

# HeartMate II<sup>®</sup> LVAS

LEFT VENTRICULAR ASSIST SYSTEM

## OPERATING MANUAL



**T H O R A T E C<sup>®</sup>**  
C O R P O R A T I O N

6035 Stoneridge Drive  
Pleasanton, CA 94588  
Tel: 925/847-8600  
Fax: 925/847-8574  
[www.thoratec.com](http://www.thoratec.com)

Thoratec Europe Limited  
5 Brunel Court, Burrell Road  
St. Ives, Cambridgeshire, PE17 4LE UK  
Tel: +44 (0)1480 409070

**Emergency HeartLine™ USA: (800) 456-1477**  
**Emergencies outside USA: (925) 847-8600**

R<sub>x</sub> Only



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## FOREWORD

This manual contains information needed to properly and safely operate the Thoratec HeartMate II<sup>®</sup> Left Ventricular Assist System (LVAS). The *Operating Manual* and the *Instructions for Use* are intended to serve as both clinical textbook and reference; the new user should read both documents in their entirety, before system operation. For experienced practitioners, this manual may serve as a reference for detailed information.

Users of the HeartMate II LVAS should have a practical knowledge of the principles of mechanical circulatory assist and should be aware of the physiological and psychological needs of a patient undergoing mechanical ventricular support.

The first section offers the reader an overall perspective of the system. It describes the indications for use, contraindications, and potential complications. The discussion also addresses how the HeartMate II LVAS differs from others and why it is needed. *Principles of Operation* explains how the system works. *Features and Main Components* describes the technical features and operation of each system component and includes descriptions of a variety of situations likely to arise during and after pump implantation. *Patient and Device Management* describes in detail the procedures necessary to operate the HeartMate II LVAS along with cleaning and maintenance. The fifth section is devoted to troubleshooting and answering frequently asked questions. The last section contains reference information such as technical specifications and testing and classification.

As with all prescription medical devices, all clinical procedures are under the direction of the prescribing physician. The professional staff at Thoratec regularly provides laboratory training and on-site, in-service programs. Additional training materials are available for independent learning.

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# Warnings and Precautions

## WARNINGS

- **A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire booklet and the *HeartMate II LVAS Instructions for Use* prior to attempting implantation. Completion of the Thoratec Corporation user training program, including animal implantation and device operation, is required prior to the use of the HeartMate II Left Ventricular Assist System (LVAS).**
- Do not use the power base unit (PBU) in the presence of flammable anesthetic agents or an explosion could occur.
- Connect the PBU and any peripheral devices only to properly tested, grounded, and dedicated AC outlets. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.
- Do not connect the PBU to an outlet controlled by a wall switch or it may be left inoperable.
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock.
- Never operate the Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- Do not use this device in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus will dislodge the pump, which may result in device failure or fatal hemorrhage.
- Do not subject patients implanted with the HeartMate II LVAS to Magnetic Resonance Imaging (MRI) as the LVAD contains Ferromagnetic components, and MRI could cause device failure or patient injury.
- There may be risks associated with performing external chest compressions in the event of cardiac arrest, due to the location of the outflow graft conduit and the presence of ventricular apical anastomosis. Performing external chest compressions may result in damage to the outflow graft conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent device implant (prior to mediastinal healing).

- Do not apply high power electrical treatment (e.g., application of diathermy) directly to the patient.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (e.g. ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device, and the damage may not be immediately detectable.
- Avoid strong static discharges (e.g., television or computer monitor screens) as these can damage the electrical parts of the system and cause the LVAD to stop.
- To prevent device damage and personal injury, refer servicing to authorized Thoratec trained service personnel only.

### **WARNINGS - Specific Implantation Issues**

- Do not implant the HeartMate II LVAD if it has been dropped.
- During the implant process, a complete backup system (LVAD implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedures must be either removed or adequately secured so as not to become dislodged and interfere with the operation of the HeartMate II LVAS.
- Prior to advancing the inflow conduit into the left ventricle through the apical sewing ring, remove the glove tip from the inflow conduit and the centering tool from the sewing ring. Inspect the ventricle and remove any previously formed clots and trabecula that may impede flow, or an embolic event or pump stoppage may occur.
- Ensure that the thread protectors have been removed from the outflow elbow and graft prior to attempting connection, or connection will not be possible.
- All entrapped air must be removed from the blood pump and cannulae in order to minimize the risk of air embolus.
- HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure (LAP) at greater than 10 mm Hg at all times to prevent air entrainment.
- Initial weaning of cardiopulmonary bypass should ensure a minimum of two liters per minute (lpm) of blood flow to the LVAD in order to

prevent air embolism. Prolonged de-airation may be due to inadequate blood supply to the LVAD.

- Do not autoclave the pump. Doing so will cause damage to the pump and percutaneous lead.
- A minimum of two fully charged batteries are required at the time of implantation in order to power the system when transporting the patient out of the operating room. The PBU will charge and test up to six batteries in eight hours or less depending on the initial state of discharge.

### **WARNINGS - Patient/System Management Issues**

- System components must never be immersed. Showers and washing are permitted when the clinician approves wound site readiness. During showers, the HeartMate shower kit must be employed.
- In the event that the LVAD stops operating, attempt to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted. There is also the potential for retrograde flow within the LVAD.
- **Disconnecting both system controller power sources at the same time will result in loss of pump function.** One system controller lead must be connected to a battery or the PBU at all times to maintain support. The following will cause the LVAD to stop and blood pumping to cease:
  - Disconnection of both power leads from the PBU when operating on the power base unit.
  - Removal of both batteries at the same time from their respective battery clips when operating on batteries.
  - Complete depletion of battery charge when operating on batteries.
- **Disconnecting the percutaneous lead from the system controller will result in loss of pump function.** The system controller must be reconnected as quickly as possible to resume pump function.
  - For pump speeds < 8,000 rpm (typical of device implantation), reconnect the system controller and then press the alarm silence and/or pump start button as quickly as possible to resume pump function.
  - For pump speeds  $\geq$  8,000 rpm (typical of clinical use), reconnect the system controller as quickly as possible to resume pump function. Power will automatically be supplied to the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed prior to initiation of cardiopulmonary bypass and stoppage of LVAD pumping.

- Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the HeartMate II with other devices, resulting in potential interference between the HeartMate II LVAS and other devices.
- The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.
- Do not clean or service the following equipment while it is connected to a LVAS patient: system controller, PBU, PBU cable, system monitor, batteries, battery clips, emergency power pack (EPP), and EPP cable.

## PRECAUTIONS

- **The *HeartMate II LVAS Operating Manual*, which addresses the LVAD postoperative and patient management issues, must be used in conjunction with the *HeartMate II LVAS Instructions for Use*, which addresses preparation and implantation issues. These manuals are not intended to replace comprehensive laboratory or educational programs or to supersede appropriate medical judgment.**
- Sterile components of the HeartMate II LVAS are intended for single use only. Do not use the device if sterile packaging is compromised. Contact Thoratec customer service for Return Materials Authorization (RMA). Do not reuse sterile device components.
- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with LVADs.
- Ensure the pump is stopped before disconnecting the pump from the system controller.
- The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for the patient's location. Replacement of the fuse should be performed only by qualified service personnel.
- Only use Thoratec's PBU to charge batteries. Other battery chargers may damage the batteries.
- The HeartMate II LVAS rechargeable batteries should be fully charged prior to beginning the implantation procedure to allow patient transfer following the procedure.
- Do not use batteries below 15°F (-10°C) or above 105°F (40°C) or they may fail suddenly. If batteries are below room temperature (68-72°F,

20-23°C) during use, their capacity will be reduced. At the low end of the temperature range (15°F, -10°C), run time will be reduced by 50%.

- The batteries should be routinely replaced when a marked reduction in operating time is detected (about twice per year).
- To prevent deterioration or damage to the battery:
  - Do not drop or subject batteries to strong physical shock. Dropped batteries should be replaced.
  - Do not leave or store batteries in hot areas (car trunks, etc.) or battery life will be shortened.
  - Do not directly connect the negative and positive battery terminals.
- Do not store or use the EPP below 32°F (0°C) or above 122°F (50°C) or it may fail suddenly. If the EPP is below room temperature (68-72°F, 20-23°C) during use, it will run the pump for less than 12 hours. At the low end of the temperature range (32°F, 0°C), run time will be reduced by 50%.
- To prevent deterioration or damage to the EPP:
  - Do not leave or store the EPP in hot areas (car trunk, etc.) or battery life will be shortened.
  - Do not use the EPP beyond the expiration date.
- Dispose of expired, used, or damaged batteries and EPPs according to local, state, or federal regulations. Do not incinerate.
- Avoid unnecessary pulling or movement of the external portion of the percutaneous lead, especially as the skin exit site is healing. Pulling or movement could prolong the healing process or disrupt an already healed exit site. Disruption of the percutaneous lead exit site increases the patient's risk of acquiring a serious infection.
- Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand-tighten only. Using tools may damage the connectors and cause the pump to stop.
- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the PBU may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient: only use those devices necessary for patient safety and well-being.
- Avoid discharging static electricity to the system controller or LVAD percutaneous lead.
- Pump flow readings will vary with changes in blood viscosity.
- It is advised that the HeartMate II LVAS be disconnected during the use of open-heart defibrillation.

- Ensure that all backup system controllers are programmed with identical settings (e.g., fixed speed setting) as the primary controller. Controllers are shipped with factory settings, and therefore backup controllers must be programmed at the time they are assigned to a patient.

## **PRECAUTIONS - Specific Implantation Issues**

- Care must be taken to prevent blood from entering and collecting in the lumen of the cannulae. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must therefore be rinsed thoroughly prior to attachment to the LVAD.
- Do not over-tighten thread protectors.
- Do not allow the apical coring knife to involve the ventricular septum while performing the left ventricle coring.
- Do not remove the centering tool in the apical sewing ring until ready to insert the inflow conduit.
- Do not clamp the bend relief segment of the outflow graft.
- The outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.
- Do not clamp the flexible silicone segment of the inflow conduit.
- All entrapped air must be removed from the LVAD blood path prior to fully releasing the outflow graft cross-clamp.
- Once the LVAD is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the LVAD. Whenever possible, maintain the HeartMate II at a pump flow greater than 3 lpm and a pump speed greater than 8,000 rpm.
- Remove all vents on the inflow side of the LVAD, including needles in the pulmonary vein, left atrium, and left ventricle prior to initiation of pumping.
- Left atrial pressure must always be maintained at a positive value to reduce the potential for entrained air. A left atrial pressure greater than 10 mm Hg is recommended.
- Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning off cardiopulmonary bypass should provide a minimum of 2 lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered.



- The clinical trial experience indicates that certain models of implantable cardiac defibrillators (ICDs) and certain implantable pace makers (IPMs) may, in some cases, not be able to establish telemetry and be reprogrammed due to electromagnetic interference when used with the HeartMate II. In such cases the ICDs or IPMs have continued to function properly and only their ability to communicate with the programmer was affected. The HeartMate II system complies with all applicable electromagnetic compatibility standards and is not influenced in any way by such devices. Specific information on the reported cases can be obtained on Thoratec's website at [www.Thoratec.com/professionals](http://www.Thoratec.com/professionals). No such difficulties have been reported other than those observed with the devices listed on the website.
- Prior to implanting an ICD or IPM in a HeartMate II patient the device to be implanted should be placed in close proximity to the pump (approximately 10cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously implanted device that is found to be susceptible to this programming interference, Thoratec Corporation recommends replacing the ICD device with one that is not prone to programming interference.

#### **PRECAUTIONS - Patient/System Management Issues**

- Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous lead exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- The use of automated blood pressure monitoring devices may not yield accurate blood pressure data. Manual auscultation to assess blood pressure is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring or the use of Doppler ultrasound may be required.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.
- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit LVAS effectiveness due to reduced filling of the LVAD.
- An electrocardiogram may be indicated to rule out fibrillation if a patient complains of feeling "different."

- Reports of change in sounds and/or motion of the systems by the patient should prompt evaluation for cause, including the possibility of device malfunction.
- Physiological factors that affect the filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows as long as the condition persists. Pump flows will not be restored to normal unless such conditions are treated.
- The externalized portion and the lumen of the percutaneous lead at explant are not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.
- When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.
- A backup system controller and spare batteries must be with the patient at all times for use in an emergency.
- Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.
- Recharge used batteries within 12 hours or battery life will be shortened.

# General Information

## 1.0 Introduction to the HeartMate II LVAS

The HeartMate II LVAS is an axial-flow, rotary left ventricular assist system. Designed for long-term implantation, the Left Ventricular Assist Device (LVAD) can generate flows up to 10 liters per minute (lpm) independent to the left ventricular flow. Attached to the apex of the left ventricle and the ascending aorta, the pump diverts blood from the weakened left heart and propels it forward. The system controller, via its internal computer program regulates the pump.

### 1.1 System Overview

The HeartMate II LVAD is capable of pumping the entire output delivered to the left ventricle from the pulmonary circulation, and improvement in right heart function is common following LVAD implantation. Occasionally, however, high pulmonary vascular resistance may limit LVAD flow. There are currently no recognized preoperative predictors of right ventricular failure in patients requiring LVAD implantation. As a result, patients that develop right heart dysfunction may require short-term pharmacologic support and/or a period of right-sided circulatory support.

The internal surfaces of the HeartMate II LVAD (rotor, thin-walled duct, inlet stator, and outlet stator) have smooth polished titanium surfaces. The inflow conduit and outflow elbow have a textured titanium microsphere surface similar to the textured blood contacting surface on the HeartMate XVE LVAD.

Following suitable postoperative recovery, the patient may be completely mobile for extended periods, requiring only a wearable system controller and portable batteries.

#### **WARNING!**

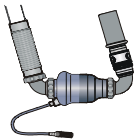
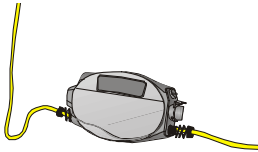

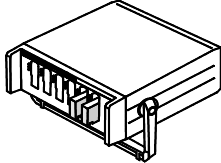
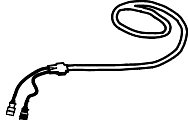
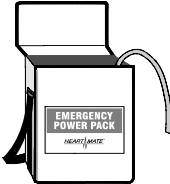


A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire booklet and the *HeartMate II LVAS Instructions for Use* prior to attempting implantation. Completion of Thoratec's training program, including animal implantation and device operation, is required prior to the use of the HeartMate II Left Ventricular Assist System (LVAS).

## 1.2 System Components

### 1.2.1 Hardware

Table 1 identifies the HeartMate II LVAS components and accessories. The chapters that follow describe each component in detail. Component specifications can be found in Appendix I.

**WARNING!**  
Refer servicing to authorized, Thoratec trained service personnel only.

HeartMate II LVAD		The LVAD consists of the implanted blood pump, inflow conduit, outflow graft, and a percutaneous lead.
System Controller		The system controller is a small computer control package that regulates LVAD function and serves as the primary user interface.
Batteries and Battery Clips		Batteries and battery clips are used for battery-powered operation.
Power Base Unit (PBU)		The PBU powers the LVAD during tethered operation and is used to charge and test the batteries.
PBU Cable		The PBU cable is used to connect the PBU to the system controller. The connectors are color coded: black mates with black and white mates with white.
Emergency Power Pack (EPP)		The EPP provides up to 12 hours of power. The EPP is used outside the hospital in the event of a power outage that lasts longer than the capacity of standard system batteries.
System Monitor		The system monitor functions as an enhanced display and control monitor connected to the PBU. Its use during implantation is required.
Display Module		When connected to the PBU, the display module provides a small display of system performance; its use is optional.

**Table 1. HeartMate II LVAS Hardware**

## 1.2.2 Primary, Backup, and Optional Components

The HeartMate II LVAS is designed for use both in and out of the hospital setting. The primary, back-up, and optional components required to operate the system in each setting are listed in Table 2, Table 3, and Table 4.

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 2 hours from a healthcare facility with trained personnel that are capable of treating a HeartMate II patient.

### **CAUTION!**

Ensure all backup system controllers are programmed with settings identical to the primary controller. Backup controllers with settings that differ from the primary controller may result in diminished support or patient harm.

Component	Primary (required)	Backup (required)	Optional*
LVAD Implant Kit	X	X	--
System Controller	X	X	--
PBU	X	X	--
System Monitor	X	X	--
Rechargeable Batteries (set of 6)	X	--	--
Battery Clips (set of 2)	X	--	--
Tunneler	--	--	X
Inflow Conduit & Outflow Graft	--	--	X
Apical Coring Knife	--	--	X
Skin Coring Punch	--	--	X
System Controller Battery Module (previously known as driver cell)	--	--	X
Apical Sewing Ring	--	--	X
Thread Protectors	--	--	X

\* Some of the items in the optional column are included in the implant kit.

**Table 2. Implantation Components (Required and Optional)**

### **CAUTION!**

A backup HeartMate II system controller and spare batteries must be with the patient **at all times** for use in an emergency.

Component	Primary (required)	Backup (required)	Optional
Implanted HeartMate II LVAD	X	X	--
System Controller	X	X	--
Rechargeable Batteries (2 sets)	X	X	--
Battery Clips (set of 2)	X	--	Backup Optional
HeartWear™ Accessories*	X	--	Backup Optional
PBU	X	X	--
System Controller Battery Module (previously known as driver cell)	--	X	--
System Monitor	X	X	--
Display Module	--	--	X

\* HeartWear accessories include battery holster, shower kit, travel case, and PocketPak™.

**Table 3. Post Implant Hospitalization Components (Required and Optional)**

Component	Primary (required)	Backup (required)	Optional
Implanted HeartMate II LVAD	X	--	--
System Controller	X	X	--
Rechargeable Batteries (2 sets)	X	X	--
Battery Clips (set of 2)	X	--	Backup Optional
Emergency Power Pack (EPP)	X	--	--
Display Module	X	--	--
HeartWear Accessories*	X	--	Backup Optional
PBU	X	--	--
System Controller Battery Module	--	X	--
Patient Handbook	X	--	--

\* HeartWear accessories include battery holster, shower kit, travel case, and PocketPak.

**Table 4. Post Discharge Outpatient Components (Required and Optional)**

## 2.0 Indications for Use

The HeartMate II LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II LVAS is intended for use both inside and outside the hospital, or for transportation of VAD patients via ground ambulance, fixed-wing aircraft, or helicopter.

## 3.0 Contraindications

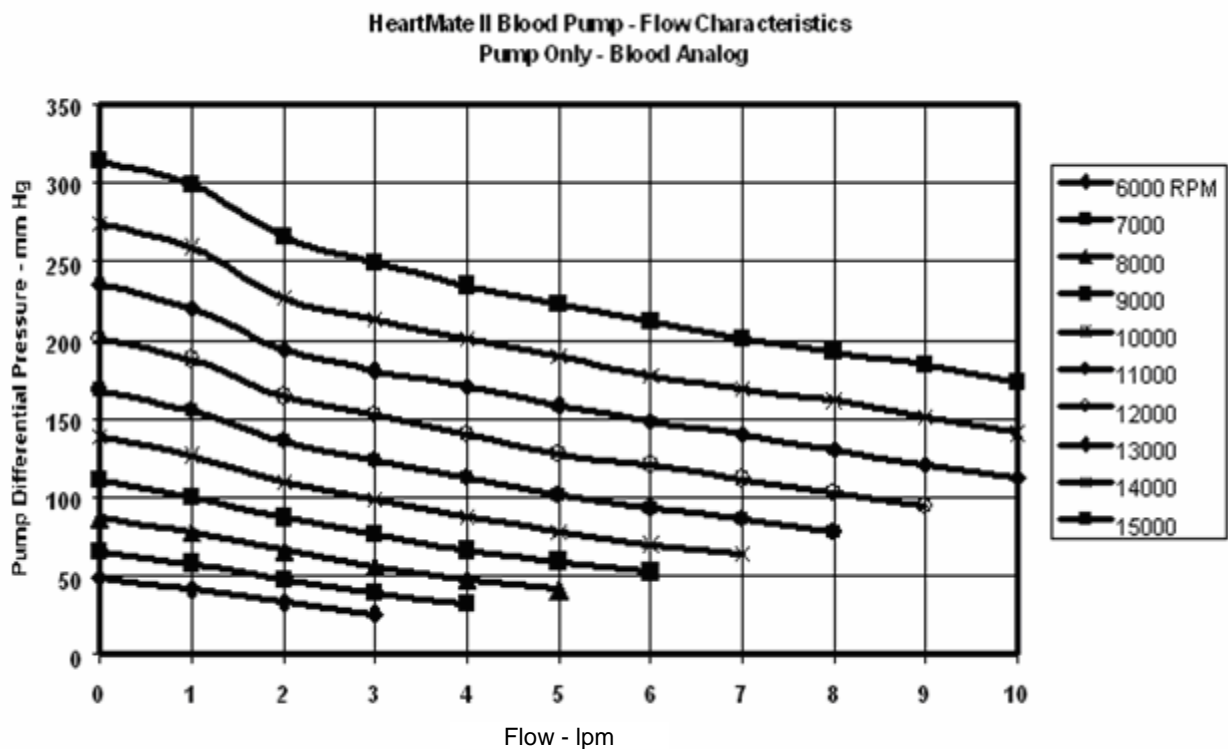
The HeartMate II LVAS is contraindicated for patients whose body surface area is less than 1.2 m<sup>2</sup>.

# Principles of Operation

## 4.0 Principles of Operation

The volume of flow generated by the HeartMate II Left Ventricular Assist Device (LVAD) is determined by the speed of rotation of the rotor and by the differential pressure that exists across the pump. For a specified speed, flow varies inversely with pressure, so increasing the pump differential pressure will decrease flow. The pressure-flow curves, also known as the H-Q curves (Figure 1), illustrate this relationship.

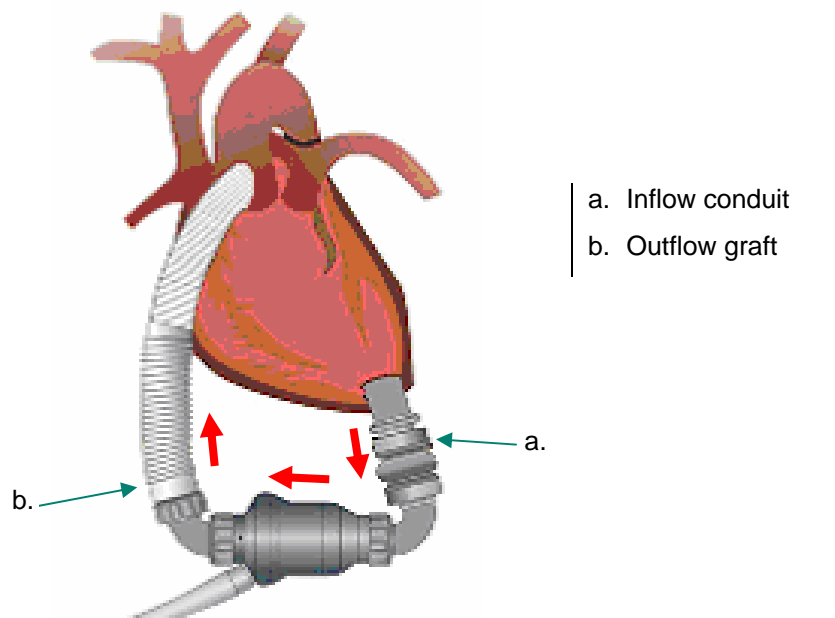
The H-Q curves were created by operating the HeartMate II LVAD in a mock loop, where for each speed, the pump outlet resistance was progressively increased and the resulting flow and pressure were measured. Speed was varied from 6,000 to 15,000 rotations per minute (rpm).



**Figure 1. HeartMate II Flow Characteristics (typical)**



The LVAD is connected to the circulation via an inflow conduit and outflow graft attached to the left ventricle and aorta, respectively (Figure 2). With these connections, during the cardiac cycle, the pump differential pressure is equal to aortic pressure minus left ventricular pressure, plus the combined pressure loss across the inflow conduit and outflow graft.



**Figure 2. LVAD Configuration**

Typically, a patient's aortic pressure is within a normal range and the net cannula pressure drop, although related to flow (for example, 10 mm Hg at 6 lpm), is low and does not greatly affect the overall differential pressure. Therefore, the dynamic parameter that determines pump differential pressure is left ventricular pressure, which in turn is dependent upon the contractile state of the ventricle. Even a severely depressed heart will have some residual rhythmic contraction that will create a pressure pulse.

This pressure fluctuation at the pump inflow will change the pump differential pressure which in turn will alter the flow accordingly. As shown in the slopes of the H-Q curves in Figure 1, a relatively small increase in pump differential pressure causes a significant reduction in flow. This means that any contraction by the left ventricle will be amplified as a flow pulse delivered to the aorta. Therefore, under most circumstances, systemic flow will be pulsatile. It takes a completely flaccid heart or one in fibrillation to have no left ventricular contribution to the flow.

In an equilibrium state, blood flow delivered by the right heart matches that delivered by the pump and left ventricle. If for a particular speed, pump capacity exceeds the flow delivered by the right heart (that is, the right heart is not feeding blood into the left ventricle fast enough), the pump will inherently lower the inflow (left ventricular) pressure, thereby increasing the pump differential pressure and reducing the flow to match the right heart flow according to the H-Q characteristics.

Similarly, should flow delivered by the right heart exceed the capacity of the pump at a particular speed, the pump inflow pressure will rise. This will cause the pump differential pressure to decrease and the flow generated by the pump to increase. Therefore, within certain limits, a rotary pump auto-regulates its flow to match the volume delivered by the right heart.

In extreme cases, the left ventricular pressure can become sufficiently negative to collapse the ventricle walls, creating a suction event. A key feature of the HeartMate II system is a speed control circuit that automatically decreases the excessive pump speed during a suction event and slowly returns the pump to an appropriate speed after the suction event has been resolved.

Alternatively, if the flow state causes the pump to decrease its differential pressure, the inflow pressure may be forced to increase to significantly high pressures. Extreme cases will cause the left ventricular pressure to rise to a level slightly greater than the aortic pressure, causing the aortic valve to open and the pump differential pressure to become essentially equal to the net cannula loss. This moves the flow to the far right of the H-Q curves, and the pump experiences maximum flow. For a speed of 12,000 rpm, the flow swing could range from approximately 5 to 9 lpm across a cardiac cycle in which the differential pressure varies between 90 and 120 mm Hg as shown in Figure 1.

## 5.0 Explanation of Parameters

### 5.1 Pump Speed

The LVAD operates at a fixed speed determined by the physician during a speed ramp study (chapter 11.2.3). The low speed limit is the lowest speed at which the LVAD can operate while maintaining patient stability. A suction event will precipitate a drop in speed to the low speed limit until the suction event has ended, at which time the speed will gradually increase to the fixed speed setting. Large changes in speed may indicate an abnormal condition.

### 5.2 Pump Power

Pump power is a direct measurement of 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 a deposition or thrombus inside the pump. Depending on the speed, power values greater than 10 to 12 watts (W) may also indicate the presence of a thrombus. Abrupt changes in power should also be evaluated.

### 5.3 Pump Flow

The pump flow and power generally retain a linear relationship at a given speed. However, the power is directly measured by the system controller while the reported flow is estimated based on power. Since the displayed flow is an approximate value, it becomes imprecise at the low and high regions of the linear power-flow relationship.

This means that any increase in power not related to increased flow, such as a thrombus, will cause an erroneously high flow. Conversely, an occlusion of the flow path will decrease flow and cause a corresponding decrease in power. In either situation, an independent assessment of pump output should be performed. It is important to note that no single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.

## 5.4 Pulsatility Index

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 intervals of 15 seconds to produce a pulsatility index (PI).

The PI calculation represents cardiac pulsatility, and 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 LVAD. Higher values indicate more ventricular filling and higher pulsatility (pump is providing less support to the left ventricle) and lower values indicate less ventricular filling and lower pulsatility (pump is providing greater support, thereby further unloading of the ventricle).

PI values should be routinely monitored and should not vary significantly during resting conditions. Under otherwise stable conditions, a significant drop in PI may indicate a decrease in circulating blood volume. Additionally, PI values around 10 or higher are a cause for concern, and clinicians are recommended to contact Thoratec.

# Features and Main Components

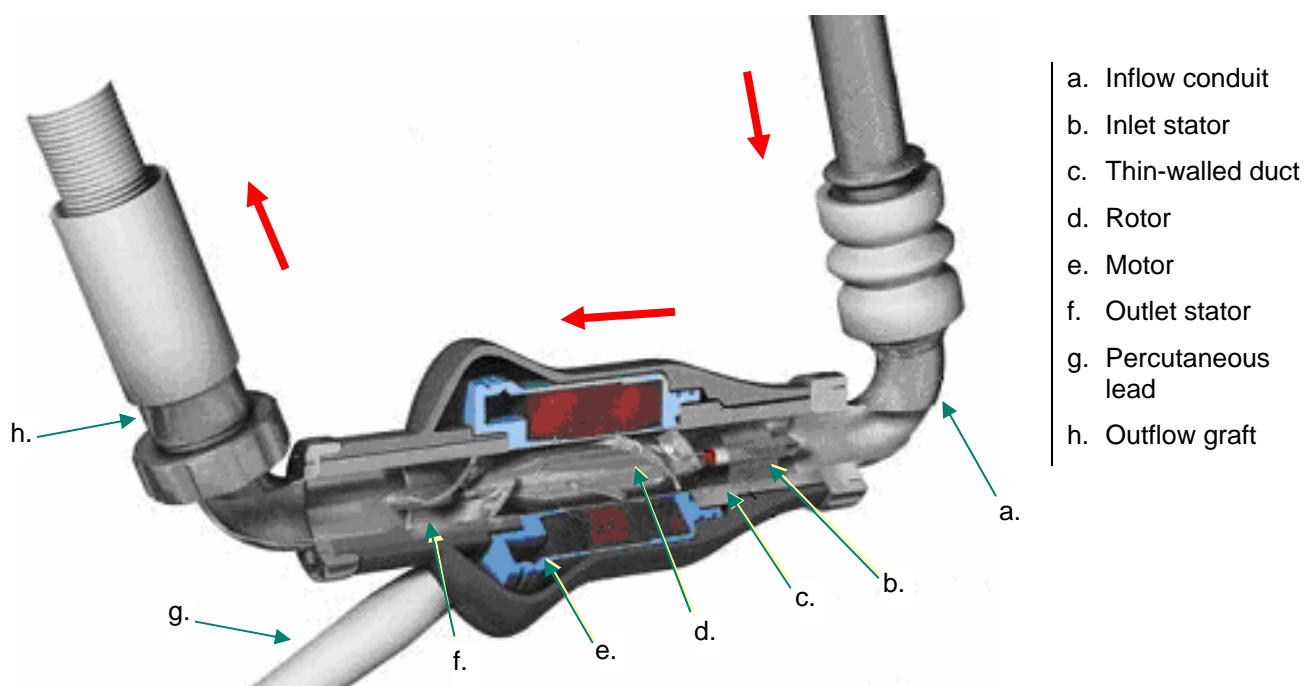
## 6.0 HeartMate II LVAD

### 6.1 Overview

The HeartMate II Left Ventricular Assist Device (LVAD) is part of the HeartMate II Left Ventricular Assist System (LVAS) that includes a system controller, pump assembly, power base unit (PBU), PBU cable, PBU power cord, batteries, battery clips, and system monitor with cable.

