HeartMate II®
Left Ventricular Assist System (LVAS)

Featuring the Mobile Power Unit

Patient Handbook

Abbott
Patient Handbook

Your guide to understanding the HeartMate II heart pump
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.

<table>
<thead>
<tr>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ____________________________</td>
</tr>
<tr>
<td>Address: ____________________________________________</td>
</tr>
<tr>
<td>Contact Person: ____________________________</td>
</tr>
<tr>
<td>Contact Person Telephone Number: ____________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ____________________________</td>
</tr>
<tr>
<td>Address: ____________________________________________</td>
</tr>
<tr>
<td>Telephone Number: ____________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ambulance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name: ____________________________</td>
</tr>
<tr>
<td>Address: ____________________________________________</td>
</tr>
<tr>
<td>Telephone Number: ____________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emergency Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dial 911 (Confirm 911 is operational in your area.)</td>
</tr>
</tbody>
</table>

**Other Important Information**

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

1 Introduction - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 1
   Why Reading This Handbook is Important- - - - - - - - - - - - - - - - - - 3
   Understanding Warnings & Cautions - - - - - - - - - - - - - - - - - - - - - 5
   General Warnings - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 6
   General Cautions - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 7
   Equipment Overview - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 8

2 How Your Heart Pump Works - - - - - - - - - - - - - - - - - - - - - - - - 15
   Your Heart Pump - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 17
   The Driveline - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 18
   The System Controller - - - - - - - - - - - - - - - - - - - - - - - - - - - 20
   System Controller Backup Power- - - - - - - - - - - - - - - - - - - - - - 53
   The Backup System Controller - - - - - - - - - - - - - - - - - - - - - - 55

3 Powering the System - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 59
   Power Overview - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 61
   Using the Mobile Power Unit- - - - - - - - - - - - - - - - - - - - - - - 62
   Using HeartMate 14 Volt Lithium-Ion Batteries - - - - - - - - - - - - - - - 76
   Using the Battery Charger - - - - - - - - - - - - - - - - - - - - - - - - - 98
   Battery Charging Overview - - - - - - - - - - - - - - - - - - - - - - - 104
   Viewing Battery Information on the Battery Charger - - - - - - - - - - 108
   Calibrating HeartMate 14 Volt Lithium-Ion Batteries - - - - - - - - - - 110

4 Living with the HeartMate II - - - - - - - - - - - - - - - - - - - - - - - - 113
   Keeping Your Home Safe - - - - - - - - - - - - - - - - - - - - - - - - - 115
   Electrostatic Discharge - - - - - - - - - - - - - - - - - - - - - - - - - - 116
   Staying Active and Safe - - - - - - - - - - - - - - - - - - - - - - - - - - - 116
   Hand Washing- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 116
   Eating - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 119
   Showering - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 120
# Contents

Caring for the Driveline Exit Site .......................... 132  
Caring for the Driveline ........................................ 134  
Using the Stabilization Belt .................................. 137  
Wearing and Carrying the System Controller ............. 141  
Sleeping ........................................................... 182  
Traveling ............................................................ 184  

5 **Alarms and Troubleshooting** - - - - - - - - - - - - - - - 187  
System Controller Alarms ...................................... 189  
Mobile Power Unit Alarms .................................... 208  
Battery Charger Alarms ....................................... 210  
Guidelines for Power Cable Connectors ..................... 215  
What Not To Do: Driveline and Cables ...................... 216  

6 **Caring for the Equipment** - - - - - - - - - - - - - - - - - - - - 219  
Acceptable Operating Conditions ........................... 221  
Cleaning and Caring for the Equipment ..................... 222  
Product Disposal ................................................ 228  

7 **Frequently Asked Questions** - - - - - - - - - - - - - - - - - - - - 229  
Corporate Information ........................................... 231  
System Use ......................................................... 231  
Showers and Exercise .......................................... 233  
Travel ............................................................... 233  

8 **Handling Emergencies** - - - - - - - - - - - - - - - - - - - - - - 235  
What Is An Emergency? ....................................... 237  

9 **Testing & Classification** - - - - - - - - - - - - - - - - - - - - - - 239  
Safety Testing and Classification ............................ 241  
Declaration Concerning General Safety Standards ........ 243  
Declaration and Guidance for Electromagnetic Disturbances for the Mobile Power Unit ........................................ 246
# Contents

Testing and Classification: Battery Charger  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 251  
Declaration Concerning General Safety Standards for Battery Charger  -  - 252  
Declaration and Guidance for Electromagnetic Disturbances for Battery  
Charger  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 253  
Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries  -  -  -  -  -  -  -  -  -  - 258  
Declaration Concerning General Safety Standards for HeartMate 14 Volt  
Lithium-Ion Batteries  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 259  
Declaration and Guidance for Electromagnetic Disturbances for HeartMate II  
Powered by 14V Lithium-Ion Batteries  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 260  

## 10 Safety Checklists  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 265  
Daily Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 267  
Weekly Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 269  
Monthly Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 270  
Six Month Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 272  
Yearly Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 273  
As-Needed Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 274  
Clinic Visit Safety Checklist  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 275  

## 11 Survey  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 277  

## 12 Glossary  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 281  
Abbreviations  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 283  
Terms  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 284  

Index  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 288
INTRODUCTION

This section provides some introductory information about the HeartMate II Left Ventricular Assist Device and how to use this manual.

Why Reading This Handbook is Important - - - - - - - - - - - - - - - - - - - - - - - -3
Understanding Warnings & Cautions- - - - - - - - - - - - - - - - - - - - - - - - - - - - - -5
General Warnings - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -6
General Cautions - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -7
Equipment Overview - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -8
Why Reading This Handbook is Important

Be Informed
This handbook is about your HeartMate II 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 219).

• Review and practice emergency steps (see Handling Emergencies on page 235).

• Keep a list of emergency contacts (see Emergency Contact List on page v).
**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.

The figure above shows the following:

- Implanted HeartMate II Left Ventricular Assist Device ("heart pump")
- HeartMate batteries, with battery clips and worn in holsters (during battery-powered operation)
- Driveline (connects the pump to the System Controller) exiting the body
- HeartMate II System Controller (controls and checks the pump)
Understanding Warnings & 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 II 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.

- Before using any HeartMate II power accessory ((Mobile Power Unit (MPU), Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries)), all users (clinicians, patients, and caregivers) must be trained on their use.

- Do not take showers unless your doctor approves you for showering. If you are approved for showering, you must use the Shower Bag 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, disrupt communication, and cause the Left Ventricular Assist Device to stop. Maintaining a relative humidity level of at least 20% is acceptable. The risk for electrostatic discharge (ESD) events is increased below 20% relative humidity. 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 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 II Left Ventricular Assist System, as the device contains Ferromagnetic components. MRI may cause pump failure or injury.

\[\text{MR unsafe. Do not subject to magnetic resonance imaging.}\]

- 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.

- Do not try to repair any of the HeartMate II system components. If it seems broken or in need of service, call your hospital contact.

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 Abbott for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate II Left Ventricular Assist System and other devices.
Introduction

CAUTION !  (Continued)

- The HeartMate II 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 controller, fully-charged spare batteries, battery cables, and compatible battery clips nearby at all times in case of emergency.

- The HeartMate II Left Ventricular Assist System has been extensively tested for electromagnetic compatibility (EMC). The system will operate under normal conditions of everyday living. However, conditions and situations that can generate abnormally high levels of electromagnetic energy should be avoided. Examples are:
  - Very high currents (arc welding, industrial power generation)
  - High-powered broadcasting and communication equipment
  - High-power antenna systems
  - Industrial processes that can generate high levels of electromagnetic energy
- Risk of static discharge is increased in low humidity environments.

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 II Left Ventricular Assist Device (often called the pump) is implanted 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, that goes through the skin, connects the pump to the System Controller. For more information, see page 17. |

Table 1 System Components
| **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 users about operating status and alarm conditions.  
*For more information, see page 20.* |
|---|---|
| **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 batteries can power the system for 10–12 hours.  
*For more information, see page 76.* |
| **Mobile Power Unit** | The Mobile Power Unit plugs into an AC outlet to provide power to the HeartMate II 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 62.* |
| **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 98.* |

---

Table 1 System Components (Continued)
# Introduction

| **Stabilization Belt and Lead Locks** | The HeartMate Stabilization Belt is used to keep the driveline from moving. Reduced movement protects the exit site from tissue damage that can increase the risk of infection.  
*For more information, see page 137.* |
| **Shower Bag** | The Shower Bag is used to protect 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 120.* |
| **System Controller Neck Strap** | The System Controller Neck Strap attaches to the System Controller and is used to wear the System Controller around your neck or across the body.  
*For more information, see page 143.* |
| **Belt Attachment** | The Belt Attachment provides another way to wear the System Controller.  
*For more information, see page 147.* |

Table 1 System Components (Continued)
Consolidated Bag

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

For more information, see page 151.

Battery Holster

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

For more information, see page 164.

Holster Vest

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

For more information, see page 173.

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 162.

Protection Bag

The Protection Bag stores and protects the backup System Controller.

For more information, see page 160.

Table 1 System Components (Continued)
HOW YOUR HEART PUMP WORKS

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

Your Heart Pump - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 17
The Driveline - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 18
The System Controller - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 20
System Controller Backup Power - - - - - - - - - - - - - - - - - - - - - - - - - - - 53
The Backup System Controller- - - - - - - - - - - - - - - - - - - - - - - - - - - - 55
2 How Your Heart Pump Works
Your Heart Pump

Your heart pump is called the HeartMate II 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).

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.

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.
The Driveline

As shown in Figure 3, a thin cable (called a driveline) goes through your abdomen. It connects the pump to the System Controller.

![Figure 3 The Driveline Connects the Pump to the System Controller](image)

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

The driveline is covered with a special material. It lets skin cells grow into the driveline. Skin growth on the driveline is a barrier that can lower the risk of infection. Keeping the skin clean and dry near the driveline exit site also lowers infection risks. See Caring for the Driveline Exit Site on page 132 for details on exit site care.

“Percutaneous” means “through the skin.” You may hear this term used to describe 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.

**CAUTION !**

- To avoid pulling on or moving the driveline at the exit site, wear the HeartMate Stabilization Belt (or other abdominal binder) 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 harm or tissue damage can increase the risk of serious infection.

- 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. See **What Not To Do: Driveline and Cables** on page 216.
The System Controller

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 4).

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.
- 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:

- **System Controller Warnings and Cautions.** See page 22.

- **The System Controller User Interface.**
The System Controller user interface provides a visual display of system operations and on-screen messages that provide instructions on how to respond to alarms and other situations. See page 26.

- **The System Controller Driveline Connector.**
This section provides instructions on connecting and disconnecting the driveline. See page 32.

- **System Controller Power Cable Connectors.**
Two power cables on the System Controller (one white and one black) connect the System Controller to either the Mobile Power Unit or two 14 Volt Lithium-Ion batteries. See page 37.

- **The System Controller Self Test.**
Perform a self test daily to check the function of the System Controller’s audible and visual alarms. See page 40.

- **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 power cables. See page 42.

- **System Controller Operating Modes.**
The System Controller has three operating modes: Run, Sleep, and Charge. This section provides an overview with instructions on how to switch between modes. See page 45.
System Controller Warnings and Cautions

**WARNING !**

- Check the System Controller driveline connector often to confirm that the driveline is secure in the driveline socket. If the driveline disconnects from the System Controller, the pump will stop.

- 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.

- The System Controller may reach a maximum temperature of 124°F (51°C) if BOTH of the following conditions are present:
  - The System Controller is covered by the body or insulating material, such as a blanket
  - The internal battery is charging

  Avoid contact on bare skin under these conditions because burns may occur. A sedated or sleeping patient, especially in ICU, may not react if the System Controller becomes hot.

- 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. You may be allowed to shower, but only after sufficient driveline exit site healing and with a doctor’s permission.

- If you are approved for showering, you must always use the Shower Bag for every shower. The Shower Bag protects external system components from water or moisture. If external system components have contact with water or moisture, you may get a bad electric 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.

• Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer’s instructions.

• Malfunction of internal backup battery may cause the controller to become excessively hot. If this occurs, switch to the backup System Controller.
CAUTION !

- The System Controller uses lights, sounds, and on-screen messages to tell you how the system is running. HeartMate II 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.

- Tell your hospital contact right away if you drop the System Controller. 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. See What Not To Do: Driveline and Cables on page 216.

- 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.
  - Feeling pump vibrations.
  - Fluid oozing from the external portion of the driveline.
  - Pump stopping.

- Keep a backup System Controller and at least two fully-charged batteries with you at all times for use in an emergency.

- Confirm that a backup System Controller is programmed with settings that are the same as the running System Controller. Using a backup System Controller with settings that are not the same as the running System Controller may result in diminished support or harm.
• The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be charged 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.

• Use only those accessories specified or sold by Abbott. Do not cover the System Controller with insulating material, such as a blanket, to avoid elevated temperature.
The System Controller User Interface

The user interface on the System Controller (Figure 5) uses sounds, lights, symbols, and on-screen messages to tell you how the system is working.

![Figure 5 System Controller User Interface](image)

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.

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 189.

Table 2 introduces the main parts of the user interface. These parts are described in more detail later in this section.
### How Your Heart Pump Works

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pump Running Symbol</strong></td>
<td>The Pump Running symbol on the user interface remains illuminated green as long as the Left Ventricular Assist Device is running.</td>
<td></td>
</tr>
<tr>
<td><strong>Low Battery Alarm Symbol</strong></td>
<td>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 is a <strong>Hazard</strong> 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. <strong>For more information, see page 201.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yellow Wrench Alarm Symbol</strong></td>
<td>The yellow wrench symbol comes on when the System Controller detects a mechanical, electrical, or software issue with the system. This is an <strong>Advisory</strong> alarm. When the yellow wrench symbol comes on, follow the on-screen instructions. Do this as soon as possible. <strong>For more information, see page 189.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Red Heart Alarm Symbol</strong></td>
<td>The red heart symbol comes on for a serious condition. A red heart condition could harm or kill you if it is not fixed. This is a <strong>Hazard</strong> alarm. When the red heart symbol comes on, follow the on-screen instructions. Do this immediately or you could be seriously harmed or killed. <strong>For more information, see page 189.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Black Power Cable Alarm Symbol</strong></td>
<td>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 <strong>Advisory</strong> alarm. If this light comes on, fix the connection as soon as possible. <strong>For more information, see page 202.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>White Power Cable Alarm Symbol</strong></td>
<td>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 <strong>Advisory</strong> alarm. If this light comes on, fix the connection as soon as possible. <strong>For more information, see page 202.</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 2 System Controller User Interface
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 197.**

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 42.**

**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.

The battery button is used for the following:

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

  **For more information, see page 42.**

- **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.

  **For more information, see page 41.**

- **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 52.**
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 189).

  **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 (апример) and the display button (например) at the same time to display the last six System Controller alarms on the screen.

  For more information, see page 191.

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 (например) and the display button (например) at the same time to display the last six System Controller alarms on the screen.

For more information, see page 191.

