



HeartMate II®

Left Ventricular Assist System (LVAS)

For Use with the HeartMate Touch™
Communication System

Instructions for Use



Abbott

HEARTMATE II® LEFT VENTRICULAR ASSIST SYSTEM

Instructions for Use

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Preface-	ix
1 Introduction	1-1
Understanding Warnings and Cautions	1-3
Overview-	1-4
Indications	1-7
Contraindications	1-7
Adverse Events	1-7
Pre-Use Requirements-	1-8
Equipment Overview	1-9
Required, Backup, and Optional Components & Equipment-	1-13
Principles of Operation-	1-15
Explanation of Parameters	1-17
2 System Operations	2-1
HeartMate II Left Ventricular Assist Device Overview	2-3
System Controller Overview	2-10
The Backup System Controller	2-47
3 Powering the System	3-1
Power Overview	3-3
Using the Power Module	3-4
Using the Mobile Power Unit-	3-30
Using HeartMate 14 Volt Lithium-Ion Batteries	3-45
Switching Power Sources-	3-59
Battery Charger Overview	3-66
Charging HeartMate Batteries	3-73
Calibrating HeartMate 14 Volt Lithium-Ion Batteries	3-76
Using the Charger to Check Battery Power	3-78
Care and Maintenance of the Battery Charger	3-79
4 HeartMate Touch™ Communication System	4-1
Overview-	4-3
Set Up the HeartMate Touch™ Communication System	4-8
Connect the HeartMate Touch™ Wireless Adapter to the	

Contents

	Tablet for use with the HeartMate Touch App - - - - -	4-12
	Interface Overview - - - - -	4-20
	HeartMate Touch™ App Views - - - - -	4-22
	Settings Panel - - - - -	4-24
	Alarms- - - - -	4-40
	Pump Parameters - - - - -	4-49
	Monitor View - - - - -	4-53
	Clinical View - - - - -	4-54
	Historical View - - - - -	4-60
5	Surgical Procedures - - - - -	5-1
	Surgical Considerations - - - - -	5-3
	Equipment and Supplies Required for Implant- - - - -	5-5
	Preimplant Procedures- - - - -	5-7
	Implant Procedures - - - - -	5-27
	Postimplant Procedures - - - - -	5-47
	Device Explant- - - - -	5-53
6	Patient Care and Management - - - - -	6-1
	Postoperative Patient Care- - - - -	6-3
	Ongoing Patient Assessment and Care - - - - -	6-8
	Unique Treatment Options and Important Clinical Considerations - - - - -	6-11
	Using the Shower Bag- - - - -	6-15
	Using the Stabilization Belt - - - - -	6-25
	Wearing and Carrying the System Components - - - - -	6-28
	Preparing for Sleep - - - - -	6-63
	Ongoing System Assessment and Care - - - - -	6-65
	Educating and Training Patients, Families, and Caregivers - - - - -	6-68
7	Alarms and Troubleshooting - - - - -	7-1
	System Controller Alarms - - - - -	7-3
	HeartMate Touch Alarms - - - - -	7-23
	Power Module Alarms- - - - -	7-35
	Mobile Power Unit Alarms- - - - -	7-38
	Battery Charger Alarms - - - - -	7-40
	Guidelines for Power Cable Connectors- - - - -	7-43
	What Not To Do: Driveline and Cables- - - - -	7-44

8	Equipment Storage and Care	8-1
	Storage and Transport	- 8-3
	Cleaning and Maintenance	- 8-4
	Product Disposal	- 8-10
A	Summary of Clinical Studies	A-1
	Post-Approval Overview of Risk of Thrombosis-	- A-59
B	Technical Specifications	B-1
C	HeartMate II Product List	C-1
D	Safety Testing and Classification	D-1
E	Symbols	E-1
F	Safety Checklists	F-1
G	Conversion Patients	G-1
H	Survey	H-1
	Glossary	-Glossary-1
	Index	Index-1

Preface

This manual contains information needed to properly and safely operate the HeartMate II® Left Ventricular Assist System. Users of the HeartMate II Left Ventricular Assist System should have a practical knowledge of the principles of mechanical circulatory support and should be aware of the physiological and psychological needs of a patient undergoing mechanical ventricular support. New users should read this document in its entirety, before system operation. For experienced practitioners, this manual may serve as a reference.

As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. The professional staff at Abbott regularly provides laboratory training and on-site, in-service programs. Additional training materials are available for independent learning.

INTRODUCTION

This section provides an introduction to the HeartMate II Left Ventricular Assist System.

Understanding Warnings and Cautions	- 1-3
Overview	- 1-4
Indications	- 1-7
Contraindications	- 1-7
Adverse Events	- 1-7
Pre-Use Requirements	- 1-8
Equipment Overview	- 1-9
Required, Backup, and Optional Components & Equipment	- 1-13
Principles of Operation	- 1-15
Explanation of Parameters	- 1-17

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

WARNING !

Warnings appear in the manual in this format.

CAUTION !

Cautions appear in the manual in this format.

1 Introduction

Overview

The HeartMate II Left Ventricular Assist System is an axial-flow, rotary ventricular assist system that generates flows up to 10 liters per minute (lpm). One end of the Left Ventricular Assist Device is attached to the apex of the left ventricle; the other end of the device connects to the ascending aorta. The Left Ventricular Assist Device diverts blood from the weakened left ventricle and propels it to the aorta.

A small external computer, the System Controller, monitors system operation. A driveline, which passes through the patient's abdomen, connects the implanted pump to the System Controller. The system is powered by a Power Module or Mobile Power Unit (MPU) that is connected to an AC electrical outlet, or by two HeartMate 14 Volt Lithium-Ion batteries.

Figure 1.1 shows the HeartMate II system during battery-powered operation.

The HeartMate II Left Ventricular Assist Device (frequently called the “pump”), is capable of pumping the entire output delivered to the left ventricle from the pulmonary circulation. Improvement in right heart function is common following pump implant. However, high pulmonary vascular resistance may limit blood flow. As a result, patients who develop right heart dysfunction may require short-term pharmacologic support and/or a period of right-side circulatory support (see *Postoperative Patient Care* on page 6-3).



Figure 1.1 HeartMate II System During Battery-Powered Operation

WARNING !

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using the HeartMate II Left Ventricular Assist System. Read this entire manual before attempting implantation of the Left Ventricular Assist Device or before caring for HeartMate II patients. Completion of Abbott's HeartMate II Surgical Training Program is also required prior to use.
- Understanding the operating and safety aspects of the HeartMate II Left Ventricular Assist System is critical for safe and successful use.
- All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use.
- All users, including clinicians, patients, and caregivers, must be trained on any HeartMate II power accessories (Power Module, Mobile Power Unit, Battery Charger, or HeartMate 14 Volt Lithium-Ion batteries) before use.
- Do not use the HeartMate II Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Certain parts of the HeartMate II Left Ventricular Assist System are not compatible with other HeartMate systems (such as the XVE Left Ventricular Assist System). Only use HeartMate II parts with the HeartMate II system.
- No modification of this equipment is allowed. Do not use equipment or supplies other than those specified or sold by Abbott.
- Do not modify this equipment without authorization from Abbott. The use of unauthorized replacement parts may affect the electromagnetic compatibility of the Mobile Power Unit with other devices. Potential interference may occur between the Mobile Power Unit and other devices.
- Do not try to repair any of the HeartMate II system components. If components need service, contact appropriate personnel.

1 Introduction

CAUTION !

- Notify appropriate personnel if there is a change in how the pump works, sounds, or feels.
- Counsel the patient to avoid contact sports and jumping activities while implanted with the pump. Contact sports or jumping can cause bleeding or damage the pump.
- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.
- If HeartMate II patients are approved for showering, they must always use the Shower Bag. When installed properly, the Shower Bag protects external system components from water or moisture. If external system components have contact with water or moisture, the pump may stop. See *Using the Shower Bag* on page 6-15 for detailed instructions on using the Shower Bag.

Indications

The HeartMate II Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

Contraindications

The HeartMate II Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

Adverse Events

Adverse events that may be associated with the use of the HeartMate II Left Ventricular Assist System are listed below. Adverse events are listed in decreasing order of frequency, except for death, which appears first because it is a non-reversible complication:

- Death
- Bleeding (perioperative or late)
- Cardiac arrhythmia
- Local infection
- Respiratory failure
- Device malfunction
- Sepsis
- Right heart failure
- Driveline or pump pocket infection
- Renal failure
- Stroke
- Neurologic dysfunction
- Psychiatric episode
- Peripheral thromboembolic event
- Hemolysis

1 Introduction

- Hepatic dysfunction
- Device thrombosis
- Myocardial infarction

Pre-Use Requirements

A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is required before using the HeartMate II Left Ventricular Assist System.

It is suggested that patients possess a minimum 5th grade educational level and shall be versed in basic computer literacy (ie, Microsoft® Windows® and Office software).

This manual contains important warnings, cautions, and instructions for use. Read this entire manual before implanting a HeartMate II Left Ventricular Assist Device or before caring for HeartMate II patients. Completion of Abbott's HeartMate II Surgical Training Program is also required.

If you have questions after reading this manual, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual.

Equipment Overview

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

Note: Not all device models are available in all countries.

Left Ventricular Assist Device



The HeartMate II Left Ventricular Assist Device (frequently called the “pump”) is implanted below the heart. One end is sewn into the apex of the left ventricle; the other end connects to the ascending aorta. The pump diverts blood from the weakened left ventricle and pumps it to the aorta.

For more information, see page 1-15.

System Controller



The System Controller is a small computer that controls and monitors system operation. The System Controller uses lights, sounds, and on-screen messages to communicate with users about operating status and alarm conditions. A driveline, which passes through the patient’s abdomen, connects the implanted pump to the System Controller.

For more information, see page 2-10.

14 Volt Lithium-Ion Batteries & 14 Volt Battery Clips



Two HeartMate 14 Volt Lithium-Ion batteries are used to power the system during battery-powered operation, such as when AC electricity is not wanted or unavailable. Batteries are used in pairs and are inserted into a 14 Volt battery clip. When fully charged, a pair of HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 10–12 hours, depending on the activity level of the patient.

For more information, see page 3-45.

Power Module



The Power Module is for clinical use. The Power Module plugs into an AC outlet to provide power to the HeartMate II system. The Power Module is used in the clinical setting when the patient requires monitoring using the HeartMate Touch™ Communication System. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller.

For more information, see page 3-4.

Table 1.1 HeartMate II System Components

1 Introduction

Power Module Patient Cable



The Power Module patient cable connects the Power Module to the System Controller. Connections are made between white-to-white and black-to-black connectors.

For more information, see page 3-13.

Mobile Power Unit



The Mobile Power Unit is for home or clinical use when the patient does not require monitoring using the HeartMate Touch™ Communication System. The Mobile Power Unit is used when the patient is indoors, stationary, or sleeping, as a sleeping patient may not hear low battery power alarms. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.

For more information, see page 3-30.

HeartMate Touch Communication System



The HeartMate Touch™ Communication System provides clinicians with the ability to wirelessly monitor a patient's HeartMate system, program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data. Its use during Left Ventricular Assist Device implantation is required.

For more information, see page 4-3.

Battery Charger



The Battery Charger calibrates, charges, and tests the HeartMate 14 Volt Lithium-Ion batteries that are used to power the system during battery-powered operation.

For more information, see page 3-66.

Shower Bag



The Shower Bag is used to protect external system components from water or moisture—outside in heavy rain or snow, and always for every shower. HeartMate II patients may be allowed to shower when the driveline exit site has healed and with permission of their doctor. If external system components have contact with water or moisture, the system may fail to operate properly or the patient may get an electric shock.

For more information, see page 6-15.

Table 1.1 HeartMate II System Components (Continued)

Stabilization Belt and Lead Locks



The Stabilization Belt is used to keep the driveline from moving. Reduced movement protects the exit site from tissue damage that can increase the risk of infection.

For more information, see page 6-25.

System Controller Neck Strap



The System Controller Neck Strap attaches to the System Controller and is used to wear the System Controller around the neck or across the body.

For more information, see page 6-31.

Belt Attachment



The Belt Attachment provides another way to wear the System Controller.

For more information, see page 6-35.

Consolidated Bag



The Consolidated Bag is a convenient way to carry two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips during battery-powered operation.

For more information, see page 6-39.

Battery Holster



The Battery Holster provides a convenient way to wear two HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.

For more information, see page 6-47.

Table 1.1 HeartMate II System Components (Continued)

1 Introduction

Holster Vest



The Holster Vest provides another way to wear the HeartMate 14 Volt Lithium-Ion batteries and attached battery clips.

For more information, see page 6-53.

Travel Bag



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

For more information, see page 6-61.

Protection Bag



The Protection Bag stores and protects the backup System Controller.

For more information, see page 6-60.

Table 1.1 HeartMate II System Components (Continued)

Required, Backup, and Optional Components & Equipment

The HeartMate II Left Ventricular Assist System is designed for use both inside and outside of the hospital. Specific system components and equipment may be required for each setting. Components and equipment that are required for implant and ICU transfer are listed in **Table 1.2**.

Components Required for Implantation and ICU Transfer	Primary	Backup
HeartMate II Implant Kit*	Required	Required
System Controller with 11 Volt Lithium-Ion Backup Battery	Required	Required
Power Module with patient cable	Required	Required
Tablet for use with the HeartMate Touch App and HeartMate Touch Wireless Adapter	Required	Required
One set of 4 rechargeable HeartMate 14 Volt Lithium-Ion batteries	Required	Not required
One set of 2 HeartMate 14 Volt battery clips and battery clip cables	Required	Not required
Battery Charger	Required	Not required
Driveline tunneler**	Optional	
Apical coring knife**	Optional	
Skin coring punch**	Optional	
Apical sewing ring**	Optional	
Thread protectors**	Optional	
HeartMate II Sizer**	Optional	

Table 1.2 Components for Implant

* Some "Optional" items are included in the HeartMate II Implant Kit.

** Also available separately.

1 Introduction

Components and equipment that are required for a discharged patient are listed in **Table 1.3**. Patients discharged to a lower care facility or to their homes must be trained in device use, maintenance, and troubleshooting. In addition, device malfunction may necessitate emergency treatment. Therefore, patients should not be more than two hours from a healthcare facility that has trained personnel who are capable of treating a HeartMate II patient.

Components for a Discharged Patient	Primary	Backup
Implanted HeartMate II Left Ventricular Assist Device	Required	n/a
System Controller with 11 Volt Lithium-Ion backup battery	Required	Required
Mobile Power Unit	Required	Not Required
One set of 4 rechargeable HeartMate 14 Volt Lithium-Ion batteries	Required	Required
One set of 2 HeartMate 14 Volt battery clips	Required	Not Required
Battery Charger	Required	Not Required
One set of wear & carry accessories, including: Shower Bag, Protection Bag for backup System Controller, Holster Vest, Belt Attachment accessory, and System Controller Neck Strap	Required	Not Required
<i>HeartMate II Patient Handbook</i>	Required	Not Required

Table 1.3 Components for Discharged Patients

CAUTION !

- Confirm that backup System Controllers are programmed with settings that are identical to the patient's running System Controller. Using a backup System Controller with settings different from the patient's running System Controller may result in diminished support or patient harm. See *The Backup System Controller* on page 2-47 for further information.
- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial need.

Principles of Operation

The volume of flow generated by the HeartMate II Left Ventricular Assist Device is determined by the pump speed and by the differential pressure across the pump. For a specified speed, flow varies inversely with pressure. For example, increasing the differential pressure decreases flow. The pressure-flow curves, also known as the H-Q curves, illustrate this relationship (**Figure 1.2**).

The H-Q curves were created by operating the HeartMate II Left Ventricular Assist Device in a mock loop. For each speed, the pump outlet resistance was progressively increased, and the resulting flow and pressure were measured. For the example, speed varied from 6,000 to 15,000 rotations per minute (rpm).

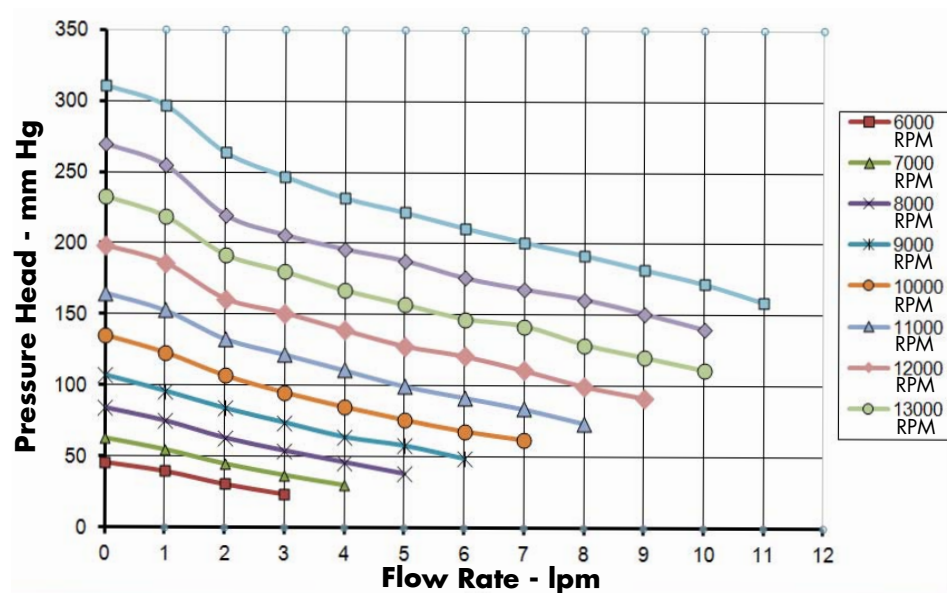


Figure 1.2 H-Q Pressure-Flow Curves

1 Introduction

The HeartMate II Left Ventricular Assist Device is connected to the circulation via a sealed inflow conduit and sealed outflow graft that are attached to the left ventricle and ascending aorta, respectively (**Figure 1.3**).

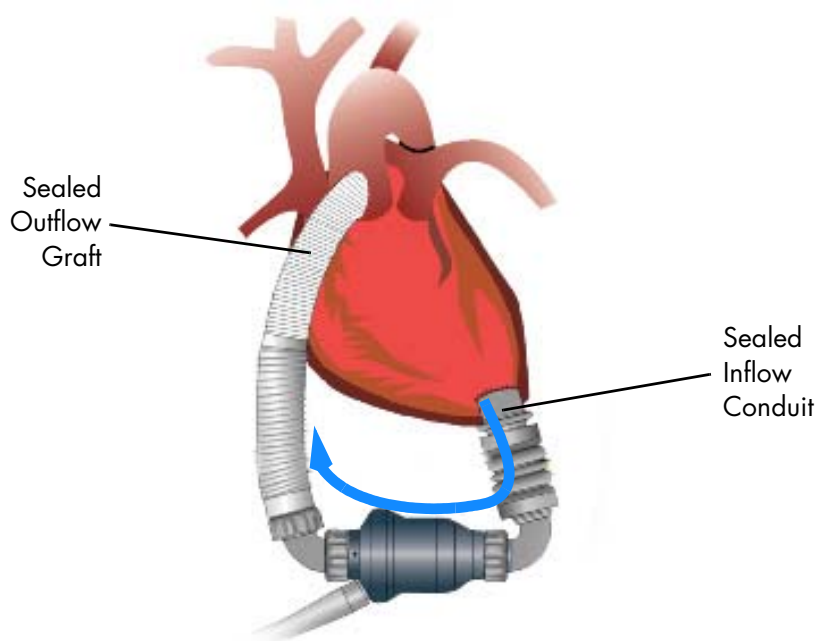


Figure 1.3 Left Ventricle and Ascending Aorta Connection Points

During the cardiac cycle, the differential pressure is equal to aortic pressure, minus left ventricular pressure, plus the combined pressure loss across the inflow conduit and outflow graft.

Typically, a patient's aortic pressure is within a normal range and the net cannula pressure drop, although related to flow (for example, 10 mmHg at 6 lpm), is low and does not greatly affect the overall differential pressure.

Left ventricular pressure is the dynamic parameter that determines differential pressure for the device. Left ventricular pressure is dependent upon the contractile state of the ventricle. Even a severely depressed heart has some residual rhythmic contraction that creates a pressure pulse.

Pressure fluctuations at the inflow conduit will change the differential pressure of the device, which will alter the flow. As shown in the slopes of the H-Q curves, a relatively small increase in device differential pressure causes a significant reduction in flow. This means that any contraction by the left ventricle is amplified as a flow pulse is delivered to the aorta. Therefore, under most circumstances, systemic flow is pulsatile with the HeartMate II Left Ventricular Assist Device. Only a completely flaccid heart, or one in fibrillation, has no left ventricular contribution to flow.

In an equilibrium state, blood flow delivered by the right heart matches that delivered by the device and left ventricle. If Left Ventricular Assist Device capacity exceeds the flow delivered by the right heart (ie, the right heart is not feeding blood into the left ventricle fast enough), the inflow (left ventricular) pressure is lowered. This increases the differential pressure for the device and reduces the flow to match right heart flow, which is consistent with H-Q characteristics. Similarly, if flow delivered by the right heart exceeds the capacity of the device, the device inflow pressure rises. This causes the differential pressure for the device to decrease and the device flow to increase. Therefore, within certain limits, the Left Ventricular Assist Device auto-regulates its flow to match the volume delivered by the right heart.

In extreme cases, left ventricular pressure can become sufficiently negative to collapse the ventricle walls and create a “suction event.” A speed-control circuit that automatically decreases device speed during a suction event is a key feature of the HeartMate II system. Once the suction event resolves, the device resumes operation at its previously set fixed speed setting.

If a flow state causes the device to decrease its differential pressure, the inflow pressure may be forced to increase to significantly high pressures. Extremely high pressures will cause the left ventricular pressure to rise to a level slightly greater than the aortic pressure, causing the aortic valve to open and the pump differential pressure to become essentially equal to the net cannula loss. This moves the flow to the far right of the H-Q curves, and the device experiences maximum flow. For a speed of 12,000 rpm, the flow could range from approximately 5 to 9 lpm across a cardiac cycle, in which the differential pressure varies between 90 and 120 mmHg, as shown in **Figure 1.2**.

Explanation of Parameters

Speed

The HeartMate II Left Ventricular Assist Device operates at a fixed speed (see *Optimal Fixed Speed* on page 4-28) determined by the physician during a speed ramp study. The “low speed limit” for the device is the lowest speed at which it can operate while maintaining patient stability.

During a suction event, device speed drops to the “low speed limit” and then ramps up to the fixed speed unless another pulsatility index (PI) event is detected, at which point the device drops to the “low speed limit” again and then ramps back up. This cycle repeats as long as PI events are detected. Large changes in speed may indicate an abnormal condition that should be evaluated for cause.

1 Introduction

Power

Device power is a direct measurement of pump motor voltage and current. Changes in pump speed, flow, or physiological demand can affect pump power. Gradual power increases (over hours or days) may signal thrombus deposits inside the pump. Depending on the speed of the pump, power values greater than 10 to 12 watts (W) also can indicate the presence of a thrombus. Abrupt changes in power should be evaluated for cause.

Flow

Device flow and power generally retain a linear relationship at a given speed. However, while power is directly measured by the System Controller, the reported flow is estimated, based on power. Since the flow displayed on the System Controller is a calculated value, it becomes imprecise at the low and high ends of the linear power-flow relationship.

Any increase in power not related to increased flow (such as thrombus) causes erroneously high flow readings. Conversely, an occlusion of the flow path decreases flow and causes a corresponding decrease in power. In either situation, pump output should be assessed.

Pulsatility Index (PI)

When the left ventricle contracts, the increase in ventricular pressure causes an increase in pump flow during cardiac systole. The magnitude of these flow pulses are measured and averaged over 15-second intervals to produce a "Pulsatility Index" (occasionally shortened to "PI" for on-screen messages).

The PI calculation represents cardiac pulsatility. PI values typically range from 1 to 10. In general, the magnitude of the PI value is related to the amount of assistance provided by the pump. Higher values indicate more ventricular filling and higher pulsatility (ie, the pump is providing less support to the left ventricle). Lower values indicate less ventricular filling and lower pulsatility (ie, the pump is providing greater support and further unloading the ventricle).

PI values should be routinely monitored and should not vary significantly during resting conditions. Under otherwise stable conditions, a significant drop in value may indicate a decrease in circulating blood volume. Pulsatility index values near or above 10 may indicate potential problems. For PI values near 10 or above, please contact Abbott. For Abbott contact information, see the *Back Cover* of this manual.

IMPORTANT! One single pump parameter is not a surrogate for monitoring the overall clinical status of the patient. Any change in parameters should be evaluated with all clinical considerations in mind.

SYSTEM OPERATIONS

This section describes the primary system operations of the HeartMate II Left Ventricular Assist System.

HeartMate II Left Ventricular Assist Device Overview - - - - -	-2-3
System Controller Overview- - - - -	2-10
The Backup System Controller- - - - -	2-47

HeartMate II Left Ventricular Assist Device Overview

The HeartMate II Left Ventricular Assist Device (**Figure 2.1**) is an axial flow rotary heart pump that is connected in parallel to the native circulation. The sealed inflow conduit of the Left Ventricular Assist Device attaches to the apex of the left ventricle. Its sealed outflow graft connects to the ascending aorta (**Figure 2.2**). Frequently, the HeartMate II Left Ventricular Assist Device is called the “pump.”



Figure 2.1 HeartMate II Left Ventricular Assist Device

A rotor assembly inside the pump contains a magnet and rotates by the electromotive force generated by the motor. Rotation of the rotor provides the driving force to propel blood from the left ventricle through the pump and out to the natural circulation. Pump output is dependent upon the rotational speed of the rotor as well as the pressure difference between the inlet and outlet of the pump.

The HeartMate II Left Ventricular Assist Device operates in a fixed speed mode. In fixed speed mode, the pump operates at a constant speed, which may be varied by qualified clinical personnel via commands from the HeartMate Touch Communication System. In fixed speed mode, the set speed can be reduced below the normal range to allow for: a) evaluation of the patient under reduced levels of augmented flow, or b) slow start of the pump at implant to reduce risk of air embolism. Patients do not have the ability to change the fixed speed setpoint.

The internal surfaces of the pump (rotor, thin-walled duct, inlet stator, and outlet stator) have a smooth polished titanium surface. The sealed inflow conduit and outflow elbow have a textured titanium microsphere surface. An anticoagulation protocol is specified in *Anticoagulation* on page 6-10.

2 System Operations

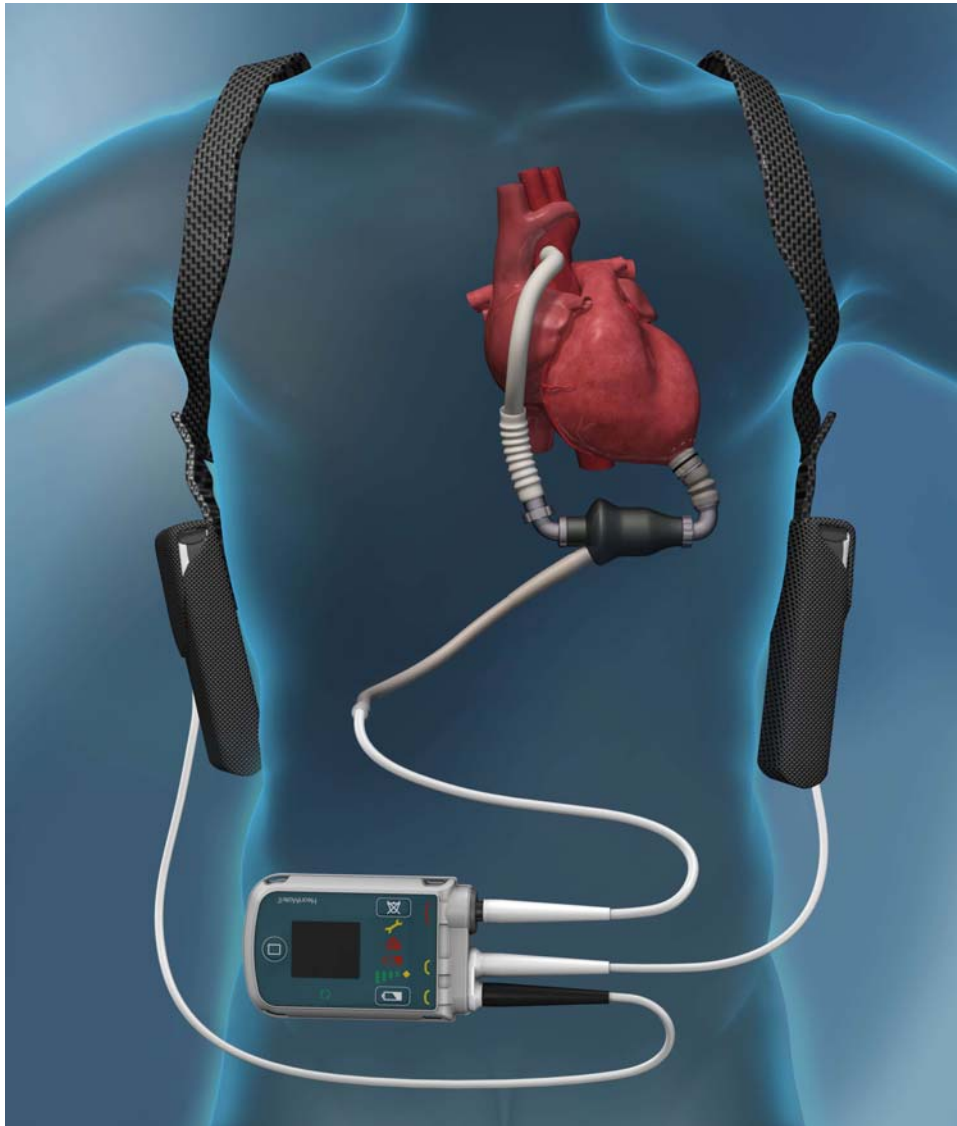


Figure 2.2 Implanted Pump with System Controller during Battery-Powered Operation

Operational control and power to the pump is transmitted percutaneously via a driveline. The driveline connects the pump to the System Controller, which then connects to a power source. The HeartMate II Left Ventricular Assist System is powered by an external power source: either the Power Module or Mobile Power Unit that connects to an AC electrical outlet, or two portable 14 Volt Lithium-Ion batteries (see *Powering the Pump Motor* on page 2-8).

Function

The Left Ventricular Assist Device uses a rotary blood pump to generate flow and assist the left ventricle. It is an axially-configured device so that the path of the entering and exiting flow stream is parallel to the pump's axis. The device has only one moving part, the rotor assembly, which spins on bearings located at either end of the assembly. The pump is driven by an external power source via a driveline.

The pump operates in parallel with the heart, such that either can supply blood to the aorta. The Left Ventricular Assist Device can generate a blood flow up to 10 liters per minute (lpm). Blood enters the pump from the left ventricle through an inflow conduit. Blades on the spinning rotor move the blood through the pump to an outflow graft and ultimately to the native circulation.

Implant Location

The HeartMate II Left Ventricular Assist Device may be implanted beneath the diaphragm in either the preperitoneal or intra-abdominal location. The surgical technique of preperitoneal placement requires creating a pocket for the pump above the posterior rectus sheath and transversalis fascia and below the rectus abdominis and internal oblique muscles. For intra-abdominal placement, the pump is inserted intra-peritoneally in the left upper abdominal quadrant. The decision between these two locations is based on the preference of the implanting surgeon. For more information, see *Considerations for Preperitoneal or Intra-abdominal Placement* on page 5-31.

An inflow conduit is inserted into the left ventricular apex of the heart as shown in **Figure 2.3**. An outflow graft is attached to the ascending aorta.

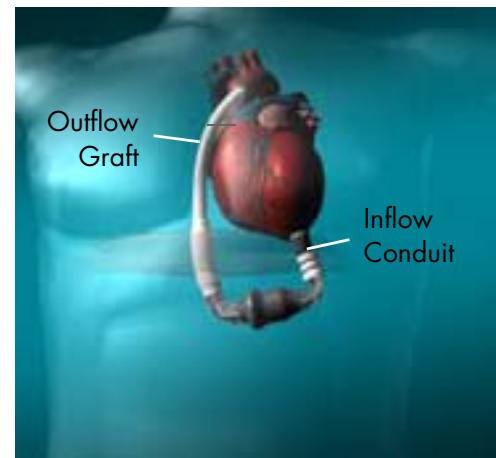


Figure 2.3 HeartMate II Implant Configuration

2 System Operations

Pump Components

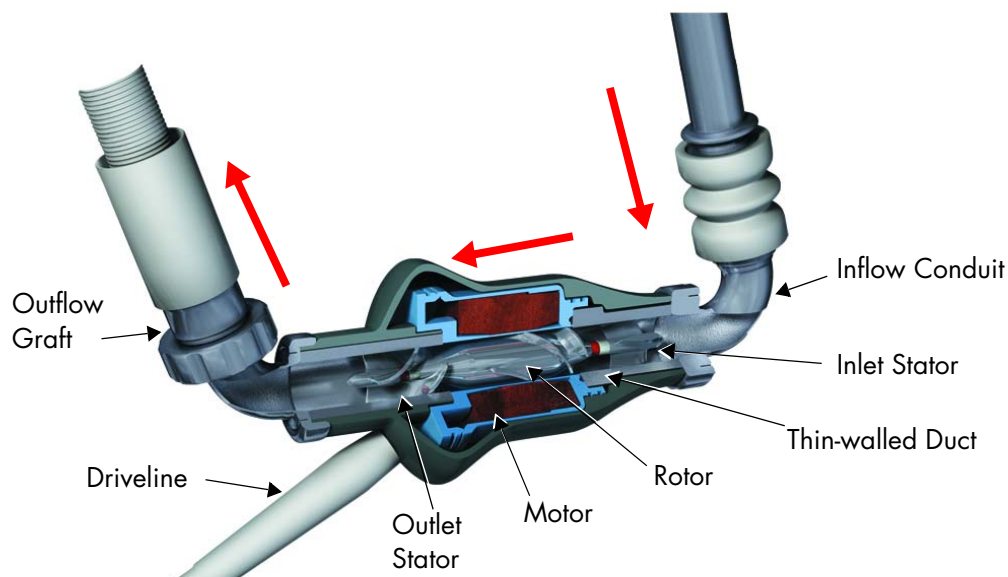


Figure 2.4 Left Ventricular Assist Device Components

Motor

The Left Ventricular Assist Device contains an electric motor that generates torque to drive the rotor. The motor creates a magnetic field that spins a permanent magnet located within the rotor. The subsequent rotary motion pumps blood.

Rotor

The motor's rotor is a permanent magnet located inside a thin-walled, titanium duct 12 mm in diameter that passes through the bore of the motor. A magnetic field produces rotary motion and torque, thereby initiating blood flow.

Blood entering the Left Ventricular Assist Device flows across three blades that structurally support the inlet stator. These blades straighten the flow field before entering the rotor. Three blades on the rotor impart kinetic energy to the flow field in the form of radial velocity. Upon leaving the rotor, the flow field encounters the exit stator whose three blades convert the radial velocity created by the rotor back to axial velocity.

The pump rotor, thin-walled duct, inlet stator, and outlet stator have a smooth, polished blood-contacting surface to reduce the formation of thrombi.

The bearings on the inlet and outlet sides of the rotor assembly are shaped in the form of balls and cups and withstand radial and axial loads. The outer boundary of the bearing surfaces are washed directly by the main flow field.

Inflow Conduit and Outflow Graft

Blood enters the Left Ventricular Assist Device through an inflow conduit and exits via an outflow graft. Inflow conduits and outflow grafts are available in sealed and unsealed versions. In both versions, textured surfaces coat the inner lumen of the inflow conduit and the outflow elbow. The textured surfaces stimulate tissue growth and create a natural lining.

IMPORTANT! Unsealed grafts require pre-clotting before use (see the *HeartMate II Left Ventricular Assist System Instructions for Use*, document number 105747 or 103883).

Characteristics that identify a ***sealed*** inflow conduit include:

- A Thoratec logo on the flexible silicone sleeve
- Two holes on the flexible silicone sleeve
- A blue screw ring that attaches to the pump
- A foil pouch that contains the inflow conduit

Characteristics that identify a ***sealed*** outflow graft include:

- A blue dashed line on the bend relief
- A blue screw ring that attaches to the blood pump
- A foil pouch that contains the sealed outflow graft

Driveline

The driveline consists of a single cable that extends from the Left Ventricular Assist Device through the skin to the System Controller. The driveline contains six wires—three primary wires and three backup wires—that power the pump motor.

To reduce infection, the driveline is covered with woven polyester which encourages tissue ingrowth at the skin line. Over time, tissue bonds to the textured material and anchors the external surface of the driveline to the surrounding tissue. After emerging from the body, the driveline terminates at an electric connector that attaches to the System Controller.

Clinical trials, as well as commercial use outside of the United States, have shown that wear and fatigue of the driveline may result in damage that can interrupt device function. Such damage may require another operation to replace the pump, or result in death. For information about caring for the driveline, see *Care of the Driveline* on page 8-5.

Driveline damage due to wear and fatigue occurs in both the externalized and implanted portions of the lead. Damage to the conductors within the driveline may or may not be preceded by visible damage to the outer layer of the driveline.

2 System Operations

Driveline damage may be evidenced by the following:

- Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
- 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 the driveline or driveline connector appears damaged, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual. X-ray images and System Controller log files are useful to assess the extent and location of the damage. If the driveline or driveline conductors are damaged, the pump 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 the System Controller requires changing as a result of damage, consider supporting the patient using batteries rather than the Power Module or Mobile Power Unit, to reduce the potential of further damage to the System Controller.

Powering the Pump Motor

The Left Ventricular Assist Device motor is powered through the System Controller by one of several sources: the Power Module or Mobile Power Unit, which connect to an AC electrical outlet (see *Using the Power Module* on page 3-4 and *Using the Mobile Power Unit* on page 3-30), or two HeartMate 14 Volt Lithium-Ion direct current (DC) batteries (see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45).

Acceptable Operating Conditions

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

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Power Module	32°F to 104°F (0°C to 40°C)	20% to 75%	525 to 795 (700 to 1060)
Mobile Power Unit	32°F to 104°F (0°C to 40°C)	20% to 93%	525 to 795 (700 to 1060)
Tablet for use with the HeartMate Touch App	32°F to 95°F (0°C to 35°C)	20% to 95%	535 to 795 (710 to 1060)
HeartMate Touch Wireless Adapter	32°F to 104°F (0°C to 40°C)	20% to 75%	525 to 795 (700 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries†	32°F to 104°F (0°C to 40°C)	20% to 75%	525 to 795 (700 to 1060)
Battery Charger	32°F to 104°F (0°C to 40°C)	20% to 75%	525 to 795 (700 to 1060)
System Controller, Backup System Controller*†	32°F to 104°F (0°C to 40°C)	20% to 93%	525 to 795 (700 to 1060)
11 Volt Lithium-Ion Backup Battery	32°F to 104°F (0°C to 40°C)	20% to 93%	525 to 795 (700 to 1060)

Table 2.1 Operating Conditions

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

*Once every six months, the “sleeping” backup System Controller must be connected to a power source to charge the 11 Volt Lithium-Ion backup battery inside. If the 11 Volt Lithium-Ion backup battery inside the backup System Controller is not charged every six months, its charge level will diminish and there may not be sufficient power to support the pump if the backup System Controller is in use during a power emergency (see *Maintaining Backup System Controller Readiness: Charging and Self Test* on page 2-53).

2 System Operations

System Controller Overview

The HeartMate II System Controller is a small computer that controls and monitors system operation. It sends power and operating signals to the Left Ventricular Assist Device and adjusts device operation to maintain programmed levels of cardiac support. The System Controller identifies alarm conditions and initiates Hazard and Advisory alarms. It records device performance and alarm data, and transfers the information to the HeartMate Touch Communication System.

The System Controller connects to the Left Ventricular Assist Device via a driveline that passes through the patient's abdomen. The driveline carries power to the pump. The driveline also supplies information from the pump to the System Controller (**Figure 2.5**).

The System Controller uses sounds, lights, symbols, and on-screen messages to communicate with users (**Figure 2.6**).

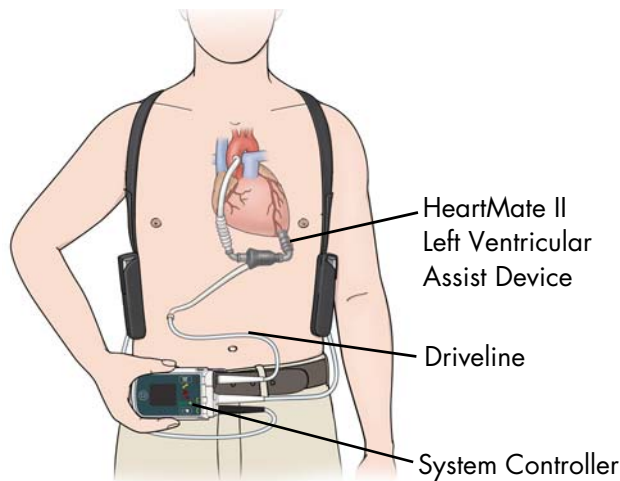


Figure 2.5 HeartMate II Left Ventricular Assist System



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

Figure 2.6 System Controller Major Components

The System Controller is described in the following sections:



System Controller Warnings and Cautions

See page 2-13.



System Controller User Interface

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

See page 2-17.



System Controller Driveline Connector

This section provides instructions on connecting and disconnecting the driveline.

See page 2-23.



System Controller Power Cable Connectors

Two power cables on the System Controller (one white and one black) connect the System Controller to the Power Module, Mobile Power Unit, or two 14 Volt Lithium-Ion batteries.

See page 2-27.



Performing a System Controller Self Test

Perform a self test daily to check the function of the System Controller's audible and visual alarms.

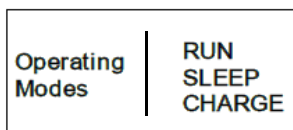
See page 2-29.



System Controller Battery Power Gauge

The battery power gauge shows the approximate charge status of the power source that is connected to the System Controller's power cables.

See page 2-31.



System Controller Operating Modes

The System Controller has three operating modes: Run, Sleep, and Charge. This section provides an overview with instructions on how to switch between modes.

See page 2-34.

2 System Operations



System Controller Backup Battery Power.

This section provides a functional overview with instructions on how to replace the 11 Volt Lithium-Ion backup battery that is inside the System Controller.

See page 2-40.

System Controller Warnings and Cautions

WARNING !

- Check the System Controller driveline connector to confirm that the driveline is securely inserted in the socket. The driveline safety tab on the System Controller cannot move to the locked position unless the driveline is fully and properly inserted. If the driveline disconnects from the System Controller, the pump stops. Promptly reconnect it to resume pump operation. If the System Controller does not work, replace it with a backup System Controller that is programmed with patient-specific settings. See *Replacing the Running System Controller with a Backup Controller* on page 2-55 for instructions.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- The System Controller may reach a maximum temperature of 124°F (51°C) if BOTH of the following conditions are present:
 - The System Controller is covered by the body or insulating material, such as a blanket
 - AND
 - The internal battery is chargingAvoid contact on bare skin under these conditions because burns may occur. A sedated or sleeping patient, especially in ICU, may not react if the System Controller becomes hot.
- 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.
- Do not allow patients to swim or take tub baths while implanted with the Left Ventricular Assist Device. Patient immersion in water may cause the device to stop.
- Do not allow patients to shower without a doctor's permission. HeartMate II patients may be allowed to shower, but only after sufficient post-operative healing and with a doctor's permission.
- If a HeartMate II patient is approved for showering, he or she must always use the Shower Bag during every shower. The Shower Bag protects external system components from water or moisture. If external system components have contact with water or moisture, the pump may stop.
- Use only an Abbott-supplied HeartMate 11 Volt Lithium-Ion battery with the HeartMate II System Controller. Use of another battery may cause the pump to stop.

2 System Operations

WARNING ! (Continued)

- 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 HeartMate II System Controller provides enough power to run the implanted HeartMate II pump for at least 15 minutes if the main power source (Power Module, 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.
- Do not use damaged, defective, or expired 11 Volt Lithium-Ion backup batteries in the System Controller. Using a damaged, defective, or expired System Controller backup battery may cut operating time during an emergency or cause the pump to stop.
- Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer's instructions.
- Malfunction of the 11 Volt Lithium-Ion backup battery may cause the controller to become excessively hot. If this occurs, switch to the backup System Controller.

CAUTION !

- Do not drop the System Controller or subject it to extreme physical shock.
- Instruct patients (and family member or caregiver) to advise hospital personnel immediately if they drop the System Controller. Emphasize to users the importance of not waiting to report 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 patient's risk of serious infection.
- To avoid pulling on or moving the driveline at the exit site, the patient must wear the HeartMate Stabilization Belt (or other abdominal binder) at all times. Pulling on or moving the driveline can keep the exit site from healing or damage an already healed exit site. Exit site 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, Power Module patient cable, 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. See *What Not To Do: Driveline and Cables* on page 7-46.
- The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be charged once every six months. Failure to charge the 11 Volt Lithium-Ion backup battery inside the backup System Controller may result in diminished or no support during a power-loss emergency when the backup System Controller is in use. See *Maintaining Backup System Controller Readiness: Charging and Self Test* on page 2-53 for details.
- Damage to the redundant electrical wires inside the driveline can occur that is not visible to the user. Signs of driveline damage include (but are not limited to):
 - The System Controller alarming when the driveline is moved or when the patient changes position.
 - An active driveline fault displayed on the HeartMate Touch Communication System (*System Controller Alarms* on page 7-3).
 - High pulsatility index (PI) readings on the System Controller.
 - Feeling pump vibrations.
 - Fluid oozing from the external portion of the driveline.
 - Pump stoppage.

2 System Operations

CAUTION ! (Continued)

- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- Never use tools to tighten power cable connectors; securely hand tighten only. Using tools may damage the connectors.
- Confirm that a backup System Controller is programmed with settings that are identical to the running System Controller. Using a backup System Controller with settings different from the running System Controller may result in diminished support or patient harm.
- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial requirement.
- The System Controller uses lights, sounds, and on-screen messages to communicate with users about system operation. HeartMate II patients with sight or hearing impairment may need extra help using the System Controller.
- Use only those accessories specified or sold by Abbott. Do not cover the System Controller with insulating material, such as a blanket, to avoid elevated temperature.

System Controller User Interface

The user interface on the System Controller is the primary interface for users during routine system operation. It uses sounds, lights, symbols, and on-screen messages to communicate about how the system is working. The user interface provides a visual display of system operation and on-screen messages that instruct how to respond to alarms and other situations (**Figure 2.7**).

HeartMate II patients (and their family members/caregivers) must be thoroughly trained on how to interpret and use the user interface prior to discharge (see *Educating and Training Patients, Families, and Caregivers* on page 6-68).

For situations that require attention, and depending on the urgency, the System Controller issues one of two types of alarms: hazard and advisory. Hazard alarms occur for conditions that are potentially life threatening for the patient and require immediate attention. Advisory alarms are important, but not life threatening. For more information on System Controller alarms and how to resolve them, see *System Controller Alarms* on page 7-3.

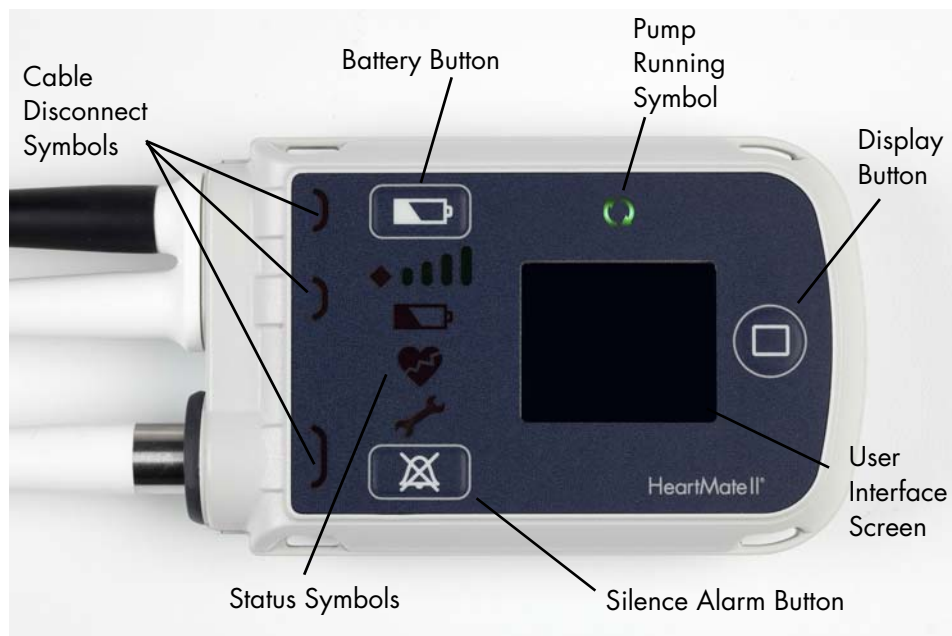


Figure 2.7 System Controller User Interface

2 System Operations

User Interface Components

The buttons, lights, symbols, and display screen on the user interface are introduced below in **Table 2.2**. Additional details follow after the table.

Pump Running Symbol 	The Pump Running symbol on the user interface is illuminated green when the Left Ventricular Assist Device is running.
Low Battery Alarm 	The red low battery symbol illuminates when less than 5 minutes of battery power remain (applicable only during 14 Volt Lithium-Ion battery-powered operation). This is a Hazard alarm. When the red battery symbol illuminates, immediately replace the depleted batteries with a fully-charged pair, or switch to the Power Module or Mobile Power Unit. For more information, see page 7-16.
Yellow Wrench Alarm 	The yellow wrench symbol illuminates when the System Controller detects a mechanical, electrical, or software issue with the system. This is an Advisory alarm. When the yellow wrench illuminates, check the screen for troubleshooting instructions. For more information, see page 7-10.
Red Heart Alarm 	The red heart symbol illuminates when the System Controller detects a problem that could cause serious injury or death. This is a Hazard alarm. When the red heart illuminates, check the screen for instructions and take immediate action to resolve the problem. For more information, see page 7-9.
Black Power Cable Alarm 	The yellow light near the black power cable connector illuminates when the black power cable becomes loose or disconnects from the System Controller. This is an Advisory alarm. If the black power cable disconnects or becomes loose, promptly restore the connection. For more information, see page 7-17.

Table 2.2 System Controller User Interface Components

White Power Cable Alarm

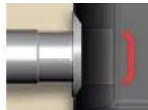


The yellow light near the white power cable connector illuminates when the white power cable becomes loose or disconnects from the System Controller.

This is an **Advisory** alarm. If the white power cable disconnects or becomes loose, promptly restore the connection.

For more information, see page 7-17.

Driveline Connector Alarm



The red light near the driveline connector illuminates when the driveline becomes loose or disconnects from the System Controller.

This is a **Hazard** alarm. If the driveline loosens or disconnects from the System Controller, promptly restore the connection. If the driveline is not reconnected immediately, the pump stops.

For more information, see page 7-13.

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 Module, the Mobile Power Unit, or two 14 Volt Lithium-Ion batteries. The number of green bars means power remaining. The more green bars mean more power remaining.

For more information, see page 2-31.

Yellow diamond = less than 15 minutes of battery power remain.

Appearance of this symbol indicates an **Advisory** alarm. If the yellow diamond comes on, promptly replace the low batteries with two fully-charged batteries, or switch to the Power Module or Mobile Power Unit. Do this as soon as possible.

For more information, see page 7-18.

IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller). To check the status of the System Controller's backup battery, see *Viewing Pump and System Information on the System Controller Screen* on page 2-21.

Table 2.2 System Controller User Interface Components (Continued)

2 System Operations

The battery button is used for the following:

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

For more information, see page 2-31.

Battery Button



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

For more information, see page 2-29.

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

For more information, see page 2-39.

The silence alarm button is used for the following:

- **Silencing an active alarm:** Press and release the silence alarm button to silence an active alarm on the System Controller. How long it is silenced depends on the alarm (see *System Controller Alarms* on page 7-3).

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

Silence Alarm Button



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

For more information, see page 7-5.

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

Display Button



For more information, see page 2-21.

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

For more information, see page 7-5.

Table 2.2 System Controller User Interface Components (Continued)

Viewing Pump and System Information on the System Controller Screen

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

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

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

2 System Operations

Table 2.3 shows the display sequence.

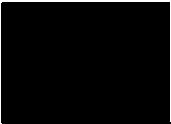
Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press display button ONCE	Pump Speed 9200 RPM 	Pump speed in revolutions per minute (RPM)
Press 	Press display button a SECOND time	Flow 4.6 LPM 	Pump flow in liters per minute (LPM)
Press 	Press display button a THIRD time	PI 4.2 	Pulsatility Index (PI)
Press 	Press display button a FOURTH time	Power 5.9 W 	Power in watts (W)
Press 	Press display button a FIFTH time	Backup Battery Charged 	The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states: 1. Charged (ready for use). 2. Charging (actively charging). 3. Fault (there is a fault or problem with the backup battery that could affect its reliability).
Press 	Press display button a SIXTH time		Blank screen indicates the screen is off, which is normal.

Table 2.3 System Controller Display Screen Sequence

Note: On-screen messages come in many different languages and can be changed from the HeartMate Touch App to support your patient's needs. See *System Controller Language* on page 4-39.

System Controller Driveline Connector

The driveline connector attaches the driveline to the System Controller. The driveline connector uses a double-lock feature that lowers the risk of accidentally disconnecting the driveline (**Figure 2.8**).



Figure 2.8 System Controller Driveline Connector

The driveline is initially connected to the patient's System Controller during the procedure to implant the Left Ventricular Assist Device. The same System Controller remains in use unless it requires replacement for clinical or technical reasons (see *The Backup System Controller* on page 2-47).

The System Controller continually monitors the connection status of the driveline connector. If the System Controller detects a problem, it immediately alarms. For more information about the alarm, see *Driveline Disconnected Alarm* on page 7-13.

It is impossible to connect (or disconnect) the driveline without first rotating the safety tab on the back of the System Controller into the "unlocked" position.

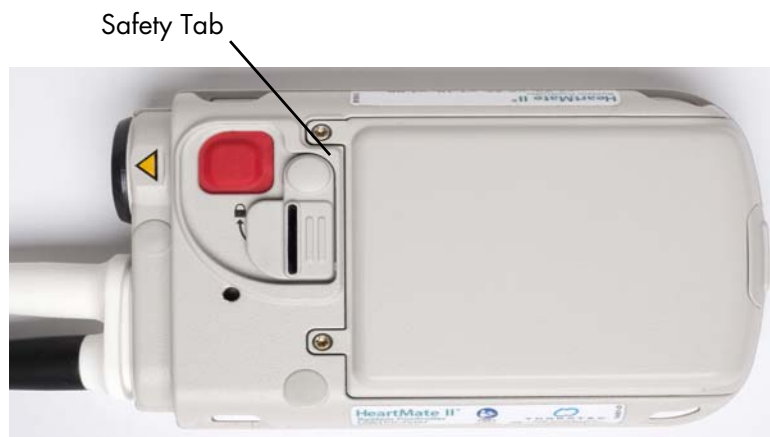


Figure 2.9 The Safety Tab Covers the Red Button

2 System Operations

When the driveline is properly and fully inserted into the driveline connector socket, the driveline cannot be removed without firmly pressing the red button under the raised safety tab (**Figure 2.9**).

If there is a problem with the driveline connection, the System Controller alarms immediately (see *Driveline Disconnected Alarm* on page 7-13).

Connecting the Driveline to the System Controller

FOR THIS TASK YOU NEED:

- A running System Controller, programmed with patient-specific settings

TO CONNECT THE DRIVELINE TO THE SYSTEM CONTROLLER:

1. Gather equipment.
2. Move the driveline connector safety tab to the unlocked position (**Figure 2.10**).

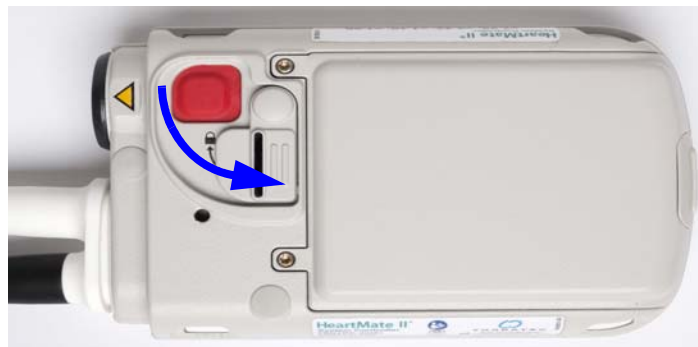


Figure 2.10 Unlock the Safety Tab

3. Align the arrow/alignment mark on the driveline with the arrow on the System Controller socket (**Figure 2.11**).



Figure 2.11 Align the Arrows

4. Insert the driveline into the socket (**Figure 2.12**), pressing firmly until it snaps into place. The Left Ventricular Assist Device immediately starts running when the driveline is fully and properly inserted in the socket.

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



Figure 2.12 Insert the Driveline Into the Socket

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

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

6. Tug on the inserted metal end of the driveline to check the connection. Do not pull on or bend the driveline. If there is a problem with the connection, the System Controller immediately alarms with a Driveline Disconnected alarm. This is a Hazard alarm. See *Driveline Disconnected Alarm* on page 7-13 for details.

2 System Operations

Disconnecting the Driveline from the System Controller

WARNING !

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

FOR THIS TASK YOU NEED:

- A running System Controller, programmed with patient-specific settings

TO DISCONNECT THE DRIVELINE FROM THE SYSTEM CONTROLLER:

1. Gather equipment.
2. Move the driveline connector safety tab into the unlocked position (**Figure 2.13**).



Figure 2.13 Unlock the Safety Tab

3. Firmly press the red button under the safety tab, while pulling the driveline from the socket. Grasp only the metal end of the driveline while removing it. Do not pull on or bend the driveline (**Figure 2.14**).



Figure 2.14 Grasp the Metal End and Remove the Driveline

System Controller Power Cable Connectors

Two power cables on the System Controller (a black connector and a white connector) connect the System Controller to the Power Module, Mobile Power Unit, or two 14 Volt Lithium-Ion batteries (**Figure 2.15**).

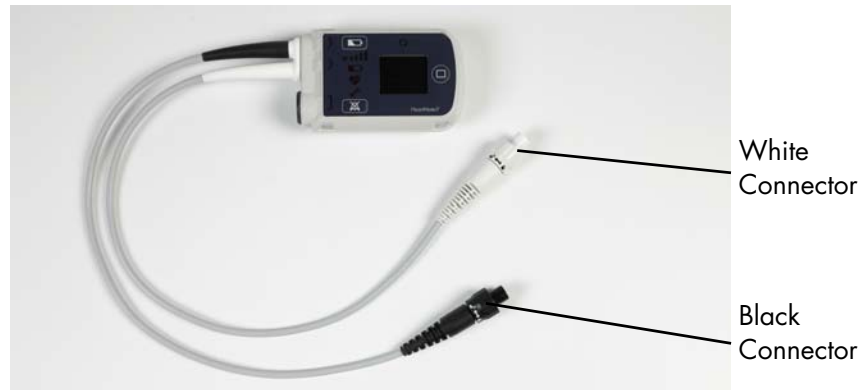


Figure 2.15 Black and White Power Cable Connectors on the System Controller

The System Controller power cable connectors are color coded, one black and one white, so they can be easily paired with the corresponding connectors on the Power Module patient cable or Mobile Power Unit patient cable. Always connect black-to-black and white-to-white. Both System Controller power cables provide equal power. However, the cable with the white connector transmits signals between the System Controller and HeartMate Touch Communication System (see *Set Up the HeartMate Touch™ Communication System* on page 4-8). The data link does not work without a white-to-white connection.

During routine operation, the HeartMate II Left Ventricular Assist System is powered by one of the following power sources:

- **Power Module**—The Power Module can be used when the patient is indoors, stationary, or sleeping. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller. See *Using the Power Module* on page 3-4 for details.
- **Mobile Power Unit**—The Mobile Power Unit can be used when the patient is indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller. See *Using the Mobile Power Unit* on page 3-30 for details.
- **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

2 System Operations

power the system for up to 10–12 hours, depending on the activity level of the patient. See *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45 for details.

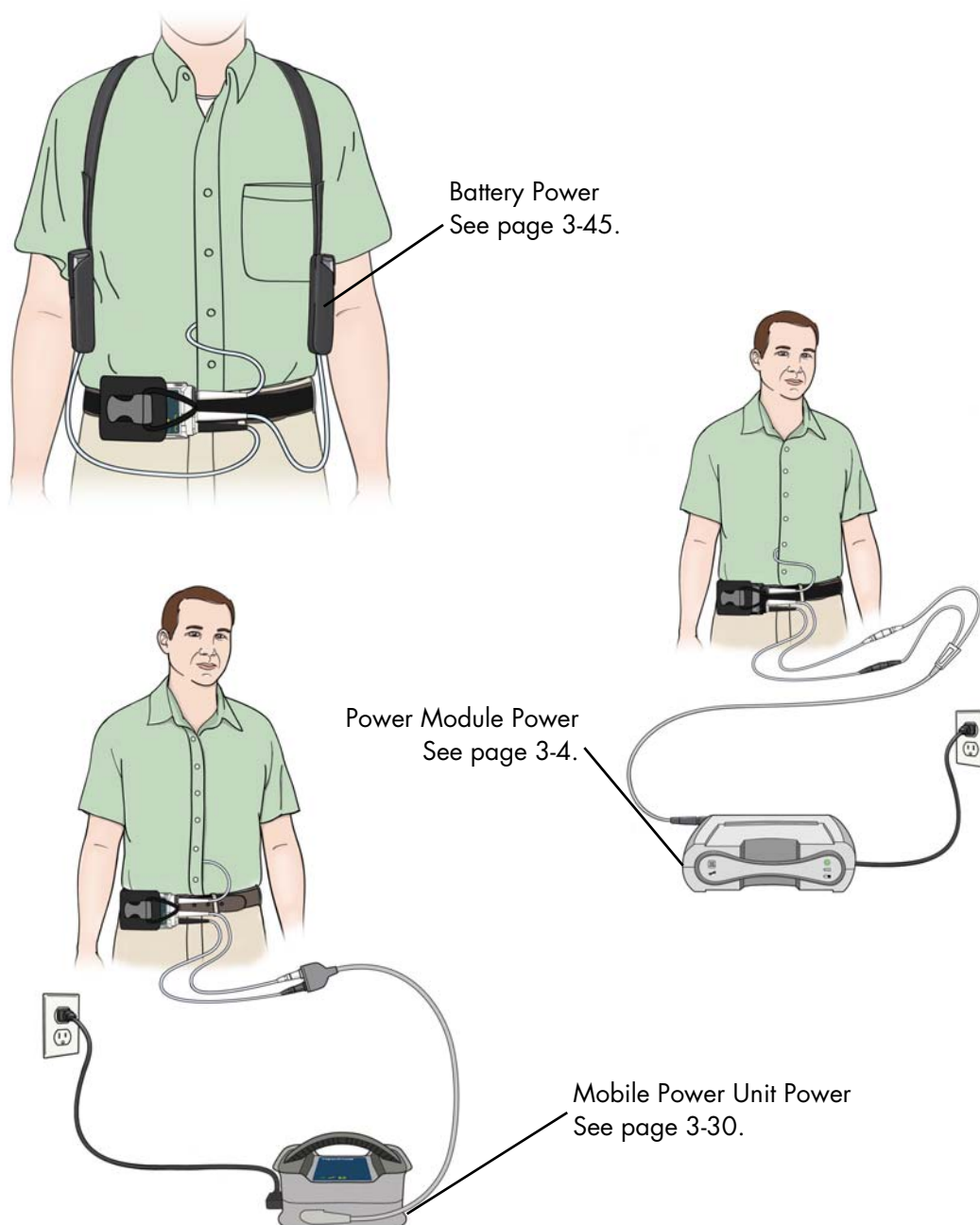


Figure 2.16 The HeartMate II Left Ventricular Assist Device on Battery Power (top), Power Module Power (right), and Mobile Power Unit Power (bottom)

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 about the alarm, see *Power Cable Disconnected Alarm* on page 7-17.

Performing a System Controller Self Test

Use a daily System Controller self test to check the audible and visual alarm indicators on the user interface, as well as the status of the backup battery for the System Controller.

The System Controller self test is a loud and bright function. All of the audible and visual indicators should come on and "Self Test" should appear on the screen (**Figure 2.17**).



Figure 2.17 User Interface During System Controller Self Test

Perform the self test at least daily on the running System Controller. A backup System Controller in Charge Mode can be tested as well, if needed.

Consider testing the System Controller at the same time daily to establish a routine.

TO PERFORM A SYSTEM CONTROLLER SELF TEST:

1. Press and hold the battery button () for five seconds.
2. Check that:
 - ☒ "Self Test" (first briefly white, then black) appears on the screen.
 - ☒ All symbols and indicators on the user interface illuminate at the same time.
 - ☒ System Controller is making a loud, steady, audio alarm tone.
3. Release the battery button (). All the audible indicators/lights should remain on for 15 seconds, after which the audible indicators/lights stop, the screen goes black, and the self test is complete.

2 System Operations

If all of the alarms and lights come on together as described above, the System Controller passed the self test. If any of the lights remain off, or if the audible indicators do not sound or they produce sounds other than a loud steady tone, there is a problem with the System Controller. Do not use a System Controller that fails its self test. Replace it with the backup System Controller and contact Abbott for a new backup controller.

IMPORTANT! If an alarm occurs during a self test, the self test terminates and the alarm's on-screen indicator remains active. A System Controller self test cannot be initiated during an active alarm.

System Controller 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 Module or two 14 Volt Lithium-Ion batteries. The number of green bars means power remaining. The more green bars mean the more power remaining.



Figure 2.18 Battery Power Gauge Showing Full Charge

To activate the battery power gauge, press and release the battery button () on the user interface (**Figure 2.18**).

IMPORTANT! The battery power gauge does not show the charge status of the System Controller's backup battery (the battery inside the System Controller). To check the status of the System Controller's backup battery, see *Viewing Pump and System Information on the System Controller Screen* on page 2-21.

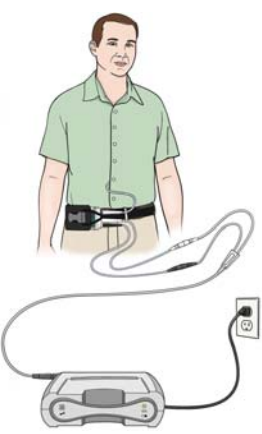
2 System Operations

On 14 Volt Lithium-Ion battery power:

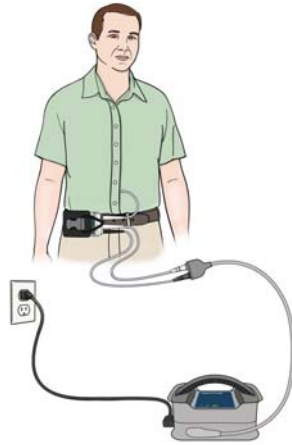
		4 green bars = 75%–100% of battery power remains.
		3 green bars = 50%–75% of battery power remains.
		2 green bars = 25%–50% of battery power remains.
		1 green bar = less than 25% of battery power remains.

IMPORTANT! Every HeartMate 14 Volt Lithium-Ion battery also has its own on-battery gauge. It shows the power level for that battery. The on-battery readout communicates information about a single source using five green bars. The System Controller battery power gauge communicates information about a combined source of power using four green bars. For more information, see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-49.

On Power Module power:

		4 green bars = Normal operation.
		3 green bars = Running on the Power Module backup battery and 50%–75% of battery power remains.
		2 green bars = Running on the Power Module backup battery and 25%–50% of battery power remains.
		1 green bar = Running on the Power Module backup battery and less than 25% of battery power remains.

On Mobile Power Unit power:



4 green bars = Normal Mobile Power Unit operation.

Recognizing Low Battery Alarms

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



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

For more information, see *Low Battery Power Alarm (less than 15 minutes remain)* on page 7-18.



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

For more information, see *Low Battery Power Alarm (less than 5 minutes remain)* on page 7-16.

If either the yellow diamond or the red battery illuminate, immediately replace the depleted batteries with a fully-charged pair, or switch to the Power Module or Mobile Power Unit (see *Switching Power Sources* on page 3-59).

2 System Operations

System Controller Operating Modes

The System Controller has three operating modes:

- Run Mode—The system is functioning and is in use.
- Sleep Mode—The system is not in use, but is ready to function. The backup System Controller is predominantly in Sleep Mode.
- Charge Mode—The system is not connected to a driveline, but is connected to a power source to charge and maintain readiness of its internal 11 Volt Lithium-Ion backup battery.

IMPORTANT! The backup System Controller must be put into Charge Mode once every six months to ensure backup battery readiness.

Each mode has a distinct function, which is described in more detail below.

Run Mode

Run Mode is the usual state for the running System Controller. **Figure 2.19** shows a System Controller in Run Mode.



Figure 2.19 System Controller in Run Mode While on Battery Power (left) and the Power Module (right)

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

- Connected to a power source (the Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
- Connected to the Left Ventricular Assist Device via the driveline.
- Sending power to the pump via the driveline.
- Controlling and monitoring physiological and operating conditions.

- Displaying data about physiological and operating conditions.
- Using user interface indicators to reflect System Controller and pump conditions.
- Responding to user interface button pushes.
- Charging the 11 Volt Lithium-Ion backup battery inside the System Controller.
- Communicating with the HeartMate Touch, if connected.
- Able to perform a System Controller self test.

For instructions on switching from Run Mode to Sleep Mode, see *Switching Operating Modes* on page 2-37.

Sleep Mode

Sleep Mode is the usual state for a backup System Controller. **Figure 2.20** shows the System Controller in Sleep Mode.



Figure 2.20 System Controller in Sleep Mode

The backup System Controller remains in Sleep Mode until either: 1) it is put into Charge Mode (connected to power) or 2) it is used in Run Mode (used to replace the running System Controller).

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

- Disconnected from an external power source and powered off.
- Disconnected from the driveline.
- Not displaying operating/alarm data on the information display screen.
- Not responding to user interface button pushes.
- Not charging the 11 Volt Lithium-Ion backup battery inside the System Controller.
- Disconnected from and not communicating with the HeartMate Touch.

2 System Operations

For instructions on switching from Sleep Mode to Run Mode or Charge Mode, see *Switching Operating Modes* on page 2-37.

Charge Mode

The backup System Controller must be connected to power for the 11 Volt Lithium-Ion backup battery to charge. **Figure 2.21** shows the System Controller in Charge Mode while connected to the Power Module (left) and batteries (right).



Figure 2.21 System Controller in Charge Mode

Depending upon a patient's clinic schedule, once every six months the "sleeping" backup System Controller must be connected to an external power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Connecting to power and putting the System Controller into Charge Mode allows its 11 Volt Lithium-Ion backup battery to charge. A fully-depleted 11 Volt Lithium-Ion backup battery takes up to three hours to charge.

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

- Charging the 11 Volt Lithium-Ion backup battery inside the System Controller.
- Able to perform a System Controller self test.
- Disconnected from the driveline.
- Displaying charging status or any active alarms.
- Not responding to silence alarm (⏻) or display (⏻) buttons.

Switching Operating Modes

Figure 2.22 shows how to transition between operating modes.

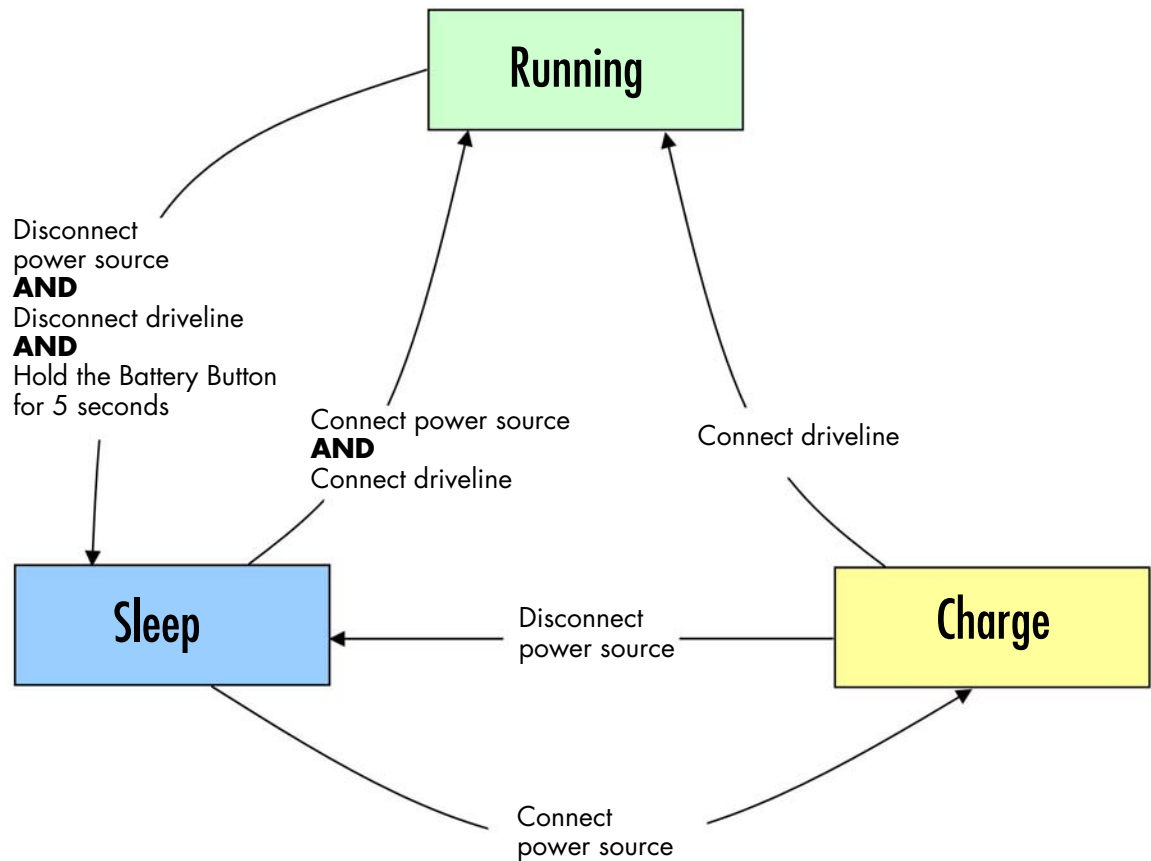


Figure 2.22 System Controller Operating Modes

TO SWITCH FROM SLEEP MODE TO RUN MODE:

1. Connect the System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
2. Connect the driveline to the System Controller (see *Connecting the Driveline to the System Controller* on page 2-24).
3. The Pump Running symbol is illuminated green (🔄) and the System Controller is in Run Mode.

2 System Operations

TO SWITCH FROM CHARGE MODE TO RUN MODE:

This procedure assumes that the System Controller is not in use, but is connected to a power source and is in Charge Mode.

1. Connect the driveline to the System Controller (see *Connecting the Driveline to the System Controller* on page 2-24).
2. The Pump Running symbol is illuminated green (🔄) and the System Controller is in Run Mode.

TO SWITCH FROM CHARGE MODE TO SLEEP MODE:

1. Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).

TO SWITCH FROM SLEEP MODE TO CHARGE MODE:

IMPORTANT! Do not permit patients to perform this task without approval and proper training.

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

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



Figure 2.23 System Controller Charging or Charging Complete

"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.

TO SWITCH FROM RUN MODE TO SLEEP MODE:

1. Disconnect the driveline from the System Controller. Press and release the silence alarm button  to silence the Driveline Disconnected alarm.
2. Disconnect the System Controller from its power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Press and release the silence alarm button  to silence the Power Cable Disconnected alarm.
3. Press and hold the battery button  for five seconds. The following appears on the screen:
"Hold" accompanied by a reverse countdown from five dots to one dot (5 dots, 4 dots, 3 dots, 2 dots, 1 dot).
4. When the countdown ends, the screen goes black, the Pump Running symbol is black , and the System Controller is in Sleep Mode.

2 System Operations

System Controller Backup Battery Power

To maintain continuous operation of the HeartMate II Left Ventricular Assist Device during an unexpected power loss, the System Controller uses an internal 11 Volt Lithium-Ion backup battery, which is installed in a running System Controller after the sterile field is broken, and after pump implantation. A properly installed and fully-charged backup battery provides at least 15 minutes of emergency power if power is disconnected or fails. For installation details, see *Installing the Backup Battery in the System Controller* on page 5-49.

The 11 Volt Lithium-Ion backup battery is intended only for backup power during a power emergency. It takes about three hours to charge a fully-depleted 11 Volt Lithium-Ion backup battery, during which time the System Controller must remain connected to a power source. To begin charging, set the System Controller to Charge mode. See *Charge Mode* on page 2-36. When charging is complete, "Charging Complete" appears on the information display screen. After the initial charge, the system automatically maintains a full-capacity charge in the primary System Controller.

The backup System Controller is also equipped with an 11 Volt Lithium-Ion backup battery. Because the backup System Controller is normally not connected to power, the backup battery charge is not automatically maintained. To maintain the charge, the backup System Controller must be connected to power and set to Charge mode at least once every six months. For details, see *Maintaining Backup System Controller Readiness: Charging and Self Test* on page 2-53.

The 11 Volt Lithium-Ion backup battery remains at or above capacity for 36 months from the date of manufacture, but as with all batteries, its capacity begins to gradually decline at the end of its life cycle. Replace the backup battery before it expires.

At every patient visit, check the backup battery expiration dates for both the primary and backup System Controllers. Use the HeartMate Touch™ App Settings panel (**Settings** ) > **Backup Battery**) to check the expiration date of the 11 Volt Lithium-Ion backup battery within the patient's primary and backup System Controllers. The Backup Battery Information screen on the HeartMate Touch App indicates the number of months remaining on the battery if there are more than 6 months before expiration. (**Figure 2.24**).



Figure 2.24 Backup Battery Information Panel

2 System Operations

The number of months remaining until the backup battery will expire is displayed on the HeartMate Touch App Monitor View Reminders panel as “Replace Backup Battery in XX Month(s)”. The number of months remaining until expiration is a number between 36 (maximum) and 0 (expired).

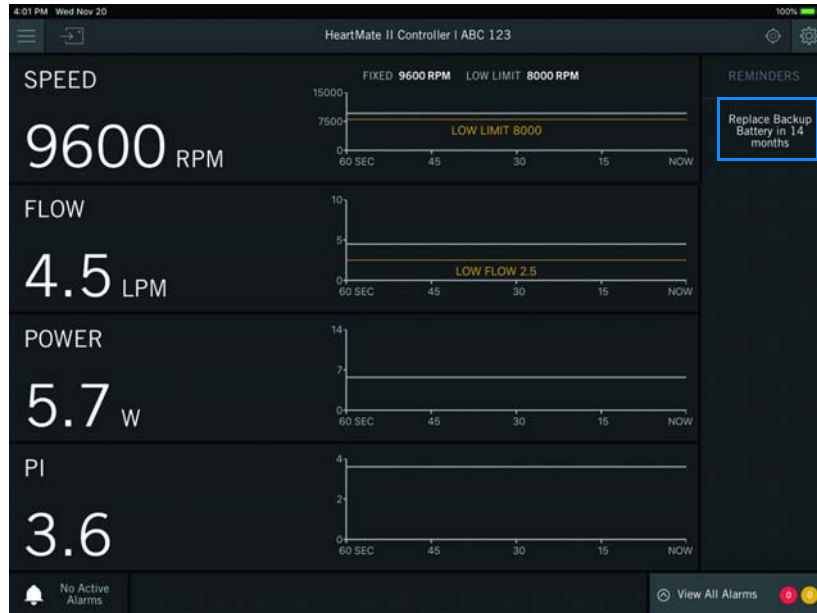


Figure 2.25 Monitor View Reminders Panel

Replacing a Backup Battery in the System Controller

IMPORTANT! Replace the 11 Volt Lithium-Ion backup battery before it expires; or immediately, in the event of a Backup Battery Fault alarm.

When planning replacement, keep in mind that patient visits may not occur as scheduled. For this reason, replacement should not be scheduled too close to the expiration date. To ensure patient safety, replace the backup battery as soon as possible when 6 or fewer months remain before expiration.

Because backup battery expiration events are triggered by the System Controller's internal clock, it is important to verify that the date and time are correct before attempting to replace the backup battery. If the date and time are incorrect, you can modify this information on the HeartMate Touch **Settings > Controller** screen. See *Controller Date & Time* on page 4-35.

FOR THIS TASK YOU NEED:

- 1 replacement 11 Volt Lithium-Ion backup battery (obtained from Abbott)
- 1 lever to remove the screw cover of the battery compartment (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 screwdriver to loosen the four battery cover screws (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 spare screw cover (included with the replacement 11 Volt Lithium-Ion backup battery)
- 1 running System Controller that is connected to a power source (Power Module, Mobile Power Unit, or two 14 Volt Lithium-Ion batteries)

The System Controller can remain running and attached to the patient's driveline while replacing the 11 Volt Lithium-Ion backup battery.

IMPORTANT! Before you begin, review the Warnings and Cautions related to the 11 Volt Lithium-Ion backup battery included in *Installing the Backup Battery in the System Controller* on page 5-49.

TO REPLACE THE BACKUP BATTERY IN THE SYSTEM CONTROLLER:

1. Confirm that the date and time on the running System Controller are correct before attempting to replace the backup battery. If the date or time is incorrect, the System Controller's Backup Battery Alarm may occur (see *System Controller Alarms* on page 7-3).
2. Gather equipment (**Figure 2.26**); place within easy reach.

2 System Operations



Figure 2.26 11 Volt Backup Battery Replacement Kit

3. Use the lever to remove the screw cover on the System Controller (**Figure 2.27**).



Figure 2.27 Use the Lever to Remove the Screw Cover

4. Use the screwdriver to loosen the four screws on the battery compartment cover (**Figure 2.28**).



Figure 2.28 Use the Screwdriver to Loosen the Screws

5. Remove the battery compartment cover.

6. Remove the current 11 Volt Lithium-Ion battery from the battery compartment:
 - a. Grasp the end of the ribbon cable that is attached to the current battery.
 - b. Gently remove the ribbon cable from the battery socket (**Figure 2.29**).



Figure 2.29 Remove Ribbon Cable from Battery Socket

- c. Discard the used battery (see *Product Disposal* on page 8-10).
7. Retrieve the replacement 11 Volt Lithium-Ion backup battery.
8. Align the arrow on the ribbon cable with the arrow on the replacement backup battery.
9. Insert the end of the ribbon cable into the battery socket.
10. Confirm that the 11 Volt Lithium-Ion backup battery is properly connected by verifying that the backup battery installation graphic no longer appears on the System Controller.
11. Place the backup battery inside the battery compartment (**Figure 2.30**).



Figure 2.30 Place the Battery Inside the Battery Compartment

12. Place the cover over the battery compartment.

2 System Operations

13. Use the screwdriver to tighten the four screws on the cover. Do not overtighten the screws (**Figure 2.31**).



Figure 2.31 Tighten the Screws

14. Replace the screw cover.

IMPORTANT! A newly replaced battery needs to finish charging before it can reliably provide backup power. It takes approximately 3 hours for a fully-depleted 11 Volt Lithium-Ion backup battery to become fully charged. “Charged” appears on the information display screen when the newly-installed 11 Volt Lithium-Ion backup battery has finished charging (see *Viewing Pump and System Information on the System Controller Screen* on page 2-21).

Setting the System Controller Clock

The System Controller has an internal clock. The clock tracks the timing of system events and monitors the expiration date of the System Controller’s 11 Volt Lithium-Ion backup battery.

IMPORTANT! Be aware that installing an 11 Volt Lithium-Ion backup battery may prompt a System Controller Clock Not Set advisory alarm (**Figure 2.32**).



Figure 2.32 System Controller Clock Not Set Advisory Alarm

To resolve a System Controller Clock Not Set advisory alarm, use the HeartMate Touch App to reset the System Controller clock (see ***Controller Date & Time*** on page 4-35). Make sure the HeartMate Touch App clock is correct before relying on it.

The Backup System Controller

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



Overview: Running Versus Backup System Controller

See page 2-48.



Programming and Configuring the Backup System Controller

The backup System Controller must be programmed with the same settings as the running System Controller.

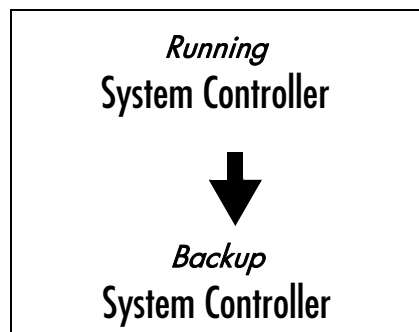
See page 2-49.



Maintaining Backup System Controller Readiness: Charging and Self Test

Once every six months, the backup System Controller's internal backup battery must be charged and a self test must be performed.

See page 2-53.



Replacing the Running System Controller with a Backup Controller

If the running System Controller experiences a failure, it must be replaced.

See page 2-55.

2 System Operations

Overview: Running Versus Backup System Controller

Every HeartMate II patient receives a backup System Controller, which is identical to the running System Controller and is programmed with the same settings as the running System Controller. If a failure occurs on the running System Controller, it may need to be replaced with the backup System Controller. For this reason, and in case of an emergency, the backup System Controller must remain with the patient at all times (**Figure 2.33**).

Running System Controller	Backup System Controller
 On Power Module or Mobile Power Unit	If needed, ready to use  Backup is not connected to: • Power • Driveline
 On Batteries	

Figure 2.33 System Controller States

IMPORTANT! To replace the running System Controller with the backup System Controller, see *Replacing the Running System Controller with a Backup Controller* on page 2-55.

Programming and Configuring the Backup System Controller

A doctor determines the System Controller settings for his or her patient. After approved settings are entered into the running System Controller, a clinician must program the backup System Controller with the same settings. Additionally, the backup System Controller's internal backup battery must be installed. This way the backup System Controller is ready with identical settings if the running controller needs to be replaced.

IMPORTANT! The settings for the running System Controller may require changes over time, for example, as the patient's physiologic and hemodynamic needs change. Confirm that the backup System Controller is adjusted to match any running System Controller setting changes.

FOR THIS TASK YOU NEED:

- Programmed settings for the running System Controller
- 1 new and packaged System Controller complete with 11 Volt Lithium-Ion backup battery and *Patient Handbook*
- 1 working Power Module with patient cable and AC power cord connected
- 1 HeartMate Touch connected to the Power Module
- 1 Wireless Adapter
- 1 functioning and grounded (3-prong) AC electrical outlet

TO PROGRAM AND CONFIGURE THE BACKUP SYSTEM CONTROLLER

1. Remove the System Controller, the 11 Volt Lithium-Ion backup battery, and the *Patient Handbook* from the System Controller packaging.
2. Connect the backup System Controller to the Power Module.

