



EMERGENCY GUIDE

2024-2025



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 across the globe. 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.

Disclaimer: The purpose of this reference guide is to provide education for permanent (durable) devices in patients that are discharged from the hospital. The information provided by International Consortium of Circulatory Assist Clinicians is for educational and convenience purposes only to illustrate concepts and considerations and may not cover or be complete for all situations. They are general resources to consider and adapt as you deem appropriate. International Consortium of Circulatory Assist Clinicians makes no claims, promises or guarantees about the appropriateness or completeness of the content, examples or information for any intended use. In addition, the information provided to you does not constitute legal, business or medical advice, and should not be relied on as such. You are solely responsible for understanding and complying with all applicable laws, rules and regulations associated with the subject matter of the information contained herein, including but not limited to laws, rules and regulations relating to marketing and business practices, medical practice and judgment, advertising, data privacy and security. Please also refer to the manufacturers' prescribing information and instructions for use for the indications, contraindications, warnings, risks, and precautions associated with any medications and devices referenced in these materials. International Consortium of Circulatory Assist Clinicians recommends that you consult your legal and business advisors for guidance.

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 (durable) 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.

Non-pulsatile or Pulsatile

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. 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 TAH pump is a pulse generating device.

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. These devices can be attached to the Left (LVAD), Right (RVAD), or (BiVADs) ventricles of the heart. Most patients have an LVAD. Less common are RVADs and BiVADs.

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 bag 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 3 Page 4



HEARTMATE EPC Page 12



EVAHEART Page 17



JARVIK 2000 Page 23



HEARTMATE 2 Page 8



HEARTWARE HVAD Page 13

What is a TAH?

The Total Artificial Heart (TAH) is a pneumatically driven pulsatile device that replaces the native heart. Cannulas connect the device to an external power source outside the body. This is used for people who have inadequate function of both ventricles (biventricular failure).

What are the parts of TAH?

The TAH is comprised of 3 components: 2 inflow cuffs sewn to the atria, 2 ventricles and 2 outflow grafts sewn to the pulmonary artery and the aorta. Blood is circulated by active emptying and passive filling of the ventricles. Native blood flow is maintained. 2 Cannulae exit the body to connect the external pneumatic driver.

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.



TOTAL ARTIFICIAL HEART (TAH) Page 30

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.

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 a continuous flow device, you should hear a mechanical “humming sound”.**
4. **Assess vital signs. Non-pulsatile or continuous flow devices provide continuous blood flow that may result in a narrow pulse pressure. This means it may be difficult to obtain a pulse or blood pressure reading. To obtain a blood pressure an automated cuff or doppler method can be used. If unable to obtain, rely on other methods to assess perfusion.**
5. **Start IV if indicated.**
6. **Assess the device for information and alarms located on the controller display.**
7. **Intervene appropriately based on the type of alarm. See specific device alarm guides.**
8. **Refer to the patient’s medication list. Most are on some type of anticoagulation.**
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.**

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. 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.

3. Can the patient be defibrillated, cardioverted and paced while connected to the device?

Yes, you can defibrillate, cardiovert and externally pace per protocols and do not have to disconnect anything.

4. Can the same doses of emergency medications be given?

All ACLS drugs may be given at the same doses.

5. 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 small bolus of normal saline at provider discretion and transport to a VAD center.

6. What are acceptable vital sign parameters?

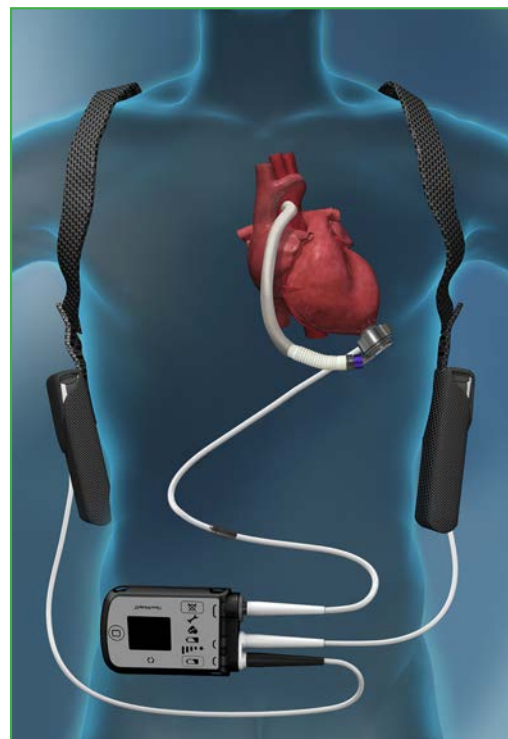
MAP 70-90 mmHg with a narrow pulse pressure.

