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Warnings and Precautions

Warnings

- Understanding the operating and safety aspects of HeartMate products is essential for safe and successful use. All users (including clinicians, patients and caregivers) must be trained on system operation and use.

- A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support is necessary before using this product. Read this entire HeartMate Power Module Instructions for Use (IFU) and the corresponding (HeartMate II or HeartMate XVE LVAS) Instructions for Use, Operating Manual, and/or Patient Handbook before attempting use.

- Before using any HeartMate power accessories (Power Module, batteries, Universal Battery Charger), all users (including clinicians, patients, and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
  - HeartMate 12 Volt NiMH Battery Instructions for Use (IFU) (document # 103769)
  - HeartMate 14 Volt Li-Ion Battery IFU (document # 103770)
  - HeartMate Universal Battery Charger IFU (document # 103771)
  - HeartMate Power Module IFU (document # 103772)

- The HeartMate Power Module (PM) generates, and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the Power Module. Interference can be determined by unplugging the Power Module and seeing the affect on devices in the area. If interference is detected, attempt to correct it by FIRST SWITCHING TO BATTERY POWER and then:
  - Re-orienting or moving the affected device(s).
  - Increasing the distance between the PM and the affected device(s).
  - Connecting the affected device(s) to an electrical outlet different from the outlet used to power the Power Module.
  - Consulting Thoratec’s Technical Services Department for advice and assistance.

- Connect the HeartMate PM only to properly-tested, grounded (3-prong) AC outlets that are dedicated to PM use. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.

- Do not connect the PM to electrical outlets controlled by a wall switch, or the PM may be left inoperable.

- The PM like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3-prong) AC mains electrical outlet that is dedicated to its use, except during transport or service/maintenance. The PM’s internal
battery (that provides limited backup power to the LVAD in the event of AC mains power failure) remains charged as long as the PM is connected to AC power.

- The PM contains an internal battery. When new, the internal battery provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS and 45 minutes to the XVE LVAS, in the event of AC mains interruption/failure. If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes. The PM is shipped with its internal battery disconnected. It must be connected prior to initial use. If the internal battery is not connected, the backup power source will not work. Make sure the internal battery is connected before initial use and after any time the PM is shipped for service or maintenance.

- Transfer from the PM to batteries during AC mains power failure. The PM has an internal backup battery that will power the pump while you transfer to batteries. The internal backup battery should not be used as a backup power source for the system during AC mains power failure. The Display Module or System Monitor will not work if connected to the PM during a power failure. In addition, the PM’s battery charge status indicators will not work during AC mains power failure.

- At least one System Controller power lead must be connected to a power source (PM or batteries) at ALL times. Disconnecting both power leads at the same time will cause the pump to stop.

- Using equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the PM with other devices. This may result in potential interference between the PM and other devices.

- A patient’s primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car’s power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car’s DC power is inadequate to power the LVAS, the PM will alarm or switch to back-up battery power. If this occurs, switch to portable battery power and discontinue the use of DC input power to the PM.

- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, the patient should have at least one set of charged HeartMate batteries and cables in close proximity (see Section 8.0, Traveling by Car).

- The automobile engine must be ON and RUNNING BEFORE connecting the PM to its DC power outlet.

- Keep the PM away from water or moisture. If the PM has contact with water/moisture, shower spray, rain/snow or wet surfaces, you may receive a serious electric shock or your PM may fail to operate properly.

- The PM is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Do not use the PM in the presence of flammable anesthetic agents (e.g., nitric oxide), or an explosion may occur.
Precautions

- The PM requires preventive maintenance at least once every 12 months for the best possible operation. Preventive maintenance includes (but need not be limited to): checking, cleaning, and inspecting all internal connections, replacing the internal battery (the internal battery is rechargeable, but has a limited life), and replacing the PM patient cable.

- PM service and maintenance should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

- Do not clean or service the PM while it is providing power to the system.

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

- PM connectors should be kept clean and dry. Do not expose PM connectors to water, moisture, dirt, etc.

- When connecting PM connectors, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
INTRODUCTION

WARNING! A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support is necessary before using this product. Read this entire HeartMate Power Module Instructions for Use (IFU) and the corresponding (HeartMate II or HeartMate XVE VAS) IFU, Operating Manual, and/or Patient Handbook before attempting use.

1.0 Overview

The HeartMate Power Module (PM) (Figure 1) works with either the HeartMate II or HeartMate XVE LVAS. The PM performs the following functions:

- Provide power to the LVAS during tethered operation. See Section 3.0, Tethered Operation (Overview).
- Provide power to the Display Module or System Monitor.
- Connect the Display Module/System Monitor to the System Controller for monitoring purposes.
- Echoes System Controller alarms.

Figure 1  HeartMate Power Module (front view)
2.0 Setting Up the Power Module (PM) Prior to Use

Before using the Power Module (PM) to power the HeartMate II or XVE LVAS (and optional display module or system monitor, if desired) prepare the PM for use by connecting its internal battery and attaching the power cord and patient cable.

2.1 Connecting the Internal Backup Battery

PMs are shipped to customers with the internal battery disconnected. After receiving the PM, the hospital’s biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device.

Follow these steps to connect the internal backup battery:

1. Place the PM on a flat, sturdy surface while the device is UNPLUGGED from AC mains electrical power and DISCONNECTED from the patient.
2. Inspect the PM for dents, chips, cracks, or other signs of damage. Do NOT use a PM that appears damaged. Obtain a replacement, if needed.
3. Use a Phillips screwdriver to remove the two ¼-turn screws (Figure 2). Note: The screws will remain in the screw holes once loosened.
4. Open the battery compartment cover on the rear of the PM.
5. Unscrew and remove the metal bracket that is holding the internal battery in place (Figure 3).

Figure 2  Removing rear panel of PM to connect internal backup battery
a) Rear Panel (note screws)  b) Unscrewing rear panel
6. Remove the internal backup battery from its battery compartment.

7. Place the black battery connector over the metal contact end of the internal backup battery (Figure 4). The contacts should “snap” into place. Gently pull on the connection to make sure it is secure. **Note:** The PM will begin to alarm (audio and visual) indicating the unit is disconnected from input power. This alarm can be silenced by pressing the Alarm Silence button on the user panel. The alarm will clear once the PM is connected to power.

![Figure 3 Unscrewing and removing metal bracket](image)

![Figure 4 Attaching black battery connectors](image)
8 Return the internal backup battery to its compartment, as shown in Figure 5.

