

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

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Table of Contents

Warnings and Precautions	1
General Information	
1.0 Introduction	10
2.0 Indications for Use	10
3.0 Contraindications	10
4.0 Clinical Study Information	11
4.1 Study Overview	11
4.2 Study Design	11
4.3 Patient Population	11
4.4 Primary Objective: Transplant or Survival to 6 Months	13
4.5 Overall Patient Outcomes	14
4.6 Secondary Objectives	20
Major System Components	
5.0 HeartMate II LVAD	23
6.0 System Controller	24
7.0 Power Base Unit (PBU)	25
8.0 Batteries and Battery Clips	26
9.0 System Monitor	27
9.1 System Monitor Interface	27
9.2 Clinical Screen	27
9.2.1 Pump Flow	29
9.2.2 Pump Speed	31
9.2.3 Pulsatility Index	31
9.2.4 Pump Power	31
9.2.5 Alarm Messages	31
9.3 Settings Screen	33
9.3.1 Fixed Speed Adjust	34
9.3.2 Low Speed Limit	34
9.3.3 Pump Stop	34
9.4 Alarms Screen	36
9.4.1 Hazard Alarms	37
9.4.2 Advisory Alarms	38
9.4.3 Silencing Alarms	38
9.5 Save Data Screen	38
9.6 History Screen	39
9.7 Admin Screen	39
Implant Procedures	
10.0 Equipment and Supplies Required for Implant	40
10.1 Thoratec-Supplied Equipment	40
10.2 Hospital-Supplied Equipment	41
11.0 Implant Procedure	42
11.1 Setting up and Initializing the System	42
11.2 Initializing the System Controller	43
11.3 Preparing the Pump	46

11.4	Pre-Clotting the Inflow Conduit and Outflow Graft	49
11.4.1	Flexible Inflow Conduit	49
11.4.2	Outflow Graft	51
11.5	Priming the Pump / Inflow Conduit Assembly	52
12.0	Surgical Implantation	54
12.1	Choosing Between Preperitoneal vs. Intra-Abdominal Placement.....	54
12.1.1	Surgical Technique for Preperitoneal Placement	55
12.1.2	Surgical Technique for Intra-Abdominal Placement	56
12.2	Preparing for Implantation	56
12.3	Creating the Percutaneous Lead Exit Site	57
12.4	Preparing the Ventricular Apex Site	57
12.5	Inserting the Inflow Conduit.....	60
12.6	Attaching the Outflow Graft	61
12.7	De-Airing the LVAD.....	62
12.8	Securing the Pump and Connections.....	68
12.9	Transferring Patient Out of the Operating Room.....	68
12.10	Other Patient Considerations	69
 Patient Management		
13.0	Patient Management.....	70
13.1	Unique Treatment Issues	70
13.2	Exit Site Treatment.....	72
13.3	Anticoagulation Therapy.....	73
13.4	Diagnosing Blood Leaks.....	74
13.5	Right Heart Failure	74
13.6	Avoiding Static Electric Discharge.....	74
13.7	Backup System Controller.....	75
14.0	Patient Discharge	76
 Device Explant		
15.0	Explanting the LVAD.....	77
Device Tracking & Reporting Requirements		
16.0	Device Tracking.....	78
 Service & Maintenance		
17.0	Service.....	79
18.0	Testing and Classification.....	80
18.1	Declaration Concerning General Safety Standards	80
18.1.1	Declaration and Guidance Concerning Electromagnetic Emissions	81
18.1.2	Declaration and Guidance Concerning Electromagnetic Immunity	82

List of Figures

Figure 1. Enrollment & Patient Follow Up	13
Figure 2. Kaplan Meier Plot Illustrating the Probability of Survival to Transplant or Weaning	15
Figure 3. Competing Outcomes Graph Showing Proportion of Patients who Underwent Transplant, Weaning, Study Withdrawal, Died on Support, or Remained Ongoing as of November 30, 2006.....	17
Figure 1. LVAS Configuration with PBU.....	25
Figure 2. HeartMate II LVAS Battery-Powered Configuration.....	26
Figure 3. System Monitor Screen Tabs (with Clinical Tab Selected)	27
Figure 4. Clinical Screen (typical)	28
Figure 5. Clinical Screen with Pump Disconnected Hazard Alarm	29
Figure 6. Clinical Screen with Hazard and Advisory Alarms	32
Figure 7. Setting Screen (typical).....	33
Figure 8. Settings Screen with Pump Stop Countdown Complete.....	35
Figure 9. Alarms Screen with Multiple Alarms and Advisories Displayed Simultaneously (typical).....	37
Figure 10. HeartMate II LVAS Configuration.....	42
Figure 11. System Monitor with Not Receiving Data Message	43
Figure 12. Insert Battery Module into System Controller Receptacle	44
Figure 13. System Monitor Clinical Screen when Initially Connected to the System Controller .	45
Figure 14. Alarms Screen when Initially Connected to the System Controller.....	46
Figure 15. Perc Lock – Unlocked (left) and Locked (right) Positions	47
Figure 16. Attaching Percutaneous Lead to System Controller	47
Figure 17. Settings Screen – Pump Stop.....	48
Figure 18. Pre-Clotting External Surface of Polyester Graft	49
Figure 19. Pre-Clotting External Surface of Outflow Graft	51
Figure 20. Assembling Inflow Conduit to Pump	52
Figure 21. HeartMate II Implantation Configuration	54
Figure 22. Preparing the Ventricular Apex Site.....	59
Figure 23. Correct Inflow Conduit Silicone Tube Orientation	60
Figure 24. Attaching Proximal End of Outflow Graft to Pump Outflow Elbow	61
Figure 25. Clinical Screen – Initial Pump Startup.....	63
Figure 26. Perc Lock – Unlocked (left) and Locked (right) Positions	64
Figure 27. Attaching Percutaneous Lead to System Controller	64
Figure 28. Clinical Screen During Initial Pump Startup (typical)	65
Figure 29. Settings Screen During Initial Pump Startup (typical)	65
Figure 30. Typical HeartMate II Flow Characteristics	67

List of Tables

Table 1. HeartMate II Survival with HeartMate VE LVAS Clinical Trial Data as Comparison	16
Table 2. All Adverse Events	18
Table 3. Serious Adverse Events.....	19
Table 4. Adverse Event Rate per Patient Year by Time Interval.....	20
Table 1. System Controller Factory Settings.....	24
Table 2. Equipment for In-Hospital Patients.....	70
Table 3. Equipment for Home Discharge Patients	76
Table 4. Declaration Concerning General Safety Standards	80

Table 5. Declaration and Guidance Concerning Electromagnetic Emissions	81
Table 6. Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate II Equipment, Including the Power Base Unit and System Monitor	82
Table 7. Declaration and Guidance Concerning Electromagnetic Immunity for Life- Sustaining HeartMate II LVAS Equipment, Including LVAD, System Controller & Batteries	84

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, including animal implantation and system operation, 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.
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock.
- Never operate the Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- Do not use this device in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus will dislodge the pump, which may result in device failure or fatal hemorrhage. 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 ferromagnetic 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 under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent device implant (prior to mediastinal healing).
- Do not apply high power electrical treatment (e.g., application of diathermy) directly to the patient.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (e.g., ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.
- Avoid strong static discharges (e.g., television or computer monitor screens) as these can damage the electrical parts of the system and cause the LVAD to stop.
- To prevent device damage and personal injury, refer any servicing to authorized Thoratec trained service personnel only.

WARNINGS - Specific Implantation Issues

- Do not implant the HeartMate II LVAD if it has been dropped.
- During the implant process, a complete backup system (LVAD implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedures must be either removed or adequately secured so as not to become dislodged and interfere with the operation of the HeartMate II LVAS.
- Prior to advancing the inflow conduit into the left ventricle through the apical sewing ring, remove the glove tip from the inflow conduit and the centering tool from the sewing ring. Inspect the ventricle and remove any previously formed clots and 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 cannulae in order to minimize the risk of air embolus.
- HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure 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 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 chapter 12.10, 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 \geq 8,000 rpm (typical of clinical use), reconnect the system controller as quickly as possible to resume pump function. Power will automatically be supplied to the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the pump or cannulae is performed prior to initiation of cardiopulmonary bypass and stoppage of LVAD pumping.
- Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the HeartMate II with other devices, resulting in potential interference between the HeartMate II LVAS and other devices.
- The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.

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.
- Sterile components of the HeartMate II LVAS are intended for single use only. Do not use the device if sterile packaging is compromised. Contact Thoratec customer service for Return Materials Authorization (RMA). Do not reuse sterile device components.
- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- Ensure the pump is stopped before disconnecting the pump from the system controller.
- The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for the patient's location. Replacement of the fuse should be performed only by qualified service personnel.
- Only use Thoratec's PBU to charge HeartMate batteries. Other battery chargers may damage the batteries.
- The HeartMate II LVAS rechargeable batteries should be fully charged prior to beginning the implantation procedure to allow patient transfer following the procedure.
- Do not use batteries below 15° F (-10° C) or above 105° F (40° C) or they may fail suddenly. If batteries are below room temperature (68-72° F, 20-23° C) during use, their capacity will be reduced. At the low end of the temperature range (15° F, -10° C), run time will be reduced by 50%.
- The batteries should be routinely replaced when a marked reduction in operating time is detected (about twice per year).
- To prevent deterioration or damage to the battery:
 - Do not drop or subject batteries to strong physical shock. Dropped batteries should be replaced.

- Do not leave or store batteries in hot or cold areas (car trunks, etc.) or battery life will be shortened.
 - Do not directly connect the negative and positive battery terminals.
- Do not store or use the 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) as the primary controller.

Controllers are shipped with factory settings, and therefore backup controllers must be programmed at the time they are assigned to a patient.

PRECAUTIONS - Specific Implantation Issues

- Care must be taken to prevent blood from entering and collecting in the lumen of the cannulae. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must therefore be rinsed thoroughly prior to attachment to the LVAD.
- Do not use pre-clotting agents that require heat, 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.

- Left atrial pressure (LAP must always be maintained at a positive value to reduce the potential for entrained air. A left atrial pressure greater than 10 mm Hg is recommended.
- Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning off cardiopulmonary bypass should provide a minimum of 2 lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.
- The clinical trial experience indicates that certain models of implantable cardiac defibrillators (ICDs) and certain implantable pace makers (IPMs) may, in some cases, not be able to establish telemetry and be reprogrammed due to electromagnetic interference when used with the HeartMate II. In such cases the ICDs or IPMs have continued to function properly and only their ability to communicate with the programmer was affected. The HeartMate II system complies with all applicable electromagnetic compatibility standards and is not influenced in any way by such devices. Specific information on the reported cases can be obtained on Thoratec's website at **www.Thoratec.com/professionals**. No such difficulties have been reported other than those observed with the devices listed on the website.
- Prior to implanting an ICD or IPM in a HeartMate II patient, the device to be implanted should be placed in close proximity to the pump (approximately 10cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously implanted device that is found to be susceptible to this programming interference, Thoratec Corporation recommends replacing the ICD device with one that is not prone to programming interference.

PRECAUTIONS - Patient/System Management Issues

- Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous lead exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- The use of automated blood pressure monitoring devices may not yield accurate blood pressure data. Manual auscultation to assess blood pressure is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring or the use of Doppler ultrasound may be required.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No

single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.

- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit LVAS effectiveness due to reduced filling of the LVAD.
- An electrocardiogram may be indicated to rule out fibrillation if a patient complains of feeling “different.”
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction.
- Physiological factors that affect the filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows as long as the condition persists. Pump flows will not be restored to normal unless such conditions are treated.
- The externalized portion and the lumen of the percutaneous lead at explant are not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.
- When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.
- A backup system controller and spare batteries must be with the patient at all times for use in an emergency.
- Use of expired or defective batteries may result in reduced operating time or abrupt loss of LVAD function.
- Recharge used batteries within 12 hours or battery life will be shortened.

GENERAL INFORMATION

1.0 Introduction

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

2.0 Indications for Use

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

3.0 Contraindications

The HeartMate II LVAS is contraindicated in patients whose body surface area is less than 1.3 m².

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, including animal implantation and system operation, is required prior to use of the HeartMate II Left Ventricular Assist System.



NOTE:

Thoratec reserves the right to change specifications without notice.

4.0 Clinical Study Information

4.1 Study Overview

The HeartMate II (HMII) Bridge to Transplantation (BTT) Pivotal Study was conducted from February 2005 to September 2006 at 32 investigational sites across the U.S. The primary objective of the study was to determine the safety and efficacy of the HM II as a Bridge to Transplant (BTT) in end-stage heart failure patients who are listed for cardiac transplant but at imminent risk of dying. The safety of the HMII was documented by the incidence of adverse events and the incidence of device malfunctions and failure.

In addition, a number of secondary objectives were evaluated during the study, including functional status, quality of life and 30 day and 1 year post-transplant survival.

4.2 Study Design

The study was a multi-center, non-blinded, non-randomized, prospective study in which 194 patients were enrolled. The study had 2 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 the study was safe to continue.

This study was designed to demonstrate non-inferiority to an Objective Performance Criteria (OPC) of 75%, which was derived from Thoratec's BTT experience. Patients were considered to be study successes if they survived to transplantation or recovery or 180 days of LVAD support with no irreversible contraindication for transplant. After reaching the 180 day study outcome, patients continued to be followed until transplantation, explantation or death.

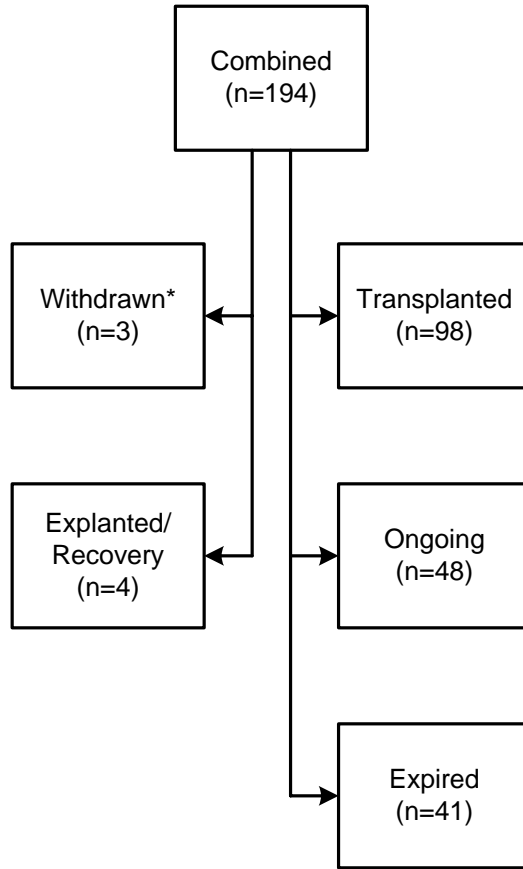
4.3 Patient Population

The patients enrolled into the HMII study were patients listed for transplant in end-stage heart failure who demonstrated no evidence of severe end-organ damage that would make LVAS implantation futile. The BTT inclusion and exclusion criteria were based on study criteria used in previously approved VAD BTT studies. The criteria included patients in NYHA class IV heart failure, patients on inotropic support, and patients without contraindication to 1A or 1B transplant listing. If the patient was 1B, they also needed to

meet certain hemodynamic criteria to qualify. The exclusion criteria excluded patients with severe end-organ damage, as evidenced by high total bilirubin, high creatinine values, low platelet counts and also excluded patients that may not be able to tolerate the management of the LVAS system due to intolerance to anticoagulation or compliance issues.

A total of 194 BTT patients were enrolled from March 8, 2005 to September 17, 2006 (Figure 1). Study data presented includes all follow up data as of March 16, 2007.

The overall mean age in the HeartMate II study was 51 years (range 16-69 years) and the majority of patients were male (77% males vs. 23% females). The smallest patient implanted had a BSA of 1.33m^2 and the largest patient, a BSA of 2.62m^2 , with a mean BSA of 1.99m^2 . The mean BMI was 27 kg/m^2 (range 15.6 – 44 kg/m^2). 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).



* HeartMate® II Replaced with other devices
(2 received XVE, 1 PVAD devices)

Figure 1. Enrollment & Patient Follow Up
(Data as of March 16, 2007)

4.4 Primary Objective: Transplant or Survival to 6 Months

Hypothesis testing required that the lower 95% confidence interval of successful outcomes be greater than 65% to demonstrate non-inferiority to the Objective Performance Criteria. HeartMate II achieved a success rate of 76% (95% CI 70–82%).

As of March 16, 2007, 98 of the 194 HeartMate II patients had received a heart transplant, were explanted due to recovery (4 patients), or have been supported for more than 180 days with no irreversible medical condition that would prohibit transplant (45 patients).

4.5 Overall Patient Outcomes

After reaching the 180 day study outcome, patients continued to be followed until transplantation, explantation, or death. As of March 16, 2007, 98/194 or 51% of patients have received a heart transplant, 4/194 or 2% of patients have been explanted for myocardial recovery, 41/194 or 21% of patients have expired on support, 3/194 or 2% of patients have withdrawn from the study after re-implantation with a VAD other than the HeartMate II, and 48/194 or 25% of patients remain on HeartMate II support.

The 30 day (peri-operative) mortality was 10% (19 of 194 patients). Eighty-five percent (164 of 194) of patients survived to hospital discharge or transplant.