Table 2 System Controller User Interface (Continued)
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.
### How Your Heart Pump Works

<table>
<thead>
<tr>
<th>Button Press</th>
<th>Description</th>
<th>Screen Displayed (Example)</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press</td>
<td>Press display button <strong>ONCE</strong></td>
<td>Pump Speed <strong>9200 RPM</strong></td>
<td>Pump speed in revolutions per minute (RPM)</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>SECOND</strong> time</td>
<td>Flow <strong>4.6 LPM</strong></td>
<td>Pump flow in liters per minute (LPM)</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>THIRD</strong> time</td>
<td>PI <strong>4.2</strong></td>
<td>Pulsatility Index (Pl)</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>FOURTH</strong> time</td>
<td>Power <strong>5.9 W</strong></td>
<td>Power in watts (W)</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>FIFTH</strong> time</td>
<td>Backup Battery <strong>Charged</strong></td>
<td>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: 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).</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>SIXTH</strong> time</td>
<td></td>
<td>Blank screen indicates the screen is off, which is normal.</td>
</tr>
</tbody>
</table>

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

The 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 56).

It is impossible to connect (or disconnect) the driveline without moving the driveline safety tab into the “unlocked” position. When the driveline is secure in the socket, the driveline cannot be removed without pressing the red button under the raised safety tab (Figure 7).

The System Controller continually monitors the connection status of the driveline connector. If the System Controller detects a problem, it immediately alarms. For more information, see Driveline Disconnected Alarm on page 197.
Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

• A quiet, well-lighted location where you can focus on the task
• A running System Controller
• A 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. Move the driveline connector safety tab into the unlocked position (Figure 8).

Figure 8 Unlock the Safety Tab

3. Align the arrow/alignment mark on the driveline with the arrow on the System Controller socket (Figure 9).

Figure 9 Align Arrow on Driveline With Arrow on System Controller
4. Insert the driveline into the socket (Figure 10). Press firmly until the driveline snaps into place. The pump immediately starts running when the driveline is fully and properly inserted in the socket.

**IMPORTANT!** Only a yellow alignment mark will be showing when the driveline is properly connected.

![Figure 10 Insert the Driveline Into the Socket on the System Controller](image)

5. Move the safety tab to the locked position, so it covers the red button. The safety tab cannot move to the locked position unless the driveline is fully and properly inserted.

**IMPORTANT!** If the safety tab does not fully cover the red button, the driveline is not connected. Disconnect and reconnect the driveline.

6. Tug on the inserted metal end of the driveline 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. See *Driveline Disconnected Alarm* on page 197 for details.
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:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller
- A 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. Move the driveline connector safety tab into the unlocked position ([Figure 11](#)).
3. Firmly press the red button under the safety tab, while removing the driveline from the socket ([Figure 12](#)). Grasp only the metal end. Do not pull on or bend the driveline.
How Your Heart Pump Works

**Figure 12 Remove Driveline from Socket on System Controller**

*IMPORTANT* Call your hospital contact if you are unable to remove the driveline.
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.

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 202.
During routine use, the HeartMate II 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 15** shows the Mobile Power Unit in use.

![Mobile Power Unit in Use](image)

Figure 15 Mobile Power Unit in Use
• **Two HeartMate 14 Volt Lithium-Ion batteries**: Use 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 fully charged, two HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 10–12 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 16** shows the batteries in use.

![Figure 16 Batteries in Holsters](image)

**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.

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 17).

![Figure 17 System Controller During Self Test](image)

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.
Performing a System Controller Self Test

FOR THIS TASK YOU NEED:

• A quiet, well-lighted location where you can focus on the task
• 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. 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 ( ). All the lights, symbols, and sounds should remain on for 15 seconds.
4. When the lights, symbols, and sounds turn off or stop, and the screen goes black, the System Controller self test is complete.

If an alarm occurs during a self test, the self test ends. The active alarm overrides the self test (see System Controller Alarms on page 189). A self test cannot be started during an active alarm.

If all of the lights, symbols, and sounds come on at the same time as described above, the System Controller has passed the self test.

If any of the lights remain off, or if the sounds do not work, or if they produce sounds other than a loud steady tone, there is a problem with the System Controller.

Do not use a System Controller that fails its self test. It may need to be replaced (see Replacing the Running System Controller with a Backup Controller on page 56). If the System Controller fails the self test, call your hospital contact.
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 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 18).

**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.
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 84.

On Mobile Power Unit power:

| 4 green bars | Normal Mobile Power Unit operation. |
Recognizing Low Battery Alarms

If the yellow diamond or the red battery illuminate, the system’s power level is dangerously low. This condition prompts a Low Battery Power alarm (Figure 19).

**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 203.

**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 201.

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 Changing from Batteries to Mobile Power Unit Power on page 96).
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. (Your hospital contact puts your backup System Controller into Charge Mode once every six months to maintain the backup System Controller and the charge of the backup battery).

Each mode is described in more detail below.

**Run Mode**

Run Mode is the usual mode for the running System Controller. **Figure 20** shows the System Controller in Run Mode.

**Figure 20** System Controller in Run Mode While Connected to the Mobile Power Unit (left) and to Batteries (right)

In Run Mode, the Pump Running symbol is illuminated green (🚫) 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.
2 How Your Heart Pump Works

- 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 48.

Sleep Mode
This is the usual mode for the backup System Controller. Figure 21 shows the backup 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 black (■) 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 48.

**Charge Mode**

Your hospital contact puts your backup System Controller in Charge Mode once every six months to maintain the backup System Controller and the charge of the backup battery. Figure 22 shows the System Controller in Charge Mode.

![Figure 22 System Controller in Charge Mode on Mobile Power Unit Power (left) and Using Fully-Charged HeartMate Batteries (right)](image)

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 53). It can take up to 3 hours for the backup battery to charge.

In Charge Mode, the Pump Running symbol is black (●) 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.
Switching Operating Modes

Figure 23 summarizes the steps required to switch between operating modes.

Figure 23 System Controller Operating Modes

- **Running**
  - Disconnect power source
  - Disconnect driveline
  - Hold the Battery Button for 5 seconds

- **Sleep**
  - Disconnect power source

- **Charge**
  - Connect power source
  - Connect driveline

Running:
- Connect power source
- Connect driveline

Sleep:
- Disconnect power source

Charge:
- Connect power source
Switching from Sleep Mode to Run Mode

For this task you need:
- A quiet, well-lighted location where you can focus on the task
- A 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 driveline 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 Pump Running symbol is illuminated green on the System Controller.
Switching from Sleep Mode to Charge Mode

FOR THIS TASK YOU NEED:

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

IMPORTANT! Do not perform this task without your hospital contact’s approval. Talk with your hospital contact first before performing this task.

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 (Figure 24).

   “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.
Switching from Charge Mode to Run Mode

FOR THIS TASK YOU NEED:
• A quiet, well-lighted location where you can focus on the task
• A 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 driveline 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 Pump Running symbol is illuminated green on the System Controller.

Switching from Charge Mode to Sleep Mode

FOR THIS TASK YOU NEED:
• A quiet, well-lighted location where you can focus on the task
• A 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:**
- A quiet, well-lighted location where you can focus on the task
- 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. Disconnect the driveline from the System Controller, if connected (see *Disconnecting the Driveline from the System Controller* on page 35).

2. Press and release the silence alarm button ( savory ) to silence the Driveline Disconnected alarm.

3. Disconnect the System Controller from power.

4. Press and release the silence alarm button ( savory ) to silence the Power Cable Disconnected alarm.

5. Press and hold the battery button ( savory ) 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 ( savory ) until the countdown ends.

7. After five seconds, the screen goes black. The System Controller is now in Sleep Mode.
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 backup System Controller must be charged 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.
2 How Your Heart Pump Works

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 or she will talk with you about the reasons for this.

Your running System Controller automatically monitors and charges its backup battery while it is connected to power (either the Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). You can check the backup battery charge status on your running System Controller by pressing the display button five times to get to the backup battery status screen (see Viewing Pump and System Information on the Screen on page 30).

Your backup System Controller also has a backup battery that periodically needs to be charged because the backup battery loses power when the System Controller is not connected to power. That is why your hospital contact needs you to bring your backup System Controller to him or her once every six months so that it can be checked for readiness and charged.
The Backup System Controller

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

The backup System Controller 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, keep the backup System Controller with you at all times.

<table>
<thead>
<tr>
<th>Running System Controller</th>
<th>Backup System Controller</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Running System Controller" /></td>
<td><img src="image2" alt="Backup System Controller" /></td>
</tr>
<tr>
<td><strong>On Mobile Power Unit</strong></td>
<td><strong>If needed, ready to use</strong></td>
</tr>
<tr>
<td><img src="image3" alt="On Mobile Power Unit" /></td>
<td></td>
</tr>
<tr>
<td><img src="image4" alt="On Batteries" /></td>
<td><strong>Backup is not connected to:</strong></td>
</tr>
<tr>
<td><img src="image5" alt="On Batteries" /></td>
<td>• Power</td>
</tr>
<tr>
<td></td>
<td>• Driveline</td>
</tr>
</tbody>
</table>
Replacing the Running System Controller with a Backup Controller

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

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A backup System Controller, programmed to match the settings on the running System Controller
- A running System Controller, connected to a power source (either Mobile Power Unit or 14 Volt Lithium-Ion batteries and clips)
- Optional: a power source in addition to the in-use power source (either Mobile Power Unit or 14 Volt Lithium-Ion batteries and clips)

**IMPORTANT!** If at all possible, 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 if instructed.

**TASK**
1. **Setup:**
   a. Place the backup System Controller within reach.
   b. Sit or lie down (you may get dizzy if the pump briefly stops).
   c. Unlock the driveline safety tab on the running System Controller ([Figure 25](#)).

![Figure 25 Unlock the Safety Tab on the Running System Controller](image)
2. Replace the System Controller.

<table>
<thead>
<tr>
<th>With In-use Power Source Only (Mobile Power Unit OR Batteries and Clips)</th>
<th>Multiple Power Sources Available (Mobile Power Unit AND Batteries and Clips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Move the <strong>white</strong> connector’s power source from the running controller to the backup System Controller. <strong>IMPORTANT!</strong> Keep the running System Controller connected to power. b. Promptly move the driveline from the running controller to the backup System Controller. <strong>IMPORTANT!</strong> Before inserting, align the marking on the driveline with the arrow on the System Controller.</td>
<td><strong>IMPORTANT!</strong> Keep the running System Controller connected to power. a. Connect both the white and black connectors on the backup System Controller to power. b. Promptly move the driveline from the running controller to the backup System Controller. <strong>IMPORTANT!</strong> Before inserting, align the marking on the driveline with the arrow on the System Controller.</td>
</tr>
<tr>
<td><strong>For more information, see</strong> Powering the System on page 59. <strong>For more information, see</strong> Powering the System on page 59.</td>
<td><strong>For more information, see</strong> Powering the System on page 59. <strong>For more information, see</strong> Powering the System on page 59.</td>
</tr>
<tr>
<td></td>
<td>• The System Controller Driveline Connector on page 32 • Connecting the Driveline to the System Controller on page 33 • Disconnecting the Driveline from the System Controller on page 35</td>
</tr>
<tr>
<td>c. Move the <strong>black</strong> connector’s power source from the running controller to the backup System Controller.</td>
<td>c. Disconnect the old, replaced System Controller from power.</td>
</tr>
</tbody>
</table>
3. The backup System Controller is now running with the driveline connected and both power cables connected to power.

**IMPORTANT!** When the driveline is connected to the backup System Controller, the controller will alarm and then clear. This is normal. The pump will start, the Pump Running symbol will be illuminated green ( ), and you can access system information by pressing the display button ( ). If the Pump Running symbol is black ( ), check:

- The driveline to make sure it is fully inserted into the controller. Tug on the metal end of the driveline to make sure it is connected.

- That the System Controller’s black and white power cables are connected to a working power source.

4. Lock the driveline safety tab on the backup System Controller. The safety tab cannot move to the locked position unless the driveline is fully and properly inserted. If the driveline safety tab will not lock, align the driveline and firmly press it into the System Controller until it snaps into place (Figure 26).

![Figure 26 Lock the Safety Tab on the Backup System Controller]

5. Put the old, replaced System Controller into Sleep Mode by pressing and holding the battery button ( ) for five seconds.

   **See Switching from Run Mode to Sleep Mode on page 52.**

6. Do not use the old, replaced System Controller ever again. Contact your hospital contact to request a new backup System Controller and for instructions on returning the old one.
POWERING THE SYSTEM

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

- Power Overview - 61
- Using the Mobile Power Unit - 62
- Using HeartMate 14 Volt Lithium-Ion Batteries - 76
- Using the Battery Charger - 98
- Battery Charging Overview - 104
- Viewing Battery Information on the Battery Charger - 108
- Calibrating HeartMate 14 Volt Lithium-Ion Batteries - 110
Power Overview

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 10–12 hours, depending on your activity level.

See page 76.

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 62.

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 98.
3 Powering the System

Using the Mobile Power Unit

The Mobile Power Unit (Figure 27):

• 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 189).

Required Components

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

• A Mobile Power Unit with batteries inserted
• A Mobile Power Unit AC power cord
• A running System Controller

Figure 27 The Mobile Power Unit
**WARNING !**

- The Mobile Power Unit is intended for use with the System Controller REF:105109 or a system controller with a serial number beginning with “PC.” Connecting a version of the System Controller REF:103696, REF:105472, or a system controller with a serial number beginning with “EPC” or “PSD” will cause a low voltage alarm. The pump will stop if there is a loss of power to the Mobile Power Unit while it is connected to the System Controller REF:103696, REF:105472, or a system controller with a serial number beginning with “EPC” or “PSD.”

Compatible with Mobile Power Unit

![System Controller REF:105109 or a system controller with a serial number beginning with “PC.”](image)

NOT Compatible with Mobile Power Unit

![System Controller REF:103696, REF:105472, or a system controller with a serial number beginning with “EPC” or “PSD.”](image)

- 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, unplug the Mobile Power Unit and observe the effect on devices in the area. If interference is detected, switch to battery power 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.

- You must always connect to the Mobile Power Unit when sleeping, or when there is a chance of sleep. You may not hear the system alarms when you are 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.
### Powering the System

#### WARNING! (Continued)

- 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 you transfer to batteries. Do not rely on the 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 (see Switching Power Sources on page 94).

- 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 you may get an electric 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.

#### 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.

- 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.
**CAUTION !  (Continued)**

- 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).

- 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 (see Switching Power Sources on page 94).

- 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 alkaline 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 Abbott. 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.
3 Powering the System

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.

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:

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

IMPORTANT! 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.

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 28).

![Figure 28 Loosen the Screw](image)

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 29).

![Figure 29 Remove the Battery Compartment Cover](image)

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

7. Place the Alkaline AA batteries in the battery compartment. Orient the batteries as shown on the orientation markings on the battery clip (Figure 30).
3 Powering the System

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 31).

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:

• A quiet, well-lighted location where you can focus on the task
• A Mobile Power Unit
• A 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 32).

Figure 32 Plug Power Cord into Mobile Power Unit

4. Plug the Mobile Power Unit into an AC electrical outlet that is dedicated to Mobile Power Unit use. Do not use an outlet that is controlled by a wall switch. Do not use portable, multiple outlet (power strip) adapters.
5. Check the top panel of the Mobile Power Unit. When initially connected to power, the Mobile Power Unit automatically performs a self test, all the lights flash, and the Mobile Power Unit beeps twice. After the self test, the green "Power On" light should remain lit (Figure 33). The Mobile Power Unit is ready for use.

**Figure 33 Mobile Power Unit Ready for Use**

**Note:** If the green “Power On” light does not come on, try another electrical outlet. If the green light still does not come on, the Mobile Power Unit may have a problem. Do not use it. Call your hospital contact.

