

Instructions for Use

HeartMate II®

Left Ventricular Assist System (LVAS)



Thoratec Corporation 6035 Stoneridge Drive, Pleasanton, CA 94588 | (925) 847-8600
 Fax: (925) 847-8374 | Heartline: 1-800-456-1477 | www.thoratec.com

Thoratec Europe Limited Burnell House, Lakesview Court, Ermine Business Park, Hittingdon, Cambs
 PE29 6JA, UK +44 (0) 1480 455200, Fax: +44 (0) 1480 454126, U.Gear/24470, Tel: +44 (0) 7359 877901

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Rx Only

HeartMate II[®] LVAS

LEFT VENTRICULAR ASSIST SYSTEM

INSTRUCTIONS FOR USE



T H O R A T E C
C O R P O R A T I O N

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

Thoratec Europe Limited
Burnett House
Lakeview Court, Ermine Business Park
Huntingdon, Cambs, PE29 6UA, UK
Tel: +44(0)1480 455200
Fax: +44(0)1480 454126

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

R_x Only

CE 0197

103537.B
April 2008

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GENERAL INFORMATION

1.0 Introduction

The HeartMate II Left Ventricular Assist System (LVAS) is an axial-flow, rotary 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.

2.0 Indications for Use

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

3.0 Contraindications

The HeartMate II LVAS is contraindicated for patients who cannot tolerate anticoagulation therapy.

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 Operating Manual* prior to attempting implantation. Completion of Thoratec Corporation's HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System.

4.0 Warnings and Precautions

WARNINGS

- **A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire booklet and the *HeartMate II® LVAS Operating Manual* prior to attempting implantation. Completion of Thoratec® Corporation's HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System (LVAS).**
- Do not use the power base unit (PBU) in the presence of flammable anesthetic agents or an explosion could occur.
- Connect the PBU and any peripheral devices only to properly tested, grounded, and dedicated AC outlets. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.
- Do not connect the PBU to an outlet controlled by a wall switch or the PBU may be left inoperable.
- The PBU, like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3 prong) AC mains electrical outlet, except during transport. The PBU'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 PBU is connected to AC power and turned "on."
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock.
- Do not use this device 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) as the LVAD contains ferro-magnetic components, and 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).

- Do not apply high power electrical treatment (e.g., application of diathermy) directly to 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 to authorized Thoratec trained service personnel only.

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/professionals. 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.

General Information

- Do not implant the HeartMate II LVAD if it has been dropped.
- Never operate the Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- 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 2 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 battery clips are required at the time of implantation in order to power the system when transporting the patient out of the operating room. The PBU will charge and test up to six batteries in eight hours or less, depending on the initial state of discharge.

WARNINGS - Patient/System Management Issues

- System components must never be immersed. Showers and washing are permitted when the clinician approves wound site readiness. During showers, the HeartMate shower kit must be employed.
- In the event that the LVAD stops operating, attempt to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted. There is also the potential for retrograde flow within the LVAD. See *Other Patient Considerations*, in section 14.10, for more information.
- **Disconnecting both system controller power leads at the same time will result in loss of pump function.** One system controller lead must be connected to a battery or the PBU at all times to maintain support. The following will cause the LVAD to stop and blood pumping to cease:
 - Disconnecting both power leads from the PBU when operating on the power base unit.
 - Removing both batteries at the same time from their respective battery clips when operating on batteries.
 - Completely depleting the battery charge when operating on batteries.
- **Disconnecting the percutaneous lead from the system controller will result in loss of pump function.** The system controller must be reconnected as quickly as possible to resume pump function.
 - For pump speeds < 8,000 rpm (typical of device implantation), reconnect the system controller and then press the alarm silence and/or pump start button as quickly as possible to resume pump function.
 - For pump speeds ≥ 8,000 rpm (typical of clinical use), reconnect the system controller as quickly as possible to resume pump function. Power will automatically be supplied to the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the 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.

PRECAUTIONS

- **The *HeartMate II LVAS Instructions for Use*, which addresses LVAD preparation and implantation issues, must be used in conjunction with the *HeartMate II LVAS Operating Manual*, which addresses postoperative and patient management issues. 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).
- The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for the patient's location. Replacement of the fuse should be performed only by qualified service personnel.
- Only use Thoratec's PBU to charge HeartMate batteries. Other battery chargers may damage the batteries.
- Do not use batteries below 15° F (-10° C) or above 105° F (40° C) or they may fail suddenly. If batteries are below room temperature (68–72° F, 20–23° C) during use, their capacity will be reduced. At the low end of the temperature range (15° F, -10° C), run time will be reduced by 50%.
- The batteries should be routinely replaced, approximately every six months, or if operating time is reduced to two hours.
- To prevent deterioration or damage to batteries:
 - Do not drop or subject batteries 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 the negative and positive battery terminals.
 - Do not use expired or defective batteries. Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.
 - Recharge used batteries within 12 hours or battery life will be shortened.
- Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.
- Do not store or use the Emergency Power Pack (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 batteries and EPPs according to local, state, or federal regulations. Do not incinerate.
- Avoid unnecessary pulling or movement of the external portion of the percutaneous lead, especially as the skin exit site is healing. Pulling or movement could prolong the healing process or disrupt an already healed exit site. Disruption of the percutaneous lead exit site increases the patient's risk of acquiring a serious infection.
- Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand-tighten only. Using tools may damage the connectors and cause the pump to stop.
- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the PBU may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient, 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.
- It is advised that the HeartMate II LVAS be disconnected during the use of open-heart defibrillation.
- Ensure that all backup system controllers are programmed with identical settings (e.g., fixed speed setting 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.

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 2 lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.

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.
- The externalized portion and the lumen of the percutaneous lead at explant are not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.
- When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.
- A backup system controller, spare batteries, and a pair of battery clips must be with the patient at all times for use in an emergency.

5.0 Potential Complications

Adverse events that may be associated with the use of the HeartMate II left ventricular assist system (LVAS) are listed below. Other than death, adverse events are listed in decreasing order of frequency observed in the clinical study.

- Death
- Bleeding, perioperative or late
- Cardiac arrhythmia
- Local infection
- Respiratory failure
- Device malfunction
- Sepsis
- Right heart failure
- Percutaneous or pocket infection
- Renal failure
- Stroke
- Neurologic dysfunction
- Psychiatric episode
- Thromboembolic event, peripheral
- Hemolysis
- Hepatic dysfunction
- Device thrombosis
- Myocardial infarction

**NOTE:**

Thoratec reserves the right to change specifications without notice.

6.0 Summary of Clinical Studies

6.1 Study Overview

One hundred twenty-six (126) patients were enrolled in the HeartMate II (HMII) Bridge-to-Transplantation (BTT) Primary Study Cohort between March 2005 and March 2007 at 26 investigational sites across the United States as the pivotal study sample size. The primary objective of the study was to determine the safety and effectiveness of the HeartMate II LVAS as a BTT device in end-stage heart failure patients who are listed for cardiac transplant and at imminent risk of death. Effectiveness of the device was assessed on the basis of the percentage of patients surviving either to cardiac transplantation or 180 days of LVAS support while being listed UNOS 1A/1B. Safety of the HeartMate II LVAS was assessed by the incidence of adverse events during LVAS support.

A number of secondary objectives were also evaluated during the study, including clinical reliability (malfunctions/failures), functional status (6-minute walk and patient activity score), quality of life (Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire), re-operations, neuro-cognitive assessment (memory, language, visual/spatial perception, processing speed and abstract/executive function), and 30-day and 180-day post-transplant survival.

After completion of enrollment in the Primary Study Cohort, enrollment continued under a Continued Access Protocol (CAP), which was identical to the Primary Study Cohort protocol. Patients who were originally enrolled into these two study cohorts but who had a body surface area (BSA) less than 1.5m² were separated out into a Small BSA Patient cohort for analysis.

6.2 Study Design

The study was a multi-center, non-blinded, non-randomized, prospective study. The study had two oversight committees, a Clinical Events Committee which adjudicated all adverse events and deaths and a Data and Safety Monitoring Board which reviewed the study data periodically to ensure that continuation of the study did not present any unacceptable risk. The members of these committees were independent of Thoratec, the investigational sites and the principal investigators.

The primary study outcomes were defined as death, cardiac transplantation, device explantation due to myocardial recovery, or survival to 180 days on LVAS support while remaining listed UNOS 1A/1B. After reaching the 180 day assessment point, patients continued to be followed until transplantation, explantation or death.

6.3 Patient Population

The patients enrolled into the HeartMate II study were patients listed for cardiac transplant in end-stage heart failure who demonstrated no evidence of severe end-organ damage that would make HeartMate II LVAS implantation futile. The BTT inclusion and exclusion criteria were based on study criteria used in previously approved LVAD BTT studies. The criteria included patients in New York Heart Association (NYHA) class IV heart failure, on inotropic support, and without contraindication to listing for cardiac transplantation as UNOS Status 1A or 1B. If the patient was 1B, they also needed to meet hemodynamic criteria to qualify, including pulmonary capillary wedge pressure (PCWP) or pulmonary artery diastolic pressure (PAD) > 20 mmHg and either a cardiac index <2.2 L/min/m² or systolic blood pressure <90 mmHg. The exclusion criteria excluded patients with moderately severe end-organ damage, as evidenced by elevated total bilirubin, elevated creatinine values, or low platelet counts, and also excluded patients that may not be able to tolerate the management of the HeartMate II LVAS due to intolerance to anticoagulation or compliance issues.

Two hundred and seventy-nine (279) patients were enrolled at 33 study sites between March 2005 and March 2007. Twenty-six (26) sites enrolled patients into both the Primary Study Cohort and the Continued Access Protocol Cohort (CAP). Seven additional sites enrolled patients only under the Continued Access Protocol. Of the 279 patients enrolled into the three cohorts of the HeartMate II study (Primary Study, Continued Access, and Small BSA), 194 patients have been followed to a study outcome point, and if ongoing on HeartMate II LVAS support, for at least one year as of September 14, 2007, and are presented in the following clinical summary. As shown in **Figure 1**, the 194 patients are divided among three cohorts; 126 patients in the Primary Study cohort and 58 patients in the Continued Access Protocol cohort. An additional 10 patients were originally enrolled in these two cohorts but were separated out for analysis in the Small BSA Patient cohort ($1.2\text{m}^2 \leq \text{BSA} < 1.5\text{m}^2$). Data are presented for each cohort separately and also in the aggregate for all 194 patients.

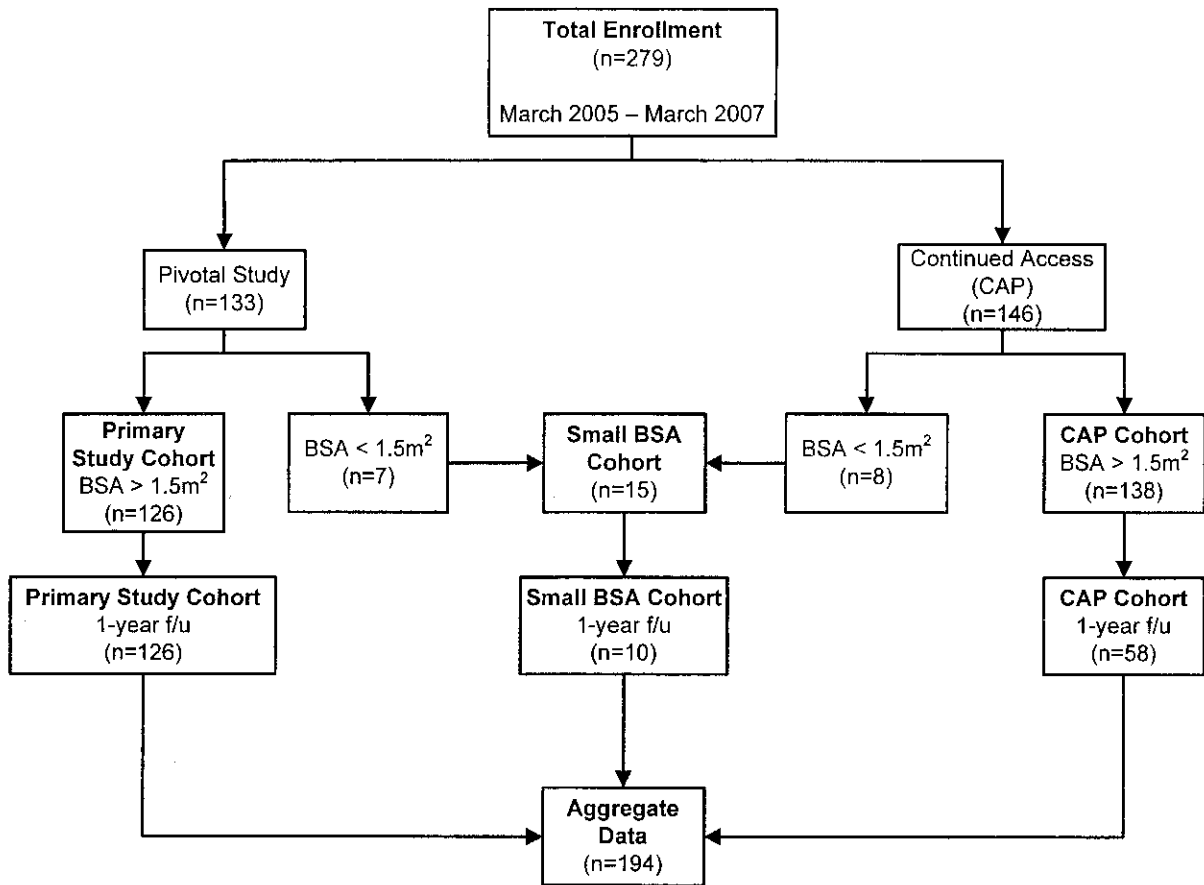


Figure 1 HeartMate II Study Enrollment

The overall mean age in the HeartMate II LVAS study was 51 years (range 16-69 years). The smallest patient implanted had a BSA of 1.33m² and the largest patient, a BSA of 2.62m², with a mean BSA of 1.99m². The mean body mass index (BMI) was 27 kg/m² (range 15.6 – 44.0 kg/m²). The most prevalent etiology was idiopathic cardiomyopathy (48%) followed by ischemic cardiomyopathy (41%). Of note in the cardiovascular history is that 78% of the patients had pre-existing arrhythmias and 76% of the patients entered the study with implantable cardiac defibrillators (ICD). Patient demographics and cardiovascular history for each of the three study cohorts and the aggregate data are shown in **Table 1** and **Table 2**.

General Information

	Primary Cohort (n = 126)	CAP Cohort (n = 58)	Small BSA Cohort (n = 10)	Aggregate Data (n = 194)
Age (years)*	55 (17 -68)	56 (16-69)	47 (20 – 69)	55 (16-69.1)
Etiology	39% Ischemic	50% Ischemic	10% Ischemic	41% Ischemic
Gender	83% Male 17% Female	78% Male 22% Female	0% Male 100% Female	77% Male 23% Female
BMI (kg/m²)*	26.5 (10–40)	27.6 (18-44)	17.0 (15.6-20.8)	26.6 (15.6-44.0)
BSA (m²)*	1.99 (1.5 – 2.6)	2.00 (1.52 – 2.57)	1.40 (1.33 – 1.47)	1.99 (1.33-2.62)

*Median and range

Table 1 Patient Demographics

	Primary Cohort (n = 126)	CAP Cohort (n = 58)	Small BSA Cohort (n = 10)	Aggregate Data (n = 194)
Arrhythmias	101 (80%)	46 (79%)	5 (50%)	152 (78%)
Ventricular Arrhythmias	71 (56%)	34 (59%)	0 (0%)	109 (56%)
Ventricular Pacing	77 (61%)	35 (60%)	5 (50%)	117 (60%)
Biventricular Pacing	61 (48%)	30 (52%)	0 (0%)	95 (49%)
Implantable Cardioverter / Defibrillator	96 (76%)	45 (78%)	6 (60%)	147 (76%)
Stroke	12 (10%)	6 (10%)	1 (10%)	19 (10%)

Table 2 Cardiovascular History

6.4 Primary Objective: Transplant or Survival to 180 Days While Listed UNOS 1A/1B

6.4.1 Overall Patient Outcomes:

After reaching the 180 day assessment point, patients continued to be followed until transplantation, explantation or death. Patient outcomes for each study cohort (Primary, CAP, Small BSA and Aggregate Data) as of September 14, 2007 are presented in **Table 3** and **Table 4** below.

The pre-specified primary endpoint for the Primary Study Cohort of HeartMate II LVAS BTT pivotal study was “patient survival to cardiac transplantation or 180 days of LVAS support while remaining listed status 1A or 1B.” The HeartMate II pivotal study was to be prospectively determined successful if the one-sided 95% lower confidence limit of the true success rate exceeded 65%, the Performance Goal. The results show that the lower confidence limit (LCL) of success was 64.0% in the Primary Study Cohort, thereby not quite meeting the pre-specified agreed-upon LCL endpoint, > 65%. Although outcomes were similar in the CAP and Small BSA cohorts, the LCLs are lower due to the smaller sample sizes.

General Information

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
Cardiac Transplantation ¹	72 (57%)	33 (57%)	7 (70%)	112 (58%)
Myocardial Recovery ¹	4 (3%)	2 (3%)	0 (0%)	6 (3%)
Supported ≥ 180 days and:				
Listed UNOS Status 1A or 1B ¹	13 (10%)	5 (9%)	0 (0%)	18 (9%)
Not listed Status 1A or 1B ^{2,3}	9 (7%)	7 (12%)	3 (30%)	19 (10%)
Expired < 180 days on LVAD ²	25 (20%)	11 (19%)	0 (0%)	36 (19%)
Treatment failure; received other VAD ²	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Pre-specified Lower 95% Confidence Limit of True Success Rate	65.0%			
Observed Lower 95% Confidence Limit of Study Success Rate	64.0%	59.0%	46.2%	64.7%

¹ Classified as success per pre-specified study criteria

² Classified as failure per pre-specified study criteria

³ Reasons for not listing included medical ineligibility, elective withdrawal from transplant list, substance abuse and non-compliance with medical therapy

Table 3 Primary Study Outcomes (as of September 14, 2007)

General Information

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
30 day (peri-operative) mortality	12 (10%)	7 (12%)	0 (0%)	19 (10%)
Patient survival to hospital discharge/transplant	105 (83%)	48 (83%)	10 (100%)	163 (84%)
Median time to transplant (days)	102.5	152	194	117
Median duration of device support (days)	117	163.5	374	131.5
Cumulative support duration (patient-years)	71	29	9	109

Table 4 Additional Study Results (as of September 14, 2007)

Plots of the competing outcomes (transplantation, weaning due to myocardial recovery, expiration, ongoing LVAS support and study withdrawal) are provided in **Figure 2** and **Figure 3** for the Primary Study Cohort and the Aggregate Data, respectively.

