Thoratec Corporation

HEARTMATE II® **L**EFT **V**ENTRICULAR **A**SSIST **S**YSTEM (LVAS)

Patient Handbook

Your guide to understanding the HeartMate II LVAS Heart Pump

℞ Only

CE 0197

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Document No. 103539.B

Table of Contents

List of Emergency Contacts

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

HOSPITAL

Name of Hospital

Name of Hospital Contact Person

Hospital Address

Hospital (Contact Person) Telephone Number

DOCTOR

Doctor's Name

Address

Telephone Number

AMBULANCE

Name

Address

Telephone number

AMBULANCE/ EMERGENCY SERVICES

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

Glossary

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

A

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

B

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

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

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

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

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

C

D

Display Module: When connected to the PBU, the display module displays information about how the system is operating, such as the current operating mode, pump speed, flow rate, pulsatility index, power, and alarm message(s) – if any.

E

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

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

F

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

G

H

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

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

I

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

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

J

K

L

Low Battery Hazard Symbol: Red light on system controller. It lights when power to the system controller is critically low.

Low Flow Hazard Symbol: Red light on system controller. It lights when HeartMate II LVAD flow is critically low.

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

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

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

M

N

O

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

P

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

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

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

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

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

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

Percutaneous Lead: A long lead containing wires that is permanently attached to the HeartMate II pump and that connects the implanted pump to the external system controller.

PocketPak™: A HeartMate accessory that lets patients wear HeartMate batteries and/or system controller around the waist during battery-powered operation.

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

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

Power Sources: Three power sources can power the HeartMate II LVAS: 1) a set of wearable, rechargeable batteries/battery clips for battery-powered operation, 2) the PBU when connected to an electrical outlet, and 3) the Emergency Power Pack, which

is a large battery that can power the system for up to 12 hours in the event of an extended power outage or emergency.

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

Pump: The implanted device inserted into the left ventricle of the heart that sends blood taken from the inflow conduit through the outflow graft and into the aorta, which sends the blood to the rest of the body. In the blood path the pump contains titanium stators, a rotor, a blood tube, and ceramic bearings. The motor capsule that surrounds the rotor is powered through the percutaneous lead.

Q

R

S

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

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

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

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

System Controller Battery Module: A small, replaceable battery cell that powers the lights and audible alarms on the system controller audio tone when both power leads are disconnected from the power source (batteries, PBU or EPP) at the same time. Note: The system controller battery module only powers the system controller and its alarms. It does not provide back up power to the implanted pump.

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

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

T

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

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

U

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

V

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

W

X

Y

Z

Figure 1 Implanted and Worn Components of the HeartMate II LVAS During Battery-Power Operation

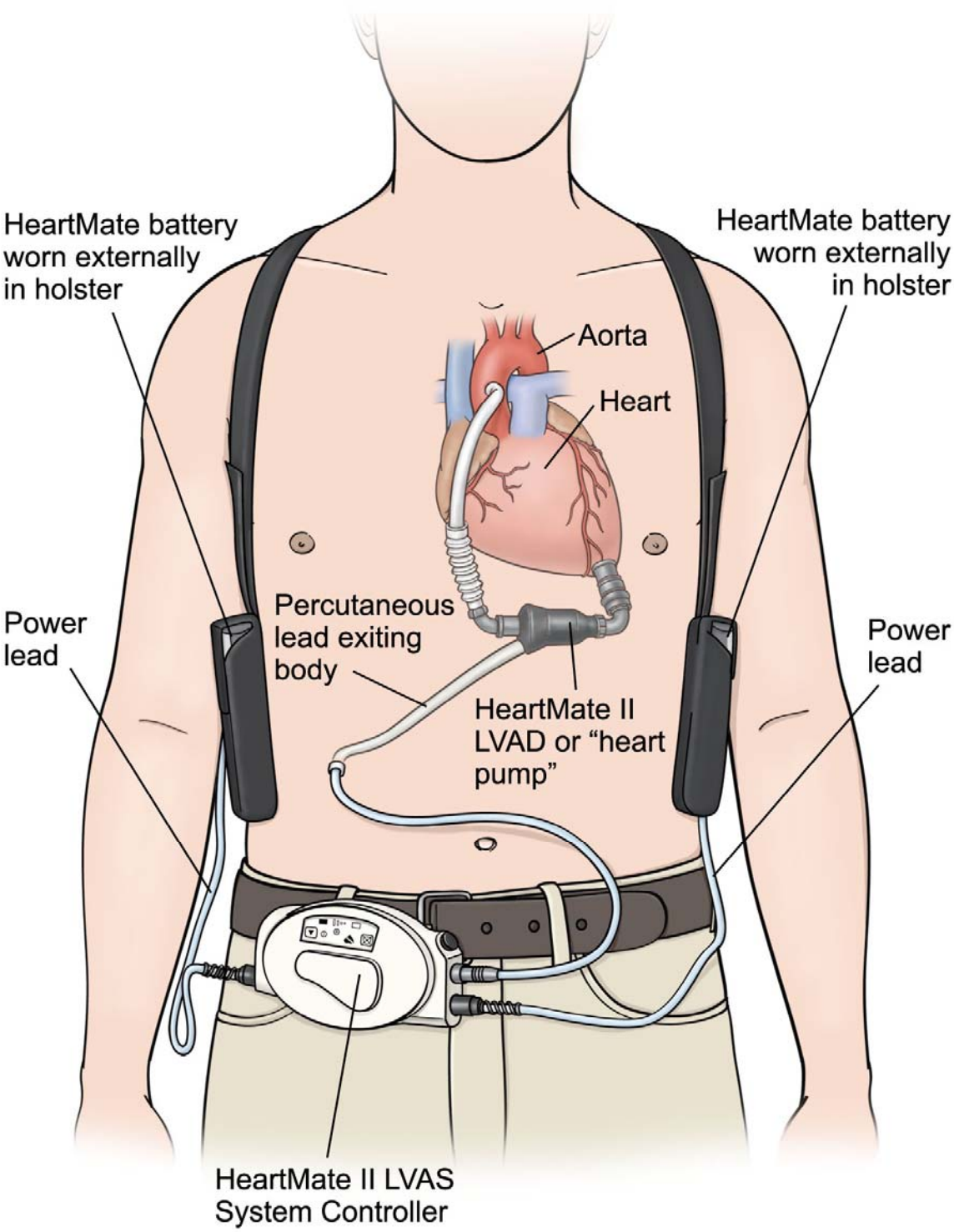
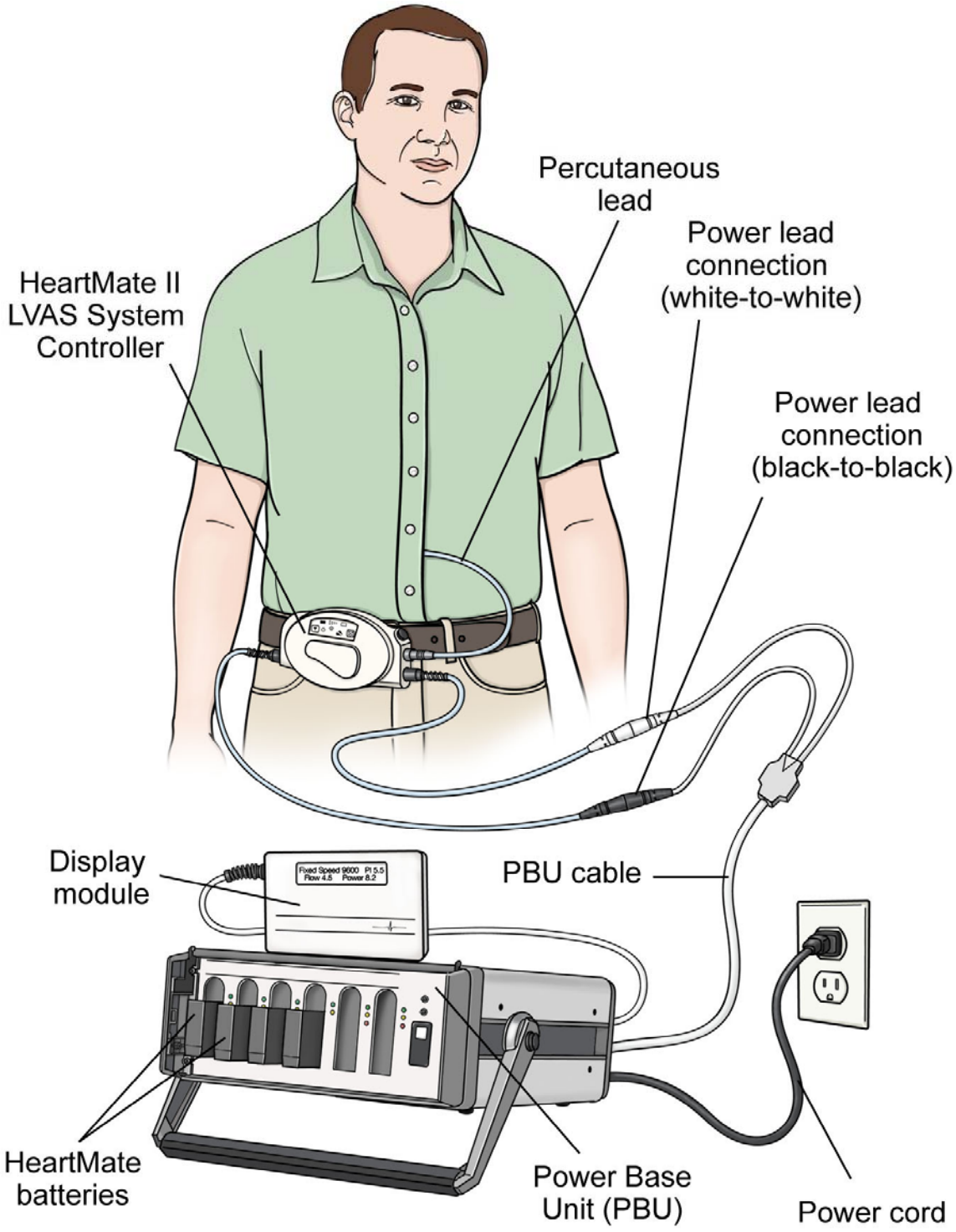