**IMPORTANT** The power symbol (🔴) is illuminated green when the Mobile Power Unit is powered and functioning properly.
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 controller’s alarms. If it is not echoing alarms, the Mobile Power Unit may have a problem. Do not use it. For steps on getting ready for sleep, see Sleeping on page 182.

You need the Mobile Power Unit patient cable (Figure 34) to connect the System Controller to the Mobile Power Unit.

Figure 34 Mobile Power Unit Patient Cable

Do not kink or sharply bend the 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 34). 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 215.
Connecting the System Controller to the Mobile Power Unit

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller
- A Mobile Power Unit that is ready for use
- A 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 66).
3. Place the black and white System Controller power cable connectors within easy reach ([Figure 35](#)).

![Figure 35 System Controller Power Cable Connectors](image)

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!
7. Promptly align opposite half circles inside the white System Controller power cable connector and the white Mobile Power Unit patient cable connector (*Figure 36*). Do not try to join together misaligned connectors, which can damage them.

*Figure 36 Carefully Align the Connectors*

8. Firmly push together the two connectors (*Figure 37*).

*Figure 37 Push Together the Two Connectors*

9. Tighten the connector nut until secure (*Figure 38*). Hand tighten only—do not use tools.

*Figure 38 Tighten the Connector Nut*
3 Powering the System

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. Do not try to join together misaligned connectors, which 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 39).

Figure 39 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 (Figure 40). This also a convenient way to prepare the device and patient cable for travel.

Figure 40 Storing the Mobile Power Unit

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 225.

**IMPORTANT!** Periodically, and as needed, use a clean, damp (not wet) cloth to clean the exterior surfaces of the Mobile Power Unit. You may use a mild detergent, if necessary. Do not put the Mobile Power Unit into water or liquid. Never clean the Mobile Power Unit while it is providing power to your pump; switch to battery power first. Before cleaning the Mobile Power Unit, unplug all connections.
3 Powering the System

Using HeartMate 14 Volt Lithium-Ion Batteries

HeartMate batteries (Figure 41) are the other routine power source for the HeartMate II Left Ventricular Assist System.

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 42).
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 II Left Ventricular Assist System. See About the HeartMate 14 Volt Lithium-Ion Batteries on page 80.

**WARNING !**

- Use only Abbott-supplied HeartMate 14 Volt Lithium-Ion batteries with the HeartMate II Left Ventricular Assist System. Using the wrong batteries may cause the pump to stop.

- You must charge HeartMate 14 Volt Lithium-Ion batteries before you use them. Before you remove a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After you remove the battery from the charger, use the battery power gauge to check the battery charge level.

- Use only Abbott-supplied 14 Volt battery clips 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.

- Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer’s instructions.
CAUTION!

- Use only the Abbott-supplied Battery Charger 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 recalibrated. The Battery Charger indicates when a battery needs recalibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted, to prevent a backlog of uncalibrated batteries. See Calibrating HeartMate 14 Volt Lithium-Ion Batteries on page 110.

- 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. See Caring for HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips on page 226.

- 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 your skin or eyes, wash the affected area with plenty of water and seek medical advice.
CAUTION! (Continued)

- To prevent deterioration or damage to a 14 Volt Lithium-Ion backup 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 because it will only power the pump for a limited amount of time.
Powering the System

About the HeartMate 14 Volt Lithium-Ion Batteries

Two new HeartMate 14 Volt Lithium-Ion batteries provide ten to twelve 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 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 84).

**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 84).

See *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 106 for instructions on charging HeartMate batteries.
Using Battery Clips
To transfer power to the System Controller, two HeartMate batteries must be placed into special battery clips (Figure 43). 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 43 HeartMate 14 Volt Lithium-Ion Battery and 14 Volt Battery Clip

Power cable connectors on the System Controller connect to each battery clip (Figure 44). In this way, battery power is supplied to the System Controller through the power cables.

Figure 44 The System Controller Power Cable Attaches to the Battery Clip
3 Powering the System

Inserting a HeartMate Battery into a Battery Clip

FOR THIS TASK YOU NEED:

• A 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 45).

Figure 45 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.
Removing a HeartMate Battery from a Battery Clip

FOR THIS TASK YOU NEED:

- A 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 46) and withdraw the 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.
Powering the System

Checking a Battery’s Charge Level

After a HeartMate battery is charged, (see Charging HeartMate 14 Volt Lithium-Ion Batteries on page 106), 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 47). 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.

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- A Battery Charger
- A 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.
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.

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

7. If all five green power gauge bars light up, the battery is between 80%–100% charged.

If four or fewer bars come on, the battery is not fully charged. Return it 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. Contact your hospital contact for a replacement, if needed.

**Table 4** describes the on-battery power gauge on a 14 Volt Lithium-Ion battery.

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

**Table 4 14 Volt Lithium-Ion Battery On-Battery Power Gauge**
3 Powering the System

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

**IMPORTANT!** A green light next to the Battery Charger pocket is the only assurance that a battery in the 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.

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.

**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.
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:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 HeartMate 14 Volt battery clips
- A 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 48).

Figure 48 Insert Battery into Battery Clip
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 49).

![Figure 49 System Controller Power Cables with Black and White Connectors](image)

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 50). Do not try to join together misaligned connectors, which can damage them.

![Figure 50 Carefully Match the Connectors](image)

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. Do not try to join together misaligned connectors, which 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 51)*.

See *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 76 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.

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 in an effort to provide the maximum amount of operating time from the remaining battery capacity. Running at reduced speed is a critical situation. You may become dizzy or short of breath. It is important that you switch to a new pair of charged batteries or to the Mobile Power Unit right away.

The Left Ventricular Assist System remains in Power Saver Mode until fresh batteries are installed, the Mobile Power Unit is connected, or until no further power remains. The red battery hazard alarm requires an immediate response. Immediately switch 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.
Replacing Low Batteries with Fully-Charged Batteries

**FOR THIS TASK YOU NEED:**
- A 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
- 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. 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 52); 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 52) on the 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.
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 53).

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.
**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 comes on, along with a continuous audio tone.

Running at reduced speed is a critical situation. You may become dizzy or short of breath. It is important that you switch to two new fully-charged batteries or the Mobile Power Unit immediately. Switching 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 changing batteries or switching to a different power source, call your hospital contact. You may need to replace the System Controller or the Mobile Power Unit patient cable.

**Caring for 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 226.

**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 215.

FOR THIS TASK YOU NEED:
• A quiet, well-lighted location where you can focus on the task
• A running System Controller
• A working, in-use Mobile Power Unit with its batteries installed
• 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.

<table>
<thead>
<tr>
<th>TASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gather equipment listed above; place within easy reach.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>3. Pull gently on the battery to confirm that the connection is tight.</td>
</tr>
<tr>
<td>4. Repeat Steps 2–3 for the second battery and battery clip.</td>
</tr>
<tr>
<td>5. Place the batteries with attached battery clips within easy reach.</td>
</tr>
</tbody>
</table>

Figure 54 Insert Battery into Battery Clip
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. Put aside the white Mobile Power Unit patient cable connector.

9. 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 55). Do not try to join together misaligned connectors, which can damage them. The alarm will stop when the white System Controller power cable is connected.

10. Firmly push together the two connectors.

11. Tighten the connector nut until secure. Hand tighten only—do not use tools.

12. 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.

13. Put aside the black Mobile Power Unit patient cable connector.

14. 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. Do not try to join together misaligned connectors, which can damage them. The alarm will stop when the black System Controller power cable is connected.

15. 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 141).

16. Place at least two additional fully-charged batteries in your travel case.

**Note:** Make sure you store the Mobile Power Unit patient cable so 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 215.

For this task you need:

- A quiet, well-lighted location where you can focus on the task
- A running System Controller connected to battery power
- 2 HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- A Mobile Power Unit power cord
- A Mobile Power Unit that is ready for use (see Setting Up the Mobile Power Unit for Use on page 66)

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 plugged into an AC electrical outlet. Make sure that nothing else is plugged into the same outlet. Make sure the outlet is not controlled by a wall switch. Do not use an adapter plug or a power strip, or you may receive an electric shock or the pump may 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.
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 84).
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.

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.

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 106).
Using the Battery Charger

The Battery Charger (Figure 56) 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 106).
- Determine when a 14 Volt Lithium-Ion battery needs calibration.
- Calibrate a 14 Volt Lithium-Ion battery (see Calibrating HeartMate 14 Volt Lithium-Ion Batteries on page 110).
- 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 108).
**WARNING!**

- The HeartMate 14 Volt Lithium-Ion batteries must be charged before use. Before you remove a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After you remove the battery from the 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 Abbott. 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 electric shock, the Battery Charger must be plugged into a properly-tested and grounded (3-prong) AC electrical 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.

- 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 you may get an electric shock.

- Do not touch the metal contacts inside the Battery Charger when the charger is connected to AC power and turned on or you may get an electric shock.
3 Powering the System

**CAUTION !**

- Use only the Abbott-supplied Battery Charger 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, cleaning, and inspection. Service and maintenance of the Battery Charger should be performed only by Abbott-trained personnel.

- 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!
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:**

- A quiet, well-lighted location where you can focus on the task
- A Battery Charger
- An 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.
6. Plug the female end of the power cord into the power entry module on the rear of the charger (Figure 57). Make sure the cord is fully inserted and secure.

7. Plug the charger into a properly-tested AC electrical outlet that is dedicated to 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.

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 58). The charger beeps once and performs a self test for about 10 seconds.
9. After a successful self test, all lights turn off and "HeartMate CHARGER" appears on the display panel (Figure 59). The charger is ready for use.

![Figure 59 The Battery Charger is Ready to Use]

OR

If the charger detects a problem, an error message appears on the display panel (Figure 60) 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 214 for information on how to respond to advisory messages.

![Figure 60 An Error Message on the Battery Charger]

**IMPORTANT!** If you will be traveling internationally, you will need an Abbott power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Contact 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 a "smart" technology that measures available battery power and counts battery usage/charge cycles. When a battery is placed in a charging pocket (Figure 61), 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 61 Batteries Inserted in Battery Charger Pockets for Charging
Depending on the status of the battery, a green, yellow, or red light is illuminated next to the pocket (Figure 62). 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 5 for a description of charger pocket light codes.

![Figure 62 A Green Light Indicates that the Battery is Charged](image.png)

<table>
<thead>
<tr>
<th>Color</th>
<th>Status/ Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Green</strong></td>
<td>Battery is charged and ready for use.</td>
</tr>
<tr>
<td><strong>Yellow</strong></td>
<td>Battery is undergoing charge, test, or calibration.</td>
</tr>
<tr>
<td><strong>Yellow (Blinking)</strong></td>
<td>Battery requires calibration.</td>
</tr>
<tr>
<td><strong>Red</strong></td>
<td>Battery or charging pocket is defective. Do not use battery.</td>
</tr>
</tbody>
</table>

*Table 5 Description of Battery Charger Pocket Lights*
Charging HeartMate 14 Volt Lithium-Ion Batteries

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A Battery Charger, set up for use (see *Setting Up the Battery Charger Before Use* on page 101)
- 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 63).

![Figure 63 The Battery Charger Can Charge Four Batteries at a Time](image)

**Note:** Avoid covering or blocking the vents on the top of the charger during use. Covering or blocking the vents may affect 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 14 Volt Lithium-Ion Batteries on page 110.
   - 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 214 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 212 for information on how to handle red light conditions.

5. Repeat Steps 2–4 for up to three more batteries.
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 64).

Figure 64 View Battery Charge Level Information on the Battery Charger
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 65):

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

Figure 65 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 14 Volt Lithium-Ion Batteries

HeartMate 14 Volt Lithium-Ion batteries use a "smart" 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 66). The circled number switches between a filled and unfilled circle as the display panel screen flashes.

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.
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 67).

Figure 67 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 calibrate the battery 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: You should calibrate a battery as soon as possible after being prompted to do so, to ensure the best possible battery performance. Be sure to have enough fully-charged batteries available before you begin calibration, which can take up to 12 hours. Under normal conditions, you should have four fully-charged batteries available so that you can exchange batteries twice during a 12-hour calibration cycle.
LIVING WITH THE HEARTMATE II

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

Keeping Your Home Safe - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 115
Staying Active and Safe - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 116
Hand Washing - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 116
Eating - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 119
Showering- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 120
Caring for the Driveline Exit Site - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 132
Caring for the Driveline- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 134
Using the Stabilization Belt - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 137
Wearing and Carrying the System Controller- - - - - - - - - - - - - - - - - - - - - - - - - - - - 141
Sleeping- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 182
Traveling - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 184
4 Living with the HeartMate II
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.
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. Maintaining a relative humidity level of at least 20% is acceptable. The risk of electrostatic discharge (ESD) events is increased below 20% relative humidity. 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 should you 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.

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 growing on it)

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

<table>
<thead>
<tr>
<th>TASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gather supplies; place within easy reach.</td>
</tr>
<tr>
<td>2. Use a clean, dry paper towel to turn on the faucet(s) for clean, running water.</td>
</tr>
<tr>
<td>3. Wet your hands and wrists with clean, running water.</td>
</tr>
<tr>
<td>4. Apply soap to hands.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>6. Rinse well under a stream of clean, running water. Point fingers, hands, and wrists down so water carries away dirt and microbes.</td>
</tr>
<tr>
<td>7. Use a new paper towel to dry hands.</td>
</tr>
<tr>
<td>8. Use a paper towel to turn off the faucet. Do not touch the faucet with your clean hands.</td>
</tr>
</tbody>
</table>
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. This keeps the dispenser from becoming a breeding ground for microbes.
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.
Showering

Although the external components of the HeartMate II 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 an 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 68).
The Shower Bag (Figure 69) 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.
WARNING!

- Never swim or take tub baths while you have the pump. Immersion in water will cause the pump to stop.

- You may be able to shower, but only after the exit site has healed and if your doctor gives permission. Do not shower without your doctor’s approval.

- If you are 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.

- While in the Shower Bag for an hour or more, the System Controller may reach temperatures as high as 120°F (49°C). Avoid contact on bare skin under these conditions because burns may occur. After opening the Shower Bag, wait for at least 4 minutes before handling the System Controller.
### CAUTION!

- **To avoid pulling on or moving the driveline at the exit site, the patient must wear the HeartMate Stabilization Belt (or other abdominal binder) 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 harm or tissue damage can increase the risk of serious infection.

- **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. See [What Not To Do: Driveline and Cables](#) on page 216.

- **Keep the exit site as clean and dry as possible** (see [Caring for the Driveline Exit Site](#) on page 132).

- **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 II equipment in the wearable accessories.** Placing objects other than HeartMate II equipment in a wearable accessory may damage the accessory.
Assembling the Shower Bag

FOR THIS TASK YOU NEED:
• A Shower Bag
• A Shower Bag shoulder strap
• A 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 70).

![Figure 70 Attach the Shoulder Strap to the Shower Bag](image)

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 71).

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

![Figure 71 Slide the Belt Through the Loop on the Side of the Shower Bag](image)

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:**
- An assembled Shower Bag that is clean and dry
- A 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 72](#)).

   ![Figure 72 Make Sure the Power Cables and Driveline are Not Twisted](image)

3. Unclip the top cover of the Shower Bag by squeezing the clip prongs together and sliding the clip out of the buckle ([Figure 73](#)).

   ![Figure 73 Open the Clip and Buckle on the Top of the Shower Bag](image)
4. Pull back the top lid to reveal the double zipper (Figure 74).