![Figure 5 Attaching contacts to the internal backup battery and returning the battery to its compartment](image)

9 Use the Phillips screwdriver to reattach the metal bracket. Make sure the connection is secure (Figure 6).

![Figure 6 Attaching metal bracket](image)

10 Replace the battery compartment cover (Figure 7).

![Figure 7 Replacing cover](image)
11 Use the Phillips screwdriver to tighten the two ¼-turn screws (Figure 8). Make sure the screws are tight and the cover is securely closed.

Figure 8  Closing the rear panel of the PM

12 Repeat Steps 1 – 11 any time the internal backup battery is disconnected or when the PM is transported or shipped for service/maintenance, since the battery is disconnected for shipping.
2.2 Connecting the PM Power Cord and PM Patient Cable

The HeartMate Power Module (PM) provides AC mains electrical power to either the HeartMate II or HeartMate XVE system. In addition to powering the LVAS, the PM can simultaneously power the HeartMate Display Module or System Monitor, if desired. Before being used to power the system, the PM power cord and patient cable first need to be attached. Follow these steps for connecting the PM power cord and patient cable:

1. Place the PM on a flat, sturdy surface.
2. Obtain the grey AC power cord and place the female end of the connector into the PM’s power entry module (Figure 9a).
3. Once the cord is inserted into the power entry module, lift the power cord retention clip into the locked position; insert the two ends of the clip into the holes, as shown in Figure 9b. Engaging the clip will ensure that the AC power cord does not fall out accidentally (Figure 9c).
4. Plug the PM’s grey power cord into a properly-tested and grounded (3-prong) AC mains electrical outlet that is dedicated to PM use and that is not controlled by a wall switch. **Note:** If traveling internationally, you will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Obtain a Thoratec power cord set, if needed.

**WARNING!** Connect the HeartMate Power Module (PM) only to properly-tested and grounded (3-prong) AC mains outlets that are dedicated to PM use. Do not use outlets that are controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets.

5. After plugging the power cord into the AC mains electrical outlet, observe the front panel of the PM. The green “power on” light should come on (Figure 10). **Note:** If the light does not come on after plugging the PM into a functioning AC mains outlet, the device may be defective. Do not use it. Obtain a replacement, if needed.
Figure 9  Connecting the AC power cord and the retention clip
6 Obtain the PM patient cable (Figure 11) from product packing.

7 Line up the red dots between the patient cable and the “HeartMate” logo socket located on the side of the PM and then insert the patient cable into the “Power On” logo socket (Figure 12). Note: The cable will click into place if fully engaged in the socket. The “click” is the sound of the locking feature engaging.
After inserting the connector snugly into the socket, check that the connection is tight. Tug gently on the strain relief portion of the connector (Figure 13). Do NOT pull on the cable!

**Note**: If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and so that it will not cause tripping or falls.
2.3 Connecting the Display Module

When connected to the Power Module (PM) and System Controller, the Display Module (Figure 14) reports data received from the System Controller through the PM. It displays information about system performance on its display panel screen.

For HeartMate II patients, the following information is displayed:
- Current pumping mode (fixed or power saver mode)
- Current pump speed in revolutions per minute (rpm)
- Pulsatility index
- Estimated flow in liters per minute (lpm)
- Power in watts

For HeartMate XVE patients, the following information is displayed:
- Operating mode (fixed or auto rate)
- Beat rate in beats per minute (bpm)
- Stroke volume (ml)
- Flow in liters per minute (lpm)

Patients at home will use the Display Module to monitor the system. Nurses, doctors and clinicians will usually use System Monitor (see Section 2.4, Connecting the System Monitor).

Figure 14 HeartMate Display Module
Follow these steps for setting up the Display Module for use with the PM:

1. Ensure the patient cable is attached to the PM. See Section 2.2, *Connecting the PM Power Cord and PM Patient Cable*.

2. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock.

3. Obtain the Display Module cable adapter ([Figure 15](#)) from product packaging.

4. Insert the male end of the adapter into the female end of the data cable receptacle of the Display Module. Firmly press together the connectors to ensure a tight connection ([Figure 16](#)).
Tighten the two thumb screws on the adapter connector to secure the connection.

Align the grooves between the adapter connector and the “□” socket found on the side of the PM (Figure 17); insert the connector into the “□” socket.

Note: The PM (with its round receptacle for the Display Module/System Monitor interface) replaces many of the functions of the Power Base Unit (PBU). You will need an adapter (described above) to connect the Display Module to the PM (see Steps 3 – 6). Contact Thoratec for an adapter, if needed.
Reference the Display Module screen. If the patient is connected to the PM and System Controller, the following should immediately appear once the cable is successfully connected (otherwise the screen remains blank):

<table>
<thead>
<tr>
<th>For HeartMate II, the Display Shows:</th>
<th>For HeartMate XVE, the Display Shows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current pumping mode (i.e., fixed or power saver mode)</td>
<td>Operating Mode (i.e., fixed rate or auto rate)</td>
</tr>
<tr>
<td>Current pump speed, in revolutions per minute (RPM)</td>
<td>Beat rate in beats per minute (BPM)</td>
</tr>
<tr>
<td>Pulsatility index (PI)</td>
<td>Stroke volume (ml)</td>
</tr>
<tr>
<td>Estimated flow in liters per minute (LPM)</td>
<td>Flow in liters per minute (LPM)</td>
</tr>
<tr>
<td>Power in watts (W)</td>
<td></td>
</tr>
</tbody>
</table>

7 If the patient is connected to the PM and System Controller, and the screen appears as described above, the Display Module is functioning properly and ready for use with the PM.

OR

7 If the patient is connected to the PM and System Controller and the screen does not appear as described above, check the following:
- The patient cable is fully inserted into the “♥” socket on the side of the PM.
- The Display Module adapter cable is fully inserted into the “☐” socket on the side of the PM.
- The System Controller power leads are properly connected (white-to-white and black-to-black).

8 If the screen still does not appear, contact Thoratec Corporation for assistance.

Note: At any time, if an alarm condition arises, an alarm message will immediately replace performance data appearing on the display module screen.
2.4 Connecting the System Monitor

When connected to the PM, the System Monitor (Figure 18) reports data from the System Controller through the PM. Like the Display Module, the System Monitor displays information about system performance, including current control mode (i.e., “fixed”), pump flow, pump speed, and overall operational status.

In addition to displaying performance data, the System Monitor also enables clinicians to control system operation using touch-screen prompts/messages. Typically, the System Monitor is used in clinical settings. Patients at home will use the Display Module to monitor the system (see Section 2.3, Connecting the Display Module).