Ninety-eight (51%) of patients have received a cardiac transplant. The median time to transplant for patients who received a transplant was 96 days with a range between 15 and 498 days. Post-transplant survival for these patients is presented in Section 5.16

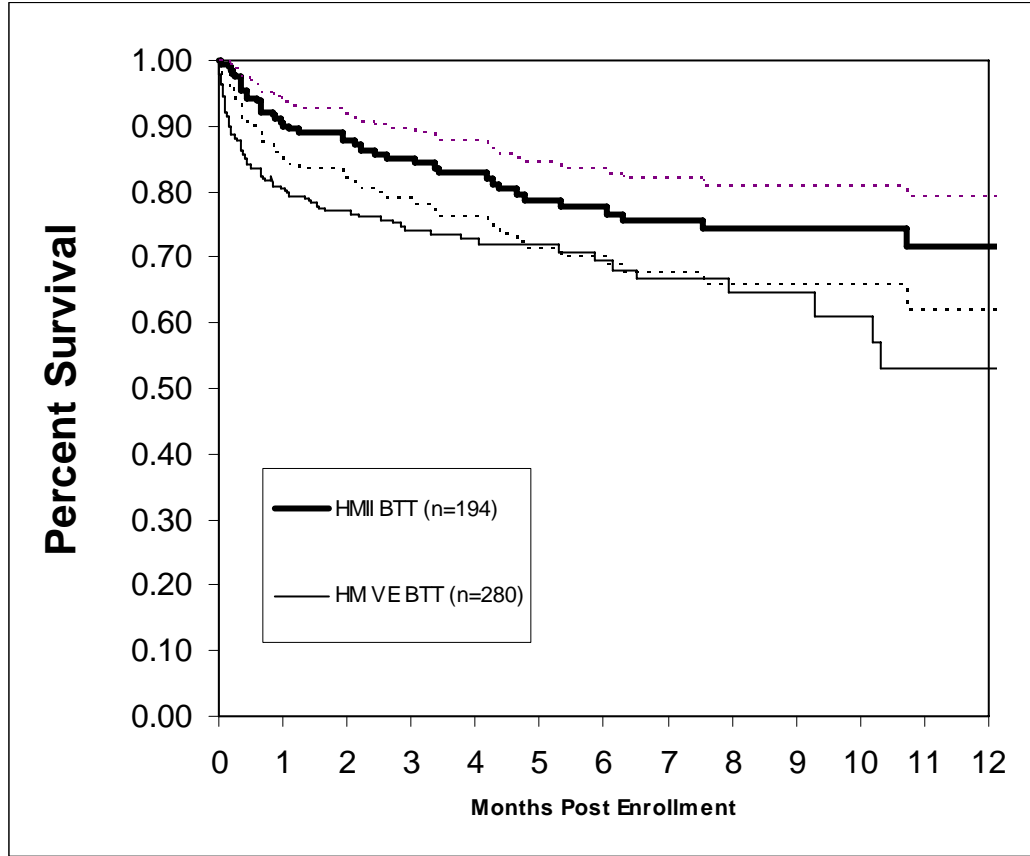
The overall median duration of support was 131.5 days (mean = 173.8 days, range = 1– 672 days). The cumulative duration of support was 92 patient years.

A Kaplan-Meier curve demonstrating survival to transplant or recovery is provided in Figure 17 and Table 165. The Kaplan-Meier only counts patient deaths as an event and patients are censored at the time of transplant, recovery, study withdrawal, or ongoing day at the time of analysis. The 30 day survival was $90.0\% \pm 2.2\%$ (survival \pm SE %), the 90 day survival was $85.1\% \pm 2.7\%$, the 180 day survival = $77.7\% \pm 3.4\%$, and the 360 days survival = $71.7 \pm 4.4\%$. For comparison purposes the Kaplan-Meier curve of the HeartMate VE LVAS Bridge to transplant trial is included.¹

Eighty-eight of 91 patients (97%) who were transplanted prior to February 16, 2007, and therefore due to complete 30 day post-transplant follow-up by March 16, 2007, have survived 30 days post transplant. Three (3) of the three (100%) of patients who were weaned from support due to myocardial recovery have survived 30 days post explant.

¹ HeartMate VE LVAS; IDE G900049, PMA P920014/S7

Twenty (20) of the 24 patients (83%) who were transplanted and due to complete 1-year post-transplant follow up by March 16, 2007, were alive by the cutoff date. The one patient weaned from support that was due to complete 1-year post explant follow up is still alive.



Note: Dotted lines represent 95% confidence interval for HeartMate II patients

Figure 2. Kaplan Meier Plot Illustrating the Probability of Survival to Transplant or Weaning

HeartMate II								
	Time Interval (Months)							
	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 12	12 - 24
Number of patients starting interval	194	165	140	120	103	87	76	23
Number of patients who died this interval	19	4	4	3	5	1	4	1
Number of cumulative patient deaths	19	23	27	30	35	36	40	41
Number of patients censored in interval	10	21	16	14	11	10	49	22
Number of cumulative censored patients	10	31	47	61	72	82	131	153
Probability of surviving interval	0.901	0.877	0.851	0.829	0.787	0.777	0.717	0.000
+/- 95% Confidence Limit at end of interval	0.04	0.05	0.06	0.07	0.08	0.08	0.16	---
HeartMate VE LVAS								
	Time Interval (Months)							
	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 12	12 - 24
Number of patients starting interval	280	215	179	129	96	66	53	13
Number of patients who died this interval	54	9	6	2	1	2	6	2
Number of cumulative patient deaths	54	63	69	71	72	74	80	82
Number of patients censored in interval	11	27	44	31	29	11	34	2
Number of cumulative censored patients	11	38	82	113	142	153	187	189
Probability of surviving interval	0.805	0.770	0.741	0.728	0.720	0.695	0.531	0.000
+/- 95% Confidence Limit at end of interval	0.05	0.05	0.07	0.08	0.09	0.10	0.20	---

Table 1. HeartMate II Survival with HeartMate VE LVAS Clinical Trial Data as Comparison

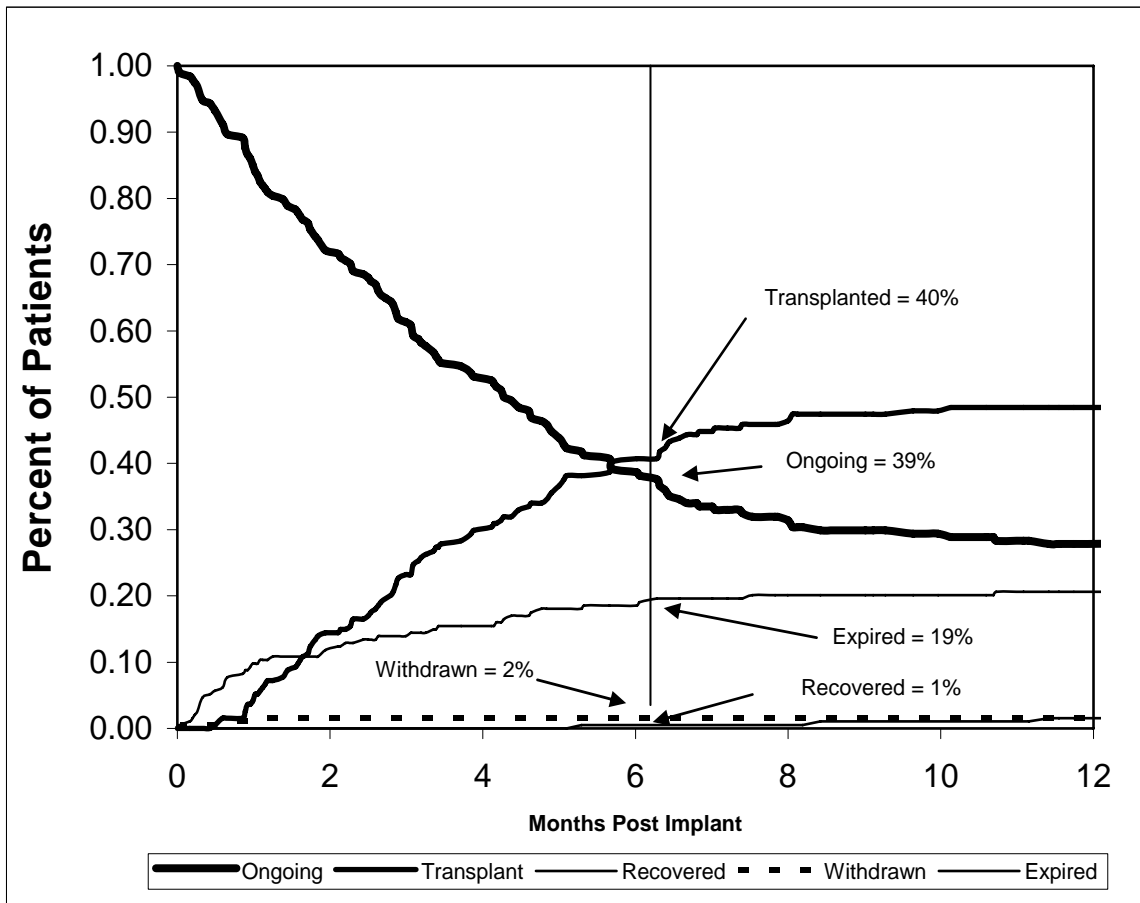


Figure 3. Competing Outcomes Graph Showing Proportion of Patients who Underwent Transplant, Weaning, Study Withdrawal, Died on Support, or Remained Ongoing as of March 16, 2007

Safety: Adverse events

Table 2 and Table 3 present the number of patients, percent of patients and the total number of events for each anticipated adverse events in the HMII BTT study. The adverse events are presented as events regardless of severity and as serious adverse events.

Adverse Events were classified as serious if they resulted in a fatality, were life threatening, resulted in permanent disability, required hospitalization or prolonged a hospital stay. In addition the time to adverse events are presented in Table 4.

General Information

	n = 194				
	# Pts	% Pts	UCL	LCL	# Events
Bleeding*	128	66%	73%	59%	253
Bleeding requiring surgery	55	28%	35%	22%	65
Stroke	16	8%	12%	4%	17
Peri-operative (\leq POD2)	5	3%	5%	0%	5
Post-operative ($>$ POD2)	11	6%	10%	3%	12
Other Neurological**	16	8%	12%	4%	19
Local Infection	57	29%	36%	23%	104
Percutaneous Lead Infection	23	12%	16%	7%	30
Pocket Infection	3	2%	3%	0%	3
Sepsis	34	18%	23%	12%	45
Right Heart Failure	35	18%	23%	13%	36
Peripheral TE	11	6%	9%	2%	12
Respiratory Failure	50	26%	32%	20%	63
Cardiac Arrhythmias	107	55%	62%	48%	188
Renal Failure	25	13%	18%	8%	26
Hepatic Dysfunction	3	2%	3%	0%	3
Device Thrombosis	3	2%	3%	0%	3
Hemolysis	6	3%	6%	1%	6
Psychological	12	6%	10%	3%	14
Myocardial Infarction	2	1%	2%	0%	2
Confirmed malfunctions	55	28%	35%	22%	84

*Bleeding requiring PRBC \geq 2 units or surgery.

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

Table 2. All Adverse Events

General Information

	n = 194				
	# Pts	% Pts	UCL	LCL	# Events
Bleeding*	113	58%	65%	51%	210
Bleeding requiring surgery	55	28%	35%	22%	65
Stroke	16	8%	12%	4%	17
Peri-operative (\leq POD2)	5	3%	5%	0%	5
Post-operative ($>$ POD2)	11	6%	10%	3%	12
Other Neurological**	14	7%	11%	4%	17
Local Infection	41	21%	27%	15%	64
Percutaneous Lead Infection	13	7%	10%	3%	15
Pocket Infection	3	2%	3%	0%	3
Sepsis	33	17%	22%	12%	44
Right Heart Failure	35	18%	23%	13%	35
Peripheral TE	10	5%	8%	2%	11
Respiratory Failure	50	26%	32%	20%	62
Cardiac Arrhythmias	77	40%	47%	33%	125
Renal Failure	25	13%	18%	8%	26
Hepatic Dysfunction	3	2%	3%	0%	3
Device Thrombosis	3	2%	3%	0%	3
Hemolysis	4	2%	4%	0%	4
Psychological	3	2%	3%	0%	5
Myocardial Infarction	2	1%	2%	0%	2
Confirmed Malfunctions	15	8%	11%	4%	15

*Bleeding requiring PRBC \geq 2 units or surgery.

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

Table 3. Serious Adverse Events

	n = 194				
	0 - 7 days	8 - 30 days	31 - 90 days	91 - 180 days	> 180 days
Cumulative years support	3.68	11.22	23.37	23.50	30.60
Adverse Event					
Bleeding	34.78	4.81	1.54	0.81	0.52
Stroke	1.36	0.27	0.13	0.21	0.03
Other Neurological*	0.54	0.45	0.26	0.17	0.07
Local Infection	8.42	2.41	1.33	0.43	0.16
Percutaneous Lead Infection	0.00	0.00	0.26	0.51	0.39
Pocket Infection	0.00	0.09	0.00	0.00	0.07
Sepsis	1.63	1.52	0.34	0.26	0.26
Right Heart Failure	2.72	1.69	0.21	0.00	0.07
Peripheral TE	1.09	0.53	0.09	0.00	0.00
Respiratory Failure	8.15	1.60	0.39	0.21	0.03
Cardiac Arrhythmias	20.65	4.28	1.20	0.89	0.49
Renal Failure	3.80	0.62	0.09	0.13	0.00
Hepatic Dysfunction	0.27	0.09	0.04	0.00	0.00
Device Thrombosis	0.54	0.00	0.04	0.00	0.00
Hemolysis	0.82	0.00	0.00	0.09	0.03
Psychological	1.90	0.18	0.04	0.17	0.00
Myocardial Infarction	0.00	0.00	0.04	0.04	0.00
Confirmed Malfunctions	6.50	1.10	0.43	0.86	0.59

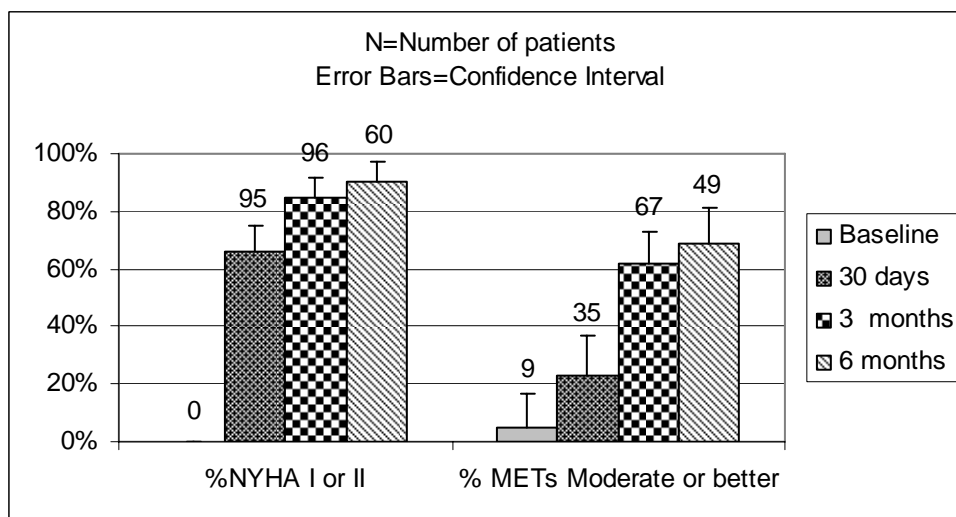
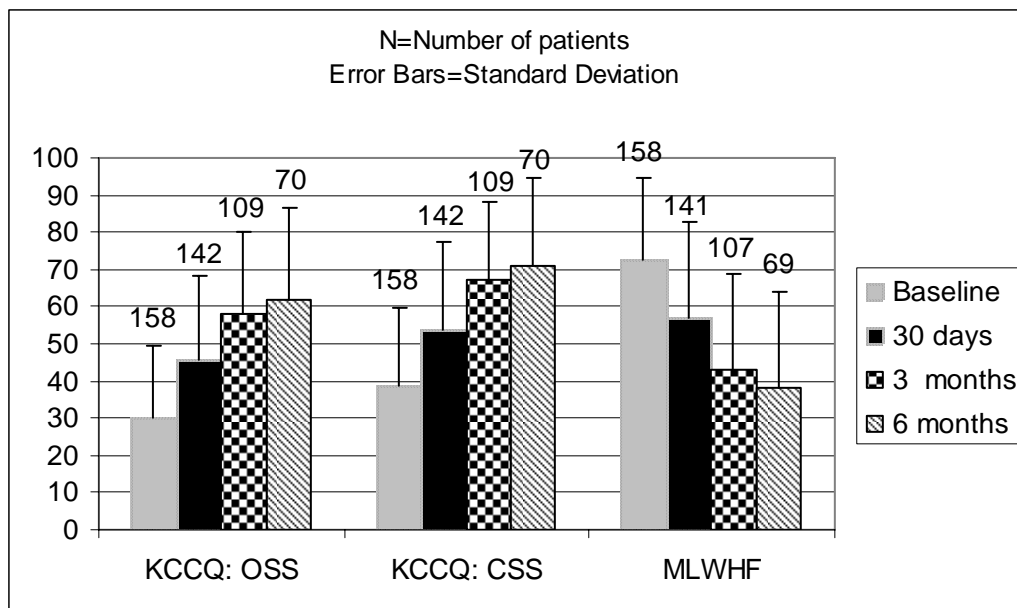
*Includes transient ischemic attacks (TIA) and non-stroke neurological events.

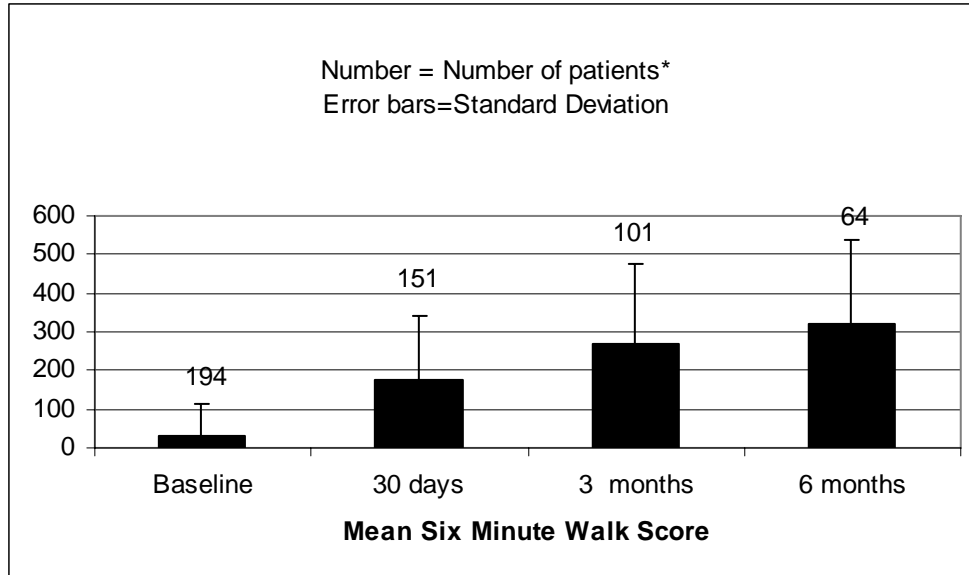
Table 4. Adverse Event Rate per Patient Year by Time Interval

4.6 Secondary Objectives

The secondary objectives that were studied included functional evaluations based on NYHA class and 6-minute walk; quality of life measured via the Minnesota Living with Heart Failure Questionnaire (MLHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ). These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome).

