EMERGENCY GUIDE

2020-2021

International Consortium of Circulatory Assist Clinicians

This guide was created in 2008 by the innovation of VAD Coordinators from some of the largest and most successful VAD implantation hospitals in the United States. ICCAC has ensured that this document continues to be a current resource for not only emergency medical services but to all healthcare workers providing care to the mechanical circulatory support patient population. The purpose is to be a quick emergency guide and should not replace the manufacturers' Instructions For Use as the primary source of information for each device listed in this guide.

Questions and Answers
MECHANICAL CIRCULATORY SUPPORT

Mechanical Circulatory Support Devices (MCS) are heart pumps that move blood from the heart to the body. They are temporary or permanent devices that either supplement or replace the action of a failing heart. MCS devices implanted are assisting the left ventricle (LVAD), the right ventricle (RVAD), or both ventricles (BiVAD) and the total heart (Total Artificial Heart – TAH). They consist of two major categories: Pulse generating (pulsatile) and pulseless devices (non-pulsatile/continuous flow). Patient management varies greatly between the two device categories.

Pulsatile or Non-pulsatile

Pulse generating devices have a chamber that fills with blood and ejects the blood similar to the rhythmic action of the human heart. These devices replace the majority of the heart and move the full amount of blood the patient needs. The Total Artificial Heart pump is a pulse generating device. Non-pulsatile or continuous flow devices use a motor at a fixed speed leading to a constant ejection of blood to the body. This is the reason patients with continuous flow VADs often lack a pulse upon palpation. The most common VADs are non-pulsatile/continuous flow devices.

What is a VAD?

A ventricular Assist Device (VAD) is an implantable mechanical heart pump that helps to pump blood from the lower chambers of the heart to the rest of the body in patients with advanced heart failure. The device helps move partial or full amount of blood meeting the patient needs. These devices can be attached to the Left (LVAD) or Right (RVAD) ventricles of the heart. Most patients have an LVAD and less common are RVADs and BiVADs (both left and right or Biventricular support).

What are the parts of a VAD?

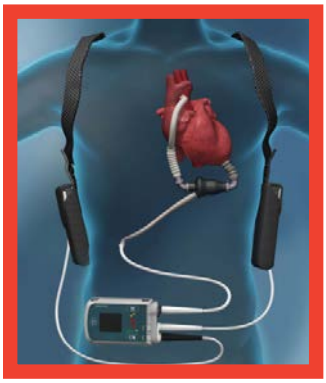
All VADs have at least 4 components. (1) A heart pump unit consisting of a short tube placed inside the ventricle pulling blood thru the pump and out a tube, delivering blood to the body's great vessel; (2) A power cord called a driveline that exits the abdomen and connects to a controller and power source; (3) A controller that displays information; (4) A power source.

What does the controller do?

The controller is a computer that operates the heart pump. It provides messages and audible alarms to help monitor the pump. It gives information about pump performance such as blood flow through the pump (L/min), pump speed (RPM) and the amount of power consumed (Watts). It also gives warnings and alarms if there is an alert/problem with the pump or with the power source, such as low battery or low flow.

What is the power source?

All VADs can be powered by two power sources: rechargeable batteries or AC (electricity) power. Batteries are used when patients are active throughout the day and often are kept in a holster, vest or belt for safety. AC power is recommended when the patient is planning to remain stationary. AC power should NOT be used when transporting the patient.



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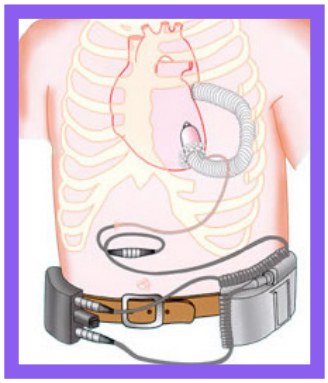

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What is a TAH?

A Total Artificial Heart (TAH) is a mechanical device that replaces the two lower ventricles of the heart. Tubes connect the TAH to a power source that is outside the body. The TAH then pumps blood through the heart's major artery to the lungs and the rest of the body. This is used for people who have inadequate function of both ventricles (biventricular failure).

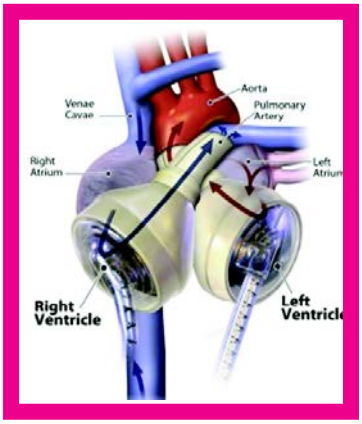
What are the parts of TAH?

The TAH has 3 components. (1) A pump assembly consisting of 2 short tubes attached to the top of the heart and 2 chambers that fill and empty using air that pushes and pulls a membrane back and forth; (2) Air tubes that exit the body and attach to a console; (3) A power source.

