

HeartMate II® LVAS Clinical Operation & Patient Management

Abbreviated and extracted from the HeartMate II® LVAS Operating Manual

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Table of Contents

INTRODUCTION.....	1	HANDLING EMERGENCIES.....	37
Program Description.....	1	Defibrillation/Cardioversion.....	37
Program Objective.....	1	Cardiac Arrest.....	38
Learning Objectives.....	1		
SYSTEM OVERVIEW.....	2	PATIENT MANAGEMENT.....	39
Description.....	2	Patient Assessment.....	39
Warnings & Precautions.....	2	Potential Risks & Adverse Events.....	39
		Potential Late	
		Post-Implant Complications.....	39
SYSTEM COMPONENTS.....	6	Caring for the Exit Site.....	40
HeartMate II LVAD or “Blood Pump”.....	6	Caring for the Percutaneous Lead.....	40
How the Pump Works.....	6	Controlling Infection.....	41
· Pump Parameters.....	9	Measuring Blood Pressure.....	41
· Flow.....	9	Anticoagulation.....	41
· Power.....	9	Activities of Daily Living.....	41
· Pulsatility Index (PI).....	9	· Sleeping.....	43
· Operating Mode.....	10	· Showering.....	44
PERIPHERAL COMPONENTS.....	11	THORATEC RESOURCES.....	45
System Controller.....	11	Thoratec HeartLine™.....	45
Power Base Unit (PBU).....	13	Published Reference Materials.....	45
Batteries & Battery Clips.....	15		
Emergency Power Pack (EPP).....	18	POST TEST.....	46
System Monitor.....	18		
Display Module.....	26	COMPETENCY ASSESSMENT	
		CHECKLIST.....	49
ALARM CONDITIONS.....	27	PROGRAM EVALUATION.....	50
ROUTINE OPERATING		NOTES.....	51
PROCEDURES.....	28		
Changing from PBU to Battery-			
Powered (Untethered) Operation.....	28		
Changing from Batteries to PBU			
(Tethered) Operation.....	30		
Changing Batteries.....	32		
Performing a System Controller			
Self Test.....	33		
Changing the System Controller			
Battery Module.....	34		
Replacing System Controllers.....	35		

Introduction

Program Description

This inservice program reviews the theory of operation, function, components, diagnostic monitoring, and related nursing management for the HeartMate II® Left Ventricular Assist System (LVAS).

Program Objective

The primary objective of this inservice program is to supplement on-site educational programs. It is designed to help prepare clinicians for assuming care of patients implanted with the HeartMate II LVAS.

Learning Objectives

After completing this program, participants should be able to:

- 1** Identify the components of the HeartMate II LVAS, their functions, and the theory of device operation.
- 2** List two potential complications associated with a HeartMate II LVAS.
- 3** Identify the purpose and function of each button and symbol on the HeartMate II LVAS System Controller.
- 4** Describe the procedure for changing a HeartMate II System Controller.
- 5** Describe appropriate interventions in the event of an emergency.

System Overview

Description

The HeartMate II is a left ventricular assist system (LVAS) consisting of a blood pump, external System Controller, and external power supply components (**Figure 1**). The HeartMate II is implanted just below the heart. The flexible inflow conduit is attached to the apex of the left ventricle and the outflow graft is attached to the ascending aorta. The HeartMate II pumps blood from the weakened left ventricle to the aorta. Both the inflow conduit and outflow elbow feature textured blood-contacting surfaces clinically proven on the HeartMate XVE to be thrombo-resistant.

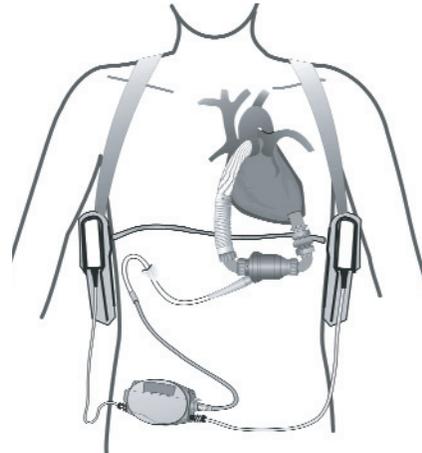


Figure 1 Implanted and worn components of the HeartMate II LVAS (shown using battery power for untethered operation).

Warnings and Precautions

General Warnings

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product.
- Keep the Power Base Unit (PBU) away from water. If the PBU has contact with water, shower spray, or wet surfaces, the pump may stop, or the patient may receive a serious electrical shock.
- Do NOT use the PBU in the presence of flammable anesthetic agents or an explosion could occur.
- Connect the PBU and any peripheral devices only to properly tested, grounded and dedicated AC outlets. Do NOT use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.
- Do NOT connect the PBU to an outlet controlled by a wall switch or the PBU may be left inoperable.
- Do NOT use this device in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus will dislodge the pump, which may result in device failure or fatal hemorrhage. In addition, anti-coagulation regimens are contraindicated during pregnancy.
- Do NOT subject patients implanted with the HeartMate II LVAS to Magnetic

Resonance Imaging (MRI), as the pump contains ferro-magnetic components, and MRI could cause device failure or patient injury.

- Do NOT apply high power electrical treatment (e.g., application of diathermy) directly to the patient.
- Disconnecting the HeartMate II LVAS from the System Controller is advised during open heart defibrillation due to the proximity of the paddles to the device. However, the LVAS should NOT be disconnected during *external* defibrillation.
- The implanted components of the LVAS should NOT be exposed to therapeutic levels of ultrasound energy (e.g., ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissues, as the device may inadvertently concentrate the ultrasound field and cause harm to the patient. This does NOT apply to diagnostic techniques, such as echocardiography.
- Therapeutic ionizing radiation may damage the device, which may not be immediately detectable.
- Avoid strong static discharges (e.g., from touching television or computer monitor screens, vacuuming carpets, etc.) as this can damage the electrical parts of the system and cause the LVAD to stop.
- To prevent device damage and personal injury, refer servicing to authorized service personnel trained by Thoratec corporation.

Warnings Specific to Patient or System Management

- System components must never be immersed in water or liquid. Showers and washing are permitted when the clinician approves wound site readiness. During showers, the HeartMate Shower Kit must be used.
- In the event that the LVAD stops operating, attempt to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted. There is also the potential for retrograde flow within the LVAD.
- Disconnecting both System Controller power leads at the same time will result in loss of pump function. One System Controller power lead must be connected to a power source (i.e., batteries, PBU, 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 PBU when operating on PBU power.
 - Removing both batteries from their respective battery clips when operating on battery power.
 - Completely depleting all battery charge when operating on battery power.
- Disconnecting the percutaneous lead from the System Controller will result in loss of pump function. The System Controller must be reconnected as quickly as possible to resume pump function:

- **For pump speeds <8,000** (typical at time of device implantation), reconnect the System Controller and then firmly press the Silence Alarm or Test Select button as quickly as possible to resume pump function.
- **For pump speeds \geq 8,000** (typical post implant), reconnect the System Controller as quickly as possible to resume pump function. The pump should automatically resume pumping once power is restored.

General Precautions

- Refer to the *HeartMate II LVAS Instructions for Use* and the *HeartMate II LVAS Operating Manual* for detailed instructions and information on device implant and system setup, function, and maintenance. These manuals are not intended to replace comprehensive laboratory or educational programs, or to supercede appropriate medical judgment, however.
- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombus on the valves when supported with left ventricular assist devices.
- Only use Thoratec Corporation's PBU to charge batteries. Other battery chargers may damage HeartMate batteries.
- Do NOT use batteries below 15°F (-10°C) or above 105°F (40°C) or they may fail suddenly. If batteries are below room temperature (68-72°F, 20-23°C) during use, their capacity will be reduced. At the low end of the temperature range (15°, -10°C), run time will be reduced by 50%.
- Use of expired or defective batteries may result in reduced operating time or abrupt loss of pump function.
- Dispose of expired, used, or damaged batteries according to local, state or federal regulations. Do not incinerate.
- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the PBU may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient:
 - Confirm that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.
 - Use only those devices necessary for patient safety and well-being.
- Do not store or use the Emergency Power Pack (EPP) below 32°F (0°C) or above 122°F (50°C) or it may fail suddenly. If the EPP is below room temperature (68-72°F, 20-23°C) during use, it will run the pump for less than 10 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 an expired, used, or damaged EPP according to local, state or fed-

eral guidelines. Do not incinerate.

- Avoid unnecessary pulling or moving of the external portion of the percutaneous lead, especially as the exit site is healing. Pulling on or moving the lead 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.
- Immobilize the external portion of the percutaneous lead at the exit site using the HeartMate Stabilization belt. Immobilizing the percutaneous lead promotes tissue ingrowth and exit site healing, which reduces the risk of exit site infection. The Stabilization Belt should be worn AT ALL TIMES.
- Connectors should be kept clean and dry. Do NOT expose connectors to water/liquid when making or breaking connections.
- Avoid discharging static electricity to the System Controller or LVAD percutaneous lead.
- Never use tools to tighten connections. Hand tighten only. Using tools may damage the connectors and cause the pump to stop.

Precautions Specific to Patient or System Management

- Diligent care throughout the course of LVAS 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 not sufficient for auscultation, Doppler or invasive blood pressure monitoring may be required.
- 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 preload to the LVAD.
- An ECG may be indicated to rule out fibrillation if a patient complains of feeling "different".
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction.
- Physiological factors that affect preload to 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.
- When connecting leads, do NOT force together connectors without initial proper alignment. Forcing together misaligned connectors may damage them.
- At least one set of fully-charged spare batteries and a backup System Controller that has been programmed with the patient's settings must remain with the patient at all times for use in an emergency.

System Components

HeartMate II system components include the implantable Left Ventricular Assist Device (LVAD) or “blood pump” with its percutaneous lead, as well as the following external peripheral components:

- System Controller
- Power Base Unit (PBU) and PBU cable
- Batteries and battery clips
- Emergency Power Pack (EPP)
- System Monitor
- Display Module

Note: The following is only an overview of major system components. Refer to the *HeartMate II LVAS Operating Manual* for complete information.

HeartMate II LVAD or “Blood Pump”

The HeartMate II left ventricular assist device (LVAD) or “blood pump” is a continuous flow rotary LVAD (**Figure 2**). The LVAD has only one moving part, a small spinning rotor that receives power from the System Controller. Vanes on the spinning rotor move blood through the pump, which is capable of providing flow from 3 to 10 liters per minute (lpm). The following pump components that come in contact with the blood have a smooth, polished titanium surface: pump rotor, stators, and pump chamber. The pump’s inlet cannula, inlet elbow, and outlet elbow have textured surfaces.

