the Language Display Mode* on page 3-70 for instructions on selecting the language and display mode.

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SET UP THE BATTERY CHARGER:

1. If not already unpacked, carefully remove the Battery Charger from its packaging.
2. Place the Battery Charger on a flat, sturdy surface.
3. Inspect the Battery Charger for dents, chips, cracks, or other signs of damage, and complete one of the following steps:
   - If the Battery Charger is undamaged, go to Step 4.
   - If the Battery Charger is damaged, contact Thoratec Corporation for a replacement if needed. Do not use a Battery Charger that appears damaged.
4. Examine the four battery charging pockets and complete the following steps:
   - Ensure that the pockets are clean and empty (no batteries).
   - Ensure that the pockets do not have dust or debris.
   - Pay particular attention to the cleanliness of the metal contacts inside the pockets.

     Dirt or objects covering the metal contacts inside the pockets may prevent proper battery charging, which can affect battery performance.
5. Obtain the grey AC power cord from the product packaging.
6. Plug the female end of the power cord into the power entry module on the rear of the charger (**Figure 3.71**).

Figure 3.71 Plugging the Power Cord Into the Battery Charger

7. Plug the Battery Charger into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Battery Charger use.
   - Do not use an outlet that is controlled by a wall switch.
   - Do not use an adapter plug for an ungrounded wall outlet.
   - Do not use portable, multiple outlet (power strip) adapters.

WARNING !

For international travel, the patient needs a Thoratec Corporation power cord. The power cord must be compatible with the local voltage, and meet applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Contact Thoratec Corporation for a power cord, if needed. Refer to page iii for Thoratec Corporation contact information.

8. Press the on/off switch on the rear of the charger from the off ("0") to the on ("I") position to turn on the Battery Charger.

   When the Battery Charger is turned on, all lights on the front panel turn on (**Figure 3.72**). The charger beeps once and performs a self test. The self test takes about 10 seconds.

Figure 3.72 Display Panel During Battery Charger Self Test

One of the following responses occurs:

- After a successful self test, all of the lights turn off and the words *HeartMate CHARGER* appear on the display panel (**Figure 3.73**). The charger is ready for use.

Figure 3.73 HeartMate CHARGER Screen on the Battery Charger

OR

- If the charger detects a problem, an error message appears on the display panel, and/or the lights and beep are not performed as described for a successful self test.

  Refer to *Using the Charger to Check Battery or Charger Status* on page 7-33 for how to respond to advisory messages if any of the following occur: an error message appears, or the lights or beep are missing, or performance is not as described (**Figure 3.74**).

Figure 3.74 Sample Error Message

Note: Any time the words *HeartMate CHARGER* appear, the display panel slowly dims, turns off for two seconds, and then resumes full brightness. This helps to prolong the life of the display. The Battery Charger may be used during this time.

Selecting the Language Display Mode

The display panel screen has two language display modes:

- Graphic Symbols (default)
- English Text

Graphic Symbols is the default display mode. The language display mode can be changed from Graphic Symbols to English Text before using the Battery Charger for the first time.

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SELECT THE LANGUAGE DISPLAY MODE BEFORE USING THE BATTERY CHARGER:

1. Unpack and plug in the Battery Charger.

   Do not turn on the Battery Charger at this time.

2. Press and hold buttons 1 and 3 on the front panel of the charger (**Figure 3.75**), while simultaneously pressing the power switch to the "on" position.

Figure 3.75 Pressing and Holding Buttons 1 and 3 to Change the Display Mode

3. After the word *English* appears on the display (**Figure 3.76**), release buttons 1 and 3.

Figure 3.76 English Text Display

4. Complete one of the following steps to set the preferred display mode:
   - Press and release the 1 button to set English Text as the preferred display mode.
   - Press and release the 2 button, scroll down to Graphic, and then press and release the 1 button to set Graphic Symbols as the preferred display mode.

   IMPORTANT! After releasing the 1 button, the charger conducts a self test. If the test is successful, the words *HeartMate CHARGER* appear.

Selecting the Language Display Mode After Startup

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SELECT THE LANGUAGE DISPLAY MODE AFTER STARTUP:

1. Remove all batteries from the charging pockets.
2. Turn off the charger by pressing the on/off switch from the on ("I") to the off ("0") position.

   Do not unplug the Battery Charger.
3. Press and hold buttons 1 and 3 on the front panel of the charger, and press the power switch to the on ("I") position.
4. After the display panel lights up, release the 1 button and the 3 button.

   The Battery Charger powers up.
5. Use the 2 button to scroll down to the preferred display mode.
6. When the preferred display mode appears, press and release the 1 button.

   IMPORTANT! After releasing the 1 button, the charger conducts a self test. If the test is successful, the words *HeartMate CHARGER* appear.

Charging HeartMate Batteries

The Battery Charger can charge up to four 14 Volt Lithium-Ion batteries at the same time. It takes up to four hours to charge from one to four batteries, depending on the charge status of the batteries. Be sure to plan battery use and charging taking into account four hours for charging.

For best battery performance, leave charged batteries in the charging pockets until ready for use. Leaving charged batteries in the Battery Charger will not damage them.

HeartMate 14 Volt Lithium-Ion batteries use technology that measures available battery power and counts battery usage/charge cycles. When a battery is placed in a charging pocket (**Figure 3.77**), the charger immediately checks the battery's status by reading the battery's on-board computer chip.

Figure 3.77 Batteries Inserted into Battery Charger Pockets

To view information about the battery's available power and total number of use/charge cycles on the charger's display panel, press the number button for that charging pocket.

Depending on the status of the battery, one of three lights (green, yellow, or red) located next to the charging pocket is illuminated (**Figure 3.78**).

- Green light: The battery is charged and ready for use.
- Steady yellow light: The battery is actively charging.
- Red light: The battery is defective or the charger has a problem.

Figure 3.78 Charge Status Lights (Green, Yellow, Red) for Pockets 1 through 4

Table 3.5 describes the charger pocket light color codes.

Table 3.5 Color Codes for Charger Pocket Lights

Color	Status/Meaning
Green 	Battery is charged and ready for use.
Yellow 	Battery is undergoing charge, test, or calibration.
Yellow (Blinking) 	Battery requires calibration cycle.
Red 	Battery or charging pocket is defective. Do not use battery.

FOR THIS TASK YOU NEED:

- 1 functioning Battery Charger
- 1 grey AC power cord to connect to an AC electrical outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries

TO CHARGE 14 VOLT LITHIUM-ION BATTERIES:

IMPORTANT! Do not force a battery into a charging pocket. A battery only fits in the pocket with the battery power gauge at the top and facing forward. When the battery is properly placed in the pocket, a beep sounds and one of the pocket lights is illuminated (green, yellow, or red).

1. Place a battery into one of the four battery charging pockets.

   The battery power gauge should be at the top and facing forward (**Figure 3.79**).

Figure 3.79 Battery Charger with Batteries Inserted in All Pockets

2. Identify which light comes on for the charging pocket:
   - Green light—The battery is charged and ready for use.

     Either remove the battery for immediate use, or leave the battery in the pocket until needed. Leaving a charged battery in the charger will not damage it.
   - Yellow light—The battery is actively charging.

     Leave the battery in the pocket to continue charging. The yellow light remains on until the battery becomes charged. When the battery is charged, the yellow light turns off and the green light comes on.
   - Blinking yellow light—Refer to *Calibrating HeartMate Batteries* on page 3-75.
   - Red light or no light at all—The battery or charger pocket has a problem.

     Remove the battery and reinsert it in the same pocket. If the same condition occurs (red light or no light), insert the battery into a different pocket.

     If the battery cannot be charged in a different pocket, the battery is defective. Do not use the defective battery. Contact Thoratec Corporation for a replacement, if needed. Refer to *Using the Charger to Check Battery or Charger Status* on page 7-33 for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on.
3. After approximately four hours, check the lights for the charging pocket for the battery.
   - If the green light is on, the battery is charged and ready for use.
   - If the yellow light is on, the battery is still charging.
   - If the red light is on, the battery has a problem or the charger interrupted the charging cycle for some reason. Refer to *Using the Charger to Check Battery or Charger Status* on page 7-33 for how to handle red light conditions.
4. Repeat Steps 1–3 for up to three more batteries.

CAUTION !

Avoid covering or blocking the vents on the top of the Battery Charger during use. Covering or blocking the vents may affect performance.

Calibrating HeartMate Batteries

HeartMate 14 Volt Lithium-Ion batteries use technology that measures available battery power and counts battery usage/charge cycles. After approximately 70 battery uses, the battery senses that it needs to calibrate its battery power gauge. Calibration helps keep the battery power gauge accurate.

During calibration, the Battery Charger drains the battery of all electrical energy, and then recharges it. The battery must be placed in the Battery Charger to be calibrated. Battery calibration can take up to 12 hours, and only one battery can be calibrated at a time. While calibrating one battery, the Battery Charger can charge three HeartMate batteries as usual.

When a battery is inserted in the charger, and the charger detects that calibration is recommended:

- The yellow light for the pocket blinks.
- A split battery symbol and the pocket number for the battery flashes on the charger display panel (**Figure 3.80**). The circled number switches between a filled and unfilled circle as the display panel screen flashes.

Figure 3.80 Calibration Prompt (in Graphic Mode) Indicating that the Battery in Pocket 4 Needs Calibration

Batteries can be calibrated when prompted or when there is a more convenient time. For example, a battery can be calibrated at night or when the patient is sleeping (when the Power Module or Mobile Power Unit is being used for power).

FOR THIS TASK YOU NEED:

- 1 functioning Battery Charger
- 1 grey AC power cord to connect to an AC electrical outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch
- 1 HeartMate 14 Volt Lithium-Ion battery ready that needs to be calibrated

TO CALIBRATE THE BATTERY WHEN PROMPTED:

Within ten seconds of the start of the blinking yellow light, press and release the number button for this pocket.

The Battery Charger begins calibrating the battery.

IMPORTANT! During calibration, the yellow light for this pocket remains on and the words *HeartMate CHARGER* appear on the display panel screen. If the number button is pressed for this pocket while the battery is being calibrated, the calibration status screen appears (**Figure 3.81**).

When calibration is complete, the yellow light turns off and the green light comes on. This indicates that the battery is charged and ready for use.

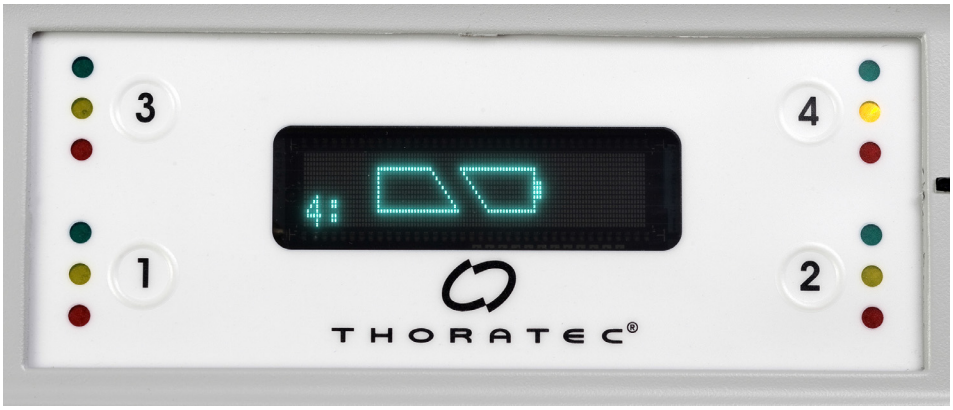


Figure 3.81 Calibration Status Screen Indicating that Battery in Pocket 4 is Being Calibrated

TO CHARGE THE BATTERY NOW (AND CALIBRATE THE BATTERY AT A FUTURE TIME):

Do nothing when the yellow light begins blinking. After ten seconds, the charger continues with a normal charge cycle.

IMPORTANT! It is acceptable to charge and reuse the battery, but it should be calibrated as soon as possible.

If the battery calibration is canceled after the calibration process has begun, complete the following steps:

1. Remove the battery from its charging pocket to cancel the calibration.
2. If the battery is removed before calibration is complete, recharge and check the battery before using it.

   If a battery is removed before calibration ends, the battery may be depleted.
3. Use the on-battery power gauge to check the battery charge status.

CAUTION !

Calibrate a battery as soon as possible after being prompted to do so to ensure the best possible battery performance. Calibration can take up to 12 hours. Therefore, be sure to have enough charged batteries available before calibration begins. Under normal conditions, have four charged batteries available so that batteries can be exchanged twice during a 12-hour calibration cycle.

Checking Battery Power

The Battery Charger can be used to check the status of a battery. To check a battery's charge status, complete the following steps:

1. Place the battery into a charging pocket.
2. Press and release the number button for that pocket.

   The following information appears on the charger display panel (**Figure 3.82**):

   - Pocket number
   - Battery symbol
   - Percentage of available charge

   For example, if approximately 50% of the battery's power is available, half of the battery symbol is filled and "50%" appears on the screen.

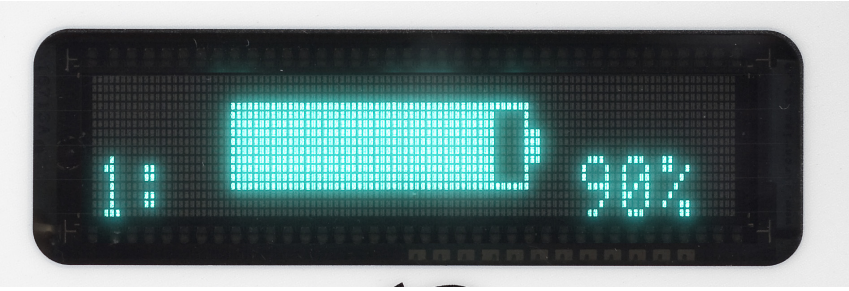


Figure 3.82 Battery Charge Level on the Battery Charger (90% Charge)

   After five seconds, the display returns to the default screen (*HeartMate CHARGER*).
3. Press the number button for that pocket again (while the battery charge level appears) for the total number of use/charge cycles.

   The following information appears on the display panel:

   - Pocket number
   - Total number or uses/charges for this battery
   - How much power the battery can potentially hold if fully charged (measured in mAh)

   After 10 seconds the display panel returns to the default (*HeartMate CHARGER*) screen.

Care and Maintenance of the Battery Charger

The Battery Charger requires periodic inspection and cleaning for the best possible performance. For detailed information on inspecting and cleaning the Battery Charger, refer to *Safety Checklists* on page D-1.

CAUTION !

Service and maintenance of the Battery Charger should be performed only by service personnel who are trained by Thoratec Corporation.

IMPORTANT! The hospital contact is responsible for coordinating annual inspection and maintenance of the Battery Charger after the patient leaves the hospital.

Disposing of the Battery Charger

Refer to *Product Disposal* on page 8-8 for information about disposing of the Battery Charger.

SYSTEM MONITOR

This section describes how to use the System Monitor to program and monitor the HeartMate III Left Ventricular Assist System.

4 System Monitor

Overview

The System Monitor gives clinicians a detailed, large-scale display of system performance. Using the System Monitor touch screen, clinicians can also enter and change operating parameters and system settings. The System Monitor is required during implant procedures and any time close monitoring of system operation is needed. Refer to *Setting Up the System Monitor for Use with the Power Module* on page 4-5 for preimplant setup instructions. The System Monitor should be mounted on top of the Power Module (**Figure 4.1**).

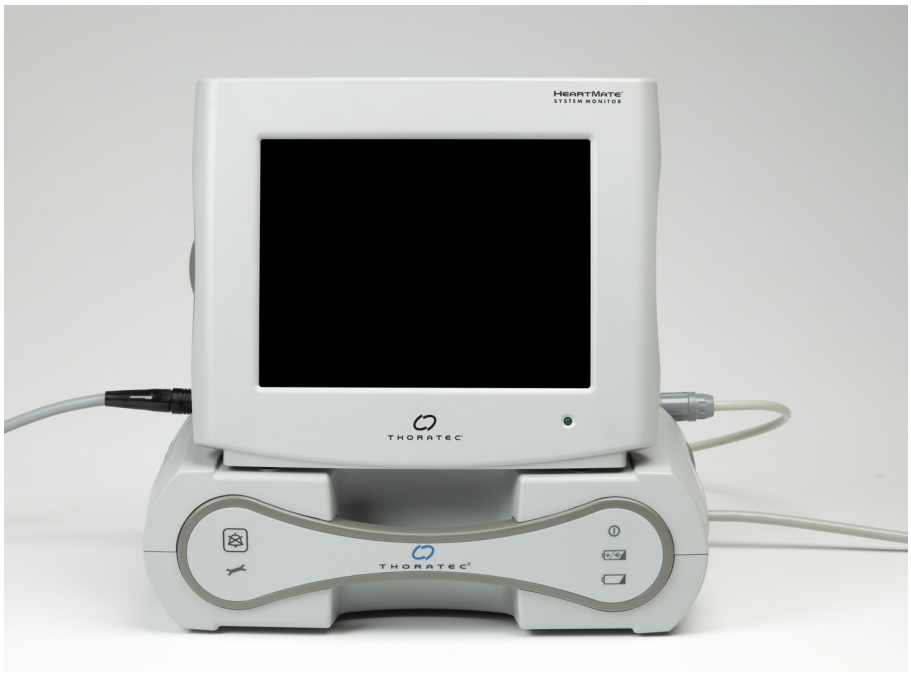


Figure 4.1 System Monitor Mounted on Top of the Power Module

Function

For the System Monitor to work, it must be connected to the Power Module via the System Monitor data cable. In addition, the Power Module must be connected to the System Controller. This allows the transfer of System Controller data through the Power Module for display on the System Monitor screen.

The System Monitor is used to:

- Closely monitor system operation during Left Ventricular Assist Device implant
- Display information about system performance, including current operating mode (that is, fixed), Pump flow, Pump speed, and overall operational status
- Program system parameters, such as Pump speed
- Assess and track alarm conditions
- View and save performance data
- Record data at specific intervals to download for review and analysis

Required Components

The data card and data cable are required for using the System Monitor with the Power Module and System Controller.

WARNING !

- Do not disconnect the Power Module patient cable from the Power Module when troubleshooting for a *Not Receiving Data* message on the System Monitor screen.
- Do not disconnect the System Controller power cable connectors from the Power Module when troubleshooting a *Not Receiving Data* message on the System Monitor screen.

CAUTION !

- To prevent system component damage and personal injury, refer any servicing of HeartMate Left Ventricular System equipment to service personnel trained by Thoratec Corporation only.
- Use of equipment and supplies, other than those specified in this manual or sold by Thoratec Corporation for replacement parts, may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices. This could result in potential interference between the Left Ventricular Assist System and other devices.
- If the System Monitor is mounted on top of the Power Module, do not attempt to lift or carry the two components together using the System Monitor handle. Doing so may damage the Power Module and/or System Monitor.
- Pump flow is estimated from Pump power. Under abnormal conditions, this may result in an overestimation of Pump flow or an undisplayed Pump flow reading.
- No single parameter is a surrogate for monitoring the clinical status of the patient, and the changes in all parameters should be considered when assessing any clinical situation.
- Position the Power Module and System Monitor away from sources of lint, dust, and pests, and away from heat and/or humidity sources such as a fireplace, radiant heater, nebulizer, or a steam kettle.

System Monitor Setup

Setting Up the System Monitor for Use with the Power Module

FOR THIS TASK YOU NEED:

- 1 running System Controller connected to the Power Module via a Power Module patient cable
- 1 working, in-use Power Module
- 1 System Monitor
- 1 System Monitor data cable
- Functioning and grounded (3-prong) AC electrical outlet
- 1 AC power cord

TO SET UP THE SYSTEM MONITOR FOR USE WITH THE POWER MODULE:

1. Complete the following steps to connect the System Monitor to the Power Module:
   a. Plug the System Monitor data cable into the socket located on the side of the Power Module (**Figure 4.2**).
   b. Check that the connection is secure.

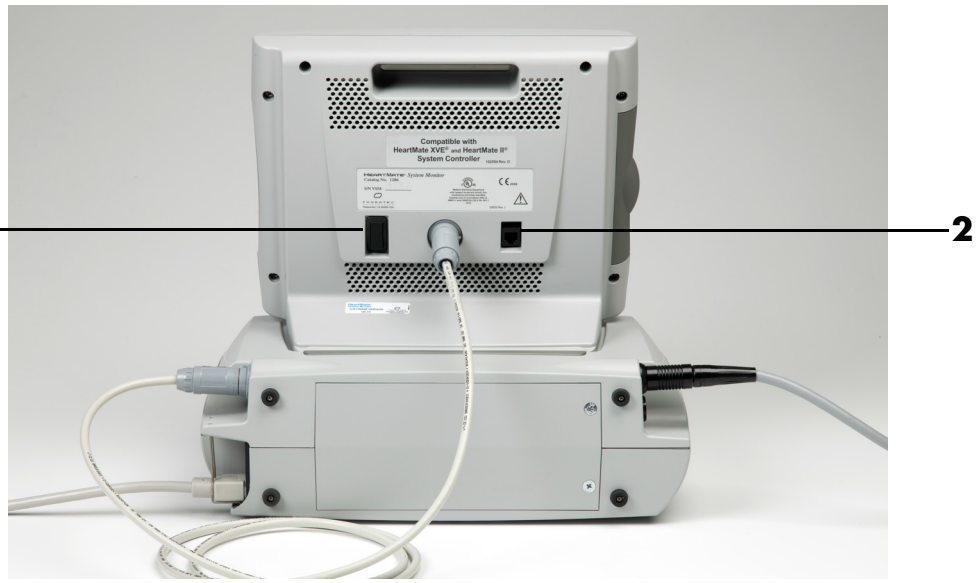


Figure 4.2 Plugging the System Monitor Data Cable into the Power Module

1	**On/Off Switch**
2	**Service Only: Do Not Use**

   c. Plug the other end of the System Monitor data cable into the rear of the System Monitor.
   d. Check that the connection is secure.

2. Confirm that the Power Module is connected to power and ready for use.

WARNING !

- Confirm that the Power Module is plugged into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use.
- Do not use an outlet that is controlled by a wall switch.
- Do not use an adapter plug for an ungrounded wall outlet.
- Do not use portable, multiple outlet (power strip) adapters.

3. Complete the following steps to turn on the System Monitor:
   a. Locate the on/off switch on the rear of the System Monitor.
   b. Press the switch to the "on" position.

      A green light should appear on the front of the System Monitor.
   c. If the green light does not appear, contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

The HeartMate logo screen appears when the System Monitor is ready for use (**Figure 4.3**).

Figure 4.3 HeartMate Logo Screen

The following section describes actions to take if the HeartMate logo screen does not appear.

- If the System Monitor screen remains black, check the following:
  - The System Monitor data cable is securely connected to the System Monitor and the Power Module.
  - The System Monitor power switch is on.
  - The Power Module is running on AC power and not its backup battery.
  - The green Power On light on the front of the System Monitor is illuminated.
- If the words *Not Receiving Data* flash on the System Monitor screen, check the following:
  - The Power Module patient cable is securely inserted into the Power Module.
  - The System Controller power cable connectors are properly connected to the Power Module power cable connectors (white-to-white and black-to-black).
- If the System Monitor still does not work, contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

Mounting the System Monitor

The System Monitor is designed to be mounted on top of the Power Module (**Figure 4.4**). This nesting feature minimizes the space needed when a patient requires continuous monitoring while connected to the Power Module.

Figure 4.4 System Monitor Mounted on the Power Module

FOR THIS TASK YOU NEED:

- 1 running System Controller connected to the Power Module via Power Module patient cable
- 1 working, in-use Power Module
- 1 System Monitor
- 1 System Monitor data cable
- Functioning and grounded (3-prong) AC electrical outlet
- 1 AC power cord

TO MOUNT THE SYSTEM MONITOR ON THE POWER MODULE:

1. Slide the back edge of the System Monitor base under the flexible edge of the ledge on the top of the Power Module (**Figure 4.5**).

Figure 4.5 Sliding the Back Edge of the System Monitor Base Under the Ledge of the Power Module

2. When the back edge of the System Monitor is secure under the ledge, press down firmly on the top of the System Monitor.

   This engages the two feet on the System Monitor into the holding grommets on the Power Module (**Figure 4.6**).

Figure 4.6 Engaging the System Monitor Feet in the Grommets on the Power Module

Removing the System Monitor from the Power Module

TO REMOVE THE SYSTEM MONITOR:

1. Pull up on the System Monitor handle to disengage the System Monitor feet from the Power Module grommets.
2. Slide the System Monitor base forward and out from under the flexible edge of the Power Module.
3. Remove the System Monitor from the Power Module.
4. Place the System Monitor on a flat, sturdy surface.
5. Leave the data cable attached to the System Monitor, and coil it gently around the System Monitor.

System Monitor Interface

The System Monitor's touch-screen interface contains menu-driven and menu-prompted operations that are accessible from six main screens. Six tabs, representing the six main screens, are continuously displayed along the top of each screen. Touching the on-screen tab allows access to the corresponding screen. Each screen has unique system functions. The tab for the in-use screen is highlighted in black (**Figure 4.7**). In this example, the Clinical screen is in use.

Figure 4.7 System Monitor Screen Tabs with Clinical Tab Selected

A flashing communication icon  appears at the lower left corner of all System Monitor screens. The flashing icon indicates active communication between the System Controller and System Monitor.

If the icon is not flashing or has disappeared, complete the following steps:

1. Check the System Monitor-Power Module cable connections.
2. Restart the System Monitor.

   Refer to *Setting Up the System Monitor for Use with the Power Module* on page 4-5.

Clinical Screen

The Clinical screen is the default screen. It displays the primary operating parameters. The System Monitor automatically returns to the Clinical screen after one minute of inactivity on any other System Monitor screen (**Figure 4.8**).

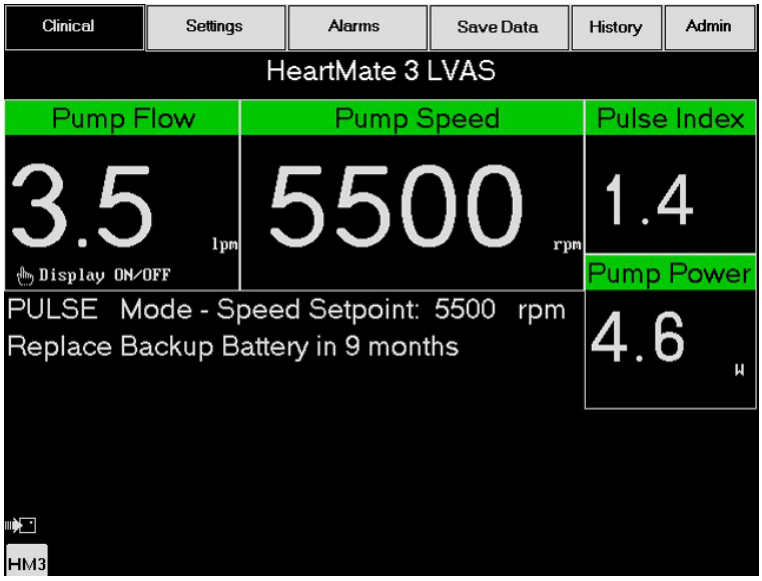


Figure 4.8 Clinical Screen

The Clinical screen contains:

- Parameter Boxes: Four boxes at the top of the screen report measured values of pump flow, Pump speed, Pulsatility Index (abbreviated on screen as Pulse Index), and Pump power.
- Operating Mode and Speed Setpoint: The operating mode and speed setpoint are displayed below the parameter boxes. Refer to *Optimal Fixed Speed* on page 4-19 for information on determining the preferred speed setpoint.
  - The speed setpoint for fixed mode has a range of 3,000 to 9,000 rpm.
  - The Operating Mode is Pulse.
- Active Alarm Messages: The two highest-priority active alarm messages are displayed below the operating mode.
- Command Buttons: Two command buttons appear during certain conditions:
  - A **Pump Start** button appears when the pump is stopped or disconnected from the System Controller. Press this button to restart the pump.
    Refer to *Pump Stop Button* on page 4-22 for more information.
  - A **Silence Alarm** button accompanies any active, audible alarm. Press this button to silence any Hazard alarm and the Power Cable Disconnect alarm for two minutes, and all other Advisory alarms for four hours. When the System Controller is connected to the Power Module, the **Silence Alarm** button on the System Monitor also silences audible alarms on the System Controller.
    Refer to *Silencing Alarms via the System Monitor* on page 4-29 for more information.

Pump Flow Display

The System Controller provides an estimate of blood flow out of the Pump. This estimate is based on Pump speed and the amount of power being provided to the Pump Motor. The relationship between power and flow at any particular speed is mostly linear.

If the flow estimate falls outside the expected operational range or acceptable linear region, a Low Flow alarm is triggered and the Pump Flow box displays "-.-" (**Figure 4.9**). This situation only occurs when Pump speed is below 4000 rpm AND the Pulse Index is greater than 9.0. This prevents the display of inaccurate flow information.

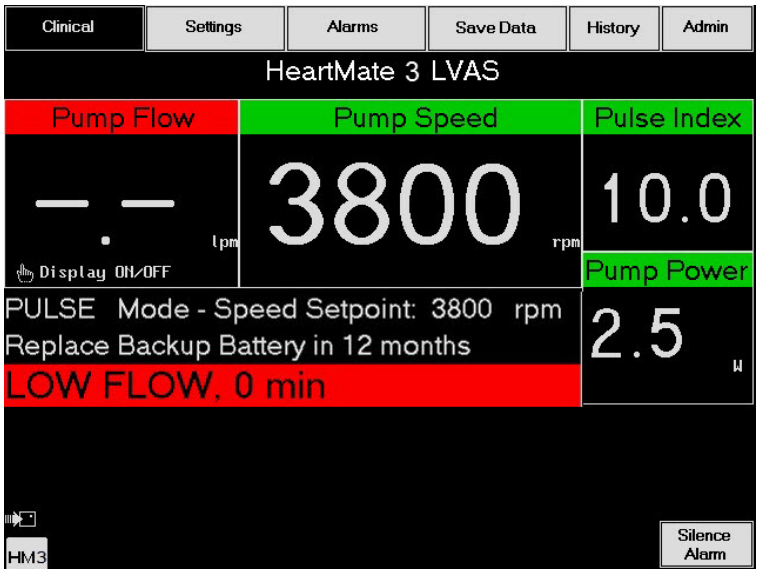


Figure 4.9 Low Flow Alarm and Pump Flow Box

When the Driveline is disconnected from the System Controller, "-.-" appears in the Pump Flow box. This condition is accompanied by a PUMP OFF Hazard alarm in a red box. A **Pump Start** button appears in the bottom left corner of the screen (**Figure 4.10**).

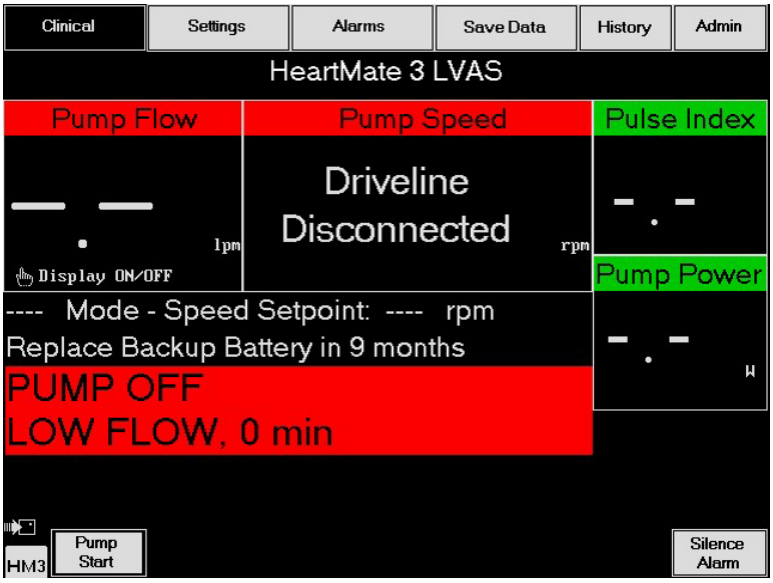


Figure 4.10 PUMP OFF Alarm

The Pump Flow box displays "-.-" (**Figure 4.11**) when any of the following occur:

- The pump is stopped.
- There is a Communication Fault.
- The estimated Pump flow is outside the expected operational range (less than 4000 rpm AND a Pulse Index greater than 9.0).

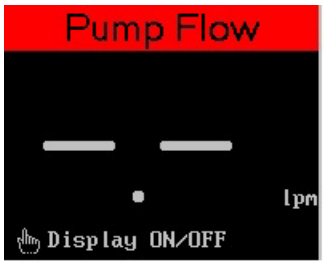


Figure 4.11 Pump Running at Fixed Speed Less Than 4,000 rpm

Under the following conditions, the Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the **Pump Start** button:

- The Fixed Speed setting is below 4,000 rpm

  AND

- The System Controller's backup battery is not installed

If the Pump stops because the Driveline is disconnected from the System Controller, the Pump restarts at the previously set speed when the Driveline is reconnected if one of the following occurs:

- The Fixed Speed setting is at least 4,000 rpm

  OR

- The System Controller's backup battery is installed and any button is pushed on the System Controller

Pump Speed

The System Monitor displays the Pump speed in revolutions per minute (rpm). This value matches the actual speed within ±100 rpm under nominal conditions (**Figure 4.12**).

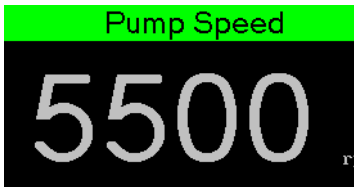


Figure 4.12 Pump Speed Displayed in Revolutions Per Minute (RPM)

If the Pump becomes disconnected from the System Controller, the Pump Speed box displays: Driveline Disconnected (**Figure 4.13**).

Figure 4.13 Driveline Disconnected Message

When the Pump is stopped using the **Pump Stop** button, a zero (0) appears in the Pump Speed box.
If a Communication Fault exists, "- - - - " appears in the pump speed box (**Figure 4.14**).

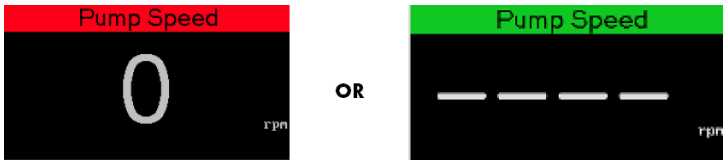


Figure 4.14 Pump Stopped

Pulsatility Index

Pulsatility Index (displayed as Pulse Index) is a calculation related to the amount of assistance that is provided by the Pump. PI values typically range from 1 to 10. Higher values indicate higher pulsatility (that is, the Pump is providing less support and the heart is providing more support). Lower values indicate lower pulsatility (that is, the Pump is providing more support and the heart is providing less support).

Pulsatility Index appears in the upper right corner of the Clinical screen (**Figure 4.15**).

Figure 4.15 Pulsatility Index

When the Pump is stopped or the Driveline is disconnected from the System Controller, "-.-" appears in the Pulse Index box (**Figure 4.16**).

Figure 4.16 Pulsatility Index When the Pump is Stopped

Pump Power

The Pump power is displayed in the Pump Power box located below the Pulse Index box. Pump power is the amount of power being provided to the Pump motor. Pump power ranges between 0.0 to 25.5 watts (**Figure 4.17**).

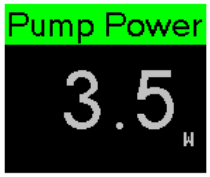


Figure 4.17 Pump Power

Alarm Messages

The two highest-priority System Controller alarms are displayed on the System Monitor screen under the Fixed Speed setpoint. They appear in order of highest priority.

IMPORTANT! If more than two alarms occur at one time, a plus sign (+) appears on the right side of the second alarm to indicate additional alarms are active. When more than two alarms occur simultaneously, go to the Alarms screen to view all active alarms. Refer to *Alarms Screen* on page 4-25 for explanations of the conditions leading to each System Monitor alarm.

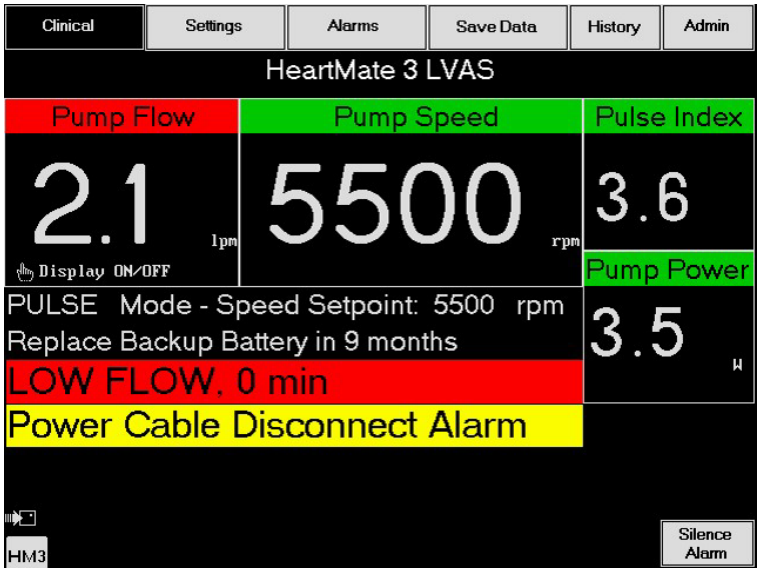


Figure 4.18 A Red Hazard Alarm and Yellow Advisory Alarm

Hazard Alarms

Hazard alarms occur for conditions that are potentially life threatening for the patient. Hazard alarms require immediate attention. Hazard alarms flash and appear as black text on a red banner. On-screen messages for hazard alarms are accompanied by a continuous audio tone from the System Controller.

Five hazard alarms are displayed on the System Monitor. The on-screen appearance of each alarm is described as follows, in order of descending priority:

- PUMP OFF: This text banner is accompanied by a red Pump Flow box regardless of whether the flow display is on or off.
- Driveline Disconnected: This message is displayed in the Pump Speed box and the Pump Speed box turns red. A red text banner does not appear.
- LOW FLOW x min: This text banner indicates the duration of the alarm (from the start of the alarm to the present, in minutes). The Pump Flow box turns red.
- LOW VOLTAGE: This text banner appears.
- NO EXTERNAL POWER: This text banner appears.

Note: A Controller Hardware Fault will not display on the System Monitor. The Monitor will remain on the startup screen.

Advisory Alarms

Advisory alarms are used to inform users about conditions that affect optimal system operation. Although important, Advisory alarms are not related to life threatening risks. Advisory alarms appear on the System Monitor screen as black text on a yellow banner. They are also accompanied by audible alarms on the System Controller.

There are eleven Advisory alarms. The on-screen appearances of each Advisory alarm is described as follows, in order of descending priority:

- Power Cable Disconnect: This text banner is accompanied by one beep every second.
- Low Voltage Advisory: This text banner is accompanied by one beep every four seconds.
- Replace System Controller: A text banner appears; and in most cases is accompanied by one beep every four seconds. There may be instances when there is no audible alarm.
- Communication Fault (Comm Fault): This text banner is accompanied by one beep every four seconds.
- Replace Backup Battery: A text banner appears; and in most cases is accompanied by one beep every four seconds. There may be instances when there is no audible alarm.
- WARNING: Low Speed Advisory: A text banner appears; however, there is no audible alarm.
- Backup Battery Not Installed: This text banner is accompanied by one beep every four seconds.
- LVAD Fault: A text banner appears; however, there is no audible alarm.
- Driveline Power Fault: This text banner is accompanied by one beep every four seconds.
- Driveline Communication Fault (Driveline Comm Fault): This text banner is accompanied by one beep every four seconds.
- Controller Clock Not Set: A text banner appears; however, there is no audible alarm.

During alarm conditions, a **Silence Alarm** button appears in the lower right corner of the screen. Press this button to temporarily silence audible alarms. Refer to *Silencing Alarms via the System Monitor* on page 4-29.

- The Silence Alarm button may still appear for alarm conditions for which there is no associated audible alarm. In this case, the button will not perform any function.
- Hazard alarms and the Power Cable Disconnect alarm can be silenced for two minutes.
- The Low Voltage Advisory can be silenced for 5 minutes.
- All other Advisory alarms with audible tones can be silenced for four hours. The exceptions are Communication Fault, Driveline Power Fault, Driveline Communication Fault, which can be silenced indefinitely or for 24 hours.

Settings Screen

The Settings screen is used to monitor system parameters, change speed settings, and manually stop the Pump. The Settings screen contains:

- System Status Boxes: Various system parameters are displayed in two System Status boxes.
- Active Alarm Messages: The two highest-priority active hazard or advisory alarm messages (including the Driveline Disconnected alarm) appear as text banners below the System Status boxes. None of the banners flash. Refer to *Alarms Screen* on page 4-25 for a detailed explanation of System Monitor alarms.
- Command Buttons: The Fixed Speed Adjust, Low Speed Limit, Hematocrit Adjust, and Pump Stop/Start command buttons are displayed at the bottom of the screen. During alarm conditions and hematocrit adjust, a **Silence Alarm** button accompanies any active alarm. Press the **Silence Alarm** button to silence Hazard and Power Cable Disconnect alarms for two minutes, and all other Advisory alarms for four hours. For details, refer to *System Controller Alarms* on page 7-3.

System Status Boxes

The System Status 1 and System Status 2 boxes display general parameters and indicate the current operating mode (**Figure 4.19**). System Status boxes provide the following information:

- Status of important parameters such as the set Fixed Speed and Low Speed Limit
- Alarm Silence Status: on, off, or extended

Figure 4.19 Settings Screen Showing System Status 1 and 2

Status of the 11 Volt Lithium-Ion Backup Battery

- Patient use: Indicates the total number of times that the System Controller's 11 Volt Lithium-Ion backup battery has been used. Frequent use may indicate that a patient is having difficulty changing from the Power Module to battery power or vice versa.
- Replace in: Indicates the number of months remaining before the System Controller's 11 Volt Lithium-Ion backup battery expires. The number is highlighted when 6 or fewer months remain.
- Cumulative time: Indicates the total number of minutes that the System Controller's 11 Volt Lithium-Ion backup battery has been used. High numbers may indicate that a patient is inappropriately relying on the backup battery for non-emergency support.

Select Fixed Speed

The buttons in the Select Fixed Speed box are used to increase or decrease the Fixed Speed of the Pump. The Fixed Speed is adjustable in increments of 100 rpm, with a range of 3,000 rpm to 9,000 rpm. A Low Speed advisory alarm appears if either the Fixed Speed has been set 200 rpm or more below the Low Speed Limit, or the System Controller is unable to maintain the speed at or above the Low Speed Limit. This Low Speed advisory alarm notification is always provided on the System Monitor (**Figure 4.20**).

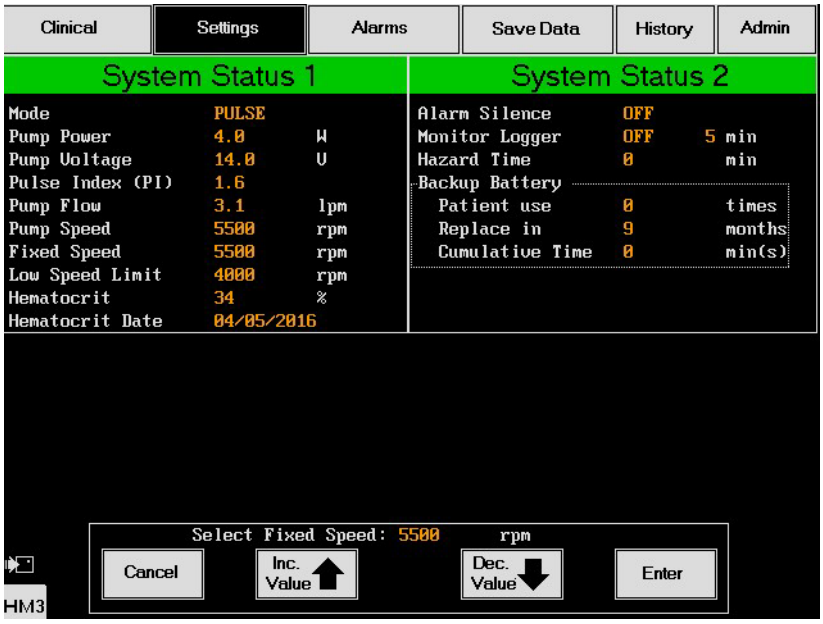


Figure 4.20 Settings Screen with Fixed Speed Adjust Box

The Select Fixed Speed box contains these buttons:

- **Cancel**: Returns to the basic Settings screen without saving any changes.
- Inc. Value ⬆: Increases the Fixed Speed by increments of 100 rpm. The new value appears above the button, after Select Fixed Speed.
- Dec. Value ⬇: Decreases the Fixed Speed by increments of 100 rpm. The new value appears above the button, after Select Fixed Speed.
- **Enter**: Accepts the selected Fixed Speed and returns to the basic Settings screen.

