HeartMate III™

Left Ventricular Assist System

Patient Handbook

THORATEC®
CORPORATION

Thoratec Corporation

HEARTMATE III™ LEFT VENTRICULAR ASSIST SYSTEM

Patient Handbook

Your guide to understanding the HeartMate III Heart Pump

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

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EMERGENCY CONTACT LIST

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

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

Hospital

Name _____

Address _____

Contact Person _____

Contact Person Telephone Number _____

Doctor

Name _____

Address _____

Telephone Number _____

Ambulance

Company Name _____

Address _____

Telephone Number _____

Emergency Services

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

Other Important Information

_____

_____

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

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INTRODUCTION

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

1 Introduction

Why Reading This Handbook is Important

Be Informed

This handbook is about your HeartMate III™ Left Ventricular Assist System. It explains how the system works. It also describes daily life using the HeartMate III Left Ventricular Assist System. It explains how to use and care for equipment, and how to take care of yourself. Emergency procedures are 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 that 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. Refer to the warnings and cautions throughout the handbook.
- Review and follow steps for equipment storage and care. Refer to *Equipment Maintenance* on page 6-1.
- Review and practice emergency steps. Refer to *How to Handle an Emergency* on page 8-4.
- Keep a list of emergency contacts. Refer to the *Emergency Contact List* on page v.

Figure 1.1 shows the approximate placement of the Pump inside your body. Details about the Pump function are described in *How Your Heart Pump Works* on page 2-1.

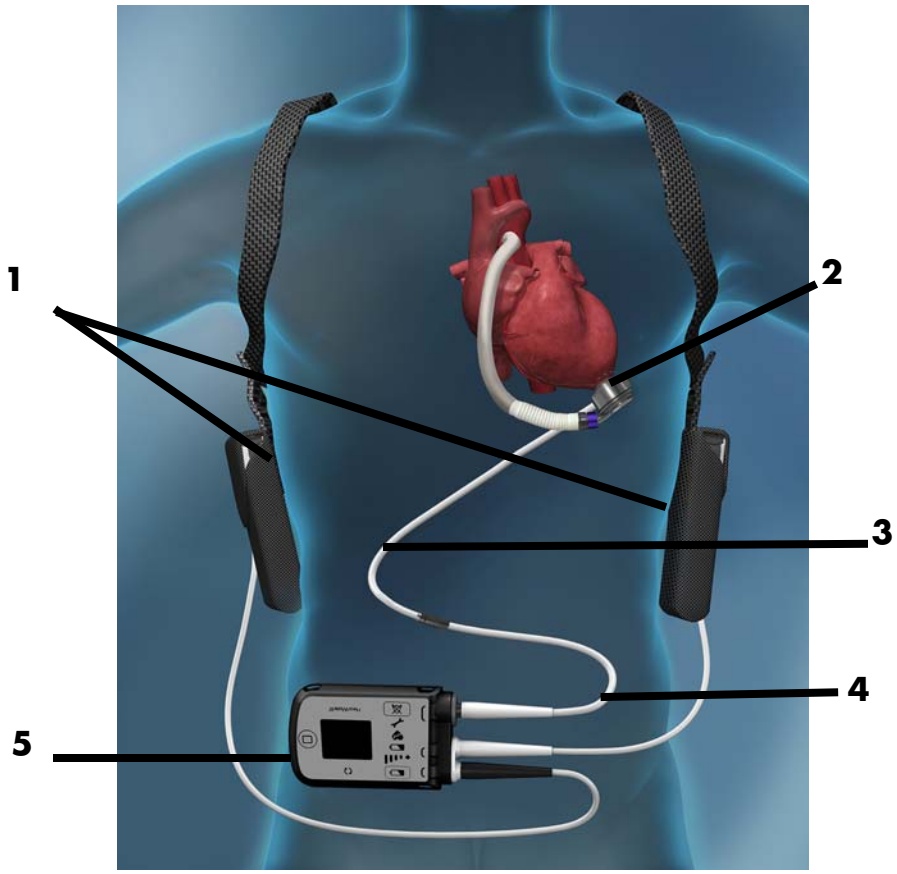


Figure 1.1 HeartMate III Left Ventricular Assist System on Battery Power

1	**HeartMate® 14 Volt Lithium-Ion Batteries**	HeartMate batteries with battery clips are worn in holsters during battery-powered operation.
2	**HeartMate III Left Ventricular Assist Device**	The implanted HeartMate III Left Ventricular Assist Device is also referred to as the Pump.
3	**Pump Cable**	When the Pump Cable and the Modular Cable are connected by the Modular In-Line connector, this combined cable is referred to as the Driveline.
4	**Modular Cable**	
5	**System Controller**	The System Controller controls and checks the Pump.

Understanding Warnings and Cautions

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

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

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

WARNING !

Warnings in this handbook look like this.

CAUTION !

Cautions in this handbook look like this.

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 III Left Ventricular Assist System is critical for safe and successful use.
- All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use.
- All users, including clinicians, patients, and caregivers, must be trained on any HeartMate III power accessories (Power Module, Mobile Power Unit™, Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries) before use.
- The HeartMate III system components must be kept dry. Never expose the System Controller, Batteries, or Mobile Power Unit to water. If these system components get wet, your Pump may stop. Never take tub baths or go swimming while implanted with the Pump. The HeartMate III Shower Bag must be used while showering to keep the System Controller and Batteries dry.
- Do not take showers unless approved by a doctor for showering. If approved for showering, the Shower Bag must be used for every shower. The Shower Bag protects outside parts of the system from water or moisture. If outside parts of the system get wet, the Pump may stop.
- Do not touch television (TV) or computer screens while you have the Pump. TV and computer screens have strong static electricity. A strong electrical shock can damage electrical parts of the system and cause the Pump to stop.
- Avoid activities and conditions that may induce strong static discharges (for example, touching a television or computer monitor screen) as electrostatic discharges may damage and/or interfere with the electrical parts of the system, and may cause the LVAD to perform improperly or stop.
- 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.

WARNING ! (Continued)

- Never have an MRI (magnetic resonance imaging) while you have the HeartMate III Left Ventricular Assist System, as the device contains Ferromagnetic components. MRI may cause Pump failure or injury.
- Therapeutic radiation, such as tissue heating therapy that uses Radio Frequency (RF) energy sources, may damage the device, and damage may not be immediately detectable. Never have therapeutic radiation while you have the Pump.
- Do not subject patients implanted with the HeartMate III Left Ventricular Assist System to magnetic Resonance Imaging (MRI) 

as the device contains Ferromagnetic components. MRI can cause Pump failure or patient injury.
- The HeartMate III Pump may cause interference with implantable cardiac defibrillators (ICD). If electromagnetic interference occurs, it may lead to inappropriate ICD therapy. The occurrence of electromagnetic interference with ICD sensing may require adjustment of device sensitivity and/or repositioning the lead.
- Do not try to repair any of the HeartMate III 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 Thoratec® Corporation for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate III Left Ventricular Assist System and other devices.
- The HeartMate III Left Ventricular Assist System uses lights, sounds, and on-screen messages to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.
- Always have a backup System Controller, fully-charged spare batteries, battery cables, and compatible battery clips nearby at all times in case of emergency.
- The Backup Battery within the System Controller should be used only for temporary support during a power-loss emergency. The Backup Battery will continue to run the Pump if both power cables are disconnected. However, the Backup Battery will not start the Pump without external power applied to the System Controller.
- Inappropriate use of the Backup Battery may result in diminished run time during a power-loss emergency.

Quick Reference

There is a Table of Contents at the beginning of this Handbook and an Index at the end. However, **Table 1.1** contains a quick reference that directs you to sections that may be more frequently used.

Note: Search the Table of Contents and Index using the term System Controller (not Controller).

Table 1.1 Quick Reference to Task Sections

Task	Refer to section
Responding to System Controller Alarms	*System Controller Alarms* on page 5-3
Testing the System Controller Daily	*Performing a System Controller Self Test* on page 2-23
Replacing Low Batteries with Fully Charged Batteries	*Replacing Low Batteries with Fully-Charged Batteries* on page 3-32
Changing from the Mobile Power Unit to Batteries	*Changing from Mobile Power Unit Power to Batteries* on page 3-35
Changing from Batteries to the Mobile Power Unit	*Changing From Batteries to the Mobile Power Unit* on page 3-37
Charging HeartMate III 14 Volt Lithium-Ion Batteries	*Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46
Showering	*Showering* on page 4-9
Caring for your Driveline Exit Site	*Caring for the Driveline* on page 4-6

Equipment Overview

Table 1.2 introduces the main parts of the system.

Table 1.2 System Components

Left Ventricular Assist Device 	The HeartMate III Left Ventricular Assist Device (often called the Pump) is implanted in the chest below the heart. One end of the Pump connects to the heart; the other end connects to the aorta (the large blood vessel that sends oxygen-rich blood through the body). A Driveline connects the Pump to the System Controller.
System Controller 	The System Controller is a small computer that controls and monitors system operation. The System Controller uses lights, sounds, and on-screen messages to communicate with you about operating status and alarm conditions.
HeartMate 14 Volt Lithium-Ion Batteries & Battery Clips  	Batteries are used to power the system when you are active or outdoors. Special batteries are required. You always need to use two batteries at a time. Each battery inserts into a battery clip, which connects the power cables to the System Controller. Two new batteries can power your system up to 17 hours.
Modular Cable 	The Driveline consists of two cables: the Pump Cable and the Modular cable. One end of the Pump Cable is connected to the Pump, the other end exits your body. One end of the Modular cable is connected to the Pump Cable at the Modular In-line Connector, and the other end connects to the System Controller.

Table 1.2 System Components (Continued)

Mobile Power Unit 	The Mobile Power Unit plugs into an AC outlet to provide power to the HeartMate III 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.
Battery Charger 	The Battery Charger charges, calibrates, and tests the HeartMate batteries that are used to power the system during battery-powered operation.

HOW YOUR HEART PUMP WORKS

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

2 How Your Heart Pump Works

Your Heart Pump

Your heart pump is called the HeartMate III Left Ventricular Assist Device, and is also referred to as the Pump (**Figure 2.1**). It helps move blood through your body. A small motor inside the Pump turns the rotor that moves the blood. The Pump is placed below the heart. One end connects to the left ventricle: the heart's main pumping chamber. The other end connects to the aorta: the large blood vessel that sends blood through the body.

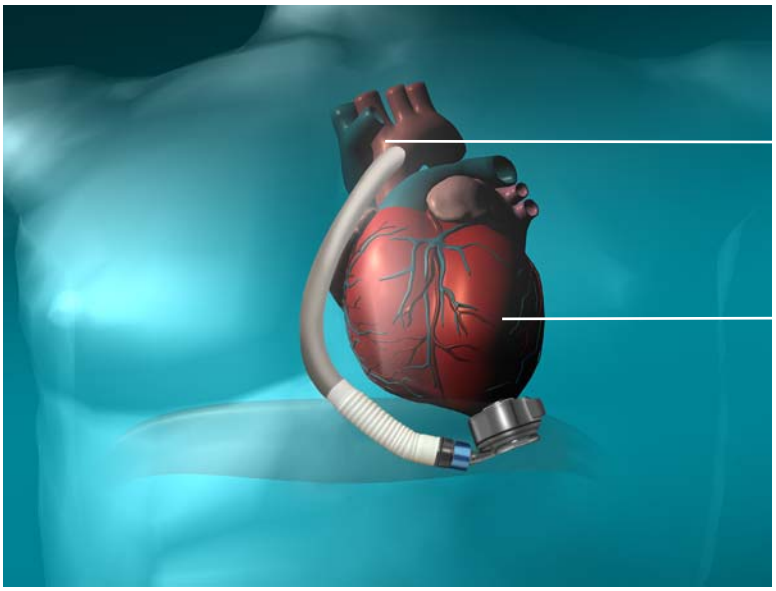


Figure 2.1 HeartMate III Left Ventricular Assist Device

1	**Aorta**
2	**Left Ventricle**

The Pump helps your heart by taking over the work of the left ventricle. It 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.

Driveline Overview

WARNING !

- Check the System Controller Driveline connector to confirm that the Driveline is securely inserted in the socket. If the Driveline disconnects from the System Controller, the Pump stops. If the Driveline disconnects from the System Controller, promptly reconnect it to resume Pump operation.
- Do not open, crush, heat above 104°F (40°C), or incinerate batteries because of the risk of fire and burns. Follow manufacturer's instructions.
- Malfunction of internal Backup Battery may cause the controller to become excessively hot. If this occurs, switch to the backup System Controller.

CAUTION !

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

A thin cable (called a Pump Cable) goes through your abdomen (**Figure 2.2**). The Pump Cable connects to the Modular Cable, which then connects the Pump to the System Controller. When the Pump Cable and Modular Cable are connected together, they are referred to as the Driveline.

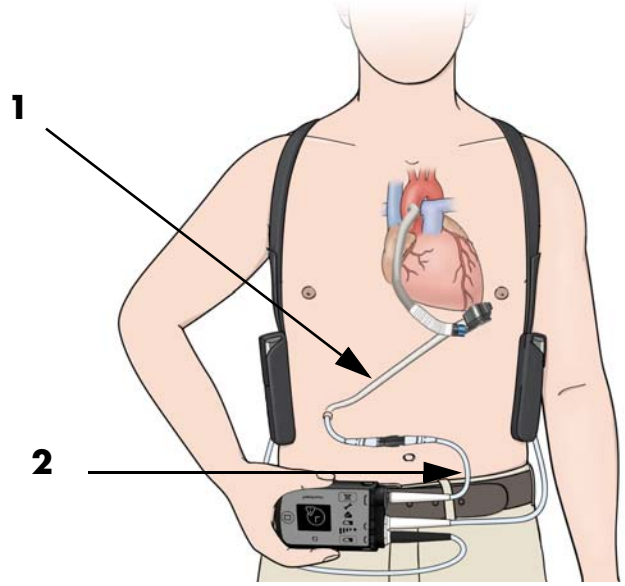


Figure 2.2 Pump Cable and Modular Cable (Driveline) Connect the Pump and the System Controller

1	**Pump Cable**	When the Pump Cable and the Modular Cable are connected, they are referred to as the Driveline.
2	**Modular Cable**	

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

Modular In-line Connector

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

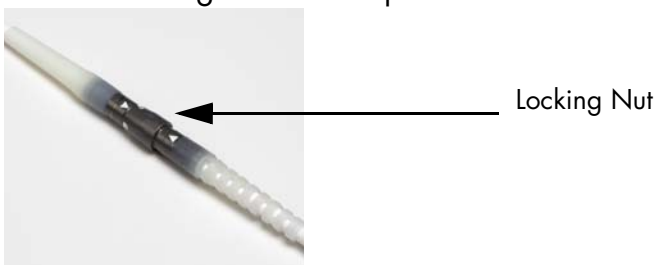


Figure 2.3 Modular In-line Connector

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

System Controller Overview

WARNING !

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

CAUTION !

- The System Controller uses lights, sounds, and on-screen messages to tell you how the system is operating. HeartMate III users with sight or hearing impairment may need extra help using the System Controller.
- Do not drop the System Controller or subject it to extreme physical shock.
- The hospital contact should be informed immediately if the System Controller is dropped. Never delay reporting a dropped System Controller, even if everything seems fine. Dropping the System Controller can cause trauma or tissue damage at the Driveline exit site, which can increase the risk of getting a serious infection. Early treatment of exit site trauma can lower the risk of infection.
- Never use tools to tighten power cable connectors. Securely hand tighten only. Using tools may damage the connectors.
- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Do not twist, kink, or sharply bend the Driveline, System Controller power cables, or Mobile Power Unit patient cable, which may cause damage to the wires inside, even if external damage is not visible. Damage to the Driveline or cables could cause the Pump to stop. If the Driveline or cables become twisted, kinked, or bent, carefully unravel and straighten.
- Damage to electrical wires inside the Driveline can occur even if not visible outside. Be alert for signs of Driveline damage, including (but not limited to):
  - The System Controller alarming when the Driveline is moved or when you change position.
  - High pulsatility index (PI) readings on the System Controller.
  - Occurrence of a Driveline Fault Alarm.
  - Feeling Pump vibrations.
  - Fluid leaking from the external portion of the Driveline.
  - Pump stopping.
- The patient should keep a backup System Controller and at least two fully-charged batteries with him or her at all times for use in an emergency.
- The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be charged at least once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in no support during a power-loss emergency when the backup System Controller is in use.
- Do not place the System Controller on bare skin for an extended time. The System Controller surface temperature can become uncomfortably warm, especially when the room temperature is above 104°F (40°C).

2 How Your Heart Pump Works

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 (**Figure 2.4**).

Figure 2.4 HeartMate III System Controller

1	**Power Cable Connectors**	Links the external power source (Mobile Power Unit or 2 HeartMate 14 Volt Lithium-Ion Batteries) to the System Controller
2	**User Interface**	Uses buttons, lights, and screen where system data, alarms, and user instructions appear
3	**Controller Driveline Connector**	Links the Pump to the System Controller
	[Not Shown] Backup Battery (inside the System Controller)	Located inside the System Controller, powers the Pump for at least 15 minutes during a power-loss emergency

The System Controller is used to:

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

This section contains the following information about the System Controller:

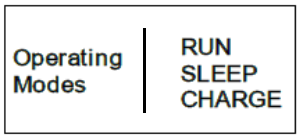
System Controller User Interface
This section describes the visual display of system operations and on-screen messages.

System Controller Driveline Connector
This section provides instructions on connecting and disconnecting the Driveline.

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

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

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



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

System Controller User Interface

The user interface on the System Controller uses sounds, lights, symbols, and on-screen messages to communicate how the system is working (**Figure 2.5**). If you have trouble hearing or seeing, you may need extra help using the System Controller.

On-screen messages inform on how to handle alarms and other situations. The messages are available in different languages. Talk with your hospital contact about selecting the language that is best for your needs.

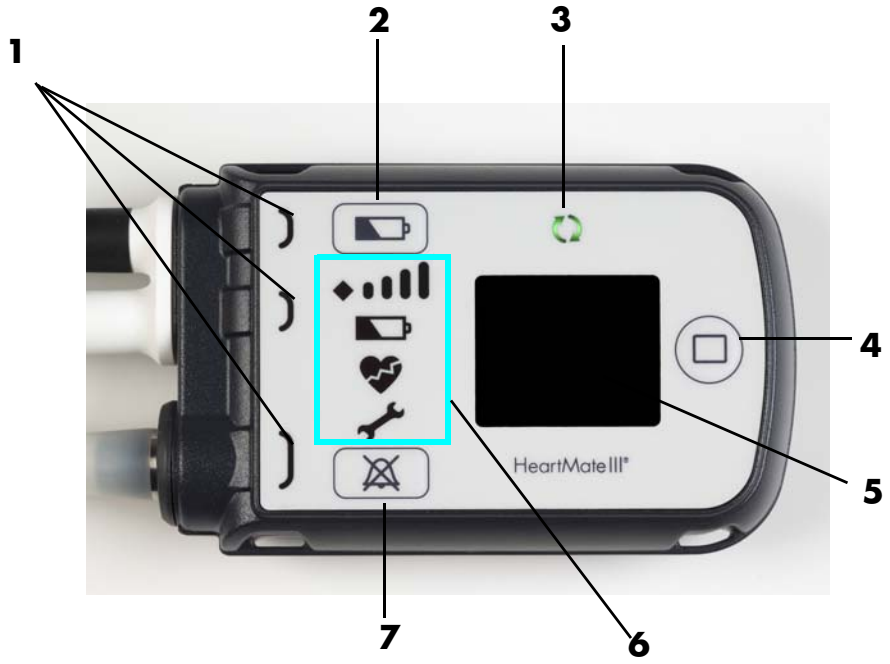


Figure 2.5 System Controller User Interface

1	**Cable Disconnect Symbols**
2	**Battery Button**
3	**Pump Running Symbol**
4	**Display Button**
5	**User Interface Screen**
6	**Status Symbols**
7	**Silence Alarm Button**

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, refer to *System Controller Alarms* on page 5-3. **Table 2.1** introduces the main parts of the user interface.

Table 2.1 System Controller User Interface Symbols and Alarms

Pump Running Symbol 	The green Pump Running light stays on as long as the Pump gets power and remains operating.
Low Battery Alarm Symbol 	The red low battery symbol comes on when less than 5 minutes of power remain for the two in-use HeartMate batteries. This alarm applies only during battery-powered operation. This alarm may also occur when connected to the Mobile Power Unit. If it does, contact your hospital. This is a **Hazard** alarm. When the red low battery symbol comes on, immediately replace the low batteries with two fully-charged batteries, or switch to the Mobile Power Unit. Do this immediately or the Pump may stop.
Yellow Wrench Alarm Symbol 	The yellow wrench symbol comes on when the System Controller detects a mechanical, electrical, or software issue with the system. This is an **Advisory** alarm. When the yellow wrench symbol comes on, follow the on-screen instructions. Do this as soon as possible.
Red Heart Alarm Symbol 	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 **Hazard** alarm. When the red heart symbol comes on, follow the on-screen instructions. Do this immediately or you could be seriously harmed or killed.
Black Power Cable Alarm 	The yellow light near the black power cable connector comes on when the black power cable is loose or disconnects from the System Controller. This is an **Advisory** alarm. If this light comes on, fix the connection as soon as possible.
White Power Cable Alarm 	The yellow light near the white power cable connector comes on when the white power cable is loose or disconnects from the System Controller. This is an **Advisory** alarm. If this light comes on, fix the connection as soon as possible.

Table 2.1 System Controller User Interface Symbols and Alarms (Continued)

Driveline Connector Alarm 	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.
Battery Power Gauge 	The battery power gauge shows the approximate charge status of the power source that is connected to the System Controller's white and black power cables. The power source can be either the 14 Volt Lithium-Ion batteries or the Mobile Power Unit. The number of green bars indicates the amount of power remaining. **Yellow diamond**: Less than 15 minutes of battery power remain. Appearance of this symbol indicates an **Advisory** alarm. If the yellow diamond comes on, promptly replace the low batteries with two fully-charged HeartMate batteries, or switch to the Mobile Power Unit. Do this as soon as possible. ***IMPORTANT!*** The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller).
Pulse Mode 	The presence of the black triangle indicates that the HeartMate III system is operating in Pulse Mode. Once every 2 seconds, the HeartMate III Pump will automatically modify its speed to create an artificial pulse.

Table 2.2 System Controller User Interface Buttons and Descriptions

Battery Button 	The **Battery** button: • Operates the battery power gauge • Starts the System Controller self test • Puts an operating System Controller into Sleep Mode
Silence Alarm Button 	The **Silence Alarm** button: • Silences an active alarm • Displays the last six System Controller alarms on the screen
Display Button 	The **Display** button activates the information display screen. The display button is functional only when a System Controller is in use.

Viewing Pump and System Information

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 operating, the user interface can display the following 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)

While the Pump is operating, an artificial pulse is generated. The Pulse Mode is in operation when a ▲ is displayed on the LCD screen of the System Controller.

Figure 2.6 shows the LCD screen display if the audio alarms have been silenced.

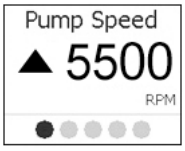
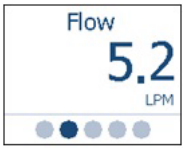
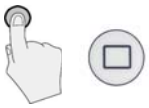
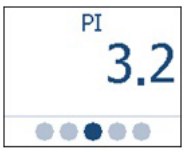
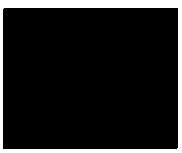
Figure 2.6 Silenced Alarms

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 Speed screen. A dot at the bottom of each screen provides navigational information about which of the five screens is in view.

Table 2.3 shows the display sequence.