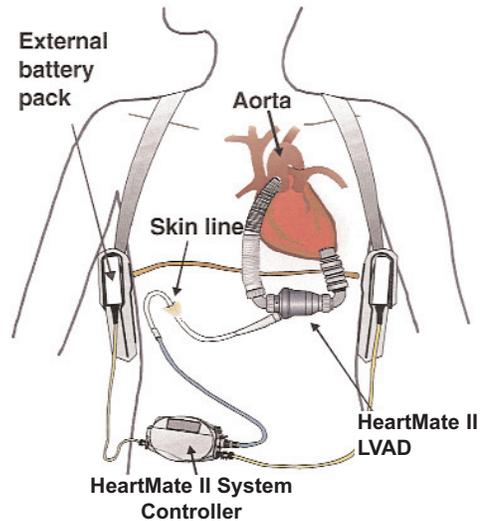


Figure 2 Implanted & worn components of the HeartMate II LVAS

The HeartMate II’s patented ball-and-cup bearings are designed for long term reliability and minimal blood damage. There are no valves in the HeartMate II.

The implanted pump lies parallel to the diaphragm in a sub-diaphragmatic position. It may be implanted preperitoneally or intra-abdominally.

How the Pump Works

Blood flow through the HeartMate II LVAD follows the native cardiac cycle and will vary during diastole and systole. Therefore, the HeartMate II LVAD is essentially synchronized with the mechanical activity of the native heart and follows the Frank

Starling Curve.

The amount of flow generated by the pump is determined by the pump speed and by the pressure gradient that exists across the pump. “Pressure gradient” is defined as the difference between the pressure at the pump outlet and pump inlet.

For a specified pump speed, flow varies inversely with pressure across the pump. Therefore, increasing pump pressure differential (gradient) decreases flow, and decreasing pump pressure differential increases flow. Hence, the dynamic parameter that determines pump differential pressure is left ventricular pressure, which is dependent upon the contractile state of the ventricle.

The simulated monitor tracings (**Figure 3**) show the ventricular and aortic pressures of a patient:

- The blue waveform represents the pressure at the pump inlet, which is the left ventricular or LV pressure.
- The red waveform represents the pressure at the pump outlet, which is the aortic pressure.
- The difference between these two pressures, indicated by the vertical yellow bar, is the pressure difference across the pump. This difference varies over the cardiac cycle, with the largest pressure difference occurring in ventricular diastole and the smallest pressure difference occurring during ventricular systole.

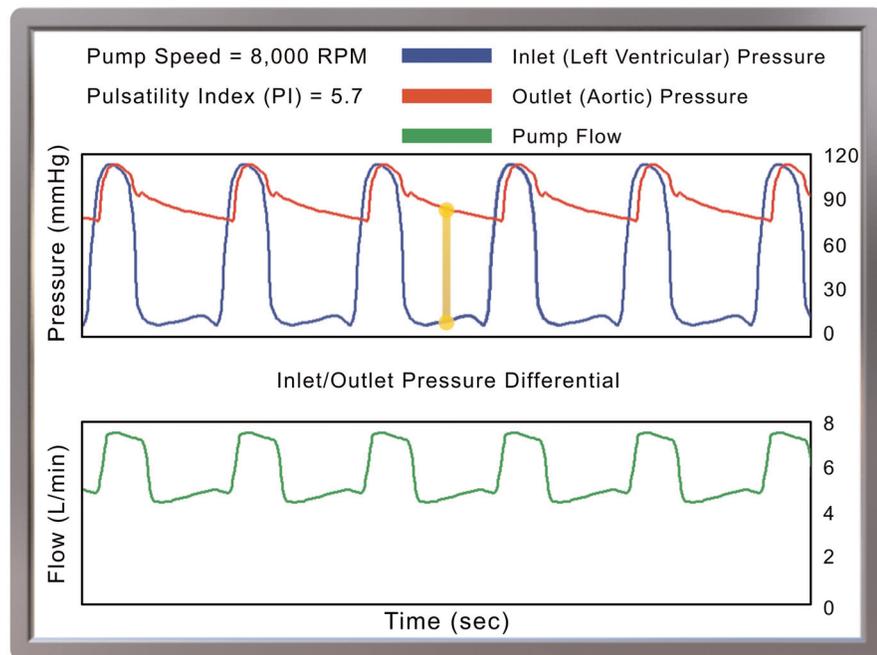


Figure 3 Tracings showing ventricular and aortic pressures

For a given pump speed, in this case 8,000 rpm, the differential pressure defines what the flow through the pump will be at any given moment.

In other words, during cardiac systole the blue waveform (LV pressure) rises and is essentially identical to the red waveform (aortic pressure), which results in a decrease in the differential pressure (gradient) and increased pump flow. As the pump inlet and outlet pressures become more equalized, it becomes easier for the pump to propel blood forward. The reverse is true during diastole at the same pump speed, where the blue waveform (inlet pressure) and red waveform (outlet pressure) separate, shown by the yellow bar. When this occurs, the differential pressure rises and the pump must overcome this increased pressure difference between LV and aortic pressure in order to propel blood forward; therefore flow decreases.

As pump speed increases, the aortic tracing and flow through the pump becomes less pulsatile as demonstrated in the tracings below (Figure 4a and 4b).

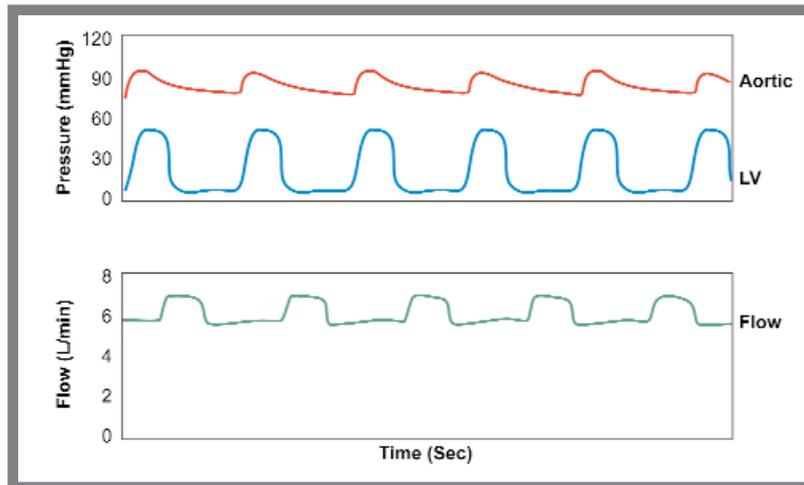


Figure 4a Aortic tracing and flow through pump at pump speed of 9,000 rpm and pulsatility index (PI) of 2.4

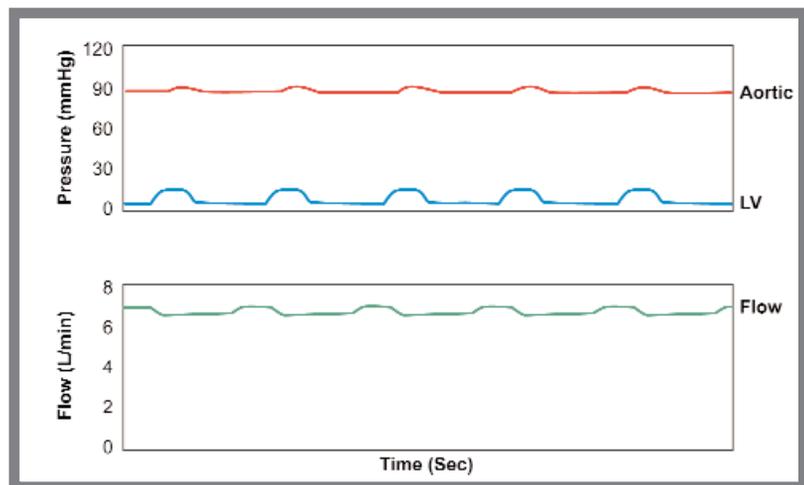


Figure 4b Decreased pulsatility (PI 0.4) when pump speed is increased to 10,000 rpm

Pump Parameters

The system-provided parameters of speed, power, flow, and pulsatility index (PI), in conjunction with echocardiography, serve as the primary indicators of device function. Once baseline values representing a satisfactory level of patient support are established, the degree of change in a parameter usually has more clinical significance than its absolute value. No single parameter is a surrogate for monitoring the clinical status of the patient, and changes in all parameters should be considered when assessing a situation.

Flow

Flow is directly related to speed and power. As the fixed speed is increased, flow will increase. Pump flow is not directly measured but is an estimated value based on pump power. Any increase in power will result in an increase in estimated flow. Any condition that causes an increase in pump power not related to increase flow, such as thrombus on the bearings or obstruction of the rotor, will display an erroneously high flow.

Power

The amount of power used by the pump is determined by pump speed and blood flow through the pump. Under normal conditions, the power increases with either pump speed or flow. Gradual power increases (over hours or days) may signal a deposition of thrombus inside the pump. Depending on the speed, power values greater than 10 to 20 watts may also indicate the presence of a thrombus. Abrupt changes in power, more than 2 watts, not accompanied by a change in pump speed should also be evaluated.

Pulsatility Index (PI)

The pulse index, or "PI," is a measure of the magnitude of the flow pulse through the pump during the cardiac cycle. It is measured and averaged over a 15-second interval and displayed on the monitor.

$$PI = \frac{\text{Max Flow} - \text{Min Flow}}{\text{Average Flow}} \times 10$$

Factors that affect PI are LV preload or contractility and pump speed. When preload increases in the native left ventricle, the Starling Curve is affected (i.e., increased contractility) and pulsatility increases. When preload decreases, PI decreases. Pump speed is inversely related to PI. As pump speed is increased, the LV is unloaded with a decrease in preload, resulting in a lower PI value. Conversely, decreasing pump speed increases LV preload, resulting in a higher PI value.

Note: Even a severely depressed heart has some residual rhythmic contraction; and, any contraction will create a pressure pulse. Thus, under most circumstances, systemic flow is pulsatile. It takes a completely flaccid heart or one in fibrillation to have no ventricular contribution to the pulse at all.

Operating Mode

The System Controller has a single primary operating mode, called fixed speed mode, which maintains operation at a constant pump speed between 6,000 and 15,000 rpm. The typical range is 8,000 to 10,000 rpms. Pump speed is adjustable in increments of 200 rpm. Adjustments can only be made through the System Monitor.

Peripheral Components

System Controller

The HeartMate II System Controller (**Figure 5**) controls LVAD operation and serves as the primary user interface of the HeartMate II LVAS.

The System Controller performs the following functions:

- Controls motor power and speed.
- Provides redundant system operation.
- Monitors, interprets, and responds to system performance.
- Performs diagnostic monitoring.
- Provides hazard and advisory alarms.
- Records and stores events in memory.
- Transfers system performance data to the System Monitor or Display Module.

The System Controller contains two computer boards. One provides primary system operation and the other provides complete backup system operation in the event the primary system malfunctions.