The HeartMate II LVAD utilizes a rotary blood pump to generate flow and assist the left ventricle. Like the left heart, this artificial ventricle provides blood pressures and flows that are pulsatile. It is an axially configured device where the path of the entering and exiting flow stream is parallel to the pump's axis. The device has only one moving part, the rotor assembly, which spins on bearings located at either end of the assembly. The pump is driven by an external power source via a percutaneous lead.

Capable of generating blood flow up to 10 liters per minute (lpm), the LVAD operates in parallel with the heart, such that either can supply blood to the aorta. Blood enters the pump from the left ventricle via the inflow conduit. Blades on the spinning rotor move the blood through the pump to an outflow graft and ultimately to the native circulation (Figure 3).



**Figure 3. LVAD Components**

## 6.2 Components

### 6.2.1 Motor

The LVAD contains an electric motor that generates torque to drive the rotor. The motor operates by creating a magnetic field that spins a permanent magnet located within the rotor and using the subsequent rotary motion of the rotor to pump blood.

### 6.2.2 Rotor

The motor's rotor is a permanent magnet located inside a thin-walled, titanium duct 12 mm in diameter that passes through the bore of the motor. A magnetic field produces rotary motion and torque, thereby initiating blood flow.

Blood entering the pump flows across three blades that structurally support the inlet stator. These blades straighten the flow field before entering the rotor. Three blades on the rotor impart kinetic energy to the flow field in the form of radial velocity. Upon leaving the rotor, the flow field

encounters the exit stator whose three blades convert the radial velocity created by the rotor back to axial velocity.

The pump rotor, thin-walled duct, inlet stator, and outlet stator have a smooth, polished blood-contacting surface to reduce the formation of thrombi.

The bearings on the inlet and outlet sides of the rotor assembly are shaped in the form of balls and cups and withstand radial and axial loads. The outer boundary of the bearing surfaces are washed directly by the main flow field.

### 6.2.3 Inflow Conduit and Outflow Graft

Blood enters and exits the pump via the inflow conduit and outflow graft. A textured surface coats the inner lumina of these two components to stimulate tissue growth and create a natural lining. This surface treatment is the same as the textured blood-contacting surface on the HeartMate XVE LVAD system.

### 6.2.4 Percutaneous Lead

The motor lead consists of a single cable that extends from the implanted LVAD through the skin to the external environment. DC power and control signals are carried to the LVAD via this lead.

To reduce the possibility of infection, the percutaneous lead is covered with woven polyester to encourage tissue bonding at the skin line. Over time, tissue bonds to the textured material, anchoring the external surface of the lead to the surrounding tissue. After emerging from the body, the lead terminates at an electric connector that attaches to the system controller.

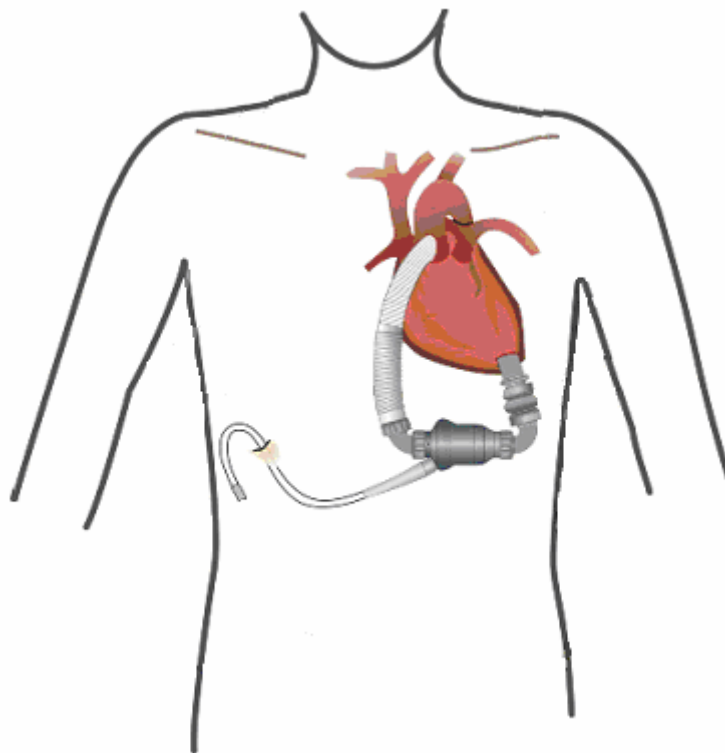
#### **WARNING!**

Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.

## 6.3 Surgical Implantation Site

The HeartMate II LVAD may be surgically implanted beneath the diaphragm in either the preperitoneal or intra-abdominal location. The preperitoneal technique requires creating a pocket for the LVAD above the posterior rectus sheath and transversalis fascia and below the rectus abdominis and internal oblique muscles. For intra-abdominal placement, the pump is inserted intra-peritoneally in the left upper abdominal quadrant. The decision between these two locations is based on the preference of the implanting surgeon.

The inflow conduit is inserted into the left ventricular apex of the heart as shown in Figure 4. The outflow graft is attached to the ascending aorta.



**Figure 4. Implantation Configuration of the HeartMate II LVAS**

## 6.4 Pump Power Source

The LVAD is powered through the system controller by two batteries or the PBU. The emergency power pack (EPP), a third power source, is used in emergency situations.



## 7.0 System Controller

### 7.1 Overview

#### 7.1.1 Function

The system controller controls LVAD operation and serves as the primary user interface of the HeartMate II LVAS.

The system controller performs the following functions:

- Controls motor power and speed
- Provides redundant system operation
- Monitors, interprets, and responds to the system
- Performs diagnostic monitoring
- Provides hazard and advisory alarms
- Records and stores events in memory
- Transfers system performance data to the system monitor and display module

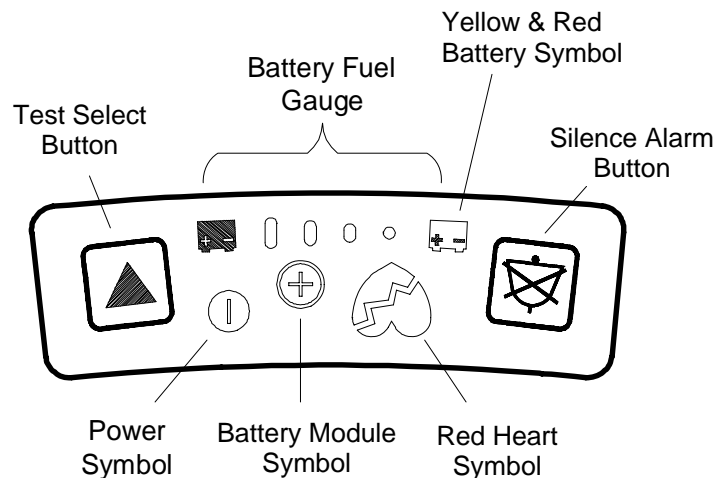
#### 7.1.2 Components

Two power leads (one with a black connector and one with a white connector) connect the system controller to its power source as shown in Figure 5. While both leads provide equal power, the white lead contains a data link cable that transmits information from the system controller to the system monitor or display module during tethered operation. An internal battery called the alarm battery module provides limited power to the system controller during situations when external power has been disrupted.

The system controller keypad is the user interface to the LVAS. As depicted in Figure 6, the keypad is composed of two push-buttons, a battery fuel gauge, and four alarm symbols. Each component is described as part of the system controller features in chapter 7.3.



**Figure 5. System Controller and Power Leads**



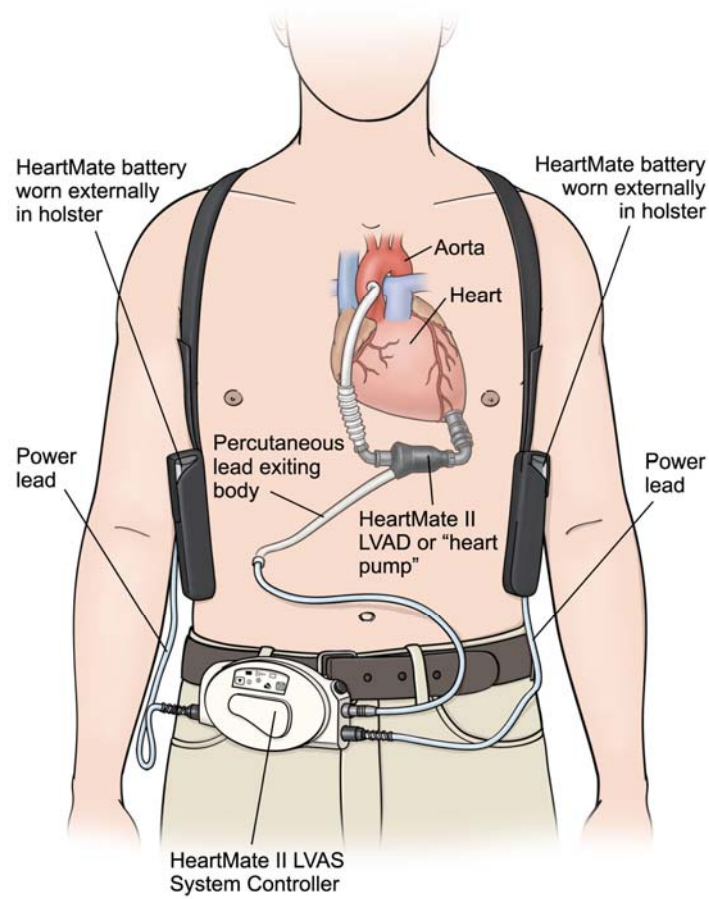
**Figure 6. System Controller Keypad**

## 7.2 Setup

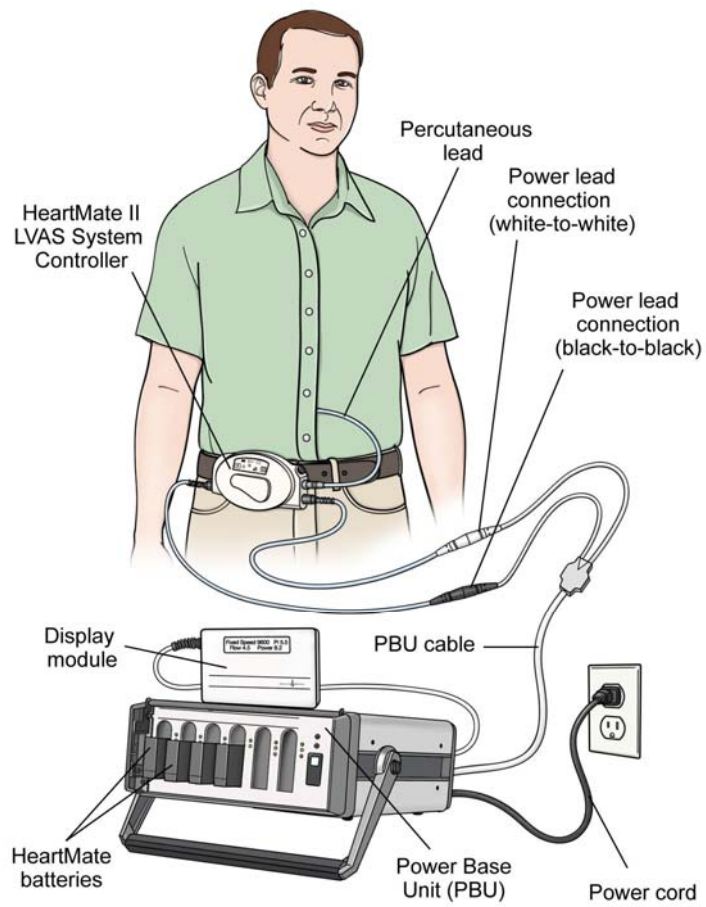
The system controller is powered from either the batteries or the power base unit (PBU). By clipping onto the right front side of the patient's belt, the system controller is readily connected to the LVAD percutaneous lead.

During battery-powered (untethered) operation, the two batteries are worn in holsters under the arms (Figure 7) or in the PocketPak (Appendix II). The short system controller power lead (black connector) is attached to the right side battery; the long power lead (white connector) is attached to the left side battery. During tethered operation (Figure 8), both power leads connect to the PBU

cable. For detailed instructions on how to set up tethered and untethered systems, refer to chapters 8.3.4 and 9.2, respectively.



**Figure 7. HeartMate II Battery-Powered Operation**



**Figure 8. HeartMate II Tethered Operation**

## 7.3 Description of Features

### 7.3.1 Modes of Operation

The system controller has one primary operating mode called fixed speed, which maintains operation at a constant pump speed. Table 5 provides the factory settings for the system controller. The controller also has a power saver mode that conserves power when voltage has decreased to a critically low level.

Function	Range	Factory Settings	Allowed Increment
Fixed Speed	6,000 – 15,000 rpm	6,000 rpm	200 rpm
Low Speed Limit	8,000 – 10,000 rpm	9,000 rpm	200 rpm

**Table 5. System Controller Factory Settings**

#### Fixed Speed Mode

Fixed speed mode maintains the blood pump at a constant speed between 6,000 and 15,000 rpm. The fixed speed, selectable in increments of 200 rpm, can only be adjusted using the system monitor. When operating at a fixed speed less than the value set for the low speed limit (lowest speed that the pump can run without the patient's condition worsening), a warning will be posted on the system monitor or display module that reads **WARNING: Low Speed Operation**. The warning is cleared when the system controller is reprogrammed to operate above the low speed limit or the low speed limit is decreased to a value below the fixed speed limit.

#### Power Saver Mode

Power saver mode, indicated by an illuminated red battery symbol on the system controller, is entered whenever the battery voltage falls to a critically low level. When in this mode, the blood pump will ramp down to a fixed speed of 8,000 rpm or the current fixed speed setting if it is less than 8,000 rpm. This allows the system to operate at a reduced but adequate level of support in an effort to provide the maximum amount of operating time (5 minutes) from the

remaining battery capacity. The pump returns to the previously set fixed speed when the power source is changed (i.e. fully charged batteries, EPP, or PBU).

### 7.3.2 Redundant System Operation

The system controller contains a primary and backup system to create redundancy in the LVAS. In the event that the primary system becomes inoperative or defective, the system controller will automatically switch to its backup system in order to maintain pump operation.

Once switched, an alarm sounds to notify the user that the system controller is now in its backup system and that the controller needs to be replaced.

### 7.3.3 System Performance Monitoring, Interpretation and Response

The system controller continuously monitors and responds to the following system performance data: pump speed, motor current, and voltage levels. When system performance falls outside of normal operating parameters, the system controller responds by initiating the appropriate alarm. During alarm conditions, changes in operating modes are initiated if necessary.

At fixed speed settings of 8,000 rpm or higher, if power to the pump is interrupted (e.g., percutaneous lead is disconnected, both batteries are disconnected simultaneously) and the pump stops, then when power is restored, the system controller will automatically restart the pump at the previously set speed. However, if the fixed speed setting is below 8,000 rpm, the user must press and hold the silence alarm or test select button for 2 seconds to restart the pump.

When connected to the PBU and system monitor, if the pump is stopped using the pump stop button on the system monitor, the system controller will not automatically restart the pump if the percutaneous lead is disconnected then reconnected to the system controller, regardless of what the fixed speed setpoint was before stopping the pump.

However, if the pump is stopped using the pump stop button and then **both power leads** are disconnected from the system controller, the system controller will



#### **NOTE:**

The system controller can be forced into its backup system by simultaneously holding down the test select and silence alarm buttons for one second **while the pump is off**. This feature is valuable when a problem with the primary system prevents the system controller from starting the pump.



#### **NOTE:**

Auscultation over the pump pocket is recommended in order to verify the pump is running.

automatically restart the pump (if the fixed speed is at least 8,000 rpm) when the power leads are reconnected.

If a suction event occurs, the system controller will automatically drop the speed down to the low speed limit and slowly ramp it back up to the fixed speed setpoint at a rate of 100 rpm per second. If the low speed limit is set at a value above or the same as the fixed speed setpoint, the pump speed will not change during a suction event.

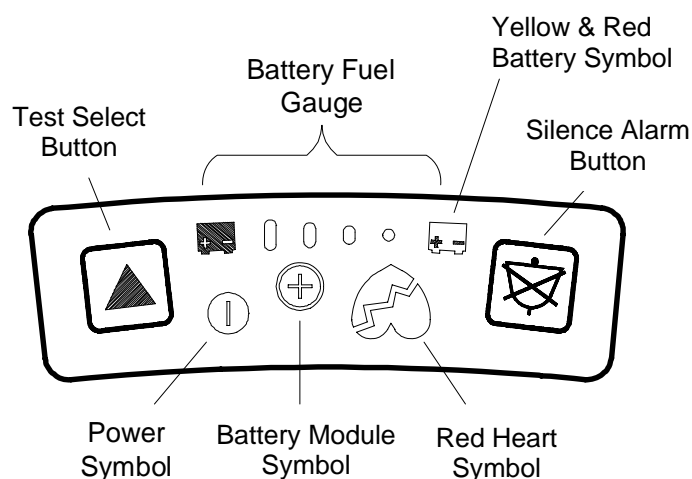
The system controller also automatically monitors and controls motor power. This function provides maximum pump efficiency and flow while preventing a stalled or laboring pump motor from drawing excessive current.

In addition to responding to performance data, the system controller records and saves changes in pump operation. The system controller event recorder automatically captures system data when there is a system event (alarm condition or change in fixed speed setting), for up to 120 alarm events. The system controller may also be configured to log performance data at scheduled intervals. See chapter 11.2.5 for more information.

The system controller automatically detects the presence of the system monitor and display module and will transmit current pump flow and other performance data via the PBU data link (white power lead). The system monitor can also display logged data in a menu-style format. Analog representations of motor voltage and current, referred to as waveforms, may be recorded onto a data card using the system monitor. System monitor operations are discussed in chapter 11.0 (waveforms in chapter 11.2.5).

### **7.3.4 Control Buttons**

The system controller has an silence alarm button and test select button (Figure 9), both of which can be used to interact with the system. Either button can be pressed and held for 2 seconds to restart the pump if the system controller does not automatically do so (for instance, if the percutaneous lead and/or power leads are disconnected from the system controller and the fixed speed setting is below 8,000 rpm). These two buttons can also be used to force the system controller into its backup system (see chapter 7.3.2).



**Figure 9. Control Buttons on System Controller Keypad**

### Silence Alarm Button

The silence alarm button has two main purposes: to display the battery fuel gauge and to silence audio alarms. An audio alarm is silenced for 2 minutes if a hazard condition or power cable disconnected advisory is active, and 4 hours if general advisories are active (see chapter 7.3.6). If the alarm condition resolves within this period, the alarm will not recur. While the audio alarm is silenced, the respective alarm symbol(s) flashes as a reminder that the alarm condition is active.

When the patient is tethered to the PBU, the PBU repeats the system controller audible alarm. This second alarm can be silenced for 5 minutes, using the alarm reset button on the PBU front panel or, to silence both the controller and the PBU, the controller silence alarm button.

Repeated attempts to prolong the silence period by pushing the silence alarm button will not add time to the silence period. An alarm condition arising during the silence period will initiate a new visual and audio alarm despite the alarm silence if the priority of the new alarm is equal to or higher than the current, silenced alarm. A new alarm condition of lesser priority will sound at the end of the silence alarm period (silent period).



## Test Select Button

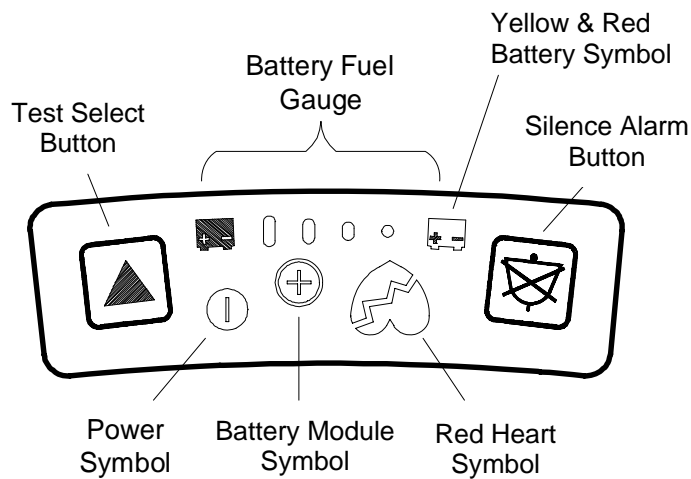
The test select button is used to initiate a system controller self-test, which should be performed daily. Refer to chapter 7.3.7 for detailed information on how to complete the self-test.

### 7.3.5 Battery Charge Level Fuel Gauge Display

The HeartMate II system controller displays a set of battery charge indicators on the battery fuel gauge (Figure 10). Pressing and holding the silence alarm button will light up the indicators, giving an approximate measure of battery charge remaining (Table 6).

The green bars indicate the approximate amount of available energy in the battery and ***do not represent battery time available***. The battery time available depends on the rate of energy usage, which varies from user to user and with patient activity level and environmental temperature. The time available also depends on the condition of the batteries: as the batteries approach their end of life, available operating time on that battery set diminishes, ***a sign that replacement is required***.

**WARNING!**  
Loss of power will cause the LVAD to stop and blood pumping to cease. Power must be restored immediately.



**Figure 10. Battery Fuel Gauge on System Controller Keypad**




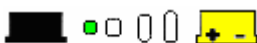
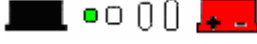


Battery Fuel Gauge	Meaning	Response
Four Green Lights 	75-100% of battery power remains.	No action needed.
Three Green Lights 	50-75% of battery power remains.	No action needed.
Two Green Lights 	25-50% of battery power remains.	No action needed.
One Green Light  	Less than 25% of battery power remains.  Yellow battery symbol: < 15 minutes remaining.  Red battery symbol: < 5 minutes remaining (power saver mode initiated).	Prepare to replace used batteries with fully charged batteries or to switch to the PBU.
<b>Flashing Four Green Lights</b>  <b>and</b> Rapidly flashing green power symbol 	Power Cable Disconnected advisory – Power lead is disconnected or damaged.  This is displayed only when the advisory is active, and not when the silence alarm button is pressed.	1. Reconnect power lead.  2. If alarm continues, check system controller and PBU power lead for damage.  3. If PBU or system controller power lead is damaged, change PBU cable or system controller.

Table 6. Battery Fuel Gauge Summary

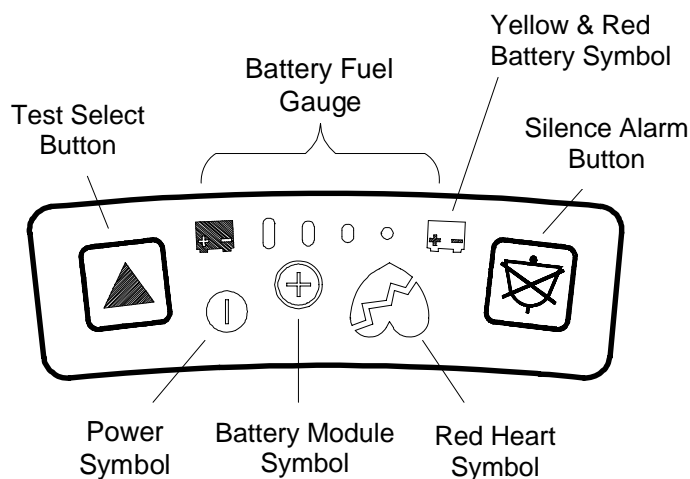
### 7.3.6 Alarms

The system controller continually checks the status of the HeartMate II LVAS for operational changes and alarm conditions. It is recommended that a system controller self-test be performed daily to further enhance system safety (see chapter 7.3.7).

#### **CAUTION!**

Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.




When a status change or alarm condition is detected, the system controller generates an audio alarm and may revert to the backup system. Visual alerts in the form of illuminated symbols on the controller keypad accompany most audio alarms (Figure 11). The alarm or status change is also communicated to the system monitor or display module.






**Figure 11. Alarm Symbols on System Controller Keypad**

There are two main categories of alarms: hazard alarms and advisory alarms. Each category has characteristic visual and audio alarm signals. Hazard alarms are the most critical and indicate that a loss of hemodynamic support has occurred or is imminent. The red heart and red battery symbols along with a continuous audio tone are used to display the presence of a hazard condition.

Advisory alarms indicate a minor malfunction, change of status, or loss of single fault tolerance that has little or no immediate effect on circulatory support. Table 7 summarizes LVAS alarm conditions and appropriate corrective actions.

Visual Symbol and Audio Alarm on System Controller	Message on Display Module and System Monitor**	Alarm Level	Meaning	Corrective Action
Continuous audio tone & red heart symbol. 	LOW FLOW (on display module)  LOW FLOW, PUMP OFF, &/or Pump Disconnected (on system monitor)	Hazard	Pump flow is < 2.5 lpm, pump has stopped, or pump is not operating correctly.	1. Check connection between system controller and LVAD.  2. Check connection between system controller and power source (batteries, PBU, or EPP).  3. If alarm continues, seek additional help immediately.  <b>See warning below table*</b>
Continuous audio tone & no warning light or green power symbol.	None	Hazard	System controller is not receiving power (no power present other than alarm battery module).	1. Check connection between system controller and power source (batteries, PBU, or EPP).  2. Change power source (chapters 8.3.4, 9.2, and 14.5).  3. Change system controller.  <b>See warning below table*</b>
Continuous audio tone & red battery symbol. 	LOW VOLTAGE	Hazard	<5 minutes of battery power remains, voltage is too low, or system controller is receiving inadequate power from PBU.	Immediately replace batteries or change to alternate power source (chapters 8.3.4, 9.2, and 14.5). LVAD will automatically go into power saver mode (8,000 rpm).  <b>NOTE:</b> Do not remove both batteries simultaneously or pump will stop.
Audio tone of 1 beep every 4 seconds & yellow battery symbol. 	Low Voltage Advisory	Advisory	<15 minutes of battery power remains, voltage is too low, or system controller is receiving inadequate power from PBU.	Replace batteries or change to alternate power source (chapters 8.3.4, 9.2, and 14.5).  <b>NOTE:</b> Do not remove both batteries simultaneously or pump will stop.

Visual Symbol and Audio Alarm on System Controller	Message on Display Module and System Monitor**	Alarm Level	Meaning	Corrective Action
<p>Audio tone of 1 beep every second</p> <p>Rapidly flashing green power symbol</p>  <p>and</p> <p>Four flashing green battery fuel gauge lights.</p> 	Power Cable Disconnected	Advisory	Power lead is disconnected or damaged.	<ol style="list-style-type: none"> <li>1. Reconnect power lead.</li> <li>2. If alarm continues, check system controller and PBU power lead for damage.</li> <li>3. If PBU or system controller power lead is damaged, change PBU cable or system controller.</li> </ol>
<p>Audio tone of 1 beep every 4 seconds &amp; yellow battery module symbol.</p> 	SC Battery Module Low	Advisory	Battery module that powers system controller is depleted.	Replace alarm battery module (chapter 7.3.8).
<p>Audio tone of 1 beep every 4 seconds &amp; no warning light when on batteries or PBU with display module.</p> <p>No audio tone or warning light when on PBU with system monitor.</p>	WARNING: Low Speed Operation	Advisory	Pump is operating below low speed limit.	<p>Connect system controller to system monitor (audio alarm will stop) and increase fixed speed setting or reduce low speed limit (chapter 11.2.3).</p> <p><b>NOTE:</b> Due to slight fluctuations in pump speed, the actual trigger point for the low speed operation alarm is 200 rpm below the low speed limit.</p>
Audio tone of 2 beeps (once per second) followed by 2 seconds of silence & no warning light.	Replace System Controller	Advisory	System controller is operating in backup mode.	<p>Replace system controller (chapter 7.3.9).</p> <p><b>See warning below table*</b></p>

\* **WARNING:** If fixed speed setting is < 8,000 rpm, silence alarm or test select button must be pressed to restart pump. If fixed speed setting is  $\geq$  8,000 rpm, pump should restart automatically.

\*\* See chapters 0 and 11.0 for information on the display module and system monitor, respectively.

**Table 7. Summary of HeartMate II LVAS Alarm Conditions**

## Low Flow or Inoperative LVAD

The system controller continuously monitors the blood flow through the pump. If the flow drops below 2.5 lpm, the system controller activates the red heart symbol and sounds a continuous audio alarm.

If the percutaneous lead becomes disconnected from the system controller, the pump will stop, resulting in a low flow condition that activates the red heart symbol and sounds a continuous audio alarm. Reconnecting the percutaneous lead will resolve the alarm and restart the pump if the fixed speed setting is at least 8,000 rpm. (If the fixed speed setting is below 8,000 rpm, the user must press and hold the silence alarm or test select button for 2 seconds to restart the pump.) Auscultate over the LVAD pocket to verify the pump is running.

### **WARNING!**

If the LVAD stops operating, all attempts should be made to restore pump function immediately. In the event that the LVAD stops operating and non-circulating blood is in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted.

## System Controller Disconnected from Power

If both power leads are disconnected from the batteries or PBU, the pump will stop and the system controller will initiate a continuous audio alarm. This alarm is powered by the system controller alarm battery module and will persist until the battery module is depleted or power is restored. The alarm will not be accompanied by the green power symbol or any other warning light.

Reconnecting the power leads will resolve the alarm and restart the pump if the fixed speed setting is at least 8,000 rpm. (If the fixed speed setting is below 8,000 rpm, the user must press and hold the silence alarm or test select button for 2 seconds to restart the pump.) Auscultate over the LVAD pocket to verify the pump is running.

### **WARNING!**

Loss of power will cause the LVAD to stop and blood pumping to cease. Power must be restored immediately.

## Low Voltage Hazard

The system controller continuously monitors the supplied voltage. If the voltage drops to a level where there is only power for less than 5 minutes of operation, a low voltage hazard condition will be indicated by the red battery symbol and a continuous audio alarm. Whenever this alarm is active, the blood pump automatically switches to power saver mode, operating at a fixed speed of 8,000 rpm or the current fixed speed setting if it less than 8,000 rpm. This allows the system to operate at a reduced but adequate level.

of support in an effort to provide the maximum amount of operating time from the remaining battery capacity. Replace the batteries or change to an alternate power source to resolve this hazard condition.

### Low Voltage Advisory

If the voltage supplied to the system controller drops to a level where there is only power for less than 15 minutes of operation, a low voltage advisory condition will be indicated by the yellow battery symbol and an audio beep once every 4 seconds. Replacing the batteries or changing to an alternate power source will resolve this alarm.

