HeartWare® Ventricular Assist System

Patient Manual

CAUTION: Federal law restricts this device to sale by or on the order of a physician.
IMPORTANT
Please read this entire manual before using the HeartWare® Ventricular Assist System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.

CONTACT INFORMATION
All problems should be promptly reported to medical or technical personnel. Before you leave the hospital, add names and contact information below. It is very important to keep this information available in case something happens to you or to your HeartWare® System.

TECHNICAL ASSISTANCE FOR HEARTWARE® VENTRICULAR ASSIST SYSTEM

<table>
<thead>
<tr>
<th>Name</th>
<th>Office</th>
<th>Pager</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Office</th>
<th>Pager</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MEDICAL ASSISTANCE

<table>
<thead>
<tr>
<th>Name</th>
<th>Office</th>
<th>Pager</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Office</th>
<th>Pager</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AMBULANCE

<table>
<thead>
<tr>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### QUICK REFERENCE GUIDE FOR ALARMS

When an alarm occurs, two lines of text appear in the Controller Display. The first line tells you what the alarm is, and the second line tells you what to do. The chart below shows all potential alarms you may see on your controller.

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Alarm Display (line 1)</th>
<th>Action (line 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“No Power” Alarm</strong></td>
<td>&lt;no message&gt;</td>
<td>&lt;no message&gt;</td>
</tr>
<tr>
<td><strong>High - Critical</strong></td>
<td>VAD Stopped</td>
<td>Connect Driveline</td>
</tr>
<tr>
<td><strong>(Flashing Red)</strong></td>
<td>VAD Stopped</td>
<td>Change Controller</td>
</tr>
<tr>
<td></td>
<td>Critical Battery 1</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td></td>
<td>Critical Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td></td>
<td>Controller Failed</td>
<td>Change Controller</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Controller Fault</td>
<td>Call</td>
</tr>
<tr>
<td><strong>(Flashing Yellow)</strong></td>
<td>Controller Fault</td>
<td>Call: ALARMS OFF</td>
</tr>
<tr>
<td></td>
<td>High Watts</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Electrical Fault</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Low Flow</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Suction</td>
<td>Call</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Low Battery 1</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td><strong>(Solid Yellow)</strong></td>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td></td>
<td>Power Disconnect</td>
<td>Reconnect Power 1</td>
</tr>
<tr>
<td></td>
<td>Power Disconnect</td>
<td>Reconnect Power 2</td>
</tr>
</tbody>
</table>
TABLE OF CONTENTS

1 GLOSSARY OF TERMS ............................................................................................................................................ 1

2 INTRODUCTION .................................................................................................................................................... 4
  2.1 WHEN VENTRICULAR ASSIST DEVICES ARE INDICATED ............................................................................ 4
  2.2 WHY YOU SHOULD READ THIS MANUAL ................................................................................................. 4
  2.3 UNDERSTANDING HOW YOUR HEARTWARE® VENTRICULAR ASSIST SYSTEM WORKS .................. 4
  2.4 HEARTWARE® VENTRICULAR ASSIST SYSTEM COMPONENTS ............................................................... 5

3 WARNINGS AND PRECAUTIONS .......................................................................................................................... 7
  3.1 WARNINGS ....................................................................................................................................................... 7
  3.2 PRECAUTIONS ................................................................................................................................................... 9

4 POTENTIAL COMPLICATIONS AND RISKS .......................................................................................................... 10

5 POTENTIAL BENEFITS ......................................................................................................................................... 12
  5.1 HOW TO DECIDE IF A HEARTWARE® SYSTEM IS THE RIGHT TREATMENT FOR YOU ......................... 12
  5.2 THE OPERATION TO PLACE THE HEARTWARE® SYSTEM ......................................................................... 12
  5.3 SUMMARY OF CLINICAL STUDY INFORMATION USING THE HEARTWARE® SYSTEM .......................... 13

6 HEARTWARE® SYSTEM ....................................................................................................................................... 13
  6.1 HVAD® PUMP .................................................................................................................................................... 13
  6.2 HEARTWARE® CONTROLLER ......................................................................................................................... 14
  6.2.1 USING THE CONTROLLER .......................................................................................................................... 15
  6.2.2 HOW TO CHANGE THE CONTROLLER ....................................................................................................... 17
  6.3 POWER SOURCES FOR THE HEARTWARE® CONTROLLER ........................................................................ 19
  6.3.1 CONNECTING POWER SOURCES ................................................................................................................ 20
  6.3.2 DISCONNECTING POWER SOURCES ........................................................................................................... 21
  6.3.3 CHANGING POWER SOURCES .................................................................................................................... 21
  6.3.4 USING BATTERY POWER ............................................................................................................................ 21
  6.3.5 RECOMMENDED PRACTICES FOR POWER MANAGEMENT ................................................................. 23
  6.3.6 CHANGING A BATTERY ............................................................................................................................... 24
  6.3.7 CARE OF BATTERIES .................................................................................................................................. 24
  6.4 HEARTWARE® BATTERY CHARGER ............................................................................................................... 25
  6.4.1 CONNECTING BATTERIES TO THE BATTERY CHARGER ......................................................................... 26
  6.4.2 DISCONNECTING BATTERIES FROM THE BATTERY CHARGER .............................................................. 26

7 ALARMS ................................................................................................................................................................. 26
  7.1 NO POWER ALARM ........................................................................................................................................... 27
  7.2 HIGH ALARMS .................................................................................................................................................. 27
  7.3 MEDIUM ALARMS .......................................................................................................................................... 28
  7.4 LOW ALARMS .................................................................................................................................................. 29
  7.5 MULTIPLE ALARMS ........................................................................................................................................ 29
  7.6 HOW TO SILENCE (MUTE) ALARMS .............................................................................................................. 30

8 EQUIPMENT CARE AND MAINTENANCE .......................................................................................................... 31
  8.1 HOW LONG HEARTWARE® EQUIPMENT SHOULD LAST ............................................................................. 31
  8.2 GENERAL CARE ............................................................................................................................................. 31
  8.3 CONTROLLER ................................................................................................................................................... 31
  8.4 BATTERIES ....................................................................................................................................................... 32
  8.5 BATTERY CHARGER ...................................................................................................................................... 32

9 ACTIVITIES OF DAILY LIVING ............................................................................................................................ 33
1 GLOSSARY OF TERMS

If you have any questions or need more information about the terms defined below, please ask your doctor or VAD coordinator.

A

AC Adapter: An adapter that uses power from an electrical outlet to run the controller.

Alarm Adapter: A small red adapter, that when inserted into the controller, will silence the “No Power” alarm if power is removed from a controller that is no longer in use.

Alarm Mute Button: A button on the front of the controller that silences low and medium level alarms. When pressed and held for 5 seconds simultaneously with the Scroll Button, it will also silence the “No Power” alarm if power is removed from a controller that is no longer in use.

Alarm Indicator: A button on the front of the controller that lights when one or more alarm conditions occur. The indicator changes colors depending on the severity of the alarm and always displays the most severe alarm in the case of multiple alarms.

Anticoagulants: Drugs that increase the time it takes blood to clot.

B

Battery: One of the power sources used to run the pump. Two batteries or one battery and an AC adapter or DC adapter are required at all times.

Battery Charger: Unit used to charge batteries. Up to four batteries may be charged at a time.

Battery Capacity Display: The Battery Capacity Display on the battery uses four green lights to show how much power remains in the battery. Each green light represents approximately 25% of available power. When a battery is charged and ready for use, all four lights will be on. As the battery loses charge, fewer lights will appear.

Cardioversion: Controlled electrical shock used to return the heart to a normal beating pattern.

Controller: A small computer that operates the pump and makes sure it is working correctly. It warns the user with words, lights and sounds if there is a problem.

Controller AC/DC Indicator: The Controller AC/DC Indicator will be green if you are using the AC adapter or DC adapter to power the controller.

Controller Battery Indicators: The Controller Battery Indicators are located on the top of the controller and are labeled “1” and “2”. Either the “1” or “2” light will be lit, depending upon which port is providing primary battery power to the controller. The Controller Battery Indicators tell you approximately how much power remains in each battery. When a battery is fully charged, all four lights will be on. As the battery loses charge, fewer lights appear.
HeartWare® Ventricular Assist System Patient Manual

D

DC Adapter: An adapter that uses power from an electrical outlet in an automobile to run the controller.

Driveline: The cable that passes through the skin and connects to the implanted pump and to the external HeartWare® System components.

Driveline Cover: A small, white cover that slides over the pump/controller connection to protect it and keep it clean.

E

ESD: Electrostatic discharge (static electricity)

Exit Site: Location where the driveline passes through the skin.

H

HeartWare® System: All of the components, both internal and external, needed to implant and run the HVAD® Pump.

High Alarm: The most serious audio and visual (flashing red) alarm. High priority alarms require immediate attention.

HVAD® Pump: A pumping device that sits inside your chest and is connected directly to your heart. It helps your heart pump blood throughout the rest of your body.

I

Impeller: The only moving part of the pump. As the impeller spins it moves blood from the heart to the rest of the body.

L

Low Alarm: An audio and visual (solid yellow) alarm that instructs you to either replace a low battery or to reconnect to a power source (battery, AC adapter or DC adapter).

L/min: Liters per minute. Measurement of how much blood the pump is pumping through the body in a minute. Shown on the Controller Display.

LVAD: Left ventricular assist device. A mechanical pump that helps the left side of the heart pump blood through the rest of the body.

LVAS: Left ventricular assist system. A heart assist system that includes an implanted pump as well as an external controller with associated power sources (batteries, AC adapter, and DC adapter) and accessories.

M

Medium Alarm: An audio and visual (flashing yellow) alarm that requires you to notify your doctor or VAD coordinator.

Multiple Alarms: Condition in which there are two or more alarms occurring at the same time.
No Power Alarm: An audible only alarm that sounds when both power sources are removed from the controller.

Pump: A device (also known as an LVAD) that moves blood from your heart to other parts of your body. The pump is implanted at the base of your heart during surgery.

RPM: Revolutions per minute. The number of times the impeller in the pump spins in a minute. Shown on the Controller Display.