The System Controller has two power leads (one with a black connector and one with a white connector) that connect the System Controller to its power source. While both leads provide equal power, the white lead contains a data link cable that transmits information from the System Controller to the System Monitor or Display Module during tethered operation. A battery inserted into the side of the Controller, called the System Controller alarm battery module, provides limited power to the System Controller's audible alarms during situations when external power has been disrupted. The System Controller alarm battery module does not provide backup power to the System Controller or pump

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



Figure 5 HeartMate II LVAS System Controller with Leads (note black and white connectors)

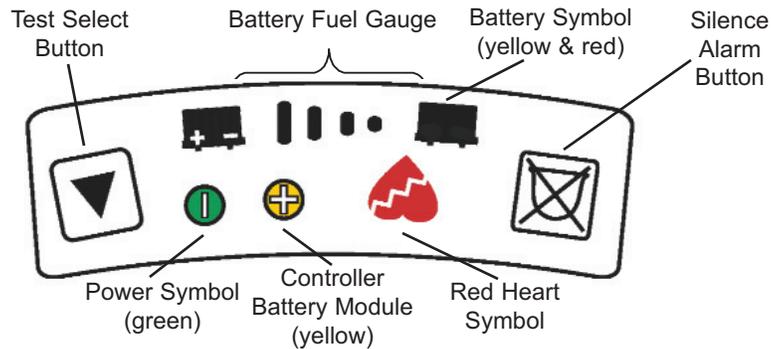


Figure 6 System Controller Keypad

The System Controller keypad (**Figure 6**) has a Silence Alarm button and a Test Select button, both of which can be used to interact with the system. Either button can be pressed and held for two seconds to restart the pump if the System Controller does not automatically do so (for instance, if the percutaneous lead and/or power leads are disconnected from the the System Controller and the fixed speed setting is below 8,000 rpm). These two buttons can also be used to force the System Controller into backup system operation by pressing both simultaneously when the pump is off or not connected to the Controller. The Silence Alarm and Test Select buttons are described in more detail below.

Silence Alarm Button

The Silence Alarm button has two main purposes: to display the battery fuel gauge and to silence audio alarms. An audio alarm is silenced for two minutes if a hazard condition or Power Cable Disconnected advisory is active; and, for four hours if general advisories are active. If the alarm condition resolves within this period, the alarm will not recur. While the audio alarm is silenced, the respective alarm symbol(s) flash(es) as a reminder that the alarm condition remains active.

When the patient is tethered to the PBU, the PBU repeats (duplicates) a System Controller audible alarm. This second alarm can be silenced for five minutes using the Alarm Reset button on the PBU front panel; or, to silence both the Controller and the PBU, press the Silence Alarm button on the System Controller or System Monitor screen.

Repeated attempts to prolong the silence period by pushing the Silence Alarm button will not add time to the silence period. Any new hazard or advisory alarm conditions arising during the four hour silence period will initiate a new visual and audio alarm. Only a new hazard alarm condition arising during a two minute silence period will initiate a new audio alarm. Audible advisory alarms will not occur until the hazard or power cable disconnected alarm has been resolved.

Test Select Button

The Test Select button is used to initiate a system controller self-test. The self-test

should be performed daily. Refer to *Performing a System Controller Self Test* located on page 33 for instructions .

System Controller Event Recorder

The System Controller event recorder automatically captures data when an alarm event occurs.

The System Controller data logger can be set up via the System Monitor Save Data Screen to record data at designated intervals of 30 minutes, or hourly from one to 24 hours. The Controller can record up to 120 events, which includes events that occur during alarm conditions and at pre-set intervals.

Power Base Unit (PBU)

The Power Base Unit (PBU) (Figure 7) provides AC power to the LVAD when the patient is connected to it via the 20-foot PBU cable; this is referred to as tethered operation. The PBU can charge up to six batteries in eight hours or less, depending on the charge status of the batteries. Battery charging can occur simultaneously with tethered operation.

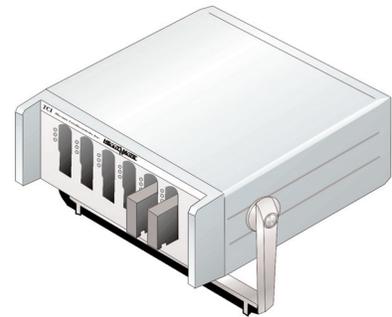


Figure 7 Power Base Unit (PBU) Front Panel

The PBU has six battery charging stations; each station has three charge indicator lights that indicate a battery’s charge status. To charge or test a battery, slide the battery into the slot with its metal terminal facing up. When the battery is in place, the yellow light will illuminate while the PBU performs a 10-second load test. After testing, one of three lights will illuminate to indicate the status of that battery (see Table 1).

Battery Charge Indicators

	<p>Green</p>	<p>Battery is fully-charged and ready for use. Note: Battery will not be damaged if left in the PBU after becoming fully-charged.</p>
	<p>Yellow</p>	<p>Ten-second load test is being performed. Note: If light remains yellow after test, battery is being charged and thus is not yet ready for use. The light will turn green once the battery becomes fully-charged (see above).</p>
	<p>Red</p>	<p>Battery may be improperly positioned in slot. Reinsert into same slot to attempt second test.</p> <p>If the battery fails the second test, remove the battery and clean the battery terminal with a lint-free cloth that has been moistened with rubbing alcohol. Allow the alcohol to dry, then reinsert the battery into a different slot.</p> <p>If it fails again, battery is defective and should be replaced. Do NOT use defective batteries.</p> <p>Note: If battery shows red light in one slot but yellow or green in another slot, consult Thoratec’s Field Service Department.</p>

Table 1 Battery Load Test Status

The patient should be connected to the PBU when sleeping or anticipating sleep. The PBU also echoes (duplicates) alarms that are generated by the System Controller. **Note:** The PBU, like any piece of electrically-powered life-sustaining equipment, should remain continually plugged into a properly-grounded (3-prong) AC mains electrical outlet, except during transport or service.

Power Base Unit (PBU) Alarms

AC FAIL Alarm

In the event of AC mains power failure, the PBU's AC Fail alarm will activate. The AC Fail alarm is indicated by the illumination of a RED LIGHT on the PBU's front panel (**Figure 8**) accompanied by a CONTINUOUS AUDIO TONE. In response to this condition, the PBU will automatically revert to its internal backup battery to power the LVAD for approximately 30 minutes and the patient should promptly switch from tethered (PBU-powered) operation to battery-powered or EPP operation until AC power is restored.

Note: Batteries in the PBU battery charging slots will not lose their charge during AC mains power failure; however, neither will they continue to charge during this time.

Pressing the Alarm Reset switch below the RED LIGHT on the PBU will silence the AC Fail alarm until the low battery alarm is activated.

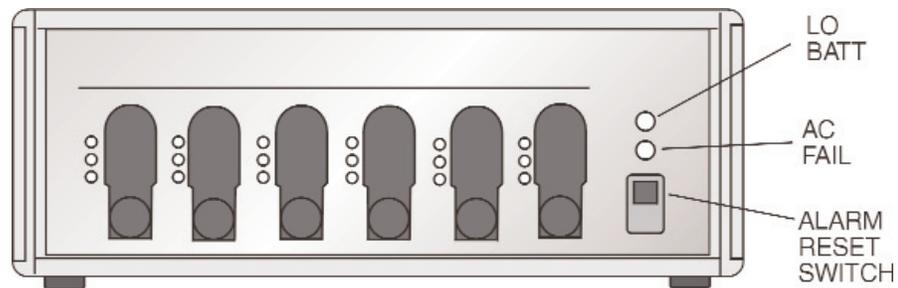


Figure 8 Power Base Unit (PBU) Front Panel

Lo Batt Alarm

When the internal backup battery in the PBU has 10 minutes of battery power remaining, the PBU's low battery alarm (ie, "Lo Batt" Alarm) will activate. The Lo Batt Alarm is represented by a RED LIGHT and a CONTINUOUS AUDIO TONE.

When the System Controller power leads are connected to the PBU cable and the LVAD is operating in tethered operation this alarm cannot be silenced. It will continue until AC power has been restored to the PBU, the internal battery is completely depleted, or the patient is switched to batteries. In response to this condition, the patient should be changed immediately from tethered operation (PBU-powered) to battery-powered operation.

Note: PBUs are shipped to customers with the internal battery disconnected.

Upon receipt of the PBU, the hospital's biomedical technician or other authorized and trained personnel must open the PBU and connect its internal battery prior to set up and use. To confirm that the PBU's internal battery has been installed and properly charged, turn off the PBU power switch or unplug the PBU power cord from the socket and verify that the AC fail alarm sounds for longer than 10 seconds and that the AC fail LED light is illuminated.

Batteries & Battery Clips

Batteries

A pair of wearable, rechargeable HeartMate batteries (**Figure 9**) will power the HeartMate II LVAD for approximately 3-5 hours, depending on the charge status of the batteries and the hemodynamic condition of the patient. Round Velcro® indicators are supplied with each battery to designate a battery's charge status. For example, when a battery is fully charged, place the indicator on the battery white-side-up; when it's depleted, turn over the indicator and place it black-side-up (**Figure 9**).

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

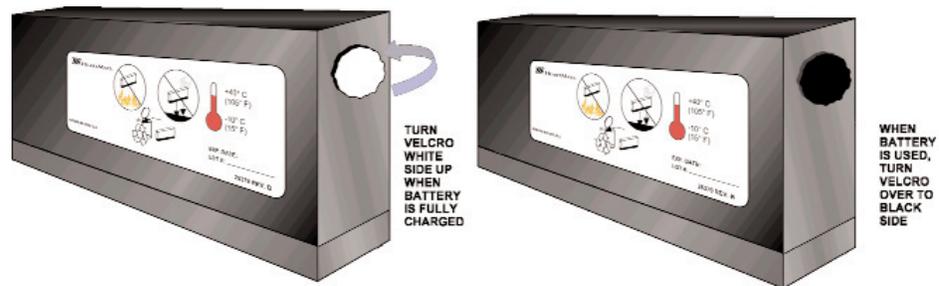


Figure 9 HeartMate Batteries with Charge Status Indicators

WARNING ! There are no backups for this system. In the event that the LVAD stops operating, all attempts should be made to restore pump function immediately. Loss of power will cause the LVAD to stop and blood pumping to cease. Power must be restored immediately. In the event that the LVAD stops operating, retrograde flow may occur; and, if non-circulating blood is in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted.

To minimize deterioration or damage to batteries:

- Do NOT drop or subject batteries to strong physical shock.
- Do NOT leave or store batteries in hot areas or battery life will be shortened.
- Do NOT use batteries in temperatures below 15°F (-10°C) or above 105°F (40°C) or they may suddenly fail.
- Do NOT connect the negative and positive battery terminals.
- Recharge used batteries within 12 hours or battery life may be shortened.