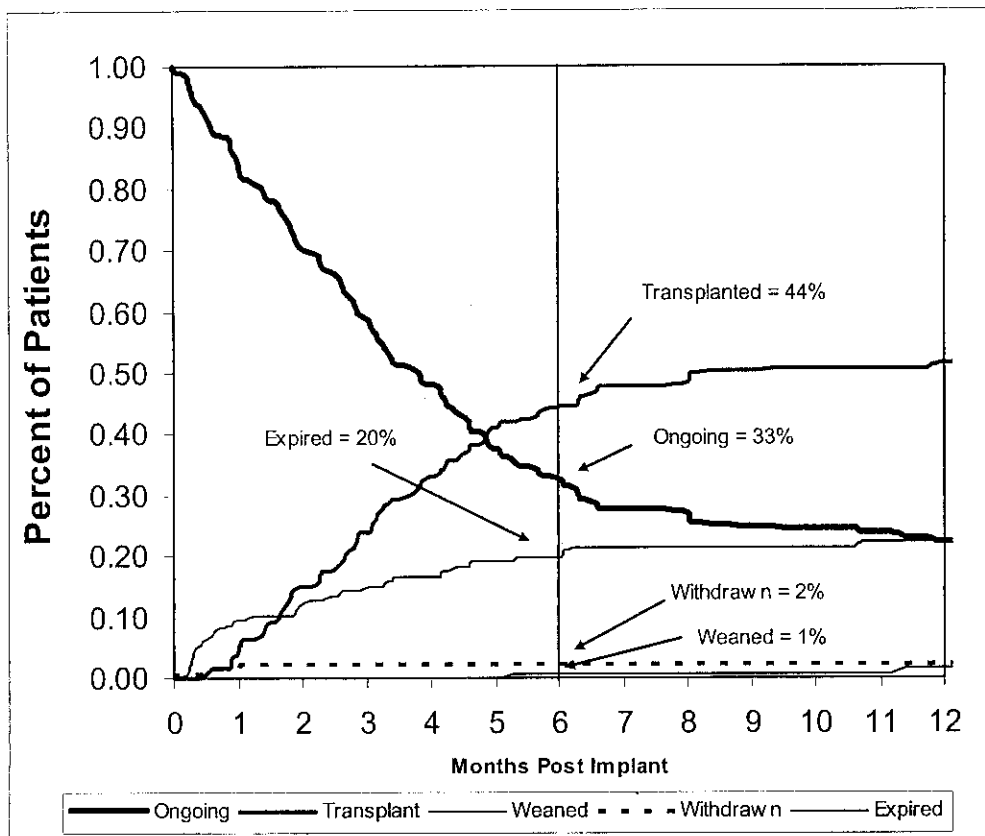


Figure 2 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Primary Study Cohort (n=126) as of September 14, 2007

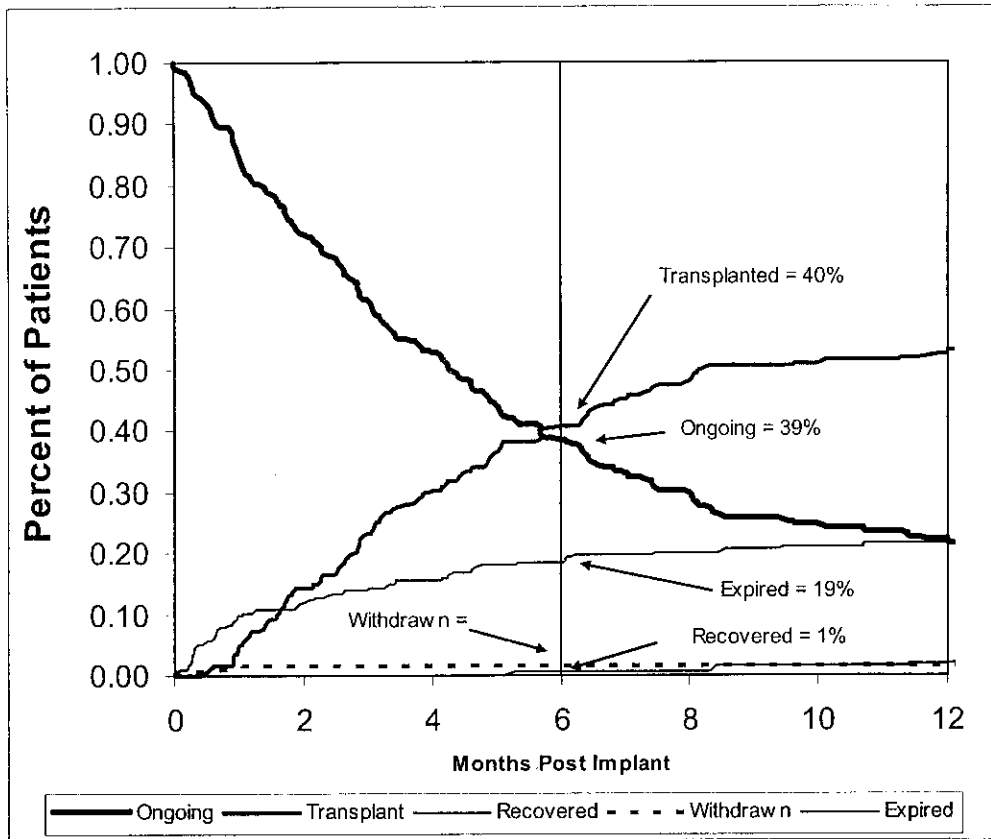


Figure 3 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Aggregate Data (n=194) as of September 14, 2007

6.4.2 Safety: Adverse Events

The incidence of all adverse events observed during the HeartMate II LVAS study, regardless of severity, is provided in **Table 5** for each data cohort. Adverse events were defined as events that occurred while on HeartMate II LVAS support that may have a deleterious effect on the patient. The incidence of adverse events defined as serious are presented in **Table 6**. Adverse Events were classified as serious if they resulted in death or permanent disability, were life threatening, required hospitalization or prolonged hospitalization. Adverse event rates during various time intervals are presented in **Table 7**, which shows that the majority of adverse events occurred during the first 30 days after implantation of the device.

General Information

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)
Bleeding (all requiring PRBC ≥ 2)*	89 (71%)	35 (60%)	9 (90%)	133 (69%)
Bleeding requiring surgery	37 (29%)	15 (26%)	4 (40%)	56 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Peri-operative (\leq POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Post-operative ($>$ POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Local Infection	36 (29%)	21 (36%)	3 (30%)	60 (31%)
Drive Line Infection	20 (16%)	4 (7%)	2 (20%)	26 (13%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	27 (21%)	7 (12%)	2 (20%)	36 (19%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	10 (8%)	1 (2%)	0 (0%)	11 (6%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	77 (61%)	28 (48%)	6 (60%)	111 (57%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	3 (30%)	8 (4%)
Psychological	8 (6%)	3 (5%)	2 (20%)	13 (7%)
Myocardial Infarction	1 (1%)	(0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	36 (29%)	11 (19%)	6 (60%)	53 (27%)

*Bleeding requiring PRBC ≥ 2 units or surgery.

**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 5 All Adverse Events as of September 14, 2007

General Information

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)
Bleeding (all requiring PRBC ≥2)*	75 (60%)	34 (59%)	8 (80%)	117 (60%)
Bleeding requiring surgery	38 (30%)	15 (26%)	4 (40%)	56 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Peri-operative (≤POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Post-operative (>POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	11 (9%)	3 (5%)	1 (10%)	15 (8%)
Local Infection	27 (21%)	16 (28%)	2 (20%)	45 (23%)
Drive Line Infection	12 (10%)	3 (5%)	1 (10%)	16 (8%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	26 (21%)	7 (12%)	2 (20%)	35 (18%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	9 (7%)	1 (2%)	0 (0%)	10 (5%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	56 (44%)	21 (36%)	5 (50%)	82 (42%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	1 (10%)	6 (3%)
Psychological	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Myocardial Infarction	1 (1%)	0 (0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	10 (8%)	4 (7%)	3 (30%)	17 (9%)

*Bleeding requiring PRBC ≥ 2 units or surgery.

**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 6 Serious Adverse Events as of September 14, 2007

General Information

Adverse Events	Cohort	0 – 7 days	8 – 30 days	31 – 90 days	91 – 180 days	> 180 days
Bleeding	Primary (n=126)	36.25	5.25	1.60	0.58	0.60
	CAP (n=58)	30.91	4.41	1.45	0.91	0.39
	Small BSA (n=10)	60.00	4.84	2.00	2.48	0.96
	Aggregate (n=194)	3.53	4.99	1.59	0.85	0.60
Stroke	Primary (n=126)	2.08	0.28	0.00	0.22	0.09
	CAP (n=58)	0.00	0.29	0.14	0.26	0.00
	Small BSA (n=10)	0.00	0.00	1.33	0.00	0.00
	Aggregate (n=194)	1.36	0.27	0.13	0.21	0.06
Other Neurological	Primary (n=126)	0.42	0.41	0.27	0.15	0.09
	CAP (n=58)	0.91	0.29	0.14	0.00	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.99	0.00
	Aggregate (n=194)	0.54	0.45	0.26	0.17	0.06
Local Infection	Primary (n=126)	8.33	2.62	1.67	0.36	0.18
	CAP (n=58)	10.00	2.65	1.45	0.39	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.50	1.34
	Aggregate (n=194)	8.42	2.58	1.55	0.38	0.27
Drive Line Infection	Primary (n=126)	0.00	0.00	0.27	0.58	0.48
	CAP (n=58)	0.00	0.00	0.29	0.26	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.99	0.38
	Aggregate (n=194)	0.00	0.00	0.26	0.51	0.37
Pocket Infection	Primary (n=126)	0.00	0.14	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.00	0.09	0.00	0.04	0.04
Sepsis	Primary (n=126)	1.67	1.80	0.47	0.36	0.24
	CAP (n=58)	1.82	0.59	0.00	0.26	0.10
	Small BSA (n=10)	0.00	1.61	0.00	0.00	0.57
	Aggregate (n=194)	1.63	1.42	0.30	0.30	0.25
Right Heart Failure	Primary (n=126)	1.67	1.80	0.33	0.00	0.03
	CAP (n=58)	3.64	2.06	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.19
	Aggregate (n=194)	2.45	1.87	0.21	0.00	0.04

Continued on following page.

Table 7 Adverse Event Rate per Patient Year by Time Interval

General Information

Adverse Events	Cohort	0 – 7 days	8 – 30 days	31 – 90 days	91 – 180 days	> 180 days
Peripheral TE	Primary (n=126)	1.25	0.83	0.13	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	1.09	0.53	0.09	0.00	0.00
Respiratory Failure	Primary (n=126)	7.92	1.66	0.47	0.22	0.03
	CAP (n=58)	10.91	1.76	0.14	0.26	0.00
	Small BSA (n=10)	10.00	1.61	0.67	0.00	0.00
	Aggregate (n=194)	8.97	1.69	0.39	0.21	0.02
Cardiac Arrhythmias	Primary (n=126)	25.00	4.01	1.47	1.09	0.48
	CAP (n=58)	14.55	5.59	0.72	0.52	0.39
	Small BSA (n=10)	20.00	4.84	0.67	1.49	0.57
	Aggregate (n=194)	21.74	4.54	1.20	0.94	0.47
Renal Failure	Primary (n=126)	3.75	0.69	0.13	0.15	0.00
	CAP (n=58)	2.73	0.59	0.00	0.13	0.00
	Small BSA (n=10)	10.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	3.80	0.62	0.09	0.13	0.00
Hepatic Dysfunction	Primary (n=126)	0.42	0.14	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.27	0.09	0.04	0.00	0.00
Device Thrombosis	Primary (n=126)	0.42	0.00	0.07	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.54	0.00	0.04	0.00	0.00
Hemolysis	Primary (n=126)	0.83	0.00	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	10.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	1.09	0.00	0.00	0.09	0.04
Psychological	Primary (n=126)	1.67	0.14	0.07	0.29	0.00
	CAP (n=58)	1.82	0.29	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.00
	Aggregate (n=194)	1.90	0.27	0.04	0.17	0.00
Myocardial Infarction	Primary (n=126)	0.00	0.00	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	0.00	0.00	0.04	0.04	0.00

No new adverse events were observed in the HeartMate II LVAS study that have not been seen in previous studies of ventricular assist devices. The study was not powered for a specific analysis of the adverse events.

6.5 Secondary Objectives

Secondary objectives were collected which included the following: re-operations, clinical reliability, functional status, quality of life, neurocognitive evaluation and post-explant follow-up.

Reoperations

Re-operations that were performed for any reason were captured as a secondary objective. In the Primary Cohort, 63% (79/126) of the patients had a re-operation. The majority (56%) of these events took place within 30 days of implant and was due to bleeding or delayed chest closure. Three patients received HMII pump replacements within 30 days of implant. Twenty-one (21%) percent of the re-operation events took place after 30 days post implant. Abdominal incision and drainage, RVAD placement or removal, dialysis catheter placement and driveline/pocket revision accounted for the majority of these events. Three patients received HMII pump replacements after 30 days post implant. As shown in **Table 8**, the incidence of reoperations was similar in both the CAP and Small BSA cohorts. The major reasons requiring reoperations were also similar to those observed in the Primary Study Cohort.

	Primary Study Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data Cohort (n=194)
Patients having reoperations	79 (63%)	36 (58%)	7 (70%)	122 (63%)
Reoperations within 30 days of implant	56%	55%	60%	56%

Table 8 Incidence and Timing of Reoperations

Clinical Reliability

During the clinical study there were 78 reports of confirmed malfunctions in 194 patients having a median support duration of 131 days (see section 6.3 , “Patient Population,” for more information on the 194 patients). Forty-four percent (44%, 34/78) involved implanted system components (i.e. pump and cannulae) and 56% (44/78) involved external system components (i.e. controllers, monitors, batteries, etc). Ten of the malfunctions of the implanted system components were classified as serious adverse events (i.e. resulted in death or permanent disability, or required prolonged hospitalization). These ten reports included percutaneous lead

separation (4), pump thrombosis (3), inflow cannula twists (2) and outflow conduit leakage (1). Seven malfunctions of the external system components were also classified as serious adverse events, including damaged printed circuit boards in the system controller (5), power base unit cable breakdown (1) and inadequate battery capacity (1).

Estimated clinical reliability of the HeartMate II LVAS blood pump is summarized in **Table 9**. Clinical reliability is estimated based on a Weibull analysis of the 10 malfunctions reported above (please note that 4 of these 10 events involved system components, which were not evaluated in the in vitro reliability test: percutaneous lead separation (3), and outflow conduit leakage (1).

Lower, One-Sided 80% Confidence Limit on Reliability R(t)	
Months	Reliability
6	0.932
12	0.896
24	0.833

Table 9 Estimated Clinical HeartMate II LVAD Reliability

Functional Status:

Functional status was evaluated based on NYHA class assessments and 6-minute walk tests as summarized in **Figure 4** and **Figure 5**, below. These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved functional capacity.

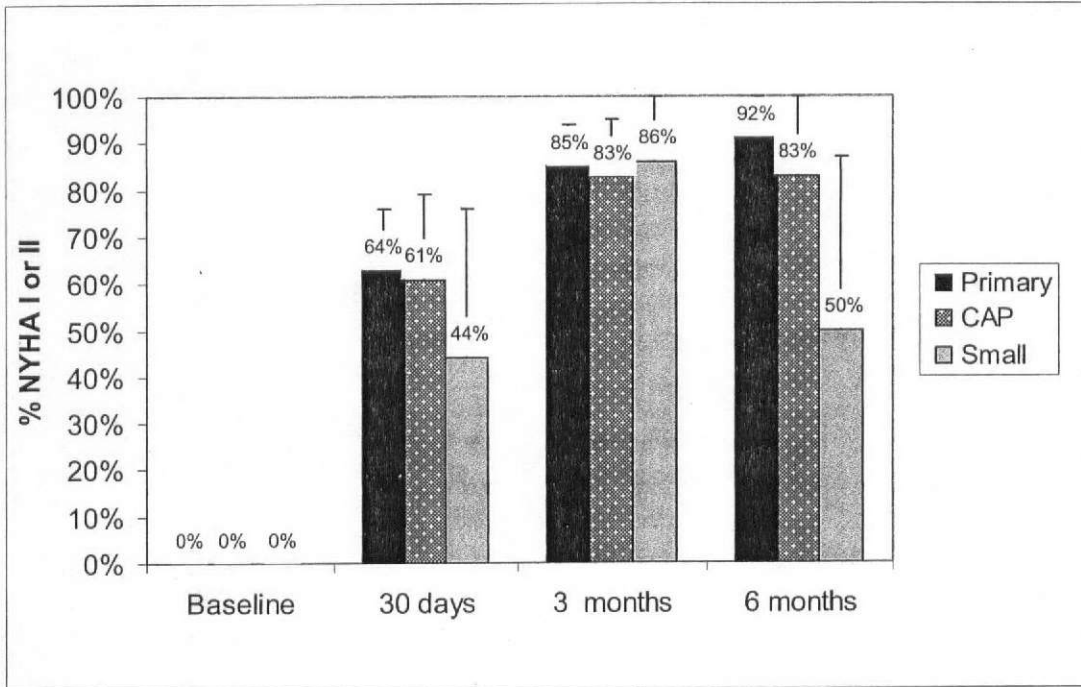


Figure 4 NYHA Class Over Time
(Error Bars = Standard Deviation)

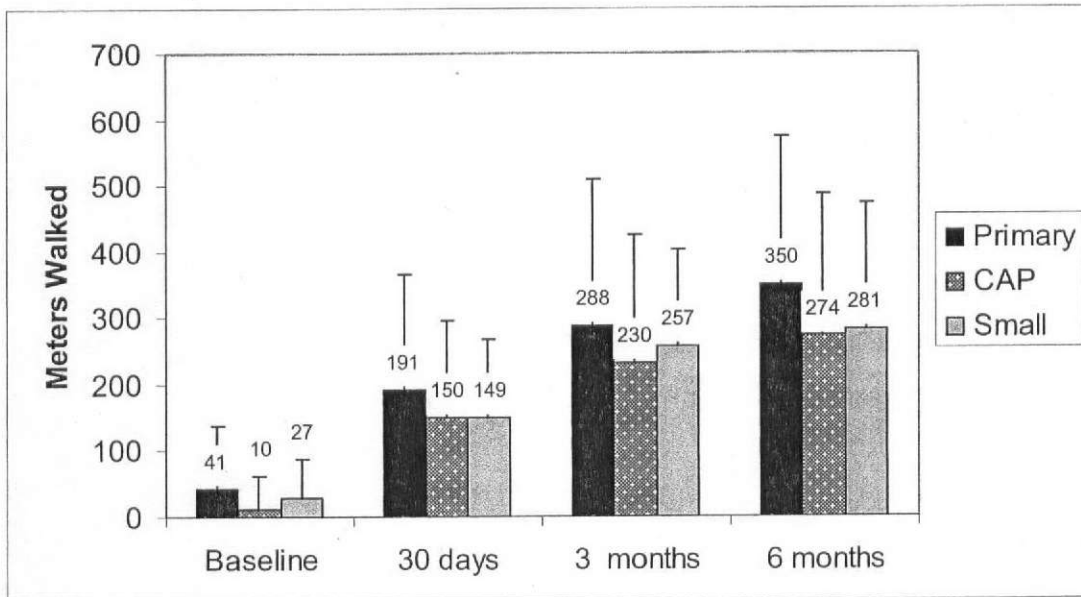
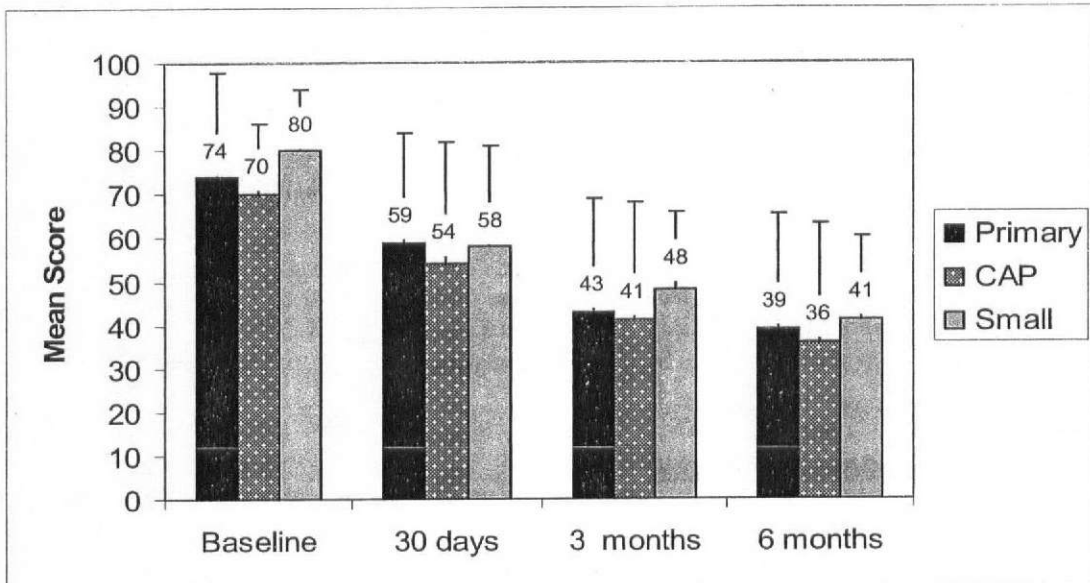


