



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.

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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?

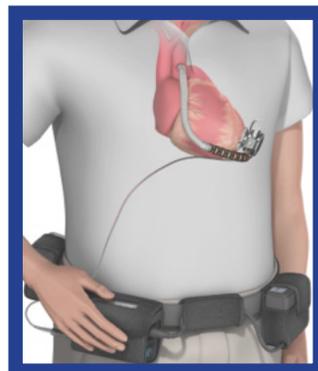
All VADs can be powered by two power sources: rechargeable batteries or AC (electricity) power. Batteries are used when patients are active throughout the day and often are kept in a holster, vest or belt for safety. AC power is recommended when the patient is planning to remain stationary. AC power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



HEARTMATE II Page 4



HEARTMATE 3 Page 9



HEARTWARE HVAD Page 13



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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).

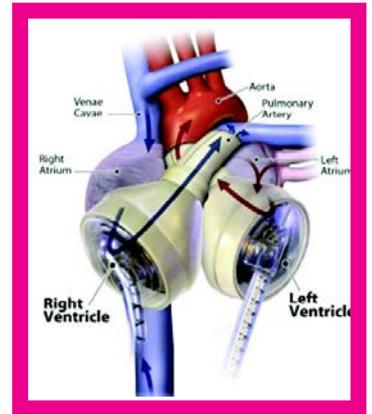
What are the parts of TAH?

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.**

HeartMate II™ Left Ventricular Assist System

1. Can I do CPR?

Yes, in the right clinical scenario. Chest compressions may pose a risk of dislodgement - use clinical judgment. If compressions are administered, confirm function and positioning of the pump.

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

Yes you can defibrillate, and you do not have to disconnect anything.

3. Can this patient be externally paced?

Yes.

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

A red heart alarm indication and steady audio alarm will sound if less than 2.5 lpm. Can give a bolus of normal saline and transport to a VAD center.

5. Can I change the speed of the device?

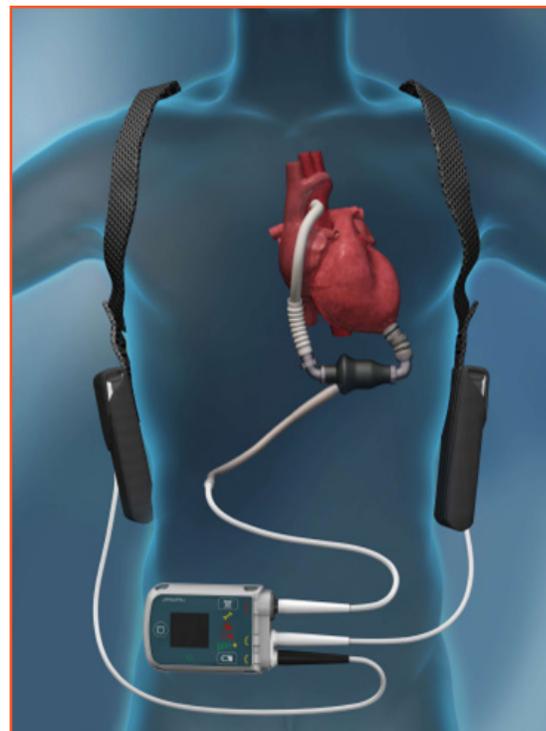
No, it is a fixed speed.

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?

MAP 70 - 90 mm Hg with a narrow pulse pressure.

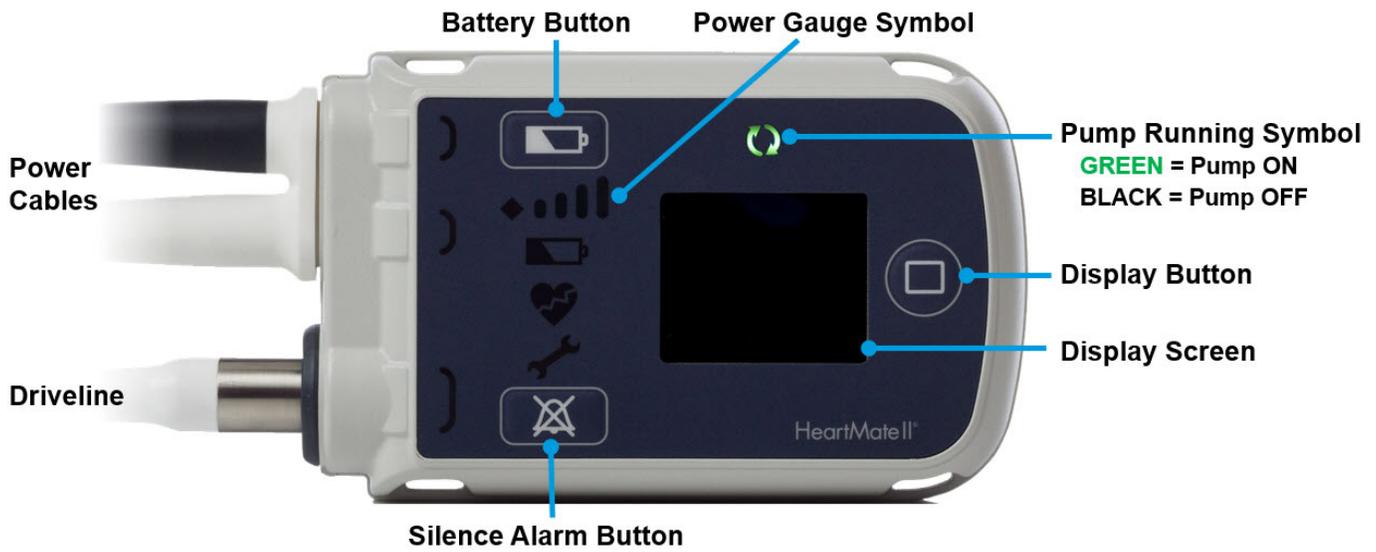


Frequently Asked Questions

- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to driveline exiting patient's abdominal area and is attached to controller which runs the pump.
- Pump does not affect ECG.
- All ACLS drugs may be given.
- No hand pump is available.
- A pair of fully charged batteries last approximately 10 - 12 hours.
- Avoid pulling, twisting, or kinking the driveline when strapping the patient to a stretcher.
- Any emergency mode of transportation is ok. These patients are permitted to fly.
- Be sure to bring **ALL** of the patient's equipment with them.

HeartMate II™ Left Ventricular Assist System

System Controller



Changing Batteries

WARNING: At least one controller power cable must be connected to a power source **AT ALL TIMES**. Do not remove both batteries at the same time or the pump will stop.

- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each battery can be assessed by pressing the button on the battery. Fully charged batteries will display 5 lights. (Figures 1 and 2)
- Check the power level on the batteries, replace the battery with the fewest lights first. Remove only **ONE** battery from the clip by pressing the release button on the clip to unlock the battery. (Figure 3)
- Controller will start beeping and flashing yellow symbols and will read **CONNECT POWER** on the front screen.
- Insert a new, fully charged battery into the empty battery clip by aligning the **RED** arrows on the battery and clip (Figure 4). The battery will click into the clip. Gently tug on battery to ensure connection. If the battery is properly secured, the beeping and yellow flashing will stop.
- Repeat previous steps with the second battery and battery clip.



Figure 1



Figure 2



Figure 3



Figure 4

Troubleshooting HeartMate II™ LVAS

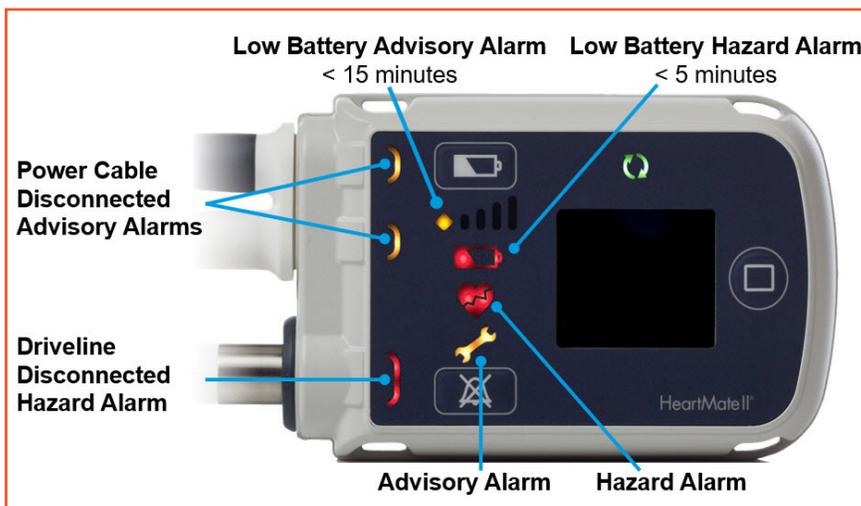
Alarms: Emergency Procedures

When an alarm occurs:

- Contact the Implant Center for direction when possible.
- Check alarm messages on controller display screen.
- Check if pump is running:
- Allow care providers trained on LVAD emergencies to remain with the patient.