2 System Operations

Note: The controller will alarm. This is normal. You will see :



Figure 2.34 HeartMate Touch (left) and System Controller (right)

- Set the "Fixed Speed" to the settings that are entered into the patient's running System Controller (**Figure 2.36**).

For more information, see *Set the Fixed Speed* on page 4-26.

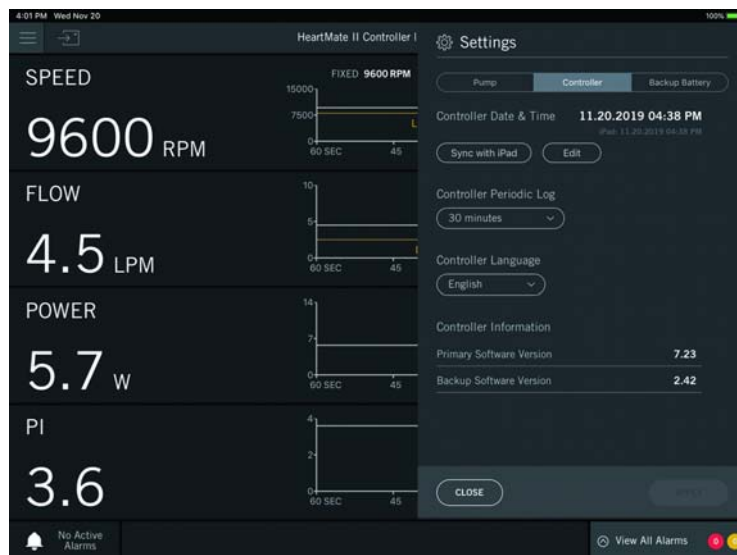


Figure 2.35 Settings Menu

- Set the “Low Speed Limit” to the settings that are entered into the patient’s running System Controller (**Figure 2.36**).

For more information, see *Low Speed Limit* on page 4-30.

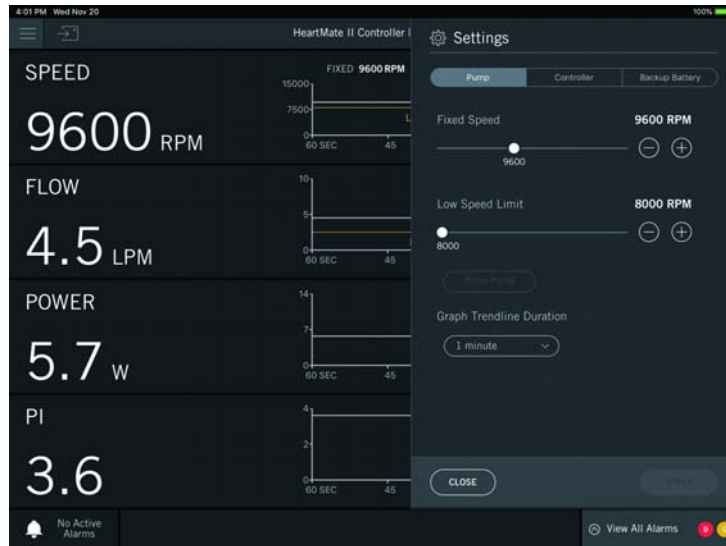


Figure 2.36 Select Low Speed Limit Screen

- Set the System Controller clock by tapping **Settings > Controller** (**Figure 2.37**).

For more information, see *Controller Date & Time* on page 4-35.

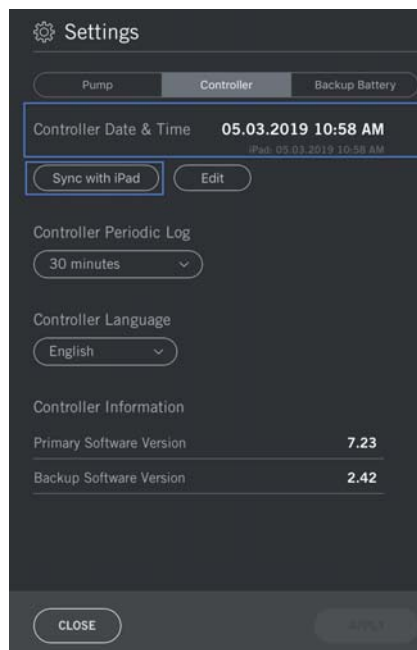


Figure 2.37 Settings View

2 System Operations

6. Set the System Controller's language, if needed. Tap **Settings** (⚙️) > **Controller**.
For more information, see *System Controller Language* on page 4-39.
7. Install the 11 Volt backup battery into the System Controller (**Figure 2.38**).
For more information, see *Installing the Backup Battery in the System Controller* on page 5-49.



Figure 2.38 Install Backup Battery

8. Disconnect power from the System Controller.
Note: The HearMate Touch App will have PUMP OFF, DRIVELINE DISCONNECTED, and LOW FLOW Xmin alarms active, and the System Controller will show a red heart alarm (❤️) and display a "Connect Driveline" message. This is normal.
9. Put the System Controller to sleep. Press and hold the battery button (🔋) for five seconds.
Note: The following "Hold" screen appears accompanied by a reverse countdown from five dots to one dot (5 dots, 4 dots, 3 dots, 2 dots, 1 dot) (**Figure 2.39**). When the countdown ends, the System Controller is in Sleep Mode.



Figure 2.39 Hold Screen

10. Remember to give the *Patient Handbook* to the patient.

Maintaining Backup System Controller Readiness: Charging and Self Test

Depending upon a patient's clinic schedule, the "sleeping" backup System Controller must be maintained and assessed for readiness once every six months. Over time, the backup battery inside the System Controller loses power and must be recharged. Connecting the backup System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) charges its internal 11 Volt Lithium-Ion backup battery. A self test should be performed and the backup System Controller's programmed settings should be assessed to confirm that they are identical to the patient's running System Controller settings.

FOR THIS TASK YOU NEED:

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

TO PERFORM BACKUP SYSTEM CONTROLLER CHARGING AND SELF TEST:

1. Connect the backup System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries)(**Figure 2.40**).



Figure 2.40 System Controller on Power Module Power (left) and Battery Power (right)

2. When the System Controller is connected to power, its user display screen shows "Charging" or "Charging Complete" (**Figure 2.41**).



Figure 2.41 System Controller Charging or Charging Complete

2 System Operations

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

3. Perform a self test on the backup System Controller. Press and hold the battery button () for five seconds (**Figure 2.42**).

For more information, see *Performing a System Controller Self Test* on page 2-29.

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



Figure 2.42 System Controller Self Test

4. Use the HeartMate Touch App to verify that the backup System Controller's programmed settings are identical to the settings on the patient's running System Controller (see *Settings Panel* on page 4-25).
5. Disconnect power from the backup System Controller. This will put the backup System Controller back into Sleep Mode. No further action is needed for six months.
6. Put the backup System Controller into its Protection Bag (**Figure 2.43**).

For more information, see *Using the Protection Bag* on page 6-60.



Figure 2.43 Backup System Controller in Protection Bag

Replacing the Running System Controller with a Backup Controller

WARNING !

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

FOR THIS TASK YOU NEED:

- 1 backup System Controller, programmed to match the settings on the running System Controller
- 1 running System Controller, connected to a power source (Power Module, Mobile Power Unit, or 14 Volt Lithium-Ion batteries and clips)
- Optional: a power source in addition to the in-use power source (Power Module, Mobile Power Unit, or 14 Volt Lithium-Ion batteries and clips)

TO REPLACE THE RUNNING SYSTEM CONTROLLER WITH A BACKUP CONTROLLER:

IMPORTANT! Ensure that the patient understands the importance of having a caregiver present during System Controller exchange if at all possible, and that all labeling instructions are followed, including calling hospital contact if instructed.

1. Setup:
 - a. Place the backup System Controller within reach.
 - b. Have the patient sit or lie down, as he or she may get dizzy if the pump briefly stops.
 - c. Unlock the driveline safety tab on the running System Controller (**Figure 2.44**).

IMPORTANT! The ability to successfully change System Controllers may be affected by several factors. These can include native cardiac output, cognitive function, etc., which may change over the course of LVAD support, and therefore, should be periodically reassessed.

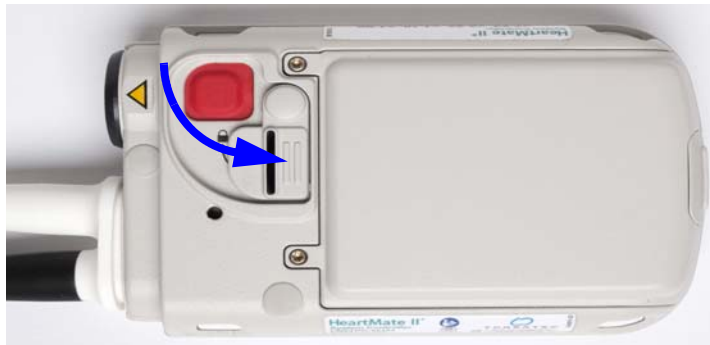


Figure 2.44 Unlock the Safety Tab on the Running System Controller

2 System Operations

2. Replace the System Controller.

With In-use Power Source Only

(Power Module OR Mobile Power Unit OR Batteries and Clips)

White
connector's
power
source

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

For more information, see *Powering the System* on page 3-1.



- b. Promptly move the driveline from the running controller to the backup System Controller. See pages 2-21–2-24.

IMPORTANT! Before inserting, align the marking on the driveline with the arrow on the System Controller.

For more information, see *System Controller User Interface* on page 2-17.

Black
connector's
power
source

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

Multiple Power Sources Available

(2 of these power sources available: Power Module, Mobile Power Unit, Batteries and Clips)



IMPORTANT! Keep the running System Controller connected to power.

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

For more information, see *Powering the System* on page 3-1.



- b. Promptly move the driveline from the running controller to the backup System Controller. See pages 2-21–2-24.

IMPORTANT! Before inserting, align the marking on the driveline with the arrow on the System Controller.

For more information, see *System Controller User Interface* on page 2-17.

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

3. The backup System Controller is now running with the driveline connected and both power cables connected to power.

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

- ☑ The driveline to make sure it is fully inserted into the controller. Tug on the metal end of the driveline to make sure it is connected.
 - ☑ That the System Controller's black and white power cables are connected to a working power source.
4. Lock the driveline safety tab on the backup System Controller. The safety tab cannot move to the locked position unless the driveline is fully and properly inserted. If the driveline safety tab will not lock, align the driveline and firmly press it into the System Controller until it snaps into place (**Figure 2.45**).



Figure 2.45 Lock the Safety Tab

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

See Switching Operating Modes on page 2-37.

6. Do not use the old, replaced System Controller ever again. To request a new backup System Controller and for instructions on returning the old one, please contact Abbott. For Abbott contact information, see the *Back Cover* of this manual.

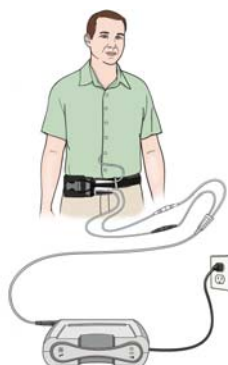
2 System Operations

POWERING THE SYSTEM

This section describes the various methods that can be used to power the HeartMate II Left Ventricular Assist System.

Power Overview - - - - -	-3-3
Using the Power Module - - - - -	-3-4
Using the Mobile Power Unit - - - - -	-3-30
Using HeartMate 14 Volt Lithium-Ion Batteries - - - - -	-3-45
Switching Power Sources - - - - -	-3-59
Battery Charger Overview - - - - -	-3-66
Charging HeartMate Batteries - - - - -	-3-73
Calibrating HeartMate 14 Volt Lithium-Ion Batteries - - - - -	-3-76
Using the Charger to Check Battery Power - - - - -	-3-78
Care and Maintenance of the Battery Charger - - - - -	-3-79

Power Overview



Power Module—The Power Module is intended for use in the clinical setting when the patient requires monitoring using the HeartMate Touch Communication System. The System Controller and the Power Module are connected through the Power Module patient cable. The cable transfers power from the Power Module to the System Controller.

See page 3-4.

Mobile Power Unit—The Mobile Power Unit is for home or clinical use when the patient does not require monitoring using the HeartMate Touch Communication System. The Mobile Power Unit is used when the patient is indoors, stationary, or sleeping. The System Controller and the Mobile Power Unit are connected through the Mobile Power Unit patient cable. The cable transfers power from the Mobile Power Unit to the System Controller.

See page 3-30.



Two HeartMate 14 Volt Lithium-Ion batteries—HeartMate batteries are used to power the system during battery-powered operation when AC electricity is not wanted or is unavailable. Batteries are used in pairs. Each battery is inserted into a 14 Volt battery clip. The clips transfer battery power to the System Controller with two power cables, one for each clip. Without battery clips, the batteries cannot transfer power to the system. When fully charged, a pair of HeartMate 14 Volt Lithium-Ion batteries can power the system for up to 10–12 hours, depending on the activity level of the patient.

See page 3-45.

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

See page 3-66.



3 Powering the System

Using the Power Module

Overview

The HeartMate II Power Module (**Figure 3.1**):

- Provides power to the System Controller and pump.
- Provides power to the Provides power to the HeartMate Touch™ Wireless Adapter.
- Connects the HeartMate Touch™ Communication System to the System Controller for monitoring purposes.
- Echoes System Controller alarms.



Figure 3.1 Power Module

Required Components

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

- HeartMate Power Module with an installed Power Module backup battery
- Power Module patient cable
- Power Module power cord
- HeartMate II System Controller

WARNING !

- To avoid the risk of electric shock, the Power Module must only be plugged into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module 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 Power Module in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide, or an explosion could occur.
- Keep the Power Module dry and away from water or liquid. If the Power Module comes into contact with water or liquid, it may fail to operate properly or you may get an electric shock.
- The Power Module contains an internal backup battery that provides approximately 30 minutes of backup power to the system during a power emergency. If the Power Module is used in cold conditions (32°F–59°F, 0°C–15°C), the Power Module backup battery runtime may be reduced to a minimum of 20 minutes. The Power Module ships with the backup battery not installed. Before using the Power Module, the hospital's biomedical technician or other Abbott-trained personnel must install the Power Module backup battery. See *Installing the Power Module Backup Battery* on page 3-7. Ensure that the internal battery is connected prior to initial use and after any time the Power Module is shipped for service or maintenance.
- Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer's instructions.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- The patient must always connect to the Power Module or Mobile Power Unit for sleeping or when there is a chance of sleep. A sleeping patient may not hear system alarms.
- 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.
- Keep the Power Module plugged into electrical power at all times. If the Power Module is without electrical power for approximately 18 hours, the Power Module backup battery may be damaged.
- Do not use equipment or supplies other than those specified or sold by Abbott. The use of unauthorized replacement parts may affect electromagnetic compatibility of the Power Module with other devices. Potential interference may occur between the Power Module and other devices.

3 Powering the System

WARNING ! (Continued)

- If the patient travels long distances, such as by aircraft, instruct the patient to ask for a travel safety plan. The travel plan must address steps necessary for safe travel, including location of the nearest HeartMate implant center.
- If traveling by aircraft, the patient should be instructed to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.
- The HeartMate Power Module radiates radio frequency energy. If not used according to instructions, the Power Module may cause harmful interference with nearby devices. To confirm interference, unplug the Power Module 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 Power Module and the affected devices.
 - Connect affected devices to an electrical outlet different from the outlet used to power the Power Module.
- Power Module service and maintenance must be performed only by Abbott-trained personnel.

CAUTION !

- The Power Module requires preventive maintenance at least once every 12 months for best possible operation. Preventive maintenance includes (but is not limited to): a functional test, replacing the Power Module backup battery (the backup battery is rechargeable but has a limited life), and replacing the Power Module patient cable.
- Do not clean or service the Power Module while it is providing power to the system.
- 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.
- Avoid positioning the Power Module such that the access to the power cord plug into the wall socket is limited and/or where disconnection of the plug from the wall socket is difficult.
- During Power Module power failure, transfer a patient from the Power Module to battery-powered operation (see *Switching Power Sources* on page 3-59).

CAUTION ! (Continued)

- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the Power Module may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient, use only those devices that are necessary for patient safety and well-being.

Setting Up the Power Module Before Use

To set up the Power Module, perform these tasks:

- Install the Power Module backup battery.
- Connect the power cord.
- Connect the Power Module patient cable.

Installing the Power Module Backup Battery

After receiving the Power Module, an Abbott-trained individual must open the Power Module to install its backup battery. This must be done prior to using the Power Module.

IMPORTANT! After the Power Module backup battery is installed, the Power Module should be plugged into electrical power at all times. If the Power Module will be unplugged from electrical power for an extended time, such as for transport for service or maintenance, disconnect the Power Module backup battery to prevent damage to the battery.

FOR THIS TASK YOU NEED:

- 1 Power Module
- 1 crosshead (Phillips) screwdriver
- 1 Power Module backup battery

TO INSTALL THE POWER MODULE BACKUP BATTERY:

1. Place the Power Module on a flat, stable surface. Make sure the Power Module is unplugged from AC power and disconnected from the patient. Transfer the patient to battery power prior to disconnecting.
2. Inspect the Power Module for dents, chips, cracks, or other signs of damage. Do not use a Power Module that appears damaged. Contact Abbott for a replacement, if needed.

3 Powering the System

3. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure they are not lost (**Figure 3.2**).



Figure 3.2 Loosen the Screws

4. Open the battery compartment cover on the rear of the Power Module (**Figure 3.3**).



Figure 3.3 Remove the Battery Compartment Cover

5. Use the crosshead (Phillips) screwdriver to remove the metal bracket that will hold the internal battery in place (**Figure 3.4**).



Figure 3.4 Remove the Metal Bracket

6. Remove the Power Module backup battery from the packaging.

Powering the System 3

- Place the black battery connector over the metal contact end of the backup battery. The contacts should "snap" into place. Gently pull on the connection to make sure it is secure (**Figure 3.5**).

Note: The Power Module alarms (audio and visual) indicating that the unit is disconnected from AC power. To silence the alarm, press the silence alarm button (☒) on the user panel. The alarm clears when AC power is applied to the Power Module.



Figure 3.5 Secure the Battery to the Battery Connector

- Place the Power Module backup battery in the battery compartment (**Figure 3.6**).



Figure 3.6 Place the Battery in the Battery Compartment

- Use the crosshead (Phillips) screwdriver to reattach the metal bracket. Make sure the white connectors and wires are not trapped under the metal bracket. Make sure the connection is secure (**Figure 3.7**).



Figure 3.7 Reattach Metal Bracket

3 Powering the System

10. Gently fold the wires and white connector along the top of the Power Module backup battery and over the metal bracket screws (**Figure 3.8**).



Figure 3.8 Fold the Wires and Connector Along the Top

11. Replace the battery compartment cover.
12. Use the crosshead (Phillips) screwdriver to tighten the two ¼-turn screws. Make sure the screws are tight and the cover is securely closed (**Figure 3.9**).



Figure 3.9 Tighten the Screws

IMPORTANT! Be sure to reconnect the Power Module backup battery after the Power Module is transported or shipped for service.

Connecting the Power Module Power Cord

FOR THIS TASK YOU NEED:

- 1 Power Module, with Power Module backup battery installed and connected
- Functioning and grounded (3-prong) AC electrical outlet dedicated to Power Module use and not controlled by a wall switch
- 1 Power Module power cord

TO CONNECT THE POWER MODULE POWER CORD:

1. Place the Power Module on a flat, sturdy surface.
2. Plug the power cord into the Power Module (**Figure 3.10**).



Figure 3.10 Plug the Power Cord into the Power Module

3. Lift the power cord retention clip into the locked position.
4. Insert the two ends of the clip into the holes. Make sure the clip is securely engaged (**Figure 3.11**).



Figure 3.11 Insert the Ends of the Clip Into the Holes

5. Plug the Power Module into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use. Do not use an outlet that is controlled by a wall switch. Do not use an adapter plug for an ungrounded wall outlet. Do not use portable, multiple outlet (power strip) adapters.

3 Powering the System

6. Observe the front panel of the Power Module. The green "Power On" light should illuminate. If the light does not illuminate, the device may be defective. Do not use a defective device. Contact Abbott for a replacement, if needed. See **Figure 3.12**.

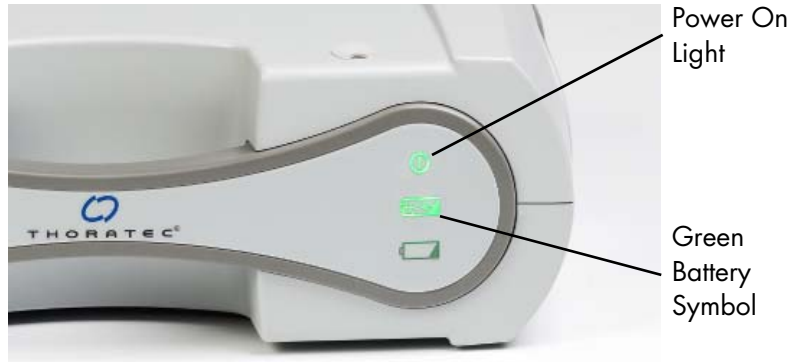


Figure 3.12 The Power Module is Ready for Use when the Power On and Charge Lights are Green

7. Within a few hours, the Power Module backup battery should be charged and ready for use, as indicated by a green battery symbol (**Figure 3.12**).

IMPORTANT! Wait for the Power Module backup battery to charge before using the Power Module for the first time, after service transportation, or after prolonged storage. It can take up to 3 hours to charge the backup battery.

Connecting the Power Module Patient Cable

The System Controller cannot connect to the Power Module without the Power Module patient cable. The 20-foot (6.1-meter) long Power Module patient cable allows patients some mobility while tethered to the Power Module.

FOR THIS TASK YOU NEED:

- 1 Power Module with backup battery installed and connected, and power cord connected to a functioning and grounded AC electrical outlet that is not controlled by a wall switch
- 1 Power Module patient cable

TO CONNECT THE POWER MODULE PATIENT CABLE:

1. Locate the Power Module patient cable (**Figure 3.13**).



Figure 3.13 Power Module Patient Cable

2. Line up the red dot on the patient cable with the red dot near the "heart" socket (♥) on the Power Module, and then insert the patient cable into the socket (**Figure 3.14**). The cable clicks into place when fully engaged in the socket.



Figure 3.14 Align the Red Dots

3 Powering the System

3. Tug gently on the black strain relief portion of the connector to confirm that the connection is tight. Do not pull on the cable. See **Figure 3.15**.

Grasp here to
check connection



Figure 3.15 Tug on the Black Strain Relief Portion to Check the Connection

After the Power Module internal battery is charged, the Power Module is plugged in, and the Power Module patient cable is connected to the “heart” socket (♥), the Power Module should be ready for use. However, before using the Power Module for the first time, be sure to perform a Power Module system self test (see *Performing a Power Module Self Test* on page 3-19).

If the Power Module patient cable remains connected to the Power Module when not in use, make sure the Power Module patient cable does not become damaged, and is placed to ensure the patient does not trip or fall.

When to Connect to the Power Module

Connect the System Controller to the Power Module (or Mobile Power Unit) when patients are stationary or relaxing indoors. Patients must always connect to the Power Module (or Mobile Power Unit) for sleeping or when sleep is likely, because they may not awaken to hear low power alarms for batteries (see *System Controller Alarms* on page 7-3).

Use the Power Module patient cable to connect the System Controller to the Power Module (**Figure 3.16**). Use care when connecting or disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 7-45.



Figure 3.16 Power Module Patient Cable

FOR THIS TASK YOU NEED:

- A running System Controller
- A working Power Module that is ready for use
- A working Power Module patient cable

TO CONNECT THE SYSTEM CONTROLLER TO THE POWER MODULE:

1. Gather equipment.
2. Confirm that the Power Module is ready for use (see *Setting Up the Power Module Before Use* on page 3-7).
3. Grasp the single-connector end of the Power Module patient cable (**Figure 3.17**).



Figure 3.17 Single-Connector End of the Power Module Patient Cable

3 Powering the System

4. Locate the red dot on the single-connector end of the Power Module patient cable connector (**Figure 3.18**).



Figure 3.18 Note the Red Dot on the Connector

5. Align the red dot on the connector with the red dot near the “heart” socket (♥) on the Power Module.
6. Firmly insert the single-connector end into the “heart” socket (♥) on the Power Module (**Figure 3.19**). The connector clicks into place when correctly inserted.



Figure 3.19 Align the Red Dot on the Connector with the Red Dot on the Power Module

7. Test the connection by tugging gently on the flexible strain-relief portion of the inserted connector. Do not pull on or bend the cable, as this could damage it.
8. Place the black and white System Controller power cable connectors within easy reach (**Figure 3.20**).



Figure 3.20 Black and White System Controller Power Cable Connectors

Powering the System 3

9. Place the black and white Power Module patient cable connectors within easy reach (**Figure 3.21**).



Figure 3.21 Black and White Power Module Patient Cable Connectors

10. If currently using battery power (see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45):
 - a. Place the batteries and attached battery clips within easy reach.
 - b. Unscrew and disconnect only the white System Controller power cable connector from the attached battery clip. Do not remove the black connector!

IMPORTANT! The Power Cable Disconnected alarm comes on when a power cable is removed from power. This is normal. The alarm continues until the connection is restored or the silence alarm button (ⓧ) is pressed.

- c. Promptly align opposite half circles inside the white System Controller power cable connector and the white Power Module patient cable connector (**Figure 3.22**). Do not try to join together misaligned connectors; doing so causes damage. Firmly push together the two connectors.

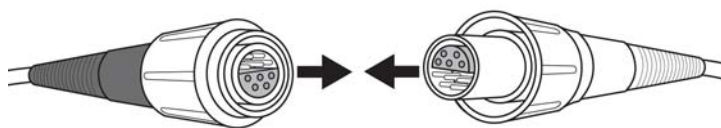


Figure 3.22 Align the Half Circles on the Connectors

- d. Securely hand tighten the connector nut. Do not use tools.
 - e. Unscrew and disconnect only the black System Controller power cable connector from the attached battery clip.
 - f. Promptly align opposite half circles inside the black System Controller power cable connector and the black Power Module patient cable connector. Do not try to join together misaligned connectors; doing so causes damage. Firmly push together the two connectors.
 - g. Securely hand tighten the connector nut. Do not use tools.

3 Powering the System



Figure 3.23 System Controller Power Cables Connected to Power Module Patient Cables

Monitoring Power Module Performance

The computer inside the Power Module is continually monitoring Power Module performance. If the Power Module computer detects a problem or malfunction, the yellow wrench symbol appears on the front of the Power Module. The yellow wrench is accompanied by an audio tone (a steady or beeping tone, depending on the condition). See on page 7-31 for guidelines on handling Power Module alarms.

Performing a Power Module Self Test

Perform a Power Module self test before using the Power Module for the first time and at least once daily to make sure that the Power Module is working properly. A self test may be performed while the Power Module is powering the pump.

FOR THIS TASK YOU NEED:

- 1 working, in-use Power Module with backup battery installed and connected

TO PERFORM A POWER MODULE SELF TEST:

1. Press and hold the Power Module's silence alarm button  for five seconds.
2. Listen for 3 beeps and watch the front of the Power Module. The lights should come on in sequence—one at a time, not all at once.
3. If any of the following occurs, the Power Module may have a problem:
 - No sound
 - Anything other than 3 beeps (such as continuous beeping or a broken tone)
 - All the lights come on at once
 - All the lights remain off
 - One of the lights does not come on
4. If any of these conditions occur, please contact Abbott. For Abbott contact information, see the *Back Cover* of this manual. Otherwise, the Power Module passed the self test and is ready for use.

For guidelines on responding to Power Module alarms, see on page 7-31.

3 Powering the System

Power Module Backup Power

The Power Module has an internal backup battery. A new Power Module backup battery provides approximately 30 minutes of backup power to the HeartMate II system if power fails or is disconnected. Over time, the internal battery may provide shorter periods of backup power.

The Power Module backup battery remains charged as long as the Power Module remains connected to AC power. If the Power Module is disconnected from external power, the Power Module backup battery operates the Left Ventricular Assist System and the Power Module alarms until the battery is depleted. The backup battery automatically disengages after power is restored.

Make sure that the Power Module backup battery is charged prior to use. See **Table 3.1** for a description of the charge status indicators for the Power Module backup battery.

Keep the Power Module plugged into AC power at all times to make sure that the Power Module backup battery is charged and ready for use in case of power interruption. If the Power Module is without AC power for approximately 18 hours, the Power Module backup battery may be damaged. If the Power Module backup battery is damaged, an alarm is generated on the Power Module (see on page 7-31). Emphasize to patients that inappropriate use during non-emergencies may reduce the power available to them in a true emergency.

If the Backup Battery Malfunction alarm occurs, replace the backup battery immediately. Only Abbott-trained personnel should replace the battery. Call Abbott for assistance, if needed.

The Power Module internal backup battery is rechargeable. However, the battery has a limited lifespan. The backup battery is replaced during annual planned Power Module maintenance (see *Cleaning and Maintenance* on page 8-4).

During Power Module power failure, transfer a patient from the Power Module to the Mobile Power Unit or battery-powered operation (see *Switching Power Sources* on page 3-59).

Checking the Charge Status of the Power Module Backup Battery

Indicator symbols on the front panel of the Power Module illuminate to indicate the charge status of the Power Module backup battery. **Table 3.1** describes the indicator symbols.

Green Charge Lamp 	The Power Module backup battery is charged and ready for use. See Figure 3.24.
Yellow Charge Lamp 	The Power Module backup battery is charging. See Figure 3.25.
Yellow Battery Advisory Symbol  <i>accompanied by beeping audio tone</i>	Less than 15 minutes of Power Module backup battery power remain. Promptly switch to another power source. See Figure 3.26.
Red Battery Hazard Symbol  <i>accompanied by beeping audio tone</i>	Less than 5 minutes of Power Module backup battery power remain. Immediately switch to another power source. See Figure 3.27.
Yellow Wrench with Red Battery Hazard Symbol  <i>accompanied by beeping audio tone</i>	The Power Module backup battery is not functioning properly or it is not installed. See Figure 3.27.

Table 3.1 Power Module Backup Battery Charge Status Indicators



Power Module Backup Battery is charged when battery symbol is green

Figure 3.24 Green Charge Symbol Indicates that the Power Module Backup Battery is Charged

3 Powering the System



Figure 3.25 Yellow Charge Symbol Indicates that the Power Module Backup Battery is Charging



Figure 3.26 Less than 15 Minutes of Power Module Backup Power Remain When Power On Light and Battery Advisory Symbol are Yellow

Wrench Malfunction symbol is yellow



Figure 3.27 Yellow Wrench and Red Battery Hazard Symbol Indicate that the Power Module Backup Battery is Not Working — Switch to Another Power Source Immediately

The Power Module is shipped with the Power Module backup battery not installed. If the Power Module backup battery is not installed or connected when the Power Module is plugged in, the Power Module alarms, indicating that it cannot provide backup power in the event of a power interruption or failure.

IMPORTANT! When the Power Module alarms, a continuous audio tone sounds and the yellow wrench and red battery symbols illuminate. To clear the alarm, first disconnect the Power Module from AC power and then connect the internal backup battery according to instructions in *Installing the Power Module Backup Battery* on page 3-7.

Storing and Shipping the Power Module

If the Power Module is without electrical power for approximately 18 hours, the internal backup battery may be damaged. If the Power Module is not being used and will be unplugged from electrical power for an extended time, such as for transport for service or maintenance, the Power Module backup battery must be disconnected to prevent damage to the battery.

Disconnecting the Power Module Backup Battery

The Power Module backup battery should be disconnected any time the Power Module is unplugged for an extended period, such as when the Power Module is shipped for service or during extended periods of time without AC power. In these situations, the battery remains in the battery compartment but is not connected.

FOR THIS TASK YOU NEED:

- 1 Power Module backup battery installed and connected
- 1 crosshead (Phillips) screwdriver

TO DISCONNECT THE POWER MODULE BACKUP BATTERY:

1. Place the Power Module on a flat, stable surface. Make sure the Power Module is unplugged from AC power and disconnected from the patient. Transfer the patient to another power source prior to disconnecting.
2. Inspect the Power Module for dents, chips, cracks, or other signs of damage. Do not use a Power Module that appears damaged. Contact Abbott for a replacement, if needed.
3. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure they are not lost (**Figure 3.28**).



Figure 3.28 Loosen the Screws

3 Powering the System

4. Open the battery compartment cover on the rear of the Power Module (**Figure 3.29**).



Figure 3.29 Remove the Battery Compartment Cover

5. Leave the metal bracket and black clip in place, and use your finger to gently pull the wires and white connectors out away from the battery (**Figure 3.30**).



Figure 3.30 Gently Pull the Wires and Connectors Away

6. Gently squeeze the white latch on the connector to free the two halves. Pull the connector halves away from each other to disconnect (**Figure 3.31**).



Figure 3.31 Gently Squeeze the Latch

Note: The Power Module alarms (audio and visual) indicating that the unit is disconnected from AC power. To silence the alarm, press the silence alarm button (☒) on the user panel. The alarm clears when AC power is applied to the Power Module.

Powering the System **3**

7. Gently fold the wires and white connector along the top of the battery and over the metal bracket screws (**Figure 3.32**).



Figure 3.32 Gently Fold the Wires and Connector Along the Top

8. Replace the battery compartment cover.
9. Use the crosshead (Phillips) screwdriver to tighten the two 1/4-turn screws. Make sure the screws are tight and the cover is securely closed (**Figure 3.33**).



Figure 3.33 Tighten the Screws

3 Powering the System

Reconnecting the Power Module Backup Battery

Make sure you reconnect the Power Module backup battery any time it may have been disconnected, such as for annual maintenance.

FOR THIS TASK YOU NEED:

- 1 Power Module backup battery installed but not connected
- 1 crosshead (Phillips) screwdriver

TO RECONNECT THE POWER MODULE BACKUP BATTERY:

1. Place the Power Module on a flat, stable surface.
2. Inspect the Power Module for dents, chips, cracks, or other signs of damage. Do not use a Power Module that appears damaged. Contact Abbott for a replacement, if needed.
3. Use a crosshead (Phillips) screwdriver to loosen the two ¼-turn screws from the rear panel. The screws remain in the screw holes to ensure they are not lost (**Figure 3.34**).



Figure 3.34 Loosen the Screws

4. Open the battery compartment cover on the rear of the Power Module (**Figure 3.35**).



Figure 3.35 Remove the Battery Compartment Cover

Powering the System 3

5. Leave the metal bracket and black clip in place, and use your finger to gently pull the wires and the two halves of the white connector out of the battery compartment (**Figure 3.36**).



Figure 3.36 Gently Pull the Wires and Connector Halves Out

6. Line up the two connector halves (**Figure 3.37**).



Figure 3.37 Line Up the Connector Halves

7. Firmly press the halves together. You should hear a click when the connector is fully engaged.
8. Gently fold the wires and white connector along the top of the battery and over the metal bracket screws (**Figure 3.38**).



Figure 3.38 Gently Fold the Wires and Connector Along the Top

9. Replace the battery compartment cover.

3 Powering the System

10. Use the crosshead (Phillips) screwdriver to tighten the two ¼-turn screws. Make sure the screws are tight and the cover is securely closed (**Figure 3.39**).



Figure 3.39 Tighten the Screws

Silencing Power Module Alarms

Press the silence alarm button () to silence a Power Module audio alarm. See **Table 3.2** for information about how long an alarm is silenced—silence periods vary by alarm type. After the silence period ends, the audio alarm resumes unless the alarm condition has been resolved. If a new alarm condition arises during a silence period, a new audio alarm sounds.

IMPORTANT! Pressing the silence alarm button only silences the alarm. The alarm condition is not resolved as indicated by persistence of the visual alarm.

Audio Alarm	How Long Alarm is Silenced
Echo System Controller alarm	5 minutes.
AC Fail	Silence lasts until cancelled by another alarm, such as yellow battery.
Yellow Battery	8 hours or until cancelled by another alarm, such as red battery.
Red Battery	Alarm cannot be silenced if patient is connected to pump.
Yellow Wrench (Advisory)	8 hours.
Yellow Wrench (Hazard/Critical)	8 hours for non-critical faults. Alarm cannot be silenced if patient is connected to pump.

Table 3.2 Audio Alarm Silence Periods

Caring for the Power Module

See *Cleaning and Maintenance* on page 8-4 for warnings, cautions, and instructions on caring for the Power Module.

3 Powering the System

Using the Mobile Power Unit

The Mobile Power Unit (**Figure 3.40**):

- Provides power to the System Controller and pump.
- Powers the system while the patient is sleeping or relaxing indoors.
- Echoes System Controller alarms.

Powering the System 3



Figure 3.40 The Mobile Power Unit

WARNING !

- The Mobile Power Unit is intended for use with the System Controller REF:105109, or a System Controller with a serial number beginning with "PC". Connecting a version of System Controller REF:103696, REF:105472, or a System Controller with a serial number beginning with "EPC" or "PSD" will cause a low voltage alarm or on a Mobile Power Unit with software version 1.02, the Mobile Power Unit will issue a Yellow Wrench alarm.. The pump will stop if there is a loss of power to the Mobile Power Unit while it is connected to the System Controller REF:103696, REF 105472, or a System Controller with a serial number beginning with "EPC: or "PSD".

Compatible with Mobile Power Unit



System Controller REF:105109 or a System Controller with a serial number beginning "PC".

NOT Compatible with Mobile Power Unit



System Controller REF:103696, REF:105472, or a System Controller with a serial number beginning with "EPC" or "PSD".

- Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.

3 Powering the System

WARNING ! (Continued)

- 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.
- The patient must always connect to the Mobile Power Unit when sleeping, or when there is a chance of sleep. A sleeping patient may not hear system alarms; the Mobile Power Unit echoes the alarms.
- 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.
- 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 you transfer to batteries. Do not rely on the controller's backup battery as a power source during AC power failure, as it will only power the pump for a limited amount of time and the pump will stop (see *Switching Power Sources* on page 3-59).
- Keep the Mobile Power Unit dry and away from water or liquid. If the Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or you may get an electric shock.
- Do not use the Mobile Power Unit in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide, or an explosion could occur.

CAUTION !

- To avoid the risk of electric shock, plug the Mobile Power Unit 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 cords.
- Avoid covering the Mobile Power Unit, such as with a blanket. Covering the Mobile Power Unit may reduce the ability to hear important system alarms or may cause the Mobile Power Unit to fail due to overheating.

CAUTION ! (Continued)

- When connecting power cable connectors, do not try to join them together without first aligning the half circles inside the connectors. Joining together misaligned power cable connectors may damage them.
- 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 controller's backup battery, because it will only power the pump for a limited amount of time.
- Do not use the Mobile Power Unit with DC to AC inverters, as they may cause the Mobile Power Unit to fail.
- Do not connect the Mobile Power Unit to electrical outlets that are controlled by a wall switch, as the Mobile Power Unit will fail to supply power.
- 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.
- Do not clean or service the Mobile Power Unit while it is plugged into an AC electrical outlet, or electrical shock may occur.
- Do not incinerate, disassemble, crush, puncture, or otherwise damage batteries, because this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Do not mix old and new Alkaline batteries or battery types (such as rechargeable and non-rechargeable), as this can cause leakage or rupture, resulting in personal injury or damage to the Mobile Power Unit.
- Mobile Power Unit power output may be affected by mobile phones, resulting in low power alarms on the System Controller, or loss of the green power LED on the Mobile Power Unit. If either of these conditions is observed, separate the mobile phone from the Mobile Power Unit by at least .6 meters (24 inches). If the condition persists after separating the devices, switch to two HeartMate 14 Volt Lithium-Ion batteries (see *Switching Power Sources* on page 3-59).
- 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.
- 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.

3 Powering the System

CAUTION ! (Continued)

- 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.
- 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).

Mobile Power Unit User Interface Components

The buttons, lights, symbols, and display screen on the Mobile Power Unit user interface are introduced below in **Table 3.3**. Additional details follow after the table.

Power On Symbol



The power symbol is illuminated green when the Mobile Power Unit is powered and functioning properly.

Yellow Wrench Alarm



The yellow wrench symbol illuminates when the Mobile Power Unit detects a mechanical, electrical, or software issue with the system.

This is an **Advisory** alarm. When the yellow wrench illuminates, switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.

For more information, see page 7-40.

Replace Mobile Power Unit Battery Alarm



The yellow Replace Mobile Power Unit Battery symbol illuminates when the Alkaline AA batteries are not installed, or are depleted and need replaced.

This is an **Advisory** alarm. When the Replace Mobile Power Unit Battery symbol illuminates, replace the internal batteries in the Mobile Power Unit.

For more information, see page 7-40.

Table 3.3 Mobile Power Unit User Interface Components

Setting Up the Mobile Power Unit For Use

To set up the Mobile Power Unit, perform these tasks:

- Install the Mobile Power Unit batteries.
- Connect the Mobile Power Unit power cord to the Mobile Power Unit and AC power.

Installing or Replacing the Mobile Power Unit Batteries

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

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

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

FOR THIS TASK YOU NEED:

- A Mobile Power Unit
- 3 fresh Alkaline AA batteries
- A flathead screwdriver or coin

TO INSTALL OR REPLACE THE MOBILE POWER UNIT BATTERIES:

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

3 Powering the System

4. Use a flathead screwdriver or coin to loosen the screw from the rear panel. The screw remains in the screw hole to ensure it is not lost (**Figure 3.41**).



Figure 3.41 Loosen the Screw

5. Open the battery compartment cover on the rear of the Mobile Power Unit (**Figure 3.42**). Remove and dispose of the battery installation reminder tag, if present.



Figure 3.42 Remove the Battery Compartment Cover

6. If replacing batteries, gently pull the ribbon to remove the depleted batteries from the case.

Powering the System 3

7. Place the Alkaline AA batteries in the battery compartment. Follow the orientation markings on the battery clip when inserting the batteries (**Figure 3.43**).



Figure 3.43 Install AA Batteries

8. Replace the battery compartment cover.
9. Use the flathead screwdriver or coin to tighten the screw. Make sure the screw is tight and the cover is securely closed (**Figure 3.44**).



Figure 3.44 Tighten the Screw

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

3 Powering the System

Connecting the Power Cord

FOR THIS TASK YOU NEED:

- A Mobile Power Unit
- A Mobile Power Unit power cord
- Functioning AC electrical outlet that is dedicated to Mobile Power Unit use and not controlled by a wall switch

TO CONNECT THE POWER CORD:

1. Place the Mobile Power Unit on a flat, sturdy surface.
2. Plug the power cord into the Mobile Power Unit (**Figure 3.45**).



Figure 3.45 Plug Power Cord into Mobile Power Unit

3. Plug the Mobile Power Unit into an AC electrical outlet that is dedicated to Mobile Power Unit use. Do not use an outlet that is controlled by a wall switch. Do not use an adapter; a portable, multiple outlet power strip; a ground fault interrupter (GFI); or a residual current device (RCD) outlet.

4. Observe the top panel of the Mobile Power Unit. When initially connected to power, the Mobile Power Unit automatically performs a self test during which the green "Power On" light turns on. The yellow wrench and the Replace Mobile Power Unit Battery lights flash and the Mobile Power Unit beeps twice. After the self test is completed, the green "Power On" light remains illuminated (**Figure 3.46**). If this behavior is not observed, contact Abbott. For Abbott contact information, see the *Back Cover* of this manual.



Figure 3.46 Mobile Power Unit Ready for Use

Note: If the green "Power On" light does not come on, plug the power cord into another electrical outlet. If the green light still does not come on, the Mobile Power Unit may have a problem. Do not use a defective device. Contact Abbott for a replacement, if needed.

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

For international travel, the patient needs an Abbott 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. Contact Abbott for a power cord, if needed. For Abbott contact information, see the *Back Cover* of this manual.

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

3 Powering the System

When to Connect to the Mobile Power Unit

Connect the System Controller to the Mobile Power Unit when the patient is stationary or relaxing indoors. Do not use the Mobile Power Unit when the patient may require monitoring using the HeartMate Touch Communication System. Patients must always connect to the Mobile Power Unit before sleeping (or when sleep is likely), because they may not awaken to hear low power alarms for batteries (see *System Controller Alarms* on page 7-3).

The Mobile Power Unit patient cable (**Figure 3.47**) connects the System Controller to the Mobile Power Unit.



Figure 3.47 Mobile Power Unit Patient Cable

Like the power cable connectors on the System Controller, the connectors on the Mobile Power Unit patient cable are also color coded (see **Figure 3.47**). When connecting the System Controller to the Mobile Power Unit patient cable, always connect white-to-white and black-to-black.

FOR THIS TASK YOU NEED:

- A running System Controller
- A working Mobile Power Unit that is ready for use
- A working Mobile Power Unit patient cable

TO CONNECT THE SYSTEM CONTROLLER TO THE MOBILE POWER UNIT:

1. Gather equipment.
2. Confirm that the Mobile Power Unit is ready for use (see *Setting Up the Mobile Power Unit For Use* on page 3-35).
3. Place the black and white System Controller power cable connectors within easy reach (**Figure 3.48**).



Figure 3.48 System Controller Power Cable Connectors

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

3 Powering the System

- c. Promptly align opposite half circles inside the white System Controller power cable connector and the white Mobile Power Unit patient cable connector (**Figure 3.49**). Do not try to join together misaligned connectors, which can damage them.



Figure 3.49 Carefully Align the Connectors

- d. Firmly push together the two connectors ().

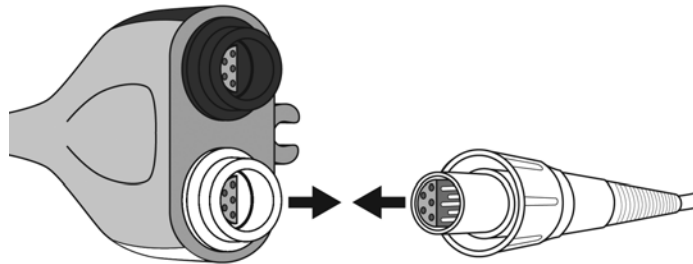


Figure 3.50 Push Together the Two Connectors

- e. Tighten the connector nut until secure (**Figure 3.51**). Hand tighten only—do not use tools.

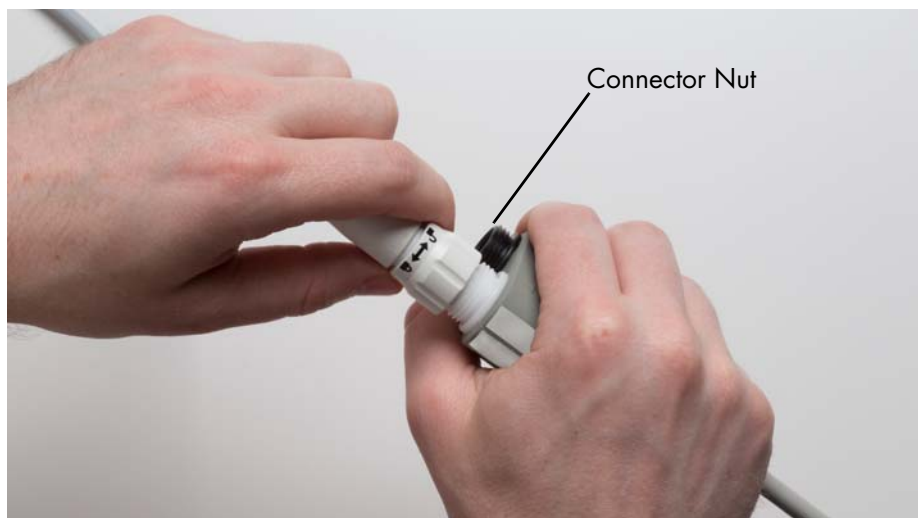


Figure 3.51 Tighten the Connector Nut

- f. Unscrew and disconnect only the black System Controller power cable connector from the attached battery clip.
- g. Promptly align opposite half circles inside the black System Controller power cable connector and the black Mobile Power Unit patient cable connector. Do not try to join together misaligned connectors, which can damage them.
- h. Firmly push together the two connectors.
- i. Tighten the connector nut until secure. Hand tighten only—do not use tools.



Figure 3.52 System Controller Power Cables Connected to Mobile Power Unit Patient Cable Connectors

3 Powering the System

Mobile Power Unit Storage

If the Mobile Power Unit will not be used for an extended time, unplug the AC power cord from power and detach the power cord from the device. Wrap the Mobile Power Unit patient cable around the Mobile Power Unit for storage (**Figure 3.53**). This also a convenient way to prepare the device and patient cable for travel.



Figure 3.53 Storing the Mobile Power Unit

Caring for the Mobile Power Unit

The Mobile Power Unit requires little planned maintenance. However, it should be inspected routinely to ensure the safest and best possible performance. For complete information about caring for the Mobile Power Unit, see *Caring for the Power Module and Mobile Power Unit* on page 8-6.

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

Using HeartMate 14 Volt Lithium-Ion Batteries

Using battery power for the HeartMate II Left Ventricular Assist System allows for greater patient mobility than when connected to the Power Module or Mobile Power Unit. On battery power, patients can enjoy activities outdoors or away from home such as shopping, gardening, or running errands. A pair of HeartMate 14 Volt Lithium-Ion batteries (**Figure 3.54**) provides direct current (DC) to the pump.



Figure 3.54 HeartMate 14 Volt Lithium-Ion Battery

Each battery is inserted into a 14 Volt battery clip (**Figure 3.55**). The batteries and attached battery clips can be worn in holsters, one under each arm, or across the body, in a bag, or in a pouch around the waist. The battery clips transfer power from the batteries to the System Controller. Their use is required with the batteries.



Figure 3.55 Inserting Battery into Battery Clip

During battery-powered operation, the System Controller battery power gauge shows overall power capacity for both batteries (see *System Controller Battery Power Gauge* on page 2-31). The System Controller's battery power gauge indicates when the batteries are running low and prompts the switch to a different power source (the Power Module, Mobile Power Unit, or a new, fully-charged pair of HeartMate 14 Volt Lithium-Ion batteries). The status of an individual battery can be checked at any time by pressing the on-battery power gauge on the individual battery (see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-49).

3 Powering the System

Required Components

Components for operating the HeartMate II system on battery power include the following:

- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 compatible 14 Volt battery clips

In addition, the System Controller must be connected to the Left Ventricular Assist Device via the driveline.

IMPORTANT! HeartMate batteries only work in matching pairs with matching compatible clips.

The HeartMate II Left Ventricular Assist System is optimized for operation with two batteries, but the system can run on only one battery for a very short period (minutes). For example, when switching from batteries to the Power Module or Mobile Power Unit (or vice versa), operation will continue on a single battery while connections are made.

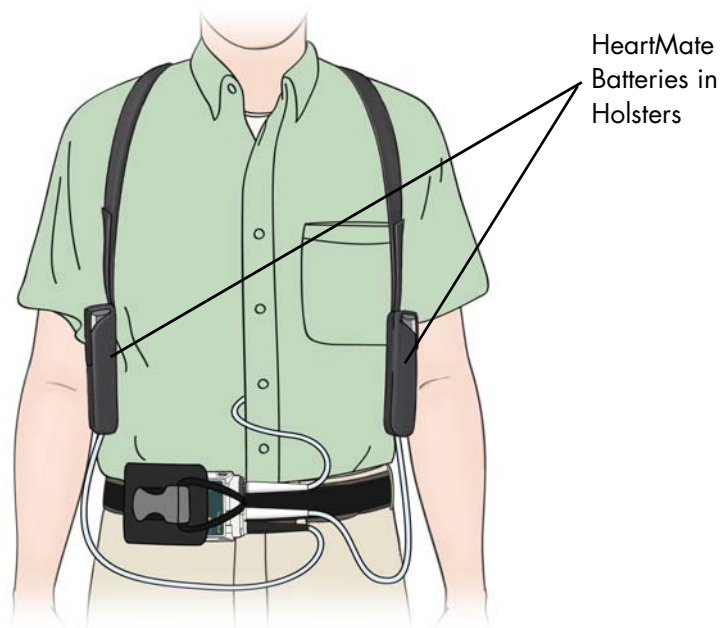


Figure 3.56 HeartMate Batteries Worn in Holsters

WARNING !

- Use only Abbott-supplied HeartMate 14 Volt Lithium-Ion batteries with the HeartMate II Left Ventricular Assist System. Using the wrong batteries may cause the pump to stop.
- HeartMate 14 Volt Lithium-Ion batteries must be charged before use (see *Charging HeartMate Batteries* on page 3-73). Before removing a battery from the Battery Charger, make sure that the battery has completed its charge or calibration cycle. After removing the battery from the Battery Charger, use the battery power gauge that is on the battery to check the battery's charge level (see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-49).
- Use only Abbott-supplied 14 Volt battery clips with HeartMate 14 Volt Lithium-Ion batteries. Other clips will not transfer electrical power to the system.
- Do not use batteries to power the system when the patient is sleeping. The patient must always connect to the Power Module or Mobile Power Unit for sleeping or when there is a chance of sleep. A sleeping patient may not hear system alarms.
- At least one System Controller power cable must be connected to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- Do not use damaged, defective, or expired batteries. Using damaged, defective, or expired batteries may reduce operating time or the pump may stop.
- Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer's instructions.
- If traveling by aircraft, patient should be instructed to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.

3 Powering the System

CAUTION !

- Use only the Abbott-supplied Battery Charger to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- After approximately 70 uses, HeartMate 14 Volt Lithium-Ion batteries may need to be recalibrated. The Battery Charger indicates when a battery needs to be 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).
- 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.
- 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 clips at least once a month. Use a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or battery clips, or before placing batteries into the Battery Charger (see *Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 8-7).
- If stored and used within recommended guidelines, HeartMate 14 Volt Lithium-Ion batteries should be usable for approximately 360 use/charge cycles or for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced.
- If a 14 Volt Lithium-Ion battery leaks, do not touch the leaking fluid. If the fluid touches your skin or eyes, wash the affected area with plenty of water and seek medical advice.

CAUTION ! (Continued)

- To prevent deterioration or damage to a 14 Volt Lithium-Ion backup battery:
 - Do not store in direct sunlight.
 - Store within approved temperatures: 14°F to 104°F (-10°C to 40°C). See *Storage and Transport* on page 8-3 for complete storage guidelines, including greater than 30 days.
 - 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 hard objects or each other.
 - Do not leave or store in extremely hot or cold temperatures, such as in automobiles or automobile trunks, or battery life will be shortened.
 - Do not expose to heat or fire.
 - Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short and a rapid discharge of the battery. This can result in battery overheating that may burn you or damage the batteries.
- Keep batteries out of the reach of children.
- Keep batteries clean and dry.
- Dispose of or recycle an expired battery in accordance with local, state, and federal regulations.

Charging a New HeartMate Battery Before Use

Every HeartMate 14 Volt Lithium-Ion battery must be charged before being used for the first time. It takes up to four hours to charge a new battery, depending on the initial charge status of the battery. Batteries are charged in the Battery Charger, which can charge up to four batteries simultaneously. Charging a battery in the Battery Charger is described in more detail in *Charging HeartMate Batteries* on page 3-73.

Checking Battery Charge Status Using the On-Battery Power Gauge

After a HeartMate battery is charged, it should be ready for use. Make sure it has finished charging, and then use the on-battery power gauge to confirm that the battery is fully charged.

3 Powering the System



Figure 3.57 Press the Battery Symbol on the Battery to Use the On-Battery Power Gauge

The on-battery power gauge on a HeartMate battery uses five green bars to show available battery power (**Figure 3.58**). Each bar represents approximately 20% of available power. When a battery is fully charged, all five bars light up when you press the power gauge button, indicating that the battery is 80%–100% charged. Fewer bars illuminate as power is depleted. When battery power drops below 10%, only one green blinking bar comes on.



Figure 3.58 On-Battery Power Gauge: Press Battery Symbol to Activate Bars

FOR THIS TASK YOU NEED:

- 1 HeartMate 14 Volt Lithium-Ion battery
- Battery Charger

TO CHECK A BATTERY'S CHARGE STATUS USING THE BATTERY POWER GAUGE:

1. Obtain a battery from one of the Battery Charger charging pockets.
2. Look at the lights next to the charging pocket for the battery. A green light on the charger means that the battery is charged and ready for use.
3. Remove the battery from the charging pocket.
4. Find the battery symbol on the battery's power gauge.
5. Press and hold the battery symbol for five seconds.
6. If all five green power gauge bars light, the battery is between 80%–100% charged.

OR

7. If four or fewer bars light, the battery is not fully charged. Return it to the pocket for more charging. If the power gauge continues to show four or fewer bars after additional charging, the battery may be defective—do not use it. Contact Abbott for a replacement, if needed.

The table below describes the on-battery power gauge on a 14 Volt Lithium-Ion battery (see **Table 3.4**).

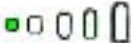
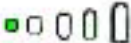
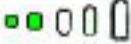
No bars 	Battery is in "sleep" mode, due to being in storage for a long period of time. Charge battery immediately.
1 bar (blinking) 	Approximately 10% or less of power remains. Do not use if battery has one blinking bar.
1 bar (steady) 	Approximately 10%–20% of power remains.
2 bars 	Approximately 20%–40% 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.

Table 3.4 14 Volt Lithium-Ion Battery On-Battery Power Gauge

3 Powering the System

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

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

If all of the power gauge bars come on 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, please contact Abbott. For Abbott contact information, see the *Back Cover* of this manual.

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

When to Connect to Batteries

Connect the System Controller to battery power when patients are active and mobile, outdoors, or when AC electricity fails or is unavailable. For more information, see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45.

FOR THIS TASK YOU NEED:

- A running System Controller
- Two charged and working HeartMate 14 Volt Lithium-Ion batteries (see *Charging HeartMate Batteries* on page 3-73)
- Two HeartMate 14 Volt Lithium-Ion battery clips
- One Battery Holster or other accessory for holding or carrying in-use batteries

TO CONNECT THE SYSTEM CONTROLLER TO 14 VOLT BATTERIES:

1. Gather equipment.
2. Insert a charged HeartMate 14 Volt Lithium-Ion battery into each 14 Volt battery clip (see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45).
3. Place the batteries with attached battery clips within reach.



Figure 3.59 Black and White System Controller Power Cable Connectors

4. Place the black and white System Controller power cable connectors within reach (**Figure 3.59**).
5. Unscrew and disconnect only the white System Controller power cable connector from its current power source. Do not disconnect the other connector.

3 Powering the System

6. 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 3.60**). Do not try to join together misaligned connectors; doing so causes damage.

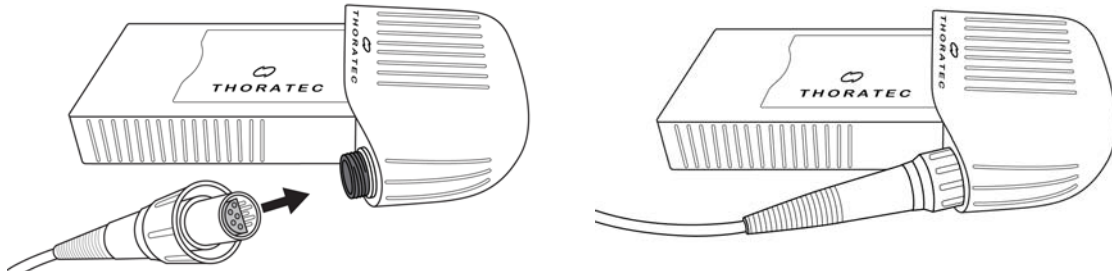


Figure 3.60 Align the Half Circles on the Connectors

7. Firmly push together the two connectors.
8. Securely hand tighten the connector nut. Do not use tools.
9. Repeat Steps 5 through 8 for the black System Controller power cable connector and the second battery clip connector.



Figure 3.61 System Controller Power Cables Connected to Battery Clips

Estimating Remaining Time for In-Use Batteries

When approximately 15 minutes of battery power are left, the System Controller initiates a Low Battery Power **Advisory** alarm, which is indicated by the following:

- Flashing yellow diamond on the System Controller's user interface.
- "Low Battery" and "Replace Power" alternate on the user interface screen.
- Alarm tone: slow beep.

When approximately five minutes of operation remain, the System Controller initiates a Low Battery Power **Hazard** alarm, which is indicated by the following:

- Flashing red battery on the System Controller's user interface.
- "Low Battery" and "Replace Power Immediately" alternate on the user interface screen.
- Alarm tone: constant tone.

The Low Battery Power Hazard alarm requires an immediate response. See *System Controller Alarms* on page 7-3 for detailed instructions on responding to System Controller alarms.

During a Low Battery Power Hazard alarm, the system reverts to power saver mode and gradually ramps down to the low speed setting. If the fixed speed setting is lower than the low speed limit, the pump remains at the lower speed setting.

The Left Ventricular Assist System remains in power saver mode until a new pair of fully-charged batteries are installed, the System Controller is connected to the Power Module or Mobile Power Unit, or until no further power remains.

When adequate power is supplied, the pump reverts to the previous mode and speed, and the red battery alarm clears.

3 Powering the System

Replacing Depleted Batteries

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 2 in-use HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO REPLACE DEPLETED BATTERIES WITH CHARGED BATTERIES:

1. Obtain two charged HeartMate batteries and place them within easy reach. If you remove batteries from the Battery Charger, make sure that the light near the charging pocket for each battery is green, indicating that the battery is charged (see *Charging HeartMate Batteries* on page 3-73).
2. Press and hold the battery symbol on each battery; make sure each battery is charged and ready for use.
3. Grasp the battery clip and attached battery for one of the batteries that is currently powering the system and remove the clip and battery from the holster/carrying case. Do not remove the battery from its clip at this time.
4. Locate the battery power gauge symbol on the battery.
5. Press and hold the battery symbol for five seconds to see how much battery power remains for this battery (ie, count the number of bars that light).
6. Repeat Steps 3–5 for the second battery that is currently in use.
7. Determine which battery has the least power.
8. If both batteries have the same amount of power, replace either battery; otherwise, replace the battery that has the least power first:
 - a. Press the battery release button on the battery clip.
 - b. Withdraw the battery from its clip. The System Controller's Power Cable Disconnected alarm will come on. This is normal.
 - c. Pick up one of the charged batteries; locate the orange arrow on the battery. Make sure you pick up a charged battery rather than a depleted battery.

Powering the System 3

- d. Align the orange arrow on the charged battery with the orange arrow on the battery clip, so the arrows point toward each other (**Figure 3.62**).



Figure 3.62 Align Arrows and Then Insert the Battery in the Clip

- e. Slide the charged battery into the battery clip. The battery should "click" into place. Gently pull on the battery and try to remove it from the clip. If the battery is properly and fully inserted, the battery remains in the clip and the System Controller's Power Cable Disconnected alarm will stop.
 - f. Remove the other depleted battery and repeat Steps a–e.
9. Return the clips and charged batteries to holsters or carrying case.
 10. Make sure the Battery Charger is plugged in and turned on, and then place the depleted batteries in the pockets for recharging.

Wearing and Carrying HeartMate Batteries/Battery Clips

For warnings, cautions, and instructions on wearing and carrying HeartMate batteries, battery clips, and the System Controller, see *Wearing and Carrying the System Components* on page 6-28.

3 Powering the System

Taking Old Batteries Out of Service

One pair of new HeartMate 14 Volt Lithium-Ion batteries provides ten to twelve hours of support under nominal operating conditions (pump speed 12,000 rpm, flow 6.0 lpm, power 10 watts). See *Cleaning and Maintenance* on page 8-4 for information on cleaning and maintaining HeartMate 14 Volt Lithium-Ion batteries and battery clips.

HeartMate 14 Volt Lithium-Ion batteries last for less time if the patient is active or emotionally stressed. As batteries get older, they power the system for shorter periods of time. If a pair of HeartMate batteries does not give at least four hours of support, take both batteries out of service.

A new battery that is stored and used according to the acceptable environmental conditions should be usable for approximately 360 cycles or 36 months from the date of manufacture, whichever comes first. After this time, battery performance cannot be guaranteed. Call Abbott for a replacement when either of these milestones is reached. See *Storage and Transport* on page 8-3.

The white battery label on each battery contains several safety symbols and the battery's expiration date. The battery may need to be replaced earlier than the expiration date, depending on usage. Batteries should not be used after their expiration date. Dispose of expired batteries according to local, state, and federal regulations. See *Product Disposal* on page 8-10 for information on disposing of HeartMate batteries.

Caring for Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning for the most reliable performance. See *Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 8-7 for detailed information on inspecting and cleaning batteries and battery clips.

Switching Power Sources

Switching from the Power Module to Battery-Powered Operation

Use care when connecting or disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 7-45.

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 working, in-use Power Module with backup battery installed and connected
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips

TO SWITCH FROM THE POWER MODULE TO BATTERIES:

1. Place two battery clips, two charged batteries (as indicated by the green light on the Battery Charger), and the white and black Power Module patient cable connectors within easy reach.
2. Place the first charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.
3. Repeat Step 2 for the second battery and battery clip.
4. Unscrew the white System Controller and white Power Module patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
5. Put aside the white Power Module patient cable connector.
6. Promptly connect the battery clip connector to the white System Controller power cable connector (**Figure 3.63**). The alarm will stop when the white System Controller power cable is connected.

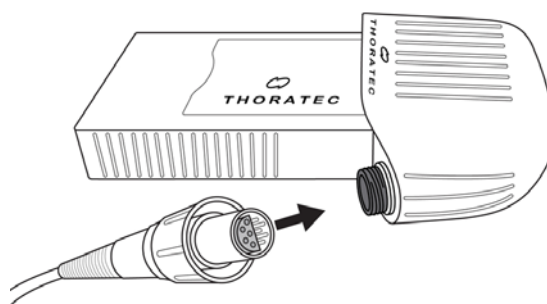


Figure 3.63 Connect the System Controller Power Cable Connector to the Battery Clip Connector

7. Unscrew the black System Controller and black Power Module patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
8. Put aside the black Power Module patient cable connector.

3 Powering the System

9. Promptly connect the battery clip connector to the black System Controller power cable connector. The alarm will stop when the black System Controller power cable is connected.
10. Place the batteries and battery clips into the holsters or carrying case.
11. If you are removing the Power Module from use, keep the Power Module patient cable connected to or near the Power Module until next use.
12. Place at least two additional charged batteries in the travel case.

IMPORTANT! If the Power Module patient cable remains connected to the Power Module when not in use, place the cable where it will not become damaged, dirty, or wet, and so it will not cause tripping or falling.

Switching from the Mobile Power Unit to Battery-Powered Operation

Use care when connecting or disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 7-45.

FOR THIS TASK YOU NEED:

- 1 running System Controller
- 1 working, in-use Mobile Power Unit with batteries installed
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries
- 2 14 Volt battery clips

TO SWITCH FROM THE MOBILE POWER UNIT TO BATTERIES:

1. Place two battery clips, two charged batteries (as indicated by the green light on the Battery Charger), and the white and black Mobile Power Unit patient cable connectors within easy reach.
2. Place the first charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place.
3. Repeat Step 2 for the second battery and battery clip.
4. Unscrew the white System Controller and white Mobile Power Unit patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
5. Put aside the white Mobile Power Unit patient cable connector.

6. Promptly connect the battery clip connector to the white System Controller power cable connector (**Figure 3.64**). The alarm will stop when the white System Controller power cable is connected.

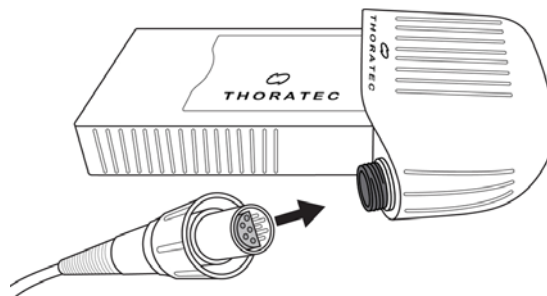


Figure 3.64 Connect the System Controller Power Cable Connector to the Battery Clip Connector

7. Unscrew the black System Controller and black Mobile Power Unit patient cable connectors. The Power Cable Disconnected alarm will come on. This is normal.
8. Put aside the black Mobile Power Unit patient cable connector.
9. Promptly connect the battery clip connector to the black System Controller power cable connector. The alarm will stop when the black System Controller power cable is connected.
10. Place the batteries and battery clips into the holsters or carrying case.
11. Place at least two additional charged batteries in the travel case.

IMPORTANT! When not in use, place the Mobile Power Unit where it will not become damaged, dirty, or wet, and so it will not cause tripping or falling.

3 Powering the System

Switching from Battery Power to the Power Module

Use care when connecting or disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 7-45.

FOR THIS TASK YOU NEED:

- 1 running System Controller on 14 Volt Lithium-Ion battery power
- 1 functioning Power Module
- Functioning and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use and not controlled by a wall switch
- 1 AC power cord to connect to an AC electrical power outlet
- 1 Battery Holster or other wear and carry accessory

TO SWITCH FROM BATTERIES TO THE POWER MODULE:

1. Confirm that the Power Module is plugged into a functioning and grounded (3-prong) AC electrical outlet that is dedicated to Power Module use and is not controlled by a wall switch.

IMPORTANT! Do not use an adapter plug for ungrounded wall outlets. Do not use a portable, multiple outlet (power strip) adapter. Using adapters or power strips may give you or the patient an electric shock or cause the pump to stop.

2. Perform a Power Module self test (see *Performing a Power Module Self Test* on page 3-19).
3. If the Power Module fails the test, please contact Abbott; otherwise, continue with Step 4.
4. Line up the red dot on the patient cable with the red dot near the “heart” socket (♥) on the Power Module, and then insert the Power Module patient cable into the socket (**Figure 3.65**). The cable clicks into place when fully engaged in the socket.



Figure 3.65 Align the Red Dots

Powering the System 3

5. Tug gently on the black strain relief portion of the connector to confirm that the connection is tight. See **Figure 3.66**.

IMPORTANT! Do not pull on the cable!

Grasp here to
check connection



Figure 3.66 Tug on the Black Strain Relief Portion to Check the Connection

6. Place the black and white Power Module patient cable connectors and System Controller power cable connectors within reach.
7. Remove the battery clips and attached batteries from the patient's holsters or carrying case.
8. Check the charge status of each battery—press the battery power gauge on each battery to determine which battery has the least power (see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-49).
9. If one battery has less charge, start with that battery and disconnect the connector from the battery; otherwise, disconnect the white connector first.
10. Unscrew the white connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
11. Put aside the battery clip and attached battery.
12. Connect the white Power Module patient cable connector to the white System Controller power cable connector. The alarm will stop.
13. Unscrew the black connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
14. Put aside the battery clip and attached battery.
15. Connect the black Power Module patient cable connector to the black System Controller power cable connector. The alarm will stop.
16. Press the battery release button on one of the battery clips to release its battery.
17. Repeat Step 16 for the second battery.

3 Powering the System

18. The System Controller is now connected to the Power Module, and the Power Module is powering the system. Store the battery clips in a clean, dry location until next use.
19. Place the depleted batteries into the Battery Charger for charging (see *Charging HeartMate Batteries* on page 3-73).

Switching from Battery Power to the Mobile Power Unit

Use care when connecting or disconnecting power cables. For more information, see *Guidelines for Power Cable Connectors* on page 7-45.

FOR THIS TASK YOU NEED:

- 1 running System Controller on 14 Volt Lithium-Ion battery power
- 1 functioning Mobile Power Unit
- Functioning AC electrical outlet that is dedicated to Mobile Power Unit use and not controlled by a wall switch
- 1 AC power cord to connect to an AC electrical power outlet
- 1 Battery Holster or other wear and carry accessory

TO SWITCH FROM BATTERIES TO THE MOBILE POWER UNIT:

1. Confirm that the Mobile Power Unit is plugged into a functioning AC electrical outlet that is dedicated to Mobile Power Unit use and is not controlled by a wall switch. Do not use a portable, multiple outlet (power strip) adapter.
2. Place the black and white Mobile Power Unit patient cable connectors and System Controller power cable connectors within reach.
3. Remove the battery clips and attached batteries from the patient's holsters or carrying case.
4. Check the charge status of each battery—press the battery power gauge on each battery to determine which battery has the least power (see *Checking Battery Charge Status Using the On-Battery Power Gauge* on page 3-49).
5. If one battery has less charge, start with that battery and disconnect the connector from the battery; otherwise, disconnect the white connector first.
6. Unscrew the white connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
7. Put aside the battery clip and attached battery.
8. Connect the white Mobile Power Unit patient cable connector to the white System Controller power cable connector. The alarm will stop.
9. Unscrew the black connector from its battery clip. The Power Cable Disconnected alarm will come on. This is normal.
10. Put aside the battery clip and attached battery.

11. Connect the black Mobile Power Unit patient cable connector to the black System Controller power cable connector. The alarm will stop.
12. Press the battery release button on one of the battery clips to release its battery.
13. Repeat Step 12 for the second battery.
14. The System Controller is now connected to the Mobile Power Unit, and the Mobile Power Unit is powering the system. Store the battery clips in a clean, dry location until next use.
15. Place the depleted batteries into the Battery Charger for charging (see *Charging HeartMate Batteries* on page 3-73).

3 Powering the System

Battery Charger Overview

The Battery Charger (**Figure 3.67**) is designed to charge the HeartMate 14 Volt Lithium-Ion batteries that are used to power the HeartMate II Left Ventricular Assist System during battery-powered operation. Specifically, the Battery Charger can:

- Charge up to four batteries in four hours or less (see *Charging HeartMate Batteries* on page 3-73).
- Monitor the need for calibration, and calibrate individual batteries (see *Calibrating HeartMate 14 Volt Lithium-Ion Batteries* on page 3-76).
- Perform diagnostic testing on up to four batteries at a time (see *Using the Charger to Check Battery Power* on page 3-78).



Figure 3.67 Battery Charger

WARNING !

- 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 different from the outlet used to power the Battery Charger.

WARNING ! (Continued)

- To avoid the risk of electric shock, the Battery Charger must only be plugged 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.
- Keep the Battery Charger dry and away from water or liquid. If the Battery Charger comes in contact with water or liquid, it may fail to operate properly or you may get an electric shock.
- 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.
- Be sure to use only equipment and supplies that are authorized by Abbott. If you use unauthorized parts, potential interference may occur between the Battery Charger and other devices.
- Do not touch the metal contacts inside the Battery Charger when the charger is connected to AC power and turned on, or you may get an electric shock.
- If traveling by aircraft, the patient should be instructed to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.

3 Powering the System

CAUTION !

- Use only the Abbott-supplied Battery Charger to charge HeartMate 14 Volt Lithium-Ion batteries. Other battery chargers may damage HeartMate batteries.
- 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 Abbott.
- Make sure the Battery Charger is plugged in and turned on ("I") before placing batteries into the pockets for charging.
- After approximately 70 uses, HeartMate 14 Volt Lithium-Ion batteries may need to be recalibrated. The Battery Charger indicates when a battery needs to be 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 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). See *Calibrating HeartMate 14 Volt Lithium-Ion Batteries* on page 3-76.

Setting Up the Battery Charger Before Use

Before using the Battery Charger to charge HeartMate batteries, it must be plugged in and turned on. The display panel on the front of the charger displays messages during setup and operation. See *Selecting Language Display Mode* on page 3-71 for instructions on selecting the language/display mode that best meets your patient's needs.

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SET UP THE BATTERY CHARGER:

1. If not already unpacked, carefully remove the charger from its packaging. Place the Battery Charger on a flat, sturdy surface.
2. Inspect the Battery Charger for dents, chips, cracks, or other signs of damage. Do not use a Battery Charger that seems damaged. Contact Abbott for a replacement, if needed.

Powering the System **3**

3. Examine the four battery charging pockets. Make sure the pockets are clean and empty (no batteries), and free of dust or debris.
4. Pay particular attention to the metal contacts inside the pockets. Dirt or objects covering the metal contacts inside the pockets may prevent proper battery charging, which can affect battery performance.
5. Obtain the grey AC power cord from the product packaging.
6. Plug the female end of the power cord into the power entry module on the rear of the charger (**Figure 3.68**).



Figure 3.68 Plug the Power Cord Into the Battery Charger

3 Powering the System

7. Plug the Battery Charger into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Battery Charger use. Do not use an outlet that is controlled by a wall switch. Do not use an adapter plug for an ungrounded wall outlet. Do not use portable, multiple outlet (power strip) adapters.

IMPORTANT! If the patient will travel internationally, the patient will need an Abbott 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. Contact Abbott for a power cord, if needed. For Abbott contact information, see the *Back Cover* of this manual.

8. Turn on the Battery Charger by pressing the on/off switch on the rear of the charger from the off ("O") to the on ("I") position. When the Battery Charger is turned on, all lights on the front panel turn on (**Figure 3.69**). The charger beeps once and performs a self test. The self test takes about 10 seconds.



Figure 3.69 Display Panel During Battery Charger Self Test

9. After a successful self test, all lights turn off and "HeartMate CHARGER" appears on the display panel (**Figure 3.70**). The charger is ready for use.



Figure 3.70 "HeartMate CHARGER" Screen on the Battery Charger

OR

10. If the charger detects a problem, an error message appears on the display panel and/or the lights and beep are not performed as described above. If an error message appears, or the lights or beep are missing or do not perform as described, see *Battery Charger Alarms* on page 7-42 for how to respond to advisory messages (**Figure 3.71**).



Figure 3.71 Sample Error Message

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

Selecting Language Display Mode

The display panel screen has two language display modes:

- Graphic Symbols
- English Text

Selecting the Language Display Mode Before Using the Charger for the First Time

Graphic Symbols is the default display mode. You can change the language display mode from Graphic Symbols to English Text.

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SELECT THE LANGUAGE DISPLAY MODE BEFORE USING THE BATTERY CHARGER:

- Unpack and plug in the Battery Charger; however, do not turn on the charger at this time.
- Press and hold buttons 1 and 3 on the front panel of the charger (**Figure 3.72**), and at the same time, press the power switch to the "on" position.



Figure 3.72 Press and Hold Buttons 1 and 3 to Change the Display Mode

- After "English" appears on the display (**Figure 3.73**), release buttons 1 and 3.



Figure 3.73 English Text Display

3 Powering the System

4. To set English Text as the desired display mode, press and release the 1 button.

OR

5. To set Graphic Symbols as the desired display mode, press and release the 2 button, scroll down to Graphic, and then press and release button 1.

IMPORTANT! After releasing the button, the charger conducts a self test. If the test is successful, "HeartMate CHARGER" appears on the screen.

Selecting the Language Display Mode After Startup

FOR THIS TASK YOU NEED:

- 1 Battery Charger
- 1 grey AC power cord to connect to an AC electrical power outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch

TO SELECT THE LANGUAGE DISPLAY MODE AFTER STARTUP:

1. Remove all batteries from the charging pockets.
2. Turn off the charger by pressing the on/off switch from the on ("I") to the off ("O") position.
3. Do not unplug the Battery Charger.
4. Press and hold buttons 1 and 3 on the front panel of the charger, and press the power switch to the on ("I") position.
5. After the display panel lights up, release buttons 1 and 3. The charger powers up.
6. Use the 2 button to scroll down to the desired display mode.
7. When the desired display mode appears, press and release the 1 button.

IMPORTANT! The charger conducts a self test. If the test is successful, "HeartMate CHARGER" appears on the screen.

Charging HeartMate Batteries

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

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

HeartMate 14 Volt Lithium-Ion batteries use a "smart" technology that measures available battery power and counts battery usage/charge cycles. When a battery is placed in a charging pocket (**Figure 3.74**), the charger immediately checks the battery's status by reading the battery's on-board computer chip.



Figure 3.74 Batteries Inserted into Battery Charger Pockets

To view information about the battery's available power and total number of use/charge cycles on the charger's display panel, press the number button for that pocket (see *Using the Charger to Check Battery Power* on page 3-78). Depending on the status of the battery, one of three lights (green, yellow, or red) located next to the pocket is illuminated (**Figure 3.75**).



Figure 3.75 Charge Status Lights (Green, Yellow, Red) for Pockets 1 through 4

3 Powering the System

A green light means the battery is charged and ready for use. A steady yellow light means the battery is actively charging. A red light means the battery is defective or the charger has a problem. See **Table 3.5** for a complete description of charger pocket light color codes.

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

Table 3.5 Color Codes for Charger Pocket Lights

FOR THIS TASK YOU NEED:

- 1 functioning Battery Charger
- 1 grey AC power cord to connect to an AC electrical outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch
- Up to 4 HeartMate 14 Volt Lithium-Ion batteries

TO CHARGE 14 VOLT LITHIUM-ION BATTERIES:

1. Place a battery into one of the four battery charging pockets, so the battery power gauge is at the top and facing forward (**Figure 3.76**).



Figure 3.76 Battery Charger with Batteries Inserted in All Pockets

IMPORTANT! 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 is illuminated (green, yellow, or red).

2. Identify which light (green, yellow, or red) comes on for the pocket:
 - Green light—The battery is charged and ready for use. Either remove the battery for immediate use, or leave the battery in the pocket until needed. Leaving a charged battery in the charger will not damage it.
 - Yellow light—The battery is actively charging. Leave the battery in the pocket to continue charging. 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—See *Calibrating HeartMate 14 Volt Lithium-Ion Batteries* on page 3-76.
 - 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 Abbott for a replacement, if needed. See *Battery Charger Alarms* on page 7-42 for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on.
3. After approximately four hours, check the lights for the charging pocket for the battery.
 - If the green light is on, the battery is charged and ready for use.
 - If the yellow light is on, the battery is still charging.
 - If the red light is on, the battery has a problem or the charger interrupted the charging cycle for some reason. See *Battery Charger Alarms* on page 7-42 for how to handle red light conditions.
4. Repeat Steps 1–3 for up to three more batteries.

IMPORTANT! Avoid covering or blocking the vents on the top of the charger during use. Covering or blocking the vents may affect performance.

3 Powering the System

Calibrating HeartMate 14 Volt Lithium-Ion Batteries

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

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

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

- The yellow light for the pocket blinks.
- A split battery symbol and the pocket number for the battery flashes on the charger display panel (**Figure 3.77**). The circled number switches between a filled and unfilled circle as the display panel screen flashes.



Figure 3.77 Calibration Prompt (in Graphic Mode) Indicates that the Battery in Pocket 4 Needs Calibration

You can calibrate a battery when prompted, or wait for a more convenient time, such as at night or when the patient is sleeping and using the Power Module or Mobile Power Unit for power.

FOR THIS TASK YOU NEED:

- 1 functioning Battery Charger
- 1 grey AC power cord to connect to an AC electrical outlet
- Functioning and grounded (3-prong) AC electrical outlet that is not controlled by a wall switch
- 1 HeartMate 14 Volt Lithium-Ion battery that needs to be calibrated

TO CALIBRATE THE BATTERY WHEN PROMPTED:

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

IMPORTANT! During calibration, the yellow light for this pocket remains on and "HeartMate CHARGER" appears on the display panel screen. If you press the number button for this pocket while the battery is being calibrated, the calibration status screen appears (**Figure 3.78**). When calibration is complete, the yellow light turns off and the green light comes on, indicating that the battery is charged and ready for use.



Figure 3.78 Calibration Status Screen Indicating that Battery in Pocket 4 is Being Calibrated

TO CHARGE THE BATTERY NOW (AND CALIBRATE THE BATTERY AT A FUTURE TIME):

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

IMPORTANT! It is acceptable to charge and reuse the battery, but you should calibrate it as soon as possible.

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 do remove a battery before calibration is complete, be sure to recharge and check the battery before using it. If you remove a battery before calibration ends, the battery may be depleted (use the on-battery power gauge to check the battery charge status).

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

Using the Charger to Check Battery Power

You can use the Battery Charger to check the status of a battery. To check a battery's charge status, place the battery into a charging pocket, and then press and release the number button for that pocket. The following information appears on the charger display panel (**Figure 3.79**):

- 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.

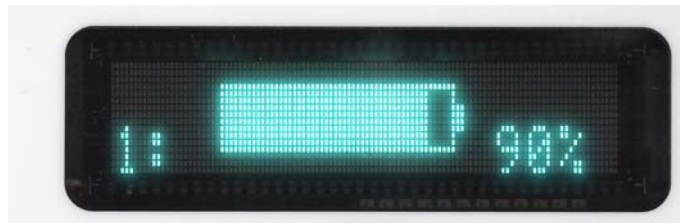


Figure 3.79 View Battery Charge Level on Battery Charger (this example shows 90% charge)

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

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

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

Care and Maintenance of the Battery Charger

The Battery Charger requires periodic inspection and cleaning for the best possible performance. For detailed information on inspecting and cleaning the Battery Charger, see *Safety Checklists* on page F-1.

CAUTION !

Service and maintenance of the Battery Charger should be performed only by Abbott-trained personnel.

IMPORTANT! The hospital contact is responsible for coordinating annual inspection and maintenance of the Battery Charger after the patient leaves the hospital.

Disposing of the Battery Charger

See *Product Disposal* on page 8-10 for information about disposing of the Battery Charger.

3 Powering the System

HEARTMATE TOUCH™ COMMUNICATION SYSTEM

This section describes how to use the HeartMate Touch™ Communication System to program and monitor the HeartMate II Left Ventricular Assist System.

Overview - - - - -	-4-3
Set Up the HeartMate Touch™ Communication System- - - - -	-4-8
Connect the HeartMate Touch™ Wireless Adapter to the Tablet for use with the HeartMate Touch App - - - - -	-4-12
Interface Overview - - - - -	-4-21
HeartMate Touch™ App Views - - - - -	-4-23
Settings Panel - - - - -	-4-25
Alarms - - - - -	-4-42
Pump Parameters - - - - -	-4-51
Monitor View - - - - -	-4-55
Clinical View - - - - -	-4-56
Historical View - - - - -	-4-62

HeartMate Touch™ Communication System 4

Overview

The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to provide a detailed, large-scale display of system performance. Using the HeartMate Touch Communication System, clinicians can also enter and change operating parameters and system settings. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. The tablet should be placed on a stable surface. The HeartMate Touch Communication System is shown on top of the Power Module (**Figure 4.2**).

The HeartMate Touch Communication System must be connected to the Power Module through a Bluetooth® pairing to the HeartMate Touch™ Wireless Adapter. In addition, the Power Module must be connected to the System Controller. These connections allow the transfer of System Controller data through the Power Module for display on the tablet display screen. The wireless communication range with the HeartMate Touch Wireless Adapter is up to 5 meters (16.40 feet). The HeartMate Touch Communication System should only be used when in direct view of the patient.

The Tablet for use with the HeartMate Touch App (**Figure 4.1**) is used to:

- Closely monitor system operation during Left Ventricular Assist Device implant.
- Display information about system performance, including pump flow, pump speed, and overall operational status.
- Program system parameters, such as pump speed.
- Assess and track alarm conditions.
- View and save performance data.
- Record data at specific intervals to download for review and analysis.

