



# HeartWare<sup>®</sup> Ventricular Assist System

## Patient Manual



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

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Name

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Office

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Pager

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### AMBULANCE

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Company

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Phone Number

# HeartWare



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## 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 which silences low and medium level alarms.

**Alarm Indicator:**  A button on the front of the controller that lights when one or more alarms 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.

### C

**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.

### D

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

**Driveline:** The cable that connects to the implanted pump and passes through the skin to connect to the external LVAS components.

**Driveline Cover:** A small, white cover that slides over the pump/controller connection and protects the controller and pump from static electricity.

### E

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

### H

**High Alarm:** The most serious audio and visual (flashing red) alarm. Requires immediate attention.

### 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 which 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 to the body in a minute. Shown on the Controller Display.

**LVAD:** Left ventricular assist device. A mechanical pump which 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 which 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.


## P

**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.

## R

**RPM:** REVOLUTIONS PER MINUTE. The number of times the impeller spins in a minute. Shown on the Controller Display.

## S

**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 and brighten the Controller Display.

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

## T

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

## V

**VAD:** Ventricular assist device. A mechanical device which assists either the left (LVAD) or right (RVAD) ventricle of the heart.

## W

**Watts:** Measurement of the amount of electricity used to run the pump. Shown on the Controller Display.

## WARNINGS

- 1) DO NOT operate the controller in temperatures less than -20°C (-4°F) or greater than 50°C (122°F) or the controller may fail.
- 2) 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.
- 3) Pressing the Alarm Mute Button does not resolve the alarm condition. ALWAYS investigate, and if possible, correct the cause of any alarm.
- 4) The driveline cover must cover the controller's silver driveline connector to protect the controller from static electricity.
- 5) Disconnecting both power sources (batteries, AC adapter, DC adapter) at the same time will stop the pump. At least one power source must be connected at all times.
- 6) Plug the AC adapter into a properly grounded outlet to reduce the possibility of serious electrical shock.
- 7) Keep a spare controller and spare, fully charged batteries available at all times in case of an emergency.
- 8) If there is a controller failure, switch to the back-up controller.
- 9) A controller with a blank display and no audible alarm should be replaced.
- 10) 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 the pump.
- 11) DO NOT shower until your doctor tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.
- 12) The controller should be connected to two batteries when you shower; it should never be plugged into an AC wall outlet.
- 13) DO NOT take a bath or swim.
- 14) DO NOT submerge any HeartWare® System component in water.
- 15) 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 doctor, nurse or VAD coordinator.
- 16) 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.
- 17) Keep mobile phones at least 25 centimeters (10 inches) from the controller to prevent interference with the controller.
- 18) DO NOT remain near equipment that generates high magnetic forces such as theft detection devices or airport security systems to prevent interference with the controller.



- 19) Performance of the HeartWare® System during airline travel has not been established.
- 20) DO NOT become pregnant while you have the HeartWare® System. 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, immediately tell your doctor and hospital contact person.
- 21) DO NOT have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® pump. Doing so could harm you or cause the pump to stop.
- 22) DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.
- 23) 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.
- 24) 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.

## PRECAUTIONS

- 1) The controller uses words, lights and sounds to tell you how the system is operating. If you have sight or hearing problems, you may need additional help. Ask your doctor.
- 2) Use only HeartWare-supplied components with your HeartWare® System.
- 3) DO NOT attempt to repair or service HeartWare® Ventricular Assist System equipment. If service is required, contact your doctor, nurse or VAD coordinator.
- 4) Confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.
- 5) When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
- 6) All connectors should be handled with care and kept free of liquid, dust and dirt.
- 7) DO NOT kink your driveline or power cables.
- 8) The DC adapter is for use in automobiles only and may not fit all automobiles.
- 9) Charge completely depleted batteries within 24 hours to avoid permanent battery damage.
- 10) Batteries exposed to temperatures less than 0°C (32°F) or greater than 45°C (113°F) may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

