HeartMate II® LVAS

LEFT VENTRICULAR ASSIST SYSTEM

INSTRUCTIONS FOR USE

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GENERAL INFORMATION

1.0 Introduction

The HeartMate II Left Ventricular Assist System (LVAS) is an axial-flow, rotary ventricular assist system and can generate flows up to 10 liters per minute (lpm). Attached to the apex of the left ventricle and the ascending aorta, the HeartMate II blood pump diverts blood from the weakened left ventricle and propels it to the rest of the body. The System Controller, via its internal computer program, regulates the pump.

WARNING!
A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire booklet and the *HeartMate II LVAS Operating Manual* prior to attempting implantation. Completion of Thoratec Corporation's HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System.

2.0 Indications for Use

The HeartMate II LVAS is intended to provide hemodynamic support in patients with end-stage, refractory left ventricular heart failure; either for temporary support, such as a bridge to cardiac transplantation or myocardial recovery, or as permanent destination therapy. The HeartMate II is intended for use inside or outside the hospital.

3.0 Contraindications

The HeartMate II LVAS is contraindicated in patients who are unable to tolerate anticoagulation therapy.

4.0 Warnings and Precautions

4.1 WARNINGS

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire *HeartMate II LVAS Instructions for Use* (IFU) and the corresponding *HeartMate II LVAS Operating Manual* (document # 103878) before attempting implantation. Completion of the HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System (LVAS). In addition, it is important to read the Instruction for Use (IFUs) for the accessories used to power the HeartMate II LVAS, including the Power Module (PM), Universal Battery Charger (UBC), and HeartMate 12 volt nickel metal hydride (NiMH) or HeartMate 14 volt lithium ion (Li-Ion) batteries. See below and section 14.1 for a list of power accessory IFUs.
- Before using any HeartMate power accessories (Power Module, batteries, Universal Battery Charger), all users (including clinicians, patients, and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
    - *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
    - *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
    - *HeartMate Universal Battery Charger IFU* (document # 103841)
    - *HeartMate Power Module IFU* (document # 103840)
- The HeartMate Power Module (PM) and Universal Battery Charger (UBC) generates and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the PM and/or UBC. Interference can be determined by unplugging/plugging in the PM and turning off/on the UBC and seeing the affect on devices in the area. If interference is detected while the patient is connected to the PM, attempt to correct it by FIRST SWITCHING THE SYSTEM TO BATTERY POWER and then:
    - Re-orienting or moving the affected device(s).
    - Increasing the distance between the PM and/or UBC and the affected device(s).
    - Connecting the affected device(s) to an AC mains outlet different from the outlet used to power the PM and/or UBC.
    - Consulting Thoratec's Technical Services Department for advice and assistance.
- Do not use the PM or the UBC in the presence of flammable anesthetic agents (e.g., nitrous oxide), or an explosion may occur.

- Connect the PM (and any peripheral devices) only to properly tested, grounded, and AC mains outlets dedicated to PM use. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or you may receive a serious electric shock or the pump may stop.
- Do not connect the PM or the UBC to an outlet controlled by a wall switch or the device may be left inoperable.
- The PM, like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3 prong) AC mains electrical outlet that is dedicated to its use, except during transport or service/maintenance. The PM's internal battery (that provides limited backup power to the LVAD in the event of AC mains power failure) remains charged as long as the PM is connected to AC power and turned "on." See the *HeartMate II LVAS Power Module IFU* (document # 103840) for detailed warnings, precautions, and instructions on using the PM.
- The PM contains an internal battery. When new it provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS in the event of AC mains interruption/ failure. If the PM is used in cold conditions (32-59°F, 0-15°C), the backup battery runtime may be reduced to a minimum of 20 minutes.
- The PM is shipped with its internal battery disconnected. It must be connected prior to initial use. If the internal battery is not connected, the backup power source will not work. Make sure the internal battery is connected prior to initial use and after any time the PM is shipped for service or maintenance. See the *HeartMate Power Module IFU* (document # 103840) for detailed warnings, precautions, and instructions on the PM's internal battery.
- Users should transfer from the PM to batteries during AC mains power failure. The PM will switch to internal back up battery during power interruption/failure. In addition, the PM's battery charge status indicators will not work during AC mains power failure. See the *HeartMate Power Module IFU* (document # 103840) for detailed warnings, precautions, and instructions on using the PM, including how to transfer to battery-powered operation.
- Keep the PM and the UBC away from water. If the PM has contact with water, shower spray, rain/snow, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock. If the UBC has contact with water, shower spray, rain/snow, or wet surfaces, it may prevent the UBC from charging batteries or the patient may receive a serious electrical shock.
- Do not use the HeartMate II LVAS in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus may dislodge the pump, which may result in device failure or fatal hemorrhage. Anticoagulation regimens are contraindicated during pregnancy.
- Do not subject patients implanted with the HeartMate II LVAS to Magnetic Resonance Imaging (MRI) as the LVAD contains ferro-magnetic components, and MRI could cause device failure or patient injury.

- There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the sealed outflow graft conduit and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the sealed outflow graft conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage should only be performed by a skilled surgeon, under direct vision in patients who have had recent (i.e., prior to mediastinal healing) device implantation.
- Do not apply high power electrical treatment (e.g., application of diathermy) directly to patient. Application of high power electrical treatments could result in electrical interference with system operation, causing the pump to stop.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (e.g., ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.
- Avoid strong static discharges (e.g., television or computer monitor screens) as these can damage the electrical parts of the system and cause the LVAD to stop.
- To prevent device damage and personal injury, refer any servicing of LVAS equipment to authorized Thoratec trained service personnel only.

4.1.1 WARNINGS - Specific Implantation Issues

- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- Moderate to severe aortic insufficiency must be corrected at time of device implant.
- Limited clinical data is available supporting safety and effectiveness of the HeartMate II LVAS in patients with a body surface area (BSA) less than 1.5m^2. The clinical decision to implant the HeartMate II in patients with a BSA less than 1.5m^2 should be based on individualized assessment of body habitus and device fit.
- Although a small number of pediatric patients (< 21 years) were enrolled in the HeartMate II study, the safety and efficacy of the device in pediatric patients has not been established.

- The clinical trial experience indicates that certain models of implantable cardiac defibrillators (ICDs) and certain implantable pacemakers (IPMs) may, in some cases, not be able to establish telemetry or permit communication between the programmer and the implanted device due to electromagnetic interference when used with the HeartMate II. In such cases the ICDs or IPMs have continued to function properly and only their ability to communicate with the programmer was affected. Specific information on reported cases can be obtained on Thoratec's website at www.thoratec.com. No such difficulties have been reported, other than those observed with device(s) listed on the website.
- Prior to implanting an ICD or IPM in a HeartMate II patient, the device to be implanted should be placed in close proximity to the pump (approximately 10cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously implanted device that is found to be susceptible to this programming interference, Thoratec Corporation recommends replacing the ICD device with one that is not prone to programming interference.
- Do not implant the HeartMate II LVAD if it has been dropped.
- Never operate the HeartMate II Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- During the implant process, a complete backup system (LVAD implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedures must be either removed or adequately secured so as not to interfere with the operation of the HeartMate II LVAS.
- Prior to advancing the sealed inflow conduit into the left ventricle through the apical sewing ring, remove the glove tip from the sealed 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 sealed outflow graft prior to attempting connection, or connection will not be possible.
- All entrapped air must be removed from the left heart, blood pump, and conduits in order to minimize the risk of air embolus.
- HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure at a value greater than 10 mm Hg at all times to prevent air entrainment.

- Always confirm whether an unsealed outflow graft/inflow conduit or sealed outflow graft/inflow conduit is being used. Unsealed outflow grafts/inflow conduits must be pre-clotted prior to use. Sealed outflow graft/inflow conduits must NOT be pre-clotted prior to use.
- A sealed outflow graft can be identified by the blue dashed line on the bend relief, as well as the blue color of the screw ring that attaches to the pump. In addition, the sealed outflow graft is packaged in a foil pouch.
- A sealed inflow conduit can be identified by the printed Thoratec logo, the holes on the flexible silicone sleeve, as well as the blue color of the screw ring that attaches it to the pump. Also, the sealed inflow conduit is packaged in a foil pouch.
- The sealed outflow graft and sealed inflow conduit contain material of bovine origin; and, therefore, should not be implanted in patients who exhibit sensitivity to such material.
- A sealed outflow graft or sealed inflow conduit does not require pre-clotting. Attempting to pre-clot a sealed outflow graft or sealed inflow conduit may disrupt or destroy the sealant and lead to profuse bleeding after implantation.
- Do not trim or cut the sealed outflow graft bend relief or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss.
- Initial weaning of cardiopulmonary bypass should ensure a minimum of two liters per minute (lpm) of blood flow to the LVAD in order to prevent air embolism. Prolonged de-airation may be due to inadequate blood supply to the LVAD or a leak in the sealed outflow graft or sealed inflow conduit.
- Do not autoclave the pump. Doing so will cause damage to the pump and percutaneous lead.
- A minimum of two fully charged batteries and a pair of compatible battery clips and power leads are required at the time of implant in order to power the system when transporting the patient out of the operating room.
- PMs are shipped to customers with the internal battery disconnected. After receiving the PM, the hospital's biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device. See section 2.1 of the *HeartMate Power Module IFU* (document #103840).
- Use only the HeartMate UBC to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. The UBC will charge and test up to four batteries in four hours or less, depending on the initial charge status of the charging batteries. See the *HeartMate Universal Battery Charger IFU* (document #103841) for detailed warnings, precautions, and instructions on using the UBC for charging HeartMate batteries.

4.1.2 WARNINGS - Patient/System Management Issues

- System components must never be immersed. Showers and washing are permitted when the physician approves wound site readiness. During showers, the HeartMate shower bag must be employed.
- In the event that the LVAD stops operating, attempt to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted. There is also the potential for retrograde flow within the LVAD. See *Other Patient Considerations*, in section 14.1, for more information.
- **Disconnecting both System Controller power leads at the same time will cause the pump to stop**. At least one System Controller lead must be connected to a power source (PM, batteries, or EPP) at all times to maintain support. The following will cause the LVAD to stop and blood pumping to cease:
  - Disconnecting both power leads from the PM when operating on PM power.
  - Removing both batteries at the same time from their respective battery clips when operating on batteries.
  - Completely depleting the battery charge when operating on batteries.
- **Disconnecting the percutaneous lead from the System Controller will result in loss of pump function**. The System Controller must be reconnected as quickly as possible to resume pump function.
  - For pump speeds < 8,000 rpm (typical of device implantation), reconnect the System Controller and then press the alarm silence and/or pump start button as quickly as possible to resume pump function.
  - For pump speeds ≥ 8,000 rpm (typical of clinical use), reconnect the System Controller as quickly as possible to resume pump function. Power will automatically be supplied to the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the pump or conduits is performed prior to initiation of cardiopulmonary bypass and stoppage of LVAD pumping.
- Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the HeartMate II with other devices, resulting in potential interference between the HeartMate II LVAS and other devices.

- The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.
- Make sure that the patient cable has fully engaged the PM socket during PM operation. If the patient cable disconnects from the PM during operation, the pump will stop.

4.2 PRECAUTIONS

- **The *HeartMate II LVAS Instructions for Use*, which addresses LVAD preparation and implantation issues, must be used in conjunction with the *HeartMate II LVAS Operating Manual*, which addresses postoperative and patient management issues. These manuals are not intended to replace comprehensive laboratory or educational programs or to supersede appropriate medical judgment.**
- Components of the HeartMate II LVAS that are supplied sterile are intended for single use only and should not be re-used or re-sterilized. Do not use sterile components if sterile packaging is compromised. Contact Thoratec customer service for Return Materials Authorization (RMA).
- Use only the Thoratec supplied UBC to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103841) for detailed warnings, precautions, and instructions on using the UBC to charge HeartMate batteries.
- Make sure the UBC is plugged in and turned on ("I") before placing batteries into charging pockets.
- The UBC cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog # 26439).
- Keep the UBC away from water or moisture. If the UBC has contact with water/moisture, shower spray, rain/snow, or wet surfaces, the user may receive a serious electric shock or the UBC may fail to operate properly.
- After approximately 70 uses, HeartMate batteries may need to be calibrated. The UBC alerts users when an inserted battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to do so to prevent a backlog of uncalibrated batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103841) for detailed warnings, precautions, and instructions on using the UBC to calibrate HeartMate batteries.
- Leave a calibrating battery in the UBC for the entire calibration cycle. Removing a battery before it is fully calibrated may result in a fully-depleted battery (the on-battery fuel gauge will reflect this).
- For optimal battery performance, leave charged batteries in their charging pockets until ready for use. Leaving charged batteries in the UBC will not damage them.

- **HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag)**. If a battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop unexpectedly. Do not use a battery if it has not been charged within the first year of receipt. Discard expired or defective batteries according to local, state, and federal regulations. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770).
- HeartMate 12 volt NiMH batteries are compatible with both the HeartMate XVE and HeartMate II LVAS and can power both systems. HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. HeartMate 14 volt Li-Ion batteries are NOT compatible with the XVE system and cannot provide power to the XVE LVAS. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for detailed warnings, precautions, and instructions on using HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries to power the HeartMate II LVAS. See **Table 21** for distinguishing characteristics of HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries.
- HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.
- Do not use batteries below 32°F (0°C) or above 104°F (40°C) or they may fail suddenly. If batteries are below room temperature (68–72°F, 20–22°C) during use, their capacity will be reduced. At the low end of the temperature range (32°F, 0°C), run time will be reduced by 50%. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770) for recommended storage guidelines.
- If stored and used within recommended guidelines, HeartMate batteries should be usable for approximately 360 use/charge cycles *or* for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770).
- Use of expired or defective batteries may result in reduced operating time or an abrupt loss of HeartMate II LVAD function.
- As batteries get older, they will support the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both batteries from service.

- To prevent deterioration or damage to batteries:
  - Do NOT drop batteries or hit them against hard objects or each other.
  - Do NOT use batteries in temperatures that are below 32°F (0°C) or above 104°F (40°C).
  - Do NOT leave or store batteries in extremely hot or cold temperatures (e.g., in cars or car trunks), or battery life will be shortened.
  - Do NOT directly connect battery contacts to each other.
  - Do NOT immerse batteries in water or liquid.
- Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short or connection between battery contacts, which can result in battery overheating that may burn the user or damage the batteries.
- The HeartMate Emergency Power Pack (EPP) is an emergency power source that can power the HeartMate II LVAS for up to 12 hours in the event of AC main power interruption or failure. The EPP is for emergency use only and is not intended as a routine power source. It is not rechargeable and must be replaced if used for a period exceeding three hours. The EPP is mandatory for HeartMate II patients. See the *HeartMate II LVAS Operating Manual* (document # 103878) for detailed warnings, precautions, and instructions on using the EPP.
- Do not store or use the EPP below 32°F (0°C) or above 122°F (50°C), or it may fail suddenly. If the EPP is below room temperature (68–72°F, 20–22°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/moisture or dirt when making or breaking connections.
- Never use tools to tighten connections. Hand-tighten only. Using tools may damage the connectors and cause the pump to stop.

- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the PM may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient, use only those devices necessary for patient safety and well-being.
- Avoid discharging static electricity to the System Controller or LVAD percutaneous lead.
- Pump flow readings will vary with changes in blood viscosity.
- If external defibrillation becomes necessary, do NOT disconnect the System Controller from the percutaneous lead prior to delivering the shock.
- If open chest defibrillation is required, it is advised that the HeartMate II LVAS be disconnected prior to delivering the shock.
- Ensure that all backup System Controllers are programmed with identical settings (e.g., fixed speed setting and low speed limit) as the primary controller. Controllers are shipped with factory settings, and therefore backup controllers must be programmed at the time they are assigned to a patient.

4.2.1 PRECAUTIONS - Specific Implantation Issues

- Care must be taken to prevent blood from entering and collecting in the lumen of the conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must therefore be rinsed thoroughly prior to attachment to the LVAD.
- Do not over tighten thread protectors.
- Do not allow the apical coring knife to involve the ventricular septum while performing the left ventricle coring.
- Do not remove the centering fixture inside the apical sewing ring until ready to insert the sealed inflow conduit.
- Do not clamp the bend relief segment of the sealed outflow graft.
- The sealed 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 sealed inflow conduit.
- All entrapped air must be removed from the LVAD blood path prior to fully releasing the sealed outflow graft cross-clamp.
- Once the LVAD is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the LVAD. Whenever possible, maintain the HeartMate II at a pump flow greater than 3 lpm and a pump speed greater than 8,000 rpm.

- Remove all vents on the inflow side of the LVAD, including needles in the pulmonary vein, left atrium, and left ventricle prior to initiation of pumping.
- Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning off cardiopulmonary bypass should provide a minimum of two lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.

4.2.2 PRECAUTIONS - Patient/System Management Issues

- Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous lead exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- The use of automated blood pressure monitoring devices may not yield accurate blood pressure data. Manual auscultation to assess blood pressure is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring or the use of Doppler ultrasound may be required.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.
- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit LVAS effectiveness due to reduced filling of the LVAD.
- An electrocardiogram may be indicated to rule out fibrillation if a patient complains of feeling “different” (e.g., heart racing, short of breath, heart pains).
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction. Sounds that could signal an issue include grinding or intermittent “whirring.”
- Physiological factors that affect the filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows as long as the condition persists. Pump flows will not be restored to normal unless such conditions are treated.
- The externalized portion and the lumen of the percutaneous lead at explant are not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.

- Damage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead. Damage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead. The damage may be evidenced by the following:
  - Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
  - High pump power associated with reduced pump speed (as recorded in the System Controller event log file).
  - High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
  - Feelings of pump vibrations.
  - Fluid leakage from the external portion of the lead.
  - Cessation of pumping
- When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.
- A backup System Controller, spare batteries, and a pair of compatible battery clips must be with the patient at all times for use in an emergency.
- A patient's primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car's power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car's DC power is inadequate to power the LVAS, the PM will alarm or switch to back-up battery power. If this occurs, switch to portable battery power and discontinue the use of DC input power to the PM.
- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, the patient should have at least one set of charged HeartMate batteries and cables in close proximity. See section 8.0, "Traveling by Car," in the *HeartMate Power Module IFU* (document #103840) for detailed warnings, precautions, and instructions on using automobile DC power
- The automobile engine must be ON and RUNNING BEFORE connecting the PM to its DC power outlet.
- The PM requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a functional check, cleaning, replacing the internal battery (the internal battery is rechargeable, but has a limited life), and replacing the PM patient cable.