General Information





Abbreviations/Definition of Terms:

KCCQ-OSS = Kansas City Cardiomyopathy Questionnaire, Overall Summary Score (OSS) -higher score indicates better QoL

KCCQ-CSS = Kansas City Cardiomyopathy Questionnaire, Clinical Summary Score (CSS) -higher score indicates better QoL

MLWHF = Minnesota Living with Heart Failure Questionnaire - lower score indicates better QoL

Six Minute Walk = Distance walked in meters – larger distance indicates better functional status

NYHA I = Patients have cardiac disease but without the resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

NYHA II = Patients have cardiac disease resulting in slight limitation of physical activity results in fatigue, palpitation, dyspnea or anginal pain.

%NYHA I or II = Percent of patients with NYHA Functional Class I or II

Moderate Activity (METs 2-4): walking 2-3mph, light gardening, vacuum or mop floor, golf, paint walls

High Activity (METs 4-6): walking 3-4mph, stationary cycling (10mph), carpentry, light shoveling, dig in garden, rake leaves

Very High Activity (METs >6): dancing, climbing stairs, stationary cycling (>10mph), heavy shoveling

%METs ≥ 2 = Percent of METs that are Moderate Activity, High Activity and Very High Activity

MAJOR SYSTEM COMPONENTS

The HeartMate II Left Ventricular Assist System (LVAS) is comprised of the Left Ventricular Assist Device (LVAD), system controller, power base unit (PBU), system monitor, rechargeable batteries, and battery clips. Each of these system components is described below.

5.0 HeartMate II LVAD

The HeartMate II LVAD is an axial flow rotary pump connected in parallel to the native circulation. The inflow conduit of the pump is attached to the apex of the left ventricle and the pump outflow graft is connected to the ascending aorta. A rotor assembly inside the pump contains a magnet and is rotated by the electromotive force generated by the motor. Rotation of the rotor provides the driving force to propel the blood from the left ventricle through the pump out to the natural circulation. Pump output is dependent upon the rotational speed of the rotor as well as the pressure difference between the inlet and outlet of the pump.

The HeartMate II LVAD's primary operating mode is fixed speed control. In the fixed speed mode the device operates at a constant speed, which may be varied via commands from the system monitor under the control of qualified personnel. In the fixed speed mode, the set speed can be reduced below the normal range to allow: a) evaluation of the patient under reduced levels of augmented flow, or b) slow start of the pump at implant to reduce risk of air embolism. The patient does not have access to change the fixed speed setpoint.

The internal pump surfaces (rotor, thin-walled duct, inlet stator, and outlet stator) have a smooth polished titanium surface. The inflow conduit and outflow elbow have a textured titanium microsphere surface similar to the textured blood contacting surface on the HeartMate XVE system. Follow the anticoagulation protocol specified in chapter 13.3.

Control and power to the LVAD is transmitted via a percutaneous lead from the external system controller and power source. The system can be powered utilizing portable batteries or with an isolated power base unit (PBU).

6.0 System Controller

The HeartMate II LVAS system controller is a microprocessor unit that controls pump operation and management. The unit sends power and operating signals to the blood pump and collects and interprets information received from the implanted device. The controller initiates pre-programmed adjustments in pump operation to maintain the selected level of cardiac support. The externally worn system controller can be powered either by PBU or rechargeable batteries and provides the patient and clinician with operating information, power supply information, and indications of significant changes in device operation. **Table 5.** System Controller Factory Settings

provides the factory settings for the system controller.

Function	Data Range	Factory Settings	Allowed Increment
Operating Mode	Fixed	Fixed	N/A
Fixed Speed	6,000 – 15,000 rpm	6,000 rpm	200 rpm
Low Speed Limit	8,000 – 10,000 rpm	9,000 rpm	200 rpm

Table 5. System Controller Factory Settings

7.0 Power Base Unit (PBU)

The PBU is attached to the LVAD according to **Figure 4** and has four purposes:

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

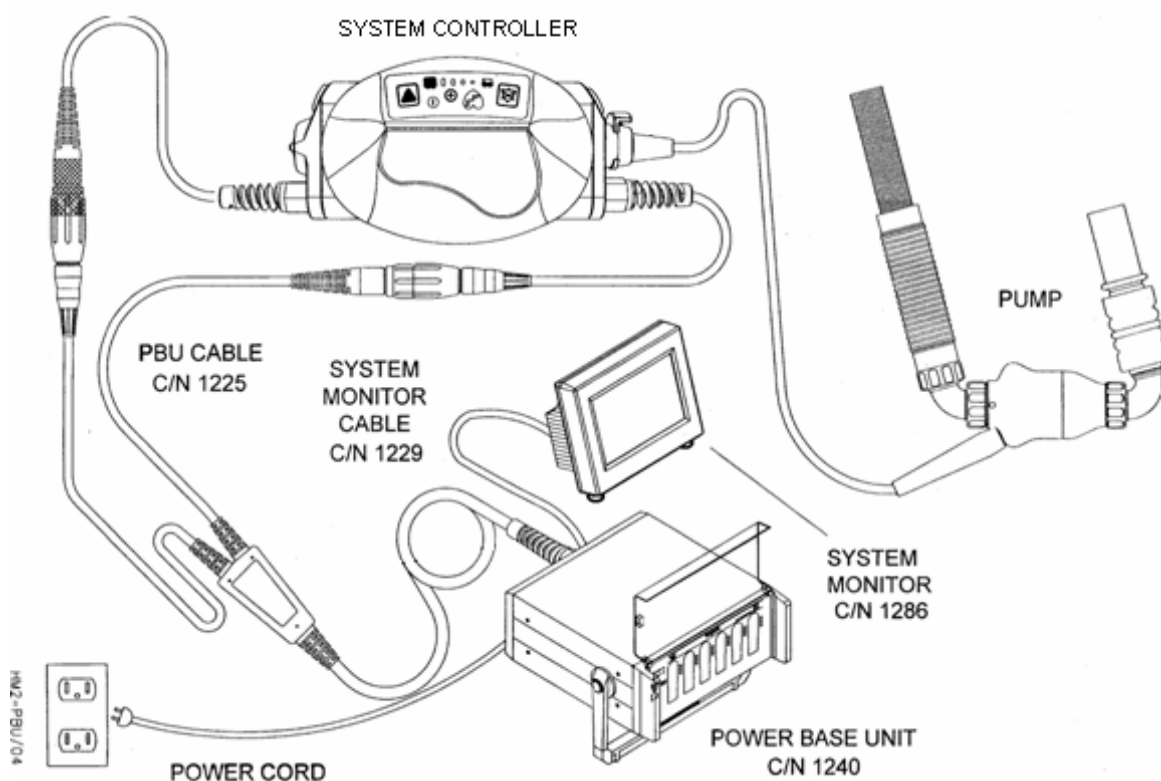


Figure 4. LVAS Configuration with PBU

8.0 Batteries and Battery Clips

When the patient is not tethered to the PBU, power is provided to the LVAD by two 12-volt DC batteries that are inserted into battery clips (**Figure 5**). The battery clips and batteries can be worn in holsters under each arm or in a pouch worn around the waist. One pair of batteries will provide power to the system for approximately 3 hours of support under normal conditions. The batteries will last for less time as the patient's physiologic demands increase.

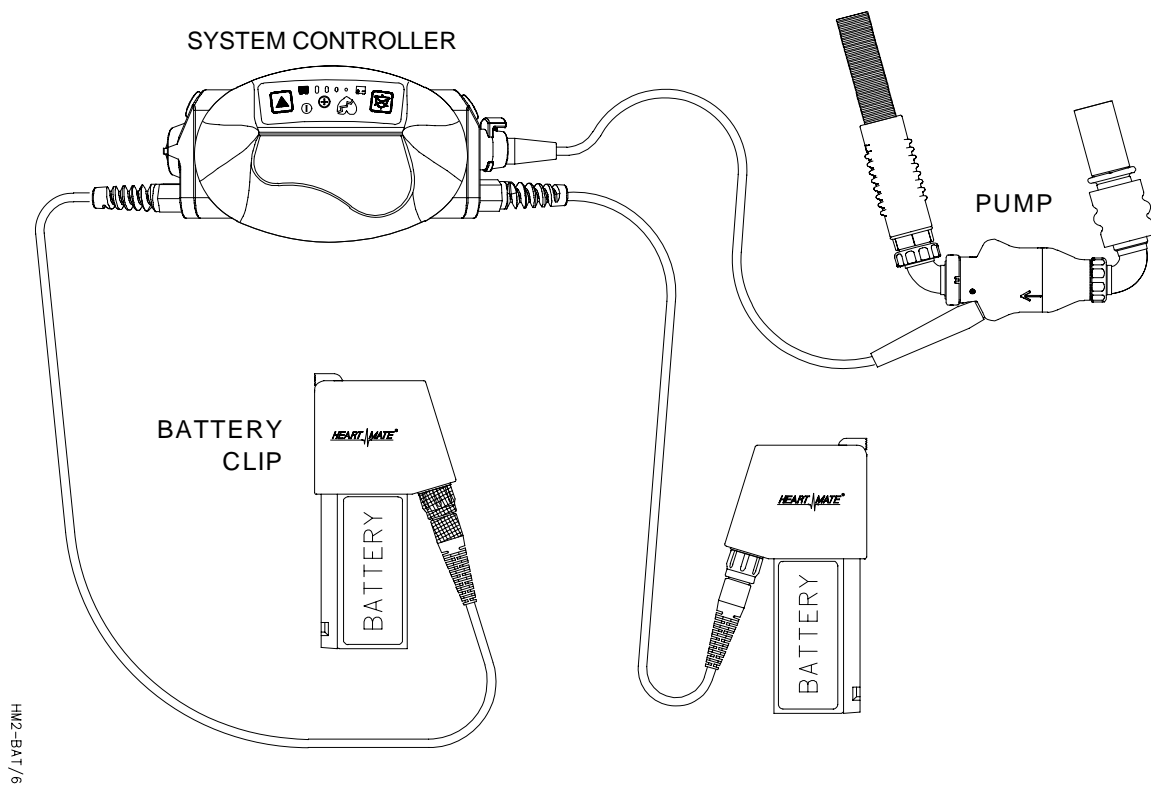


Figure 5. HeartMate II LVAS Battery-Powered Configuration

HN2-BAT/6

9.0 System Monitor

The system monitor allows the user to monitor system parameters, change speed settings, and save performance data. The system monitor communicates with the system controller through the PBU to provide a pump/system status display. The system monitor has been offered in two different versions:

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

In the following sections, references to the system monitor and monitor screens are based on the updated system monitor. For a detailed review of system monitor capabilities, please refer to the HeartMate II LVAS Operating Manual.

9.1 System Monitor Interface

The user-friendly, touch-screen operator interface of the system monitor contains menu-driven and prompted operations accessible from six main screens. Six tabs are continuously displayed along the top of the screen, allowing the user to access the various system functions. The active screen will be highlighted in black as shown in **Figure 6**.

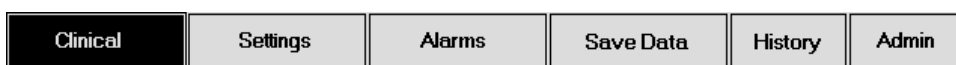


Figure 6. System Monitor Screen Tabs (with Clinical Tab Selected)

9.2 Clinical Screen

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

- **Parameter Boxes** – Four boxes at the top of the screen report measured values of the pump flow, speed, power, and pulsatility index (**Figure 7**).
- **Operating Mode and Speed Set Point** – The operating mode and speed set point are displayed below the parameter boxes as shown in **Figure 7**. The speed set point for fixed mode is displayed in revolutions per minute (rpm) and has a range of 6,000 to 15,000 rpm. Refer to the

HeartMate II Operating Manual for information on determining the optimal speed set point.

- **Active Alarm Messages** – The two highest priority active alarm messages will be displayed below the operating mode.
- **Command Buttons** – Two command buttons will appear during certain conditions:
 - A pump start button will appear when the pump is stopped or disconnected from the system controller. Pressing this button will restart the pump. See section 9.3.3 for more information.
 - A silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for 2 minutes, and all other advisory alarms for 4 hours. See section 9.4.3 for more information.

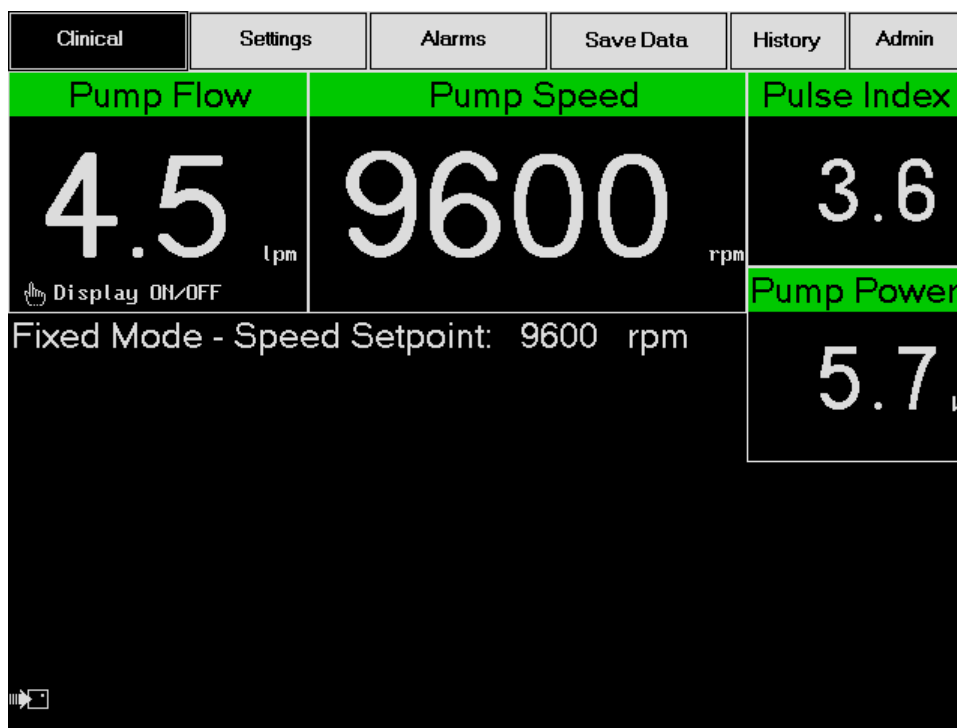


Figure 7. Clinical Screen (typical)

9.2.1 Pump Flow

The system controller provides an estimate of blood flow out of the pump based on pump speed and the amount of power being provided to the pump motor. The relationship between power and flow at any particular speed is mostly linear, but there are regions at the low and high ends where the relationship is not linear. The system controller also monitors the flow estimate and compares it to the known operational range of the pump and verifies that for the given speed and power, the flow predicted is within physiological conditions. If the flow estimate falls outside the expected operational range or acceptable linear region, the pump flow box will display “+++” or “---.”

When the pump is stopped or becomes disconnected from the system controller, “-.-” will appear in the pump flow box as shown in **Figure 5**. This will be accompanied by a pump off hazard alarm, which will turn the box red. If the pump is running at a fixed speed less than 8,000 revolutions per minute (rpm), the pump flow box will display “-.-” but remain green.

The user has the option to turn off the pump flow display by touching the screen anywhere within the pump flow box.

CAUTION!

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

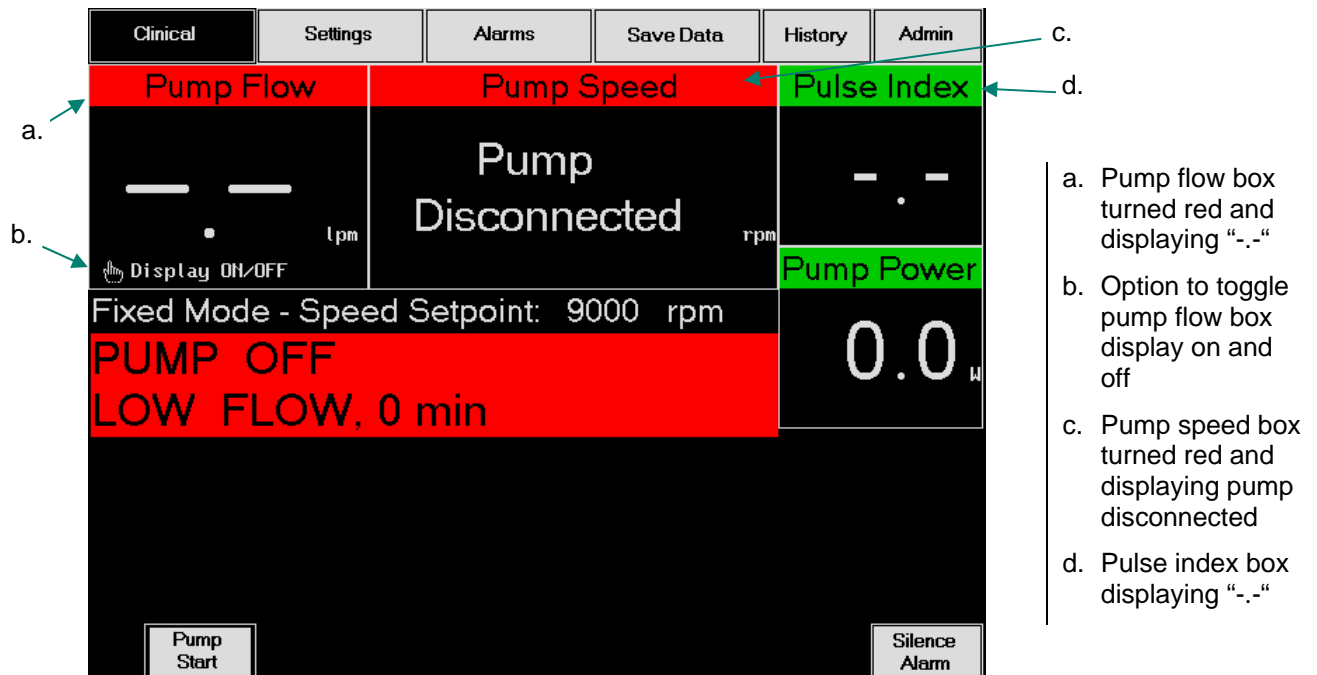


Figure 8. Clinical Screen with Pump Disconnected Hazard Alarm

9.2.2 Pump Speed

The system monitor displays the pump speed in rpms in the pump speed box as shown in **Figure 9**. If the pump is not connected to or becomes disconnected from the system controller, the pump speed box will display Pump Disconnected (**Figure 8**). When the pump is stopped by pressing the pump stop button on the settings screen (see section 9.3.3), “----” will appear in the pump speed box.