When the Pump Has Stopped

- Check the driveline and power cable connections to the controller. Fix any loose connections to restart the pump.
- If the pump does not restart and the patient is connected to batteries replace the current batteries with a new, fully-charged pair. (see *Changing Batteries section on previous page*)
- If pump does not restart, change controllers if directed by implant center. (see *Changing Controllers on next page*)
- Be sure to bring ALL of the patient's equipment with them.



HAZARD ALARMS Continuous Audible Tone

Low Flow ⌚ :03	+ Call Hospital Contact ⌚ :07		Pump is off.	See above, when pump has stopped
			Pump flow is < 2.5 lpm.	Ensure that a power source is connected to the controller. Evaluate the patient for low flow - treat the cause. Assess volume status, hypertension, arrhythmia, right heart failure, etc.
Connect Driveline ⌚ :02			Driveline disconnected.	Immediately reconnect Driveline to the controller. Check modular cable connection.
Connect Power Immediately ⌚ :05	+ Backup Battery ⌚ :01		Both power cables are disconnected.	Immediately connect to batteries or the Mobile Power Unit.
Low Battery ⌚ :06	+ Replace Power ⌚ :02		Low Battery Power < 5 min. remaining.	Immediately replace batteries or switch to the Mobile Power Unit.

ADVISORY ALARMS Intermittent Audible Tone

Low Battery ⌚ :06	+ Replace Power Immediately ⌚ :02		Low Battery Power <15 min. remaining.	Immediately replace batteries or switch to the Mobile Power Unit.
Connect Power ⌚ :04		OR	A power cable is disconnected.	Reconnect the power cable to power.

Check display for alarm type. Call VAD Coordinator at implant center for direction.

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ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE

Troubleshooting HeartMate II™ LVAS

Changing the System Controller

- Step 1:** Have the patient sit or lie down since the pump will momentarily stop during this procedure.
- Step 2:** Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.

- Step 3:** Attach the battery clips to the replacement controller by lining up half circles, firmly pushing together, and tightening connector nut. Insert the batteries into the clips by aligning the **RED** arrows.

- Step 4:** On the back of the replacement controller, slide the safety lock so the red release button is fully visible. Repeat this step on the original controller.

- Step 5:** Disconnect the drive-line from the original controller by pressing the red release button and pulling it out. The pump will stop and an alarm will sound. **Note:** The alarm will continue until the original controller is turned off. You can silence the alarm by pressing the silence alarm button.

Getting the replacement controller connected and the pump restarted is the first priority!

- Step 6:** Connect the replacement Controller by aligning the **YELLOW ARROWS** on the driveline and replacement Controller and firmly pushing the driveline into the replacement controller. The pump should restart, if not complete the following steps:

- Firmly press the Silence Alarm or Battery Button to restart the pump.
- Check the power source to ensure that power is going to the controller.
- Ensure the driveline is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the driveline.

- Step 7:** After the pump restarts, slide the safety lock on the new controller so the red release button is fully covered. If unable to close the safety lock into fully locked position, gently push the driveline into the controller to ensure proper connection. Retry to close safety lock.

- Step 8:** Disconnect power from the original Controller.

- Step 9:** Hold down battery symbol for 5 full seconds to turn off the original controller.



Step 3



Step 4



Step 7



Step 5



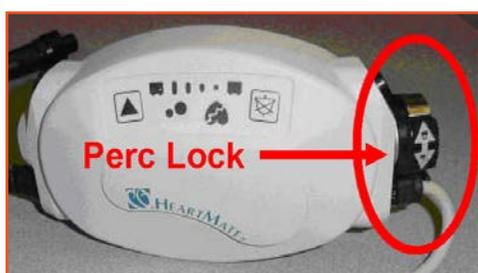
Step 6



Step 9

HeartMate II™ Left Ventricular Assist System

The following information applies to the original controller version called External Peripheral Controller (EPC). Some patients have this controller.



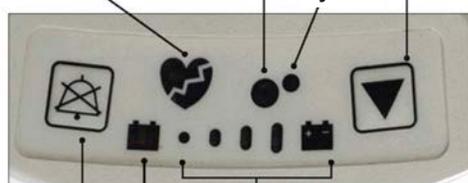
Driveline Connection: The Perc Lock must be “unlocked” in order for the driveline to be removed in a controller exchange. The Perc lock remains in locked position once the driveline has been fully inserted.

A battery clip can be attached to the EPC controller by lining up the half moons and gently pushing. Batteries can be attached to the battery clip by aligning the RED arrows on the battery and clip.



External Peripheral Controller (EPC)

Red Heart Alarm Cell Modular Alarm Power Symbol Test Select Button



Alarm Silent Button Battery Alarm Battery Gauge

2 MODES: ON, OFF

On: Driveline+Power source connected.
Off: No driveline or power source connected.

CELL MODULE BATTERY

No backup battery. The cell module battery powers an audible tone if EPC is removed from power while the driveline is connected. The cell module battery is supplied STERILE.

EVENT LOGGER

EPC does not include date/time records in event history. EPC can store 120 events.

GREEN POWER SYMBOL

 Green light only means that the controller is receiving power. Listen over the pump pocket for confirmation that the pump is running.

CONTROLLER BUTTONS

Alarm Silence Button: Displays the battery fuel gauge. Also silences hazard alarms for 2 minutes and advisory alarms for 4 hours.

Test Select Button: Activates a self test when held for 3 seconds.

Note: EPC does not include a display button or user interface screen. The Display Module is used to view pump parameter and alarm events.

SELF TEST

Press and hold the Test Select Button for 3 seconds.

LOW POWER

 **Yellow Battery Symbol:** Displayed when only 15 minutes of external power is remaining.

 **Red Battery Symbol:** Displayed when only 5 minutes of external power is remaining.

POWER SAVER MODE:

Entered when the battery voltage falls to a critically low level. Pump Speed is reduced to 8000 RPM.

STARTING THE PUMP

>8000 RPM: Pump starts automatically.

<8000 RPM: Start pump by pressing Alarm Silence Button or Test Select Button on EPC.

SYSTEM MONITOR EVENT HISTORY SCREEN

PI Event:

10/04/13 07:20	4.8	9590	5.6	5.4
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System Information:

10/04/13 01:30	4.8	6900	5.7	6.6	*
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COMPATIBILITY

System Monitors I and II, Power Module, Power Base Unit (PBU), Power Module Patient Cable (12 Volt and 14 Volt), 14 Volt Lithium-ion Batteries and Battery Clips, 12 Volt SLA and NiMH Batteries and Clips.

ALARMS

For a review of alarms and their meanings, reference the HeartMate II Alarms for Clinicians, Item 103851. Note that EPC does not include Driveline fault detection.

External Peripheral Controller (EPC): A percutaneous lock is located on the side of the controller.



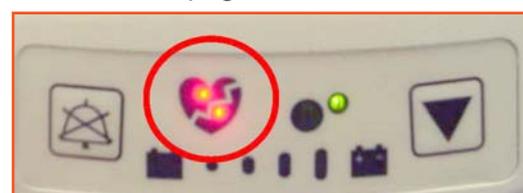
Unlock



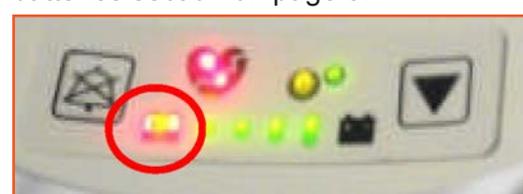
Locked

Alarms: Emergency Procedures

Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If patient is hypovolemic, give volume. If patient is in right heart failure-- treat per protocol. If the pump has stopped check connections, batteries and controllers as instructed on page 5.



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on page 5.



HeartMate 3™ Left Ventricular Assist System

1. Can I do CPR?

Yes, in the right clinical scenario. Chest compressions may pose a risk of dislodgement - use clinical judgment. If compressions are administered, confirm function and positioning of the pump.

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

Yes you can defibrillate, and you do not have to disconnect anything.

3. Can this patient be externally paced?

Yes.

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

A red heart alarm indication and steady audio alarm will sound if less than 2.5 lpm. Can give a bolus of normal saline and transport to a VAD center.

5. Can I change the speed of the device?

No, it is a fixed speed.

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

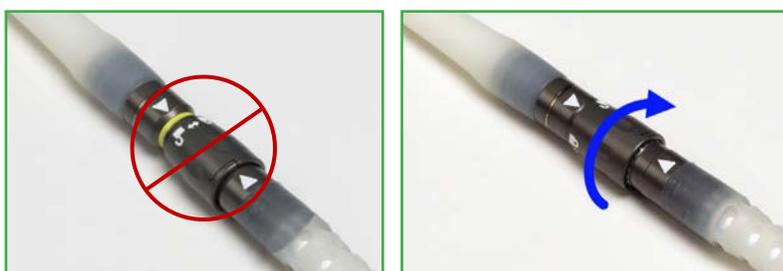
Likely they will not because it is a continuous flow device, however some patients may have a pulse.