- PM service and maintenance should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Do not clean or service the PM while it is providing power to the system.
- If the System Monitor is mounted on top of the PM, do NOT attempt to lift or carry the two devices together by using the System Monitor handle. Doing so may damage the PM and/or System Monitor.
- PM connectors should be kept clean and dry. Do not expose Power Module connectors to water, moisture, rain/snow, dirt, etc.
- When connecting PM connectors, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Do not use the PM until its internal backup battery is charged, or the backup battery may not work in the event of AC mains failure/interruption. Wait two to three hours for the PM's internal backup battery to charge before using the PM for the first time or after prolonged storage. It may take several hours for the internal backup battery to charge (see section 4.0, *Power Module (PM) Backup Power*).
- Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
- The UBC requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a functional check of the device and cleaning/inspection.
- Service and maintenance of the HeartMate UBC should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Make sure the UBC is plugged in and turned on ("I") before placing batteries into the pockets for charging.
- After approximately 70 uses, HeartMate batteries may need to be recalibrated. The UBC indicates when a battery needs to be recalibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to prevent a backlog of uncalibrated batteries. See section 4.0, "Calibrating HeartMate Batteries," in the *HeartMate Universal Battery Charger IFU* (document #103841).
- Leave a calibrating battery in the UBC for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status). See section 4.0, "Calibrating HeartMate Batteries," in the *HeartMate Universal Battery Charger IFU* (document #103841).

- The metal contacts inside the UBC pockets should be kept clean and dry. Do not expose contacts to water, moisture, dirt, etc. Do not touch these contacts when the charger is connected to AC mains power and turned on (“I”).
- Dirty metal contacts inside the battery charging pockets may prevent proper battery charging, which can affect battery operation. The metal contacts inside the pockets should be cleaned at least once a month. Turn off and unplug the UBC before cleaning. Do NOT clean the UBC while it is in use.
- Clean dirty metal contacts inside the charging pocket of the UBC with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before inserting batteries into the pocket(s) for charging.

5.0 Adverse Events

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

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

6.0 Summary of Clinical Studies

> **NOTE:**
> Thoratec reserves the right to change specifications without notice.

6.1 Study Overview

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

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

After completion of enrollment in the Primary Study Cohort, enrollment continued under a Continued Access Protocol (CAP), which was identical to the Primary Study Cohort protocol. Patients who were originally enrolled into these two study cohorts but who had a body surface area (BSA) less than 1.5m^2 were separated out into a Small BSA Patient cohort for analysis.

6.2 Study Design

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

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

6.3 Patient Population

The patients enrolled into the HeartMate II study were patients listed for cardiac transplant in end-stage heart failure who demonstrated no evidence of severe end-organ damage that would make HeartMate II LVAS implantation futile. The BTT inclusion and exclusion criteria were based on study criteria used in previously approved LVAD BTT studies. The criteria included patients in New York Heart Association (NYHA) class IV heart failure, on inotropic support, and without contraindication to listing for cardiac transplantation as UNOS Status 1A or 1B. If the patient was 1B, they also needed to meet hemodynamic criteria to qualify, including pulmonary capillary wedge pressure (PCWP) or pulmonary artery diastolic pressure (PAD) > 20 mmHg and either a cardiac index <2.2 L/min/m^2 or systolic blood pressure <90 mmHg. The exclusion criteria excluded patients with moderately severe end-organ damage, as evidenced by elevated total bilirubin, elevated creatinine values, or low platelet counts, and also excluded patients that may not be able to tolerate the management of the HeartMate II LVAS due to intolerance to anticoagulation or compliance issues.

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

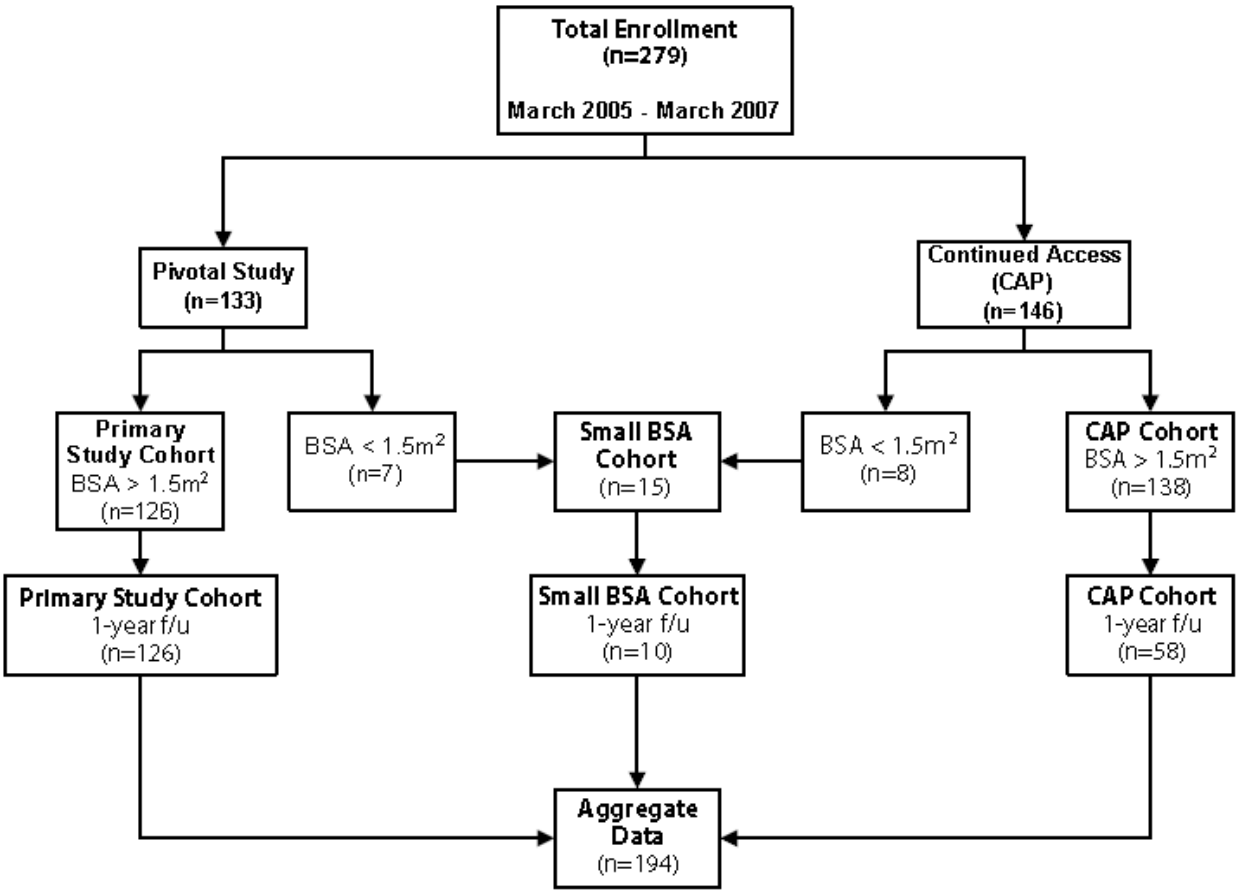


Figure 1 HeartMate II Study Enrollment

The overall mean age in the HeartMate II LVAS study was 51 years (range 16-69 years). The smallest patient implanted had a BSA of 1.33m^2 and the largest patient, a BSA of 2.62m^2, with a mean BSA of 1.99m^2. The mean body mass index (BMI) was 27 kg/m^2 (range 15.6 – 44.0 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). Patient demographics and cardiovascular history for each of the three study cohorts and the aggregate data are shown in **Table 1** and **Table 2**.

	Primary Cohort (n = 126)	CAP Cohort (n= 58)	Small BSA Cohort (n = 10)	Aggregate Data (n = 194)
Age (years)*	55 (17 -68)	56 (16-69)	47 (20 – 69)	55 (16-69.1)
Etiology	39% Ischemic	50% Ischemic	10% Ischemic	41% Ischemic
Gender	83% Male 17% Female	78% Male 22% Female	0% Male 100% Female	77% Male 23% Female
BMI (kg/m^2)*	26.5 (10–40)	27.6 (18-44)	17.0 (15.6-20.8)	26.6 (15.6-44.0)
BSA (m^2)*	1.99 (1.5–2.6)	2.00 (1.52–2.57)	1.40 (1.33–1.47)	1.99 (1.33-2.62)

*Median and range

Table 1 Patient Demographics

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

Table 2 Cardiovascular History

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

6.4.1 Overall Patient Outcomes:

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

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

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

[1] Classified as success per pre-specified study criteria

[2] Classified as failure per pre-specified study criteria

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

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

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

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

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

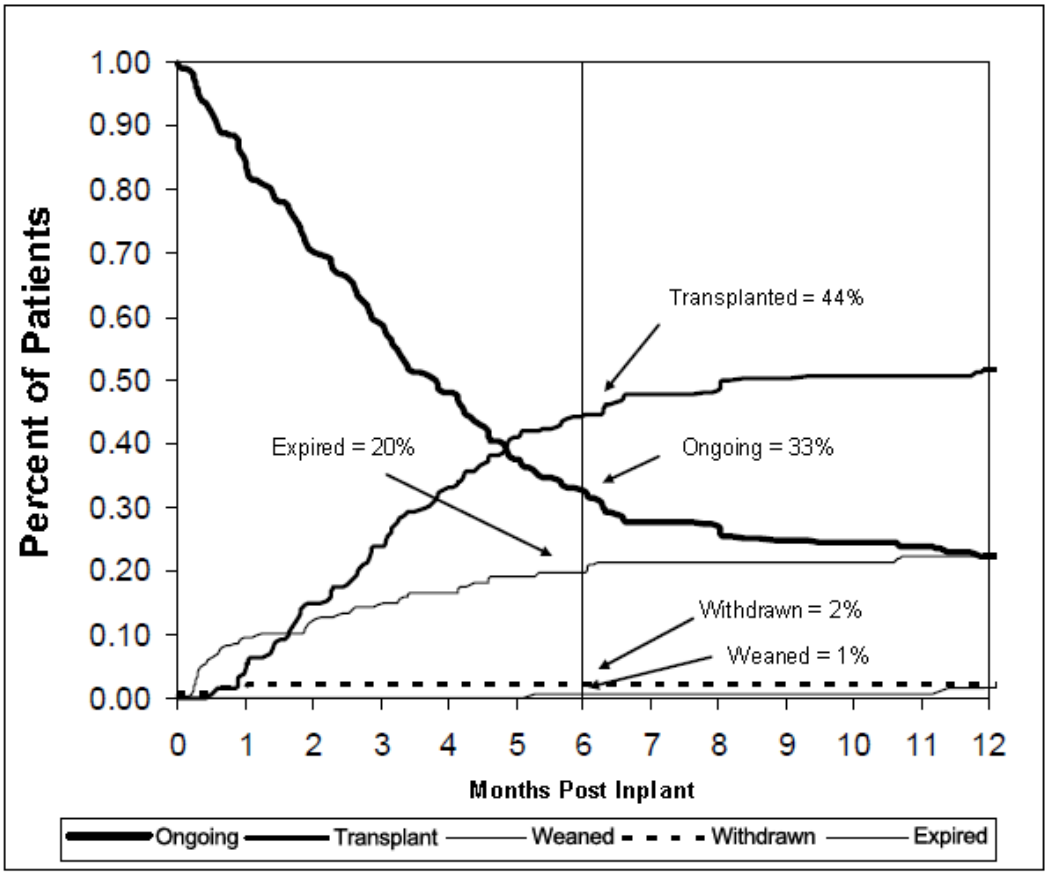


Figure 2 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Primary Study Cohort (n=126) as of September 14, 2007

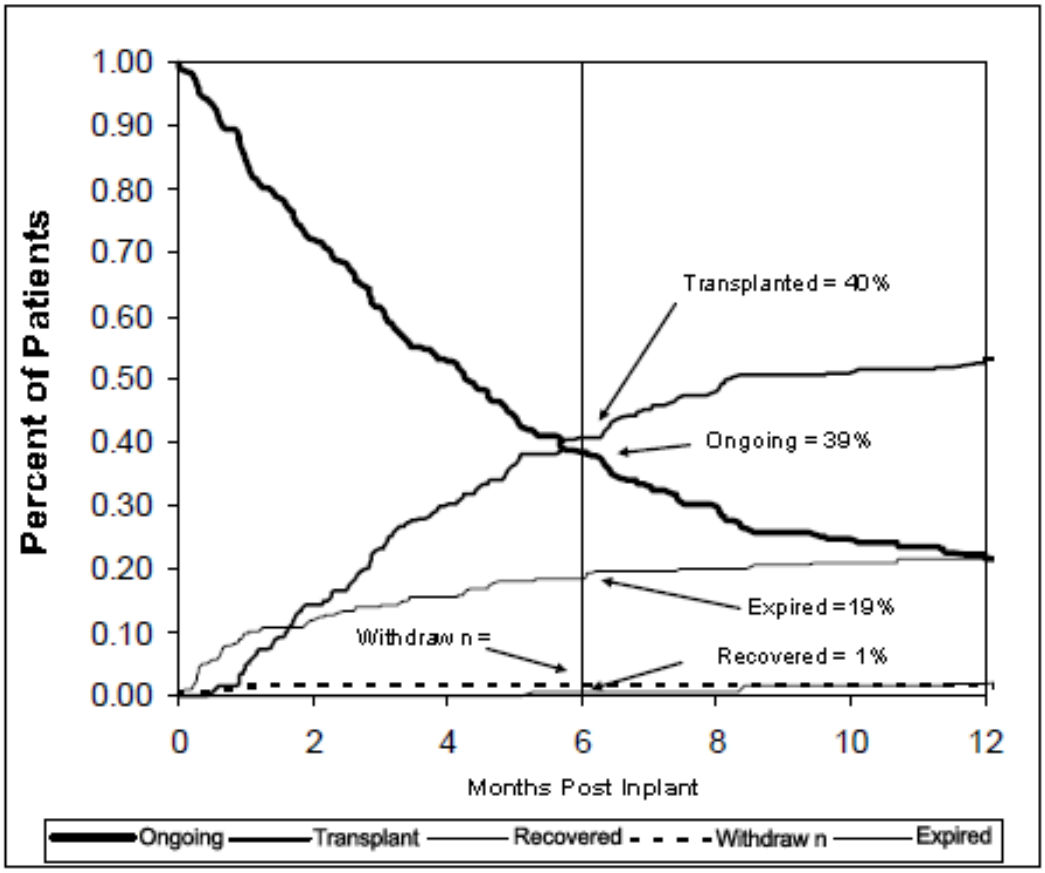


Figure 3 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Aggregate Data (n=194) as of September 14, 2007

6.4.2 Safety: Adverse Events

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

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

*Bleeding requiring PRBC ≥ 2 units or surgery.
**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 5 All Adverse Events as of September 14, 2007

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

*Bleeding requiring PRBC ≥ 2 units or surgery.
**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 6 Serious Adverse Events as of September 14, 2007

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

Continued on following page.

Table 7 Adverse Event Rate per Patient Year by Time Interval

Table 7 (continued)

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

Continued on following page.

Psychological	Primary (n=126)	1.67	0.14	0.07	0.29	0.00
	CAP (n=58)	1.82	0.29	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.00
	Aggregate (n=194)	1.90	0.27	0.04	0.17	0.00
Myocardial Infarction	Primary (n=126)	0.00	0.00	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	0.00	0.00	0.04	0.04	0.00

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

6.5 Secondary Objectives

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

Reoperations

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

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

Table 8 Incidence and Timing of Reoperations

Clinical Reliability

During the clinical study there were 78 reports of confirmed malfunctions in 194 patients having a median support duration of 131 days (see section 6.3 *Patient Population*, for more information on the 194 patients). Forty-four percent (44%, 34/78) involved implanted system components (i.e. pump and cannulae) and 56% (44/78) involved external system components (i.e. controllers, monitors, batteries, etc). Ten of the malfunctions of the implanted system components were classified as serious adverse events (i.e. resulted in death or permanent disability, or required prolonged hospitalization). These ten reports included percutaneous lead separation (4), pump thrombosis (3), inflow cannula twists (2) and outflow conduit leakage (1). Seven malfunctions of the external system components were also classified as serious adverse events, including damaged printed circuit boards in the System Controller (5), power base unit cable breakdown (1) and inadequate battery capacity (1).

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

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

Table 9 Estimated Clinical HeartMate II LVAD Reliability

The clinical experience over five years of clinical trials (both bridge–to-transplantation and destination therapy) and commercial use outside of the US has shown that wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump to the external System Controller may result in damage that has the potential to interrupt pump function that may require a re-operation to replace the pump or result in death. The need for pump replacement due to percutaneous lead damage has occurred after implant durations ranging from 6 to 38 months of HeartMate II LVAS support. The estimated probability of the need for pump replacement due to percutaneous lead damage according to this analysis is 1.3% at 12 months, 6.5% at 24 months and 11.4% at 36 months.