- 11) Avoid exposing the battery to excessive shock or vibration.
- 12) Do not disassemble, crush, or puncture a battery.
- 13) Do not short the external contacts on a battery.
- 14) Keep batteries away from children.
- 15) Do not use a damaged battery.
- 16) If a battery pack leaks, DO NOT touch the leaking fluid. Dispose of the battery. In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting the upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
- 17) Do not dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.
- 18) Use only the HeartWare-supplied battery charger to charge batteries. Other battery chargers may damage the batteries.
- 19) Wait until the green battery "Ready" light is on before disconnecting the battery from the battery charger. Otherwise, the battery may not function accurately or it may run the pump for less time than normal.
- 20) If there is a "Controller Fault" high alarm, call your clinician for appropriate action. The controller may need to be replaced with the back-up controller.
- 21) DO NOT play contact sports. You may start bleeding or could damage your pump.
- 22) DO NOT pull or tug the driveline passing through your skin. This may increase your risk of getting an infection.
- 23) 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.
- 24) Drainage, swelling or reddened skin around the driveline exit site may indicate an infection. Promptly notify your doctor.
- 25) Prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine, or neomycin bacitracin ointment should not be used. These ointments can injure the tissue adjacent to the exit site.
- 26) When changing your exit site dressing, inspect your driveline for moisture, cracks, tears or punctures. Report any damage to your doctor, nurse or VAD coordinator.
- 27) If you notice blood or fluid in the driveline, call your doctor. 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 doctor should examine the driveline to fully evaluate the situation.

## 1.0 INTRODUCTION

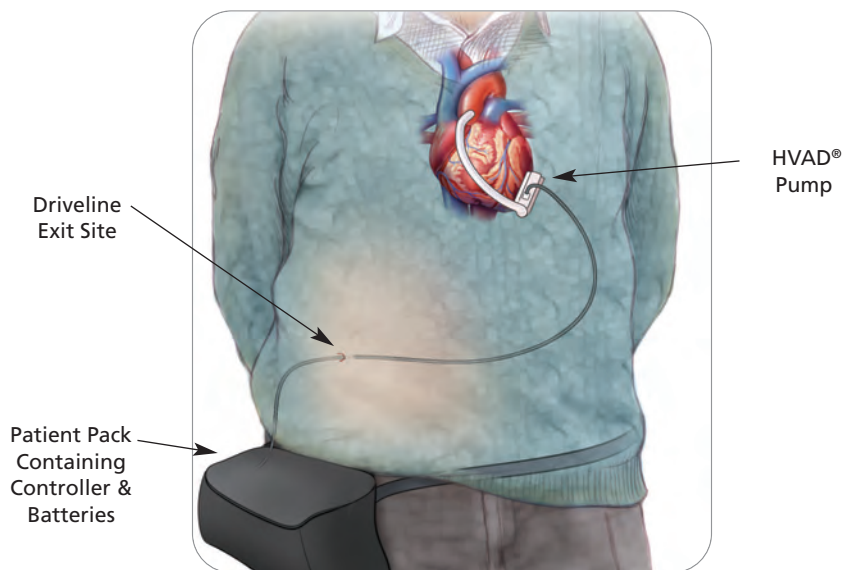
### 1.1 Why You Should Read this Manual

This Patient Manual will tell you about your HeartWare® Ventricular Assist System (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 doctor, 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 doctor, nurse or VAD coordinator.

### 1.2 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 (cable) 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 Patient Pack (carrying case).

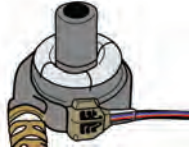









*Figure 1:*  
*Illustration of an Implanted HVAD® Pump*

# HeartWare

After pump implantation and recovery from your surgery, the hospital staff will prepare you to live at home with the HeartWare® System.

## 1.3 HeartWare® Ventricular Assist System Components

<p><b>HVAD® Pump</b></p>		<p>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.</p>
<p><b>HeartWare® Controller</b></p>		<p>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.</p>
<p><b>HeartWare® Battery</b></p>		<p>The battery is used to power the pump. Two batteries or one battery and an AC adapter or DC adapter are <b>ALWAYS</b> required.</p>
<p><b>HeartWare® Battery Charger</b></p>		<p>The battery charger charges and tests the batteries.</p>
<p><b>Driveline Cover</b></p>		<p>The white driveline cover protects the controller and pump from static electricity.</p>
<p><b>HeartWare® Controller AC Adapter</b></p>		<p>The AC adapter uses power from an electrical outlet to power the controller.</p>
<p><b>HeartWare® Controller DC Adapter</b></p>		<p>The DC adapter uses power from an electrical outlet in an automobile to power the controller.</p>
<p><b>Alarm Adapter</b></p>		<p>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.</p>

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%

## 2.0 HEARTWARE® VENTRICULAR ASSIST 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

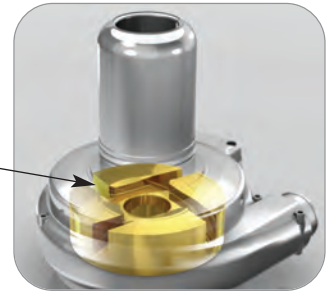


Figure 2:  
Pump with Impeller

### 2.1 HVAD® Pump

The HVAD® pump (also known as an LVAD) is small and has only 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.