Table 2.3 System Controller Display Screen Sequence

Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press display button **ONCE**		Pump speed in revolutions per minute (RPM)
Press 	Press display button **TWO** times		Pump flow in liters per minute (LPM)
Press 	Press display button **THREE** times		Pulsatility Index (PI)
Press 	Press display button **FOUR** times		Power in watts (W)
Press 	Press display button **FIVE** times		The System Controller's backup battery is located inside the System Controller and used to temporarily run the Pump during a power emergency. It has three charge status states: • Charged, ready for use • Charging, actively charging • Fault There is a fault or problem with the backup battery that could affect its reliability.
Press 	Press display button **SIX** times		Blank screen indicates the screen is off, which is normal.

System Controller Driveline Connector

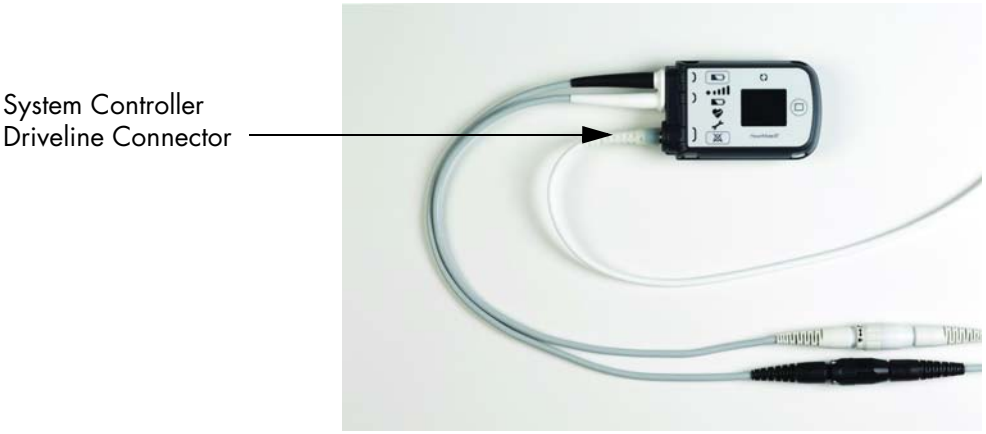


Figure 2.7 System Controller Driveline Connector

The System Controller Driveline Connector connects the Driveline to the System Controller. It has a double lock to lower the risk of accidentally detaching the Driveline. The Driveline is first connected to the operating System Controller as one of the steps to implant the Pump. It should remain connected to the same, operating System Controller at all times. Do not disconnect the Driveline unless told by your hospital contact to replace it. Refer to *Replacing the Operating System Controller with a Backup Controller* on page 2-40.

It is impossible to connect (or disconnect) the System Controller Driveline Connector without moving the Driveline Safety Lock into the unlocked position. When the System Controller Driveline Connector is secure in the socket, the Driveline cannot be removed without pressing the red button under the raised Safety Lock (**Figure 2.8**).

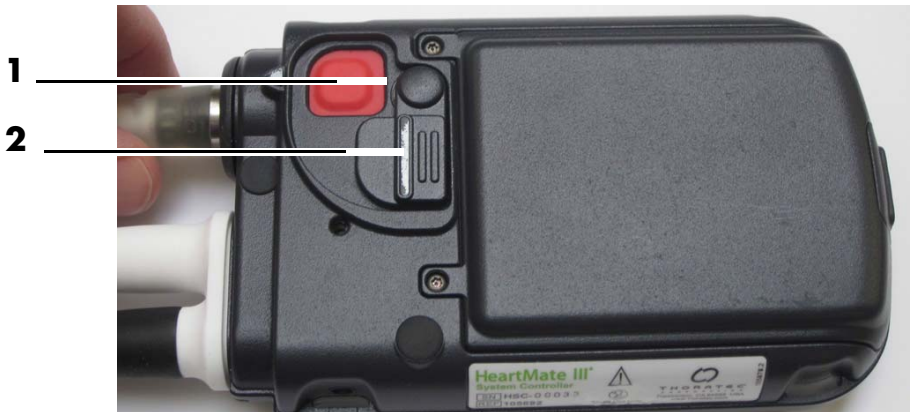


Figure 2.8 Driveline Safety Lock

1	**Red Button**
2	**Safety Lock**

The System Controller continually monitors the connection status of the System Controller Driveline Connector. If the System Controller detects a problem, it immediately alarms. For more information, refer to *Driveline Disconnected Alarm* on page 5-13.

Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- An operating 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 the equipment and place it within reach.
2. Orient the System Controller so the display is facing down.
3. Rotate the Safety Lock to the unlocked position (**Figure 2.9**).

Figure 2.9 Unlocking the Safety Lock

4. Align the BLACK arrow/alignment mark on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.10**).

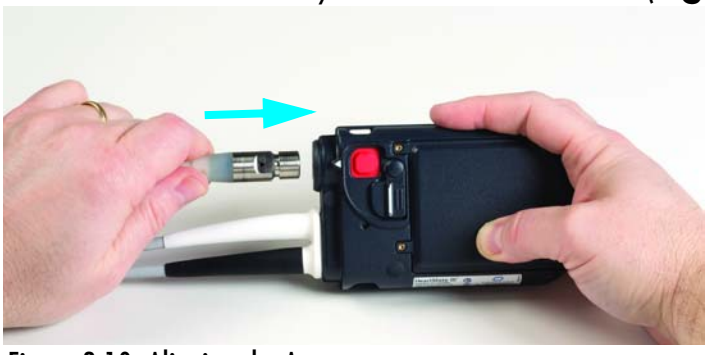


Figure 2.10 Aligning the Arrows

5. Insert the Driveline Cable Connector into the socket and press firmly until it snaps into place (**Figure 2.11**).

   The Left Ventricular Assist Device immediately starts operating when the cable is fully and properly inserted in the socket (if Pump Set Speed is set above 4,000 rpm).

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

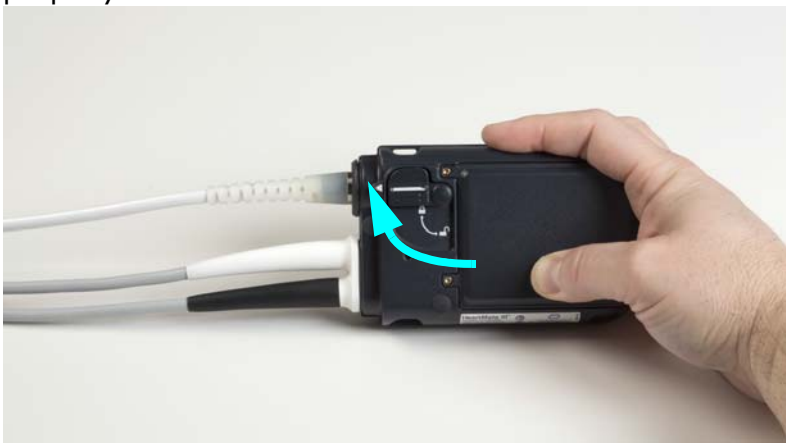


Figure 2.11 Inserting and Locking the Driveline Into the Socket

6. Move the Safety Lock to the locked position, so that it covers the red button.

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

   IMPORTANT! If the Safety Lock does not slide into place, the Driveline is not connected. Remove and reconnect the Driveline.

7. Tug on the inserted metal end of the Modular Cable to check the connection.

   Do not pull on or bend the Driveline.

   If there is a problem with the connection, the System Controller immediately alarms with a Driveline Disconnected alarm. This is a Hazard alarm.

CAUTION !

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

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
- An operating System Controller
- A Driveline that is connected to an operating 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 the equipment and place it within reach.
2. Orient the System Controller so the display is facing down.
3. Rotate the Safety Lock to the unlocked position (**Figure 2.12**).

Figure 2.12 Unlocking the Safety Lock

4. Complete the following steps:

   a. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket.

   b. Grasp the bend relief of the Modular Cable while removing it (**Figure 2.13**).

      Do not pull on or bend the System Controller Driveline Connector.

Figure 2.13 Removing the Driveline

WARNING !

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

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 operate.

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 (**Figure 2.14**).

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, refer to *Power Cable Disconnect Alarm* on page 5-17.

Figure 2.14 Power Cable Connectors

1	**White Connector**
2	**Black Connector**

Figure 2.15 Do Not Sharply Bend the Power Cables

During routine use, the HeartMate III system is powered by one of two power sources: Mobile Power Unit or batteries.

- **Mobile Power Unit**: The Mobile Power Unit plugs into an AC electrical outlet. Use it for power when indoors relaxing, and always when sleeping or when sleep is likely. Connect to the Mobile Power Unit when sleeping since the System Controller may not be heard during 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 2.16 shows the Mobile Power Unit in use. For more information, refer to page 3-4.

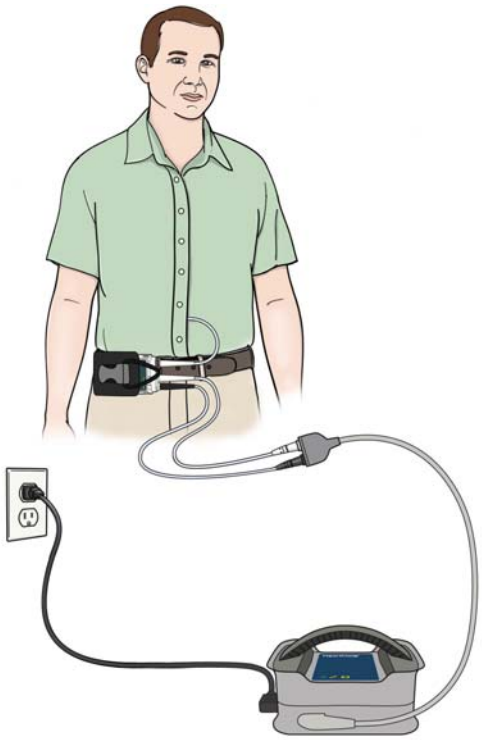


Figure 2.16 Mobile Power Unit in Use

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

  Figure 2.17 shows the batteries in use. For more information, refer to page 3-18.

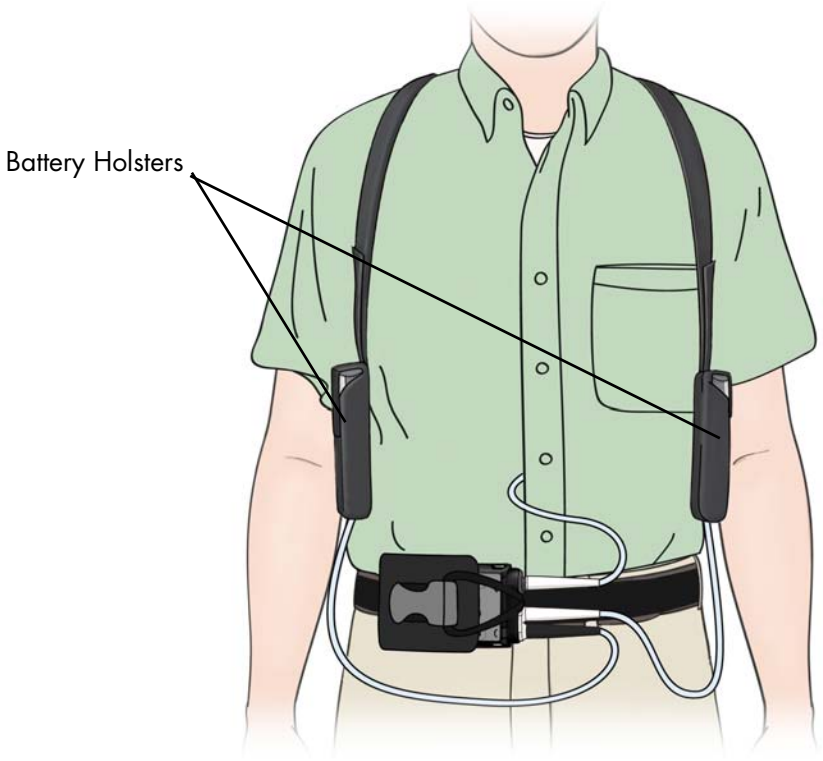


Figure 2.17 Batteries in Holsters

WARNING !

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

Performing a System Controller Self Test

The System Controller self test takes less than a minute. It can be performed when the System Controller is in either Run or Charge mode. 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, it can be determined if the components of the System Controller are working. Performing a self test will not change the speed at which the Pump is operating.

The System Controller self test is loud and bright. All of the lights, symbols, and sounds come on and the words "Self Test" appear on the screen (**Figure 2.18**).

Figure 2.18 System Controller During Self Test

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

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- An operating System Controller

Remember !

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

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

IMPORTANT! If an alarm occurs during a self test, the self test ends. The active alarm overrides the self test. For more information, refer to *System Controller Alarms* on page 5-3. A System Controller self test cannot be initiated during the following alarms: any Hazard alarm, Power Cable Disconnected Advisory alarm, Low Battery Power Advisory alarm.

TASK

1. Press and hold the **Battery** button () for five seconds.
2. Check that:

   ☑ *Self Test* (first briefly white, then black) appears on the screen.

   ☑ All symbols and indicators on the user interface illuminate at the same

   ☑ System Controller is making a loud, steady, audio alarm tone.

3. Release the **Battery** button ().

   One of the following occurs:

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

     Do not use a System Controller that fails its self test. It may need to be replaced. Refer to *Replacing the Operating System Controller with a Backup Controller* on page 2-40. If the System Controller fails the self test, call your hospital contact.

Using the Battery Power Gauge

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

To use the battery power gauge, press and release the **Battery** button ( ) on the user interface (**Figure 2.19**).

Figure 2.19 Battery Power Gauge Showing Full Charge

1	**Battery Button**
2	**Battery Power Gauge**

IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery. That is, the battery inside the System Controller. For more information about checking the status of the System Controller's backup battery, refer to *Viewing Pump and System Information* on page 2-13.

14 Volt Lithium-Ion Battery Power Indicators

4 green bars = 75–100% of battery power remains.

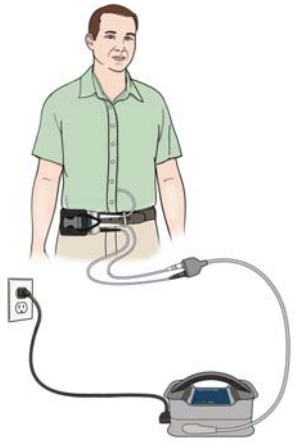
3 green bars = 50–75% of battery power remains.

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, refer to *Checking the Battery Charge Level* on page 3-25.

Mobile Power Unit Power Indicator



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. 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. Refer to *Mobile Power Unit Storage* on page 3-17.

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

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

When the system's power level is dangerously low, it prompts a Low Battery Power alarm (**Figure 2.20**).

Figure 2.20 Low Battery Power Alarm (Less Than 5 Minutes of Power Remain)

System Controller Operating Modes

The System Controller has three operating modes:

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

Using Run Mode

Run Mode is the usual mode for the operating System Controller. **Figure 2.21** shows the System Controller in Run Mode.

Figure 2.21 System Controller in Run Mode While Connected to the Mobile Power Unit (left) and to Batteries (right)

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

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

For instructions on changing from Run Mode to Sleep Mode, refer to *Changing Operating Modes* on page 2-31.

Using Sleep Mode

This is the usual mode for the backup System Controller. **Figure 2.22** shows the backup System Controller in Sleep Mode.

Figure 2.22 System Controller in Sleep Mode

The backup System Controller stays in Sleep Mode until either:

- It is put into Charge Mode (connected to power) to charge the backup battery.
- It is put into Run Mode to replace the operating System Controller.

In Sleep Mode, the Pump Running symbol ( ) is off and the backup System Controller is disconnected from power and off.

Because the backup System Controller is off and not connected to the Driveline, it **does not** perform any of the typical functions, such as:

- Showing how the system is working via the user interface
- Responding to button pushes.
- Charging the backup battery inside the System Controller

For instructions on changing from Sleep Mode to Run Mode or Charge Mode, refer to *Changing Operating Modes* on page 2-31.

Using Charge Mode

Once every six months, put the backup System Controller in Charge Mode. **Figure 2.23** shows the System Controller in Charge Mode.

Figure 2.23 System Controller in Charge Mode: Mobile Power Unit Power (left), Fully-Charged Batteries (right)

In Charge Mode, the System Controller's backup battery will be charged. If the backup battery is not charged, it may not be able to run the Pump when needed. Refer to *System Controller Backup Power* on page 2-35. It can take up to 3 hours for the backup battery to charge.

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

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

Changing Operating Modes

Figure 2.24 summarizes the steps required to change between operating modes.

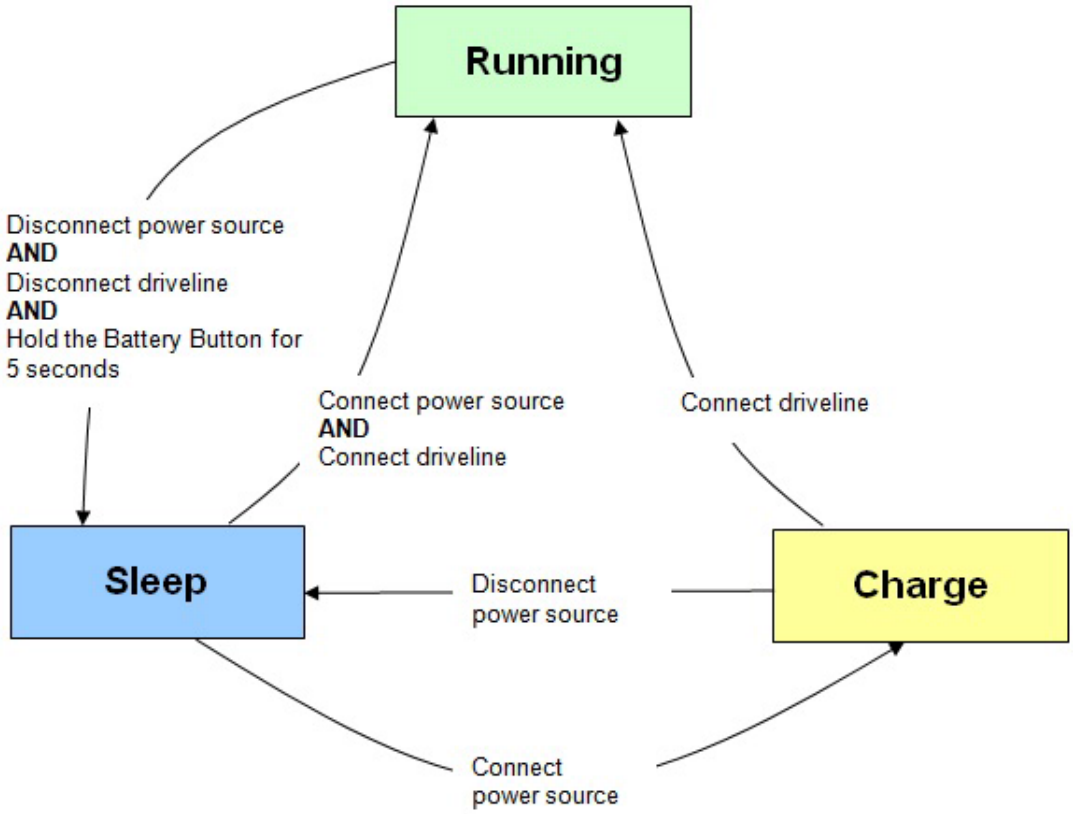


Figure 2.24 System Controller Operating Modes

Changing 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 backup System Controller that is in Sleep Mode.
2. Connect the System Controller to power.

   The power source can be either the Mobile Power Unit or two HeartMate batteries.
3. Connect the Controller Driveline Connector to the System Controller. Refer to *Connecting the Driveline to the System Controller* on page 2-16.

   The System Controller is now in Run Mode.
4. Confirm that the green Pump Running light is illuminated on the System Controller.

Changing 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

Remember !

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

TASK

1. Connect the sleeping System Controller to a power source.
2. The power source can be either the Mobile Power Unit or two HeartMate 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.
3. “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.

Changing 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. Ensure that the System Controller is in Charge Mode and already connected to power.
2. Connect the System Controller Driveline Connector to the System Controller.

   Refer to *Connecting the Driveline to the System Controller* on page 2-16. The System Controller is now in Run Mode.
3. Confirm that the green Pump Running light is illuminated on the System Controller.

Changing 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.
2. The power source can be either the Mobile Power Unit or two HeartMate batteries. The System Controller is now in Sleep Mode.

Changing from Run Mode to Sleep Mode

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- An operating 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.

   Refer to *Disconnecting the Driveline from the System Controller* on page 2-18.

2. Press and release the **Silence Alarm** button ( ) to silence the Driveline Disconnected alarm.
3. Disconnect the System Controller from power.
4. Press and release the **Silence Alarm** button ( ) to silence the Power Cable Disconnect alarm.
5. Press and hold the **Battery** button ( ) for 5 seconds.

   The following occurs:

   - Beeps will sound
   - The word "Hold" and a reverse count down of dots (5 dots, 4 dots, 3 dots, 2 dots, 1 dot) appears

6. Continue to hold down the **Battery** button ( ) until the countdown ends.

   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 System Controller must be charged at least once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in diminished or no support during a power-loss emergency when the backup System Controller is in use.
- The backup battery inside the backup System Controller is charged only when the backup System Controller is connected to power. It takes up to 3 hours to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller.

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

The backup battery is only for backup power. It automatically works if the in-use power disconnects or fails. It should not be used for non-emergencies. Inappropriate use may leave the Pump without power in a real emergency. Backup battery use is tracked by the System Controller. If your hospital contact sees that the backup battery is used often, he or she will talk with you about the reasons for this.

The backup battery is rechargeable. It automatically recharges while the System Controller is connected to power. The backup battery loses power when the System Controller is not connected to power. That is why the backup System Controller needs to be connected to power every six months. For more information, refer to *Maintaining the Backup System Controller Readiness* on page 2-38.

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

Backup System Controller

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

Backup System Controller Overview

Maintaining the Backup System Controller Readiness
Every six months, the backup System Controller's backup battery must be charged and a self test must be performed.

Running
System Controller

Backup
System Controller

Replacing the Operating System Controller with a Backup Controller
If the operating System Controller experiences a failure, it must be replaced.

Backup System Controller Overview

Every HeartMate III patient receives a backup System Controller. The backup System Controller is identical to the operating System Controller, and is programmed with the same settings as the operating System Controller. If the operating System Controller fails, it may need to be replaced with the backup System Controller. For this reason, and in case of an emergency, the backup System Controller must remain with the patient at all times.

Operating System Controller	Backup System Controller
 **Mobile Power Unit**	**If needed, ready to use**  **Backup is not connected to:** • **Power** • **Driveline**
 **Batteries**	

Maintaining the Backup System Controller Readiness

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

Performing Backup System Controller Six Month Charging and Self Test

FOR THIS TASK YOU NEED:

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

Remember !

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

TASK

1. Connect the backup System Controller to a power source (**Figure 2.25**).

   The power source can be either the Mobile Power Unit or two HeartMate batteries.

Figure 2.25 System Controller on Mobile Power Unit Power (left) and Battery Power (right)

When the System Controller is connected to power, the user display screen shows *Charging* or *Charging Complete* (**Figure 2.26**).

Figure 2.26 System Controller Charging, Charging Complete

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

2. Press and hold the **Battery** button ( ) for five seconds to perform a self test on the backup System Controller. (**Figure 2.27**).

   For more information, refer to *Performing Backup System Controller Six Month Charging and Self Test* on page 2-38.

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

Figure 2.27 System Controller Self Test

3. Disconnect power from the backup System Controller.

   This will put the backup System Controller back into Sleep Mode. No further action is needed for one month.

4. Put the backup System Controller into its Protection Bag (**Figure 2.28**).

   For more information, refer to
   Using the Protection Bag for the Backup System Controller on page 4-43.

Figure 2.28 Backup System Controller in Protection Bag

Replacing the Operating System Controller with a Backup Controller

WARNING !

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

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

Replace the System Controller using instructions in either *Replacing the Current System Controller with One Power Source* on page 2-42 or *Replacing the Current System Controller with Multiple Power Sources* on page 2-45.

