

# LIVING WITH THE HEARTWARE™ HVAD™ SYSTEM **IMPORTANT REMINDERS**

The HVAD System Patient Manual will tell you about the system and how it works. It will also provide additional information on how to take care of the HeartWare HVAD System. In addition to the Patient Manual, your clinician will provide you with instructions on operating your VAD and necessary medical care.

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Static electric discharge (ESD) is the sudden transfer of electricity from one object to another. A mild shock to your skin won't affect your controller, but ESD to the controller or its connectors may cause your controller to function improperly.

### To reduce chance of ESD damage you should:

- Make good connections when changing power sources
- Do not touch the controller connector ports, or let foreign objects or materials come near a disconnected controller power port
- Have a new battery within reach before disconnecting power source and when possible, have a caregiver nearby in case an alarm occurs
- Use 2 power sources. Only leave power source ports on the controller open for the time it takes to change the power sources. Be careful of near materials and electronic devices prone to static electricity, such as: carpeted floors, silk clothing, TV screens, microwaves when in operation, and laptop or computer screens
- Avoid changing power sources in these areas
- Avoid vacuuming and removing clothes from the dryer
- Use anti-static dryer sheets and fabric softener
- Consider using a humidifier in your house

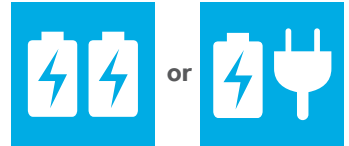


### Power Sources

The controller requires two power sources for safety: either two batteries or one battery and AC adapter or DC adapter. **Never disconnect both power sources; this would result in your pump stopping.**

**It is important to be sure that when making power connections, it is done properly and safely.**

- Connections for the power source are designed to lock into place
- Do not force connectors together without proper alignment; this may cause damage to the pins



### To prevent damage:

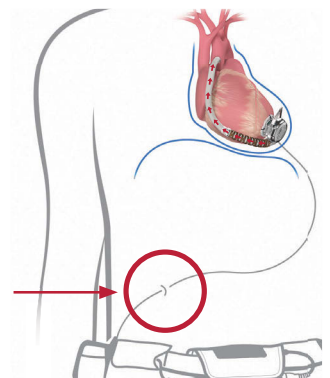
1. Grasp the back of the connector
2. Align solid white arrow and dot
3. Gently push (do not twist) until connector locks in place

It is important to keep connectors clean, free of liquid, dust or dirt. When using the DC adapter, always check to be sure the DC adapter works in your motor vehicle. It may not fit all motor vehicles.



### Driveline and Exit Site

- The driveline is the cable that passes through the skin and connects the implanted pump to the external HVAD System components
- **Do not disconnect driveline; this will result in your pump stopping.**
- Don't pull, twist or kink the driveline, because this could result in damage.
- It is important to inspect the driveline for tears, punctures or breakdown and notify your VAD clinician if you notice any damage to the driveline or blood or drainage in the driveline
- Since the driveline connects to the controller by exiting your skin, it is important to follow your clinicians' recommendations for keeping the exit site dry and clean to prevent infection
- One important measure to prevent infection is to protect the driveline from excessive movement. Always keep extra driveline length tucked under clothing and secured
- Let your clinician know promptly if there is new or worsening drainage, swelling or redness at the exit site or new trauma to exit site



Now that you have the HVAD System, it is important to remain knowledgeable about how the system works, how to care for the equipment and what to do in emergency situations. Especially for items that occur infrequently or after some time has passed since you reviewed initial information.

**It is important to:**

- Always take your anticoagulation and other medications as prescribed
- Report to your clinician any new or worsening health issues; may include shortness of breath, chest pain, dizziness, swollen legs or ankles, weight gain of 3-5lbs (or 1.3-2.2 kg), signs of infection, and stroke symptoms of changes in speech, uneven smile, numbness or tingling in extremity, weakness or inability to move one side of the body, etc.
- Report to your clinician any problems, issues or abnormal behavior of your VAD equipment (e.g., damage of equipment or driveline, medium or high priority alarms, batteries not retaining power)
- Always investigate, and if possible, correct the cause of any alarm



**Since the HeartWare™ HVAD™ Pump requires a controller and power to continue to run, you should:**

- Always have spare equipment available in case of emergency, which should include spare controller and fully charged batteries
- Handle your equipment and back up equipment with care:



**Do not drop equipment.** Dropping could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected. Also, do not use a damaged battery.



**Do not allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors.** Do not submerge equipment in water. Do not swim or take a bath. Do not plug controller into AC wall outlet during shower.

Certain environments can cause damage to the equipment or cause the pump to stop.

**To prevent damage you should never:**

- Have an MRI
- Play contact sports
- Undergo a procedure requiring high electrical treatment (e.g., diathermy)
- Be exposed to therapeutic levels of ultrasound (e.g., lithotripsy)
- Be exposed to ionizing radiation

**You should:**

- Keep the HVAD Shoulder Pack and/or Waist Pack at least six inches (15cm) away from your pacemaker or ICD (they contain magnetic closures that could interfere with normal operation of the pacemaker or ICD)



**You should read or re-review the Patient Manual in its entirety. This guide and these reminders are intended to supplement, rather than replace, the Patient Manual.**

**HVAD™ Controller**

The controller operates the pump and makes sure it is working correctly. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help. Tell your doctor if you have vision or hearing problems and always check the controller display for information regarding an alarm when using loud machinery or in the vicinity of loud noises – alarms may not be audible.

The alarm adapter should NOT be attached to a controller that is connected to a running pump.



**To ensure the controller can function properly you should:**

- Operate the controller in temperatures greater than -4 F (-20C) and less than 122 F (50C)
- Keep mobile phones at least 20 inches (50cm) away from controller
- Avoid devices/conditions that may induce strong static discharge

**>-4F (-20C)  
<122F (50C)**



**20in (50cm)**



## Brief Statement: HeartWare™ HVAD™ System

### ⚠ Additional Device Information

The HeartWare™ HVAD™ System assists a failing heart and relieves the symptoms of advanced heart failure. It may be used in advanced heart failure patients whether or not a subsequent heart transplant is planned. You should not receive an HVAD System if you are pregnant or cannot tolerate blood thinning medications.

Implantation of the HVAD System requires major surgery. Risks associated with the implant surgery and with HVAD System use include, but are not limited to, death, stroke, device malfunction, blood clots, bleeding, other types of heart failure, infection, red blood cell destruction, and total body infection. Managing your blood pressure may reduce the risk of stroke.

The HVAD System includes external components that connect to and provide power to the heart pump inside your body. After receiving an HVAD System, you will have some limitations. You will not be able to swim, or otherwise submerge external components in water. You will not be able to shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare shower bag. You may need to modify or perhaps avoid interactions with some sources of electromagnetic interference, electric or gas-powered appliances, and tools. Magnetic resonance imaging (MRI) should not be used, as it could cause severe harm to you and

the pump. You must keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

Proper use and upkeep of the HeartWare HVAD System is required to keep the system working well. Never remove both power sources (batteries or power adapters) from the controller at the same time since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected to the controller at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid kinking or twisting your driveline.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk with your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

See the HeartWare HVAD System Patient Manual for detailed information regarding instructions on operating the HeartWare HVAD System and on necessary medical care. If you have any questions after reading the manual, please ask your clinician.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

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