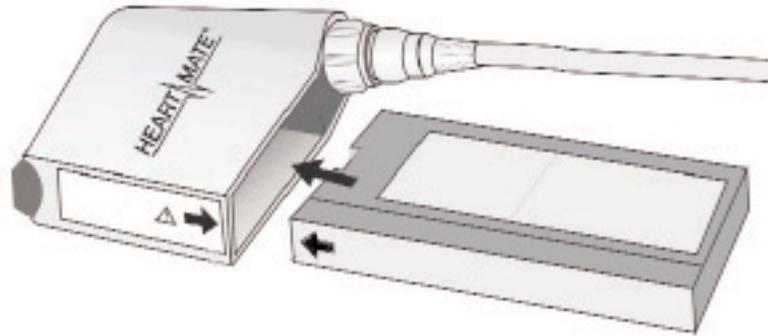


Figure 10 Battery Clip and Battery

Battery Clips

Before connecting the batteries to the System Controller, each battery must be inserted into a HeartMate battery clip (**Figure 10**). **Note:** Battery clips have an electrical connection for attaching the Controller power leads. One battery is inserted into each clip (match black arrow on battery with black arrow on clip). The battery clicks into place when properly inserted. Press the spring-loaded release button to release a battery from its clip.

NEVER disconnect both leads from batteries at the same time, or the pump will stop. This could result in serious patient injury or death. After reconnecting power, the pump will automatically restart if the fixed speed setting is at least 8,000 rpm. If the fixed speed setting is below 8,000 rpm, you must press and hold the Silence Alarm or Test Select button for a count of two in order to restart the pump. Auscultate over the LVAD pocket to verify that the pump is running.

Cleaning Battery and Battery Clip Terminals

Dirty battery terminals may prevent proper battery charging, which can affect battery operation. The metal terminals on the batteries and inside the battery clips should be cleaned at least once a week with a Q-Tip™ or lint-free cloth that has been dipped in rubbing alcohol (**Figure 11**). Allow the alcohol to dry before using the batteries or clips, or before placing batteries into PBU battery charging slots.

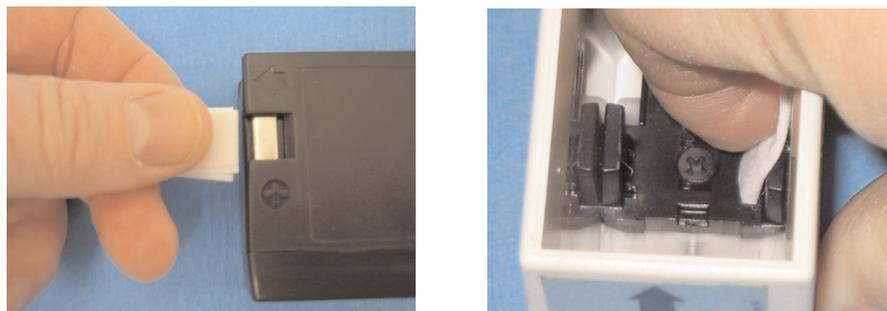


Figure 11 Cleaning Metal Battery Contacts and Metal Contacts inside a Battery Clip.

Battery Fuel Gauge

The HeartMate II System Controller has a set of indicator lights, collectively called the Battery Fuel Gauge . The Battery Fuel Gauge provides an approximate measure of available battery power. More lights indicate more battery power; fewer lights indicate less battery power (see **Table 2** below).

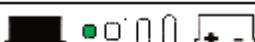
Battery Fuel Gauge	Meaning	Response
 <p>4 Green Lights</p>	75-100% of battery power remains.	No action needed.
 <p>3 Green Lights</p>	50-75% of battery power remains.	No action needed.
 <p>2 Green Lights</p>	25-50% of battery power remains.	No action needed.
 <p>1 Green Light</p>	Less than 25% of battery power remains.	Replace depleted batteries with fully-charged set or switch to PBU.

Table 2 Battery Fuel Gauge Summary

To activate the Battery Fuel Gauge, press and hold the Silence Alarm button on the System Controller keypad. Batteries should be changed when the battery fuel gauge indicates 25% of power remains (one green light).

Battery Advisories and Alarms

Yellow Battery Advisory

An illuminated YELLOW BATTERY symbol accompanied by a BEEP every four seconds means that less than 15 minutes of battery power remains.

Action: Change batteries or switch to alternate power source (ie, PBU or EPP).

Red Battery Alarm

An illuminated RED BATTERY symbol and CONTINUOUS AUDIO TONE means that less than 5 minutes of battery power remains. When this condition arises, the LVAD automatically defaults to Power Saver Mode, gradually decreasing the pump speed to 8,000 rpm. If, however, the previously selected speed is lower than 8,000 rpm, the pump will remain at the low speed setting. **Note:** Patient's may become symptomatic due to the drop in pump speed. The LVAS will remain in Power Saver Mode until fully-charged batteries are installed, the PBU is connected, or until no further power remains. Therefore, the RED BATTERY hazard alarm prompts for an immediate response; an alternate power source must be initiated. When the alarm condition clears, the LVAD will revert to the previous fixed speed.

Action: Change batteries immediately or switch to alternate power source (ie, PBU or EPP).

Emergency Power Pack (EPP)

The Emergency Power Pack (EPP) (Figure 12) is an optional, single-use power source enclosed in a plastic carrying case. It has a shoulder strap to make handling and carrying easier. The EPP may be used to power the LVAD during an emergency or during an extended power outage. The EPP provides approximately 12 hours of power to the LVAD, depending upon pump speed, flow, and afterload.

Note: The EPP is NOT rechargeable and must be replaced if used for a period exceeding three hours. See the instructions for use inside the top flap of the EPP for more information.



Figure 12 Emergency Power Pack (EPP)

System Monitor

The System Monitor (Figures 13a and 13b) communicates with the System Controller via the PBU to monitor and record pump and system status. It is used to adjust system parameters to maintain optimal pump performance, assess and track alarm conditions, view and save performance data, and record data at specific intervals to the data card during tethered operation.



Figure 13a System Monitor II (newer model)



Figure 13b System Monitor I (older model)

Note: Both newer and older models of the System Monitor work with either the HeartMate II LVAS or the HeartMate XVE LVAS. To tell if a System Monitor has been upgraded for HeartMate II, reference the HeartMate logo screen. Older models of the System Monitor will display software “version 3.0” or higher on the HeartMate

logo screen; newer models will display “version 6.10” or higher.

The System Monitor has six user interface screens that can be accessed by touching the indicated tab:

- 1) Clinical Screen
- 2) Settings Screen
- 3) Alarms Screen
- 4) Save Data Screen
- 5) History Screen
- 6) Admin (i.e., Administration) Screen

A flashing communication icon  is displayed at the lower left corner of all System Monitor screens to indicate active communication between the System Controller and the System Monitor. Screen features and functions are described below.

Note: All commands require validation by pressing the appropriate key. For example, “enter,” “cancel,” “save changes,” etc.

Clinical Screen

The Clinical Screen (**Figure 14**) is the default screen. It displays the primary operating parameters. The System Monitor automatically returns to the Clinical Screen should there be 60 seconds of inactivity on any other screen.

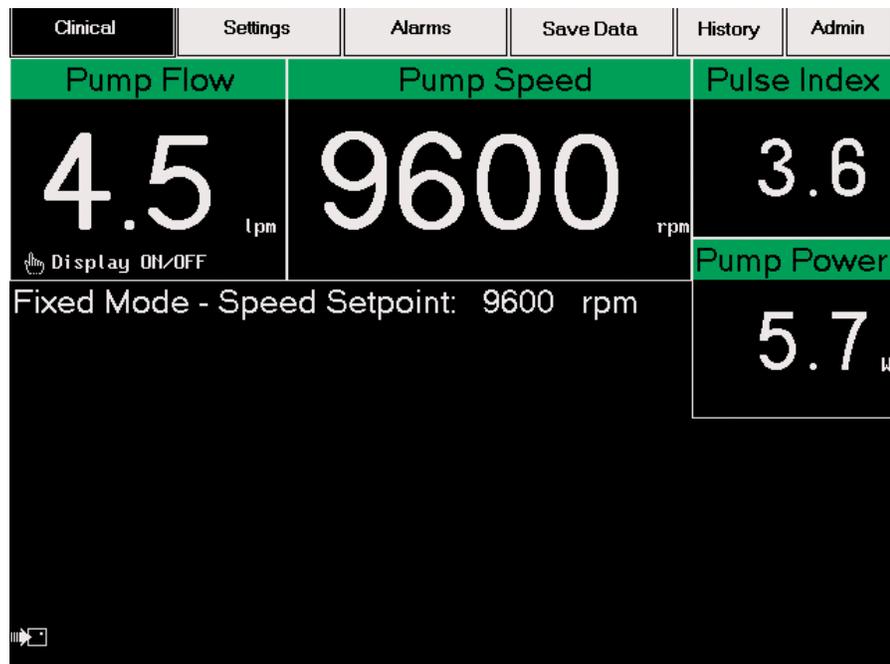


Figure 14 Sample Clinical Screen

The Clinical Screen contains:

Parameter Boxes

Four boxes at the top of the screen report measured values of the pump flow, pump speed, pulsatility index (abbreviated on screen as “Pulse Index”), and pump power.

Operating Mode and Speed Setpoint

The operating mode and speed setpoint are displayed below the parameter boxes.

Active Alarm Messages

The two highest active alarm messages appear as text banners below the operating mode. If more than two alarms are occurring simultaneously, a “+” will appear at the end of the second alarm banner, indicating that additional alarms are active.

Command Buttons (that appear during certain conditions)

- The Pump Start button appears when the pump is stopped or disconnected from the System Controller. Pressing this button restarts the pump.
- The Silence Alarm button accompanies any active audio alarms. Pressing this button silences hazard alarms and Power Cable Disconnected advisory alarms for two minutes and other advisory alarms for four hours.

Settings Screen

The Settings Screen (**Figure 15**) allows users to monitor system parameters, change speed settings, and manually stop or start the pump.



Figure 15 Sample Settings Screen

The Settings Screen contains:

System Status Boxes

Various system parameters are displayed in two System Status boxes.

Active Alarm Messages

The two highest active alarm messages appear as text banners below the operating mode. If more than two alarms are occurring simultaneously, a “+” will appear at the end of the second alarm banner, indicating that additional alarms are active.

Command Buttons

- The Fixed Speed Adjust button allows users to increase or decrease the fixed speed in increments of 200 rpm, within a range of 6,000 - 15,000 rpm.
- The Low Speed Limit button allows users to increase or decrease the low speed limit in 200 rpm increments between 8,000 and 10,000 rpm. This is the alarm limit for low speed operation advisory alarm and the speed to which pump speed will decrease when a suction event is detected.
- The Pump Stop/Start button allows users to stop or start the pump in a controlled manner. To stop the pump, press and hold the stop button. A countdown from 15 will begin. Once the Pump Off alarm message appears, the pump stop command has been accepted and the stop button can be released.
- The Silence Alarm button accompanies any active audio alarms. Pressing this button silences hazard alarms and Power Cable Disconnected advisory alarms for two minutes and other advisory alarms for four hours.

Alarms Screen

The Alarms Screen (Figure 16) shows the status of all hazard and advisory alarms.

The Alarms Screen contains:

Alarm Messages

All alarms are displayed in the Alarms box, with hazards listed in the upper portion and advisories listed in the lower portion. Alarms are listed in order of highest priority. Inactive alarms are indicated by “no alarm.” All active alarms are highlighted and indicated by “active.”