Figure 2 HeartMate LVAS during “Tethered Operation” Connected to PBU



Important Warnings

- Never put the System Controller in water. Your doctor will let you know when you can shower. When you do shower, you must use the HeartMate Shower Kit.
- Check the Perc Lock often to make sure it is in the locked position. The Perc Lock helps keep the percutaneous lead from accidentally disconnecting from the System Controller. If the percutaneous lead disconnects, your pump will stop.
- Keep the Power Base Unit (PBU) away from water. If the PBU touches water, shower spray, or wet surfaces, your pump may stop or you may get a serious electric shock.
- One (1) System Controller power lead must be connected to a power source (batteries, PBU, or EPP) at all times. If both System Controller power leads are disconnected at the same time, your pump will stop.
- The pump will stop if the System Controller is disconnected from the percutaneous lead going through your skin. If this happens, reconnect the lead as quickly as possible to restart the pump.
- When changing batteries, never disconnect both batteries at the same time or your pump will stop.
- Losing power will make the pump stop. Power must be restored right away to restart the pump.
- Plug the Power Base Unit (PBU) only into properly grounded (3-prong) outlets. Do NOT use an adapter (cheater plug) for ungrounded outlets or you may get a serious electric shock.
- Do NOT connect the Power Base Unit (PBU) to an outlet controlled by a wall switch, or the PBU may not work.
- Do NOT touch television (TV) or computer screens while you have the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and make the pump stop.
- Do NOT do anything that may create static electricity, like vacuuming. A strong electric shock can damage the electrical parts of the pump and make the pump stop.
- Do not become pregnant while you have the pump. Use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may injure you or make the pump stop.

Important Precautions

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

Important Precautions continued

- The HeartMate uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.
- Make sure the pump is fully stopped before disconnecting it from the System Controller.
- To prevent damage to the Emergency Power Pack (EPP):
  - Do NOT leave or store the EPP in hot or cold areas (car trunks, etc.), or EPP life will be shortened.
  - Do NOT use EPP after its expiration date.
  - Do NOT store or use the EPP in temperatures below 32° F (0°C) or above 122°F (50°C), or the EPP may suddenly stop working. If your EPP stays below room temperature (68-72°F, 20-23°C) during use, it will run the pump for less than 12 hours. In low temperatures (32°F -15°F, 0°C - -10°C), run time may cut by 50%.
- Dispose of an expired or used EPP according to local regulations. Do NOT burn.
- Do NOT let the connector ends of leads get dirty or wet.
- Do NOT try to fix any of your LVAS equipment yourself. If equipment needs service, call your hospital contact person.
- Do NOT pull on or move the percutaneous lead going through your skin. Pulling on or moving the lead can keep the exit site from healing. Pulling on or moving the lead can also increase the risk of getting a serious infection.
- Be extremely careful with your percutanous lead. Check your lead often to make sure it does not become twisted. If your percutaneous lead does get twisted, carefully turn the System Controller to unravel the lead. Turn until the lead is no longer twisted.
- Do NOT kink or bend the percutaneous lead. Check your lead often to make sure it is free of kinks or sharp bends. A kink or sharp bend in the percutaneous lead may damage the wires inside.
- Call your doctor if you notice a change in how your pump works, sounds, or feels.

Introduction

Why Should You Read this Handbook?

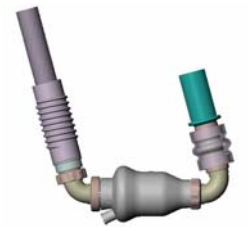
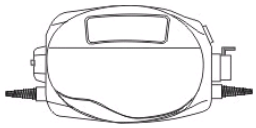
This *Patient Handbook* will teach you about your new HeartMate II heart pump. Read it to learn how the pump works and how to keep active and safe while living with the pump outside the hospital. This handbook is also important because it explains what to do in an emergency. If you have any questions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

Note: To reduce the risk of complications and avoid readmission to the hospital, the guidelines in this handbook should be closely followed.

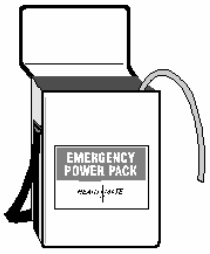
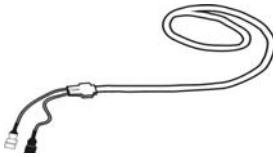
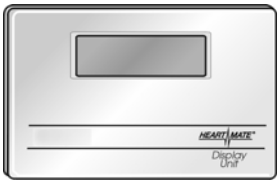
The table below lists the major parts of the pump system and gives a short description for each. Each part is explained in more detail later in this handbook.

System Components

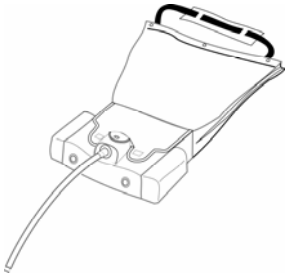
HeartMate II LVAS

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

System Components continued

Power Base Unit (PBU)		The PBU is the other routine power source for powering the pump. In addition to powering the pump, the PBU recharges the HeartMate batteries.
Emergency Power Pack (EPP)		The EPP in an emergency power source. It can provide up to 12 hours of power. For example, during a power outage caused by a storm or severe weather. **See page 40 for instructions on using the EPP.**
Power Base Unit (PBU) Cable		The PBU cable connects the PBU to the System Controller. Connections are made between white-to-white and black-to-black connectors.
Display Module		When connected to the PBU, the Display Module shows information about how the pump is working, such as: pump speed, flow rate, pulsatility index (PI), and power. The pump's operating mode and other operating information also appears on the screen.

System Components continued

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

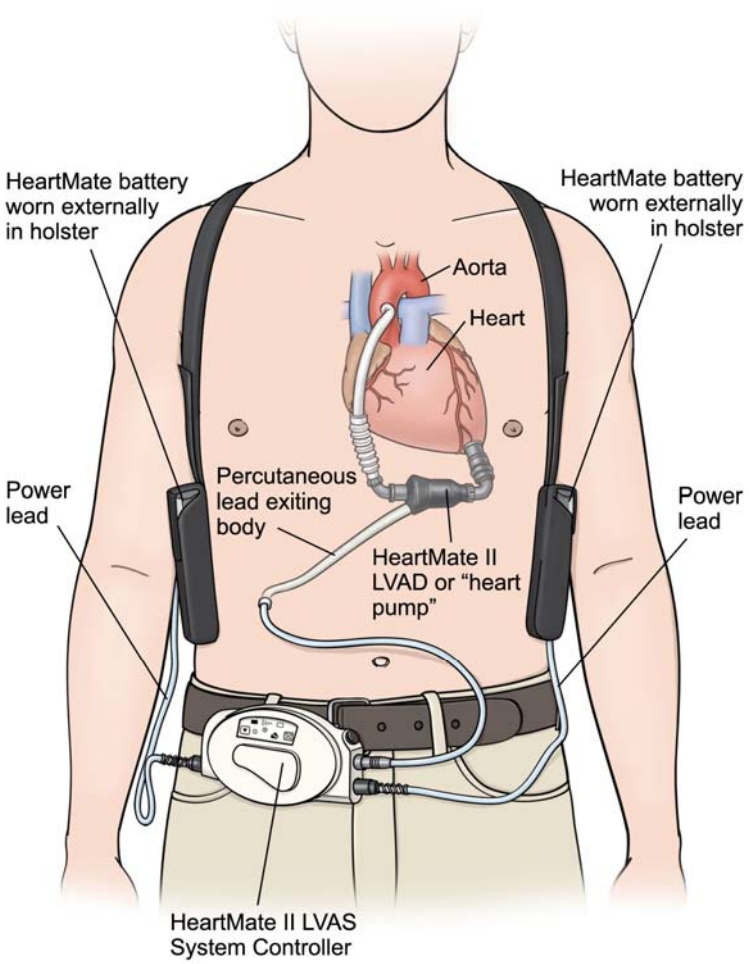
How Does It Work?