What is the power source?

The TAH uses a mobile console called a Freedom Driver when patients are ambulatory. The console is powered by two batteries or AC (electricity) power. The batteries must be well charged before moving the patient and the AC plug should be brought when transporting.

The devices in this MCS Emergency Guide are color coded for quick identification. Patients may have a color matching tag or identifier on their equipment or equipment bag. Patients will also have their primary VAD team contact information for an important resource.



TOTAL ARTIFICIAL HEART (TAH) Page 25

Patient Management For VADs

1. Treat the patient and follow your protocols. Do not focus only on the device. Most patients do not have a primary pump malfunction. Common MCS patient problems that arise are stroke, bleeding disorders (GI, nose bleeds), arrhythmias, dehydration and right heart failure.

2. Assess the patients airway and intervene per your protocol.

3. Auscultate heart sounds to determine if the device is functioning. If it is continuous flow device, you should hear a "humming sound".

4. Assess vital signs. Non-pulsatile or continuous flow devices provide continuous blood flow from the heart to the aorta. This continuous flow results in a narrow arterial pulse pressure. This means it may be difficult to obtain a pulse or blood pressure reading which may be a normal state for a continuous flow device patients. To obtain a blood pressure an automated cuff or doppler method can be used. If unable to obtain with automated cuff use the mean BP with a doppler (first sound you hear – MAP). Rely on other methods to assess perfusion e.g. mental status, skin color, capillary refill. The device flow shown on the controller display reflects the patient's cardiac output.

5. Start IV if indicated.

6. Assess the device for device information and alarms located on the controller display.

7. Intervene appropriately based on the type of alarm. See specific device alarm guides on the pages that follow.

8. Refer to the patient's medication list. They are typically, but not always, on anticoagulation and antiplatelet therapy.

9. Call the VAD Center's 24 hour emergency number on the patient's contact list, controller/equipment, or emergency bag for assistance in the management of the patient and transportation determination and location.

10. **Bring all of the patients equipment.**

11. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

HeartWare™ HVAD™ System

1. **Can I do CPR?**

   Yes, in the right clinical scenario. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump.

2. **Can the patient be defibrillated while connected to the device?**

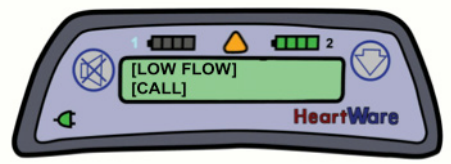
   Yes, you can defibrillate, and nothing needs to be turned off or disconnected.

3. **Can this patient be externally paced?**

   Yes.

4. **What type of alarm occurs in a low flow state?**

   If a low flow state occurs, an alarm will be heard, and the controller display will show a yellow triangle and [Low Flow] [Call] message.



5. **Can I change the speed of the device?**

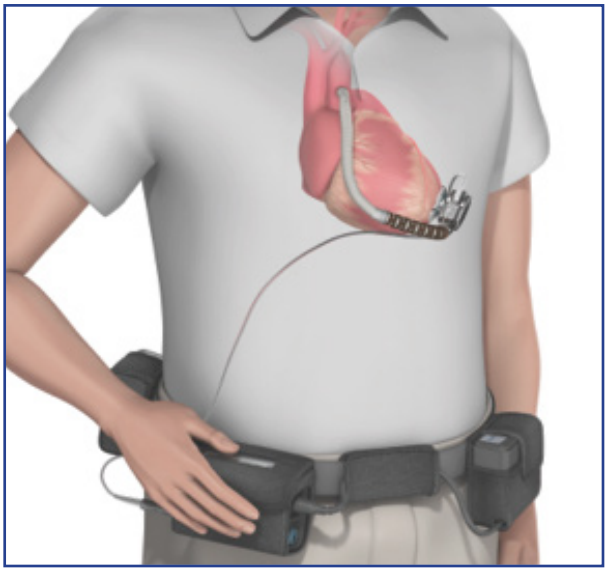
   No, the device runs at a fixed speed. It is not possible to adjust the pump speed in the pre-hospital setting.

6. **Does the patient have a pulse with this device?**

   Likely they will not because it is a continuous flow device, however some patients may have a pulse.

7. **What are acceptable vital sign parameters?**

   For patients with a palpable pulse, MAP targets should be ≤ 85 mm Hg. For patients without a palpable pulse, a manual cuff and a doppler is the preferred method with a MAP target of ≤ 90 mm Hg. If you are using a doppler, place the blood pressure cuff on the patient arm. As you release the pressure in the blood pressure cuff, the first sound you hear with the Doppler is the MAP. If that is not available, use a non-invasive BP (NIBP).



