

HeartMate II[®] LVAS

LEFT VENTRICULAR ASSIST SYSTEM

OPERATING MANUAL



T H O R A T E C[®]
C O R P O R A T I O N

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FOREWORD

This manual contains information needed to properly and safely operate the Thoratec HeartMate II[®] 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 support (MSC) and should be aware of the physiological and psychological needs of a patient undergoing mechanical ventricular support.

Sections 1-3 offer the reader an overall perspective of the system. They also describe the indications for use and the contraindications. Lastly, these sections introduce some of the unique attributes of the HeartMate II LVAS. **Sections 4-11** explain how the system works, describe the technical features and operation of each system component and include descriptions of a variety of situations likely to arise during and after pump implantation. **Sections 12-13** describe in detail the procedures necessary to support HeartMate II LVAS patients, including equipment cleaning and maintenance requirements. **Sections 14-15** are devoted to troubleshooting and answering frequently asked questions. **Section 16** contains reference information such as technical specifications and classifications.

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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GENERAL INFORMATION

1.0 Introduction to the HeartMate II LVAS

The HeartMate II LVAS is an axial-flow, rotary left ventricular assist system and can generate flows up to 10 liters per minute (lpm). Attached to the apex of the left ventricle and the ascending aorta, the HeartMate II blood pump diverts blood from the weakened left ventricle and propels it to the rest of the body. 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. 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 II 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 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 sections 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		HeartMate batteries and battery clips are used to power the LVAD during mobile or “untethered” battery-powered operation. They are used in pairs.
Power Module (PM)		The Power Module (PM) provides AC mains electrical power to the LVAD during “tethered” operation.
PM Patient Cable		The patient cable connects the Power Module to the System Controller during “tethered” operation. Connections are made between black-to-black and white-to-white connectors.

Continued on following page

Table 1 HeartMate II LVAS Hardware

Table 1 (continued)

Continued from previous page

<p>Universal Battery Charger (UBC)</p>		<p>The HeartMate universal battery charger (UBC) charges, tests, and calibrates HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries.</p>
<p>Emergency Power Pack (EPP)</p>		<p>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. The EPP is mandatory for HeartMate II patients.</p>
<p>System Monitor</p>		<p>The System Monitor functions as an enhanced display and control monitor connected to the PM. Its use during implantation is required.</p>
<p>Display Module</p>		<p>When connected to the PM, the Display Module provides a limited display of system performance. Use the System Monitor for enhanced display and control options.</p>

For safe and optimal use of external system components, in addition to this manual and the corresponding *HeartMate II LVAS IFU* (document # 103883), following power accessory IFUs also must be present and readily available:

- *HeartMate Power Module IFU* (document # 103772)
- *HeartMate Universal Battery Charger* (document # 103771)
- *HeartMate 12 Volt NiMH Battery IFU* (document # 103769)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)

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, backup, 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 two 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.

CAUTION!

A backup HeartMate II System Controller, spare batteries, and a set of battery clips must be with the patient **at all times** for use in an emergency.

General Information

Component	Primary (required)	Backup (required)	Optional*
LVAD Implant Kit	X	X	--
System Controller	X	X	--
Power Module (PM) with PM patient cable	X	X	--
System Monitor**	X	X	--
Rechargeable batteries (one set of 4); all 12 volt NiMH batteries <u>or</u> all 14 volt Li-Ion batteries	X	--	--
Battery Clips (set of 2)	X	--	--
Universal Battery Charger (UBC)	X	--	--
Tunneler	--	--	X
Inflow Conduit & Outflow Graft	--	--	X
Apical Coring Knife	--	--	X
Skin Coring Punch	--	--	X
System Controller Battery Module	--	--	X
Apical Sewing Ring	--	--	X
Thread Protectors	--	--	X

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

**The Display Module and older models of the System Monitor cable require an adapter to connect to the PM. See the *HeartMate Power Module IFU* (document #103772).

Table 2 Implantation Components (Required and Optional)

General Information

Component	Primary (required)	Backup (required)	Optional
Implanted HeartMate II LVAD	X	X	--
System Controller	X	X	--
Power Module (PM) with PM patient cable	X	X	
Rechargeable batteries (set of 4);); all 12 volt NiMH batteries <u>or</u> all 14 volt Li-Ion batteries	X	X	--
Battery Clips (set of 2)	X	--	Backup Optional
Universal Battery Charger (UBC)	X	--	--
GoGear™ Wearable Accessories*	X	--	Backup Optional
System Controller Battery Module	--	X	--
System Monitor**	X	X	--
Display Module**	--	--	X

* GoGear Wearable accessories include the holster vest, modular belt, consolidated bag, and shower bag.

**The Display Module and older models of the System Monitor cable require an adapter to connect to the PM. See the *HeartMate Power Module IFU* (document #103772).

Table 3 Post Implant Hospitalization Components (Required and Optional)

General Information

Component	Primary (required)	Backup (required)	Optional
Implanted HeartMate II LVAD	X	--	--
System Controller	X	X	--
Power Module (PM) with PM patient cable	X	--	--
Rechargeable batteries (set of 4);); all 12 volt NiMH batteries <u>or</u> all 14 volt Li-Ion batteries	X	X	--
Battery Clips (set of 2)	X	--	Backup Optional
Universal Battery Charger (UBC)	X	--	--
Emergency Power Pack (EPP)	X	--	--
Display Module**	X	--	--
GoGear™ Wearable Accessories*	X	--	Backup Optional
System Controller Battery Module	--	X	--
Patient Handbook	X	--	--

* GoGear Wearable accessories include the holster vest, modular belt, consolidated bag, and shower bag.

**The Display Module and older models of the System Monitor cable require an adapter to connect to the PM. See the *HeartMate Power Module IFU* (document #103772).

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 also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II LVAS is also intended for use both inside and outside the hospital, or for transportation of Ventricular Assist Device (VAD) patients via ground ambulance, fixed-wing aircraft, or helicopter.

3.0 Contraindications

The HeartMate II LVAS is contraindicated in patients who cannot tolerate or are allergic to anticoagulation therapy.

4.0 Warnings and Precautions

4.1 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 *HeartMate II LVAS Operating Manual* and the corresponding *HeartMate II LVAS Instructions for Use* (document # 103883) before attempting implantation. Completion of the HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System (LVAS). In addition, it is important to read the Instructions for Use (IFUs) for the accessories used to power the HeartMate II LVAS, including the Power Module (PM), Universal Battery Charger (UBC), and HeartMate 12 volt nickel metal hydride (NiMH) batteries or HeartMate 14 volt lithium ion (Li-Ion) batteries. See section 1.2 for a list of power accessory IFUs.
- Before using any HeartMate power accessories (PM, batteries, UBC), all users (including clinicians, patients, and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
 - *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
 - *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
 - *HeartMate Universal Battery Charger IFU* (document # 103771)
 - *HeartMate Power Module IFU* (document # 103772)

- The HeartMate Power Module (PM) and Universal Battery Charger (UBC) generate, use, and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the PM and/or UBC. Interference can be determined by unplugging/plugging in the PM and turning off/turning on the UBC and seeing the affect on devices in the area. If interference is detected while the patient is connected to the PM, attempt to correct it by *FIRST SWITCHING TO BATTERY POWER* and then:
 - Re-orienting or moving the affected device(s).
 - Increasing the distance between the PM and/or the UBC and the affected device(s).
 - Connecting the affected device(s) to an electrical outlet different from the outlet used to power the PM and/or the UBC.
 - Consulting Thoratec's Technical Services Department for advice and assistance.
- Do not use the PM or UBC in the presence of flammable anesthetic agents (e.g., nitrous oxide), or an explosion could occur.
- Connect the PM (and any peripheral devices, such the as the UBC) only to properly tested, grounded, and AC outlets dedicated to device use. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or you may receive a serious electric shock or the pump may stop.
- Do not connect the PM or the UBC to an outlet controlled by a wall switch or the device may be left inoperable.
- The PM, like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3 prong) AC mains electrical outlet that is dedicated to its use, except during transport or service/maintenance. The PM's internal battery (that provides limited backup power to the LVAD in the event of AC mains power failure) remains charged as long as the PM is connected to AC power and turned "on." See the *HeartMate II LVAS Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM
- The PM contains an internal battery. When new, the internal battery provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS in the event of AC mains interruption/failure. If the PM is used in cold conditions (32-59°F, 0-15°C), the backup battery runtime may be reduced to a minimum of 20 minutes. The PM is shipped with its internal battery disconnected. It must be connected prior to initial use. If the internal battery is not connected, the backup power source will not work. Make sure the internal battery is connected prior to

initial use and after any time the PM is shipped for service or maintenance. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on the PM's internal battery.

- Transfer from the PM to batteries during AC mains power failure. The PM has an internal backup battery that will power the pump while you transfer to batteries. The internal backup battery should not be used as a backup power source for the system during AC mains power failure. The Display Module or System Monitor will not work if connected to the PM during a power failure. In addition, the PM's battery charge status indicators will not work during AC mains power failure. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM, including how to transfer to battery-powered operation.
- Keep the PM and the UBC away from water. If the PM has contact with water, shower spray, rain/snow, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock. If the UBC has contact with water, shower spray, rain/snow, or wet surfaces, it may prevent the batteries from charging and/or the HeartMate II LVAS patient may receive a serious electrical shock.
- Do not use the HeartMate II LVAS in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus may dislodge the pump, which may result in device failure or fatal hemorrhage. Anticoagulation regimens are contraindicated during pregnancy.
- Do not subject patients implanted with the HeartMate II LVAS to Magnetic Resonance Imaging (MRI). The LVAD contains ferromagnetic components, and an MRI could cause device failure or patient injury.
- There may be risks associated with performing external chest compression, 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 compression may result in damage to the outflow graft conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage should only be performed by a skilled surgeon, under direct vision in patients who have had recent (i.e., prior to mediastinal healing) device implantation.
- Do not apply high power electrical treatment (e.g., application of diathermy) directly to the patient. Application of high power electrical treatments could result in electrical interference with system operation, causing the pump to stop.
- 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 any servicing of LVAS equipment to authorized Thoratec trained service personnel only.

4.1.1 WARNINGS - Specific Implantation Issues

- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- Moderate to severe aortic insufficiency must be corrected at time of device implant.
- Limited clinical data is available supporting safety and effectiveness of the HeartMate II LVAS in patients with a body surface area (BSA) less than 1.5m². The clinical decision to implant the HeartMate II in patients with a BSA less than 1.5m² should be based on individualized assessment of body habitus and device fit.
- Although a small number of pediatric patients (< 21 years) were enrolled in the HeartMate II study, the safety and efficacy of the device in pediatric patients has not been established.
- The clinical trial experience indicates that certain models of implantable cardiac defibrillators (ICDs) and certain implantable pacemakers (IPMs) may, in some cases, not be able to establish telemetry or permit communication between the programmer and the implanted device 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. Specific information on reported cases can be obtained on Thoratec's website at www.thoratec.com. No such difficulties have been reported, other than those observed with device(s) 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.

- Do not implant the HeartMate II LVAD if it has been dropped.
- Never operate the HeartMate II Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- 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 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 trabeculae 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 left heart, blood pump, and conduits 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 at a value 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 or inadequate pre-clotting of the inflow conduit or outflow graft.
- Do not autoclave the pump. Doing so will cause damage to the pump and percutaneous lead.
- A minimum of two fully charged batteries and a pair of compatible battery clips are required at the time of implant in order to power the system when transporting the patient out of the operating room.
- PMs are shipped to customers with the internal battery disconnected. After receiving the PM, the hospital's biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device. See the *HeartMate Power Module IFU*

(document #103772) for detailed warnings, precautions, and instructions on connecting the PM's internal battery.

- Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. The UBC will charge and test up to four batteries in four hours or less, depending on the initial charge status of the charging batteries. See the *HeartMate Universal Battery Charger IFU* (document #103771) for detailed warnings, precautions, and instructions on using the UBC to charge HeartMate batteries.
- The sealed outflow graft contains material of bovine origin; and, therefore, should not be implanted in patients who exhibit sensitivity to such material.

4.1.2 WARNINGS - Patient/System Management Issues

- System components must never be immersed. Showers and washing are permitted when the physician 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. See section 14.6, *Other Patient Care Considerations*, for more information.
- **Disconnecting both System Controller power leads at the same time will cause the pump to stop.** One System Controller lead must be connected to a battery or the PM at all times to maintain support. The following will cause the LVAD to stop and blood pumping to cease:
 - Disconnecting both power leads from the PM when operating on PM power.
 - Removing both batteries at the same time from their respective battery clips when operating on battery power.
 - Completely depleting the battery charge when operating on battery power.
- **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.
- If the pump is stopped when connected to the PM and System Monitor by using the pump stop button on the System Monitor, the System Controller will not automatically restart the pump if the percutaneous lead is disconnected and then reconnected to the System Controller, regardless of what the fixed speed set point was before stopping the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the pump or conduits 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.

4.2 PRECAUTIONS

- **This *HeartMate II LVAS Operating Manual*, which addresses postoperative and patient management issues, must be used in conjunction with the *HeartMate II LVAS Instructions for Use* (document # 103883). These manuals are not intended to replace comprehensive laboratory or educational programs or to supersede appropriate medical judgment.**
- Components of the HeartMate II LVAS that are supplied sterile are intended for single use only and should not be re-used or re-sterilized. Do not use sterile components if sterile packaging is compromised. Contact Thoratec customer service for Return Materials Authorization (RMA).
- Use only the Thoratec supplied universal battery charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on using the UBC to charge HeartMate batteries.
- Make sure the UBC is plugged in and turned on (“I”) before placing batteries into charging pockets.
- The UBC cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog #26439).
- Keep the UBC away from water or moisture. If the UBC has contact with water/moisture, shower spray, snow/rain, or wet surfaces, the user may receive a serious electric shock or the UBC may fail to operate properly.
- After approximately 70 uses, a HeartMate battery may need to be calibrated. The UBC alerts users when an inserted battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to do so to prevent a backlog of uncalibrated batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on using the UBC to calibrate HeartMate batteries.
- Leave a calibrating battery in the UBC for the entire calibration cycle. Removing a battery before it is fully calibrated may result in a fully-depleted battery (the on-battery fuel gauge will reflect this).
- For optimal battery performance, leave charged batteries in their charging pockets until ready for use. Leaving charged batteries in the UBC will not damage them.

- **HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag).** If a battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop unexpectedly. Do not use a battery if has not been charged within the first year of receipt. Discard expired or defective batteries according to local, state, and federal regulations. See the *HeartMate 12 Volt NiMH Battery IFU* (document #103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document #103770).
- HeartMate 12 volt NiMH batteries are compatible with both the HeartMate XVE and the HeartMate II LVAS. They can power either system. HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. HeartMate 14 volt Li-Ion batteries are NOT compatible with the XVE system and cannot provide power to the XVE LVAS. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for detailed warnings, precautions, and instructions on using HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries to power the HeartMate II LVAS. See **Table 10** for distinguishing characteristics of HeartMate 12 volt NiMH and 14 volt Li-Ion batteries.
- HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.
- Do not use batteries below 32° F (0° C) or above 104° F (40° C). If batteries are below room temperature (68–72° F, 20–22° C) during use, their capacity will be reduced. At the low end of the temperature range (32° F, 0° C), run time will be reduced. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770) for recommended storage guidelines.
- If stored and used within recommended guidelines, HeartMate batteries should be usable for approximately 360 use/charge cycles or for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770).
- Use of expired or defective batteries may result in reduced operating time or an abrupt loss of LVAD function.

- As batteries get older, they will support the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both batteries from service.
- To prevent deterioration or damage to batteries:
 - Do NOT drop batteries or hit them against hard objects or each other.
 - Do NOT use batteries in temperatures that are below 32°F (0°C) or above 104°F (40°C).
 - Do NOT leave or store batteries in extremely hot or cold temperatures (e.g., in cars or car trunks), or battery life will be shortened.
 - Do NOT connect any battery contacts.
 - Do NOT immerse batteries in water or liquid.
- Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short or connection between battery contacts, which can result in battery overheating that may burn the user or damage the batteries.
- The HeartMate Emergency Power Pack (EPP) is mandatory for HeartMate II patients. It is an emergency power source that can power the HeartMate II LVAS for up to 12 hours in the event of AC main power interruption or failure. The EPP is for emergency use only and is not intended as a routine power source. It is not rechargeable and must be replaced if used for a period exceeding three hours. The EPP is mandatory for HeartMate II patients.
- 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 used in an environment that is below room temperature (68–72°F, 20–22°C), the EPP 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 or cold 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/moisture or dirt 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 Power Module (PM) may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient, use only 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.
- If **external defibrillation** becomes necessary, do NOT disconnect the System Controller from the percutaneous lead prior to delivering the shock.
- If **open chest defibrillation** is required, it is advised that the HeartMate II LVAS be disconnected prior to delivering the shock.
- Ensure that all backup System Controllers are programmed with identical settings (e.g., fixed speed setting and low speed limit) 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.

4.2.1 PRECAUTIONS - Specific Implantation Issues

- Care must be taken to prevent blood from entering and collecting in the lumen of the conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must therefore be rinsed thoroughly prior to attachment to the LVAD.
- Do not use pre-clotting agents that require heat on the inflow conduit, as the inflow conduit cannot be autoclaved.
- Do not over tighten thread protectors.
- Do not allow the apical coring knife to involve the ventricular septum while performing the left ventricle coring.
- 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.

- Do not remove the centering fixture inside 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.
- Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning off cardiopulmonary bypass should provide a minimum of two lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.

4.2.2 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” (e.g., heart racing, short of breath, heart pains, light headedness).
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction. Sounds that could signal an issue include grinding or intermittent “whirring.”
- 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.
- A backup System Controller, spare batteries, and a pair of compatible battery clips must be with the patient at all times for use in an emergency.
- A patient’s primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car’s power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car’s DC power is inadequate to power the LVAS, the PM will alarm or switch to back-up battery power. If this occurs, switch to portable battery power and discontinue the use of DC input power to the PM. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM with automobile DC power.
- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, the patient should have at least one set of charged HeartMate batteries and cables in close proximity.
- The automobile engine must be ON and RUNNING BEFORE connecting the PM to its DC power outlet.
- The PM requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a checking, cleaning, and inspecting all internal connections, replacing the internal battery (the internal battery is rechargeable, but has a limited life), and replacing the PM patient cable.
- PM service and maintenance should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Do not clean or service the PM while it is providing power to the system.

- Do NOT connect both the AC and DC input cables to the PM at the same time.
- If the System Monitor is mounted on top of the PM, do NOT attempt to lift or carry the two devices together by using the System Monitor handle. Doing so may damage the PM and/or System Monitor.
- PM connectors should be kept clean and dry. Do not expose PM connectors to water, moisture, dirt, etc.
- When connecting PM connectors, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
- The UBC requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a functional check of the device and cleaning and inspecting all internal connections.
- Service and maintenance of the HeartMate UBC should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Make sure the UBC is plugged in and turned on (“I”) before placing batteries into the pockets for charging.
- After approximately 70 uses, HeartMate batteries may need to be recalibrated. The UBC indicates when a battery needs to be recalibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to prevent a backlog of uncalibrated batteries (see section 11.4, *Calibrating HeartMate Batteries*).
- Leave a calibrating battery in the UBC for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status) (see section 11.4 *Calibrating HeartMate Batteries*).
- The metal contacts inside the UBC pockets should be kept clean and dry. Do not expose contacts to water, moisture, dirt, etc. Do not touch these contacts when the charger is connected to AC mains and turned on (“I”).
- Dirty metal contacts inside the battery charging pockets may prevent proper battery charging, which can affect battery operation. The metal contacts inside the pockets should be cleaned at least once a month. TURN OFF and UNPLUG the UBC before cleaning. Do NOT clean the UBC while it is in use.

General Information

- Clean dirty metal contacts inside the charging pocket of the UBC with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before inserting batteries into the pocket(s) for charging.

PRINCIPLES OF OPERATION

5.0 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).

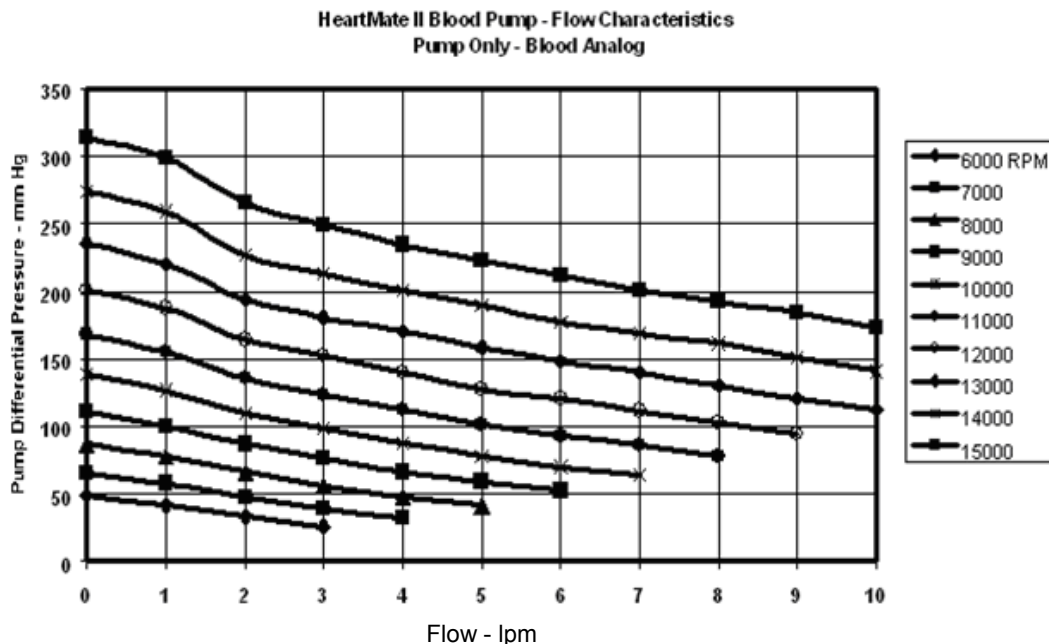


Figure 1 HeartMate II Flow Characteristics (typical)

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.

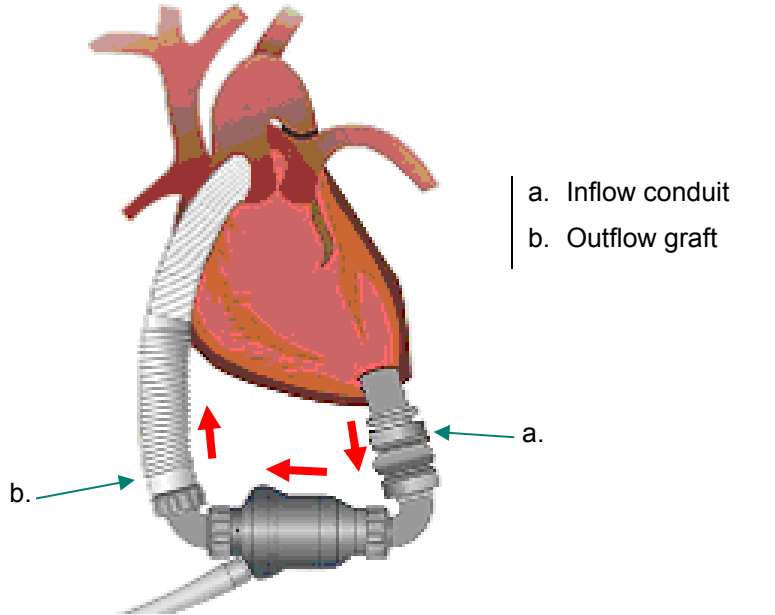


Figure 2 LVAD Configuration

Typically, a patient's aortic pressure is within a normal range and the net cannula pressure drop, although related to flow (for example, 10 mmHg 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. After the suction event has been resolved, the pump will resume operation at its previously set fixed speed setting.

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 mmHg as shown in **Figure 1**.

EXPLANATION OF PARAMETERS

6.0 Explanation of Parameters

6.1 Pump Speed

The LVAD operates at a fixed speed (see section 8.3.1) determined by the physician during a speed ramp study. 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.

6.2 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.

6.3 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 a calculated 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.

6.4 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.

HEARTMATE II LVAD

7.0 HeartMate II LVAD

7.1 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 Module (PM), PM patient cable, batteries, battery clips, Universal Battery Charger, (UBC), and System Monitor with cable.

The HeartMate II LVAD utilizes a rotary blood pump to generate flow and assist the left ventricle. 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**).

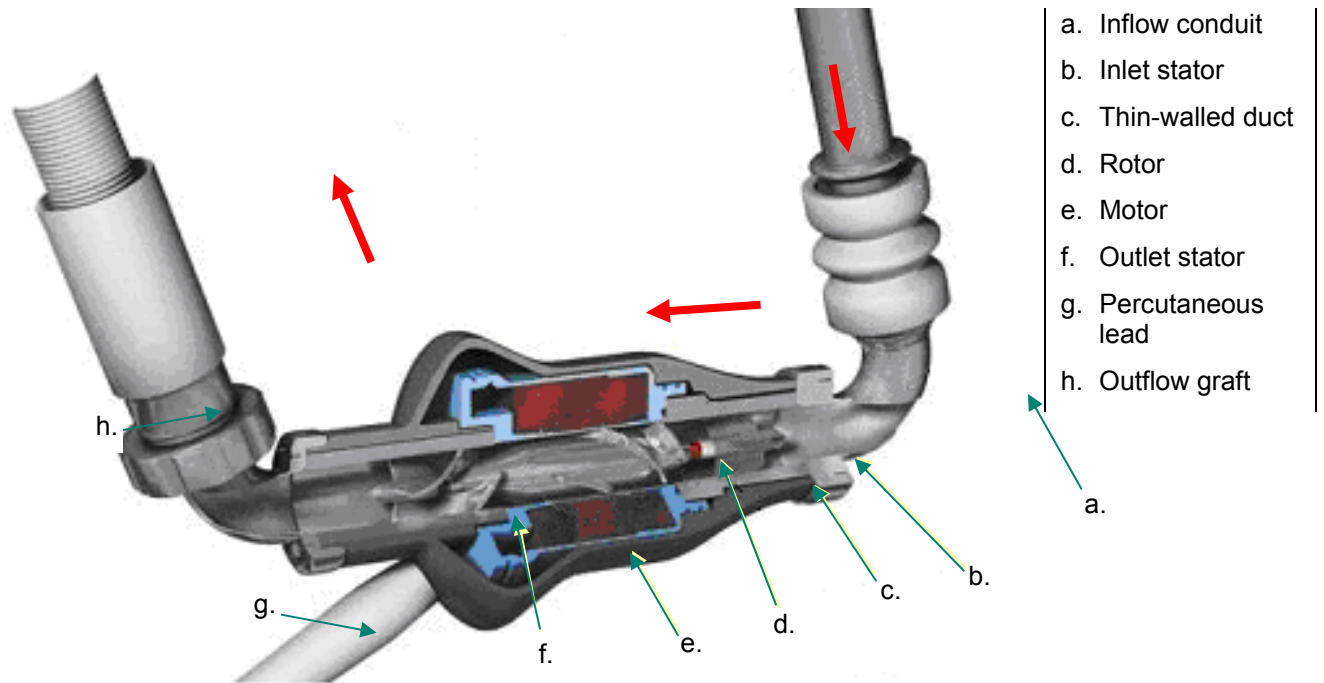


Figure 3 LVAD Components

7.2 Components

7.2.1 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.

7.2.2 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.

7.2.3 Inflow Conduit and Outflow Graft

Blood enters and exits the pump via the inflow conduit and outflow graft. A textured surface coats the inner lumen 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. The outflow graft is available in both unsealed and sealed versions. Features that identify a *sealed* outflow graft are as follows:

- 1) A blue dashed line on the bend relief;
- 2) A blue screw ring that attaches to the blood pump; and
- 3) A foil pouch that contains the sealed outflow graft.

The unsealed outflow graft requires pre-clotting before use.

The inflow conduit is only available in an unsealed version and requires pre-clotting before use.

WARNING!

The sealed outflow graft contains material of bovine origin. Therefore, it should not be implanted in patients who exhibit sensitivity to such materials. .

7.2.4 Percutaneous Lead

The percutaneous lead consists of a single cable that extends from the implanted LVAD through the skin to the external environment. The cable contains six wires, three primary wires and three back-up, which carry motor drive power to the LVAD.

To reduce the possibility of infection, the percutaneous lead is covered with woven polyester that encourages tissue ingrowth 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.

The clinical experience over five years of clinical trials (both bridge-to-transplantation and destination therapy) and commercial use outside of the US has shown that wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump to the external System Controller may result in damage that has the potential to interrupt pump function that may require a re-operation to replace the pump or result in death.

Damage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead. Damage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead. The damage may be evidenced by the following:

- Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
- High pump power associated with reduced pump speed (as recorded in the System Controller event log file).
- High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
- Feelings of pump vibrations.
- Fluid leakage from the external portion of the lead.
- Cessation of pumping.

If you suspect that a HeartMate II LVAS patient may have a damaged percutaneous lead, please contact Thoratec Technical Services (800-456-1477) for assistance. X-ray images, System Controller log files and pump waveform data may be useful to assess the extent and location of the damage. **If damage to the electrical conductors in the lead is confirmed, the HeartMate II pump should be replaced as soon as possible.**

In cases where there is a disruption to the continuity of the wires in the percutaneous lead, damage may occur to the System Controller. Should damage to the System Controller occur and the Controller require changing, consideration should be given to supporting the

patient with batteries, rather than the Power Module (PM), as this will reduce the potential of damaging the System Controller.

7.3 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.

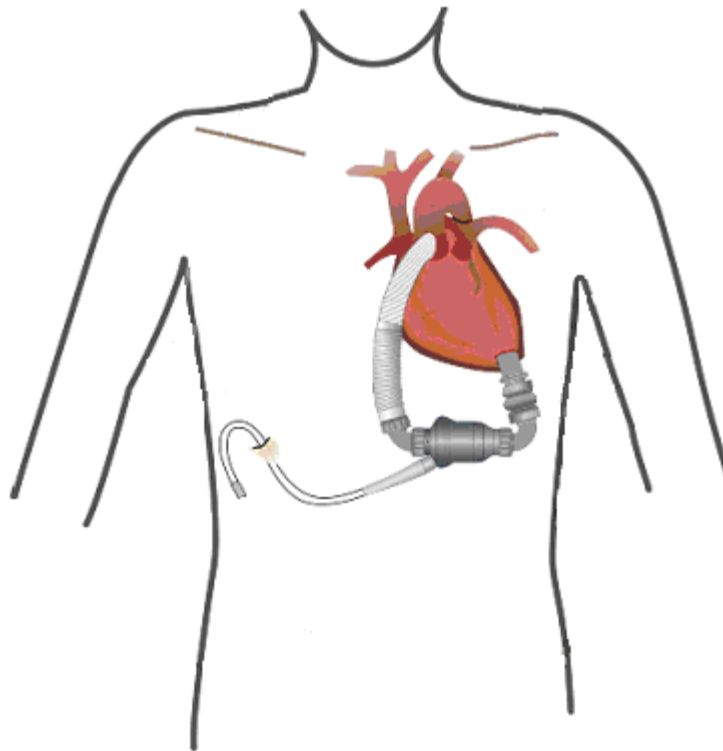


Figure 4 Implantation Configuration of the HeartMate II LVAS

7.4 Pump Power Source

The LVAD is powered through the System Controller by one of two routine power sources, either: 1) two HeartMate direct current (DC) batteries or 2) the Power Module (PM) that is connected to AC mains electrical. The emergency power pack (EPP), a third power source, is intended for use in emergency situations (i.e., not for routine operation).