Figure 5 Summary of Six-Minute Walk Over Time
(Error Bars = Standard Deviation)

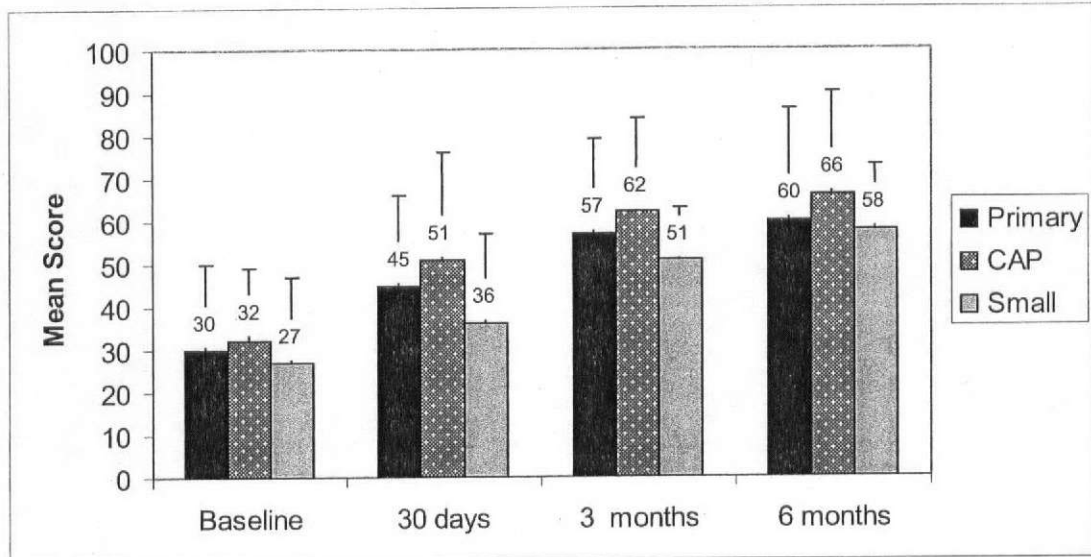
Quality of Life:

Quality of life was measured via the Minnesota Living with Heart Failure Questionnaire (MLHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ) as summarized in the **Figure 6** and **Figure 7**, below. These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved quality of life.



Note: A lower score indicates better quality of life.

Figure 6 Minnesota Living with Heart Failure (MLHF) Questionnaire (Error Bars = Standard Deviation)



Note: A higher score indicates better quality of life.

Figure 7 Kansas City Cardiomyopathy Questionnaire (KCCQ) (Error Bars = Standard Deviation)

Neurocognitive Evaluations:

Neurocognitive evaluations were performed in 11 of the 33 study sites. Eight standard neurocognitive measures with ten procedures were administered at baseline (1 month post-implant), 3 and 6 months post-implant. The tests surveyed cognitive domains involving memory, language, abstract/executive functions, visual/special perception and processing speed. Because of the small sample size (n=86), it is difficult to draw conclusions; however, important trends were seen. There was no significant cognitive decline in patients assessed between baseline and the 3 month or 6 month interval. There were significant improvements in cognitive test performance at 3 and 6 months over baseline for auditory memory, visual memory delay and processing speed. The majority of the cognitive test performance improvement was observed in the first 3 months post implant, with less change seen over extended follow-up intervals. As expected, most of the neurocognitive adverse events occurred at baseline and are likely due to cognitive instability shortly after implant. Over time, as the patients stabilized, neurocognitive functions improved and the incidence of adverse events declined.

Post-Explant Followup

Cohort	# Pts Transplanted (or recovered)	# Alive at 30 days post explant	% Alive at 30 days post explant
Primary	72 (3)	73	97%
CAP	33 (2)	35	100%
Small	7	5	71%
Aggregate Data	112 (5)	113	97%

Table 10 30-Day Post Explant Survival as of September 14, 2007

Cohort	# Pts Transplanted (or recovered)	# Alive at 1 Year post explant	% Alive at 1 year post explant
Primary	58 (2)	51 (2)	88%
CAP	7	7	100%
Small	4	2	50%
Aggregate Data	69 (2)	60 (2)	87%

Table 11 One-Year Post Explant Survival as of September 14, 2007

6.5.1 Gender Analysis

A *post hoc* analysis of the aggregate data for variations associated with gender was performed. Of the 194 patients who were followed to a study outcome or, if ongoing on HeartMate II LVAS support, for at least a year, the majority were male (77% males vs. 23% females). Some statistically significant differences were observed in some baseline hemodynamic and biochemistry parameters, but they are not considered to be clinically significant. Women were observed to have a higher incidence of strokes (18% vs. 6%), but the strokes did not have a significant effect on their overall survival compared with men. Trends toward a higher incidence of bleeding and infection events were observed in females than males. Nonetheless, the sample size of men compared to women (150 vs. 44) makes it difficult to draw any conclusions regarding differences in safety profile of the device between men and women. The results show that there do not appear to be differences with primary study outcome, NYHA Classification, 6 minute walk, MLWHF, and KCCQ assessments.



Patient Handbook

HeartMate II®
Left Ventricular Assist System (LVAS)



THORATEC
CORPORATION

Thoratec Corporation 6035 Stoneridge Drive, Pleasanton, CA 94588 (925) 847-8600,
Fax: (925) 847-6574, "Heartline™", (800) 456-1477, www.thoratec.com

Thoratec Europe Limited Burnell House, Lakeview Court, Ermine Business Park, Huntingdon, Cambs,
PE29 6JA, UK +44 (0) 1480 455200; Fax: +44 (0) 1480 454126; Urgent/24hr Tel: +44 (0) 7659 877901

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Rx Only



Thoratec Corporation

HEARTMATE II® LEFT VENTRICULAR ASSIST SYSTEM (LVAS)

Patient Handbook

Your guide to understanding the HeartMate II LVAS Heart Pump

Rx Only

CE 0197

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6035 Stoneridge Drive • Pleasanton, CA 94588 • USA
Tel. 925-847-8600 • Fax 925-847-8574
www.thoratec.com

Thoratec Europe Limited
Burnett House
Lakeview Court - Ermine Business Park
Huntingdon, Cambs PE29 6UA UK
Tel. +44 (0)1480 455200 – Fax. +44 (0)1480 454126

Document No. 103539.B

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List of Emergency Contacts

It is very important to keep a list of emergency contacts with you at all times in case something happens to you or your pump. Before leaving the hospital, fill in the list below. If, at any time, you think your pump is not working right, call your hospital contact person, or other emergency contact, right away.

HOSPITAL

Name of Hospital _____

Name of Hospital Contact Person _____

Hospital Address _____

Hospital (Contact Person) Telephone Number _____

DOCTOR

Doctor's Name _____

Address _____

Telephone Number _____

AMBULANCE

Name _____

Address _____

Telephone number _____

AMBULANCE/ EMERGENCY SERVICES

Make sure dialing "911" works in your area before using it in an emergency. Also, consider using a land-line (non-portable) telephone for making emergency calls, unless your hospital contact person tells you otherwise. Land-lines may be less likely to be affected by interference, interruptions, or power outages.

If you have questions or want more information about the terms defined below, your doctor or hospital contact person can help. You'll find these terms mentioned in this patient handbook:

A

Advisory Alarm: An audio tone (sound) and/or visual alarm (light) that tells you about a condition requiring attention. Advisory alarms have little or no immediate effect on circulatory support, but they do require attention.

B

Back Up Mode: A secondary system within the system controller that takes over system operation and control if the primary system controller fails or is unavailable.

Battery Clip: Device that connects the HeartMate battery and the system controller. Two battery clips are required for battery-powered operation.

Battery Fuel Gauge: A set of 4 lights on the system controller that indicates how much battery power is available (when connected to battery power).

Battery Holster: A HeartMate accessory that allows you to wear two HeartMate batteries with battery clips during battery-powered operation.

Battery-Powered Operation: The HeartMate II LVAS operating while connected to a pair of rechargeable, portable HeartMate batteries.

C

D

Display Module: When connected to the power base unit (or "PBU"), the display module displays information about how the system is operating, such as the current operating mode, pump speed, flow rate, pulsatility index, power, and alarm message (if there is an active alarm).

E

EPP: Short for Emergency Power Pack. The EPP is essentially a large battery that can be used as an emergency power source. It can provide up to 12 hours of power. It can be used, for example, during a power outage caused by a storm or severe weather. The EPP should not be used for routine power needs.

Exit Site: Location where the percutaneous lead passes out of the skin.

F

Fixed Speed Mode: Operating mode of the HeartMate II in which the pump speed is constant or “fixed”. This is the standard operating mode for the HeartMate II LVAS.

G

H

Hazard Alarm: An audio tone (sound) and/or visual alarm (light) that tells you that the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention.

HeartMate II LVAS: LVAS is short for Left Ventricular Assist System, which includes the implanted pump and percutaneous lead, as well as the external system controller, display module, power sources (power base unit, batteries, or emergency power pack), and accessories.

I

ICU: Short for Intensive Care Unit; location where LVAS patients receive intensive care usually immediately after implant surgery.

Inflow Conduit: A small tube that connects the pump to the heart’s left ventricle.

J

K

L

Low Battery Hazard Symbol: Red “battery” light (symbol) on the system controller. It lights when power to the system controller is critically low.

Low Flow Hazard Symbol: Red “heart” light (symbol) on the system controller. It lights when HeartMate II LVAD blood flow is critically low.

LPM: Short for Liters Per Minute (lpm). Blood flow through the pump is measured in LPM.

LVAD: Short for Left Ventricular Assist Device. Includes the implanted parts of the system, including the blood pump, inflow conduit and outflow graft, and percutaneous lead.

LVAS: Short for Left Ventricular Assist System, which includes the implanted pump and percutaneous lead, as well as the external system controller, display module, power sources (power base unit, batteries, or emergency power pack), and accessories.

N

O

Outflow Graft: Polyester graft that connects the body's main artery (aorta) to the pump's outflow elbow.

P

PBU Cable: Cable that connects the power base unit (or "PBU") to the system controller's power leads.

PBU: Short for Power Base Unit. The PBU is one of two routine power sources for powering the pump (HeartMate batteries are the other routine power source). In addition to powering the pump, the PBU is also used to recharge HeartMate batteries.

Perc Lock: A safety feature on the system controller designed to lock the percutaneous lead into the system controller socket and prevent accidental disconnection of the percutaneous lead.

Percutaneous: "Percutaneous" means "through the skin." The thin cable or lead connecting the implanted pump to the external system controller is called a *percutaneous* lead because it passes through your skin.

Percutaneous Lead: The long lead passing through your skin that is permanently attached to the HeartMate II pump. It connects the implanted pump to the external system controller. The percutaneous lead contains wires that carry power to the pump and control and monitor pump operation.

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

Polyester Velour: A synthetic biocompatible material that lets skin tissue grow into the soft covering of the percutaneous lead. This material covers the percutaneous lead inside the body at the exit site. Skin growth into the velour covering helps create a barrier that reduces the risk of percutaneous lead infections.

Power Saver Mode: The system automatically runs in power saver mode (pump speed will slow to a fixed speed of 8000 rpm) when battery power is low and the red Battery Hazard Alarm comes on.

Power Sources: Three power sources can power the HeartMate II LVAS: 1) a set of wearable, rechargeable batteries/battery clips for battery-powered operation, 2) the PBU when connected to an electrical outlet, and 3) the Emergency Power Pack (or "EPP"), which is a large battery that can power the system for up to 12 hours in the event of an extended power outage or emergency.

Pump Speed: Pump speed is measured in revolutions per minute (rpm), which reflect how fast the pump's internal rotor turns.

Pump: The implanted device connected to the left ventricle of the heart that sends blood taken from the inflow conduit through the outflow graft and into the aorta, which sends the blood to the rest of the body. The pump contains titanium stators, a rotor, a

blood tube, and ceramic bearings. The motor capsule that surrounds the rotor is powered through the percutaneous lead.

Q

R

S

Self Test: A routine system check performed daily by the patient to confirm that the system controller's audio and visual alarms are working properly.

Shower Kit: HeartMate accessory that allows patients to shower. The kit consists of a protected enclosure that holds the external parts of the system (including system controller and batteries) and protects them from shower spray and moisture. You will be allowed to shower after the exit site has sufficiently healed. Your doctor will tell you when you can take showers.

Silence Alarm Button: A button used to temporarily mute or silence system controller alarms so users can respond to alarm conditions without audio distraction. Pressing and holding this button will also display how much battery power is available (when connected to battery power).

System Controller Battery Module Symbol: A round yellow symbol on the system controller that lights when the system controller's internal battery needs to be replaced.

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, PBU 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 Power Leads: Cables or leads that connect the system controller to a power source (either batteries – via battery clips, the PBU, or EPP).

System Controller: The small computer that controls and monitors system function. It connects the implanted pump to the external power sources and may be worn on the belt or in a carrying case around the waist.

T

Test Select Button: A button found on the system controller. Pressing and holding this button starts the system controller self-test which should be performed daily to check system controller lights and audio alarm tones.

Tethered Operation: Refers to using the HeartMate II LVAS while connected or "tethered" to an electrical outlet via the PBU.

U

User Interface Panel: Set of visual indicators (symbols that light) and buttons located on the front of the system controller.

V

Visual Indicator Lamp: A light found on the system controller and on the PBU that turns on to tell users about an advisory or hazard condition.

W

X

Y

Z

Figure A Implanted and Worn Components of the HeartMate II LVAS During Battery-Power Operation

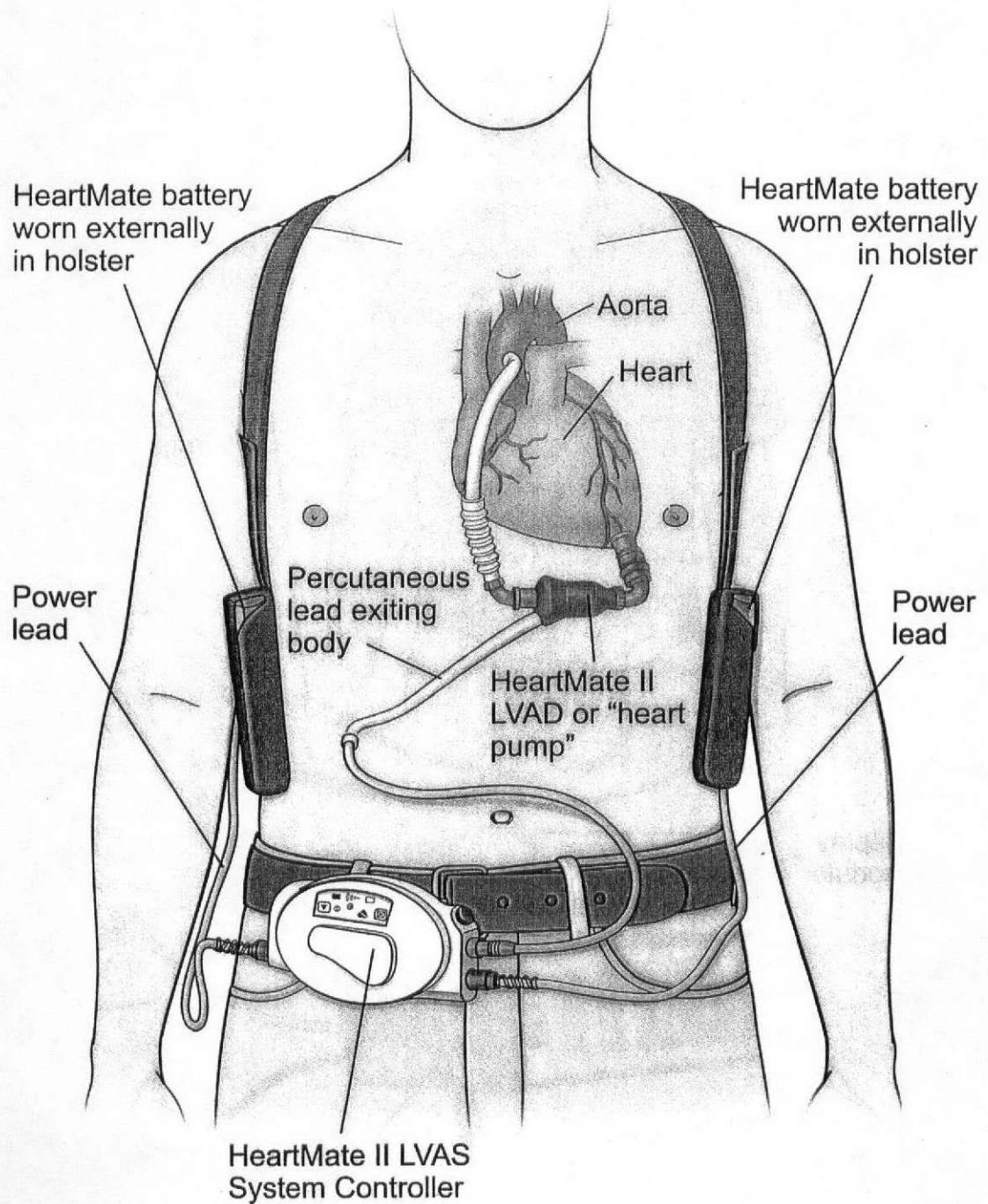
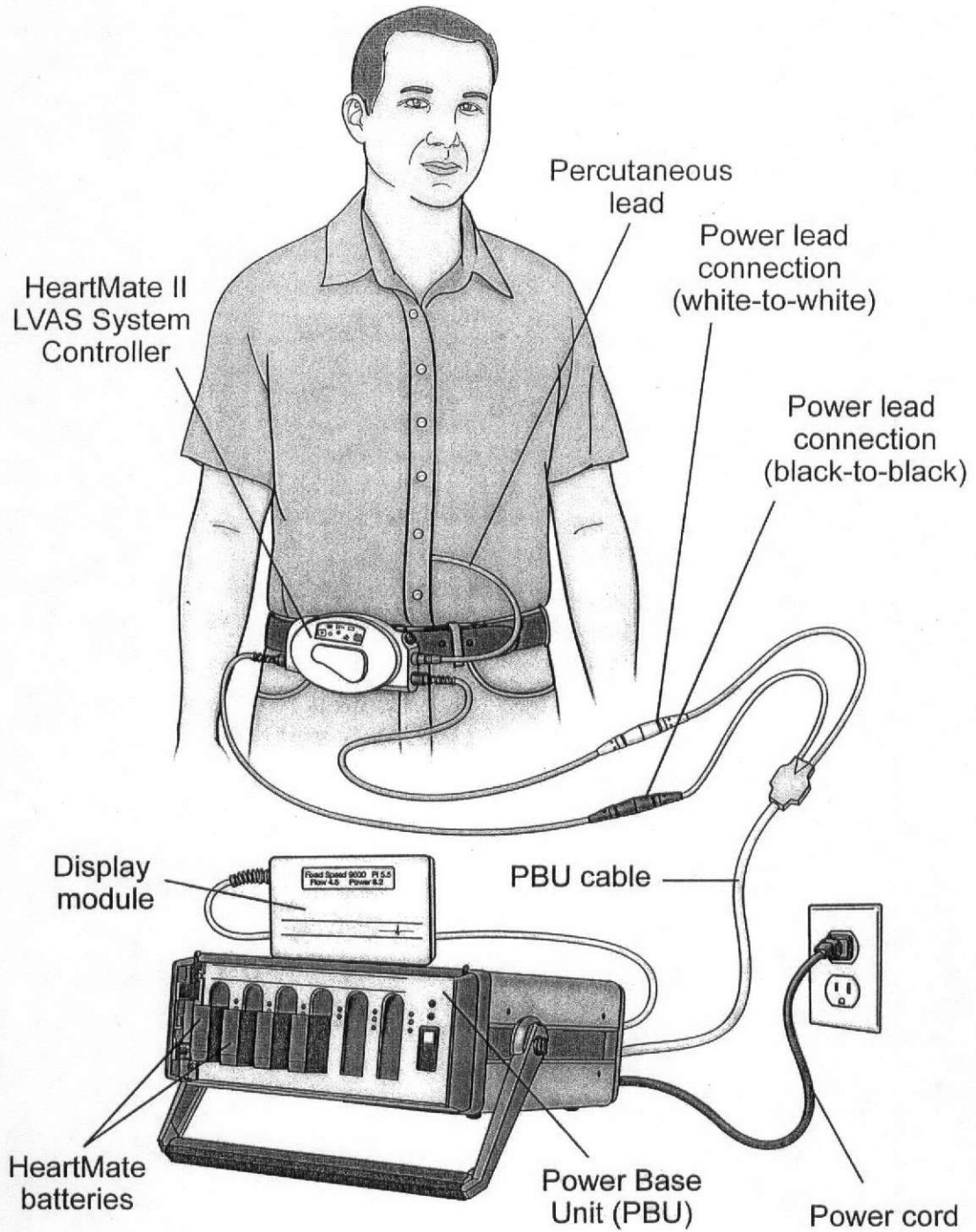


