

Thoratec Corporation

HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM

Patient Handbook

Your guide to understanding the HeartMate 3 Heart Pump



United States & Canada



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R_x Only

Thoratec Corporation continually strives to provide the highest quality of products for mechanical circulatory support. Specifications may change without notice. Therefore, please refer to the *HeartMate 3 Instructions for Use* shipped with the HeartMate 3 Left Ventricular Assist System for the most current information regarding indications, contraindications, and cautions. Thoratec and the Thoratec logo are registered trademarks, and HeartMate 3, Mobile Power Unit, and HeartLine are trademarks of Thoratec Corporation.

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EMERGENCY CONTACT LIST

It is very important that you keep a list of emergency contacts with you at all times. You may need this information if something happens to you or your pump. Before leaving the hospital, fill in the list below.

Call your hospital contact if you think that, for any reason, any portion of your equipment is not functioning as usual, is broken, or you are uncomfortable with the operation of the equipment. Your hospital contact can check the equipment and order replacements, if needed. Do not try to repair anything yourself.

Hospital

Name _____

Address _____

Contact Person _____

Contact Person Telephone Number _____

Doctor

Name _____

Address _____

Telephone Number _____

Ambulance

Company Name _____

Address _____

Telephone Number _____

Emergency Services

Dial 911 (Confirm 911 is operational in your area.)

Other Important Information

Consider making several copies of this list and leave it in different places for easy access and reference.

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INTRODUCTION

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1 Introduction

Why Reading This Handbook is Important

Be Informed

This handbook is about your HeartMate 3 Left Ventricular Assist System. It explains how the system works. It also describes what daily life is like. It tells you how to use and care for equipment and how to take care of yourself. What to do in an emergency is also covered. To lower the risk of complications, you must closely follow the instructions in this handbook.

Carefully read this handbook before leaving the hospital. Make sure you understand it.

If you have questions after reading this handbook, ask your doctor or hospital contact.

Be Safe

After healing from the operation to implant the pump—and with your doctor's approval—you can resume many of your favorite activities. Your doctor and hospital contact will explain what is safe for you.

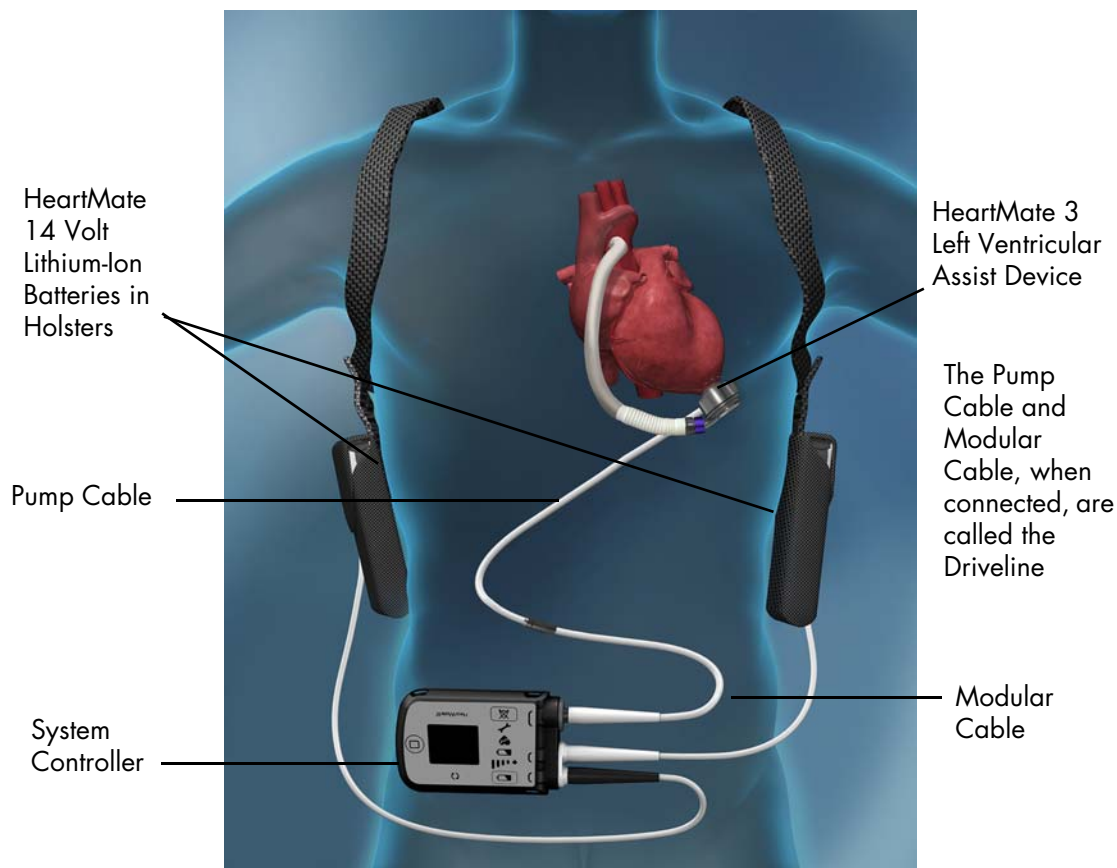
This handbook can help keep you safe. Use this handbook to:

- Review all warnings and cautions (see the warnings and cautions throughout the handbook).
- Review and follow steps for equipment storage and care (see *Caring for the Equipment* on page 243).
- Review and practice emergency steps (see *How to Handle an Emergency* on page 262).
- Keep a list of emergency contacts (see *Emergency Contact List* on page v).

1 Introduction

Figure 1 shows the approximate placement of the pump inside your body. To learn how the pump works, see *How Your Heart Pump Works* on page 15.

Figure 1 HeartMate 3 System on Battery Power



The figure above shows the following:

- Implanted HeartMate 3 Left Ventricular Assist Device ("heart pump")
- HeartMate batteries, with battery clips and worn in holsters (during battery-powered operation)
- The Driveline is the combination of the Pump Cable and the Modular Cable (when connected by the Modular In-Line connector)
- HeartMate 3 System Controller (controls and checks the pump)

Note: The System Controller is often called Controller.

Understanding Warnings and Cautions

Warnings refer to actions or hazardous conditions that could cause serious injury or death if not avoided. Ignoring a warning can cause sudden and serious injury, life-threatening harm, or death for the user or patient.

Cautions refer to actions or potentially unsafe conditions that may cause injury, damage the equipment, or affect how the system works. Ignoring a caution can cause patient or user injury, or result in equipment failure or sub-optimal system operation. Although important for maximum safety and optimal system function, usually cautions do not refer to life-threatening risks.

In this handbook, warnings and cautions that are relevant to a specific procedure or piece of equipment appear at the start of each applicable section.

WARNING !
Warnings in this handbook look like this.

CAUTION !
Cautions in this handbook look like this.


1 Introduction

General Warnings

WARNING !

- A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support are necessary before using this product. Read this entire handbook before use.
- Understanding the operating and the safety aspects of the HeartMate 3 Left Ventricular Assist System is critical for safe and successful use.
- All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use.
- All users, including clinicians, patients, and caregivers, must be trained on any HeartMate 3 power accessories (Power Module, Mobile Power Unit™, Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries) before use.
- The HeartMate 3 system components must be kept dry. Never expose the System Controller, Batteries, or Mobile Power Unit to water. If these system components get wet, your pump may stop. Never take tub baths or go swimming while implanted with the pump. The HeartMate 3 Shower Bag must be used while showering to keep the System Controller and Batteries dry.
- Do not take showers unless approved by a doctor for showering. If approved for showering, the Shower Bag must be used for every shower. The Shower Bag protects outside parts of the system from water or moisture. If outside parts of the system get wet, the Pump may stop.
- High levels of static electricity may damage and/or interfere with the electrical parts of the system and cause the Left Ventricular Assist Device to stop. The presence of electrostatic discharge (ESD) may be increased in environments with a relative humidity less than 30%. Avoid activities that may cause static electricity and discharge any buildup by touching a metal surface before handling LVAS components.
- 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.
- Avoid activities and conditions that may induce strong static discharges (for example, touching a television or computer monitor screen) as electrostatic discharges may damage and/or interfere with the electrical parts of the system, and may cause the LVAD to perform improperly or stop.

WARNING ! (Continued)

- Do not become pregnant while you have the pump. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners, which most Left Ventricular Assist Device patients receive, have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy. If you do become pregnant, immediately tell your doctor and hospital contact.
- Never have an MRI (magnetic resonance imaging) while you have the HeartMate 3 Left Ventricular Assist System, as the device contains Ferromagnetic components. MRI may cause pump failure or injury.
- Therapeutic radiation, such as tissue heating therapy that uses Radio Frequency (RF) energy sources, may damage the device, and damage may not be immediately detectable. Never have therapeutic radiation while you have the pump.
-  —MR unsafe. Do not subject patients implanted with the HeartMate 3 Left Ventricular Assist System to magnetic Resonance Imaging (MRI) as the device contains Ferromagnetic components. MRI can cause Pump failure or patient injury.
- The HeartMate 3 Pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.
- Do not try to repair any of the HeartMate 3 system components. If it seems broken or in need of service, call your hospital contact.

1 Introduction

General Cautions

CAUTION !

- Call your hospital contact right away if you notice a change in how your pump sounds, feels, or works. Even small changes should be reported.
- Avoid contact sports and jumping activities while implanted with the pump. Contact sports or jumping can cause bleeding or damage to the pump.
- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.
- Use of equipment and supplies other than those specified in the handbook or sold by Thoratec Corporation for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate 3 Left Ventricular Assist System and other devices.
- The HeartMate 3 Left Ventricular Assist System uses lights, sounds, and on-screen messages 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 backup System Controller, fully-charged spare batteries, battery cables, and compatible battery clips nearby at all times in case of emergency.
- The 11 Volt Lithium-Ion backup battery within the System Controller should be used only for temporary support during a power-loss emergency. The 11 Volt Lithium-Ion backup battery will continue to run the Pump if both power cables are disconnected. However, the 11 Volt Lithium-Ion backup battery will not start the Pump without external power applied to the System Controller.
- Inappropriate use of the 11 Volt Lithium-Ion backup battery may result in diminished run time during a power-loss emergency.
- Some radio devices such as Citizens Band (CB) radios, hand-held walkie-talkies, cordless phones and radio-controlled toys operating near 27 MHz or 40 MHz may cause interference with the HeartMate 3 LVAS and such radio device use by, or near, the patient should be avoided. If interference is suspected, turn off the radio device and/or move away when possible.

Quick Reference

There is a Table of Contents at the beginning of this Handbook and an Index at the end; however, here are a few references that might direct you to sections that may be more frequently used.

Note: The System Controller is often called the Controller. Please search the Table of Contents and Index using System Controller.

Task	Refer to section
Responding to System Controller Alarms	<i>System Controller Alarms</i> on page 209
Daily System Controller Self-Test	<i>The System Controller Self Test</i> on page 41
Replacing Low Batteries with Fully Charged Batteries	<i>Replacing Low Batteries with Fully-Charged Batteries</i> on page 111
Changing from Mobile Power Unit to Batteries	<i>Changing from Mobile Power Unit Power to Batteries</i> on page 114
Changing from Batteries to Mobile Power Unit	<i>Changing from Batteries to Mobile Power Unit Power</i> on page 117
Charging HeartMate 14 Volt Lithium-Ion Batteries	<i>Charging HeartMate 14 Volt Lithium-Ion Batteries</i> on page 127
Showering	<i>Using the Shower Bag</i> on page 147
Caring for the Driveline	<i>Caring for the Driveline</i> on page 139
Caring for the Driveline Exit Site	<i>Caring for the Driveline Exit Site</i> on page 142

1 Introduction

Equipment Overview

The table below introduces the main parts of the system, along with useful accessories. All of these items are described in more detail later in this handbook.

Left Ventricular Assist Device



The HeartMate 3 Left Ventricular Assist Device (often called the pump) is implanted in the chest below the heart. One end of the pump connects to the heart; the other end connects to the aorta (the large blood vessel that sends oxygen-rich blood through the body). A Driveline connects the pump to the System Controller.

For more information, see page 17.

System Controller



The System Controller is a small computer that controls and monitors system operation. The System Controller uses lights, sounds, and on-screen messages to communicate with you about operating status and alarm conditions.

For more information, see page 21.

HeartMate 14 Volt Lithium-Ion Batteries & Battery Clips



Batteries are used to power the system when you are active or outdoors. Special batteries are required. You always need to use two batteries at a time. Each battery inserts into a battery clip, which connects the power cables to the System Controller. Two new batteries can power your system up to 17 hours.

For more information, see page 93.

Table 1 System Components

Modular Cable



The Driveline consists of two cables: the Pump Cable and the Modular cable. One end of the Pump Cable is connected to the pump, the other end exits your body. One end of the Modular cable is connected to the Pump Cable at the Modular In-line Connector, and the other end connects to the System Controller.

Mobile Power Unit



The Mobile Power Unit plugs into an AC outlet to provide power to the HeartMate 3 system and is used while indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.

For more information, see page 78.

Battery Charger



The Battery Charger charges, calibrates, and tests the HeartMate batteries that are used to power the system during battery-powered operation.

For more information, see page 119.

Shower Bag



The Shower Bag protects external system components from water or moisture—outside in heavy rain or snow, and always for every shower. You may be allowed to shower when the Driveline exit site has healed and with permission of your doctor. If external system components have contact with water or moisture, the system may fail to operate properly or you may get an electric shock.

For more information, see page 147.

System Controller Neck Strap



The System Controller Neck Strap attaches to the System Controller and allows you to wear the System Controller around your neck or across your body.

For more information, see page 161.

Table 1 System Components (Continued)

1 Introduction

Belt Attachment



The belt attachment provides another way to wear the System Controller.

For more information, see page 166.

Consolidated Bag



The Consolidated Bag is a convenient way to wear and carry the System Controller and batteries.

For more information, see page 171.

Battery Holster



The Battery Holster provides a convenient way to wear the batteries and battery clips.

For more information, see page 184.

Holster Vest



The Holster Vest provides another way to wear the batteries and battery clips.

For more information, see page 192.

Table 1 System Components (Continued)

Travel Bag



The Travel Bag provides a convenient way to carry and transport the backup System Controller and spare batteries.

For more information, see page 182.

Protection Bag



The Protection Bag stores and protects the backup System Controller.

For more information, see page 182.

Table 1 System Components (Continued)

1 Introduction

HOW YOUR HEART PUMP WORKS

This section provides information to help you understand how the HeartMate 3 Left Ventricular Assist Device works.

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System Controller Backup Power - - - - - 56

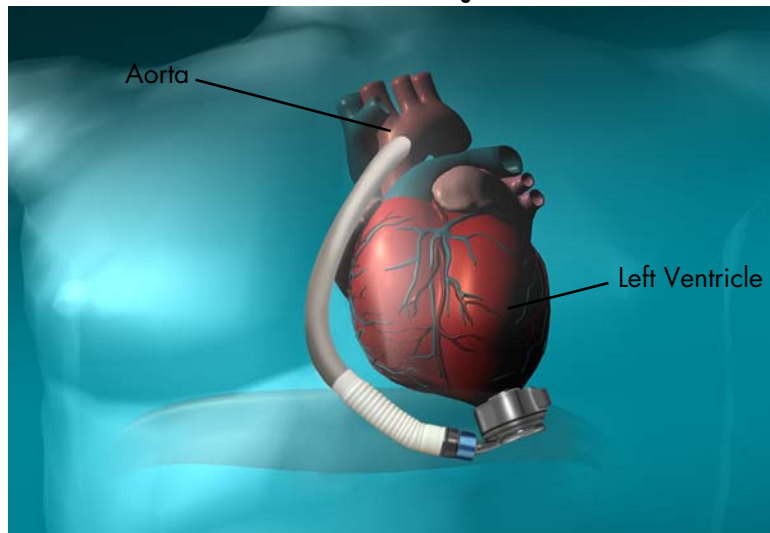
The Backup System Controller- - - - - 58

2 How Your Heart Pump Works

Your Heart Pump

Your heart pump is called the HeartMate 3 Left Ventricular Assist Device (**Figure 2**). It helps move blood through your body. A small motor inside the pump turns the rotor that moves the blood. The pump is placed below the heart. One end connects to the left ventricle (the heart's main pumping chamber). The other end connects to the aorta (the large blood vessel that sends blood through the body).

Figure 2 HeartMate 3 Left Ventricular Assist Device



The pump helps your heart by taking over the work of the left ventricle. The pump sends oxygen-rich blood from the heart to the aorta. The aorta then sends the blood to the rest of your body. In this way, your lungs, organs, and cells get the oxygen they need.

You may feel the pump working. This is normal.

2 How Your Heart Pump Works

The Driveline

WARNING !

- Check the System Controller Driveline connector often to confirm that the Driveline is securely inserted in the socket. If the Driveline disconnects from the System Controller, the pump will stop.
- Do not open, crush, heat above 104°F (40°C), or incinerate batteries because of the risk of fire and burns. Follow manufacturer's instructions.
- Malfunction of internal backup battery may cause the System Controller to become excessively hot. If this occurs, switch to the backup System Controller.

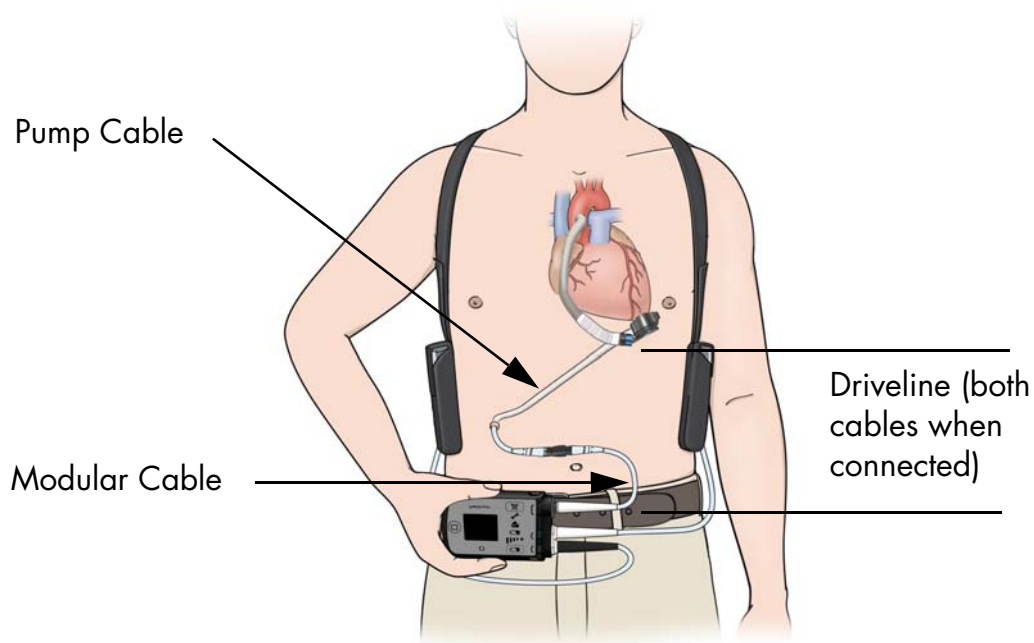
CAUTION !

- To avoid pulling on or moving the Driveline at the exit site, the patient must stabilize their Driveline at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the pump to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

As shown in **Figure 3**, a thin cable (called a Pump Cable) goes through your abdomen. It connects to the Modular cable which then connects the pump to the System Controller. When the Pump Cable and Modular cable are connected, they are referred to as the Driveline.

How Your Heart Pump Works **2**

Figure 3 The Driveline Connects the Pump to the System Controller



The Driveline sends power and operating signals to the pump. It also supplies information from the pump to the System Controller.

2 How Your Heart Pump Works

Modular In-line Connector

WARNING !

Do not disconnect the Modular In-line Connector or the pump will stop.

There is a Modular In-line Connector that connects your Pump Cable and Modular Cable. It has a locking nut that keeps both cables connected and secure.

Figure 4 Modular In-line Connector



The Pump Cable is covered with a special material. It lets skin cells grow into the cable. Skin growth on the cable is a barrier that can lower the risk of infection. Keeping the skin clean and dry near the cable exit site also lowers infection risks.

The System Controller

WARNING !

- Keep connectors clean and dry and away from water or liquid. If the connectors come into contact with water or liquid, the system may fail to operate properly or you may get an electric shock.
- Check the System Controller Driveline connector to confirm that the Driveline is securely inserted in the socket. If the Driveline disconnects from the System Controller, the Pump stops. If the Driveline disconnects from the System Controller, promptly reconnect it to resume Pump operation.
- The pump will stop if the Driveline is disconnected from the System Controller. If the Driveline disconnects from the System Controller, reconnect it right away to restart the pump. The pump cannot run without power.
- At least one System Controller power cable must be connected to a power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- Never submerge the Driveline, System Controller, or any external system components (such as the Mobile Power Unit, batteries, power cables, or battery clips) in water or liquid. Submersion in water or liquid may cause the pump to stop.
- Do not swim or take tub baths while implanted with the pump. Immersion in water may cause the device to stop.
- Do not shower without a doctor's approval. Showering may be allowed, but only after sufficient Driveline exit site healing and with a doctor's permission.
- The Shower Bag protects external system components from water and moisture. If external system components have contact with water or moisture, the patient may receive a serious electrical shock or the Pump may stop.
- The 11 Volt Lithium-Ion backup battery inside the System Controller should be used only for temporary support during a power-loss emergency. The 11 Volt Lithium-Ion backup battery can provide enough power to run the pump for at least 15 minutes if the main power source (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) disconnects or fails. Inappropriate use of the 11 Volt Lithium-Ion backup battery may result in diminished run time during a power-loss emergency.

2 How Your Heart Pump Works

CAUTION !

- The System Controller uses lights, sounds, and on-screen messages to tell you how the system is running. HeartMate 3 users with sight or hearing impairment may need extra help using the System Controller.
- Do not drop the System Controller or subject it to extreme physical shock.
- The hospital contact should be informed immediately if the System Controller is dropped. Never delay reporting a dropped System Controller, even if everything seems fine. Dropping the System Controller can cause trauma or tissue damage at the Driveline exit site, which can increase your risk of getting a serious infection. Early treatment of exit site trauma can lower the risk of infection.
- Never use tools to tighten power cable connectors. Securely hand tighten only. Using tools may damage the connectors.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the pump to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- Damage to electrical wires inside the Driveline can occur even if not visible outside. Be alert for signs of Driveline damage, including (but not limited to):
 - The System Controller alarming when the Driveline is moved or when you change position.
 - High pulsatility index (PI) readings on the System Controller.
 - Occurrence of a Driveline Fault Alarm.
 - Feeling pump vibrations.
 - Fluid from the external portion of the Driveline.
 - Pump stopping.
- The patient should keep a backup System Controller and at least two fully-charged batteries with him or her at all times for use in an emergency.

How Your Heart Pump Works 2

CAUTION ! (Continued)

- The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be charged at least once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in no support during a power-loss emergency when the backup System Controller is in use.
- Do not place the System Controller on bare skin for an extended time. The System Controller surface temperature can become uncomfortably warm, especially when the room temperature is above 104°F (40°C).

The System Controller is a small computer. It controls and checks system operation. The Driveline going through your skin connects the pump inside of your body with the System Controller outside of your body (see **Figure 5**).

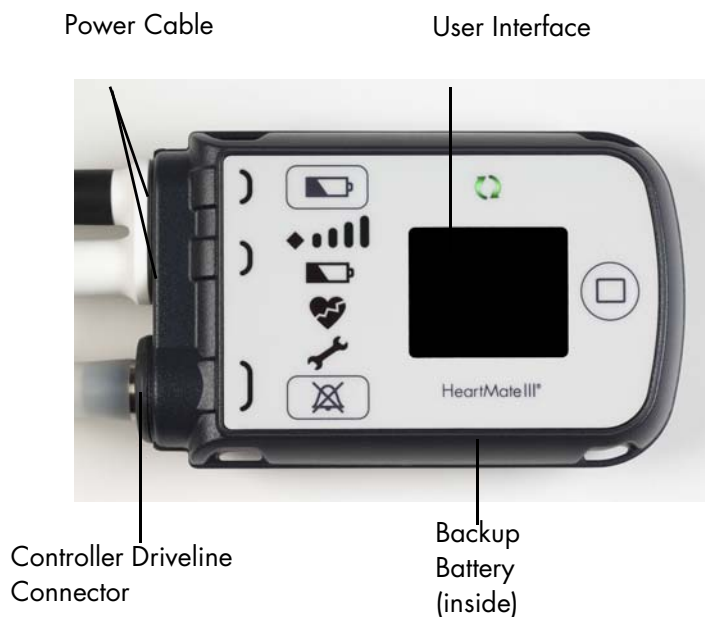


Figure 5 HeartMate 3 System Controller

- Controller Driveline Connector: links the pump to the System Controller.
- Two Power Cable Connectors: link external power source (Mobile Power Unit or 2 HeartMate 14 Volt Lithium-Ion Batteries) to the System Controller.
- User Interface: buttons, lights, and screen where system data, alarms, and user instructions appear.
- Backup battery: located inside the System Controller, powers the pump for at least 15 minutes during a power-loss emergency.

The System Controller is used to:

- Control system operation.
- Check and respond to system operation.
- Display real-time data on the System Controller user interface.
- Provide a backup system if the main system fails.
- Identify problems with system operation.

2 How Your Heart Pump Works

- Alarm with lights, sounds, and on-screen messages.
- Record and store data in its memory.
- Send data to devices that are used by nurses and doctors to control operation and to find, understand, and fix problems.

Information about the System Controller can be found on the following pages:



The System Controller User Interface

This section describes the visual display of system operations and on-screen messages.

See page 25.



The System Controller Driveline Connector

This section provides instructions on connecting and disconnecting the Driveline.

See page 32.



System Controller Power Cable Connectors

This section describes the two power cables on the System Controller (one white and one black) that connect the System Controller to either the Mobile Power Unit or two 14 Volt Lithium-Ion batteries.

See page 38.



The System Controller Self Test

This section provides instructions on how to perform a daily self test to check the function of the System Controller's audible and visual alarms.

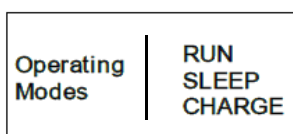
See page 41.



Using the Battery Power Gauge on the System Controller

This section describes the battery power gauge function to show the approximate charge status of the power source that is connected to the System Controller's power cables.

See page 44.



System Controller Operating Modes

This section describes the System Controller's three operating modes (Run, Sleep, and Charge) and provides an overview with instructions on how to switch between modes.

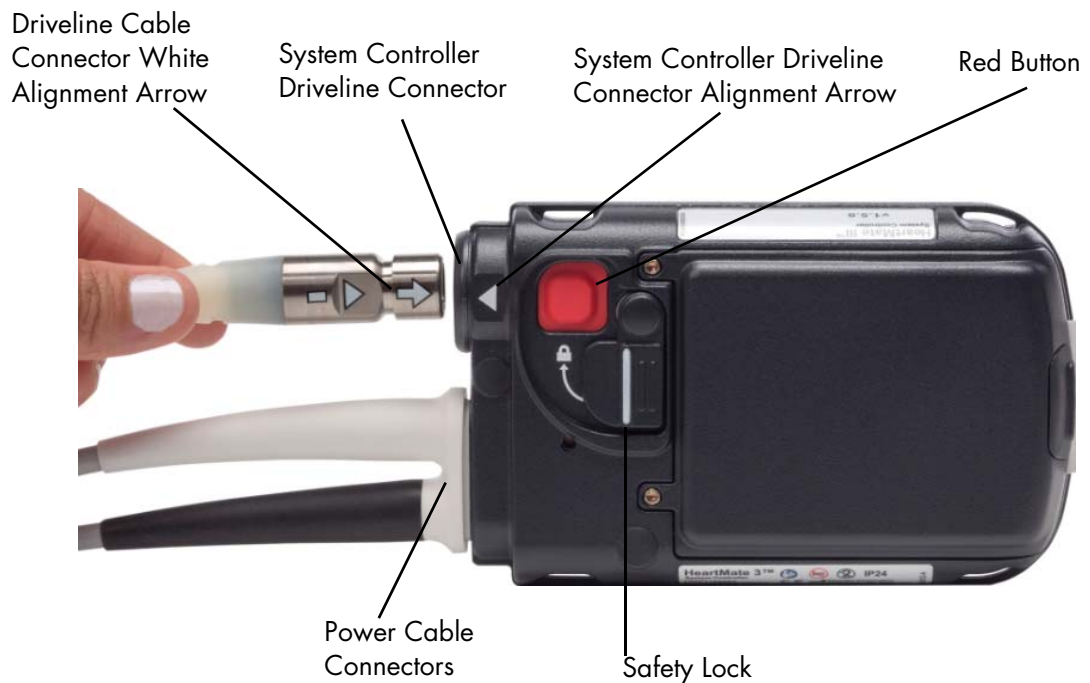
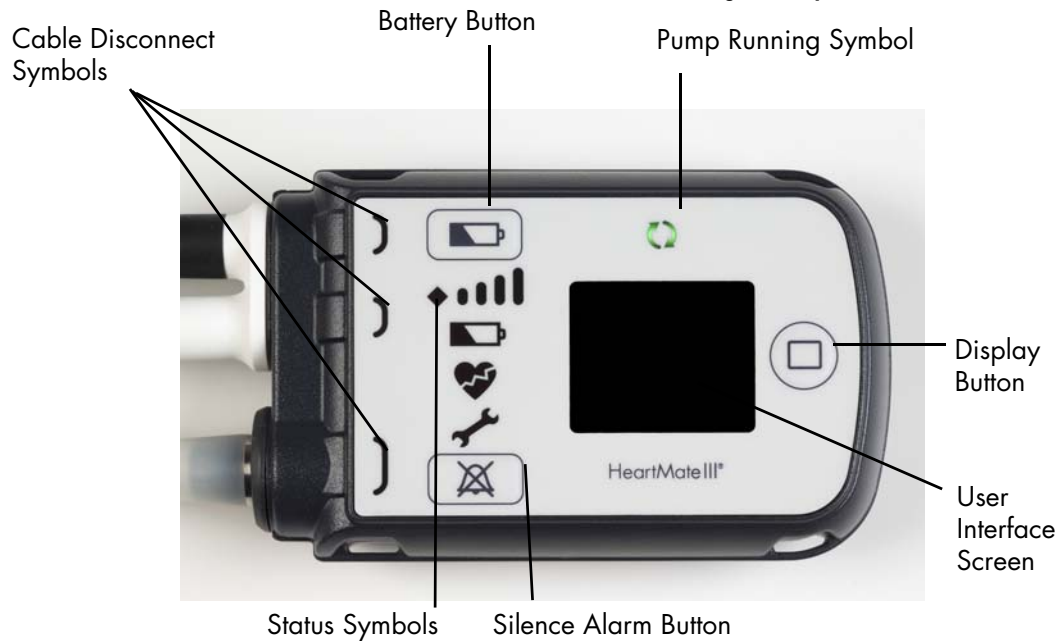
See page 47.

How Your Heart Pump Works 2

The System Controller User Interface

The user interface on the System Controller (**Figure 6**) uses sounds, lights, symbols, and on-screen messages to tell you how the system is working.

Figure 6 System Controller User Interface



On-screen messages also tell you how to handle alarms and other situations.

If you have trouble hearing or seeing, you may need extra help using the System Controller.

2 How Your Heart Pump Works

For situations that require attention, and depending on the urgency, the System Controller issues one of two types of alarms: hazard and advisory. Hazard alarms occur for conditions that are potentially life threatening for the patient and require immediate attention. Advisory alarms are important, but not life threatening. For more information on System Controller alarms and how to resolve them, see *System Controller Alarms* on page 209.

Table 2 introduces the main parts of the user interface. These parts are described in more detail later in this section.





Pump Running Symbol 	The green Pump Running light stays on as long as the pump gets power and remains running.
Low Battery Alarm Symbol 	<p>The red low battery symbol comes on when less than 5 minutes of power remain for the two in-use HeartMate batteries. This alarm applies only during battery-powered operation. This alarm may also occur when connected to the Mobile Power Unit. If it does, contact your hospital.</p> <p>This is a Hazard alarm. When the red low battery symbol comes on, immediately replace the low batteries with two fully-charged batteries, or switch to the Mobile Power Unit. Do this immediately or the pump may stop.</p>
Yellow Wrench Alarm Symbol 	<p>The yellow wrench symbol comes on when the System Controller detects a mechanical, electrical, or software issue with the system.</p> <p>This is an Advisory alarm. When the yellow wrench symbol comes on, follow the on-screen instructions. Do this as soon as possible.</p> <p>For more information, see page 209.</p>
Red Heart Alarm Symbol 	<p>The red heart symbol comes on for a serious condition. A red heart condition could harm or kill you if it is not fixed.</p> <p>This is a Hazard alarm. When the red heart symbol comes on, follow the on-screen instructions. Do this immediately or you could be seriously harmed or killed.</p> <p>For more information, see page 209.</p>

Table 2 System Controller User Interface

How Your Heart Pump Works 2

Black Power Cable Alarm Symbol



The yellow light near the black power cable connector comes on when the black power cable is loose or disconnects from the System Controller.

This is an **Advisory** alarm. If this light comes on, fix the connection as soon as possible.

For more information, see page 220.

White Power Cable Alarm Symbol



The yellow light near the white power cable connector comes on when the white power cable is loose or disconnects from the System Controller.

This is an **Advisory** alarm. If this light comes on, fix the connection as soon as possible.

For more information, see page 220.

Driveline Connector Alarm Symbol



The red light near the Driveline connector comes on when the Driveline is loose or disconnects from the System Controller.

This is a **Hazard** alarm. When the Driveline Disconnected Alarm comes on, reconnect the Driveline right away. If the Driveline is not reconnected, the pump will stop.

For more information, see page 219.

Battery Power Gauge



The battery power gauge shows the approximate charge status of the power source that is connected to the System Controller's white and black power cables—either the 14 Volt Lithium-Ion batteries or the Mobile Power Unit. The number of green bars means the more power remaining.

For more information, see page 44.



Yellow diamond = less than 15 minutes of battery power remain. Appearance of this symbol indicates an **Advisory** alarm. If the yellow diamond comes on, promptly replace the low batteries with two fully-charged batteries, or switch to the Mobile Power Unit. Do this as soon as possible.