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

6. Place the batteries and battery clips with attached power cables into the Shower Bag (Figure 75).

Figure 74 Open the Shower Bag

Figure 75 Place Batteries and Clips in the Shower Bag
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 76).

8. Prepare to close the cover by positioning the power cables inside the water resistant enclosure (Figure 77).
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 78).

Figure 78 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 79).

Figure 79 The Driveline Exiting a Closed Shower Bag
11. Snap the clip into the buckle to secure the lid (Figure 80).

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:**
- A Shower Bag loaded with batteries and System Controller
- A large, clean, dry towel to dry your body
- A small, clean, dry towel to dry the Shower Bag
- 4 in x 4 in (10.2 cm x 10.2 cm) sterile gauze bandages to dry the exit site
- 1 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 aseptic technique (see *Caring for the Driveline Exit Site* on page 132).
7. Use a clean, dry towel to dry the Shower Bag’s exterior and strap.
8. Open the Shower Bag using the clip and buckle for the lid, and the left and right zippers for the top (Figure 81).

Figure 81 Open the Clip and Buckle

9. Wait 4 minutes before handling the System Controller to allow it time to cool.

10. Remove all equipment from the enclosure; place the equipment in a clean, dry location.

11. 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 141).

12. 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 222 for complete instructions on caring for all wearable accessories, including the Shower Bag.
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.

Aseptic 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 “aseptic 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.

**CAUTION !**

- 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.
- To avoid pulling on or moving the driveline at the exit site, wear the HeartMate Stabilization Belt (or other abdominal binder) 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 harm or tissue damage can increase the risk of serious infection.
- 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. See What Not To Do: Driveline and Cables on page 216.
- Keep the driveline exit site as clean and dry as possible. A clean, dry exit site reduces the risk of infection.
Rules for Exit Site Care

• Follow strict “aseptic 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 116).

• Keep the driveline exit site clean and dry.

• Wash the driveline exit site daily. Use the cleanser prescribed by your doctor and follow the steps taught by your hospital contact.

• After washing the driveline exit site, dry it completely. Use only sterile gauze bandages to dry the driveline exit site.

• Apply a sterile gauze bandage to the driveline exit site every time after cleaning it. Follow the steps taught by your hospital contact.

• Never put ointments or creams on the driveline exit site, unless your doctor or hospital contact tells you to.

• Try to not pull on or move the driveline that goes through your skin.

• Wear the HeartMate Stabilization Belt (or other abdominal binder) at all times to keep the driveline in place. The Stabilization Belt reduces pulling on or moving the driveline (see Caring for the Driveline on page 134).

• Check the driveline exit site daily for signs of infection, including:
  - Redness
  - Swelling
  - Drainage or bleeding
  - Bad smell
  - Feeling feverish, tired, or unwell

IMPORTANT! If you notice any signs of infection, call your hospital contact right away. Do not wait! Early treatment makes a difference.
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 pump will stop if the driveline is disconnected from the System Controller. If the driveline disconnects from the System Controller, promptly reconnect it 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.

- 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.
**CAUTION!**

- Do not kink or sharply bend the driveline. Kinks or sharp bends can damage the wires inside, even if damage is not visible. Damage to the driveline may cause the pump to stop.

- Do not twist the driveline. Check the driveline often for twisting. Severe twisting could cause damage to the wires inside, even if 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 reduce pulling on or moving the driveline, you must wear the Stabilization Belt (or other abdominal binder) at all times (see Putting on the Stabilization Belt on page 139).

- The Stabilization Belt is not sterile. You must bandage the driveline exit site before putting on the Stabilization Belt.

- Report any redness or skin irritation that is caused by wearing the Stabilization Belt.

- Call your hospital contact if you notice any change 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 you change positions.
  - 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, kink, or twist the driveline (What Not To Do: Driveline and Cables on page 216).
- 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 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 driveline connector is fully inserted in the System Controller socket, gently tug on the metal end of the connector. Do not pull on the driveline.
- Wear the HeartMate Stabilization Belt (or other binder) at all times to keep the driveline in place and to prevent pulling on or moving it.
- 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).
Using the Stabilization Belt

The HeartMate Stabilization Belt (or other binder) keeps the driveline from moving. This is very important. Reduced movement protects the exit site from tissue damage that can increase the risk of infection. Wear the Stabilization Belt (or other binder) at all times (Figure 82).

Figure 82 The HeartMate Stabilization Belt and Lead Locks

Stabilization Belt

Lead Locks

Figure 83 Wearing the Stabilization Belt
**CAUTION!**

- The HeartMate Stabilization Belt is not sterile. The exit site must be bandaged before applying the Stabilization Belt. See *Caring for the Driveline Exit Site* on page 132.

- Report any redness or skin irritation that occurs as a result of wearing the belt.

- The Stabilization Belt must be worn at all times to reduce pulling or movement of the driveline. Pulling on and moving the driveline, especially as the skin exit site is healing, could prolong the healing process or interrupt an already healed driveline exit site. Tissue trauma at the driveline exit site could increase the risk of serious infection.

- Do not use bleach when washing the Stabilization Belt. Exposure to bleach may cause premature breakdown of the Stabilization Belt material.

- If the Stabilization Belt gets dirty, wash it by hand using a non-bleach detergent. Allow the Stabilization Belt to air dry on its own. Never use heat to dry the belt. Drying the Stabilization Belt at high temperatures may cause premature breakdown of the Stabilization Belt material. Make sure the Stabilization Belt is completely dry before using it.
Putting on the Stabilization Belt

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- A running System Controller
- A HeartMate Stabilization Belt
- 3–6 Stabilization Belt lead locks to secure the driveline to the Stabilization 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. If you have not already done so, bandage the driveline exit site using aseptic technique (see Caring for the Driveline Exit Site on page 132). The driveline exit site must be bandaged before putting on the Stabilization Belt.
3. Wrap the lower strap of the Stabilization Belt around your waist, below the driveline exit site.
4. Wrap the upper strap of the Stabilization Belt around your waist, above the driveline exit site. The driveline should exit between the two straps.
5. Apply a lead lock flat to the belt, on the right side of the driveline—the wide end of the lock should point toward your left side.
6. Gently place the driveline over the center of the lead lock (Figure 84).

Figure 84 Gently Place the Driveline Over the Lead Lock
7. Pick up the tab on the narrow end of the lead lock, and then:
   a. Wrap the tab around the driveline.
   b. Insert the tab through the square slot on the lead lock (Figure 85).
   c. Repeat Steps a–b with as many lead locks as needed to securely fasten the driveline to the belt.

8. Attach the tab to the Stabilization Belt (Figure 86). If needed, adjust the tab for a snug fit.
Wearing and Carrying the System Controller

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

Figure 87 Accessories to Hold or Carry External Parts of the System

- Protection Bag: See page 160.
- Belt Attachment: See page 147.
- Battery Holster: See page 164.
- Holster Vest: See page 173.
- Consolidated Bag: See page 151.
- System Controller Neck Strap: See page 143.
- Travel Bag: See page 162.
The wear and carry accessories are described in the table below.

<table>
<thead>
<tr>
<th>Wear and Carry Accessory</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Controller Neck Strap</strong></td>
<td>Worn around the neck or across the body; holds the System Controller when connected to the Mobile Power Unit or during battery-powered operation.</td>
</tr>
<tr>
<td><strong>Belt Attachment</strong></td>
<td>Worn around the waist, on a belt; holds the System Controller when connected to the Mobile Power Unit or during battery-powered operation.</td>
</tr>
<tr>
<td><strong>Protection Bag</strong></td>
<td>Stores and protects the backup System Controller.</td>
</tr>
<tr>
<td><strong>Travel Bag</strong></td>
<td>Worn on a shoulder. Stores the Protection Bag and a spare set of batteries.</td>
</tr>
<tr>
<td><strong>Consolidated Bag</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Battery Holster</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Holster Vest</strong></td>
<td>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).</td>
</tr>
</tbody>
</table>

Using these accessories, you can be active because the accessories comfortably and safely hold and 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 88) allows you to carry the System Controller around your neck or across your body. It attaches to the System Controller with two small straps.

The System Controller has four attachment points (Figure 89)—one in each corner of the casing. The Neck Strap uses two attachment points for hanging the System Controller vertically or horizontally (Figure 90).
Putting On the System Controller Neck Strap

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller on Mobile Power Unit power
- A 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 91).*

*Figure 91 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.

5. Slide the rubber strap on the Neck Strap through the first attachment point on the System Controller (Figure 92).

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 93).

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 94).
8. Repeat Steps 5–7 to attach the second strap to another attachment point on the System Controller.

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 the Neck Strap and System Controller on a flat, stable surface.

3. Unbuckle the Neck Strap tabs and remove the Neck Strap from the System Controller.

4. Store the Neck Strap in a clean, dry location (see *Acceptable Operating Conditions* on page 221).
The Belt Attachment

The Belt Attachment accessory (Figure 95) 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 95 Belt Attachment

Putting on the Belt Attachment

FOR THIS TASK YOU NEED:

• A quiet, well-lighted location where you can focus on the task
• A running System Controller on Mobile Power Unit power
• A 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 96](#)).

![Figure 96 Make Sure the Power Cables and Driveline are Not Twisted](image)

3. Slide either your belt or the nylon clip belt through the loop on the back of the Belt Attachment ([Figure 97](#)).

![Figure 97 Slide the Belt Through the Loop on the Belt Attachment](image)

4. Unclip the two-banded strap on the Belt Attachment.
5. Slide the System Controller, cable-free end first, into the Belt Attachment with the display screen facing out (Figure 98).

![Figure 98 Slide the System Controller Into the Belt Attachment](image)

6. Place the two-banded strap over the System Controller and between the white System Controller power cable connector and the driveline connector (Figure 99).

![Figure 99 Place the Strap Between the Connectors](image)

7. Clip the two-banded strap into place (Figure 100). Make sure both prongs are fully engaged in the clip.

![Figure 100 Clip the Strap Into Place so the System Controller is Secure](image)
8. Fasten the belt and Belt Attachment around your waist. Adjust and tighten the belt as necessary.

**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 101) to carry the System Controller, batteries, and battery clips together in a single place while using the batteries.

![Figure 101 Consolidated Bag](image)

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.
The Consolidated Bag is worn across the body (see Figure 102) 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 102 Wearing the Consolidated Bag
Assembling the Consolidated Bag

FOR THIS TASK YOU NEED:

- A Consolidated Bag with belt
- A 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 103).

3. Put the bag on to confirm the appropriate placement on your left or right side.

   IMPORTANT! 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.
Putting On the Consolidated Bag

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller on battery power
- An 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 104).

![Figure 104 Make Sure the Power Cables and Driveline are Not Twisted](image)

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 105).

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 106).
6. Place the first battery into the Consolidated Bag, with the battery clip and cable facing out (Figure 107).

Figure 107 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 108).

Figure 108 Carefully Position the Power Cable Around the Edge of the Bag
8. Place the second battery into the Consolidated Bag, with the battery clip and cable facing out (Figure 109).

9. Arrange the power cables so that they lay flat along the edge of the bag (Figure 110).
10. Carefully close the Consolidated Bag, with the System Controller power cables inside the bag and the driveline between the protective red tabs (Figure 111).

**Figure 111 Close the Bag so the Driveline Exits Between the Red Tabs**

11. Zip the Consolidated Bag closed (Figure 112).

**Figure 112 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:

- A quiet, well-lighted location where you can focus on the task
- A 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.
   OR
   - Transfer from battery power to Mobile Power Unit power (see Changing from Batteries to Mobile Power Unit Power on page 96).
   OR
   - Remove the components and transfer to another wearable accessory.
7. Store the Consolidated Bag in a clean, dry location.
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 113).

Figure 113 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:

- A quiet, well-lighted location where you can focus on the task
- A Protection Bag
- A 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.

<table>
<thead>
<tr>
<th>TASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unzip the Protection Bag.</td>
</tr>
<tr>
<td>2. Slide the backup System Controller into the Protection Bag.</td>
</tr>
</tbody>
</table>

**IMPORTANT!** When placing the System Controller inside the Protection Bag, do not twist, kink, or sharply bend the System Controller power cables, which may cause damage to the wires inside, even if external damage is not visible. If the cables become twisted, kinked, or bent, carefully unravel and straighten. See What Not To Do: Driveline and Cables on page 216.

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.
The Travel Bag

The Travel Bag provides an easy way to keep your backup System Controller and spare batteries with you at all times.

Storing Items in the Travel Bag

FOR THIS TASK YOU NEED:

• A quiet, well-lighted location where you can focus on the task
• A Protection Bag with backup System Controller and power cables stored inside
• 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
• A 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 114).

Figure 114 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 115).

Figure 115 Store the Batteries Inside the Travel Bag
The Battery Holster

Use the Battery Holster (Figure 116) 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 116 Battery Holster
The Belt Attachment can be used with the Battery Holster to protect and cover the System Controller (Figure 117).

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 170.
Assembling the Battery Holster

FOR THIS TASK YOU NEED:
• A quiet, well-lighted location where you can focus on the task
• A Battery Holster
• A pair of large, sharp scissors
• A 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.

<table>
<thead>
<tr>
<th>TASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gather equipment; place within easy reach.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>3. Slide your arms through the straps, so that the fabric connector is between your shoulder blades on your back.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>5. After determining appropriate fit, cut off or trim the extra length from the end of each strap.</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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:
- A running System Controller on Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- A Battery Holster
- A Belt Attachment
- A 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.

<table>
<thead>
<tr>
<th>TASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gather equipment; place within easy reach.</td>
</tr>
<tr>
<td>2. Make sure that the System Controller power cables and driveline are not twisted (Figure 118).</td>
</tr>
</tbody>
</table>

Figure 118 Make Sure the Power Cables and Driveline are Not Twisted
3. Insert the batteries and attached battery clips into each holster:
   a. Open each VELCRO® flap (Figure 119, left).
   b. Insert each battery/battery clip into a holster, so the clips point up and the batteries point down (Figure 119), right.

4. Close each Battery Holster flap after the battery/battery clip is inside the holster (Figure 120).

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 147).
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 94).
Exchanging Low-Power Batteries with Two Fully-Charged Batteries

FOR THIS TASK YOU NEED:

- A quiet, well-lit 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.

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 106).
Taking Off the Battery Holster

FOR THIS TASK YOU NEED:

• A quiet, well-lighted location where you can focus on the task
• To be wearing a Battery Holster with running System Controller on battery power
• A 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 96). 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 batteries in the Battery Charger (see Charging HeartMate 14 Volt Lithium-Ion Batteries on page 106).

9. Store the holster in a clean, dry location (see Caring for the Equipment on page 219).
The Holster Vest

Use the Holster Vest to hold the System Controller and two HeartMate batteries (with battery clips) during battery-powered operation (Figure 121).

Figure 121 The Holster Vest
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 122).

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 179.
Assembling the Holster Vest

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- A 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 123).

3. Repeat Step 2 for the second holster.

Figure 123 Insert the Vest Strap Through the Slot in the Top of the Holster
Putting On the Holster Vest

**FOR THIS TASK YOU NEED:**
- A quiet, well-lighted location where you can focus on the task
- A running System Controller on Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- An 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 124*).

*Figure 124 Make Sure the Power Cables and Driveline are Not Twisted*
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 125]).
   
   ![Figure 125 Insert Battery and Battery Clip Into Holster](image)

   b. Buckle the clip on the holster ([Figure 126]).

