Thoratec Corporation

HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM

Instructions for Use

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Preface

This manual contains information needed to properly and safely operate the HeartMate 3™ Left Ventricular Assist System. Users of the HeartMate 3 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.

Preface

INTRODUCTION

This section provides an introduction to the HeartMate 3 Left Ventricular Assist System.

1 Introduction

Understanding Warnings and Cautions

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.

Cautions refer to actions or potentially unsafe conditions that may cause injury, damage the equipment, or affect how the system works. Ignoring a caution can cause 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.

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.

WARNING !

Warnings appear in the manual in this format.

CAUTION !

Cautions appear in the manual in this format.

1 Introduction

Overview

The HeartMate 3 Left Ventricular Assist System (LVAS) is a set of 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 (LVAD), a blood pump intended for long-term implantation in such patients, an extracorporeal Controller, plus all of the features, controls, attachments, interfaces, power sources, supporting equipment, labeling, and tools required to achieve the desired therapeutic benefit. The HeartMate 3 Left Ventricular Assist System is intended for use inside or outside the hospital, or for transportation of LVAD patients via ground ambulance, airplane, or helicopter.

The LVAS may be used in any of two configurations. First, line power may be utilized through the Power Module or the Mobile Power Unit™ to run the LVAD indefinitely, convenient for sedentary or sleeping periods. Second, portable Battery power may be utilized for limited periods, convenient for active periods. Due to the bifurcation of the Patient Cable, switching among these configurations or from one set of Batteries to another (as when one set has been depleted and a fully charged set is available) may be accomplished without interrupting LVAS function. 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.

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 3 LVAD is part of the LVAS. See **Figure 1.1**.

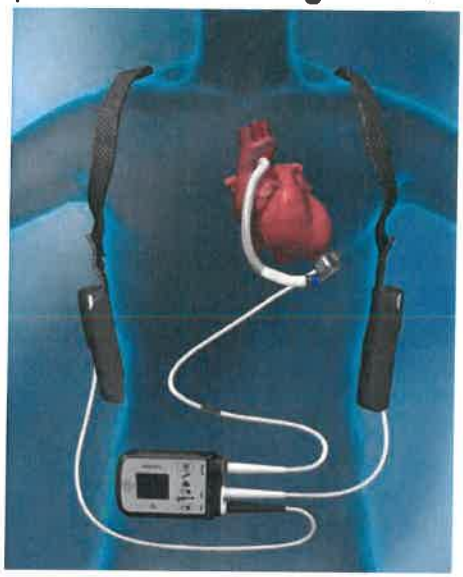


Figure 1.1 HeartMate 3 System During Battery-Powered Operation

The LVAD is a blood pump intended for implantation in the thorax of patients affected with advanced heart failure. The LVAD contains an Inflow Cannula, a Pump Cover, a Lower Housing, a Screw Ring to attach the Pump Cover to the Lower Housing, a Motor, the Outflow Graft, and a Pump Cable.

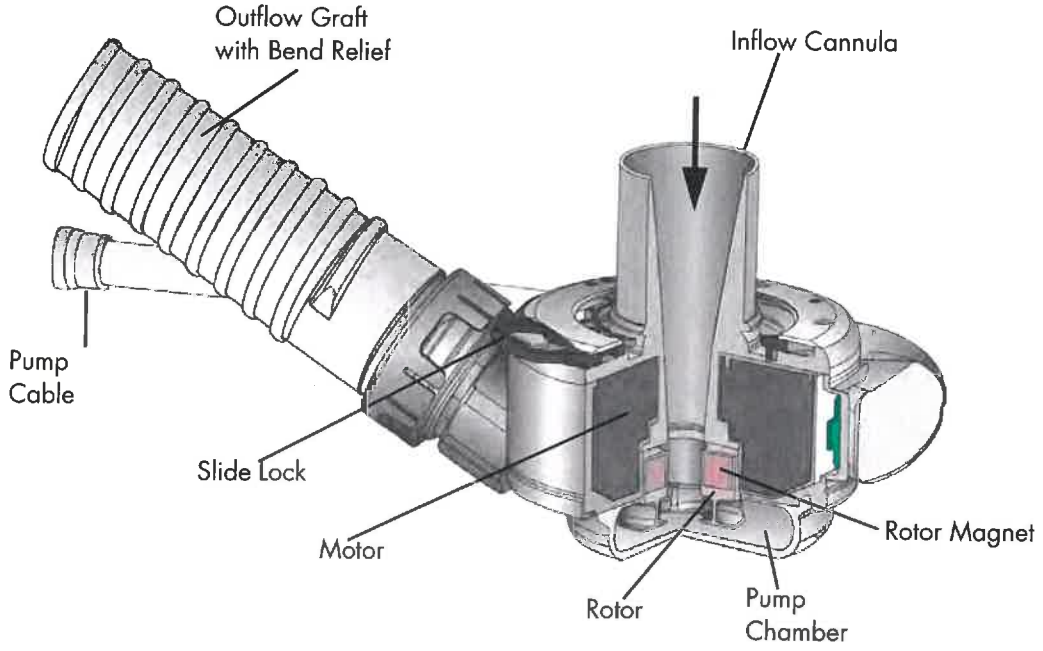


Figure 1.2 Left Ventricular Assist Device Components

The LVAD is surgically connected to the patient's circulatory system via an Inflow Cannula 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 rotating about the central axis. The fluid thus angularly accelerated collects and travels around a volute before it is diffused to a desired 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 (i.e. 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 Lower Housing with the Stator, and all of these plus the Rotor are regarded to comprise the Motor.

The Inflow Cannula is a cylindrical conduit with external size and features similar to those of the HeartMate II. 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 to allow insertion of the Inflow Cannula into the left ventricle. An Apical Attachment 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 and can be swiveled to correct any twist that may develop during pump placement. The distal end of the graft is designed to be cut to desired length and sutured to the ascending aorta by an end-to-side anastomosis (only the graft is to 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 Cover, permitting pump replacement without re-anastomosis.

A Pump Cable is permanently attached to the Lower Housing 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 and is exteriorized through a skin wound prepared with a Skin Coring Punch at a location deemed optimal for the patient and his 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 and is readily replaceable without surgery if necessary. The Pump Cable and Modular Cable, once connected, comprise the Driveline. The Driveline contains duplicate sets of three conductors: two for power and ground, and a third for communication.

The HeartMate 3 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, and appropriately delivers that 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, and
- 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 3 Left Ventricular Assist System. Read this entire manual before attempting implantation of the Left Ventricular Assist Device or before caring for HeartMate 3 patients. Completion of Thoratec Corporation HeartMate 3 Surgical Training Program is also required prior to use.
- Understanding the operating and safety aspects of the HeartMate 3 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 3 power accessories (Power Module, Mobile Power Unit, Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries) before use.
- Do not use the HeartMate 3 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 3 Left Ventricular Assist System are not compatible with other HeartMate systems. Only use HeartMate 3 parts with the HeartMate 3 system.
- The HeartMate 3 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 3 system components. If components need service, contact appropriate personnel.
- Notify 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 3 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 3 Left Ventricular Assist System is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

Contraindications

The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

Adverse Events

Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are listed below. 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
- Cardiac Arrhythmia
- Localized Infection
- Right Heart Failure
- Respiratory Failure
- Device Malfunctions
- Driveline Infection
- Renal Dysfunction
- Sepsis
- Stroke
- Other Neurological Event (not stroke-related)
- Hepatic Dysfunction
- Psychiatric Episode
- Venous Thromboembolism
- Hypertension
- Arterial Non-Central Nervous System (CNS) Thromboembolism
- Pericardial Fluid Collection
- Pump Pocket or Pseudo Pocket Infection
- Myocardial Infarction
- Wound Dehiscence
- Hemolysis (not associated with suspected device thrombosis)
- Possible Pump Thrombosis (has not occurred with HeartMate 3 in the MOMENTUM 3 Short Term Clinical Study through 180 days)

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 3 Left Ventricular Assist System.

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

This manual contains important warnings, cautions, and instructions for use. Read this entire manual before implanting a HeartMate 3 Left Ventricular Assist Device or before caring for HeartMate 3 patients. Completion of Thoratec Corporation HeartMate 3 Surgical Training Program is also required.

If you have questions after reading this manual, please contact Thoratec Corporation for assistance. See *Thoratec Corporation contact information* on page iii.

Equipment Overview

The table below introduces the main parts of the system, along with useful accessories. All of these items are described in more detail later in this manual.