SYSTEM CONTROLLER

8.0 System Controller

8.1 Overview

8.1.1 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

8.1.2 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. A battery inserted into the side of controller, called the alarm battery module, provides limited power to the System Controller audible alarms during situations when external power has been disrupted.

WARNING!
The System Controller battery module only provides power to the audible alarm tones. It does NOT provide power to the pump.

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 section 8.0.



Figure 5 System Controller and Power Leads

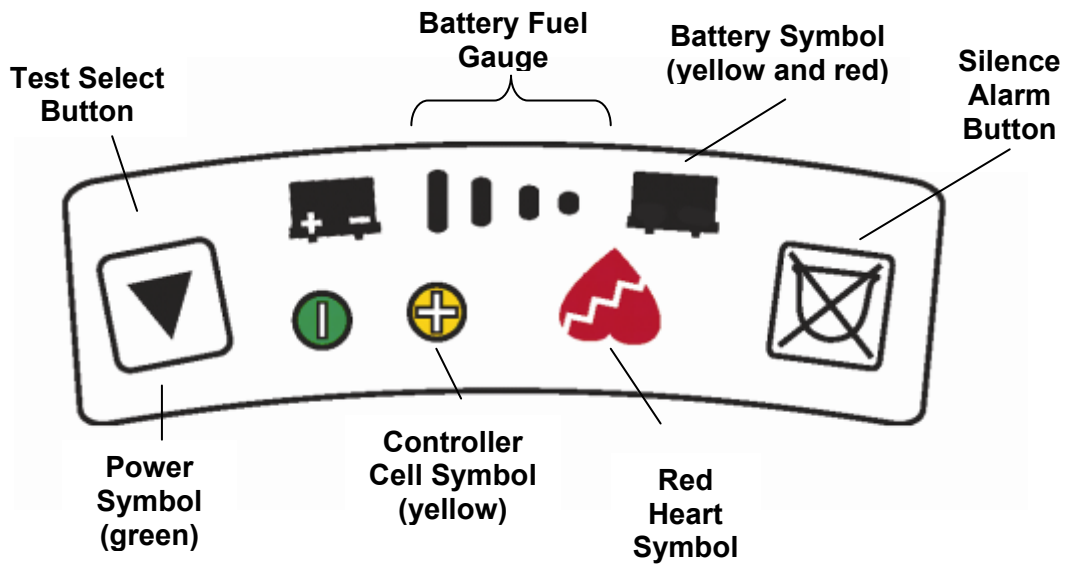


Figure 6 System Controller Keypad

8.2 Setup

The System Controller is powered by either HeartMate batteries or the Power Module (PM). When clipped onto the right front side of the patient's belt, the System Controller is readily connected to the LVAD percutaneous lead.

During battery-powered (mobile) operation, two HeartMate 12 volt NiMH or two 14 volt Li-Ion batteries are worn in holsters under the patient's arms (**Figure 7**) or in the carrying case (**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 PM patient cable. For detailed instructions on how to set up tethered and mobile configurations, refer to sections 9.2 and 10.2, respectively.

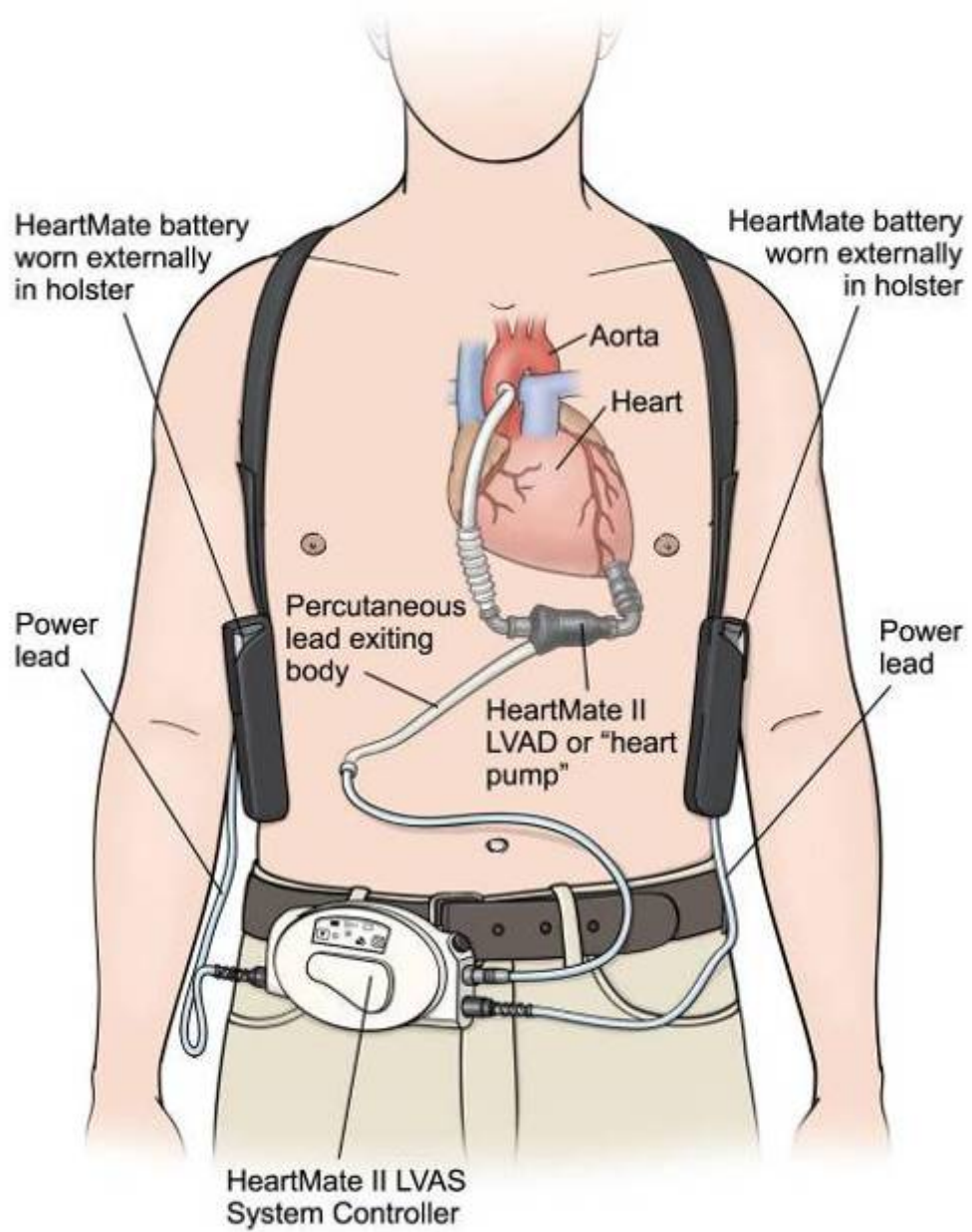


Figure 7 HeartMate II Battery-Powered Operation

System Controller

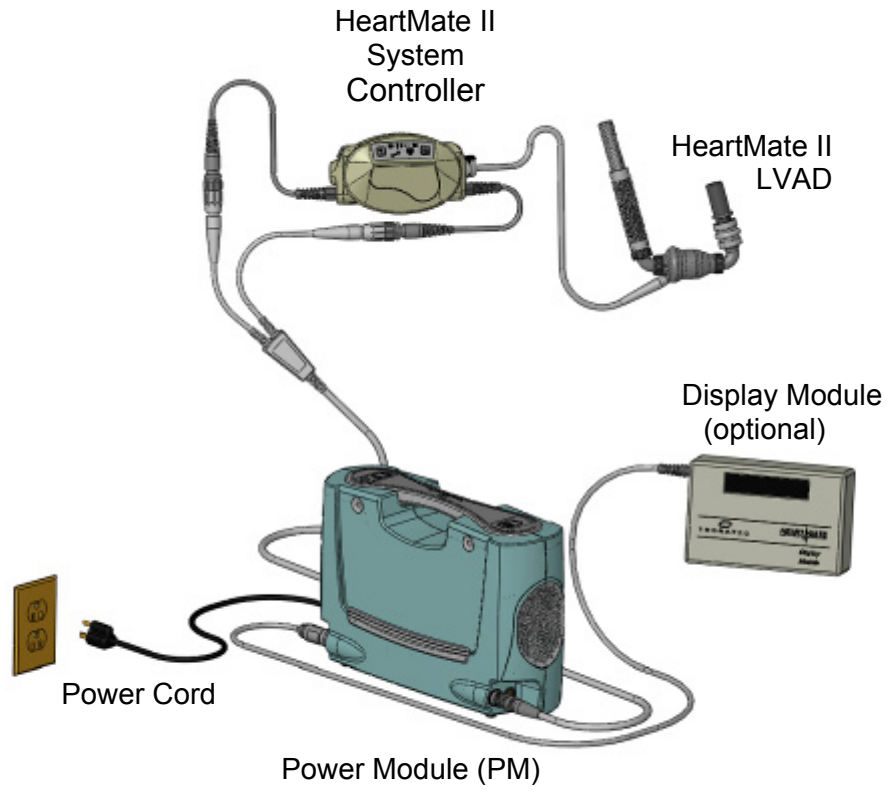


Figure 8 HeartMate II Tethered Operation

8.3 Description of Features

8.3.1 Modes of Operation

The System Controller has a single primary operating mode called “fixed speed,” which maintains operation at a constant pump speed. **Table 5** presents 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 (see *Power Save Mode*, below).

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, PM, or EPP).



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.

8.3.2 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. See Error! Reference source not found. for summary of alarms.

8.3.3 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, or 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 two seconds to restart 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 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 set point at a rate of 100 rpm. If the low speed limit is set at a value above or the same as the fixed speed set point, 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 section 13.2.5 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 PM data link



NOTE:

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

WARNING!

If the pump is stopped when connected to the PM and System Monitor by using the pump stop button on the System Monitor, the System Controller will not automatically restart the pump if the percutaneous lead is disconnected and then reconnected to the System Controller, regardless of what the fixed speed set point was before stopping the pump.

(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 section 13.0.

8.3.4 Control Buttons

The System Controller has a 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 two 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.

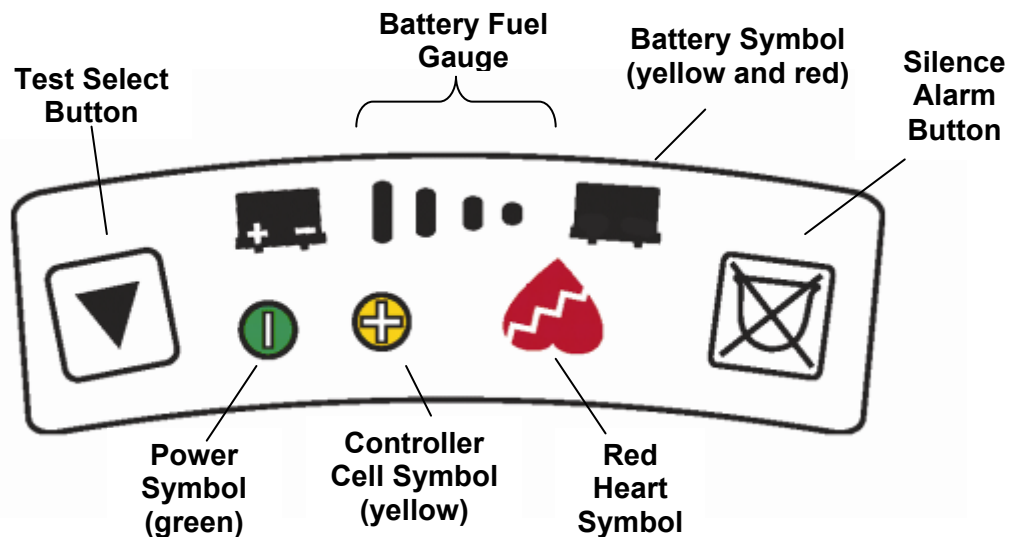


Figure 9 Control Buttons on System Controller Keypad

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 two minutes if a hazard condition or power cable disconnected advisory is active, and four hours if general advisories are active (see section 8.3.6). 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 PM, the PM duplicates the System Controller audible alarm. This second alarm can be silenced for five minutes, using the alarm reset button on the PM front panel or, to silence both the controller and the PM, press the silence alarm button on the controller or System Monitor screen.

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 section 8.3.7 for detailed information on how to complete the self-test.

8.3.5 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 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.

CAUTION!

If a pair of batteries does not give at least four hours of support, remove both batteries from service.

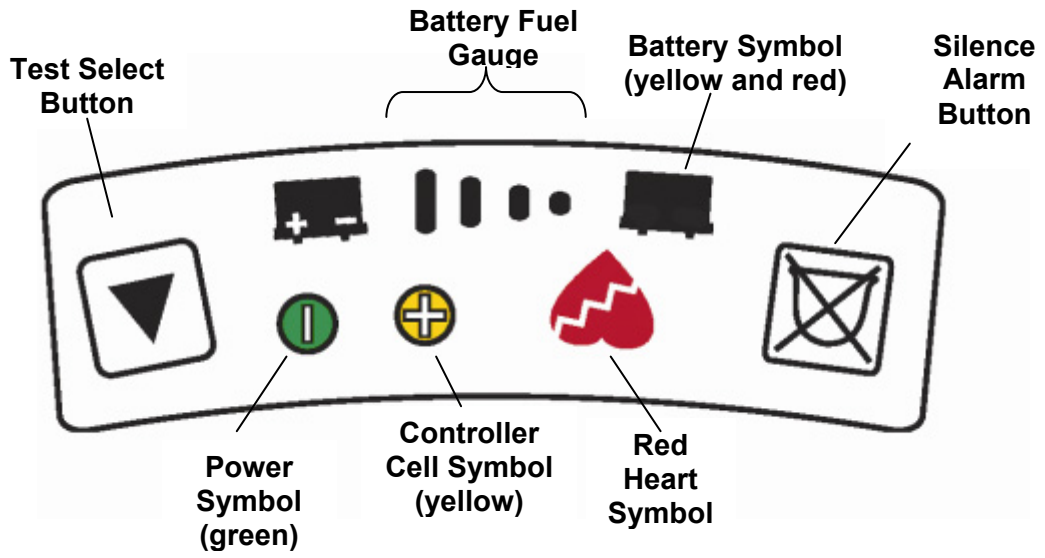


Figure 10 Battery Fuel Gauge on System Controller Keypad




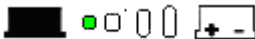


Battery Fuel Gauge	Meaning	Response
<p>Four Green Lights</p> 	75 -- 100% of battery power remains.	No action needed.
<p>Three Green Lights</p> 	50 -- 75% of battery power remains.	No action needed.
<p>Two Green Lights</p> 	25 -- 50% of battery power remains.	No action needed.
<p>One Green Light</p> 	Less than 25% of battery power remains.	Prepare to replace used batteries with fully charged batteries or to switch to the PM.
<p>Four Flashing Green Lights flash once per second</p>  <p>and</p> <p>Rapidly flashing green power symbol</p>  <p>Accompanied by 1 beep every second</p>	<p>Power Cable Disconnected advisory – Power lead is disconnected or damaged.</p> <p>This is displayed only when the advisory is active, and not when the silence alarm button is pressed.</p>	<ol style="list-style-type: none"> 1. Reconnect power lead. 2. If alarm continues, check System Controller and PM power lead for damage. 3. If PM or System Controller power lead is damaged, change PM patient cable or System Controller.

Table 6 Battery Fuel Gauge Summary

8.3.6 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 section 8.3.7).

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.

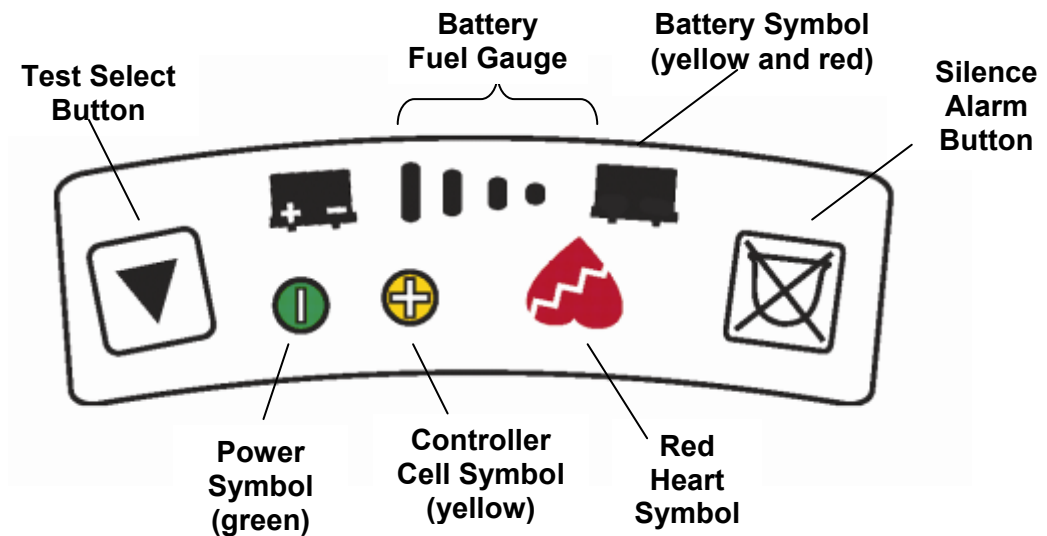




Figure 11 Alarm Symbols on System Controller Keypad

There are two main categories of alarms: hazard alarms and advisory alarms. Each category has characteristic visual and/or 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 17** 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
<p>Continuous audio tone & red heart symbol.</p> 	<p>LOW FLOW (on Display Module) LOW FLOW, PUMP OFF, &/or Pump Disconnected (on System Monitor)</p>	<p>Hazard</p>	<p>Pump flow is < 2.5 lpm, pump has stopped, percutaneous lead is disconnected, or pump is not operating correctly.</p>	<ol style="list-style-type: none"> 1. Check connection between System Controller and LVAD. 2. Check connection between System Controller and power source (batteries, PM, or EPP). 3. If alarm continues, seek additional help immediately. <p>See warning below table*</p>
<p>Continuous audio tone & no warning light or green power symbol.</p>	<p>None</p>	<p>Hazard</p>	<p>System Controller is not receiving power (no power present other than alarm battery module).</p>	<ol style="list-style-type: none"> 1. Check connection between System Controller and power source (batteries, PM, or EPP). 2. Change power source (sections 9.3.1, 9.3.2, and 10.3.2). 3. Change System Controller. <p>See warning below table*</p>
<p>Continuous audio tone & red battery symbol.</p> 	<p>LOW VOLTAGE</p>	<p>Hazard</p>	<p><5 minutes of battery power remains, voltage is too low, or System Controller is receiving inadequate power from PM.</p>	<p>Immediately replace batteries or change to alternate power source (sections 9.3.1, 9.3.2, and 10.3.2). LVAD will automatically go into power saver mode (8,000 rpm).</p> <p>WARNING: Do not remove both batteries simultaneously or pump will stop.</p>

Continued on following page

Table 7 Summary of HeartMate II LVAS Alarm Conditions

- * **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 sections 12.0 and 13.0 for information on the Display Module and System Monitor, respectively.

Table 7 (continued)

<p>1 beep every 4 seconds & yellow battery symbol.</p> 	<p>Low Voltage Advisory</p>	<p>Advisory</p>	<p><15 minutes of battery power remains, voltage is too low, or System Controller is receiving inadequate power from PM.</p>	<p>Replace batteries or change to alternate power source (sections 9.3.1, 9.3.2, and 10.3.2).</p> <p>WARNING: Do not remove both batteries simultaneously or pump will stop.</p>
<p>Broken audio tone (repeating cycle of 1 beep per second for 2 seconds, followed by 2 seconds of silence), but no warning light.</p>	<p>Replace System Controller (on System Monitor)</p> <p>Replace System Driver (on Display Module)</p>	<p>Advisory</p>	<p>System Controller is operating in back up mode.</p>	<p>Replace System Controller.</p>
<p>Controller cell</p>  <p>Yellow symbol accompanied by 1 beep every 4 seconds</p>	<p>SC Cell Module Low (on System Monitor)</p> <p>Driver Cell Low (on Display Module)</p>	<p>Advisory</p>	<p>System Controller's battery module is low on power</p>	<p>Replace System Controller battery module.</p>
<p>Rapidly flashing green power symbol</p>  <p>and</p> <p>Four flashing green battery fuel gauge lights flash once per second.</p>  <p>Accompanied by 1 beep every second.</p>	<p>Power Cable Disconnected</p>	<p>Advisory</p>	<p>Power lead is disconnected or damaged.</p>	<ol style="list-style-type: none"> 1. Reconnect power lead. 2. If alarm continues, check System Controller and PM power lead for damage. 3. If PM or System Controller power lead is damaged, change PM patient cable or System Controller.

Continued on following page

* **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 sections 12.0 and 13.0 for information on the Display Module and System Monitor, respectively.

Continued from previous page

<p>Audio tone of 1 beep every 4 seconds & no warning light when on batteries or PM with display module.</p> <p>No audio tone or warning light when on PM with System Monitor.</p>	<p>WARNING: Low Speed Operation</p>	<p>Advisory</p>	<p>Pump is operating below low speed limit.</p>	<p>Connect System Controller to System Monitor (audio alarm will stop) and increase fixed speed setting or reduce low speed limit (section 13.2.1).</p> <p>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.</p>
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* **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 sections 12.0 and 13.0 for information on the Display Module and System Monitor, respectively.

Low Flow or Inoperative LVAD

The System Controller continuously monitors the blood flow through the pump. If the calculated flow drops below 2.5 lpm, the System Controller activates the red heart symbol and sounds a continuous audio alarm. Assess the patient to identify and treat the cause(s) of low flow (e.g., right heart failure, bleeding, hypovolemia, arrhythmia, hypertension, or obstruction of the inflow conduit of outflow graft).

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 PM, 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 any warning light and the green power symbol will be absent.

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 two seconds to restart the pump).

WARNING!

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

Auscultate over the LVAD pocket to verify the pump is running

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 five 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, gradually ramping down to 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 four 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 PM patient cable or if one of the power leads is damaged, 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; or, if a power lead is damaged, replace the PM patient cable or System Controller to resolve the alarm.

System Controller Battery Module Low

The System Controller battery module provides back up power to activate a continuous audible alarm in the event both System Controller power leads become disconnected from all power and LVAD pumping stops. When the battery module is low, the yellow symbol will illuminate accompanied by one beep every four seconds. The alarm will stop once the battery module has been replaced. **The System Controller battery module only provides power to the System Controller's audible alarm tones. It does NOT provide back up power to the pump.**

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



NOTE:

If both power leads are disconnected from the batteries or PM 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 during battery or power source exchanges and if the PM patient cable is disconnected from the rear panel of the PM while the System Controller is connected.



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.

If the System Controller is connected to batteries or the PM with the Display Module, the System Controller will emit an audio beep once every four 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 repeating cycle of one beep per second for two seconds, followed by two 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.

8.3.7 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 the test select button  on the System Controller for three seconds. After three seconds, the Red Heart , Red and Yellow Battery  Yellow Controller Cell Symbol , and Fuel Gauge lights  will come on, along with CONTINUOUS AUDIO TONE.
2. Look closely at the System Controller display and make sure that all of the lights are on and the alarm is making a CONTINUOUS AUDIO TONE. *If there is a problem with the audio alarm, it will*



NOTE:

Due to slight fluctuations pressing the Test Select Button will have no effect when an alarm is active. A self test can be performed only when there are no active alarms.

beep once every two seconds instead of a continuous or steady tone.


3. Release the test select button. *All the lights should remain on and the alarm should sound for an additional five seconds. If any time you press the test select button you hear a rapid beep without any light, it means there is a problem with the System Controller. You must replace it.*
4. If all the alarms and lights come on as described above and then turn off after five seconds after letting go of the test select button, the System Controller has passed the self test.
5. Upon finishing the self test the pump will be operating in the same mode as it was prior to starting the test. If the lights or audible alarms fail, replace the System Controller.
6. If there is a repeating cycle of one beep per second for two seconds, followed by two seconds of silence, the System Controller is running on the back-up system and the self test cannot be performed. Follow the steps in section 8.3.9 to correct this problem.




NOTE:

The System Controller self-test cannot be initiated during a hazard alarm condition.

8.3.8 System Controller Alarm Battery Module Replacement

A small battery module provides limited power to the System Controller audible alarms (not the pump). When the System Controller alarm battery module is low, the yellow battery module symbol  (on top of the System Controller) illuminates, accompanied by an alternating two-tone alarm, and a System Controller Battery Module Low message appears on the System Monitor or Display Module. When this occurs, the user needs to change the battery module.

1. Examine the new, replacement battery module to determine if there is a white tape around the side of the battery module and an orange O-ring around the bottom. If the white tape or orange O-ring is damaged or missing, do not use the battery module; obtain a new one.
2. Unscrew (counter clockwise) the old battery module from the side of the System Controller. Discard the old battery module.
3. Insert the new battery module as shown in **Figure 12**. Tighten it until the orange O-ring can no longer be seen. You can use a flat object (such as a coin) to tighten the battery module. However, do not over tighten it.
4. Once the battery module is properly inserted, the yellow battery module symbol  will turn off.



NOTE:

The System Controller battery module only powers the System Controller. It does NOT power the pump and will not provide back-up power to the pump in the event of a power failure.



NOTE:

If it is difficult to unscrew the old battery module, a flat object (such as a coin) can be placed in the slot for leverage.



Figure 12 Changing System Controller Battery Module

8.3.9 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. New settings will be displayed on the monitor, verifying that the changes have been saved to the backup System Controller. See section 8.3.9 for explanations on programming controller settings.



Figure 13 System Controller Connection to LVAD Percutaneous Lead

1. Place the replacement System Controller within easy reach, along with batteries/battery clips or PM patient cable (if using PM power).
2. Have the patient sit or lie down.
3. Rotate the perc lock on the replacement controller in the direction of the “unlocked” symbol until the perc lock clicks into the fully unlocked position (**Figure 14**).
4. Repeat Step 3 for the original Controller until the perc lock clicks into the fully-unlocked position. Keep turning until the perc lock clicks into the unlocked position and the metal release tab is exposed (**Figure 15**).

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 release tab to disconnect percutaneous lead.

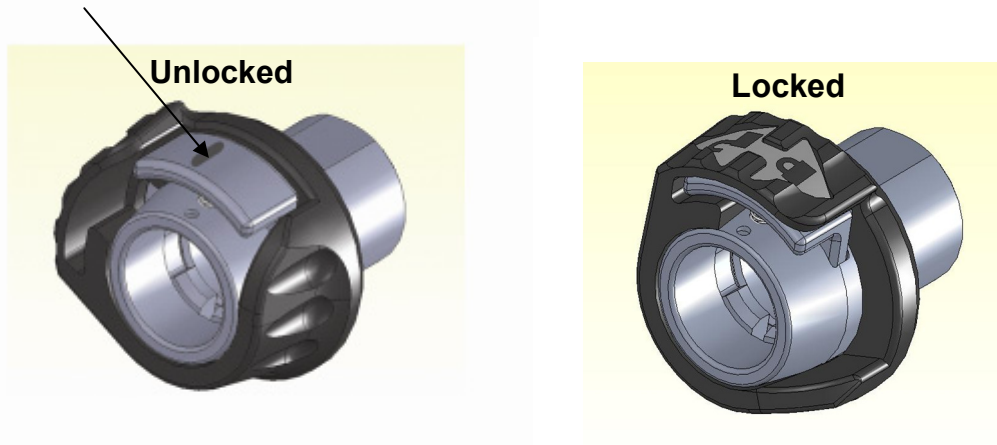


Figure 14 Perc Lock – Unlocked (left) and Locked (right) Positions

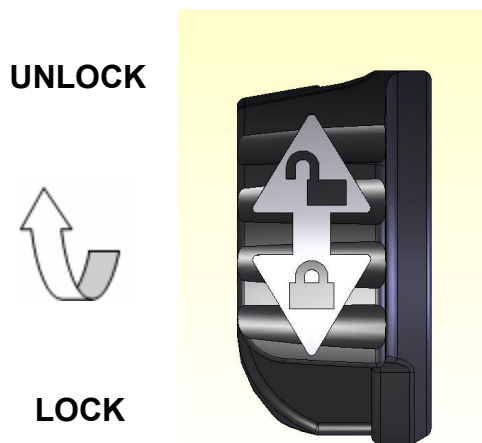







Figure 15 Unlocking the Perc Lock

1. Attach the power leads on the new, replacement Controller to the battery clips or PM patient cable (depending on the power source being used).
2. If using battery power, place charged batteries into the battery clips AFTER attaching power leads.
3. Press the Silence Alarm Button  on

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

the new replacement Controller to silence its Red Heart Alarm  for two minutes.

4. Disconnect the percutaneous lead from the original Controller by pressing the metal release tab on the connector socket (**Figure 14**). *The pump will stop and an alarm will sound until power is removed from the original Controller.*
6. Line up the mark on the perc lead connector with the mark on the metal tab of the new Controller (the marks must align to make this connection).
7. Fully insert the connector into the socket of the new Controller (**Figure 13**). *The pump should restart/alarms should stop.*
8. Gently tug on the *metal end* of the lead to make sure that it is fully engaged into the socket. Do NOT pull on the lead.
9. If the pump restarts, skip to step 12.
OR
9. If the pump does not restart and a Red Heart Alarm  continues:
 - a. Firmly press the Silence Alarm  or Test Select Button  to restart the pump.
 - b. Check the power source. Make sure that power is going to the Controller.




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:

If the pump speed is set below 8,000 rpm, the pump will *not* automatically restart when power is restored. You will need to press either the Silence Alarm or Test Select Button to restart the pump if it is set below 8,000 rpm.

- c Make sure the perc lead is fully inserted into the socket. Gently tug on the metal end. Do NOT pull on the lead.
10. If the pump still does not start and the alarm continues, immediately call emergency services, then try to restart the pump using the System Controller backup system:
 - Press and hold both the Silence Alarm  and Test Select  Buttons at the same time. *The Red Heart  Alarm will stop and you will hear a repeating cycle of one beep per second for two seconds, followed by two seconds of silence to indicate that the System Controller is operating on the backup system.*
11. After the pump restarts, rotate the perc lock on the new, *replacement* Controller in the direction of the locked symbol (**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.*

 **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.

UNLOCK



LOCK





 **NOTE:**
A steady green power symbol light  means only that power going to the System Controller. It does not mean that the pump is running.

Figure 16 Locking the Perc Lock

12. If the perc lock does not rotate, make sure the connector is fully inserted into the System Controller socket. The perc lock

will not rotate unless the connector is fully inserted.