#### **CAUTION!**

Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.

### Power Cable Disconnected

If either system controller power lead connector is not properly mated to the batteries or the PBU cable, the system controller initiates a cable disconnect advisory indicated by the flashing green power symbol and battery fuel gauge lights, and an audio beep once every second. Reattach the disconnected power lead to resolve the alarm.



#### **NOTE:**

If both power leads are disconnected from the batteries or PBU while the system controller is connected to the LVAD, the system controller will emit a continuous audio alarm, indicating loss of power. This alarm also occurs if the PBU cable is disconnected from the rear panel of the PBU while the system controller is connected.

### System Controller Battery Module Low

The system controller battery module provides power for the pump in the event that the system controller loses power while connected to the LVAD. When the system controller transfers to its internal battery, the battery module low advisory is initiated, which is indicated by the yellow battery module symbol and an audio beep once every 4 seconds. This alarm will persist until the battery module is depleted or until a new battery module is inserted into the system controller.

### Low Speed Operation

A low speed operation advisory will occur when the system is operating at a fixed speed setting below the low speed limit. If the system controller is connected to the PBU with the system monitor, the message WARNING: Low Speed Operation will appear on the monitor screen. There will be no accompanying symbol on the system controller and no audible alarm. The message will disappear once the fixed



#### **NOTE:**

Due to slight fluctuations in pump speed, the actual trigger point for the low speed operation alarm is 200 rpm below the low speed limit.

speed setting is increased or the low speed limit is decreased.

If the system controller is connected to batteries or the PBU with the display module, the system controller will emit an audio beep once every 4 seconds and the display module will display the message **WARNING: Low Speed Operation**. No symbol will light up on the system controller. The audible alarm will stop once the system controller is connected to the system monitor, but the fixed speed setting or low speed limit must be adjusted in order to resolve the alarm condition.

### **Replace System Controller**

If the system controller reverts to its backup system, the controller initiates an advisory alarm indicated by a broken audio tone of 2 beeps (once per second) followed by 2 seconds of silence. There is no accompanying symbol on the system controller, but a warning is posted on the system monitor or display module if either is connected. Replace the system controller to resolve this alarm.

## **7.3.7 System Controller Self-Test**

The system controller should be checked ***daily*** for proper operation. The system controller self-test, accomplished with a single button push by the clinician or the patient, is a functional check that finishes in less than 15 seconds. Pump operation will continue while the test is running.

The test sequence activates all of the lamps and audio alarms. The clinician or patient must determine whether the symbol lamps light and the audio alarms sound. Thus, audio-visual observation is the only verification method available to the user.

Follow the steps below to perform the system controller self-test:

1. Press and hold down the test select button on the system controller. After 3 seconds, all the lamps should light up and a continuous audio tone should sound. Continue holding down the button.
2. Look closely at the display and make sure that all of the lights are on and the alarm is making a continuous tone. If there is a problem with the



alarm, it will sound for one second every other second.

3. Release the test select button. All the lights should remain lit and the audible alarm should sound for an additional 5 seconds.
4. If all the warning lights and alarms operate as described above and turn off 5 seconds after the button is released, the system controller has passed the self-test.
5. If there is a problem that requires the replacement of the system controller, the lamps will not light up and a broken audio tone at the rate of 2 beeps per second will be heard whenever the test select button is pressed. Follow the steps in chapter 7.3.9 to correct this problem.
6. Upon finishing the self-test, the pump will be operating in the same mode as it was prior to starting the test. If the lamps or audio alarms fail, replace the system controller.



**NOTE:**

The system controller self-test cannot be initiated during a hazard alarm condition.

### 7.3.8 System Controller Alarm Battery Module Replacement

When the system controller alarm battery module is low (indicated by a lit yellow system controller battery module symbol on the controller keypad and a System Controller Battery Module Low message on the system monitor or display module), the user needs to change this battery.

1. Before placing the new battery module in the system controller, verify that an orange O-ring is in place around the bottom and that the white tape is not damaged.
2. Unscrew (counterclockwise) the old system controller battery module from the side of the system controller and discard it. If it is hard to unscrew the old battery module, a flat object (such as a coin) can be placed in the slot for leverage.
3. Insert the new system controller battery module as shown in Figure 12, and tighten it until the orange O-ring can no longer be seen. Do not make it too tight.
4. Once the battery module is properly inserted, the yellow battery module symbol, audio tone, and advisory message will clear.



**Figure 12. Changing System Controller Battery Module**

### 7.3.9 System Controller Replacement

Figure 13 illustrates the connection of the percutaneous lead to the system controller. This connection remains intact throughout support on the LVAS. However, should it become necessary to replace the system controller, the steps below are to be followed.

Backup system controllers can be programmed via the system monitor without being attached to the percutaneous lead, similar to the HeartMate XVE LVAS. New settings will be displayed on the monitor, verifying that the changes have been saved to the backup system controller. See section 11.2.3 for explanations on programming controller settings.



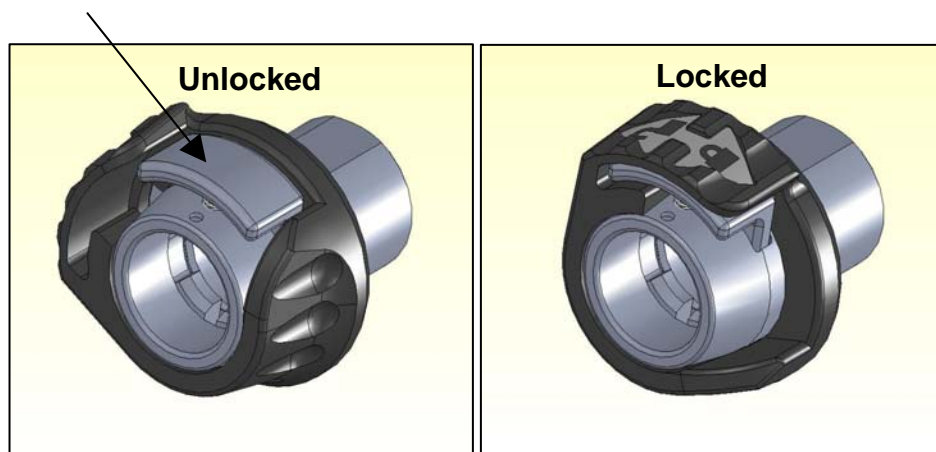
**Figure 13. System Controller Connection to LVAD Percutaneous Lead**

1. Verify that the perc lock on the replacement system controller is in the unlocked position and exposes the metal tab (Figure 14). Place this system controller within easy reach.
2. Have the patient sit or lie down.
3. Rotate the perc lock on the patient's current system controller in the direction of the unlocked icon (Figure 15) until the perc lock clicks into the fully unlocked (Figure 14) position and exposes the metal tab.

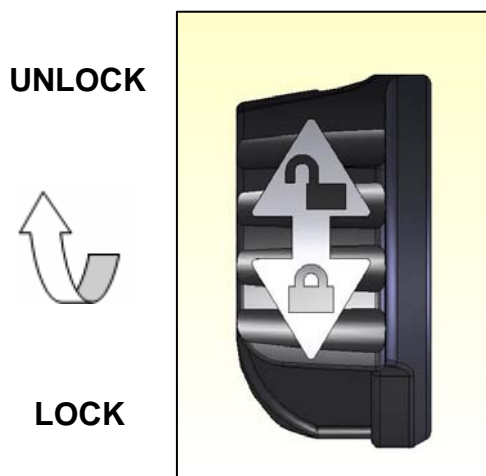
**CAUTION!**

Ensure all backup system controllers are programmed with settings identical to the primary controller. Backup controllers with settings that differ from the primary controller may result in diminished support or patient harm.

Press metal tab to disconnect percutaneous lead.



**Figure 14. Perc Lock – Unlocked (left) and Locked (right) Positions**



**Figure 15. Unlocking the Perc Lock**

4. Disconnect the white system controller power lead from the power source. The system controller alarm will sound 1 beep every second, with a rapidly flashing power symbol and 4 flashing battery fuel gauge lights.
5. Connect the white power lead of the new system controller to the current power source (PBU or battery).
6. Press the silence alarm button on the new system controller to silence the red heart alarm for 2 minutes.
7. Disconnect the percutaneous lead from the system controller by depressing the metal tab on the connector socket (Figure 14).
8. Connect the percutaneous lead to the new system controller by aligning and mating the percutaneous connector (connector on the lead coming through the patient's skin) with the system controller socket and fully inserting the connector into the socket. Push the test select button or the silence alarm button to restart the pump if it does not start automatically.
9. Connect the black power lead of the new system controller to a power source (PBU or battery).
10. If the pump does not restart and a red heart alarm sounds, check all power sources.
11. Ensure the percutaneous lead connector is fully engaged in the system controller socket and check the connection by gently tugging on the metal end of the percutaneous lead.
12. Rotate the perc lock on the new system controller in the direction of the locked icon (Figure 16) until the perc lock clicks into the fully locked position (Figure 14). ***The perc lock will not rotate unless the connector is fully inserted.***

### **CAUTION!**

When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.

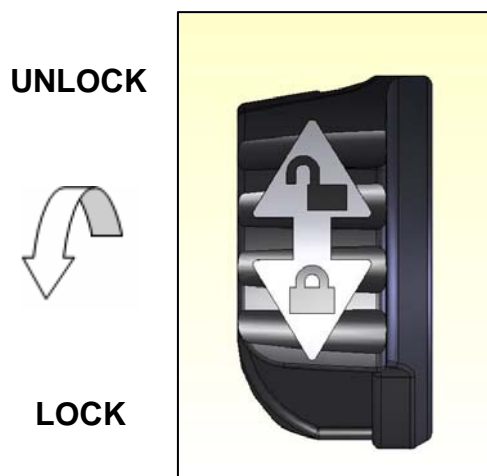
### **WARNING!**

When the system controller is disconnected from the percutaneous lead, pump function will stop. The system controller and power must be reconnected as quickly as possible to resume pump function.



### **NOTE:**

At pump speeds of 8,000 rpm or higher, if power to the pump is interrupted (e.g., percutaneous lead is disconnected, both batteries are disconnected simultaneously) and the pump stops, then when power is restored, the pump will automatically restart at the previously set mode and speed.



**Figure 16. Locking the Perc Lock**

13. Advise the patient to periodically examine his or her perc lock to ensure it is in the locked position.
14. Recheck the connection to the system controller by gently tugging on the metal end of the percutaneous lead.



**NOTE:**

If the pump fails to start, press both the test select and silence alarm buttons simultaneously before connecting the percutaneous lead. This will restart the pump in the controller backup system.

## 8.0 Power Base Unit (PBU)

### 8.1 Overview

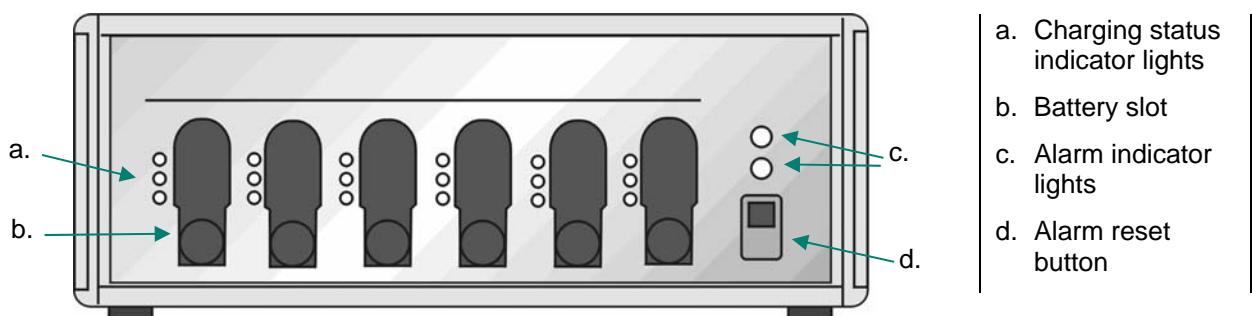
#### 8.1.1 Function

The PBU (Figure 17) has four main functions:

- Tests and charges batteries
- Provides DC power to the system controller and LVAD during tethered operation and reiterates system controller audio alarms
- Provides power to the system monitor or display module during tethered operation
- Transfers system controller data to the system monitor or display module for monitoring purposes during tethered operation

#### 8.1.2 Components

The PBU front panel includes six stations for charging batteries, two alarm indicator lights, and one alarm reset button. Each charging station contains a battery slot and three lights to indicate charging status. A power cord connects the PBU to an AC outlet and a cable with two connectors on one end (one white, one black) connects the PBU to the system controller during tethered operation.



**Figure 17. PBU Front Panel**

## 8.2 PBU Setup

To set up the PBU, follow the below steps:

1. Place the PBU on a sturdy surface and plug the PBU power cord into a grounded AC wall outlet. Do not use a wall outlet controlled by a light switch or an adapter (e.g., power strip).
2. Turn the on/off switch on the back of the unit to the on ( I ) position (Figure 18).

The PBU cable is used for tethered operation but can remain attached to the PBU when not in use:

1. Insert the PBU cable connector into the socket labeled “Patient” on the PBU rear panel (Figure 18). Rotate the connector until the keyed slot and groove are aligned and snap it into place.
2. Once the cable is inserted, rotate the barrel on the cable side of the connector until it locks (some force is required) and makes a clicking noise when turned. The connection is now complete.
3. The white and black connectors on the other end of the PBU cable can be attached to the system controller’s white and black power lead connectors during tethered operation. When the PBU cable connectors are not in use, they should be kept clean and dry.

### **WARNING!**

Connect the PBU and any peripheral devices only to properly tested, grounded, and dedicated AC outlets. Do not connect the PBU to an outlet controlled by a wall switch.

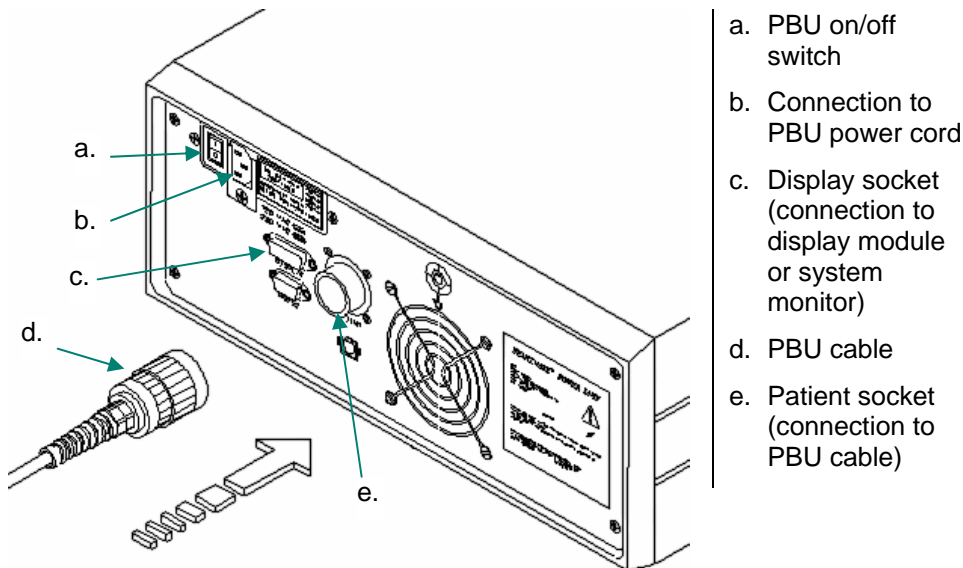
### **WARNING!**

Refer servicing to authorized Thoratec trained service personnel only.

Do not use the PBU in the presence of flammable anesthetic agents or an explosion could occur.

Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the LVAD may stop, or the patient may receive a serious electrical shock.

Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.






**Figure 18. PBU Rear Panel**

## 8.3 Description of Features

### 8.3.1 Battery Charger

The PBU will test and charge up to six batteries in 8 hours or less, depending on the initial state of discharge. Each battery station consists of a loading slot and three battery charge indicator lights that display a battery's condition. A battery should be inserted with the metal facing the top of the slot. When the battery is in place, a yellow light will turn on for about ten seconds while an electrical check is performed on the battery. After testing, one of the lights will turn on to indicate the status of that particular battery as shown in Table 8.

Indicator Light	Battery Charge Status
 Green	Battery is fully charged and ready for use. <b>NOTE:</b> Battery will not be damaged if left in PBU after being fully charged.
 Yellow	Ten-second load test is being performed. If light remains yellow after test, battery is being charged and is not ready for use.
 Red	Battery is improperly positioned in slot; reinsert into same slot to perform second load test. If battery fails second test, reinsert into different slot. If it fails again, battery is defective; DO NOT USE. <b>NOTE:</b> If battery shows red light in one slot but yellow or green light in another slot, consult Thoratec's field service department.

**Table 8. Battery Charge Indicators**

#### **CAUTION!**

Only use the Thoratec's PBU to charge batteries. Other battery chargers may damage the batteries.

Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.

Dispose of expired, used or damaged batteries according to local, state or federal regulations. Do not incinerate.



### 8.3.2 PBU Backup Power

An internal, rechargeable battery *will provide approximately 30 minutes of backup power for the LVAD* if an AC power failure (AC mains failure) occurs or if the PBU power switch is accidentally turned off while the patient is tethered to the unit. This backup battery will not power the display module or system monitor, and the battery charge status indicators will not function. The PBU will also no longer charge batteries. However, batteries in the PBU battery slots will retain the charge they had prior to the power loss.

The backup battery remains charged as long as the PBU is connected to AC power and the PBU power switch is on.

Front panel indicators, when lit, denote an AC power failure or a low internal backup battery. Refer to chapter 8.3.3 for a description of these front panel lights.

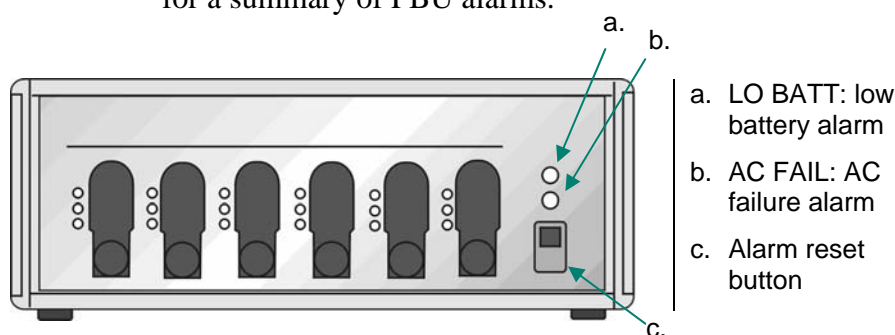


#### NOTE:

It is recommended that the patient transfer from the PBU to an alternate power source such as batteries or the emergency power pack (EPP) during an AC mains failure.

### 8.3.3 PBU Alarms

The PBU has two alarms: AC failure and low battery (Figure 19). Both alarms have LED lights and accompanying continuous audio alarms. Refer to Table 9 for a summary of PBU alarms.



**Figure 19. PBU Alarms**

When an AC power failure occurs, a continuous audio alarm will sound and the AC failure indicator will light and remain on until AC power is restored. The alarm may be silenced by pressing the alarm reset button.

During a power failure, the audio alarm will again sound and the low battery indicator will light when the internal backup battery is nearly depleted. The alarm reset button will not silence this alarm. In order to deactivate the low battery alarm, the patient must be fully transferred from the



#### NOTE:

Every 12 months the PBU needs preventive maintenance. Proper preventive maintenance consists of a functional checkout, a cleaning and inspection of all internal components and connections, and an internal battery replacement. The internal battery of the PBU is rechargeable, but has a limited life. The PBU, like any other piece of life-saving equipment, should remain continually plugged in to a properly grounded outlet except during transport.

PBU to an alternate power source such as batteries or the emergency power pack (EPP).

The PBU replicates alarms that are generated by the system controller during tethered operation. Pressing the alarm reset button will silence the PBU alarm for 5 minutes, after which it will resume if the alarm condition is still present. Silencing the PBU alarm will not silence the system controller audio alarm. However, pressing the system controller silence alarm button will silence both the controller and PBU audio alarms.

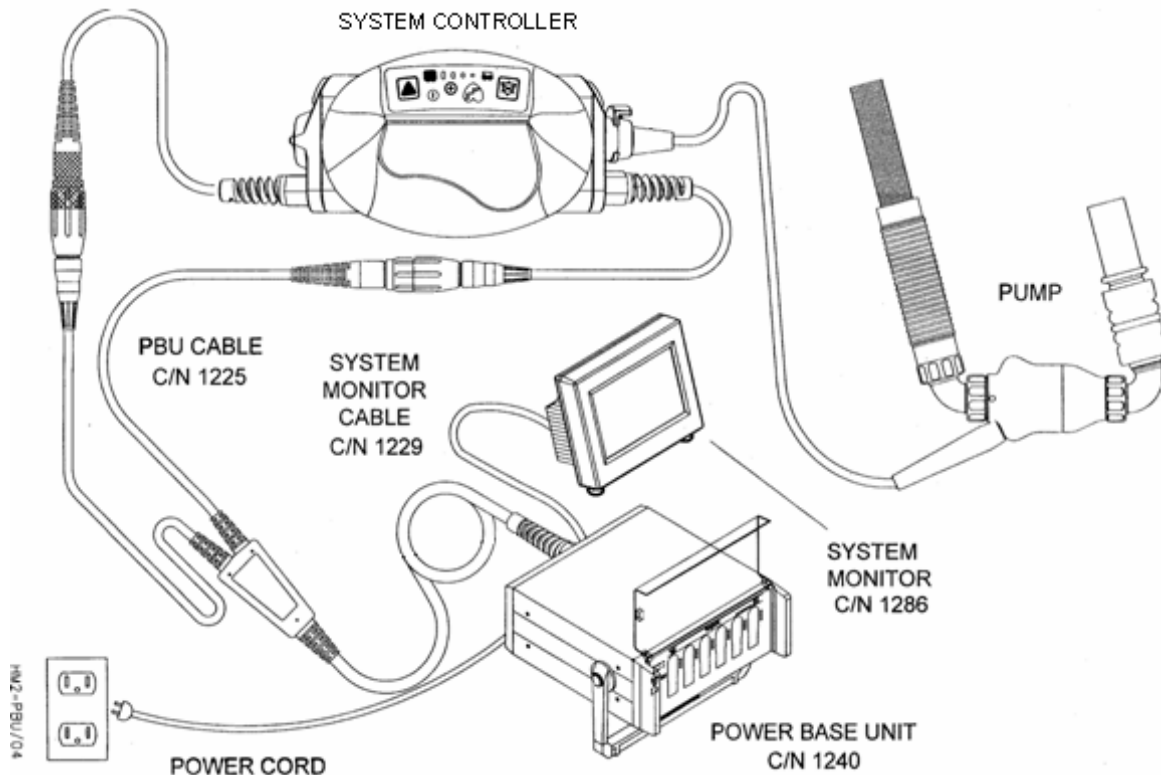
Alarm	Meaning	Corrective Action
AC FAIL light and continuous audio tone	External power to PBU is off. PBU internal battery will power pump for up to 30 minutes. PBU will not charge batteries during AC failure alarm (batteries will not lose their current charge, however).	1. Change power source from PBU to batteries.  2. If all batteries are used up before electrical power is restored, use EPP.
LO BATT light and continuous audio tone	PBU internal battery has less than 10 minutes of power remaining.	1. Change power source from PBU to batteries.  2. If all batteries are used up before electrical power is restored, use EPP.
Alarm reset button	Used to silence PBU AC failure alarm.	Press alarm reset button to silence AC failure alarm until low battery alarm occurs.

**Table 9. PBU Alarm Summary**

### 8.3.4 Tethered Operation

The components required for tethered operation are the PBU, PBU cable, and system controller (Figure 20).

Optional components for tethered operation include the system monitor or display module.



**Figure 20. Tethered Operation**

### Changing from Batteries to the PBU (Tethered Operation)

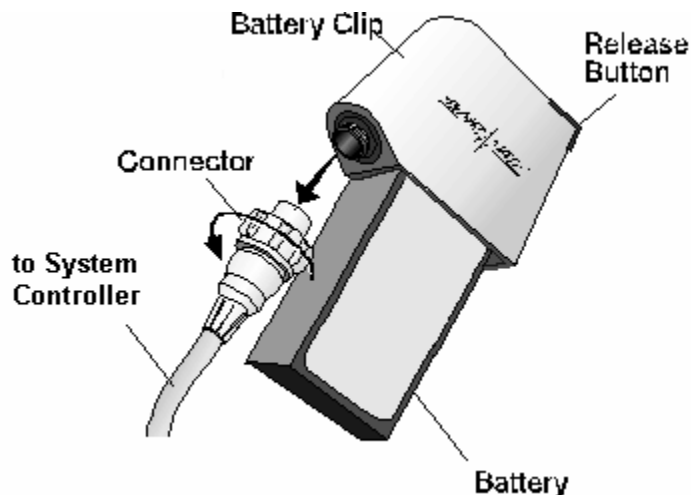
To change from mobile battery operation to tethered operation, perform the procedure below. A *Power Change Checklist* is also provided in Appendix III and should be reviewed with all patients, caregivers, and hospital personnel.

1. Verify that the PBU is plugged in and turned on and that the PBU cable is attached to the "Patient" socket on the back of the PBU (chapter 8.2). Place the black and white PBU cable connectors within easy reach.
2. Remove the batteries and battery clips from the patient's holsters or PocketPak.
3. Unscrew the white system controller power lead connector from the battery clip as shown in Figure 21. The green power symbol and all four battery fuel gauge lights will flash on the system controller and an audible alarm will sound once every second. Place the battery clip and battery aside.

#### **CAUTION!**

Never disconnect power from both controller leads at the same time or the pump will stop.

4. Connect the white PBU cable connector to the white system controller power lead connector (Figure 22). *Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stops.*

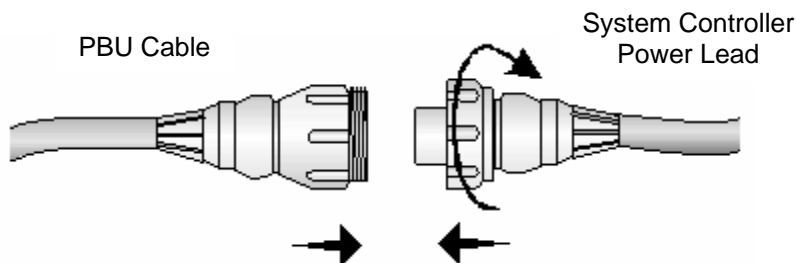


**Figure 21. Disconnecting the System Controller Power Lead from the Battery Clip**

**WARNING!**

One system controller power lead must be connected to a battery or the PBU at all times. Disconnecting both system controller power leads at the same time will result in the pump stopping and a loss of pump function.

If fixed speed is set below 8,000 rpm, the pump will not automatically restart. After restoring power, firmly press the test select or silence alarm button to restart the pump.



**Figure 22. Connecting the PBU Cable to the System Controller Power Lead**

**CAUTION!**

When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.

Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.

5. Unscrew the black system controller power lead connector from the battery clip as shown in Figure 21. The green power symbol and all four battery fuel gauge lights will flash on the system controller and an audible alarm will sound once every second. Place the battery clip and battery aside.

6. Connect the black PBU cable connector to the black system controller power lead connector (Figure 22). ***Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stops.***
7. Press the battery release button on the battery clips and remove the batteries. Place the battery clips in a safe and clean place.
8. Flip the Velcro<sup>®</sup> dots so that the black sides are facing up (chapter 9.3.1) and place the batteries into the PBU for recharging.

**WARNING!**

Do not use the PBU in the presence of Flammable Anesthetic Agents or an explosion could occur.

Keep the PBU away from water. If the PBU has contact with water, shower spray or wet surfaces, the LVAD may stop, or the patient may receive a serious electrical shock.

## 9.0 Batteries and Battery Clips

### 9.1 Overview

The HeartMate II system can be powered either by batteries or the PBU. When the patient is not tethered to the PBU, power to the implanted LVAD is provided by two 12-volt DC batteries that are inserted into battery clips as shown in Figure 23. The battery clips and batteries are worn in holsters under each arm, or in a PocketPak around the waist.

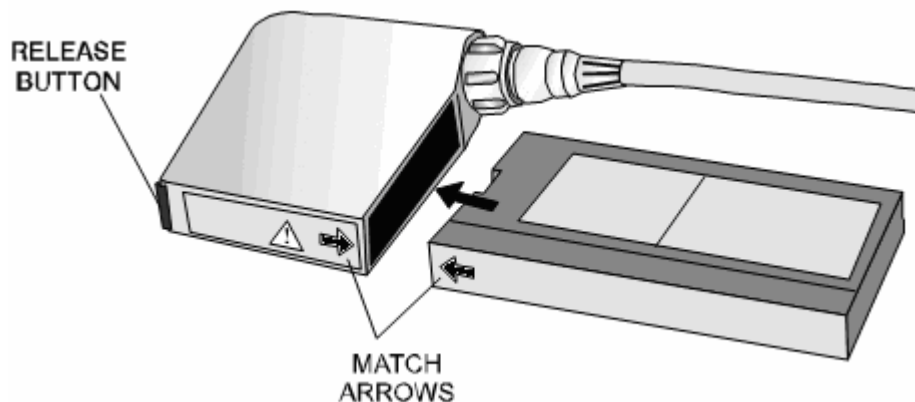


Figure 23. Battery Clip and Battery

#### 9.1.1 Function

The ability to power the LVAD by batteries allows patients to regain some of their previous freedom. Patients are not confined to the PBU and can be more mobile.

#### 9.1.2 Components

The only components required for operating the system with batteries are two battery clips, two batteries, and the system controller connected to the implanted LVAD via the percutaneous lead.

## 9.2 Battery-Powered Operation Setup

The connections between the system controller power leads and the two battery clips that the patient must become familiar with are illustrated in Figure 24. When all connections are made and batteries are inserted into their clips, the system is operational.

### **CAUTION!**

Do not use batteries below 15°F (-10°C) or above 105°F (40°C) or they may fail suddenly. If batteries are below room temperature (68-72°F, 20-23°C) during use, their capacity will be reduced. At the low end of the temperature range (15°F, -10°C), run time will be reduced by 50%.