9.2.3 Pulsatility Index

The system controller pulsatility index (shortened to “pulse index” on the screen) is shown in the upper right corner of the clinical screen. When the pump is stopped or becomes disconnected from the system controller, “-.-” will appear in the pulse index box as shown in **Figure 8**

9.2.4 Pump Power

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

9.2.5 Alarm Messages

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

Hazard alarms occur when current conditions require immediate attention. On the clinical screen, these alarms will flash and appear as black text on a red banner as shown in **Figure 9**, except for the pump disconnected message, which will be displayed in the pump speed box. The text banners will be accompanied by a continuous beep emitted from the system controller.

Advisory messages will appear as black text on a yellow banner as shown in **Figure 9**. These messages will NOT flash except for the low speed operation warning. An audible alarm from the system controller will accompany the text banners at a rate of 1 beep every 4 seconds, with the following exceptions: replace system controller advisory (2 beeps once per second, followed by 2 seconds of silence), and low speed operation advisory (no audible alarm).

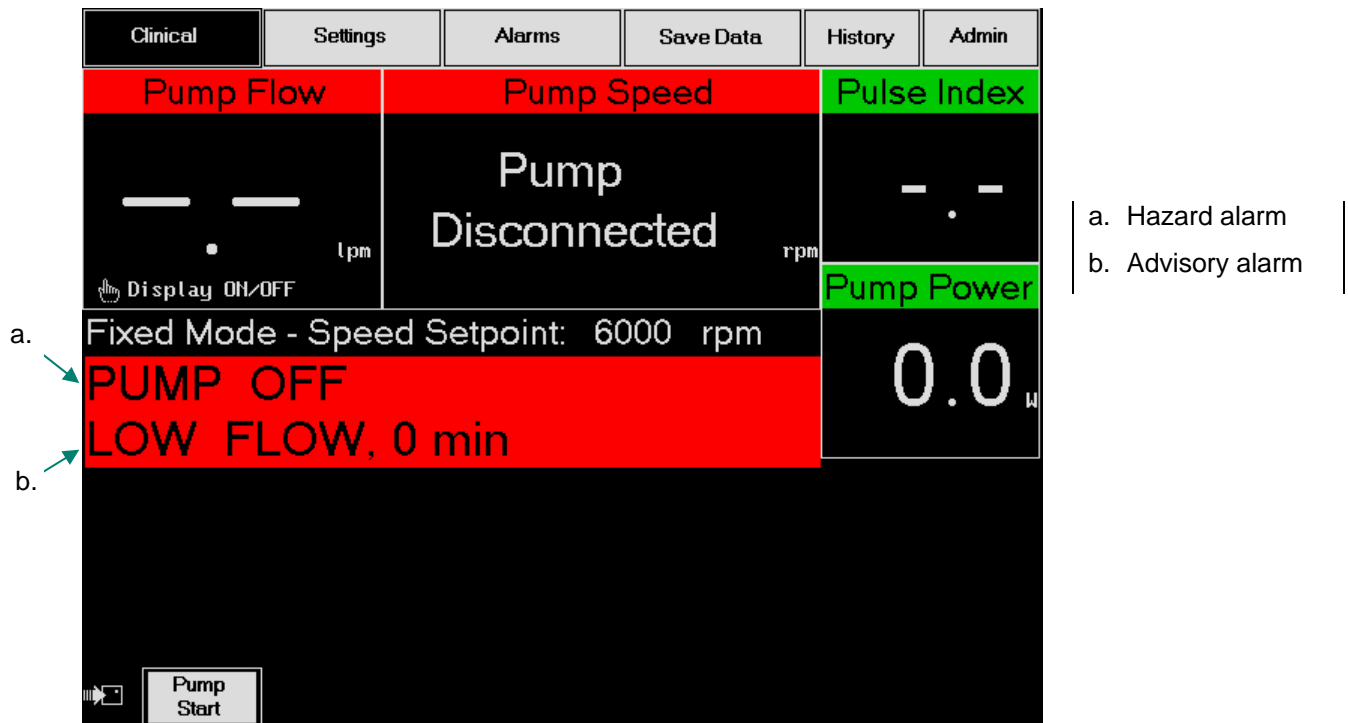


Figure 9. Clinical Screen with Hazard and Advisory Alarms

During alarm conditions, a silence alarm button will appear in the lower right corner of the screen. Pressing this button will temporarily silence audible alarms (2 minutes for hazard alarms and the power cable disconnected advisory, and 4 hours for all other advisory messages).

9.3 Settings Screen

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

- **System Status Boxes** – The system status boxes display general parameters and indicate the current operating mode. They also display the set fixed speed and low speed limit (**Figure 10**). The system status 2 box indicates whether the alarm silence is on, off, or extended. It also displays the version number of the system controller and tells whether the controller is in primary or backup mode.
- **Active Alarm Messages** – The two highest priority alarm messages (including the pump disconnected alarm) will appear as text banners below the system status boxes. None of the banners will flash. See chapter 9.4 for detailed explanations of alarms.
- **Command Buttons** – The fixed speed adjust, low speed limit, and pump stop command buttons are displayed at the bottom of the screen as shown in **Figure 10**. During alarm conditions, a silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for 2 minutes, and all other advisory alarms for 4 hours. See chapter 9.4 for more information.

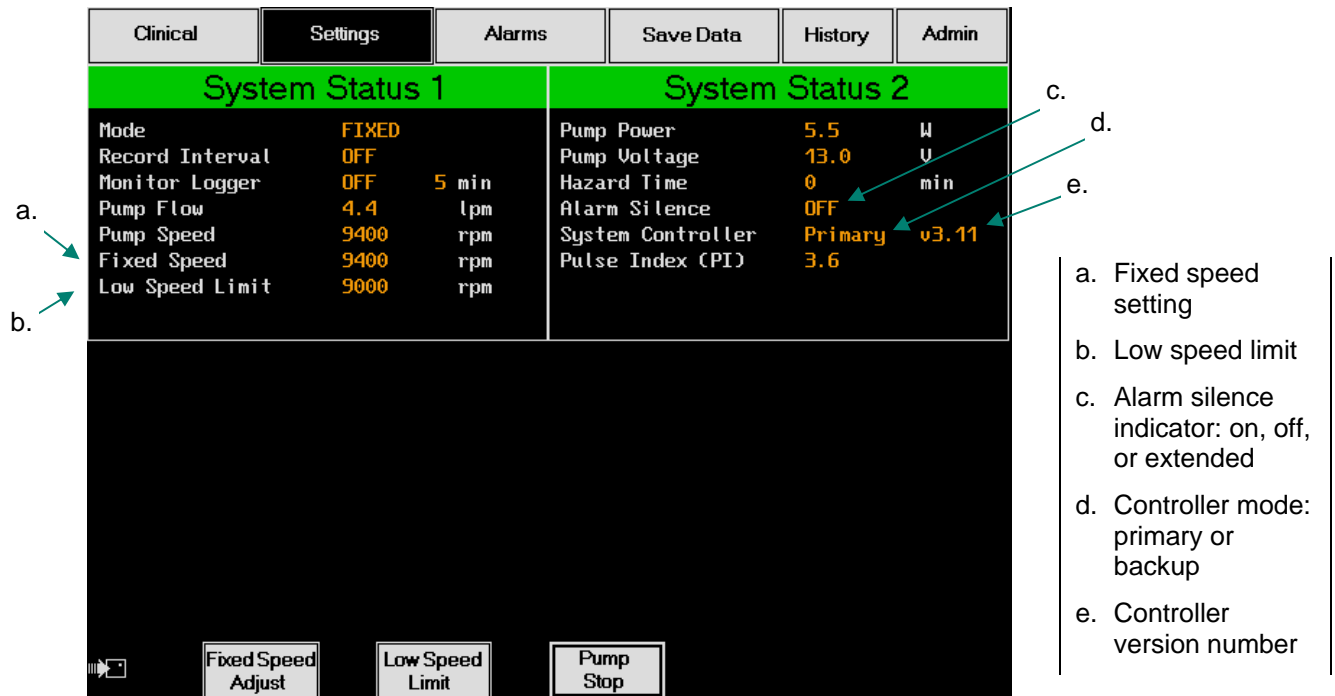


Figure 10. Setting Screen (typical)

9.3.1 Fixed Speed Adjust

The fixed speed adjust button allows the user to increase or decrease the fixed speed within the range of 6,000 to 15,000 rpm. If the operating speed drops below the value set for the low speed limit (default is 9,000 rpm), the low speed operation advisory alarm message will appear. Refer to the *HeartMate II LVAS Operating Manual* for instructions on how to select the optimal fixed speed for a patient.



NOTE:

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

9.3.2 Low Speed Limit

The select low speed limit box allows the user to increase or decrease the low speed limit. Setting the low speed limit is similar to changing the fixed speed and is generally set at a value slightly above the minimum speed determined during the speed ramp study for establishing optimal fixed speed. Clinical judgment and consideration of all factors should be used when selecting the low speed limit.

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

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

9.3.3 Pump Stop

The pump stop button is used to turn the pump off. Press and hold down the pump stop button while the pump stop countdown field counts down from fifteen (the countdown lasts approximately 10 seconds). Once the countdown nears zero, the pump off hazard will appear as shown in **Figure 11**, accompanied by a continuous audible alarm. A silence alarm button will be displayed to the right of the alarm text banners and can be pressed to silence this alarm for 2 minutes.

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

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

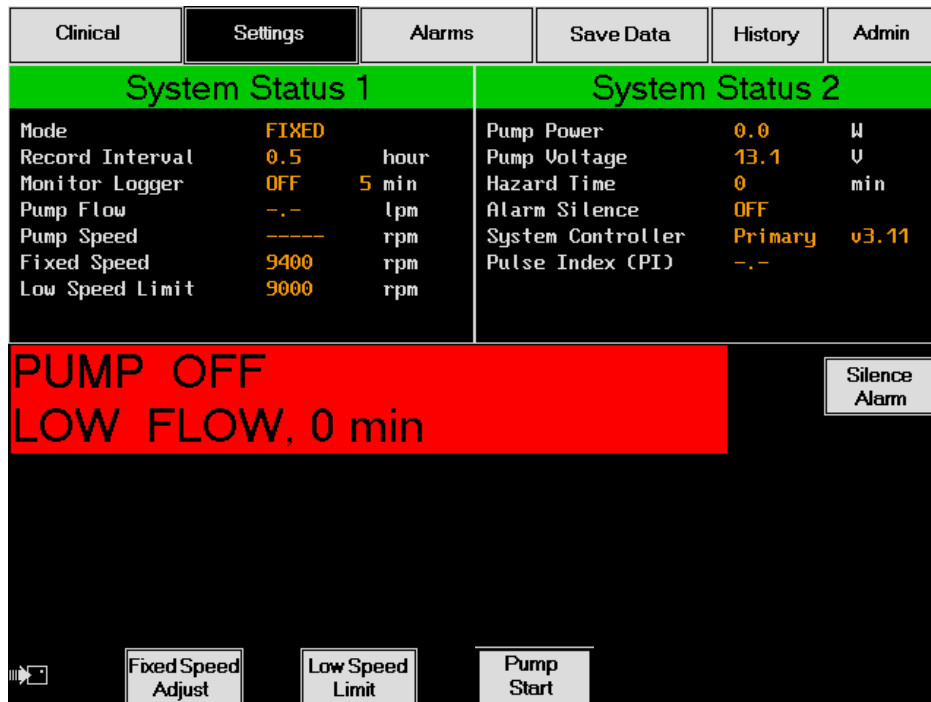


Figure 11. Settings Screen with Pump Stop Countdown Complete

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

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

However, if the pump is stopped using the pump stop button and both **power leads** are disconnected from the system controller, reconnecting the leads to the controller will cancel the “pump stop” command and automatically restart the pump (if the fixed speed is at least 8,000 rpm).

9.4 Alarms Screen

The alarms screen shows the status of all hazard and advisory alarms (**Figure 12**) and contains:

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

Under normal conditions, alarms are not highlighted and NO ALARM is displayed in the column on the right side of the screen. If alarms do occur, they will be highlighted and labeled as active (**Figure 12**). Multiple alarms may be highlighted simultaneously.

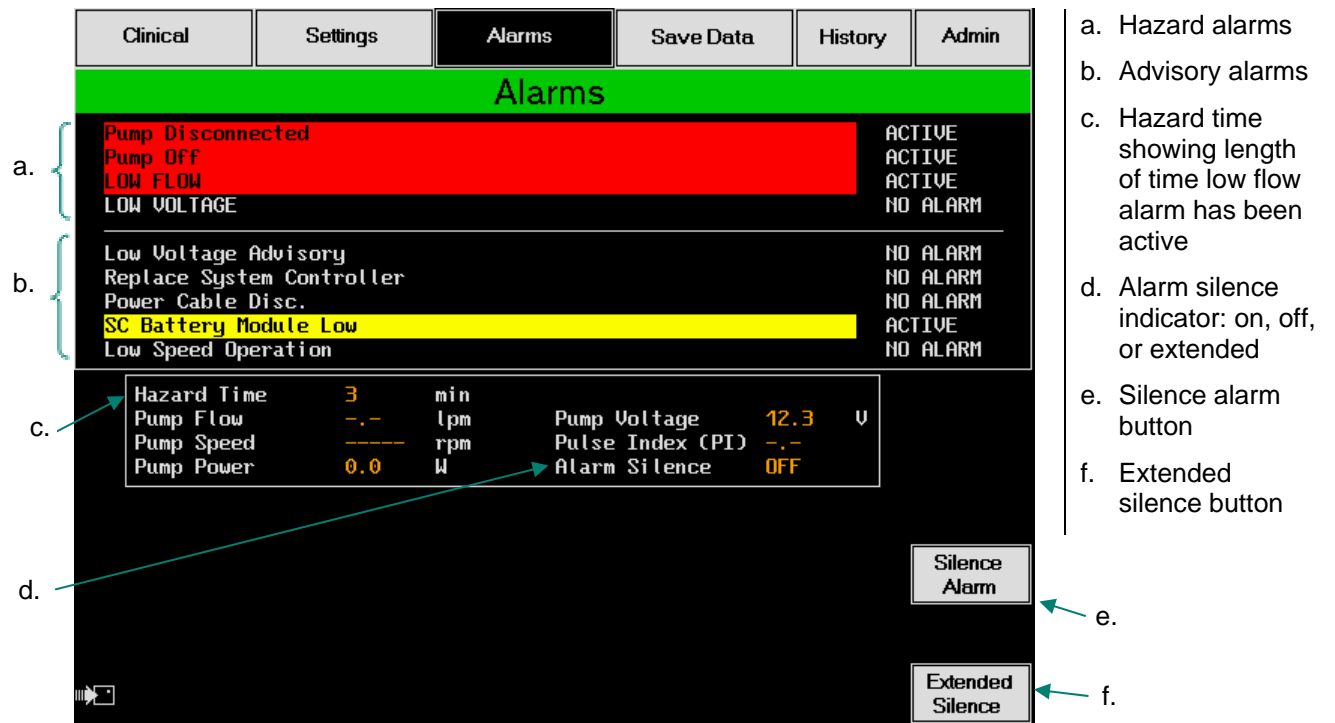


Figure 12. Alarms Screen with Multiple Alarms and Advisories Displayed Simultaneously (typical)

9.4.1 Hazard Alarms

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

1. Pump Disconnected – The percutaneous lead is disconnected from the system controller.
2. PUMP OFF – The pump has been turned off or disconnected from the system controller.
3. LOW FLOW – Pump flow is less than 2.5 lpm, the pump has stopped, or the pump is not operating properly. The hazard time listed in the parameters box refers to the number of minutes that the hazard alarm has been active as shown in **Figure 12**
4. LOW VOLTAGE – Voltage has dropped below 10.50 volts (V).

Refer to the *HeartMate II LVAS Operating Manual* for alarm troubleshooting information.

9.4.2 Advisory Alarms

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

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

9.4.3 Silencing Alarms

The silence alarm button is used to temporarily silence audible alarms and will only appear during alarm conditions (**Figure 12**). Pressing the button will silence hazard alarms and the power cable disconnected advisory 2 minutes, and all other advisory alarms 4 hours on both the system monitor and system controller. However, alarm messages will still be displayed on the screen. If the alarm condition is resolved, the alarm silence will automatically turn off.

At fixed speeds set below 8,000 rpm, the extended silence button will also be available (**Figure 12**). Pressing this button will silence all hazard and advisory audible alarms on the system monitor and system controller for 4 hours (alarm messages are still displayed on the screen).

The alarm silence indicator in the parameters box will indicate whether an alarm silence is off, on, or extended.



NOTE:

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

9.5 Save Data Screen

The save data screen allows the user to save performance information to a data card and to change the rate at which events are recorded. The waveform feature saves motor performance information to a data card. The system monitor data logger records

information on a data card at a set time interval, and the controller event recorder collects and stores information in the system controller's memory. The controller event recorder can save data at a specified record interval or as events occur (e.g., alarm occurrences, changes in speed settings). See the *HeartMate II LVAS Operating Manual* for more information about the save data screen.

9.6 History Screen

The history screen will allow the user to retrieve and view the system controller event history on the system monitor. The user will also have the option to save the history to a data card. See the *HeartMate II LVAS Operating Manual* for more information about this screen.

9.7 Admin Screen

The admin screen is used to set the system monitor date and time and to modify technical parameters. The technical parameters screen is restricted to Thoratec personnel only. Refer to the *HeartMate II LVAS Operating Manual* for instructions on how to change the clock.



NOTE:

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

Implant Procedures

10.0 Equipment and Supplies Required for Implant

The HeartMate II implant kit is supplied *sterile* and for *single use only*. Store components in a cool, dry place away from strong electromagnetic fields.

Additional inflow conduits (catalog # 103240), outflow grafts with bend relief (catalog # 103241), and a shorter, 7.6 cm (3 in.) bend relief (catalog # 102782), are also available as *sterile* stand alone items.