7. What are acceptable vital sign parameters?

MAP 70 - 90 mm Hg with a narrow pulse pressure.

The HeartMate 3™ LVAD has a modular cable connection near the exit site of the driveline (Figure 1). This allows a damaged driveline to be quickly replaced (if damage is external).

- When disconnecting a driveline, NEVER use the modular cable connection.
- If the modular cable requires replacement, it must be done at and by the implanting center. Patients are not given a backup modular cable.
- If the connection is loose, a yellow line at the connection will be showing. If the line is visible, turn the connector in the locked direction. It will ratchet and stop turning once tight.



FAQs

- Pump has “artificial pulse” created by rapid speed changes in the pump. This can be heard when auscultating the heart and differs from other continuous flow devices.
- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to driveline exiting patient’s abdominal area and is attached to controller which runs the pump.
- Pump does not affect ECG.
- All ACLS drugs may be given.
- A pair of fully charged batteries lasts up to 17 hours.
- Any emergency mode of transportation is ok. These patients are permitted to fly.
- Avoid pulling, twisting, or kinking the driveline when strapping the patient to a stretcher.
- Be sure to bring **ALL** of the patient’s equipment with them.

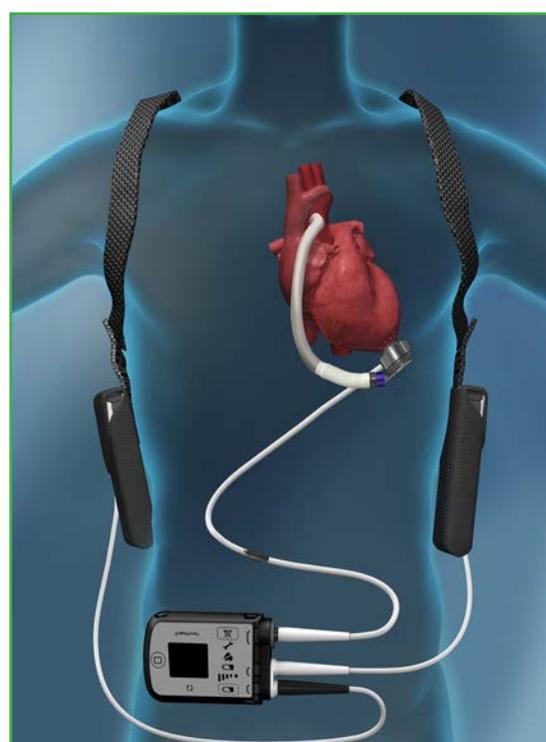
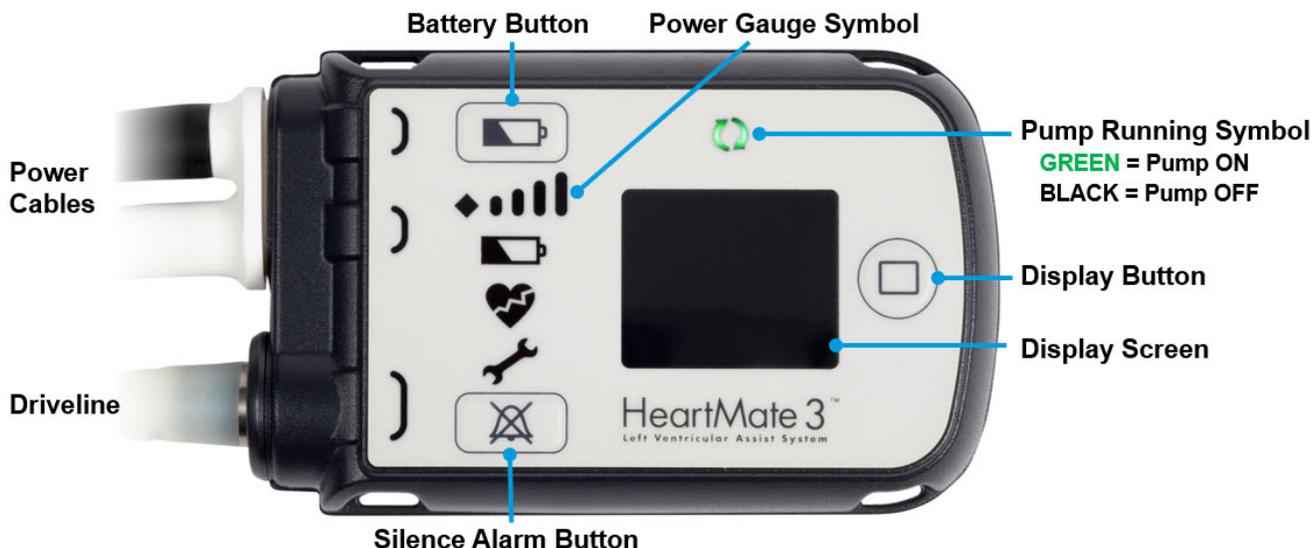


Figure 1

HeartMate 3™ Left Ventricular Assist System

System Controller



Changing Batteries

WARNING: At least one controller power cable must be connected to a power source **AT ALL TIMES**. Do not remove both batteries at the same time or the pump will stop.

- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each battery can be assessed by pressing the button on the battery. Fully charged batteries will display 5 lights. (Figures 1 and 2)
- Check the power level on the batteries, replace the battery with the fewest lights first. Remove only ONE battery from the clip by pressing the release button on the clip to unlock the battery. (Figure 3)
- Controller will start beeping and flashing yellow symbols and will read **CONNECT POWER** on the front screen.
- Insert a new, fully charged battery into the empty battery clip by aligning the **RED** arrows on the battery and clip (Figure 4). The battery will click into the clip. Gently tug on battery to ensure connection. If the battery is properly secured, the beeping and yellow flashing will stop.
- Repeat previous steps with the second battery and battery clip.

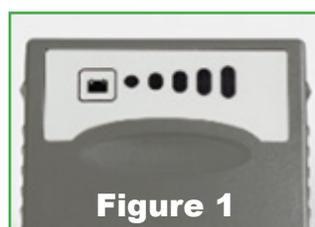


Figure 1

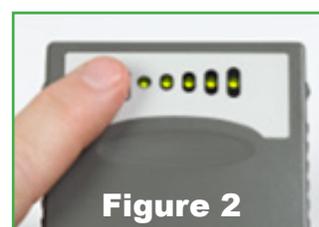


Figure 2



Figure 3



Figure 4

Troubleshooting HeartMate 3™ LVAS

Changing the System Controller

Step 1: Have the patient sit or lie down since the pump will momentarily stop during this procedure.

Step 2: Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.

Step 3: Attach the battery clips to the replacement controller by lining up half circles, firmly pushing together, and tightening connector nut. Insert the batteries into the clips by aligning the **RED** arrows.

Step 4: On the back of the replacement controller, slide the safety lock so the red release button is fully visible. Repeat this step on the original controller.

Step 5: Disconnect the drive-line from the original controller by pressing the red release button and pulling it out. The pump will stop and an alarm will sound. Note: The alarm will continue until the original controller is turned off. You can silence the alarm by pressing the silence alarm button.

Getting the replacement controller connected and the pump restarted is the first priority!

Step 6: Connect the replacement Controller by aligning the **WHITE ARROWS** on the driveline and replacement Controller and firmly pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:

- Firmly press the Silence Alarm or Battery Button to restart the pump.
- Check the power source to ensure that power is going to the controller.
- Ensure the driveline is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the driveline.

Step 7: After the pump restarts, slide the safety lock on the new controller so the red release button is fully covered. If unable to close the safety lock into fully locked position, gently push the driveline into the controller to ensure proper connection. Retry to close safety lock.

Step 8: Disconnect power from the original Controller.

Step 9: Hold down battery symbol for 5 full seconds for complete shutdown of old controller.



Step 3



Step 4



Step 7



Step 5



Step 6



Step 9

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?

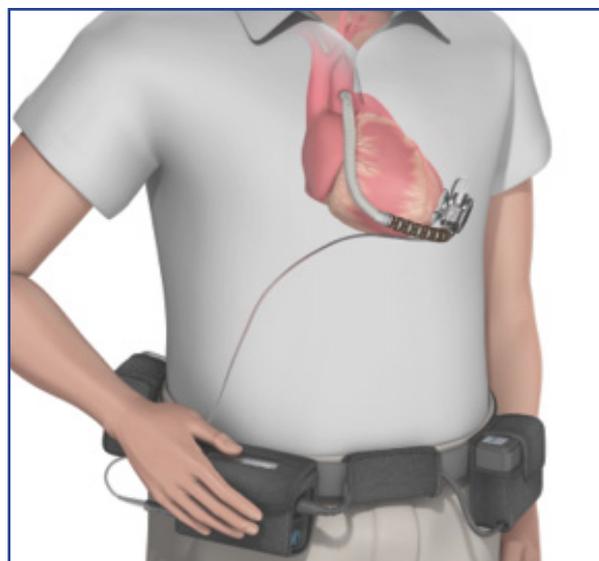
No, the device runs at a fixed speed. It is not possible to adjust the pump speed in the pre-hospital setting.