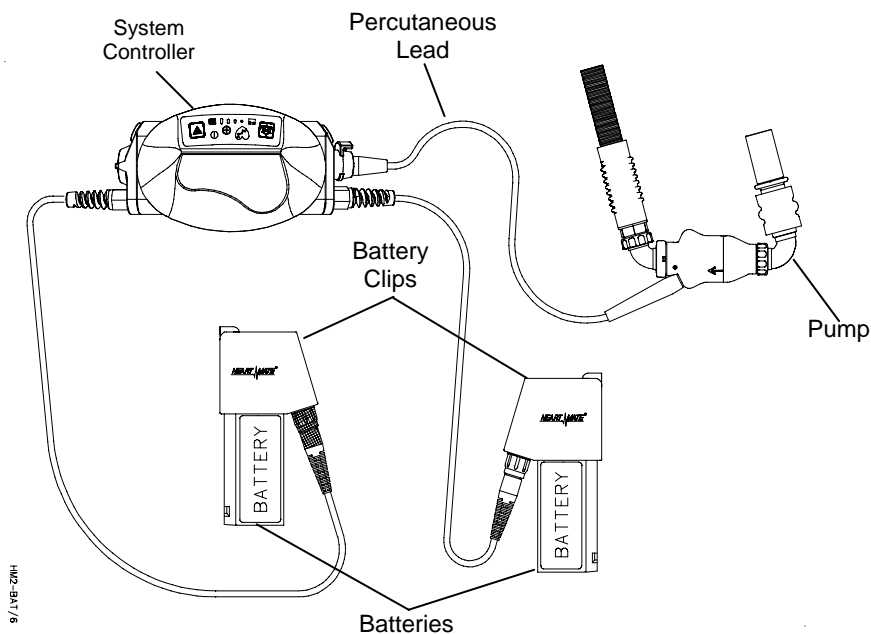
To prevent deterioration or damage to the battery:

- Do not drop or subject to strong physical shock. Dropped batteries should be replaced.
- Do not leave or store batteries in hot areas (car trunks, etc.) or battery life will be shortened.

- Do not directly connect the negative and positive battery terminals.

Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.

Dispose of expired, used or damaged batteries according to local, state and federal regulations. Do not incinerate.



**Figure 24. Battery Powered Operation**

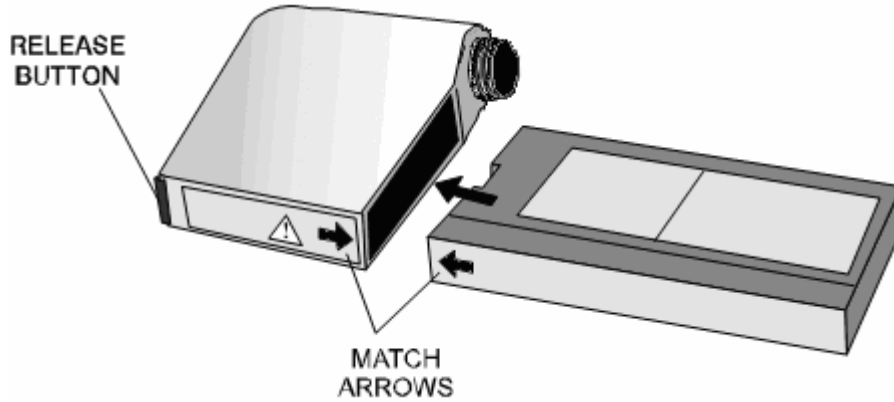
### Changing from PBU to Battery-Powered Operation

To change from the PBU to battery operation, perform the procedure below. A *Power Change Checklist* is provided in Appendix III and should be reviewed with all patients, caregivers, and hospital personnel.

1. Place two battery clips and two fully charged batteries within easy reach.
2. Place one fully charged battery into each battery clip by aligning the black arrows on the battery and battery clip (Figure 25). Push the battery into the battery clip until it clicks into place.

#### **CAUTION!**

Ensure that the pump is stopped before disconnecting the pump from the system controller.

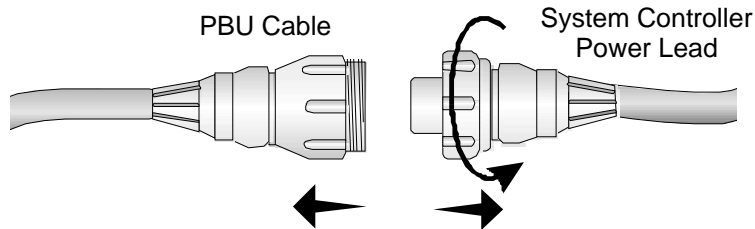


**Figure 25: Inserting Battery into Battery Clip**

3. Unscrew the white system controller power lead connector from the PBU cable connector as shown in Figure 26. The green power symbol and all four battery fuel gauge lights will flash on the system controller, and the alarm will sound once every second. Place the PBU cable connector aside.
4. Connect the white system controller power lead connector to the battery clip (Figure 27). ***Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stops.***

**CAUTION!**

Never disconnect power from both controller leads at the same time or the pump will stop.



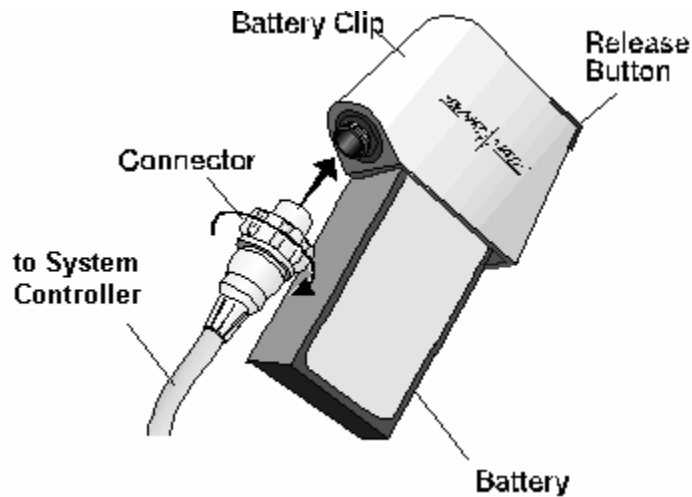
**Figure 26. Disconnecting the PBU Cable Connector from the System Controller Power Lead Connector**

**WARNING!**

One system controller lead must be connected to a battery or the PBU at all times. Disconnecting both system controller power leads at the same time will result in the pump stopping and a loss of pump function.

If fixed speed is set below 8,000 rpm, the pump will not automatically restart. After restoring power, firmly press the test select or silence alarm button to restart the pump.





**Figure 27. Connecting the System Controller Power Lead to the Battery Clip**

5. Unscrew the black system controller power lead connector from the PBU cable connector as shown in Figure 26. The green power symbol and all four battery fuel gauge lights will flash, and the alarm will sound once every second. Place the PBU cable connector aside.
6. Connect the black system controller power lead connector to the battery clip (Figure 27). ***Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stops.***
7. Turn the Velcro dots from white to black on the batteries (chapter 9.3.1) then place the battery clips and batteries in the patient's holsters or PocketPak.
8. Place the PBU cable connectors in a clean, dry place for the next use.
9. Place two additional fully charged batteries in the patient's travel case.

**WARNING!**

Loss of power will cause the LVAD to stop and blood pumping to cease. Power must be restored immediately.

**CAUTION!**

Only use Thoratec's PBU to charge batteries. Other battery chargers may damage the batteries.

## 9.3 Description of Features

### 9.3.1 Batteries

The system is optimized for operation with two batteries, but it is possible to run the system on only one. For example, when the system is being switched from batteries to the PBU or vice versa, operation will continue on a

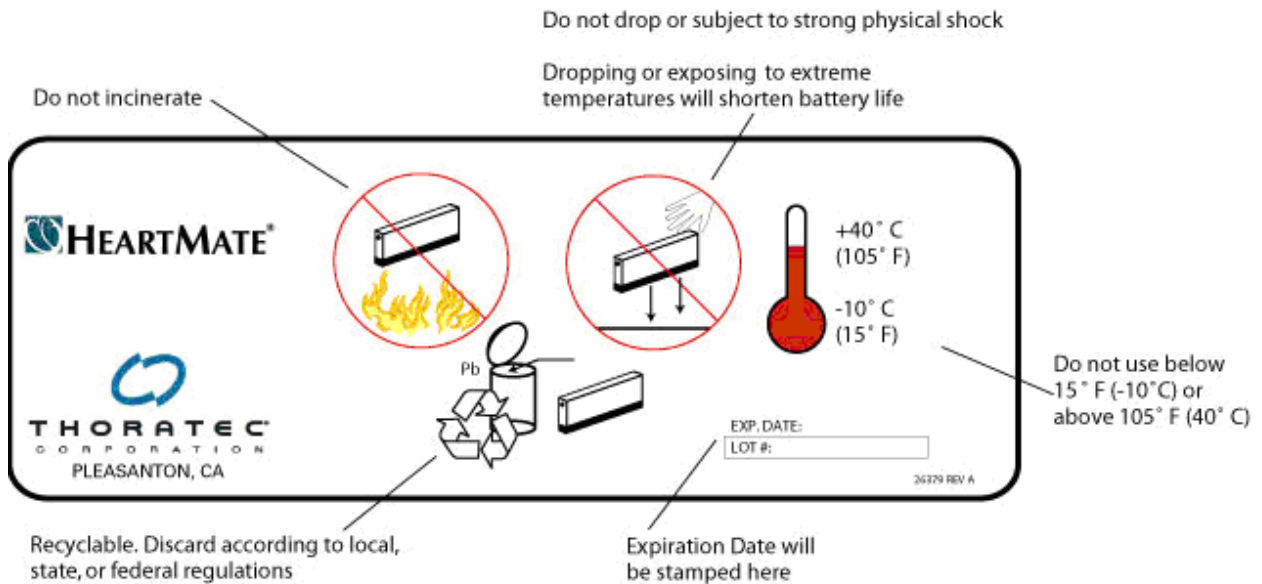
single battery while connections are made. Batteries are recharged in the PBU (see chapter 0 for details) and should provide approximately 180 charge/discharge cycles under normal conditions.

When new batteries are received, the batteries must be charged before use. The date of this initial charge should be written on the white battery label. The batteries can be used for up to one year from their initial charge date. While these batteries may last up to one year, they should be replaced when they no longer provide the expected operating time after charging.

The white battery label on each battery contains several safety symbols and the battery's expiration date as shown in Figure 28. The battery may need to be replaced earlier than the expiration date, depending on usage. Batteries should not be used after their expiration date.

**CAUTION!**

The batteries should be routinely replaced when a marked reduction in operating time is detected (about twice per year).



**Figure 28. Battery Label**

Thoratec has supplied round Velcro indicators to help the user remember which batteries are charged and which are not. When batteries have been fully charged, place the Velcro dot on the battery with the white side up (Figure 29). When batteries are used, turn the dot over so that the black side is up.

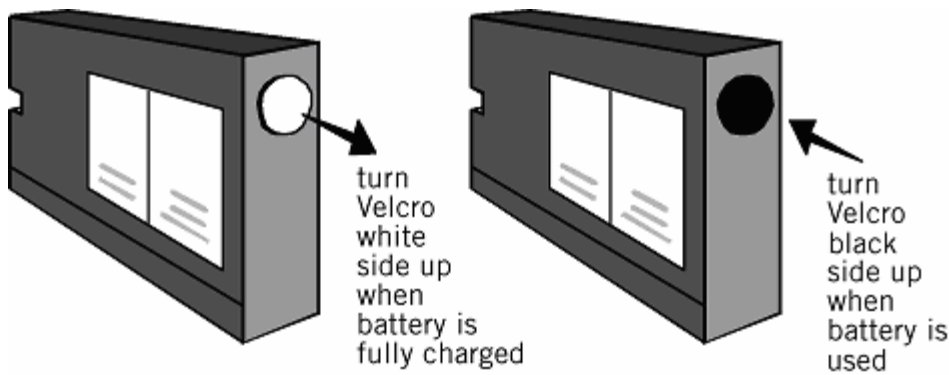


Figure 29. Battery Velcro Dots

### 9.3.2 Battery-Powered Operation

#### Estimating Battery Time

The batteries will provide about 3 hours of support under normal conditions. The batteries will last for less time as activity increases. For example, if exercise or increased emotional stress result in a demand of 9.0 lpm with a mean arterial pressure of 150mm Hg, run time will be about 2 hours. The battery fuel gauge on the system controller will provide an estimate of battery power (see chapter 7.3.5).

When approximately 15 minutes of battery power are left, a yellow battery advisory on the system controller will light and an audio beep will sound once every 4 seconds. ***This indicates that the batteries should be changed.***

A red battery hazard symbol with a continuous audio alarm will sound when approximately 5 minutes of operation remain. At this point, the system will revert to power saver mode at a fixed speed of 8,000 rpm, regardless of the previous operating mode. If the fixed speed setting is lower than 8,000 rpm, the pump will remain at the lower speed setting.

The LVAS will remain in power saver mode until fresh batteries are installed, the PBU is connected, or until no further power remains. Therefore, the red battery hazard alarm prompts for an immediate response; ***a new power source must be initiated.*** The pump will revert to the previous mode and speed when the red battery alarm clears.

## Changing Batteries

To replace depleted batteries with fully charged batteries, perform the procedure below. A *Power Change Checklist* is also provided in Appendix III and should be reviewed with all patients, caregivers, and hospital personnel.

1. Remove the battery clips and batteries from the patient's holsters or PocketPak for easy access. Verify that the Velcro dots are black side up.
2. Remove two fully charged batteries from the PBU or the patient's travel case.
3. Remove only one battery from its battery clip by pressing down on the release button on the battery clip. (The green power symbol and all four battery fuel gauge lights will flash, and an audible alarm will sound once every second.)
4. Match up the black arrows on the new battery and the battery clip. Slide the fully charged battery into the battery clip (Figure 30) until it clips into place. ***Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stops.***
5. Repeat steps 3 and 4 with the second battery clip.
6. Turn the Velcro dots from white to black on the batteries then return the batteries and battery clips to the patient's holsters or PocketPak.
7. Recharge the used batteries in the PBU.

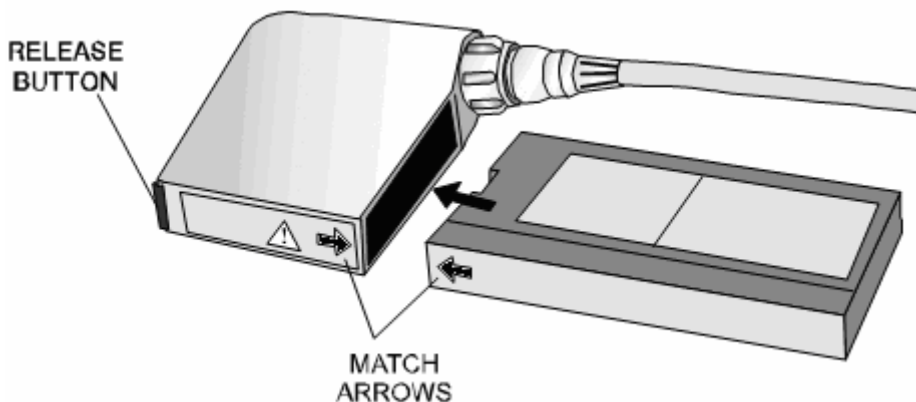
### **CAUTION!**

Never disconnect power from both controller power leads at the same time or the pump will stop.

### **WARNING!**

One system controller lead must be connected to a battery or the PBU at all times. Disconnecting both system controller power leads at the same time will result in the pump stopping and a loss of pump function.

If fixed speed is set below 8,000 rpm, the pump will not automatically restart. After restoring power, firmly press the test select or silence alarm button to restart the pump.



**Figure 30. Changing Batteries**

## 10.0 Display Module

### 10.1 Overview

#### 10.1.1 Function

When connected to the PBU, the display module (Figure 31) displays a variety of system performance data, including the current operating mode, pump speed, pump flow, pulsatility index (PI), power, and overall operational status. The display module reports data from the system controller via the power base unit (PBU).

**WARNING!**

Refer servicing to authorized, Thoratec trained service personnel only.

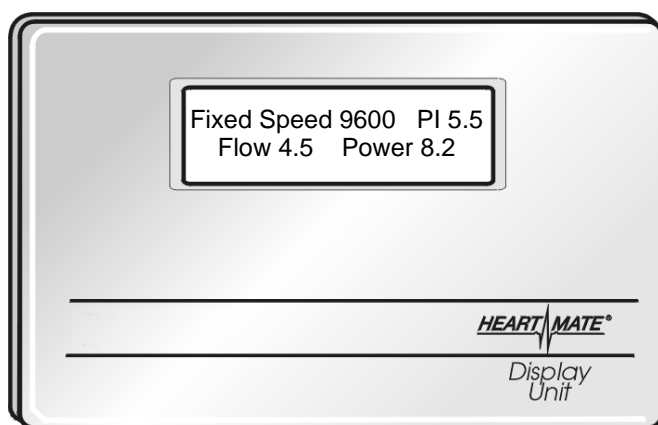


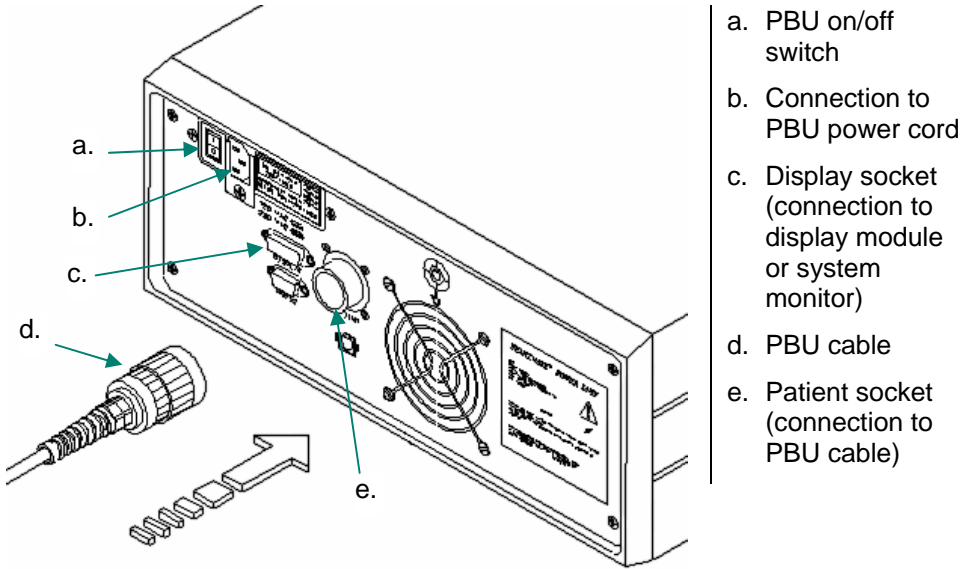
Figure 31. Display Module

#### 10.1.2 Components

The display module includes a small monitor and a cable that is connected to the PBU to receive power and system data.

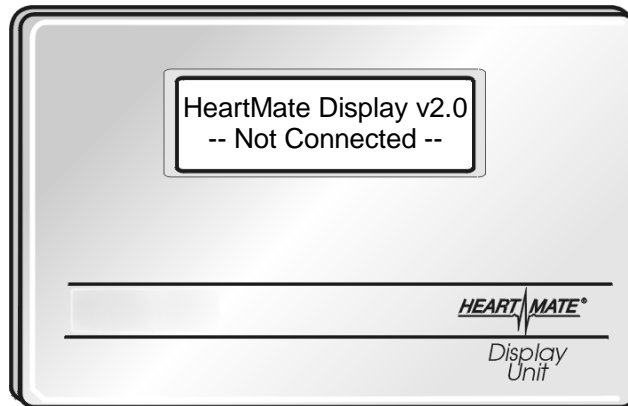
## 10.2 Display Module Setup

1. Ensure that the patient is attached to the PBU and that the PBU is plugged in and turned on.
2. Plug the display module cable into the back of the PBU, in the socket labeled “Display” as shown in Figure 32.



**Figure 32. PBU Rear Panel**

If the patient is not attached to the PBU when the display module is plugged into the PBU, a message will appear on the screen as shown in Figure 33.



**Figure 33. Display Module Screen with Not Connected Message**

### **CAUTION!**

Only use the Thoratec's PBU to charge batteries. Other battery chargers may damage the batteries.

Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.

Dispose of expired, used, or damaged batteries according to local, state, or federal regulations. Do not incinerate.

## 10.3 Description of Features

### 10.3.1 Display

After being plugged in, the display module screen will immediately begin displaying the following as shown in Figure 31:

- Current pumping mode (fixed speed)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility index
- Estimated flow in liters per minute (lpm)
- Power in watts (W)

### 10.3.2 Alarms

When an alarm is activated, the alarm status is displayed in place of the current flow and power data (**Figure 34**).

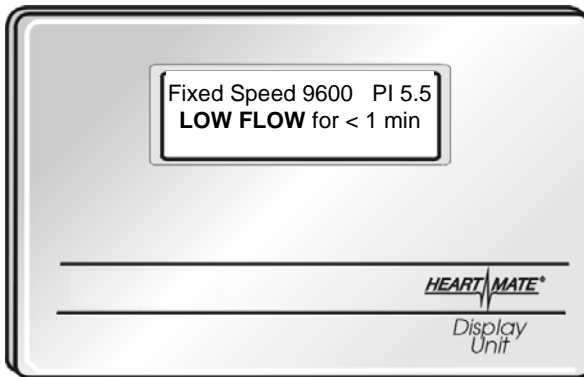


**NOTE:**

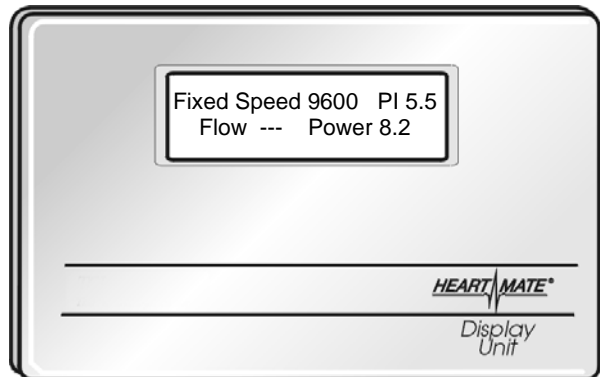
The highest priority alarm is displayed. See Table 13 in chapter 14.4 for descriptions of alarm messages.

### 10.3.3 Parameters

If the estimated flow is too low or too high to be reliably displayed, the display module will blank the estimated flow and display “Flow ---” or “Flow +++,” respectively (**Figure 35**).



**Figure 34. Display Module Screen with Sample Alarm Message**



**Figure 35. Display Module Screen with Blank Flow**

## 11.0 System Monitor

### 11.1 Overview

#### 11.1.1 Function

While the display module is sufficient for routine monitoring, the system monitor is typically used in the operating room and intensive care unit to communicate with the system controller and obtain a pump/system status display. The system monitor is used to

- Closely monitor system operation during the LVAD implant procedure
- Monitor and adjust system parameters to maintain optimal performance
- Assess and track alarm conditions
- View and save performance data
- Record data at specified intervals separate from the system controller

#### 11.1.2 Components

The system monitor has been offered in two different versions, with key features outlined in Table 10:

- Original system monitor (no longer in production)
- Updated system monitor

In the following chapters, references to the system monitor and monitor screens will be based on the updated system monitor as shown in Figure 36. Refer to Appendix IV for examples of how the new screens will look on the original, monochrome monitor and how Data is collected using a PC Card Adapter.



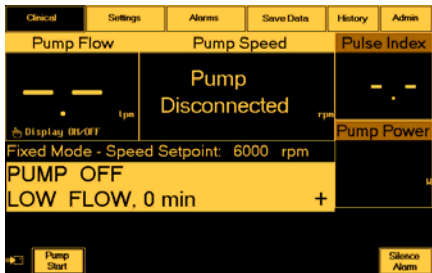
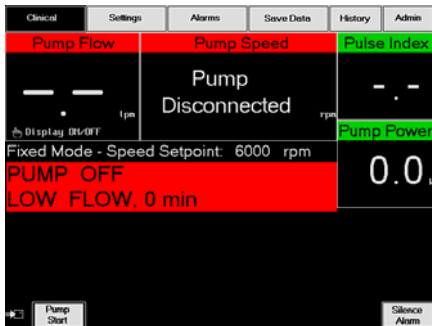
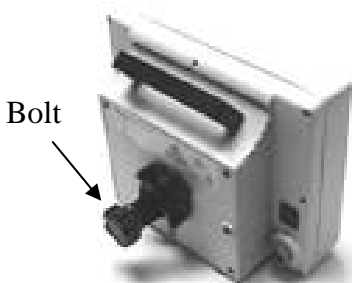

Feature	Original System Monitor	Updated Monitor
Screen	Monochrome (single color) screen 	Color screen 
Software Version	Version 3.30 or higher	Version 6.10 or higher
Data Card	Compact flash card (P/N 101609) with PC Card Adapter	Compact flash card (P/N 101609)
Method of Fastening to PBU	Large bolt on back of unit 	Adapter plate (P/N 101755) may be affixed to the PBU using the self-adhesive backing (instructions are supplied with the plate) 

Table 10. System Monitor – Original vs. Updated



**Figure 36. System Monitor Mounted on PBU with Adapter Plate**

### 11.1.3 System Monitor Setup

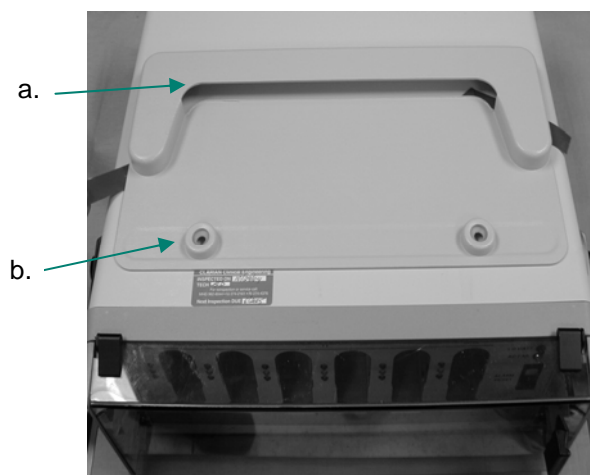
The system monitor can be mounted on an adapter plate, which sits on top of the PBU as shown in Figure 24.

To set up and turn on the system monitor, complete the following procedure:

1. Connect the patient to the PBU if not already connected.
2. Slide the system monitor base under the lip at the back of the adapter plate (Figure 37).
3. Line up the two small pegs on the bottom of the system monitor with the two holes on the adapter plate and snap into place.

#### **CAUTION!**

The adapter plate connection is only meant to hold the system monitor in place. Do not attempt to move or lift the system monitor and PBU as an assembly by lifting the system monitor. Doing so could result in damage to the PBU and/or system monitor.



- a. Adapter plate lip
- b. Holes for monitor pegs

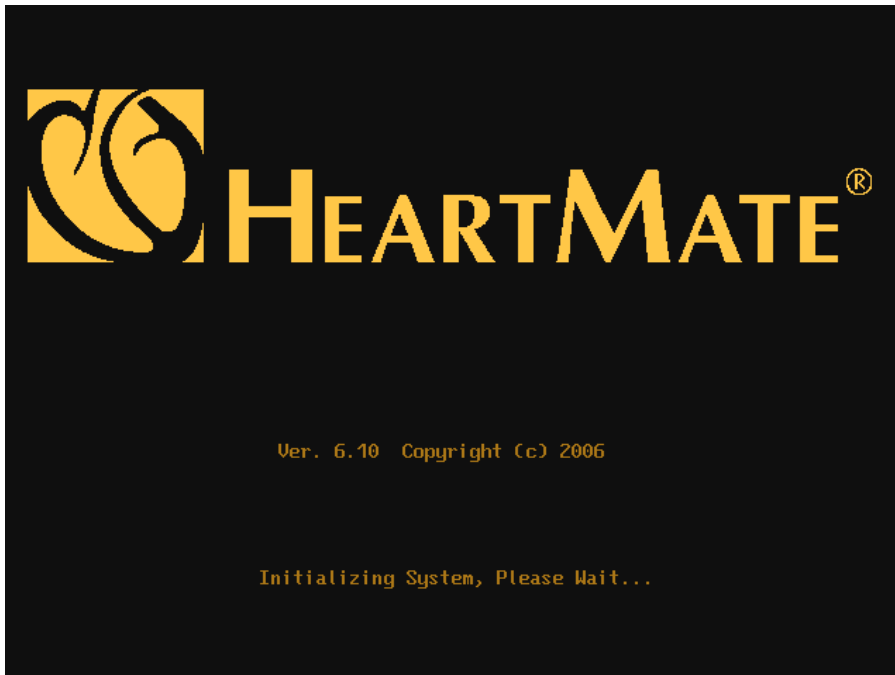
**Figure 37. System Monitor Adapter Plate**

4. Plug the system monitor cable into the “Display” connector in the back of the PBU. Ensure that the PBU is plugged into an outlet and turned on.
5. Activate the system monitor by turning on the power switch located in the back. A green indicator light on the front panel will illuminate.
6. The HeartMate logo will appear on the system monitor startup screen as shown in Figure 38 along with the software version number and copyright date.



**NOTE:**

When the system monitor is properly connected, touching any button will elicit a beep.



**Figure 38. HeartMate II System Monitor Startup Screen**

### 11.1.4 Troubleshooting

If the system monitor screen remains black, verify the following:

1. The system monitor cable is securely inserted into the PBU and system monitor.
2. The system monitor power switch is on.
3. The PBU power is on.

If an interconnect problem exists, the system monitor will detect the system controller and will display the flashing

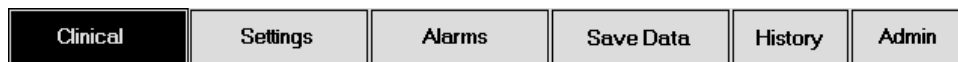
message NOT RECEIVING DATA. If this message appears, check that

1. The patient is attached to the PBU.
2. The system controller power leads are connected properly to the PBU cable (white to white, black to black).


## 11.2 Description of Features

### 11.2.1 System Monitor Interface

The user-friendly, touch-screen operator interface of the system monitor contains menu-driven and prompted operations accessible from six main screens. Six tabs are continuously displayed along the top of each screen, allowing the user to access the various system functions. The active screen will be highlighted in black as shown in Figure 39.



**Figure 39. System Monitor Screen Tabs (with Clinical Tab Selected)**

A flashing communication icon  is displayed at the lower left corner of all system monitor screens to indicate active communication between the system controller and monitor.

If the icon is not flashing or has disappeared, check lead connections and restart the monitor. If communication is stopped for more than 5 seconds, the system will automatically restart the monitor software.

### 11.2.2 Clinical Screen

The clinical screen is the default screen and displays the primary operating parameters. The system monitor will automatically return to the clinical screen should there be 60 seconds of inactivity on any other screen. The clinical screen contains

- Parameter Boxes – Four boxes at the top of the screen report measured values of the pump flow,



#### **NOTE:**

The communication icon combined with normal HeartMate II LVAS sounds during pump operation are signs of proper pump function. However, only patient examination will verify the adequacy of perfusion during HeartMate II LVAD support.

pump speed, pulsatility index (abbreviated on screen as pulse index), and pump power (Figure 40).