Figure B HeartMate LVAS during "Tethered Operation" Connected to PBU



Important Warnings

- Never put the System Controller in water. Your doctor will let you know when you can shower. When you do shower, you must use the HeartMate Shower Kit.
- Check the Perc Lock often to make sure it is in the locked position. The Perc Lock helps keep the percutaneous lead from accidentally disconnecting from the System Controller. If the percutaneous lead disconnects, your pump will stop.
- Keep the Power Base Unit (PBU) away from water. If the PBU touches water, shower spray, or wet surfaces, your pump may stop or you may get a serious electric shock.
- One (1) System Controller power lead must be connected to a power source (batteries, PBU, or EPP) at all times. If both System Controller power leads are disconnected at the same time, your pump will stop.
- The pump will stop if the System Controller is disconnected from the percutaneous lead going through your skin. If this happens, reconnect the lead as quickly as possible to restart the pump.
- When changing batteries, never disconnect both batteries at the same time or your pump will stop.
- Losing power will make the pump stop. Power must be restored right away to restart the pump.
- Plug the Power Base Unit (PBU) only into properly grounded (3-prong) outlets. Do NOT use an adapter (cheater plug) for ungrounded outlets or you may get a serious electric shock.
- Do NOT connect the Power Base Unit (PBU) to an outlet controlled by a wall switch, or the PBU may not work.
- The PBU, like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3 prong) AC mains electrical outlet, except during transport or service/maintenance. The PBU'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 PBU is connected to AC power and turned "on."
- Do NOT touch television (TV) or computer screens while you have the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and make the pump stop.
- Do NOT do anything that may create static electricity, like vacuuming. A strong electric shock can damage the electrical parts of the pump and make the pump stop.

- Do not become pregnant while you have the pump. Use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may injure you or make the pump stop.

Important Precautions


- In case of an emergency, **always** have a back-up System Controller and spare batteries with you.
- When connecting leads, do not force them together without first lining up the connectors. Forcing together unaligned lead connectors may damage them.
- Never use tools to tighten connectors. Hand tighten only. Using tools may damage connectors.
- To prevent battery damage:
 - Do NOT drop batteries or hit them against hard objects or each other. Replace a battery if it is damaged; do not use it.
 - Do NOT leave or store batteries in hot or cold areas (car trunks, etc.) or battery life will be shortened.
 - Do NOT directly connect the negative and positive ends of batteries.
 - Recharge used batteries within 12 hours or battery life will be shortened.
- Using expired or broken batteries may cut operating time or cause the pump to suddenly stop.
- Do NOT use batteries in temperatures below 15°F (-10°C) or above 105°F (40°C), or the batteries may suddenly stop working. If batteries stay below room temperature (68°F -72°F, 20°C-23°C) during use, they will run the pump for less time. In low temperatures 15°F (-10°C), run time may be cut by 50%.
- Do not store batteries together with keys, coins, or other loose metallic objects. Metal object touching the exposed battery terminals may cause an accidental short or connection between the battery terminals, which can result in battery overheating that may burn you or damage the batteries.
- Use only the HeartMate Power Base Unit (PBU) to charge your HeartMate batteries. Other battery chargers may damage HeartMate batteries.
- Dirty battery terminals may prevent proper battery charging, which can affect battery operation. The metal battery terminals in the metal battery clip should be cleaned once a week with a Q-Tip™ or lint-free cloth that has been dipped in rubbing alcohol. Let the alcohol dry before inserting any batteries.
- Do NOT play contact sports or jump while you have the pump. Contact sports or jumping can cause bleeding or damage the pump.
- Do NOT take a tub bath or swim.

Important Precautions continued

- The HeartMate uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.
- To prevent damage to the Emergency Power Pack (EPP):
 - Do NOT leave or store the EPP in hot or cold areas (car trunks, etc.), or EPP life will be shortened.
 - Do NOT use EPP after its expiration date.
 - Do NOT store or use the EPP in temperatures below 32° F (0°C) or above 122°F (50°C), or the EPP may suddenly stop working. If your EPP stays below room temperature (68°F–72°F, 20°C–23°C) during use, it will run the pump for less than 12 hours. In low temperatures (32°F–5°F, 0°C – -10°C), run time may cut by 50%.
- Dispose of an expired or used EPP according to local regulations. Do NOT burn.
- Do NOT let the connector ends of leads get dirty or wet.
- Do NOT try to fix any of your LVAS equipment yourself. If equipment needs service, call your hospital contact person.
- Do NOT drop the System Controller or subject it to extreme physical shock.
- Do NOT pull on or move the percutaneous lead going through your skin. Pulling on or moving the lead can keep the exit site from healing. Pulling on or moving the lead can also increase the risk of getting a serious infection.
- Be extremely careful with your percutaneous lead. Check your lead often to make sure it does not get twisted. If your percutaneous lead does become twisted, carefully turn the System Controller to unravel the lead. Turn until the lead is no longer twisted.
- Do NOT kink or bend the percutaneous lead. Check your lead often to make sure it is free of kinks or sharp bends. A kink or sharp bend in the percutaneous lead may damage the wires inside.
- Call your doctor if you notice a change in how your pump works, sounds, or feels.
- Wear the HeartMate Stabilization Belt (or other abdominal binder) at all times to keep your percutaneous lead in place.

Why Should You Read this Handbook?

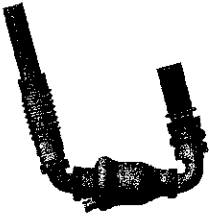


This *Patient Handbook* will teach you about your new HeartMate II heart pump. Read it to learn how the pump works and how to keep active and safe while living with the pump outside the hospital. This handbook is also important because it explains what to do in an emergency. If you have any questions after reading this handbook, ask your doctor or hospital contact person.

 **Note:** To reduce the risk of complications, the guidelines in this handbook should be closely followed.

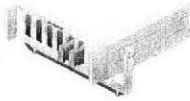

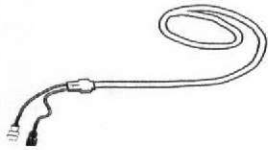
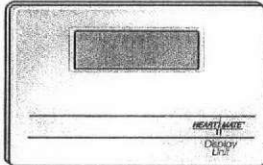
The table below lists the major parts of the pump system and gives a short description for each. Each part is explained in more detail later in this handbook.

System Components

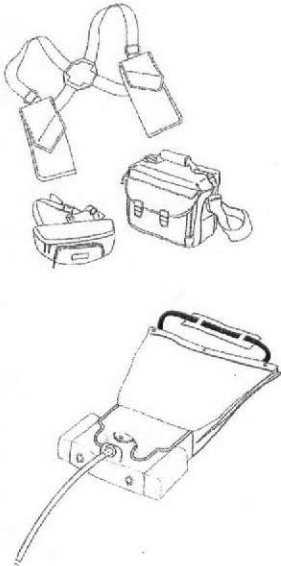
HeartMate II LVAS

<p>Pump</p>		<p>The pump moves blood from your heart to other parts of your body. The pump is implanted below your heart.</p>
<p>System Controller</p>		<p>The System Controller is a small computer that makes sure your pump is working right. It uses lights and sounds to tell you how the system is working.</p>
<p>Batteries and Battery Clips</p>		<p>HeartMate batteries are one type of routine power source used for powering the pump. Battery clips hold the batteries and connect them to the System Controller.</p>

System Components continued

<p>Power Base Unit (PBU)</p>		<p>The PBU is the other routine power source for powering the pump. In addition to powering the pump, the PBU recharges the HeartMate batteries.</p>
<p>Emergency Power Pack (EPP)</p>		<p>The EPP is an emergency power source. It can provide up to 12 hours of power. For example, during a power outage caused by a storm or severe weather.</p> <p>See page 43 for instructions on using the EPP.</p>
<p>Power Base Unit (PBU) Cable</p>		<p>The PBU cable connects the PBU to the System Controller. Connections are made between white-to-white and black-to-black connectors.</p>
<p>Display Module</p>		<p>When connected to the PBU, the Display Module shows information about how the pump is working, such as: pump speed, flow rate, pulsatility index (PI), and power. The pump's operating mode and other operating information also appears on the screen.</p>

System Components continued

HeartWear™ Accessories		<p>HeartWear™ accessories include: 1) Holsters for carrying batteries during battery-powered operation; 2) Carrying Case for carrying (around your waist) the System Controller, batteries, battery clips and extra length of power leads, the 3) Travel Case for carrying emergency or back-up HeartMate equipment, such as spare batteries and a back up System Controller. 4) The Shower Kit for keeping the external parts of your LVAS dry when showering (once approved by your doctor).</p>
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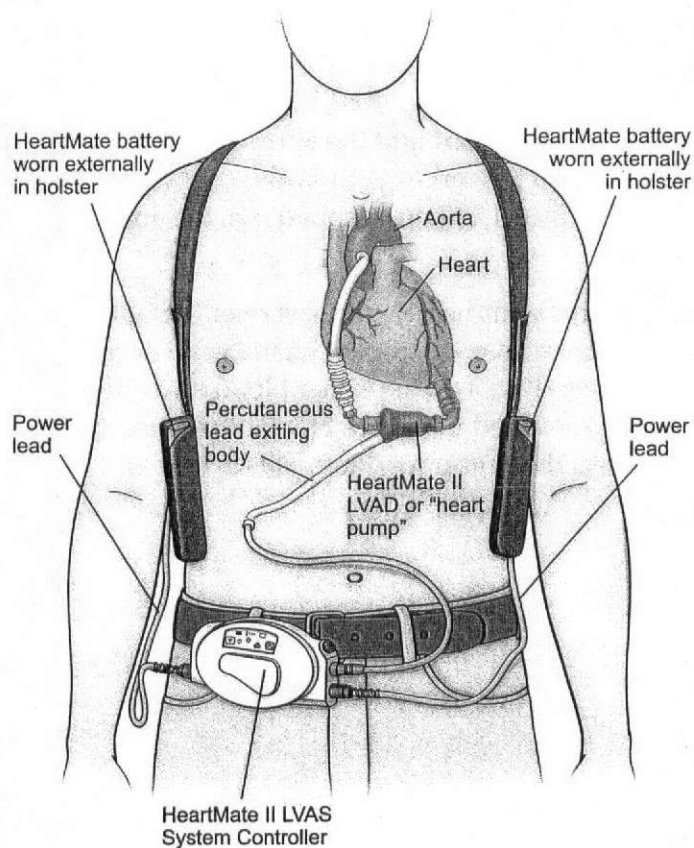
Your Heart Pump

Your heart pump is called the HeartMate II Left Ventricular Assist Device (LVAD). The LVAD helps your heart pump blood through your body. A small electric motor inside the LVAD drives the pump. The LVAD is placed (implanted) below your heart. It is attached to your heart and the aorta (the large blood vessel that carries blood from your heart to the rest of your body) (**Figure 1**). Blood from your heart flows into the LVAD. Blood is then pumped into the aorta ; and, from there, to the rest of your body.


Your heart pump helps your heart by taking over the function of the diseased left ventricle (your heart's primary pumping chamber). The electric motor drives a small rotor (similar to a propeller), which pushes blood into the aorta and out to the body. Your heart pump is designed to restore blood circulation to the body and its primary organs.. You may feel the pump working. This is normal.

Your Heart Pump continued

Figure 1



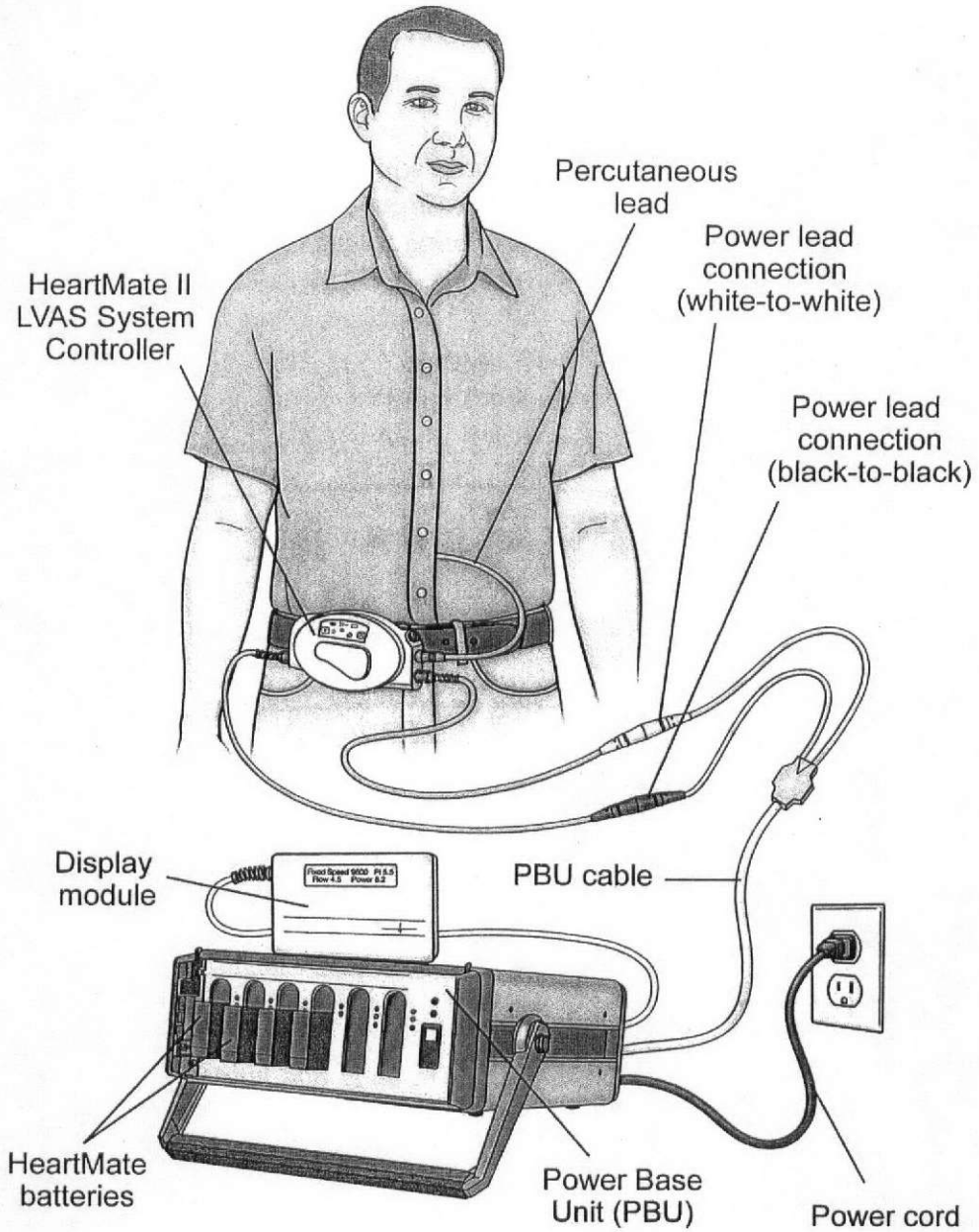
As shown in **Figure 1**, a percutaneous lead passes through your skin. The outside of the lead is covered with a special material that lets skin cells grow into it. This helps the exit site heal. A well-healed exit site can lower the risk of infection. You will need to keep the exit site very clean and dry. A clean, dry exit site also helps lower infection risk (see "Caring for the Exit Site" on page 55).

 **Note:** "Percutaneous" means "through the skin."

Power leads connect the System Controller to a power source (batteries, PBU or EPP). When the System Controller is connected to battery power, you'll wear 2 batteries, either in "holsters" under the arms (**Figure 1**) or in a Carrying Case around your waist. The System Controller can also be powered by the Power Base Unit (PBU) that is plugged into a wall outlet (**Figure 2**).

Your Heart Pump continued

Figure 2

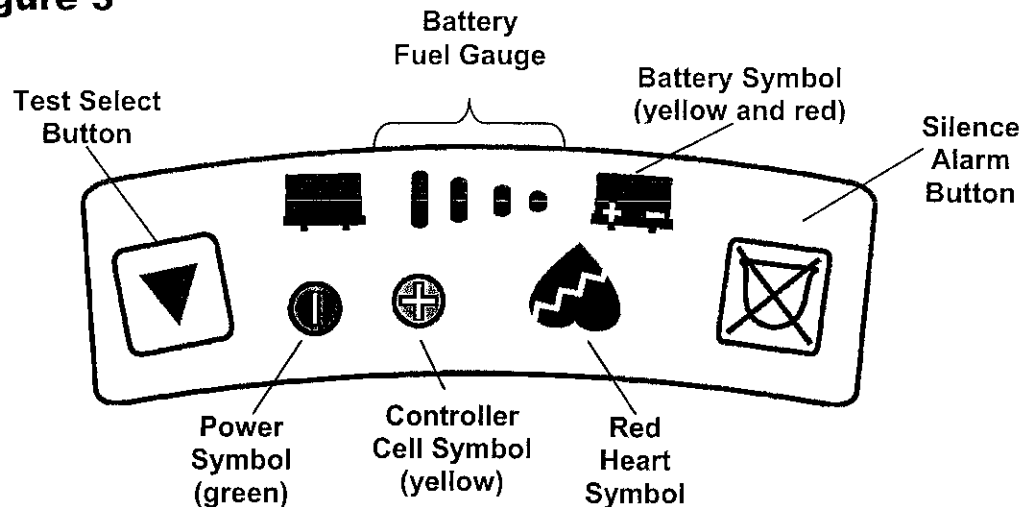


The System Controller

The System Controller is a small computer that makes sure your pump is working properly. It is connected to both the pump and a power supply (batteries, PBU, or EPP). The System Controller is usually worn on the belt or waistband.