13. After it clicks into place, inspect the perc lock to make sure it is fully locked and covering the metal release tab.
14. Disconnect power from the old System Controller. It will stop alarming once power is disconnected.
15. Obtain another System Controller and pre-program it for this patient, for use as a back up.



NOTE:

The old System Controller will continue to alarm until it is disconnected from power. It is OK for the old System Controller to alarm while you are connecting power to the new one. Getting power to the new controller should be your first priority. After the new Controller has power, you can disconnect the old one. Do not waste time disconnecting the old Controller until after the new one has power.



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.

POWER MODULE (PM)

9.0 Power Module (PM)

9.1 Overview

9.1.1 Function

The Power Module (PM) (**Figure 17**) performs these functions:

- Provides AC mains electrical power to the LVAS during tethered operation.
- Provides AC mains electrical power to the Display Module or System Monitor when either device is connected to the PM.
- Connects the Display Module/System Monitor to the System Controller for monitoring purposes.
- Echoes System Controller alarms.

See the *HeartMate Power Module IFU* (document # 103772) for detailed instructions on setting up and using the PM.

WARNING!

Refer servicing to authorized Thoratec trained service personnel only.

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

Keep the PM away from water. If the PM 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.

Power Module (PM)



Figure 17 Power Module (PM) Front Panel

9.1.2 Components

The following components are required for tethered operation with the PM:

- HeartMate Power Module (PM)
- PM patient cable
- PM power cord
- HeartMate II System Controller

9.2 Power Module (PM) Setup

Before using the Power Module (PM) to power the HeartMate II LVAS and optional Display Module or System Monitor, prepare the PM for use by connecting its internal battery and attaching the power cord and patient cable. See section 9.2.3 for set up procedures.

9.2.1 Connecting the Internal Backup Battery

PMs are shipped to customers with the internal battery disconnected. Upon receipt of the PM, the hospital's biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device.

Follow these steps to connect the internal backup battery:

1. Place the PM on a flat sturdy surface while the device is UNPLUGGED from AC mains electrical power and DISCONNECTED from the patient.
2. Inspect the PM for dents, chips, cracks, or other signs of damage. Do NOT use a PM that appears damaged. Contact Thoratec Corporation for a replacement, if needed.
3. Use a Phillips screwdriver to remove the two ¼-turn screws **Figure 18**. The screws will remain in the screw holes once loosened.

WARNING!

The PM contains an internal battery that provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS in the event of AC mains interruption/failure. The PM is shipped with its internal battery disconnected. The battery must be connected prior to initial use. If the internal battery is not connected, the backup power source will not work. Make sure the internal battery is connected prior to initial use and after any time the PM is shipped for service or maintenance.



Figure 18 Removing Rear Panel of PM to Connect Internal Backup Battery
a) Rear Panel (note screws); b) Unscrewing Rear Panel

4. Open the battery compartment cover on the rear of the PM.
5. Unscrew and remove the metal bracket that is holding the internal battery in place (**Figure 19**).



Figure 19 Unscrewing and Removing Metal Bracket


6. Remove the internal backup battery from its battery compartment.
7. Place the black battery connector over the metal contact end of the internal backup battery (**Figure 20**). The contacts should “snap” into place. Gently pull on the connection to make sure it is secure. The PM will begin to alarm (audio and visual) indicating the unit is disconnected from input power. This alarm can be silenced by pressing the Alarm Silence button  on the user panel. The alarm will clear once power is going to the PM.



Figure 20 Attaching Black Battery Connectors

8. Return the internal backup battery to its compartment, as shown in **Figure 21**.



Figure 21 Attaching Contacts to the Internal Backup Battery and Returning the Battery to Its Compartment

9. Use the Phillips screwdriver to reattach the metal bracket. Make sure the connection is secure (**Figure 22**).



Figure 22 Attaching Metal Bracket

10. Replace the battery compartment cover (**Figure 23**).



Figure 23 Replacing Cover

11. Use the Phillips screwdriver to tighten the two $\frac{1}{4}$ -turn screws (**Figure 24**). Make sure the screws are tight and the cover is securely closed.



Figure 24 Closing the Rear Panel of the PM

12. Repeat Steps 1 – 11 any time the internal backup battery is disconnected or when the PM is transported or shipped for service/ maintenance, since the battery is disconnected for shipping.

9.2.2 Connecting the PM Power Cord and PM Patient Cable

Follow these steps for connecting the PM power cord and patient cable:

1. Place the PM on a flat, sturdy surface.
2. Obtain the grey AC power cord and place the female end of the connector into the PM's power entry module (**Figure 25a**)
3. Once the cord is inserted into the power entry module, lift the power cord retention clip into the locked position; insert the two ends of the clip into the holes, as shown in **Figure 25b**. Engaging the clip will ensure that the AC power cord does not fall

WARNING!

Connect the HeartMate Power Module (PM) only to properly-tested and grounded (3-prong) AC mains outlets that are dedicated to PM use. Do NOT use outlets that are controlled by a wall switch. Do NOT use an adapter plug for ungrounded wall outlets. Do NOT use portable, multiple outlet (power strip) adapters.

out accidentally (**Figure 25c**).

4. Plug the PM's grey power cord into a properly-test and grounded (3-prong) AC mains electrical outlet that is dedicated to PM use and that is not controlled by a wall switch.
5. After plugging the power cord into the AC mains electrical outlet, observe the front panel of the PM. The green "power on" light should come on (**Figure 26**). If the light does not come on after plugging the PM into a functioning AC mains outlet, the device may be defective. Do not use it. Contact Thoratec Corporation for a replacement, if needed.



NOTE:

If the patient will be traveling internationally, he or she will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Obtain a Thoratec power cord set, if needed.

Power Module (PM)



a)



b)



c)

Figures 25a, b, and c Connecting the AC Power Cord and the Retention Clip



Figure 26 "Power On" Light on Front Panel of PM

6. Obtain the PM patient cable (**Figure 27**) from product packing.



Figure 27 Patient Cable




7. Line up the red dots between the patient cable and the “” socket located on the side of the PM and then insert the patient cable into the “” socket (**Figure 28**). The cable will click into place if fully engaged in the socket. The “click” is the sound of the locking feature engaging.



Figure 28 Patient Cable Socket. Note "Heart" Symbol

8. After inserting the connector snugly into the socket, check that the connection is tight. Tug *gently* on the strain relief portion of the connector (**Figure 29**). Do NOT pull on the cable!

 **NOTE:**
If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and, so that it will not cause tripping or falling.

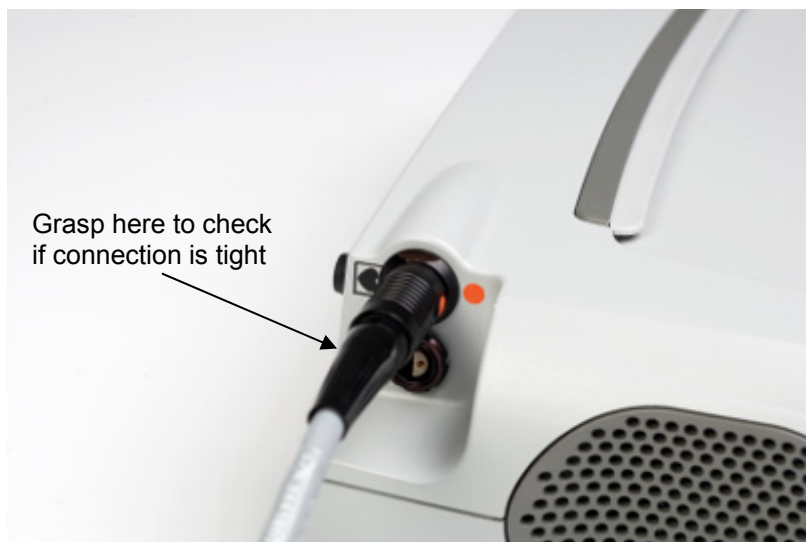



Figure 29 Where to Grasp Connector


After the PM's internal battery has been charged, and once the PM is plugged in and the PM patient cable is connected to the “” socket, the PM should be ready for use. However, before using the PM for the first time, be sure to perform a Power Module System Self Test (see section 9.2.3, *Monitoring PM Performance and Performing a PM System Self Test*).

9.2.3 Monitoring PM Performance and Performing a PM System Self Test

The computer inside the Power Module (PM) is continually monitoring PM performance. If the PM computer detects a problem or malfunction, the yellow wrench symbol on the front of the PM comes on. The yellow wrench will be accompanied by an audio tone (a steady or beeping tone, depending on the condition). See section 9.3.5, *Power Module (PM) Alarms* for guidelines on handling PM alarms.

Performing a PM System Self Test

Perform a PM System Self Test before using the PM for the first time and at least once daily to ensure that the PM is working properly:

- 1 Press and hold the PM's Alarm Silence Button  for five seconds.
- 2 Listen for the intermittent audio tone (3 beeps) and watch the front of the PM to see if all the lights come on in sequence (i.e., one-at-a-time; *not* all at once).
- 3 If any of the following occurs, there may be a problem with the PM:
 - No sound
 - Anything other than a continuous audio tone (such as beeping or broken tone)
 - All the lights come on at once
 - All the lights remain off
 - One of the lights does not come on

WARNING!

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

Keep the PM away from water or moisture. If the PM has contact with water, shower spray, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or the PM may fail to operate properly.

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

CAUTION!

Do NOT connect both the AC and DC input cables to the Power Module (PM) at the same time.

- 4 If any of the conditions listed above occur, call Thoratec's Technical Service Department. Otherwise, the PM has passed the self test and is ready for use.

See section 9.3.5, *Power Module (PM) Alarms*, for guidelines on responding to PM alarms.

9.3 Description of Features

Using the PM to power the system is called “tethered” operation, since the patient is “tethered” (connected) to electrical power by the PM.

The following components are required for tethered operation with the PM:

- HeartMate Power Module (PM)
- PM power cord
- PM patient cable
- HeartMate II System Controller

The Display Module and System Monitor (used to monitor and/or control system operation) are optional components for tethered operation (see sections 9.3.6 and 9.3.7). If you will be using the Display Module or System Monitor with the PM, the Display Module/System Monitor data cable is also required. **Figure 30** shows how the HeartMate II LVAS is configured during tethered operation.

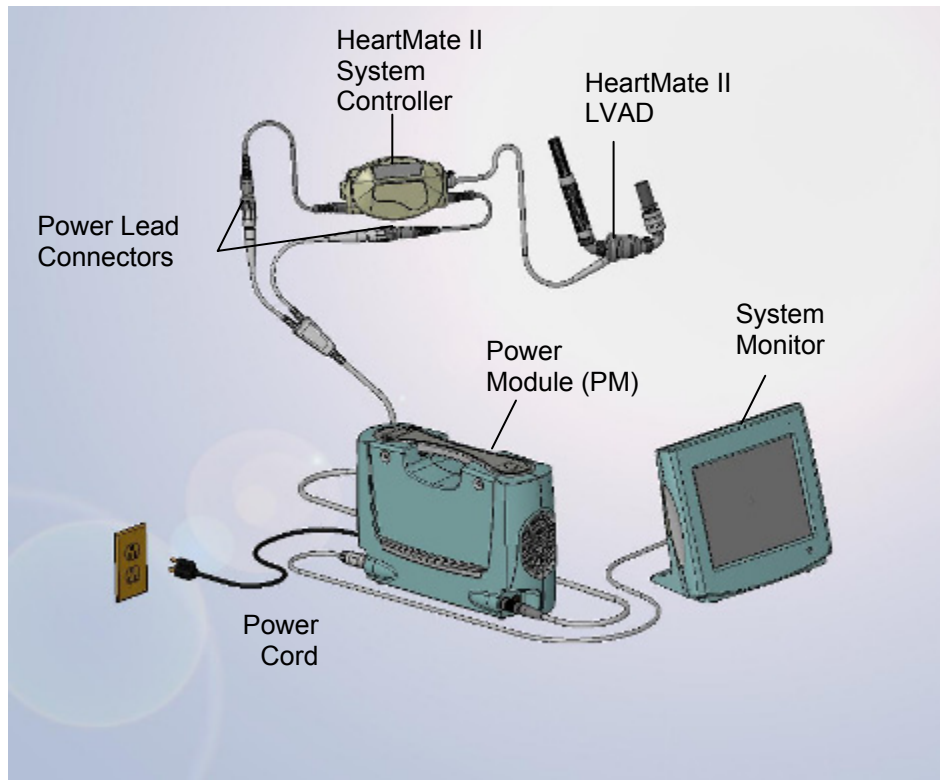






Figure 30 HeartMate II LVAS Connected to PM During Tethered Operation

9.3.1 Switching from PM-Power to Batteries

Changing from PM-powered to battery-powered operation (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from PM to battery power:

1. Place two battery clips, two charged batteries (as indicated by the green light on the UBC), and the white and black patient cable power lead connectors within easy reach.
2. Place the 1st charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.
3. Repeat step 2 for the 2nd battery/battery clip.

4. Unscrew the **black** System Controller/patient cable connectors. The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.
5. Put aside the patient cable connector; then connect the battery clip connector to the **black** System Controller connector. *Wait until the flashing symbol(s) and the audio alarm stop before continuing with step 6.*
6. Unscrew the **white** System Controller/patient cable connectors. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.*
7. Put aside the patient cable connector; then connect the battery clip connector to the **white** System Controller connector. *Wait until the flashing symbol(s) and the alarm stop before continuing with step 8.*
8. Place the batteries and battery clips into the holsters or carrying case.
9. Keep the patient cable connected to or near the PM until next use.
10. Place at least two additional charged batteries in the travel case.

A *Power Change Checklist* is included in **Appendix III** of this manual. All PM users (including nurses, patients, and patients' caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.

WARNING!

At least one System Controller power lead must be connected to a power source (PM, batteries or EPP) at all times.

Disconnected both power leads at the same time will cause the pump to stop.

If power to the System Controller is interrupted, and the pump speed is below 8,000 rpm, firmly press the Test Select and Alarm Reset buttons on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.





NOTE:

If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and so that it will not cause tripping or falling.

9.3.2 Switching from Batteries to PM Power

Changing from PM-powered to battery-powered to operation (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from batteries to PM power:

1. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.
2. Perform a Power Module System Test (see section 9.2.3, *Monitoring PM Performance and Performing a PM System Self Test*).
3. If the PM fails the test, contact Thoratec Corporation; otherwise, continue with Step 4.
4. Line up the red dots between the patient cable and the “” socket located on the side of the PM and then insert the patient cable into the “” socket (**Figure 31**). The cable will click into place if fully engaged in the socket. The “click” is the sound of the locking feature engaging.

WARNING!

At least once System Controller power lead must be connected to a power source (PM, batteries, or EPP) at all times.

Disconnecting both power leads at the same time will cause the pump to stop.

If power to the System Controller is interrupted, firmly press the Test Select or Alarm Reset button to restart the pump.

CAUTION!

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

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



Figure 31 Lining Up Red Dots and Inserting Cable into Socket

5. After inserting the connector snugly into the socket, check that the connection is tight. Tug *gently* on the strain relief portion of the connector (**Figure 32**). Do NOT pull on the cable!

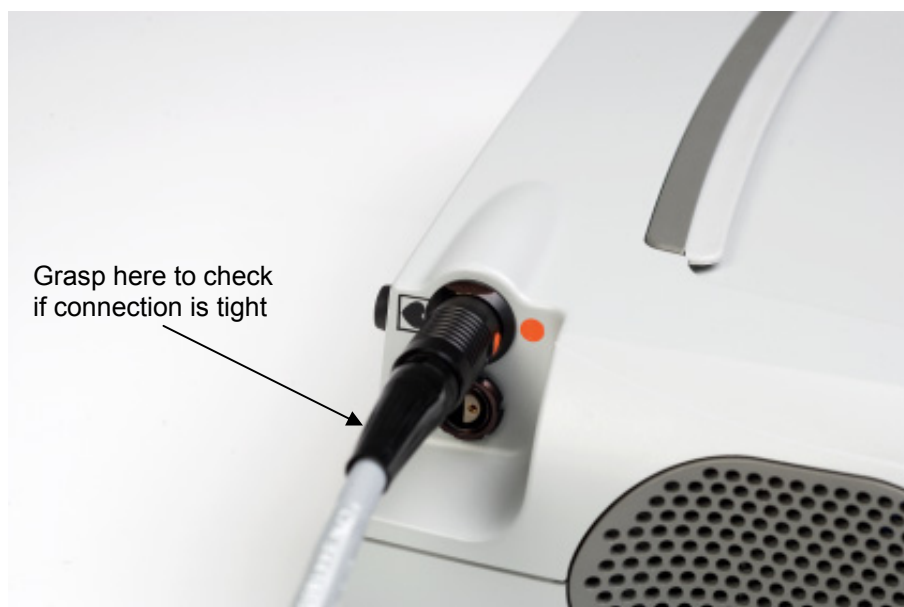






Figure 32 Where to Grasp Connector

6. Place the black and white PM-System Controller power lead connectors within each reach.
7. Remove the battery clips and attached batteries from the patient's holsters or carrying case.
8. Before switching from battery power, first check the charge status of each battery: Press the battery fuel gauge on each of the batteries; determine which battery has the least power (see the *HeartMate 12 NiMH Battery IFU* or the *HeartMate 14 Volt Li-Ion IFU*).
9. If the lights differ, disconnect the connector from the battery with the least power first (otherwise, disconnect the **white** connector first).
10. Unscrew the **white** connector from its battery clip. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.*
11. Put aside the battery clip and attached battery.
12. Connect the **white** PM power lead connector to the **white** System Controller connector (always connect white-to-white). ***Wait until the symbol(s) stops flashing and the audio alarm stop before continuing with Step 12.***
13. Unscrew the **black** connector from its battery clip. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.*
14. Put aside the battery clip and attached battery.
15. Connect the **black** PM power lead connector to the **black** System Controller connector (always connect black-to-black). ***Wait until the symbol(s) stops flashing and the audio alarm stop before continuing with Step 15.***
16. Press the battery release button on one of the battery clips to release its battery.
17. Repeat Step 15 for the 2nd battery/battery clip.
18. Store the battery clips in a clean, dry location until next use.
19. Place the used batteries into the HeartMate UBC for charging (see *HeartMate Universal Battery Charger IFU*).

A *Power Change Checklist* is included in **Appendix III** of this manual. All PM users (including nurses, patients, and patients' caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.

9.3.3 Power Module (PM) Backup Power

The Power Module (PM) has an internal backup battery. When new, the internal battery provides approximately 30 minutes of backup power to the HM II LVAS in the event of AC mains power interruption or failure (e.g., the power cord plug is removed from the AC mains electrical outlet or power fails during tethered operation). Over time, the internal battery may provide shorter periods of backup power.

The PM's internal backup battery remains charged as long as the PM remains connected to AC mains power or automobile DC power. If the PM is disconnected from external power, the internal battery will operate the LVAS and the PM will alarm until the battery is depleted. The internal backup battery automatically engages if PM input power is lost. It will automatically disengage once power is restored. See **Table 8** for description of charge status symbols for the PM's internal backup battery.

The PM's internal backup battery is rechargeable. However, it has a limited lifespan. It will be replaced during annual PM service/maintenance service for the PM (see section 15.3).

During AC mains power failure, patients should transfer from PM to battery-powered operation (see section 9.3.1, *Switching from PM-Power to Batteries*). If connected, the Display Module/System Monitor will not operate during AC mains power failure. Ensure the PM's internal battery is charged

CAUTION!

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

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

prior to use, otherwise the patient will be without an adequate backup battery power source.

9.3.4 Determining the PM’s Internal Battery Charge Status

Indicator symbols on the front panel of the PM illuminate to indicate the charge status of the internal backup battery.




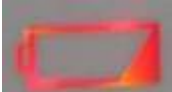
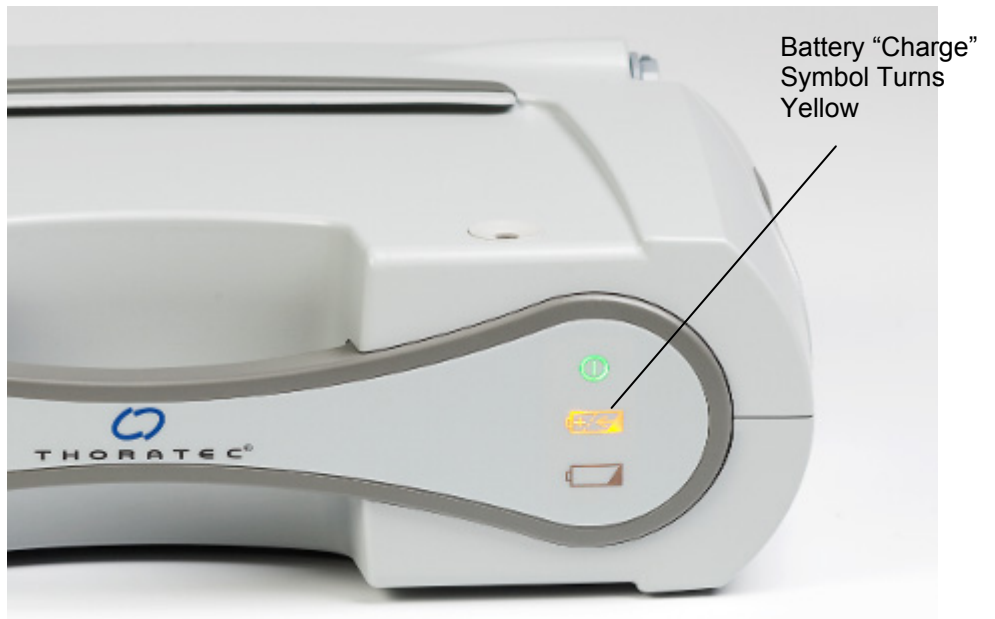
Indicator Symbol/Color	Meaning	See Figure #
A green charge lamp 	The PM’s internal backup battery is charged and ready for use, if needed.	See Figure 33 below
A yellow charge lamp 	The PM’s internal backup battery is being recharged.	See Figure 34 below
Yellow Battery “Advisory” Symbol  accompanied by a beeping audio tone	Less than 15 minutes of backup battery power remains. Promptly switch to another power source (e.g., charged batteries).	See Figure 35 below
Red Battery “Hazard” Symbol  accompanied by a continuous audio tone	Less than 5 minutes of backup battery remains. IMMEDIATELY switch to another power source. Without power the pump will stop.	See Figure 36 below

Table 8 Charge Status Indicators for the PM’s Internal Backup Battery



**Figure 33 Green Charge Symbol
(Internal Backup Battery Ready for Use)**



**Figure 34 Yellow Charge Symbol
(Internal Backup Battery is Charging)**

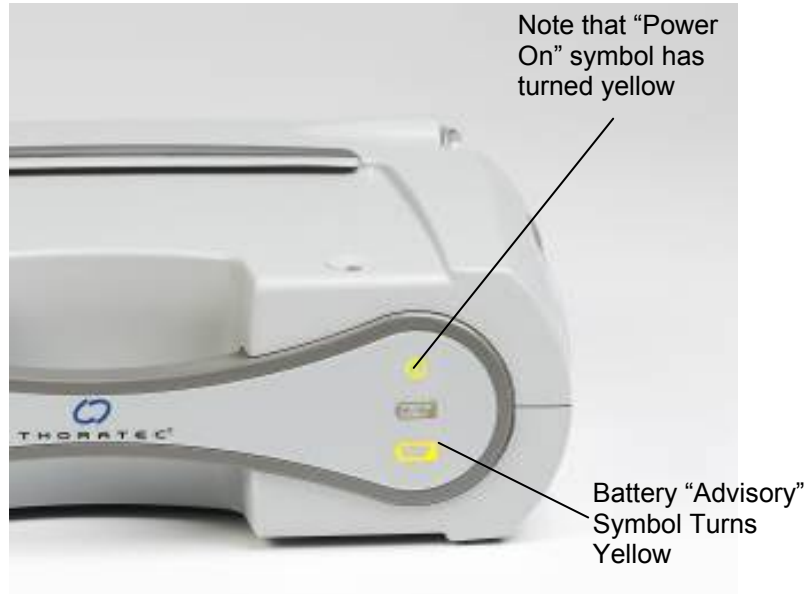


Figure 35 Yellow Battery "Advisory" Symbol (Less than 15 Minutes of Backup Power Remain)



Figure 36 Red Battery "Hazard" Symbol (Less than 5 Minutes of Backup Power Remain) Switch IMMEDIATELY to Another Power Source

The PM is shipped with its internal battery disconnected. **The internal battery must be connected prior to initial use or any time after the PM is shipped or transported for service or maintenance** (see section 9.2.1, *Connecting the Internal Backup Battery*). If the internal battery is not connected, it cannot provide emergency backup power to the LVAS in the event of AC mains power interruption/failure. If the internal battery is not connected, when the PM is plugged in, the device will alarm (continuous audio tone and the yellow wrench and red battery light illuminated).

9.3.5 Power Module (PM) Alarms

The Power Module's internal computer is continually monitoring PM performance. It will alert you if it detects a problem. There are four alarm conditions:

- AC Fail
- Advisory LO BATT (i.e., low battery)
- Hazard LO BATT (i.e., CRITICALLY low battery)
- PM MALFUNCTION

All PM alarm conditions are accompanied by a visual indicator (**Figure 37**) and audio tone. Different lights illuminate and/or different tones sound, depending on the alarm condition. See **Table 9** for a description of PM alarms and how to respond to them.



Figure 37 Visual Alarm Indicators on Front Panel of PM



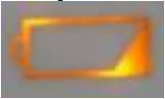





Alarm	Meaning	What You Should Do
<p>AC FAIL “Power On” indicator changes from green to yellow</p>  <p>accompanied by beeping audio tone.</p>	<p>AC mains power off or disconnected. When new, the internal backup battery will power the HM II LVAS for approximately 30 minutes. The PM’s internal backup battery will not be recharged during AC FAIL.</p>	<ol style="list-style-type: none"> 1 Press the PM’s Alarm Silence Button  to silence the alarm (it remains silenced “forever” or until cancelled by another alarm). 2 Promptly switch to another power source, either: a new set of charged batteries or Emergency Power Pack (EPP).** 3 Call VAD Coordinator or hospital contact.
<p>Advisory LO BATT (i.e., low battery) Yellow Internal Backup Battery Indicator</p>  <p>accompanied by beeping audio tone.</p>	<p>Less than 15 minutes of internal backup battery power remain.</p>	<ol style="list-style-type: none"> 1 Press the PM’s Alarm Silence Button  to silence the alarm for 8 hours. 2 Promptly switch to another power source (either a new set of charged batteries or EPP).** 3 Call VAD Coordinator or hospital contact.
<p>Hazard LO BATT (i.e., low battery) Red Internal Backup Battery Indicator</p>  <p>accompanied by continuous audio tone.</p>	<p>Less than 5 minutes of internal backup battery power remain.</p>	<ol style="list-style-type: none"> 1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).** 2 Call VAD Coordinator or hospital contact.
<p>Advisory Fault Yellow Wrench Indicator</p>  <p>accompanied by beeping audio tone.</p>	<p>Internal malfunction detected within the PM.</p>	<ol style="list-style-type: none"> 1 Switch to another power source (either a new set of charged batteries or EPP) at earliest convenience. 2 Call VAD Coordinator or hospital contact.
<p>Critical Fault Yellow Wrench Indicator</p>  <p>accompanied by continuous audio tone.</p>	<p>Internal malfunction detected within the PM.</p>	<ol style="list-style-type: none"> 1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).** 2 Call VAD Coordinator or hospital contact.

Table 9 Power Module (PM) Alarms

** If you remain connected to the PM using its internal backup battery for power, the internal backup battery indicator will turn yellow and then red as the internal battery is depleted to 15 minutes and then 5 minutes of remaining power. See Section 9.2.1, *Connecting the Internal Backup Battery*. When only 5 minutes of power remain, the PM’s audio tone becomes constant and you will no longer be able to silence the alarm. Switching to another power source is the only way to silence a Red Battery Hazard Alarm.

Silence Alarm Button

Pressing the Silence Alarm Button  silences an audio alarm (see **Table 9** or the list below for how long; silence periods vary by alarm type). If a new alarm condition arises during a silence period, a new audio alarm will sound. After the silence period ends, the audio alarm will resume, unless the alarm condition has been resolved. Pressing the Alarm Silence Button only silences the alarm; it does NOT fix the alarm condition.

- **Echo of System Controller Alarm** 5 Minutes
- **AC Fail** No time out (silence lasts “forever” or until cancelled by another alarm)
- **Yellow Battery** 8 Hours
- **Red Battery** Alarm Silence/Reset not possible if connected to LVAD
- **Battery Fault** 2 Minutes
- **Yellow Wrench** 8 Hours for non-critical faults.
Alarm Silence/Reset not possible for some alarms (see **Table 9**).

9.3.6 Using the PM with the Display Module

When connected to the PM, the Display Module (**Figure 38**) reports data received from the System Controller through the PM. It displays information about system performance on its display panel screen, including:

- Current pumping mode (i.e., fixed or power saver mode)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility index (PI)
- Estimated flow in liters per minute (lpm)
- Power in watts (W)

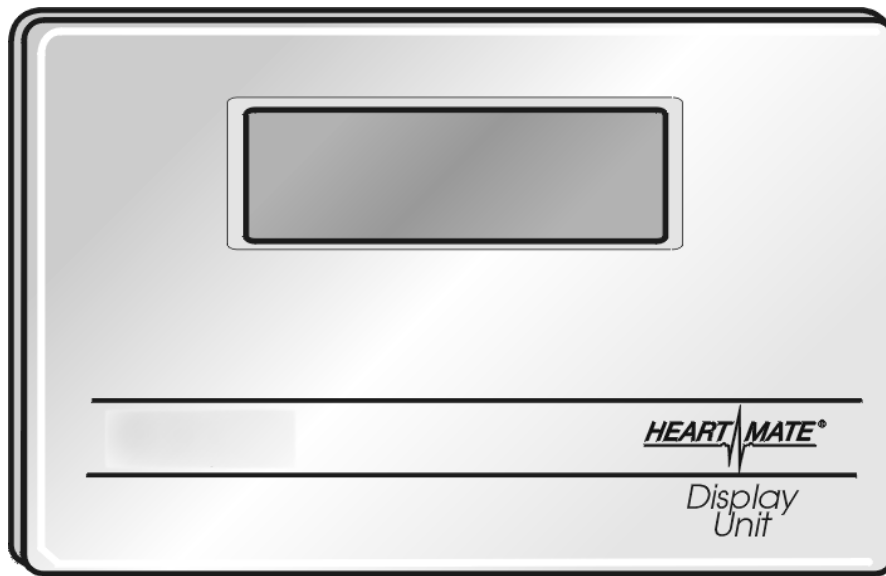


Figure 38 HeartMate Display Module

Setting up the Display Module for Use with the PM

Follow these steps for setting up the Display Module for use with the PM:

1. Ensure the patient cable is attached to the PM. See section 9.2.1, *Connecting the PM Power Cord and PM Patient Cable*.
2. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.

3. Obtain the Display Module cable adapter (**Figure 39**) from product packaging.



Figure 39 Display Module / System Monitor Adapter Cable

4. Insert the male end of the adapter into the female end of the data cable receptacle. Firmly press together the connectors to ensure a tight connection (**Figure 40**).