FAQs

- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to electric line (driveline) exiting patient's abdominal area and is attached to controller which runs the pump.
- Pump does not affect ECG, but patient may or may not be symptomatic even with ventricular arrhythmias.
- All ACLS drugs may be given.
- This is a rotary (continuous flow) pump with typical speed ranges of 2400 – 3200 RPMs. The patient should have back-up equipment e.g. controller & charged batteries.
- The controller draws power from one battery at a time. A fully charged battery will provide 4-7 hours of power. Both the battery and controller have status lights to indicate the amount of power remaining.
- Transport by ground or flight to the implanting facility if possible.
- Be sure to bring **ALL** of the patient's equipment with them. e.g. back-up controller, charged batteries, ac adapter and charger.

HeartWare™ HVAD™ System

Driveline

Power Source #2

Battery Charge Indicator

ALARM ADAPTER

- Used to silence the [No Power] alarm.
- Should only be used on a controller that is NOT connected to a patient's pump.
- Insert into data port covered with a dust cap of the original controller after a controller exchange BUT before the power sources are disconnected or the [No Power] alarm will sound for up to two hours.

Red Alarm Adapter

DRIVELINE CONNECTION

To Connect to Controller:

- Align the two red marks and push the driveline connector straight into the silver driveline port. (Figure A)
- The Driveline Cover must completely cover the Controller's silver driveline connector to protect against static discharge. (Figure B)

Figure A

Figure B

NOTE: an audible click should be heard when connecting the Driveline to the controller. Failure to use the Driveline Cover may cause an Electrical Fault Alarm.

TO DISCONNECT A DEPLETED BATTERY

- Make sure there is a fully charged battery available to replace the depleted one.
- Disconnect the depleted battery by turning the connector sleeve counterclockwise until it stops.
- Pull the connector straight out from the controller.

CONNECTING POWER TO CONTROLLER

To Connect a Charged Battery:

- Grasp the cable of the charged battery at the back end of the connector (leaving front end of connector free to rotate)
- Line up the solid white arrow on the connector with the white dot on the Controller.
- Gently push (but DO NOT twist) the battery cable into the Controller until it naturally locks into place; you should hear an audible click.
- Confirm that the battery cable is properly locked on the controller by gently pulling the cable near the controller power connector.
- **DO NOT force the battery cable into** the controller connector without correct alignment as it may result in damaged connectors .

Power Source Connection

HeartWare™ HVAD™ System Emergency Operation

STEPS TO EXCHANGE THE CONTROLLER

Exchange the controller when the controller display indicates [Change Controller]. Priority is to restart the pump quickly.

It may be helpful to remember the 4 P's:

1. **POWER...** Connect a power source to the new controller.

2. **PUMP...** Restart the pump by connecting the driveline to the new controller.

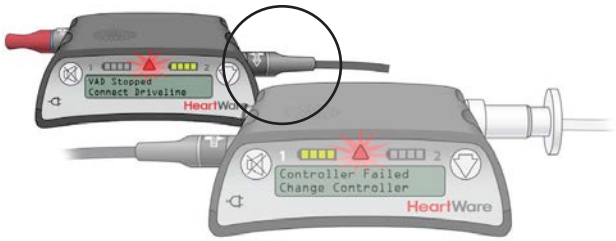
3. **PREVENT...** Prevent the [No Power] alarm on the original controller with the red alarm adapter or by pressing the Scroll and Mute buttons at the same time until a "beep" is heard, or for at least 5 seconds.

4. **POWER...** Connect a second power source to the new controller.

Step 1: Have patient sit or lie down and place the back-up controller within easy reach. The backup controller will become the new controller.

Step 2: Connect one **POWER** source to the new controller.

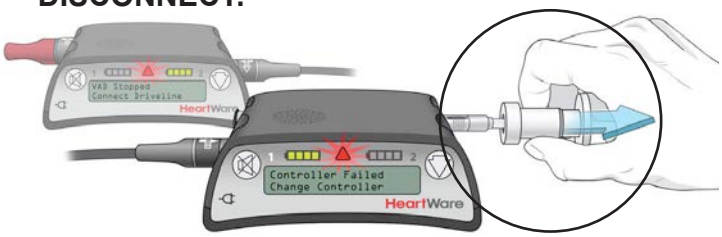
NOTE: The new controller may alarm after 10 seconds with a [VAD Stopped, Connect Driveline] high alarm. This is expected behavior.



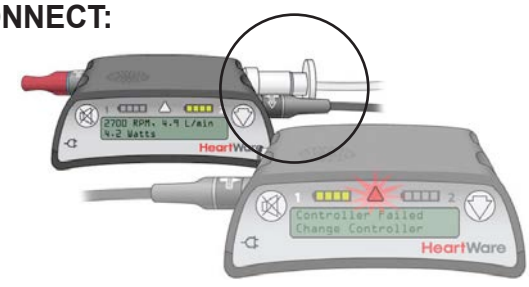
Step 3: Disconnect the driveline from the original controller and connect the driveline to the new controller. This should restart the **PUMP.**

• Verify that the pump is working. The RPM, L/min and Watts numbers should show on the Controller Display. If the pump does not restart, re-check driveline and power source connections, if it still doesn't start, call the patient's VAD team for assistance.