4 HeartMate Touch™ Communication

IMPORTANT! For a getting started guide to using the HeartMate Touch Communication System and a troubleshooting guide see the HeartMate Touch Communication System Quick Start Guide.



Figure 4.1 Tablet for use with the HeartMate Touch App



Figure 4.2 HeartMate Touch™ Communication System on top of the Power Module

HeartMate Touch™ Communication System 4

Required Components

HeartMate Touch™ App. The HeartMate Touch App provides clinicians with the ability to wirelessly monitor a patient's HeartMate system, program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data. Its use during Left Ventricular Assist Device implantation is required.



Tablet for use with the HeartMate Touch™ App. The tablet deployed with HeartMate Touch App serves as the screen display and is installed in a protective case.



HeartMate Touch™ Wireless Adapter. The HeartMate Touch Wireless Adapter facilitates Bluetooth® pairing, when it is connected to the Power Module. The wireless communication range with the HeartMate Touch Wireless Adapter is up to 5 meters (16.40 feet). Every HeartMate Touch Wireless Adapter has its unique ID number, to ensure correct pairing.



Power Adapter and USB cable. The Power Adapter and 2-meter (6.56 feet) USB cable with Lightning† connector are used to charge the tablet from a power outlet.



Flash Drive. The Flash Drive has a Lightning connector and USB connector. The Flash Drive is used for exporting, transferring, and storing data generated from the HeartMate Touch App.



4 HeartMate Touch™ Communication

WARNING !

- Do not disconnect the Power Module patient cable from the Power Module when troubleshooting for a "Connection lost to HeartMate II Controller" notification on the HeartMate Touch™ App.
- Do not disconnect the System Controller power cable connectors from the Power Module when troubleshooting a "Connection lost to HeartMate II Controller" notification on the HeartMate Touch App.
- To prevent system component damage and personal injury, refer any servicing of HeartMate Left Ventricular Assist System equipment to Abbott-trained service personnel only.
- The HeartMate Touch System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

CAUTION !

- Use of equipment and supplies, other than those specified in this manual or sold by Abbott for replacement parts, may affect the electromagnetic compatibility of the Left Ventricular Assist System with other devices, resulting in potential interference between the Left Ventricular Assist System and other devices.
- If the Tablet for use with the HeartMate Touch App is mounted on top of the Power Module, do not attempt to lift or carry the two components. Doing so may damage the Power Module and/or Tablet for use with the HeartMate Touch App.
- Pump flow is estimated from pump power. Under abnormal conditions this may result in an overestimation of pump flow or an undisplayed pump flow reading (see *Pump Flow* on page 4-52).
- Pump flow readings will vary with changes in blood viscosity.
- No single parameter is a surrogate for monitoring the clinical status of the patient, and the changes in all parameters should be considered when assessing any clinical situation.
- Keep the Power Module 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 Power Module may fail to operate properly.
- Use the HeartMate Touch Communication System only when in the direct view of the patient.

HeartMate Touch™ Communication System **4**

The HeartMate Touch Wireless Adapter contains a radio transmitter/receiver with the following parameters.

Radio transmitter/receiver parameters:

- Frequency (range): 2.402 to 2.480 GHz
- Channels: 40 logical channels using Adaptive Frequency Hopping (AFH)
- Bandwidth: 2 MHz
- Modulation: Gaussian Frequency Shift Keying (GFSK)
- Effective Radiated Power (ERP): +5.53 dBm (3.45 mW) maximum

4 HeartMate Touch™ Communication

Set Up the HeartMate Touch™ Communication System

Set Up the HeartMate Touch™ Wireless Adapter

FOR THIS TASK YOU NEED:

- 1 Power Module with an installed backup battery. The Power Module must be connected to a functioning and grounded (3-prong) AC electrical outlet dedicated to Power Module use and is not 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.
- 1 Tablet for use with the HeartMate Touch™ App
- 1 HeartMate Touch™ Wireless Adapter
- 1 Tablet Power Adapter and Cable
- 1 Patient Cable, attached to the Power Module

TO SET UP THE HEARTMATE TOUCH WIRELESS ADAPTER FOR USE WITH THE POWER MODULE:

1. Power on the Power Module. See *Using the Power Module* on page 3-4 for instructions.
2. Observe the front panel of the Power Module. The green "Power On" light should illuminate. If the light does not illuminate, the device may be defective. Do not use a defective device. Contact Abbott for a replacement, if needed. See **Figure 4.3**.

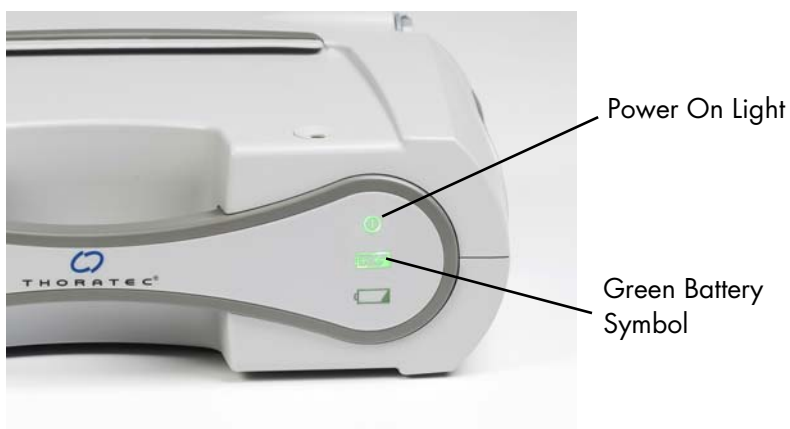


Figure 4.3 Power On and Battery Symbols are Green — Power Module is Ready for Use

HeartMate Touch™ Communication System 4

3. Gently press inward on the Power Module retention clip to disengage the clip ends from the slots on the Power Module (**Figure 4.4**).



Figure 4.4 Disengage the Retention Clip

4. Slide the loop of the HeartMate Touch Wireless Adapter tether onto the retention clip.



Figure 4.5 Loop Tether on Retention Clip

4 HeartMate Touch™ Communication

5. With the tether still attached, lift the power cord retention clip into the locked position.
6. Insert the two ends of the clip into the slots. Ensure the clips are securely engaged (**Figure 4.6**).



Figure 4.6 Insert Clip Ends into Slots

7. Insert the HeartMate Touch Wireless Adapter into the socket located on the side of the Power Module (**Figure 4.7**) above the Power Module power cord.



Figure 4.7 Insert the HeartMate Touch™ Wireless Adapter into the Power Module Socket

HeartMate Touch™ Communication System 4

Note: The HeartMate Touch Wireless Adapter light displays a white light for 1 second upon connection (**Figure 4.8**).



Figure 4.8 Adapter Light Flashes White

4 HeartMate Touch™ Communication

Connect the HeartMate Touch™ Wireless Adapter to the Tablet for use with the HeartMate Touch App

CAUTION !

The Tablet for use with the HeartMate Touch App should have its AC power adapter connected to an AC electrical power outlet during the surgical procedure.

1. To turn on the tablet, press and hold the top button until the logo appears.

IMPORTANT! Keep the Wi-Fi and software automatic updates turned off in the Tablet for use with HeartMate Touch App. Follow Abbott's instructions regarding when to connect to Wi-Fi and the process for maintaining approved software. Installing iOS updates without Abbott notification may impact product use. If you have any questions, contact your local Abbott representative at any time.

Note: Before launching the HeartMate Touch App, setup the Table (in Settings) for the specific region, time zone, the language and time format that the Tablet is going to be used. Date and time display may vary and is dependent on your Settings and HeartMate Touch App language selected. Date and time displayed in the header (**Figure 4.9**) may also vary and is dependent on your Settings. Header format and content is subject to change.



Figure 4.9 Header

2. Tap  to launch the HeartMate Touch™ App.
3. Tap the **Language** drop-down to select a language that matches the language for the Table (in the Settings). A language change confirmation message appears.

HeartMate Touch™ Communication System 4

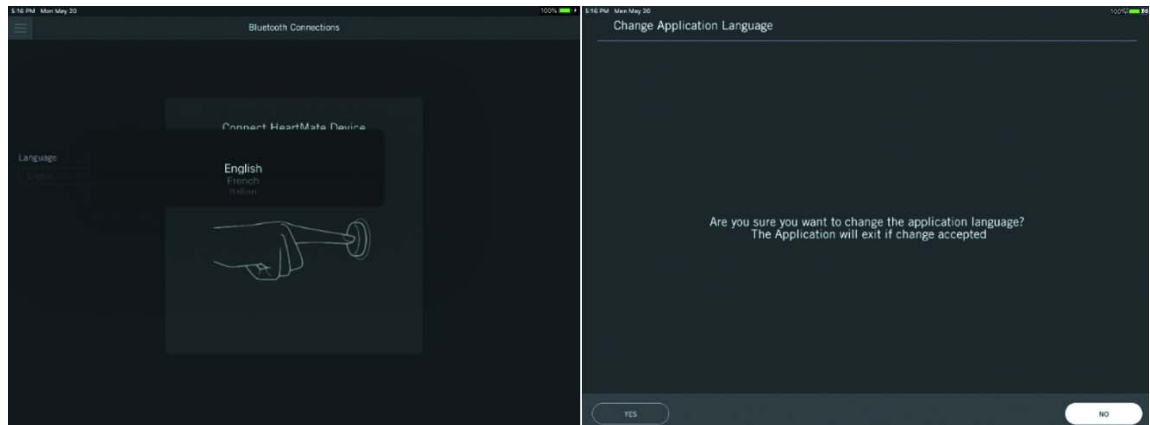


Figure 4.10 Select a Language / Confirm

4. Tap **YES**. The HeartMate Touch App closes.
5. Tap  to launch the HeartMate Touch™ App. Press and hold the button on the HeartMate Touch Wireless Adapter.

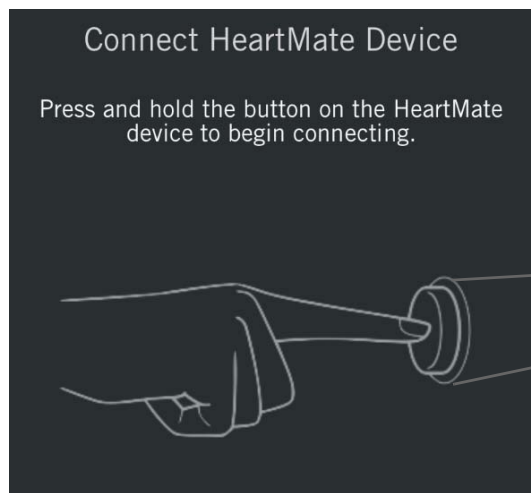


Figure 4.11 Turn on Bluetooth® Wireless Technology

4 HeartMate Touch™ Communication

A blinking blue light appears. See *HeartMate Touch™ Wireless Adapter Status* on page 4- 19 for more information regarding the HeartMate Touch™ Wireless Adapter status.

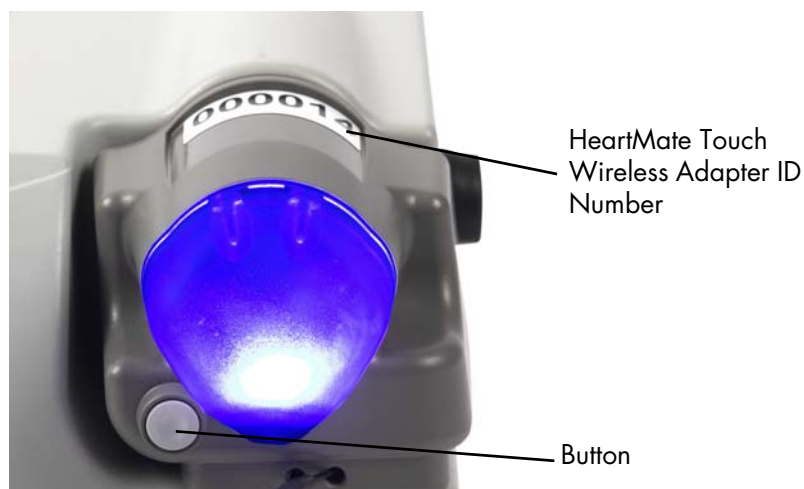


Figure 4.12 HeartMate Touch™ Wireless Adapter Button

The HeartMate Touch App displays the available HeartMate Touch Wireless Adapters(s) chronologically from top to bottom.

6. Read the HeartMate Touch Wireless Adapter ID and match it to the available HeartMate Touch Wireless Adapters displayed on the screen. Tap **Connect** to connect to the HeartMate Touch Wireless Adapter.

CAUTION !

Select the Adapter ID number that matches the number on the HeartMate Touch Wireless Adapter label.



Figure 4.13 Select a Wireless Device

HeartMate Touch™ Communication System 4

Note: If the HeartMate Touch Wireless Adapter that you intend to connect to is not listed, check that the HeartMate Touch Wireless Adapter is ready to connect (e.g., displays a blinking blue light) and tap **Refresh** (⌂).

7. Enter the HeartMate Touch Wireless Adapter code displayed on the screen in the Bluetooth® Pairing Request field.

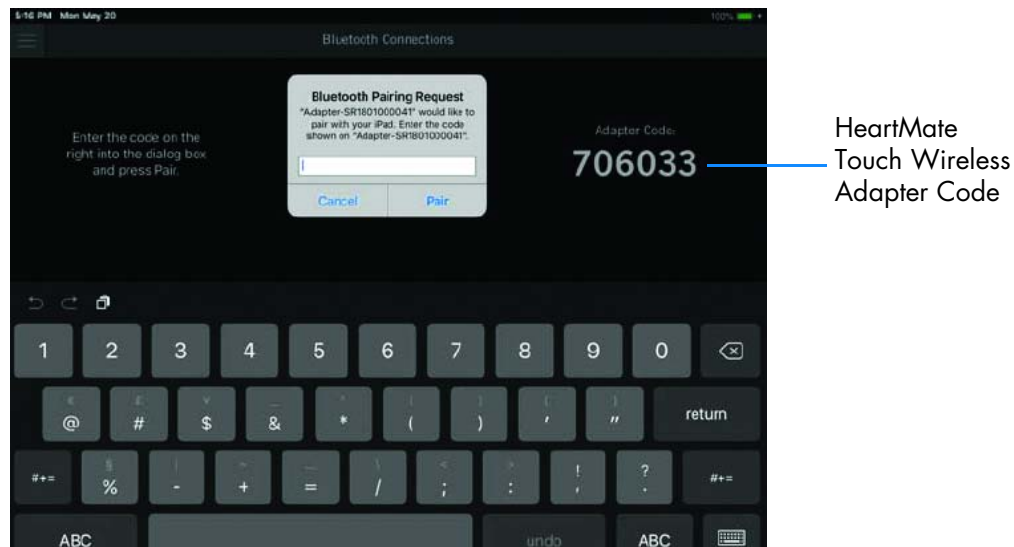


Figure 4.14 Passcode

8. Tap **Pair**.

Note: The passcode is for first time pairing of a HeartMate Touch Wireless Adapter to the tablet only.

Note: If the HeartMate Touch Wireless Adapter is not paired within 30 seconds, the connection process (pair) will be canceled.

9. Connect the System Controller to the Power Module and then wait for **CONTINUE** to become active (⏻).

Note: It may take a few seconds after the System Controller is connected for **CONTINUE** to become active.

4 HeartMate Touch™ Communication

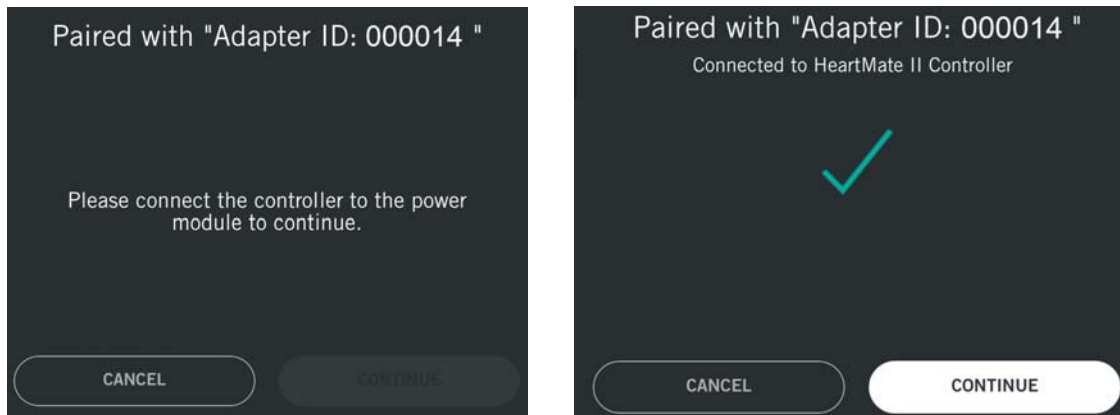


Figure 4.15 Connected to HeartMate II Controller

10. Confirm the ID number before moving on to the next step.
 - a. Confirm that the HeartMate Touch Wireless Adapter ID number displayed matches the number on the HeartMate Touch Wireless Adapter label. If the displayed ID number does not match, tap **CANCEL** and restart the connection process.

WARNING !

Confirm that the HeartMate Touch Wireless Adapter ID number displayed matches the number on the HeartMate Touch Wireless Adapter label. If the displayed HeartMate Touch Wireless Adapter ID number does not match, you are not connected to the correct HeartMate device. Tap **CANCEL** and restart the connection process.

HeartMate Touch™ Communication System 4

11. Create a name for this session and tap **Done**.

IMPORTANT! Only create names that identify the session. Do not enter any protected health information or individually identifiable health information. Follow your organization's policies, procedures, and employee training that correspond to HIPAA regulatory standards.

IMPORTANT! You should restrict the characters to a through z, 0 through 9, underscores (_), and periods (.).

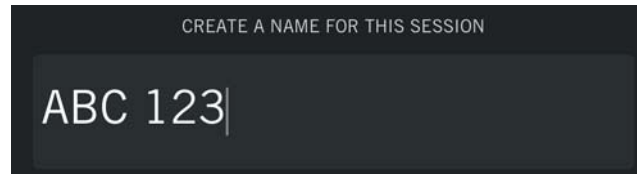


Figure 4.16 Create a Session Name

12. The HeartMate Touch App displays the Monitor view. The session name appears at the top of the view.

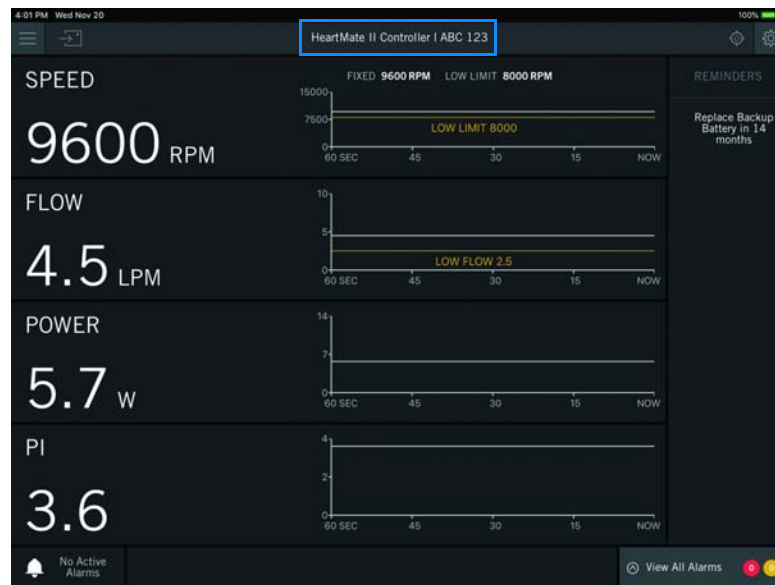


Figure 4.17 Monitor View

4 HeartMate Touch™ Communication

Disconnect

TO DISCONNECT THE HEARTMATE TOUCH™ WIRELESS ADAPTER FROM THE HEARTMATE TOUCH™ COMMUNICATION SYSTEM:

1. Tap **Menu** (☰).

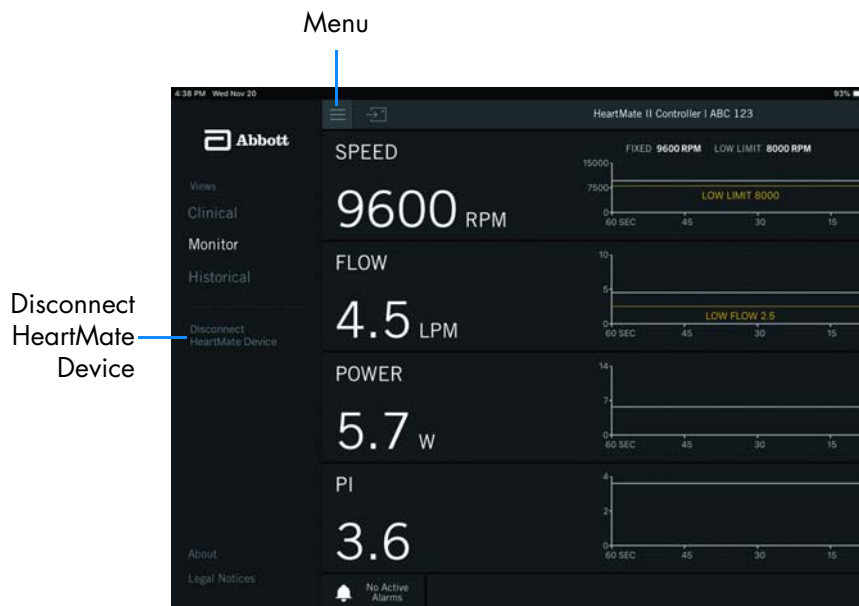


Figure 4.18 Menu Panel

2. Tap **Disconnect HeartMate Device**. A confirmation message appears asking you to confirm.
3. Tap **YES** to disconnect the HeartMate Touch™ App from the HeartMate Touch Wireless Adapter.

TO DISCONNECT THE HEARTMATE TOUCH WIRELESS ADAPTER FROM THE POWER MODULE:

1. Gently press inward on the Power Module retention clip until one side of the clip is disengaged.
2. Slide the loop of the HeartMate Touch Wireless Adapter tether off the retention clip.
3. Lock the retention clip into its original position.
4. Remove the HeartMate Touch Wireless Adapter from the socket located on the side of the Power Module.

HeartMate Touch™ Communication System 4

HeartMate Touch™ Wireless Adapter Status

When the HeartMate Touch™ Wireless Adapter is connected to the Power Module the HeartMate Touch Wireless Adapter light will illuminate to indicate its operating status. The HeartMate Touch Wireless Adapter status conditions are shown below.

Powered On. The HeartMate Touch Wireless Adapter will illuminate a solid white light for 1 second upon connection to the Power Module.



Figure 4.19 Solid White Light for 1 Second

Standby Mode. The HeartMate Touch Wireless Adapter is in standby mode and is not yet wirelessly connected to the HeartMate Touch App.



Figure 4.20 Light is Off

Ready to Connect. After pressing and holding the round button, the HeartMate Touch Wireless Adapter will illuminate a blinking blue light. This light indicates the HeartMate Touch Wireless Adapter is ready to accept a wireless connection to a HeartMate Touch App for up to 60 seconds. If the HeartMate Touch Wireless Adapter is not responding, change to a new HeartMate Touch Wireless Adapter.

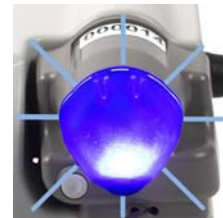


Figure 4.21 Blinking Blue Light

Connected. The HeartMate Touch Wireless Adapter will illuminate a solid blue light when it is connected to and communicating with the HeartMate Touch App.



Figure 4.22 Solid Blue Light

4 HeartMate Touch™ Communication

Locate. The HeartMate Touch Wireless Adapter will illuminate a blinking blue and white light when the HeartMate Touch App is locating and identifying the HeartMate Touch Wireless Adapter. The light will blink for up to 10 seconds.

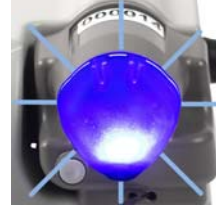


Figure 4.23 Blinking Blue and White Light

HeartMate Touch™ Communication System 4

Interface Overview

The regions discussed on this page are displayed in all views (Clinical, Monitor, Historical).



Figure 4.24 Global Navigation

1 Menu. Tap **Menu** (). You can then choose from these views: Clinical, Monitor, Historical. You can also disconnect the HeartMate Device.

2 Communication Icon. The flashing communication icon () indicates active communication between the System Controller and HeartMate Touch™ App. If the icon is not flashing or has disappeared, restart the connection. Refer to *Connect the HeartMate Touch™ Wireless Adapter to the Tablet for use with the HeartMate Touch App* on page 4-12.

3 Connected Device Information. Displays the session name.

4 Locate. Tap **Locate** () and the HeartMate Touch™ Wireless Adapter to which you are connected will blink blue and white. This feature helps identify the device to which you are connected.

5 Settings. Tap **Settings** () to access the Pump, Controller, and Backup Battery settings and information.

6 Alarm Silence. Displays the alarm silence status. You can also silence active alarms by tapping  **Silence Alarms**.

7 Alarm Status. Displays the top two active alarms.

4 HeartMate Touch™ Communication

8 View All Alarms. Tap **View All Alarms** to view a full list of active and inactive alarms.

HeartMate Touch™ Communication System 4

HeartMate Touch™ App Views

The HeartMate Touch™ Communication System touchscreen interface contains 3 views: Clinical, Monitor, Historical.

To select a view, tap **Menu** (☰) > **Clinical**, **Monitor**, or **Historical**.

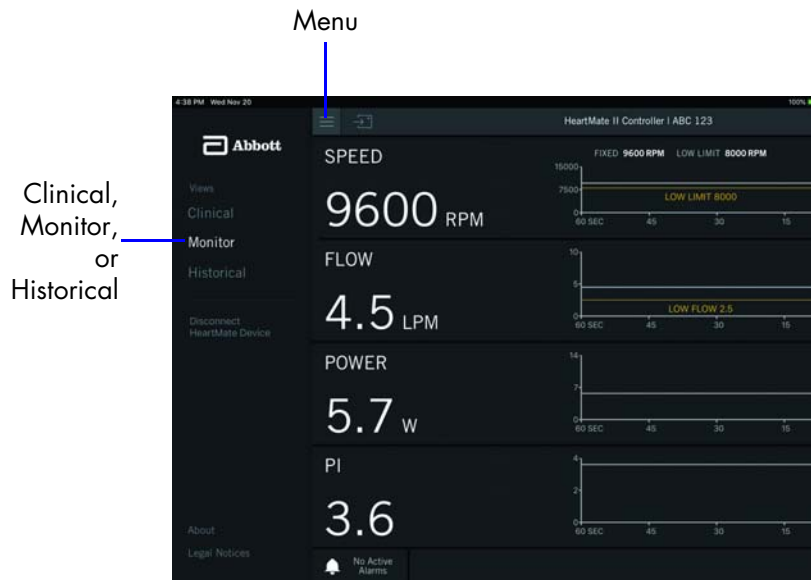


Figure 4.25 Menu > Clinical, Monitor, or Historical

Monitor View. The Monitor view is the default view displayed upon connection. It displays primary operating parameters (Speed, Flow, Power, and Pulsatility Index (PI)) with trendlines. The Monitor view also has a Reminders panel (right). The Reminders panel provides reminders such as when to replace the System Controller backup battery.

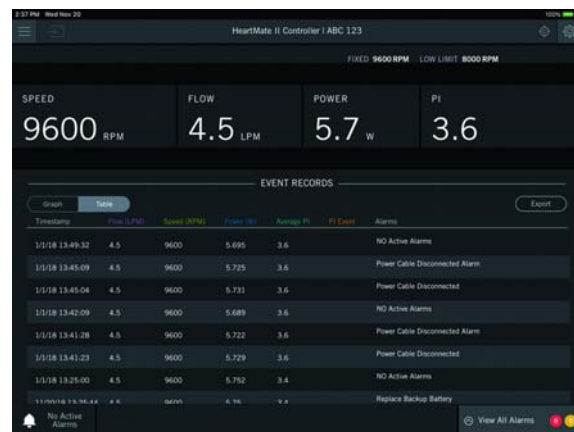


4 HeartMate Touch™ Communication

Clinical View. The Clinical view is intended to be used during the implant procedure. It is the only view with the ability to start, prime, and stop the pump. It displays the primary operating parameters (Speed, Flow, Power, PI) with trendline information for pump speed and flow.



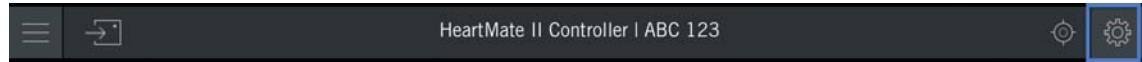
Historical View. The Historical view displays the event and periodic records that are stored in the System Controller. Primary operating parameters (Speed, Flow, Power, and PI) are shown at the top of the window without trendlines.



HeartMate Touch™ Communication System 4

Settings Panel

Tap **Settings** () to access the Settings panel. The Settings panel has three tabs: 1. Pump, 2. Controller, 3. Backup Battery.



Pump Tab

The Pump tab lets you view and set the pump settings.

CAUTION !

Verify that the HeartMate Touch™ Communication System is connected to the intended HeartMate LVAS when making changes to LVAS settings.

Fixed Speed. Sets the fixed speed for the pump. For more information, refer to *Fixed Speed* on page 4-26.

Low Speed Limit. Sets the low speed limit for the pump. For more information, refer to *Low Speed Limit* on page 4-30.

Graph Trendline Duration. Sets trendline duration for pump parameter settings. See *Graph Trendline Duration* on page 4-33 for more information.

4 HeartMate Touch™ Communication

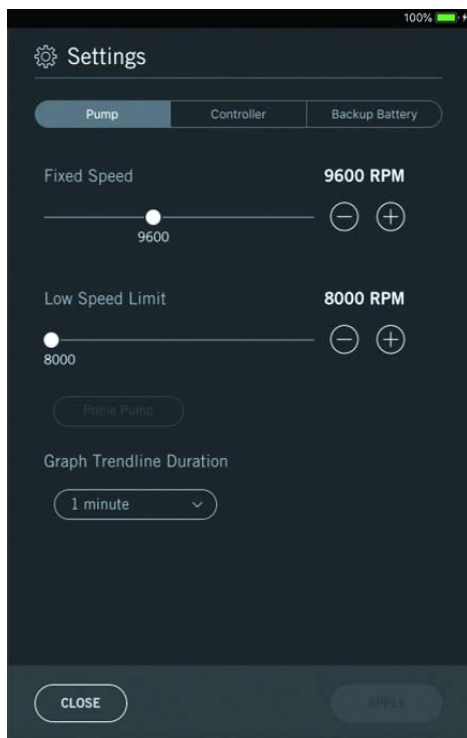


Figure 4.26 Pump Settings Panel

Fixed Speed

The fixed speed is adjustable in increments of 200 rpm, with a range of 6,000 to 15,000 rpm. A low speed advisory alarm appears if either the fixed speed has been set 200 rpm or more below the low speed limit, or the System Controller is unable to maintain the speed at or above the low speed limit. This low speed advisory alarm notification is always provided on the HeartMate Touch™ App (**Figure 4.33**).

Set the Fixed Speed

1. Tap **—** or **+** or move the slider to decrease or increase the fixed speed.
2. Tap **APPLY** to confirm changes.

HeartMate Touch™ Communication System 4

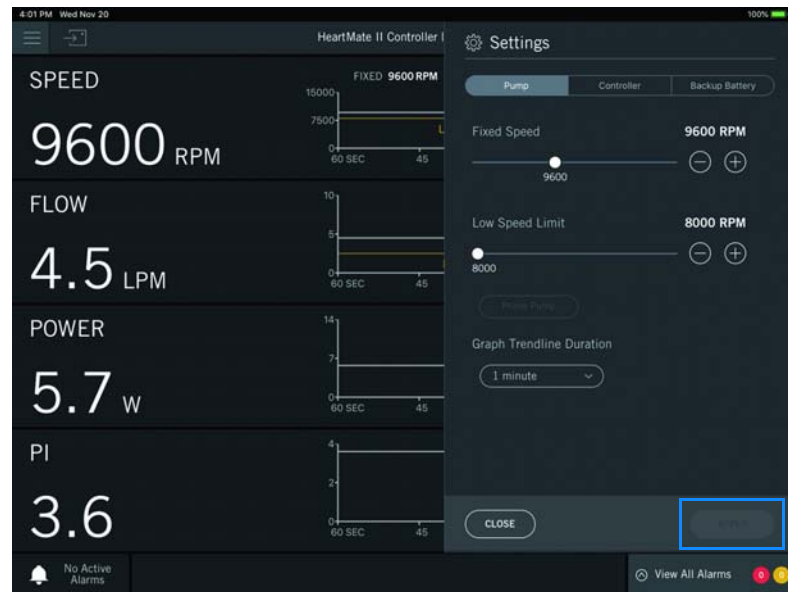


Figure 4.27 Settings Panel with Pump Parameters

These actions have the following conditions.

- **—** —Decreases the fixed speed by increments of 200 rpm. The new value appears above the feature.
- **+** —Increases the fixed speed by increments of 200 rpm. The new value appears above the feature.
- **APPLY** —Accepts the selected fixed speed and returns to the basic Settings panel. A Sending Command message is displayed, and the new set value is sent to the System Controller.
- **CLOSE** —Returns to the main view. If the fixed speed is changed, yet not applied, you will be prompted to apply or discharge the changes before the Settings panel is closed.

IMPORTANT! Tap **APPLY** to save a new speed setting. If another button is used to exit, or if the screen automatically returns to the main view, changes are not saved.

4 HeartMate Touch™ Communication

Optimal Fixed Speed

A ramped speed study using echocardiography is the most direct method for determining the optimal fixed speed that will provide the desired level of cardiac support for each patient. The fixed speed setting generally falls midway between the minimum and maximum speeds and is based on changes in ventricular shape and function and the patient's physiological response to changing pump speeds.

Perform a Ramped Speed Study

A ramped speed study is intended for hemodynamically stable, euvolemic patients in the postoperative or later periods. During the study, left ventricular size, position of the septum, and aortic valve opening should be monitored to determine the appropriate fixed speed setting. The final decision is ultimately dependent on the physician's clinical judgment and will vary from patient to patient.

TO DETERMINE THE OPTIMAL FIXED SPEED FOR A PATIENT:

1. With echocardiography available, have the patient sit or lie in a comfortable position.
2. Connect a HeartMate Touch Communication System to the Power Module to adjust the pump speed and monitor pump parameters.
3. Record the patient's current heart rate, blood pressure, and pump speed.
4. Using echocardiography, record the patient's left ventricular diameter, septum's position, and frequency of aortic valve opening.
5. Determine the minimum fixed speed:
 - a. Starting from the current fixed speed, lower the speed gradually to a value as low as possible without the patient experiencing signs of worsening heart failure (eg, shortness of breath, lightheadedness). Allow the patient to stabilize at each speed setting.

IMPORTANT! Do not allow the fixed speed to drop below 8,000 rpm under any circumstances.

 - b. Reduce the speed until the aortic valve opens with each beat or the patient starts to become symptomatic.
 - c. Record the patient's current heart rate, blood pressure, and pump speed.
 - d. Using echocardiography, record the patient's left ventricular diameter and position of the septum.
6. Determine the maximum fixed speed:
 - a. Starting from the minimum fixed speed as determined above, increase the pump speed gradually until echocardiography shows a flattening of the interventricular septum (or is clinically acceptable based on the echocardiographic evaluation).
 - b. Record the patient's current heart rate, blood pressure, and pump speed.

HeartMate Touch™ Communication System 4

- c. Using echocardiography, record the patient's left ventricular diameter and frequency of aortic valve opening.
7. Based on findings from the speed study, determine the optimum fixed speed, which usually falls midway between the minimum and maximum speeds.

IMPORTANT! The selected speed may be adjusted based on clinical judgment regarding the desire for periodic aortic valve opening and a palpable pulse. To accommodate normal shifts in volume and hemodynamic status, the fixed speed should generally be set at least 400 rpm below the maximum fixed speed determined above.

4 HeartMate Touch™ Communication

Low Speed Limit

The low speed limit should be set at the lowest speed at which the pump can run while maintaining patient stability. It is important to establish a low speed limit that can sustain a patient safely to maximize the protective benefits during PI events or when the pump is in 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. Note that alarms cannot be silenced while the System Controller is in power saver mode.

Set Low Speed Limit

1. Tap **—** or **+** or move the slider to decrease or increase the low speed limit (**Figure 4.27**).
2. Tap **APPLY** to confirm the changes.

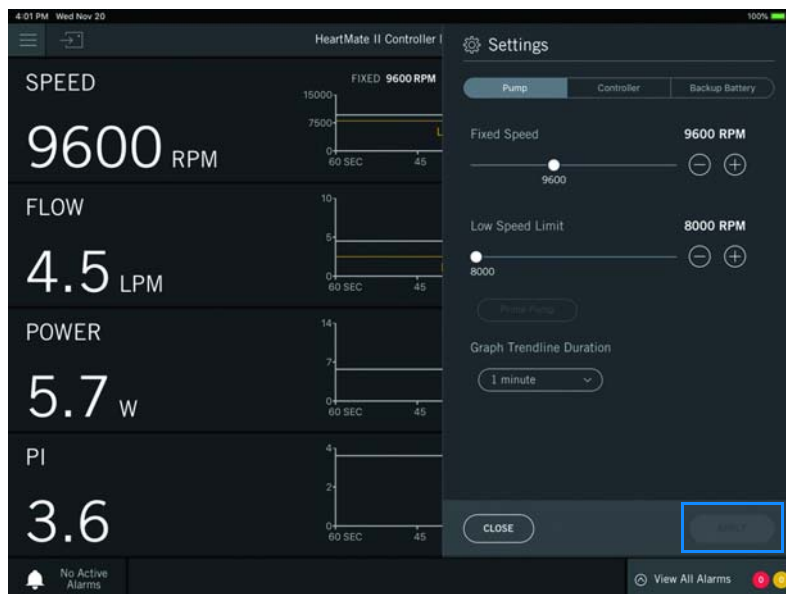


Figure 4.28 Settings Panel to Set Low Speed Limit

The low speed limit is generally set at a value slightly above the minimum speed determined during the speed ramp study discussed above. Clinical judgment and consideration of all factors should be used when selecting the low speed limit.

The low speed limit default setting is 9,000 rpm, but it can be adjusted between 8,000 and 10,000 rpm. If the operating speed drops below the value set for the low speed limit, the Low Speed Advisory alarm message appears.

HeartMate Touch™ Communication System 4

If the system detects a PI event, the pump speed automatically drops to the low speed limit and slowly ramps back up at a rate of 100 rpm per second to the fixed speed setpoint. This drop in speed is accompanied by a reduced pump flow. If the low speed limit is set at a value above or the same as the fixed speed setpoint, the pump speed does not change during a PI event. There are no audible alarms with a PI event.

PI events are assumed by the system during cases when there are sudden and substantial changes in the pulsatility index. These events are also referred to as PI events, and may be initiated for reasons other than true PI events. Some reasons include sudden changes in a patient's volume status, arrhythmias, sudden changes in power, and sudden changes in pump speed. These types of PI events are more likely to be triggered in cases of low pulsatility.

4 HeartMate Touch™ Communication

Prime Pump

The Prime Pump button is only available for use in the implant procedure to prepare the pump for implant. It is available only when the Settings panel is opened from the Clinical view. See for more details.

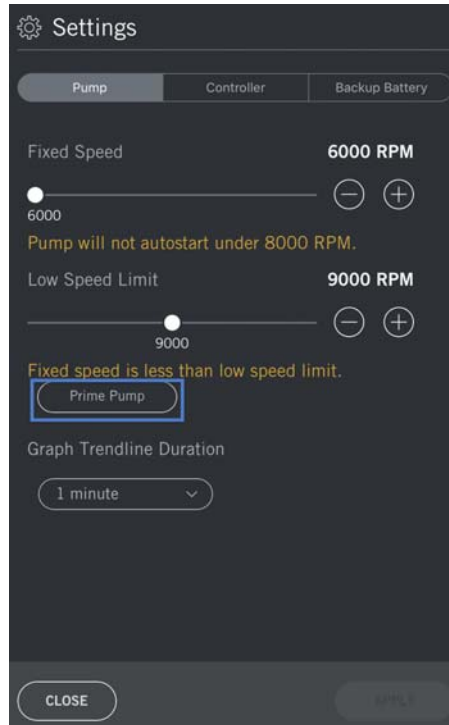


Figure 4.29 Prime Pump

HeartMate Touch™ Communication System 4

Graph Trendline Duration

Graph trendlines are displayed on the Clinical and Monitor views to track pump parameters. There are four pump parameters that have graph trendline durations: 1. Speed, 2. Flow, 3. Power, 4. PI. The graph trendline duration controls the maximum amount of time displayed on the graph at a given time. When the time is exceeded the most recent information will remain on the graph and the older information is removed from the graph.

1. Scroll through the graph trendline duration options.
2. Tap **APPLY** to update the setting.

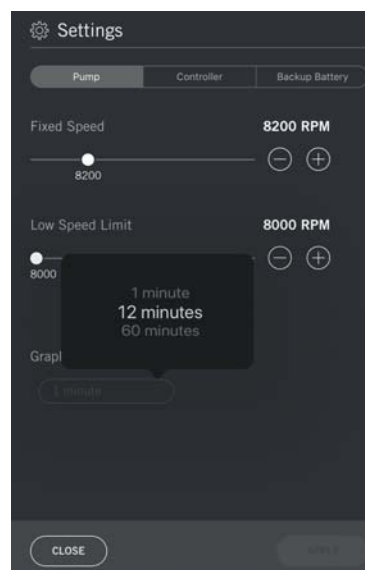
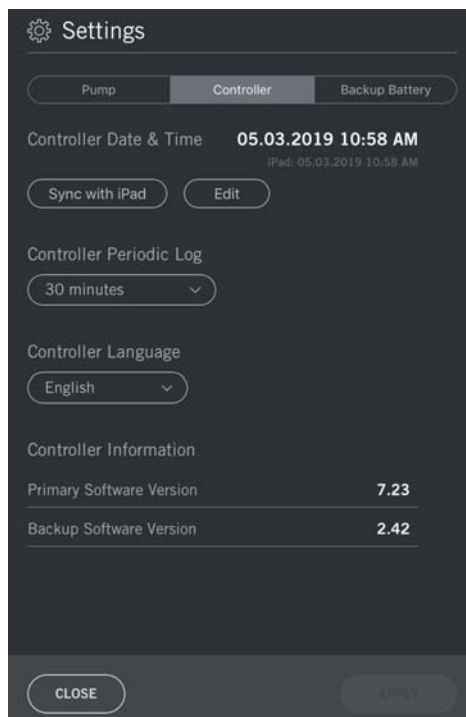


Figure 4.30 Graph Trendline Duration Information

4 HeartMate Touch™ Communication

Controller Tab

The Controller tab lets you access System Controller parameters and view detailed System Controller information.



Controller Date & Time. The System Controller date and time can be synced to the tablet date and time or entered in manually. Refer to *Controller Date & Time* on page 4-35.

Controller Periodic Log. The System Controller log can be configured to take a “snapshot” of system performance parameters at a set frequency of time. The System Controller can record 240 events. When the log is full, the oldest record is replaced with newest record.

Controller Language. Allows the user to select the language for on-screen messages. See *System Controller Language* on page 4-39.

Controller Information. The System Controller Information section provides System Controller primary and backup software version.

Figure 4.31 Controller Settings Panel

HeartMate Touch™ Communication System 4

Controller Date & Time

The HeartMate Touch™ Communication System and System Controller have separate clocks and can be set independently from each other. The current date and time stored in the System Controller is displayed to the right of the Controller Date & Time settings. The current tablet date and time is displayed below the System Controller date and time. The System Controller event log always reflects the date and time on the System Controller's clock.

The System Controller date and time can be synchronized with the tablet date and time, or it can be entered in manually.

Set the Tablet Date and Time.

1. On the tablet, tap **Settings** > **General** > **Date & Time**.
2. Visit www.apple.com to get help with the date and time on your tablet.

Synchronize System Controller and Tablet Date and Time

1. Tap **Settings** (⚙️) > **Controller**. View the tablet date and time to ensure that it is correct.

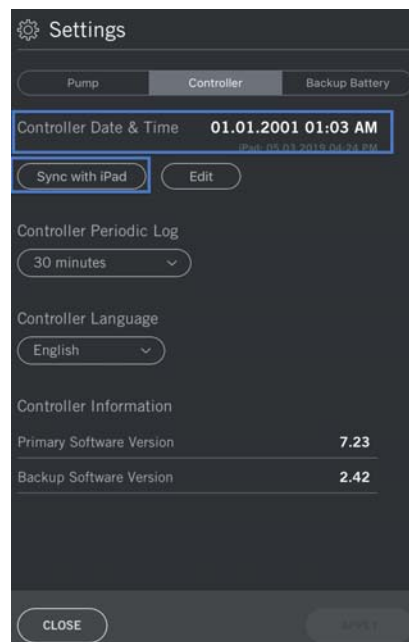


Figure 4.32 Controller Date & Time, Sync with Tablet

2. Tap **Sync with iPad**. A confirmation to synchronize the System Controller with the iPad[†] message appears.

4 HeartMate Touch™ Communication

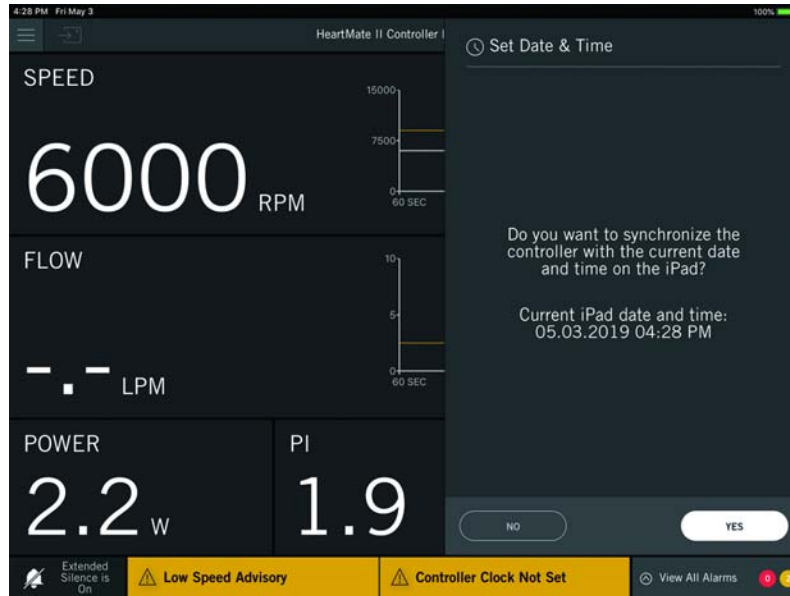


Figure 4.33 Confirm Message

3. Tap **YES**. The System Controller date and time will be updated to match the tablet date and time and will be displayed to the right of the Controller Date & Time setting.

HeartMate Touch™ Communication System 4

Edit System Controller Date and Time

1. Tap **Settings** (⚙️) > **Controller**. This panel appears (**Figure 4.33**).

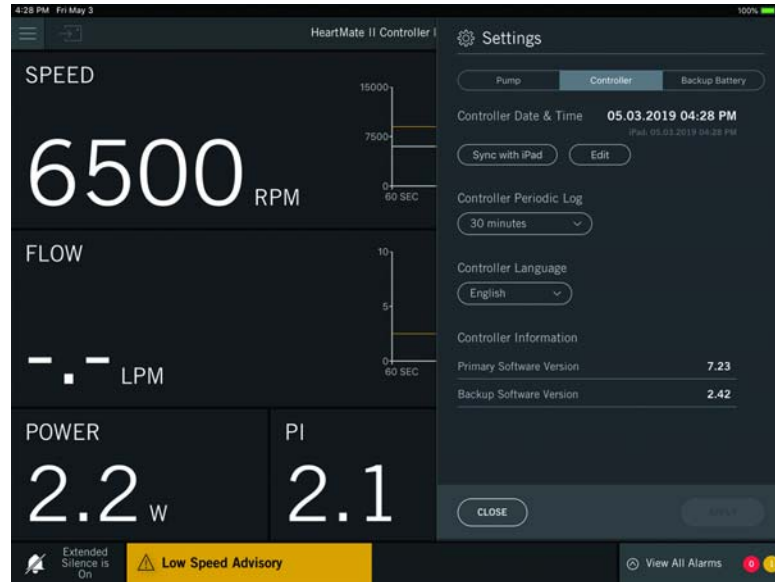


Figure 4.34 Set Date and Time

2. Tap **Edit**. The Set Date & Time controls appear. (**Figure 4.35**)



Figure 4.35 Confirm Date and Time

3. Set the date, time, and year; and then tap **APPLY**. The updated System Controller date and time is displayed to the right of the Controller Date & Time setting.

4 HeartMate Touch™ Communication

System Controller Periodic Log

The System Controller log can be configured to take a “snapshot” of system performance parameters at a set frequency of time. The System Controller can record 240 events. When the log is full, the oldest record is replaced with newest record.

The Settings panel Controller tab is used to change the rate at which data is recorded for the System Controller. The current frequency will be displayed in the button.

1. Tap **Settings** (⚙️) > **Controller**.
2. Tap the **Controller Periodic Log** duration drop-down.

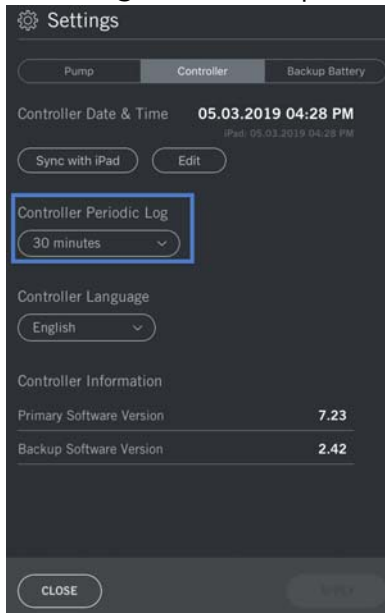


Figure 4.36 Period Log Settings

3. Select the desired duration. Frequency options are off, 0.5 hour, and hourly increments from 1 to 24 hours. Tap **APPLY**.

HeartMate Touch™ Communication System 4

System Controller Language

The System Controller's on-screen messages are available in multiple languages. The current language in use on the System Controller is displayed on the Controller tab of the Settings panel ().

Set System Controller Language

1. Tap **Settings** (⚙️) > **Controller**.
2. Tap the Controller Language drop-down (📄). The language control appears.
3. Select a language. Tap **APPLY**.

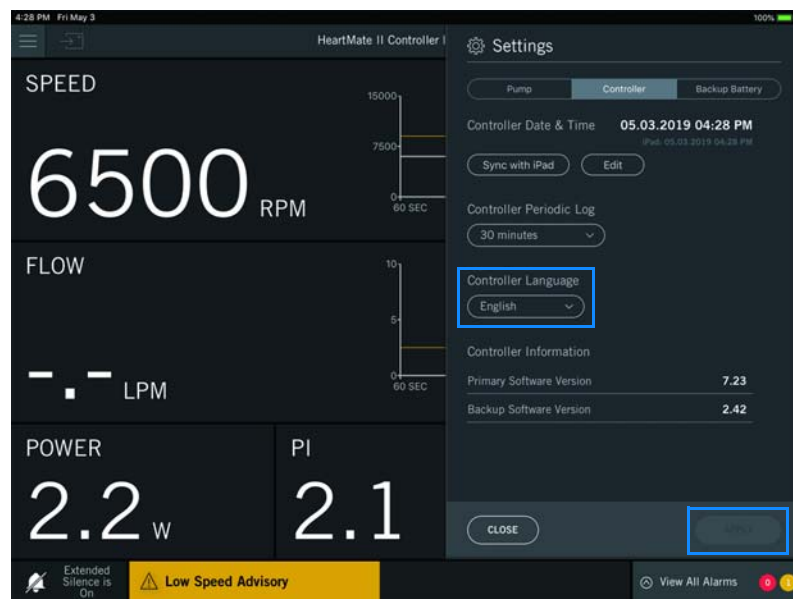


Figure 4.37 System Controller Information Panel

4 HeartMate Touch™ Communication

Controller Information

The Controller tab has specific System Controller information (primary and backup software versions).

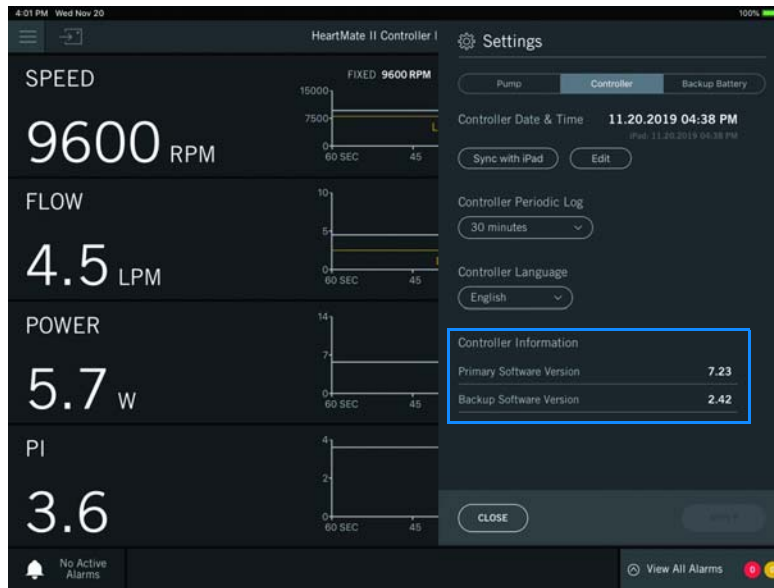


Figure 4.38 Controller Information

Backup Battery Tab

The Backup Battery tab provides information on the System Controller 11 Volt Lithium-Ion backup battery.



The screenshot shows the 'Settings' screen with three tabs: 'Pump', 'Controller', and 'Backup Battery'. The 'Backup Battery' tab is selected. Below the tabs is a section titled 'Backup Battery Information' containing a table of battery details. At the bottom of the screen are 'CLOSE' and 'APPLY' buttons.

Backup Battery Information	
Status	Installed
Serial Number	SR179-042
Manufacture Date	06.28.2017
Maximum Time	10950 minutes
Maximum Service Life	36 months
Maximum Shelf Life	24 months
Last Full Recharge Date	03.02.2017
Cumulative Time	36 minutes
Patient Use	17 times
Replace Information	27 months

Backup Battery Information. The backup battery inside the System Controller can power the pump for at least 15 minutes during a power loss emergency. Certain items (Serial Number, Manufacture Date, Maximum Time, Maximum Service Life, and Maximum Shelf Life) are backup battery fixed characteristics.

Other items (Last Full Recharge Date, Cumulative Time, Patient Use, and Replace Information) are variable and change with backup battery use.

Figure 4.39 Backup Battery Tab

- Patient use—total number of times that the System Controller's 11 Volt Lithium-Ion backup battery has been used. Frequent use may indicate that a patient is having difficulty changing from the Power Module to battery power or vice versa.
- Replace Information—indicates the number of months remaining before the System Controller's 11 Volt Lithium-Ion backup battery expires.
- Cumulative time—the total number of minutes that the System Controller's 11 Volt Lithium-Ion backup battery has been used. High numbers may indicate that a patient is inappropriately relying on the backup battery for non-emergency support.

4 HeartMate Touch™ Communication

Alarms

Alarm Status Bar

IMPORTANT! When more than two alarms occur simultaneously, you must go to the View All Alarms Panel to view all active alarms. See *Hazard Alarms* on page 4-47 and *Advisory Alarms* on page 4-48 for explanations of the conditions leading to each HeartMate Touch App alarm.

The alarm status bar displays the current alarm silence status, the two highest priority active alarms, the number of active hazard and advisory alarms, and access to view all hazard and advisory alarms. It is displayed at the bottom of all views.



Alarm Silence

Highest Priority Active Alarms

View All Alarms

Figure 4.40 Alarm Status Bar

Alarm Silence

You can silence active alarms by tapping  **Silence Alarms**. This action will temporarily silence the alarm on both the System Controller and the Power Module. Tap  **Silence Alarms** to silence all Hazard and the Power Cable Disconnected alarms for two minutes, the Low Voltage Advisory alarm for 5 minutes, and all other Advisory alarms for four hours.

Tap  **Silence Alarms** and the alarms will be temporarily silenced and *Alarm Silence is On* will be displayed (see **Figure 4.41**).



Figure 4.41 Alarm Silence is On

Note: When the pump is in the process of starting or stopping, active alarms cannot be silenced by tapping  **Silence Alarm**. The Silence Alarm button may still appear for alarm conditions for which there is no associated audible alarm. In this case, the button will not perform any function.

Once the pump has completed starting or stopping, tap  **Silence Alarm** to silence the alarm.

HeartMate Touch™ Communication System 4

Alarm Silence Status

- **No Active Alarms.** No alarms are active.
- **Silence Alarms.** There are one or more active audio alarms that can be silenced by tapping  **Silence Alarms.** You can also press the silence alarm button on the System Controller.
- **Alarm Silence is On.** One or more active alarms have been silenced.
- **Extended Silence is On.** All Hazard and Advisory audio alarms have been silenced for four hours. See *Extended Alarm Silence* on page 4- 45.

4 HeartMate Touch™ Communication

Active Alarms

The two active highest priority alarms are displayed at the bottom center of the screen. Hazard alarms are designated by red backgrounds and advisory alarms are designated by yellow backgrounds. To view all active and inactive alarms, tap **View All Alarms**.



Figure 4.42 Alarms Panel

View All Alarms

1. Tap **View All Alarms**. The Alarms panel appears (**Figure 4.42**).



Figure 4.43 Alarms Panel

The Alarms panel displays the following information.

- **Alarm messages.** All alarms (active and inactive) are displayed in the Alarms panel in order of highest priority from top to bottom.
 - Active alarms are highlighted white and have a red dot (■) for hazard alarms.
 - Advisory alarms are highlighted white and have a yellow dot (■).
- Inactive alarms remain gray. If there are multiple active alarms, the active alarms will be highlighted at the same time.

HeartMate Touch™ Communication System 4

- **Extended Alarm Silence.** This feature is available when there are active audible alarms and the Fixed Speed is set below 8,000 rpm. Tap **Extended Alarm Silence** to silence all Hazard and Advisory alarms for four hours.

Extended Alarm Silence

At fixed speeds set below 8,000 rpm and with any active alarm, Extended Alarm Silence is available. Use this feature to silence all Hazard and Advisory alarms on the Power Module and System Controller for four hours. During this time alarm messages continue to display even though the audible alarm is silent.

Enable Extended Alarm Silence

1. Tap **View All Alarms.**

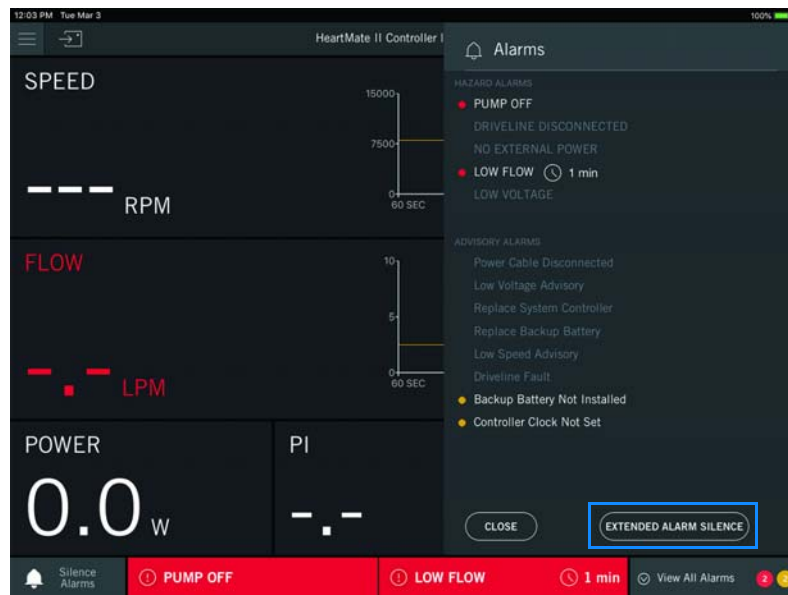


Figure 4.44 Extended Alarm Silence

2. Tap **EXTENDED ALARM SILENCE.** An override alarms confirmation message appears.

4 HeartMate Touch™ Communication

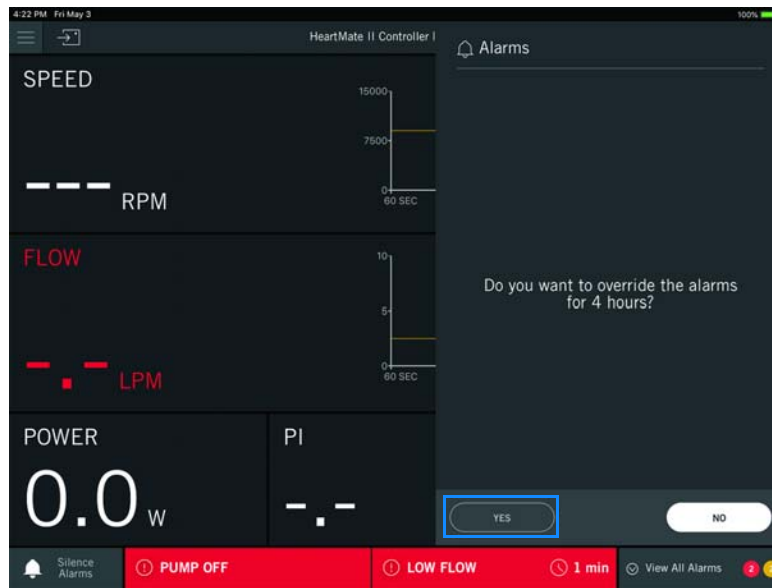


Figure 4.45 Extended Alarm Silence

3. Tap **YES** to confirm that extended silence should be enabled.

IMPORTANT! If the Silence Alarm button on the System Controller is pressed, the HeartMate Touch Communication System extended silence is canceled.

HeartMate Touch™ Communication System 4

Hazard Alarms

Hazard alarms occur for conditions that are potentially life-threatening for the patient. Hazard alarms require immediate attention.

Note: All Hazard Alarms are designated by red backgrounds when they appear in the Alarm Status bar. On-screen messages for hazard alarms are accompanied by a continuous audio tone from the System Controller.

The five hazard alarms are listed here in order of priority:

- **PUMP OFF**—The pump has been turned off or its Driveline is disconnected from the System Controller. Immediately turn on the pump or reconnect the Driveline to the System Controller.
- **DRIVELINE DISCONNECTED**—The Driveline is disconnected from the System Controller. Immediately reconnect the Driveline to the System Controller.
- **NO EXTERNAL POWER**—The System Controller is not receiving external power from either power cable, and pump function is being supported by the System Controller's backup battery. Immediately connect the System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
- **LOW FLOW**—Pump flow is less than 2.5 liters per minute (LPM), the pump has stopped, the pump is not operating properly, or the Driveline is disconnected from the System Controller. The count up time listed in the parameters box indicates how long this alarm has been active. Changes in patient conditions can result in low flow, such as hypertension.
- **LOW VOLTAGE**—Less than five minutes of combined power remain for the two HeartMate 14 Volt Lithium-Ion batteries (during battery-powered operation), or the System Controller is receiving inadequate power from the Power Module or Mobile Power Unit. Immediately connect the System Controller to a functioning power source.

4 HeartMate Touch™ Communication

Advisory Alarms

Advisory alarms are used to inform users about conditions that affect optimal system operation. Although important, Advisory alarms are not related to life-threatening risks.

Note: All Advisory alarms are designated by yellow backgrounds when they appear in the Alarm Status bar.

The eight Advisory alarms are listed here in order of priority:

- **Power Cable Disconnected**—One of the System Controller power cable connectors (white or black) is broken or disconnected from power (the Power Module or two HeartMate 14 Volt Lithium-Ion batteries). Immediately connect the indicated power cable to a power source.
- **Low Voltage Advisory**—Less than 15 minutes of combined power remain for the two HeartMate 14 Volt Lithium-Ion batteries (during battery-powered operation), or the System Controller is receiving inadequate power from the Power Module. Immediately connect the System Controller to a functioning power source.
- **Replace System Controller**—Indicates the need for clinician assistance and may be a sign of a System Controller malfunction. Ultimately, the alarm may not be able to be resolved, necessitating the replacement of the running System Controller with the backup System Controller (see *Replacing the Running System Controller with a Backup Controller* on page 2-55). After successfully switching to the backup System Controller, return the faulted System Controller to Abbott for diagnosis.
- **Replace Backup Battery**—This alarm could be a sign that the 11 Volt Lithium-Ion backup battery inside the System Controller is compromised or unable to fully support pump function. Promptly replace the faulted battery (see *Replacing the Running System Controller with a Backup Controller* on page 2-55).
- **Low Speed Advisory**—Either the fixed speed has been set 200 rpm or more below the low speed limit, or the System Controller is unable to maintain the speed at or above the low speed limit.
- **Driveline Fault**—One or more of the redundant wires inside the driveline is broken or damaged. The damage could be anywhere between the pump and System Controller. Investigation and troubleshooting is required to determine location of damage and the best next steps.
- **Backup Battery Not Installed**—Either the System Controller's 11 Volt Lithium-Ion backup battery has not been installed, the connection between the backup battery and System Controller is not being made, or the backup battery is damaged or malfunctioning. See *Installing the Backup Battery in the System Controller* on page 5-49.
- **Controller Clock Not Set**—The System Controller's clock has not been set via the HeartMate Touch App Settings panel. See *Controller Date & Time* on page 4-35.

HeartMate Touch™ Communication System 4



Figure 4.46 Alarms Panel with Multiple Active Alarms

Note: If necessary, contact Abbott to determine best next steps. Refer to the *Back Cover* of this manual for Abbott contact information.

4 HeartMate Touch™ Communication

Driveline Fault Alarm

Follow the instructions below to clear an active Driveline Fault alarm. This alarm must be the only fault that is active.

- **Disable Permanent Silence** – This action resets the alarm status from active to inactive. If the alarm condition persists, this alarm will be reactivated. If it was a transient condition, this alarm will not be reactivated. See .

Disable Permanent Silence Driveline Fault Alarm

1. Tap **View All Alarms**.
2. Tap the Driveline Power Fault drop-down (☑) to display additional buttons.
3. Tap **Disable Permanent Silence**.

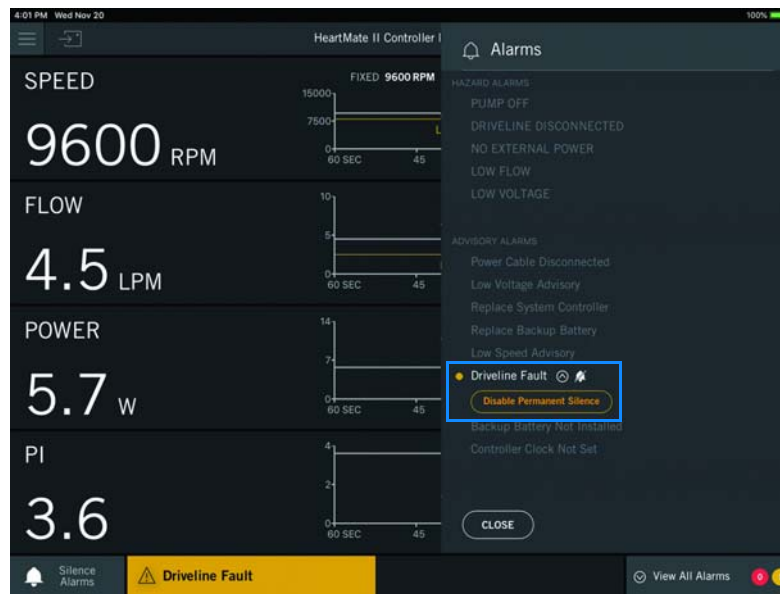


Figure 4.47 Driveline Fault Alarm Buttons

HeartMate Touch™ Communication System 4

Pump Parameters

All views (Clinical, Monitor, Historical) display the pump parameters (Speed, Flow, Power, and PI) and pump settings (Fixed Speed and Low Speed Limit).

Pump Speed

The HeartMate Touch™ App displays the pump speed in revolutions per minute (RPM). This value matches the actual speed within ± 100 rpm under nominal conditions (**Figure 4.48**).

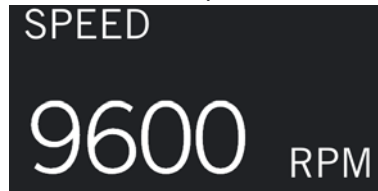


Figure 4.48 Pump Speed is Displayed in RPM

If the pump is disconnected from the System Controller, the HeartMate Touch App displays speed as "--- RPM" (**Figure 4.49**).

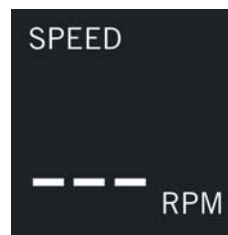


Figure 4.49 Pump Driveline is Disconnected

When the pump is stopped by tapping **STOP PUMP**, the speed is zero and displays as "--- RPM" (**Figure 4.50**).

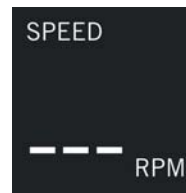


Figure 4.50 Pump Stopped with Driveline Connected

4 HeartMate Touch™ Communication

Pump Flow

The System Controller provides an estimate of blood flow out of the pump. This estimate is based on pump speed and the amount of power being provided to the pump motor. The relationship between power and flow at any particular speed is mostly linear.

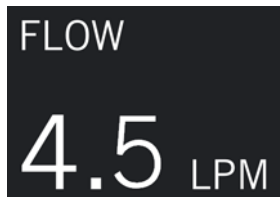


Figure 4.51 Pump Flow Display

Pump Flow (FLOW) displays "-.- LPM" (**Figure 4.52**) when any of these conditions occur:

- The estimated pump flow is outside the expected operational range (less than 8,000 rpm AND a PI greater than 9.0).
- The pump is stopped.
- The driveline is disconnected.

If the flow estimate falls outside the expected operational range or acceptable linear region, a LOW FLOW alarm is triggered and FLOW displays "-.- LPM" as shown in **Figure 4.52**. This situation only occurs when SPEED is below 8,000 rpm AND the Pulse Index (PI) is greater than 9.0. This condition prevents the display of inaccurate flow information.



Figure 4.52 LOW FLOW Alarm and Pump Flow

Under the following conditions, the pump can only be started from the HeartMate Touch App Clinical view by pressing the Pump Start button:

- The fixed speed setting is below 8,000 rpm.
- AND**
- The System Controller's backup battery is not installed.

If the pump stops because the Driveline is disconnected from the System Controller, the pump restarts at the previously set speed when the Driveline is reconnected, if:

- The fixed speed setting is at least 8,000 rpm.
- OR**
- The System Controller's backup battery is installed and any button is pushed on the System Controller.

HeartMate Touch™ Communication System 4

When the Driveline is disconnected from the System Controller, FLOW displays "-.- LPM". This condition is accompanied by these Hazard alarms: PUMP OFF, DRIVELINE DISCONNECTED. START PUMP appears in the bottom right corner (**Figure 4.53**) in the Clinical view only.



Figure 4.53 Clinical View - DRIVELINE DISCONNECTED Alarm

Pump Power

The Power region displays pump power. Pump power is the amount of power being provided to the pump motor. Pump power ranges between 0.0 to 25.5 watts ().



Figure 4.54 Pump Power

When the Driveline is disconnected from the System Controller, "0.0 W" appears under Power (**Figure 4.55**).



Figure 4.55 Power when Driveline is Disconnected

4 HeartMate Touch™ Communication

Pulsatility Index

Pulsatility Index (displayed as PI) is a calculation related to the amount of assistance that is provided by the pump. PI values typically range from 1 to 10. Higher values indicate higher pulsatility (that is, the pump is providing less support and the heart is providing more support). Lower values indicate lower pulsatility (that is, the pump is providing more support and the heart is providing less support). Pulsatility Index appears in all views ().



Figure 4.56 Pulsatility Index

When the pump is stopped or the Driveline is disconnected from the System Controller, "-.-" appears under PI (**Figure 4.57**).

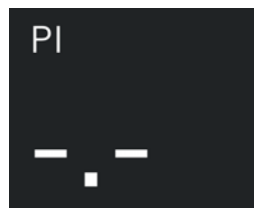


Figure 4.57 Pulsatility Index when Pump is Stopped

HeartMate Touch™ Communication System 4

Monitor View

The Monitor View (**Menu** (☰) > **Monitor**) is the first view displayed when the HeartMate Touch™ Communication System is connected to the HeartMate™ LVAS.

It displays Pump parameters (Speed, Flow, Power, and PI) with trendlines. It also displays pump settings (Fixed Speed and Low Speed Limit). The Monitor View also has a Reminders panel (right) that provides reminders. A typical reminder might remind you to replace the System Controller backup battery. The System Controller backup battery expiration status is only displayed when a backup battery is installed and the System Controller clock is set.

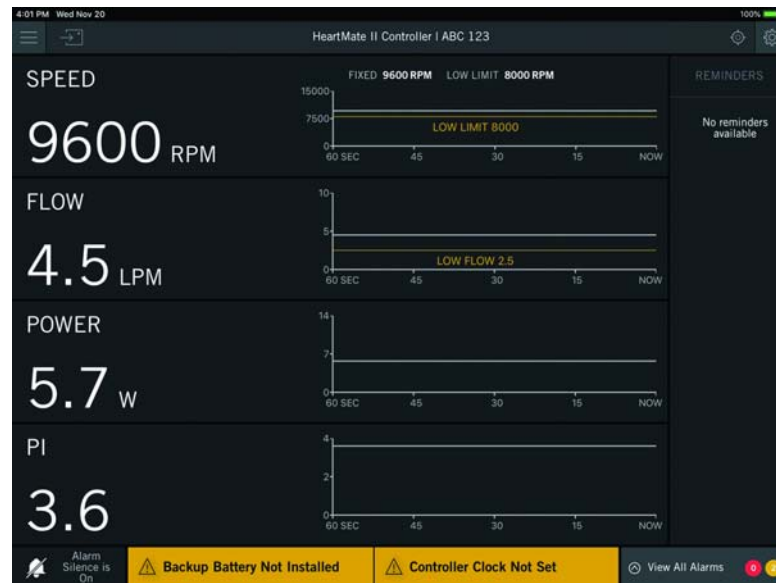


Figure 4.58 Monitor View

The Reminders panel displays three different messages depending on the status of the backup battery:

Replace Backup Battery in X Months (White Text Display). The backup battery is more than 6 months from expiration. X is the number of months remaining before the backup battery expires.

Replace Backup Battery in X Months (Orange Text Display). The backup battery is less than 6 months from expiration and should be replaced.

Replace Backup Battery. The backup battery is less than 1 month from expiration, has expired, there is a Backup Battery Fault, or the backup battery is not installed. A new backup battery should be installed.

4 HeartMate Touch™ Communication

Clinical View

The Clinical view (tap **Menu** (☰) > **Clinical**) displays the primary operating parameters, parameter settings, and trendline information for speed and flow only. The Pump Parameter value's font size is slightly larger than the Monitor view. The Clinical view is used during the implant procedure as it is the only view that provides information on starting, priming, and stopping the pump.

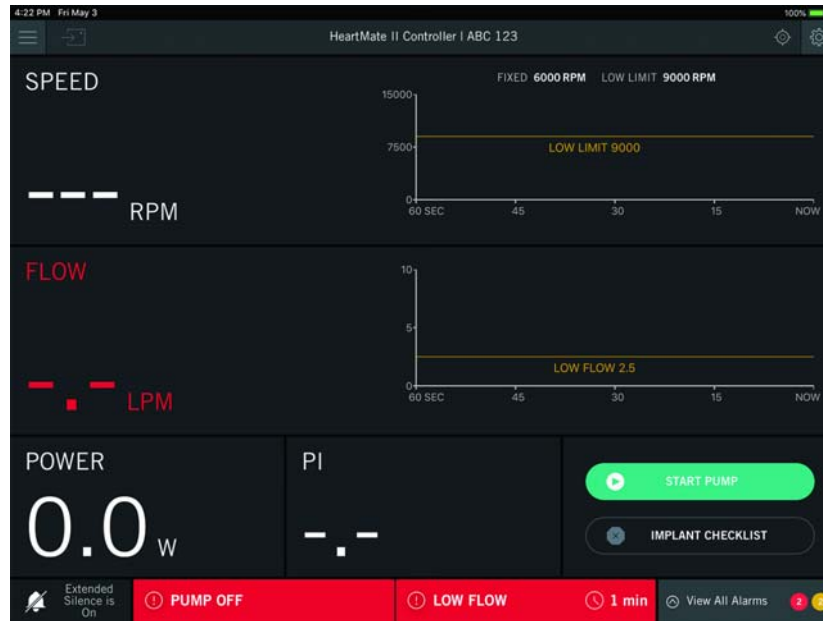


Figure 4.59 Clinical View

HeartMate Touch™ Communication System 4

Start Pump

The Start Pump button is only accessible from the Clinical view. The Start Pump button is displayed when the pump is off and connected to the System Controller.

Start the Pump

1. Check the Fixed Speed and adjust it as necessary. Refer to *Fixed Speed* on page 4-26 for instructions.
2. Tap **START PUMP** to start the pump. A start pump confirmation message appears as shown in **Figure 4.59**.

IMPORTANT! The pump will remain off until you tap **START PUMP**.

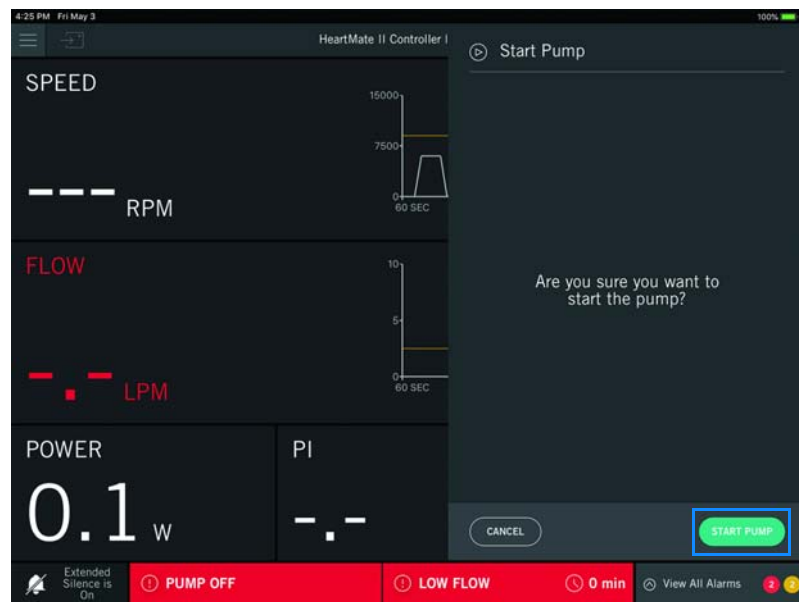


Figure 4.60 Pump Start Message

3. Tap **START PUMP**.

When the pump is running, the Start Pump panel will close and the Clinical view will be displayed. The **START PUMP** button is changed to a **STOP PUMP** button.

IMPORTANT! If you tap **CANCEL** in response to "Are you sure you want to start the pump?" the pump will remain off.

4 HeartMate Touch™ Communication

Stop Pump

The Stop Pump feature is only accessible from the Clinical view. Stop Pump is displayed when the pump is running.

Stop the Pump

1. Tap **STOP PUMP** to turn off the pump. A stop pump confirmation message appears (**Figure 4.60**).

IMPORTANT! The pump will remain running until the command is confirmed on the next screen.

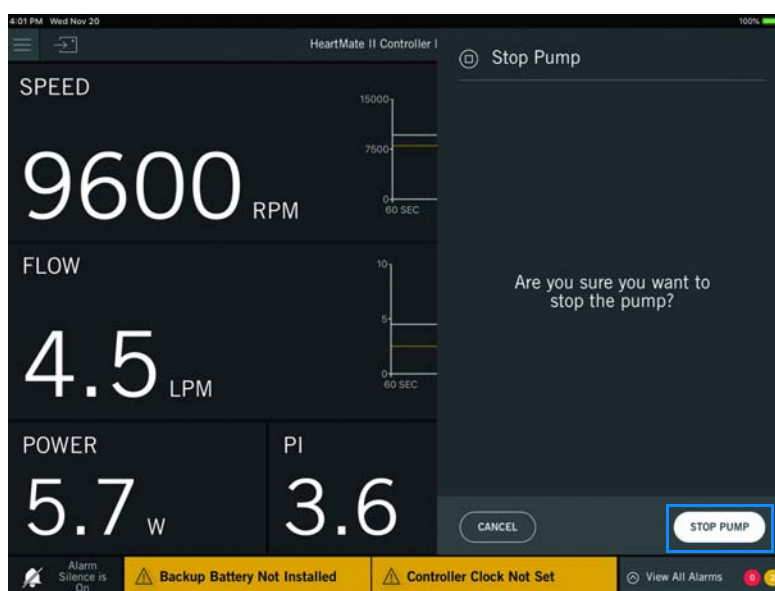


Figure 4.61 Clinical View with STOP PUMP

Note: If you tap **CANCEL**, the pump remains running at the previously set speed.

HeartMate Touch™ Communication System 4

2. Tap **STOP PUMP** to confirm. A progress bar appears and the pump will stop within a few seconds.

IMPORTANT! The PUMP OFF alarm appears a few seconds after you tap **STOP PUMP**. This action is accompanied by a continuous audible alarm; unless Extended Silence is on. Active audio alarms cannot be silenced using the HeartMate Touch™ App while the pump is in the process of stopping.

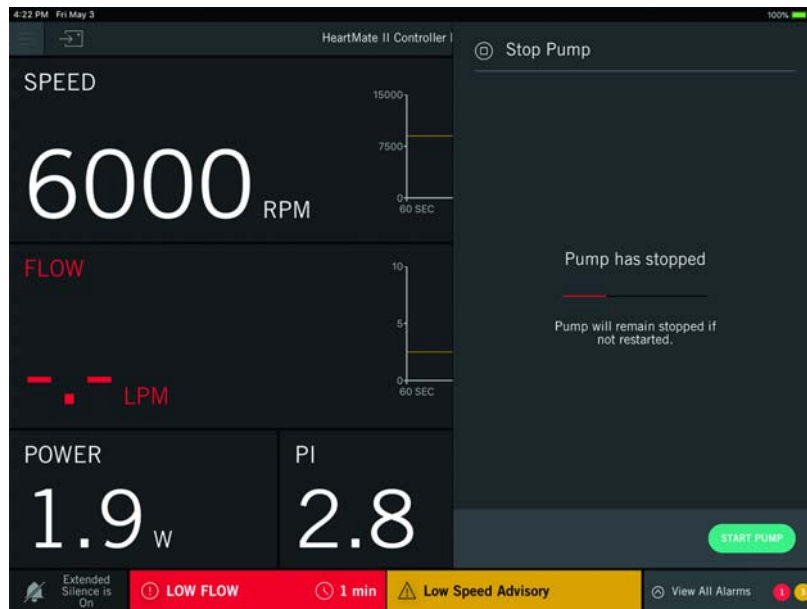


Figure 4.62 Pump Stop Progress Bar

If you tap **START PUMP** while the stop pump progress bar is displayed, the pump will restart and return to the previously set speed. Initially, the Low Speed Advisory alarm and then the LOW FLOW hazard alarm appear, both without an audible alarm.

After the Pump Stop completes, **START PUMP** appears and the pump may be restarted. See *Start Pump* on page 4- 57 for more information.

After the pump has stopped, the Stop Pump panel will close and the Clinical view will be displayed. The **STOP PUMP** feature is changed to **START PUMP**.

3. Tap  **Silence Alarms** on the lower left side of the screen to silence the active audible alarms.

IMPORTANT! If the backup battery is installed in the System Controller, pressing the System Controller Alarm Silence button will restart the pump. Silence audio alarms using the HeartMate Touch App instead.

4 HeartMate Touch™ Communication

Restart the Pump

Once the driveline is connected to the System Controller, starting the pump will depend on the fixed speed setting.

Pump Speed < 8000 RPM. Pump start is not automatic.

- System Controller back up battery not installed, tap **START PUMP** on the HeartMate Touch™ App.
- System Controller backup battery installed and external power source available, press any button on the System Controller.

Pump Speed ≥ 8000 RPM. Pump starts automatically.

- System Controller is powered by an external power source. (Power Module, Mobile Power Unit™, or 14 volt Lithium Ion batteries)
- The pump will not start if the only power source is the System Controller backup battery.

HeartMate Touch™ Communication System 4

Implant Checklist

The Implant Checklist provides a list of actions that should be completed at the end of an implant procedure and prior to the patient leaving the operating room.

CAUTION !

Verify that the HeartMate Touch™ Communication System is connected to the intended HeartMate LVAS when making changes to LVAS settings.

Access the Implant Checklist

1. Tap **IMPLANT CHECKLIST**. The Implant Checklist panel appears (**Figure 4.62**).

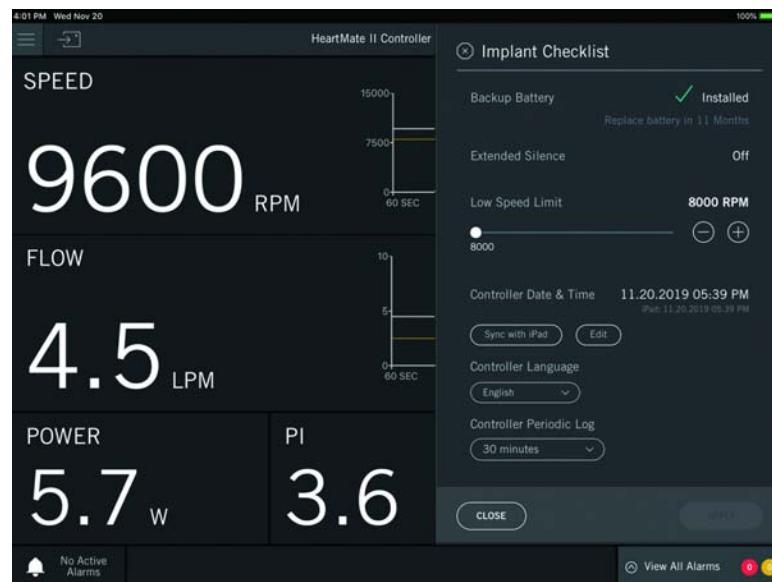


Figure 4.63 Implant Checklist

2. Install the backup battery.
3. Turn off Extended Silence by pressing the System Controller silence alarm button ().
4. Set the Pump and Controller settings. See *Pump Tab* on page 4-25 and *Controller Tab* on page 4-34 for more information on pump and System Controller settings.