Figure 40 Display Module / System Monitor Adapter Cable Attached to Display Module/System Monitor

5. Tighten the two thumb screws on the adapter connector to secure the connection.
6. Align the grooves between the adapter connector and the “□” socket found on the side of the PM (**Figure 41**); insert the connector into the connector into the “□” socket.



Figure 41 Inserting Round Adapter Connector into PM Socket (close up)

7. Reference the Display Module screen. If the patient is connected to the PM and System Controller, the following should immediately appear once the cable is successfully connected (otherwise, the screen remains blank):
 - Current pumping mode (i.e., fixed or power saver mode)
 - Current pump speed, in revolutions per minute (rpm)
 - Pulsatility index (PI)
 - Estimated flow in liters per minute (lpm)
 - Power in Watts (W)





NOTE:

The PM (with its round receptacle for the Display Module/System Monitor interface) replaces many of the features of the Power Base Unit (PBU). You will need an adapter (described above) to connect the Display Module to the PM (see Steps 3 – 6). Contact Thoratec Corporation for an adapter, if needed.

8. If the patient is connected to the PM and the System Controller and the screen appear as described above, the Display Module is functioning properly and ready for use with the PM.

OR

8. If the patient is connected to the PM and the System Controller and the screen does not appear as described, check the following:
 - The patient cable is fully inserted into the “” socket on the side of the PM.
 - The Display Module adapter cable is fully inserted into the “” socket on the side of the PM.
 - The System Controller power leads are properly connected (white-to-white and black-to-black).
 - The male end of the Display Module adapter is not fully connected into the female end of the data cable receptacle of the Display Module.
9. If the screen still does not appear, contact Thoratec Corporation for assistance.



NOTE:

At any time, if an alarm condition arises, an alarm message will immediately replace performance data appearing on the Display Module screen.

9.3.7 Using PM with the System Monitor

When connected to the PM, the System Monitor (**Figure 42**) reports data from the System Controller through the PM. Like the Display Module, the System Monitor displays information about system performance, including current control mode (i.e., “fixed”), pump flow, pump speed, and overall operational status. In addition to displaying performance data, the System Monitor also enables clinicians to control system operation using touch-screen prompts/messages. Typically, the System Monitor is used in clinical settings. See section 13.0, *System Monitor*, for information on using the System Monitor.



Figure 42 System Monitor Mounted Atop the Power Module (PM)

The System Monitor has been offered in two different versions:

- Original System Monitor (no longer in production)
- Updated System Monitor (**Figure 42**)

In the following sections of this manual, references to the System Monitor and monitor screens are based on the updated System Monitor unless otherwise noted. For information regarding the original System Monitor, refer to **Appendix IV** or call Thoratec Corporation.

Setting Up the System Monitor for Use with the PM

1. Plug the “System Monitor” cable into the “□” socket located on the side of the PM.
2. Plug the other end of the cable into the System Monitor, if not already connected.
3. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.
4. Ensure the PM “Patient” cable is attached to the PM (see section 9.2.2, *Connecting the PM Power Cord and PM Patient Cable*).
5. Turn on the System Monitor by pressing the on/off switch at the rear of the System Monitor (**Figure 43**) to the on (“I”) position. A green light on the front of the System Monitor should come on once power is going to the device. Contact Thoratec Corporation if the System Monitor will not power on.

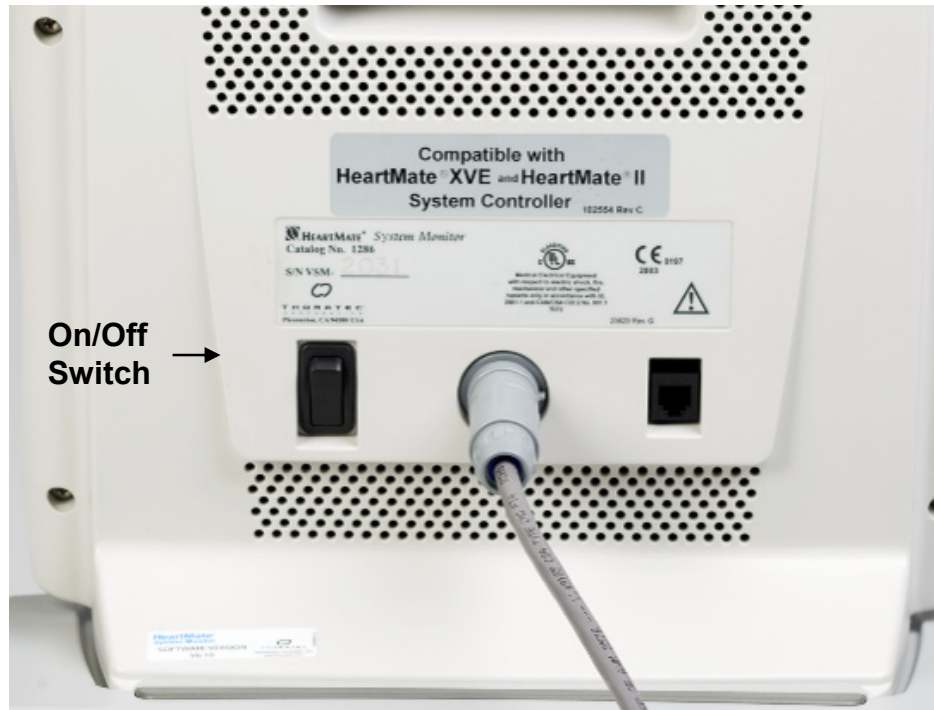


Figure 43 System Monitor On/Off Switch (Rear of System Monitor)


6. Observe the System Monitor screen. Once power is turned on, the HeartMate logo screen should appear (**Figure 44**).




Figure 44 HeartMate Logo Screen

7. If the HeartMate logo screen appears, the System Monitor is ready for use with the PM.

OR

7. If the System Monitor screen remains black, check the following:
 - The System Monitor cable is securely connected to the System Monitor and fully inserted into the “” socket located on the side of the PM.
 - The System Monitor power switch is “on.”
 - The PM is receiving adequate power from a functioning AC mains outlet (green “power on” light is illuminated).

OR

7. If “NOT RECEIVING DATA” is flashing on the System Monitor screen, the System Monitor cannot recognize or “see” the System Controller. If this occurs, check the following:
 - The “Patient” cable is securely inserted into the “” socket located on the side of the PM.
 - The “Display Module/System Monitor” cable is securely connected to the System Monitor and fully inserted into the

“□” socket located on the side of the PM.

- The System Controller power lead connectors are properly connected to the PM power lead connector (i.e., white-to-white and black-to-black).

8. If the System Monitor still does not work, call Thoratec’s Technical Service Department.

WARNING!

Do NOT disconnect the patient cable connection when trouble shooting for a “Not Receiving Data” message.

Disconnecting the patient cable will cause the pump to stop.

Mounting the System Monitor on the PM

Some versions of the System Monitor are designed to be mounted atop the PM (**Figure 45**). This “nesting” feature minimizes the space needed when a patient requires continuous monitoring during tethered operation.



Figure 45 System Monitor mounted on PM

Follow these steps to mount the System Monitor on top of the PM:

1. Tip the back edge of the System Monitor base into the receiving ledge of the PM (**Figure 46**).
2. Once the back edge of the System Monitor base is secure under the rubber lip of the ledge, press down firmly onto the top of the PM to engage the two front feet into the holding grommets (**Figures 47 and 48**).

CAUTION!

If the System Monitor is mounted on top of the Power Module, **do NOT attempt to lift or carry the two devices together by the System Monitor handle**. Doing so may damage the Power Module and/or System Monitor.



Figure 46 Sliding the System Monitor base Under Lip of PM Ledge



Figure 47 Pressing Down on front of System Monitor to insert Feet into Holding Grommets of the PM



Figure 48 Close up of System Monitor feet being inserted into PM holding grommets

Removing the System Monitor

- 1 Pull up on the System Monitor handle to disengage the System Monitor feet from the PM grommets.
- 2 Slide the System Monitor base forward and out from under the PM ledge.
- 3 Remove the System Monitor from the PM; place the System Monitor onto a flat sturdy surface.

BATTERIES & BATTERY CLIPS

10.0 Batteries & Battery Clips

10.1 Overview

HeartMate batteries are a routine power source for the HeartMate II LVAS. During battery-powered operation, the LVAS is powered by a pair of direct current (DC) batteries that are inserted into battery clips (**Figure 50**). The battery clips and attached batteries can be worn in holsters (**Figure 51**), one under each arm, across the body, in a bag, or in pouch worn around the waist.

Two types of HeartMate batteries can power the HeartMate II LVAS. Either one pair of:

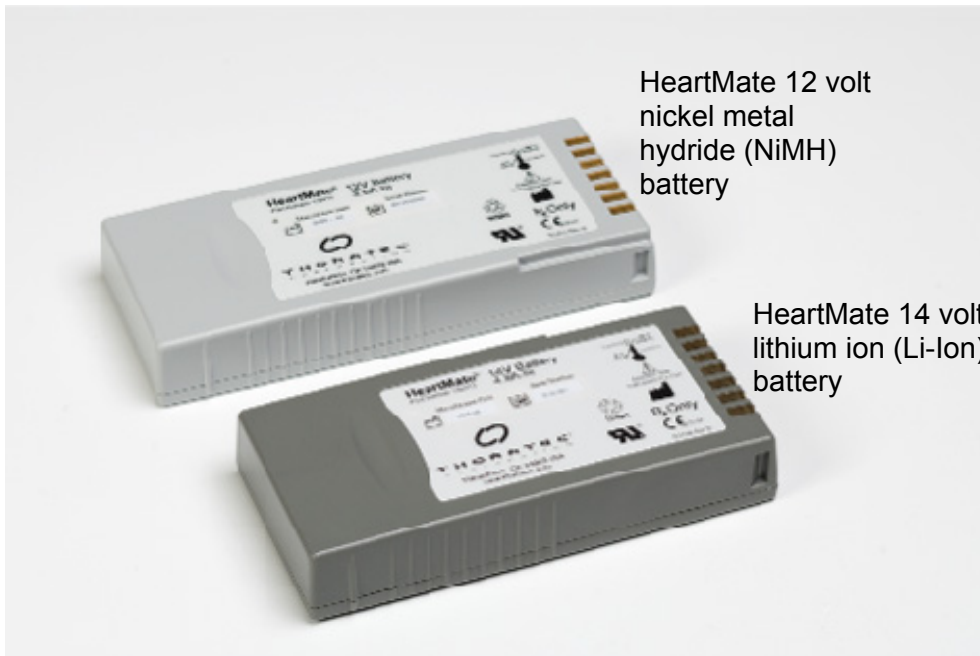
- HeartMate 12 volt nickel metal hydride (NiMH) batteries; or
- HeartMate 14 volt lithium ion (Li-Ion) batteries.

Both batteries work in the same manner. However, there are differences in color, size and weight (**Figure 49**). Differences are described in the table below. Also see section 10.3.2 for approximate run time for 12 volt NiMH and 14 volt Li-Ion batteries.

	Catalog Number for Set of 4	Part Number for Single Battery	Size/Weight	Color
HeartMate 12 Volt NiMH Batteries	2060	102474	L: 180mm (7.1") W: 76mm (3.0") H: 25mm (1.0") 0.65kg (1.44lb)	Light Grey*
HeartMate 14 Volt Li-Ion Batteries	2465	102515	L: 160mm (6.3") W: 76mm (3.0") H: 25mm (1.0") 0.50kg (1.1lb)	Dark Grey*

Table 10 Battery Characteristics

* Batteries are the same color as their corresponding clips.



HeartMate 12 volt
nickel metal
hydride (NiMH)
battery

HeartMate 14 volt
lithium ion (Li-Ion)
battery

Figure 49 Different HeartMate Batteries

HeartMate batteries only work in matching pairs with matching compatible clips (two 12 volt batteries using 12 volt clips or two 14 volt batteries use 14 volt clips). Since HeartMate 12 volt NiMH and 14 volt Li-Ion batteries and battery clips are NOT interchangeable, the patient should be given only one type of batteries and corresponding clips at the same time. See the *HeartMate 12 Volt NiMH Battery IFU* and *HeartMate 14 Volt Li-Ion Battery IFU* for detailed warnings, precautions, and instructions.

WARNING!

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.



Figure 50 Inserting a Battery into its Compatible Battery Clip

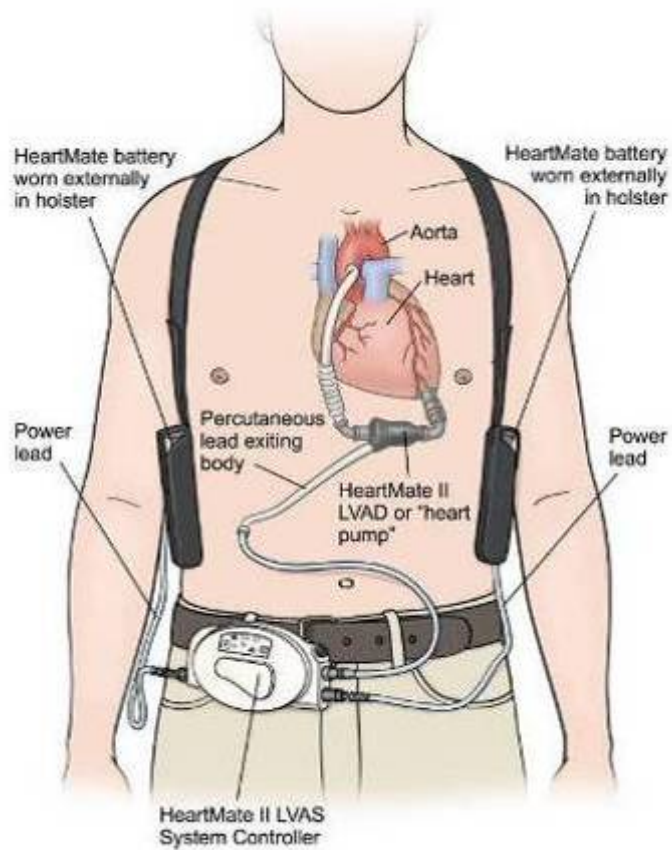


Figure 51 HeartMate Batteries Worn in Holsters

10.1.1 Function

Using batteries to power the system is called mobile operation, since the patient is not connected to electricity via the PM. With battery power, patients can enjoy many activities, such as shopping, gardening, running errands, or performing other activities outside or away from home.

During battery-powered operation, the System Controller shows overall power capacity (for both batteries) on the System Controller's battery fuel gauge. The System Controller's battery fuel gauge will tell you if the batteries are running low. If the current power source is low, the Controller prompts you switch to a different power source (a new pair of charged batteries or the PM). The status of an individual battery can be checked any time by pressing the battery fuel gauge on that battery (see section 10.3.2, *Checking a Battery's Charge Level*).

WARNING!

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.



10.1.2 Components

The only components required for operating the system with batteries are two charged batteries (either two 12 volt NiMH batteries or two 14 volt Li-Ion batteries) and two compatible battery clips. In addition, the System Controller must be connected to the implanted LVAD via the percutaneous lead.

10.2 Setup for Battery-Powered Operation

The connections between the System Controller power leads and the two battery clips are illustrated in **Figure 52**. When all connections are made and batteries are inserted into their compatible clips, the system is operational.

Follow these steps to prepare for battery-powered operation:

1. Place two battery clips, two charged batteries (as indicated by the green light on the UBC), and the white and black patient cable power lead connectors within easy reach. If obtaining batteries from the UBC, make sure the light near the charging pocket for each battery is green (i.e., battery is ready for use) (see section 10.3.2, *Checking Battery Charge Level*).
2. Press and hold the battery symbol on each battery to confirm they are charged and ready for use (see section 10.3.2, *Checking Battery Charge Level*).
3. Place the 1st charged battery into a compatible battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.
4. Repeat step 2 – 3 for the 2nd battery/battery clip.
5. Unscrew the **black** System Controller/patient cable connectors. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four battery fuel gauge lights  will flash.*
6. Put aside the patient cable connector; then connect the battery clip connector to the **black** System Controller connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. **Wait until the flashing symbol(s) and audio alarm stop before continuing with step 7.***
7. Unscrew the **white** System Controller/patient cable connector. *The power disconnect alarm*

CAUTION!



Do not use batteries below 32°F (0°C) or above 104°F (40°C) or they may fail suddenly.

To prevent deterioration or damage to the batteries:

- Do NOT drop or subject to strong physical shock. Dropped batteries should be replaced.
- Do NOT leave or store batteries in hot or cold areas (car trunks, etc.) or battery life will be shortened.
- Do NOT directly connect any of the battery contacts.

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.

will come on: A alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.

8. Put aside the patient cable connector; then connect the battery clip connector to the **white** System Controller connector. *The alarm will stop and both the green power symbol and the battery fuel gauge lights will stop flashing. **Wait until the flashing symbol(s) and audio alarm stop before continuing with step 9.***
9. Place the batteries and the battery clips into the patient's holster vest, modular belt, or consolidated bag. At a convenient time, recharge depleted batteries in the UBC (see section 11.3.2, *Charging Batteries*).
10. Keep the patient cable connected to or near the PM until next use. If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and so that it will not cause tripping or falling.
11. Place at least two additional charged batteries into the patient's travel case for back up.

A *Power Change Checklist* is included in **Appendix III** of this manual. All PM users (including nurses, patients, and patients' caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.

WARNING!

At least one System Controller power lead must be connected to a power source (PM, batteries, or EPP) at all times.

Disconnecting both power leads at the same time will cause the pump to stop.

If power to the System Controller is interrupted, firmly press the Test Select or Alarm Reset button to restart the pump

CAUTION!

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

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

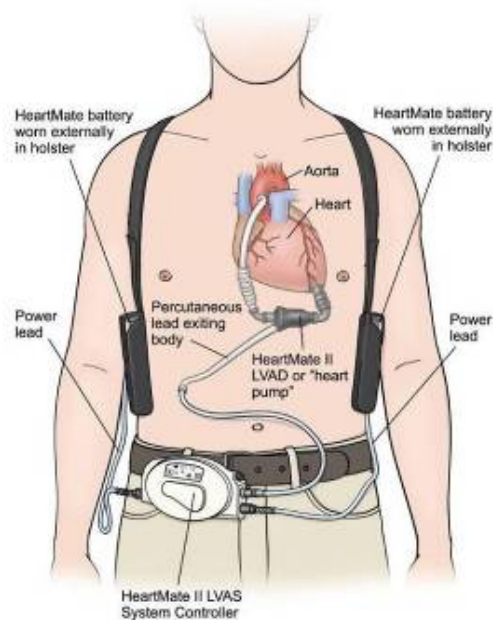


Figure 52 Battery Powered Operation

10.3 Description of Features

10.3.1 Batteries

The HeartMate II LVAS is optimized for operation with two batteries, but it is possible to run the system on only one for a very short period (60 seconds or less). For example, when switching from batteries to the PM or vice versa, operation will continue on a single battery while connections are made.

You must fully-charge each HeartMate battery before using it for the first time. It takes four hours or less to charge a new battery, depending on the initial charge status of the batteries being charged. Batteries are charged in the HeartMate Universal Battery Charger (UBC), which can charge up to four batteries simultaneously. The UBC is described in more detail in section 11.0.

CAUTION!

As batteries get older, they will support the system for shorter periods of time. If batteries do not give at least four hours of support, take them out of service.

If a battery is stored and used according to the conditions outlined in its *Instructions for Use*, it should be usable for approximately 360 cycles or 36 months from the date of manufacturer, whichever comes first. After this time, battery performance cannot be guaranteed. Call Thoratec for a replacement when either of these milestones is reached for a HeartMate battery.

The white battery label on each battery contains several safety symbols and the battery's expiration date. The battery may need to be replaced earlier than the expiration date, depending on usage. Batteries should not be used after their expiration date. Dispose of expired batteries according to local, state, and federal regulations.

WARNING!

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.

10.3.2 Battery-Powered Operation

Estimating Battery Time

One pair of new HeartMate 12 volt NiMH batteries provides at least six hours of support at the “higher end” of nominal operating conditions (pump speed 12,000 rpm, flow 6.0 lpm, power 10 watts).

One pair of new HeartMate 14 volt Li-Ion batteries provide six to ten hours of support under nominal operating conditions (pump speed 12,000 rpm, flow 6.0 lpm, power 10 watts).

Both 12 and 14 volt batteries will last for less time if the patient is active or emotionally stressed. As batteries get older, they will power the system for shorter periods of time. If a pair of HeartMate batteries does not give at least four hours of support, take both out of service. The on-battery battery fuel gauge on the System Controller will provide an estimate of battery power (see section 8.3.5, *Battery Charge Level Fuel Gauge Display*).

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 four seconds. ***This indicates that the batteries should be changed.***

A red battery hazard symbol with a continuous audio alarm will sound when approximately five minutes of operation remain. The system will revert to power saver mode, gradually ramping down to

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 PM is connected, or until no further power remains.

The red battery hazard alarm requires an immediate response.


Immediately switch to a reliable alternate power source. The pump will revert to the previous mode and speed when the red battery alarm clears.

Checking a Battery's Charge Level

Once properly charged (see section 11.3.2, *Charging Batteries*), a new HeartMate battery should be ready for use. But, before using any battery, first make sure that it has finished charging and check its status with the battery fuel gauge.

The battery's fuel gauge (**Figure 53**; **Table 11**) shows a battery's charge status using five green lights. Each light represents approximately 20% of available power. When the battery is charged and ready for use, all five lights turn on. Fewer lights illuminate as power is depleted. When battery power drops below 10%, only one green light comes on and it will be blinking.

Follow these instructions for checking a battery's charge status:

- 1 Go to the Universal Battery Charger (UBC); locate a battery inside one of the charging pockets.
- 2 Look at the three lights next to the charging pocket for this battery. A green light means the battery is charged and ready for use.
- 3 If the pocket light is green, remove the battery from the charging pocket.
- 4 Find the battery symbol  on the battery's fuel gauge.
- 5 Press and hold the battery symbol for five seconds.
- 6 If all five of the green fuel gauge lights come on, the battery is between 80 - 100% charged (**Table 11**).

OR



NOTE: A green light next to the pocket is the only assurance the battery is 100% charged. If the yellow light is on, the battery is still charging. If the red light is on, there is a problem with the battery – do not use it. See Section 3.0, “Charging Batteries,” in the *HeartMate Universal Battery Charger IFU* for full details.

- 6 If four or fewer lights come on, the battery is not yet ready for use. Return it to the pocket for more charging. If the fuel gauge continues to show four or fewer lights after additional charging, the battery may be defective. Do NOT use it. Contact Thoratec Corporation for a replacement, if needed.



Figure 53 On-Battery Fuel Gauge; Pressing Battery Symbol to Activate Lights

Understanding Battery Fuel Gauge Displays

The battery fuel gauge on a HeartMate battery uses five green lights to show available battery power. Each light represents approximately 20% of available power. All five lights come on when the battery is between 80 – 100% charged. Fewer lights come on as power is depleted. When battery power drops below 10%, one blinking light comes on.








Number for Lights Illuminated	Meaning
 1 Light (blinking)	Approximately 10% or less of power remains. Do NOT use if battery has one blinking light.
 1 Light (steady)	Approximately 10–20% of power remains
 2 Lights	Approximately 20–40% of power remains
 3 Lights	Approximately 40–60% of power remains
 4 Lights	Approximately 60–80% of power remains
 5 Lights	Approximately 80–100% of power remains

Table 11 On-Battery Battery Fuel Gauge Lights

A battery’s fuel gauge may show five lights illuminated, while the UBC still indicates a “charging yellow” light. This is normal, because five lights on the battery does not indicated “fully-charged,” but rather, 80 – 100% charged. See **Table 11** above.



If all of the lights come on, except for one in the middle of the sequence, it may be that the light emitting diode (LED) for this light has broken or burned out. If this happens, call Thoratec Corporation.

 **NOTE:**
 Depending on how long a battery has been in storage, its fuel gauge may not work until after the battery undergoes its first charge (see *Checking a Battery’s Charge Status*, above).

Exchanging Depleted Batteries with Charged Batteries

Replacing used, depleted batteries with a charged pair is a routine procedure. With experience the steps become familiar.

Follow these steps for exchanging HeartMate batteries:

- 1 Obtain two charged HeartMate batteries and place them within easy reach. If getting batteries from the UBC, make sure the light near the charging pocket for each battery is green (i.e., battery ready for use) (see section 10.3.2, *Checking Battery's Charge Level*).
- 2 Press and hold the battery symbol  on each of the new batteries; make sure they are charged and ready for use (see section 10.3.2, *Checking Battery Charge Level*).
- 3 Grasp the battery clip (and attached battery) for one of the two batteries currently powering the system. Remove the clip and attached battery from the holster/carrying case and place it within each reach. **Do NOT remove the battery from its clip at this time.**
- 4 Locate the battery fuel gauge symbol  on one of the batteries that is currently in use (**Figure 54**).

WARNING!

At least one (1) System Controller power lead must be connected to a power source (batteries, Power Module/PBU, or Emergency Power Pack) at all times. If both System Controller power leads are disconnected at the same time, the pump will stop.

It is essential that neither System Controller power lead (used to connect the System Controller to a power source) is ever disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the risk of pump stoppage increases.

Never disconnect both batteries at the same time or the pump will stop.



Figure 54 Battery Symbol (close up)

- 5 Press and hold the battery symbol on the 1st battery for five seconds to see how much battery power remains for this battery (i.e., count the number of lights that come on).
- 6 Repeat Steps 3 – 5 for the 2nd battery currently in use.
- 7 Determine which of the two batteries has the least power (i.e., fewer lights).
- 8 If both batteries have the same amount of power, switch either battery; otherwise, exchange the battery with the FEWER number of lit lights first:
 - a Press the battery release button on the battery clip.
 - b Withdraw the battery from its clip. *The System Controller will sound a once-per-second BEEP and the green power symbol and fuel gauge lights will flash.*
- 9 Pick up one of the charged batteries; locate the orange arrow on the battery. Make sure to pick up a charged battery and not one of the old, depleted batteries.



Figure 55 Inserting Battery into Battery Clip

- 10 Line up the orange arrow on the new battery with the orange arrow on the empty battery clip, so that the two arrows are facing each other (**Figure 55**).
- 11 Slide one of the new, charged batteries into the empty battery clip. The battery should “click” into place. However, after inserting it, gently pull on the battery and try to remove it from the clip. If properly and fully inserted, the battery will remain inside. In addition, the once-per-second BEEP will stop if the battery is properly inserted. It may take a few seconds for the beeping to stop.
- 12 Remove other discharged battery and repeat steps 9 – 11 to exchange the 2nd battery.
- 13 Return the clips (now containing the charged batteries) to holsters or carrying case.
- 14 Make sure the charger is plugged in and turned on (“I”) *before* placing batteries into pockets for charging.
- 15 Place the depleted batteries into the UBC for recharging. See the *Universal Battery Charger IFU*.

WARNING!

Make sure the Universal Battery Charger is plugged in and turned on (“I”) before placing batteries into the pockets for charging.

WARNING!

Never disconnect power from both controller power leads at the same time or the pump will stop. It is essential that the System Controller power leads (used to connect the System Controller to a power source) are never disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the pump will stop.

At least one (1) System Controller power lead must be connected to a power source (batteries, Power Module, or Emergency Power Pack) at all times. If both System Controller power leads are disconnected at the same time, or the pump will stop.

Ensure you are using the correct batteries and compatible battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.

Monitoring Battery Life

A number of factors influence battery life for a HeartMate battery. The two most important are the number of uses and the number of months since the battery was manufactured). The month and year of battery manufacture appears on the battery's label.

If a battery is stored and used according to the conditions outlined in its *Instructions for Use*, it should be usable for approximately 360 cycles or 36 months from the date of manufacturer, whichever comes first.

After this time, battery performance cannot be guaranteed. Call Thoratec for a replacement when either of these milestones is reached for a HeartMate battery.

See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for detailed warnings, precautions, and instructions on 12 volt NiMH and 14 volt Li-Ion batteries.

UNIVERSAL BATTERY CHARGER (UBC)

11.0 Universal Battery Charger (UBC)

11.1 Overview

The HeartMate Universal Battery Charger (UBC) (Figure 56) is designed to charge HeartMate batteries that are used to power the LVAS during mobile operation. Specifically, the HeartMate UBC can:

- Charge up to four HeartMate batteries in four hours or less.
- Monitor the need for calibration and calibrate individual HeartMate batteries.
- Perform diagnostic testing on up to four HeartMate batteries at once.

CAUTION!
Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries.

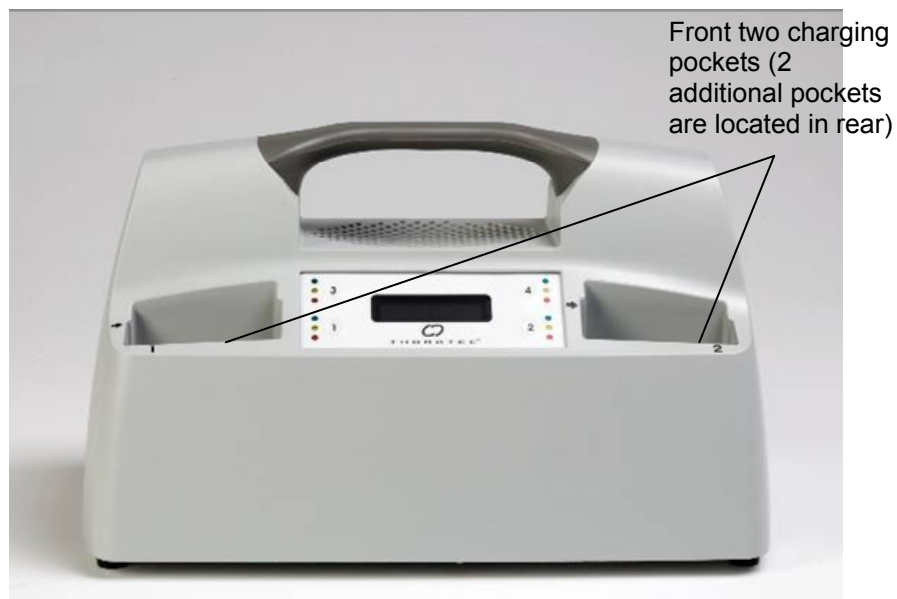


Figure 56 HeartMate Universal Battery Charger (UBC)

11.1.1 Function

The HeartMate Universal Battery Charger (UBC) can charge up to four HeartMate batteries simultaneously in approximately four hours, depending on the initial charge status of the battery(ies) being charged.

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

Both HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries utilize a “smart” technology that measures available battery power and counts battery usage/charge cycles. Once a battery is placed into a UBC charging pocket (**Figure 62**), the charger immediately checks that battery’s status by reading the battery’s on board computer chip. Information about the battery (i.e., available power and total number of use/charge cycles) can be viewed on the UBC’s display panel by pressing the number button for that pocket. See section 11.3.1, *Determining a Battery’s Charge Status Using the UBC*.

CAUTION!

The UBC cannot test or charge the black sealed lead acid (SLA) batteries originally used with the HeartMate Power Base Unit (PBU) (catalog #26439). Black HeartMate SLA batteries should be charged in the PBU.