  A Sending Command message is displayed, and the new set value is sent to the System Controller. The new value is displayed in the System Status 1 box, when the command is accepted.

IMPORTANT! The **Enter** button must be pressed to save a new speed setting. If another button is used to exit, or if the screen automatically returns to the Clinical screen, changes are not saved.

Optimal Fixed Speed

A ramped speed study using echocardiography is the most direct method for determining the optimal Fixed Speed that will provide the preferred level of cardiac support for each patient. The Fixed Speed setting generally falls midway between the minimum and maximum speeds. It is based on changes in ventricular shape and function, and the patient's physiological response to changing Pump speeds.

Performing a Ramped Speed Study

A ramped speed study is intended for hemodynamically stable, euvolemic patients in the postoperative or later periods. During the study, left ventricular size, position of the septum, and the aortic valve opening should be monitored to determine the appropriate Fixed Speed setting. The final decision is ultimately dependent on the physician's clinical judgment, and will vary from patient to patient.

TO DETERMINE THE OPTIMAL FIXED SPEED FOR A PATIENT:

1. Ensure that the echocardiography is available.
2. Ask the patient to sit or lie in a comfortable position.
3. Connect a System Monitor to the Power Module to adjust the Pump speed and monitor Pump parameters.
4. Record the patient's current heart rate, blood pressure, and Pump speed.
5. Using echocardiography, record the patient’s left ventricular diameter, septum position, and frequency of aortic valve opening.

6. Determine the minimum Fixed Speed:
    a. Starting from the current Fixed Speed, lower the speed gradually to a value as low as possible without the patient experiencing signs of worsening heart failure. For example, shortness of breath or lightheadedness.
    b. Allow the patient to stabilize at each speed setting.

       IMPORTANT! Do not allow the Fixed Speed to drop below 3,000 rpm under any circumstances.

    c. Reduce the speed until the aortic valve opens with each beat or the patient starts to become symptomatic.
    d. Record the patient's current heart rate, blood pressure, and Pump speed.
    e. Using echocardiography, record the patient's left ventricular diameter and position of the septum.
7. Determine the maximum Fixed Speed:
    a. Starting from the minimum Fixed Speed (determined in Step 6), increase the pump speed gradually until echocardiography shows a flattening of the interventricular septum (or is clinically acceptable based on the echocardiographic evaluation).
    b. Record the patient's current heart rate, blood pressure, and Pump speed.
    c. Using echocardiography, record the patient's left ventricular diameter and frequency of aortic valve opening.
8. Based on findings from the speed study, determine the optimum Fixed Speed, which usually falls midway between the minimum and maximum speeds.

IMPORTANT! The selected speed may be adjusted based on clinical judgment regarding the need for periodic aortic valve opening and a palpable pulse. To accommodate normal shifts in volume and hemodynamic status, the Fixed Speed should generally be set at least 400 rpm below the maximum Fixed Speed determined previously.

Low Speed Limit

The Low Speed Limit should be set at the lowest speed at which the Pump can run while maintaining patient stability. It is important to establish a Low Speed Limit that can sustain a patient safely. Establishing a Low Speed Limit will maximize the protective benefits during PI events or when the Pump is in Power Saver mode.

In Power Saver mode, the System Controller slows the Pump speed to save power. If power is removed or fails, the System Controller provides 15 minutes of full power before entering Power Saver mode. Note that alarms cannot be silenced while the System Controller is in Power Saver mode.

Use the buttons in the Select Low Speed Limit box to increase or decrease the Low Speed Limit (**Figure 4.21**).

Figure 4.21 Select Low Speed Limit Box (Settings Screen)

Setting the Low Speed Limit is similar to setting the Fixed Speed. The Low Speed Limit is generally set at a value slightly above the minimum speed determined during the speed ramp study. Clinical judgment and consideration of all factors should be used when selecting the Low Speed Limit.

The Low Speed Limit default setting is 5,000 rpm, but it can be adjusted between 4,000 rpm and 6,000 rpm. If the operating speed drops below the value set for the Low Speed Limit, the WARNING: Low Speed Advisory alarm message appears.

If the system detects a PI event, the Pump speed automatically drops to the Low Speed Limit and slowly ramps back up at a rate of 100 rpm per second to the Fixed Speed setpoint. This drop in speed is accompanied by a reduced Pump flow. If the Low Speed Limit is set at a value above or the same as the Fixed Speed setpoint, the Pump speed does not change during a PI event. There are no audible alarms with a PI event.

PI events are assumed by the system during cases when there are sudden and substantial changes in the pulsatility index. These events are also referred to as PI events, and may be initiated for reasons other than true PI events. Some reasons include sudden changes in a patient's volume status, arrhythmias, sudden changes in power, and sudden changes in Pump speed. These types of PI events are more likely to be triggered in cases of low pulsatility.

Pump Stop Button

Use the **Pump Stop** button to turn off the Pump. Complete the following steps to use this feature.

1. Press and hold **Pump Stop** while the Pump Stop Countdown counts down from 10 to 1.

   The Pump stops within the first few seconds of holding down the **Pump Stop** button. However, if the button is released before the countdown is complete, the Pump resumes at the previously set mode and speed.

   After the countdown, the Stopping Pump message appears. The countdown lasts for approximately 10 seconds (**Figure 4.22**).

Figure 4.22 Pump Stop Countdown Starts

Initially, the WARNING: Low Speed advisory alarm, and then the LOW FLOW Hazard alarm appear. Both alarms appear without an audible alarm (**Figure 4.23**).

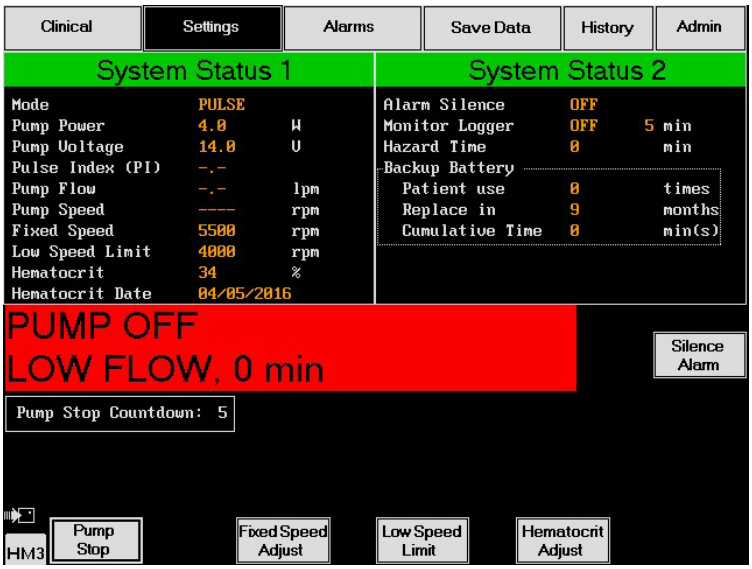


Figure 4.23 Pump Stop Countdown in Process

When the countdown nears zero, the PUMP OFF alarm appears, accompanied by a continuous audible alarm after the Pump is off.

2. Locate the **Silence Alarm** button to the right of the alarm text.

   IMPORTANT! During the Pump Stop Countdown, an audible alarm sounds after approximately two seconds of holding the **Pump Stop** button. When the PUMP OFF alarm appears, a continuous audible alarm sounds.

3. After the Pump Stop countdown is complete, press **Silence Alarm** to silence this alarm for two minutes (**Figure 4.24**).

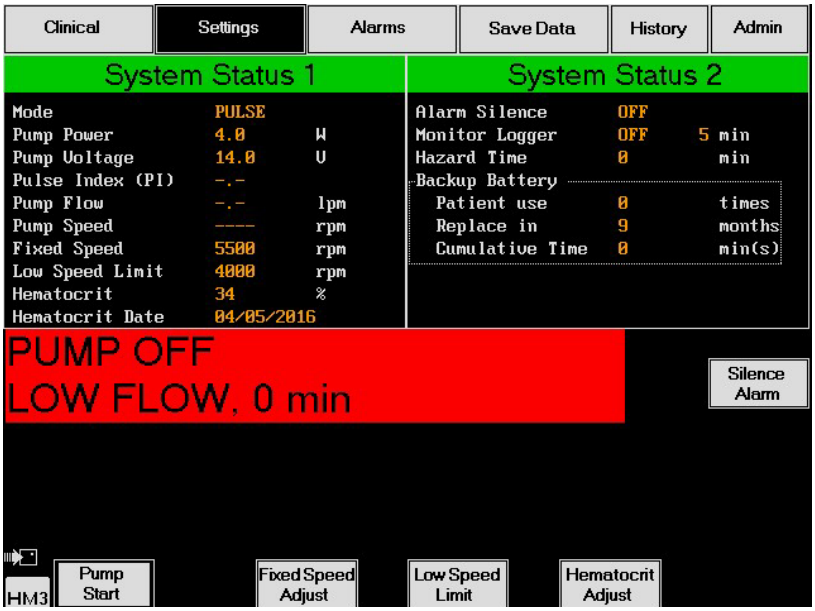


Figure 4.24 Pump Stop Countdown Completion

After the Pump Stop Countdown ends, a **Pump Start** button appears.

4. Press **Pump Start** to restart the Pump at the previously set mode and speed.

   The following message appears:

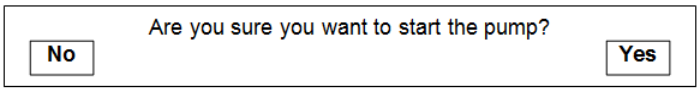


Figure 4.25 Pump Start Message

5. Press **Yes** to restart the pump at the previously set mode and speed.

   IMPORTANT! Auscultation over the pump implant location is recommended to verify that the pump is running.

Restarting the Pump

The Pump may stop because the Driveline is disconnected from the System Controller. If one of the following is true, the Pump restarts at the previously set speed when the Driveline is reconnected to the System Controller:

- The Fixed Speed setting is at least 4,000 rpm.

  OR

- The System Controller's backup battery is installed and any button is pushed on the System Controller.

The Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the **Pump Start** button when the Fixed Speed setting is below 4,000 rpm.

Pump Flow and Hematocrit

The System Controller provides an estimate of blood flow out of the Pump. To have a more accurate prediction, the System Controller uses the patient's hematocrit level as a surrogate for the patient's blood viscosity. Viscosity is a fluid property that can influence the flow estimate algorithm.

The System Controller has a default hematocrit value of 35%. To assure the most accurate flow estimation from the pump, enter the patient's actual hematocrit % via the Settings screen (**Figure 4.26**). The initial hematocrit value may be entered using pre-op hematocrit values. Periodic assessment of the patient's hematocrit should be conducted and adjustments made to the stored value in the System Controller as required (that is, during post-operative recovery, pre-hospital discharge, at hospital discharge, periodic clinic visits).

Figure 4.26 Settings Screen

Alarms Screen

The Alarms screen shows the status of all Hazard and Advisory alarms. The Alarms screen displays the following:

- Alarm messages: All alarms (active and inactive) are displayed in the Alarms box. Hazard alarms are listed on the left and Advisory alarms are listed on the right. Alarms are listed in order of highest priority.
- Parameters box: A box below the Alarms box displays system parameters, hazard time elapsed (for low flow hazards only), and whether the alarm silence is on, off, or extended.
- Command buttons: Command buttons appear only during alarm conditions.
  - A **Silence Alarm** button accompanies any active, audible alarm. Press this button to silence the Hazard and the Power Cable Disconnect alarms for two minutes, and all Advisory alarms for four hours.
  - An **Extended Silence** button accompanies active, audible alarms when the Fixed Speed is set below 4,000 rpm. Press this button to silence all Hazard and Advisory alarms for four hours.

Figure 4.27 Alarms Screen

IMPORTANT! Active alarm messages are only shown on the Clinical, Settings, and Alarms screens. If an alarm occurs while viewing the Save Data, History, or Admin screen, an audible alarm sounds, but no message is displayed. When this happens, switch to the Alarms screen for details.

Alarms are only highlighted when they are active. When an alarm condition occurs, it is highlighted and labeled as active on the Alarms screen. There are no adjustable alarm presets, and alarm conditions are not user adjustable in the HeartMate III LVAS. There are no alarm delays in the HeartMate III LVAS. Multiple alarms may be highlighted at the same time.

Hazard Alarms

IMPORTANT! If communication is lost between the System Controller and the Pump, this causes a Controller Fault Hardware hazard alarm. The System Monitor will not display that alarm. Only the System Controller displays the Controller Fault Hardware alarm.

There are five hazard alarms that display on the System Monitor. These hazard alarms are listed in order of priority:

- PUMP OFF: The Pump has been turned off or its Driveline is disconnected from the System Controller. Immediately turn on the Pump or reconnect the Driveline to the System Controller.
- DRIVELINE DISCONNECTED: The Driveline is disconnected from the System Controller. Immediately reconnect the Driveline to the System Controller.
- NO EXTERNAL POWER: The System Controller is not receiving external power from either power cable, and Pump function is being supported by the System Controller's backup battery. Immediately connect the System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
- LOW FLOW: Pump flow is less than 2.5 lpm, the Pump has stopped, the Pump is not operating properly, or the Driveline is disconnected from the System Controller. The count up time listed in the parameters box indicates how long this alarm has been active. Changes in patient conditions can result in low flow, such as hypertension.
- LOW VOLTAGE: Less than five minutes of combined power remain for the two HeartMate 14 Volt Lithium-Ion batteries (during battery-powered operation), or the System Controller is receiving inadequate power from the Power Module or Mobile Power Unit. Immediately connect the System Controller to a functioning power source.

Advisory Alarms

The Advisory alarms are listed in order of priority:

- Power Cable Disconnect: Indicates that one of the System Controller power cable connectors (white or black) is broken or disconnected from power (the Power Module or two HeartMate 14 Volt Lithium-Ion batteries). Immediately connect the indicated power cable to a power source.
- Low Voltage Advisory: Indicates that either less than 15 minutes of combined power remain for the two HeartMate 14 Volt Lithium-Ion batteries (during battery-powered operation), or the System Controller is receiving inadequate power from the Power Module. Immediately connect the System Controller to a functioning power source.
- Replace System Controller: Indicates the need for clinician assistance and may be a sign of a System Controller malfunction. Ultimately, the alarm may not be able to be resolved, necessitating the replacement of the running System Controller with the backup System Controller. Refer to *Replacing the Current System Controller* on page 2-46 if this is the case. After successfully switching to the backup System Controller, return the malfunctioning System Controller to Thoratec Corporation for diagnosis.
- Communication Fault: Indicates that either the data transfer between the LVAD and the System Controller has been lost due to a problem with the internal communication system, or the primary and back-up communication wires in the Driveline are not functioning. Use the System Monitor to silence the alarm while awaiting resolution, if needed. Also, exchanging the Modular Cable of the Driveline may resolve the problem. Refer to *Replacing the Modular Cable* on page 2-51. If exchanging the Modular Cable does not correct the alarm, contact Thoratec Corporation to determine the best next steps. Refer to page iii for Thoratec Corporation contact information.
- Replace Backup Battery: Indicates that either the 11 Volt Lithium-Ion backup battery inside the System Controller is compromised or unable to fully support Pump function. Promptly replace the faulted battery. Refer to *Replacing a Backup Battery* on page 2-37.
- WARNING: Low Speed Advisory: Indicates that either the Fixed Speed has been set 200 rpm or more below the Low Speed Limit, or the System Controller is unable to maintain the speed at or above the Low Speed Limit.
- Backup Battery Not Installed: Indicates that the System Controller's 11 Volt Lithium-Ion backup battery has not been installed, the connection between the backup battery and System Controller is not being made, or the backup battery is damaged or malfunctioning. Refer to *Installing the Backup Battery* on page 5-52.
- LVAD Fault: The LVAD has determined that one or more operating parameters is out of range. Contact Thoratec Corporation to determine best next steps. Use the System Monitor to silence the alarm while awaiting resolution, if needed.

- Driveline Power Fault: Indicates that one of the redundant power handling wires inside the Driveline may be damaged or broken. Contact Thoratec Corporation to determine best next steps. Use the System Monitor to silence the alarm while awaiting resolution, if needed.

  Note: The alarm must be the highest priority active alarm to access the alarm silence.

- Driveline Communication Fault: Indicates that one of the redundant communication handling wires inside the Driveline may be damaged or broken. Contact Thoratec Corporation to determine best next steps. Use the System Monitor to silence the alarm while awaiting resolution, if needed.

  Note: The alarm must be the highest priority active alarm to access the alarm silence.

- Controller Clock Not Set: Indicates that the System Controller's clock has not been set via the System Monitor's administration screen. Refer to *Date and Time* on page 4-40.

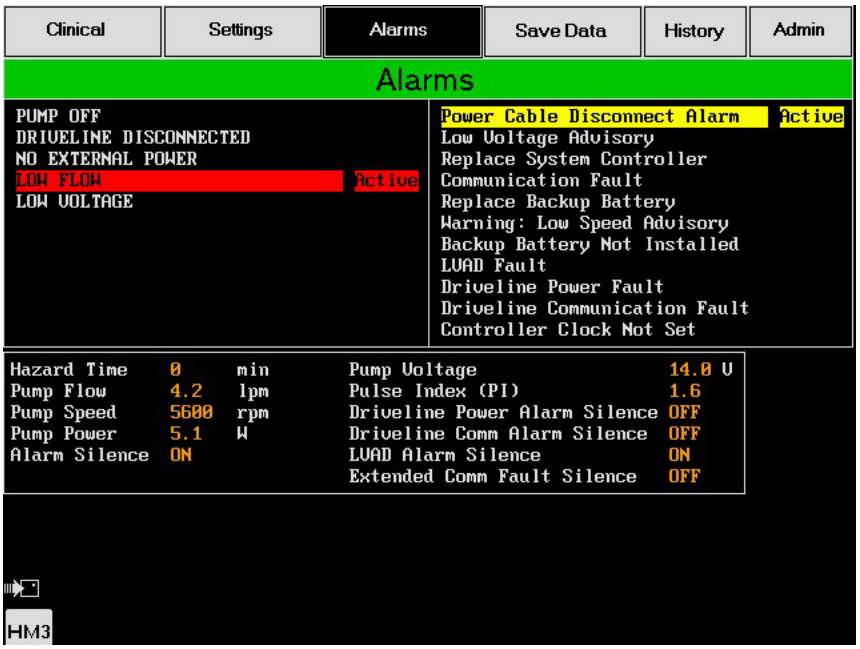


Figure 4.28 Alarms Screen with Multiple Active Alarms

Silencing Alarms via the System Monitor

The **Silence Alarm** button appears on the System Monitor screen only during alarm conditions. It is used to temporarily silence audible Power Module and System Controller alarms. Use this button to silence all Hazard alarms and the Power Cable Disconnect Advisory alarm for two minutes, the Low Power Advisory for 5 minutes, and all other Advisory alarms for four hours on both the Power Module and System Controller. Alarm messages display on the screen and the audible alarm is silent.

The Silence Alarm button may still appear for alarm conditions for which there is no associated audible alarm. In this case, the button will not perform any function. When an alarm is silenced, the Alarm Silence indicator in the parameters box displays ON. When the alarm condition is resolved, the alarm automatically turns off and the Alarm Silence indicator displays OFF.

The **Silence Alarm** button is not available for LVAD Fault, Driveline Power Fault, or Driveline Communication Fault.

Extended Silence Alarm Button

At fixed speeds set below 4,000 rpm, and with any active alarm, the **Extended Silence** button is available. Use this button to silence all Hazard and Advisory alarms on the Power Module and System Controller for four hours. Alarm messages display on the screen and the audible alarm is silent.

When the **Extended Silence** button is selected, the following message appears (**Figure 4.29**):

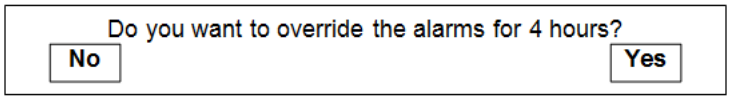


Figure 4.29 Override Alarms Message

Press **Yes** to use the Extended Silence alarm feature, which silences audible alarms for four hours. The Alarm Silence indicator in the parameters box will display Extended.

IMPORTANT! If the **Silence Alarm** button on the System Controller is pressed, the System Monitor's extended silence is canceled.

Using the Driveline Power Fault Alarm Buttons

To clear or silence an active Driveline Power Fault alarm, it must be the only fault that is active or is active concurrently with the Driveline Communication Fault and/or LVAD Fault alarms.

- Clear Driveline Power Fault Alarm: Clearing this alarm resets the alarm status from active to inactive.

  To clear the alarm, access the Alarm screen of the System Monitor and press the **Clear Driveline Power Alarm** button.

  If the alarm condition persists, this alarm will be reactivated. If it was a transient condition, this alarm will not be reactivated (**Figure 4.30**).

- Silence Driveline Power Fault Alarm: This action will permanently silence the audio portion of the Driveline Power Fault Alarm, and the System Controller will no longer display this alarm. The visual alarm on the System Monitor is maintained.

  To silence the alarm, access the Alarm screen of the System Monitor and press the **Silence Driveline Power Alarm** button (**Figure 4.30**).

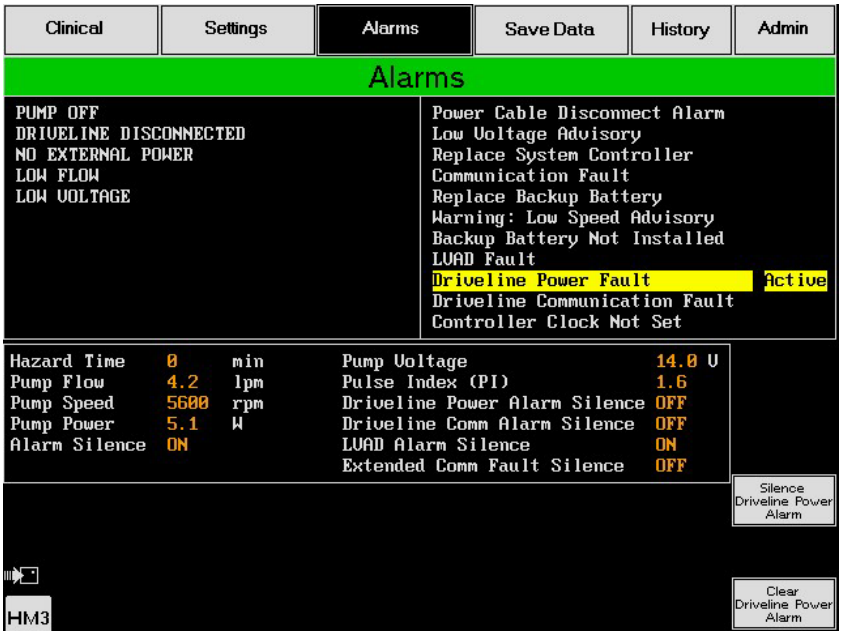


Figure 4.30 Driveline Fault Alarm Buttons

Using the Driveline Communication Fault Alarm Buttons

To clear or silence an active Driveline Communication Fault alarm, it must be the only fault that is active or is active concurrently with the Driveline Power Fault and/or LVAD Fault alarms.

- Clear Driveline Communication Fault Alarm: Clearing this alarm resets the alarm status from active to inactive.

  To clear the alarm, access the Alarm screen of the System Monitor and press the **Clear Driveline Comm Fault Alarm** button.

  If the alarm condition persists, this alarm will be reactivated. If it was a transient condition, this alarm will not be reactivated (**Figure 4.31**).

- Silence Driveline Communication Fault Alarm: This action will permanently silence the audio portion of the Driveline Communication Fault Alarm. The System Controller will no longer display this alarm. The visual alarm on the System Monitor is maintained.

  To silence the alarm, access the Alarm screen of the System Monitor and press the **Silence Driveline Comm Fault Alarm** button (**Figure 4.31**).

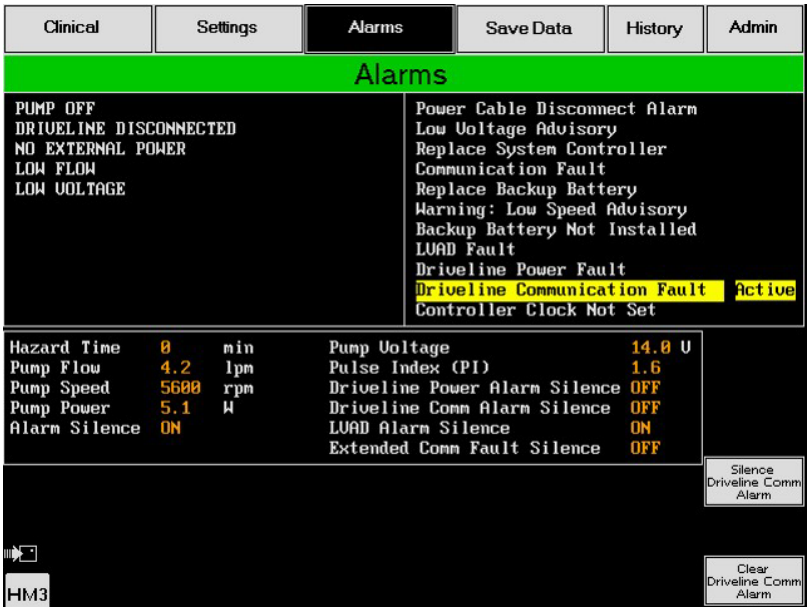


Figure 4.31 Driveline Communication Fault Buttons

Save Data Screen

Use the Save Data screen to change the rate at which periodic data from the System Controller and LVAD are recorded and saved. Save the System Controller and LVAD periodic data to the data card.

The Save Data screen contains these boxes (**Figure 4.32)**:

- System Controller Periodic Data
- LVAD Periodic Data
- Periodic and Event History

Figure 4.32 Save Data Screen

IMPORTANT! Alarm messages do not appear on the Save Data, History, or Admin Screens. Go to the Alarms screen to view alarm messages.

Data Card

Information recorded by the System Controller and LVAD can be saved on a data card. The data card is inserted into the slot located behind the door on the left side of the System Monitor, with the white side facing the front of the System Monitor. The System Monitor beeps when the card is correctly inserted (**Figure 4.33**).

If an action requires a data card and no card is inserted, the *Insert Memory Card in Slot* message appears.

IMPORTANT! The System Monitor automatically returns to the Clinical screen after 60 seconds of inactivity on any other screen. Any of the following buttons can be used to confirm changes as indicated on the active screen: **Continue**, **Enter**, or **Save**. If one of these buttons is not pressed, the changes will not be saved.

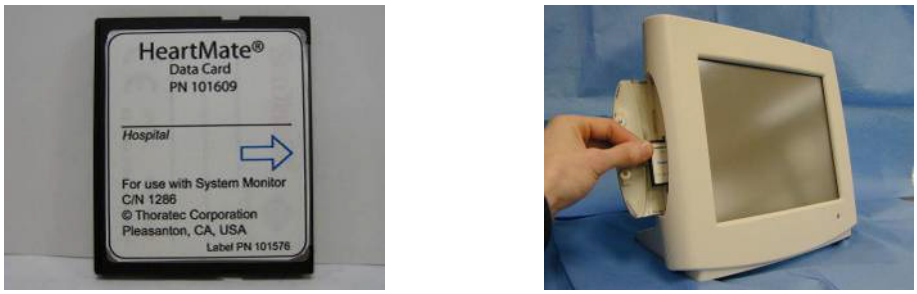


Figure 4.33 Data Card (left) and Inserting Data Card into System Monitor (right)

IMPORTANT! When information is saved to a data card for a specific patient, be sure to use the same patient identification (ID) number every time information is saved for that patient. Using different ID numbers makes it difficult to identify, track, or compare entries.

System Controller Event Recorder

The Event Recorder is a built-in feature of the System Controller that allows performance data to be collected and stored. The System Controller can store 256 events. When the memory is full, the oldest events are deleted as new ones are saved. The System Monitor is used to set the time interval for recording events by the System Controller. Information about events can be viewed on the System Monitor screen.

The Controller Event Recorder is always on. It automatically records any alarm.

System Controller Event History

Both the System Controller and the LVAD can be configured to take a snapshot of system performance parameters at a set frequency of time. This data is independent of the System Controller Event Log, which is initiated by events vs. time. The System Controller and LVAD can record 256 periodic logs. When the log is full, the oldest record is replaced with newest record. Frequencies include 10 minutes, 20 minutes, 30 minutes, and 1 hour to 24 hours in one hour increments.

To enable and configure the System Controller Periodic Data log, complete the following steps:

1. Select the Save Data screen on the System Monitor.
2. Press **Modify** located under Controller Periodic Data (**Figure 4.34**).
3. Increase or decrease the Record Interval to the preferred setting. This also enables the data collection.
4. Press **Save Changes** to confirm the interval.

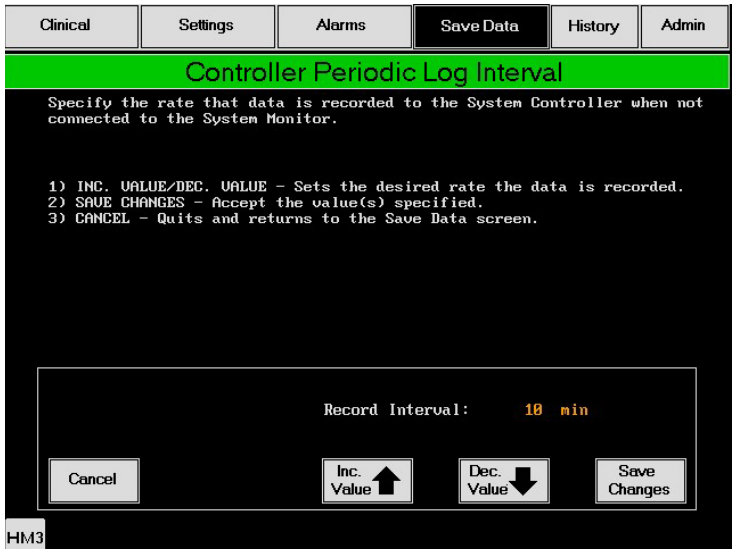


Figure 4.34 System Controller Periodic Log

To enable and configure the LVAD Periodic Data log, complete the following steps:

1. Select the Save Data screen on the System Monitor.
2. Press **Modify** located under LVAD Periodic Data (**Figure 4.35**).
3. Increase or decrease the Record Interval to the preferred setting. This also enables the data collection.
4. Press **Save Changes** to confirm the interval.

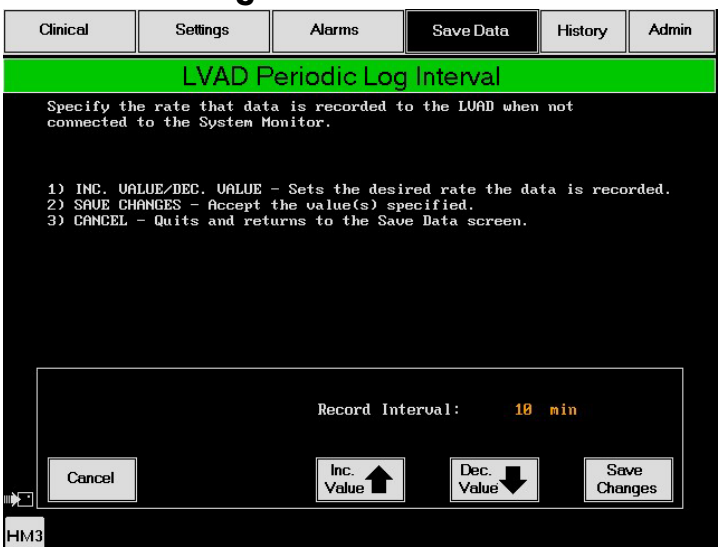


Figure 4.35 LVAD Periodic Log

TO SAVE SYSTEM CONTROLLER EVENTS THAT ARE LOGGED IN THE SYSTEM MONITOR:

1. Ensure that a data card is inserted into the System Monitor.
2. Press **Save to Card**.

   The Patient ID screen appears.
3. Verify that the date and time (top left corner of the screen) are correct, and complete one of the following steps:
   - If the date and time are correct, go to Step 4.
   - If the date and time are not correct, go to the Admin screen to set the time and date. Refer to *Date and Time* on page 4-40 for specific instructions on setting the clock.
4. Use the on-screen keypad to enter a patient identification description (up to 15 characters).
5. Press **Continue** to record the event history to the data card.

The following message appears: Retrieving history record (**Figure 4.36**).

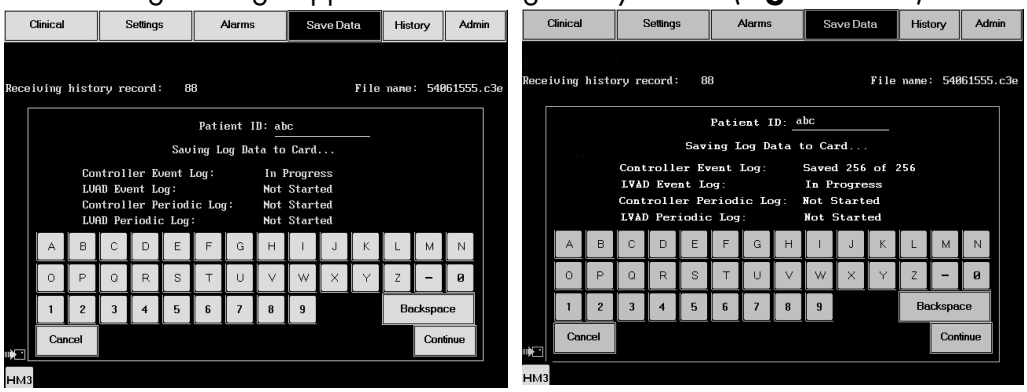


Figure 4.36 Retrieving History Data

When the data is successfully saved, the Monitor displays the following messages: All Data Captured Successfully and Press any button to continue (**Figure 4.37**).

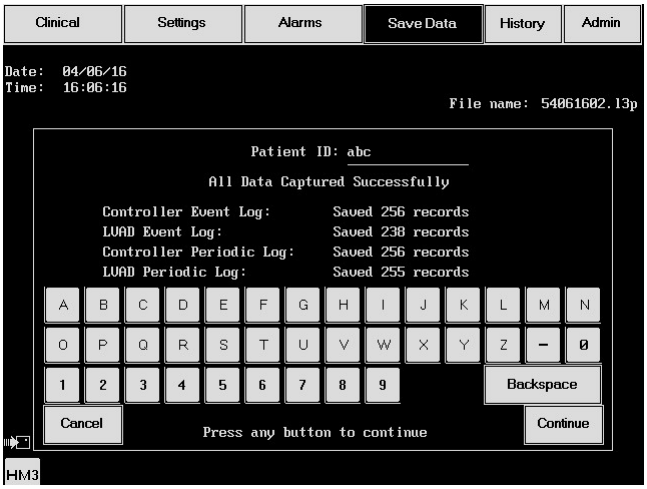


Figure 4.37 Data Captured Successfully

6. Press any button to return to the Save Data screen.

   If a button is not pressed, the Clinical screen automatically appears after 60 seconds.

7. Remove the data card from the System Monitor.

   Contact Thoratec Corporation regarding questions about accessing or understanding event history data. Refer to page iii for Thoratec Corporation contact information.

Sending Information to Thoratec Corporation

To send data such as log files to Thoratec Corporation for diagnostic purposes, the card reader must work with CompactFlash® media. A card reader is necessary to transmit data from CompactFlash media to a computer so that the data can then be sent via e-mail. A card reader is available through Thoratec Corporation (**Figure 4.38**).

The card reader plugs into any USB port on a personal computer (PC) and acts as a removable drive. Note that the drive designation may differ based on the PC's specific configuration.

Figure 4.38 Card Reader

IMPORTANT! A PC running Microsoft® Windows® 2000 or higher is required for most card readers.

Contact Thoratec Corporation for the e-mail address to send the data or for further assistance. Refer to page iii for Thoratec Corporation contact information.

Using the History Screen

The History screen displays System Controller event history on the System Monitor. Refer to *System Controller Event History* on page 4-34. System alarm and log data are retained even after powering down the system, or after a complete and total loss of power even for a brief moment.

Figure 4.39 History Screen

The History screen contains:

- Seven-Column Table: System parameters, alarms, and event times are displayed in a seven-column table (**Figure 4.40**).

EVENT LOG DAY-TIME	PUMP MODE	PUMP FLOW	PUMP SPEED	PUMP POWER	PULSE INDEX	ALARM
Date / time of event displayed as Month/ Day/ Year Hours/ Minutes/ Seconds	Pump mode setting for the patient.	Pump flow in lpm at time of event.	Pump speed in rpm at time of event.	Pump power in watts at time of event.	Pulsatility index at time of event.	Alarm type at time of event.

Figure 4.40 History Screen Table Columns

- Four Navigation Buttons: The navigation buttons, located in the lower right of the screen, allow users to move through the multiple screens of events. The left-most button opens the first page, the second and third buttons move between pages one at a time, and the right-most button opens the last page.
- Command Button: A **Save to Card** button appears at the bottom left corner of the screen. Refer to *Data Card* on page 4-33 for specific instructions on saving events to a data card.

1. Select the History tab.

   The following screen appears (**Figure 4.41**):

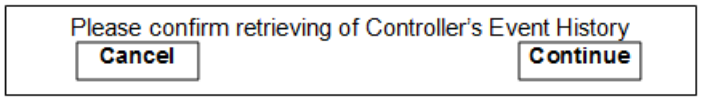


Figure 4.41 Retrieve Controller Event History Screen

2. Press **Continue** to download the logged events that are stored in the System Controller.

   The following screen appears (**Figure 4.42**):

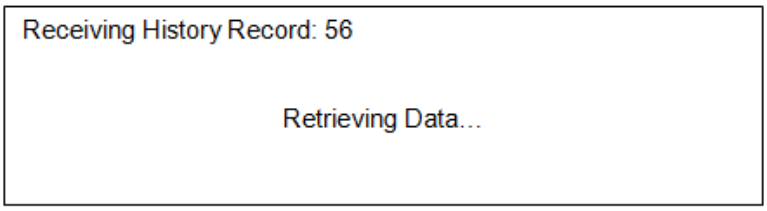


Figure 4.42 Retrieving Data Screen

When the logged events are successfully retrieved, the History screen appears. It displays the most up-to-date controller event history that is stored in the System Controller.

Reviewing Events

A maximum of 256 events can be stored and retrieved for display. The event history data are displayed in reverse chronological order, with the most recent events at the top of the screen.

*System Information: indicates that those data were recorded as part of an Event History interval record. These events may or may not include alarms. Data without asterisks indicate that those data were recorded at undesignated times due to an event.

Pulsatility (PI) Event: indicates a PI event occurred.

Admin Screen

Use the Admin screen to set the System Monitor and System Controller date and time, and to modify technical parameters such as Pump speed, power, flow, or the pulsatility index (**Figure 4.43**).

Figure 4.43 Admin Screen

Date and Time

The System Monitor and System Controller have separate clocks. They can be set independently from each other.

Logs and event history always reflect the date and time on the System Controller's clock. To synchronize the date and time on the System Controller with the System Monitor, press **Synch**.

The steps are the same to set the date and time on the System Monitor and the System Controller. The date and time box displays the current date and time.

TO CHANGE THE DATE AND TIME:

1. Determine which date and time settings to modify: System Monitor Clock or System Controller.
2. Press the corresponding **Modify** button.

   The corresponding Set Date and Time screen (System Monitor or System Controller) appears. It has on-screen instructions (**Figure 4.44**).

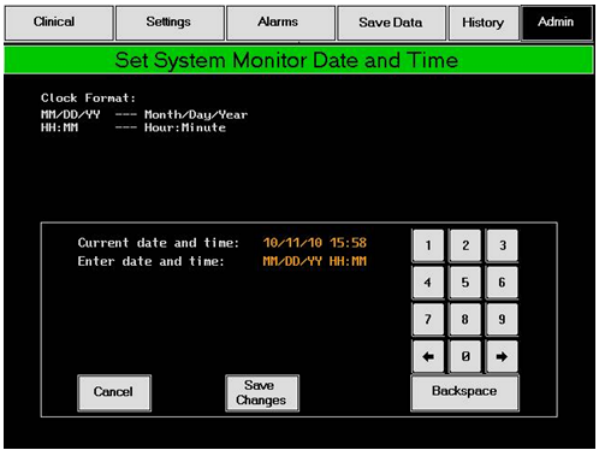


Figure 4.44 Set Date and Time Screen for System Monitor

3. Use the numerical keypad to enter the date and time. Include zeros, so that ten digits are entered.

   For example, to enter the date and time 10/11/10 15:58, type: 1011101558
   If less than ten digits are entered, an error message appears.
4. Press **Save Changes** to save the new date and time.

   A prompt appears to confirm the date and time (**Figure 4.45**).
5. Press **Yes** if the date and time are correct.

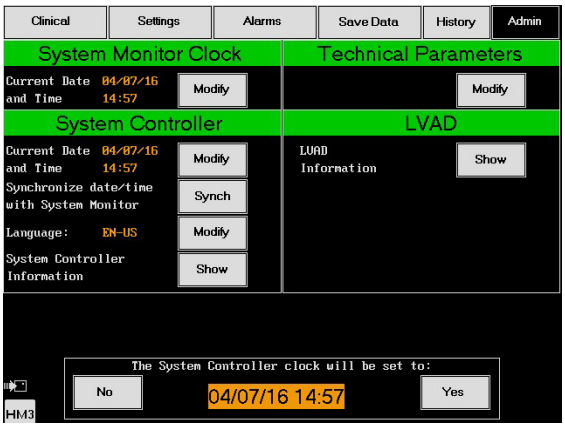


Figure 4.45 Confirm Date and Time

IMPORTANT! The System Monitor does not automatically update for Daylight Savings Time. Daylight Savings Time changes must be entered manually.

System Controller Language

The System Controller's on-screen messages are available in multiple languages.

To select a language for the System Controller, complete the following steps:

1. Press **Modify** for Language.
2. Use the buttons at the bottom of the screen to view and select the preferred language.

   Available languages are listed in alphabetic order. The first language listed is the one currently in use on the System Controller (**Figure 4.46**).

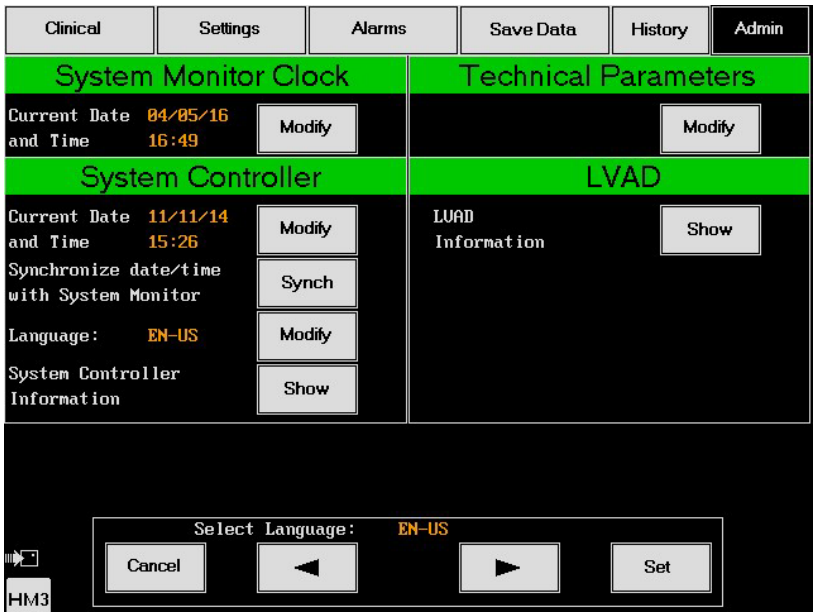


Figure 4.46 Select Language Screen

System Controller Information

This screen provides information on the System Controller and its 11 Volt Lithium-Ion backup battery. The backup battery inside the System Controller can power the Pump for at least 15 minutes during a power-loss emergency. Items capitalized are fixed characteristics of the backup battery. Items in mixed case are variable and change with backup battery use (**Figure 4.47**).