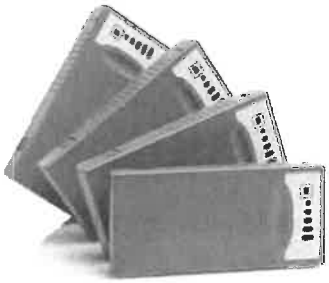
Left Ventricular Assist Device 	The HeartMate 3 Left Ventricular Assist Device (frequently called the "pump") is implanted in the chest below the heart. One end is inserted into the apex of the left ventricle; the other end connects to the ascending aorta. The pump diverts blood from the weakened left ventricle and pumps it to the aorta. **For more information, see page 1-19.**
System Controller 	The System Controller is a small computer that controls and monitors system operation. The System Controller uses lights, sounds, and on-screen messages to communicate with users about operating status and alarm conditions. A Driveline, which passes through the patient's abdomen, connects the implanted pump to the System Controller. **For more information, see page 2-8.**
14 Volt Lithium-Ion Batteries & 14 Volt Battery Clips  	Two HeartMate 14 Volt Lithium-Ion batteries are used to power the system during battery-powered operation, such as when AC electricity is not wanted or unavailable. 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 10–17 hours, depending on the activity level of the patient. **For more information, see page 3-51.**

Table 1.1 HeartMate 3 System Components

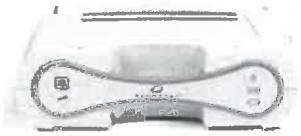
Modular Cable 	The Driveline consists of two cables: the Pump Cable and the Modular Cable. One end of the Pump Cable connects to the pump implanted in the patient's abdomen. The other end of that cable exits the patient's body. One end of the Modular Cable is connected to the Pump Cable and the other end connects to the System Controller.
Power Module 	The Power Module plugs into an AC to provide power to the HeartMate 3 system. The Power Module is used when the patient is indoors, stationary, or sleeping. A sleeping patient may not hear low battery power alarms. 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. **For more information, see page 3-5.**
Power Module Patient Cable 	The Power Module patient cable connects the Power Module to the System Controller. Connections are made between white-to-white and black-to-black connectors. **For more information, see page 3-16.**
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, as a sleeping patient may not hear low battery power alarms. 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. **For more information, see page 3-35.**
System Monitor 	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. Its use during Left Ventricular Assist Device implantation is required. **For more information, see page 4-6.**

Table 1.1 HeartMate 3 System Components (Continued)

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.

For more information, see page 3-73.

Shower Bag

The Shower Bag is used to protect external system components from water or moisture—outside in heavy rain or snow, and always for every shower. HeartMate 3 patients may be allowed to shower when the Driveline exit site has healed and with permission from their doctor. If external system components have contact with water or moisture, the system may fail to operate properly or the patient may get a serious electric shock.

For more information, see page 6-14.

System Controller Neck Strap

The System Controller Neck Strap attaches to the System Controller and is used to wear the System Controller around the neck or across the body.

For more information, see page 6-29.

Belt Attachment

The belt attachment provides another way to wear the System Controller.

For more information, see page 6-34.

Table 1.1 HeartMate 3 System Components (Continued)

Consolidated Bag

The Consolidated Bag is a convenient way to carry two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips during battery-powered operation.

For more information, see page 6-38.

Battery Holster

The Battery Holster provides a convenient way to wear two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.

For more information, see page 6-47.

Holster Vest

The Holster Vest provides another way to wear the HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.

For more information, see page 6-53.

Table 1.1 HeartMate 3 System Components (Continued)

Travel Bag

The Travel Bag provides a convenient way to carry and transport the backup System Controller and spare batteries.

For more information, see page 6-62.

Protection Bag

The Protection Bag stores and protects the backup System Controller.

For more information, see page 6-61.

Table 1.1 HeartMate 3 System Components (Continued)

Required, Backup, and Optional Components and Equipment

The HeartMate 3 Left Ventricular Assist System is designed for use both inside and outside of the hospital. Specific system components and equipment may be required for each setting. Components and equipment that are required for implant and ICU transfer are listed in **Table 1.2**.

Components Required for Implantation and ICU Transfer	Primary	Backup
HeartMate 3 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 and battery clip cables	Required	Not required
Battery Charger	Required	Not required
HeartMate 3 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	

Table 1.2 Components for Implant

* Some "Optional" items are included in the HeartMate 3 Implant Kit.

** Also available separately.

Components and equipment that are required for a discharged patient are listed in **Table 1.3**. 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 3 patient.

Components for a Discharged Patient	Primary	Backup
Implanted HeartMate 3 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 & carry accessories, including: Shower Bag, Protection Bag for backup System Controller, holster vest, belt attachment accessory, and System Controller Neck Strap	Required	Not Required
HeartMate 3 Patient Handbook	Required	Not Required

Table 1.3 Components for Discharged Patients

CAUTION !

Confirm that the patient's backup System Controller has had the 11 Volt Lithium-Ion backup battery installed and the time and date have been set.

WARNING !

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 3 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 upon the degree of the patient's cardiac function and the set-speed of the LVAD.

As for 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. HeartMate 3 H-Q curves are shown in **Figure 1.3**.

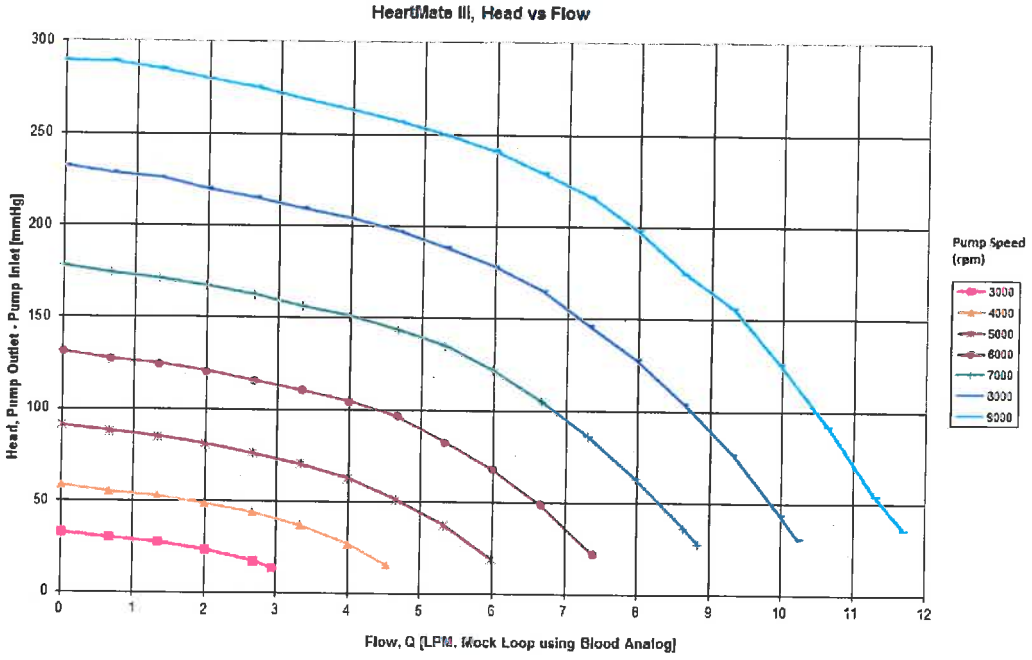


Figure 1.3 Pressure Head-Flow (H-Q) Relationship

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, which 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 high*, the inflow pressure may fall to the extent that it attempts to recruit blood from the left ventricle, left atrium, and pulmonary vasculature that simply is not there, resulting in collapse of the left ventricle and potential arrhythmia. The HeartMate 3 LVAS employs a feature called Pulsatility Index (PI) 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, then immediately but gradually returns the rotor to its original speed. The HeartMate 3 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 3 LVAS uses the same Low Speed Limit mentioned above to limit how low the speed may be set. This is to avoid profound retrograde flow (aorto-ventricular shunt). The Low Speed Limit is settable within a range to accommodate customization for a variety of patients.

The HeartMate 3 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 in order 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.

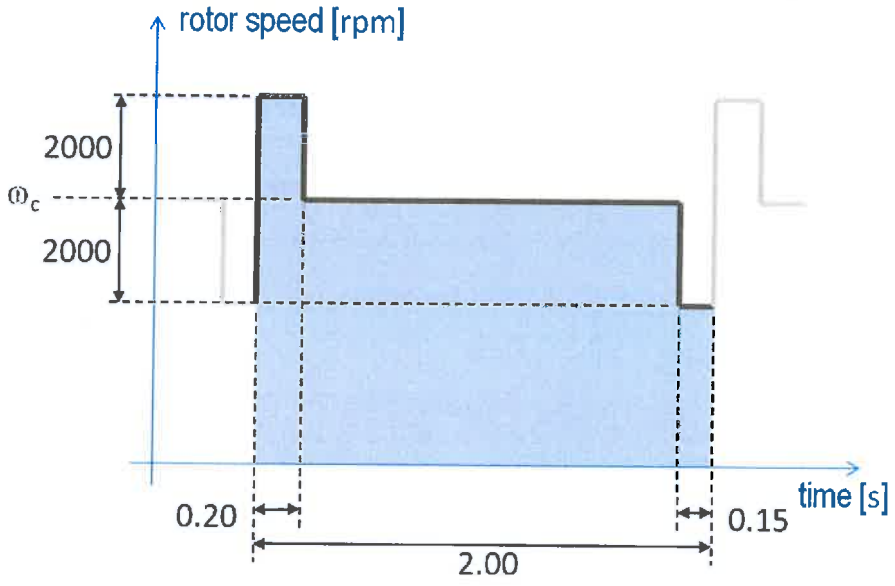


Figure 1.4 Artificial Pulse

Explanation of Parameters

Speed

The HeartMate 3 Left Ventricular Assist Device operates at a fixed speed (see *Optimal Fixed Speed* on page 4-23) determined by the physician during a speed ramp study.