![Figure 18 System Monitor mounted atop PM](image)

System Monitor Features and Clinical Applications

The System Monitor’s touch-screen feature permits clinicians to:

- Change LVAS operating parameters (i.e., the fixed speed and/or fixed rate set points)
- Change the system operating mode (for XVE only)
- Access screen that displays additional information on performance and alarm status
- Save LVAD motor waveforms and data records to a memory card for review, trending, and analysis (see the *HeartMate II LVAS Operating Manual* or the *HeartMate XVE LVAS Operating Manual*).

The System Monitor is used by physicians and nurses in the operating room during device implant, immediately post implant in the intensive care unit, and when:
• Close reading of system performance is required (during the LVAD implant procedure, for example)
• System settings need to be changed
• Performance data need to be recorded and downloaded to a memory card for review, trending, and analysis

2.5 Setting Up the System Monitor for Use with the PM

1. Plug the “System Monitor” cable into the “□” socket located on the side of the PM.

2. Plug the other end of the cable into the System Monitor, if not already connected.

3. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock.

4. Ensure the “Patient” cable is attached to the PM (see Section 2.2, Connecting the PM Power Cord and PM Patient Cable).

5. Turn on the System Monitor by pressing the on/off switch at the rear of the System Monitor (Figure 19) to the on (“I”) position. A green light on the front of the System Monitor should come on once the PM is receiving power. Contact Thoratec Corporation if the System Monitor will not power on.
Observe the System Monitor screen. Once power is turned on, the HeartMate logo screen should appear (Figure 20).

![HeartMate Logo Screen](image)

6

**Figure 19** System Monitor on/off switch (rear of System Monitor)

**Figure 20** HeartMate logo screen
7 If the HeartMate logo screen appears, the System Monitor is ready for use with the PM.

OR

7 If the System Monitor screen remains black, check the following:

- The System Monitor cable is securely connected to the System Monitor and fully inserted into the “□” socket located on the side of the PM.
- The System Monitor power switch is “on.”
- The PM is receiving adequate power from a functioning AC mains outlet (green “power on” light is illuminated).

OR

7 If “NOT RECEIVING DATA” is flashing on the System Monitor screen, the System Monitor cannot recognize or “see” the System Controller. If this occurs, check the following:

- The “Patient” cable is securely inserted into the “♡” socket located on the side of the PM.
- The “Display Module/System Monitor” cable is securely connected to the System Monitor and fully inserted into the “□” socket located on the side of the PM.
- The System Controller power lead connectors are properly connected to the PM power lead connector (i.e., white-to-white and black-to-black).

8 If the System Monitor still does not work, call Thoratec’s Technical Service Department.
2.6 Mounting the System Monitor onto the PM

Some versions of the System Monitor are designed to be mounted atop the PM (Figure 21). This “nesting” feature minimizes the space needed when a patient requires continuous monitoring during tethered operation.

Figure 21 System Monitor mounted on PM

Mounting the System Monitor

Follow these steps to mount the System Monitor on top of the PM:

1. Tip the back edge of the System Monitor base into the receiving ledge of the PM (Figure 22).

2. Once the back edge of the System Monitor base is secure under the rubber lip of the ledge, press down firmly onto the top of the PM to engage the two front feet into the holding grommets (Figures 23 and 24).

CAUTION! If the System Monitor is mounted on top of the Power Module, do NOT attempt to lift or carry the two devices together by the System Monitor handle. Doing so may damage the Power Module and/or System Monitor.
Figure 22  Sliding the System Monitor base under lip of PM ledge

Figure 23  Pressing down on front of System Monitor to insert feet into holding grommets of the PM
Removing the System Monitor

1. Pull up on the System Monitor handle to disengage the System Monitor feet from the PM grommets.

2. Slide the System Monitor base forward and out from under the PM ledge.

3. Remove the System Monitor from the PM; place the System Monitor onto a flat sturdy surface.
2.7 Monitoring PM Performance and Performing a PM System Self Test

The computer inside the Power Module (PM) is continually monitoring PM performance. If the PM computer detects a problem or internal malfunction, the yellow wrench symbol on the front of the PM is illuminated. The yellow wrench will be accompanied by an audio tone (a continuous or beeping tone, depending on the condition). If this occurs, immediately contact your VAD Coordinator or hospital contact person for guidance and a replacement, if needed. **Note:** See *Responding to Alarms* for additional information.

**Performing a PM System Self Test**

Perform a PM System Self Test at least once daily to ensure that the PM is working properly:

1. **Press and hold the PM’s Alarm Silence Button** for five seconds (Figure 25).

2. **Listen for the intermittent audio tone (3 beeps) to sound and watch the front of the PM to see if all the lights come on in sequence (i.e., one-at-a-time; not all at once).**

3. **If any of the following occurs, there may be a problem with the PM; contact Thoratec Corporation:**
   - No sound
   - Anything other than a continuous audio tone (such as beeping or broken tone)
   - All the lights come on at once
   - All the lights remain off
   - One of the lights does not come on

*Figure 25*  Silence Alarm Button on front of PM
3.0 Tethered Operation (Overview)

Both the HeartMate II LVAS and the HeartMate XVE LVAS are powered either by electrical power when connected to an AC mains electrical outlet, or by battery power with a pair of rechargeable HeartMate batteries (see the HeartMate 12 Volt NiMH Battery IFU and the HeartMate 14 Volt Li-Ion Battery IFU).

Using the PM to power the system is called “tethered” operation, since the patient is “tethered” (connected) to electrical power by the PM.

The following components are required for tethered operation:
- HeartMate Power Module (PM)
- PM power cord
- PM patient cable
- HeartMate II System Controller or HeartMate XVE System Controller

Note: The Display Module and System Monitor (used to monitor and/or control system operation) are optional components for tethered operation (see Section 2.3, Connecting the Display Module).

Figure 26 and Figure 27 show how the HeartMate II LVAS and HeartMate XVE LVAS are configured during tethered operation.
3.1 **Changing from PM Power to Batteries**

Changing from PM-powered to battery-powered operation (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from PM to battery power:

1. Place two battery clips, two charged batteries (as indicated by the green light on the Universal Battery Charger), and the white and black patient cable power lead connectors within easy reach.