Parameters Box

A box below the alarm messages box displays system parameters, hazard time elapsed, and whether the alarm silence is on, off, or extended (see Extended Silence button below).

Command Buttons (that appear only during alarm conditions)

- The Silence Alarm button allows users to silence hazard alarms and power cable disconnected advisory alarms for two minutes and other advisory alarms for four hours. The Silence Alarm button accompanies any active audio alarm.
- The Extended Silence button allows users to silence all hazard alarms and all advisory alarms for four hours. The Extended Silence button accompanies any active audio alarm only when the fixed speed is set below 8,000 rpm (typical during device implant). The extended silence can be cancelled by pressing the Silence Alarm button on the System Controller keypad or by removing all power from the System Controller.



Figure 16 Sample Alarms Screen

Save Data Screen

The Save Data Screen (**Figure 17**) allows users to change the status of and the rate at which events are recorded on the System Monitor data logger and System Controller event recorder. It is also used to save waveforms with motor performance or information stored in the System Controller event recorder to a data card.

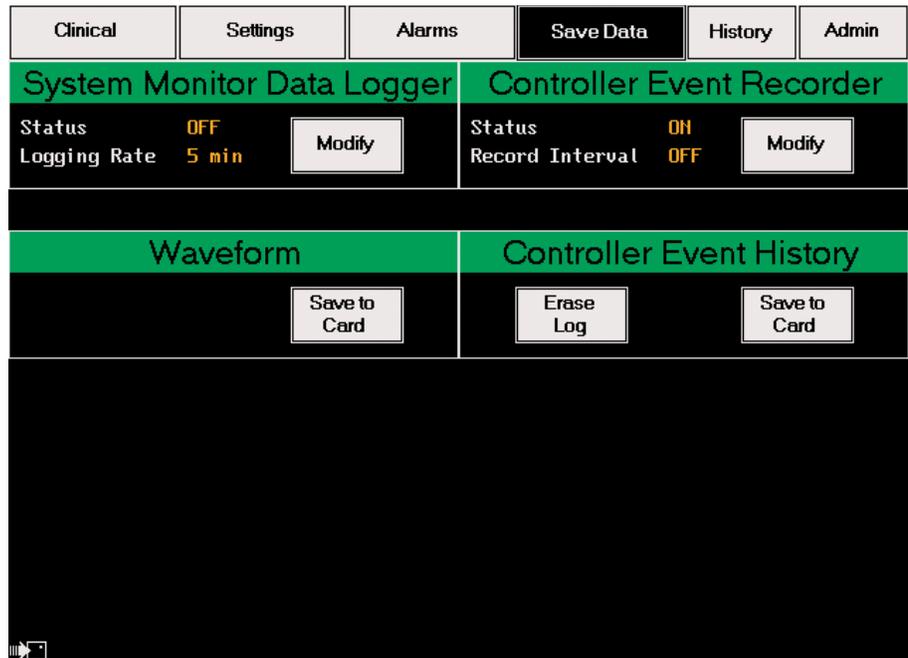


Figure 17 Sample Save Data Screen

The System Monitor data logger collects and stores system performance data at a set time interval directly onto a data card inserted into the side of the System Monitor. The status indicator (**Figure 17**) specifies whether the logging feature is on or off. The logging rate indicator specifies the frequency with which data is collected and stored to the data card. Frequency options are 15 seconds, 30 seconds, and one minute intervals from 1 to 60 minutes. The data logger automatically turns off when the patient is disconnected from the PBU and must be turned back on when the patient is reconnected.

The System Controller event recorder is a feature built into the System Controller that allows performance data to be collected and stored in the System Controller’s memory. This memory capacity is capable of storing 120 events; and, once it becomes full, the oldest events are deleted as new ones are saved. Events may be recorded in one of two ways:

- 1) **As events occur:** The System Controller will automatically record any alarm or change in fixed speed as it occurs. Therefore, the status indicator in the Controller event recorder box (**Figure 17**) will always specify that the recording feature is on.

- 2) **At a specified record interval:** The System Controller can record data at set time intervals. The record interval indicator specifies the frequency with which information is collected. Frequency options are: off, 0.5 hour, and then hourly increments from one to 24 hours. By default, the record interval is set to off.

History Screen

The History Screen (**Figure 18**) allows users to retrieve and view System Controller event history on the System Monitor. Events are displayed in reverse chronological order, with the most recent events appearing at the top of the screen. An asterisk (*) in the alarm column indicates data recorded as part of a specified record interval.

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

Figure 18 Sample History Screen

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

Occasionally, “Clock Reset” appears in the alarms column. This indicates that all power was removed from the System Controller. Since the System Monitor has no way of knowing how much time elapsed before power was restored, it cannot calculate events recorded prior to the System Controller’s loss of power.

Therefore, events recorded prior to power loss are displayed in terms of the controller’s initial startup. *For example, a day-time of 0d 00:13 means that the System Controller recorded an event 13 minutes after initially receiving power.*

Then, power was lost and some time later restored. Event times after this point are displayed as dates and times.

The History Screen also allows users to save event history to a data card. A maximum of 120 events can be displayed on the History Screen.

Admin Screen

The Admin (i.e., administration) Screen (**Figure 19**) allows users to set the date and time on the System Monitor and to modify the System Monitor's technical parameters. **Note:** Only designated Thoratec personnel can modify technical parameters.

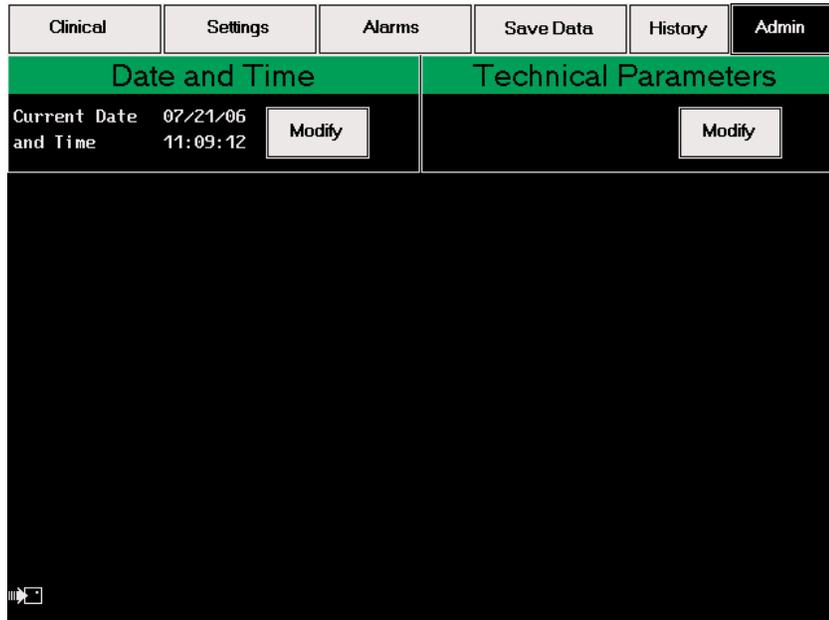


Figure 19 Admin (Administration) Screen

Display Module

When connected to the PBU, the Display Module (**Figure 20**) provides an abbreviated, small-scale display of system performance. The Display Module reports data from the System Controller via the PBU. The Display Module displays current pump mode, speed, and pulse index; as well as pump power and flow data.

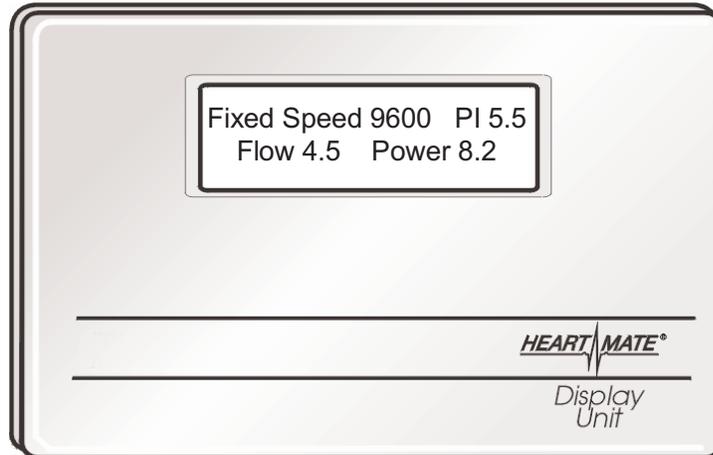


Figure 20 Display Module with Sample Display

When an alarm is active (**Figure 21**), the highest priority alarm message alternates with the pump power and flow information. Hazard alarms appear in upper case letters and advisory alarms appear in lower case.

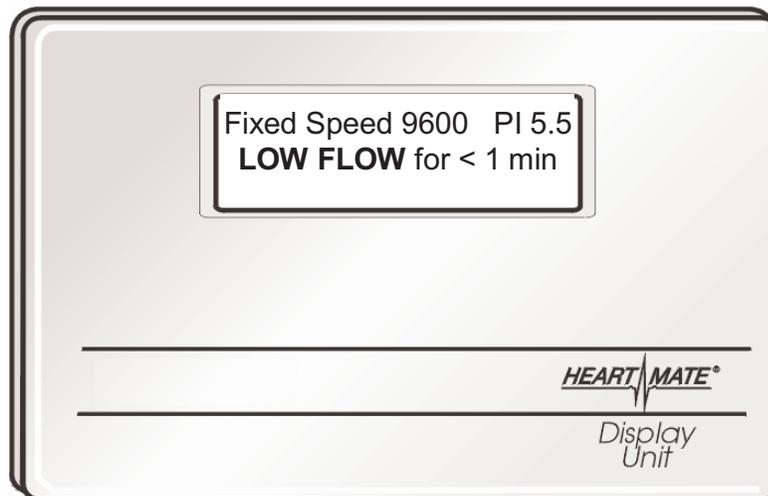


Figure 21 Sample Alarm Message on Display Module Screen

Alarm Conditions

The HeartMate II System Controller diagnoses and generates advisory and hazard alarms. If the patient is connected to the PBU, alarm messages are displayed on the System Monitor or Display Module. A summary of alarm conditions, and appropriate corrective actions are described in **Table 3** below.