### 2.2 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 supply connected to your controller.

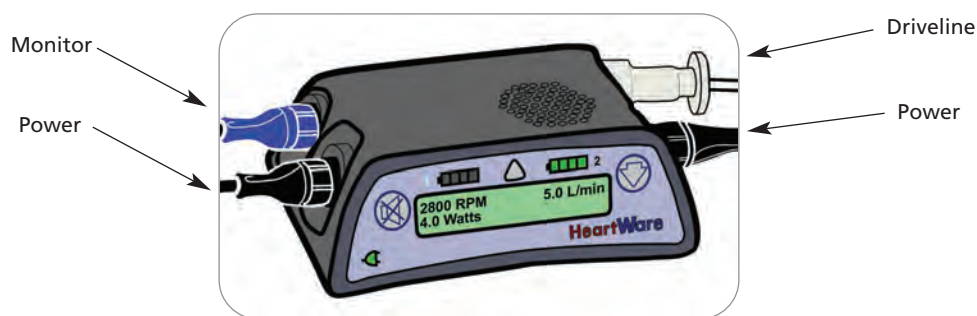


Figure 3:  
Controller

#### **WARNING**

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

## CAUTION

The controller uses words, lights and sounds to tell you how the system is operating. If you have sight or hearing problems you may need additional help. Ask your doctor.

## 2.2.1 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, which is also used for the alarm adapter (see Section 2.2.2 How to Change the Controller).

- ▶ 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 not up and about.
- ▶ 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 parameters 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

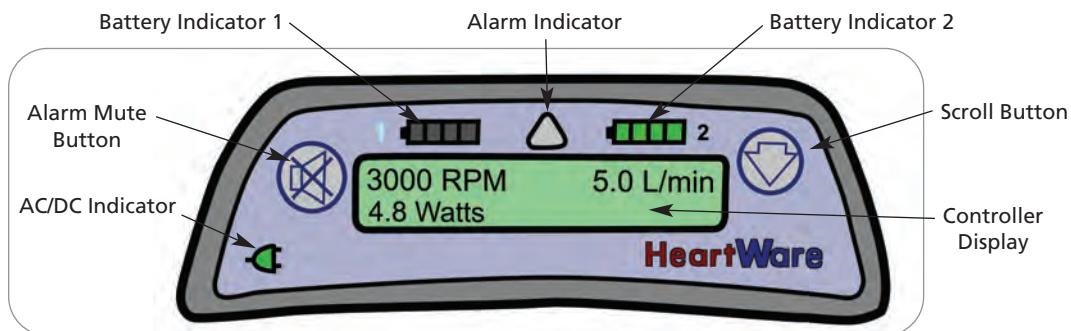
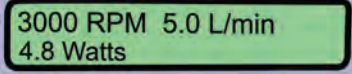

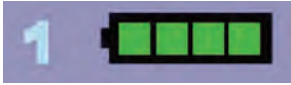





Figure 4:  
Controller Display with Pump Parameters

## Guide to Controller Display, Buttons and Indicators (Refer to Figure 4)

	<p>The <b>CONTROLLER DISPLAY</b> 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 3.0 describes alarms in detail.</p>
	<p>The <b>AC/DC INDICATOR</b> will be green if you are using the AC adapter or DC adapter to power the controller.</p>
	<p>The two <b>BATTERY INDICATORS</b> 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.</p> <p>The Battery Indicators tell you approximately how much power remains in each battery.</p> <ul style="list-style-type: none"> <li>▶ 75-100% battery capacity: 4 GREEN lights</li> <li>▶ 50-74% battery capacity: 3 GREEN lights</li> <li>▶ 25-49% battery capacity: 2 YELLOW lights</li> <li>▶ ≤ 24% battery capacity: 1 RED light</li> </ul> <p>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.</p>
	<p>The <b>ALARM INDICATOR</b> 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:</p> <ul style="list-style-type: none"> <li>▶ High Alarm: Flashing Red</li> <li>▶ Medium Alarm: Flashing Yellow</li> <li>▶ Low Alarm: Solid Yellow</li> </ul>
	<p>The <b>ALARM MUTE BUTTON</b> 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.</p> <div style="border: 1px solid gray; padding: 5px; background-color: #f0f0f0;"> <p><b>WARNING</b></p> <p>Pressing the Alarm Mute Button does not resolve the alarm condition. ALWAYS investigate and if possible, correct the cause of any alarm.</p> </div>
	<p>The <b>SCROLL BUTTON</b> 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.</p>