- Operating Mode and Speed Setpoint – The operating mode and speed setpoint are displayed below the parameter boxes as shown in Figure 40. The speed setpoint for fixed mode has a range of 6,000 to 15,000 rpm. Refer to *Optimal Fixed Speed* in chapter 11.2.3 for information on determining the desired speed setpoint.
- Active Alarm Messages – The two highest active alarm messages will be displayed below the operating mode.
- Command Buttons – Two command buttons will appear during certain conditions:
  - A pump start button will appear when the pump is stopped or disconnected from the system controller. Pressing this button will restart the pump. See *Pump Stop* in chapter 11.2.3 for more information.
  - A silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for 2 minutes, and all other advisory alarms for 4 hours. See *Silencing Alarms* in chapter 11.2.4 for more information.

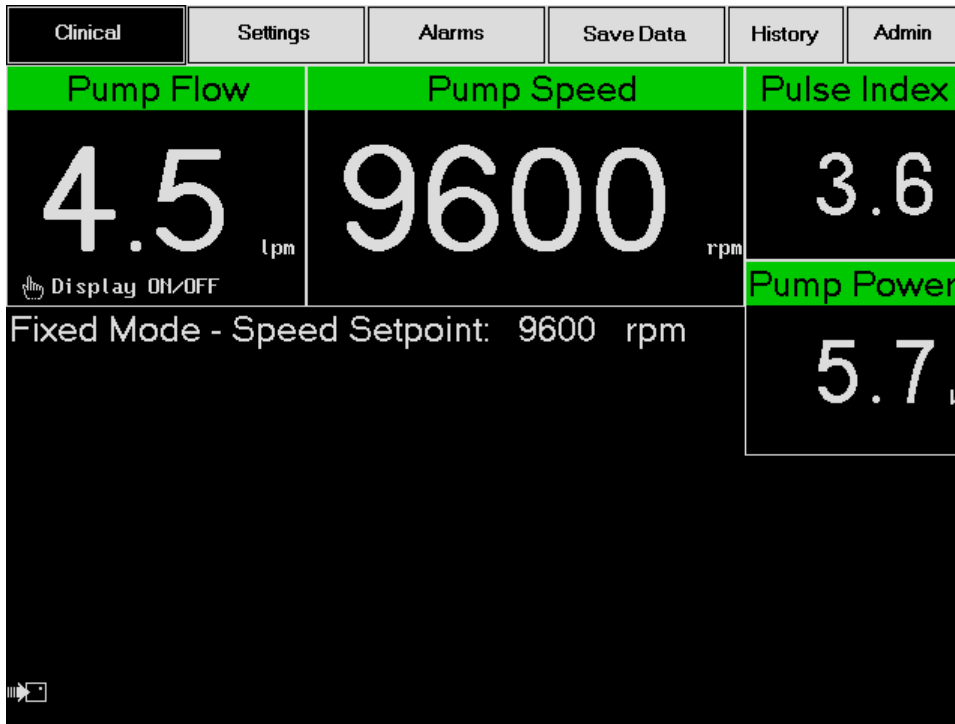


Figure 40. Clinical Screen (typical)

### Pump Flow

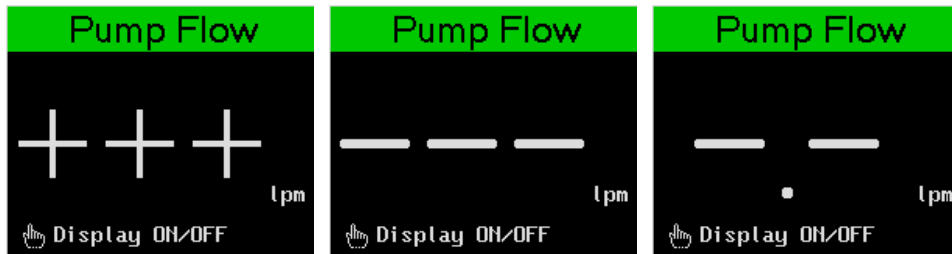
The system controller provides an estimate of blood flow out of the pump. This estimate is based on pump speed and the amount of power being provided to the pump motor. The relationship between power and flow at any particular speed is mostly linear, but there are regions at the low and high ends where the relationship is not linear. The system controller also monitors the flow estimate and compares it to the known operational range of the pump and verifies that for the given speed and power, the flow predicted is within physiological conditions.

If the flow estimate falls outside the expected operational range or acceptable linear region, the pump flow box will display “+++” or “---” as shown in Figure 41. This is done in order to prevent inaccurate flow information.

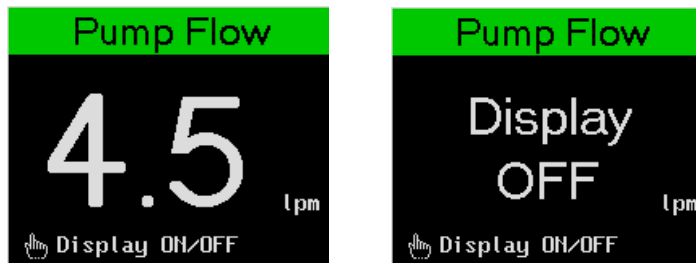
The pump flow display may be turned off by touching the screen anywhere within the pump flow box (Figure 42).

### **CAUTION!**

Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.



**Figure 41. Pump Flow Above (left) and Below (right) Region of Accurate Flow Estimation**



**Figure 42. Pump Flow Display On (left) and Off (right)**

When the pump is stopped or becomes disconnected from the system controller, “-.-” will appear in the pump flow box as shown in Figure 43. This will be accompanied by a pump off hazard alarm, which will turn the box red. A pump start button will appear in the bottom left corner of the screen.

If the pump is running at a fixed speed less than 8,000 revolutions per minute (rpm), the pump flow box will display “-.-” but remain green (Figure 41).



**NOTE:**

If the fixed speed is set to a value below 8,000 rpm, the pump will not automatically restart when reconnected to the system controller. The pump start button must be pressed.

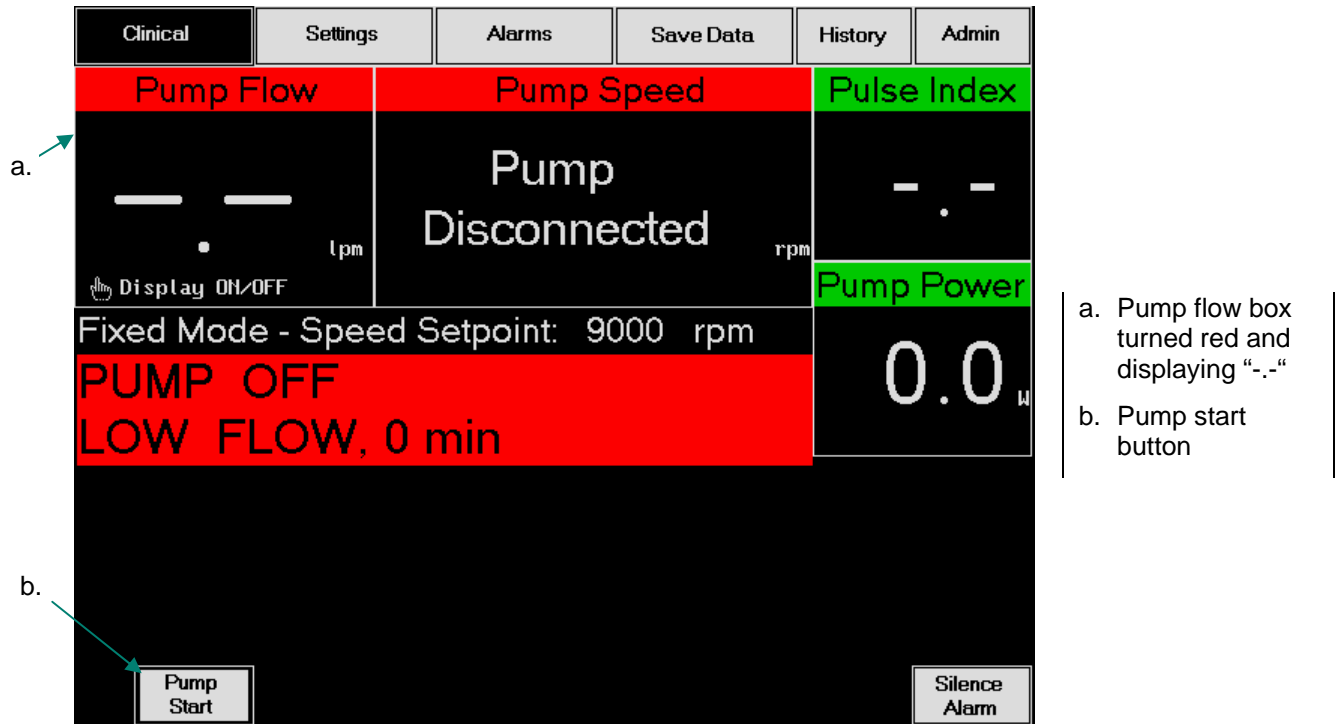


Figure 43. Clinical Screen with Pump Off Alarm

### Pump Speed

The system monitor displays the pump speed in revolutions per minute (rpm) as shown in Figure 44. This value will match the actual speed within  $\pm 100$  rpm under normal conditions. If the pump is not connected to or becomes disconnected from the system controller, the pump speed box will display Pump Disconnected (Figure 44). When the pump is stopped using the pump stop button (chapter 11.2.3), “----” will appear in the pump speed box.

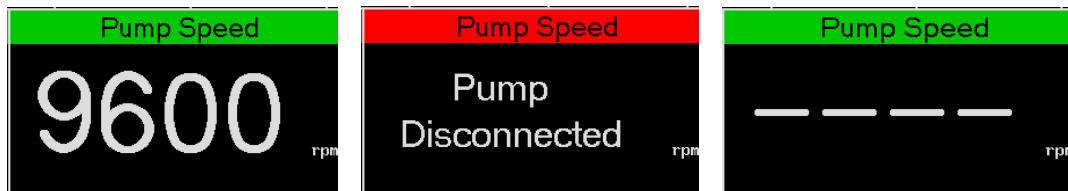


Figure 44. Pump Speed Display—From Left: Pump On, Pump Disconnected, and Pump Stopped

### Pulsatility Index

The system controller pulsatility index (shortened to pulse index on the monitor) is shown in the upper right corner of



the clinical screen. When the pump is stopped or becomes disconnected from the system controller, “-.-” will appear in the pulse index box as shown in Figure 45.



**Figure 45. Pulsatility Index under Normal Conditions (left) and when the Pump Is Stopped or Disconnected (right)**

### Pump Power

The pump power is displayed in the pump power box immediately below the pulse index box on the clinical screen. Pump power is the amount of power being provided to the pump motor and has a range of 0.0 to 25.5 watts.

### Alarm Messages

The two highest priority hazard and/or advisory alarm messages generated by the system controller will be displayed under the fixed speed setpoint in order of highest priority. If more than two alarms are occurring at one time, a “+” sign will appear on the right side of the second alarm banner, indicating that the user must go to the alarms screen to view all active alarms. See chapter 11.2.4, *Alarms Screen*, for explanations of the conditions leading to each alarm. Refer to chapter 14.4 for troubleshooting information.

Hazard alarms occur when current conditions require immediate attention. These alarms will flash and appear as black text on a red banner as shown in Figure 46. The text banners will also be accompanied by a continuous beep emitted from the system controller. There are four hazard alarms (listed in order of descending priority):

- **Pump Disconnected** – The message Pump Disconnected will be displayed in the pump speed box and the box will turn red. The hazard will NOT display a red text banner on the clinical screen (Figure 43)

- PUMP OFF – This text banner will be accompanied by a red pump flow box (Figure 43) regardless of whether the flow display is on or off.
- LOW FLOW x min – This text banner will indicate the duration of the alarm (from the start of the hazard alarm to the present, in minutes). The hazard alarm will also turn the pump flow box red (Figure 46).
- LOW VOLTAGE – This hazard will appear as a text banner with only the continuous audible alarm accompanying it.

Advisory messages will appear as black text on a yellow banner as shown in Figure 46. These messages will ***not*** flash except for the low speed operation warning. There are five advisory messages (listed in order of descending priority):

- Low Voltage Advisory – This text banner will be accompanied by an audible alarm of one beep every 4 seconds.
- Replace System Controller – This text banner will be accompanied by an audible alarm of 2 beeps per second.
- Power Cable Disconnected – This text banner will be accompanied by an audible alarm of one beep every second.
- System Controller Battery Module Low – This text banner will be accompanied by an audible alarm of one beep every 4 seconds.
- WARNING: Low Speed Operation – This text banner ***will flash*** and have ***no*** audible alarm.



**Figure 46. Clinical Screen—Hazard and Advisory Alarms**

During alarm conditions, a silence alarm button will appear in the lower right corner of the screen. Pressing this button will temporarily silence audible alarms (2 minutes for hazard alarms and 4 hours for advisory messages). Refer to *Silencing Alarms* in chapter 11.2.4 for more information.

### 11.2.3 Settings Screen

The settings screen allows the user to monitor system parameters, change speed settings, and manually stop the pump. The settings screen contains

- **System Status Boxes** – Various system parameters are displayed in two system status boxes as shown in Figure 47.
- **Active Alarm Messages** – The two highest active alarm messages (including the pump disconnected alarm) will appear as text banners below the system status boxes. None of the banners will flash. See chapter 11.2.4 for a detailed explanation of alarms.
- **Command Buttons** – The fixed speed adjust, low speed limit, and pump stop command buttons are



**NOTE:**

The system monitor will automatically return to the clinical screen should there be 60 seconds of inactivity on any other screen.

displayed at the bottom of the screen as shown in Figure 47. During alarm conditions, a silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for 2 minutes, and all other advisory alarms for 4 hours. See *Silencing Alarms* in chapter 11.2.4 for more information.

## System Status Boxes

The system status boxes display general parameters and indicate the current operating mode. They also display the set fixed speed and low speed limit. The system status 1 box tells whether the system monitor data logger is on or off and displays its set logging rate (Figure 47). The current record interval of the controller event recorder is also displayed. See chapter 11.2.5 for more information on recording data.

The system status 2 box indicates whether the alarm silence is on, off, or extended. It also displays the version number of the system controller and tells whether the controller is in primary or backup mode (Figure 47).

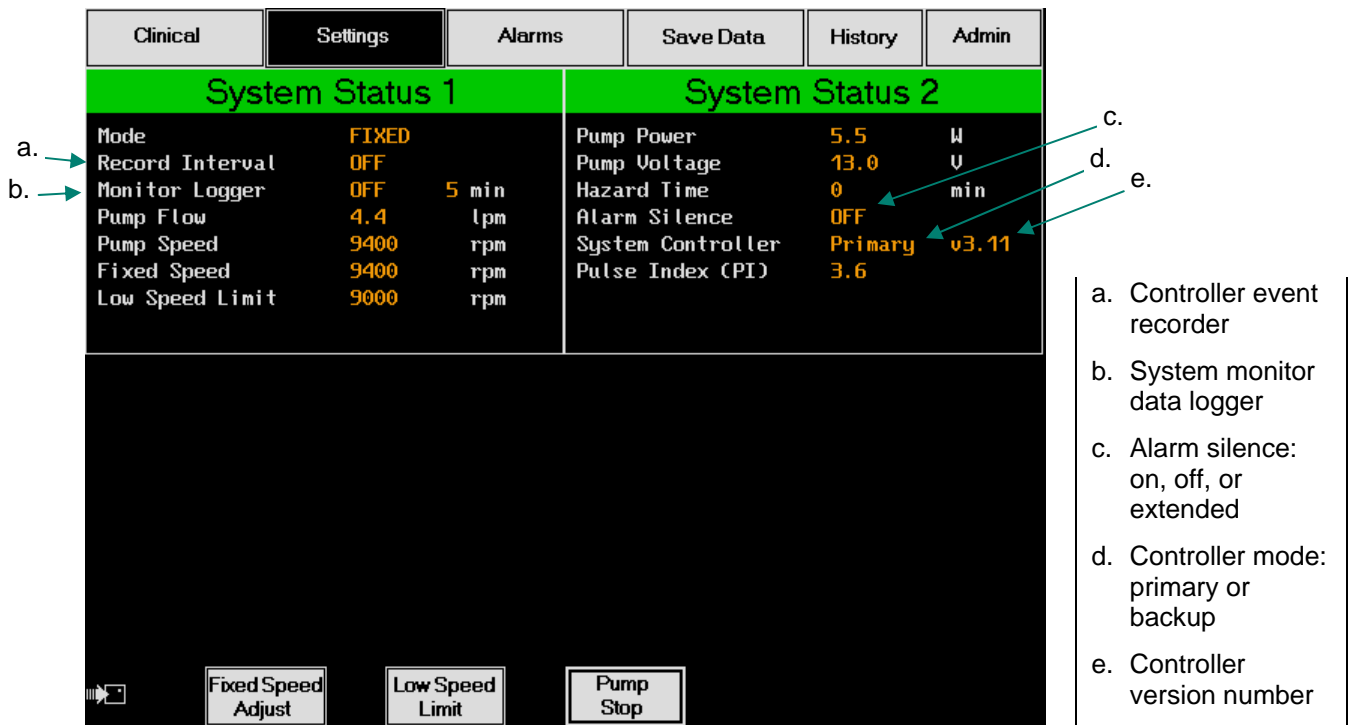


Figure 47. Settings Screen (typical)

## Fixed Speed Adjust

The fixed speed adjust button allows the user to increase or decrease the fixed speed as shown in Figure 48. The fixed speed is selectable in increments of 200 rpm with a range of 6,000 to 15,000 rpm. If the operating speed drops below the value set for the low speed limit (default is 9,000 rpm), the low speed operation advisory alarm message will appear. Refer to *Optimal Fixed Speed* in this chapter for instructions on how to select the desired fixed speed for a patient.

Clinical	Settings	Alarms	Save Data	History	Admin
System Status 1			System Status 2		
Mode	FIXED		Pump Power	5.5	W
Record Interval	OFF		Pump Voltage	13.0	V
Monitor Logger	OFF	5 min	Hazard Time	0	min
Pump Flow	4.4	lpm	Alarm Silence	OFF	
Pump Speed	9400	rpm	System Controller	Primary	v3.11
Fixed Speed	9400	rpm	Pulse Index (PI)	3.6	
Low Speed Limit	9000	rpm			



a. Select fixed speed box (opened by pressing fixed speed adjust button)

a. Select Fixed Speed: 9600

Cancel Inc. Value Dec. Value Enter

**Figure 48. Settings Screen with Fixed Speed Adjust Box**

The select fixed speed box contains four active buttons:

- **Cancel:** Pressing this button returns the user to the basic settings screen without saving any changes.
- **Inc. Value** : This button increases the fixed speed by increments of 200 rpm. The new value will appear above the button after **Select Fixed Speed**.
- **Dec. Value** : This button decreases the fixed speed by increments of 200 rpm. The new value will appear above the button after **Select Fixed Speed**.
- **Enter:** Pressing this button accepts the selected fixed speed and returns the user to the basic settings screen. A **Sending Command** message will be displayed, and the new set value will be sent to the system controller. The new value will be displayed in the system status 1 box.



**NOTE:**

The user must press enter in order to save the new speed. If the user exits by means of another button or lets the screen automatically return to the clinical screen after 60 seconds, any changes made will not be saved.

## Optimal Fixed Speed

A ramped speed study using echocardiography provides the most direct method for determining the optimal fixed speed that will provide the desired level of cardiac support for each patient. This fixed speed setting will generally fall midway between the minimum and maximum speeds and is based on changes in ventricular shape and function and the patient's physiological response to changing pump speeds.

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

To determine the optimal fixed speed for a patient, complete the following procedure:

1. Have the patient sit or lie in a comfortable position and have echocardiography available.
2. Connect the system controller to the system monitor and initiate the system monitor data logger for a capture interval of 15 seconds (see chapter 4.8.7 for detailed instructions).

3. Record the patient's current heart rate, blood pressure, and pump speed. Using echocardiography, record the left ventricular diameter, septum's position, and frequency of aortic valve opening.
4. Determine the minimum fixed speed:
  - a. Starting from the current fixed speed, lower the speed gradually to a value as low as possible without the patient experiencing signs of worsening heart failure (e.g., shortness of breath, lightheadedness). Allow the patient to stabilize at each speed setting. ***Do not allow the fixed speed to drop below 8,000 rpm under any circumstances.*** Reduce the speed until the aortic valve opens with each beat or the patient starts to become symptomatic.
  - b. Record the patient's current heart rate, blood pressure, and pump speed. Using echocardiography, record the left ventricular diameter and position of the septum.
5. Determine the maximum fixed speed:
  - c. Starting from the minimum fixed speed as determined above, increase the pump speed gradually until echocardiography shows a flattening of the interventricular septum (or is clinically acceptable based on the echocardiographic evaluation).
  - d. Record the patient's current heart rate, blood pressure, and pump speed. Using echocardiography, record the left ventricular diameter and frequency of aortic valve opening.
6. Determine the optimum fixed speed, which will usually fall midway between the minimum and maximum speeds. The selected speed may be adjusted based on clinical judgment regarding the desire for periodic aortic valve opening and a palpable pulse. To accommodate normal shifts in volume and hemodynamic status, the fixed speed should generally be set at least 400 rpm below the maximum fixed speed determined above.

## Low Speed Limit

The low speed limit is the lowest speed at which the pump can run while maintaining patient stability. The select low speed limit box allows the user to increase or decrease the low speed limit as shown in Figure 49. Setting the low speed limit is similar to setting the fixed speed and is generally set at a value slightly above the minimum speed determined during the speed ramp study discussed above. Clinical judgment and consideration of all factors should be used when selecting the low speed limit.

The low speed limit default setting is 9,000 rpm, but it can be adjusted between 8,000 and 10,000 rpm. If the operating speed drops below the value set for the low speed limit, the **WARNING: Low Speed Operation** advisory alarm message will appear.

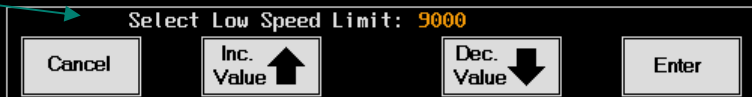
If the system detects a suction event, the pump speed will automatically drop to the low speed limit and slowly ramp back up at a rate of 100 rpm per second to the fixed speed setpoint. This drop in speed is accompanied by a reduced pump flow. If the low speed limit is set at a value above or the same as the fixed speed setpoint, the pump speed will not change during a suction event.

Clinical	Settings	Alarms	Save Data	History	Admin
System Status 1			System Status 2		
Mode	FIXED		Pump Power	5.5	W
Record Interval	OFF		Pump Voltage	13.0	V
Monitor Logger	OFF	5 min	Hazard Time	0	min
Pump Flow	4.4	lpm	Alarm Silence	OFF	
Pump Speed	9400	rpm	System Controller	Primary	v3.11
Fixed Speed	9400	rpm	Pulse Index (PI)	3.6	
Low Speed Limit	9000	rpm			

a. Select low speed limit box (opened by pressing low speed limit button)

a. 

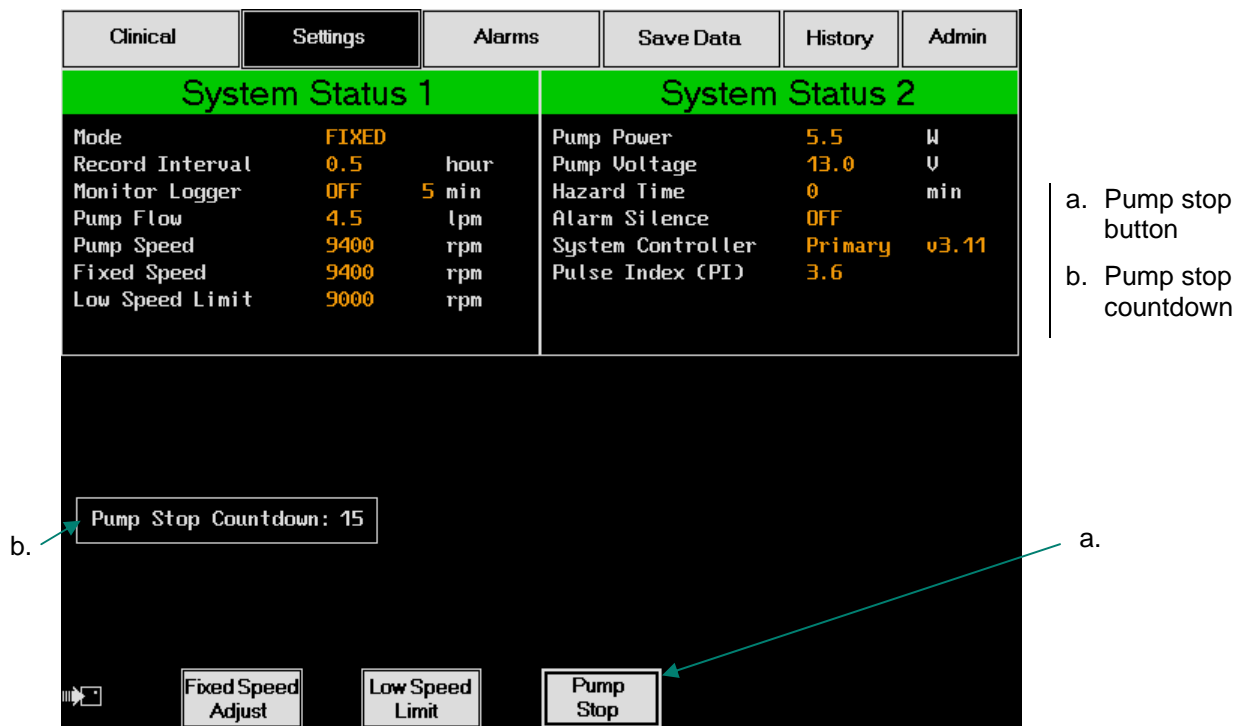
The dialog box titled "Select Low Speed Limit: 9000" contains four buttons: "Cancel", "Inc. Value" (with an upward arrow), "Dec. Value" (with a downward arrow), and "Enter".

**Figure 49. Settings Screen with Low Speed Limit Box**



## Pump Stop

The pump stop button is used to turn the pump off. Press and hold down the pump stop button while the pump stop countdown field counts down from 15 (the countdown last approximately 10 seconds) as shown in Figure 50.



**Figure 50. Settings Screen – Pump Stop Countdown Start**

During the countdown, a low speed operation advisory warning will initially appear, followed by a low flow hazard alarm (Figure 51). A silence alarm button will also appear shortly after the initial warning and will be displayed to the right of the alarm text banners. Once the countdown nears zero, the pump off hazard alarm message will appear as shown in Figure 52, accompanied by a continuous audible alarm.

The pump will stop within the first few seconds of holding down the button, but if the pump stop button is released before the pump off alarm message appears, the pump will resume at the previous set mode and speed.



### NOTE:

During the pump stop countdown, no audible alarms will accompany alarm messages. Once the Pump Off alarm appears, a continuous audible alarm will sound.

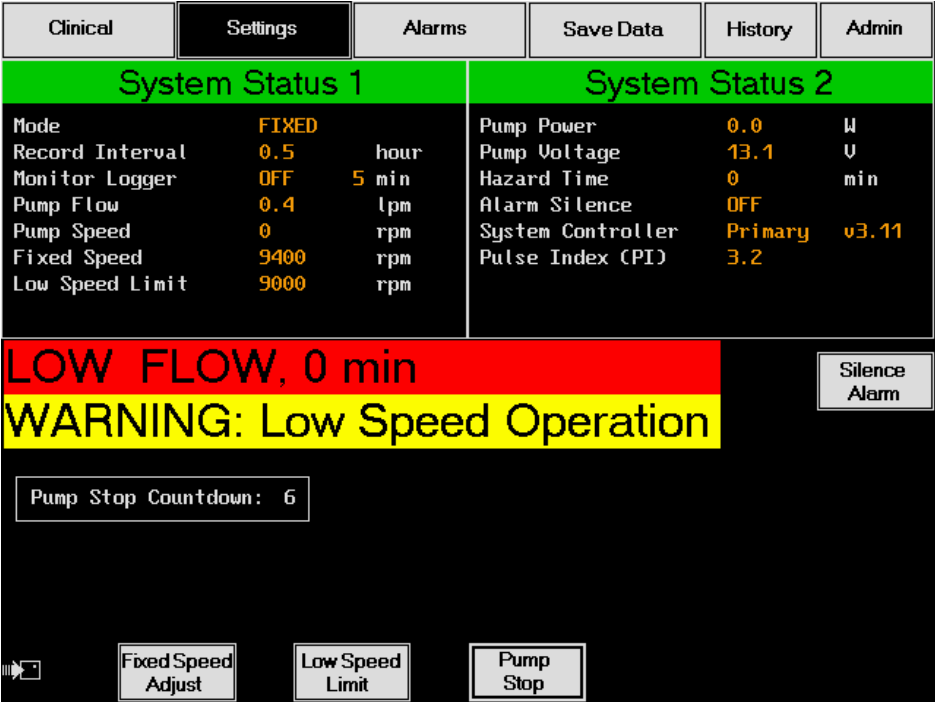
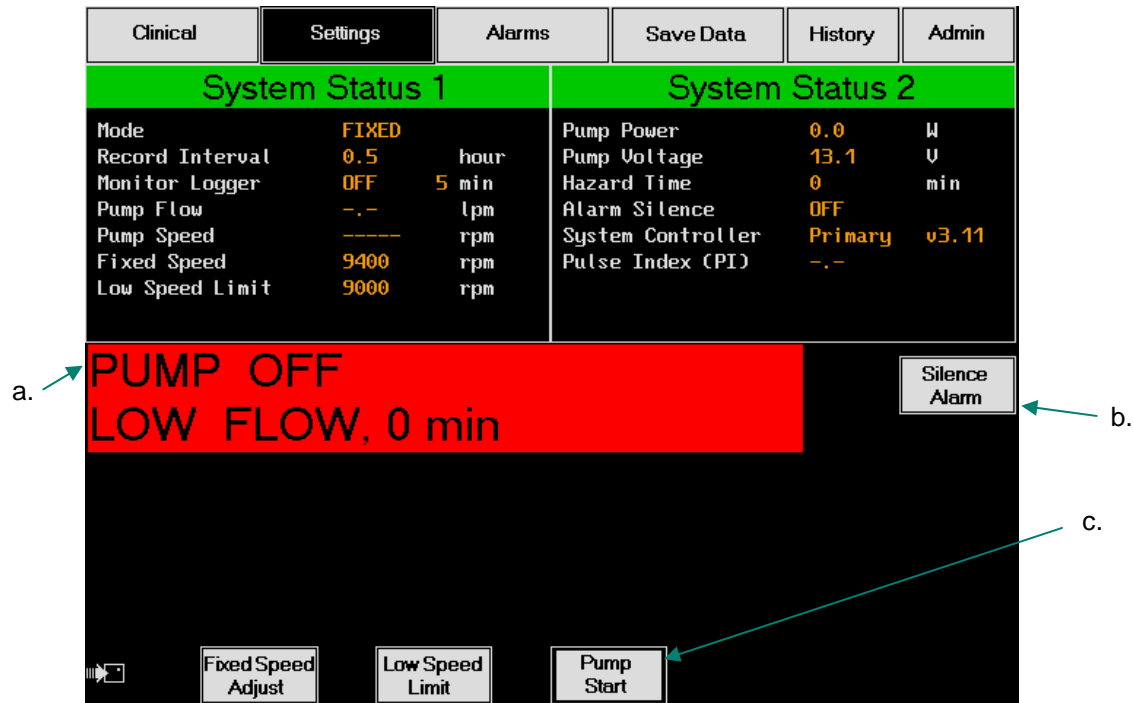


Figure 51. Settings Screen – Pump Stop Countdown

- a. Pump off alarm
- b. Silence alarm button
- c. Pump start button



**Figure 52. Settings Screen – Pump Stop Countdown Completion**

A pump start button replaces the pump stop button after the pump stop countdown has finished (Figure 52). Pressing the pump start button will display the message:

Are you sure you want to start the pump?	
No	Yes

Pressing the yes button will restart the pump at the previous mode and speed.