Warning Lights	Audio Tone	Alarm Message	Meaning	Action
Red Heart 	Steady Audio Tone	LOW FLOW HAZARD (on Display Module) LOW FLOW, PUMP OFF and/or PUMP DISCONNECTED (on System Monitor)	Pump flow < 2.5 lpm, pump has stopped, per lead is disconnected, or pump is not working properly.	<ol style="list-style-type: none"> 1. Make sure System Controller is connected to the pump. 2. Make sure the System Controller is connected to a power source (batteries, PBU, or EPP). 3. If alarm continues, immediately seek additional help.
NONE: No Warning Light and No Green Power Symbol	Steady Audio Tone	NONE	System Controller is not receiving power.	<ol style="list-style-type: none"> 1. Make sure System Controller is connected to a power source (batteries, PBU, or EPP). 2. If connected and alarm continues, switch to alternate power source. 3. If alarm continues after switching power source, replace System Controller.
Red Battery 	Steady Audio Tone	LOW VOLTAGE	Less than 5 minutes of battery power remain, voltage is too low, or the System Controller is not getting enough power from the PBU.	Immediately replace depleted batteries with new, fully-charged set. Change batteries one at a time . If fully-charged batteries are not available, switch to PBU or EPP. WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop. Note: Pump speed will gradually decrease to "Power Saver Mode" until the condition is resolved and the alarm clears.
Yellow Battery 	1 Beep Every 4 Seconds	Low Voltage Advisory	Less than 15 minutes of battery power remain, voltage is too low, or the System Controller is not getting enough power from the PBU.	Immediately replace depleted batteries with new, fully-charged set. Change batteries one at a time . If fully-charged batteries are not available, switch to PBU or EPP. WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop.
NONE: No Warning Light	Broken Audio Tone (repeating cycle of 1 beep/sec. for 2 seconds, followed by 2 seconds of silence)	REPLACE SYSTEM CONTROLLER (on System Monitor) REPLACE SYSTEM DRIVER (on Display Module)	System Controller is operating on backup system.	<ol style="list-style-type: none"> 1. Replace the System Controller. 2. Notify the patient's physician. 3. Obtain a new backup System Controller. 4. Program the new backup Controller with settings prescribed for this patient.
Yellow Controller Cell 	1 Beep Every 4 Seconds	SC CELL MODULE LOW (on System Monitor) DRIVER CELL LOW (on Display Module)	The battery module that powers the System Controller audible alarm is depleted.	Replace the System Controller Battery Module.
Rapidly Flashing Green Power Symbol  and 4 Green Battery Fuel Gauge Lights  Flashing Once Per Second	1 Beep Every Second	POWER CABLE DISCONNECTED	One of the power leads is damaged or disconnected.	<ol style="list-style-type: none"> 1. Reconnect or tighten disconnected/loose power lead. 2. If alarm continues, check System Controller power lead and PBU power lead for damage. 3. If System Controller power lead or PBU power lead is damaged, replace the Controller and/or replace the PBU cable. 4. Obtain a new backup System Controller for this patient, if necessary.
NONE: No Warning Light	NONE on PBU w/System Monitor 1 Beep Every 4 Seconds when on Batteries or PBU w/Display Module	WARNING: Low Speed Operation	Pump is operating below low speed limit.	Connect System Controller to System Monitor (audio alarm will stop) and increase fixed speed setting or reduce low speed limit.

Routine Operating Procedures

Changing from PBU to Battery-Powered (Untethered) Operation

To change from PBU (tethered) power to battery (untethered) operation:

- 1 Explain procedure to patient.
- 2 Place two battery clips, two fully charged HeartMate batteries, and the white and black PBU cable connectors within easy reach.
- 3 Place the 1st fully-charged battery into a battery clip by aligning the arrows on the battery and clip and pushing the battery into the battery clip until it “clicks” into place (**Figure 22**). Repeat for the 2nd battery/battery clip.

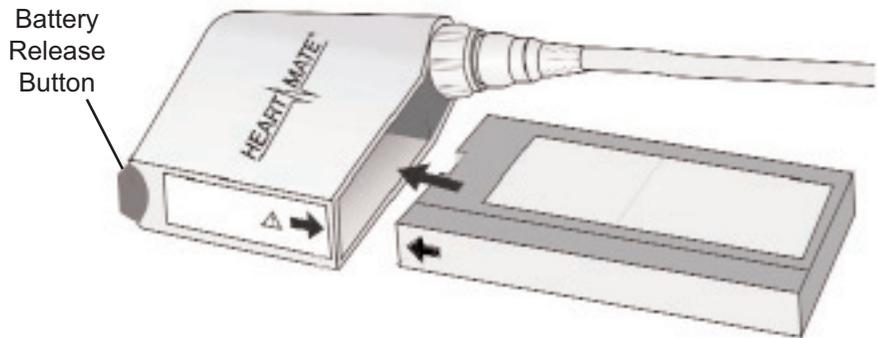


Figure 22 Battery and Battery Clip. Note Location of Release Button on Clip.

- 4 Unscrew the **black** System Controller / PBU cable connector (**Figure 23**).
An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.

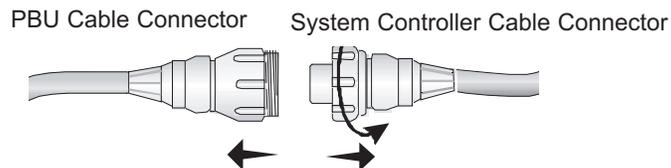


Figure 23 Unscrewing the PBU and System Controller Cables

WARNING ! At least 1 System Controller power lead must be connected to a power source (batteries or PBU) at all times. Disconnecting both power leads at the same time will cause the pump to stop. This could result in serious patient injury or death.

- 5** Put aside the PBU connector then connect the battery clip connector to the **black** System Controller connection by aligning the pins, pushing the connectors together snugly, and then hand tightening the connectors. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops sounding before continuing with Step 6.*

CAUTION !

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

- 6** Unscrew the **white** System Controller/PBU connectors. *An alarm will sound one beep per second, the green power symbol will flash rapidly, and the four green battery fuel gauge lights will come on.*
- 7** Put aside the PBU connector, then connect the battery clip to the **white** System Controller connector by aligning the pins, pushing the connectors together snugly, and then hand tightening the connectors. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops sounding before continuing with Step 8.*
- 8** Turn over the Velcro circles on the batteries from white to black (to show that the batteries will need to be recharged after use), then put the batteries/clips in to the patient's holster or carrying case.
- 9** Store the PBU connectors in a clean, dry location.
- 10** Place at least two fully-charged batteries in the patient's travel case for backup use.

Changing from Batteries to PBU (Tethered Operation)

To change from mobile (battery) operation to tethered (PBU) operation:

- 1 Explain procedure to patient.
- 2 Insure that the PBU is plugged in and turned on and the PBU cable is attached to the "Patient" socket on the back of the PBU (**Figure 24**).

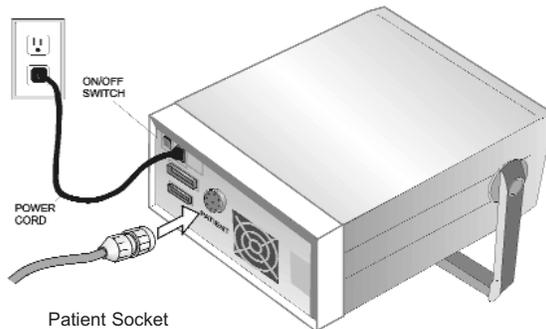


Figure 24 PBU Rear Panel (note Patient Socket)

- 3 Place the black and white PBU connectors within easy reach. **Note:** Periodically inspect the connectors and connector pins to ensure they are not damaged or dirty. Dirty or damaged connectors/connector pins/pin sockets may prevent connection, which can affect performance.
- 4 Remove batteries and battery clips from the patient's holster or carrying case.
- 5 Unscrew the **white** connector from the 1st battery clip.
An alarm will sound one beep per second, the green power symbol  will flash rapidly, and the four green battery fuel gauge lights  will flash.

WARNING ! At least 1 System Controller power lead must be connected to a power source (batteries or PBU) at all times. Disconnecting both power leads at the same time will cause the pump to stop. This could result in serious patient injury or death.

- 6 Connect the **white** PBU cable connector by aligning the pins, pushing the connectors together snugly, and then hand tightening the connectors (**Figure 25**). *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops sounding before continuing with Step 7. **Note:** Always connect connectors of the same color (i.e., white-to-white and black-to-black).*

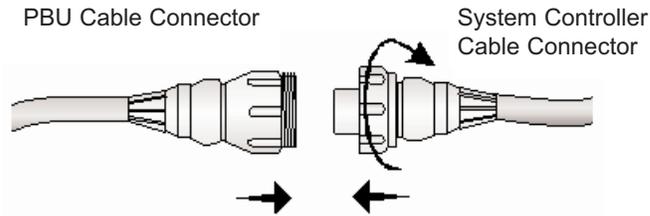


Figure 25 Unscrewing the PBU and System Controller Cables

- 7 Put aside the 1st battery/battery clip.
- 8 Unscrew the **black** connector from the 2nd battery clip. *An alarm will sound one beep per second, the green power symbol will flash rapidly, and the four green battery fuel gauge lights will come on.*
- 9 Put aside the 2nd battery clip.
- 10 Connect the **black** PBU power lead connector to the **black** System Controller connector by aligning the pins, pushing the connectors together snugly, and then hand tightening the connectors (**Figure 26**). *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops sounding before continuing with Step 11.*
- 11 Press the battery release button to remove the 1st battery from its clip (**Figure 27**); repeat for the 2nd battery.
- 12 Verify that the Velcro circles on the batteries are black-side-up. If not, turn them from white to black.
- 13 Place depleted batteries into the PBU for recharging.
- 14 Store battery clips in clean, dry location.

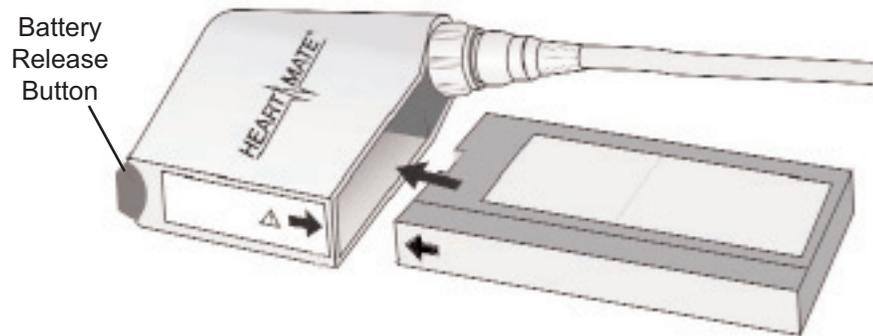


Figure 26 Battery Clip and Battery. Note Battery Release Button.

Changing Batteries

To replace depleted batteries with fully-charged batteries:

- 1 Explain procedure to patient.
- 2 Remove batteries and battery clips from the patient's holsters or carrying case.
- 3 Remove a set of fully-charged spare batteries from the patient's travel case or from the PBU.
- 4 Verify that the Velcro circles on the used batteries are black-side-up. If not, turn them from white to black.
- 5 Remove only one battery from its battery clip by pressing the battery release button (**Figure 26**, previous page).

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

- 6 Align the arrow on the new battery and the arrow on the battery clip (**Figure 26**; previous page).

WARNING ! At least 1 System Controller power lead must be connected to a power source (batteries or PBU) at all times. Disconnecting both power leads at the same time will cause the pump to stop. This could result in serious patient injury or death.