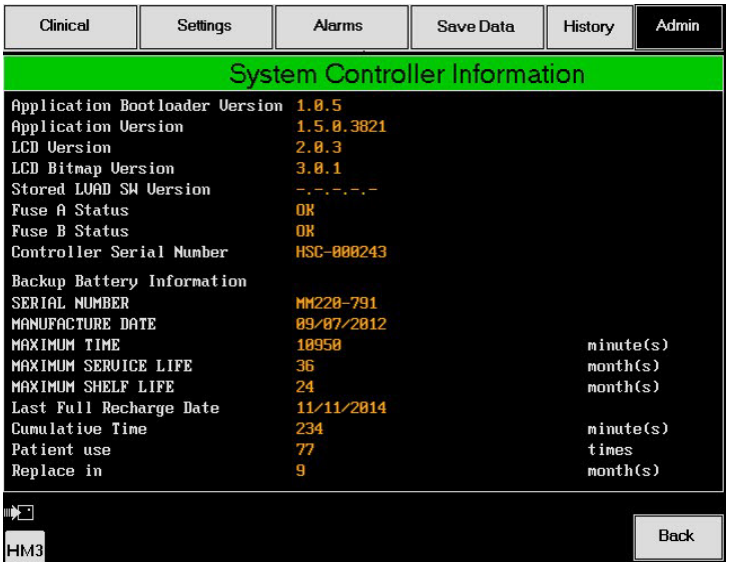


Figure 4.47 System Controller Information Screen

Technical Parameters

This screen provides access to the parameters. Access to this screen is restricted to Thoratec Corporation personnel only.

SURGICAL PROCEDURES

This section describes the surgical considerations necessary to prepare, implant, and explant the HeartMate III Left Ventricular Assist System.

5 Surgical Procedures

Surgical Considerations

This section describes the preimplant, implant, and explant procedures for the HeartMate III Left Ventricular Assist System.

WARNING !

- Moderate to severe aortic insufficiency must be corrected at time of device implant.
- Before using the Power Module, the hospital's biomedical technician or other personnel trained by Thoratec Corporation must install the Power Module backup battery.
- A minimum of two fully-charged HeartMate 14 Volt Lithium-Ion batteries, a pair of compatible battery clips, and a System Controller are required during device implant to power the LVAS when the patient is being transferred out of the operating room.
- All users (including clinicians, patients, and caregivers) must be trained on HeartMate III power accessories (Power Module, Mobile Power Unit, Battery Charger, and batteries) before use.
- Certain parts of the HeartMate III Left Ventricular Assist System are not compatible with other HeartMate systems (such as the HeartMate II Left Ventricular Assist System). Only use HeartMate III parts with the HeartMate III System.
- During the implant process, a complete backup system (implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedure must be either removed or adequately secured so as to not interfere with the operation of the HeartMate III Left Ventricular Assist Device.

WARNING ! (Continued)

- The sealed Outflow Graft contains material of bovine origin. It should not be implanted in patients who are sensitive to such materials.
- The HeartMate III pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.
- Keep connectors clean and dry and away from water or liquid. If the connectors come into contact with water or liquid, the system may fail to operate properly or cause a serious electrical shock.
- Do not use the HeartMate III Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the Pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Do not apply high power mains treatment (for example, application of diathermy) directly to the patient. Application of high power mains treatments could result in mains interference with system operation, causing the Pump to stop.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (for example, ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue, as the device may inadvertently concentrate the ultrasound field and cause harm. This does not apply to diagnostic techniques such as echocardiography.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.

CAUTION !

- After the Apical Cuff has been sewn to the heart, the metal ring on the Apical Cuff should extend above the felt surface to allow proper engagement and locking with the Slide Lock of the HeartMate III LVAD.
- Ensure that apposition between the myocardial tissue and the cuff felt is continuous and sufficiently forceful to prevent bleeding.
- If the Slide Lock mechanism on the HeartMate III LVAD fails to engage, do not make further attempts to engage until retracting the Slide Lock mechanism. Evidence of the Slide Lock mechanism failing to engage will be either visual evidence of the yellow "wings," or a tactile feel of three ridges versus one. The Slide Lock will not engage the Apical Cuff unless initially fully retracted.
- If difficulty persists when engaging the Slide Lock mechanism, the LVAD should be removed from the Apical Cuff to visualize what might be preventing the connection.

Equipment and Supplies Required for Implant

The HeartMate III Left Ventricular Assist System Implant Kit is supplied sterile and for single use only. Store components in a cool, dry place away from strong electromagnetic fields. For more information about storing components, refer to *Equipment Storage and Care* on page 8-1.

Thoratec-Supplied Equipment

CAUTION !

- Components of the HeartMate III Left Ventricular Assist System that are supplied sterile are intended for single use only, and should not be re-used or re-sterilized.
- Do not use sterile components if sterile packaging is compromised. Contact Thoratec Corporation for Return Authorization number.

WARNING !

Moderate to severe aortic insufficiency must be corrected at time of device implant. If not addressed, the LVAD will not be able to provide the intended flow.

This section describes both the sterile and non-sterile components purchased from Thoratec Corporation.

Sterile Components of the LVAS

Sterile components of the HeartMate III Left Ventricular Assist System (LVAS) Implant Kit include the following:

- Left Ventricular Assist Device (LVAD) Assembly
- 14mm Sealed Outflow Graft with Bend Relief
- Apical Cuff
- Apical Coring Knife (20mm)
- Skin Coring Punch (6mm)
- Outflow Thread Protectors (1 set)
- Modular Cable (with Modular Cable Cap)
- Tunneling Adapter
- System Controller

Non-Sterile Components of LVAS

- Power Module with Patient Cable

WARNING !

Power Modules are shipped to customers with the internal battery disconnected. After receiving the Power Module, the hospital's biomedical technician (or other authorized and trained personnel) must open the Power Module and connect its internal battery prior to using the device.

- System Monitor with System Monitor cable
- Battery Clips (set of 2) for HeartMate 14 Volt Lithium-Ion batteries

WARNING !

A minimum of two fully-charged batteries, and a pair of compatible battery clips are required at time of implant to power the system when transporting the patient out of the operating room.

- HeartMate 14 Volt Lithium-Ion batteries (set of 4, fully charged)
- Backup Battery (packaged with the System Controller)
- HeartMate III Tunneler and Handle
- User Document: *HeartMate III™ Left Ventricular Assist System Instructions for Use*

Hospital-Supplied Equipment

This section describes the components supplied by the hospital. Each site needs to provide a System Monitor and Power Module (**Figure 5.1**).

In addition, the following items are required:

- Small Drip Basin
- Sterile Graduated Pitcher (1,000 cc)
- Emesis Basins (2)
- Vent Needle
- CV Major Surgical Set
- Heavy Non-Absorbable Ligature
- Catheter-Tipped Syringe with Sterile Normal Saline
- 12 pledgeted horizontal mattress 2-0 braided sutures

Preimplant Procedures

WARNING !

- The sealed Outflow Graft contains material of bovine origin. It should not be implanted in patients who are sensitive to such materials.
- The sealed Outflow Graft does not require pre-clotting. Attempting to pre-clot a sealed Outflow Graft may disrupt or destroy the sealant, and lead to profuse bleeding after implantation.
- Do not implant the HeartMate III Left Ventricular Assist Device if it has been dropped.
- Never operate the HeartMate III Left Ventricular Assist Device in air, as this will immediately damage the device. Liquid must always be present in the Pump for proper function.
- Do not autoclave the Pump. This damages the Pump and Driveline.
- All entrapped air must be removed from the Pump/sealed Outflow Graft assembly blood path to minimize the risk of air embolus.

CAUTION !

- Operators must prevent blood from entering and collecting in the lumen of the conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must, therefore, be rinsed thoroughly prior to attachment to the Left Ventricular Assist Device.
- Never use tools to tighten the thread protector; securely hand tighten only. Using tools may cause damage.
- Do not allow the apical Coring Knife to involve the ventricular septum while performing left ventricle coring.
- The sealed Outflow Graft must not be kinked or positioned where it could abrade against a Pump component or body structure.
- Stretch the sealed Outflow Graft completely prior to measuring and cutting the graft to the appropriate length.

Preparing the Patient

Transport the patient to a cardiovascular operating room. Prep and anesthetize the patient according to standard procedures.

Initializing the Power Module and System Monitor

Prior to implant, ensure that all equipment is in good working order and ready, including what is on-hand in the operating room. This section describes how to initialize the Power Module and System Monitor.

During implant, the HeartMate III LVAD must be operated with the Power Module and System Monitor (**Figure 5.1**).

Note: If an older model of the System Monitor cable is used, use an adapter to connect the System Monitor to the Power Module.

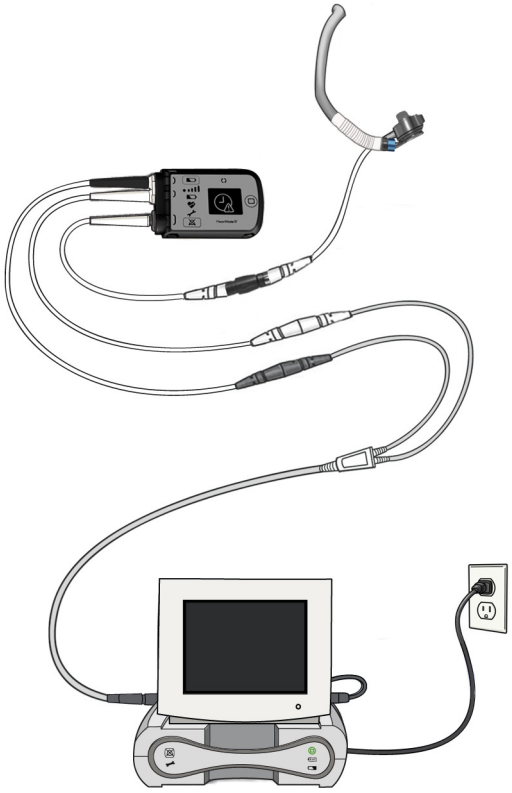


Figure 5.1 HeartMate III LVAS Connected to the Power Module

WARNING !

- Connect the Power Module and any peripheral devices only to properly tested, grounded, and dedicated AC outlets.
- Do not connect the Power Module to an outlet controlled by a wall switch.

To initialize the Power Module and System Monitor:

1. Plug the System Monitor cable into the socket located on the side of the Power Module.
2. Plug the other end of the cable into the System Monitor, if not already connected.
3. Ensure that the Power Module is plugged into a properly tested and grounded (3-prong) AC main outlet that is dedicated to Power Module use and is not controlled by a wall switch.

WARNING !

- Do not use an adapter plug for ungrounded wall outlets.
- Do not use a portable multiple socket outlet (power strip), or it may cause a serious electrical shock or the Pump may stop.

4. Ensure that the Patient Cable is attached to the Power Module.
5. Locate the on/off switch at the rear of the System Monitor.
6. Press the switch to the "on" (I) position and complete one of the following steps:
   - If a green light on the front of the System Monitor illuminates, go to Step 7.
   - If the System Monitor does not power on, perform troubleshooting steps to resolve the issue. Refer to *Setting Up the System Monitor for Use with the Power Module* on page 4-5.
7. Observe the System Monitor screen and complete one of the following steps:
   - If the HeartMate logo screen appears, the System Monitor is ready for use with the Power Module (**Figure 5.2**).
   - If the logo screen does not appear, perform troubleshooting. Refer to *Setting Up the System Monitor for Use with the Power Module* on page 4-5.

Figure 5.2 HeartMate Logo Screen

Unpacking the Implant Kit

Thoratec Corporation ships the implant kit in a large cardboard box.

1. Remove all the trays from the cardboard box.
2. Place the System Controller backup battery aside for later use.

IMPORTANT! **Note that the backup battery is not sterile.**

The Pump and surgical accessories are packaged in separate plastic tray containers and are packaged together within a common plastic container. The LVAD inner tray has a snap on plastic lid cover, which is sealed by a Tyvek® lid to maintain sterility.

WARNING !

- If any items are dropped, a new kit must be opened. Dropped items cannot be flash sterilized.
- Only personnel using sterile technique should touch sterile components such as the Pump, System Controller, and Modular Cable.

Note: The operating room has several sterile fields. Use care when unpacking items, as several of the items must be placed in the sterile fields.

Unpack the components in the following order:

- Left Ventricular Assist Device LVAD (Pump) and Accessories Tray
- System Controller
- Modular Cable
- Sealed Outflow Graft

Unpacking the Pump and Accessories Tray

WARNING !

Only sterilized personnel using sterile technique should make contact with sterilized implant kit accessories.

To unpack the Pump and Accessories trays:

1. Peel back and remove the cover from the main packaging tray (**Figure 5.3**).

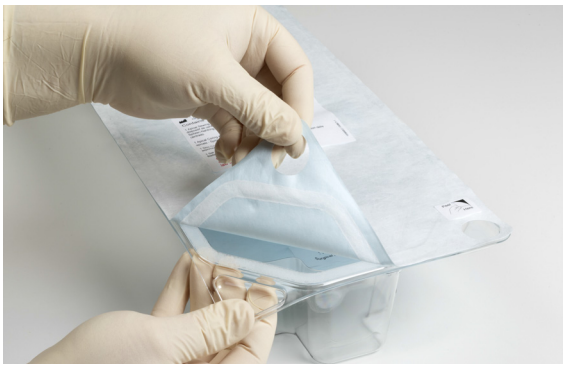


Figure 5.3 Main Packaging Tray

2. Remove the Pump and accessories trays from the main packaging tray (**Figure 5.4**).

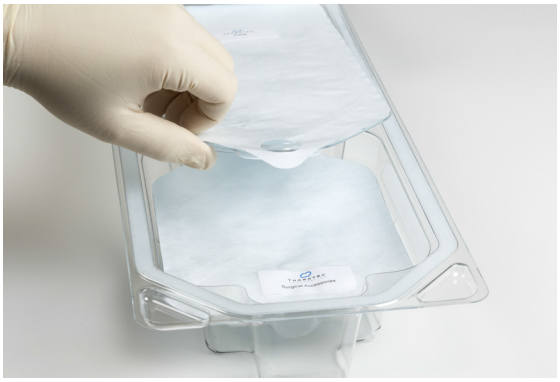


Figure 5.4 Pump and Accessories Trays

3. Peel back and remove the lid from the Pump Tray (**Figure 5.5**).

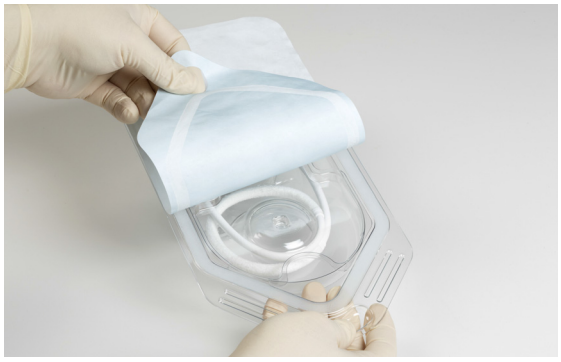


Figure 5.5 Pump and Accessories Tray

4. Grip the cutout in the plastic cover and separate it from the tray.
5. Remove the sterile Pump from the tray and avoid touching the threaded outflow portion of the Pump or any textured surfaces (**Figure 5.6**).

CAUTION !

Gently guide the Pump Cable and Tunneling Adapter out of the tray as the Pump is lifted. Do not remove the Pump by the Pump Cable.

Figure 5.6 Proper Removal of Pump and Cable from the Tray

6. Move the sterile Pump to the pump preparation sterile area.
7. Inspect the quality of the white washer in the outlet.
8. Maintaining strict sterile technique, screw the sterile Tunneling Adapter on to the Pump Cable connector.
9. Ensure that the adapter is completely screwed down tight by covering the yellow line on the in-line connector.

10. Grip the notched cutout of the Accessories Tray and peel back the lid (**Figure 5.7**).

Figure 5.7 Accessories: Apical Sewing Cuff, Thread Protectors, Coring Knife, and Skin Punch

11. Remove all the sterile components from the Accessories Tray and place them in the sterile work area.

Unpacking the Sealed Outflow Graft

The sealed Outflow Graft comes in a foil pouch and double plastic trays with sealed covers.

To unpack:

1. Open the sealed Outflow Graft box and foil pouch-containing desiccant.

   The foil pouch is a protective cover only and should not be introduced into the sterile field.

2. Remove the outer tray from the foil pouch (**Figure 5.8**).

   The outer tray is not sterile. Only the innermost tray may be introduced into the sterile field.

Figure 5.8 HeartMate III Sealed Graft With Bend Relief

3. Peel back the lid to expose the sealed Outflow Graft.
4. Remove the sealed Outflow Graft and Bend Relief from the inner tray.
5. Move the Outflow Graft and Bend Relief to the sterile preparation area.

Preparing the Sealed Outflow Graft

Characteristics that identify and distinguish a HeartMate III sealed Outflow Graft from a HeartMate II sealed Outflow Graft are as follows:

- The product packaging label indicates it is a HeartMate III Sealed Outflow Graft.
- A purple screw ring that attaches to the Pump (the HeartMate II has a blue screw ring).

WARNING !

- The sealed Outflow Graft should not be implanted in patients who exhibit sensitivity to materials of bovine origin.
- A sealed Outflow Graft (**Figure 5.9**) does not require pre-clotting. Attempting to pre-clot a sealed Outflow Graft may disrupt or destroy the sealant and lead to profuse bleeding after implantation.

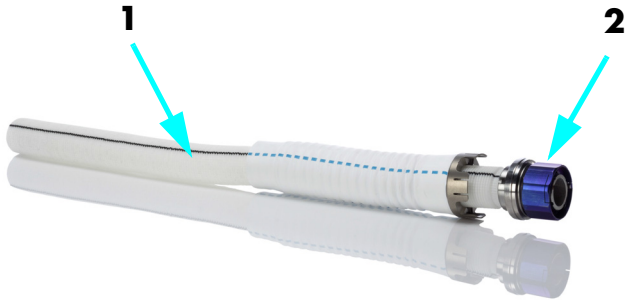


Figure 5.9 HeartMate III Sealed Outflow Graft

1	**Sealed Graft**
2	**Screw Ring**

Prepare a HeartMate III sealed Outflow Graft for implantation, in a sterile environment, using a strict sterile technique. Complete the following procedure:

1. Remove the Bend Relief from the graft.
2. Inspect the interior of the graft and remove any debris.
3. Attach the open thread protector.
4. Place the Bend Relief over the graft, with the metal end sliding toward the screw ring.

   The Bend Relief should be disengaged for the de-airing procedure. Only the Vascular Graft is intended to be cut or clamped, not the Outflow Graft Bend Relief.

Unpacking the System Controller

The System Controller comes in a double plastic tray setup with a sealed cover.

1. Peel back the cover of the outer plastic tray, and then peel back the lid of the inner tray.
2. Remove the inner tray from the packaging (**Figure 5.10**).

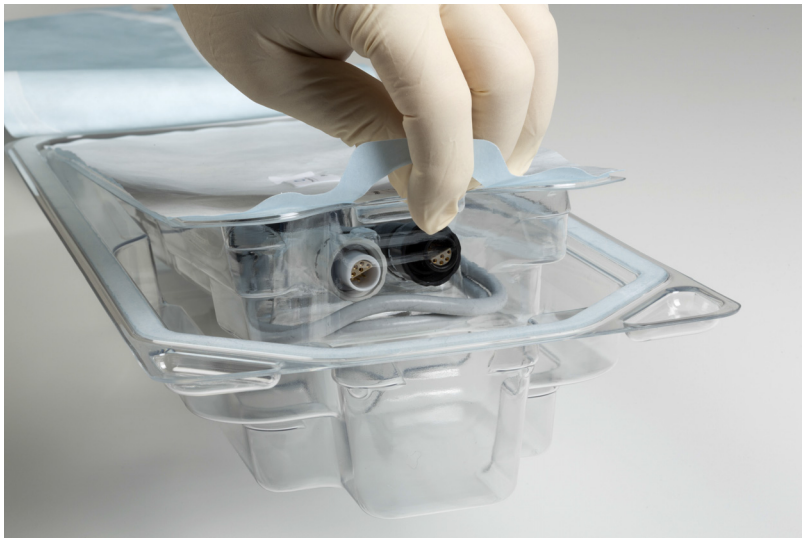


Figure 5.10 Controller in Tray

3. Peel back the cover of the inner tray to expose the System Controller (**Figure 5.11**).

Figure 5.11 System Controller

4. Remove the System Controller from the tray and move it to the sterile working area.
5. Secure the power cables so that they stay within the sterile field.

Unpacking the Modular Cable

The Modular Cable is packaged in a sealed plastic tray inside another sealed plastic tray.

1. Open the box containing the Modular Cable and remove the plastic tray (**Figure 5.12**).

Figure 5.12 Modular Cable in Packaging

2. Peel back the lid of the outer plastic tray, and then peel back the lid of the inner tray (**Figure 5.13**).

Figure 5.13 Outer and Inner Plastic Trays with Lids Peeled Back from Modular Cable

3. Remove the sterile Modular Cable and the Modular Cable Cap from the packaging.

   The Modular Cable Cap protects the connector from fluids and debris.

4. Install the Modular Cable Cap onto the Modular In-Line Connector by completing the following steps:
   a. Insert the Modular In-Line Connector into the Modular Cable Cap.
   b. Press firmly until the Modular In-Line Connector bottoms inside the Modular Cable Cap.
   c. Ensure that the Modular In-Line Connector is fully inserted into the Modular Cable Cap.
   d. Wrap a clean and dry sterile towel around the Modular Cable Cap and Modular In-Line Connector.
   e. Move the Modular Cable to the sterile work area (**Figure 5.14**).

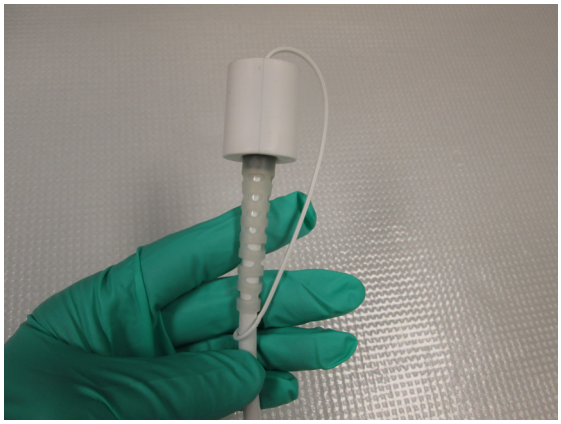


Figure 5.14 Covering the Modular In-Line Connector with the Modular Cable Cap

Connecting and Initializing the Sterile System Controller

This section describes how to connect and initialize the sterile System Controller to non-sterile equipment.

WARNING !

- At least one System Controller power cable must be connected to a power source at all times. Disconnecting both power cables at the same time will cause the Pump to stop.
- Never disconnect the patient cable from the Power Module unless the patient first switches to battery-powered operation.

To connect and initialize the sterile System Controller:

1. Pass the two System Controller power cable ends out of the sterile field and connect them to the bifurcated ends of the Power Module patient cable, white-to-white and black-to-black.

   Both the Power Module and System Controller will indicate a hazard alarm condition signifying that the System Controller is powered, but not connected to the HeartMate III LVAD.

   Do NOT connect the System Controller to the Pump.

2. Silence the alarm via the System Monitor (**Figure 5.15**).

   Do not silence the alarm signal using the System Controller.

3. Verify that a flashing communication icon  is shown in the lower left corner of the System Monitor screen.

   This icon is displayed on all screens. It establishes that the System Monitor is properly connected to the System Controller and that the correct monitoring software is running.

   Note: If the communication icon is not flashing, check connections and restart the monitor.

4. Go to the Admin screen.
5. Check the time and date on the System Monitor, and complete one of the following steps:
   - If the time and date are correct, go to Step 6.
   - If the time and date are not correct, go to *Date and Time* on page 4-40 for instructions on setting the date and time on the System Monitor.
6. Use the System Monitor to set the System Controller clock.

7. Verify that the screen displays the pump off, low flow, and Driveline Disconnected alarm messages and indicates Pulse Mode with dashes "–" in the Setpoint display (**Figure 5.15**).

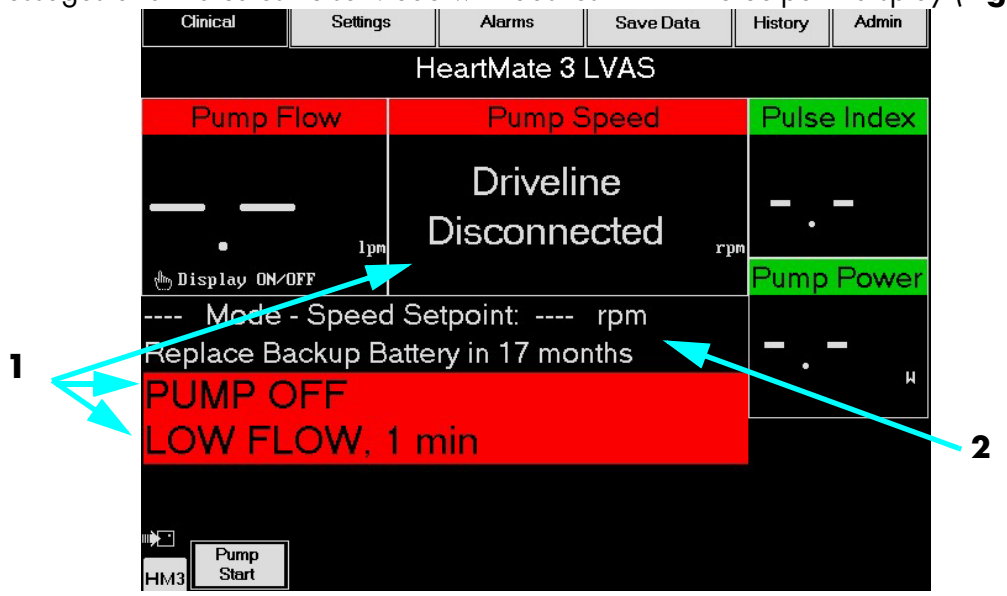


Figure 5.15 System Monitor Clinical Screen When Initially Connected to the System Controller

1	**Active Hazard Alarms**
2	**Fixed Speed Setpoint**

8. Go to the Alarms screen by pressing the Alarms tab (**Figure 5.16**).

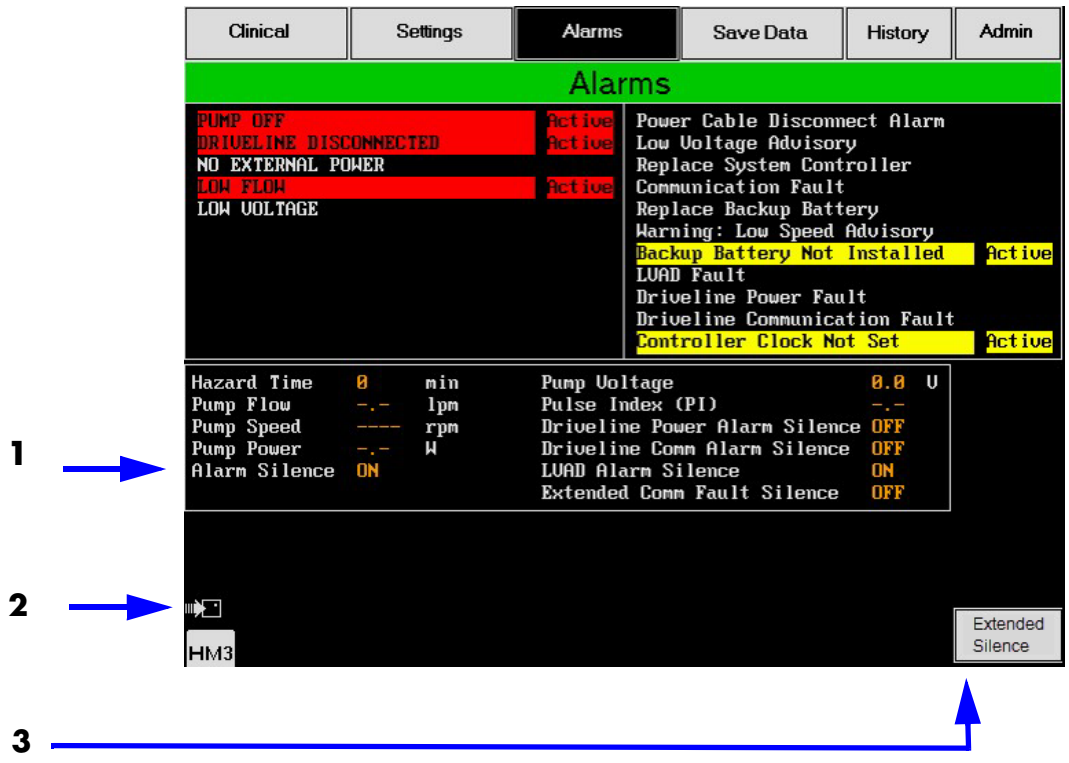


Figure 5.16 Alarms Screen when Initially Connected to the System Controller

1	**Alarm Silence Indicator**	This will display both the **Silence Alarm** and **Extended Silence** buttons.
2	**Communication Icon**	
3	**Extended Silence Button**	

9. Press the **Extended Silence** button.

   This will silence all hazard and advisory alarms for four hours to ensure that they will not sound in the O.R. The alarm silence indicator should display extended.

10. Cancel the extended silence alarm by completing one of the following steps:
    - Press the **Silence Alarm** button on the System Controller's user interface panel.
    - Disconnect the System Monitor from the Power Module.

    System Controller configuration is now complete. The Driveline Disconnected alarm will remain active until the System Controller is connected to the LVAD. The Pump Off alarm message will remain active until the LVAD is turned on via the System Monitor pump start command.

Preparing, Operating, and Priming the Pump

This section provides instructions for submerging the Pump in saline and operating it for a minimum of five minutes at 3,000 rpm to verify Pump operation.

WARNING !

- Only sterile personnel should perform the following procedures.
- Never operate the HeartMate III Left Ventricular Assist Device in air, as this will immediately damage the device. Liquid must always be present in the Pump for proper function.

1. Attach the Controller Driveline Connector of the Modular Cable to the System Controller by completing the following steps:
   a. Rotate the Safety Lock to the open position (**Figure 5.17**).

Figure 5.17 Locking Mechanism on System Controller

   b. Align the arrows on the Modular Cable Controller Connector and System Controller.
   c. Insert the Modular Cable Controller Connector into the System Controller until the connector clicks and locks into place.
   d. Gently tug on the end of the Modular Cable Controller Connector to ensure proper engagement.
   e. Lock the Modular Cable connection to the System Controller by sliding the cable Safety Lock in the direction of the lock symbol until the red button is no longer visible.

CAUTION !

If the Safety Lock cannot fully close to cover the red button, the connector is not fully connected.

2. Prepare a sterile graduated pitcher (1000 cc) with a minimum of 1 liter of sterile saline.

3. Examine the Pump Outflow connector to verify the presence of a white washer and complete one of the following steps:
   - If the white washer is present and undamaged (**Figure 5.18**), go to Step 4.
   - If the white washer is missing or damaged, obtain another Pump before continuing with the following steps.

Figure 5.18 HeartMate III LVAD

4. Complete the following steps:
   a. Submerge and fully cover the Pump in the saline filled graduated pitcher.
   b. Take care to exit the In-line Connector side of the Pump Cable up and over the edge of the basin.
5. Gently tap and shake the Pump while it is submerged to release any trapped air within the Pump.

   Note: When the adapter and cap are removed, the connection can be made between the Pump and the System Controller.

6. Remove the adapter and cap by completing the following steps:
   a. If the Pump Cable connector and Tunneling Adapter are wet, dry the connector area with a clean and dry sterile towel.
   b. Using a clean and dry sterile towel, grip the connector area and disconnect the Tunneling Adapter, orienting the Tunneling Adapter downward.
   c. Leave the Tunneling Adapter tied to the Pump Cable.
   d. Visually confirm that the inside of the Pump Cable connector is dry.
   e. If the Pump Cable connector is not dry, discard the Pump and obtain a new one.
   f. Remove the towel that is wrapped around the Modular Cable in-line connector and Modular Cable Cap.
   g. If the Modular Cable and/or the Modular Cable Cap are wet, dry them with a clean dry sterile towel.
   h. Leave the cap tethered to the Modular Cable.
   i. Visually confirm that the inside of the Modular Cable connector is dry.
   j. If the Modular Cable in-line connector is not dry, discard the Modular Cable and obtain a new one.

7. Connect the sterile Pump and Modular cables by completing the following steps:

   Note: Connecting the sterile Pump and the Modular cables makes the connection between the Pump and the System Controller.

   a. Verify the in-line connectors of the Pump Cable and Modular Cable connectors are secure in the sterile area.
   b. Align the in-line connection triangles on the connectors to ensure proper pin alignment.
   c. Apply firm force to engage the in-line connector and rotate the locking nut in the locking direction.
   d. Push the In-Line Connectors firmly together.
   e. Rotate the locking nut of the in-line connector to the locked position as indicated on the markings (**Figure 5.19**).

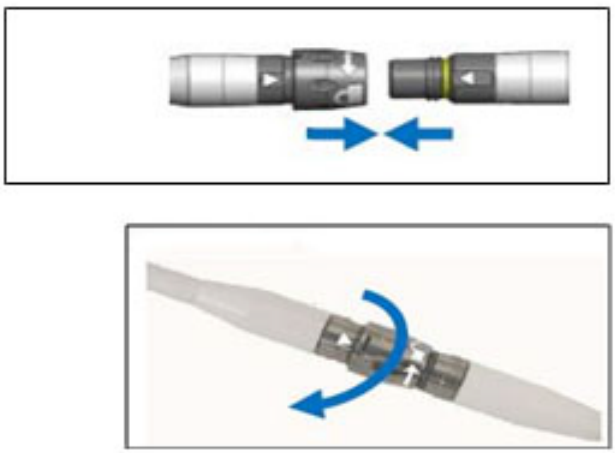


Figure 5.19 Pushing the In-Line Connectors Together and Rotating the Locking Nut

   f. Listen for a clicking sound as the locking nut is rotated.

      The clicking sound is normal.

   g. Continue to tighten until the clicking sound stops.
   h. Turn the locking nut until the yellow line on the threaded portion of the connector is no longer visible.

      After the in-line connection is made, the Pump is electrically connected.

WARNING !

- The Modular In-Line Connector on the Driveline is for external to the body use only. The Modular In-Line Connector must not be implanted.
- Only personnel using sterile technique should touch sterile components such as the Pump, System Controller, and Modular Cable.

Note: The sterile personnel may instruct the non-sterile personnel to initiate commands on the System Monitor.

On the System Monitor, the Pump Disconnected message should disappear and the Pump Speed box should now display "0"

8. Initiate Pump operation at 3,000 rpm by completing the following steps:
   a. On the System Monitor, press the Settings tab.
   b. Push the **Pump Start** button (**Figure 5.20**).

      The Pump may take up to 10 seconds to start. The PUMP OFF message should disappear.

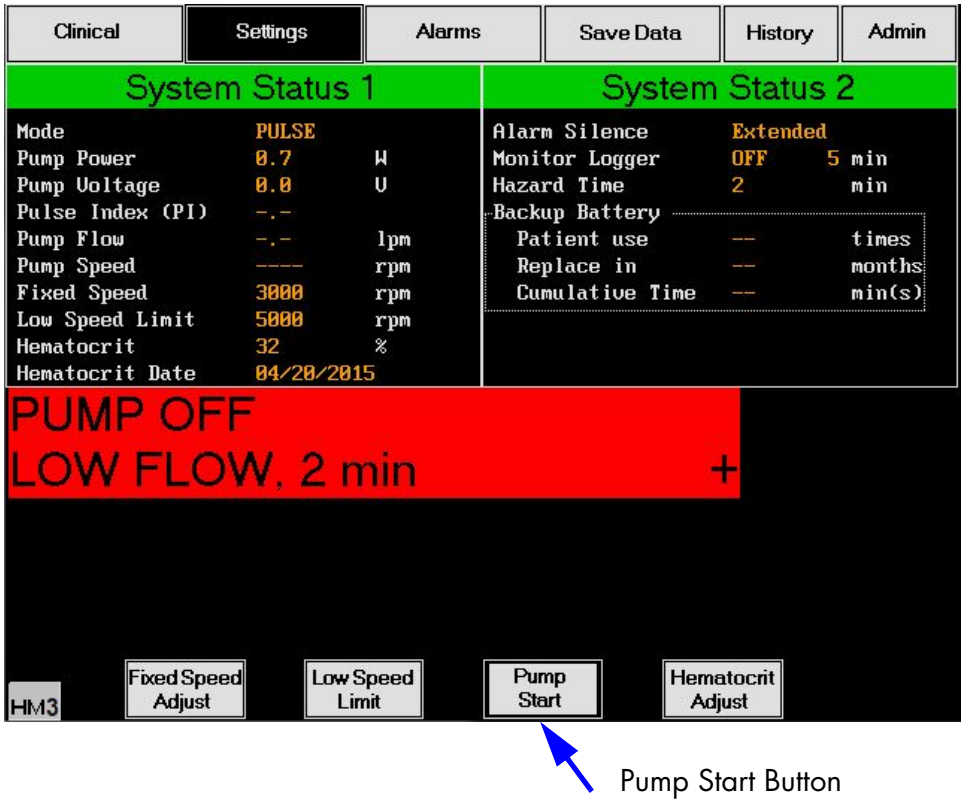


Figure 5.20 Pump Settings Screen

9. If the speed setpoint is not 3,000 rpm, complete the following steps:
   a. On the System Monitor, access the Settings screen.
   b. Press the **Fixed Speed Adjust** button.
   c. Follow the on-screen instructions to set the speed to 3,000 rpm.
   d. During the next five minutes, ensure that the Pump continues to operate.

WARNING !

If the Pump fails to operate properly, do not implant it. Utilize the back-up HeartMate III LVAD in its place.

10. Enter the Patient Hematocrit by completing the following steps:
    a. On the System Monitor, access the Settings screen.
    b. Determine the patient's hematocrit via blood analysis (in %).
    c. Enter the value on the Settings screen.
    d. Press **Enter**.

       This is required to ensure a proper flow estimation performance (**Figure 5.21**).

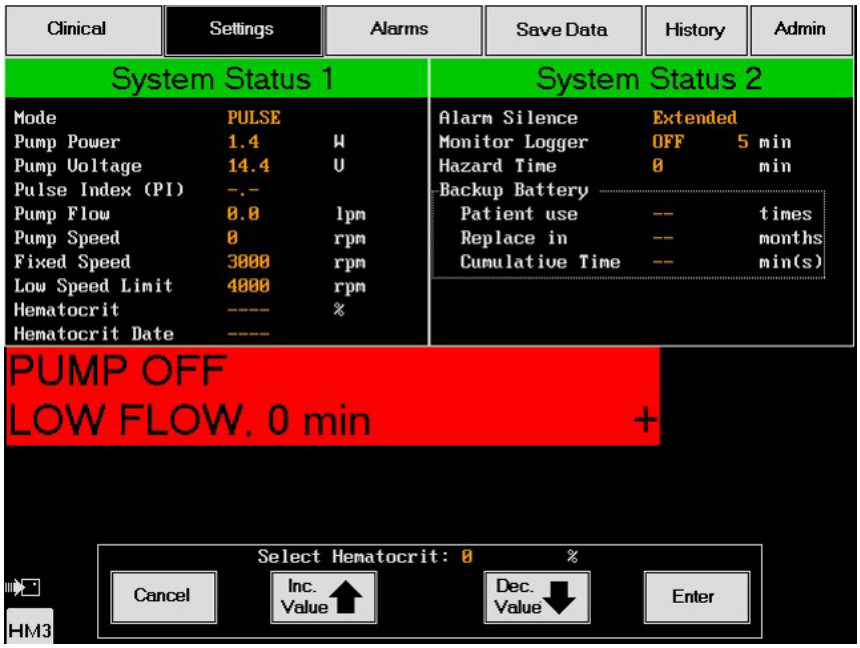


Figure 5.21 Hematocrit Screen

11. Wait for 5 minutes to elapse.
12. Press and hold the **Pump Stop** button on the Settings screen for 10 seconds until the **Pump Stop** button disappears.

    The Pump Off message appears and the **Pump Stop** button changes to **Pump Start**.

13. Disconnect the in-line connector by completing the following steps:
    a. Unthread the locking nut in the direction of the unlock symbol.
    b. Listen for a clicking sound as the locking nut is rotated.

       The clicking sound is normal.

    c. Continue to unthread the locking nut until the clicking sound stops.
    d. When the clicking sound has stopped, pull the connectors apart.
14. Leave the Pump in the sterile graduated pitcher of sterile saline.
15. Maintaining strict sterile technique and using dried gloved hands, attach the sterile Tunneling Adapter to the Pump Cable connector.

16. Ensure that the adapter is completely screwed down tight by covering the yellow line on the in-line connector (**Figure 5.22**).

Figure 5.22 Attaching the Tunneling Adapter to the Pump Cable

17. Install the Modular Connector Cap onto the end of the Modular Cable.
18. Wrap a clean and dry sterile towel around the Modular Connector Cap and in-line connector.

    The Modular Connector Cap protects the connector from fluids and debris.

    Do not disconnect the Modular Cable from the System Controller.

19. Ensure that the cable stays sterile.
20. Secure the length of the Modular Cable (attached to the System Controller) so it does not fall out of the sterile field.
21. Leave the System Controller power cables connected to the Power Module.

    If the power cables are disconnected, the extended alarm silence will be reset.

22. While still in the sterile area, complete the following steps:
    a. Remove the Pump from the graduated pitcher.
    b. Install the thread protector with the Luer-Lok™ cap on the Pump Outlet (**Figure 5.23**).

CAUTION !

Do not over-tighten the thread protector and the Tunneling Adapter.

23. Open the Luer-Lok cap to allow air to escape.

Figure 5.23 Attaching the Luer-Lok Connector to the Pump Outlet

24. With the Inflow Cannula facing upward, fill the Pump with sterile saline through the Inflow Cannula until it flows out of the cap.
25. Close the Luer-Lok cap.
26. Gently tap the side of the Pump and observe air bubbles rising to the surface.
27. Tap and add saline until the Pump appears full and no further air bubbles can be observed.
28. Remove all entrapped air from the Pump blood path to minimize the risk of air embolus.
29. Cut a fingertip off of a powder-less sterile glove and use it to cover the Inlet extension of the inflow.
30. Place antibiotic-soaked laps over the Pump and velour portion of the Pump Cable, and then set aside the Pump in a sterile, safe place.
31. Secure the entire length of the Pump Cable so it does not fall out of the sterile field.

Preparing the Coring Knife

WARNING !

The cutting end of the Coring Knife is extremely sharp and should be handled with care to prevent injury.

The Coring Knife has two protective end caps held in place by a string. Using strict sterile technique, complete the following procedure:

1. Cut the string securing the end caps to the Coring Knife (**Figure 5.24**).

Figure 5.24 Coring Knife

2. Take the Coring Knife handle and insert it through the holes in the side of the Coring Knife (**Figure 5.25**).

Figure 5.25 Assembling the Coring Knife Handle

3. Insert the handle so it creates a "T" handle (**Figure 5.26**).

   This enables handling of the tool during surgical procedure.

Figure 5.26 Assembled Coring Knife

Implant Procedures

Figure 5.27 shows the proper orientation of the Left Ventricular Assist Device. The Inflow Cannula is placed utilizing left ventricle (LV) apical cannulation, with the Pump placed within the pericardial space between the ventricular apex and the diaphragm. An abdominal pocket is not required for implantation. Therefore, entry into the abdominal cavity will not be performed. The sealed Outflow Graft attached to the ascending aorta and the Pump Cable exits the right upper quadrant of the abdomen and connects to the external equipment.

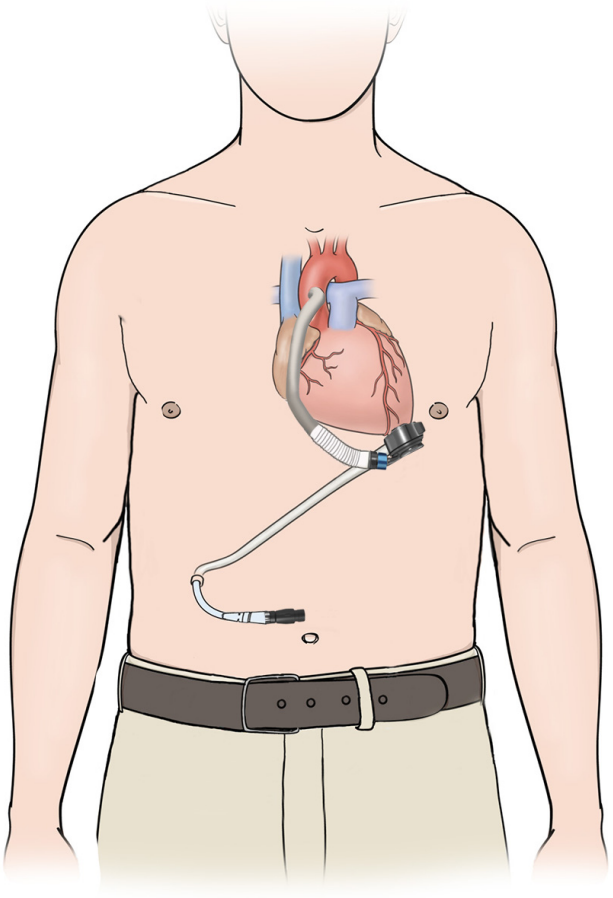


Figure 5.27 HeartMate III Implantation Configuration

WARNING !