Your Heart Pump

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

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

Figure 1



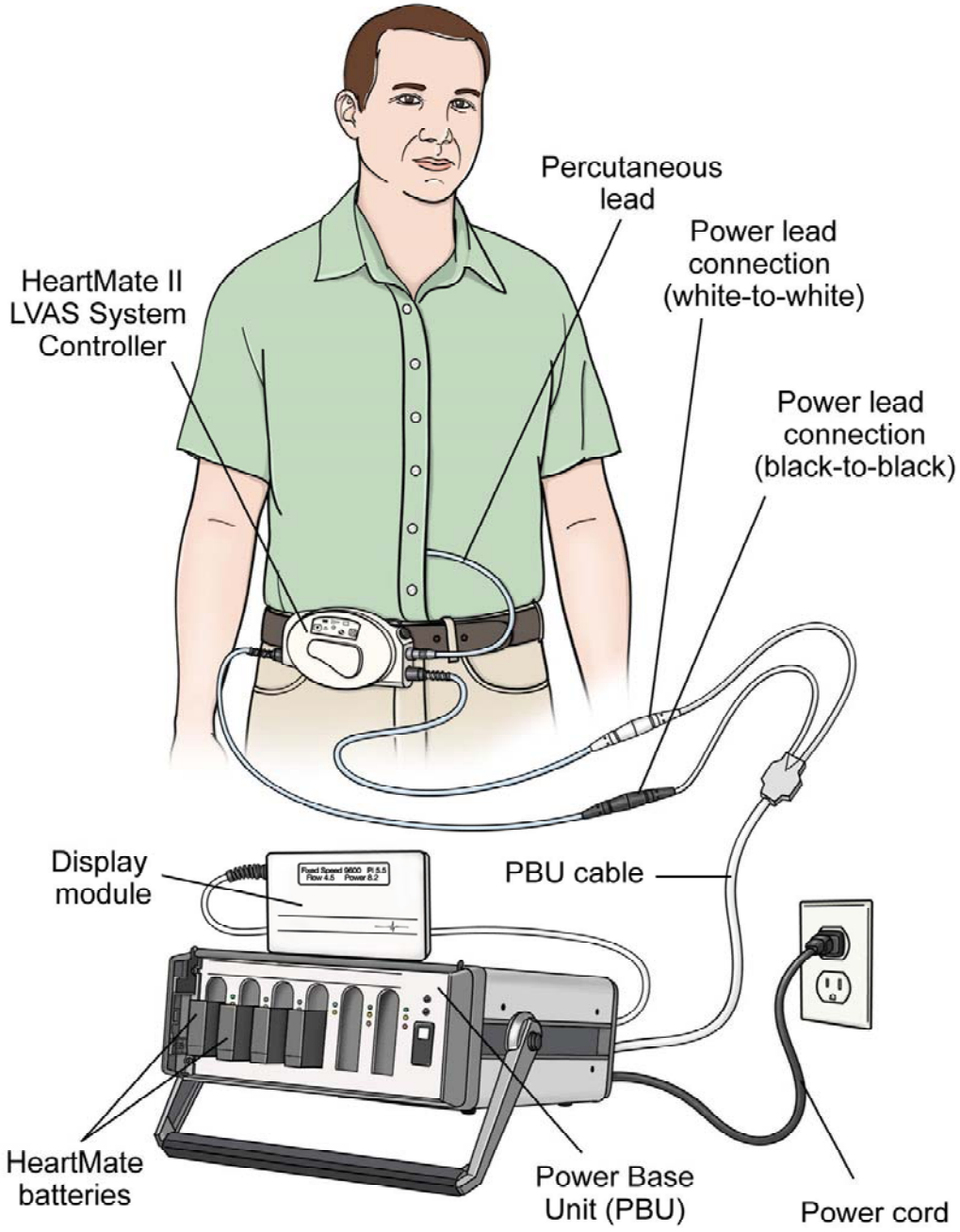
As shown in **Figure 1**, a percutaneous lead passes through your skin. The outside of the lead is covered with a special material that lets skin cells grow into it. This helps the exit site heal. A well-healed exit site can lower the risk of infection. You will need to keep the exit site very clean and dry. A clean, dry exit site also helps lower infection risk (see "Caring for the Exit Site" on page 53).

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

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

Your Heart Pump continued

Figure 2

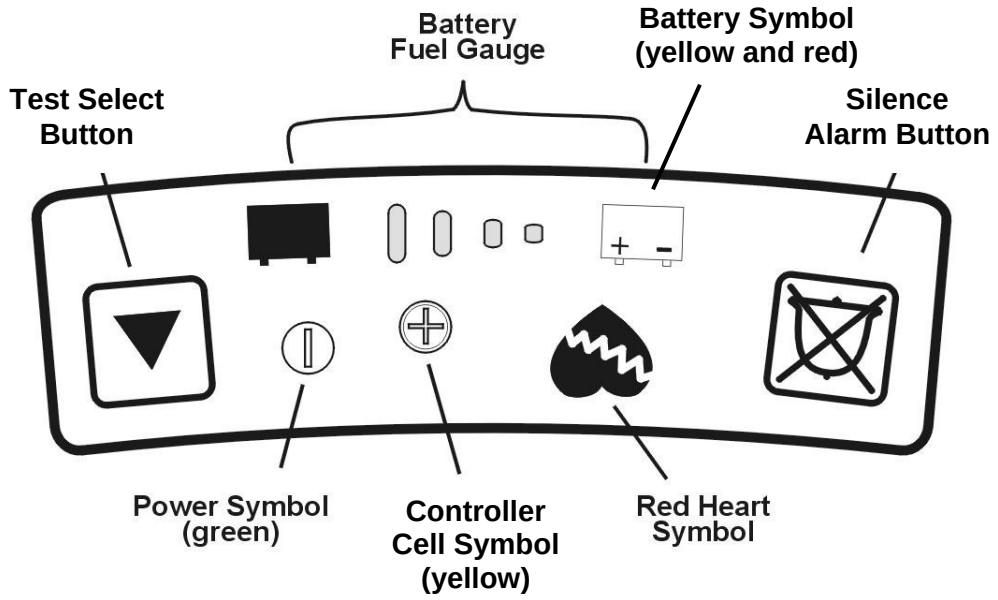


The System Controller

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

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

Figure 3



CAUTION !

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

The System Controller continued

System Controller Warning Lights and Sounds

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
Red Heart *STEADY AUDIO TONE* 	Pump has stopped or is not working right.	1 Make sure System Controller is connected to pump and that PBU cable is connected to PBU. 2 Switch to fully-charged batteries. 3 Call emergency services (dial 911). 4 Follow emergency procedures (page 56).
Red Battery *STEADY AUDIO TONE* 	Less than 5 minutes of battery power remain.	Change batteries, **one at a time**. If batteries are not available, switch to PBU or EPP power. **Note**: Pump speed will slow down to save power until the alarm clears (see "Power Saver Mode" on page 32). Warning: Do NOT remove both batteries at the same time or your pump will stop.
Yellow Battery *1 beep every 4 seconds* 	Less than 15 minutes of battery power remain.	Switch to fully-charged batteries or to PBU or EPP power. **Warning**: Do NOT remove both batteries at the same time or your pump will stop.
STEADY AUDIO TONE, but no warning light and no green power symbol.	System Controller is not getting power.	Make sure both power leads are connected to power source (batteries, PBU or EPP).
Broken AUDIO TONE (repeating cycle of 2 beeps followed by 2 seconds of silence), but no warning light.	System Controller is operating in back-up mode.	Replace the System Controller. Call your hospital contact person.

continued

The System Controller continued

System Controller Warning Lights and Sounds continued

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
Controller Cell *Yellow symbol; 1 beep every 4 seconds* 	The System Controller's battery module is low on power.	Replace the System Controller's battery module.
Rapidly Flashing Power Symbol  **Four (4) Flashing Green Lights (on Battery Fuel Gauge)** *flash once per second*  *1 beep every second*	One of the power leads is damaged or disconnected.	Check for loose power leads. If on PBU power, check that the power lead is not damaged or disconnected.

The System Controller continued

System Controller Buttons

SWITCH	PURPOSE	HOW TO USE
Test Select Button 	Starts the System Controller Self Test.	Push and hold for 3 seconds to start Self Test. See "System Controller Self-Test" on page 15. **Note**: Pressing this button will have no effect when an alarm is active. A self-test can be done only when there are no active alarms.
Silence Alarm Button 	Allows you to: ▪ Silence Advisory Alarms for 4 hours. ▪ Silence RED Hazard Alarms for 2 minutes. ▪ Silence the Power Cable Disconnect Alarm for 2 minutes if one of the power leads is disconnected or damaged ▪ Silence both the System Controller and the PBU if you are attached to the PBU when the System Controller alarms.	Firmly press and hold for a count of 2, then let go.
Silence Alarm Button 	Lets you check how much battery power remains (see "Battery Fuel Gauge" next page).	Press and hold Silence Alarm Button.

The System Controller continued

Battery Fuel Gauge

BATTERY FUEL GAUGE LIGHTS	MEANING	WHAT YOU SHOULD DO
One (1) Green Light 	Less than 25% of battery power remains (batteries are less than ¼ charged).	Prepare to replace used batteries with fully-charged ones, or switch to PBU or EPP.
Two (2) Green Lights 	Between 50% – 25% of battery power remains (batteries are ½ charged).	No Action Needed.
Three (3) Green Lights 	Between 75% – 50% of battery power remains (batteries are 3/4 charged).	No Action Needed.
Four (4) Green Lights 	Between 100% – 75% of battery power available (batteries fully charged).	No Action Needed.
Four (4) Flashing Green Lights **(on Battery Fuel Gauge)** *flash once per second*  **Rapidly Flashing Power Symbol**  *1 beep every second*	One of the power leads is damaged or disconnected.	Check for loose power leads. If on PBU power, check that the power lead is not damaged or disconnected.

The System Controller continued

System Controller Self-Test

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

How to Perform a System Controller Self-Test

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

Note: Pressing the Test Select Button will have no effect when an alarm is active. A self-test can be performed only when there are no active alarms.

2 Look closely at the display. Make sure that all of the lights are on and the alarm is making a STEADY AUDIO TONE. *If there is a problem with the audio alarm, it will beep once every 2 seconds instead of a continuous or steady tone.*

3 Release the Test Select Button.
All the lights should remain on and the alarm should sound for an additional 5 seconds.
If any time you press the Test Select Button you hear a rapid beep without any light, it means there is a problem with the System Controller. You must replace it.

4 If there is no rapid beep (2 beeps every second) and all the alarms and lights come on as described above and then turn off 5 seconds after letting go of the button, the System Controller has passed the Self-Test.

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

The System Controller continued

System Controller Perc Lock

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

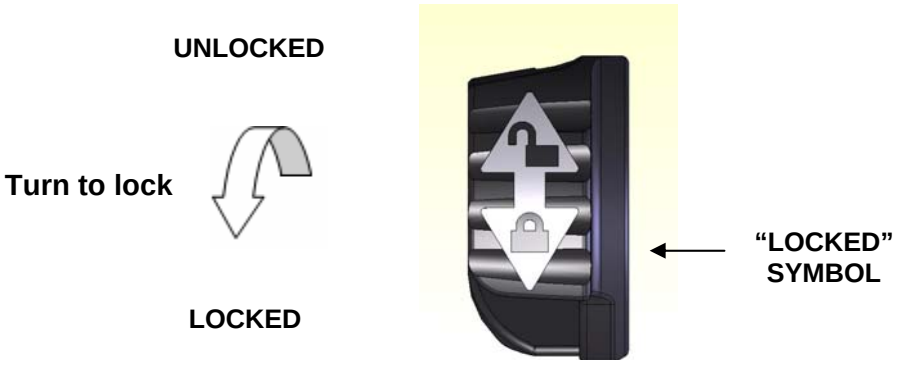
How to Use and Check the Perc Lock

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

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

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

Figure 4



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

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

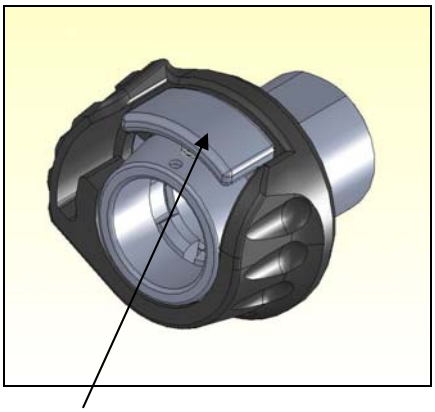
3 After it clicks into place, inspect the Perc Lock to make sure it is fully locked.