IMPORTANT! 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.

Table 2.4 System Controller Replacement

With In-use Power Source Only Mobile Power Unit OR Batteries and Clips	**Multiple Power Sources Available** Mobile Power Unit AND Batteries and Clips
 a. Move the **white** connector's power source from the operating System Controller to the backup System Controller. **For more information, refer to *Powering the System* on page 3-1.**	 a. Connect both the white and black connectors on the backup System Controller to power. ***IMPORTANT!*** Keep the operating System Controller connected to power. **For more information, refer to *Powering the System* on page 3-1.**
 ***IMPORTANT!*** Before inserting, align the marking on the System Controller Driveline Connector with the arrow on the System Controller. b. Promptly move the System Controller Driveline Connector from the running System Controller to the backup System Controller. It may take up to 10 seconds for your Pump to start. c. Close the Safety Lock.  **For more information, refer to *System Controller Driveline Connector* on page 2-15.**	 ***IMPORTANT!*** Before inserting, align the marking on the System Controller Driveline Connector with the arrow on the System Controller. b. Promptly move the System Controller Driveline Connector from the running System Controller to the backup System Controller. It may take up to 10 seconds for your Pump to start. c. Close the Safety Lock.  **For more information, refer to *System Controller Driveline Connector* on page 2-15.**
 d. Move the **black** connector's power source from the operating System Controller to the backup System Controller.	d. Disconnect the old, replaced System Controller from power.

Replacing the Current System Controller with One Power Source

Complete the following steps to replace the current System Controller with the replacement System Controller.

FOR THIS TASK YOU NEED:

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

TASK

1. Place the backup System Controller within reach.
2. Sit or lie down in case of dizziness if the Pump briefly stops.
3. If the current System Controller is alarming, press the **Alarm Silence** button () to silence the audio alarms for 2 minutes.
4. Locate the replacement HeartMate III System Controller.
5. Complete the following steps:
   a. Disconnect the White Power connection from the current System Controller.
   b. Connect the White Power connection to the replacement System Controller.
   c. Fully secure the white nut until tight.

6. Complete the following steps to disconnect the Driveline from the current System Controller:

   a. Orient the System Controller so the display is facing down.

   b. Rotate the Safety Lock to the unlocked position (**Figure 2.29**).

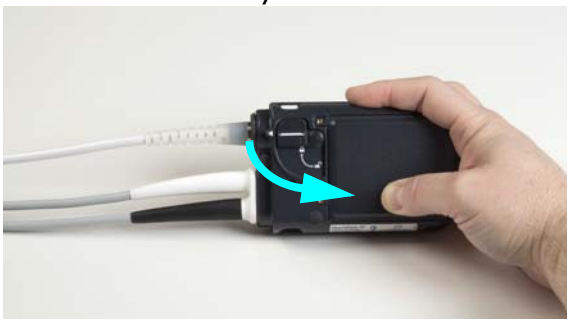


Figure 2.29 Unlocking the Safety Lock

   c. Firmly press the red button under the Safety Lock, while pulling the System Controller Driveline Connector from the socket.

   d. Grasp the bend relief of the Driveline while removing it.

      Do not pull on or bend the System Controller Driveline Connector (**Figure 2.30**).

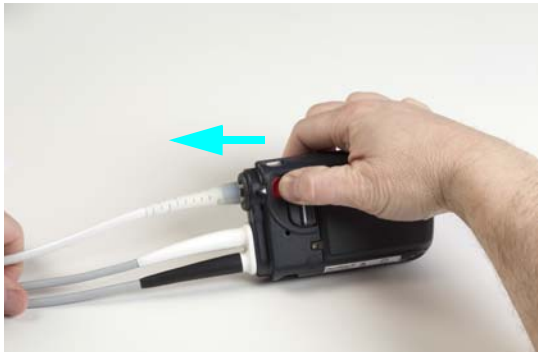


Figure 2.30 Removing the Driveline

7. Complete the following steps to connect the Driveline to the replacement System Controller:

   a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.31**).

Figure 2.31 Aligning the Arrows

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

      The Left Ventricular Assist Device immediately starts operating when the cable is fully and properly inserted in the socket, and if the Pump Set Speed is set above 4000 rpm.

8. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.32**).

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

Figure 2.32 Closing the Safety Lock

9. Complete the following steps:

   a. Disconnect the Black Power connection from the previously operating System Controller.

   b. Connect the Black Power connection to the replacement System Controller

   c. Fully secure the black nut until tight, which is now supporting the patient.

Replacing the Current System Controller with Multiple Power Sources

Complete the following steps to replace the current System Controller with the replacement System Controller using multiple power sources.

TASK

1. If your current System Controller is alarming, silence the audio alarms for 2 minutes by pressing the **Alarm Silence** button ( ).
2. Locate your replacement HeartMate III System Controller and second power source.
3. Complete the following steps to power the replacement System Controller:
   a. Connect both the White and Black Power connections.
   b. Fully secure both the white and black nuts until tight.
4. Complete the following steps to disconnect the Driveline from the current System Controller:
   a. Orient the System Controller so the display is facing down.
   b. Rotate the Safety Lock to the unlocked position (**Figure 2.33**).

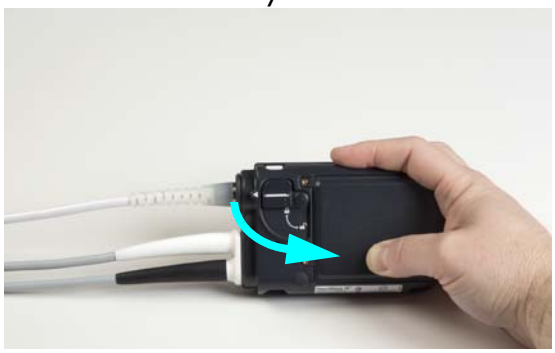


Figure 2.33 Unlocking the Safety Lock

   c. Firmly press the red button under the Safety Lock, while pulling the Controller Driveline Connector from the socket. Grasp the bend relief of the Driveline while removing it.

      Do not pull on or bend the Controller Driveline Connector (**Figure 2.34**).

Figure 2.34 Removing the Driveline

5. Complete the following steps to connect the Driveline to the replacement System Controller:

   a. Align the BLACK arrow on the Driveline Cable Connector with the WHITE arrow on the System Controller socket (**Figure 2.35**).

Figure 2.35 Aligning the Arrows

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

      The Left Ventricular Assist Device immediately starts operating when the cable is fully and properly inserted in the socket (if Pump Set Speed is set above 4000 rpm).

6. Move the Safety Lock to the locked position, so that it covers the red button (**Figure 2.36**).

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

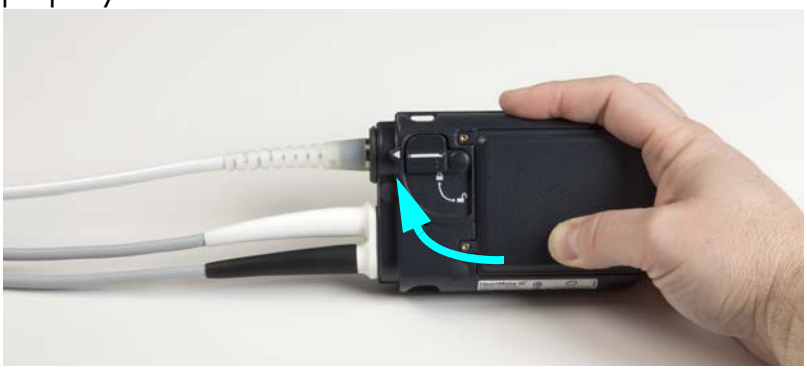


Figure 2.36 Closing the Safety Lock

7. Complete the following steps:

   a. Disconnect the Black Power connection from the previously operating System Controller.

   b. Connect the Black Power connection to the replacement System Controller.

   c. Fully secure the black nut until tight, which is now supporting the patient.

Turning Off the System Controller (Sleep Mode)

TASK

1. Disconnect the Driveline from the System Controller.
2. Press and release the **Silence Alarm** button ( ) to silence the Driveline Disconnected Alarm.
3. Disconnect the System Controller from its power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries).
4. Press and release the **Silence Alarm** button ( ) to silence the Power Cable Disconnect Alarm.
5. Press and hold the **Battery** button ( ) for five seconds.

   The following appears on the screen:

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

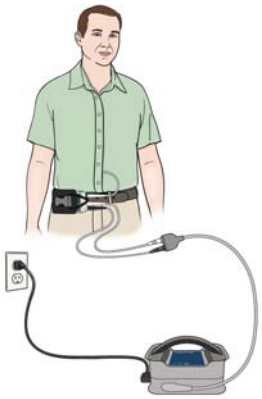
   When the countdown ends, the following occurs:
   The screen goes black, the Pump Running symbol is black ( ), and the System Controller is in Sleep Mode. If this sequence is not fully completed, the System Controller will not enter Sleep Mode.

POWERING THE SYSTEM

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

3 Powering the System

Power Source Overview



Mobile Power Unit

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

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 17 hours, depending on your activity level.

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.

Using the Mobile Power Unit

The Mobile Power Unit (**Figure 3.1**):

- Provides power to the System Controller and Pump
- Powers the system while sleeping or relaxing indoors
- Echoes System Controller alarms

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 System Controller

Figure 3.1 Mobile Power Unit

1	**Speakers**
2	**Status Symbols**
3	**Patient Cable**
4	**AC Power Receptacle**

WARNING !

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

CAUTION !

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

CAUTION ! (Continued)

- Do not incinerate, disassemble, crush, puncture, or otherwise damage batteries, as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not mix old and new batteries or battery types (such as rechargeable with non-rechargeable), as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may affect the electromagnetic compatibility of the Mobile Power Unit with other devices. Potential interference may occur between the Mobile Power Unit and other devices.
- Inspect the Mobile Power Unit patient and power cables for damage. Do not use the Mobile Power Unit if either cable shows signs of damage.
- When moving the Mobile Power Unit to a different location or AC power source, first connect the System Controller to HeartMate 14 Volt batteries.
- Do not change the Mobile Power Unit batteries while the Mobile Power Unit is powering the HeartMate system. Switch to another power source and then disconnect the Mobile Power Unit power cord from the wall socket prior to replacing the Mobile Power Unit batteries.

Setting Up the Mobile Power Unit

This section provides information about preparing the Mobile Power Unit before use. It includes:

- Inserting the Mobile Power Unit batteries
- Replacing 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. Mobile Power Unit batteries must be installed 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

CAUTION !

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

Remember !

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

TASK

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Ensure that the power cord is unplugged from the Mobile Power Unit.

3. Inspect the Mobile Power Unit for dents, chips, cracks, or other signs of damage and complete one of the following steps:
   - If it appears undamaged, go to Step 4.
   - If it appears damaged, 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 3.2**).

Figure 3.2 Loosening the Screw

5. Open the battery compartment cover on the rear of the Mobile Power Unit and dispose of the battery installation reminder tag, if present (**Figure 3.3**).

Figure 3.3 Removing the Battery Compartment Cover

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

7. Lay the ribbon on the bottom of the compartment and complete the following steps:
   a. Place the Alkaline AA batteries in the battery compartment.
   b. Orient the batteries as shown on the orientation markings on the battery clip (**Figure 3.4**).

Figure 3.4 Inserting AA Batteries

8. Replace the battery compartment cover.
9. Use the flathead screwdriver or coin to tighten the screw, and complete the following steps:
   a. Ensure that the screw is tight.
   b. Ensure that the cover is securely closed (**Figure 3.5**).

Figure 3.5 Tightening the Screw

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

Connecting the Power Cord

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- A Mobile Power Unit (with 3 AA Alkaline batteries included)
- 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 3.6**).

Figure 3.6 Plugging the 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.

CAUTION !

- 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.

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

   When initially connected to power, the following occur:

   - The Mobile Power Unit automatically performs a self test
   - The green Power On symbol is illuminated
   - The yellow wrench and Replace MPU Battery lights flash
   - The Mobile Power Unit beeps twice

   After the self test, the green Power On light should remain lit (**Figure 3.7**). The Mobile Power Unit is ready for use.

Figure 3.7 Mobile Power Unit Ready for Use

6. If the green Power On light does not illuminate, complete the following steps:

   a. Plug the Mobile Power Unit into a different AC electrical outlet that is dedicated to Mobile Power Unit use.

CAUTION !

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

   b. Observe the top panel of the Mobile Power Unit and complete one of the following steps:

      - If the green light illuminates and the functions described in Step 5 occur, the Mobile Power Unit is ready for use.
      - If the green light still does not illuminate, call your hospital contact.

        The Mobile Power Unit may have a problem. Do not use it.

Connecting to the Mobile Power Unit

Use the Mobile Power Unit when relaxing indoors and always when sleeping. The Mobile Power Unit must be connected when sleeping (or when sleep is likely) because the System Controller's low battery alarms may not be heard. The Mobile Power Unit will echo the System Controller's alarms. For steps on getting ready for sleep, refer to *Sleeping* on page 4-62.

The Mobile Power Unit patient cable is needed to connect the System Controller to the Mobile Power Unit.

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 (**Figure 3.8**). When connecting the System Controller to the Mobile Power Unit patient cable, always connect white-to-white and black-to-black.

Use care when connecting and disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 5-33

Figure 3.8 Mobile Power Unit Patient Cable

1	**White Connector**
2	**Black Connector**

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 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 the equipment and place it within reach.
2. Verify that all of the steps to set up the Mobile Power Unit have been completed.

   Refer to *Setting Up the Mobile Power Unit* on page 3-8 for complete instructions.
3. Place the black and white System Controller power cable connectors within reach (**Figure 3.9**).

Figure 3.9 System Controller Power Cable Connectors

1	**White Connector**
2	**Black Connector**

4. Place the black and white Mobile Power Unit patient cable within reach.
5. Place the batteries with their attached battery clips within 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 3.10**).

CAUTION !

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

Figure 3.10 Carefully Aligning the Connectors

8. Firmly push together the two connectors (**Figure 3.11**).

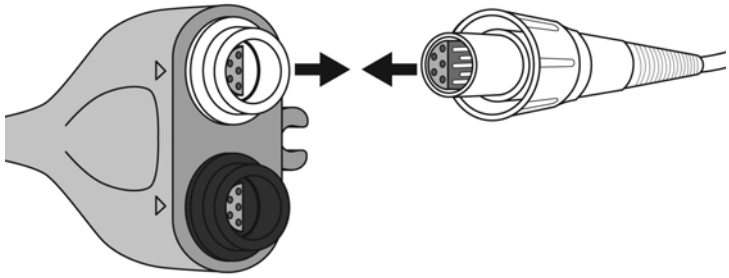


Figure 3.11 Pushing Together the Two Connectors

9. Tighten the connector nut until secure (**Figure 3.12**).

   Hand tighten only. Do not use tools.

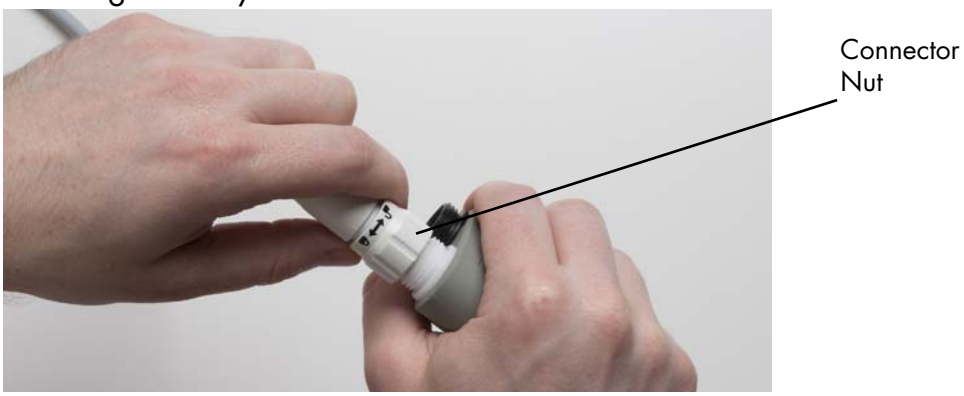


Figure 3.12 Tightening the Connector Nut

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

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

12. Firmly push together the two connectors.
13. Tighten the connector nut until secure.

    Hand tighten only. Do not use tools.
14. Both System Controller power cables are now connected to the Mobile Power Unit (**Figure 3.13**).

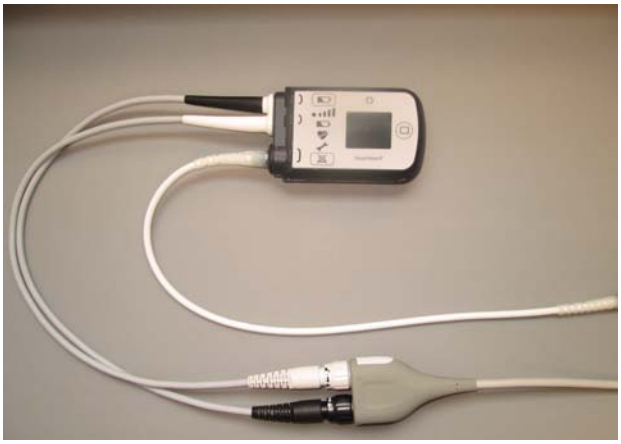


Figure 3.13 System Controller Power Cables Connected to Mobile Power Unit Patient Cable Connectors

Mobile Power Unit Storage

If the Mobile Power Unit will not be used for an extended time, complete the following steps:

TASK

1. Unplug the AC power cord from power.
2. Detach the power cord from the device.
3. Wrap the Mobile Power Unit patient cable around the Mobile Power Unit for storage.

   This is also a convenient way to prepare the device and patient cable for travel.

Figure 3.14 Mobile Power Unit

Maintaining the Mobile Power Unit

The Mobile Power Unit requires little planned maintenance. However, it needs to be inspected routinely to ensure the safest and best possible performance. For complete information about caring for the Mobile Power Unit, refer to *Caring for the Mobile Power Unit* on page 6-5.

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

WARNING !

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

TASK

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

Using HeartMate 14 Volt Lithium-Ion Batteries

WARNING !

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

CAUTION !

- Use only the Battery Charger supplied by Thoratec Corporation to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- After approximately 70 uses, HeartMate 14 Volt Lithium-Ion batteries may need to be re-calibrated. The Battery Charger indicates when a battery needs re-calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted, to prevent a backlog of uncalibrated batteries.
- Leave a calibrating 14 Volt Lithium-Ion battery in the Battery Charger for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery power gauge will reflect this status).
- Dirty battery contacts on the 14 Volt Lithium-Ion battery may prevent proper charging, which can affect operation. Clean the metal contacts on the batteries and inside the battery clip at least once a month. Use a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or battery clips, or before placing batteries into the Battery Charger.
- As 14 Volt Lithium-Ion batteries get older, they support the system for shorter periods of time. If batteries do not give at least four hours of support, take them out of service.

CAUTION ! (Continued)

- If stored and used within recommended guidelines, HeartMate 14 Volt Lithium-Ion batteries should be usable for approximately 360 use/charge cycles or for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced.
- If a 14 Volt Lithium-Ion battery leaks, do not touch the leaking fluid. If the fluid touches skin or eyes, wash the affected area with plenty of water and seek medical advice.
- To prevent deterioration or damage to a 14 Volt Lithium-Ion battery:
  - Do not store in direct sunlight.
  - Do not use in temperatures that are below 32°F (0°C) or above 104°F (40°C), or the battery may fail suddenly.
  - Do not dismantle, open, or shred.
  - Do not drop or hit against hard objects or each other.
  - Do not leave or store in extremely hot or cold temperatures such as automobiles or automobile trunks, or battery life will be shortened.
  - Do not expose to heat or fire.
- 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 (the Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium Ion batteries) at all times. Do not rely on the System Controller's backup battery, as it will only power the Pump for a limited amount of time.

HeartMate 14 Volt Lithium-Ion Batteries Overview

HeartMate batteries (**Figure 3.15**) are another power source for the HeartMate III Left Ventricular Assist System. Two HeartMate 14 Volt Lithium-Ion batteries are always used to power the HeartMate III Left Ventricular Assist System.

Figure 3.15 HeartMate 14 Volt Lithium-Ion Battery

During battery-powered operation, the Left Ventricular Assist System is powered by two direct current (DC) batteries that are inserted into battery clips. The battery clips and attached batteries can be worn in holsters, one under each arm (**Figure 3.16**).

Figure 3.16 HeartMate III System on Battery Power

Mobile Operation: Using batteries to power the system is called mobile operation, since there is no connection to electricity. Use battery power when mobile and relatively active. Examples of battery power use would be while shopping or performing other activities outside the home.

Battery Support Time: Two, new, fully charged HeartMate 14 Volt Lithium-Ion batteries provide 17 hours of support. Batteries last for less time if 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.

Battery Power Gauge: During battery-powered operation, the battery power gauge on the System Controller shows overall power capacity for both batteries. The battery power gauge shows when the batteries are low. If the current power source is low, the System Controller prompts to switch to a different power source (two new fully-charged batteries or the Mobile Power Unit). *Checking the Battery Charge Level* on page 3-25 provides more detailed information.

New Batteries

HeartMate batteries are *not* charged. Each HeartMate battery must be charged before use, including the first time a battery is used. 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. For more information, refer to *Checking the Battery Charge Level* on page 3-25.

For instructions on charging HeartMate batteries, refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

Battery Clips

HeartMate batteries cannot power the system without battery clips. HeartMate 14 Volt Lithium-Ion batteries only work with 14 Volt battery clips. Other battery clips will not transfer power.

Two HeartMate batteries must be placed into special battery clips to transfer power to the System Controller (**Figure 3.17**).

Figure 3.17 HeartMate 14 Volt Lithium-Ion Battery and 14 Volt Battery Clip

Power cable connectors on the System Controller connect to each battery clip (**Figure 3.18**). When the power cables are connected to the battery clips, battery power is supplied to the System Controller.

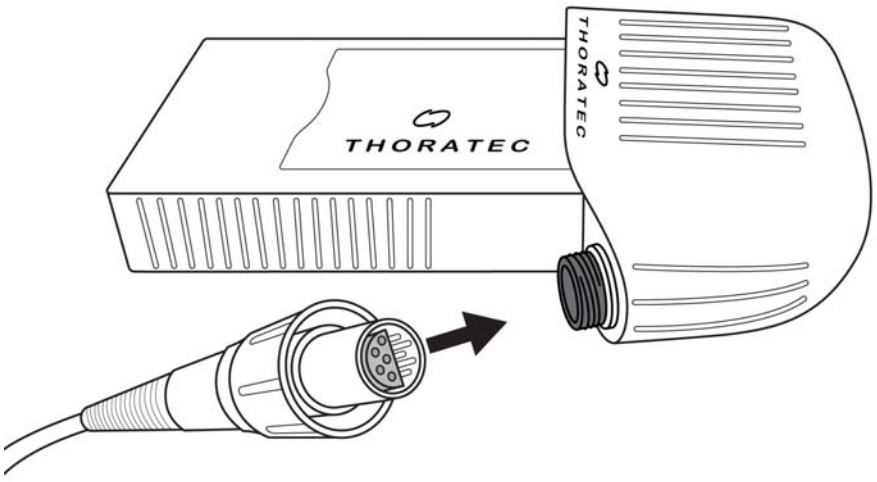


Figure 3.18 Attaching the System Controller Power Cable to the Battery Clip

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 the equipment and place it within 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 3.19**).

Figure 3.19 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 the equipment and place it within 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 3.20**) and withdraw the battery.

Figure 3.20 Pressing the Battery Release Button and Withdrawing Battery

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

Checking the Battery Charge Level

After a HeartMate battery is charged, it should be ready for use.

The on-battery power gauge on a HeartMate battery uses five green bars to indicate available battery power. Each bar represents approximately 20% of available power.

When a battery is a fully charged, all five bars turn on, indicating that the battery is 80–100% charged. Fewer bars illuminate as power diminishes. When battery power drops below 10%, only one green blinking bar illuminates.