- Do not open the foil pouch until ready to use the sealed Outflow Graft. Store sealed grafts inside the foil pouch. Once removed from the pouch, the sealed Outflow Graft must be implanted within 24 hours.
- Stretch the sealed Outflow Graft completely prior to measuring and cutting the graft to the appropriate length.
- Prior to advancing the Inflow Cannula into the left ventricle through the Apical Cuff, remove the glove tip from the inlet extension. Inspect the ventricle and remove any previously formed clots that may cause embolism or any trabeculae that may impede flow.
- Confirm that the thread protectors have been removed from the sealed Outflow Graft and the Pump prior to attempting connection.
- Maintain left atrial pressure (LAP) at greater than 10 mm Hg at all times to prevent air entrainment. The HeartMate III Left Ventricular Assist Device is capable of producing negative pressure when the Pump output exceeds blood flow from the left ventricle.
- All entrapped air must be removed from the device blood-pumping chamber and conduits to reduce the risk of air embolus.
- All entrapped air must be removed from the device blood-pumping chamber and conduits prior to fully releasing the sealed Outflow Graft cross-clamp.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- A minimum of two fully-charged batteries, a pair of compatible battery clips, and a System Controller are required at the time of implant to power the LVAS when transporting the patient out of the O.R.
- Do not use the HeartMate III Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the Pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Do not subject patients implanted with the HeartMate III Left Ventricular Assist System to Magnetic Resonance Imaging (MRI)  as the device contains Ferromagnetic components. MRI can cause Pump failure or patient injury.

WARNING ! (Continued)

- Prior to implanting an implantable cardiac defibrillator or implantable pacemaker in a HeartMate III patient, the device to be implanted should be placed in close proximity to the Pump (approximately 10 cm) and the telemetry verified. If a patient receives a HeartMate III and has a previously implanted device that is found to be susceptible to this programming interference, Thoratec Corporation recommends replacing the implantable cardiac defibrillator device with one that is not prone to programming interference.
- The HeartMate III pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.
- Initial weaning of cardiopulmonary bypass should ensure a minimum of two liters per minute (lpm) of blood flow to the Left Ventricular Assist Device to prevent air embolism. Prolonged de-airing may be due to inadequate blood supply to the Left Ventricular Assist Device or a leak in the sealed Outflow Graft or Inflow Cannula.
- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- A sealed HeartMate III Outflow Graft must be used. A sealed HeartMate II Outflow Graft is not appropriate for use with the HeartMate III LVAS.
- Do not trim or cut the bend relief of the sealed Outflow Graft or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss.

CAUTION !

- Sharp bends, twists, or kinks in the Driveline may make it more susceptible to wear and fatigue over time.
- Do not allow the apical Coring Knife to involve the interventricular septum while performing left ventricle coring.
- The sealed Outflow Graft and Pump Cable must not be kinked or positioned where it could abrade against a Pump component, surgical element, or body structure.
- Remove all vents on the inflow side of the Left Ventricular Assist Device, including needles in the pulmonary vein, left atrium, and left ventricle prior to initiation of pumping.
- Failure to connect the bend relief to the sealed Outflow Graft so that it is fully and evenly connected can allow kinking and abrasion of the graft. This may lead to serious adverse events such as low Left Ventricular Assist Device flow and/or bleeding.
- Care should be taken to ensure that the sealed Outflow Graft bend relief remains connected during sternal closure.
- After the Left Ventricular Assist Device is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the Left Ventricular Assist Device. Whenever possible, maintain the HeartMate III at a pump flow greater than 3 lpm and a pump speed greater than 4,000 rpm.

Final Check of Prepared Equipment

Prior to implantation, confirm that:

- The bend relief is in place over the sealed graft and disengaged from the metal fitting.
- The Left Ventricular Assist Device is completely primed with Sterile Saline for Injection.
- The HeartMate III pump has been run for at least 5 minutes successfully in Sterile Saline for Injection.
- The patient's hematocrit has been entered into the System Monitor (after the Pump and System Controller are connected to the Power Module).

Opening the Chest

A midline chest incision is made not to extend below the xiphoid process. The pericardium is opened and reflected laterally to allow exposure of the LV apex.

Creating the Driveline Exit Site

The tunnel created for the Pump Cable should be as long as possible to maximize ingrowth along the cable's polyester velour covering and to minimize the risk of exit site infection. The Pump Cable has been designed to allow for velour or silicone to cross the exit site. If the Pump Cable is externalized, a length of 1-2 cm will ensure the Modular In-line Connector is positioned close to the exit site.

FOR THIS TASK YOU NEED:

- 1 HeartMate III Left Ventricular Assist Device, prepared for use
- 1 HeartMate III Tunneling Lance and Handle
- 1 6 mm skin coring punch

TO CREATE THE DRIVELINE EXIT SITE:

CAUTION !

The HeartMate III Tunneling Lance and Handle are provided non-sterile. Ensure that the Tunneling Lance and Handle have been cleaned, inspected, and sterilized in accordance with the provided instructions and hospital policy.

1. Place the HeartMate III LVAD in the chest to approximate where the device will be positioned to visualize the path of the Pump Cable.
2. Connect the Tunneling Adapter to the Tunneling Lance.
3. Confirm the yellow line in the Tunneling Adapter is fully covered for a secure connection.
4. Identify proposed exit site location (one that minimizes future Driveline interference with clothing or belts).
5. Insert the pointed tip of the tunneler into a small incision appropriately positioned on the inner abdominal wall.
6. Starting from the inferior aspect of the pocket, create a long and gently curved tunnel that passes through the right rectus abdominis and subcutaneous tissue to an exit site in the upper right quadrant.
7. Prior to exiting the dermis, place a mark at the exit site.
8. Use the 6 mm skin coring punch, supplied in the implant kit, to create a circular incision at this position.
9. Externalize the tip of the lance through the circular incision.
10. If using the Tunneling Handle, connect the handle to the lance by retracting the handle flange and inserting the tip and hexagonal feature until captured in the handle.
11. Carefully advance the lance to externalize the Pump Cable.
12. Disconnect the Tunneling Lance from the Tunneling Adapter, but leave the Tunneling Adapter connected to the Pump Cable.
13. Inspect the Driveline to ascertain that it is free from any sharp bends or kinks.

14. Consideration should also be given to the potential for sharp bends and kinks occurring postimplant with ventricular remodeling during HeartMate III Left Ventricular Assist System support.
15. Ensure that the Pump Cable is clear of anatomical or surgical elements that could cause wear.
16. Consider that the exit site may also be impacted by body habitus changes after implantation.

    The Pump Cable has been designed to allow a silicone-skin or velour-skin interface at the exit site.
17. Place the prepared Pump into the prepared space.

Attaching the Sealed Outflow Graft to the Aorta

FOR THIS TASK YOU NEED:

1 sealed Outflow Graft with bend relief

TO ATTACH THE SEALED OUTFLOW GRAFT:

1. Confirm that the bend relief is added to the sealed Outflow Graft prior to attaching it to the aorta with the thread protector on the graft.
2. Place the Pump in the anatomical position.
3. Stretch the graft completely, measure and cut the sealed Outflow Graft to the appropriate length.
4. Anastomose the graft to the ascending aorta in an end-to-side fashion using 4-0 polypropylene running sutures.
5. Ensure that the suture line is secure with no blood loss.
6. Clamp the graft near the aorta.

Preparing the Ventricular Apex Site

FOR THIS TASK YOU NEED:

- 1 Apical Coring Knife (20 mm)
- 1 Apical Cuff

TO PREPARE THE VENTRICULAR APEX SITE:

Note: The Apical Cuff can be affixed to the Left Ventricle via two methods: Sew Then Cut, or Cut Then Sew.

CAUTION !

- After the Apical Cuff has been sewn to the heart, the metal ring on the Apical Cuff should extend above the felt surface to allow proper engagement and locking with the Slide Lock of the HeartMate III LVAD.
- Ensure that apposition between the myocardial tissue and the cuff felt is continuous and sufficiently forceful to prevent bleeding.

SEW THEN CUT METHOD

1. Cannulate and initiate cardiopulmonary bypass.
2. Choose the coring location slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery.
3. Ensure that the metal skeletal structure is facing away from the myocardium, and that the black markings are visible on the Apical Cuff.

4. Complete the following steps:
   a. Target the placement of the sutures on the black circumferential line marked on the Apical Cuff (**Figure 5.28**).

      This will help ensure that a hemostatic connection between the Apical Cuff and the heart tissue, for which uninterrupted opposition between the myocardial tissue and the Apical Cuff felt is required.

CAUTION !

When placing sutures into the myocardium, ensure they will not be cut by the Coring Knife.

   b. Approximately one and a half centimeters from the core, suture the sewing ring cuff with at least 12 pledgeted horizontal mattress 2–0 braided sutures almost full thickness.
   c. Apply corresponding sutures to the felt sewing cuff.

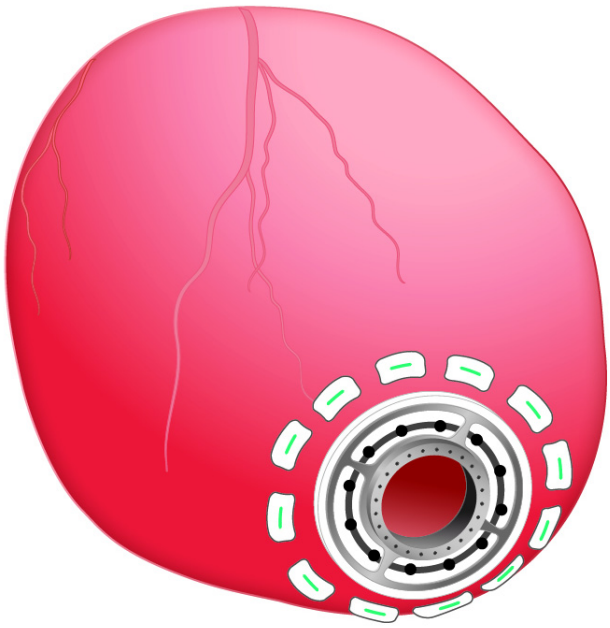


Figure 5.28 Placement of Sutures Between the Metal Ring and the Circumferential Line on the Apical Cuff

5. Ensure that the sutures do not approximate or traverse any of the metallic surfaces.

6. Place the sutures and pledgets such that the resulting Apical Cuff and surrounding tissue produces no interfering tissue that would prevent the VAD from approximating the Apical Cuff (**Figure 5.29**).

   Figure 5.29 shows suturing that results in an Apical Cuff without protruding myocardial tissue, and that will allow proper engagement of the Slide Lock. Either a full backstitch or partial backstitch (one of each shown) can be considered for approximation of epicardium and felt, and hemostasis.

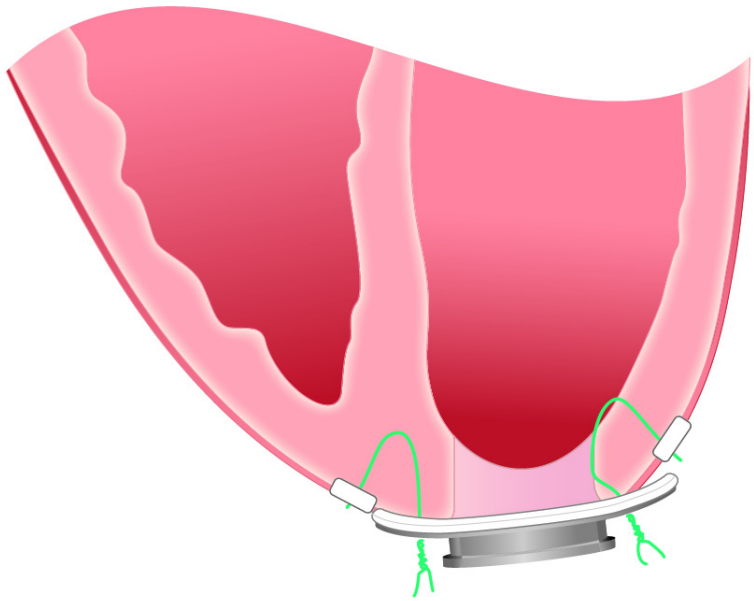


Figure 5.29 Suturing Resulting in an Apical Cuff Without Protruding Myocardial Tissue

7. Complete the following steps to gather the myocardium around the felt cuff:
   a. Separate the sutures.
   b. Tie the sutures tight with 6 to 7 throws on each knot.

CAUTION !

Ensure that apposition between the myocardial tissue and the cuff felt is continuous and sufficiently forceful to prevent bleeding.

8. Complete the following steps when sewing the Apical Cuff to the exterior of the heart:
   a. Ensure that the suture knots are not interfering with the connection.
   b. If a sealing agent is used on or near the Apical Cuff, ensure that it does not interfere with the Slide Lock mechanism.

9. Complete the following steps:
   a. Apply the cutting edge of the coring knife to the epicardium, and maintain pressure while rotating the knife until the ventricular cavity is entered (**Figure 5.30**).
   b. Align the orientation of the Coring Knife toward the mitral valve.
   c. Take care to avoid orienting the inlet towards the interventricular septum.

      Pump function will be compromised in the presence of inlet obstruction.

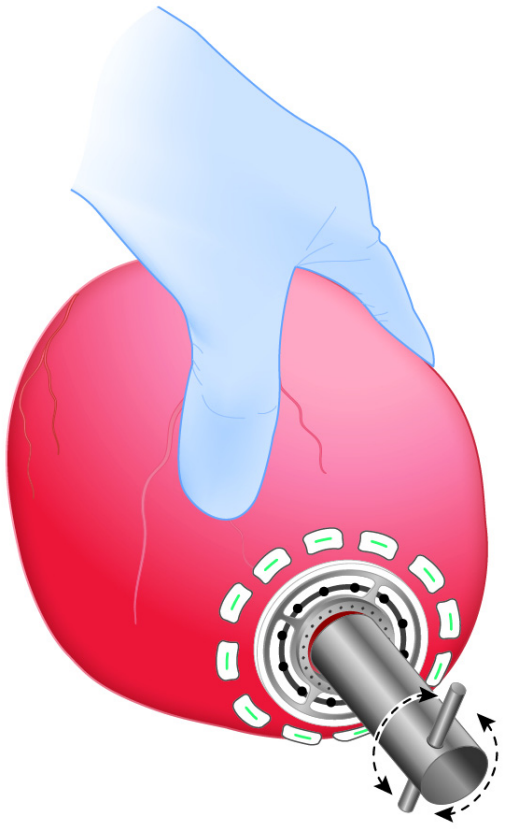


Figure 5.30 Coring Ventricular Apex

10. Complete the following steps:
    a. Remove the core and inspect the ventricular chamber for mural thrombi and crossing trabeculae.
    b. Address one or both, as needed.

CUT THEN SEW METHOD

The Apical Cuff may be sewn to the exterior of the ventricle (as described in Steps 3–8 in the Sew Then Cut Method section), after the ventriculotomy is created by advancing the Coring Knife into the heart (as described in Steps 9 and 10 in the Sew Then Cut Method section).

Inserting the Pump in the Ventricle

FOR THIS TASK YOU NEED:

1 Pump with Thread Protector Installed

TO INSERT THE PUMP IN THE VENTRICLE:

Carefully perform the following steps to ensure proper placement of the Pump and Inflow Cannula:

1. Remove glove tip.
2. Retract the Slide Lock so that it is in the fully opened position as far as it will go (**Figure 5.31**).

Figure 5.31 Retracting the Slide Lock

3. Insert the Inflow Cannula into the opening within the cuff.
4. Rotate the Pump so that the Outflow Graft is directed to the midline of the thorax and the Pump Cable is oriented toward the midline (**Figure 5.32**).

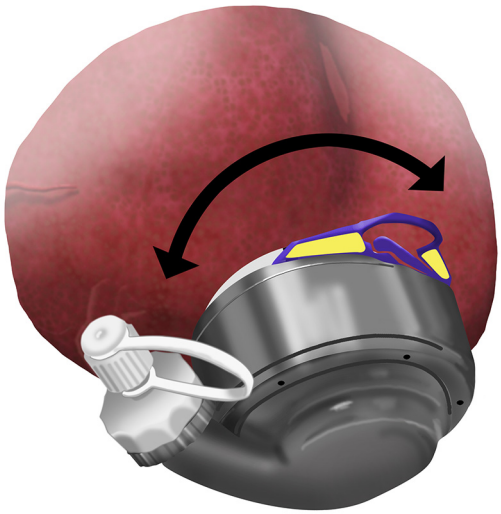


Figure 5.32 Inserting Inflow Cannula and Rotating Pump

5. When the Inflow is inserted into the ventricle, ensure that the thread protector is secure and the luer fitting is tight to prevent air entrainment.
6. Push the Slide Lock on the Pump inward to engage and lock the Pump into position (**Figure 5.33**).

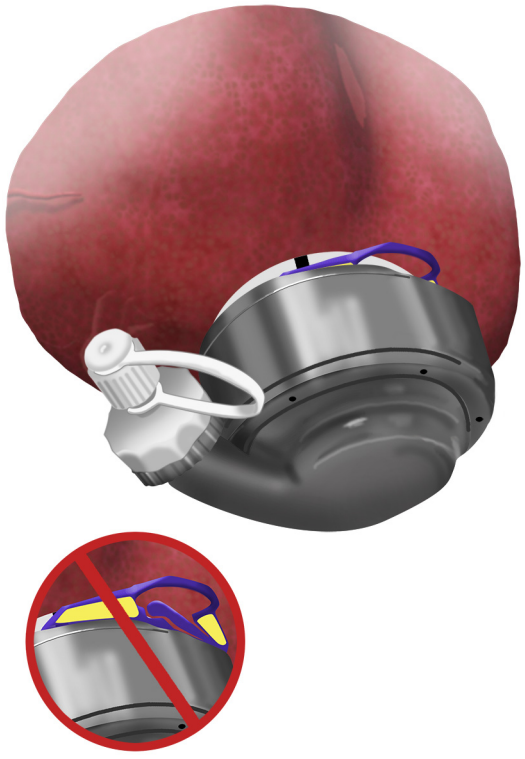


Figure 5.33 Pushing the Slide Lock Inward to Engage and Lock the Pump Into Position

7. Gently pull on the Slide Lock to ensure that it is properly engaged.
8. If the Slide Lock mechanism on the HeartMate III LVAD fails to engage, do not make further attempts to engage until retracting the Slide Lock mechanism.

   Evidence of the Slide Lock mechanism failing to engage will be either visual evidence of the yellow "wings," or a tactile feel of three ridges versus one.

   The Slide Lock will not engage the Apical Cuff unless initially fully retracted.
9. Inspect the entire circumference of the Pump-cuff junction to ensure that the LVAD is properly seated.

   The Slide Lock (with the exception of the tab) will be fully inserted, and no "yellow zone" is visible.
10. If the yellow zone is visible, fully retract the Slide Lock and repeat Steps 4–6.
11. Position the heart and Pump in the position that will be expected upon chest closure.
12. If the orientation of the Pump requires adjustment, complete the following steps:
    a. Use a sterile surgical tool to unlatch the Slide Lock, if necessary.
    b. Retract the Slide Lock so that it is in the fully opened position as far as it will go.
    c. Rotate the Pump to the preferred location.
    d. Fully engage the Slide Lock.
    e. Confirm the seating, as described in Step 7.

Attaching the Sealed Outflow Graft to the Pump

FOR THIS TASK YOU NEED:

- 1 sealed Outflow Graft with bend relief (attached to the Aorta)
- 1 Pump (inserted into the Apical Cuff)

TO ATTACH THE SEALED OUTFLOW GRAFT:

1. Remove the thread protector from the Pump and the Outflow Graft.

CAUTION !
Only hand tighten the ring.

2. Using the Screw Ring, turn the ring clockwise to attach the Outflow Graft to the Pump Cover (**Figure 5.34**).

   There is a clicking sound as the Screw Ring is tightened. This is normal.

Figure 5.34 Attaching the Graft

3. Continue turning the ring clockwise until it comes to a complete stop and stops clicking.
4. Verify that the graft is not twisted or kinked as follows:
   - Check the position of the black line on the graft above and below the Bend Relief.
   - Ensure that the line is straight.

De-Airing the Pump

When the Pump is in place and the sealed Outflow Graft anastomoses is completed, residual air must be completely evacuated from the device blood chamber prior to initiating device activation. Transesophageal echocardiography (TEE) should be utilized to monitor for air emboli. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mm Hg.

FOR THIS TASK YOU NEED:

- 1 HeartMate III Left Ventricular Assist Device, prepared for use

  Refer to *Preparing, Operating, and Priming the Pump* on page 5-22.
- 1 System Monitor and Power Module, prepared for use

  Refer to *System Monitor Setup* on page 4-5.
- 1 or more clamps
- 1 vent needle

TO DE-AIR THE PUMP:

1. Cross-clamp the sealed Outflow Graft at the distal end and move the Bend Relief toward the aortic anastomosis.
2. Place the patient in the Trendelenburg position.
3. Position the sealed Outflow Graft in a vertical position, such that an arch forms the highest point.
4. Insert a vent needle at the highest point in the graft between the clamp and the sealed Outflow Graft connection.
5. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and Left Ventricular Assist Device by diverting at least two liters per minute (lpm) of blood to the ventricle.
6. Connect the Pump Cable connector to the Modular Cable to initiate HeartMate III Pump operation by completing the following steps:
   a. Dry the Pump Cable connector and Tunneling Adapter with a clean and dry sterile towel.
   b. Using a clean and dry sterile towel, grip the connector area and disconnect the Tunneling Adapter, orienting the adapter downward.
   c. Leave the adapter tied to the Pump Cable.
   d. Visually confirm that the inside of the Pump Cable connector is dry.
   e. If the connector is not dry, discard the Pump and obtain a new one.
   f. Remove the towel that is wrapped around the Modular Cable In-line connector and Modular Cable Cap.
   g. Visually confirm that the inside of the modular cable connector is dry.
   h. If the connector is not dry, discard the cable and obtain a new one.
   i. If the Modular Cable and/or the Modular Cable Cap are wet, use a clean dry sterile towel to dry them.

j. Connect the inline connector by firmly pushing the connectors together.

k. Rotate the locking nut to the locked position as indicated on the markings.

There is a clicking sound as the locking nut is tightened. This is normal.

l. Ensure that the yellow line is fully covered for a secure connection.

7. On the System Monitor, complete the following steps:

a. Press the Clinical tab.

b. Verify that the PUMP OFF and LOW FLOW alarm messages appear.

c. Verify that the screen indicates a Pulse Mode with a speed setpoint of 3,000 rpm (**Figure 5.35**).

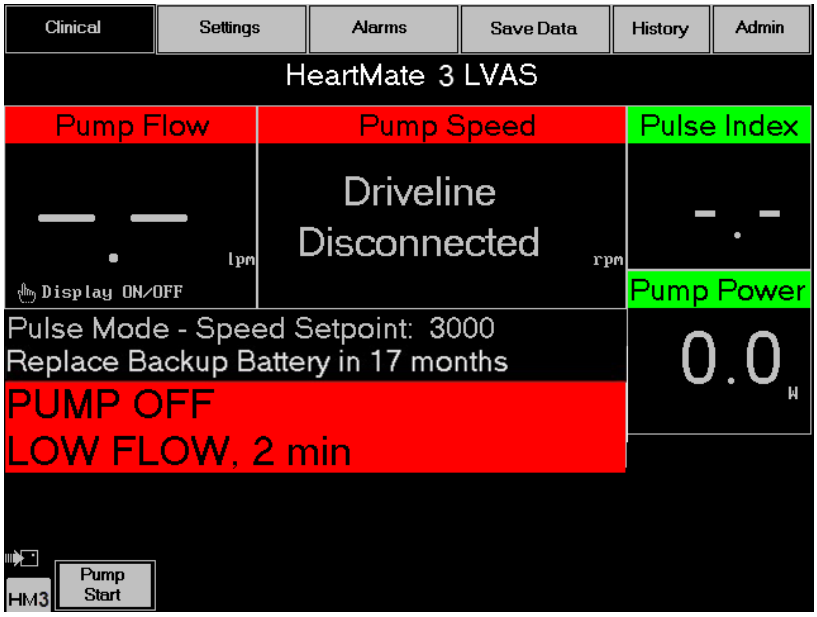


Figure 5.35 Clinical Screen—Initial Pump Startup

8. If the speed setpoint is not 3,000 rpm, complete the following steps:

a. On the System Monitor, press the Settings tab.

b. Press the **Fixed Speed Adjust** button.

c. Follow the on-screen instructions to set the speed to 3,000 rpm.

IMPORTANT! The needle vent should be placed in the sealed Outflow Graft in the highest point in the lumen (anterior side to optimize air removal).

9. (Optional) Flood the surgical field with sterile saline or CO_2 to further minimize the risk of air entry and possible embolization.

10. Initiate Pump speed at 3,000 rpm by completing the following steps:

a. On the System Monitor, access the Settings screen.

b. Press the **Pump Start** button.

The Pump may take up to 10 seconds to start. The PUMP OFF message should disappear and the WARNING: Low Speed Advisory message should appear.

Figure 5.36 and **Figure 5.37** show the typical Clinical and Settings screens that are displayed by the System Monitor when the Pump is running.

The Pump Flow box displays "-.-" when any of the following occur:

- The Pump is stopped.
- The Driveline is disconnected.
- Communication Fault.
- The estimated pump flow is outside the expected operational range (less than 4000 rpm AND a Pulse Index greater than 9.0).

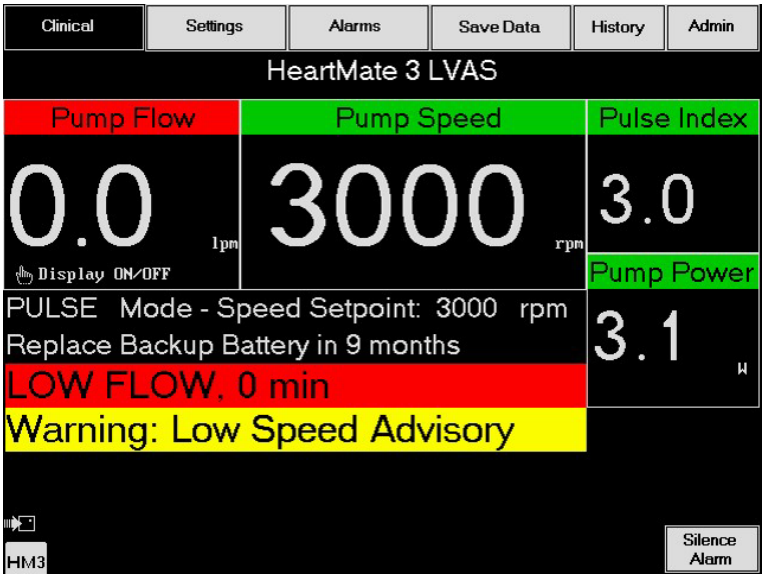


Figure 5.36 Clinical Screen During Initial Pump Startup (typical)

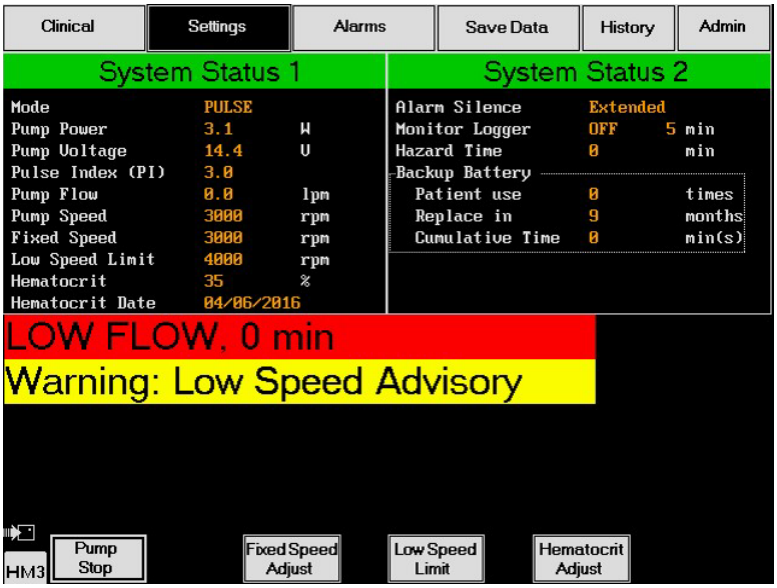


Figure 5.37 Settings Screen During Initial Pump Startup (typical)

11. Watch for air being expelled through the venting needle.
12. Throughout the de-airing process, always monitor for the presence of air in the aorta and left heart using intraoperative TEE, and keep the left heart full.
13. When de-airing is completed, complete the following steps:
    a. Partially remove the sealed Outflow Graft cross-clamp while continuing to operate the Left Ventricular Assist Device.
    b. Shift blood volume from cardiopulmonary bypass to the patient to allow for adequate pump flow.
14. Remove the vent needle from the sealed Outflow Graft and repair the site only when air can no longer be observed exiting through the needle.
15. If air persists in the Pump sealed Outflow Graft for a prolonged period (more than 5–10 minutes), rule out leaks at the Inflow Cannula/Pump connection.
16. Slide the Bend Relief over the metal fitting of the sealed Outflow Graft toward the locking screw ring until it engages into place.

WARNING !

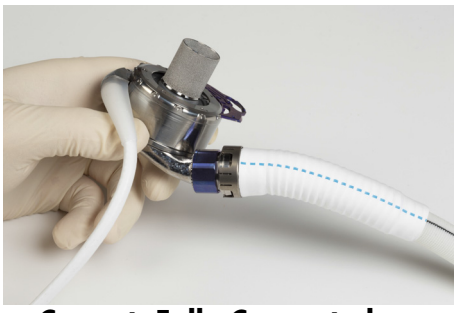
Failure to connect the Bend Relief so that it is fully and evenly connected can allow kinking and abrasion of the graft. This may lead to serious adverse events such as low Left Ventricular Assist Device flow and/or bleeding.

17. Confirm that the Bend Relief is fully connected and seated to the sealed Outflow Graft by completing the following steps:
    a. Visually inspect the Bend Relief (**Figure 5.38**).

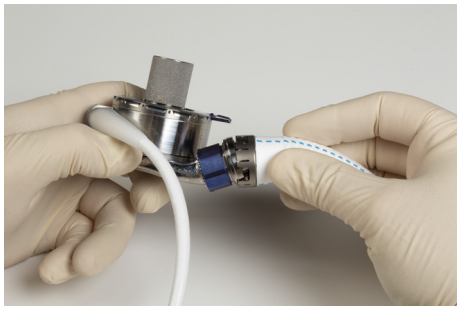
CAUTION !

Do not rotate/twist the sealed graft. Check the alignment of the black line on the graft to verify that the sealed graft is not twisted or kinked.

Note: The HeartMate III LVAD may create electromagnetic interference with ECG monitoring. Adjustment of ECG lead placement may reduce the level of interference.



Correct: Fully Connected



Incorrect: Not Fully Connected

Figure 5.38 Bend Relief Connection to the Sealed Outflow Graft (Correct and Incorrect)

    b. Try to unseat the connected Bend Relief from the metal fitting by gently pulling the Bend Relief back toward the anastomosis, and then towards the Pump.

The Bend Relief should remain captured and move approximately 0.5 mm without disengaging from the graft. (**Figure 5.39**).

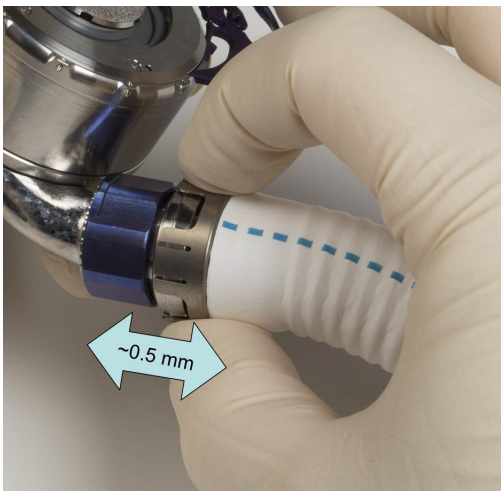


Figure 5.39 Confirming the Bend Relief Connection by Moving Back and Forth

When all air has been removed from the blood pump, it is safe to increase the pump speed (rpm).

18. Adjust the Fixed Speed setpoint by completing the following steps:
    a. On the System Monitor, access the Settings screen.
    b. Press the **Fixed Speed Adjust** button.
    c. Follow the on-screen instructions to select the preferred pump speed setting.
    d. After the preferred speed is selected, press **Enter** to send the command to the Pump.
19. Terminate cardiopulmonary bypass to provide ample blood flow to the Left Ventricular Assist Device.

    The goal at this time is to achieve and maintain appropriate flow levels by adjusting the Fixed Speed of the Pump.
20. Monitor flow, the LV size, position of the septum, and aortic valve opening to determine the appropriate Fixed Speed setting.

    The final decision is ultimately dependent on the physician's clinical judgment and will vary from patient to patient.
21. Adjust the pump speed (flow) by completing the following steps:
    a. On the System Monitor, access the Settings screen.
    b. Press the **Fixed Speed Adjust** button.
    c. Change the speed using the adjustment buttons.
    d. When the preferred speed is set, press **Enter**.

       The speed will only change after the **Enter** button is pressed. The actual flow increase for a given change in speed is dependent on many factors and could vary significantly.

Pump flow is dependent upon the pressure difference across the Pump, aortic pressure at the outflow minus left ventricular pressure at the inflow, and will fluctuate throughout the cardiac cycle.

Figure 5.40 illustrates that, when left ventricular pressure equals aortic pressure, a Pump running at 5,000 rpm will result in a 6.5 lpm pump flow rate. At an aortic pressure of 80 mmHg and a left ventricular pressure of 10 mmHg, a pressure difference across the Pump of 80-10=70 mmHg, a Pump running at the same speed would flow 3 lpm. By increasing the speed to 6,000 rpm, the same 70 mmHg pressure difference across the Pump would result in a 6 lpm pump flow. This relationship demonstrates that the flow generated by the Pump is directly related to the pressure difference across the Pump and heavily dependent upon left ventricular pressure.

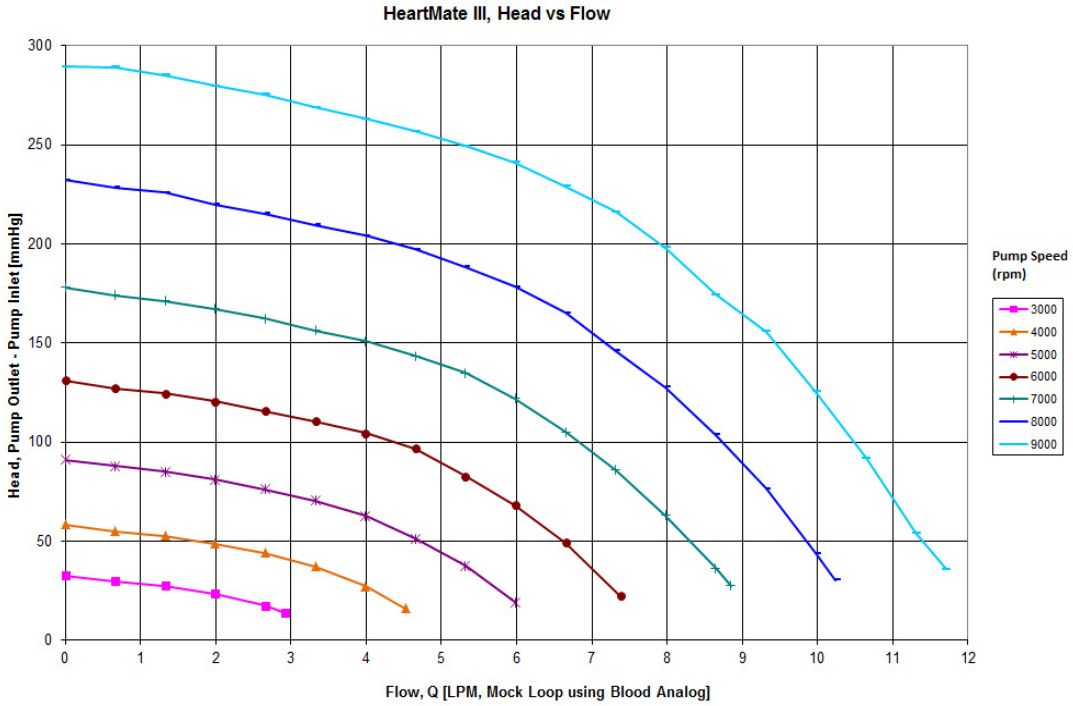


Figure 5.40 Typical HeartMate III Flow Characteristics

IMPORTANT! **The Pump will start when the System Controller is connected to a Driveline and a power source if one of the following is true:**

- The Fixed Speed is set to 4,000 rpm or higher.

  OR

- The System Controller's backup battery is installed and any button is pushed on the System Controller.

IMPORTANT! The Pump can only be started from the System Monitor's Clinical or Settings screen if both the following conditions are present:

- The Fixed Speed setting is below 4,000 rpm.

  AND

- The System Controller's backup battery is not installed.

If both conditions exist, start the Pump by pressing the **Pump Start** button.

IMPORTANT! **Auscultation over the Pump is recommended to verify the Pump is running.**

Securing the Pump and Connections

CAUTION !

Care should be taken to ensure that the sealed Outflow Graft bend relief remains connected during sternal closure.

When the flow through the blood Pump is satisfactory, ensure that the sealed outflow connections are dry and secure. Obtain hemostasis and close all wounds in the standard fashion. Prior to leaving the operating room, immobilize the Driveline and System Controller.

CAUTION !

The use of electrocautery devices may temporarily interfere with HeartMate III Pump operation. When electrocautery has been discontinued, there is no interference with Pump operation.

Postimplant Procedures

Transferring the Patient Out of the Operating Room

1. Cancel the extended alarm silence by pressing the **Silence Alarm** button on the System Controller's user interface panel.
2. Switch the HeartMate III Left Ventricular Assist System from the Power Module to battery power. Refer to *Switching from the Power Module to Battery-Powered Operation* on page 3-58.
3. Tuck the batteries securely beside the patient so that the System Controller, power cables, and Driveline are not subjected to strain during patient transport.
4. After the patient reaches the ICU, complete the following steps:
   a. Return to Power Module power.
   b. Go to the Alarms screen and verify the alarm silence is off.

      As a reminder that the backup battery needs to be installed, a yellow wrench flashes and a graphic is displayed on the System Controller. Refer to *System Controller Backup Battery Not Installed Alarm* on page 7-22.
5. Install the Backup Battery in the backup System Controller. Refer to *Configuring the Backup System Controller* on page 2-42.

IMPORTANT! **It is recommended that patient specific hemodynamics continue to be monitored during transport to the ICU. HeartMate III Pump parameters can be visualized by pressing the display button (▢) on the System Controller's user interface. A cart containing the Power Module and System Monitor can closely follow the patient, and should be re-attached when the patient arrives at his or her destination.**

Installing the Backup Battery

After the sterile field has been broken, proceed with installing the System Controller backup battery. As an additional measure, a plastic tab is attached to the System Controller to indicate that backup battery installation needs to occur.

WARNING !

- Do not use damaged, defective, or expired batteries. Using a damaged, defective, or expired battery may reduce operating time during a power-loss emergency or cause the Pump to stop.
- Do not open, crush, heat above 104°F (40°C), or incinerate batteries because of the risk of fire and burns. Follow manufacturer's instructions.

CAUTION !

- Charging of the 11 Volt Lithium-Ion backup battery inside the System Controller occurs only when the battery has been installed in a System Controller. After the 11 Volt Lithium-Ion backup battery is installed, a full charge occurs within 3 hours.
- If an 11 Volt Lithium-Ion backup battery leaks, do not touch the leaking fluid. If the fluid touches skin or eyes, wash the affected area with plenty of water and seek medical advice.
- To prevent deterioration or damage to an 11 Volt Lithium-Ion backup battery:
  - Store within approved temperatures: 59°F to 77°F (15°C to 25°C).
  - Do not use in temperatures that are below 32°F (0°C) or above 104°F (40°C), or the battery may fail suddenly.
  - Do not dismantle, open, or shred.
  - Do not drop or hit against hard objects or each other.
  - Do not leave or store in extremely hot or cold temperatures (for example, in automobiles or automobile trunks), or battery life will be shortened.
  - Do not store in direct sunlight.
  - Do not expose to heat or fire.
  - Do not short circuit a battery or store it haphazardly in a box or drawer where it may short circuit or be short circuited by contact with metal objects.
  - Do not remove a battery from its original packaging until required for use.
- Dispose of or recycle an expired battery in accordance with local, state, and federal regulations. Malfunction of the 11 Volt Lithium-Ion backup battery may cause the controller to become excessively hot. If this occurs, switch to the backup System Controller.

FOR THIS TASK YOU NEED:

- 1 11 Volt Lithium-Ion backup battery (included with System Controller)
- 1 lever to remove the screw cover of the battery compartment (included with 11 Volt Lithium-Ion backup battery)
- 1 screwdriver to loosen the four battery cover screws (included with 11 Volt Lithium-Ion backup battery)
- 1 spare screw cover (included with 11 Volt Lithium-Ion backup battery)

TO INSTALL THE BACKUP BATTERY IN THE SYSTEM CONTROLLER:

1. Use the lever to lift up the screw cover (**Figure 5.41**).

Figure 5.41 Using the Lever to Lift up the Cover

2. Use the screwdriver to loosen the four captive screws on the battery compartment cover (**Figure 5.42**).

Figure 5.42 Loosening the Screws

3. Lift off the battery compartment cover.

4. Remove the plastic advisory “install backup battery” tab.
5. Align the arrow on the ribbon cable with the arrow on the backup battery, and then insert the cable into the battery socket (**Figure 5.43**):

Figure 5.43 Aligning the Arrow on the Cable with the Arrow on the Battery

6. Confirm that the 11 Volt Lithium-Ion backup battery is properly connected by verifying that the backup battery installation graphic no longer appears on the System Controller.
7. Place the backup battery inside the battery compartment (**Figure 5.44**).

Figure 5.44 Placing the Battery Inside the Compartment

8. Place the cover over the battery compartment.
9. Use the screwdriver to tighten the four screws. Do not over tighten the screws.
10. Replace the screw cover.
11. Install the backup battery in the patient’s backup System Controller (by following steps 1–10).

IMPORTANT! **Be aware that installing an 11 Volt Lithium-Ion backup battery may prompt a System Controller Clock Not Set advisory alarm on the System Monitor. Refer to *Controller Clock Not Set - System Monitor* on page 7-28. To resolve the advisory, use the System Monitor to reset the System Controller clock. Refer to *Date and Time* on page 4-40. Be sure the System Monitor clock is correct before relying on it.**

Device Tracking and Reporting Requirements

The HeartMate III Left Ventricular Assist System is considered a life-sustaining medical device and must be tracked per foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device-tracking paperwork shipped with the device must be completed and promptly returned to Thoratec Corporation. In addition, any device malfunctions must be reported to Thoratec Corporation by the implanting center.

Device Explant

Explanting the Left Ventricular Assist Device

WARNING !

There is a risk of embolism at the Left Ventricular Assist Device explant or reoperation if manipulation of the Pump or Outflow Graft is performed prior to initiation of cardiopulmonary bypass and stoppage of device pumping.

CAUTION !

The Driveline at explant is not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the Driveline after it is cut to minimize the risk of contact with the sterile field.

FOR THIS TASK YOU NEED:

- 1 CV major surgical set
- 1 HeartMate explant kit

TO EXPLANT THE LEFT VENTRICULAR ASSIST DEVICE:

1. Expose the device and carefully dissect it free.
2. Place the patient on cardiopulmonary bypass and establish flow.
3. Disconnect power from the System Controller, and then disconnect the in-line connection to stop pumping.
4. Cross-clamp the sealed Outflow Graft just distal to the bend relief and divide the graft.
5. Expose the Slide Lock mechanism and pull it radially to disengage the Pump from the Apical Cuff.
6. Disengage the Pump from the ventricle.
7. Repair or plug the ventricle as necessary.
8. Dissect the Pump Cable between the device body and the abdominal wall.
9. Cut the Pump Cable and then remove the externalized portion.