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?

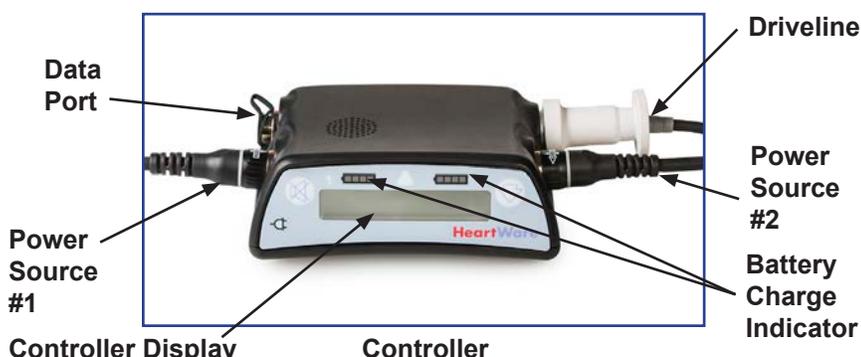
For patients with a palpable pulse, MAP targets should be ≤ 85 mm Hg. For patients without a palpable pulse, a manual cuff and a doppler is the preferred method with a MAP target of ≤ 90 mm Hg. If you are using a doppler, place the blood pressure cuff on the patient arm. As you release the pressure in 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



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

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)

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

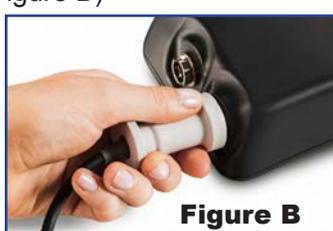


Figure B

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.



Battery test button

Battery charge indicator



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:

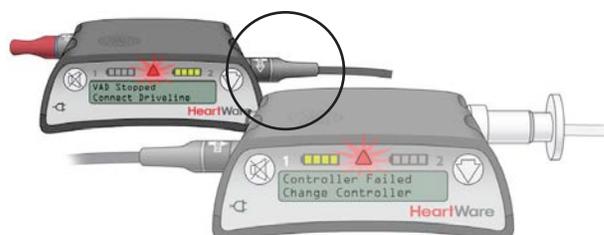
- 1. POWER...** Connect a power source to the new controller.
- 2. PUMP...** Restart the pump by connecting the driveline to the new controller.
- 3. PREVENT...** Prevent the [No Power] alarm on the original controller with the red alarm adapter or by pressing the Scroll and Mute buttons at the same 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.

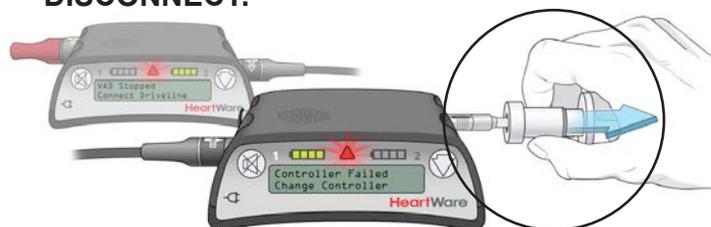
NOTE: The new controller may alarm after 10 seconds with a [VAD Stopped, Connect Driveline] high alarm. This is expected behavior.



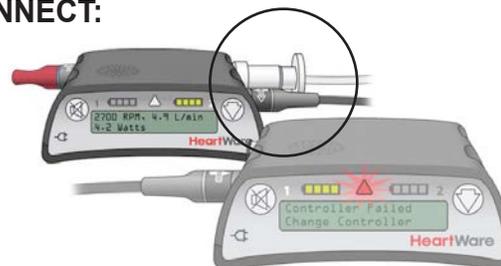
Step 3: Disconnect the driveline from the original controller and connect the driveline to the new controller. This should restart the **PUMP**.

- 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.

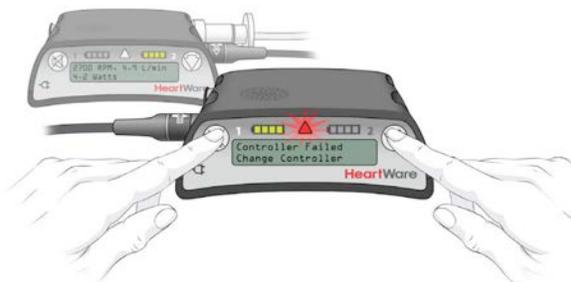
HeartWare™ HVAD™ System Emergency Operation

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.

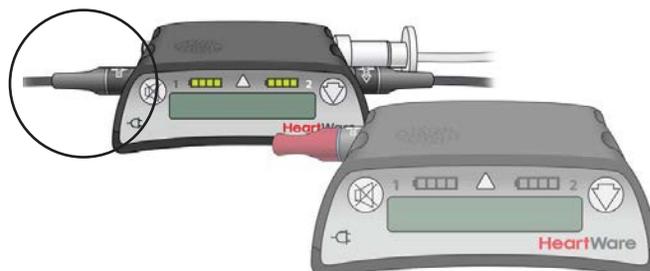


- If no red alarm adapter is available:
 - Press and hold the “Alarm Mute” and “Scroll” buttons on the original controller until a “beep” is heard, or for at least 5 seconds.
 - Release the “Alarm Mute” and “Scroll” buttons.
 - You can now remove all power from the original controller and no alarm should sound.

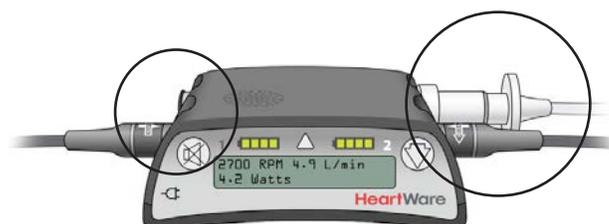


- If you removed power before silencing the [No Power] alarm, reconnect a power source and follow the steps above to silence it.

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

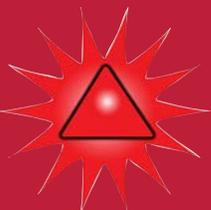
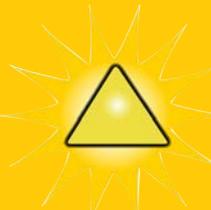


Step 6: Be sure the driveline cover is over the silver driveline connector and the data port is covered by the dust cap. If the red alarm adapter is connected to the controller that is now running the pump, remove it and close the cap on the data port.



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.

Jarvik 2000[®] Ventricular Assist System (VAS)

1. Can I do external CPR?

Yes, in the right clinical scenario. Chest compressions may pose a risk of dislodgement - use clinical judgment. If compressions are administered, confirm function and positioning of the pump.

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

Yes, you can defibrillate, and you do not have to disconnect anything.

3. Can this patient be externally paced?

Yes.

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

No alarm for low flow. If pump is off, the red "Pump Stop" symbol will light with a continuous alarm.

5. Does the patient have a pulse with this device?

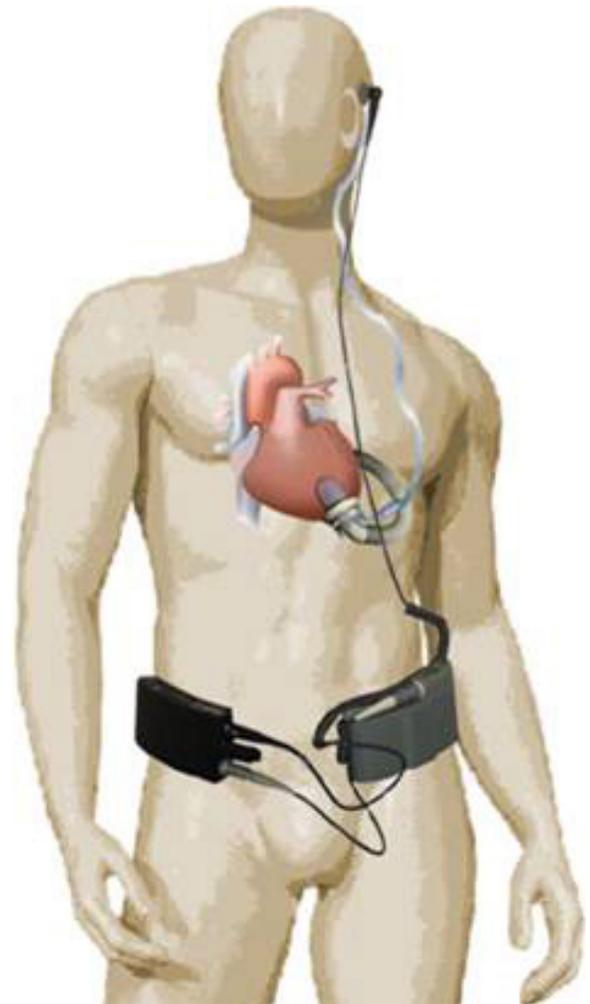
Most patients have a faint palpable pulse. If the controller is marked "ILS" (see below), the speed is automatically reduced every minute for 8 seconds & the patients pulse may increase during this time.