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

The System Controller continued

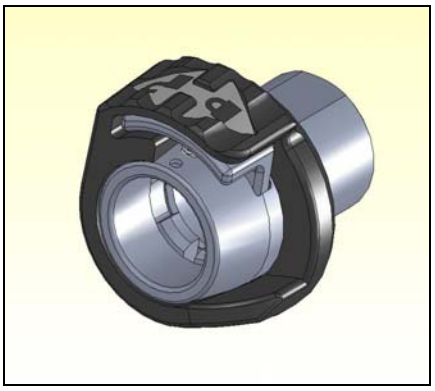
Figure 5

Unlocked – Tab Uncovered



Metal Tab

Locked – Tab Covered

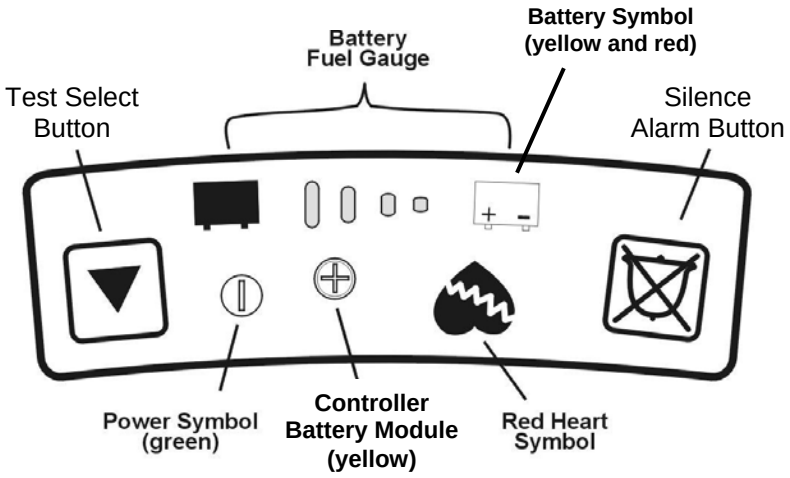


Changing the System Controller Battery Module

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

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

Figure 6



Follow these steps to change the System Controller battery module:

1 Obtain a new System Controller battery module.

2 Examine the new battery module. Make sure there is white tape around the sides of the battery module and an orange O-ring around the bottom. If the white tape or orange O-ring is missing, do NOT use the battery module. Get a new one.

3 Unscrew (counterclockwise) the old battery module from the side of the System Controller. Throw away the old battery module.

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

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

Changing the System Controller Battery Module continued

5 Turn the new battery module clockwise until you can no longer see the orange O-ring. You can use a flat object (like a coin) to tighten the battery module. **But do not over tighten it**.

6 Once the battery module is properly inserted, the yellow battery module symbol will turn off.

Figure 7

Replacing System Controllers

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

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

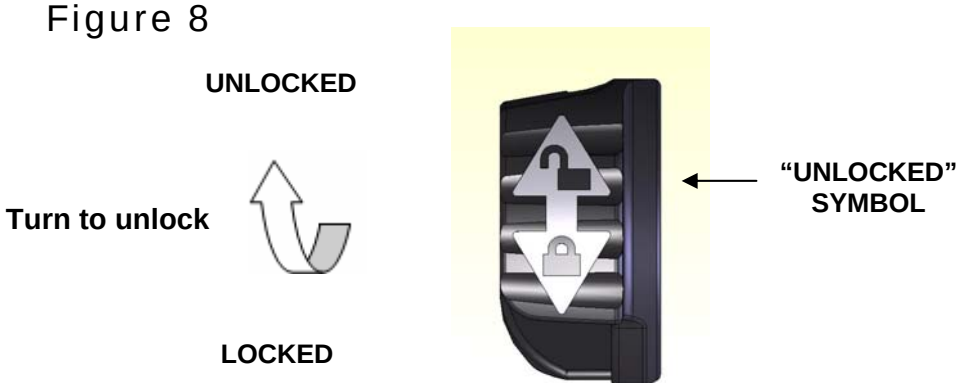
Follow these steps to replace your System Controller:

1 Put the replacement System Controller within easy reach.

2 Turn (rotate) the Perc Lock on the replacement Controller towards the "unlocked" symbol (**Figure 8**).

Note: Keep turning until the Perc Lock clicks into the unlocked position and the metal release tab is showing (**Figure 9**).

Figure 8



3 Sit or lie down.

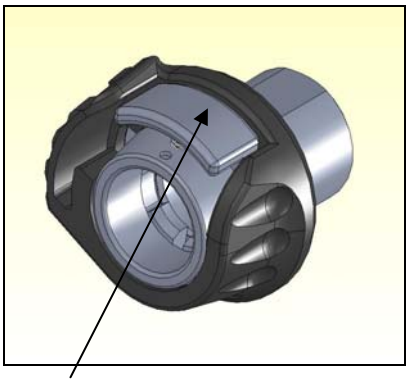
4 Turn (rotate) the Perc Lock on your Controller towards the "unlocked" symbol (**Figure 7**).

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

Replacing System Controllers continued

Figure 9

Unlocked – Tab Uncovered



Metal Tab

Locked – Tab Covered

5 Disconnect the current power source (batteries, PBU, or EPP) from your **white** power lead, then connect power to the new, replacement System Controller. *The System Controller will alarm.*

6 Press the Silence Alarm Button  to silence the Power Cable Disconnect Alarm.

7 Disconnect the percutaneous lead from your original System Controller by pressing the metal release tab on the connector socket. *The pump will stop and the System Controller will alarm.*

8 Connect the new System Controller:

8a Line up the mark on the percutaneous lead connector with the mark on the metal tab of the new System Controller (the marks must line up to make this connection).

8b Fully insert the connector into the System Controller socket (**Figure 10)**.

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

Replacing System Controllers continued

Figure 10

9 Connect the **black** power lead from the new System Controller to a power source (batteries, PBU, or EPP).

10 If pump does not restart and the Red Heart Alarm continues, make sure power is going to the System Controller.

Note: A steady green power symbol light means only that power is going to the System Controller (**Figure 6**); it doesn't mean that the pump is running.

11 If the power source is connected and the Red Heart Alarm continues, immediately call emergency services (dial 911). Otherwise, continue with step 12.

12 Make sure the connector is fully inserted into the System Controller socket by gently tugging on the metal end of the percutaneous lead.

13 Turn (rotate) the Perc Lock on the new Controller toward the "locked" symbol .

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

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

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

Note: If fully locked, the Perc Lock will cover the metal release tab (**Figure 9**).

15 Disconnect power from the old System Controller.

Note: The old System Controller will continue to alarm until it is disconnected from power.

The Power Base Unit (PBU)

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

At least once a year, the PBU should be inspected, cleaned, and serviced by a trained Thoratec representative or authorized hospital employee. Service can take place at your home if necessary. Usually the PBU will be inspected during a routine hospital visit, however. Talk with your hospital contact person about routine preventative maintenance for your PBU.

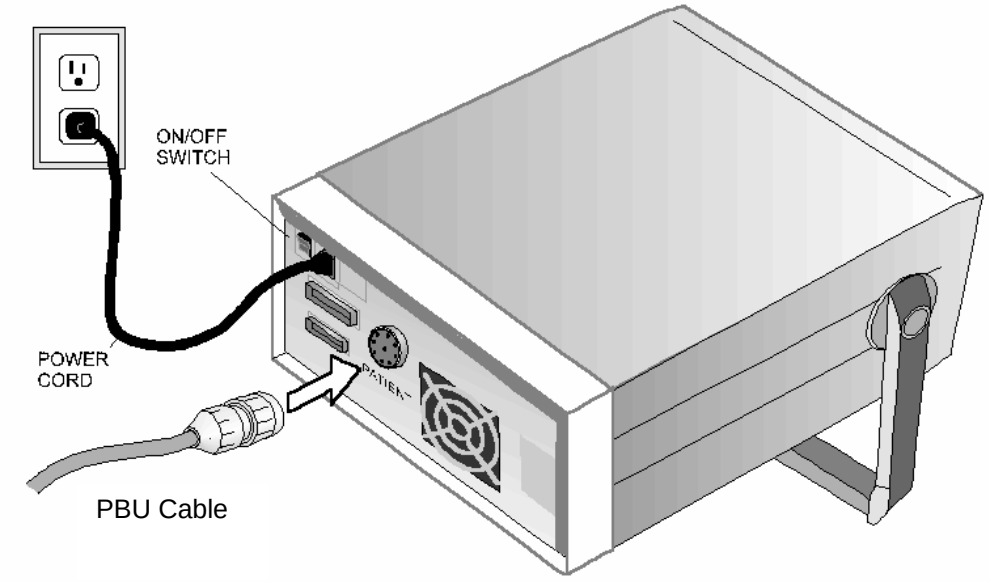
How to Set Up the PBU

1 Place the PBU on a flat, sturdy surface, like a table.

2 Plug the PBU power cord into a 3-prong wall outlet. Do NOT use an adapter (cheater) plug or a wall outlet controlled by a light switch.

3 Turn the ON/OFF switch (on the back of the PBU) to the ON (I) position (**Figure 11**).

Figure 11



4 Plug the PBU cable into the socket labeled "Patient" (**Figure 11**).

The Power Base Unit (PBU) continued

5 Attach the white System Controller connector to the white PBU power lead connector; then attach the black System Controller connector to the black PBU power lead connector.

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

WARNING !

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

CAUTION !