Functional Status:

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

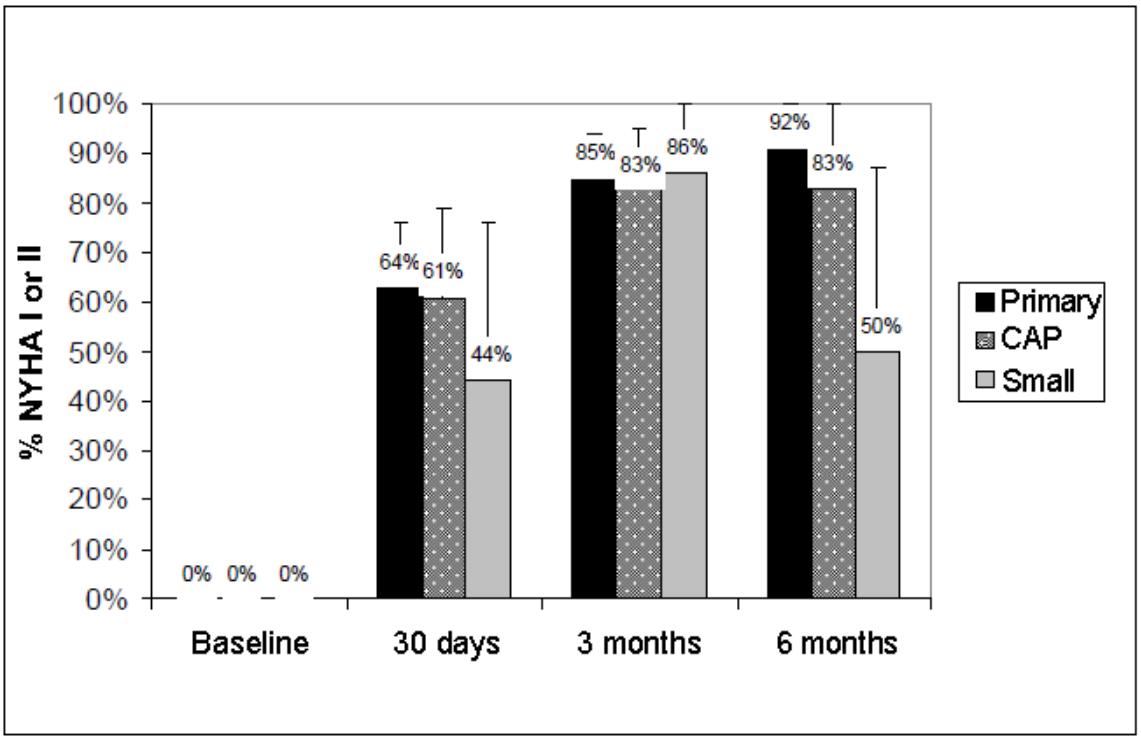


Figure 4 NYHA Class Over Time (Error Bars = Standard Deviation)

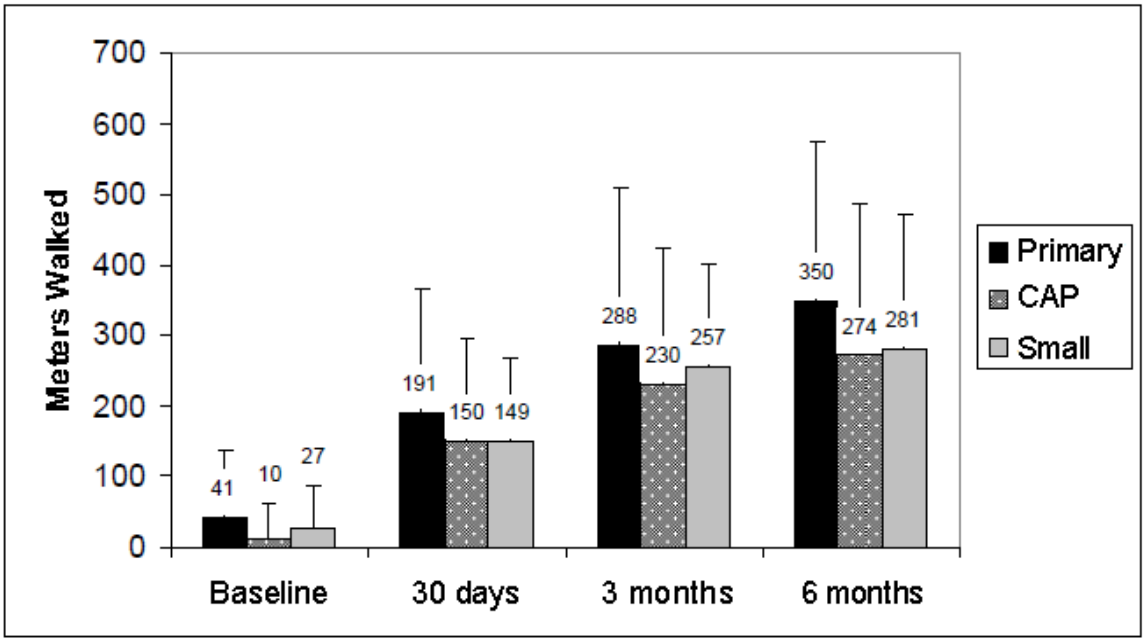
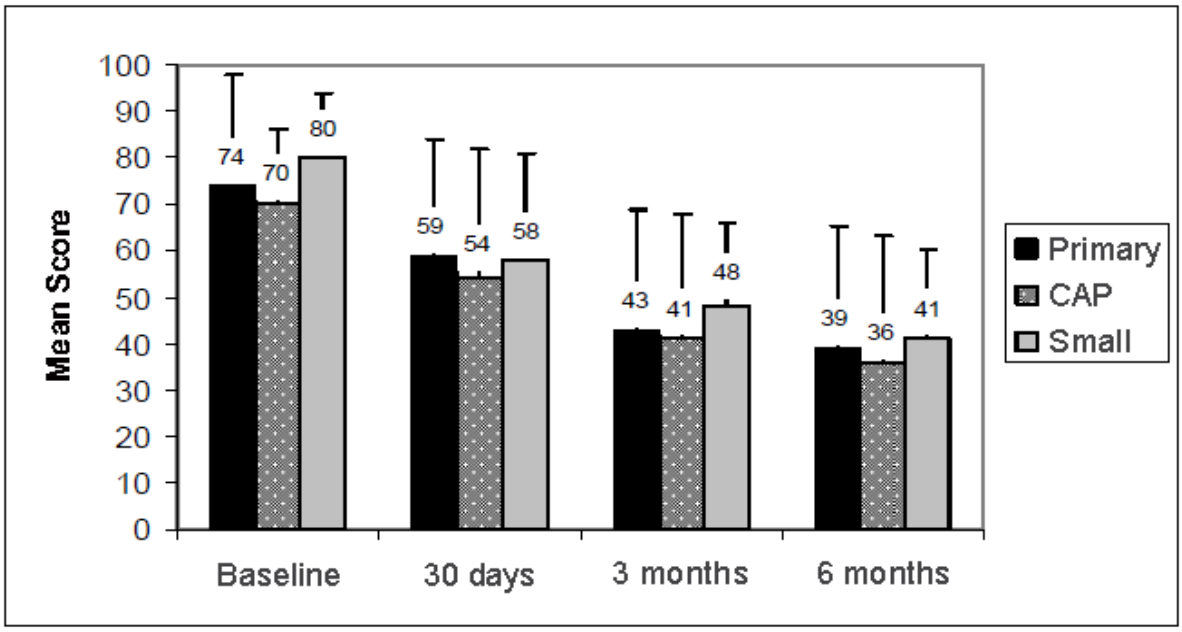


Figure 5 Summary of Six-Minute Walk Over Time (Error Bars = Standard Deviation)

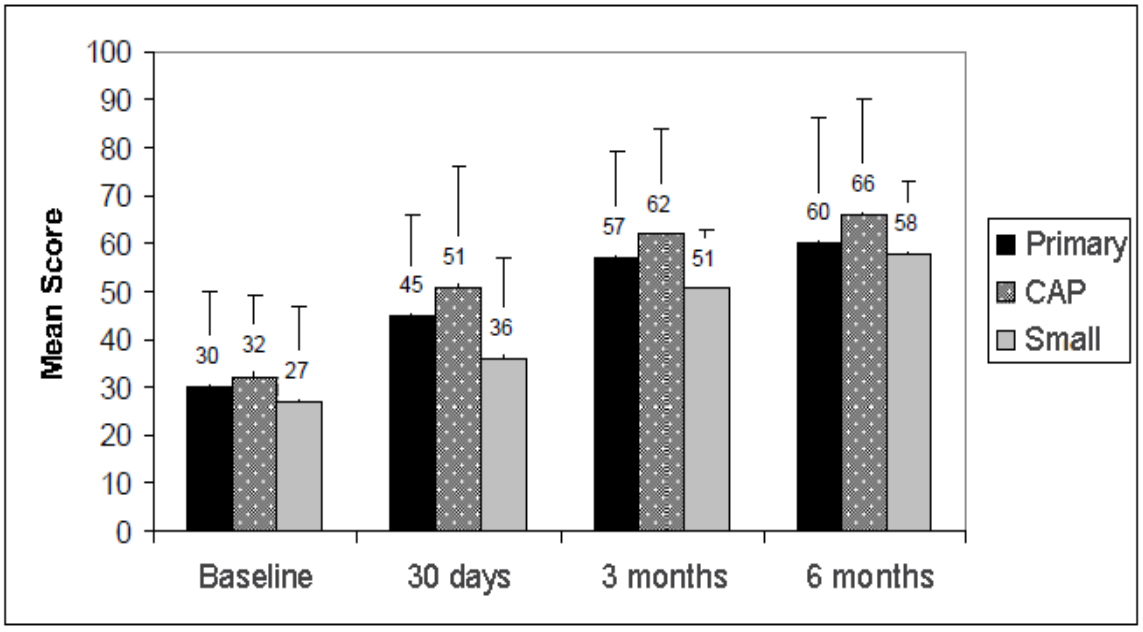
Quality of Life:

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



Note: A lower score indicates better quality of life.

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



Note: A higher score indicates better quality of life.

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

Neurocognitive Evaluations:

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

Post-Explant Follow up

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

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

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

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

6.5.1 Gender Analysis

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

7.0 Post-Approval Studies

7.1 Bridge-to-Transplantation (BTT) Post-Approval Study Overview

A Post-Approval Study (PAS) of the HeartMate II (HMII) for the bridge-to-transplantation (BTT) indication was conducted as a condition of FDA approval. The purpose of the PAS was to assess whether the commercial use of the HMII was comparable to other available commercial devices which were approved in the US for the same indication for use, bridge-to-transplant. The primary objective of the PAS was to assess survival to transplantation following HeartMate II implantation for bridge-to-transplant in a commercial setting. A number of secondary objectives were also evaluated during the PAS, including quality of life (EuroQoL).

A total of 338 patients were enrolled in the PAS at 77 institutions across the United States from April 21, 2008 to February 28, 2009. All data was collected via INTERMACS, the Interagency Registry of Mechanically Assisted Circulatory Support. The patients included the first consecutive 169 HeartMate II patients who gave their consent for inclusion in the INTERMACS registry and an equal number of patients from a concurrent control which included patients that were implanted with other LVAD devices and enrolled in INTERMACS.

7.1.1 Study Design

The study was a multi-center, non-blinded, non-randomized, prospective study. The primary PAS outcomes were defined as death, cardiac transplantation, device explantation due to myocardial recovery and survival for at least 60 days, or survival to 180 days on LVAS support. After reaching 180 days, patients continued to be followed for 1 year, or transplantation, explantation or death, whichever occurred first. All data was collected via INTERMACS and all oversight committees were per INTERMACS protocol.

7.1.2 Patient Population

To be enrolled into the INTERMACS registry patients received a commercially marketed LVAS and the patient or their legal representative signed an informed consent for INTERMACS registry participation. Patients who were enrolled in premarket clinical studies of VADs or incarcerated persons (prisoners) could not participate.

All patients who were identified pre-implant in the INTERMACS database as “Bridge-to-Transplant (patient currently listed for transplant)” or “Possible Bridge to Transplant – Likely to be eligible” were enrolled in the PAS. Patients implanted

with the HeartMate II comprised the study group and patients implanted with any other LVAD comprised a concurrent comparator group.

Per the approved protocol, once the first 169 HeartMate II patients were enrolled, data would be compared to an equal number of BTT patients from the prospective concurrent INTERMACS non HeartMate II comparison group. Since the 169 concurrent comparison patients had not been enrolled by the end of the six month study enrollment extension, comparison patients previously enrolled in INTERMACS were included to make up the difference by selecting the most recent consecutive retrospective non HeartMate II patients from the INTERMACS registry. **Table 12** describes the patients that comprised the study and comparator group.

Device	Group	N	Group total
HMII LVAD	HMII	164	
HMII LVAD with PVAD[1] RVAD	HMII	2	
HMII LVAD with Non-Thoratec RVAD	HMII	3	169
HMXVE LVAD	Comparison	130	
HM XVE with IVAD[2] RVAD	Comparison	1	
HM XVE with Non Thoratec RVAD	Comparison	4	
IVAD[2] LVAD	Comparison	18	
IVAD[2] with Non-Thoratec RVAD	Comparison	1	
IVAD[2] with IVAD RVAD	Comparison	15	169

[1] PVAD: Thoratec Paracorporeal VAD
[2] IVAD: Thoratec Implantable VAD

Table 12 HeartMate II Post-Approval Study: Device Type

Patient demographic data for the both the HeartMate II and the Comparison group were collected at baseline. **Table 13** summarizes the baseline characteristics of the two groups. There were no statistical differences between the two groups, except for medical history; the HeartMate II patients having a significantly greater incidence of previous coronary artery bypass graft (CABG) procedures.

Variable	HMII (n=169)	Comparison (n=169)	P*
Gender			
Males	131 (78%)	141 (83%)	
Females	38 (22%)	28 (17%)	0.2167
Age			
0 - 18years	3 (2%)	6 (4%)	
19 - 39 years	26 (15%)	22 (13%)	
40 - 59 years	81 (48%)	87 (51%)	
60 - 79 years	59 (35%)	54 (32%)	0.6309
Race			
Caucasian	125 (74%)	113 (67%)	
Black	29 (17%)	37 (22%)	
Other	15 (9%)	19 (11%)	0.3799
BSA (m^2)	2.03 ± 0.25	2.06 ± 0.25	0.1818
BMI (Kg/m^2)	28.2 ± 6.8	30.1 ± 16.0	0.1516
BSA < 1.5 m^2 (Small Size Cohort)	1 (1%)	5 (3%)	0.2145
History			
CABG	37 (22%)	17 (10%)	0.0045
Valve	7 (4%)	11 (7%)	0.4684
Cancer	11 (7%)	7 (4%)	0.4681
Diabetes	57 (33%)	53 (31%)	0.7277

***Fisher Exact Test or Unpaired t-test as appropriate**

Table 13 Post-Approval Study: Baseline Demographics

7.1.3 Overall Patient Outcomes

As specified in the HeartMate II LVAS Post-Approval Study protocol, the study would be considered a success if the success rate of the HMII patients were as good or better then the success rate of the comparison group. Success was defined as LVAS support for at least 180 days or to transplant, or to explant due to myocardial recovery and survival for at least 60 days post explant. As of this report, all patients have been followed for at least 180 days or to an outcome (transplant, death or explant). As seen on **Table 13**, 90% of the HeartMate II patients achieved success compared to 80% of the comparison patients. This represents a significant improvement in success (P=0.0253 using a Fisher Exact Test) and thus the study can be considered a success.

In addition, HMII patients have a significant overall survival advantage over comparison patients (P=0.0008, Logrank analysis) (**Figure 8**, **Table 14**).

Study Endpoint Status	Patient Status	HM II (n=169)	Controls (n=169)
Met Success Criteria	VAD support > 180 Days, ongoing	74 (44%)	16 (9%)
	VAD support > 180 Days, explanted for recovery	0 (0%)	3 (2%)
	VAD support > 180 Days, explanted for other reason	1 (1%)	10 (6%)
	VAD support > 180 days, expired	8 (5%)	10 (6%)
	VAD support < 180 days, explanted for recovery and alive ≥ 60 days post explant	2 (1%)	1 (1%)
	Transplanted	67 (40%)	95 (56%)
	Total Success	***152 (90%)***	***135 (80%)***
Did not meet Success Criteria	VAD support < 180 days, Expired	16 (9%)	32 (19%)
	VAD support < 180 days, Explant other than recovery	1 (1%)	2 (1%)
	Total Not Success	***17 (10%)***	***34 (20%)***

Table 14 HeartMate II Post-Approval Study: Patient Status

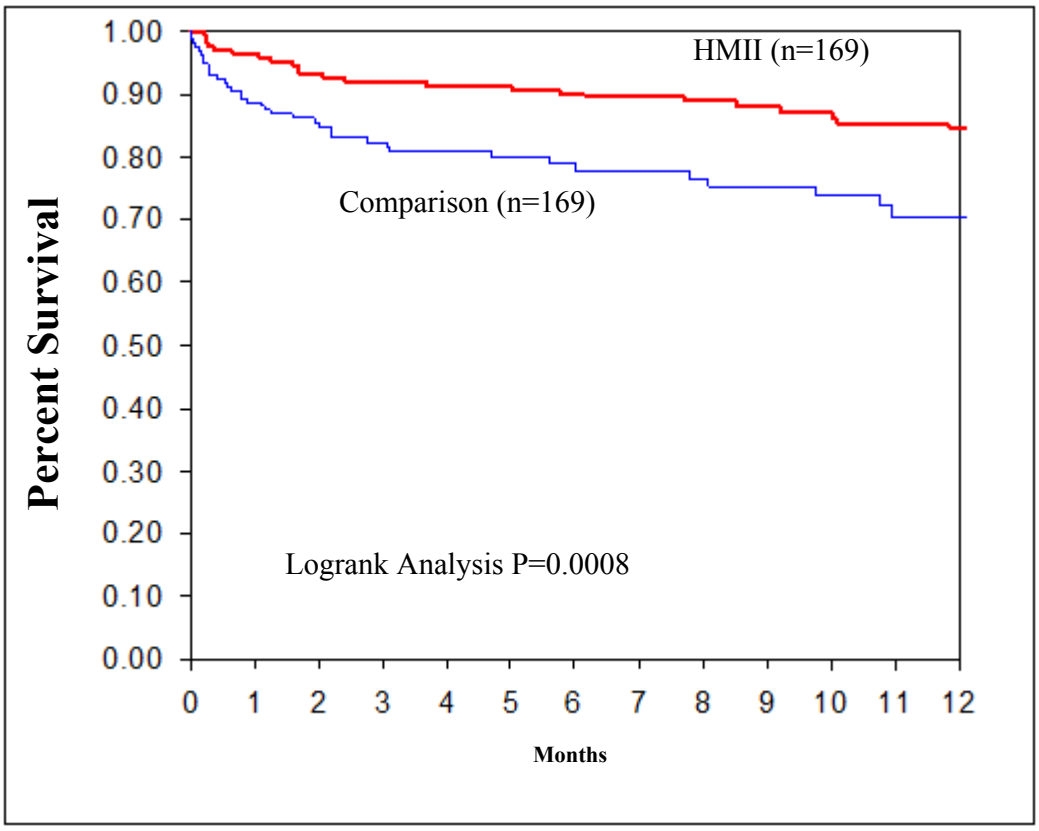


Figure 8 HeartMate II Post-Approval Study: Kaplan-Meier Analysis of Survival

HeartMate II							
	Time Interval (Months)						
	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 12
Number of patients starting interval	169	158	143	136	131	125	117
Number of patients who died this interval	6	5	2	1	0	2	6
Number of cumulative patient deaths	6	11	13	14	14	16	22
Number of patients censored in interval	5	10	5	4	6	6	24
Number of cumulative censored patients	5	15	20	24	30	36	60
Probability of surviving interval event free	0.964	0.933	0.920	0.913	0.913	0.898	0.845
+/- 95% Confidence Limit at end of interval	0.03	0.04	0.04	0.04	0.04	0.05	0.06

Comparison							
	Time Interval (Months)						
	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 12
Number of patients starting interval	169	144	119	105	95	85	77
Number of patients who died this interval	19	5	4	2	1	1	6
Number of cumulative patient deaths	19	24	28	30	31	32	38
Number of patients censored in interval	6	20	10	8	9	7	34
Number of cumulative censored patients	6	26	36	44	53	60	94
Probability of surviving interval event free	0.887	0.854	0.824	0.808	0.799	0.789	0.705
+/- 95% Confidence Limit at end of interval	0.05	0.05	0.06	0.06	0.06	0.07	0.09

Patients are censored at time of transplant, weaning off device or last follow up on LVAD support

Table 15 Kaplan-Meier Analysis of Survival

7.1.4 Safety: All Cause Adverse Events

Adverse events, as defined by the INTERMACS protocol, were collected and are reported in **Table 16**. The study was not powered for a specific analysis of the adverse events.