Note: The term "fixed speed" is a speed fixed, or set, by the clinician, i.e., 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 pump speed. The "low speed limit" for the device is the lowest speed at which it 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, aortic or 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 (ie, the pump is providing less support to the left ventricle). Lower values indicate less ventricular filling and lower pulsatility (ie, 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, please contact Thoratec Corporation. For Thoratec Corporation contact information, see page iii.

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 3 Left Ventricular Assist System.

2 System Operations

HeartMate 3 Left Ventricular Assist Device Overview

The HeartMate 3 Left Ventricular Assist Device (**Figure 2.1**) is a centrifugal flow rotary heart pump that is connected in parallel to the native circulation. The inflow cannula of the Left Ventricular Assist Device attaches to the apex of the left ventricle. Its sealed outflow graft connects to the ascending aorta (**Figure 2.2**). Frequently, the HeartMate 3 Left Ventricular Assist Device is called the "pump."

Figure 2.1 HeartMate 3 Left Ventricular Assist Device

2 System Operations

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, which is fully (i.e., 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 3 Left Ventricular Assist Device is implanted in the chest (see **Figure 2.2**). For more information, see *Implant Procedures* on page 5-32.

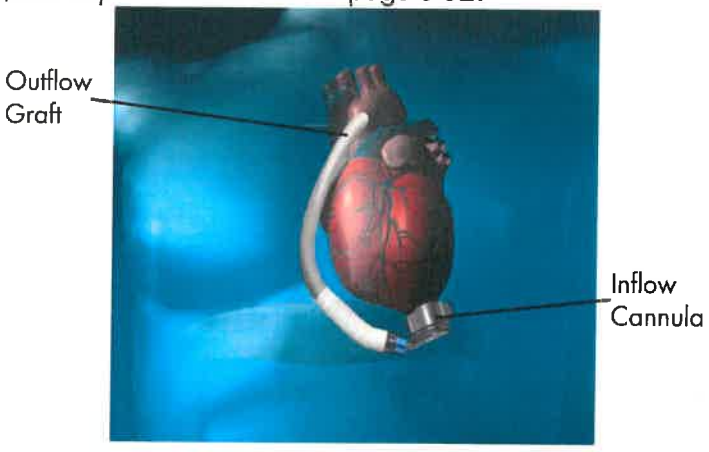


Figure 2.2 HeartMate 3 Implant Configuration

The HeartMate 3 LVAD is part of the Left Ventricular Assist System (**Figure 2.3**).

Figure 2.3 HeartMate 3 LVAS During Battery-Powered Operation

Driveline

The Driveline consists of two cables: the Pump Cable, that extends from the Left Ventricular Assist Device through the skin, and the Modular Cable which connects the Pump Cable to the System Controller. The Driveline contains six wires—three primary wires and three backup wires—that power the Pump Motor and facilitates communication with the System Controller.

To reduce infection, the Driveline is covered with woven polyester, which encourages tissue ingrowth at the skin line. 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 LVADs 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 result in death. For information about caring for the Driveline, see *Care of the Driveline* on page 8-5.

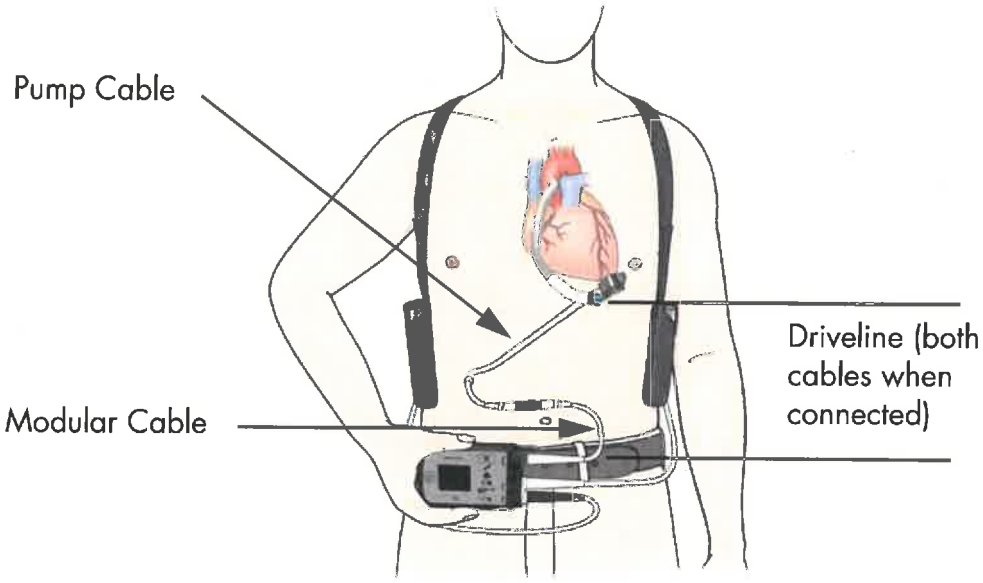


Figure 2.4 Driveline

Driveline damage due to wear and fatigue may occur in both the externalized (Modular Cable) and implanted portions (Pump Cable) 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. Please refer to *Replacing the Modular Cable* on page 2-62 for the procedure for exchanging the Modular Cable.

Powering the Pump Motor

The Left Ventricular Assist Device Motor is powered through the System Controller by one of three sources: the Power Module or the Mobile Power Unit that is connected to an AC electrical outlet (see *Using the Power Module* on page 3-5), or two HeartMate 14 Volt Lithium-Ion Direct Current (DC) Batteries (see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-51).

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 here. Operating system components outside of the environmental parameters listed below may affect device operation or result in equipment failure.

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[a]	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)

Table 2.1 Operating Conditions

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. 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.

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 (see *Maintaining Backup System Controller Readiness: Six Month Charging and Self Test* on page 2-51).

System Controller Overview

The HeartMate (HM) 3 System Controller acts as the central power and communication hub for the HeartMate 3 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 HM 3 System Controller constantly monitors system performance through communication with the implanted LVAD and Controller internal measurements and 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 by the user 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 (e.g. 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 pump 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, either by passing a command sent by the System Monitor or when in Power Saver mode or 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**).

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

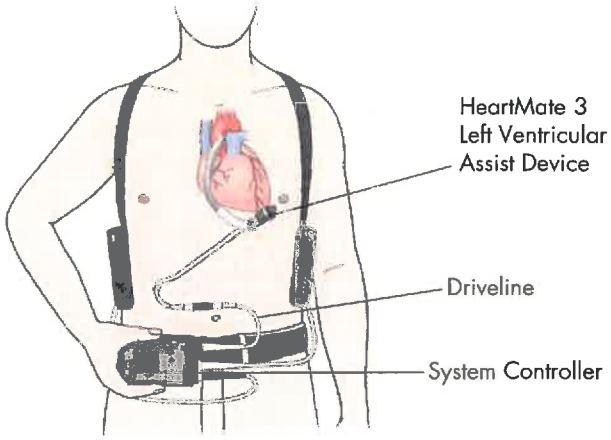
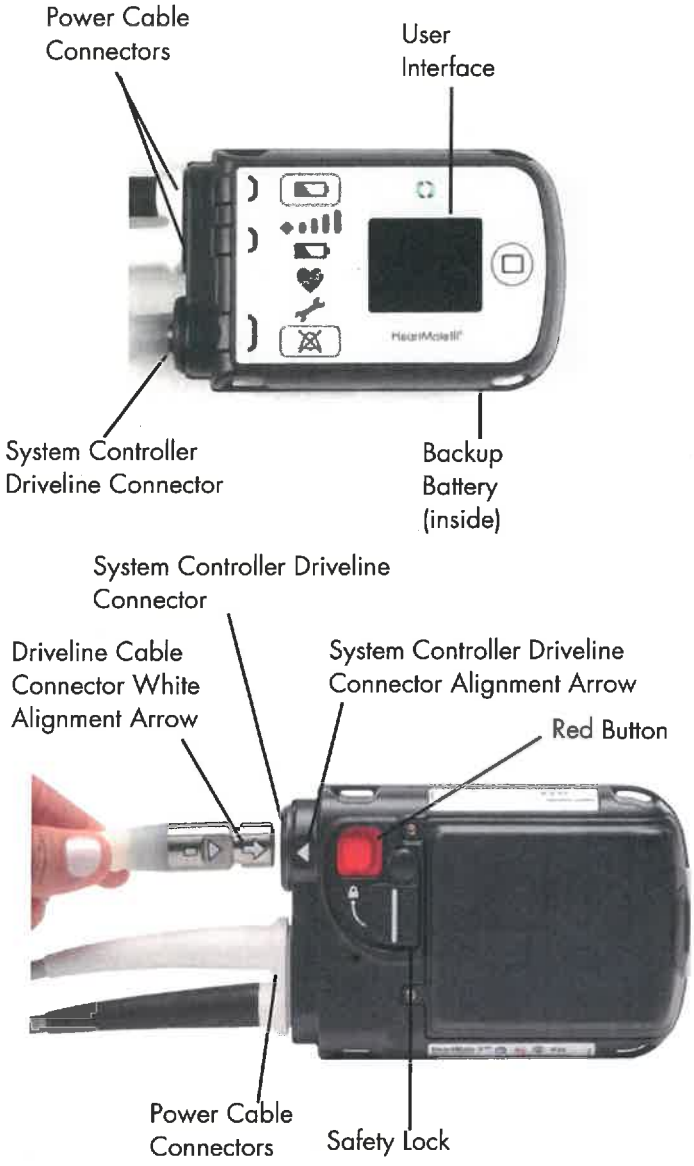


Figure 2.5 HeartMate 3 Left Ventricular Assist System



- System Controller Driveline Connector: links the Modular Cable portion of the Driveline to the System Controller.
- Power Cable Connectors: link external power source (Power Module, Mobile Power Unit, or 2 HeartMate 14 Volt Lithium-Ion Batteries) to the System Controller.
- User Interface: buttons, lights, and screen where system data, alarms, and user instructions appear.
- Backup battery: located inside the System Controller, powers the pump for at least 15 minutes during a power-loss emergency.