- 7 Slide the new, fully-charged battery into the battery clip until it “clicks” into place. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops sounding before continuing with Step 8.*
- 8 Repeat steps 5 - 7 for the 2nd battery/battery clip.
- 9 Check the Battery Fuel Gauge on the System Controller to ensure that the new batteries are fully-charged.
- 10 Turn over the Velcro circles on the new, fully-charged batteries from white to black, then place the new batteries and clips into the patient's holster or carrying case.
- 11 Place depleted batteries into the PBU for recharging.

Performing a System Controller Self Test

A System Controller self test should be performed daily to ensure that the System Controller's lights and audio tones are working properly. The patient should be connected to the PBU for the test.

- 1 Explain procedure to patient.
- 2 Press and hold the Test Select button on the System Controller keypad (**Figure 27**) for three seconds until all the lights come on and a steady audio tone sounds.

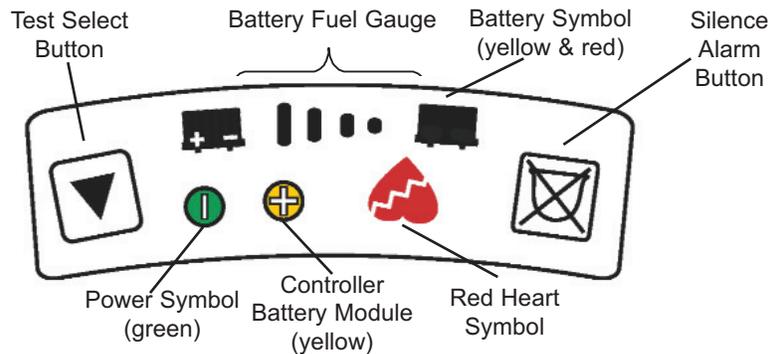


Figure 27 HeartMate II System Controller Keypad.

- 3 Release the Test Select button.
All lights will remain lit and the alarms will continue to sound for 5 seconds.
- 4 If all of the warning lights and alarms operate as described above and then turn off* five seconds after the button is released, the System Controller has passed the self test. *Except for the solid green power symbol , which remains on.
- 5 If any of the lights do not illuminate or if the audio tone is intermittent (beeping), replace the System Controller (see *Replacing System Controllers*, page 35).
- 6 If there is a repeating cycle of one beep per second, followed by two seconds of silence, the System Controller is running on the backup system and a self test cannot be performed. Replace the System Controller (see *Replacing System Controllers*, page 35).

Note: The self test cannot be initiated when any alarm is active. If an alarm occurs during the self test, the self test will be terminated to display the alarm condition.

Changing the System Controller Battery Module

The HeartMate II System Controller battery module should last approximately one year. It should be replaced when the yellow battery module symbol on the System Controller keypad illuminates accompanied by one beep every four seconds:

- 1 Obtain a new System Controller battery module.
- 2 Examine the new battery module. You should see an orange O-ring around the bottom of the module and a white tape around the sides. If the orange O-ring or white tape are damaged or missing, do not use the battery module. Obtain a new one.
- 3 Unscrew (counterclockwise) the current battery module from the bottom of the System Controller and discard it. *The yellow battery module symbol will continue to illuminate and an audio tone will sound.*
- 4 Insert the new battery module into the System Controller (**Figure 28**).
- 5 Tighten (clockwise) the new battery module until the orange O-ring is no longer visible. Hand tighten only.
- 6 If the battery module is properly inserted, the yellow battery module symbol and accompanying audio tone will clear.
- 7 If the light and tone do not clear, try reinserting the battery module or repeat the procedure with another new battery module.



Figure 28 Inserting Battery Module into the HeartMate II System Controller

Replacing System Controllers

Note: If using battery power, ensure that the batteries are fully-charged before replacing the current System Controller. In addition, before replacing the current Controller, ensure that the replacement Controller has been programmed with settings that are appropriate for this patient.

- 1 Place the *replacement* Controller within easy reach, along with the batteries/battery clips or PBU cable.
- 2 Explain the procedure to the patient; have the patient sit or lie down.
- 3 Rotate the perc lock on the *replacement* Controller in the direction of the “unlocked” icon until the perc lock clicks into the fully-unlocked position (**Figure 29**).
- 4 Repeat Step 3 for the *original* Controller until the perc lock clicks into the fully-unlocked position.
- 5 Attach the power leads on the new, *replacement* Controller to the PBU cable or to the battery clips, depending on the power source being used.



Figure 29 Rotate Perc Lock

- 6 If using battery power, place fully-charged batteries into the clips after attaching the power leads.
 - 7 Press the Silence Alarm Button on the new, *replacement* Controller to silence its Red Heart Alarm for two minutes.
 - 8 Disconnect the perc lead from the *original* Controller by pressing the metal release tab on the connector socket. *The pump will stop and a continuous alarm will sound.*
Note: The alarm will continue until power is removed from the original Controller. Getting the new Controller connected and the pump restarted is the first priority.
 - 9 Connect the perc lead to the new, *replacement* Controller:
 - a Line up the mark on the perc lead connector with the mark on the metal tab of the new Controller.
 - b Fully insert the connector into the socket of the new Controller (**Figure 30**). *The pump should restart/alarms should stop.* **Note:** Gently tug on *metal end* of the lead to assure that it is fully engaged into the socket. Do NOT pull on the lead.
 - 10 If the pump restarts, skip to Step 12.
- OR
- 10 If the pump does not restart and the RED HEART ALARM continues:
 - a Firmly press the Silence Alarm or Test Select button to restart the pump.*
 - b Check the power source. Assure that power is going to the Controller.
 - c Assure the perc lead is fully inserted into the socket. Gently tug on the *metal end*. Do NOT pull the lead.

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



Figure 30 Inserting Connector into HeartMate II System Controller Socket

- 11 If the pump still does not restart, attempt to restore pump function using the System Controller backup system:
 - a Simultaneously press and hold the Test Select and Silence Alarm buttons. *The Red Heart Alarm will stop and an Advisory Alarm will occur with a repeating cycle of one beep per second for two seconds, followed by two seconds of silence to indicate that the System Controller is operating on the backup system.*
 - b Notify the patient's physician of the situation and be prepared to switch to another Controller.
- 12 After the pump restarts, rotate the perc lock on the new, *replacement* Controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position.
- 13 Disconnect power from the old, *original* Controller. *The original Controller will stop alarming once power is removed.*
- 14 Record the serial number for the new Controller and the date that the original Controller was replaced on the Device Tracking Form and chart for this patient.
- 15 Obtain another back up System Controller and program it with the patient's settings.

Handling Emergencies

An emergency condition exists whenever the device is potentially or actually unable to pump an adequate amount of blood. These conditions are signified by a HAZARD ALARM symbol and accompanied by a CONTINUOUS AUDIO TONE.

There are no backups for the HeartMate II LVAS. In the event that the LVAD stops operating, all attempts must be made to restore pump function immediately by:

- Checking the percutaneous lead connection to the System Controller;
- Switching power sources, and/or
- Replacing the System Controller (see *Replacing System Controllers*, page 35).

Loss of power will cause the LVAD to stop and blood pumping to cease. Power must be restored immediately. If the LVAD stops, retrograde flow may occur; and, if non-circulating blood is in the pump for more than a few minutes (depending on the anticoagulation status of the patient), there is a risk of stroke or thromboembolism if or when the device is restarted.

If the pump's fixed speed is set at or above 8,000 rpm, the pump should restart automatically once power is restored. If the pump's fixed speed is below 8,000 rpm, firmly press the Silence Alarm or Test Select button and hold for a count of two to restart the pump. If the pump does not restart, check all power sources and the percutaneous lead connection. If power source and perc lead connections are intact and the pump still does not resume pumping after attempting restart, replace the System Controller (see *Replacing System Controllers*, page 35). If replacing the System Controller does not restore pump function, immediately call for additional help and notify the patient's physician.

Note: Conditions that affect pump flow, such as decreased preload (LV filling), mechanical defects, or hypertension, may limit the restoration of normal pump flows until the condition(s) is/are resolved.

Defibrillation / Cardioversion

If **external defibrillation** is necessary, leave the pump running. Do NOT disconnect the System Controller from the percutaneous lead before delivering the shock.

If **open-chest defibrillation** is required, it is advised that the LVAS be disconnected from the System Controller due to the proximity of the paddles to the device. **Note:** Since retrograde flow may occur through the pump when it is off, it may be necessary to clamp the outflow graft while the device is stopped.

Cardiac Arrest

There may be risks associated with performing external chest compressions in the event of cardiac arrest, due to the location of the outflow graft and the presence of ventricular apical anastomosis. Performing external chest compressions may result in disruption of the aortic anastomosis or dislodgement of the LVAD inflow tract. Clinical judgement should be used when deciding whether or not to perform external chest compressions.

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

Patient Management

Patient Assessment

HeartMate II patient assessment may include, but not be limited to, assessment of the following:

- Pump function
- Pump speed, flow, motor power, pulse index (PI), mode of operation
- Percutaneous lead connection to System Controller and perc lock is in the locked position
- Exit site status, immobilization of percutaneous lead
- Vital signs, peripheral circulation
- Mental status, level of consciousness
- 12 lead EKG
- ECHO

Potential Risks & Adverse Events

- Hypovolemia
- Right Heart failure
- Pulmonary hypertension
- Cardiac tamponade
- Bleeding
- Arrhythmia
- Infection
- Hemolysis
- Thromboembolism
- Neurologic dysfunction

Potential Late Post-Implant Complications

- Hypovolemia
- Arrhythmia
- Thromboembolism
- Infection
- Psycho-social issues
- Neurological dysfunction

Caring for the Exit Site

The percutaneous lead exit site dressing should be changed daily using strict aseptic technique (sterile gloves and mask minimally). Gently cleanse the site with a mild disinfectant soap (preferably chlorhexidine solution), then rinse with sterile normal saline solution. Dry the cleansed site using a sterile 4”X4” gauze pad. Cover the cleansed and dried site with a dry, sterile dressing. Do NOT apply prophylactic topical agents to the exit site wound unless ordered by the patient's physician.

Immobilize the percutaneous lead with a Thoratec Stabilization Belt or abdominal binder to reduce trauma to the exit site. Trauma to the exit site will disrupt tissue ingrowth and increase the risk of infection (see *Controlling Infection* below). A Stabilization Belt or abdominal binder should be placed on the patient before leaving the OR or upon arrival in the intensive care unit (ICU) and thereafter worn at all times (except while showering or when being removed and replaced with a newly cleaned belt or binder).

Caring for the Percutaneous Lead

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

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

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

- Don't allow the percutaneous lead to catch or snag on anything that will pull on or move the lead.
- Check the percutaneous lead daily for signs of damage (cuts, holes, tears).

Controlling Infection

Infection among implantable LVAD patients is common, especially in patients with multi-system organ failure who require prolonged stays in the ICU. Infection rates can be minimized, however, by applying the following approaches to patient management:

- Strict adherence to aseptic technique during exit site care (as outlined above).
- Remove all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer antibiotic prophylaxis in the post-operative period and for suspected or confirmed infections and antibiotics for surgical drainage (as indicated) in patients with evidence of pump pocket infection.
- Adhere to strict blood glucose control.
- Initiate nutritional support to correct nutritional deficits.