For more information, see page 224.

IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller).

Table 2 System Controller User Interface (Continued)

2 How Your Heart Pump Works

Battery Button



The battery button is used for the following:

- **Operating the battery power gauge:** Press and release the battery button.

For more information, see page 44.

- **Starting System Controller self test:** Press and hold the battery button for 5 seconds and then release it. Perform a self test daily on your running System Controller, and every six months on your backup System Controller, when it is in Charge Mode.

For more information, see page 42.

- **Putting a running System Controller into Sleep Mode:** When a System Controller is no longer in use, it can be put to sleep by disconnecting the Driveline and power source, and pressing and holding the battery button for 5 seconds and then releasing it.

For more information, see page 55.

Silence Alarm Button



The silence alarm button is used for the following:

- **Silencing an active alarm:** Press and release the silence alarm button to silence an active alarm on the System Controller. How long it is silenced depends on the alarm (see *System Controller Alarms* on page 209). You will see the alarm silence symbol on the LCD screen of the System Controller.

IMPORTANT! Using the silence alarm button only silences the alarm. It does not fix the alarm condition.

- **Viewing the last six System Controller alarms on the screen:** Press and release the silence alarm button (⌫) and the display button (⏏) at the same time to display the last six System Controller alarms on the screen.

For more information, see page 210.

Table 2 System Controller User Interface (Continued)

How Your Heart Pump Works 2

Display Button



The display button activates the information display screen. Press and release the display button to display information about pump speed, power, flow, pulsatility index, and the charge status of the System Controller's 11 Volt Lithium-Ion backup battery. The display button is functional only when a System Controller is in use.

For more information, see page 30.

Press and release the silence alarm button (⌂) and the display button (□) at the same time to display the last six System Controller alarms on the screen.

For more information, see page 210.

Table 2 System Controller User Interface (Continued)

2 How Your Heart Pump Works

Viewing Pump and System Information on the Screen

Viewing information about the pump is useful when recording daily values or trying to resolve system problems on the telephone with your hospital contact. When the System Controller is running, the user interface can display information about the current system operations:

- Speed
- Flow
- Pulsatility Index (abbreviated as “PI” on the screen)
- Power
- Charge status of the System Controller’s backup battery (11 Volt Lithium-Ion)

To view information on the user interface screen, press and release the display button (◻). Each push of the display button brings up a new screen. Each screen comes on for 15 seconds before it goes black, unless another button is pushed. The screens are always displayed in the same order, starting with the first (Speed) screen. A dot at the bottom of each screen provides navigational information about which of the five screens is in view. **Table 3** shows the display sequence.

While your pump is operating, an artificial pulse is generated. You can tell that Pulse Mode is in operation when you see a ▲ displayed on the LCD screen of your System Controller.

Figure 7 shows the LCD screen display if the audio alarms have been silenced.

Figure 7 Silence Alarms



How Your Heart Pump Works 2



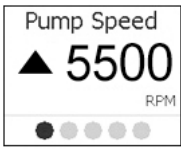


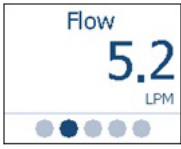


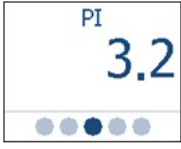


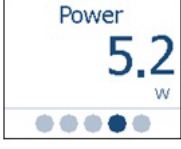





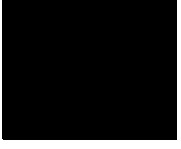
Button Press	Description	Screen Displayed (Example)	Meaning
Press  	Press display button ONCE		Pump speed in revolutions per minute (RPM)
Press  	Press display button TWO times		Pump flow in liters per minute (LPM)
Press  	Press display button THREE times		Pulsatility Index (PI)
Press  	Press display button FOUR times		Power in watts (W)
Press  	Press display button FIVE times		<p>The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states:</p> <ol style="list-style-type: none"> 1. Charged (ready for use). 2. Charging (actively charging). 3. Fault (there is a fault or problem with the backup battery that could affect its reliability).
Press  	Press display button SIX times		Blank screen indicates the screen is off, which is normal.

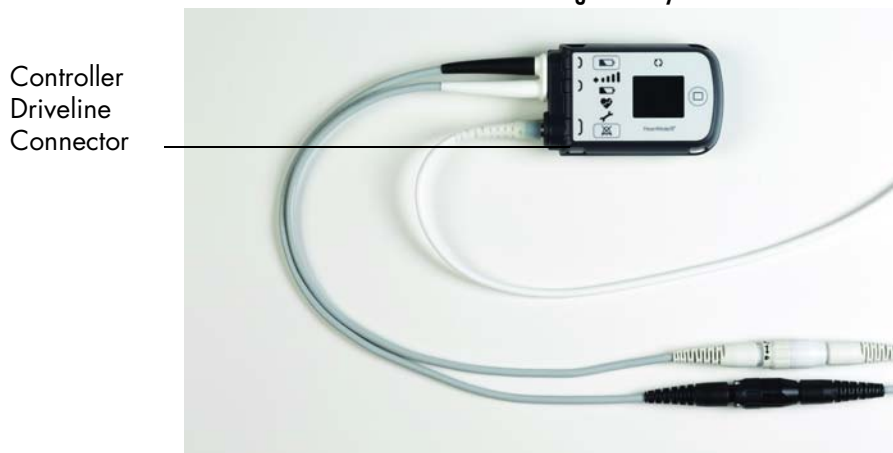
Table 3 System Controller Display Screen Sequence

Note: On-screen messages come in many different languages. Talk with your hospital contact about selecting the language that is best for your needs.

2 How Your Heart Pump Works

The System Controller Driveline Connector

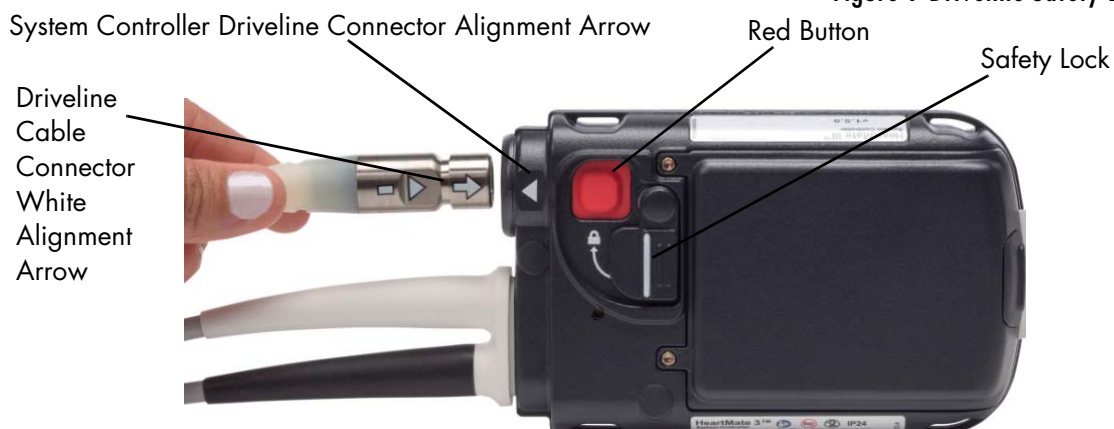
Figure 8 System Controller Driveline Connector



The Controller Driveline Connector connects the Driveline to the System Controller. It has a double lock to lower the risk of accidentally detaching the Driveline. The Driveline is first connected to the running System Controller as one of the steps to implant the pump. It should remain connected to the same, running System Controller at all times—unless told by your hospital contact to replace it (see *Replacing the Running System Controller with a Backup Controller* on page 63).

It is impossible to connect (or disconnect) the Controller Driveline Connector without moving the Driveline Safety Lock into the “unlocked” position. When the Controller Driveline Connector is secure in the socket, the Driveline cannot be removed without pressing the red button under the raised Safety Lock (**Figure 9**).

Figure 9 Driveline Safety Lock



The System Controller continually monitors the connection status of the Controller Driveline Connector. If the System Controller detects a problem, it immediately alarms. For more information, see *Driveline Disconnected Alarm* on page 219.

Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- Driveline

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Orient the System Controller so the display is facing down.
3. Rotate the Safety Lock to the unlocked position (**Figure 10**).

Figure 10 Unlock the Safety Lock



CAUTION !

- Do NOT insert a misaligned Driveline Cable Connector.
- When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

2 How Your Heart Pump Works

4. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 11**).

Figure 11 Align the Arrows



5. **Insert** the Driveline Cable Connector into the socket (**Figure 12**), pressing firmly until it snaps into place. The Left Ventricular Assist Device immediately starts running when the cable is fully and properly inserted in the socket (if pump set speed is set above 4000 rpm).

IMPORTANT! The arrow/alignment mark on the driveline is no longer visible when properly connected.

Figure 12 Insert and Lock the Driveline Into the Socket



6. Move the Safety Lock to the locked position, so that it covers the red button. The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

IMPORTANT! If the Safety Lock does not fully cover the red button, the driveline is not connected. Disconnect and reconnect the driveline.

How Your Heart Pump Works 2

7. Tug on the inserted metal end of the Modular Cable to check the connection. Do not pull on or bend the Driveline. If there is a problem with the connection, the System Controller immediately alarms with a Driveline Disconnected alarm. This is a Hazard alarm.

CAUTION !

Do not pull on or bend the Driveline that connects the pump to the System Controller. Pulling on or bending the Driveline may damage wires inside, even if external Driveline damage is not visible.

2 How Your Heart Pump Works

Disconnecting the Driveline from the System Controller

WARNING !

- Failure to connect to a running System Controller may result in serious injury or death.
- The pump will stop running as soon as the driveline is disconnected.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- Driveline that is connected to a running System Controller

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Orient the System Controller so the display is facing down.
3. Rotate the Safety Lock to the unlocked position (see **Figure 13**).

Figure 13 Unlock the Safety Lock



How Your Heart Pump Works 2

4. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket. Grasp the bend relief of the Modular Cable while removing it. Do not pull on or bend the Controller Driveline Connector (see **Figure 14**).

Figure 14 Grasp the Metal End and Remove the Driveline



WARNING !

The Left Ventricular Assist Device stops if the Driveline is disconnected from the System Controller. If the Driveline is disconnected, reconnect it as quickly as possible to restart the pump. If the System Controller does not work, replace with a backup System Controller.

2 How Your Heart Pump Works

System Controller Power Cable Connectors

The pump cannot work without a power source. As long as the pump is connected to power, it will continue to run.

Two power cables on the System Controller connect to a power source (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). One power cable has a black connector. The other cable has a white connector. (See **Figure 15.**)

The System Controller continually monitors the connection status of the power cable connectors. If the System Controller detects a problem, it immediately alarms. For more information, see *Power Cable Disconnected Alarm* on page 223.

Figure 15 Power Cable Connectors

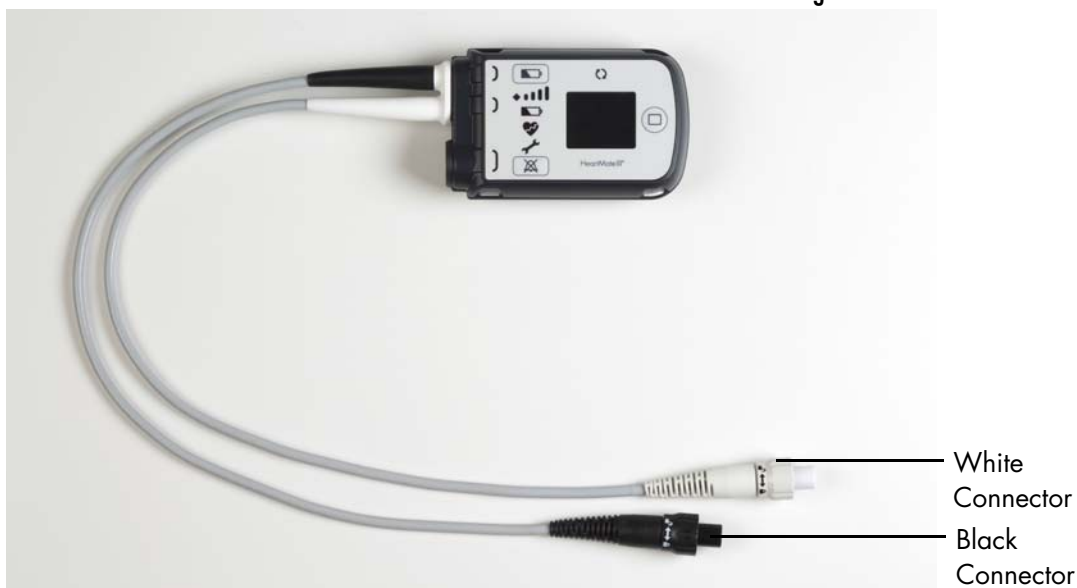


Figure 16 Do Not Sharply Bend the Power Cables

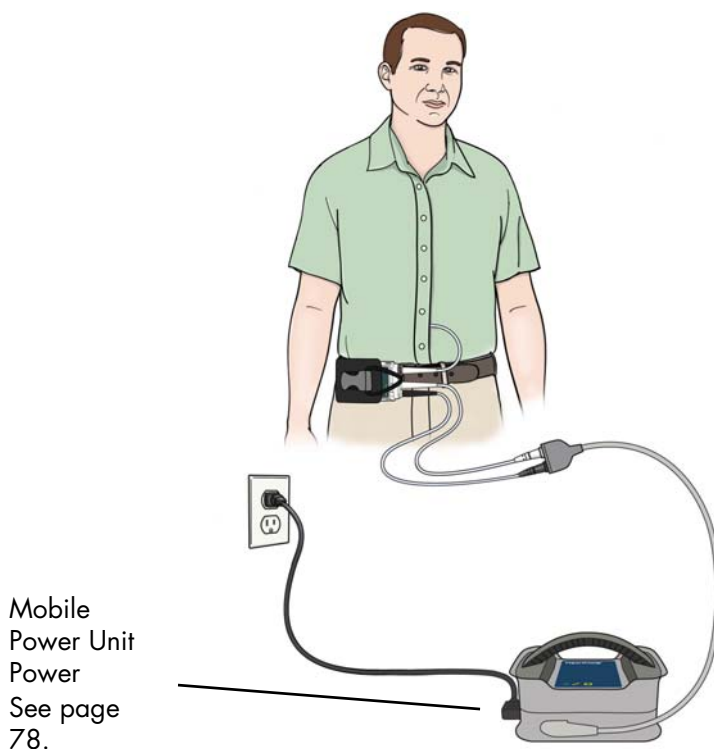


How Your Heart Pump Works 2

During routine use, the HeartMate 3 system is powered by one of two power sources, the Mobile Power Unit or batteries, as described below.

- **Mobile Power Unit:** The Mobile Power Unit plugs into an AC electrical outlet. Use it for power when you are indoors relaxing—and always when sleeping (or when sleep is likely). You must connect to the Mobile Power Unit when sleeping since you may not hear the System Controller alarms. Electrical power from the AC outlet is carried to the system through the Mobile Power Unit patient cable. This cable connects the Mobile Power Unit to the System Controller. The Mobile Power Unit patient cable is required to transfer power to the System Controller. **Figure 17** shows the Mobile Power Unit in use.

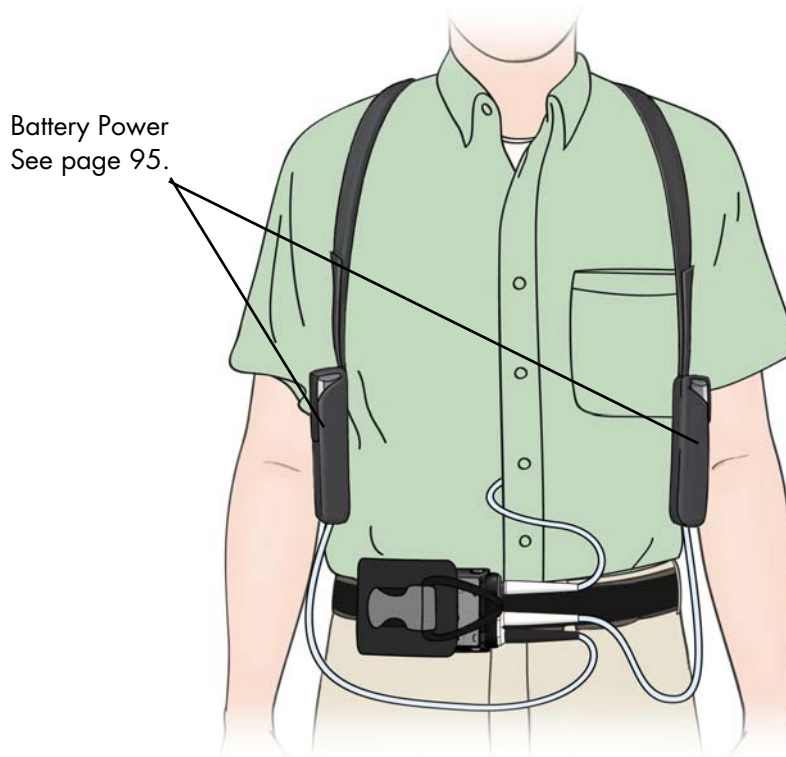
Figure 17 Mobile Power Unit in Use



2 How Your Heart Pump Works

- **Two HeartMate 14 Volt Lithium-Ion batteries:** Use two HeartMate batteries to power the system when AC power is not wanted or not available (for example, when being active outdoors). Batteries are used two at a time. Each battery is inserted into a 14 Volt battery clip. The clips transfer power to the System Controller through two power cables (one for each battery clip). Without battery clips, the batteries cannot power the system. When new, two fully charged HeartMate 14 Volt Lithium-Ion batteries can power the system for 17 hours. How long the batteries can power the system depends on your activity level. If you are more active, the run time will be less. **Figure 18** shows the batteries in use.

Figure 18 Batteries in Holsters



WARNING !

The System Controller must be connected to either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries at all times.

The System Controller Self Test

The System Controller self test takes less than a minute and can be run in both Run and Charge modes. It is brief, but very important. During the self test, the System Controller checks the lights, symbols, and sounds on the user interface. With the self test, you can tell if they are working. Performing a self test will not change the speed at which your pump is running.

The System Controller self test is loud and bright. All of the lights, symbols, and sounds come on and “Self Test” appears on the screen (**Figure 19**).

Figure 19 System Controller During Self Test



The self test should be done at least once per day on the running System Controller. Try to perform the self test at the same time each day so that it becomes part of your daily routine. When charging the backup System Controller every six months, self test the backup System Controller when it is in Charge mode.

2 How Your Heart Pump Works

Performing a System Controller Self Test

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller



Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

Note: A self test can only be performed when power is connected to the System Controller.

IMPORTANT! If an alarm occurs during a self test, the self test ends. The active alarm overrides the self test. For more information, refer to *System Controller Alarms* on page 209. A System Controller self test cannot be initiated during the following alarms: any Hazard alarm, Power Cable Disconnected Advisory alarm, Low Battery Power Advisory alarm.

TASK

1. Press and hold the battery button () for five seconds.
2. Check that:
 - ☒ “Self Test” (first briefly white, then black) appears on the screen.
 - ☒ All symbols and indicators on the user interface illuminate at the same time.
 - ☒ System Controller is making a loud, steady, audio alarm tone.
3. Release the battery button ().

One of the following occurs:

 - If all the lights, symbols, and sounds remain on for 15 seconds. Then the lights, symbols, and sounds turn off or stop, and the screen goes black, the self test is complete and the System Controller has passed.
 - If any of the following occur, there is a problem with the System Controller:
 - The lights remain off
 - The sounds do not work

How Your Heart Pump Works **2**


- A sound is produced other than a loud steady tone

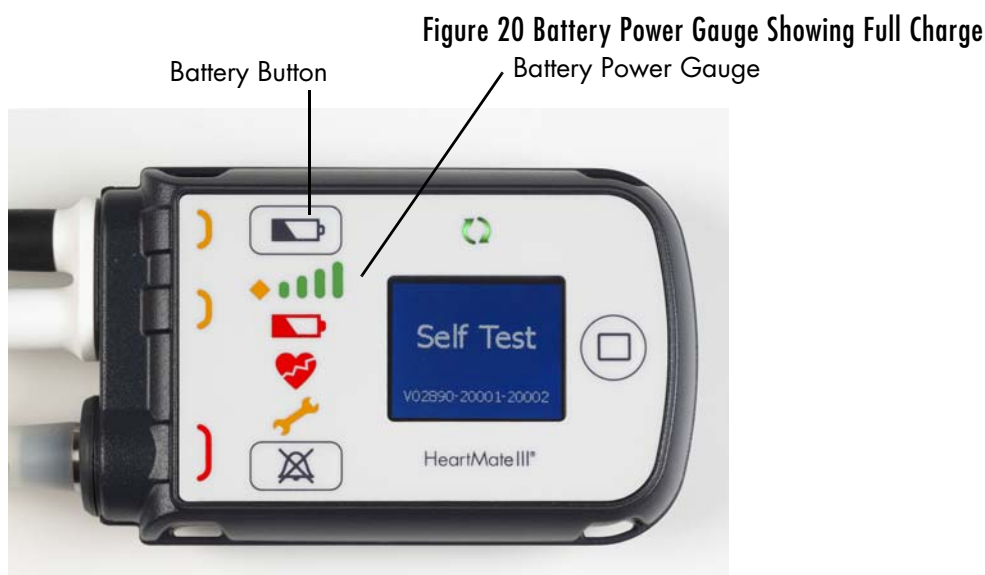
Do not use a System Controller that fails its self test. It may need to be replaced. Refer to *Replacing the Running System Controller with a Backup Controller* on page 63. If the System Controller fails the self test, call your hospital contact.

2 How Your Heart Pump Works

Using the Battery Power Gauge on the System Controller

The battery power gauge shows the approximate charge status of the power source that is connected to the System Controller's white and black power cables—either the 14 Volt Lithium-Ion batteries or the Mobile Power Unit. The number of green bars means the amount of power remaining. The more green bars mean the more power remaining.






To use the battery power gauge, press and release the battery button () on the user interface (**Figure 20**).



IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller). To check the status of the System Controller's backup battery, see *Viewing Pump and System Information on the Screen* on page 30.

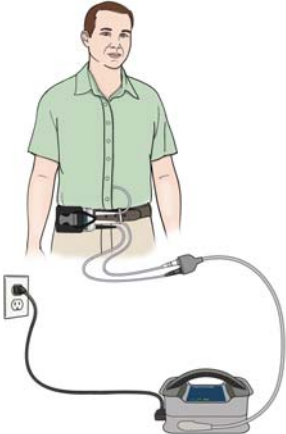

How Your Heart Pump Works 2

On 14 Volt Lithium-Ion battery power:

		4 green bars = 75–100% of battery power remains.
		3 green bars = 50–75% of battery power remains.
		2 green bars = 25–50% of battery power remains.
		1 green bar = less than 25% of battery power remains.

IMPORTANT! Every HeartMate 14 Volt Lithium-Ion battery also has its own on-battery gauge. It shows the power level for that battery. The on-battery readout communicates information about a single source using five green bars. The System Controller battery power gauge communicates information about a combined source of power using four green bars. For more information, see *Checking a Battery's Charge Level* on page 103.

On Mobile Power Unit power:

		4 green bars = Normal Mobile Power Unit operation.
---	---	---

2 How Your Heart Pump Works

Recognizing Low Battery Alarms

If the yellow diamond or the red battery illuminate, the system's power level is dangerously low. If either the yellow diamond or the red battery illuminate, immediately replace the depleted batteries with a fully-charged pair, or switch to the Mobile Power Unit (see *Mobile Power Unit Storage* on page 93). When the system's power level is dangerously low, it prompts a Low Battery Power alarm (**Figure 21**).



Yellow diamond symbol: Less than 15 minutes of battery power remain. This is an **Advisory** alarm.

For more information, see *Low Battery Power Alarm (less than 15 minutes remain)* on page 224.



Red battery symbol: Less than 5 minutes of battery power remain. This is a **Hazard** alarm.

For more information, see *Low Battery Power Alarm (less than 5 minutes remain)* on page 221.

Figure 21 Low Battery Power Alarm (Less Than 5 Minutes of Power Remain)



System Controller Operating Modes

The System Controller has three operating modes:

- **Run Mode**—Running and in use.
- **Sleep Mode**—Not in use, but ready for use (the backup System Controller is in Sleep Mode until needed).
- **Charge Mode**—Connected to a power source and charging the System Controller's backup battery. (The backup System Controller must be put into Charge Mode every six months to charge its backup battery).

2 How Your Heart Pump Works

Run Mode

Run Mode is the usual mode for the running System Controller. **Figure 22** shows the System Controller in Run Mode.

Figure 22 System Controller in Run Mode While Connected to the Mobile Power Unit (left) and to Batteries (right)



In Run Mode, the green Pump Running (🔄) light is on and the System Controller is:

- Connected to power (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries).
- Connected to the Driveline.
- Sending power to the pump through the Driveline.
- Controlling and checking operating conditions.
- Using the user interface to show how the system is working.
- Responding to button pushes.
- Charging the backup battery inside the System Controller.
- Able to run a System Controller self test.

For instructions on switching from Run Mode to Sleep Mode, see *Switching Operating Modes* on page 51.

Sleep Mode

This is the usual mode for the backup System Controller. **Figure 23** shows the backup System Controller in Sleep Mode.

Figure 23 System Controller in Sleep Mode




The backup System Controller stays in Sleep Mode until either:

1. It is put into Charge Mode (connected to power) to charge the backup battery.

OR

2. It is put into Run Mode to replace the running System Controller.

In Sleep Mode, the Pump Running symbol () is off and the backup System Controller is:

- Disconnected from power and off.
- Not connected to the Driveline.
- Not using the user interface to show how the system is working.
- Not responding to button pushes.
- Not charging the backup battery inside the System Controller.

For instructions on switching from Sleep Mode to Run Mode or Charge Mode, see *Switching Operating Modes* on page 51.

2 How Your Heart Pump Works


Charge Mode

Once every six months, you must put the backup System Controller in Charge Mode. **Figure 24** shows the System Controller in Charge Mode.

Figure 24 System Controller in Charge Mode on Mobile Power Unit Power (left) and Using Fully-Charged HeartMate Batteries (right)



In Charge Mode, the System Controller's backup battery will be charged. If the backup battery is not charged, it may not be able to run the pump if needed (see *System Controller Backup Power* on page 56). It can take up to 3 hours for the backup battery to charge.

In Charge Mode, the Pump Running () is off and the backup System Controller is:

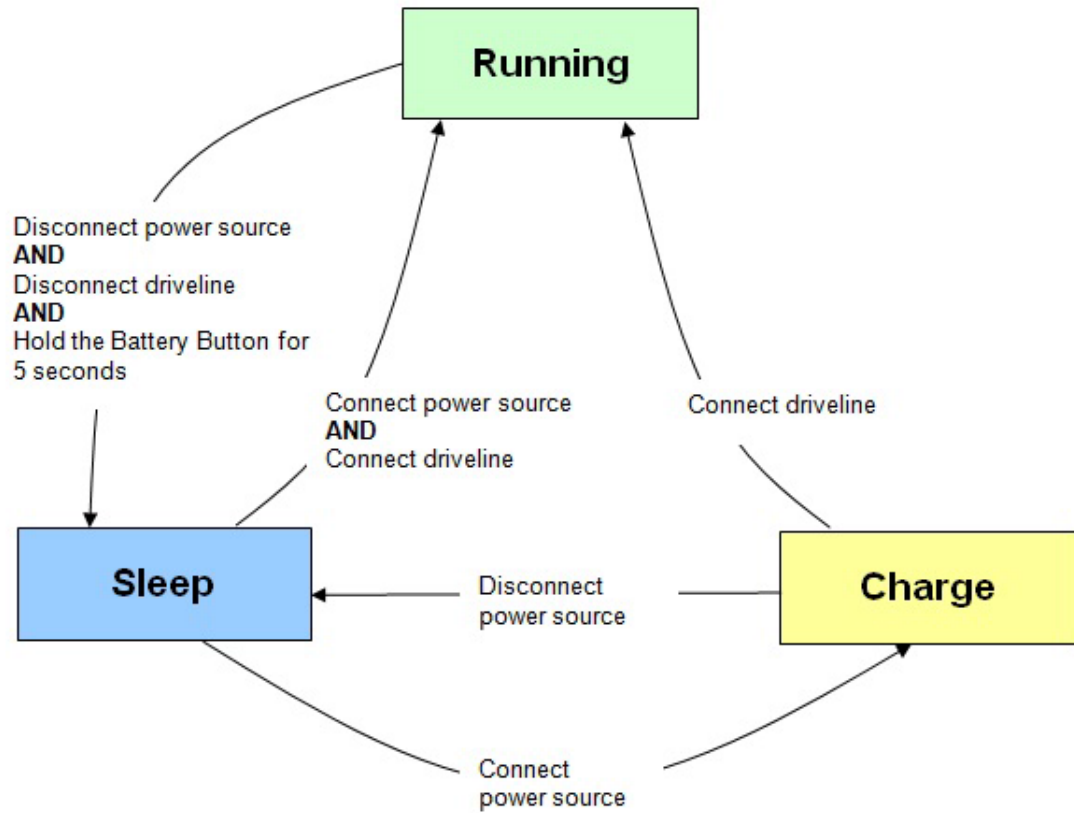
- Connected to power.
- Charging the 11 Volt Lithium-Ion backup battery inside the System Controller.
- Able to run System Controller self test.
- Not connected to the Driveline.
- Not using the user interface to show how the system is working.
- Not responding to button pushes.

How Your Heart Pump Works 2

Switching Operating Modes

Figure 25 summarizes the steps required to switch between operating modes.

Figure 25 System Controller Operating Modes



2 How Your Heart Pump Works

Switching from Sleep Mode to Run Mode

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Sleeping, backup System Controller with a charged backup battery

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Obtain the “sleeping” backup System Controller.
2. Connect the sleeping System Controller to power (either the Mobile Power Unit or two HeartMate batteries).
3. Connect the Controller Driveline Connector to the System Controller (see *Connecting the Driveline to the System Controller* on page 33).
4. The System Controller is now in Run Mode. Confirm that the green Pump Running light is illuminated on the System Controller.

Switching from Sleep Mode to Charge Mode

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Sleeping backup System Controller
- Mobile Power Unit or two fully-charged HeartMate 14 Volt Lithium-Ion batteries

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Connect the sleeping System Controller to a power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries).

It can take up to 3 hours to charge the 11 Volt Lithium-Ion backup battery. During this time, "Charging" and five dashes scroll across the bottom of the screen. This indicates that the 11 Volt Lithium-Ion backup battery is actively charging.

"Charging Complete" appears on the screen when the battery has finished charging. After the backup battery is charged, the System Controller can either be put into Run Mode for immediate use or into Sleep Mode to await future use.

2 How Your Heart Pump Works

Switching from Charge Mode to Run Mode

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Charging backup System Controller with a charged backup battery

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. If the System Controller is in Charge Mode (and already connected to power), connect the Controller Driveline Connector to the System Controller (see *Connecting the Driveline to the System Controller* on page 33). The System Controller is now in Run Mode. Confirm that the green Pump Running light is illuminated on the System Controller.

Switching from Charge Mode to Sleep Mode

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Charging backup System Controller with a charged backup battery

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Disconnect the backup System Controller from power (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). The System Controller is now in Sleep Mode.

Switching from Run Mode to Sleep Mode





FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Disconnect the Driveline from the System Controller, if connected (see *Disconnecting the Driveline from the System Controller* on page 36).
2. Press and release the silence alarm button () to silence the Driveline Disconnected Alarm.
3. Disconnect the System Controller from power.
4. Press and release the silence alarm button () to silence the Power Cable Disconnected Alarm.
5. Press and hold the battery button () for 5 seconds. You hear beeps and the following appears on the screen:
"Hold" and a reverse count down of dots (5 dots, 4 dots, 3 dots, 2 dots, 1 dot)
6. Continue to hold down the battery button () until the countdown ends.
7. After five seconds, the screen goes black. The System Controller is now in Sleep Mode.

2 How Your Heart Pump Works

System Controller Backup Power

An 11 Volt Lithium-Ion backup battery inside the System Controller gives at least 15 minutes of power to the pump if the in-use power source is disconnected or fails.

WARNING !

The 11 Volt Lithium-Ion backup battery should be used only for temporary support during a power-loss emergency. The 11 Volt Lithium-Ion backup battery inside the System Controller can provide enough power to run the pump for at least 15 minutes if the main power source (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) is disconnected or fails. Inappropriate use of the 11 Volt Lithium-Ion backup battery may result in diminished run time during a power-loss emergency.

CAUTION !

- The 11 Volt Lithium-Ion backup battery inside the System Controller must be charged at least once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in diminished or no support during a power-loss emergency when the backup System Controller is in use. See *Maintaining the Backup System Controller's Readiness: Six Month Charging and Self Test* on page 60 for instructions on charging the 11 Volt Lithium-Ion backup battery.
- The backup battery inside the backup System Controller is charged only when the backup System Controller is connected to power. It takes up to 3 hours to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller.

To power the pump in an emergency, the backup battery must be fully charged.

The backup battery is only for backup power. It automatically works if the in-use power disconnects or fails. It should not be used for non-emergencies.

Inappropriate use may leave the pump without power in a real emergency. Backup battery use is tracked by the System Controller. If your hospital contact sees that the backup battery is used often, he/she will talk with you about the reasons for this.

How Your Heart Pump Works **2**

The backup battery is rechargeable. It automatically recharges while the System Controller is connected to power (either the Mobile Power Unit or two HeartMate batteries). The backup battery loses power when the System Controller is not connected to power. That is why the backup System Controller needs to be connected to power every six months (see *Maintaining the Backup System Controller's Readiness: Six Month Charging and Self Test* on page 60).

Connecting the backup System Controller to a power source recharges its backup battery. It takes up to three hours to charge a backup battery that is without a charge.

2 How Your Heart Pump Works

The Backup System Controller

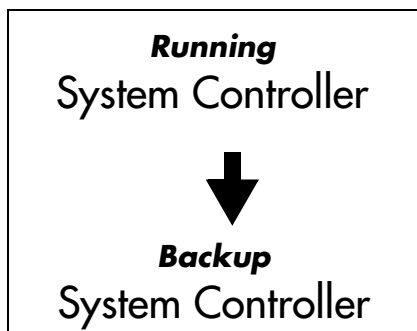
HeartMate 3 patients receive two System Controllers: one to actively use (running), and a reserve (backup) in case the running System Controller experiences a failure.