6. Can I change the speed of the device?

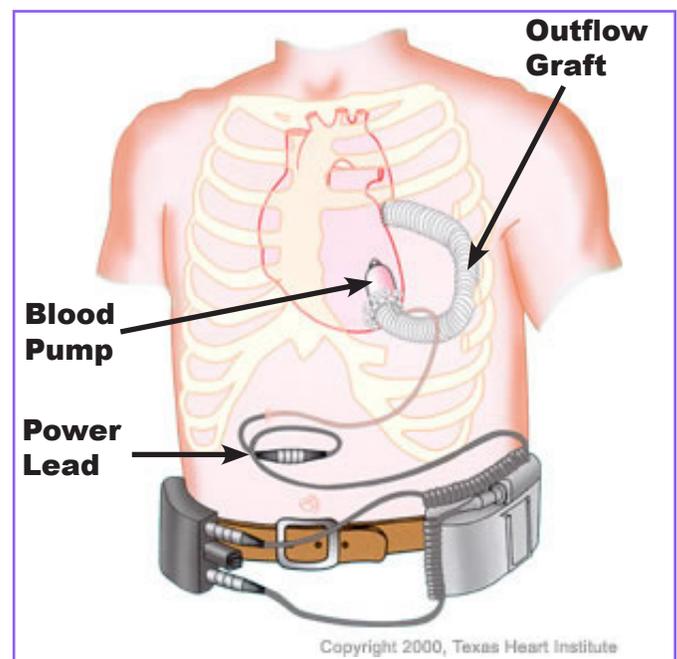
There is a speed dial on the side of the controller (see picture on next page). Turning the dial in the direction of the arrow increases the speed. Each increment is 1,000 RPM. It is recommended not to change the speed without consulting the implanting center.

7. What are acceptable vital sign parameters?

MAP 65 - 80mm Hg.

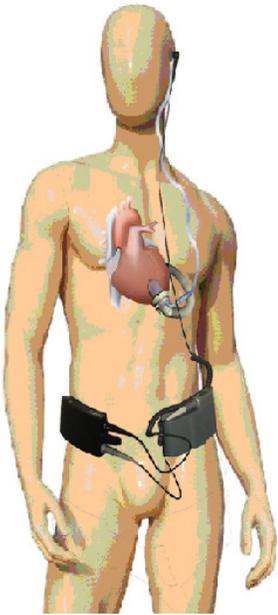


Jarvik 2000 with Post-Auricular exit site.

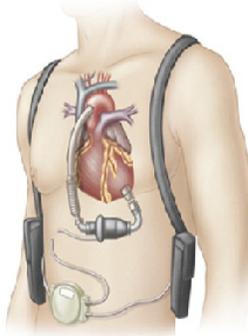


Jarvik 2000 with Abdominal exit site.

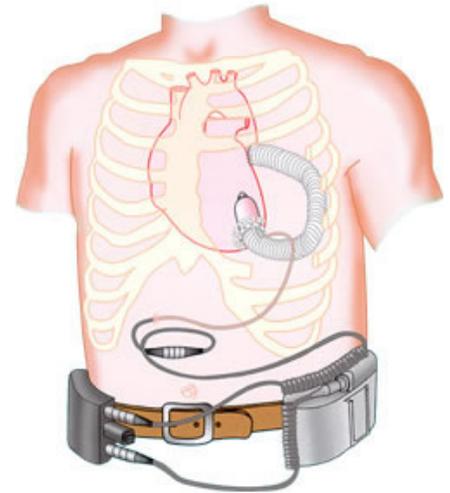
Jarvik 2000® VAS



**Jarvik 2000® VAS,
Post-Auricular Cable.**

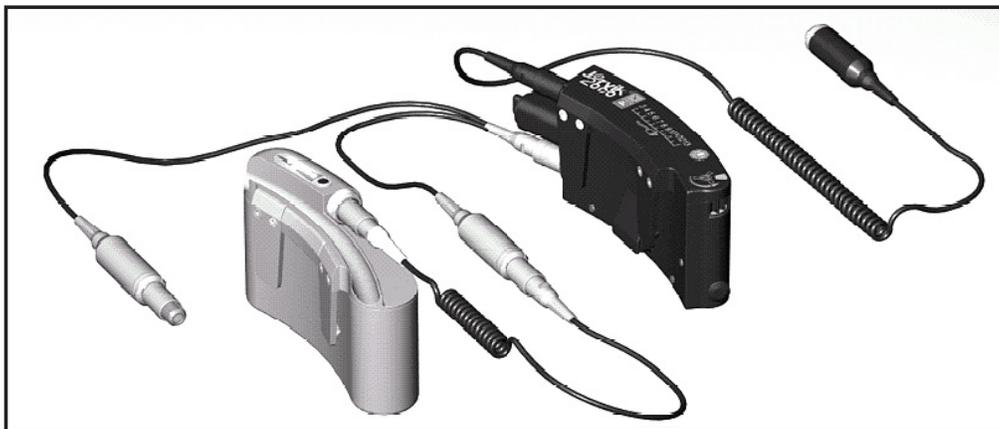


The Jarvik 2000® VAS is available in two models: the Jarvik 2000® VAS, Post-Auricular Cable (JHI-001) and the Jarvik 2000® VAS, Abdominal Cable (JHI-002). The main difference between the two models is the exit site of the drive cable. The drive cable of the Jarvik 2000® VAS, Abdominal Cable exits the abdomen and the drive cable of the Jarvik 2000® VAS, Post-Auricular Cable exits at a Pedestal surgically attached to the skull behind the ear.

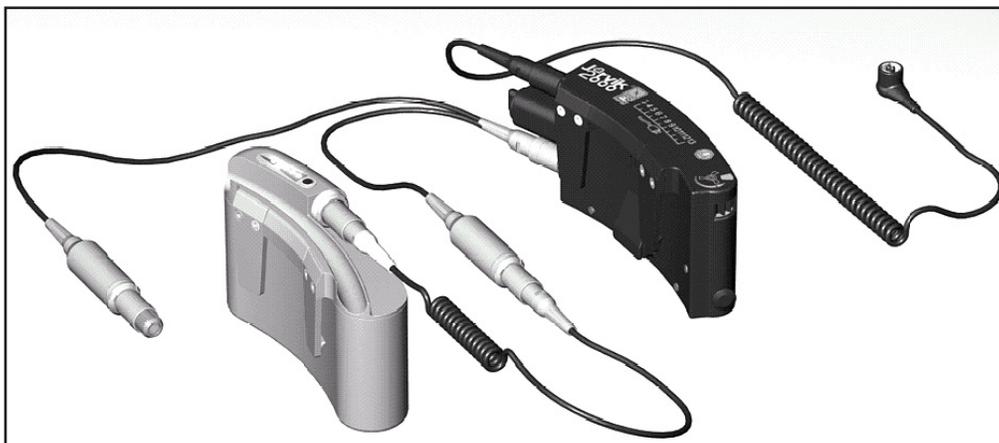


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**Jarvik 2000® VAS,
Abdominal Cable.**



External Equipment for Jarvik 2000® VAS, Abdominal Cable.



External Equipment for Jarvik 2000® VAS, Post-Auricular Cable.

NOTE: This Guide is NOT intended to replace the Operator Manual and Patient Handbook.

Jarvik 2000® VAS



Li-ion Battery.



Reserve Battery/Charger.



FlowMaker® Controller.

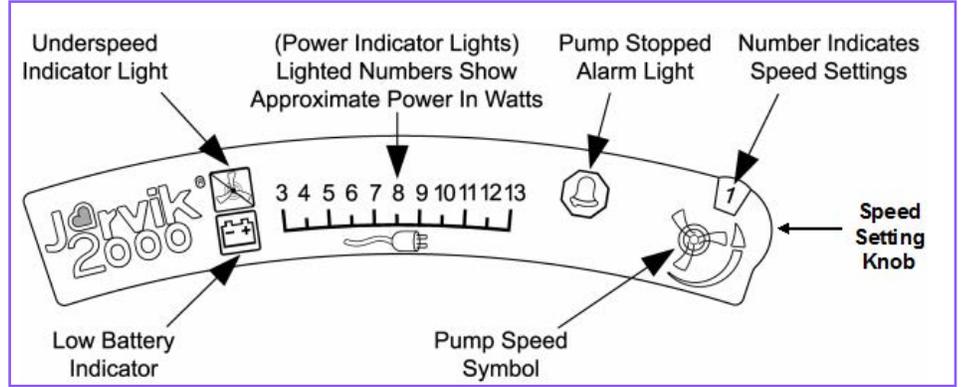


Diagram of FlowMaker® Controller Top Panel.