10.1 Thoratec-Supplied Equipment

Sterile HeartMate II Implant Kit (catalog # 1355):

- Left Ventricular Assist Device (LVAD) Assembly
- 20 mm Flexible Inflow conduit
- 16 mm Outflow Cannula with 10.2 mm (4 in.) Bend Relief
- Apical Sewing Ring
- Apical Coring Knife
- Skin Coring Punch
- Thread Protectors (1 set)
- Tunneling Bullet
- System Controller with Battery Module

Non-Sterile:

- Power Base Unit
- System Monitor
- Battery Clips (2)
- Fully-Charged Battery Set (6)
- Tunneler
- HeartMate II Sizer (catalog # 102773)

10.2 Hospital-Supplied Equipment

- Standard pre-clotting agent(s) or 60 ml Non-Heparinized Autologous Whole Blood in a Syringe (without needle)
- Small Drip Basin
- Large Basin
- Emesis Basins (2)
- Vent Needle
- CV Major Surgical Set
- Heavy Non-Absorbable Ligature
- Catheter-Tipped Syringe with Sterile Normal Saline for injection
- Swan-Ganz Catheter
- Arterial line
- Transesophageal ECHO

11.0 Implant Procedure

The patient is transported to a cardiovascular operating room (OR), prepped, and anesthetized according to standard procedures. A sternotomy with extended midline abdominal incision is made and cardiopulmonary bypass instituted.

11.1 Setting up and Initializing the System

During implant, the HeartMate II Left Ventricular Assist System (LVAS) must be operated with the power base unit (PBU) as shown in **Figure 13**.

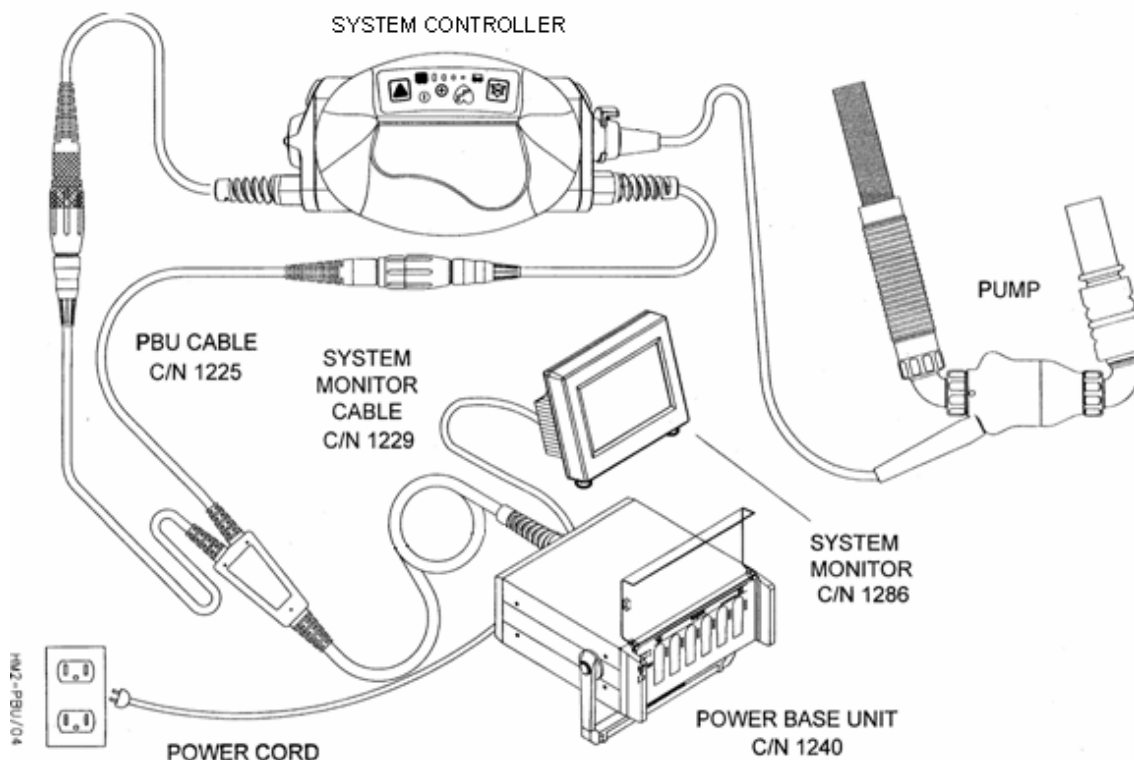


Figure 13. HeartMate II LVAS Configuration

1. Plug the large circular connector end of the PBU cable into the socket labeled “**Patient**” in the rear of the PBU.
2. Plug the PBU into the AC mains and turn it on.

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

3. Connect the system monitor to the back panel “Display” connector and turn it on. When system monitor initialization is complete, the flashing NOT RECEIVING DATA message will appear at the bottom of the screen, indicating that the system monitor is not yet linked to the system controller (**Figure 14**).

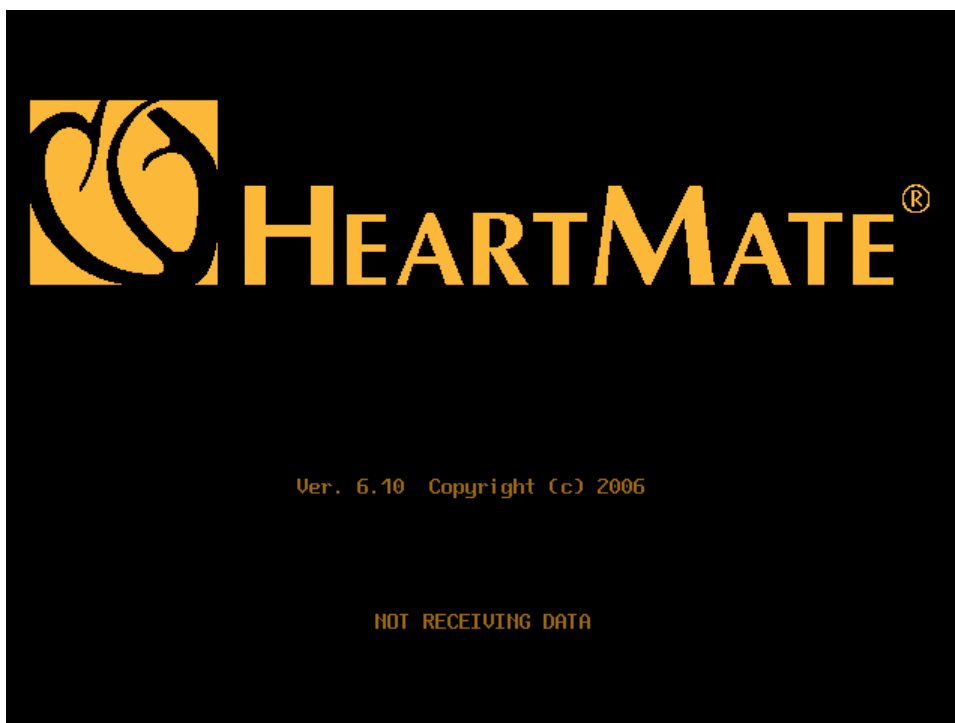


Figure 14. System Monitor with Not Receiving Data Message

4. Insert a minimum of four batteries into the PBU charging slots. Ensure that at least two batteries are fully charged (green indicator light next to the battery slot is illuminated) so that they will be available for patient transport from the OR.

11.2 Initializing the System Controller

1. Remove the system controller and battery module from their sterile package. Do not touch the metal contact point on the battery module while handling it. Insert the system controller battery module into the system controller body and screw it down until it is finger tight (**Figure 15**). Hand-tighten only; do not use tools. This battery module enables the system controller alarm to sound if the system controller

CAUTION!

Only use the Thoratec power base unit (PBU) to charge batteries. Other battery chargers may damage the batteries.

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.

loses power while connected to a patient. The battery module does not provide backup power to the pump.

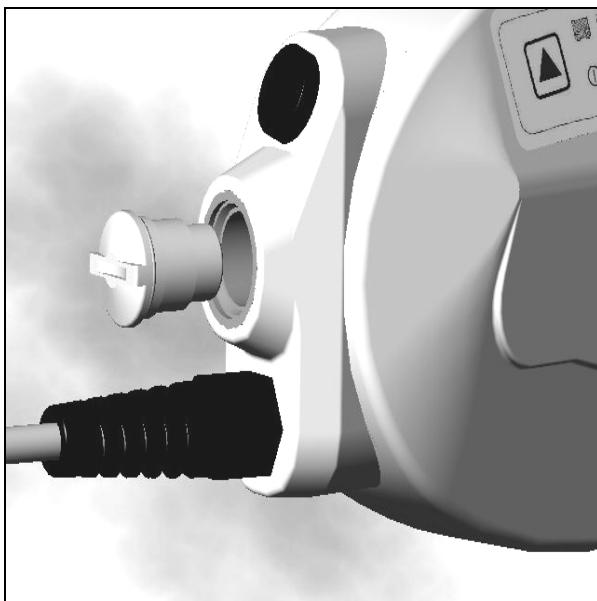


Figure 15. Insert Battery Module into System Controller Receptacle

2. Pass the two system controller power lead ends out of the sterile field and connect them to the bifurcated ends of the PBU cable, white-to-white and black-to-black. Both the PBU and system controller will indicate a hazard alarm condition signifying that the system controller is powered but not connected to the HeartMate II LVAD. Do NOT connect the system controller to the pump.
3. The system monitor will default to the clinical screen. Press the silence alarm button to silence the hazard alarm for 2 minutes. Verify that the screen displays the pump off, low flow, and pump disconnected alarm messages and indicates fixed mode with a speed setpoint of 6,000 rpm (**Figure 16**). If the speed setpoint is not 6,000 rpm, go to the settings screen by pressing the settings tab, press the fixed speed adjust button, and follow the onscreen instructions to set the speed to 6,000 rpm.

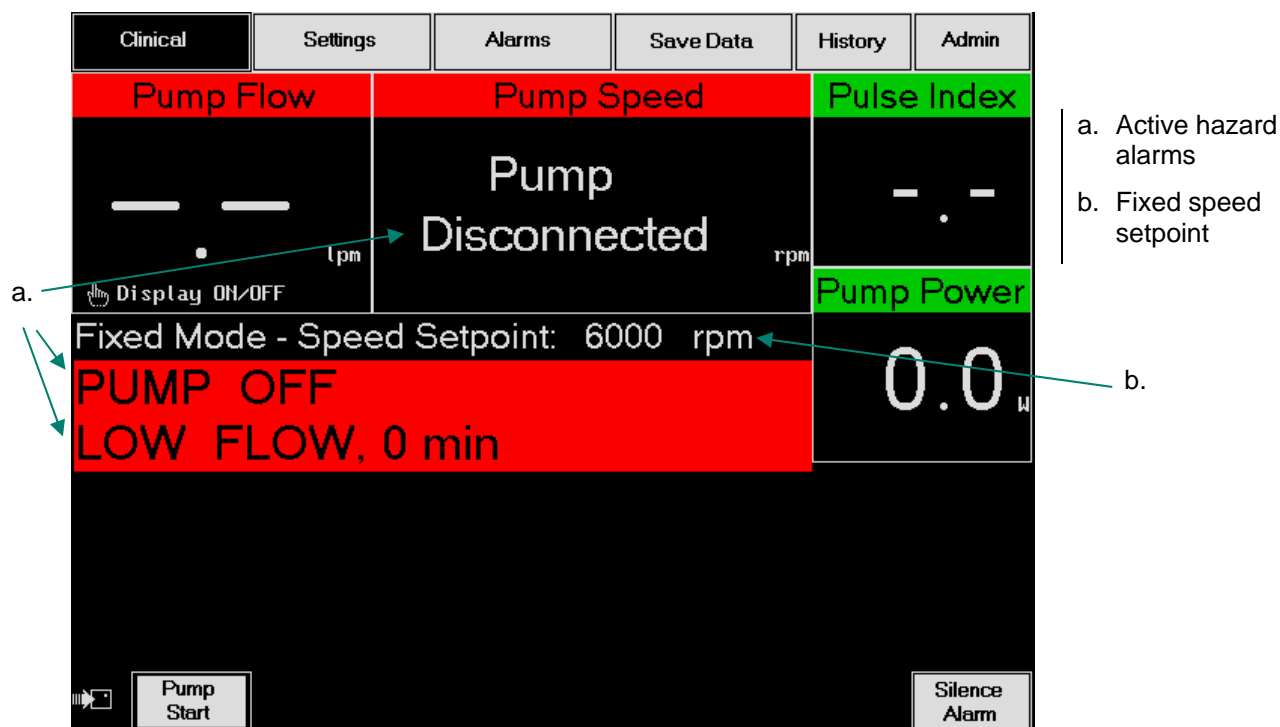



Figure 16. System Monitor Clinical Screen when Initially Connected to the System Controller

4. Go to the alarms screen by pressing the alarms tab. Press the extended silence button (**Figure 17**). This will silence all hazard and advisory alarms for four hours to ensure that they will not be sounded in the OR. The alarm silence indicator should display extended. The extended silence can be canceled by depressing the alarm reset button on the system controller's user interface panel.
5. Verify that a flashing communication icon  is shown in the lower left hand corner of the system monitor screen (will be displayed on all screens). This icon establishes that the system monitor is properly connected to the system controller and the correct monitoring software is running. If the icon is not flashing or has disappeared, the system might have frozen. Check lead connections and restart the monitor.

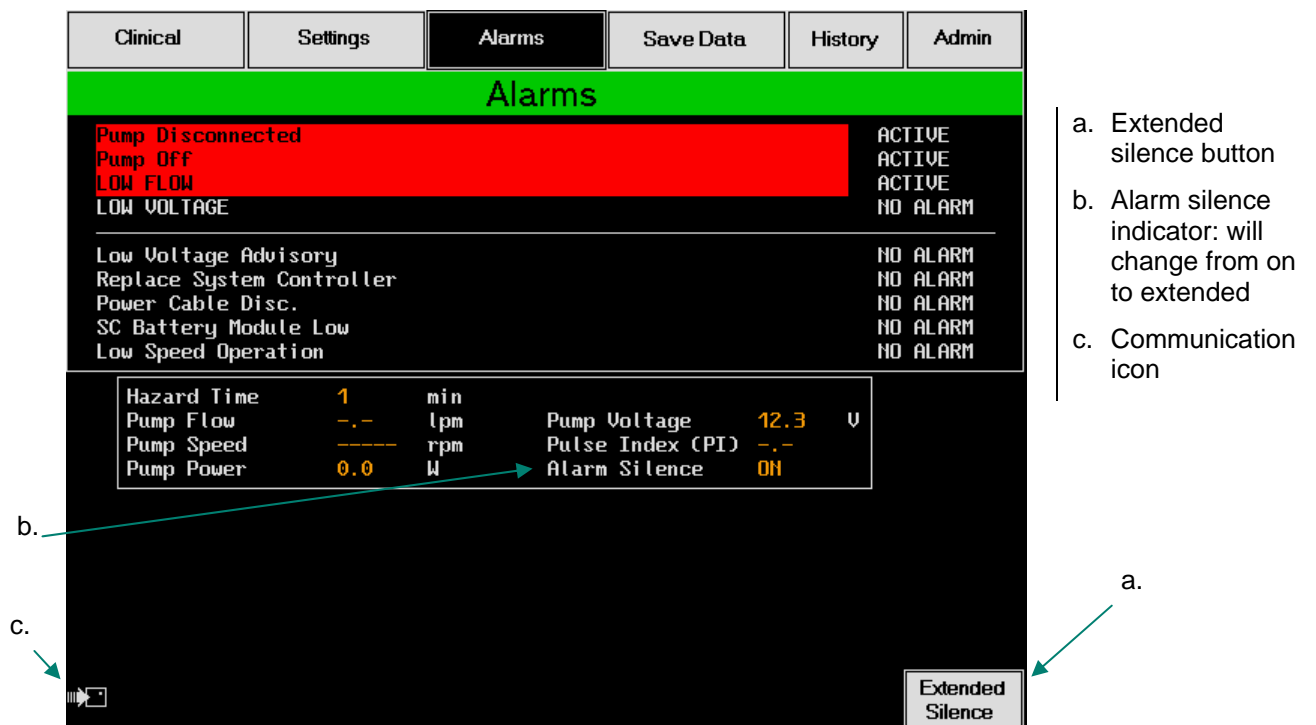


Figure 17. Alarms Screen when Initially Connected to the System Controller

6. Go to the admin screen and ensure that the time and date have been properly entered in the system monitor. Refer to the *HeartMate II LVAS Operating Manual* for instructions on setting the date and time.
7. System controller initialization is now complete. The pump disconnected alarm message will remain active until the system controller is connected to the LVAD, and the pump off alarm message will remain active until the LVAD is turned on via the system monitor pump start command.

CAUTION!

When the pump is on, do not run the pump dry or allow air to enter, as this may damage the bearings.

11.3 Preparing the Pump

To prepare the pump for implantation, remove the red caps and fully submerge the pump in a sterile basin with 2-3 liters of sterile saline for injection. Run the pump for a minimum of 5 minutes at 6,000 rpm by following the below procedure:

1. Attach the LVAD's percutaneous lead to the system controller:
 - a. Verify that the perc lock on the system controller is in the unlocked position. If it is not, rotate the perc lock in the direction of the unlocked icon until it clicks into the fully unlocked position and exposes the metal tab (**Figure 18**).

- b. Align the marker on the percutaneous lead connector with the marker on the system controller socket and fully insert the connector into the socket until it clicks into place (**Figure 19**). Check the connection by gently tugging on the metal end of the percutaneous lead.
- c. On the system monitor, the pump disconnected message should disappear and the pump speed box should now display “- - -.”
- d. Rotate the perc lock on the system controller in the direction of the locked icon until the perc lock clicks into the fully locked position (**Figure 18**). *The perc lock will not rotate unless the connector is fully inserted.*

Press metal tab to disconnect percutaneous lead.