The System Controller warns you if there is a problem with your pump or its power supply. The System Controller's warning lights, buttons, and battery fuel gauge are on the top of the Controller (Figure 3). Lights, buttons, and the battery fuel gauge are described on the following pages.

Figure 3






CAUTION !

The HeartMate II LVAS uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.

The System Controller continued




System Controller Warning Lights and Sounds

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
<p>Red Heart STEADY AUDIO TONE</p> 	<p>Pump flow is less than 2.5 lpm, pump has stopped, perc lead is disconnected, or pump is not working properly.</p>	<ol style="list-style-type: none"> 1 Make sure System Controller is connected to the pump. 2 Make sure System Controller is connected to a power source (batteries, PBU, or EPP). 3 If alarm continues, immediately call for emergency help (dial 911 if available), then call your Hospital Contact Person.
<p>STEADY AUDIO TONE, but no warning light and no green power symbol.</p>	<p>System Controller is not receiving power.</p>	<ol style="list-style-type: none"> 1 Make sure System Controller is connected to a power source (batteries, PBU, or EPP). 2 If connected and alarm continues, switch to a different power source. 3 If alarm continues after switching power source, replace Controller (see page 21 for instructions).
<p>Red Battery STEADY AUDIO TONE</p> 	<p>Less than 5 minutes of battery power remain, voltage is too low, or the System Controller is not getting enough power from the PBU.</p>	<p>Immediately replace depleted batteries with new, fully-charged set. Change batteries one at a time. If fully-charged batteries are not available, switch to PBU or EPP. WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop. Note: Pump speed will gradually decrease to save power (i.e., Power Saver Mode) until the condition is resolved and the alarm clears.</p>
<p>Yellow Battery 1 beep every 4 seconds</p> 	<p>Less than 15 minutes of battery power remain, voltage is too low, or System Controller is not getting enough power from the PBU.</p>	<p>Immediately replace depleted batteries with new, fully-charged set. Change batteries one at a time. If fully-charged batteries are not available, switch to PBU or EPP. WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop.</p>

continued




The System Controller continued

System Controller Warning Lights and Sounds continued

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
<p><i>Broken AUDIO TONE (repeating cycle of 1 beep per second for 2 seconds, followed by 2 seconds of silence), but NO warning light.</i></p>	<p>System Controller is operating in back-up mode.</p>	<ol style="list-style-type: none"> 1 Replace the System Controller (see page 21). 2 Call your hospital contact person. 3 Obtain a new, backup System Controller from your Hospital Contact Person.
<p>Controller Cell <i>Yellow symbol; 1 beep every 4 seconds</i></p> 	<p>The battery module that power the System Controller audible alarm is low on power.</p>	<p>Replace the System Controller battery module.</p>
<p>Rapidly Flashing Power Symbol</p>  <p><i>and</i></p> <p>Four (4) Flashing Green Lights (on Battery Fuel Gauge) <i>flash once per second</i></p>  <p><i>1 beep every second</i></p>	<p>One of the power leads is damaged or disconnected.</p>	<ol style="list-style-type: none"> 1 Reconnect or tight disconnected/loose power lead. 2 If alarm continues, check System Controller power lead and PBU power lead for damage. 3 If System Controller power lead or PBU power lead is damaged, replace the System Controller (see page 21) and/or replace the PBU cable. 4 Obtain a new, backup System Controller from your Hospital Contact Person.
<p><i>1 beep every 4 seconds</i> <i>No Warning Light;</i></p>	<p>Pump is operating below low speed limit.</p>	<p>Call your Hospital Contact Person.</p>




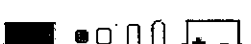


The System Controller continued

System Controller Buttons

SWITCH	PURPOSE	HOW TO USE
<p data-bbox="409 577 563 643">Test Select Button</p> 	<p data-bbox="601 643 926 703">Starts the System Controller Self Test.</p>	<p data-bbox="948 555 1433 650">Push and hold for 3 seconds to start Self Test. See "System Controller Self-Test" on page 16.</p> <p data-bbox="948 665 1455 791">Note: Pressing this button will have no effect when an alarm is active. A self-test can be done only when there are no active alarms.</p>
<p data-bbox="398 842 579 909">Silence Alarm Button</p> 	<p data-bbox="601 814 773 842">Allows you to:</p> <ul data-bbox="601 853 921 1329" style="list-style-type: none"> <li data-bbox="601 853 921 913">▪ Silence Advisory Alarms for 4 hours. <li data-bbox="601 924 921 984">▪ Silence RED Hazard Alarms for 2 minutes. <li data-bbox="601 995 921 1165">▪ Silence the Power Cable Disconnect Alarm for 2 minutes if one of the power leads is disconnected or damaged. <li data-bbox="601 1176 921 1329">▪ Silence both the System Controller and the PBU if you are attached to the PBU when the System Controller alarms. 	<p data-bbox="948 953 1443 1013">Firmly press and hold for a count of 2, then let go.</p> <p data-bbox="948 1024 1460 1190">Note: Do not silence an alarm without first finding out why it is occurring. Silencing the alarm does not fix the problem. Be sure to have a plan for fixing the problem before silencing any alarm.</p>
<p data-bbox="398 1340 579 1406">Silence Alarm Button</p> 	<p data-bbox="601 1384 915 1517">Lets you check how much battery power remains (see "Battery Fuel Gauge" next page).</p>	<p data-bbox="948 1451 1372 1479">Press and hold Silence Alarm Button.</p>

The System Controller continued

Battery Fuel Gauge






BATTERY FUEL GAUGE LIGHTS	MEANING	WHAT YOU SHOULD DO
<p>Four (4) Green Lights</p> 	<p>Between 100% - 75% of battery power available (batteries fully charged).</p>	<p>No Action Needed.</p>
<p>Three (3) Green Lights</p> 	<p>Between 75% - 50% of battery power remains (batteries are 3/4 charged).</p>	<p>No Action Needed.</p>
<p>Two (2) Green Lights</p> 	<p>Between 50% - 25% of battery power remains (batteries are 1/2 charged).</p>	<p>No Action Needed.</p>
<p>One (1) Green Light</p> 	<p>Less than 25% of battery power remains (batteries are less than 1/4 charged).</p>	<p>Replace used batteries with fully-charged ones, or switch to PBU or EPP.</p>
<p>Four (4) Flashing Green Lights (on Battery Fuel Gauge) <i>flash once per second</i></p>  <p>and</p> <p>Rapidly Flashing Power Symbol</p>  <p><i>1 beep every second</i></p>	<p>One of the power leads is damaged or disconnected.</p>	<p>Check for loose or damaged power leads. If on PBU power, check that the power lead is not damaged or disconnected.</p>


The System Controller continued

System Controller Self-Test


At least once a day you should do a System Controller Self-Test to make sure that your System Controller is working properly. The Self-Test takes about 10 seconds. During the Self-Test your pump will continue to run. For your comfort, we recommend that you sit down during the test. Place the System Controller where you can easily push the buttons and see the lights during the test.

How to Perform a System Controller Self-Test

- 1 To start the Self-Test, press and hold the Test Select Button  for 3 seconds. After 3 seconds, the Red Heart , Red and Yellow Battery , Yellow Controller Cell Symbol , and Fuel Gauge lights  will come on, along with a STEADY AUDIO TONE.

 **Note:** 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.

- 2 Look closely at the display. Make sure that all of the lights are on and the alarm is making a STEADY AUDIO TONE. *If there is a problem with the audio alarm, it will beep once every 2 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 5 seconds.
- 4 If all the alarms and lights come on as described above and then turn off 5 seconds after letting go of the button, the System Controller has passed the Self-Test.

 **Note:** If there are any problems or if your System Controller fails the test, call your hospital contact person.


The System Controller continued

System Controller Perc Lock

The Perc Lock keeps the percutaneous lead from accidentally disconnecting from the Controller (if you accidentally hit the release tab, for example). If the lead disconnects, your pump will stop. Therefore, it is important to have the Perc Lock in the locked position at all times.

How to Use and Check the Perc Lock

Follow these steps to make sure the Perc Lock is properly locked:

- 1 While sitting down, turn (rotate) the Perc Lock on the System Control towards the "locked" symbol  (Figure 4).


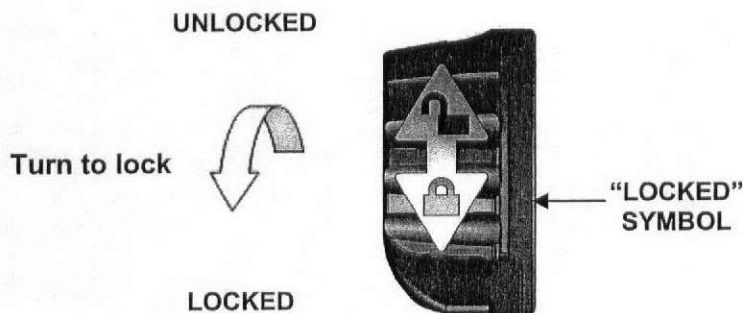

 **Note:** Keep turning until the Perc Lock "clicks" into place.


Figure 4



- 2 If the Perc Lock does not rotate, make sure the connector is fully inserted into the System Controller socket.

 **Note:** The Perc Lock will not rotate unless the connector is fully inserted.

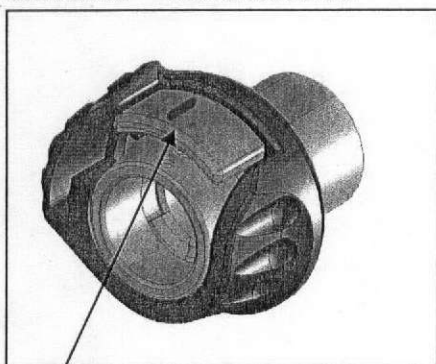
- 3 After it clicks into place, inspect the Perc Lock to make sure it is fully locked.

 **Note:** If fully locked, the Perc Lock will cover the metal release tab (Figure 5).

The System Controller continued

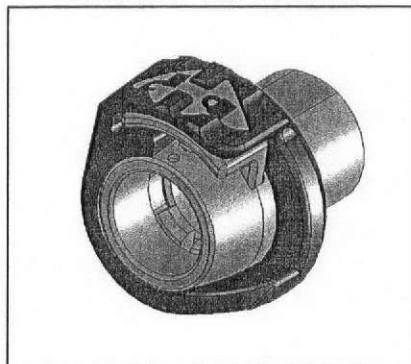
Figure 5

Unlocked – Tab Uncovered




Metal Release Tab

Locked – Tab Covered



Changing the System Controller Battery Module

A small battery module powers the System Controller (not the pump). When the battery module is running low, the yellow battery module symbol  (on top of the System Controller) comes on (Figure 6).


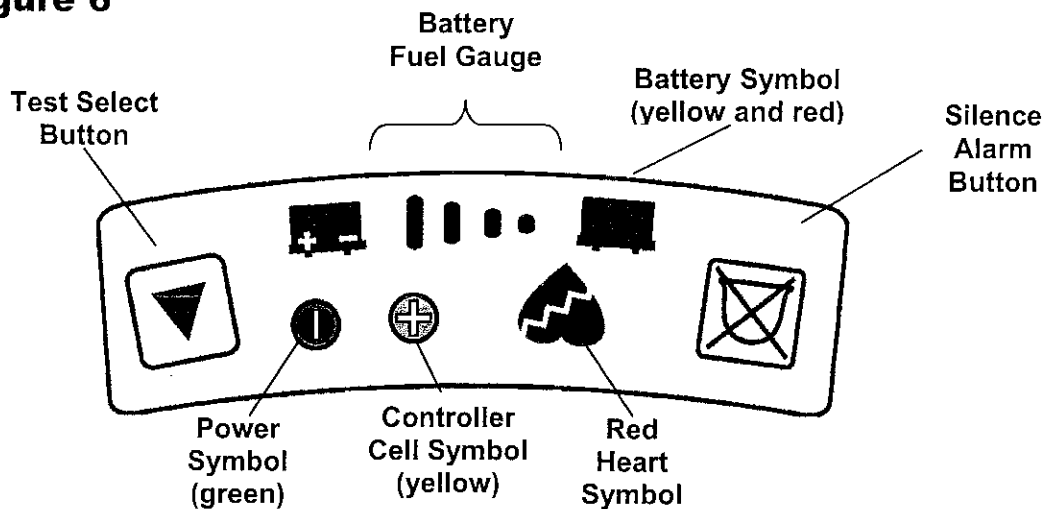

 **Note:** The System Controller battery module only powers the System Controller audio tone. It does NOT power the pump and will not provide back-up power to the pump in the event of a power failure.

Figure 6



Follow these steps to change the System Controller battery module:

- 1 Obtain a new System Controller battery module.
- 2 Examine the new battery module. Make sure there is white tape around the sides of the battery module and an orange O-ring around the bottom. If the white tape or orange O-ring is missing, do NOT use the battery module. Get a new one.
- 3 Unscrew (counterclockwise) the old battery module from the side of the System Controller. Throw away the old battery module.

 **Note:** If the old battery module is hard to remove, you can use a flat object (like a coin) in the slot for leverage.

- 4 Insert the new battery module into the System Controller (Figure 7).

Changing the System Controller Battery Module continued


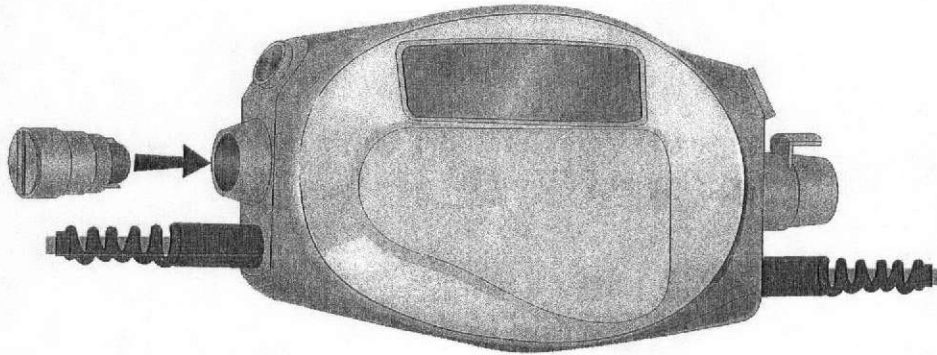

- 5 Turn the new battery module clockwise until you can no longer see the orange O-ring. You can use a flat object (like a coin) to tighten the battery module. **But do not over tighten it.**
- 6 Once the battery module is properly inserted, the yellow battery module symbol  will turn off.


Figure 7




Replacing System Controllers

If your pump stops, the System Controller will alarm. The Red Heart Symbol  will light and there will be a STEADY AUDIO TONE.

If your pump stops, switching to the back up System Controller might restart it. But, BEFORE trying to switch Controllers, make sure you fully understand how to do it. Have someone help, if possible. Help could make it faster and easier to replace the Controller.

 **Note:** When pump power is interrupted (e.g., perc lead disconnected or both batteries disconnected at the same time), the pump will stop. When power is restored, the System Controller will automatically restart the pump at the previously-set speed.

Follow these steps to replace your System Controller:

- 1 Place the *replacement* System Controller within easy reach, along with the batteries/battery clips or PBU cable.
- 2 Sit or lie down.
- 3 Rotate the perc lock on the new, *replacement* Controller in the direction of the “unlocked” icon  until the perc lock clicks into the fully-unlocked position.
- 4 Repeat Step 3 for the *original* Controller until the perc lock clicks into the fully-unlocked position.


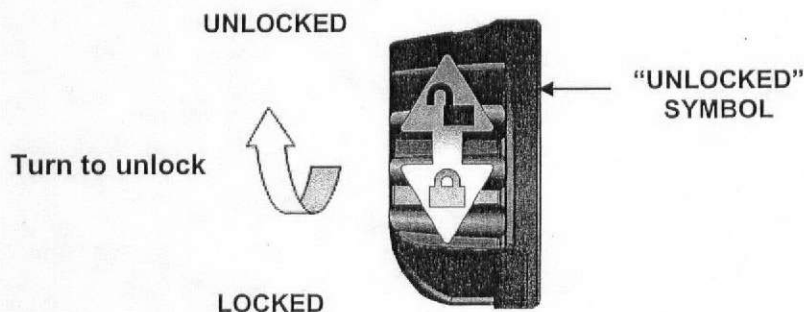
 **Note:** Keep turning until the Perc Lock clicks into the unlocked position and the metal release tab is showing (Figure 8).

Figure 8



Replacing System Controllers continued





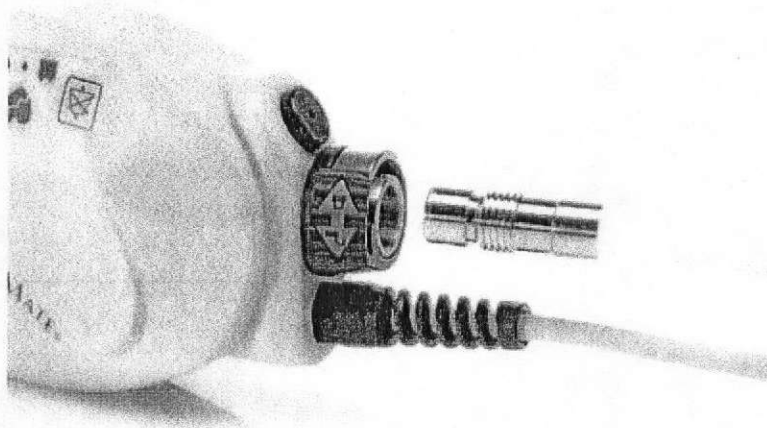
- 5 Attach the power leads on the new, *replacement* Controller to the PBU cable or to the battery clips, depending on the power source being used.
- 6 If using battery power, place fully-charged batteries into the battery clips after attaching the power leads.
- 7 Press the Silence Alarm  Button on the new, *replacement* Controller to silence its Red Heart  Alarm for 2 minutes.
- 8 Disconnect the perc lead from the *original* Controller by pressing the metal release tab on the connector socket. *The pump will stop and an alarm will sound until power is removed from the original Controller.*
 -  **Note:** Getting the new Controller connected and the pump restarted is the first priority. Ignore the alarm for the old Controller for now. You can disconnect the old Controller and stop its alarm once the new Controller is connected
- 9 Connect the new, *replacement* Controller:
 - a Line up the mark on the perc lead connector with the mark on the metal tab of the new Controller.
 - b Fully insert the connector into the socket of the new Controller (**Figure 9**). *The pump should restart/alarms should stop.*
 -  **Note:** Gently tug on *metal end* of the lead to make sure that it is fully engaged into the socket. Do NOT pull on the lead.

Figure 9

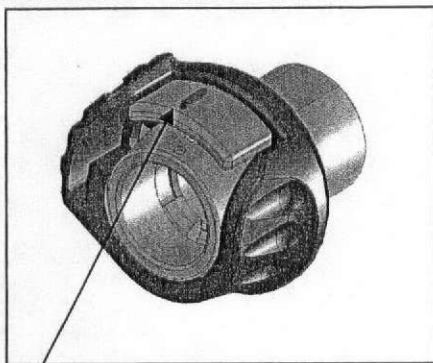


Replacing System Controllers continued

- 10 If the pump restarts, skip to Step 12.
OR
- 10 If the pump does not restart and the Red Heart ♥ Alarm continues:
- Firmly press the Silence Alarm ☒ or Test Select ▲ Button to restart the pump.*
 - Check the power source. Make sure that power is going to the Controller.
 - Make sure the perc lead is fully inserted into the socket. Gently tug on the metal end. Do NOT pull on the lead.
- 11 If the pump still does not restart, call for emergency help (dial 911 if available), 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 1 beep per second for 2 seconds, followed by 2 seconds of silence to indicate that the System Controller is operating on the backup system.*
 - Call your Hospital Contact Person right away.
- 12 After the pump restarts, rotate the perc lock on the new, replacement Controller in the direction of the "locked" 🔒 icon until the perc lock clicks into the fully-locked position (Figure 10).