2. Place the 1st charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.

3. Repeat step 2 for the 2nd battery/battery clip.
4 Unscrew the black System Controller/patient cable connectors. *The power disconnected alarm will come on:*

<table>
<thead>
<tr>
<th>For the HeartMate II</th>
<th>For the HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>An alarm will sound one beep per second, the green power symbol <img src="image" alt="Green Symbol" /> will flash rapidly, and the four green battery fuel gauge lights <img src="image" alt="Battery Gauges" /> will flash.</td>
<td>The Yellow Wrench <img src="image" alt="Yellow Wrench" /> will flash and an alarm will sound once every second</td>
</tr>
</tbody>
</table>

5 Put aside the patient cable connector; then connect the battery clip connector to the System Controller connector. *Wait until the flashing symbol(s) and audio alarms stop before continuing with step 6.*

**WARNING!**
- At least one System Controller power lead must be connected to a power source (Power Module or batteries) at all times. Disconnecting both power leads at the same time will cause the pump to stop.
- If power to the System Controller is interrupted:
  - **For HeartMate II,** if the pump speed is below 8,000 rpm, firmly press the Test Select ![Test Select](image) or Alarm Reset ![Alarm Reset](image) switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
  - **For HeartMate XVE,** the pump will restart automatically in Fixed Rate Mode once power is restored (check that this is the correct/desired mode).
6 Unscrew the white System Controller/patient cable connectors. The power disconnected alarm will come on:

<table>
<thead>
<tr>
<th>For the HeartMate II</th>
<th>For the HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>An alarm will sound one beep per second, the green power symbol (\text{●}) will flash rapidly, and the four green battery fuel gauge lights (\text{●●●●}) will flash.</td>
<td>The Yellow Wrench (\text{黄色扳手} ) will flash and an alarm will sound once every second</td>
</tr>
</tbody>
</table>

7 Put aside the patient cable connector; then connect the battery clip connector to the white System Controller connector. *Wait until the flashing symbol(s) and audio alarm stop before continuing with step 8.*

8 Place the batteries and battery clips into the holsters or carrying case.

**CAUTION!**
- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, rain/snow, dirt, etc. when making or breaking connections.

9 Keep the patient cable connected or near the PM until next use. **Note:** If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and so that it will not cause tripping or falls.

10 Place at least two additional charged batteries in the travel case.

**Note:** For HeartMate II patients, a *Power Change Checklist* is included in the Appendix 3 of this manual. All PM users (including nurses, patients, and patients’ caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.
3.2 Changing from Batteries to PM Power

Changing from battery-powered to PM-powered operation (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from battery power to PM power:

1. Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock.

2. Perform a PM system self test (see Section 2.7, Monitoring PM Performance and Performing a PM System Self Test).

3. If the PM fails the self test, contact Thoratec Corporation; otherwise, continue with Step 4.

4. Line up the red dots between the patient cable and the “♥” socket located on the side of the PM and then insert the patient cable into the “♥” socket (Figure 28). **Note:** The cable will click into place if fully engaged in the socket. The “click” is the sound of the locking feature engaging.

![Figure 28 Lining up red dots between patient cable and PM socket](image)

5. After inserting the connector snugly into the socket, check that the connection is tight. Tug gently on the strain relief portion of the connector (Figure 29). Do NOT pull on the cable!
6 Place the black and white PM-System Controller power lead connectors within each reach.

7 Remove the battery clips and attached batteries from the patient’s holsters or carrying case.

8 Before switching from battery power, first check the charge status of each battery: Press the battery fuel gauge on each of the batteries; determine which battery has the least power (see HeartMate 12 Volt NiMH Battery IFU or HeartMate 14 Volt Li-Ion Battery IFU).

9 If the lights differ, disconnect the connector from the battery with the least power first (otherwise, disconnect the white connector first).

10 Unscrew the white connector from its battery clip. The power disconnected alarm will come on:

<table>
<thead>
<tr>
<th>For the HeartMate II:</th>
<th>For the HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The Yellow Wrench will flash and an alarm will sound once every second.</td>
</tr>
</tbody>
</table>

11 Put aside the battery clip and attached battery.
12 Connect the white PM power lead connector to the white System. *Wait until the symbol(s) and audio alarm stops before continuing with Step 13.*

**WARNING!**
- At least one System Controller power lead must be connected to a power source (Power Module or batteries) at all times. Disconnecting both power leads at the same time will cause the pump to stop.
- If power to the System Controller is interrupted:
  - **For HeartMate II**, if the pump speed is below 8,000 rpm, firmly press the Test Select or Alarm Reset switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
  - **For HeartMate XVE**, the pump will restart automatically in Fixed Rate Mode once power is restored (check that this is the correct/desired mode).
- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your PM may not work properly.

13 Unscrew the **black** connector from its battery clip. *The power disconnected alarm will come on:*

<table>
<thead>
<tr>
<th>For HeartMate II</th>
<th>For HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The Yellow Wrench will flash and an alarm will sound once every second.</td>
</tr>
</tbody>
</table>

14 Put aside the battery clip and attached battery.

15 Connect the **black** PM power lead connector to the **black** System Controller connector (always connect black-to-black).
16 Press the battery release button on one of the battery clips to release its battery.

17 Repeat Step 16 for the 2nd battery/battery clip.

18 Store the battery clips in a clean, dry location until next use.

19 Place the used batteries into the HeartMate Universal Battery Charger (UBC) for charging (see HeartMate Universal Battery Charger IFU).

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

- If power to the System Controller is interrupted:
  - For HeartMate II, if the pump speed is below 8,000 rpm, firmly press the Test Select or Alarm Reset switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
  - For HeartMate XVE, the pump will restart automatically in Fixed Rate Mode once power is restored (check that this is the correct/desired mode).

- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.

- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your Power Module may not work properly.

CAUTION!
- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.

- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, dirt, etc. when making or breaking connections.
For HeartMate II users, a *Power Change Checklist* is included in the Appendix 3 of this manual. All PM users (including nurses, patients, and patients’ caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.
4.0 Power Module (PM) Backup Power

The Power Module (PM) has an internal backup battery. When new, the internal battery provides approximately 30 minutes of backup power for the HM II LVAS and approximately 45 minutes for the HM XVE LVAS, in the event of AC mains power interruption or failure (e.g., the power cord plug is removed from the AC mains electrical outlet or power fails during tethered operation). Over time, the internal battery may provide shorter periods of backup power. If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes.

The PM’s internal backup battery remains charged as long as the PM remains connected to AC mains power. If the PM is disconnected from AC mains power, the internal battery will operate the LVAS and the PM alarms until the battery is depleted. The internal backup battery automatically engages if PM input power is lost. It will automatically disengage once power is restored. See Table 1 for description of charge status symbols for the PM’s internal backup battery.

The PM’s internal backup battery is rechargeable. However, it has a limited lifespan. It will be replaced during annual PM service/maintenance service for the PM (see Section 11.0, Routine Maintenance).