Backup System Controller Overview
See page 59.



Maintaining the Backup System Controller's Readiness: Six Month Charging and Self Test
Every six months, the backup System Controller's backup battery must be charged and a self test must be performed.
See page 60.






Replacing the Running System Controller with a Backup Controller
If the running System Controller experiences a failure, it must be replaced.
See page 63.

How Your Heart Pump Works 2

Backup System Controller Overview

Every HeartMate 3 patient receives a backup System Controller, which is identical to the running System Controller and is programmed with the same settings as the running System Controller. If a failure occurs on the running System Controller, it may need to be replaced with the backup System Controller. For this reason, and in case of an emergency, the backup System Controller must remain with the patient at all times.

Running System Controller	Backup System Controller
	<p>If needed, ready to use</p> 
<p>On Mobile Power Unit</p> 	<p>Backup is not connected to:</p> <ul style="list-style-type: none">• Power• Driveline
<p>On Batteries</p>	

2 How Your Heart Pump Works

Maintaining the Backup System Controller's Readiness: Six Month Charging and Self Test

Over time, the backup battery inside the System Controller loses power and must be recharged. Most of the time, the backup System Controller remains in Sleep Mode. However, once every six months, you must "awaken" it, connect it to power, and put it into Charge Mode. Connecting the backup System Controller to power charges its 11 Volt Lithium-Ion backup battery. While the backup System Controller is in Charge Mode, you should perform a self test.

Performing Backup System Controller Six Month Charging and Self Test

FOR THIS TASK YOU NEED:

- 1 backup System Controller
- 1 power source (either Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries)

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Connect the backup System Controller to a power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) **(Figure 26)**.

Figure 26 System Controller on Mobile Power Unit Power (left) and Battery Power (right)



How Your Heart Pump Works 2

2. When the System Controller is connected to power, its user display screen shows "Charging" or "Charging Complete" (**Figure 27**).

Figure 27 System Controller Charging or Charging Complete



IMPORTANT! Do not remove power until "Charging Complete" is displayed. It can take up to three hours to charge the System Controller's backup battery.

3. Perform a self test on the backup System Controller. Press and hold the battery button () for five seconds (**Figure 28**).

For more information, see *Performing Backup System Controller Six Month Charging and Self Test* on page 60.

Note: A self test can only be performed when power is connected to the System Controller.

Figure 28 System Controller Self Test



2 How Your Heart Pump Works

4. Disconnect power from the backup System Controller. This will put the backup System Controller back into Sleep Mode. No further action is needed for one month.
5. Put the backup System Controller into its Protection Bag (**Figure 29**).

For more information, see *The Travel Bag* on page 182.

Figure 29 Backup System Controller in Protection Bag



Replacing the Running System Controller with a Backup Controller

WARNING !

Failure to adhere to the following instructions may result in serious injury or death.

There are two ways in which the System Controller can be exchanged. The first method assumes that only the System Controller is exchanged and that a second power source is not available. The second exchange method involves exchanging the System Controller using a second power source.

Replace the System Controller using instructions in either *Replacing the Current System Controller with One Power Source* on page 65 or *Replacing the Current System Controller with Multiple Power Sources* on page 69.

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

Do **NOT** attempt to change your System Controller without having a trained, competent caregiver at your side to assist. Follow all alarm instructions, including calling the hospital.

2 How Your Heart Pump Works

With In-use Power Source Only (Mobile Power Unit OR Batteries and Clips)



a. Move the **white** connector's power source from the running System Controller to the backup System Controller.

For more information, see *Powering the System* on page 75.



IMPORTANT! Before inserting, **align** the WHITE arrow/ alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector.

b. Promptly move the Controller Driveline Connector from the running System Controller to the backup System Controller. It may take up to 10 seconds for your pump to start. Close the Safety Lock.



For more information, see *The System Controller Driveline Connector* on page 32.



c. Move the **black** connector's power source from the running System Controller to the backup System Controller.

Multiple Power Sources Available (Mobile Power Unit AND Batteries and Clips)



a. Connect both the white and black connectors on the backup System Controller to power.

IMPORTANT! Keep the running System Controller connected to power.

For more information, see *Powering the System* on page 75.



IMPORTANT! Before inserting, **align** the WHITE arrow/ alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector.

b. Promptly move the Controller Driveline Connector from the running System Controller to the backup System Controller. It may take up to 10 seconds for your pump to start. Close the Safety Lock.



For more information, see *The System Controller Driveline Connector* on page 32.

c. Disconnect the old, replaced System Controller from power.

Table 4 Replacing the System Controller

How Your Heart Pump Works 2

Replacing the Current System Controller with One Power Source

To replace the current System Controller with the replacement System Controller:

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- 1 backup System Controller
- 1 running System Controller, connected to a power source (either Mobile Power Unit or 14 Volt Lithium-Ion batteries and clips)
- Optional: A second power source to power the backup System Controller (either Mobile Power Unit or 14 Volt Lithium-Ion batteries and clips)

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

Do **NOT** attempt to change your System Controller without having a trained, competent caregiver at your side to assist. Follow all alarm instructions, including calling the hospital.

TASK

1. Place the backup System Controller within reach.
2. Sit or lie down (you may get dizzy if the pump briefly stops).
3. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button (⊗).
4. Locate your replacement HeartMate 3 System Controller.
5. Move the white connector's power source from the running controller to the backup System Controller. Fully secure the white nut until tight.

2 How Your Heart Pump Works

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

- Do NOT insert a misaligned Driveline Cable Connector.
- When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

6. To disconnect the Driveline from the current System Controller:
 - a. Orient the System Controller so the display is facing down.
 - b. Rotate the Safety Lock to the unlocked position (see **Figure 30**).

Figure 30 Unlock the Safety Lock



How Your Heart Pump Works 2

- c. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket. Grasp the bend relief of the Driveline while removing it. Do not pull on or bend the Controller Driveline Connector (see **Figure 31**).

Figure 31 Grasp the Metal End and Remove the Driveline



7. To connect the Driveline to the replacement System Controller:
 - a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector (**Figure 32**).

Figure 32 Align the Arrows



- b. **Insert** the Driveline Cable Connector into the socket pressing firmly until it snaps into place.

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

2 How Your Heart Pump Works

8. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 33**).

Figure 33 Closing the Safety Lock



9. Orient the System Controller so the display is facing up. **Confirm the green Pump Running symbol (🔄) is on.**
10. Disconnect the Black Power connection from the previously running System Controller and connect it to the replacement System Controller (and fully secure the black nut until tight) which is now supporting the patient.
11. Put the previously running System Controller into Sleep Mode. For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 73.

How Your Heart Pump Works 2

Replacing the Current System Controller with Multiple Power Sources

To replace the current System Controller with the replacement System Controller using multiple power sources:

WARNING !

Failure to connect to a running System Controller may result in serious injury or death

CAUTION !

Do **NOT** attempt to change your System Controller without having a trained, competent caregiver at your side to assist. Follow all alarm instructions, including calling the hospital.

TASK

1. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the silence alarm button (⊗).
2. Locate your replacement HeartMate 3 System Controller and second power-source.
3. Power the replacement System Controller by connecting both the White and Black Power connections (fully secure both the white and black nuts until tight).

2 How Your Heart Pump Works

WARNING !

Failure to connect to a running System Controller may result in serious injury or death.

CAUTION !

- Do NOT insert a misaligned Driveline Cable Connector.
- When inserting the Driveline Cable Connector, do NOT orient the System Controller so the display is facing up.

4. To disconnect the Driveline from the current System Controller:
 - a. Orient the System Controller so the display is facing down.
 - b. Rotate the Safety Lock to the unlocked position (see **Figure 34**).

Figure 34 Unlock the Safety Lock



- c. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket. Grasp the bend relief of the Driveline while removing it. Do not pull on or bend the Controller Driveline Connector (see **Figure 35**).

Figure 35 Grasp the Metal End and Remove the Driveline



How Your Heart Pump Works 2

5. To connect the Driveline to the replacement System Controller:
 - a. **Align** the WHITE arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector(**Figure 36**).

Figure 36 Align the Arrows



- b. **Insert** the Driveline Cable Connector into the socket pressing firmly until it snaps into place. The Left Ventricular Assist Device immediately starts running when the cable is fully and properly inserted in the socket (if pump set speed is set above 4000 rpm).

Note: The Safety Lock cannot move to the locked position unless the Driveline is fully and properly inserted.

6. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 37**).

Figure 37 Closing the Safety Lock






7. Orient the System Controller so the display is facing up. **Confirm the green Pump Running symbol (🔄) is on.**
8. Disconnect the Black Power connection and the White Power connection from the previously running System Controller.


2 How Your Heart Pump Works

9. Put the previously running System Controller into Sleep Mode. For further instructions, refer to *Turning Off the System Controller (Sleep Mode)* on page 73.

Turning Off the System Controller (Sleep Mode)

1. Disconnect the Driveline from the System Controller. Press and release the silence alarm button () to silence the Driveline Disconnected Alarm.
2. Disconnect the System Controller from its power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). Press and release the silence alarm button () to silence the Power Cable Disconnected Alarm.
3. Press and hold the battery button () for five seconds. The following appears on the screen:

“Hold” accompanied by a reverse countdown from five dots to one dot (5 dots, 4 dots, 3 dots, 2 dots, 1 dot).

When the countdown ends, the screen goes black, the Pump Running symbol is black () , and the System Controller is in Sleep Mode. If this sequence is not fully completed, the System Controller will not enter Sleep Mode.

2 How Your Heart Pump Works

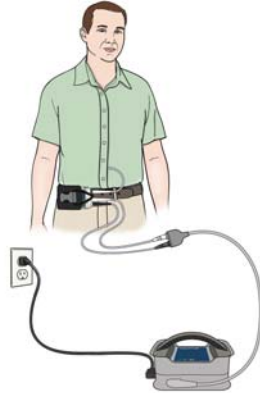
POWERING THE SYSTEM

This section provides information about the various ways to power the HeartMate 3 Left Ventricular Assist System.

Power Overview - - - - -	77
Using the Mobile Power Unit - - - - -	78
Using HeartMate 14 Volt Lithium-Ion Batteries - - - - -	95
Using the Battery Charger- - - - -	119
Battery Charging Overview- - - - -	125
Viewing Battery Information on the Battery Charger - - - - -	129
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3 Powering the System

Power Overview



Mobile Power Unit—Use the Mobile Power Unit when you are indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.

See page 78.

Two HeartMate 14 Volt Lithium-Ion batteries—HeartMate batteries are used to power the system during battery-powered operation when AC electricity is not wanted or is unavailable. Batteries are used in pairs. Each battery is inserted into a 14 Volt battery clip. The clips transfer battery power to the System Controller with two power cables, one for each clip. Without battery clips, the batteries cannot transfer power to the system. When fully charged, a pair of HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 6–17 hours, depending on your activity level.



See page 93.



Battery Charger—The Battery Charger is needed to charge, test, and calibrate the 14 Volt Lithium-Ion batteries. The Battery Charger can accommodate up to four batteries at one time.

See page 119.

3 Powering the System

Using the Mobile Power Unit

The Mobile Power Unit (**Figure 38**):

- Provides power to the System Controller and pump.
- Powers the system while you are sleeping or relaxing indoors.
- Echoes System Controller alarms (*System Controller Alarms* on page 209).

Required Components

The following components are required for connecting the Mobile Power Unit to the System Controller:

- Mobile Power Unit with batteries inserted
- Mobile Power Unit AC power cord
- Running System Controller

Figure 38 The Mobile Power Unit



WARNING !

- The Mobile Power Unit radiates radio frequency energy. If not used according to instructions, the Mobile Power Unit may cause harmful interference with nearby devices. To confirm interference, switch to battery power, and then unplug the Mobile Power Unit and observe the effect on devices in the area. If interference is detected, switch to another power source and then:
 - Re-orient or move the affected devices.
 - Increase the distance between the Mobile Power Unit and the affected devices.
 - Connect the affected devices to an electrical outlet different from the outlet used to power the Mobile Power Unit.
- Always connect to the Mobile Power Unit when sleeping, or when there is a chance of sleep. The system alarms may not be heard when asleep, resulting in injury or death.
- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.
- Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the System Controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.
- If there is a power failure, transfer from the Mobile Power Unit to another power source. The backup battery in the System Controller will temporarily power the pump while transferring to battery power. Do not rely on the System Controller's backup battery as a power source during AC power failure, as it will only power the pump for a limited amount of time and the pump will stop.
- Keep the Mobile Power Unit dry and away from water or liquid. If the Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or cause an electrical shock.
- Do not use the Mobile Power Unit in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide, or an explosion could occur.

3 Powering the System

CAUTION !

- To avoid the risk of electric shock, the Mobile Power Unit must be plugged into a properly-tested AC electrical outlet that is dedicated to Mobile Power Unit use. Do not use portable, multiple outlet (power strip) adapters or extension cables.
- Do not connect the Mobile Power Unit to electrical outlets that are controlled by a wall switch, as the Mobile Power Unit may be left inoperable.
- Do not use the Mobile Power Unit with DC to AC inverters, as they may cause the Mobile Power Unit to fail.
- Avoid positioning the Mobile Power Unit where access to the power cord plug into the wall socket is limited or where disconnection of the plug from the wall socket is difficult.
- The Mobile Power Unit has an AC Power Cord and Patient Cable, both of which may be a tripping hazard. Ensure that the patient, caregivers, and all other persons near the Power Module are aware of this potential hazard.
- Avoid covering the Mobile Power Unit, such as with a blanket. Covering the Mobile Power Unit may reduce your ability to hear important system alarms or may cause the Mobile Power Unit to fail due to overheating.
- Keep the Mobile Power Unit free of excessive lint and dust, and away from heat or humidity sources such as a fireplace, radiant heater, nebulizer, or steam kettle, as the Mobile Power Unit may fail to operate properly.
- At least one System Controller power cable must be connected to a power source (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) at all times. Do not rely on the System Controller's backup battery, as it will only power the Pump for a limited amount of time.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Do not carry or touch the Mobile Power Unit for an extended time. To avoid the risk of burns, do not touch the top surface of the Mobile Power Unit for longer than one minute. The Mobile Power Unit surface temperature can become uncomfortably warm, especially when the room temperature is above 104°F (40°C). Surface temperatures can approach 131°F (55°C).

CAUTION ! (Continued)

- Do not clean or service the Mobile Power Unit while it is plugged into an AC electrical outlet, or electrical shock may occur.
- Mobile Power Unit power output may be affected by mobile phones, resulting in low power alarms on the System Controller, or loss of the green power LED on the Mobile Power Unit. If either of these conditions is observed, separate the mobile phone from the Mobile Power Unit by at least .6 meters (24 inches). If the condition persists after separating the devices, switch to two HeartMate 14 Volt Lithium-Ion batteries.
- Do not incinerate, disassemble, crush, puncture, or otherwise damage batteries, as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not mix old and new batteries or battery types (such as rechargeable with non-rechargeable), as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may affect the electromagnetic compatibility of the Mobile Power Unit with other devices. Potential interference may occur between the Mobile Power Unit and other devices.
- Inspect the Mobile Power Unit patient and power cables for damage. Do not use the Mobile Power Unit if either cable shows signs of damage.
- When moving the Mobile Power Unit to a different location or AC power source, first connect the System Controller to HeartMate 14 Volt batteries.
- Do not change the Mobile Power Unit batteries while the Mobile Power Unit is powering the HeartMate system. Switch to another power source and then disconnect the Mobile Power Unit power cord from the wall socket prior to replacing the Mobile Power Unit batteries.

Setting Up the Mobile Power Unit for Use


Before using the Mobile Power Unit, you must prepare it for use. This section provides information about the following:

- Inserting the Mobile Power Unit batteries.
- Connecting the Mobile Power Unit power cord to the Mobile Power Unit and AC power.

3 Powering the System

Inserting or Replacing the Mobile Power Unit Batteries

The Mobile Power Unit uses three Alkaline AA batteries to power its alarms. You must install the Mobile Power Unit batteries before using the Mobile Power Unit. The batteries power the alarm echo function when an AC power failure occurs or the power cord is disconnected.

The yellow Mobile Power Unit battery symbol () illuminates and a beeping audio tone sounds when the Alkaline AA batteries are not installed or are depleted and need to be changed.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Mobile Power Unit
- 3 new Alkaline AA batteries
- Flathead screwdriver or coin

CAUTION !

Never change the Mobile Power Unit batteries while the Mobile Power Unit is powering the HeartMate system. Switch to another power source, and then disconnect the Mobile Power Unit power cord from the wall socket prior to replacing the Mobile Power Unit batteries.

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Ensure that the power cord is unplugged from the Mobile Power Unit.
3. Inspect the Mobile Power Unit for dents, chips, cracks, or other signs of damage. Do not use a Mobile Power Unit that appears damaged. Contact your hospital contact if a replacement is needed.

Powering the System 3

4. Use a flathead screwdriver or coin to loosen the screw from the rear panel. The screw will remain in the screw hole to ensure it is not lost (**Figure 39**).

Figure 39 Loosen the Screw



5. Open the battery compartment cover on the rear of the Mobile Power Unit and dispose of the battery installation reminder tag, if present (**Figure 40**).

Figure 40 Remove the Battery Compartment Cover



6. If replacing the batteries, pull the ribbon to remove the depleted batteries out of the case.

3 Powering the System

7. Lay the ribbon on the bottom of the compartment. Place the Alkaline AA batteries in the battery compartment. Orient the batteries as shown on the orientation markings on the battery clip (**Figure 41**).

Figure 41 Insert AA Batteries



8. Replace the battery compartment cover.
9. Use the flathead screwdriver or coin to tighten the screw. Make sure the screw is tight and the cover is securely closed (**Figure 42**).

Figure 42 Tighten the Screw



10. Dispose of or recycle the depleted batteries in compliance with all applicable local, state, and federal regulations.

Connecting the Power Cord

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Mobile Power Unit (with 3 AA Alkaline batteries included)
- Black AC power cord to connect the Mobile Power Unit to an AC electrical outlet
- Functioning AC electrical outlet that is dedicated to Mobile Power Unit use and not controlled by a wall switch

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Obtain the black AC power cord.
3. Plug the female end of the power cord into the power entry module on the Mobile Power Unit (**Figure 43**).

Figure 43 Plug Power Cord into Mobile Power Unit



3 Powering the System

4. Pull back on the end of the power cord to ensure a secure connection to the Mobile Power Unit (**Figure 44**).

Figure 44 Pull Back to Ensure Secure Connection



5. Plug the Mobile Power Unit into an AC electrical outlet that is dedicated to Mobile Power Unit use.

CAUTION !

- Do not use an outlet that is controlled by a wall switch.
- Do not use portable, multiple outlet (power strip) adapters.

Powering the System 3

6. Check the top panel of the Mobile Power Unit. When initially connected to power, the Mobile Power Unit automatically performs a self test, the green power symbol is illuminated, and the yellow wrench and Replace MPU Battery lights flash, and the Mobile Power Unit beeps twice. After the self test, the green "Power On" light should remain lit (**Figure 45**). The Mobile Power Unit is ready for use.

Figure 45 Mobile Power Unit Ready for Use



IMPORTANT! The power symbol (🔌) is illuminated green when the Mobile Power Unit is powered and functioning properly.

7. If the green Power On light does not illuminate, complete the following steps:
 - a. Plug the Mobile Power Unit into a different AC electrical outlet that is dedicated to Mobile Power Unit use.

CAUTION !

- Do not use an outlet that is controlled by a wall switch.
- Do not use portable, multiple outlet (power strip) adapters.

- b. Observe the top panel of the Mobile Power Unit and complete one of the following steps:
 - If the green light illuminates and the functions described in Step 5 occur, the Mobile Power Unit is ready for use.
 - If the green light still does not illuminate, call your hospital contact. The Mobile Power Unit may have a problem. Do not use it.

3 Powering the System

Disconnecting the Power Cord

FOR THIS TASK YOU NEED:

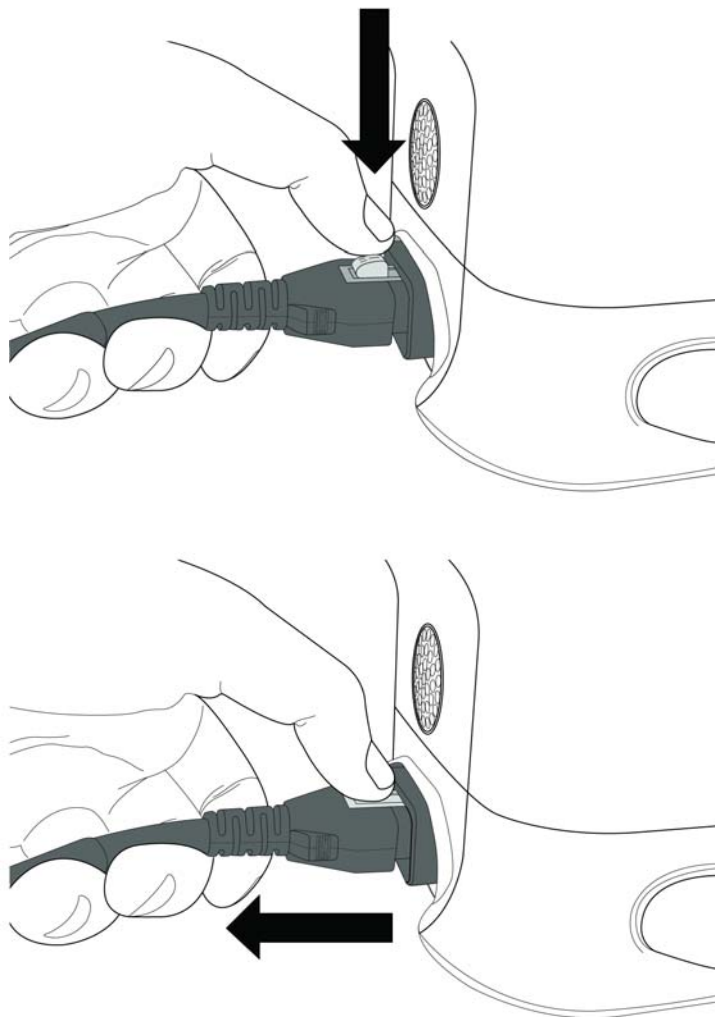
- Mobile Power Unit
- Black AC power cord connected to the Mobile Power Unit.

TO DISCONNECT THE V-LOCK POWER CORD:

TASK

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Press down and hold the yellow button on the top of the plug to disengage the locking mechanism (**Figure 46**).
3. Pull out and unplug the power cord from the Mobile Power Unit.

Figure 46 Press Yellow Locking Button Down and Pull Out



When to Connect to the Mobile Power Unit

Use the Mobile Power Unit when relaxing indoors and always when sleeping. You must connect to the Mobile Power Unit when sleeping (or when sleep is likely) since you may not hear the System Controller's low battery alarms; the Mobile Power Unit will echo the System Controller's alarms. For steps on getting ready for sleep, see *Sleeping* on page 201.

You need the Mobile Power Unit patient cable (**Figure 47**) to connect the System Controller to the Mobile Power Unit.

Figure 47 Mobile Power Unit Patient Cable



CAUTION !

Do not allow the cable to come into contact with sharp edges and use care to prevent it from being pinched or bent.

Like the power cable connectors on the System Controller, the connectors on the Mobile Power Unit patient cable are also color coded (see **Figure 47**). When connecting the System Controller to the Mobile Power Unit patient cable, always connect white-to-white and black-to-black. To connect the System Controller to the Mobile Power Unit, follow the steps below.

Use care when connecting and disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 238.

3 Powering the System

Connecting the System Controller to the Mobile Power Unit

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- Mobile Power Unit that is ready for use
- Mobile Power Unit patient cable

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Confirm that the Mobile Power Unit is ready for use (see *Setting Up the Mobile Power Unit for Use* on page 81).
3. Place the black and white System Controller power cable connectors within easy reach (**Figure 48**).

Figure 48 System Controller Power Cable Connectors



4. Place the black and white Mobile Power Unit patient cable within easy reach.
5. Place the batteries with their attached battery clips within easy reach.
6. Unscrew and disconnect only the white System Controller power cable connector from the attached battery clip. Do not remove the black connector!

Powering the System 3

7. Promptly align opposite half circles inside the white System Controller power cable connector and the white Mobile Power Unit patient cable connector (**Figure 49**).

CAUTION !

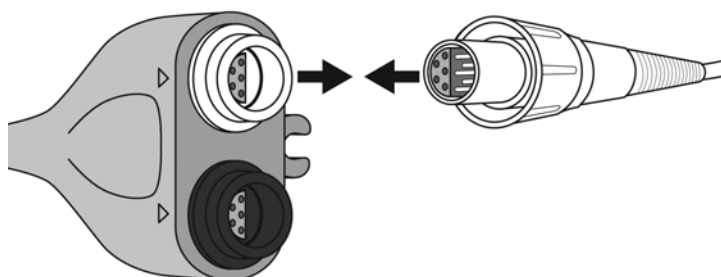
Do not try to join together misaligned connectors. This can damage them.

Figure 49 Carefully Align the Connectors



8. Firmly push together the two connectors (**Figure 50**).

Figure 50 Push Together the Two Connectors



3 Powering the System

9. Tighten the connector nut until secure (**Figure 51**). Hand tighten only—do not use tools.

Figure 51 Tighten the Connector Nut



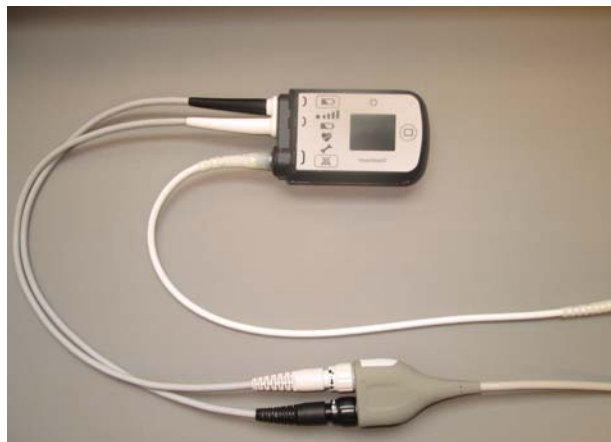
10. Unscrew and disconnect only the black System Controller power cable connector from the attached battery clip.
11. Promptly align opposite half circles inside the black System Controller power cable connector and the black Mobile Power Unit patient cable connector.

CAUTION !

Do not try to join together misaligned connectors. This can damage them.

12. Firmly push together the two connectors.
13. Tighten the connector nut until secure. Hand tighten only—do not use tools.
14. Both System Controller power cables are now connected to the Mobile Power Unit (**Figure 52**).

Figure 52 System Controller Power Cables Connected to Mobile Power Unit Patient Cable Connectors



Mobile Power Unit Storage

If the Mobile Power Unit will not be used for an extended time, unplug the AC power cord from power and detach the power cord from the device. Wrap the Mobile Power Unit patient cable around the Mobile Power Unit for storage. This is also a convenient way to prepare the device and patient cable for travel.

Figure 53 The Mobile Power Unit



3 Powering the System

Mobile Power Unit Maintenance

The Mobile Power Unit requires little planned maintenance. However, you need to inspect it routinely to ensure the safest and best possible performance. For complete information about caring for the Mobile Power Unit, see *Caring for the Mobile Power Unit* on page 247.

Periodically, and as needed, complete the following steps to clean the exterior surfaces of the Mobile Power Unit.

WARNING !

- Never clean the Mobile Power Unit while it is providing power to the Pump.
- Do not put the Mobile Power Unit into water or liquid.

TASK

1. Change to battery power.
2. Unplug all connections.
3. Clean the exterior surfaces of the Mobile Power Unit using a mild detergent, and a clean, damp (not wet) cloth.

Using HeartMate 14 Volt Lithium-Ion Batteries

HeartMate batteries (**Figure 54**) are the other routine power source for the HeartMate 3 Left Ventricular Assist System.

Figure 54 HeartMate 14 Volt Lithium-Ion Battery



During battery-powered operation, the Left Ventricular Assist System is powered by two direct current (DC) batteries that are inserted into battery clips. The battery clips and attached batteries can be worn in holsters, one under each arm (**Figure 55**).

Figure 55 HeartMate 3 System on Battery Power



3 Powering the System

Using batteries to power the system is called mobile operation, since you are not connected to electricity. Use battery power when you want to be mobile and relatively active, for example, while shopping, running errands, or performing other activities outside the home.

Use two HeartMate 14 Volt Lithium-Ion batteries to power the HeartMate 3 Left Ventricular Assist System. See *About the HeartMate 14 Volt Lithium-Ion Batteries* on page 99.

WARNING !

- Use only HeartMate 14 Volt Lithium-Ion batteries supplied by Thoratec Corporation with the HeartMate 3 Left Ventricular Assist System. Using the wrong batteries may cause the pump to stop.
- Charge the HeartMate 14 Volt Lithium-Ion batteries before using them. Before a battery is removed from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After the battery is removed from the Battery Charger, use the battery power gauge to check the battery charge level.
- Use only 14 Volt battery clips supplied by Thoratec Corporation with HeartMate 14 Volt Lithium-Ion batteries. Other clips will not transfer electrical power to the system.
- Always connect to the Mobile Power Unit when sleeping or when there is a chance of sleep. If you are sleeping, you may not hear System Controller alarms.
- Do not use damaged, defective, or expired batteries. Using damaged, defective, or expired batteries may cut operating time.

CAUTION !

- Use only the Battery Charger supplied by Thoratec Corporation to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- After approximately 70 uses, HeartMate 14 Volt Lithium-Ion batteries may need to be re-calibrated. The Battery Charger indicates when a battery needs to be re-calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted, to prevent a backlog of uncalibrated batteries.
- Leave a calibrating 14 Volt Lithium-Ion battery in the Battery Charger for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery power gauge will reflect this status).
- Dirty battery contacts on the 14 Volt Lithium-Ion battery may prevent proper charging, which can affect operation. Clean the metal contacts on the batteries and inside the battery clip at least once a month. Use a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or battery clips, or before placing batteries into the Battery Charger.
- As 14 Volt Lithium-Ion batteries get older, they support the system for shorter periods of time. If batteries do not give at least four hours of support, take them out of service.
- If stored and used within recommended guidelines, HeartMate 14 Volt Lithium-Ion batteries should be usable for approximately 360 use/charge cycles or for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced.
- If a 14 Volt Lithium-Ion battery leaks, do not touch the leaking fluid. If the fluid touches skin or eyes, wash the affected area with plenty of water and seek medical advice.

3 Powering the System

CAUTION ! (Continued)

- To prevent deterioration or damage to a 14 Volt Lithium-Ion battery:
 - Do not store in direct sunlight.
 - Do not use in temperatures that are below 32°F (0°C) or above 104°F (40°C), or the battery may fail suddenly.
 - Do not dismantle, open, or shred.
 - Do not drop or hit against hard objects or each other.
 - Do not leave or store in extremely hot or cold temperatures such as automobiles or automobile trunks, or battery life will be shortened.
 - Do not expose to heat or fire.
 - Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short and a rapid discharge of the battery. This can result in battery overheating that may burn you or damage the batteries.
- Keep batteries out of the reach of children.
- Keep batteries clean and dry.
- Dispose of expired or defective batteries in accordance with local, state, and federal regulations.
- Avoid touching metal battery contacts with two separate hands, which will increase the chance that battery energy could pass through your body.
- At least one System Controller power cable must be connected to a power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) at all times. Do not rely on the System Controller's backup battery, as it will only power the Pump for a limited amount of time.

About the HeartMate 14 Volt Lithium-Ion Batteries

Two, new, fully charged HeartMate 14 Volt Lithium-Ion batteries provide 17 hours of support.

Batteries last for less time if you are active or emotionally stressed. As batteries get older, they power the system for shorter periods of time. If two HeartMate 14 Volt Lithium-Ion batteries do not give at least four hours of support, take both batteries out of service and tell your hospital contact.

Batteries are always used two at a time. However, the system will operate using just one battery for a very short period (minutes). For example, system operation continues on a single battery while switching from battery power to Mobile Power Unit power, or vice versa.

During battery-powered operation, the battery power gauge on the System Controller shows overall power capacity for both batteries. The battery power gauge tells you when the batteries are running low. If the current power source is low, the System Controller prompts you to switch to a different power source (two new fully-charged batteries or the Mobile Power Unit). To check the status of an individual battery, press the battery power gauge on that battery (see *Checking a Battery's Charge Level* on page 103).

Charging New Batteries for the First Time

You must charge each HeartMate battery before use, including the very first time you use a battery. It takes approximately four hours or less to charge a low battery. Batteries are charged in the Battery Charger, which can charge up to four batteries at a time.

Depending on how long a battery has been in storage, the on-battery power gauge may not work until after the battery goes through its first charge cycle (see *Checking a Battery's Charge Level* on page 103).

See *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127 for instructions on charging HeartMate batteries.

3 Powering the System

Using Battery Clips

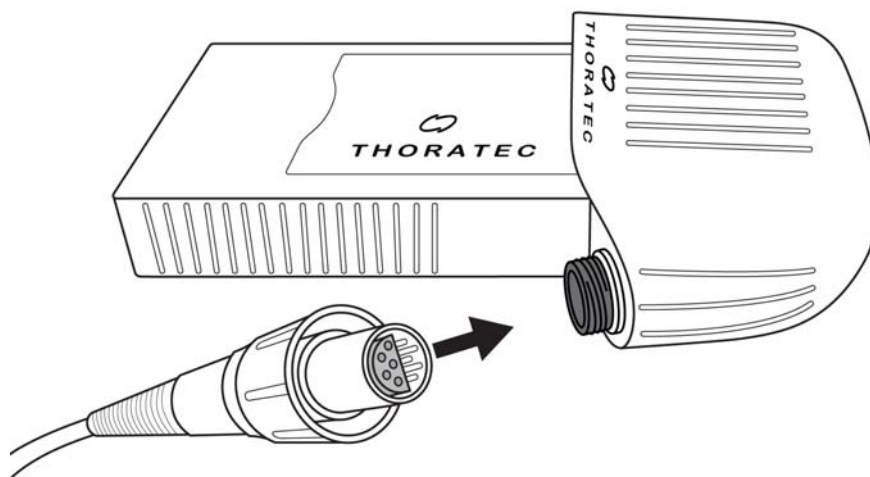
To transfer power to the System Controller, two HeartMate batteries must be placed into special battery clips (**Figure 56**). HeartMate 14 Volt Lithium-Ion batteries only work with 14 Volt battery clips. Other battery clips will not transfer power. HeartMate batteries cannot power the system without battery clips.