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.

Complete the following steps before using any battery:

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 the equipment and place it within reach.
2. Locate a battery in one of the Battery Charger charging pockets.

   IMPORTANT! A green light next to the Battery Charger pocket is the only assurance that a battery in the Battery Charger is 100% charged. If the yellow light is on, the battery is still charging. If the red light is on, the battery has a problem. Do not use it.
3. Complete the following steps to ensure that the battery is charged and ready for use:
   a. Locate the lights next to the charging pocket for the battery.
   b. Verify that a green light is illuminated on the Battery Charger.
4. Remove the battery from the charging pocket.
5. Find the **Battery** button  on the battery's power gauge.

6. Press and hold the **Battery** button for five seconds (**Figure 3.21**).

Figure 3.21 Pressing the Battery Button to Check the Battery Charge Level

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

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

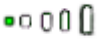
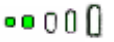
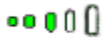
7. If four or fewer bars illuminate, return the battery to the pocket for more charging.

   If the power gauge continues to show four or fewer bars after additional charging, the battery may be defective. Do not use it.

8. If the battery is defective, obtain a replacement battery, if needed.

Table 3.1 on page 3-27 describes the on-battery power gauge on a 14 Volt Lithium-Ion battery.

Table 3.1 14 Volt Lithium-Ion Battery On-Battery Power Gauge

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

Connecting to Batteries

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

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 System Controller
- 2 fully-charged HeartMate14 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 the equipment and place it within reach.
2. Place two battery clips and two fully-charged batteries within reach.
3. Complete the following steps to insert a fully-charged battery into a battery clip:
   a. Line up the arrows on the battery and battery clip.
   b. Push the battery into the clip until the battery clicks into place (**Figure 3.22**).

Figure 3.22 Inserting the Battery Into the 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 reach (**Figure 3.23**).

Figure 3.23 System Controller Power Cables With Black and White Connectors

1	**White Connector**
2	**Black Connector**

6. Unscrew and disconnect only the white System Controller power cable connector from its current power source. Do not disconnect the black connector.

   Note: An 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 3.24**).

CAUTION !

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

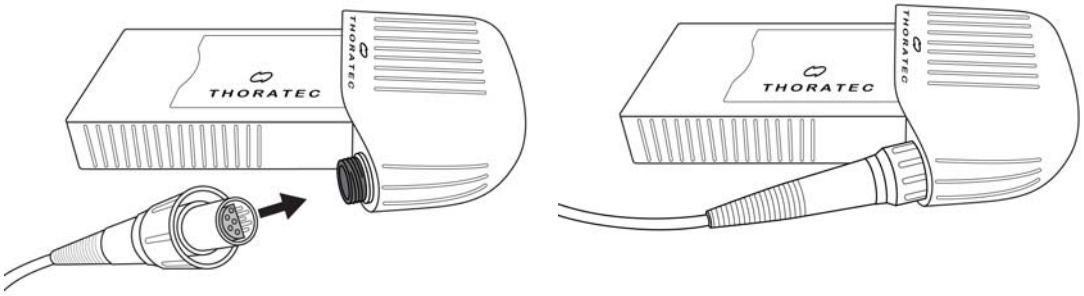


Figure 3.24 Carefully Matching the Connectors

8. Firmly push together the two connectors.
9. Tighten the connector nut until secure.

   Hand tighten only. Do not use tools.
10. Unscrew and disconnect only the black System Controller power cable connector from its current power source.

    Do not disconnect the white connector.

    Note: An alarm will sound.
11. Promptly align the opposite half circles inside the black System Controller power cable connector and the power cable connector for one of the battery clips.

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

12. Firmly push together the two connectors.
13. Tighten the connector nut until secure.

    Hand tighten only. Do not use tools.

    Both System Controller power cables are now connected to battery power (**Figure 3.25**).

Figure 3.25 System Controller Connected to Batteries

Refer to *Mobile Power Unit Storage* on page 3-17 for information on using HeartMate 14 Volt Lithium-Ion batteries to power 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 to provide the maximum amount of operating time from the remaining battery capacity. Running at reduced speed is a critical situation. It may cause dizziness or shortness of breath. It is important to immediately change to a new pair of charged batteries or to the Mobile Power Unit.

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

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

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

Power Saver Mode

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

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

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

Replacing Low Batteries with Fully-Charged Batteries

FOR THIS TASK YOU NEED:

- 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. Obtain two fully-charged HeartMate batteries and place them within reach.
2. If batteries are removed from the Battery Charger, ensure that the light near the charging pocket for each battery is green.

   This indicates that the battery is charged.
3. Complete the following steps to confirm that each replacement battery is fully charged:
   a. Press and hold the **Battery** button on one of the batteries (**Figure 3.26**).

Figure 3.26 Battery Power Gauge Symbol on 14 Volt Lithium-Ion Battery

   b. Verify that the battery is fully charged and ready for use.
   c. Repeat Steps a and b for the second battery.
4. Complete the following steps to determine the amount of power remaining in the batteries currently powering the system:
   a. Grasp the battery clip and attached battery.
   b. Remove the clip and battery from the holster or carrying case.

      Do not remove the battery from its clip at this time.

   c. Locate the **Battery** button on the battery.
   d. Press and hold the **Battery** button for five seconds.
   e. Count the number of lights that illuminate to determine how much battery power remains for this battery.
   f. Repeat Steps a–e for the second battery that is currently in use.
   g. Determine which battery has the least power.

Replace the battery that has the least amount of remaining power first. If both batteries have the same amount of power remaining, select either battery to replace first.

5. Complete the following steps to remove the depleted battery:
   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. The green power symbol and power gauge lights will flash.

   c. Place the depleted battery in a separate area from the fully-charged batteries.
6. Pick up one of the fully-charged batteries, ensuring that it is a fully-charged battery rather than a depleted battery.
7. Complete the following steps to insert a fully–charged battery into a battery clip:
   a. Locate the orange arrow on the battery.
   b. Line up the arrows on the battery and battery clip.
   c. Push the battery into the clip until the battery clicks into place (**Figure 3.27**).

Figure 3.27 Aligning Orange Arrows and Inserting the Battery Into the Battery Clip

   d. 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.

8. Repeat Steps 5–7 to replace the other depleted battery.
9. When both batteries have been replaced, return the clips with the fully-charged batteries to holsters or carrying case.
10. Complete the following steps to recharge the depleted batteries:
    a. Ensure that the Battery Charger is plugged in and turned on ("I").
    b. Place each depleted battery in a Battery Charger pocket.

Maintaining Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. For complete information about maintaining 14 Volt Lithium-Ion batteries and battery clips, refer to *Caring for HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 6-5.

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 day, 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.

Changing Power Sources

Changing from Mobile Power Unit Power to Batteries

Use care when connecting and disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 5-33.

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- A 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
- Holster or Carry Accessory

Remember !

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

TASK

1. Gather the equipment and place it within reach.
2. Complete the following steps to insert a fully-charged battery into a battery clip:
   a. Line up the arrows on the battery and battery clip.
   b. Push the battery into the clip until the battery clicks into place.

Figure 3.28 Inserting the Battery into the Battery Clip

   c. Pull gently on the battery to confirm that the connection is tight.
3. Repeat Step 2 for the second battery and battery clip.
4. Place the batteries with attached battery clips within reach.
5. Place the black and white System Controller power cable connectors within reach.
6. Unscrew and disconnect only the white System Controller and white Mobile Power Unit patient cable connectors.

   The Power Cable Disconnect alarm will come on. This is normal.

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 3.29**).

CAUTION !

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

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

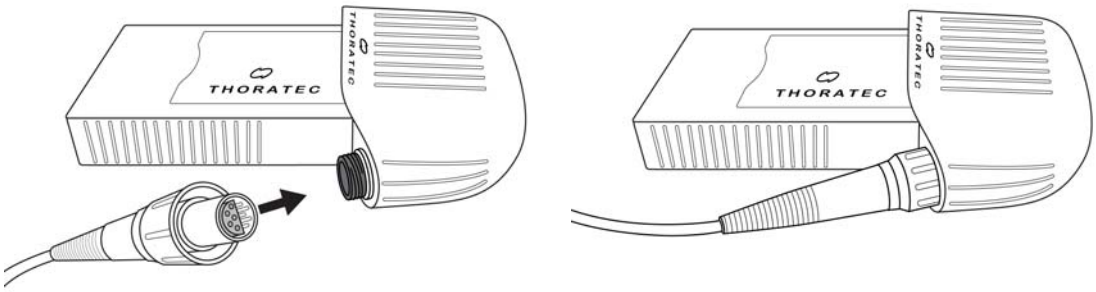


Figure 3.29 Connecting the Power Cable Connector to the Battery Clip Connector

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 and black Mobile Power Unit patient cable connectors.

    The Power Cable Disconnect alarm will come on. This is normal.
11. Promptly align the opposite half circles inside the black System Controller power cable connector and the power cable connector for one of the battery clips.

CAUTION !

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

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

12. Tighten the connector nut until secure.
13. Place the batteries and battery clips into a wear and carry accessory, such as battery holsters or the Consolidated Bag.

    Refer to *Wearing and Carrying the System Controller* on page 4-22.
14. Place at least two additional fully-charged batteries in your travel case.

CAUTION !

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

Changing From Batteries to the Mobile Power Unit

Use care when connecting and disconnecting power cables. For more information, refer to *Guidelines for Power Cable Connectors* on page 5-33.

FOR THIS TASK YOU NEED:

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

  Refer to *Setting Up the Mobile Power Unit* on page 3-8.

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

WARNING !

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

3. Place the black and white Mobile Power Unit patient cable connectors and System Controller power cable connectors within reach.
4. Remove the battery clips and attached batteries from the holsters or carrying case.
5. Check the charge status of each battery to determine which battery has the least power. Refer to *Checking the Battery Charge Level* on page 3-25.

   If one battery has less charge, start with that battery. Otherwise, disconnect the white connector first.
6. Disconnect the connector from the depleted battery.

7. Unscrew the white connector from its battery clip.

   The Power Cable Disconnect alarm will come on. This is normal.

8. Put aside the battery clip and attached depleted battery.
9. Connect the white Mobile Power Unit patient cable connector to the white System Controller connector.

   The alarm will stop.

10. Tighten the connector nut until secure.
11. Unscrew the black connector from its battery clip.

    The Power Cable Disconnect alarm will come on. This is normal.

12. Put aside the battery clip and attached depleted battery.
13. Connect the black Mobile Power Unit patient cable connector to the black System Controller connector.

    The alarm will stop.

14. Tighten the connector nut until secure.
15. Complete the following steps to remove a battery clip from the depleted battery:
    a. Pick up a depleted battery.
    b. Press the Battery Release button on the battery clip.
    c. Repeat Steps a and b for the second battery.
16. Store the battery clips in a clean, dry location until next use.
17. Complete the following steps to recharge the depleted batteries:
    a. Ensure that the Battery Charger is plugged in and turned on ("I").
    b. Place each depleted battery in a Battery Charger pocket.

       For more information about recharging batteries, refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

Using the Battery Charger

WARNING !

- The HeartMate 14 Volt Lithium-Ion batteries must be charged before use. Before removing a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After the battery is removed from the Battery Charger, use the battery power gauge on the battery to check the battery's charge level.
- Be sure to use only equipment and supplies that are authorized by Thoratec Corporation. If unauthorized parts are used, potential interference may occur between the Battery Charger and other devices.
- Do not use the Battery Charger next to other equipment. Do not stack the Battery Charger on top of other equipment.
- The Battery Charger radiates radio frequency energy. If the Battery Charger is not used according to instructions, it may cause harmful interference with nearby devices. To confirm if interference is occurring, turn off/on the Battery Charger and observe the effect on devices in the area. If interference is detected:
  - Re-orient or move the affected devices.
  - Increase the distance between the Battery Charger and the affected devices.
  - Connect the affected devices to an electrical outlet that is different from the outlet that is used to power the Battery Charger.
- To avoid the risk of electrical shock, plug the Battery Charger into a properly tested and grounded (3-prong) AC electrical power outlet that is dedicated to Battery Charger use.
  - Do not use an outlet that is controlled by a wall switch.
  - Do not use an adapter plug for an ungrounded wall outlet.
  - Do not use portable, multiple outlet (power strip) adapters.
- Do not use the Battery Charger in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide, or an explosion could occur.
- Keep the Battery Charger dry and away from water or liquid. If the Battery Charger comes into contact with water or liquid, it may fail to operate properly or cause an electrical shock.
- Do not touch the metal contacts inside the Battery Charger when the Battery Charger is connected to AC power and turned on, or it may cause an electrical shock.

CAUTION !

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

The Battery Charger (**Figure 3.30**) 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
- Determine when a 14 Volt Lithium-Ion battery needs calibration
- Calibrate a 14 Volt Lithium-Ion battery
- Perform diagnostic testing on up to four HeartMate 14 Volt Lithium-Ion batteries at a time.

Figure 3.30 Battery Charger

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. Consider the four-hour time frame when planning battery use and charging time.

For best battery performance, leave charged batteries in the charging pockets until they are needed for use. Leaving charged batteries in the Battery Charger will not damage them.

HeartMate 14 Volt Lithium-Ion batteries use a technology that measures available battery power and counts battery usage/charge cycles. When a battery is placed in a charging pocket (**Figure 3.31**), the Battery Charger immediately checks the battery's status by reading the battery's built-in computer chip. Information about the battery's available power and total number of use/charge cycles can be viewed by pressing the button labeled with the number of the pocket containing the battery to check. The information is displayed on the Battery Charger display panel.

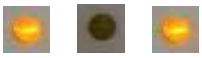
Figure 3.31 Batteries Inserted in Battery Charger Pockets for Charging

Each Battery Charger pocket has a set of lights: green, yellow, and red. The light illuminated next to the pocket indicates the charge status of the battery (**Figure 3.32**).

Figure 3.32 Green Light Indicating a Charged Battery

Table 3.2 describes what each light color indicates for the battery in the Battery Charger pocket.

Table 3.2 Battery Charger Pocket Light Descriptions

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

Setting Up the Battery Charger

To use the Battery Charger, it must be plugged in and turned 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 Battery Charger from its packaging.
2. Place the Battery Charger on a sturdy surface.
3. Inspect the Battery Charger for dents, chips, cracks, or other signs of damage, and complete one of the following steps:
   - If the Battery Charger is not damaged, go to Step 4.
   - If the Battery Charger is damaged, call your hospital contact for a replacement, if needed.

     Do not use a Battery Charger that seems damaged.
4. Examine each of the four battery charging pockets and ensure that the pockets are:
   - Clean and empty (no batteries)
   - Clear of dust or debris
5. Carefully inspect the metal contacts inside the pockets.
6. Clear away any dirt or objects covering the metal contacts inside the pockets.

   Dirt or objects covering the metal contacts may prevent proper battery charging. This can affect battery performance.
7. Obtain the grey AC power cord from the product packaging.

8. Complete the following steps:
   a. Locate the socket on the back of the Battery Charger.
   b. Plug the female end of the power cord into the AC power receptacle (**Figure 3.33**).
   c. Ensure that the cord is fully inserted and secure.

Figure 3.33 Plugging the Power Cord into the Back of the Battery Charger

9. Plug the Mobile Power Unit into a properly-tested and grounded (3-prong) AC electrical outlet that is dedicated to Battery Charger use.

CAUTION !

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

10. Complete the following steps to turn on the Battery Charger:
    a. Locate the on/off switch on the back of the Battery Charger.
    b. Press the switch from the off ("0") to the on ("I") position.

       When the Battery Charger is turned on, all lights on the front panel illuminate (**Figure 3.34**). The Battery Charger beeps once and performs a self test for about 10 seconds.

Figure 3.34 All Battery Charger Lights Illuminated Turned On

After a successful self test, all lights turn off and *HeartMate CHARGER* appears on the display panel (**Figure 3.35**). The Battery Charger is ready for use.

Figure 3.35 Battery Charger Ready for Use

If the Battery Charger detects a problem, an error message appears on the display panel (**Figure 3.36**) and/or the lights and beep are not performed as described previously. If any of these occur, refer to *Battery Charger Display Panel Messages* on page 5-28 for information on how to respond to advisory messages.

Figure 3.36 Battery Charger Error Message

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

Note: Any time the *HeartMate CHARGER* message is displayed, the display panel slowly dims, turns off for two seconds, and then resumes full brightness. This helps to prolong the life of the display. The Battery Charger may be used during this time.

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. Refer to *Setting Up the Battery Charger* on page 3-43.
- 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 the equipment and place it within reach.
2. Place a HeartMate battery into one of the four battery charging pockets.
3. Ensure that the battery power gauge is at the top and faces forward (**Figure 3.37**).

Figure 3.37 Battery Charger With Four Batteries

CAUTION !

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

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

4. Identify which light (green, yellow, or red) comes on for the pocket:
   - Green light: The battery is charged and ready for use. Remove the battery for immediate use or leave the battery in the pocket until needed. Leaving a charged battery in the Battery 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. Refer to *Calibrating HeartMate Batteries* on page 3-49.
   - 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. Refer to *Battery Charger Display Panel Messages* on page 5-28for information on how to read alarm codes when a red light comes on.
5. 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 charging cycle was interrupted. Refer to *Confirming a Pocket Fault* on page 5-31 for information on how to handle red light conditions.
6. Repeat Steps 2–5 for up to three more batteries.

Viewing Battery Information

The Battery Charger can be used to check the status of a battery. 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. **Figure 3.38** shows 90% of the battery's power is available.

Figure 3.38 View Battery Charge Level Information on the Battery Charger

After five seconds, the display returns to the default *HeartMate CHARGER* screen. If the button is pressed 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 3.39**):

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

Figure 3.39 Press the Button a Second Time to Display Battery Charge Cycle Information

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

Calibrating HeartMate Batteries

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

The battery must be placed in the Battery Charger to be calibrated. During calibration, the Battery 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 Battery Charger can charge three HeartMate batteries as usual.

When a battery is inserted in the Battery Charger, and the Battery Charger detects that calibration is recommended, the following occurs:

- The yellow light for the pocket blinks.
- A split battery symbol and the pocket number for the battery flashes on the Battery Charger display panel (**Figure 3.40**).
- The circled number switches between a filled and unfilled circle as the display panel screen flashes.

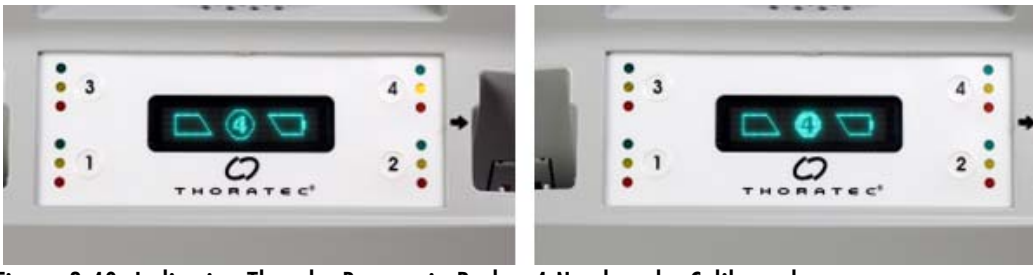


Figure 3.40 Indication That the Battery in Pocket 4 Needs to be Calibrated

Batteries can be calibrated when prompted or when there is a more convenient time. For example, a battery can be calibrated at night or when sleeping (when the Power Module or Mobile Power Unit is being used for power).

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 Battery 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 the number button for this pocket is pressed while the battery is being calibrated, the calibration status screen appears (**Figure 3.41**).

Figure 3.41 Battery in Pocket 4 During Calibration

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):

1. Do nothing when the yellow light begins blinking. After ten seconds, the Battery Charger continues with a normal charge cycle.
2. You can skip calibration, and instead charge and reuse the battery. However, if you skip calibration, be sure to do it as soon as possible after the prompt. The Battery Charger will remind you that the battery needs calibration the next time you insert the battery into a pocket for charging.
3. If you choose to calibrate the battery, and then decide to cancel the calibration after the process has begun, you can cancel calibration by removing the battery from its pocket. If you remove a battery before calibration is complete, make sure to recharge and check the battery before using it. If you remove a battery before calibration ends, the battery may be low. Use the on-battery power gauge to check the battery charge status.

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

LIVING WITH THE HEARTMATE III

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

4 Living with the HeartMate III

Keeping Your Home Safe

You may need to check your home for safety and electrical readiness. The following 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.

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 potentially 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. Complete the following steps for proper hand washing.

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

FOR THIS TASK YOU NEED:

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

TASK

1. Gather the supplies and place them within reach.
2. Use a clean, dry paper towel to turn on the faucet(s) for clean, running water.
3. Wet your hands and wrists with clean, running water.
4. Apply soap to hands.
5. Wash for at least 15 seconds while completing the following steps:
   a. Rub together all parts of both hands (including wrists and backs of hands).
   b. Wash under rings, around cuticles, and under fingernails.
   c. Rub hard.

      Friction helps remove dirt and microbes.
6. Rinse well under a stream of clean, running water.
7. Point fingers, hands, and wrists down so water carries away dirt and microbes.
8. Use a new paper towel to dry hands.
9. Use a paper towel to turn off the faucet.

   Do not touch the faucet with clean hands.
10. Repeat steps 1–9 every time before and after exit site bandage changes, any time the exit site is touched, or any time hands are dirty (or could be dirty).

Eating

Why Eating Well is Important

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

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

Talk with your hospital contact about tips for healthy eating.

Caring for the Driveline

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

WARNING !

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

CAUTION !

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

Rules for Driveline Care

- Do not sharply bend or kink the Driveline (refer to *What Not To Do: Driveline and Cables* on page 34).
- If you carry the System Controller in a carrying case, be careful that you do not "catch" the Driveline in the zipper.
- Allow for a gentle curve for your Driveline. Do not severely bend or kink the Driveline. Do not wrap the Driveline tightly.
- Keep your Driveline clean. Wipe off any dirt or grime. If the Driveline gets dirty, use a towel with mild dish soap and warm water to gently clean it. Never submerge the Driveline or other system components in water or liquid.
- Do not pull on or move the Driveline going through the skin.
- When checking that the Controller Driveline Connector is fully inserted in the system controller socket, gently tug on the end of the connector. Do not pull on the Driveline.
- To avoid pulling on or moving the Driveline at the exit site, stabilize the Driveline at all times.
- Be aware of where your System Controller is at all times. It is important to protect it from falling. Dropping the Driveline can make it pull on the Driveline exit site. Report any drops of the System Controller to your hospital contact. Do this right away, even if everything seems fine.
- If the Driveline is damaged, the Pump may need to be replaced. It should be replaced as soon as possible to prevent serious injury or death.
- Use care to keep the Driveline from snagging or catching on anything that can pull on or move the Driveline.
- Check the Driveline daily for signs of damage (cuts, holes, tears). Call your hospital contact right away if the Driveline is damaged (or might be damaged).

Driveline Exit Site

It is 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 the risk of infection.

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

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

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

CAUTION !

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

Rules for Exit Site Care

- Refer to the Caring for the Driveline Exit Site section *Caring for the Driveline* on page 4-6.
- Follow strict sterile technique every time you change the bandage or touch the Driveline exit site.
- Wash your hands before and after every bandage change. Refer to *Hand Washing* on page 4-4.
- Keep the Driveline exit site clean and dry.
- Care for your Driveline exit site as your doctor or medical professional tells you.
- Try to not pull on or move the Driveline that goes through your skin.
- Check the Driveline exit site daily for signs of infection, including:
  - Redness
  - Swelling
  - Drainage or bleeding
  - Bad smell
  - Feeling feverish, tired, or unwell

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

Showering

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

Keeping the Driveline Exit Site Dry

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

Warnings and Cautions

WARNING !

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

CAUTION !

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

Applying the Moisture Barrier

TASK

1. Make a sheet of multi-purpose sealing wrap large enough to completely cover the driveline management system with at least six inches on all sides.
2. Center the sheet of multi-purpose sealing wrap over the driveline management system and adhere to skin (**Figure 4.1**).