Event	HMII (n=169)			Comparison Group (n=169)		
	# pts	% pts	# events	# pts	% pts	# events
Arterial Non -CNS Thromboembolism	1	0.6%	1	2	1.2%	3
Bleeding	75	44.4%	204	65	38.5%	172
Cardiac Arrythmia	46	27.2%	69	47	27.8%	85
Hemolysis	5	3.0%	5	2	1.2%	2
Hepatic Dysfunction	11	6.5%	12	9	5.3%	11
Hypertension	3	1.8%	4	26	15.4%	35
Infection*	78	46.2%	142	72	42.6%	204
Driveline	30	17.8%	45	27	16.0%	44
Pump Pocket	3	1.8%	4	12	7.1%	16
Pump Interior	1	0.6%	2	0	0.0%	0
Blood	32	18.9%	47	36	21.3%	71
Line Sepsis	3	1.8%	3	9	5.3%	10
Other Infection	49	29.0%	86	50	29.6%	119
Myocardial Infarction	3	1.8%	3	1	0.6%	1
Stroke**	11	6.5%	11	9	5.3%	11
Other Neurological Dysfunction	7	4.1%	7	13	7.7%	16
Pericardial Drainage	17	10.1%	20	20	11.8%	22
Psychiatric Episode	14	8.3%	17	17	10.1%	23
Renal Dysfunction	17	10.1%	19	21	12.4%	28
Respiratory Failure	34	20.1%	41	43	25.4%	53
Right Heart Failure	25	14.8%	26	20	11.8%	22
Venous Thromboembolism	11	6.5%	13	13	7.7%	15
Wound Dehiscence	3	1.8%	3	3	1.8%	3

* Event may have multiple sites of infection
**May include transient ischemic attack, or confusion

Table 16 HeartMate II Post-Approval Study: All Cause Adverse Events

7.1.5 Secondary Objectives

Quality of life, as measured by EuroQol was collected as a secondary objective. **Table 17** displays the quality of life data. A higher score indicates an improved quality of life. In addition, 6 minute walk and NYHA classification were also collected.

	HMII Cohort	Comparison Cohort
Interval: Pre-Implant		
Patients at start of Interval	169	169
Patients completing Test	71	62
Total Score (mean+/- sd)	9.3 +/- 2.5	9.6 +/- 2.3
Thermometer (mean +/- sd)	37.5 +/- 22.2	36.0 +/- 29.8
Interval : 3 months		
Patients at start of Interval	136	104
Patients completing Test	80	49
Total Score (mean+/- sd)	6.7 +/- 1.5	7.9 +/- 1.8
Thermometer (mean +/- sd)	75.0 +/- 18.5	62.3 +/- 25.3
Interval : 6 months		
Patients at start of Interval	116	76
Patients completing Test	63	37
Total Score (mean+/- sd)	7.2 +/- 1.8	6.9 +/- 1.6
Thermometer (mean +/- sd)	70.7 +/- 19.2	71.9 +/- 19.3
Interval : 12 months		
Patients at start of Interval	87	37
Patients completing Test	39	21
Total Score (mean+/- sd)	7.0 +/- 1.9	7.3 +/- 1.7
Thermometer (mean +/- sd)	76.4 +/- 14.7	68.8 +/- 17.2

Total Score: Lower score indicates improved Qol
Thermometer: Higher score indicates improved Qol

Table 17 HeartMate II Post-Approval Study: Quality of Life (EuroQol)

Functional Analysis

The functional status of patients within the HeartMate II and comparison cohort were assessed via Six Minute Walk Test, and New York Heart Association (NYHA) classification. **Table 18** and **19** include data collected for this analysis.

	HMII Cohort	Comparison Cohort
Interval: Pre-Implant		
Patients at start of Interval	169	169
# Patients who walk	11	3
Feet walked (Mean +/- SD)	772.1 +/- 399.5	703.3 +/- 51.1
Not Done: Too sick	115	128
Not Done: Other reason	36	34
Not Done: Unknown reason	7	4
Interval : 3 months		
Patients at start of Interval	136	104
# Patients who walk	38	25
Feet walked (Mean +/- SD)	1130.3 +/- 409.5	1032.0 +/- 409.9
Not Done: Too sick	7	12
Not Done: Other reason	75	54
Not Done: Unknown reason	16	10
No reason provided	0	3
Interval : 6 months		
Patients at start of Interval	116	76
# Patients who walk	31	19
Feet walked (Mean +/- SD)	1117.0 +/- 343.6	1018.2 +/- 362.7
Not Done: Too sick	5	12
Not Done: Other reason	57	32
Not Done: Unknown reason	12	7
No reason provided	11	6
Interval : 12 months		
Patients at start of Interval	87	37
# Patients who walk	22	10
Feet walked (Mean +/- SD)	1159.2 +/- 399.5	1218.9 +/- 619.3
Not Done: Too sick	3	4
Not Done: Other reason	37	14
Not Done: Unknown reason	3	2
No reason provided	22	7

Table 18 HeartMate II Post-Approval Study: Six Minute Walk Test

	HMII Cohort	Comparison Cohort
Interval: Pre-Implant		
Patients at start of Interval	169	169
Class I	0 (0%)	0 (0%)
Class II	3 (2%)	0 (0%)
Class III	28 (17%)	12 (7%)
Class IV	127 (75%)	138 (82%)
Unknown	11 (7%)	19 (11%)
Interval : 3 months		
Patients at start of Interval	136	104
Class I	24 (18%)	9 (9%)
Class II	41 (30%)	43 (41%)
Class III	29 (21%)	21 (20%)
Class IV	12 (9%)	7 (7%)
Unknown	30 (22%)	24 (23%)
Interval : 6 months		
Patients at start of Interval	116	76
Class I	24 (21%)	14 (18%)
Class II	35 (30%)	25 (33%)
Class III	16 (14%)	4 (5%)
Class IV	5 (4%)	9 (12%)
Unknown	36 (31%)	24 (32%)
Interval : 12 months		
Patients at start of Interval	87	37
Class I	24 (28%)	8 (22%)
Class II	23 (26%)	14 (38%)
Class III	4 (5%)	2 (5%)
Class IV	4 (5%)	1 (3%)
Unknown	32 (37%)	12 (32%)

Table 19 HMII Post-Approval Study: NYHA Classification

MAJOR SYSTEM COMPONENTS

The HeartMate II Left Ventricular Assist System (LVAS) is comprised of the HeartMate II Left Ventricular Assist Device (LVAD), System Controller, Power Module (PM), System Monitor, Universal Battery Charger (UBC), rechargeable batteries, and battery clips. Each of these system components is described in following sections.

8.0 HeartMate II LVAD

The HeartMate II LVAD is an axial flow rotary pump connected in parallel to the native circulation. The sealed inflow conduit of the pump is attached to the apex of the left ventricle and the pump sealed 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 operates in a fixed speed mode. In 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 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 set point.

The internal pump surfaces (rotor, thin-walled duct, inlet stator, and outlet stator) have a smooth polished titanium surface. The sealed inflow conduit and outflow elbows have a textured titanium microsphere surface similar to the textured blood contacting surface on the HeartMate® XVE LVAD. Follow the anticoagulation protocol specified in section 17.4.

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 PM.

9.0 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 the PM or rechargeable batteries and provides the patient and clinician with operating information, power supply information, and indications of significant changes in device operation.

Table 20 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 20 System Controller Factory Settings

10.0 Power Module (PM)

The HeartMate Power Module (PM) (**Figure 9**) works with the HeartMate II LVAS. The PM is designed to:

- Provide power to the LVAS during tethered operation (i.e., while connected to a functioning AC mains electrical outlet).
- Provide power to the Display Module or System Monitor.
- Connect the Display Module/System Monitor to the System Controller for monitoring purposes.
- Echo System Controller alarms.

Figure 9 HeartMate Power Module (PM)

NOTE:

A rechargeable battery inside the PM provides approximately 30 minutes of backup power to the LVAD in the event of AC mains power interruption or failure. The internal battery remains charged as long as the PM remains connected to AC mains power. The internal battery is rechargeable, but has limited life and must be replaced annually.

See the *HeartMate Power Module IFU* (doc. no. 103840) for detailed warnings, precautions, and instructions on using the PM.

11.0 Batteries and Battery Clips

When the patient is not tethered to the PM, power is provided to the LVAD by two HeartMate DC 12 volt NiMH batteries or two 14 volt Li-Ion batteries that are inserted into compatible (i.e., 12 volt or 14 volt) battery clips (**Figure 10**). The battery clips and batteries can be worn in holsters under each arm, across the body in a bag, or around the waist. One pair of new HeartMate 12 volt NiMH batteries provides at least six hours of support at the "higher end" or nominal operating conditions (pump speed 12,000 rpm, flow 6.0 lpm, power 10 Watts). One pair of new HeartMate 14 volt Li-Ion batteries provides six to ten hours of support under nominal operating conditions (pump speed 12,000 rpm, flow 6.0 lpm, power 10 Watts). The batteries will last for less time as the patient's physiologic demands increase.

The HeartMate II LVAS is optimized for operation with two batteries. However, it is possible to run the system with one battery for a very short period of time (60 seconds or less); for example, when the system is being switched from batteries to PM power, or vice versa.

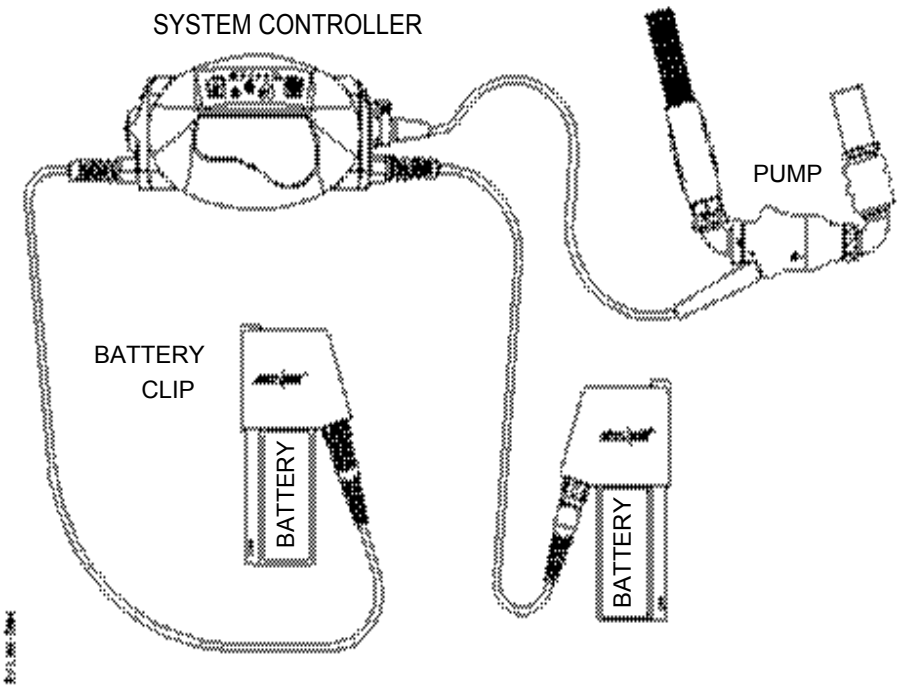


Figure 10 HeartMate II LVAS Battery-Powered Configuration

NOTE:
See the *HeartMate 12 Volt NiMH Battery IFU* (doc. no. 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (doc. no. 103770) for detailed warnings, precautions, and instructions on using HeartMate 12 volt NiMH and 14 volt Li-Ion batteries.

WARNING!
HeartMate 12 volt NiMH and 14 volt Li-Ion batteries are compatible only with their corresponding (i.e., 12 volt or 14 volt) battery clips. Ensure you have the correct battery clips before relying on them to transfer power to the system. Using incompatible clips will result in pump failure.

CAUTION!
Do NOT use a battery if it has not been charged within the first year of receipt from Thoratec. HeartMate batteries must be charged at least once within the first year of being received from Thoratec.

Because 12 volt NiMH and 14 volt Li-Ion batteries are compatible only with their corresponding (i.e., 12 volt or 14 volt) battery clips, ensure you have the correct battery clips before relying on them to transfer power to the system. HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries can be distinguished by their catalog and part numbers and by color and size (**Table 21**) (**Figure 11**).

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

Table 21 Distinguishing Characteristics of HeartMate 12 Volt NiMH and 14 Volt Li-Ion Batteries

*Batteries are the same color as their corresponding battery clips.

Figure 11 HeartMate 12 Volt NiMH and 14 Volt Li-Ion Batteries (note difference in size and color)

12.0 Universal Battery Charger (UBC)

The HeartMate Universal Battery Charger (UBC) (**Figure 12**) is designed to charge the HeartMate batteries that are used to power the HeartMate II LVAS during mobile operation. Specifically, the HeartMate UBC can:

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

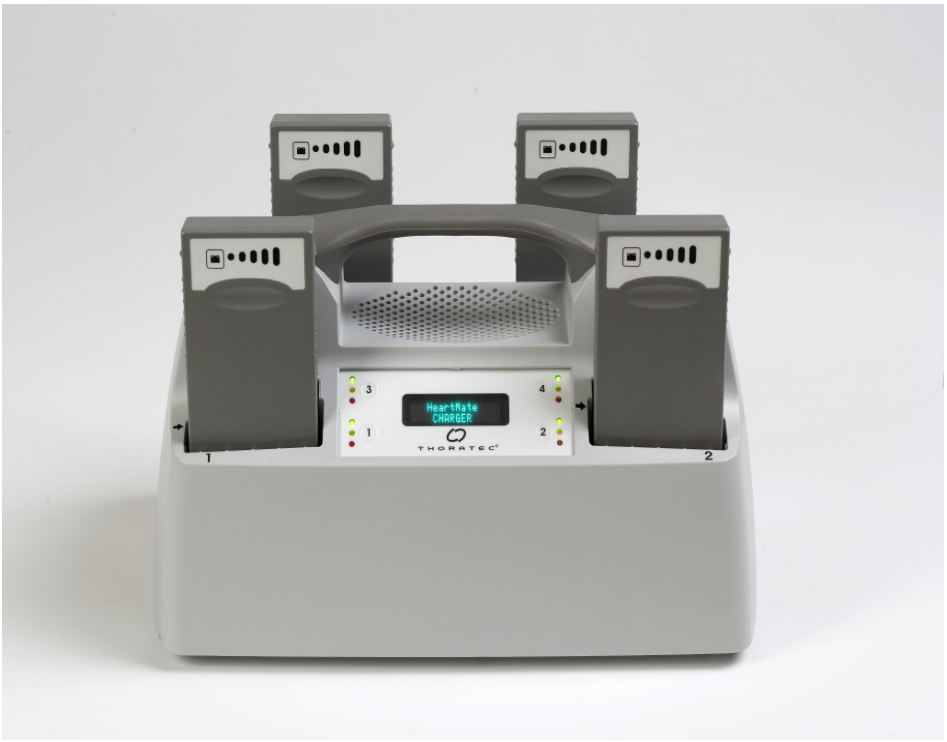


Figure 12 HeartMate Universal Battery Charger (UBC)

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

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

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

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries utilize a "smart" technology that measures available battery power and counts battery usage/charge cycles. Once a battery is placed into a UBC charging pocket, the charger immediately checks that battery's status by reading the battery's on board computer chip. Information about the battery (i.e., available power and total number of use/charge cycles) can be viewed on the UBC's display panel by pressing the number button for that pocket.

See the *HeartMate Universal Battery Charger IFU* (document #103841) for detailed warnings, precautions, and instructions on using the HeartMate UBC.

WARNING!
A minimum of two fully-charged HeartMate batteries and compatible battery clips are required at time of implant to power the system when transporting the patient out of the operating room.

The HeartMate UBC will charge and test up to 4 batteries in four hours or less, depending on the initial charge status of the battery(ies) being charged.

Use only the HeartMate UBC to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries.

13.0 System Monitor

The System Monitor allows the user to monitor system parameters, change speed settings, view stored events, and save performance data. The System Monitor communicates with the System Controller through the PM 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 (**Figure 13**)

NOTE:
If you are using an older model of the System Monitor cable, you will need an adapter to connect the System Monitor cable to the PM. See section 2.5 of the *HeartMate Power Module IFU* (doc. no. 103840) for instructions on using the adapter.

Figure 13 System Monitor (updated version)

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* (document # 103878) for detailed warnings, precautions, and instructions on using the System Monitor.

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

13.1 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 14**.

Figure 14 System Monitor Screen Tabs (with Clinical Tab Selected)

13.2 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 15**).
- **Operating Mode and Speed Set Point** – The operating mode and speed set point are displayed below the parameter boxes as shown in **Figure 15**. 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 13.3.3 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 13.4.3 for more information.