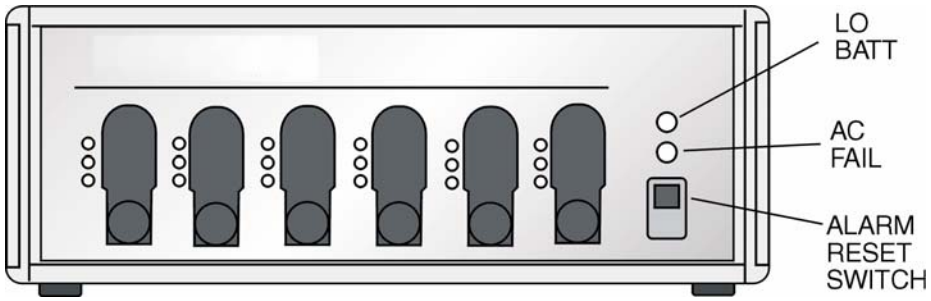
Do NOT let connector ends get dirty or wet.

Power Base Unit (PBU) Warning Lights & Sounds

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

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

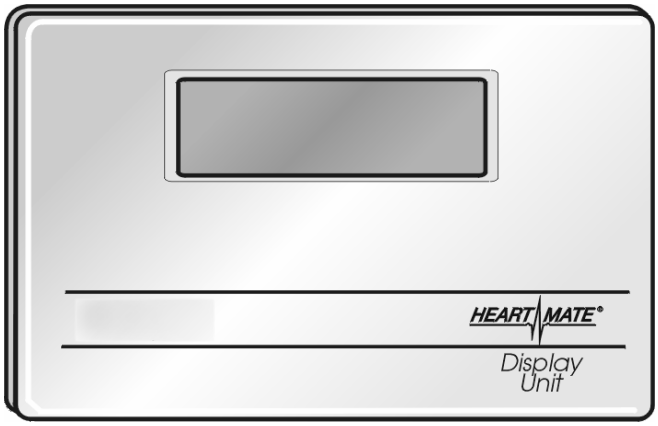
Figure 12



Display Module

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

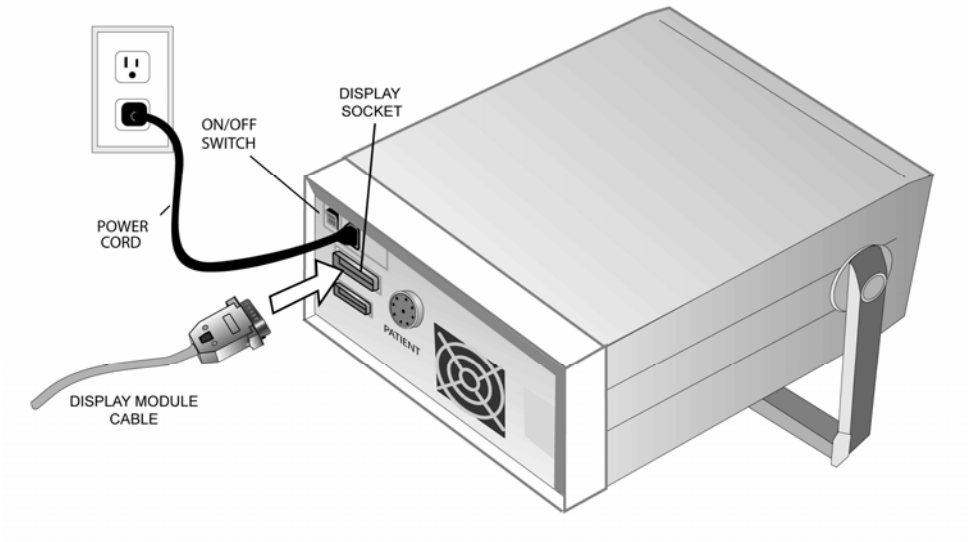
Figure 13a



How to Set-Up the Display Module

1 Plug the Display Module cable into the socket labeled "Display" found on the back of the PBU (**Figure13b**).

Figure 13b

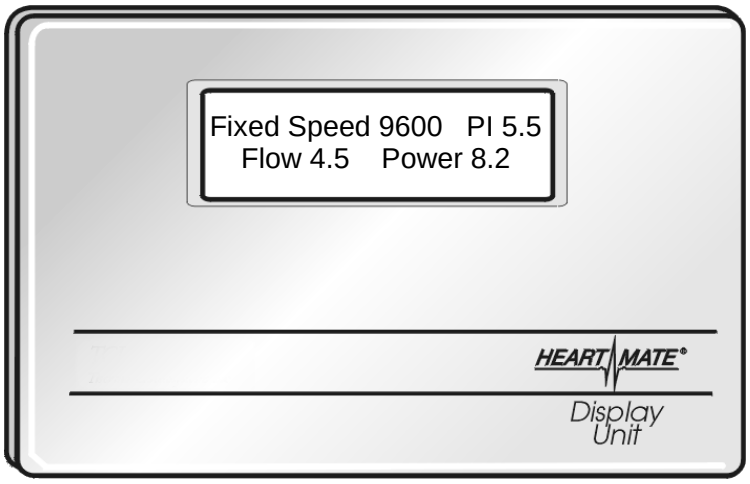


Display Module continued

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

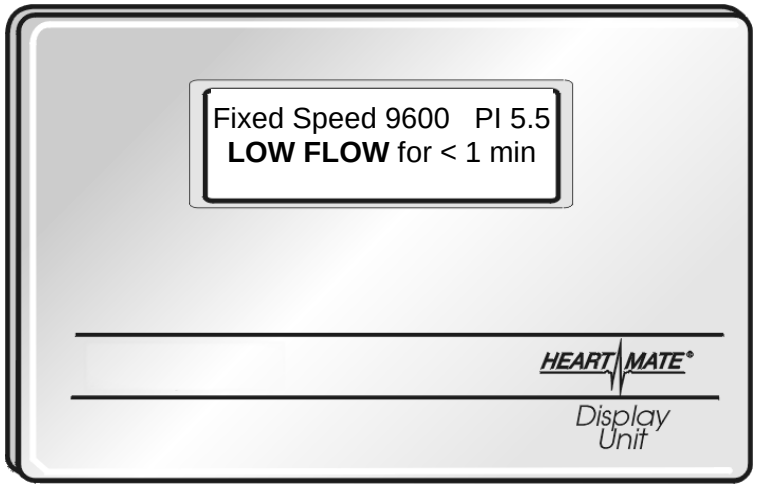
- **Current pumping mode** (Fixed Mode)
- **Current pump speed** in revolutions per minute (rpm)
- **Pulsatility Index (PI)** (your doctor can explain this)
- **Estimated flow** in liters per minute (lpm)
- **Power in watts (W)**

Figure 13c



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

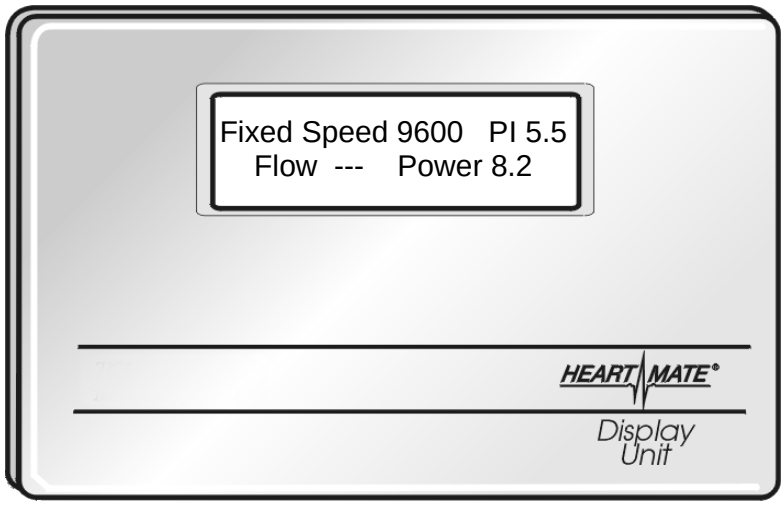
Figure 13d



Display Module continued

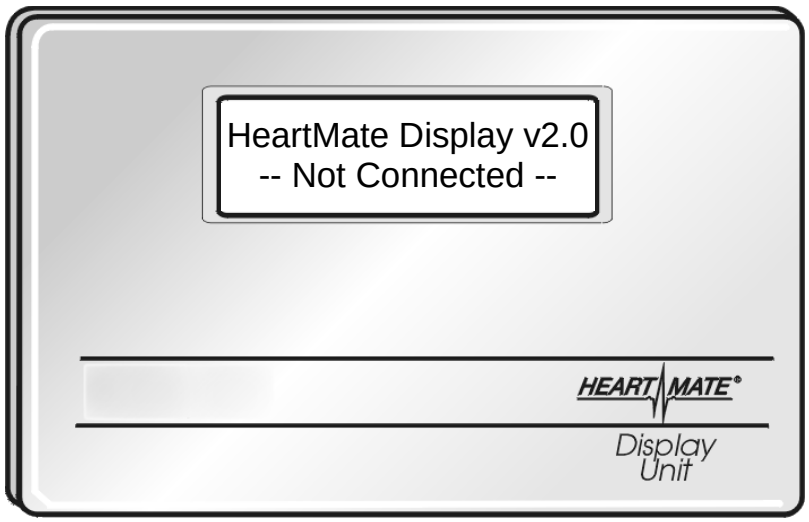
If the estimated flow is too high or too low to show on the screen, the Display Module will insert plus or minus signs instead of numbers. For example, "Flow - - - " appears on the screen if the low limit is reached. "Flow + + + " if the high limit is reached **Figure 13e**).