   ![Figure 126 Buckle the Clip on the Holster](image)

   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 into 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 94).

12. Use the VELCRO tabs on the back of the holsters to hold the power cables in place and to stabilize the holsters (Figure 127).

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

- A quiet, well-lighted location where you can focus on the task
- A running System Controller connected to two in-use HeartMate batteries during battery-powered operation
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- A 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 128):
   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 low battery. Remove only one battery from its clip 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.

   f. Repeat Steps a–e to exchange the second low battery.

3. Recharge the low batteries in the Battery Charger (see Charging HeartMate 14 Volt Lithium-Ion Batteries on page 106).
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 96). 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 the nylon clip 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 batteries in the Battery Charger (see *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 106).

9. Store the Holster Vest in a clean, dry location (*Caring for the Equipment* on page 219).
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 below.

**PRE-SLEEP CHECKLIST**

- ☑ Connect to Mobile Power Unit power before going to sleep or any time you might fall asleep.
- ☑ Ensure that the System Controller is not covered by insulating materials, such as a blanket, or placed against the patient’s bare skin while sleeping.
- ☑ Make sure the Stabilization Belt is on and tight.
- ☑ 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.
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. Wear your HeartMate Stabilization Belt 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.

**WARNING !**

- For international travel, you must use Abbott power cords that are compatible with the local voltage and that meet 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 power cords, if needed.

- If traveling by aircraft, bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on the aircraft.

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

- Always keep at least one set of fully-charged HeartMate batteries and compatible battery clips near you in the automobile.

- 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 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 II
ALARMS AND TROUBLESHOOTING

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

System Controller Alarms - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 189
Mobile Power Unit Alarms - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 208
Battery Charger Alarms - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 210
Guidelines for Power Cable Connectors - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 215
What Not To Do: Driveline and Cables - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 216
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.

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 56) 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 7 and Table 8 on the following pages for a complete list of prioritized System Controller alarms.
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 129 shows the alarm screen layout.

Figure 129 Alarm Screen

Replace Power

Alarm Message

Duration Timer

:02
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
- Low Speed alarm

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 130).

```
2012-08-01 09:16

Low Flow

03:13

Figure 130 Sample Alarm History Screen
```

Date and Time of Alarm
Alarm Type
Duration of Alarm
Navigation Information
Table 6 shows how to access the alarm history screens.

<table>
<thead>
<tr>
<th>Button Press</th>
<th>Description</th>
<th>Alarm Screen Displayed (Example)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press AND</td>
<td>Press display button and silence alarm button at the same time to access first alarm.</td>
<td>00:12:06 01:20:23 Low Voltage Advisory 00:23</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button <strong>ONCE</strong> to display the second alarm.</td>
<td>00:12:06 01:23 Low Voltage Hazard 01:17</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>SECOND</strong> time to display the third alarm.</td>
<td>00:12:06 01:25 Low Flow 03:13</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>THIRD</strong> time to display the fourth alarm.</td>
<td>00:12:07 01:22:45 Power Cable Disconnect 00:20</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>FOURTH</strong> time to display the fifth alarm.</td>
<td>00:12:07 01:22:50 External Power Disconnect 01:03</td>
</tr>
<tr>
<td>Press</td>
<td>Press display button a <strong>FIFTH</strong> time to display the sixth alarm.</td>
<td>00:12:07 01:23 Driveline Disconnect 00:31</td>
</tr>
</tbody>
</table>

Table 6 Viewing Alarm History Screens
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 (筛选) and display (显示) buttons. To exit from the alarm history feature, simultaneously press the two buttons again.

Alarms That Do Not Appear in Alarm History
The Backup Battery Fault and Replace Controller Fault alarms 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, 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.

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

<table>
<thead>
<tr>
<th>Priority</th>
<th>System Controller Screen</th>
<th>Active Symbols</th>
<th>Alarm Means</th>
<th>To Resolve Alarm</th>
</tr>
</thead>
</table>
|          |                          | ![HeartMate II Pump Running Symbol](image) | **Pump is off.** The Pump Running symbol ( ) is black. | 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 196.** |
|          |                          | ![HeartMate II Driveline Symbol](image) | **Driveline is disconnected.** The Pump Running symbol ( ) is black. | 1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position.
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 programmed backup System Controller.
4. If alarm persists, call your hospital contact immediately.  
**For more information, see page 197.** |
|          | ![HeartMate II Both Power Cables Disconnected Symbol](image) | **Both power cables are disconnected** | | 1. Immediately connect to a working 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 198.** |
|          | ![HeartMate II Low Flow Symbol](image) | **Low flow, flow is less than 2.5 lpm** | | Call your hospital contact immediately for diagnosis and instructions.  
**For more information, see page 200.** |
|          | ![HeartMate II Low Battery Symbol](image) | **Low Battery, Power input is extremely low with less than 5 min. remaining** | | 1. Immediately connect to a working 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 201.** |

Table 7 System Controller Hazard Alarms

**IMPORTANT!** The Pump Running symbol ( ) is always lit green when the pump is running.
### Alarms and Troubleshooting

**HeartMate II Left Ventricular Assist System Patient Handbook**

#### Table 8 System Controller Advisory Alarms

**IMPORTANT!** The Pump Running symbol (_RUN__) is always lit green when the pump is running.

<table>
<thead>
<tr>
<th>Priority</th>
<th>System Controller Screen</th>
<th>Active Symbols</th>
<th>Alarm Means</th>
<th>To Resolve Alarm</th>
</tr>
</thead>
</table>
| LOW      | Connect Power              | 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. |
|          |                            |                |             | **For more information, see page 202.** |
| LOW      | Replace Power              |                | 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. |
|          |                            |                |             | **For more information, see page 203.** |
| ADVISORY| Call Hospital Contact      |                | System Controller hardware fault | Call your hospital contact as soon as possible for diagnosis and instructions. |
|          | Controller Fault           |                |             | **For more information, see page 204.** |
| ADVISORY| Call Hospital Contact      |                | System Controller Backup Battery fault | Call your hospital contact as soon as possible for diagnosis and instructions. |
|          | Backup Battery Fault       |                |             | **For more information, see page 205.** |
| LOW      | Low Speed                  |                | Low Speed advisory warning | Call your hospital contact as soon as possible for diagnosis and instructions. |
|          |                            |                |             | **For more information, see page 206.** |
| LOW      | Call Hospital Contact      |                | System Controller Backup Battery not installed | Call your hospital contact as soon as possible for diagnosis and instructions. |
|          |                            |                |             | **For more information, see page 207.** |
Pump Off Alarm

This is a Hazard alarm

The screens look like this:

(alternating screens)

<table>
<thead>
<tr>
<th>Behavior and appearance:</th>
<th>Pump Off Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flashing Red Heart (▶) on the user interface.</td>
<td>1. Connect to a working power source (Mobile Power Unit or two HeartMate batteries) right away.</td>
</tr>
<tr>
<td>• The driveline is connected.</td>
<td>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.</td>
</tr>
<tr>
<td>• “Low Flow” and “Call Hospital Contact” alternate on the screen.</td>
<td></td>
</tr>
<tr>
<td>• The “Pump Running” symbol (◉) is black.</td>
<td></td>
</tr>
<tr>
<td>• Alarm tone: Constant tone.</td>
<td></td>
</tr>
</tbody>
</table>

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

Alarm silence period:

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

Table 9 Pump Off Alarm
Driveline Disconnected Alarm

This is a Hazard alarm

The screen looks like this:

<table>
<thead>
<tr>
<th>Behavior and appearance:</th>
<th>The screen looks like this:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flashing Red Heart ( ) on the user interface.</td>
<td>![Image of driveline disconnected alarm screen]</td>
</tr>
<tr>
<td>• Flashing red light near driveline connector.</td>
<td></td>
</tr>
<tr>
<td>• “Connect Driveline” flashes on the screen.</td>
<td></td>
</tr>
<tr>
<td>• The “Pump Running” symbol ( ) is black.</td>
<td></td>
</tr>
<tr>
<td>• Alarm tone: Constant tone.</td>
<td></td>
</tr>
</tbody>
</table>

Alarm means: The driveline is disconnected from the System Controller.

To resolve alarm:

1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position. (See page 33.)

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 the System Controller with a programmed backup System Controller.

4. Immediately call hospital contact if Steps 1–3 do 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 ( ).

**Note:** In some cases, you may have to push the silence alarm button twice to silence this alarm. This is normal.

Table 10 Driveline Disconnected Alarm
No External Power Alarm

This is a Hazard alarm

The screens look like this:

(Alternating screens)

- Flashing Red Battery ( ) on the user interface.
- Backup Battery graphic and “Connect Power Immediately” alternate on the screen.

Behavior and appearance:

- 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 11 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. See System Controller Backup Power on page 53 for details about the 11 Volt Lithium-Ion backup battery inside the System Controller.
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.
Low Flow Alarm

This is a Hazard alarm

The screens look like this:
( alternating screens )

Behavior and appearance:
• Flashing Red Heart ( ) on the user interface.
• “Low Flow” and “Call Hospital Contact” 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:
• 2 minutes or until a new hazard alarm occurs.
• To silence this alarm, press the silence alarm button ( ).

Table 12 Low Flow Alarm
Low Battery Power Alarm (less than 5 minutes remain)

**This is a Hazard alarm**

**The screens look like this:**
(alternating screens)

<table>
<thead>
<tr>
<th>Behavior and appearance:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flashing Red Battery ( ) on the user interface.</td>
<td></td>
</tr>
<tr>
<td>• “Replace Power Immediately” and “Low Battery” alternate on the screen.</td>
<td></td>
</tr>
<tr>
<td>• Alarm tone: Constant tone.</td>
<td></td>
</tr>
</tbody>
</table>

**Alarm means:**
1. Less than 5 minutes of battery power remain (when using battery power).

**OR**
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 fully-charged HeartMate batteries) right away.
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 13 Low Battery Power Alarm (< 5 minutes)
### 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**

<table>
<thead>
<tr>
<th>Behavior and appearance:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flashing yellow light near the black or white power cable connector, depending on which cable is disconnected.</td>
<td></td>
</tr>
<tr>
<td>• “Connect Power” appears on the screen.</td>
<td></td>
</tr>
<tr>
<td>• Alarm tone: Fast beep.</td>
<td></td>
</tr>
</tbody>
</table>

**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:**

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

*Table 14 Power Cable Disconnected Alarm*
Low Battery Power Alarm (less than 15 minutes remain)

This is an Advisory alarm

The screens look like this:

( alternating screens)

Behavior and appearance:

• Flashing yellow diamond ( ) on the user interface.
• “Replace Power” and “Low Battery” alternate on the screen.
• Alarm tone: Slow beep.

Alarm means:
Low battery, power input to the System Controller is low. Less than 15 minutes of battery power remain.

To resolve alarm:

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

Alarm silence period:

• 5 minutes or until any new alarm occurs.
• To silence this alarm, press the silence alarm button ( ).

Table 15 Low Battery Power Alarm (< 15 minutes)
System Controller Fault Alarm

**This is an Advisory alarm**

The screen looks like this:

<table>
<thead>
<tr>
<th>Behavior and appearance:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flashing yellow wrench (🔧) on the user interface.</td>
<td></td>
</tr>
<tr>
<td>• “Call Hospital Contact; Controller Fault” displays on the screen.</td>
<td></td>
</tr>
<tr>
<td>• Alarm tone: Slow beep.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alarm means:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>An internal malfunction or other issue has occurred that requires clinician diagnosis and resolution.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To resolve alarm:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Call your hospital contact as soon as possible for diagnosis and instructions.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alarm silence period:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 4 hours or until any new alarm occurs.</td>
<td></td>
</tr>
<tr>
<td>• To silence this alarm, press the silence alarm button (猗).</td>
<td></td>
</tr>
</tbody>
</table>

**IMPORTANT!** A backup System Controller is identical to the running System Controller and is programmed with identical patient-specific settings. It should remain with you at all times for easy access in an emergency. For replacement instructions, see Replacing the Running System Controller with a Backup Controller on page 56.
System Controller Backup Battery 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; Backup Battery Fault” on the screen.
• Alarm tone: Slow beep.

Alarm means:
1. The System Controller’s 11 Volt Lithium-Ion backup battery is compromised.

OR

2. It is unable to fully support pump function.

OR

3. There is an issue that requires clinician diagnosis and resolution.

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 (ဆ)

Table 17 System Controller Backup Battery Fault Alarm
### Low Speed Operation Alarm

#### This is an Advisory alarm

<table>
<thead>
<tr>
<th>The screens look like this:</th>
<th><img src="image1" alt="Screen1" /></th>
<th><img src="image2" alt="Screen2" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>(alternating screens)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Behavior and appearance:                |                    |                    |
|-----------------------------------------|                    |                    |
| • Flashing yellow wrench (🔧) on the user interface. |                    |                    |
| • “Low Speed” and “Call Hospital Contact” alternate on the screen. |                    |                    |
| • Alarm tone: Slow beep.                |                    |                    |

| Alarm means:                            | OR                 |                    |
|-----------------------------------------|--------------------|                    |
| 1. Either the fixed speed has been set 200 rpm or more below the low speed limit. |                    |                    |
| 2. The System Controller is not able to maintain the speed at or above the low speed limit. |                    |                    |

| 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 18 Low Speed Alarm**
**System Controller Backup Battery Not Installed Alarm**

**This is an Advisory alarm**

The screen looks like this:

- Flashing yellow wrench (징) on the user interface.
- An “install battery” graphic on the screen.
- Alarm tone: Slow beep.

**Behavior and appearance:**

- Flashing yellow wrench (징) on the user interface.
- An “install battery” graphic on the screen.
- Alarm tone: Slow beep.

**Alarm means:**

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

   OR

2. It 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 (/AIDS).

---

Table 19 System Controller Backup Battery Not Installed 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

All Mobile Power Unit alarms are accompanied by a light (Figure 131) and sound. Different lights and sounds come on, depending on the alarm. See Table 20 for a description of the Mobile Power Unit alarms and how to resolve each alarm.

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 189.
**Note:** If you hear an alarm for the Mobile Power Unit but no light comes on, call your hospital contact.

<table>
<thead>
<tr>
<th>Alarm Symbol</th>
<th>Meaning</th>
<th>What You Should Do</th>
</tr>
</thead>
</table>
| ![Advisory Alarm](image) | Internal Alkaline AA Mobile Power Unit batteries need to be replaced. | 1. Immediately switch to a new set of fully-charged batteries.  
2. Replace Mobile Power Unit batteries (see Inserting or Replacing the Mobile Power Unit Batteries on page 66). |
| ![Advisory Alarm](image) | Internal malfunction detected within the Mobile Power Unit. | 1. Promptly switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.  
2. Call hospital contact. |

**IMPORTANT!** Ensure that the System Controller power cables are connected correctly, white-to-white and black-to-black. If the System Controller power cables are not connected correctly, a low battery power advisory alarm will occur after five minutes.

A low battery power advisory alarm is indicated by:

- Flashing yellow diamond (◇) on the user interface.
- “Replace Power” and “Low Battery” alternate on the screen.
- Alarm tone: Slow beep.

To resolve the alarm:

1. Promptly connect to two fully-charged HeartMate batteries.
2. Reconnect to the Mobile Power Unit, ensuring that the power cables are connected correctly—white-to-white and black-to-black.
3. Call your hospital contact if reconnecting to the Mobile Power Unit does not resolve the alarm.
Alarms and Troubleshooting

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 21 on page 214 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 132).

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.