10. Remove the device from the chest pocket, and remove the remaining portion of the Pump Cable from the inside-out by careful dissection.
11. Close the site in standard fashion.
12. Remove the sealed Outflow Graft remnant from the aorta and repair the anastomotic site.
13. If returning the device to Thoratec Corporation for disposal, use the HeartMate Explant Kit.

PATIENT CARE AND MANAGEMENT

This section describes postoperative patient care.

6 Patient Care and Management

Postoperative Patient Care

Proper care of a patient who is supported by the HeartMate III Left Ventricular Assist System requires a thorough understanding of the system operation and patient condition.

WARNING !

- There is risk of embolism at Pump explant or reoperation if manipulation of the Pump or conduit is performed prior to the initiation of cardiopulmonary bypass and stoppage of Left Ventricular Assist Device pumping.
- If the Left Ventricular Assist Device stops operating and blood is stagnant in the Pump and conduits for more than a few minutes (depending on the anticoagulation status of the patient), there is a risk of stroke or thromboembolism should the Pump be restarted.
- If the Left Ventricular Assist Device stops operating, counsel the patient to seek immediate medical attention to treat retrograde flow within the Pump. Treatment measures may include heparinization, standard interventions for acutely decompensated congestive heart failure, and surgical exploration.
- Before using any HeartMate power accessories (Power Module, Mobile Power Unit, Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries), all users (including clinicians, patients, and caregivers) must be trained on their use.
- Certain parts of the HeartMate III Left Ventricular Assist System are not compatible with other HeartMate systems (such as the HeartMate II Left Ventricular Assist System). Only use HeartMate III parts with the HeartMate III system.
- If the Pump loses external power, it may stop. If the Pump stops, connect to external power immediately. The HeartMate III Pump will not re-start unless external power is applied to the System Controller.
- Do not allow patients to swim or take tub baths while implanted with the Left Ventricular Assist Device. Patient immersion in water or liquid may cause the Pump to stop.
- Do not allow HeartMate III patients to shower without a doctor's permission. Patients may be allowed to shower, but only after sufficient postoperative healing and only with a doctor's permission. If a patient is approved for showering, he or she must always use the Shower Bag for every shower. The Shower Bag protects external system components from water and moisture. If external system components have contact with water or moisture, the patient may receive a serious electrical shock or the Pump may stop.
- Keep the Power Module and the Mobile Power Unit dry and away from water or liquid. If the Power Module or the Mobile Power Unit comes into contact with water or liquid, either may fail to operate properly or cause a serious electrical shock.

WARNING ! (Continued)

- Never submerge the Driveline, Modular Connector, System Controller, or any external system components (such as the Power Module, the Mobile Power Unit, batteries, power cables, or battery clips) in water or liquid. Submersion in water or liquid may cause the Left Ventricular Assist Device to stop.
- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial requirement.
- High levels of static electricity may damage and/or interfere with the electrical parts of the system and cause the Left Ventricular Assist Device to stop. The presence of ESD may be increased in environments with a relative humidity less than 30%. Advise the patient to avoid activities that may cause static electricity and discharge any built up.
- Do not use the HeartMate III Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the Pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Do not subject patients implanted with the HeartMate III Left Ventricular Assist System to Magnetic Resonance Imaging (MRI)  as the device contains Ferromagnetic components. MRI can cause Pump failure or patient injury. Keep patients away from the RF-shielded room of MRI suites.
- Therapeutic radiation, such as tissue heating therapy using Radio Frequency (RF) energy sources, may damage the device, and damage may not be immediately detectable.
- The patient must always connect to the Power Module or Mobile Power Unit for sleeping, or when there is a chance of sleep. A sleeping patient may not hear the System Controller alarms.
- There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the Outflow Graft and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the Outflow Graft or the dislodgement of the Left Ventricular Assist Device inflow tract.
- Cardiac massage should only be performed by a skilled surgeon in patients who have had recent (that is, prior to mediastinal healing) device implantation.
- If external defibrillation becomes necessary, do not disconnect the System Controller from the Driveline prior to delivering the shock.
- If open chest defibrillation is required, it is advised that the HeartMate III Left Ventricular Assist System be disconnected prior to delivering the shock.

WARNING ! (Continued)

- For international travel, the patient must use a Thoratec power cord that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications for the Mobile Power Unit and Battery Charger. Other power cords must not be used. Contact Thoratec Corporation for a power cord, if needed. Refer to Thoratec Corporation contact information on page iii.
- If traveling by aircraft, the patient should be instructed to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.

CAUTION !

- Right heart failure can occur following implantation of the Pump. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit the effectiveness of the Left Ventricular Assist System due to reduced filling of the Pump.
- Do not try to fix any of the equipment yourself. If HeartMate III equipment needs service, contact the appropriate personnel trained by Thoratec Corporation.
- Notify the appropriate personnel if there is a change in how the Pump works, sounds, or feels.
- Counsel the patient to avoid contact sports and jumping activities while implanted with the Pump. Contact sports or jumping can cause bleeding or damage the Pump.
- The Driveline exit site must be dressed prior to applying stabilization.
- To achieve the desired outcome, stabilization should be applied in the operating room, post implant.
- Keep the Driveline exit site as clean and dry as possible.
- To avoid pulling on or moving the Driveline at the exit site, the Driveline must be stabilized at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, the Power Module patient cable, or the Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

CAUTION ! (Continued)

- Carefully wash hands every time before and after changing the Driveline exit site bandages, or whenever the Driveline exit site is touched or handled.
- Do not place objects other than the HeartMate III system components into the wearable accessories. Placing objects other than HeartMate III components into a wearable accessory may damage the wearable accessory.
- During showers, use care to keep the exit site as clean and dry as possible. Also avoid pulling on or moving the Driveline during a shower. Position the Shower Bag so that it will not pull on or move the Driveline.

Ongoing Patient Assessment and Care

Patient Assessment

HeartMate III patient assessment may include, but is not limited to, assessment of the following:

- Pump function
- Pump speed, flow, motor power, pulse index (PI), mode of operation
- Driveline is securely connected to the System Controller and the Controller Driveline Connector Safety Lock is in the locked position
- Modular connector is properly connected and locked
- Exit site status, immobilization of Driveline
- Vital signs, peripheral circulation
- Mental status, level of consciousness
- 12 lead EKG
- ECHO

Potential Risks and Adverse Events

- Hypovolemia
- Right heart failure
- Pulmonary hypertension
- Cardiac tamponade
- Bleeding
- Arrhythmia
- Infection
- Hemolysis
- Thromboembolism
- Neurologic dysfunction
- LVAD flow obstruction

Potential Late Postimplant Complications

- Hypovolemia
- Arrhythmia
- Thromboembolism
- Infection
- Psychosocial issues
- Neurological dysfunction

Caring for the Driveline Exit Site

Currently, no clinical trials delineate the best regimen for care of the Driveline exit site. Physician judgment and experience may vary.

Nevertheless, the following points should be considered:

- A driveline management system, supplied by the implanting center, should be used at all times. The driveline management system should consist of a dressing and stabilizer.
- The risk of systemic infection may be reduced by withdrawing all intravascular lines as soon as is practical.
- Parenteral treatment with antibiotics and surgical drainage has, on occasion, eradicated infection. However, infections may persist and can result in septicemia and death.
- Fungal infection resulting from organisms such as *Candida albicans* may be associated with vegetative growth on the Pump. Persistent systemic fungal infection, refractory to antimicrobial treatment, may necessitate Pump replacement or removal.
- Systemic prophylaxis with anti-fungal agents, such as fluconazole, is reported to have met with moderate success in preventing fungal infection. However, no clinical trials have been conducted to verify the efficacy of anti-fungal prophylaxis.

Controlling Infection

Infection among implantable Left Ventricular Assist Device patients is common, especially in patients with multi-system organ failure who require prolonged stays in the ICU. Infection rates can be minimized, however, by applying the following approaches to patient management:

- Strict adherence to sterile technique during exit site care.
- Remove all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer antibiotic prophylaxis in the postoperative period, and for suspected or confirmed infections, and antibiotics for surgical drainage, as indicated, in patients with evidence of Pump pocket infection.
- Adhere to strict blood glucose control.
- Initiate nutritional support to correct nutritional deficits.

Measuring Blood Pressure

Automatic blood pressure monitors may not be accurate. Manual auscultation with a Doppler is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring (arterial line) may be required.

Blood Pressure Management

Post-implantation hypertension may be treated at the discretion of the attending physician. Any therapy that consistently maintains mean arterial blood pressure less than 90 mm Hg should be considered adequate.

Anticoagulation

TO TREAT FOR ANTICOAGULATION:

1. Prior to leaving the O.R., completely reverse the anticoagulation.
2. Optional: Postimplantation, as early as possible, administer 10% LMW dextran at 25 ml/hr.

   This step is optional until the benefit of dextran administration is further delineated.
3. Begin IV heparin after 12–24 hours or when chest tube drainage is less than 50 ml/hr over a 2–3 hour period:
   - Initially titrate to a PTT of 45–50 for 24 hours (1.2–1.4 times control).
   - After 24 hours, increase heparin and titrate to PTT 50–60 (1.4–1.7 times control).
   - After another 24 hours, increase heparin and titrate to PTT 55–65 (1.5–1.8 times control).
4. On postoperative day 2–3, initiate aspirin 81–100 mg QD.
5. On postoperative day 3–5, when there is no evidence of bleeding and the chest tubes have been removed, complete the following steps:
   a. Begin warfarin (overlapping with the heparin).
   b. Discontinue heparin after obtaining an acceptable, stable INR.

      The INR should be maintained in the range of 2.0–3.0.
6. Maintain the patient throughout support on aspirin and warfarin.

Conditions that May Require Possible Modification to Anticoagulation

Consider the need for the following modifications to anticoagulation:

1. Sustained low pump flow states (< 3.0 lpm):

   Consider increasing anticoagulation to upper limits of normal.
2. Risk of bleeding:

   Consider initiating antiplatelet medications and decreasing heparin/warfarin (INR 1.7–2.3). Antiplatelet effect should be confirmed with lab studies (for example, TEG).

Important Clinical Considerations for HeartMate III Patients

Magnetic Resonance Imaging (MRI)

Use of diagnostic MRI is contraindicated in any patient with an implanted HeartMate III Left Ventricular Assist Device. The presence of ferromagnetic parts within the Pump makes exposure to strong electromagnetic fields a risk factor for acute Pump failure. Keep patients away from the RF-shielded room of MRI suites.

External Chest Compressions

There may be risks associated with performing external chest compressions in the event of cardiac arrest, due to the location of the Outflow Graft and the presence of ventricular apical anastomosis. External chest compressions may damage the Outflow Graft or dislodge the Left Ventricular Assist Device inflow.

Cardiac massage under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent Pump implantation (prior to mediastinal healing).

Defibrillation

WARNING !

- If open chest defibrillation is required, be sure to disconnect the HeartMate III Left Ventricular Assist System prior to delivering the shock.
- If external defibrillation becomes necessary, do not disconnect the System Controller from the Driveline prior to delivering the shock.

Blood Leak Diagnosis

A blood leak from any implanted component of the system is typically identified through one of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distension of the abdomen or tamponade.
- Blood draining from the Driveline exit site.
- Evidence of decreased hemoglobin/hematocrit.

These symptoms may also occur due to bleeding from native tissue.

Right Heart Failure

Some patients suddenly develop right ventricular failure during or shortly after Pump implantation. The onset of right ventricular dysfunction in patients is often accompanied by the inability of the Left Ventricular Assist Device to fill, and drastically reduced flow rates. Limited filling is further exacerbated in the presence of right heart failure with an elevated transpulmonary pressure gradient or high pulmonary vascular resistance.

Treatment for patients in right heart failure typically consists of inotropes to augment right ventricular contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. As a last resort, a right ventricular assist device may be employed.

Static Electric Discharge

Electrostatic discharge (ESD) is the release of static electricity when two objects come into contact. Familiar examples of ESD include the shock received when walking across a carpet and touch a metal doorknob, and the static electricity felt after drying clothes in a clothes dryer. The presence of ESD may be increased in environments with a relative humidity less than 30%. High levels of static electricity may damage and/or interfere with the electrical parts of the system and cause the Left Ventricular Assist Device to stop.

Advise the patient to:

- Avoid activities that may cause static electricity.
- Discharge any built up ESD by touching a metal surface before handling LVAS components.

Implantable Defibrillators or Pacemakers

WARNING !

- Prior to implanting an implantable cardiac defibrillator (ICD) or implantable pacemaker (IPM) in a HeartMate III patient, the ICD or IPM device to be implanted should be placed in close proximity to the Pump (approximately 10 cm) and the telemetry verified. If a patient receives a HeartMate III Pump and has a previously-implanted device that is found to be susceptible to electromagnetic interference, that could affect programming, Thoratec Corporation recommends replacing the ICD or IPM device with one that is not prone to programming interference. Specific information on reported cases can be obtained on Thoratec's website at www.thoratec.com. No such difficulties have been reported, other than those observed with ICD or IPM devices listed on the website.
- The HeartMate III pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.

Educating and Training Patients, Families, and Caregivers

During the patient selection, preimplant, and postoperative period, the patient must receive instructions regarding the operation and care of every system component. Consider using a Competency Assessment Checklist to test and measure discharge readiness of patients, and their family members or caregivers.

At a minimum, discuss the following topics when training the patient, and his or her family members or caregivers:

1. Remember to give the *Patient Handbook* to the patient.
2. General information
   - General assessment of caregiver/patient support systems
   - Concept of ventricular assistance
   - How the Left Ventricular Assist Device pumps blood
   - Control modes
   - Battery-powered versus Mobile Power Unit operation
   - Battery use regimen
   - Advisory and Hazard alarms: including their meaning and how to recognize and respond to them
   - Medical Alert ID Bracelet (recommended)
   - Maintenance and periodic safety checks
   - Daily, weekly, monthly, six month, and yearly safety checklists
   - Anticoagulation
3. System components
   - Left Ventricular Assist Device
   - Driveline
   - System Controller
   - System Controller connectors for Driveline and power cables
   - System Controller power cables
   - Charging the backup battery in the backup System Controller
   - HeartMate 14 Volt Lithium-Ion batteries and battery clips
   - Using, charging, testing, and calibrating HeartMate 14 Volt Lithium-Ion batteries
   - Battery Charger
   - Mobile Power Unit
4. Using the wear and carry accessories to hold and carry system components.

5. Operating the system.
   - Making connections
   - Changing power sources
   - Performing a System Controller self test
6. What to do in an emergency.
   - What is an emergency (clinical emergency versus equipment emergency)
   - Steps to take in an emergency
   - Emergency transportation plan
   - Preparing for and practicing emergency procedures
   - How to diagnose power or connector problems
   - Emergency telephone contacts
   - Replacing the running System Controller with the backup System Controller
7. Driveline Exit Site Management
8. Showering
9. Preparing for sleep
10. Travel
11. Warnings and cautions

Ongoing System Assessment and Care

Caring for the Driveline

It is extremely important that the Driveline be protected from extreme or frequent bending or kinking. Damage to the Driveline, depending on the degree, may cause the Pump to stop.

The patient must be educated about the importance of keeping the Driveline free from damage. Routinely reinforce the importance of adhering to the following guidelines for Driveline care:

- Manage the Driveline exit site in accordance with the procedure provided by the clinician.
- Do not severely bend or kink the Driveline.
- Do not let the Driveline become twisted.
- If the System Controller is in a carrying case, keep the Driveline away from the zipper.
- Allow for a gentle curve of the Driveline. Do not severely bend the Driveline multiple times or wrap it tightly.
- Keep the Driveline clean.

  Wipe off any dirt or grime that may appear. If necessary, use a towel with soap and warm water to gently clean the Driveline. However, never submerge the Driveline or other system components in water or liquid. Refer to *Care of the Driveline* on page 8-5 for information about caring for the Driveline.
- Do not pull on or move the Driveline going through the skin.
- When checking to ensure that the Driveline connector is fully inserted into the System Controller Driveline socket, gently tug on the metal end of the connector. Do not move or pull on the Driveline.
- Check that the Modular In-line Connector is properly connected and that the lock is secured.
- Be mindful of where the System Controller is at all times. Protect the System Controller from falling or from pulling on the Driveline.
- Do not allow the Driveline to snag on anything that can pull on or move the Driveline.
- Check the Driveline daily for signs of damage, such as cuts, holes, or tears. Counsel patients to inform you immediately if they find signs of Driveline damage.
- Damage due to wear and fatigue of the Driveline has occurred in both the externalized and implanted portions of the Driveline. Damage to the electrical conductors within the Driveline may or may not be preceded by visible damage to the outer layer of the Driveline. Driveline damage may be evidenced by the following:
  - A Driveline Communication Fault (Driveline Comm Fault) or Driveline Power Fault on the System Controller.
  - Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
  - Fluid leakage from the external portion of the Pump Cable.
  - Pump stopping.

If the Driveline or Modular In-line Connector appears damaged, contact Thoratec Corporation for assistance. Refer to the Thoratec Corporation contact information on page iii.

X-ray images and System Controller log files are useful to assess the extent and location of the damage. If the Driveline or Driveline conductors are damaged internal to the patient's body, the Pump should be replaced as soon as possible. If it has been determined that the damage has been detected in the Modular Cable portion of the Driveline, it can be replaced. Refer to *Replacing the Modular Cable* on page 2-51 for the procedure for exchanging the Modular Cable.

CAUTION !

- The HeartMate III Left Ventricular Assist System uses lights and sounds to indicate how it is working. If the patient has trouble hearing or seeing, he or she may need extra help to hear or see the lights and sounds.
- To avoid pulling on or moving the Driveline at the exit site, the patient must stabilize their Driveline at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, Power Module patient cable, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

Caring for the System Controller Power Cables

It is extremely important that the System Controller power cables be protected from kinks, sharp bends, and repeated bending. This is especially applicable if the patient is active. Damage to the power cables, depending on the degree, may impair Pump function.

The patient must be educated about the importance of keeping the System Controller power cables free from damage. Routinely reinforce the importance of adhering to the following guidelines for power cable care:

- Do not kink or sharply bend the power cables, especially near the strain relief portion of the System Controller connectors where the connector and cable meet (**Figure 6.1**).
- Avoid repeated bending of the power cables, especially near the connectors.
- When carrying the System Controller in a bag, case, or other carrier, do not kink or sharply bend the power cables, especially near the connectors.
- When carrying the System Controller in a zippered carrying case, do not snag the power cables in the carrying case zipper.
- Do not let the power cables become twisted.

Figure 6.1 Do Not Bend System Controller Power Cables

Showering

If the patient obtains doctor approval to shower, these instructions must be used each time.

Keeping the Driveline Exit Site Dry

It is important to keep the Driveline exit site dry while showering. This helps prevent infection and helps extend the use of the driveline management system. When applied correctly, covering the driveline management system with a moisture barrier consisting of a sheet of multi-purpose sealing wrap, sealed with adhesive tape on the edges, should keep moisture away.

Warnings and Cautions

WARNING !

The HeartMate III System Components must be kept dry. Never expose the System Controller, batteries, Power Module, or Mobile Power Unit to water. If these system components get wet, the Pump may stop. Never take tub baths or go swimming while implanted with the Pump. The HeartMate® GoGear® Shower Bag must be used while showering to keep the System Controller and batteries dry.

CAUTION !

- Do not take a shower until your doctor says you can.
- Refer to the *HeartMate III Left Ventricular Assist System Patient Handbook* for detailed instructions and information on system function and maintenance.
- The Moisture Barrier is not a replacement for the driveline management system. It will only be used to keep the driveline management system dry during a shower.
- Apply the Moisture Barrier to clean dry skin. Do not use lotion or cream before applying.
- Do not lift or attempt to reposition the Moisture Barrier after it is placed.
- After it is applied, the Moisture Barrier should only be used one time.

Applying the Moisture Barrier

1. Make a sheet of the multi-purpose sealing wrap large enough to completely cover the driveline management system with at least six inches on all sides.
2. Complete the following steps:
   a. Center the sheet of multi-purpose sealing wrap over the driveline management system and adhere to skin (**Figure 6.2**).

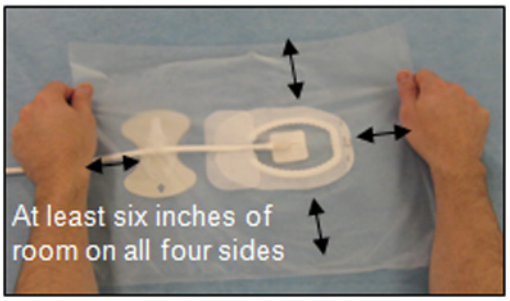


Figure 6.2 Multi-Purpose Sealing Wrap Centered Over the Driveline Management System

   b. Press the sheet of multi-purpose sealing wrap into place with fingers so that it is smooth to the skin with no gaps.
   c. If needed, ask for help.
3. Complete the following steps to seal around the edges of the multi-purpose sealing wrap (**Figure 6.3**):
   a. Apply the tape to all four edges of the sheet of multi-purpose sealing wrap so that there are no gaps.
   b. Press the tape into place with fingers so that it is smooth on the skin.
   c. Check all edges and ensure that the sheet completely adheres to the skin with no gaps.

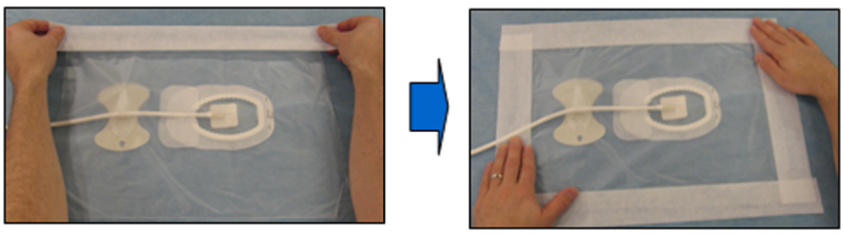


Figure 6.3 Tape Used to Seal Around the Edges of the Multi-Purpose Sealing Wrap Sheet

Removing the Moisture Barrier After Showering

1. Towel dry body and the outside of the multi-purpose sealing wrap.
2. Gently peel away the multi-purpose sealing wrap and tape from the skin (**Figure 6.4**).

   As the wrap is removed, be careful to not disturb the driveline management system.

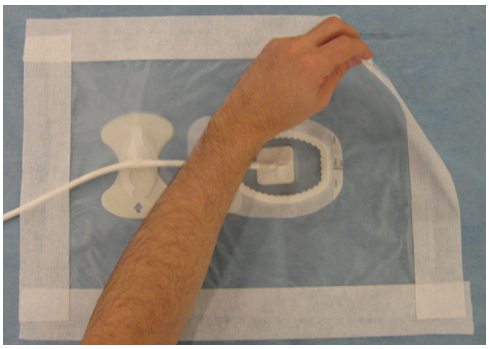


Figure 6.4 Multi-Purpose Sealing Wrap and Tape Gently Peel Away From Skin

3. If the driveline management system gets wet, change it as instructed in the previous sections.

Using the Shower Bag

Although the external components of the HeartMate III Left Ventricular Assist System are moisture-resistant (including a properly connected Driveline Modular In-Line connection), they are not waterproof. Take care to protect external system components from water or moisture when the patient is outside in heavy rain or snow, and always for every shower. If the external system components have contact with water or moisture, the patient may receive a serious electric shock or the Pump may stop.

When taking a shower, the patient must shield all external components from water by placing them into the water-resistant Shower Bag. This includes protecting the System Controller, System Controller power cables, Driveline, and two HeartMate 14 Volt Lithium-Ion batteries with attached battery clips. The Shower Bag must be used for every shower (**Figure 6.5**).

Figure 6.5 Shower Bag

The Shower Bag features a translucent top panel that allows a patient to view the System Controller's user interface while showering. The Driveline and System Controller power cables exit the Shower Bag through double zippers along the side. The Shower Bag has an adjustable shoulder strap for optimal positioning to reduce pulling on the Driveline exit site. The Shower Bag also incorporates two loops and a belt. It can be worn around the waist to further secure the bag to the patient's body. Two belt loops, one on each side of the bag, allow the bag and belt to be worn on either the patient's right or left side.

Figure 6.6 shows the Shower Bag in use.

IMPORTANT! **Figure 6.6** shows an uncovered Driveline exit site. Keep the exit site as clean and dry as possible.

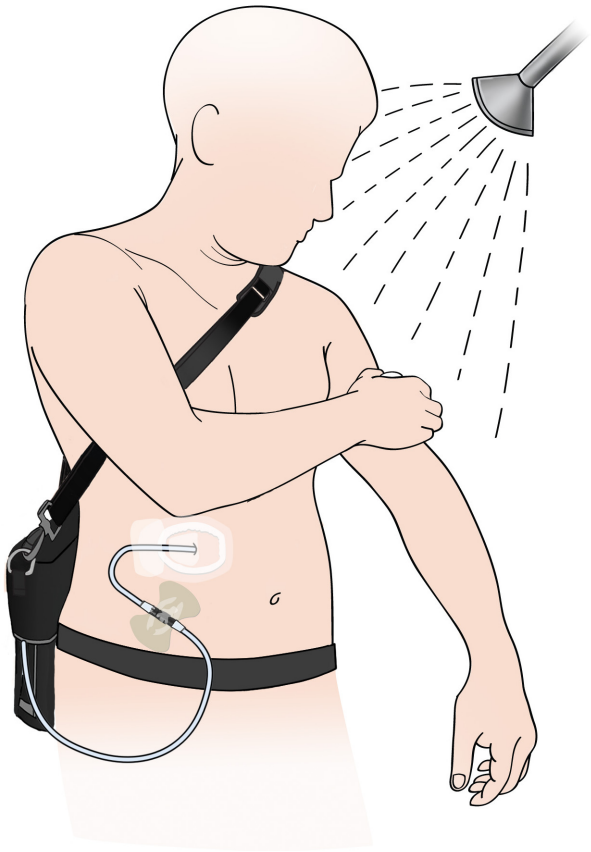


Figure 6.6 Using the Shower Bag

WARNING !

- Do not allow patients to shower without a doctor's permission. HeartMate III patients may be allowed to shower, but only after sufficient postoperative healing, and only with a doctor's permission.
- Do not allow patients to swim or take tub baths while implanted with the Pump. Patient immersion in water will cause the Pump to stop.
- Never expose the System Controller or batteries to water. The System Controller must be kept dry at all times.
- Do not submerge the Shower Bag in water.
- Patients should not shower while connected to the Power Module or the Mobile Power Unit. Use the Shower Bag only while on battery power.

CAUTION !

- To avoid pulling on or moving the Driveline at the exit site, the patient must stabilize their Driveline at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, the System Controller power cables, the Power Module patient cable, or the Mobile Power Unit patient cable which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- Keep the exit site as clean and dry as possible.
- Carefully wash hands every time before and after changing the Driveline exit site bandages, or whenever the Driveline exit site is touched or handled.
- Do not place objects other than HeartMate III equipment in the wearable accessories. Placing objects other than HeartMate III equipment in a wearable accessory may damage the accessory.

Assembling the Shower Bag

FOR THIS TASK YOU NEED:

- 1 Shower Bag
- 1 Shower Bag shoulder strap
- 1 Shower Bag clip-style belt

TO ASSEMBLE THE SHOWER BAG:

1. Clip the shoulder strap to the Shower Bag using the two rings located on the top of the bag (**Figure 6.7**).

Figure 6.7 Attaching the Shoulder Strap

2. Slide the belt through the loop on the side of the bag that will be against the patient's body to attach the clip-style belt (**Figure 6.8**).

   The Shower Bag can be worn on a patient's left or right side depending on the selected belt loop.

Figure 6.8 Attaching the Optional Belt

3. Adjust the shoulder strap so that the Shower Bag fits the patient without pulling on or moving the Driveline.
4. Tighten or lengthen the straps until they are secure, but still comfortable.

Wearing the Shower Bag

FOR THIS TASK YOU NEED:

- 1 assembled Shower Bag that is clean and dry
- 1 running System Controller on battery power

TO WEAR THE SHOWER BAG:

1. Gather the Shower Bag and System Controller (on battery power), and place both within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.9**).

Figure 6.9 Power Cables and Driveline Not Twisted

3. Unclip the lid of the Shower Bag by squeezing the clip prongs together, and then pulling the slide out of the buckle (**Figure 6.10**).

Figure 6.10 Squeezing the Clip Prongs Together

4. Pull back the Shower Bag lid to reveal the double zipper (**Figure 6.11**).

Figure 6.11 Removing the Shower Bag Lid

5. Unzip and open the cover of the water-resistant enclosure.
6. Place the batteries, battery clips, and attached power cables into the Shower Bag (**Figure 6.12**).

Figure 6.12 Batteries and Battery Clips in the Shower Bag

IMPORTANT! When putting the System Controller into the pocket, the end without the cable goes in first and the user interface should be facing up.

7. Slide the System Controller into the pocket on the inside cover of the bag.
8. Position the power cables inside the water-resistant enclosure (**Figure 6.13**).

Figure 6.13 Power Cables Inside the Bag

9. Close and zip the cover.
10. Ensure that the System Controller power cables are inside the Shower Bag, and that the Driveline exits through the protective red tabs (**Figure 6.14**).

Figure 6.14 Closed and Zipped Cover

11. Close the Shower Bag lid over the zippered enclosure, carefully positioning the Driveline down the side of the bag (**Figure 6.15**).

Figure 6.15 Driveline Exiting a Closed Shower Bag

12. Snap the clip into the buckle to secure the Shower Bag lid into place (**Figure 6.16**).

Figure 6.16 Clip Snapped Into the Buckle to Secure the Shower Bag Lid

13. Use the Shower Bag strap to hang the Shower Bag over the patient's head and shoulder, so the Shower Bag hangs at his or her side.
14. Clip the belt around the patient's waist.

    The belt secures the Shower Bag and prevents it from dropping if it slips from the patient's shoulder. It also keeps the Shower Bag from swinging away from the patient's body if he or she bends over.

15. Adjust the shoulder strap so that the Shower Bag does not pull on the Driveline exit site.

Removing the Shower Bag

FOR THIS TASK YOU NEED:

- 1 Shower Bag that is loaded with batteries and running System Controller
- 1 large, clean, dry towel to dry the patient's body
- 1 small, clean, dry towel to dry the Shower Bag
- 4-inch x 4-inch sterile gauze bandages to dry the exit site
- 1 or more sterile bandages to dress the exit site
- Wearable accessories to hold or carry the System Controller, batteries, and battery clips after showering

TO REMOVE AND DRY THE SHOWER BAG:

1. Unclip the belt from the patient's waist.
2. Carefully lift and remove the Shower Bag shoulder strap from around the patient's neck.
3. Place the Shower Bag on a stable surface.

CAUTION !

Do not move or pull on the Driveline exit site. Do not kink or sharply bend the Driveline.

4. Use a clean towel to dry the patient's body, excluding the area around the Driveline exit site.
5. Use a sterile 4-inch x 4-inch gauze bandage to dry the Driveline exit site.
6. Apply a sterile dressing to the exit site, using a sterile technique. Refer to *Caring for the Driveline Exit Site* on page 6-8.
7. Use a clean, dry towel to dry the Shower Bag's exterior and strap.
8. Open the Shower Bag using the clip and buckle for the lid, and the left and right zippers for the top.
9. Remove all equipment from the Shower Bag enclosure.
10. Place the equipment in a clean, dry location.
11. Transfer system components to a wearable accessory, such as the Holster Vest, Consolidated Bag, Belt Attachment, or System Controller Neck Strap. Refer to *Wearing and Carrying System Components* on page 6-30.
12. Allow the Shower Bag to drip dry completely before using it again. Refer to *Cleaning HeartMate Wear and Carry Accessories* on page 8-7.

Caring for the Shower Bag

Always hang the Shower Bag and allow it to air dry. Ensure that the Shower Bag is completely dry before using it for another shower. Refer to *Cleaning and Maintenance* on page 8-4 for complete instructions on caring for all wearable accessories, including the Shower Bag.

WARNING !

The Left Ventricular Assist Device will stop if the Driveline is disconnected from the System Controller. If the Driveline is disconnected, reconnect it as quickly as possible to restart the Pump. If the System Controller does not work, replace it with a backup System Controller that is programmed with patient-specific settings.

IMPORTANT! Do not store or carry the backup System Controller or spare batteries outside of recommended environmental conditions. Refer to *Equipment Storage and Care* on page 8-1.

Preparing for Sleep

HeartMate III patients must be attached to the Power Module or the Mobile Power Unit during sleep or any time when sleep is likely. During sleep, the System Controller and Driveline must be immobilized to reduce movement or pulling on the Driveline exit site. Driveline stabilization must be used to immobilize the Driveline and System Controller.

WARNING !

The patient must always connect to the Power Module or the Mobile Power Unit for sleeping, or when there is a chance of sleep. A sleeping patient may not hear the System Controller alarms.

- A patient should sleep or plan to sleep only when connected to the Power Module or the Mobile Power Unit. If a patient falls asleep during battery-powered operation, the low battery alarms may not awaken the patient before battery depletion.
- Prior to sleep, inspect and ensure that all electrical connections are secure.
- A patient should not sleep on his or her stomach.
- Keep the replacement System Controller nearby for convenient access in the event of an emergency that requires replacement of the running System Controller.
- Keep a flashlight, fully-charged batteries, and battery clips within reach to be prepared for a power outage.

Wearing and Carrying System Components

Various wearable accessories are available to comfortably and securely hold or carry the external system components, such as the System Controller, System Controller power cables, Driveline, batteries, and battery clips. The accessories are designed to allow patients to be active.

Using wearable accessories, patients can stand, sit, walk, crouch, bend over, reach, turn, and lean. Common activities may include, but are not limited to: exercising, dressing, traveling, playing with children, gardening, hiking, cooking, and dancing. The patient should consult with his or her doctor about daily activities and any changes in activity level or routine.

Table 6.1 describes the wear and carry accessories.

Table 6.1 Wear and Carry Accessories

System Controller Neck Strap 	Use the System Controller Neck Strap to wear the System Controller around the neck or across the body. The System Controller Neck Strap attaches to the System Controller when the System Controller is connected to the Power Module, the Mobile Power Unit, or during battery-powered operation.
Belt Attachment 	Use the Belt Attachment to wear the System Controller around the waist, on a belt. The Belt Attachment holds the System Controller when the System Controller is connected to the Power Module, the Mobile Power Unit, or during battery-powered operation.
Consolidated Bag 	Use the Consolidated Bag to carry the System Controller, and two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips in a single bag during battery-powered operation.

Table 6.1 Wear and Carry Accessories (Continued)

Battery Holster 	Use the Battery Holster to wear two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips around the shoulders and under the arms. It is designed to distribute equipment weight across the shoulders and back. The Battery Holster holds the System Controller, and two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.
Holster Vest 	Use the Holster Vest to wear two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips around the shoulders and under the arms. It is designed to distribute equipment weight across the shoulders and back. The Holster Vest includes a chest strap and works with or without the Belt Attachment. The Holster Vest holds the System Controller, and two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips during battery-powered operation.
Protection Bag 	Use the Protection Bag to store and protect the backup System Controller.
Travel Bag 	Use the Travel Bag to carry and transport the backup System Controller (in the Protection Bag) and a spare set of two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips on a shoulder. The Travel Bag stores the Protection Bag (with a backup System Controller) and a spare set of two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.

Using the System Controller Neck Strap

The System Controller Neck Strap (**Figure 6.17**) can be worn around the neck or across the body. It attaches to the System Controller with two small straps.

Figure 6.17 System Controller Neck Strap

The System Controller has an attachment point built into each corner of the System Controller casing (**Figure 6.18**).

Figure 6.18 Horizontal Attachment Points on the System Controller

Use one pair of attachment points to suspend the System Controller, either vertically or horizontally (**Figure 6.19**).

Figure 6.19 System Controller Suspended on the Neck Strap: Horizontally (left) and Vertically (right)

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 System Controller Neck Strap

TO ATTACH AND WEAR THE SYSTEM CONTROLLER NECK STRAP:

1. Gather the equipment and place within reach.
2. Place the System Controller on a flat, stable surface.

3. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.20**).

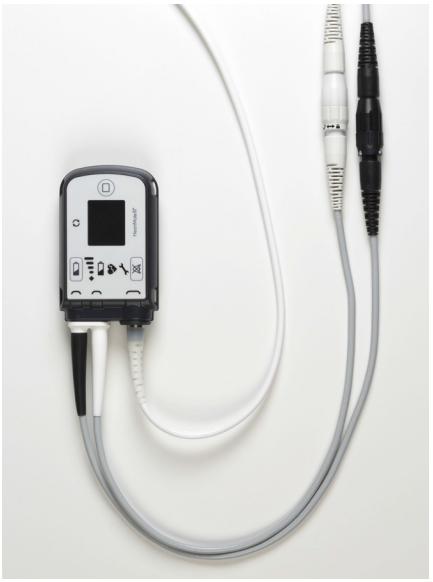


Figure 6.20 Power Cables and Driveline

4. Choose two attachment points on the System Controller, for either vertical or horizontal wearing of the Neck Strap.
5. Slide the rubber strap on the Neck Strap through an attachment point on the System Controller (**Figure 6.21**).

Figure 6.21 Rubber Strap Through the Attachment Point

6. Complete the following steps to buckle the strap:
   a. Thread the rubber strap through the metal buckle on the Neck Strap.
   b. Ensure that the metal prong on the buckle goes through the hole in the strap (**Figure 6.22**).

Figure 6.22 Buckle the Strap

7. Hold the System Controller in one hand and give the Neck Strap a tug with the other hand.This helps to ensure that the buckle is securely connected to the System Controller (**Figure 6.23**).

Figure 6.23 Tug on the Strap

8. Repeat Step 5 through Step 7 to attach the other end of the Neck Strap to the second attachment point on the System Controller.
9. Place the Neck Strap around the patient's neck so that the System Controller is located either on the patient's chest or on the left or right side of the patient.
10. Adjust the length of the Neck Strap, as needed.

TO REMOVE THE SYSTEM CONTROLLER NECK STRAP:

1. Carefully remove the Neck Strap and the System Controller from around the patient's neck.
2. Place the Neck Strap and the System Controller on a stable surface.
3. Unbuckle the two straps.
4. Remove the Neck Strap from the System Controller.

Using the Belt Attachment

The Belt Attachment accessory (**Figure 6.24**) is similar to accessories that are used to wear or carry a cell phone. The Belt Attachment can be attached to the patient's belt or to the provided nylon clip belt.

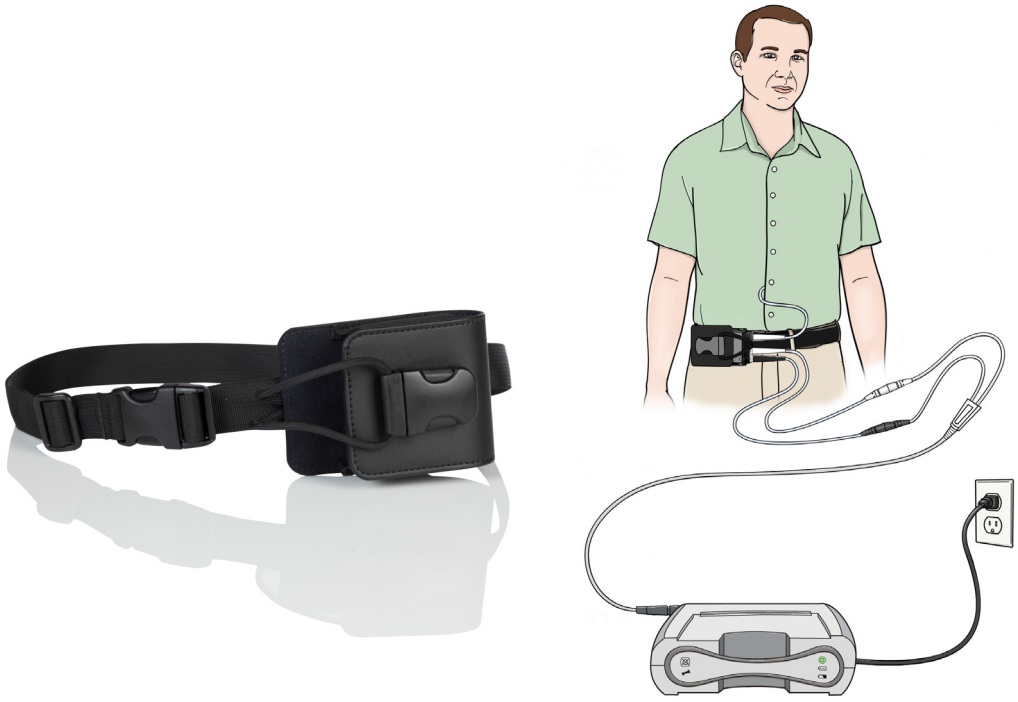


Figure 6.24 Wearing the Belt Attachment

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 Belt Attachment
- 1 personal belt (up to 2″ wide) or 1 provided nylon clip belt

TO PUT ON THE BELT ATTACHMENT:

1. Gather the equipment and place within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.25**).

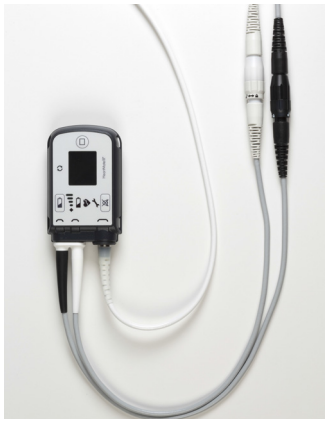


Figure 6.25 Power Cables and Driveline

3. Slide either the patient's belt or the provided nylon belt through the loop on the back of the Belt Attachment (**Figure 6.26**).

Figure 6.26 Belt Through the Loop on Belt Attachment

4. Unclip the two-banded strap on the Belt Attachment.
5. Slide the System Controller, the end without the cable first, into the Belt Attachment with the display screen facing out (**Figure 6.27**).

Figure 6.27 System Controller in Belt Attachment

6. Place the two-banded strap over the System Controller, and between the white System Controller power cable connector and the Driveline connector (**Figure 6.28**).

Figure 6.28 Place the Strap Between the Connectors

7. Clip the two-banded strap into place and ensure that both prongs are fully engaged in the clip (**Figure 6.29**).

Figure 6.29 Clip the Strap Into Place

8. Fasten the belt and Belt Attachment around the patient's waist.
9. Adjust and tighten the belt as necessary, until it is secure but still comfortable.

TO REMOVE THE BELT ATTACHMENT:

1. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
2. Complete one of the following steps:
   - If the patient is wearing the nylon clip belt, go to Step 3.
   - If the patient is wearing their own belt, go to Step 4.
3. Complete the following steps to remove the Belt Attachment from the nylon clip belt:
   a. Unclip the nylon clip belt.
   b. Remove the Belt Attachment, System Controller, and belt from around the patient's waist.
   c. Place the Belt Attachment, System Controller, and belt on a stable surface.
   d. Go to Step 5.
4. Complete the following steps to remove the Belt Attachment from the patient's belt:
   a. Unfasten the belt.
   b. Slide the Belt Attachment off the belt.
   c. Place the Belt Attachment and System Controller on a flat, stable surface.
   d. Go to Step 5.
5. Complete the following steps to remove the System Controller from the Belt Attachment:
   a. Unclip the two-banded strap from the Belt Attachment.
   b. Slide the System Controller out of the Belt Attachment and place both items on a stable surface.

Using the Consolidated Bag

The Consolidated Bag (**Figure 6.30**) is a slim profile shoulder bag. It allows HeartMate patients to comfortably and securely wear and carry system components together in a single bag while using batteries.

Figure 6.30 Consolidated Bag

The Consolidated Bag can be worn across the body using a shoulder strap and supported at the waist using a waist strap.

The compartment that holds the system components is closed using a double zipper. The bag is designed so that the Driveline exits the bag through the protective red tabs on the side (**Figure 6.31**).

Figure 6.31 Consolidated Bag (with Waist Strap)

The Consolidated Bag allows the patient to view the System Controller's user interface. The user interface is visible through a transparent panel beneath a small hook-and-loop fastener flap on the outside of the bag.

The Consolidated Bag is available in one color (black) and two configurations, depending upon the placement of the patient's Driveline exit site. One configuration for wearing on the right side and one configuration for wearing on the left side.

Assembling the Consolidated Bag

FOR THIS TASK YOU NEED:

- 1 Consolidated Bag with belt
- 1 Consolidated Bag shoulder strap

TO ASSEMBLE THE CONSOLIDATED BAG:

1. Gather the equipment and place within reach.
2. Clip the shoulder strap to the Consolidated Bag using the two rings located on the top of the Consolidated Bag (**Figure 6.32**).

Figure 6.32 Attaching the Strap to the Consolidated Bag

3. Confirm which side (left or right) the Consolidated Bag is meant to be worn on by the patient.
4. Put the bag on the patient to confirm the appropriate placement on the left or right side.