Dial Setting	Speed Rpm	Flow L/min	Power Watts
1	8,000	1-2	3-4
2	9,000	2-3	4-5
3	10,000	4-5	5-6-7
4	11,000	5-7	7-8-9
5	12,000	7-8.5	8-9-10

The FlowMaker Controller provides:

1. power to the implanted blood pump,
2. user settable speeds at which the pump runs, and
3. alarms and warnings.

The **FlowMaker®** Controller does not monitor the actual blood flow that the **Jarvik 2000® Ventricular Assist Device (VAD)** is pumping. In general, the higher the setting number the more blood the Jarvik 2000 VAD will pump. The tabulated flow estimates are based on research measurements in healthy animals. The actual blood flow may vary and will depend on several factors including blood pressure and the condition of the natural heart.



Jarvik 2000® VAS

Speed Setting, Alarms, and Warnings



Only one control adjustment to the **Jarvik 2000® VAD** can be made. The **Jarvik 2000® VAD speed** can be selected by turning the knob on the side of the **FlowMaker® Controller**. The setting number appears in the window on the top panel. The arrow indicates the direction to turn the knob to increase the speed.



Power Indicator Lights The numbers indicate the electrical power (Watts) that the VAD is using. One, two, or three numbers may be lit at any moment, and the lights may change rhythmically with the heartbeat of the natural heart. A power measure of 13 watts or more indicates malfunction. The High Power Indicator, number 13, will light yellow. This condition should receive prompt medical attention.



When the battery powering the **Jarvik 2000® VAD** is low, the **Low Battery Alarm** on the **FlowMaker® Controller** lights yellow and the alarm sound beeps. Remaining running time with the portable Li-ion Battery is about 5-10 minutes.



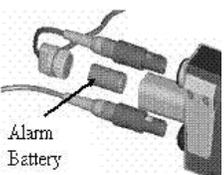
If the **Jarvik 2000® VAD** stops or if the VAD speed drops to below 5,000 RPM for any reason, a steady alarm sound is heard and the **Pump Stopped Alarm** on the **FlowMaker® Controller** lights red. The **Pump Stopped Alarm** will also sound if the intermittent low speed featured on the ILS FlowMaker® Controller fails to function for any reason. Immediate attention is required. **Follow the Pump Stopped Alarm procedure for the appropriate Jarvik 2000® VAS model (Post-Auricular Cable or Abdominal Cable) which is included in this guide.**



The **Underspeed Indicator light will glow yellow** when the **Flowmaker® Controller** detects that the **Jarvik 2000® VAD** speed is slower than the dial setting selected. The most common reason is the battery voltage is too low.

In this case, corrective actions are to:

1 Select a lower speed setting on the **Flowmaker® Controller** and/or **2** Change the battery to a fully charged Li-ion Battery. If the underspeed indicator light is still lit, then the cause may be a fault in the system. Replace all external components; and if the underspeed light is still on after replacing all external components, treat the situation as an emergency and seek immediate medical attention. See *Patient Handbook and Operator Manual* for more details.



Alarm Battery

A non-rechargeable **Alarm Battery** is used to assure that the **FlowMaker Controller** has enough power for the alarms if the main battery fails, if the battery cable fails, or if the main battery becomes accidentally disconnected.

This **Alarm Battery** is located in a small housing on the end of the **FlowMaker® Controller** between the connectors for the cables. Be sure that the **Alarm Battery Cap** holding the Alarm Battery in place on the **FlowMaker® Controller** is screwed on finger tight whenever the **FlowMaker® Controller** is used. If the **Alarm Battery Cap** is not screwed finger tight in place, the backup power for the alarms will not function. Every time the **Alarm Battery Cap** is tightened, the Controller's back-up Alarm needs to be tested. With a caregiver present, briefly disconnect the main battery (Li-ion Battery or Reserve Battery/Charger) to be sure the Pump Stopped Alarm sounds. The disconnection should be brief and the main battery should be reconnected almost immediately. If the Pump Stopped Alarm does not sound, retighten the Alarm Battery Cap and repeat the test. Contact the implant center immediately if the alarm does not sound during this test.



Jarvik 2000® VAS

Procedure to Resolve Pump Stopped Alarm Jarvik 2000® VAS, Post-Auricular Cable

The most likely reason for the Jarvik® 2000 VAD (pump) to stop is a completely **discharged battery** or a **disconnected** or **damaged cable**. If the cause of a component failure is clearly identifiable (i.e. low battery, physical damage, etc.) replace that cable or component **first**.

If the cause is unknown, follow these step-by-step instructions with the assistance of a support person. The patient should sit down or lie down. This procedure should be completed quickly. Back-up equipment must be immediately available.

1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Pedestal Cable from the Pedestal at the skull, and set aside all the attached components.** Disconnect the Li-ion Battery Cable and also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller to silence the alarm.
 - b. Plug in a backup Pedestal Cable into the Pedestal and into a backup FlowMaker® Controller. Make sure the FlowMaker® Controller is set at speed setting 1. Make sure to tighten the Alarm Battery Cap on the backup FlowMaker® Controller to activate the alarm.
 - c. Using the backup Li-ion Battery Cable, plug a fully charged Li-ion Battery into the FlowMaker® Controller.
 - d. If the Jarvik 2000® VAD now runs, and the patient is feeling well, red tag the original components that were set aside in step 2a.
 - e. Set the FlowMaker® Controller back at the speed the user was using prior to the alarm.
3. **If the Jarvik 2000 VAD (pump) is still stopped call the medical emergency number immediately.**
4. Red tag all components of the system that were set aside before changing to the backup components in step 2a. This should be done with the assistance of a medical support person if possible.
5. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
6. If the Jarvik 2000® VAD still has not started, the patient should lie down and the support person should double check batteries and connectors. Try changing batteries again. It is possible that a discharged battery was removed and the same discharged battery was accidentally plugged back into the system. It is possible that neither battery is charged. If no lights illuminate on either battery, use a third battery. It is also possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
7. If all of the above steps have been followed and all cables and components have been replaced without successfully restarting the Jarvik 2000® VAD, **disconnect the power to the Jarvik 2000® VAD by unplugging the battery.** Also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller. **(The alarm should stop sounding).** If the Li-ion Battery or Reserve Battery/Charger is not disconnected, the FlowMaker® Controller will apply power to the Jarvik 2000® VAD which could be harmful. Disconnecting the battery reduces the chance of a clot forming inside the Jarvik 2000® VAD by allowing the rotor to spin as blood flows across it.

Note: Return any failed or suspect component(s) to your Clinical Center for evaluation by Jarvik Heart, Inc.



Jarvik 2000® VAS

Procedure to Resolve Pump Stopped Alarm Jarvik 2000® VAS, Abdominal Cable

The most likely reason for the Jarvik 2000® VAD (pump) to stop is a completely **discharged battery** or a **disconnected** or **damaged cable**. If the cause of a component failure is clearly identifiable (i.e. low battery, physical damage, etc.) replace that cable or component **first**.

If the cause is unknown, follow these step-by-step instructions with the assistance of a support person. The patient should sit down or lie down. This procedure should be completed quickly. Back-up equipment must be immediately available.