4 HeartMate Touch™ Communication

Historical View

The Historical view displays the data stored in the System Controller log. Pump, Flow, Power, and PI is stored in the System Controller. The System Controller logs can also be exported to an Abbott approved Flash Drive from this view.

Tap **Menu** (☰) > **Historical**. You will be prompted to confirm loading the data. It may take a few minutes to load the data.

IMPORTANT! While loading data, viewing information and making changes will not be available. If an alarm occurs while loading records or saving data, an audible alarm sounds, but no message is displayed.

The loaded data can be displayed as a graph or table. (**Figure 4.63**)

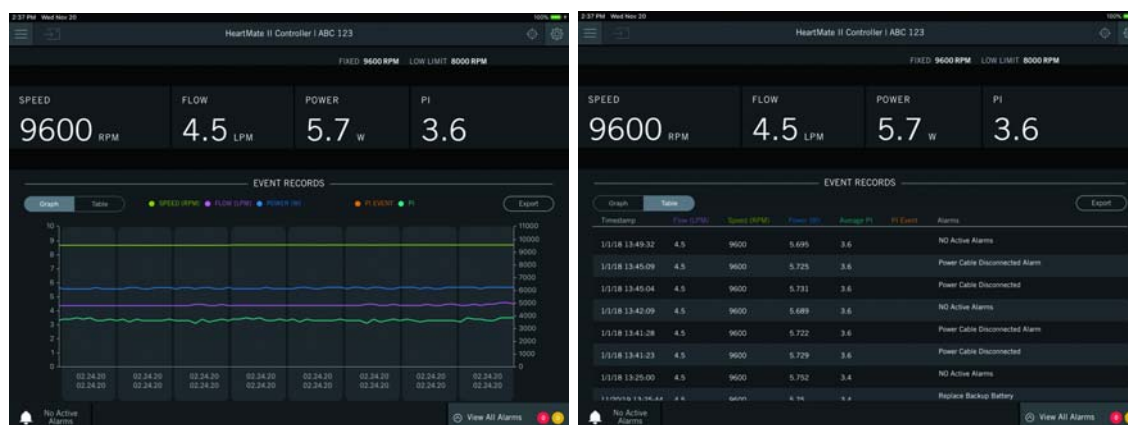


Figure 4.64 Graph Historical View | Table Historical View

The Event Recorder is a built-in feature of the System Controller that allows performance data to be collected and stored. The System Controller can store 240 events. When the memory is full, the oldest events are deleted as new ones are saved. The HeartMate Touch Communication System is used to set the time interval for recording events by the System Controller. Information about events can be viewed on the HeartMate Touch Communication System screen. The System Controller Event Recorder is always on. It automatically records any alarm.

To set the frequency, see **System Controller Periodic Log** on page 4-38.

HeartMate Touch™ Communication System 4

Event Records | Periodic Records

You can view both event records and periodic records. Records can be displayed as a graph or table.

Event Records. System performance parameters are logged when an event occurs. An event is defined as an alarm, disconnected cable, or pump stop action.

Periodic Records. A periodic record is defined as a log of the system performance parameters at an adjustable interval (e.g., every 30 minutes). The system will display the timestamp that the data was recorded in the table view. e.g., 6/7/19 09:**14**:02 → 6/7/19 09:**44**:02.



Figure 4.65 Historical Records

4 HeartMate Touch™ Communication

Tap **Table**. A graph or table appears that displays a timestamp, along with pump parameters, and alarms. Tap **Graph** to view the event records as a graph.

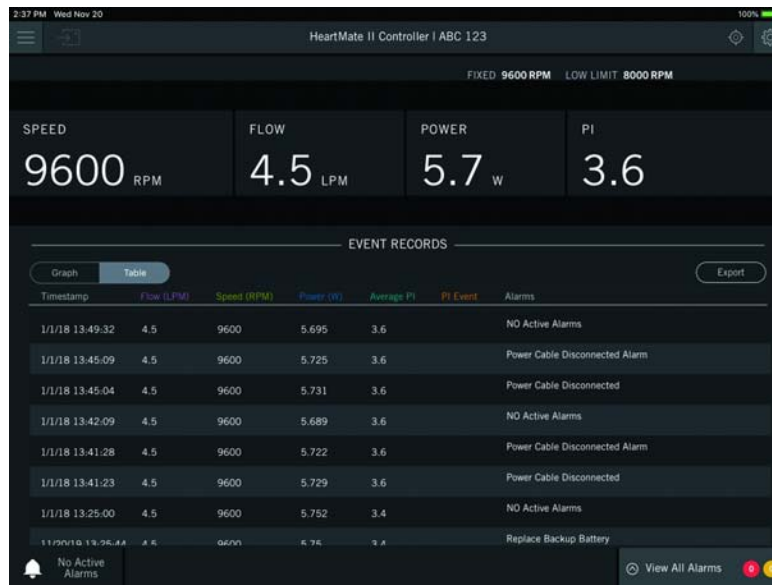


Figure 4.66 Historical Records

shows event records loaded and displayed as a table. From this view the following features are provided:

- View event records as a graph or table
- Export data from the tablet

A maximum of 240 events can be stored and retrieved for display. The event history data are displayed in reverse chronological order with the most recent events at the top.

HeartMate Touch™ Communication System **4**

Sending Information to Abbott

To send data such as HeartMate Log Reports to Abbott for diagnostic purposes, you will need to export the data and save it to a Flash Drive. Follow the instructions in the *HeartMate Touch Communication System Quick Start Guide* to save files to an Abbott approved Flash Drive.

The Flash Drive plugs into any USB port on a personal computer (PC) and acts as a removable drive. Note that the drive designation may differ based on the PC configuration.

IMPORTANT! A PC running Microsoft® Windows® 2007 or higher is required for most Abbott approved Flash Drives.

Contact Abbott for the e-mail address to send the data or for further assistance. Refer to the *Back Cover* of this manual for Abbott contact information.

4 HeartMate Touch™ Communication

Export Data

Use the export feature to export device data to the tablet.

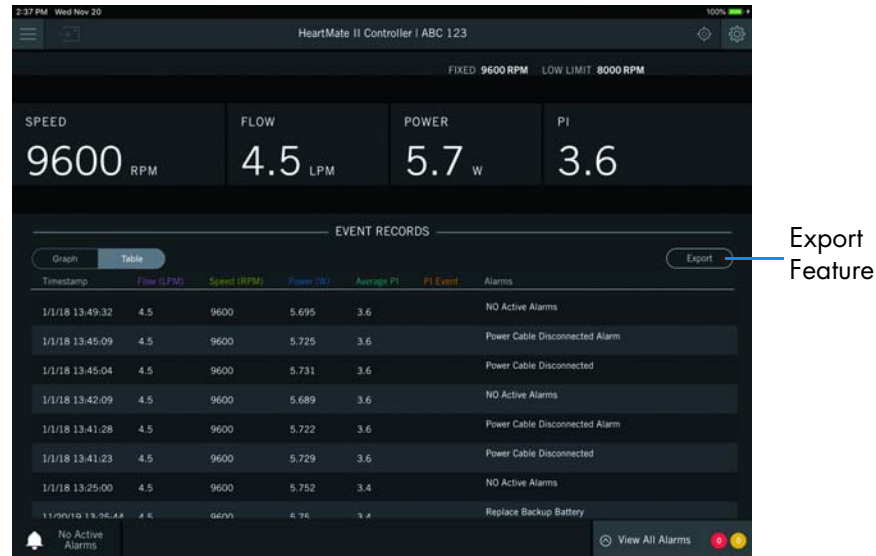


Figure 4.67 Exporting Data Confirmation

1. Tap **Export**. The message below will appear on the screen while exporting data, viewing and making changes message appears.

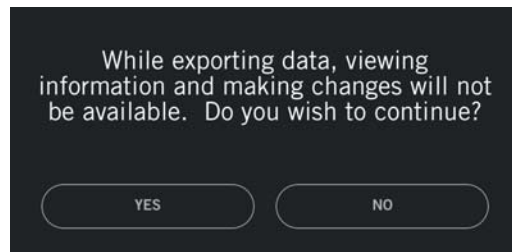


Figure 4.68 Export Data Message

HeartMate Touch™ Communication System 4

2. Tap **YES**. A window appears prompting you to provide a name.

IMPORTANT! Only create export names that identify the export file. Do not enter any protected health information or individually identifiable health information. Follow your organization's policies, procedures, and employee training that correspond to HIPAA regulatory standards.

IMPORTANT! You should restrict the characters to a through z, 0 through 9, underscores (_), and periods (.).

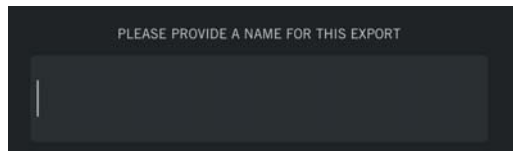


Figure 4.69 Provide Export Name

3. Enter a name for the export (e.g., ABC_123) and then tap **Done**. An exporting data window appears briefly. An export was successful window appears.

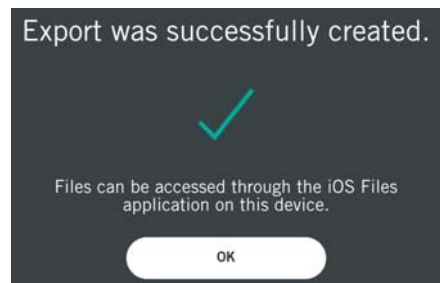


Figure 4.70 Successful Export

4. Tap **OK**. The Historical view appears.

The exported files can now be accessed in the iOS Files application on the tablet. Follow the instructions in the *HeartMate Touch Communication System Quick Start Guide* to save files to an Abbott approved Flash Drive.

4 HeartMate Touch™ Communication

SURGICAL PROCEDURES

This section describes the surgical considerations necessary to prepare, implant, and explant the HeartMate II Left Ventricular Assist System.

Surgical Considerations-	-5-3
Equipment and Supplies Required for Implant	-5-5
Preimplant Procedures-	-5-7
Implant Procedures	-5-27
Postimplant Procedures	-5-47
Device Explant	-5-53

Surgical Considerations

This section describes the preimplant, implant, and explant procedures for the HeartMate II Left Ventricular Assist System.

WARNING !

- Moderate to severe aortic insufficiency must be corrected at time of device implant.
- Before using the Power Module, the hospital's biomedical technician or other Abbott-trained personnel must install the Power Module backup battery. See *Installing the Power Module Backup Battery* on page 3-7.
- A minimum of two fully-charged HeartMate 14 Volt Lithium-Ion batteries, a pair of compatible battery clips, and a System Controller are required during device implant to power the system when the patient is being transferred out of the operating room. For details, see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45.
- All users (including clinicians, patients, and caregivers) must be trained on HeartMate II power accessories (Power Module, Mobile Power Unit, Battery Charger, and batteries) before use.
- Certain parts of the HeartMate II Left Ventricular Assist System are not compatible with other HeartMate systems (such as the XVE Left Ventricular Assist System). Only use HeartMate II parts with the HeartMate II System.
- During the implant process, a complete backup system (implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- During the implant process, a complete HeartMate Touch Communication System backup system must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedure must be either removed or adequately secured so as to not interfere with the operation of the HeartMate II Left Ventricular Assist Device.

5 Surgical Procedures

WARNING ! (Continued)

- The sealed outflow graft contains material of bovine origin. It should not be implanted in patients who are sensitive to such materials.
- Keep connectors clean and dry and away from water or liquid. If the connectors come into contact with water or liquid, the system may fail to operate properly or you may get an electric shock.
- Do not use the HeartMate II Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- Do not apply high power mains treatment (eg, application of diathermy) directly to the patient. Application of high power mains treatments could result in mains interference with system operation, causing the pump to stop.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (eg, ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.
- It is the responsibility of the user to ensure that the cleaning process as performed achieves the desired result. All cleaning should be performed in a manner designed to minimize exposure to bloodborne pathogens.
- Devices require a cool down of approximately 20 minutes after sterilization and prior to use.
- Automated cleaning is not recommended. Devices should not be subjected to automated cleaning using washer-disinfectors.

CAUTION !

- The HeartMate II Sizer is supplied non-sterile and must be sterilized prior to use.
- The HeartMate II Sizer approximates the size and shape of the HeartMate II device and should not be considered an exact replica.

Equipment and Supplies Required for Implant

The HeartMate II Left Ventricular Assist System Implant Kit (with Sealed Grafts) is supplied sterile and for single use only. Store components in a cool, dry place away from strong electromagnetic fields (see *Equipment Storage and Care* on page 8-1).

Additional sealed inflow conduits, sealed outflow grafts with bend relief, and short bend reliefs are also available as sterile standalone items. Contact Abbott to order additional supplies. For a detailed product list and catalog numbers, see *HeartMate II Product List* on page C-1.

CAUTION !

Components of the HeartMate II Left Ventricular Assist System that are supplied sterile are intended for single use only and should not be re-used or re-sterilized. Do not use sterile components if sterile packaging is compromised. Contact Abbott for Return Materials Authorization (RMA).

Abbott-Supplied Equipment

The Implant Kit contains the following items:

- Left Ventricular Assist Device assembly*
- 20 mm flexible sealed inflow conduit*
- 14 mm sealed outflow graft with 10.2 cm (4 in) bend relief*
- Apical sewing ring*
- Apical coring knife* (20 mm)
- Skin coring punch* (8 mm)
- Thread protectors* (1 set)
- Tunneling bullet*
- System Controller* with backup battery

(* Supplied Sterile)

Additional items:

- Power Module with backup battery and Power Module patient cable
- Tablet for use with the HeartMate Touch™ App
- HeartMate Touch™ Wireless Adapter
- Battery clips (set of 2) for HeartMate 14 Volt Lithium-Ion batteries
- HeartMate 14 Volt Lithium-Ion batteries (set of 4)
- Wearable Accessories Kit

5 Surgical Procedures

The following optional items are also available:

- Driveline tunneler
- HeartMate II Sizer

Hospital-Supplied Equipment

Ensure that the following additional items are available:

- Large basin
- Vent needle
- CV major surgical set
- Heavy nonabsorbable ligature
- Catheter-tipped syringe with Sterile Saline for Injection
- Swan-Ganz catheter
- Arterial line
- Transesophageal ECHO

Preimplant Procedures

WARNING !

- The sealed outflow graft contains material of bovine origin. It should not be implanted in patients who are sensitive to such materials.
- A sealed inflow conduit does not require pre-clotting. Attempting to pre-clot a sealed inflow conduit may disrupt or destroy the sealant and lead to profuse bleeding after implantation.
- A sealed outflow graft does not require pre-clotting. Attempting to pre-clot a sealed outflow graft may disrupt or destroy the sealant and lead to profuse bleeding after implantation.
- Do not implant the HeartMate II Left Ventricular Assist Device if it has been dropped.
- Never operate the HeartMate II Left Ventricular Assist Device in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- Do not autoclave the pump. This damages the pump and driveline.
- All entrapped air must be removed from the pump/sealed inflow conduit assembly blood path to minimize the risk of air embolus.

CAUTION !

- Operators must prevent blood from entering and collecting in the lumen of the conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must, therefore, be rinsed thoroughly prior to attachment to the Left Ventricular Assist Device.
- Never use tools to tighten the thread protector; securely hand tighten only. Using tools may cause damage.
- Do not allow the apical coring knife to involve the ventricular septum while performing left ventricle coring.
- Do not remove the centering fixture inside the apical sewing ring until ready to insert the sealed inflow conduit.
- The sealed outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.
- Stretch the sealed outflow graft completely prior to measuring and cutting the graft to the appropriate length.
- Do not clamp the flexible silicone segment of the sealed inflow conduit. See Figure 5.11, *Sealed Inflow Conduit*, on page 5-23.

5 Surgical Procedures

Preparing the HeartMate II Sizer

The HeartMate II Sizer is a surgical accessory that is intended to facilitate implantation of the HeartMate II pump by simulating the size and shape of the actual device. It is not required for the HeartMate II pump implantation surgical procedure. It is intended to support intra-operative placement of the pump and sizing of the pocket. Additionally, it can be used to assist in HeartMate II outflow cannula length optimization.

IMPORTANT! The HeartMate II Sizer is supplied non-sterile and must be cleaned and sterilized prior to use.

Indication for Use

The HeartMate II Sizer is intended for use with the Abbott HeartMate II System.

Contraindications

The HeartMate II Sizer is not designed, sold, or intended for use except as indicated.



Figure 5.1 HeartMate II Sizer

Decontamination and Sterilization Processing

Point of Use	The HeartMate II Sizer is a reusable device. Clean and sterilize using the procedures listed below. Thorough cleaning and rinsing should begin as soon as possible after use of the device. Containment devices are cleaned separately from the instruments and therefore have separate cleaning methods. Follow standard cleaning procedures for containment devices approved at your facility.
Preparing for Decontamination	No particular requirements. It is recommended that devices be sterilized as soon as cleaning is completed.
Automated Cleaning	Not recommended.
Manual Cleaning	Equipment: Detergent, water, cleaning brushes Method: 1. Soak the contaminated device in a warm mixture of water and detergent and allow sitting for 20 minutes. Use soft bristle brush to remove any blood soil while soaking. 2. Remove the contaminated device from the soaking bath and rinse in hot water at 55°C – 60°C (131°F – 140°F) until there are no visible signs of contaminated soil remains. 3. Place the device in a sonic bath filled with an enzymatic cleaner prepared per the manufacturer's instructions. Sonicate for 10 minutes. 4. Rinse thoroughly with warm water. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the parts for thorough rinsing at these locations. 5. For a device with internal surfaces, it is necessary to pay particular attention to the cleanliness of internal surfaces. 6. Check the device for visible soil. Repeat cleaning if soil is visible.
Disinfecting	No particular requirements.
Drying	No particular requirements.
Maintenance, Inspection and Testing	No particular requirements. Each HeartMate II Sizer should be carefully inspected upon receipt and prior to each surgical procedure for damage to surfaces of the device that could affect the performance of the device or cause harm during implantation. Such damage may include dents, deep scratches, cracks, and rough edges that could cause tears to tissue during use. If damage is noted upon initial receipt of the product, return to Abbott for a replacement.

5 Surgical Procedures

Packaging	No particular requirements. Double wrapping in an autoclave suitable towel for sterilization is acceptable.
Storage	Reusable devices that will be stored between cleaning and sterilization should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments. Store the sterilized device protected from direct contact with possible sources of corrosion or other surface damage consistent with the procedures for sterile instrument storage approved by your facility.
Additional Information	Recommendations: Detergents: Detergents with a pH range between 6.0 and 8.0 should be used. Enzymatic detergents aid in the removal of organic soil such as blood. Water: The use of de-ionized water will reduce the mineral deposits on the devices. Ultrasonic Cleaner: Ultrasonic cleaning should be used only after gross oil has been removed from the devices. Ultrasonic cleaners are used to remove adherent tissue from inner lumen and other difficult to access locations. Automatic Washer/Disinfector: Washer-disinfectors are not only used to clean devices, but also to provide intermediate to high level disinfection with a hot water rinse. Manual Cleaning Instruments: Non-abrasive or soft bristle cleaning brushes, pipe cleaners, or a non-abrasive low-linting cloth should be used.
Limitations on Reprocessing	Repeat processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Sterilization	Sterilize using a validated steam autoclave with sterilization cycles at or above the minimum requirements shown in the table below.			
	Method	Temperature	Sterilization Time	Drying Time
	Gravity cycle (wrapped)	132°C (270°F)	15 minutes	70 minutes
	Flash cycle (unwrapped)	132°C (270°F)	10 minutes	N/A
	Pre-vacuum cycle (wrapped)	132°C (270°F)	3 minutes	50 minutes
	The HeartMate II Sizer will require a cool down of approximately 20 minutes after sterilization and prior to use.			

IMPORTANT! It is the responsibility of the user to ensure that the sterilization process as performed achieves the desired result. Recommended procedures are intended as a general guide for sterilization of reusable medical devices. It is the responsibility of the users to validate their sterilization equipment to ensure that the recommended minimum parameters are achieved.

5 Surgical Procedures

Preparing the Patient

Transport the patient to a cardiovascular operating room (O.R.). Prep and anesthetize the patient according to standard procedures. Perform a median sternotomy incision extending approximately 2–3cm below the xyphoid process. Institute cardiopulmonary bypass.

Setting Up and Initializing the HeartMate Touch

FOR THIS TASK YOU NEED:

- 1 working Tablet for use with the HeartMate Touch App with SM cable
- 1 HeartMate Touch Wireless Adapter for connecting the HeartMate Touch Communication System to the Power Module, through a Bluetooth® pairing
- 1 Power Module for connection to an AC electrical outlet
- 1 Power Module patient cable

IMPORTANT! During implant, the HeartMate II Left Ventricular Assist System must be operated using the HeartMate Touch Communication System and Power Module as shown in **Figure 5.2**.

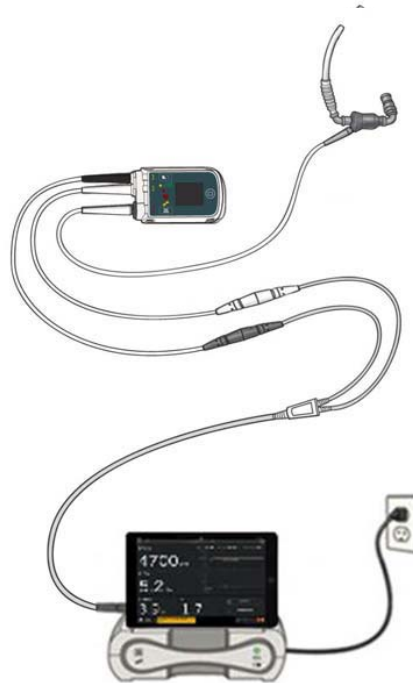


Figure 5.2 Connection Points With System Controller Connected to the Power Module

CAUTION !

The Tablet for use with the HeartMate Touch App should be fully charged, or its AC power cord connected to an AC electrical power outlet during the surgical procedure.

To initialize the Power Module and HeartMate Touch Communication System:

1. Ensure the HeartMate Touch Communication System is set up and the HeartMate Touch Wireless Adapter is engaged and connected. Ensure the Power Module and the HeartMate Touch power adapter are connected to power and ready for use. See *Set Up the HeartMate Touch™ Communication System* on page 4-8 for instructions.
 - a. Confirm that the Power Module is plugged into a properly tested and grounded (3-prong) AC electrical outlet that is dedicated to Power Module 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.
 - b. Confirm that the Power Module patient cable is attached to the Power Module.
2. To turn on the Tablet, press and hold the top button until the logo appears. Enter the passcode if applicable.
3. Tap **HeartMate Touch App**. Connect the HeartMate Touch Communication System to the HeartMate Touch Wireless Adapter. See *Set Up the HeartMate Touch™ Communication System* on page 4-8 for instructions.

5 Surgical Procedures

Setting Up and Initializing the System Controller

FOR THIS TASK YOU NEED:

- 1 running System Controller (without the 11 Volt Lithium-Ion backup battery installed)
- 1 working HeartMate Touch Communication System
- 1 Power Module for connection to an AC electrical outlet
- 1 HeartMate Touch Wireless Adapter for connecting the HeartMate Touch Communication System to the Power Module, through a Bluetooth® pairing
- 1 Power Module patient cable for connecting the System Controller to the Power Module

TO SET UP AND INITIALIZE THE SYSTEM CONTROLLER:

1. Remove the System Controller and the 11 Volt Lithium-Ion backup battery from the System Controller packaging (**Figure 5.3**).



Figure 5.3 System Controller Packaging

2. Set the System Controller backup battery and the backup battery installation components aside for use after the sterile field has been broken, after the device implant.



System Controller Package



System Controller Backup Battery
System Controller Sterile Contents

Figure 5.4 System Controller Sterile and Non-Sterile Packaged Components

3. Wirelessly connect the Tablet for use with the HeartMate Touch App to the HeartMate Touch Wireless Adapter. See *Set Up the HeartMate Touch™ Communication System* on page 4-8.

CAUTION !

Do not install the System Controller 11 Volt Lithium-Ion backup battery until after completing the device implant procedure and the sterile field has been broken.

4. Pass the two System Controller power cable ends out of the sterile field and connect them to the bifurcated ends of the Power Module patient cable, white-to-white and black-to-black. Both the Power Module and System Controller will alarm signifying that the System Controller is powered but not connected to the HeartMate II Left Ventricular Assist Device. Do not connect the System Controller to the Left Ventricular Assist Device at this time. The System Controller will also flash the yellow wrench, indicating that the backup battery is not installed.
5. Tap **CONTINUE** and enter a session name.

IMPORTANT! Only create names that identify the session. Do not enter any protected health information or individually identifiable health information. Follow your organization's policies, procedures, and employee training that correspond to HIPAA regulatory standards.

IMPORTANT! You should restrict the characters to a through z, 0 through 9, underscores (_), and periods (.).

6. Use the HeartMate Touch App to silence the alarm by tapping  **Silence Alarms**. Do not silence the alarm signal using the System Controller.
7. Verify that a flashing communication icon  is shown in the top left corner of the HeartMate Touch App (will be displayed on all views). This icon establishes that the HeartMate Touch Communication System is properly connected to the System Controller and the correct monitoring software is running.

Note: If the communication icon is not flashing, check connections and restart the HeartMate Touch.

8. Tap **Menu** () > **Clinical**.
9. Tap **Settings** () > **Controller** and verify that the time and date are correct on the HeartMate Touch App. Then use the HeartMate Touch App to set the System Controller clock. See *Controller Date & Time* on page 4-35 for instructions on setting the date and time on the HeartMate Touch App.
10. Verify that the HeartMate Touch displays PUMP OFF and DRIVELINE DISCONNECTED alarm messages (see **Figure 5.5**).

5 Surgical Procedures

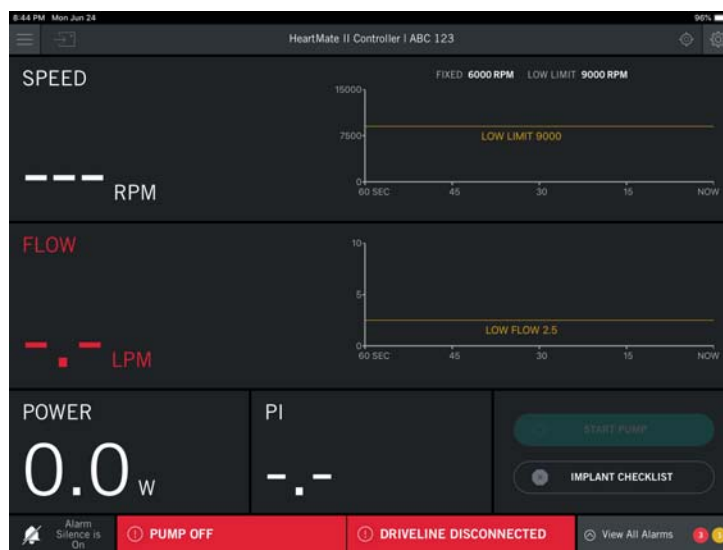


Figure 5.5 HeartMate Touch When Initially Connected to the System Controller

11. Verify that the HeartMate Touch App displays FIXED as 6000 RPM and LOW LIMIT as 9000 RPM (see **Figure 5.5**).
 - a. If the speed setpoint is not 6,000 rpm, tap **Settings** (⚙️) > **Pump**. Adjust the Fixed Speed to 6,000 rpm.
 - b. If the low speed Limit setpoint is not 9,000 rpm, tap **Settings** (⚙️) > **Pump**. Adjust the Low Speed Limit to 9,000 rpm.
12. Tap **View All Alarms** > **EXTENDED ALARM SILENCE** > **YES**. This action will silence all hazard and advisory alarms for four hours to ensure that they will not sound in the OR. The alarm silence indicator should display **Extended Silence is On**. The extended silence can be canceled by pressing the Silence Alarm button on the System Controller's user interface panel or by disconnecting the HeartMate Touch from the Power Module.



Figure 5.6 Alarms View - Initially Connected to the System Controller

13. System Controller initialization is now complete. The Driveline Disconnected alarm will remain active until the System Controller is connected to the LVAD, and the pump off alarm message will remain active until the LVAD is turned on by tapping **START PUMP** on the HeartMate Touch App.

5 Surgical Procedures

Preparing the Pump

FOR THIS TASK YOU NEED:

- 1 HeartMate II Left Ventricular Assist Device with driveline
- 1 HeartMate II System Controller
- 1 HeartMate Touch Wireless Adapter, connected to the Power Module
- 1 Power Module plugged into an AC electrical outlet
- 1 sterile basin with at least 3 liters of Sterile Saline for Injection

CAUTION !

Never operate the pump in the air, as this will immediately damage the device. Make sure that the pump is fully submerged.

TO PREPARE THE PUMP:

1. Examine the outflow elbow of the pump to verify the presence of a white washer. If the white washer is missing or damaged, do not use the pump. Obtain another pump device before continuing.
2. Fully submerge the pump in a sterile basin with at least 3 liters of Sterile Saline for Injection.
3. Follow the procedure below to run the pump for a minimum of 5 minutes at 6,000 rpm:
 - a. Attach the pump's driveline to the System Controller; confirm that the connection is secure (see *Connecting the Driveline to the System Controller* on page 2-24).

Note: The sterile personnel may instruct the non-sterile personnel to initiate commands on the HeartMate Touch App.

On the HeartMate Touch App, the Driveline Disconnected alarm should disappear and the pump speed box should now display "- - -" (**Figure 5.7**).

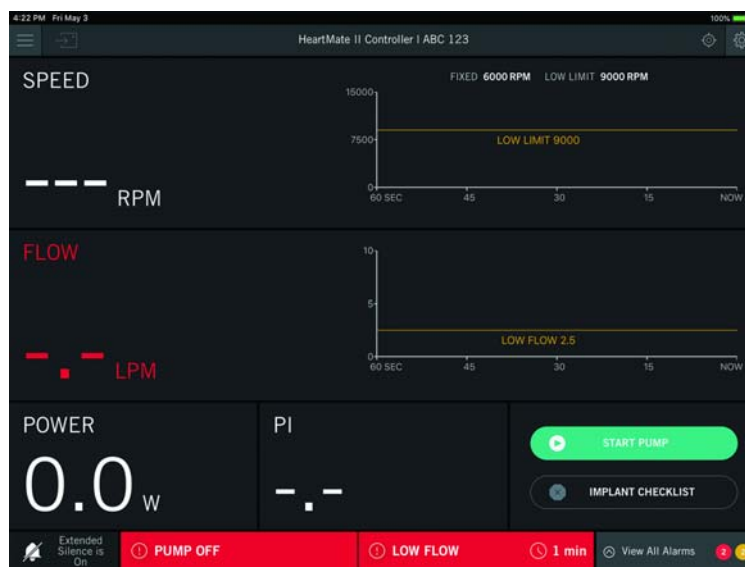


Figure 5.7 Clinical View

5 Surgical Procedures

4. If the speed setpoint is not 6,000 rpm, tap **Settings** (⚙️) > **Pump**. If necessary, adjust the Fixed Speed to 6,000 rpm.
5. You will need to prime the pump.
 - a. Tap **Settings** (⚙️) > **Pump** to initiate the Pump priming operation (**Figure 5.8**).

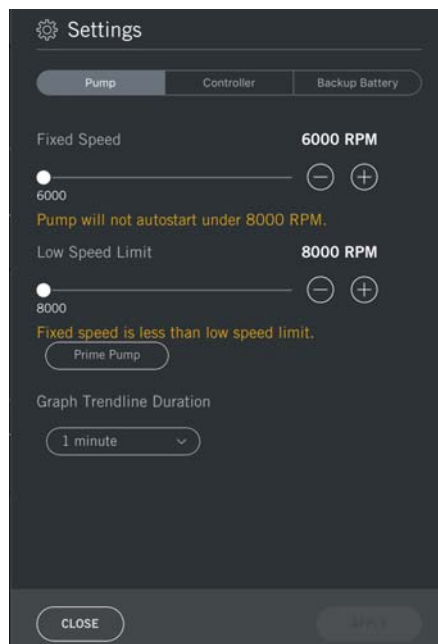


Figure 5.8 Settings > Pump

- b. Tap **Prime Pump**. A message appears (**Figure 5.9**). Ensure that the pump is submerged before priming.

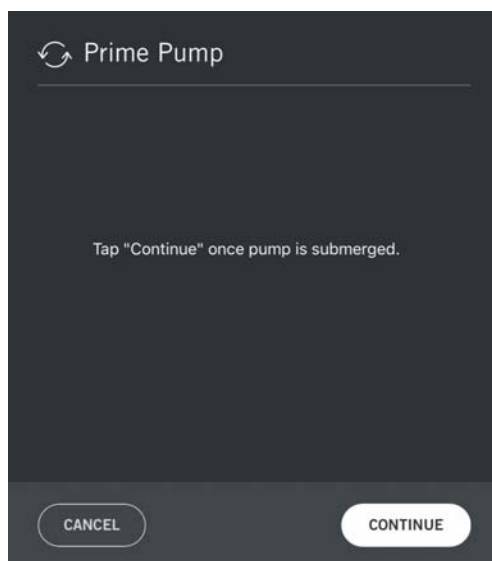


Figure 5.9 Submerge Pump Message

WARNING !

The pump should be submerged before priming.

c. Tap **CONTINUE**.

Note: Tap **CANCEL** if you do not want to begin the priming process.

d. Ensure the pump continues to operate. A five minute countdown timer appears.

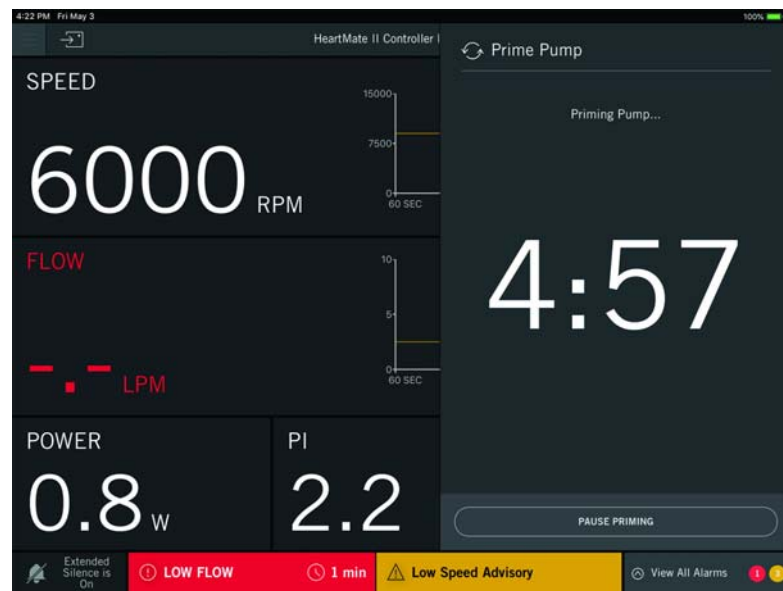


Figure 5.10 Prime Pump

Note: You can tap **PAUSE PRIMING** during this process.

If you tap **PAUSE PRIMING**, the timer will pause and the pump will stop.

If you tap **RESUME PRIMING** the process continues (pump will continue) and the timer will continue where it left off.

If you tap **CANCEL** and then confirm, the priming pump feature and the pump will stop.

- e. When the timer reaches zero the pump stops and the "Priming is complete" message appears. Tap **CONTINUE** to close the pump priming panel. The Clinical view appears.
- f. Leave the pump in the sterile basin of Sterile Saline for Injection.
- g. Disconnect the driveline from the System Controller. For more information, see *Disconnecting the Driveline from the System Controller* on page 2-26.

5 Surgical Procedures

6. Attach the tunneling bullet to the driveline connector. Confirm that the bullet is screwed on securely.
7. Leave the System Controller power cables connected to the Power Module. If the power cables are disconnected, the Extended Alarm Silence will be reset.

WARNING !

If the Pump fails to operate properly, do not implant it. Utilize the back-up HeartMate II LVAD in its place.

Preparing a Sealed Inflow Conduit

FOR THIS TASK YOU NEED:

- 1 sealed inflow conduit

Characteristics that identify a sealed inflow conduit and distinguish it from an unsealed inflow conduit include:

- Thoratec logo on the flexible silicone sleeve
- Two holes on the flexible silicone sleeve
- Blue screw ring that attaches it to the pump
- A foil pouch that contains the sealed inflow conduit

IMPORTANT! A sealed inflow conduit does not require pre-clotting. Attempting to pre-clot a sealed inflow conduit may disrupt or destroy the sealant and lead to profuse bleeding after implantation. Do not pre-clot a sealed inflow conduit (**Figure 5.11**).

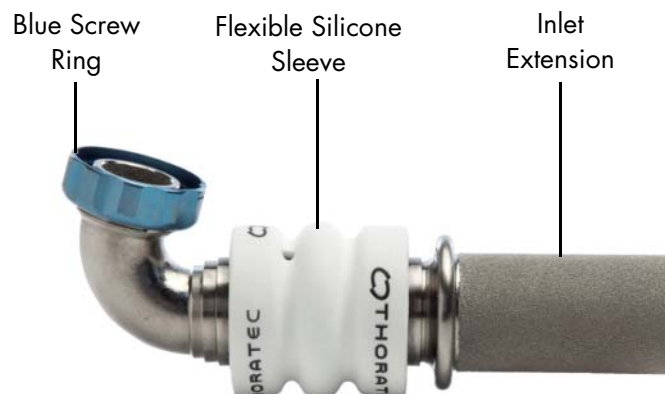


Figure 5.11 Sealed Inflow Conduit

TO PREPARE A SEALED INFLOW CONDUIT:

1. Open the sealed inflow conduit box and foil pouch. The foil pouch is a protective cover only. The pouch is not sterile; do not introduce it into the sterile field.

IMPORTANT! Do not open the foil pouch until ready to use the sealed inflow conduit. Store the sealed inflow conduit inside the foil pouch. Once removed from the pouch, the sealed inflow conduit must be implanted within 24 hours.

2. Remove the outer tray from the foil pouch. The outer tray is not sterile. Only the inner-most tray may be introduced into the sterile field.
3. Remove the sealed inflow conduit from the inner tray. The inner tray is sterile; it may be introduced into the sterile field.

5 Surgical Procedures

Preparing a Sealed Outflow Graft

FOR THIS TASK YOU NEED:

- 1 sealed outflow graft

Characteristics that identify a sealed outflow graft and distinguish it from an unsealed outflow graft include:

- A blue dashed line on the bend relief
- A blue screw ring that attaches to the pump
- A foil pouch that contains the sealed outflow graft

IMPORTANT! A sealed outflow graft does not require pre-clotting. Attempting to pre-clot a sealed outflow graft may disrupt or destroy the sealant and lead to profuse bleeding after implantation. Do not pre-clot a sealed outflow graft (**Figure 5.12**).



Figure 5.12 Preparing a Sealed Outflow Graft

TO PREPARE A SEALED OUTFLOW GRAFT:

1. Open the sealed outflow graft box and foil pouch. The foil pouch is a protective cover only, and should not be introduced into the sterile field.

IMPORTANT! Do not open the foil pouch until ready to use the sealed outflow graft. Store the sealed graft inside the foil pouch. Once removed from the pouch, the sealed outflow graft must be implanted within 24 hours.

2. Remove the outer tray from the foil pouch. The outer tray is not sterile. Only the innermost tray may be introduced into the sterile field.
3. Remove the sealed outflow graft and bend relief from the inner tray.
4. Inspect the interior of the graft and remove any debris.
5. Attach the open thread protector.
6. Ensure that the bend relief (10.2 cm [4 in]) is on the graft, with the metal end toward the screw ring. The bend relief should be disengaged for the de-airing procedure (see *De-Airing the Pump* on page 5-38).
7. The thread protectors should remain attached to the screw-ring connector for use with the attachment to the HeartMate II Sizer.

Priming the Pump/Sealed Inflow Conduit Assembly

FOR THIS TASK YOU NEED:

- 1 HeartMate II Left Ventricular Assist Device, prepared for use (see *Preparing the Pump* on page 5-18)
- 1 sealed inflow conduit
- Sterile laps
- Antibiotic solution
- 1 sterile towel to cover the pump after priming

TO PRIME THE PUMP/SEALED INFLOW CONDUIT ASSEMBLY:

1. Verify that the tunneling bullet is completely screwed down tight onto the connector end of the driveline.

IMPORTANT! Arrows on the pump housing indicate direction of flow to illustrate the correct orientation of the inflow versus the outflow.

2. Using strict aseptic technique, attach the sealed inflow conduit to the Left Ventricular Assist Device (**Figure 5.13**) by inserting the conduit elbow into the device port, just to the point where the thread halves become engaged. Full engagement of the conduit elbow into the pump should be made by the threads pulling the parts together.

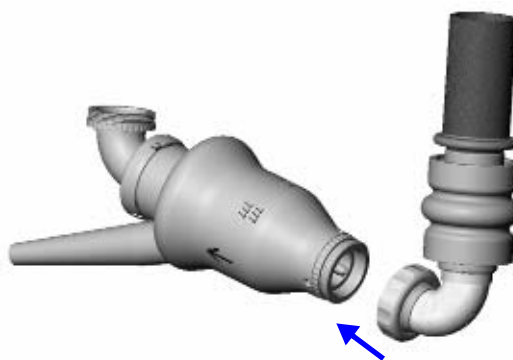


Figure 5.13 Connecting Sealed Inflow Conduit to Pump

IMPORTANT! Do not push the elbow fully into the pump to engage and tighten the threads.

IMPORTANT! Arrows on the pump housing indicate direction of flow to illustrate the correct orientation of the inflow versus the outflow.

3. Attach the thread protector with the Luer-Lok™ cap to the outflow elbow. Open the Luer-Lok cap to allow air to escape.

5 Surgical Procedures

4. Hold the Left Ventricular Assist Device/sealed inflow conduit assembly in a horizontal position with the sealed inflow conduit and outflow elbow pointing upward.
5. Fill the Left Ventricular Assist Device with Sterile Saline for Injection through the sealed inflow conduit until it flows out of the cap. Close the Luer-Lok cap.
6. While raising the inflow end to a position slightly higher than the outflow end, gently tap the side of the device and observe air bubbles rising to the surface.
7. Tap and add saline until the device appears full and no further air bubbles can be observed.
8. Cut a fingertip off a powderless sterile glove and use it to cover the inlet extension of the sealed inflow conduit.
9. Place antibiotic-soaked laps over the device and velour portion of the driveline, and then set aside the device with the sealed inflow conduit positioned up and covered with a sterile towel.

IMPORTANT! Some fluid leakage will occur through the connections. However, the sealed inflow conduit graft should not leak. If leaking occurs from the sealed inflow conduit, replace it with a new sealed inflow conduit.

Implant Procedures

The proper orientation of the Left Ventricular Assist Device is shown in **Figure 5.14**. The sealed inflow conduit is placed utilizing left ventricle (LV) apical cannulation with the pump positioned inferior to the diaphragm and the sealed outflow graft attached to the ascending aorta.

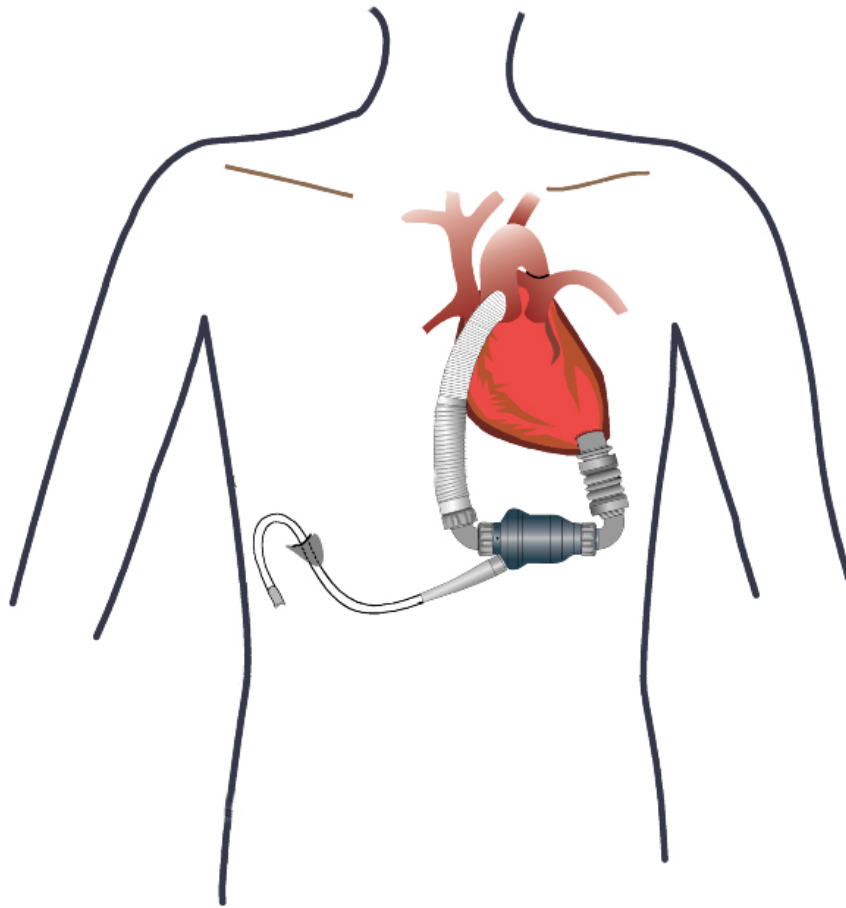


Figure 5.14 HeartMate II Implantation Configuration

5 Surgical Procedures

WARNING !

- Do not open the foil pouch until ready to use the sealed outflow graft or sealed inflow conduit. Store sealed grafts and conduits inside the foil pouch. Once removed from the pouch, the sealed outflow graft and sealed inflow conduit must be implanted within 24 hours.
- Stretch the sealed outflow graft completely prior to measuring and cutting the graft to the appropriate length.
- Prior to advancing the sealed inflow conduit into the left ventricle through the apical sewing ring, remove the glove tip from the sealed inflow conduit and the centering fixture from the apical sewing ring. Inspect the ventricle and remove any previously formed clots that may cause embolism or any trabeculae that may impede flow.
- If the sealed inflow graft and silicone sleeve are twisted, flow will be restricted through the conduit. See Figure 5.17, *Flexible Silicone Sleeve on the Sealed Inflow Conduit (Correct and Incorrect)*, on page 5-36.
- Confirm that the thread protectors have been removed from the sealed outflow graft and the outflow elbow prior to attempting connection.
- The HeartMate II Left Ventricular Assist Device is capable of producing negative pressure when the pump output exceeds blood flow from the left ventricle. Maintain left atrial pressure (LAP) at greater than 10 mm Hg at all times to prevent air entrainment.
- All entrapped air must be removed from the device blood-pumping chamber and conduits to reduce the risk of air embolus.
- All entrapped air must be removed from the device blood-pumping chamber and conduits prior to fully releasing the sealed outflow graft cross-clamp.
- At least one System Controller power cable must be connected to a power source (Power Module or two HeartMate 14 Volt Lithium-Ion batteries) at all times.
- A minimum of two fully-charged batteries, a pair of compatible battery clips, and a System Controller are required at the time of implant to power the system when transporting the patient out of the O.R. The Battery Charger can charge up to four batteries in four hours or less, depending on the initial charge status of the batteries.
- Do not use the HeartMate II Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.

WARNING ! (Continued)

-  —MR unsafe. Do not subject patients implanted with the HeartMate II Left Ventricular Assist System to Magnetic Resonance Imaging (MRI) as the device contains Ferromagnetic components. MRI can cause pump failure or patient injury. Keep patients away from the RF-shielded room of MRI suites.
- The clinical trial experience indicates that certain models of implantable cardiac defibrillators and certain implantable pacemakers may, in some cases, not be able to establish telemetry or permit communication between the programmer and the implanted device due to electromagnetic interference when used with the HeartMate II. In such cases the implantable cardiac defibrillators or implantable pacemakers have continued to function properly and only their ability to communicate with the programmer was affected. Specific information on reported cases can be obtained on Abbott's website at www.abbott.com. No such difficulties have been reported, other than those observed with devices listed on the website.
- Prior to implanting an implantable cardiac defibrillator or implantable pacemaker in a HeartMate II patient, the device to be implanted should be placed in close proximity to the pump (approximately 10 cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously implanted device that is found to be susceptible to this programming interference, Abbott recommends replacing the implantable cardiac defibrillator device with one that is not prone to programming interference.
- Initial weaning of cardiopulmonary bypass should ensure a minimum of two liters per minute (lpm) of blood flow to the Left Ventricular Assist Device in order to prevent air embolism. Prolonged de-airation may be due to inadequate blood supply to the Left Ventricular Assist Device or a leak in the sealed outflow graft or sealed inflow conduit.
- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- Available clinical data supports safety and effectiveness of the HeartMate II LVAS in patients with a body surface area (BSA) greater than 1.2m². The clinical decision to implant the HeartMate II in patients with a BSA between 1.2m² and 1.5m² should be based on individualized assessment of underlying anatomy, body habitus and device fit. No clinical data is available supporting safety and effectiveness of the HeartMate II LVAS in patients with a BSA less than 1.2m².
- Although a small number of pediatric patients (< 21 years) were enrolled in the HeartMate II study, the safety and efficacy of the device in pediatric patients has not been established.

5 Surgical Procedures

WARNING ! (Continued)

- Always confirm whether an unsealed outflow graft/inflow conduit or sealed outflow graft/inflow conduit is being used. Unsealed outflow grafts/inflow conduits must be pre-clotted prior to use. Sealed outflow graft/inflow conduits must not be pre-clotted prior to use.
- Do not trim or cut the bend relief of the sealed outflow graft or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss.

CAUTION !

- Sharp bends, twists, or kinks in the driveline may make it more susceptible to wear and fatigue over time.
- Do not allow the apical coring knife to involve the interventricular septum while performing left ventricle coring.
- Do not remove the centering fixture inside the apical sewing ring until ready to insert the sealed inflow conduit.
- The sealed outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.
- Remove all vents on the inflow side of the Left Ventricular Assist Device, including needles in the pulmonary vein, left atrium, and left ventricle prior to initiation of pumping.
- Failure to connect the bend relief to the sealed inflow graft so that it is fully and evenly connected can allow kinking and abrasion of the graft, which may lead to serious adverse events such as low Left Ventricular Assist Device flow and/or bleeding. See Figure 5.22, *Bend Relief Connection to the Sealed Outflow Graft (Correct and Incorrect)*, on page 5-41.
- Care should be taken to ensure that the sealed outflow graft bend relief remains connected during sternal closure.
- Once the Left Ventricular Assist Device is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the Left Ventricular Assist Device. Whenever possible, maintain the HeartMate II at a pump flow greater than 3 lpm and a pump speed greater than 8,000 rpm.

Considerations for Preperitoneal or Intra-abdominal Placement

The HeartMate II Left Ventricular Assist Device may be surgically implanted in either the preperitoneal or intra-abdominal location. As described below, the preperitoneal technique requires creating a pocket for the device above the posterior rectus sheath and transversalis fascia and below the rectus abdominis and internal oblique muscles. The pump should be fixated (e.g. to the diaphragm or the chest wall) to prevent migration. For intra-abdominal placement, the device is inserted intraperitoneally in the left upper abdominal quadrant. The decision between these two locations is based on the preference of the implanting surgeon. Potential advantages and disadvantages of each approach are discussed below.

- Preperitoneal placement appears preferable for patients who have undergone previous abdominal surgery or patients with a short torso. Another positive aspect of the preperitoneal approach is that the device is placed outside the abdominal viscera where bowel adhesions are unlikely. Potential disadvantages of using the preperitoneal approach include the risk of pocket hematoma, pocket and exit site infection, wound dehiscence, and erosion of the skin overlying the implanted device.
- Intra-abdominal placement may be preferable for thin patients in whom the risk of erosion of the device through the skin is a concern. Also, thin patients may not permit adequate “tunneling” of the driveline to allow sufficient ingrowth as a barrier to infection. Risks of intra-abdominal placement include diaphragmatic herniation into the pericardial space, wound dehiscence, abdominal (bowel) adhesions, bowel obstruction, bowel perforation, and erosion of the stomach, colon, liver, and abdominal viscera.

Surgical Technique for Preperitoneal Placement

The pump should be positioned below the diaphragm in an adequately sized pump pocket, located inferiorly deep and lateral. After the sternum is divided, the left anterior rectus sheath is opened medially, and electrocautery is used to create a pocket behind the rectus muscle. The dissection is extended laterally, and a pocket is formed between the posterior rectus sheath and transversalis fascia underneath and the rectus abdominis and internal oblique muscles above. The pericardium is opened and reflected laterally to allow exposure of the LV apex. The peritoneum is dissected away from the diaphragm. Further dissection is performed to facilitate insertion of the sealed inflow conduit into the LV apex.

After cardiopulmonary bypass is established and the LV apex is prepared for the insertion of the sealed inflow conduit, the driveline is passed from the inferior aspect of the pocket through the right rectus abdominus muscle and subcutaneous tissue to the right upper quadrant of the abdomen 2 to 3 fingerbreadths below the right costal margin in the midclavicular line. The pump is adjusted in the pocket, and the sealed inflow conduit is inserted into the LV apex and secured. A small preperitoneal pocket is also made behind the right rectus muscle to allow for the sealed outflow graft. The sealed outflow graft is directed to the ascending aorta.

5 Surgical Procedures

Using the HeartMate II Sizer

The HeartMate II Sizer is available as a standalone, reusable item and may help to visualize and create the pump pocket.

FOR THIS TASK YOU NEED:

- 1 HeartMate II Sizer
- 1 Outflow cannula thread protector (optional)

TO CHECK POCKET USING THE HEARTMATE II SIZER:

1. Verify that the HeartMate II Sizer has been inspected, cleaned, and sterilized according to the instructions in *Preparing the HeartMate II Sizer* on page 5-8.
2. After creating the pocket, place the Sizer in the pocket in lieu of the HeartMate II pump.
3. Make any adjustments to pocket size based on the fit and positioning of the Sizer within the pocket.
4. If desired, attach the outflow cannula thread protector to the outflow adapter on the Sizer for the purpose of determining the appropriate outflow graft length (**Figure 5.15**).

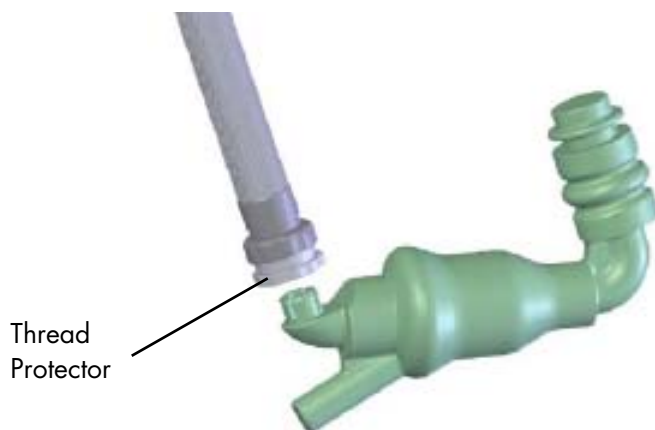


Figure 5.15 Attaching the Outflow Cannula Thread Protector to the Outflow Adapter

5. Remove the Sizer from the patient prior to implanting the actual device.

Surgical Technique for Intra-Abdominal Placement

A midline chest incision is made and extended 2–3 cm below the xiphoid process. Once cardiopulmonary bypass is instituted, the LV apex is prepared for insertion of the sealed inflow conduit. The pump is placed intraperitoneally in the left upper quadrant, and the sealed inflow conduit is positioned to allow insertion of the sealed inflow conduit into the LV apex. The sealed outflow graft is placed over the diaphragm and anastomosed onto the ascending aorta. Typically the driveline exits the body through the right upper quadrant.

Final Check of Prepared Equipment

Prior to implantation, confirm that:

- The bend relief is in place over the sealed graft and unengaged from the metal fitting.
- The Left Ventricular Assist Device is correctly assembled and all joints including the sealed inflow conduit are tight.
- The Left Ventricular Assist Device is completely primed with Sterile Saline for Injection.
- Pump has been run for at least 5 minutes in Sterile Saline for Injection.
- The System Controller has been initialized.

Creating the Driveline Exit Site

The tunnel created for the driveline should be as long as possible to maximize ingrowth along the driveline's polyester velour covering and to minimize the risk of exit site infection. However, at least 1–2 cm (0.4–0.8 in) of the driveline's velour covering should be outside the exit site after the driveline has been tunneled into place.

FOR THIS TASK YOU NEED:

- 1 HeartMate II Left Ventricular Assist Device, prepared for use (see *Preparing the Pump* on page 5-18)
- 1 HeartMate II tunneler or other tunneling tool
- 1 coring punch (8 mm)

TO CREATE THE DRIVELINE EXIT SITE:

1. Identify proposed exit site location (one that minimizes future driveline interference with clothing or belts).
2. Insert the pointed tip of the tunneler into a small incision appropriately positioned on the inner abdominal wall.
3. Starting from the inferior aspect of the pocket, create a long and gently curved tunnel that passes through the right rectus abdominus and subcutaneous tissue to an exit site in the upper right quadrant.
4. Prior to exiting the dermis, place a mark at the exit site. Use the 8 mm skin coring punch supplied in the implant kit to create a circular incision at this position.
5. Thread the bullet on the driveline onto the end of the tunneler. Carefully advance the tunneler to exit through the circular incision, and pull it through to exteriorize the driveline in an upward or superior fashion.
6. Inspect the driveline to ascertain that it is free from any sharp bends or kinks. Consideration should also be given to the potential for sharp bends and kinks occurring postimplant with ventricular remodeling during HeartMate II Left Ventricular Assist System support.

5 Surgical Procedures

7. Place the prepared pump into the prepared space.
8. Remove the centering fixture after securing the sewing cuff, but before inserting the sealed inflow conduit (see *Inserting the Sealed Inflow Conduit* on page 5-36).

IMPORTANT! The tunnel can also be created using a different instrument and the driveline pulled through with the tape attached to the bullet. Also, the bullet tip is threaded and can be attached to appropriately-sized tunneling tools.

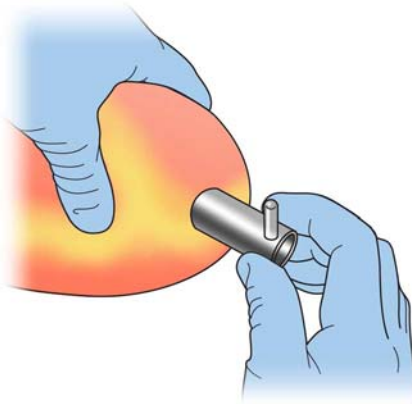
Preparing the Ventricular Apex Site

FOR THIS TASK YOU NEED:

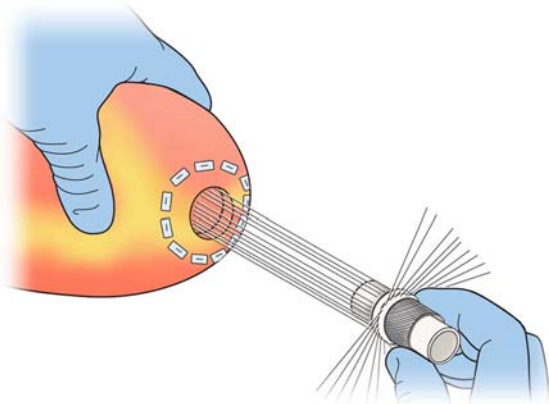
- 1 apical coring knife (20 mm)
- 1 apical sewing ring

TO PREPARE THE VENTRICULAR APEX SITE:

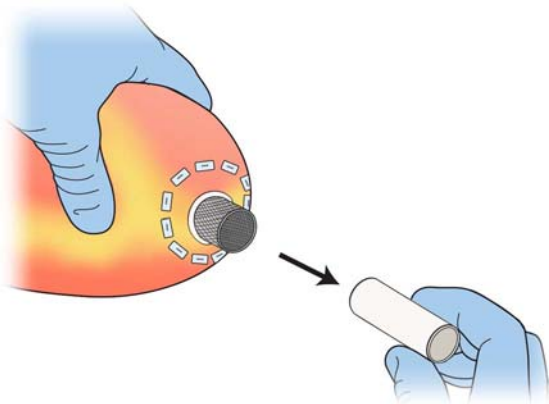
1. Cut the ligature securing the coring knife and remove the plastic plugs from each end. Pull the handle through the hole in the knife cylinder to make a “T” handle.
2. Choose the coring location slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery. Align the orientation of the coring knife toward the mitral valve (**Figure 5.16**). Take care to avoid orienting the inlet towards the interventricular septum. Pump function will be compromised in the presence of inlet obstruction.
3. Apply the cutting edge to the epicardium, and maintain pressure while rotating the knife in one direction until the ventricular cavity is entered. Remove the core and inspect the ventricular chamber for mural thrombi and crossing trabeculae, addressing both as needed.
4. Remove the sewing ring from the package and loosen the green ligature.
5. Wet the sewing ring prior to positioning it over the core for easier removal of the centering fixture.
6. Have an assistant hold the centering fixture of the sewing ring assembly so that the felt portion is directed toward the heart and the silicone tubular portion of the sewing ring is facing outward.
7. Suture the sewing ring cuff with at least 12 pledgeted horizontal mattress 2–0 braided sutures almost full thickness, approximately one and a half centimeters from the core, and apply corresponding sutures to the felt sewing cuff. Then separate the sutures and tie them tight—with 6 to 7 throws on each knot—to gather the myocardium around the felt cuff.



Core the left ventricular apex by rotating the coring knife in one direction.



Place 12 pledgeted horizontal mattress sutures almost full thickness between the left ventricle and felt sewing cuff.



Remove the centering fixture after securing the sewing cuff, but before inserting the sealed inflow conduit.

Figure 5.16 Preparing the Ventricular Apex Site

5 Surgical Procedures

Inserting the Sealed Inflow Conduit

FOR THIS TASK YOU NEED:

- 1 sealed inflow conduit

TO INSERT THE SEALED INFLOW CONDUIT:

1. Select the optimal sealed inflow conduit orientation at the ventricular apex. The following is critical in determining orientation:
 - The opening of the sealed inflow conduit should be directed toward the mitral valve.
 - Position the inflow cannula parallel to the septum, oriented to the central LV.
 - Care must be taken to avoid excessive angulation of the sealed inflow conduit once the Left Ventricular Assist Device is in-situ.
 - The ideal orientation will anticipate that the dilated LV may shrink in size as its workload is assumed by the pump.
2. When the alignment is satisfactory, firmly secure the inlet extension to the apical suture ring using the attached green non-absorbable suture.
 - Employ additional ligatures to ensure that this connection is secure and leak-tight.
 - After ligatures have been applied, do not rotate the pump and cause the sealed inflow graft and flexible silicone sleeve to twist as shown on the right in **Figure 5.17**.



Correct: Silicone Sleeve is Not Twisted



Incorrect: Twisted Silicone Sleeve

Figure 5.17 Flexible Silicone Sleeve on the Sealed Inflow Conduit (Correct and Incorrect)

Attaching the Sealed Outflow Graft

FOR THIS TASK YOU NEED:

- 1 sealed outflow graft with 10.2 cm (4 in) bend relief

TO ATTACH THE SEALED OUTFLOW GRAFT:

1. Confirm that the bend relief is added to the sealed outflow graft prior to attaching it to the aorta.
2. Stretch the graft completely, measure and cut the sealed outflow graft to the appropriate length. The outflow graft should be long enough to be positioned right of the sternal midline to avoid compression of the RV. Anastomose the graft to the ascending aorta in an end-to-side fashion using 4-0 polypropylene running sutures. Make sure that the suture line is secure with no blood loss.
3. Remove the thread protectors from the sealed outflow graft and pump outflow elbow. Allow the graft to back-fill with blood from the aorta. Cross-clamp the graft and attach the proximal end to the outflow elbow using the threaded metal connecting ring (**Figure 5.18**).
4. Hand-tighten the metal connecting ring by turning clockwise until a clicking noise is heard and then continue to turn until tight.
5. Verify that the graft is not twisted or kinked by checking the position of the black line on the graft above and below the bend relief. The line should be straight.

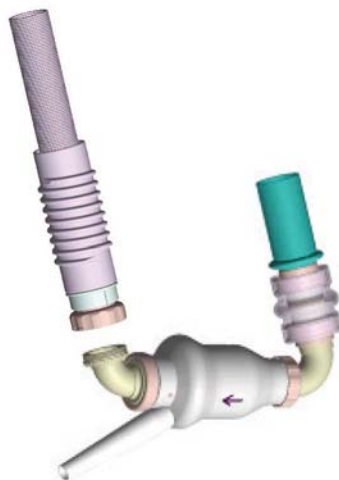


Figure 5.18 Attaching Proximal End of Sealed Outflow Graft to Pump Outflow Elbow

IMPORTANT! A shorter 7.6 cm (3 in) bend relief is available as a standalone, sterile item. For details, see *HeartMate II Product List* on page C-1.

5 Surgical Procedures

Use of the HeartMate II Sizer may help in determining the appropriate graft length. When using the Sizer, the thread protector must be attached to the screw ring connector on the sealed outflow graft. For more information, see *Using the HeartMate II Sizer* on page 5-32.

De-Airing the Pump

When the pump is in place and the sealed inflow conduit and sealed outflow graft anastomoses are completed, residual air must be completely evacuated from the device blood chamber prior to initiating device activation. Transesophageal echocardiography (TEE) should be utilized to monitor for air emboli. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mm Hg.

FOR THIS TASK YOU NEED:

- 1 HeartMate II Left Ventricular Assist Device, prepared for use (see *Preparing the Pump* on page 5-18)
- 1 HeartMate Touch Communication System and Power Module, prepared for use (see *Set Up the HeartMate Touch™ Communication System* on page 4-8)
- 1 HeartMate Touch Wireless Adapter for connecting the Tablet for use with the HeartMate Touch App to the Power Module, through a Bluetooth® pairing
- 1 or more clamps
- 1 vent needle

TO DE-AIR THE PUMP:

1. Cross-clamp the sealed outflow graft at the distal end and move the bend relief toward the aortic anastomosis.
2. Position the sealed outflow graft in a vertical position, such that an arch forms the highest point.
3. Insert a vent needle at the highest point in the graft between the clamp and the sealed outflow graft connection.

IMPORTANT! The needle vent should be placed in the sealed outflow graft in the highest point in the lumen (anterior side to optimize air removal).

IMPORTANT! The surgical field may be optionally flooded with sterile saline or CO₂ to further minimize the risk of air entry and possible embolization.

4. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and Left Ventricular Assist Device by diverting at least two liters per minute (lpm) of blood to the ventricle.
5. Place the patient in the Trendelenburg position.
6. Verify that the HeartMate Touch™ App Clinical view displays the PUMP OFF and LOW FLOW alarm messages, and indicates a speed setpoint of 6,000 rpm (**Figure 5.19**).

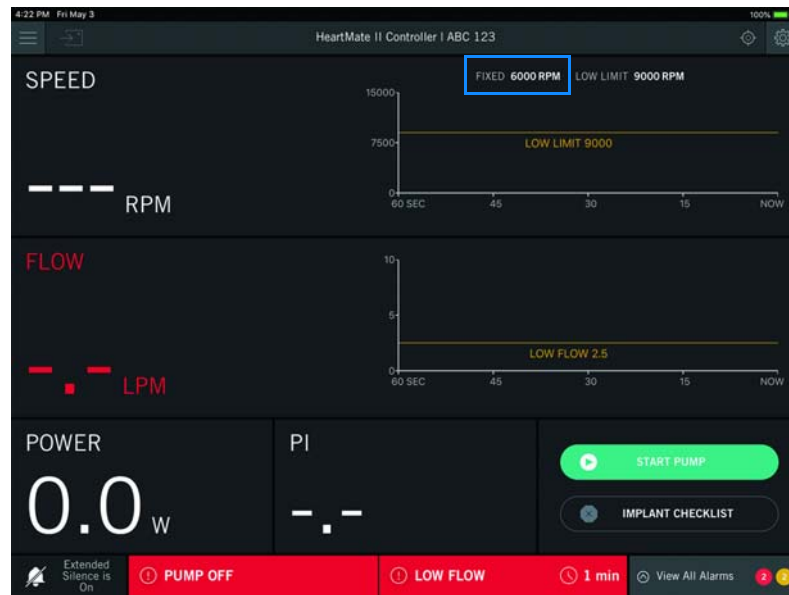


Figure 5.19 Clinical View — Initial Pump Startup

If the speed setpoint is not 6,000 rpm, tap **Settings** (⚙️) > > **Pump** and adjust the Fixed Speed to 6,000 rpm.

The surgical field may be optionally flooded with sterile saline or CO₂ to further minimize the risk of air entry and possible embolization.

7. To initiate HeartMate II pump operation, remove the tunneling bullet from the device driveline and attach the driveline to the System Controller. For more information, see *Connecting the Driveline to the System Controller* on page 2-24.
8. Tap **START PUMP** to initiate Pump speed at 6,000 rpm. A confirmation message appears. Tap **START PUMP** to start. Tap **CANCEL** to return to the Clinical view.

Note: The PUMP OFF message should disappear and the Low Speed Advisory message should appear. **Figure 5.20** and **Figure 5.21** show the typical Clinical View displayed by the HeartMate Touch App during and after initial pump startup. The Pump Flow box displays "-.-" when any of the following occur:

- The pump is stopped.
- The driveline is disconnected.

5 Surgical Procedures

- The pump speed is below 8000 rpm.

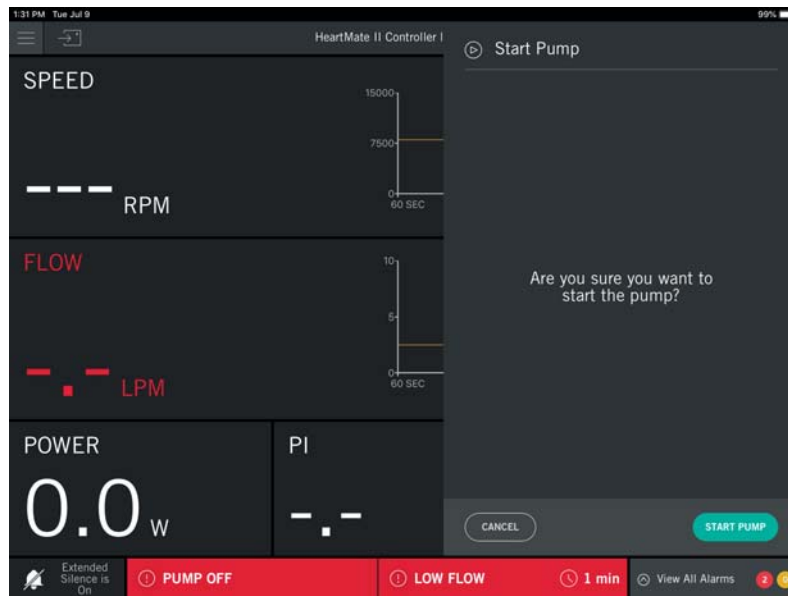


Figure 5.20 Clinical View During Initial Pump Startup (typical)

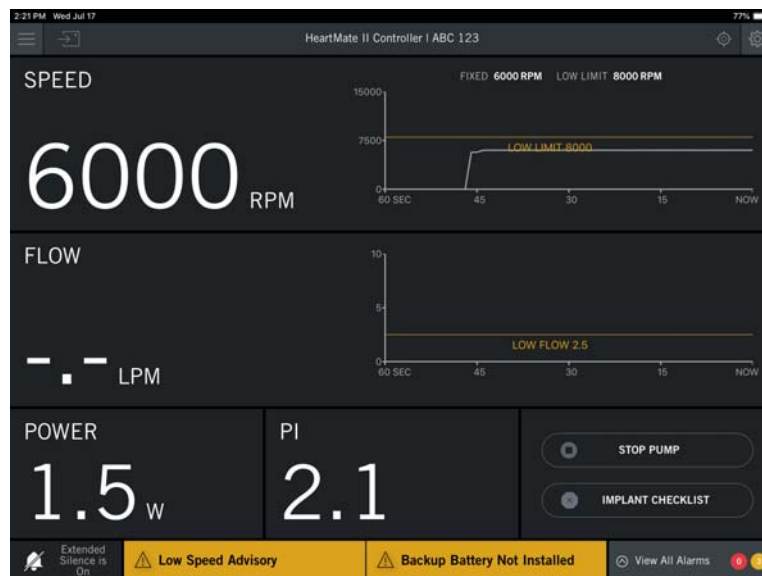


Figure 5.21 Clinical View After Initial Pump Startup (typical)

9. Watch for air being expelled through the venting needle. Throughout the de-airing process, always monitor for the presence of air in the aorta and left heart using intraoperative TEE, and keep the left heart full.

10. When de-airing is completed, partially remove the sealed outflow graft cross-clamp while continuing to operate the Left Ventricular Assist Device. Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate pump flow.
11. Remove the vent needle from the sealed outflow graft and repair the site only when air can no longer be observed exiting through the needle. If air persists in the pump sealed outflow graft for a prolonged period (more than 5–10 minutes), rule out leaks at the sealed inflow conduit/pump connection.
12. Slide the bend relief over the metal fitting of the sealed outflow graft toward the locking screw ring until it snaps into place.

CAUTION !

Failure to connect the bend relief so that it is fully and evenly connected can allow kinking and abrasion of the graft, which may lead to serious adverse events such as low Left Ventricular Assist Device flow and/or bleeding.

Visually inspect the bend relief to confirm that it is fully connected and seated to the sealed outflow graft (**Figure 5.22**). For confirmation, perform the following steps:

- a. Try to unseat the connected bend relief from the metal fitting by gently pulling the bend relief back toward the anastomosis.

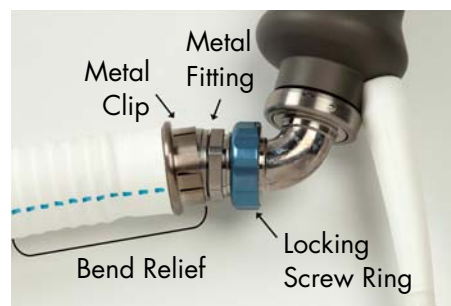
AND

- b. Try to rotate the connected bend relief by rotating the metal clip around the entire circumference of the metal fitting. When the bend relief is fully and evenly connected, the metal clip rotates with ease and does not detach from the snap ring metal fitting (**Figure 5.23**).

IMPORTANT! Ensure that when you rotate the bend relief, you do not rotate/twist the sealed graft. Check the alignment of the black line on the graft to verify that the sealed graft is not twisted or kinked.



Correct: Fully Connected



Incorrect: Not Fully Connected

Figure 5.22 Bend Relief Connection to the Sealed Outflow Graft (Correct and Incorrect)

5 Surgical Procedures



Figure 5.23 Rotate the Bend Relief Connection to Confirm the Connection

13. When all air has been removed from the blood pump, it is safe to increase the pump speed (rpm). Adjust the fixed speed setpoint by pressing the Fixed Speed Adjust button on the Settings screen and following the on-screen instructions to select the desired pump speed setting. Once the desired speed is selected, press the Enter button to send the command to the System Controller.
14. Terminate cardiopulmonary bypass to provide ample blood flow to the Left Ventricular Assist Device. The goal at this time is to achieve and maintain appropriate flow levels by adjusting the fixed speed of the pump. Along with flow, the LV size, position of the septum, and aortic valve opening should be monitored to determine the appropriate fixed speed setting. The final decision is ultimately dependent on the physician's clinical judgment and will vary from patient to patient.
15. Adjustment in pump speed and therefore flow can be made by pressing the Fixed Speed Adjust button on the Settings screen and changing the speed using the adjustment buttons. Speed will only change after pressing the Enter button. The actual flow increase for a given change in speed is dependent on many factors and could vary significantly.

IMPORTANT! The pump flow displays "---" or "+ + +" when flow cannot be accurately calculated.

Recognizing that arterial pressure (device outlet pressure) is closely regulated by the intrinsic cardiovascular regulatory mechanisms of the body, the principal factor influencing pump flow is the inlet pressure (left ventricular pressure). **Figure 5.24** illustrates that running the pump at 6,000 rpm will result in a maximum flow of 4 lpm, provided left ventricular pressure equals arterial pressure. A pressure difference of 20 mm Hg would be required to obtain 2.5 lpm flow at 6,000 rpm, which would result in a left ventricular pressure of $100 - 20 = 80$ mm Hg at an arterial pressure of 100 mm Hg. By increasing the pump speed to 10,000 rpm, a 100 mm Hg pressure difference would be needed to maintain a 2.5 lpm flow rate. This relationship demonstrates that the flow generated by the pump is directly proportional to left ventricular pressure.

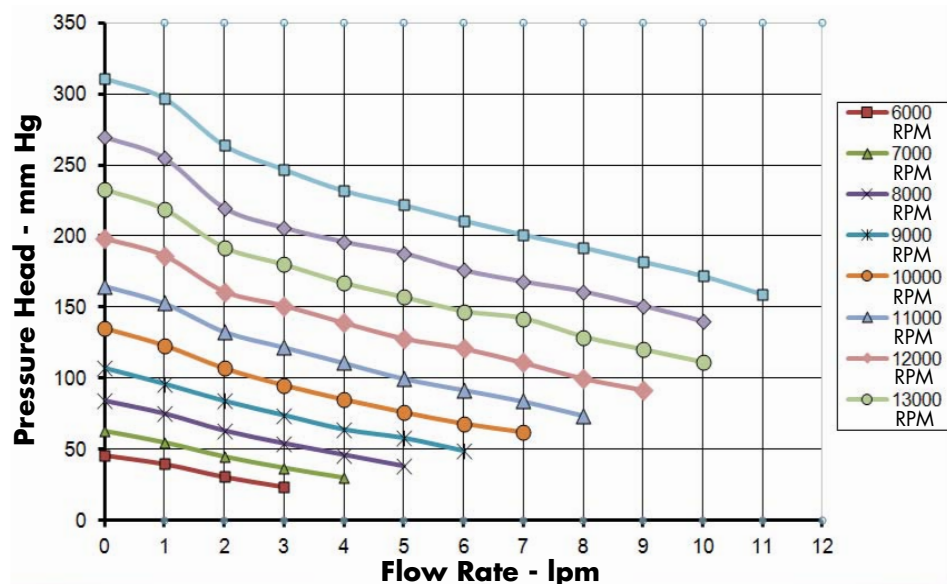


Figure 5.24 Typical HeartMate II Flow Characteristics

IMPORTANT! The pump will start when the System Controller is connected to a driveline and a power source if:

- The fixed speed is set to 8,000 rpm or higher.

OR

- The System Controller's backup battery is installed and any button is pushed on the System Controller.

5 Surgical Procedures

IMPORTANT! Under the following conditions, the pump can only be started from the HeartMate Touch App's Clinical view by tapping **START PUMP**:

- The fixed speed setting is below 8,000 rpm.

AND

- The System Controller's backup battery is not installed.

IMPORTANT! Auscultation over the pump pocket is recommended to verify the pump is running.

Securing the Pump and Connections

CAUTION !

Care should be taken to ensure that the sealed outflow graft bend relief remains connected during sternal closure.

FOR THIS TASK YOU NEED:

- 1 Sealed Outflow Bend Relief Collar
- Sutures should be size 1, non-absorbable, braided sutures with a taper point needle, such as an ETHIBOND® size 1 with a CT-1, CTX, or XLH needle

TO SECURE THE SEALED OUTFLOW BEND RELIEF COLLAR:

1. Once the flow through the blood pump is satisfactory, ensure that all sealed inflow and sealed outflow connections are dry and secure.
2. Attach the Sealed Outflow Bend Relief Collar:
 - a. Place the Sealed Outflow Bend Relief Collar, shown on the left in **Figure 5.25**, around the connection of the bend relief and outflow graft so that the blue of the collar is next to the blue screw ring located on the sealed outflow graft. The Sealed Outflow Bend Relief Collar should be placed as shown on the right in **Figure 5.25** so that the collar spans from the metal clip of the bend relief to the groove of the outflow graft metal fitting.

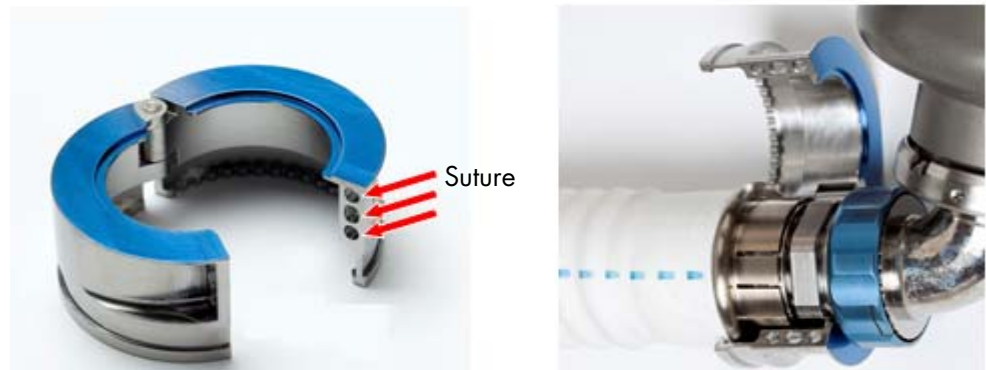


Figure 5.25 Sealed Outflow Bend Relief Collar (left) and Placement of the Sealed Outflow Bend Relief Collar (right)

- b. Close the collar around the connection until the collar halves touch together.

5 Surgical Procedures

3. Secure the Sealed Outflow Bend Relief Collar with sutures:
 - a. Place one suture through suture holes 1 and 2 and tie tight with 6 to 7 throws on each knot as shown in **Figure 5.26**. The knotted suture should lie within the groove of the Sealed Outflow Bend Relief Collar, as shown in **Figure 5.28**.

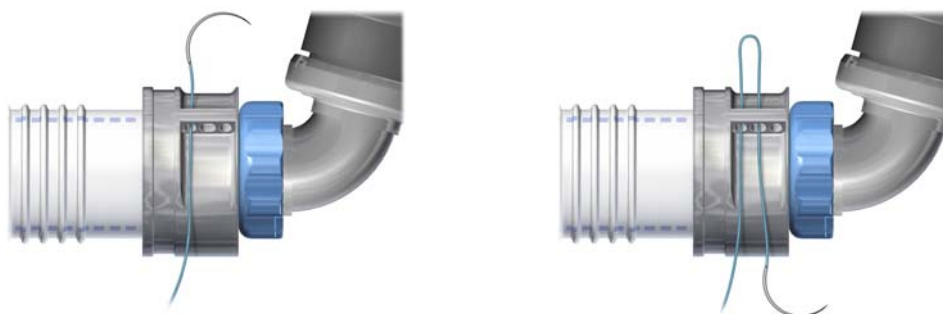


Figure 5.26 Suture Through Suture Holes 1 (left) and 2 (right)

- b. Place a second suture through suture holes 2 and 3 and tie tight with 6 to 7 throws on each knot (**Figure 5.27**).

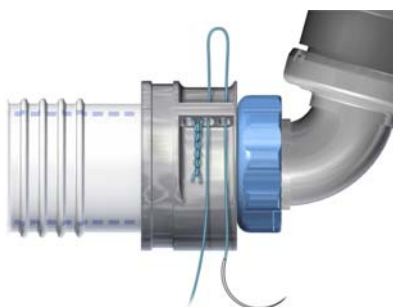


Figure 5.27 Suture Through Holes 2 and 3

- c. The closed and sutured collar should look similar to **Figure 5.28**.

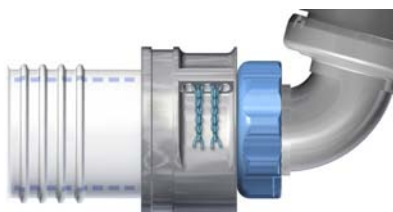


Figure 5.28 Sealed Outflow Bend Relief Collar Closed and Sutured

4. Obtain hemostasis and close all wounds in the standard fashion. Prior to leaving the O.R., immobilize the driveline with the HeartMate Stabilization Belt or other abdominal binder.

Postimplant Procedures

Transferring the Patient Out of the Operating Room

1. Cancel the extended alarm silence by pressing the **Silence Alarm** button on the System Controller's user interface panel.
2. Tap **IMPLANT CHECKLIST**. Review the checklist and ensure that all settings are correct and that no additional modifications are needed.

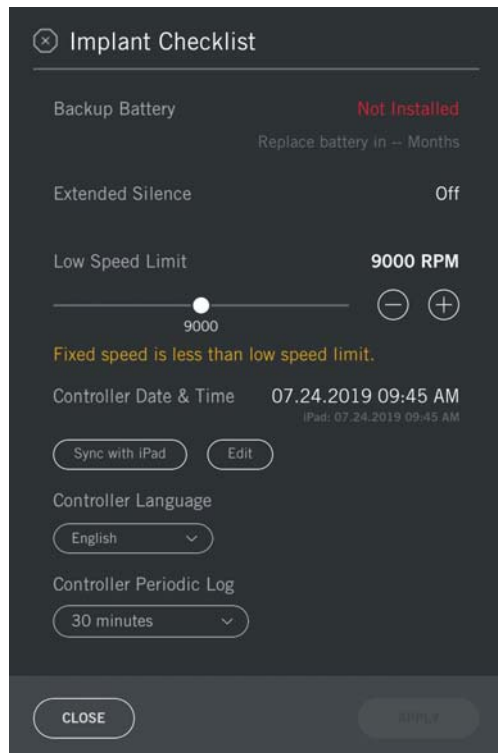


Figure 5.29 Review Implant Checklist Settings

3. Switch the HeartMate II Left Ventricular Assist System from the Power Module to battery power (see *Switching from the Power Module to Battery-Powered Operation* on page 3-59). This step will stop the HeartMate Touch Communication system session with the System Controller.
4. Tuck the batteries securely beside the patient so that the System Controller, power cables, and driveline are not subjected to strain during patient transport.
5. The backup System Controller needs to be programmed. See *Programming and Configuring the Backup System Controller* on page 2-49.
6. After the patient reaches the ICU, return to Power Module power. Press the Silence Alarm button on the System Controller's user interface panel to cancel the extended

5 Surgical Procedures

alarm silence. Go to the HeartMate Touch App Alarms screen and verify the alarm silence is off.

7. As a reminder that the backup battery needs to be installed, a yellow wrench flashes and a graphic is displayed on the System Controller (see *System Controller Backup Battery Not Installed Alarm* on page 7-22).