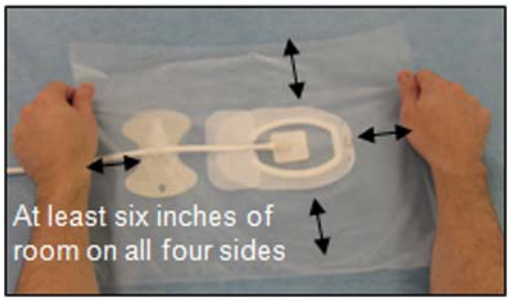


Figure 4.1 Centering the Multi-Purpose Sealing Wrap Over the Driveline Management System

   a. Press the sheet of multi-purpose sealing wrap into place with your fingers so that it is smooth to the skin with no gaps.
   b. If you have difficulties, ask your caregiver or spouse for help.
3. Seal around the edges of the sheet of multi-purpose sealing wrap with the tape (**Figure 4.2**).
   a. Apply the tape to all four edges of the sheet of multi-purpose sealing wrap so that there are no gaps.
   b. Press the tape into place with fingers so that it is smooth on the skin.
   c. Check all edges and ensure that the sheet completely adheres to the skin with no gaps.

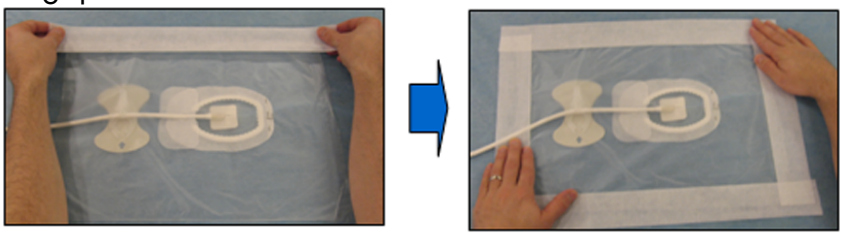


Figure 4.2 Sealing Around the Edges of the Sheet of Multi-Purpose Sealing Wrap With the Tape

Removing the Moisture Barrier After Showering

TASK

1. Towel dry body and the outside of the multi-purpose sealing wrap.
2. Gently peel away the multi-purpose sealing wrap and tape from the skin (**Figure 4.3**).

   As the wrap is removed, be careful to not disturb the driveline management system.

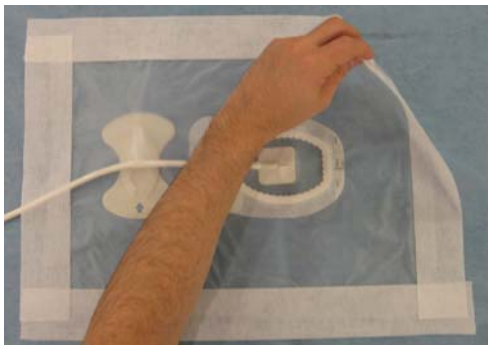


Figure 4.3 Gently Peeling Away the Multi-Purpose Sealing Wrap and Tape

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

Using the Shower Bag

Although the external components of the HeartMate III 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, it may cause a serious electrical shock or the Pump may stop.

You cannot take tub baths with the Pump, but you may be able to shower after the Driveline exit site heals. Your doctor decides if you can shower. Do not shower without your doctor's approval. After you are approved for showering, the Shower Bag must be used for every shower. It protects the outside parts of the system from water and moisture (**Figure 4.4**).

Figure 4.4 Shower Bag

WARNING !

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

CAUTION !

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

IMPORTANT! **Figure 4.5** shows an uncovered exit site. Keep the exit site as clean and dry as possible.

Figure 4.5 Using the Shower Bag to Shower

1	**See-through Panel (on top of bag)**
2	**Shoulder Strap**

The Shower Bag (**Figure 4.4**) has a see-through top panel for viewing 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. 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.

Assembling the Shower Bag

FOR THIS TASK YOU NEED:

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

TASK

1. Gather the equipment and place it within reach.
2. Clip the shoulder strap to the two rings on the top lid of the Shower Bag (**Figure 4.6**).

Figure 4.6 Attaching the Shoulder Strap to the Shower Bag

3. Complete the following steps to attach the clip-style belt to the Shower Bag:
   a. Slide the belt through the loop on the side of the bag that will be against your body (**Figure 4.7**).

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

Figure 4.7 Sliding the Belt Through the Loop on the Side of the Shower Bag

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

Putting On the Shower Bag

FOR THIS TASK YOU NEED:

- 1 assembled Shower Bag that is clean and dry
- 1 operating 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 the equipment and place it within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 4.8**).

Figure 4.8 Power Cables and Driveline are Not Twisted

3. Unclip the top cover of the Shower Bag by squeezing the clip prongs together and sliding the clip out of the buckle (**Figure 4.9**).

Figure 4.9 Open the Clip and Buckle on the Top of the Shower Bag

4. Pull back the top lid to reveal the double zipper (**Figure 4.10**).

Figure 4.10 Opening the Shower Bag

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 4.11**).

Figure 4.11 Placing the 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.

8. Complete the following steps to close the Shower Bag:
   a. Position the power cables inside the water resistant enclosure (**Figure 4.12**).

Figure 4.12 Carefully Positioning the Power Cables in the Shower Bag

   b. Close and zip the cover.
   c. Make sure that both of the System Controller's power cables are inside the bag with only the Driveline exiting through the protective red tabs (**Figure 4.13**).

Figure 4.13 Carefully Closing the Shower Bag; Driveline Exits Through the Protective Red Tabs

d. Close the lid over the zippered enclosure, carefully positioning the Driveline down the side of the bag (**Figure 4.14**).

Figure 4.14 Driveline Exiting a Closed Shower Bag

e. Snap the clip into the buckle to secure the lid (**Figure 4.15**).

Figure 4.15 Fastening the Clip and Buckle on the Top of the Shower Bag

9. Use the Shower Bag strap to hang the bag over your head and shoulder so the bag hangs at your side.
10. Adjust the Shower Bag so it does not pull on the exit site while showering.
11. 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 with batteries and the System Controller
- A large, clean, dry towel to dry your body
- A small, clean, dry towel to dry the Shower Bag
- 4" X 4" (10.2 cm x 10.2 cm) sterile gauze bandages to dry the exit site
- One or more sterile bandages to dress the exit site
- Wearable accessories to hold or carry the System Controller, batteries, and battery clips after showering

Remember !

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

TASK

1. Unclip the 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 a sterile technique.
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 4.16**).

Figure 4.16 Opening the Clip and Buckle

9. Remove all equipment from the enclosure.

10. 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.

    Refer to *Wearing and Carrying the System Controller* on page 4-22.
12. Allow the Shower Bag to 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. Refer to *Cleaning and Maintaining the Equipment* on page 6-3 for complete instructions on caring for all wearable accessories, including the Shower Bag.

Wearing and Carrying the System Controller

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

Shower Bag

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

System Controller Neck Strap

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

Belt Attachment

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

Consolidated Bag

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

Battery Holster

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

Holster Vest

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

Travel Bag

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

Protection Bag

The Protection Bag stores and protects the backup System Controller.

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

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

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

Different accessories provide different wear and carry options.

Using the System Controller Neck Strap

The System Controller Neck Strap (**Figure 4.17**) allows you to carry the System Controller around your neck or across your body. It attaches to the System Controller with two small straps.

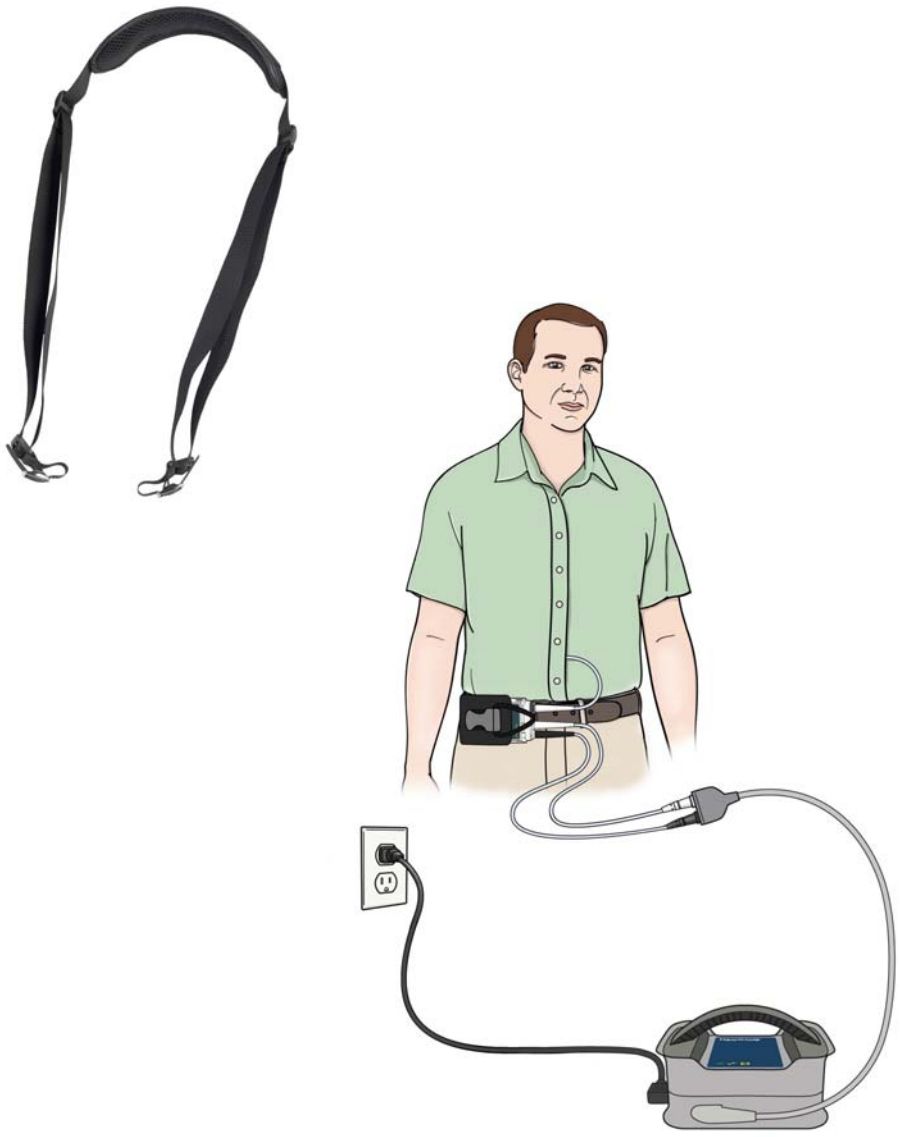


Figure 4.17 Using the System Controller Neck Strap

The System Controller has four attachment points (**Figure 4.18**): one in each corner of the casing. The Neck Strap uses two attachment points for hanging the System Controller vertically or horizontally (**Figure 4.19**).

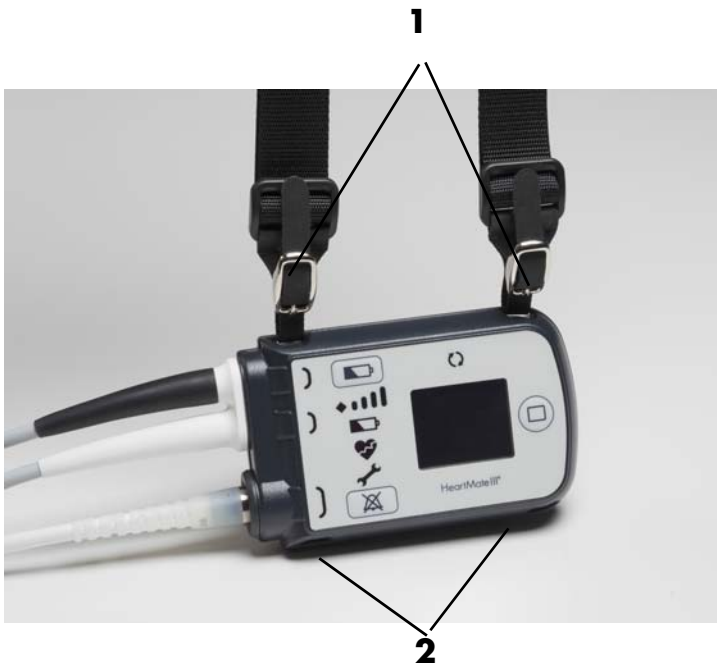


Figure 4.18 Attachment Points on System Controller

1	**2 of 4 Attachment Points**
2	**2 of 4 Attachment Points**

Figure 4.19 System Controller Suspended Horizontally (left) and Vertically (right) from Neck Strap

Putting On the System Controller Neck Strap

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- 1 operating System Controller
- 1 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 the equipment and place it within reach.
2. Place the System Controller on a flat, stable surface.
3. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 4.20**).

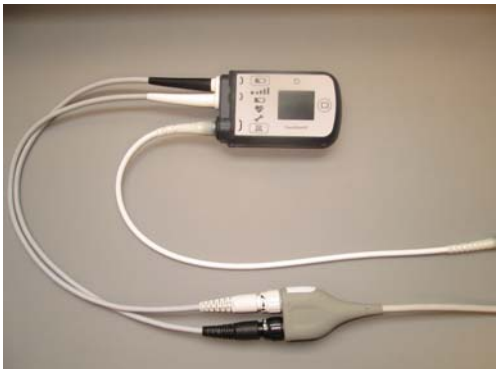


Figure 4.20 Power Cables and Driveline are Not Twisted

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 4.21**).

Figure 4.21 Sliding the Strap Through an Attachment Point

6. Complete the following steps to buckle the strap:
   a. Thread the rubber strap through the metal buckle on the Neck Strap.
   b. Ensure that the metal prong on the buckle goes through the strap, similar to buckling a belt (**Figure 4.22**).

Figure 4.22 Buckling the Strap

7. Hold the System Controller in one hand and tug the Neck Strap with the other hand (**Figure 4.23**).

   This confirms that the buckle is securely connected to the System Controller.

Figure 4.23 Tugging the Neck Strap

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

Taking Off the Neck Strap

TASK

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

Using the Belt Attachment

The Belt Attachment accessory (**Figure 4.24**) is similar to accessories that are used to wear or carry a cell phone. It can be attached to any belt or attached to the provided nylon clip belt.

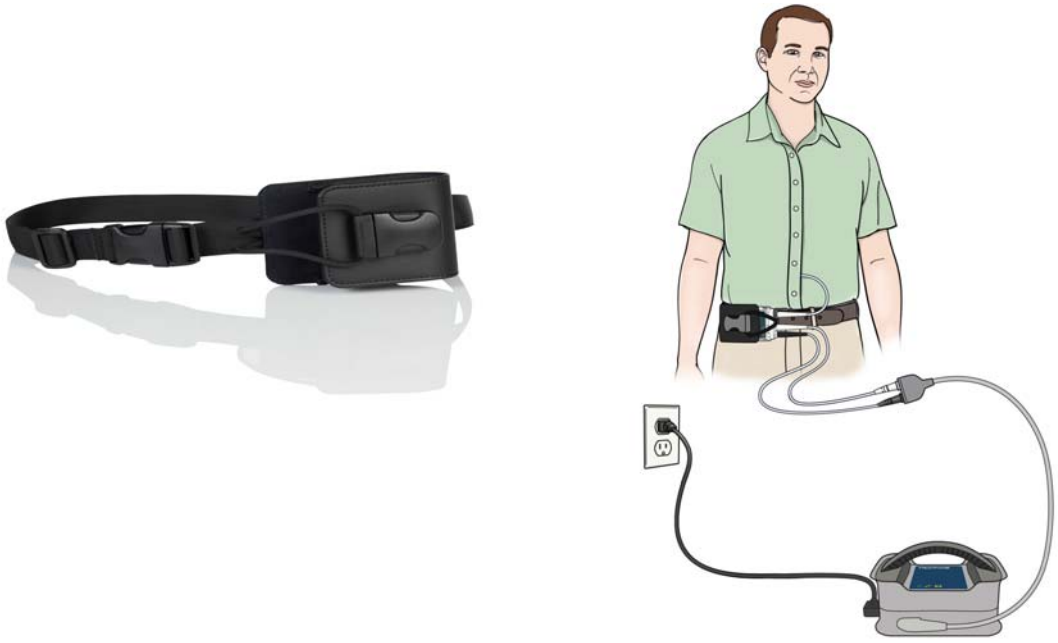


Figure 4.24 Belt Attachment

Putting on the Belt Attachment

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- 1 System Controller
- 1 Belt Attachment
- 1 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 the equipment and place it within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 4.25**).

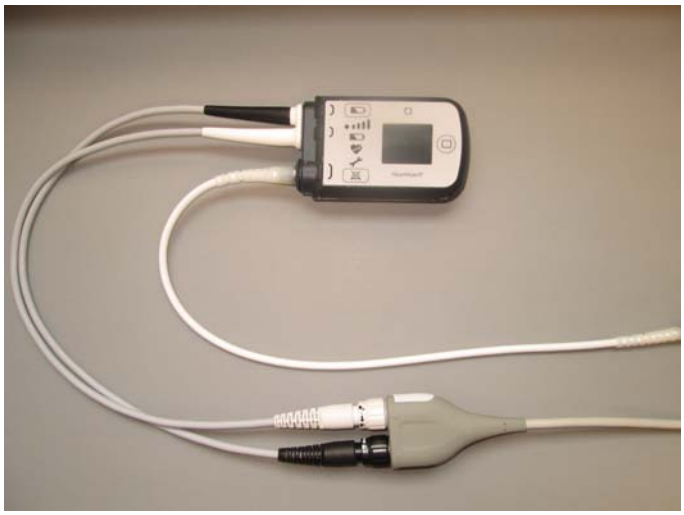


Figure 4.25 Power Cables and Driveline are Not Twisted

3. Slide either your belt or the nylon clip belt through the loop on the back of the Belt Attachment (**Figure 4.26**).

Figure 4.26 Sliding the Belt Through the Loop on the Belt Attachment

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 4.27**).

Figure 4.27 Sliding the System Controller Into the Belt Attachment

6. Place the two-banded strap over the System Controller and between the white System Controller power cable connector and the Driveline connector (**Figure 4.28**).

Figure 4.28 Placing the Strap Between the Connectors

7. Clip the two-banded strap into place to secure the System Controller (**Figure 4.29**).

Figure 4.29 Clipping the Strap Into Place

8. Ensure that both prongs are fully engaged in the clip.
9. Fasten the belt and Belt Attachment around your waist.
10. 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. Complete one of the following steps:
   - If using the nylon clip belt, go to Step 3.
   - If using your own belt, go to Step 4.
3. 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.
   d. Go to Step 5.
4. 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.
   d. Go to Step 5.
5. 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.
6. Store the Belt Attachment in a clean, dry location.

Using the Consolidated Bag

Use the Consolidated Bag (**Figure 4.30**) to carry the System Controller, batteries, and battery clips together in a single place while using the batteries. 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.

Figure 4.30 Consolidated Bag

1	**Shoulder Strap**
2	**Red Protective Tabs**

The Consolidated Bag is worn across the body using a shoulder strap or around the waist using a waist strap (**Figure 4.31**). 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.

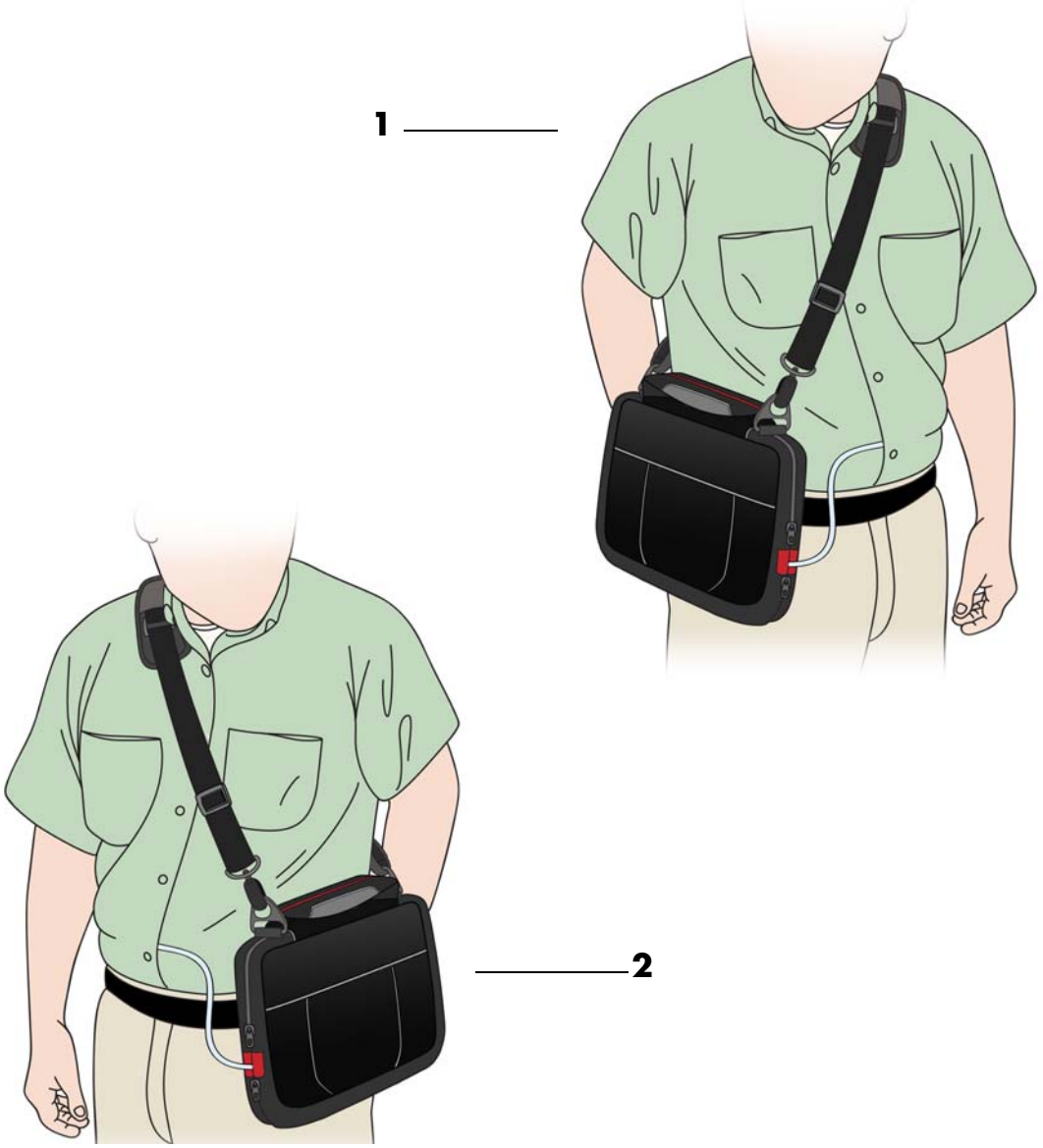


Figure 4.31 Wearing the Consolidated Bag

1	**Consolidated Bag: version for wearing on the right side**
2	**Consolidated Bag: version for wearing on the left side**

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 the equipment and place it within reach.
2. Clip the shoulder strap to the Consolidated Bag using the two rings located on the top of the Consolidated Bag (**Figure 4.32**).

Figure 4.32 Attaching the Shoulder Strap

3. Put on the bag to confirm the appropriate placement on your left or right side, and complete the following steps:

   Note: The bag type (left or right) can be found on a tag inside the Consolidated Bag.

   a. Adjust the shoulder strap and belt so the bag fits you properly.

   b. Tighten or lengthen the strap until it is secure, but still comfortable.

   c. Tighten or lengthen the belt until it is 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
- 1 operating System Controller on battery power
- 1 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 the equipment and place it within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 4.33**).