Figure 13e



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

Figure 13f



Display Module continued

Display Module Alarm Messages

ALARM MESSAGES	MEANING	WARNING LIGHTS & SOUNDS	WHAT YOU SHOULD DO
LOW Flow for X min.	Pump has stopped or is not working right.	RED HEART  with STEADY AUDIO TONE on System Controller	1 Make sure System Controller is connected to pump and PBU cable is connected to PBU. 2 Switch to fully-charged batteries. 3 Call emergency services (dial 911). 4 Follow emergency procedures (page 56).
LOW VOLTAGE	Less than 5 min. of battery power left.	RED BATTERY with STEADY AUDIO TONE	Change batteries, **one at a time**. If batteries not available, switch to PBU or EPP. **Note**: Pump speed will slow down to save power until the alarm clears (see Power Saver Mode, page 32). **Warning**: Do NOT remove both batteries at the same time or your pump will stop.
Power Cable Disconnected	One of the power leads is disconnected.	FLASHING POWER SYMBOL and FLASHING BATTERY FUEL GAUGE LIGHTS on System Controller with 1 beep every second	Check for loose power leads. If on PBU power, check that power lead is not damaged/ disconnected.

continued

Display Module continued

Display Module Alarm Messages cont.

ALARM MESSAGES	MEANING	WARNING LIGHTS & SOUNDS	WHAT YOU SHOULD DO
LOW VOLTAGE Advisory	Less than 15 min. of battery power left. System Controller not getting enough power.	YELLOW BATTERY with 1 beep every 4 seconds	Switch to fully charged batteries or switch to PBU or EPP. **Warning**: Do NOT remove both batteries at the same time or your pump will stop.
DRIVER CELL LOW Advisory	System Controller's battery module is low on power.	YELLOW DRIVER CELL symbol on System Controller with 1 beep every 4 seconds.	Replace System Controller battery module.
REPLACE SYSTEM DRIVER Advisory	System Controller is operating in back-up mode.	REPLACE SYSTEM DRIVER (on Display Module). BROKEN AUDIO TONE (on System Controller) with repeating cycle of 2 beeps followed by 2 seconds of silence	1 Replace System Controller. 2 Call your hospital contact person.
LOW SPEED	Pump is operating below the low speed limit set by your doctor.	**Warning**: Low Speed. 1 beep every 4 seconds.	1 Confirm that doctor has not ordered this speed setting. 2 Call your hospital contact person.

HeartMate Batteries

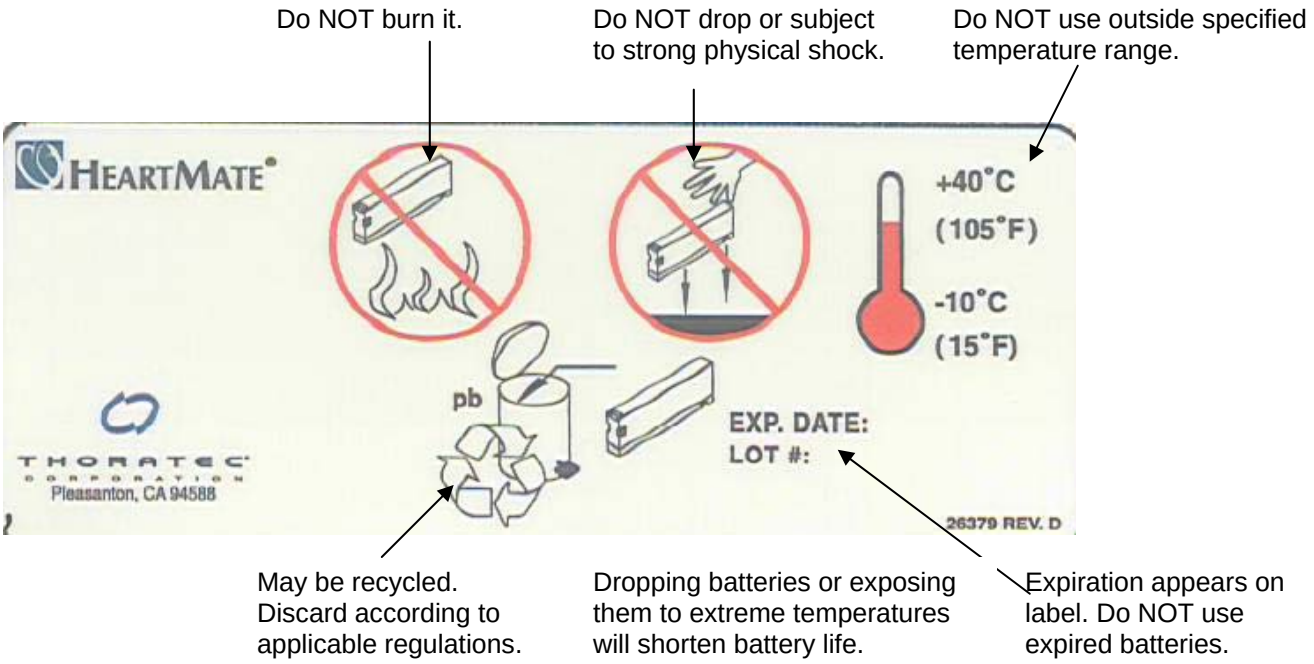
A pair of fully-charged HeartMate batteries will power the pump for about 3 hours under "normal" conditions (such as reading, casual walking). Batteries will last for less time if you are more active. For example, while exercising you could get up to 25% less time. While on battery power keep at least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

When you first get a new battery, you will need to charge it before using it. Charge it in the PBU (see "Recharging HeartMate Batteries" on page 32). Write the date of the first charge on the battery's label. Unless there are problems with the battery (damage from dropping, etc.), you should be able to use it for up to 1 year after the first charge. Never use expired batteries and always use batteries according to instructions!

Note: Dirty battery terminals may prevent proper battery charging, which can affect battery operation. The metal battery terminals and the insides of the metal battery clip contacts should be cleaned once a week with a Q-Tip™ or lint-free cloth that has been dipped in rubbing alcohol.

CAUTION !

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



HeartMate Batteries continued

CAUTION !

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

Power Saver Mode

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

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

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

Recharging HeartMate Batteries

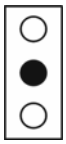
The Power Base Unit (PBU) is the only battery charger you should use to charge HeartMate batteries. Using any other battery charger may damage the batteries. The PBU can charge up to 6 batteries in about 8 hours, depending on the charge level of the battery(ies) being charged.

How to Charge Batteries Using the PBU

1 Slide the battery into a slot of the PBU, with the metal terminal facing up.
The yellow light will come on for about 30 seconds while the battery is tested.

Note: Do not touch the metal battery terminals.

2 After testing, 1of 3 lights will come on (green, yellow, or red). The light color depends on the battery's charge level or status (see table below).

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

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

Note: Sometimes the red light comes on if the battery is put into the slot wrong. If a battery fails the 1st test, put it into a different slot and try again. If it fails the 2nd test, there is something wrong with the battery. Do not use it; replace it. If a battery passes the test, a **yellow** light comes on and then the battery starts recharging. After it is charged, the **green** light comes on.

Recharging HeartMate Batteries continued

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

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

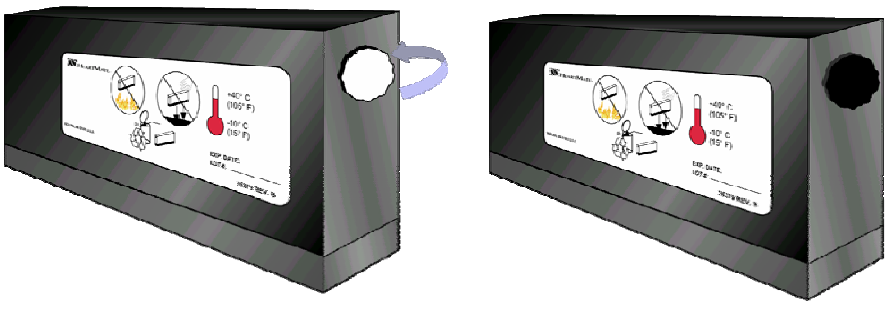
Note: Dirty battery terminals may prevent proper charging. Battery terminals should be cleaned once a week with a Q-Tip® or lint-free cloth that has been dipped in rubbing alcohol.

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

White = Charged; ready for use.

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

Figure 14



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

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

Changing Batteries

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

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

1 Remove the battery clips and attached batteries from your holsters or Pocket Pak™.

2 Remove spare (fully-charged) batteries from your travel case or from the PBU.

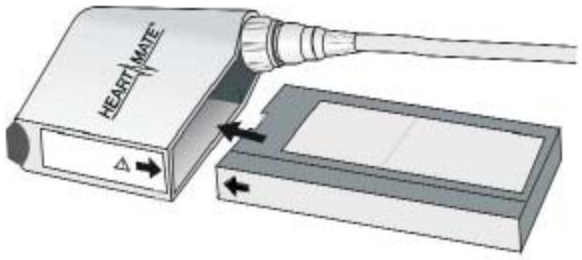
3 Take out only 1 battery from its battery clip. *An alarm will sound and the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*

Note: Press the battery release button to remove the 1st battery from its clip.

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

4 Match the arrows on the new battery and the battery clip (**Figure 15**).

Figure 15



5 Slide the new, fully-charged battery into the battery clip. *The alarm will stop and both the green power symbol and the battery fuel gauge lights will stop flashing. Wait until the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 6.*

Changing Batteries continued

6 Repeat steps 2 – 5 with the 2nd battery/battery clip.

7 Turn over the Velcro to show that the batteries need to be recharged.

8 Put the new, fully-charged batteries/battery clips into the holsters or Pocket Pak.

9 Put the used batteries into PBU for recharging.

WARNING !

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

Switching Power Sources

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

1 Make sure PBU is plugged in and turned on.

2 Make sure that the PBU cable is attached to the "Patient" socket found on the back of the PBU.

3 Place black and white PBU connectors within easy reach.

4 Remove batteries from their holsters or Pocket Pak™.

Note: Press the battery release button to remove the 1st battery from its clip (**Figure 16**).