Do NOT charge HeartMate 12 volt NiMH batteries in the HeartMate PBU. Use the UBC to charge HeartMate 12 volt NiMH batteries. Any other battery charger will damage HeartMate 12 volt NiMH batteries.

11.1.2 Components

The only components required for charging HeartMate batteries are the HeartMate UBC, up to four depleted batteries, and a functioning AC mains electrical outlet that is grounded and not controlled by a wall switch.

11.2 UBC Set Up

Follow these steps for setting up the UBC:

- 1 If not already unpacked, carefully remove the UBC from its product packaging. Place the charger on a flat, sturdy surface.
- 2 Inspect the UBC for dents, chips, cracks, or other signs of damage. Do NOT use a UBC that appears damaged. Contact Thoratec for a replacement, if needed.
- 3 Examine the UBC’s four battery charging pockets. Make sure the pockets are clean and empty (no batteries), and free of dust or debris.

Pay particular attention to the metal contacts inside the pockets. Dirt or objects covering the metal contacts inside the pockets may prevent proper battery charging, which can affect battery performance.

- 4 Obtain the grey AC power cord from product packaging.
- 5 Plug the female end of the power cord into the power entry module in the rear of the charger (**Figure 57**). Make sure the cord is fully inserted and secure.



Figure 57 Power Cord Inserted into Power Entry Module (Rear of UBC)

- 6 Plug the male end of the power cord into a properly-tested and grounded (3-prong) AC mains electrical outlet that is not controlled by a light switch.
- 7 Turn on the UBC by pressing the on/off switch in the rear of the charger from the off (“0”) to the on (“I”) position (**Figure 58**). Once the charger is turned on, all lights on the front panel will turn on, and the charger will beep once. This means the charger is performing a self test. The test takes approximately 10 seconds to complete. When done, all the lights will turn off, unless there is problem (see Step 8).

CAUTION!
Connect the HeartMate Universal Battery Charger (UBC) only to properly-tested and grounded (3-prong) AC outlets. Do not use an adapter plug for ungrounded wall outlets.

Ensure the UBC is connected to AC power and is turned “on” before placing batteries into the pockets for charging.


 **NOTE:**
If the patient will be traveling internationally, he or she will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications for both the UBC and PM. Contact the Thoratec Technical Service Department for a power cord set, if needed.



Figure 58 On/Off Switch in the On (“I”) Position (Rear of UBC)


- 8 If the UBC detects a problem during the self test, an error message appears on the display panel screen (**Figure 59**) and/or the lights and beep will not perform as described above. If you do get an error message, and/or the lights or beep are missing or do not perform as described above, refer to section 5.0 of the *HeartMate Universal Battery Charger IFU*, or contact Thoratec.



Figure 59 Sample Error Message (in Graphics Mode)

OR

- 8 If the UBC passes the self test, “HeartMate CHARGER” appears on the display panel (**Figure 61**). The charger is now ready for use.

 **NOTE:**
Any time the “HeartMate CHARGER” message is displayed, the display panel will slowly dim, turn off for two seconds, and then brighten again to full brightness. This helps to prolong the life of the display panel. You may use the UBC during this process.

Universal Battery Charger (UBC)

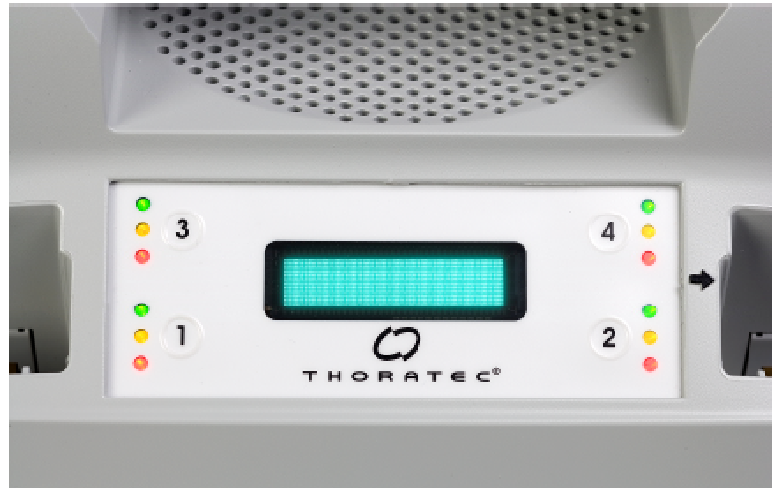


Figure 60 Display Panel During Self Test

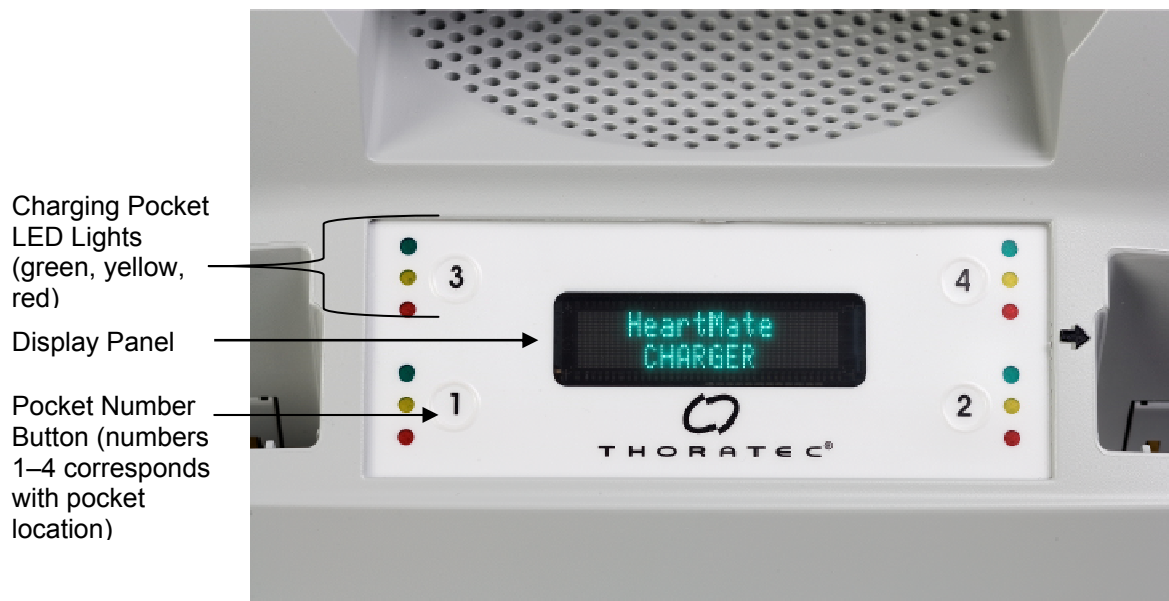


Figure 61 “HeartMate CHARGER” Message (UBC Default Screen)

Universal Battery Charger (UBC)

“Graphic Symbols” is the default display panel setting for the UBC. See “Selecting Language/Display Panel Settings,” found in section 2.2 of the *Universal Battery Charger IFU* (document # 103771) for instructions on selecting language/display options.

CAUTION!

The Universal Battery Charger (UBC) cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog #26439). Black SLA HeartMate batteries should be charged only in the PBU.

Do NOT charge HeartMate 12 volt NiMH or 14 volt Li-Ion batteries in the HeartMate PBU.

11.3 Description of Features

11.3.1 Determining a Battery's Charge Status Using the UBC

Once a battery is placed into a UBC charging pocket, one of three lights will illuminate, depending on the charge status of the inserted battery.

A steady **yellow** light means that the battery is actively charging. If the yellow light is blinking it means the battery should be calibrated (see section 11.4, *Calibrating HeartMate Batteries*). **Green** means the battery is charged and ready for use. **Red** means the battery is defective or that there is a problem with the charger. Do not use a battery that has a red light.

See **Table 12** below for a summary of UBC light color codes. Color codes apply for both 12 volt NiMH and 14 volt Li-Ion batteries.



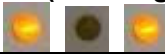

UBC Pocket Light Indicators	
Light Color	Status/Meaning
Green 	Battery is charged and ready for use
Yellow 	Battery is undergoing test, charge, or calibration
Yellow (Blinking) 	Battery requires calibration cycle
Red 	Battery or charging pocket is defective, Do not use battery

Table 12 Color Codes for UBC Charging Pockets (Color Indicates Battery's Status)

11.3.2 Charging Batteries

Follow these steps for charging HeartMate 12 volt NiMH or 14 volt Li-Ion batteries:

- 1 Obtain one or more HeartMate batteries.
- 2 Place one of the HeartMate batteries into one of the four UBC battery charging pockets. with the battery fuel gauge on the top and facing forward. Do NOT force a battery into a charging pocket. Batteries will only fit with the fuel gauge at the top and facing forward, as shown in **Figure 62**. A beep and the illumination of a colored light (red, yellow, or green) confirms that the battery has been properly inserted.

CAUTION!

Do not attempt to charge non-HeartMate batteries in the HeartMate Universal Battery Charger (UBC). Doing so may damage the charger or the batteries, or injure the user.

Before inserting a battery into the UBC for charging, inspect the battery for signs of damage. Do NOT use batteries that appear damaged



Batteries inserted into charging pockets 2 and 4

Figure 62 Inserting Battery into Charging Pocket

- 3 After hearing the beep, look at the three lights (yellow, green, and red) adjacent to the number button for this pocket.



Figure 63 LED Lights Adjacent to Charging Pocket Numbers

- 4 Identify which of the three lights (yellow, green, or red) comes on for this pocket.
- 5 If the **yellow** light comes on, the battery is actively charging. Do nothing with the battery. Leave it in the pocket to continue charging and skip to Step 7. The light will remain yellow until the battery is charged. Once the battery is charged, the yellow light turns off and the green light comes on.

OR

- 5 If the **yellow light is blinking**, battery calibration is being requested. Leave the battery in the pocket to be calibrated, if possible (see section 11.4, *Calibrating HeartMate Batteries*). If you choose to not calibrate, after 10 seconds the battery continues charging.

OR

- 5 If the **green** light comes on, the battery is already charged and ready for use. Either remove the battery for immediate use, or leave it in the pocket until needed. Leaving charged batteries in the charger will not damage them.

 **NOTE:**

The Universal Battery Charger has four charging pockets. Numbers “1” through “4” on the front panel of the charger correspond to the location of each pocket. For example, “1” on the panel stands for the front left pocket; “2” stands for the front right pocket; “3” stands for the rear left; and “4” stands for the rear right pocket.

CAUTION!

Leave a calibrating battery in the Universal Battery Charger (UBC) for the entire calibration cycle. Removing a battery before it is fully calibrated, may result in a fully-depleted battery (the on-battery fuel gauge will reflect this).

OR

- 5 If the **red** light comes on (or no light at all), there is a problem with the battery or the charging pocket. Remove the battery and:
 - a Reinsert it into the same pocket.
 - b If again there is a red light (or no light), insert the battery into a different pocket.
 - c If the battery cannot be charged in a different pocket, the battery is defective. Do not use it. Contact Thoratec for a replacement, if needed. See “Monitoring Performance,” found in section 5.0 of the *HeartMate Universal Battery Charger IFU* (doc # 103771) for information on handling red light conditions.
- 6 After approximately four hours, look at the three lights near the charging pocket for this battery.
- 7 If the **yellow** light is on, the battery is still charging.

OR
- 7 If the **green** light is on, the battery is charged and ready for use.

OR
- 7 If the **red** light is on, there is a problem with the battery or pocket, and/or the charger interrupted the charging cycle for some reason. See “Monitoring Performance,” found in section 5.0 of the *HeartMate Universal Battery Charger IFU* (doc # 103771) for information on handling red light conditions.
- 8 Repeat Steps 2 – 8 for as many as three additional batteries, to charge up to four batteries simultaneously (**Figure 64**).



Figure 64 All Four Charging Pockets Being Used to Charge Batteries

Viewing Battery Information on the Universal Battery Charger (UBC) Screen

To check a battery's charge status, place the battery into a charging pocket, then press and release the number button for that pocket. The following will appear on the display panel (**Figure 65**):

- Pocket Number
- Battery symbol
- Percentage of available charge

For example, if approximately 50% of the battery's power is available (i.e., battery is 1/2 charged), half of the battery symbol is filled and "50%" appears on the screen.

After five seconds, the display returns to the default screen ("HeartMate CHARGER"), unless the number button for this pocket is pressed again. Pressing the button a second time brings up the total number of use/charge cycles (see immediately below).



Figure 65 Viewing Available Power for the Battery in Pocket #1 (in Graphics mode). In this case, the battery is approximately 90% charged.

Viewing Use/Charge Cycles

To see how many times a battery has been used/charged, press and release the number button while the Charge Status Screen (**Figure 65**) is still on. The following will appear on the display panel (**Figure 66**):

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

After 10 seconds, the display panel returns to the default (“HeartMate CHARGER”) screen (**Figure 61**).



Figure 66 Pressing the Button a Second Time Reveals the Charge/Use Cycle Count (in this case 7 cycles) and the Charge Capacity (in mAh) for the battery (in this case, the battery in pocket #1)

If a battery is being calibrated (see section 11.4), the pocket number and a split battery symbol appear on the display panel when the number button for that pocket is pressed. Five seconds after pressing the button, the display returns to the default (“HeartMate CHARGER”) screen (**Figure 61**).

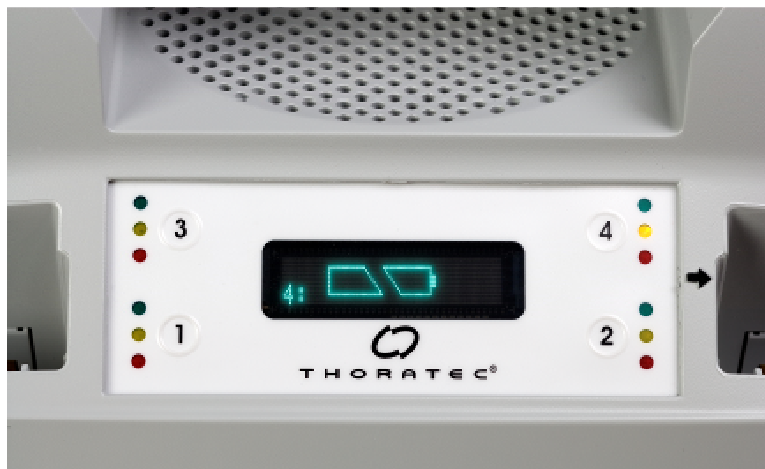


Figure 67 Display panel screen (in Graphics mode) when button is pressed to start battery calibration cycle. In this case, the battery in pocket #4 needs calibration

11.4 Calibrating HeartMate Batteries

Both HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries utilize a “smart” technology that measures available battery power and counts battery usage/charge cycles. Periodically (approximately every 70 battery uses), a battery may sense that it needs to calibrate its battery fuel gauge. Calibration helps keep the battery’s fuel gauge accurate.

During calibration, the charger drains the battery of all electrical energy and then recharges it. The battery must be placed into the UBC to be calibrated. Battery calibration can take up to 12 hours, and only one battery can be calibrated at a time. During calibration, the other three HeartMate batteries can be charged as usual.

If a battery needs to be calibrated, the charger will tell you when that battery is inserted into one of the charging pockets. The following occurs if calibration is recommended:

- The yellow light for this pocket blinks
- A split battery symbol and the pocket number for this battery flashes on the display panel screen (**Figure 67**). The circled number will alternate between a filled and unfilled circle as the display panel screen flashes (**Figure 68**).



Figure 68 Calibration prompt (in Graphics mode). In this case, the battery in pocket #4 needs calibration.

You have the option of calibrating the battery when prompted or waiting for another, more convenient time (e.g., at night while the patient sleeping). If you choose to not calibrate at the prompt, after 10 seconds, the UBC will continue with a normal charge cycle for that battery (see section 11.3.2, *Charging Batteries*). Once it is charged, you may use a battery for which you have delayed calibration. **However, you should still calibrate it as soon as possible.**

If you choose to calibrate a battery, and then decide to stop calibration after the process has already begun, you can cancel calibration by removing the battery from its pocket. **If you do remove a battery before calibration is complete, make sure to recharge and check the battery before using it.** Removing a battery before calibration ends may result in a depleted battery (the on-battery battery fuel gauge will reflect this status).

See “Calibrating HeartMate Batteries,” found in section 4.0 of the *HeartMate Universal Battery Charger IFU* (doc # 103771) for detailed warnings, precautions and instructions on calibrating HeartMate batteries.



NOTE:

It is important to calibrate a battery as soon as possible after being prompted to do so. This helps ensure the best possible battery performance. Be sure to have enough charged batteries when planning for calibration, which can take up to 12 hours.

CAUTION!

Leave a calibrating battery in the Universal Battery Charger (UBC) for the entire calibration cycle. Removing a battery before it is fully calibrated, may result in a fully-depleted battery (the on-battery fuel gauge will reflect this).

Monitoring Performance


The HeartMate Universal Battery Charger (UBC) is continually monitoring its own performance and that of any battery placed into a charging pocket. Actual or potential problems, or “faults,” appear as “advisory messages” on the UBC’s display panel screen (e.g., “Call Service” message, (Figure 69)



Figure 69 Sample Advisory Message (Call Service)

Battery-Related Advisories

If the charger detects a problem with a battery (e.g., voltage too high or too low, open circuit, etc.), the red light for the battery’s pocket comes on and a telephone symbol appears on the display panel screen. Refer to “Battery-Related Advisory Messages” found in section 5.1 of the *HeartMate Universal Battery Charger IFU* (document #103771) for instructions on handling battery-related advisories.

 **NOTE:**
Before assuming a battery is defective, make sure dirt or debris is not blocking the connection between the battery and the charging pocket contacts.

Charger-Related Advisories

The UBC can detect a problem or “fault” condition with up to four charging *pockets* at once (with or without batteries inside), or with the *entire charger unit*.

If the UBC detects a pocket fault, the red light for the affected pocket(s) (with or without battery(ies) inside) will illuminate. In addition, the UBC will immediately stop charging/calibrating the battery(ies) inside the affected pocket(s). See “Charger-Related Advisory Messages,” found in section 5.2 of the *HeartMate*

Universal Battery Charger (UBC)

Universal Battery Charger IFU (document # 103771) for a summary of fault conditions and how to respond to each.

Do not use a damaged or defective pocket or UBC until it is repaired or until the charger is replaced. Until you have a safe and reliable way to recharge the batteries, use an alternate power source to power the HeartMate system. For example, instead of batteries, use the HeartMate Power Module (PM) or Power Base Unit (PBU) to power the HeartMate II system.

DISPLAY MODULE

12.0 Display Module

12.1 Overview

12.1.1 Function

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

When connected to the Power Module (PM) and System Controller, the Display Module (**Figure 70**) displays a variety of system performance data, including:

- Current pumping mode (i.e., fixed or power saver mode)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility Index (PI)
- Estimated flow in liters per minute (lpm)
- Power in watts (W)

The Display Module reports data from the System Controller via the PM.

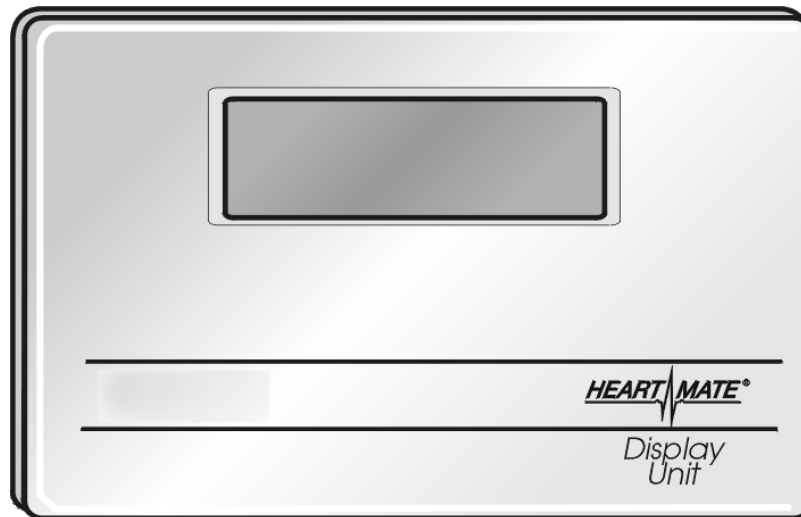


Figure 70 Display Module

12.1.2 Components

The Display Module includes a small monitor and a cable adapter that is connected to the PM to receive power and system data.

12.2 Display Module Setup

Refer to section 9.3.6, *Using the PM with the Display Module*, for instructions on setting up the Display Module for use with the PM.

12.3 Description of Features

12.3.1 Display

If the patient is connected to the PM and System Controller, the following will immediately begin displaying on the screen once the Display Module is plugged in, as shown in **Figure 70**:

- Current pumping mode (i.e., fixed speed or power saver mode)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility index (PI)
- Estimated flow in liters per minute (lpm)
- Power in watts (W)

12.3.2 Alarms

When an alarm is activated, the alarm message will alternate with the current flow and power data (**Figure 71**). See **Table 17** for a complete list of LVAS alarms.



NOTE:

The highest priority alarm is displayed. See **Table 13** on page 168 for descriptions of alarm messages.

12.3.3 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 +++,” to indicate “too low” or “too high,” respectively (**Figures 71** and **72**).

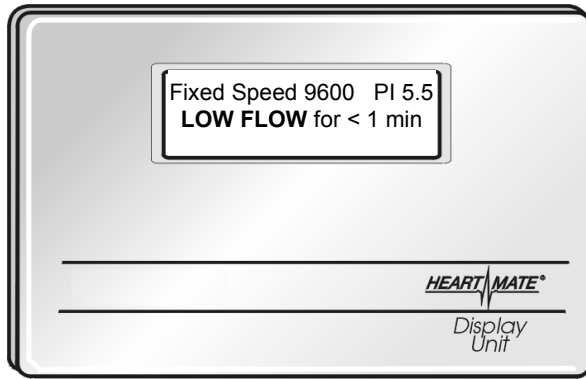


Figure 71 Display Module Screen with Sample Alarm Message

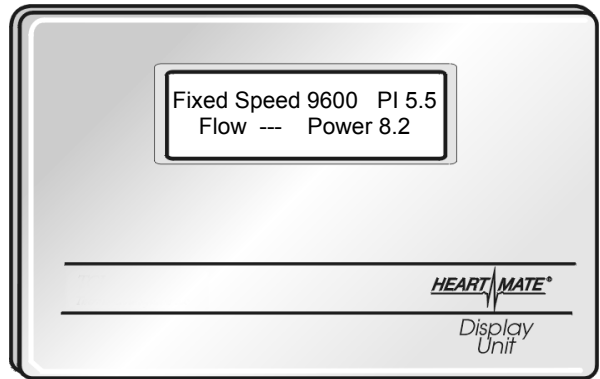


Figure 72 Display Module Screen with Blank Flow

SYSTEM MONITOR

13.0 System Monitor

13.1 Overview

13.1.1 Function

The System Monitor is typically used in the operating room during device implant and in the intensive care unit immediately post implant. The system monitor is used to:

- Closely monitor system operation during LVAD implant
- Monitor and adjust system parameters to maintain optimal performance
- Assess and track alarm conditions
- View and save performance data
- Record data at specific intervals to download for review and analysis

13.1.2 Components

The System Monitor, the Power Module (PM), and the System Monitor data cable are the only components required for using the System Monitor with the PM.

The System Monitor has been offered in two different versions:

- Original System Monitor (no longer in production)
- Updated System Monitor

In the following sections of this manual, references to the System Monitor and monitor screens are based on the updated System Monitor unless otherwise noted. For information regarding the original System Monitor, refer to **Appendix IV** or call Thoratec Corporation.

13.1.3 System Monitor Setup

Refer to section 9.3.7, *Using the PM with the System Monitor*, for instructions on setting up the System Monitor for use with the PM.

CAUTION!
Do not attempt to move or lift the System Monitor and PM as an assembly by lifting the System Monitor. Doing so could result in damage to the PM and/or System Monitor.


13.2 Description of Features

13.2.1 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 73**.



Figure 73 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 five seconds, the system will automatically restart the monitor software.

 **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.

13.2.2 Clinical Screen

The clinical screen (**Figure 74**) 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, pump speed, pulsatility index (abbreviated on screen as pulse index), and pump power.
- **Operating Mode and Speed Set Point** – The operating mode and speed set point are displayed below the parameter boxes as shown in **Figure 75**. The speed set point for fixed mode has a range of 6,000 to 15,000 rpm. Refer to *Optimal Fixed Speed* in section 13.2.3 for information on determining the desired speed set point.
- **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 section 13.2.3 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 two minutes, and all other advisory alarms for four hours. See *Silencing Alarms* in section 13.2.4 for more information.

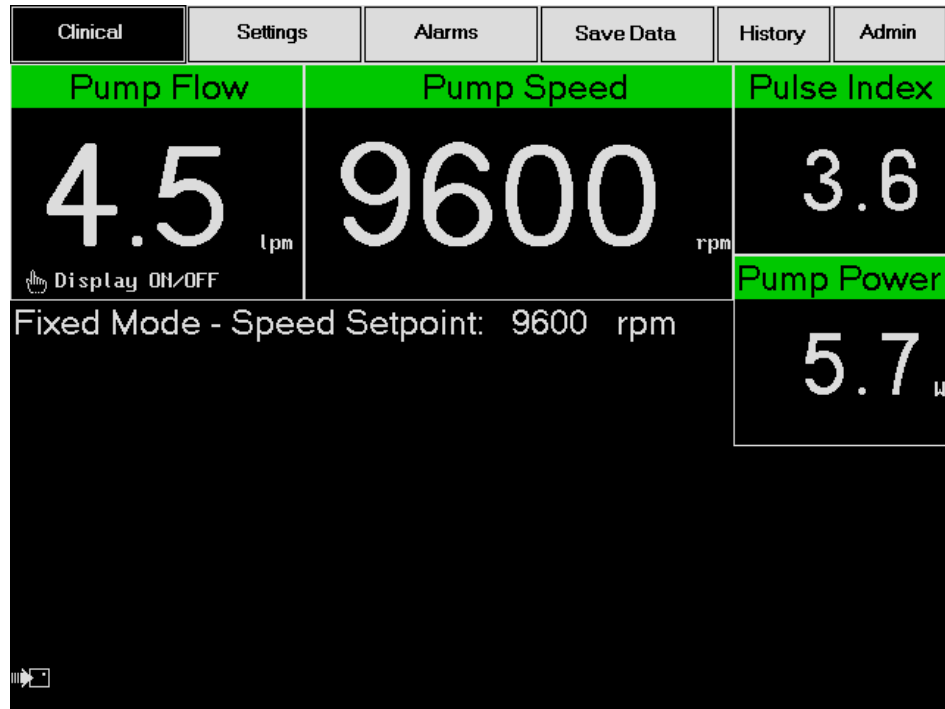


Figure 74 Clinical Screen (typical)

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 75**. This is done in order to prevent inaccurate flow information.

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.

The pump flow display may be turned off by touching the screen anywhere within the pump flow box (**Figure 76**).

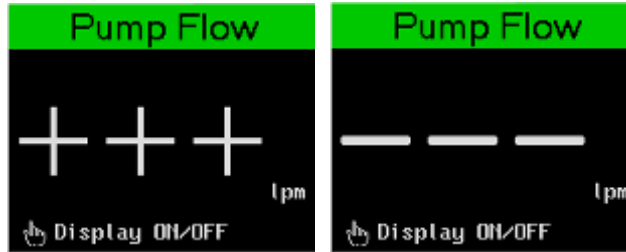


Figure 75 Pump Flow Above (left) and Below (right) Region of Accurate Flow Estimation

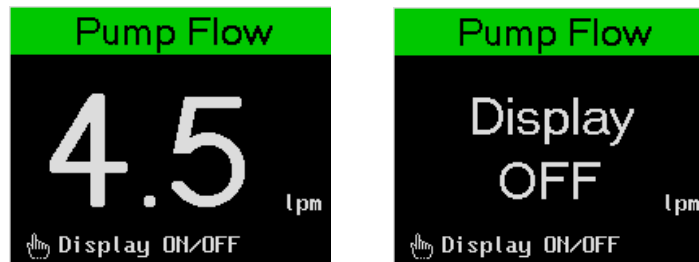



Figure 76 Pump Flow Display On (left) and Off (right)

When the pump is stopped or becomes disconnected from the System Controller, “-.-” will appear in the pump flow box as shown in **Figure 78**. 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 77**).

 **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.

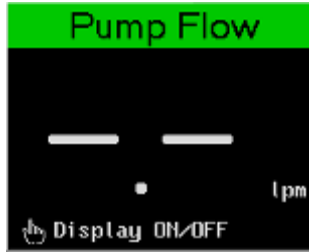
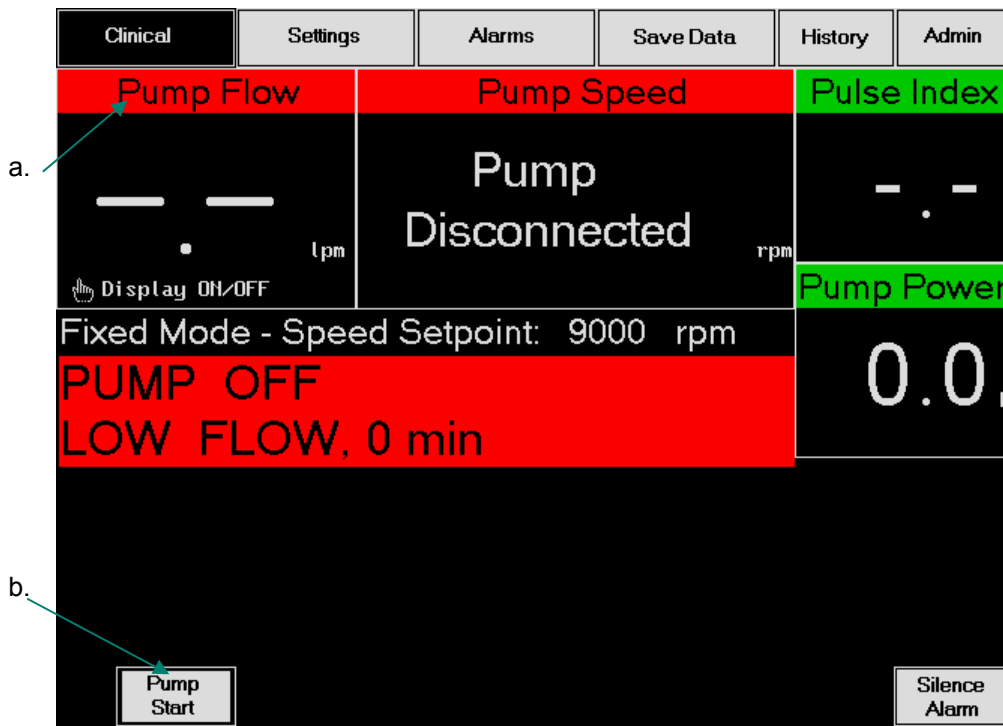


Figure 77 Pump Running at Fixed Speed Less than 8,000 rpm



- a. Pump flow box turned red and displaying "-."
- b. Pump start button

Figure 78 Clinical Screen with Pump Off Alarm

Pump Speed

The System Monitor displays the pump speed in revolutions per minute (rpm) as shown in Error! Reference source not found.. This value will match the actual speed within ± 100 rpm under nominal conditions. If the pump is not connected to or becomes disconnected from the System Controller, the pump speed box will display Pump Disconnected (Figure 79). When the pump is stopped using the pump stop button (see page 147), “----” will appear in the pump speed box.