7. Can I change the speed of the device?

No, it is a fixed speed.

8. What is the best way to transport a patient with this device?

Patients and all their equipment are safe to travel by any means of transport including flight. Avoid twisting, kinking or pulling the driveline. Transport to a VAD center whenever possible. Allow LVAD trained caregiver to travel with patient whenever possible.

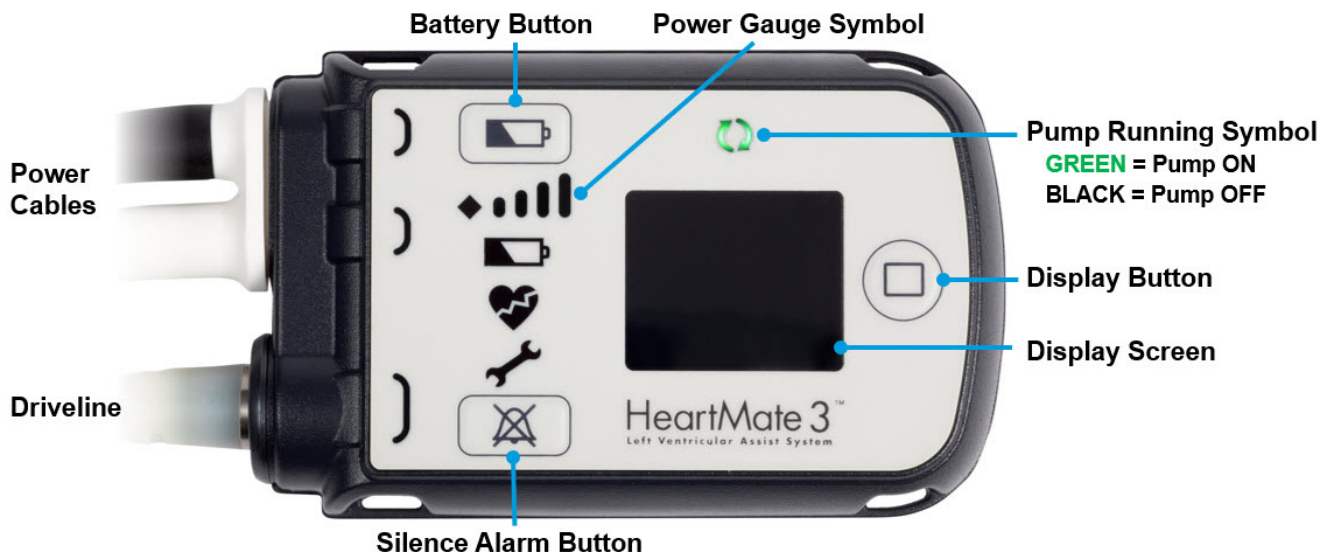


Additional Information

- 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 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.
- Operating speed 4700-6200 RPM
- No hand pump is available.
- A pair of fully charged batteries last up to 17 hours. The controller will draw power from both batteries simultaneously.
- 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 3™ Left Ventricular Assist System

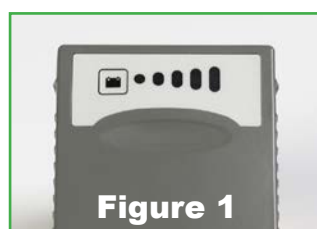
System Controller



Changing Batteries

WARNING: At least one controller power cable must be connected to a power source **AT ALL TIMES.**

- 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 display 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.



Troubleshooting HeartMate 3™ LVAS

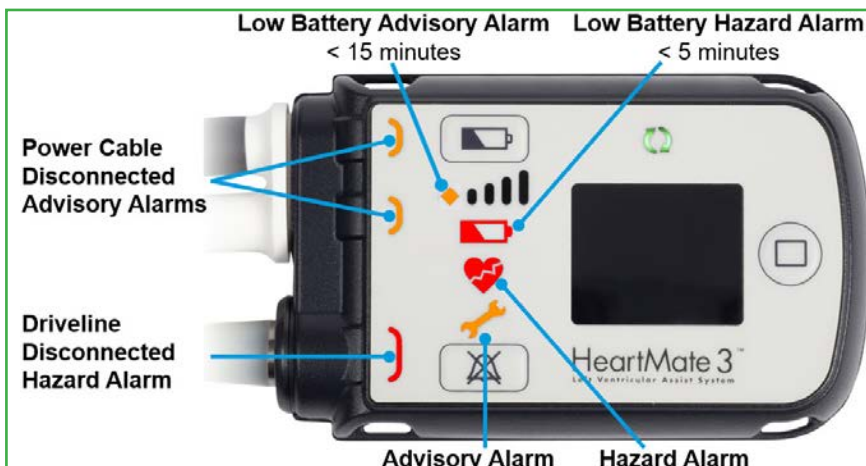
Alarms: Emergency Procedures

When an alarm occurs:

- Contact the Implant Center for direction when possible.
- Read message to determine action.
- Check if pump is running.
- Allow care providers trained on LVAD emergencies to remain with the patient.