Note: Refer to Thoratec's *Infection Control Guidelines* (document number 102512) for detailed information about approaches to successful infection control used by experienced LVAD implant centers with low rates of infection.

Measuring Blood Pressure

Automatic blood pressure monitors may not be accurate. Manual auscultation with a Doppler is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring (arterial line) may be required.

Anticoagulation

HeartMate II patients are placed on Warfarin® to **maintain an INR of 2 - 3** and antiplatelet therapy consisting of aspirin 81mg daily combined with Dipyridamole 75mg TID.

Activities of Daily Living

Sleeping

HeartMate II patients must be attached to the PBU while sleeping or anticipating sleep. During sleep the System Controller and percutaneous lead must be immobilized to reduce pulling on the exit site. The HeartMate Stabilization Belt or an abdominal binder may be used to immobilize the perc lead and Controller

- Patients should sleep or plan to sleep only when they are connected to the PBU.
- Patients should not sleep on their stomach.
- Keep a spare System Controller near a sleeping patient for convenient access in the event of an emergency.

- Keep a flashlight, fully-charged batteries, and battery clips within reach in case of a power outage.
- Prior to sleeping, inspect all electrical connections and ensure they are secure.

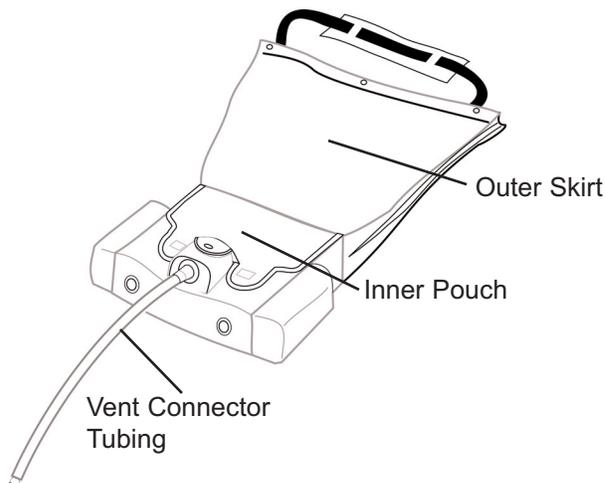
Showering

Although the external components of the HeartMate II LVAS are moisture-resistant, they are not waterproof and care must be taken to not expose them to water or a wet environment. When taking a shower, the patient must shield all external components from water by placing them in a waterproof pouch (HeartMate Shower Kit).

- Do NOT permit HeartMate LVAS patients to shower unless their physician has given permission after inspecting the exit site wound and confirming that sufficient healing has occurred.
- Never permit HeartMate II patients to sit in a tub of water, take a tub bath, or swim.
- Keep the exit site as clean and dry as possible.
- Avoid excessive pulling on the percutaneous lead to minimize exit site trauma.
- Follow established *HeartMate Shower Kit Instructions for Use*.

Preparing to Shower

- 1** Remove the vent connector tubing from the small round pocket near the inner pouch of the shower kit (**Figure 31**). Throw away the tubing (it is not needed for this version of the pump).



- 2 Use the Shower Kit strap to hang the kit over one shoulder so it's hanging at the patient's side.

OR

- 2 Put the strap around the patient's neck and hang the kit in front of him or her. **Note:** The strap is adjustable.
- 3 Raise the outer "skirt" of the Shower Kit to expose the inner pouch underneath.
- 4 Lift the Velcro tabs on the inner pouch cover.
- 5 Open the inner pouch cover.
- 6 Place the System Controller, leads, and connectors inside the pouch.
- 7 Reseal the pouch by pressing down the Velcro tabs.
- 8 If the patient will be using PBU power during his or her shower, skip to Step 9.

OR

- 8 If the patient will be using battery power during his or her shower, transfer the batteries to the Shower Kit:
 - a Remove the 1st battery from the holster or carrying case. **Note:** Remove batteries one at a time. Wearing the holster or carrying case until all equipment is transferred into the Shower Kit may reduce pulling on the exit site.
 - b Insert the 1st battery into one of the pockets located on either side of the inner pouch. **Note:** Insert the battery with the battery clip at the top and the lead connector facing away from the patient.
 - c Repeat steps "a" and "b" for the 2nd battery.
 - d Remove the empty holster or carrying case.
- 9 Pull the outer "skirt" down over the inner pouch.
- 10 Press together the snaps at the bottom of the "skirt."
- 11 Adjust the Shower Kit so it does not pull on the exit site while showering. **Note:** Keep the PBU away from water and shower spray!

After Showering

- 1 Use a clean, dry towel to dry the Shower Kit's strap and outer "skirt."
- 2 Undo the snaps at the bottom of the outer "skirt" and then lift up the "skirt."
- 3 Lift the Velcro tabs on the inner pouch cover; open the pouch.
- 4 Remove all equipment from the inner pouch and return it to the holster/carrying case or PBU.
- 5 Remove Shower Kit and allow it to drip dry.

- 6** Perform exit site care and reapply the stabilization belt to immobilize the percutaneous lead.

Caring for the Shower Kit

Keeping the Shower Kit clean helps it work properly.

If the Shower Kit gets dirty, wash it using mild soap and warm water. Once the kit has been washed, hang it to drip dry. Always allow the kit air dry on its own. Never heat the Shower Kit to dry it. Make sure the Shower Kit is completely dry before taking another shower. Refer to the instructions for use accompanying the Shower Kit for complete instructions on Shower Kit use and care.

Thoratec Resources

HeartLine™ (24-Hour Clinical & Technical Support)

Clinicians in the United States may contact Thoratec's 24-hour HeartLine by dialing: 1-800-456-1477. For emergencies outside the U.S., dial 1-925-847-8600. **Note:** The HeartLine is not intended for patient use. Patients should contact their care providers.

Published Reference Materials

- *HeartMate II LVAS Instructions for Use*
- *HeartMate II LVAS Operating Manual*
- *HeartMate II LVAS Patient Handbook*
- *HeartMate II LVAS Troubleshooting Guide*
- *Infection Control Guidelines*
- *HeartMate II LVAS Patient Management Guidelines*
- *Pocket Guide to Care & Maintenance for the Perc Lead, Batteries, and Power Base Unit (PBU)*
- Various educational slides and videos

Published reference materials and related supplies may be obtained through Thoratec's Clinical Consultants or Sales Representatives. In addition, many published reference materials may be downloaded from the Thoratec website: www.thoratec.com.

Post Test

Name _____ Date _____
Institution/ Affiliation _____

1 HeartMate II system components include:

- a. System Controller
- b. Power Base Unit (PBU)
- c. System Monitor
- d. Emergency Power Pack (EPP)
- e. All the above

2 What type of valves are used in the HeartMate II?

- a. Medtronic 25mm stentless porcine
- b. Bjork-Shiley monostrut tilting-disc
- c. Carbomedics
- d. St. Jude
- e. None

3 The HeartMate II pump speed can be adjusted between:

- a. 6,000 and 15,000 rpm
- b. 5,000 and 25,000 rpm
- c. 8,000 and 12,000 rpm
- d. 100 and 1,000 rpm

4 Pulsatility Index (PI) is:

- a. Increases when pump speed is increased
- b. A measure of ventricular contractility
- c. Adjustable on the System Monitor
- d. All the above

5 The System Controller:

- a. Provides complete backup system operation
- b. Has event recording and data logging capacity
- c. Has two separate controller boards
- d. All of the above

6 The displayed pump flow is:

- a. Measured by a flow probe located at the pump outlet
- b. An estimate of pump flow based on pump power and speed
- c. More accurate than Swan Ganz cardiac output
- d. A very reliable calculation of pump output

7 The non-flashing, round green light  on the System Controller indicates:

- a. The System Controller is receiving power from both power leads
- b. The pump is receiving power from the System Controller
- c. The pump is ON
- d. All of the above
- e. None of the above

8 The red heart hazard alarm  :

- a. Indicates pump flow is < 2.5 L/minute
- b. Indicates the pump has stopped
- c. Can be silenced for two minutes
- d. Is accompanied by a continuous audio tone
- e. All of the above

9 A yellow symbol  indicates:

- a. The pump has stopped
- b. Less than 15 minutes of battery power remain
- c. The System Controller battery module needs to be replaced
- d. A power lead is disconnected

10 The steps that should be taken if the pump has stopped include all except:

- a. Check the percutaneous lead connection to the System Controller and the System Controller power lead connections to the power source
- b. Disconnect then reconnect the percutaneous lead to the System Controller
- c. Change power sources
- d. Change the System Controller

11 The appropriate action(s) for a repeating audible alarm of 1 beep per second for 2 seconds, followed by 2 seconds of silence and no visual alarm on the System Controller is/are:

- a. Change the power source
- b. Change the System Controller
- c. Perform a System Controller self test
- d. A & B
- e. All of the above

12 The information stored in the System Controller event recorder can be viewed on the System Monitor's:

- a. Admin Screen
- b. Clinical Screen
- c. History Screen
- d. Save Data Screen

13 The Extended Silence Button will silence:

- a. All alarms for 4 hours
- b. Advisory alarms for 4 hours
- c. Hazard alarms and Power Cable Disconnected advisory alarms for 2 minutes
- d. None of the above

Competency Assessment Checklist

Competency Criteria	Verification	
	YES	NO
1. Name the components of the HM II system.		
2. Interpret the buttons and symbols on the System Controller.		
3. Verbalize typical battery times; estimate time remaining using Battery Fuel Gauge.		
4. Identify differences between red heart hazard alarms and yellow & green advisory alarms. Understands appropriate responses to alarm conditions.		
5. Demonstrate how to perform a System Controller self test and explain reasons for performing this test.		
6. Demonstrate changing the System Controller.		
7. Identify 2 methods to start the pump and how to assess that the pump has been restarted.		
8. Explain the significance of the System Controller battery module.		
9. Identify Silence Alarm button and verbalize mute times for hazard and advisory alarms.		
10. Explain the function of the system monitor data logger and how to turn it on/off.		
11. Explain the difference between the event recorder and data logger in the System Controller.		
12. Describe the steps to perform cardioversion/defibrillation.		

Print Name _____

Signature _____

Date _____

Program Evaluation

PROGRAM TITLE:

HeartMate II LVAS Clinical Operation & Patient Management

Program Date:

Presenter:

Location:

Program Evaluation

- 1 Program met stated objectives.
- 2 Content covered topic adequately.
- 3 Rate overall this program.
- 4 Rate the program facilities.

Excellent	Good	Fair	Poor	N/A

Speaker Evaluation

- 5 Rate overall quality of speakers.
- 6 Speaker was organized & effective
- 7 Speaker was qualified.
- 8 Speaker held interest.

Excellent	Good	Fair	Poor	N/A

The most useful part of this presentation was:

The least useful part of this presentation was:

Additional suggestions:

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