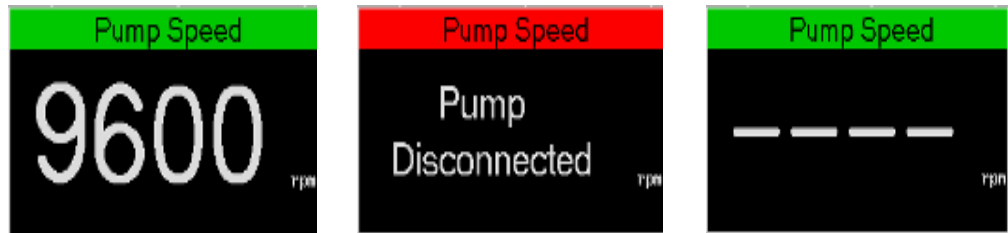


Figure 79 Pump Speed Display—From Left: Pump On, Pump Disconnected, and Pump Stopped

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 80.



Figure 80 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 set point 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 section 13.2.4, *Alarms Screen*, for explanations of the conditions leading to each alarm. Refer to section 18.4 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 81**. 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 78**)
- PUMP OFF – This text banner will be accompanied by a red pump flow box (**Figure 78**) 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 81**).
- 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 81**. These messages will *not* flash except for the low speed operation warning. An audible alarm from the System Controller will accompany the text banners as described below. 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 a repeating cycle of one beep per second for two seconds, followed by two seconds of silence.
- 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 four seconds.
- WARNING: Low Speed Operation – This text banner *will flash* and have *no* audible alarm.



Figure 81 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 (two minutes for hazard alarms and power cable disconnected advisory, and four hours for all other advisory messages). Refer to *Silencing Alarms* in section 13.2.4 for more information.

13.2.3 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

NOTE:
The System Monitor will automatically return to the clinical screen should there be 60 seconds of inactivity on any other screen.

status boxes as shown in **Figure 82**.

- **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 *Alarms Screen* in section 13.2.4 for a detailed explanation of alarms.
- **Command Buttons** – The fixed speed adjust, low speed limit, and pump stop/start command buttons are displayed at the bottom of the screen as shown in **Figure 82**. 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 two minutes, and all other advisory alarms for four hours. See *Silencing Alarms* in section 13.2.4 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 82**). The current record interval of the controller event recorder is also displayed. See *Silencing Alarms* in section 13.2.4 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 82**).

Clinical	Settings	Alarms	Save Data	History	Admin
System Status 1			System Status 2		
a. →	Mode	FIXED	Pump Power	5.5	W
b. →	Record Interval	OFF	Pump Voltage	13.0	U
	Monitor Logger	OFF 5 min	Hazard Time	0	min
	Pump Flow	4.4 lpm	Alarm Silence	OFF	
	Pump Speed	9400 rpm	System Controller	Primary	v4.0
	Fixed Speed	9400 rpm	Pulse Index (PI)	3.6	
	Low Speed Limit	9000 rpm			
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> Fixed Speed Adjust Low Speed Limit Pump Stop </div>					

c.

d.

e.

a. Controller event recorder

b. System Monitor data logger

c. Alarm silence: on, off, or extended

d. Controller mode: primary or backup

e. Controller version number

Figure 82 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 83**. 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 section 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	U
Record Interval	OFF		Pump Voltage	13.0	U
Monitor Logger	OFF	5 min	Hazard Time	0	min
Pump Flow	4.4	lpm	Alarm Silence	OFF	
Pump Speed	9400	rpm	System Controller	Primary	v4.00
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 83 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 section 13.2.5 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:
 - a. 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).
- b. 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 84**. 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 set point. 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 set point, the pump speed will not change during a suction event. There are no audible alarms with 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	v4.00
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.

Select Low Speed Limit: 9000			
Cancel	Inc. Value ↑	Dec. Value ↓	Enter

Figure 84 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 lasts approximately 10 seconds) as shown in **Figure 85**. Initially, the low speed operation advisory and then the low flow hazard appear without an audible alarm. Once the countdown nears zero, the pump off hazard will appear as shown in **Figure 87** accompanied by a continuous audible alarm. A silence alarm button will be displayed to the right of the alarm text banners and can be pressed to silence this alarm for two minutes.

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

Clinical	Settings	Alarms	Save Data	History	Admin
System Status 1			System Status 2		
Mode	FIXED		Pump Power	5.5	W
Record Interval	0.5	hour	Pump Voltage	13.0	V
Monitor Logger	OFF	5 min	Hazard Time	0	min
Pump Flow	4.5	lpm	Alarm Silence	OFF	
Pump Speed	9400	rpm	System Controller	Primary	v4.00
Fixed Speed	9400	rpm	Pulse Index (PI)	3.6	
Low Speed Limit	9000	rpm			

Pump Stop Countdown: 15

Fixed Speed Adjust

Low Speed Limit

Pump Stop

a. Pump stop button
 b. Pump stop countdown

b.

a.

Figure 85 Settings Screen – Pump Stop Countdown Start

A pump start button replaces the pump stop button after the pump stop countdown has finished. Pressing the pump start button will restart the pump at the previous 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.

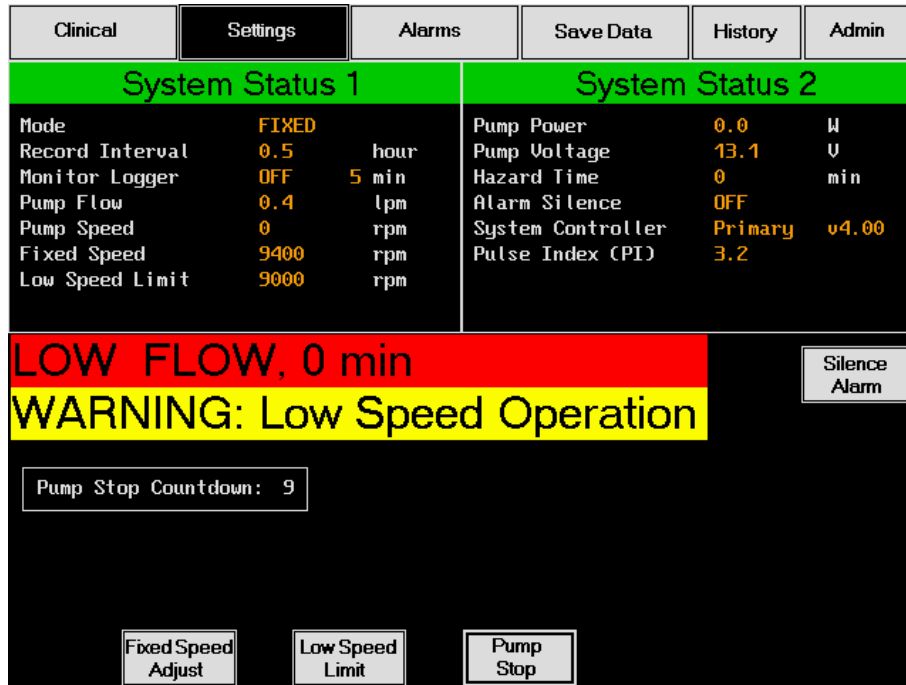


Figure 86 Settings Screen – Pump Stop Countdown

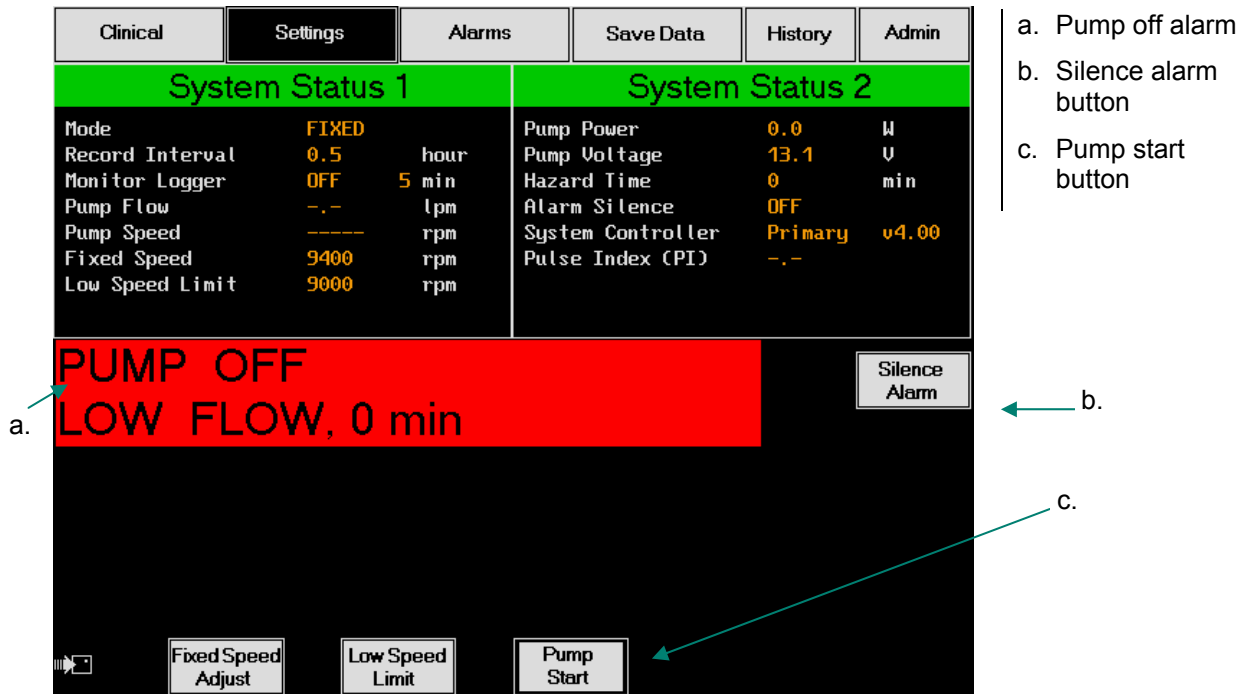
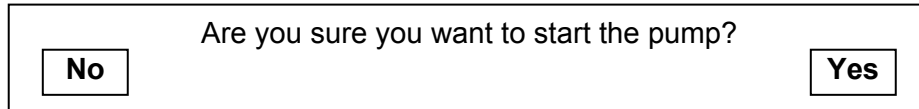


Figure 87 Settings Screen – Pump Stop Countdown Completion


A pump start button replaces the pump stop button after the pump stop countdown has finished (**Figure 87**). Pressing the pump start button will display the message:



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 set point 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” 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.

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

13.2.4 Alarms Screen

The alarms screen shows the status of all hazard and advisory alarms as shown in **Figure 88**. 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.

 **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.

- Parameters Box – A box below the alarms box displays system parameters, hazard time elapsed (for low flow hazards only), and whether the alarm silence is on, off, or extended.
- Command Buttons – 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 two minutes, and all other advisory alarms for four hours. See *Silencing Alarms* in this section 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 section 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 88**). Multiple alarms may be highlighted simultaneously.

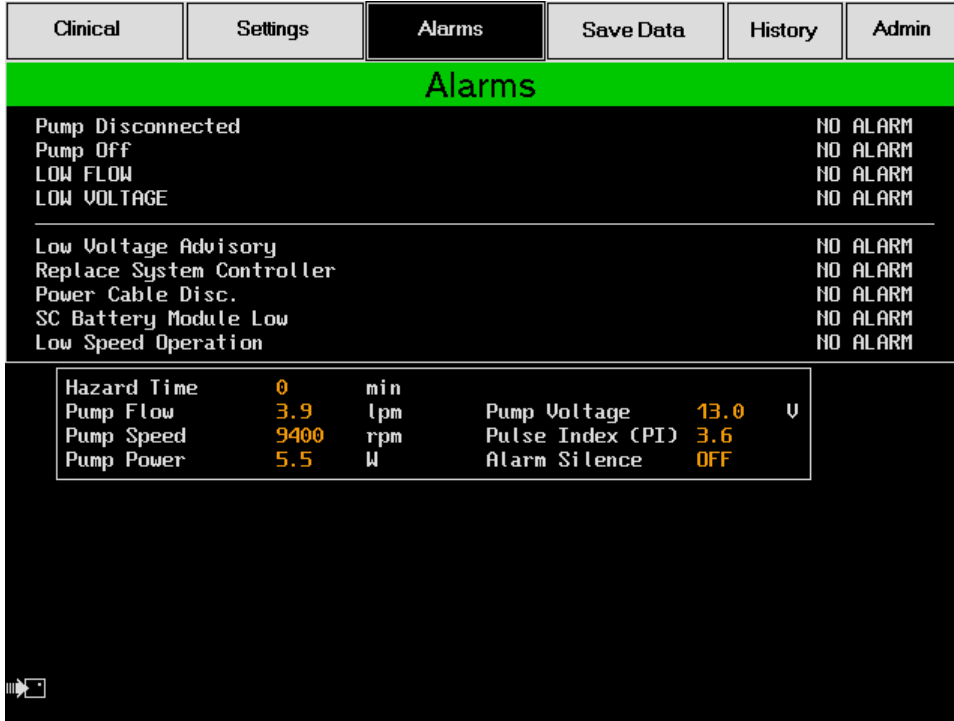


Figure 88 Alarms Screen (typical)

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 or has been disconnected from the System Controller. 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 89**.
- LOW VOLTAGE – Voltage has dropped below 10.50 V.

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 PM 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.

Alarm/Advisory	Status
Pump Disconnected	NO ALARM
Pump Off	NO ALARM
LOW FLOW	ACTIVE
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	ACTIVE

Hazard Time	3	min	Pump Voltage	12.3	V
Pump Flow	---	lpm	Pulse Index (PI)	3.1	
Pump Speed	7600	rpm	Alarm Silence	OFF	
Pump Power	4.0	W			

Figure 89 Alarms Screen with Multiple Alarms and Advisories Displayed Simultaneously

Silencing Alarms

The silence alarm button is used to temporarily silence audible PM and System Controller alarms and will only appear during alarm conditions (**Figure 89**).

Pressing the button will silence hazards and the power cable disconnected advisory for two minutes, and all other advisories for four hours on both the PM 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 89**). Pressing this button will silence all hazard and advisory audible alarms on the PM 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?	
<input type="button" value="No"/>	<input type="button" value="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.

13.2.5 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 90**:

- System Monitor Data Logger
- Waveform
- Controller Event Recorder



NOTE:

Alarm messages do NOT appear on the Save Data, History, or Admin Screens. Go to the alarm screen to view alarm messages.

- Controller Event History



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.

Figure 90 Save Data Screen

Data Card

Information recorded by the System Controller and System Monitor must be saved on a data card (**Figure 91**). 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 92** (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 91 Data Card (p/n 101609)



Figure 92 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 93**) 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.

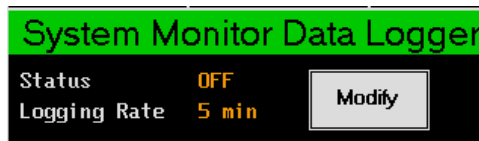


Figure 93 Save Data Screen – System Monitor Data Logger

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 94**. Onscreen instructions are provided to help the user change the logging settings.

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

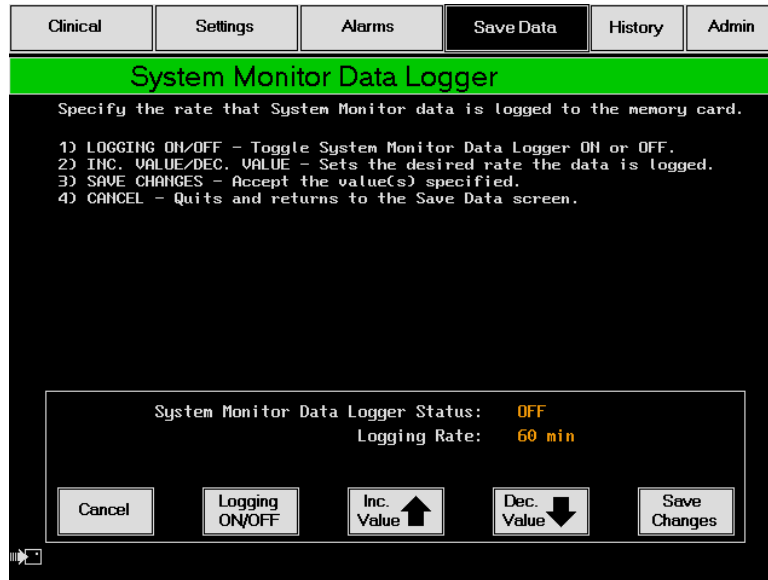


Figure 94 System Monitor Data Logger Screen

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 section 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.
- 3 Select the desired logging rate and press the save changes button. This will open the patient ID screen as shown in **Figure 95**.
- 4 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 section 13.2.7 for specific instructions on setting the clock.
- 5 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.



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.



NOTE:

When saving information to a data card for a specific patient, be sure to use the same patient identification (ID) number every time you save information for him or her. Using different ID numbers makes it difficult to identify, track, and/or compare multiple entries.

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.

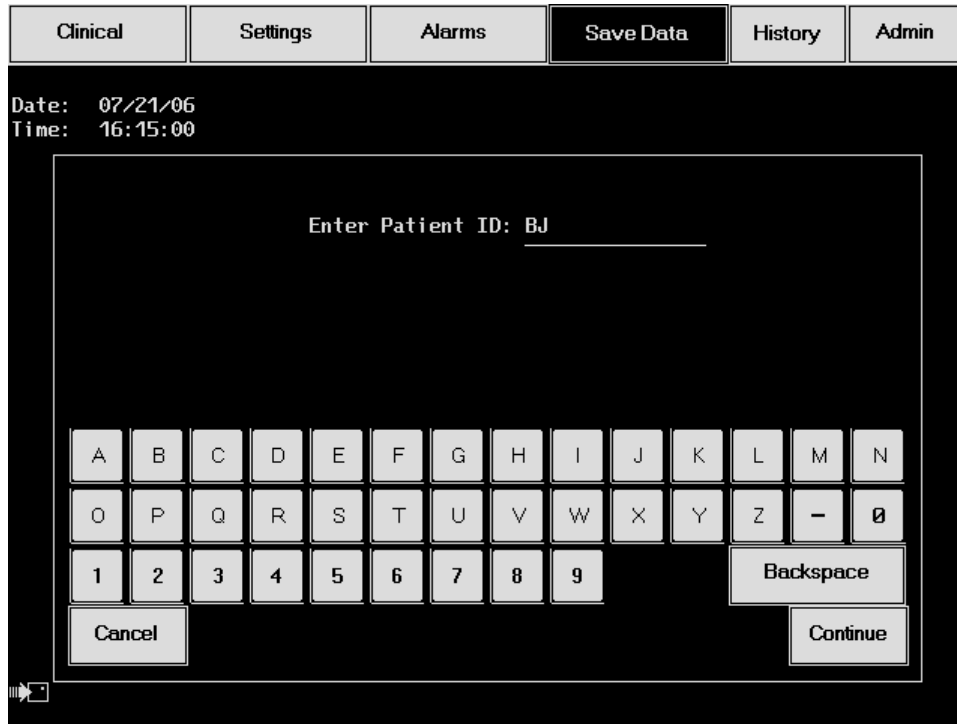


Figure 95 Patient Identification Information

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 section for instructions on how to insert a data card.
2. Press the save to card button (**Figure 96**). The patient ID screen will appear (**Figure 95**).

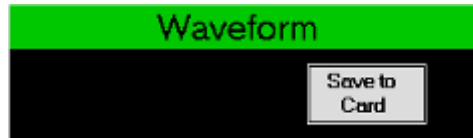
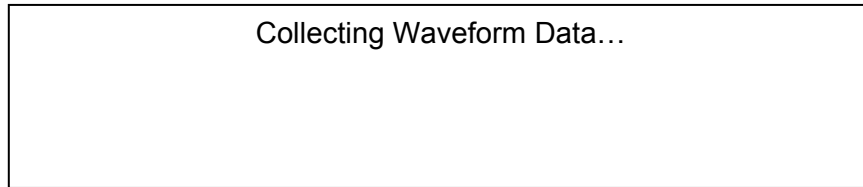


Figure 96 Save Data Screen – Waveform

- 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.
- 4 Refer to section 13.2.7 for specific instructions on setting the clock.
- 5 Enter a patient identification number up to 15 characters by using the onscreen keypad (**Figure 95**). Press the continue button. The following message should appear:



- 6 Once the information is collected, a patient related data screen will appear as shown in **Figure 97**.
- 7 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 all parameters, press the continue button to begin saving data. Do not press “continue” until



NOTE:

Do not press the continue button until the information for all parameters has been entered. Once you press continue you cannot go back to enter additional information.

information for all parameters has been entered.

- 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 19051042.tci
 Time: 10:45:31 Patient ID: D

Enter Data & Time Obtained
 Example: 16@5:15am

Enter B/P	B/P: <u>100/55@11:40AM</u>	@	1	2	3
Enter CO	CO: <u>3.9@11:40AM</u>	:	4	5	6
Enter PCWP	PCWP: <u>12@11:40AM</u>	AM	7	8	9
Enter CVP	CVP: <u>16@11:40AM</u>	PM	.	0	/
Continue		Backspace			

Figure 97 Patient Related Data

- 8 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

System Monitor

- 9 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.
- 10 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, PM, 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.



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.

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 90**) 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.



Figure 98 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 99**. Onscreen instructions are provided to help the user change the recording settings.

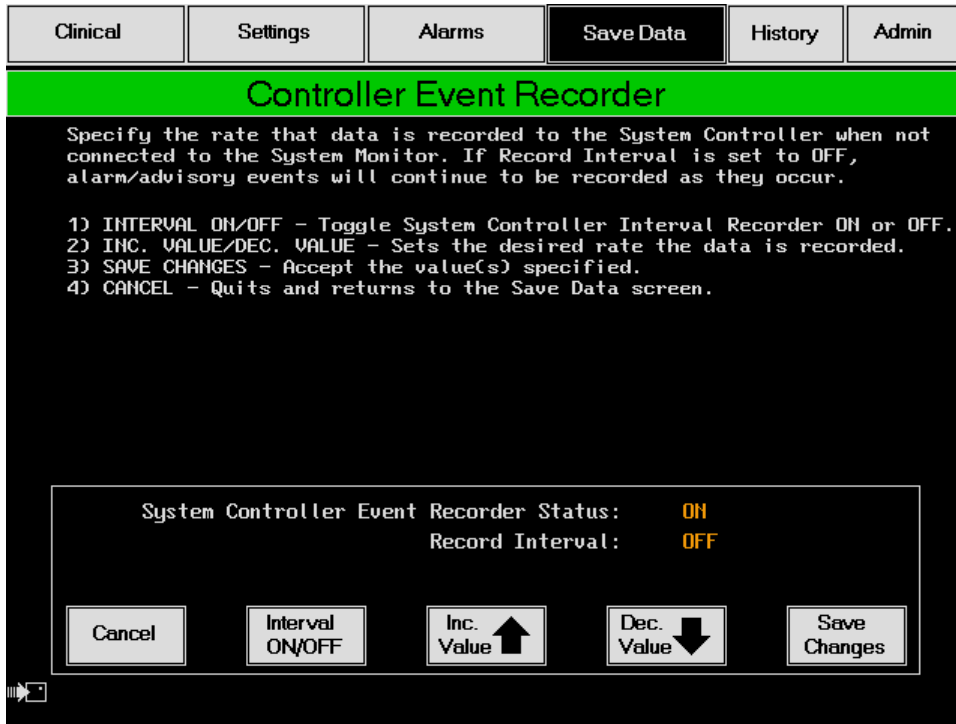


Figure 99 Controller Event Recorder Settings Screen

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 100**).

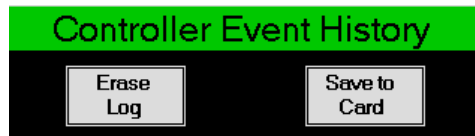
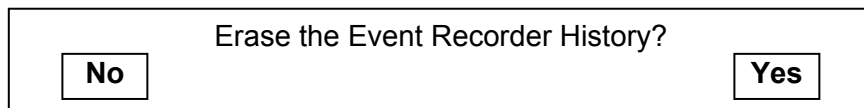


Figure 100 Save Data Screen – Controller Event History

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

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



- 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 stored 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 section for instructions on how to insert a data card.
- 2 Press the save to card button. The patient ID screen will appear (**Figure 95**).
- 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 section 13.2.7 for specific instructions on setting the clock.
- 4 Enter a patient identification number up to 15 characters by using the onscreen keypad (**Figure 95**). Press the Continue button to record the event history to the data card. The message Retrieving History Data should appear as shown in **Figure 101**. If the data is successfully saved, the monitor will display Data captured successfully, Press any button to continue as shown in **Figure 102**.
- 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



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, PM, and System Monitor.

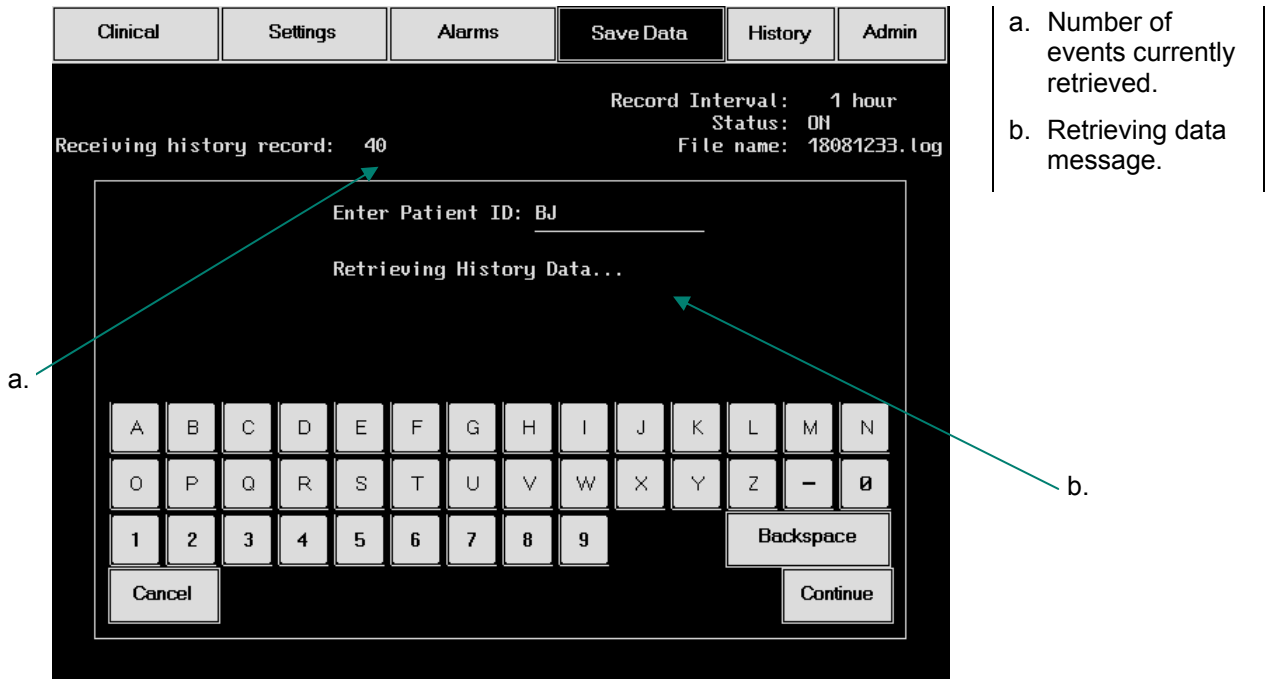


Figure 101 Controller Event History Retrieving Data

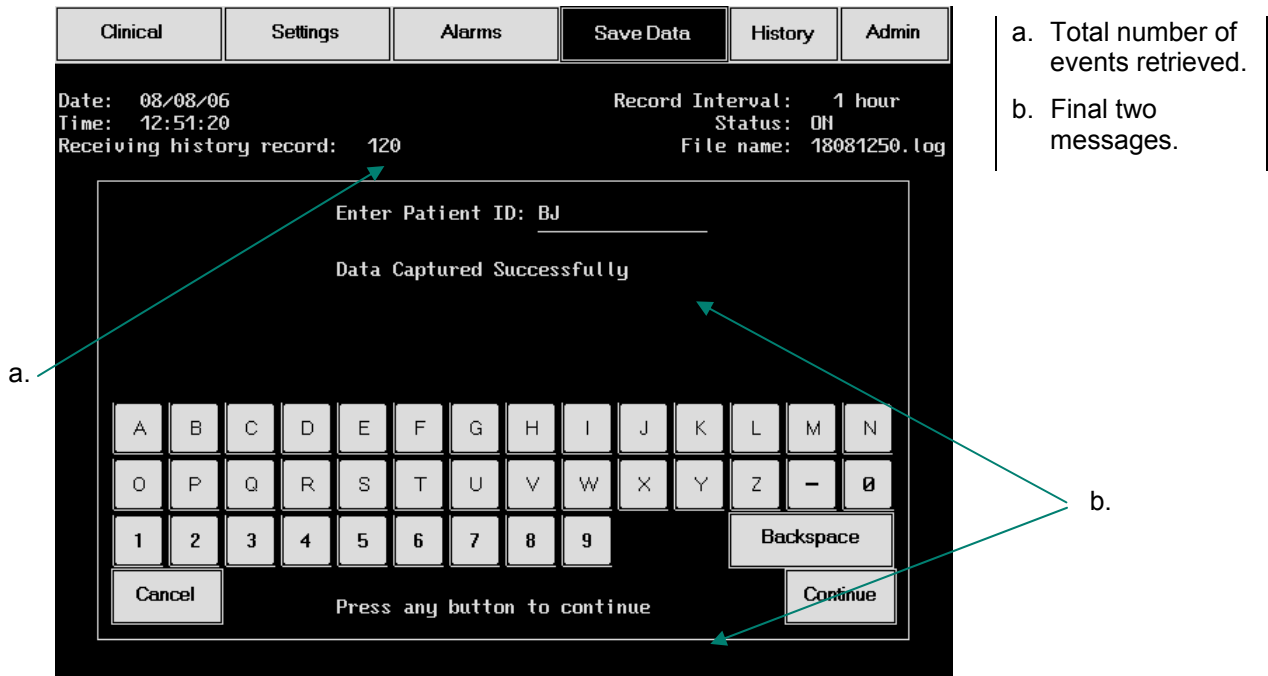


Figure 102 Controller Event History Data Captured Successfully

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 103**) 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. Users in the United States should dial 925-847-8600 during regular business hours or call the 24-hour HeartLine™: 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.