During AC mains power failure, you should transfer from PM to battery-powered operation (see Section 3.1, Changing from PM Power to Batteries). If connected, the Display Module/System Monitor will not operate during AC mains power failure. Ensure the PM’s internal battery is charged prior to use, otherwise you will be vulnerable without an adequate backup battery power source.
Determining the Internal Backup Battery’s Charge Status

Indicator symbols on the front panel of the PM light up to indicate the charge status of the internal backup battery.

<table>
<thead>
<tr>
<th>Indicator Symbol/Color</th>
<th>Meaning</th>
<th>See Figure #</th>
</tr>
</thead>
<tbody>
<tr>
<td>A green charge lamp</td>
<td>The PM’s internal backup battery is charged and ready for use, if needed.</td>
<td>See Figure 30 below</td>
</tr>
<tr>
<td>A yellow charge lamp</td>
<td>The PM’s internal backup battery is being recharged.</td>
<td>See Figure 31 below</td>
</tr>
<tr>
<td>Yellow Battery “Advisory” Symbol</td>
<td>Less than 15 minutes of backup battery power remains. Promptly switch to another power source (e.g., charged batteries).</td>
<td>See Figure 32 below</td>
</tr>
<tr>
<td>Red Battery “Hazard” Symbol</td>
<td>Less than 5 minutes of backup battery remains. IMMEDIATELY switch to another power source. Without power the pump will stop.</td>
<td>See Figure 33 below</td>
</tr>
</tbody>
</table>

Table 1  Internal Backup Battery Charge Status
Figure 30 Green "charge" symbol (internal battery is ready for use)

Figure 31 Yellow "charge" symbol in the middle illuminated (internal backup battery is charging)
Note: The PM is shipped with its internal battery disconnected. The **internal battery must be connected prior to initial use or any time after the PM is shipped or transported** for service or maintenance (see Section 2.1, *Connecting the Internal Backup Battery*). If the internal battery is not connected, it cannot provide emergency backup power to the LVAS. If the internal battery is not connected, when the PM is turned on the PM will alarm. You will hear a continuous audio tone and the yellow wrench and red battery will light.
RESPONDING TO ALARMS

5.0 Power Module (PM) Alarm Conditions

The PM’s internal computer is continually monitoring PM performance. It will alert you if it detects a problem. There are four alarm conditions:

- AC Fail
- Advisory LO BATT (i.e., low battery)
- Hazard LO BATT (i.e., CRITICALLY low battery)
- PM MALFUNCTION

All PM alarm conditions are accompanied by a visual indicator (Figure 34) and audio tone. Certain lights come on and different tones sound, depending on the alarm condition. See Table 2 for a description of PM alarms and how to respond to them.

![Figure 34 Visual alarm indicators on front panel of PM](Image)
<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>What You Should Do</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AC FAIL</strong></td>
<td>“Power On” indicator changes from green to yellow accompanied by beeping audio tone. AC mains power off or disconnected. When new, the internal backup battery will power the HM II LVAS for approximately 30 minutes (45 minutes for the HM XVE LVAS). The PM’s internal backup battery will not be recharged during AC FAIL.</td>
<td>1 Press the PM’s Alarm Silence Button to silence the alarm (it remains silenced “forever” or until cancelled by another alarm). 2 Promptly switch to another power source, either a new set of charged batteries or Emergency Power Pack (EPP).** 3 Call VAD Coordinator or hospital contact.</td>
</tr>
<tr>
<td><strong>Advisory LO BATT</strong> (i.e., low battery)</td>
<td>Yellow Internal Backup Battery Indicator accompanied by beeping audio tone. Less than 15 minutes of internal backup battery power remain.</td>
<td>1 Press the PM’s Alarm Silence Button to silence the alarm for 8 hours. 2 Promptly switch to another power source (either a new set of charged batteries or EPP).** 3 Call VAD Coordinator or hospital contact.</td>
</tr>
<tr>
<td><strong>Hazard LO BATT</strong> (i.e., low battery)</td>
<td>Red Internal Backup Battery Indicator accompanied by continuous audio tone. Less than 5 minutes of internal backup battery power remain.</td>
<td>1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).** 2 Call VAD Coordinator or hospital contact.</td>
</tr>
<tr>
<td><strong>Advisory Fault</strong></td>
<td>Yellow Wrench Indicator accompanied by beeping audio tone. Internal malfunction detected within the PM.</td>
<td>1 Switch to another power source (either a new set of charged batteries or EPP) at earliest convenience. 2 Call VAD Coordinator or hospital contact.</td>
</tr>
<tr>
<td><strong>Critical Fault</strong></td>
<td>Yellow Wrench Indicator accompanied by continuous audio tone. Internal malfunction detected within the PM.</td>
<td>1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).** 2 Call VAD Coordinator or hospital contact.</td>
</tr>
</tbody>
</table>

**Table 2** Power Module (PM) Alarms

** If you remain connected to the PM using its internal backup battery for power, the internal backup battery indicator will turn yellow and then red as the internal battery is depleted to 15 minutes and then 5 minutes of remaining power. See Section 4.0, Power Module (PM) Backup Power. When only 5 minutes of power remain, the PM’s audio tone becomes constant and you will no longer be able to silence the alarm. Switching to another power source is the only way to silence a Red Battery Hazard Alarm.
**Silence Alarm Button**

Pressing the Silence Alarm Button silences an audio alarm (see Table 2 or list below for how long; silence periods vary by alarm type). If a new alarm condition arises during a silence period, a new audio alarm will sound. After the silence period ends, the audio alarm will resume, unless the alarm condition has been resolved. Pressing the Alarm Silence Button only silences the alarm; it does NOT fix the alarm condition.

- **Echo of System Controller Alarm** 5 Minutes
- **AC Fail** No time out (silence lasts “forever” or until cancelled by another alarm)
- **Yellow Battery** 8 Hours
- **Red Battery** Alarm Silence/Reset not possible if connected to LVAD
- **Yellow Wrench** 8 Hours
- **Battery Fault** 2 Minutes
- **Yellow Wrench** 8 Hours for non-critical faults. Alarm Silence/Reset not possible for some alarms (see Table 2).
6.0 Sleeping

You must ALWAYS be attached to the PM when sleeping (or anticipating sleep). 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 Controller from falling or the lead from moving or pulling on the exit site, use the HeartMate Stabilization Belt to hold the percutaneous lead in place. Stabilization Belts are available from your VAD Coordinator or hospital contact person (see HeartMate Stabilization Belt IFU).