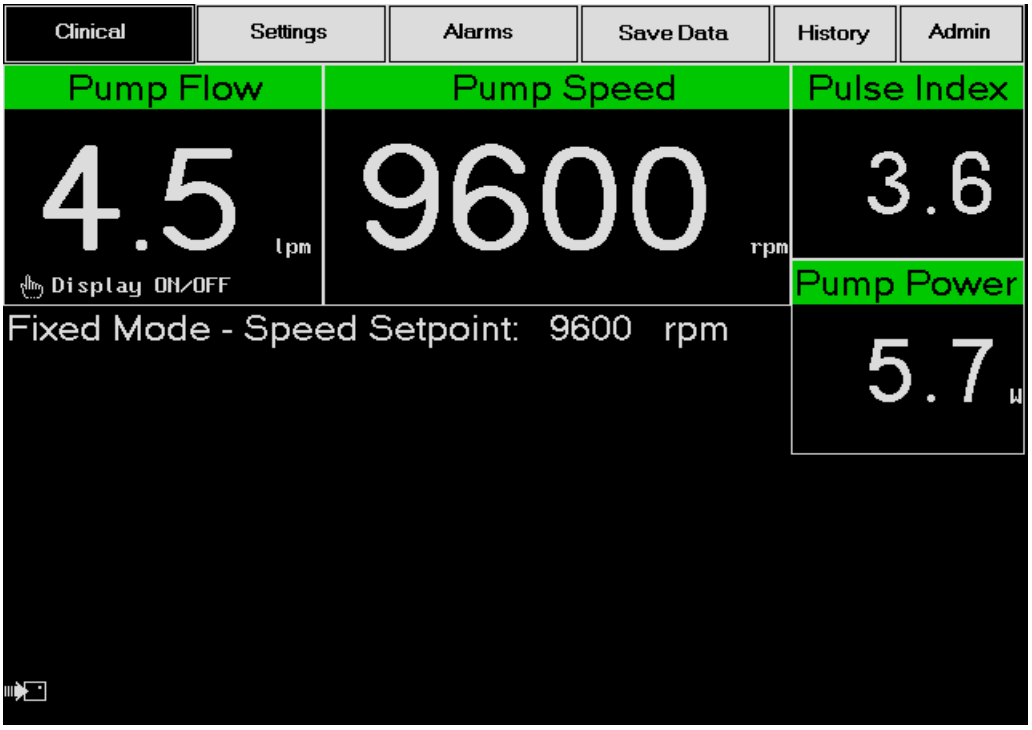


Figure 15 Clinical Screen (typical)

13.2.1 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 16**. 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.

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

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

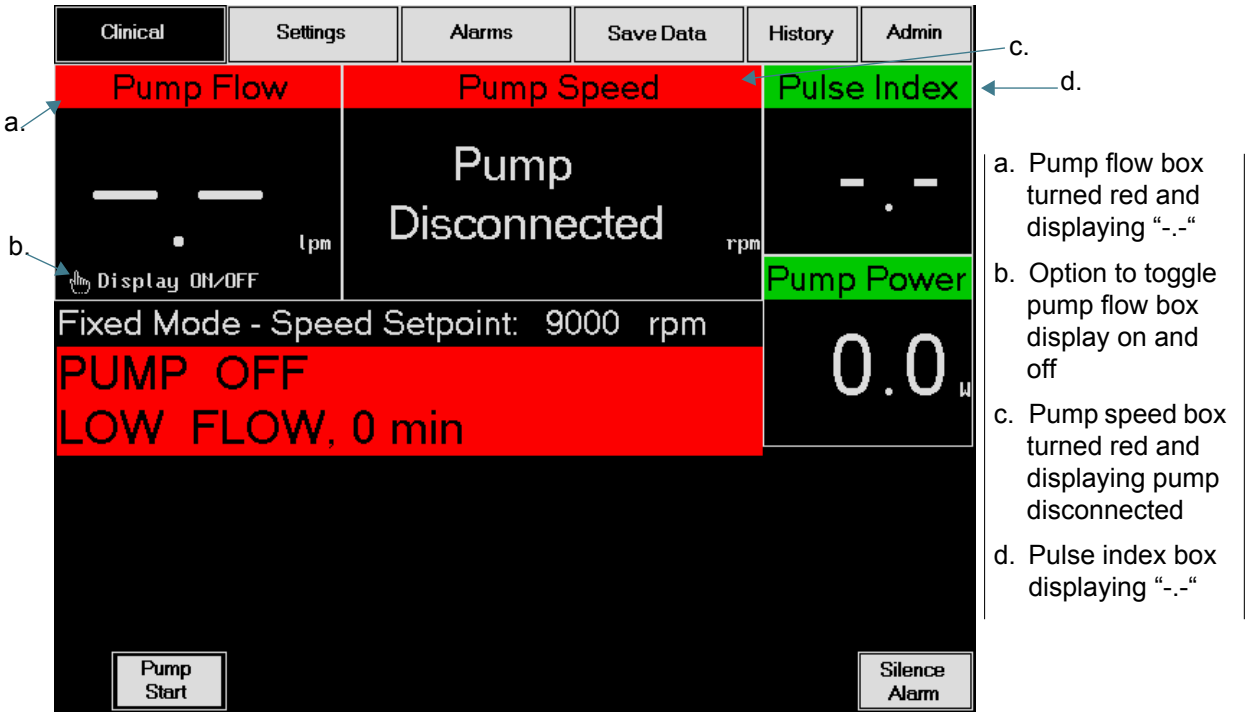


Figure 16 Clinical Screen with Pump Disconnected Hazard Alarm

13.2.2 Pump Speed

The System Monitor displays the pump speed in rpms in the pump speed box as shown in **Figure 16**. If the pump is not connected to or becomes disconnected from the System Controller, the pump speed box will display Pump Disconnected (**Figure 16**). When the pump is stopped by pressing the pump stop button on the settings screen (see section 13.3.3) (**Figure 17**), "**----**" will appear in the pump speed box.

13.2.3 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 (**Figure 16**). When the pump is stopped or becomes disconnected from the System Controller, "**-.-**" will appear in the pulse index box as shown in **Figure 16**.

13.2.4 Pump Power

The pump power is displayed in the pump power box (**Figure 16**) 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.

13.2.5 Alarm Messages

The two highest priority hazard and/or advisory alarm messages generated by the System Controller will be displayed under the fixed speed set point in order of highest priority. If more than two alarms are occurring at one time, a "**+**" sign will appear on the right side of the second alarm banner, indicating that the user must go to the alarms screen to view all active alarms. See *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 17**, 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 17**. 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 one beep every four seconds, with the following exceptions: replace System Controller advisory (repeating cycle of one beep per second for two seconds, followed by two seconds of silence), low speed operation advisory (no audible alarm), and power cable disconnected (one beep per second).

Figure 17 Clinical Screen with Hazard and Advisory Alarms

During alarm conditions, a silence alarm button will appear in the lower right corner of the screen (**Figure 17**). 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).

13.3 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 18**). 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 section 13.4 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 18**. During alarm conditions, a silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for two minutes, and all other advisory alarms for 4 hours. See section 13.4 for more information.

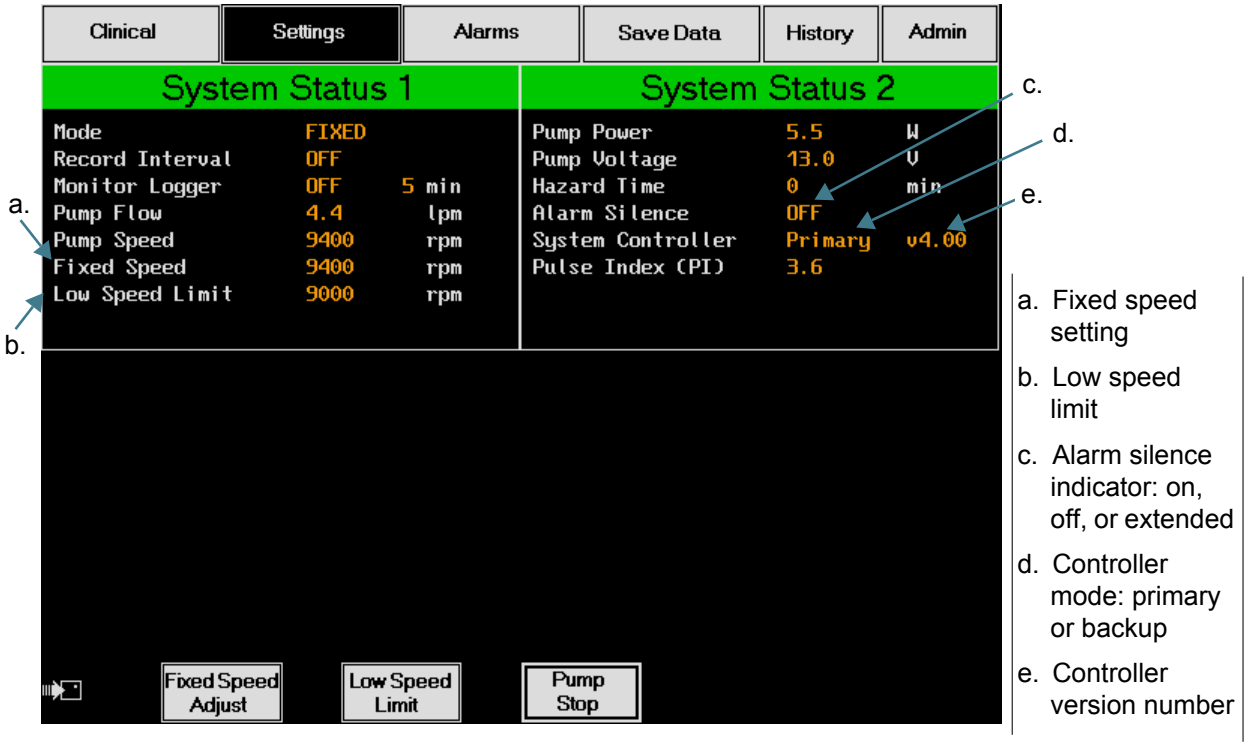


Figure 18 Setting Screen (typical)

13.3.1 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* (document # 103878) 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.

13.3.2 Low Speed Limit

The low speed limit button 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 set point. This drop in speed is accompanied by a reduced pump flow. If the low speed limit is set at a value above or the same as the fixed speed set point, the pump speed will not change during a suction event. There is no audible alarm during suction events.

13.3.3 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). Initially, the low speed operation advisory and then the low flow hazard appears without an audible alarm. Once the countdown nears zero, the pump off hazard will appear as shown in **Figure 19**, accompanied by a continuous audible alarm. A silence alarm button will be displayed to the right of the alarm text banners and can be pressed to silence this alarm for two minutes.

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

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.

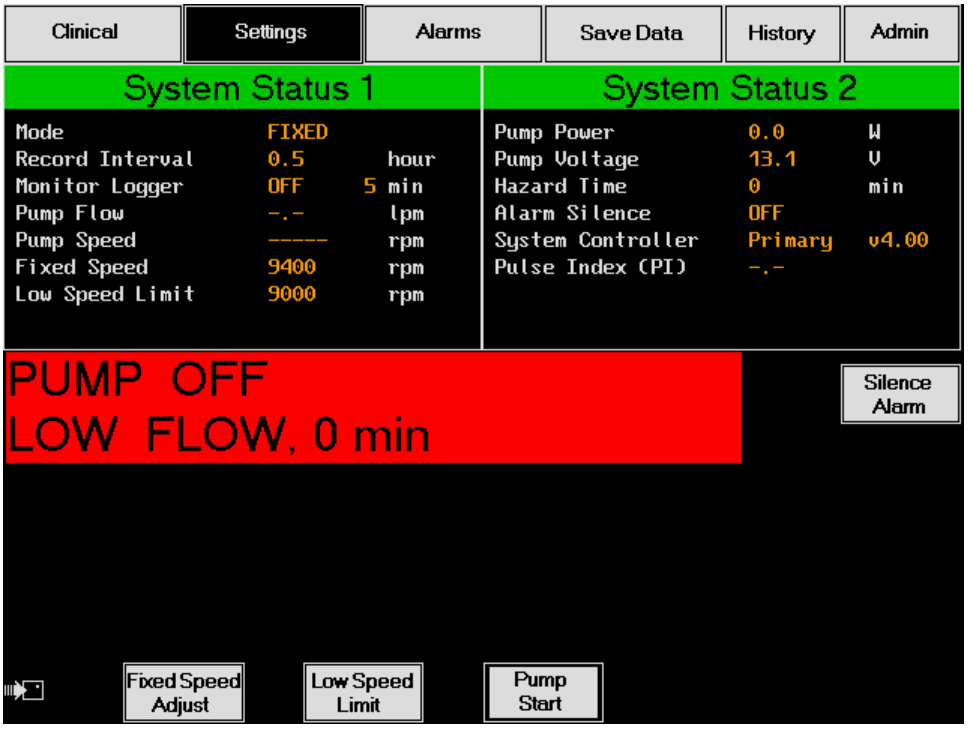


Figure 19 Settings Screen with Pump Stop Countdown Complete

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 and 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 set point 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).

13.4 Alarms Screen

The alarms screen shows the status of all hazard and advisory alarms (**Figure 20**) 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 (for low flow hazards only), and whether the alarm silence is on, off, or extended.
- **Command Buttons** – Two command buttons will appear only during alarm conditions:
    - A silence alarm button will accompany any active, audible alarms. Pressing this button will silence hazard alarms and the power cable disconnected advisory for two minutes and all other advisory alarms for four hours. See section 12.4.3 for more information on silencing alarms.
    - 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 up to four hours. See section 12.4.3, *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 20**). Multiple alarms may be highlighted simultaneously.

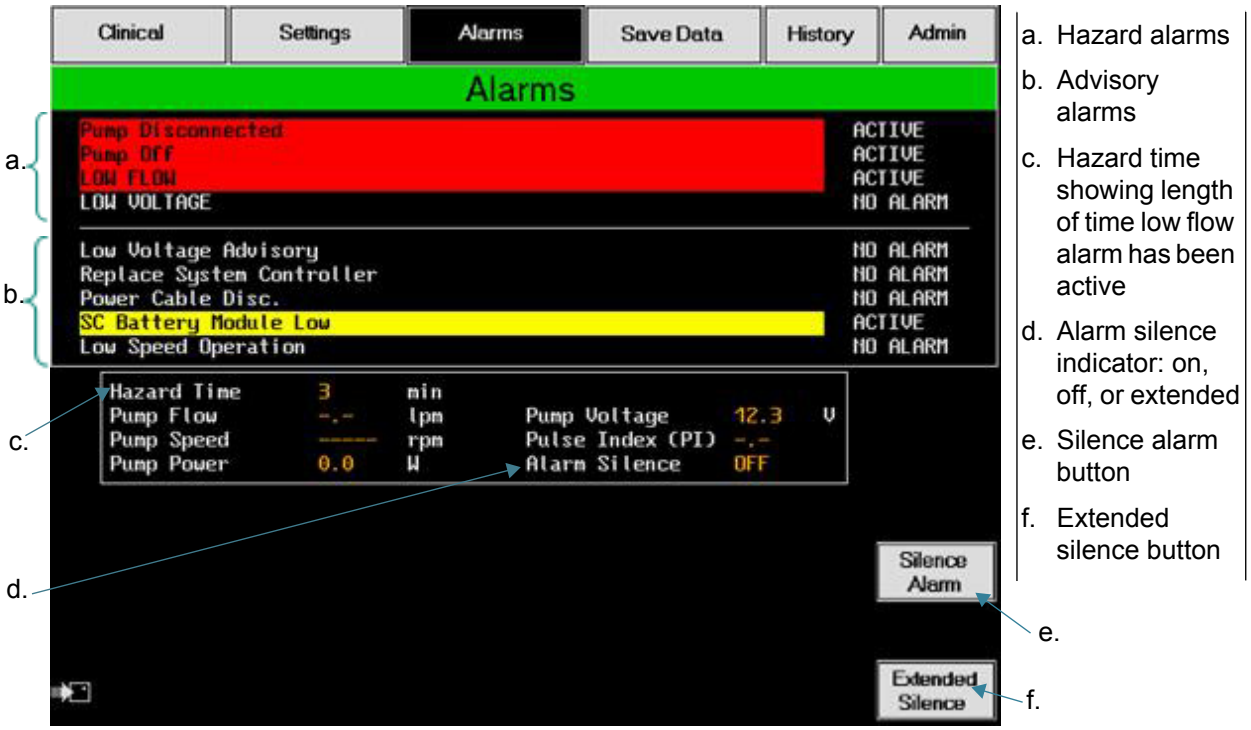


Figure 20 Alarms Screen with Multiple Alarms and Advisories Displayed Simultaneously (typical)

13.4.1 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, the pump is not operating properly, or has been disconnected from the System Controller. The hazard time listed in the parameters box refers to the number of minutes that the hazard alarm has been active as shown in **Figure 20**.
4. LOW VOLTAGE – Voltage has dropped below 10.50 volts (V).

Refer to the *HeartMate II LVAS Operating Manual* (document # 103878) for information on troubleshooting alarms.

13.4.2 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 PM 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.

13.4.3 Silencing Alarms

The silence alarm button is used to temporarily silence audible alarms and will only appear during alarm conditions (**Figure 20**). Pressing the button will silence hazard alarms and the power cable disconnected advisory for two minutes, and all other advisory alarms for up to four hours on both the PM and System Controller. However, alarm messages will still be displayed on the System Monitor screen. If the alarm condition is resolved, the alarm silence will automatically turn off.

> ***NOTE:***
> If both power leads are disconnected from the System Controller or the silence alarm button on the System Controller is pressed, the extended silence will be cancelled.

At fixed speeds set below 8,000 rpm, the extended silence button will also be available (**Figure 20**). Pressing this button will silence all hazard and advisory audible alarms on the PM and System Controller for four hours (alarm messages are still displayed on the System Monitor screen).

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

13.5 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* (document # 103878) for more information about the save data screen.

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

13.6 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* (document # 103878) for more information about this screen.

> **NOTE:**
> The date and time must be updated manually for daylight savings time. Daylight savings time is not adjusted automatically on the System Monitor.

13.7 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* (document # 103878) for instructions on how to change the clock.

SURGICAL CONSIDERATIONS & PROCEDURES

14.0 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 electromagn□etic fields.

Additional sealed inflow conduits (catalog # 102564), sealed outflow grafts with bend relief (catalog # 102563), and sealed outflow short bend reliefs (catalog # 102781), are also available as ***sterile*** stand alone items.