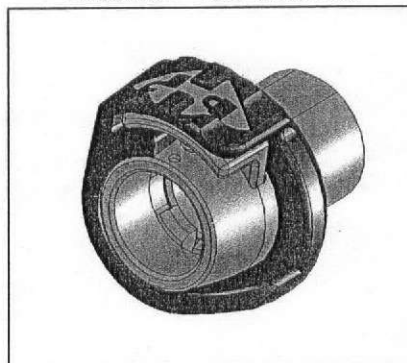
Figure 10

Unlocked – Tab Uncovered



Metal Release Tab

Locked – Tab Covered



Replacing System Controllers continued


- 13 Disconnect the power source from the original System Controller. *It will stop alarming once power is disconnected.*
- 14 Return the old, original System Controller to your Hospital Contact Person and get another backup System Controller.

* If the pump speed is set below 8,000 rpm, the pump will not automatically restart when power is restored. Either the Silence Alarm or Test Select Button must be pressed to restart the pump if the pump is set below 8,000 rpm.

The Power Base Unit (PBU)

The PBU has 2 functions: 1) powering your pump when you're connected to the PBU and 2) charging and testing HeartMate batteries.

At least once a year, the PBU should be inspected, cleaned, and serviced by a trained Thoratec representative or authorized hospital employee. Annual service also includes replacing the PBU's internal battery.

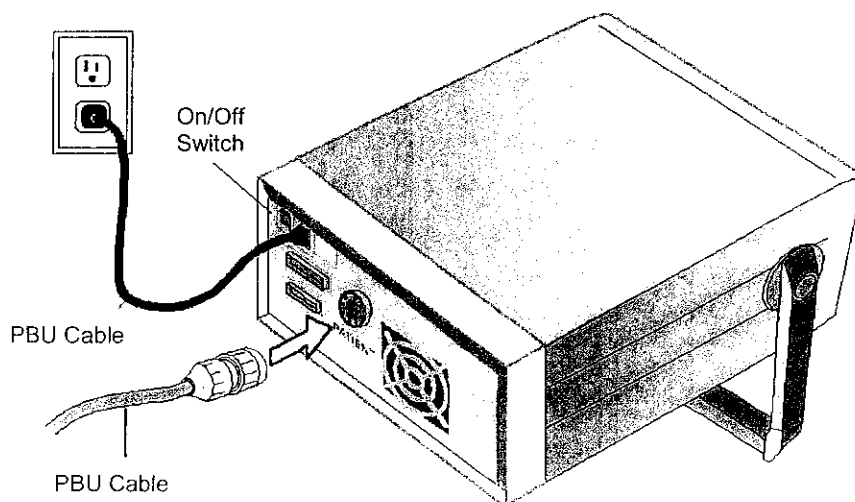
 **Note:** A rechargeable battery inside the PBU provides approximately 45 minutes of backup power to the system if AC electrical power fails. The internal battery stays charged as long as the PBU is connected to AC power and the power switch is "on." The internal battery is rechargeable, but has limited life and must be replaced once a year.

Service can take place at your home if necessary. However, usually the PBU will be inspected during a routine hospital visit. Talk with your hospital contact person about routine preventative maintenance for your PBU.

How to Set Up the PBU


- 1 Place the PBU on a flat, sturdy surface, such as a table.
- 2 Plug the PBU power cord into a 3-prong wall outlet. Do NOT use an adapter (cheater) plug or a wall outlet controlled by a light switch.
- 3 Turn the ON/OFF switch (on the back of the PBU) to the ON (I) position (**Figure 11**).

Figure 11



The Power Base Unit (PBU) continued

- 4 Plug the PBU cable into the socket labeled "Patient" (Figure 11).
- 5 Attach the **white** System Controller connector to the **white** PBU power lead connector; then attach the **black** System Controller connector to the **black** PBU power lead connector.

 **Note:** Always connect white-to-white and black-to-black.

WARNING !

- Plug the PBU **ONLY** into properly grounded (3-prong) outlets. Do **NOT** use an adapter (cheater plug) for ungrounded wall outlets or you may get a serious electric shock.
- Do **NOT** connect the PBU to an outlet controlled by a wall switch or the PBU may not work.
- Keep the PBU away from water. If the PBU has contact with water, shower spray or wet surfaces, the pump may stop or you may get a serious electric shock.

CAUTION !

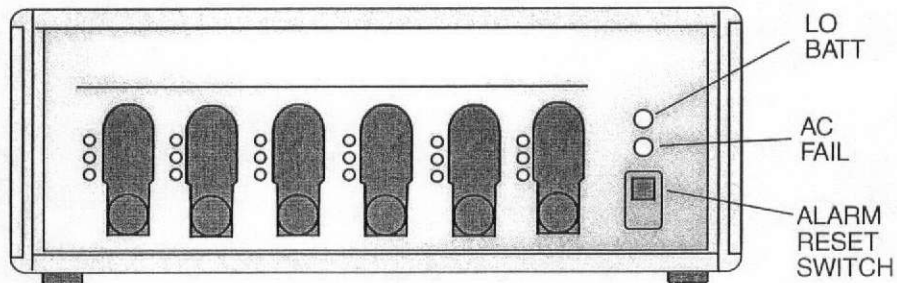
Do **NOT** let connector ends get dirty or wet.

Power Base Unit (PBU) Warning Lights & Sounds

WARNING LIGHTS & SOUNDS	MEANING/FUNCTION	WHAT YOU SHOULD DO
AC FAIL STEADY AUDIO TONE	External power to PBU is disconnected/off. The PBU's internal battery will power the pump for up to 30 minutes. Note: PBU will NOT recharge batteries during AC FAIL.	Change power source: switch from PBU power to battery power - or use the Emergency Power Pack (EPP) if you do not have charged batteries.
LO BATT STEADY AUDIO TONE	PBU internal battery is almost used up. Note: This alarm cannot be silenced.	Change power source immediately : switch from PBU power to battery power - or use the Emergency Power Pack (EPP) if you do not have charged batteries.
ALARM RESET	Used to silence the PBU AC FAIL alarm.	Press the Alarm Reset Button. This will silence the AC Fail Alarm. It will not come back on. Note: You cannot silence this alarm by pressing the System Controller Silence Alarm Button. Note: The Lo Batt (low battery) alarm cannot be silenced when your System Controller is connected to the PBU.

Note: When you are connected to the PBU (Figure 12), the PBU will repeat (duplicate) any active System Controller alarms. You can silence System Controller alarms by pressing the Silence Alarm Button on the System Controller.

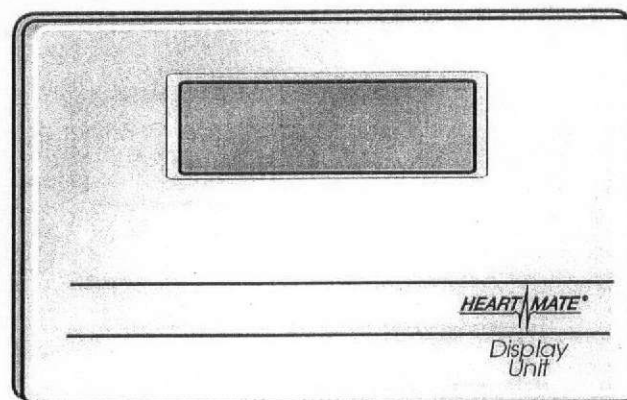
Figure 12



Display Module

You must be connected to the Power Base Unit (PBU) in order to use the Display Module (Figure 13a). The Display Module gets information from the System Controller through the PBU. The Display Module screen shows pump speed, flow, pulsatility index (PI), and power information. It also shows the current operating mode and tells you how the system is working (for example, listing the highest priority alarm message).

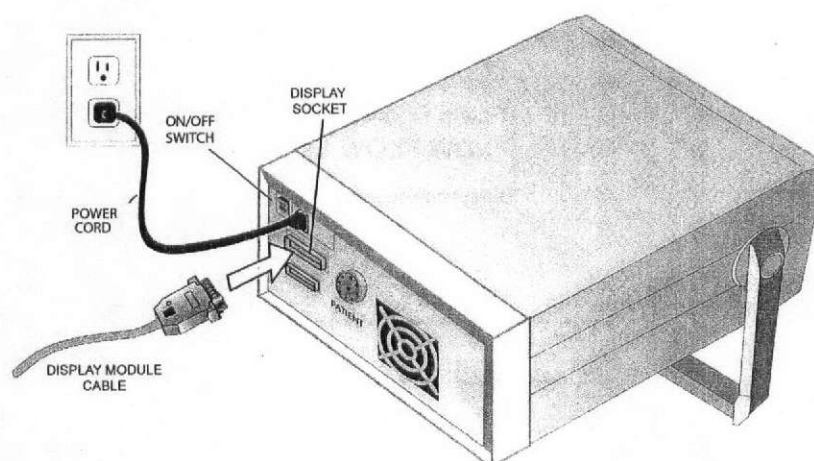
Figure 13a



How to Set-Up the Display Module

- 1 Plug the Display Module cable into the socket labeled "Display" found on the back of the PBU (Figure 13b).

Figure 13b

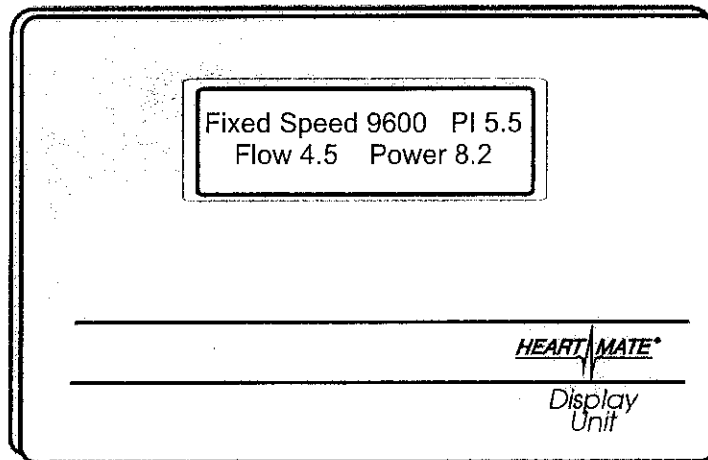


Display Module continued

2 The Display Module screen will immediately begin showing the following (Figure 13c):

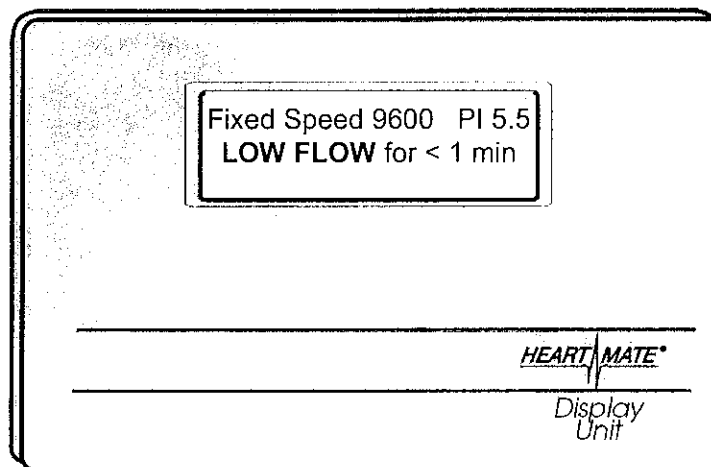
- Current pumping mode (Fixed Mode)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility Index (PI) (your doctor can explain this)
- Estimated flow in liters per minute (lpm)
- Power in watts (W)

Figure 13c



When there's an alarm, the alarm message will alternate with pump flow and power information on the screen (Figure 13d).

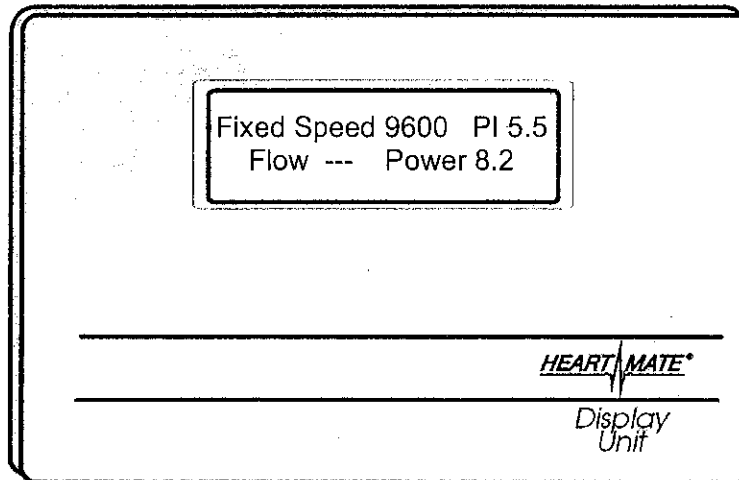
Figure 13d



Display Module continued

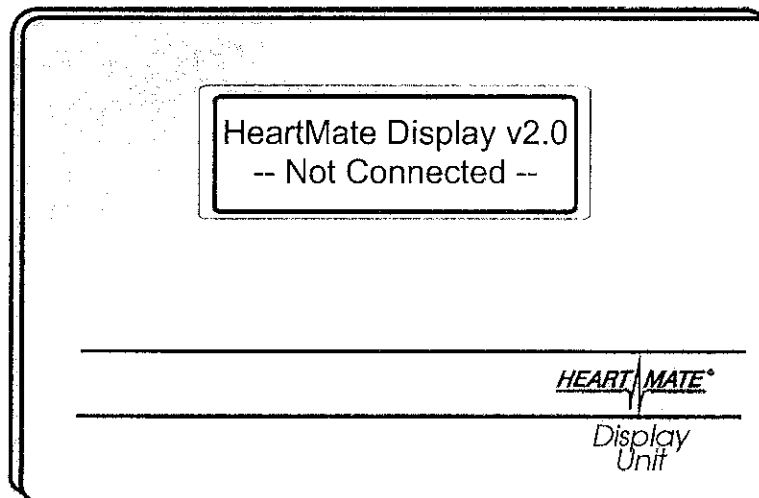
If the estimated flow is too high or too low to show on the screen, the Display Module will insert plus or minus signs instead of numbers. For example, "Flow ---" appears on the screen if the low limit is reached. "Flow +++" if the high limit is reached (**Figure 13e**).

Figure 13e



The following screen appears if you are disconnected from the PBU when the Display Module is plugged into the PBU (**Figure 13f**).




Figure 13f



Display Module continued**Display Module Alarm Messages**

SYSTEM CONTROLLER WARNING LIGHTS & SOUNDS	ALARM MESSAGES	MEANING	WHAT YOU SHOULD DO
 RED HEART with STEADY AUDIO TONE	LOW FLOW HAZARD	Pump flow is less than 2.5 lpm, pump has stopped, pericardial lead is disconnected, or pump is not working properly.	<ol style="list-style-type: none"> 1 Make sure System Controller is connected to the pump. 2 Make sure System Controller is connected to a power source (batteries, PBU, or EPP). 3 If alarm continues, immediately seek additional help.
 RED BATTERY with STEADY AUDIO TONE	LOW VOLTAGE	Less than 5 min. of battery power remain, voltage is too low, or the System Controller is not getting enough power from the PBU.	Immediately replace depleted batteries with new, fully-charged set. Change batteries one at a time . If fully-charged batteries are not available, switch to PBU or EPP. WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop. <i>Note:</i> Pump speed will gradually decrease to save power (i.e., Power Saver Mode) until condition is resolved and alarm is cleared.
 YELLOW BATTERY symbol with 1 beep every 4 seconds	LOW VOLTAGE Advisory	Less than 15 min. of battery power left. System Controller not getting enough power.	Switch to fully-charged batteries or switch to PBU or EPP. WARNING: Do NOT remove batteries at the same time, or your pump will stop.


continued

SYSTEM CONTROLLER WARNING LIGHTS & SOUNDS	ALARM MESSAGES	MEANING	WHAT YOU SHOULD DO
Broken Audio Tone (repeating cycle: 1 beep per second for 2 seconds, followed by 2 seconds of silence)	REPLACE SYSTEM DRIVER	System Controller is operating in backup mode.	<ol style="list-style-type: none"> 1 Replace the System Controller (see page 21). 2 Contact your Hospital Contact Person. 3 Obtain a new, replacement System Controller from your Hospital Contact Person.
Yellow Controller Cell  1 beep every 4 seconds	DRIVER CELL LOW	The battery module that powers the System Controller audible alarm is low on power.	Replace the System Controller battery module.
FLASHING POWER SYMBOL  and FLASHING BATTERY FUEL GAUGE LIGHTS  with 1 beep every second	Power Cable Disconnected	One of the power leads is damaged or disconnected.	<ol style="list-style-type: none"> 1 Reconnect or tighten disconnected/loose power lead. 2 If alarm continues, check System Controller power lead and PBU power lead for damage. 3 If System Controller power lead is damaged, replace the Controller (see page 21). 4 Obtain a new, backup System Controller from your Hospital Contact Person.
1 Beep Every 4 Seconds; No Warning Light	WARNING: Low Speed Operation	Pump is operating below low speed limit.	Immediately contact your Hospital Contact person.

HeartMate Batteries

A pair of fully-charged HeartMate batteries will power the pump for about 3 hours under "normal" conditions (such as reading or casual walking). Batteries will last for less time if you are more active. For example, while exercising you could get up to 25% less time. While on battery power keep at least 2 extra fully-charged batteries with you for back up. That way they will be ready if the first pair runs low.

When you first get a new battery, you will need to charge it before using it. Charge it in the PBU (see "Recharging HeartMate Batteries" on page 34). Write the date of the first charge on the battery's label. Unless there are problems with the battery (damage from dropping, etc.), you should be able to use it for up to 1 year after the first charge. Never use expired batteries and always use batteries according to instructions!

 **Note:** Dirty battery terminals may prevent proper battery charging, which can affect battery operation. The metal battery terminals and the metal contacts inside of the battery clips should be cleaned once a week with a Q-Tip™ or lint-free cloth that has been dipped in rubbing alcohol. Let the alcohol dry before inserting any batteries.

CAUTION !

Run batteries in matched pairs, especially if you have older and newer ones. Old and new batteries should not be mixed or your pump may run for a shorter time.

Do NOT burn it.

Do NOT drop or subject to strong physical shock.

Do NOT use outside specified temperature range.

HEARTMATE

THOMASCO
Plantation, CA 94556

pb

EXP. DATE:
LOT #:

26370 REV. D

+40°C
(105°F)

-10°C
(15°F)

May be recycled. Discard according to applicable regulations.

Dropping batteries or exposing them to extreme temperatures will shorten battery life.


Expiration appears on label. Do NOT use expired batteries.

HeartMate Batteries continued


CAUTION !

- To prevent battery damage:
 - Do NOT drop batteries or hit them against hard objects or each other. Replace a battery if it is damaged; do not use it.
 - Do NOT leave or store batteries in hot or cold areas (car trunks, etc.) or battery life will be shortened.
 - Do NOT directly connect the negative and positive battery ends.
 - Recharge used batteries within 12 hours or battery life will be shortened.
- Using expired or broken batteries may cut operating time or cause the pump to suddenly stop working.
- Do NOT use batteries in temperatures below 15°F (-10°C) or above 105°F (40°C), or the batteries may suddenly stop working. If your batteries stay below room temperature (68-72°F, 20-23°C) during use, they will run the pump for less time. In low temperatures (15°F, -10°C), run time may be cut by 50%.