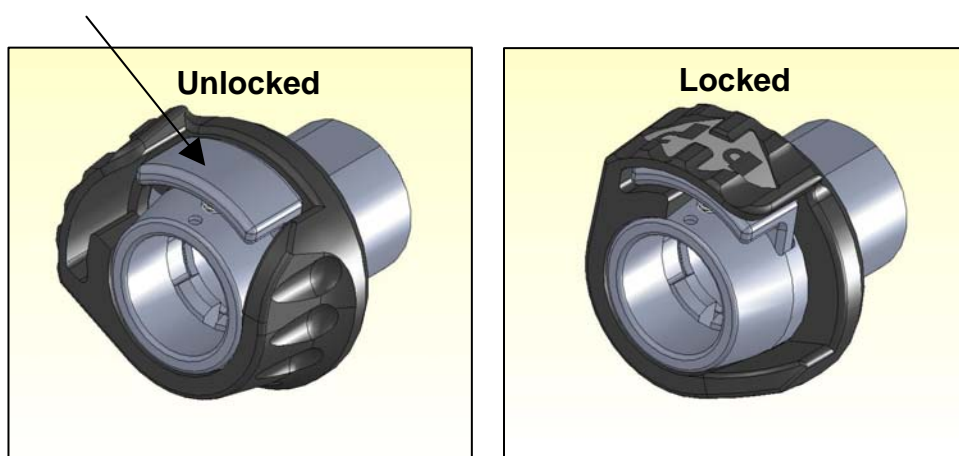


Figure 18. Perc Lock – Unlocked (left) and Locked (right) Positions



Figure 19. Attaching Percutaneous Lead to System Controller

2. Initiate pump flow at 6,000 rpm by pressing the pump start button on the settings screen of the system monitor. The pump off message should disappear.
3. After 5 minutes have elapsed, stop the pump by pressing and holding the pump stop button on the settings screen for 10 seconds until the pump off alarm occurs (**Figure 20**). The pump off message should appear and the pump stop button should change to pump start.

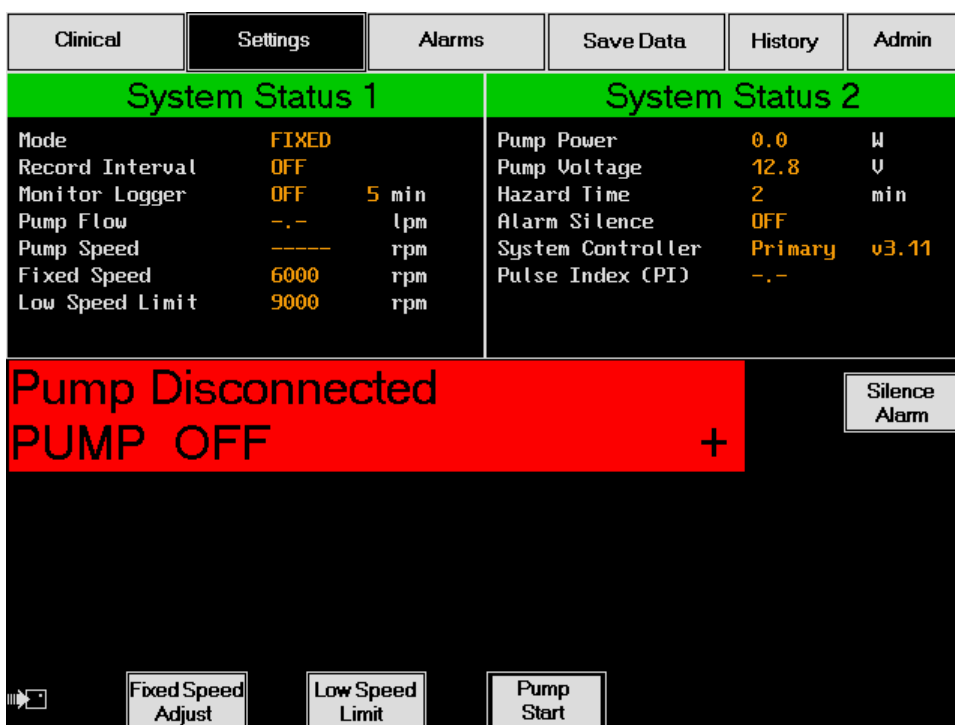


Figure 20. Settings Screen – Pump Stop

4. Disconnect the percutaneous lead and leave the pump in the sterile basin of sterile saline for injection.
5. Attach the tunneling bullet to the percutaneous lead connector. Ensure that the bullet is completely screwed down tight.
6. Leave the system controller power leads connected to the PBU. If the power leads are disconnected, the extended alarm silence will be reset.

11.4 Pre-Clotting the Inflow conduit and Outflow Graft

The flexible inflow section of the inflow conduit and the outflow graft must be pre-clotted prior to use in order to facilitate hemostasis. The next two sections describe the pre-clotting steps. Care must be taken to ensure that pre-clotting occurs as indicated.

11.4.1 Flexible Inflow conduit

Follow the procedure below to pre-clot the external surface of the polyester graft within the flexible inflow conduit (**Figure 21**) using an approved pre-clotting agent(s) or whole blood.

CAUTION!

Do not use pre-clotting agents that require heat, as the inflow conduit cannot be autoclaved.

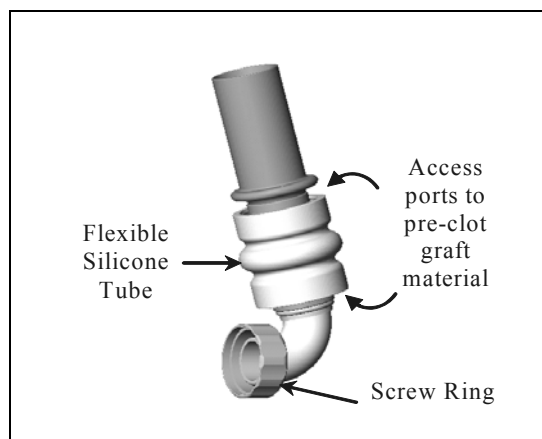


Figure 21. Pre-Clotting External Surface of Polyester Graft

1. Remove the inflow conduit from the tray.
2. If using whole blood, draw 60 ml of non-heparinized blood from the patient. Otherwise, obtain approved pre-clotting agent(s).
3. Holding the cannula in a horizontal position, slowly expel the clotting material over the exterior of the woven polyester graft material positioned inside of the flexible white silicone tube using the four upper and lower slots. Allow excess flow to drip into a small container so that it can be redrawn into the syringe for repeated use.

CAUTION!

If a react-in-place sealant such as Tisseel® (Baxter Healthcare Corp) or CoSeal® (Baxter Healthcare Corp) is used, special care must be taken to deliver the sealant into this space before reaction is complete.

4. Rotate the cannula to coat the graft material while allowing the clotting agent to coagulate. It may take 30-40 minutes for an acceptable clot to form if using whole blood.
5. Make sure the clotting agent does not come into contact with the fine threads of the screw ring used to attach the cannula to the pump.
6. Continue the procedure, manipulating the flexible portion of the cannula in order to allow the clotting agent to coat all surfaces of the polyester vascular graft.
7. Inspect the cannula for complete coating. Resume the pre-clotting procedure, if necessary, to complete the pre-clotting process.
8. Inspect the inner lumen of the inflow conduit; and, if necessary, flush with sterile saline to remove any clots.

WARNING!

Hemostatic matrix materials such as Surgiflo® (Ethicon) or FloSeal® (Fusion Medical Technologies) should not be used, as the material does not produce a layer with sufficient strength to ensure that the graft is sealed.

CAUTION!

The entire external surface of the polyester vascular graft must be coated with the pre-clotting agent(s).

11.4.2 Outflow Graft

Coat the external surface of the outflow graft (**Figure 22**) with whole blood, albumin, or other standard approved pre-clotting agent(s) by following the procedure below.

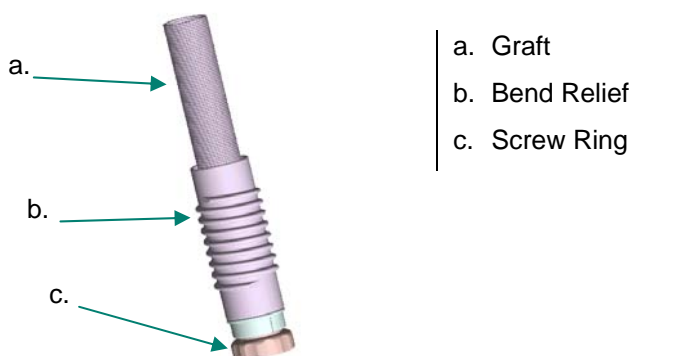


Figure 22. Pre-Clotting External Surface of Outflow Graft

1. Remove the outflow graft and bend relief from the tray.
2. Using strict aseptic technique, remove the bend relief from the graft and reserve for use after the pre-clotting procedure.
3. Attach the open thread protector to the screw ring connector.
4. Coat the outside of the graft evenly with whole blood, albumin, or other approved pre-clotting agent(s) in an emesis basin. Ensure that the seam between the graft and its metal connector is adequately coated to prevent leaks. Once fully coated, drain and place the graft in a dry basin.
5. Heat the graft in an autoclave if necessary to coagulate the pre-clotting agent(s). Allow the graft to cool after heating.
6. Inspect the interior of the graft and remove any debris or clots.
7. Place the bend relief (10.2 mm [4 in.]) over the graft with the metal end sliding toward the screw ring. Do not slide it to the end position; instead leave the bend relief un-engaged to facilitate easier de-airing.

CAUTION!

Do not over tighten thread protector.



NOTE:

A shorter, 7.6 cm (3 in.) bend relief (catalog # 102782) is available as a stand-alone, sterile item.

8. The thread protector should be left attached to the screw ring connector for use with, and attachment to the HeartMate II surgical sizer.

CAUTION!
Do not over-tighten the thread protector.

11.5 Priming the Pump / Inflow conduit Assembly

After pre-clotting the inflow conduit, assemble the inflow conduit to the pump (**Figure 23**). Using strict aseptic technique, complete the following procedure:

1. Verify that the bullet is completely screwed down tight onto the connector end of the percutaneous lead.
2. To prevent damaging the O-ring located at the distal end of the cannula elbow, be careful when first engaging the cannula with the pump. Initially, insert the cannula elbow into the pump port just to the point where the thread halves become engaged. Full engagement of the cannula elbow into the pump should be made by the threads pulling the parts together. ***Do not push the elbow fully into the pump to engage and tighten the threads.*** Arrows on the pump housing indicate direction of flow to illustrate the correct orientation of the inflow versus outflow cannula.

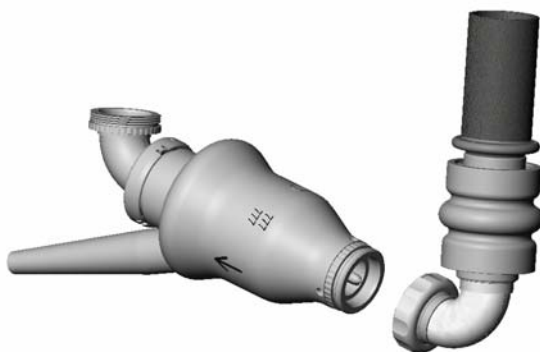


Figure 23. Assembling Inflow conduit to Pump

3. Attach the thread protector with the luer-lok cap to the pump outflow elbow. Open the luer-lok cap to allow air to escape.
4. Hold the pump / inflow conduit assembly in a horizontal position with the inflow conduit and outflow elbow pointing upward.

CAUTION!
Do not over-tighten the thread protector.

5. Fill the pump with sterile saline for injection through the inflow conduit until it flows out of the cap. Close the luer-lok cap.
6. While raising the inflow end to a position slightly higher than the outflow end, gently tap the side of the pump and observe air bubbles rising to the surface.
7. Tap and add saline until the pump appears full and no further air bubbles can be observed.
8. Cut a fingertip off of a powderless sterile glove and use it to cover the inlet extension of the inflow conduit.
9. Place antibiotic-soaked laps over the pump and velour portion of the percutaneous lead then set aside the pump with the inflow conduit positioned up and covered with a sterile towel.

WARNING!

All entrapped air must be removed from the pump / inflow conduit Assembly blood path in order to minimize the risk of air embolus.



NOTE:

Some fluid leakage will occur through the polyester graft and connections.

12.0 Surgical Implantation

The proper orientation of the components may be seen in **Figure 24**. The inflow conduit is placed utilizing left ventricle (LV) apical cannulation with the pump positioned inferior to the diaphragm and the outflow graft attached to the ascending aorta.

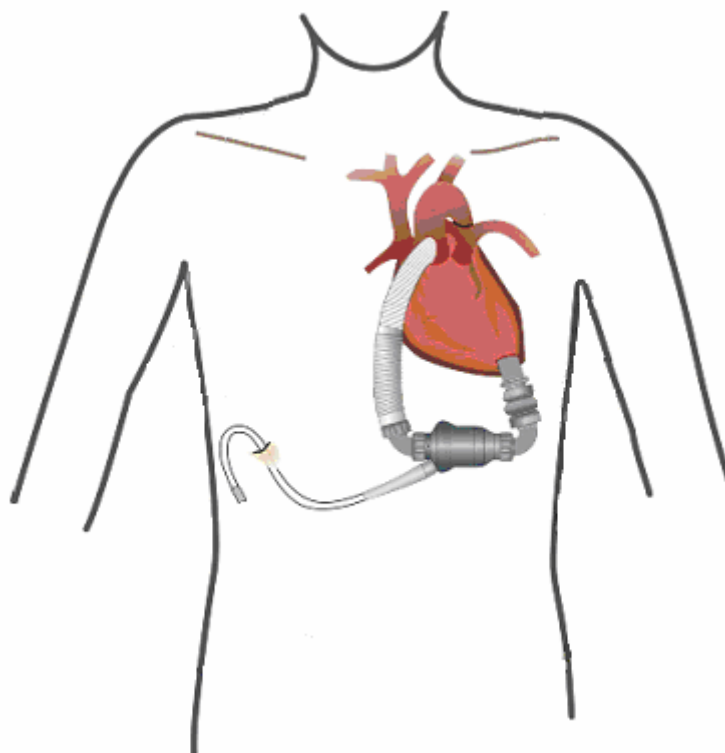


Figure 24. HeartMate II Implantation Configuration

12.1 Choosing Between Preperitoneal vs. Intra-Abdominal Placement

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

Preperitoneal placement appears preferable for patients that have undergone previous abdominal surgery or patients with a short torso. Another positive aspect of the preperitoneal approach is that the device is placed outside the abdominal viscera where bowel adhesions are unlikely. Potential disadvantages of using the preperitoneal approach include the risk of pocket hematoma, pocket and exit site infection, wound dehiscence, and erosion of the skin overlying the implanted device.

Intra-abdominal placement may be preferable for thin patients in whom the risk of erosion of the pump through the skin is a concern. Also, thin patients may not permit adequate “tunneling” of the percutaneous lines to allow sufficient ingrowth as a barrier to infection. The intra-abdominal location may also be preferable for patients that have been previously treated with an Automatic Implantable Cardioverter Defibrillator (AICD). The ability to create a preperitoneal pocket may be hampered by the placement of the AICD. Risks of intra-abdominal placement include diaphragmatic herniation into the pericardial space, wound dehiscence, abdominal (bowel) adhesions, bowel obstruction, bowel perforation, and erosion of the stomach, colon, liver, and abdominal viscera.

12.1.1 Surgical Technique for Preperitoneal Placement

Once the sternum is divided, the left anterior rectus sheath is opened medially, and electrocautery is used to create a pocket behind the rectus muscle. The dissection is extended laterally, and a pocket is formed between the posterior rectus sheath and transversalis fascia underneath and the rectus abdominis and internal oblique muscles above. The pericardium is opened and reflected laterally to allow exposure of the LV apex. The peritoneum is dissected away from the diaphragm. Further dissection is performed to facilitate insertion of the inflow conduit into the LV apex.

Once cardiopulmonary bypass is established and the LV apex is prepared for the insertion of the inflow conduit, the percutaneous lead is passed from the inferior aspect of the pocket through the right rectus abdominus muscle and subcutaneous tissue to the right upper quadrant of the abdomen 2 to 3 fingerbreadths below the right costal margin in the midclavicular line. The pump is adjusted in the pocket, and the inflow conduit is inserted into the LV apex through the left hemidiaphragm and secured. A small preperitoneal pocket is also made behind the right rectus



NOTE:

The HeartMate II surgical sizer (catalog # 102773) is available as a stand-alone, reusable item and may help to visualize and create the pump pocket.

muscle to allow for the outflow cannula. The outflow cannula is directed to the ascending aorta.

12.1.2 Surgical Technique for Intra-Abdominal Placement

A midline chest incision is made and extended to the umbilicus. Once cardiopulmonary bypass is instituted, and the aorta cross-clamped, the LV apex is prepared for insertion of the inflow conduit. The pump is placed intraperitoneally in the left upper quadrant, and the inflow conduit is passed through the anterior portion of the left hemidiaphragm to allow insertion of the inflow conduit into the LV apex. The outflow graft is placed over the diaphragm and anastomosed onto the ascending aorta. The percutaneous lead exits the body through the right upper quadrant.

12.2 Preparing for Implantation

Prior to implantation, ensure that:

- The outflow graft is pre-clotted on the external surface with serum or other standard pre-clotting agent and that the bend relief is in place over the graft and un-engaged to the metal fitting
- The inflow conduit is pre-clotted on the external surface of the polyester graft (under white silicone sleeve)
- The LVAD is correctly assembled and all joints including the inflow conduit and outflow elbow connections are tight
- The LVAD is completely primed with sterile saline for injection
- Pump has been run for 5 minutes in sterile saline
- The system controller is initialized

12.3 Creating the Percutaneous Lead Exit Site

The tunnel created for the percutaneous lead should be as long as possible in order to maximize ingrowth along the lead's polyester velour covering and to minimize the risk of exit site infection. However, at least 1-2 cm (0.4-0.8 in.) of the lead's velour covering should be outside the exit site after the lead has been threaded into place.

Follow the procedure below to create the exit site:

1. Ensure that the exit site location (**Figure 24**) does not interfere with clothing.
2. Insert the pointed tip of the tunneler into a small incision appropriately positioned on the inner abdominal wall.
3. Starting from the inferior aspect of the pocket, create a long and gently curved tunnel that passes through the right rectus abdominus and subcutaneous tissue to an exit site in the upper right quadrant.
4. Prior to exiting the dermis, place a mark at the exit site. Use the 8-mm skin coring punch supplied in the implant kit to create a circular incision at this position.
5. Thread the bullet on the percutaneous lead onto the end of the tunneler. Carefully advance the tunneler to exit through the circular incision, and pull it through to exteriorize the percutaneous lead in an upward or superior fashion.
6. Inspect the lead to ascertain that it is free from any sharp bends or kinks. Place the pump in the prepared space.