14.1 Thoratec-Supplied Equipment

Sterile HeartMate II LVAS Implant Kit (with sealed grafts) (catalog # 103693):

- Left Ventricular Assist Device (LVAD) Assembly
- 20mm Flexible Sealed Inflow Conduit
- 14mm Sealed Outflow Graft with 10.2 mm (4 in.) Bend Relief
- Apical Sewing Ring
- Apical Coring Knife (20mm)
- Skin Coring Punch (8mm)
- Thread Protectors (1 set)
- Tunneling Bullet
- System Controller with Battery Module

> ***WARNING!***
> Moderate to severe aortic insufficiency must be corrected at a time of device implant.

Non-Sterile:

- Power Module (PM) with PM patient cable (catalog # 103868)
- System Monitor (catalog # 1286A)

- Battery Clips (set of 2) for *either* HeartMate 12 volt NiMH batteries (catalog # 2265) *or* 14 volt Li-Ion batteries (catalog # 2865)
- HeartMate Batteries (set of 4) *either* 12 volt NiMH batteries (catalog # 2060) *or* 14 volt Li-Ion batteries (catalog # 2465)
- Tunneler (catalog # 102137)
- HeartMate II Sizer (catalog # 102772)

In addition to this manual and the corresponding *HeartMate II LVAS Operating Manual* (document # 103878), which is provided with the System Monitor, the following power accessory IFUs also must be present and readily available during the implant procedure:

- *HeartMate Power Module IFU* (document # 103840)
- *HeartMate Universal Battery Charger* (document # 103841)
- *HeartMate 12 Volt NiMH Battery IFU* (document # 103769)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)

WARNING!
Power Modules (PMs) are shipped to customers with the internal battery disconnected. After receiving the PM, the hospital's biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device. See section 2.1 of the *HeartMate Power Module IFU*.

WARNING!
A minimum of two fully charged batteries and a pair of compatible battery clips and power leads are required at time of implant in order to power the system when transporting the patient out of the operating room (see the *HeartMate Universal Battery Charger IFU* and the *HeartMate 12 Volt NiMH Battery IFU or HeartMate 14 Volt Li-Ion Battery IFU)* for detailed warnings, precautions, and instructions on charging HeartMate 12 Volt NiMH or 14 volt Li-Ion batteries.

14.2 Hospital-Supplied Equipment

- 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

15.0 Pre-Implant Procedures

The patient is transported to a cardiovascular operating room (OR), prepped, and anesthetized according to standard procedures. A median sternotomy incision extending approximately 2–3 cm below the xyphoid process is made and cardiopulmonary bypass is instituted.

15.1 Setting Up and Initializing the System

During implant, the HeartMate II Left Ventricular Assist System (LVAS) must be operated with the Power Module (PM) as shown in **Figure 21**.

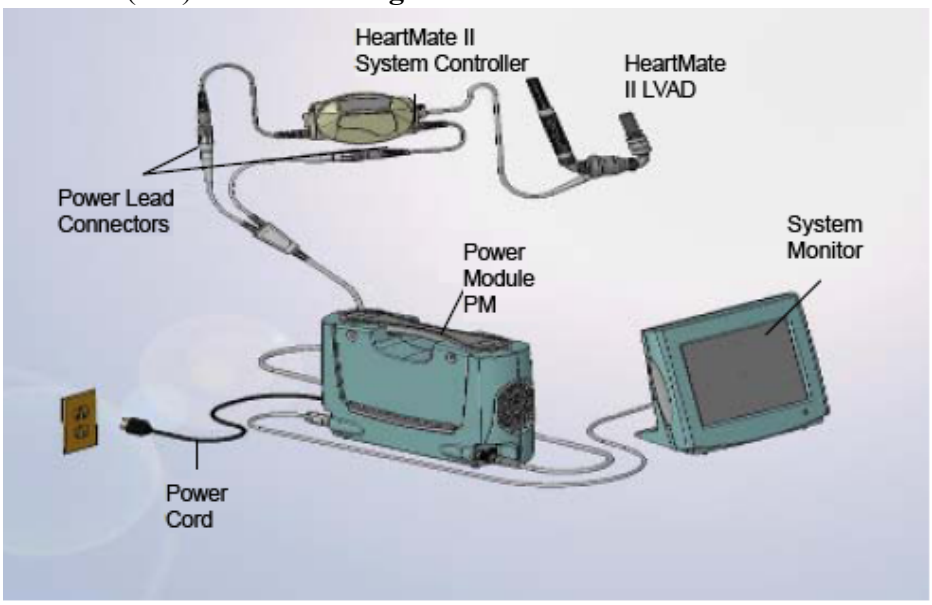


Figure 21 HeartMate II LVAS Connected to PM

NOTE:
If you are using an older model of the System Monitor cable, you will need an adapter to connect the System Monitor to the PM. See section 2.5 of the *HeartMate Power Module IFU* (doc. no. 103841) for instructions on using the adapter.

1. Plug the System Monitor cable into the "▭" socket located on the side of the PM.
2. Plug the other end of the cable into the System Monitor, if not already connected.

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

3. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. In addition, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.
4. Ensure the patient cable is attached to the PM (see "Connecting the PM Power Cord and "Patient" Cable," *Section 2.2 of the Power Module IFU*).
5. Turn on the System Monitor by pressing the on/off switch at the rear of the System Monitor to the "on" (I) position. A green light on the front of the System Monitor should come on once power is going to the device. Call Thoratec's Technical Service Department if the System Monitor will not power on.
6. Observe the System Monitor screen. Once the monitor is turned on, the HeartMate logo screen (**Figure 22**) should appear.

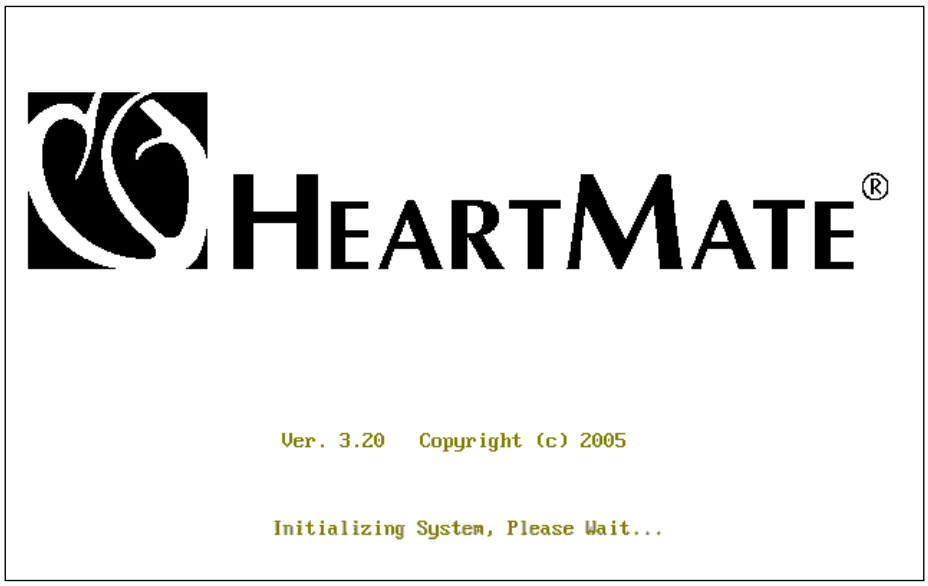


Figure 22 HeartMate Logo Screen

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

OR

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

OR

7. If "NOT RECEIVING DATA" is flashing on the System Monitor screen, the System Monitor cannot recognize or "see" the System Controller. If this occurs, check the following:
   - The patient cable is securely inserted into the "  " socket located on the side of the PM.
   - The System Monitor cable is securely connected to the System Monitor and fully inserted into the "" socket located on the side of the PM.
   - The System Controller power lead connectors are properly connected to the PM power lead connector (i.e., white-to-white and black-to-black).
8. If the System Monitor still does not work, call Thoratec's Technical Service Department.

WARNING!
At least one System Controller power lead must be connected to a power source at all times.
Disconnecting both power leads at the same time will cause the pump to stop.

Never disconnect the patient cable from the PM unless the patient first switches to battery-powered operation.

15.2 Initializing the System Controller

1. Remove the System Controller and battery modules from their sterile package. Do not touch the metal contact point on the battery module while handling it.
2. Inspect the battery module and verify that the orange "O" ring and white tape are intact. If not, obtain another battery module. If the "O" ring and tape are intact, continue with step 3.

3. Insert the System Controller battery module into the System Controller body and screw it down until it is finger tight (**Figure 23**). Hand-tighten only; do not use tools. This battery module enables the System Controller alarm to sound if the System Controller loses power while connected to a patient. The battery module does NOT provide backup power to the pump.

Figure 23 Insert Battery Module into System Controller Receptacle

4. Pass the two System Controller power lead ends out of the sterile field and connect them to the bifurcated ends of the PM patient cable, white-to-white and black-to-black. Both the PM 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.
5. The System Monitor will default to the clinical screen. Press the silence alarm button to silence the hazard alarm for two minutes. Verify that the screen displays the pump off, low flow, and pump disconnected alarm messages and indicates fixed mode with a speed set point of 6,000 rpm (**Figure 23**). If the speed set point 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.

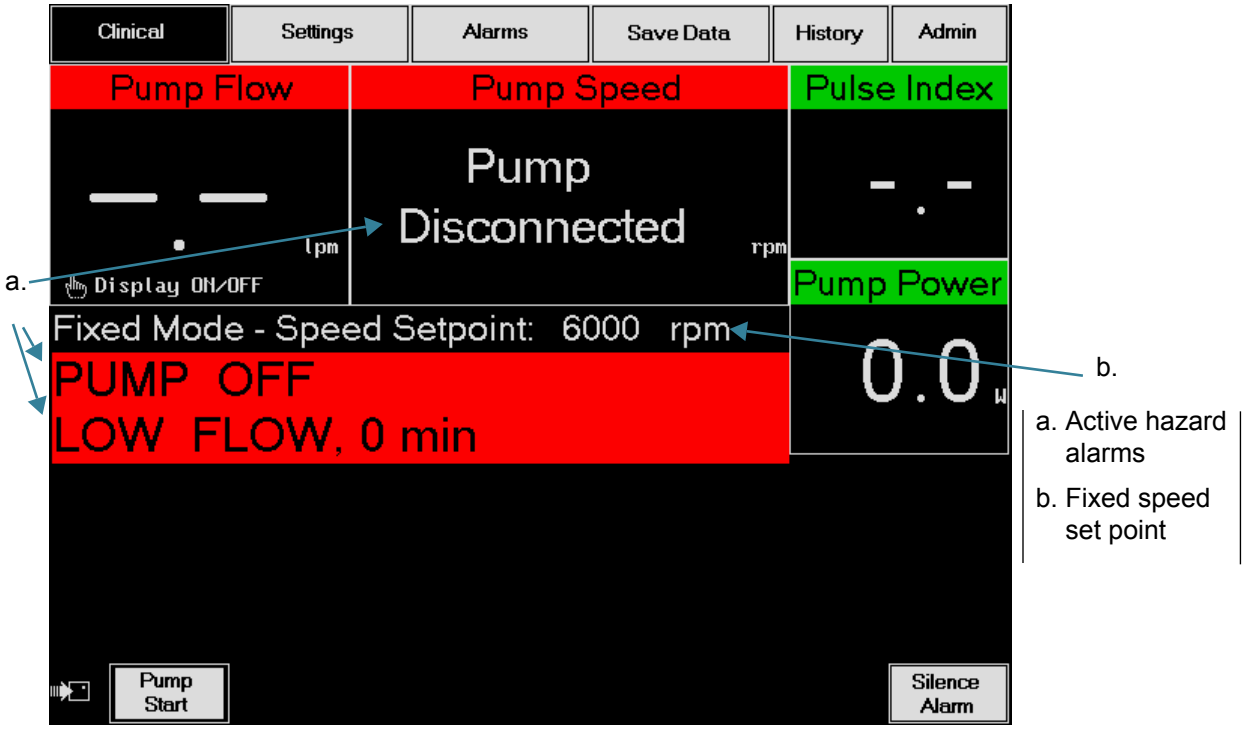


Figure 24 System Monitor Clinical Screen when Initially Connected to the System Controller

6. Go to the alarms screen by pressing the alarms tab. Press the extended silence button (**Figure 25**). This will silence all hazard and advisory alarms for four hours to ensure that they will not sound in the OR. The alarm silence indicator should display extended. The extended silence can be canceled by depressing the silence alarm button on the System Controller's user interface panel or by removing power from both power leads.

7. 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.

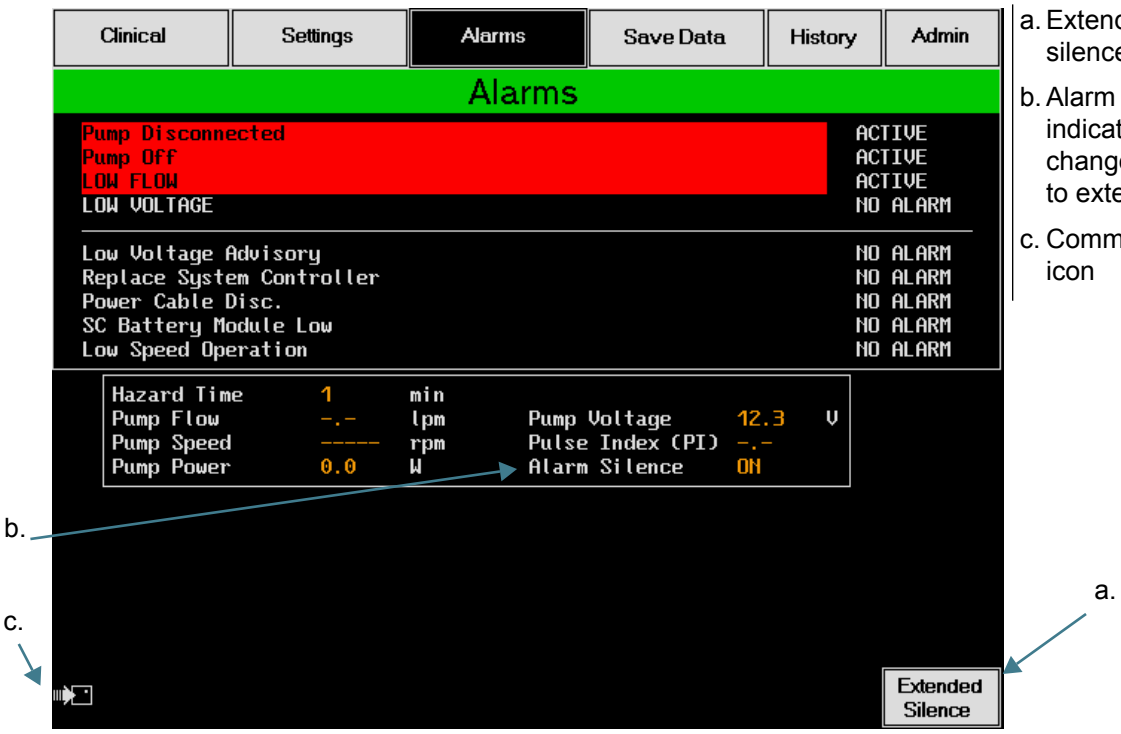


Figure 25 Alarms Screen when Initially Connected to the System Controller

8. 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* (document # 103878) for instructions on setting the date and time.
9. 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.

15.3 Preparing the Pump

To prepare the pump for implantation, first examine the outflow elbow of the pump to verify the presence of a white washer. If the white washer is missing or damaged, obtain another pump before continuing with the steps outlined below.

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 release tab (**Figure 26**).

   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 26**). 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 26**). ***The perc lock will not rotate unless the connector is fully inserted.***

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

Press metal release tab to disconnect percutaneous lead.

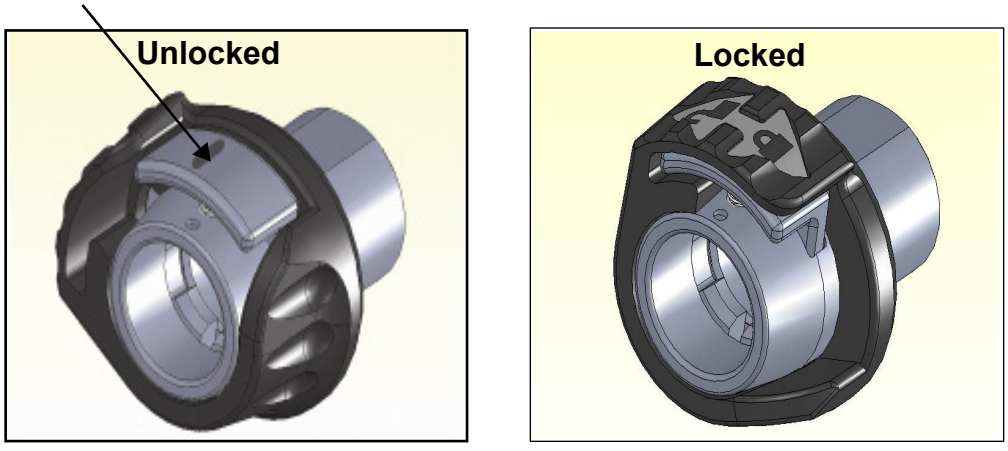


Figure 26 Perc Lock – Unlocked (left) and Locked (right) Positions

Figure 27 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 28**). The pump off message should appear and the pump stop button should change to pump start.
4. Disconnect the percutaneous lead and leave the pump in the sterile basin of sterile saline for injection.