Figure 56 HeartMate 14 Volt Lithium-Ion Battery and 14 Volt Battery Clip



Power cable connectors on the System Controller connect to each battery clip (**Figure 57**). In this way, battery power is supplied to the System Controller through the power cables.

Figure 57 The System Controller Power Cable Attaches to the Battery Clip



Inserting a HeartMate Battery into a Battery Clip

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Hold the battery in one hand and the battery clip in the other hand.
3. Line up the arrows on the battery and battery clip (**Figure 58**).

Figure 58 Line Up Arrows



4. Insert the battery into the battery clip. The battery clicks into place when fully and properly inserted.
5. Pull gently on the battery to confirm that the connection is tight.
6. Repeat Steps 2 through 5 for the second battery clip.

3 Powering the System

Removing a HeartMate Battery from a Battery Clip

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- 2 HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Hold the battery in one hand and the battery clip in the other hand.
3. Press the battery release button on the battery clip (**Figure 59**) and withdraw the battery.

Figure 59 Press Battery Release Button and Withdraw Battery



4. Repeat Steps 2 and 3 for the second battery and attached battery clip.
5. Put the batteries and battery clips in a clean, dry location for safe storage until next use. Place the batteries in the Battery Charger to recharge, if needed.

Checking a Battery's Charge Level

After a HeartMate battery is charged, (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127), it should be ready for use. However, before using the battery, check the charging pocket to make sure it has finished charging, and then use the on-battery power gauge to confirm that it is fully charged.

The on-battery power gauge on a HeartMate battery uses five green bars to indicate available battery power (**Figure 60**). Each bar represents approximately 20% of available power. When you press the power gauge button on a fully-charged battery, all five bars turn on, indicating that the battery is 80–100% charged. Fewer bars illuminate as power is low. When battery power drops below 10%, only one green blinking bar comes on.

IMPORTANT! Depending on how long a battery has been in storage, its power gauge may not work until after the battery is charged for the first time.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Battery Charger
- HeartMate 14 Volt Lithium-Ion battery


Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Locate a battery in one of the Battery Charger charging pockets.

IMPORTANT! A green light next to the Battery Charger pocket is the only assurance that a battery in the Battery Charger is 100% charged. If the yellow light is on, the battery is still charging. If the red light is on, the battery has a problem. Do not use it.

3. Look at the lights next to the charging pocket for the battery. A green light on the charger means that the battery is charged and ready for use.
4. Remove the battery from the charging pocket.
5. Find the battery symbol  on the battery's power gauge.

3 Powering the System

6. Press and hold the battery symbol for five seconds.

Figure 60 Press the Power Gauge Button to Check the Battery Charge Level



- If all five green power gauge bars illuminate, the battery power is between 80–100% charged.
- If four or fewer bars illuminate, the battery is not fully charged.
- If all of the battery power gauge bars light up except for one in the middle of the sequence, the light emitting diode (LED) for the bar may be broken or burned out. If this happens, contact your hospital contact.

Note: A battery's power gauge may show five bars illuminated, while the Battery Charger indicates a charging yellow light. This is normal. Five bars illuminated on the battery do not indicate that the battery is fully charged, but rather that it is 80–100% charged.

7. If four or fewer bars illuminate, return the battery to the pocket for more charging.
If the power gauge continues to show four or fewer bars after additional charging, the battery may be defective. Do not use it.
8. If the battery is defective, obtain a replacement battery, if needed.

Table 5 describes the on-battery power gauge on a 14 Volt Lithium-Ion battery.








Number of Bars Illuminated	Meaning
 <p>No Bars Illuminated</p>	Battery is in “sleep” mode, due to being in storage for a long period of time. Charge battery immediately.
 <p>1 Bar (blinking)</p>	Approximately 10% or less of power remains. Do not use if battery has one blinking bar.
 <p>1 Bar (steady)</p>	Approximately 10–20% of power remains.
 <p>2 Bars</p>	Approximately 20–40% of power remains.
 <p>3 Bars</p>	Approximately 40–60% of power remains.
 <p>4 Bars</p>	Approximately 60–80% of power remains.
 <p>5 Bars</p>	Approximately 80–100% of power remains.

Table 5 14 Volt Lithium-Ion Battery On-Battery Power Gauge

3 Powering the System

When to Connect to Batteries

Use HeartMate batteries for power when active or outdoors, or when electricity fails or is not available. To connect the System Controller to batteries, follow the steps below.

Connecting the System Controller to HeartMate Batteries

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 HeartMate 14 Volt battery clips
- Battery Holster or other accessory for holding or carrying in-use batteries

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Place two battery clips and two fully-charged batteries within easy reach.
3. To insert a fully-charged battery into a battery clip, line up the arrows on the battery and battery clip and then push the battery into the clip until the battery clicks into place (**Figure 61**).

Figure 61 Insert Battery into Battery Clip



Powering the System 3

4. Repeat Step 3 for the second battery and battery clip.
5. Place the black and white System Controller power cable connectors within easy reach (**Figure 62**).

Figure 62 System Controller Power Cables with Black and White Connectors



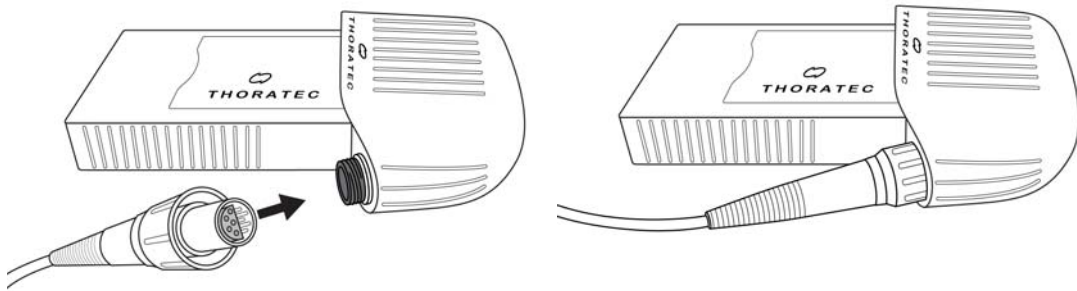
6. Unscrew and disconnect only the white System Controller power cable connector from its current power source. Do not disconnect the black connector!
- Note:** Alarm will sound.
7. Promptly align the opposite half circles inside the white System Controller power cable connector and the power cable connector for one of the battery clips (**Figure 63**).

CAUTION !

Do not try to join together misaligned connectors. This can damage them.

3 Powering the System

Figure 63 Carefully Match the Connectors



8. Firmly push together the two connectors.
 9. Tighten the connector nut until secure. Hand tighten only—do not use tools.
 10. Unscrew and disconnect only the black System Controller power cable connector from its current power source. Do not disconnect the white connector!
- Note:** Alarm will sound.
11. Promptly align the opposite half circles inside the black System Controller power cable connector and the power cable connector for one of the battery clips.

CAUTION !

Do not try to join together misaligned connectors. This can damage them.

12. Firmly push together the two connectors.
13. Tighten the connector nut until secure. Hand tighten only—do not use tools.
14. Both System Controller power cables are now connected to battery power (**Figure 64**).

Powering the System 3

Figure 64 System Controller Connected to Batteries



See *Mobile Power Unit Storage* on page 93 for information on using HeartMate 14 Volt Lithium-Ion batteries to power the system.

3 Powering the System

Low Battery Power Operation

When approximately 15 minutes of battery power are left, a yellow battery advisory will light on the System Controller and an audio beep will sound once every four seconds. This advisory indicates that the batteries should be changed. For more information, see *Low Battery Power Alarm (less than 15 minutes remain)* on page 224.

When approximately five minutes of operation remain, a red battery hazard symbol will light and a continuous audio alarm will sound. When this occurs, the system reverts to Power Saver Mode and gradually ramps down to a lower speed set by your doctor. This allows the system to operate at a reduced, but adequate, level of support to provide the maximum amount of operating time from the remaining battery capacity. Running at reduced speed is a critical situation. It may cause dizziness or shortness of breath. It is important to immediately change to a new pair of charged batteries or to the Mobile Power Unit. For more information, see *Low Battery Power Alarm (less than 5 minutes remain)* on page 221

The Left Ventricular Assist System remains in Power Saver Mode until one of the following occurs:

- Charged batteries are installed
- The Mobile Power Unit is connected
- No further power remains

The red battery hazard alarm requires an immediate response. Immediately change to a reliable alternate power source. When adequate power is supplied, the Pump reverts to the previous mode and speed, and the red battery alarm clears.

Power Saver Mode

When your batteries have less than five minutes of power remaining, the Pump automatically slows down and begins pumping at a reduced speed. This is called Power Saver Mode. When this happens, the System Controller's red battery light illuminates and a continuous audio tone sounds.

Running at reduced speed is a critical situation. It may cause dizziness or shortness of breath. It is important to immediately change power sources to either two new fully-charged batteries or the Mobile Power Unit. Changing to a different power source will stop the alarm and return the Pump to its original speed.

Note: If the alarm does not stop after replacing batteries or changing to a different power source, call your hospital contact. The System Controller or the Mobile Power Unit patient cable may need to be replaced.

Replacing Low Batteries with Fully-Charged Batteries

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- 2 low HeartMate 14 Volt Lithium-Ion batteries
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- Running System Controller

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Obtain two fully-charged HeartMate batteries and place them within easy reach. If you remove batteries from the Battery Charger, make sure that the light near the charging pocket for each battery is green, indicating that the battery is charged.
2. To confirm that the battery is fully charged, press and hold the battery symbol on each battery (**Figure 65**); make sure each battery is fully charged and ready for use.
3. Grasp the battery clip and attached battery for one of the batteries that is currently powering the system and remove the clip and battery from the holster or carrying case. Do not remove the battery from its clip at this time.
4. Locate the battery power gauge symbol (**Figure 65**) on the battery.

Figure 65 Battery Power Gauge Symbol on 14 Volt Lithium-Ion Battery



5. Press and hold the battery symbol for five seconds to see how much battery power remains for this battery (count the number of lights that come on).
6. Repeat Steps 3–5 for the second battery that is currently in use.
7. Determine which battery has the least power.

3 Powering the System

8. If both batteries have the same amount of power, replace either battery; otherwise, replace the battery that has the least power first:
 - a. Press the battery release button on the battery clip.
 - b. Withdraw the battery from its clip. The System Controller will sound a once-per-second beep, and the green power symbol and power gauge lights will flash.
9. Pick up one of the fully-charged batteries; locate the orange arrow on the battery. Make sure that you pick up a fully-charged battery rather than a low battery.
10. To insert a fully-charged battery into a battery clip, line up the arrows on the battery and battery clip, and then push the battery into the clip until the battery clicks into place (**Figure 66**).

Figure 66 Align Orange Arrows and then Insert Battery into Battery Clip



11. Pull gently on the battery to confirm that the connection is tight. If the battery is properly and fully inserted, the battery remains in the clip and the once-per-second beep stops. (It may take a few seconds for the beeping to stop.)
12. Remove the other low battery and repeat Steps 9–11.
13. Return the clips and fully-charged batteries to holsters or carrying case.
14. Make sure the Battery Charger is plugged in and turned on ("I"), and then place the low batteries in the pockets for recharging.

Maintaining Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. For complete information about caring for 14 Volt Lithium-Ion batteries and battery clips, see *Caring for HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 248.

Monitoring Battery Life

A number of factors influence battery life for a HeartMate battery. The two most important factors are the number of uses and the number of months since the battery was manufactured. The month and year of manufacture appears on every HeartMate battery label.

If a battery is stored and used according to the conditions outlined, the battery should be usable for approximately 360 cycles *OR* 36 months from the date of manufacturer, whichever comes first. After this time, battery performance cannot be guaranteed. Call your hospital contact when a HeartMate battery reaches either of these milestones.

3 Powering the System

Switching Power Sources

Changing from Mobile Power Unit Power to Batteries

Use care when connecting and disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 238.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- Working, in-use Mobile Power Unit with its batteries installed
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- Holster or Carry Accessory

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment listed above; place within easy reach.
2. To insert a fully-charged battery into a battery clip, line up the arrows on the battery and battery clip, and then push the battery into the clip until the battery clicks into place.

Figure 67 Insert Battery into Battery Clip



3. Pull gently on the battery to confirm that the connection is tight.
4. Repeat Steps 2–3 for the second battery and battery clip.

Powering the System 3

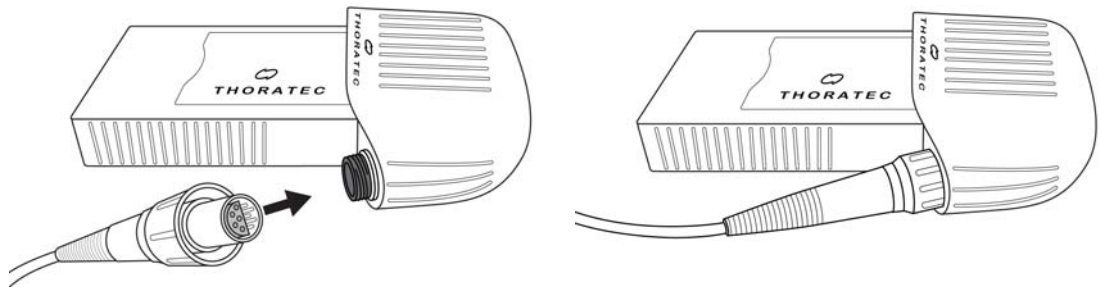
5. Place the batteries with attached battery clips within easy reach.
6. Place the black and white System Controller power cable connectors within easy reach.
7. Unscrew and disconnect only the white System Controller and white Mobile Power Unit patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
8. Promptly align the opposite half circles inside the white System Controller power cable connector and the power cable connector for one of the battery clips (**Figure 68**).

CAUTION !

Do not try to join together misaligned connectors. This can damage them.

The alarm will stop when the white System Controller power cable is connected.

Figure 68 Connect Power Cable Connector to Battery Clip Connector



9. Firmly push together the two connectors.
10. Tighten the connector nut until secure. Hand tighten only—do not use tools.

3 Powering the System

11. Unscrew and disconnect only the black System Controller and black Mobile Power Unit patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
12. Promptly align the opposite half circles inside the black System Controller power cable connector and the power cable connector for one of the battery clips.

CAUTION !

Do not try to join together misaligned connectors. This can damage them.

The alarm will stop when the black System Controller power cable is connected. Tighten the connector nut until secure.

13. Place the batteries and battery clips into a wear and carry accessory, such as battery holsters or the Consolidated Bag (see *Wearing and Carrying the System Controller* on page 159).
14. Place at least two additional fully-charged batteries in your travel case.

CAUTION !

The Mobile Power Unit patient cable should be stored so that it will not get damaged, dirty, or wet, and so it will not cause tripping or falling.

Changing from Batteries to Mobile Power Unit Power

Use care when connecting and disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 238.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller connected to battery power
- 2 HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- Mobile Power Unit power cord
- Mobile Power Unit that is ready for use (see *Setting Up the Mobile Power Unit for Use* on page 81)

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Verify that the Mobile Power Unit is plugged into an AC electrical outlet that meets **all** of the following criteria:
 - Dedicated to Mobile Power Unit use
 - Not controlled by a wall switch
 - Not connected to an adapter plug or a power strip

WARNING !

Do not use an adapter plug or a power strip with the Mobile Power Unit. Doing so may cause an electrical shock or may cause the Pump to stop.

3. Place the black and white Mobile Power Unit patient cable connectors and System Controller power cable connectors within reach.
4. Remove the battery clips and attached batteries from the holsters or carrying case.

3 Powering the System

5. Check the charge status of each battery—press the battery power gauge on each battery to determine which battery has the least power. (See *Checking a Battery's Charge Level* on page 103).
6. If one battery has less charge, start with that battery and disconnect the connector from the battery; otherwise, disconnect the white connector first.
7. Unscrew the white connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
8. Put aside the battery clip and attached battery.
9. Connect the white Mobile Power Unit patient cable connector to the white System Controller connector. The alarm will stop. Tighten the connector nut until secure.
10. Unscrew the black connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
11. Put aside the battery clip and attached battery.
12. Connect the black Mobile Power Unit patient cable connector to the black System Controller connector. The alarm will stop. Tighten the connector nut until secure.
13. Press the battery release button on one of the battery clips to release its battery.
14. Repeat Step 13 for the second battery.
15. Store the battery clips in a clean, dry location until next use.
16. Place the used batteries into the Battery Charger for charging (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).

Using the Battery Charger

WARNING !

- Before removing a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After the battery is removed from the Battery Charger, use the battery power gauge on the battery to check the battery's charge level.
- Be sure to use only equipment and supplies that are authorized by Thoratec Corporation. If unauthorized parts are used, potential interference may occur between the Battery Charger and other devices.
- Do not use the Battery Charger next to other equipment. Do not stack the Battery Charger on top of other equipment.
- The Battery Charger radiates radio frequency energy. If the Battery Charger is not used according to instructions, it may cause harmful interference with nearby devices. To confirm if interference is occurring, turn off/on the Battery Charger and observe the effect on devices in the area. If interference is detected:
 - Re-orient or move the affected devices.
 - Increase the distance between the Battery Charger and the affected devices.
 - Connect the affected devices to an electrical outlet that is different from the outlet that is used to power the Battery Charger.
- To avoid the risk of electrical shock, plug the Battery Charger into a properly tested and grounded (3-prong) AC electrical power outlet that is dedicated to Battery Charger use.
 - Do not use an outlet that is controlled by a wall switch.
 - Do not use an adapter plug for an ungrounded wall outlet.
 - Do not use portable, multiple outlet (power strip) adapters.

3 Powering the System

WARNING ! (Continued)

- Do not use the Battery Charger in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide, or an explosion could occur.
- Keep the Battery Charger dry and away from water or liquid. If the Battery Charger comes into contact with water or liquid, it may fail to operate properly or cause an electrical shock.
- Do not touch the metal contacts inside the Battery Charger when the charger is connected to AC power and turned on, or it may cause an electrical shock.

CAUTION !

- Use only the Battery Charger supplied by Thoratec Corporation to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- Make sure the Battery Charger is plugged in and turned on before placing batteries into the pockets for charging.
- Do not attempt to test or charge non-HeartMate batteries in the Battery Charger. Doing so may damage the charger or the batteries, or injure the user.
- The Battery Charger requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but is not limited to) a functional check of the device and cleaning/inspecting all internal connections. Service and maintenance of the Battery Charger should be performed only by service personnel who are trained by Thoratec Corporation.
- Before inserting a battery into the Battery Charger for charging or recharging, inspect the battery for signs of damage. Do not use a battery that appears damaged.
- Dispose of or recycle expired, used, or damaged batteries according to local, state, and federal regulations. Do not incinerate!

The Battery Charger (**Figure 69**) is designed to charge HeartMate 14 Volt Lithium-Ion batteries. Specifically, the Battery Charger can:

- Charge up to four 14 Volt Lithium-Ion batteries in four hours or less (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).
- Determine when a 14 Volt Lithium-Ion battery needs calibration.
- Calibrate a 14 Volt Lithium-Ion battery (see *Calibrating HeartMate Batteries* on page 131).
- Perform diagnostic testing on up to four HeartMate 14 Volt Lithium-Ion batteries at a time (see *Viewing Battery Information on the Battery Charger* on page 129).

Figure 69 Battery Charger



3 Powering the System

Setting Up the Battery Charger Before Use

To use the Battery Charger, you must plug it in and turn it on. The display panel on the front of the charger displays messages during setup and operation. On-screen messages can be displayed in either English or graphic symbols. Talk with your hospital contact about selecting the screen display option that is best for your needs.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Battery Charger
- AC power cord to connect the Battery Charger to an AC electrical outlet

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. If not already unpacked, carefully remove the charger from its packaging. Place the charger on a sturdy surface.
2. Inspect the charger for dents, chips, cracks, or other signs of damage. Do not use a charger that seems damaged. Contact your hospital contact for a replacement, if needed.
3. Examine the four battery charging pockets. Make sure the pockets are clean and empty (no batteries), and free of dust or debris.
4. Carefully inspect the metal contacts inside the pockets. Dirt or objects covering the metal contacts inside the pockets may prevent proper battery charging, which can affect battery performance.
5. Obtain the grey AC power cord from the product packaging.

Powering the System 3

6. Plug the female end of the power cord into the power entry module on the rear of the charger (**Figure 70**). Make sure the cord is fully inserted and secure.

Figure 70 Plug the Power Cord into the Rear of the Battery Charger



7. Plug the battery charger into a functioning AC electrical outlet that is dedicated to battery charger use.

CAUTION !

- Do not use an outlet that is controlled by a wall switch.
- Do not use an adapter plug for an ungrounded wall outlet.
- Do not use portable, multiple outlet (power strip) adapters.

8. Turn on the charger by pressing the on/off switch on the rear of the charger from the off ("O") to the on ("I") position. When the charger is turned on, all lights on the front panel turn on (**Figure 71**). The charger beeps once and performs a self test for about 10 seconds.

Figure 71 All Lights Turn On When the Charger is Turned On



3 Powering the System

9. After a successful self test, all lights turn off and "HeartMate CHARGER" appears on the display panel (**Figure 72**). The charger is ready for use.

Figure 72 The Battery Charger is Ready to Use



OR

If the charger detects a problem, an error message appears on the display panel (**Figure 73**) and/or the lights and beep are not performed as described above. If an error message appears, or the lights or beep are missing or do not perform as described, see *Battery Charger Display Panel Messages* on page 237 for information on how to respond to advisory messages.

Figure 73 An Error Message on the Battery Charger



IMPORTANT! If traveling internationally, a Thoratec Corporation power cord set is needed. This power cord set is compatible with the local voltage and meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Call your hospital contact for a power cord set, if needed.

Note: Any time the "HeartMate CHARGER" message is displayed, the display panel slowly dims, turns off for two seconds, and then resumes full brightness. This helps to prolong the life of the display. You may use the charger during this time.

Battery Charging Overview

The Battery Charger can charge up to four 14 Volt Lithium-Ion batteries at the same time. It takes up to four hours to charge from one to four batteries, depending on the charge status of the batteries. Be sure to plan battery use and charging time with the four hours in mind.

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

HeartMate 14 Volt Lithium-Ion batteries use technology that measures available battery power and counts battery usage/charge cycles. When a battery is placed in a charging pocket (**Figure 74**), the charger immediately checks the battery's status by reading the battery's built-in computer chip. To view information about the battery's available power and total number of use/charge cycles, press the button labeled with the number of the pocket containing the battery you want to check. The information is displayed on the charger display panel.

Figure 74 Batteries Inserted in Battery Charger Pockets for Charging



3 Powering the System

Depending on the status of the battery, a green, yellow, or red light is illuminated next to the pocket (**Figure 75**). A green light means the battery is charged and ready for use. A steady yellow light means the battery is actively charging. A red light means the battery or charger has a problem. See **Table 6** for a description of charger pocket light codes.

Figure 75 A Green Light Indicates that the Battery is Charged







Color	Status/Meaning
Green 	Battery is charged and ready for use.
Yellow 	Battery is undergoing charge, test, or calibration.
Yellow (Blinking) 	Battery requires calibration.
Red 	Battery or charging pocket is defective. Do not use battery.

Table 6 Description of Battery Charger Pocket Lights

Charging HeartMate 14 Volt Lithium-Ion Batteries

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Battery Charger, set up for use (see *Setting Up the Battery Charger Before Use* on page 122)
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Place a HeartMate battery into one of the four battery charging pockets, so the battery power gauge is at the top and faces forward (**Figure 76**).

Figure 76 The Battery Charger Can Charge Four Batteries at a Time



3 Powering the System

CAUTION !

Avoid covering or blocking the vents on the top of the Battery Charger during use. Covering or blocking the vents may affect Battery Charger performance.

Note: Do not force a battery into a charging pocket. A battery only fits in the pocket with the battery power gauge at the top and facing forward. When the battery is properly placed in the pocket, a beep sounds and one of the pocket lights illuminates (green, yellow, or red).

3. Identify which light (green, yellow, or red) comes on for the pocket:
 - Green light—The battery is charged and ready for use. Either remove the battery for immediate use, or leave the battery in the pocket until needed. Leaving a charged battery in the charger will not damage it.
 - Yellow light—The battery is actively charging. Leave the battery in the pocket to continue charging.

Note: The yellow light remains on until the battery becomes charged. When the battery is charged, the yellow light turns off and the green light comes on.
 - Blinking yellow light—The battery requires calibration. See *Calibrating HeartMate Batteries* on page 131.
 - Red light or no light at all—The battery or charger pocket has a problem. Remove the battery and reinsert it in the same pocket. If the same condition occurs (red light or no light), insert the battery into a different pocket. If the battery cannot be charged in a different pocket, the battery is defective. Do not use the defective battery. Contact your hospital contact for help and for a replacement, if needed. See *Battery Charger Display Panel Messages* on page 237 for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on.
4. After about four hours, check the lights for the charging pocket for the battery.
 - If the green light is on, the battery is charged and ready for use.
 - If the yellow light is on, the battery is still charging.
 - If the red light is on, the battery has a problem or the charger interrupted the charging cycle for some reason. See *Confirming a Pocket Fault* on page 235 for information on how to handle red light conditions.
5. Repeat Steps 2–4 for up to three more batteries.

Viewing Battery Information on the Battery Charger

You can use the Battery Charger to check the status of a battery. To check a battery's charge status, place the battery into a charging pocket, and then press and release the number button for that pocket. The following information appears on the charger display panel:

- Pocket number
- Battery symbol
- Percentage of available charge

For example, if approximately 50% of the battery's power is available, half of the battery symbol is filled and "50%" appears on the screen. In the example below, 90% of the battery's power is available (**Figure 77**).

Figure 77 View Battery Charge Level Information on the Battery Charger



3 Powering the System

After five seconds, the display returns to the default "HeartMate CHARGER" screen. If you press the button again—while the battery charge level still appears—the display shows the total number of use/charge cycles. The following information appears on the display panel (**Figure 78**):

- Pocket number
- Total number or uses/charges for this battery
- How much power the battery can potentially hold if fully charged (measured in mAh)

Figure 78 Press the Button a Second Time to Display Battery Charge Cycle Information



After 10 seconds, the display panel returns to the default "HeartMate CHARGER" screen.

Calibrating HeartMate Batteries

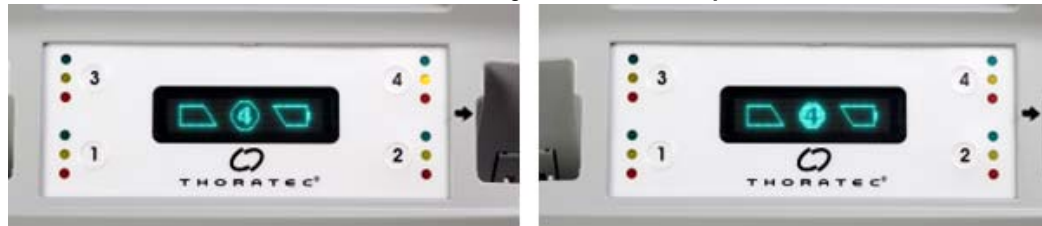
HeartMate 14 Volt Lithium-Ion batteries use technology that measures available battery power and counts battery usage/charge cycles. After approximately 70 battery uses, the battery senses that it needs to calibrate its battery power gauge. Calibration helps keep the battery power gauge accurate.

The battery must be placed in the charger to be calibrated. During calibration, the charger drains the battery of all electrical energy and then recharges it. Battery calibration can take up to 12 hours, and only one battery can be calibrated at a time. While calibrating one battery, the charger can charge three HeartMate batteries as usual.

When a battery is inserted in the charger, and the charger detects that calibration is recommended:

- The yellow light for the pocket blinks.
- A split battery symbol and the pocket number for the battery flashes on the charger display panel (**Figure 79**). The circled number switches between a filled and unfilled circle as the display panel screen flashes.

Figure 79 The Battery in Pocket 4 Needs to be Calibrated



You can calibrate a battery when prompted, or wait for a more convenient time, such as at night.

To calibrate the battery when prompted:

Within ten seconds of the start of the blinking yellow light, press and release the number button for this pocket. The charger begins calibrating the battery.

3 Powering the System

During calibration, the yellow light for this pocket remains on and "HeartMate CHARGER" appears on the display panel screen. If you press the number button for this pocket while the battery is being calibrated, the calibration status screen appears (**Figure 80**).

Figure 80 The Battery in Pocket 4 is Being Calibrated



When calibration is complete, the yellow light turns off and the green light comes on, indicating that the battery is fully charged and ready for use.

To charge the battery now (and calibrate the battery at a future time):

Do nothing when the yellow light begins blinking. After ten seconds, the charger continues with a normal charge cycle.

You can skip calibration and instead charge and reuse the battery. However, if you skip calibration, be sure to do it as soon as possible after the prompt. The Battery Charger will remind you that the battery needs calibration the next time you insert the battery into a pocket for charging.

If you choose to calibrate the battery, and then decide to cancel the calibration after the process has begun, you can cancel calibration by removing the battery from its pocket. If you remove a battery before calibration is complete, make sure to recharge and check the battery before using it. If you remove a battery before calibration ends, the battery may be low (use the on-battery power gauge to check the battery charge status).

Note: Calibrate a battery as soon as possible after being prompted to do so to ensure the best possible battery performance. Calibration can take up to 12 hours. Therefore, be sure to have enough charged batteries available before calibration begins. Under normal conditions, have four charged batteries available so that batteries can be exchanged twice during a 12-hour calibration cycle.

LIVING WITH THE HEARTMATE 3

This section provides information to help you manage daily activities with the HeartMate 3 Left Ventricular Assist Device.

- Keeping Your Home Safe - - - - - 135
- Staying Active and Safe - - - - - 136
- Hand Washing - - - - - 136
- Eating - - - - - 138
- Caring for the Driveline - - - - - 139
- Caring for the Driveline Exit Site - - - - - 142
- Showering- - - - - 144
- Wearing and Carrying the System Controller- - - - - 159
- Sleeping- - - - - 201
- Traveling - - - - - 203

4 Living with the HeartMate 3

Keeping Your Home Safe

You may need to check your home for safety and electrical readiness. Here are some items to consider checking:

- ☐ 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 tub baths while you have the pump, and showers are allowed only with your doctor's approval.
- ☐ Is the home electrically safe, with enough safe and working electric outlets? (At least one outlet must be dedicated to powering the Mobile Power Unit).
- ☐ Does the home have adequate telephones for emergency calls (for example, speed dial for emergency calling)?
- ☐ Are any occupational or physical therapy aids needed (for example, a shower chair)?
- ☐ Has the electric company been notified in writing of the need for priority power restoration during a power loss?

IMPORTANT! Get a land-line (non-portable) telephone for emergency calls (unless your hospital contact says not to). Land-lines are often less affected by interference, interruptions, or power outages.

You are responsible for keeping your home safe after returning from the hospital. If you are not comfortable testing the electrical system, you can hire an electrician to do it.

Talk with your hospital contact if you have questions or concerns about home safety.

4 Living with the HeartMate 3

Electrostatic Discharge

Electrostatic discharge (ESD) is the release of static electricity when two objects come into contact. Familiar examples of ESD include the shock received when walking across a carpet and touching a metal doorknob, and the static electricity felt after drying clothes in a clothes dryer. The presence of ESD may be increased in environments with a relative humidity less than 30%. High levels of static electricity may damage and/or interfere with the electrical parts of the system and cause the Left Ventricular Assist Device to stop.

WHAT YOU SHOULD DO:

- Avoid activities that may cause static electricity.
- Discharge any built up static electricity by touching a metal surface before handling LVAS components.

Staying Active and Safe

The HeartMate system was designed to let you stay active. Be sure to tell your doctor about any changes in activity level or routine. Because each person is different, your doctor can give the best advice for your needs. To keep safe while being active, be sure to follow the guidelines in this handbook.

Hand Washing

Why Hand Washing is Important

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

Wash your hands often, for example, every time you use the bathroom, come in from outside, after shaking hands or being in public, or anytime you touch dirty (or maybe dirty) objects. You must also wash your hands every time before and after changing the exit site bandages or any time you touch the exit site.

Proper hand washing means using soap and clean, running water. You also need to wash for at least 15 seconds to get your hands really clean. Follow the steps below for proper hand washing.

IMPORTANT! Before refilling an empty soap dispenser, wash it first.

Washing Your Hands to Lower Infection

FOR THIS TASK YOU NEED:

- Clean, dry paper towels
- Clean, running water
- Liquid soap (liquid is better than bar soap that can have microbes on it)

TASK

1. Gather supplies; place within easy reach.
2. Use a clean, dry paper towel to turn on the faucet(s) for clean, running water.
3. Wet your hands and wrists with clean, running water.
4. Apply soap to hands.
5. Rub together all parts of both hands (including wrists and backs of hands). Get under rings, around cuticles, and under fingernails. Rub hard. Friction helps remove dirt and microbes. Wash for at least 15 seconds.
6. Rinse well under a stream of clean, running water. Point fingers, hands, and wrists down so water carries away dirt and microbes.
7. Use a new paper towel to dry hands.
8. Use a paper towel to turn off the faucet. Do not touch the faucet with your clean hands.
9. Repeat steps 1–8 every single time before and after exit site bandage changes, any time you touch the exit site, or any time your hands are dirty (or could be dirty).

IMPORTANT! Before refilling an empty soap dispenser, wash it first.

4 Living with the HeartMate 3

Eating

Why Eating Well is Important

A healthy, well-balanced diet helps you heal from the operation to implant the pump. It also fuels an active lifestyle that can improve your quality of life.

Because of where the pump is located, some new pump users lose their appetite at first. This usually goes away over time. If you feel full quickly, try eating smaller meals more often. Eating more small—but healthy—meals can help you get enough calories. An easy way to get calories and nutrition is by drinking healthy, high-calorie drinks and shakes. You can make them yourself or buy them pre-made at most grocery stores and pharmacies.

Talk with your hospital contact about tips for healthy eating.