FOR THIS TASK YOU NEED:
• A quiet, well-lighted location where you can focus on the task
• An 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:
• A quiet, well-lighted location where you can focus on the task
• An 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."
   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.
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:
• A quiet, well-lighted location where you can focus on the task
• An 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."
   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 system.
### Battery Charger Display Panel Messages

**Table 21** describes the messages that appear on the charger display panel.

<table>
<thead>
<tr>
<th>Meaning</th>
<th>English Mode</th>
<th>Graphics Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready</td>
<td>HeartMate CHARGER</td>
<td>HeartMate CHARGER</td>
</tr>
<tr>
<td>Battery Charge Status</td>
<td>X:   █     █     █     █</td>
<td>1:  50%</td>
</tr>
<tr>
<td>Battery Information (3rd screen)</td>
<td># = X</td>
<td># = X</td>
</tr>
<tr>
<td></td>
<td>X: mAh =</td>
<td>X: mAh =</td>
</tr>
<tr>
<td>Charge Complete</td>
<td>READY</td>
<td>1:</td>
</tr>
<tr>
<td>Request Calibration</td>
<td>CALIBRATE? PRESS X</td>
<td></td>
</tr>
<tr>
<td>Accept Calibration</td>
<td>PROGRESS X: CALIBRATING</td>
<td></td>
</tr>
<tr>
<td>Change Display Mode to English</td>
<td>OK ▼ OK</td>
<td>ENGLISH ▼ ENGLISH</td>
</tr>
<tr>
<td>Change Display Mode to Graphics</td>
<td>OK ▼ OK</td>
<td>GRAPHICS ▼ GRAPHICS</td>
</tr>
<tr>
<td>Battery Fault</td>
<td>CALL SERVICE</td>
<td></td>
</tr>
<tr>
<td>Charger Fault</td>
<td>CALL SERVICE</td>
<td></td>
</tr>
<tr>
<td>Battery Fault (Button Push)</td>
<td>CALL SERVICE BXXXX</td>
<td></td>
</tr>
<tr>
<td>Charger or Pocket Fault (Button Push)</td>
<td>CALL SERVICE SXXXX</td>
<td></td>
</tr>
</tbody>
</table>

Where:
- X:—Charger pocket number
- BXXXX—Battery fault with alarm code
- SXXXX—Charger pocket (slot) fault with alarm code
- # = X—"X" equals the battery charge cycle count
- mAh = XXXX—Battery charge capacity in milliamp-hour

---

**Table 21 Battery Charger Display Panel Messages**
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 133**.
- 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 134**). 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 133 Carefully Align the Connectors](image)

![Figure 134 Tighten the Connector Nut](image)
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.
CAUTION!
Do not twist, kink, or sharply bend the System Controller power cables.
**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.
CARING FOR THE EQUIPMENT

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

Acceptable Operating Conditions  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  -  - 221
Cleaning and Caring for the Equipment - - - - - - - - - - - - - - - - - - 222
Product Disposal - - - - - - - - - - - - - - - - - - - - - - - - - - 228
Acceptable Operating Conditions

For safe and optimal use of HeartMate system components, follow the operating guidelines listed here. Operating system components outside of the environmental parameters listed below may affect device operation.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Acceptable Temperature Range °F (°C)</th>
<th>Relative Humidity</th>
<th>Air Pressure mm Hg (hPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile Power Unit</td>
<td>32°F to 104°F (0°C to 40°C)</td>
<td>20% to 93%</td>
<td>525 to 795 (700 to 1060)</td>
</tr>
<tr>
<td>HeartMate 14 Volt Lithium-Ion Batteries†</td>
<td>32°F to 104°F (0°C to 40°C)</td>
<td>20% to 75%</td>
<td>525 to 795 (700 to 1060)</td>
</tr>
<tr>
<td>Battery Charger</td>
<td>32°F to 104°F (0°C to 40°C)</td>
<td>20% to 75%</td>
<td>525 to 795 (700 to 1060)</td>
</tr>
<tr>
<td>System Controller, Backup System Controller+†</td>
<td>32°F to 104°F (0°C to 40°C)</td>
<td>20% to 93%</td>
<td>525 to 795 (700 to 1060)</td>
</tr>
<tr>
<td>11 Volt Lithium-Ion Backup Battery</td>
<td>32°F to 104°F (0°C to 40°C)</td>
<td>20% to 93%</td>
<td>525 to 795 (700 to 1060)</td>
</tr>
</tbody>
</table>

Table 22 Operating Conditions

†Standby components (Backup System Controller, extra 14V Lithium-Ion Batteries) should be maintained at conditions within the acceptable ranges so that they are available for immediate use should the need arise.

*Once every six months, the “sleeping” backup System Controller must be connected to a power source to charge the 11 Volt Lithium-Ion backup battery inside. If the 11 Volt Lithium-Ion backup battery inside the backup System Controller is not charged every six months, its charge level will diminish and there may not be sufficient power to support the pump if the backup System Controller is in use during a power emergency.
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 detergent, 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. Submersion in water or liquid may damage equipment or cause the pump 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 one of the following:

- Alcohol (70% ethyl rubbing alcohol (C₂H₆O))
- Alcohol (90+% isopropyl)
- Diluted bleach (household)

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 41), 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 55).
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 one of the following:

- Alcohol (70% ethyl rubbing alcohol (C₂H₆O))
- Alcohol (90+% isopropyl)
- Diluted bleach (household)

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

Clinical experience from over five years of clinical trials (both bridge-to-transplantation and destination therapy), and commercial use outside of the United States, have shown that 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, or may result in death if not resolved.

The need for pump replacement due to driveline damage has occurred after implant durations ranging from 6 to 38 months.

According to this analysis, the estimated probability of the need for pump replacement due to driveline damage is 1.3% at 12 months, 6.5% at 24 months, and 11.4% at 36 months.

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.
Driveline damage may be evidenced by the following:

- 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 265 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.

**IMPORTANT!** Do not clean the Mobile Power Unit while it is powering the system.
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 265 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 or clips while in use. See Figure 135.

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 265.
Caring for the Wear and Carry Accessories

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

- Shower Bag
- Consolidated Bag
- System Controller Neck Strap
- Belt attachment
- Holster vest
- Battery holster
- Travel Bag
- 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.

Caring for the Stabilization Belt

If the HeartMate Stabilization Belt gets dirty, wash it by hand using a non-bleach detergent. Allow the Stabilization Belt to air dry on its own. Never use heat to dry the Stabilization Belt. Make sure it is completely dry before using it. With two Stabilization Belts, you can wear one while the other is drying.

Periodically inspect the Stabilization Belt for damage or wear. If it appears damaged or worn, do not use it. Contact your hospital contact for a replacement.
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.
FREQUENTLY ASKED QUESTIONS

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

Corporate Information - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 231
System Use - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 231
Showers and Exercise- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 233
Travel - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 233
Corporate Information

How can I learn more about Abbott Corporation?
Information about the company is available on our website: www.abbott.com.
In an emergency, do not call Abbott. Call your hospital contact for all emergencies.

Can I order equipment or accessories directly from Abbott Corporation?
No. Equipment and accessories should be ordered by your hospital contact. Call your hospital contact for any reorders.

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 II system?
No. Only use the HeartMate 14 Volt Lithium-Ion batteries that you got from the hospital at discharge. Other batteries will not power the HeartMate II 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.

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 aseptic 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 II 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 II 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 II system?**

The HeartMate II 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 work 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. If traveling by aircraft, bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.
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 traveling (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 II 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?

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

If the system is not working right, the System Controller will alarm (see System Controller Alarms on page 189).

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.
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 187 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:

You should:

1. Check the connection between the System Controller and the pump, and then check the connection between the System Controller and power source (Mobile Power Unit or batteries).
2. Fix any loose connections.
3. 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.
4. Switch to the backup System Controller (see Replacing the Running System Controller with a Backup Controller on page 56).
5. 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.
TESTING & CLASSIFICATION

This section provides information about safety testing and classification for the HeartMate II Left Ventricular Assist System.
Safety Testing and Classification

The HeartMate II 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 60601-1-11:2015
- EN 60601-1:2006/A1:2013 (ed. 3.1)
- EN 60601-1:2006 + Corr. 2:2010 (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)
### Declaration Concerning General Safety Standards

<table>
<thead>
<tr>
<th>Type</th>
<th>Degree of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Method of Sterilization</td>
<td>100% EtO for blood pump and all sterile accessories</td>
</tr>
<tr>
<td>Type of protection against electrical shock</td>
<td>Class II with Mobile Power Unit (Home Use)</td>
</tr>
<tr>
<td>Degree of protection against electric shock</td>
<td>Type CF (Cardiac Floating)</td>
</tr>
<tr>
<td>Degree of safety of application in the presence</td>
<td>Equipment not suitable for use in the presence of a flammable anesthetic mixture with</td>
</tr>
<tr>
<td>of a flammable anesthetic mixture with air or</td>
<td>or with oxygen or nitrous oxide</td>
</tr>
<tr>
<td>with oxygen or nitrous oxide</td>
<td></td>
</tr>
<tr>
<td>Degree of protection against harmful</td>
<td>• System Controller–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water</td>
</tr>
<tr>
<td>ingress of water and particulate matter</td>
<td>• Mobile Power Unit–IP22:Protection against ingress of solid foreign objects the size of a finger and from vertically dripping water</td>
</tr>
<tr>
<td></td>
<td>• Shower Bag–IPX3:Protection against ingress of spraying water</td>
</tr>
<tr>
<td></td>
<td>• 14 V Battery &amp; Battery Clip–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water. Only when connected to System Controller.</td>
</tr>
<tr>
<td></td>
<td>• Battery Charger–IPX0:Non-protected against ingress of water</td>
</tr>
<tr>
<td>Applied parts</td>
<td>• HeartMate II Left Ventricular Assist Device</td>
</tr>
<tr>
<td></td>
<td>• System Controller</td>
</tr>
</tbody>
</table>

**Table 23 Declaration Concerning General Safety Standards**

For additional information on testing and classification for the HeartMate II Left Ventricular Assist System, please see the *HeartMate II Instructions for Use*. Your hospital contact can get a copy for you.
**CAUTION !**

Use of equipment and supplies other than those specified in the manuals or sold by Abbott for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate II Left Ventricular Assist System and other devices.
The HeartMate II Left Ventricular Assist System has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2014, Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests, with the exception of the Battery Charger, which was tested according to the recommendations of IEC TR 60601-4-2: Medical Electrical Equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate II 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 devices are connected.
- Consult Abbott for assistance.

**Note:** Special precautions are required for installing and using the HeartMate II Left Ventricular Assist System within portable and RF communication environments.
### Declaration and Guidance for Electromagnetic Disturbances for the Mobile Power Unit

The HeartMate II LVAS (powered by the Mobile Power Unit) is suitable for use in the following environments:

- Hospitals, including operating rooms, and emergency rooms
- Treatment areas near active HF Surgical equipment.
- Homes, workplaces and retail places.

**Note:** Public or private passenger watercraft/boats, ferries, etc.

<table>
<thead>
<tr>
<th>HeartMate II LVAS Powered By the Mobile Power Unit</th>
<th>EM Disturbance type / Standards</th>
<th>IEC 60601-1-2 (2014) Compliance Level</th>
<th>Use Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions / CISPR 11 EN 55011</td>
<td>Group 1, Class B 30 – 1,000 MHz</td>
<td>The HeartMate II LVAS with Mobile Power Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings.</td>
<td></td>
</tr>
<tr>
<td>Harmonic Emissions / IEC 61000-3-2 EN 61000-3-2</td>
<td>Class A</td>
<td>The HeartMate II LVAS with Mobile Power Unit uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations &amp; Flicker Emissions / IEC 61000-3-3 EN 61000-3-3</td>
<td>Complies fully</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2</td>
<td>±8 kV Contact ±15 kV Air</td>
<td>The relative humidity where the HeartMate II LVAS with Mobile Power Unit is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.</td>
<td></td>
</tr>
</tbody>
</table>

Table 24 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit
<table>
<thead>
<tr>
<th>Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3</th>
<th>10 V/m</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 MHz – 2.7 GHz</td>
<td>80% AM at 1 kHz</td>
</tr>
</tbody>
</table>

For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with Mobile Power Unit are recommended:

- 80 - 800 MHz: 1.7 m (5.7 feet)
- 800 MHz – 2.7 GHz: 3.3 m (10.8 feet)

Note: At 800 MHz, the separation distance for the higher frequency range applies.

For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with Mobile Power Unit are recommended:

- 80 - 800 MHz: 3.8 m (12.5 feet)
- 800 MHz – 2.7 GHz: 7.3 m (24.0 feet)

Note: At 800 MHz, the separation distance for the higher frequency range applies.

Equipment examples: Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers.

Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:

![Radio Signal Symbol](radio_signal.png)

Note: 1,000 MHz = 1.0 GHz

[a] – List is not comprehensive.

Table 24 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)
### Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3

<table>
<thead>
<tr>
<th>Frequency Range</th>
<th>Immunity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>380 - 390 MHz, 42 V/m[1];</td>
<td></td>
</tr>
<tr>
<td>430 - 470 MHz, 42 V/m[3];</td>
<td></td>
</tr>
<tr>
<td>704 - 787 MHz, 13 V/m[2];</td>
<td></td>
</tr>
<tr>
<td>800 - 960 MHz, 42 V/m[1];</td>
<td></td>
</tr>
<tr>
<td>1.7 - 1.99 GHz, 42 V/m[2];</td>
<td></td>
</tr>
<tr>
<td>2.4 - 2.57 GHz, 42 V/m[2];</td>
<td></td>
</tr>
<tr>
<td>and</td>
<td></td>
</tr>
<tr>
<td>5.1 - 5.8 GHz, 13 V/m[2]</td>
<td></td>
</tr>
</tbody>
</table>

[1] 18 Hz Pulse Modulation  
[2] 217 Hz Pulse Modulation  
[3] FM at +/- 5 kHz Deviation

**Portable RF Communication Equipment** (up to 2-Watt of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate II LVAS with Mobile Power Unit, and its parts, than 0.2 m (8 inches).

Equipment[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth®, WLAN, Wi-Fi, and RFID systems.

---

### Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4

<table>
<thead>
<tr>
<th>Immunity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>± 2 kV for power supply lines</td>
</tr>
<tr>
<td>± 1 kV for input / output lines</td>
</tr>
<tr>
<td>100 kHz repetition rate</td>
</tr>
</tbody>
</table>

Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used.

---

### Surge Immunity / IEC 61000-4-5 EN 61000-4-5

<table>
<thead>
<tr>
<th>Immunity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>± 0.5, ± 1 kV line to line</td>
</tr>
</tbody>
</table>

---

**Table 24** Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)
### Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6

<table>
<thead>
<tr>
<th>Voltage (Vrms)</th>
<th>Minimum Separation Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Vrms</td>
<td>Outside ISM/Amateur bands - 150 kHz - 80 MHz: 1.7 m (5.7 feet)</td>
</tr>
<tr>
<td>6 Vrms (within ISM and Amateur bands)</td>
<td>In ISM/Amateur bands - 150 kHz - 80 MHz: 2.8 m (9.2 feet)</td>
</tr>
<tr>
<td>150 kHz – 80 MHz</td>
<td>Equipment examples include: CB Radios, Amateur “HAM” radios, Diathermy medical devices,</td>
</tr>
<tr>
<td>80% AM at 1 kHz</td>
<td>Note: 1,000 kHz = 1.0 MHz</td>
</tr>
</tbody>
</table>

**Note:** “ISM” = Industrial, Scientific and Medical devices, as per the International Technical Union

[a] – List is not comprehensive.

### Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8

<table>
<thead>
<tr>
<th>Magnetic Field (A/m)</th>
<th>Liens Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used.</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 A/m (50 or 60 Hz)</td>
<td>Power Frequency Magnetic Field should be</td>
</tr>
</tbody>
</table>

### Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11

<table>
<thead>
<tr>
<th>Voltage Dip Duration</th>
<th>Voltage Drop (UT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 % of UT; ½ cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used.</td>
</tr>
<tr>
<td>0 % of UT; 1 cycle</td>
<td>Note – UT: A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)</td>
</tr>
<tr>
<td>and</td>
<td></td>
</tr>
<tr>
<td>70 % of UT; 25 or 30 cycles (0.5 sec.)</td>
<td></td>
</tr>
<tr>
<td>0 % of UT; 250 or 300 cycles (5 sec.)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 24** Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)
Field strengths from fixed RF 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 (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) “site survey” (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS 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 II LVAS.

These guidelines may not apply in all situations.

**WARNING !**

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate II LVAS (powered by the Mobile Power Unit), including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.

- To help ensure good electromagnetic performance throughout the usable life of the HeartMate II LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.

- Avoid use of the HeartMate II LVAS (and its cables and parts) within 5 cm (2 inches) of a microwave oven or its cord. Keep all HeartMate II LVAS components and their cables away from other electronic devices and their cables/cords.

- The HeartMate II Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate II Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.

- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- No modification of this equipment is allowed.
Testing and Classification: Battery Charger

The Battery Charger complies with the following safety standards:

- EN 60950-1
- CAN/CSA-C22.2 No. 601.1-M90 (R2005)

This equipment was tested according to the recommendations of IEC TR 60601-4-2: Medical Electrical Equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. 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 Abbott for assistance.
# Declaration Concerning General Safety Standards for Battery Charger

<table>
<thead>
<tr>
<th>Type</th>
<th>Degree of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Type of protection against mains shock</td>
<td>Class I (grounded)</td>
</tr>
<tr>
<td>Degree of protection against harmful ingress of water</td>
<td>IPX0</td>
</tr>
</tbody>
</table>

Table 25 Declaration Concerning General Safety Standards for Battery Charger
Declaration and Guidance for Electromagnetic Disturbances for Battery Charger

The HeartMate Battery Charger is suitable for use in the following environments:

- Hospitals, including operating rooms and emergency rooms
- Home, workplaces and retail places
- Public or private passenger watercraft/boats, ferries, etc.

<table>
<thead>
<tr>
<th>HEARTMATE BATTERY CHARGER</th>
<th>IEC TR 60601-4-2 Compliance Level</th>
<th>Use Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions / CISPR 11 EN 55011</td>
<td>Group 1, Class B 30 – 1,000 MHz</td>
<td>The HeartMate Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings.</td>
</tr>
<tr>
<td>Harmonic Emissions / IEC 61000-3-2 EN 61000-3-2</td>
<td>Class A</td>
<td>The HeartMate Battery Charger uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Voltage Fluctuations &amp; Flicker Emissions / IEC 61000-3-3 EN 61000-3-3</td>
<td>Complies fully</td>
<td></td>
</tr>
<tr>
<td>Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2</td>
<td>±6 kV Contact ±8 kV Air</td>
<td>The relative humidity should be at least 20%. Higher relative humidity will reduce the severity of ESD events.</td>
</tr>
</tbody>
</table>

Table 26 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger
### Radiated RF Immunity / IEC 61000-4-3
EN 61000-4-3

<table>
<thead>
<tr>
<th>3 V/m</th>
<th>For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended:</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 MHz – 2.7 GHz</td>
<td>80 - 800 MHz: 1.7 m (5.7 feet)&lt;br&gt;800 MHz – 2.7 GHz: 3.3 m (10.8 feet)</td>
</tr>
<tr>
<td>80% AM at 1 kHz</td>
<td>Note: At 800 MHz, the separation distance for the higher frequency range applies.</td>
</tr>
</tbody>
</table>

For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended:

<table>
<thead>
<tr>
<th>80 MHz – 2.7 GHz</th>
<th>80 - 800 MHz: 3.8 m (12.5 feet)&lt;br&gt;800 MHz – 2.7 GHz: 7.3 m (24.0 feet)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80% AM at 1 kHz</td>
<td>Note: At 800 MHz, the separation distance for the higher frequency range applies.</td>
</tr>
</tbody>
</table>

Equipment examples: Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers.

Interference to the HeartMate Battery Charger may occur near equipment or areas that are marked with the following symbol:

![Symbol](image)

Note: 1,000 MHz = 1.0 GHz

[a] – List is not comprehensive.

Table 26 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)
<table>
<thead>
<tr>
<th>Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3</th>
<th>380 - 390 MHz, 27 V/m&lt;sup&gt;[1]&lt;/sup&gt;; 430 - 470 MHz, 28 V/m&lt;sup&gt;[1]&lt;/sup&gt;; 704 - 787 MHz, 9 V/m&lt;sup&gt;[2]&lt;/sup&gt;; 800 - 960 MHz, 28 V/m&lt;sup&gt;[1]&lt;/sup&gt;; 1.7 - 1.99 GHz, 28 V/m&lt;sup&gt;[2]&lt;/sup&gt;; 2.4 - 2.57 GHz, 28 V/m&lt;sup&gt;[1]&lt;/sup&gt;; and 5.1 - 5.8 GHz, 9 V/m&lt;sup&gt;[2]&lt;/sup&gt;</th>
</tr>
</thead>
</table>
|  | [1] 18 Hz Pulse Modulation  
[2] 217 Hz Pulse Modulation  
[3] FM at +/- 5 kHz Deviation |
| Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate Battery Charger, and its parts, than 0.3 m (12 inches). |
| Equipment<sup>[a]</sup> examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. |

---

| Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4 | ± 2 kV for power supply lines  
100 kHz repetition rate |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surge Immunity / IEC 61000-4-5 EN 61000-4-5</th>
<th>± 0.5, ± 1 kV line to line and ± 0.5, ± 1 kV, and ± 2 kV line to earth</th>
</tr>
</thead>
</table>

---

Table 26 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)
### Conducted RF Immunity

/ IEC 61000-4-6  
EN 61000-4-6

<table>
<thead>
<tr>
<th>3 Vrms and 6 Vrms (within ISM and Amateur bands)</th>
<th>For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate Battery Charger is recommended:</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz – 80 MHz: 1.7 m (5.7 feet)</td>
<td>Equipment[a] examples include: CB Radios, Amateur “HAM” radios, and Diathermy medical devices.</td>
</tr>
<tr>
<td>80% AM at 1 kHz</td>
<td>Note: 1,000 kHz = 1.0 MHz</td>
</tr>
<tr>
<td></td>
<td>Note: “ISM” = Industrial, Scientific and Medical devices, as per the International Technical Union</td>
</tr>
<tr>
<td></td>
<td>[a] – List is not comprehensive.</td>
</tr>
</tbody>
</table>

### Power Frequency Magnetic Field Immunity

/ IEC 61000-4-8  
EN 61000-4-8

| 3 A/m (50 or 60 Hz) | Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used. |

### Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity

/ IEC 61000-4-11  
EN 61000-4-11

<table>
<thead>
<tr>
<th>0 % of $U_T$; ½ cycle</th>
<th>Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 % of $U_T$; 1 cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$U_T$: A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)</td>
</tr>
<tr>
<td>70 % of $U_T$: 25 or 30 cycles (0.5 sec.)</td>
<td></td>
</tr>
<tr>
<td>0 % of $U_T$: 250 or 300 cycles (5 sec.)</td>
<td></td>
</tr>
</tbody>
</table>

Table 26 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)
Field strengths from fixed RF 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 (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) “site survey” (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS 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 II LVAS.

These guidelines may not apply in all situations.

**WARNING !**

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HeartMate Battery Charger, including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.

- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- 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.
9 Testing & Classification

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
### Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

<table>
<thead>
<tr>
<th>Type</th>
<th>Degree of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mode of Operation</strong></td>
<td>Continuous</td>
</tr>
<tr>
<td><strong>Degree of protection against electric shock</strong></td>
<td>Not an Applied Part</td>
</tr>
<tr>
<td><strong>Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide</strong></td>
<td>Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide</td>
</tr>
<tr>
<td><strong>Degree of protection against harmful ingress of water and particulate matter</strong></td>
<td>IP24 only when connected to System Controller through Battery Clip</td>
</tr>
</tbody>
</table>

Table 27 Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries
Declaration and Guidance for Electromagnetic Disturbances for HeartMate II Powered by 14V Lithium-Ion Batteries

The HeartMate II 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 II Left Ventricular Assist System should assure that it is used in such an environment. The HeartMate II LVAS (powered by 14V Li-Ion batteries) is suitable for use in the following environments:

- Hospitals, including operating rooms and emergency rooms
- Treatment areas near active HF Surgical equipment
- Homes, workplaces and retail places
- Passenger automobiles, ambulances, buses, etc.
- Commercial aircraft, including helicopters and air ambulances
- Public or private passenger watercraft/boats, ferries, etc.

<table>
<thead>
<tr>
<th>HeartMate II LVAS Powered By the 14V Li-Ion Batteries</th>
<th>EM (Electromagnetic) Disturbance type / Standards</th>
<th>IEC 60601-1-2 (2014) Compliance Level</th>
<th>Use Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions / CISPR 11 EN 55011</td>
<td></td>
<td>Group 1, Class B (radiated only)</td>
<td>The HeartMate II LVAS with 14V Li-Ion Batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30 – 1,000 MHz</td>
<td>The HeartMate II LVAS with 14V Li-Ion Batteries uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.</td>
</tr>
</tbody>
</table>

Table 28 Declaration and Guidance Concerning Electromagnetic Disturbances for HeartMate II Powered by 14V Lithium-Ion Batteries
### Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2

<table>
<thead>
<tr>
<th>±8 kV Contact</th>
<th>±15 kV Air</th>
<th>The relative humidity where the HeartMate II LVAS with 14V Li-Ion Batteries is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.</th>
</tr>
</thead>
</table>

For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with 14V Li-Ion Batteries are recommended:

- **80 - 800 MHz**: 0.85 m (2.8 feet)
- **800 MHz – 2.7 GHz**: 1.7 m (5.6 feet)

**Note:** At 800 MHz, the separation distance for the higher frequency range applies.

For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with 14V Li-Ion Batteries are recommended:

- **80 - 800 MHz**: 1.9 m (6.2 feet)
- **800 MHz – 2.7 GHz**: 3.8 m (12 feet)

**Note:** At 800 MHz, the separation distance for the higher frequency range applies.

**Equipment[a] examples:** Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers.

Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:

![Radio](radio_icon.png)

**Note:** 1,000 MHz = 1.0 GHz

**[a]** – List is not comprehensive.

### Radiated RF Immunity / IEC 61000-4-3

<table>
<thead>
<tr>
<th>20 V/m</th>
<th>80 MHz – 2.7 GHz</th>
<th>80% AM at 1 kHz</th>
<th>Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:</th>
</tr>
</thead>
</table>

**Note:** At 800 MHz, the separation distance for the higher frequency range applies.

**Equipment[a]** examples: Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers.

**Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:**

![Radio](radio_icon.png)

**[a]** – List is not comprehensive.
<table>
<thead>
<tr>
<th>Frequency Range</th>
<th>Electric Field Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>380 - 390 MHz</td>
<td>42 V/m [1]</td>
</tr>
<tr>
<td>430 - 470 MHz</td>
<td>42 V/m [3]</td>
</tr>
<tr>
<td>704 - 787 MHz</td>
<td>13 V/m [2]</td>
</tr>
<tr>
<td>800 - 960 MHz</td>
<td>42 V/m [1]</td>
</tr>
<tr>
<td>1.7 - 1.99 GHz</td>
<td>42 V/m [2]</td>
</tr>
<tr>
<td>2.4 - 2.57 GHz</td>
<td>42 V/m [2]</td>
</tr>
<tr>
<td>5.1 - 5.8 GHz</td>
<td>13 V/m [2]</td>
</tr>
</tbody>
</table>

[1] 18 Hz Pulse Modulation
[2] 217 Hz Pulse Modulation
[3] FM at +/- 5 kHz Deviation

Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate II LVAS with 14V Li-Ion Batteries, and its parts, than 0.2 m (8 inches).

Equipment examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems.

Note: 1,000 MHz = 1.0 GHz

Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate3 LVAS with 14V Batteries.

[a] – List is not comprehensive.
<table>
<thead>
<tr>
<th>Conducted RF Immunity  / IEC 61000-4-6</th>
<th>3 Vrms and 6 Vrms (within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate II LVAS with 14V Li-Ion Batteries is recommended:</td>
<td></td>
</tr>
<tr>
<td>Outside ISM bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet)</td>
<td></td>
</tr>
<tr>
<td>In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet)</td>
<td></td>
</tr>
<tr>
<td>Equipment examples include: CB Radios, Amateur “HAM” radios, Diathermy medical devices,</td>
<td></td>
</tr>
<tr>
<td>Note: 1,000 kHz = 1.0 MHz</td>
<td></td>
</tr>
<tr>
<td>Note: “ISM” = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power Frequency Magnetic Field Immunity  / IEC 61000-4-8 EN 61000-4-8</th>
<th>30 A/m (50 or 60 Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate II LVAS with 14V Li-Ion Batteries is used.</td>
<td></td>
</tr>
</tbody>
</table>

Table 28 Declaration and Guidance Concerning Electromagnetic Disturbances for HeartMate II Powered by 14V Lithium-Ion Batteries (Continued)
Field strengths from fixed RF 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.

The HeartMate II LVAS with 14V Li-Ion Batteries meets the electromagnetic radiated emissions requirements of RTCA/DO-160G (also EUROCAE ED-14G), Sec. 21, for Category "M" location devices.

The HeartMate II LVAS with 14V Li-Ion Batteries meets the radiated and conducted (due to RF) electromagnetic immunity requirements of RTCA/DO-160G (also EUROCAE ED-14G), Sec. 20, for Category "R" location devices.

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) “site survey” (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS 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 II LVAS.

These guidelines may not apply in all situations.
SAFETY CHECKLISTS

This section provides checklists to assist you in performing routine maintenance of the HeartMate II Left Ventricular Assist Device.

Daily Safety Checklist - 267
Weekly Safety Checklist - 269
Monthly Safety Checklist - 270
Six Month Safety Checklist - 272
Yearly Safety Checklist - 273
As-Needed Safety Checklist - 274
Clinic Visit Safety Checklist - 275
Daily Safety Checklist

Daytime Checklist:

☑ Perform System Controller self test (see The System Controller Self Test on page 40).

☑ When using a new power source, inspect System Controller power cable connectors for dirt, grease, or damage.

☑ When switching between battery power and the Mobile Power Unit, inspect the connector pins and sockets for dirt, grease, or damage.

☑ Unless instructed otherwise by your physician, wash the driveline exit site using the prescribed cleanser.

☑ Unless instructed otherwise by your physician, change the exit site bandages using aseptic technique (see Caring for the Driveline Exit Site on page 132).

☑ Inspect the driveline exit site for signs of infection, including redness, tenderness, swelling, discharge, or a foul odor. Use aseptic technique to touch or handle the exit site.