When the Pump Has Stopped

- Check modular cable connection, driveline and power cable connections to the controller. Fix any loose connections to restart the pump.
- If the pump does not restart press any button on the system controller.
- 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.



System Controller Hardware Fault Alarm

HAZARD ALARMS Continuous Audible Tone

| | | | | | |
|---|---|---------------------------------------|--|---------------------------------------|---|
| Low Flow Ⓢ :03 | + | Call Hospital Contact Ⓢ :07 | | Pump is off. | See above, when pump has stopped |
| Low Flow Ⓢ :03 | + | Call Hospital Contact Ⓢ :07 | | Pump flow is < 2.5 lpm. | Evaluate the patient for low flow - treat the cause. Assess volume status, hypertension, arrhythmia, right heart failure, etc. Ensure that a power source is connected to the controller. |
| 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.

GREEN

GREEN

GREEN

GREEN

GREEN

GREEN

GREEN

GREEN

GREEN

GREEN

Troubleshooting HeartMate 3™ LVAS

Changing the System Controller. Power - Pump/Patient - Power.

Step 1: Have the patient sit or lie down as the pump has and/or will stop during this procedure. Visualize the patient's live Controller, driveline and batteries/clips. Check all connections intact.

Step 2: Place the replacement Controller within easy reach. The spare Controller is usually found in the patient's travel case. On the back of the replacement Controller, slide the safety lock so the red release button is fully visible. Repeat step on original controller.

Step 3: Unscrew one power source from the controller and reattach it to the replacement Controller by lining up the half circles, firmly pushing together and tightening the connector nut.

Step 4: 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! The HeartMate 3™ LVAD has a modular cable connection near the exit site of the driveline. 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.

Step 5: 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 6: After the pump restarts, slide the safety lock on the replacement 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 7: Change over 2nd power source to replacement Controller.

Step 8: Hold down battery symbol for 5 full seconds for complete shutdown of old Controller.

If the pump does not restart, support the patient per protocols and urgently transfer to hospital. Even if the pump does restart, transport any patient who has needed a controller exchange to a VAD center

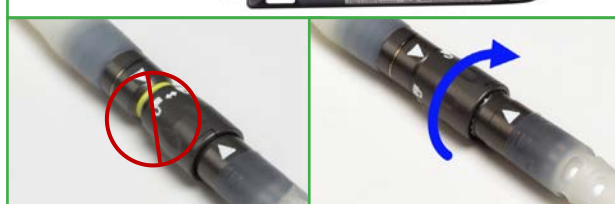


Step 3



SAFETY LOCK UNLOCKED

Step 4



Step 5



Step 6

SAFETY LOCK LOCKED Step 6



Step 8

This guide does not supersede manufacturer instructions.

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. 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.

3. Can the patient be defibrillated, cardioverted and paced while connected to the device?

Yes, you can defibrillate, cardiovert and externally pace per protocols and do not have to disconnect anything.

4. Can the same doses of emergency medications be given?

All ACLS drugs may be given at the same doses.

5. 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 small bolus of normal saline at provider discretion and transport to a VAD center.

6. What are acceptable vital sign parameters?

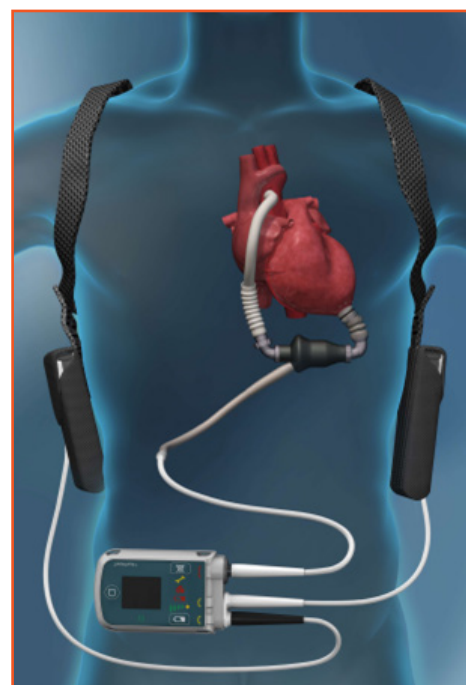
MAP 70-90 mmHg with a narrow pulse pressure.

7. Can I change the speed of the device?

No, it is a fixed speed.