Scroll Button: Located on the right side of the controller, the Scroll Button is used to see all active alarms and pump information (RPM, L/min, Watts) on the Controller Display. The Scroll Button will also clear resolved medium alarms from the Controller Display, will silence a “No Power” alarm when pressed with the Alarm Mute Button (see Alarm Mute Button), and will brighten the Controller Display.

Shower Bag: A bag that holds the controller and two batteries during a shower.

Test Button: A button on the battery that displays battery capacity when pressed.

VAD: Ventricular Assist Device. A mechanical device that assists the heart.

Watts: Measurement of the amount of electricity used to run the pump. Shown on the Controller Display.
HeartWare® Ventricular Assist System Patient Manual

2 INTRODUCTION

Congestive heart failure is a condition in which a heart cannot pump enough blood to meet the body’s needs. A failing heart works, but not as efficiently as it should. As blood flow leaving the heart slows, blood flow returning to the heart will back-up, causing congestion in the tissues. Along with congestion in the tissues, swelling (edema) often results. Swelling most often occurs in the legs and ankles but it can happen in other parts of the body, too. Fluid may collect in the lungs and interfere with breathing, causing shortness of breath, especially when a person is lying down. Heart failure also affects the kidneys' ability to dispose of waste and extra fluid. Fluid retained by the kidneys increases swelling. People with heart failure cannot exert themselves because they become short of breath and tired. With advanced heart failure, symptoms of tissue wasting and weight loss can occur. Severe heart failure can progress to shock (shock due to inadequate oxygen and nutrients delivered by the heart) and eventual death.

2.1 When Ventricular Assist Devices are Indicated

Doctors use VADs such as the HeartWare® System to treat patients who are waiting to receive a heart transplant and have severe heart failure that has not improved despite using all other treatment methods available.

The HeartWare® System should not be used in patients who cannot take blood thinning medications.

2.2 Why You Should Read this Manual

This Patient Manual will tell you about your HeartWare® System and explain how it works. It also provides information about proper care of the HeartWare® System and what to do in case of an emergency.

In addition to this manual, your physician, nurse or VAD coordinator will provide you with instructions on operating the HeartWare® System and on necessary medical care. Prior to leaving the hospital you should understand how the HeartWare® System works, how to care for the equipment and what to do in emergency situations. If you have any questions after reading this manual, please ask your physician, nurse or VAD coordinator.

2.3 Understanding How Your HeartWare® Ventricular Assist System Works

The HeartWare® System helps your weakened heart pump blood throughout your body. The pump, called the HVAD® Pump, circulates blood by removing it from the left side of your heart and pumping it into your aorta (large blood vessel that carries blood from your heart to the rest of your body). The pump rests inside your chest and two small motors inside the pump circulate the blood (Figure 1). A driveline (electrical wire) exits your skin and connects the pump to a controller. The controller is powered by two batteries or a battery and electricity from the wall or car outlet. The controller operates the pump and tells you if there are any problems with your system. The controller and batteries are contained in a Carrying Case.
2.4 HeartWare® Ventricular Assist System Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVAD® Pump</td>
<td>The pump moves blood from your heart to other parts of your body. The pump is implanted at the base of your heart during surgery.</td>
</tr>
<tr>
<td>HeartWare® Controller</td>
<td>The controller operates the pump and makes sure it is working correctly. It warns you with words, lights and sounds if there is a problem.</td>
</tr>
<tr>
<td>HeartWare® Battery</td>
<td>The battery is used to power the controller and the pump. Two batteries or one battery and an AC adapter or DC adapter are <strong>ALWAYS</strong> required.</td>
</tr>
</tbody>
</table>
### HeartWare® Ventricular Assist System Patient Manual

<table>
<thead>
<tr>
<th>HeartWare® Battery Charger</th>
<th>The battery charger charges and tests the batteries.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driveline Cover</td>
<td>A small, white cover that slides over the pump/controller connection and protects the controller and pump connector.</td>
</tr>
<tr>
<td>HeartWare® Controller AC Adapter</td>
<td>The AC adapter uses power from an electrical outlet to power the controller and pump.</td>
</tr>
<tr>
<td>HeartWare® Controller DC Adapter</td>
<td>The DC adapter uses power from an electrical outlet in a motor vehicle to power the controller and pump.</td>
</tr>
<tr>
<td>Alarm Adapter</td>
<td>The red alarm adapter is for emergency use only. The adapter is used to silence the “No Power” alarm when power is removed from a controller that is no longer in use.</td>
</tr>
</tbody>
</table>

**Recommended environmental conditions for general use of the HeartWare® System:**

- Temperature range within 10°C to 31°C (50°F to 88°F)
- Relative humidity range within 30% to 75%
3 WARNINGS and PRECAUTIONS

3.1 Warnings

1. **WARNING!** Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

2. **WARNING!** Please read this entire manual before using the HeartWare® System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.

3. **WARNING!** DO NOT become pregnant while you have the HeartWare® System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most LVAS patients receive) have been associated with birth defects. If you do become pregnant, tell your physician and hospital contact person immediately.

4. **WARNING!** DO NOT operate the controller in temperatures less than -4°F (-20°C) or greater than 122°F (50°C) or the controller may fail.

5. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

6. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

7. **WARNING!** ALWAYS keep a spare controller and fully-charged spare batteries available at all times in case of an emergency.

8. **WARNING!** DO NOT attach the alarm adapter to a controller that is connected to a running pump. The alarm adapter silences the “No Power” alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.

9. **WARNING!** DO NOT plug the AC adapter into an electrical outlet that is not properly grounded or you may receive a serious electrical shock.

10. **WARNING!** ALWAYS replace a controller with a blank display and/or no audible alarms.

11. **WARNING!** NEVER disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the No Power alarm. At least one power source must be connected at all times.

12. **WARNING!** ALWAYS switch to the backup controller if there is a “Controller Failed” alarm.

13. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected.

14. **WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises since under these conditions, the controller and battery alarms may not be audible.

15. **WARNING!** DO NOT have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® System. Doing so could harm you or cause the pump to stop.
HeartWare® Ventricular Assist System Patient Manual

16. **WARNING!** Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

17. **WARNING!** DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.

18. **WARNING!** AVOID exposure to therapeutic levels of ultrasound energy. Consult your physician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.

19. **WARNING!** AVOID therapeutic ionizing radiation. Consult your physician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.

20. **WARNING!** Avoid devices and conditions that may induce strong static discharges (e.g., television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the LVAD to perform improperly or stop.

21. **WARNING!** Always have a backup controller handy and, whenever possible, a caregiver nearby when changing power sources or controllers. Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

22. **WARNING!** DO NOT shower until your physician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare® Shower Bag. If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

23. **WARNING!** DO NOT plug the controller into an AC wall outlet during showers; it should be connected to two batteries.

24. **WARNING!** DO NOT take a bath or swim.

25. **WARNING!** DO NOT submerge any HeartWare® System component in water.

26. **WARNING!** DO NOT allow water or other fluids to enter the controller, power (AC/DC) adapters, batteries, battery charger, or connectors. If this happens, contact your physician, nurse or VAD coordinator.

27. **WARNING!** AVOID areas with high magnetic forces such as theft detection devices, airport security systems or induction cooktops, as these may affect HeartWare® Systems operation.

28. **WARNING!** Damaged equipment should be reported to your VAD coordinator and inspected.

29. **WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.

30. **WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

31. **WARNING!** NEVER clean the battery charger with the power on, as this may lead to an electrical shock.
3.2 Precautions

1. **CAUTION:** Tell your physician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.

2. **CAUTION:** ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.

3. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

4. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

5. **CAUTION:** DO NOT pull, twist or kink the driveline or power cables, especially while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag.

6. **CAUTION:** ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

7. **CAUTION:** Use only HeartWare-supplied power adapters with the HeartWare® System.

8. **CAUTION:** ALWAYS recharge completely depleted batteries within 24 hours to avoid permanent battery damage.

9. **CAUTION:** DO NOT place batteries in water or liquid.

10. **CAUTION:** DO NOT expose batteries to temperatures less than 32°F (0°C) or greater than 113°F (45°C) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

11. **CAUTION:** DO NOT expose batteries to excessive shock or vibration.

12. **CAUTION:** DO NOT disassemble, crush, or puncture a battery.

13. **CAUTION:** DO NOT short the external contacts on a battery.

14. **CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.

15. **CAUTION:** DO NOT use a damaged battery.

16. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

17. **CAUTION:** DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

18. **CAUTION:** NEVER use other battery chargers to charge HeartWare® Batteries. Other battery chargers may damage the batteries.

19. **CAUTION:** ALWAYS wait until the “Ready” light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.
HeartWare® Ventricular Assist System Patient Manual

20. **CAUTION:** ALWAYS call your clinician for appropriate action if there is a “Controller Fault” alarm. The controller may need to be replaced with the back-up controller.

21. **CAUTION:** DO NOT attempt to repair or service HeartWare® System equipment. If service is required, contact your physician, nurse or VAD coordinator.

22. **CAUTION:** Use only HeartWare-supplied components with your HeartWare® System.

23. **CAUTION:** DO NOT play contact sports. You may start bleeding or could damage your equipment.

24. **CAUTION:** DO NOT pull, kink or twist the driveline or the power cables. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

25. **CAUTION:** ALWAYS keep extra driveline length tucked under clothing or secured with an abdominal binder or dressing. Do not let any portion of driveline hang freely where it might get caught on external items such as doorknobs or the corners of furniture.

26. **CAUTION:** ALWAYS notify your physician promptly if there is drainage, swelling or reddened skin around the driveline exit site, these may indicate an infection.

27. **CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine, or polymyxin-neomycin-bacitracin ointment. These ointments can injure the tissue adjacent to the exit site.

28. **CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your physician, nurse or VAD coordinator.

29. **CAUTION:** ALWAYS notify your physician promptly, if you notice blood or fluid in the driveline. The section of the driveline inside your body may have been damaged during HVAD® Pump implantation or during another operation. The driveline has built in features that minimize the effect of blood or fluid entering it, so the HVAD® Pump should continue to operate normally. However, your physician should examine the driveline to fully evaluate the situation.