Power Saver Mode

If there is less than 5 minutes of power left in your batteries, the pump will automatically slow down and begin pumping at a reduced speed. This is called Power Saver Mode. When this happens, the System Controller's Red Battery  light comes on, along with a STEADY AUDIO TONE.


Running at reduced speed is a critical situation. You may become dizzy or short of breath. It is important that you switch to fresh batteries or to another power source (PBU or EPP) right away. Switching to new batteries or another power source will stop the alarm and bring the pump back to its original speed.




 **Note:** If the alarm does not stop after changing batteries or switching to a different power source, call your hospital contact person. You may need to replace the System Controller or PBU cable.

Recharging HeartMate Batteries


The Power Base Unit (PBU) is the only battery charger you should use to charge HeartMate batteries. Using any other battery charger may damage the batteries. The PBU can charge up to 6 batteries in about 8 hours, depending on the charge level of the battery(ies) being charged.

How to Charge Batteries Using the PBU


- Slide the battery into a slot of the PBU, with the metal terminal facing up. *The yellow light will come on for about 30 seconds while the battery is tested.*
 **Note:** Do not touch the metal battery terminals.
- After testing, 1 of 3 lights will come on (green, yellow, or red). The light color depends on the battery's charge level or status (see table below).

LIGHT	MEANING
Green 	Fully charged; ready for use.
Yellow 	Battery being charged; NOT yet ready for use.
Red 	Defective Battery, DO NOT USE.

When a battery is put into the PBU, the PBU tests the battery before recharging it. If the battery fails the initial test, the **red light** comes on.


 **Note:** Sometimes the red light comes on if the battery is put into the slot the wrong way. If a battery fails the 1st test, put it into a same slot and try again. If it fails the 2nd test, put the battery into a different slot. If the battery fails again, there is something wrong with the battery. Do not use it; it should be replaced. If a battery passes the test, a **yellow** light comes on and then the battery starts recharging. After it is charged, the **green** light comes on. If a battery fails the test in the first slot but then works in the 2nd slot, tell your hospital contact person. There may be a problem with the slot (and not with the battery) and the PBU may need to be fixed or replaced.

Recharging HeartMate Batteries continued

 **Note:** Batteries will not be damaged if left in the PBU after charging.

CAUTION !

Use ONLY the HeartMate Power Base Unit (PBU) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries.

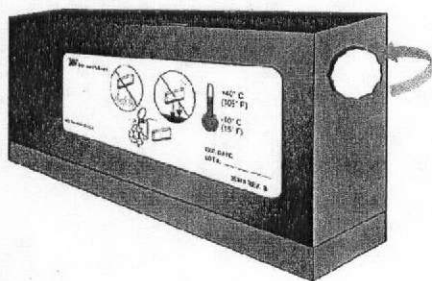
 **Note:** Dirty battery terminals may prevent proper charging. Battery terminals should be cleaned once a week with a Q-Tip® or lint-free cloth that has been dipped in rubbing alcohol. Let the alcohol dry before inserting any batteries.

For your convenience, Velcro® circles are included with your batteries. Use them to identify the batteries that need to be recharged. *For example, when a battery is fully charged, put the Velcro circle on the battery with the white side facing up. When a battery needs to be recharged, turn over the Velcro so that the black side is up (Figure 14).*

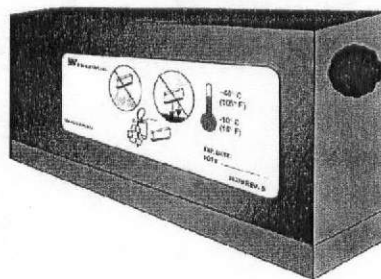
White = Charged; ready for use.

Black = Used or charging. Do NOT use until fully charged.

Figure 14



Turn Velcro white-side-up when battery is fully charged




Turn Velcro to black-side-up when battery needs to be recharged



Changing Batteries


When batteries have about 15 minutes of power left, the System Controller's YELLOW BATTERY symbol will come on and a BEEP will sound about once every 4 seconds. This means it's time to change the batteries.

How to Change Batteries (see Appendix for Power Change Checklist)

- 1 Remove the battery clips and attached batteries from your holsters or carrying case.
- 2 Remove spare (fully-charged) batteries from your travel case or from the PBU.
- 3 Turn over the Velcro circles on these batteries so you won't get confused about which batteries need to be recharged later.

 **Note:** Consider turning over the Velcro circles right after charging the batteries and just before putting them into the battery clips. This way you won't forget to turn them over later or get confused about which batteries need recharging.

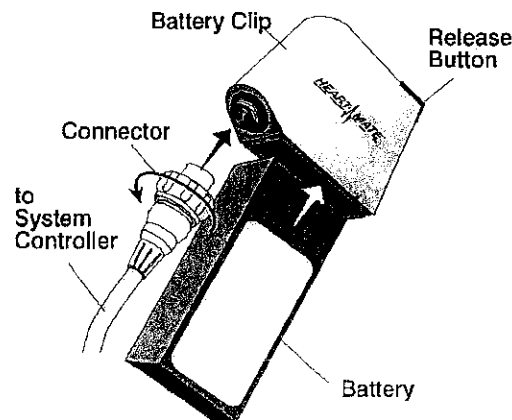
- 4 Take out only 1 battery from its battery clip by pressing its battery release button (Figure 15). An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the 4 green battery fuel gauge lights  will flash.

 **Note:** You must press the battery release button to remove a battery from its clip.

WARNING !

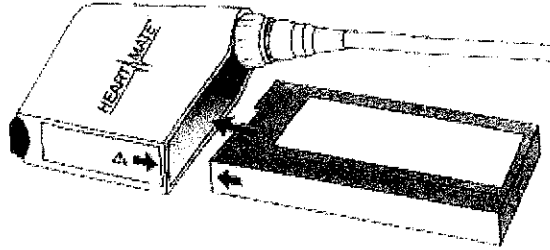
At least 1 System Controller power lead must be connected to a power source (battery, PBU, or EPP) at all times. Disconnecting both Controller power leads at the same time will cause the pump to stop.


Figure 15



Changing Batteries continued

Figure 16





- 5 Match the arrows on the new battery and the battery clip (**Figure 16**).
 - 6 Slide the new, fully-charged battery into the battery clip. *The alarm will stop and both the green power symbol and the battery fuel gauge lights will stop flashing. Wait until the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 6.*
 - 7 Repeat Steps 4-6 for the 2nd battery/battery clip.
 - 8 If you have not already done so, turn over the Velcro to show that the batteries need to be recharged.
-  **Note:** Consider turning over the Velcro circles right after charging the batteries and just before putting them into the battery clips. This way you won't forget to turn them over later or get confused about which batteries need recharging.
- 9 Put the new, fully-charged batteries/battery clips into the holsters or carrying case.
 - 10 Put the used batteries into PBU for recharging.

WARNING !

- Your pump will stop if both batteries are removed at the same time.
- If power to the Controller is interrupted, restoring power will restart your pump.

Switching Power Sources


Going from Batteries to PBU (see Appendix for Power Change Checklist)

- 1 Make sure PBU is plugged in and turned on.
- 2 Make sure that the PBU cable is attached to the "Patient" socket found on the back of the PBU.
- 3 Place black and white PBU connectors within easy reach.
- 4 Remove batteries from their holsters or carrying case.
- 5 Unscrew the white connector from the 1st battery clip. *An alarm with sound 1 beep per second, the green power symbol  will flash rapidly, and the 4 green battery fuel gauge lights  will flash.*

WARNING !

At least 1 System Controller power lead must be connected to a power source (battery, PBU, or EPP) at all times. Disconnecting both power leads at the same time will cause the pump to stop.

- 6 Put aside the battery and battery clip.
- 7 Connect the **white** PBU power lead connector to the **white** System Controller connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 8.*

 **Note:** Always connect white-to-white and black-to-black connectors.

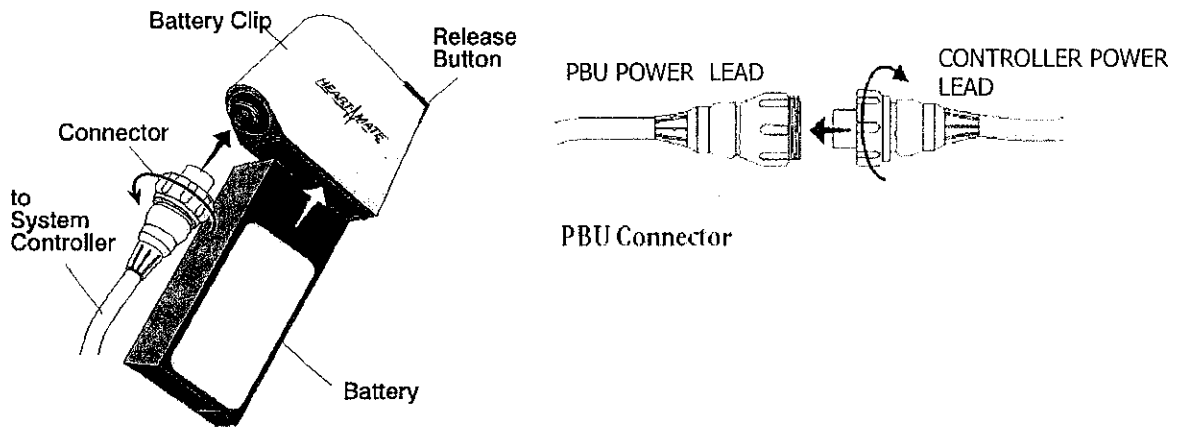
WARNING !

- Your pump will stop if both batteries are removed at the same time.
- If power to the Controller is interrupted, restoring power will restart your pump.

Switching Power Sources continued

Going from Batteries to PBU

Figure 17



- 8 Unscrew the **black** connector from the 2nd battery clip. *An alarm will sound, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*
- 9 Put aside the battery and battery clip.
- 10 Connect the **black** PBU power lead 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 power symbol and battery fuel gauge lights stop flashing and the alarm stops before going to Step 11.*
- 11 Press the battery release button to remove the 1st battery from its clip.
- 12 Repeat Step 11 for the 2nd battery clip/battery.
- 13 Turn over the Velcro to show that the batteries need to be recharged.
- 14 Put batteries into PBU for recharging.
- 15 Store battery clips in a clean, dry place.

Switching Power Sources continued

Going from PBU to Batteries (see Appendix for Power Change Checklist)



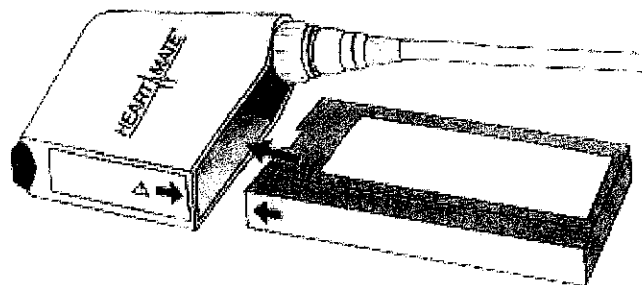
- 1 Place 2 battery clips, 2 fully charged batteries, and the white and black PBU power lead connectors within easy reach.
- 2 Place the 1st fully-charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until it "clicks" into place (**Figure 18**). Pull the battery to make sure it is fully inserted. Repeat for the 2nd battery/battery clip.
- 3 Unscrew the **black** System Controller/PBU connectors. *An alarm will sound 1 beep per second, the green power symbol  will flash rapidly, and the 4 green battery fuel gauge lights  will flash.*

Figure 18



WARNING !

At least 1 System Controller power lead must be connected to a power source (battery, PBU, or EPP) at all times. Disconnecting both Controller power leads at the same time will cause the pump to stop.

Switching Power Sources continued

Going from PBU to Batteries

WARNING !

- Your pump will stop if both batteries are removed at the same time.
- If power to the Controller is interrupted, restoring power will restart your pump.

- 4 Put aside the PBU 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 power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 5.*

CAUTION !

- When connecting leads, do not force them together without first lining up connectors. Forcing together unaligned connectors may damage them.
- Never use tools to tighten connections. Hand tighten only. Using tools may damage the connectors.
- Do NOT let the connector ends get dirty or wet.



- 5 Unscrew the **white** System Controller/PBU connectors. *An alarm will sound 1 beep per second, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*
- 6 Put aside the PBU 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 power symbol and battery fuel gauge lights stop flashing and the alarm stops before going to Step 7.*
- 7 Flip the Velcro dots to black then put the batteries and clips into the holsters or carrying case.
- 8 Store the PBU connectors in a clean, dry place.
- 9 Put at least 2 fully-charged batteries into your travel case.

Using the Emergency Power Pack (EPP)

The EPP is a large, single use-battery. It is meant for emergencies when the power goes out (for example, during a storm or other emergency). Each EPP provides about 12 hours of power under “normal” conditions (reading a book, casual walking). The EPP will last for less time if you are more active. For example, if you exercise or have increased emotional stress, the EPP will last for less time.

Each EPP is labeled with an expiration date. Do NOT use an expired EPP. If you have used your EPP for more than 3 hours, it needs to be replaced. Contact your hospital contact person for replacement.

How to Use the EPP

- 1 Open the top of the EPP and read the instructions inside.
- 2 Plug the cable provided with the EPP into the cable socket (found inside the top of the EPP). Use the screw provided to secure the cable into the EPP socket. A screwdriver (not provided) should be used for this connection.
- 3 Unscrew the **black** System Controller connector from the battery clip or PBU. *An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the 4 battery fuel gauge lights  will flash.*
- 4 Connect the **black** System Controller connector to the **black** EPP connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the lights stop flashing and the alarm stops sounding before going to Step 5.*
- 5 Unscrew the **white** System Controller connector from the battery clip or PBU. *An alarm will sound 1 beep per second, the green power symbol will flash rapidly, and the 4 battery fuel gauge lights will flash.*
- 6 Connect the **white** System Controller connector to the **white** EPP connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the lights stop flashing and the alarm stops sounding before going to Step 7.*
- 7 You are now connected to the EPP (Figure 19).
- 8 Contact your hospital contact person or local emergency service provider to make other arrangements if the power outage is expected to last more than 12 hours.

Using the Emergency Power Pack (EPP) continued

How to Use the EPP

- 9 If you use your EPP for more than 3 hours, it will need to be replaced. Call your hospital contact person for a replacement.


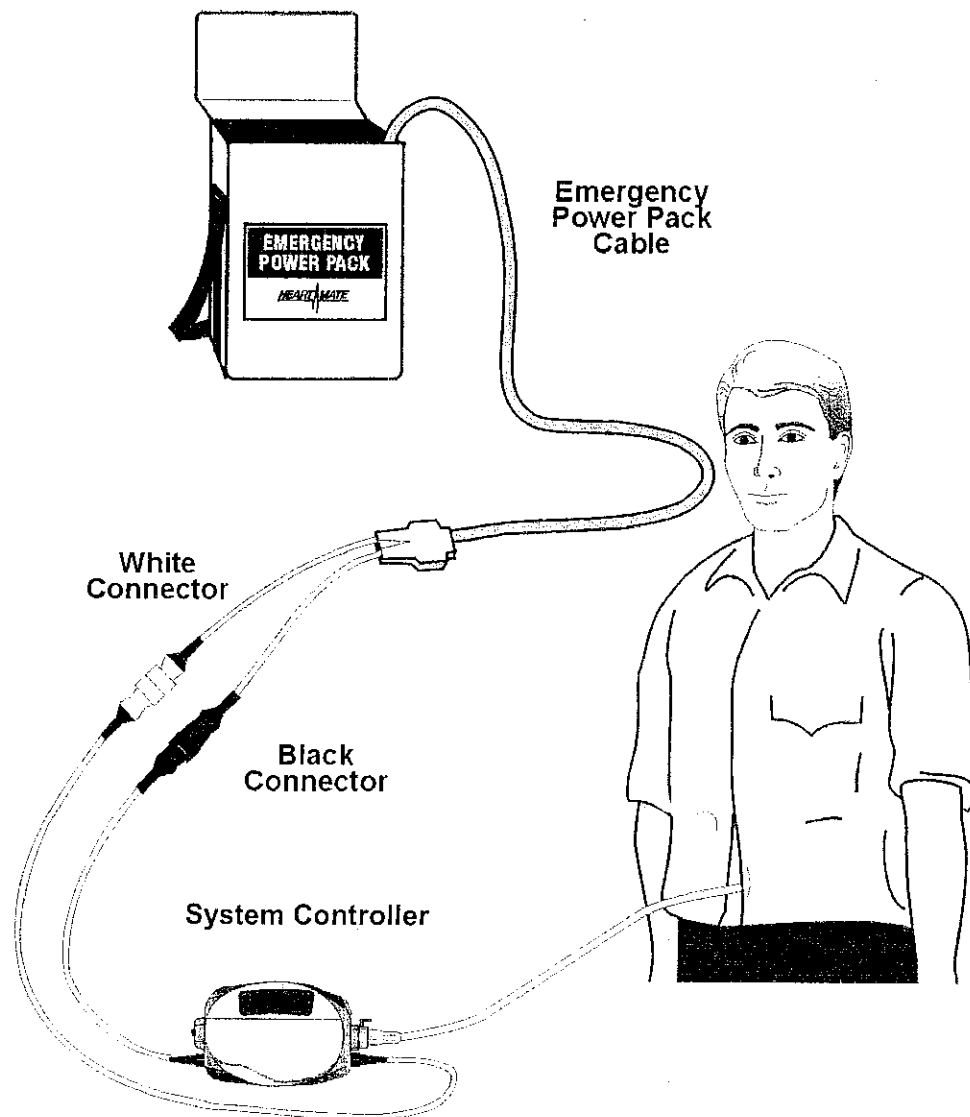
 **Note:** Throw out the used EPP according to local regulations for battery disposal. Do not burn it.

Figure 19



Using the Emergency Power Pack (EPP) continued**WARNING !**

- At least 1 System Controller power lead must be connected to A power source (batteries, PBU or EPP) at all times. a Disconnecting both Controller power leads at the same time will cause your pump to stop.
- Losing power will make your pump stop. Power must be restored as soon as possible. If power cannot be restored, immediately call emergency services (dial 911).
- If power to the Controller is interrupted, restoring power will restart your pump


CAUTION !

- When connecting power leads, do not force them together without first lining up connectors. Forcing together unaligned connectors may damage them.
- Never use tools to tighten connectors. Hand tighten only. Using tools may damage the connectors.
- Do not let the connector ends get dirty or wet.
- To prevent deterioration or damage to the EPP:
 - Do NOT leave or store EPP in hot or cold areas (car trunks, etc.) or EPP life will be shortened.
 - Do NOT use an expired EPP.
- Do NOT store or use the EPP in temperatures below 0°C (32°F) or above 50° C (122°F), or it may fail suddenly. If your EPP stays below room temperature (20°C–23°C, 68°F–72°F) during use, it will run the pump for less than 12 hours. In low temperatures (0°C– -10°C, 32°F–15°F), run time may be cut by 50%.
- Dispose of expired or used EPP according to local laws and regulations. Do NOT burn it.