   IMPORTANT! The bag type (left or right) can be found on a tag inside the Consolidated Bag and on the box that it ships in.

5. Adjust the shoulder strap and belt so the bag fits the patient properly.
6. Tighten or lengthen the strap and belt until they are secure but still comfortable.

Putting on the Consolidated Bag

FOR THIS TASK YOU NEED:

- 1 running System Controller on battery power
- 1 assembled Consolidated Bag

TO PUT ON THE CONSOLIDATED BAG:

1. Gather the equipment and place within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.33**).

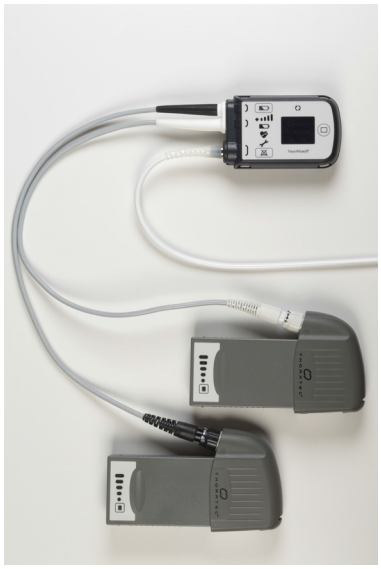


Figure 6.33 Power Cables and Driveline

3. Unzip both Consolidated Bag zippers to open.
4. Slide the System Controller into its holder so the user interface faces out (**Figure 6.34**).

Figure 6.34 System Controller in the Holder in the Consolidated Bag

5. Stretch the two-banded strap over the System Controller, and between the white System Controller power cable and the Driveline connector.

6. Fasten the clip to hold the System Controller in place (**Figure 6.35**).

Figure 6.35 Strap Over the System Controller and Between the Cables

7. Place one battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 6.36**).

Figure 6.36 Battery in the Bag

8. Arrange the power cable for the battery and battery clip so that the cable lays flat along the edge of the bag (**Figure 6.37**).

Figure 6.37 Arranging the Cables Around the Edge of the Bag

9. Place the second battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 6.38**).

Figure 6.38 Placing the Second Battery in the Bag

10. Arrange the power cables so they lay flat along the edge of the bag (**Figure 6.39**).

Figure 6.39 Batteries and Cables in Consolidated Bag

11. Carefully close the Consolidated Bag.
12. Ensure that:
    - The System Controller power cables are inside the Consolidated Bag.
    - The Driveline exits the Consolidated Bag between the protective red tabs (**Figure 6.40**).

Figure 6.40 Closing the Bag: Driveline Exits Between the Red Tabs

13. Zip both Consolidated Bag zippers to close (**Figure 6.41**).

Figure 6.41 Zip Both Zippers Closed

14. Hold the Consolidated Bag by the handle so it does not drop.
15. Put the shoulder strap over the patient's head and across his or her chest (on either the left or right side of the patient's body, depending on the type of bag), so that the Consolidated Bag rests on the patient's body.
16. Place the waist belt around the patient's body and clip it into place.

    The belt stabilizes the bag and prevents it from moving.

Removing the Consolidated Bag

TO REMOVE THE CONSOLIDATED BAG:

1. Unclip the belt.
2. Hold the Consolidated Bag using the handle so it does not drop.
3. Remove the shoulder strap: Either unclip it at one side, or lift it up and over the patient's head.
4. Remove the Consolidated Bag and place it in front of the patient.
5. Unzip and open the Consolidated Bag and complete one of the following steps:
   - Exchange the depleted batteries for a new, fully-charged pair. Refer to *Replacing Depleted Batteries* on page 3-55.
   - Transfer from battery power to the Power Module or Mobile Power Unit. Refer to *Switching from Battery Power to the Power Module* on page 3-61.
   - Remove components from the Consolidated Bag.

Using the Battery Holster

The Battery Holster (**Figure 6.42**) allows the patient to comfortably and securely wear and carry the system components (batteries, battery clips, System Controller) during battery-powered operation.

This wearable accessory is designed to secure the batteries and battery clips in holsters, with the weight of the system components distributed across the patient's shoulders and back. The Belt Attachment is designed to conceal and carry the System Controller. The Battery Holster is available in one size and is adjustable to accommodate most HeartMate III patients.

Figure 6.42 Battery Holster

Assembling the Battery Holster

FOR THIS TASK YOU NEED:

- 1 Battery Holster
- 1 pair of large, sharp scissors
- 1 small tube of strong epoxy glue

TO ASSEMBLE THE BATTERY HOLSTER:

1. Gather the equipment and place within reach.
2. Place the Battery Holster on a flat surface, arranged so the fabric connecting the two straps is in the center.
3. Have the patient slide his or her arms through the straps, so that the fabric connector is between the patient's shoulder blades on his or her back.
4. Pull the loose ends of the strap to adjust the fit.

   The holsters should fit securely, but comfortably, against the patient's sides and under the arms.
5. After determining the appropriate fit, cut off or trim the extra length from the end of each strap.

   Note: Extra strap length can be used later for further adjustment should the patient gain weight.
6. Apply a strong epoxy glue to the cut off ends of each strap to reduce fraying.
7. Allow the glue to dry before wearing the Battery Holster.

IMPORTANT! The straps can also be stitched together through the fabric to prevent the fabric connector from moving and changing the fit.

Wearing the Battery Holster

FOR THIS TASK YOU NEED:

- 1 running System Controller on Power Module or Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- 1 battery holster
- 1 belt attachment
- 1 clip-style belt or the patient's own belt

TO WEAR THE BATTERY HOLSTER:

1. Gather the equipment and place within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.43**).

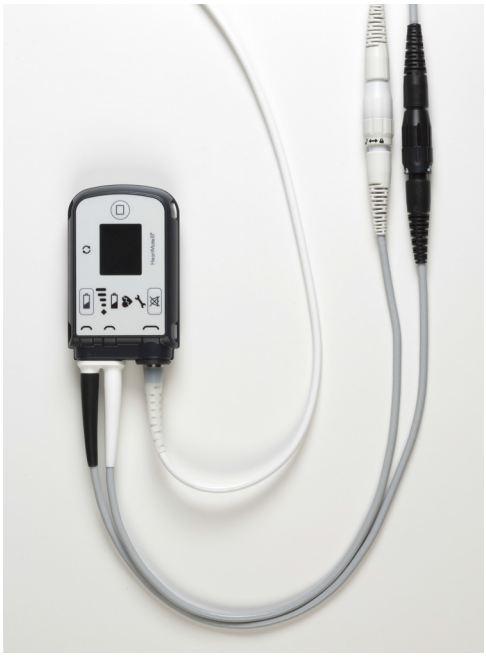


Figure 6.43 Power Cables and Driveline

3. Complete the following steps to insert the batteries and attached battery clips into each holster:
   a. Open each hook-and-loop fastener flap on the Battery Holster (**Figure 6.44**).

Figure 6.44 Hook-and-Loop Fastener Flap

b. Insert each battery and attached battery clip into the Battery Holster, so that the battery points down and the battery clip points up (**Figure 6.45**).

Figure 6.45 Battery and Battery Clip in Battery Holster

c. Close each Battery Holster flap (**Figure 6.46**).

Figure 6.46 Battery in Holster with Flap Closed

d. Repeat Step 3a through 3c for the second battery and battery clip.

4. Have the patient put on the Battery Holster.
5. Put on and secure the Belt Attachment around the patient's waist.
6. Adjust and tighten the belt, as needed, until it is secure but still comfortable.
7. Slide the System Controller into the Belt Attachment.
8. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller, and between the white System Controller power cable connector and the Driveline connector.
9. Slide the clip ends of the two-banded strap into the clip socket.

   The clip clicks into place when securely fastened.
10. Transfer from the Power Module or Mobile Power Unit to battery power.

    Refer to *Switching from the Power Module to Battery-Powered Operation* on page 3-58.

Exchanging Depleted Batteries with Charged Batteries

WARNING !

At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.

FOR THIS TASK YOU NEED:

- The patient wearing a Battery Holster with a running System Controller on battery power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO EXCHANGE DEPLETED BATTERIES WITH A FULLY-CHARGED PAIR:

1. Obtain two fully-charged batteries and place them within reach.
2. Open the flap on one of the holsters.

WARNING !

Be sure to remove only one depleted battery from its clip at this time.

3. Remove the depleted battery and battery clip from the holster.
4. Press the battery release button on the battery clip.
5. Withdraw the depleted battery from its battery clip and put the depleted battery aside.

   A Power Cable Disconnect advisory will sound. This is normal.
6. Retrieve one of the fully-charged batteries and insert it into the battery clip.

   The battery clicks into place when fully inserted. The alarm stops when the fully-charged battery is properly inserted.
7. Place the fully-charged battery and attached battery clip into the empty holster.
8. Close the Battery Holster flap.
9. Repeat Step 2 through Step 8 for the second depleted battery.
10. Recharge the depleted batteries in the Battery Charger.

    Refer to *Charging HeartMate Batteries* on page 3-72.

Removing the Battery Holster

FOR THIS TASK YOU NEED:

- The patient wearing a Battery Holster with a running System Controller on battery power
- 1 Power Module or Mobile Power Unit

TO REMOVE THE BATTERY HOLSTER:

1. Switch from battery power to the Power Module or Mobile Power Unit. Refer to *Switching from Battery Power to the Power Module* on page 3-61.

   IMPORTANT! Complete Step 1 before taking off the Battery Holster.

2. Remove the Battery Holster with the batteries.
3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
4. Complete one of the following steps:
   - If the patient is wearing the nylon clip belt, go to Step 5.
   - If the patient is wearing their own belt, go to Step 6.
5. Complete the following steps to remove the Battery Holster from the nylon clip belt:
   a. Unclip the nylon clip belt.
   b. Remove the Belt Attachment, System Controller, and belt from around the patient's waist.
   c. Place the Belt Attachment, System Controller, and belt on a stable surface.
   d. Go to Step 7.
6. Complete the following steps to remove the Battery Holster from the patient's belt:
   a. Unfasten the belt.
   b. Slide the Belt Attachment off the belt.
   c. Place the Belt Attachment and System Controller on a stable surface.
   d. Go to Step 7.
7. Remove the System Controller from the Belt Attachment:
   a. Unclip the two-banded strap from the Belt Attachment.
   b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
8. Remove the batteries and attached battery clips from the Battery Holster, and place them on a stable surface.
9. Recharge the low-charged batteries. Refer to *Charging HeartMate Batteries* on page 3-72.
10. Store the battery holsters in a clean, dry location. Refer to *Equipment Storage and Care* on page 8-1.

Using the Holster Vest

The Holster Vest (**Figure 6.47**) allows the patient to comfortably and securely wear and carry system components (batteries, battery clips, System Controller) during battery-powered operation. Refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

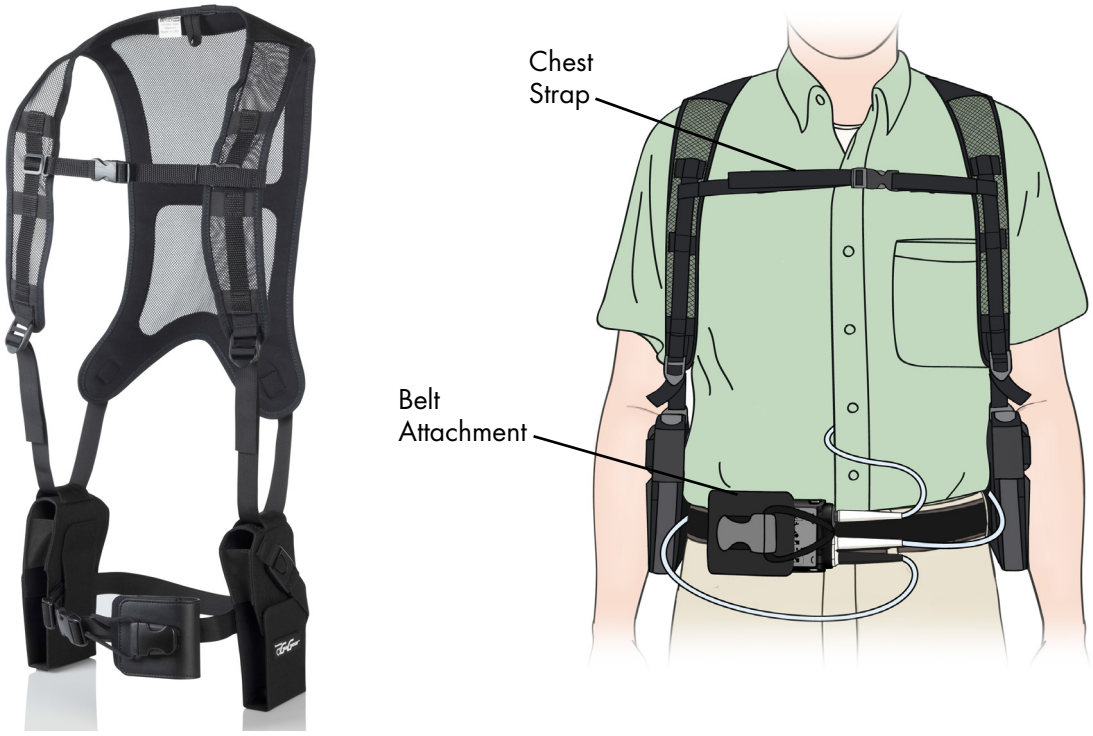


Figure 6.47 Holster Vest

The Holster Vest is designed to distribute the weight of the HeartMate III system components across the patient's shoulders and back with holsters for the batteries and an optional chest strap.

The Holster Vest is available in three sizes: small, medium, and large. A Belt Attachment cover is provided to conceal, protect, and wear the System Controller with the Holster Vest. The Belt Attachment cover provides visibility and immediate access to the user interface on the System Controller.

Assembling the Holster Vest

FOR THIS TASK YOU NEED:

1 Holster Vest with Belt Attachment

TO ASSEMBLE THE HOLSTER VEST:

1. Gather the equipment and place within reach.
2. Insert one Holster Vest strap through the slot in the top of one of the holsters.

   The buckle should point down and the holster should face forward when the patient wears the Holster Vest (**Figure 6.48**).

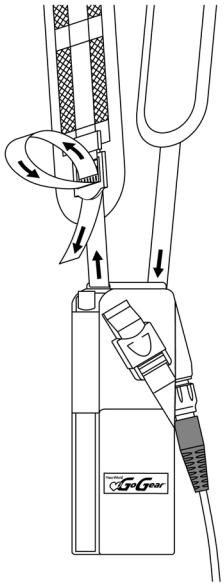


Figure 6.48 Holster Vest Strap Through Slot in Top of the Holster

3. Repeat Step 2 for the second holster.

Wearing the Holster Vest

FOR THIS TASK YOU NEED:

- 1 running System Controller on Power Module or Mobile Power Unit power
- 1 assembled holster vest with belt attachment
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO WEAR THE HOLSTER VEST:

1. Gather the equipment and place within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 6.49**).

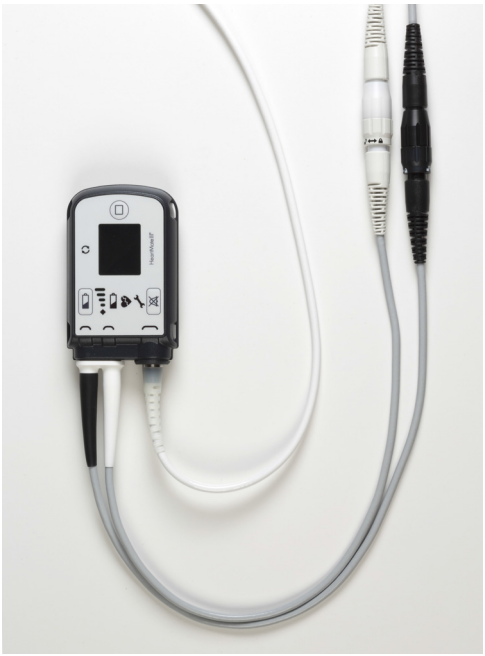


Figure 6.49 Power Cables and Driveline

3. Complete the following steps to place the batteries and attached battery clips into the holsters:
   a. Insert one battery and attached battery clip into the holster.

      The clip point should point up and the battery should point down (**Figure 6.50**).

Figure 6.50 Inserting Battery and Clip into Holster

b. Buckle the clip on the holster (**Figure 6.51**).

Figure 6.51 Buckle the Clip on the Holster

c. Close the flap on the holster.

d. Repeat Step 3a through 3c for the second battery and battery clip.

4. Have the patient put on the Holster Vest.
5. Adjust and tighten the straps until they are secure, but still comfortable.
6. If the optional chest strap is used, position it higher or lower on the vest until it is secure and comfortable.
7. Complete the following Belt Attachment steps:

   a. Secure the Belt Attachment around the patient's waist.

   b. Adjust and tighten the belt until it is secure, but still comfortable.

   c. Slide the System Controller into the Belt Attachment.

   d. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller, and between the white System Controller power cable connector and the Driveline connector.

   e. Slide the clip ends of the two-banded strap into the clip socket.

      The clip will click into place when securely fastened.

8. Transfer from the Power Module or the Mobile Power Unit to battery power. Refer to *Switching from the Power Module to Battery-Powered Operation* on page 3-58.

9. Use the hook-and-loop fastener tabs on the back of the holsters to hold the power cables in place and to stabilize the holsters (**Figure 6.52**).

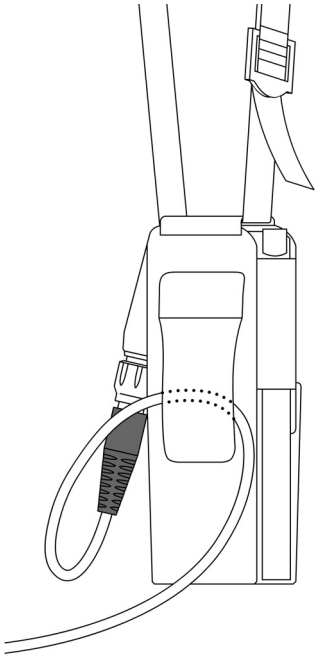


Figure 6.52 Hook-and-Loop Fastener Tabs Hold the Power Cables in Place

10. Put the patient's belt through the hook-and-loop fastener tabs to help secure the holsters in place.

Exchanging Depleted Batteries

WARNING !

At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.

The Holster Vest allows the convenience of exchanging depleted batteries with a new, fully-charged pair without taking off the vest or disrupting the power cables.

TO EXCHANGE DEPLETED BATTERIES:

1. Obtain two fully-charged HeartMate 14 Volt Lithium-Ion batteries and place them within reach.
2. Open the flap on one of the holsters to access the depleted battery and its attached battery clip (**Figure 6.53**).

WARNING !

Remove only one depleted battery at this time.

3. Hold the depleted battery while pressing the battery release button on the battery clip.
4. Withdraw the depleted battery from its battery clip.

   An alarm will sound when the battery is removed. This is normal.
5. Retrieve one of the fully-charged batteries and insert it into the empty battery clip.

   The battery clicks into place when fully inserted. The alarm stops when the battery is inserted.
6. Close the flap on the holster.

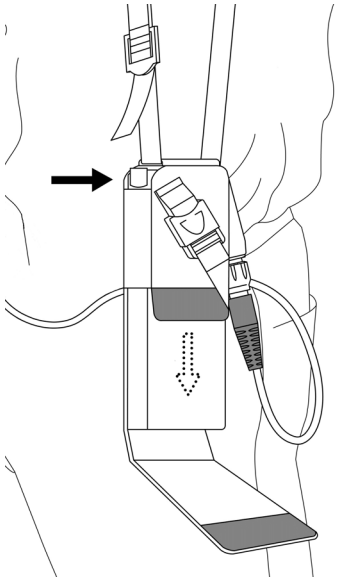


Figure 6.53 Exchanging a Battery

7. Repeat Step 2 through Step 6 to exchange the second depleted battery.

8. Recharge the depleted batteries. Refer to *Charging HeartMate Batteries* on page 3-72.

Removing the Holster Vest

TO REMOVE THE HOLSTER VEST:

1. Switch from battery power to the Power Module or the Mobile Power Unit. Refer to *Switching from Battery Power to the Power Module* on page 3-61.

   IMPORTANT! Complete Step 1 before taking of the Holster Vest.

2. Remove the Holster Vest with batteries.
3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
4. Complete one of the following steps:
   - If the patient is wearing the nylon clip belt, go to Step 5.
   - If the patient is wearing their own belt, go to Step 6.
5. Complete the following steps if the patient is wearing the nylon clip belt:
   a. Unclip the nylon clip belt.
   b. Remove the Belt Attachment, System Controller, and belt from around the patient's waist.
   c. Place the Belt Attachment, System Controller, and belt on a stable surface.
   d. Go to Step 7.
6. Complete the following steps if the patient is wearing his or her own belt:
   a. Unfasten the belt.
   b. Slide the Belt Attachment and System Controller off the belt.
   c. Place the Belt Attachment and System Controller on a stable surface.
   d. Go to Step 7.
7. Remove the System Controller from the Belt Attachment:
   a. Unclip the two-banded strap from the Belt Attachment.
   b. Slide the System Controller out of the Belt Attachment.
   c. Place the System Controller and Belt Attachment on a stable surface.
8. Remove the batteries and attached battery clips from the Holster Vest, and place them on a stable surface.
9. Recharge the low-charged batteries.

   Refer to *Charging HeartMate Batteries* on page 3-72).
10. Store the Holster Vest in a clean, dry location. Refer to *Equipment Storage and Care* on page 8-1.

Using the Protection Bag

The Protection Bag (**Figure 6.54**) stores and protects the backup System Controller while it is in Sleep Mode. The Protection Bag has a clear window for easy viewing of the System Controller and power cables inside. The bag protects the equipment from dust, dirt, moderate water, and debris. It also provides a convenient way to store or carry the backup System Controller, which must remain with the patient at all times. The Protection Bag fits into the Travel Bag.

FOR THIS TASK YOU NEED:

- 1 Protection Bag
- 1 backup System Controller and cables

TO USE THE PROTECTION BAG:

1. Unzip the Protection Bag.
2. Slide the backup System Controller into the Protection Bag.
3. Carefully coil the cables around the System Controller inside the Protection Bag.
4. Zip close the Protection Bag (**Figure 6.54**).

Figure 6.54 Protection Bag with Backup Controller and Cables Stored Inside

IMPORTANT! When placing the System Controller inside the Protection Bag, do not twist, kink, or sharply bend the System Controller power cables. Doing so may cause damage to the wires inside, even if external damage is not visible. If the cables become twisted, bent, or kinked, carefully unravel and straighten. Refer to *What Not to Do: Driveline and Cables* on page 7-37.

IMPORTANT! Do not store or carry anything in the Protection Bag other than the backup System Controller and attached power cables.

IMPORTANT! Do not store or carry the backup System Controller outside of recommended environmental conditions. Refer to *Equipment Storage and Care* on page 8-1.

Using the Travel Bag

The Travel Bag accommodates a System Controller in its Protection Bag and spare batteries. The Travel Bag provides a convenient way to carry and transport the backup System Controller and spare batteries. The Travel Bag can also be used at home to hold the backup System Controller (**Figure 6.55**).

Figure 6.55 Travel Bag

FOR THIS TASK YOU NEED:

- 1 Protection Bag with backup System Controller and cables stored inside
- 2 spare fully-charged 14 Volt Lithium-Ion batteries
- 1 Travel Bag

TO USE THE TRAVEL BAG:

1. Open the top lid and unzip the inner compartment.
2. Open the Travel Bag.
3. Place the Protection Bag (with the backup System Controller and cables inside) into the Travel Bag (**Figure 6.56**).

Figure 6.56 Inserting Protection Bag Into Travel Bag

4. Place the fully-charged, spare batteries into the side pockets of the Travel Bag (**Figure 6.57**).

Figure 6.57 Inserting Spare Batteries Into Travel Bag

5. Zip close the inner compartment and snap shut the top lid.

ALARMS AND TROUBLESHOOTING

This section describes the primary alarms and troubleshooting of the HeartMate III Left Ventricular Assist System.

7 Alarms and Troubleshooting

System Controller Alarms

Patient-Resolvable Versus Clinician-Resolvable Alarms

Note: Patients can resolve and troubleshoot many System Controller alarms on their own, without clinician intervention. Primarily, patient-resolvable alarms involve maintaining connections to the Driveline and external power sources. There are, however, many situations where clinician help is needed. In these situations, a "Call Hospital Contact" message appears on the information display screen. Depending on the hospital center, the clinician may ask the patient to replace his or her System Controller. In other cases, the clinician may arrange for the patient to be admitted for additional diagnostics and resolution by clinicians.

Handling System Controller Alarms

Common System Controller alarms are described on the following pages. Each section addresses the likely cause and typical steps for resolving most System Controller alarms. Alarms are presented in order of priority. Hazard alarms appear first, followed by Advisories. Refer to **Table 7.2** through **Table 7.3** on the following pages for a complete list of prioritized System Controller alarms.

IMPORTANT! System Controller alarms cannot be silenced when the System Controller is in power saver mode. For more information about power saver mode, refer to *Low Speed Limit* on page 4-20.

Alarm Screen Overview

When an alarm occurs, messages appear on the System Controller's user interface screen to help resolve the problem. These screen messages indicate the alarm type and shows a timer. The timer on the screen counts up in seconds, indicating how long the alarm has been occurring. **Figure 7.1** shows the alarm screen layout.

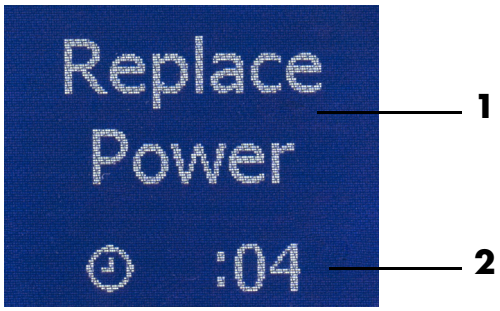


Figure 7.1 Alarm Screen

1	**Alarm Message**
2	**Duration Timer**

Viewing Alarm History on the User Interface Screen

Alarm history can be viewed on the System Controller user interface. The last six relevant System Controller alarms are displayed. The alarm history includes alarms that are transient, have clinical value, or that do not interfere with access to more critical alarms. The alarms displayed on the user interface screen are:

- Power Cable Disconnect Alarm (lasting over 30 seconds)
- External Power Disconnected Alarm
- Driveline Disconnected Alarm
- Low Battery Power Advisory Alarm
- Low Battery Power Hazard Alarm
- Low Flow Alarm

Only a subset of alarms is displayed on the System Controller; a history of all alarms is available through the System Monitor. Refer to *System Controller Event Recorder* on page 4-33.

To view the six most recent alarms on the user interface screen, simultaneously press and release the silence alarm ( ) and display ( ) buttons. Up to six of the most recent alarms are displayed. The most recent alarm appears first. To view the next alarm, press and release the display ( ) button. Each push of the display button brings up a new screen. After the sixth alarm is displayed, the next button push returns to the first alarm screen.

Alarm history screens show the date and time of the alarm occurrence at the top of the screen. A dot at the bottom of each screen provides navigational information about which screen is in view (**Figure 7.2**).

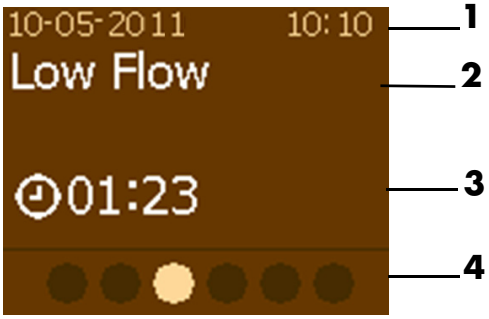
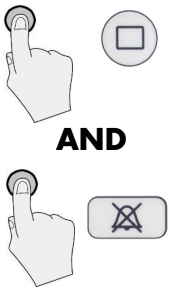
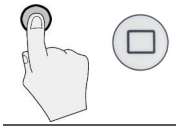
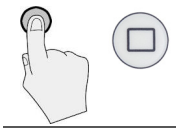
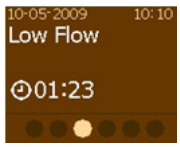
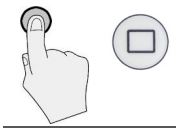
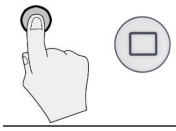
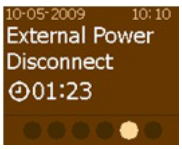
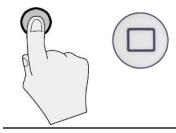
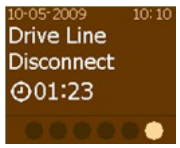


Figure 7.2 Sample Alarm History Screen

1	**Date (mm-dd-yyyy) and time (hh:mm) of Alarm**
2	**Alarm Type**
3	**Duration of Alarm**
4	**Navigation Information**

Table 7.1 shows how to access the alarm history screens.

Table 7.1 Alarm History Screens

Button Press	Description	Alarm Screen Displayed (Example)
Press  **AND**	Press display button and silence alarm button at the same time to access first alarm.	
Press 	Press display button **ONCE** to display the second alarm.	
Press 	Press display button **TWO** times to display the third alarm.	
Press 	Press display button **THREE** times to display the fourth alarm.	
Press 	Press display button **FOUR** times to display the fifth alarm.	
Press 	Press display button **FIVE** times to display the sixth alarm.	

If the System Controller detects an alarm condition while displaying alarm history, the screen immediately transitions to the real-time alarm screen. However, the alarm history screens can still be accessed during an active alarm by simultaneously pressing the silence alarm ( ) and display ( ) buttons. To exit from the alarm history feature, simultaneously press the two buttons again.

Alarms That Do Not Appear in Alarm History

The Driveline Power Fault, Driveline Communication Fault (Driveline Comm Fault), System Controller Backup Battery Fault, and System Controller Fault alarms are examples of non-transient alarms that require specific user action to resolve the alarm condition. These alarms remain on the user interface screen until the alarm condition is resolved or permanently disabled and therefore do not appear in alarm history.

In addition, a Power Cable Disconnect advisory alarm (that lasts less than 30 seconds) and Pulsatility Index (PI) events are examples of routine events that might interfere with access to more critical information. For this reason, these events also do not appear in alarm history.

The following alarms do not appear on the System Controller: Low Speed, LVAD Fault, System Controller Clock Not Set.

Available Languages

On-screen messages on the user interface can be displayed in multiple languages. Use the System Monitor to view and select the desired language. Refer to *System Controller Language* on page 4-42.

Alarm Silence Indicator – System Controller LCD Screen

If the audio alarm silence has been activated from either the System Controller or the System Monitor, the System Controller LCD screen will display the alarm silence indicator ( ).

Figure 7.3 Sample Alarm Silence Indicator

Table 7.2 System Controller Hazard Alarms

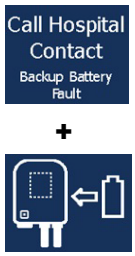
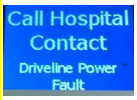
Priority	System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
HAZARD	Call Hospital Contact 23:01 + Low Flow 23:02	 	2 minutes	**Pump off**	1. Check if the Fixed Speed setting is below 4,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt Pump start. 2. Switch to the backup System Controller and attempt to restart the Pump. 3. Clinically evaluate patient. Refer to page 7-10.
	Call Hospital Contact 23:01 + Low Flow 23:02	 	2 minutes	**Low flow, flow is less than 2.5 lpm**	1. Ensure that the Driveline is connected to System Controller. **OR** Ensure that a power source is connected to System Controller. 2. Clinically evaluate patient. Refer to page 7-11.
	Connect Driveline :01	  + 	2 minutes	**Driveline disconnected**	1. Immediately reconnect the Driveline to System Controller and move the Driveline Safety Lock on the System Controller to the locked position. If alarm persists after reconnecting the Driveline, press any button on the System Controller to attempt Pump start. Also, check that the Modular In-Line Connector is secure. Otherwise, check if the Fixed Speed setting is below 4,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. 2. If Driveline is connected and alarm persists, replace System Controller with a backup System Controller. Refer to page 7-12.
	Connect Power Immediately 3:01 + Backup Battery 23:01	 +  + 	2 minutes	**Both power cables are disconnected**	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Refer to page 7-13.
	Call Hospital Contact Controller Fault	 	None - the audio tone cannot be silenced	**System Controller Hardware Fault (Microcontroller Failure)**	No active symbols (constant audio tone). 1. Immediately switch to the backup System Controller. 2. Provide patient with a new System Controller. Refer to page 7-15.
	Low Battery 23:01 + Replace Power Immediately 23:02		2 minutes	**Low Battery, Power input is extremely low with less than 5 min. remaining**	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Refer to page 7-14.

Table 7.3 System Controller Advisory Alarms

Priority	System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
ADVISORY	Connect Power 23:01	 OR	2 minutes	**One of the two power cables is disconnected**	Promptly connect the disconnected power cable to power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). **Refer to page 7-16.**
	Replace Power :02 + Low Battery :06	◆	5 minutes	**Low Battery, Power input is low with less than 15 min. remaining** OR **System Controller power cables are crossed when connected to the Mobile Power Unit**	Promptly connect to a working or different power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). Ensure the power cables are connected correctly, white-to-white and black-to-black.  **Note:** The second condition (meaning / resolution) will not apply for Mobile Power Units with software version 1.02. **Refer to page 7-17.**
	Call Hospital Contact Controller Fault	🔧	4 hours	**System Controller Hardware Fault**	1. Switch to the backup System Controller. 2. Provide patient with a new System Controller. **Refer to page 7-19.**
	Call Hospital Contact Comm Fault	🔧	4 hours	**Communication Fault (Comm Fault)**	Contact Thoratec to determine best next steps: Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active to access the extended alarm silence for this situation. **Refer to page 7-20.**
	Call Hospital Contact Backup Battery Fault	🔧	4 hours	**System Controller Backup Battery Fault**	Replace the 11 Volt Lithium-Ion backup battery. **Note:** If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Thoratec with questions. **Refer to page 7-21.**

Table 7.1 System Controller Advisory Alarms (Continued)

IMPORTANT! The Pump Running ( ) light is always green on when the Pump is running.

Priority	System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
ADVISORY			4 hours	**System Controller Backup Battery not installed**	1. Install the 11 Volt Lithium-Ion backup battery in the System Controller. 2. Obtain a new backup battery replacement kit. **Note:** If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Thoratec Corporation with questions. Refer to page 7-22.
			4 hours	**Driveline Power Fault**	Contact Thoratec Corporation to determine best next steps. Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active in order to access the alarm silence for this situation. Refer to page 7-23.
			4 hours	**Driveline Communication Fault (Driveline Comm Fault)**	Contact Thoratec Corporation to determine best next steps. Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active to access the alarm silence for this situation. Refer to page 7-24.

Pump Off Alarm

Table 7.2 Pump Off Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Heart ( ) on the user interface. • The Driveline is connected. • *Call Hospital Contact* and *Low Flow* alternate on the screen. • Green "pump running" symbol ( ) is off. • Alarm tone: Constant tone. • System Monitor alarm active: PUMP OFF
Alarm means:	Pump has stopped running, possibly because power has been disconnected or failed.
To resolve alarm:	Patient must immediately connect to a power source (if disconnected/failed). If restoring power does not resolve, patient should press any button on the System Controller to attempt Pump start, and immediately call hospital contact for diagnosis and instructions. Clinicians: 1. Check if the Fixed Speed setting is below 4000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt Pump start. 2. Switch to backup System Controller and attempt to restart the Pump. Refer to page 2-46. 3. Clinically evaluate patient.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

Low Flow Alarm

Table 7.3 Low Flow Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Heart ( ) on the user interface. • *Call Hospital Contact* and *Low Flow* alternate on the screen. • Alarm tone: Constant tone. • System Monitor alarm active: LOW FLOW
Alarm means:	Pump flow is less than 2.5 lpm.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Ensure the Driveline is connected to the System Controller. Refer to page 2-21. 2. Ensure that a power source is connected to the System Controller. 3. Clinically evaluate patient.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

Driveline Disconnected Alarm

Table 7.4 Driveline Disconnected Alarm

This is a Hazard alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing Red Heart ( ) on the user interface. • Flashing red light near Driveline connector. • *Connect Driveline* flashes on the screen. • Green "pump running" symbol ( ) is off. • Alarm tone: Constant tone. • System Monitor alarm active: DRIVELINE DISCONNECTED
Alarm means:	The Driveline is disconnected from the System Controller. Refer to page 2-20.
To resolve alarm:	1. Immediately reconnect the Driveline to the System Controller and move the Driveline Safety Lock on the System Controller to the locked position. Refer to page 2-21. 2. If alarm persists after reconnecting the Driveline, press any button on the System Controller to attempt Pump start. Also, check that the Modular In-Line Connector is secure. Otherwise, check if the Fixed Speed setting is below 4,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the Pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. 3. If Driveline is connected and alarm persists, replace the System Controller with a backup System Controller.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

No External Power Alarm

Table 7.5 No External Power Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Battery ( ) on the user interface. • *Connect Power Immediately* and Backup Battery graphic alternate on the screen. • Yellow light near the black power cable connector is flashing. • Yellow light near the white power cable connector is flashing. • Alarm tone: Constant tone. • System Monitor alarm active: NO EXTERNAL POWER
Alarm means:	The System Controller is not receiving power from either power cable. **AND** The Pump is being powered by the System Controller's 11 Volt Lithium-Ion backup battery.
To resolve alarm:	Immediately connect to a functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries to ensure the Pump does not stop.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

The 11 Volt Lithium-Ion backup battery inside the System Controller provides power to the Pump for at least 15 minutes when fully charged if the main power source is disconnected or fails. Refer to *System Controller Backup Battery Power* on page 2-36 for details about the 11 Volt Lithium-Ion backup battery inside the System Controller.

IMPORTANT! If external power is not restored, the Pump gradually slows to the Low Speed Limit to save power in an effort to prevent the Pump from stopping. When adequate power is supplied, the Pump reverts to the previous speed and the red battery alarm clears.

Low Battery Power Alarm (less than 5 minutes remain)

Table 7.6 Low Battery Power Alarm (< 5 minutes)

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Battery ( ) on the user interface. • *Low Battery* and *Replace Power Immediately* alternate on the screen. • Alarm tone: Constant tone. • System Monitor alarm active: LOW VOLTAGE
Alarm means:	• Less than 5 minutes of battery power remains (when using battery power). **OR** • The System Controller is receiving inadequate power from the Power Module or Mobile Power Unit.
To resolve alarm:	Immediately connect to a working or different power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

System Controller Hardware Fault

Table 7.7 System Controller Hardware Fault

This is a Hazard alarm	
The screen looks like this:	
Behavior and appearance:	• All symbols are off, including the "pump running" symbol ( ) and wrench( ). • *Call Hospital Contact Controller Fault* displays on the screen. • The Driveline is connected and power is connected. • Alarm tone: Constant tone. • All Controller buttons are non-functional. • No System Monitor communication, alarm will not appear on the System Monitor.
Alarm means:	The microcontroller inside the System Controller is not functioning. Power is passing directly from the source, through the System Controller to the Pump. The Pump will continue to operate as long as power is applied to the System Controller and no other malfunction occurs. All other monitoring and alarms are not functional (including an indication of pump operation).
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Switch to the backup System Controller if instructed to. Clinicians should: 1. Switch to the backup System Controller 2. Provide patient with a new System Controller
Alarm silence period:	None. The audio tone cannot be silenced.

IMPORTANT! A backup System Controller is identical to the running System Controller. It should remain with the patient at all times for easy access in an emergency. Refer to *Backup System Controller Overview* on page 2-41 for details about the backup System Controller, including replacement instructions. Refer to page 2-46.

Power Cable Disconnect Alarm

Table 7.8 Power Cable Disconnect Alarm

This is an Advisory alarm	
The screens look like this: (Screen 1 for black cable; Screen 2 for white cable)	Screen 1—Black Cable  Screen 2—White Cable 
Behavior and appearance:	• Flashing yellow light near the black or white power cable connector, depending on which cable is disconnected. • *Connect Power* displays on the screen. • Alarm tone: Fast beep. • System Monitor alarm active: Power Cable Disconnect
Alarm means:	One of the System Controller power cables is disconnected from power. If it is the cable with the black connector, the top light comes on. If it is the cable with the white connector, the center light comes on.
To resolve alarm:	Promptly connect the disconnected power cable to a power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

Low Battery Power Alarm (less than 15 minutes remain)

Table 7.9 Low Voltage Alarm (< 15 minutes)

This is an Advisory alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing yellow diamond (◆) on the user interface. • *Low Battery* and *Replace Power* alternate on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Low Voltage Advisory
Alarm means:	Low voltage, power input to the System Controller is low with less than 15 minutes of battery power remaining. **OR** System Controller power cables are crossed when connected to the Mobile Power Unit. **Note:** The second condition (crossed power cables) will not apply for Mobile Power Units with software version 1.02.
To resolve alarm:	Promptly connect to a working or different power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 5 minutes or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

IMPORTANT! The low battery power alarm will occur if the white and black power cables from the System Controller are incorrectly connected (white-to-black and black-to-white) to the Mobile Power Unit. The alarm will occur after five minutes.
This alarm will not apply for Mobile Power Units with software version 1.02.

WARNING !

Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the System Controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.

To resolve the alarm:

1. Promptly connect to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.

2. Reconnect to the Mobile Power Unit. Make sure that the power cables are connected correctly—white-to-white and black-to-black.
3. If reconnecting to the Mobile Power Unit does not resolve the alarm, promptly connect to a different power source. Refer to *Connecting to the Mobile Power Unit* on page 3-42.

Note: This alarm and resolution will not apply for Mobile Power Units with software version 1.02.

System Controller Fault Alarm

Table 7.10 System Controller Fault Alarm

This is an Advisory alarm	
The screens look like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact* displays on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Replace System Controller
Alarm means:	An internal malfunction in the System Controller has occurred that requires clinician diagnosis and resolution.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Switch to the backup System Controller if instructed to do so. Clinicians should: 1. Switch to the backup System Controller. 2. Provide patient with a new System Controller.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

IMPORTANT! A backup System Controller is identical to the programmed System Controller. It should remain with the patient at all times for easy access in an emergency. Refer to *Backup System Controller Overview* on page 2-41 for details about the backup System Controller, including replacement instructions.

IMPORTANT! The System Controller will not display all alarms. Certain alarms will be displayed on the System Monitor only.

Communications Fault (Comm Fault) Alarm

Table 7.11 Communication Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact; Comm Fault* displays on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Communication Fault
Alarm means:	The data transfer between the LVAD and the System Controller has been lost. **OR** The primary and back-up communication wires in the Driveline are not functioning.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Contact Thoratec Corporation to determine best next steps. 2. Use the System Monitor to silence the alarm while awaiting resolution, if needed.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ). • Or - 24 hours if EXTENDED ALARM RESET is selected from the System Monitor. This selection should only be made while the patient is under supervised medical care. Refer to *Silencing Alarms via the System Monitor* on page 4-29. **Note:** If EXTENDED ALARM RESET is selected, the System Controller will no longer display this alarm. The visual alarm on the System Monitor is maintained.

System Controller Backup Battery Fault Alarm

Table 7.12 System Controller Backup Battery Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact; Backup Battery Fault* displays on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Replace Backup Battery
Alarm means:	The System Controller's 11 Volt Lithium-Ion backup battery is compromised. **OR** It is unable to fully support Pump function. **OR** There is an issue that requires clinician diagnosis and resolution.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should replace the System Controller 11 Volt Lithium-Ion backup battery. Refer to page 2-37. **Note:** In most cases, replacing the battery will resolve the alarm. However, it may be necessary to replace the System Controller, or additional steps may be required for resolution. Call Thoratec with questions.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button ( ).

IMPORTANT! The System Controller will not display all alarms. Certain alarms will be displayed on the System Monitor only.

System Controller Backup Battery Not Installed Alarm

Table 7.13 System Controller Backup Battery Not Installed Alarm

This is an Advisory alarm	
The screen looks like this: (alternating screens)	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • "Call Hospital Contact; Backup Battery Fault" and "install battery" graphic alternate on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Backup Battery Not Installed
Alarm means:	The System Controller's11 Volt Lithium-Ion backup battery is not installed. **OR** It is installed incorrectly.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Install the 11 Volt Lithium-Ion backup battery in the System Controller. Refer to *Replacing a Backup Battery* on page 2-37. 2. Obtain a new 11 Volt Lithium-Ion backup battery replacement kit. **Note:** In most cases, installing the battery will resolve the alarm. However, it may be necessary to replace the System Controller, or additional steps may be required for resolution. Call Thoratec with questions.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ).