DISCONNECT:



CONNECT:



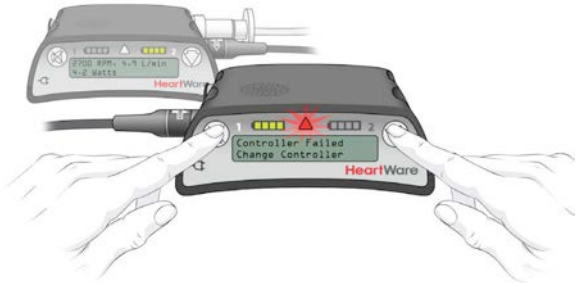
• If you have only connected 1 power source to the new controller, you will also have a [Power Disconnect, Reconnect Power] alarm.

HeartWare™ HVAD™ System Emergency Operation

Step 4: PREVENT the [No Power] alarm from sounding on the original controller. This needs to be done before removing all power. There are 2 options, see below:

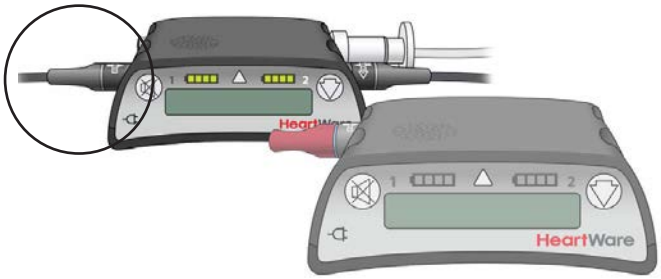
- If a red alarm adapter is available:
  - – Insert it into the connector data port on the original controller
  - – You can now remove all power from the original controller and no alarm should sound.

- If no red 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.
  - – You can now remove all power from the original controller and no alarm should sound.

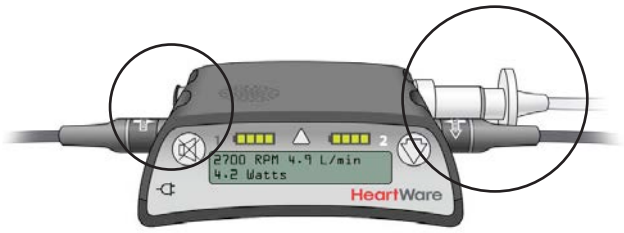


- If you removed power before silencing the [No Power] alarm, reconnect a power source and follow the steps above to silence it.

Step 5: Connect a second **POWER** source to the new controller.

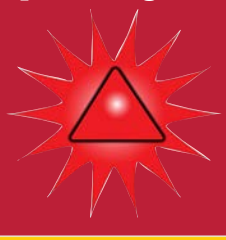
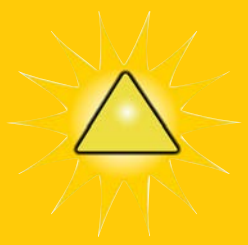


Step 6: Be sure the driveline cover is over the silver driveline connector and the data port is covered by the dust cap. If the red alarm adapter is connected to the controller that is now running the pump, remove it and close the cap on the data port.



Call the patients VAD team to obtain a new back-up controller.

HeartWare™ HVAD™ System Troubleshooting

Alarm Type	Alarm Display (Line 1)	Action (Line 2)
ALARM [No Power]	[no message]	[no message]
	When both power sources (2 batteries or 1 battery and an AC adapter or DC adapter) are removed. NO message will display on the controller. The [No Power] alarm will sound but the Alarm Indicator on the controller WILL NOT light. This indicates the pump has stopped. You should immediately connect two power sources.	
HIGH-CRITICAL [Flashing Red] 	[VAD Stopped]	[Connect Driveline]
	[VAD Stopped]	[Change Controller]
	[Critical Battery]	[Replace Battery 1]
	[Critical Battery]	[Replace Battery 2]
	[Controller Failed]	[Change Controller]
MEDIUM [Flashing Yellow] 	[Controller Fault]	[Call]
	[Controller Fault]	[Call: ALARMS OFF]
	[High Watts]	[Call]
	[Electrical Fault]	[Call]
	[Low Flow]	[Call]
	[Suction]	[Call]
LOW [Solid Yellow] 	[Low Battery 1]	[Replace Battery 1]
	[Low Battery 2]	[Replace Battery 2]
	[Power Disconnect]	[Reconnect Battery 1]
	[Power Disconnect]	[Reconnect Power 2]

[CALL] VAD team listed on the patient's contact sheet.