If the pump stops because the percutaneous lead becomes disconnected from the system controller, it will automatically restart at the previously set speed once reconnected if the fixed speed setting is at least 8,000 rpm. However, if the fixed speed is set **below 8,000 rpm**, the pump **will not automatically** restart after being disconnected then reconnected. The user must press the pump start button.

If the pump is stopped using the pump stop button, it will not automatically restart if the percutaneous lead is disconnected then reconnected to the system controller, regardless of what the fixed speed setpoint was before stopping the pump. However, if the pump is stopped using the pump stop button and then both **power leads** are disconnected from the system controller, the “pump stop”



**NOTE:**

Auscultation over the pump pocket is recommended in order to verify the pump is running.

command in the controller will be canceled and the pump will automatically restart (if the fixed speed is at least 8,000 rpm) when the power leads are reconnected.

### 11.2.4 Alarms Screen

The alarms screen shows the status of all hazard and advisory alarms as shown in Figure 53. The alarms screen contains

- Alarm Messages – All alarms (active and inactive) are displayed in the alarms box, with hazards listed in the upper portion and advisories in the lower portion. Alarms are listed in order of highest priority.
- Parameters Box – A box below the alarms box displays system parameters, hazard time elapsed, and whether the alarm silence is on, off, or extended.
- Command Buttons – Two command buttons will appear only during alarm conditions:
  - A silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for 2 minutes, and all other advisory alarms for 4 hours. See *Silencing Alarms* in this chapter for more information.
  - An extended silence button will accompany active, audible alarms when the fixed speed is set below 8,000 rpm. Pressing this button will silence all hazard and advisory alarms for 4 hours. See *Silencing Alarms* in this chapter for more information.

Under normal conditions, alarms are not highlighted and NO ALARM is displayed in the column on the right side of the screen. If alarms do occur, they will be highlighted and labeled as active (Figure 54). Multiple alarms may be highlighted simultaneously.



#### **NOTE:**

Active alarm messages will only be shown on the first three screens of the system monitor. If an alarm occurs while the user is on the save data, history, or admin screen, the user will hear an audible alarm but will not see a message. The user must switch to the alarm screen for full details.

Clinical	Settings	Alarms	Save Data	History	Admin
----------	----------	--------	-----------	---------	-------

Alarms

Pump Disconnected	NO	ALARM
Pump Off	NO	ALARM
LOW FLOW	NO	ALARM
LOW VOLTAGE	NO	ALARM

---

Low Voltage Advisory	NO	ALARM
Replace System Controller	NO	ALARM
Power Cable Disc.	NO	ALARM
SC Battery Module Low	NO	ALARM
Low Speed Operation	NO	ALARM

Hazard Time	0	min	Pump Voltage	13.0	V
Pump Flow	3.9	lpm	Pulse Index (PI)	3.6	
Pump Speed	9400	rpm	Alarm Silence	OFF	
Pump Power	5.5	W			

Figure 53. Alarms Screen (typical)

## Hazard Alarms

There are four hazard alarms (listed in the order of highest priority):

- Pump Disconnected – The percutaneous lead is disconnected from the system controller.
- PUMP OFF – The pump has been turned off or disconnected from the system controller.
- LOW FLOW – Pump flow is less than 2.5 lpm, the pump has stopped, or the pump is not operating properly. The hazard time listed in the parameters box refers to the number of minutes that the hazard alarm has been active as shown in Figure 54.
- LOW VOLTAGE – Voltage has dropped below 10.50 V.

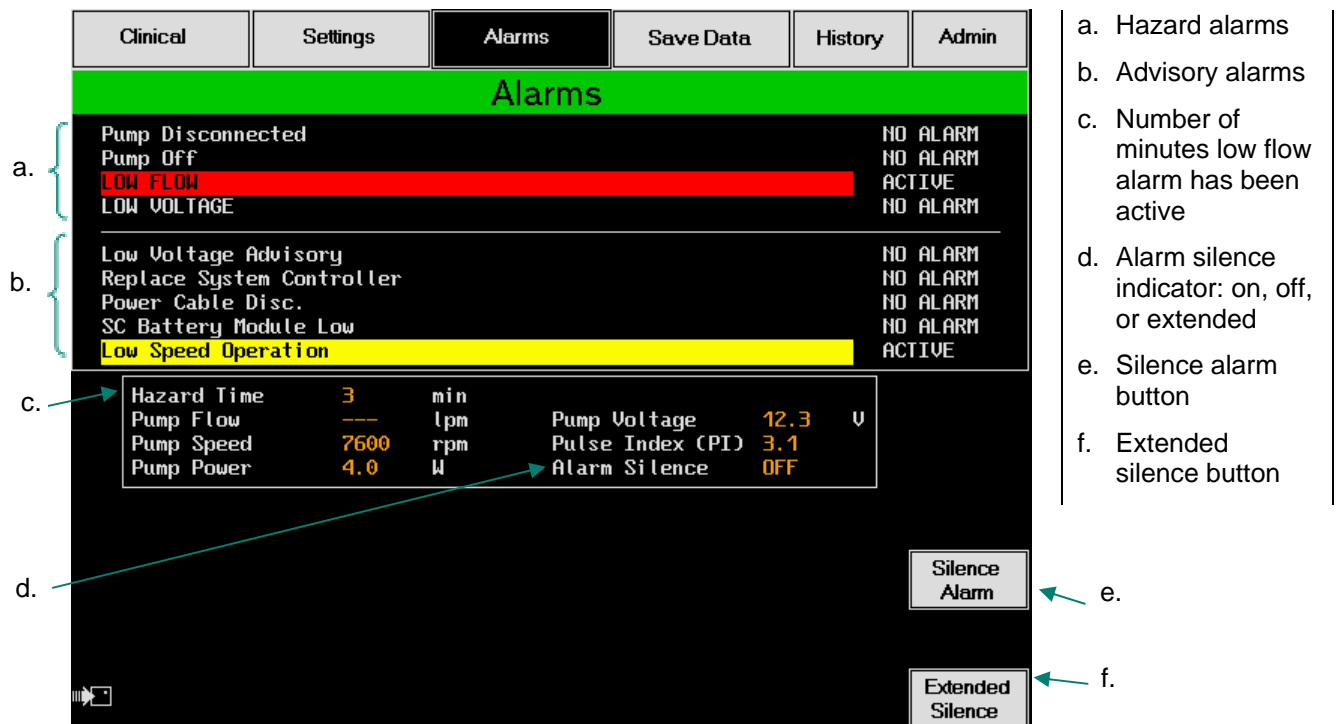
Refer to chapter 6.4 for troubleshooting information.

## Advisory Alarms

There are five advisory alarms (listed in the order of highest priority):

- Low Voltage Advisory – Voltage has dropped below 11.20 V.
- Replace system controller – The system controller is operating in backup mode and should be replaced.
- Power Cable Disc. – One of the power leads to the system controller or PBU is disconnected or broken.
- SC battery Module Low – The system controller battery module has been depleted and should be replaced.
- Low Speed Operation – The pump is operating below the low speed limit.

Refer to chapter 6.4 for troubleshooting information.



**Figure 54. Alarms Screen with Multiple Alarms and Advisories Displayed Simultaneously**

## Silencing Alarms

The silence alarm button is used to temporarily silence audible system monitor and system controller alarms and will only appear during alarm conditions (Figure 54). Pressing the button will silence hazards and the power

cable disconnected advisory for 2 minutes, and all other advisories for 4 hours on both the system monitor and system controller. However, alarm messages will still be displayed on the screen.

When an alarm is silenced, the alarm silence indicator in the parameters box will display on. If the alarm condition is resolved, the alarm silence will automatically turn off and display off after the alarm silence indicator.

At fixed speeds set below 8,000 rpm, the extended silence button will also be available (Figure 54). Pressing this button will silence all hazard and advisory audible alarms on the system monitor and system controller for 4 hours (alarm messages are still displayed on the screen). When the extended silence button is selected, it will display the following message:

Do you want to override the alarms for 4 hours?

No
Yes

Pressing the yes button will provide four hours of alarm silence. The alarm silence indicator in the parameters box will display extended.



**NOTE:**

If both power leads are disconnected from the system controller or the silence alarm button on the system controller is pressed, the extended silence will be cancelled.

## 11.2.5 Save Data Screen

The save data screen allows the user to change the rate at which events are recorded and to save performance data to a data card.

The save data screen contains four boxes as shown in Figure 55:

- System Monitor Data Logger
- Waveform
- Controller Event Recorder
- Controller Event History



Figure 55. Save Data Screen

**NOTE:**

The system monitor will automatically return to the Clinical screen should there be 60 seconds of inactivity on any other screen. Unless the user confirms changes by pressing the continue, enter, or save buttons as indicated on the screen, any changes made to the active screen will not be saved.

### Data Card

Information recorded by the system controller and system monitor must be saved on a data card (**Figure 56**). If one is not already in the monitor, insert a data card into the slot located behind the door on the left side of the system monitor as shown in Figure 57 (white side facing the front of the monitor). The system monitor will beep when the card is correctly inserted.

If a user tries to perform an action requiring a data card and no card has been inserted, the message Insert Memory Card in slot will appear on the screen.





**Figure 56. Data Card (p/n 101609)**

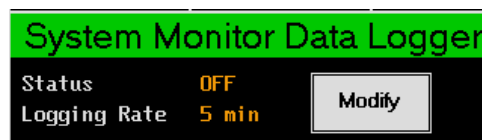


**Figure 57. Inserting Data Card into System Monitor Slot**

### System Monitor Data Logger

The system monitor data logger collects system performance data at a set time interval and stores the information on a data card in the system monitor. It is also used to monitor a patient during the speed ramp study for determining the patient's optimal fixed speed.

The status indicator (Figure 58) specifies whether the logging feature is on or off. The logging rate indicator specifies the frequency with which data is collected and stored to the data card. Frequency options are 15 seconds, 30 seconds, and 1 minute intervals from 1 to 60 minutes.



**Figure 58. Save Data Screen – System Monitor Data Logger**

The modify button allows the operator to turn the logging feature on or off as well as specify a time interval for data collection. Pressing this button displays the system monitor data logger screen as shown in Figure 59. Onscreen instructions are provided to help the user change the logging settings.



**NOTE:**

The system monitor and patient must be connected to the PBU in order to collect system performance data. If the system monitor or patient is disconnected from the PBU, the data logger will turn off while data already stored on the data card will not be affected.



**Figure 59. System Monitor Data Logger Screen**

To turn on the data logger, follow the below procedure:

1. Check to make sure a data card has been inserted into the system monitor. See *Data Card* earlier in this chapter for instructions on how to insert a data card.
2. Press the modify button to open the system monitor data logger screen and press the logging on/off button to turn the data logger on. Select the desired logging rate and press the save changes button. This will open the patient ID screen as shown in Figure 60.
3. Verify that the date and time (top left corner of the screen) are correct. If they are incorrect, go to the admin screen to set the date and time before continuing on to step 4. Refer to chapter 5.8.9 for specific instructions on setting the clock.



**NOTE:**

If there is no data card in the system monitor, the message Error Saving Log, check memory card will appear briefly every ten seconds.

4. Enter a patient identification number up to 15 characters by using the onscreen keypad. Press the continue button to save the patient ID and to return to the save data screen.

When only the logging rate is changed, pressing the save changes button on the system monitor data logger screen will return the user to the save data screen without requiring patient identification information to be entered.

Clinical Settings Alarms **Save Data** History Admin

Date: 07/21/06  
Time: 16:15:00

Enter Patient ID: BJ

A	B	C	D	E	F	G	H	I	J	K	L	M	N
O	P	Q	R	S	T	U	V	W	X	Y	Z	-	0
1	2	3	4	5	6	7	8	9	Backspace				
Cancel									Continue				

**Figure 60. Patient Identification Information**

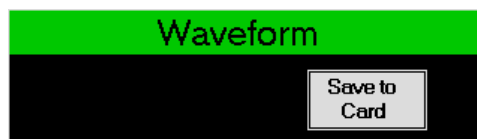
## Waveform

The waveform feature saves motor performance information to a data card. The waveform record contains the following data:

- Current waveforms over ten consecutive seconds.
- Current waveforms for one second (detailed waveform).

To save waveforms, follow the below procedure:

1. Check to make sure a data card has been inserted into the system monitor. See *Data Card* earlier in this chapter for instructions on how to insert a data card.
2. Press the save to card button (Figure 61). The patient ID screen will appear (Figure 60).



**Figure 61. Save Data Screen – Waveform**

3. Verify that the date and time (top left corner of the screen) are correct. If they are incorrect, go to the admin screen to set the date and time before continuing on to step 4. Refer to chapter 5.8.9 for specific instructions on setting the clock.
4. Enter a patient identification number up to 15 characters by using the onscreen keypad (Figure 60). Press the continue button. The following message should appear:

Collecting Waveform Data...

Once the information is collected, a patient related data screen will appear as shown in Figure 62.

5. Enter patient related data: blood pressure (B/P), cardiac output (CO), pulmonary capillary wedge pressure (PCWP), and central venous pressure (CVP):
  - a. Select each parameter by pressing the corresponding button on the screen (e.g., Enter B/P). An example of how to enter the data is provided at the top of the screen.
  - b. Once information has been entered for each parameter, press the continue button to begin saving data.

- c. If no patient data are available or needed, press the continue button to begin saving data.

Clinical	Settings	Alarms	Save Data	History	Admin
----------	----------	--------	-----------	---------	-------

Date: 09/05/06

Time: 10:45:31

19051042.tci

Patient ID: D

Enter Data & Time Obtained

Example: 16@5:15am

Enter B/P

B/P:
100/55@11:40AM

Enter CO

CO:
3.9@11:40AM

Enter PCWP

PCWP:
12@11:40AM

Enter CVP

CVP:
16@11:40AM

Continue

Backspace

@	1	2	3
:	4	5	6
AM	7	8	9
PM	.	0	/

Figure 62. Patient Related Data

6. If the data are successfully saved to the data card, the monitor will display the following message in the center of the screen:

Data captured successfully  
Press any button to exit

7. Press any button to return to the save data screen or allow the system monitor to automatically return to the clinical screen after 60 seconds.
8. The data card may be removed from the system monitor.

**NOTE:**

If the waveforms are not captured successfully, the message Check A/D Connections, press Cancel will appear. Check all power leads to verify they are properly connected to the system controller, PBU, and system monitor.

## Controller Event Recorder

The controller event recorder is a feature built into the system controller that allows performance data to be collected and stored in the system controller's memory.

This memory is capable of storing 120 events, and once it becomes full, the oldest events are deleted as new ones are saved.

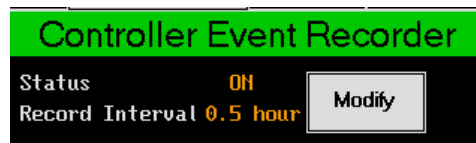
Events may be recorded in two ways:

1. As events occur – The system controller will automatically record any alarm or change in fixed speed as it occurs. Therefore, the status indicator in the controller event recorder box (Figure 63) will always specify that the recording feature is on.
2. At a specified record interval – The system controller can record data at set time intervals. The record interval indicator specifies the frequency with which information is collected. Frequency options are off, 0.5 hour, and then hourly increments from 1 to 24 hours. By default, the record interval is set to off.



**NOTE:**

If the record interval is set to off, events such as alarms and changes in fixed speed will continue to be recorded as they occur.



**Figure 63. Save Data Screen – Controller Event Recorder**

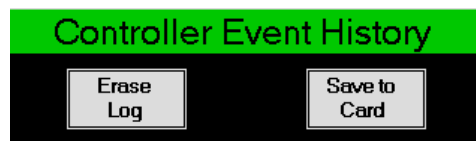
The modify button allows the user to turn the record interval on or off as well as specify a time interval for data collection. Pressing this button displays the controller event recorder screen shown in Figure 64. Onscreen instructions are provided to help the user change the recording settings.



**Figure 64. Controller Event Recorder Settings Screen**

## Controller Event History

The controller event history accesses the recorded events stored in the system controller's memory. This history can either be saved to the data card in the system monitor or erased (Figure 65).



**Figure 65. Save Data Screen – Controller Event History**

To erase the logged controller events, follow the below procedure:

1. Press the erase log button.
2. The screen will display the following question:

Erase the Event Recorder History?	
<input type="button" value="No"/>	<input type="button" value="Yes"/>

- a. Press No to return to the save data screen.

- b. Press **Yes** to erase all recorded events in the system controller and to return to the save data screen.

To save the logged controller events, follow the below procedure:

1. Check to make sure a data card has been inserted into the system monitor. See *Data Card* earlier in this chapter for instructions on how to insert a data card.
2. Press the save to card button. The patient ID screen will appear (Figure 60).
3. Verify that the date and time (top left corner of the screen) are correct. If they are incorrect, go to the admin screen to set the date and time before continuing on to step 4. Refer to chapter 4.8.9 for specific instructions on setting the clock.
4. Enter a patient identification number up to 15 characters by using the onscreen keypad (Figure 60). Press the Continue button to record the event history to the data card. The message Retrieving History Data should appear as shown in Figure 66. If the data were successfully saved, the monitor will display Data captured successfully, Press any button to continue as shown in Figure 67.



**NOTE:**

If the waveforms are not captured successfully, the message Check A/D Connections, press Cancel will appear. Check all power leads to verify they are properly connected to the system controller, PBU, and system monitor.



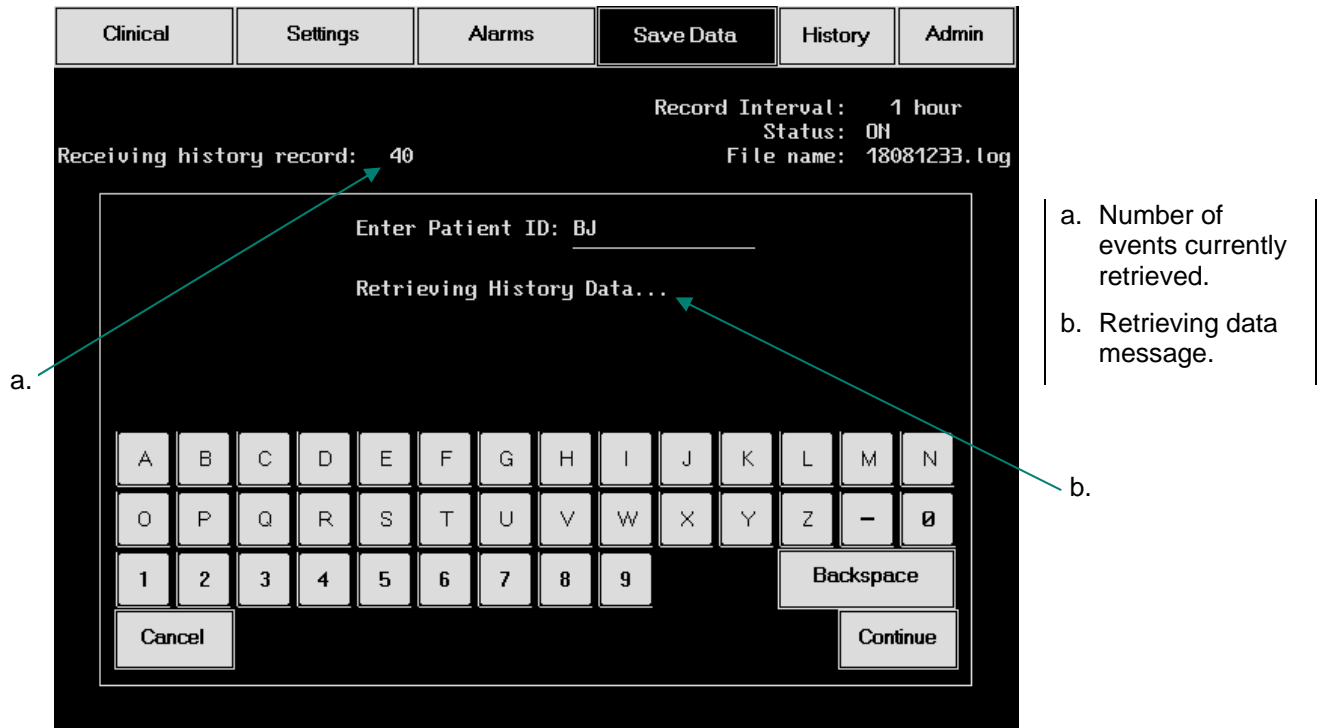


Figure 66. Controller Event History Retrieving Data

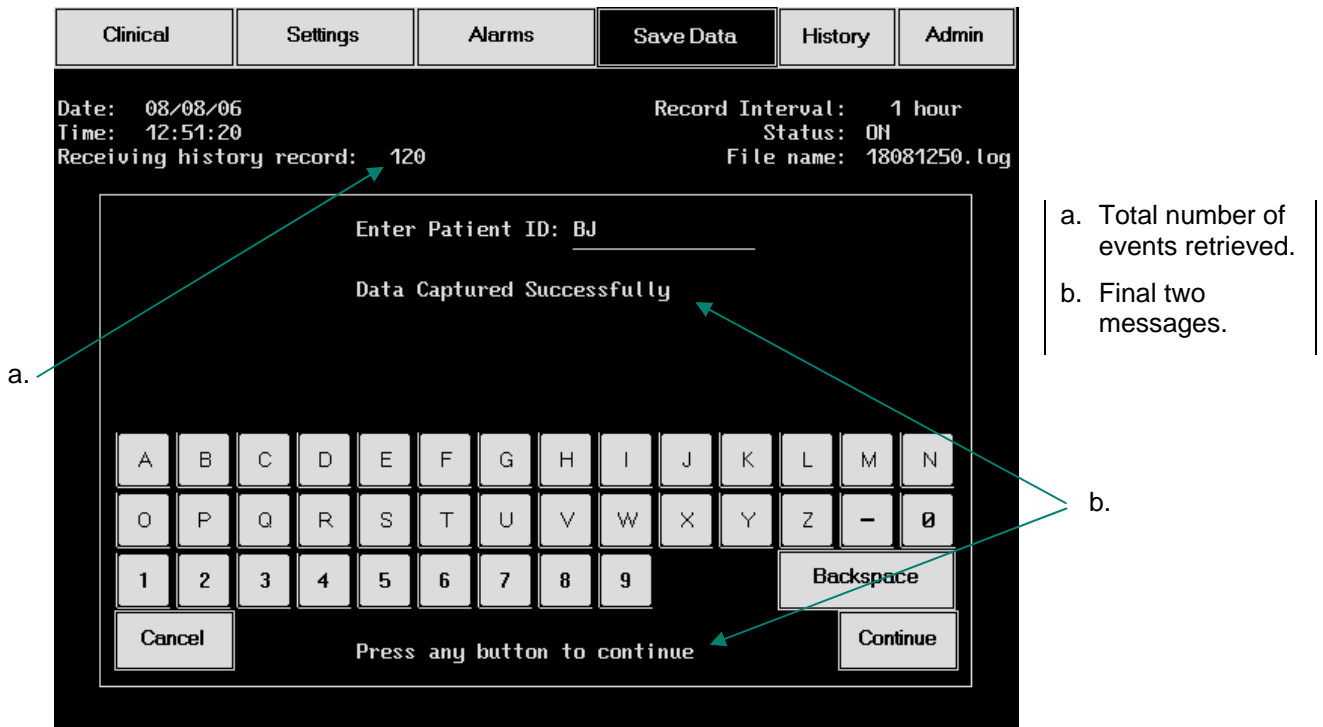


Figure 67. Controller Event History Data Captured Successfully

5. Press any button to return to the save data screen or allow the system monitor to automatically return to the clinical screen after 60 seconds.
6. The data card may be removed from the system monitor.

### **Sending Waveform Information to Thoratec**

In order to email waveforms and other data (e.g., log files) to Thoratec for diagnostic purposes, you will need a card reader that works with CompactFlash™ media. Waveform information and other diagnostic data should be sent to: **waveforms@thoratec.com**.

The card reader (Figure 68) plugs into any USB port on a personal computer (PC) and acts as a removable drive. Note that the drive designation may differ based on the PC's specific configuration.

If you have any questions, please contact Thoratec Technical Services. In the United States dial 781-272-0139 or 800-456-1477.



**NOTE:**

A card reader may be obtained from a local computer store. A card reader is necessary for transmitting data from CompactFlash™ media to a computer so that data can be sent via email.



**NOTE:**

A PC running Window™ 2000™ or higher is required for most card readers.



**Figure 68. Card Reader**

## **11.2.6 History Screen**

The history screen will allow the user to retrieve and view the system controller event history on the system monitor.

The user will also have the option to save the history to a data card.

When the history tab on the system monitor toolbar is selected, the screen will display the message:

Please confirm retrieving of Controller's Event History	
<b>Cancel</b>	<b>Continue</b>

Pressing the cancel button will return the user to the clinical screen.

Pressing the continue button will instruct the system monitor to download the logged events stored in the system controller. The screen will display the message:

Receiving History Record: 56
Retrieving Data...

Once the logged events have been successfully retrieved, the history screen will appear as shown in Figure 69. This screen displays the most up-to-date controller event history stored in the system controller.

The history screen contains:

- **Six-Column Table** – System parameters, alarms, and event times are displayed in a six-column table as shown in Table 11.
- **Four Navigation Buttons** – Four navigation buttons at the lower right portion of the screen allow the user to scroll through the multiple screens of events. Press the leftmost button to go to the first page, the second and third buttons to move between pages one at a time, and the rightmost button to go to the last page.

- Command Button – A save to card button is displayed at the bottom left corner of the screen. See chapter 11.2.5 for specific instructions on saving events to a data card.

DAY-TIME	PUMP FLOW	PUMP SPEED	PUMP POWER	PULSE INDEX	ALARM
Date /time of event displayed as Month/Day/Year Hour:Minutes.	Pump flow in lpm at time of event.	Pump speed in rpm at time of event.	Pump power in Watts at time of event.	Pulsatility index at time of event.	Type of alarm at time of event.

Table 11. History Screen Table Columns






Clinical	Settings	Alarms	Save Data	History	Admin
DAY-TIME	PUMP FLOW	PUMP SPEED	PUMP POWER	PULSE INDEX	ALARM
08/08/06 12:31	0.0	0	0.0	0.7	* Pump Disconnected PUMP OFF LOW FLOW LOW VOLTAGE Low Voltage Advisory System Controller Cell Low --- Clock Reset ---
0d 02:00	7.6	11590	11.4	1.5	*
0d 01:00	6.9	11000	9.8	1.9	*
0d 00:13	5.5	6040	10.3	3.2	WARNING: Low Speed Operation
0d 00:00	0.3	7940	34.8	0.5	LOW FLOW WARNING: Low Speed Operation
Records 8-12 of 120					
<div>  <div>Save to Card</div> <div>     </div> </div>					

Figure 69. History Screen (Typical)

## Reviewing Events

A maximum of 120 events can be stored and retrieved for display. The event history data are displayed in reverse chronological order with the most recent events on the first page at the top of the screen.

Asterisks (\*) displayed in the alarms column indicate data recorded as part of a specified record interval. These events

may or may not include alarms. Data without asterisks are those that were recorded at undesignated times due to an alarm or change in fixed speed occurring. (A change in fixed speed is displayed as a line left completely blank in the alarms column.)

The system controller does not have a clock and therefore records only time intervals between events. When the events log is downloaded to the system monitor, the monitor counts backward from the current date and time and calculates event dates and times.

Occasionally, a line appears with Clock Reset in the alarms column. This line indicates that both power leads were disconnected from the system controller at some point in the past. Since the system monitor does not know how much time elapsed before power was restored, it cannot calculate events recorded before the system controller lost power. Events recorded before the clock reset are therefore displayed in terms of the controller's initial startup.

For example, a day-time of 0d 00:13 means that the system controller recorded an event 13 minutes after initially receiving power. Then, power was lost and some time later restored. Event times after this point are displayed as dates and times.

### 11.2.7 Admin Screen

Pressing the admin tab on the system monitor toolbar displays the admin screen as shown in Figure 70. This screen is used to set the system monitor date and time and to modify technical parameters.



Figure 70. Admin Screen

### Date and Time

The date and time box displays the current date and time. Pressing the modify button opens the screen shown in Figure 71, which has onscreen instructions for setting the date and time.

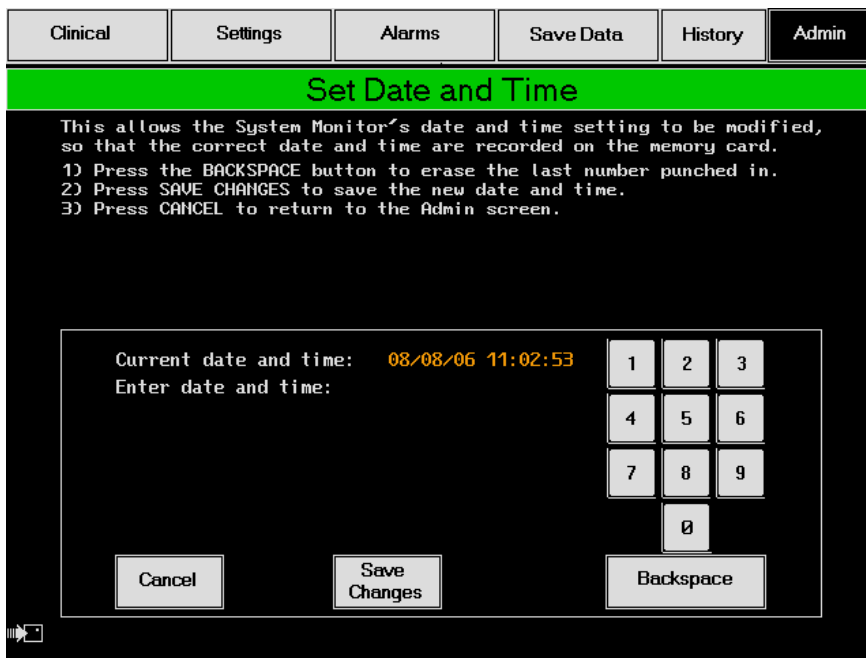


Figure 71. Set Date and Time Screen

To change the date and time, follow the below procedure:

1. Use the numerical keypad to enter the appropriate date and time (enter time as military time). Include zeros so that twelve digits are entered. For example, to enter the date and time 8/8/06 11:02:53, type “080806110253.” If less than twelve digits are entered, an error message will appear asking the user to complete the date and time.
2. Press the save changes button to save the new date and time entered. The message The time and date have been set will appear.
3. Pressing either the save changes or cancel button will return the user to the admin screen.