IMPORTANT! It is recommended that patient specific hemodynamics continue to be monitored during transport to the ICU. HeartMate II pump parameters can be visualized by pressing the display button () on the System Controller's user interface. A cart containing the Power Module and HeartMate Touch Communication System can closely follow the patient and should be re-attached when the patient arrives at his or her destination. Re-establish wireless communication to the System Controller. After the patient has been transferred to batteries, consider programming the backup System Controller because the Power Module is now free to connect to it.

Installing the Backup Battery in the System Controller

After the sterile field has been broken, proceed with installing the System Controller backup battery. As an additional measure, a plastic tab is attached to the System Controller to indicate that backup battery installation needs to occur.

WARNING !

- Do not use damaged, defective, or expired batteries. Using a damaged, defective, or expired battery may reduce operating time during a power-loss emergency or cause the pump to stop.
- Risk of fire and burns. Do not open, crush, heat above 104°F (40°C), or incinerate a battery. Follow manufacturer's instructions.
- If the 11-Volt backup battery becomes excessively hot, switch to the backup System Controller.

CAUTION !

- Charging of the 11 Volt Lithium-Ion backup battery inside the System Controller occurs only when the battery has been installed in a System Controller. Once the 11 Volt Lithium-Ion backup battery is installed, a full charge occurs within 3 hours.
- If an 11 Volt Lithium-Ion backup battery leaks, do not touch the leaking fluid. If the fluid touches your skin or eyes, wash the affected area with plenty of water and seek medical advice.
- To prevent deterioration or damage to an 11 Volt Lithium-Ion backup battery:
 - Store within approved temperatures: 59°F to 77°F (15°C to 25°C).
 - Do not use in temperatures that are below 32°F (0°C) or above 122°F (50°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 in automobiles or automobile trunks, or battery life will be shortened.
 - Do not store in direct sunlight.
 - Do not expose to heat or fire.
 - Do not short circuit a battery or store it haphazardly in a box or drawer where it may short circuit or be short circuited by contact with metal objects.
 - Do not remove a battery from its original packaging until required for use.

5 Surgical Procedures

CAUTION ! (Continued)

- Dispose of or recycle an expired battery in accordance with local, state, and federal regulations.

FOR THIS TASK YOU NEED:

- 1 11 Volt Lithium-Ion backup battery (included with System Controller)
- 1 lever to remove the screw cover of the battery compartment (included with 11 Volt Lithium-Ion backup battery)
- 1 screwdriver to loosen the four battery cover screws (included with 11 Volt Lithium-Ion backup battery)
- 1 spare screw cover (included with 11 Volt Lithium-Ion backup battery)

TO INSTALL THE BACKUP BATTERY IN THE SYSTEM CONTROLLER:

1. Use the lever to remove the screw cover on the System Controller (**Figure 5.30**).



Figure 5.30 Use the Lever to Remove the Screw Cover

2. Use the screwdriver to loosen the four screws on the battery compartment cover (**Figure 5.31**).



Figure 5.31 Use the Screwdriver to Loosen the Screws

3. Remove the battery compartment cover.
4. Remove the plastic advisory "install backup battery" tab.
5. Align the arrow on the ribbon cable with the arrow on the backup battery (**Figure 5.32**).



Figure 5.32 Align the Arrow on the Cable with the Arrow on the Battery

6. Insert the end of the ribbon cable into the battery socket.
7. Confirm that the 11 Volt Lithium-Ion backup battery is properly connected by verifying that the backup battery installation graphic no longer appears on the System Controller.
8. Place the backup battery inside the battery compartment (**Figure 5.33**).



Figure 5.33 Place the Battery Inside the Battery Compartment

9. Place the cover over the battery compartment.
10. Use the screwdriver to tighten the four screws on the cover. Do not overtighten the screws.
11. Replace the screw cover.

IMPORTANT! Be aware that installing an 11 Volt Lithium-Ion backup battery may prompt a System Controller Clock Set Clock advisory (see *HeartMate Touch Alarms* on page 7-23). To resolve the advisory, use the HeartMate Touch App to reset the System Controller clock (see *Controller Date & Time* on page 4-35). Be sure the HeartMate Touch App clock is correct before relying on it.

Device Tracking & Reporting Requirements

The HeartMate II Left Ventricular Assist System is considered a life-sustaining medical device and must be tracked per US Food and Drug Administration (FDA), Health Canada, and other foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device-tracking paperwork shipped with the device must be completed and promptly returned to Abbott. In addition, any device malfunctions must be reported to Abbott by the implanting center.

Device Explant

Explanting the Left Ventricular Assist Device

WARNING !

There is a risk of embolism at device explant or reoperation if manipulation of the pump or conduits are performed prior to initiation of cardiopulmonary bypass and stoppage of Left Ventricular Assist Device pumping.

CAUTION !

The driveline at explant is not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the driveline once cut to minimize the risk of contact with the sterile field.

FOR THIS TASK YOU NEED:

- 1 CV major surgical set
- 1 HeartMate explant kit

TO EXPLANT THE LEFT VENTRICULAR ASSIST DEVICE:

1. Expose the device and carefully dissect it free.
2. Place the patient on cardiopulmonary bypass and establish flow. Disconnect power from the System Controller, and then disconnect the System Controller from the driveline to stop pumping.
3. Cross-clamp the sealed outflow graft just distal to the bend relief and divide the graft.
4. Divide the ligatures securing the apical sewing ring to the sealed inflow conduit and remove the sealed inflow conduit from the ventricle.
5. Repair or plug the ventricle as necessary.
6. Dissect the driveline between the device body and the abdominal wall. Cut the driveline and then remove the externalized portion.
7. Remove the device from the abdomen or preperitoneal pocket, and remove the remaining portion of the driveline from the inside-out by careful dissection. Close the site in standard fashion.
8. Remove the sealed outflow graft remnant from the aorta and repair the anastomotic site.
9. Dispose of all explanted components in accordance with local regulations for biohazardous materials. Alternatively, use the HeartMate Explant Kit to return the explanted components to Abbott for disposal.

5 Surgical Procedures

Using the HeartMate Explant Kit

An explanted HeartMate II Left Ventricular Assist Device should be shipped to Abbott for analysis within 48 hours of explant. Ship overnight for weekday delivery, using the HeartMate Explant Kit.

IMPORTANT! Do not place dry ice into the box for shipment.

IMPORTANT! The pump cannot be shipped before the freezer bricks are frozen.

FOR THIS TASK YOU NEED:

- 1 HeartMate Explant Kit¹

Note: All of the kit contents may not be used; the balance can be discarded.

- 1 explanted HeartMate II Left Ventricular Assist Device

TO PACKAGE AN EXPLANTED HEARTMATE II LEFT VENTRICULAR ASSIST DEVICE FOR ABBOTT ANALYSIS:

1. Obtain a Return Goods Authorization number (RGA) by calling Abbott (see the *Back Cover* of this manual for contact information).
2. Place the freezer bricks in the freezer for 24 hours at which time they will be ready for shipment with the prepared pump.
3. Remove any excess tissue from the exterior of the pump and wipe off excess blood.
4. Place the pump in the large resealable bag with 1 absorbent sheet. Seal the bag.
5. Place four absorbent pads in the pail (**Figure 5.34**).
6. Place the resealable bag with pump into the pail.
7. Firmly place the cover on the pail.
8. Install the locking ring around the cover, using the wire tie to secure the cover to the pail.
9. Place the pail in the refrigerator until shipment (when freezer bricks are frozen and overnight weekday delivery is possible).

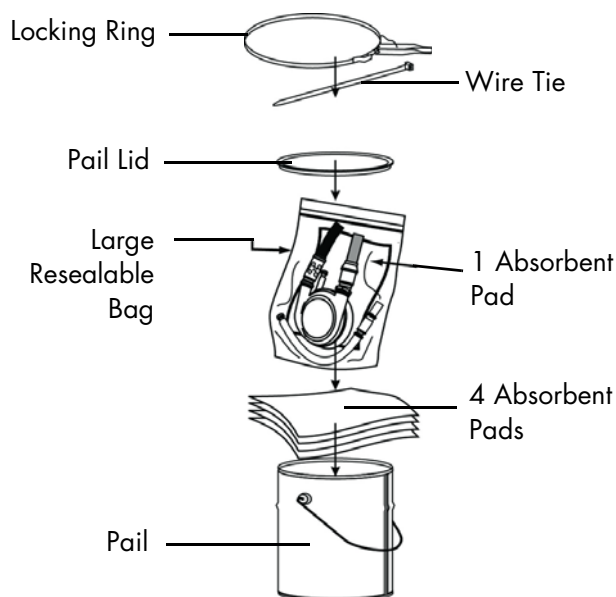


Figure 5.34 Packaging the Pump in the Explant Kit

¹ 29 CFR 1910.1200, Department of Labor, Occupational Safety and Health Administration, Hazardous Communication Standard 42 CFR 72, Public Health, Interstate Shipment of Etiologic Agents 49 CFR, 171-180, Department of Transportation, Hazardous Material Regulation H5-A3, NCCLS. Approved Standard (1994), Procedure for Handling and Transport of Diagnostic Specimens and Etiologic Agents.

10. When ready to ship, remove the freezer bricks from the freezer and the pail from the refrigerator. Place all the components into the shipping box (**Figure 5.35**).

Note: Firmly press all components into the shipping box. Components will fit tightly if properly aligned.

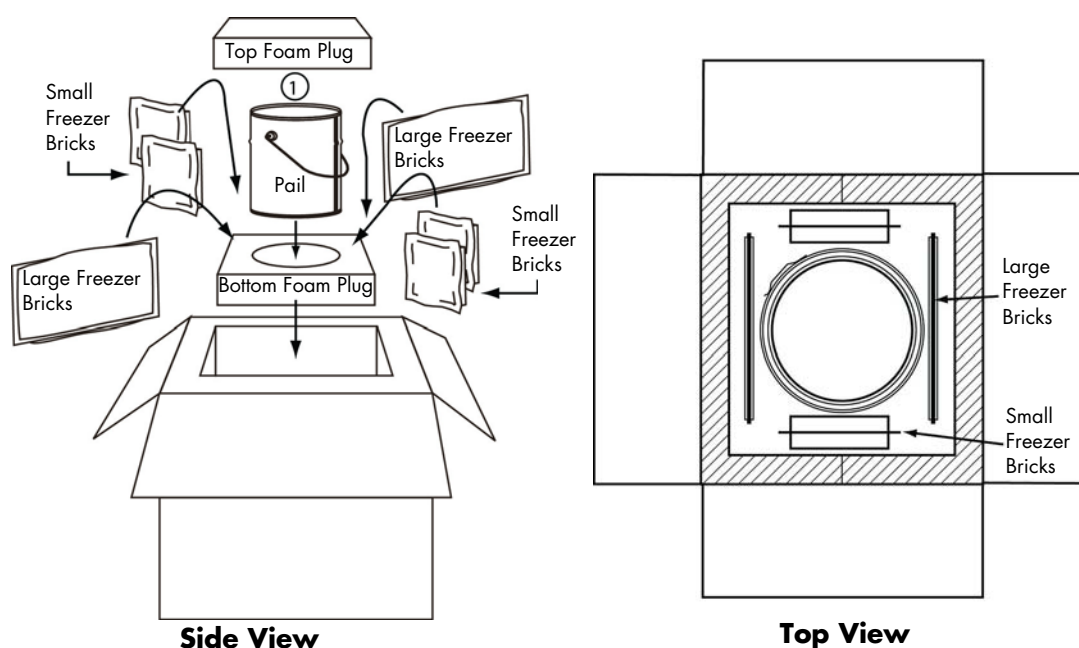


Figure 5.35 Final Explant Kit Packaging for Shipment

11. Create a memo (clearly printed in indelible ink or typewritten) that contains the following information. Place the memo on top of the foam insert.
 - Patient study number (if appropriate)
 - Date of explant
 - Date the shipping box was packed for shipment
12. Close and tape the shipping box securely. Place the Abbott return address label on the outside of the shipping box. Clearly write the RGA number in the space provided on the label.
13. Place the "Used Medical Equipment" label on the outside of the shipping box. Ship via overnight, weekday delivery to:

Abbott Laboratories
23 4th Ave.
Burlington, MA 01803

5 Surgical Procedures

PATIENT CARE AND MANAGEMENT

This section describes postoperative patient care.

Postoperative Patient Care - - - - -	6-3
Ongoing Patient Assessment and Care - - - - -	6-8
Unique Treatment Options and Important Clinical Considerations	6-11
Using the Shower Bag - - - - -	6-15
Using the Stabilization Belt - - - - -	6-25
Wearing and Carrying the System Components - - - - -	6-28
Preparing for Sleep - - - - -	6-63
Ongoing System Assessment and Care- - - - -	6-65
Educating and Training Patients, Families, and Caregivers- - - -	6-68

6 Patient Care and Management

Postoperative Patient Care

Proper care of a patient who is supported by the HeartMate II Left Ventricular Assist System requires a thorough understanding of the system operation and patient condition.

WARNING !

- There is risk of embolism at pump explant or reoperation if manipulation of the pump or conduit is performed prior to the initiation of cardiopulmonary bypass and stoppage of Left Ventricular Assist Device pumping.
- If the Left Ventricular Assist Device stops operating, attempt to restore pump function immediately. When the pump stops operating and blood is stagnant in the pump and conduits for more than a few minutes (depending on the anticoagulation status of the patient), there is a risk of stroke or thromboembolism should the pump be restarted. There is also the potential for retrograde flow within the Left Ventricular Assist Device.
- In the event that the Left Ventricular Assist Device stops operating, counsel the patient to seek immediate medical attention to treat retrograde flow within the pump. Treatment measures may include heparinization, standard interventions for acutely decompensated congestive heart failure, and surgical exploration.
- The patient must always connect to the Power Module or Mobile Power Unit for sleeping, or when there is a chance of sleep. A sleeping patient may not hear system alarms.
- The System Controller may reach a maximum temperature of 124°F (51°C) if BOTH of the following conditions are present:
 - The System Controller is covered by the body or insulating material, such as a blanket
 - AND
 - The internal battery is chargingAvoid contact on bare skin under these conditions because burns may occur. A sedated or sleeping patient, especially in ICU, may not react if the System Controller becomes hot.
- Do not allow patients to swim or take tub baths while implanted with the Left Ventricular Assist Device. Patient immersion in water or liquid will cause the pump to stop.

6 Patient Care and Management

WARNING ! (Continued)

- Do not allow HeartMate II patients to shower without a doctor's permission. Patients may be allowed to shower, but only after sufficient postoperative healing and only with a doctor's permission. If a patient is approved for showering, he or she must always use the Shower Bag for every shower. 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 an electric shock or the pump may stop. See *Using the Shower Bag* on page 6-15 for detailed instructions on using the Shower Bag.
- Keep the Power Module and Mobile Power Unit dry and away from water or liquid. If the Power Module or Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or you may get an electric shock.
- Never submerge the driveline, System Controller, or any external system components (such as the Power Module, 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.
- A backup System Controller and charged batteries must remain with the patient at all times for use in an emergency. Patient and caregiver training must address this crucial requirement.
- High levels of static electricity may damage and/or interfere with the electrical parts of the system, disrupt HeartMate Touch communication, and cause the Left Ventricular Assist Device to stop. In the hospital environment, maintaining a relative humidity level of at least 20% is acceptable. The risk for electrostatic discharge (ESD) events is increased below 20% relative humidity. Avoid activities that may cause static electricity and discharge any buildup by touching a metal surface before handling LVAS components.
- Fluctuations and disturbances in AC mains may interfere with the system and disrupt HeartMate Touch communication.
- Do not use the HeartMate II Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.

WARNING ! (Continued)

-  —MR unsafe. Do not subject patients implanted with the HeartMate II Left Ventricular Assist System to Magnetic Resonance Imaging (MRI) as the device contains Ferromagnetic components. MRI can cause pump failure or patient injury. Keep patients away from the RF-shielded room of MRI suites.
- Therapeutic radiation, such as tissue heating therapy using Radio Frequency (RF) energy sources, may damage the device, and damage may not be immediately detectable.
- There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the outflow graft conduit and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the outflow graft conduit or the dislodgement of the Left Ventricular Assist Device inflow tract.
- Cardiac massage should only be performed by a skilled surgeon, under direct vision in patients who have had recent (ie, prior to mediastinal healing) device implantation.
- If external defibrillation becomes necessary, do not disconnect the System Controller from the driveline prior to delivering the shock.
- If open chest defibrillation is required, it is advised that the HeartMate II Left Ventricular Assist System be disconnected prior to delivering the shock.
- Do not try to fix any of the equipment yourself. If HeartMate II equipment needs service, contact appropriate, Abbott-trained personnel.
- For international travel, the patient must use an Abbott 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 the Mobile Power Unit and Battery Charger. Other power cords must not be used. Contact Abbott for a power cord, if needed. See Abbott contact information on the *Back Cover* of this manual.
- If traveling by aircraft, make sure to bring sufficient battery power to power the system until the destination is reached. Neither the Mobile Power Unit nor the Battery Charger should be used on aircraft.
- Only connect authorized devices to USB ports and to the Tablet Lightning Connector. The connection of unauthorized devices may result in device malfunction.

6 Patient Care and Management

CAUTION !

- Right heart failure can occur following implantation of the pump. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit the effectiveness of the Left Ventricular Assist System due to reduced filling of the pump.
- Notify appropriate personnel if there is a change in how the pump works, sounds, or feels.
- Counsel the patient to avoid contact sports and jumping activities while implanted with the pump. Contact sports or jumping can cause bleeding or damage the pump.
- The driveline exit site must be bandaged prior to applying the HeartMate Stabilization Belt.
- To achieve the desired outcome, apply the HeartMate Stabilization Belt in the operating room, post implant (see *Transferring the Patient Out of the Operating Room* on page 5-47).
- Keep the driveline exit site as clean and dry as possible (see *Caring for the Driveline Exit Site* on page 6-9).
- To avoid pulling on or moving the driveline at the exit site, the patient must wear the HeartMate Stabilization Belt (or other abdominal binder) at all times. Pulling on or moving the driveline can keep the exit site from healing or damage an already healed exit site. Exit site 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, Power Module patient cable, 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. See *What Not To Do: Driveline and Cables* on page 7-46.
- Carefully wash your hands every single time before and after changing the driveline exit site bandages or whenever you touch or handle the driveline exit site. Proper handwashing is one of the easiest and best ways to reduce the spread of infection.
- Do not place objects other than the HeartMate II system components into the wearable accessories. Placing objects other than HeartMate II components into a wearable accessory may damage the wearable accessory.
- During showers, use care to keep the exit site as clean and dry as possible. Also avoid pulling on or moving the driveline during a shower. Position the Shower Bag so that it will not pull on or move the driveline. See *Using the Shower Bag* on page 6-15 for detailed instructions on using the Shower Bag.

CAUTION ! (Continued)

- Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the driveline exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- An electrocardiogram may be indicated to rule out fibrillation if a patient complains of feeling "different" (eg, heart racing, short of breath, heart pains).
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction. Sounds that could signal an issue include grinding or intermittent "whirring."
- Physiological factors that affect the filling of the pump, such as hypovolemia or postural hypotension, results in reduced pump flows as long as the condition persists. Pump flows are not restored to normal unless such conditions are treated.

6 Patient Care and Management

Ongoing Patient Assessment and Care

Patient Assessment

HeartMate II patient assessment may include, but is not limited to, assessment of the following:

- Pump function
- Pump speed, flow, motor power, pulse index (PI), mode of operation
- Driveline is securely connected to the System Controller and the driveline connector safety tab is in the locked position
- Exit site status, immobilization of driveline
- Vital signs, peripheral circulation
- Mental status, level of consciousness
- 12 lead EKG
- ECHO

Potential Risks & Adverse Events

- Hypovolemia
- Right heart failure
- Pulmonary hypertension
- Cardiac tamponade
- Bleeding
- Arrhythmia
- Infection
- Hemolysis
- Thromboembolism
- Neurologic dysfunction

Potential Late Postimplant Complications

- Hypovolemia
- Arrhythmia
- Thromboembolism
- Infection
- Psychosocial issues
- Neurological dysfunction

Caring for the Driveline Exit Site

Currently, no clinical trials delineate the best regimen for care of the driveline exit site. Physician judgment and experience may vary. Nevertheless, the following points should be considered:

- Daily exit site care is recommended. Use a persistent antiseptic cleansing agent such as chlorhexidine containing scrub solutions. Following aseptic cleansing, the site should be dried to avoid tissue maceration. Aseptic technique should be adhered to whenever the exit site is inspected, dressed, or otherwise handled.
- The exit site must be kept clean and dry. Do not apply prophylactic topical agents such as silver sulfadiazine or polymixin-neomycin-bacitracin. These ointments applied to the exit site may macerate the tissues and increase the risk of selecting for resistant microorganisms. The use of a sterile bandage, if applied daily, may be effective in reducing the risk of infection.
- Once the patient is ambulating, the exit site becomes susceptible to trauma from movement or pulling on the driveline. Trauma to the wound in the early stages of tissue ingrowth may increase the risk of infection. Immobilizing the driveline with abdominal wraps or binders reduces trauma to the exit site. Immobilizing the driveline prior to transporting the patient out of the operating room is recommended.
- The risk of systemic infection may also be reduced by withdrawing all intravascular lines as soon as is practical.
- Parenteral treatment with antibiotics and surgical drainage has, on occasion, eradicated infection. However, infections may persist and can result in septicemia and death.
- Fungal infection resulting from organisms such as *Candida albicans* may be associated with vegetative growth on the pump. Persistent systemic fungal infection, refractory to antimicrobial treatment, may necessitate pump replacement or removal.
- Systemic prophylaxis with antifungal agents, such as fluconazole, is reported to have met with moderate success in preventing fungal infection. However, no clinical trials have been conducted to verify the efficacy of antifungal prophylaxis.

6 Patient Care and Management

Controlling Infection

Infection among implantable Left Ventricular Assist Device patients is common, especially in patients with multisystem organ failure who require prolonged stays in the ICU. Infection rates can be minimized, however, by applying the following approaches to patient management:

- Strict adherence to aseptic technique during exit site care.
- Remove all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer antibiotic prophylaxis in the postoperative period and for suspected or confirmed infections, and antibiotics for surgical drainage, as indicated, in patients with evidence of pump pocket infection.
- Adhere to strict blood glucose control.
- Initiate nutritional support to correct nutritional deficits.

Refer to Abbott's *Infection Control Guidelines* (document number 102512) for detailed information about approaches to successful infection control that are used by experienced Left Ventricular Assist Device implant centers that have low rates of infection.

Blood Pressure Measurement and Management

Automatic blood pressure monitors may not be accurate. Manual auscultation with a Doppler is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring (arterial line) may be required.

- Mean arterial pressure should be maintained at <90 mmHg.

Anticoagulation

TO TREAT FOR ANTICOAGULATION:

1. Prior to leaving the O.R., completely reverse the anticoagulation.
2. In patients without persistent bleeding, begin bridging with unfractionated heparin or low molecular weight heparin (LMWH) within 48 hours of device implant with a goal PTT of 40-45 sec in the first 48 hours, followed by titration up to PTT 50-60 by 96 hours. If heparin is contraindicated, consider other alternatives including argatroban, intravenous warfarin, and bivalirudin.
3. Initiate warfarin within 48 hours to obtain a goal INR of 2.0-2.5 by POD 5-7, at which time heparin therapy may be discontinued.
4. Once there is no evidence of bleeding, initiate ASA therapy (81-325 mg daily) 2 to 5 days post HMII implantation.
5. Maintain the patient throughout LVAD support on aspirin and Coumadin with a goal INR of 2.0-2.5.

Conditions that May Require Possible Modification to Anticoagulation

Consider the need for the following modifications to anticoagulation:

1. Sustained low pump flow states (< 3.0 lpm):

Consider increasing anticoagulation to upper limits of normal.

2. Risk of bleeding:

Consider increasing antiplatelet medications and decreasing heparin/warfarin (INR 1.7–2.3). Antiplatelet effect should be confirmed with lab studies (eg, TEG).

Unique Treatment Options and Important Clinical Considerations

Magnetic Resonance Imaging (MRI)

Use of diagnostic MRI is contraindicated in any patient with an implanted HeartMate II Left Ventricular Assist Device. The presence of ferromagnetic parts within the pump makes exposure to strong electromagnetic fields a risk factor for acute pump failure. Keep patients away from the RF-shielded room of MRI suites.

External Chest Compressions

There may be risks associated with performing external chest compressions in the event of cardiac arrest, due to the location of the outflow graft and the presence of ventricular apical anastomosis. External chest compressions may damage the outflow graft conduit or dislodge the Left Ventricular Assist Device inflow tract.

Cardiac massage under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent pump implantation (prior to mediastinal healing).

6 Patient Care and Management

Defibrillation

If external defibrillation becomes necessary, do not disconnect the System Controller from the driveline prior to delivering the shock.

IMPORTANT! If open chest defibrillation is required, be sure to disconnect the HeartMate II Left Ventricular Assist System prior to delivering the shock.

Blood Leak Diagnosis

A blood leak from any implanted component of the system is typically identified through one of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distension of the abdomen.
- Blood draining from the driveline exit site.
- Evidence of decreased hemoglobin/hematocrit.

These symptoms may also occur due to bleeding from native tissue.

Right Heart Failure

Right heart failure may occur at any time following implantation. Follow up closely and intervene with nitric oxide, vasodilators, diuretics, inotropic drugs, or mechanical right ventricular assist device as indicated. Some patients suddenly develop right ventricular failure during or shortly after pump implantation. The onset of right ventricular dysfunction in patients is often accompanied by the inability of the Left Ventricular Assist Device to fill, and drastically reduced flow rates. Limited filling is further exacerbated in the presence of right heart failure with an elevated transpulmonary pressure gradient or high pulmonary vascular resistance.

Treatment for patients in right heart failure typically consists of inotropes to augment right ventricular contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. As a last resort, a right ventricular assist device may be employed.

Electrostatic Discharge

Electrostatic discharge (ESD) is the release of static electricity when two objects come into contact. Familiar examples of ESD include the shock received when walking across a carpet and touching a metal doorknob and the static electricity felt after drying clothes in a clothes dryer. In the hospital environment, maintaining a relative humidity level of at least 20% is acceptable. The risk for electrostatic discharge (ESD) events is increased below 20% relative humidity. High levels of static electricity may damage and/or interfere with the electrical parts of the system, disrupt HeartMate Touch communication, and cause the Left Ventricular Assist Device to stop.

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

Implantable Defibrillators or Pacemakers

Prior to implanting an implantable cardiac defibrillator (ICD) or implantable pacemaker (IPM) in a HeartMate II patient, the ICD or IPM device to be implanted should be placed in close proximity to the pump (approximately 10 cm) and the telemetry verified. If a patient receives a HeartMate II pump and has a previously-implanted device that is found to be susceptible to electromagnetic interference, which could affect programming, Abbott recommends replacing the ICD or IPM device with one that is not prone to programming interference. Specific information on reported cases can be obtained on Abbott's website at www.abbott.com. No such difficulties have been reported, other than those observed with ICD or IPM devices listed on the website.

Pump Performance Monitoring

A feature of this design is that device flow is a function of the pressure difference between the inlet and the outlet to the pump. Therefore, pump performance is sensitive to changes in systemic vascular resistance and left ventricular filling. The following treatment issues are considered critical to the achievement of positive outcomes:

- Close surveillance for physiologic, pathophysiologic, or iatrogenic changes in left ventricular filling (preload) and systemic vascular resistance (after load) is required following implantation. Small increases in after-load or small decreases in preload may result in diminished pump flow, a reduction that may manifest in a clinically relevant decrease in perfusion.
- Standard methods for assessing pump flow may not be helpful under all physiologic conditions. As described above, changes in preload or after load should prompt an immediate patient assessment that includes physical examination to confirm the adequacy of peripheral perfusion. In shock states, physical examination may not provide adequate evidence of perfusion restoration. The use of right heart catheterization under conditions of hemodynamic instability is highly recommended. Mixed venous oxygen saturation measured intermittently or continuously will provide the most sensitive guide to perfusion in post-implantation shock states. If right heart catheterization is not possible, a mixed-venous O₂ saturation from a right atrial catheter may be substituted.
- Auscultation over the pump pocket is recommended in order to verify the pump is running.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.

6 Patient Care and Management

- Complaints of dizziness should prompt immediate evaluation of the patient and system.
- Post-implantation hypertension may be treated at the discretion of the attending physician. Any therapy that consistently maintains mean arterial blood pressure less than 90 mm Hg should be considered adequate. Antihypertensive therapies must be documented.
- Early ambulation and resumption of dietary intake are encouraged. Patient mobilization may occur after the driveline is immobilized.
- Social and family support during rehabilitation is encouraged. Exercise physiotherapy is recommended post-implantation.
- It is critical to use trans-thoracic echo to monitor the left ventricle during speed adjustments. Verify that the septum does not shift, which could compromise right ventricular function.
- Maintain pump speeds above 9000 RPMs and avoid speeds below 8600 RPMS when possible. Adjust pump speed to allow for intermittent aortic valve opening only after the above goals are achieved.
- Thrombus can affect all four parameters of the device: speed, power, flow, and pulsatility index. If the thrombus is sufficiently large, it can obstruct the flow through the pump. If a large thrombus is in contact with the rotor or bearings, it can increase the drag on the rotor and increase the power requirement. With the increased power, the pulsatility index is reduced because the pulsatile component of power becomes relatively small compared with the steady component of power required to overcome the drag. In cases where thrombus increases pump power, the flow will be overestimated and displayed flow could appear in normal range even though pump flow is very low. In cases of identified thrombus formation, pump replacement should be considered.
- Damage due to wear and fatigue of the driveline has occurred in both the externalized and implanted portions of the driveline. Damage to the redundant wires within the driveline may or may not be preceded by visible damage to the outer layer of the driveline. Driveline damage may be evidenced by the following:
 - Transient alarms due to short or open circuits, often associated with movement of the patient or the lead.
 - 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 lead.
 - Cessation of pumping.

If you suspect a damaged driveline, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual.

Using the Shower Bag

Although the external components of the HeartMate II Left Ventricular Assist System are moisture-resistant, they are not waterproof. Take care to protect external system components from water or moisture—outside in heavy rain or snow, and always for every shower. If the external system components have contact with water or moisture, the patient may receive an electric shock or the pump may stop.

When taking a shower, the patient must shield all external components from water by placing them into the water-resistant Shower Bag. This includes protecting the System Controller, System Controller power cables, driveline, and two HeartMate 14 Volt Lithium-Ion batteries with attached battery clips. The Shower Bag must be used for every shower (**Figure 6.1**).



Figure 6.1 Shower Bag

The Shower Bag features a translucent top panel that allows a patient to view the System Controller's user interface while showering. The driveline and System Controller power cables exit the Shower Bag through double zippers along the side. The Shower Bag has an adjustable shoulder strap for optimal positioning to reduce pulling on the driveline exit site. The Shower Bag also incorporates two loops and a belt. It can be worn around the waist to further secure the bag to the patient's body. Two belt loops, one on each side of the bag, allow the bag and belt to be worn on either the patient's right or left side.

6 Patient Care and Management

Figure 6.2 shows the Shower Bag in use.

IMPORTANT! **Figure 6.2** shows an uncovered driveline exit site. Keep the exit site as clean and dry as possible (see *Caring for the Driveline Exit Site* on page 6-9).

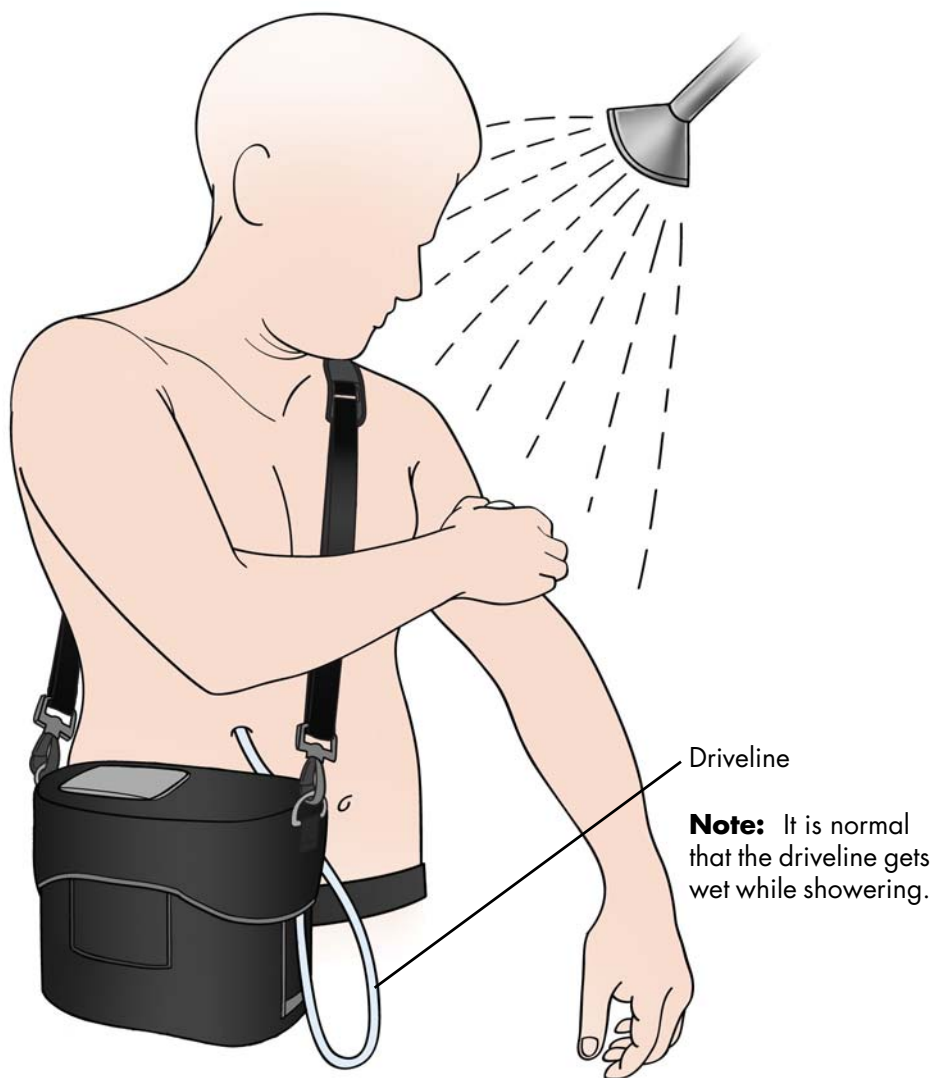


Figure 6.2 Shower Bag in Use

WARNING !

- Do not allow patients to shower without a doctor's permission. HeartMate II patients may be allowed to shower, but only after sufficient postoperative healing, and only with a doctor's permission.
- Do not allow patients to swim or take tub baths while implanted with the pump. Patient immersion in water will cause the pump to stop.
- Never expose the System Controller or batteries to water. The System Controller must be kept dry at all times.
- Do not submerge the Shower Bag in water.
- Patients should not shower while connected to the Power Module or Mobile Power Unit. Use the Shower Bag only while on battery power.
- While in the Shower Bag for an hour or more, the System Controller may reach temperatures as high as 120°F (49°C). Avoid contact on bare skin under these conditions because burns may occur. After opening the Shower Bag, wait for at least 4 minutes before handling the System Controller.

CAUTION !

- To avoid pulling on or moving the driveline at the exit site, the patient must wear the HeartMate Stabilization Belt (or other abdominal binder) at all times. Pulling on or moving the driveline can keep the exit site from healing or damage an already healed exit site. Exit site 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, Power Module patient cable, 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. See *What Not To Do: Driveline and Cables* on page 7-46.
- Keep the exit site as clean and dry as possible (see *Caring for the Driveline Exit Site* on page 6-9).
- Carefully wash your hands every single time before and after changing the exit site bandages or whenever you touch or handle the exit site. Proper hand washing is one of the easiest and best ways to reduce the spread of infection.
- Do not place objects other than HeartMate II equipment in the wearable accessories. Placing objects other than HeartMate II equipment in a wearable accessory may damage the accessory.

6 Patient Care and Management

Assembling the Shower Bag

FOR THIS TASK YOU NEED:

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

TO ASSEMBLE THE SHOWER BAG:

1. Clip the shoulder strap to the Shower Bag using the two rings located on the top of the bag (**Figure 6.3**).



Figure 6.3 Attach the Shoulder Strap

2. To attach the clip-style belt, slide the belt through the loop on the side of the bag that will be against the patient's body (**Figure 6.4**). The Shower Bag can be worn on a patient's left or right side depending on the belt loop chosen.



Figure 6.4 Attach the Optional Belt

3. Adjust the shoulder strap so the Shower Bag fits the patient without pulling on or moving the driveline. Tighten or lengthen the straps until they are secure but still comfortable.

Putting On the Shower Bag

FOR THIS TASK YOU NEED:

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

TO PUT ON THE SHOWER BAG:

1. Gather equipment; place within easy reach.
2. Make sure that the System Controller power cables and driveline are not twisted (**Figure 6.5**).



Figure 6.5 Make Sure the Power Cables and Driveline are Not Twisted

3. Unclip the top of the Shower Bag by squeezing the clip prongs together and pulling the slide out of the buckle (**Figure 6.6**).



Figure 6.6 Squeeze the Clip Prongs Together and Slide Out the Buckle

6 Patient Care and Management

4. Pull back the lid to reveal the double zipper (**Figure 6.7**).



Figure 6.7 Pull Back the Lid

5. Unzip and open the cover of the water-resistant enclosure.
6. Place the batteries, battery clips, and attached power cables into the Shower Bag (**Figure 6.8**).



Figure 6.8 Place the Batteries and Battery Clips Into the Bag

Patient Care and Management **6**

7. Slide the System Controller into the pocket on the inside cover of the bag, cable-free end first and with the user interface facing up (**Figure 6.9**).



Figure 6.9 Slide Controller Into Pocket

8. Prepare to close the cover by positioning the power cables inside the water-resistant enclosure (**Figure 6.10**).



Figure 6.10 Position the Power Cables Inside the Bag

6 Patient Care and Management

9. Close and zip the cover. Make sure the System Controller power cables are inside the bag, and the driveline exits through the protective red tabs (**Figure 6.11**).



Figure 6.11 Close and Zip the Cover

10. Close the lid over the zippered enclosure, carefully positioning the driveline down the side of the bag (**Figure 6.12**).



Figure 6.12 The Driveline Exiting a Closed Shower Bag

11. Snap the clip into the buckle to secure the lid into place (**Figure 6.13**).



Figure 6.13 Snap the Clip into the Buckle to Secure the Lid

12. Use the Shower Bag strap to hang the Shower Bag over the patient's head and shoulder, so the Shower Bag hangs at his or her side.
13. Clip the belt around the patient's waist. The belt secures the Shower Bag and prevents it from dropping if it slips from the patient's shoulder. It also keeps the Shower Bag from swinging away from the patient's body if he or she bends over.
14. Adjust the shoulder strap so that the Shower Bag does not pull on the driveline exit site.

Taking Off the Shower Bag

FOR THIS TASK YOU NEED:

- 1 Shower Bag that is loaded with batteries and running System Controller
- 1 large, clean, dry towel to dry the patient's body
- 1 small, clean, dry towel to dry the Shower Bag
- 4 in x 4 in (10.2 cm x 10.2 cm) sterile gauze bandages to dry the exit site
- 1 or more sterile bandages to dress the exit site
- Wearable accessories to hold or carry the System Controller, batteries, and battery clips after showering

TO TAKE OFF AND DRY THE SHOWER BAG:

1. Unclip the belt from the patient's waist.
2. Carefully lift and remove the Shower Bag shoulder strap from around the patient's neck.
3. Place the Shower Bag on a stable surface.

IMPORTANT! Do not move or pull on the driveline exit site. Do not kink or sharply bend the driveline.

6 Patient Care and Management

4. Use a clean towel to dry the patient's body, excluding the area around the driveline exit site.
5. Use a sterile gauze bandage to dry the driveline exit site.
6. Apply a sterile dressing to the exit site, using an aseptic technique (see *Caring for the Driveline Exit Site* on page 6-9).
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.
9. Remove all equipment from the Shower Bag enclosure; place the equipment in a clean, dry location.
10. Transfer system components to a wearable accessory such as the Holster Vest, Consolidated Bag, Belt Attachment, or System Controller Neck Strap (see *Wearing and Carrying the System Components* on page 6-28).
11. Allow the Shower Bag to drip dry completely before using it again (see *Cleaning HeartMate Wear and Carry Accessories* on page 8-8).

Caring for the Shower Bag

Always hang the Shower Bag and allow it to air dry. Make sure the Shower Bag is completely dry before using it for another shower. See *Cleaning and Maintenance* on page 8-4 for complete instructions on caring for all wearable accessories, including the Shower Bag.

Using the Stabilization Belt

The HeartMate Stabilization Belt is used to immobilize the driveline (**Figure 6.14**). Minimizing driveline movement and pulling can reduce exit site tissue trauma that increases the risk of infection. The Stabilization Belt should be used at all times to reduce driveline movement (**Figure 6.15**).

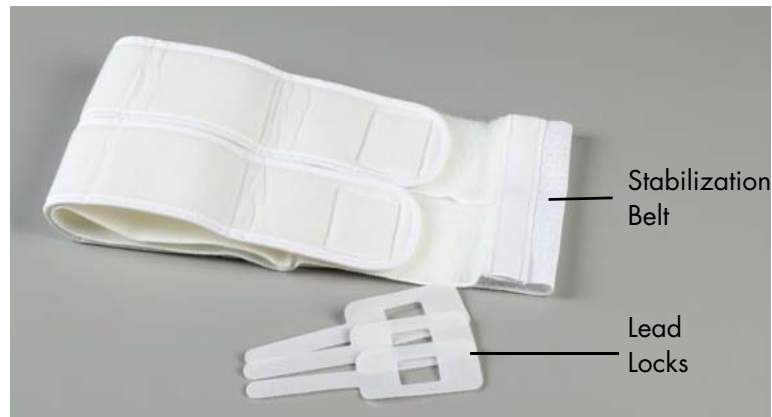


Figure 6.14 Stabilization Belt and Lead Locks

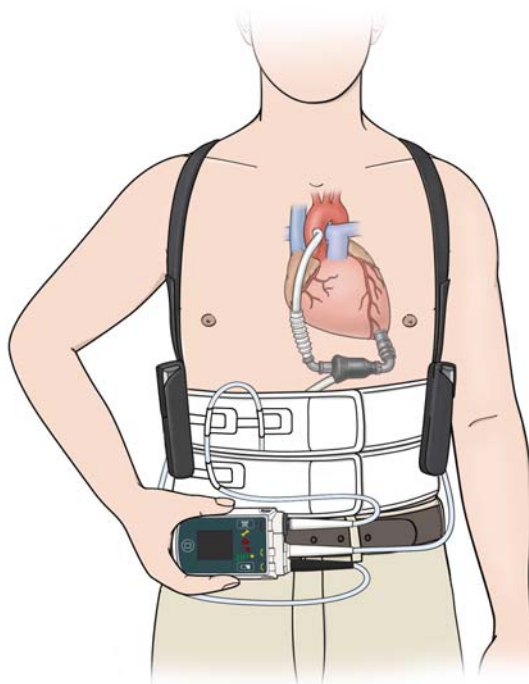


Figure 6.15 Wearing the Stabilization Belt

IMPORTANT! The Stabilization Belt is not sterile. The exit site must be bandaged before applying the Stabilization Belt (see *Caring for the Driveline Exit Site* on page 6-9).

6 Patient Care and Management

CAUTION !

- To achieve the desired outcome, apply the Stabilization Belt in the operating room, post implant (see *Transferring the Patient Out of the Operating Room* on page 5-47).
- Avoid unnecessary pulling or movement of the external portion of the driveline, especially as the exit site is healing. Pulling on or moving the driveline could prolong the healing process or interrupt an already healed exit site, which could increase the risk of serious infection.
- The HeartMate Stabilization Belt must be worn at all times to reduce pulling or movement of the driveline. Pulling on and moving the driveline, especially as the skin exit site is healing, could prolong the healing process or disrupt an already healed driveline exit site. Tissue trauma at the driveline exit site could increase the risk of serious infection.
- The Stabilization Belt is not sterile. The driveline exit site must be bandaged before putting on the Stabilization Belt (see *Caring for the Driveline Exit Site* on page 6-9).
- Instruct the patient to report any redness or skin irritation that occurs as a result of wearing the Stabilization Belt.
- Do not use bleach when washing the Stabilization Belt. Exposure to bleach may cause premature breakdown of the Stabilization Belt material.
- If the Stabilization Belt gets dirty, wash it by hand using a non-bleach detergent. Allow the Stabilization Belt to air dry on its own. Never use heat to dry the belt. Drying the Stabilization Belt at high temperatures may cause premature breakdown of the Stabilization Belt material. Make sure the Stabilization Belt is completely dry before using it.

FOR THIS TASK YOU NEED:

- A running System Controller
- 1 HeartMate Stabilization Belt
- 3–6 Stabilization Belt lead locks to secure the driveline to the Stabilization Belt

TO PUT ON THE STABILIZATION BELT:

1. Gather equipment; place within easy reach.
2. Wrap the lower strap of the Stabilization Belt around the patient's waist, below the driveline exit site.
3. Wrap the upper strap of the Stabilization Belt around the patient's waist, above the driveline exit site. Make sure the driveline exits between the two straps.

Patient Care and Management 6

4. Apply a lead lock flat to the belt on the right side of the driveline—the wide end of the lock should point to the left side of the patient.
5. Gently place the driveline over the center of the lead lock, as shown in **Figure 6.16**.

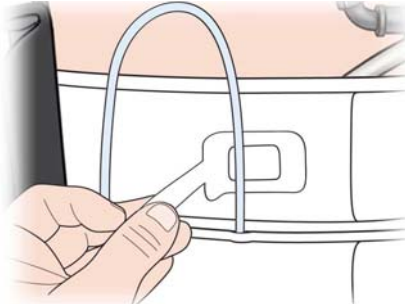


Figure 6.16 Place the Driveline Over the Lead Lock

6. Pick up the tab on the narrow end of the lead lock and then:
 - a. Wrap the tab around the driveline.
 - b. Insert the tab through the square slot on the lead lock (**Figure 6.17**).

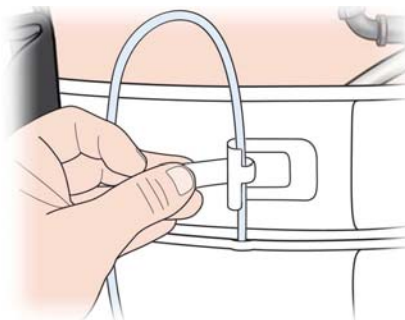


Figure 6.17 Wrap the Tab Around the Driveline and Insert it Through the Slot

- c. Repeat Steps a–b with as many lead locks as needed to securely fasten the driveline to the belt.
7. Attach the tab to the belt. Readjust as required (**Figure 6.18**).

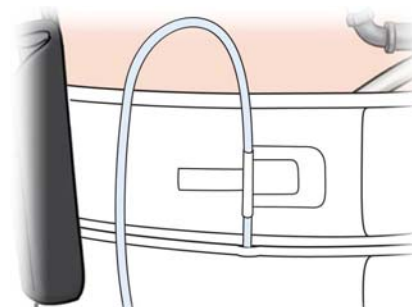


Figure 6.18 Attach the Tab to the Belt

6 Patient Care and Management

Wearing and Carrying the System Components

Various wearable accessories are available to comfortably and securely hold or carry the external system components, such as the System Controller, System Controller power cables, driveline, batteries, and battery clips. The accessories are designed to allow patients to be active. See **Figure 6.19**.



Figure 6.19 Wearable Accessories to Hold or Carry External System Components

The wear and carry accessories are described in **Table 6.1**.

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 Power Module, 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 Power Module, 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).

Table 6.1 Wear and Carry Accessories

Using wearable accessories, patients can stand, sit, walk, crouch, bend over, reach, turn, and lean. Common activities may include, but are not limited to: exercising, dressing, traveling, playing with children, gardening, hiking, cooking, and dancing. The patient should consult with his or her doctor about daily activities and any changes in activity level or routine.

6 Patient Care and Management

CAUTION !

- The HeartMate II Left Ventricular Assist System uses lights and sounds to indicate how it is working. If the patient has trouble hearing or seeing, he or she may need extra help to hear or see the lights and sounds.
- To avoid pulling on or moving the driveline at the exit site, the patient must wear the HeartMate Stabilization Belt (or other abdominal binder) at all times. Pulling on or moving the driveline can keep the exit site from healing or damage an already healed exit site. Exit site 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, Power Module patient cable, 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. See *What Not To Do: Driveline and Cables* on page 7-46.

Using the System Controller Neck Strap

The System Controller Neck Strap (**Figure 6.20**) can be worn around the neck or across the body. It attaches to the System Controller with two small straps.

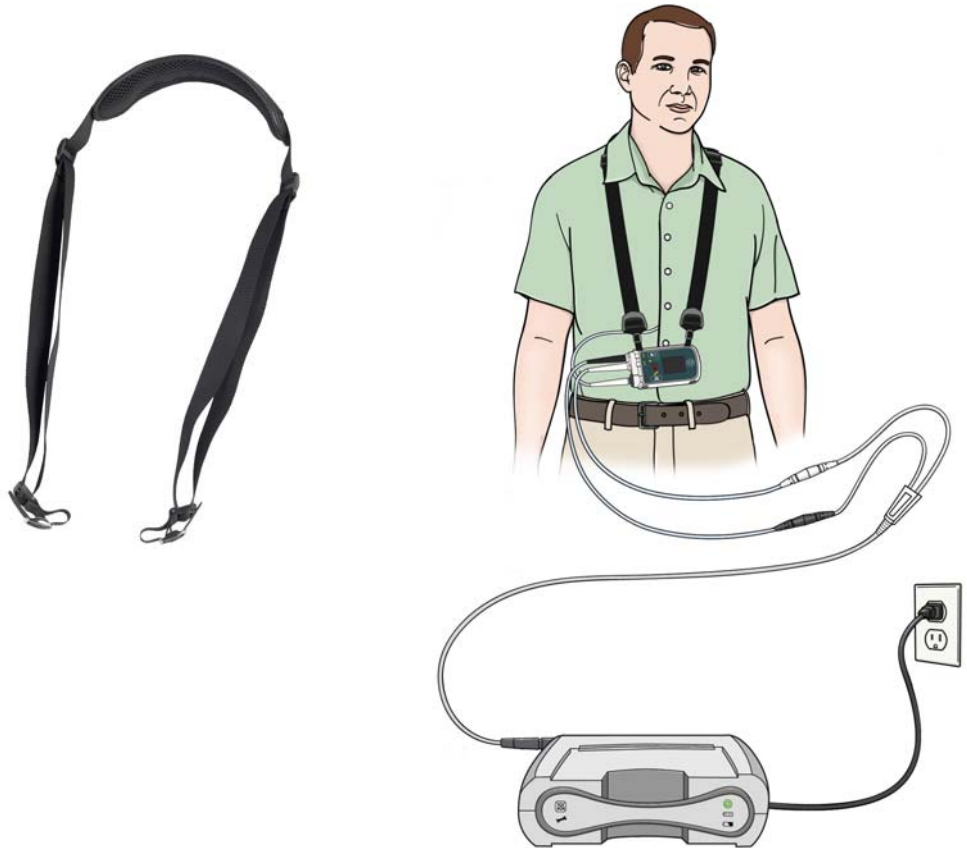


Figure 6.20 Wearing the System Controller Neck Strap

6 Patient Care and Management

The System Controller has an attachment point built into each corner of the System Controller casing (**Figure 6.21**). Use two attachment points to suspend the System Controller, either vertically or horizontally (**Figure 6.22**).



Figure 6.21 Attachment Points on the System Controller



Figure 6.22 System Controller Suspended on System Controller Neck Strap Horizontally (left) and Vertically (right)

FOR THIS TASK YOU NEED:

- 1 running System Controller on Power Module or Mobile Power Unit power
- 1 System Controller Neck Strap

TO ATTACH AND WEAR THE SYSTEM CONTROLLER NECK STRAP:

1. Gather equipment; place within easy reach.
2. Place the System Controller on a flat, stable surface.
3. Make sure the System Controller power cables and driveline are not twisted (**Figure 6.23**).



Figure 6.23 Make Sure the Power Cables and Driveline are Not Twisted

4. Choose two attachment points on the System Controller, for either vertical or horizontal wearing of the Neck Strap.
5. Slide the rubber strap on the Neck Strap through an attachment point on the System Controller (**Figure 6.24**).



Figure 6.24 Slide the Rubber Strap Through the Attachment Point

6 Patient Care and Management

6. To buckle the strap, thread the rubber strap through the metal buckle on the Neck Strap. Make sure the metal prong on the buckle goes through the hole in the strap (**Figure 6.25**).



Figure 6.25 Buckle the Strap

7. Hold the System Controller in one hand and give the Neck Strap strap a tug with the other hand. This will help ensure that the buckle is securely connected to the System Controller (**Figure 6.26**).



Figure 6.26 Tug on the Strap

8. Repeat Step 5 through Step 7 to attach the second strap to another attachment point on the System Controller.
9. Place the Neck Strap around the patient's neck so that the System Controller is located either on the patient's chest or on the left or right side of the patient. Adjust the length of the Neck Strap as needed.

TO TAKE OFF THE SYSTEM CONTROLLER NECK STRAP:

1. Carefully remove the Neck Strap and System Controller from around the patient's neck and place them on a stable surface.
2. Unbuckle the two straps and remove the Neck Strap from the System Controller.

Using the Belt Attachment

The Belt Attachment accessory (**Figure 6.27**) is similar to accessories that are used to wear or carry a cell phone. The Belt Attachment can be attached to the patient's own belt or attached to the provided nylon clip belt.



Figure 6.27 Wearing the Belt Attachment

FOR THIS TASK YOU NEED:

- 1 running System Controller on Power Module or Mobile Power Unit power
- 1 Belt Attachment
- 1 personal belt (up to 2 in or 5.1 cm wide) or 1 provided nylon clip belt

6 Patient Care and Management

TO PUT ON THE BELT ATTACHMENT:

1. Gather equipment; place within easy reach.
2. Make sure the System Controller power cables and driveline are not twisted (**Figure 6.28**).



Figure 6.28 Make Sure the Power Cables and Driveline are Not Twisted

3. Slide either the patient's belt or the provided nylon belt through the loop on the back of the Belt Attachment (**Figure 6.29**).



Figure 6.29 Slide 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 6.30**).



Figure 6.30 Slide the System Controller Into the Belt Attachment

Patient Care and Management **6**

6. Place the two-banded strap over the System Controller and between the white System Controller power cable connector and the driveline connector (**Figure 6.31**).



Figure 6.31 Place the Strap Between the Connectors

7. Clip the two-banded strap into place (**Figure 6.32**). Make sure both prongs are fully engaged in the clip.



Figure 6.32 Clip the Strap Into Place

8. Fasten the belt and Belt Attachment around the patient's waist. Adjust and tighten the belt as necessary.

6 Patient Care and Management

TO TAKE OFF THE BELT ATTACHMENT:

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

OR

3. If using the patient's own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the Belt Attachment and System Controller on a flat, stable surface.
4. To 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.

Using the Consolidated Bag

The Consolidated Bag (**Figure 6.33**) is a slim profile shoulder bag. It allows HeartMate patients to comfortably and securely wear and carry system components together in a single bag while using batteries.



Figure 6.33 Consolidated Bag

The Consolidated Bag can be worn across the body using a shoulder strap and supported at the waist using a waist strap.

6 Patient Care and Management

The compartment that holds the system components is closed using a double zipper. The bag is designed so that the driveline exits the bag through the protective red tabs on the side (**Figure 6.34**).



Figure 6.34 Wearing the Consolidated Bag (Note Waist Strap)

The Consolidated Bag allows the patient to view the System Controller's user interface. The user interface is visible through a transparent panel beneath a small VELCRO® flap on the outside of the bag.

The Consolidated Bag is available in one color (black) and two configurations depending upon the placement of the patient's driveline exit site—one configuration for wearing on the right side and one configuration for wearing on the left side. A tag inside the Consolidated Bag indicates whether the bag is intended to be worn on the right or left side.

Assembling the Consolidated Bag

FOR THIS TASK YOU NEED:

- 1 Consolidated Bag with belt
- 1 Consolidated Bag shoulder strap

TO ASSEMBLE THE CONSOLIDATED BAG:

1. Gather equipment; place within easy reach.
2. Clip the shoulder strap to the Consolidated Bag using the two rings located on the top of the Consolidated Bag (**Figure 6.35**).



Figure 6.35 Clip the Strap to the Bag

3. Confirm which side (left or right) the Consolidated Bag is meant to be worn on by the patient.
4. Put the bag on the patient to confirm the appropriate placement on the left or right side.

IMPORTANT! The bag type (left or right) can be found on a tag inside the Consolidated Bag and on the box that it ships in.

5. Adjust the shoulder strap and belt so the bag fits the patient properly. Tighten or lengthen the strap and belt until they are secure but still comfortable.

6 Patient Care and Management

Putting on the Consolidated Bag

FOR THIS TASK YOU NEED:

- 1 running System Controller on battery power
- 1 assembled Consolidated Bag

TO PUT ON THE CONSOLIDATED BAG:

1. Gather equipment; place within easy reach.
2. Make sure the System Controller power cables and driveline are not twisted (**Figure 6.36**).



Figure 6.36 Make Sure the Power Cables and Driveline are Not Twisted

3. Prepare the Consolidated Bag for use—unzip the double zippers to open the Consolidated Bag.
4. Slide the System Controller into its holder so the user interface faces out (**Figure 6.37**).



Figure 6.37 Slide the System Controller Into the Holder in the Consolidated Bag

Patient Care and Management **6**

5. Stretch the two-banded strap over the System Controller and between the white System Controller power cable and the driveline connector. Fasten the clip to hold the System Controller in place (**Figure 6.38**).



Figure 6.38 Stretch the Strap Over the System Controller and Between the Cables

6. Place the first battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 6.39**).



Figure 6.39 Place the Battery in the Bag

6 Patient Care and Management

7. Arrange the power cable for the first battery and battery clip so that the cable lays flat along the edge of the bag (**Figure 6.40**).



Figure 6.40 Arrange the Cables Around the Edge of the Bag

8. Place the second battery into the Consolidated Bag, with the battery clip and cable facing out (**Figure 6.41**).



Figure 6.41 Place the Second Battery in the Bag

Patient Care and Management **6**

9. Arrange the power cables so that they lay flat along the edge of the bag (**Figure 6.42**).



Figure 6.42 Batteries and Cables in Consolidated Bag

10. Carefully close the Consolidated Bag, with the System Controller power cables inside the bag and the driveline between the protective red tabs (**Figure 6.43**).



Figure 6.43 Close the Bag so the Driveline Exits Between the Red Tabs

6 Patient Care and Management

11. Zip both zippers on the Consolidated Bag closed (**Figure 6.44**).



Figure 6.44 Zip Both Zippers Closed

12. Hold the Consolidated Bag by the handle so it does not drop.
13. Put the shoulder strap over the patient's head and across his or her chest (on either the left or right side of the patient's body, depending on the type of bag), so that the Consolidated Bag rests on the patient's body. Place the waist belt around the patient's body and clip it into place. The belt stabilizes the bag and prevents it from moving.

Taking off the Consolidated Bag

TO TAKE OFF THE CONSOLIDATED BAG:

1. Unclip the belt.
 2. Hold the Consolidated Bag using the handle so it does not drop.
 3. Take off the shoulder strap—either unclip it at one side, or lift it up and over the patient's head.
 4. Take off the Consolidated Bag; place it in front of the patient.
 5. Unzip and open the Consolidated Bag and either:
 - Exchange the depleted batteries for a new, fully-charged pair (see *Replacing Depleted Batteries* on page 3-56).
- OR**
- Transfer from battery power to the Power Module or Mobile Power Unit (see *Switching Power Sources* on page 3-59).
- OR**
- Remove components from the Consolidated Bag and place them into another wearable accessory.

Using the Battery Holster

The Battery Holster allows the patient to comfortably and securely wear and carry the system components (batteries, battery clips, and the System Controller) during battery-powered operation.



Figure 6.45 Wearing the Battery Holster

This wearable accessory is designed to secure the batteries and battery clips in holsters, with the weight of the system components distributed across the patient's shoulders and back. A Belt Attachment is designed to conceal and carry the System Controller. The Battery Holster is available in one size and is adjustable to accommodate most HeartMate II patients (**Figure 6.45**).

6 Patient Care and Management

Assembling the Battery Holster

FOR THIS TASK YOU NEED:

- 1 Battery Holster
- 1 pair of large, sharp scissors
- 1 small tube of strong epoxy glue, such as Super Glue™

TO ASSEMBLE THE BATTERY HOLSTER:

1. Gather equipment; place within easy reach.
2. Place the holster on a flat surface, arranged so the fabric connecting the two straps is in the center.
3. Have the patient slide his or her arms through the straps, so that the fabric connector is between the patient's shoulder blades on his or her back.
4. Pull the loose ends of the strap to adjust the fit. The holsters should fit securely but comfortably against the patient's sides and under the arms.
5. After determining appropriate fit, cut off or trim the extra length from the end of each strap. Consider keeping extra strap length to allow for further adjustment should the patient gain weight.
6. Apply a strong epoxy glue to the cut off ends of each strap to reduce fraying. Allow the glue to dry before wearing the holster.

IMPORTANT! 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 running System Controller on Power Module or 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 the patient's own belt

TO PUT ON THE BATTERY HOLSTER:

1. Gather equipment; place within easy reach.
2. Make sure the System Controller power cables and driveline are not twisted (**Figure 6.46**).



Figure 6.46 Make Sure the Power Cables and Driveline are Not Twisted

3. To insert the batteries and attached battery clips into each holster:
 - a. Open each VELCRO flap (**Figure 6.47**).



Figure 6.47 Open the VELCRO Flap

6 Patient Care and Management

- b. Insert each battery and attached battery clip into a holster, so the battery points down and the battery clip points up (**Figure 6.48**).



Figure 6.48 Insert a Battery and Battery Clip Into the Holster

- c. Close each holster flap (**Figure 6.49**).



Figure 6.49 Battery in Holster with Flap Closed

- d. Repeat Steps a-c for the second battery and battery clip.
4. Have the patient put on the holster.
5. Put on and secure the Belt Attachment around the patient's waist. Adjust and tighten the belt as needed.
6. Slide the System Controller into the Belt Attachment.

7. 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.
8. Slide the clip ends of the two-banded strap into the clip socket. The clip clicks into place when securely fastened.
9. Transfer from the Power Module or Mobile Power Unit to battery power (see *Switching from the Power Module to Battery-Powered Operation* on page 3-59).

Exchanging Depleted Batteries with Charged Batteries

FOR THIS TASK YOU NEED:

- Patient is wearing a Battery Holster with running System Controller on battery power
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO EXCHANGE DEPLETED BATTERIES WITH A FULLY-CHARGED PAIR:

1. Obtain two fully-charged batteries and place them within easy reach.
2. Exchange each battery, one at a time:
 - a. Open the flap on one of the holsters.
 - b. Remove the battery and battery clip from the holster.
 - c. Press the battery release button on the battery clip.
 - d. Withdraw the depleted battery from its battery clip and put aside the depleted battery. A Power Cable Disconnected advisory will sound. This is normal.

IMPORTANT! Remove only one battery from its clip at this time.

- e. Retrieve one of the fully-charged batteries and insert it into the battery clip. It clicks into place when fully inserted. The alarm stops when the fully-charged battery is properly inserted.
 - f. Place the fully-charged battery and attached battery clip into the empty holster.
 - g. Close the holster flap.
 - h. Repeat Steps a-g for the second depleted battery.
3. Recharge the depleted batteries in the Battery Charger (see *Charging HeartMate Batteries* on page 3-73).

6 Patient Care and Management

Taking Off the Battery Holster

FOR THIS TASK YOU NEED:

- Patient is wearing a Battery Holster with running System Controller on battery power
- 1 Power Module or Mobile Power Unit

TO TAKE OFF THE BATTERY HOLSTER:

1. Switch from battery power to the Power Module or Mobile Power Unit (see *Switching Power Sources* on page 3-59). Do this before taking off the holster.
2. Take off the Battery Holster with batteries.
3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
4. If using the nylon clip belt:
 - a. Unclip the nylon clip belt.
 - b. Remove the Belt Attachment, System Controller, and belt from around the patient's waist.
 - c. Place the items on a stable surface.

OR

5. If using the patient's own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the Belt Attachment and System Controller on a stable surface.
6. Remove the System Controller from the Belt Attachment:
 - a. Unclip the two-banded strap from the Belt Attachment.
 - b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
7. Remove the batteries and attached battery clips from the holster and place them on a stable surface.
8. Recharge the low-charged batteries (see *Charging HeartMate Batteries* on page 3-73).
9. Store the Battery Holsters in a clean, dry location (see *Equipment Storage and Care* on page 8-1).

Using the Holster Vest

The Holster Vest (**Figure 6.50**) allows the patient to comfortably and securely wear and carry system components (batteries, battery clips, and the System Controller) during battery-powered operation (see *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45).

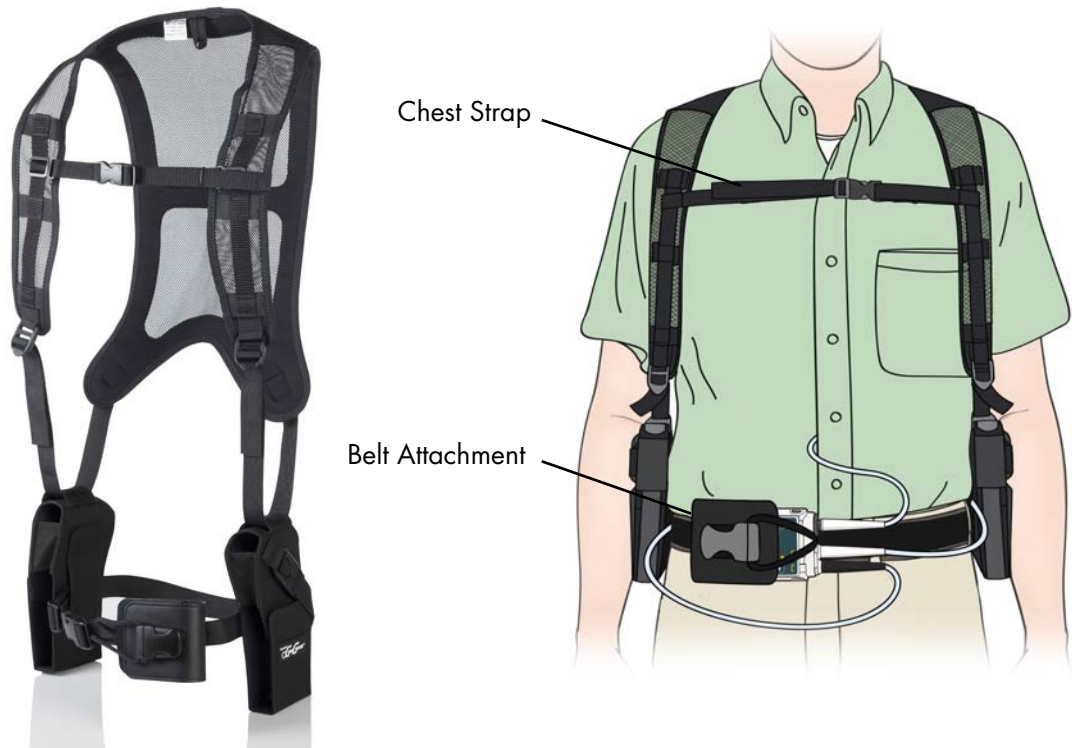


Figure 6.50 Wearing the Holster Vest

The Holster Vest is designed to distribute the weight of the HeartMate system components across the patient's shoulders and back with holsters for the batteries and an optional chest strap.

The Holster Vest is available in three sizes: small, medium, and large. A Belt Attachment cover is provided to conceal, protect, and wear the System Controller with the Holster Vest. The Belt Attachment cover provides visibility and immediate access to the user interface on the System Controller.

6 Patient Care and Management

Assembling the Holster Vest

FOR THIS TASK YOU NEED:

- 1 Holster Vest with Belt Attachment

TO ASSEMBLE THE HOLSTER VEST:

1. Gather equipment; place within easy reach.
2. Insert one vest strap through the slot in the top of one of the holsters. The buckle should point down and the holster should face forward when the patient wears the vest (**Figure 6.51**).

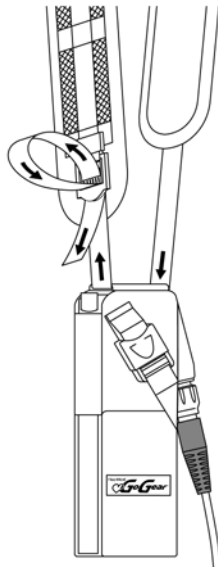


Figure 6.51 Insert Vest Strap Through Slot in Top of Holster

3. Repeat Step 2 for the second holster.

Putting on the Holster Vest

FOR THIS TASK YOU NEED:

- 1 running System Controller on Power Module or Mobile Power Unit power
- 1 assembled Holster Vest with Belt Attachment
- 2 fully-charged HeartMate 14 Volt Lithium-Ion batteries

TO PUT ON THE HOLSTER VEST:

1. Gather equipment; place within easy reach.

2. Make sure the System Controller power cables and driveline are not twisted (**Figure 6.52**).



Figure 6.52 Make Sure the Power Cables and Driveline are Not Twisted

3. To place the batteries and attached battery clips into the holsters:
 - a. Insert one battery and attached battery clip into the holster, so the clip points up and the battery points down (**Figure 6.53**).



Figure 6.53 Insert Battery and Clip into Holster

6 Patient Care and Management

- b. Buckle the clip on the holster (**Figure 6.54**).



Figure 6.54 Buckle the Clip on the Holster

- c. Close the flap on the holster.
- d. Repeat Steps a–c for the second battery and battery clip.
4. Have the patient put on the Holster Vest.
 5. Adjust and tighten the straps as needed.
 6. If the optional 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 the patient's waist. Adjust and tighten the belt as needed.
 8. Slide the System Controller into the Belt Attachment.
 9. Stretch the two-banded strap on the Belt Attachment over the end of the System Controller, and between the white System Controller power cable connector and the driveline connector.
 10. Slide the clip ends of the two-banded strap into the clip socket. The clip will click into place when securely fastened.
 11. Transfer from the Power Module or Mobile Power Unit to battery power (see *Switching from the Power Module to Battery-Powered Operation* on page 3-59).

12. Use the VELCRO tabs on the back of the holsters to hold the power cables in place and to stabilize the holsters (**Figure 6.55**).

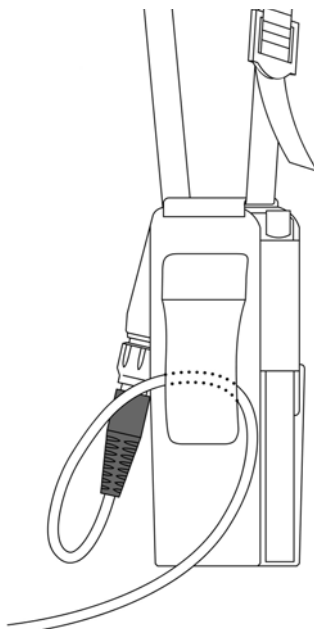


Figure 6.55 Use the VELCRO Tabs to Hold the Power Cables in Place

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

6 Patient Care and Management

Exchanging Depleted Batteries

The Holster Vest allows the convenience of exchanging depleted batteries with a new, fully-charged pair without taking off the vest or disrupting the power cables.

TO EXCHANGE DEPLETED BATTERIES:

1. Obtain two fully-charged HeartMate 14 Volt Lithium-Ion batteries and place them within easy reach.
2. To exchange a depleted battery (**Figure 6.56**):
 - a. Open the flap on one of the holsters to access one of the batteries and 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. Remove only this battery at this time. An alarm will sound when the battery is removed. This is normal.
 - d. Retrieve one of the fully-charged batteries and insert it into the empty battery clip. It clicks into place when fully inserted. The alarm stops when the battery is inserted.
 - e. Close the flap on the holster.

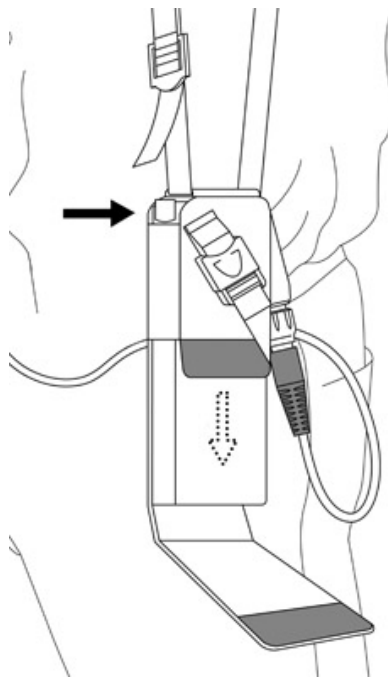


Figure 6.56 Exchanging a Battery

3. Repeat Step 2 to exchange the second depleted battery.
4. Recharge the depleted batteries (see *Charging HeartMate Batteries* on page 3-73).

Taking Off the Holster Vest

TO TAKE OFF THE HOLSTER VEST:

1. Switch from battery power to the Power Module or Mobile Power Unit (see *Switching Power Sources* on page 3-59). Do this before taking off the Holster Vest.
2. Take off the Holster Vest with batteries.
3. Hold the Belt Attachment and System Controller securely in one hand, so that the System Controller does not fall.
4. If using the nylon clip belt:
 - a. Unclip the nylon clip belt.
 - b. Remove the Belt Attachment, System Controller, and belt from around the patient's waist.
 - c. Place the items on a stable surface.

OR

5. If using the patient's own belt:
 - a. Unfasten the belt.
 - b. Slide the Belt Attachment off the belt.
 - c. Place the items on a stable surface.
6. Remove the System Controller from the Belt Attachment:
 - a. Unclip the two-banded strap from the Belt Attachment.
 - b. Slide the System Controller out of the Belt Attachment and place the items on a stable surface.
7. Remove the batteries and attached battery clips from the Holster Vest and place them on a stable surface.
8. Recharge the low-charged batteries (see *Charging HeartMate Batteries* on page 3-73).
9. Store the Holster Vest in a clean, dry location (see *Equipment Storage and Care* on page 8-1).

6 Patient Care and Management

Using the Protection Bag

The Protection Bag (**Figure 6.57**) stores and protects the backup System Controller while it is in Sleep Mode. The Protection Bag has a clear window for easy viewing of the System Controller and power cables inside. The bag protects the equipment from dust, dirt, moderate water, and debris. It also provides a convenient way to store or carry the backup System Controller, which must remain with the patient at all times. The Protection Bag fits into the Travel Bag.

FOR THIS TASK YOU NEED:

- 1 Protection Bag
- 1 backup System Controller and cables

TO USE THE PROTECTION BAG:

1. Unzip the Protection Bag.
2. Slide the backup System Controller into the Protection Bag.
3. Carefully coil the cables around the System Controller inside the Protection Bag.
4. Zip closed the Protection Bag (**Figure 6.57**).



Figure 6.57 Protection Bag with Backup Controller and Cables Stored Inside

IMPORTANT! When placing the System Controller inside the Protection Bag, do not twist, kink, or sharply bend the System Controller power cables, which may cause damage to the wires inside, even if external damage is not visible. If the cables become twisted, bent, or kinked, carefully unravel and straighten. See *What Not To Do: Driveline and Cables* on page 7-46.

IMPORTANT! Do not store or carry anything in the Protection Bag other than the backup System Controller and attached power cables.

IMPORTANT! Do not store or carry the backup System Controller outside of recommended environmental conditions (see *Equipment Storage and Care* on page 8-1).

Using the Travel Bag

The Travel Bag accommodates a System Controller in its Protection Bag, along with spare batteries. The Travel Bag provides a convenient way to carry and transport the backup System Controller and spare batteries. The Travel Bag can also be used at home to hold the backup System Controller (**Figure 6.58**).



Figure 6.58 Travel Bag

FOR THIS TASK YOU NEED:

- 1 Protection Bag with backup System Controller and cables stored inside
- 2 spare fully-charged 14 Volt Lithium-Ion batteries
- 1 Travel Bag

6 Patient Care and Management

TO USE THE TRAVEL BAG:

1. Open the top lid, unzip the inner compartment, and open the Travel Bag.
2. Place the Protection Bag (with the backup System Controller and cables inside) into the Travel Bag (**Figure 6.59**).



Figure 6.59 Insert the Protection Bag Into the Travel Bag

3. Place fully-charged, spare batteries into the side pockets of the Travel Bag (**Figure 6.60**).



Figure 6.60 Insert Spare Batteries Into the Travel Bag

4. Zip closed the inner compartment and snap shut the top lid.

WARNING !

The Left Ventricular Assist Device will stop 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 it with a backup System Controller that is programmed with patient-specific settings. See *System Controller Alarms* on page 7-3 for warnings, cautions, and instructions.

IMPORTANT! Do not store or carry the backup System Controller or spare batteries outside of recommended environmental conditions (see *Equipment Storage and Care* on page 8-1).

Preparing for Sleep

HeartMate II patients must be attached to the Power Module or Mobile Power Unit during sleep or any time when sleep is likely. During sleep, the System Controller and driveline must be immobilized to reduce movement or pulling on the driveline exit site. The HeartMate Stabilization Belt or an abdominal binder may be used to immobilize the driveline and System Controller.

WARNING !

- The patient must always connect to the Power Module or Mobile Power Unit for sleeping, or when there is a chance of sleep. A sleeping patient may not hear system alarms.
- The System Controller may reach a maximum temperature of 124°F (51°C) if BOTH of the following conditions are present:
 - The System Controller is covered by the body or insulating material, such as a blanketAND
 - The internal battery is charging

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

- A patient should sleep or plan to sleep only when connected to the Power Module or Mobile Power Unit. If a patient falls asleep during battery-powered operation, the low battery alarms may not awaken the patient before battery depletion.
- Prior to sleep, inspect and make sure that all electrical connections are secure.
- A patient should not sleep on his or her stomach.
- Keep the replacement System Controller nearby for convenient access in the event of an emergency that requires replacement of the running System Controller.

6 Patient Care and Management

- Keep a flashlight, fully-charged batteries, and battery clips within reach to be prepared for a power outage.

Ongoing System Assessment and Care

Caring for the Driveline

It is extremely important that the driveline be protected from extreme or frequent bending or kinking. Damage to the driveline, depending on the degree, may cause the pump to stop.

The patient must be educated about the importance of keeping the driveline free from damage. Routinely reinforce the importance of adhering to the following guidelines for driveline care:

- Do not severely bend or kink the driveline.
- Do not let the driveline become twisted.
- If carrying the System Controller in a carrying case, do not “catch” the driveline in the zipper.
- Allow for a gentle curve of the driveline. Do not severely bend the driveline multiple times or wrap it tightly.
- Keep the driveline clean. Wipe off any dirt or grime that may appear. If necessary, use a towel with soap and warm water to gently clean the driveline. However, never submerge the driveline or other system components in water or liquid. See *Care of the Driveline* on page 8-5 for information about caring for the driveline.
- Do not pull on or move the driveline going through the skin.
- When checking to ensure that the driveline connector is fully inserted into the System Controller driveline socket, gently tug on the metal end of the connector. Do not move or pull on the driveline.
- Wear the HeartMate Stabilization Belt or another abdominal binder at all times to keep the driveline in place and to prevent moving and pulling on the driveline.
- Be mindful of where the System Controller is at all times. Protect the System Controller from falling or from pulling on the driveline.
- Do not allow the driveline to catch or snag on anything that can pull on or move the driveline.
- Check the driveline daily for signs of damage, such as cuts, holes, or tears. Counsel patients to inform you immediately if they find signs of driveline damage.
- Damage due to wear and fatigue of the driveline has occurred in both the externalized and implanted portions of the driveline. Damage to the electrical conductors within the driveline may or may not be preceded by visible damage to the outer layer of the driveline. Driveline damage may be evidenced by the following:
 - Transient alarms due to short or open circuits, often associated with movement of the patient or the driveline.
 - High pump power associated with reduced pump speed (as recorded in the System Controller event log file).

6 Patient Care and Management

- 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.

IMPORTANT! If you suspect that a HeartMate II patient has a damaged driveline, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual. X-ray images and System Controller event history (log files) may be useful to assess the extent and location of the damage. If damage to the electrical conductors in the driveline is confirmed, the pump should be replaced as soon as possible. If damage to the driveline is visible, please send a photograph along with the log file to assist with problem resolution.

When there is a disruption to the continuity of the wires in the driveline, damage may occur to the System Controller. If damage occurs to the System Controller and the System Controller requires replacement, consider supporting the patient with batteries, rather than the Power Module or Mobile Power Unit, to reduce the potential System Controller damage.

Caring for the System Controller Power Cables

It is extremely important that the System Controller power cables be protected from kinks, sharp bends, and repeated bending. This is especially applicable if the patient is active. Damage to the power cables, depending on the degree, may impair pump function.

The patient must be educated about the importance of keeping the System Controller power cables free from damage. Routinely reinforce the importance of adhering to the following guidelines for power cable care:

- Do not kink or sharply bend the power cables, especially near the strain relief portion of the System Controller connectors (where the connector and cable meet). See **Figure 6.61**.
- Avoid repeated bending of the power cables, especially near the connectors.
- When carrying the System Controller in a bag, case, or other carrier, do not kink or sharply bend the power cables, especially near the connectors.
- When carrying the System Controller in a zippered carrying case, do not “catch” the power cables in the carrying case zipper.
- Do not let the power cables become twisted.



Figure 6.61 Do Not Bend System Controller Power Cables

6 Patient Care and Management

Educating and Training Patients, Families, and Caregivers

During the patient selection, preimplant, and postoperative period, the patient must receive instructions regarding the operation and care of every system component. Consider using a Competency Assessment Checklist to test and measure discharge readiness of patients and their family members or caregivers.

At a minimum, you must discuss the following topics when training the patient (and his or her family members or caregivers):

1. General information
 - Concept of ventricular assistance
 - How the Left Ventricular Assist Device pumps blood
 - Control modes
 - Battery-powered versus Mobile Power Unit operation
 - Battery use regimen
 - Advisory and Hazard alarms: including their meaning and how to recognize and respond to them
 - Medical Alert ID Bracelet (recommended)
 - Maintenance and periodic safety checks
 - Daily, weekly, monthly, six months, and yearly safety checklists
 - Anticoagulation
2. System components
 - Left Ventricular Assist Device
 - Driveline
 - System Controller
 - System Controller connectors for driveline and power cables
 - System Controller power cables
 - Charging the backup battery in the backup System Controller
 - HeartMate 14 Volt Lithium-Ion batteries and battery clips
 - Using, charging, testing, and calibrating HeartMate 14 Volt Lithium-Ion batteries
 - Battery Charger
 - Mobile Power Unit
 - Stabilization Belt
3. Using the wear and carry accessories to hold and carry system components

4. Operating the system
 - Making connections
 - Changing power sources
 - Performing a System Controller self test
5. What to do in an emergency
 - What is an emergency (clinical emergency versus equipment emergency)
 - Steps to take in an emergency
 - Emergency transportation plan
 - Preparing for and practicing emergency procedures
 - How to diagnose power or connector problems
 - Emergency telephone contacts
 - Replacing the running System Controller with the backup System Controller
6. Exit site care
7. Showering
8. Preparing for sleep
9. Travel
10. Warnings and cautions

6 Patient Care and Management

ALARMS AND TROUBLESHOOTING

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

System Controller Alarms - - - - -	-7-3
HeartMate Touch Alarms - - - - -	-7-23
Power Module Alarms - - - - -	-7-37
Mobile Power Unit Alarms - - - - -	-7-40
Battery Charger Alarms - - - - -	-7-42
Guidelines for Power Cable Connectors - - - - -	-7-45
What Not To Do: Driveline and Cables- - - - -	-7-46

System Controller Alarms

Patient-Resolvable Versus Clinician-Resolvable Alarms

Patients can resolve and troubleshoot many System Controller alarms on their own, without clinician intervention. Primarily, patient-resolvable alarms involve maintaining connections to the driveline and external power sources. There are, however, many situations where clinician help is needed. In these situations, a “Call Hospital Contact” message appears on the information display screen. Depending on the hospital center, the clinician may ask the patient to replace his or her System Controller. In other cases, the clinician may arrange for the patient to be admitted for additional diagnostics and resolution by clinicians.

There are some Advisory alarms that are displayed only on the HeartMate Touch App with the intent of being resolved in the clinic. They indicate potential issues that do not impact the ability of the System Controller to provide support, but should be addressed when the patient is in the clinic.

These alarms are displayed as an active alarm on the HeartMate Touch App but are not displayed on the System Controller. These alarms include Driveline Fault Alarm and Controller Clock Not Set Alarm.

There are various conditions that may cause a Controller Fault or a Backup Battery Fault Alarm to occur. Some of these conditions do not need to be addressed when the condition is identified, and will only be displayed as active alarms when the controller is connected to the HeartMate Touch App.

Table 7.1 details which Advisory alarms are displayed only on the HeartMate Touch App or depending on the alarm cause displayed, on both the HeartMate Touch App and the System Controller.

Alarm	Alarms that will only be displayed on the HeartMate Touch App	Alarms that will be displayed on the HeartMate Touch App and may also be displayed on the System Controller	Alarms that will always be displayed on both the HeartMate Touch App and the System Controller
Controller Clock not set	X		
Driveline Fault	X		
Internal Fault		X	
Backup Battery Fault		X	
Backup Battery not installed			X

7 Alarms and Troubleshooting

Alarm	Alarms that will only be displayed on the HeartMate Touch App	Alarms that will be displayed on the HeartMate Touch App and may also be displayed on the System Controller	Alarms that will always be displayed on both the HeartMate Touch App and the System Controller
Connect Power			X
Low Battery			X
Low Speed Warning			X

Table 7.1 Advisory Alarm Display Locations

Handling System Controller Alarms

Common System Controller alarms are described on the following pages. Each section addresses the likely cause and typical steps for resolving most System Controller alarms. Alarms are presented in order of priority. Hazard alarms appear first, followed by Advisories. See **Table 7.3** and **Table 7.4** on the following pages for a complete list of prioritized System Controller alarms.

IMPORTANT! System Controller alarms cannot be silenced when the System Controller is in power saver mode. For more information about power saver mode, see *Low Speed Limit* on page 4-30.

Alarm Screen Overview

When an alarm occurs, messages appear on the System Controller's user interface screen to help resolve the problem. These screen messages indicate the alarm type as well as how long the alarm has been occurring. The timer on the screen counts up in seconds, indicating how long the alarm has been occurring. **Figure 7.1** shows the alarm screen layout.