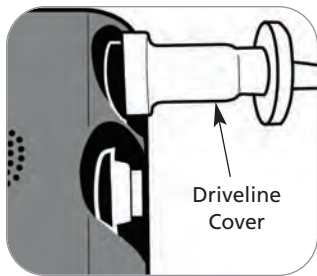


Figure 5:  
Driveline Cover Over  
Connector

## 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.

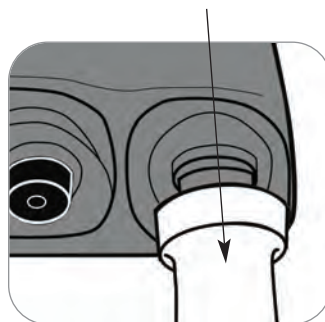
### WARNING

The driveline cover must cover the controller's silver driveline connector to protect the controller from static electricity.

## 2.2.2 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.

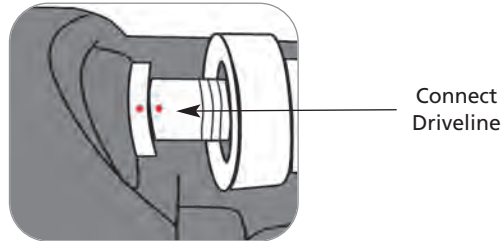
Remove White  
Driveline Cover



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 the pump is working (RPM, flow, Watts). **If your pump does not restart, call for medical assistance immediately.**

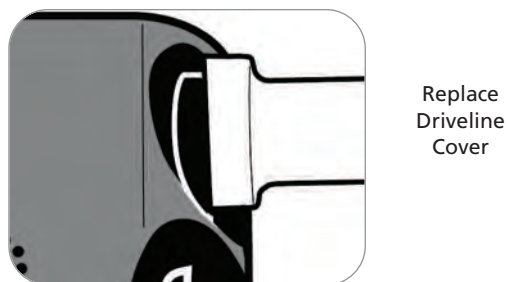


7. Insert the red alarm adapter into the blue connector on the **original** controller.<sup>1</sup>

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



8. Slide the white driveline cover up to cover **new** controller's silver connector.



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

## WARNING

- ▶ Keep a spare controller and spare, fully charged batteries available at all times in case of an emergency.
- ▶ 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 the pump.

<sup>1</sup> If the alarm adapter is not inserted prior to removing both power sources, the controller may alarm for up to 2 hours.



Figure 6:  
Battery



Figure 7:  
AC Adapter



Figure 8:  
DC Adapter

Align White Arrow  
and White Dot



Figure 9:  
Connect Power Supply

## 2.3 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.

### WARNING

Disconnecting both power sources (batteries, AC adapter, DC adapter) at the same time will stop the pump. At least one power source must be connected at all times.

### 2.3.1 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.

### CAUTION

- ▶ Confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.
- ▶ When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
- ▶ All connectors should be handled with care and kept free of liquid, dust and dirt.
- ▶ DO NOT kink the power cables.

## 2.3.2 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.

## 2.3.3 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 2.3.1 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**

Plug the AC adapter into a properly grounded outlet or you may receive a serious electrical shock.

#### **CAUTION**

- ▶ The DC adapter is for use in automobiles only and may not fit in all automobiles.
- ▶ 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.