5 Unscrew the white connector from the 1st battery clip. *An alarm will sound, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*

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

6 Put aside the battery and battery clip.

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

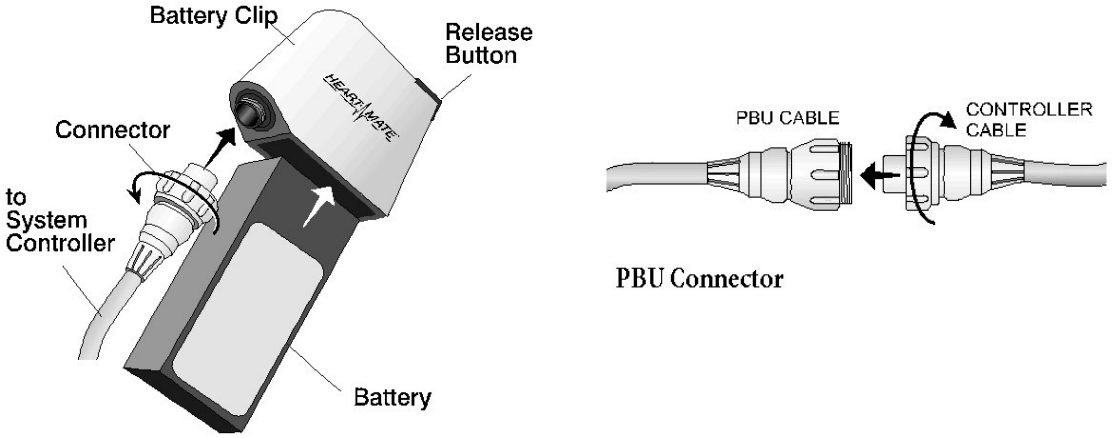
Note: Always connect white-to-white and black-to-black connectors.

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

Switching Power Sources continued

Going from Batteries to PBU

Figure 16



8 Unscrew the **black** connector from the 2nd battery clip. *An alarm will sound, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash*.

9 Put aside the battery and battery clip.

10 Connect the **black** PBU power lead connector to the **black** System Controller connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and battery fuel gauge lights stop flashing and the alarm stops before going to Step 11.*

11 Press the battery release button to remove the 1st battery from its clip.

12 Repeat Step 11 for the 2nd battery clip/battery.

13 Turn over the Velcro to show that the batteries need to be recharged.

14 Put batteries into PBU for recharging.

15 Store battery clips in a clean, dry place.

Switching Power Sources continued

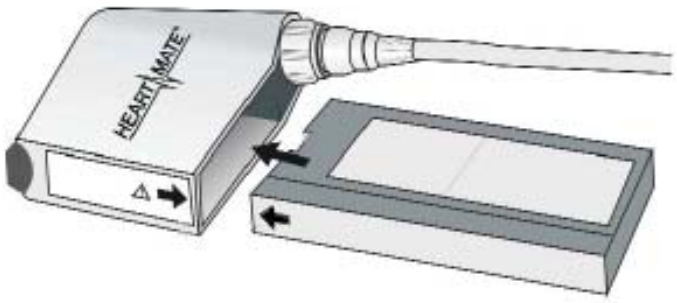
Going from PBU to Batteries (see Appendix for Power Change Checklist)

1 Place 2 battery clips, 2 fully charged batteries, and the white and black PBU power lead connectors within easy reach.

2 Place the 1st fully-charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until it "clicks" into place (**Figure 17**). Repeat for the 2nd battery/battery clip.

3 Unscrew the **white** System Controller/PBU connectors. *An alarm will sound, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*

Figure 17



WARNING !

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

Switching Power Sources continued

Going from PBU to Batteries

WARNING !

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

4 Put aside the PBU Connector then connect the battery clip connector to the **white** System Controller connector. *The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing. Wait until the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 5.*

CAUTION !

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

5 Unscrew the **black** System Controller/PBU connectors. *An alarm will sound, the green power symbol will flash rapidly, and the 4 green battery fuel gauge lights will flash.*

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

7 Put the batteries and clips into the holsters or Pocket Pak.

8 Store the PBU connectors in a clean, dry place.

9 Put at least 2 fully-charged batteries into your travel case.

Using the Emergency Power Pack (EPP)

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

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

How to Use the EPP

1 Open the top of the EPP and read the instructions inside.

2 Plug the cable provided with the EPP into the cable socket (found inside the top of the EPP). Use the screw provided to secure the cable into the EPP socket. A screwdriver (not provided) should be used for this connection.

3 Unscrew the **white** System Controller connector from the battery clip or PBU. *An alarm will sound, the green power symbol will flash rapidly, and the 4 battery fuel gauge lights will flash.*

4 Connect the **white** System Controller connector to the **white** EPP connector.
The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing.

5 Unscrew the **black** System Controller connector from the battery clip or PBU. *An alarm will sound, the green power symbol will flash rapidly, and the 4 battery fuel gauge lights will flash.*

6 Connect the **black** System Controller connector to the **black** EPP connector.
The alarm will stop and both the green power symbol and battery fuel gauge lights will stop flashing.

7 You are now connected to the EPP (**Figure 18**).

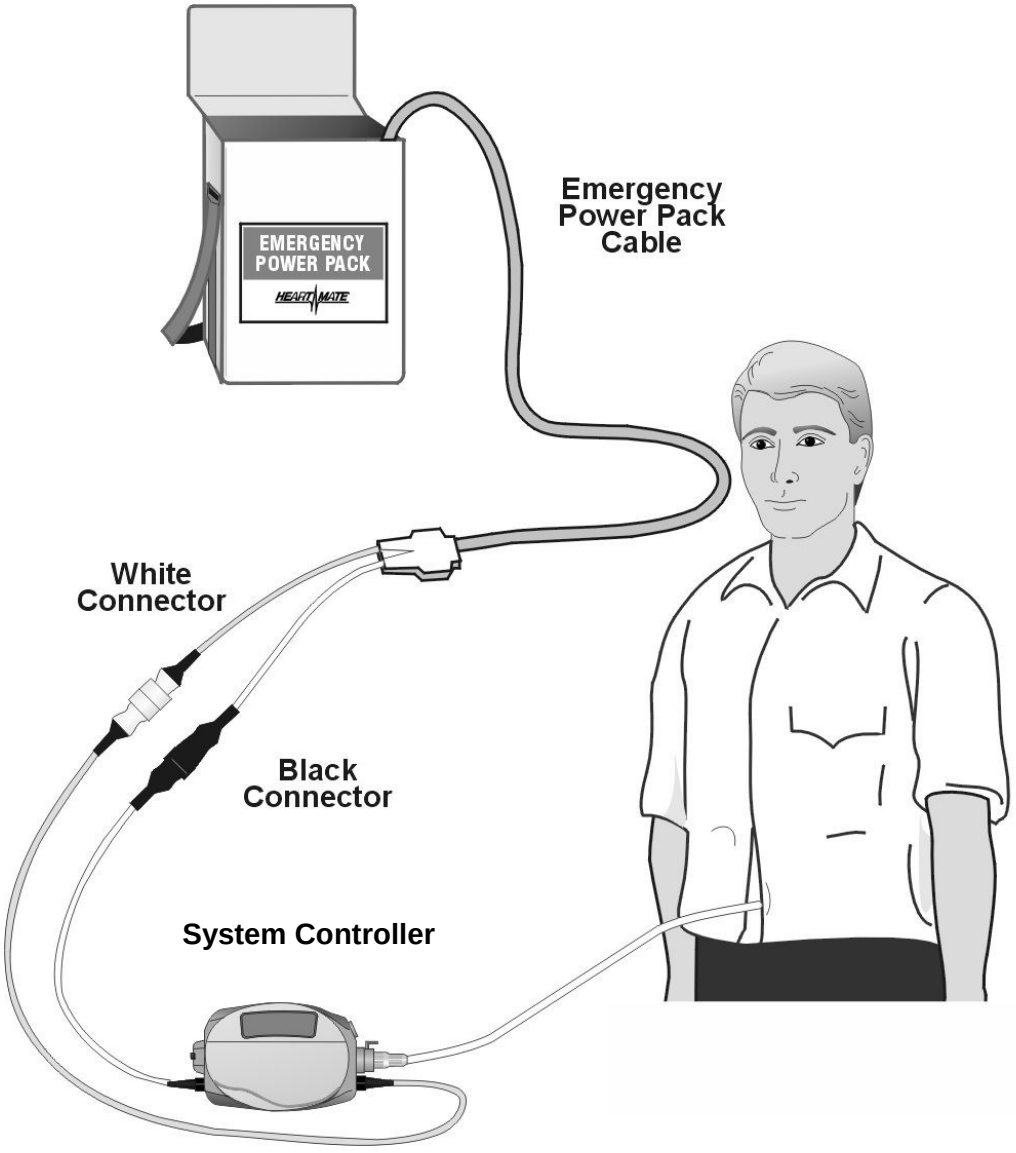
8 Contact your hospital contact person or local emergency service provider to make other arrangements if the power outage is expected to last more than 12 hours.

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

Using the Emergency Power Pack (EPP) continued

How to Use the EPP

Figure 18



Using the Emergency Power Pack (EPP) continued

WARNING !

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

CAUTION !

- When connecting leads, do not force them together without first lining up connectors. Forcing together unaligned connectors may damage them.
- Never use tools to tighten connectors. Hand tighten only. Using tools may damage the connectors.
- Do not let the connector ends to get dirty or wet.
- To prevent deterioration or damage to the EPP:
  - Do NOT leave or store EPP in hot or cold areas (car trunks, etc.) or EPP life will be shortened.
  - Do NOT use an expired EPP.
- Do NOT store or use the EPP in temperatures below 0° C (32°F) or above 50° C (122° F), or it may fail suddenly. If your EPP stays below room temperature (20-23° C, 68-72° F) during use, it will run the pump for less than 24 hours. At the low end of the temperature range (0° C, 32° F), run time will be reduced by 50%.
- Dispose of expired or used EPP according to local laws and regulations. Do NOT burn it.

Living With Your Heart Pump

Keeping Your Home Safe

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

___ Is the home free of clutter and dangerous objects?

___ Are there stairs? If so, how many?

___ Is there a bedroom on the first floor?

___ Is there a bathroom on the first floor; and does the bathroom have a shower? *Remember, no baths while implanted with the pump.*

___ Is the home electrically safe, with enough safe, grounded (3-prong), and working electric outlets? (at least one outlet must be dedicated to powering the PBU).