Figure 2.6 System Controller Major Components

2 System Operations

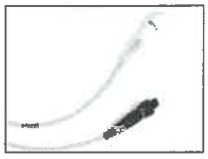
The System Controller is described in the following sections:

System Controller User Interface Overview
This section describes the visual display of system operations and on-screen messages.

See page 2-15.

System Controller Driveline Connector
This section provides instructions on connecting and disconnecting the Driveline.

See page 2-21.



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

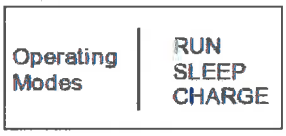
See page 2-27.

Performing a System Controller Self Test
This section provides instructions on how to perform a daily self test to check the function of the System Controller's audible and visual alarms.

See page 2-30.

System Controller Battery Power Gauge
This section describes the battery power gauge function to show the approximate charge status of the power source that is connected to the System Controller's power cables.

See page 2-31.



System Controller Operating Modes
This section describes the System Controller's three operating modes (Run, Sleep, and Charge) and provides an overview with instructions on how to switch between modes.

See page 2-34.

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.

See page 2-40.

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 you may get a serious electric 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.

WARNING !

- Do not allow patients to shower without a doctor's permission. HeartMate 3 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 3 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 3 System Controller provides enough power to run the implanted HeartMate 3 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-supplied Heartmate 14 Volt Lithium-ion battery with the HeartMate 3 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 patients (and family member or caregiver) 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 (see *System Controller User Interface Components* on page 2-16).
  - Fluid oozing 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.

CAUTION ! (Continued)

- 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 11 Volt Lithium-Ion 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 requirement.
- The System Controller uses lights, sounds, and on-screen messages to communicate with users about system operation. HeartMate 3 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 3 patients (and their family members/caregivers) must be thoroughly trained on how to interpret and use the user interface prior to discharge (see *Educating and Training Patients, Families, and Caregivers* on page 6-68).

For situations that require attention, and depending on the urgency, the System Controller issues include 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, see *System Controller Alarms* on page 7-3.

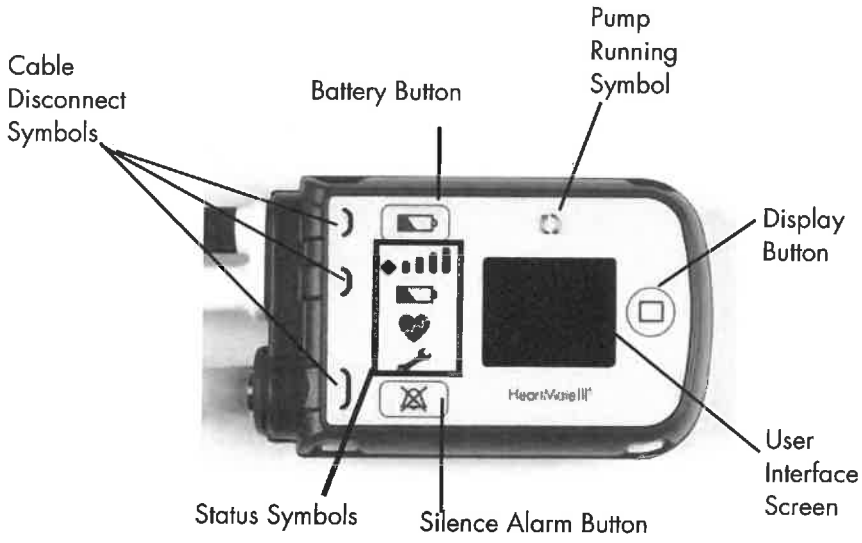


Figure 2.7 System Controller User Interface

System Controller User Interface Components

The buttons, lights, symbols, and display screen on the user interface are introduced below in **Table 2.2**.

Pump Running Symbol 	The Pump Running symbol on the user interface is illuminated 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 (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. **For more information, see page 7-14.**
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. **For more information, see page 7-8.**
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. **For more information, see page 7-7.**
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. **For more information, see page 7-16.**

Table 2.2 System Controller Symbols, Alarms, Buttons

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. **For more information, see page 7-16.**
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. **For more information, see page 7-12.**
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—either the 14 Volt Lithium-Ion batteries or the Power Module. The number of green bars means power remaining. The more green bars mean more power remaining. **For more information, see page 2-31.**
	**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. **For more information, see page 7-17.**
	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, see Viewing Pump and System Information on page 2-19.*

Table 2.2 System Controller Symbols, Alarms, Buttons (Continued)

Battery Button 	The battery button is used for the following: • **Operating the battery power gauge:** Press and release the battery button. **For more information, see page 2-31.** • **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 your running System Controller, and monthly on your backup System Controller when it is in Charge Mode. **For more information, see page 2-30.** • **Putting a running System Controller into Sleep Mode:** When a System Controller is no longer in use, it can be put to sleep by disconnecting the Driveline and power source, and pressing and holding the battery button for 5 seconds and then releasing it. **For more information, see page 2-39.**
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 (see *System Controller Alarms* on page 7-3). The LCD screen on the System Controller will display 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. **For more information, see page 7-4.**
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. **For more information, see page 2-19.**
Pulse Mode 	The presence of the black triangle indicates that the HeartMate 3 system is operating in Pulse Mode. Once every 2 seconds, the HeartMate 3 pump will automatically modify its speed to create an artificial pulse.

Table 2.2 System Controller Symbols, Alarms, Buttons (Continued)

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 2.3 shows the display sequence.

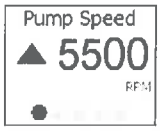
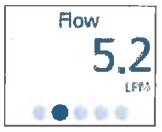
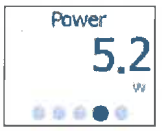
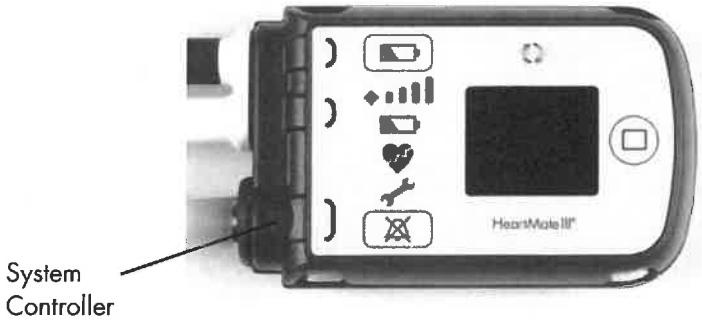
Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press display button **ONCE**		Pump speed in revolutions per minute (RPM) ▲ Triangle indicates that the pump is in Pulse Mode.
Press 	Press display button **TWO** times		Pump flow in liters per minute (LPM)
Press 	Press display button **THREE** times		Pulsatility Index (PI)
Press 	Press display button **FOUR** times		Power in watts (W)
Press 	Press display button **FIVE** times		The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states: 1. Charged (ready for use). 2. Charging (actively charging). 3. Fault (there is a fault or problem with the backup battery that could affect its reliability).
Press 	Press display button **SIX** times		Blank screen indicates the screen is off, which is normal.

Table 2.3 System Controller Display Screen Sequence

Note: On-screen messages come in many different languages and can be changed from the System Monitor to support your patient's needs. See *System Controller Language* on page 4-50.

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.



System Controller Driveline Connector

Figure 2.8 System Controller Driveline Connector on 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 Left Ventricular Assist Device. The same System Controller remains in use unless it requires replacement for clinical or technical reasons (see *The Backup System Controller* on page 2-46).

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.

Figure 2.9 Move the Safety Lock to the Unlocked Position

When the Driveline is properly and fully inserted into the System 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.

Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

A running System Controller, programmed with patient-specific settings

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 Unlock the Safety Lock

CAUTION !

Do NOT insert a misaligned Driveline Cable Connector. When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

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

Figure 2.11 Align the Arrows

4. **Insert** the Driveline Cable Connector into the socket (**Figure 2.12**), 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.