Caring for the Driveline

It is very important to protect the Driveline, especially if you are active. Always keep the Driveline protected and damage-free. Damage to the Driveline may cause the pump to stop.

WARNING !

- The Left Ventricular Assist Device stops if the Driveline is disconnected from the System Controller. If the Driveline is disconnected, reconnect it as quickly as possible to restart the Pump. If the System Controller does not work, replace with a backup System Controller.
- At least one System Controller power cable must be connected to a power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- Check the System Controller Driveline connector often to confirm that the Driveline is securely inserted in the socket. If the Driveline disconnects from the System Controller, the pump will stop.
- Never put the Driveline, System Controller, or any external equipment (such as the Mobile Power Unit, batteries, power cables, or battery clips) into water or liquid. Immersion in water or liquid may cause the pump to stop.

4 Living with the HeartMate 3

CAUTION !

- Do not twist, kink, or sharply bend the Driveline. Twists, kinks, or sharp bends can cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline could cause the pump to stop. If the driveline does become twisted, carefully turn the System Controller to unravel the Driveline, turning until the Driveline is no longer twisted.
- Avoid pulling on or moving the Driveline, especially as the skin exit site is healing. Pulling on or moving the Driveline can damage tissue at the exit site. Exit site trauma or tissue damage can increase the risk of getting a serious infection.
- To avoid pulling on or moving the Driveline at the exit site, stabilize the Driveline at all times.
- Call hospital contact if any change is observed in how the Pump works, sounds, or feels.
- Never use tools to tighten power cable connectors. Securely hand tighten only. Using tools may damage the connectors.
- Damage to electrical wires inside the Driveline can occur even if the damage is not visible. Be alert for signs of Driveline damage, including, but not limited to:
 - The System Controller alarming when the Driveline moves or when body position changes.
 - High pulsatility index (PI) readings on the System Controller.
 - Feeling pump vibrations.
 - Fluid oozing from the external portion of the Driveline.
 - Device stoppage.

Rules for Driveline Care

- Do not sharply bend or kink the Driveline (see *What Not To Do: Driveline and Cables* on page 239).
- If you carry the System Controller in a carrying case, be careful that you do not “catch” the Driveline in the zipper.
- Allow for a gentle curve for your Driveline. Do not severely bend or kink the Driveline. Do not wrap the Driveline tightly.
- Keep your Driveline clean. Wipe off any dirt or grime. If the Driveline gets dirty, use a towel with mild dish soap and warm water to gently clean it. Never submerge the Driveline or other system components in water or liquid.
- Do not pull on or move the Driveline going through the skin.
- When checking that the Controller Driveline Connector is fully inserted in the System Controller Driveline Connector, gently tug on the end of the connector. Do not pull on the Driveline.
- To avoid pulling on or moving the Driveline at the exit site, stabilize the Driveline at all times.
- Be aware of where your System Controller is at all times. It is important to protect it from falling. Dropping the Driveline can make it pull on the Driveline exit site. Report any drops of the System Controller to your hospital contact. Do this right away, even if everything seems fine.
- If the Driveline is damaged, the pump may need to be replaced. It should be replaced as soon as possible to prevent serious injury or death.
- Use care to keep the Driveline from snagging or catching on anything that can pull on or move the Driveline.
- Check the Driveline daily for signs of damage (cuts, holes, tears). Call your hospital contact right away if the Driveline is damaged (or might be damaged).

4 Living with the HeartMate 3

Caring for the Driveline Exit Site

It is very important to keep the Driveline exit site (where the Driveline goes through the skin) clean and dry at all times. Keeping the exit site clean and dry lowers your risk for infection.

Sterile technique is a set of specific practices and steps used under carefully controlled conditions with the goal of minimizing contamination by pathogens.

While you are in the hospital, nurses take care of the exit site. Before leaving, you are shown how to care for it. This includes learning “sterile technique” for dressing changes. You are also taught how to recognize signs of infection. After leaving the hospital, you are responsible for caring for the exit site. Be sure to always follow the steps provided by your nurse or hospital contact.

Manage the Driveline exit site in accordance with the procedure provided by the clinician. A driveline management system, supplied by the implanting center, should be used at all times. The driveline management system should consist of a dressing and stabilizer.

CAUTION !

- Carefully wash your hands every time before and after changing the exit site bandages or whenever the exit site is touched and handled. Proper hand washing is one of the easiest and best ways to reduce the spread of infection.
- To avoid pulling on or moving the Driveline at the exit site, the Driveline must be stabilized at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient’s risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the pump to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- Keep the Driveline exit site as clean and dry as possible.

Rules for Exit Site Care

- Refer to the Caring for the Driveline Exit Site section *Caring for the Driveline* on page 139.
- Follow strict “sterile technique” every time you change the bandage or touch the Driveline exit site.
- Wash your hands before and after every bandage change (see *Hand Washing* on page 136).
- Keep the Driveline exit site clean and dry.
- Care for your Driveline exit site as your doctor or medical professional tells you.
- Try to not pull on or move the Driveline that goes through your skin.
- Check the Driveline exit site daily for signs of infection, including:
 - Redness
 - Swelling
 - Drainage or bleeding
 - Bad smell
 - Feeling feverish, tired, or unwell

If you notice any signs of infection, call your hospital contact right away. Do not wait! Early treatment makes a difference.

4 Living with the HeartMate 3

Showering

If your doctor says it is okay for you to shower, follow these instructions each time you shower.

Keeping your Driveline Exit Site Dry

It is important to keep the Driveline exit site dry while showering. This helps prevent infection and helps extend the use of the Driveline management system. When applied correctly, covering the kit with a moisture barrier consisting of multi-purpose sealing wrap, sealed with adhesive tape on the edges, should keep moisture away.

Warnings and Precautions

WARNING !

The HeartMate 3 System Components must be kept dry. Never expose the System Controller, Batteries, Mobile Power Unit or Power Base Unit to water. If these system components get wet, your pump may stop. Never take tub baths or go swimming while implanted with the pump. The HeartMate® GoGear® Shower Bag must be used while showering to keep the System Controller and Batteries dry.

CAUTION !

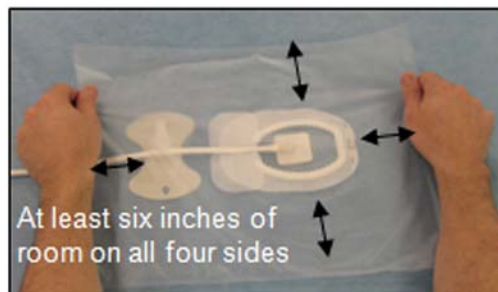
- Do not take a shower until your doctor says you can.
- Refer to the *HeartMate 3 Left Ventricular Assist System Patient Handbook* for detailed instructions and information on system function and maintenance.
- The Moisture Barrier is not a replacement for the Driveline management system. It will only be used to keep the Driveline management system dry during a shower.
- Apply the Moisture Barrier to clean dry skin. Do not use lotion or cream before applying.
- Do not lift or attempt to reposition the Moisture Barrier after it is placed.
- Once applied, the Moisture Barrier should only be used one time.

Applying the Moisture Barrier

TASK

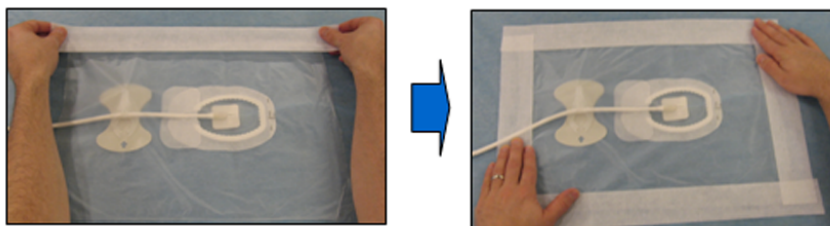
1. Make a sheet of multi-purpose sealing wrap large enough to completely cover the Driveline management system with at least six inches on all sides.
2. Center sheet of multi-purpose sealing wrap over the Driveline management system and adhere to skin (see **Figure 81**).

Figure 81 Center the Multi-Purpose Sealing Wrap Over the Driveline Management System



- a. Press the sheet of multi-purpose sealing wrap into place with your fingers so that it is smooth to the skin with no gaps.
 - b. If you have difficulties, ask your caregiver or spouse for help.
3. Seal around the edges of the sheet of multi-purpose sealing wrap with the tape (see **Figure 82**).
 - a. Apply the tape to all four edges of the sheet of multi-purpose sealing wrap so that there are no gaps.
 - b. Rub the tape into place with fingers so that it is smooth on the skin.
 - c. Check all edges and make sure the sheet is completely stuck to the skin with no gaps.

Figure 82 Seal Around the Edges of the Sheet of Multi-Purpose Sealing Wrap with the Tape



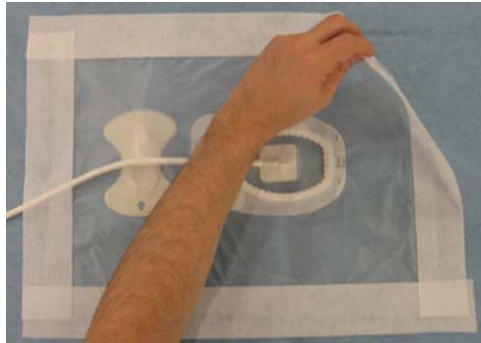
4 Living with the HeartMate 3

Removing After Showering

TASK

1. Towel dry body and the outside of the multi-purpose sealing wrap.
2. Gently peel away the multi-purpose sealing wrap and tape from the skin (see **Figure 83**).
 - a. As you remove, be careful to not disturb the Driveline management system.

Figure 83 Gently Peel Away Multi-Purpose Sealing Wrap and Tape from Skin



3. If the Driveline management system gets wet, change it as instructed in the previous sections.

Using the Shower Bag

Although the external components of the HeartMate 3 Left Ventricular Assist System are moisture-resistant, they are not waterproof. Take care to protect system components from water or moisture, whether indoors showering or outdoors in a heavy rain. If the components have contact with water or moisture, you may receive a serious electrical shock or the pump may stop.

You cannot take tub baths with the pump, but you may be able to shower after the Driveline exit site heals. Your doctor decides if you can shower. Do not shower without your doctor's approval. After you are approved for showering, you must use the Shower Bag for every shower. It protects the outside parts of the system from water and moisture (**Figure 84**).

Figure 84 Shower Bag



4 Living with the HeartMate 3

WARNING !

- Never swim or take tub baths. Immersion in water will cause the pump to stop.
- Showering may be allowed, but only after the exit site has healed and only with a doctor's permission. Do not shower without a doctor's approval.
- If approved for showers, always use the Shower Bag for every shower. Never shower without the Shower Bag.
- Never expose the System Controller or batteries to water. The System Controller must be kept dry at all times.
- Do not shower while connected to the Mobile Power Unit. Only shower while on battery power.
- Do not submerge the Shower Bag in water.

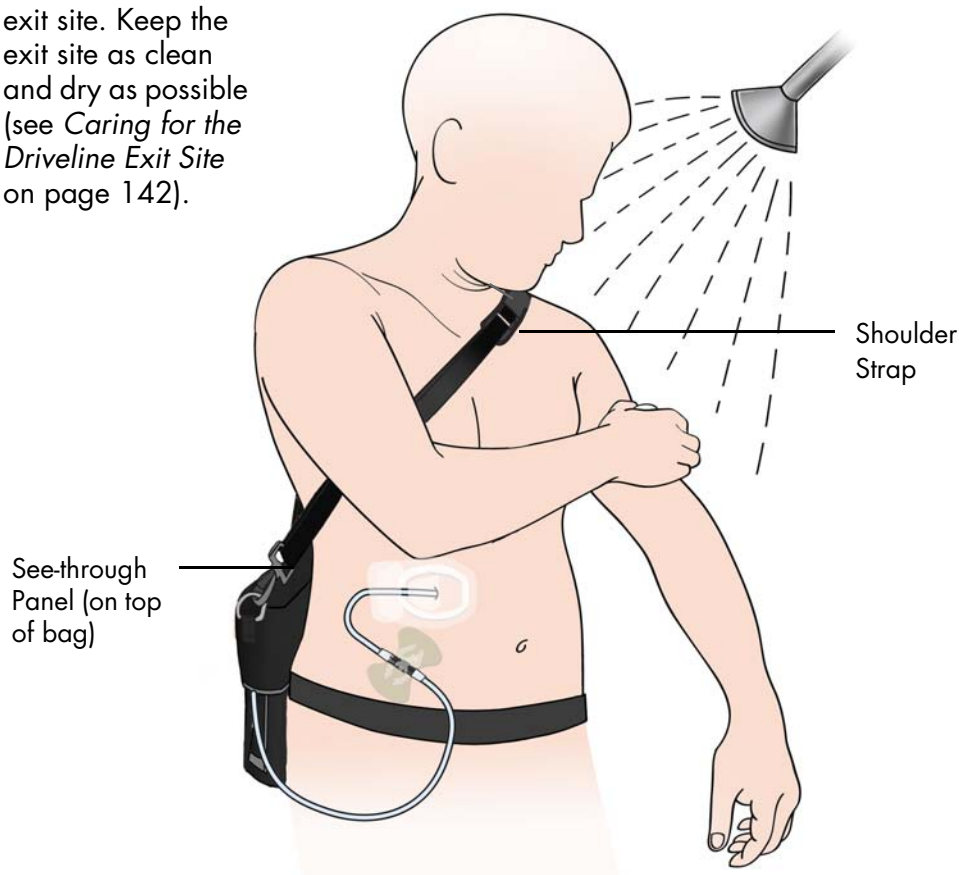
CAUTION !

- To avoid pulling on or moving the Driveline at the exit site, the Driveline must be stabilized at all times. Pulling on or moving the Driveline can keep the exit site from healing or damage an already healed exit site. Exit site trauma or tissue damage can increase the patient's risk of getting a serious infection. Emphasize to the patient and/or family member or caregiver the importance of not pulling on or moving the Driveline.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- Keep the exit site as clean and dry as possible.
- Carefully wash your hands every single time before and after changing the exit site bandages or whenever you touch or handle the exit site. Proper hand washing is one of the easiest and best ways to reduce the spread of infection.
- Do not place objects other than HeartMate 3 equipment in the wearable accessories. Placing objects other than HeartMate 3 equipment in a wearable accessory may damage the accessory.

Figure 85 Use the Shower Bag to Shower

IMPORTANT!

Illustration shows uncovered exit site. Keep the exit site as clean and dry as possible (see *Caring for the Driveline Exit Site* on page 142).



The Shower Bag (**Figure 84**) has a see-through top panel. This lets you view the System Controller's user interface while showering. The Driveline exits the Shower Bag through double zippers along the side. The Shower Bag has an adjustable shoulder strap and a waist strap. Adjust the straps as needed. The Shower Bag should be placed so that it does not pull on or move the Driveline.

Showering is safe when the Shower Bag is used properly. Your hospital contact may teach you how to use the Shower Bag before leaving the hospital. To keep safe for showers at home, be sure to follow the guidelines in this handbook, including the warnings and cautions below.

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Assembling the Shower Bag

FOR THIS TASK YOU NEED:

- 1 Shower Bag
- 1 Shower Bag shoulder strap
- 1 Shower Bag clip-style belt

TASK

1. Gather equipment; place within easy reach.
2. Clip the shoulder strap to the two rings on the top lid of the Shower Bag (**Figure 86**).

Figure 86 Attach the Shoulder Strap to the Shower Bag



3. To attach the clip-style belt to the Shower Bag, slide the belt through the loop on the side of the bag that will be against your body (**Figure 87**).

Note: The Shower Bag can be worn on your left or right side, depending on the belt loop chosen.

Figure 87 Slide the Belt Through the Loop on the Side of the Shower Bag



4. Adjust the shoulder strap and belt so that the bag fits properly. Tighten or lengthen the straps until they are secure, but still comfortable.

Putting on the Shower Bag

FOR THIS TASK YOU NEED:

- 1 assembled Shower Bag that is clean and dry
- 1 running System Controller on battery power

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Make sure that the System Controller power cables and Driveline are not twisted (**Figure 88**).

Figure 88 Make Sure the Power Cables and Driveline are Not Twisted



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3. Unclip the top cover of the Shower Bag by squeezing the clip prongs together and sliding the clip out of the buckle (**Figure 89**).

Figure 89 Open the Clip and Buckle on the Top of the Shower Bag



4. Pull back the top lid to reveal the double zipper (**Figure 90**).

Figure 90 Open the Shower Bag



5. Unzip and open the cover of the water-resistant enclosure inside.

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6. Place the batteries and battery clips with attached power cables into the Shower Bag (**Figure 91**).

Figure 91 Place Batteries and Clips in the Shower Bag



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7. Slide the System Controller into the pocket on the inside cover of the bag, cable-free end in first and the user interface facing up (**Figure 92**).

Figure 92 Slide the System Controller into the Pocket



8. Prepare to close the cover by positioning the power cables inside the water resistant enclosure (**Figure 93**).

Figure 93 Carefully Position the Power Cables in the Shower Bag



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9. Close and zip the cover. Make sure that both the System Controller's power cables are inside the bag with only the Driveline exiting through the protective red tabs (**Figure 94**).

Figure 94 Carefully Close the Shower Bag so the Driveline Exits the Bag through the Protective Red Tabs



10. Close the lid over the zippered enclosure, carefully positioning the Driveline down the side of the bag (**Figure 95**).

Figure 95 The Driveline Exiting a Closed Shower Bag



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11. Snap the clip into the buckle to secure the lid (**Figure 96**).

Figure 96 Fasten the Clip and Buckle on the Top of the Shower Bag



12. Use the Shower Bag strap to hang the bag over your head and shoulder so the bag hangs at your side. Adjust the Shower Bag so it does not pull on the exit site while showering.
13. Clip the belt around your waist and adjust to tighten. The belt secures the Shower Bag and prevents it from dropping if it slips off your shoulder. It also keeps the Shower Bag from swinging away from your body if you bend over.

During your shower, keep the Driveline exit site as clean and dry as you can.

Talk with your hospital contact for tips on keeping the exit site dry during showers.

Taking Off the Shower Bag

FOR THIS TASK YOU NEED:

- Shower Bag loaded with batteries and System Controller
- Large, clean, dry towel to dry your body
- Small, clean, dry towel to dry the Shower Bag
- 4" X 4" (10.2 cm x 10.2 cm) sterile gauze bandages to dry the exit site
- One or more sterile bandages to dress the exit site
- Wearable accessories to hold or carry the System Controller, batteries, and battery clips after showering

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Unclip the clip-style belt from your waist.
2. Carefully lift and remove the Shower Bag shoulder strap from around your neck.
3. Place the Shower Bag on a stable surface.
4. Use a clean towel to dry yourself, except the area around the Driveline exit site.
5. Use a sterile gauze bandage to dry the Driveline exit site.
6. Apply a sterile dressing to the exit site, using an sterile technique (see *Caring for the Driveline Exit Site* on page 142).
7. Use a clean, dry towel to dry the Shower Bag's exterior and strap.

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8. Open the Shower Bag using the clip and buckle for the lid, and the left and right zippers for the top (**Figure 97**).

Figure 97 Open the Clip and Buckle



9. Remove all equipment from the enclosure; place the equipment in a clean, dry location.
10. Transfer system components to a wearable accessory, such as the Holster Vest, Consolidated Bag, Belt Attachment, or Neck Strap (see *Wearing and Carrying the System Controller* on page 159).
11. Allow the Shower Bag to drip dry completely before using it again.

Caring for the Shower Bag

Always hang the bag to dry. Allow it to air dry on its own. Never use a clothes dryer or hair dryer to dry the bag. Make sure the bag is completely dry before using it again. See *Cleaning and Caring for the Equipment* on page 244 for complete instructions on caring for all wearable accessories, including the Shower Bag.

Living with the HeartMate 3 4

Wearing and Carrying the System Controller

Several wear and carry accessories are available for the HeartMate 3 system.

Figure 98 Accessories to Hold or Carry External Parts of the System



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The wear and carry accessories are described in the table below.

Wear and Carry Accessory	Use
System Controller Neck Strap	Worn around the neck or across the body; holds the System Controller when connected to the Mobile Power Unit or during battery-powered operation.
Belt Attachment	Worn around the waist, on a belt; holds the System Controller when connected to the Mobile Power Unit or during battery-powered operation.
Protection Bag	Stores and protects the backup System Controller.
Travel Bag	Worn on a shoulder. Stores the Protection Bag and a spare set of batteries.
Consolidated Bag	Worn on a shoulder or around the waist; used to carry the System Controller and 2 batteries/battery clips together in a single bag during battery-powered operation.
Battery Holster	Worn around the shoulders and under the arms; holds the System Controller and 2 batteries/battery clips during battery-powered operation. Designed to distribute equipment weight across the shoulders and back. Comes in one size, but is adjustable to fit most.
Holster Vest	Worn around the shoulders and under the arms; holds the System Controller and 2 batteries/battery clips during battery-powered operation. Designed to distribute equipment weight across the shoulders and back. Includes a chest strap and works with or without the belt attachment. Comes in 3 sizes (small, medium, and large).

Using these accessories, you can be active because the accessories comfortably and safely hold/carry the System Controller (and other equipment, at times).

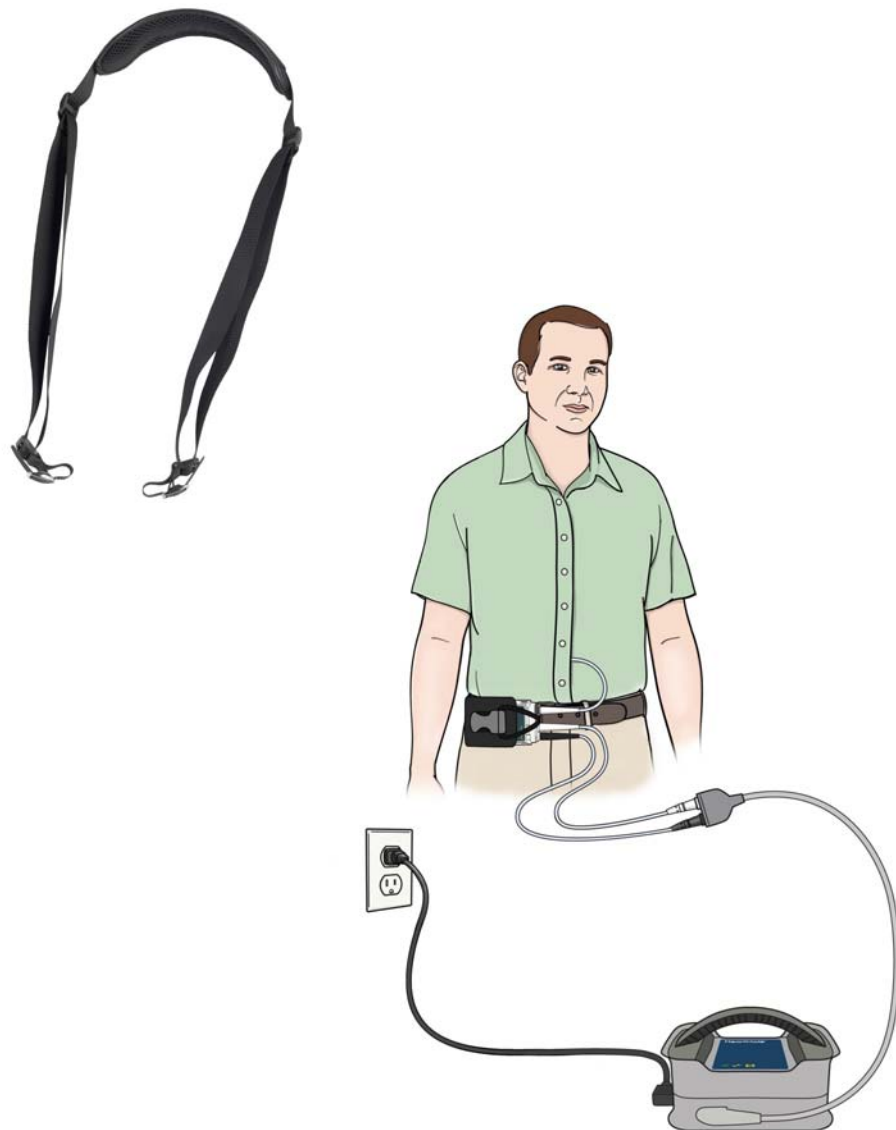
With all of the accessories, you can stand, sit, walk, crouch, bend over, reach, turn, and lean. Common activities may include (but are not limited to) exercising, traveling, playing with children, gardening, hiking, cooking, and dancing. Talk with your doctor about any changes in activity level or routine.

Different accessories provide different wear and carry options.

The System Controller Neck Strap

The System Controller Neck Strap (**Figure 99**) allows you to carry the System Controller around your neck or across your body. It attaches to the System Controller with two small straps.

Figure 99 Using the System Controller Neck Strap to Carry the System Controller



4 Living with the HeartMate 3

The System Controller has four attachment points (**Figure 100**): one in each corner of the casing. The Neck Strap uses two attachment points for hanging the System Controller vertically or horizontally (**Figure 101**).

Figure 100 Attachment Points on System Controller

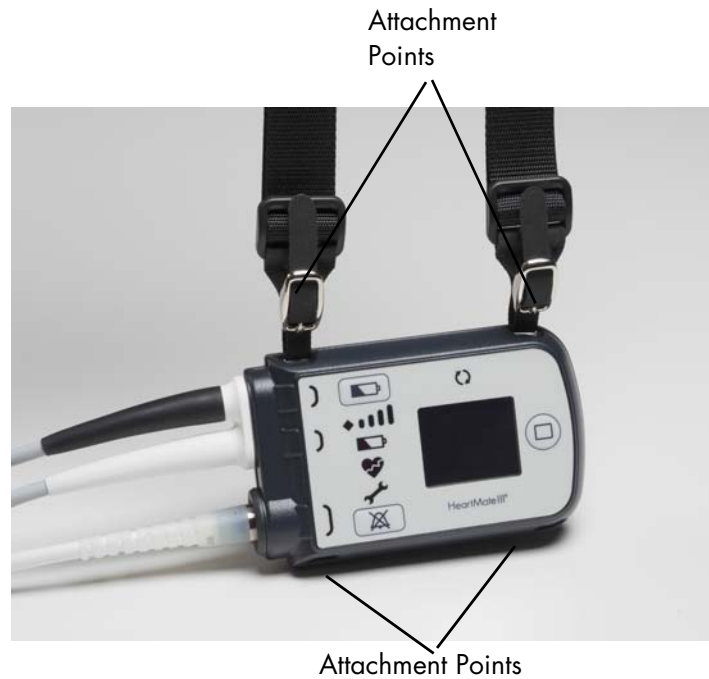


Figure 101 System Controller Suspended Horizontally (left) and Vertically (right) from Neck Strap



Putting On the System Controller Neck Strap

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller
- System Controller Neck Strap

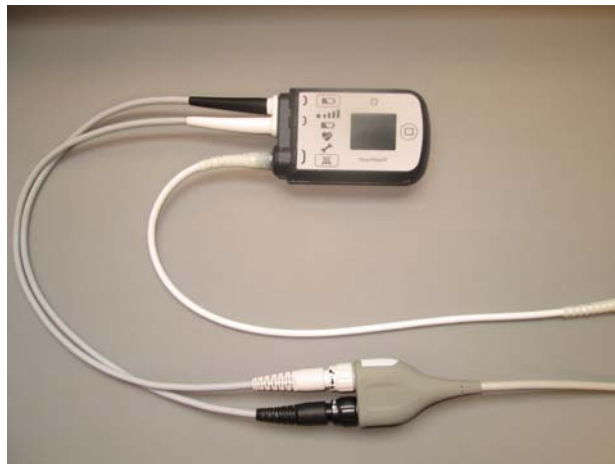
Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Place the System Controller on a flat, stable surface.
3. Make sure the System Controller power cables and Driveline are not twisted (**Figure 102**).

Figure 102 Make Sure the Power Cables and Driveline are Not Twisted



4. Choose two attachment points on the System Controller, for either vertical or horizontal wear.

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5. Slide the rubber strap on the Neck Strap through the first attachment point on the System Controller (**Figure 103**).

Figure 103 Slide Strap Through Attachment Point



6. To buckle the strap, thread the rubber strap through the metal buckle on the Neck Strap. Make sure the metal prong on the buckle goes through the strap, similar to buckling a belt (**Figure 104**).

Figure 104 Buckle the Strap



7. Hold the System Controller in one hand and give the Neck Strap a tug with the other hand. This helps to confirm that the buckle is securely connected to the System Controller (**Figure 105**).

Figure 105 Give the Neck Strap a Tug



8. Repeat Steps 5–7 to attach the second strap tab on the System Controller attachment point.
9. Put on the Neck Strap—around your neck or across your body.
10. Adjust the strap so that the cushioned band on the strap is comfortable on your body.

Taking Off the Neck Strap

TASK

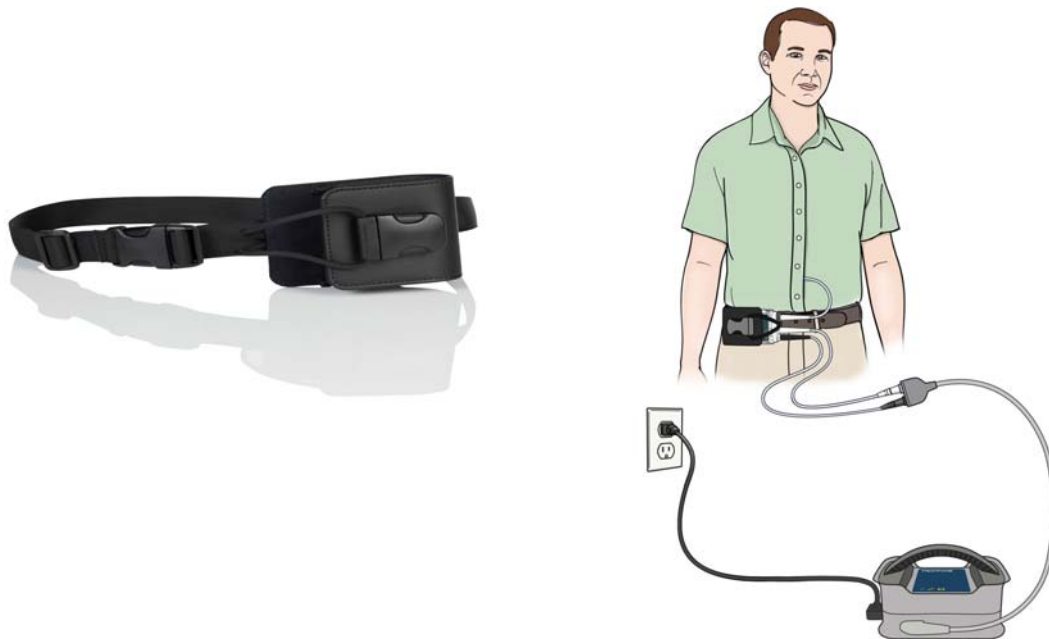
1. Carefully remove the Neck Strap and attached System Controller.
2. Place Neck Strap and System Controller on a flat, stable surface.
3. Unbuckle the Neck Strap tabs and remove lanyard from the System Controller.
4. Store the Neck Strap in a clean, dry location.

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The Belt Attachment

The belt attachment accessory (**Figure 106**) is similar to accessories that are used to wear or carry a cell phone. You can attach it to your own belt, or attach it to the provided nylon clip belt.

Figure 106 Belt Attachment



Putting on the Belt Attachment

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller on Mobile Power Unit power
- Belt attachment
- Your own belt or the nylon belt that is provided

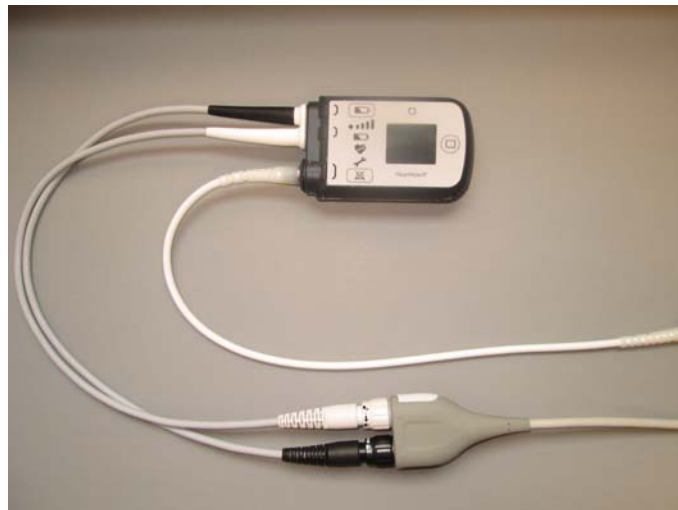
Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Make sure the System Controller power cables and Driveline are not twisted (**Figure 107**).

Figure 107 Make Sure the Power Cables and Driveline are Not Twisted



3. Slide either your belt or the nylon clip belt through the loop on the back of the belt attachment (**Figure 108**).

Figure 108 Slide the Belt Through the Loop on the Belt Attachment



4. Unclip the two-banded strap on the belt attachment.

4 Living with the HeartMate 3

5. Slide the System Controller, cable-free end first, into the belt attachment with the display screen facing out (**Figure 109**).

Figure 109 Slide the System Controller Into the Belt Attachment



6. Place the two-banded strap over the System Controller and between the white System Controller power cable connector and the Driveline connector (**Figure 110**).

Figure 110 Place the Strap Between the Connectors



7. Clip the two-banded strap into place (**Figure 111**). Make sure both prongs are fully engaged in the clip.

Figure 111 Clip the Strap Into Place so the System Controller is Secure



8. Fasten the belt and belt attachment around your waist. Adjust and tighten the belt as necessary.

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Taking Off the Belt Attachment

TASK

1. Hold the belt attachment and System Controller securely in one hand, so that the System Controller does not fall.
2. If using the nylon clip belt:
 - a. Unclip the nylon clip belt.
 - b. Remove the Belt Attachment, System Controller, and belt from around your waist.
 - c. Place the Belt Attachment and System Controller on a stable surface.

OR
3. If using your own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the Belt Attachment and System Controller on a stable surface.
4. Remove the System Controller from the Belt Attachment:
 - a. Unclip the two-banded strap from the Belt Attachment.
 - b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
5. Store the Belt Attachment in a clean, dry location.