30. **CAUTION:** The HeartWare® Waist Pack and the HeartWare® Shoulder Pack contain magnetic closures. Patients with an internal cardiac defibrillator (ICD) or pacemaker should keep the pack away from their chest and should not sleep with the pack to avoid proximity to the ICD or pacemaker. The Patient Pack without magnets should be used when sleeping. Per pacemaker and ICD manufacturer guidelines, magnets should be kept at least 6 inches (15 cm) away from the pacemaker or ICD (please refer to manufacturer guidelines for additional information).

### 4 POTENTIAL COMPLICATIONS AND RISKS

During the two clinical studies a variety of potential complications were identified. Many of these complications were well known from prior experience with other ventricular assist devices however, it is important that you understand all of the potential complications that may occur with the HeartWare® Ventricular Assist System. Implantation of any ventricular assist device is a major operation requiring general anesthesia, an incision that splits the breast bone, being on a heart-lung
machine and a breathing machine. Each of these procedures may lead to serious complications. Complications associated with HeartWare® System use and the percentages of patients who develop these complications are shown in the table below. It is possible that a complication not listed in this table may occur.

**WARNING!** Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

### Complications That May Occur with the HeartWare® System:

<table>
<thead>
<tr>
<th>Complication</th>
<th>Percent Chance for Patients to Have this Complication</th>
<th>Result of Having a Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>40%</td>
<td>Hospitalization, medication, death</td>
</tr>
<tr>
<td>Bleeding</td>
<td>39%</td>
<td>Hospitalization, blood transfusion, surgery, death</td>
</tr>
<tr>
<td>Irregular Heart Beat</td>
<td>32%</td>
<td>Hospitalization, medication, cardioversion*, death</td>
</tr>
<tr>
<td>Failure of the Right Side of the Heart</td>
<td>22%</td>
<td>Hospitalization, medication, pump for right side of heart, death</td>
</tr>
<tr>
<td>Lung Problems</td>
<td>18%</td>
<td>Hospitalization, medication, ventilator, death</td>
</tr>
<tr>
<td>HeartWare® System Malfunction/Failure</td>
<td>16%</td>
<td>Hospitalization, medication, surgery, death</td>
</tr>
<tr>
<td>Nervous System (brain or nerve) Problems</td>
<td>15%</td>
<td>Confusion, loss of memory, pain, death</td>
</tr>
<tr>
<td>Stroke</td>
<td>12%</td>
<td>Hospitalization, medication, surgery, rehabilitation, death</td>
</tr>
<tr>
<td>Blood Clots in the Bloodstream</td>
<td>10%</td>
<td>Hospitalization, medication, death</td>
</tr>
<tr>
<td>Psychological Problems</td>
<td>8%</td>
<td>Hospitalization, medication, depression</td>
</tr>
<tr>
<td>Kidney Problems</td>
<td>8%</td>
<td>Hospitalization, medication, dialysis, death</td>
</tr>
<tr>
<td>Liver Problems</td>
<td>5%</td>
<td>Hospitalization, medication, death</td>
</tr>
</tbody>
</table>
HeartWare® Ventricular Assist System Patient Manual

<table>
<thead>
<tr>
<th>Complication</th>
<th>Percent Chance for Patients to Have this Complication</th>
<th>Result of Having a Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damage to Blood Cells</td>
<td>3%</td>
<td>Hospitalization, medication</td>
</tr>
<tr>
<td>Heart Attack</td>
<td>0.3%</td>
<td>Hospitalization, medication, death</td>
</tr>
</tbody>
</table>

*Cardioversion: Controlled electrical shock used to return the heart to a normal beating pattern*

5  POTENTIAL BENEFITS

The HeartWare® System was designed to assist a failing heart. The potential benefit of having the HeartWare® System is the relief of the symptoms of advanced heart failure while you are waiting for a heart transplant. However, there is no guarantee of this and your symptoms may remain unchanged. As a result of the relief of symptoms of heart failure you will feel stronger and have the ability to be more active.

5.1  How to Decide if a HeartWare® System is the Right Treatment for You

Only you, in consultation with your doctor can decide if having the HeartWare® System is right for you. Your doctor will talk with you about the potential benefits and risks of surgery and implantation of the HeartWare® System. Be sure to talk to your doctor about any concerns or questions you may have.

5.2  The Operation to Place the HeartWare® System

Placement of the HeartWare® System requires a major operation. An incision will be made on the breastbone so the surgeons can gain access to your heart. You will be temporarily placed on a heart-lung machine that will do the work of your heart and lungs while the surgeons are placing the HVAD® Pump. Part of the HVAD® Pump will be inside the heart and part will sit in the chest cavity, right next to the heart. An electrical wire called a driveline will be tunneled under the skin and come out through the skin just above the abdomen. The driveline wire will connect the external computer (controller) that runs the pump and the power sources to the implanted pump. After the pump is in place and working, you will be weaned from the heart–lung machine and the incisions will be sutured closed.

Once the HVAD® Pump has been implanted, you will be taken to the Intensive Care Unit where nurses and doctors will provide you with the level of care you need. You will be on a breathing machine for 12-24 hours and will have to spend some time in the Intensive Care Unit. You will also be connected to several intravenous lines and drainage tubes. During this time you will receive antibiotics to reduce the risk of infection and medications to help keep your heart beating regularly. You may also need to get some blood transfusions. None of these treatments are unusual; they are all intended to reduce the chances that a complication may occur. As you regain your strength, you will be taken off the breathing machine and the intravenous lines and the tubes will be removed. You may also be moved from the Intensive Care Unit to a general hospital floor. While you are in the
hospital, you will begin a rehabilitation program designed to help you return to a more active lifestyle. As part of this program, you and your caregiver will be given training on the HeartWare® System. For example, you will be trained on how to use your HeartWare® System at home and how to interpret and handle the messages and alarms that may appear on your controller.

5.3 Summary of Clinical Study Information using the HeartWare® System

The HeartWare® System when used to bridge patients to heart transplantation has been evaluated in two clinical studies. The first clinical study was conducted in Europe and Australia. This study included 50 patients of which 90% successfully reached the study success point. The definition of success was:

- Being alive on the HeartWare® System for 180 days or
- Receiving a heart transplant within 180 days of having the HVAD® Pump implanted or
- Having the HVAD® Pump successfully removed after the patient’s own heart recovered within 180 days of HVAD® Pump implant.

Six patients from this study still have the HeartWare® System; with the longest patient being on the system 4.5 years.

A second, larger bridge to heart transplantation study was performed in the United States. This study included 140 patients. Of the 140 patients who received the HeartWare® System as bridge to heart transplantation in the United States, 91% reached the study success point. In both these studies, there were improvements in the patients’ quality of life and their ability to better perform physical activities with at least 92% of the patients being able to return home after the HeartWare® System was placed. The risks identified in the clinical trials are described in Section 4, “Potential Complications and Risks”.

6 HEARTWARE® SYSTEM

The HeartWare® System includes the following major components:

1. HVAD® Pump
2. Controller
3. External power – battery, AC adapter and DC adapter
4. Battery charger

6.1 HVAD® Pump

The HVAD® Pump (also known as an LVAD) is small and has one moving part, called an impeller (Figure 2). As the impeller spins it moves blood from the heart to the body. The amount of blood flowing through your pump depends on the speed of the impeller and your blood pressure. The driveline passes through your skin and connects the pump to the controller.
6.2 HeartWare® Controller

The controller (Figure 3) operates your pump and makes sure that it is working correctly. The controller is connected to your driveline and should have two power supplies (batteries, AC adapter or DC adapter) connected at all times. The display on the controller gives information about pump performance that includes the blood flow through the pump (L/min), impeller speed (RPM) and the amount of power consumed (Watts). The controller also warns you if there is a problem with your pump or with the power supplies connected to your controller.

**Figure 3: Controller**

1. Monitor Connection
2. Power Connection
3. Driveline Connection
4. Power Connection

**CAUTION:** Tell your physician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.
6.2.1 Using the Controller

Controller Connections

There are four connectors on the controller (see Figure 3): 2 power supply connectors, 1 driveline connector, and 1 monitor connector.

- The **power supply connectors** are identical and are used to provide power to the controller. The controller should always be connected to two power sources, either 2 batteries, or 1 battery and an AC adapter or DC adapter (car adapter). To preserve battery life, use the AC adapter when you are resting or sleeping.

- The driveline is attached to a silver **driveline connector**. Never disconnect the driveline from the controller unless an emergency controller exchange is required.

  **WARNING! DO NOT** disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

- The **monitor connector** (blue) is used by clinicians to change pump settings and to collect information about your pump. For emergency situations, you may put the alarm adapter in this connector to silence the “No Power” alarm.

**Controller Display, Buttons and Indicators**

![Controller Display with Pump Parameters](image)

*Figure 4: Controller Display with Pump Parameters:*
1. AC/DC Indicator
2. Alarm Mute
3. Battery Indicator #1
4. Alarm Indicator
5. Battery Indicator #2
6. Scroll Button
7. Controller Display
### Guide to Controller Display, Buttons, and Indicators (Refer to Figure 4)

<table>
<thead>
<tr>
<th><strong>The CONTROLLER DISPLAY</strong> gives pump information including impeller speed (RPM), power (Watts), and blood flow (L/min). When an alarm occurs, the pump information is replaced by two lines of text that tell you what the alarm is and what to do. Section 7, “Alarms”, describes alarms in detail.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![3000 RPM 5.0 L/min 4.8 Watts]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>The AC/DC INDICATOR</strong> will be green if you are using the AC adapter or DC adapter to power the controller.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![AC/DC Indicator]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>The two BATTERY INDICATORS</strong> located on the top of the controller are labeled “1” and “2”. Either the “1” or “2” will be lit, depending upon which port is providing primary power. If an AC or DC adapter is connected, this will be the primary power source. The Battery Indicators tell you approximately how much power remains in each battery.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Battery Indicator 1]</td>
</tr>
</tbody>
</table>
- 75-100% battery capacity: 4 GREEN lights
- 50-74% battery capacity: 3 GREEN lights
- 25-49% battery capacity: 2 YELLOW lights
- 24% or less battery capacity: 1 RED light

**Note:** If the AC adapter or DC adapter is connected to the controller, the corresponding Battery Indicator will not display lights but the corresponding “1” or “2” will be lit.