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

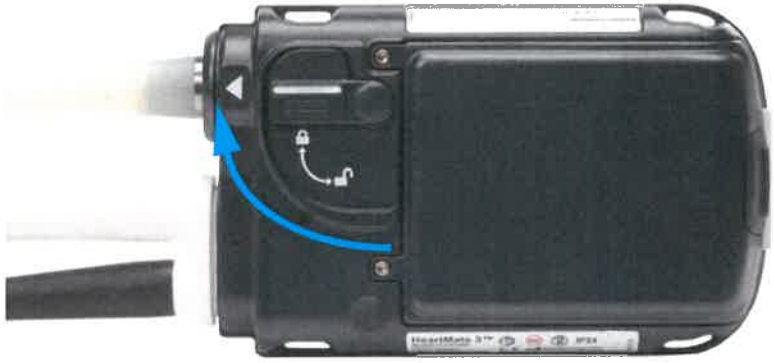


Figure 2.12 Insert and Lock the Driveline Into the Socket

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.

IMPORTANT! If the Safety Lock does not fully cover the red button, the driveline is not connected. Disconnect and reconnect the driveline.

6. Tug on the inserted metal end of 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 (see **Figure 2.13**).

Figure 2.13 Unlock the Safety Lock

3. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket. Grasp the bend relief of the Modular Cable while removing it. Do not pull on or bend the System Controller Driveline Connector (see **Figure 2.14**).

Figure 2.14 Grasp the Metal End and Remove 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**).

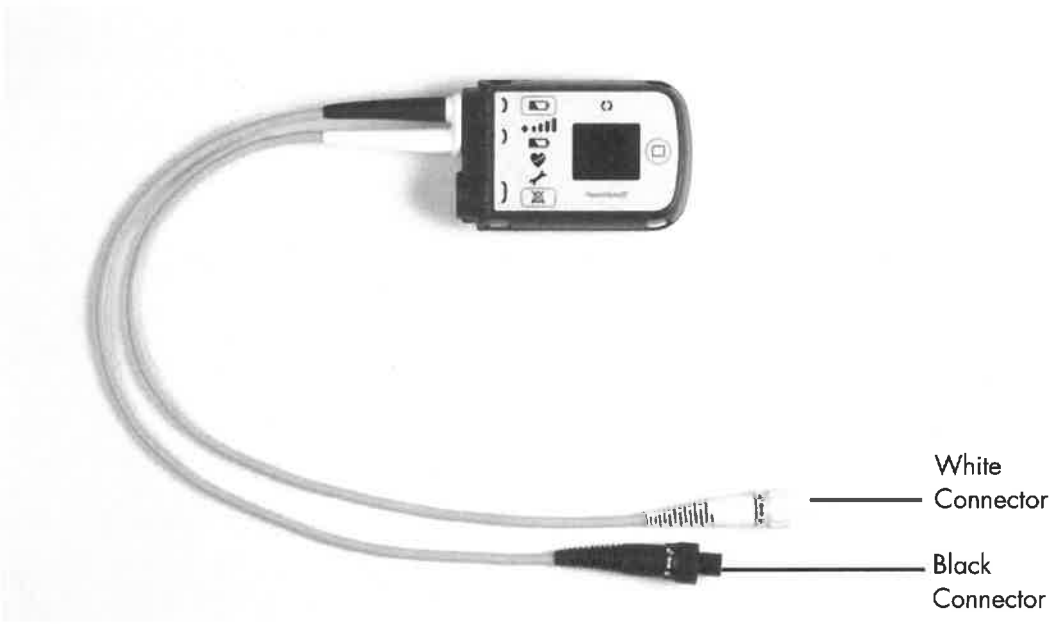


Figure 2.15 Black and White Power Cable Connectors on the System Controller

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 (see *System Monitor Setup* on page 4-6). The data link does not work without a white-to-white connection.

During routine operation, the HeartMate 3 Left Ventricular Assist System 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. See *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. See *Using the Mobile Power Unit* on page 3-35 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. See *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-51 for details.

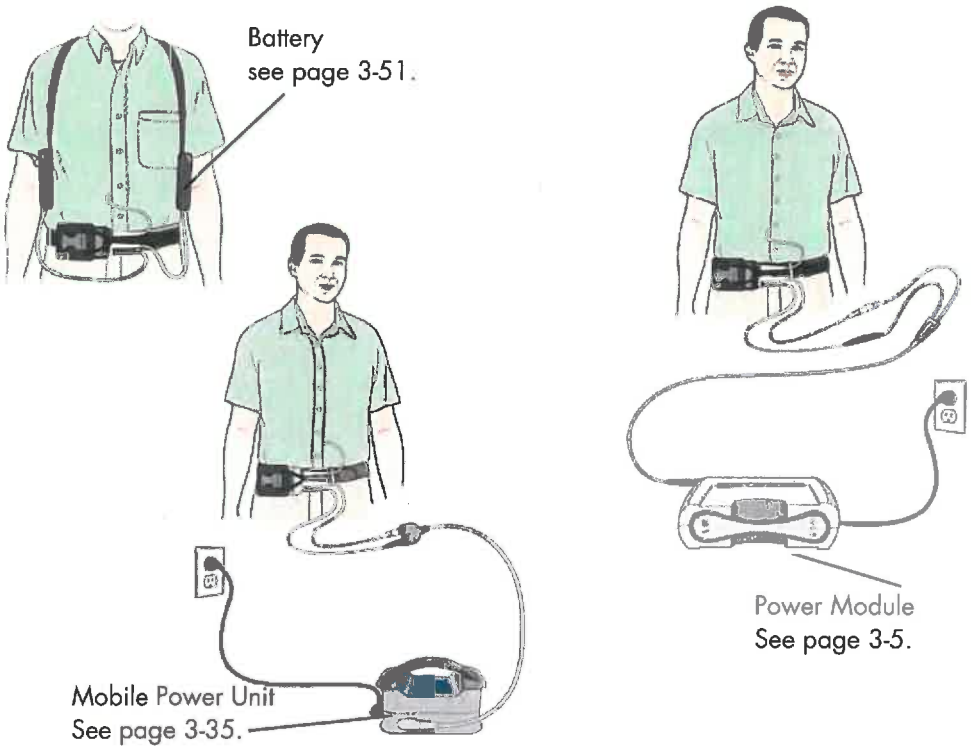


Figure 2.16 The HeartMate 3 Left Ventricular Assist Device on Battery Power (top), Power Module Power (right), and Mobile Power Unit Power (bottom)

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, see *Power Cable Disconnected 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 "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 daily 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:

   - ☐ "Self Test" (first briefly white, then black) appears on the screen.
   - ☐ All symbols and indicators on the user interface illuminate at the same time.
   - ☐ 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 which 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 described above, 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:
   Replace it with the backup System Controller and contact Thoratec Corporation 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 14 Volt Lithium-Ion batteries, the Power Module, or the Mobile Power Unit. The number of green bars means power remaining. The more green bars mean the more power remaining.

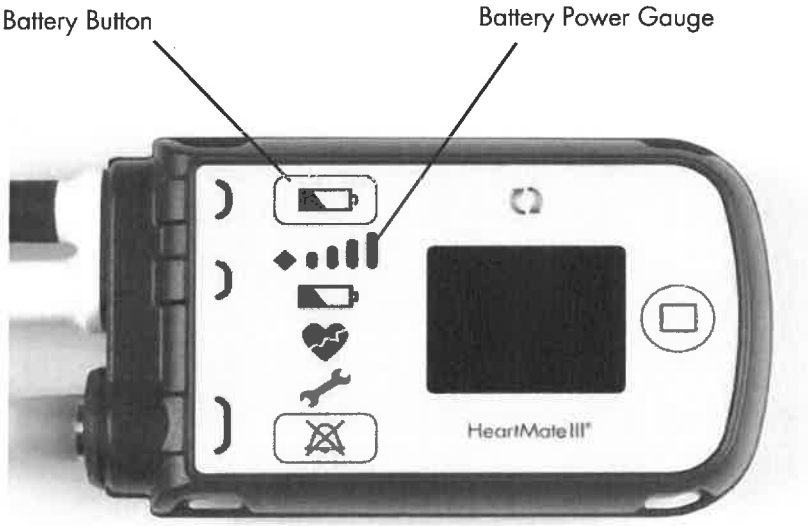


Figure 2.18 Battery Power Gauge Showing Full Charge

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

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 2-19.

14 Volt Lithium-Ion battery power:

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

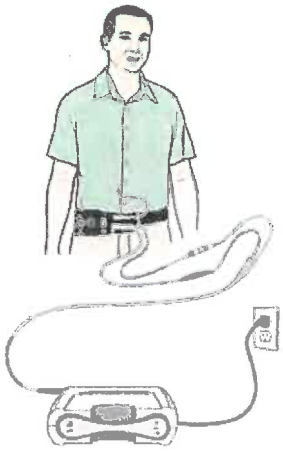
3 green bars = 50–75% of battery power remains.

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, see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-56.

Power Module power:



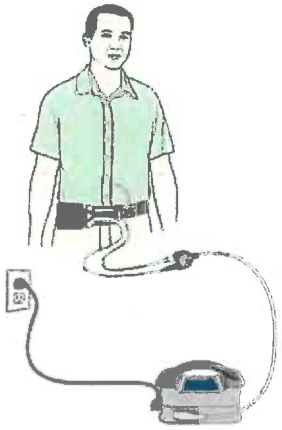
4 green bars = Normal Power Module operation.