Figure 7.1 Alarm Screen

Viewing Alarm History on the User Interface Screen

You can view alarm history on the System Controller user interface. The last six relevant System Controller alarms are displayed. The alarm history 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 Disconnected Alarm (lasting over 30 seconds)
- External Power Disconnected Alarm
- Driveline Disconnected Alarm
- Low Battery Power Advisory Alarm
- Low Battery Power Hazard Alarm
- Low Flow Alarm
- Low Speed Alarm

Only a subset of alarms is displayed on the System Controller; a history of all alarms is available through the HeartMate Touch App (see *System Controller Periodic Log* on page 4-38).

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

Alarm history screens show the date and time of the alarm occurrence at the top of the screen. A dot at the bottom of each screen provides navigational information about which screen is in view (see **Figure 7.2**).

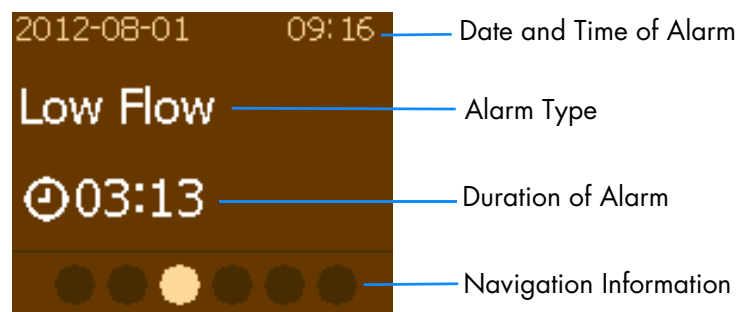


Figure 7.2 Sample Alarm History Screen

7 Alarms and Troubleshooting

Table 7.2 shows how to access the alarm history screens.

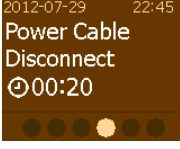
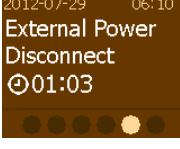
Button Press	Description	Alarm Screen Displayed (Example)
Press   AND  	Press display button and silence alarm button at the same time to access first alarm.	
Press  	Press display button ONCE to display the second alarm.	
Press  	Press display button a SECOND time to display the third alarm.	
Press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

Table 7.2 Viewing Alarm History Screens

Alarms and Troubleshooting 7

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

7 Alarms and Troubleshooting

Alarms That Do Not Appear in Alarm History

The System Controller Backup Battery Fault and System Controller Fault alarms are examples of non-transient alarms that require specific user action to resolve the alarm condition. These alarms remain on the user interface screen until the alarm condition is resolved, and therefore do not appear in alarm history.

In addition, a Power Cable Disconnected advisory alarm (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.

Available Languages

On-screen messages on the user interface can be displayed in multiple languages. Use the HeartMate Touch App to view and select the desired language (see *System Controller Language* on page 4-39).

Alarms and Troubleshooting 7

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
HAZARD	Low Flow  :03 + Call Hospital Contact  :07		Pump is off. The Pump Running symbol (⌚) is black.	1. Check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the HeartMate Touch App's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt pump start. 2. Switch to the backup System Controller and attempt to restart pump. 3. Clinically evaluate patient.
	Connect Driveline  :02	 + 	Driveline is disconnected. The Pump Running symbol (⌚) is black.	1. Immediately reconnect the driveline to System Controller and move the driveline safety tab on the System Controller to the locked position. 2. If alarm persists after reconnecting the driveline, press any button on the System Controller to attempt pump start. Otherwise, check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the HeartMate Touch App's Clinical or Settings screen by pressing the Pump Start button. 3. If driveline is connected and alarm persists, replace System Controller with a programmed backup System Controller. See page 7-13.
	Backup Battery  :01 + Connect Power Immediately  :05	 +  + 	Both power cables are disconnected	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). See page 7-14.
	Low Flow  :03 + Call Hospital Contact  :07		Low flow, flow is less than 2.5 lpm	1. Ensure that the driveline is connected to System Controller. 2. Ensure that a power source is connected to System Controller. 3. Clinically evaluate patient. See page 7-15.
	Replace Power Immediately  :02 + Low Battery  :06		Low Battery, Power input is extremely low with less than 5 min. remaining	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). See page 7-16.

Table 7.3 System Controller Hazard Alarms

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

7 Alarms and Troubleshooting

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
A D V I S O R Y	Connect Power ⊖ :04	 OR 	One of the two power cables is disconnected	Promptly connect the disconnected power cable to power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). See page 7-17.
	Replace Power ⊖ :02 + Low Battery ⊖ :06		Low Battery, Power input is low with less than 15 min. remaining OR System Controller power cables are crossed when connected to the Mobile Power Unit	Promptly connect to a working or different power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). OR Ensure the power cables are connected correctly, white-to-white and black-to-black. This does not apply for Mobile Power Units with software version 1.02.  See page 7-18.
	Call Hospital Contact Controller Fault		System Controller hardware fault	1. Switch to the backup System Controller. 2. Provide patient with a new System Controller. Note: This alarm will be displayed on the HeartMate Touch App and may also be displayed on the System Controller. See page 7-19.
	Call Hospital Contact Backup Battery Fault		System Controller Backup Battery fault	Replace the 11 Volt Lithium-Ion backup battery. Note: If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Abbott with questions. Note: This alarm will be displayed on the HeartMate Touch App and may also be displayed on the System Controller. See page 7-20.
	Low Speed ⊖ :03 + Call Hospital Contact ⊖ :07		Low Speed advisory warning	1. Use the HeartMate Touch App to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient. See page 7-21.
	None	None	Driveline fault	1. Contact Abbott to determine best next steps. Note: Displayed as an active alarm only when connected to the HeartMate Touch Communication System. See page 7-26.

Table 7.4 System Controller Advisory Alarms

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

Alarms and Troubleshooting 7

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
ADVISORY	 Call Hospital Contact  :07		System Controller Backup Battery not installed	1. Install the 11 Volt Lithium-Ion backup battery in the System Controller. 2. Obtain a new backup battery replacement kit. Note: If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Abbott with questions. See page 7-22.
	None	None	Controller Clock not set	Use the HeartMate Touch App to set the System Controller's internal clock. Note: Be sure the Tablet for use with the HeartMate Touch App clock is correct. Note: Displayed as an active alarm only when connected to the HeartMate Touch Communication System. See page 7-27.

Table 7.4 (Continued) System Controller Advisory Alarms

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

7 Alarms and Troubleshooting

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 driveline is connected. • “Low Flow” and “Call Hospital Contact” alternate on the screen. • The “pump running” symbol (⌚) is black. • Alarm tone: Constant tone. • HeartMate Touch App alarm active: PUMP OFF
Alarm means:	Pump has stopped running, possibly because power has been disconnected or failed.
To resolve alarm:	Patient must immediately connect to a power source (if disconnected/failed). If restoring power does not resolve, patient should press any button on the System Controller to attempt pump start, and immediately call hospital contact for diagnosis and instructions. Clinicians: 1. Check if the fixed speed setting is below 8,000 rpm AND the System Controller’s backup battery is not installed. Under these conditions, the pump can only be started from the HeartMate Touch App Clinical view by tapping START PUMP. Otherwise, press any button on the System Controller to attempt pump start. 2. Switch to backup System Controller and attempt to restart pump. 3. Clinically evaluate patient.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 7.5 Pump Off Alarm

Alarms and Troubleshooting 7

Driveline Disconnected Alarm

This is a Hazard alarm

The screen looks like this:



Behavior and appearance:

- Flashing Red Heart (❤️) on the user interface.
- Flashing red light near driveline connector.
- "Connect Driveline" flashes on the screen.
- The "pump running" symbol (⌚) is black.
- Alarm tone: Constant tone.
- HeartMate Touch App alarm active: **DRIVELINE DISCONNECTED**

Alarm means:

The driveline is disconnected from the System Controller. See page 2-24.

To resolve alarm:

1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position.
2. If alarm persists after reconnecting the driveline, press any button on the System Controller to attempt pump start. Otherwise, check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the HeartMate Touch App Clinical view by tapping **START PUMP**.
3. If driveline is connected and alarm persists, replace the System Controller with a programmed backup System Controller.

Alarm silence period:

- 2 minutes or until a new hazard alarm occurs.
 - To silence this alarm, press the silence alarm button (⌘).
- Note:** You may have to push the silence alarm button twice to silence the alarm. This is normal.

Table 7.6 Driveline Disconnected Alarm

7 Alarms and Troubleshooting

No External Power Alarm

This is a Hazard alarm	
The screens look like this: (alternating screens)	
Behavior and appearance:	• Flashing Red Battery () on the user interface. • Backup Battery graphic and “Connect Power Immediately” 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:	Immediately connect to a functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries to ensure the pump does not stop.
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button ()

Table 7.7 No External Power Alarm

The 11 Volt Lithium-Ion backup battery inside the System Controller provides power to the pump for at least 15 minutes when fully charged if the main power source is disconnected or fails. See *System Controller Backup Battery Power* on page 2-40 for details about the 11 Volt Lithium-Ion backup battery inside the System Controller.

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

Low Flow Alarm

This is a Hazard alarm

The screens look like this:

(alternating screens)



Behavior and appearance:

- Flashing Red Heart (❤️) on the user interface.
- "Low Flow" and "Call Hospital Contact" alternate on the screen.
- Alarm tone: Constant tone.
- HeartMate Touch App alarm active: **LOW FLOW**

Alarm means:

Pump flow is less than 2.5 lpm.

To resolve alarm:

Patients must call their hospital contact immediately for diagnosis and instructions.

Clinicians should:

1. Ensure the driveline is connected to the System Controller.
2. Ensure that a power source is connected to the System Controller.
3. Clinically evaluate patient.

Alarm silence period:

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

Table 7.8 Low Flow Alarm

7 Alarms and Troubleshooting

Low Battery Power Alarm (less than 5 minutes remain)

This is a Hazard alarm	
The screens look like this: (alternating screens)	
Behavior and appearance:	• Flashing Red Battery (🔋) on the user interface. • “Replace Power Immediately” and “Low Battery” alternate on the screen. • Alarm tone: Constant tone. • HeartMate Touch App alarm active: LOW VOLTAGE
Alarm means:	• Less than 5 minutes of battery power remains (when using battery power). OR • The System Controller is receiving inadequate power from the Power Module or Mobile Power Unit.
To resolve alarm:	Immediately connect to a working or different power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 7.9 Low Battery Power Alarm (< 5 minutes)

Power Cable Disconnected 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” appears on the screen. • Alarm tone: Fast beep. • HeartMate Touch App alarm active: Power Cable Disconnected
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:	Promptly connect the disconnected power cable to a power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 2 minutes or until a new hazard alarm occurs. • To silence this alarm, press the silence alarm button .

Table 7.10 Power Cable Disconnected Alarm

7 Alarms and Troubleshooting

Low Battery Power Alarm (less than 15 minutes remain)

This is an Advisory alarm	
The screens look like this: (alternating screens)	
Behavior and appearance:	• Flashing yellow diamond (◆) on the user interface. • “Low Battery” and “Replace Power” alternate on the screen. • Alarm tone: Slow beep. • HeartMate Touch App alarm active: Low Voltage Advisory
Alarm means:	Low battery, power input to the System Controller is low with less than 15 minutes of battery power remaining. OR System Controller power cables are crossed when connected to the Mobile Power Unit. Note: This does not apply for Mobile Power Units with software version 1.02.
To resolve alarm:	Promptly connect to a working or different power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
Alarm silence period:	• 5 minutes or until any new alarm occurs. • To silence this alarm, press the silence alarm button (ⓧ).

Table 7.11 Low Battery Power Alarm (< 15 minutes)

IMPORTANT! The low battery power alarm will occur if the white and black power cables from the System Controller are incorrectly connected (white-to-black and black-to-white) to the Mobile Power Unit. The alarm will occur after five minutes. This does not apply for Mobile Power Units with software version 1.02.

To resolve the alarm:

1. Promptly connect to two fully-charged HeartMate batteries.
2. Reconnect to the Mobile Power Unit. Make sure that the power cables are connected correctly—white-to-white and black-to-black.
3. If reconnecting to the Mobile Power Unit does not resolve the alarm, promptly connect to a different power source. See *When to Connect to the Mobile Power Unit* on page 3-40.

System Controller 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; Controller Fault” displays on the screen. • Alarm tone: Slow beep. • HeartMate Touch App alarm active: Replace System Controller
Alarm means:	An internal malfunction has occurred that requires clinician diagnosis and resolution.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Switch to the backup System Controller if instructed to do so. Clinicians should: 1. Switch to the backup System Controller. See <i>Replacing the Running System Controller with a Backup Controller</i> on page 2-55. 2. Provide patient with a new System Controller.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 7.12 System Controller Fault Alarm

IMPORTANT! A backup System Controller is identical to the running System Controller and is programmed with identical patient-specific settings. It should remain with the patient at all times for easy access in an emergency. See *The Backup System Controller* on page 2-47 for details about the backup System Controller.

7 Alarms and Troubleshooting

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. - HeartMate Touch App alarm active: Replace Backup Battery
Alarm means:	- The System Controller’s 11 Volt Lithium-Ion backup battery is compromised. OR - It is unable to fully support pump function. OR - There is an issue that requires clinician diagnosis and resolution.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should replace the System Controller 11 Volt Lithium-Ion backup battery (see <i>Replacing a Backup Battery in the System Controller</i> on page 2-43). Note: In most cases, replacing the battery will resolve the alarm. However, it may be necessary to replace the System Controller, or additional steps may be required for resolution. Call Abbott with questions.
Alarm silence period:	4 hours or until any new alarm occurs. - To silence this alarm, press the silence alarm button (🔇).

Table 7.13 System Controller Backup Battery Fault Alarm

Low Speed Operation Alarm

This is an Advisory alarm

The screens look like this: (alternating screens)	
Behavior and appearance:	• Flashing yellow wrench (🔧) on the user interface. • “Low Speed” and “Call Hospital Contact” alternate on the screen. • Alarm tone: Slow beep. • HeartMate Touch App alarm active: Low Speed Advisory
Alarm means:	Either the fixed speed has been set 200 rpm or more below the low speed limit or the System Controller is unable to maintain the speed at or above the low speed limit. While alarm notification is always provided on the HeartMate Touch App, this “Low Speed” alarm is only displayed on the System Controller when disconnected from the HeartMate Touch App. Note: The Low Speed alarm can take up to 4 minutes from disconnection from the HeartMate Touch App to appear on the System Controller. This is normal.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Use the HeartMate Touch App to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 7.14 Low Speed Alarm

7 Alarms and Troubleshooting

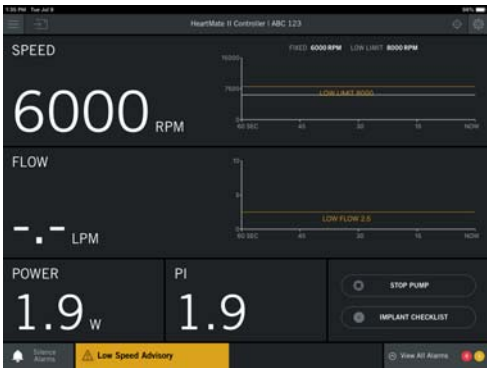
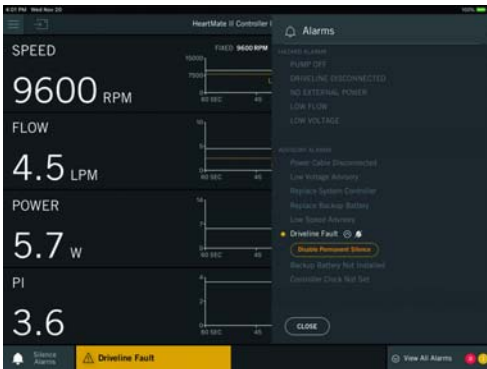
System Controller Backup Battery Not Installed Alarm

This is an Advisory alarm	
The screens look like this:	
Behavior and appearance:	• Flashing yellow wrench (🔧) on the user interface. • An "install battery" graphic on the screen. • Alarm tone: Slow beep. • HeartMate Touch App alarm active: Backup Battery Not Installed
Alarm means:	1. The System Controller's 11 Volt Lithium-Ion backup battery is not installed. OR 2. It is installed incorrectly.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Install the 11 Volt Lithium-Ion backup battery in the System Controller (see <i>Installing the Backup Battery in the System Controller</i> on page 5-49). 2. Obtain a new 11 Volt Lithium-Ion backup battery replacement kit. Note: In most cases, installing the battery will resolve the alarm. However, it may be necessary to replace the System Controller, or additional steps may be required for resolution. Call Abbott with questions.
Alarm silence period:	• 4 hours or until any new alarm occurs. • To silence this alarm, press the silence alarm button (🔇).

Table 7.15 System Controller Backup Battery Not Installed Alarm

HeartMate Touch Alarms

Certain Advisory alarms only appear on the HeartMate Touch App: Low Speed Advisory, Driveline Fault, and Controller Clock Not Set. A text banner appears; however, there is no audible alarm.

Priority	HeartMate Touch App	To Resolve Alarm
A D V I S O R Y		1. Use the HeartMate Touch App to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient. See page 7-25.
	Low Speed Advisory 	Clinicians should: 1. Contact Abbott to determine best next steps. See page 7-26.
	Driveline Fault 	Use the HeartMate Touch App to set the System Controller's internal clock. See page 7-27.
	Controller Clock Not Set	

7 Alarms and Troubleshooting

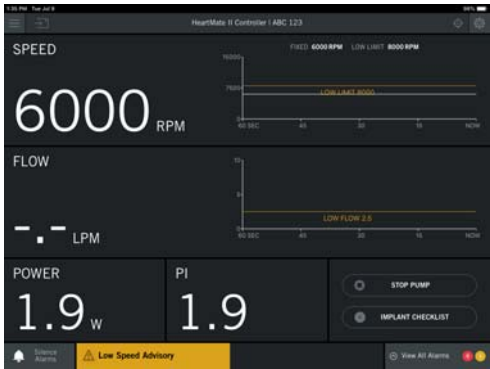
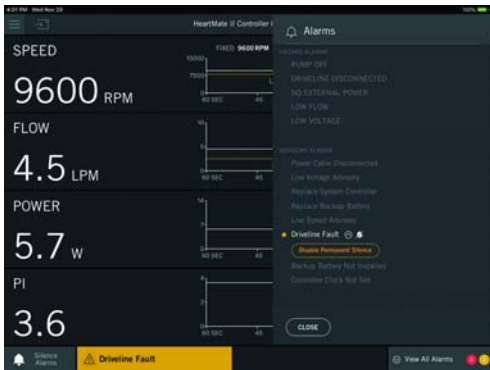
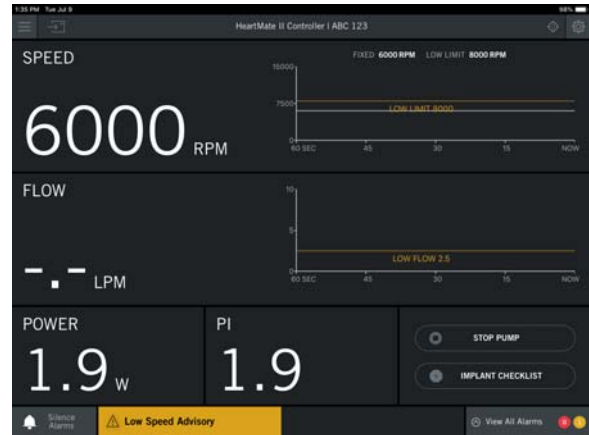
Priority	HeartMate Touch App	To Resolve Alarm
A D V I S O R Y	 Low Speed Advisory	1. Use the HeartMate Touch App to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient. See page 7-25.
	 Driveline Fault	Clinicians should: 1. Contact Abbott to determine best next steps. See page 7-26.
	 Controller Clock Not Set	Use the HeartMate Touch App to set the SystemController's internal clock. See page 7-27.

Table 7.16 HeartMate Touch App Advisory Alarms

Low Speed Advisory - HeartMate Touch App

This is an Advisory alarm

HeartMate Touch App view:



Behavior and appearance:

HeartMate Touch App alarm active: **Low Speed Advisory**

Alarm means:

Either the fixed speed has been set 200 rpm or more below the low speed limit or the System Controller is unable to maintain the speed at or above the low speed limit.

To resolve alarm:

Clinicians should:

1. Use the HeartMate Touch App to check that the fixed speed and low speed limit have been appropriately set.
2. Replace the System Controller. See page 2-55.
3. Clinically evaluate the patient.

Alarm silence period:

The Silence Alarm button will appear for this alarm condition. In this case, the button will not perform any function.

Table 7.17 Low Speed Advisory Alarm

7 Alarms and Troubleshooting

Driveline Fault - HeartMate Touch App

This is an Advisory alarm

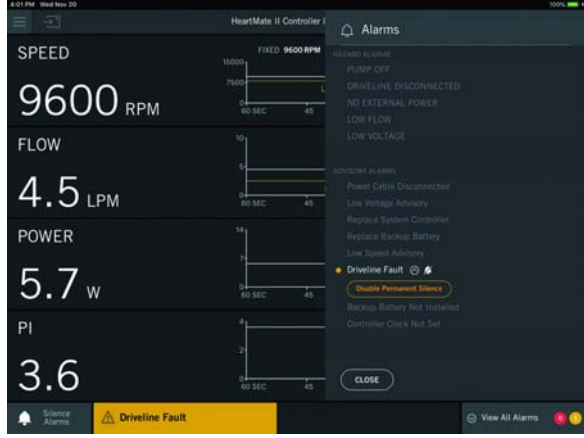
HeartMate Touch App view:	
Behavior and appearance:	- The Driveline Fault Alarm only displays on the HeartMate Touch App. - HeartMate Touch App alarm active: Driveline Fault
Alarm means:	One or more of the redundant wires inside the driveline may be damaged or broken.
To resolve alarm:	Patients must call their hospital contact immediately for diagnosis and instructions. Clinicians should: 1. Contact Abbott to determine best next steps.

Table 7.18 Driveline Fault Alarm

Controller Clock Not Set - HeartMate Touch App

This is an Advisory alarm

HeartMate Touch App view:



Behavior and appearance:

HeartMate Touch App alarm active: **Controller Clock Not Set**

Alarm means:

The System Controller's internal clock needs to be set. Installing a new 11 Volt Lithium-Ion backup battery in the System Controller may prompt this alarm.

To resolve alarm:

Clinicians should use the HeartMate Touch to set the System Controller's internal clock (See *Controller Date & Time* on page 4- 35).

Note: Be sure the HeartMate Touch™ Communication System clock is correct.

Alarm silence period:

The Silence Alarm button will appear for this alarm condition. In this case, the button will not perform any function as there is no active audible alarm on the controller.

Table 7.19 Controller Clock Not Set Alarm

7 Alarms and Troubleshooting

Wireless Connection Lost - HeartMate Touch App

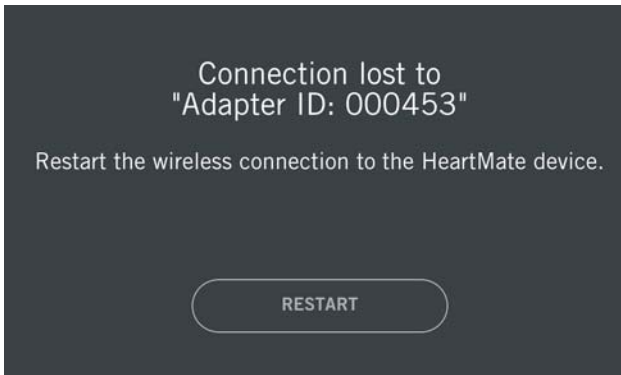
Notification	
The HeartMate Touch App view:	
HeartMate Touch Wireless Adapter Status: light is off	Light is off. 
Behavior and appearance:	HeartMate Touch notification: Connection lost to a Wireless Device. No audible alarms.
Notification means:	The HeartMate Touch App is no longer wirelessly communicating with the Wireless Adapter.
To resolve notification:	Clinicians should use the HeartMate Touch App to reconnect to the HeartMate Touch Wireless Adapter. 1. Tap RESTART. 2. Press and hold the button on the HeartMate Touch Wireless Adapter for 3 seconds to turn on Bluetooth® wireless technology. A blinking blue light appears. 3. Use the HeartMate Touch App to connect to the HeartMate Touch Wireless Adapter. Note: Be sure the Tablet clock is correct.

Table 7.20 Wireless Connection Lost Notification

Disconnected System Controller - HeartMate Touch App

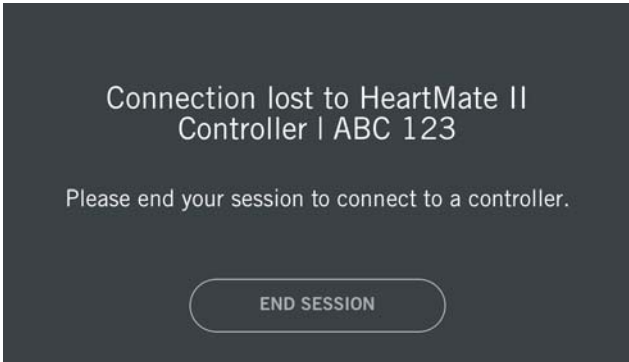
Notification	
The HeartMate Touch App view:	
HeartMate Touch Wireless Adapter Status:	Solid blue light. 
Behavior and appearance:	HeartMate Touch notification: Connection lost to a System Controller. No audible alarms.
Notification means:	The HeartMate Touch Communication System is no longer communicating with the System Controller.
To resolve notification:	1. Tap END SESSION. 2. Check that the System Controller is fully connected. 3. Tap CONTINUE.

Table 7.21 Disconnected System Controller Notification

7 Alarms and Troubleshooting

Connection Failed - HeartMate Touch App

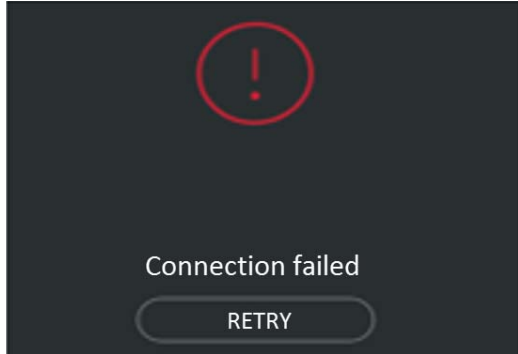
Notification	
HeartMate Touch App message:	
HeartMate Touch Wireless Adapter Status:	Light is off or blinking. 
Behavior and appearance:	HeartMate Touch App notification: Connection failed. No audible alarms.
Notification means:	The HeartMate Touch App connection to the HeartMate Touch Wireless Adapter has failed.
To resolve notification:	1. Tap RETRY. 2. Quit and restart the HeartMate Touch App. 3. Remove the HeartMate Touch Wireless Adapter from the Power Module. 4. Re-insert the HeartMate Touch Wireless Adapter into the Power Module. 5. Press and hold the button on the HeartMate Touch Wireless Adapter for 3 seconds to turn on Bluetooth® wireless technology. A blinking blue light appears. 6. Use the HeartMate Touch App to connect to the HeartMate Touch Wireless Adapter.

Table 7.22 Disconnected System Controller Notification

7 Alarms and Troubleshooting

Communication Lost to Adapter - HeartMate Touch App

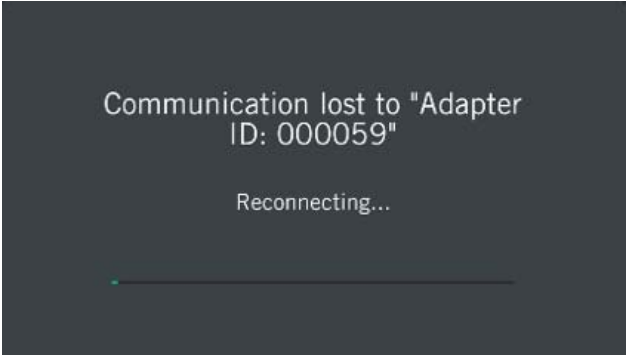
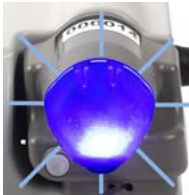
Notification	
HeartMate Touch App message:	
HeartMate Touch Wireless Adapter Status:	Blinking blue light. 
Behavior and appearance:	HeartMate Touch App notification: Communication lost to "Adapter ID: 123456"...Reconnecting. No audible alarms.
Notification means:	The HeartMate Touch App is attempting to reconnect to the HeartMate Touch Wireless Adapter. Note: During the reconnection process, the LVAD will continue to operate at its current settings.
To resolve notification:	No action required. It may take 30 seconds to reconnect the HeartMate Touch App to the HeartMate Touch Wireless Adapter. The blinking blue light indicates that the HeartMate Touch Wireless Adapter is ready to reconnect to the HeartMate Touch App.

Table 7.23 Communication Lost to Adapter

Other Troubleshooting Basics

If you experience any of these issues, review the troubleshooting guide below.

Issues

The HeartMate Touch App shuts down.

The System Controller is not detected on the wireless connection screen. CONTINUE is grey and you cannot confirm the HeartMate Touch Wireless Adapter number.

The HeartMate Touch App freezes.

A Connection failed message appears when connecting.

Resolution

1. Quit the HeartMate Touch App.
 - a. Double-click the Home button to show your most recently used apps.
 - b. Swipe right or left to find the app that you want to close.
 - c. Swipe up on the app's preview to close the app.
2. Gently pull the HeartMate Touch Wireless Adapter from the Power Module socket.
3. Insert the HeartMate Touch Wireless Adapter back in to the Power Module socket.
4. Restart the App and connect the HeartMate Touch Wireless Adapter to the Tablet for use with the HeartMate Touch App.

If the issue is not resolved with the above steps, perform the steps below:

5. Press and hold the Top (or Side) button until the power off slider appears.
6. Drag the slider to turn your device completely off.
7. After your device turns off, press and hold the Top (or Side) button again until you see the Apple logo.
8. Once device turns on, perform steps 2-4 above.

7 Alarms and Troubleshooting

Issue

The System Controller is not detected on the wireless connection screen. CONTINUE is grey and you cannot confirm the HeartMate Touch Wireless Adapter number.

Resolution

1. Make sure the System Controller power cables are securely connected to the Power Module patient cable.
2. Make sure the Power Module patient cable is connected to the Power Module.

If the System Controller *is* securely connected:

1. Quit the HeartMate Touch App.
 - a. Double-click the Home button to show your most recently used apps.
 - b. Swipe right or left to find the app that you want to close.
 - c. Swipe up on the app's preview to close the app.
2. Gently pull the HeartMate Touch Wireless Adapter from the Power Module socket.
3. Insert the HeartMate Touch Wireless Adapter back in to the Power Module socket.
4. Restart the App and connect the HeartMate Touch Wireless Adapter to the Tablet for use with the HeartMate Touch App.

If the issue is not resolved with the above steps, perform the steps below:

5. Press and hold the Top (or Side) button until the power off slider appears.
6. Drag the slider to turn your device completely off.
7. After your device turns off, press and hold the Top (or Side) button again until you see the Apple logo.
8. Once device turns on, perform steps 2-4 above.

Issue

The HeartMate Touch App does not detect the HeartMate Touch Wireless Adapter ID number - even when the HeartMate Touch Wireless Adapter is ready to connect. (HeartMate Touch Wireless Adapter is illuminating a blinking blue light.)

Resolution

1. Tap **Refresh** (.
2. On the tablet, go to **Settings > Bluetooth** and make sure that Bluetooth is on.

Issue

Tablet clock is incorrect.

Resolution

1. On the tablet, go to **Settings > General > Date & Time**.
2. Visit www.apple.com to get help with the date and time on your tablet.

Issue

HeartMate Touch App cannot be updated.

Resolution

1. Quit the HeartMate Touch App.
2. Please contact Abbott for assistance.

7 Alarms and Troubleshooting

Issue

The HeartMate Touch Wireless Adapter does not illuminate a blinking blue light even though the following conditions for set up and connection have been met. (See Set Up the HeartMate Touch™ Communication System on page 4- 8.)

- *The Power Module is set up and powered on.*
- *The HeartMate Touch Wireless Adapter has been inserted into the socket located on the side of the Power Module.*
- *The tablet is on.*
- *The HeartMate Touch App has been launched.*

Resolution

1. Gently pull the HeartMate Touch Wireless Adapter from the Power Module socket.
2. Insert the HeartMate Touch Wireless Adapter back in to the Power Module socket.
3. Ensure that the HeartMate Touch Wireless Adapter is fully connected to the Power Module socket.
4. Press and hold the button on the HeartMate Touch Wireless Adapter for more than 3 seconds.
5. If the issue persists, replace the HeartMate Touch Wireless Adapter.

Power Module Alarms

The Power Module's internal computer continually monitors Power Module performance. The Power Module issues an alert for the following alarm conditions:

- AC Fail
- Advisory LO BATT (low battery)
- Hazard LO BATT (critically low battery)
- Power Module Backup Battery Malfunction

All Power Module alarm conditions are accompanied by a visual indicator (**Figure 7.3**) and audio tone. Different visual and audio indicators are active, depending on the alarm condition. See **Table 7.24** for a description of Power Module alarms and how to respond to them.

IMPORTANT! If an audio alarm sounds from the Power Module without an accompanying visual indicator illuminating at the same time, please contact Abbott for assistance. For Abbott contact information, see the *Back Cover* of this manual.



Figure 7.3 Alarm Indicators on Front of Power Module

7 Alarms and Troubleshooting

Alarm	Meaning	What You Should Do
AC FAIL Power On indicator changes from green to yellow  accompanied by beeping audio tone	AC power off or disconnected. When new, the Power Module backup battery will power the HeartMate II system for approximately 30 minutes. The Power Module backup battery is not recharged during AC FAIL.	1. Press the Power Module's silence alarm button (ⓧ) to silence the alarm (it remains silenced indefinitely or until cancelled by another alarm). 2. Promptly switch to a new set of charged batteries.*
Advisory LO BATT yellow internal backup battery  indicator accompanied by beeping audio tone	Less than 15 minutes of Power Module backup battery power remain.	1. Press the Power Module's silence alarm button (ⓧ) to silence the alarm for 8 hours. 2. Promptly switch to a new set of charged batteries.*
Hazard LO BATT red internal backup battery  indicator accompanied by continuous audio tone	Less than 5 minutes of Power Module backup battery power remain.	Immediately switch to a new set of charged batteries.*
Advisory Fault yellow wrench indicator  accompanied by beeping audio tone	Internal malfunction detected within the Power Module.	Switch to a new set of charged batteries at earliest convenience.
Advisory Fault yellow wrench indicator  accompanied by continuous audio tone	Internal malfunction detected within the Power Module.	Switch to a new set of charged batteries.

Table 7.24 Power Module Alarms

Alarm	Meaning	What You Should Do
Critical Fault yellow wrench and red internal backup battery indicators   accompanied by continuous audio tone	The Power Module backup battery is not functioning properly or is not installed.	Immediately switch to a new set of charged batteries.*

Table 7.24 Power Module Alarms (Continued)

* The Backup Battery indicator turns yellow and then red as the internal battery is depleted. When only 5 minutes of power remain, the Power Module audio tone becomes constant and you can no longer silence the alarm. You can only silence a red Hazard LO BATT alarm by switching to another power source.

7 Alarms and Troubleshooting

Mobile Power Unit Alarms

The Mobile Power Unit issues an alarm for the following conditions:

- Replace Mobile Power Unit Batteries
- Mobile Power Unit Internal Malfunction

IMPORTANT! When the Mobile Power Unit is connected to the System Controller, the Mobile Power Unit duplicates any active System Controller alarms. See *Handling System Controller Alarms* on page 7-4.

All Mobile Power Unit alarms are accompanied by an illuminated symbol (**Figure 7.4**) and sound. Different lights and sounds come on, depending on the alarm. See **Table 7.25** for a description of the Mobile Power Unit alarms and how to resolve each alarm.



Figure 7.4 Indicators on the Mobile Power Unit

Note: If you hear an alarm for the Mobile Power Unit but no light comes on, please contact Abbott for assistance. For Abbott contact information, see the *Back Cover* of this manual.

Alarm Symbol	Meaning	What You Should Do
 Advisory Alarm Yellow Mobile Power Unit battery indicator with beeping audio tone	Internal AA Mobile Power Unit batteries need replaced.	1. Promptly switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries. 2. Replace Mobile Power Unit batteries (see <i>Installing or Replacing the Mobile Power Unit Batteries</i> on page 3-35).
 Advisory Alarm Yellow wrench light with beeping audio tone	Internal malfunction detected within the Mobile Power Unit.	Promptly switch to two fully-charged HeartMate 14 Volt Lithium-Ion batteries.

Table 7.25 Mobile Power Unit Alarms

7 Alarms and Troubleshooting

Battery Charger Alarms

The Battery Charger continually monitors its own performance and that of any battery placed into a pocket. Actual or potential problems, or "faults," appear as "advisory messages" on the display panel.

Battery-Related Advisory Messages

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 to indicate a battery fault (**Figure 7.5**).



Figure 7.5 Advisory Display in Graphics Mode. Note Red Light for Pocket 1.

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.

TO CONFIRM A BATTERY FAULT:

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

Charger-Related Advisory Messages

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

Detecting Pocket Faults

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

TO REPORT A BATTERY CHARGER POCKET FAULT:

1. Remove the battery from the affected pocket, if one is inserted.
2. Record the alarm code for the defective pocket, if possible:
 - a. Press and hold the number button for this pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes related to pocket problems begin with the letter "S."
 - b. Record the alarm code and save it for future reference.

IMPORTANT! 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.

Detecting Faults with the Entire Charger

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

TO REPORT A FAULT FOR THE ENTIRE CHARGER:

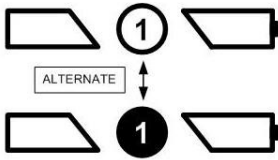
1. Remove all batteries from all pockets.
2. Record the alarm code for the fault condition, if possible:
 - a. Press and hold the number button for any pocket. The alarm code appears on the screen. The alarm code is one letter followed by four numbers. Alarm codes for the entire charger begin with the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

IMPORTANT! Do not use a damaged or defective charger until it is repaired or replaced. Until you have a safe and reliable way to recharge batteries, use the HeartMate Power Module to power your HeartMate system.

7 Alarms and Troubleshooting

Battery Charger Display Panel Messages

Table 7.26 describes the messages that appear on the charger display panel.

Meaning	English Mode	Graphics Mode
Ready	HeartMate CHARGER	HeartMate CHARGER
Battery Charge Status	X: 	1:  50%
Battery Information (3rd screen)	# = X X: mAh =	# = X X: mAh =
Charge Complete	READY X: 	1:  ✓
Request Calibration	CALIBRATE? PRESS X	
Accept Calibration	PROGRESS X: CALIBRATING	1: 
Change Display Mode to English	OK ENGLISH ▼	OK ENGLISH ▼
Change Display Mode to Graphics	OK GRAPHICS ▼	OK GRAPHICS ▼
Battery Fault	CALL SERVICE	
Charger Fault	CALL SERVICE	
Battery Fault (Button Push)	CALL SERVICE BXXXX	 B 0 0 0 1
Charger or Pocket Fault (Button Push)	CALL SERVICE SXXXX	 S 0 0 0 1

Where:

X:—Charger pocket number

BXXXX—Battery fault with alarm code

SXXXX—Charger pocket (slot) fault with alarm code

= X—"X" equals the battery charge cycle count

mAh = XXXX—Battery charge capacity in milliamp-hour

Table 7.26 Battery Charger Display Panel Messages

Guidelines for Power Cable Connectors

Use care when connecting and disconnecting power cable connectors.

Be sure to:

- Line up the half circles inside the connectors, as shown in **Figure 7.6**.
- 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 engage, push them together firmly until fully connected, without twisting or forcing the connectors.
- Secure the connection between the connectors by turning the connector nut on the connector (**Figure 7.7**). Hand tighten the connector nut; do not use tools. Do not twist the connectors when turning the nut.
- When disconnecting connectors, turn the connector nut on the connector until the connection is loose and then gently pull the connectors apart.
- Never twist connectors or pull them apart at an angle.



Figure 7.6 Align Half Circles



Connector Nut

Figure 7.7 Turn Nut on the Connector

7 Alarms and Troubleshooting

What Not To Do: Driveline and Cables

Check the driveline, System Controller power cables, Mobile Power Unit patient cable, and Power Module 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.



7 Alarms and Troubleshooting

CAUTION !

Do not twist, kink, or sharply bend the Power Module patient cable.



CAUTION !

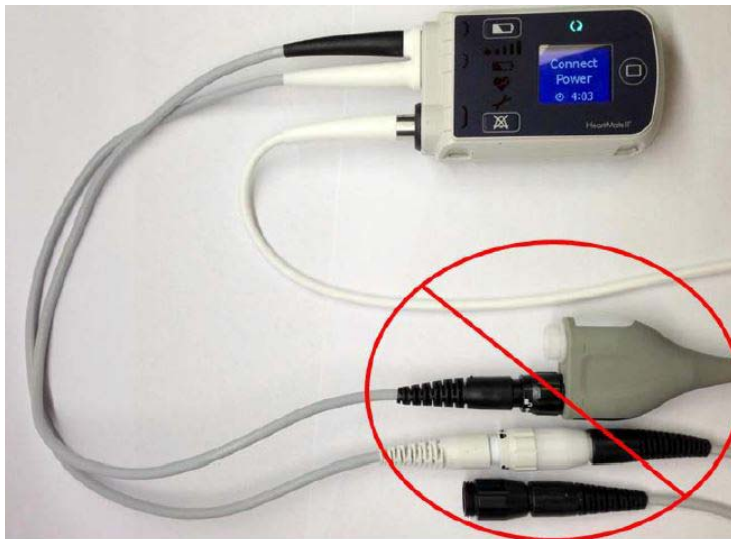
- Do not twist, kink, or sharply bend the Mobile Power Unit patient cable.
- Route the patient cable so it will not cause a tripping or falling hazard.
- Take care when moving around while connected to the Mobile Power Unit, that it is not inadvertently pulled off of furniture.



WARNING !

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.

7 Alarms and Troubleshooting



EQUIPMENT STORAGE AND CARE

This section provides information on how to store and care for the HeartMate II Left Ventricular Assist System.

Storage and Transport	- - - - -	-8-3
Cleaning and Maintenance	- - - - -	-8-4
Product Disposal	- - - - -	-8-10

Storage and Transport

Acceptable Packaged Storage and Transport Conditions

Storing and transporting the equipment outside of the environmental parameters listed below may affect operation or result in equipment failure.

Equipment	Acceptable Temperature Range °F (°C)	Relative Humidity	Air Pressure mm Hg (hPA)
Power Module with Backup Battery	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Power Module Patient Cable	5°F to 122°F (-15°C to 50°C)	10% to 93%	375 to 795 (500 to 1060)
Tablet for use with the HeartMate Touch App	-4°F to 113°F (-20°C to 45°C)	5% to 95%	535 to 795 (710 to 1060)
HeartMate Touch Wireless Adapter	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Mobile Power Unit	-13°F to 158°F (-25°C to 70°C)	Up to 93%	375 to 795 (500 to 1060)
HeartMate 14 Volt Lithium-Ion Batteries	14°F to 104°F (-10°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
HeartMate 14 Volt Battery Clips	5°F to 104°F (-15°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Battery Charger	-4°F to 140°F (-20°C to 60°C)	10% to 93%	375 to 795 (500 to 1060)
System Controller, Backup System Controller	-4°F to 104°F (-20°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
11 Volt Lithium-Ion Backup Battery	-4°F to 104°F (-20°C to 40°C)	10% to 93%	375 to 795 (500 to 1060)
Wear and Carry Accessories, including Shower Bag	-4°F to 131°F (-20°C to 55°C)	20% to 85%	Not applicable

Table 8.1 Acceptable Environmental Conditions for Packaged Storage and Transport

8 Equipment Storage and Care

Cleaning and Maintenance

Although the HeartMate II Left Ventricular Assist System does not have external moving components and thus requires little planned maintenance, the external components should undergo routine and periodic inspections, cleaning, and maintenance as prescribed in this section.

General Cleaning Guidelines for All Equipment

Use a damp cloth to clean exterior surfaces of the system components, as needed. Water, with or without a mild detergent, may be used as a surface cleaner. Do not allow water to penetrate into the interior of the equipment. Do not immerse equipment in water or liquid. Immersion in water or liquid may cause the pump to stop.

Cleaning the System Controller

As needed, clean exterior surfaces of the System Controller with a damp, lint-free cloth. If more aggressive cleaning is needed, use one of the following:

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

Never submerge the System Controller into water or liquid. Submersion in water or liquid may cause the pump to stop.

Periodically inspect the System Controller's power connector pins for dirt or grease. If you find damage, dirt, or contamination on the pins, do not attempt to clean the pins yourself. Report the condition to Abbott. Cleaning and service for the System Controller's power connector pins should be performed only by authorized and Abbott-trained technicians.

Periodically inspect the System Controller's audio speakers for dirt or grease. If you notice a change in tone or in loudness during a System Controller self test (see *Performing a System Controller Self Test* on page 2-29), 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 (such as a toothpick or pin) into the audio speaker sockets. Inserting a sharp object into the socket may damage the speakers inside.

IMPORTANT! Do not disconnect the System Controller from the driveline for cleaning. Disconnecting the driveline from the System Controller will cause the pump to stop. The System Controller driveline connector should be inspected only when replacing the System Controller (see *Replacing the Running System Controller with a Backup Controller* on page 2-55).

Cleaning System Controller Power Cables

As needed, clean exterior surfaces of the System Controller power cables with a damp, lint-free cloth. If more aggressive cleaning is needed, use one of the following:

- Alcohol (70% ethyl rubbing alcohol (C_2H_6O))
- Alcohol (90+% isopropyl)
- Diluted bleach (household)

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

Care of the Driveline

Clinical experience from over five years of clinical trials (both bridge-to-transplantation and destination therapy), and commercial use outside of the US, have shown that wear and fatigue of the driveline that connects the pump to the System Controller may result in damage. Such damage has the potential to interrupt pump function. Resolution of this situation may require reoperation to replace the pump, or may result in death if not resolved.

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

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

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

Driveline damage may be evidenced by the following:

- Transient alarms due to short or open circuits, often associated with movement of the patient 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, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual.

8 Equipment Storage and Care

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 supporting the patient using batteries to reduce the potential of further damage to the System Controller.

Caring for the Power Module and Mobile Power Unit

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

IMPORTANT! Do not disconnect the System Controller from the driveline. This connection should be inspected only when replacing the System Controller (see *Replacing the Running System Controller with a Backup Controller* on page 2-55).

Cleaning the Power Module and Mobile Power Unit

Periodically, and as needed, unplug the Power Module and Mobile Power Unit and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild detergent, if necessary. Keep the Power Module and Mobile Power Unit dry and away from water or liquid. If the Power Module or Mobile Power Unit comes into contact with water or liquid, it may fail to operate properly or you may get an electric shock. Do not clean the Power Module or Mobile Power Unit while it is being used to power the Left Ventricular Assist System.

If the Mobile Power Unit is left in storage for a long period of time with the batteries installed, the alkaline batteries may corrode. If corrosion is observed, report the condition to Abbott. For Abbott contact information, see the *Back Cover* of this manual.

Cleaning and service should be performed only by Abbott-trained personnel. Do not attempt to clean or repair equipment on your own. Thoroughly wash any areas where contact with corroded batteries is made.

IMPORTANT! Ensure that the Power Module backup battery is reconnected after service or shipping (see *Reconnecting the Power Module Backup Battery* on page 3-26).

Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips

HeartMate batteries require periodic inspection and cleaning to ensure the best possible performance. Follow the guidelines and instructions in the *Safety Checklists* on page F-1.

Clean the metal battery contacts and the interior contacts of battery clips monthly using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use. See **Figure 8.1**.



Figure 8.1 Clean the Battery Contacts and Clips

Cleaning the Battery Charger

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

8 Equipment Storage and Care

Cleaning HeartMate Wear and Carry Accessories

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

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

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

Periodically inspect the wear and carry accessories for damage or wear. If an accessory appears damaged or worn, do not use it. Contact Abbott with questions or to order a replacement, if needed.

Cleaning the HeartMate Stabilization Belt

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

Periodically inspect the Stabilization Belt for damage or wear. If it appears damaged or worn, do not use it. Contact Abbott with questions or to order a replacement, if needed.

Cleaning the Tablet

The tablet that is deployed with the HeartMate Touch App serves as the display screen. A protective case protects the tablet.

Note: Battery life varies by use and configuration; see www.apple.com/batteries for more information. The tablet should be charged sufficiently and connected to AC power prior to use.

Before cleaning the tablet:

- Unplug all cables, Abbott approved Flash Drives, and any other accessories.
- Turn off the tablet (Press and hold the top button until the slider appears, then drag the slider.)

When cleaning the tablet:

- Use a soft lint-free cloth slightly damp with isopropyl alcohol or alcohol-based disposable wipes for cleaning and disinfection.
- Do not oversaturate the cloth and avoid spraying isopropyl alcohol directly on the screen.
- Do not allow moisture into any openings.
- Do not use bleach when cleaning the tablet.

The tablet screen has an oleophobic coating for resistance to fingerprints, smudge marks, and scratches. To maintain the integrity of this coating, avoid using the following items or chemical ingredients:

- Abrasive Cloths, Towels, Paper Towels, and similar abrasive items.
- Window cleaners, house hold cleaners, solvents, bleach (NaClO , 6%), or ammonia (NH_3 , 10%).
- Cleaners containing nitric acid (HNO_3 , 10%), hydrogen peroxide (H_2O_2 , 3%), or sodium hydroxide (NaOH , 10%).
- Abrasives, compressed air, aerosol sprays, and any other solvent.

Cleaning the HeartMate Touch Wireless Adapter

Periodically, and as needed, unplug the HeartMate Touch Wireless Adapter from the Power Module and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild detergent, if necessary. Keep the HeartMate Touch Wireless Adapter dry and away from water or liquid. If the HeartMate Touch Wireless Adapter comes into contact with water or liquid, it may fail to operate properly or you may get an electric shock. Do not clean the HeartMate Touch Wireless Adapter while it is connected to a Power Module.

Cleaning and service should be performed only by Abbott-trained personnel. Do not attempt to clean or repair equipment on you own.

Product Disposal

Specific product disposal considerations for certain HeartMate equipment appear below. Otherwise, dispose of all expired or damaged equipment according to applicable local, state, and federal regulations. For additional product disposal information, please contact Abbott for assistance. See Abbott contact information on the *Back Cover* of this manual.

Batteries

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

The Power Module backup battery and 11 Volt Lithium-Ion backup battery contain lead. Dispose of the Power Module backup battery and 11 Volt Lithium-Ion backup battery in compliance with all applicable local, state, and federal regulations. Never incinerate the discarded Power Module backup battery or 11 Volt Lithium-Ion backup battery.

Power Module

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

Mobile Power Unit

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

Battery Charger

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

Tablet for use with the HeartMate Touch App

The Tablet for use with the HeartMate Touch App contains a Lithium-Ion battery (non-serviceable). Dispose of or recycle the tablet in compliance with all applicable local, state, and federal regulations.

Note: Follow battery storage instructions detailed on the Apple[®] website – visit www.apple.com/batteries/maximizing-performance for more information.

HeartMate Touch Wireless Adapter

Dispose of or recycle the HeartMate Touch Wireless Adapter and HeartMate Touch Wireless Adapter electronics in compliance with all applicable local, state, and federal regulations.

Medical Waste

The explanted HeartMate II Left Ventricular Assist Device and attached driveline must be disposed of in compliance with all applicable local, state, and federal regulations concerning medical waste.

8 Equipment Storage and Care

SUMMARY OF CLINICAL STUDIES

This section contains summaries of the HeartMate II Left Ventricular Assist System clinical studies.

Bridge-to-Transplantation (BTT) Study Overview- - - - -	A-3
Destination Therapy (DT) Study Overview- - - - -	A-20
Post-Approval Studies - - - - -	A-46
Post-Approval Overview of Risk of Thrombosis - - - - -	A-59

Bridge-to-Transplantation (BTT) Study Overview

One hundred twenty-six (126) patients were enrolled in the HeartMate II (HMII) Bridge-to-Transplantation (BTT) Primary Study Cohort between March 2005 and May 2006 at 26 investigational sites across the United States as the pivotal study sample size. The primary objective of the study was to determine the safety and effectiveness of the HeartMate II LVAS as a BTT device in end-stage heart failure patients who are listed for cardiac transplant and at imminent risk of death. Effectiveness of the device was assessed on the basis of the percentage of patients surviving either to cardiac transplantation or 180 days of LVAS support while being listed UNOS 1A/1B. Safety of the HeartMate II LVAS was assessed by the incidence of adverse events during LVAS support.

A number of secondary objectives were also evaluated during the study, including clinical reliability (malfunctions/failures), functional status (6-minute walk and patient activity score), quality of life (Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire), reoperations, neurocognitive assessment (memory, language, visual/spatial perception, processing speed and abstract/executive function), and 30-day and 180-day posttransplant survival.

After completion of enrollment in the Primary Study Cohort, enrollment continued under a Continued Access Protocol (CAP), which was identical to the Primary Study Cohort protocol. Patients who were originally enrolled into these two study cohorts but who had a body surface area (BSA) less than 1.5m² were separated out into a Small BSA Patient Cohort for analysis.

BTT Study Design

The study was a multicenter, nonblinded, nonrandomized, prospective study. The study had two oversight committees: a Clinical Events Committee that adjudicated all adverse events and deaths, and a Data and Safety Monitoring Board that reviewed the study data periodically to ensure that continuation of the study did not present any unacceptable risk. The members of these committees were independent of Abbott, the investigational sites, and the principal investigators.

The primary study outcomes were defined as death, cardiac transplantation, device explantation due to myocardial recovery, or survival to 180 days on LVAS support while remaining listed UNOS 1A/1B. After reaching the 180 day assessment point, patients continued to be followed until transplantation, explantation, or death.

BTT Patient Population

The patients enrolled into the HeartMate II study were patients who were listed for cardiac transplant in end-stage heart failure and who demonstrated no evidence of severe end-organ damage that would make HeartMate II LVAS implantation futile.

A Summary of Clinical Studies

The BTT inclusion and exclusion criteria were based on study criteria used in previously approved LVAD BTT studies. The criteria included patients in New York Heart Association (NYHA) class IV heart failure, on inotropic support, and without contraindication to listing for cardiac transplantation as UNOS Status 1A or 1B. If the patient was 1B, the patient also needed to meet hemodynamic criteria to qualify, including pulmonary capillary wedge pressure (PCWP) or pulmonary artery diastolic pressure (PAD) > 20 mm Hg, and either a cardiac index < 2.2 L/min/m² or systolic blood pressure < 90 mm Hg. Patients were excluded from the study if they had moderately severe end-organ damage, as evidenced by elevated total bilirubin, elevated creatinine values, or low platelet counts. Patients were also excluded if they were unlikely to tolerate the management of the HeartMate II LVAS due to intolerance to anticoagulation or compliance issues.

Two hundred and seventy-nine (279) patients were enrolled at 33 study sites between March 2005 and March 2007. Twenty-six (26) sites enrolled patients into both the Primary Study Cohort and the Continued Access Protocol Cohort (CAP). Seven additional sites enrolled patients only under the Continued Access Protocol. Of the 279 patients enrolled, 194 patients have been followed to a study outcome point, and if ongoing on HeartMate II LVAS support, for at least one year as of September 14, 2007, and are presented in the following clinical summary. As shown in **Figure A.1**, the 194 patients were divided among the two cohorts: 126 patients in the Primary Study Cohort and 58 patients in the Continued Access Protocol Cohort. An additional 10 patients were originally enrolled in these two cohorts but were separated out for analysis in the Small BSA Patient Cohort ($1.2\text{m}^2 \leq \text{BSA} < 1.5\text{m}^2$). Data are presented for each cohort separately and also in the aggregate for all 194 patients.

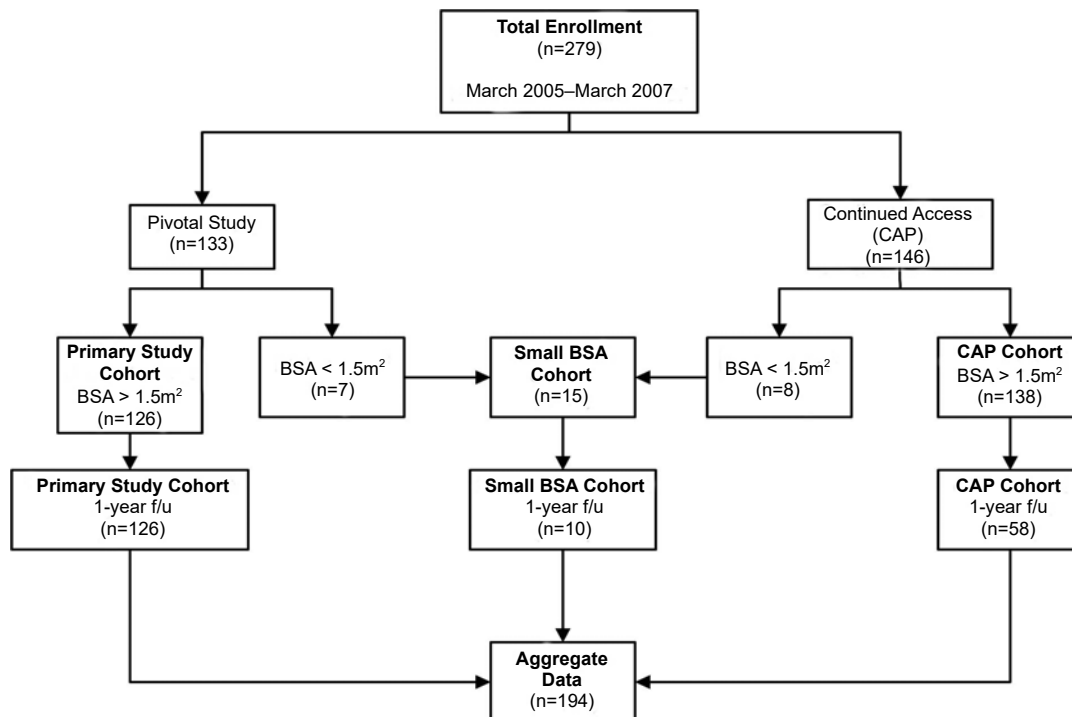


Figure A.1 HeartMate II Study Enrollment

Summary of Clinical Studies **A**

The overall mean age in the HeartMate II LVAS study was 51 years (range 16–69 years). The smallest patient implanted had a BSA of 1.33m². The largest patient had a BSA of 2.62m². The mean BSA was 1.99m². The mean body mass index (BMI) was 27 kg/m² (range 15.6–44.0 kg/m²). The most prevalent etiology was idiopathic cardiomyopathy (48%), followed by ischemic cardiomyopathy (41%). Of note in the cardiovascular history is that 78% of the patients had preexisting arrhythmias, and 76% of the patients entered the study with implantable cardiac defibrillators (ICD). Patient demographics and cardiovascular history for each of the three study cohorts and the aggregate data are shown in **Table A.1** and **Table A.2**.

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
Age (years)*	55 (17–68)	56 (16–69)	47 (20–69)	55 (16–69.1)
Etiology	39% Ischemic	50% Ischemic	10% Ischemic	41% Ischemic
Gender	83% Male 17% Female	78% Male 22% Female	0% Male 100% Female	77% Male 23% Female
BMI (kg/m²)*	26.5 (10–40)	27.6 (18–44)	17.0 (15.6–20.8)	26.6 (15.6–44.0)
BSA (m²)*	1.99 (1.5–2.6)	2.00 (1.52–2.57)	1.40 (1.33–1.47)	1.99 (1.33–2.62)

* Median and range

Table A.1 Patient Demographics

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
Arrhythmias	101 (80%)	46 (79%)	5 (50%)	152 (78%)
Ventricular Arrhythmias	71 (56%)	34 (59%)	4 (40%)	109 (56%)
Ventricular Pacing	77 (61%)	35 (60%)	5 (50%)	117 (60%)
Biventricular Pacing	61 (48%)	30 (52%)	4 (40%)	95 (49%)
Implantable Cardioverter/Defibrillator	96 (76%)	45 (78%)	6 (60%)	147 (76%)
Stroke	12 (10%)	6 (10%)	1 (10%)	19 (10%)

Table A.2 Cardiovascular History

A Summary of Clinical Studies

Primary Objective: Transplant or Survival to 180 Days While Listed on UNOS 1A/1B

Overall BTT Patient Outcomes

After reaching the 180-day assessment point, patients continued to be followed until transplantation, explantation, or death. Patient outcomes and additional results for each study cohort (Primary, CAP, and Small BSA) and Aggregate Data as of September 14, 2007 are presented in **Table A.3** and **Table A.4**.

The prespecified primary endpoint for the Primary Study Cohort of HeartMate II LVAS BTT pivotal study was “patient survival to cardiac transplantation or 180 days of LVAS support while remaining listed status 1A or 1B.” The HeartMate II pivotal study was to be prospectively determined successful if the one-sided 95% lower confidence limit of the true success rate exceeded 65%, the Performance Goal. The results show that the lower confidence limit (LCL) of success was 64.0% in the Primary Study Cohort, thereby not quite meeting the prespecified agreed-upon LCL endpoint, > 65%. Although outcomes were similar in the CAP and Small BSA cohorts, the LCLs are lower due to the smaller sample sizes.

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
Cardiac Transplantation¹	72 (57%)	33 (57%)	7 (70%)	112 (58%)
Myocardial Recovery¹	4 (3%)	2 (3%)	0 (0%)	6 (3%)
Supported ≥ 180 days and:				
Listed UNOS Status 1A or 1B¹	13 (10%)	5 (9%)	0 (0%)	18 (9%)
Not listed Status 1A or 1B^{2,3}	9 (7%)	7 (12%)	3 (30%)	19 (10%)
Expired < 180 days on LVAD²	25 (20%)	11 (19%)	0 (0%)	36 (19%)
Treatment failure; received other VAD²	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Prespecified Lower 95% Confidence Limit of True Success Rate	65.0%			
Observed Lower 95% Confidence Limit of Study Success Rate	64.0%	59.0%	46.2%	64.7%

¹ Classified as success per prespecified study criteria

² Classified as failure per prespecified study criteria

³ Reasons for not listing included medical ineligibility, elective withdrawal from transplant list, substance abuse, and noncompliance with medical therapy

Table A.3 Primary Study Outcomes

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
30 day (perioperative) mortality	12 (10%)	7 (12%)	0 (0%)	19 (10%)
Patient survival to hospital discharge/transplant	105 (83%)	48 (83%)	10 (100%)	163 (84%)
Median time to transplant (days)	102.5	152	194	117
Median duration of device support (days)	117	163.5	374	131.5
Cumulative support duration (patient-years)	71	29	9	109

Table A.4 Additional Study Results

Figure A.2 and **Figure A.3** plot the competing outcomes (transplantation, weaning due to myocardial recovery, expiration, ongoing LVAS support, and study withdrawal) for the Primary Study Cohort and the Aggregate Data, respectively.

A Summary of Clinical Studies

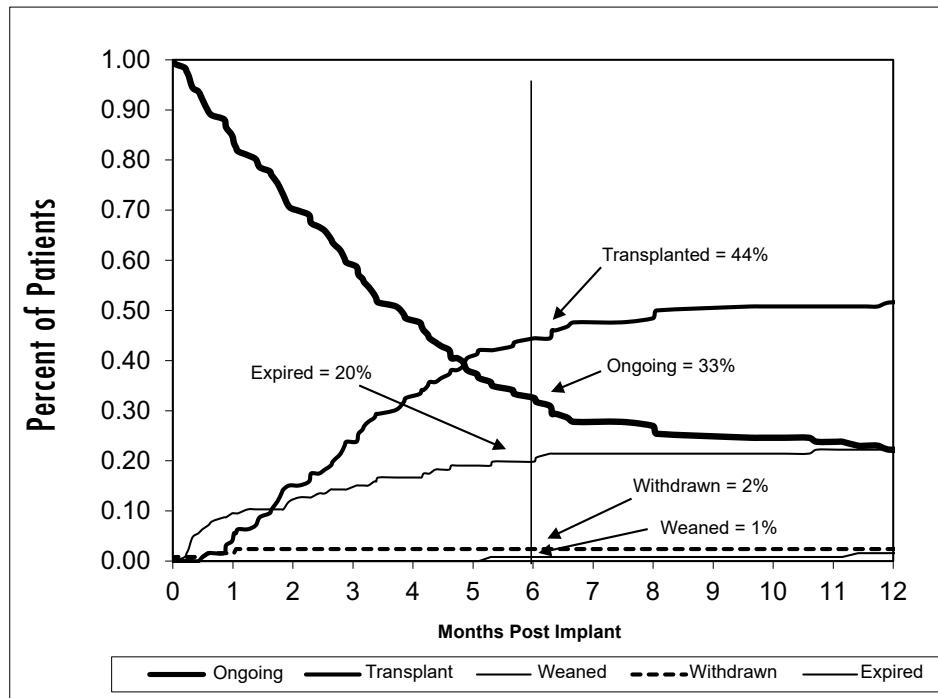


Figure A.2 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Primary Study Cohort (n=126)

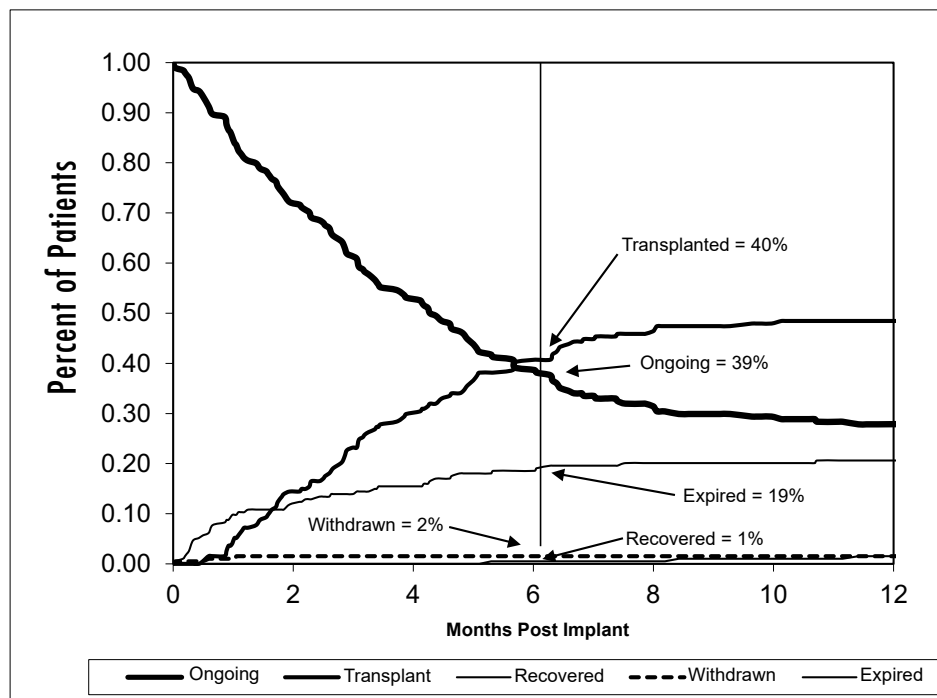


Figure A.3 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Aggregate Data (n=194)

Adverse Events

The incidence of all adverse events observed during the HeartMate II LVAS study, regardless of severity, is provided in **Table A.5** for each data cohort. Adverse events were defined as events that occurred while on HeartMate II LVAS support that may have a deleterious effect on the patient. The incidence of adverse events defined as serious are presented in **Table A.6**. Adverse Events were classified as serious if they resulted in death or permanent disability, were life threatening, required hospitalization, or prolonged hospitalization. Adverse event rates during various time intervals are presented in **Table A.7**, which shows that the majority of adverse events occurred during the first 30 days after implantation of the device.

A Summary of Clinical Studies

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	No. Pts (% Pts)	No. Pts (% Pts)	No. Pts (% Pts)	No. Pts (% Pts)
Bleeding (all requiring PRBC $\geq$ 2)*	89 (71%)	35 (60%)	9 (90%)	133 (69%)
Bleeding requiring surgery	37 (29%)	15 (26%)	4 (40%)	56 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Perioperative ($\leq$ POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Postoperative ($>$ POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Local Infection	36 (29%)	21 (36%)	3 (30%)	60 (31%)
Drive Line Infection	20 (16%)	4 (7%)	2 (20%)	26 (13%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	27 (21%)	7 (12%)	2 (20%)	36 (19%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	10 (8%)	1 (2%)	0 (0%)	11 (6%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	77 (61%)	28 (48%)	6 (60%)	111 (57%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	3 (30%)	8 (4%)
Psychological	8 (6%)	3 (5%)	2 (20%)	13 (7%)
Myocardial Infarction	1 (1%)	0 (0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	36 (29%)	11 (19%)	6 (60%)	53 (27%)

* Bleeding requiring PRBC $\geq$ 2 units or surgery

** Includes transient ischemic attacks (TIA) and nonstroke neurological events

Table A.5 All Adverse Events

Summary of Clinical Studies **A**

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	No. Pts (% Pts)	No. Pts (% Pts)	No. Pts (% Pts)	No. Pts (% Pts)
Bleeding (all requiring PRBC $\geq$ 2)*	75 (60%)	34 (59%)	8 (80%)	117 (60%)
Bleeding requiring surgery	38 (30%)	15 (26%)	4 (40%)	57 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Perioperative ($\leq$ POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Postoperative ($>$ POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	11 (9%)	3 (5%)	1 (10%)	15 (8%)
Local Infection	27 (21%)	16 (28%)	2 (20%)	45 (23%)
Drive Line Infection	12 (10%)	3 (5%)	1 (10%)	16 (8%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	26 (21%)	7 (12%)	2 (20%)	35 (18%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	9 (7%)	1 (2%)	0 (0%)	10 (5%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	56 (44%)	21 (36%)	5 (50%)	82 (42%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	1 (10%)	6 (3%)
Psychological	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Myocardial Infarction	1 (1%)	0 (0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	10 (8%)	4 (7%)	3 (30%)	17 (9%)

* Bleeding requiring PRBC $\geq$ 2 units or surgery

** Includes transient ischemic attacks (TIA) and nonstroke neurological events

Table A.6 Serious Adverse Events

A Summary of Clinical Studies

Adverse Events	Cohort	0-7 days	8-30 days	31-90 days	91-180 days	>180 days
Bleeding	Primary (n=126)	36.25	5.25	1.60	0.58	0.60
	CAP (n=58)	30.91	4.41	1.45	0.91	0.39
	Small BSA (n=10)	60.00	4.84	2.00	2.48	0.96
	Aggregate (n=194)	36.14	4.99	1.59	0.85	0.60
Stroke	Primary (n=126)	2.08	0.28	0.00	0.22	0.09
	CAP (n=58)	0.00	0.29	0.14	0.26	0.00
	Small BSA (n=10)	0.00	0.00	1.33	0.00	0.00
	Aggregate (n=194)	1.36	0.27	0.13	0.21	0.06
Other Neurological	Primary (n=126)	0.42	0.41	0.27	0.15	0.09
	CAP (n=58)	0.91	0.29	0.14	0.00	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.99	0.00
	Aggregate (n=194)	0.54	0.45	0.26	0.17	0.06
Local Infection	Primary (n=126)	8.33	2.62	1.67	0.36	0.18
	CAP (n=58)	10.00	2.65	1.45	0.39	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.50	1.34
	Aggregate (n=194)	8.42	2.58	1.55	0.38	0.27
Drive Line Infection	Primary (n=126)	0.00	0.00	0.27	0.58	0.48
	CAP (n=58)	0.00	0.00	0.29	0.26	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.99	0.38
	Aggregate (n=194)	0.00	0.00	0.26	0.51	0.37
Pocket Infection	Primary (n=126)	0.00	0.14	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.00	0.09	0.00	0.04	0.04
Sepsis	Primary (n=126)	1.67	1.80	0.47	0.36	0.24
	CAP (n=58)	1.82	0.59	0.00	0.26	0.10
	Small BSA (n=10)	0.00	1.61	0.00	0.00	0.57
	Aggregate (n=194)	1.63	1.42	0.30	0.30	0.25
Right Heart Failure	Primary (n=126)	1.67	1.80	0.33	0.00	0.03
	CAP (n=58)	3.64	2.06	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.19
	Aggregate (n=194)	2.45	1.87	0.21	0.00	0.04
Peripheral TE	Primary (n=126)	1.25	0.83	0.13	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00

Table A.7 Adverse Event Rate per Patient-Year by Time Interval

Summary of Clinical Studies **A**

Adverse Events	Cohort	0-7 days	8-30 days	31-90 days	91-180 days	>180 days
Respiratory Failure	Aggregate (n=194)	1.09	0.53	0.09	0.00	0.00
	Primary (n=126)	7.92	1.66	0.47	0.22	0.03
	CAP (n=58)	10.91	1.76	0.14	0.26	0.00
	Small BSA (n=10)	10.00	1.61	0.67	0.00	0.00
Cardiac Arrhythmias	Aggregate (n=194)	8.97	1.69	0.39	0.21	0.02
	Primary (n=126)	25.00	4.01	1.47	1.09	0.48
	CAP (n=58)	14.55	5.59	0.72	0.52	0.39
	Small BSA (n=10)	20.00	4.84	0.67	1.49	0.57
Renal Failure	Aggregate (n=194)	21.74	4.54	1.20	0.94	0.47
	Primary (n=126)	3.75	0.69	0.13	0.15	0.00
	CAP (n=58)	2.73	0.59	0.00	0.13	0.00
	Small BSA (n=10)	10.00	0.00	0.00	0.00	0.00
Hepatic Dysfunction	Aggregate (n=194)	3.80	0.62	0.09	0.13	0.00
	Primary (n=126)	0.42	0.14	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
Device Thrombosis	Aggregate (n=194)	0.27	0.09	0.04	0.00	0.00
	Primary (n=126)	0.42	0.00	0.07	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
Hemolysis	Aggregate (n=194)	0.54	0.00	0.04	0.00	0.00
	Primary (n=126)	0.83	0.00	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	10.00	0.00	0.00	0.50	0.00
Psychological	Aggregate (n=194)	1.09	0.00	0.00	0.09	0.04
	Primary (n=126)	1.67	0.14	0.07	0.29	0.00
	CAP (n=58)	1.82	0.29	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.00
Myocardial Infarction	Aggregate (n=194)	1.90	0.27	0.04	0.17	0.00
	Primary (n=126)	0.00	0.00	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	0.00	0.00	0.04	0.04	0.00

Table A.7 Adverse Event Rate per Patient-Year by Time Interval (Continued)

A Summary of Clinical Studies

No new adverse events were observed in the HeartMate II LVAS study that have not been seen in previous studies of ventricular assist devices. The study was not powered for a specific analysis of the adverse events.

Secondary Objectives

Secondary objectives that were collected included the following: reoperations, clinical reliability, functional status, quality of life, neurocognitive evaluation, and postimplant follow-up.

Reoperations

Reoperations that were performed for any reason were captured as a secondary objective. In the Primary Study Cohort, 63% (79/126) of the patients had a reoperation. The majority (56%) of these events took place within 30 days of implant and were due to bleeding or delayed chest closure. Three patients received HeartMate II pump replacements within 30 days of implant. Twenty-one percent (21%) of the reoperation events took place after 30 days post implant. Abdominal incision and drainage, RVAD placement or removal, dialysis catheter placement, and driveline/pocket revision accounted for the majority of these events. Three patients received HeartMate II pump replacements after 30 days post implant. As shown in **Table A.8**, the incidence of reoperations was similar in both the CAP and Small BSA cohorts. The major reasons that reoperations were required were also similar to those observed in the Primary Study Cohort.

	Primary Study Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data Cohort (n=194)
Patients having reoperations	79 (63%)	36 (58%)	7 (70%)	122 (63%)
Reoperations within 30 days of implant	56%	55%	60%	56%

Table A.8 Incidence and Timing of Reoperations

Clinical Reliability

There were 78 reports of confirmed malfunctions in 194 patients having a median support duration of 131 days. Forty-four percent (44%, 34/78) involved implanted system components (such as pump and cannulae) and 56% (44/78) involved external system components (such as controllers, monitors, and batteries). Ten of the malfunctions of the implanted system components were classified as serious adverse events (resulted in death or permanent disability, or required prolonged hospitalization). These 10 reports included percutaneous lead separation (4), pump thrombosis (3), inflow cannula twists (2), and outflow conduit leakage (1). Seven malfunctions of the external system components were also classified as serious adverse events, including damaged printed circuit boards in the System Controller (5), power base unit cable breakdown (1), and inadequate battery capacity (1).

Estimated clinical reliability of the HeartMate II LVAS blood pump, based on the bridge-to-transplantation study, is summarized in **Table A.9**. Clinical reliability is estimated based on a Weibull analysis of the 10 malfunctions reported above. Note that 4 of these 10 events involved system components that were not evaluated in the in vitro reliability test: percutaneous lead separation (3) and outflow conduit leakage (1).

Lower, One-Sided 80% Confidence Limit on Reliability R(t)	
Months	Reliability
6	0.932
12	0.896
24	0.833

Table A.9 Estimated Clinical HeartMate II LVAD Reliability

Wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump to the external System Controller may result in damage that has the potential to interrupt pump function, which may require a reoperation to replace the pump, or result in death. This observation has been confirmed through clinical experience over five years of clinical trials (both bridge-to-transplantation and destination therapy) and commercial use outside the United States. The need for pump replacement due to percutaneous lead damage has occurred after implant durations ranging from 6 to 38 months of HeartMate II LVAS support. The estimated probability of the need for pump replacement due to percutaneous lead damage according to this analysis is 1.3% at 12 months, 6.5% at 24 months, and 11.4% at 36 months.

A Summary of Clinical Studies

Functional Status

Functional status was evaluated based on NYHA class assessments and six-minute walk tests as summarized in **Figure A.4** and **Figure A.5**. These measures were obtained at baseline, 1 month, 3 months, and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved functional capacity.

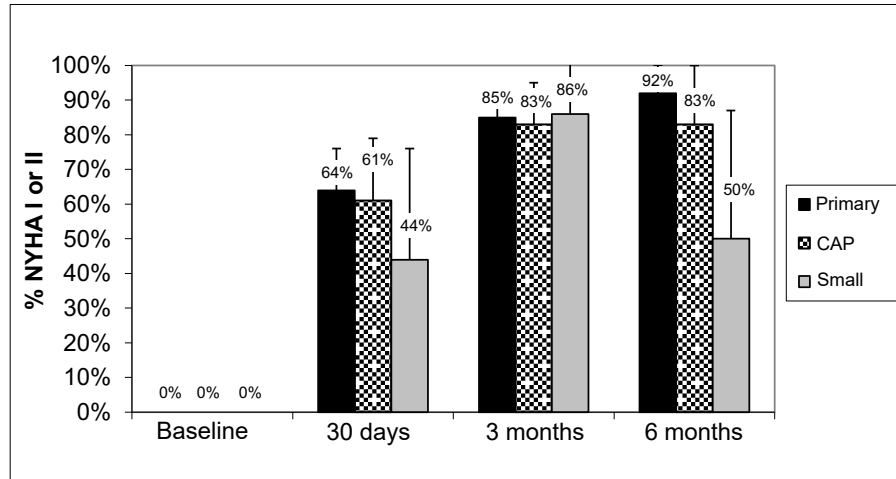


Figure A.4 NYHA Class Over Time (Error Bars = Standard Deviation)

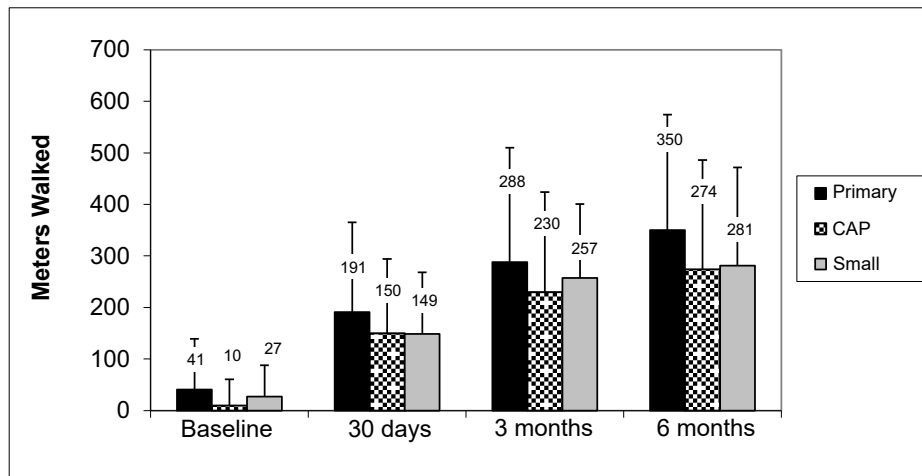
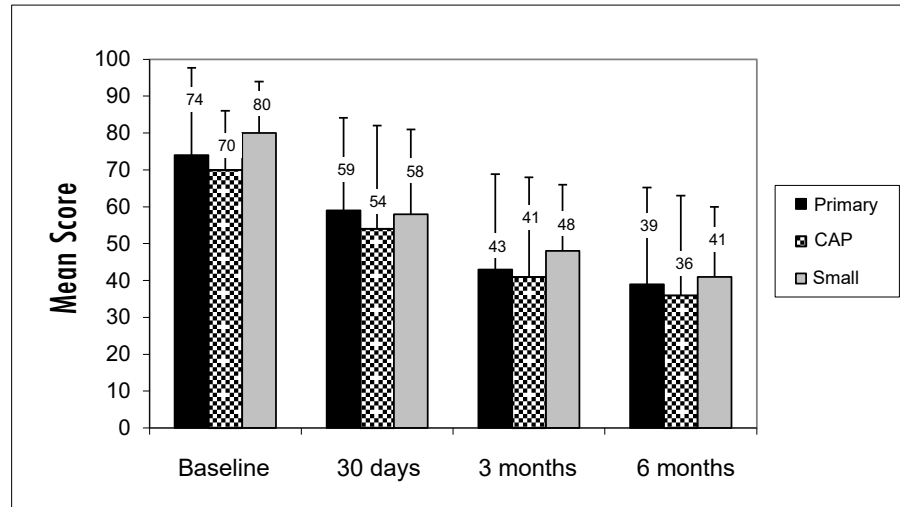


Figure A.5 Summary of Six-Minute Walk Over Time (Error Bars = Standard Deviation)

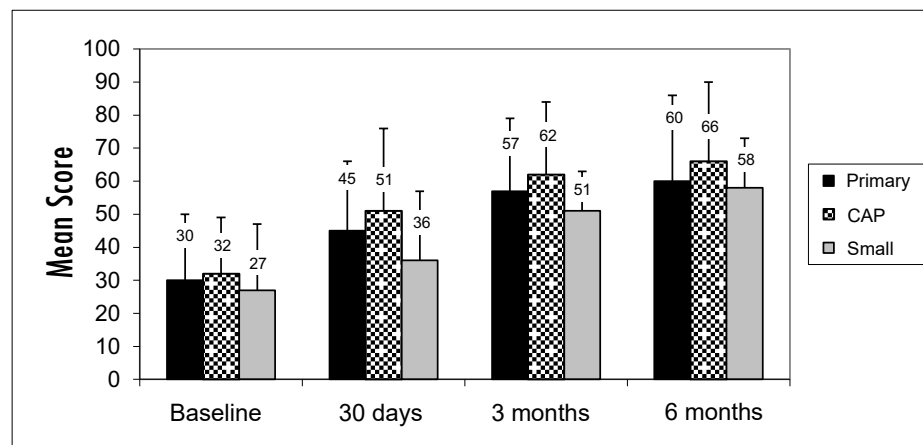
Quality of Life

Quality of life was measured via the Minnesota Living with Heart Failure Questionnaire (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ) as summarized in **Figure A.6** and **Figure A.7**, below. These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved quality of life.



Note: A lower score indicates better quality of life.

Figure A.6 Minnesota Living with Heart Failure (MLWHF) Questionnaire (Error Bars = Standard Deviation)



Note: A higher score indicates better quality of life.

Figure A.7 Kansas City Cardiomyopathy Questionnaire (KCCQ) (Error Bars = Standard Deviation)

A Summary of Clinical Studies

Neurocognitive Evaluations

Neurocognitive evaluations were performed at 11 of the 33 study sites. Eight standard neurocognitive measures consisting of ten procedures were administered at baseline (1 month postimplant), and 3 and 6 months postimplant. The tests surveyed cognitive domains involving memory, language, abstract/executive functions, visual/special perception, and processing speed. Because of the small sample size (n=86), it is difficult to draw conclusions; however, important trends were seen. There was no significant cognitive decline in patients assessed between baseline and the 3 month or 6 month interval. There were significant improvements in cognitive test performance at 3 and 6 months over baseline for auditory memory, visual memory delay, and processing speed. The majority of the cognitive test performance improvement was observed in the first 3 months post implant, with less change seen over extended follow-up intervals. As expected, most of the neurocognitive adverse events occurred at baseline and are likely due to cognitive instability shortly after implant. Over time, as the patients stabilized, neurocognitive functions improved and the incidence of adverse events declined.

Post Explant Follow Up

Cohort	No. Patients Transplanted (or Recovered)	No. Alive at 30 Days Post Explant	% Alive at 30 Days Post Explant
Primary	72 (3)	73	97%
CAP	33 (2)	35	100%
Small	7	5	71%
Aggregate Data	112 (5)	113	97%

Table A.10 30-Day Postexplant Survival

Cohort	No. Patients Transplanted (or Recovered)	No. Alive at 1 Year Post Explant	% Alive at 1 Year Post Explant
Primary	58 (2)	51 (2)	88%
CAP	7	7	100%
Small	4	2	50%
Aggregate Data	69 (2)	60 (2)	87%

Table A.11 One-year Postexplant Survival

Gender Analysis

A post hoc analysis of the aggregate data for variations associated with gender was performed. Of the 194 patients who were followed to a study outcome or, if ongoing on HeartMate II LVAS support, for at least a year, the majority were male (77% males versus 23% females). Some statistically significant differences were observed in some baseline hemodynamic and biochemistry parameters, but they are not considered to be clinically significant. Women were observed to have a higher incidence of strokes (18% versus 6%), but the strokes did not have a significant effect on their overall survival compared with men. Trends toward a higher incidence of bleeding and infection events were observed in females than males. Nonetheless, the sample size of men compared to women (150 versus 44) makes it difficult to draw any conclusions regarding differences in the safety profile of the device between men and women. The results show that there do not appear to be differences with primary study outcome, NYHA Classification, 6-minute walk, MLWHF, and KCCQ assessments.