<table>
<thead>
<tr>
<th><strong>The ALARM INDICATOR</strong> lights when one or more alarms occur. The Alarm Indicator changes colors depending on the severity of the alarm and always displays the most severe alarm in the case of multiple alarms. The display for each alarm priority includes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Alarm Indicator]</td>
</tr>
</tbody>
</table>
- High Alarm: Flashing Red
- Medium Alarm: Flashing Yellow
- Low Alarm: Solid Yellow

<table>
<thead>
<tr>
<th><strong>The ALARM MUTE BUTTON</strong> will silence (mute) a low or medium alarm for 5 minutes or until a new alarm occurs. A high alarm cannot be silenced. Call your clinician for all medium and high alarms.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Alarm Mute Button]</td>
</tr>
</tbody>
</table>
The **SCROLL BUTTON** on the right side of the controller is used to see all active alarms as well as pump information (RPM, L/min, Watts) on the Controller Display. The Scroll Button will also clear resolved medium alarms from the Controller Display and will brighten the Controller Display.

Simultaneously pressing and holding the **ALARM MUTE** Button and the **SCROLL** button for 5 seconds will prevent the “No Power” alarm from sounding when power is removed during a controller exchange (see Section 6.2.2, “How to Change the Controller”). Use only on a controller not connected to a pump.

### Other Controller Components: Driveline Cover

The driveline cover should always cover the silver driveline connector (Figure 5) unless an emergency controller exchange is required. With proper driveline cover position you should NOT see the silver driveline connector.

![Figure 5: Driveline Cover (1) Over Connector](image)

### 6.2.2 How to Change the Controller

1. Sit or lie down.
2. Place the new controller within easy reach.
3. Connect back-up power sources to the new controller.
   - Confirm that the power cables are properly locked on the controller by gently pulling on the cable near the connector.
   - A “Power Disconnect” alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up.
   - A “VAD Stopped” alarm will activate if the pump driveline is not connected to the new controller within 10 seconds. This alarm will resolve once the pump driveline is connected.
4. Pull back the white driveline cover from the original controller’s silver connector.

5. Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A “VAD Stopped” alarm may activate. Don’t panic. You can silence the alarm after you get your pump restarted. Restarting your pump is the priority.

6. Connect the driveline to the new controller (align the two red marks and push together). If the “VAD Stopped” alarm was active on the new controller, it will now resolve.

   - The pump should restart. Verify that the pump is working. The RPM, L/min and Watts numbers should show on controller display. **If your pump does not restart, call for medical assistance immediately.**

7. To prevent the controller alarm from sounding after the power is removed, follow these instructions:

   - If a red alarm adapter is available, insert it into the blue connector on the original controller.

   - If no alarm adapter is available:
     - Press and hold the Alarm Mute and Scroll buttons on the original controller until a “beep” is heard, or for at least 5 seconds.
     - Release the Alarm Mute and Scroll buttons.
**NOTE:** If the “No Power” alarm is not disabled prior to removing both power sources, the controller alarm may sound for up to 2 hours.

8. Disconnect both power sources from the original controller. The controller will be turned off and all alarms silenced.

9. Slide the white driveline cover up to cover new controller’s silver connector.

10. Contact your VAD coordinator or hospital to obtain a new back-up controller.

**WARNING!** ALWAYS keep a spare controller and fully-charged spare batteries available at all times in case of an emergency.

**WARNING!** DO NOT attach the alarm adapter to a controller that is connected to a running pump. The alarm adapter silences the “No Power” alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.

### 6.3 Power Sources for the HeartWare® Controller

The controller requires two power sources for safety: either two batteries (Figure 6), or one battery and an AC adapter (Figure 7) or DC adapter (Figure 8). While active, you will typically use two batteries. While relaxing or sleeping, you should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. Remember, the batteries must be exchanged when their charge becomes low and an extra set of fully charged batteries should always be available.
HeartWare® Ventricular Assist System Patient Manual

6.3.1 Connecting Power Sources

1. To connect all power supplies (battery, AC adapter or DC adapter) grasp the power cable near its connector. Leave the connector free to rotate.

2. Line up the solid white arrow on the cable connector with the white dot on the controller (Figure 9).

3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click.

**NOTE:** When pushing the connector into the controller the white arrow will shift slightly. Correct locking position: White arrow aligned with white dot on controller.

4. Confirm that the power cable is properly locked to the controller (Figure 10) by gently pulling on the cable near the connector.

5. Repeat steps above for second power source.

Figure 9: Connect Power Supply: Align White Arrow and White Dot

Figure 10: Correct Locking Position: White Arrow Aligned to White Dot

**CAUTION:** ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.

**CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

**CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

**CAUTION:** DO NOT pull, twist or kink the driveline or power cables, especially while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.
6.3.2 Disconnecting Power Sources

1. Turn the connector counterclockwise until it stops.
2. Pull the connector straight out from the controller.
3. If another power source is not connected within 20 seconds, the “Power Disconnect” message will be displayed on the Controller Display and an alarm will sound.

**NOTE:** The alarm will automatically clear when another power source is connected to the controller.

6.3.3 Changing Power Sources

**Changing from two batteries to a battery and AC/DC adapter:**

1. Plug the AC adapter into a grounded electrical outlet or the DC adapter into a power port found in most cars.
2. Disconnect the battery with the least remaining charge.
3. Connect AC or DC adapter per Section 6.3.1, “Connecting Power Sources”.

Proper connection is verified when the AC/DC Indicator on the controller turns green and the corresponding Battery Indicator turns off. If the AC/DC Indicator doesn’t turn green, the controller is using battery power and the “Power Disconnect” alarm will sound.

**WARNING!** DO NOT plug the AC adapter into an electrical outlet that is not properly grounded or you may receive a serious electrical shock.

**CAUTION:** ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

**CAUTION:** Use only HeartWare-supplied power adapters with the HeartWare® System.

**Changing from an AC/DC adapter and battery to two batteries:**

Before switching from AC or DC power to battery power, make sure that a fully charged battery is available. Connect the fully charged battery after disconnecting the AC or DC adapter.

6.3.4 Using Battery Power

Each fully charged battery provides approximately 4 to 6 hours of use for normal activities such as reading or watching TV. The battery may last for less time as your activity level increases. However, if any battery provides less than 2 hours of support, it should be replaced.

Similar to the battery in a cell phone (or mobile phone), the HeartWare® Batteries lose charge over time. If a fully charged battery lasts less than 2 hours, take it out of service and replace it with a new one.
HeartWare® Ventricular Assist System Patient Manual

During your clinic visit, your health care provider might inspect your battery and download information from your controller to determine the number of times your battery has been charged and discharged. The batteries are expected to have a useful operating life of 500 charge and discharge cycles. Batteries that reach the end of their useful life should be taken out of service and replaced.

If you rotate the use of your batteries, you should get 1 year of battery service.

![Battery Diagram]

**Figure 11: Battery**

1. Battery Capacity Display
2. Test Button

<table>
<thead>
<tr>
<th>Battery Buttons and Indicators (refer to Figure 11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Battery Icon]</td>
</tr>
<tr>
<td>![Battery Icon]</td>
</tr>
</tbody>
</table>

The Battery Capacity Display (Figure 11) on the battery is similar to the Battery Indicator on the controller (see Section 6.2.1, “Using the Controller”), except that only green lights are used on the battery. For example, at 25-49% capacity, 2 green lights will be displayed on the battery while 2 yellow lights will be displayed on the controller (see chart below).

<table>
<thead>
<tr>
<th>Battery Capacity</th>
<th>Battery Capacity Display on BATTERY</th>
<th>Battery Indicator on CONTROLLER</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-100%</td>
<td>4 GREEN lights</td>
<td>4 GREEN lights</td>
</tr>
<tr>
<td>50-74%</td>
<td>3 GREEN lights</td>
<td>3 GREEN lights</td>
</tr>
<tr>
<td>25-49%</td>
<td>2 GREEN lights</td>
<td>2 YELLOW lights</td>
</tr>
<tr>
<td>≤ 24%</td>
<td>1 GREEN light</td>
<td>1 RED light</td>
</tr>
</tbody>
</table>
When one battery is depleted to less than 25% capacity, the controller will automatically switch to the other battery. An intermittent “beep” will sound, the Alarm Indicator (△) will be yellow, and a message will be displayed to replace the depleted battery (Figure 12). If the battery is NOT changed within 5 minutes, the alarm volume will escalate until the battery is exchanged with a fully charged battery.

![Battery Indicator](image1.png)  ![Active Battery Indicator](image2.png)  ![Controller Display](image3.png)  ![Alarm Indicator](image4.png)

**Figure 12: Controller Display with a Low Battery Alarm**

When a depleted battery is not exchanged and there are only a few minutes of battery time remaining in both batteries, a high priority alarm will sound, the Alarm Indicator will be flashing RED and the message on the Controller Display will read “Critical Battery.” If this happens, there are only a few minutes of power remaining before the pump stops. The batteries should be exchanged immediately.

### 6.3.5 Recommended Practices for Power Management

**Check your batteries throughout the day. Pay attention to any unusual activity.**

- The HeartWare® System’s *expected* behavior is as follows: A controller alerts and changes to the second power source only when the battery has less than (<) 25% capacity (1 indicator light) remaining.

- The HeartWare® System’s *abnormal* behaviors are as follows:
  - **Abnormal behavior:** A controller changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more indicator lights) still remaining.
    **Action:** Replace the first battery and remove from service.
  - **Abnormal behavior:** There is sudden change in charge capacity on a battery (for example, a sudden change from 4 lights to 1 light).
    **Action:** Replace the abnormally behaving battery and remove from service.
  - **Abnormal behavior:** You hear “beeping” and the controller rapidly switches back and forth between batteries.
    **Action:** Replace the battery with more indicator lights first, then replace the battery with fewer lights. Remove the battery with more lights from service as it may be a faulty battery.
HeartWare® Ventricular Assist System Patient Manual

- Any of these abnormal behaviors could lead to a critically low battery or possible loss of power. Batteries that exhibit abnormal behavior must be taken out of service and replaced.
- Similar to the battery in a cell phone, the HeartWare® Batteries lose charge over time. If a fully charged battery lasts less than 2 hours, take it out of service and replace it with a new one.