Follow these important sleep guidelines:

- Plan to sleep only when connected to the PM.
- 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 backup System Controller, charged batteries and battery clips, and a flashlight nearby for emergencies.

7.0 Showering

Do NOT take tub baths while implanted with the pump. You may be able to shower once your exit site has healed, however. Your doctor will tell you if you can shower. In the meantime, the HeartMate patient education video shows alternatives to tub baths. Your VAD Coordinator or hospital contact person has copies of this educational video.

When you do shower with your doctor’s approval, you must use the HeartMate Shower Kit to protect the System Controller and other external system components from getting wet. Although these components are water resistant, they are NOT waterproof. They must not be directly exposed to water or moisture. During showers, the exit site also needs to be kept as dry as possible. This helps reduce the risk of infection.

Note: See the HeartMate II LVAS or XVE LVAS Patient Handbook, Operating Manual and/or the HeartMate Shower Kit IFU for instructions on showering safely.
WARNING!

- Do NOT take tub baths or swim while implanted with the pump.
- 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 PM away from water or moisture. If the PM has contact with water, moisture, shower spray, rain/snow, dirt, etc., the LVAD may stop or you may receive a serious electrical shock or your Power Module may not work properly.
- If showering while connected to PM power, be sure to locate the PM higher than your exit site to prevent water from flowing along the power cable and back to the PM.
- When making or breaking connections, do not expose connectors to water, moisture, rain/snow, dirt, etc.
8.0 Traveling by Car

As a convenience, the Power Module (PM) can be plugged into an automobile DC power outlet (e.g. cigarette lighter socket) to power the LVAS while traveling by car. You will need a Thoratec-provided automobile DC power cable (Figure 35) to do this. DC power can vary from vehicle to vehicle. If a car’s DC power is inadequate to power the PM and LVAS, the PM will alarm or switch to back up battery power. If this occurs, switch to portable battery power and discontinue the use of DC input power to the PM.

**Note:** The PM’s internal back up battery continues to charge when the PM is connected to functioning 12 V DC automobile power, just as it does when the PM is connected to AC mains power (see Section 4.0, *Power Module (PM) Backup Power*).

![Automobile DC power cable](image)

**Figure 35** Automobile DC power cable

**Follow these important travel guidelines:**

- Always keep at least one set of charged batteries in compatible battery clips nearby when using DC power and traveling by car.
- Bring your Universal Battery Charger (UBC) and enough batteries for charging/recharging and use at your destination.
- Bring battery clips and black & white power lead connectors for using battery power at your destination.
- Remember to bring the PM power cord for plugging into AC mains power at your destination.
8.1 Connecting to DC Power When Traveling by Car

1. If you have not already done so, switch to battery-powered operation.

2. Obtain the PM, PM patient cable, and automobile DC power cable (Figure 35).

3. Before disconnecting the PM from power, verify that the backup battery is charged (the green internal backup battery light is on; see Figure 30).

4. Bring the PM, PM patient cable, DC power cable, a backup set of charged batteries, and compatible battery clips to the car.

5. Enter the vehicle. With the vehicle properly parked, start the motor.

6. Make sure the car motor is running.

7. Connect the DC power cable to the PM, at the female connector labeled 13.5V

8. Plug the PM patient cable into the “” socket found on the side of the PM (Figure 36). Note: The cable will click into place if fully engaged in the socket. The “click” is the sound of the locking feature engaging. After inserting the connector snugly into the socket, check that the connection is tight. Tug gently on the strain relief portion of the connector. Do NOT pull on the cable!

WARNING!
- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your Power Module may not work properly.
9  Plug the car end of the automobile DC power cable into the DC power socket in the vehicle.

10  If properly connected, the green power on light on the front of the PM will come on. Continue with Step 11.

OR

10  If the green light does not come on, there may be a problem with the car’s power socket. Do not use automobile DC power until the problem can be identified/fixed.

11  Before switching from battery power, first check the charge status of each battery: Press the battery fuel gauge on each of the batteries; determine which battery has the least power (see HeartMate 12 Volt NiMH Battery IFU or HeartMate 14 Volt Li-Ion Battery IFU).

12  If the lights differ, disconnect the connector from the battery with the least power first. Note: The Power Cable Disconnected Alarm will sound while transferring power:

<table>
<thead>
<tr>
<th>For the HeartMate II</th>
<th>For the HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The Yellow Wrench will flash and an alarm will sound once every second.</td>
</tr>
</tbody>
</table>
13 Connect the power lead for the 1st battery to the patient cable that is attached to the PM. Always connect black-to-black and white-to-white. *Wait until the flashing symbol(s) and audio alarm stop before continuing with step 14.*

14 Repeat Steps 12 and 13 for the 2nd battery. Always connect black-to-black and white-to-white. *You are now connected to automobile DC power.* **Note:** Make sure that the System Controller and PM are free of any advisory and/or hazard alarms.

15 Keep the batteries and battery clips nearby, in a clean, dry location while not in use. Keep the batteries/clips inside the vehicle so that you can get them quickly if needed.

16 Place the PM on a low flat location, so it is stable and less likely to move during sudden vehicle starts and stops. Turn the PM so you can see its lights on the front panel. Make sure the DC power cable and patient cable remain free of tangles or snags.

**IMPORTANT REMINDER**
Be sure to bring everything you’ll need for battery-powered and electrical-powered operation at your final destination, including:

- ✔ Universal Battery Charger
- ✔ Spare batteries
- ✔ Battery clips
- ✔ PM patient cable
- ✔ PM power cord for connecting to AC mains power
- ✔ Backup System Controller
- ✔ Emergency hand pump (for XVE only)

**WARNING!**
- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, the patient should have at least one set of charged HeartMate batteries and compatible battery clips in close proximity.

- Be sure to switch to battery power and then unplug the DC adapter cable before attempting to “jump start” a car that is being used to power the LVAS. The PM can be damaged if it remains connected to the car’s power outlet during a jump start.
8.2 Disconnecting from Automobile DC Power

1. When you arrive at your destination, safely park the vehicle.

2. LEAVE THE CAR RUNNING. Do NOT turn off the car until you have switched to battery power!

3. Obtain a pair of charged batteries, compatible battery clips, and black and white power lead connectors. Place them within easy reach.

4. Place the 1st charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.

5. Repeat step 2 for the 2nd battery/battery clip.

6. Unscrew the black System Controller/patient cable connectors.

<table>
<thead>
<tr>
<th>For the HeartMate II</th>
<th>For the HeartMate XVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>The Yellow Wrench [ ] will flash and an alarm will sound once every second.</td>
</tr>
</tbody>
</table>

7. Put aside the patient cable connector; then connect the battery clip connector to the black system controller connector. Always connect black-to-black. **Wait until the flashing symbol(s) and audio alarm stop before continuing with step 8.**

**WARNING!**

- At least one System Controller power lead must be connected to a power source (Power Module or batteries) at all times. Disconnecting both power leads at the same time will cause the pump to stop.