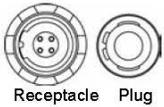
1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Extension Cable from the drive cable at the abdomen, and set aside all the attached components.** Disconnect the Li-ion Battery Cable and also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller to silence the alarm.
 - b. Plug the drive cable (the cable exiting the skin at the abdomen) directly into the backup FlowMaker® Controller (eliminating the Extension Cable). Make sure the FlowMaker® Controller is set at speed setting 1. Make sure to tighten the Alarm Battery Cap on the backup FlowMaker® Controller to activate the alarm.
 - c. Using the backup Li-ion Battery Cable, plug a fully charged Li-ion Battery into the FlowMaker® Controller.
 - d. If the Jarvik 2000® VAD now runs and the patient is feeling well, red tag the original components that were set aside in step 2a.
 - e. Set the FlowMaker® Controller back at the speed the user was using prior to the alarm.
3. **If the Jarvik 2000® VAD (pump) is still stopped call your medical emergency number immediately.**
4. Red tag all components of the system that were set aside before changing to the backup components in step 2a.
5. Be sure that all external cables and connectors have been changed and check to see if the connector at the end of the drive cable exiting the skin at the abdomen is broken. If it is broken and has come apart – try to put it back together where it is broken. If the Jarvik 2000® VAD does not run, take the connector apart again – rotate the parts 90° and put the connector back together again. Repeat three times. The Jarvik 2000 VAD may start. The connector may then be held together with tape while the patient is transported to the hospital for it to be repaired.
6. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
7. If the Jarvik 2000® VAD still has not started, the patient should lie down and the support person should double check batteries and connectors. Try changing batteries again. It is possible that a discharged battery was removed and the same discharged battery was accidentally plugged back into the system. It is possible that neither battery is charged. If no lights illuminate on either battery, use a third battery. It is also possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
8. If all of the above steps have been followed and all cables and components have been replaced without successfully restarting the Jarvik 2000® VAD, **disconnect the power to the Jarvik 2000 VAD by unplugging the battery.** Also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller. **(The alarm should stop sounding).** If the Li-ion Battery or Reserve Battery/Charger is not disconnected, the FlowMaker® Controller will apply power to the Jarvik 2000® VAD which could be harmful. Disconnecting the battery reduces the chance of a clot forming inside the Jarvik 2000® VAD by allowing the rotor to spin as blood flows across it.

Note: Return any failed or suspect component(s) to your Clinical Center for evaluation by Jarvik Heart, Inc.



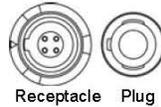
Jarvik® 2000

Jarvik 2000® Adult Ventricular Assist System—Quick Reference Guide



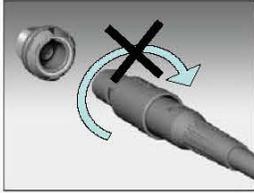
Receptacle Plug

Connection from Jarvik 2000 VAD to FlowMaker Controller: The black receptacle on the FlowMaker Controller is located above the housing for the small back-up Alarm Battery. The receptacle has double key slots for a black plug. The Extension Cable and the Pedestal Cable (depending on the model of the device used) also have double key slots.



Receptacle Plug

Connection from FlowMaker Controller to Y Cable or battery: The gray receptacle on the FlowMaker Controller is located below the housing for the small back-up Alarm Battery. This receptacle has a single key slot for the gray plug of the Y Cable, Li-ion Battery Cable, and Reserve Battery/Charger.



Note that the single and double keys on the plugs and receptacles are easily visible and must be placed in the proper rotational position, with the arrows on receptacle and plug lined up, for the connectors to go together. The connectors are attached and removed by a push-pull latch mechanism, not by a screw thread. Place the plug into the receptacle with slight pressure and gently rotate the plug until the key-way engages. Then push the connector together. The connector should click into place and should not come apart if the cable is tugged. To remove the plug, hold it close to the receptacle and pull.

- Never attempt to disconnect any connector by twisting.
- Do not attempt to pull the connector apart by the wire or by the strain relief.
- Never force a connector together. If the plug does not go into the receptacle easily, gently rotate it until it is aligned properly. When it is fully engaged, a soft click can be heard.
- If a connector is damaged or pins are bent, do not attempt to repair but replace the cable instead.

The Y Cable for the Jarvik 2000 VAS is used to allow battery changes without removing power from the Jarvik 2000 VAD. Before unplugging a discharged battery, a recharged battery should be plugged into the Y Cable. If the battery cable is unplugged prior to attaching a charged battery to the other end of the Y Cable, the Jarvik 2000 VAD stops, but the natural heart continues to beat. If this occurs, the beeping tone of the alarm will change to a steady tone, indicating that the Jarvik 2000 VAD is stopped. After the used battery is replaced with a fresh one, always remove the discharged battery from the Y Cable.



The portable Li-ion Battery will run the Jarvik 2000 VAS for 7-12 hours under usual conditions. The Li-ion Battery has an indicator with 5 lights that indicates how much power is remaining. Depress the black button to turn on the indicator lights:

Indicator	Approximate Remaining Time
All 5 LEDs lit	8-12 hours
4 LEDs lit	6-10 hours
3 LEDs lit	5-8 hours
2 LEDs lit	3-5 hours
1 LED lit	5 minutes - 2 hours

Li-ion Battery Charger

When the Li-ion Battery Charger is first connected to wall power, the green light next to the vertical green bar will turn on. The second light will simultaneously turn on green for approximately 1-3 seconds, followed by the startup sequence below:

- Flashing yellow for approximately 18-24 seconds
- Solid green for approximately 1-3 seconds
- Off

The Li-ion Battery Charger is not required to go through the startup sequence each time it is connected to a Li-ion Battery. It will only occur when wall power is first applied to the Li-ion Battery Charger.

Never connect the Li-ion Battery to the Li-ion Battery Charger while the second light is green. If a connection is made during this brief period of time, the Li-ion Battery will not charge.

When disconnecting the Li-ion Battery Charger from a fully charged Li-ion Battery, always wait for the second light to turn off before connecting another Li-ion Battery.

The Reserve Battery/Charger has both a battery and a charger built into a single unit; however, they are not electrically connected to each other.

Reserve Battery Use:

1. Unplug the gray cable from the battery charger and plug it into the gray connector of the Y cable or the FlowMaker Controller.
2. Unplug the black power cord from the Reserve Battery/Charger and the wall plug.
3. If the Reserve Battery/Charger is used for under 12 hours and then recharged, it will last for more than 1000 recharge cycles. If it is not recharged until it is fully discharged (>24 hrs capacity) and the low battery alarm sounds, it will last for fewer than 200 recharge cycles.
4. Use the Reserve Battery/Charger for less than 12 hours each night and recharge it each morning after switching to the Li-ion Battery.



Reserve Battery Use



Charging the Reserve Battery

Charging the Reserve Battery:

Disconnect the gray plug from the Y Cable or FlowMaker Controller and plug it into the gray receptacle on the Reserve Battery/Charger.

A yellow light next to the Charge label on the Reserve Battery/Charger will turn on to indicate charging. When the Reserve Battery/Charger is near fully charged, the yellow light will turn off and automatically start to safely slow charge the battery. Continue charging the battery after the yellow light goes out and whenever the battery is not in use.

The green light next to the Power label on the Reserve Battery only indicates that wall power is connected to the charger section of the unit. The green light does not indicate the Reserve Battery/Charger is fully charged.

The Reserve Battery/Charger is near fully charged only when the Charge light turns off and the gray cable is plugged into the gray receptacle on the unit.

If the gray cable is not plugged into the receptacle on the Reserve Battery/Charger while the unit is also plugged into the wall, the Reserve Battery/Charger will not charge.

It is not possible to run the Jarvik 2000 VAS from wall power even if the Reserve Battery/Charger is plugged into wall power. It is also not possible to charge the Reserve Battery/Charger while the same Reserve Battery/Charger is being used to run the Jarvik 2000 VAD. At all times, the Jarvik 2000 VAD is run only from battery power.

Patient Management For TAHs

1. Assess the patients airway and intervene per your protocol.
2. Auscultate heart sounds but you can usually hear them without a stethoscope. Since this is pulsatile you should hear two sounds if properly functioning.
3. Assess the device for device information and alarms located on the driver.
4. Intervene appropriately based on the type of alarm. See specific device alarm guide on the pages that follow.
5. Assess Vital Signs. REMEMBER THERE IS NO ECG. THE PATIENT IS ASYSTOLIC.
6. Start IV if indicated.
7. You should be able to get a systolic and diastolic blood pressure.
8. 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.
9. **Bring all of the patients equipment.**
10. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

Total Artificial Heart Freedom™ Driver System

This Patient is on an ARTIFICIAL HEART (not a left ventricular assist device-LVAD)

1. Can I do CPR?

No. Will need to rapidly exchange to the backup driver.

2. Can the patient be defibrillated or externally paced?

No, there is no native heart rhythm.

3. Does the patient have a pulse with this device?

Yes. The device produces pulsatile flow. The device is pneumatically driven and is normally loud.

4. What are acceptable vital sign parameters?

The BP will vary. Normal range 100-130 systolic and 60-90 diastolic.

5. What kind of cardiac rhythm will be displayed on a monitor?

Asystole.

6. Is there a “hand pump”.

No. The priority is to secure connections to the Freedom Driver to ensure gas delivery.

7. Can I give vasopressor IV drugs like epinephrine, dopamine or dobutamine?

Never give vasopressor drugs, especially epinephrine. Most IV vasopressor drugs can be fatal to a TAH patient. IV fluids are usually not required and may be unhelpful if the patient is already fluid overloaded. These patients primarily have symptomatic hypertension and rarely have symptoms of hypotension.