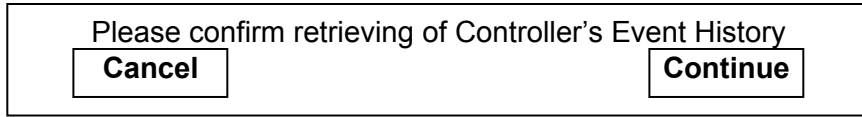


Figure 103 Card Reader

13.2.6 History Screen

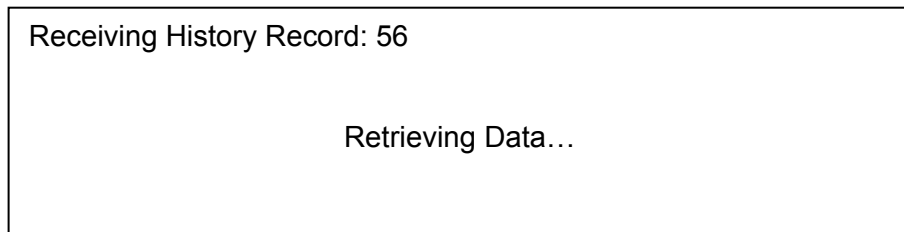
The history screen will allow the user to retrieve and view the System Controller event history on the System Monitor. The user will also have the option to save the history to a data card.

When the history tab on the System Monitor toolbar is selected, the screen will display the message:



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:



Once the logged events have been successfully retrieved, the history screen will appear as shown in **Figure 104**. 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 13**.
- 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 section 13.2.5 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 13 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						
Save to Card		<input type="button" value="◀"/> <input type="button" value="◀"/> <input type="button" value="▶"/> <input type="button" value="▶"/>				

Figure 104 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.

13.2.7 Admin Screen

Pressing the admin tab on the System Monitor toolbar displays the admin screen as shown in **Figure 105**. This screen is used to set the System Monitor date and time and to modify technical parameters.



Figure 105 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 106**, which has onscreen instructions for setting the date and time.



Figure 106 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 107**, which provides access to the parameters. However, access to this screen is restricted to Thoratec personnel only.

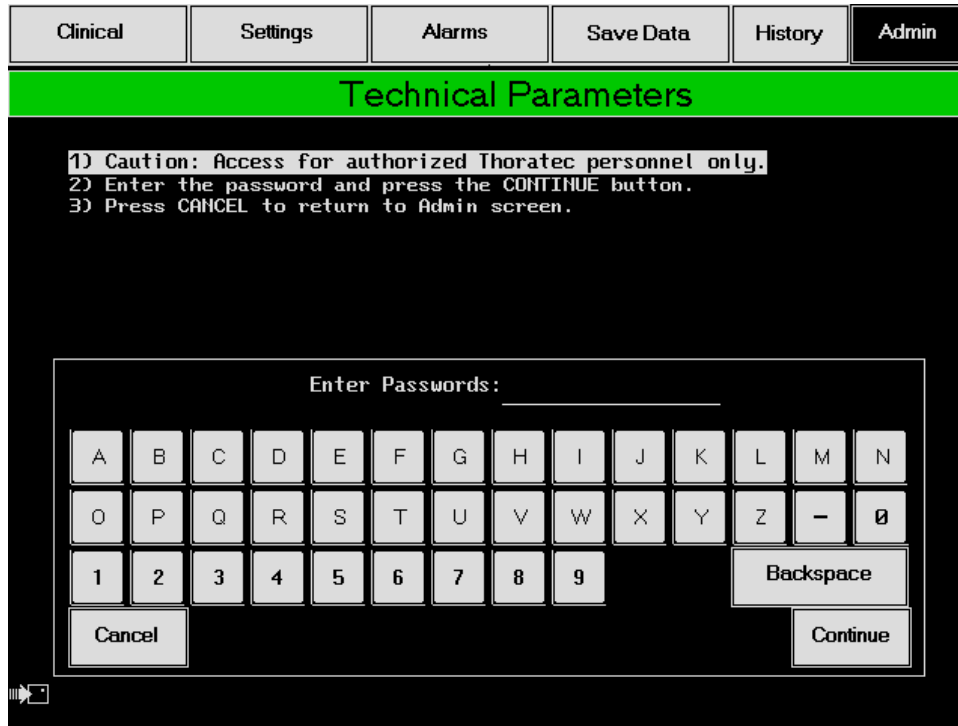


Figure 107 Technical Parameters Screen

PATIENT & DEVICE MANAGEMENT

14.0 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.

14.1 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 PM 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

- PM
 - PM patient cable
 - Universal Battery Charger (UBC)
 - Display Module
 - Travel kit, shoulder holster, carrying case, 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. Travel
 9. Warnings and Precautions

14.2 Exit Site Care

Currently, there are no clinical trials delineating the best regimen for care of the LVAD percutaneous lead (driveline) 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. Immobilizing the percutaneous lead prior to transporting the patient out of the O.R. is recommended.
- 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.

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.

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.

14.3 Caring for the Percutaneous Lead

It is extremely important that the percutaneous lead is protected from extreme or frequent bending or kinking. Damage to the percutaneous lead, depending on the degree, may cause the pump to stop.

The patient must be educated about the importance of keeping his or her lead free from damage. Following these recommendations can reduce damage to the percutaneous lead:

- Do not severely bend or kink the percutaneous lead.
- Do not let the percutaneous lead become twisted.
- If carrying the System Controller in a carrying case, don't "catch" the percutaneous lead in the zipper.
- Allow for a gentle curve of the percutaneous lead. Do not severely bend the lead multiple times or wrap it tightly.
- Keep the percutaneous lead clean. Wipe off any dirt or grime that may appear. If necessary, use a towel with soap and warm water to gently clean the percutaneous lead. However, never submerge the lead or other system components in water or liquid.
- Do not pull on or move the lead going through the skin.
- When checking to assure that the percutaneous lead connector is fully inserted into the System Controller socket, gently tug on the *metal end* of the connector. Do NOT pull on the lead.
- Wear the HeartMate Stabilization Belt or another abdominal binder AT ALL TIMES to keep the lead in place and to prevent pulling on or moving the lead.
- Be mindful of where the System Controller is at all times. Protect the controller from falling or from pulling on the lead.

- Don't allow the percutaneous lead catch or snag on anything that will pull on or move the lead.
- Check the percutaneous lead daily for signs of damage (cuts, holes, tears).
- Damage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead. Damage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead. The damage may be evidenced by the following:
 - Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
 - High pump power associated with reduced pump speed (as recorded in the System Controller event log file).
 - High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
 - Feelings of pump vibrations.
 - Fluid leakage from the external portion of the lead.
 - Cessation of pumping.

IMPORTANT! If you suspect that a HeartMate II LVAS patient may have a damaged percutaneous lead, please contact Thoratec Technical Services (800-456-1477) for assistance. X-ray images, System Controller log files and pump waveform data may be useful to assess the extent and location of the damage. **If damage to the electrical conductors in the lead is confirmed, the pump should be replaced as soon as possible.**

In cases where there is a disruption to the continuity of the wires in the percutaneous lead, damage may occur to the System Controller. Should damage to the System Controller occur and the Controller require changing, consideration should be given to supporting the patient with batteries, rather than the Power Module (PM), as this will reduce the potential of damaging the System Controller.

14.4 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 or by using the HeartMate

GoGear™ Shower Bag. Furthermore, the exit site must be kept dry. Adhere to the following guidelines for patient showers:

- 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 swim or take tub baths.
- Keep the exit site as dry as possible.
- Avoid excessive pulling on the percutaneous lead.
- Follow the *HeartMate GoGear ShowerBag IFU* (document #104614)

14.4.1 Getting Ready to Shower

1. Unzip and open the shower bag's water resistant enclosure (**Figure 108**).
2. Clip the System Controller into place and secure it using the two Velcro stabilization straps.
3. Put all connectors and cables inside the GoGear shower bag enclosure

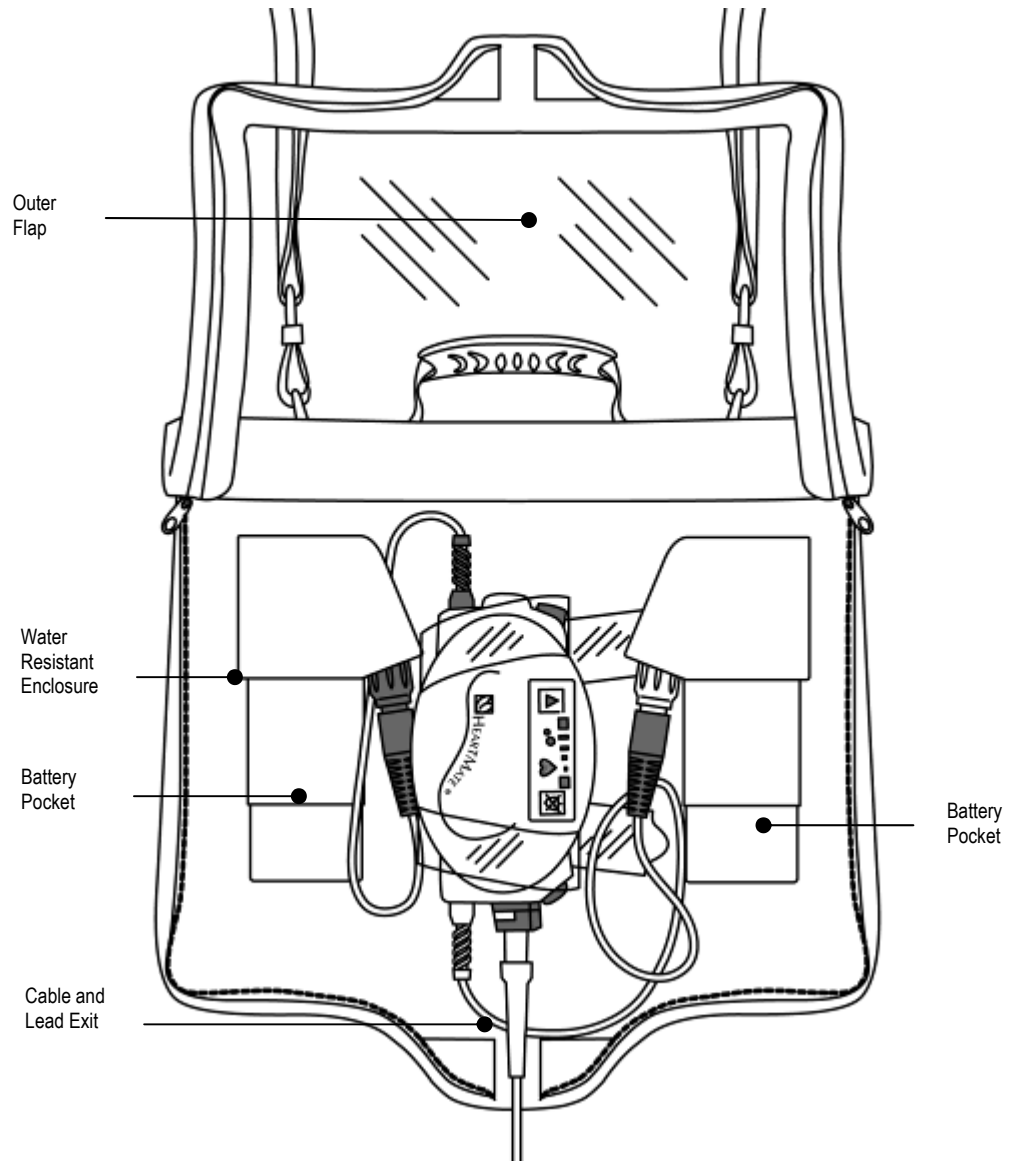


Figure 108 Shower Bag Enclosure and Compartments

14.4.2 Showering while Connected to Batteries

After following the directions in *Getting Ready to Shower*, the System Controller should be properly installed into the shower bag. The patient is either on PM power and ready to switch to battery power or is already on battery power wearing a GoGear holster vest, modular belt, or consolidated bag.

If the Patient is on PM Power and Wants to Switch to Batteries for Showering

- 1 Place two charged batteries and battery clips within easy reach.
- 2 Insert charged batteries into compatible battery clips.
- 3 Insert each battery/battery clip, one at a time, into each pocket on either side of the shower bag enclosure.
- 4 Unscrew the **black** System Controller/ PM power lead connectors. *An alarm will sound.*
- 5 Put aside the **black** PM power lead connector; then connect the **black** system controller connector to the battery clip connector. *The alarm will stop.*
- 6 Unscrew the **white** system controller/ PM power lead connectors. *An alarm will sound.*
- 7 Put aside the **white** PM power lead connector; then connect **white** system controller connector to the battery clip connector. *The alarm will stop.*
- 8 Keep the PM patient cable connected to, or nearby, the PM until next use. If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet, and so that it will not cause tripping or falling.

Transferring Batteries to the Shower Bag

- 1 Insert each battery/battery clip, one at a time, into each pocket on either side of the shower bag enclosure.
- 2 Once you have transferred the batteries/battery clips remove the GoGear wearable accessory (holster vest, modular belt, or consolidated bag).

WARNING!

Keep the PM away from water or moisture. If the PM has contact with water, moisture, shower spray, rain/snow, etc, the LVAD may stop or you may receive a serious electric shock or the PM may not work properly.

14.4.3 Showering on PM Power

After following the directions in the *Getting Ready to Shower*, the System Controller should be properly installed into the shower bag. The patient is already on PM power.

- 1 Place the percutaneous lead and the PM patient cable so that they will both exit through the bottom of the shower bag.
- 2 Place the PM higher than the patient's exit site to keep water from flowing down the power cable and into the PM.

If showering while connected to PM Power, be sure to locate the PM higher than the patient's exit site to prevent water from flowing along the power cable and back to the PM.

14.4.4 Putting on the Shower Bag

After following the directions in either *Showering on Battery Power* or *Showering on PM Power*, the patient is now ready to put on the shower bag.

- 1 Use the left and right zippers to close and seal the shower bag.
- 2 Use the shower bag strap to hang the bag either:
 - Over the patient's head and shoulder so it's hanging at his or her side
 - Around the patient's neck so it's hanging in front of the patient.
- 3 Keep the exit site as dry as possible.



NOTE:

The strap is adjustable. Adjust the shower bag so it does not pull on the exit site while showering.

14.4.5 After Showering

1. Use a sterile 4" X 4" gauze bandage to dry the exit site.
2. Apply a sterile dressing to the exit site, using the "sterile" technique taught to you by your hospital contact person (see section 14.2, *Exit Site Care* for guidelines).
3. Use a clean, dry towel to dry the GoGear shower bag's exterior and strap.
4. Use the left and right zippers to open the shower bag.
5. Remove all equipment from the shower bag enclosure and return it to your GoGear Wearable accessories (holster vest, modular belt, or consolidated bag).
6. Remove the shower bag and allow it to drip dry. Let the bag dry completely before using it again.

14.4.6 Caring for the Shower Bag

Keeping the GoGear shower bag clean helps it work properly. If the shower bag gets dirty, it can be washed *by hand* using mild detergent and cold water. Once the bag has been washed, hang it to drip dry. Never heat the shower bag to dry it; always let it dry on its own. Make sure the shower bag is completely dry before using it for another shower.

Periodically inspect the GoGear shower bag for damage or wear. If you have problems or questions about using the shower bag, refer to the *HeartMate GoGear Shower Bag IFU* (document #104614) or contact Thoratec Corporation.

14.5 Preparing for Sleep

The patient must always be attached to the PM while sleeping or when anticipating sleep. 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 his or her abdomen. The System Controller clips onto the stabilization belt to reduce System Controller movement.

Nightly, the following guidelines must be observed:

- The patient must plan on sleeping only when connected to the PM. 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.
- The patient should not sleep on his or her stomach. Generally, HeartMate patients will be most comfortable sleeping on their backs.
- A spare System Controller should always be kept near the patient during sleep. Charged batteries, battery clips, and a flash light should also be kept within reach in case of a power outage.

14.6 Other Patient Care Considerations

14.6.1 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.

14.6.2 External Chest Compressions

There may be risks associated with performing external chest compressions in the event of cardiac arrest, due to the location of the outflow graft and the presence of ventricular apical anastomosis. Performing external chest

compressions may result in damage to the outflow graft conduit or 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 implantation (prior to mediastinal healing).

14.6.3 Defibrillation

If **external defibrillation** becomes necessary, do NOT disconnect the System Controller from the percutaneous lead prior to delivering the shock.

If **open chest defibrillation** is required, it is advised that the HeartMate II LVAS be disconnected prior to delivering the shock.

14.6.4 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.
- Blood draining from the percutaneous lead exit site.
- Evidence of decreased hemoglobin/hematocrit.



NOTE:

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

WARNING!

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

14.6.5 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.

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.

14.6.6 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.

14.6.7 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.

WARNING!

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

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).

14.6.8 Implantable Defibrillators or Pacemakers

Prior to implanting an implantable cardiac defibrillator (ICD) or implantable pacemaker (IPM) in a HeartMate II patient, the device to be implanted should be placed in close proximity to the pump (approximately 10 cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously-implanted device that is found to be susceptible to electromagnetic interference, which could affect programming, Thoratec Corporation recommends replacing the ICD device with one that is not prone to programming interference. Specific information on reported cases can be obtained on Thoratec's website at www.thoratec.com. No such difficulties have been reported, other than those observed with device(s) listed on the website.

PERIODIC INSPECTION, CLEANING & MAINTENANCE

15.0 Periodic Inspection, Cleaning & Maintenance

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

15.1 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 (section 14.2).

CAUTION!

Do NOT clean or service the following equipment while it is connected to a LVAS patient: System Controller, PM, PM patient cable, System Monitor, batteries, battery clip, EPP, and EPP cable.

Sterile components are intended for single use only.

15.2 System Controller

Perform the System Controller self-test (section 8.37) 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 PM. Check both System Controller connectors and both PM 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 call Thoratec for technical support. Users in the United States should dial 925-847-8600 during regular business hours or call the 24-hour HeartLine™: 800-456-1477.

15.3 Power Module (PM)

The HeartMate PM requires little maintenance. However, it should be inspected routinely for the safest and best possible performance:

- **Once a day**, perform a PM System Self Test (see section 9.2.3, *Monitoring PM Performance and Performing a PM System Self Test*).
- **Any time you switch** from batteries to PM-powered operation (e.g., before the patient goes to bed at night), inspect the connector pins and sockets for damage, dirt, grease, etc.
- **At least once a week**, inspect the power cord used to connect the PM to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from Thoratec
- **At least once a week**, inspect the patient cable used to connect the patient to the PM. Make sure the cable is not kinked, split, cut, cracked, or frayed. Do not use the cable if it shows signs of damage. Obtain a replacement from Thoratec Corporation, if needed.
- **Once a month**, inspect the pins and sockets of the PM patient cable/lead connectors for damage, dirt, grease, etc.
- **Once a month**, inspect the pins and sockets of the automobile DC input cable for damage, dirt, grease, etc.

CAUTION!

Service and maintenance of the HeartMate Power Module should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

If you discover damage or contamination on the pins/sockets, do **NOT** attempt to clean the pins/sockets yourself. Report the condition to Thoratec. Cleaning and service should be performed only by Thoratec-trained and authorized technicians. Do **NOT** attempt to clean or repair equipment on your own.

Do NOT disconnect the connectors between the System Controller and percutaneous lead. The pins/sockets for this connection should be inspected only when replacing System Controllers (see section 8.3.9, *System Controller Replacement*).

WARNING!

NEVER clean the PM while it is connected to the patient and powering the system. Switch to battery power first. Before cleaning the PM, turn off the device and unplug all connections.



NOTE:

Avoid blocking or covering the air vents on the PM when the device is in use. Blocking or covering the vents during use can affect device performance.

Cleaning the PM

Periodically and as needed, UNPLUG the PM and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner if necessary. Do NOT immerse the PM in water or liquid. Do not clean the PM while it is being used to power the LVAS.

Routine Service/Maintenance for the PM

At least once a year bring the HeartMate PM to an authorized service technician for a thorough inspection and cleaning that includes (but need not be limited to) the following:

- -Functional test of device
- -Cleaning and inspection of all internal components
- -Replacement of internal backup battery

CAUTION!

Service and maintenance of the HeartMate PM should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

Contact Thoratec to coordinate an annual PM inspection/ maintenance. Be sure the PM's internal backup battery is re-connected after service/maintenance or shipping/ transportation (see section 9.2.1, *Connecting the Internal Backup Battery*).

The PM's internal backup battery contains lead. Dispose of the PM's internal backup battery in compliance with all applicable local, state, and federal laws and regulations. Never incinerate discarded PM batteries.

Dispose of or recycle PM and PM electronics in compliance with all applicable local, state, and federal laws and regulations.

15.4 Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. Follow these guidelines and instructions for inspecting and cleaning batteries:

- **Once a week**, inspect batteries for physical damage, including checking the battery contacts for denting or damage. Do NOT use batteries that appear damaged. Damaged batteries must be replaced.
- **Once a month**, check the manufacture date on the label on all batteries to see if any batteries are older than three years. If it has been three years or more since a battery was manufactured, that battery has expired. Do NOT use expired batteries. Expired batteries must be replaced.
- **Once a month**, check the number of use/charge cycles for each battery to see if the batteries have exceeded 360 cycles. Do NOT use batteries that have exceeded 360 cycles. Batteries that have exceeded 360 cycles must be replaced. Insert a battery into the UBC to read the number of cycles. This information will be displayed on the charger's display panel screen (see section 11.3.2, *Viewing Battery Information on the Display Panel*).
- **Once a month**, clean the metal battery contacts and the interior contacts of battery clips using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol (**Figure 109**). Do NOT clean batteries while using them to power the LVAS. Allow the alcohol dry before using newly cleaned batteries or clips.
- **Periodically and as needed**, clean the exterior surfaces of batteries using a clean, dry cloth. Do NOT use liquids (e.g., water or liquid cleaning solvent) to clean batteries. Do NOT immerse batteries in water or liquid.



Figure 109 Cleaning Battery Contacts and Contacts Inside Battery Clips

15.5 Emergency Power Pack (EPP)

- **Once a month, check the expiration date** on the EPP. An EPP should NOT be used past its expiration date.
- **Once a week, inspect the EPP for physical damage.** 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.**
- **Once a month, inspect the EPP cable connector pins** for dirt and grease. Do NOT attempt to clean the connector pins if you find contamination. Instead, report the condition to the hospital's technical support staff or call Thoratec technical support. Users in the United States should dial 925-847-8600 during regular business hours or call the 24-hour HeartLine™: 800-456-1477.

CAUTION!

Service and maintenance of the HeartMate EPP should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

15.6 Universal Battery Charger (UBC)

The HeartMate Universal Battery Charger (UBC) requires little maintenance. However, it should be inspected routinely for the safest and best possible performance:

- **Once a week**, inspect the UBC for signs of physical damage, such as dents, chips, or cracks. Do NOT use the charger if it shows signs of damage. Obtain a replacement from your VAD Coordinator or hospital contact person.
- **Once a week**, inspect the power cord used to connect the UBC to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your VAD Coordinator or hospital contact person.
- **Once a month**, UNPLUG the UBC and clean the metal contacts inside all four charging pockets with a lint-free cloth or swab that has been moistened

CAUTION!

Service and maintenance of the HeartMate UBC should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

(not dripping) with rubbing alcohol. Allow the alcohol to dry before inserting batteries into pockets.

- **Periodically, and as needed**, UNPLUG the charger and clean the exterior surfaces of the UBC using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner if necessary. Do NOT immerse the charger in water or liquid.
- **At least once a year** bring the HeartMate UBC to an authorized service technician for a thorough safety inspection and cleaning that includes (but need not be limited to) the following:
 - Functional test of device
 - Cleaning and inspection of all internal components

16.0 Acceptable Environmental Conditions

For safe and optimal use of HeartMate equipment, adhere to the guidelines outlined below. Transporting, sorting, or operating equipment outside the environmental parameters outlined below may affect device operation or result in equipment failure.

16.1 Transportation and Storage

Environmental conditions acceptable for the transportation and storage of HeartMate equipment appear in **Table 14** below.

EQUIPMENT	ACCEPTABLE TEMPERATURE RANGE °F (°C)	RELATIVE HUMIDITY	AIR PRESSURE mmHg (hPA)
Power Module (PM)	5° F to 104° F (-15°C to 40°C)	10 to 93%	375 to 795 (500 to 1060)
PM Patient Cable	5°F to 122°F (-15°C to 50°C)	10 to 93%	375 to 795 (500 to 1060)
System Monitor	5° F to 104° F (-15°C to 40°C)	10 to 93%	375 to 795 (500 to 1060)
Batteries	14°F to 104°F (-10°C to 40°C)	10 to 93%	375 to 795 (500 to 1060)
Universal Battery Charger (UBC)	-4°F to 140°F (-20°C to 60°C)	10 to 93%	375 to 795 mmHg 500 to 1060 hPA (14.8 to 31.3 inHg)
Emergency Power Pack (EPP)	5°F to 122°F (-15°C to 50°C)	10 to 93%	375 to 795 (500 to 1060)
EPP Cable	5°F to 122°F (-15°C to 50°C)	10 to 93%	375 to 795 (500 to 1060)

Table 14 Acceptable Environmental Conditions for Transportation & Storage

16.2 Operation

Environmental conditions acceptable for operating HeartMate equipment appear in **Table 15** below.

EQUIPMENT	ACCEPTABLE TEMPERATURE RANGE °F (°C)	RELATIVE HUMIDITY	AIR PRESSURE mmHg (hPA)
Power Module (PM)	32° F to 104° F (0°C to 40°C)	30 to 75%	525 to 795 (700 to 1060)
System Monitor	50° F to 104° F (10°C to 40°C)	30 to 75%	525 to 795 (700 to 1060)
Batteries	32°F to 104°F (0°C to 40°C)	30 to 75%	525 to 795 (700 to 1060)
Universal Battery Charger (UBC)	32°F to 104°F (0°C to 40°C)	30 to 75%	525 to 795 mmHg 700 to 1060 hPA (20.7 to 1.3 inHg))
Emergency Power Pack (EPP)	32°F to 122°F (0°C to 50°C)	30 to 75%	525 to 795 (700 to 1060)
EPP Cable	5°F to 122°F (-15°C to 50°C)	30 to 75%	525 to 795 (700 to 1060)

Table 15 Acceptable Environmental Conditions for Operating HeartMate Equipment

17.0 Product Disposal

Specific product disposal considerations for certain HeartMate equipment appear below. Otherwise, dispose of all expired or damaged equipment according to applicable local, state, and federal laws and regulations. For additional product disposal support and information, call the Thoratec HeartLine (1-800-456-1477 in the United States).

Batteries

HeartMate 12-volt NiMH battery cells and 14 volt Li-Ion battery cells do NOT contain lead. Dispose of/recycle HeartMate batteries in compliance with all applicable local, state, and federal laws and regulations. Do NOT incinerate.

Power Module (PM)

The PM's internal backup battery contains lead. Dispose of the PM's internal backup battery in compliance with all applicable local, state, and federal laws and regulations. Never incinerate discarded PM batteries. Dispose of or recycle PM and PM electronics in compliance with all applicable local, state, and federal laws and regulations.

System Monitor

The System Monitor contains a lithium battery (non serviceable). Dispose of/recycle the System Monitor's internal battery in compliance with all applicable local, state, and federal laws and regulations. Never incinerate discarded System Monitor batteries.

Medical Waste Disposal

The explanted HeartMate II LVAD and interconnect cables must be disposed of in compliance with all applicable local, state, and federal laws and regulations concerning medical waste.

TROUBLESHOOTING

18.0 Troubleshooting

The Troubleshooting section 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.

18.1 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 16** 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 16 Hazard Alarms

18.2 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 PM.
3. If alarm continues, change the power source (charged batteries or PM).
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.

18.3 Advisory Events

Advisory events require immediate attention. The System Controller signals for advisory events are

- Visual Signal: Flashing green power symbol, battery fuel gauge lights, yellow battery, or yellow battery module
- Audible Signal: Audible alarms are different for almost every alarm, ranging from no audible alarm, to an alarm every four seconds, every second, or for two seconds followed by two seconds of silence.

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 Cell Low
- WARNING: Low Speed Operation

The Display Module messages for advisory events are displayed in descending order of priority:

- Power Cable Disc (i.e., Power Cable Disconnected)
- SC Battery Module Low (i.e., System Controller battery module cell low)
- LOW VOLTAGE
- LOW VOLTAGE Advisory
- Replace System Controller

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 PM power.
2. If the yellow battery symbol is illuminated while connected to the PM, switch to charged batteries.
3. If an audio tone at one beep every four seconds is the only advisory warning (i.e., 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.

18.4 Alarm Corrective Actions

Table 17 provides a summary of all HeartMate II LVAS alarm conditions and corrective actions. See section 8.3.6 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"> 1. Check connection between System Controller and LVAD. 2. Check connection between System Controller and power source (batteries, PM, or emergency power pack). 3. If alarm continues, seek additional help immediately. See warning below table*
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"> 1. Check connection between System Controller and power source (batteries, PM, or emergency power pack). 2. Change power source. 3. Change System Controller. See warning below table*
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 PM.	Immediately replace batteries or change to alternate power source. LVAD will automatically go into power saver mode (8,000 rpm). WARNING: 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 PM.	Replace batteries or change to alternate power source.

Continued on following page

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 > 8,000 rpm, pump should restart automatically.

Table 17 Alarm Condition Corrective Actions

Table 17 (continued)

<p>Audio tone of 1 beep every second & flashing green power symbol and flashing battery fuel gauge lights</p>	<p>Power Cable Disconnected</p>	<p>Advisory</p>	<p>One of the power leads is disconnected or damaged.</p>	<p>1. Reconnect power lead. 2. If alarm continues, check System Controller and PM power lead for damage. 3. If PM or System Controller power lead is damaged, change PM patient cable or System Controller.</p>
<p>Audio tone of 1 beep every 4 seconds & yellow battery module symbol.</p>	<p>Low (on System Monitor) Driver Cell Low (on Display Module)</p>	<p>Advisory</p>	<p>Battery module that provides back-up power to System Controller audible alarms is depleted.</p>	<p>Replace alarm battery module.</p>
<p>Audio tone of 1 beep every 4 seconds & no warning light when on batteries or PM with Display Module. No audio tone or warning light when on PM with System Monitor.</p>	<p>WARNING: Low Speed Operation</p>	<p>Advisory</p>	<p>Pump is operating below low speed limit.</p>	<p>Connect System Controller to System Monitor (audio alarm will stop) and increase fixed speed or reduce low speed limit.</p>
<p>Audio tone: repeating cycle of 1 beep per second for two seconds, followed by 2 seconds of silence; but no warning light.</p>	<p>Replace System Controller (on System Monitor) Replace System Driver (on Display Module)</p>	<p>Advisory</p>	<p>System Controller is operating in backup mode.</p>	<p>Replace System Controller. See warning below table*</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 > 8,000 rpm, pump should restart automatically.

18.5 Emergency Power Pack (EPP)

The EPP is a single use battery pack enclosed in a plastic carrying case with a shoulder strap (**Figure 110**). 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 nominal conditions (flow of 6.0 lpm with a mean arterial pressure of 115 mmHg). 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. It is mandatory for HeartMate II patients.

- 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 PM patient cable. 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.

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 or cold 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.

4. Unscrew the black System Controller power lead connector from the patient's battery clip or PM patient cable. 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.