Keeping Your Home Safe

Before being discharged from the hospital, your home will be checked by the hospital's Discharge Planner. He or she will check for safety and electrical readiness using a checklist similar to the following:

- ___ Is the home free of clutter and dangerous objects?
- ___ Are there stairs? If so, how many?
- ___ Is there a bedroom on the first floor?
- ___ Is there a bathroom on the first floor; and does the bathroom have a shower?
Remember, no tub baths while implanted with the pump and showers only after the doctor gives permission.
- ___ Is the home electrically safe, with enough safe, grounded (3-prong), and working electric outlets? (at least one outlet must be dedicated to powering the PBU).
- ___ Does the home have adequate telephones for emergency communication (for example, speed dial for emergency calling)?
- ___ Are any occupational or physical therapy aids needed (for example, shower chair)?
- ___ Has the electric company been notified in writing of the need for priority power restoration in the event of a power loss?

 **Note:** After your home passes the safety check, you and your family are responsible for making sure that it remains safe. If you have any questions or concerns about keeping your home safe, talk with your hospital contact person.

If you are not comfortable testing your home's electrical system, you can hire a local electrician to do it for you.

 **Note:** Consider keeping a land-line (non-portable) telephone in your home for emergency calls, unless your hospital contact person tells you otherwise. Land-lines are less likely to be affected by interference, interruptions, or power outages.

Activities of Daily Living

Your HeartMate system was designed to let you stay active. Be sure to talk to your doctor about your usual activities. Also tell your doctor about any changes in activity level or routine. Because each person is different, your doctor can give you the best advice for your needs. Any time you have questions or worries, call your hospital contact person.

CAUTION !

- Do NOT play contact sports or jump while you have the pump. Contact sports or jumping could cause bleeding or damage your pump.
- The HeartMate II LVAS uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.
- Always have a back-up System Controller and spare batteries nearby at all times in case of emergency.
- Do NOT swim or take a tub bath.
- Do NOT try to fix any of your LVAS equipment yourself. If it needs service, call your hospital contact person.
- Call your doctor or hospital contact person right away if you notice a change in how your pump sounds, feels, or works.

WARNING !

- Do NOT touch television (TV) or computer screens while you have the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and cause the pump to stop.
- Do NOT do anything that may create static electricity, like vacuuming. A strong electric shock can damage the electrical parts of the system and make the pump to stop.
- Do not become pregnant while you have the pump. Use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may cause injury or make the pump stop.

Eating

Healthy eating is a good idea for everyone; but it is especially important for people living with a heart pump. A healthy, well-balanced diet can help you recover faster from your surgery. It will give you more energy to be active.

Because of where the pump is located, some patients lose their appetite after implant surgery. This usually goes away over time. If you feel “full” quickly during meals, try eating more (6 - 8) smaller meals throughout the day (instead of 2 or 3 large meals). Eating more small - but healthy - meals will help you get enough calories and nutrients. Until your appetite comes back, you can also try healthy, high-calorie “shakes.” They are found in most food stores and pharmacies.

Your hospital contact person can give you more information and ideas on healthy eating.

Sleeping

You must ALWAYS be attached to the PBU when sleeping (or when there's a chance you might fall asleep). This is very important because you may not hear the System Controller's alarms if you fall asleep while connected to batteries.

Try to sleep so that you do not pull on or move the percutaneous lead going through your skin. Don't let the lead get tangled in clothing or blankets. To help keep your System Controller from falling or the lead from moving or pulling on the exit site, you can use the HeartMate Stabilization Belt. You can get a Stabilization Belt from your hospital contact person.

Remember these important sleep guidelines:

- Plan to sleep only when connected to the PBU.
- Before going to sleep, inspect all electrical connections to make sure they are tight.
- Do NOT sleep on your stomach – most HeartMate patients are more comfortable sleeping on their back.
- Keep a back-up System Controller, charged batteries in battery clips, and a flashlight near you during sleep.

Intimacy

Sex is an important and normal part of a healthy lifestyle. You should be able to resume sexual activities after recovering from the operation to implant the pump – usually 6-8 weeks after surgery. Check with your doctor or hospital contact person.

WARNING !

Do not become pregnant while you have the pump. Use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.


Traveling

Being able to travel freely is a big part of everyone's quality of life, whether it's going to the neighborhood store, or traveling out-of-town for a family vacation. But, remember – **with freedom comes responsibility**. If you want to enjoy the freedom of travel, you will need to be able to travel safely.

Talk with your doctor before making any travel plans. He or she will let you know if and when you can travel away from home. Once the doctor approves you for travel, your hospital contact person will help you prepare for traveling safely.

To keep safe during trips away from home, remember to:


- Keep at least one spare set of fully-charged batteries with you at all times.
- Bring the Power Base Unit (PBU) for recharging batteries and/or powering the system if you are going to be traveling far or gone for a long time.
- Bring your Emergency Power Pack (EPP) to power the pump in the event of power outage (for long-distance travel).
- Never leave or store batteries or the EPP in extremely hot or cold places (such as the trunk of your car), or battery life will be shortened.
- Never store or use batteries or the EPP in temperatures below -10°C (15°F) or above 40°C (105°F) or the batteries may fail suddenly.

 **Note:** If you will be traveling internationally, talk with your hospital contact person about adapters or converters needed for using electrical power in some foreign countries.

Automobile Travel


Car airbags deploy with great force. The force could harm you or cause bleeding if an airbag hits your abdomen or chest. Therefore, you should avoid riding in the front seat of cars that have airbags (also known as supplemental restraint systems, or "SRS" for short). Sit in the back seat instead.

Your doctor will decide if you may drive a car or operate heavy machinery while implanted with a heart pump. Some states have laws against patients driving if they have a history of fainting or heart trouble. Usually, you will need to wait at least 6-8 weeks after surgery before being considered for driving privileges.

 **Note:** You can wear a seatbelt while implanted with the pump.

Showering

You cannot take tub baths while implanted with the pump, but you may be able to shower once your exit site has healed. Your doctor will tell you if you can shower. When you do shower, you must use the HeartMate Shower Kit to protect the System Controller from getting wet. The exit site also needs to be kept as dry as possible. A dry exit site reduces the risk of infections.

 **Note:** See the HeartMate patient education video for alternatives to tub baths.

WARNING !

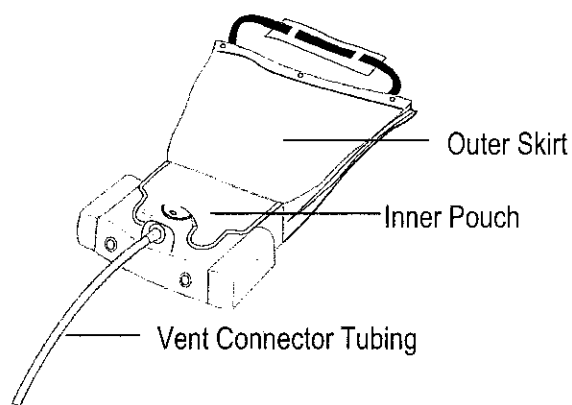
- NEVER place the System Controller or HeartMate batteries in water.
- **Do NOT take a shower without your doctor's approval.** When you do shower, you must use the HeartMate Shower Kit according to directions.
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the pump may stop or you may get a serious electrical shock.


CAUTION !

Do NOT swim or take a tub bath. You may be able to take showers using the HeartMate Shower Kit once the exit site has healed and if your doctor gives you permission.



Getting Ready to Shower

- 1 Remove the vent connector tubing from the small round pocket near the inner pouch of the shower kit (Figure 20). Throw away the tubing (it is not needed for this version of the pump).


Showering continued**Figure 20****Getting Ready to Shower**

- 2 Use the Shower Kit strap to hang the kit over one shoulder so it's hanging at your side.
OR
- 2 Put the strap around your neck and hang the kit in front of you.
 **Note:** The strap is adjustable.
- 3 Raise the outer "skirt" of the Shower Kit to expose the inner pouch underneath.
- 4 Lift the Velcro tabs on the inner pouch cover.
- 5 Open the inner pouch cover.
- 6 Place the System Controller, leads, and connectors inside the pouch.
- 7 Reseal the pouch by pressing down the Velcro tabs.

Showering continued


- 8 If you plan on **using battery power** during your shower, transfer the batteries to the Shower Kit:
- a Remove the 1st battery from the holster or carrying case.
 -  **Note:** Remove batteries **one at a time**. Wearing your holster or carrying case until all equipment is transferred into the Shower Kit may reduce pulling on the exit site.
 - b Insert the 1st battery into one of the pockets located on either side of the inner pouch.
 -  **Note:** Insert the battery with the battery clip at the *top* and the lead connector facing *away from you*.
 - c Repeat steps “a” and “b” for the 2nd battery.
 - d Remove the empty holster or carrying case.

OR

- 8 If you plan on **using PBU power** during your shower, skip to Step 9.
- 9 Pull the outer “skirt” down over the inner pouch.
- 10 Press together the snaps at the bottom of the “skirt.”
- 11 Adjust Shower Kit so it does not pull on the exit site while showering.
 -  **Note:** Keep PBU away from water and shower spray!

Showering continued

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 "Caring for the Exit Site" on the next page for guidelines).
- 3 Use a clean, dry towel to dry the Shower Kit's strap and outer "skirt."
- 4 Undo the snaps at the bottom of the outer "skirt" and then lift up the "skirt."
- 5 Lift the Velcro tabs on the inner pouch cover; open the pouch.
- 6 Remove all equipment from the inner pouch and return it to the holster/carrying case or PBU.
- 7 Remove Shower Kit and allow it to drip dry.
 **Note** Let the kit dry completely before using it again.

Caring for your Shower Kit

Keeping the Shower Kit clean helps it work properly.

If your Shower Kit gets dirty, it can be washed *by hand* using mild soap and warm water. Once the kit has been washed, hang it to drip dry. Always let the kit dry on its own. Never heat the Shower Kit to dry it. Make sure the Shower Kit is completely dry before taking another shower.

If you have questions about using the Shower Kit, ask your hospital contact person.

Caring for the Exit Site (where the lead passes through your skin)

It is extremely important to keep the exit site (where the percutaneous lead goes through your skin) clean and dry at all times. While you are in the hospital, a nurse will take care of the exit site.

Your nurse will teach you how to use aseptic “sterile” technique to change the bandage, clean the site, and check for signs of infection.

Once you leave the hospital, you will be responsible for caring for the exit site.

Keeping the exit site clean and dry will lower the risk of infection. Here are some tips for keeping your exit site infection free:

- Follow strict “sterile technique” any time you change the bandage or touch or handle the exit site.
- Wash your hands thoroughly before and after bandage changes. *See hand washing instructions on the following page.*
- Keep the exit site clean and dry.
- Wash the exit site daily using cleanser prescribed by your doctor.
- After washing the exit site, dry the area completely using a sterile 4” X 4” gauze bandage.
- Apply a sterile 4” X 4” bandage to the exit site every time after cleaning it.
- Never put ointments/creams on the site, unless your doctor or nurse says to.
- Try to not pull on or move the lead going through your skin.
- Wear the HeartMate Stabilization Belt at all times to keep the lead in place and to prevent pulling on or moving the lead.

IMPORTANT: Watch the exit site for signs of infection. These include redness, swelling, drainage, bleeding, or a bad smell. **IMMEDIATELY** tell your doctor or hospital contact person if there are any signs of infection.

CAUTION !

- Try to not pull on or move the lead going through your skin. Pulling on or moving the lead could slow healing or hurt a site that has already healed. This could increase your chances of getting a serious infection.
- Do NOT swim or take a tub bath. You may be able to take showers using the HeartMate Shower Kit once the exit site has healed and if your doctor gives you permission.

Caring for the Exit Site (where the lead passes through your skin)


Proper Hand Washing

Proper hand washing is one of the easiest and best ways to reduce the spread of infection.

Carefully wash your hands *every single time* before and after changing the exit site bandage(s) or whenever you touch or handle the exit site. Family members or caregivers who help with exit site care must also wash their hands *every single time* before changing the bandages(s) or touching the exit site.

Follow these instructions for washing your hands:

- 1 Use a paper towel to turn on the faucet(s) for clean, running water.
- 2 Wet your hands and wrists with the clean, running water.
- 3 Apply soap to hands. Liquid soap is preferred over bar soap to minimize micro-organism growth.
- 4 Vigorously rub together all surfaces of the lathered hands for a **minimum of 15 seconds**. Friction helps to remove dirt and microorganisms. Wash around the backs of both hands as well as under rings, around cuticles, and under fingernails.
- 5 Rinse hands thoroughly under stream of clean, running water. Running water carries away dirt and microorganisms. Point fingers down so water and contamination won't drip toward elbows.
- 6 Dry hands completely with clean, dry paper towel.
- 7 Use a paper towel to turn off running water.
- 8 Repeat Steps 1 - 7 every single time before and after dressing changes and touching the percutaneous lead exit site.


 **Note** To keep soap from becoming a breeding ground for micro-organisms, thoroughly clean an empty soap dispenser before refilling with new soap.

Caring for the Percutaneous Lead

While your heart pump should allow you to return to many of your daily activities, it is extremely important to protect your percutaneous lead, especially if you are active. Always keep your percutaneous lead protected and damage-free. Damage to the percutaneous lead, depending on the degree, may cause the pump to stop.

Remember to follow these recommendations:

- Do not severely bend or kink your percutaneous lead.
- Do not let the percutaneous lead become twisted.
- If you carry your System Controller in a carrying case, don't "catch" the percutaneous lead in the zipper.
- Allow for a gentle curve for your percutaneous lead. Do not severely bend your percutaneous lead multiple times or wrap it tightly.
- Keep your 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 your percutaneous lead. But, 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 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 your System Controller is at all times. It is important to protect your controller from falling or from pulling on your lead. Report any drops of the System Controller or snags on the percutaneous lead to your hospital contact person.
- Don't let your percutaneous lead catch or snag on anything that will pull on or move the lead.
- Check your percutaneous lead daily for signs of damage (cuts, holes, tears). If you discover damage to your lead, report it immediately to your hospital contact person.

 **Note** Use the NOTES section at the end of this handbook to write down any additional information from your doctor or hospital contact person.

Pump Replacement

A heart pump, like any piece of mechanical equipment, may need to be replaced. This is especially true if the heart needs long-term help. How long it takes before your pump needs to be replaced depends on several factors. These include how much help your heart needs and how long the pump stays inside you. Your doctor and nurses know this. They will keep track of how your pump is working.

There is no one list of symptoms for when a pump needs to be replaced. But some signs to look for include:

- A return of your heart failure symptoms (like being tired or short of breath)
- Alarms happening more often (this also may be your Controller)
- A percutaneous lead that shows damage or wear
- New or strange noises
- New or strange sensations (such as a vibration in your chest)

You have an important role in pump replacement. After all, YOU are living with the pump. So, YOU are one of the best experts in how your pump works, sounds, and feels. If you notice any changes in how you feel, how your pump is working, or how it sounds or feels, call your doctor or hospital contact person right away.


What Is An Emergency?

An “emergency” is any time the heart pump cannot pump enough blood to your body. Examples of emergencies include (but are not limited to):

- Loss of power to the pump
- Broken wires
- Damage to the pump motor or System Controller
- Health changes affecting your heart

If the system is not working right, the System Controller will alarm (see “System Controller Warning Lights and Sounds” on page 12).

Call your doctor right away if you notice a sudden change in how your pump is working (even if there is no alarm). Remember, you know best what is normal for you and your pump.

 **Note:** Consider keeping a land-line (non-portable) telephone in your home for emergency calls, unless your hospital contact person tells you otherwise. Land-lines are less likely to be affected by interference, interruptions, or power outages.


How to Handle an Emergency

It is important to stay calm during an emergency! Most pump problems are easy to solve.

When the Pump is Running

If a problem arises while the pump is running, you should...

- 1 Check all lead connections.
- 2 Reconnect any loose or disconnected leads.
- 3 Call your hospital contact person if reconnecting the leads does not fix the problem.


 **Note:** See the *Emergency Response Checklist* in the back of this handbook for instructions on handling emergencies.

What Is An Emergency? continued

When the Pump has Stopped (Red Heart Alarm)

If the pump stops running, you should. . .

- 1 Check the connection between the System Controller and the pump and then check the connection between the System Controller and power source (batteries, PBU or EPP).
- 2 Fix any loose connection then continue with Step 3.
- 3 Switch to a different power source. If you are on batteries, switch to PBU. If you are on PBU power, switch to batteries.
- 4 Switch to the back-up System Controller (see "Replacing System Controllers" on page 21).
- 5 If checking connections, switching power sources, or changing System Controllers does not fix the problem, call emergency services (dial 911) right away, then call your hospital contact person.

 **Note:** Consider keeping a land-line (non-portable) telephone in your home for emergency calls, unless your hospital contact tells you otherwise. Land-lines are less likely to be affected by interference, interruptions, or power outages.

CAUTION !

- Do NOT let the connector ends get dirty or wet.

Authorized European Union Representative

Thoratec Europe, Ltd.
Burnett House
3 Lakeview Court, Ermine Business Park
Huntingdon, Cambs PE29 6UA, UK

Safety Testing and Classification

The HeartMate II LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 2601-1. In addition, the HeartMate II LVAS meets the following European EN safety standards: EN 60601-1: 1987, Amendment 1: 1993 and Amendment 2:1995.

WARNING !

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

WARNING !

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.



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


Appendix

Before leaving the hospital, you and your family member(s) and/or caregiver(s) will be taught:

- **How to change power sources** (changing batteries and switching from batteries to PBU or from PBU to batteries)
- **What to do in an emergency**









These important instructions are outlined in the following checklists. You and your family member(s)/caregiver(s) need to be able to quickly and safely perform these steps. Doing them incorrectly may make your pump stop. Review these steps until you know how to perform them correctly and without hesitating.

You may be asked to review these steps during follow up visits with your doctor or hospital contact person.

 **Note:** Consider making several copies of the following checklists. Keep copies in your travel case or in your wallet or purse. Put the checklists where you and your family member(s)/caregiver(s) can easily see them and practice the steps. The refrigerator door is an example of a good place to put checklists.

Power Change Checklist

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

- 1 Prepare for power change (see *Switching Powers Sources* on page 39).
- 2 Remove only 1 battery from its battery clip or remove the white PBU power lead from the System Controller.
The power symbol  will flash rapidly, the 4 green battery fuel gauge lights  will flash, and the alarm will sound once every second.
- 3 Connect the fully-charged battery or white PBU power lead to the System Controller.
- 4 Wait until both the power symbol  and the battery fuel gauge lights  stop flashing and the alarm stops before going to Step 5.
- 5 Remove the 2nd battery from its clip or remove the black PBU power lead from the System Controller.
The power symbol  will flash rapidly, the 4 green battery fuel gauge lights  will flash, and the alarm will sound once every second.
- 6 Connect the fully-charged battery or black PBU power lead to the System Controller.
- 7 Wait until both the power symbol  and the 4 green battery fuel gauge lights  stop flashing and the alarm stops before going to Step 8.
- 8 Check fuel gauge and then continue with appropriate steps to complete the power change:
 - See *Changing Batteries*, page 37, or
 - See *Going from Batteries to PBU*, page 39, or
 - See *Going from PBU to Batteries*, page 41.

WARNING:

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

HeartMate II Emergency Response Checklist

Red Heart



with Continuous Audio Tone

Urgent Controller Alarms = *OR*

Continuous Audio Tone and no lights on System Controller

WHAT TO DO:

1 CHECK THE CONNECTIONS

Make sure the pump is connected to the System Controller and the power leads are connected to batteries or to the PBU cable and PBU.

2 If this does not restart the pump, go to step 3.

3 CHANGE THE POWER SOURCE

3a If alarm continues, change power source (switch from PBU to fully-charged batteries or from batteries to PBU).

3b If this does not restart the pump, go to step 4.

4 CHANGE THE CONTROLLER

4a Replace System Controller with back-up Controller.

4b If this does not restart the pump, go to step 5.

5 GET ADDITIONAL HELP

If alarm continues, call emergency services (dial 911), then call your hospital contact person.