The Consolidated Bag

Use the Consolidated Bag (**Figure 112**) to carry the System Controller, batteries, and battery clips together in a single place while using the batteries.

Figure 112 Consolidated Bag



The Consolidated Bag comes in one color (black) and two designs (for right-sided carrying or left-sided carrying). A tag on the bag tells you if it is for right- or left-sided wear.

4 Living with the HeartMate 3

The Consolidated Bag is worn across the body (see **Figure 113**) using a shoulder strap or around the waist using a waist strap. Either strap can be used alone or together. A double zipper secures the System Controller and batteries in a compartment inside the bag. The System Controller user interface is visible through a see-through panel beneath a small flap on the outside of the bag. The Driveline exits the bag through the protective red tabs on the side.

Figure 113 Wearing the Consolidated Bag



Assembling the Consolidated Bag

FOR THIS TASK YOU NEED:

- Consolidated Bag with belt
- Consolidated Bag shoulder strap

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Clip the shoulder strap to the Consolidated Bag using the two rings located on the top of the Consolidated Bag (**Figure 114**).

Figure 114 Attach the Shoulder Strap



3. Put the bag on to confirm the appropriate placement on your left or right side.
Note: The bag type (left or right) can be found on a tag inside the Consolidated Bag.
4. Adjust the shoulder strap and belt so the bag fits you properly. Tighten or lengthen the strap and belt until they are secure but still comfortable.

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Putting On the Consolidated Bag

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller on battery power
- Assembled Consolidated Bag

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Make sure the System Controller power cables and Driveline are not twisted (**Figure 115**).

Figure 115 Make Sure the Power Cables and Driveline are Not Twisted



3. Prepare the Consolidated Bag for use. Unzip the double zippers and open the bag.

4. Slide the System Controller into its holder so the user interface faces out (**Figure 116**).

Figure 116 Slide the System Controller Into the Consolidated Bag



5. Stretch the two-banded strap over the System Controller and between the white System Controller power cable and the Driveline connector. Fasten the clip to hold the System Controller in place (**Figure 117**).

Figure 117 Stretch the Strap Over the System Controller and Between the Cables



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6. Place the first battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 118**).

Figure 118 Place Battery and Attached Battery Clip into Consolidated Bag



7. Adjust the power cable so that it lays flat along the edge of the bag (**Figure 119**).

Figure 119 Carefully Position the Power Cable Around the Edge of the Bag



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8. Place the second battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 120**).

Figure 120 Insert Second Battery



9. Arrange the power cables so that they lay flat along the edge of the bag (**Figure 121**).

Figure 121 Arrange the Cables Around the Inside of the Bag



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10. Carefully close the Consolidated Bag, with the System Controller power cables inside the bag and the Driveline between the protective red tabs (**Figure 122**).

Figure 122 Close the Bag so the Driveline Exits Between the Red Tabs



11. Zip the Consolidated Bag closed (**Figure 123**).

Figure 123 Zip the Consolidated Bag Closed



12. Hold the Consolidated Bag by the handle so it does not drop.
13. To put on the Consolidated Bag, put the shoulder strap over your head and across your chest, so the bag rests against your body, on the side of your body for which it was intended. Put the waist belt around your body and clip it into place. The belt stabilizes the bag and prevents it from moving.

Taking off the Consolidated Bag

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller on battery power, stowed in the Consolidated Bag

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Unclip the belt.
2. Use the handle on the top of the Consolidated Bag to hold the bag securely so it does not drop.
3. Take off the shoulder strap—either unclip it at one side, or lift it up and over your head to take off the Consolidated Bag.
4. Place the bag in front of you on a stable surface.
5. Unzip the bag and open it.
6. Do one of the following:
 - Exchange low batteries with fully-charged batteries.
 - Transfer from battery power to Mobile Power Unit power (see *Changing from Batteries to Mobile Power Unit Power* on page 117).
 - Remove the components and transfer to another wearable accessory.
7. Store the Consolidated Bag in a clean, dry location.

4 Living with the HeartMate 3

The Protection Bag

A special bag protects and stores the backup System Controller while it is in Sleep Mode. It is called the Protection Bag (**Figure 124**).

Figure 124 Store Your Backup System Controller in the Protection Bag



The Protection Bag has a clear window for easy viewing of the System Controller and power cables inside. The bag protects the System Controller from dust, dirt, moderate water, and debris. It also provides a convenient way to carry the backup System Controller, which must remain with you at all times. The Protection Bag fits into the Travel Bag.

Do not store or carry anything in the Protection Bag, except the backup System Controller and attached power cables.

Using the Protection Bag for the Backup System Controller

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Protection Bag
- Backup System Controller with attached power cables

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Unzip the Protection Bag.
2. Slide the backup System Controller into the Protection Bag.

IMPORTANT! When placing the System Controller inside the Protection Bag, do not twist, kink, or sharply bend the System Controller power cables. This may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Pump to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

3. Carefully coil the cables around the System Controller inside the Protection Bag.
4. Zip the Protection Bag closed.
5. The backup System Controller is now stored in the Protection Bag. Keep the backup System Controller with you at all times.

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The Travel Bag

The Travel Bag provides an easy way to keep your backup System Controller and spare batteries with you at all times (see **Figure 125**).

Figure 125 Travel Bag



Storing Items in the Travel Bag

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Protection Bag with backup System Controller and power cables stored inside
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- Travel Bag

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Store the Protection Bag (with backup System Controller and cables inside) in the Travel Bag (**Figure 126**).

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Figure 126 Store the Protection Bag with Backup System Controller Inside the Travel Bag



2. Place the spare batteries inside the Travel Bag, on either side of the Protection Bag (**Figure 127**).

Figure 127 Store the Batteries Inside the Travel Bag



4 Living with the HeartMate 3

The Battery Holster

Use the Battery Holster (**Figure 128**) to hold the System Controller and two HeartMate batteries (with battery clips) during battery-powered operation. This accessory distributes equipment weight across the shoulders and back. The Battery Holster comes in one size. It is adjustable to fit most users.

Figure 128 Battery Holster



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The Belt Attachment can be used with the Battery Holster to protect and cover the System Controller (**Figure 129**).

Figure 129 Belt Attachment Used with Battery Holster



When you wear the Battery Holster, you can exchange low-charged batteries for fully-charged batteries without taking off the holster. See *Exchanging Low-Power Batteries with Two Fully-Charged Batteries* on page 189.

4 Living with the HeartMate 3

Assembling the Battery Holster

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Battery Holster
- Pair of large, sharp scissors
- Small tube of strong epoxy glue

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Place the Battery Holster in front of you on a flat surface, arranged so the fabric connecting the two straps is in the center.
3. Slide your arms through the straps, so that the fabric connector is between your shoulder blades on your back.
4. Pull the loose ends of the strap to adjust the fit. The holsters should fit securely but comfortably against your sides and under your arms.
5. After determining appropriate fit, cut off or trim the extra length from the end of each strap.
6. Apply a strong epoxy glue to the cut off ends of each strap to reduce fraying. Allow the glue to dry before wearing the holster.

Note: The straps can also be stitched together through the fabric to prevent the fabric connector from moving and changing the fit.

Putting On the Battery Holster

FOR THIS TASK YOU NEED:

- Running System Controller connected on Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- Battery Holster
- Belt Attachment
- Clip-style belt or your own belt

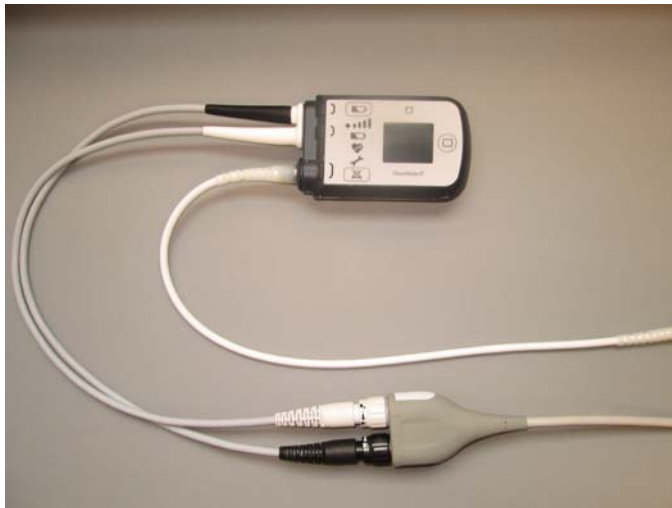
Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Make sure that the System Controller power cables and Driveline are not twisted (**Figure 130**).

Figure 130 Make Sure the Power Cables and Driveline are Not Twisted



4 Living with the HeartMate 3

3. Insert the batteries and attached battery clips into each holster:
 - a. Open each VELCRO® flap (**Figure 131**, left).
 - b. Insert each battery/battery clip into a holster, so the clips point up and the batteries point down (**Figure 131**, right).

Figure 131 Open VELCRO Flap and Insert Battery with Attached Battery Clip



4. Close each Battery Holster flap after the battery/battery clip is inside the holster (**Figure 132**).

Figure 132 Close VELCRO Flap to Secure Battery/Battery Clip Inside



5. Put on the Battery Holster with the inserted batteries/battery clips.
6. Put on and secure the Belt Attachment around your waist. Adjust and tighten the belt as needed (see *Putting on the Belt Attachment* on page 166).
7. Slide the System Controller into the Belt Attachment.
8. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller and between the white System Controller power cable connector and the Driveline connector.
9. Slide the clip ends of the two-banded strap into the clip socket. The clip will click into place when securely fastened.
10. Transfer from the Mobile Power Unit to battery power (see *Changing from Mobile Power Unit Power to Batteries* on page 114).

Exchanging Low-Power Batteries with Two Fully-Charged Batteries

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- To be wearing a battery holster with running System Controller on battery power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

4 Living with the HeartMate 3

TASK

1. Gather equipment; place within easy reach.
2. Exchange each battery, one at a time:
 - a. Open one flap on a Battery Holster.
 - b. Remove the battery/battery clip from the Battery Holster.
 - c. Hold the battery while pressing the battery release button on the battery clip.
 - d. Withdraw the low battery from its battery clip and put aside the low battery. Remove only one battery from its clip at this time. A power cable disconnected advisory will sound. This is normal.
 - e. Retrieve one of the fully-charged batteries and insert it into the battery clip. It will click into place when fully inserted. The alarm stops when the fully-charged battery is properly inserted.
 - f. Place the fully-charged battery/attached battery clip into the empty Battery Holster.
 - g. Close the Battery Holster flap.
 - h. Repeat Steps a–g for the second low battery.
3. Recharge the low batteries in the Battery Charger (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).

Taking Off the Battery Holster

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- To be wearing a Battery Holster with running System Controller on battery power
- Mobile Power Unit

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Switch from battery power to the Mobile Power Unit (see *Changing from Batteries to Mobile Power Unit Power* on page 117). Do this before taking off the holster.
2. Take off the Battery Holster with batteries.
3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
4. If using the nylon clip belt:
 - a. Unclip the nylon clip belt.
 - b. Remove the Belt Attachment, System Controller, and belt from around your waist.
 - c. Place the Belt Attachment and System Controller on a stable surface.**OR**
5. If using your own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the Belt Attachment and System Controller on a stable surface.
6. Remove the System Controller from the Belt Attachment:
 - a. Unclip the two-banded strap from the Belt Attachment.
 - b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
7. Remove the batteries and attached battery clips from the holster and place them on a stable surface.
8. Recharge the low-charged batteries (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).
9. Store the holster in a clean, dry location (see *Caring for the Equipment* on page 243).

4 Living with the HeartMate 3

The Holster Vest

Use the Holster Vest to hold the System Controller and two HeartMate batteries (with battery clips) during battery-powered operation (**Figure 133**).

Figure 133 The Holster Vest



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This accessory distributes equipment weight across the shoulders and back. A chest strap is also available. Use it to add extra support. The Belt Attachment can be used with the Holster Vest to protect and cover the System Controller (**Figure 134**).

Figure 134 Holster Vest with Belt Attachment and Shoulder Strap



The Holster Vest is available in three sizes: small, medium, and large.

When you wear the Holster Vest, you can exchange low-charged batteries for fully-charged batteries without taking off the vest. See *Exchanging Batteries While Wearing the Holster Vest* on page 198.

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Assembling the Holster Vest

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Holster Vest with Belt Attachment

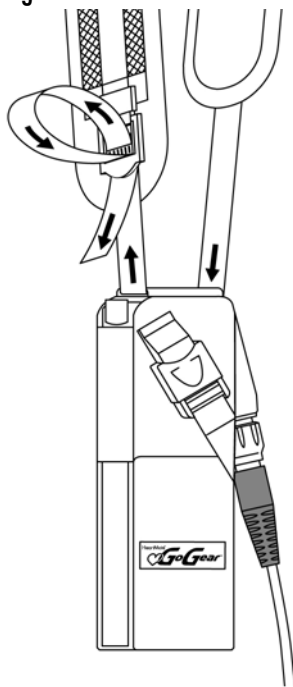
Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Insert one vest strap through the slot in the top of one of the holsters. The buckle should be pointing down and the holster should face forward when you wear the vest (**Figure 135**).

Figure 135 Insert the Vest Strap Through the Slot in the Top of the Holster



3. Repeat Step 2 for the second holster.

Putting On the Holster Vest

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller on Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- Assembled Holster Vest with Belt Attachment

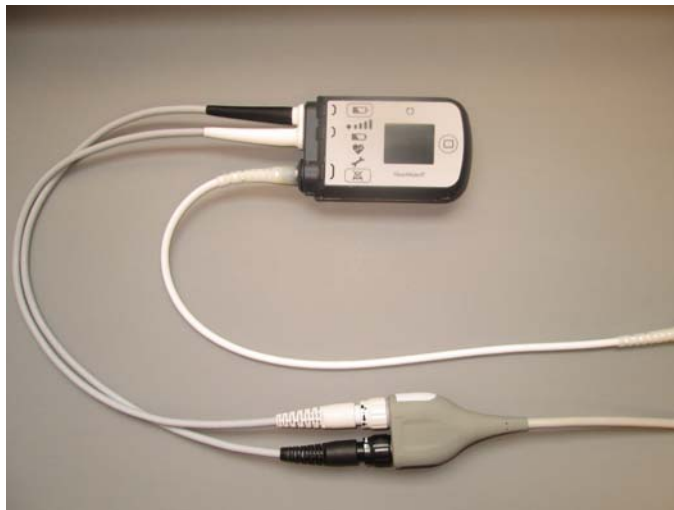
Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Gather equipment; place within easy reach.
2. Make sure that the System Controller power cables and Driveline are not twisted (**Figure 136**).

Figure 136 Make Sure the Power Cables and Driveline are Not Twisted



4 Living with the HeartMate 3

3. Place the batteries and attached battery clips into the holsters:
 - a. Insert one battery and attached battery clip into the holster, with the battery pointing down and the battery clip pointing up (**Figure 137**).

Figure 137 Insert Battery and Battery Clip Into Holster



- b. Buckle the clip on the holster (**Figure 138**).

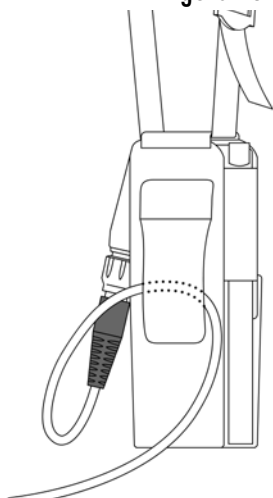
Figure 138 Buckle the Clip on the Holster



- c. Repeat Steps a–b for the second battery and battery clip.
4. Put on the Holster Vest with the attached batteries/battery clips.
5. Adjust and tighten the straps as needed.
6. If the chest strap is used, position it higher or lower on the vest as needed, so it is secure and comfortable.

7. Put on and secure the belt attachment around your waist. Adjust and tighten the belt as needed.
8. Slide the System Controller into the Belt Attachment.
9. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller and between the white System Controller power cable connector and the Driveline connector.
10. Slide the clip ends of the two-banded strap in to the clip socket. The clip will click into place when securely fastened.
11. Transfer from the Mobile Power Unit to battery power (see *Changing from Mobile Power Unit Power to Batteries* on page 114).
12. Use the VELCRO tabs on the back of the holsters to hold the power cables in place and to stabilize the holsters (**Figure 139**).

Figure 139 Use VELCRO Tabs to Hold the Power Cables



13. Put the belt through the VELCRO tabs to help secure the holsters in place.

4 Living with the HeartMate 3

Exchanging Batteries While Wearing the Holster Vest

The Holster Vest allows you to exchange low-power batteries with two new, fully-charged batteries, without taking off the Holster Vest or disrupting the power cables.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- Running System Controller connected to two in-use HeartMate batteries during battery-powered operation
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- Holster Vest

Remember !

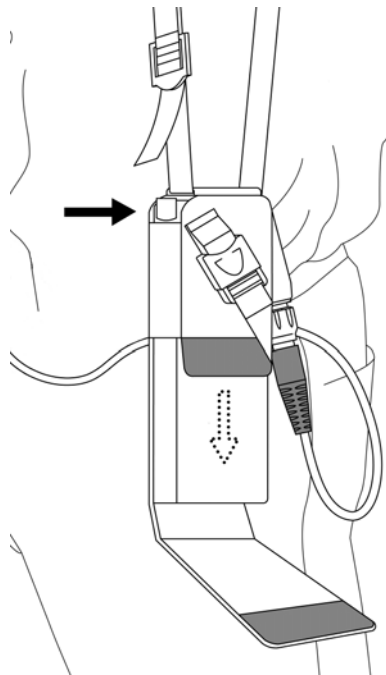
Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Obtain two fully-charged HeartMate batteries; place them within easy reach.

2. Exchange the first low-power battery (**Figure 140**):
 - a. Open the flap on one of the holsters to access one of the batteries and its attached battery clip.
 - b. Hold the battery while pressing the battery release button on the battery clip.
 - c. Withdraw the low battery from its battery clip and put aside the lower battery. Remove only this battery at this time. A Power Cable Disconnected advisory will sound. This is normal.
 - d. Retrieve one of the fully-charged batteries and insert it into the battery clip. It will click into place when fully inserted. The alarm stops when the fully-charged battery is properly inserted.
 - e. Close the flap on the holster.

Figure 140 Exchanging a Battery



- f. Repeat Steps a–e to exchange the second low battery.
3. Recharge the low-power batteries (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).

4 Living with the HeartMate 3

Taking Off the Holster Vest

TASK

1. Switch from battery power to the Mobile Power Unit (see *Changing from Batteries to Mobile Power Unit Power* on page 117). Do this before taking off the Holster Vest.
 2. Take off the Holster Vest with batteries.
 3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
 4. If using the nylon clip belt:
 - a. Unclip the nylon clip belt.
 - b. Remove the Belt Attachment, System Controller, and belt from around your waist.
 - c. Place the Belt Attachment and System Controller on a stable surface.
- OR**
5. If using your own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the Belt Attachment and System Controller on a stable surface.
 6. Remove the System Controller from the Belt Attachment:
 - a. Unclip the two-banded strap from the Belt Attachment.
 - b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
 7. Remove the batteries and attached battery clips from the Holster Vest and place the items on a stable surface.
 8. Recharge the low-charged batteries (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 127).
 9. Store the holster vest in a clean, dry place (*Cleaning and Caring for the Equipment* on page 244).

Sleeping

Pre-Sleep Safety Check

Sleep safety means adding a few extra steps to your routine. For example, before going to sleep, check all electrical and system connections to make sure they are tight. See the pre-sleep checklist.

PRE-SLEEP CHECKLIST

- ☐ **Connect to Mobile Power Unit power before going to sleep or any time you might fall asleep.**
- ☐ Make sure the Driveline is stabilized.
- ☐ Check all electrical and system connections to make sure they are tight. Check:
 - ☐ Between System Controller and power cables
 - ☐ Between power cables and Mobile Power Unit patient cable
 - ☐ Between Mobile Power Unit and electrical outlet
- ☐ Check that the bedside flashlight has working batteries.
- ☐ Place backup equipment nearby:
 - ☐ Backup System Controller
 - ☐ Fully-charged HeartMate batteries (already in their clips)
- ☐ Make sure your emergency contact list is nearby.
- ☐ Inspect the Driveline Cable for signs of damage, such as cracking, fraying, wear, exposed wires, sharp bends or kinks.
- ☐ Inspect that the Modular In-line Connector is fully connected and the locking nut is in the fully locked position. Also inspect the Modular In-Line Connector for signs of damage, such as cracking, fraying, wear, exposed wires, sharp bends, or kinks.
- ☐ Inspect all cables for signs of damage.

4 Living with the HeartMate 3

Connect to the Mobile Power Unit

You must always connect to the Mobile Power Unit when sleeping (or when sleep is likely). This is very important! If you fall asleep on battery power, you might not hear low power alarms. The batteries could run out of power, and the pump could stop before you hear the alarms.

Safe Positions

Try to sleep so that you do not bend, pull on, or move the Driveline. Do not sleep on your stomach. Arrange clothes, sheets, and blankets so they do not pull on or get tangled in the Driveline. Stabilize the Driveline at all times, including during sleep.

Equipment to Keep Nearby

Keep a flashlight (with well-charged batteries) nearby, along with your emergency contact list. All backup equipment should also be nearby when sleeping, including the backup System Controller and fully-charged batteries (already in their clips). This way, in an emergency, everything you need is nearby.

Traveling

Being able to travel freely is a big part of everyone's quality of life. If you want to enjoy the freedom of travel, it takes some extra planning to do it safely.

Talk with your hospital contact about any travel plans, especially if you will travel long distances (such as by aircraft).

You need a travel plan and emergency action plan for long-distance trips. Your hospital contact can help create them. Your hospital contact will also talk with you about travel safety rules for equipment, like the Mobile Power Unit and its backup battery.

CAUTION !

For international travel, use a Thoratec Corporation power cord that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications for both the Mobile Power Unit and Battery Charger. Other power cords must not be used. Contact your hospital contact for a power cord, if needed.

4 Living with the HeartMate 3

Always follow these important guidelines for local and long-distance travel:

- Be sure to bring everything you need for battery-powered and electrical-powered operation at your final destination, including:
 - Battery Charger and power cord
 - Spare batteries
 - Battery clips
 - Mobile Power Unit
 - Mobile Power Unit patient cable
 - Mobile Power Unit power cord for connecting to AC power
 - Backup System Controller
- Never leave or store batteries in extremely hot or cold places (such as the trunk of your automobile), or battery life will be shortened.
- Never carry or store batteries in temperatures below -10°C (14°F) or above 40°C (104°F) or they may fail suddenly.
- Never use batteries in temperatures below 0°C (32°F) or above 40°C (104°F) or they may fail suddenly.

Automobile Travel

Automobile airbags deploy with great force. If an airbag hits your abdomen or chest, the force could cause serious damage or bleeding. For this reason, avoid riding in the front seat of cars with airbags (also known as supplemental restraint systems, or "SRS" for short).

Your doctor decides if you can drive an automobile while implanted with the pump. Some states have laws against letting patients drive if they have a history of fainting, dizziness, or cardiac arrest. Usually, you need to wait at least 6–8 weeks after surgery before being considered for driving privileges.

4 Living with the HeartMate 3

ALARMS AND TROUBLESHOOTING

This section describes the primary alarms and troubleshooting of the HeartMate 3 Left Ventricular Assist System.

System Controller Alarms - - - - -	209
Mobile Power Unit Alarms - - - - -	231
Battery Charger Alarms - - - - -	233
Guidelines for Power Cable Connectors - - - - -	238
What Not To Do: Driveline and Cables- - - - -	239

5 Alarms and Troubleshooting

System Controller Alarms

Alarms that You Can Handle

Many System Controller alarms are easy to resolve. You can expect to troubleshoot common alarms after you are trained by your hospital contact. Driveline Disconnected and Power Cable Disconnected alarms are examples of alarms that are resolvable by users, caregivers, and family members. In most cases, these alarms are handled by following simple on-screen instructions. **Table 7** shows how to access the alarm history screens.

Alarms for Clinicians to Handle

Other alarms need special help. For most of these cases, “Call Hospital Contact” appears on the screen. Besides the on-screen message, you will learn from your hospital contact when to call for help. Depending on the hospital and situation, you may be told to replace the System Controller (see *Replacing the Running System Controller with a Backup Controller* on page 63) or be admitted to the hospital for testing and care.

Handling System Controller Alarms

System Controller alarms are described on the following pages. Each section gives the likely cause and typical steps for resolving the alarm. Alarms are listed in order of priority. Hazard alarms are listed first, followed by Advisories. See **Table 8** and **Table 9** on the following pages for a complete list of prioritized System Controller alarms.

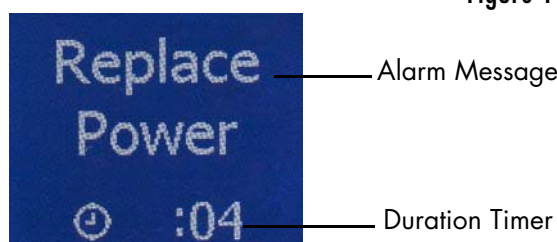
IMPORTANT! System Controller alarms cannot be silenced when the System Controller is in power saver mode.

5 Alarms and Troubleshooting

Alarm Screen Overview

When an alarm occurs, messages appear on the System Controller's user interface screen to help resolve the problem. These screen messages indicate the alarm type as well as how long the alarm has been occurring. The timer on the screen counts up in seconds, indicating how long the alarm has been occurring. **Figure 141** shows the alarm screen layout. On-screen messages come in many different languages. Talk with your hospital contact about selecting the language that is best for your needs.

Figure 141 Alarm Screen



Viewing Alarm History on the User Interface Screen

You can view alarm history on the System Controller user interface. The last six relevant System Controller alarms are displayed. Only a subset of alarms is displayed on the System Controller - alarms that are transient, have clinical value, or that do not interfere with access to more critical alarms. Examples of alarms that are displayed include:

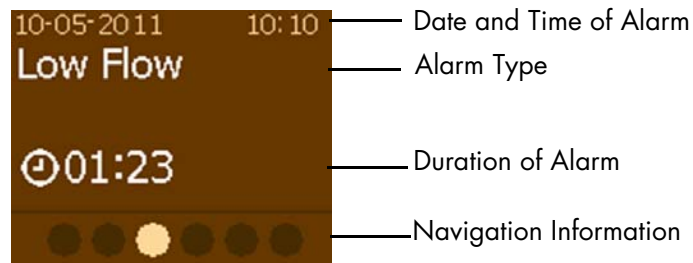
- Power Cable Disconnected alarm (lasting over 30 seconds)
- External Power Disconnected alarm
- Driveline Disconnected alarm
- Low Battery Power Advisory alarm
- Low Battery Power Hazard alarm
- Low Flow alarm

Alarms and Troubleshooting 5

To view the six most recent alarms on the user interface screen, simultaneously press and release the silence alarm (⌫) and display (⏏) buttons. Up to six of the most recent alarms are displayed. The most recent alarm appears first. To view the next alarm, press and release the display (⏏) button. Each push of the display button brings up a new screen. After the sixth alarm is displayed, the next button push returns you to the first alarm screen.

Alarm history screens show the date and time of the alarm occurrence at the top of the screen. A dot at the bottom of each screen provides navigational information about which screen is in view (see **Figure 142**).

Figure 142 Sample Alarm History Screen



5 Alarms and Troubleshooting

Table 7 shows how to access the alarm history screens.




















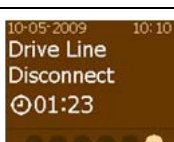
Button Press	Description	Alarm Screen Displayed (Example)
Press   AND  	Press display button and silence alarm button at the same time to access the first alarm.	
Press  	Press display button ONCE to display the second alarm.	
Press  	Press display button a SECOND time to display the third alarm.	
Press  	Press display button a THIRD time to display the fourth alarm.	
Press  	Press display button a FOURTH time to display the fifth alarm.	
Press  	Press display button a FIFTH time to display the sixth alarm.	

Table 7 Viewing Alarm History Screens

Alarms and Troubleshooting 5

If the System Controller detects an alarm condition while displaying alarm history, the screen immediately transitions to the real-time alarm screen. However, you can still access the alarm history screens during an active alarm by simultaneously pressing the silence alarm (ⓧ) and display (Ⓚ) buttons. To exit from the alarm history feature, simultaneously press the two buttons again.

Alarms that Do Not Display on the Controller Alarm History Screen

The Driveline Power fault, Driveline Communication fault (Driveline Comm Fault), Communication fault (Comm fault), Backup Battery fault, and Replace Controller fault are examples of non-transient alarms that require specific user action to resolve the alarm condition. These alarms remain on the user interface screen until the alarm condition is resolved or permanently disabled by a clinician, and therefore do not appear in alarm history.

In addition, a Power Cable Disconnected advisory (that lasts less than 30 seconds) and Pulsatility Index (PI) events are examples of routine events that might interfere with access to more critical information. For this reason, these events also do not appear in alarm history.

When the audio alarms are silenced, an alarm silence indicator displays (see **Figure 143**) on the LCD screen on the System Controller.

Figure 143 Alarm Silence Indicator



IMPORTANT! The green Pump Running (⦿) light is always on when the pump is running

5 Alarms and Troubleshooting













Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
H A Z A R D	Call Hospital Contact Ⓢ23:01 +		Pump is off. The Pump is Running symbol is black.	<ol style="list-style-type: none"> 1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). 2. If connecting to power does not resolve the problem, press any button on the System Controller to attempt pump start and call your hospital contact immediately. For more information, see page 217.
	Low Flow Ⓢ23:02			
	Call Hospital Contact Ⓢ23:01 +		Low flow, flow is less than 2.5 lpm	Call your hospital contact immediately for diagnosis and instructions. For more information, see page 218.
	Low Flow Ⓢ23:02			
	Connect Driveline Ⓢ :01	  	Driveline is disconnected. The Pump Running symbol is black.	<ol style="list-style-type: none"> 1. Immediately reconnect the Driveline to the System Controller and move the Driveline Safety Lock on the System Controller to the locked position. Also, check that the Modular In-Line connector is secure. 2. If alarm persists after reconnecting the Driveline, press any button on the System Controller to potentially resolve. 3. If Driveline is connected and alarm persists, replace System Controller with a configured backup System Controller. See page 63. 4. If alarm persists, call your hospital contact immediately. For more information, see page 219.
	Connect Power Immediately Ⓢ 3:01 +		Both power cables are disconnected.	<ol style="list-style-type: none"> 1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. For more information, see page 220.
	Backup Battery Ⓢ23:01			
	Call Hospital Contact Controller Fault	 	System Controller Hardware Fault (Microcontroller Failure)	<ol style="list-style-type: none"> 1. No active symbols (constant audio tone). 2. Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 222.
	Low Battery Ⓢ23:01 +		Low Battery, Power input is extremely low with less than 5 min. remaining.	<ol style="list-style-type: none"> 1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. For more information, see page 221.
	Replace Power Immediately Ⓢ23:02			

Table 8 System Controller Hazard Alarms







Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
A D V I S O R Y	Connect Power ⌚ 23:01	 OR 	One of the two power cables is disconnected.	1. Promptly connect the disconnected power cable to power source (functioning Mobile Power Unit or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. For more information, see page 223.
	Replace Power ⌚ :02 + Low Battery ⌚ :06		Low Battery, Power input is low with less than 15 min. remaining.	1. Promptly connect to a working or different power source (Mobile Power Unit or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. For more information, see page 224.
	Call Hospital Contact Controller Fault		System Controller Hardware Fault	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 225.
	Call Hospital Contact Comm Fault		Communication Fault (Comm Fault)	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 226.
	Call Hospital Contact Backup Battery Fault		System Controller Backup Battery Fault	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 227.

Table 9 System Controller Advisory Alarms

5 Alarms and Troubleshooting



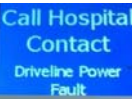



Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
A D V I S O R Y			System Controller Backup Battery Not Installed	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 228.
			Driveline Power Fault	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 229.
			Driveline Communication Fault (Driveline Comm Fault)	Call your hospital contact as soon as possible for diagnosis and instructions. For more information, see page 230.

Table 10 System Controller Advisory Alarms continued

IMPORTANT! The Pump Running () light is always green on when the pump is running.

Pump Off Alarm

This is a Hazard alarm

The screens look like this:

(alternating screens)



Behavior and appearance:

- Flashing Red Heart (❤) on the user interface.
- The “Pump Running” symbol (⌚) is black.
- The Driveline is connected.
- “Low Flow” and “Call Hospital Contact” alternate on the screen.
- Alarm tone: Constant tone.

Alarm means:

Pump has stopped running, possibly because power has been disconnected or failed.

To resolve alarm:

1. Connect to a working power source (Mobile Power Unit or two HeartMate batteries) right away.
2. If connecting to power does not resolve, press any button on the System Controller to attempt pump start and call your hospital contact immediately. It may take up to 10 seconds for the pump to restart.

Alarm silence period:

- 2 minutes or until a new hazard alarm occurs.
- To silence this alarm, press the silence alarm button.

Table 11 Pump Off Alarm

5 Alarms and Troubleshooting

Low Flow Alarm

This is a Hazard alarm

The screens look like this:

(alternating screens)




Behavior and appearance:	<ul style="list-style-type: none">• Flashing Red Heart () on the user interface.• "Call Hospital Contact" and "Low Flow" alternate on the screen.• Alarm tone: Constant tone.
	Alarm means: Pump flow is less than 2.5 lpm.
	To resolve alarm: Call your hospital contact immediately for diagnosis and instructions.
Alarm silence period:	<ul style="list-style-type: none">• 2 minutes or until a new hazard alarm occurs.• To silence this alarm, press the silence alarm button.