A Summary of Clinical Studies

Destination Therapy (DT) Study Overview

The objective of the study was to determine the safety and effectiveness of the HeartMate II LVAS as a destination therapy (DT) device in end-stage heart failure patients who were not candidates for cardiac transplantation. Effectiveness of the device was compared to the HeartMate XVE by evaluating a composite endpoint that included survival at two years, survival free of stroke resulting in a Modified Rankin Score > 3, or reoperation to repair or replace the device. The safety of the HeartMate II was documented by the incidence of adverse events and the incidence of device malfunctions and failures during LVAS support, and was compared to the HeartMate XVE results.

In addition, a number of secondary objectives were evaluated, including separate evaluations of each component of the composite endpoint (2-year survival, stroke rates, and device reliability), functional status (6-minute walk, patient activity score, and NYHA classification), quality of life (Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire), assessment of all adverse events, reoperations, re-hospitalizations, and neurocognitive assessments (memory, language, visual/spatial perception, processing speed, and abstract/executive function).

The Destination Therapy (DT) pivotal study was a prospective, randomized, nonblinded, noninferiority evaluation of the HeartMate II LVAS in end-stage left ventricular failure patients who were not candidates for cardiac transplantation and were refractory to optimal medical therapy. The statistical analysis plan in the study protocol specified testing for superiority once noninferiority was established. Patients were randomly assigned to treatment with the HeartMate XVE (control group) or to treatment with the HeartMate II. Two patients were randomized to the HeartMate II for every one patient randomized to the HeartMate XVE. The randomization was stratified by study center and blocked to maintain the 2:1 ratio over time. Block sizes of 3, 6, or 9 patients were randomly selected to prevent manipulation of the treatment assignment. Two hundred (200) patients were enrolled into the Primary Study Cohort (134 HeartMate II and 66 HeartMate XVE) at 38 investigational sites from March 2005 to May 2007. All 200 patients enrolled into the Primary Study Cohort were followed for at least two years.

This study also enrolled patients into four additional study cohorts. Unless otherwise noted, the data presented in this summary reflects study patients enrolled as of December 15, 2008 and followed through May 15, 2009. Refer to **Figure A.8** for a summary of the cohorts and number of patients enrolled.

Summary of Clinical Studies **A**

The cohorts included:

- **Small BSA Cohort:** Patients who had a BSA of less than 1.5m^2 ; and, therefore, could not be randomized to the HeartMate XVE due to its size.
- **XVE Exchange Cohort:** Destination Therapy patients who received the HeartMate II as a replacement for a failed HeartMate XVE that was originally implanted under commercial use.
- **Randomized Continued Access Protocol (CAP) Cohort:** Upon completing enrollment in the Primary Study Cohort, patient enrollment continued under CAP, using the same study protocol as the Primary Study Cohort.
- **Anatomic Deviation Cohort:** This cohort included patients that had a BSA $> 1.5\text{m}^2$ but could not be randomized to the HeartMate XVE due to their body habitus or other anatomic considerations.

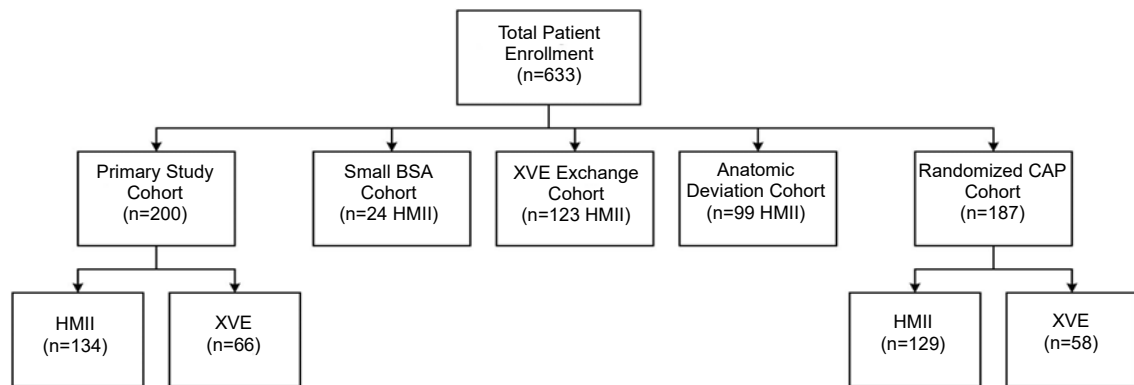


Figure A.8 Total Number of Patient Enrolled in Each Cohort as of December 15, 2008

The study had two oversight committees: a Clinical Events Committee (CEC), which adjudicated all adverse events and deaths, and a Data and Safety Monitoring Board (DSMB), which reviewed the study data periodically to ensure that the study was safe to continue. The members of these committees were independent of Abbott, the investigational sites, and the principal investigators.

The primary endpoint of the study was a composite endpoint: two-year survival free of stroke resulting in a Modified Rankin Score > 3 , or reoperation to repair or replace the device. Patients were considered a success if they achieved the composite endpoint and a failure if they did not. Patients who were urgently transplanted due to device failure were considered a failure. Patients who were electively transplanted after reversal of a pre-enrollment co-morbidity were followed and considered a success if they achieved two years of survival from the day of their VAD implant without experiencing a stroke resulting in a Modified Rankin Score > 3 . The HeartMate II was judged a success if the proportion of HeartMate II patients who achieved the composite endpoint was equal to or better than the HeartMate XVE comparison group.

A Summary of Clinical Studies

Primary Study Cohort DT Patient Population

The HeartMate II was implanted as destination therapy in patients who were not candidates for cardiac transplantation. Patients were ineligible for transplant primarily due to age (28%), recent history of cancer (9%), obesity (7%), and substance abuse or insufficient social support (7%). The patients' ages ranged from 26 to 81 years, with a median of 64 years. The majority of patients were Caucasian males with ischemic heart disease. No significant differences were seen in age, BSA, body mass index (BMI), etiology, or ethnicity between the HeartMate II and HeartMate XVE groups. Despite randomization, the HeartMate II arm included a significantly larger number of females than the HeartMate XVE arm. A gender analysis was performed and determined that there was no influence on the treatment effect (see *Gender Analysis* on page A-44). Patient demographics are presented in **Table A.12**.

	HeartMate II (n=134)	HeartMate XVE (n=66)	P*
Age (years)**	64 (26–79)	65 (29–81)	0.8125
Etiology	66% Ischemic	68% Ischemic	0.7526
Gender	81% Male 19% Female	92% Male 8% Female	0.0369
BSA (m²)**	2.0 (1.6–2.8)	2.0 (1.6–2.8)	0.5438
BMI (kg/m²)**	27.4 (18.0–43.4)	27.9 (18.2–40.1)	0.9913

* Unpaired t-test or Fisher's exact test, as appropriate

** Median and range

Table A.12 Primary Study Cohort: Baseline Demographics

The baseline laboratory assessments, hemodynamic values, and cardiovascular history did not reveal any statistically significant differences between the HeartMate II and HeartMate XVE group. Of note in the cardiovascular history is that 82% of the patients entered the study with implantable cardiac defibrillators (ICD) and 16% of the patients had a history of stroke (see **Table A.13**). Overall, 79% of the patients were on inotropes at baseline, 23% on intra-aortic balloon pump (IABP), and 8% on mechanical ventilation, thus indicating an end-stage heart failure patient population. The similarity in baseline characteristics indicates that the two treatment arms are comparable.

	HeartMate II (n=134)		HeartMate XVE (n=66)		
Cardiovascular	No. Pts	% Pts	No. Pts	% Pts	P*
Arrhythmias	115	86%	55	83%	0.6762
Ventricular Arrhythmias	65	49%	38	58%	0.2337
Ventricular Pacing	105	78%	45	68%	0.1225
Biventricular Pacing	85	63%	39	59%	0.6423
Implantable Cardiac Defibrillator (ICD)	111	83%	52	79%	0.5619
Stroke	21	16%	11	17%	0.8403

* Fisher's exact test

Table A.13 Primary Study Cohort: Baseline Cardiovascular History

A Summary of Clinical Studies

Primary Study Endpoint

Overall DT Patient Outcomes

The primary endpoint of the trial was a composite endpoint: two-year survival free of stroke resulting in a Modified Rankin Score > 3, or reoperation to repair or replace the device. Complete follow-up was obtained for all 200 Primary Study Cohort patients. The results of the analysis demonstrated statistical superiority of the HeartMate II ($P < 0.0001$). Forty-six percent (62/134) of the patients randomized into the HeartMate II cohort successfully achieved the composite endpoint, while only 11% (7/66) of patients randomized into the HeartMate XVE cohort achieved the composite endpoint. This analysis is displayed in **Table A.14**.

Endpoint Analysis	HeartMate II (n=134)	HeartMate XVE (n=66)	P Value ¹
	No. Pts (%) [95% CI]	No. Pts (%) [95% CI]	
Primary Composite Endpoint²	62 (46%) [38%–55%]	7 (11%) [3%–18%]	0.000000246
Components of Primary Composite Endpoint³			
1) Stroke w/ Rankin Score > 3	15 (11%) [6%–17%]	8 (12%) [4%–0%]	
2) Reoperation to repair or replace pump⁴	13 (10%) [5%–15%]	24 (36%) [25%–48%]	
3) Death < 2 years	44 (33%) [25%–41%]	27 (41%) [29%–53%]	
Total of Composite Events	72 (54%) [45%–62%]	59 (89%) [82%–97%]	

¹ Fisher's exact test

² Two-year survival free of stroke resulting in a Modified Rankin Score > 3 or reoperation to repair or replace the device

³ Only the first event was counted, that is, if a patient had a stroke and then subsequently died, only the stroke was counted

⁴ Reoperation to repair or replace pump included urgent heart transplantation or device explantation

Table A.14 Primary Study Cohort (Intent to Treat): Final Analysis Results

Overall Survival As Treated

Subsequent to randomization, eight patients were not implanted and four patients were implanted with the alternate device. Therefore, 133 patients were implanted with the HeartMate II and 59 patients were implanted with the HeartMate XVE.

Figure A.9 and **Table A.15** present the overall survival in an As Treated analysis. Patients who were transplanted, explanted, or had their HeartMate XVE exchanged to a HeartMate II were censored at that time in the analysis. As seen in **Figure A.9**, there is a clinically significant difference in overall As Treated survival favoring the HeartMate II when compared to the HeartMate XVE. Patients supported with the HeartMate II have a two-year predicted survival of 58% compared to 24% for patients supported with the HeartMate XVE. **Table A.15** provides details of the analysis including the number of patients at each interval.

Competing outcomes (ongoing, transplant, death, etc) over time for each of the two devices are shown in **Figure A.10** and **Figure A.11**. Competing outcomes at two years are tabulated in **Table A.16**, with a breakdown of the number of ongoing patients who received a pump replacement. The protocol specified that the HeartMate XVE patients could have the HeartMate II implanted if their device needed replacement, at the discretion of the investigator. The HeartMate II patients could also cross over to the HeartMate XVE, but none did. Causes of death while on LVAS support are listed in **Table A.17**.

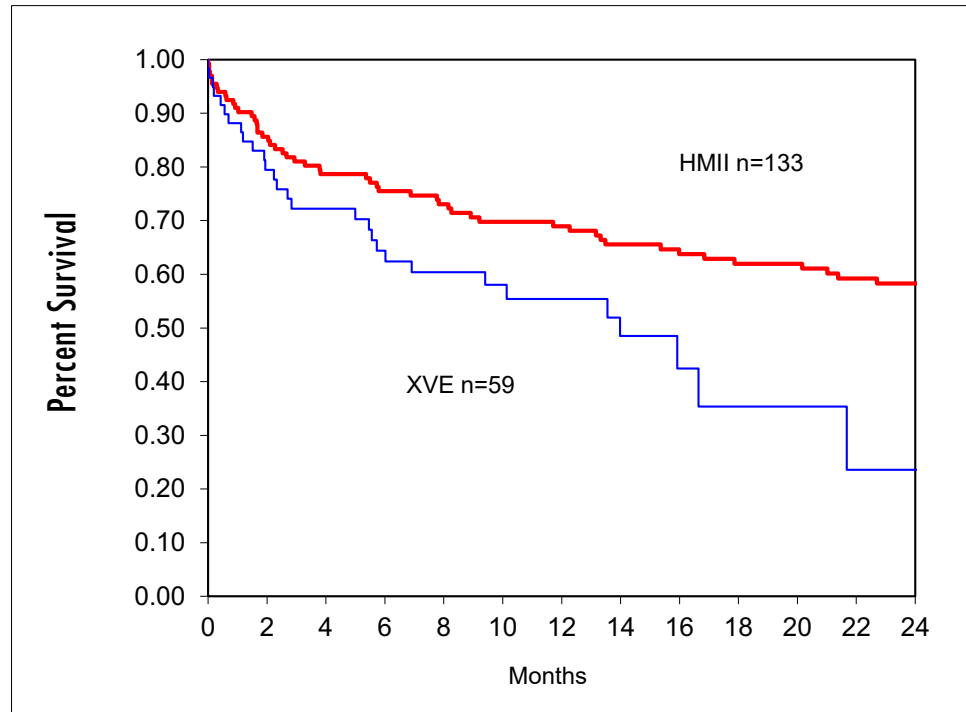


Figure A.9 Primary Study Cohort As Treated: Kaplan-Meier of Overall Survival

A Summary of Clinical Studies

HeartMate II							
Time Interval (Months)							
	0-1	1-3	3-6	6-9	9-12	12-18	18-24
Number of patients starting interval	133	121	105	95	86	82	69
Number of patients who died this interval	12	13	7	6	2	8	4
Number of cumulative patient deaths	12	25	32	38	40	48	52
Number of patients censored in interval	0	3	3	3	2	5	3
Number of cumulative censored patients	0	3	6	9	11	16	19
Probability of surviving interval	0.910	0.810	0.755	0.706	0.690	0.620	0.583
+/- 95% Confidence Limit at end of interval	0.05	0.07	0.07	0.08	0.08	0.09	0.09
HeartMate XVE							
Time Interval (Months)							
	0-1	1-3	3-6	6-9	9-12	12-18	18-24
Number of patients starting interval	59	52	39	32	26	19	5
Number of patients who died this interval	7	9	4	2	2	4	1
Number of cumulative patient deaths	7	16	20	22	24	28	29
Number of patients censored in interval	0	4	3	4	5	10	2
Number of cumulative censored patients	0	4	7	11	16	26	28
Probability of surviving interval	0.881	0.722	0.644	0.604	0.554	0.354	0.236
+/- 95% Confidence Limit at end of interval	0.08	0.12	0.13	0.13	0.14	0.19	0.23

Note: Censored = at time of transplant, explant, or crossover from XVE to HeartMate II

Table A.15 Primary Study Cohort As Treated: Kaplan-Meier of Overall Survival

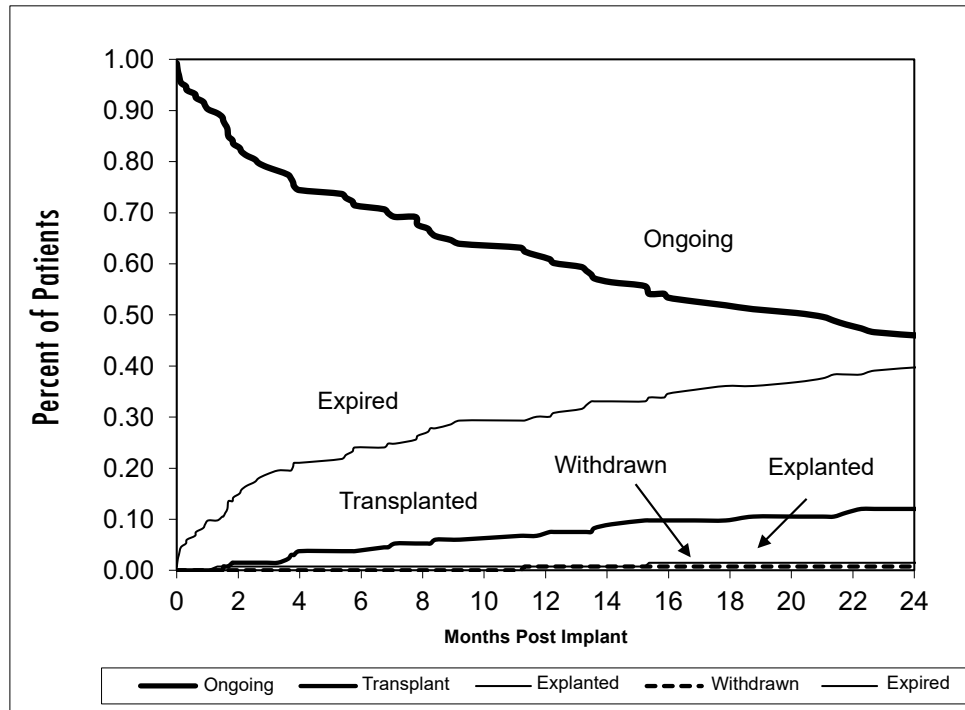


Figure A.10 Competing Outcomes for HeartMate II LVAS As Treated

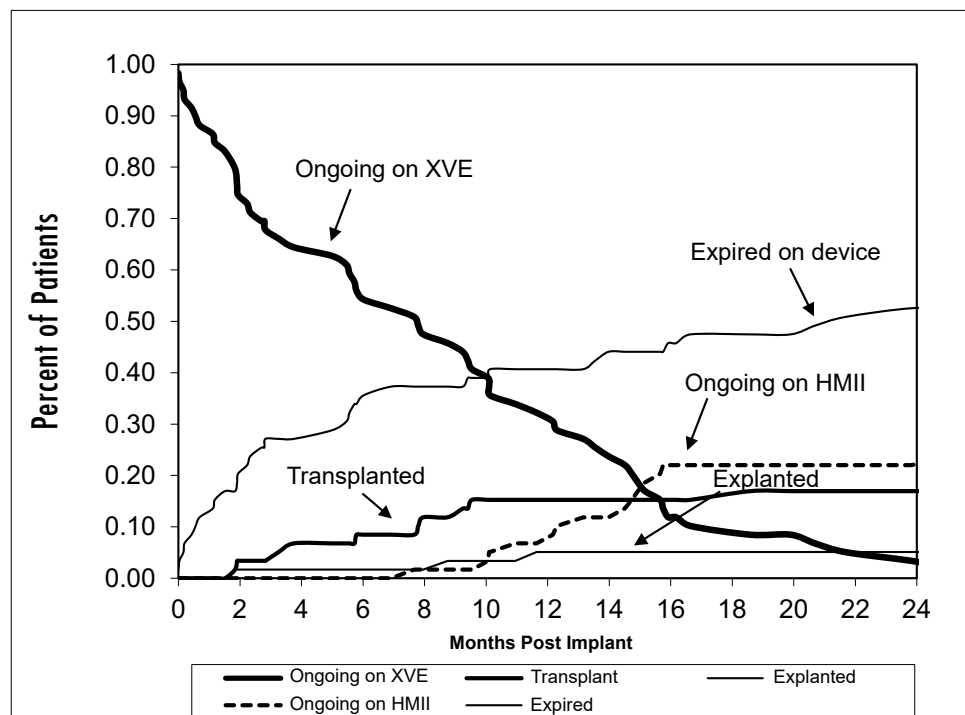


Figure A.11 Competing Outcomes for HeartMate XVE LVAS As Treated

A Summary of Clinical Studies

Status at 2 Years	Original Implanted Device	
	HeartMate II (n=133)	HeartMate XVE (n=59)
Ongoing on original implanted device	50 (38%)	0 (0%)
Ongoing with replacement of original device with same type	12 (9%)	2 (3%)
Ongoing with replacement of original device with alternate type	0 (0%)	13 (22%)
Transplanted	16 (12%)	10* (17%)
Explanted for recovery	2 (2%)	3 (5%)
Withdrew from study	1 (1%)	0 (0%)
Expired on LVAS Support	52 (39%)	31 (53%)

Note: Includes one patient who crossed over to HeartMate II and was subsequently transplanted

Table A.16 Competing Outcome Status at Two Years As Treated

Summary of Clinical Studies **A**

	HeartMate II (n=133)		HeartMate XVE (n=59)	
	No. Pts	% Pts	No. Pts	% Pts
Bleeding	4	3%	1	2%
Brain related:				
Air Embolism	1	1%	0	0%
Anoxic Brain Injury	0	0%	1	2%
Stroke	13	10%	11	19%
Traumatic Brain Injury	2	2%	1	2%
Cardiopulmonary:				
Cardiac Arrest	4	3%	1	2%
Heart Failure	1	1%	1	2%
Respiratory Failure	4	3%	2	3%
Myocardial Infarction	1	1%	0	0%
Right Heart Failure	8	6%	5	8%
Device Malfunctions/Failure:				
Loss of Power	5	4%	0	0%
Device Thrombosis	2	2%	0	0%
Inflow Obstruction	0	0%	1	2%
VAD Dysfunction/fail	3	2%	2	3%
Infection	5	4%	6	10%
Miscellaneous:				
Amyloidosis	1	1%	0	0%
Cancer	2	2%	0	0%
Ischemic Bowel	0	0%	1	2%
Unknown	5	4%	0	0%
Withdrawal of Support	2	2%	1	2%
Multisystem Organ Failure	3	2%	4	7%

Table A.17 Primary Study Cohort As Treated: Causes of Death During LVAS Support

A Summary of Clinical Studies

Adverse Events

The incidence of serious adverse events is presented in **Table A.18**. Serious adverse events were defined as those that resulted in death, were life-threatening, resulted in permanent disability, required hospitalization, or prolonged a hospital stay. The study was not powered for a specific analysis of the adverse events. To account for differences in patient durations, adverse events were normalized to events per patient-year and analyzed using Poisson regression to obtain risk ratios with 95% confidence intervals. **Table A.19** presents the results of this As Treated analysis for all serious adverse events. The rate of serious adverse events by time intervals is shown in **Table A.20**.

	HeartMate II (n=133)			HeartMate XVE (n=59)		
	No. Pts	% Patients [95% Confidence interval]	No. Events	No. Pts	% Patients [95% Confidence interval]	No. Events
Bleeding	102	77% [70%–84%]	278	41	69% [58%–81%]	70
Bleeding requiring surgery	40	30% [22%–38%]	50	9	15% [6%–24%]	12
Stroke	24	18% [12%–25%]	27	8	14% [5%–22%]	9
Perioperative (≤ POD2)	3	2% [0%–5%]	3	1	2% [0%–5%]	1
Postoperative (> POD2)	21	16% [10%–22%]	24	7	12% [4%–20%]	8
Other Neurological*	27	20% [13%–27%]	32	9	15% [6%–24%]	11
Local Infection	40	30% [22%–38%]	60	19	32% [20%–44%]	30
Drive Line Infection	39	29% [22%–37%]	75	14	24% [13%–35%]	22
Pocket Infection	12	9% [4%–14%]	19	8	14% [5%–22%]	10
Pump Housing	1	1% [0%–2%]	1	2	3% [0%–8%]	2
Sepsis	48	36% [28%–44%]	80	26	44% [31%–57%]	45
Right Heart Failure	31	23% [16%–30%]	34	19	32% [20%–44%]	22
Inotropes Only	27	20% [13%–27%]	29	16	27% [16%–38%]	19
RVAD	5	4% [1%–7%]	5	3	5% [0%–11%]	3

Table A.18 Primary Study Cohort As Treated: Incidence of Serious Adverse Events

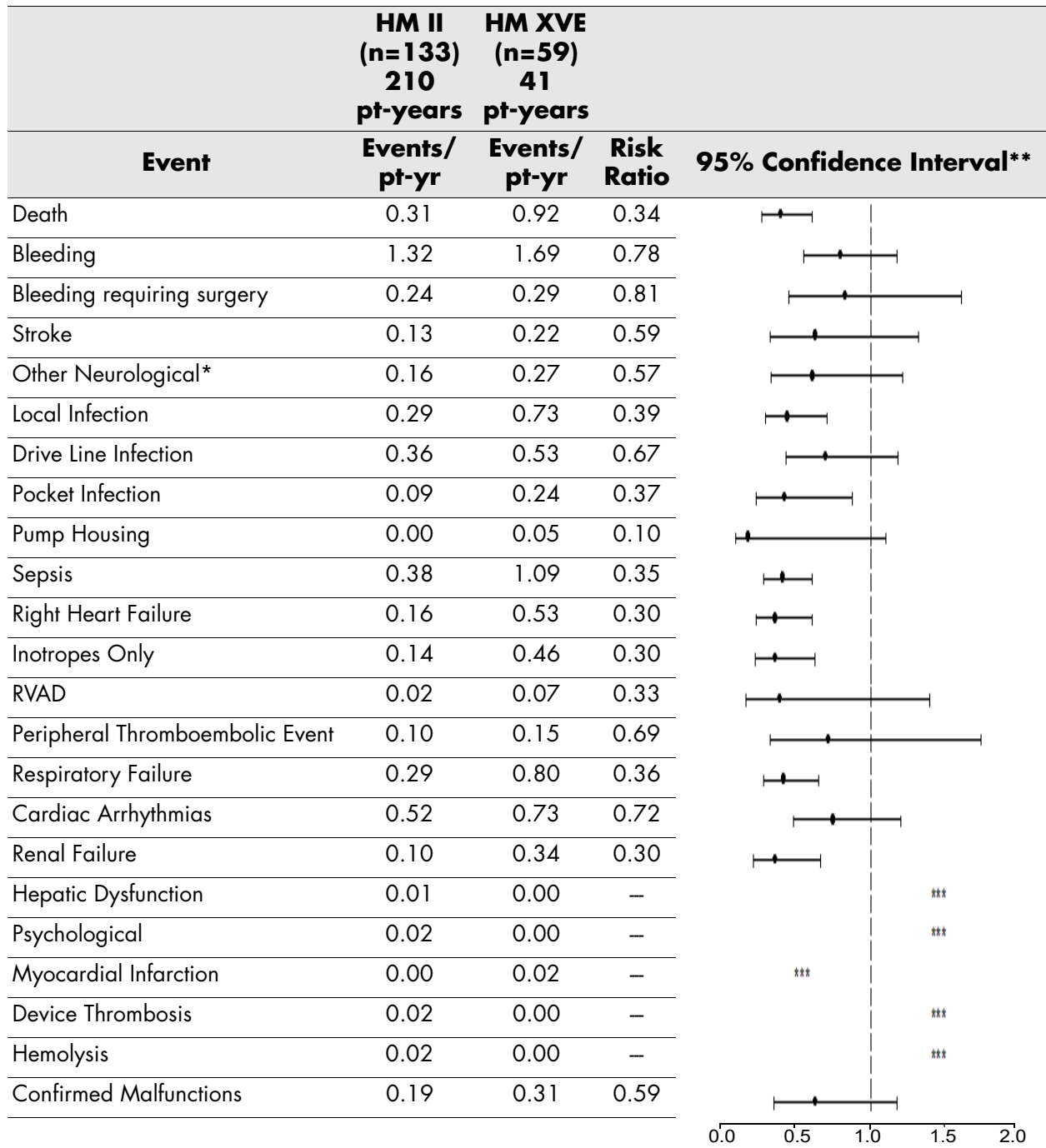
Summary of Clinical Studies **A**

	HeartMate II (n=133)			HeartMate XVE (n=59)		
	No. Pts	% Patients [95% Confidence interval]	No. Events	No. Pts	% Patients [95% Confidence interval]	No. Events
Peripheral Thromboembolic Event	14	11% [5%–16%]	21	6	10% [2%–18%]	6
Respiratory Failure	47	35% [27%–43%]	61	24	41% [28%–53%]	33
Cardiac Arrhythmias	62	47% [38%–55%]	110	21	36% [23%–48%]	30
Renal Failure	21	16% [10%–22%]	21	14	24% [13%–35%]	14
Hepatic Dysfunction	3	2% [0%–5%]	3	0	0% [0%–0%]	0
Psychological	4	3% [0%–6%]	4	0	0% [0%–0%]	0
Myocardial Infarction	0	0% [0%–0%]	0	1	2% [0%–5%]	1
Device Thrombosis	5	4% [1%–7%]	5	0	0% [0%–0%]	0
Hemolysis	5	4% [1%–7%]	5	0	0% [0%–0%]	0
Confirmed Malfunctions	30	23% [15%–30%]	39	12	20% [10%–31%]	13

* Includes transient ischemic attacks (TIA) and nonstroke neurological events

Table A.18 Primary Study Cohort As Treated: Incidence of Serious Adverse Events (Continued)

A Summary of Clinical Studies



* Includes transient ischemic attacks (TIA) and nonstroke neurological events.

** No adjustments made for multiplicity; no conclusions may be drawn regarding statistical significance

*** Unable to calculate risk ratio; no events occurred with one device

Favors HM II

Favors HM XVE

Table A.19 Primary Study Cohort As Treated: Rates of Serious Adverse Events

Summary of Clinical Studies **A**

	Group	0-30 days	31-180 days	181-365 days	366-730 Days
Cumulative years support	HMII	10.30	43.10	44.4	70.0
	XVE	4.40	16.60	12.8	7.1
Adverse Event					
Bleeding¹	HMII	12.33	0.86	1.01	0.81
	XVE	10.91	1.08	0.16	0.28
Stroke²	HMII	0.49	0.09	0.16	0.13
	XVE	0.91	0.18	0.00	0.28
Other Neurological³	HMII	0.78	0.23	0.00	0.16
	XVE	0.45	0.24	0.23	0.14
Local Infection	HMII	2.14	0.32	0.14	0.21
	XVE	3.18	0.66	0.23	0.28
Drive Line Infection	HMII	0.00	0.37	0.65	0.30
	XVE	0.23	0.60	0.63	0.42
Pocket Infection	HMII	0.39	0.14	0.09	0.06
	XVE	0.45	0.30	0.16	0.14
Pump Housing Infection	HMII	0.00	0.00	0.00	0.01
	XVE	0.00	0.12	0.00	0.00
Sepsis	HMII	1.65	0.37	0.29	0.40
	XVE	2.95	1.08	0.94	0.28
Right Heart Failure	HMII	2.33	0.07	0.02	0.04
	XVE	3.86	0.18	0.08	0.14
Peripheral Thromboembolic Event	HMII	0.87	0.14	0.14	0.00
	XVE	0.91	0.00	0.16	0.00
Respiratory Failure	HMII	3.50	0.21	0.11	0.10
	XVE	1.82	0.48	0.23	0.00
Cardiac Arrhythmias	HMII	3.98	0.51	0.32	0.39
	XVE	4.09	0.48	0.16	0.14
Renal Failure	HMII	1.36	0.07	0.02	0.03
	XVE	2.27	0.18	0.08	0.00
Hepatic Dysfunction	HMII	0.19	0.00	0.00	0.00
	XVE	0.00	0.00	0.00	0.00
Psychological	HMII	0.19	0.02	0.00	0.01
	XVE	0.00	0.00	0.00	0.00
Myocardial Infarction	HMII	0.00	0.00	0.00	0.00
	XVE	0.23	0.00	0.00	0.00
Device Thrombosis	HMII	0.10	0.02	0.02	0.03
	XVE	0.00	0.00	0.00	0.00

Table A.20 Primary Study Cohort As Treated: Serious Adverse Event Rate per Patient-Year by Time Interval

A Summary of Clinical Studies

	Group	0-30 days	31-180 days	181-365 days	366-730 Days
Hemolysis	HMII	0.19	0.00	0.02	0.03
	XVE	0.00	0.00	0.00	0.00

¹ HM II: 80.52 events/pt-yr over 0–1 days; 6.78 events/pt-yr over 2–30 days

HM XVE: 100.00 events/pt-yr over 0–1 days; 3.92 events/pt-yr over 2–30 days

² HM II: 2.75 events/pt-yr over 0–1 days; 0.31 events/pt-yr over 2–30 days

HM XVE: 3.13 events/pt-yr over 0–1 days; 0.76 events/pt-yr over 2–30 days

³ Includes transient ischemic attacks (TIA) and nonstroke neurological events

Table A.20 Primary Study Cohort As Treated: Serious Adverse Event Rate per Patient-Year by Time Interval (Continued)

Device Complications

Ninety-three percent (93%, 25/27) of the HeartMate XVE malfunctions that resulted in adverse clinical effects were related to the implanted pump, primarily the result of wearout of either the bearings or valve conduit (**Table A.22**). In contrast, only 53% of the HeartMate II malfunctions with adverse clinical effects were related to the implanted pump. The balance of the malfunctions was primarily associated with the System Controller, an external component of the system that is designed for easy and rapid exchange in the event of a malfunction.

The malfunctions of the HeartMate II pump were primarily related to the percutaneous lead that connects the implanted pump with the external System Controller. Repair procedures were developed that can extend the useful life of the external portion of the percutaneous lead; however, failures of the internal portion of the percutaneous lead require immediate pump replacement.

The serious complications of device thrombosis and hemolysis each occurred in 4% (5 patients) of the HeartMate II patients. The HeartMate XVE patients did not experience any of these events. Three of the 5 (60%) hemolysis events were associated with device thrombosis. The other two hemolysis events resolved over time with no intervention.

Clinical Reliability

Clinical reliability was evaluated by taking into account all HeartMate II study experience through January 20, 2009, regardless of study cohort. One hundred and one (101) reports of suspected malfunctions related to the implanted components of the HeartMate II LVAS were received from the 509 HeartMate II patients enrolled into the Destination Therapy clinical study. Eighty-five percent (85%) of those reports were related to the percutaneous lead. There were 28 reports of malfunction that resulted in hemodynamic compromise, reoperations for pump replacement, pump explantation, or death, 27 of which were related to the percutaneous lead. As shown in **Table A.21**, reliability of the current configuration of the percutaneous lead is improved compared to the overall reliability, as a result of design modifications to the external strain relief intended to reduce the most frequent failure modes.

Percutaneous Driveline Configuration	Type of Malfunction	Reliability ¹ at:		
		1 yr	2 yr	3 yr
All configurations²	All malfunctions	85%	62%	39%
	Reoperation/Death	96%	87%	75%
Current Configuration³	All malfunctions	95%	91%	87%
	Reoperation/Death	97%	95%	92%

¹ Reliability estimates based on Weibull analysis

² Both original external strain relief and current external strain relief design

³ External strain relief design at time of PMA approval

Table A.21 Percutaneous Lead Reliability (All Cohorts)

The mean time to failure (malfunction resulting in hemodynamic compromise, reoperations for pump replacement, pump explantation, or death) was 1677 days (at the 80% confidence level). The 28 individual failures described above occurred between 36 to 1277 days of VAD support. The observed clinical reliability is less than the original reliability estimates based on in vitro testing because the in vitro test environment did not reflect all of the factors associated with the LVAD user environment.

Twenty-five (25) clinical failures (malfunctions or damage resulting in pump replacement, urgent transplant, or death) occurred in 59 HeartMate XVE patients in the Primary Study Cohort and 58 HeartMate XVE patients in the Randomized Continuous Access Protocol (CAP) Cohort. In contrast to the HeartMate II in which failures were predominately related to one component, the percutaneous lead, the HeartMate XVE had several failure modes, as shown in **Table A.22**.

A Summary of Clinical Studies

Failure Mode	Number of Failures
Valve and/or conduit wear	8
Bearing wear	7
Low flow and/or pump	5
Other	5
Total	25

Table A.22 HeartMate XVE Failure Modes

These 25 failures occurred over a range of 0 to 676 days. A Weibull analysis of the clinical reliability of the HeartMate XVE observed in this study is provided in **Table A.23**.

Time (months)	Clinical Reliability* at 80% Confidence Level
6	84%
12	69%
18	55%

*Weibull analysis parameters: beta = 1.1515, eta = 1023.9663, rho = 0.9023

Table A.23 Clinical Reliability Calculations

Secondary Objectives

Secondary objectives were collected, which included the following: reoperations, clinical reliability, functional status, quality of life, neurocognitive evaluation, and postexplant follow-up.

Reoperations

Reoperations included any return to the operating room for any reason following implant. Reoperations were device- or patient- related such as driveline debridement or bleeding, and included routine operations such as appendectomy and orthopedic procedures. As shown in **Table A.24**, the incidence of reoperations was similar between the groups. A higher percentage of patients in the HeartMate II group required reoperation. However, when normalized to events per patient-year, the HeartMate II group had a lower rate of reoperations per patient-year (risk ratio 0.53).

	No. Pts	No. Pts with Reoperations	% Pts with Reoperations	No. Events	Reops/ Pt-Yr	Risk Ratio
HMII	133	106	80%	325	1.55	0.53
XVE	59	43	73%	120	2.91	

Table A.24 Primary Study Cohort As Treated: Reoperations

Thirty-six (36) of the reoperations that occurred in the Primary Study Cohort were due to the need for pump replacements (21 in the HeartMate XVE and 15 in the HeartMate II). Of the 59 patients implanted with the HeartMate XVE, 20 patients received 21 pump exchanges. Of the 133 patients implanted with the HeartMate II, 14 patients received 15 pump exchanges.

Of the patients who were originally implanted with the HeartMate XVE, 18 were exchanged to the HeartMate II and 3 patients were exchanged to the HeartMate XVE. The 21 pump exchanges were due to: inflow or outflow valve malfunction (4), bearing wear (11), and infection (1). In 5 cases, pumps were exchanged in patients who had clinical symptoms and diagnostic indicators such as waveforms or vent filter analysis that was suggestive of end of pump life or fluid ingress. Pumps were functional during explant analysis but fluid ingress was noted in 3 of the 5 and bearing wear was noted in the other 2.

All of the patients originally implanted with the HeartMate II who needed pump replacements were exchanged to another HeartMate II pump. Reasons for exchange included: suspected pump thrombus (2), suspected percutaneous lead wire breakage in external portion of driveline (7), percutaneous lead breakage at pump end (5), and disconnected outflow elbow (1).

A Summary of Clinical Studies

Functional Status, Quality of Life, and Neurocognitive Measures

The secondary objectives studied included functional evaluations based on NYHA class, 6-minute walk, and Metabolic Equivalents scores (METs). Health Status including quality of life (QoL) was measured via the Minnesota Living with Heart Failure Questionnaire (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ). A battery of neurocognitive evaluations was also performed.

In summary, significant improvement was seen in both device groups in quality of life scores and in functional status over baseline and over time through 12 months, as can be seen in **Figure A.12** through **Figure A.16** below. After 12 months, there were too few HeartMate XVE patients to analyze. No significant difference in QoL was seen between HeartMate II and HeartMate XVE groups. An additional measure of QoL was time spent out of hospital. Once implanted, HeartMate II patients spent 87% of their support time out of hospital compared to 69% for patients implanted with the HeartMate XVE (As Treated analysis). No decline in neurocognitive function was observed, and trends toward improvement over time were observed for some neurocognitive measures with both devices.

The number of patients able to perform tests of functional status and quality of life decreases at each time interval as patients expire, are transplanted, are weaned off the device, or are crossed over to the alternate device. Some patients were not tested due to patient issues (such as patient too sick to perform the testing), management issues (such as scheduling, or site staff oversight), patient refusal, or, in some cases, no reason was provided. The tables following the graphs indicate the number and percentage of patients performing each test (**Table A.25** through **Table A.28**).

In **Figure A.12** through **Figure A.16**, the number of patients analyzed at each interval is shown above each bar. Error bars extending beyond the data bars in the figures denote 95% confidence intervals or standard deviation, as noted in each figure.

Summary of Clinical Studies **A**

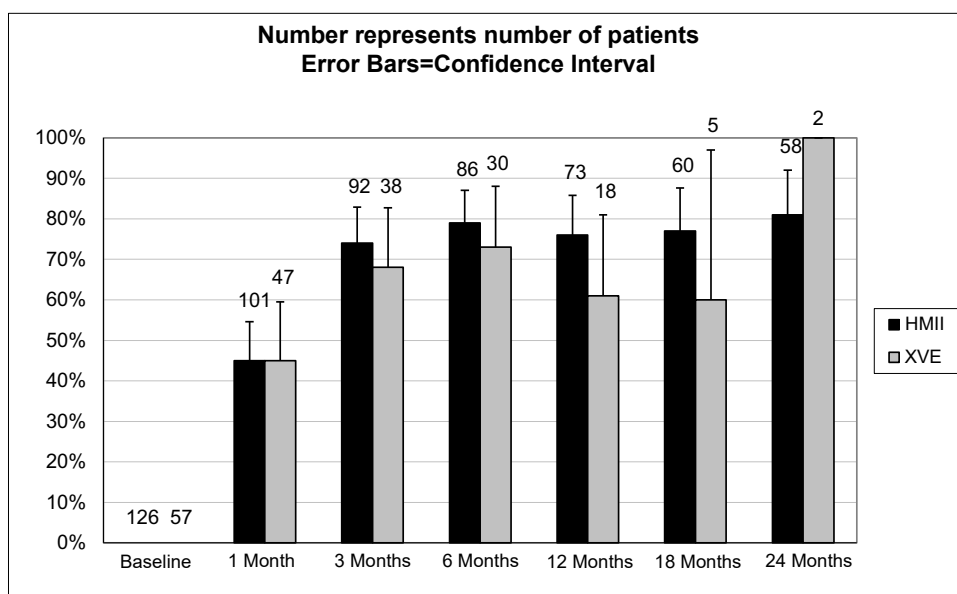


Figure A.12 Primary Study Cohort As Treated: NYHA Class I or II Over Time

		Base- line	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
No. pts at interval	HM II	133	121	105	95	82	70	59
	XVE	59	52	39	32	19	5	2
No. pts perform- ing test	HM II	126	101	92	86	73	60	58
	XVE	57	47	38	30	18	5	2
% pt perform- ing test	HM II	95%	83%	88%	91%	89%	86%	98%
	XVE	97%	90%	97%	94%	95%	100%	100%

Table A.25 Primary Study Cohort As Treated: NYHA Class I or II Compliance

A Summary of Clinical Studies

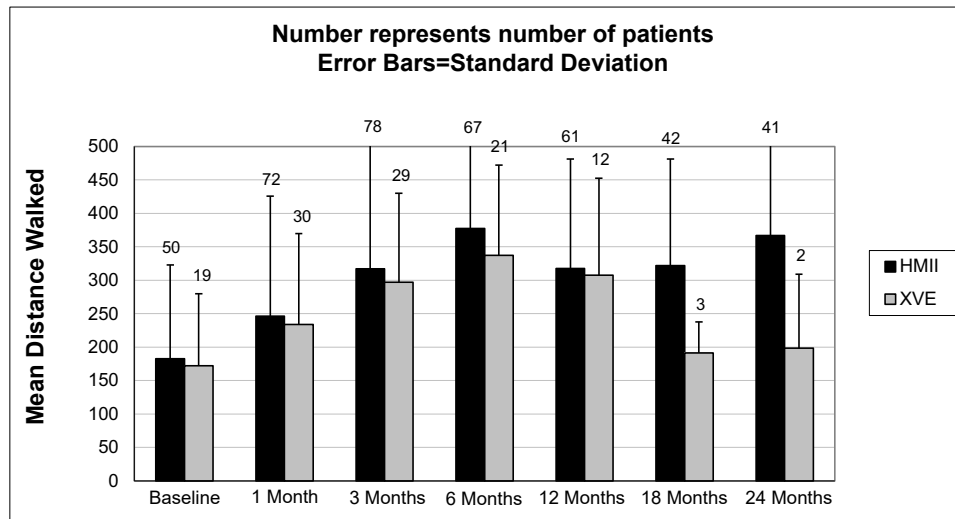


Figure A.13 Primary Study Cohort As Treated: Six-Minute Walk; Meters Walked Over Time

		Base- line	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
No. pts at interval	HM II	133	121	105	95	82	70	59
	XVE	59	52	39	32	19	5	2
No. pts perform- ing test	HM II	50	72	78	67	61	42	41
	XVE	19	30	29	21	12	3	2
% pt perform- ing test	HM II	38%	60%	74%	71%	74%	60%	69%
	XVE	32%	59%	74%	66%	63%	60%	100%

Table A.26 Primary Study Cohort As Treated: Six-Minute Walk Test Compliance

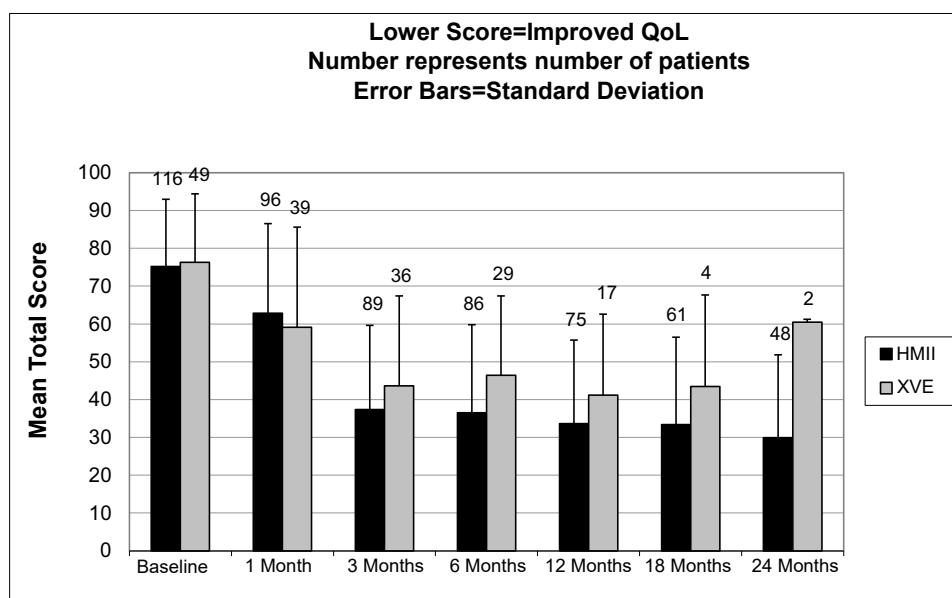


Figure A.14 Primary Study Cohort As Treated: MLWHF Scores Over Time

		Base- line	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
No. pts at interval	HM II	133	121	105	95	82	70	59
	XVE	59	52	41	34	20	5	2
No. pts perform- ing test	HM II	116	96	89	86	75	61	48
	XVE	49	39	36	29	17	4	2
% pt perform- ing test	HM II	87%	79%	85%	91%	91%	87%	81%
	XVE	83%	75%	87%	85%	85%	80%	100%

Table A.27 Primary Study Cohort As Treated: MLWHF Testing Compliance

A Summary of Clinical Studies

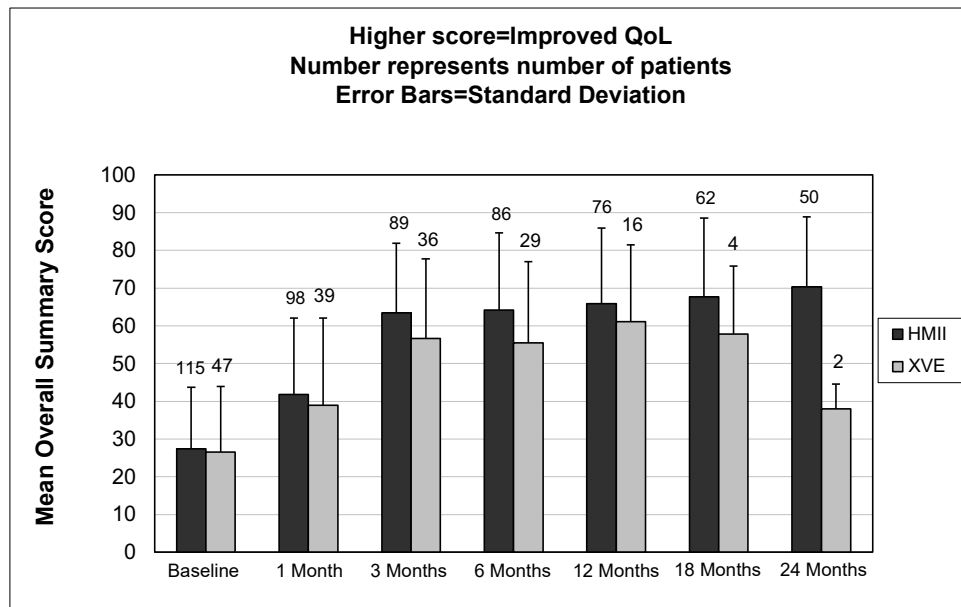


Figure A.15 Primary Study Cohort As Treated: KCCQ Overall Summary Score Over Time

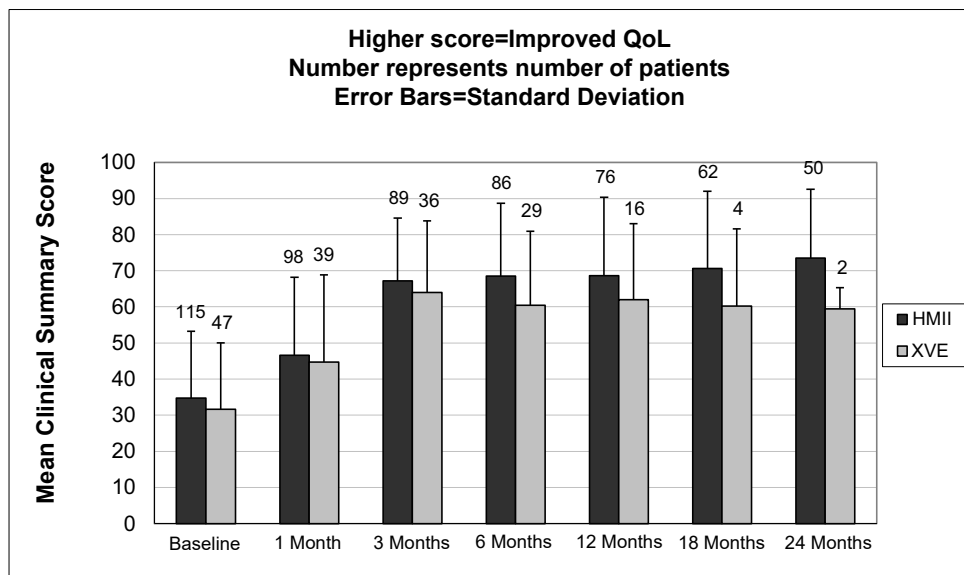


Figure A.16 Primary Study Cohort As Treated: KCCQ Clinical Summary Score Over Time

Summary of Clinical Studies **A**

		Base- line	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
No. pts at interval	HM II	133	121	105	95	82	70	59
	XVE	59	52	40	33	19	5	2
No. pts perform- ing test	HM II	115	98	89	86	76	62	50
	XVE	47	39	36	29	16	4	2
% pt perform- ing test	HM II	86%	81%	85%	91%	84%	89%	85%
	XVE	80%	75%	90%	88%	90%	80%	100%

Table A.28 Primary Study Cohort As Treated: KCCQ Testing Completion by Follow-up Intervals

A Summary of Clinical Studies

Gender Analysis

An analysis was performed to determine if the treatment effect observed in the trial was influenced by the gender differences between treatment groups. In addition, Kaplan-Meier analyses were performed by gender to determine if the superior results obtained by patients supported with the HeartMate II were experienced by both males and females.

In the Primary Study Cohort, despite randomizing patients into treatment arms, 16% of patients randomized into the HeartMate II cohort were female compared to 8% in the HeartMate XVE cohort. This difference in gender was statistically significant ($P = 0.0369$). Logistic regression was used to determine that this gender difference did not influence the treatment effect seen in the trial. A Kaplan-Meier analysis of the study's primary composite endpoint, stratified by gender, was limited due to the small number of females enrolled in the trial.

A post hoc analysis was conducted that included patients from other cohorts. Patients enrolled in the Primary Study Cohort were combined with patients randomized into the Continued Access Protocol (CAP) for the trial. This pooled cohort is referred to as the Randomized Cohort. Sixteen percent (16%) of patients randomized into the HeartMate II group were female, compared to ten percent (10%) in the HeartMate XVE Cohort. This difference in gender was no longer significant ($P = 0.2094$). The Randomized Cohort provided 54 female patients to evaluate. An analysis of baseline demographics and etiology demonstrated that the groups remained comparable.

A Kaplan-Meier analysis comparison of the Randomized Cohort males (222 HeartMate II versus 111 HeartMate XVE) and females (41 HeartMate II versus 13 HeartMate XVE), of the study's primary composite endpoint resulted in a significant survival advantage ($P < 0.0001$) for HeartMate II patients irrespective of gender. This analysis provides evidence that gender differences have not influenced the outcome results observed in the trial and that the superior results of the HeartMate II are shared by both males and females.

Adverse event rates between males who received the HeartMate II compared to males who received the HeartMate XVE were similar to overall study results for the Primary Study Cohort, with differences in adverse event rates favoring the males implanted with the HeartMate II. The same result was also true for females implanted with the HeartMate II.

A second post hoc analysis was performed to provide additional females by combining patients enrolled in the Small BSA Cohort (patients with $BSA < 1.5\text{m}^2$) and the HeartMate II Anatomical Deviation Cohort (patients with $BSA \geq 1.5\text{m}^2$ but who could not receive a HeartMate XVE due to body habitus or surgical issues) with the HeartMate II patients from the Randomized Cohort described above. This combined cohort included 286 males and 100 females, all supported with the HeartMate II. A Kaplan-Meier analysis of survival free of stroke (Rankin > 3), or reoperation to repair or replace the device, resulted in no significant difference between males supported with the HeartMate II compared to females supported with the HeartMate II ($P = 0.2650$).

Summary of Clinical Studies **A**

Males supported with the HeartMate II had better adverse event rates for local infection and peripheral thromboembolic events when compared to females supported with the HeartMate II (**Table A.29**). The thromboembolic event rate was influenced by 1 female who had 8 thromboembolic events to her lower extremities.

In conclusion, the gender analysis shows that the benefits and risks of the HeartMate II are similar for males and females and that the observed treatment effect was not influenced by gender.

Adverse Event	Males (n=279)	Females (n=102)
Local infection	0.62	0.95
Peripheral thromboembolic events	0.08	0.12

Table A.29 Adverse Event Differences As Treated, Males versus Females (Events/Patient-Year)

A Summary of Clinical Studies

Post-Approval Studies

Bridge-to-Transplant Post-Approval Study Overview

A Post-Approval Study (PAS) of the HeartMate II (HMII) for the bridge-to-transplantation (BTT) indication was conducted as a condition of FDA approval. The purpose of the PAS was to assess whether the commercial use of the HeartMate II was comparable to other available commercial devices that were approved in the US for the same indication for use, bridge-to-transplant. The primary objective of the PAS was to assess survival to transplantation following HeartMate II implantation for bridge-to-transplant in a commercial setting. A number of secondary objectives were also evaluated during the PAS, including quality of life (EuroQoL).

Study Design

The study was a multicenter, nonblinded, nonrandomized, prospective study. The primary PAS outcomes were defined as death, cardiac transplantation, device explantation due to myocardial recovery and survival for at least 60 days, or survival to 180 days on LVAS support. After reaching 180 days, patients continued to be followed for 1 year, or transplantation, explantation, or death. All data were collected via INTERMACS and all oversight committees were per INTERMACS protocol.

Study Population

To be enrolled into the INTERMACS registry, patients received a commercially marketed LVAS and the patient or their legal representative signed an informed consent for INTERMACS registry participation. Patients who were enrolled in premarket clinical studies of VADs or incarcerated persons (prisoners) could not participate.

All patients who were identified preimplant in the INTERMACS database as "Bridge-to-Transplant (patient currently listed for transplant)" or "Possible Bridge to Transplant - Likely to be eligible" were enrolled in the PAS. Patients implanted with the HeartMate II comprised the study group and patients implanted with any other LVAD comprised a comparison group.

Per the approved protocol, once the first 169 HeartMate II patients were enrolled, data would be compared to an equal number of BTT patients from the prospective INTERMACS non HeartMate II comparison group. Since the 169 concurrent comparison patients had not been enrolled by the end of the six month study enrollment extension, comparison patients previously enrolled in INTERMACS were included to make up the difference by selecting the most recent consecutive retrospective non HeartMate II patients from the INTERMACS registry. **Table A.30** describes the patients that comprised the study and comparison group.

Device	Group	N	Group total
HMII LVAD	HMII	164	169
HMII LVAD with PVAD¹ RVAD	HMII	2	
HMII LVAD with Non-Abbott RVAD	HMII	3	
HMXVE LVAD	Comparison	130	166
HM XVE with IVAD² RVAD	Comparison	1	
HM XVE with Non-Abbott RVAD	Comparison	4	
IVAD² LVAD	Comparison	15	
IVAD² with Non-Abbott RVAD	Comparison	1	
IVAD² with IVAD RVAD	Comparison	15	

¹ PVAD: Abbott Paracorporeal VAD

² IVAD: Abbott Implantable VAD

Table A.30 HeartMate II Post-Approval Study: Device Type

Patient demographic data for both the HeartMate II and the Comparison group were collected at baseline. **Table A.31** summarizes the baseline characteristics of the two groups. There were no statistical differences between the two groups, except for medical history; the HeartMate II patients had a significantly greater incidence of previous coronary artery bypass graft (CABG) procedures.

A Summary of Clinical Studies

Variable	HeartMate II (n=169)	Comparison (n=169)	P*
Gender			
Males	131 (78%)	139 (84%)	0.1500
Females	38 (22%)	27 (16%)	
Age			
0–18 years	3 (2%)	5 (3%)	0.7373
19–39 years	26 (15%)	22 (13%)	
40–59 years	81 (48%)	86 (52%)	
60–79 years	59 (35%)	53 (32%)	
Race			
Caucasian	125 (74%)	111 (67%)	0.3773
Black	29 (17%)	37 (22%)	
Other	15 (9%)	18 (11%)	
BSA (m²)	2.03 ± 0.26	2.06 ± 0.25	0.3267
BMI (Kg/m²)	28.3 ± 6.9	30.1 ± 16.1	0.2100
BSA < 1.5 m² (Small Size Cohort)	1 (1%)	5 (3%)	0.1189
History			
Coronary Bypass Graft	37 (22%)	16 (10%)	0.0021
Valve	7 (4%)	10 (6%)	0.4326
Cancer	11 (7%)	7 (4%)	0.3593
Diabetes	57 (33%)	52 (31%)	0.6837

* Fisher's exact test or unpaired t-test as appropriate

Table A.31 Post-Approval Study: Baseline Demographics

Data Source

All data were collected via INTERMACS, the Interagency Registry of Mechanically Assisted Circulatory Support. The patients included the first consecutive 169 HeartMate II patients who gave their consent for inclusion in the INTERMACS registry and an equal number of patients from a comparison group that included patients who were implanted with other LVAD devices and enrolled in INTERMACS.

Key Study Endpoints

As specified in the HeartMate II LVAS Post-Approval Study protocol, the study would be considered a success if the success rate of the HeartMate II patients were as good or better than the success rate of the comparison group. Success was defined as LVAS support for at least 180 days or to transplant, or to explant due to myocardial recovery and survival for at least 60 days postexplant.

Total Number of Enrolled Study Sites and Subjects, Follow-Up Rate

A total of 335 patients were enrolled in the PAS at 77 institutions across the United States from April 21, 2008 to February 28, 2009. All patients (100%) were followed for at least 180 days or to an outcome (transplant, death, or explant).

Study Visits and Length of Follow-Up

Study visits were assessed at 1 week, 1 month, 3 months, and 6 months postimplant. Study patients were followed until death, cardiac transplantation, device explantation due to myocardial recovery and survival for at least 60 days, or survival to 180 days on LVAS support. After reaching 180 days, patients continued to be followed for one year, or transplantation, explantation, or death, whichever occurred first.

Final Effectiveness Findings

As seen on **Table A.32**, 90% of the HeartMate II patients achieved success compared to 79% of the comparison patients. This represents a significant improvement in success ($P = 0.0064$ using a Fisher's exact test).

In addition, HeartMate II patients have a significant overall survival advantage over comparison patients ($P = 0.0004$, Logrank analysis) (**Figure A.17**, **Table A.33**).

A Summary of Clinical Studies

Study Endpoint Status	Patient Status	HeartMate II (n=169)	Controls (n=166)
Met Success Criteria	VAD support ≥ 180 Days, ongoing	37 (22%)	4 (2%)
	VAD support ≥ 180 Days, explanted for recovery	1 (1%)	3 (2%)
	VAD support ≥ 180 Days, explanted for other reason	4 (2%)	15 (8%)
	VAD support ≥ 180 days, expired	17 (10%)	10 (6%)
	Transplanted	93 (56%)	99 (60%)
	Total Success*	152 (90%)	131 (79%)
Did not meet Success Criteria	VAD support < 180 days, Expired	16 (9%)	33 (20%)
	VAD support < 180 days,	1 (1%)	2 (1%)
	Explant other than recovery		
	Total Not Success	17 (10%)	35 (21%)

* P = 0.0064 using Fisher's exact test

Table A.32 HeartMate II Post-Approval Study: Patient Status

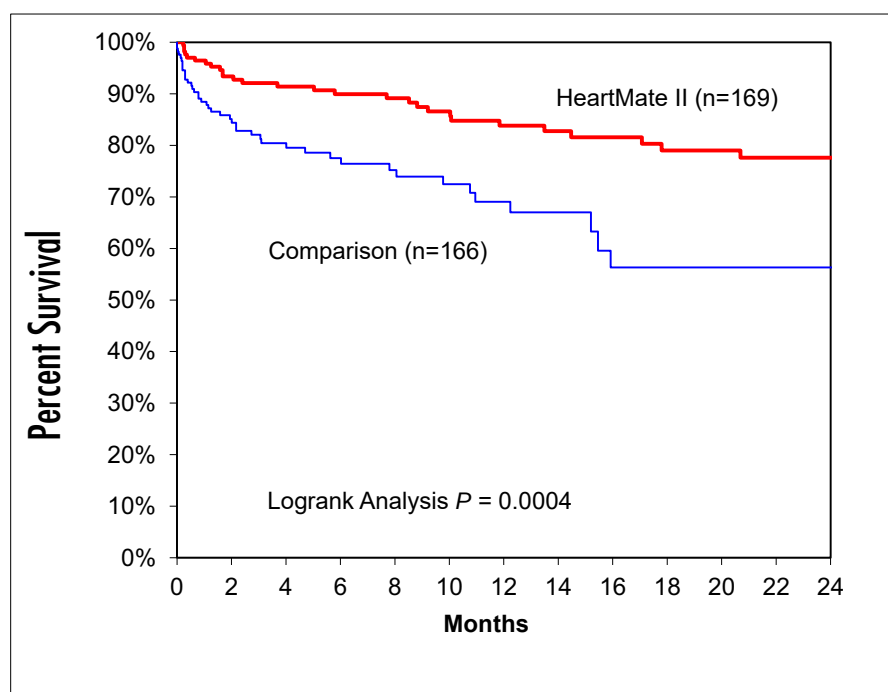


Figure A.17 HeartMate II Post-Approval Study: Kaplan-Meier Analysis of Survival

A Summary of Clinical Studies

HeartMate II							
	Time Interval (Months)						
	0-1	1-2	2-3	3-6	6-12	12-24	24+
Number of patients starting interval	169	161	146	139	117	86	50
Number of patients who died this interval	6	5	2	3	7	5	5
Number of cumulative patient deaths	6	11	13	16	23	28	33
Number of patients censored in interval	2	10	5	19	24	31	45
Number of cumulative censored patients	2	12	17	36	60	91	136
Probability of surviving interval event free	0.964	0.934	0.921	0.900	0.838	0.776	0.691
+/- 95% Confidence Limit at end of interval	0.03	0.04	0.04	0.05	0.06	0.08	0.10
Comparison							
	Time Interval (Months)						
	0-1	1-2	2-3	3-6	6-12	12-24	24+
Number of patients starting interval	166	140	116	102	72	35	3
Number of patients who died this interval	19	5	4	5	6	4	0
Number of cumulative patient deaths	19	24	28	33	39	43	43
Number of patients censored in interval	7	19	10	25	31	28	3
Number of cumulative censored patients	7	26	36	61	92	120	123
Probability of surviving interval event free	0.885	0.851	0.821	0.775	0.690	0.553	0.553
+/- 95% Confidence Limit at end of interval	0.05	0.06	0.06	0.07	0.09	0.14	0.14

Patients are censored at time of transplant, weaning off device, or last follow-up on LVAD support.

Table A.33 Kaplan-Meier Analysis of Survival

Final Safety Findings: All Cause Adverse Events

Adverse events, as defined by the INTERMACS protocol, were collected and are reported in **Table A.34**. The study was not powered for a specific analysis of the adverse events.

Event	HeartMate II (n=169)			Comparison Group (n=166)		
	No. pts	% pts	No. events	No. pts	% pts	No. events
Arterial Non-Central Nervous System Thromboembolism	1	0.6%	1	3	1.8%	3
Bleeding	83	49.1%	236	68	41.0%	183
Cardiac Arrhythmia	50	29.6%	74	51	30.7%	91
Hemolysis	6	3.6%	7	2	1.2%	2
Hepatic Dysfunction	12	7.1%	13	12	7.2%	15
Hypertension	3	1.8%	4	26	15.7%	35
Infection*	90	53.3%	196	73	44.0%	212
Driveline	39	23.1%	70	26	15.7%	40
Pump Pocket	8	4.7%	12	11	6.6%	15
Pump Interior	2	1.2%	3	0	0.0%	0
Blood	37	21.9%	58	37	22.3%	71
Line Sepsis	3	1.8%	3	10	6.0%	12
Other Infection	57	33.7%	88	51	30.7%	116
Myocardial Infarction	3	1.8%	3	1	0.6%	1
Stroke**	16	9.5%	21	11	6.6%	15
Other Neurological Dysfunction	9	5.3%	9	14	8.4%	17
Pericardial Drainage	17	10.1%	20	22	13.3%	24
Psychiatric Episode	15	8.9%	19	21	12.7%	29
Renal Dysfunction	18	10.7%	20	22	13.3%	29
Respiratory Failure	40	23.7%	48	46	27.7%	59
Right Heart Failure	26	15.4%	28	19	11.4%	21
Venous Thromboembolism	12	7.1%	14	15	9.0%	17
Wound Dehiscence	3	1.8%	3	3	1.8%	3

* Event may have multiple sites of infection

** May include transient ischemic attack, or confusion

Table A.34 HeartMate II Post-Approval Study: All Cause Adverse Events

A Summary of Clinical Studies

Secondary Objectives

Quality of life, as measured by EuroQol, was collected as a secondary objective. **Table A.35** displays the quality of life data. A higher score indicates an improved quality of life. In addition, 6-minute walk and NYHA classification were also collected.

	HeartMate II Cohort	Comparison Cohort
Interval: Preimplant		
Patients at start of Interval	169	166
Patients completing Test	71	58
Total Score (mean +/- SD)	9.3 +/- 2.5	9.6 +/- 2.3
Thermometer (mean +/- SD)	37.5 +/- 22.2	36.3 +/- 30.1
Interval: 3 months		
Patients at start of Interval	146	114
Patients completing Test	80	47
Total Score (mean +/- SD)	6.8 +/- 1.5	7.9 +/- 1.8
Thermometer (mean +/- SD)	75.0 +/- 18.5	62.1 +/- 25.5
Interval: 6 months		
Patients at start of Interval	127	85
Patients completing Test	66	37
Total Score (mean +/- SD)	7.2 +/- 1.8	6.9 +/- 1.6
Thermometer (mean +/- SD)	70.8 +/- 18.9	71.4 +/- 19.3
Interval: 12 months		
Patients at start of Interval	92	43
Patients completing Test	42	22
Total Score (mean +/- SD)	7.0 +/- 1.8	7.5 +/- 1.6
Thermometer (mean +/- SD)	75.0 +/- 16.1	65.5 +/- 21.7
Interval: 18 months		
Patients at start of Interval	66	15
Patients completing Test	26	2
Total Score (mean +/- SD)	6.8 +/- 1.5	7.5 +/- 0.7
Thermometer (mean +/- SD)	66.6 +/- 23.4	60.0
Interval: 2 years		
Patients at start of Interval	48	10
Patients completing Test	14	2
Total Score (mean +/- SD)	7.1 +/- 2.2	6.5 +/- 0.7
Thermometer (mean +/- SD)	76.6 +/- 16.2	55.0 +/- 21.2

SD = standard deviation

Total Score: Lower score indicates improved QoL

Thermometer: Higher score indicates improved QoL

Table A.35 HeartMate II Post-Approval Study: Quality of Life (EuroQol)

Functional Analysis

The functional status of patients within the HeartMate II and comparison cohort were assessed via Six-Minute Walk Test, and New York Heart Association (NYHA) classification.

Table A.36 and **Table A.37** include data collected for this analysis.

	HeartMate II Cohort	Comparison Cohort
Interval: Preimplant		
Patients at start of Interval	169	166
No. Patients who walk	11	3
Feet walked (mean +/- SD)	772.1 +/- 399.5	703.3 +/- 51.1
Not Done: Too sick	115	125
Not Done: Other reason	37	34
Not Done: Unknown reason	6	4
Interval: 3 months		
Patients at start of Interval	146	114
No. Patients who walk	38	24
Feet walked (mean +/- SD)	1130.3 +/- 409.5	1045.0 +/- 413.4
Not Done: Too sick	7	12
Not Done: Other reason	77	57
Not Done: Unknown reason	24	21
Interval: 6 months		
Patients at start of Interval	127	85
No. Patients who walk	31	18
Feet walked (mean +/- SD)	1117.0 +/- 343.6	1026.9 +/- 371.2
Not Done: Too sick	5	12
Not Done: Other reason	68	36
Not Done: Unknown reason	23	19
Interval: 12 months		
Patients at start of Interval	92	43
No. Patients who walk	24	9
Feet walked (mean +/- SD)	1129.3 +/- 404.7	1231.2 +/- 655.6
Not Done: Too sick	3	4
Not Done: Other reason	46	20
Not Done: Unknown reason	19	10
Interval: 18 months		
Patients at start of Interval	66	15
No. Patients who walk	15	2
Feet walked (mean +/- SD)	1036.6 +/- 396.5	1218.0 +/- 455.4

Table A.36 HeartMate II Post-Approval Study: Six-Minute Walk Test

A Summary of Clinical Studies

	HeartMate II Cohort	Comparison Cohort
Not Done: Too sick	7	2
Not Done: Other reason	19	6
Not Done: Unknown reason	25	5
Interval: 2 years		
Patients at start of Interval	48	10
No. Patients who walk	7	1
Feet walked (mean +/- SD)	1034.0 +/- 518.0	1724
Not Done: Too sick	2	1
Not Done: Other reason	17	1
Not Done: Unknown reason	22	7

SD = standard deviation

Table A.36 HeartMate II Post-Approval Study: Six-Minute Walk Test (Continued)

Summary of Clinical Studies **A**

NYHA Classification	HeartMate II Cohort	Comparison Cohort
Interval: Preimplant		
Patients at start of Interval	169	166
Class I	1 (1%)	0 (0%)
Class II	2 (1%)	0 (0%)
Class III	27 (16%)	9 (5%)
Class IV	128 (76%)	137 (83%)
Unknown	11 (7%)	20 (12%)
Interval: 3 months		
Patients at start of Interval	146	114
Class I	26 (18%)	10 (9%)
Class II	43 (29%)	45 (39%)
Class III	29 (20%)	21 (18%)
Class IV	11 (8%)	7 (6%)
Unknown	37 (25%)	31 (27%)
Interval: 6 months		
Patients at start of Interval	127	85
Class I	26 (20%)	14 (16%)
Class II	39 (31%)	28 (33%)
Class III	17 (13%)	5 (6%)
Class IV	5 (4%)	9 (11%)
Unknown	40 (32%)	29 (34%)
Interval: 12 months		
Patients at start of Interval	92	43
Class I	26 (28%)	8 (19%)
Class II	27 (29%)	16 (37%)
Class III	5 (5%)	3 (7%)
Class IV	4 (4%)	1 (2%)
Unknown	30 (33%)	15 (35%)
Interval: 18 months		
Patients at start of Interval	66	15
Class I	18 (27%)	3 (20%)
Class II	15 (23%)	5 (33%)
Class III	6 (9%)	0 (0%)
Class IV	2 (3%)	0 (0%)
Unknown	25 (38%)	7 (47%)
Interval: 2 years		
Patients at start of Interval	48	10
Class I	9 (19%)	2 (20%)

Table A.37 HeartMate II Post-Approval Study: NYHA Classification

A Summary of Clinical Studies

NYHA Classification	HeartMate II Cohort	Comparison Cohort
Class II	12 (25%)	0 (0%)
Class III	3 (6%)	0 (0%)
Class IV	2 (4%)	0 (0%)
Unknown	22 (46%)	8 (80%)

Table A.37 HeartMate II Post-Approval Study: NYHA Classification (Continued)

Study Strength and Weaknesses

The trial was conducted according to a prespecified protocol approved by the FDA. The study was hypothesis driven and powered to detect a difference between treatment groups. All study patients (100%) were followed for at least 180 days or to an outcome (transplant, death, or explant). Survival and quality of life trends were similar to those seen in the HeartMate II pivotal trial.

The study had a number of limitations. The study data was collected by a national registry called INTERMACS and was not monitored against medical records. Adverse events were not adjudicated by an independent clinical events committee. The control group was collected in two phases. As prespecified in the protocol, if there were too few control patients recruited upon the end of the PAS enrollment period, control patients could be entered into the PAS retrospectively. This was in anticipation of a reduction in use of the HeartMate XVE and IVAD control devices after FDA approval of the HeartMate II as a bridge to transplant. In all, 114 of the 166 control patients were retrospective and thus were not concurrent to the HeartMate II study patients. To reduce bias, the most current consecutive retrospective patients were enrolled.

Post-Approval Overview of Risk of Thrombosis

Pump thrombosis is a serious adverse event that may require intravenous medical therapy or a reoperation to replace the pump. As such, it was specifically tracked in both the Bridge to Transplant and Destination Therapy clinical trials. In addition, as part of post-market surveillance, Abbott collects and investigates all reports of pump thrombosis for reporting under the U.S. FDA Medical Device Reporting (MDR) regulations and similar reporting requirements in other regulatory jurisdictions. **Table A.38**, below, presents the incidence of pump thrombosis (suspected and/or confirmed) observed in the Bridge to Transplant (BTT) clinical trial, the Destination Therapy (DT) clinical trial, and the world-wide experience (BTT and DT) that was reported to Abbott as of January 11, 2013.

Clinical Experience	Dates	Implants	Reports of Thrombosis	Percent [95% Conf. Int.]
Bridge to Transplant US Clinical Trial	Mar 2005 – Sep 2007 ¹	126	2 (confirmed)	1.6% [0% - 4%]
Destination Therapy US Clinical Trial	Mar 2005 – May 2009 ²	133	5 (confirmed)	3.8% [1% - 7%]
World-wide postmarket experience ³	Sep 2005 – Jan 2013	11,647	750 (suspected or confirmed) 334 (confirmed)	6.4% 2.9%

¹ Including 1 year of follow-up after implant

² Including 2 years of follow-up after implant

³ Analysis of complaint and device tracking records

Table A.38 Incidence of Pump Thrombosis

Note that comparisons of rates between the clinical studies and the postmarket experience are confounded by more recently recognized definitions of suspected pump thrombosis and significant variance in reporting between centers. During the clinical trials device thrombosis was defined as,

“Any obstructive thrombus in the device or its conduits associated with clinical symptoms of impaired pump performance (e.g. decreased pump flow, need to increase pump speed, increased power, hemolysis) or the need for thrombolytic or surgical intervention.”

A Summary of Clinical Studies

Subsequent to regulatory approval and commercial distribution, users of the HeartMate II LVAS have reported suspected pump thrombosis when observing some of the following:

- Clinical hemolysis along with elevated lactate dehydrogenase (LDH) and/or plasma free hemoglobin (PFHgb) levels
- Low flow as evidenced by echo and other means
- Elevated LDH and/or PFHgb levels without clinical signs of hemolysis
- Sustained power elevations
- Congestive heart failure symptoms
- Inability of the HeartMate II LVAS to unload the left ventricle with the aortic valve opening at each heartbeat
- Cardiogenic shock

Additionally, there is overlap between the symptoms of device thrombosis, hemolysis due to other reasons, and other unrelated adverse events. Device thrombosis can only be confirmed through disassembly and examination of an explanted pump. The propensity for pump thrombosis is multi-factorial in nature, including pump-related factors, patient-related factors, and patient management-related factors. There has been variability among centers in the reported incidence of confirmed device thrombosis, ranging from 0% to 15% within 6 months of implantation for centers that have implanted at least 10 HeartMate II LVADs.

Starling et al. reported that in their three-center experience, the rate of HeartMate II LVAS pump thrombosis at 3 months increased from 2.2% before March 2011 to 8.4% after March 2011.¹ Other reports have not identified this type of increased pump thrombosis rate.^{2,3,4,5,6} Schmitto et al. reported that 2.2% of patients were confirmed to have pump thrombosis at 3 months in their single-center experience from 2004-2013.⁵ Hoefer et al. reported no premature losses of HeartMate II devices due to suspected or confirmed pump thrombosis at their center.⁴

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1. Starling RC, Moazami N, Silvestry SC, et al.: Unexpected abrupt increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:33-40.
 2. Frazier OH: Increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:1464-5.
 3. Goldstein D, John R, Salerno C: Increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:1465.
 4. Hoefer D, Velik-Salchner C, Antretter H: Increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:1464.
 5. Schmitto JD, Avsar M, Haverich A: Increase in left ventricular assist device thrombosis. *N Engl J Med* 2014;370:1463-4.
 6. Stulak JM, Maltais S: A different perspective on thrombosis and the HeartMate II. *N Engl J Med* 2014;370:1467-8.

A multi-center analysis of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry reported a decrease in the freedom from pump thrombosis at 6 months from 98% in 2010 to 94% in 2012.¹ However, the analysis also showed that there was no decrease in the overall survival with HeartMate II patients during the same time periods, and that the survival rate exceeded the rate observed in the premarket clinical trials. A 2014 review of pump thrombosis indicated that the incidence of pump thrombosis was increasing concurrently with changes in clinical practice, such as modified anticoagulation targets and reduction of pump speeds.²

Although pump thrombosis has been proposed to be multi-factorial in etiology, approximately 25% of the events are subsequently identified to have had a mechanical cause such as inflow cannula/outflow graft obstruction.³ A recent update has been published by INTERMACS on patients implanted through 2014, that has suggested that 6 month rates of pump thrombosis (as defined as suspected pump thrombosis resulting in pump exchange, urgent transplantation or death) had initially increased from 2.0% in 2010 to 8.0% in 2013, but had decreased in 2014 to 5.0%⁴.

The following key clinical practices have been identified that may help in the prevention of pump thrombosis:

- Optimization of pump and cannula position during implantation to prevent inflow obstruction
- Optimization of pump speeds to avoid low flows through the pump in order to facilitate pump washing
- Maintenance of strict anticoagulation with an INR target of over 2.0

Goldstein et al. have developed an algorithm for the diagnosis and management of patients presenting with suspected pump thrombosis.⁵

-
1. Kirklin JK, Naftel DC, Kormos RL, et al.: Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) analysis of pump thrombosis in the HeartMate II left ventricular assist device. *J Heart Lung Transplant* 2014;33:12-22.
 2. Mehra MR, Stewart GC, Uber PA: The vexing problem of thrombosis in long-term mechanical circulatory support. *J Heart Lung Transplant* 2014;33:1-11.
 3. Uriel N, Han J, Morrison KA, et al.: Device thrombosis in HeartMate II continuous-flow left ventricular assist devices: a multifactorial phenomenon. *J Heart Lung Transplant* 2014;33:51-9.
 4. Kirklin JK, Naftel DC, Pagani FD, et al.: Pump Thrombosis in the Thoratec HeartMate II device: An update analysis of the INTERMACS registry. *J Heart Lung Transplant* 2015; 34: 1515-1526
 5. Goldstein DJ, John R, Salerno C, et al.: Algorithm for the diagnosis and management of suspected pump thrombus. *J Heart Lung Transplant*. 2013 Jul;32(7):667-70.

A Summary of Clinical Studies

Results from the PREVENT Study

To address the current risk of pump thrombosis, and variability in surgical implantation, anticoagulation, and pump speed management, the PREVENTion of HeartMate II Pump Thrombosis through Clinical Management (PREVENT) study was initiated. PREVENT was a prospective, multi-center, non-randomized study, where the primary study objective was to assess the incidence of HeartMate II pump thrombosis at 3 and 6 months after LVAD implant when recommended practices for clinical management outlined are adopted. Additionally the study sought to utilize the current definitions of pump thrombosis, inclusive of hemolysis, abnormal pump parameters, and heart failure symptoms in order to provide an accurate assessment of pump thrombosis with the HeartMate II¹.

Summary of PREVENT Recommended Practices

The PREVENT practices outlined in this section are aimed at maximizing flow through the LVAD, reducing risk of cannula malposition, and ensuring that the patient is adequately anti-coagulated while on LVAD support. These recommendations are similar to what is published in the HM II instructions for use (IFU) with modifications derived from clinical practice². Additional recommendations have also been provided regarding the HM II implantation technique itself, as recent publications have highlighted that pump migration and cannula obstruction can increase the risk of device thrombosis^{3,4}.

Implantation Technique

- Create an adequately sized pump pocket, located inferiorly deep and lateral.
- Position the inflow cannula parallel to the septum, oriented to the central LV.
- Position outflow graft right of the sternal midline to avoid compression of the RV.
- Position the pump below the diaphragm.
- Fixate the pump (e.g. to the diaphragm or the chest wall) to prevent migration.

-
1. Maltais S, Kilic A, Nathan S, et al. PREVENTion of HeartMate II Pump Thrombosis Through Clinical Management: The PREVENT multi-center study. J Heart Lung Transplant. 2017 Jan;36(1):1-12.
 2. Klodell CT, Massey HT, Adamson RM et al.: Factors Related to Pump Thrombosis With the Heartmate II Left Ventricular Assist Device. J Card Surg. 2015 Oct;30(10):775-80.
 3. Taghavi S, Ward C, Jayarajan SN, et al.: Surgical technique influences HeartMate II left ventricular assist device thrombosis. Ann Thorac Surg 2013;96:1259-65.
 4. Uriel N, Han J, Morrison KA, et al.: Device thrombosis in HeartMate II continuous-flow left ventricular assist devices: a multifactorial phenomenon. J Heart Lung Transplant 2014;33:51-9.

Anticoagulation/Antiplatelet Management

- In patients without persistent bleeding, begin bridging with unfractionated heparin or low molecular weight heparin (LMWH) within 48 hours of device implant with a goal PTT of 40-45 sec in the first 48 hours, followed by titration up to PTT 50–60 by 96 hours. If heparin is contraindicated, consider other alternatives including argatroban, intravenous warfarin, and bivalirudin.
- Initiate warfarin within 48 hours to obtain a goal INR of 2.0-2.5 by POD 5-7, at which time heparin therapy may be discontinued.
- Once there is no evidence of bleeding, initiate ASA therapy (81 – 325 mg daily) 2 to 5 days post HMII implantation.
- Maintain the patient throughout LVAD support on aspirin and Coumadin with a goal INR of 2.0-2.5.

Pump Speed Management

- Run pump speeds above 9000 RPMs and avoid speeds below 8600 RPMs when possible.
- Adjust pump speed to allow for intermittent aortic valve opening only after the above goals are achieved.

Blood Pressure Management

- Maintain a mean arterial pressure (MAP) < 90 mm Hg.

PREVENT Study Design

The PREVENT study design and details are outlined in [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/NCT02158403) (<https://clinicaltrials.gov/ct2/show/NCT02158403>). Briefly, PREVENT was a prospective, non-randomized multi-center study, which 300 patients at 23 sites across the United States. The primary endpoint was confirmed pump thrombosis at 3 months, and each patient was followed for up to 6 months post implantation. The primary hypothesis of the study was that when the PREVENT recommendations are adopted, the rate of confirmed pump thrombosis will be < 4.0% at 3 months. The study enrolled patients from September 24th, 2014 through November 5th, 2015, and the 6 month follow-up on the last patient was completed on June 5th, 2016.

Definitions for suspected and confirmed thrombosis were based on the current INTERMACS definition and the events were adjudicated by an independent physician.

Pump thrombosis was defined as an event in which the pump or its conduits contain a thrombus that results in or could potentially induce circulatory failure.

A Summary of Clinical Studies

Suspected Pump Thrombus

An event in which clinical or mechanical circulatory support device (MCS) parameters suggest thrombus on the blood contacting components of the pump, cannulae, or grafts. Signs and symptoms should include at least 2 of the 3 following criteria:

- Presence of hemolysis
- Worsening heart failure (or lack of LV unloading when a ramp test is performed)
- Abnormal pump parameters

Suspected pump thrombus should be accompanied by 1 or more of the following events or interventions:

- Treatment with intravenous anticoagulation (e.g., heparin), intravenous thrombolytics (e.g., tPA), or intravenous antiplatelet therapy (e.g., eptifibatide, tirofiban)
- Pump replacement
- Pump explantation
- Urgent transplantation (UNOS status 1A)
- Stroke
- Death

Confirmed Pump Thrombus

A suspected pump thrombosis event in which a thrombus is confirmed within the blood contacting surfaces of device inflow cannula or outflow conduit or grafts. This can be reported via direct visual inspection (documented by a photograph if available) upon pump explantation or by sending the pump back to Abbott for evaluation. Any pump explanted for suspected device thrombosis should be sent back to Abbott for analysis.

Results of the PREVENT Study

The incidence of suspected and confirmed pump thrombosis at 3 months (**Table A.39**) and at 6 months (**Table A.40**) as reported in the study are shown below:

Event	Number of Patients (%) (N=300)
Suspected Pump Thrombosis	11 (3.6%)
Confirmed Pump Thrombosis	9 (3.0%)
Pump Replacements for Suspected Pump Thrombosis	7 (2.7%)
Pump Replacements, urgent transplantation or deaths due to suspected thrombosis	10 (3.3%)

Table A.39 Incidence of Pump Thrombosis at 3 months

Event	Number of Patients (%) (N=300)
Suspected Pump Thrombosis	18 (6.0%)
Confirmed Pump Thrombosis	15 (5.0%)
Pump Replacements for Suspected Pump Thrombosis	13 (4.3%)
Pump Replacements, urgent transplantation or deaths due to suspected thrombosis	16 (5.3%)

Table A.40 Incidence of Pump Thrombosis at 6 months

A Summary of Clinical Studies

Additionally a descriptive analysis was performed to determine the incidence of pump thrombosis when 100% adherence was achieved to the surgical recommendations, heparin bridging, and keeping pump speeds higher than 9000 RPMs. Analysis of that descriptive analysis are shown in the table (**Table A.41**) below:

Event	Good Adherence (N=157)	Partial Adherence (N=124)
Suspected Pump Thrombosis	5 (3.2%)	12 (9.7%)
Confirmed Pump Thrombosis	3 (1.9%)	11 (8.9%)
Pump Replacements for Suspected pump thrombosis	3 (1.9%)	9 (7.3%)
Pump Replacements, urgent transplantation, or deaths due to suspected thrombosis	4 (2.5%)	11 (8.9%)

Table A.41 Incidence of Pump Thrombosis at 6 months when 100% adherence to the surgical recommendations, heparin bridging, and pump speed management was achieved (good adherence) compared to partial adherence*

*Only patients alive and ongoing as of 30 days were included in the analysis

In addition to pump thrombosis, adverse events pertaining to bleeding, and stroke were also collected (**Table A.42**). Standard INTERMACS definitions were utilized.