6.3.6 Changing a Battery

Make sure there is a fully-charged battery available to replace the depleted battery. Disconnect the depleted battery and replace it with the fully-charged battery. (See Section 6.3.1 and Section 6.3.2 for details on how to connect and disconnect power sources.) After a depleted battery is disconnected, the “Low Battery” alarm will resolve, as the controller will automatically switch to the second power source. If the second power source is not connected within 20 seconds, the “Power Disconnect” message will be displayed on the Controller Display and an alarm will sound. The alarm will automatically clear when the second power source is connected. When the battery is connected correctly, the Battery Indicator on the controller should light.

6.3.7 Care of Batteries

Your batteries include many features to make them safe and dependable. However, you must care for them properly.

Things to do:

1. To preserve battery life, batteries should be stored at room temperature. Protect batteries from extreme high and low temperatures.
2. Use all of your batteries. There is a serial number on each battery so you can rotate batteries.
3. Don't leave home without extra, fully charged batteries.
4. Protect the battery connector from moisture, dirt and metal at all times.
5. Handle connectors so as to avoid touching the inside.
6. Batteries should be left in the battery charger and charging when not in use.
7. Rotate the use of your batteries. If you rotate the use of your batteries, you should get 1 year of battery service.

CAUTION: ALWAYS recharge completely depleted batteries within 24 hours to avoid permanent battery damage.

Things NOT to do:

1. Avoid leaving the batteries exposed to extreme heat, especially in direct sunlight or in a closed car in the sun. The temperature can easily reach 60-65°C (140° to 150°F) which can damage the batteries.
2. DO NOT drop the batteries or let them hit hard objects.
3. DO NOT let the batteries get wet.
4. DO NOT kink or twist the battery cables.
5. DO NOT force connections to the controller or battery charger.

6.4 HeartWare® Battery Charger

The battery charger is used to charge up to 4 batteries at a time. It takes about 4 to 5 hours to fully charge a battery. The battery charger (Figure 13) must be plugged into an AC power outlet to charge batteries. The power indicator is green when the battery charger is properly connected to electrical power. Each battery slides into a slot and the battery is connected to the battery charger. It is safe to leave the battery connected to the charger when not in use.

![Battery Charger Image](image)

**Figure 13: Battery Charger**

When a battery is connected, the battery charger checks the battery and begins charging. The battery charger power light is located next to “HeartWare” (Figure 14); when lit, it means the battery charger is connected to AC power (plugged into a wall outlet). Each battery charging slot has two lights that tell you the status of the battery. A green light next to “Ready” means the battery is fully charged. The light next to “Status” may mean different things, depending upon the color. The table below describes the lights that appear next to “Status”.

![Indicator Lights on Battery Charger Image](image)

**Figure 14: Indicator Lights on Battery Charger:**

1. Ready Light
2. Status Light
3. Battery Charger Power Light
HeartWare® Ventricular Assist System Patient Manual

<table>
<thead>
<tr>
<th>Battery Charger “Status” Light</th>
<th>What it Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>Battery being charged; NOT ready for use.</td>
</tr>
<tr>
<td>Flashing Yellow</td>
<td>Battery not charging. Check battery connections. If connections are intact, switch to another battery slot. If problem persists, return battery to Clinician.</td>
</tr>
<tr>
<td>Red</td>
<td>Battery too cold or too hot; waiting to charge.</td>
</tr>
<tr>
<td>Flashing Red</td>
<td>Defective battery. Do NOT use. Mark battery and return to Clinician.</td>
</tr>
</tbody>
</table>

6.4.1 Connecting Batteries to the Battery Charger

The battery connects to the battery charger the same way it connects to the controller.

1. Grasp the cable of the battery near the connector, leaving the connector free to rotate.
2. Line up the solid white arrow on the connector with the white dot on the battery charger.
3. Gently push the cable into the battery charger until it locks in place.

6.4.2 Disconnecting Batteries from the Battery Charger

Disconnect the battery by turning the connector counterclockwise until it stops, then pull the connector straight out from the battery charger.

**CAUTION:** NEVER use other battery chargers to charge HeartWare® Batteries. Other battery chargers may damage the batteries.

**CAUTION:** ALWAYS wait until the “Ready” light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.

7 ALARMS

Alarms tell you about the pump, controller, connections, and power supplies (batteries, AC adapter, DC adapter). Alarm conditions are classified as high, medium or low. Each of these alarms has a 1) unique sound, 2) visual display (flashing RED, flashing YELLOW or YELLOW) and 3) a message. When an alarm occurs, two lines of text appear in the Controller Display. The first line tells you what the alarm is and the second line tells you what to do. When an alarm is resolved, there is no longer an alarm sound or a light displayed in the Alarm Indicator (◻). A high alarm is very serious. If you have
a high alarm, you need to take immediate action. Please call your physician, nurse or VAD coordinator for any high alarm or medium alarm. A low alarm reminds you to exchange a low battery with a fully charged battery or to reconnect to a power supply (battery or AC/DC adapter). In addition to the high, medium and low alarms, there is a “No Power” alarm that sounds if both power sources are removed from the controller. (See “Quick Reference Guide for Alarms” in the front of this manual, for a complete list of high, medium and low alarms.)

**WARNING!** ALWAYS replace a controller with a blank display or and/or no audible alarms.

### 7.1 No Power Alarm

When both power supplies (batteries, AC adapter, DC adapter) are removed, there will be NO message on the Controller Display. A loud continuous alarm will sound but the Alarm Indicator WILL NOT light. Your pump has stopped. You need to connect two power supplies immediately. If this does not resolve the alarm, immediately replace the controller with the back-up controller.

**WARNING!** NEVER disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the No Power alarm. At least one power source must be connected at all times.

### 7.2 High Alarms

A high alarm is the loudest alarm; the Alarm Indicator on the controller is flashing RED and the text message demands immediate action for VAD (pump) stoppage, controller failure or limited power to run the pump. High alarms include the following:

<table>
<thead>
<tr>
<th>Alarm (Line 1 on controller)</th>
<th>Action (Line 2 on controller)^</th>
<th>Meaning</th>
<th>Alarm Indicator</th>
<th>Alarm Sound</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAD Stopped</td>
<td>Connect Driveline</td>
<td>Driveline disconnected or connector malfunction/ broken</td>
<td>Flashing RED</td>
<td>Loud</td>
</tr>
<tr>
<td>VAD Stopped</td>
<td>Change Controller</td>
<td>Controller failure</td>
<td></td>
<td>Unable to mute alarm</td>
</tr>
<tr>
<td>Controller Failed Critical Battery 1</td>
<td>Change Controller</td>
<td>Controller failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Battery 2</td>
<td>Replace Battery 1</td>
<td>Limited battery 1 and battery 2 time remaining</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Battery 2</td>
<td>Replace Battery 2</td>
<td>Limited battery 2 and battery 1 time remaining</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
HeartWare® Ventricular Assist System Patient Manual

^ Immediate action required, and then call your physician, nurse or VAD coordinator

ALL high alarms will display a message on the Controller Display and the Alarm Indicator will flash red. The VAD will stop if the driveline is disconnected or if the controller fails. For a “VAD Stopped” alarm, the text message will tell you whether to connect the driveline or change the controller, as both of these situations may trigger this alarm.

The “Controller Failed” alarm indicates a potential controller failure; the controller should be exchanged with the back-up controller.

**WARNING!** ALWAYS switch to the backup controller if there is a “Controller Failed” alarm.

The “Critical Battery” alarm is displayed when both batteries only have a few minutes of battery time remaining to power your pump. Replace the depleted batteries with fully charged batteries or use your AC adapter or DC adapter.

### 7.3 Medium Alarms

The medium alarm starts at a low volume and gets louder over the next minute, unless the Alarm Mute button is pressed. A medium alarm is indicated by a flashing YELLOW Alarm Indicator, and the text message tells you to call medical personnel. Please call your doctor or nurse immediately to receive instructions.

<table>
<thead>
<tr>
<th>Alarm (Line 1 on controller)</th>
<th>Action (Line 2 on controller)</th>
<th>Meaning</th>
<th>Alarm Indicator</th>
<th>Alarm Sound</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Watts</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical Fault</td>
<td>Call*</td>
<td>A change in the status of your VAD is detected</td>
<td>Flashing YELLOW</td>
<td>Gradual increase in volume over the first minute if alarm not muted.</td>
</tr>
<tr>
<td>Low Flow</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Controller Fault^</td>
<td>Call*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Controller Fault^</td>
<td>Call: ALARMS OFF*</td>
<td>Possible controller malfunction</td>
<td></td>
<td>Able to mute alarm for 5 minutes by pressing Alarm Mute Button.</td>
</tr>
</tbody>
</table>

^ Controller Fault indicates a possible controller malfunction, call your clinician for appropriate action. The controller may need to be replaced with the back-up controller.

* Call your doctor, nurse or VAD coordinator immediately.

When a medium alarm resolves there is no alarm sound or light displayed in the Alarm Indicator. However, the message on the Controller Display will remain until you clear this message by pressing the Scroll button 🎯. A new alarm will also clear a resolved medium alarm from the Controller Display.
7.4 Low Alarms

A low alarm is indicated by a solid YELLOW Alarm Indicator. The message tells you to replace a low battery or reconnect to a power source (battery, AC adapter or DC adapter).

<table>
<thead>
<tr>
<th>Alarm (Line 1 on controller)</th>
<th>Action (Line 2 on controller)</th>
<th>Meaning</th>
<th>Alarm Indicator</th>
<th>Alarm Sound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Battery 1</td>
<td>Replace Battery 1</td>
<td>Battery 1 is low</td>
<td>△</td>
<td>Alarm gets louder after 5 minutes and even louder after 10 minutes, if alarm not muted.</td>
</tr>
<tr>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
<td>Battery 2 is low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power Disconnect</td>
<td>Reconnect Power 1</td>
<td>Power source 1 disconnected or defective</td>
<td>△</td>
<td></td>
</tr>
<tr>
<td>Power Disconnect</td>
<td>Reconnect Power 2</td>
<td>Power source 2 disconnected or defective</td>
<td>△</td>
<td>Able to mute alarm for 5 minutes by pressing Alarm Mute Button.</td>
</tr>
</tbody>
</table>

7.5 Multiple Alarms

You may have more than one alarm condition at the same time. For multiple alarms, the Alarm Indicator (△) will display the most severe alarm and the alarm will sound the most severe alarm. As mentioned previously, when an alarm occurs, two lines of words appear on the Controller Display. The first line tells you what the alarm is, and the second line tells you what to do. An arrow (⬇️) is displayed on the right side of the alarm if there is more than one alarm (Figure 15).