Figure 4.33 Power Cables and Driveline are Not Twisted

3. Unzip the double zippers on the Consolidated Bag and open it.

4. Slide the System Controller into its holder so the user interface faces out (**Figure 4.34**).

Figure 4.34 Sliding the System Controller Into the Consolidated Bag

5. Stretch the two-banded strap over the System Controller and between the white System Controller power cable and the Driveline connector.
6. Fasten the clip to hold the System Controller in place (**Figure 4.35**).

Figure 4.35 Strap Stretched Over the System Controller and Between the Cables

7. Place the first battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 4.36**).

Figure 4.36 Placing Battery and Attached Battery Clip into Consolidated Bag

8. Adjust the power cable so that it lays flat along the edge of the bag (**Figure 4.37**).

Figure 4.37 Carefully Positioning the Power Cable Around the Edge of the Bag

9. Place the second battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 4.38**).

Figure 4.38 Inserting the Second Battery

10. Arrange the power cables so that they lay flat along the edge of the bag (**Figure 4.39**).

Figure 4.39 Arranging the Cables Around the Inside of the Bag

11. Carefully close the Consolidated Bag.

    The System Controller power cables inside the bag and the Driveline between the protective red tabs (**Figure 4.40**).

Figure 4.40 Closing the Bag; Driveline Exits Between the Red Tabs

12. Zip the Consolidated Bag closed (**Figure 4.41**).

Figure 4.41 Zipping the Consolidated Bag Closed

13. Hold the Consolidated Bag by the handle so it does not drop.
14. Complete the following steps to put on the Consolidated Bag:
    a. Put the shoulder strap over your head and across your chest.

       The bag should rest against your body, on the side of your body for which it was intended.

    b. 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
- 1 operating System Controller on battery power and stored 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 one of two ways:
   - Unclip it at one side.
   - Lift it up and over your head.
4. Place the bag in front of you on a stable surface.
5. Unzip the bag and open it.
6. Complete one of the following steps:
   - Exchange low batteries with fully-charged batteries.
   - Transfer from battery power to Mobile Power Unit power.

     For more information, refer to *Changing From Batteries to the Mobile Power Unit* on page 3-37.

   - Remove the components and transfer to another wearable accessory.
7. Store the Consolidated Bag in a clean, dry location.

Using 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 4.42**).

Figure 4.42 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
- 1 Protection Bag
- 1 backup 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. Unzip the Protection Bag.
2. Slide the backup System Controller into the Protection Bag.

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

   The backup System Controller is now stored in the Protection Bag.
5. Keep the backup System Controller with you at all times.

Using the Travel Bag

The Travel Bag provides a way to keep your backup System Controller and spare batteries with you at all times (**Figure 4.43**).

Figure 4.43 Travel Bag

Storing Items in the Travel Bag

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- 1 Protection Bag with backup System Controller and power cables stored inside
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 1 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 4.44**).

Figure 4.44 Placing 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 4.45**).

Figure 4.45 Storing the Batteries Inside the Travel Bag

Using the Battery Holster

Use the Battery Holster (**Figure 4.46**) 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 can be adjusted to fit most users.

Figure 4.46 Battery Holster

The Belt Attachment can be used with the Battery Holster to protect and cover the System Controller (**Figure 4.47**).

When you wear the Battery Holster, you can exchange low-charged batteries for fully-charged batteries without taking off the holster. Refer to *Exchanging Low-Power Batteries with Two Fully-Charged Batteries* on page 4-51.

Figure 4.47 Belt Attachment Used With Battery Holster

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.

TASK

1. Gather the equipment and place it within reach.
2. Place the Battery Holster in front of you on a flat surface, arranged so the fabric connecting the two straps is in the center.
3. Slide your arms through the straps, so that the fabric connector is between your shoulder blades on your back.
4. Pull the loose ends of the strap to adjust the fit.

   The holsters should fit securely but comfortably against your sides and under your arms.
5. After determining appropriate fit, cut off or trim the extra length from the end of each strap.
6. Apply a strong epoxy glue to the cut off ends of each strap to reduce fraying.
7. Allow the glue to dry before wearing the holster.

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

Putting On the Battery Holster

FOR THIS TASK YOU NEED:

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

Remember !

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

TASK

1. Gather the equipment and place it within reach.
2. Ensure that the System Controller power cables and Driveline are not twisted (**Figure 4.48**).

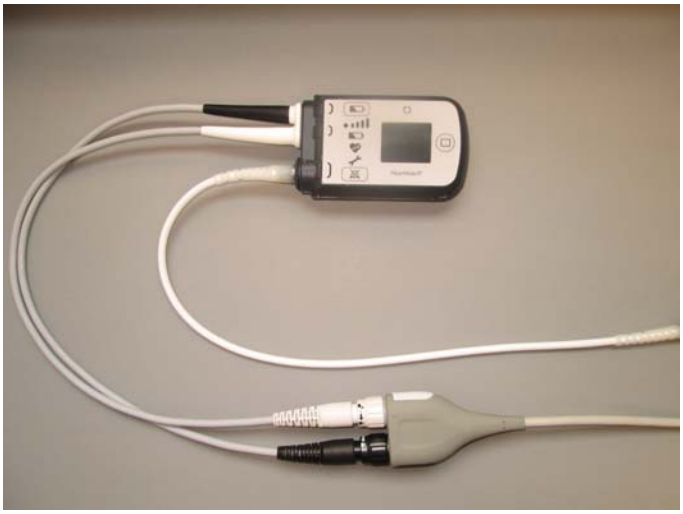


Figure 4.48 Power Cables and Driveline are Not Twisted

3. Complete the following steps to insert a battery and its attached battery clip into each holster:

   a. Open each hook-and-loop fastener flap (**Figure 4.49**, left).

   b. Insert each battery with battery clip into a holster.

      The clip should point up and the battery should point down (**Figure 4.49**, right).

Figure 4.49 Opening the Hook-and-Loop Fastener Flap and Inserting the Battery with Attached Battery Clip

   c. Close each Battery Holster flap after the battery with battery clip is inside the holster (**Figure 4.50**).

Figure 4.50 Closing the Hook-and-Loop Fastener Flap to Secure the Battery/Battery Clip Inside

   d. Repeat Steps a–c for the second battery with battery clip.

4. Put on the Battery Holster with the inserted batteries with battery clips.
5. Put on and secure the Belt Attachment around your waist.
6. Adjust and tighten the belt as needed.

   Refer to *Putting on the Belt Attachment* on page 4-29.

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.

    Refer to *Changing from Mobile Power Unit Power to Batteries* on page 3-35.

Exchanging Low-Power Batteries with Two Fully-Charged Batteries

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- To be wearing a Battery Holster with an operating 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 the equipment and place it within 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 depleted battery from its battery clip and put aside the low battery.

      You should 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.

      The battery 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 depleted batteries in the Battery Charger.

   Refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

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 an operating System Controller on battery power
- 1 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. Before taking off the holster, change from battery power to the Mobile Power Unit

   Refer to *Changing From Batteries to the Mobile Power Unit* on page 3-37.
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. Complete one of the following steps:
   - If you are using the nylon clip belt, go to Step 5.
   - If you are using your own belt, go to Step 6.
5. Complete the following steps if you are 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.
   d. Go to Step 7.
6. Complete the following steps 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.
   d. Go to Step 7.
7. 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.

8. Remove the batteries and attached battery clips from the holster and place them on a stable surface.
9. Recharge the low-charged batteries.

   Refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.
10. Store the holster in a clean, dry location.

    Refer to *Equipment Maintenance* on page 6-1.

Using the Holster Vest

Use the Holster Vest to hold the System Controller and two HeartMate batteries (with battery clips) during battery-powered operation (**Figure 4.51**).

Figure 4.51 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 4.52**).

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. Refer to *Exchanging Batteries While Wearing the Holster Vest* on page 4-59.

Figure 4.52 Holster Vest With Belt Attachment and Shoulder Strap

1	**Chest Strap**
2	**Belt Attachment**

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 the equipment and place it within 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 4.53**).

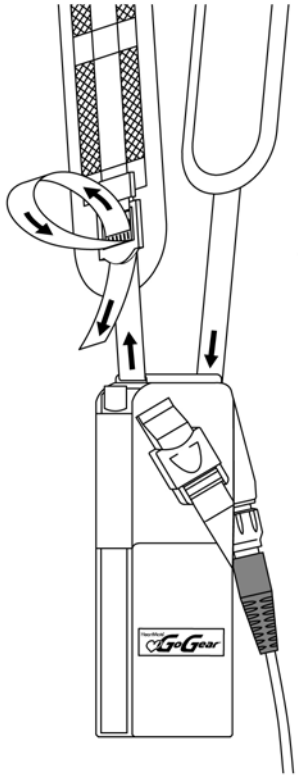


Figure 4.53 Inserting the Vest Strap Through the Slot in the Top of the Holster

3. Repeat Step 2 for the second holster.

Putting On the Holster Vest

FOR THIS TASK YOU NEED:

- A quiet, well-lighted location where you can focus on the task
- 1 operating System Controller on Mobile Power Unit power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 1 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 the equipment and place it within reach.
2. Make sure that the System Controller power cables and Driveline are not twisted (**Figure 4.54**).

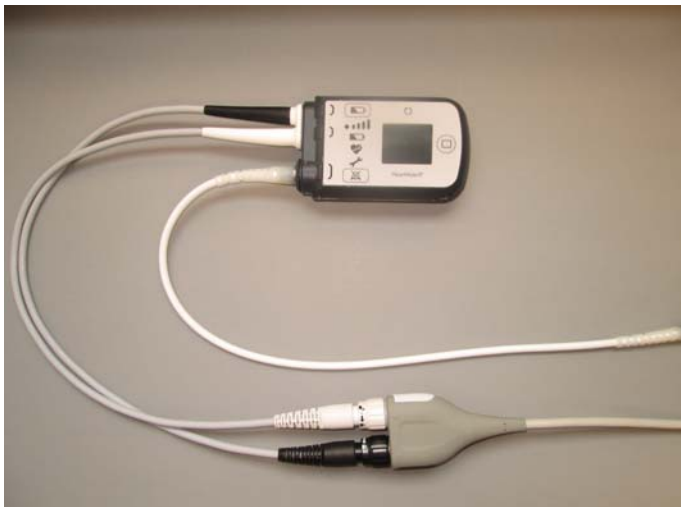


Figure 4.54 Power Cables and Driveline are Not Twisted

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 4.55**).

Figure 4.55 Inserting the Battery and Battery Clip Into the Holster

   b. Buckle the clip on the holster (**Figure 4.56**).

Figure 4.56 Buckling the Clip on the Holster

   c. Repeat Steps a and b for the second battery and battery clip.

4. Put on the Holster Vest with the attached batteries and battery clips.
5. Adjust and tighten the straps as needed.
6. If the chest strap is used, position it higher or lower on the vest as needed, so it is secure and comfortable.
7. Put on and secure the belt attachment around your waist. Adjust and tighten the belt as needed.
8. Slide the System Controller into the Belt Attachment.

9. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller and between the white System Controller power cable connector and the Driveline connector.
10. Slide the clip ends of the two-banded strap in to the clip socket.

    The clip will click into place when securely fastened.
11. Transfer from the Mobile Power Unit to battery power.

    Refer to *Changing from Mobile Power Unit Power to Batteries* on page 3-35.
12. Use the hook-and-loop fastener tabs on the back of the holsters to hold the power cables in place and to stabilize the holsters (**Figure 4.57**).

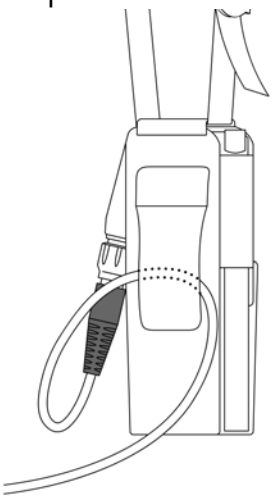


Figure 4.57 Using Hook-and-Loop Fastener Tabs to Hold the Power Cables

13. Put the belt through the hook-and-loop fastener 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
- 1 operating System Controller connected to two in-use HeartMate batteries during battery-powered operation
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 1 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 and place them within reach.
2. Complete the following steps to exchange the first depleted battery (**Figure 4.58**):
   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 depleted battery from its battery clip and put it aside.

      Remove only this battery at this time. A Power Cable Disconnected advisory will sound. This is normal.

   d. Retrieve one of the fully-charged batteries and insert it into the battery clip.

      The battery will click into place when fully inserted. The alarm stops when the fully-charged battery is properly inserted.

   e. Close the flap on the holster.

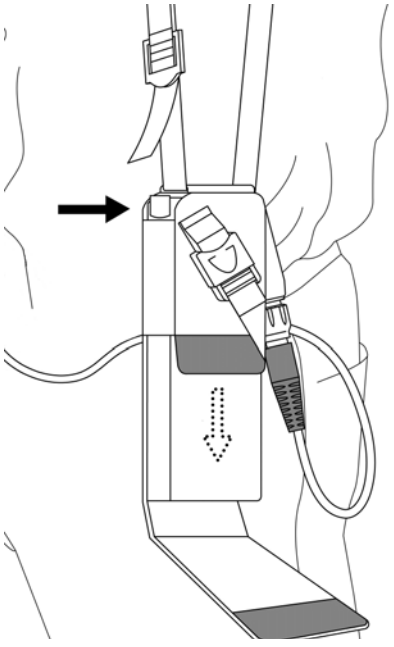


Figure 4.58 Exchanging a Battery

   f. Repeat Steps a–e to exchange the second depleted battery.
3. Recharge the depleted batteries.
4. For more information, refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

Taking Off the Holster Vest

TASK

1. Before taking off the Holster Vest, change from battery power to the Mobile Power Unit.

   Refer to *Changing From Batteries to the Mobile Power Unit* on page 3-37.

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. Complete one of the following steps:
   - If you are using the nylon clip belt, go to Step 5.
   - If you are using your own belt, go to Step 6.
5. Complete the following steps if you are 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.
   d. Go to Step 7.
6. Complete the following steps if you are 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.
   d. Go to Step 7.
7. 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.
8. Remove the batteries and attached battery clips from the Holster Vest and place the items on a stable surface.
9. Recharge the depleted batteries.

   Refer to *Charging HeartMate 14 Volt Lithium-Ion Batteries* on page 3-46.

10. Store the holster vest in a clean, dry place.

    Refer to *Cleaning and Maintaining the Equipment* on page 6-3.

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. Refer to the pre-sleep checklist.

PRE-SLEEP CHECKLIST

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

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.

Static Electricity

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 touch a metal doorknob, and the static electricity felt after drying clothes in a clothes dryer. The presence of ESD may be increased in environments with a relative humidity less than 30%. High levels of static electricity may damage and/or interfere with the electrical parts of the system and cause the Left Ventricular Assist Device to stop.

While on LVAD support:

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

Safe Positions

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

Equipment to Keep Nearby

Before you go to sleep, ensure that the following items are nearby:

- A flashlight with well-charged batteries
- Your emergency contact list
- All backup equipment, including the backup System Controller and fully-charged batteries (already in their clips)

This way, in an emergency, everything you need is nearby.

Traveling

Extra planning is required to travel safely.

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

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

CAUTION !

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

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

- Be sure to bring everything you need for battery-powered and electrical-powered operation at your final destination, including:
  - Battery Charger and power cord
  - Spare batteries
  - Battery clips
  - Mobile Power Unit
  - Mobile Power Unit 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.

If the Mobile Power Unit is without electrical power for approximately 18 hours, the internal backup battery may be damaged. If the Mobile Power Unit is not being used and will be unplugged from electrical power (AC) for an extended time, the Mobile Power Unit backup battery must be disconnected to prevent damage to the battery. Examples may be travel or if the Mobile Power Unit will be in transport for service or maintenance. For more information, refer to *Inserting or Replacing the Mobile Power Unit Batteries* on page 64.

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. Airbags are also referred to as supplemental restraint systems or SRS.

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

ALARMS AND TROUBLESHOOTING

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

5 Alarms and Troubleshooting

System Controller Alarms

Alarms that You Can Manage

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 can be resolved by users, caregivers, and family members. In most cases, these alarms are handled by following simple on-screen instructions. **Table 5.1** shows how to access the alarm history screens.

Alarms That Clinicians Manage

Other alarms require Clinician assistance. For most of these cases, the following text appears on the screen: Call Hospital Contact

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, or you may be admitted to the hospital for testing and care.

System Controller Alarm Management

This chapter provides information about the likely cause of an alarm and typical steps for resolving it. Alarms are listed in order of priority. Hazard alarms are listed first, followed by Advisories. Refer to **Table 5.2** and **Table 5.3** for a complete list of prioritized System Controller alarms.

IMPORTANT! System Controller alarms cannot be silenced when the System Controller is in Power Saver Mode.

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.

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

Figure 5.1 shows the alarm screen layout.

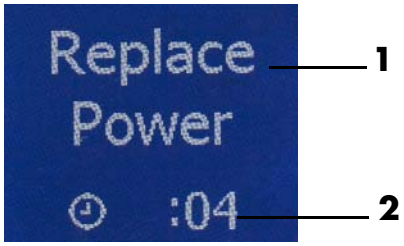


Figure 5.1 Alarm Screen

1	**Alarm Message**
2	**Duration Timer**

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. The subset includes 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 Disconnect 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

To view the six most recent alarms on the user interface screen, simultaneously press and release the **Silence Alarm** ( ) button and the **Display** ( ) button.

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 (**Figure 5.2**).

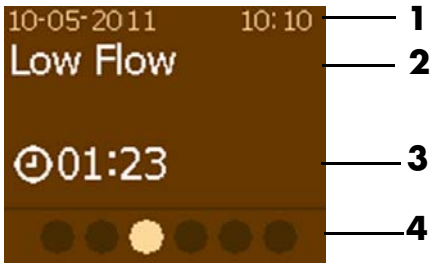
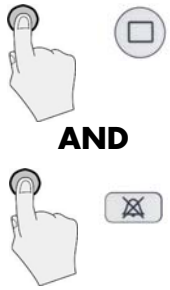
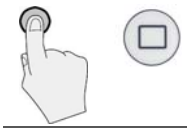
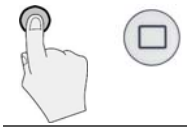
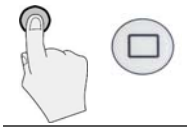
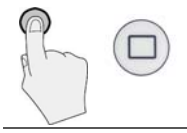
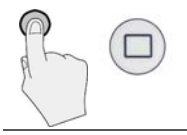


Figure 5.2 Sample Alarm History Screen

1	**Date and Time of Alarm**	Date Format: mm-dd-yyyy Time Format: mm:ss
2	**Alarm Type**	
3	**Duration of Alarm**	
4	**Navigation Information**	

Table 5.1 Viewing Alarm History Screens

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

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** ( ) button and **Display** ( ) button.

To exit from the alarm history feature, simultaneously press the **Silence Alarm** ( ) button and **Display** ( ) button again.

Alarms that Do Not Display on the Controller Alarm History Screen

The following are examples of non-transient alarms that require specific user action to resolve the alarm condition:

- Driveline Power fault
- Driveline Communication fault (Driveline Comm Fault)
- Communication fault (Comm fault)
- Backup Battery fault
- Replace Controller fault

These alarms remain on the user interface screen until the alarm condition is resolved or permanently disabled by a clinician, and therefore do not appear in alarm history.

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

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

When the audio alarms are silenced, an alarm silence indicator displays (**Figure 5.3**) on the LCD screen on the System Controller.

Figure 5.3 Alarm Silence Indicator

Table 5.2 System Controller Hazard Alarms

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
HAZARD	Call Hospital Contact 23:01 + Low Flow 23:02		**Pump is off. The Pump is 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, refer to page 5-11.**
	Call Hospital Contact 23:01 + Low Flow 23:02		**Low flow, flow is less than 2.5 lpm**	Call your hospital contact immediately for diagnosis and instructions. **For more information, refer to page 5-12.**
	Connect Driveline :01		**Driveline is disconnected The Pump Running symbol is black.**	1. Immediately reconnect the Driveline to the System Controller and move the Driveline Safety Lock on the System Controller to the locked position. Also, check that the Modular In-Line connector is secure. 2. If alarm persists after reconnecting the Driveline, press any button on the System Controller to potentially resolve. 3. If Driveline is connected and alarm persists, replace System Controller with a configured backup System Controller. See page 2-40. 4. If alarm persists, call your hospital contact immediately. **For more information, refer to page 5-13.**
	Connect Power Immediately 3:01 + Backup Battery 23:01		**Both power cables are disconnected**	1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. **For more information, refer to page 5-14.**
	Call Hospital Contact Controller Fault		**System Controller Hardware Fault (Microcontroller Failure)**	No active symbols (constant audio tone). Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-16.**
	Low Battery 23:01 + Replace Power Immediately 23:02		**Low Voltage, Power input is extremely low with less than 5 min. remaining**	1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. **For more information, refer to page 5-15.**

Table 5.3 System Controller Advisory Alarms

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
ADVISORY	Connect Power 23:01		**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, refer to page 5-17.**
	Replace Power :02 + Low Battery :06		**Low Battery, Power input is low with less than 15 min. remaining**	1. Promptly connect to a working or different power source (Mobile Power Unit or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact. **For more information, refer to page 5-18.**
	Call Hospital Contact Controller Fault		**System Controller Hardware Fault**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-19.**
	Call Hospital Contact Comm Fault		**Communication Fault (Comm Fault)**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-20.**
	Call Hospital Contact Backup Battery Fault		**System Controller Backup Battery Fault**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-21.**

Table 5.3 System Controller Advisory Alarms (Continued)

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
ADVISORY	Call Hospital Contact Backup Battery Fault + 		**System Controller Backup Battery not installed**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-22.**
	Call Hospital Contact Driveline Power Fault		**Driveline Power Fault**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-23.**
	Call Hospital Contact Driveline Comm Fault +		**Driveline Communication Fault (Driveline Comm Fault)**	Call your hospital contact as soon as possible for diagnosis and instructions. **For more information, refer to page 5-24.**

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

Pump Off Alarm

Table 5.4 Pump Off Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Heart ( ) on the user interface. • The "Pump Running" symbol ( ) is black. • The Driveline is connected. • "Low Flow" and "Call Hospital Contact" alternate on the screen. • Alarm tone: Constant tone.
Alarm means:	Pump has stopped; possibly because power has been disconnected or failed.
To resolve alarm:	1. Connect to a working power source (Mobile Power Unit or two HeartMate batteries) right away. 2. If connecting to power does not resolve, press any button on the System Controller to attempt Pump start and call your hospital contact immediately. It may take up to 10 seconds for the Pump to restart.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button.

Low Flow Alarm

Table 5.5 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. • "Call Hospital Contact" and "Low Flow" alternate on the screen. • Alarm tone: Constant tone.
Alarm means:	Pump flow is less than 2.5 lpm.
To resolve alarm:	Call your hospital contact immediately for diagnosis and instructions.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button.

Driveline Disconnected Alarm

Table 5.6 Driveline Disconnected Alarm

This is a Hazard alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing Red Heart ( ) on the user interface. • Green "Pump Running" symbol ( ) is black. • Flashing red light near Driveline connector. • "Connect Driveline" flashes on the screen. • Alarm tone: Constant tone.
Alarm means:	The Driveline is disconnected from the System Controller.
To resolve alarm:	1. Immediately reconnect the Driveline to the System Controller and move the Driveline Safety Lock on the System Controller to the locked position. (See page 2-16.) It may take up to 10 seconds for the Pump to start. 2. Check that the Modular In-Line connector is secure. 3. If alarm persists after reconnecting the Driveline, press any button on the System Controller to potentially resolve. 4. If Driveline is connected and alarm persists, replace the System Controller with a programmed backup System Controller. See page 2-40. 5. 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.

No External Power Alarm

Table 5.7 No External Power Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Battery ( ) on the user interface. • "Connect Power Immediately" and Backup Battery graphic alternate on the screen. • Yellow light near the black power cable connector is flashing. • Yellow light near the white power cable connector is flashing. • Alarm tone: Constant tone.
Alarm means:	1. The System Controller is not receiving power from either power cable. **AND** 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( ).