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.

For more information, see *Low Battery Power Alarm (less than 15 minutes remain)* on page 7-17.

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

For more information, see *Low Battery Power Alarm (less than 5 minutes remain)* on page 7-14.

If either the yellow diamond or the red battery illuminate, immediately replace the depleted batteries with a fully-charged pair, or switch to the Power Module or Mobile Power Unit (see *Switching from Battery Power to the Power Module* on page 3-69 or *When to Connect to the Mobile Power Unit* on page 3-46.

System Controller Operating Modes

The System Controller has three operating modes:

- Run Mode—The system is functioning 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 to charge and maintain 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 charge its backup battery.

Each mode has a distinct function, which is described in more detail below.

Run Mode

Run Mode is the usual state for the running System Controller. **Figure 2.19** shows a System Controller in Run Mode.

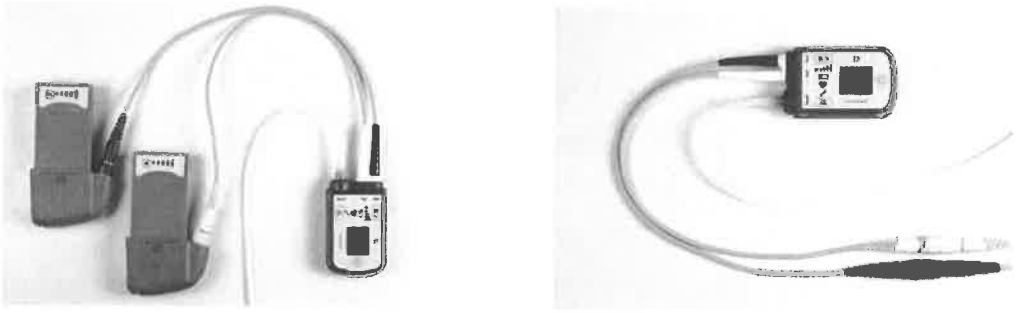


Figure 2.19 System Controller in Run Mode While on Battery Power (left) and the Power Module (right)

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

- Connected to a power source (the Power Module, the Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
- Connected to the Left Ventricular Assist Device via the Driveline.
- Sending power to the pump via the Driveline.
- Controlling and monitoring physiological and operating conditions.
- Displaying data about physiological and operating conditions.
- Using user interface indicators to reflect System Controller and pump conditions.
- Responding to user interface button pushes.
- Charging the 11 Volt Lithium-Ion backup battery inside the System Controller.
- Communicating with the System Monitor, if connected.
- Able to perform a System Controller self test.

For instructions on switching from Run Mode to Sleep Mode, see *Switching Operating Modes* on page 2-37.

Sleep Mode

Sleep Mode is the usual state for a backup System Controller. **Figure 2.20** shows the System Controller in Sleep Mode.

Figure 2.20 System Controller in Sleep Mode

The backup System Controller remains in Sleep Mode until either: 1) it is put into Charge Mode (connected to power) or 2) 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, see *Switching Operating Modes* on page 2-37.

Charge Mode

The backup System Controller must be connected to power for the 11 Volt Lithium-Ion backup battery to charge. **Figure 2.21** shows the System Controller in Charge Mode while connected to the Power Module (left) and batteries (right).

Figure 2.21 System Controller in Charge Mode

Once every six months, the "sleeping" 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 to power and putting the System Controller 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.

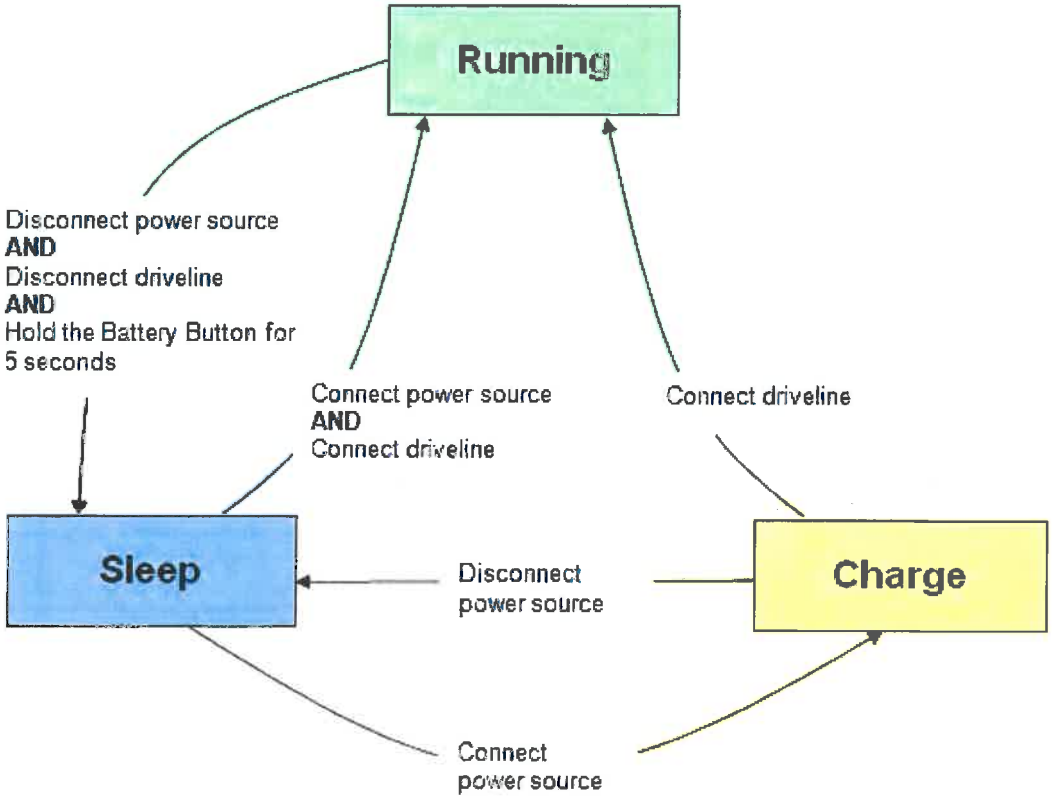


Figure 2.22 System Controller Operating Modes

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 (see *Connecting the Driveline to the System Controller* on page 2-23).
3. 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.

1. Connect the Driveline to the System Controller (see *Connecting the Driveline to the System Controller* on page 2-23).
2. 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, "Charging" and five dashes scroll across the bottom of the screen. This indicates that the 11 Volt Lithium-Ion backup battery is actively charging.

"Charging Complete" appears 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. Press and release the silence alarm button ( ) to silence the Driveline Disconnected Alarm.
2. Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Press and release the silence alarm button ( ) to silence the Power Cable Disconnected Alarm.
3. Press and hold the battery button ( ) for five seconds. The following appears on the screen:

   "Hold" accompanied by a reverse countdown from five dots to one dot.
4. 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 inside the System Controller, that is installed post-implant, provides at least 15 minutes of backup power to the Left Ventricular Assist Device 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. See *System Controller Information* on page 4-51 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 (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). 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 (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 (see *Maintaining Backup System Controller Readiness: Six Month Charging and Self Test* on page 2-51).

WARNING !

The 11 Volt Lithium-Ion back up battery inside the System Controller will not by itself start a HeartMate 3 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 3 Pump will restart during a System Controller exchange.

Replacing a Backup Battery in the System Controller

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 (see *Installing the Backup Battery in the System Controller* on page 5-54). 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. See *Installing the Backup Battery in the System Controller* on page 5-54 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 upon 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. Confirm that the date and time on the running System Controller are correct before attempting to replace the backup battery. If the date or time is incorrect, the System Controller's Backup Battery Alarm may occur (see *System Controller Alarms* on page 7-3).
2. Gather equipment (**Figure 2.24**); place within easy 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 Use 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 Use 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:
   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 Remove Ribbon Cable from Battery Socket

   c. Discard the used battery (see *Product Disposal* on page 8-10).
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 that:
    - Either a green or amber indicator light appears on the battery (green indicates that the backup battery is fully charged; amber 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 (**Figure 2.27**).
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 Tighten 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. "Charging Complete" appears on the information display screen when the newly-installed 11 Volt Lithium-Ion backup battery has finished charging (see *Charge Mode* on page 2-36).

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.

To resolve a System Controller Clock Not Set advisory alarm, use the System Monitor to reset the System Controller clock (see *Date and Time* on page 4-48). Make sure the System Monitor clock is correct before relying on it.

The Backup System Controller

HeartMate 3 patients receive two System Controllers: one to actively use (running), and a reserve (backup) in case the running System Controller experiences a failure.

Overview: Running Versus Backup System Controller

See page 2-47.

Configuring the Backup System Controller

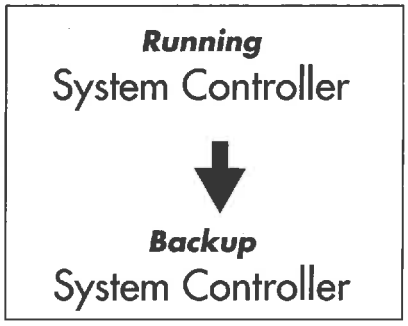
The backup System Controller must have its 11 Volt Lithium-Ion backup battery installed.