8. How can symptomatic hypertension be treated?

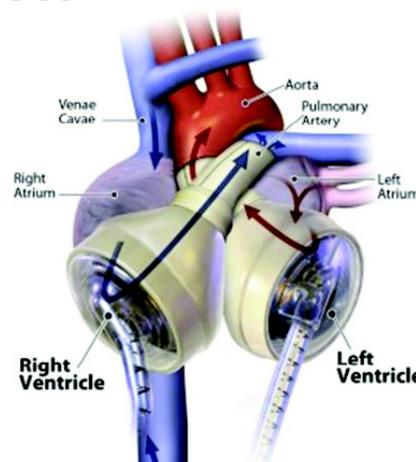
Sublingual nitroglycerin.

9. Can I speed up the rate of the device?

No. The device has a fixed rate between 120-140 BPM

10. What if the patient is symptomatic and the Freedom Driver is alarming with a continuous alarm and the red light?

If the pump has failed or a line is disconnected or kinked, the patient may pass out within 30 seconds. Even with alarming, the device will continue to pump. Confirm the drivelines are connected and are not damaged or kinked. If the patient is conscious and can participate, assist the patient to immediately change out the Freedom Driver.



Trouble Shooting Freedom™ Driver System

**This Patient is on an ARTIFICIAL HEART
(not a left ventricular assist device -LVAD)**



Freedom™ Driver System

IN THE EVENT OF AN EMERGENCY

Immediately notify VAD coordinator listed on the medical alert bracelet or tag attached to the console - please identify the device as a total artificial heart.

HOW TO RESPOND TO FREEDOM™ DRIVER ALARMS

There is no way to mute an Alarm.

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Battery Alarm	Loud Intermittent Tone	Yellow Battery LED Flashing	One or both of the Onboard Batteries have less than 35% remaining charge (only two green lights display on the Battery Fuel Gauge).	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power (NOTE: Once the batteries are charged above 35% the Battery Alarm will stop).
			Onboard Battery is incorrectly installed.	Reinsert Onboard Battery until locked in place. If Battery Alarm continues, insert a new Onboard Battery.
			One Onboard Battery missing.	Insert charged Onboard Battery into Freedom™ Driver until locked in place.
Temperature Alarm	Loud Intermittent Tone	Red Alarm LED Flashing	The temperature of the Driver is too hot or too cold.	Remove any objects that are blocking the Filter Cover and/or Fan and check the filter.
			The internal temperature of the Driver is too hot.	Move the Freedom Driver to a cooler or warmer area.
Fault Alarm	Loud Continuous Tone	Red Alarm LED Solid	Valsalva Maneuver: Strenuous coughing or laughing, vomiting, straining during a bowel movement, or lifting a heavy weight.	Relax/interrupt Valsalva Maneuver.
			Kinked or disconnected drive lines.	Straighten or connect drive lines.
			Driver is connected to External Power without at least one correctly inserted Onboard Battery.	Insert a charged Onboard Battery into the Freedom™ Driver until locked into place.
			One or both of the Onboard Batteries have less than 30% remaining charge.	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power. (NOTE: the Fault Alarm will continue and will change into a Battery Alarm as the Onboard Batteries recharge. Once the Onboard Batteries are charged above 35%, the Battery Alarm will stop.)
			Malfunction of the Driver	If the steps above do not stop the Fault Alarm, switch to Backup Freedom Driver. Return to implant hospital.
Temperature Alarm	Loud Intermittent Tone	Red Alarm LED Flashing	The internal temperature of the Driver is too hot.	Remove any objects that are blocking the Filter Cover and / or Fan and check filter.
			The temperature of the Onboard Batteries is too hot or too cold.	Move the Freedom Driver to a cooler or warmer area.

You must immediately address the issue that caused the Alarm.

Switching from Primary to Backup Freedom™ Driver

CAUTION: It is recommended to have TWO people exchange the primary Freedom Driver for the backup Freedom Driver. Make sure all items and accessories are closely available before attempting to exchange Drivers.

Setting up the Backup Freedom™ Driver

1. Remove the drive line caps from the ends of the Drive lines.
2. Insert one charged Onboard Battery. The driver will immediately start pumping. (*Figure 1*)
3. Remove the Orange Dummy Battery. (*Figure 1*)
4. Insert the second charged Onboard Battery. (*Figure 2*)
5. If possible, connect the backup Driver into a wall power outlet.
6. Your Freedom™ Driver is now ready to connect to the patient.



FIGURE 1



FIGURE 2



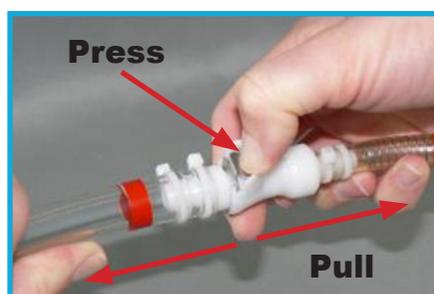
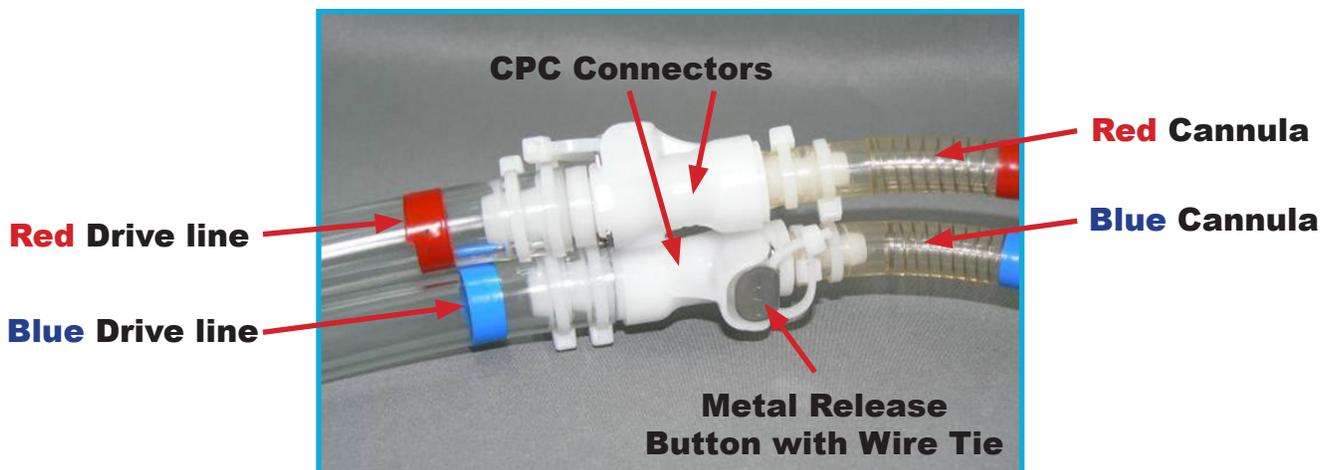
FIGURE 3

BEATS PER MINUTE, FILL VOLUME AND CARDIAC OUTPUT

Continued on next page.

Switching from Primary to Backup Freedom™ Driver

Continued on from previous page



1. With the Wire Cutter Tool, cut the Wire Tie under the metal release button of the CPC Connector that secures the **RED** TAH-t Cannula to the **RED** Freedom Drive line. Gently pull to remove the Wire Tie and discard. **DO NOT DISCONNECT THE CANNULA FROM THE DRIVE LINE YET.**
2. With the Wire Cutter Tool, cut the Wire Tie under the metal release button of the CPC Connector that secures the **BLUE** TAH-t Cannula to the **BLUE** Freedom Drive line. Gently pull to remove the Wire Tie and discard. **DO NOT DISCONNECT THE CANNULA FROM THE DRIVE LINE YET.**

CAUTION: Before disconnecting the Drive lines of the primary Freedom Driver, you must have the Drive lines of the backup Freedom Driver within reach. The backup Driver must be turned on. Perform steps 3 and 4 simultaneously.

3. Disconnect the **RED** Cannula from the **RED** Drive line of the primary Freedom Driver:
 - Simultaneously Press and hold down the metal release button. Pull the **RED** Cannula away from the **RED** Drive line.
 - Immediately insert the **RED** Cannula into the new **RED** Drive line from the backup Freedom Drive Insert until a click is heard and lightly tug on the connection to make sure that it is secure.
4. Simultaneously disconnect the **BLUE** Cannula from the **BLUE** Drive line of the primary Freedom Driver:
 - Press and hold down the metal release button. Pull the **BLUE** Cannula away from the **BLUE** Drive line.
 - Immediately insert the **BLUE** Cannula into the new **BLUE** Drive line from the backup Freedom Driver.
 - Insert until a click is heard and lightly tug on the connection to make sure that it is secure.
5. Slide a Wire Tie under the metal release button of each CPC connector. Create a loose loop in the tie, taking care not to depress and disconnect the connectors. Cut off the excess length of both Wire Ties.
6. Patient must notify Hospital Contact Person of the switch.
7. The Hospital should notify SynCardia Systems that the Driver has been switched and return the faulty Driver.