8. What is the best way to transport a patient with this device?

Patients and all their equipment are safe to travel by any means of transport including flight. Avoid twisting, kinking or pulling the driveline. Transport to a VAD center whenever possible. Allow LVAD trained caregiver to travel with patient whenever possible.

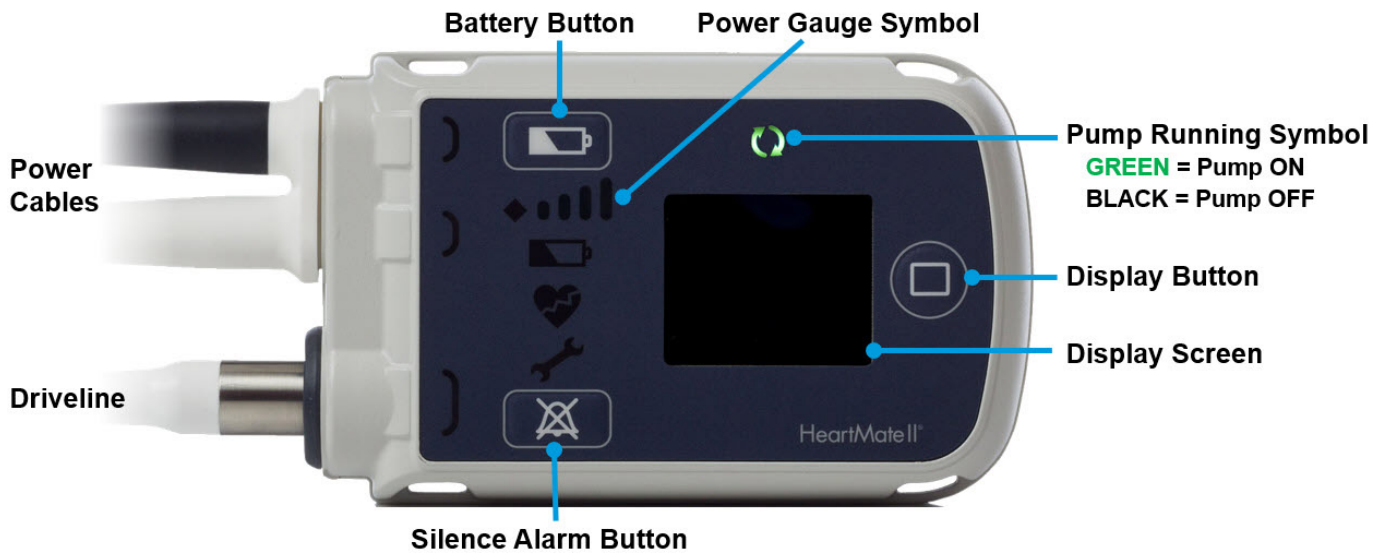


Additional Information

- 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. Patient may or may not be symptomatic with ventricular arrhythmias.
- Operating speed 8200-9600 RPM
- No hand pump is available.
- A pair of fully charged batteries last approximately 10-12 hours. The controller will draw power from both batteries simultaneously.
- 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

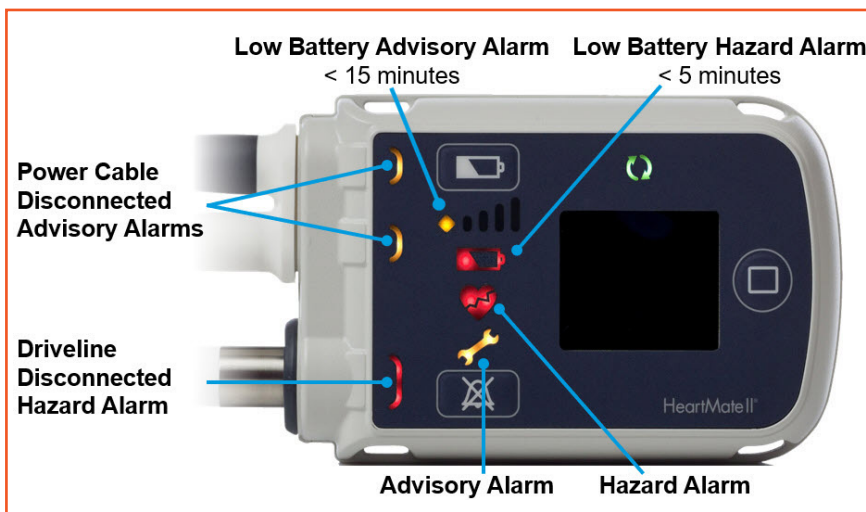
Alarms: Emergency Procedures

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 |
| Low Flow ⌚ :03 | + | Call Hospital Contact ⌚ :07 | | Pump flow is < 2.5 lpm. | 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.

ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE

ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE ORANGE

Troubleshooting HeartMate II™ LVAS

Changing the Pocket Controller. Power - Pump/Patient - Power.

Step 1: Have the patient sit or lie down as the pump has and/or will stop during this procedure. Visualize the patient's live Controller, driveline and batteries/clips. Check all connections intact.

Step 2: Place the replacement Controller within easy reach. The replacement Controller is usually found in the patient's travel case. On the back of the replacement Controller, slide the safety lock so the red release button is fully visible. Repeat step on original controller.

Step 3: Unscrew one power source from the controller and reattach it to the replacement Controller by lining up the half circles, firmly pushing together and tightening the connector nut.

Step 4: 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 5: 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 6: After the pump restarts, slide the safety lock on the replacement 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 7: Change over 2nd power source to new Controller.

Step 8: Hold down battery symbol for 5 full seconds for complete shutdown of old Controller.

If the pump does not restart, support the patient per protocols and urgently transfer to hospital. Even if the pump does restart, transport any patient who has needed a controller exchange to a VAD center.



Step 3



Step 4



Step 6



Step 4



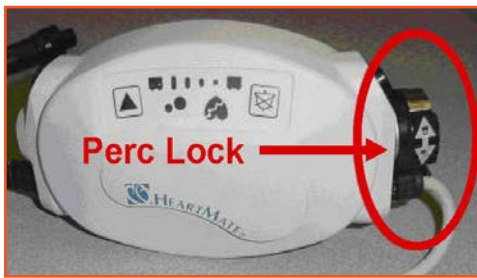
Step 5



Step 8

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.

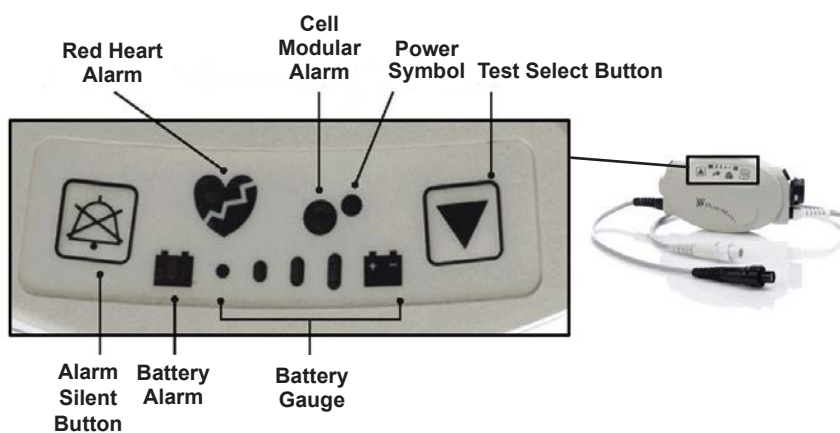


Driveline Connection: The Perc Lock must be “unlocked” in order for the driveline to be removed in a controller exchange. The Perc lock remains in locked position once the driveline has been fully inserted.

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)



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



Unlock



Locked

Alarms: Emergency Procedures

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.

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.

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

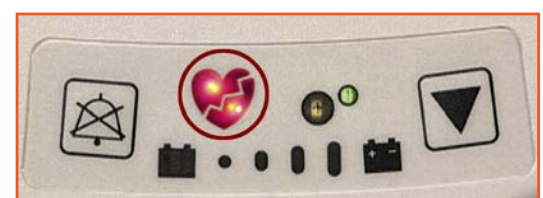
>8000 RPM: Pump starts automatically.

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

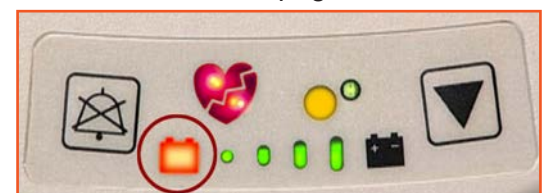
ALARMS

For a review of alarms and their meanings, reference the HeartMate II Alarms for Clinicians, Item 103851.

Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If a low flow occurs - Can give a small bolus of normal saline at provider discretion and transport to a VAD center. If a controller change is required, please see HeartMate II EPC Controller Exchange Quick Guide.



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on page 9.



HeartWare™ HVAD™ System

1. Can I do CPR?

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

2. 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.

3. Can the patient be defibrillated, cardioverted and paced while connected to the device?

Yes, you can defibrillate, cardiovert and externally pace per protocols and do not have to disconnect anything.

4. Can the same doses of emergency medications be given?

All ACLS drugs may be given at the same doses.

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

A yellow triangle and intermittent audio alarm will sound. The controller display screen will show [Low Flow] [Call] message. Can give a small bolus of normal saline at provider discretion and transport to a VAD center.