NOTE:

If the tunneler is not used, the tunnel can be created with another instrument and the cable pulled through using the abdominal tape attached to the bullet. Also, the bullet tip is threaded and can be attached to appropriately-sized tunneling tools.

12.4 Preparing the Ventricular Apex Site

1. Cut the ligature securing the coring knife and remove the plastic plugs from each end. Pull the handle through the hole in the knife cylinder to make a "T" handle.
2. Choose the coring location slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery. Align the orientation of the coring knife toward the mitral valve (**Figure 25**). Take care to avoid orienting the inlet towards the interventricular septum. Device function will be compromised in the presence of inlet obstruction.
3. Apply the cutting edge to the epicardium, and maintain pressure while rotating the knife in one direction until the ventricular cavity is entered. Remove the core and inspect

CAUTION!

Do not allow the knife to involve the interventricular septum while performing LV coring.

the ventricular chamber for mural thrombi and crossing trabeculae, addressing both as needed.

4. Remove the sewing ring from the package and loosen the green ligature.
5. Wet the sewing ring prior to positioning it over the core for easier removal of the centering fixture.
6. Have an assistant hold the centering fixture of the sewing ring assembly so that the felt portion is directed toward the heart and the silicone tubular portion of the sewing ring is facing outward.
7. Suture the sewing ring cuff with at least 12 pledgeted horizontal mattress 2-0 braided sutures almost full thickness, approximately one and a half centimeters from the core and apply corresponding sutures to the felt sewing cuff. Then separate the sutures and tie them tight – with 6 to 7 throws on each knot – to gather the myocardium around the felt cuff.

CAUTION!

Do not remove the centering fixture until ready to insert the inflow conduit.

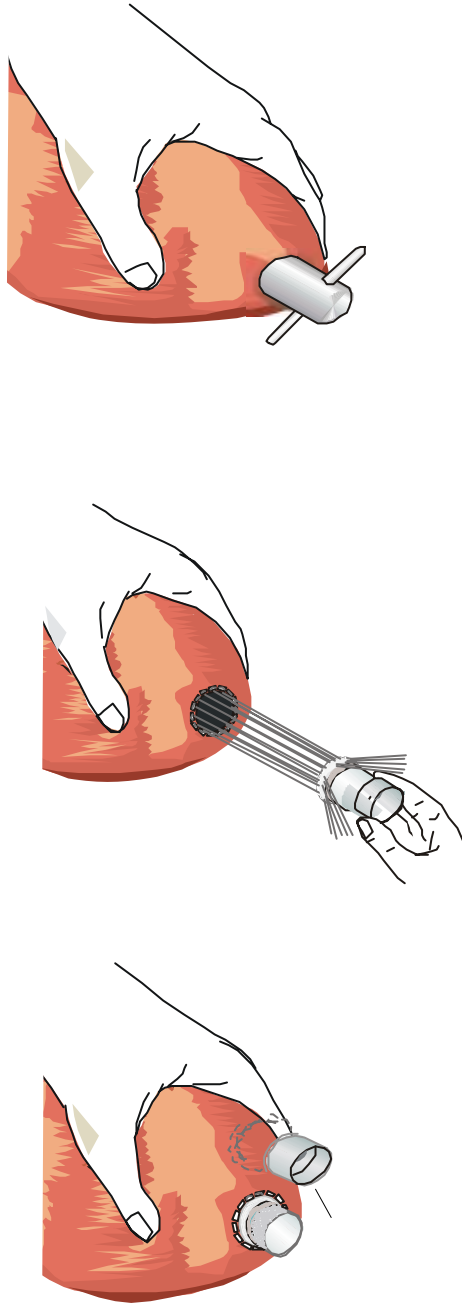


Figure 25. Preparing the Ventricular Apex Site

12.5 Inserting the Inflow conduit

1. Select the optimal inflow conduit orientation at the ventricular apex. The following is critical in determining orientation:
 - The opening of the inflow conduit should be directed toward the mitral valve and away from the interventricular septum.
 - Care must be taken to avoid excessive angulation of the inflow conduit once the LVAD is in-situ.
 - The ideal orientation will anticipate that the dilated LV may shrink in size as its workload is assumed by the LVAD.
2. Once the alignment is satisfactory, firmly secure the inlet extension to the apical suture ring with the attached green non-absorbable suture.
 - Employ additional ligatures to ensure that this connection is secure and leak-tight.
 - Once ligatures have been applied, do not rotate the pump and cause the inflow graft and flexible silicone tube to twist as shown in **Figure 26**.

WARNING!

Prior to advancing the inlet extension into the left ventricle through the apical sewing ring, remove the glove tip from the inlet extension and the centering fixture from the apical sewing ring. Inspect the ventricle and remove any previously formed clots that may cause embolism or any trabeculae that may impede flow.

WARNING!

If the inflow graft and silicone tube are twisted, flow will be restricted through the cannula.



Correct: untwisted silicone tube



Incorrect: twisted silicone tube

Figure 26. Correct Inflow conduit Silicone Tube Orientation

12.6 Attaching the Outflow Graft

1. Ensure that the bend relief is added to the graft prior to attaching it to the aorta.
2. Measure and cut the outflow graft to the appropriate length and then anastomose the graft to the ascending aorta in an end-to-side fashion using 4-0 polypropylene running sutures. Ensure that the suture line is secure with no blood loss.
3. Remove the thread protectors from the outflow graft and pump outflow elbow. Cross-clamp the graft and attach the proximal end to the outflow elbow using the threaded metal connecting ring (**Figure 27**).
4. Allow the graft to back-fill with blood from the aorta. Hand-tighten the metal connecting ring by turning clockwise until a clicking noise is heard and then continue to turn until tight.



NOTE:

A shorter, 7.6 cm (3 in.) bend relief (catalog # 102782) is available as a stand-alone, sterile item.



NOTE:

Use of the HeartMate II surgical sizer (catalog # 102773) may help in determining the appropriate graft length. When using the surgical sizer, the thread protector must be attached to the screw ring connector on the outflow graft.

WARNING!

Ensure that the thread protectors have been removed from the outflow graft and the outflow elbow prior to attempting connection.

CAUTION!

Ensure that the graft is not kinked or positioned where it could abrade against a pump component or body structure.

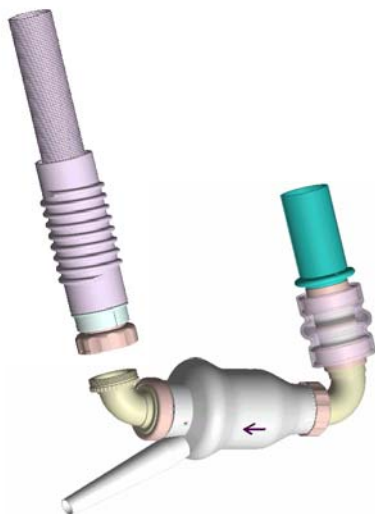


Figure 27. Attaching Proximal End of Outflow Graft to Pump Outflow Elbow

12.7 De-Airing the LVAD

Once the LVAD is in place and the inflow and outflow anastomoses are completed, residual air must be completely evacuated from the LVAD blood chamber prior to initiating LVAD activation. Transesophageal echocardiography (TEE) should be utilized to monitor for air emboli. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mm Hg.

1. Cross-clamp the outflow graft at the distal end and move the bend relief toward the aortic anastomosis.
2. Position the outflow graft in a vertical position, such that an arch forms the highest point.
3. Insert a vent needle at the highest point in the graft between the clamp and the outflow cannula connection.
4. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and LVAD by diverting at least 2 liters per minute (lpm) of blood to the ventricle.
5. Place the patient in the Trendelenburg position.
6. Verify that the system monitor clinical screen displays the pump off, low flow, and pump disconnected alarm messages and indicates fixed mode with a speed setpoint of 6,000 rpm (**Figure 28**). If the speed setpoint is not 6,000 rpm, go to the settings screen by pressing the settings tab, press the fixed speed adjust button, and follow the onscreen instructions to set the speed to 6,000 rpm.

WARNING!

The HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure (LAP) at greater than 10 mm Hg at all times to prevent air entrainment.

WARNING!

All entrapped air must be removed from the LVAD blood pumping chamber and cannulae in order to reduce the risk of air embolus.

CAUTION!

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.



NOTE:

The needle vent should be placed in the outflow graft in the highest point in the lumen (anterior side to optimize air removal).



NOTE:

The surgical field may be optionally flooded with sterile saline to further minimize the risk of air entry and possible embolization.

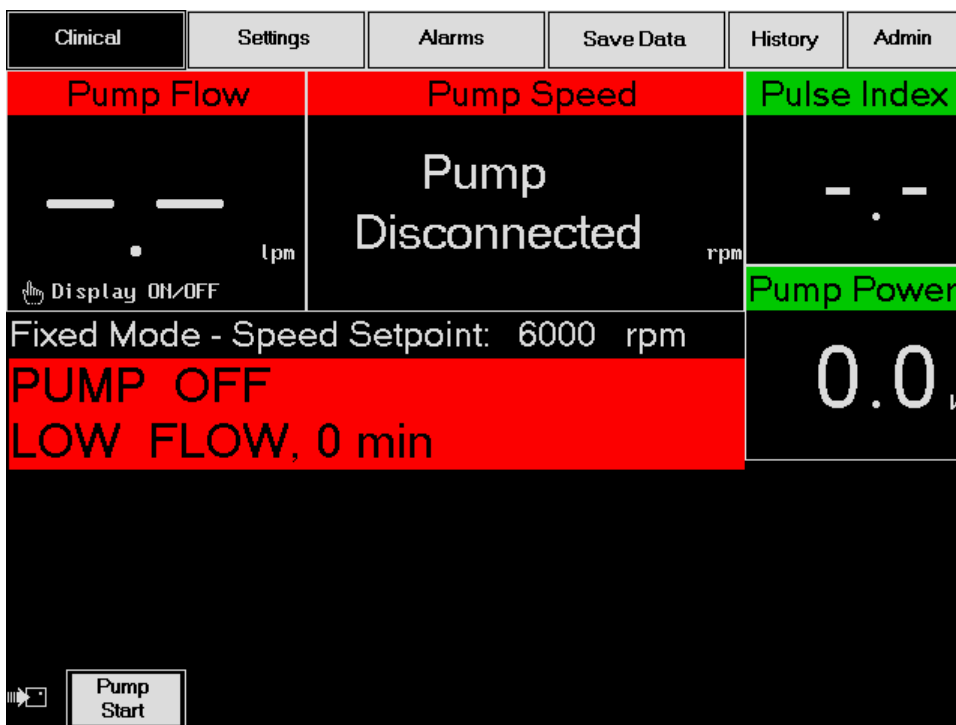


Figure 28. Clinical Screen – Initial Pump Startup

7. To initiate HeartMate II pump operation, remove the bullet from the LVAD's percutaneous lead and attach the lead to the system controller:
 - a. Rotate the perc lock on the system controller in the direction of the unlocked icon until the perc lock clicks into the fully unlocked position and exposes the metal tab (**Figure 29**).
 - b. Align the marker on the percutaneous lead connector with the marker on the system controller socket and fully insert the connector into the socket until it clicks into place (**Figure 30**). Check the connection by gently tugging on the metal end of the percutaneous lead.
 - c. The pump disconnected message should disappear and the pump speed box should now display “- - - -.”
 - d. Rotate the perc lock on the system controller in the direction of the locked icon until the perc lock clicks into the fully locked position (**Figure 29**).
The perc lock will not rotate unless the connector is fully inserted.

Press metal tab to disconnect percutaneous lead.

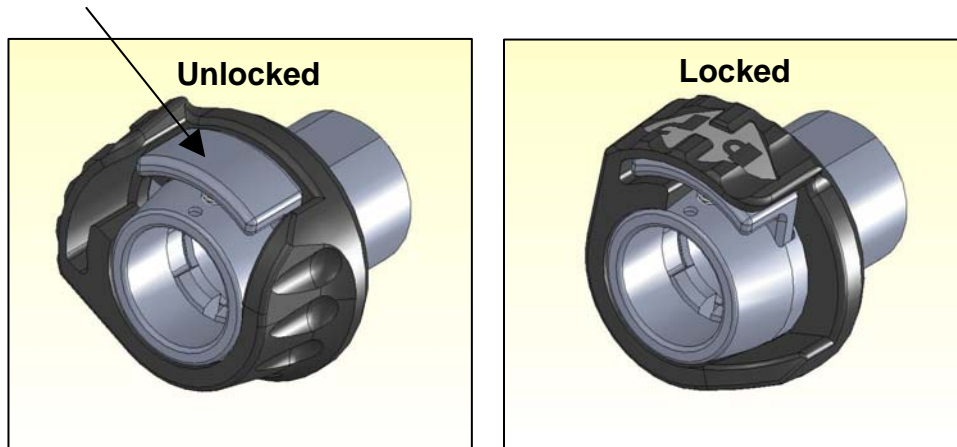


Figure 29. Perc Lock – Unlocked (left) and Locked (right) Positions



Figure 30. Attaching Percutaneous Lead to System Controller

8. Initiate pump flow at 6,000 rpm by pressing the pump start button on the settings screen. The pump off message should disappear and the low speed operation message should appear. **Figure 31** and **Figure 32** demonstrate typical clinical and settings screens that will be displayed by the system monitor once the pump is running.



NOTE:

The pump flow will display “- - -” when the speed is below 8,000 rpm and the low flow is active; otherwise, it will display “-.-” when the speed is below 8,000 rpm and the low flow alarm is inactive.

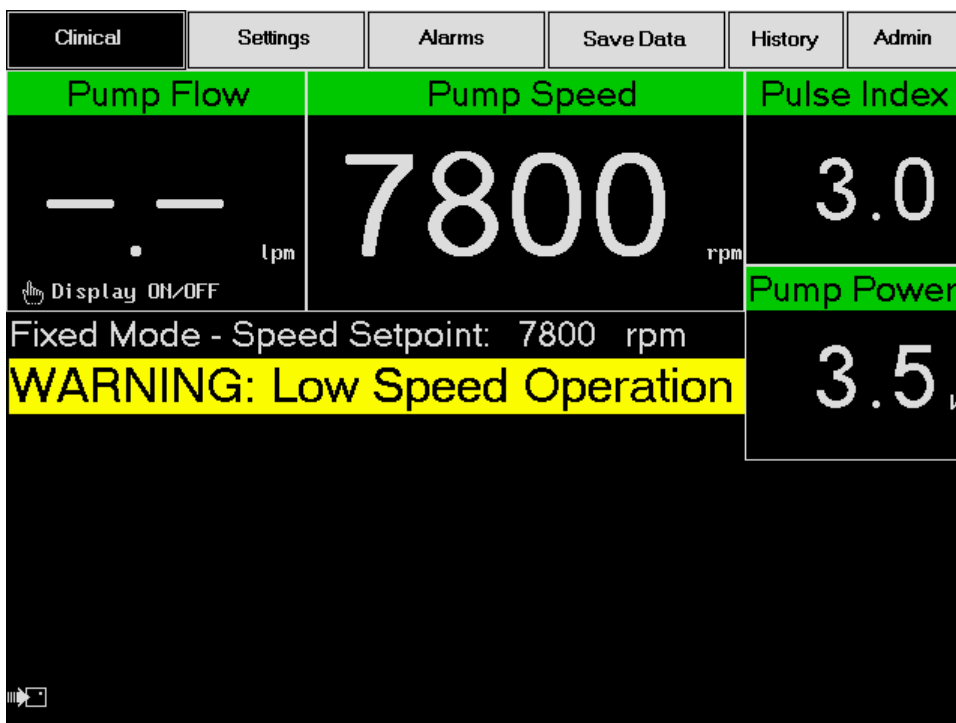


Figure 31. Clinical Screen During Initial Pump Startup (typical)

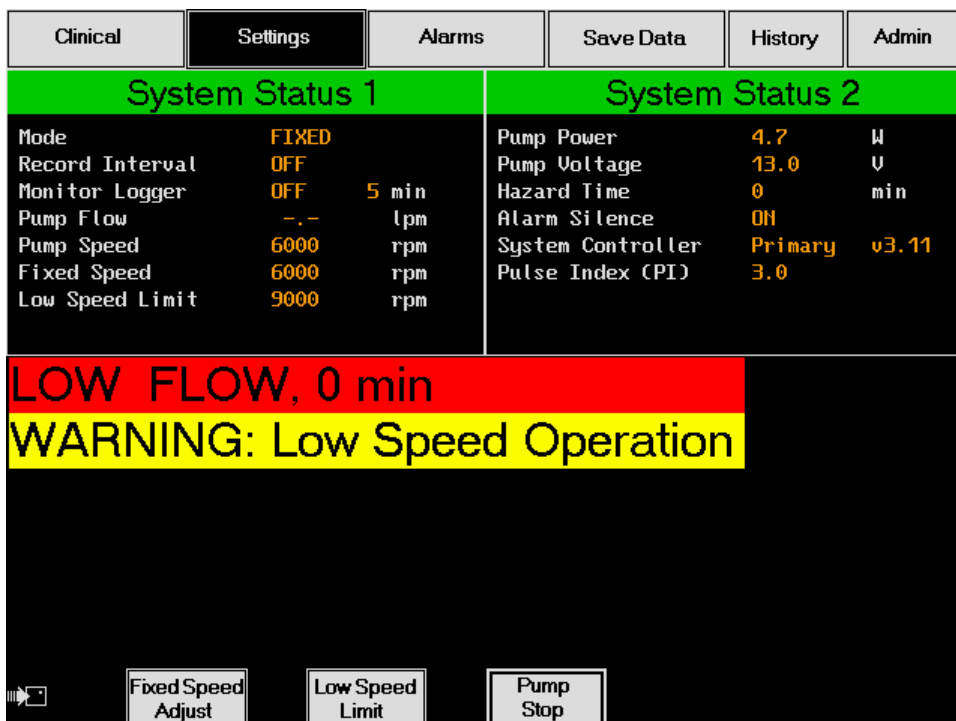


Figure 32. Settings Screen During Initial Pump Startup (typical)

9. Watch for air being expelled through the venting needle. Throughout the de-airing process, always monitor for the presence of air in the aorta and/or left heart using intraoperative TEE, and keep the left heart full.
10. When de-airing is completed, partially remove the outflow graft cross-clamp while continuing to operate the LVAD. Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate pump flow.
11. Remove the vent needle from the outflow graft and repair the site only when air can no longer be observed exiting through the needle. If air persists in the pump outflow graft for a prolonged period (more than 5-10 minutes), rule out leaks at the inflow conduit/pump connection.
12. Slide the bend relief over the metal fitting toward the locking screw ring until it snaps into place. This is confirmed by the inability of the bend relief to slide back toward the anastomosis.
13. When all air has been removed from the blood pump, it is safe to increase the pump speed (rpm). Adjust the fixed speed setpoint by pressing the fixed speed adjust button on the settings screen and following the onscreen instructions to select the desired pump speed setting. Once the desired speed is selected, press the enter button to send the command to the system controller.
14. Terminate cardiopulmonary bypass to provide ample blood flow to the LVAD. The goal at this time is to achieve and maintain appropriate flow levels by adjusting the fixed speed of the LVAD. Along with flow, the LV size, position of the septum, and aortic valve opening should be monitored to determine the appropriate fixed speed setting. The final decision is ultimately dependent on the physician's clinical judgment and will vary from patient to patient.
15. Adjustment in pump speed and therefore flow can be made by pressing the Fixed Speed Adjust button on the Settings screen and changing the speed using the adjustment buttons. Speed will only change after pressing the Enter button. The actual flow increase for a given change in speed is dependent on many factors and could vary significantly.