- If power to the System Controller is interrupted:
  - **For HeartMate II**, if the pump speed is below 8,000 rpm, firmly press the Test Select \[ \] or Alarm Reset \[ \] switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
  - **For HeartMate XVE**, the pump will restart automatically in Fixed Rate Mode once power is restored (check that this is the correct/desired mode).
8 Unscrew the white System Controller/patient cable connectors.

For the HeartMate II

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.

For the HeartMate XVE

The Yellow Wrench will flash and an alarm will sound once every second.

9 Put aside the patient cable connector; then connect the battery clip connector to the white System Controller connector. You are now connected to battery power. Wait until the flashing symbol(s) and audio alarm stop before continuing with step 10.

10 Place the battery clips and attached batteries into the holsters or carrying case.

CAUTION!

- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, rain/snow, dirt, etc. when making or breaking connections.

Note: See the HeartMate II LVAS or XVE LVAS Patient Handbook and/or Operating Manual for additional guidelines on traveling with a HeartMate LVAS.
INSPECTION, CLEANING & MAINTENANCE

9.0 Routine Inspection

The HeartMate PM requires little preventive maintenance. However, it should be inspected routinely for the safest and best possible performance:

- **Once a day**, perform a PM System Self Test (see Section 2.7, *Monitoring PM Performance and Performing a PM System Self Test*).

- **Any time you switch** from batteries to PM-powered operation (e.g., before going to bed at night), inspect the connector pins and sockets for damage, dirt, grease, etc.

- **At least once a week**, inspect the power cord used to connect the PM to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement, if needed.

- **At least once a week**, inspect the PM patient cable used to connect the patient to the PM. Make sure the cable is not kinked, split, cut, cracked, or frayed. Do not use the cable if it shows signs of damage. Obtain a replacement, if needed.

- **Once a month**, inspect the pins and sockets of the PM cable/lead connectors for damage, dirt, grease, etc.

- **Once a month**, inspect the pins and sockets of the automobile DC input cable for damage, dirt, grease, etc.

If you discover damage or contamination on the pins/sockets, do NOT attempt to clean the pins/sockets yourself. Report the condition to Thoratec. Cleaning and service should be performed only by Thoratec-trained and authorized technicians. **Do NOT attempt to clean or repair equipment on your own.**

Do NOT disconnect the percutaneous lead from the System Controller. The pins/sockets for this connection should be inspected only when replacing the System Controller (see the *HeartMate II* or *HeartMate XVE LVAS Operating Manual* and/or corresponding *Patient Handbook* for instructions on System Controller replacement).

**Note:** Avoid blocking or covering the PM’s air vents during use. Blocking or covering the vents during use can affect device performance.
10.0 Periodic Cleaning

**WARNING!** Do NOT clean or service the following equipment while it is in use or connected to a HeartMate LVAS patient: System Controller, PM, PM cable, Display Module, System Monitor, HeartMate batteries, battery clips, Emergency Power Pack (EPP), and EPP cable.

Periodically, and as needed, clean the exterior surfaces of the PM using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner if necessary. Do NOT immerse the PM in water or liquid. **NEVER clean the PM while using it to power your pump; switch to battery power first. Before cleaning the PM, UNPLUG all connections.**

11.0 Routine Maintenance

At least once a year bring the HeartMate PM to an authorized service technician for a thorough inspection and cleaning that includes (but need not be limited to) the following:

- Functional test of device
- Cleaning and inspecting all internal components
- Replacing internal backup battery
- Replacing PM patient cable
- Inspecting and replacing the power cord, if needed

Contact Thoratec to coordinate an annual PM inspection/maintenance. Be sure the PM’s internal backup battery is re-connected after service/maintenance or shipping/transportation (see Section 2.1 *Connecting the Internal Backup Battery*).

**CAUTION!** Service and maintenance of the HeartMate Power Module should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
12.0 Product Disposal

The PM’s internal backup battery contains lead. Dispose of the PM’s internal backup battery in compliance with all applicable local, state, and federal laws and regulations. Never incinerate discarded PM batteries.

Dispose of or recycle PM and PM electronics in compliance with all applicable local, state, and federal laws and regulations. Before discarding a PM, first remove and properly dispose of its internal backup battery.

13.0 Testing and Classification

The HeartMate Power Module (PM) complies with the following safety standards:

- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98 (National Difference for Canada)
- CSA C22.2 No. 601.1:1994

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the area. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures (AFTER SWITCHING TO BATTERY POWER):

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Technical Service for assistance.
### Declaration Concerning General Safety Standards

<table>
<thead>
<tr>
<th>Type</th>
<th>Degree of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Type of protection against electrical shock</td>
<td>Class I (grounded) and internally powered</td>
</tr>
<tr>
<td>Degree of protection against electric shock</td>
<td>Type CF (Cardio AP, Floating)</td>
</tr>
<tr>
<td>Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.</td>
<td>Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.</td>
</tr>
<tr>
<td>Degree of protection against harmful ingress of water</td>
<td>IPX0</td>
</tr>
</tbody>
</table>

![UL Logo](image)

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

For more information regarding Compliance and EMC testing, please refer to the following LVAS System Manuals:

- *HeartMate II LVAS Operating Manual* (document #103884)
- *HeartMate XVE LVAS Operating Manual* (document #103887)

Manuals for HeartMate power accessories include:

- *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
- *HeartMate Universal Battery Charger IFU* (document # 103771)
- *HeartMate Power Module IFU* (document # 103772)
## APPENDIX 1
### TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Power Module (PM)</th>
<th>Catalog #1340 (North America)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACTIVE FUNCTIONS</strong></td>
<td>Isolated power to patient during tethered operation. Communication interface between System Controllers and System Monitor / Display Module. Mains failure back-up Battery (30 minutes for HM II LVAS when new; 45 minutes for XVE LVAS when new). If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes.</td>
</tr>
<tr>
<td><strong>MONITORING FUNCTIONS</strong></td>
<td>Isolated bidirectional data link to external Display Module or System Monitor Isolated dual-channel analog uplink Advisory / Hazard LO BATT alarm for internal Back-up Battery “Echoes” System Controller Audio Alarm System Malfunction Alarm (Yellow Wrench)</td>
</tr>
<tr>
<td><strong>POWER REQUIREMENTS</strong></td>
<td>100-240 VAC, 50/60 Hz, 1 A maximum 13.5 VDC, 5 A maximum</td>
</tr>
<tr>
<td><strong>FUSE RATING</strong></td>
<td>T 2A, 250 V (Mains), T 7A, 250V (DC Vehicle Adapter)</td>
</tr>
<tr>
<td><strong>DIMENSIONS</strong></td>
<td>381 mm (15&quot;) 254 mm (10&quot;) 127 mm (5&quot;)</td>
</tr>
<tr>
<td><strong>WEIGHT</strong></td>
<td>4.8 Kg (with back-up Battery) (10.5 lbs)</td>
</tr>
</tbody>
</table>
### OPERATING ENVIRONMENT