6. What are acceptable vital sign parameters?

MAP 70-85 mmHg with a narrow pulse pressure.

7. Can I change the speed of the device?

No, it is a fixed speed.

8. What is the best way to transport a patient with this device?

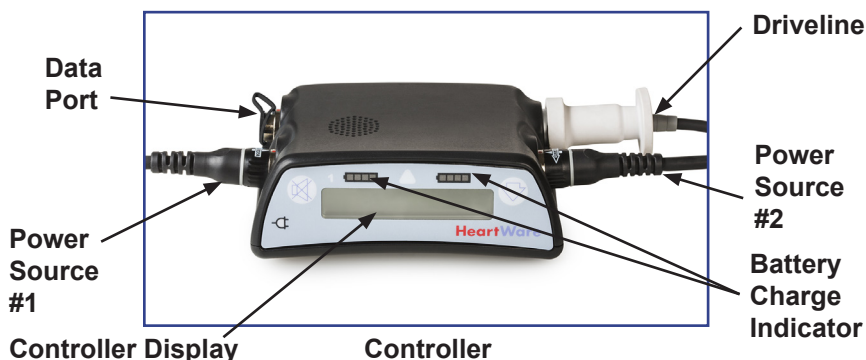
Patients and all their equipment are safe to travel by any means of transport including flight. Avoid twisting, kinking or pulling the driveline. Transport to a VAD center whenever possible. Allow LVAD trained caregiver to travel with patient whenever possible.



Additional Information

- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to driveline which exits 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 with ventricular arrhythmias.
- This is a continuous flow pump operating speed ranges of 2400 – 3200 RPMs. The patient should have back-up equipment e.g. controller & charged batteries.
- One fully charged battery lasts approximately 4-7 hours. The controller will draw power from one battery at a time.
- 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. backup 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).
- 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 .**

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. (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

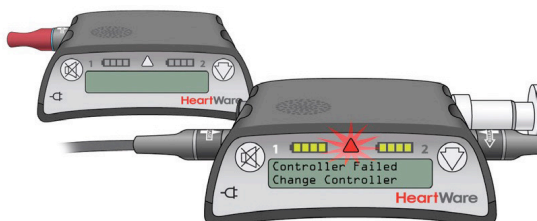
- Make sure there is a fully charged battery available to replace the depleted one.
- Disconnect the depleted battery by turning the connector sleeve counterclockwise until it stops. Never disconnect both power sources at the same time or the pump will stop.
- Pull the connector straight out from the controller.



HeartWare™ HVAD™ System Emergency Operation

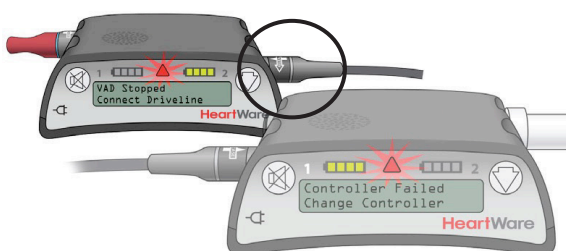
STEPS TO EXCHANGE THE CONTROLLER

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. Use AC adapter if available.

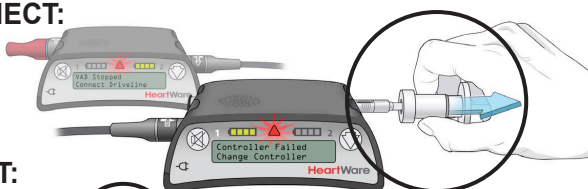
NOTE: The new controller may alarm after 10 seconds with a [VAD Stopped, Connect Driveline] high alarm. This is expected behavior and will resolve when the driveline is connected.



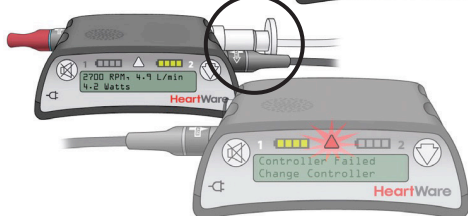
Step 3: Disconnect the driveline from the original controller by using two fingers grasp silver area with 'ridges' and pull driveline straight out. Connect the driveline to the new controller by aligning red dots on controller and driveline. This should restart the **pump**.

- 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:

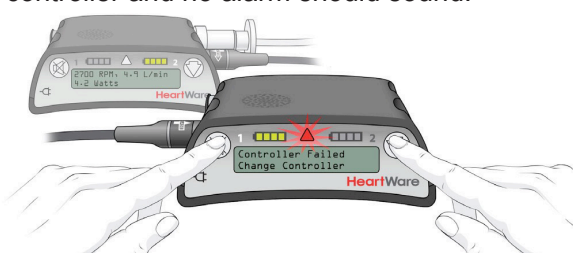


- If you have only connected 1 power source to the new controller, you will also have a [Power Disconnect, Reconnect Power] alarm.