CAUTION!

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.

WARNING!

All entrapped air must be removed from the LVAD blood pumping chamber and cannulae prior to fully releasing the outflow graft cross-clamp.

Recognizing that arterial pressure (pump outlet pressure) is closely regulated by the intrinsic cardiovascular regulatory mechanisms of the body, the principle factor influencing pump flow is the inlet

pressure (left ventricular pressure). **Figure 33** illustrates that running the pump at 6,000 rpm will result in a maximum flow of 4 lpm, provided left ventricular pressure equals arterial pressure. A pressure difference of 20 mm Hg would be required to obtain 2.5 lpm flow at 6,000 rpm, which would result in a left ventricular pressure of $100 - 20 = 80$ mm Hg at an arterial pressure of 100 mm Hg. By increasing the pump speed to 10,000 rpm, a 100 mm Hg pressure difference would be needed to maintain a 2.5 lpm flow rate. This relationship demonstrates that the flow generated by the pump is directly proportional to left ventricular pressure.

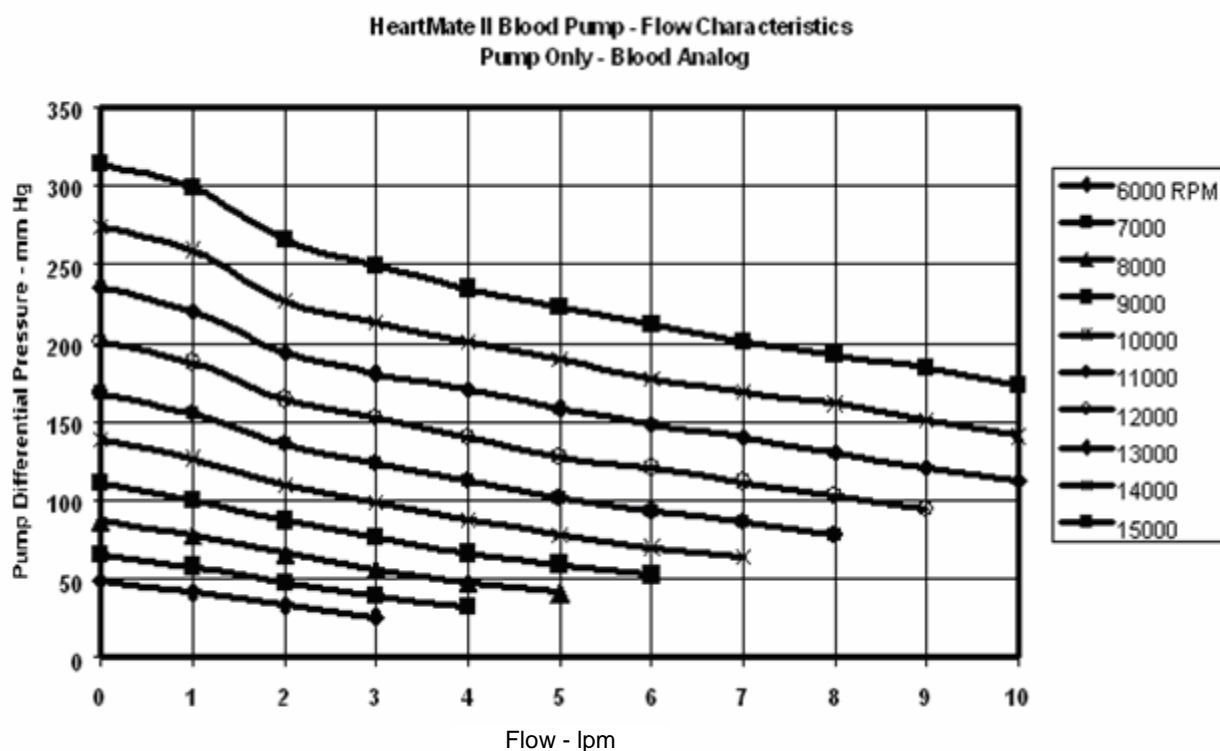


Figure 33. Typical HeartMate II Flow Characteristics

At fixed speed settings of 8,000 rpm or higher, if complete power to the pump is interrupted (e.g., percutaneous lead is disconnected, both batteries are disconnected simultaneously), causing the pump to stop, the pump will automatically restart at the previously set speed when power is restored. However, if the fixed speed setting is **below 8,000 rpm**, the pump **will not automatically restart** after being disconnected and reconnected. The user must press the pump start button on the system monitor settings screen.

If the pump is stopped using the pump stop button, it will not automatically restart if the percutaneous lead is disconnected then



NOTE:

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

reconnected to the system controller, regardless of what the fixed speed setpoint was before stopping the pump.

However, if the pump is stopped using the pump stop button and then both **power leads** are disconnected from the system controller, the pump stop command in the controller will be canceled and the pump will automatically restart (if the fixed speed is at least 8,000 rpm) when the power leads are reconnected.

12.8 Securing the Pump and Connections

Once the flow through the blood pump is satisfactory, assure that all inflow and outflow connections are dry and secure. Obtain hemostasis and close all wounds in the standard fashion.

12.9 Transferring Patient Out of the Operating Room

When it is time to transfer the patient out of the operating room, the HeartMate II LVAD system must be transferred from PBU power to battery power. Cancel the extended alarm silence by pressing the alarm reset button on the system controller's user interface panel. Go to the alarms screen and verify the alarm silence is off. To enable the transfer, insert a battery into each of the two battery clips. Unplug either of the system controller power leads from the PBU cable and connect it to a battery clip. When the first connection is complete, disconnect the second system controller power lead from the PBU cable and connect it to the other battery clip. Tuck the batteries safely beside the patient so that the system controller leads are not under strain.

Once the patient has been transferred to batteries, it may be beneficial to program the backup system controller because the PBU is now free to connect to it (see section 13.7).



NOTE:

It is not possible to monitor speed during transport. A portable blood pressure monitor is recommended for use during transport to gauge the effectiveness of support during periods of fluctuating pre-and after-load. A cart containing the PBU and system monitor can closely follow the patient and should be reattached when the patient arrives at his or her destination.

12.10 Other Patient Considerations

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 Ferromagnetic components. MRI can 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 under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent device implant (prior to mediastinal healing).

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 may result in erroneous readings. 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.

PATIENT MANAGEMENT

13.0 Patient Management

Support of a HeartMate II LVAS patient in the hospital requires that the equipment in **Table 6** be on hand and readily available:

Component	Primary (Required)	Back-Up (Required)	Optional
Implanted HeartMate II LVAD	X	X	--
System Controller	X	X	--
Rechargeable Batteries (set of 6)	X	X	--
Battery Clips (set)	X	--	X
HeartWear™ Accessories *	X	--	X
Power Base Unit	X	X	--
System Monitor	X	X	--
Display Module	--	--	X
System Controller Battery Module	X	--	X

Table 6. Equipment for In-Hospital Patients

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

Proper care of a patient supported by the HeartMate II LVAS requires thorough understanding of system operation, the patient's condition, and the unique physiologic support provided by axial flow rotary devices. Physician judgment and experience may vary, but the points discussed in this chapter should be considered.

13.1 Unique Treatment Issues

A feature of this design is that device flow is a function of the pressure difference between the inlet and the outlet to the pump. Therefore, pump performance is sensitive to changes in systemic resistance and left ventricular filling.

The following treatment issues are considered critical to the achievement of positive outcomes:

- Close surveillance for physiologic, pathophysiologic, or iatrogenic changes in left ventricular filling (preload) and systemic vascular resistance (after load) is required following implantation. Small increases in after load or small decreases in preload may result in diminished pump flow, a reduction that may manifest in a clinically relevant decrease in perfusion.
- Standard methods for assessing pump flow may not be helpful under all physiologic conditions. As described above, changes in preload or after load should prompt an immediate patient assessment that includes physical examination to confirm the adequacy of peripheral perfusion. In shock states, physical examination may not provide adequate evidence of perfusion restoration. The use of right heart catheterization under conditions of hemodynamic instability is highly recommended. Mixed venous oxygen saturation measured intermittently or continuously will provide the most sensitive guide to perfusion in post-implantation shock states. If right heart catheterization is not possible, a mixed-venous O₂ saturation from a right atrial catheter may be substituted.
- Under stable physiologic conditions, 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.
- Auscultation over the pump pocket is recommended in order to verify the pump is running.
- 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.
- Complaints of dizziness should prompt immediate evaluation of the patient and system.
- Right heart failure may occur at any time following implantation. Follow up closely and intervene with nitric oxide, vasodilators, diuretics, inotropic drugs, or mechanical right ventricular assist device as indicated.

- Post-implantation hypertension may be treated at the discretion of the attending physician. Any therapy that consistently maintains mean arterial blood pressure less than 90 mm Hg should be considered adequate. Antihypertensive therapies must be documented.
- Early ambulation and resumption of dietary intake are encouraged. Patient mobilization may occur after the percutaneous line is immobilized.
- Social and family support during rehabilitation is encouraged. Exercise physiotherapy is recommended post-implantation.
- It is critical to use trans-thoracic echo to monitor the left ventricle during speed adjustments. Verify that the septum does not shift, which could compromise right ventricular function.

13.2 Exit Site Treatment

The following points are considered in treating percutaneous lead exit sites in the HeartMate LVAS:

- Daily exit site care is performed using an antiseptic cleansing agent such as chlorhexidine scrub solutions. Following aseptic cleansing, the site should be rinsed and dried to avoid tissue maceration. Aseptic technique should be adhered to whenever the exit site is inspected, dressed, or otherwise handled.
- When performing site care, be sure to use a sterile cap, mask, gown, and gloves.
- Prophylactic topical agents such as silver sulfadiazine or polymixin-neomycin-bacitracin are avoided. These ointments can macerate the tissues.
- The percutaneous lead should be immobilized with abdominal wraps or binders to reduce trauma to the exit site, especially when the patient is ambulatory. Trauma to the exit site can increase the risk of infection.

- Intravascular lines are withdrawn as soon as is practical to reduce the risk of systemic infection.
- Parenteral treatment with antibiotics and surgical drainage are used if evidence of pump pocket infection exists.
- Fungal infections resulting from organisms such as *Candida species* have been associated with vegetative growth on LVADs. Persistent systemic fungal infection refractory to antifungal treatment may require LVAD replacement.

WARNING!

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

13.3 Anticoagulation Therapy

1. Prior to leaving the OR, completely reverse the anticoagulation.
2. **Optional:** Post implantation, as early as possible, administer 10% LMW Dextran™ at 25ml/hr. Note: this step is optional until the benefit of Dextran administration is further delineated.
3. Begin IV heparin after 12-24 hours or when chest tube drainage is less than 50 ml/hr:
 - Initially titrate to a PTT of 45-50 for 24 hours (1.2-1.4 times control)
 - After 24 hours, increase heparin and titrate to PTT 50-60 (1.4-1.7 times control)
 - After another 24 hours, increase heparin and titrate to PTT 55-65 (1.5-1.8 times control)
4. On post-operative day 2-3, initiate aspirin 81-100 mg QD and dipyridamole 75 mg TID.
5. On post-operative day 3-5, once there is no evidence of bleeding and the chest tubes have been removed, begin Warfarin™ (overlapping with the heparin). Discontinue heparin after obtaining an acceptable, stable INR. The INR should be maintained in the range of 2.0 to 3.0.
6. Maintain the patient throughout support on aspirin and dipyridamole and Warfarin.

WARNING!

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

Conditions requiring possible modification to anticoagulation:

1. **Sustained low pump flow states (< 3.0L/min):**
 - Consider increasing anti-coagulation to upper limits of normal.

2. Risk of bleeding:

- Consider increasing anti-platelet medications and decreasing heparin/Warfarin (INR 1.7-2.3). Anti-platelet effect should be confirmed with lab studies, e.g., TEG.

13.4 Diagnosing Blood Leaks

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

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distension of the abdomen
- Blood draining from the percutaneous lead exit site
- Evidence of decreased hemoglobin/hematocrit



NOTE:

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

13.5 Right Heart Failure

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

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

WARNING!

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

CAUTION!

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

13.6 Avoiding Static Electric Discharge

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

13.7 Backup System Controller

Ensure that all backup system controllers are programmed with settings (e.g., fixed speed setpoint and low speed limit) identical to the primary controller. Remember, controllers are shipped with factory settings (see **Table 5**), and therefore, backup controllers must be programmed at the time they are assigned to a patient.

Programming the backup system controller is done the same way as programming the primary controller (section 12.7) except that the backup controller is not connected to the patient. It is programmed via the system monitor without being attached to the percutaneous lead, and new settings are displayed on the monitor, verifying that the changes have been saved to the backup system controller. See the *HeartMate II LVAS Operating Manual* for detailed explanations on setting the fixed speed and low speed limit.

Once the backup system controller is programmed, store the controller with the perc lock in the unlocked position. This will facilitate the controller change process should it be required.

CAUTION!

Backup controllers with settings that differ from the primary controller may result in diminished support or patient harm.

14.0 Patient Discharge

Patients discharged to a lower care facility, or to home, must be trained in device use, maintenance, and trouble-shooting as described in the *HeartMate II LVAS Operating Manual*. In addition, device malfunction may necessitate emergency treatment. Therefore, patients should not be more than 2 hours from a healthcare facility with trained personnel that are capable of treating a HeartMate II patient.

The equipment in **Table 7** is required for patients who reside outside a hospital setting:

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

Table 7. Equipment for Home Discharge Patients

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

CAUTION!

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

CAUTION!

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

DEVICE EXPLANT

15.0 Explanting the LVAD

The LVAD may be removed by following these steps:

1. Expose the LVAD and carefully dissect it free.
2. Place the patient on cardiopulmonary bypass and establish flow. Disconnect power from the system controller, and then disconnect the system controller from the percutaneous lead to stop pumping.
3. Cross-clamp the outflow graft just distal to the bend relief and divide the graft.
4. Divide the ligatures securing the apical sewing ring to the inflow conduit and remove the inflow conduit from the ventricle.
5. Dissect the percutaneous lead between the LVAD body and the abdominal wall. Cut the percutaneous lead and the remove the externalized portion.
6. Remove the LVAD from the abdomen or preperitoneal pocket, and remove the remaining portion of the percutaneous lead from the inside-out by careful dissection. The percutaneous site is then closed in the standard fashion.
7. Remove the outflow graft remnant from the aorta and repair the anastomotic site.
8. Once the LVAD has been explanted, all explanted components should be disposed of in accordance with local regulations for biohazardous materials. Alternatively, explanted components may be returned to Thoratec in the appropriate explant kit for disposal.

WARNING!

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

CAUTION!

The percutaneous lead at explant is not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.

DEVICE TRACKING AND REPORTING REQUIREMENTS

16.0 Device Tracking

The LVAS is considered a life-sustaining medical device and must be tracked per US Food and Drug Administration (FDA), Health Canada, and other foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device-tracking paperwork shipped with the device must be completed and promptly returned to Thoratec. In addition, any device malfunctions must be reported to Thoratec by the implanting center.

SERVICE & MAINTENANCE

17.0 Service

Thoratec employs highly trained representatives and engineers located throughout the world to serve its customers and, upon request, to provide additional training to qualified hospital personnel in the use of Thoratec products. In addition, Thoratec maintains a professional staff to provide technical and medical consultation to product users. For supplemental information, contact a local representative or Thoratec.

18.0 Testing and Classification

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

18.1 Declaration Concerning General Safety Standards

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

Table 8. Declaration Concerning General Safety Standards



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

18.1.1 Declaration and Guidance Concerning Electromagnetic Emissions

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT—GUIDANCE
RF emissions CISPR 11	Group 1	The HeartMate II LVAS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HeartMate II LVAS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Radiated emissions, magnetic field MIL-STD-461E	RE101	The HeartMate II LVAS generates magnetic fields due to the presences of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Table 9. Declaration and Guidance Concerning Electromagnetic Emissions

18.1.2 Declaration and Guidance Concerning Electromagnetic Immunity

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

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

Table 10. Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate II Equipment, Including the Power Base Unit and System Monitor

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT—GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate II LVAD, system controller, and batteries including cables), than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF IEC 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	[3] Vrms	$d = \left[\frac{3.5}{3} \right] / P$
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	[10] Vrms	$d = \left[\frac{12}{10} \right] / P$
Radiated RF IEC 61000-4-3	Min. 10 V/m 80 MHz to 2.5 GHz	[10] V/m	$d = \left[\frac{12}{10} \right] / P$ 80 MHz to 800 MHz $d = \left[\frac{23}{10} \right] / P$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b
			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.</p>

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Notes for Table 7

- a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.
- b Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (*min.* 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate II LVAS is used exceeds the applicable RF compliance level above, HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

Table 11. Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate II LVAS Equipment, Including LVAD, System Controller & Batteries

- The HeartMate II LVAS has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate II LVAS generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:
 1. Reorient or relocate the receiving device
 2. Increase the separation between the equipment.
 3. Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
 4. Consult Thoratec Corporation for help.



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

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

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The HeartMate II LVAS was authorized to bear the CE Mark in 2005.