See page 2-48.

Maintaining Backup System Controller Readiness: Six Month Charging and Self Test

Every six months, the backup System Controller's internal backup battery must be charged and a self test must be performed.

See page 2-51.



Changing Controllers

If the running System Controller experiences a failure, it must be replaced.

See page 2-54.

Overview: Running Versus Backup System Controller

Every HeartMate 3 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**).

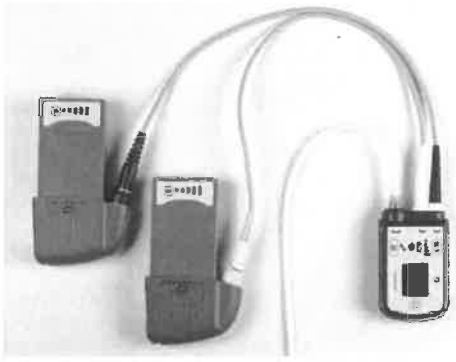
Running System Controller	Backup System Controller
 **On Power Module or Mobile Power Unit**	**If needed, ready to use** 
 **On Batteries**	**Backup is not connected to:** • **Power** • **Driveline**

Figure 2.29 System Controller States

IMPORTANT! To replace the running System Controller with the backup System Controller, see *Replacing the Current System Controller* on page 2-54.

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

Note: The System Controller will alarm. This is normal. You will see **Figure 2.30**:

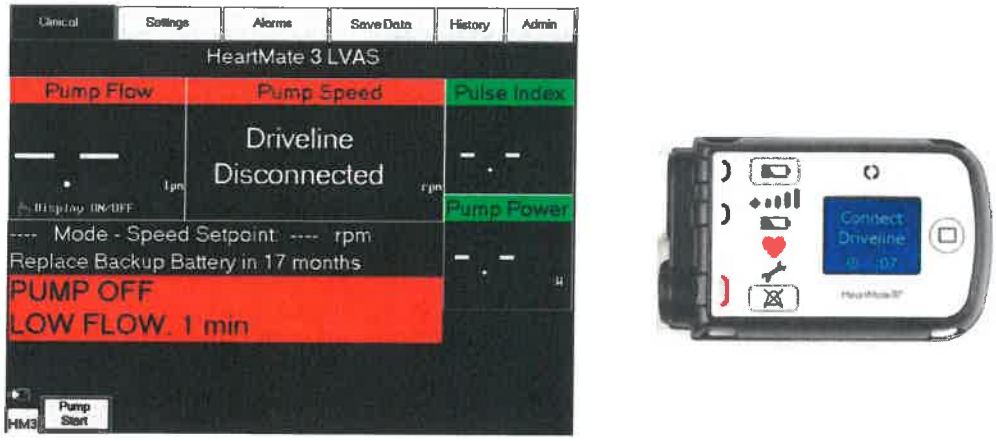


Figure 2.30 System Monitor (left) and System Controller (right)

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

For more information, see *Admin Screen* on page 4-47.

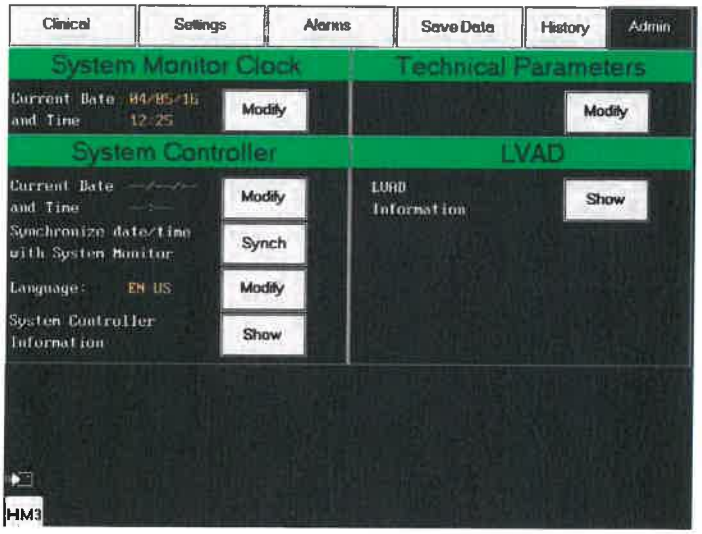


Figure 2.31 Admin Screen

4. Set the System Controller's language, if needed, via the Admin screen (shown above).

For more information, see *System Controller Language* on page 4-50.

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

For more information, see *Installing the Backup Battery in the System Controller* on page 5-54.

Figure 2.32 Install Backup Battery

6. Disconnect power from the System Controller.

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

7. Put the System Controller to sleep. Press and hold the battery button ( ) for five seconds.

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 Hold Screen

Maintaining Backup System Controller Readiness: Six Month Charging and Self Test

Over time, the backup battery inside the System Controller loses power and must be recharged every six months. You must "awaken" it, connect it to power, and put it 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, you should perform a self test.

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**).

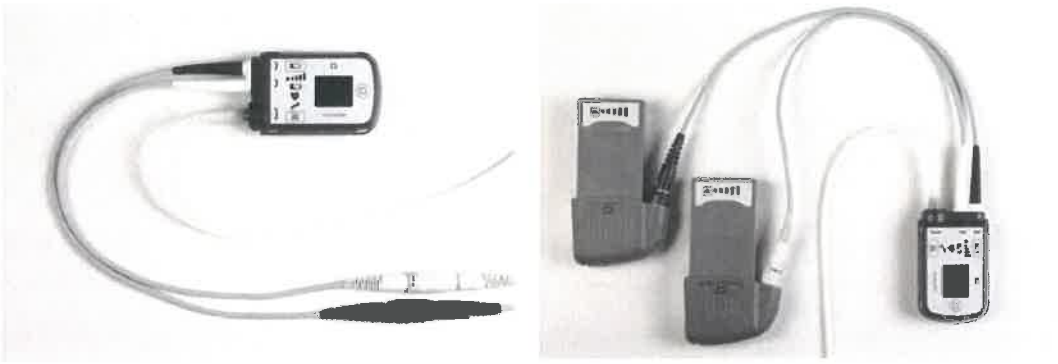


Figure 2.34 System Controller on Power Module Power (left) and Battery Power (right)

2. When the System Controller is connected to power, its 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.

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

   For more information, see *The Backup System Controller* on page 2-46.

   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, see *Using the Protection Bag* on page 6-61.

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.

CAUTION !

Ensure that the patients understand the need for having a caregiver present during System Controller exchange and that all labeling instructions are followed, including calling the hospital contact.

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 your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button (⊠).
2. Locate your replacement HeartMate 3 System Controller.
3. Move the white connector's power source from the running controller to the backup System Controller. Fully secure the white nut until tight.

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

- Do NOT insert a misaligned Driveline Cable Connector.
- When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

4. 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 (see **Figure 2.38**).

Figure 2.38 Unlock the Safety Lock

c. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket. Grasp the bend relief of the Driveline while removing it. Do not pull on or bend the System Controller Driveline Connector (see **Figure 2.39**).

Figure 2.39 Grasp the Metal End and Remove the Driveline

5. To connect the Driveline to the replacement System Controller:

   a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 2.40**).

Figure 2.40 Align 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. Orient the System Controller so the display is facing up. **Confirm the green Pump Running symbol ( ) is on.**
8. Disconnect the Black Power connection from the previously running System Controller and connect it to the replacement System Controller (and fully secure the black nut until tight) which is now supporting the patient.
9. Put the previously running System Controller into Sleep Mode. For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 2-61.

Replacing the Current System Controller with Multiple Power Sources

CAUTION !

Ensure that the patients understand the need for having a caregiver present during System Controller exchange and that all labeling instructions are followed, including calling the hospital contact.

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

1. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button ( ).
2. Locate your replacement HeartMate 3 System Controller and second power source.
3. Power the replacement System Controller by connecting both the White and Black Power connections (fully secure both the white and black nuts until tight).

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

- Do NOT insert a misaligned Driveline Cable Connector.
- When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

4. 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 (see **Figure 2.42**).

Figure 2.42 Unlock the Safety Lock

c. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket. Grasp the bend relief of the Driveline while removing it. Do not pull on or bend the System Controller Driveline Connector (see **Figure 2.43**).

Figure 2.43 Grasp the Metal End and Remove the Driveline

5. To connect the Driveline to the replacement System Controller:

   a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 2.44**).

Figure 2.44 Align 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 2.45**).

Figure 2.45 Closing the Safety Lock

7. Orient the System Controller so the display is facing up. **Confirm the green Pump Running symbol ( ) is on.**
8. Disconnect the Black Power connection and the White Power connection from the previously running System Controller.
9. Put the previously running System Controller into Sleep Mode. For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 2-61.

Turning Off the System Controller (Sleep Mode)

1. Disconnect the Driveline from the System Controller. Press and release the silence alarm button ( ) to silence the Driveline Disconnected Alarm.
2. Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Press and release the silence alarm button ( ) to silence the Power Cable Disconnected Alarm.
3. Press and hold the battery button ( ) for five seconds. The following appears on the screen:

   "Hold" accompanied by a reverse countdown from five dots to one dot.