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Acceptable Temperature Range</th>
<th>Relative Humidity</th>
<th>Air Pressure inHg (MMHG / HPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM (including Battery - connected)</td>
<td>0°C to 40°C (32° F to 104° F)</td>
<td>30 to 75%</td>
<td>525 to 795 / 700 to 1060 (20.7 to 31.3)</td>
</tr>
</tbody>
</table>

### STORAGE ENVIRONMENT

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Acceptable Temperature Range</th>
<th>Relative Humidity</th>
<th>Air Pressure inHg (mmHg / hPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM (including Battery - not connected)</td>
<td>-15°C to 40°C (5° F to 104° F)</td>
<td>10 to 93%</td>
<td>375 to 795 / 500 to 1060 (14.8 to 31.3)</td>
</tr>
</tbody>
</table>

### PRODUCT LIFE

Two years from date of first use
### POWER MODULE PATIENT CABLE 
**Catalog # 2225**

<table>
<thead>
<tr>
<th>TYPE</th>
<th>A Cable assembly with one straight plug connector with sliding interlock and composite strain relief for connection to the PM, and one standard two custom thread-locking power connectors for connection to the System Controller.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTION</td>
<td>To provide electrical connection between the System Controller and the PM.</td>
</tr>
<tr>
<td>LENGTH</td>
<td>6.1 meters (20 feet)</td>
</tr>
<tr>
<td>PRODUCT LIFE</td>
<td>One year</td>
</tr>
<tr>
<td><strong>TYPE</strong></td>
<td>A Cable assembly with one straight plug connector with sliding interlock and composite strain relief for connection to the PM and one 12 volt DC automotive type plug.</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>FUNCTION</strong></td>
<td>To provide electrical connection between automotive type 12 volt DC Input Power and the PM (i.e. car power receptacle).</td>
</tr>
<tr>
<td><strong>LENGTH</strong></td>
<td>1.8 meters (6 feet) when fully stretched</td>
</tr>
<tr>
<td><strong>PRODUCT LIFE</strong></td>
<td>Three years from date of first use</td>
</tr>
</tbody>
</table>
### APPENDIX 2

**Graphic Symbols Found on Power Module (PM)**

**Labels and Labeling**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Serial Number" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image" alt="Reference Number" /></td>
<td>Reference Number (Catalog Number)</td>
</tr>
<tr>
<td><img src="image" alt="Type CF" /></td>
<td>Type CF applied part (patient connection – Power Module to System Controller)</td>
</tr>
<tr>
<td><img src="image" alt="Attention" /></td>
<td>Attention, consult accompanying documents</td>
</tr>
<tr>
<td><img src="image" alt="Rx Only" /></td>
<td>Caution: US federal law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td><img src="image" alt="Fuse Symbol" /></td>
<td>Fuse symbol</td>
</tr>
<tr>
<td><img src="image" alt="Alternating Current" /></td>
<td>Alternating current (ac)</td>
</tr>
<tr>
<td><img src="image" alt="Power Indicator" /></td>
<td>Power Indicator (Green= On, Yellow= back up power)</td>
</tr>
<tr>
<td><img src="image" alt="Alarm Silence &amp; System Self Test Switch" /></td>
<td>Alarm Silence &amp; System Self Test Switch</td>
</tr>
<tr>
<td><img src="image" alt="Power Module Malfunction" /></td>
<td>Power Module Malfunction</td>
</tr>
<tr>
<td><img src="image" alt="Connection for System Monitor and/or Display Module" /></td>
<td>Connection for System Monitor and/or Display Module</td>
</tr>
<tr>
<td>Icon</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image" alt="Battery Discharging" /></td>
<td>Back-Up battery is discharging (in use) – Advisory &amp; Hazard</td>
</tr>
<tr>
<td><img src="image" alt="Battery Recharging" /></td>
<td>Back-Up Battery recharging</td>
</tr>
<tr>
<td><img src="image" alt="13.5V 5A DC Input Power" /></td>
<td>DC – Input Power</td>
</tr>
</tbody>
</table>
APPENDIX 3

HeartMate II® Power Change Checklist

| WARNING: | Never disconnect power (batteries, PM, or EPP) from both controller power leads at the same time or the pump will stop. |

1 Prepare to change power source (see Section 3.0, Tethered Operation).
2 Remove only 1 battery from its battery clip or remove the white Power Module (PM) power lead from the System Controller.
   The power symbol \( \text{●} \) will flash rapidly, the 4 green battery fuel gauge lights \( \text{●●●●} \) will flash, and the alarm will sound once every second.
3 Connect the charged battery or white PM power lead to the System Controller.
4 Wait until both the power symbol \( \text{●} \) and the battery fuel gauge lights \( \text{●●●●} \) stop flashing and the alarm stops before going to Step 5.
5 Remove the 2nd battery from its clip or remove the black PM power lead from the System Controller.
   The power symbol \( \text{●} \) will flash rapidly, the 4 green battery fuel gauge lights \( \text{●●●●} \) will flash, and the alarm will sound once every second.
6 Connect the charged battery or black PM power lead to the System Controller.
7 Wait until both the power symbol \( \text{●} \) and the 4 green battery fuel gauge lights \( \text{●●●●} \) 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, either:
   - Changing from PM Power to Batteries (Section 3.1); or
   - Changing from Batteries to PM Power (Section 3.2)
   Also see the HeartMate II LVAS or HeartMate XVE LVAS Operating Manual or Patient Handbook for more details on power exchange

<table>
<thead>
<tr>
<th>WARNING:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• When changing batteries, never disconnect both batteries at the same time or your pump will stop.</td>
</tr>
<tr>
<td>• Your pump will stop if power is removed from both Controller power leads at the same time.</td>
</tr>
<tr>
<td>• Your pump will automatically restart only after power is restored.</td>
</tr>
</tbody>
</table>