White Arrow Aligned  
to White Dot



Figure 10:  
Correct Locking Position

## 2.3.4 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.

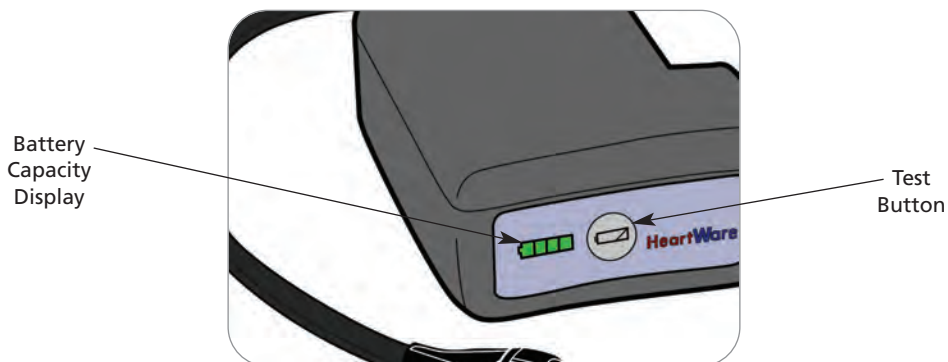












Figure 11:  
Battery

### Battery Buttons and Indicators (refer to Figure 11)

	Pressing the TEST BUTTON will light up the Battery Capacity Display.
	The BATTERY CAPACITY DISPLAY will tell you how much power remains in the battery.

The Battery Capacity Display on the battery is similar to the Battery Indicator on the controller (see Section 2.2.1 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).

Battery Capacity	Battery Capacity Display on BATTERY	Battery Indicator on CONTROLLER
75-100%	4 GREEN lights 	4 GREEN lights 
50-74%	3 GREEN lights 	3 GREEN lights 
25-49%	2 GREEN lights 	2 YELLOW lights 
≤24%	1 GREEN light 	1 RED light 

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 ( $\triangle$ ) 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.

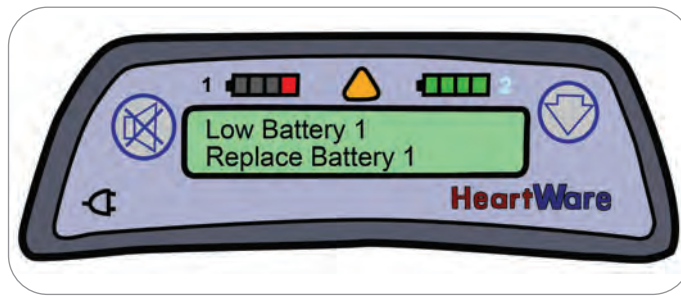


Figure 12:  
Controller Display with a Low Battery Alarm

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.

### 2.3.5 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 2.3.1 and Section 2.3.2 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.

### 2.3.6 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.

#### 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 twist or kink battery cables.
5. Do not force connections to the controller or battery charger.

#### CAUTION

- ▶ Charge completely depleted batteries within 24 hours to avoid permanent battery damage.
- ▶ Batteries exposed to temperatures less than 0°C (32°F) or greater than 45°C (113°F) may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.
- ▶ Avoid exposing the battery to excessive shock or vibration.
- ▶ Do not disassemble, crush, or puncture a battery.
- ▶ Do not short the external contacts on a battery.
- ▶ Keep batteries away from children.
- ▶ Do not use a damaged battery.
- ▶ If a battery pack leaks, DO NOT touch the leaking fluid. Dispose of the battery. In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting the upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
- ▶ Do not dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

## 2.4 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.

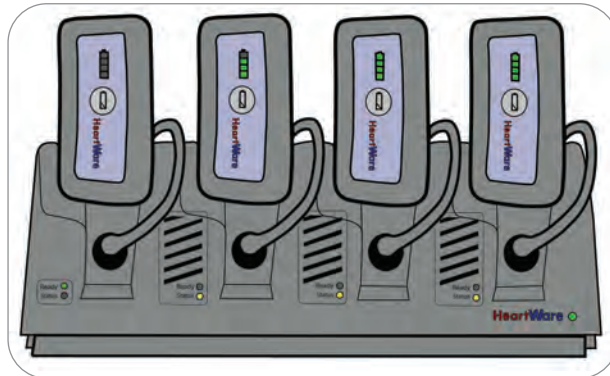


Figure 13:  
Battery Charger

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.”