Event	Number of Patients (%) (N=300)
Overall Bleeding	134 (45%)
Bleeding requiring surgery	49 (16%)
<i>Early Bleeding (<30 days)</i>	101 (34%)
GI Bleeding	64 (21%)
Hemorrhagic Stroke	8 (2.7%)
Ischemic Stroke	12 (4.0%)

Table A.42 Incidence of Bleeding, hemorrhagic stroke, and pump thrombosis:

Summary of PREVENT Findings

The PREVENT study addressed specifically the early incidence of pump thrombosis in patients implanted with the HMII LVAD. The primary endpoint was met and demonstrated that a strict adherence to a set of predetermined surgical and medical recommendations can lead to a low incidence of confirmed PT with the HeartMate II three months post-implantation. It emphasized the need to conform to good surgical strategies, postoperative heparin bridging and early optimal speed management (≥ 9000 RPM). While further studies are still needed to pinpoint specific risk factors, the current study has increased our understanding of best practices using the HMII device. The results support the adoption of the PREVENT recommendations in order to reduce pump thrombosis risk and center-to-center variability.

A Summary of Clinical Studies

TECHNICAL SPECIFICATIONS

This section provides the technical specifications for the HeartMate II Left Ventricular Assist System.

Specifications

The technical specifications for the HeartMate II Left Ventricular Assist System are listed here. For ordering information and catalog numbers, see *HeartMate II Product List* on page C-1.

HeartMate II Left Ventricular Assist System Implant Kit (Sealed)

BLOOD VOLUMES-FLUID CAPACITY

Dimensions (pump body)

Diameter	4.3 cm (1.7 in)
Length	8.1 cm (3.2 in)—excluding conduits
Weight (pump body)	281 g (9.9 oz)
Gross Volume	63 cc (3.8 cu in)
Priming Volume	7 cc (0.43 cu in)

BLOOD CONTACTING SURFACES

Titanium	Polished titanium
Sealed Outflow Graft	Gelatin-impregnated woven polyester
Sealed Inflow Conduit	Gelatin-impregnated knitted polyester with polypropylene reinforcement

CONSTRUCTION

Outer Shell	Titanium
Apical Cannula	19 mm titanium
Sewing Ring	PTFE-covered reinforced silicone
Sealed Outflow Graft	Gelatin-impregnated 14 mm woven polyester
Sealed Inflow Graft	Gelatin-impregnated 14 mm knitted polyester with polypropylene reinforcement
Sealed Outflow Bend Relief Collar	Titanium (not included in implant kit)
Electric Line	6-conductor shielded silicone sheath

PERFORMANCE DATA

Power Consumption	14 watts nominal
Operating Voltage	10–14 Volts DC
Nominal Pump Speed	6,000–15,000 rpm
Minimum Pump Speed	6,000 rpm

B Technical Specifications

Sterile HeartMate II System Controller

ACTIVE FUNCTIONS

Implements Selected Mode

Reverts to Power Saver Mode during low battery operation

OPERATING MODES

Fixed Speed Mode	Speed Range from 6,000–15,000 rpm
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Power Saver Mode	Selected low speed setting
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MONITORING FUNCTIONS

Fault detection and alarms

Performance data processing and storage

Battery state-of-charge indicators and alarms

Bidirectional data link

Driveline continuity check

Backup battery state of charge

ALARM SOUND PRESSURE LEVEL (SPL)

Hazard Alarms: 85 dB 2300 Hz $\pm$ 300 Hz

Advisory Alarms: 85 dB 2300 Hz $\pm$ 300 Hz

DIMENSIONS

Length	12.7 cm (5 in)
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Width	3.5 cm (1.375 in)
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Height	8.0 cm (3.125 in)
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WEIGHT	336 g (12 oz)
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PRODUCT LIFE	Three years from date of first use
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PERFORMANCE DETERMINED TO BE ESSENTIAL PERFORMANCE

1. Maintain Pump Speed (Note: Pump Speed is the characteristic that the physician uses to set the desired blood flow.)
 2. Alarm for Pump Speed performance outside of the essential performance limits.
 3. Prevent Leakage in Blood Path.
-

11 Volt Lithium-Ion Backup Battery

PERFORMANCE DATA

Type	11 Volt Lithium-Ion
Capacity	12.2 watt-hour
Discharge Time	15 minutes at 10 watts (pump speed = 12,000 rpm, flow = 6.0 lpm)
Charge Time	3 hours maximum, with a minimum voltage of 13.0V

DIMENSIONS

Length	6.9 cm (2.7 in)
Width	5.1 cm (2 in)
Height	2.3 cm (0.9 in)

WEIGHT	84.6 g (2.98 oz)
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PRODUCT LIFE	10950 cumulative discharge minutes, as tracked by the System Controller and reported on the HeartMate Touch App, or 3 years from the date of manufacture, whichever comes first.
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B Technical Specifications

Power Module

ACTIVE FUNCTIONS

Isolated power to patient during tethered operation

Communication interface between System Controller and HeartMate Touch™ Communication System

When new, AC power failure backup battery (30 minutes to operate HeartMate II Left Ventricular Assist System)

MONITORING FUNCTIONS

Isolated bidirectional data link to external HeartMate Touch™ Communication System

Isolated dual-channel analog uplink AC power failure alarm

Advisory/Hazard LO BATT alarm for internal backup battery

"Echoes" System Controller Audio Alarm

System Malfunction Alarm (Yellow Wrench)

ALARM SOUND PRESSURE LEVEL (SPL)

Hazard Alarms: 80 dB

Advisory Alarms: 80 dB

POWER REQUIREMENTS

100–240 VAC, 50–60 Hz, 1 A maximum

13.5 VDC, 5 A maximum

To isolate the system from the AC wall power, pull the power cord from the wall socket.

FUSE RATING T 2A, 250 V

DIMENSIONS

Length 381 mm (15 in)

Width 254 mm (10 in)

Height 127 mm (5 in)

WEIGHT 4.8 kg (10.5 lb)—with backup battery

PRODUCT LIFE Two years from date of first use

Power Module Patient Cable

TYPE	A cable assembly that has one straight plug connector with sliding interlock and composite strain relief for connecting to the Power Module, and two thread-locking power connectors for connecting to the System Controller
FUNCTION	To provide connection between the System Controller and the Power Module
LENGTH	6.1 m (20 ft)
PRODUCT LIFE	One year from date of first use

B Technical Specifications

Mobile Power Unit

ACTIVE FUNCTIONS

Isolated power to patient during tethered operation

MONITORING FUNCTIONS

Fault detection and alarms

"Echoes" System Controller Audio Alarm

ALARM SOUND PRESSURE LEVEL (SPL)

Hazard Alarms: 80 dB

Advisory Alarms: 80 dB

POWER REQUIREMENTS

100–240 VAC, 50/60 Hz, 2.0–1.0 A maximum

To isolate the system from the AC wall power, remove the power cord from the wall socket.

DIMENSIONS

Length	18.4 cm (7.25 in)
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Width	12.7 cm (5.0 in)
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Height	12.7 cm (5.0 in)
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CABLE LENGTH	6.1 m (20 ft)
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WEIGHT	1.4 kg (3.0 lb) - with three AA (LR6) batteries
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PRODUCT LIFE	Two years from date of first use
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HeartMate 14 Volt Lithium-Ion Battery

PERFORMANCE DATA

Type	14 Volt, Lithium-Ion
Capacity	4.8 amp-hour each or 71 watt-hour
Discharge Time	One pair of new HeartMate 14 Volt Lithium-Ion batteries provides ten to twelve hours of support under nominal operating conditions for a HeartMate II Left Ventricular Assist System (pump speed = 12,000 rpm, flow 6.0 lpm, 10 watts)
Power Gauge	5-LED, button activated
Charge Time	4 hours maximum (using Battery Charger)

DIMENSIONS

Length	160 mm (6.3 in)
Width	76 mm (3.0 in)
Height	25 mm (1.0 in)

WEIGHT	0.50 kg (1.1 lb)—System accommodates two batteries
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PRODUCT LIFE	360 cycles (as reported when the battery is inserted into a charging pocket of the Battery Charger), or 3 years from the date of manufacture, whichever comes first
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14 Volt Lithium-Ion Battery Clip

DIMENSIONS

Length	80 mm (3.15 in)
Width	92 mm (3.75 in)
Height	32 mm (1.25 in)

WEIGHT	104 g (3.7 oz)—without battery
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PRODUCT LIFE	Two years from date of first use
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B Technical Specifications

Battery Charger

ACTIVE FUNCTIONS

Four pockets for simultaneous battery charging for HeartMate 14 Volt Lithium-Ion batteries

Battery calibration and diagnostics

MONITORING FUNCTIONS

Battery fault monitoring (with alarm codes)

Battery charger fault monitoring (with alarm codes)

POWER REQUIREMENTS

100–240 VAC, 50–60 Hz, 3 A (maximum)

Fuse Rating - T5A, 250 V

DIMENSIONS

Length	370 mm (14.5 in)
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Width	216 mm (8.5 in)
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Height	227 mm (9 in)
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WEIGHT	3.6 kg (8 lb)
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PRODUCT LIFE	Two years from date of first use
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HeartMate Touch Wireless Adapter

ACTIVE FUNCTIONS

Facilitates Bluetooth® pairing of the Tablet for use with the HeartMate Touch App to the Power Module.

DIMENSIONS

Length	7.6 cm (3 in)
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Width	5.1 cm (2 in)
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Height	5.1 cm (2 in)
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WEIGHT	45.4 g (1.6 oz)
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PRODUCT LIFE

HeartMate Touch Wireless Adapter	At least 3 years.
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RADIO DECLARATIONS - Wireless Adapter:

Contains FCC ID: TFB-1005

Modifications made to the product, unless expressly approved by Abbott, could void the user's authority to operate the equipment.

CAUTION: To comply with FCC and Industry Canada RF radiation exposure limits for general population, the Touch Wireless Adapter must be installed such that a minimum separation distance of 20 cm (8 in.) is maintained between it and all persons at all times and must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED/IC: Contains IC: 5969A-1005

The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Warning

This is a Class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

B Technical Specifications

Tablet for use with the HeartMate Touch App

TYPE	iPad [®] with HeartMate Touch App
RESOLUTION	2224-by-1668 resolution at 264 pixels per inch (ppi)
FUNCTION	
Monitor View	Displays speed, flow (lpm), power, pulsatility index (PI). Displays prioritized alerts and advisories.
Clinical View	Displays speed, flow (lpm), power, pulsatility index (PI). Displays the primary operating parameters and provides the critical information needed during the surgical procedure.
Historical View	Displays speed, flow (lpm), power, pulsatility index (PI). Displays the history of the patient's LVAS.
DIMENSIONS	
Height	270 mm (10.63 in)
Width	209.6 mm (8.25 in)
Depth	17.5 mm (0.69 in)
WEIGHT	0.84 kg (1.86 lbs)
PRODUCT LIFE	
Tablet for use with the HeartMate Touch App	At least 3 years.
Accessories (Power Adapter and USB cable, Flash Drive)	At least 1 year.

USB Power Cable

Use only the Abbott-supplied 2-meter (80 in.) USB to Lightning cable to power or charge the tablet.

HeartMate Consolidated Bag

TYPE	Slim profile shoulder bag for use with HeartMate II Left Ventricular Assist System
FUNCTION	Allows patient to wear and carry HeartMate II batteries, battery clips, and System Controller
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
CONFIGURATION	Right-side driveline exit/right-side wear Left-side driveline exit/left-side wear
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

HeartMate Shower Bag

TYPE	Water-resistant Shower Bag for use with HeartMate II Left Ventricular Assist System
FUNCTION	Protects external system components from moisture during showering
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

B Technical Specifications

HeartMate Battery Holster

TYPE	Battery holder
FUNCTION	Allows patient to wear two HeartMate 14 Volt Lithium-Ion batteries close to the body while performing daily activities
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	Two years of continuous use

HeartMate Holster Vest

TYPE	Vest
FUNCTION	Allows patient to wear two HeartMate 14 Volt Lithium-Ion batteries close to the body while performing daily activities
PRODUCT COMPATIBILITY	For use with: System Controller Batteries Battery Clips
STRENGTH	Accommodates the weight of the batteries, battery clips, and System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZES	For small users less than 160 lb (73 kg) For medium users 160–240 lb (73–109 kg) For large users greater than 240 lb (109 kg)
PRODUCT LIFE	Two years of continuous use

HeartMate Wearable Accessories Kit

TYPE	System Controller Neck Strap, Belt Attachment, and Protection Bag
FUNCTION	• System Controller Neck Strap and Belt Attachment provide options for the patient to wear HeartMate II System Controller • Protection Bag protects the backup System Controller and cables when not in use
PRODUCT COMPATIBILITY	For use with HeartMate II System Controller
STRENGTH	Each accessory accommodates the weight of the System Controller with a significant safety factor to allow for forces imparted by daily activities
COLOR	Black
SIZE	One size fits most
PRODUCT LIFE	At least two years of continuous use

HeartMate Stabilization Belt

TYPE	Belt
FUNCTION	Stabilize external driveline
PRODUCT COMPATIBILITY	For use with HeartMate II Left Ventricular Assist Device
STRENGTH	The Stabilization Belt is for use with patients of BSA 1.5 m ² —2.5 m ² . The Stabilization Belt accommodates up to 1.5 pounds (0.680 kilos) of weight, with a significant safety factor to allow for forces imparted by daily activities.
COLOR	White
SIZES	Small/Medium Large/Extra Large
PRODUCT LIFE	6 months of continuous use

HeartMate Travel Bag

TYPE	Shoulder Bag
FUNCTION	Provides a convenient way to carry and transport the backup System Controller and spare batteries
PRODUCT COMPATIBILITY	For use with HeartMate II Left Ventricular Assist System
STRENGTH	The Travel Bag accommodates the weight of the batteries and System Controller with a significant safety factor to allow for forces imparted by daily activities.
COLOR	Black
SIZES	One size fits most
PRODUCT LIFE	At least two years of continuous use

B Technical Specifications

HEARTMATE II PRODUCT LIST

This section lists the HeartMate II products.

C HeartMate II Product List

HeartMate II Left Ventricular Assist System Products

All Abbott products are supported with a comprehensive one-year warranty, including parts and labor. For a complete list of all Abbott products, including country specific catalog numbers, contact Abbott (see the *Back Cover* of this manual for contact information) for Customer Service assistance or reference a current-year Abbott product catalog.

CAUTION !

For the safe repair and replacement of components, contact Abbott (see the *Back Cover* of this manual for contact information) for Customer Service assistance. Failure to heed this caution may cause the pump to stop.

Surgical Procedure

ITEM	CATALOG NUMBER
HeartMate II Left Ventricular Assist System Implant Kit with Sealed Grafts	106015
Supplied Sterile:	
• 1 HeartMate II Left Ventricular Assist Device (blood pump) • 1 Sealed Inflow Conduit • 1 Sealed Outflow Graft with Bend Relief 4 in (10.2 cm) • 1 HeartMate II System Controller • 1 Apical Coring Knife • 1 Apical Sewing Ring • 1 Skin Coring Punch • 1 Set of Thread Protectors	
Also Included:	
• 1 <i>HeartMate II Left Ventricular Assist System Instructions for Use</i> • 1 <i>HeartMate II Left Ventricular Assist System Patient Handbook</i> • 1 Wearable Accessories Kit (includes 1 System Controller Neck Strap, 1 Belt Attachment, and 1 Protection Bag) • 1 System Controller 11 Volt Lithium-Ion Backup Battery	

C HeartMate II Product List

ITEM	CATALOG NUMBER
HeartMate II Sealed Standalone Inflow Conduit Supplied sterile.	104142
HeartMate II Sealed Standalone Outflow Graft with Bend Relief Supplied sterile, 4 in (10.2 cm)	103393
HeartMate II Sealed Standalone Short Bend Relief Supplied sterile, 3 in (7.6 cm)	104692
HeartMate II Sealed Outflow Bend Relief Collar Supplied sterile.	107315
Skin Coring Punch Supplied sterile.	105557
Set of Thread Protectors Supplied sterile, 5 per set.	105558
HeartMate II Driveline Tunneler Supplied non-sterile.	102137
HeartMate II Sizer Supplied non-sterile.	102772
HeartMate II Spanner Wrench Supplied non-sterile.	102138
HeartMate II Functional Demo Pump Not for clinical use, subject to availability.	107794
Apical Coring Knife Supplied sterile.	1050
Sewing Ring with Centering Fixture Kit 3 per kit.	1065
HeartMate Explant Kit Supplied non-sterile. No charge with Returned Materials Authorization for explanted pump.	28717
HeartMate II Patient Support Kit* - "Pocket Controller" with Equipment • 1 Power Module • 1 Battery Charger • 1 HeartMate II System Controller ("Pocket Controller") • 1 11 Volt Lithium-Ion System Controller ("Pocket Controller") Backup Battery • 2 HeartMate 14 Volt Lithium-Ion Battery Sets (4 per set)	106101
• 2 14 Volt Battery Clip Sets (2 per set) • 1 Automobile DC Power Cable • 1 Power Module Patient Cable (14 Volt) • 1 Travel Bag • 1 Box of Shower Bags (set of 2) • 1 Patient Handbook	

HeartMate II Product List C

ITEM	CATALOG NUMBER
HeartMate II Patient Support Kit* - "Pocket Controller" with Equipment	
• 1 HeartMate II System Controller ("Pocket Controller") • 1 11 Volt Lithium-Ion System Controller ("Pocket Controller") Backup Battery • 2 HeartMate 14 Volt Lithium-Ion Battery Sets (4 per set) • 2 14 Volt Battery Clip Sets (2 per set)	106102
• 1 Automobile DC Power Cable • 1 Power Module Patient Cable (14 Volt) • 1 Travel Bag • 1 Box of Shower Bags (set of 2) • 1 Patient Handbook	
HeartMate II Functional Demo Kit Upgrade, System Controller Standalone	107859
Not for clinical use, subject to availability.	

C HeartMate II Product List

System Operations

ITEM	CATALOG NUMBER
Sterile HeartMate II System Controller A small computer that controls and monitors system operation. Uses lights, sounds, and on-screen messages to communicate with users about operating status and alarm conditions.	106762
11 Volt Lithium-Ion System Controller Backup Battery When fully-charged and properly installed in System Controller, provides at least 15 minutes of emergency power to the pump if the in-use power disconnects or fails.	106128

Powering the System

ITEM	CATALOG NUMBER
Power Module - Provides power to the HeartMate II system when connected via a power cord to a functioning AC electrical outlet, for use in the clinical environment. - Connects to the HeartMate Touch Communication System (Catalog Number HMT1100) for purposes of transferring data from the System Controller for display on the Tablet for use with the HeartMate Touch App. - Connects to System Controller through the Power Module patient cable (Catalog Number 103426).	1340
Mobile Power Unit Provides power to the HeartMate II system when connected via a power cord to a functioning AC electrical outlet, for home use.	107754
Battery Charger Used to charge, calibrate, and test the HeartMate 14 Volt Lithium-Ion batteries used to power the HeartMate II system during battery-powered operation.	1440
HeartMate 14 Volt Lithium-Ion Battery Set Set of 4 rechargeable 14 Volt Lithium-Ion batteries used for mobile operation. Batteries are recharged using the Battery Charger (Catalog Number 1440).	2465
14 Volt Battery Clip Set Set of 2 battery clips that are compatible with 14 Volt Lithium-Ion batteries (Catalog Number 2465) and used for mobile operation.	2865
Power Module Backup Battery A backup power source inside the Power Module that gives up to 30 minutes of support if power to the Power Module fails or is disconnected.	102808
Power Module Patient Cable Connects System Controller to Power Module.	103426

HeartMate II Product List C

ITEM	CATALOG NUMBER
Power Module/Battery Charger AC Power Cord AC power cord that is compatible with both devices for use in North America.	103860
Mobile Power Unit AC Power Cord AC power cord that is compatible with the Mobile Power Unit for use in North America.	107760

HeartMate Touch Communication System

ITEM	CATALOG NUMBER
HeartMate Touch™ Communication System The HeartMate Touch Communication System includes the following components: Tablet for use with the HeartMate Touch App, HeartMate Touch Wireless Adapter, Power Adapter, USB Cable, and the Flash Drive.	HMT1100
Flash Drive USB 3.0 Flash Drive for the tablet. Used for collecting HeartMate Touch Communication System Log Report file information found on the System Controller. Used for troubleshooting.	HMT2900
HeartMate Touch Wireless Adapter - Bluetooth Low Energy The HeartMate Touch Wireless Adapter is required for using the Tablet for use with the HeartMate Touch App with the Power Module and System Controller.	HMT2100
USB Cable for HeartMate Touch Communication System The USB Cable is plugged into the Tablet and Power Adapter and supplies AC power from an AC electrical power outlet to the tablet.	HMT2166
Power Adapter for HeartMate Touch Communication System The Power Adapter is plugged into an AC electrical power outlet and the USB Cable for the HeartMate Touch Communication System plugs into the Power Adapter.	HMT2133

C HeartMate II Product List

Wear and Carry Accessories

ITEM	CATALOG NUMBER
Wearable Accessories Kit Includes: • 1 System Controller Neck Strap • 1 Belt Attachment • 1 Protection Bag	106129
Consolidated Bag, Left Configured for wear on the left side of the body (black only).	106449
Consolidated Bag, Right Configured for wear on the right side of the body (black only).	104233
Holster Vest, Small For wearing 14 Volt Lithium-Ion batteries.	104229
Holster Vest, Medium For wearing 14 Volt Lithium-Ion batteries	104230
Holster Vest, Large For wearing 14 Volt Lithium-Ion batteries.	104231
Battery Holster Set of 2.	104234
Shower Bag Set of 2.	104232
Travel Bag	1260
HeartMate Stabilization Belt, Medium/Large Two stabilization belts with six lead locks. Supplied non-sterile.	100760
HeartMate Stabilization Belt, Small Two stabilization belts with six lead locks. Supplied non-sterile.	100759

SAFETY TESTING AND CLASSIFICATION

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

Safety Testing and Classification - - - - -	-D-3
Testing and Classification: Power Module - - - - -	-D-6
Testing and Classification: Mobile Power Unit - - - - -	-D-12
Testing and Classification: Battery Charger- - - - -	-D-17
Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries -	-D-24

Safety Testing and Classification

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

- IEC 60601-1:2012 (ed. 3.1)
- IEC 60601-1:2005 + 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. 601.151-94, and CAN/CSA-C22.2
No. 601.1B-98 (National Difference for Canada)
No. 601.1 7D72

D Safety Testing and Classification

Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and internally powered with Power Module (Clinical Use) Class II with Mobile Power Unit (Home Use)
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 • Power Module–IPX0:Non-protected against ingress of water • Tablet for use with the HeartMate Touch App–IPX0:Non-protected against ingress of water • HeartMate Touch Wireless Adapter–IPX0:Non-protected against ingress of water • Shower Bag–IPX3:Protection against ingress of spraying water • 14 V Battery & Battery Clip–IP24:Protection against ingress of solid foreign objects the size of a finger and from splashing water. Only when connected to System Controller. • Battery Charger–IPX0:Non-protected against ingress of water
Applied parts	• HeartMate II Left Ventricular Assist Device • System Controller

Table D.1 Declaration Concerning General Safety Standards

The HeartMate II Left Ventricular Assist System has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2014, Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests, with the exception of the Battery Charger, which was tested according to the recommendations of IEC TR 60601-4-2: Medical Electrical Equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate II Left Ventricular Assist System can generate, use, and radiate radio frequency energy and, if not installed and

used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Note: Special precautions are required for installing and using the HeartMate II Left Ventricular Assist System within portable and RF communication environments. The HeartMate II LVAS and its accessories need special precautions regarding EMC and needs to be put into service according to the EMC information provided in this Instructions for Use.

CAUTION !

Be sure to keep all persons at least 20 cm (8 in.) from the HeartMate Touch Wireless Adapter when on the Power Module.

The HeartMate II 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 II Left Ventricular Assist System be disconnected from the System Controller during the use of open-heart defibrillation.

D Safety Testing and Classification

Testing and Classification: Power Module

Declaration and Guidance for Electromagnetic Disturbances for HeartMate Power Module

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

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

HEARTMATE II LVAS Powered By the Power Module (with HeartMate Touch™ Communication System)		
EM Disturbance type / Standards	IEC 60601-1-2 (2014) Compliance Level	Use Environment Guidance
RF Emissions / CISPR 11 EN 55011	Group 1, Class A 30 – 1,000 MHz	The HeartMate II LVAS with Power Module is not suitable for use in domestic establishments or those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings.
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 fully	The HeartMate II LVAS with Power Module (PM) and HeartMate Touch™ Communication System uses RF energy only for its internal purposes and thus have low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±8 kV Contact ±15 kV Air	The relative humidity where the HeartMate II LVAS with PM is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.

Table D.2 Declaration and Guidance Concerning Electromagnetic Disturbances for Power Module

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz – 6.0 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 6.0 GHz range, the following minimum separation distances to the HeartMate II LVAS with PM are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 6.0 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 6.0 GHz range, the following minimum separation distances to the HeartMate II LVAS with PM are recommended: 80 - 800 MHz: 3.8 m (12.5 feet) 800 MHz – 6.0 GHz: 7.3 m (24.0 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment^[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
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Table D.2 Declaration and Guidance Concerning Electromagnetic Disturbances for Power Module (Continued)

D Safety Testing and Classification

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m^[1]; 430 - 470 MHz, 42 V/m^[3]; 704 - 787 MHz, 13 V/m^[2]; 800 - 960 MHz, 42 V/m^[1]; 1.7 - 1.99 GHz, 42 V/m^[2]; 2.4 - 2.57 GHz, 42 V/m^[2]; and 5.1 - 5.8 GHz, 13 V/m^[2] [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate II LVAS with Power Module, and its parts, than 0.2 m (8 inches). Equipment^[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth®, WLAN, Wi-Fi®, and RFID systems. Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate II LVAS with Power Module.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Power Module is used.
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line and ± 0.5, ± 1 kV, and ± 2 kV line to earth	

Table D.2 Declaration and Guidance Concerning Electromagnetic Disturbances for Power Module (Continued)

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate II LVAS with PM is recommended: Outside ISM bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment^[a] examples: CB Radios, Amateur "HAM" radios, and Diathermy medical devices. Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union. [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate II LVAS with PM is used.

Table D.2 Declaration and Guidance Concerning Electromagnetic Disturbances for Power Module (Continued)

D Safety Testing and Classification

Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T ; ½ cycle	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with PM is used. Note - U_T : A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)
	0 % of U_T ; 1 cycle	
	and	
	70 % of U_T ; 25 or 30 cycles (0.5 sec.)	
	0 % of U_T ; 250 or 300 cycles (5 sec.)	

Table D.2 Declaration and Guidance Concerning Electromagnetic Disturbances for Power Module (Continued)

WARNING !

- The HeartMate II Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate II Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate II LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.
- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate II LVAS (powered by the Power Module), including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

These guidelines may not apply in all situations.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

D Safety Testing and Classification

Testing and Classification: Mobile Power Unit

Declaration and Guidance for Electromagnetic Disturbances for the Mobile Power Unit

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

- Hospitals, including operating rooms and emergency rooms
- Treatment areas near active HF Surgical equipment
- Homes, workplaces and retail places
- Public or private passenger watercraft/boats, ferries, etc.

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

Table D.3 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with Mobile Power Unit are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 2.7 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with Mobile Power Unit are recommended: 80 - 800 MHz: 3.8 m (12.5 feet) 800 MHz – 2.7 GHz: 7.3 m (24.0 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment^[a] examples: Garage door remote controls, emergency services radios, "walkie-talkie" radios, Amateur "HAM" radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol: Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
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Table D.3 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)

D Safety Testing and Classification

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m^[1]; 430 - 470 MHz, 42 V/m^[3]; 704 - 787 MHz, 13 V/m^[2]; 800 - 960 MHz, 42 V/m^[1]; 1.7 - 1.99 GHz, 42 V/m^[2]; 2.4 - 2.57 GHz, 42 V/m^[2]; and 5.1 - 5.8 GHz, 13 V/m^[2] [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate II LVAS with Mobile Power Unit, and its parts, than 0.2 m (8 inches). Equipment^[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate II LVAS with Mobile Power Unit. [a] – List is not comprehensive.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used.
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line	

Table D.3 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)

Safety Testing and Classification **D**

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate II LVAS with Mobile Power Unit is recommended: Outside ISM/Amateur bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment ^[a] examples include: CB Radios, Amateur “HAM” radios, Diathermy medical devices, Note: 1,000 kHz = 1.0 MHz Note: “ISM” = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T ; ½ cycle 0 % of U_T ; 1 cycle and 70 % of U_T ; 25 or 30 cycles (0.5 sec.) 0 % of U_T ; 250 or 300 cycles (5 sec.)	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate II LVAS with Mobile Power Unit is used. Note – U_T : A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)

Table D.3 Declaration and Guidance Concerning Electromagnetic Disturbances for Mobile Power Unit (Continued)

D Safety Testing and Classification

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate II LVAS (powered by the Mobile Power Unit), including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate II LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.
- Avoid use of the HeartMate II LVAS (and its cables and parts) within 5 cm (2 inches) of a microwave oven or its cord. Keep all HeartMate II LVAS components and their cables away from other electronic devices and their cables/cords.
- The HeartMate II Left Ventricular Assist System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HeartMate II Left Ventricular Assist System should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

These guidelines may not apply in all situations.

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

This equipment was tested according to the recommendations of IEC TR 60601-4-2:

Medical Electrical Equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

D Safety Testing and Classification

Declaration Concerning General Safety Standards for Battery Charger

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

Table D.4 Declaration Concerning General Safety Standards for Battery Charger



Declaration and Guidance for Electromagnetic Disturbances for Battery Charger

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

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

HEARTMATE BATTERY CHARGER		
EM Disturbance type / Standards	IEC TR 60601-4-2 Compliance Level	Use Environment Guidance
RF Emissions / CISPR 11 EN 55011	Group 1, Class B 30 – 1,000 MHz	The HeartMate Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate Battery Charger uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
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 fully	
Radiated Emissions, Magnetic Field MIL-STD-461F	RE101	The HeartMate 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.
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±6 kV Contact ±8 kV Air	The relative humidity should be at least 20%. Higher relative humidity will reduce the severity of ESD events.

Table D.5 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger

D Safety Testing and Classification

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended: 80 - 800 MHz: 1.7 m (5.7 feet) 800 MHz – 2.7 GHz: 3.3 m (10.8 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate Battery Charger are recommended: 80 - 800 MHz: 3.8 m (12.5 feet) 800 MHz – 2.7 GHz: 7.3 m (24.0 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment^[a] examples: Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate Battery Charger may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
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Table D.5 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 27 V/m^[1]; 430 - 470 MHz, 28 V/m^[3]; 704 - 787 MHz, 9 V/m^[2]; 800 - 960 MHz, 28 V/m^[1]; 1.7 - 1.99 GHz, 28 V/m^[2]; 2.4 - 2.57 GHz, 28 V/m^[2]; and 5.1 - 5.8 GHz, 9 V/m^[2] [1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate Battery Charger, and its parts, than 0.3 m (12 inches). Equipment^[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems. Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
Electrical Fast Transient & Burst Immunity / IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines 100 kHz repetition rate	
Surge Immunity / IEC 61000-4-5 EN 61000-4-5	± 0.5, ± 1 kV line to line and ± 0.5, ± 1 kV, and ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.

Table D.5 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)

D Safety Testing and Classification

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (Within ISM and Amateur Bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate Battery Charger is recommended: 150 kHz - 80 MHz: 1.7 m (5.7 feet) Equipment ^[a] examples include: CB Radios, Amateur "HAM" radios, and Diathermy medical devices. Note: 1,000 kHz = 1.0 MHz Note: "ISM" = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	3 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines Immunity / IEC 61000-4-11 EN 61000-4-11	0 % of U_T ; ½ cycle 0 % of U_T ; 1 cycle and 70 % of U_T ; 25 or 30 cycles (0.5 sec.) 0 % of U_T ; 250 or 300 cycles (5 sec.)	Mains power quality should be that of a typical commercial or hospital environment where the HeartMate Battery Charger is used. U_T : A.C. Mains voltage supply, either 50 or 60 Hz (cycles per sec.)

Table D.5 Declaration and Guidance Concerning Electromagnetic Disturbances for Battery Charger (Continued)

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HeartMate Battery Charger, including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use the Battery Charger next to other equipment.
- Do not stack the Battery Charger on top of other equipment.
- No modification of this equipment is allowed.

Field strengths from fixed RF transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

These guidelines may not apply in all situations.

D Safety Testing and Classification

Testing and Classification: HeartMate 14 Volt Lithium-Ion Batteries

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

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

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

Type	Degree of Protection
Mode of Operation	Continuous
Degree of protection against electric shock	Not an 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 of water and particulate matter	IP24 only when connected to System Controller through Battery Clip

Table D.6 Declaration Concerning General Safety Standards for HeartMate 14 Volt Lithium-Ion Batteries

Declaration and Guidance for Electromagnetic Disturbances for HeartMate II Powered by 14 V Li-Ion Batteries

The HeartMate II LVAS (powered by 14V Li-Ion batteries) is suitable for use in the following environments:

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

HeartMate II LVAS Powered By the 14V Li-Ion Batteries		
EM (Electromagnetic) Disturbance type / Standards	IEC 60601-1-2 (2014) Compliance Level	Use Environment Guidance
RF Emissions / CISPR 11 EN 55011	Group 1, Class B (radiated only) 30 – 1,000 MHz	The HeartMate II LVAS with 14V Li-Ion Batteries is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply (mains) network that supplies domestic (residential) buildings. The HeartMate II LVAS with 14V Li-Ion Batteries uses RF energy only for its internal purposes and thus has low unintentional RF emissions and is unlikely to cause interference in nearby electronic equipment.
Electrostatic Discharge (ESD) Immunity / IEC 61000-4-2 EN 61000-4-2	±8 kV Contact ±15 kV Air	The relative humidity where the HeartMate II LVAS with 14V Li-Ion Batteries is used should be at least 5%. Higher relative humidity will reduce the severity of ESD events.

Table D.7 Declaration and Guidance Concerning Electromagnetic Disturbances for 14V Li-Ion Batteries

D Safety Testing and Classification

Radiated RF Immunity / IEC 61000-4-3 EN 61000-4-3	20 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with 14V Li-Ion Batteries are recommended: 80 - 800 MHz: 0.85 m (2.8 feet) 800 MHz – 2.7 GHz: 1.7 m (5.6 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. For many common 10-Watt (maximum) transmitters in the 80 MHz to 2.7 GHz range, the following minimum separation distances to the HeartMate II LVAS with 14V Li-Ion Batteries are recommended: 80 - 800 MHz: 1.9 m (6.2 feet) 800 MHz – 2.7 GHz: 3.8 m (12 feet) Note: At 800 MHz, the separation distance for the higher frequency range applies. Equipment^[a] examples: Garage door remote controls, emergency services radios, “walkie-talkie” radios, Amateur “HAM” radios, Cellular telephone base stations, and RFID readers. Interference to the HeartMate II LVAS may occur near equipment or areas that are marked with the following symbol:  Note: 1,000 MHz = 1.0 GHz [a] – List is not comprehensive.
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Table D.7 Declaration and Guidance Concerning Electromagnetic Disturbances for 14V Li-Ion Batteries (Continued)

Portable RF Communication Equipment Immunity / IEC 61000-4-3 EN 61000-4-3	380 - 390 MHz, 42 V/m ^[1] ; 430 - 470 MHz, 42 V/m ^[3] ; 704 - 787 MHz, 13 V/m ^[2] ; 800 - 960 MHz, 42 V/m ^[1] ; 1.7 - 1.99 GHz, 42 V/m ^[2] ; 2.4 - 2.57 GHz, 42 V/m ^[2] ; and 5.1 - 5.8 GHz, 13 V/m ^[2]	Portable RF Communication Equipment (up to 2-Watt max. of transmit power) and its parts (cables, antennas, etc.) operating in the frequencies shown here should not be closer to the HeartMate II LVAS with 14V Li-Ion Batteries, and its parts, than 0.2 m (8 inches). Equipment ^[a] examples: TETRA 400, GMRS, LTE Bands, GSM and CDMA Phones, UMTS, Bluetooth, WLAN, Wi-Fi, and RFID systems.
	[1] 18 Hz Pulse Modulation [2] 217 Hz Pulse Modulation [3] FM at +/- 5 kHz Deviation	Note: 1,000 MHz = 1.0 GHz Note: The recommended minimum separation distance above is a deviation from IEC 60601-1-2 (2014) based on the use-environment of the HeartMate II LVAS with 14V Batteries. [a] – List is not comprehensive.

Table D.7 Declaration and Guidance Concerning Electromagnetic Disturbances for 14V Li-Ion Batteries (Continued)

D Safety Testing and Classification

Conducted RF Immunity / IEC 61000-4-6 EN 61000-4-6	3 Vrms and 6 Vrms (within ISM and Amateur bands) 150 kHz – 80 MHz 80% AM at 1 kHz	For many common 2-Watt (maximum) transmitters and some ISM products and their parts (cables, antennas, etc.) operating in the 150 kHz to 80 MHz range, the following minimum separation distance to the HeartMate II LVAS with 14V Li-Ion Batteries is recommended: Outside ISM bands – 150 kHz - 80 MHz: 1.7 m (5.7 feet) In ISM/Amateur bands – 150 kHz - 80 MHz: 2.8 m (9.2 feet) Equipment ^[a] examples include: CB Radios, Amateur “HAM” radios, Diathermy medical devices, Note: 1,000 kHz = 1.0 MHz Note: “ISM” = Industrial, Scientific and Medical devices, as per the International Technical Union [a] – List is not comprehensive.
Power Frequency Magnetic Field Immunity / IEC 61000-4-8 EN 61000-4-8	30 A/m (50 or 60 Hz)	Power Frequency Magnetic Field should be that of a typical commercial or hospital environment where the HeartMate II LVAS with 14V Li-Ion Batteries is used.

Table D.7 Declaration and Guidance Concerning Electromagnetic Disturbances for 14V Li-Ion Batteries (Continued)

WARNING !

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the HeartMate II LVAS (powered by the 14V Li-Ion Batteries), including cables specified by Abbott. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories or cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid use of HeartMate II LVAS (and its cables and parts) within 5 cm (2 inches) of a microwave oven or its cord.
- To help ensure good electromagnetic performance throughout the usable life of the HeartMate II LVAS, be certain to follow the maintenance schedule and procedures as described in Equipment Storage and Care.

Field strengths from fixed RF transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

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

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

To assess the electromagnetic environment (home, office, etc.) due to fixed RF transmitters, an electromagnetic (EMC) "site survey" (measurement) should be considered. If the measured field strength (in Volts per meter, V/m) in the location(s) in which the HeartMate II Left Ventricular Assist System is used exceeds the applicable RF compliance level for the frequency bands above, the HeartMate II LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate II LVAS.

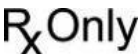
These guidelines may not apply in all situations.

SYMBOLS

This section describes the symbols that are used on the HeartMate II Left Ventricular Assist System components, accessories, or packaging.

Description of Labeling Symbols

General Symbols

SYMBOL	DESCRIPTION
	Manufacturer
	Date of manufacture
	Reference Number (Catalog Number)
	Serial Number
	Batch Code (Lot Number)
	Caution: US federal law restricts this device to sale by or on the order of a physician
	European Conformity
	Authorized representative in the European community
	Storage Temperature
	Sterilized by Irradiation
	Sterilized by Ethylene Oxide
	Operating Instructions
	Do not use if package damaged
	Do not reuse. Single patient use only.
	Quantity of contents
	Peel Tab

E Symbols

SYMBOL	DESCRIPTION
	« Caution » «Attention, See instructions for use »
IPxx	Degrees of protection provided by enclosures
	Operating Temperature
	UL Recognized Component
	Contains Lithium-Ion, recycle in accordance with local, state, and federal regulations.
	Separate collection for batteries and accumulators
	Separate collection for waste electrical and electronic equipment
	Expiration Date: Use by (Expiration Date)
	Keep dry
	See instructions for use
	Japan - Giteki Type Certification Mark
	Australia / New Zealand - Regulatory Compliance Mark (RCM)
	Non-ionizing radiation
	Fragile
	This end up

SYMBOL	DESCRIPTION
	Alternating current
	UL product safety mark
	MR unsafe—do not subject to magnetic resonance imaging
	Contents Quantity
	Tablet for use with the HeartMate Touch App
	Accessories
	UDI Identification
	Follow instructions for use on this website
	Consult instructions for use

Specific 14 Volt Lithium-Ion Battery Symbols

Symbol	Description
On-product symbols	See <i>Checking Battery Charge Status Using the On-Battery Power Gauge</i> on page 3-49
	Charge By. HeartMate 14 Volt Lithium-Ion batteries must be charged at least once by the end of the month marked on the label affixed to battery packaging (box and protective bag).
	Product Use by

Specific 11 Volt Lithium-Ion Backup Battery Symbols

E Symbols

Symbol	Description
	Backup Battery Use by

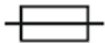
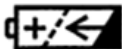
Specific System Controller Symbols

Symbol	Description
On-product symbols	See <i>System Controller User Interface</i> on page 2-17

Specific Mobile Power Unit Symbols

Symbol	Description
On-product symbols	See <i>Mobile Power Unit User Interface Components</i> on page 3-34

Specific Power Module Symbols

Symbol	Description
On-product symbols	- See on page 7-31 - See <i>Checking the Charge Status of the Power Module Backup Battery</i> on page 3-21
	Monitor
	Type "CF" Symbol: Patient cable connection
	Power ON/OFF: When the Power Module is plugged into a wall socket, this symbol illuminates green. When the Power Module is operating on internal battery power with less than 15 minutes of power left, this symbol illuminates yellow.
	Fuse Rating: T 2A, 250 V
	Direct Current
	Rechargeable Battery: When the Power Module is recharging the internal battery, this symbol illuminates yellow. When the internal battery is fully charged, this battery symbol illuminates green.

Symbol	Description
	Battery Check: When the Power Module is operating on internal battery power with less than 15 minutes of power left, this symbol illuminates yellow as an Advisory alarm. When only 5 minutes of internal battery power remain, this symbol illuminates red as a Hazard alarm.

E Symbols

SAFETY CHECKLISTS

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

Daily Safety Checklist - - - - -	F-3
Weekly Safety Checklist - - - - -	F-5
Monthly Safety Checklist - - - - -	F-6
Six Month Safety Checklist - - - - -	F-8
Yearly Safety Checklist - - - - -	F-10
As-Needed Safety Checklist- - - - -	F-11
Clinic Visit Safety Checklist - - - - -	F-12

Daily Safety Checklist

Daytime Checklist:

- ☒ Perform System Controller self test (see *Performing a System Controller Self Test* on page 2-29).
- ☒ When using a new power source, inspect System Controller power cable connectors for dirt, grease, or damage.
- ☒ When using a new power source, inspect connectors on battery clips for dirt, grease, or damage.
- ☒ When switching from the battery power to the Power Module or Mobile Power Unit, inspect the connector pins and sockets for dirt, grease, or damage.
- ☒ Perform a Power Module self test (see *Performing a Power Module Self Test* on page 3-19).
- ☒ Maintain the Power Module connection to the AC power source. If not properly monitored, the internal battery drains, causing potential damage.
- ☒ Unless instructed otherwise by the patient's physician, wash the driveline exit site using the prescribed cleanser.
- ☒ Unless instructed otherwise by the patient's physician, change the exit site bandages using aseptic technique.
- ☒ Inspect the driveline exit site for signs of infection, including redness, tenderness, swelling, discharge, or a foul odor. Use aseptic technique to touch or handle the exit site.
- ☒ When the Mobile Power Unit is initially connected to power, check the top panel to ensure that the Power On () symbol is illuminated green.
- ☒ Ensure that the Mobile Power Unit echoes the System Controller's alarms.

F Safety Checklists

Sleep Checklist:

- ☒ Check all electrical connections between the System Controller and power cables, the power cables and the Power Module patient cable, and the Power Module and AC electrical outlet.
- ☒ Always connect to the Power Module or Mobile Power Unit for sleeping or when there is a chance of sleep, as a sleeping patient may not hear system alarms (see *Switching Power Sources* on page 3-59).
- ☒ Ensure that the System Controller is not covered by insulating materials, such as a blanket, or placed against the patient's bare skin while sleeping.
- ☒ Secure the Stabilization Belt (see *Using the Stabilization Belt* on page 6-25).
- ☒ Confirm bedside items are in place:
 - Working flashlight with charged batteries.
 - Backup System Controller.
 - Two charged HeartMate 14 Volt Lithium-Ion batteries and two 14 Volt battery clips.
- ☒ Inspect the driveline and all cables for signs of damage, such as cracking, fraying, wear, exposed wires, twists, sharp bends, or kinks (see *What Not To Do: Driveline and Cables* on page 7-46).

Weekly Safety Checklist

- ☒ Review Replacing the Running System controller with a Backup Controller instructions in Section 2.
- ☒ Clean the metal battery terminals and contacts inside the battery clips (see *Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 8-7).
- ☒ Inspect the Power Module or Mobile Power Unit power cord, used to connect the Power Module or Mobile Power Unit to the AC electrical outlet, for damage or wear. Ensure 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 Abbott, if needed.
- ☒ Inspect the Power Module or Mobile Power Unit patient cable, used to connect the System Controller to the Power Module or Mobile Power Unit, for damage or wear. Ensure that the cable is not kinked, split, cut, cracked, or frayed. Do not use the patient cable if it shows signs of damage. Obtain a replacement from Abbott, 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 Abbott, if needed.
- ☒ Inspect the power cord that is used to connect the Battery Charger to an AC outlet. Ensure 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 Abbott, if needed.
- ☒ Inspect wear and carry accessories (including the Consolidated Bag, Travel Bag, Protection Bag, System Controller Neck Strap, Holster Vest, and Belt Attachment accessory) for damage or wear.
- ☒ Inspect the HeartMate Stabilization Belt for damage or wear.
- ☒ Inspect the Shower Bag for damage or wear.
- ☒ Inspect the Battery Holster for damage or wear.
- ☒ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

F Safety Checklists

Monthly Safety Checklist

- ☒ Review Alarms and Troubleshooting in Section 7.
- ☒ Check the expiration date of the 11 Volt Lithium-Ion backup battery by following the steps below:

1. Ensure that you advise all HeartMate II LVAS patients to bring their backup System Controller with them to all clinic visits.
2. Use the HeartMate Touch to check the expiration date of the 11 Volt Lithium-Ion backup battery within the patient's primary and backup System Controllers.
3. The remaining months until the 11 Volt Lithium-Ion backup battery will expire is displayed on the backup battery Information screen on the HeartMate Touch (review the *Backup Battery Tab* on page 4-41).

Note: The number of months remaining until the backup battery will expire is displayed on the HeartMate Touch as "Replace in XX month(s)". The number of months remaining until expiration is a number between 36 (maximum) and 0 (expired)).

IMPORTANT! Once the number of months remaining reaches 6 months or less, the number will be highlighted to remind Hospital Staff to replace the backup battery. Depending upon a patient's clinic schedule, replacement of the 11 Volt Lithium-Ion backup battery should be considered when less than 6 months remain before the mandatory replacement date (see *Replacing a Backup Battery in the System Controller* on page 2-43).

WARNING !

Failure to replace the 11 Volt Lithium-Ion backup battery prior to its expiration date will result in an Advisory alarm (see *System Controller Backup Battery Fault Alarm* on page 7-20) at 12:00 am (midnight) on the first day of the month in which the actual expiration date is reached, which could potentially lead to **serious injury to the patient or patient death**. It is critical that the clinician regularly check the backup battery expiration date and replace the backup battery as required (see *Replacing a Backup Battery in the System Controller* on page 2-43).

- ☒ 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.

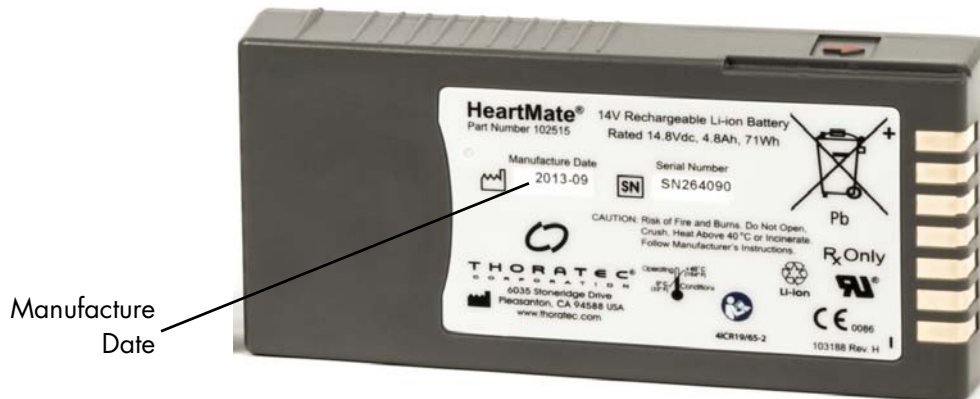


Figure F.18 Check the Manufacture Date to Determine Battery Expiration

- ☒ Check the number of use/charge cycles for each battery. Insert a battery into the Battery Charger to read the number of cycles. The cycle information is displayed on the charger's display panel screen (see *Battery Charger Display Panel Messages* on page 7-44). Replace batteries that have exceeded 360 cycles. Do not use batteries that have exceeded 360 cycles.
- ☒ Clean the metal battery contacts and the interior contacts of battery clips using a cotton swab or lint-free cloth that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to completely air dry before using newly cleaned batteries or clips. Do not clean batteries while the batteries are in use. See *Cleaning HeartMate 14 Volt Lithium-Ion Batteries and Battery Clips* on page 8-7.
- ☒ Inspect the Power Module or 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 Abbott. For Abbott contact information, see the *Back Cover* of this manual. Cleaning and service should be performed only by Abbott-trained personnel. Do not attempt to clean or repair equipment on your own.
- ☒ If the Mobile Power Unit will be stored for more than one 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

- ☒ Depending upon the patient's clinic schedule, once in a six month period the backup System Controller must be maintained and assessed for readiness (see *Maintaining Backup System Controller Readiness: Charging and Self Test* on page 2-53). This involves:
 - Connect the backup System Controller to a power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). Connection to power allows charging of the backup System Controller's 11 Volt Lithium-Ion backup battery.
 - Perform a self test on the backup System Controller, after the System Controller is connected to power.
 - Using a HeartMate Touch, verify that the backup System Controller's programmed settings are identical to the settings in the patient's running System Controller.
- ☒ Practice and evaluate your patient's ability to perform necessary core skills. Advise your patient to bring his or her Patient Handbook to the clinic visit.
 - Review how to identify an emergency (see *Patient Handbook* section 8, "Handling Emergencies").
 - Review emergency contact lists (see *Patient Handbook* "Emergency Contact List" on page iii).
 - Review replacing the running system controller with a backup system controller (see page 2-55 or *Patient Handbook* section 2).
 - Review changing power sources (see page 3-59 or *Patient Handbook* section 3).
 - Review System Controller alarms and troubleshooting including Hazard and Advisory alarm handling and accessing alarm history on the System Controller (see page 7-3 or *Patient Handbook* section 5).
 - Review Power Module alarms and troubleshooting (see page 7-31).
 - Review Mobile Power Unit alarms and troubleshooting (see page 7-40 or *Patient Handbook* section 5).
 - Review guidelines for connecting power cable connectors (see page 7-45 or *Patient Handbook* section 5).
 - Review HeartMate 14 Volt Lithium-Ion battery calibration steps (see page 3-76 or *Patient Handbook* section 3).
 - Review *What Not To Do: Driveline and Cables* on page 7-46 or *Patient Handbook* section 5.
 - Review using the Shower Bag and showering (see page 6-15 or *Patient Handbook* section 4).

- Review caring for the driveline exit site including cleansing, dressing, and immobilizing the driveline (see page 6-9 or *Patient Handbook* section 4).
- Replace the Mobile Power Unit batteries with three new Alkaline AA batteries. If corrosion is observed, report the condition to Abbott. For Abbott contact information, see the *Back Cover* of this manual. Cleaning and service should be performed only by Abbott-trained personnel. Do not attempt to clean or repair equipment on your own.

F Safety Checklists

Yearly Safety Checklist

- ☒ Schedule a Power Module inspection and cleaning with Abbott-trained personnel. The inspection and cleaning includes (but is not limited to) functional testing, cleaning, inspection, and replacement of the Power Module backup battery.

IMPORTANT! Ensure that the Power Module backup battery is reconnected after service or shipping (see *Installing the Power Module Backup Battery* on page 3-7).

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

As-Needed Safety Checklist

- ☒ Unless instructed otherwise by the patient's physician, clean the exit site and bandages daily.
- ☒ Clean the exterior surfaces of batteries using a clean, dry cloth. Do not use liquids such as water or liquid cleaning solvent to clean batteries. Keep batteries dry and away from water or 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 submerge the charger in water or liquid.
- ☒ REPLACE ANY EQUIPMENT OR SYSTEM COMPONENT THAT APPEARS DAMAGED OR WORN.

F Safety Checklists

Clinic Visit Safety Checklist

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

- ☒ Review replacing the running System Controller with a backup System Controller (IFU Section 2 or *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 (IFU Section 2 or *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 (IFU Section 7 or *Patient Handbook* Section 5).
- ☒ Review Mobile Power Unit alarms and troubleshooting (IFU Section 7 or *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 iii).
- ☒ Review guidelines for connecting power cable connectors (IFU Section 7 or *Patient Handbook* Section 5).
- ☒ Review changing power sources (IFU Section 3 or *Patient Handbook* Section 3).
- ☒ Review HeartMate 14 Volt Lithium-Ion battery calibration steps (IFU Section 3 or *Patient Handbook* Section 3).
- ☒ Review *What Not To Do: Driveline and Cables* on page 7-46 or *Patient Handbook* section 5.
- ☒ Review using the Shower Bag and showering (see page 6-15 or *Patient Handbook* section 4).
- ☒ Review caring for the driveline exit site including cleansing, dressing, and immobilizing the driveline (see page 6-9 or *Patient Handbook* section 4).
- ☒ System Controller must be maintained and assessed for readiness (IFU Section 2).

CONVERSION PATIENTS

This section describes items to consider when converting patients to the Pocket System Controller.

Considerations for Patients Converted from Previous Models of System Controllers to the Pocket System Controller

The Pocket Controller described in the Instructions for Use is designed to meet a higher standard for water ingress than the previous models of the System Controller to support the more active lifestyles of today's patients. Among other differences that are noticed by the clinician and patient is the "feel" of the connection of the HeartMate II pump driveline to the Pocket Controller. In addition, there are differences in the presentation of the alarm conditions and actions to take in response to each of these alarms.

Therefore, it is recommended that patients who are converting from previous models of the System Controller to the Pocket Controller are given enough training to become confident, proficient, and comfortable with the driveline connection "feel" differences. Additionally, the patient/caregiver must be proficient in understanding and responding appropriately to all alarm conditions and able to demonstrate these competencies. The Clinic Visit Safety Checklist (Appendix F) is recommended to be used as a guide for reviewing patient/caregiver training on the HeartMate II LVAS.

- Presentation of alarm conditions has changed (IFU Section 5)
 - Are the patient and caregiver able to demonstrate the ability to understand and respond appropriately to the alarms?
- The "feel" of the connection of the driveline to the System Controller has changed
 - Are the patient and caregiver able to demonstrate the ability to repeatedly connect and disconnect a demonstration driveline to the demonstration System Controller in a timely manner as these are important steps in the process of System Controller exchanges if necessary? (IFU page 2-51)

IMPORTANT! The patient and the caregiver should demonstrate the ability to make System Controller exchanges using demonstration equipment, specifically repeatedly completing the driveline connection to the Pocket Controller, under urgent conditions where time is of the essence.

- Past history of compliance with hospital follow-up and instructions.
- If the patient and caregiver are not able to demonstrate consistent ability to perform the tasks above, consider keeping the patient on the previous models of System Controller.

IMPORTANT! These items should be considered due to the differences between the two controllers.

SURVEY

This section provides an opportunity for you to provide Abbott with valuable information that will help to improve this manual.

ABBOTT SURVEY: HEARTMATE II® INSTRUCTIONS FOR USE (Document 100168923.B)

1. How satisfied are you with the quality of documentation that Abbott provides?
☐ Very satisfied
☐ Satisfied
☐ Not satisfied
2. The printed materials and media that Abbott provides are available in the languages I need.
☐ Yes
☐ No
3. I use the HeartMate II Patient Information Kit (pre-decision booklet) as an effective resource for my prospective VAD patients and their cardiologists.
☐ Yes
☐ No
4. Topics covered in the *HeartMate II Left Ventricular Assist System Patient Handbook* meet the information needs of my patients.
☐ Yes
☐ No
5. The reading level of the *HeartMate II Left Ventricular Assist System Patient Handbook* is appropriate for HeartMate II patients and their caregivers.
☐ Yes
☐ No
- If no, describe a problem or suggest how this manual could be changed to make it better or easier to use.

-
- If yes, how do you use this manual (check all that apply):
- ☐ Understanding the principals of operation
 - ☐ Setting up and using the System Controller
 - ☐ Setting up and using the HeartMate Touch
 - ☐ Setting up and using the Power Module, Battery Charger, batteries, & battery clips
 - ☐ Troubleshooting alarms
 - ☐ Guidelines for inspecting, cleaning, storing, etc.
 - ☐ Clinical guidelines for postop patient care
 - ☐ Safety testing and classification info for biomed department
 - ☐ Implant procedures
 - ☐ Other

ABBOTT HEARTMATE II SURVEY *continued*

6. What other topics would you like covered in this manual?
- _____
7. What other lists, forms, samples, or information can we add to the Appendix section of this manual?
- _____
8. If this manual existed online, would you use the digital version?
- __ Yes
- If yes, where would you use a digital version?
- __ At the nurses' station
- __ At the patient's bedside
- __ Other _____
- __ No
9. What do you like most about this manual?
- _____
10. What do you like least about this manual?
- _____
11. Are you interested in reviewing and commenting on future draft copies of this or other HeartMate II manuals?
- __ Yes
- __ No

If yes, please print your contact information below.

Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ e-mail _____

To share your feedback about this manual, mail or fax a copy of your completed survey to:

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Pleasanton, CA 94588

Fax: 925-847-8574

GLOSSARY

This section provides a glossary of terms for the HeartMate II Left Ventricular Assist System.

Abbreviations - - - - - Glossary-3

Terms - - - - - Glossary-4

Abbreviations

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

Terms

A

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

Alarm: A sound, light, or lighted symbol that tells users about a problem that may affect system operation or cause harm. See *System Controller Alarms* on page 7-3.

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

B

Backup System Controller: A backup System Controller is used to replace the running System Controller, if needed. The backup is identical to the running System Controller and is pre-set with the same settings. Patients should keep their backup System Controller with them at all times (along with other emergency or backup items). The 11 Volt Lithium-Ion backup battery inside the backup System Controller must be recharged once every six months. See *Maintaining Backup System Controller Readiness: Charging and Self Test* on page 2-53.

Battery: A device that provides direct current (DC) power to the system. The HeartMate II Left Ventricular Assist System can be powered by a pair of 14 Volt Lithium-Ion batteries. See *Using HeartMate 14 Volt Lithium-Ion Batteries* on page 3-45. An 11 Volt Lithium-Ion battery inside the System Controller gives at least 15 minutes of backup power to the system if the main source of power is disconnected or fails. See *System Controller Backup Battery Power* on page 2-40.

Battery Button: A button on the System Controller user interface that shows a small battery symbol . Depending on the mode of operation, pressing this button either: 1) works the battery power gauge on the System Controller, 2) starts the System Controller self test, 3) puts the battery to “sleep” for storage purposes, or 4) recharges the System Controller’s 11 Volt Lithium-Ion backup battery. See *System Controller Battery Power Gauge* on page 2-31.

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

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

Battery-Powered Operation: Using two HeartMate 14 Volt Lithium-Ion batteries to power the system. Using batteries to power the system is appropriate when users 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.

D

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

Display Button: A button on the System Controller user interface. Press this button (⏏) to bring up data on the user interface's display screen (such as current function and alarm history). See *User Interface Components* on page 2-18.

Driveline: The cable that goes through the skin. It links the implanted pump 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. The driveline may also be referred to as the percutaneous lead.

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

Driveline Fault: An advisory alarm. It occurs when one or more of the wires inside the driveline is damaged. See *System Controller Alarms* on page 7-3.

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 pump is set at a constant or "fixed" speed. Doctors and nurses decide and control pump speed.

G

H

Hazard Alarm: Hazard alarms occur when the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention. Hazard alarms are indicated by a red light and continuous audio tone.

HeartMate II Left Ventricular Assist System: Includes the implanted pump and driveline, as well as the System Controller, power sources (Power Module, Mobile Power Unit, or batteries), and accessories. You may sometimes hear the term "LVAS," which is short for Left Ventricular Assist System.

Glossary

HeartMate Touch App: The HeartMate Touch App provides clinicians with the ability to wirelessly monitor a patient's HeartMate system, program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

HeartMate Touch Communication System: The HeartMate Touch Communication System gives clinicians a detailed, large-scale display of system performance. Using the HeartMate Touch Communication System, clinicians can also enter and change operating parameters and system settings.

HeartMate Touch Wireless Adapter: The HeartMate Touch Wireless Adapter facilitates Bluetooth® pairing, when it is connected to the Power Module.

I

Inflow Conduit: A small tube that connects the pump to the left ventricle of the heart.

Intensive Care Unit: Abbreviated ICU. This special hospital unit is where new Left Ventricular Assist System patients receive intensive care, usually just after pump implant.

J

K

L

Left Ventricular Assist Device: The implanted device 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 device is powered through the driveline. You may sometimes hear the device called a "pump," "heart pump," or "LVAD," which is short for Left Ventricular Assist Device.

Left Ventricular Assist System: The HeartMate II Left Ventricular Assist System includes the implanted pump and all related external equipment. Sometimes the Left Ventricular Assist System is called an "LVAS". LVAS is not the same as LVAD, which refers only to the implanted pump.

Liters Per Minute: Abbreviated lpm. Blood flow through the pump is measured in lpm. "LPM" shows on the System Controller user interface along with blood flow data.

Low Battery Hazard Symbol: Red "battery" light () on the System Controller. It lights when power to the System Controller is critically low.

Low Flow Alarm: Blood flow is less than 2.5 lpm. This condition is accompanied by a flashing red heart on the user interface. "Call Hospital Contact" and "Low Flow" alternate on the screen, and a constant audio tone is emitted from the System Controller. This is a Hazard alarm condition that requires immediate attention.

Low Flow Hazard Symbol: Red "heart" light () on the System Controller. It lights when HeartMate II pump blood flow is critically low.

Low Speed Limit: The lowest speed at which the HeartMate II pump can operate while maintaining patient stability.

LPM: Short for liters per minute (lpm). Blood flow through the pump is measured in lpm.

LVAS: Short for Left Ventricular Assist System. The HeartMate II Left Ventricular Assist System includes the implanted pump and driveline, as well as the System Controller, power sources (Power Module, Mobile Power Unit, or batteries), and accessories.

M

Mobile Power Unit: The Mobile Power Unit connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. Patients must always connect to the Power Module or Mobile Power Unit for sleep (or when sleep is possible). Connecting to the Mobile Power Unit is also appropriate when patients are stationary or relaxing indoors. See *Using the Mobile Power Unit* on page 3-30.

N

O

Operating Modes: There are three modes of System Controller operation: 1) Run Mode (actively running), 2) Sleep Mode (off and unused), and 3) Charge Mode (connected to power and charging the internal backup battery). See *System Controller Operating Modes* on page 2-34.

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.” This term describes the driveline that goes through the skin of the abdomen and connects the implanted pump to the System Controller.

Percutaneous Lead (also frequently called the “driveline”): The cable passing through the patient’s skin that is permanently attached to the HeartMate II pump. It connects the implanted pump to the System Controller. It contains wires that carry power to the pump, and that control and monitor pump operation.

Polyester Velour: A synthetic biocompatible material that lets skin tissue grow into the soft covering of the driveline. This material covers the driveline inside the body at the exit site. Skin growth into the velour covering helps create a barrier that reduces the risk of driveline infections.

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

Power Module: The Power Module connects to an AC electrical outlet. It provides AC electrical power to the Left Ventricular Assist System. Patients must always connect to the Power Module or Mobile Power Unit for sleep (or when sleep is possible). Connecting to the Power Module is also appropriate when patients are stationary or relaxing indoors. See *Using the Power Module* on page 3-4.

Power Module Backup Battery: A backup power source inside the Power Module that gives up to 30 minutes of support if power to the Power Module fails or is disconnected. The backup battery works only if it is charged and properly connected. See *Setting Up the Power Module Before Use* on page 3-7.

Power Saver Mode: In power saver mode, the System Controller slows pump speed to save power. If power is removed or fails, the System Controller gives 15 minutes of full power before entering power saver mode. Alarms cannot be silenced while in power saver mode. See *Estimating Remaining Time for In-Use Batteries* on page 3-55.

Power Sources: Three power sources can power the HeartMate II Left Ventricular Assist System: 1) a pair of wearable, rechargeable 14 Volt Lithium-Ion batteries worn in battery clips, 2) the Power Module that plugs into an AC electrical outlet, or 3) the Mobile Power Unit that plugs into an AC electrical outlet.

Pulsatility Index (PI): Pulsatility Index (PI) is a calculation related to the amount of assistance provided by the pump. PI values typically range from 1 to 10. Higher values indicate more ventricular filling and higher pulsatility (ie, the pump is providing less support to the left ventricle). Lower values indicate less ventricular filling and lower pulsatility (ie, the pump is providing greater support and further unloading the ventricle).

Pump Running Symbol: A green-colored symbol () on the System Controller user interface that illuminates when the pump is receiving power and running.

Pump Speed: Pump speed is measured in revolutions per minute (RPM). The number of RPMs reflects how fast the pump's internal rotor turns.

Q

R

Red Battery Alarm: A red-colored battery-shaped symbol () on the System Controller user interface that illuminates when less than 5 minutes of combined battery power remain for the in-use HeartMate 14 Volt Lithium-Ion batteries, during battery-powered operation.

Red Heart Alarm: A red-colored heart-shaped symbol () on the System Controller user interface that illuminates during a hazard alarm condition. Red heart alarms occur for conditions that are immediately life-threatening. Red heart alarms should prompt an immediate response to avoid serious patient injury or death.

Revolutions Per Minute: Abbreviated RPM. The number of RPMs reflects how fast the pump's internal rotor turns.

Running System Controller: The System Controller that is currently in use and connected to the implanted pump. In addition to the running System Controller, users also get a backup System Controller. The backup is identical to the running System Controller. The backup is also programmed with patient-specific settings.

S

Sealed Outflow Bend Relief Collar: A titanium collar that reinforces the connection of the bend relief to the sealed outflow graft.

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

Glossary

Silence Alarm Button: A button on the System Controller  or Power Module  that silences an audio alarm. How long the alarm is silenced depends on the type of alarm. The silence period varies from 2 minutes to 4 hours.

IMPORTANT! Pressing the Silence Alarm button only silences the alarm. It does not fix the alarm condition. See *System Controller Alarms* on page 7-3.

Strap Attachment Points: Four places on the System Controller where straps can be easily connected. Attachment points allow for holding or carrying the System Controller. The System Controller can be worn on a strap around the neck, on a belt, or in a carrying case. See *Wearing and Carrying the System Components* on page 6-28.

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

System Controller 11 Volt Lithium-Ion Backup Battery: A backup power source inside the System Controller. It powers the system for up to 15 minutes if the main power source fails or is disconnected. The 11 Volt Lithium-Ion backup battery is rechargeable. It charges automatically any time the System Controller is connected to a power source (Power Module, Mobile Power Unit, or batteries). The backup battery inside the backup System Controller must be recharged once every six months. Although rechargeable, the 11 Volt Lithium-Ion backup battery has a limited life (36 months from manufacture date). A message on the System Controller screen indicates when it is time to replace the 11 Volt Lithium-Ion backup battery. See *System Controller Backup Battery Power* on page 2-40.

System Controller Battery Power Gauge: A set of four bars on the System Controller. The bars show the approximate charge level for a pair of batteries being used to power the system. Four green bars mean the batteries are between 75%–100% charged. One green bar means the batteries are less than 25% charged. A yellow diamond-shaped light means that only 15 minutes of battery power remain. If the yellow diamond comes on, promptly replace the depleted batteries, or switch to the Power Module or Mobile Power Unit. Failure to replace batteries or switch to the Power Module or Mobile Power Unit may cause the implanted pump to stop. See *System Controller Battery Power Gauge* on page 2-31.

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 (batteries, Power Module, or Mobile Power Unit). Both cables provide equal power. However, the white cable contains a data link that sends information to the Power Module.

T

Tablet with the HeartMate Touch App: The tablet deployed with HeartMate Touch App serves as the display screen and is installed in a protective case.

Tethered Operation: Refers to using the HeartMate II Left Ventricular Assist System while connected to an electrical outlet via the Power Module or Mobile Power Unit.

U

User Interface: Set of visual indicators (symbols that illuminate) and buttons located on the front of the System Controller.

User Interface Screen: The screen on the System Controller that allows users to view real-time data about system operation. Alarm information and instructions also appear on the screen. See *System Controller User Interface* on page 2-17.

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 patient can carry the System Controller with a strap around the neck, on a belt, or in a carrying case. A Battery Holster is used for carrying batteries and battery clips. See the *Wearing and Carrying the System Components* on page 6-28.

X

Y

Yellow Diamond Alarm: A yellow-colored symbol () on the System Controller user interface that illuminates when less than 15 minutes of combined battery power remain from the in-use HeartMate 14 Volt Lithium-Ion batteries that are providing power during battery-powered operation.

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

Z

Glossary

Numerics

- 11 Volt Lithium-Ion backup battery
 - charging 36, 38
 - charging in backup System Controller 36
 - disposal 10
 - environmental requirements
 - for operation 9
 - for storage and transport 3
 - installing in System Controller 49
- 14 Volt Lithium-Ion batteries 45
 - calibrating 76
 - charge status 51
 - charging 73
 - cleaning 7
 - environmental requirements
 - for operation 9
 - for storage and transport 3
 - inserting in battery clip 59, 60
 - low battery alarms 33
 - on-battery power gauge 49
 - power gauge on System Controller 19
 - recycling 10
 - viewing charge status on System Controller 32
 - when to remove from service 58

A

- acceptable environmental conditions
 - for operation 9
 - for storage and transport 3
- accessories 28
 - Battery Holster 47
 - Belt Attachment 35
 - Consolidated Bag 39
 - Holster Vest 53
 - Protection Bag 60
 - Shower Bag 15
 - Stabilization Belt 25
 - System Controller Neck Strap 31
 - Travel Bag 61
 - wear and carry 28
- advisory alarms 48
 - driveline fault 22
 - low speed 21
 - low voltage 18
 - power cable disconnected 17
 - System Controller
 - backup battery fault 22
 - backup battery not installed 22
 - clock not set 23
 - fault 18
 - table of 10
- air pressure, acceptable range
 - for operation 9

- for storage and transport 3
- alarm history, viewing 5
- alarms
 - advisory 48
 - advisory, table of 10
 - backup battery fault 22
 - call hospital contact 12, 15, 18, 21, 22
 - connect driveline 13
 - connect power 17
 - connect power immediately 14
 - controller fault 18
 - driveline disconnected 13
 - driveline fault 22
 - hazard 47
 - hazard, table of 9
 - history, viewing 5
 - low battery advisory 18
 - low battery hazard 16
 - low battery, overview 33
 - low flow 15
 - low speed 21
 - low voltage advisory 18
 - low voltage hazard 16
 - Mobile Power Unit 40
 - no external power 14
 - power cable disconnected 17
 - Power Module 37
 - pump off 12
 - replace controller 18
 - replace power 18
 - replace power immediately 16
 - silencing on
 - Power Module 29
 - System Controller 20
 - System Controller 3
 - backup battery fault 22
 - backup battery not installed 22
 - clock not set 23
 - fault 18
 - tables 9
 - troubleshooting 3
- anticoagulation 10
- antifungal prophylaxis 9
- as-needed checklist 11
- aspirin 10

B

- backup battery
 - for Power Module 5
 - charging 20
 - checking charge status 21
 - connecting 7
 - disconnecting 23
 - disposal 10
 - installing 7

Index

- for System Controller
 - battery not installed alarm 22
 - checking charge status 21
 - disposal 10
 - environmental requirements 9, 3
 - installing 49
 - backup battery fault alarm 22
 - Backup Battery screen on System Controller 14
 - backup System Controller 47
 - programming and configuring 49
 - replacing running System Controller 55
 - storing 60
 - Bag
 - Consolidated 39
 - Protection 60
 - Shower 15
 - Travel 61
 - bathing 15
 - batteries
 - 11 Volt Lithium-Ion
 - charging 36, 38
 - charging in backup System Controller 36
 - environmental requirements 9, 3
 - installing in System Controller 49
 - not installed alarm 22
 - 14 Volt Lithium-Ion 45
 - alarms 33
 - calibrating 76
 - charge status 51
 - charging 73
 - environmental requirements 9, 3
 - inserting in battery clip 59, 60
 - on-battery power gauge 49
 - power gauge on System Controller 19
 - viewing charge status on System Controller 32
 - wear and carry accessories 28
 - when to remove from service 58
 - cleaning 7
 - disposal 10
 - Mobile Power Unit 35
 - Power Module backup battery 5
 - battery button on System Controller 20
 - Battery Charger 66
 - advisory messages 42
 - calibrating 14 Volt Lithium-Ion batteries in 76
 - charge indicator lights 73
 - charging 14 Volt Lithium-Ion batteries in 73
 - checking battery status in 78
 - cleaning 7
 - display panel messages 44
 - disposal 10
 - environmental requirement 9, 3
 - language display mode 71
 - power cord for international travel 70
 - setting up 68
 - battery clips
 - cleaning 7
 - inserting 14 Volt Lithium-Ion battery in 59, 60
 - Battery Holster 47
 - battery power gauge
 - on 14 Volt Lithium-Ion battery 49
 - on System Controller 19, 31
 - Belt Attachment 35
 - Belt, Stabilization 25
 - blood leak 12
 - blood pressure, measuring 10
 - buttons
 - HeartMate Touch App
 - clear driveline power alarm 50
 - low speed limit 30
 - pump start 53
 - silence driveline power alarm 50
 - Power Module, silence alarm button 29, 37
 - System Controller
 - battery button 17
 - display button 17
 - silence alarm button 17
- ## C
- calibrating 14 Volt Lithium-Ion batteries 76
 - call hospital contact
 - backup battery fault screen 22
 - controller fault screen 18
 - driveline fault screen 22
 - low flow alarm screen 15
 - low speed alarm screen 21
 - pump off alarm screen 12
 - cardiac massage 11
 - caring for
 - driveline 65
 - driveline exit site 9
 - Mobile Power Unit 6
 - Power Module 6
 - System Controller power cables 67
 - cautions, defined 3
 - Charge Mode, System Controller 36
 - charge status
 - 14 Volt Lithium-Ion batteries 51
 - Power Module backup battery 21
 - charging
 - 11 Volt Lithium-Ion battery 36

- 14 Volt Lithium-Ion batteries 73
- checklists 1
- chest compressions, external 11
- cleaning 6
 - batteries and battery clips 7
 - Battery Charger 7
 - driveline 5
 - general guidelines 4
 - Mobile Power Unit 44, 6
 - Stabilization Belt 8
 - System Controller 4
 - System Controller power cables 5
 - wear and carry accessories 8
- clear alarm button
 - driveline power fault 50
- clinical screen 56
 - pulsatility index 54
 - pump flow 52
 - pump power 53
 - pump speed 51
- clinical studies 3
 - bridge-to-transplantation 3
 - destination therapy 20
 - post-approval 46
- clock, setting in System Controller 46
- competency assessment checklist 68
- complications, potential 8
- components required for implant 13
- connect driveline screen 13
- connect power immediately screen 14
- connect power screen 17
- connectors
 - guidelines for handling 45
 - Mobile Power Unit patient cable 40
 - Power Module patient cable 15
 - System Controller power cable 27
- Consolidated Bag 39
- controller fault alarm 18
- controlling infection 10
- creating driveline exit site 33
- D**
 - daily checklist 3
 - date and time, setting 35
 - defibrillation 12
 - destination therapy clinical study 20
 - device tracking and reporting 52
 - dextran 10
 - differential pressure 16
 - dipyridamole 10
 - discharge readiness 68
 - disconnecting Power Module backup battery 23
 - display button on System Controller 17, 20
 - disposal
 - battery 10
 - Battery Charger 10
- HeartMate Touch 10
- medical waste 11
- Mobile Power Unit 10
- Power Module 10
- driveline
 - care 65
 - characteristics 7
 - cleaning 5
 - connecting to System Controller 24
 - connector on System Controller 17
 - disconnected, hazard alarm 13
 - disconnecting from System Controller 26
 - evidence of damage 5
 - fault alarm 22
- driveline exit site
 - caring for 9
 - creating 33
- driveline power fault alarm
 - silencing and clearing 50
- E**
 - educating patient and caregivers 68
 - environmental requirements
 - for operation 9
 - for storage and transport 3
 - equipment required
 - explant 53
 - implant 13
 - patient discharge 14
 - exit site
 - caring for 9
 - creating 33
 - explant procedures 53
 - extended alarm silence
 - cancelling 45
 - setting 45
 - external chest compressions 11
- F**
 - fixed speed, determining optimal 28
 - flow parameter for pump 18
 - fungal infection 9
- G**
 - guidelines for power cable connectors 45
- H**
 - hazard alarms 47
 - driveline disconnected 13
 - low battery power 16
 - low flow 15
 - no external power 14
 - on System Controller, table of 9
 - pump off 12
 - HeartMate II Left Ventricular Assist Device
 - components 6
 - differential pressure 16

Index

- disposal 11
- explant procedures 53
- implant procedures 27
- overview 3
- placement 31
- pump parameters 17
- HeartMate II Left Ventricular Assist System
 - contraindications 7
 - environmental requirements
 - for operation 9
 - for storage and transport 3
 - implant kit 5
 - indications 7
 - potential complications 7, 8
 - potential risks 8
 - product list 3
 - technical specifications 3
- HeartMate II Sizer
 - preparing 8
 - sterilizing 11
 - using 32
- HeartMate Touch
 - disposal 10
 - environmental requirements
 - for operation 9
 - for storage and transport 3
 - setting up 12
- HeartMate Touch App
 - date and time 35
 - extended alarm silence
 - cancelling 45
 - setting 45
 - pump flow 52
 - pump power 53
 - pump speed 51
 - screens
 - clinical 56
 - selecting System Controller language on 39
- HeartMate Touch Communication System 3
 - pulsatility index 54
 - setting up 8
- heparin 10
- Holster Vest 53
- Holster, Battery 47
- hospital-supplied equipment for implant 6
- humidity, acceptable range
 - for operation 9
 - for storage and transport 3
- I**
- implant
 - hospital-supplied equipment 6
 - kit 5
 - preparing patient for 12
 - required components 13
- implant procedures 27
 - attaching outflow graft 37
 - creating driveline exit site 33
 - de-airing the pump 38
 - final check before implant 33
 - inserting inflow conduit 36
 - preparing ventricular apex site 34
 - securing the pump 45
- implantable cardiac defibrillator (ICD) 13
- implantable pacemaker (IPM) 13
- infection
 - controlling 10
 - fungal 9
- inflow conduit
 - characteristics 7
 - inserting 36
 - introduction 16
 - preparing for implant 23
- initializing
 - HeartMate Touch 12
 - System Controller 14
- installing
 - Mobile Power Unit batteries 35
 - Power Module backup battery 7
 - System Controller backup battery 49
- internal bleeding, unexplained 12
- international travel
 - Battery Charger power cord for 70
- intra-abdominal placement, surgical technique 32
- L**
- language display mode on Battery Charger 71
- languages available on System Controller 39
- low battery advisory alarm 18
- low battery alarms, recognizing 33
- low battery hazard alarm 16
- low battery screen 16, 18
- low flow alarm 12, 15
- low speed alarm 21
- low voltage advisory alarm 18
- low voltage hazard alarm 16
- M**
- magnetic resonance imaging (MRI) 11
- measuring blood pressure 10
- medical waste, disposal of 11
- Mobile Power Unit 30
 - alarms 40
 - cleaning 6
 - disposal 10
 - installing batteries 35
 - maintenance 44
 - patient cable connectors 40
 - power cord 38

- setting up 35
- storage 44
- Mobile Power Unit (MPU) 4
- monthly checklist 6

N

- Neck Strap 31
- no external power alarm 14

O

- on-battery power gauge 49
- operating modes for System Controller 34
 - switching 37
- optimal fixed speed, determining 28
- outflow graft
 - attaching 37
 - characteristics 7
 - introduction 16
 - preparing for implant 24

P

- pacemaker 13
- patient care
 - assessment 8
 - education 68
 - potential complications 8
 - potential risks 8
 - preimplant preparation 12
- post-approval studies 46
- postimplant procedures 47
 - device tracking 52
 - installing System Controller backup battery 49
 - transferring patient out of OR 47
- potential complications 8
- power cable disconnected alarm 17
- power cables
 - caring for 67
 - connecting to System Controller 27
 - connectors on System Controller 17
 - System Controller, cleaning 5
- power gauge on 14 Volt Lithium-Ion battery 49
- Power Module 4, 6
 - alarms 37
 - alarms, silencing 29
 - backup battery 5
 - charge status 21
 - charging 20
 - connecting 7
 - disconnecting 23
 - disposal 10
 - installing 7
 - cleaning 6
 - connecting to System Controller 15
 - disposal 10

- environmental requirements
 - for operation 9, 3
 - for storage and transport 3
- patient cable 13
- self test 19
- power parameter for pump 18
- power saver mode 55
- preimplant procedures 7
 - initializing HeartMate Touch 12
 - initializing System Controller 14
 - preparing inflow conduit 23
 - preparing outflow graft 24
 - preparing patient 12
 - preparing the pump 18
 - priming the pump assembly 25
 - warnings and cautions 7
- preparing for sleep 63
- preparing ventricular apex site 34
- preperitoneal placement, surgical technique 31
- preperitoneal versus intra-abdominal placement 31
- product list 3
- Protection Bag for backup System Controller 60
- pulsatility index parameter 18
 - viewing on clinical screen 54
- pump
 - components 6
 - de-airing 38
 - disposal 11
 - explant procedures 53
 - overview 3
 - parameters
 - flow 18
 - power 18
 - pulsatility index 18
 - speed 17
 - viewing on clinical screen 52
 - preparing for implant 18
 - preperitoneal versus intra-abdominal placement 31
 - priming 25
 - securing 45
 - viewing status on System Controller 21
- pump off alarm 12
- pump running symbol 18

R

- recycling batteries 10
- red battery symbol
 - on Power Module 21
 - on System Controller 18
- red heart symbol 18
- replace controller, controller fault alarm 18
- replace power immediately screen 16

Index

- replace power screen 18
- replace System Controller
 - instructions 55
 - screen 18
- reporting requirements and device tracking 52
- right heart failure 12
- rotations per minute (rpm) 15
- Run Mode, System Controller 34

S

- safety checklists 1
- safety tab on System Controller 23
- Sealed Outflow Bend Relief Collar 45
- self test
 - performing on Power Module 19
 - performing on System Controller 29
- Shower Bag 15
 - caring for 24
 - cleaning 8
- showering 15
- Silence Alarm button
 - on Power Module 37
 - on System Controller 20
- silencing Power Module alarms 29
- Sizer
 - preparing 8
 - sterilizing 11
 - using 32
- Sleep Mode, System Controller 35
- sleep, preparing for 63
- specifications, technical 3
- speed parameter for pump 17
- Stabilization Belt 25
 - cleaning 8
- static electric discharge, avoiding 12
- storage, environmental requirements 3
- suction event 17
- surgical technique
 - creating driveline exit site 33
 - intra-abdominal placement 32
 - preparing ventricular apex site 34
 - preperitoneal placement 31
- symbols 1
- System Controller 10
 - accessories 28
 - alarm history 5
 - alarms 3
 - backup battery fault alarm 22
 - backup System Controller 47
 - battery power gauge 19, 31
 - buttons 17
 - cleaning 4
 - clock, setting 46
 - connecting to
 - 14 Volt Lithium-Ion batteries 53
 - Mobile Power Unit 40

- Power Module 15
- connectors 17
- display button 20
- driveline
 - connecting 24
 - disconnecting 26
- environmental requirements
 - for operation 9
 - for storage and transport 3
- fault alarm 18
- installing backup battery in 49
- language, selecting on HeartMate Touch App 39
- Neck Strap 31
- operating modes 34
- power cable connectors 27
- power cables, cleaning 5
- pump status 21
- red battery symbol 18
- red heart symbol 18
- replacing with backup System Controller 55
- safety tab 23
- self test, performing 29
- setting date and time in 35
- setting up 14
- silence alarm button 20
- switching operating modes 37
- user interface 17
- viewing alarm history on 5
- wear and carry accessories 28
- yellow diamond symbol 19
- yellow wrench symbol 18

System Controller Neck Strap 31

T

- taking a shower 15
- technical specifications 3
- temperature, acceptable ranges
 - for operation 9
 - for storage and transport 3
- transport, environmental requirements for 3
- Travel Bag 61
- travel, power cord considerations 70
- troubleshooting alarms 3

U

- user interface on System Controller 17

V

- ventricular apex site, preparing 34
- Vest, Holster 53

W

- warnings, defined 3
- wear and carry accessories 28

- Battery Holster 47
- Belt Attachment 35
- cleaning 8
- Consolidated Bag 39
- Holster Vest 53
- Protection Bag 60
- Shower Bag 15
- System Controller Neck Strap 31
- Travel Bag 61
- weekly checklist 5

X

- x-rays, using to determine driveline damage
6

Y

- yearly checklist 10
- yellow diamond symbol 19
- yellow wrench symbol
 - on Power Module 21
 - on System Controller 18

Index



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