Driveline Power Fault Alarm

Table 7.14 Driveline Power Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact; Driveline Power Fault* displays on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Driveline Power Fault
Alarm means:	One of the redundant power handling wires inside the Driveline may be damaged or broken.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Contact Thoratec to determine best next steps. 2. Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active in order to access the alarm silence for this situation.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ). • In addition, it can be **permanently** silenced and cleared for troubleshooting purposes, but only by clinicians through the System Monitor and when it is the only active alarm (or in conjunction with Driveline Communication Fault and/or LVAD Fault). Refer to *Silencing Alarms via the System Monitor* on page 4-29. • If this alarm condition is permanently silenced, it will no longer appear on the System Controller LCD screen. The System Monitor will maintain a visual alarm.

Driveline Communication Fault (Driveline Comm Fault) Alarm

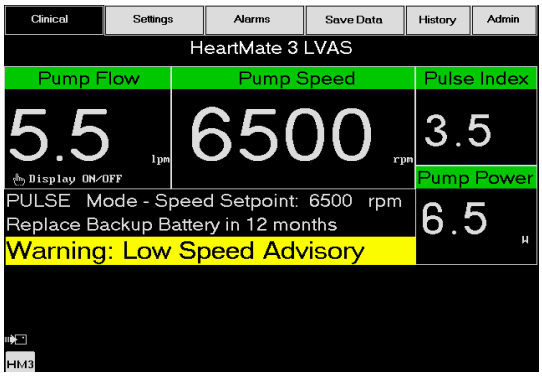
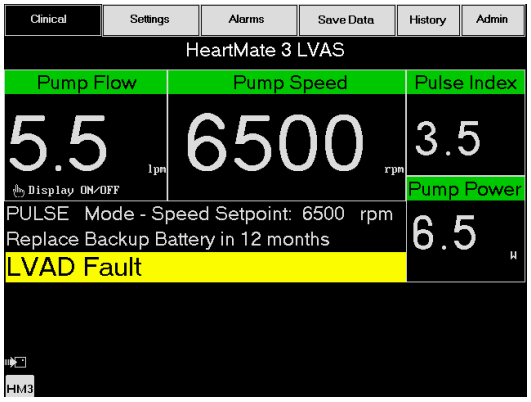
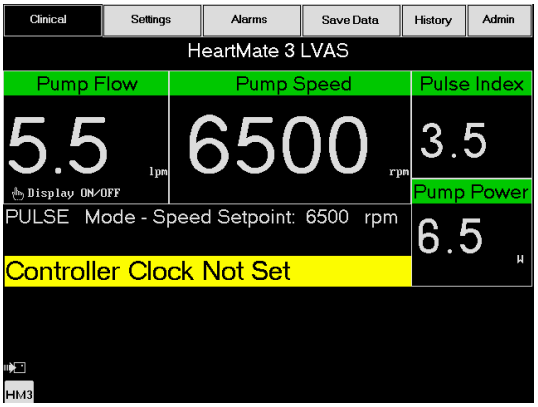
Table 7.15 Driveline Communication Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact; Driveline Comm Fault* displays on the screen. • Alarm tone: Slow beep. • System Monitor alarm active: Driveline Communication Fault
Alarm means:	One of the redundant communication wires inside the Driveline may be damaged or broken.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Contact Thoratec Corporation to determine best next steps. 2. Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active to access the alarm silence for this situation.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the **Silence Alarm** button ( ). • In addition, it can be **permanently** silenced and cleared for troubleshooting purposes, but only by clinicians through the System Monitor and when it is the only active alarm (or in conjunction with Driveline Power Fault and/or LVAD Fault). Refer to page 4-30. • If this alarm condition is permanently silenced, it will no longer appear on the System Controller LCD screen. The System Monitor will maintain a visual alarm.

System Monitor Alarms

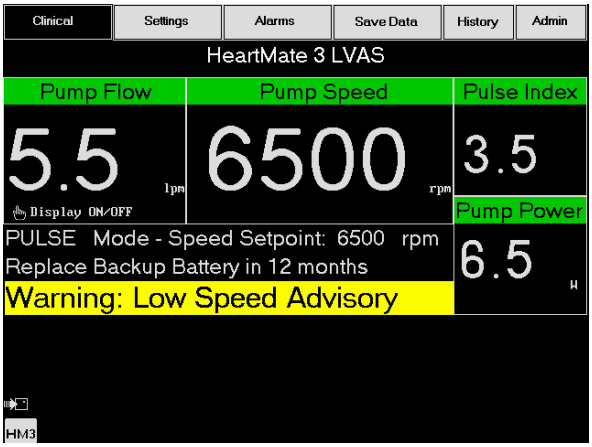
Certain Advisory alarms only appear on the System Monitor: Warning: Low Speed Advisory, LVAD Fault, and Controller Clock Not Set. A text banner appears; however, there is no audible alarm.

Table 7.16 System Monitor Advisory Alarm

Priority	System Monitor Screen	To Resolve Alarm
ADVISORY	 Warning: Low Speed Advisory	1. Use the System Monitor to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient. **Refer to page 7-26.**
	 LVAD Fault	Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active in order to access the alarm silence for this situation. **Refer to page 7-27.**
	 Controller Clock Not Set	Use the System Monitor to set the System Controller's internal clock. **Refer to page 7-28.**

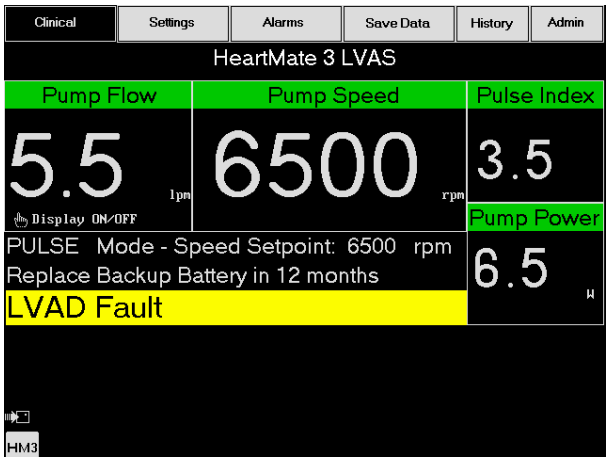
Warning: Low Speed Advisory - System Monitor

Table 7.17 Warning: Low Speed Advisory Alarm

This is an Advisory alarm	
The System Monitor screen looks like this:	
Behavior and appearance:	System Monitor alarm active: WARNING-Low Speed Advisory
Alarm means:	Either the fixed speed has been set 200 rpm or more below the low speed limit or the System Controller is unable to maintain the speed at or above the low speed limit.
To resolve alarm:	Clinicians should: 1. Use the System Monitor to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. Refer to page 2-46. 3. Clinically evaluate the patient.
Alarm silence period:	The Silence Alarm button will appear for this alarm condition. In this case, the button will not perform any function.

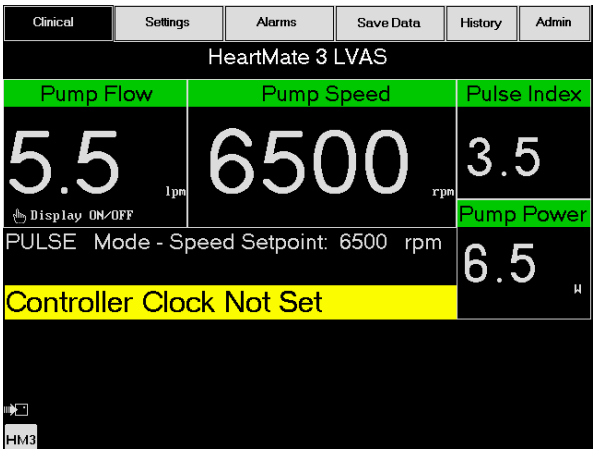
LVAD Fault - System Monitor

Table 7.18 LVAD Fault Alarm

This is an Advisory alarm	
The System Monitor screen looks like this:	
Behavior and appearance:	System Monitor alarm active: LVAD Fault
Alarm means:	The LVAD has determined that one or more internal LVAD operating conditions are out of range.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Contact Thoratec Corporation to determine best next steps. 2. Use the System Monitor to silence the alarm while awaiting resolution, if needed.
Alarm silence period:	The Silence Alarm button will appear for this alarm condition. In this case, the button will not perform any function.

Controller Clock Not Set - System Monitor

Table 7.19 Controller Clock Not Set Alarm

This is an Advisory alarm	
The System Monitor screen looks like this:	
Behavior and appearance:	System Monitor alarm active: Controller Clock Not Set
Alarm means:	The System Controller's internal clock needs to be set. Installing a new 11 Volt Lithium-Ion backup battery in the System Controller may prompt this alarm.
To resolve alarm:	Clinicians should use the System Monitor to set the System Controller's internal clock (See *Date and Time* on page 4- 40). **Note:** Be sure the System Monitor clock is correct.
Alarm silence period:	The Silence Alarm button will appear for this alarm condition. In this case, the button will not perform any function.

Handling Power Module Alarms

The Power Module's internal computer continually monitors Power Module performance. The Power Module issues an alert for the following alarm conditions:

- AC Fail
- Advisory LO BATT (low battery)
- Hazard LO BATT (critically low battery)
- Power Module Backup Battery Malfunction

All Power Module alarm conditions are accompanied by a visual indicator (**Figure 7.4**) and audio tone. Different visual and audio indicators are active, depending on the alarm condition. Refer to **Table 7.20** for a description of Power Module alarms and how to respond to them.

IMPORTANT! If an audio alarm sounds from the Power Module without an accompanying visual indicator illuminating at the same time, please contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

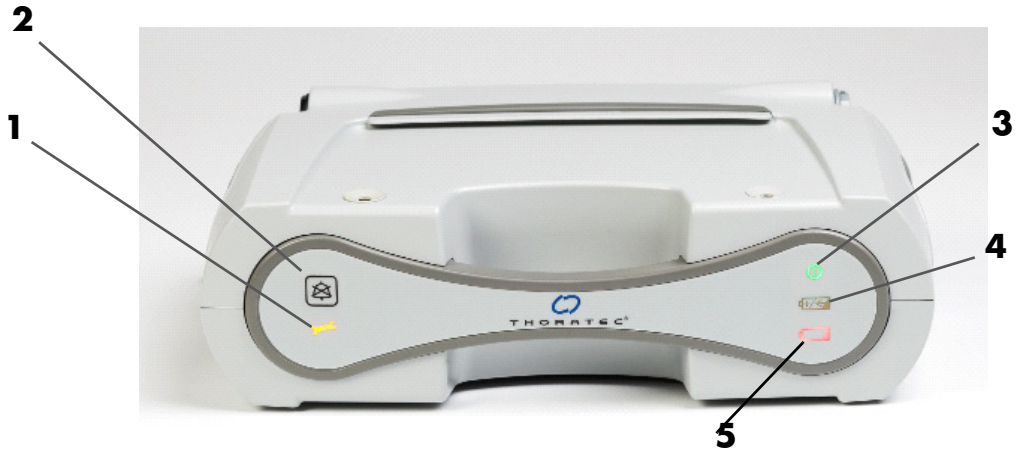


Figure 7.4 Alarm Indicators on Front of Power Module

1	**Wrench Malfunction Symbol**
2	**Silence Alarm Button**
3	**Power On Light**
4	**Power Module Backup Battery Charge Status**
5	**Power Module Backup Battery Indicator**

Table 7.20 Power Module Alarms

IMPORTANT! The Backup Battery indicator turns yellow and then red as the internal battery is depleted. When only 5 minutes of power remain, the Power Module audio tone becomes constant and the alarm can no longer be silenced. A red Hazard LO BATT alarm can only be silenced by switching to another power source.

Alarm	Meaning	What You Should Do
AC FAIL Power On indicator changes from green to yellow  accompanied by beeping audio tone	AC power off or disconnected. When new, the Power Module backup battery will power the HeartMate III system for approximately 30 minutes. The Power Module backup battery is not recharged during AC FAIL.	1. Press the Power Module's silence alarm button (⊠) to silence the alarm (it remains silenced indefinitely or until cancelled by another alarm). 2. Promptly switch to a new set of charged batteries.
Advisory LO BATT yellow internal backup battery  indicator accompanied by beeping audio tone	Less than 15 minutes of Power Module backup battery power remain.	1. Press the Power Module's silence alarm button (⊠) to silence the alarm for 8 hours. 2. Promptly switch to a new set of charged batteries.
Hazard LO BATT red internal backup battery  indicator accompanied by continuous audio tone	Less than 5 minutes of Power Module backup battery power remain.	Immediately switch to a new set of charged batteries.
Advisory Fault yellow wrench indicator  accompanied by beeping audio tone	Internal malfunction detected within the Power Module.	Switch to a new set of charged batteries at earliest convenience.

Table 7.20 Power Module Alarms (Continued)

IMPORTANT! The Backup Battery indicator turns yellow and then red as the internal battery is depleted. When only 5 minutes of power remain, the Power Module audio tone becomes constant and the alarm can no longer be silenced. A red Hazard LO BATT alarm can only be silenced by switching to another power source.

Alarm	Meaning	What You Should Do
Critical Fault yellow wrench indicator  accompanied by continuous audio tone	Internal malfunction detected within the Power Module.	Immediately switch to a new set of charged batteries.
Critical Fault yellow wrench and red internal backup battery indicators   accompanied by continuous audio tone	The Power Module backup battery is not functioning properly or is not installed.	Immediately switch to a new set of charged batteries.

Mobile Power Unit Alarms

The Mobile Power Unit issues an alarm for the following conditions:

- Replace Mobile Power Unit Batteries
- Mobile Power Unit Internal Malfunction

IMPORTANT! When the Mobile Power Unit is connected to the System Controller, the Mobile Power Unit duplicates any active System Controller alarms. Refer to *Handling System Controller Alarms* on page 7-3.

All Mobile Power Unit alarms are accompanied by an illuminated symbol (**Figure 7.5**) and sound. Different lights and sounds come on, depending on the alarm.

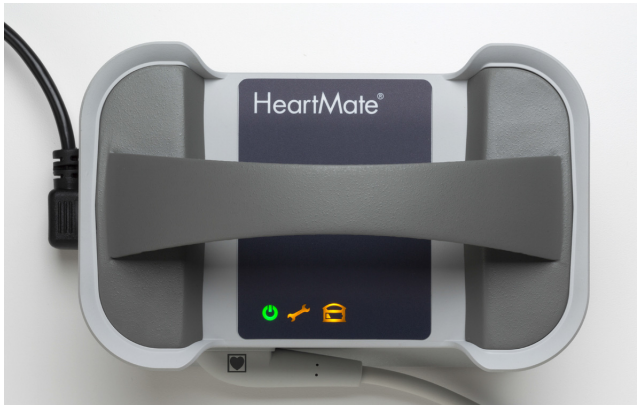
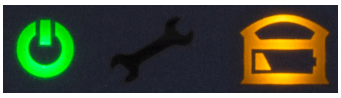


Figure 7.5 Indicators on the Mobile Power Unit

Table 7.21 provides a description of the Mobile Power Unit alarms and how to resolve each alarm.

Note: If there is an alarm for the Mobile Power Unit but no light comes on, contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

Table 7.21 Mobile Power Unit Alarms

Alarm Symbol	Meaning	What You Should Do
 **Advisory Alarm** Yellow Mobile Power Unit battery indicator with beeping audio tone	Internal AA Mobile Power Unit batteries need to be replaced.	1. Promptly switch to two batteries. 2. Replace Mobile Power Unit batteries.
 **Advisory Alarm** Yellow wrench light with beeping audio tone	Internal malfunction detected within the Mobile Power Unit.	Promptly switch to batteries.

Using the Charger to Check Battery or Charger Status

The Battery Charger continually monitors its own performance and that of any battery placed into a pocket. Actual or potential problems, or "faults," appear as "advisory messages" on the display panel.

Battery-Related Advisory Messages

If the Battery Charger detects a problem with a battery, such as battery voltage too high or too low, or open battery circuit, the red light for the pocket comes on and a telephone symbol appears on the display panel to indicate a battery fault (**Figure 7.6**).

Figure 7.6 Advisory Display in Graphics Mode. Note Red Light for Pocket 1.

Before assuming that the battery is defective, make sure that the connection between the battery and charging pocket contacts is not blocked by dirt or debris.

TO CONFIRM A BATTERY FAULT:

1. Remove the battery. Examine the battery's metal contact and the contact inside the charging pocket. If there is no dirt, debris, or obstruction, continue to Step 2.
2. Reinsert the battery into the same pocket.
3. If the red light comes on again, insert the battery into a different pocket.
4. If the red light comes on in a second pocket, the battery is defective. Do not use it.
5. Obtain the alarm code for the battery, if possible:
   a. Press and hold the number button for this pocket.

      The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes related to batteries begin with the letter "B."

   b. Record the alarm code and save it for future reference.
6. Remove the defective battery from use.

Charger-Related Advisory Messages

The Battery Charger can detect a problem or fault condition in up to four charging pockets at once (with or without batteries inserted), or with the entire charger unit. The Battery Charger alerts immediately of any problems.

Detecting Pocket Faults

When the charger detects a pocket fault, the red light for the affected pocket comes on, with or without a battery inserted in the pocket. In addition, the charger immediately stops charging or calibrating the battery in the affected pocket, if one is present.

TO REPORT A BATTERY CHARGER POCKET FAULT:

1. Remove the battery from the affected pocket, if one is inserted.
2. Record the alarm code for the defective pocket, if possible:
    a. Press and hold the number button for this pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes related to pocket problems begin with the letter "S."
    b. Record the alarm code and save it for future reference.

IMPORTANT! Do not use a defective charging pocket until it is repaired or until the Battery Charger is replaced. The pockets that are *not* defective can still be used.

Detecting Faults with the Entire Charger

If the charger detects a fault with the entire charger, all four red lights come on and all charging and calibrating stops.

TO REPORT A FAULT FOR THE ENTIRE CHARGER:

1. Remove all batteries from all pockets.
2. Record the alarm code for the fault condition, if possible:
    a. Press and hold the number button for any pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes for the entire charger begin with the letter "S."
    b. Record the alarm code and save it for future reference.
3. Turn off the charger; unplug it from the electrical outlet.

IMPORTANT! Do not use a damaged or defective Battery Charger until it is repaired or replaced. Until there is a safe and reliable way to recharge batteries, use the HeartMate Power Module or Mobile Power Unit to power the HeartMate system.

Battery Charger Display Panel Messages

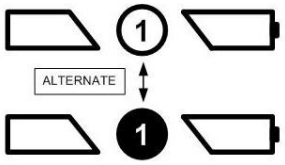
The English mode always displays first. The following shows the screens to select the mode.

Change Display Mode to English	ENGLISH OK ▼
Change Display Mode to Graphics	GRAPHICS OK ▼

Table 7.22 describes the messages that appear on the Battery Charger display panel.

KEY for Table 7.22	
Y	Battery Charger pocket number
# = X	Battery charge cycle count
mAh	milliamp-hour
C	Battery capacity
B0001	Battery fault with alarm code, example
S0001	Battery Charger pocket (slot) fault with alarm code, example

Table 7.22 Battery Charger Display Panel Messages

Meaning	English Mode	Graphics Mode
Ready for Use	HeartMate CHARGER	HeartMate CHARGER
Battery Charge Status	Y: ▮▮▮▮	1:  50%
Battery Information (3rd screen)	# = X X: mAh = C	# = X X: mAh = C
Charge Complete	READY Y: ▮▮▮▮	1: 
Request Calibration	CALIBRATE? PRESS Y	
Accept Calibration	PROGRESS Y: CALIBRATING	1: 
Charger Fault	CALL SERVICE	
Battery Fault (Button Push)	CALL SERVICE B0001	
Charger or Pocket Fault (Button Push)	CALL SERVICE S0001	

Guidelines for Power Cable Connectors

Use care when connecting and disconnecting power cable connectors.

Be sure to:

- Line up the half circles inside the connectors (**Figure 7.7**).
- Gently bring the connectors together, turning them slightly to make the connection, if needed.
- Never pull, turn, or twist the strain relief portion of the connectors (where the connector and cable meet).
- When the connectors engage, push them together firmly until fully connected, without twisting or forcing the connectors.
- Secure the connection between the connectors by turning the connector nut on the connector (**Figure 7.8**).
- Hand tighten the connector nut. Do not use tools. Do not twist the connectors when turning the nut.
- When disconnecting connectors, turn the connector nut on the connector until the connection is loose and then gently pull the connectors apart.
- Never twist connectors or pull them apart at an angle.

Figure 7.7 Align Half Circles

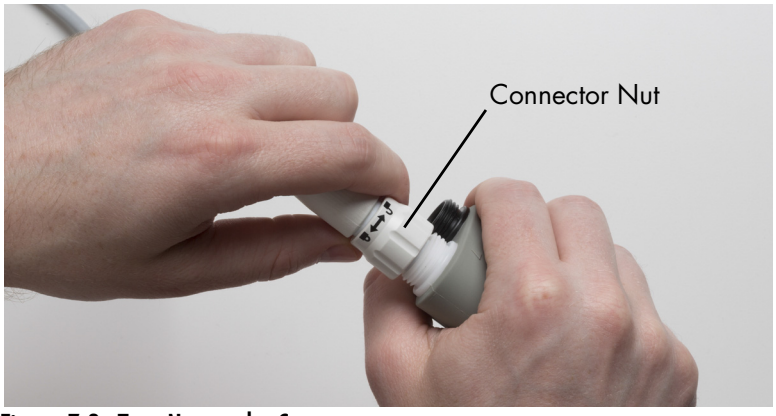


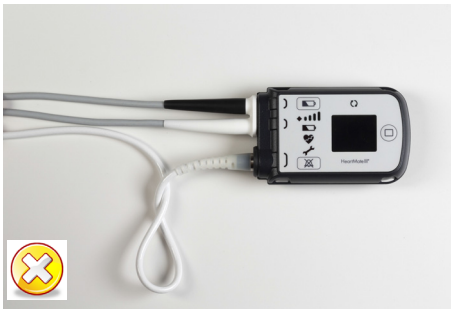
Figure 7.8 Turn Nut on the Connector

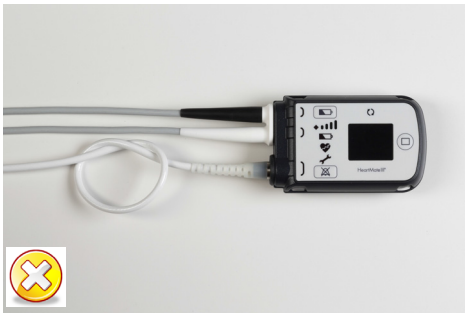
What Not to Do: Driveline and Cables

Check the Driveline, System Controller power cables, Power Module patient cable, and Mobile Power Unit patient cable for twisting, kinking, or bending. Any of these can cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

CAUTION !

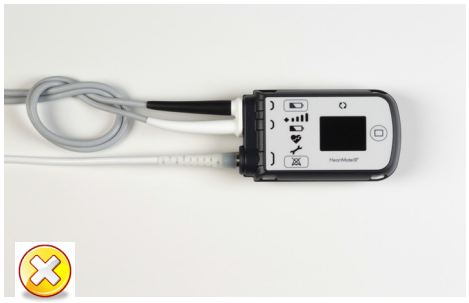
Use care and do not twist, kink, or sharply bend the Driveline.





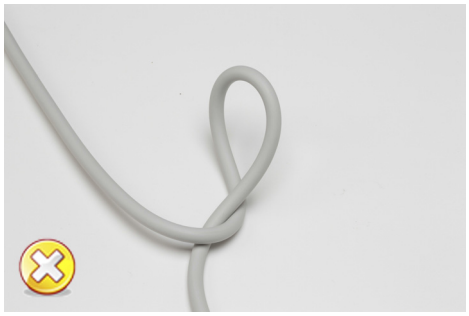
CAUTION !

Use care and do not twist, kink, or sharply bend the System Controller power cables.



CAUTION !

- Do not twist, kink, or sharply bend the Mobile Power Unit patient cable.
- Route the patient cable so it will not cause a tripping or falling hazard.
- Take care when moving around while connected to the Mobile Power Unit, that it is not inadvertently pulled off of furniture.

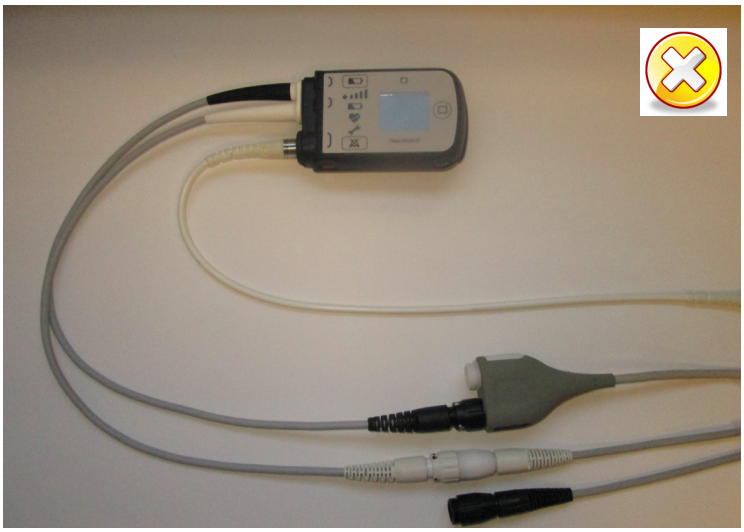


CAUTION !

Use care and do not twist, kink, or sharply bend the Power Module patient cable.

WARNING !

Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.



EQUIPMENT STORAGE AND CARE

This section provides information on how to store and care for the HeartMate III Left Ventricular Assist System.

8 Equipment Storage and Care

Storage and Transport

Acceptable Packaged Storage and Transport Conditions

Storing and transporting the equipment outside of the environmental parameters listed in **Table 8.1** may affect operation or result in equipment failure.

Table 8.1 Acceptable Environmental Conditions for Packaged Storage and Transport

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Power Module with Backup Battery	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Power Module Patient Cable	5°F to 122°F (-15°C to 50°C)	10% to 93%	375 to 795 (500 to 1060)
System Monitor	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Mobile Power Unit	-13°F to 158°F (-25°C to 70°C)	Up to 93%	375 to 795 (500 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries	14°F to 104°F (-10°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
HeartMate 14 Volt Battery Clips	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Battery Charger	-4°F to 140°F (-20°C to 60°C)	10% to 93%	375 to 795 (500 to 1060)
System Controller, Backup System Controller	-13°F to 104°F (-25°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
11 Volt Lithium-Ion Backup Battery	-13°F to 104°F (-25°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Wear and Carry Accessories, including Shower Bag	-4°F to 131°F (-20°C to 55°C)	20% to 85%	Not applicable

8 Equipment Storage and Care

Cleaning and Maintenance

Although the HeartMate III LVAS does not have external moving components, the external components should undergo routine and periodic inspections, cleaning, and maintenance as prescribed in this section.

General Cleaning Guidelines for All Equipment

Use a damp cloth to clean exterior surfaces of the system components, as needed. Water, with or without a mild dish soap, may be used as a surface cleaner.

WARNING !

- Do not allow water to penetrate into the interior of the equipment.
- Do not immerse equipment in water or liquid. Immersion in water or liquid may cause the Pump to stop.

Cleaning the System Controller

As needed, clean exterior surfaces of the System Controller with a damp, lint-free cloth. If more aggressive cleaning is needed, use warm water and a mild dish soap.

WARNING !

Never submerge the System Controller into water or liquid. Submersion in water or liquid may cause the Pump to stop.

Periodically inspect the System Controller's power connector pins for dirt or grease. If damage, dirt, or contamination on the pins is found, do not attempt to clean the pins yourself. Report the condition to Thoratec Corporation. Cleaning and service for the System Controller's power connector pins should be performed only by authorized technicians trained by Thoratec Corporation.

Periodically inspect the System Controller's audio speakers for dirt or grease. If a change in tone or in loudness is noticed during a System Controller self test, the audio speaker sockets may be obstructed. Audio speaker sockets may be cleaned using a small cotton swab that is moistened (not dripping) with rubbing alcohol. Never insert anything sharp (such as a toothpick or pin) into the audio speaker sockets.

CAUTION !

Inserting a sharp object into the System Controller audio socket may damage the speakers inside.

WARNING !

Do not disconnect the System Controller from the Driveline for cleaning.

Disconnecting the Driveline from the System Controller will cause the Pump to stop. The System Controller Driveline connector should be disconnected only when replacing the System Controller. Refer to *Backup System Controller Overview* on page 2-41.

Cleaning System Controller Power Cables

As needed, clean exterior surfaces of the System Controller power cables with a damp, lint-free cloth. If more aggressive cleaning is needed, use warm water and mild dish soap. Keep the System Controller power cables dry and away from water or liquid.

If the System Controller power cables come into contact with water or liquid, the system may fail to operate properly or cause a serious electrical shock.

Care of the Driveline

Damage due to wear and fatigue of the Driveline has occurred in both the externalized and implanted portions of the Driveline of commercially available implantable LVADs. Damage to the redundant wires within the Driveline may or may not be preceded by visible damage to the outer layer of the Driveline.

Driveline damage may be evidenced by the following:

- Driveline faults may occur on Battery or Power Module operation.
- Transient alarms due to short or open circuits, often associated with movement of the patient or the Driveline.
- High pump power associated with reduced pump speed, as recorded in the System Controller event log file.
- High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
- Feelings of pump vibrations.
- Fluid leakage from the external portion of the Driveline.
- Cessation of pumping.

If the Driveline is suspected of damage, contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

X-ray images may be useful to assess the extent and location of the Driveline damage. If damage to the electrical conductors in the Driveline is confirmed, the Left Ventricular Assist Device should be replaced as soon as possible.

A disruption to the continuity of the wires in the Driveline may cause damage to the System Controller. If damage to the System Controller occurs and the System Controller requires replacement, consider supporting the patient using batteries to reduce the potential of further damage to the System Controller.

Cleaning the Driveline

As needed, clean exterior surfaces of the Driveline cables with a damp, lint-free cloth. If more aggressive cleaning is needed, use warm water and mild dish soap.

Caring for the Power Module and Mobile Power Unit

Inspect the HeartMate Power Module and the Mobile Power Unit routinely as described in *Safety Checklists* on page D-1 for the safest and best possible performance.

IMPORTANT! Do not disconnect the System Controller from the Driveline. This connection should be inspected only when replacing the System Controller. Refer to *Replacing the Current System Controller* on page 2-46.

Cleaning the Power Module and Mobile Power Unit

Periodically, and as needed, unplug the Power Module and Mobile Power Unit and clean the exterior surfaces using a clean, damp (not wet) cloth. Use a mild detergent, if necessary. Keep the Power Module and Mobile Power Unit dry and away from water or liquid.

If the Power Module or Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or cause an electrical shock.

Do not clean the Power Module or Mobile Power Unit while it is being used to power the Left Ventricular Assist System.

If the Mobile Power Unit is left in storage for a long period of time with the batteries installed, the alkaline batteries may corrode. If corrosion is observed, report the condition to Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information.

Cleaning and service should be performed only by personnel trained by Thoratec Corporation. Do not attempt to clean or repair equipment. Thoroughly wash any areas where contact with corroded batteries is made.

IMPORTANT! Ensure that the Power Module backup battery is reconnected after service or shipping. Refer to *Reconnecting the Power Module Backup Battery* on page 3-30.

Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. Follow the guidelines and instructions in the *Safety Checklists* on page D-1.

Clean the metal battery contacts and the interior contacts of battery clips monthly using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the

alcohol to dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use (**Figure 8.1**).

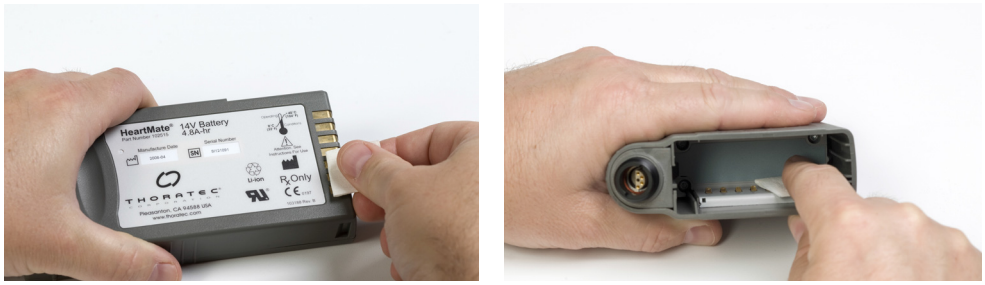


Figure 8.1 Cleaning the Battery Contacts and Clips

Cleaning the Battery Charger

The Battery Charger requires little maintenance. However, it should be inspected routinely for the safest and best possible performance. For more information, refer to the *Safety Checklists* on page D-1.

Cleaning HeartMate Wear and Carry Accessories

HeartMate wear and carry accessories are designed to securely hold or protect HeartMate III components. The accessories include:

- Shower Bag
- Consolidated Bag
- System Controller Neck Strap
- Belt attachment
- Holster vest
- Battery holster
- Protection Bag

Keep the wear and carry accessories clean to help them work properly. If an accessory gets dirty, wash it by hand using mild detergent, a medium-bristle brush, and cold water. Never use a washing machine to wash a wear and carry accessory. Hang the accessory to drip dry. Always allow it to air dry on its own. Never use a clothes dryer or hair dryer to dry a wear and carry accessory. Mechanical washers and heated dryers can damage the accessories. Make sure an accessory is completely dry before using it—this includes the Shower Bag.

Periodically inspect the wear and carry accessories for damage or wear. If an accessory appears damaged or worn, do not use it. Contact Thoratec Corporation with questions or to order a replacement, if needed.

Product Disposal

Specific product disposal considerations for certain HeartMate equipment appear below. Otherwise, dispose of all expired or damaged equipment according to applicable local, state, and federal regulations. For additional product disposal information, please contact Thoratec Corporation for assistance. Refer to page iii for Thoratec Corporation contact information.

Batteries

HeartMate 14 Volt Lithium-Ion batteries do not contain lead. Dispose of or recycle HeartMate 14 Volt batteries in compliance with all applicable local, state, and federal regulations. Do not incinerate.

The Power Module backup battery and 11 Volt Lithium-Ion backup battery contain lead. Dispose of the Power Module backup battery and 11 Volt Lithium-Ion backup battery in compliance with all applicable local, state, and federal regulations. Never incinerate the discarded Power Module backup battery or 11 Volt Lithium-Ion backup battery.

Power Module

Dispose of or recycle Power Module and Power Module electronics in compliance with all applicable local, state, and federal regulations.

Mobile Power Unit

Dispose of or recycle Mobile Power Unit and Mobile Power Unit electronics in compliance with all applicable local, state, and federal regulations.

Battery Charger

Dispose of or recycle the Battery Charger and Battery Charger electronics in compliance with all applicable local, state, and federal regulations.

System Monitor

The System Monitor contains a lithium battery (non-serviceable). Dispose of or recycle the System Monitor's internal battery in compliance with all applicable local, state, and federal regulations. Never incinerate discarded System Monitor batteries.

TECHNICAL SPECIFICATIONS

This section provides the technical specifications for the HeartMate III Left Ventricular Assist System.

Specifications

The technical specifications for the HeartMate III Left Ventricular Assist System are listed here. For ordering information and catalog numbers, refer to the *HeartMate III™ Product List* at www.thoratec.com.

HeartMate III Left Ventricular Assist System Implant Kit

BLOOD VOLUMES-FLUID CAPACITY	
Dimensions (pump body)	
Diameter	50.3 mm (2.0 in.)
Height	55.8 mm (2.2 in.) Includes Inflow Cannula 33.8 mm (1.3 in.) Excludes Inflow Cannula
Weight (pump body)	200 g (7.0 oz)
Displaced Volume	80 cc (4.9 cu in.)
Priming Volume	21 cc (1.3 cu in.)
BLOOD CONTACTING SURFACES	
Titanium	Fused titanium microspheres
Sealed Outflow Graft	Gelatin-impregnated woven polyester
Inflow Cannula	Integrated titanium with fused titanium microspheres
CONSTRUCTION	
Outer Shell	Titanium
Apical Cannula	20.5 mm (0.8 in.) titanium
Apical Cuff	PTFE Felt with integrated locking ring
Sealed Outflow Graft	Gelatin-impregnated 14 mm woven polyester, with 10.0N attachment force to the Pump
Electric Line	6-conductor shielded silicone sheath - 2 piece Driveline (Pump Cable connected to the Modular Cable via an in-line modular connection)
PERFORMANCE DATA	
Power Consumption	4 watts nominal
Operating Voltage	10–17 Volts DC
Pump Speed Range	3,000–9,000 rpm
Minimum Pump Speed	3,000 rpm

Sterile HeartMate III System Controller

ACTIVE FUNCTIONS
• Monitoring of System Performance • Communication with implanted LVAD • Communication with System Monitor (via the Power Module)

OPERATING MODES	
Run Mode	Connected to LVAD
Charge Mode	No LVAD Connected for Backup Battery Charging
Sleep Mode	Internal Clock Maintenance
Power Saver Mode	During low battery hazard operation
MONITORING FUNCTIONS	
Fault detection and alarms	
Performance data processing and storage	
Battery state-of-charge indicators and alarms	
LVAD Status	
Driveline continuity check	
Backup battery charge status	
ALARM SOUND PRESSURE LEVEL (SPL)	
Hazard Alarms: 85 dB 2300 Hz ± 300 Hz	
Advisory Alarms: 85 dB 2300 Hz ± 300 Hz	
DIMENSIONS	
Length	12.7 cm (5 in.)
Height	3.5 cm (1.375 in.)
Width	8.0 cm (3.125 in.)
WEIGHT	336 g (12 oz)
PRODUCT LIFE	Three years from date of first use

11 Volt Lithium-Ion Backup Battery

PERFORMANCE DATA	
Type	11 Volt Lithium-Ion
Capacity	12.2 watt-hour
Discharge Time	15 minutes at 10 Watts (pump speed = 9,000 rpm, flow = 10.0 L/min)
Charge Time	3 hours maximum, with a minimum voltage of 13.0V
DIMENSIONS	
Length	7.1 cm (2.8 in.)
Width	5.1 cm (2 in.)
Height	1.5 cm (0.6 in.)
WEIGHT	84.6 g (2.98 oz)
PRODUCT LIFE	10950 cumulative discharge minutes, as tracked by the System Controller and reported on the System Monitor, or 3 years from the date of manufacture, whichever comes first.

Power Module

ACTIVE FUNCTIONS
Isolated power to patient during tethered operation
Communication interface between System Controller and System Monitor
When new, AC power failure backup battery (30 minutes to operate HeartMate III Left Ventricular Assist System)
MONITORING FUNCTIONS
Isolated bidirectional data link to external System Monitor
Isolated dual-channel analog uplink AC power failure alarm
Advisory/Hazard LO BATT alarm for internal backup battery
"Echoes" System Controller Audio Alarm
System Malfunction Alarm (Yellow Wrench)
ALARM SOUND PRESSURE LEVEL (SPL)
Hazard Alarms: 80 dB
Advisory Alarms: 80 dB
POWER REQUIREMENTS
100–240 VAC, 50–60 Hz, 1 A maximum

To isolate the system from the AC wall power, pull the power cord from the wall socket.

FUSE RATING	T 2A, 250 V
DIMENSIONS	
Length	381 mm (15 in.)
Width	254 mm (10 in.)
Height	127 mm (5 in.)
WEIGHT	4.8 kg (10.5 lb)—with backup battery
PRODUCT LIFE	Two years from date of first use

Power Module Patient Cable

TYPE	A cable assembly that has one straight plug connector with sliding interlock and composite strain relief for connecting to the Power Module, and two thread-locking power connectors for connecting to the System Controller
FUNCTION	To provide connection between the System Controller and the Power Module
LENGTH	6.1 m (20 ft)
PRODUCT LIFE	One year from date of first use

Mobile Power Unit

ACTIVE FUNCTIONS	
Isolated power to patient during tethered operation	
MONITORING FUNCTIONS	
Fault detection and alarms	
"Echoes" System Controller Audio Alarm	
ALARM SOUND PRESSURE LEVEL (SPL)	
Hazard Alarms: 80 dB	
Advisory Alarms: 80 dB	
POWER REQUIREMENTS	
100–240 VAC, 50/60 Hz, 2.0–1.0 A maximum	
To isolate the system from the AC wall power, remove the power cord from the wall socket.	
DIMENSIONS	
Length	18.4 cm (7.25 in.)
Width	12.7 cm (5.0 in.)
Height	12.7 cm (5.0 in.)
CABLE LENGTH	6.1 m (20 ft)
WEIGHT	1.4 kg (3.0 lb) - with three AA (LR6) batteries
PRODUCT LIFE	Two years from date of first use

HeartMate 14 Volt Lithium-Ion Battery

PERFORMANCE DATA	
Type	14 Volt, Lithium-Ion
Capacity	4.8 amp-hour each or 71 watt-hour
Discharge Time	One pair of new HeartMate 14 Volt Lithium-Ion batteries provides 17 hours of support under nominal operating conditions for a HeartMate III Left Ventricular Assist System (5.4 lpm)
Power Gauge	5-LED, button activated
Charge Time	4 hours maximum (using Battery Charger)

DIMENSIONS	
Length	160 mm (6.3 in.)
Width	76 mm (3.0 in.)
Height	25 mm (1.0 in.)
WEIGHT	0.50 kg (1.1 lb)—System accommodates two batteries
PRODUCT LIFE	360 cycles (as reported when the battery is inserted into a charging pocket of the Battery Charger), or 3 years from the date of manufacture, whichever comes first

14 Volt Lithium-Ion Battery Clip

DIMENSIONS	
Length	80 mm (3.15 in.)
Width	92 mm (3.75 in.)
Height	32 mm (1.25 in.)
WEIGHT	104 g (3.7 oz)—without battery
PRODUCT LIFE	Two years from date of first use

Battery Charger

ACTIVE FUNCTIONS	
Four pockets for simultaneous battery charging for HeartMate 14 Volt Lithium-Ion batteries	
Battery calibration and diagnostics	
MONITORING FUNCTIONS	
Battery fault monitoring (with alarm codes)	
Battery charger fault monitoring (with alarm codes)	
POWER REQUIREMENTS	
100–240 VAC, 50–60 Hz, 3 A (maximum)	
Fuse Rating - T5A, 250 V	
DIMENSIONS	
Length	370 mm (14.5 in.)
Width	216 mm (8.5 in.)
Height	227 mm (9 in).
WEIGHT	3.6 kg (8 lb)
PRODUCT LIFE	Two years from date of first use

System Monitor

TYPE	Backlit Color LCD display with touch-screen interface
RESOLUTION	640 x 480 pixels
FUNCTION	
Clinical Screen	• Displays speed, flow (lpm), pulsatility index, power, mode (fixed), and Fixed Speed setpoint. • Displays prioritized alerts and advisories.
Settings Screen	• Displays system status and prioritized alerts/advisories. • Permits control of Fixed Speed values, Low Speed Limit values, and pump stop/start.
Alarms Screen	Displays all alerts and advisories. Permits control of extended alarm silence.
Save Data Screen	Permits control of data collection.
History Screen	Displays controller event recorder data.
Admin Screen	• Displays current date and time. • Permits control of date/time and technical parameters.
DIMENSIONS	
Length	305 mm (12.0 in.)
Depth	165 mm (6.5 in.)
Height	245 mm (10.0 in.)
WEIGHT	2.49 kg (5.5 lb)

HeartMate Consolidated Bag

TYPE	Slim profile shoulder bag for use with HeartMate III Left Ventricular Assist System
FUNCTION	Allows patient to wear and carry HeartMate III batteries, battery clips, and System Controller
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
CONFIGURATION	Right-side Driveline exit/right-side wear Left-side Driveline exit/left-side wear
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

HeartMate Shower Bag

TYPE	Water-resistant Shower Bag for use with HeartMate III Left Ventricular Assist System
FUNCTION	Protects external system components from moisture during showering
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

HeartMate Battery Holster

TYPE	Battery holder
FUNCTION	Allows patient to wear two HeartMate 14 Volt Lithium-Ion batteries close to the body while performing daily activities
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

HeartMate Holster Vest

TYPE	Vest
FUNCTION	Allows patient to wear two HeartMate 14 Volt Lithium-Ion batteries close to the body while performing daily activities
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZES	For small users less than 160 lb (73kg) For medium users 160–240 lb (73–109 kg) For large users greater than 240 lb (109 kg)
PRODUCT LIFE	Two years of continuous use

HeartMate Wearable Accessories Kit

TYPE	• System Controller Neck Strap • System Controller Belt Attachment • System Controller Protection Bag
FUNCTION	• System Controller Neck Strap and System Controller Belt Attachment provide options for the patient to wear HeartMate III System Controller • System Controller Protection Bag protects the backup System Controller and cables when not in use
PRODUCT COMPATIBILITY	For use with HeartMate III System Controller
STRENGTH	Each accessory accommodates the weight of the System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	At least two years of continuous use

HeartMate Travel Bag

TYPE	Shoulder Bag
FUNCTION	Provides a convenient way to carry and transport the backup System Controller and spare batteries
PRODUCT COMPATIBILITY	For use with HeartMate III Left Ventricular Assist System
STRENGTH	The Travel Bag accommodates the weight of the batteries and System Controller with a significant safety factor to allow for forces imparted by daily activities.
COLOR	Black
SIZES	One size fits most
PRODUCT LIFE	At least two years of continuous use

SAFETY TESTING AND CLASSIFICATION

This section provides safety testing and classification information for the HeartMate III Left Ventricular Assist System.