☑ When the Mobile Power Unit is initially connected to power, check the top panel to ensure that the Power On ( ) symbol is illuminated green.

☑ Ensure that the Mobile Power Unit echoes the System Controller’s alarms.
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 (see Changing from Batteries to Mobile Power Unit Power on page 96).
- Ensure that the System Controller is not covered by insulating materials, such as a blanket, or placed against the patient’s bare skin while sleeping.
- Secure the Stabilization Belt (see Using the Stabilization Belt on page 137).
- 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 and all cables for signs of damage, such as cracking, fraying, wear, exposed wires, twists, sharp bends, or kinks (see What Not To Do: Driveline and Cables on page 216).
Weekly Safety Checklist

☑ Review Replacing the Running System Controller with a Backup Controller instructions in Section 2.

☑ Clean the metal battery terminals and contacts inside the battery clips (see Cleaning Battery Contacts and Clips on page 226).

☑ 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.

☑ 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 Consolidated Bag, Travel Bag, Protection Bag, System Controller Neck Strap, Holster Vest, and Belt Attachment accessory) for damage or wear.

☑ Inspect the HeartMate Stabilization Belt 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.
Monthly Safety Checklist

- Review Alarms and Troubleshooting 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 136 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 214). 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 (see Cleaning Battery Contacts and Clips on page 226).

- 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. Do not attempt to clean or repair equipment on your own.

- If the Mobile Power Unit is going to be stored for over a 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.
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 66).
Yearly Safety Checklist

☑ Schedule a Battery Charger inspection and cleaning with Abbott-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

- Unless instructed otherwise by your physician, clean the exit site and bandages daily.
- 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.
Clinic Visit Safety Checklist

☑ 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 controller instructs the patient to do so.

☑ Review how to identify an emergency (Patient Handbook Section 8).

☑ Review emergency contact lists (refer to the Back Cover of this manual).

☑ 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 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.
10 Safety Checklists
SURVEY

This section includes a survey about this handbook.
ABBOtt SURVEY: HEARTMATE II® PATIENT HANDBOOK (Document 100175722.A)

1. How satisfied are you with the quality of documentation that Abbott provides?
   __ Very satisfied
   __ Satisfied
   __ Not satisfied

2. The printed materials and media that Abbott provides are available in the languages I need.
   __ Yes
   __ No

3. Topics covered in the HeartMate II Patient Handbook meet my information needs.
   __ Yes
   __ No

4. The HeartMate II Patient Handbook is easy-to-read.
   __ Yes
   __ No

5. The quality of drawings/photos in this manual is:
   __ Poor
   __ Fair
   __ Good
   __ Excellent

6. The number of drawings/photos in this manual meets my information needs:
   __ Yes
   __ No
   If no, describe what other drawings/photos you would like to add:
   ____________________________________________________________________________

7. What other topics would you like covered in this manual?
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________
8. What other lists, forms, or samples can we add to this manual?

9. If this manual existed online, would you use the digital version?
   __ Yes
   __ No
   If yes, where would you use a digital version?
   __ Home computer reading from CD-ROM
   __ Online at a hospital website
   __ Other

10. What do you like most about this manual?

11. What do you like least about this manual?

12. Are you interested in reviewing and commenting on future draft copies of this or other HeartMate II manuals?
   __ Yes
   __ No
   If yes, please print your contact information below.

   Name ____________________________________________

   Address __________________________________________

   City ________________________________ State __________ Zip ________

   Phone ____________________________ e-mail __________________________

To share your feedback about this manual, mail or fax a copy of your completed survey to:
Marketing Communication Manager
Abbott
6035 Stoneridge Drive
Pleasanton, CA 94588
GLOSSARY

This section defines important terms and abbreviations.

Abbreviations - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 283
Terms - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 284
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC</td>
<td>Alternating Current</td>
</tr>
<tr>
<td>CM</td>
<td>Centimeter</td>
</tr>
<tr>
<td>DC</td>
<td>Direct Current</td>
</tr>
<tr>
<td>EKG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>ESD</td>
<td>Electrostatic Discharge</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>IMP</td>
<td>Implantable Pacemaker</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalized Ratio</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Li-Ion</td>
<td>Lithium-Ion</td>
</tr>
<tr>
<td>LPM</td>
<td>Liters Per Minute</td>
</tr>
<tr>
<td>LVAD</td>
<td>Left Ventricular Assist Device</td>
</tr>
<tr>
<td>LVAS</td>
<td>Left Ventricular Assist System</td>
</tr>
<tr>
<td>LMW</td>
<td>Low Molecular Weight</td>
</tr>
<tr>
<td>ml/hr</td>
<td>Milliliter per hour</td>
</tr>
<tr>
<td>MPU</td>
<td>Mobile Power Unit</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
</tr>
<tr>
<td>OR</td>
<td>Operating Room</td>
</tr>
<tr>
<td>PI</td>
<td>Pulsatility Index</td>
</tr>
<tr>
<td>PTT</td>
<td>Partial Thromboplastin time</td>
</tr>
<tr>
<td>QD</td>
<td>Once daily</td>
</tr>
<tr>
<td>RPM</td>
<td>Revolutions Per Minute</td>
</tr>
<tr>
<td>TID</td>
<td>Three times daily</td>
</tr>
<tr>
<td>V</td>
<td>Volt</td>
</tr>
</tbody>
</table>
Terms

A

Advisory Alarm: Alarms that are important, but not life threatening.

Alarm: A sound, light, or lighted symbol that tells you about a problem that may affect system operation or cause harm. See The 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.

B

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 once every six months.

Battery: A device that provides direct current (DC) power to the system. The HeartMate II Left Ventricular Assist System can be powered by two 14 Volt Lithium-Ion batteries. See Using HeartMate 14 Volt Lithium-Ion Batteries on page 76. 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 53.

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 26.

Battery Charger: A device that charges, calibrates, and tests the HeartMate 14 Volt Lithium-Ion batteries that are used to power the HeartMate II 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 Volt 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.

**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.

**Direct Current**: Abbreviated DC. The type of electricity that comes from a battery. The HeartMate II system uses two 14 Volt Lithium-Ion batteries.

**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 26.

**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. The driveline may also be referred to as the percutaneous lead.

**Driveline Connector**: Connector permanently attached to the driveline that connects the pump to the System Controller.

**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. Doctors 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 II 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 II 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:** Abbreviated lpm. Blood flow through the pump is measured in lpm. “LPM” shows on the System Controller user interface along with blood flow data.

**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 Controller. 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 II pump blood flow is critically low.

**Low Speed Limit:** The lowest speed at which the HeartMate II 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 II 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**

**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 59.

**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 66.
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 45.

Outflow Graft: The polyester tube that connects the pump to the aorta (the large blood vessel that sends blood through the body).

Percutaneous: “Percutaneous” means “through the skin.” This term describes the driveline (or percutaneous lead) that goes through the skin of the abdomen and connects the pump to the System Controller.

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. Skin growth into the velour covering helps create a barrier that reduces the risk of driveline infections.

Power Cable: A cable containing electrical wires that transfers electrical power to the System Controller from a routine power source (two 14 Volt Lithium-Ion batteries or the Mobile Power Unit).

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 Power Saver Mode on page 93.

Power Sources: Two power sources can power the HeartMate II 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).

Pump Running Symbol: A green-colored 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 Battery Alarm: A red-colored 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.

Red Heart Alarm: A red-colored 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. In addition to the running System Controller, you also get a backup System Controller. The backup is identical to the running System Controller. The backup is programmed with patient-specific settings.

S

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 ( ) 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 189.

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 on a strap around the neck, on a belt, or in a carrying case. See Wearing and Carrying the System Controller on page 141.

System Controller: The small computer that controls and checks system function. It connects the pump to the external power sources. It can be worn on a strap around the neck, on a belt, or in a carrying case.
**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). 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 189.

**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 26.

**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 II 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.

**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 26.

**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 carrying case. A Battery Holster is used for carrying batteries and battery clips. See *Wearing and Carrying the System Controller* on page 141.

**X**

**Y**

**Yellow Diamond Alarm:** A yellow-colored 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 Alarm:** A yellow-colored symbol (🔧) on the System Controller user interface that illuminates during alarm conditions that are important, but not immediately life-threatening.
INDEX

Numerics
11 Volt Lithium-Ion backup battery 53
   charging 47
   disposal 228
   environmental requirements for operation 221
   fault advisory alarm 207
14 Volt Lithium-Ion batteries 76
   battery life 93
   calibrating 110
   charging 104
   checking charge level 84
   connecting to System Controller 87
   disposal 228
   environmental requirements for operation 221
   estimating available charge 90
   Power Saver Mode 93

A
acceptable environmental conditions for operation 221
accessories 141
   Battery Holster 164
   Belt Attachment 147
   cleaning 227
   Consolidated Bag 151
   Holster Vest 173
   Protection Bag 160
   Shower Bag 121
   Stabilization Belt 137
   System Controller Neck Strap 143
   Travel Bag 162
advisory alarms
   11 Volt Lithium-Ion backup battery fault 207
   backup battery not installed 207
   low battery power 203
   low speed 205
   power cable disconnected 202
   System Controller fault 204
   table of 195
air pressure, acceptable range for operation 221
alarm history, viewing 191
alarms
   backup battery fault 205
   backup battery not installed advisory 207
   connect driveline 197
   connect power 202
   connect power immediately 198
   driveline disconnected hazard 197
   history, viewing 191
   low battery power advisory 203
   low battery power hazard 201
   low flow hazard 200
   low speed advisory 205
   Mobile Power Unit 208
   no external power hazard 198
   power cable disconnected advisory 202
   pump off hazard 196
   replace power advisory 203
   replace power immediately 201
   System Controller 189, 204
      backup battery fault 205
      backup battery not installed 207
      troubleshooting 189
   as needed checklist 274
B
backup battery
   for System Controller
      environmental requirements 221
backup battery for System Controller
   backup battery fault alarm 205
   battery not installed advisory alarm 207
   checking charge status 30
backup System Controller
   battery 53
   Charge Mode 47
   replacing running controller 56
   Sleep Mode 46
   storing 160
batteries
   11 Volt Lithium-Ion 53
      charging 47
      disposal 228
      environmental requirements 221
      fault alarm 207
Index

not installed alarm 207
14 Volt Lithium-Ion 76
  battery life 93
  calibrating 110
  charging 104
  checking charge level 84
  connecting to System Controller 87
  disposal 228
  environmental requirements 221
  estimating available charge 90
  Power Saver Mode 93
  disposal of 228
  Mobile Power Unit 66
battery button on System Controller 28
Battery Charger 98
  advisory messages 210
  charger faults 213
  display panel messages 214
  environmental requirement 221
  information available on display panel 108
  pocket faults 212
  setting up 101
Battery Holster 164
battery power gauge
  on 14 Volt Lithium-Ion batteries 84
  on System Controller 42
Belt Attachment 147
buttons on System Controller
  battery button 28
  display button 29
  silence alarm button 29

C
  calibrating batteries 110
  call hospital contact screen 196, 200, 206
    backup battery fault 205
  caring for driveline exit site 132
  cautions, defined 5
  Charge Mode for System Controller 47
  charging
    11 Volt Lithium-Ion backup battery 47
    14 Volt Lithium-Ion batteries 104, 106
  checklist before sleeping 182
  checklists 265
  cleaning equipment 222
  connect driveline screen 197
  connect power immediately screen 198
  connect power screen 202
  connectors
driveline 32
  Mobile Power Unit patient cable 71
  power cable 37
  Consolidated Bag 151

D
daily checklist 267
display button on System Controller 29
disposing of equipment 228
driveline 18
  care 136
  cleaning 223
  connecting to System Controller 33
  connector 32
  disconnected, hazard alarm 197
  disconnecting from System Controller 35
  evidence of damage 224
  exit site care 132

E
emergencies, how to handle 237
environmental requirements
  for operation 221
equipment
  cleaning 222
disposal 228
  overview 8
estimating battery time 90

F
frequently asked questions 231

G
Glossary 281

H
hand washing 116
hazard alarms
  driveline disconnected 197
  low battery power 201
  low flow 200
  no external power 198
  pump off 196
  table of 194
HeartMate II Left Ventricular Assist Device 17
HeartMate II Left Ventricular Assist System
  environmental requirements
    for operation 221
Holster Vest 173
Holster, Battery 164
humidity, acceptable range
for operation 221

L
low battery power advisory alarm 203
low battery power hazard alarm 201
low battery screen 201, 203
low flow hazard alarm 200
low flow screen 196, 200
low speed advisory alarm 205
low speed screen 206

M
Mobile Power Unit (MPU) 6, 62, 71
alarms 208
connecting to System Controller 72
inserting batteries 66
maintenance 75
patient cable connectors 71
power cord 69
setting up 66
storage 75
monitoring battery life 93
monthly checklist 271

N
no external power hazard alarm 198

O
on-battery power gauge 84
operating modes for System Controller 45

P
power cable
   cleaning 223
   connectors 37
   disconnected alarm 202
power gauge
   on 14 Volt Lithium-Ion batteries 84
   on System Controller 42
Power Module
   environmental requirements
      for operation 221
Power Saver Mode 93
pre-sleep checklist 182
Protection Bag for System Controller 160
pump 17
pump off hazard alarm 196
pump running symbol 27
pump status 30

R
red battery symbol on System Controller 27, 44
red heart symbol on System Controller 27
replace power immediately screen 201
replace power screen 203
replace System Controller
   instructions 56
Run Mode for System Controller 45

S
safety checklists 265
safety testing and classification 241
self test for System Controller 40
Shower Bag 121
showering 120
silence alarm button on System Controller 29
Sleep Mode for System Controller 46
sleep, preparing for 182
Stabilization Belt 137
System Controller 20
   accessories 141
   alarm history 191
   alarms 189
   and preparing for sleep 182
   backup battery in 53
   battery button 28
   battery power gauge 42
   buttons 26
   Charge Mode 47
   cleaning 222
   connecting to batteries 87
   connecting to driveline 33
   connecting to Mobile Power Unit 72
   disconnecting from driveline 35
   display button 29
   driveline
      connecting 33
      disconnecting 35
   environmental requirements
      for operation 221
   fault advisory 204
   Neck Strap 143
   operating modes 45
   pump status 30
   red battery symbol 27, 44
   red heart symbol 27
   Run Mode 45
   self test 40
   silence alarm button 29
Index

Sleep Mode 46
  storing backup 160
  user interface 26
  when to connect to batteries 87
  when to connect to Mobile Power Unit 71
  yellow diamond symbol 44
  yellow wrench symbol 27

T
  temperature, acceptable ranges
    for operation 221
  travel
    by automobile 185
    general considerations 184
  Travel Bag 162
  troubleshooting 189

U
  user interface on System Controller 26

V
  Vest, Holster 173

W
  warnings, defined 5
  wear and carry accessories 141
    Battery Holster 164
    Belt Attachment 147
    cleaning 227
    Consolidated Bag 151
    Holster Vest 173
    Protection Bag 160
    System Controller Neck Strap 143
    Travel Bag 162

X
  x-rays, using to determine driveline damage
    224

Y
  yellow diamond symbol 44
  yellow wrench symbol 27
United States & Canada

Thoratec Corporation
6035 Stoneridge Drive,
Pleasanton, CA 94588
Telephone: +1-925-847-8600,
Fax: +1-925-847-8574,
Emergency HeartLine™: +1-800-456-1477
www.abbott.com
Note: Thoratec is now part of Abbott.