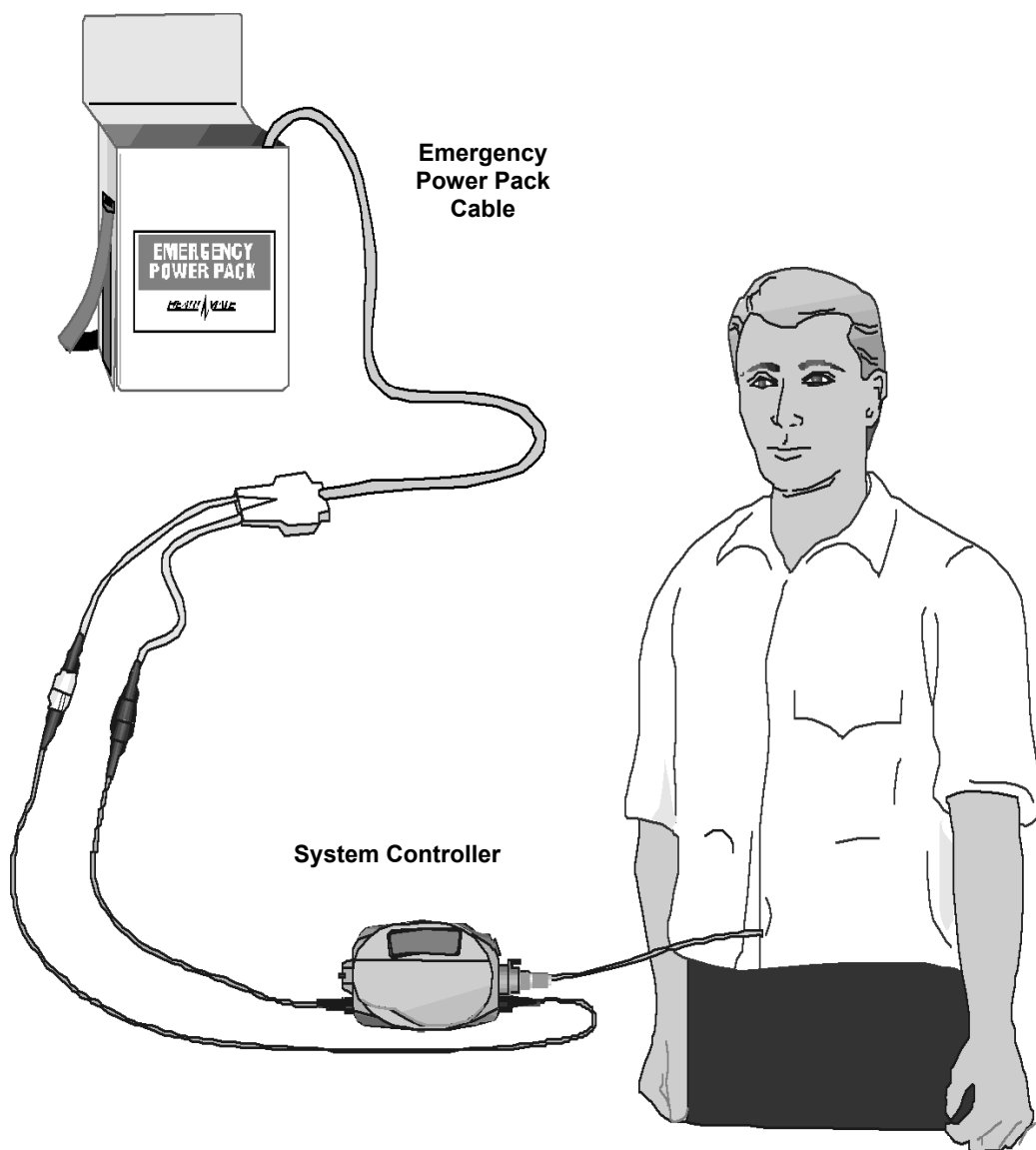


Figure 110 Emergency Power Pack Configuration

FREQUENTLY ASKED QUESTIONS

19.0 Frequently Asked Questions

Q: After inserting a good battery into the universal battery charger (UBC), the red light for this charging pocket turns red. Why is that and what do I do?

A: The battery may not be fully into the charging pocket. Remove the battery and reinsert it into the same pocket. If the red battery illuminates again, repeat the process with another charging pocket. If the red light illuminates for the new pocket, the battery is defective. Do not use it. Contact Thoratec for a replacement.

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

A: Make sure the UBC is plugged in and the AC mains outlet is functioning.

TESTING & CLASSIFICATION

20.0 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 60601-1:2006 and CAN/CSA-C22.2 No. 601.1-M90: 2002. In addition, the HeartMate II LVAS meets the following safety standards EN 60601-1:1990 and IEC 60601-1: 1998, 2nd Edition, A1:1991, A2:1995.

20.1 Classification Concerning General Safety

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) or battery powered
Degree of protection against electric shock	Type CF (Cardio AP, 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 Batteries w/ Clips – IPX3 Power Module (PM) & Universal Battery Charger (UBC) - IPX0 System Monitor IPX0 (s/n <2000) System Monitor IPX1(s/n >2000)

20.2 Testing and Classification: Power Module (PM)

The HeartMate Power Module (PM) complies with the following safety standards:

- IEC 60601-1: 1998, 2nd Edition, A1:1991, A2:1995.
- UL 60601-1, 1st Edition, 2006-04-26 (included National Differences for USA)
- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98(National Difference for Canada)

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the 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 Technical Service for assistance.

Classification Concerning General Safety

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type CF (Cardio AP, 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	IPX0



Medical Electric Equipment
 with respect to shock, fire,
 mechanical and other specified
 hazards only in accordance with
 UL 60601-1 and CAN/CSA C22.2
 No.601.1-M90 (R1997), CAN/CSA C22.2
 No.601.1S1-94, and CAN/CSA C22.2
 No.601.1B-98 (National Difference for Canada)

Declaration and Guidance Concerning Electromagnetic Emissions

The HeartMate II LVAS (with Power Module) 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 EN 55011	Group 1	The HeartMate HM 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 EN 55011	Class B	The HeartMate HM II LVAS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 EN 61000-3-3	Complies	
Radiated emissions, magnetic field MIL-STD-461E	RE101-1	The HeartMate HM 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.

Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate II LVAS equipment, including the Power Module & System Monitor

The HeartMate II LVAS (with Power Module) 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. ± 6 kV contact min. ± 8 kV air	System Monitor (s/n below 2000) and Display Module [± 6] kV contact [± 8] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	min. ± 6 kV contact min. ± 8 kV air	Power Module, System Monitor (s/n above 2000), LVAD, and System Driver [± 8] kV contact [± 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 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	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s where $U_T = 100$ VAC, 120 VAC, 230 VAC, or 240 VAC,	Mains power quality should be that of a typical commercial or hospital environment. The Power Module contains an internal battery, which will provide uninterruptible power for a minimum of $\frac{1}{2}$ hr. NOTE: U_T 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	30 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.

Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate II LVAS Equipment, including LVAD, System Controller, and Power Module

The HeartMate II left ventricular assist device (LVAD), System Controller, and Power Module are intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate II LVAD, System Controller, and Power Module 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.	
			Recommended Separation Distances	
Conducted RF IEC 61000-4-6 EN 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	[10] Vrms	$d = \left[\frac{12}{10} \right] / P$	
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	[10] Vrms	$d = \left[\frac{12}{10} \right] / P$	
Radiated RF IEC 61000-4-3 EN 61000-4-3	Min. 10 V/m 80-825 MHz, 960-1400 MHz, and 2.0-2.5 GHz 825-960 MHz and 1.4-2.0 GHz	AC Operation [10] V/m DC Operation [20] V/m AC/DC Operation [56] V/m	AC Operation 12 $d = \left[\frac{12}{10} \right] / P$ 10 80 MHz to 800 MHz	DC Operation 12 $d = \left[\frac{12}{20} \right] / P$ 20 80 MHz to 800 MHz
			23 $d = \left[\frac{23}{10} \right] / P$ 10 800-825, 960-1400 MHz and 2.0-2.5 GHz	23 $d = \left[\frac{23}{20} \right] / P$ 20 800-825, 960-1400 MHz and 2.0-2.5 GHz
			AC/DC Operation 23 $d = \left[\frac{23}{56} \right] / P$ 56 825-960 MHz and 1.4- 2.0 GHz	
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b	

Testing & Classification

			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.</p> 
Radiated RF	Frequency Range	137 V/m	
MicroWave Ovens	890-940 MHz CW and 2.4-2.5 GHz CW		

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.

- ^a 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.
- ^b 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.
- ^c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment 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.

WARNING!

Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emissions or decreased immunity of the HeartMate II LVAS guidelines. Do not incinerate.

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.

20.3 Testing and Classification: Universal Battery Charger (UBC)

The HeartMate Universal Battery Charger (UBC) complies with the following safety standards:

- IEC 60601-1: 1998, 2nd Edition, A1:1991, A2:1995.
- UL 60601-1, 1st Edition, 2006-04-26 (included National Differences for USA)
- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98(National Difference for Canada)

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the 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 Technical Service for assistance.

Classification Concerning General Safety

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against electrical shock	Class I (grounded)
Degree of protection against electric shock	No Applied Part
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Degree of protection against harmful ingress of water	IPX0



Medical Electric Equipment
 with respect to shock, fire,
 mechanical and other specified
 hazards only in accordance with
 UL 60601-1 and CAN/CSA C22.2
 No.601.1-M90 (R1997), CAN/CSA C22.2
 No.601.1S1-94, and CAN/CSA C22.2
 No.601.1B-98 (National Difference for Canada)

Declaration and Guidance Concerning Electromagnetic Emissions

The HeartMate Universal Battery Charger (UBC) is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate UBC should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment Guidance
RF emissions CISPR 11 EN 55011	Group 1	The HeartMate Universal Battery Charger 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 EN 55011	Class B	The HeartMate Universal Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 EN 61000-3-3	Complies	
Radiated emissions, magnetic field MIL-STD-461E	RE101-1	The HeartMate Universal Battery Charger 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.


Declaration and Guidance Concerning Electromagnetic Immunity for the HeartMate Universal Battery Charger (UBC)

The HeartMate Universal Battery Charger (UBC) is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate UBC 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. ± 6 kV contact min. ± 8 kV air	UBC [± 6] kV contact [± 8] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 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	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s where $U_T = 100$ VAC, 120 VAC, 230 VAC, or 240 VAC,	Mains power quality should be that of a typical commercial or hospital environment. The Power Module contains an internal battery, which will provide uninterruptible power for a minimum of $\frac{1}{2}$ hr. NOTE: U_T 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 Universal Battery Charger 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.

Declaration and Guidance Concerning Electromagnetic Immunity for the HeartMate Universal Battery Charger (UBC)

The HeartMate Universal Battery Charger (UBC) is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate UBC should assure that they are used in such an electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			<p>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.</p> <p style="text-align: center;">Recommended Separation Distances</p>
<p>Conducted RF</p> <p>IEC 61000-4-6 EN 61000-4-6</p>	<p>Min. 3 Vrms</p> <p>150 kHz to 80 MHz outside ISM bands^a</p>	[3] Vrms	$d = \left[\frac{12}{3} \right] / P$
<p>Radiated RF</p> <p>IEC 61000-4-3 EN 61000-4-3</p>	<p>Min. 3 V/m</p> <p>80 MHz to 2.5 GHz</p>	[3] V/m	$d = \left[\frac{12}{3} \right] / P$ <p style="text-align: center;">80 MHz to 800 MHz</p> $d = \left[\frac{23}{3} \right] / P$ <p style="text-align: center;">800 MHz to 2.5 GHz</p> <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).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.</p> <div style="text-align: right;">  <p><i>continued</i></p> </div>

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.

- ^a 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.
- ^b 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.
- ^c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate Universal Battery Charger is used exceeds the applicable RF compliance level above, HeartMate Universal Battery Charger 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 Universal Battery Charger.

WARNING!

Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emissions or decreased immunity of the HeartMate II LVAS.

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

20.4 Testing and Classification: HeartMate 12 NiMH Batteries & 14 VoltLi-Ion Batteries

HeartMate 12 volt nickel metal hydride (NiMH) batteries and 14 volt lithium ion (Li-Ion) batteries comply with the following safety standards:

- IEC 62133
- UL 2054

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the 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 Technical Service for assistance.

Classification Concerning General Safety

Type	Degree of Protection
Degree of protection against electric shock:	No Applied Part
Degree of protection against ingress of water:	Batteries w/ Clips – IPX3
Degree of safety in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:	Not suitable
Mode of operation:	Continuous



Declaration and Guidance Concerning Electromagnetic Emissions

The HeartMate II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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 EN 55011	Group 1	The HeartMate HM II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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 EN 55011	Class B	The HeartMate HM II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated emissions, magnetic field MIL-STD-461E	RE101-1	The HeartMate HM II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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.
Radiated emissions Avionics RTCA/DO-160E Section 21	Class M	The HeartMate HM II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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.

Declaration and Guidance Concerning Electromagnetic Immunity for the HeartMate II LVAS with 12 Volt NiMH Batteries or 14 Volt Li-Ion Batteries

The HeartMate II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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. ± 6 kV contact min. ± 8 kV air	NiMH and Li-ION Batteries and System Controller with LVAD [± 8] kV contact [± 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	If disturbance occurs, it may be necessary to position the HeartMate II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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.


Testing & Classification

The HeartMate II left ventricular assist system (LVAS), with 12 volt NiMH batteries or 14 volt Li-Ion batteries is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion 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.
			Recommended Separation Distances
Conducted RF IEC 61000-4-6 EN 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	[10] Vrms	12 $d = [\frac{\quad}{10}] / P$
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	[10] Vrms	12 $d = [\frac{\quad}{10}] / P$
Radiated RF IEC 61000-4-3 EN 61000-4-3	Min. 10 V/m 80-825 MHz, 960-1400 MHz, and 2.0-2.5 GHz	Battery Operation [20] V/m	Battery Operation 12 $d = [\frac{\quad}{20}] / P$ 80 MHz to 800 MHz
	825-960 MHz and 1.4-2.0 GHz	AC/DC Operation [56] V/m	23 $d = [\frac{\quad}{20}] / P$ 800-825, 960-1400 MHz and 2.0-2.5 GHz
			Battery Operation 23 $d = [\frac{\quad}{56}] / P$ 825-960 MHz and 1.4- 2.0 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b

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			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.</p> 
<p>Radiated RF</p> <p>MicroWave Ovens</p>	<p>Frequency Range</p> <p>890-940 MHz CW and 2.4-2.5 GHz CW</p>	<p>137 V/m</p>	
<p>Avionics</p> <p>Radiated and conducted RF</p> <p>RTCA/DO-160E Section 20</p>	<p>Frequency Range</p> <p>Conducted 10 kHz to 400 MHz</p> <p>Radiated 100 MHz to 8 GHz</p>	<p>Class R</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.

^a 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.

^b 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.

- ^c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment 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 with 12 volt NiMH batteries or 14 volt Li-Ion batteries is used exceeds the applicable RF compliance level above, HeartMate II LVAS with 12 volt NiMH batteries or 14 volt Li-Ion batteries 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 with 12 volt NiMH batteries or 14 volt Li-Ion batteries.

WARNING!

Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emissions or decreased immunity of the HeartMate II LVAS.

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

Appendix I HeartMate II Technical Specifications

Rotary Left Ventricular Assist Device (LVAD)

Cat. #103695

BLOOD VOLUMES-FLUID CAPACITY

DIMENSIONS (pump body)

Diameter	4.3 cm (1.7")
Length	(excluding conduits) 8.1 cm (3.2")
WEIGHT (pump body)	281.3 g (9.9 oz)
GROSS VOLUME	63 cc (3.8 ci)
PRIMING VOLUME	7 cc (0.43 ci)

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 HeartMate II System ControllerCat. # 1315

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

17.8 cm
(7")

Width

5.7 cm
(2 1/4")

Height

9.5 cm
(3 3/4")**WEIGHT**650 g
(23 oz)

Power Module (PM)

Cat. #1340 (No. America)

ACTIVE FUNCTIONS	<p>Isolated power to patient during tethered operation</p> <p>Communication interface between System Controllers and System Monitor / Display Module</p> <p>When new, mains failure back-up battery (30 minutes)</p>
MONITORING FUNCTIONS	<p>Isolated bidirectional data link to external Display Module or System Monitor</p> <p>Isolated dual-channel analog uplink Mains failure Advisory / Hazard LO BATT alarm for internal Back- up Battery</p> <p>“Echoes” System Controller Audio Alarm</p> <p>System Malfunction Alarm (Yellow Wrench)</p>
POWER REQUIREMENTS	<p>100-240 VAC, 50/60 Hz, 1 A maximum</p> <p>13.5 VDC, 5 A maximum</p>
FUSE RATING	T 2A, 250 V
DIMENSIONS	
Length	381 mm (15")
Width	254 mm (10")
Height	127 mm (5")
WEIGHT	4.8 Kg (with back-up Battery) (10.5 lbs)
PRODUCT LIFE	Two years from date of first use

Power Module (PM) Patient CableCat. # 2225

TYPE	A Cable assembly with one straight plug connector with sliding interlock and composite strain relief for connection to the PM, and one standard two custom thread-locking power connectors for connection to the System Controller.
FUNCTION	To provide electrical connection between the System Controller and the PM.
LENGTH	6.1 meters (20 feet)
PRODUCT LIFE	One year from date of first use

Cat. # (set of 4): 1260
 Part # (single battery):
 102474

HeartMate 12 Volt NiMH Battery

PERFORMANCE DATA

Type	12 volt, nickel metal hydride batteries (NiMH).
Capacity	3.6 amp-hour each.
Discharge Time	One pair of new HeartMate 12 volt NiMH batteries will provide at least six hours of support at the "higher end" of nominal operating conditions for a HeartMate II LVAS (pump speed = 12K rpm, flow 6.0 lpm, 10 watts).
Fuel Gauge	5-LED, button activated
Charge Time	Four (4) hours max. (using HeartMate Universal Battery Charger).
Cycle Life	360 cycles (as reported when the battery is inserted in to a charging pocket of the HeartMate Universal Battery Charger) or three (3) years from the date of manufacture, whichever comes first.

DIMENSIONS

Length	180mm (7.1")
Width	76mm (3.0")
Height	25mm (1.0")

WEIGHT

0.65Kg (1.44 lb) System accommodates two batteries

12 Volt Battery Clip (one pair)

Cat. # 2665

DIMENSIONS

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

WEIGHT

104g (3.7 oz) without battery

Cat. # (set of 4): 2465
 Part # (single battery):
 102515

HeartMate 14 Volt Li-Ion Battery

PERFORMANCE DATA

Type	14 volt, lithium ion (Li-Ion)
Capacity	3.6 amp-hour each.
Discharge Time	One pair of new HeartMate 14 volt Li-Ion batteries will provide six to ten hours of support under nominal operating conditions for a HeartMate II LVAS (pump speed = 12,000 rpm, flow 6.0 lpm, 10 watts).
Fuel Gauge	5-LED, button activated
Charge Time	Four (4) hours max. (using HeartMate Universal Battery Charger).
Cycle Life	360 cycles (as reported when the battery is inserted in to a charging pocket of the HeartMate Universal Battery Charger) or three (3) years from the date of manufacture, whichever comes first.

DIMENSIONS

Length	160mm (6.3")
Width	76mm (3.0")
Height	25mm (1.0")

WEIGHT

0.65Kg (System accommodates two batteries)
 (1.44 lb)

14 Volt Battery Clip (one pair)

Cat. # 2865

DIMENSIONS

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

WEIGHT

104g (without battery)
(3.7 oz)

Display ModuleCat. # 1280N

Type 2-line vacuum fluorescent

Function
(PI).

Displays speed (rpm), Flow (lpm) and Pulsatility Index

Displays speed mode, power (watts), and prioritized alerts and advisories.

DIMENSIONS

Length	254mm (10")
Width	190mm (7.5")
Height	76mm (3")

WEIGHT

0.7 Kg (1.54 lb)

Universal Battery Charger (UBC) Cat. #1440 (No. America)

ACTIVE FUNCTIONS Four pocket simultaneous battery charging for HeartMate 12 volt NiMH batteries (part no. 102474) and 14 volt Li-Ion batteries (part no. 102515).
Battery Chemistry: 12 volt batteries are nickel metal hydride (NiMH); 14 volt batteries are lithium ion (Li-Ion).

Battery calibration and diagnostics

MONITORING FUNCTIONS Battery fault monitoring (with alarm codes)
Battery charger fault monitoring (with alarm codes)

POWER REQUIREMENTS 100-240 VAC, 50-60 Hz, 3A (maximum)
Fuse Rating - T5A, 250 V

DIMENSIONS

Length 370mm
 (14.5")

Width 216mm
 (8.5")

Height 227mm
 (9")

WEIGHT 3.6 Kg
 (8 lbs)

OPERATING ENVIRONMENT

Equipment	Acceptable Temperature Range	Relative Humidity	Air Pressure
Universal Battery Charger	0°C to 40°C (32°F to 104°F)	30 to 75%	525 to 795 mmHg 700 to 1060 hPA (20.7 to 31.3 inHg)

STORAGE AND TRANSPORT ENVIRONMENT

Equipment	Acceptable Temperature Range	Relative Humidity	Air Pressure
Universal Battery Charger	-20°C to 60°C (-4°F to 140°F)	10 to 93%	375 to 795 mmHg 500 to 1060 hPA (14.8 to 31.3 inHg)

Emergency Power Pack (EPP)Cat. #2020

PERFORMANCE DATA

Type	12 volt, sealed alkaline primary (one-time)
Capacity	20 amp-hours
Discharge Time	Nominal value: 12 hours, under normal conditions; reduced at cold temperature by up to 50%
Charge Time	N/A
Shelf Life	Labeled with expiration date

DIMENSIONS

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

WEIGHT

4.8 Kg
(10.6 lb)

System Monitor

Cat. #1286

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

Power Module (PM) Car Power Adapter

Cat. #1342

TYPE

A Cable assembly with one straight plug connector with sliding interlock and composite strain relief for connection to the PM and one 12 volt DC automotive type plug.

FUNCTION

To provide electrical connection between automotive type 12 volt DC Input Power and the PM (i.e. Car power receptacle).

LENGTH

1.8 meters (6 feet)

PRODUCT LIFE

Three years from date of first use

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 Module (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 mandatory for HeartMate II patients. It 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 Vest

The HeartMate GoGear holster vest is a shoulder-worn harness that carries two system batteries and attached battery clips. The patient should adjust the holster vest straps so 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. Refer to the *HeartMate GoGear Holster Vest IFU* (document # 104615) for detailed information.

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









HeartMate II 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.

HeartMate II Power Change Checklist

WARNING: Never disconnect power (PM, battery, or EPP) from both controller power leads at the same time.

1. Prepare for power change.
2. Remove only one battery or the white PM power lead from the System Controller's white power lead.
(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 PM power lead to the System Controller's white power lead.
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 PM power lead from the System Controller's black power lead.
(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 PM power lead to the System Controller's black power lead.
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 the pump will stop.
- The pump will stop if power is removed from both controller power leads at the same time.
- The 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 PM patient cable and the PM.
2. **CHANGE POWER SOURCE** — If alarm continues, change power source (fully charged batteries or to PM).
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 section 13.0. 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 111**, **Figure 112**, and **Figure 113**.

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.

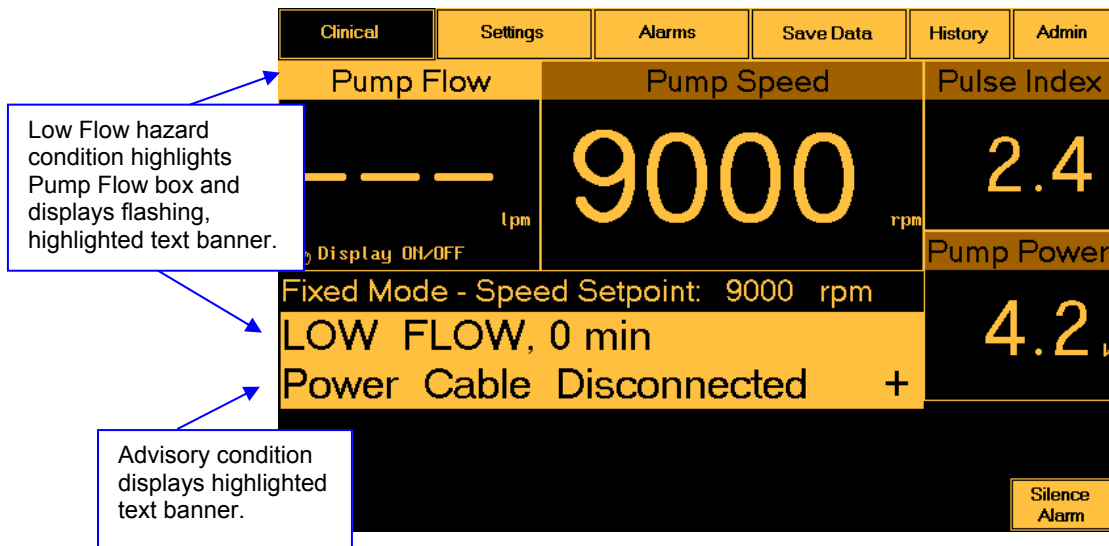


Figure 111 Clinical Screen - Monochrome

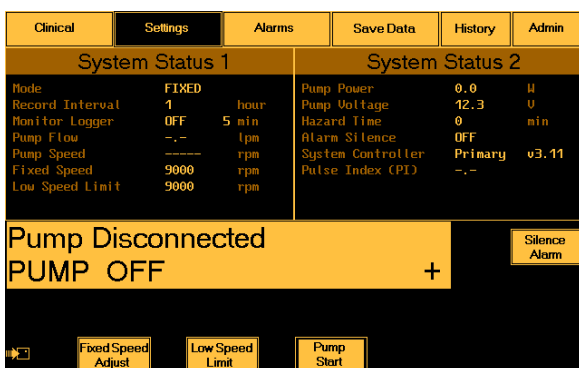


Figure 112 Settings Screen – Monochrome

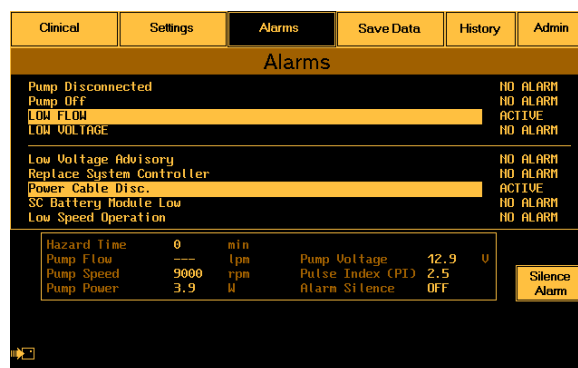


Figure 113 Alarms Screen – Monochrome

Saving Data with the Original System Monitor

The procedure for Saving Data using an Original System Monitor (see section 13.2.5) 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 116**).

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

1. Obtain a PC Card Adapter (**Figure 114**).
2. Insert the PC Card Adapter into the card slot on the right side of the System Monitor (**Figure 115**).
3. Insert the data card into the PC Card Adapter (**Figure 116**).
4. Follow the steps outlined in section 13.2.5 for Saving Data



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 prevent it from being lost.



NOTE:

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



Figure 114 PC Card Adapter



Figure 115 Inserting Adapter into System Monitor (rear view)



Figure 116 Inserting Data Card into PC Card Adapter inside System Monitor

Glossary of Terms

A

Advisory Alarm: Advisory alarms have little or no immediate affect on circulatory support, but they do require attention and should be addressed as soon as possible. Advisory alarms are indicated by a yellow light and beeping audio tone..

Annunciators: Audio tone generators found in the Power Module (PM) 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 Gauge (on individual batteries): Every HeartMate 12 volt NiMH and 14 volt Li-Ion battery has a set of 5 green lights that show the battery's charge status. Pressing the battery symbol on the battery causes the lights to illuminate. Each light represent approximately 20% of charge capacity. When a battery is charged and ready for use, all 5 lights come on. Fewer lights come on as power is depleted.

Battery Fuel Gauge (on the System Controller): During battery-powered operation, the 4 lights on the System Controller battery fuel gauge show overall power capacity for both batteries. Each light represents approximately 25% of charge capacity. All 4 lights illuminate when charged batteries are inserted into their clips. Few lights come on as battery power is depleted. The System Controller battery fuel gauge advises users if battery power is running low and prompt users to switch to a new pair of batteries or alternate power source, if needed.

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: Short for Central Venous Pressure, the venous pressure as measured at the right atrium, done by means of a catheter introduced through the subclavian or jugular vein to the superior vena cava, the distal end of the catheter being attached to pressure transducer.

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 Power Module (PM), and the patient must be connected to the PM in order to collect this system performance data.

Display Module: When connected to the PM, 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: Short for Electromagnetic Compatibility.

EPP: Short for Emergency Power Pack- Catalog # 2020. The EPP is mandatory for HeartMate II patients. It 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.

Event Recorder: System Controller captures and stores 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 the System Controller for four 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 via the System Monitor for a prescribed fixed pump speed and stored in the System Controller.

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: Hazard alarm conditions occur when the pump has stopped or is about to stop working. Hazard alarms are serious conditions that require immediate attention. They are indicated by a red light and steady audio tone.

HeartMate Battery: HeartMate batteries are a routine power source for the HeartMate II LVAS. During battery-powered operation, the LVAS is powered by a pair of direct current (DC) batteries that are inserted into battery clips. Using batteries to power the system is called “untethered” operation; since you are not connected to the PM. Battery-powered operation allows you to be mobile and relatively active. Do NOT use batteries to power the LVAS during sleep or when there is a chance you may fall asleep, since you may not hear the System Controller’s low battery alarms if you are sleeping.

HeartMate II LVAS: Left Ventricular Assist System configuration consisting of a HeartMate II pump assembly with percutaneous lead, System Controller, System Monitor or Display Module, power sources (Power Module, 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: Short for 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 conduit 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: Short for 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, Display Module, power sources, and accessories.

M

Mock Circulatory Loop (Pulsatile): Same as a mock circulatory loop. However, a mock ventricle (e.g., HeartMate II 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-intima: 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

Power Module (PM) Patient Cable: Cable connecting the PM to the System Controller's power leads.

PM: Short for Power Module.

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.

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

Power Entry Module: AC input on back of PM. 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, PM, 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 Test Button: 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.

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 small, replaceable battery cell that powers the audio alarms on the System Controller when both power leads are disconnected from the power source (batteries, PM or EPP) at the same time.

Note: The System Controller battery module only powers the System Controller audio alarms. It does NOT provide back up power to the implanted pump.

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: Two power leads (one with a black connector and one with a white connector) connect the System Controller to its power source (either batteries, PM, or EPP). Both leads provide equal power. However, the white lead contains a data link cable that sends information to the Power Module and/or Display Module during tethered operation (i.e., when

using the PM for power).

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 during which ventricular contraction occurs.

T

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

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.

Tunneler: A device that provides blunt dissection for the percutaneous lead during device implantation.

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 PM).

W

Waveforms: Current and voltage traces of motor performance as captured by the System Monitor.

X

Y

Z