Table 12 Low Flow Alarm

Driveline Disconnected Alarm

This is a Hazard alarm

The screen looks like this:



Behavior and appearance:	<ul style="list-style-type: none"> • Flashing Red Heart (❤) on the user interface. • Green “Pump Running” symbol (↻) is black. • Flashing red light near Driveline connector. • “Connect Driveline” flashes on the screen. • Alarm tone: Constant tone.
Alarm means:	The Driveline is disconnected from the System Controller.
To resolve alarm:	<ol style="list-style-type: none"> 1. Immediately reconnect the Driveline to the System Controller and move the Driveline Safety Lock on the System Controller to the locked position. (See page 33.) It may take up to 10 seconds for the pump to start. 2. Check that the Modular In-Line connector is secure. 3. If alarm persists after reconnecting the Driveline, press any button on the System Controller to potentially resolve. 4. If Driveline is connected and alarm persists, replace the System Controller with a programmed backup System Controller. See page 63. 5. Immediately call hospital contact if Steps 1–3 do not resolve the alarm.
Alarm silence period:	<ul style="list-style-type: none"> • 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button. <p>Note: In some cases, you may have to push the silence alarm button twice to silence this alarm. This is normal.</p>

Table 13 Driveline Disconnected Alarm

5 Alarms and Troubleshooting

No External Power Alarm


This is a Hazard alarm

The screens look like this:

(alternating screens)



Behavior and appearance:

- Flashing Red Battery () on the user interface.
- "Connect Power Immediately" and Backup Battery graphic alternate on the screen.
- Yellow light near the black power cable connector is flashing.
- Yellow light near the white power cable connector is flashing.
- Alarm tone: Constant tone.

Alarm means:

AND

1. The System Controller is not receiving power from either power cable.
2. The pump is being powered by the System Controller's 11 Volt Lithium-Ion backup battery.

To resolve alarm:

1. Immediately connect the System Controller power cables to a working power source (functioning Mobile Power Unit or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
2. Call your hospital contact immediately if connecting to power does not resolve the alarm.

Alarm silence period:


- 2 minutes or until a new hazard alarm occurs.
- To silence this alarm, press the silence alarm button().

Table 14 No External Power Alarm

The 11 Volt Lithium-Ion backup battery inside the System Controller provides power to the pump for at least 15 minutes when fully charged if the main power source is disconnected or fails.

IMPORTANT! If external power is not restored, the system enters power saver mode. The pump gradually slows to the low speed limit to save power in an effort to prevent the pump from stopping. When adequate power is supplied, the pump reverts to the previous speed and the red battery alarm clears.

Alarms and Troubleshooting 5

Low Battery Power Alarm (less than 5 minutes remain)


This is a Hazard alarm

The screens look like this:

(alternating screens)



Behavior and appearance:

- Flashing Red Battery () on the user interface.
- “Low Battery” and “Replace Power Immediately” alternate on the screen.
- Alarm tone: Constant tone.
- The pump will enter Power Save Mode.

Alarm means:

OR

1. Low Battery Hazard - there is less than 5 minutes of battery power remaining (when using battery power).
2. The System Controller is receiving inadequate power from the Mobile Power Unit.

To resolve alarm:

1. Connect to a working power source (Mobile Power Unit or two HeartMate batteries) right away. See *Connecting the System Controller to the Mobile Power Unit* on page 90
2. Call your hospital contact right away if connecting to power does not resolve the alarm.

Alarm silence period:


- 2 minutes or until a new hazard alarm occurs.
- To silence this alarm, press the silence alarm button().

Table 15 Low Battery Power Alarm (< 5 minutes)

5 Alarms and Troubleshooting



System Controller Hardware Fault

This is a Hazard alarm

The screen looks like this:



Behavior and appearance:

- All symbols are off, including the “pump running” symbol () and wrench ().
- “Call Hospital Contact; Controller Fault” displayed on the screen.
- The Driveline is connected and power is connected.
- Alarm tone: Constant tone.
- All System Controller buttons are non-functional.

Alarm means:

A serious internal malfunction has occurred in the System Controller that requires clinician diagnosis and resolution. The pump is still running if the “Call Hospital Contact Controller Fault” message is displayed.

To resolve alarm:

Call your hospital contact as soon as possible for diagnosis and instructions.

Alarm silence period:

None - the audio tone cannot be silenced

Table 16 System Controller Hardware Fault

IMPORTANT! A backup System Controller is identical to the running System Controller. It should remain with you at all times for easy access in an emergency. For instructions on replacing the System Controller, see page 63.

Power Cable Disconnected Alarm

This is an Advisory alarm

Screen 1 — Black cable



The screens look like this:

(Screen 1 for black cable;
Screen 2 for white cable)

Screen 2 — White cable



Behavior and appearance:

- Flashing yellow light near the black or white power cable connector, depending on which cable is disconnected.
- “Connect Power” appears on the screen.
- Alarm tone: Fast beep.

Alarm means:

One of the System Controller power cables is disconnected from power. If it is the cable with the black connector, the top light comes on. If it is the cable with the white connector, the center light comes on.

To resolve alarm:

1. Promptly connect the disconnected power cable to a working power source (Mobile Power Unit or two fully-charged HeartMate batteries).
2. Call your hospital contact if reconnecting the power cable does not resolve the alarm.

Alarm silence period:

The alarm cannot be silenced.

Table 17 Power Cable Disconnected Alarm

5 Alarms and Troubleshooting

Low Battery Power Alarm (less than 15 minutes remain)

This is an Advisory alarm

The screens look like this:

(alternating screens)



Behavior and appearance:	<ul style="list-style-type: none"> • Flashing yellow diamond (◆) on the user interface. • “Low Battery” and “Replace Power” alternate on the screen. • Alarm tone: Slow beep.
Alarm means:	Low Battery Advisory - Low battery, power input to the System Controller is low. Less than 15 minutes of battery power remain.
To resolve alarm:	<ol style="list-style-type: none"> 1. Promptly connect to a working or different power source (Mobile Power Unit or two HeartMate batteries). 2. Call your hospital contact if connecting to power does not resolve the alarm.
Alarm silence period:	<ul style="list-style-type: none"> • 5 minutes or until any new alarm occurs. • To silence this alarm, press the silence alarm button(⏏).

Table 18 Low Battery Power Alarm (< 15 minutes)

System Controller Fault Alarm

This is an Advisory alarm

The screen looks like this:





Behavior and appearance:	<ul style="list-style-type: none"> • Flashing yellow wrench () on the user interface. • “Call Hospital Contact; Controller Fault” on the screen. • Alarm tone: Slow beep.
Alarm means:	An internal malfunction or other issue has occurred in the System Controller that requires clinician diagnosis and resolution.
To resolve alarm:	Call your hospital contact as soon as possible for diagnosis and instructions.
Alarm silence period:	<ul style="list-style-type: none"> • 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button().

Table 19 System Controller Fault Alarm

IMPORTANT! A backup System Controller is identical to the running System Controller. It should remain with you at all times for easy access in an emergency. For instructions on replacing the System Controller, see page 63.

5 Alarms and Troubleshooting

Communications Fault (Comm Fault) Alarm




This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	<ul style="list-style-type: none"> • Flashing yellow wrench () on the user interface. • "Call Hospital Contact; Comm Fault" on the screen. • Alarm tone: Slow beep.
Alarm means:	<ul style="list-style-type: none"> • Communication between the LVAD and the System Controller has been lost. <p>OR</p> <ul style="list-style-type: none"> • The primary and back-up communication wires in the Driveline are not functioning. <p>In both cases, the pump is still running.</p>
To resolve alarm:	Call your hospital contact immediately for diagnosis and instructions.
Alarm silence period:	<ul style="list-style-type: none"> • 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button ().

Table 20 Communication Fault Alarm

System Controller Backup Battery Fault Alarm

This is an Advisory alarm

The screen looks like this:



Behavior and appearance:	<ul style="list-style-type: none"> • Flashing yellow wrench (🔧) on the user interface. • “Call Hospital Contact; Backup Battery Fault” on the screen. • Alarm tone: Slow beep.
Alarm means:	<ol style="list-style-type: none"> 1. The System Controller’s 11 Volt Lithium-Ion backup battery is compromised. <p>OR</p> <ol style="list-style-type: none"> 2. It is unable to fully support pump function. <p>OR</p> <ol style="list-style-type: none"> 3. There is an issue that requires clinician diagnosis and resolution.
To resolve alarm:	<p>Call your hospital contact as soon as possible for diagnosis and instructions.</p>
Alarm silence period:	<ul style="list-style-type: none"> • 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 21 System Controller Backup Battery Fault Alarm

5 Alarms and Troubleshooting

System Controller Backup Battery Not Installed Alarm


This is an Advisory alarm

The screens look like this:

(alternating screens)



Behavior and appearance:

- Flashing yellow wrench () on the user interface.
- "Call Hospital Contact; Backup Battery Fault" and "install battery" graphic alternate on the screen.
- Alarm tone: Slow beep.

Alarm means:

OR

1. The System Controller's 11 Volt Lithium-Ion backup battery is not installed.
2. The System Controller's 11 Volt Lithium-Ion backup battery is installed incorrectly.

To resolve alarm:

Call your hospital contact as soon as possible for diagnosis and instructions.

Alarm silence period:


- 4 hours or until any new alarm occurs.
- To silence this alarm, press the silence alarm button ().

Table 22 System Controller Backup Battery Not Installed Alarm

Driveline Power Fault Alarm

This is an Advisory alarm

The screen looks like this:



Behavior and appearance:

- Flashing yellow wrench () on the user interface.
- "Call Hospital Contact; Driveline Power Fault" on the screen.
- Alarm tone: Slow beep.

Alarm means:

One of the two power handling wires inside the Driveline may be damaged or broken. The pump is still running.

To resolve alarm:

Call your hospital contact immediately for diagnosis and instructions.

Alarm silence period:


- 4 hours or until any new alarm occurs.
- To silence this alarm, press the silence alarm button ().

Table 23 Driveline Power Fault Alarm

5 Alarms and Troubleshooting

Driveline Communication Fault (Driveline Comm Fault) Alarm

This is an Advisory alarm




The screen looks like this:	
Behavior and appearance:	<ul style="list-style-type: none"> • Flashing yellow wrench () on the user interface. • "Call Hospital Contact; Driveline Comm Fault" on the screen. • Alarm tone: Slow beep.
Alarm means:	One of the two communication wires inside the Driveline may be damaged or broken. The pump is still running.
To resolve alarm:	Call your hospital contact immediately for diagnosis and instructions.
Alarm silence period:	<ul style="list-style-type: none"> • 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button ().

Table 24 Driveline Communication Fault Alarm

Mobile Power Unit Alarms

The Mobile Power Unit continually checks the system. The Mobile Power Unit issues an alarm for the following conditions:



Replace Mobile Power Unit Batteries



Mobile Power Unit Internal Malfunction

Note: If you hear an alarm for the Mobile Power Unit but no light comes on, call your hospital contact.

All Mobile Power Unit alarms are accompanied by a light (**Figure 144**) and sound. Different lights and sounds come on, depending on the alarm.

Figure 144 Indicators on the Mobile Power Unit



Note: When the Mobile Power Unit is connected to the System Controller, the Mobile Power Unit duplicates any active audio System Controller alarms. See *Handling System Controller Alarms* on page 209.

5 Alarms and Troubleshooting

Note: If you hear an alarm for the Mobile Power Unit but no light comes on, call your hospital contact.



Alarm Symbol	Meaning	What You Should Do
 Advisory Alarm Yellow Mobile Power Unit battery indicator with beeping audio tone	Internal Alkaline AA Mobile Power Unit batteries need to be replaced.	<ol style="list-style-type: none">1. Promptly switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.2. Replace Mobile Power Unit batteries (see <i>Inserting or Replacing the Mobile Power Unit Batteries</i> on page 82).
 Advisory Alarm Yellow wrench light with beeping audio tone	Internal malfunction detected within the Mobile Power Unit.	<ol style="list-style-type: none">1. Promptly switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.2. Call hospital contact.

Table 25 Mobile Power Unit Alarms

Battery Charger Alarms

The Battery Charger continually checks its own performance and that of any battery placed into a slot or pocket. Actual or potential problems, or “faults,” appear as “advisory messages” on the charger’s display screen.

The Battery Charger can detect a problem or fault condition in up to four charging pockets at once (with or without batteries inserted), or with the entire charger unit. The charger alerts you immediately of any problem.

See **Table 26** for a summary of English text and graphic symbols that appear on the Battery Charger’s display screen.

Confirming a Battery Fault

If the Battery Charger detects a problem with a battery, such as battery voltage too high or too low, or open battery circuit, the red light for the pocket comes on and a telephone symbol appears on the display panel (**Figure 145**).

Figure 145 Telephone Symbol and Red Light by Pocket 1 Indicate that the Charger Detects a Problem



Before assuming that the battery is defective, make sure that the connection between the battery and charging pocket contacts is not blocked by dirt or debris.

5 Alarms and Troubleshooting

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- In-use Battery Charger
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries in the charging pockets

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Remove the battery from the pocket. Examine the battery's metal contact and the contact inside the charging pocket. If there is no dirt, debris, or obstruction, continue to Step 2.
2. Reinsert the battery into the same pocket.
3. If the red light comes on again, insert the battery into a different pocket.
4. If the red light comes on in a second pocket, the battery is defective. Do not use it.
5. Obtain the alarm code for the battery, if possible:
 - a. Press and hold the number button for this pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes related to batteries begin with the letter B.
 - b. Record the alarm code and save it for future reference.
6. Remove the defective battery from use.

Confirming a Pocket Fault

When the charger detects a pocket fault, the red light for the affected pocket comes on, with or without a battery inserted in the pocket. In addition, the charger immediately stops charging or calibrating the battery in the affected pocket, if one is present.

FOR THIS TASK YOU NEED:

- Quiet, well-lighted location where you can focus on the task
- In-use Battery Charger
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries in the charging pockets

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Remove the battery from the affected pocket, if one is inserted.
2. Record the alarm code for the defective pocket, if possible:
 - a. Press and hold the number button for this pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes related to pocket problems begin with the letter S (English only).
 - b. Record the alarm code and save it for future reference.
3. Call your hospital contact for help. The hospital contact may ask for the alarm code.

Note: Do not use the defective charging pocket until it is repaired or until the Battery Charger is replaced. You can continue to use the other pockets.

5 Alarms and Troubleshooting

Confirming a Battery Charger Fault

If the charger detects a fault with the entire charger, all four red lights come on, and all charging and calibrating stops.

For this task you need:

- Quiet, well-lighted location where you can focus on the task
- In-use Battery Charger
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries

Remember !

Before starting this task, be sure you know how to do it safely. If you have questions, call your hospital contact.

TASK

1. Remove all batteries from all pockets.
2. Record the alarm code for the fault condition, if possible:
 - a. Press and hold the number button for any pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes for the entire charger begin with the letter S (English only).
 - b. Record the alarm code and save it for future reference.
3. Turn off the charger; unplug it from the electrical outlet.
4. Call your hospital contact for help. The hospital contact may ask for the alarm code.

Note: Do not use a damaged or defective Battery Charger until it is repaired or replaced. Until you have a safe and reliable way to recharge batteries, use the Mobile Power Unit to power your HeartMate 3 system.

Alarms and Troubleshooting 5

Battery Charger Display Panel Messages

The English mode always displays first. The following shows the screens to select the mode.

Change Display Mode to English	OK ENGLISH ▼	OK ENGLISH ▼
Change Display Mode to Graphics	OK GRAPHICS ▼	OK GRAPHICS ▼

KEY for Table

Y	Battery Charger pocket number
# = X	Battery charge cycle count
mAh	milliamp-hour
C	Battery capacity
B0001	Battery fault with alarm code, example
S0001	Battery Charger pocket (slot) fault with alarm code, example

Table 26 describes the messages that appear on the charger display panel.



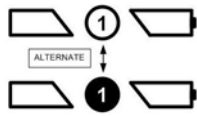




Meaning	English Mode	Graphics Mode
Ready	HeartMate CHARGER	HeartMate CHARGER
Battery Charge Status	Y: ■■■■■	1:  50%
Battery Information (3rd screen)	# = X X: mAh = C	# = X X: mAh = XC
Charge Complete	READY Y: ■■■■■	1:  ✓
Request Calibration	CALIBRATE? PRESS Y	
Accept Calibration	PROGRESS Y: CALIBRATING	1: 
Charger Fault	CALL SERVICE	
Battery Fault (Button Push)	CALL SERVICE B0001	 B 0 0 0 1
Charger or Pocket Fault (Button Push)	CALL SERVICE S0001	 S 0 0 0 1

Table 26 Battery Charger Display Panel Messages

5 Alarms and Troubleshooting

Guidelines for Power Cable Connectors

Use care when connecting and disconnecting connections to power. Be sure to:

- Line up the half circles inside the connectors, as shown in **Figure 146**.
- Gently bring the connectors together, turning them slightly to make the connection, if needed.
- Never pull, turn, or twist the strain relief portion of the connectors (where the connector and cable meet).
- When you feel the connectors line up, push them together firmly until fully connected, without twisting or forcing the connectors.
- Tighten the connection between the connectors by turning the nut on the connector (**Figure 147**). Hand tighten the nut; do not use tools. Do not twist the connectors when turning the nut.
- When disconnecting, turn the nut on the connector until the connection is loose and then gently pull the connectors apart.
- Never twist connectors or pull them apart at an angle.

Figure 146 Carefully Align the Connectors



Figure 147 Tighten the Connector Nut



What Not To Do: Driveline and Cables

Check the Driveline, System Controller power cables, and Mobile Power Unit patient cable for twisting, kinking, or bending, which could cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Left Ventricular Assist Device to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.

CAUTION !

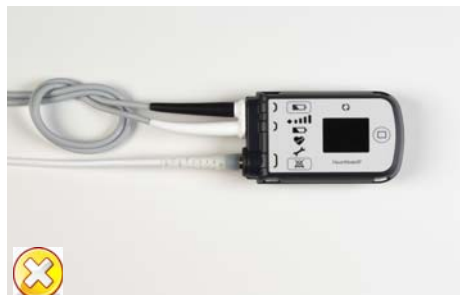
Do not twist, kink, or sharply bend the Driveline.



5 Alarms and Troubleshooting

CAUTION !

Do not twist, kink, or sharply bend the System Controller power cables.



Alarms and Troubleshooting 5

CAUTION !

- Do not twist, kink, or sharply bend the Mobile Power Unit patient cable.
- Route the patient cable so it will not cause a tripping or falling hazard.
- Take care when moving around while connected to the Mobile Power Unit, that it is not inadvertently pulled off of furniture.



Do not connect a System Controller to both the Mobile Power Unit and the Power Module at the same time, or damage to the System Controller and injury to the patient may occur. First connect to HeartMate 14 Volt batteries.



5 Alarms and Troubleshooting

Do not insert a misaligned Driveline Cable Connector into the System Controller Driveline Connector.

Align the WHITE arrow/ alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller Driveline Connector.



Do not orient the System Controller so the display is facing up.

Align the WHITE arrow/ alignment mark on the Driveline Cable Connector with the WHITE arrow on the rear of the System Controller Driveline Connector.



CARING FOR THE EQUIPMENT

This section provides information about how to care for the HeartMate 3 Left Ventricular Assist System and the wear and carry accessories.

Cleaning and Caring for the Equipment - - - - - 244

Product Disposal - - - - - 250

6 Caring for the Equipment

Cleaning and Caring for the Equipment

General Cleaning Rules for all Equipment

Use a damp cloth to clean exterior surfaces of the external parts of equipment. Do this as needed. Water, with or without a mild dish soap, may be used as a surface cleaner. Do not allow water to enter the interior of devices. Do not put equipment in water or liquid.

WARNING !

Never submerge the Driveline, Modular Connector, System Controller, or any external system components (such as the Power Module, the Mobile Power Unit, batteries, power cables, or battery clips) in water or liquid. Submersion in water or liquid may cause the Left Ventricular Assist Device to stop.

Cleaning the System Controller

As needed, clean the outside parts of the System Controller with a damp, lint-free cloth. If more aggressive cleaning is needed, use warm water and a mild dish soap.

WARNING !

Never put the System Controller into water or liquid. Submersion in water or liquid may cause the Pump to stop.

At least monthly, check the System Controller's power cable connector pins for dirt or grease. If you find dirt or damage, do not try to clean or fix the pins yourself. Tell your hospital contact.

At least monthly, inspect the System Controller's audio sounders for dirt or grease. If you notice a change in tone or in loudness during a System Controller self test (*Performing a System Controller Self Test* on page 42), the audio speaker sockets may be obstructed. Audio speaker sockets may be cleaned using a small cotton swab that is moistened (not dripping) with rubbing alcohol. Never insert anything sharp (like a toothpick or pin) into the sounder holes. This can damage the speakers inside.

IMPORTANT! Do not disconnect the System Controller from the Driveline for cleaning. Disconnecting the Driveline will make the pump stop. The Driveline connector should be inspected only if the running System Controller is replaced (see *The Backup System Controller* on page 58).

Cleaning the System Controller Power Cables

As needed, clean the outside parts of the System Controller power cables with a damp, lint-free cloth. If more aggressive cleaning is needed, use warm water and mild dish soap.

Keep the System Controller power cables dry and away from water or liquid. If the System Controller power cables come into contact with water or liquid, the system may fail to operate properly or you may get an electric shock.

Driveline Care

Wear and fatigue of the Driveline that connects the pump to the System Controller may result in damage. Such damage has the potential to interrupt device function. Resolution of this situation may require reoperation to replace the pump, replacement of the Modular Cable, or may result in death if not resolved.

Damage due to wear and fatigue of the Driveline has occurred in both the externalized and implanted portions of the Driveline. Damage to the redundant wires within the Driveline may or may not be preceded by visible damage to the outer layer of the Driveline.

6 Caring for the Equipment

Driveline damage may be evidenced by the following:

- Driveline faults may occur on Battery or Mobile Power Unit operation.
- Transient alarms due to short or open circuits, often associated with movement of you or the Driveline.
- High pump power associated with reduced pump speed, as recorded in the System Controller event log file.
- High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
- Feelings of pump vibrations.
- Fluid leakage from the external portion of the Driveline.
- Cessation of pumping.

If you suspect a damaged Driveline, contact your hospital contact immediately.

X-ray images may be useful to assess the extent and location of the Driveline damage. If damage to the electrical conductors in the Driveline is confirmed, the Left Ventricular Assist Device should be replaced as soon as possible.

A disruption to the continuity of the wires in the Driveline may cause damage to the System Controller. If damage to the System Controller occurs and the System Controller requires replacement, consider using batteries to reduce the potential of further damaging the System Controller.

Caring for the Mobile Power Unit

Inspect the Mobile Power Unit routinely as described in the *Safety Checklists* on page 293 for the safest and best possible performance.

Cleaning the Mobile Power Unit

Periodically, and as needed, unplug the Mobile Power Unit and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild detergent, if necessary. Allow the Mobile Power Unit to dry completely before use.

CAUTION !

Do not clean or service the Mobile Power Unit while it is plugged into an AC electrical outlet, or electrical shock may occur.

6 Caring for the Equipment

Caring for HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. Follow the instructions in the *Safety Checklists* on page 293 to perform routine inspections on the batteries and battery clips.

Cleaning Battery Contacts and Clips

Clean the metal battery contacts and the interior contacts of battery clips monthly using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use. See **Figure 148**.

Figure 148 Clean the Contacts on the Batteries and Battery Clips



Caring for the Battery Charger

The Battery Charger requires little maintenance. However, it should be inspected routinely for the safest and best possible performance. For more information, see *Safety Checklists* on page 293.

Caring for the Wear and Carry Accessories

HeartMate wear and carry accessories are designed to securely hold, carry, and protect HeartMate 3 components. The accessories include:

- Shower Bag
- Consolidated Bag
- Lanyard
- Belt attachment
- Holster vest
- Battery holster
- Protection Bag

If an accessory gets dirty, wash it by hand using mild detergent, a medium-bristle brush, and cold water. Never use a washing machine to wash a wear and carry accessory. Hang the accessory to drip dry. Always allow it to air dry on its own. Never use a clothes dryer or hair dryer to dry a wear and carry accessory. Mechanical washers and heated dryers can damage the accessories. Make sure an accessory is completely dry before using it—this includes the Shower Bag.

Periodically inspect the wear and carry accessories for damage or wear. If an accessory appears damaged or worn, do not use it. Call your hospital contact for a replacement.

6 Caring for the Equipment

Product Disposal

Talk with your hospital contact before throwing away any equipment. Specific disposal rules for certain equipment appear below. Otherwise, dispose of all expired or damaged equipment according to applicable local, state, and federal regulations. If you are unsure how to dispose of something, call your hospital contact.

Battery Disposal

HeartMate 14 Volt Lithium-Ion batteries do not contain lead. Dispose of or recycle HeartMate 14 Volt Lithium-Ion batteries in compliance with all applicable local, state, and federal regulations. Do not incinerate.

Dispose of the Mobile Power Unit batteries in compliance with all applicable local, state, and federal regulations. Never incinerate discarded Mobile Power Unit batteries.

Mobile Power Unit Disposal

Dispose of or recycle Mobile Power Unit and Mobile Power Unit electronics in compliance with all applicable local, state, and federal regulations.

Battery Charger Disposal

Dispose of or recycle the Battery Charger and Battery Charger electronics in compliance with all applicable local, state, and federal regulations.

6 Caring for the Equipment

FREQUENTLY ASKED QUESTIONS

This section provided answers to commonly asked questions about the HeartMate 3 Left Ventricular Assist Device.

System Use - - - - -	255
Showers and Exercise- - - - -	257
Travel - - - - -	257

7 Frequently Asked Questions

System Use

Who should I call if I think my equipment is broken?

Call your hospital contact if you think your equipment is broken. Your hospital contact can check the equipment and order replacements, if needed. Do not try to repair anything yourself.

Can I use other batteries to power the HeartMate 3 system?

No. Only use the HeartMate 14 Volt Lithium-Ion batteries that you received from the hospital at discharge. Other batteries will not power the HeartMate 3 system. Trying to use other batteries for power may cause your pump to stop. If you need new or extra batteries, call your hospital contact.

Can I charge other batteries in the Battery Charger?

No. Only HeartMate 14 Volt Lithium-Ion batteries can be placed into the Battery Charger. Inserting other batteries may damage the charger.

What should I do if I drop my System Controller?

If you drop your System Controller, call your hospital contact RIGHT AWAY, even if everything seems fine. The System Controller casing is tough. A drop is unlikely to damage the System Controller. However, a drop can move or pull on the Driveline exit site. This can hurt the skin at the site and increase your risk of infection. Early treatment can be the key to successful infection control.

7 Frequently Asked Questions

What should I do if my System Controller gets wet?

The System Controller is water resistant. It is not waterproof. Placing the System Controller into water or liquid can damage the System Controller. This can affect system operation or cause the pump to stop. You may need to replace the System Controller. Call your hospital contact for instructions if the System Controller gets wet.

What should I do if the bandages covering the Driveline exit site get wet?

The Driveline exit site must be kept as clean and dry as possible to lower your risk of infection. If the bandages covering the exit site get wet, change them right away. Use the sterile technique that you learned from your hospital contact.

Are there medications that will interfere with my pump?

Consult your doctor before starting any new medications or dietary supplements.

Showers and Exercise

Can I shower with the HeartMate 3 system?

Maybe. You may be allowed to shower after the Driveline exit site heals, if your doctor gives approval. Your doctor will decide if you can shower. If approved for showering, you must use the Shower Bag for every shower. Do not shower without the Shower Bag.

Can I exercise, play sports, or go to the gym?

Many HeartMate 3 patients enjoy an active lifestyle. However, it is not safe to play contact sports or engage in jumping activities while you have the pump. These activities could cause bleeding or could damage the pump. If you have questions about a specific sport or activity, talk with your hospital contact.

Travel

Can I travel/fly with the HeartMate 3 system?

The HeartMate 3 Left Ventricular Assist System is approved for air travel. Talk with your physician or hospital contact before traveling, especially if it is a long distance. He or she can help you with a travel safety plan. If you are going outside of North America, you need power cords that works with the local voltage and that meet applicable safety agency marks and standards (for both the Mobile Power Unit and Battery Charger). Ask your hospital contact for approved power cords, if needed.

7 Frequently Asked Questions

Can I go through a metal detector/body scanner?

No. These devices use types of energy that can interfere with the pump. You should request a hand search.

For tips on airline travel for passengers with medical conditions, go to the TSA's website at: <http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm>

What if I have a VAD-related problem while I am away from home?

Please call your hospital contact if you have a problem or concern. It is also advisable to obtain contact information for the nearest VAD center at your travel destination PRIOR to travelling (and along your travel route, if you are driving).

Can I do anything to hurt or stop the pump?

Many new users worry about doing something that could stop the pump. Try not to worry. The HeartMate 3 system is designed for safe and easy use at home. It has built-in backups. As long as the pump is connected to power (the Mobile Power Unit or two HeartMate batteries), it will continue to run. Over time you will get to know and trust the system.

HANDLING EMERGENCIES

This section provides information to assist you in dealing with an emergency.


IMPORTANT! Make sure you read and understand this information so you are prepared in case of an emergency.

What Is An Emergency? - - - - -	261
How to Handle an Emergency - - - - -	262

8 Handling Emergencies

What Is An Emergency?

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

- Loss of power to the pump ( symbol appears on the System Controller)
- Broken wires (indicated by Driveline Power or Communication faults or Communications fault)
- Damage to the pump motor or System Controller (indicated by a Replace Controller alarm or Low Flow alarm)
- Health changes affecting your heart

If the system is not working right, the System Controller will alarm (see *System Controller Alarms* on page 209).

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, unless your hospital contact tells you otherwise. Land-line telephones may be less likely to be affected by interference, interruptions, or power outages.

Make sure you have completed the Emergency Contact List on page v and keep it available at all times.

8 Handling Emergencies

How to Handle an Emergency

Try 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 Driveline connections.
2. Reconnect any loose or disconnected cables.
3. Call your hospital contact if reconnecting the cables does not fix the problem.

Note: See *Alarms and Troubleshooting* on page 207 for instructions on handling alarms.

When the Pump has Stopped (Red Heart Alarm)

If the pump stops running, you will see the Red Heart alarm and the pump running symbol is black:



You should:

1. Check the connection between the System Controller and the pump, and then check the connection between the System Controller and Driveline power source (Mobile Power Unit or batteries).
2. Check that the Modular In-Line connector on the Driveline is connected and secure.
3. Fix any loose connections. Loose connections may not resolve the situation if other Driveline problems exist.
4. Switch to a different power source. If you are on batteries, switch to the Mobile Power Unit. If you are on Mobile Power Unit power, switch to batteries.
5. Switch to the backup System Controller (see *Replacing the Running System Controller with a Backup Controller* on page 63).
6. If checking connections, switching power sources, or changing System Controllers does not fix the problem, call emergency services right away (dial 911 if available), and then call your hospital contact.

8 Handling Emergencies

TESTING & CLASSIFICATION

This section provides information about safety testing and classification for the HeartMate 3 Left Ventricular Assist System.

Safety Testing and Classification - - - - -	267
Acceptable Operating Conditions - - - - -	268
Declaration Concerning General Safety Standards- - - - -	269

9 Testing & Classification

Safety Testing and Classification

The HeartMate 3 Left Ventricular Assist System has been thoroughly tested and Classified by Underwriters Laboratories, LLC (UL) to the fire, casualty, and electric shock hazard requirements of the following safety standards, as applicable:

- IEC 60601-1:2012 (ed. 3.1)
- IEC 60601-1:2005 + Corr. 1:2006 + Corr. 2:2007 (ed. 3.0)
- IEC 60601-1-11:2015
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-1-6:2010 + A1:2013
- IEC 62366:2007 + A1:2014
- EN 60601-1:2012 (ed. 3.1)
- EN 60601-1:2006 + Corr. 2:2010 (ed. 3.0)
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012 (ed. 3.1)
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1:14 (ed. 3.1)
- CAN/CSA C22.2 No. 60601-1:08 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1-11:15

These standards require making the following declarations and stating the type and degree of protection for listed hazards.

- UL 60601-1, 1st ed., 2006-04-26
- CAN/CSA-C22.2 No. 601.1-M90 (R2005)



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)
No.601.1 7D72

9 Testing & Classification

Acceptable Operating Conditions

For safe and optimal use of your HeartMate system components, follow the operating guidelines listed here. If you use the equipment outside these ranges, it may result in a failure or may impact your LVAD support.

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Mobile Power Unit	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries^a	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
Battery Charger	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
System Controller, Backup System Controller^{a, b}	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
11 Volt Lithium-Ion Backup Battery	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)

Table 27 Operating Conditions

- a. Standby components (extra 14 Volt Lithium-Ion batteries, backup System Controller) should be maintained at conditions within the acceptable ranges so that they are available for immediate use.
- b. Every six months, the “sleeping” backup System Controller must be connected to a power source to recharge the backup battery inside it. If the 11 Volt Lithium-Ion backup battery inside the backup System Controller is not charged every six months, it will lose its charge. If this happens, there may not be enough power to run the pump if the in-use power disconnects or fails. See *Maintaining the Backup System Controller’s Readiness: Six Month Charging and Self Test* on page 60.

Note: Patients must maintain the equipment in Table 27 within the stated operating conditions at all times.

Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous/Pulse
Method of Sterilization	100% EtO for blood pump, Controller, and all sterile accessories
Type of protection against electrical shock	Mobile Power Unit: • Class II Lithium-Ion Batteries: • Class II Battery Charger: • Class I
Degree of protection against electric shock	Type CF (Cardiac Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water and particulate matter	<ul style="list-style-type: none"> • System Controller–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water • Mobile Power Unit–IP22:Protection against ingress of solid foreign objects the size of a finger and from vertically falling water drops when the enclosure is tilted up to 15° • System Monitor–IPX1:Protection against ingress of vertically dripping water • Shower Bag–IPX3: Protection against ingress of spraying water • 14 V Battery and Clip (only when connected to the System Controller) –IP24: Protection against ingress of solid foreign objects the size of a finger and from splashing water • Battery Charger–IPX0: Non-protected against ingress of water
Applied parts	<ul style="list-style-type: none"> • HeartMate 3 Left Ventricular Assist Device • System Controller

Table 28 Declaration Concerning General Safety Standards

9 Testing & Classification

Type	Degree of Protection
Performance Determined to be Essential Performance	<ul style="list-style-type: none">• Maintain Pump Speed (Note: Pump Speed is the characteristic that the physician uses to set the desired blood flow).• Alarm for Pump Speed performance outside of the essential performance limits.• Prevent Leakage in Blood Path.

Table 28 Declaration Concerning General Safety Standards (Continued)

For additional information on testing and classification for the HeartMate 3 Left Ventricular Assist System, please see the *HeartMate 3 Instructions for Use*. Your hospital contact can get a copy for you.