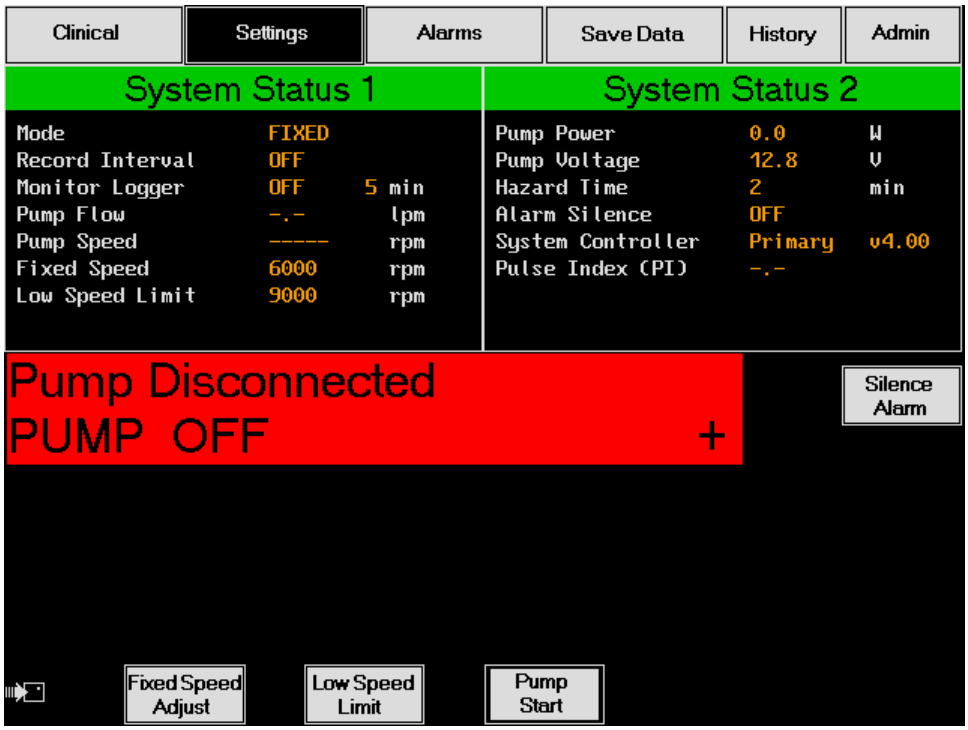


Figure 28 Settings Screen – Pump Stop

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 PM. If the power leads are disconnected, the extended alarm silence will be reset.

15.4 Preparing a Sealed Inflow Conduit

Characteristics that identify a sealed inflow conduit and distinguish it from an unsealed inflow conduit are as follows:

1 Thoratec logo on the flexible silicone sleeve;

2 Two holes on the flexible silicone sleeve;

3 Blue screw ring that attaches it to the pump; and

4 A foil pouch that contains the sealed inflow conduit.

WARNING!
The sealed outflow graft should not be implanted in patients who exhibit sensitivity to materials of bovine origin.

A sealed inflow conduit (**Figure 29**) does not require pre-clotting. Attempting to pre-clot a sealed inflow conduit may disrupt or destroy the sealant and lead to profuse bleeding after implantation. Do NOT pre-clot a sealed inflow conduit.

a. Flexible Silicone Sleeve

b. Blue Screw Ring

Figure 29 Preparing a Sealed Inflow Conduit

WARNING!
A sealed inflow conduit does not require pre-clotting. Attempting to pre-clot a sealed inflow conduit may disrupt or destroy the sealant and lead to profuse bleeding after implantation.

To prepare a sealed inflow conduit for implantation, complete the following procedure:

1 Open the sealed inflow conduit box and foil pouch. The foil pouch is a protective cover only. The pouch is not sterile; do not introduce it into the sterile field.

2 Remove the outer tray from the foil pouch. The outer tray is not sterile; do not introduce it into the sterile field.

3 Remove the sealed inflow conduit from the inner tray. The inner tray is sterile; it may be introduced into the sterile field.

4 Examine the sealed inflow conduit; verify that the black "O" ring and white washer are present and intact at the screw-ring end of the conduit.

WARNING!
Do not trim or cut the sealed outflow graft bend relief or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss.

15.5 Preparing a Sealed Outflow Graft

Characteristics that identify a sealed outflow graft and distinguish it from an unsealed outflow graft are as follows:

1 A blue dashed line on the bend relief;

2 A blue screw ring that attaches to the pump; and

3 A foil pouch that contains the sealed outflow graft.

WARNING!
The sealed outflow graft should not be implanted in patients who exhibit sensitivity to materials of bovine origin.

A sealed outflow graft (**Figure 30**) does not require pre-clotting. Attempting to pre-clot a sealed outflow graft may disrupt or destroy the sealant and lead to profuse bleeding after implantation.

a. Sealed Graft
b. Bend Relief
c. Screw Ring

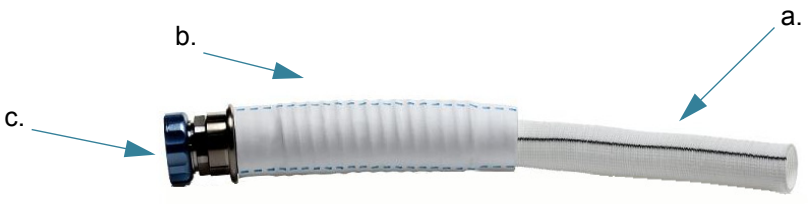


Figure 30 Preparing a Sealed Outflow Graft

To prepare a sealed outflow graft for implantation, complete the following procedure:

1 Open the sealed outflow graft box and foil pouch. The foil pouch is a protective cover only, and should not be introduced into the sterile field.

2 Remove the outer tray from the foil pouch. The outer tray is not sterile. Only the innermost tray may be introduced into the sterile field.

3 Remove the sealed outflow graft and bend relief from the inner tray.

4 Using strict aseptic technique, remove the bend relief from the graft.

5 Examine the graft; verify that the black "O" ring and white washer are present and intact at the screw-ring end of the conduit.

6 Inspect the interior of the graft and remove any debris.

7 Attach the open thread protector.

8 Place the bend relief (10.2mm [4 in.]) over the graft, with the metal end sliding toward the screw ring. The bend relief should be disengaged for the de-airing procedure.

9 The thread protectors should be left attached to the screw-ring connector for use with the attachment to the HeartMate II surgical sizer.

WARNING!
A sealed outflow graft does not require pre-clotting. Attempting to pre-clot a sealed outflow graft may disrupt or destroy the sealant and lead to profuse bleeding after implantation.

CAUTION!
Do not over tighten the thread protector.

15.6 Priming the Pump/Sealed Inflow Conduit Assembly

Assemble the sealed inflow conduit to the pump (**Figure 31**). 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 Insert the conduit elbow into the pump port just to the point where the thread halves become engaged. Full engagement of the conduit 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 the outflow.

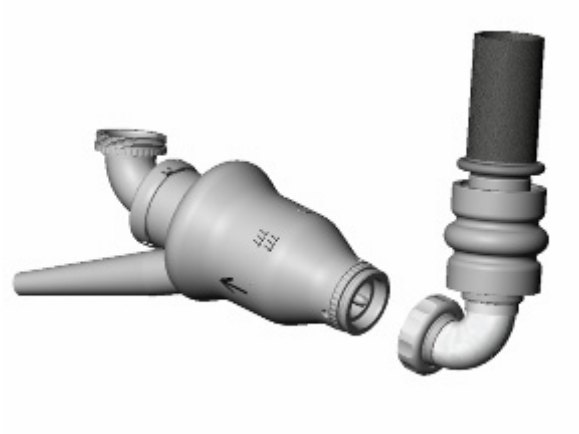


Figure 31 Connecting the Sealed Inflow Conduit to Pump

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 / sealed inflow conduit assembly in a horizontal position with the sealed 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 sealed 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.

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

8 Cut a fingertip off of a powderless sterile glove and use it to cover the inlet extension of the sealed inflow conduit.

9 Place antibiotic-soaked laps over the pump and velour portion of the percutaneous lead then set aside the pump with the sealed inflow conduit positioned up and covered with a sterile towel.

NOTE:
Some fluid leakage will occur through the connections. However, the sealed inflow conduit graft should not leak.
If leaking occurs from the sealed inflow conduit, replace it with a new sealed inflow conduit.

16.0 Device Implant

The proper orientation of the components may be seen in **Figure 32**. The sealed inflow conduit is placed utilizing left ventricle (LV) apical cannulation with the pump positioned inferior to the diaphragm and the sealed outflow graft attached to the ascending aorta.

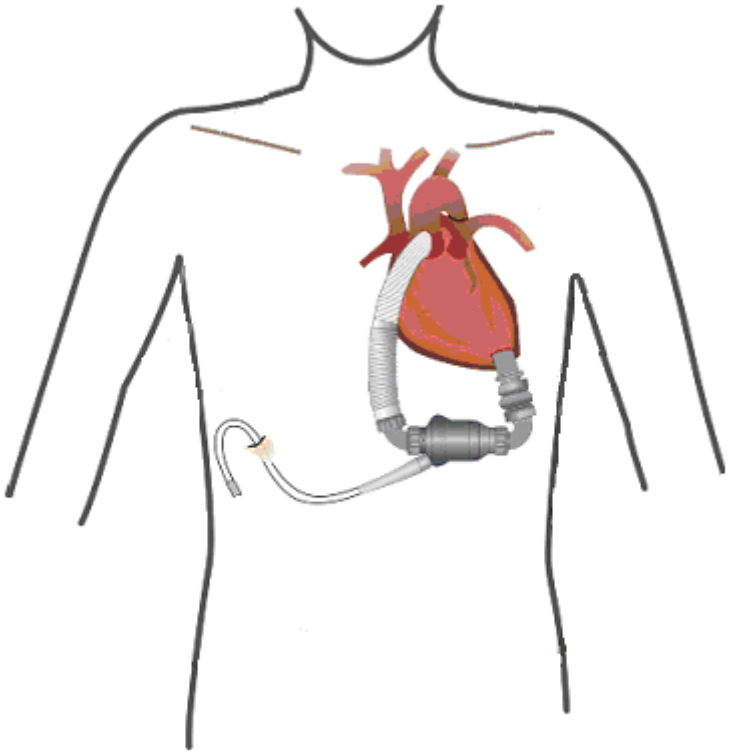


Figure 32 HeartMate II Implantation Configuration

16.1 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.

16.1.1 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 sealed inflow conduit into the LV apex.

> ***NOTE:***
> The HeartMate II surgical sizer (catalog # 102772) is available as a stand-alone, reusable item and may help to visualize and create the pump pocket.

Once cardiopulmonary bypass is established and the LV apex is prepared for the insertion of the sealed 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 sealed inflow conduit is inserted into the LV apex and secured. A small preperitoneal pocket is also made behind the right rectus muscle to allow for the sealed outflow graft. The sealed outflow graft is directed to the ascending aorta.

16.1.2 Surgical Technique for Intra-Abdominal Placement

A midline chest incision is made and extended 2 – 3cm below the xiphoid process. Once cardiopulmonary bypass is instituted, the LV apex is prepared for insertion of the sealed inflow conduit. The pump is placed intraperitoneally in the left upper quadrant, and the sealed inflow conduit is positioned to allow insertion of the sealed inflow conduit into the LV apex. The sealed outflow graft is placed over the diaphragm and anastomosed onto the ascending aorta. The percutaneous lead exits the body through the right upper quadrant.

16.2 Preparing for Implantation

Prior to implantation, ensure that:

- The bend relief is in place over the sealed graft and un-engaged to the metal fitting.
- The LVAD is correctly assembled and all joints including the sealed inflow conduit and outflow elbow connections are tight.
- The LVAD is completely primed with sterile normal saline for injection.
- Pump has been run for at least 5 minutes in sterile injectible normal saline.
- The System Controller has been initialized.

16.3 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 tunneled into place.

Follow the procedure below to create the exit site:

1. Ensure that the exit site location (**Figure 33**) 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. Consideration should also be given to the potential for sharp bends and kinks occurring post-implant with ventricular remodeling during HeartMate II LVAS support.
7. Place the pump in the prepared space.

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

CAUTION!
Sharp bends or kinks in the percutaneous lead may make it more susceptible to wear and fatigue over time.

16.4 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 33**). Take care to avoid orienting the inlet towards the interventricular septum. Device function will be compromised in the presence of inlet obstruction.

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

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 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.

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

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.

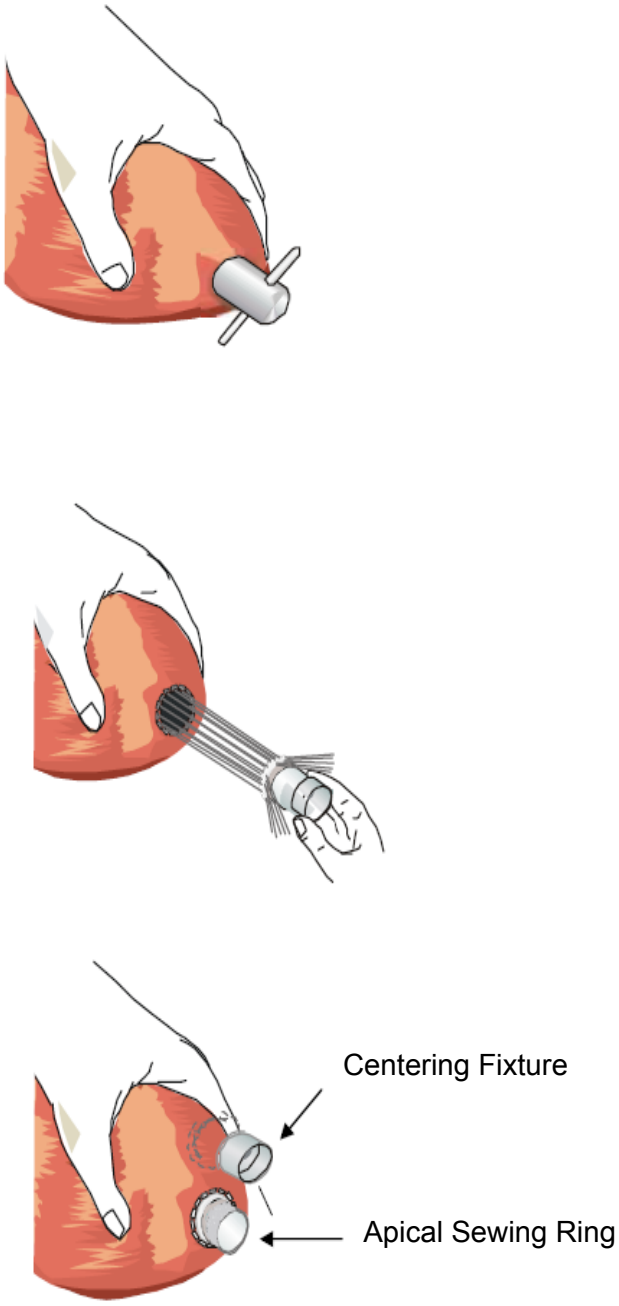


Figure 33 Preparing the Ventricular Apex Site

16.5 Inserting the Sealed Inflow Conduit

1. Select the optimal sealed inflow conduit orientation at the ventricular apex. The following is critical in determining orientation:
   - The opening of the sealed 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 sealed 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 sealed inflow graft and flexible silicone sleeve to twist as shown in **Figure 34**.

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 sealed inflow graft and silicone sleeve are twisted, flow will be restricted through the conduit.

Correct: untwisted silicone sleeve

Incorrect: twisted silicone sleeve

Figure 34 Correct Orientation of Flexible Silicone Sleeve on the Sealed Inflow Conduit

16.6 Attaching the Sealed Outflow Graft

1. Ensure that the bend relief is added to the sealed outflow graft prior to attaching it to the aorta.
2. Measure and cut the sealed 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 sealed 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 35**).
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.
5. Verify that the graft is not twisted or kinked by checking the position of the black line on the graft above and below the bend relief. The line should be straight

NOTE:
A shorter, 7.6 cm (3 in.) bend relief (catalog # 102781) is available as a stand-alone, sterile item.

NOTE:
Use of the HeartMate II surgical sizer (catalog # 102772) 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 sealed outflow graft.

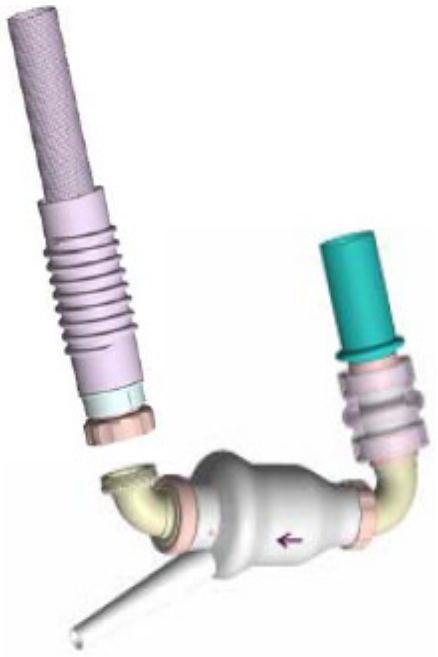


Figure 35 Attaching Proximal End of Sealed Outflow Graft to Pump Outflow Elbow

WARNING!
Ensure that the thread protectors have been removed from the sealed 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

16.7 De-Airing the LVAD

Once the LVAD is in place and the sealed inflow conduit and sealed outflow graft 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 sealed outflow graft at the distal end and move the bend relief toward the aortic anastomosis.
2. Position the sealed outflow graft in a vertical position, such that an arch forms the highest point.

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.

3. Insert a vent needle at the highest point in the graft between the clamp and the sealed outflow graft connection.
4. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and LVAD by diverting at least two 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 set point of 6,000 rpm (**Figure 36**). If the speed set point 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!
All entrapped air must be removed from the LVAD blood pumping chamber and conduits 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 sealed 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 or CO_2 to further minimize the risk of air entry and possible embolization.

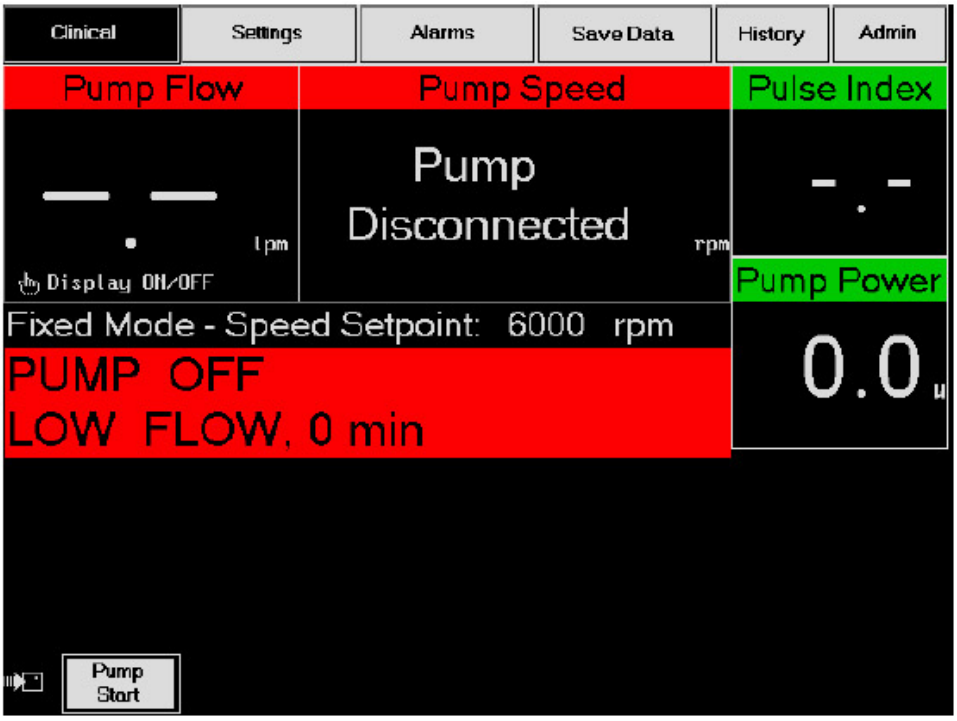


Figure 36 Clinical Screen – Initial Pump Startup

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 37**).