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

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 Battery Power Alarm (less than 5 minutes remain)

Table 5.8 Low Battery Power Alarm (< 5 minutes)

This is a Hazard alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing Red Battery ( ) on the user interface. • "Low Battery" and "Replace Power Immediately" alternate on the screen. • Alarm tone: Constant tone. • The Pump will enter Power Save Mode.
Alarm means:	1. Low Voltage Hazard - there is less than 5 minutes of battery power remaining (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 HeartMate batteries) right away. Refer to *Connecting the System Controller to the Mobile Power Unit* on page 3-14. 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( ).

System Controller Hardware Fault

Table 5.9 System Controller Hardware Fault

This is a Hazard alarm	
The screen looks like this:	
Behavior and appearance:	• All symbols are off, including the pump symbol ( ) and wrench( ). • *Call Hospital Contact Controller Fault* displays on the screen. • The Driveline is connected and power is connected. • Alarm tone: Constant tone. • All Controller buttons are non-functional.
Alarm means:	A serious internal malfunction has occurred in the System Controller that requires clinician diagnosis and resolution. The Pump is still operating if the "Call Hospital Contact Controller Fault" message is displayed.
To resolve alarm:	Call your hospital contact as soon as possible for diagnosis and instructions.
Alarm silence period:	None: The audio tone cannot be silenced

IMPORTANT! A backup System Controller is identical to the System Controller. It should remain with you at all times for easy access in an emergency. For instructions on replacing the System Controller, refer to page 2-40.

Power Cable Disconnect Alarm

Table 5.10 Power Cable Disconnect Alarm

This is an Advisory alarm	
The screens look like this: (Screen 1 for black cable; Screen 2 for white cable)	Screen 1— Black cable  Screen 2—White cable 
Behavior and appearance:	• Flashing yellow light near the black or white power cable connector, depending on which cable is disconnected. • *Connect Power* displays on the screen. • Alarm tone: Fast beep.
Alarm means:	One of the System Controller power cables is disconnected from power. If it is the cable with the black connector, the top light comes on. If it is the cable with the white connector, the center light comes on.
To resolve alarm:	1. Promptly connect the disconnected power cable to a working power source (Mobile Power Unit or two fully-charged HeartMate batteries). 2. Call your hospital contact if reconnecting the power cable does not resolve the alarm.
Alarm silence period:	None: The alarm cannot be silenced.

Low Battery Power Alarm (less than 15 minutes remain)

Table 5.11 Low Voltage Alarm (< 15 minutes)

This is an Advisory alarm	
The screens look like this: (alternating screens)	 
Behavior and appearance:	• Flashing yellow diamond (◆) on the user interface. • "Low Battery" and "Replace Power" alternate on the screen. • Alarm tone: Slow beep.
Alarm means:	Low Voltage Advisory - Low voltage, 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 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( ).

System Controller Fault Alarm

Table 5.12 System Controller Fault Alarm

This is an Advisory alarm	
The screens look like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • *Call Hospital Contact* displays on the screen. • Alarm tone: Slow beep.
Alarm means:	An internal malfunction or other issue has occurred in the System Controller that requires clinician diagnosis and resolution.
To resolve alarm:	Call your hospital contact as soon as possible for diagnosis and instructions.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button( ).

IMPORTANT! A backup System Controller is identical to the System Controller. It should remain with you at all times for easy access in an emergency. For instructions on replacing the System Controller, refer to page 2-40.

Communications Fault (Comm Fault) Alarm

Table 5.13 Communication 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; Comm Fault" on the screen. • Alarm tone: Slow beep.
Alarm means:	• Communication between the LVAD and the System Controller has been lost. **OR** • The primary and back-up communication wires in the Driveline are not functioning. In both cases, the Pump is still operating.
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 ( ).

System Controller Backup Battery Fault Alarm

Table 5.14 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( ).

System Controller Backup Battery Not Installed Alarm

Table 5.15 System Controller Backup Battery Not Installed Alarm

This is an Advisory alarm	
The screen looks like this: (alternating screens)	 
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • "Call Hospital Contact; Backup Battery Fault" and "install battery" graphic alternate on the screen. • Alarm tone: Slow beep.
Alarm means:	1. The System Controller's11 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( ).

Driveline Power Fault Alarm

Table 5.16 Driveline Power Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • "Call Hospital Contact; Driveline Power Fault" on the screen. • Alarm tone: Slow beep.
Alarm means:	One of the two power handling wires inside the Driveline may be damaged or broken. The Pump is still operating.
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 ( ).

Driveline Communication Fault (Driveline Comm Fault) Alarm

Table 5.17 Driveline Communication Fault Alarm

This is an Advisory alarm	
The screen looks like this:	
Behavior and appearance:	• Flashing yellow wrench ( ) on the user interface. • "Call Hospital Contact; Driveline Comm Fault" on the screen. • Alarm tone: Slow beep.
Alarm means:	One of the two communication wires inside the Driveline may be damaged or broken. The Pump is still operating.
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 ( ).

Mobile Power Unit Alarms

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

Replace Mobile Power Unit Batteries

Mobile Power Unit Internal Malfunction

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

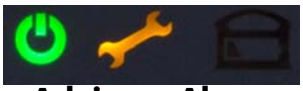
All Mobile Power Unit alarms are accompanied by a light (**Figure 5.4**) and sound. Different lights and sounds come on, depending on the alarm.

Figure 5.4 Indicators on the Mobile Power Unit

Note: When the Mobile Power Unit is connected to the System Controller, the Mobile Power Unit duplicates any active audio System Controller alarms. Refer to *System Controller Alarm Management* on page 5-3.

Table 5.18 describes the Mobile Power Unit alarms and how to resolve each alarm.

Table 5.18 Mobile Power Unit Alarms

Alarm Symbol	Meaning	What You Should Do
 **Advisory Alarm** Yellow Mobile Power Unit battery indicator with beeping audio tone	Internal Alkaline AA Mobile Power Unit batteries need to be replaced.	1. Immediately switch to a new set of fully-charged batteries. 2. Replace Mobile Power Unit batteries. Refer to *Inserting or Replacing the Mobile Power Unit Batteries* on page 3-8.
 **Advisory Alarm** Yellow wrench light with beeping audio tone	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.

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 Battery 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 Battery Charger unit. The Battery Charger alerts you immediately of any problem.

Battery Charger Display Panel Messages

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

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

Table 5.19 describes the messages that appear on the Battery Charger display panel.

KEY for Table 5.22	
Y	Battery Charger pocket number
# = X	Battery charge cycle count
mAh	milliamp-hour
C	Battery capacity
B0001	Battery fault with alarm code, example
S0001	Battery Charger pocket (slot) fault with alarm code, example

Table 5.19 Battery Charger Display Panel Messages

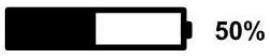
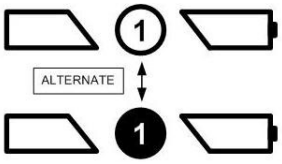
Meaning	English Mode	Graphics Mode
Ready	HeartMate CHARGER	HeartMate CHARGER
Battery Charge Status	Y: ▮▮▮▮▮	1:  50%
Battery Information (3rd screen)	# = X X: mAh = C	# = X X: mAh = XC
Charge Complete	READY Y: ▮▮▮▮▮	1: 
Request Calibration	CALIBRATE? PRESS Y	
Accept Calibration	PROGRESS Y: CALIBRATING	1: 
Charger Fault	CALL SERVICE	

Table 5.19 Battery Charger Display Panel Messages (Continued)

Meaning	English Mode	Graphics Mode
Battery Fault (Button Push)	CALL SERVICE B0001	☎ B0001
Charger or Pocket Fault (Button Push)	CALL SERVICE S0001	☎ S0001

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 5.5**).

Figure 5.5 Telephone Symbol and Red Light by Pocket 1 Indicate that the Charger Detects a Problem

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

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.
2. Examine the battery's metal contact and the contact inside the charging pocket.
3. Ensure that there is no dirt, debris, or obstruction.
4. Reinsert the battery into the same pocket.
5. If the red light comes on again, insert the battery into a different pocket.

   If the red light comes on in a second pocket, the battery is defective. Do not use it.
6. 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.
7. Remove the defective battery from use.

Confirming a Pocket Fault

When the Battery 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 Battery 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 four HeartMate 14 Volt Lithium-Ion batteries in the charging pockets

Remember !

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

TASK

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

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

Confirming a Battery Charger Fault

If the Battery 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 (English only).
   b. Record the alarm code and save it for future reference.
3. Turn off the Battery Charger.
4. Unplug the Battery Charger from the electrical outlet.
5. 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 III system.

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 (**Figure 5.6**).

Figure 5.6 Aligning the Connectors

- 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 5.7**).

  Hand tighten the nut; do not use tools.

  Do not twist the connectors when turning the nut.

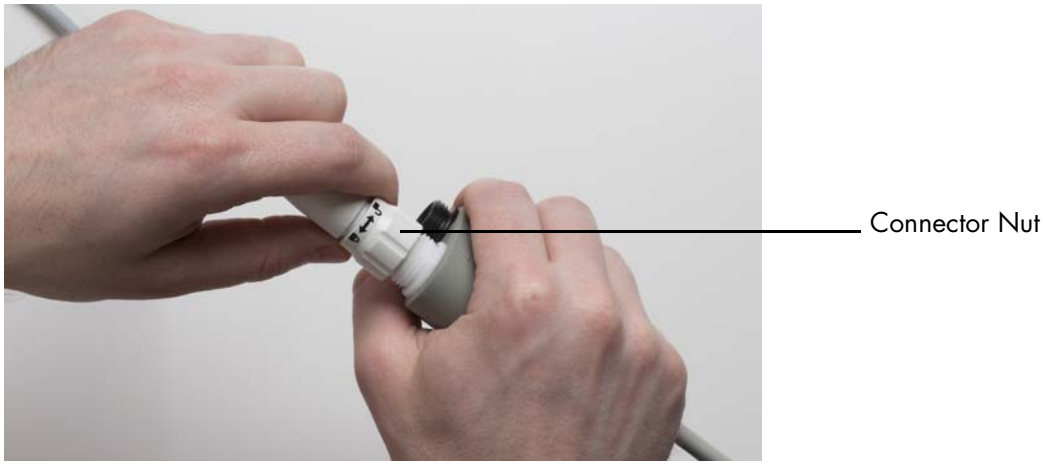


Figure 5.7 Tightening the Connector Nut

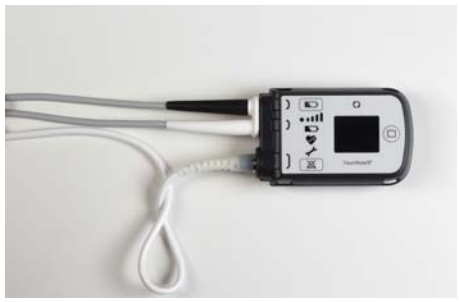
- When disconnecting, turn the nut on the connector until the connection is loose, and then gently pull the connectors apart.
- Never twist connectors or pull them apart at an angle.

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.

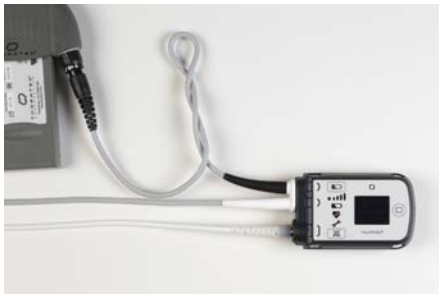
CAUTION !

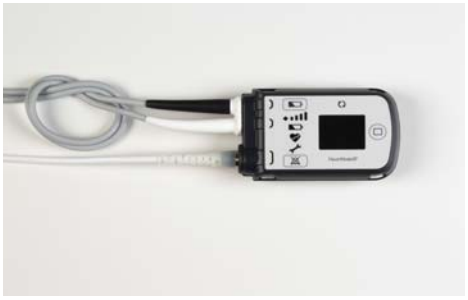
Do not twist, kink, or sharply bend the Driveline.



CAUTION !

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

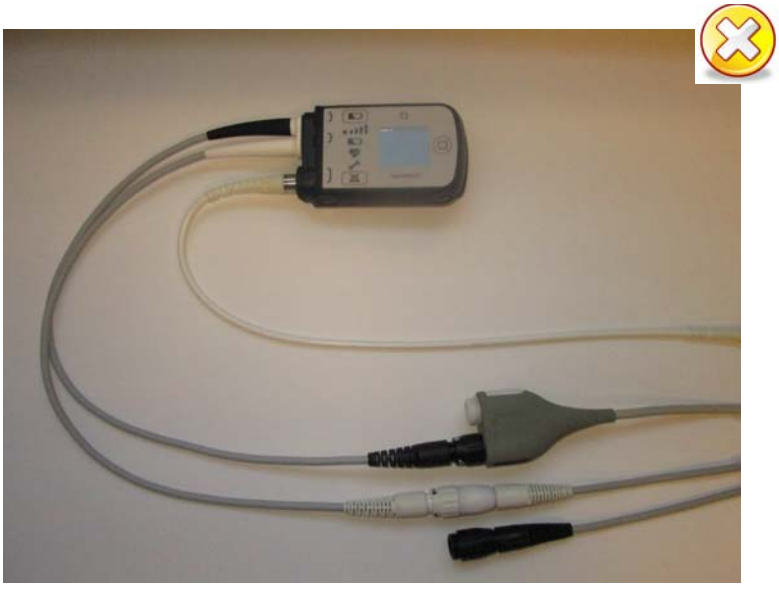




CAUTION !

- 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.

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



EQUIPMENT MAINTENANCE

This section provides information about how to clean and maintain the HeartMate III Left Ventricular Assist System, and the wear and carry accessories.

6 Equipment Maintenance

Cleaning and Maintaining the Equipment

General Cleaning Rules

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

WARNING !

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

Cleaning the System Controller

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

WARNING !

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

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

At least monthly, inspect the System Controller's audio sounders for dirt or grease. If you notice a change in tone or in loudness during a System Controller self test, 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 System Controller is replaced. Refer to *Backup System Controller* on page 2-36.

Cleaning the System Controller Power Cables

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

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

Driveline Care

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

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

Driveline damage may be evidenced by the following:

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

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

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

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

Caring for the Mobile Power Unit

Inspect the Mobile Power Unit routinely as described in the *Safety Checklists* on page 10-1 for the safest and best possible performance.

Cleaning the Mobile Power Unit

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

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

IMPORTANT! Do not clean the Mobile Power Unit while it is powering the system.

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 10-1 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 (**Figure 6.1**).

Allow the alcohol to dry before using newly cleaned batteries or clips.

Do not clean batteries while the batteries are in use.

Figure 6.1 Cleaning the Contacts on the Batteries and Battery Clips

Caring for the Battery Charger

The Battery Charger requires little maintenance. However, it should be inspected routinely for the safest and best possible performance. For more information, refer to *Safety Checklists* on page 10-1.

Caring for the Wear and Carry Accessories

HeartMate wear and carry accessories are designed to securely hold, carry, and protect HeartMate III components. 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.

The accessories include:

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

1. 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.

2. 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.

3. Ensure that the accessory is completely dry before using it. This includes the Shower Bag.

Product Disposal

Talk with your hospital contact before throwing away any equipment. This section describes specific disposal rules for certain equipment. If the equipment is not listed in this section, 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 III Left Ventricular Assist Device.

7 Frequently Asked Questions

System Use

Who should I call if I think my equipment is broken?

Call your hospital contact if you think your equipment is broken. Your hospital contact can check the equipment and order replacements, if needed. Do not try to repair anything yourself.

Can I use other batteries to power the HeartMate III system?

No. Only use the HeartMate 14 Volt Lithium-Ion batteries that you received from the hospital at discharge. Other batteries will not power the HeartMate III 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 sterile technique that you learned from your hospital contact.

Are there medications that will interfere with my Pump?

Consult your doctor before starting any new medications or dietary supplements.

Showers and Exercise

Can I shower with the HeartMate III 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 III 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 III system?

The HeartMate III Left Ventricular Assist System is approved for air travel. Talk with your physician or hospital contact before traveling, especially if it is a long distance. He or she can help you with a travel safety plan. If you are going outside of North America, you need power cords that works with the local voltage and that meet applicable safety agency marks and standards (for both the Mobile Power Unit and Battery Charger). Ask your hospital contact for approved power cords, if needed.

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 III 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.

7 Frequently Asked Questions

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.

8 Handling Emergencies

What Is An Emergency?

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

- Loss of power to the Pump (symbol appears on the System Controller)
- Broken wires (indicated by Driveline Power or Communication faults or Communications fault)
- Damage to the Pump motor or System Controller (indicated by a Replace Controller alarm or Low Flow alarm)
- Health changes affecting your heart

If the system is not working right, the System Controller will alarm. Refer to *System Controller Alarms* on page 5-3.

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 Operating

If a problem arises while the Pump is operating, 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: Refer to *Alarms and Troubleshooting* on page 5-1 for instructions on handling alarms.

When the Pump has Stopped (Red Heart Alarm)

If the Pump stops operating, you will see the Red Heart alarm and the Pump Running symbol is black:

You should:

1. Check the connection between the System Controller and the Pump, and then check the connection between the System Controller and Driveline power source (Mobile Power Unit or batteries).
2. Check that the Modular In-Line connector on the Driveline is connected and secure.
3. Fix any loose connections. Loose connections may not resolve the situation if other Driveline problems exist.
4. Switch to a different power source. If you are on batteries, switch to the Mobile Power Unit. If you are on Mobile Power Unit power, switch to batteries.
5. Switch to the backup System Controller. Refer to *Replacing the Operating System Controller with a Backup Controller* on page 2-40.
6. If checking connections, switching power sources, or changing system controllers does not fix the problem, call emergency services right away (dial 911 if available), and then call your hospital contact.

8 Handling Emergencies

TESTING AND CLASSIFICATION

This section provides information about safety testing and classification for the HeartMate III Left Ventricular Assist System.

9 Testing and Classification

Safety Testing and Classification

The HeartMate III Left Ventricular Assist System has been thoroughly tested and Classified by Underwriters Laboratories, LLC (UL) to the fire, casualty, and electric shock hazard requirements of the following safety standards, as applicable:

- IEC 60601-1:2012 (ed. 3.1)
- IEC 60601-1:2005 + Corr. 1:2006 + Corr. 2:2007 (ed. 3.0)
- IEC 60601-1-11:2015
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-1-6:2010 + A1:2013
- IEC 62366:2007 + A1:2014
- EN 60601-1:2006/A1:2013 (ed. 3.1)
- EN 60601-1:2006 +Corr. 2:2010 (ed. 3.0)
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012 (ed. 3.1)
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1:14 (ed. 3.1)
- CAN/CSA C22.2 No. 60601-1:08 (ed. 3.0)
- CAN/CSA C22.2 No. 60601-1-11:15

These standards require making the following declarations and stating the type and degree of protection for listed hazards.

- UL 60601-1, 1st ed., 2006-04-26
- CAN/CSA C22.2 No. 601.1-M90 (R2005)

Medical Electric Equipment
with respect to shock, fire,
mechanical and other specified
hazards only in accordance with
UL 60601-1 and CAN/CSA C22.2
No.601.1-M90 (R1997), CAN/CSA C22.2
No.601.1S1-94, and CAN/CSA-C22.2
No.601.1B-98 (National Difference for Canada)
No.601.1 7D72

Acceptable Operating Conditions

For safe and optimal use of your HeartMate system components, follow the operating guidelines listed here. If you use the equipment outside these ranges, it may result in a failure or may impact your LVAD support.

Table 9.1 Operating Conditions

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Mobile Power Unit	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
Battery Charger	32°F to 104°F (0°C to 40°C)	30% to 75%	525 to 795 (700 to 1060)
System Controller, Backup System Controller[a,b]	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)
11 Volt Lithium-Ion Backup Battery	32°F to 104°F (0°C to 40°C)	15% to 93%	525 to 795 (700 to 1060)

[a] Standby components (extra 14 Volt Lithium-Ion batteries, backup System Controller) should be maintained at conditions within the acceptable ranges so that they are available for immediate use.

[b] Every six months, the Sleeping backup System Controller must be connected to a power source to recharge the backupbattery inside it. If the 11 Volt Lithium-Ion backup battery inside the backup System Controller is not charged every six months, it will lose its charge. If this happens, there may not be enough power to run the Pump if the in-use power disconnects or fails. Refer to Maintaining the Backup System Controller Readiness on page 2-36.

Note: Patients must maintain the equipment in Table 9.1 within the stated operating conditions at all times.

Declaration Concerning General Safety Standards

Table 9.2 Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous/Pulse
Method of Sterilization	100% EtO for blood pump, Controller, and all sterile accessories
Type of protection against electrical shock	Mobile Power Unit: • Class II Lithium-Ion Batteries: • Class II Battery Charger: • Class I
Degree of protection against electric shock	Type CF (Cardiac Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress of water and particulate matter	• System Controller–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water • Mobile Power Unit–IP22:Protection against ingress of solid foreign objects the size of a finger and from vertically falling water drops when the enclosure is filled up to 15° • System Monitor–IPX1:Protection against ingress of vertically dripping water • Shower Bag–IPX3: Protection against ingress of spraying water • 14 V Battery and Clip (only when connected to the System Controller) –IP24: Protection against ingress of solid foreign objects the size of a finger and from splashing water • Battery Charger–IPX0: Non-protected against ingress of water
Applied parts	• HeartMate III Left Ventricular Assist Device • System Controller

For additional information on testing and classification for the HeartMate III Left Ventricular Assist System, refer to the *HeartMate III Instructions for Use*. Your hospital contact can get a copy for you.

Testing and Classification: HeartMate III LVAS

The HeartMate III Left Ventricular Assist System has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007 Medical electrical equipment—Part 1-2: General requirements for Basic safety and essential performance—Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate III Left Ventricular Assist System can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Corporation for assistance.

Note: Special precautions are required for installing and using the HeartMate III Left Ventricular Assist System within portable and RF communication environments.

The HeartMate III Left Ventricular Assist System is protected against the effects of external cardiac defibrillation within the limits established per EN 45502-1:1997. However, it is advised that the HeartMate III Left Ventricular Assist System be disconnected from the System Controller during the use of open-heart defibrillation.

Testing and Classification: Mobile Power Unit

Declaration and Guidance for Electromagnetic Emissions for the Mobile Power Unit

The HeartMate III Left Ventricular Assist System with Mobile Power Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate III Left Ventricular Assist System should assure that it is used in such an environment.

Table 9.3 Declaration and Guidance Concerning Electromagnetic Emissions for Mobile Power Unit

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions **CISPR 11** **EN 55011**	Group 1	The HeartMate III Left Ventricular Assist System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions **CISPR 11** **EN 55011**	Class B	The HeartMate III Left Ventricular Assist System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions **IEC 61000-3-2** **EN 61000-3-2**	Class A	
Voltage Fluctuations/ **Flicker Emissions** **IEC 61000-3-3** **EN 61000-3-3**	Complies	

Declaration and Guidance for Electromagnetic Immunity

The HeartMate III Left Ventricular Assist System (powered by the Mobile Power Unit) is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate III Left Ventricular Assist System should assure that it is used in such an environment.

Table 9.4 Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate III Left Ventricular Assist System Equipment including Mobile Power Unit

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power supply Input Lines IEC 61000-4-11 EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HM III Left Ventricular Assist System requires continued operation during power mains interruptions, it is recommended that the HM III Left Ventricular Assist System be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment.

The HeartMate III Left Ventricular Assist Device, System Controller, and Mobile Power Unit are intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate III, Left Ventricular Assist Device, System Controller, and Mobile Power Unit should assure that they are used in such an electromagnetic environment.