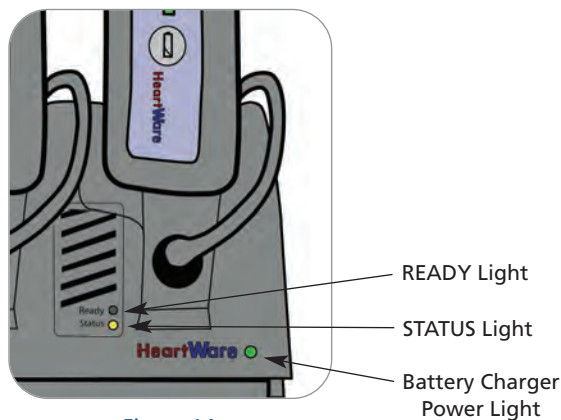


Figure 14:  
Indicator Lights on Battery Charger

Battery Charger “Status” Light	What it Means
Red ●	Battery too cold or too hot; waiting to charge.
Flashing Red ✨	Defective battery. Do NOT use. Mark battery and return to clinician.
Yellow ●	Battery being charged; NOT ready for use.
Flashing Yellow ✨	Battery not charging. Check battery connections. If connections are intact, switch to another battery slot.
No Lights On	Battery resting after charge. Wait for green ready light.

## 2.4.1 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.


## 2.4.2 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

- ▶ Use only the HeartWare-supplied battery charger to charge batteries. Other battery chargers may damage the batteries.
- ▶ Wait until the green battery “Ready” light is on before disconnecting the battery from the battery charger unless you need the battery urgently. Otherwise, the battery may not function accurately or may run the pump for less time than normal.

## 3.0 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 resolves 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 doctor, 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 Section 8.0 Quick Reference Guide for Alarms for a complete list of high, medium and low alarms.

### WARNING

A controller with a blank display and no audible alarm should be replaced.



## 3.1 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

Disconnecting both power sources at the same time will stop the pump. At least one power source must be connected at all times.

## 3.2 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:

Alarm (Line 1 on controller)	Action (Line 2 on controller)^	Meaning	Alarm Indicator 	Alarm Sound
VAD Stopped	Connect Driveline	Driveline disconnected or connector malfunction/broken	Flashing RED	Loud  Unable to mute alarm
VAD Stopped	Change Controller	Controller failure		
Controller Failed	Change Controller	Controller failure		
Critical Battery 1	Replace Battery 1	Limited battery 1 and battery 2 time remaining		
Critical Battery 2	Replace Battery 2	Limited battery 2 and battery 1 time remaining		

**^ Immediate action required, then call your doctor, 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

If there is a controller failure, switch to the back-up controller.

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.


## 3.3 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.

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


**^ 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.

## 3.4 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).

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

## 3.5 Multiple Alarms

You may have more than one alarm condition at the same time. For multiple alarms, the Alarm Indicator ( $\triangle$ ) 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).

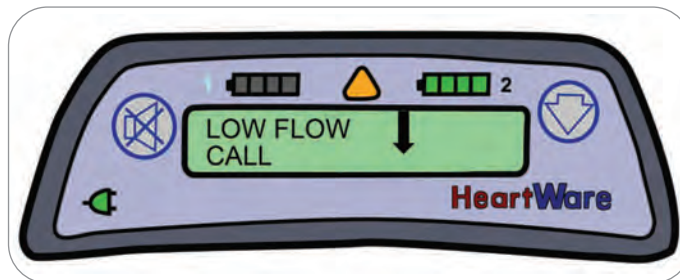




Figure 15:  
Controller with Multiple Alarms (Note Arrow in Controller Display)

### Alarm Indicator ( $\triangle$ ) and Alarm Sound for Multiple Alarms

Multiple Alarm Condition	Alarm Indicator $\triangle$	Alarm Sound
$\geq 2$ High Alarms	Flashing RED	Loud, continuous, unable to mute
High and Medium Alarms	Flashing RED	Loud, continuous, unable to mute
High and Low Alarms	Flashing RED	Loud, continuous, unable to mute
$\geq 2$ Medium Alarms	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
Medium and Low Alarms	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
$\geq 2$ Low Alarms	YELLOW	Gradual increase in volume if alarm NOT muted

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.

## 3.6 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**

Pressing the Alarm Mute Button does not resolve the alarm. ALWAYS investigate, and if possible, correct the cause of any alarm.

## **CAUTION**

If there is a “Controller Fault” high alarm, call your clinician for appropriate action. Your controller may need to be replaced with the back-up controller.

## **4.0 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 2.2.2 How to Change the Controller). Call your doctor 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 doctor, if possible.

### **Contact your doctor 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
- ▶ 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

## 5.0 EQUIPMENT CARE AND MAINTENANCE

### 5.1 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).
2. Moisten the soft cloth with mild soap and water. Make sure that the cloth is moist and not too damp to avoid damaging the equipment.
3. Gently clean the equipment. Avoid hard rubbing.