___ Does the home have adequate telephones for emergency communication (for example, speed dial for emergency calling)?

___ Are any occupational or physical therapy aids needed (for example, shower chair)?

___ Has the electric company been notified in writing of the need for priority power restoration in the event of a power loss?

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

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

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

Activities of Daily Living

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

CAUTION !

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

WARNING !

- Do NOT touch television (TV) or computer screens while you have the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and cause the pump to stop.
- Do NOT do anything that may create static electricity, like vacuuming. A strong electric shock can damage the electrical parts of the system and make the pump to stop.
- Do not pregnant while you have the pump.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may cause injury or make the pump stop.

Eating

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

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

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

Sleeping

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

Try to sleep so that you do not pull on or move the percutaneous lead going through your skin. Don't let the lead get tangled in clothing or blankets. To help keep the lead from moving, you can wrap an elastic bandage lightly around your thigh, with the lead crossing through one of the layers. Another option is to use the HeartMate Stabilization Belt. You can get a Stabilization Belt from your hospital contact person.

Remember these important sleep guidelines:

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

Intimacy

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

WARNING !

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

Traveling

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

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

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

- Keep at least 1 spare set of fully-charged batteries with you at all times.
- Bring your Emergency Power Pak (EPP) to power the pump in the event of power outage (for long-distance travel).
- NOT leave or store batteries or the EPP in extremely hot or cold places (such as the trunk of your car), or battery life will be shortened.
- Never store or use batteries or the EPP in temperatures below -10°C (15°F) or above 40° C (105°F) or the batteries may fail suddenly.

Note: If you will be traveling outside the United States and Canada, talk with your hospital contact person about adapters or converters needed for using electrical power in some foreign countries.

Automobile Travel

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

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

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

Showering

You cannot take tub baths while implanted with the pump, but you may be able to shower once your exit site has healed. Your doctor will tell you if you can shower.

Note: While your exit site is healing, please consult your physician regarding appropriate cleansing methods.

When you do shower, you must use the HeartMate Shower Kit to protect the System Controller from getting wet. The exit site also needs to be kept as dry as possible. A dry exit site reduces the risk of infections.

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

WARNING !

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

CAUTION !

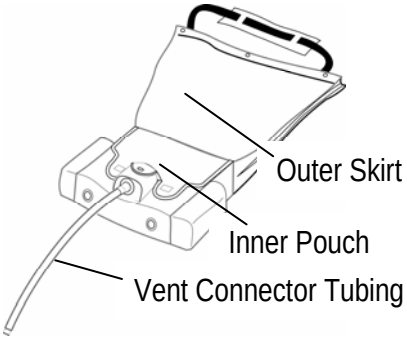
Do NOT swim or take a bath. You may be able to take showers using the HeartMate Shower Kit once the exit site has healed and if your doctor gives you permission.

Getting Ready to Shower

1 Remove the vent connector tubing from the small round pocket near the inner pouch (**Figure 19**). Throw away the tubing (it is not needed for this version of the pump).

Showering continued

Figure 19



Getting Ready to Shower

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

OR

2 Put the strap around your neck and hang the kit in front of you.

Note: The strap is adjustable.

3 Raise the outer "skirt" of the Shower Kit to expose the inner pouch underneath.

4 Lift the Velcro tabs on the inner pouch cover.

5 Open the inner pouch cover.

6 Place the System Controller, leads, and connectors inside the pouch.

7 Reseal the pouch by pressing down the Velcro tabs.

Showering continued

8 If you plan on **using battery power** during your shower, transfer the batteries to the Shower Kit:

a Remove the 1st battery from the holster or PocketPak

Note: Remove batteries **one at a time**. Wearing your holster or PocketPak until all equipment is transferred into the Shower Kit may reduce pulling on the exit site.

b Insert the 1st battery into one of the pockets located on either side of the inner pouch.

Note: Insert the battery with the battery clip at the *top* and the lead connector facing *away from* you.

c Repeat steps "a" and "b" for the 2nd battery.

d Remove the empty holster or PocketPak.

OR

8 If you plan on **using PBU power** during your shower, skip to Step 9.

9 Pull the outer "skirt" down over the inner pouch.

10 Press together the snaps at the bottom of the "skirt."

11 Adjust Shower Kit so it does not pull on the exit site while showering.

Note: Keep PBU away from water and shower spray!

Showering continued

After Showering

1 Use a sterile 4" X 4" gauze bandage to dry the exit site.

2 Use a clean, dry towel to dry the Shower Kit's strap and outer "skirt."

3 Undo the snaps at the bottom of the outer "skirt" and then lift up the "skirt."

4 Lift the Velcro tabs on the inner pouch cover; open the pouch.

5 Remove all equipment from the inner pouch and return it to the holster/Pocket Pak or PBU.

6 Remove Shower Kit and allow it to drip dry.

Note Let it dry completely before using it again.

Caring for your Shower Kit

Keeping the Shower Kit clean helps it work properly.

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

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

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

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

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

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

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

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

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

CAUTION !

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

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

Proper Hand Washing

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

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

Follow these instructions for washing your hands:

1 Use a paper towel to turn on the faucet(s) for clean , running water.

2 Wet your hands and wrists with the clean, running water.

3 Apply soap to hands. Liquid soap is preferred over bar soap to minimize micro-organism growth.

4 Vigorously rub together all surfaces of the lathered hands for a **minimum of 15 seconds**. Friction helps to remove dirt and microorganisms. Wash around the backs of both hands as well as under rings, around cuticles, and under fingernails.

5 Rinse hands thoroughly under stream of clean, running water. Running water carries away dirt and microorganisms. Point fingers down so water and contamination won't drip toward elbows.

6 Dry hands completely with clean, dry paper towel.

7 Use a paper towel to turn off running water.

8 Repeat steps 1 – 7 every single time before and after dressing changes and touching the percutaneous lead exit site.

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

Note Use the **NOTES** section at the end of this booklet to write down any additional information that your doctor has recommended.

Caring for the Percutaneous Lead

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

Remember the following recommendations:

- Do not severely bend or kink your percutaneous lead.
- Do not let the percutaneous lead become twisted.
- If you carry your System Controller in a carrying case, don't "catch" the percutaneous lead in the zipper.
- Allow for a gentle curve for your percutaneous lead. Do not severely bend your percutaneous lead multiple times or wrap it tightly.
- Keep your percutaneous lead clean. Wipe off any dirt or grime that may appear. If necessary, use a towel with soap and warm water to gently clean your percutaneous lead. 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.
- Wear the HeartMate Stabilization Belt AT ALL TIMES to keep the lead in place and to prevent pulling on or moving the lead.
- Be mindful of where your System Controller is at all times. It is important to protect your controller from falling or from pulling on your lead. Report any drops or snags on the percutaneous lead to your hospital contact person.
- Don't let your percutaneous lead catch or snag on anything that will pull on or move the lead.
- Check your percutaneous lead daily for signs of damage (cuts, holes, tears). If you discover damage to your lead, report it immediately to your hospital contact person.

Note Use the **NOTES** section at the end of this booklet to write down any additional information that your doctor has recommended.

Pump Replacement

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

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

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

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

Handling Emergencies

What Is An Emergency?

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

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

If the system is not working right, the System Controller will alarm (see "System Controller Warning Lights and Sounds" on page 11).

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

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

How to Handle an Emergency

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

When the Pump is Running

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

1 Check all lead connections.

2 Reconnect any loose or disconnected leads.

3 Call your hospital contact person if reconnecting the leads does not fix the problem.

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

What Is An Emergency? continued

When the Pump has Stopped (Red Heart Alarm)

If the pump stops running, you should. . .

1 Check the connection between the System Controller and the pump and then check the connection between the System Controller and power source (batteries, PBU or EPP).

2 Fix any loose connection then continue with Step 3.

3 Switch to a different power source. If you are on batteries, switch to PBU. If you are on PBU power, switch to batteries.

4 Switch to the back-up System Controller (see "Replacing System Controllers" on page 20).

5 If checking connections, switching power sources, or changing System Controllers does not fix the problem, call emergency services (dial 911) right away, then call your hospital contact person.

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

CAUTION !

- Make sure the pump is fully stopped before disconnecting it from the System Controller by disconnecting both power leads.
- Do NOT let the connector ends get dirty or wet.

Authorized European Union Representative

Thoratec Europe, Ltd.
5 Brunel Court, Burrel Road
St. Ives, Cambridgeshire PE27 3LW United Kingdom

Safety Testing and Classification

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

WARNING !

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

WARNING !

The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.

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

Appendix

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

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

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

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

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

Power Change Checklist

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

1 Prepare for power change (see *Switching Powers Sources on* page 36).

2 Remove only 1 battery from its battery clip or remove the white PBU power lead from the System Controller.

The power symbol will flash rapidly, the 4 green battery fuel gauge lights will flash, and the alarm will sound once every second.

3 Connect the fully-charged battery or white PBU power lead to the System Controller.

4 Wait until both the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 5.

5 Remove the 2nd battery from its clip or remove the black PBU power lead from the System Controller.

The power symbol will flash rapidly, the 4 green battery fuel gauge lights will flash, and the alarm will sound once every second.

6 Connect the fully-charged battery or black PBU power lead to the System Controller.

7 Wait until both the power symbol and the 4 green battery fuel gauge lights stop flashing and the alarm stops before going to Step 8.

8 Check fuel gauge and then continue with appropriate steps to complete the power change:

- See *Changing Batteries*, page 35, or
- See *Going from Batteries to PBU*, page 38, or
- See *Going from PBU to Batteries*, page 39.

WARNING:

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

HeartMate II Emergency Response Checklist

Red Heart 
with Continuous Audio Tone

Urgent Controller Alarms = ***OR***

Continuous Audio Tone and no lights on System Controller

WHAT TO DO:

1 CHECK THE CONNECTIONS

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

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

3 CHANGE THE POWER SOURCE

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

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

4 CHANGE THE CONTROLLER

4a Replace System Controller with back-up Controller.

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

5 GET ADDITIONAL HELP

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

Notes