Table 9.5 Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate III Left Ventricular Assist System Equipment, including Left Ventricular Assist Device, System Controller, and Mobile Power Unit

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate III Left Ventricular Assist Device, System Controller, and Mobile Power Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6 EN 61000-4-6			**Recommended Separation Distances**
	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	$d = 1.2\sqrt{P}$
		Mains Powered 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz		Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment that is marked with the following symbol: 

Table 9.5 Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate III Left Ventricular Assist System Equipment, including Left Ventricular Assist Device, System Controller, and Mobile Power Unit (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Radiated RF Microwave Ovens	N/A	890-940 MHz and 2.4-2.5 GHz 137 V/m	Based on 21CFR Chapter 1 performance standard for microwave ovens: field strength at 5 cm from external oven surface. Tested with Mobile Power Unit powered by AC Mains.
Radiated RF Cell Phones	N/A	825-960 MHz and 1.4-2.0 GHz 30 V/m	$d = 0.77\sqrt{P}$

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.

[b] Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (min. 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate III Left Ventricular Assist System is used exceeds the applicable RF compliance level above, HeartMate III Left Ventricular Assist System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III Left Ventricular Assist System.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

WARNING !

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

Table 9.6 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the HeartMate III Left Ventricular Assist System with the Mobile Power Unit

The HeartMate III Left Ventricular Assist System with the Mobile Power Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartMate III Left Ventricular Assist System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartMate III Left Ventricular Assist System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter** m				
	150 kHz to 80 MHz outside ISM bands	**150 kHz to 80 MHz in ISM bands**	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**	**Cellular Telephone 825 MHz to 960 MHz and 1.4 GHz to 2.0 GHz**
W	$d = 1.2\sqrt{P}$ **Mains Powered**	$d = 1.2\sqrt{P}$ Mains Powered	$d = 1.2\sqrt{P}$ Mains Powered	$d = 2.3\sqrt{P}$ Mains Powered	$d = 0.77\sqrt{P}$ Mains Powered
0,01	0.12	0.12	0.12	0.23	0.08
0,1	0.38	0.38	0.38	0.73	0.25
1	1.2	1.2	1.2	2.3	0.77
10	3.8	3.8	3.8	7.3	2.5
100	12	12	12	23	7.7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Testing and Classification: Battery Charger

The Battery Charger complies with the following safety standards:

- EN 60950-1: 2006 + A11: 2009 + A1: 2010 + A12: 2011
- IEC 60950-1: 2005, 2nd Edition + Am1:2009
- UL 60950-1, 2nd Edition, 2011
- CSA C22.2 No. 60950-1-07, 2nd Edition, 2011
- IEC 60601-1: 1988, 2nd Edition, A1:1991, A2:1995
- UL 60601-1, 1st Edition, 2003-04-26 (included National Differences for USA)
- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98 (National Difference for Canada)

This equipment has been tested and found to comply with the limits for devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult Thoratec Corporation for assistance.

Declaration Concerning General Safety Standards for Battery Charger

Table 9.7 Declaration Concerning General Safety Standards for Battery Charger

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against mains shock	Class I (grounded)
Degree of protection against harmful ingress of water	IPX0

Declaration and Guidance for Electromagnetic Emissions for Battery Charger

The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment.

Table 9.8 Declaration and Guidance Concerning Electromagnetic Emissions for Battery Charger

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11 EN 55011	Group 1	The Battery Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 EN 55011	Class B	The Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 EN 61000-3-3	Complies	
Radiated Emissions, Magnetic Field MIL-STD-461F	RE101	The Battery Charger generates magnetic fields due to the presence of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Declaration and Guidance for Electromagnetic Immunity for the Battery Charger

The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment.

Table 9.9 Declaration and Guidance Concerning Electromagnetic Immunity for the Battery Charger

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5 EN 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power supply Input Lines IEC 61000-4-11 EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Battery Charger requires continued operation during power mains interruptions, it is recommended that the Battery Charger be powered from an uninterruptible power supply or a battery. **Note:** U_T is the AC mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment.

Table 9.10 Declaration and Guidance Concerning Electromagnetic Immunity for the Battery Charger

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Battery Charger than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF IEC 61000-4-6 EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
			$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of the equipment that is marked with the IEC symbol for non-ionizing radiation: 

Table 9.10 Declaration and Guidance Concerning Electromagnetic Immunity for the Battery Charger (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Battery Charger is used exceeds the applicable RF compliance level above, Battery Charger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Battery Charger

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

WARNING !

- Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may result in increased emissions or decreased immunity of the HeartMate Left Ventricular Assist System.
- Do not use the Battery Charger next to other equipment.
- Do not stack the Battery Charger on top of other equipment.
- No modification of this equipment is allowed.

Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries

HeartMate 14 Volt Lithium-Ion batteries comply with the following safety standards:

- IEC/EN 62133
- UL 2054
- UN 38.3 T1-8

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

Table 9.11 Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

Type	Degree of Protection
Degree of protection against electric shock	No Applied Part
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of protection against harmful ingress	IP24 only when connected to the System Controller through Clip

Declaration and Guidance for Electromagnetic Emissions for HeartMate III Powered by 14 V Li-Ion Batteries

The HeartMate III 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 III Left Ventricular Assist System should assure that it is used in such an environment.

Table 9.12 Declaration and Guidance Concerning Electromagnetic Emissions for HeartMate III Powered by 14 Volt Lithium-Ion Batteries

HeartMate III Powered by 14 V Li-Ion Batteries		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF Emissions CISPR 11 EN 55011	Group 1	The HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 EN 55011	Class B	The HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated Emissions Avionics RTCA/DO-160G Section 21	Cat. M	The HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Declaration and Guidance for Electromagnetic Immunity for HeartMate 14 Volt Lithium-Ion Batteries

The HeartMate III 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 III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should assure that it is used in such an environment.

Table 9.13 Declaration and Guidance Concerning Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 EN 61000-4-8	3 A/m	30 A/m	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment.

The HeartMate III 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 III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should assure that it is used in such an electromagnetic environment.

Table 9.14 Declaration and Guidance Concerning Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate III Left Ventricular Assist Device, System Controller, and batteries, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF **IEC 61000-4-6** **EN 61000-4-6**	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	$d = 1.2\sqrt{P}$

Table 9.14 Declaration and Guidance Concerning Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Radiated RF **IEC 61000-4-3** **EN 61000-4-3**	10 V/m 80 MHz to 2.5 GHz	20 V/m	Battery Operation $d = 0.6\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of the equipment that is marked with the IEC symbol for non-ionizing radiation: 
Radiated RF **Microwave Ovens**		Frequency Range 890-940 MHz and 2.4-2.5 GHz 137 V/m	Based on 21 CFR Chapter 1 performance standard for microwave ovens: field strength at 5 cm from external oven surface.
Avionics **Radiated and conducted RF** **RTCA/DO-160G Section 20**		Frequency Range Conducted 10 kHz to 400 MHz Radiated 100 MHz to 8 Ghz Cat. R	
Radiated RF Cell Phones	N/A	825-960 MHz and 1.4-2.0 GHz 56 V/m	$d = 0.41\sqrt{P}$

Table 9.14 Declaration and Guidance Concerning Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.

[b] Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (min. 10/3) is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries is used exceeds the applicable RF compliance level above, the HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate III Left Ventricular Assist System with 14 Volt Lithium-Ion batteries.

WARNING !

Do not use equipment or supplies other than those specified or sold by Thoratec Corporation. The use of unauthorized replacement parts may result in increased emissions or decreased immunity of the HeartMate Left Ventricular Assist System.

Table 9.15 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the HeartMate III Left Ventricular Assist System with 14 V Li-Ion Batteries

The HeartMate III Left Ventricular Assist System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartMate III Left Ventricular Assist System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartMate III Left Ventricular Assist System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m				
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz	Cellular Telephone 825 MHz to 960 MHz and 1.4 GHz to 2.0 GHz
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 0.6\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 0.41\sqrt{P}$
0,01	0.12	0.12	0.060	0.12	0.04
0,1	0.38	0.38	0.19	0.38	0.13
1	1.2	1.2	0.60	1.2	0.41
10	3.8	3.8	1.9	3.8	1.3
100	12	12	6.0	12	4.1

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Corporation for assistance.

CAUTION !

Use of equipment and supplies other than those specified in the manuals or sold by Thoratec Corporation for replacement parts may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the HeartMate III Left Ventricular Assist System and other devices.

SAFETY CHECKLISTS

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

10 Safety Checklists

Daily Safety Checklist

Daytime Checklist:

- ☐ Perform System Controller self test.
- ☐ When using a new power source, inspect System Controller power cable connectors for dirt, grease, or damage.
- ☐ When changing power sources, inspect connectors on battery clips for dirt, grease, or damage.
- ☐ When switching from the battery power to the Mobile Power Unit, inspect the connector pins and sockets for dirt, grease, or damage.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the locking nut.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Driveline exit site for signs of infection, including redness, tenderness, swelling, discharge, or a foul odor. Use sterile technique to touch or handle the exit site.

Sleep Checklist:

- ☐ Check all electrical connections between the System Controller and power cables, the power cables and the Mobile Power Unit patient cable, and the Mobile Power Unit and AC electrical outlet.
- ☐ Always connect to the Mobile Power Unit for sleeping or when there is a chance of sleep, as you may not hear System Controller alarms.
- ☐ Make sure the Driveline is stabilized.
- ☐ Confirm bedside items are in place:
  - ☐ Working flashlight with charged batteries.
  - ☐ Backup System Controller.
  - ☐ Two charged HeartMate 14 Volt Lithium-Ion batteries and two 14 Volt battery clips.
- ☐ Inspect the Driveline Cable for signs of damage, such as cracking, fraying, wear, exposed wires, sharp bends or kinks.
- ☐ Ensure that the Modular In-line Connector is secure and the connector locking nut is in the locked position. Ensure no yellow indicator is seen under the in-line locking nut.
- ☐ Inspect all cables for signs of damage.

Weekly Safety Checklist

- ☐ Review Replacing Running System Controller with a Backup Controller Instructions in Section 2.
- ☐ Clean the metal battery terminals and contacts inside the battery clips.
- ☐ Inspect the Mobile Power Unit power cord, used to connect the Mobile Power Unit to the AC electrical outlet, for damage or wear. Confirm that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Inspect the Mobile Power Unit patient cable, used to connect the System Controller to the Mobile Power Unit, for damage or wear. Confirm that the cable is not kinked, split, cut, cracked, or frayed. Do not use the Mobile Power Unit patient cable if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect HeartMate 14 Volt Lithium-Ion batteries for damage. Check the battery contacts for denting or damage. Replace damaged batteries. Do not use batteries that appear damaged.
- ☐ Inspect the Battery Charger for signs of physical damage, such as dents, chips, or cracks. Do not use the Battery Charger if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect the power cord that is used to connect the Battery Charger to an AC outlet. Confirm that the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your hospital contact, if needed.
- ☐ Inspect wear and carry accessories (including the consolidation bag, Travel Bag, Protection Bag, System Controller Neck Strap, Holster Vest, and Belt Attachment accessory) for damage or wear.
- ☐ Inspect the Battery Holster for damage or wear.
- ☐ Inspect the Shower Bag for damage or wear.
- ☐ Replace any equipment or system component that appears damaged or worn.

Monthly Safety Checklist

- ☐ Review Alarms and Troubleshooting Guides in Section 5.
- ☐ Check the manufacture date on the label of all batteries. If a battery was manufactured more than three years ago, the battery has expired. Replace expired batteries. Do not use expired batteries.

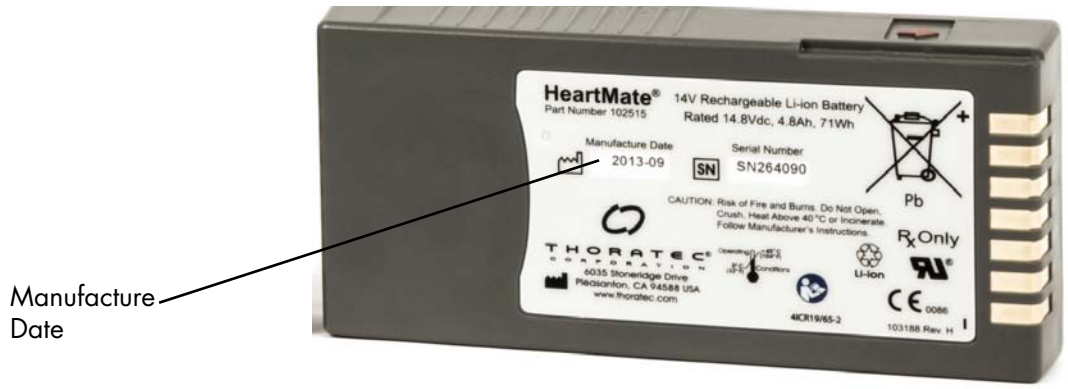


Figure 10.1 Check the Manufacture Date to Determine Battery Expiration

- ☐ 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. Refer to *Battery Charger Display Panel Messages* on page 5-28. Replace batteries that have exceeded 360 cycles. Do not use batteries that have exceeded 360 cycles.
- ☐ Clean the metal battery contacts and the interior contacts of battery clips using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use.
- ☐ Inspect the Mobile Power Unit patient cable and power cable connector pins and sockets for dirt, grease or damage. If the pins or sockets are damaged or contaminated, do not attempt to clean them. Report the condition to your hospital contact. Cleaning and service should be performed only by Thoratec-trained personnel. Do not attempt to clean or repair equipment on your own.
- ☐ If the Mobile Power Unit is going to be stored for over 1 month, remove the Mobile Power Unit batteries.

- ☐ Unplug the Battery Charger and clean the metal contacts inside all four charging pockets with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before inserting batteries into the pockets. Do not clean the Battery Charger while it is plugged in.
- ☐ Replace any equipment or system component that appears damaged or worn.

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 operating 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. Refer to *Inserting or Replacing the Mobile Power Unit Batteries* on page 3-8.

Yearly Safety Checklist

- ☐ Schedule a Battery Charger inspection and cleaning with Thoratec-trained personnel. The safety inspection and cleaning includes (but is not limited to) functional testing, cleaning, and inspection.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

As-Needed Safety Checklist

- ☐ Manage the Driveline exit site in accordance with the instructions provided by the clinician.
- ☐ Clean the exterior surfaces of batteries using a clean, dry cloth. Do not use liquids such as water or liquid cleaning solvent to clean batteries. Keep the batteries dry and away from water and liquid.
- ☐ Unplug the Battery Charger and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild detergent, if necessary. Do not immerse the charger in water or liquid.
- ☐ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

Clinic Visit Safety Checklist

Advise your patient to bring his or her Patient Handbook to the clinic visit. The following safety check should be performed at each clinical follow-up visit:

- ☐ Review replacing the operating 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 (*Patient Handbook* page v).
- ☐ Review guidelines for connecting power cable connectors (*Patient Handbook* Section 5).
- ☐ Review changing power sources (*Patient Handbook* Section 3).
- ☐ Review HeartMate 14 Volt Lithium-Ion battery calibration steps (*Patient Handbook* Section 3).
- ☐ Review What Not To Do: Driveline and Cables (*Patient Handbook* section 5.)
- ☐ Review using the Shower Bag and showering (*Patient Handbook* section 4).
- ☐ Review caring for the Driveline exit site including cleansing, dressing, and immobilizing the Driveline (*Patient Handbook* section 4).
- ☐ System Controller must be maintained and assessed for readiness.

GLOSSARY

This section defines important terms and abbreviations.

11 Glossary

Abbreviations

Abbreviation	Term
AC	Alternating Current
CM	Centimeter
DC	Direct Current
EKG	Electrocardiogram
ICD	Implantable Cardiac Defibrillators
ICU	Intensive Care Unit
IPM	Implantable Pacemaker
INR	International Normalized Ratio
IV	Intravenous
LPM	Liters Per Minute
LVAD	Left Ventricular Assist Device
LVAS	Left Ventricular Assist System
LMW	Low Molecular Weight
Ml/hr	Milliliter per hour
MRI	Magnetic Resonance Imaging
O.R.	Operating Room
PI	Pulsatility Index
PTT	Partial Thromboplastin time
QD	Once daily
RPM	Revolutions Per Minute
TID	Three times daily
V	Volt

Terms

A

Advisory Alarm: Alarms that are important, but not life threatening. Advisory alarms can be silenced for a short time using the Silence Alarm Button that is found on the System Controller user interface.

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

Alternating Current: Abbreviated AC. The type of electricity that is common for electrical outlets in North American households.

Apical Cuff: The Apical Cuff is the interface between the heart and the HeartMate III LVAD. It is sewn to the exterior of the heart and anchors it to the LVAD via the Slide Lock.

B

Backup Battery: The 11 volt Li-Ion battery inside the System Controller that will continue to run the pump for a short period of time until the System Controller is reconnected to external power.

Backup System Controller: A backup System Controller used to replace the System Controller, if needed. The backup is identical to the System Controller and is pre-set with the same settings. Keep the backup System Controller with you at all times (along with other emergency or backup items).

Battery: A device that provides direct current (DC) power to the system. The HeartMate III Left Ventricular Assist System can be powered by two 14 Volt Lithium-Ion batteries. Refer to *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-18. 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. Refer to *System Controller Backup Power* on page 2-35.

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.

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

Battery Power Gauge: A set of lighted bars that indicates how much battery power is available. Each HeartMate 14 Volt Lithium-Ion battery has its own 5-bar on-board battery power gauge that shows the battery charge level. The System Controller also has a battery power gauge. The power gauge on the System Controller has four bars and one diamond-shaped light. The System Controller battery power gauge is used during battery-powered operation. It shows the approximate charge level of the two batteries currently in use.

Battery-Powered Operation: Using two HeartMate 14-V Lithium-Ion batteries to power the system. Using batteries to power the system is appropriate when you are active, outdoors, or when electrical power is unavailable.

C

Cautions: Actions to avoid that could damage equipment or affect how the system works. Although important for system function, cautions do not usually relate to life-threatening risks.

Communication Fault (Comm Fault): An Advisory alarm indicating the HeartMate III LVAD and System Controller cannot properly exchange information.

Controller: *See System Controller.*

Controller Alarm Fault: An advisory alarm that occurs when an internal malfunction in the System Controller has occurred that requires clinician diagnosis and resolution.

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

Controller Hardware Fault Alarm: A hazard alarm that occurs when a serious internal malfunction occurs in the System Controller that requires clinician diagnosis and resolution.

D

Direct Current: Abbreviated DC. The type of electricity that comes from a battery.

Display Button: A button on the System Controller user interface. Press this button to bring up data on the user interface's display screen (such as current function and alarm history).

Driveline: The Driveline connects the Pump to the System Controller, which then connects to a power source. The Driveline consists of two cables: the Pump Cable and the Modular Cable. One end of the Pump Cable connects to the pump implanted in the patient's abdomen. The other end of that cable exits the patient's body. One end of the Modular Cable is connected to the Pump Cable and the other end connects to the System Controller. The Driveline brings power to the motor inside the implanted Pump. Data about system operation is transferred through the Driveline to the System Controller.

Driveline Communication Fault (Driveline Comm Fault): An Advisory Alarm. It occurs when one of the two communication wires inside the Driveline is damaged.

Driveline Power Fault: An Advisory Alarm. It occurs when one of the two power wires inside the Driveline is damaged.

E

Exit Site: The place where the Driveline goes through the skin. The exit site must be kept clean and dry to lower the risk of infection.

F

Fixed Speed Mode: An operating mode where the device is set at a constant or fixed speed. Doctor and nurses decide and control pump speed.

G

H

Hazard Alarm: Hazard alarms occur when the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention. Hazard alarms are indicated by a red light and continuous audio tone.

HeartMate III Left Ventricular Assist System: Includes the pump and Driveline, as well as the System Controller, power sources (Mobile Power Unit or batteries), and accessories. The term LVAS is the abbreviation 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 as 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. Other terms for the device are Pump, heart pump, or LVAD (the acronym for Left Ventricular Assist Device).

Left Ventricular Assist System: The HeartMate III Left Ventricular Assist System includes the pump and all related external equipment. Sometimes the Left Ventricular Assist System is called an "LVAS". LVAS is NOT the same as LVAD. LVAD refers only to the Pump.

Liters Per Minute: Abbreviate as LPM. Blood flow through the Pump is measured in LPM. LPM appears on the System Controller user interface along with blood flow data.

Low Battery Hazard Alarm: A red-colored battery-shaped symbol ( ) on the System Controller user interface that illuminates when less than 5 minutes ot combined battery power remain for the in-use HeartMate 14 Volt Lithium-Ion batteries, during battery-powered operation.

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 III pump blood flow is critically low.

Low Speed Limit: The lowest speed at which the HeartMate III pump can operate while maintaining patient stability.

M

Magnetic Resonance Imaging ( ) MR is unsafe for HeartMate III patients. Do not subject to Magnetic Resonance Imaging.

Mobile Power Unit: The Mobile Power Unit connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. 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.

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.

Modular In-line Cable: One of the two cables that make up the Driveline. One end of the Modular Cable connects to the Pump Cable that exits the patient's abdomen. The other end of the Modular Cable connects to the System Controller.

N

O

Operating Modes: There are three modes of System Controller operation:

- Run Mode (actively running)
- Sleep Mode (off and unused)
- Charge Mode (connected to power and charging the internal backup battery)

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

P

Percutaneous: Percutaneous means "through the skin."

Pump Cable: One of the two cables that make up the Driveline. The Pump Cable is permanently attached to the pump housing. The other end of the Pump Cable exits the patient's abdomen and is connected to the Modular Cable which connects to the System Controller.

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

Power Saver Mode: In Power Saver Mode, the System Controller slows pump speed to save power. If power is removed or fails, the System Controller gives 15 minutes of full power before entering Power Saver Mode. Alarms cannot be silenced while in Power Saver Mode.

Power Sources: Three power sources can power the HeartMate III Left Ventricular Assist System:

- A pair of wearable, rechargeable 14 Volt Lithium-Ion batteries worn in battery clips
- The Power Module that plugs into an AC electrical outlet
- 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.

Pulse Mode: The Pump is able to create an artificial pulse while it is operating. You will know it is operating in Pulse Mode when you see the ▲ on the LCD of the System Controller.

Pump: *See Left Ventricular Assist Device.*

Pump Running Symbol: A green-colored symbol ( ) on the System Controller user interface that illuminates when the pump is receiving power and operating.

Pump Speed: Pump speed is measured in revolutions per minute (RPM). The number of RPMs reflects how fast the Pump's internal rotor turns.

Q

R

Red Heart Indicator: A red-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.

S

Safety Lock: The feature on the System Controller that ensures the Controller Driveline Connector is properly inserted (when the lock can be fully closed).

Self Test: A routine system check that you should perform daily to confirm that the System Controller's audio and visual alarms are working properly.

Silence Alarm Button: A button on the System Controller or Mobile Power Unit ( ) that silences an audio alarm. How long the alarm is silenced depends on the type of alarm. The silence period varies from 2 minutes to 4 hours. Pressing the Silence Alarm button only silences the alarm. It does not fix the alarm condition.

Silence Alarm Screen: When the audio portion of the alarms are silenced, the symbol will display on the LCD screen of the System Controller.

Strap Attachment Points: Four places on the System Controller where straps can be easily connected. Attachment points allow for holding or carrying the System Controller. The System Controller can be worn or carried on a belt or strap, or inside a pocket.

System Controller: The small computer that controls and checks system function. It connects the pump to the external power sources and may be worn at the waist on a belt or in a carrying case around the waist.

System Controller 11 Volt Lithium-Ion Backup Battery: A backup power source inside the System Controller. It powers the system for up to 15 minutes if the main power source fails or is disconnected.

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.

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

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.

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, the System Controller can be carried with a strap around the neck, on a belt around the waist, or in a pocket. A battery holster is used for carrying batteries and battery clips.

X

Y

Yellow Diamond Indicator: A yellow-colored symbol (♦) on the System Controller user interface that illuminates when less than15 minutes of combined battery power remain from the in-use HeartMate 14 Volt Lithium-Ion batteries providing power during battery-powered operation.

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

Z

11 Glossary

Numerics

A

B

THORATEC®
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