![Figure 15: Controller with Multiple Alarms (Note Arrow in Controller Display)](image-url)
HeartWare® Ventricular Assist System Patient Manual

Alarm Indicator and Alarm Sound for Multiple Alarms

<table>
<thead>
<tr>
<th>Multiple Alarm Condition</th>
<th>Alarm Indicator</th>
<th>Alarm Sound</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 or More High Alarms</td>
<td>Flashing RED</td>
<td>Loud, continuous, unable to mute</td>
</tr>
<tr>
<td>High and Medium Alarms</td>
<td>Flashing RED</td>
<td>Loud, continuous, unable to mute</td>
</tr>
<tr>
<td>High and Low Alarms</td>
<td>Flashing RED</td>
<td>Loud, continuous, unable to mute</td>
</tr>
<tr>
<td>2 or More Medium Alarms</td>
<td>Flashing YELLOW</td>
<td>Gradual increase in volume if alarm NOT muted</td>
</tr>
<tr>
<td>Medium and Low Alarms</td>
<td>Flashing YELLOW</td>
<td>Gradual increase in volume if alarm NOT muted</td>
</tr>
<tr>
<td>2 or More Low Alarms</td>
<td>YELLOW</td>
<td>Gradual increase in volume if alarm NOT muted</td>
</tr>
</tbody>
</table>

Use the Scroll button 🔄 to see all alarm conditions. Press the Scroll button each time you want to advance to the next alarm or to the pump parameters (L/min, RPM and Watts). If the Scroll button is not touched for 1 minute, the controller automatically displays the most severe alarm on the Controller Display. Also, if a new alarm occurs, the Controller Display will show you the new alarm. Remember, if an arrow is displayed on the right side of the alarm message; use the Scroll button to see all alarms.

7.6 How to Silence (Mute) Alarms

High alarms CANNOT be silenced. However, medium and low alarms can be silenced for 5 minutes by pressing the Alarm Mute button 🔄. The alarm will sound again if a new alarm condition occurs or five minutes has passed. The low and medium alarm sound will increase to the next highest alarm volume level if the alarm condition is not resolved or is not muted within 5 minutes.

**WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

**CAUTION:** ALWAYS call your clinician for appropriate action if there is a “Controller Fault” alarm. The controller may need to be replaced with the back-up controller.
8  EQUIPMENT CARE AND MAINTENANCE

8.1  How Long HeartWare® Equipment Should Last
The HeartWare® System components were designed and tested to function without failing for the following periods:

- HVAD® Pump at least two years.
- The controller is expected to function for at least one year.
- The battery charger is expected to function for at least one year.
- The battery is expected to function through 500 charge and discharge cycles; this should provide patient support for one year. Batteries that reach the end of their useful life should be taken out of service and replaced.

8.2  General Care
The HeartWare® Ventricular Assist System is made of durable materials that will need occasional cleaning. The following steps should be used to clean the equipment:

1. Use a clean, soft cloth when cleaning the system (controller, batteries, battery charger).

**WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.

**WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

**WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected.

**WARNING!** Damaged equipment should be reported to your VAD coordinator and inspected.

**CAUTION:** DO NOT attempt to repair or service any components of the HeartWare® System. If service is required, contact your physician, nurse or VAD coordinator.

**CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

8.3  Controller
**Once a week:** Inspect the power connectors and connector pins on the controller for dirt or grime. This inspection can be done when you are changing power sources. Check the controller power connectors one at a time. DO NOT disconnect both power sources at the same time – your pump
HeartWare® Ventricular Assist System Patient Manual

will stop. DO NOT disconnect the driveline to examine its connector. The only time the driveline connector should be inspected is during a controller exchange. DO NOT attempt to clean the controller connectors. If any dirt is found, report the condition to your VAD coordinator.

8.4 Batteries

Once a week: Inspect batteries for physical damage, including the battery cable and connectors. DO NOT use batteries that appear damaged. Damaged batteries must be replaced.

Periodically or as needed:

- Note how long your batteries last. If a battery lasts less than 2 hours after being fully charged, contact your VAD coordinator for a replacement.
- Clean the exterior surfaces of batteries using a clean cloth. A damp cloth may be used but a wet cloth should not be used.
- When you come in for clinic visits, remember to bring all your batteries with you.

Disposal: Consult your VAD coordinator, nurse or physician.

**CAUTION:** DO NOT place batteries in water or liquid.

**CAUTION:** DO NOT expose batteries to temperatures less than 32°F (0°C) or greater than 113°F (45°C) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

**CAUTION:** DO NOT expose batteries to excessive shock or vibration.

**CAUTION:** DO NOT disassemble, crush, or puncture a battery.

**CAUTION:** DO NOT short the external contacts on a battery.

**CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.

**CAUTION:** DO NOT use a damaged battery.

**CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

**CAUTION:** DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

8.5 Battery Charger

Once a week:

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. DO NOT use the charger if it shows signs of damage. Obtain a replacement from your VAD coordinator.
Inspect the power cord that connects the battery charger to a wall electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. DO NOT use the cord if it shows signs of damage. Obtain a replacement power cord from your VAD coordinator.

Periodically or as needed: To clean the battery charger, remove the batteries and unplug the charger from the electrical outlet. Clean the exterior surface of the charger using a clean, dry cloth. DO NOT place the charger in water or liquid.

WARNING! NEVER clean the battery charger with the power on, as this may lead to an electrical shock.

9 ACTIVITIES OF DAILY LIVING

Talk to your physician about your usual activities as well as any changes in your daily routine. Your HeartWare® System is designed to help you stay active. However, each person is different and your physician can give you the best advice. Anytime you have questions or concerns, talk to your physician, nurse or VAD coordinator.

CAUTION: DO NOT play contact sports. You may start bleeding or could damage your equipment.

WARNING! ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises since under these conditions, the controller and battery alarms may not be audible.

WARNING! DO NOT become pregnant while you have the HeartWare® System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most LVAS patients receive) have been associated with birth defects. If you do become pregnant, tell your physician and hospital contact person immediately.

WARNING! DO NOT have a magnetic resonance imaging (MRI) procedure while implanted with the HeartWare® System. Doing so could harm you or could cause the pump to stop.

WARNING! Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

WARNING! DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.

WARNING! AVOID exposure to therapeutic levels of ultrasound energy. Consult your physician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.
HeartWare® Ventricular Assist System Patient Manual

WARNING! AVOID therapeutic ionizing radiation. Consult your physician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.

9.1 Electrostatic Discharge (ESD)

What is electrostatic discharge?
Electrostatic discharge (ESD) is the sudden transfer of electricity from one object to another. It is most noticeable in dry environments and near certain materials such as silk and carpeting. A mild shock to your skin will not affect your controller. However, ESD to the controller or its connectors may cause your controller to function improperly.

WARNING! Avoid devices and conditions that may induce strong static discharges (e.g., television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the LVAD to perform improperly or stop.

WARNING! Always have a backup controller handy and, whenever possible, a caregiver nearby when changing power sources or controllers. Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

Signs of ESD in the controller:
ESD damage to the controller can cause a “Controller Failed” alarm or a high priority audible alarm without accompanying alarm text on the controller screen. If either of these alarms occurs, the controller should be switched to the backup controller.

If the “Controller Fault” alarm occurs, contact your VAD coordinator for instructions so that the cause can be determined. If the alarm will not clear, switch to the backup controller.

What you can do:
To reduce the chance of ESD damage to the controller, follow connection instructions in the patient manual. Do not touch the controller connector pins or let foreign objects or material come near a disconnected controller power port. Always use 2 power sources and do not leave the controller power port disconnected for more than the time it takes to change the power source.

When changing batteries, have the new battery within arm’s reach before disconnecting the depleted battery and when possible, have a caregiver nearby in case an alarm occurs.

Ensure that the driveline cover is in place and firmly positioned against the controller. Be careful near materials (e.g. carpeted floors, silk clothing, etc.) and electronic devices (TV screens, microwaves when in operation, and laptop or computer screens) prone to static electricity. Avoid changing power sources in these areas. Avoid vacuuming and removing clothes from the dryer and always use anti-static dryer sheets and fabric softener. Consider using a humidifier in the house.
9.2 Driveline Exit Site Care

Proper care of your skin around the driveline exit site is very important to prevent infection in this area. Prior to leaving the hospital, your nurse should explain and demonstrate proper care of the exit site. One of the most important measures you can take to prevent exit site infections is to protect the driveline from excessive movement. Take care not to pull on the driveline or get it caught on objects where the result may be sudden pulling or yanking.

The dressing around your exit site should be changed according to your doctor’s instructions. Always thoroughly wash your hands with soap and water prior to any dressing change. Always use sterile technique with every dressing change. General guidelines include:

1. Obtain all necessary materials
2. Wash your hands thoroughly
3. Remove dressing
4. Observe exit site for redness, swelling or drainage
5. Open new dressings
6. Use sterile gloves
7. Cleanse the exit site with saline or other agent (start close to the driveline and then move away)
8. Apply sterile dressings
9. Tuck any excess driveline length under an abdominal binder or dressing or keep it secured close to the body by clothing

**CAUTION:** DO NOT pull, kink or twist the driveline or the power cables. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

**CAUTION:** ALWAYS keep extra driveline length tucked under clothing or secured with an abdominal binder or dressing. Do not let any portion of driveline hang freely where it might get caught on external items such as doorknobs or the corners of furniture.

**CAUTION:** ALWAYS notify your physician promptly if there is drainage, swelling or reddened skin around the driveline exit site, these may indicate an infection.

**CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine, or polymyxin-neomycin-bacitracin ointment. These ointments can injure the tissue adjacent to the exit site.

**CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your physician, nurse or VAD coordinator.

**CAUTION:** ALWAYS notify your physician promptly if you notice blood or fluid in the driveline. The section of the driveline inside your body may have been damaged during HVAD® Pump implantation or during another operation. The driveline has built in features that minimize the effect of blood or fluid entering it, so the HVAD® Pump should continue to operate normally. However, your physician should examine the driveline to fully evaluate the situation.
HeartWare® Ventricular Assist System Patient Manual

9.3  Showering

Your doctor will let you wash your incisions after your wounds have healed. When you wash, the controller, batteries and connectors must be protected from water and you should take care so that water doesn’t run down the driveline onto the controller. The exit site should also be kept as dry as possible. Keeping the exit site dry helps avoid infections.

Your doctor will decide if it is safe for you to shower. If your doctor gives you permission to shower, you must use the HeartWare® Shower Bag to protect the controller and batteries. For instructions on shower bag use, please see Section 11.3 “HeartWare® Shower Bag”.

**WARNING!** DO NOT shower until your physician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare® Shower Bag. If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

**WARNING!** DO NOT plug the controller into an AC wall outlet during showers; it should be connected to two batteries.

**WARNING!** DO NOT take a bath or swim.

**WARNING!** DO NOT submerge any HeartWare® System component in water.

9.4  Medications

Talk with your doctor about your medications. Get an explanation of the purpose of each medication that your doctor prescribes for you. Write down the medication and how often you need to take it and ask your doctor to check the list to make sure it is correct. Talk with your doctor about what you should do if you accidentally forget to take your medicine. Discuss what to do for each medicine because it may be different for each one. You may also want to make a list of medications that you should not take. Some non-prescription medications and natural supplements may react with your prescribed medications.

You are probably taking medication (anticoagulation) to thin your blood and reduce the risk of clot formation in your blood or pump. It is very important that you take this medication as prescribed and that you have your blood checked frequently to be sure that you are receiving a dose that is not too high (blood too thin) or too low (blood too thick).

You may notice bleeding as a result of your medication. If you are unsure whether the bleeding represents a problem, it is best to call your doctor or nurse.

**NOTE:** You should always remain on your anticoagulation dose schedule as written or as told to you by your doctor or nurse.
10 DISCHARGE INSTRUCTIONS

At the time of discharge from the hospital, be certain to follow the instructions for the patient and their caregiver/companion below.

10.1 Daily Care

1. Change your LVAD lead exit site dressing once a day following the sterile technique taught to you while in the hospital. During dressing changes look for signs of infection, such as redness, swelling, drainage or pain. Call your hospital contact person if you notice any of these symptoms.

2. Call the hospital if your LVAD flow falls to less than ____ LPM, the power (Watts) goes above _______ or the RPM changes more than 100 RPM.

3. Call the hospital if your temperature is above _____ degrees.

4. Check your weight each morning and record it on your flow sheet. Call your hospital contact person if you gain more than ____ pounds in one week.

5. Call your hospital contact if you notice any swelling in your ankles or changes in your girth. This may be a sign of water retention.

6. Notify your hospital contact if there is a change in how the LVAD sounds or feels.

7. Record your LVAD RPM, power (Watts) and flow once a day.

10.2 Care of Equipment

1. Do NOT twist, kink or lay on your LVAD lead exit site.

2. Keep all your LVAD equipment in a dry, room temperature (around 72 degrees F) environment. Store all extra equipment in your house. Be sure the equipment is stable if stored in closets or shelves. Dropping LVAD components may lead to damage.

3. When not in use keep Batteries plugged into the Charger – the Charger should always be plugged into an AC outlet.

4. If you have any questions about operating, cleaning or storing your LVAD equipment, ask your hospital contact.

5. Do not try to repair or modify any of your LVAD equipment.

10.3 Pain

By the time you are ready to go home, you should not be having much pain. You will be sent home with pain medication which should be taken as prescribed. If you experience an increase in pain or pain where you never had pain before, call your contact person.
10.4 Diet

1. Follow the diet suggested by the dietician.

2. If you have diabetes, be aware that your diabetes medications may need to be adjusted after LVAD implantation. Consult your doctor.

10.5 Tobacco Products

If you smoke - you must quit smoking.

Note: Avoid second-hand smoke as it has negative effects on your blood vessels.

10.6 Alcohol

Alcohol can interfere or interact with certain medications and leads to dehydration. Alcohol can impair your ability to understand and react to system alarms.

10.7 Weather

1. Avoid activity in very hot or very cold temperatures.

2. If you go outdoors during very hot or humid weather, be sure to drink plenty of water or non-alcoholic beverages.

3. If you are wearing heavy clothing, take care to avoid kinking or bending your LVAD lead.

10.8 Limitations

1. Do NOT take baths, get in a hot tub, or go swimming while implanted with the LVAD. After the LVAD implant, while still in the hospital, Occupational Therapists will instruct you on the method and equipment needed for daily hygiene.

2. Do NOT drive a car or operate heavy machinery unless your doctor gives you permission.

3. Do NOT play contact sports or engage in any activity that may lead to stitches, trauma or broken bones while implanted with the LVAD.

10.9 Miscellaneous

1. You are responsible for making sure that your surroundings continue to be safe. If you have any questions or concerns about your home environment, call your contact person.

2. Be familiar with the warnings and cautions associated with having an LVAD and for safe LVAD operation.
11 EQUIPMENT NEEDED FOR HOME USE

At the time of discharge from the hospital, be certain that all of the following equipment and accessories are available and have been checked for proper function.

11.1 Home Discharge Equipment Requirements

- 1 Patient Manual
- 2 Controllers with AC adapters (1 set is for back-up) and alarm adapters
- 1 Driveline cover
- 1 DC adapter
- 4 - 6 Batteries
- 1 Battery charger
- 1 or more carrying cases (Shoulder Pack, Waist Pack or Patient Pack)
- 1 Shower bag

11.2 Carrying Cases

The HeartWare® Shoulder Pack and HeartWare® Waist pack are used to safely secure, store and carry the controller and batteries. They can be used in or out of the hospital, when resting, sleeping or ambulating. One controller and two batteries fit into the packs. For care instructions, see Section 11.2.3 (“Care of the HeartWare® Shoulder Pack and Waist Pack”).

CAUTION: The HeartWare® Waist Pack and the HeartWare® Shoulder Pack contain magnetic closures. Patients with an internal cardiac defibrillator (ICD) or pacemaker should keep the pack away from their chest and should not sleep with the pack to avoid proximity to the ICD or pacemaker. The Patient Pack without magnets should be used when sleeping. Per pacemaker and ICD manufacturer guidelines, magnets should be kept at least 6 inches (15 cm) away from the pacemaker or ICD (please refer to manufacturer guidelines for additional information).

11.2.1 HeartWare® Shoulder Pack

The HeartWare® Shoulder Pack holds the controller and two batteries in a shoulder bag. A viewing window allows you to see the controller display. Magnetic snaps keep the bag closed and allow easy access. The shoulder pack can be attached to the waist belt for additional support if desired. A belt extender is included to make the belt bigger if necessary.
Using the HeartWare® Shoulder Pack
To load the controller and batteries into the HeartWare® Shoulder Pack:

1. Place the shoulder pack on a table or other flat surface with the clear window facing you. Open the flaps and zippers (see #1) to access the equipment pockets. The Patient ID Card may be placed in the clear pocket.

2. Open the snaps on the controller pocket and insert the controller as shown in #2. Fasten the snaps to secure the controller.

3. Insert the batteries into the two battery pockets. The extra battery cable length can be tucked into the compartment with the battery. (see #3)

4. Close the flap and zip up both zippers.

5. Close the side flaps, leaving the driveline between the top of the zipper and the side flap. Fold the top closed (see #4).
6. The shoulder pack is ready to be worn. (see #5) Check the driveline and battery cables to make sure that they are not twisted or kinked. Adjust the pack as necessary to remove kinks in the driveline or cables.

7. For added support, attach the waist belt to the shoulder pack, using the belt loops on the back of the pack. If necessary, use the belt extender to make the belt bigger.

11.2.2 HeartWare® Waist Pack

The HeartWare® Waist Pack is designed to hold the controller and two batteries around the waist. The waist pack comes with a support strap to help in putting on or taking off the pack, and a belt extender to make the waist pack belt bigger. A viewing window allows the patient to see the controller display. Magnetic snaps keep the equipment pockets closed and allow easy access.

Using the HeartWare® Waist Pack

To load the controller and batteries into the HeartWare® Waist Pack:

1. Place the waist pack on a table or other flat surface with the clear window facing you (#1). Attach the support strap as shown. Open the cover and undo the snaps of the controller pocket.
2. Place the controller as shown in #2.

3. Fasten the snaps and fold the cover closed. (See #3)

4. To load the batteries:
5. Disconnect one battery from the controller. Refer to the HeartWare® Ventricular Assist System Patient Manual instructions.
6. Open the battery pocket and feed the battery cable through the hole (see #4) and then place the battery in the pocket.
7. Re-connect the battery to the controller and fold the battery pocket cover closed.

8. Secure the cable in the cable sleeve by opening the flap, placing the cable inside, and closing the flap. (#5).

9. Repeat steps 4 and 5 for the other battery. (See #6 and #7)
10. Lift the support strap over the head to hold the HeartWare® Waist Pack up, then buckle the belt around the waist and adjust it to fit. (See #8.) If necessary, use the belt extender to make the belt bigger. Check the driveline and battery cables to make sure that they are not twisted or kinked. Adjust the pack as necessary to remove kinks in the driveline or cables.

11. Adjust the belt so that the controller display is visible at all times (see #9). When the HeartWare® Waist Pack is comfortably fastened around the waist, the support strap can be removed, but should be used whenever putting on or taking off the waist pack.

NOTE: Always use the support strap when putting on or taking off the waist pack.