   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 your pump is not running while changing the Modular Cable.

Before you begin, check that:

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

PROCEDURE:

1. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button (🔕).
2. Gather all the replacement equipment: replacement Modular Cable and replacement System Controller.
3. Connect the additional power source (this can be batteries, the Power Module patient cable, or the Mobile Power Unit patient cable) to your replacement System Controller.

CAUTION !

Do NOT insert a misaligned Driveline Cable Connector. When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

4. To connect the replacement Modular Cable to the replacement System Controller:
   a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 2.46**).

Figure 2.46 Align the Arrows

   b. **Insert** the Driveline Cable Connector into the socket, pressing 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. Disconnect your currently connected Modular Cable from the Pump Cable by rotating the locking nut of the inline connector until the locking nut spins freely (**Figure 2.48**). You will hear a clicking sound as you rotate the locking nut (this is normal). When the clicking sound has stopped, and the locking nut spins freely, then pull the connectors apart as shown in **Figure 2.49**).

Figure 2.48 Rotate the Locking Nut

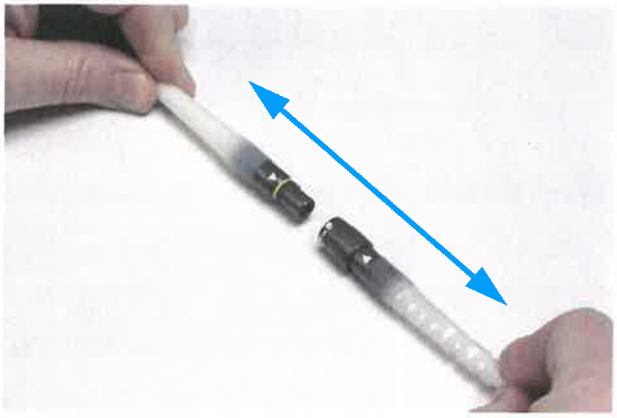


Figure 2.49 Pull the Connectors Apart

7. Connect the replacement Modular Cable (which has already been connected to the replacement System Controller) to the Pump Cable by aligning the white triangles and pushing the connectors firmly together (see **Figure 2.50**).

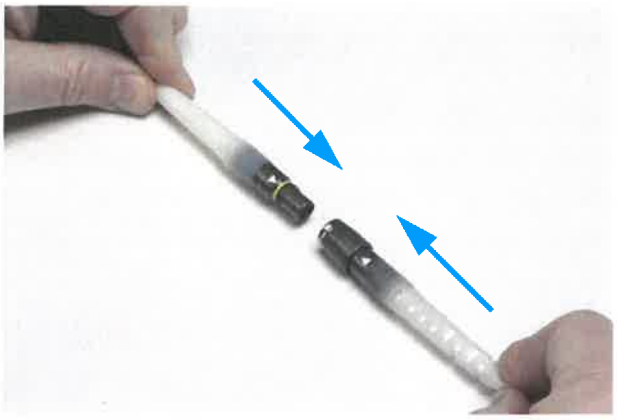


Figure 2.50 Align the White Triangles

8. Rotate the locking nut of the Modular inline connector until the clicking sound has stopped and the yellow line is hidden by the locking nut (see **Figure 2.51**).

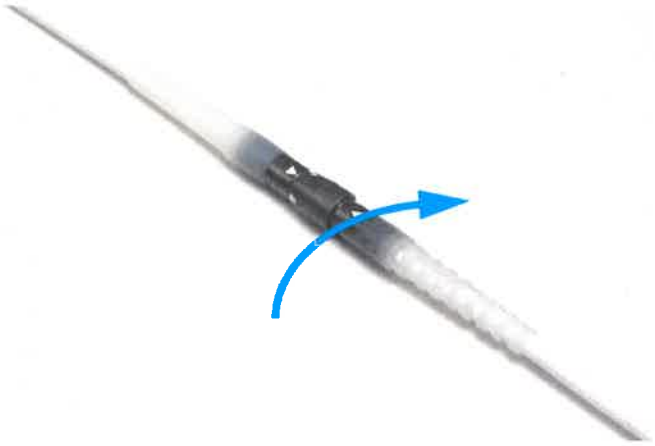


Figure 2.51 Rotate the Locking Nut

9. Disconnect power and Modular Cable from the original System Controller and 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

Before you begin, check that the replacement Modular Cable is available.

PROCEDURE:

1. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button (🔕).
2. 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 (see **Figure 2.52**).

Figure 2.52 Unlock the Safety Lock

   c. Unlock the Locking Nut on your currently connected Modular Cable from the Pump Cable by rotating the locking nut of the inline connector until the locking nut spins freely (see **Figure 2.53**). You will hear a clicking sound as you rotate the locking nut (this is normal). When the clicking sound has stopped, and the locking nut spins freely, the locking nut has been unlocked.

Figure 2.53 Rotate the Locking Nut

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

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

Figure 2.54 Grasp the Metal End and Remove the Driveline

CAUTION !

Do NOT insert a misaligned Driveline Cable Connector. When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

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

   a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 2.55**).

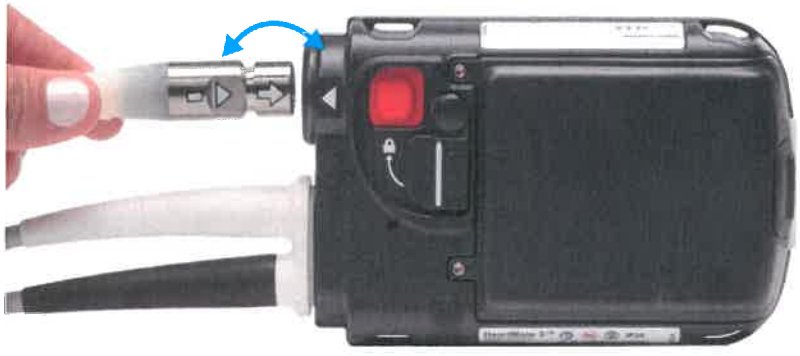


Figure 2.55 Align the Arrows

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

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

4. 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

5. Pull apart the Modular inline Connector as shown in **Figure 2.57**.

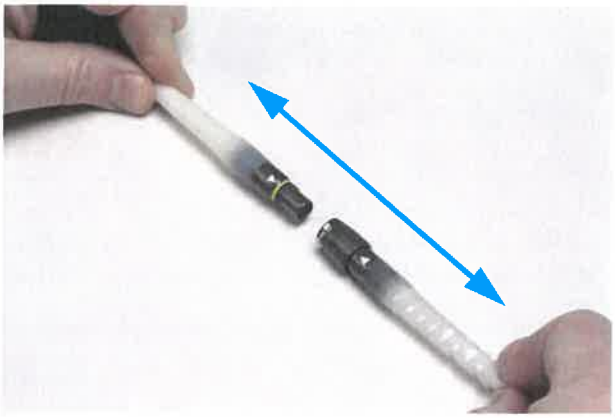


Figure 2.57 Pull the Connectors Apart

6. Connect the replacement Modular Cable (which has already been connected to the replacement System Controller) to the Pump Cable by aligning the white triangles and pushing the connectors firmly together (see **Figure 2.58**).

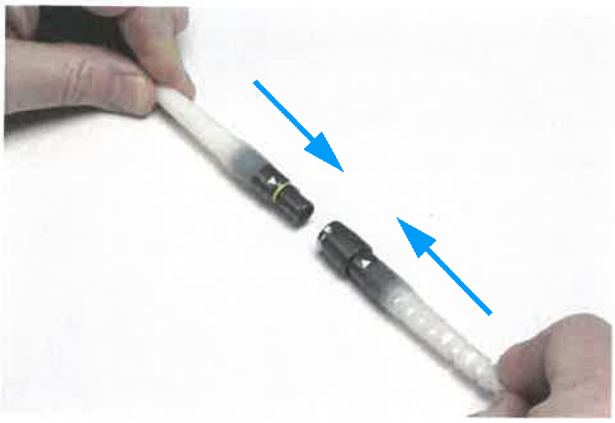


Figure 2.58 Align the White Triangles

7. Rotate the locking nut of the Modular inline connector until the clicking sound has stopped and the yellow line is hidden by the locking nut (see **Figure 2.59**).

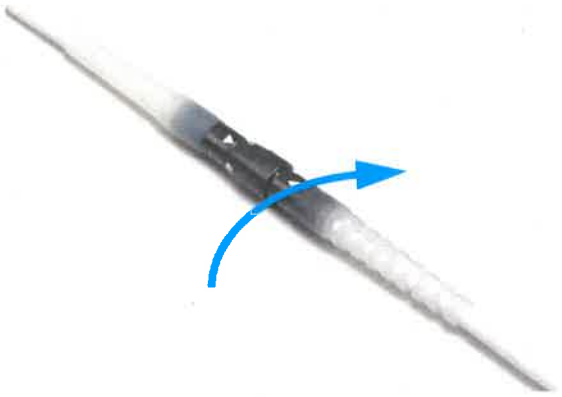


Figure 2.59 Rotate the Locking Nut