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:

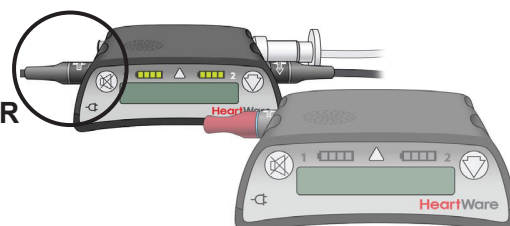


- If a red alarm adapter is available:
 - Insert it into the connector data port on the original controller
 - You can now remove all power from the original controller and no alarm should sound.



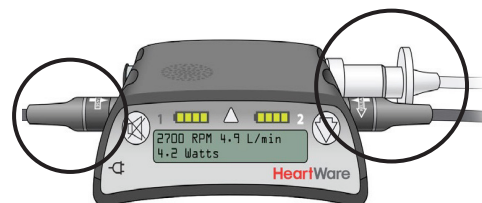
- If no red alarm adapter is available:
 - Press and hold the "Alarm Mute" and "Scroll" buttons on the original controller until a "beep" is heard, or for at least 5 seconds.
 - Release the "Alarm Mute" and "Scroll" buttons.
 - You can now remove all power from the original controller and no alarm should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




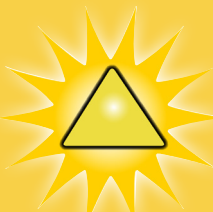

Step 6:

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 patient's VAD center 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 center listed on the patient's contact sheet.

Evaheart 2 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. After compressions are administered, confirm function and positioning of the pump.

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

Ideally, yes. However it is possible for the aortic valve to stop opening, rendering the patient "pulseless".

3. Can the patient be defibrillated, cardioverted and paced while connected to the device?

Yes, you can defibrillate, cardiovert and externally pace per protocols and do not have to disconnect anything.

4. Can the same doses of emergency medications be given?

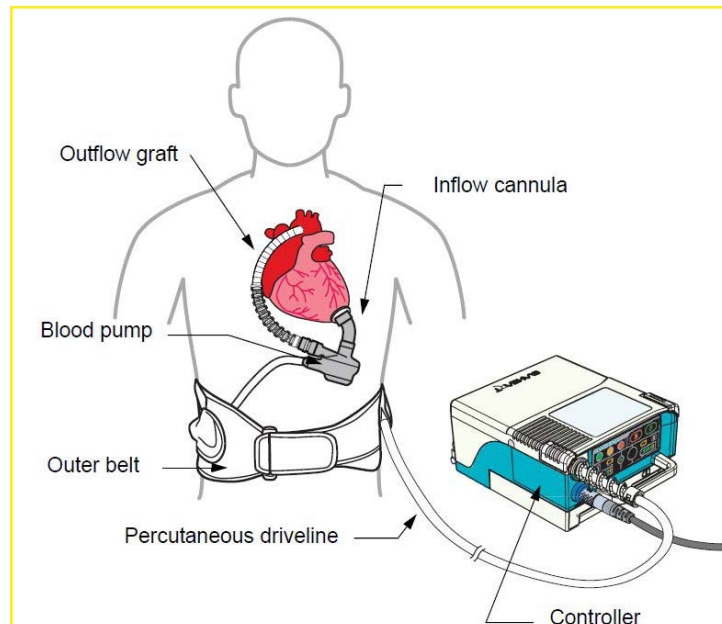
All ACLS drugs may be given at the same doses.

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

No specific alarm exists for low flow, as there is no flow reading displayed on the controller. "Urgent" or "critical" alarms should be addressed promptly, with a small bolus of saline and transport to a VAD center.

6. What are acceptable vital sign parameters?

MAP 65-80 mmHg with a narrow pulse pressure.



7. Can I change the speed of the device?

No, it is a fixed speed.

8. What is the best way to transport a patient with this device?

Patients and all their equipment are safe to travel by any means of transport including flight. Avoid twisting, kinking or pulling the driveline. Transport to a VAD center whenever possible. Allow LVAD trained caregiver to travel with patient whenever possible.