Testing and Classification: HeartMate 3 LVAS

The HeartMate 3 Left Ventricular Assist System has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2007 Medical electrical equipment—Part 1-2: General requirements for Basic safety and essential performance—Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate 3 Left Ventricular Assist System can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- 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 Corporation for assistance.

Note: Special precautions are required for installing and using the HeartMate 3 Left Ventricular Assist System within portable and RF communication environments.

The HeartMate 3 Left Ventricular Assist System is protected against the effects of external cardiac defibrillation within the limits established per EN 45502-1:1997. However, it is advised that the HeartMate 3 Left Ventricular Assist System be disconnected from the System Controller during the use of open-heart defibrillation.

9 Testing & Classification

Testing and Classification: Mobile Power Unit

Declaration and Guidance for Electromagnetic Emissions for the Mobile Power Unit

The HeartMate 3 Left Ventricular Assist System with Mobile Power Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3 Left Ventricular Assist System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment— Guidance
RF Emissions CISPR 11 EN 55011	Group 1	The HeartMate 3 Left Ventricular Assist System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 EN 55011	Class B	The HeartMate 3 Left Ventricular Assist System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 EN 61000-3-3	Complies	

Table 29 Declaration and Guidance Concerning Electromagnetic Emissions for Mobile Power Unit

Declaration and Guidance for Electromagnetic Immunity

The HeartMate 3 Left Ventricular Assist System (powered by the Mobile Power Unit) is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3 Left Ventricular Assist System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Electrical Fast Transient/Burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power supply Input Lines IEC 61000-4-11 EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HM 3 Left Ventricular Assist System requires continued operation during power mains interruptions, it is recommended that the HM 3 Left Ventricular Assist System be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment.

Table 30 Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate 3 Left Ventricular Assist System Equipment including Mobile Power Unit

9 Testing & Classification

The HeartMate 3 Left Ventricular Assist Device, System Controller, and Mobile Power Unit are intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3, Left Ventricular Assist Device, System Controller, and Mobile Power Unit should assure that they are used in such an electromagnetic environment.


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6 EN 61000-4-6			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate 3 Left Ventricular Assist Device, System Controller, and Mobile Power Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	Recommended Separation Distances $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	$d = 1.2\sqrt{P}$
		Mains Powered 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz		Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^c , should be less than the compliance level in each frequency range ^d .
Interference may occur in the vicinity of equipment that is marked with the following symbol:			
			

Table 31 Declaration and Guidance Concerning Electromagnetic Immunity for HeartMate 3 Left Ventricular Assist System Equipment, including Left Ventricular Assist Device, System Controller, and Mobile Power Unit

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Radiated RF Microwave Ovens	N/A	890-940 MHz and 2.4-2.5 GHz 137 V/m	Based on 21CFR Chapter 1 performance standard for microwave ovens: field strength at 5 cm from external oven surface. Tested with Mobile Power Unit powered by AC Mains.
Radiated RF Cell Phones	N/A	825-960 MHz and 1.4-2.0 GHz 30 V/m	$d = 0.77\sqrt{P}$

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^aThe ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.

^bCompliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (min. 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

^cField strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate 3 Left Ventricular Assist System is used exceeds the applicable RF compliance level above, HeartMate 3 Left Ventricular Assist System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate 3 Left Ventricular Assist System.

^dOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 31 Declaration and Guidance Concerning Electromagnetic Immunity for HeartMate 3 Left Ventricular Assist System Equipment, including Left Ventricular Assist Device, System Controller, and Mobile Power Unit (Continued)

WARNING !

The HeartMate 3 Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate 3 Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.

9 Testing & Classification

Recommended separation distances between portable and mobile RF communications equipment and the HeartMate 3 Left Ventricular Assist System with the Mobile Power Unit

The HeartMate 3 Left Ventricular Assist System with the Mobile Power Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartMate 3 Left Ventricular Assist System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartMate 3 Left Ventricular Assist System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m				
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz	Cellular Telephone 825 MHz to 960 MHz and 1.4 GHz to 2.0 GHz
W	$d = 1.2\sqrt{P}$ Mains Powered	$d = 1.2\sqrt{P}$ Mains Powered	$d = 1.2\sqrt{P}$ Mains Powered	$d = 2.3\sqrt{P}$ Mains Powered	$d = 0.77\sqrt{P}$ Mains Powered
0,01	0.12	0.12	0.12	0.23	0.08
0,1	0.38	0.38	0.38	0.73	0.25
1	1.2	1.2	1.2	2.3	0.77
10	3.8	3.8	3.8	7.3	2.5
100	12	12	12	23	7.7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 32 Recommended Separation Distances

Testing and Classification: Battery Charger

The Battery Charger complies with the following safety standards:

- EN 60950-1: 2006 + A11: 2009 + A1: 2010 + A12: 2011
- IEC 60950-1: 2005, 2nd Edition + Am1:2009
- UL 60950-1, 2nd Edition, 2011
- CSA C22.2 No. 60950-1-07, 2nd Edition, 2011
- IEC 60601-1: 1988, 2nd Edition, A1:1991, A2:1995
- UL 60601-1, 1st Edition, 2003-04-26 (included National Differences for USA)
- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
- 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)

This equipment has been tested and found to comply with the limits for devices to IEC 60601-1-2:2007. 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 and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult Thoratec Corporation for assistance.

9 Testing & Classification

Declaration Concerning General Safety Standards for Battery Charger

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against mains shock	Class I (grounded)
Degree of protection against harmful ingress of water	IPX0

Table 33 Declaration Concerning General Safety Standards for Battery Charger



Declaration and Guidance for Electromagnetic Emissions for Battery Charger

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

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11 EN 55011	Group 1	The Battery Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 EN 55011	Class B	The Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 EN 61000-3-3	Complies	
Radiated Emissions, Magnetic Field MIL-STD-461F	RE101	The Battery Charger generates magnetic fields due to the presence of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Table 34 Declaration and Guidance Concerning Electromagnetic Emissions for Battery Charger

9 Testing & Classification

Declaration and Guidance for Electromagnetic Immunity for the Battery Charger

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power supply Input Lines IEC 61000-4-11 EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Battery Charger requires continued operation during power mains interruptions, it is recommended that the Battery Charger be powered from an uninterruptible power supply or a battery. Note: U_T is the AC mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 35 Declaration and Guidance Concerning Electromagnetic Immunity for the Battery Charger


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Battery Charger than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF IEC 61000-4-6 EN 61000-4-6	3 Vrms	3 Vrms	$d = 1.2\sqrt{P}$
	150 kHz to 80 MHz		
			$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3 EN 61000-4-3	3 V/m	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b
	80 MHz to 2.5 GHz		Interference may occur in the vicinity of the equipment that is marked with the IEC symbol for non-ionizing radiation:
			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Battery Charger is used exceeds the applicable RF compliance level above, Battery Charger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Battery Charger			
^b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 36 Declaration and Guidance Concerning Electromagnetic Immunity for the Battery Charger

9 Testing & Classification

WARNING !

- Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may result in increased emissions or decreased immunity of the HeartMate Left Ventricular Assist System.
- Do not use the Battery Charger next to other equipment.
- Do not stack the Battery Charger on top of other equipment.
- No modification of this equipment is allowed.

Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries

HeartMate 14 Volt Lithium-Ion batteries comply with the following safety standards:

- IEC/EN 62133
- UL 2054
- UN 38.3 T1-8

9 Testing & Classification

Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

Type	Degree of Protection
Degree of protection against electric shock	No Applied Part
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress	IP24 only when connected to the System Controller through Clip

Table 37 Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries



Declaration and Guidance for Electromagnetic Emissions for HeartMate 3 Powered by 14 Volt Lithium-Ion Batteries

The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3 Left Ventricular Assist System should assure that it is used in such an environment.

HeartMate 3 Powered by 14 V Lithium-Ion Batteries		
Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11 EN 55011	Group 1	The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 EN 55011	Class B	The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated Emissions Avionics RTCA/DO-160G Section 21	Cat. M	The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Table 38 Declaration and Guidance Concerning Electromagnetic Emissions for HeartMate 3 Powered by 14 Volt Lithium-Ion Batteries

9 Testing & Classification

Declaration and Guidance for Electromagnetic Immunity for HeartMate 14 Volt Lithium-Ion Batteries

The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 39 Declaration and Guidance Concerning Electromagnetic Immunity

The HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should assure that it is used in such an electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate 3 Left Ventricular Assist Device, System Controller, and batteries, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Min. 3 Vrms			
Conducted RF			
IEC 61000-4-6 EN 61000-4-6	150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	$d = 1.2\sqrt{P}$
Min. 10 Vrms			
	150 kHz to 80 MHz in ISM bands ^a	10 Vrms	$d = 1.2\sqrt{P}$

Table 40 Declaration and Guidance Concerning Electromagnetic Immunity

9 Testing & Classification


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			<p>Battery Operation</p> $d = 0.6\sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 1.2\sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of the equipment that is marked with the IEC symbol for non-ionizing radiation:</p> 
Radiated RF	10 V/m	20 V/m	
IEC 61000-4-3 EN 61000-4-3	80 MHz to 2.5 GHz		
		Frequency Range	
Radiated RF		890-940 MHz and 2.4-2.5 GHz	Based on 21 CFR Chapter 1 performance standard for microwave ovens: field strength at 5 cm from external over surface.
Microwave Ovens		137 V/m	
Avionics		Frequency Range	
Radiated and conducted RF		Conducted 10 kHz to 400 MHz Radiated 100 MHz to 8 GHz	
RTCA/DO-160G Section 20		Cat. R	
Radiated RF Cell Phones	N/A	825-960 MHz and 1.4-2.0 GHz	$d = 0.41\sqrt{P}$
		56 V/m	

Table 40 Declaration and Guidance Concerning Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.

^b Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (min. 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

^c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is used exceeds the applicable RF compliance level above, the HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate 3 Left Ventricular Assist System with 14 Volt Lithium-Ion batteries.

Table 40 Declaration and Guidance Concerning Electromagnetic Immunity (Continued)

WARNING !

Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may result in increased emissions or decreased immunity of the HeartMate Left Ventricular Assist System.

9 Testing & Classification

Recommended separation distances between portable and mobile RF communications equipment and the HeartMate 3 Left Ventricular Assist System with 14 V Li-Ion Batteries

The HeartMate 3 Left Ventricular Assist System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartMate 3 Left Ventricular Assist System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartMate 3 Left Ventricular Assist System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter				
	m				
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz	Cellular Telephone 825 MHz to 960 MHz and 1.4 GHz to 2.0 GHz
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 0.6\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 0.41\sqrt{P}$
0,01	0.12	0.12	0.06	0.12	0.04
0,1	0.38	0.38	0.19	0.38	0.13
1	1.2	1.2	0.60	1.2	0.41
10	3.8	3.8	1.9	3.8	1.3
100	12	12	6.0	12	4.1

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 41 Recommended Separation Distances

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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:

- Reorient or relocate the equipment.
- 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 Corporation for assistance.

CAUTION !

Use of equipment and supplies other than those specified in the manuals or sold by Thoratec Corporation for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate 3 Left Ventricular Assist System and other devices.

9 Testing & Classification

SAFETY CHECKLISTS

This section provides checklists to assist you in performing routine maintenance of the HeartMate 3 Left Ventricular Assist Device.

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As-Needed Safety Checklist- - - - -	301
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10 Safety Checklists

Daily Safety Checklist

Daytime Checklist:

- ☐ Perform System Controller self test.
- ☐ When using a new power source, inspect System Controller power cable connectors for dirt, grease, or damage.
- ☐ When changing power sources, inspect connectors on battery clips for dirt, grease, or damage.
- ☐ When switching from the battery power to the Mobile Power Unit, inspect the connector pins and sockets for dirt, grease, or damage.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the locking nut.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Driveline exit site for signs of infection, including redness, tenderness, swelling, discharge, or a foul odor. Use sterile technique to touch or handle the exit site.

10 Safety Checklists

Sleep Checklist:

- ☐ Check all electrical connections between the System Controller and power cables, the power cables and the Mobile Power Unit patient cable, and the Mobile Power Unit and AC electrical outlet.
- ☐ Always connect to the Mobile Power Unit for sleeping or when there is a chance of sleep, as you may not hear System Controller alarms.
- ☐ Make sure the Driveline is stabilized.
- ☐ Confirm bedside items are in place:
 - ☐ Working flashlight with charged batteries.
 - ☐ Backup System Controller.
 - ☐ Two charged HeartMate 14 Volt Lithium-Ion batteries and two 14 Volt battery clips.
- ☐ Inspect the Driveline Cable for signs of damage, such as cracking, fraying, wear, exposed wires, sharp bends or kinks.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the in-line locking nut.
- ☐ Inspect all cables for signs of damage.

Weekly Safety Checklist

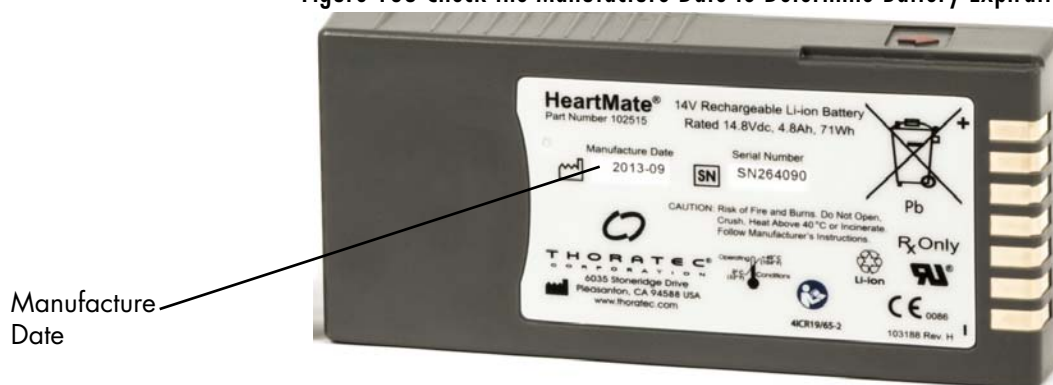
- ☐ Review Replacing Running System Controller with a Backup Controller Instructions in Section 2.
- ☐ Clean the metal battery terminals and contacts inside the battery clips.
- ☐ Inspect the Mobile Power Unit power cord, used to connect the Mobile Power Unit to the AC electrical outlet, for damage or wear. Confirm that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Mobile Power Unit patient cable, used to connect the System Controller to the Mobile Power Unit, for damage or wear. Confirm that the cable is not kinked, split, cut, cracked, or frayed. Do not use the Mobile Power Unit patient cable if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect HeartMate 14 Volt Lithium-Ion batteries for damage. Check the battery contacts for denting or damage. Replace damaged batteries. Do not use batteries that appear damaged.
- ☐ Inspect the Battery Charger for signs of physical damage, such as dents, chips, or cracks. Do not use the Battery Charger if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect the power cord that is used to connect the Battery Charger to an AC outlet. Confirm that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect wear and carry accessories (including the consolidation bag, Travel Bag, Protection Bag, System Controller Neck Strap, Holster Vest, and Belt Attachment accessory) for damage or wear.
- ☐ Inspect the Battery Holster for damage or wear.
- ☐ Inspect the Shower Bag for damage or wear.
- ☐ Replace any equipment or system component that appears damaged or worn.

10 Safety Checklists

Monthly Safety Checklist

- ☐ Review Alarms and Troubleshooting Guides in Section 5.
- ☐ Check the manufacture date on the label of all batteries. If a battery was manufactured more than three years ago, the battery has expired. Replace expired batteries. Do not use expired batteries.

Figure 163 Check the Manufacture Date to Determine Battery Expiration



- ☐ Check the number of use/charge cycles for each battery. Insert a battery into the Battery Charger to read the number of cycles. The cycle information is displayed on the charger's display panel screen (see *Battery Charger Display Panel Messages* on page 237). Replace batteries that have exceeded 360 cycles. Do not use batteries that have exceeded 360 cycles.
- ☐ Clean the metal battery contacts and the interior contacts of battery clips using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use.
- ☐ Inspect the Mobile Power Unit patient cable and power cable connector pins and sockets for dirt, grease or damage. If the pins or sockets are damaged or contaminated, do not attempt to clean them. Report the condition to your hospital contact. Cleaning and service should be performed only by Thoratec-trained personnel. Do not attempt to clean or repair equipment on your own.
- ☐ If the Mobile Power Unit is going to be stored for over 1 month, remove the Mobile Power Unit batteries.

- ☐ Unplug the Battery Charger and clean the metal contacts inside all four charging pockets with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before inserting batteries into the pockets. Do not clean the Battery Charger while it is plugged in.
- ☐ Replace any equipment or system component that appears damaged or worn.

10 Safety Checklists

Six Month Safety Checklist

- ☐ Talk to your hospital contact about maintaining your backup System Controller and checking it for readiness. To make sure your backup System Controller is always ready to use in an emergency, once in a six-month period, your hospital contact will need to charge the backup battery inside your backup System Controller, perform a self test on the backup System Controller, and make sure that the backup System Controller's programmed settings are identical to the settings in your running System Controller.
- ☐ Replace the Mobile Power Unit batteries with three new AA Alkaline batteries. If corrosion is observed, discontinue use of the Mobile Power Unit and call your hospital contact. (See *Inserting or Replacing the Mobile Power Unit Batteries* on page 82).

Yearly Safety Checklist

- ☐ Schedule a Battery Charger inspection and cleaning with Thoratec-trained personnel. The safety inspection and cleaning includes (but is not limited to) functional testing, cleaning, and inspection.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

As-Needed Safety Checklist

- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Clean the exterior surfaces of batteries using a clean, dry cloth. Do not use liquids such as water or liquid cleaning solvent to clean batteries. Keep the batteries dry and away from water and liquid.
- ☐ Unplug the Battery Charger and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild detergent, if necessary. Do not immerse the charger in water or liquid.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

10 Safety Checklists

Clinic Visit Safety Checklist

Advise your patient to bring his or her Patient Handbook to the clinic visit. The following safety check should be performed at each clinical follow-up visit:

- ☐ Review replacing the running System Controller with a backup System Controller (*Patient Handbook* Section 2).
- ☐ With demonstration equipment, both patient and primary caregiver must be able to repeatedly demonstrate ability to successfully complete connection of a driveline to the Pocket Controller in a timely manner (*Patient Handbook* Section 2).

Evaluate, and if necessary, review your patient's ability to perform the following core skills:

- ☐ Review System Controller alarms and troubleshooting including Hazard and Advisory alarm handling and accessing alarm history on the System Controller (*Patient Handbook* Section 5).
- ☐ Review Mobile Power Unit alarms and troubleshooting (*Patient Handbook* Section 5).
- ☐ Remind the patient to follow all hazard and advisory alarm instructions, for example, call the hospital when the System Controller instructs the patient to do so.
- ☐ Review how to identify an emergency (*Patient Handbook* Section 8).
- ☐ Review emergency contact lists (*Patient Handbook* page v).
- ☐ Review guidelines for connecting power cable connectors (*Patient Handbook* Section 5).
- ☐ Review changing power sources (*Patient Handbook* Section 3).
- ☐ Review HeartMate 14 Volt Lithium-Ion battery calibration steps (*Patient Handbook* Section 3).
- ☐ Review What Not To Do: Driveline and Cables (*Patient Handbook* section 5.)
- ☐ Review using the Shower Bag and showering (*Patient Handbook* section 4).
- ☐ Review caring for the driveline exit site including cleansing, dressing, and immobilizing the driveline (*Patient Handbook* section 4).
- ☐ System Controller must be maintained and assessed for readiness.

GLOSSARY

This section defines important terms and abbreviations.

Abbreviations - - - - - 305

Terms - - - - - 306

11 Glossary

Abbreviations

Abbreviation	Term
AC	Alternating Current
CM	Centimeter
DC	Direct Current
EKG	Electrocardiogram
ICU	Intensive Care Unit
IMP	Implantable Pacemaker
INR	International Normalized Ratio
IV	Intravenous
LPM	Liters Per Minute
LVAD	Left Ventricular Assist Device
LVAS	Left Ventricular Assist System
LMW	Low Molecular Weight
ml/hr	Milliliter per hour
MRI	Magnetic Resonance Imaging
OR	Operating Room
PI	Pulsatility Index
PTT	Partial Thromboplastin time
QD	Once daily
RPM	Revolutions Per Minute
TID	Three times daily
V	Volt

Terms

A

Advisory Alarm: Alarms that are important, but not life threatening. Advisory alarms can be silenced for a short time using the Silence Alarm Button that is found on the System Controller user interface. See *System Controller Alarms* on page 209.

Alarm: A sound, light, or lighted symbol that tells you about a problem that may affect system operation or cause harm. See *System Controller User Interface* on page 26.

Alternating Current: Abbreviated AC. The type of electricity that is common for electrical outlets in North American households.

Apical Cuff: The Apical Cuff is the interface between the heart and the HeartMate 3 LVAD. It is sewn to the exterior of the heart and anchors it to the LVAD via the slide lock.


B

Backup Battery: The 11 volt Li-Ion battery inside the System Controller that will continue to run the pump for a short period of time until the System Controller is reconnected to external power.

Backup System Controller: A backup System Controller used to replace the running System Controller, if needed. The backup is identical to the running System Controller and is pre-set with the same settings. You should keep your backup System Controller with you at all times (along with other emergency or backup items). The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be recharged every six months. See *Performing Backup System Controller Six Month Charging and Self Test* on page 60.

The System Controller has an 11 Volt Lithium-Ion battery inside the System Controller gives at least 15 minutes of backup power to the system if the main source of power is disconnected or fails. See *System Controller Backup Power* on page 56.

Battery: A device that provides direct current (DC) power to the system. The HeartMate 3 Left Ventricular Assist System can be powered by two 14 Volt Lithium-Ion batteries. See *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 95. An 11 Volt Lithium-Ion battery inside the System Controller gives at least 15 minutes of backup power to the system if the main source of power is disconnected or fails. See *System Controller Backup Power* on page 56.

Battery button: A button on the System Controller user interface that shows a small battery symbol (). Depending on the mode of operation, pressing this button either: 1) works the battery power gauge on the System Controller, 2) starts the System Controller self test, 3) puts the battery to “sleep” for storage purposes, or 4) recharges the System Controller’s 11 Volt Lithium-Ion backup battery. See *The System Controller User Interface* on page 25.

Battery Charger: A device that charges, calibrates, and tests the HeartMate 14 Volt Lithium-Ion batteries that are used to power the HeartMate 3 Left Ventricular Assist System.

Battery Power Gauge: A set of lighted bars that indicates how much battery power is available. Each HeartMate 14 Volt Lithium-Ion battery has its own 5-bar on-board battery power gauge that shows the battery charge level. The System Controller also has a battery power gauge. The power gauge on the System Controller has four bars and one diamond-shaped light. The System Controller battery power gauge is used during battery-powered operation. It shows the approximate charge level of the two batteries currently in use.

Battery-Powered Operation: Using two HeartMate 14-V Lithium-Ion batteries to power the system. Using batteries to power the system is appropriate when you are active, outdoors, or when electrical power is unavailable.

C

Cautions: Actions to avoid that could damage equipment or affect how the system works. Although important for system function, cautions do not usually relate to life-threatening risks.

Communication Fault (Comm Fault): An Advisory alarm indicating the HeartMate 3 LVAD and System Controller cannot properly exchange information. See *System Controller Alarms* on page 209.

Controller: See *System Controller*.

Controller Alarm Fault: An advisory alarm that occurs when an internal malfunction in the System Controller has occurred that requires clinician diagnosis and resolution. See “System Controller Alarms” on page 209.

11 Glossary

Controller Driveline Connector: Connector permanently attached to the Driveline that connects the pump to the System Controller.

Controller Hardware Fault Alarm: A hazard alarm that occurs when a serious internal malfunction occurs in the System Controller that requires clinician diagnosis and resolution. See “System Controller Alarms” on page 209.

D

Direct Current: Abbreviated DC. The type of electricity that comes from a battery.

Display Button: A button on the System Controller user interface. Press this button to bring up data on the user interface’s display screen (such as current function and alarm history). See *The System Controller User Interface* on page 25.

Driveline: The cable that goes through the skin. It links the pump to the System Controller. The Driveline contains wires that carry power to the pump. Data about system operation is transferred through the Driveline to the System Controller.

Driveline Communication Fault (Driveline Comm Fault): An Advisory Alarm. It occurs when one of the two communication wires inside the Driveline is damaged.

Driveline Power Fault: An Advisory Alarm. It occurs when one of the two power wires inside the Driveline is damaged.

E

Exit Site: The place where the Driveline goes through the skin. The exit site must be kept clean and dry to lower the risk of infection.

F

Fixed Speed Mode: An operating mode where the device is set at a constant or “fixed” speed. Doctor and nurses decide and control pump speed.

G

H

Hazard Alarm: Hazard alarms occur when the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention. Hazard alarms are indicated by a red light and continuous audio tone.

HeartMate 3 Left Ventricular Assist System: Includes the pump and Driveline, as well as the System Controller, power sources (Mobile Power Unit or batteries), and accessories. You may sometimes hear the term “LVAS,” which is short for Left Ventricular Assist System.

I

Inflow Conduit: A small tube that connects the pump to the left ventricle of the heart.

Intensive Care Unit: Abbreviated ICU. This special hospital unit is where new Left Ventricular Assist System patients receive intensive care, usually just after device implant.

J


K

L


Left Ventricular Assist Device: The pump connected to 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. The motor inside the pump is powered through the Driveline. You may sometimes hear the device called a “heart pump” or “LVAD,” which is short for Left Ventricular Assist Device.

Left Ventricular Assist System: The HeartMate 3 Left Ventricular Assist System includes the pump and all related external equipment. Sometimes the Left Ventricular Assist System is called an “LVAS”. LVAS is NOT the same as LVAD. LVAD refers only to the pump.


Liters Per Minute: Abbreviate LPM. Blood flow through the pump is measured in LPMs. “LPM” shows on the System Controller user interface along with blood flow data.

Low Battery Hazard Alarm: A red battery-shaped symbol () on the System Controller user interface that illuminates when less than 5 minutes of combined battery power remain for the in-use HeartMate 14 Volt Lithium-Ion batteries, during battery-powered operation.

11 Glossary

Low Battery Hazard Symbol: Red “battery” light () on the System Controller. It lights when power to the System Controller is critically low.

Low Flow Alarm: Blood flow is less than 2.5 lpm. This condition is accompanied by a flashing red heart on the user interface. “Call Hospital Contact” and “Low Flow” alternate on the screen, and a constant audio tone is emitted from the System Controllers sounders. This is a Hazard alarm condition that requires immediate attention.


Low Flow Hazard Symbol: Red “heart” light () on the System Controller. It lights when HeartMate 3 pump blood flow is critically low.

Low Speed Limit: The lowest speed at which the HeartMate 3 pump can operate while maintaining patient stability.

LPM: Short for liters per minute (lpm). Blood flow through the pump is measured in lpm.

LVAS: Short for Left Ventricular Assist System. The HeartMate 3 Left Ventricular Assist System includes the pump and Driveline, as well as the System Controller, power sources (Mobile Power Unit or batteries), and accessories.

M

Magnetic Resonance Imaging () MR is unsafe for HeartMate 3 patients. Do not subject to Magnetic Resonance Imaging.

Mobile Power Unit: The Mobile Power Unit connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. You must always connect to the Mobile Power Unit when sleeping (or when sleep is possible). Connecting to the Mobile Power Unit is also appropriate when you are stationary or relaxing indoors. See *Powering the System* on page 75.

Mobile Power Unit Batteries: The batteries inside the Mobile Power Unit power an alarm if power to the Mobile Power Unit fails or is disconnected. The Mobile Power Unit batteries work only if they are properly connected and not discharged. See *Inserting or Replacing the Mobile Power Unit Batteries* on page 82.

Modular In-line Cable: One of the two cables that make up the Driveline. One end of the Modular Cable connects to the Pump Cable that exits the patient’s abdomen. The other end of the Modular Cable connects to the System Controller.

N

O

Operating Modes: There are three modes of System Controller operation: 1) Run Mode (actively running), 2) Sleep Mode (off and unused), and 3) Charge Mode (connected to power and charging the backup battery). See *System Controller Operating Modes* on page 47.

Outflow Graft: The polyester tube that connects the pump to the aorta (the large blood vessel that sends blood through the body).

P

Percutaneous: “Percutaneous” means “through the skin.”

Pump Cable: One of the two cables that make up the Driveline. The Pump Cable is permanently attached to the pump housing. The other end of the Pump Cable exits the patient’s abdomen and is connected to the Modular Cable which connects to the System Controller.


The Pump Cable contains wires that carry power and data to the pump, and that control and monitor pump operation.

Polyester Velour: A synthetic biocompatible material that lets skin tissue grow into the soft covering of the Driveline. This material covers the Driveline inside the body at the exit site and is on the external portion of the Pump Cable. Skin growth into the velour covering helps create a barrier that reduces the risk of Driveline infections.


Power Saver Mode: In Power Saver Mode, the System Controller slows pump speed to save power. If power is removed or fails, the System Controller gives 15 minutes of full power before entering Power Saver Mode. Alarms cannot be silenced while in Power Saver Mode. See *System Controller Alarms* on page 209.

Power Sources: Two power sources can power the HeartMate 3 Left Ventricular Assist System: 1) two wearable, rechargeable 14 Volt Lithium-Ion batteries worn in battery clips, or 2) the Mobile Power Unit that plugs into an AC electrical outlet.

Pulsatility Index: Pulsatility Index (PI) is a calculation related to the amount of assistance provided by the pump. PI values typically range from 1 to 10. Higher values indicate higher pulsatility (that is, the pump is providing less support and the heart is providing more support). Lower values indicate lower pulsatility (that is, the pump is providing more support and the heart is providing less support).

Pulse Mode: Your pump is able to create an artificial pulse while it is operating. You will know it is operating in Pulse Mode when you see the  on the LCD of the System Controller.


Pump: See *Left Ventricular Assist Device*.

Pump Running Symbol: A green symbol () on the System Controller user interface that illuminates when the pump is receiving power and running.

Pump Speed: Pump speed is measured in revolutions per minute (RPM). The number of RPMs reflects how fast the pump's internal rotor turns.

Q

R

Red Heart Indicator: A red heart shaped symbol () on the System Controller user interface that illuminates during a Hazard alarm condition. Red heart alarms occur for conditions that are immediately life-threatening. Red heart alarms should prompt an immediate response to avoid serious patient injury or death.


Revolutions Per Minute: Abbreviated RPM. The number of RPMs reflects how fast the pump's internal rotor turns.

Running System Controller: The System Controller that is currently in use and connected to the pump.


S

Safety Lock: The feature on the System Controller that ensures the Controller Driveline Connector is properly inserted (when the lock can be fully closed).

Self Test: A routine system check that you should perform daily to confirm that the System Controller's audio and visual alarms are working properly.

Silence Alarm Button: A button on the System Controller or Mobile Power Unit () that silences an audio alarm. How long the alarm is silenced depends on the type of alarm. The silence period varies from 2 minutes to 4 hours.

IMPORTANT! Pressing the Silence Alarm button only silences the alarm. It does not fix the alarm condition. See *System Controller Alarms* on page 209.

Silence Alarm Screen: When the audio portion of the alarms are silenced, the  symbol will display on the LCD screen of the System Controller.

Slide Lock: The mechanical feature on the HeartMate 3 LVAD that affixes the pump to the Apical Cuff.

Strap Attachment Points: Four places on the System Controller where straps can be easily connected. Attachment points allow for holding or carrying the System Controller. The System Controller can be worn or carried on a belt or strap, or inside a pocket. See *Wearing and Carrying the System Controller* on page 159.

System Controller: The small computer that controls and checks system function. It connects the pump to the external power sources and may be worn at the waist on a belt or in a carrying case around the waist.

System Controller 11 Volt Lithium-Ion Backup Battery: A backup power source inside the System Controller. It powers the system for up to 15 minutes if the main power source fails or is disconnected. The 11 Volt Lithium-Ion backup battery is rechargeable. It charges automatically any time the System Controller is connected to a power source (Mobile Power Unit or batteries). You need to be sure to recharge the backup battery inside the backup System Controller every six months (*Performing Backup System Controller Six Month Charging and Self Test* on page 60). Although rechargeable, the 11 Volt Lithium-Ion backup battery has a limited life (36 months from manufacture date). A message on the System Controller screen tells you when it is time to replace the 11 Volt Lithium-Ion backup battery. See *System Controller Alarms* on page 209.

System Controller Battery Power Gauge: A set of four bars on the System Controller. The bars show the approximate charge level for two batteries being used to power the system. Four green bars mean the batteries are between 75–100% charged. One green bar means the batteries are less than 25% charged. A yellow diamond-shaped light means that only 15 minutes of battery power remain. If the yellow diamond comes on, promptly replace the used batteries or switch to the Mobile Power Unit. Failure to replace batteries or switch to the Mobile Power Unit may cause the pump to stop. See *The System Controller User Interface* on page 25.

System Controller Power Cables: Two power cables (one with a black connector and one with a white connector) connect the System Controller to its power source (either batteries or Mobile Power Unit). Both cables provide equal power. However, the white cable contains a data link that sends information to the Mobile Power Unit.

T

Tethered Operation: Refers to using the HeartMate 3 Left Ventricular Assist System while connected to an electrical outlet via the Mobile Power Unit.

U

User Interface: The lights, symbols, and buttons that appear on the front of the System Controller and provide information about the system.

11 Glossary

User Interface Screen: The screen on the System Controller user interface that provides information about how the system is operating. Alarm information and instructions also appear on the screen. See *The System Controller User Interface* on page 25.

V


W


Warnings: Hazards that could cause serious harm or death if not avoided. If you ignore a warning, you could be seriously harmed or killed.

Wear and Carry Accessories: Wear and carry accessories are used to safely hold or carry the System Controller. For example, you can carry the System Controller with a strap around your neck, on a belt, or in a pocket. A battery holster is used for carrying batteries and battery clips. See *Wearing and Carrying the System Controller* on page 159.

X

Y

Yellow Diamond Indicator: A yellow symbol () on the System Controller user interface that illuminates when less than 15 minutes of combined battery power remain from the in-use HeartMate 14 Volt Lithium-Ion batteries providing power during battery-powered operation.

Yellow Wrench Indicator: A yellow symbol () on the System Controller user interface that illuminates during alarm conditions that are important, but not immediately life-threatening.

Z

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