**NOTE:**

The minutes and seconds next to the Current date and time field run continuously as the new time is entered.



**NOTE:**

The date and time must be updated manually for daylight savings time. Daylight savings is not adjusted automatically on the system monitor.

## Technical Parameters

The technical parameters box contains a modify button that allows technical parameters to be changed. Pressing this button will display the screen shown in Figure 72, which provides access to the parameters. However, this screen is restricted to Thoratec personnel only.

Clinical	Settings	Alarms	Save Data	History	Admin
----------	----------	--------	-----------	---------	-------

Technical Parameters

1) Caution: Access for authorized Thoratec personnel only.  
 2) Enter the password and press the CONTINUE button.  
 3) Press CANCEL to return to Admin screen.

Enter Passwords: \_\_\_\_\_

A	B	C	D	E	F	G	H	I	J	K	L	M	N
O	P	Q	R	S	T	U	V	W	X	Y	Z	-	0
1	2	3	4	5	6	7	8	9	Backspace				
Cancel									Continue				

**Figure 72. Technical Parameters Screen**

HeartMate II Operating Manual 101





# Patient and Device Management

## 12.0 Post-Operative Patient Care

Proper care of a patient supported by the HeartMate II LVAS requires a thorough understanding of the system operation and patient condition.

### 12.1 Daily Routine

During the postoperative period, the patient must receive instructions regarding the operation and care of every system component. The following are topics to be discussed by the hospital staff when training the patient:

1. General Information
  - Concept of ventricular assistance
  - How the LVAD pumps blood
  - Control modes
  - Battery versus PBU operation
  - Battery charging
  - Battery use regimen
  - Advisory and hazard alarms
  - Medical Alert ID Bracelet (recommended)
  - Maintenance and periodic safety checks
  - Anticoagulation
2. System Components
  - LVAD
  - Percutaneous LVAD lead
  - System controller
  - Batteries and battery clips
  - PBU
  - PBU cable

- Display module
- Travel kit, shoulder holster, PocketPak, stabilization belt
- EPP

3. Operating the System

- Making connections
- Changing power sources
- Changing system controllers
- Performing a system controller self-test

4. What to do in an Emergency

- What is an emergency?
- Steps to take in an emergency
- How to diagnose power or connector problems
- Emergency telephone contacts
- Emergency transportation plan

5. Exit Site Care

6. Showering

7. Preparation for Sleep

8. Warnings and Precautions

## 12.2 Exit Site Care

Currently, there are no clinical trials delineating the best regimen for care of the LVAD percutaneous lead (drive-line) exit site. Physician judgment and experience may vary. Nevertheless, the following points should be considered:

- Daily exit site care is recommended. Use a persistent antiseptic cleansing agent such as chlorhexidine containing scrub solutions. Following aseptic cleansing, the site should be dried to avoid tissue maceration. Aseptic technique should be adhered to whenever the exit site is inspected, dressed or otherwise handled.
- The exit site must be kept clean and dry. ***Do not apply prophylactic topical agents*** such as silver sulfadiazine or polymixin-neomycin-bacitracin; these ointments applied to the exit site may macerate the tissues and increase the risk of selecting for resistant microorganisms. The use of a sterile bandage, if applied daily, may be effective in reducing the risk of infection.
- Once the patient is ambulating, the exit site will be very susceptible to trauma from traction on the percutaneous lead. Trauma to the wound in the early stages of tissue ingrowth may increase the risk of infection. Immobilizing the percutaneous line with abdominal wraps or binders reduces trauma to the exit site.
- The risk of systemic infection may also be reduced by withdrawing all intravascular lines as soon as is practical.
- Parenteral treatment with antibiotics and surgical drainage has, on occasion, eradicated infection. However, infections may persist and can result in septicemia and death.
- Fungal infection resulting from organisms such as *Candida albicans* may be associated with vegetative growth on the device. Persistent systemic fungal infection, refractory to antimicrobial treatment, may necessitate LVAD replacement or removal.
- Systemic prophylaxis with antifungal agents, such as fluconazole, is reported to have met with moderate success in preventing fungal infection. However, no clinical trials have been conducted to verify the efficacy of antifungal prophylaxis.

**CAUTION!**

Avoid unnecessary pulling or movement of the external portion of the percutaneous lead, especially as the skin exit site is healing. Pulling or movement could prolong the healing process or interrupt an already healed exit site. This could increase the risk of serious infection.

## 12.3 Showering

Although the externally-worn components of the HeartMate II are moisture-resistant; HeartMate components are *not waterproof* and must not be directly exposed to a wet environment. When taking a shower, all external components must be shielded from water by placing them in a waterproof pouch. Furthermore, the exit site must be kept dry. Adhere to the following guideline when considering taking a shower:

- Do not permit patients to shower unless the attending physician has inspected the skin site and confirms that sufficient healing has occurred.
- Never permit patient to take baths or swim.
- Keep the exit site as dry as possible.
- Avoid excessive pulling on the percutaneous lead.
- Follow the HeartMate shower kit *Directions for Use*.

### 12.3.1 Showering while Connected to the Batteries

The HeartMate shower kit inner pouch has a pocket on each side. Each pocket will hold one battery with the battery clip at the top of the pocket. The leads and their connectors will be kept inside the pouch itself with the system controller, and none of the cabling will extend beyond the shower kit outer skirt. The outer skirt of the shower kit covers the inner pouch and all of the components of the HeartMate system held inside the kit.

To set up the shower kit for showering with batteries, follow the below procedure:

1. Remove the battery holsters or PocketPak containing the batteries and battery clips.
2. Hang the shower kit diagonally over the patient's shoulder using the black strap. As an alternative, the shower kit may be hung straight in front of the patient.
3. Raise the outer skirt of the shower kit to expose the inner pouch. Open the Velcro tabs of the inner pouch to access the pouch itself.
4. Place one battery in each pocket located on the sides of the inner pouch, with the battery clip at the

top and the lead connection facing away from the patient.

5. Place the system controller, leads, and connectors inside the inner pouch of the shower kit. Cover the pouch opening by closing the Velcro tabs.
6. Pull the outer skirt of the shower kit down over the inner pouch and close using the snaps along the bottom of the skirt.
7. Adjust the shower kit position so that the percutaneous motor lead is not pulled on by the shower kit. The position can be changed by adjusting the length of the black shoulder strap.

### 12.3.2 Showering while Connected to the PBU

The HeartMate shower kit inner pouch will hold the system controller, system controller leads and the lead connections. The length of lead from the connector to the PBU will run from the pouch to the PBU outside of the patient's shower enclosure. The outer skirt of the shower kit covers the inner pouch and all of the components of the HeartMate system held inside the shower kit.

To set up the shower kit for showering with the PBU, follow the below procedure:

1. Remove the battery holsters or PocketPak containing the batteries and battery clips.
2. Change to tethered operation. (chapter 8.3.4)
3. Hang the shower kit diagonally over the patient's shoulder using the black strap. As an alternative, the shower kit may be hung straight in front of the patient.
4. Raise the outer skirt of the shower kit to expose the inner pouch. Open the Velcro tabs of the inner pouch to access the pouch itself.
5. Place the system controller, leads and connectors inside the inner pouch of the shower kit. Cover the pouch opening by closing the Velcro tabs.
6. Pull the outer skirt of the shower kit down over the inner pouch and close using the snaps along the bottom of the skirt.
7. Adjust the shower kit position so that the percutaneous motor lead is not pulled on by the

#### **WARNING!**

Keep the PBU away from water. If the PBU has contact with water, shower spray or wet surfaces, the LVAD may stop, or the patient may receive a serious electric shock.

shower kit. The position can be changed by adjusting the length of the black shoulder strap.

### 12.3.3 After Showering

Using a towel, dry excess moisture from the shower kit strap and outer skirt. Carefully undo the snaps and raise the outer skirt to gain access to the HeartMate components.

Remove all components from the shower kit. Keep components dry. Allow the HeartMate shower kit to dry completely between uses.

### 12.3.4 Care of the HeartMate Shower Kit

Wash the shower kit by hand using mild soap and warm water. Rinse thoroughly and drip dry completely, prior to the next use.

## 12.4 Preparation for Sleep

***The patient must always be attached to the PBU while sleeping.***

Also, the percutaneous lead must not pull on the exit site. An elastic bandage, lightly wrapped around the patient's thigh, with the lead crossing through one of the layers, should be sufficient. Otherwise, the patient can use the stabilization belt, which wraps around the patient's abdomen and clips to the system controller, preventing the controller from moving.

Nightly, the following guidelines must be observed:

- The patient must plan on sleeping only when connected to the PBU. Were the patient to fall asleep during battery-powered operation, the low battery advisory and hazard alarms may not awaken the patient before battery depletion.
- The patient should inspect and ensure that all electrical connections are secure.
- Patients should not sleep on their stomach. They will generally be most comfortable sleeping on their backs.
- A spare system controller should always be kept near the patient during sleep. Fully charged batteries, battery clips, and a flash light should also be kept within reach in case of a power outage.

## 12.5 Other Patient Care Considerations

### 12.5.1 Magnetic Resonance Imaging (MRI)

Use of diagnostic MRI *is contraindicated in any patient with an implanted HeartMate II LVAD*. The presence of ferromagnetic parts within the device makes exposure to strong electromagnetic fields a risk factor for acute pump failure.

### 12.5.2 External Chest Compressions

In the event of cardiac arrest, external chest compressions pose a risk due to the location of the LVAD outflow graft and the presence of an apical ventricular anastomosis. Clinical judgment should be used when deciding whether or not to perform external compressions.

Cardiac massage under direct vision, performed by a skilled surgeon may be effective in patients who have had recent device implantation (prior to mediastinal healing).

### 12.5.3 Defibrillation

If external defibrillation becomes necessary, do not disconnect the system controller from the percutaneous lead prior to delivering the shock.

However, if open-chest defibrillation is required, it is advised that the HeartMate II LVAS be disconnected during the use of open-heart defibrillation.

### 12.5.4 Blood Leak Diagnosis

A blood leak from any implanted component of the system is typically identified through presence of one of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distension of the abdomen.



**NOTE:**

These symptoms may also occur due to bleeding from native tissue.

- Blood draining from the percutaneous lead exit site.
- Evidence of decreased hemoglobin/hematocrit.

### 12.5.5 Right Heart Failure

Some patients suddenly develop right ventricular (RV) failure during or shortly after device implantation. The onset of RV dysfunction in these patients is often accompanied by the inability of the LVAD to fill and drastically reduced flow rates. Limited filling is further exacerbated in the presence of right heart failure with an elevated transpulmonary pressure gradient or high pulmonary vascular resistance.

Treatment for patients in right heart failure typically consists of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. As a last resort, a right ventricular assist device may be employed.

#### **WARNING!**

There is risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed prior to the initiation of cardiopulmonary bypass and stoppage of LVAD pumping.

### 12.5.6 Static Electric Discharge

Avoid strong static discharges (e.g. television or computer monitor screens) as this can damage the electrical parts of the system and cause of the LVAD to stop.

#### **CAUTION!**

Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit LVAS effectiveness due to reduced filling of the LVAD.

## 12.6 Anticoagulation

1. Prior to leaving the OR, completely reverse the anticoagulation.
2. **Optional:** Post implantation, as early as possible, administer 10% LMW Dextran at 25ml/hr (this step is optional until the benefit of Dextran administration is further delineated)
3. Begin IV Heparin after 12-24 hours or when chest tube drainage is less than 50 ml/hr:
  - Initially titrate to a PTT of 45-50 for 24 hours (1.2-1.4 times control)
  - After 24 hrs increase Heparin and titrate to PTT 50-60 (1.4-1.7 times control)
  - After another 24 hours increase Heparin and titrate to PTT 55-65 (1.5-1.8 times control)

#### **WARNING!**

In the event that the LVAD stops operating, the patient should seek immediate medical attention to treat retrograde flow within the LVAD. Treatment measure may include heparinization, standard interventions for acutely decompensated congestive heart failure, and surgical exploration.



4. On post-operative day 2-3, initiate aspirin 81-100 mg QD and dipyridamole 75 mg TID.
5. On post-operative day 3-5, once there is no evidence of bleeding and the chest tubes have been removed, begin Warfarin (overlapping with the Heparin). Discontinue Heparin after obtaining an acceptable, stable INR. The INR should be maintained in the range of 2.0 to 3.0.
6. Maintain the patient throughout support on aspirin, dipyridamole, and Warfarin.

Conditions requiring possible modification to anticoagulation:

1. **Sustained low pump flow states (< 3.0L/min):**
  - Consider increasing anti-coagulation to upper limits of normal.
2. **Risk of bleeding:**
  - Consider increasing anti-platelet medications and decreasing Heparin/Warfarin (INR 1.7-2.3). Anti-platelet effect should be confirmed with lab studies, e.g. TEG.

**WARNING!**

In the event that the LVAD stops operating and blood is stagnant in the pump and cannulae for more than a few minutes (depending on the anticoagulation status of the patient), there is a risk of stroke and/or thromboembolism should the device be restarted.

## 13.0 Periodic Inspection and Maintenance

Although the HeartMate II LVAS has no external moving components and thus requires little preventive maintenance, there are several tasks that should be performed at the prescribed intervals given in this chapter.

### 13.1 General Care

**Clean exterior surfaces** of the HeartMate II LVAS components as necessary with a damp cloth. Water with or without a mild detergent may be used. Do not allow water to penetrate into the interior of these devices.

**Inspect the percutaneous lead exit site** for redness or swelling. Perform exit site care and dressing changes as prescribed (chapter 12.2).

#### **CAUTION!**

Do not clean or service the following equipment while it is connected to a LVAS patient: system controller, PBU, PBU cable, system monitor, batteries, battery clip, EPP, and EPP cable.

Sterile components are intended for single use only.

### 13.2 System Controller

**Perform the system controller self-test** (chapter 7.3.7) at any convenient time once a day.

**Inspect the system controller power connector pins and sockets for dirt or grease.** This inspection can be performed nightly while changing batteries or changing from batteries to the PBU. Check both system controller connectors and both PBU connectors. Do *not* disconnect the system controller to the percutaneous lead connection. This connector should be inspected only during a system controller replacement procedure.

Do *not* attempt to clean any of these connectors. If contamination is found, report the condition to the hospital technical support staff or the Thoratec HeartLine for technical support at 1-800-456-1477 USA or (925)-847-8600 outside the USA.

### 13.3 Power Base Unit (PBU)

**Perform preventative maintenance** at least once a year. Preventative maintenance includes (but is not limited to) a functional test, cleaning, inspection of all internal components and connections, and replacement of the internal battery. Only service personnel trained by Thoratec should perform PBU maintenance.

**Unplug all cables connected to the PBU and remove all batteries prior to cleaning.** Wipe the external surfaces of the PBU

with a clean, dry cloth. Do not use liquids (e.g., water or liquid cleaning solvent) to clean the PBU.

**Inspect the PBU cable connector pins** once a month for dirt and grease. Do not attempt to clean the connector pins if contamination is found. Instead, report the condition to the hospital's technical support staff or call Thoratec technical support at 1-800-456-1477 USA or (925)-847-8600 outside the USA.

## 13.4 Batteries

**Clean the battery terminals and the interior contacts of the battery clips** with an alcohol-moistened swab/cloth weekly after changing from batteries to the PBU. The batteries are handled constantly and rapidly accumulate a contaminating film that may be difficult to see.

**Check the expiration date on all the batteries including the EPP** once a month. . Batteries should not be used past their expiration date.

**Inspect batteries for physical damage** weekly. Do not use batteries that show signs of physical damage.

**Clean battery terminals** weekly using alcohol-moistened cotton swabs. Allow alcohol on terminals to evaporate before using the battery.

**Clean batteries as necessary** with a clean, dry cloth. Do not use liquids (e.g., water or liquid cleaning solvent) to clean batteries.

## 13.5 Emergency Power Pack (EPP)

**Check the expiration date** on the EPP once a month. An EPP should not be used past its expiration date.

**Inspect the EPP for physical damage** weekly. Do not use an EPP that shows signs of physical damage.

**Clean the EPP as necessary** with a clean, dry cloth. Do not use liquids (e.g., water or liquid cleaning solvent) to clean the EPP.

**Do not clean the EPP when it is being used to power the patient's LVAD.**

**Inspect the EPP cable connector pins** once a month for dirt and grease. Do not attempt to clean the connector pins if contamination is found. Instead, report the condition to the hospital's technical support staff or call Thoratec technical support at 1-800-456-1477 USA or (925)-847-8600 (outside the USA).

# Troubleshooting

## 14.0 Troubleshooting

The *Troubleshooting* chapter provides a ready reference for alarm conditions, answers some frequently asked questions, and provides a few procedural hints.

Thoratec employs highly trained representatives and engineers worldwide to serve users and will, upon request, provide additional training in the use of its products. Thoratec also maintains a professional staff for technical consultation. Contact a local Thoratec representative for additional information.

The clinical staff, caregiver, and patient must be familiar with what to do should an emergency situation arise. The following discussion outlines potential emergencies and appropriate corrective actions.

### 14.1 What is an Emergency?

An emergency condition exists whenever the device is potentially or actually unable to pump an adequate amount of blood. This condition is signified by a hazard alarm (red heart or red battery) symbol with a continuous audio alarm on the system controller. If the system monitor or display module is connected, one of the alarm messages in Table 12 is displayed.

The system monitor and display module will show the length of time in minutes that is spent in an emergency condition, except for a low voltage hazard condition.

Alarm Message	Message Location	Meaning
Pump Disconnected	system monitor	Percutaneous lead is disconnected from the system controller.
PUMP OFF	system monitor	Pump is stopped or disconnected from the system controller.
LOW FLOW, x min.	display module or system monitor	Flow is below 2.5 lpm
LOW VOLTAGE	display module or system monitor	Voltage is below 10.25 V

**Table 12. Hazard Alarms**

## 14.2 Emergency Corrective Actions

It is essential in an emergency to remain calm. The majority of problems can be resolved in a timely fashion. Follow the steps below:

1. Check the connection between the system controller and LVAD.
2. Check the connection between the system controller and the batteries or PBU.
3. If alarm continues, change the power source (fully charged batteries or PBU).
4. If the alarm continues, change the system controller
5. If the device still fails to operate, contact emergency services or implant center support staff.

### **WARNING!**

In the event that the LVAD stops operating, all attempts should be made to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted.

## 14.3 Advisory Events

Advisory events require immediate attention. The system controller signals for advisory events are

- Visual Signal: Flashing green power symbol, yellow battery, or yellow battery module
- Audible Signal: One beep every 4 seconds

The system monitor messages for advisory events are displayed in descending order of priority:

- Low Voltage Advisory
- Replace System Controller
- Power Cable Disconnected
- System Controller Battery Module Low
- WARNING: Low Speed Operation

The display module messages for advisory events are displayed in descending order of priority:

- Power Cable Disconnected
- Low Voltage Advisory
- System Controller Battery Module Low
- Replace System Controller
- WARNING: Low Speed Operation

The response to an advisory event is as follows:

1. If the yellow battery symbol is illuminated while operating on batteries, switch to fully charged batteries. If the yellow battery alarm persists, switch to the PBU.
2. If the yellow battery symbol is illuminated while connected to the PBU, switch to fully charged batteries.
3. If a broken audio tone is the only advisory warning (no visual), the system is in the low speed operation range. To exit this mode, connect the system controller to the system monitor if it is not already. Select a fixed speed rate above 8,000 rpm and above the low speed limit value or lower the low speed limit value below the fixed speed setting.

## 14.4 Alarm Corrective Actions

Table 13 provides a summary of all HeartMate LVAS alarm conditions and corrective actions. See chapter 7.3.6 for the same table in larger text.

Warning Light and Sound on System Controller	Message on Display Module and System Monitor	Alarm Level	Meaning	Corrective Action
Continuous audio tone & red heart symbol.	LOW FLOW on display module  LOW FLOW, PUMP OFF, &/or Pump Disconnected on system monitor	Hazard	Pump flow is < 2.5 lpm, pump has stopped, or pump is not operating correctly.	<ol style="list-style-type: none"> <li>1. Check connection between system controller and LVAD.</li> <li>2. Check connection between system controller and power source (batteries, PBU, or emergency power pack).</li> <li>3. If alarm continues, seek additional help immediately.</li> </ol> <b>See warning below table*</b>
Continuous audio tone & no warning light or green power symbol.	None	Hazard	System controller is not receiving power (no power present other than alarm battery module).	<ol style="list-style-type: none"> <li>1. Check connection between system controller and power source (batteries, PBU, or emergency power pack).</li> <li>2. Change power source.</li> <li>3. Change system controller.</li> </ol> <b>See warning below table*</b>
Continuous audio tone & red battery symbol.	LOW VOLTAGE	Hazard	<5 minutes of battery power remains, voltage is too low, or system controller is receiving inadequate power from PBU.	<p>Immediately replace batteries or change to alternate power source. LVAD will automatically go into power saver mode (8,000 rpm).</p> <p><b>NOTE:</b> Do not remove both batteries simultaneously or pump will stop.</p>
Audio tone of 1 beep every 4 seconds & yellow battery symbol.	Low Voltage Advisory	Advisory	<15 minutes of battery power remains, voltage is too low, or system controller is receiving inadequate power from PBU.	Replace batteries or change to alternate power source.
Audio tone of 1 beep every second & flashing green power symbol and flashing battery fuel gauge lights.	Power Cable Disconnected	Advisory	One of the power leads is disconnected or damaged.	<ol style="list-style-type: none"> <li>1. Reconnect power lead.</li> <li>2. If alarm continues, check system controller and PBU power lead for damage.</li> <li>3. If PBU or system controller power lead is damaged, change PBU cable or system controller.</li> </ol>
Audio tone of 1 beep every 4 seconds & yellow battery module symbol.	SC Battery Module Low	Advisory	Battery module that powers system controller is depleted.	Replace alarm battery module.
<p>Audio tone of 1 beep every 4 seconds &amp; no warning light when on batteries or PBU with display module.</p> <p>No audio tone or warning light when on PBU with system monitor.</p>	WARNING: Low Speed Operation	Advisory	Pump is operating below low speed limit.	Connect system controller to system monitor (audio alarm will stop) and increase fixed speed or reduce low speed limit.
Audio tone of 2 beeps (once per second) followed by 2 seconds of silence & no warning light.	Replace System Controller	Advisory	System controller is operating in backup mode.	<p>Replace system controller.</p> <p><b>See warning below table*</b></p>

\* **WARNING:** If fixed speed setting is < 8,000 rpm, silence alarm or test select button must be pressed to restart pump. If fixed speed setting is  $\geq$  8,000 rpm, pump should restart automatically.

**Table 13. Alarm Condition Corrective Actions**

## 14.5 Emergency Power Pack

The EPP is a single use battery pack enclosed in a plastic carrying case with a shoulder strap (Figure 73). If electrical power is lost for an extended period of time, the EPP will provide battery power to run the LVAD. The EPP will provide about 12 hours of support under normal conditions (flow of 6.0 lpm with a mean arterial pressure of 115 mm Hg). The EPP will last for less time as activity increases. For example, if exercise or increased emotional stress result in increased flow, the patient will get less time on the EPP. The EPP is intended for use outside the hospital and is not intended for use as a routine power source. Although recommended, the EPP is optional equipment.

- The EPP is not rechargeable and must be replaced if used for a period exceeding 3 hours.
- Each EPP is labeled with an expiration date and should not be used past expiration.
- Discard an expired EPP by following all applicable local, state, and federal regulations; do not incinerate.

To set up the EPP, follow the below procedure:

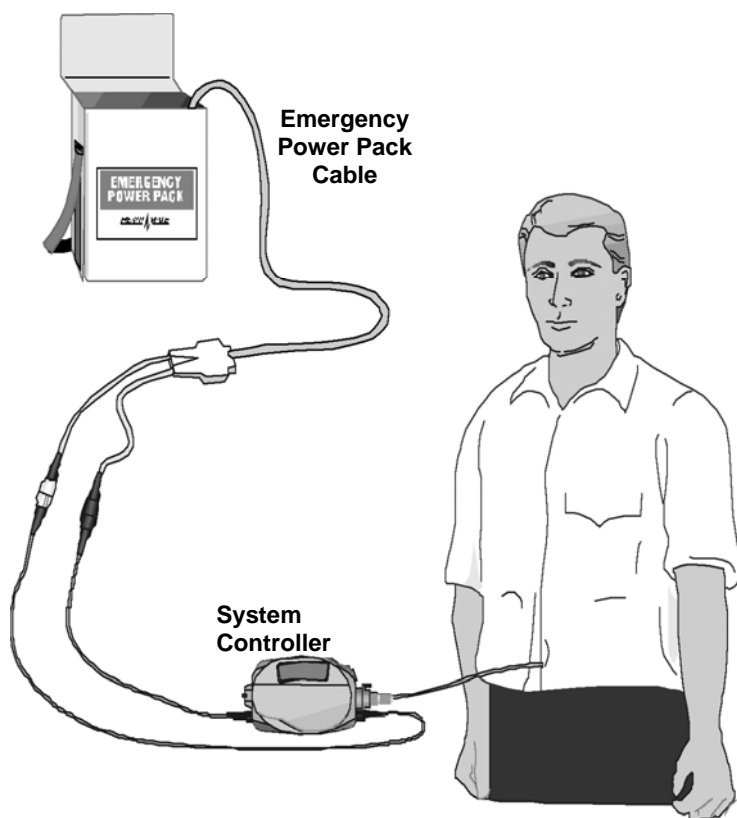
1. Open the top of the EPP and read the instructions.
2. Plug the cable provided into the EPP cable receptacle found inside the top of the EPP. A set screw on the EPP cable may need to be loosened prior to connecting. Once this cable and EPP are connected, tighten the set screw.
3. Unscrew the white system controller power lead connector from the patient's battery clip or PBU. An advisory alarm will sound once every second, and both the power symbol and battery fuel gauge lights will flash. Connect the white EPP connector to the white system controller power lead connector. The advisory alarm and flashing lights will stop.
4. Unscrew the black system controller power lead connector from the patient's battery clip or PBU. An advisory alarm will sound once every second, and both the power symbol and battery fuel gauge lights will flash. Connect the black EPP connector to the black system controller power lead connector. The one advisory alarm and flashing lights will stop.
5. The patient is now connected to the EPP.

### **CAUTION!**

Do not store or use the EPP below 32°F (0°C) or above 122°F (50°C) or it may fail suddenly. If the EPP is below room temperature (68-72°F, 20-23°C) during use, it will run the pump for less than 12 hours. At the low end of the temperature range (32°F, 0°C), run time will be reduced by 50%.

To prevent deterioration or damage to the EPP:  
 -- Do not leave or store the EPP in hot areas (car trunk, etc.) or battery life will be shortened.  
 -- Do not use the EPP beyond the expiration date.  
 -- Dispose of expired, used, or damaged EPPs according to local, state, or federal guidelines. Do not incinerate.





**Figure 73. Emergency Power Pack Configuration**

## 15.0 Frequently Asked Questions

Q: After inserting a good battery into the PBU battery charger, the charger indicator light turns red. Why is that and what do I do?

A: The battery was probably not inserted fully into the PBU in one smooth motion. The battery must be inserted into the PBU in one smooth motion so that it makes contact with the charging terminals in the back of the PBU slot before the yellow “testing” indicator light comes on. Remove that battery and reinsert it in a different PBU slot.

Q: When placing a battery into the PBU, no indicator lights are lighting.

A: Make sure the PBU is plugged in and turned on. Verify that the battery’s white label is not obscured. The PBU detects the battery’s presence by the white label. If the label is covered or removed, the PBU is unaware that a battery has been inserted for testing and charging.

## Reference

### 16.0 Testing and Classification

The HeartMate II LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 2601-1. In addition, the HeartMate II LVAS meets the following European EN safety standards: EN 60601-1: 1990, Amendment 1:1993, and Amendment 2:1995. These standards require making the following declarations and stating the type and degree of protection for listed hazards.

#### 16.1 Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type CF (Cardio Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water	System Controller - IPX3 PBU - IPX0 System Monitor (s/n <2000 – IPX0) System Monitor (s/n >2000 – IPX1)

**Table 14. Declaration Concerning General Safety Standards**



Medical Electric Equipment with  
respect to shock, fire,  
mechanical and other specified  
hazards only in accordance with  
UL 2601-1 and CAN/CSA C22.2  
No.601-1 7D72

## 16.2 Declaration and Guidance for Electromagnetic Emissions

The HeartMate II LVAS is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate II LVAS should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The HeartMate II LVAS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Radiated emissions, magnetic field MIL-STD-461E	RE101	The HeartMate II LVAS generates magnetic fields due to the presences of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

**Table 15. Declaration and Guidance Concerning Electromagnetic Emissions**

## 16.3 Declaration and Guidance for Electromagnetic Immunity

The HeartMate II LVAS is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate II LVAS should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test Level	Compliance level	Electromagnetic environment— guidance
Electrostatic discharge (ESD)  IEC 61000-4-2 EN 61000-4-2	min. $\pm 6$ kV contact  min. $\pm 8$ kV air	power base unit and system monitor (s/n below 2000) [ $\pm 6$ ] kV contact [ $\pm 8$ ] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic discharge (ESD)  IEC 61000-4-2 EN 61000-4-2	min. $\pm 6$ kV contact  min. $\pm 8$ kV air	system monitor (s/n above 2000), LVAD, and system controller [ $\pm 8$ ] kV contact [ $\pm 15$ ] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst  IEC 61000-4-4 EN 61000-4-4	$\pm 2$ kV for power supply lines  $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines  $\pm 1$ kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5 EN61000-4-5	$\pm 1$ kV differential mode  $\pm 2$ kV common mode	$\pm 1$ kV differential mode  $\pm 2$ kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11 EN 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The Power Base Unit contains an internal battery which will provide uninterruptible power for a minimum of ½ hr. NOTE: UT is the A.C. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8 EN 61000-4-8	3 A/m	3 A/m	If disturbance occurs, it may be necessary to position the HeartMate II LVAS further from sources of power frequency magnetic fields or install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

**Table 16. Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate II LVAS Equipment, including Power Base Unit and System Monitor**

The HeartMate II left ventricular assist device (LVAD), system controller, and batteries are intended for use in the electromagnetic environment specified below. The customer or the user of the *HeartMate II LVAD, system controller, and batteries* should assure that they are used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate II LVAD, system controller, and batteries (including cables), than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
<b>Recommended Separation Distances</b>			
Conducted RF IEC 61000-4-6 EN 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands <sup>a</sup>	[3] Vrms	<i>CENTER TEXT W/IN CELL</i> $d = \left[ \frac{3.5}{3} \right] / P$
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands <sup>a</sup>	[10] Vrms	$d = \left[ \frac{12}{10} \right] / P$
Radiated RF IEC 61000-4-3 EN 61000-4-3	Min. 10 V/m 80 MHz to 2.5 GHz	[10] V/m	$d = \left[ \frac{12}{10} \right] / P$ 80 MHz to 800 MHz $d = \left[ \frac{23}{10} \right] / P$ 800 MHz to 2.5 GHz <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>c</sup> should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.</p>
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<sup>a</sup> The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.			