#### 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 doctor, nurse or VAD coordinator.
- ▶ 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.

#### CAUTION

- ▶ DO NOT attempt to repair or service HeartWare® Ventricular Assist System equipment. If service is required, contact your doctor, nurse or VAD coordinator.
- ▶ Use only HeartWare-supplied components with your HeartWare® System.

## 5.2 Controller

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**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 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.

## 5.3 Batteries

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### 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 when fully charged, contact your VAD coordinator for a replacement.
- ▶ Clean the exterior surfaces of batteries using a clean, damp (not wet) cloth. DO NOT use water or liquid soap to clean batteries. DO NOT place batteries in water or liquid.

### Disposal:

- ▶ Do not dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

### CAUTION

- ▶ Do not use a damaged battery.
- ▶ Do not dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

## 5.4 Battery Charger

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### 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 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:

- ▶ Unplug the battery charger from the wall outlet, remove the batteries, and clean the exterior surface of the charger using a clean, dry cloth. DO NOT place the charger in water or liquid.

## 6.0 ACTIVITIES OF DAILY LIVING

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

### CAUTION

DO NOT play contact sports. You may start bleeding or could damage your LVAS.

### WARNING

- ▶ DO NOT become pregnant while you have the pump. 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, immediately tell your doctor and hospital contact person.
- ▶ 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.
- ▶ Keep mobile phones at least 25 centimeters (10 inches) from the controller to prevent interference with the controller.
- ▶ DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.
- ▶ 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.
- ▶ 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.
- ▶ Do not remain near equipment which generates high magnetic forces such as theft detection devices or airport security systems to prevent interference with the controller.
- ▶ Performance of the HeartWare® System during airline travel has not been established.

## 6.1 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 or tug the driveline passing through your skin. This may increase your risk of getting an infection.
- ▶ 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.
- ▶ Drainage, swelling or reddened skin around the driveline exit site may indicate an infection. Promptly notify your doctor.
- ▶ Prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine, or neomycin bacitracin ointment should not be used. These ointments can injure the tissue adjacent to the exit site.
- ▶ When changing your exit site dressing, inspect your driveline for moisture, cracks, tears or punctures. Report any damage to your doctor, nurse or VAD coordinator.
- ▶ If you notice blood or fluid in the driveline, call your doctor. 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 doctor should examine the driveline to fully evaluate the situation.



## 6.2 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. Your doctor or VAD coordinator will help you obtain a shower bag and will explain how to use it. The shower bag will also come with detailed instructions on its proper use.

### WARNING

- ▶ DO NOT shower until your doctor tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.
- ▶ The controller should be connected to two batteries when you shower; it should never be plugged into an AC wall outlet.
- ▶ DO NOT take a bath or swim.
- ▶ DO NOT submerge any HeartWare® System component in water.
- ▶ 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 doctor, nurse or VAD coordinator.

## 6.3 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.

## 7.0 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.

### Recommended Equipment & Materials

- ▶ 1 Patient Manual
- ▶ 2 Controllers with alarm adapters and AC adapters (1 set is for back-up)
- ▶ 1 Driveline cover
- ▶ 1 DC adapter
- ▶ 4 - 6 Batteries
- ▶ 1 Battery charger
- ▶ 1 Patient Pack (carrying case)
- ▶ 1 Shower bag

## 8.0 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.

Alarm Type	Alarm Display (line 1)	Action (line2)
<b>High - Critical (Flashing Red)</b>	VAD Stopped	Connect Driveline
	VAD Stopped	Change Controller
	Critical Battery 1	Replace Battery 1
	Critical Battery 2	Replace Battery 2
	Controller Failed	Change Controller
<b>Medium (Flashing Yellow)</b>	Controller Fault	Call
	Controller Fault	Call: ALARMS OFF
	High Watts	Call
	Electrical Fault	Call
	Low Flow	Call
	Suction	Call
<b>Low (Solid Yellow)</b>	Low Battery 1	Replace Battery 1
	Low Battery 2	Replace Battery 2
	Power Disconnect	Reconnect Power 1
	Power Disconnect	Reconnect Power 2

**NOTE:** When both power sources (batteries, AC adapter, DC adapter) are removed, NO message will display on the controller. The “No Power” alarm will sound but the Alarm Indicator WILL NOT light. Your pump has stopped. Immediately connect two power sources.





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