    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 38**). 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 37**). ***The perc lock will not rotate unless the connector is fully inserted.***

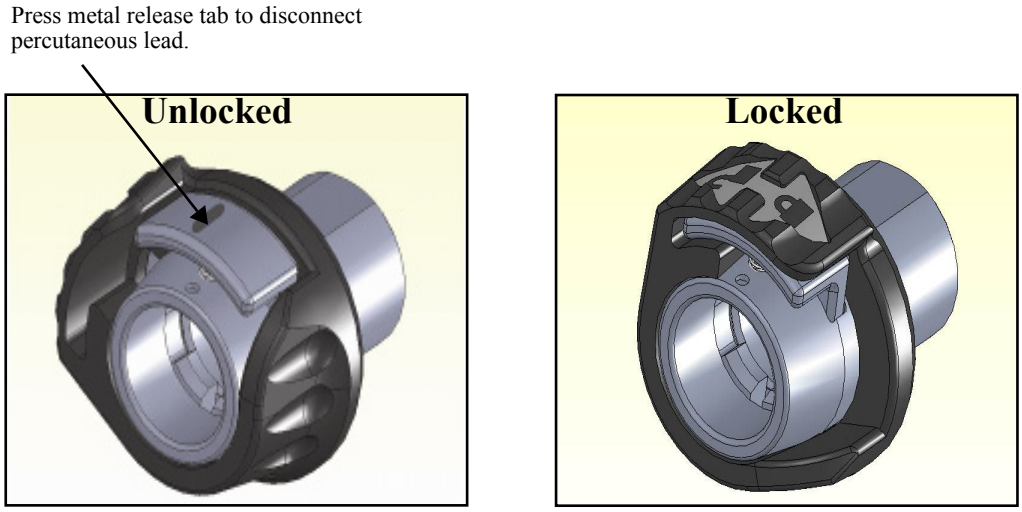


Figure 37 Perc Lock – Unlocked (left) and Locked (right) Positions

Figure 38 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 39** and **Figure 40** 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 39 Clinical Screen During Initial Pump Startup (typical)

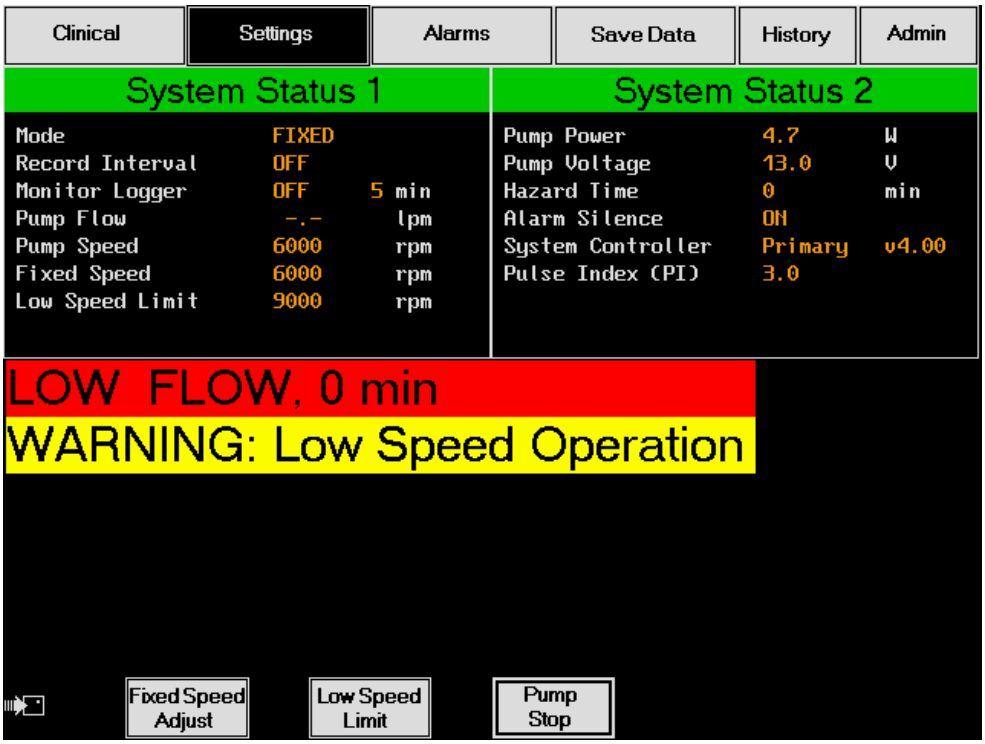


Figure 40 Settings Screen During Initial Pump Startup (typical)

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 left heart using intraoperative TEE, and keep the left heart full.
10. When de-airing is completed, partially remove the sealed 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 sealed outflow graft and repair the site only when air can no longer be observed exiting through the needle. If air persists in the sealed outflow graft for a prolonged period (more than 5-10 minutes), rule out leaks at the sealed inflow conduit/pump connection.

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.

12. Slide the bend relief over the metal fitting toward the locking screw ring until it snaps into place. Visually inspect the bend relief to assure it is fully connected and seated to the sealed outflow graft. 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 set point 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.

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

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.

NOTE:
Pump flow will not be displayed on the System Monitor when pump speed is < 8,000 rpm (**Figure 40**).

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 41** 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.

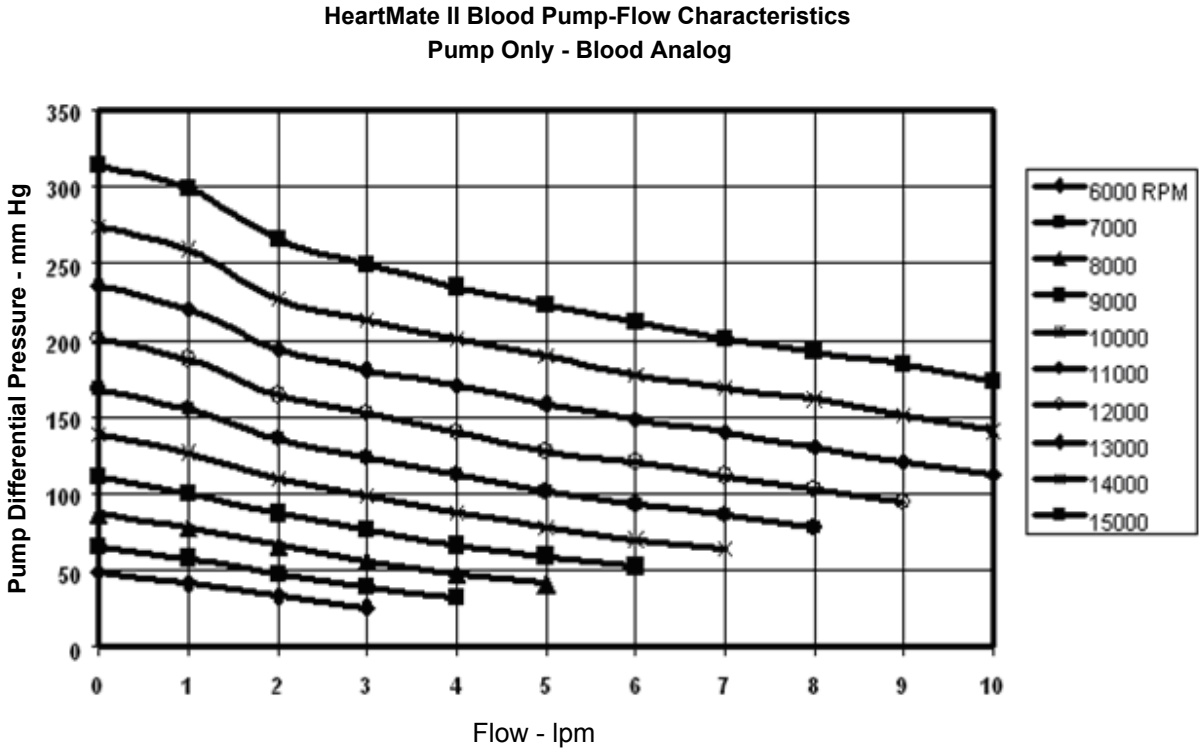


Figure 41 Typical HeartMate II Flow Characteristics

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 power leads 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 or the test select or silence alarm button on the System Controller to restart the pump.

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

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

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

16.8 Securing the Pump and Connections

Once the flow through the blood pump is satisfactory, assure that all sealed inflow and sealed outflow connections are dry and secure. Obtain hemostasis and close all wounds in the standard fashion. Prior to leaving the O.R., immobilize the percutaneous lead with a stabilization belt or abdominal binder.

WARNING!
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 power source (batteries, PM, or EPP) at all times to maintain support.

16.9 Transferring Patient Out of the Operating Room

When it is time to transfer the patient out of the operating room, switch the HeartMate II LVAS from PM to battery power.

1. Obtain two fully-charged HeartMate 12 volt NiMH batteries or two HeartMate 14 volt Li-Ion batteries.
2. Insert one battery into each battery clip.
3. Unplug one of the System Controller power leads from the PM patient cable and connect it to the first battery clip. **Do NOT unplug both power leads at the same time or the pump will stop.**
4. Repeat Step 2 for the 2nd battery/battery clip.
5. Tuck the batteries securely beside the patient so that the System Controller leads are not under strain during patient transport.
6. After the patient reaches the ICU, return to PM-powered operation.
7. Press the silence alarm button on the System Controller's user interface panel to cancel the extended alarm silence. Go to the alarms screen and verify the alarm silence is off.

NOTE:

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

Once the patient has been transferred to batteries, it may be beneficial to program the backup System Controller because the PM is now free to connect to it.

Refer to Sections 3.1 and 3.2 of the *HeartMate Power Module IFU* (document # 103840) for detailed warnings, precautions, and instructions on switching from PM power to batteries and vice versa.

WARNING!
A minimum of two fully charged batteries and a pair of compatible battery clips are required at the time of implant in order to power the system when transporting the patient out of the O.R. The HeartMate UBC can charge up to four batteries in four hours or less, depending on the initial charge status of the battery(ies) being charged.

16.10 Other Patient Considerations

There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the sealed outflow graft conduit and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the sealed 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 (prio 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.

Pulse oximetry, if obtainable, may be unreliable due to the diminished pulse pressure. Cerebral oximetry may be useful in assessing the hemodynamic condition of patients during unconscious sedation or in situations where more invasive monitoring (e.g., direct blood gas measurement) is not available.

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.

WARNING!
Do NOT use the HeartMate II LVAS in pregnant women or in 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.

PATIENT MANAGEMENT

17.0 Patient Management

Support of a HeartMate II LVAS patient in the hospital requires that the equipment in **Table 22** be on hand and readily available:

Component	Primary (Required)	Back-Up (Required)	Optional
Implanted HeartMate II LVAD	X	X	--
System Controller	X	X	--
Rechargeable HeartMate batteries (one set of 4); all 12 volt NiMH *or* all 14 volt Li-Ion	X	X	--
Battery Clips (set)	X	--	X
GoGear® Wearable Accessories *	X	--	X
Power Module (PM) with cable	X	X	--
Universal Battery Charger (UBC)	X	X	--
System Monitor**	X	X	--
Display Module**	--	--	X
System Controller Battery Module	X	--	X

Table 22 Equipment for In-Hospital Patients

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

** The Display Module and older models of the System Monitor cable require an adapter to connect to the PM. See the *HeartMate Power Module IFU* (document # 103840).

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.

17.1 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 vascular 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 (afterload) is required following implantation. Small increases in afterload 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 afterload 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.
- Thrombus can affect all four parameters of the device: speed, power, flow and pulsatility index. If the thrombus is sufficiently large, it can obstruct the flow through the pump. If a large thrombus is in contact with the rotor or bearings, it can increase the drag on the rotor and increase the power requirement. With the increased power, the pulsatility index is reduced because the pulsatile component of power becomes relatively small compared with the steady component of power required to overcome the drag. In cases where thrombus increases pump power, the flow will be overestimated and displayed flow could appear in normal range even though pump flow is very low. In cases of identified thrombus formation, pump replacement should be considered.
- Damage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead. Damage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead. The damage may be evidenced by the following:
  - Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
  - High pump power associated with reduced pump speed (as recorded in the System Controller event log file).
  - High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
  - Feelings of pump vibrations.
  - Fluid leakage from the external portion of the lead.
  - Cessation of pumping.

If you suspect that a HM II LVAS patient may have a damaged percutaneous lead, please contact Thoratec Technical Services (dial 800-456-1477 in the US; +44(0) 7659 877901 in Europe) for assistance. X-ray images, System Controller log files and pump waveform data may be useful to assess the extent and location of the damage. **If damage to the electrical conductors in the lead is confirmed, the HeartMate II pump should be replaced as soon as possible.**

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

17.2 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 disrupt tissue ingrowth and 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.

17.3 Caring for the Percutaneous Lead

The clinical experience over five years of clinical trials (both bridge–to-transplantation and destination therapy) and commercial use outside of the US has shown that wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump to the external System Controller may result in damage that has the potential to interrupt pump function that may require a re-operation to replace the pump or result in death. The need for pump replacement due to percutaneous lead damage has occurred after implant durations ranging from 6 to 38 months of HeartMate II LVAS support. The estimated probability of the need for pump replacement due to percutaneous lead damage according to this analysis is 1.3% at 12 months, 6.5% at 24 months and 11.4% at 36 months.

Consideration should also be given to the potential for sharp bends and kinks occurring post-implant with ventricular remodeling during HeartMate II LVAS support.

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

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

CAUTION!
Sharp bends or kinks in the percutaneous lead may make the lead more susceptible to wear and fatigue over time.

If you suspect that a HM II LVAS patient may have a damaged percutaneous lead, please contact Thoratec Technical Services (dial 800-456-1477 in the US; +44(0) 7659 877901 in Europe) for assistance. X-ray images, System Controller log files and pump waveform data may be useful to assess the extent and location of the damage. **If damage to the electrical conductors in the lead is confirmed, the HeartMate II pump should be replaced as soon as possible.**

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

17.4 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, dipyridamole, and Warfarin.

WARNING!
In the event that the LVAD stops operating and blood is stagnant in the pump and conduits for more than a few minutes, (depending on the 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.

17.5 Diagnosing Blood Leaks

A blood leak from any implanted component of the system is typically identified through the 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.

17.6 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 flows. 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 conduits are 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.

17.7 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.

17.8 Backup System Controller

Ensure that all backup System Controllers are programmed with settings (e.g., fixed speed set point and low speed limit) identical to the primary controller. Remember, controllers are shipped with factory settings (see **Table 12**), and therefore, backup controllers must be programmed at the time they are assigned to a patient.

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

Programming the backup System Controller is done the same way as programming the primary controller (section 15.2) 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* (document # 103878) 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.

18.0 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* (document # 103878) and *HeartMate II LVAS Patient Handbook* (document # 103879). In addition, device malfunction may necessitate emergency treatment. Therefore, patients should not be more than 2 hours from a healthcare facility with trained personnel that are capable of treating a HeartMate II patient.

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

The equipment in **Table 15** 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 HeartMate batteries (2 sets of 4) all 12 volt NiMH *or* all 14 volt Li-Ion	X	X	--
Battery Clips	X	--	--
Emergency Power Pack (EPP)	X	--	--
Display Module**	X	--	--
GoGear® Wearable Accessories*	X	--	Backup Optional
Power Module (PM) with cable	X	--	--
Universal Battery Charger (UBC)	X	--	--
System Controller Battery Module	--	X	--
Patient Handbook	X	--	--

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.

Table 23 Equipment for Home Discharge Patients

* GoGear wearable accessories include the holster vest, consolidated bag, modular belt, and shower bag.
** The Display Module requires an adapter to connect to the PM. See the HeartMate Power Module IFU (document # 103840).

DEVICE EXPLANT

19.0 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 sealed outflow graft just distal to the bend relief and divide the graft.
4. Divide the ligatures securing the apical sewing ring to the sealed inflow conduit and remove the sealed inflow conduit from the ventricle.
5. After removing the conduit, repair or plug the ventricle as appropriate or necessary.
6. Dissect the percutaneous lead between the LVAD body and the abdominal wall. Cut the percutaneous lead and the remove the externalized portion.
7. 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.
8. Remove the sealed outflow graft remnant from the aorta and repair the anastomotic site.
9. 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 conduits are 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 filed. 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 & REPORTING REQUIREMENTS

20.0 Device Tracking and Reporting Requirements

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

21.0 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.

CAUTION!
Service and maintenance of HeartMate system components and equipment, including accessories used to power the LVAS, should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

22.0 Inspection, Cleaning, and Maintenance Guidelines

For safe and optimal performance, external HeartMate II LVAS components should undergo routine and periodic inspection, cleaning, and maintenance as described in the *HeartMate II LVAS Operating Manual* (document # 103878) and in the corresponding power accessory IFUs, including the:

- *HeartMate Power Module IFU* (document # 103840)
- *HeartMate Universal Battery Charger* (document # 103841)
- *HeartMate 12 Volt NiMH Battery IFU* (document # 103769)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)

23.0 Environmental Conditions for Transport, Storage, and Use

For safe and optimal performance, users should adhere to the guidelines for transporting, storing, and using system components, as outlined in the *HeartMate LVAS Operating Manual* (document # 103878) and in the corresponding power accessory IFUs listed in section 22.0 above.

24.0 Testing and Classification

The HeartMate II LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 60601-1:2006 and CAN/CSA-C22.2 No. 601.1-M90: 2002. In addition, the HeartMate II LVAS meets the following safety standards EN 60601-1:1990 and IEC 60601-1: 1998, 2nd Edition, A1:1991, A2:1995.

Classification Concerning General Safety

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

Table 24 Classification Concerning General Safety

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

For additional information regarding testing and classification, refer to the *HeartMate II Operating Manual* (document #103878).

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