- <sup>b</sup> Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (min. 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- <sup>c</sup> Field strengths from fixed transmitters, such as base stations for radios (battery modular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate II LVAS is used exceeds the applicable RF compliance level above, HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

**Table 17. Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate II LVAS Equipment, including LVAD, System Controller, and Batteries**

The HeartMate II LVAS has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate II LVAS can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec for help.

NOTE: Special precautions are required for installing and using the HeartMate II LVAS within portable and RF communication environments.

The HeartMate II LVAS is protected against the effects of external cardiac defibrillation within the limits established per EN 45502-1:1997. However, it is advised that the HeartMate II LVAS be disconnected during the use of open-heart defibrillation.

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## Appendix I – HeartMate II Technical Specifications

### HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM CONDENSED TECHNICAL SPECIFICATIONS

#### Rotary Left Ventricular Assist Pump

Catalog #1355

#### BLOOD VOLUMES-FLUID CAPACITY

##### DIMENSIONS (pump body)

Diameter	1.7" (4.3 cm)
Length	(excluding conduits) 3.2" (8.1 cm)

**WEIGHT** (pump body) 9.9 oz (281.3 g)

**GROSS VOLUME** 3.8 ci (63 cc)

**PRIMING VOLUME** 0.43 ci (7 cc)

#### BLOOD CONTACTING SURFACES

Titanium	Polished titanium
Graft	Woven polyester

#### CONSTRUCTION

Outer Shell	Titanium
Apical Cannula	19 mm titanium
Sewing Ring	PTFE-covered reinforced silicone
Outlet Conduit	16mm woven polyester
Electric Line	6-conductor shielded. PTFE sheath

#### PERFORMANCE DATA

Power Consumption	14 watts nominal
Operating Voltage	10-14 volts DC
Nominal Pump Speed	6,000-15,000 rpm
Minimum Pump Speed	6,000 rpm



**STERILE SYSTEM CONTROLLER****Catalog # 1315**

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**ACTIVE FUNCTIONS**

Implements Selected Mode

Reverts to Power Saver Mode during low battery operation

**Operating Modes**

Fixed Speed Mode

Speed Range from 6,000-15,000 rpm

Power Saver Mode

Fixed speed: 8,000 rpm

**MONITORING FUNCTIONS**

Fault detection and alarms

Performance data processing/storage

Battery state-of-charge indicators and alarms

Bi-directional data link

Analog waveform processing

**DIMENSIONS**

Length

7" (17.8 cm)

Width

2 1/4" (5.7 cm)

Height

3 3/4" (9.5 cm)

**WEIGHT**

23 oz (650 g)

**POWER BASE UNIT****Catalog #1240**

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**ACTIVE FUNCTIONS**

Isolated power to patient during tethered operation  
 Charges/checks up to six batteries at one time  
 Mains failure back-up battery (30 minutes)

**MONITORING FUNCTIONS**

Isolated bidirectional data link to external display module or system monitor  
 Isolated dual-channel analog uplink  
 Mains failure Alarm  
 LO BATT advisory for internal back-up battery  
 Red/yellow/green state-of-charge indicators

**POWER REQUIREMENTS**

100/120/230/240 VAC, 50-60 Hz, 175 watts max

**DIMENSIONS**

Length	16.2" (411 mm)
Width	16.2"/17.9" with handle (411 mm/ 455 mm)
Height	6" (153 mm)

**WEIGHT**

29 lbs without batteries (13.2 Kg)

**BATTERIES****Catalog # 2025****PERFORMANCE DATA**

Type	12-volt, sealed lead-acid
Capacity	2.3 amp-hours each
Discharge Time	Nominal value: 3 hours per pair under normal conditions (flow 6.0 lpm, 115 mmHg arterial pressure), reduced at cold temperature by up to 50%.
Charge Time	8 hours max (on C/N 1240)
Cycle Life	150 - 300 cycles (nominal 180 cycles)

**DIMENSIONS**

Length	7.25" (184mm)
Width	2.4" (61 mm)
Height	1" (25 mm)

**WEIGHT**

1.44 lbs (.650 Kg) each

**DISPLAY MODULE****Catalog # 1280N**

Type	2-line vacuum fluorescent
Function	· Displays speed (rpm), Flow (lpm) and Pulsatility Index (PI). · Displays speed mode and prioritized alerts and advisories.
Charge Time	8 hours max (on C/N 1240)
Cycle Life	150 - 300 cycles (nominal 180 cycles)

**DIMENSIONS**

Length	1" (254mm)
Width	7.5" (190mm)
Height	3" (75mm)

<b>WEIGHT</b>	1.54 lb (0.7 Kg)
---------------	------------------

**EMERGENCY POWER PACK (EPP)****Catalog #2020**

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**PERFORMANCE DATA**

Type	12-volt, sealed alkaline primary (one-time)
Capacity	20 amp-hours
Discharge Time	Nominal value: 12 hours, under normal conditions (flow 6.0 lpm, 115 mmHg arterial pressure), reduced at cold temperature by up to 50%
Charge Time	NA
Shelf Life	Labeled with expiration date

**DIMENSIONS**

Length	11" (280 mm)
Width	8" (200 mm)
Height	3" (76 mm)

<b>WEIGHT</b>	10.6 lb (4.8 Kg)
---------------	------------------

**SYSTEM MONITOR****Catalog #1286**

	<b>Original System Monitor</b>	<b>Updated System Monitor</b>
<b>TYPE</b>	Electroluminescent (EL) display w/ touch-screen interface.	Backlit Color LCD display w/ touch-screen interface.
<b>RESOLUTION</b>	640x400 pixels	640 x 480 pixels
<b>FUNCTION</b>		
<b>Clinical Screen</b>	Displays speed, flow (lpm), pulsatility index, power, mode (fixed), and fixed speed setpoint.	Displays speed, flow (lpm), pulsatility index, power, mode (fixed), and fixed speed setpoint.
	Displays prioritized alerts and advisories.	Displays prioritized alerts and advisories.
<b>Settings Screen</b>	Displays system status and prioritized alerts/advisories.	Displays system status and prioritized alerts/advisories.
	Permits control of fixed speed values, low speed limit values, and pump stop/start.	Permits control of fixed speed values, low speed limit values, and pump stop/start.
<b>Alarms Screen</b>	Displays all alerts and advisories.	Displays all alerts and advisories.
<b>Save Data Screen</b>	Permits control of data collection.	Permits control of data collection.
<b>History Screen</b>	Displays controller event recorder data.	Displays controller event recorder data.
<b>Admin Screen</b>	Displays current date and time.	Displays current date and time.
	Permits control of date/time and technical parameters.	Permits control of date/time and technical parameters.
<b>DIMENSIONS</b>		
<b>Length</b>	10.125" (257mm)	12.0" (305mm)
<b>Height</b>	8.0" (203mm)	10.0" (245mm)
<b>Depth</b>	4.5" (114mm)	6.5" (165mm)
<b>WEIGHT</b>	5.8 lbs (2.63 kg)	5.5 lb (2.49 kg)

**BATTERY CLIP****Catalog #1237**

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**DIMENSIONS**

Length	3.15" (80 mm)
Width	1.25" (32 mm)
Height	3.75" (92 mm)

**WEIGHT**            3.7 oz. without battery (104 g)

**PERFORMANCE DATA**

ESD protection      2 kV in excess of severity level 4 as specified in IEC 801-2  
Impact resistance    Meets drop test requirement as specified in IEC 601-1

**POWER BASE UNIT CABLE****Catalog # 1225**

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<b>TYPE</b>	One straight plug connector with heavy duty extended coupling nut composite back shell and composite strain relief for connection to the PBU, and two custom thread-locking power connectors for connection to the system controller.
<b>FUNCTION</b>	To provide electrical connection between the system controller and the PBU.
<b>LENGTH</b>	20 feet (6.1 meters)



## Appendix II – HeartMate II Product List

This operating manual addresses the routine operation and troubleshooting of the HeartMate II Left Ventricular Assist System (LVAS). Major system components utilized during routine operations, such as the implanted LVAD, system controller and either batteries (untethered operation) or a power base unit (tethered operation), are discussed in detail. Other elements of the complete HeartMate II LVAS listed below may be addressed or referenced peripherally, as the subject requires.

### Emergency Power Pack (EPP)

The EPP is a single-use battery pack in a plastic carrying case with a shoulder strap. If AC mains power is lost for an extended period of time, the EPP provides battery power to run the LVAD for approximately 12 hours. The EPP is intended for use outside the hospital and is equipped with an extension cable for direct connection to the system controller power leads. The EPP is not intended for use as a routine power source.

### Battery Clips

The battery clips provide a means of powering the LVAS with two rechargeable batteries. A charged battery is inserted into each battery clip and automatically locks into place. The circuit is completed when the power leads from the system controller are attached to the battery clips. To replace the batteries, the patient pushes the release button on each battery clip to unlock the battery, and the battery slides out freely.

### Battery Holster

The battery holster is a shoulder-worn harness that carries two system batteries and attached battery clips. The patient should adjust the battery holster straps such that the pockets hang comfortably under his or her arms. The batteries are inserted into the pocket with the connections to the battery clips facing to the front of the patient. The Velcro retaining straps are used to secure the batteries in the holster pocket. When changing batteries, the patient removes the retaining strap, lifts the battery clip out of its pocket, releases the depleted battery from the clip, installs a fully charged one, and inserts the battery clip back into the holster pocket.

### **PocketPak**

The PocketPak is a small pouch worn on the patient's waist. It is designed to carry the system controller, battery clips, and excess cable. The patient should adjust the PocketPak so that it wears comfortably around his or her waist. The system controller switch panel should face up so that the indicators are visible and the switches on the panel are not inadvertently actuated. The zipper should be closed to insure that the equipment within does not fall out. Enough excess cable length should be remaining outside the PocketPak so that the percutaneous exit site is not stressed.

### **Travel Case**

The travel case facilitates the ambulatory lifestyle of the LVAS patient. It contains sufficient room to carry a spare system controller and two spare batteries. It is made from a water proof, rugged, and easily cleaned material. The case has two outside zipper pockets for quick removal of its contents. Along with a comfortable rubber handgrip on top, it has a wide shoulder strap with a non-skid pad for added security.









## Appendix III – Power Change and Emergency Response Checklists

The following checklists should be reviewed with all patients, caregivers and hospital staff. Patients and caregivers should be asked to review these steps during all follow-up visits to reinforce proper power changing and emergency procedures.

**It is recommended that copies of these checklists be provided to patients and caregivers upon discharge. They should be instructed to post them in a convenient location where they can review them on a regular basis.**

## Power Change Checklist

**CAUTION:** Never disconnect power (PBU or battery) from both controller power leads at the same time.

1. Prepare for power change (See your Patient Handbook)
2. Remove only one battery or the white PBU power lead from the controller  
*(The power symbol  will flash rapidly, the 4 green battery fuel gauge lights  will flash, and the alarm will sound once every second.)*
3. Connect the fully charged battery or white PBU power lead to the controller
4. Wait until the power symbol  and the battery fuel gauge lights  stop flashing and the alarm stops
5. Remove the second battery or black PBU power lead from the controller.  
*(The power symbol  will flash rapidly, the 4 green battery fuel gauge lights  will flash, and the alarm will sound)*
6. Connect the fully charged battery or black PBU power lead to the controller.
7. Wait until the power symbol  and the battery fuel gauge lights  stop flashing and the alarm stops
8. Check fuel gauge and complete steps in the Patient Handbook.

### WARNING:

- When changing batteries, never disconnect both batteries at the same time or your pump will stop.
- Your pump will stop if power is removed from both controller power leads at the same time.
- Your pump will automatically restart only after power is restored.

## **HeartMate II Emergency Response Checklist**

### **URGENT CONTROLLER ALARMS:**



Red Heart with continuous audio tone

**OR:** Continuous audio tone, no lights on controller

### **WHAT TO DO:**

1. **CHECK CONNECTIONS**—Make sure the pump is connected to the controller and the power leads are connected to batteries or the PBU cable and PBU
2. **CHANGE POWER SOURCE**—If alarm continues, change power source (fully charged batteries or to PBU).
3. **CHANGE CONTROLLER**—If alarm continues, change the system controller.
4. **GET ADDITIONAL HELP**—If alarm continues, seek additional help

## Appendix IV – Original System Monitor with New Software (no longer in production)

The original system monitor has been replaced by the updated version discussed in chapter 11.0. However, the new software will be added to original monitors still in use. Therefore, although these screens will remain monochrome, they will look and act like those on the updated monitor.

The main difference between the original, monochrome monitor and the updated, color monitor is the way in which alarm conditions are displayed. While the updated monitor displays alarms as red and yellow text banners, all alarm messages on the original monitor will be highlighted one color as shown in Figure 74, Figure 75, and Figure 76.

On the Clinical screen, hazards will flash but advisories will not. Also on the Clinical screen, along with text banners, PUMP OFF and LOW FLOW alarm conditions will highlight the Pump Flow box, and the Pump Disconnected alarm condition will highlight the Pump Speed box.

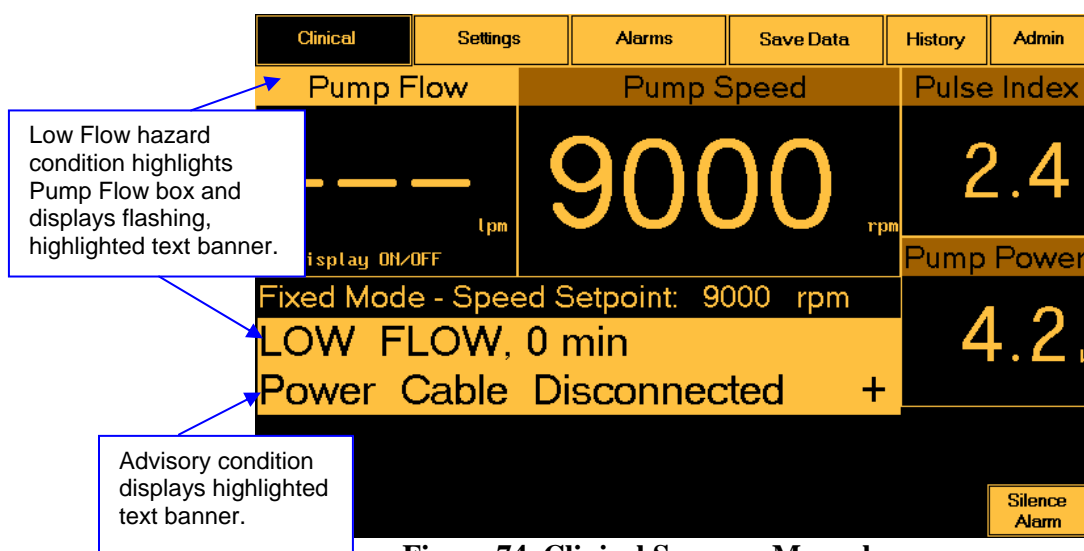


Figure 74. Clinical Screen – Monochrome

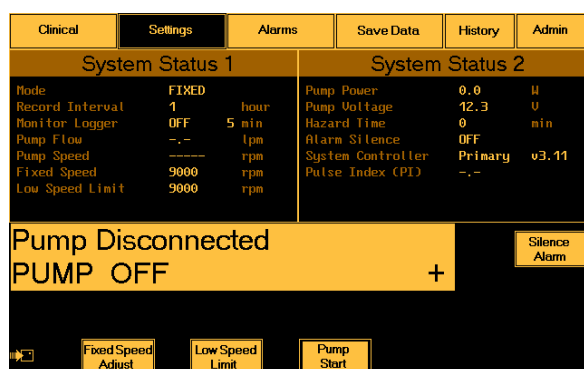


Figure 75. Settings Screen – Monochrome

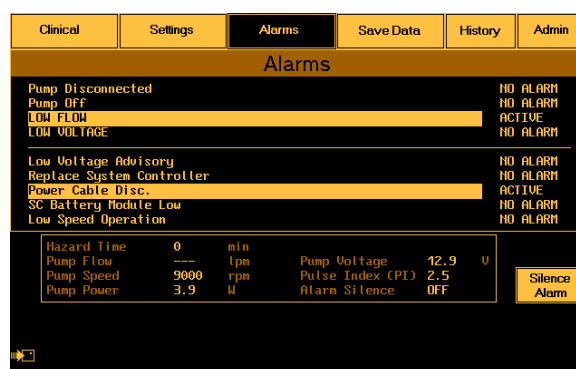


Figure 76. Alarms Screen – Monochrome

## Saving Data with the Original System Monitor

The procedure for Saving Data using an Original System Monitor (Table 10) is similar to the Updated System Monitor, with the exception that the storage media is different. The Original System Monitor uses a Data Card (P/N 101609) AND a PC Card Adapter (Figure 77).

If using an Original version of the System Monitor, complete the following steps:

1. Obtain a PC Card Adapter (Figure 77).
2. Insert the PC Card Adapter into the card slot on the right side of the System Monitor (Figure 78).
3. Insert the data card into the PC Card Adapter (Figure 79).
4. Follow the steps outlined in Section 11.2.5 for Saving Data



**Figure 77. PC Card Adapter**



**NOTE:**

A PC Card Adapter is necessary in order to use CompactFlash™ media with older versions of the System Monitor. PC Card Adapters may be obtained from a local computer store

The PC Card Adapter may be left in the System Monitor slot to avoid it from being lost.



**NOTE:**

The System Monitor will beep if both components are installed correctly.



**Figure 78. Inserting Adapter into System Monitor (rear view)**



**Figure 79. Inserting Data Card into PC Card Adapter inside System Monitor**



## Glossary of Terms

### A

**Advisory Alarm:** An audio or visual indication that the HeartMate II LVAD is approaching a region where it may operate outside its intended region. An audio or visual alarm indicates a condition with little or no immediate effect on circulatory support but requiring attention.

**Annunciators:** Audio tone generators found in the PBU and system controller.

**Apical Coring Knife:** Circular knife used to core the left ventricle during implantation.

**Apical Sewing Ring:** Silicone sleeve device sewn to the exterior of the heart to affix the inlet extension to the left ventricle.

**Axial flow:** Type of pump that pumps fluid in the same axis as the spinning rotor.

**Axial load:** Forces generated in the same axis as the spinning rotor. Also defined as thrust loads.

### B

**Back Up Mode:** The deployment of the redundant circuitry within the system controller.

**Battery Clip:** Interface device between the HeartMate battery and the system controller.

**Battery Fuel Gauges:** Visual battery charge indicator on the system controller.

**Battery Holster:** A two pocket HeartMate accessory that facilitates wearing two batteries with battery clip.

**Battery-Powered Operation:** The HeartMate II LVAS operating while connected to portable batteries.

**Bearings:** The ceramic features of the pump that allow the rotor to spin within the blood path.

**Bend Relief:** Portion of outflow graft that provides abrasion and kink resistance for the outflow graft.

**Blood Analog:** A process fluid that approximates the specific gravity and viscosity of blood. The blood analog is used in various mock circulatory loops for LVAS evaluation.

**Bullet:** Protective end cap applied to the percutaneous lead connector while the lead is being implanted.

### C

**Cardiac output:** The total output of blood from the native left ventricle.

**Clinical Screen:** Primary screen found on the system monitor used when the primary function is to monitor system performance.

**Communication Icon:** Flashing symbol displayed on the system monitor once the system monitor recognizes communication with the system controller.

**CVP:** Central Venous Pressure, the venous pressure as measured at the right atrium, done by means of a catheter introduced through the median cubital vein to the superior vena cava, the distal end of the catheter being attached to a manometer.

### D

**Data Logger:** Feature within the system monitor to collect system performance data and store it to the data card. This feature has the ability to select the frequency of data collection (B/P, CO, PCWP, CVP). The system monitor must be connected to the PBU, and the patient must be connected to the PBU in order to collect this system performance data.

**Display Module:** When connected to the PBU, the display module displays a variety of system performance data, including the current operating mode, pump speed, flow rate, pulsatility index, power, and overall operational status

### E

**EMC:** Electromagnetic Compatibility.

EPP: Emergency Power Pack- Catalog # 2020.

Event Recorder: Captures system data whenever there is a system alarm event.

Exit Site: Location on the patient where the percutaneous lead crosses the skin line.

Extended Self Test: Function within the system controller that verifies critical attributes of hardware and software during a clinician initiated sequence via the system monitor only.

Extended Silence: A command sent to the system controller from the system monitor to mute the audio alarms (on SD) for 4 hours.

F

Fibrillation: Erratic and irregular rhythm of either the atria or ventricles in the native heart.

Final Functional Test: Final manufacturing test to ensure device meets intended function (i.e. system controller final functional test)

Fixed Speed Control: The continuous closed loop feedback control of the HeartMate II system controller that controls motor speed at a prescribed fixed speed.

Fixed Speed Mode: Operating mode of the HeartMate II in which the rotor speed is constant.

Fixed Speed Setpoint: Operating speed set in the system monitor for a prescribed fixed pump speed.

Flexible Inlet: Section of inlet cannula that allows articulation of the inlet extension with respect to the pump.

Fluid film: The thin layer of fluid that forms between the fixed and rotating bearing surface while the rotor is spinning.

Frank-Starling mechanism: The native hearts intrinsic capability of increasing its force of contraction when preload is increased.

G

H

Hazard Alarm: Audio and visual indication that a loss of support exists or is imminent.

HeartMate II LVAS: Left Ventricular Assist System configuration consisting of a HeartMate II pump assembly with percutaneous lead, system controller, system monitor, power sources (power base unit, batteries, or emergency power pack), and accessories.

Hemodynamics: a branch of physiology that deals with the circulation of the blood, or the forces or mechanisms involved in circulation.

H-Q Curve: The characteristic set of pressure (H) vs. flow (Q) curves that define the hydraulics of an axial flow pump.

Hydrodynamic: The state in which the bearings are spinning and are separated from each other by a thin fluid film.

I

ICU: Intensive Care Unit, where most LVAS maintenance will occur.

Inflow Conduit Assembly: Comprised of the inlet extension, flexible inflow section, inflow elbow, and locking screw ring.

Inflow Conduit: Conduit connecting the left ventricle to the pump.

Inflow Elbow: Segment of the inflow conduit that connects the cannula to the pump via a locking screw ring.

Inflow Graft: Interior portion of the flexible inflow section that is pre-clotted prior to implantation.

Inlet Extension: The segment of the inflow conduit that is inserted into the left ventricle.

Inlet Housing: Pump component that interfaces to inflow conduit assembly via a locking screw ring.

Inlet Pressure: Pressure measured at the inlet of the pump.

**Inlet Stator:** Straightens flow of blood path at pump inlet. Attaches to inlet housing and supports bearings.

J

K

L

**Locking Screw Ring:** Means of attaching the inflow conduit assembly to the pump, and the outflow graft assembly to the outflow elbow.

**Low Battery Hazard Symbol:** Red visual indicator on system controller alerting the user when power into the system controller is critically low.

**Low Flow Hazard Symbol:** Red visual indicator on system controller alerting the user when HeartMate II LVAD flow is critically low.

**lpm:** Liters Per Minute. Units of measurement of blood flow through the pump.

**LVAD:** Left Ventricular Assist Device. Includes the blood pump, inflow conduit and outflow graft, and percutaneous lead.

**LVAS:** Left Ventricular Assist System. Includes the LVAD, system controller, system monitor, power sources, and accessories.

M

**Mock Circulatory Loop (Pulsatile):** Same as a mock circulatory loop. However, a mock ventricle (a HeartMate IP or XVE LVAD) is provided in the flow path prior to the device under test (DUT) to supply a pulsatile inlet pressure.

**Mock Circulatory Loop (simple):** A rudimentary mock circulation which provides a means to regulate inlet pressure and outlet pressure. Resistance is achieved via a variable orifice and compliance via a column of air. This type of loop is used to assess relative changes in LVAS performance.

**Mock Circulatory Loop:** A bench top means for simulating properties of systemic cardiovascular resistance and compliance. Typically instrumented to measure flow, inlet pressure, and outlet pressure. Used in conjunction with various process fluids (water, saline, or blood analog) to characterize mechanical circulatory support devices. Modeled after designs approved by NHLBI circa 1970.

**Motor Capsule:** Sealed assembly that encapsulates the motor armature outside of the titanium blood tube. Interfaces with inlet and outlet pump housings.

**Motor Current Advisory:** An alarm condition alerting the user that the motor current has exceeded normal operating range.

**Motor Current:** Real time motor current in amperes as measured by the system controller.

N

**Neo-intimal:** Description of the biological surface formed on textured biomaterials inside the LVAD.

O

**Outflow Bend Relief:** Protective sleeve over segment of the outflow graft that inhibits kinking of the outflow graft and is connected to the outflow graft after LVAD de-airing.

**Outflow Elbow:** Permanently attached to the blood pump at the outlet housing to connect the outflow graft with a locking screw ring.

**Outflow Graft Assembly:** Comprised of the outflow graft and outflow bend relief, and locking screw ring.

**Outflow Graft:** Polyester graft connected to the aorta and outflow elbow.

**Outlet Housing:** Pump component that interfaces to outflow elbow via a permanent screw ring.

**Outlet Pressure:** Pressure measured at the outlet of the pump.

Outlet Stator: Component of the HeartMate II pump which straightens the flow as it exist the Rotor. Is a support for the bearings and rotor, and interfaces to the outlet housing.

Outlet Stator: Straightens flow of blood path at pump outlet. Attaches to outlet housing and supports bearings.

## P

PBU Cable: Cable connecting the power base unit to the system controller's power leads.

PBU: Power Base Unit

PCWP: Pulmonary Capillary Wedge Pressure, the pressure obtained when a catheter is passed from the right side of the heart into the pulmonary artery as far as it will go and wedged into an end artery. PCWP is measured by letting pulmonary blood flow guide a balloon-flotation catheter into a small pulmonary end artery. The pressure distal to the wedged catheter is an approximation of cardiac left atrial pressure. The pressure recorded with the balloon deflated is pulmonary artery pressure.

Perc Lock: A component fixed to the bulkhead connector of the system controller intended to prevent inadvertent disconnection of the percutaneous lead.

Percutaneous Lead Connector: Connector permanently attached to the percutaneous lead and connects to the system controller.

Percutaneous Lead: A long motor lead attached to the HeartMate II pump at the factory with a quick locking connector for attachment to the system controller.

PocketPak: A HeartMate accessory that allows for the batteries or system controller to be worn around the waist.

Polyester Velour: A synthetic biocompatible material that allows tissue ingrowth for securing the percutaneous lead.

Power Entry Module: AC input on back of PBU. Adjusts for various input voltages.

Power Saving Mode: LVAS operates at a speed of 8000 rpm when motor voltage is < 10.5 v.

Power Sources: Current equipment used on the HeartMate II LVAS. Items include batteries, battery clips, PBU, and EPP.

Pressure / Flow (H-Q) Curves: The pressure vs. flow characteristic of the pump. Expressed with "Pressure Across Pump (mmHg)" in the Y axis and "Pump Flow (lpm)" in the X axis.

Pressure Across LVAD: The pressure difference between the inflow conduit and outflow graft.

Pressure Across Pump: The difference in pressure between the inlet and outlet of the pump.

Pump Speed: Revolutions per minute of the pump rotor.

Pump: Blood pump to propel blood taken from the inflow conduit and delivered to the outflow graft. In the blood path the pump contains titanium stators, rotor, blood tube, and ceramic bearings. The motor capsule surrounds a portion of the blood path and is powered via the percutaneous lead.

## Q

Qavg: Average LVAD flow over a given time interval.

Qmax: Maximum pump flow measured over a given time interval.

Qmin: Minimum pump flow measured over a given time interval.

## R

Radial load: Forces generated at a right angle to the axis of the spinning rotor. Also defined as side loads.

Reverse Flow: Blood flow that travels retrograde in the LVAD.

Rotary Pump: A pump that generates flow via a rotating rotor with blades.

Rotor Magnet: Magnet embedded within the rotor.

Rotor: The titanium spinning element with blades that rotates via the Bearings to expel blood

from the Pump. Located in the blood path.

## S

**Self Test:** Function within the system controller that demonstrates the system controller's audio and visual alarm indicators during a user initiated sequence.

**Self TestButton:** Located on the system controller, pressing this button activates the self-test of the HeartMate II LVAD and system controller.

**Settings Screen:** A secondary screen on the system monitor that displays more in-depth information regarding HeartMate II LVAS performance.

**Shower Kit:** HeartMate accessory that allows patients to shower. Consists of a protected enclosure that holds the system controller and batteries.

**Silence Alarm Button:** A means to mute the annunciators for a fixed period of time allowing the user to respond to alarm conditions without audio distraction

**Single Fault Tolerant:** Redundant circuitry that provides a backup if there is a problem with the primary source.

**System Controller battery module Symbol:** A yellow visual indicator on the system controller alerting the user when the system controller battery module needs replacement.

**System Controller Battery Module:** A replaceable assembly that provides backup power to system controller alarms.

**System Controller Data Stack:** An event based record of prior alarms recorded by the system controller and communicated via the system monitor.

**System Controller Power Leads:** Leads that connect the system controller to battery clips or the PBU cable.

**System Controller Status String:** Information sent from the system controller to show the operating status and parameters.

**System Controller:** External control unit of the HeartMate II LVAS which connects to the percutaneous lead of the LVAD and to power sources.

**System Monitor:** Touch screen two-way communication link to the system controller.

**Systole:** The time at which ventricular contraction occurs.

## T

**Tethered Operation:** Use of the HeartMate II LVAS while connected to the PBU.

**Thread Protectors:** Devices that engage the threads of the outflow elbow and outflow graft conduit to prevent the build-up of biological debris and contamination of the pump during implantation of the HeartMate II LVAD.

**Tunnelers:** A device that provides blunt dissection for the percutaneous lead during device implantation. The tunneler is able to attach to the bullet in order to facilitate the placement of the lead.

## U

**User Interface Panel:** Display of visual indicators and buttons mounted on the front surface of the system controller.

## V

**Visual Indicator Lamp:** Used to visually convey status and advisory or hazard conditions to the user (found on system controller and PBU).

## W

**Waveforms:** Current and voltage traces of motor performance as captured by the system monitor.

## X

## Y