Safety Testing and Classification

The HeartMate III Left Ventricular Assist System has been thoroughly tested and Classified by Underwriters Laboratories, LLC (UL) to the fire, casualty, and electric shock hazard requirements of the following safety standards, as applicable:

- IEC 60601-1:2012 (ed. 3.1)
- IEC 60601-1:2005 + Corr. 1:2006 + Corr. 2:2007 (ed. 3.0)
- IEC 60601-1-11:2015
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-1-6:2010 + A1:2013
- IEC 62366:2007 + A1:2014
- EN 60601-1:2006/A1:2013 (ed. 3.1)
- EN 60601-1:2006 +Corr. 2:2010 (ed. 3.0)
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012 (ed. 3.1)
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1:14 (ed. 3.1)
- CAN/CSA C22.2 No. 60601-1:08 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1-11:15

These standards require making the following declarations and stating the type and degree of protection for listed hazards.

- UL 60601-1, 1st ed., 2006-04-26
- CAN/CSA-C22.2 No. 601.1-M90 (R2005)

Medical Electric Equipment
with respect to shock, fire,
mechanical and other specified
hazards only in accordance with
UL 60601-1 and CAN/CSA C22.2
No.601.1-M90 (R1997), CAN/CSA C22.2
No.601.1S1-94, and CAN/CSA-C22.2
No.601.1B-98 (National Difference for Canada)
No.601.1 7D72

Declaration Concerning General Safety Standards

Table B.1 Declaration Concerning General Safety Standards

Mode of Operation	Continuous/Pulse
Method of Sterilization	100% EtO for blood pump, Controller, and all sterile accessories
Type of protection against electrical shock	Power Module: • Class I (grounded) when connected to AC Mains • Class II when connected to Backup Battery Lithium-Ion Batteries: Class II Battery Charger: Class I Mobile Power Unit: Class II
Degree of protection against electric shock	Type CF (Cardiac Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water and particulate matter	• System Controller–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water • Power Module–IPX0:Non-protected against ingress of water • System Monitor–IPX1:Protection against ingress of vertically dripping water • Shower Bag–IPX3: Protection against ingress of spraying water • 14 V Battery and Clip (only when connected to the System Controller)–IP24: Protection against ingress of solid foreign objects the size of a finger and from splashing water • Battery Charger–IPX0: Non-protected against ingress of water • Mobile Power Unit–IP22: Protection against ingress of solid foreign objects the size of a finger and vertically falling water drops when the enclosure is tilted up to 15°
Applied parts	• HeartMate III Left Ventricular Assist Device • System Controller
Performance Determined to be Essential Performance	• Maintain Pump Speed (Note: Pump Speed is the characteristic that the physician uses to set the desired blood flow.) • Alarm for Pump Speed performance outside of the essential performance limits. • Prevent Leakage in Blood Path.

Testing and Classification: HeartMate III LVAS

The HeartMate III Left Ventricular Assist System has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate III Left Ventricular Assist System can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Corporation for assistance.

Note: Special precautions are required for installing and using the HeartMate III Left Ventricular Assist System within portable and RF communication environments.

The HeartMate III Left Ventricular Assist System is protected against the effects of external cardiac defibrillation within the limits established per EN 45502-1:1997. However, it is advised that the HeartMate III Left Ventricular Assist System be disconnected from the System Controller during the use of open-heart defibrillation.

Testing and Classification: Power Module

Declaration and Guidance for Electromagnetic Disturbances

The HeartMate III LVAS (powered by the Power Module) is suitable for use in the following environments:

- Hospitals, including ORs and emergency rooms
- Treatment areas near active HF Surgical equipment.

Table B.2 Declaration and Guidance Concerning Electromagnetic Emissions for HeartMate III Powered by the Power Module

HEARTMATE III LVAS Powered By the Power Module (with System Monitor)		
EM Disturbance type / Standards	**IEC 60601-1-2 (2014) Compliance Level**	**Use Environment Guidance**
RF Emissions / CISPR 11 EN 55011	Group 1, Class A 30 – 1,000 MHz	The HeartMate III LVAS with Power Module is not suitable for use in domestic establishments or those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate III LVAS with Power Module (PM) and System Monitor uses RF energy only for its internal purposes and thus have low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Harmonic Emissions / IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations & Flicker Emissions / IEC 61000-3-3 EN 61000-3-3	Complies fully	
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±8 kV Contact ±15 kV Air	The relative humidity where the HeartMate III LVAS with PM is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with PM are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 2.7 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with PM are recommended: 80 - 800 MHz: 3.8 m (12.7 feet) 800 MHz – 2.7 GHz: 7.3 m (24.3 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate III LVAS may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m[1]; 430 - 470 MHz, 42 V/m[3]; 704 - 787 MHz, 13 V/m[2]; 800 - 960 MHz, 42 V/m[1]; 1.7 - 1.99 GHz, 42 V/m[2]; 2.4 - 2.57 GHz, 42 V/m[2]; and 5.1 - 5.8 GHz, 13 V/m[2] [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate III LVAS with Power Module, and its parts, than 0.2 m (8 inches). Equipment[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate III LVAS with Power Module.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate III LVAS with Power Module is used.
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line and ± 0.5, ± 1 kV, and ± 2 kV line to earth	

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate III LVAS with PM is recommended: Outside ISM/Amateur bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment[a] examples: CB Radios, Amateur "HAM" radios, and Diathermy medical devices. Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union. [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate III LVAS with PM is used.

Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T; ½ cycle 0 % of U_T; 1 cycle and 70 % of U_T; 25 or 30 cycles (0.5 sec.) 0 % of U_T; 250 or 300 cycles (5 sec.)	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate III LVAS with PM is used. Note - U_T: A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)

WARNING !

- The HeartMate III Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate III Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate III LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.
- Use of accessories or cables other than those specified or provided by Thoratec Corp. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate III LVAS (powered by the Power Module), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (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 (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate III Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate III LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III LVAS.

These guidelines may not apply in all situations.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Testing and Classification: Mobile Power Unit

Declaration and Guidance for Electromagnetic Disturbances for the Mobile Power Unit

The HeartMate III LVAS (powered by the Mobile Power Unit) is suitable for use in the following environments:

- Hospitals, including ORs and emergency rooms
- Treatment areas near active HF Surgical equipment.
- Homes, workplaces and retail places.
- Public or private passenger watercraft/boats, ferries, etc.

Table B.3 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit

HeartMate III LVAS Powered By the Mobile Power Unit		
EM Disturbance type / Standards	**IEC 60601-1-2 (2014) Compliance Level**	**Use Environment Guidance**
RF Emissions / CISPR 11 EN 55011	Group 1, Class B 30 – 1,000 MHz	The HeartMate III LVAS with Mobile Power Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate III LVAS with Mobile Power Unit uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Harmonic Emissions / IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations & Flicker Emissions / IEC 61000-3-3 EN 61000-3-3	Complies fully	
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±8 kV Contact ±15 kV Air	The relative humidity where the HeartMate III LVAS with Mobile Power Unit is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with Mobile Power Unit are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 2.7 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with Mobile Power Unit are recommended: 80 - 800 MHz: 3.8 m (12.5 feet) 800 MHz – 2.7 GHz: 7.3 m (24.0 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate III LVAS may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m[1]; 430 - 470 MHz, 42 V/m[3]; 704 - 787 MHz, 13 V/m[2]; 800 - 960 MHz, 42 V/m[1]; 1.7 - 1.99 GHz, 42 V/m[2]; 2.4 - 2.57 GHz, 42 V/m[2]; and 5.1 - 5.8 GHz, 13 V/m[2] _____ [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate III LVAS with Mobile Power Unit, and its parts, than 0.2 m (8 inches). Equipment[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate III LVAS with Mobile Power Unit. [a] – List is not comprehensive.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate III LVAS with Mobile Power Unit is used.
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line	

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM and amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate III LVAS with Mobile Power Unit is recommended: Outside ISM/Amateur bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment[a] examples include: CB Radios, Amateur "HAM" radios, Diathermy medical devices, Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate III LVAS with Mobile Power Unit is used.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T; ½ cycle 0 % of U_T; 1 cycle and 70 % of U_T; 25 or 30 cycles (0.5 sec.) 0 % of U_T; 250 or 300 cycles (5 sec.)	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate III LVAS with Mobile Power Unit is used. Note – U_T: A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate III LVAS (powered by the Mobile Power Unit), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate III LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.
- Avoid use of the HeartMate III LVAS (and its cables and parts) within 5 cm (2 inches) of a microwave oven or its cord. Keep all HeartMate III LVAS components and their cables away from other electronic devices and their cables/cords.
- The HeartMate III Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate III Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories or cables other than those specified or provided by Thoratec Corp. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (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 (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate III Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeatMate III LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III LVAS.

These guidelines may not apply in all situations.

Testing and Classification: Battery Charger

The Battery Charger complies with the following safety standards:

- EN 60950-1: 2006 + A11: 2009 + A1: 2010 + A12: 2011
- IEC 60950-1: 2005, 2nd Edition + Am1:2009
- UL 60950-1, 2nd Edition, 2011
- CSA C22.2 No. 60950-1-07, 2nd Edition, 2011
- IEC 60601-1: 1988, 2nd Edition, A1:1991, A2:1995
- UL 60601-1, 1st Edition, 2003-04-26 (included National Differences for USA)
- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98 (National Difference for Canada)

This equipment has been tested and found to comply with the limits for devices to IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult Thoratec Corporation for assistance.

Declaration Concerning General Safety Standards for Battery Charger

Table B.4 Declaration Concerning General Safety Standards for Battery Charger

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against mains shock	Class I (grounded)
Degree of protection against harmful ingress of water	IPX0

Declaration and Guidance for Electromagnetic Disturbances for Battery Charger

The HeartMate Battery Charger is suitable for use in the following environments:

- Hospitals, including ORs and emergency rooms
- Homes, workplaces and retail places
- Public or private passenger watercraft/boats, ferries, etc.

Table B.5 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger

HEARTMATE BATTERY CHARGER		
EM Disturbance type / Standards	**IEC 60601-1-2 (2014) Compliance Level**	**Use Environment Guidance**
RF Emissions / CISPR 11 EN 55011	Group 1, Class B 30 – 1,000 MHz	The HeartMate Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate Battery Charger uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Harmonic Emissions / IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations & Flicker Emissions / IEC 61000-3-3 EN 61000-3-3	Complies fully	
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±6 kV Contact ±8 kV Air	Flooring material should be wood or tile. If flooring is synthetic, the relative humidity should be at least 30%. Higher relative humidity will reduce the severity of ESD events.

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 2.7 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended: 80 - 800 MHz: 3.8 m (12.5 feet) 800 MHz – 2.7 GHz: 7.3 m (24.0 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate Battery Charger may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 27 V/m[1]; 430 - 470 MHz, 28 V/m[3]; 704 - 787 MHz, 9 V/m[2]; 800 - 960 MHz, 28 V/m[1]; 1.7 - 1.99 GHz, 28 V/m[2]; 2.4 - 2.57 GHz, 28 V/m[2]; and 5.1 - 5.8 GHz, 9 V/m[2] _____ [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate Battery Charger, and its parts, than 0.3 m (12 inches). Equipment[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line and ± 0.5, ± 1 kV, and ± 2 kV line to earth	

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (Within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate Battery Charger is recommended: 150 kHz - 80 MHz: 1.7 m (5.7 feet) Equipment[a] examples include: CB Radios, Amateur "HAM" radios, and Diathermy medical devices. Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	3 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T; ½ cycle 0 % of U_T; 1 cycle and 70 % of U_T; 25 or 30 cycles (0.5 sec.) 0 % of U_T; 250 or 300 cycles (5 sec.)	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used. U_T: A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HeartMate III Battery Charger, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories or cables other than those specified or provided by Thoratec Corp. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use the Battery Charger next to other equipment.
- Do not stack the Battery Charger on top of other equipment.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (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 (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate III Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate III LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III LVAS.

These guidelines may not apply in all situations.

Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries

HeartMate 14 Volt Lithium-Ion batteries comply with the following safety standards:

- IEC/EN 62133
- UL 2054
- UN 38.3 T1-8

Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

Table B.6 Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

Type	Degree of Protection
Degree of protection against electric shock	No Applied Part
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress	IP24 only when connected to the System Controller through Clip

Declaration and Guidance for Electromagnetic Disturbances for HeartMate III Powered by 14 V Li-Ion Batteries

The HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is intended for use in the electromagnetic environment specified in **Table B.18**. The customer or the user of the HeartMate III Left Ventricular Assist System should assure that it is used in such an environment.

The HeartMate III LVAS (powered by 14V Li-Ion batteries) is suitable for use in the following environments:

- Hospitals, including ORs and emergency rooms
- Treatment areas near active HF Surgical equipment
- Homes, workplaces and retail places
- Passenger automobiles, ambulances, buses, etc.
- Commercial aircraft, including helicopters and air ambulances
- Public or private passenger watercraft/boats, ferries, etc.

Table B.7 Declaration and Guidance for Electromagnetic Disturbances for HeartMate III Powered by 14 V Li-Ion Batteries

HeartMate III LVAS Powered By the 14V Li-Ion Batteries		
EM (Electromagnetic) Disturbance type / Standards	**IEC 60601-1-2 (2014) Compliance Level**	**Use Environment Guidance**
RF Emissions / CISPR 11 EN 55011	Group 1, Class B (radiated only) 30 – 1,000 MHz	The HeartMate III LVAS with 14V Li-Ion Batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate III LVAS with 14V Li-Ion Batteries uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±8 kV Contact ±15 kV Air	The relative humidity where the HeartMate III LVAS with 14V Li-Ion Batteries is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	20 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with 14V Li-Ion Batteries are recommended: 80 - 800 MHz: 0.85 m (2.8 feet) 800 MHz – 2.7 GHz: 1.7 m (5.6 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate III LVAS with14V Li-Ion Batteries are recommended: 80 - 800 MHz: 1.9 m (6.2 feet) 800 MHz – 2.7 GHz: 3.8 m (12 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate III LVAS may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m[1]; 430 - 470 MHz, 42 V/m[3]; 704 - 787 MHz, 13 V/m[2]; 800 - 960 MHz, 42 V/m[1]; 1.7 - 1.99 GHz, 42 V/m[2]; 2.4 - 2.57 GHz, 42 V/m[2]; and 5.1 - 5.8 GHz, 13 V/m[2] _____ [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate III LVAS with 14V Li-Ion Batteries, and its parts, than 0.2 m (8 inches). Equipment[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate3 LVAS with 14V Batteries. [a] – List is not comprehensive.

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate III LVAS with 14V Li-Ion Batteries is recommended: Outside ISM bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment[a] examples include: CB Radios, Amateur "HAM" radios, Diathermy medical devices, Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate III LVAS with14V Li-Ion Batteries is used.

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate III LVAS (powered by the 14V Li-Ion Batteries), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories or cables other than those specified or provided by Thoratec Corp. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid use of HeartMate III LVAS (and its cables and parts) within 5 cm (2 inches) of a microwave oven or its cord.
- Use of accessories or cables other than those specified or provided by Thoratec Corp. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate III LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.

Field strengths from fixed RF transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

The HeartMate III LVAS with 14V Li-Ion Batteries meets the electromagnetic radiated emissions requirements of RTCA/DO-160G (also EUROCAE ED-14G), Sec. 21, for Category "M" location devices.

The HeartMate III LVAS with 14V Li-Ion Batteries meets the radiated and conducted (due to RF) electromagnetic immunity requirements of RTCA/DO-160G (also EUROCAE ED-14G), Sec. 20, for Category "R" location devices.

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) “site survey” (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate III Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate III LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III LVAS.

These guidelines may not apply in all situations.

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device or devices are connected.
- Consult Thoratec Corporation for assistance.

CAUTION !

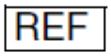
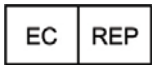
Use of equipment and supplies other than those specified in the manuals or sold by Thoratec Corporation for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate III Left Ventricular Assist System and other devices.

SYMBOLS

This section describes the symbols that are used on the HeartMate III Left Ventricular Assist System components, accessories, or packaging.

Description of Labeling Symbols

General Symbols

SYMBOL	DESCRIPTION
	Manufacturer
	Date of manufacture
	Catalogue number
	Serial number
	Batch code
	Caution: US federal law restricts this device to sale by or on the order of a physician
	European Conformity
	Authorized representative in the European community
	Temperature limit
	Sterilized using irradiation
	Sterilized using ethylene oxide
	Consult instructions for use
	Do not use if package is damaged
	MR Unsafe - Do not subject to magnetic resonance imaging

SYMBOL	DESCRIPTION
	Do not re-use
1	Quantity of contents
	Peel Tab
	Caution
IPxx	Degrees of protection provided by enclosures
	Operating Temperature
	UL Recognized Component
	Contains Lithium-Ion, recycle in accordance with local, state, and federal regulations.
	Separate collection for batteries and accumulators
	Use-by date
	Keep dry
	See instructions for use
	Non-ionizing radiation
	Fragile, handle with care
	This end up

SYMBOL	DESCRIPTION
~	Alternating current
CLASSIFIED C UL US	UL product safety mark

Specific 14 Volt Lithium-Ion Battery Symbols

Symbol	Description
On-product symbols	Refer to *Checking Battery Charge Status* on page 3-50.
	Charge By. HeartMate 14 Volt Lithium-Ion batteries must be charged at least once by the end of the month marked on the label affixed to battery packaging (box and protective bag).
YYYY-MM	Product Use by

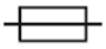
Specific 11 Volt Lithium-Ion Backup Battery Symbols

Symbol	Description
YYYY-MM	Backup Battery Use by

Specific System Controller Symbols

Symbol	Description
On-product symbols	Refer to *System Controller User Interface Overview* on page 2-14.
▲	Indicates the HeartMate III LVAS is operating in Pulse Mode (as shown on the System Controller LCD display).

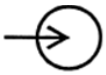
Specific Power Module Symbols

Symbol	Description
On-product symbols	• Refer to *Handling Power Module Alarms* on page 7-29. • Refer to *Checking the Charge Status of the Power Module Backup Battery* on page 3-24.
	Monitor
	Type “CF” Symbol: Patient cable connection
	Power ON/OFF: When the Power Module is plugged into a wall socket, this symbol illuminates green. When the Power Module is operating on internal battery power with less than 15 minutes of power left, this symbol illuminates yellow.
	Fuse Rating: T 2A, 250
	Direct Current
	Rechargeable Battery: When the Power Module is recharging the internal battery, this symbol illuminates yellow. When the internal battery is fully charged, this battery symbol illuminates green.
	Battery Check: When the Power Module is operating on internal battery power with less than 15 minutes of power left, this symbol illuminates yellow as an **Advisory** alarm. When only 5 minutes of internal battery power remain, this symbol illuminates red as a **Hazard** alarm.

Specific Mobile Power Unit Symbols

Symbol	Description
On-product symbols	Refer to *Mobile Power Unit User Interface Components* on page 3-37.

Specific System Monitor Symbols

Symbol	Description
	Power OFF
	Power ON
	Input: System Monitor only. For cable connection from Power Module to port on back of System Monitor.

SAFETY CHECKLISTS

This section provides checklists to assist in performing routine maintenance of the HeartMate III Left Ventricular Assist Device.

Daily Safety Checklist

Daytime Checklist:

- ☐ Perform System Controller self test.
- ☐ When using a new power source, inspect System Controller power cable connectors for dirt, grease, or damage.
- ☐ When changing power sources, inspect connectors on battery clips for dirt, grease, or damage.
- ☐ When switching from the battery power to the Power Module or the Mobile Power Unit, inspect the connector pins and sockets for dirt, grease, or damage.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the in-line locking nut.
- ☐ Perform a Power Module self test.
- ☐ Maintain the Power Module connection to the AC power source. If not properly monitored, the internal battery drains, causing potential damage.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Driveline exit site for signs of infection, including redness, tenderness, swelling, discharge, or a foul odor. Use sterile technique to touch or handle the exit site.

Sleep Checklist:

- ☐ Always connect to the Power Module or the Mobile Power Unit for sleeping or when there is a chance of sleep, as a sleeping patient may not hear system alarms. Refer to *Connecting to the Power Module* on page 3-17 or *Connecting to the Mobile Power Unit* on page 3-42.
- ☐ Check all electrical connections between the System Controller and power cables, the power cables and the Power Module patient cable or the Mobile Power Unit patient cable, and the Power Module or the Mobile Power Unit and AC electrical outlet.
- ☐ Confirm bedside items are in place:
  - ☐ Working flashlight with charged batteries.
  - ☐ Backup System Controller.
  - ☐ Two charged HeartMate 14 Volt Lithium-Ion batteries and two 14 Volt battery clips.
- ☐ Inspect the Driveline Cable for signs of damage, such as cracking, fraying, wear, exposed wires, sharp bends or kinks.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the in-line locking nut.
- ☐ Inspect all cables for signs of damage.

Weekly Safety Checklist

- ☐ Review Replacing the Running System Controller with a Backup Controller instructions in section 2.
- ☐ Clean the metal battery terminals and contacts inside the battery clips.
- ☐ Inspect the Power Module or Mobile Power Unit power cord, used to connect the Power Module to the AC electrical outlet, for damage or wear. Ensure that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from Thoratec Corporation, if needed.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Power Module patient cable or Mobile Power Unit patient cable, used to connect the System Controller to the Power Module or the Mobile Power Unit, for damage or wear. Ensure that the cable is not kinked, split, cut, cracked, or frayed. Do not use the Power Module patient cable or the Mobile Power Unit patient cable if it shows signs of damage. Obtain a replacement from Thoratec Corporation, if needed.
- ☐ Inspect HeartMate 14 Volt Lithium-Ion batteries for damage. Check the battery contacts for denting or damage. Replace damaged batteries. Do not use batteries that appear damaged.
- ☐ Inspect the Battery Charger for signs of physical damage, such as dents, chips, or cracks. Do not use the Battery Charger if it shows signs of damage. Obtain a replacement from Thoratec Corporation, if needed.
- ☐ Inspect the power cord that is used to connect the Battery Charger to an AC outlet. Ensure that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from Thoratec Corporation, if needed.
- ☐ Inspect wear and carry accessories (including the Consolidated Bag, Travel Bag, Protection Bag, System Controller Neck Strap, holster vest, and belt attachment accessory) for damage or wear.
- ☐ Inspect the HeartMate battery holster for damage or wear.
- ☐ Inspect the HeartMate Shower Bag for damage or wear.
- ☐ REPLACE ANY EQUIPMENT COMPONENT THAT APPEARS DAMAGED OR WORN.

Monthly Safety Checklist

- ☐ Review Alarms and Troubleshooting guides in section 7.
- ☐ Check the manufacture date on the label of all batteries. If a battery was manufactured more than three years ago, the battery has expired. Replace expired batteries. Do not use expired batteries.

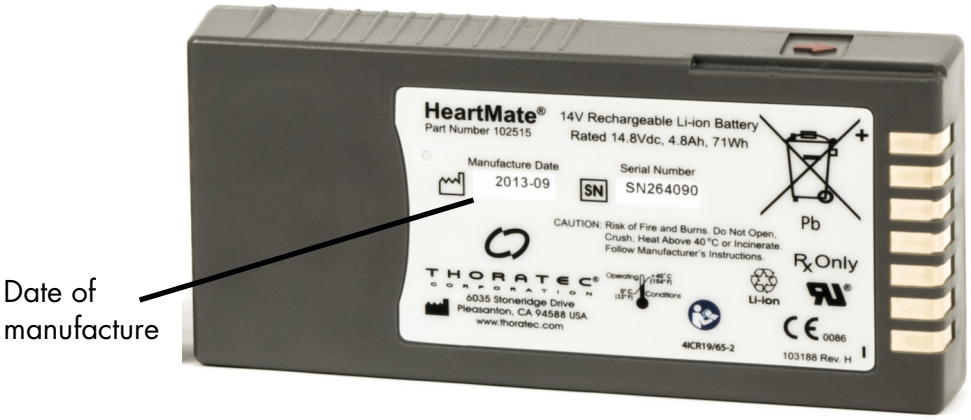


Figure D.1 Check the Manufacture Date to Determine Battery Expiration

- ☐ Check the number of use/charge cycles for each battery. Insert a battery into the Battery Charger to read the number of cycles. The cycle information is displayed on the charger's display panel screen. Refer to *Battery Charger Display Panel Messages* on page 7-35.

  Replace batteries that have exceeded 360 cycles. Do not use batteries that have exceeded 360 cycles.
- ☐ Clean the metal battery contacts and the interior contacts of battery clips using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use.
- ☐ Inspect the Power Module patient cable or Mobile Power Unit patient cable and power cable connector pins and sockets for dirt, grease, or damage. If the pins or sockets are damaged or contaminated, do not attempt to clean them.

  Report the condition to Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information. Cleaning and service should be performed only by personnel trained by Thoratec Corporation.

  Do not attempt to clean or repair equipment on your own.
- ☐ If the Mobile Power Unit will be stored for more than one month, remove the Mobile Power Unit batteries.

- ☐ Unplug the Battery Charger and clean the metal contacts inside all four charging pockets with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before inserting batteries into the pockets. Do not clean the Battery Charger while it is plugged in.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

FOR HOSPITAL STAFF ONLY: Use the System Monitor to check the expiration date and battery usage on the 11 Volt Lithium-Ion backup battery.

Six Month Safety Checklist

☐ Depending upon the patient's clinic schedule, once in a six month period the backup System Controller must be maintained and assessed for readiness. Refer to ***System Controller Power Cable Connectors*** on page 2-24. This involves:

- ☐ Connect the backup System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Connection to power allows charging of the backup System Controller's 11 Volt Lithium-Ion backup battery.
- ☐ Perform a self test on the backup System Controller, after the System Controller is connected to power.
- ☐ Using a System Monitor, verify that the correct date and time have been programmed into the backup System Controller.

☐ Replace the Mobile Power Unit batteries with three new Alkaline AA batteries. If corrosion is observed, report the condition to Thoratec Corporation. Refer to page iii for Thoratec Corporation contact information. Cleaning and service should be performed only by personnel trained by Thoratec Corporation.

Do not attempt to clean or repair equipment on your own.

☐ Practice and evaluate your patient's ability to perform necessary care skills. Advise your patient to bring his or her Patient Handbook to the clinic visit.

- Review how to identify an emergency. Refer to Patient Handbook section 8, "What is an Emergency?".
- Review emergency contact list. Refer to Patient Handbook "Emergency Contact List" on page v.
- Review replacing the running System Controller with a backup System Controller. Refer to ***Replacing the Current System Controller*** on page 2-46 or Patient Handbook section 2.
- Review changing power sources. Refer to ***Switching Power Sources*** on page 3-58 or Patient Handbook section 3.
- Review System Controller alarms and troubleshooting including Hazard and Advisory alarm handling and accessing alarm history on the System Controller. Refer to ***System Controller Alarms*** on page 7-3 or Patient Handbook section 5.
- Review Power Module alarms and troubleshooting. Refer to ***Handling Power Module Alarms*** on page 7-29 or Patient Handbook section 5.
- Review Mobile Power Unit alarms and troubleshooting. Refer to ***Mobile Power Unit Alarms*** on page 7-32 or Patient Handbook section 5.
- Review how to replace the Modular Cable (if applicable).
- Review guidelines for connecting power cable connectors. Refer to ***Guidelines for Power Cable Connectors*** on page 7-36 or Patient Handbook section 5.
- Review HeartMate 14 Volt Lithium-Ion battery calibration steps. Refer to ***Calibrating HeartMate Batteries*** on page 3-75 or Patient Handbook section 3.

- Review ***What Not to Do: Driveline and Cables*** on page 7-37 or Patient Handbook section 5.
- Review using the Shower Bag and showering. Refer to ***Using the Shower Bag*** on page 6-20 or Patient Handbook section 4.
- Review caring for the Driveline exit site including cleansing, dressing, and immobilizing the Driveline. Refer to ***Caring for the Driveline Exit Site*** on page 6-8 or Patient Handbook section 4 (if applicable).

Yearly Safety Checklist

- ☐ Schedule a Power Module inspection and cleaning with Thoratec-trained personnel. The inspection and cleaning includes (but is not limited to) functional testing, cleaning, inspection, and replacement of the Power Module backup battery.

WARNING !

Ensure that the Power Module backup battery is reconnected after service or shipping. Refer to ***Installing the Power Module Backup Battery*** on page 3-9.

- ☐ Schedule a Battery Charger inspection and cleaning with Thoratec-trained personnel. The safety inspection and cleaning includes (but is not limited to) functional testing, cleaning, and inspection.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

As-Needed Safety Checklist

- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Clean the exterior surfaces of batteries using a clean, dry cloth. Do not use liquids such as water or liquid cleaning solvent to clean batteries. Keep batteries dry and away from water or liquid.
- ☐ Unplug the Battery Charger and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner, if necessary. Do not submerge the charger in water or liquid.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

Clinic Visit Safety Checklist

Advise your patient to bring his or her Patient Handbook to the clinic visit. The following safety check should be performed at each clinical follow-up visit:

- ☐ Review replacing the running System Controller with a backup System Controller (IFU section 2 or *Patient Handbook* section 2).
- ☐ With demonstration equipment, both patient and primary caregiver must be able to repeatedly demonstrate ability to successfully complete connection of a driveline to the Pocket Controller in a timely manner (IFU section 2 or *Patient Handbook* section 2).

Evaluate, and if necessary, review your patient's ability to perform the following core skills:

- ☐ Review System Controller alarms and troubleshooting including Hazard and Advisory alarm handling and accessing alarm history on the System Controller (IFU section 7 or *Patient Handbook* section 5).
- ☐ Review Power Module and/or Mobile Power Unit alarms and troubleshooting (IFU section 7 or *Patient Handbook* section 5).
- ☐ Remind the patient to follow all hazard and advisory alarm instructions, for example, call the hospital when the controller instructs the patient to do so.
- ☐ Review how to identify an emergency (*Patient Handbook* section 8).
- ☐ Review emergency contact lists (*Patient Handbook* page v).
- ☐ Review guidelines for connecting power cable connectors (IFU section 3 or *Patient Handbook* section 5).
- ☐ Review changing power sources (IFU section 3 or *Patient Handbook* section 3).
- ☐ Review HeartMate 14 Volt Lithium-Ion battery calibration steps (IFU section 3 or *Patient Handbook* section 3).
- ☐ Review *What Not to Do: Driveline and Cables* on page 7-37 or *Patient Handbook* section 5.
- ☐ Review using the Shower Bag and showering. Refer to page 6-20 or *Patient Handbook* section 4.
- ☐ Review caring for the Driveline exit site including cleansing, dressing, and immobilizing the Driveline.
- ☐ System Controller must be maintained and assessed for readiness (IFU section 2).

GLOSSARY

This section provides a glossary of terms for the HeartMate III Left Ventricular Assist System.

E

Abbreviations

Abbreviation	Term
AC	Alternating Current
CM	Centimeter
DC	Direct Current
EKG	Electrocardiogram
ESD	Electrostatic Discharge
FML	Fully Magnetically Levitated
ICD	Implantable Cardiac Defibrillators
ICU	Intensive Care Unit
IPM	Implantable Pacemaker
INR	International Normalized Ratio
IV	Intravenous
LPM	Liters Per Minute
LVAD	Left Ventricular Assist Device
LVAS	Left Ventricular Assist System
LMW	Low Molecular Weight
Ml/hr	Milliliter per hour
MRI	Magnetic Resonance Imaging
O.R.	Operating Room
PI	Pulsatility Index
PTT	Partial Thromboplastin time
QD	Once daily
RPM	Revolutions Per Minute
TID	Three times daily
V	Volt

Terms

A

Advisory Alarm: Alarms that are important, but not life threatening. Advisory alarms can be silenced for a short time using the Silence Alarm button that is found on the System Controller user interface.

Alarm: A sound, light, or lighted symbol that tells users about a problem that may affect system operation or cause harm.

Alternating Current: Abbreviated AC. The type of electricity that is common for electrical outlets in North American households.

Apical Cuff: The Apical Cuff is the interface between the heart and the HeartMate III LVAD. It is sewn to the exterior of the heart and anchors it to the LVAD via the Slide Lock.

B

Backup System Controller: A backup System Controller used to replace the running System Controller, if needed. The backup is identical to the running System Controller and is pre-set with the same settings. A patient should keep their backup System Controller with them at all times (along with other emergency or backup items). The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be recharged every 6 months.

Battery: A device that provides direct current (DC) power to the system. The HeartMate III Left Ventricular Assist System can be powered by a pair of 14 Volt Lithium-Ion batteries. An 11 Volt Lithium-Ion battery inside the System Controller gives at least 15 minutes of backup power to the system if the main source of power is disconnected or fails.

Battery button: A button on the System Controller user interface that shows a small battery symbol. Depending on the mode of operation, pressing this button either:

- Works the battery power gauge on the System Controller
- Starts the System Controller self test
- Puts the battery to “sleep” for storage purposes.

Battery Charger: A device that charges, calibrates, and tests the HeartMate 14 Volt Lithium-Ion batteries that are used to power the HeartMate III Left Ventricular Assist System.

Battery Power Gauge: A set of lighted bars that indicate how much battery power is available. Each HeartMate 14 Volt Lithium-Ion battery has its own 5-light on-board battery power gauge that shows the battery charge level. The System Controller also has a battery power gauge. The power gauge on the System Controller has four bars and one diamond-shaped light. The System Controller battery power gauge is used during battery-powered operation. It shows the approximate charge level of the two batteries currently in use.

Battery-Powered Operation: Using two HeartMate 14-V Lithium-Ion batteries to power the system. Using batteries to power the system is appropriate when users are active, outdoors, or when electrical power is unavailable.

C

Cautions: Actions to avoid that could damage equipment or affect how the system works. Although important for system function, cautions do not usually relate to life-threatening risks.

Communication Fault (Comm Fault): An Advisory alarm indicating the HeartMate III LVAD and System Controller cannot properly exchange information.

Controller Alarm Fault: An advisory alarm that occurs when an internal malfunction in the System Controller has occurred that requires clinician diagnosis and resolution.

Controller Driveline Connector: Connector permanently attached to the Driveline that connects the pump to the System Controller.

D

Direct Current: Abbreviated DC. The type of electricity that comes from a battery. The HeartMate III system uses two types of DC power: either 1) two 14 Volt Lithium-Ion batteries, or 2) an automobile power outlet.

Display button: A button on the System Controller user interface. Press this button () to bring up data on the user interface's display screen (such as current function and alarm history).

Driveline: The Driveline connects the Pump to the System Controller, which then connects to a power source. The Driveline consists of two cables: the Pump Cable and the Modular Cable. One end of the Pump Cable connects to the pump implanted in the patient's abdomen. The other end of that cable exits the patient's body. One end of the Modular Cable is connected to the Pump Cable and the other end connects to the System Controller. The Driveline brings power to the motor inside the implanted pump. Data about system operation is transferred through the Driveline to the System Controller.

Driveline Communication Fault (Driveline Comm Fault): An Advisory Alarm. It occurs when one of the communication wires inside the Driveline is damaged.

Driveline Power Fault: An Advisory Alarm. It occurs when one of the power wires inside the Driveline is damaged.

E

Exit Site: The place where the Driveline goes through the skin.

Extended Alarm Silence: Allows the audio portion of the alarm to be silenced to allow the user to troubleshoot the situation without the audio alarm present.

F

Fixed Speed Mode: An operating mode where the pump is set at a constant or "fixed" speed. Doctor and nurses decide and control pump speed.

G

H

Hazard Alarm: Hazard alarms occur when the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention. Hazard alarms are indicated by a red light and continuous audio tone.

HeartMate III Left Ventricular Assist System: Includes the implanted pump and Driveline (including the Modular Cable), as well as the System Controller, power sources (Power Module, Mobile Power Unit, or batteries), and accessories. LVAS is the acronym for Left Ventricular Assist System.

I

Inflow Cannula: A small tube that connects the pump to the left ventricle of the heart.

Intensive Care Unit: Abbreviated as ICU. This special hospital unit is where new Left Ventricular Assist System patients receive intensive care, usually just after Pump implant.

J

K

L

Left Ventricular Assist Device: The implanted device connected to the left ventricle of the heart that sends blood taken from the Inflow Cannula through the Outflow Graft and into the aorta, which sends the blood to the rest of the body. The motor inside the device is powered through the Driveline. Other terms for the device are Pump, heart pump, or LVAD (the acronym for Left Ventricular Assist Device).

Left Ventricular Assist System: The HeartMate III Left Ventricular Assist System includes the implanted pump and all related external equipment. Sometimes the Left Ventricular Assist System is called an LVAS. LVAS is not the same as LVAD, which refers only to the implanted Pump.

Liters Per Minute: Abbreviated as LPM. Blood flow through the pump is measured in LPMs. "LPM" appears on the System Controller user interface with blood flow data.

Low Battery Hazard Alarm: A red-colored battery-shaped symbol ( ) on the System Controller user interface that illuminates when less than 5 minutes of combined battery power remain for the in-use HeartMate 14 Volt Lithium-Ion batteries, during battery-powered operation.

E

Low Battery Hazard Symbol: Red "battery" light ( ) on the System Controller. It lights when power to the System Controller is critically low.

Low Flow Alarm: Blood flow is less than 2.5 lpm. This condition is accompanied by a flashing red heart on the user interface. *Call Hospital Contact* and *Low Flow* alternate on the screen, and there is a constant audio tone emitting from the System Controller. This is a Hazard alarm condition that requires immediate attention.

Low Flow Hazard Symbol: Red heart light ( ) on the System Controller. It lights when HeartMate III pump blood flow is critically low.

Low Speed Limit: The lowest speed at which the HeartMate III pump can operate while maintaining patient stability.

LVAD Fault: An advisory alarm that occurs when the LVAD has determined that one or more internal LVAD operating conditions are out of range.

M

Mobile Power Unit: The Mobile Power Unit connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. Patients must always connect to the Power Module or Mobile Power Unit for sleep (or when sleep is possible). Connecting to the Mobile Power Unit is also appropriate when patients are stationary or relaxing indoors.

Modular Cable: One of the two cables that make up the Driveline. One end of the Modular Cable connects to the Pump Cable that exits the patient's abdomen. The other end of the Modular Cable connects to the System Controller.

Modular In-line Connector: The electrical connection between the Pump Cable and the Modular Cable.

Modular Cable Cap: The protective cap that covers the Modular Connector on the Modular Cable from fluid ingress during LVAD implantation.

N

O

Operating Modes: There are three modes of System Controller operation:

- Run Mode (actively running)
- Sleep Mode (off and unused)
- Charge Mode (connected to power and charging the internal backup battery)

Outflow Graft: The polyester tube that connects the Pump to the aorta (the large blood vessel that sends blood through the body).

P

Percutaneous: Percutaneous means "through the skin."

Pump Cable: One of the two cables that make up the Driveline. The Pump Cable is permanently attached to the pump housing. The other end of the Pump Cable exits the patient's abdomen and is connected to the Modular Cable which connects to the System Controller. The Pump Cable contains wires that carry power and data to the pump, and that control and monitor pump operation.

Polyester Velour: A synthetic biocompatible material that lets skin tissue grow into the soft covering of the Driveline. This material covers the Driveline inside the body at the exit site and is on the external portion of the Pump Cable. Skin growth into the velour covering helps create a barrier that reduces the risk of Driveline infections.

Power Cable: A cable containing electrical wires that transfers electrical power to the System Controller from a routine power source (two 14 Volt Lithium-Ion batteries or the Power Module or the Mobile Power Unit).

Power Module: The Power Module connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. Patients must always connect to the Power Module or the Mobile Power Unit for sleep (or when sleep is possible). Connecting to the Power Module is also appropriate when patients are stationary or relaxing indoors.

Power Module Backup Battery: A backup power source inside the Power Module that gives up to 30 minutes of support if power to the Power Module fails or is disconnected. The backup battery works only if it is charged and properly connected.

Power Saver Mode: In power saver mode, the System Controller slows pump speed to save power. If power is removed or fails, the System Controller gives 15 minutes of full power before entering power saver mode. Alarms cannot be silenced while in power saver mode.

Power Sources: Three power sources can power the HeartMate III Left Ventricular Assist System:

- A pair of wearable, rechargeable 14 Volt Lithium-Ion batteries worn in battery clips
- The Power Module that plugs into an AC electrical outlet
- The Mobile Power Unit that plugs into an AC electrical outlet

Pulsatility Index (PI): Pulsatility Index (PI) is a calculation related to the amount of assistance provided by the pump. PI values typically range from 1 to 10.

Pulse Mode: The HeartMate III LVAS automatically develops an induced pulse X times per minute by increasing/decreasing rotor speed in a rapid fashion. The (▲) symbol indicates the pump is operating in Pulse Mode.

Pump Running Symbol: A green-colored symbol ( ) on the System Controller user interface that illuminates when the pump is receiving power and running.

Pump Speed: Pump speed is measured in revolutions per minute (RPM). The number of RPMs reflects how fast the Pump's internal rotor turns.

Q

R

Red Heart Indicator: A red-colored heart shaped symbol () on the System Controller user interface that illuminates during a hazard alarm condition. Red heart alarms occur for conditions that are immediately life-threatening. Red heart alarms should prompt an immediate response to avoid serious injury or death.

Revolutions Per Minute: Abbreviated as RPM. The RPM number reflects how fast the Pump's internal rotor turns.

Running System Controller: The System Controller that is currently in use and connected to the implanted Pump.

S

Safety Lock: The feature on the System Controller that ensures the Controller Driveline Connector is properly inserted (when the lock can be fully closed).

Self Test: A routine system check performed daily to confirm that the audio and visual alarms on the System Controller and Power Module are working properly.

Silence Alarm button: A button on the System Controller () or Power Module () that silences an audio alarm. How long the alarm is silenced depends on the type of alarm. The silence period varies from 2 minutes to 4 hours. Pressing the Silence Alarm button only silences the alarm. It does not fix the alarm condition.

Slide Lock: The mechanical feature on the HeartMate III LVAD that affixes the pump to the Apical Cuff.

Strap Attachment Points: Four places on the System Controller where straps can be easily connected. Attachment points allow for holding or carrying the System Controller. The System Controller can be worn or carried on a belt or strap, or inside a pocket.

System Controller: The small computer that controls and checks system function. It connects the implanted pump to the external power sources.

System Controller 11 Volt Lithium-Ion Backup Battery: A backup power source inside the System Controller. It powers the system for up to 15 minutes if the main power source fails or is disconnected.

System Controller Battery Power Gauge: A set of four bars on the System Controller. The bars show the approximate charge level for a pair of batteries being used to power the system.

System Controller Power Cables: Two power cables (one with a black connector and one with a white connector) connect the System Controller to its power source (batteries, Power Module, or Mobile Power Unit). Both cables provide equal power. However, the white cable contains a data link that sends information to the Power Module.

T

Tethered Operation: Refers to using the HeartMate III Left Ventricular Assist System while connected to an electrical outlet via the Power Module or the Mobile Power Unit.

U

User Interface: Set of visual indicators (symbols that illuminate) and buttons located on the front of the System Controller.

User Interface Screen: The screen on the System Controller that allows users to view real-time data about system operation. Alarm information and instructions also appear on the screen.

V

W

Warnings: Hazards that could cause serious harm or death if not avoided. If warnings are ignored, serious harm or death could occur.

Wear and Carry Accessories: Wear and carry accessories are used to safely hold or carry the System Controller. For example, the System Controller can be carried with a strap around the neck, on a belt around the waist, or in a pocket. A battery holster is used for carrying batteries and battery clips.

X

Y

Yellow Diamond Indicator: A yellow-colored symbol on the System Controller user interface that illuminates when less than 15 minutes of combined battery power remain from the in-use HeartMate 14 Volt Lithium-Ion batteries that are providing power during battery-powered operation.

Yellow Wrench Indicator: A yellow-colored symbol ( ) on the System Controller user interface that illuminates during alarm conditions that are important, but not immediately life-threatening.

Z

Numbers

A

C

D

R

S

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