11.2.3 Care of the HeartWare® Shoulder Pack and Waist Pack:
The HeartWare® Shoulder Pack and Waist Pack can be washed by hand using a mild detergent and cold water, or machine washed using the delicate cycle. Do not use bleach. Allow the pack to air dry. Do not use a clothes dryer to dry the pack. Make sure that pack is completely dry before using, and inspect it for damage or wear before each use.
11.3 HeartWare® Shower Bag

**NOTE:** Please see Section 11.3.1 “Getting Ready to Shower”, for additional instructions and warnings related to showering with your HeartWare® System.

The HeartWare® Shower Bag provides the ability to comfortably and securely shower with your HeartWare® Ventricular Assist System. The shower bag is water resistant, not water proof, and protects the controller and batteries from direct water spray and moisture. A small amount of water accumulation in the bag is acceptable and will not affect proper function of the system. The shower bag permits one (1) controller and two (2) batteries to be placed into a single compartment.

The cover of the bag has a zipper closure that allows the driveline to exit on the right side of the bag. An adjustable shoulder strap is used to wear the bag during showering. When showering, always use two batteries as the controller power sources. DO NOT use the HeartWare® Controller AC Adapter as one of the controller power sources. Always use the HeartWare® Shower Bag to protect the controller and batteries when showering.

**Recommendations:**

- Keep the driveline exit site covered and as dry as possible while showering.
- Try not to pull or move the driveline. Pulling or moving the driveline could injure an already healed exit site. DO NOT kink or bend the driveline.
- Be careful not to catch the driveline in the zipper when closing the shower bag.
- Prior to showering, make sure both batteries are completely charged.
- If you are hearing impaired, your ability to hear alarms will be reduced. If any alarm is heard during showering, immediately turn off the shower and address the alarm condition. If you require hearing aids, make sure someone will be close by to hear alarms.
- The shower stall floor should be made of a non-slip surface or have a textured rubber mat.
- The shower stall should have a handrail and shower chair.

11.3.1 Getting Ready to Shower

Please follow these steps to use the shower bag:

1. Unzip and open the shower bag. Inspect the shower bag for rips or tears and be sure the inside of the bag is dry. If the integrity of the bag is compromised in any way, do not use the bag and do not proceed to shower. If needed, contact your VAD coordinator to get a replacement.
2. Remove the controller and two batteries from their carrying case and carefully place them inside the inner pouch of shower bag. Pull the drawstring closed.

3. With the shower bag opening away from you, position the driveline towards the farthest right corner of the zipper. You will see an area of the zipper that has no teeth. Place the driveline between the upper and lower nylon guards prior to zipping the cover shut. Fold the flap down over the zipper.

4. Guide the portion of the driveline that exits the bag between the two Velcro strips on the side of the bag; firmly fasten the two strips around the driveline. The driveline will form a “U” shape as it exits the bag, thus minimizing the likelihood that water will drain from the driveline into the bag.
5. Place the shower bag strap over your head and across your shoulder so it is hanging at your side.

**NOTE:** The strap is adjustable. Adjust the strap so the bag does not pull on the driveline while showering. There should be some slack in the driveline so that the flap is completely folded over the zipper.

Keep the exit site as dry as possible while you shower. Proper hand washing and a dry exit site will help reduce the risk of infection. Your VAD coordinator will give you suggestions to maintain a dry exit site.

### 11.3.2 After Showering

1. Set the shower bag on a flat, stable surface and dry the bag, controller, and batteries, using a clean towel.

2. Transfer the controller and batteries to the carrying case.

3. Change the driveline exit site dressing using your normal procedure. If the area around the exit site is wet, dry off with a sterile gauze bandage before applying the new dressing.

4. Allow the shower bag to drip dry before using it again.

### 11.3.3 Caring for Your HeartWare® Shower Bag

Keeping your shower bag clean will help ensure it works properly and lasts longer. It can be washed by hand using a mild detergent and cold water. Once the bag has been washed, allow it to drip dry. Never heat the shower bag to dry it or place it in an electric or gas heated clothes dryer. Make sure your shower bag is completely dry before taking the next shower. Inspect your shower bag for damage or wear before each use. If you have problems or questions about your HeartWare® Shower Bag, your VAD coordinator can assist you.
12 HANDLING AN EMERGENCY

A back-up controller and charged batteries must be available at all times. The controller should be exchanged if it fails. A controller failure is a high alarm and the Controller Display will tell you to “Change Controller” (see Section 6.2.2, “How to Change the Controller”). Call your physician immediately if you notice a sudden change in how your pump works, feels or sounds (even if there is no alarm). If there is an emergency such as an urgent or life-threatening problem, call your local emergency medical services and then your physician, if possible.

Contact your physician for any of the following conditions:

- Numbness, tingling or weakness in any limb
- Blurred vision or speech problems
- Shortness of breath or dizziness
- Any pain, including chest pain, unrelieved headache
- Fever (take your temperature daily)
- Any redness, swelling or drainage around the driveline exit site
- Unusual bleeding or bruising
- Unusually dark urine
- Any condition where you feel “unwell”
- High and medium controller alarms

Call Emergency Medical Services (EMS) for any of the following conditions:

- Seizure or convulsion
- Loss of consciousness
- Awake but unresponsive
- Sudden fall or collapse
- Inability to talk or move body parts
- Heart stops
- VAD stops

13 TRAVELING AND TRANSPORT

As you resume activities of daily living, you may wish to travel away from home. Prior to making travel plans, talk with your physician to make sure it is safe for you to travel. Once you are approved for travel, your physician or VAD coordinator will work with you to ensure you are prepared for traveling safely. Always remember to take all prescribed medication with you and to make sure you have emergency contact information.
When you travel, please make sure you have the following:

- Back-up controller
- Fully-charged, spare batteries
- Battery charger
- Controller AC adapter
- Controller DC adapter

Equipment should be kept with you at all times for safety and security. If traveling by air, carry equipment with you on board the aircraft. During the flight, you should power the controller with two batteries or with one battery and an AC adapter.

**NOTES**

- Store and operate all equipment within the recommended temperature conditions listed in the WARNINGS and PRECAUTIONS section of this manual.
- Avoid passing through security screening equipment, as this may affect your VAD. Instead, request to be hand screened with special care given to the driveline exit site.
- If you are traveling on a long haul flight, talk with your clinician about whether you should purchase extra batteries.
- If traveling internationally, talk with your clinician about purchasing international power cords for use with your equipment

**WARNING!** AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as these may affect HeartWare® Systems operation.

In case of emergency, it is safe for you to be transported by ground or air to the implanting facility or nearest hospital.

### 14 ADDITIONAL INFORMATION ABOUT HEART FAILURE

Additional information about heart failure can be found at:

- www.HeartWare.com
- http://www.nhlbi.nih.gov/health/topics/topics/hf/

Unless otherwise noted, ® designates a registered trademark of HeartWare, Inc.
Appendix A: Patient and Caregiver Training

1. Match the word on the right with the correct function:

   a) △ This icon located at the front of the controller lights up when one or more alarms occurs. ___ AC Adapter

   b) □ This button silences the low and medium audible alarms. ___ Alarm Indicator

   c) This is an adapter/cable that transfers power from an electric outlet to run the controller. ___ Alarm Mute Button

2. Match the picture to the definition:

   a) Test button on battery

   b) Driveline Exit Site

   c) Battery charger
3. Label the controller:

AC/DC Indicator

Alarm Indicator

Battery Indicator 1

Battery Indicator 2

Controller Display

Alarm Mute Button

Scroll Button

4. Label the cable connectors on the controller:

Monitor Cable / Alarm Adapter

Power Source

Power Source

Driveline

5. Please circle True or False for the following:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A flashing red alarm requires immediate attention.</td>
<td>True</td>
</tr>
<tr>
<td>2. It is ok to have moisture, cracks, tears or punctures in your driveline.</td>
<td>True</td>
</tr>
<tr>
<td>3. It is safe to take a tub bath or swim.</td>
<td>True</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>4.</td>
<td>This button is used to see all active alarms and pump information on the controller display.</td>
</tr>
<tr>
<td>5.</td>
<td>The driveline cover must cover the controller’s silver driveline connector to protect the controller from water.</td>
</tr>
<tr>
<td>6.</td>
<td>A controller with a blank display and no audible alarm should be replaced.</td>
</tr>
<tr>
<td>7.</td>
<td>When an alarm occurs, line one of the controller display tells you which alarm is occurring, line two tells you what to do.</td>
</tr>
<tr>
<td>8.</td>
<td>A green indicator light on the AC or DC adapter will indicate proper connection to an electrical outlet or a car power port.</td>
</tr>
<tr>
<td>9.</td>
<td>When there is a controller failure alarm, you should switch to the back-up controller.</td>
</tr>
<tr>
<td>10.</td>
<td>The controller AC/DC indicator will be green if you are using the AC Adapter or DC Adapter (car adapter) to power the controller?</td>
</tr>
</tbody>
</table>

6. **List 2 items you should have with you when you leave your house:**

7. **List 2 signs or symptoms of a driveline exit site infection:**

8. **How long does one battery usually provide power?**

9. **Why do you take blood thinner medicine?**

10. **What should you do every time before changing from AC Adapter/Battery operation to Battery/Battery operation or before replacing a Battery?**
11. When looking at the controller, how much power is remaining in a battery if there are:

- 4 green lights _____ %
- 3 green lights _____ %
- 2 yellow lights _____ %
- 1 red light _____ %

12. Place a check beside activities that will cause the HeartWare® System to stop:

- Disconnecting the AC adapter while only one fully charged battery remains connected to the controller.
- Disconnecting both batteries at the same time.
- Disconnecting the driveline from the controller.
- Unplugging the DC adapter without a back-up battery connected to the controller.

13. Two power sources should be connected to the controller at all times. What are the 3 different power options?

   Battery and __________________
   Battery and __________________
   Battery and __________________

14. Place a check beside activities that are not allowed while on the HVAD® Pump:

- Chest x-ray
- Cardiac catheterization
- MRI Scan
- Swimming
- CT Scan
- Walking

15. On the battery charger there are several status light indicators. Which status light will you see if the battery is charging and is not ready for use?

- Blue
- Flashing Red
- Yellow
- No lights

16. When an alarm occurs, what 3 indicators should you look for to determine the severity of the alarm?

- A unique sound
- Visual display (flashing RED, flashing YELLOW, or YELLOW)
- Vibrating
- A message