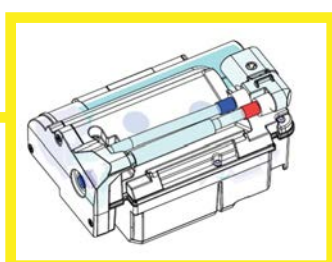
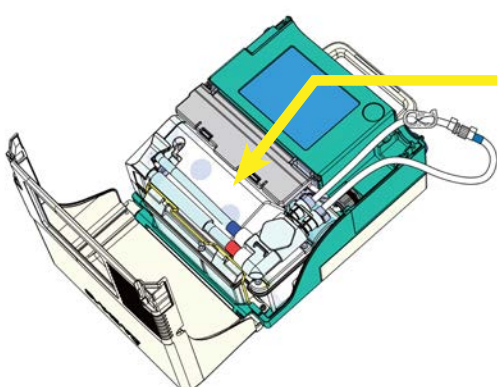
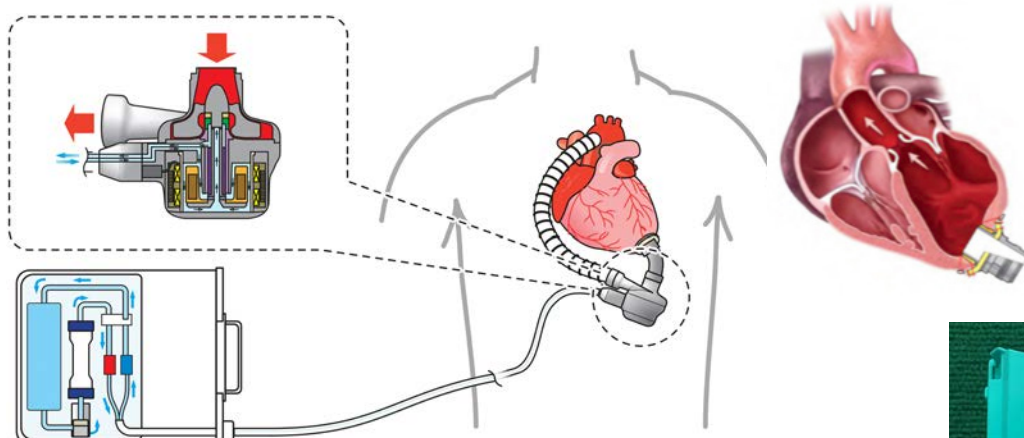
Additional Information

- Pump has a tipless inflow cannula (does not project into the left ventricle).
- Like the Heartmate 3 (HM3), pump has a speed modulation feature. It differs from the HM3 in that the speed modulation is individualized to the patient, with the goal of opening the aortic valve every beat.
- Patients are generally anticoagulated with warfarin (INR 2-3) and 81mg aspirin.
- Instead of a duplicate backup controller, patients have an emergency controller.
- There is no flow reading displayed on the controller.
- There are two components within the driveline, which are separated out in the controller: the blood pump and the cool seal unit (CSU).
- The CSU circulates sterile water between the controller and blood pump via 2 tubes in the driveline, and serves to levitate the blood pump impeller.
- Should the CSU malfunction, the pump can run using the blood pump for up to 24 hours. If the blood pump or driveline is disconnected, the VAD will stop.
- Blood pressure may be obtained using an automated cuff, as patients are generally pulsatile.
- Pump does not affect ECG.
- No hand pump is available.
- A pair of fully charged batteries lasts approximately 8 to 12 hours.
- Patients wear a dressing on their abdomen to protect the driveline insertion site. Avoid pulling, twisting or kinking the driveline when moving the patient.
- Any emergency mode of transportation is ok; patients are permitted to fly.
- Be sure to bring ALL of the patient's equipment with them when transporting.

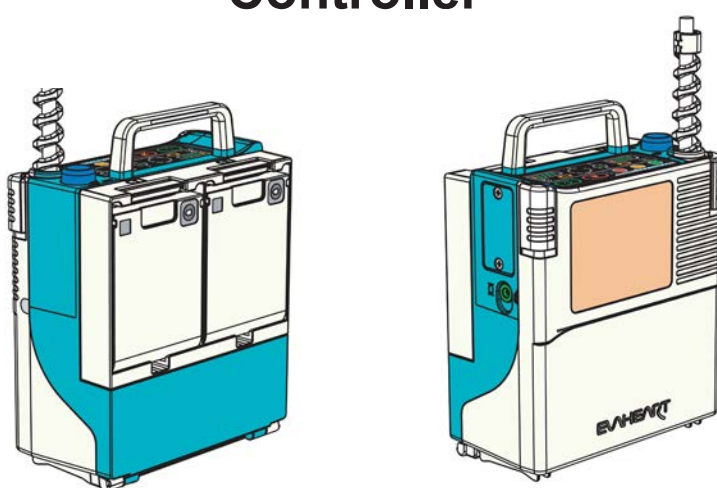
Evaheart 2 LVAS Components

Cool Seal Unit (CSU)

Tipless inflow



Controller



System alarm indicator:

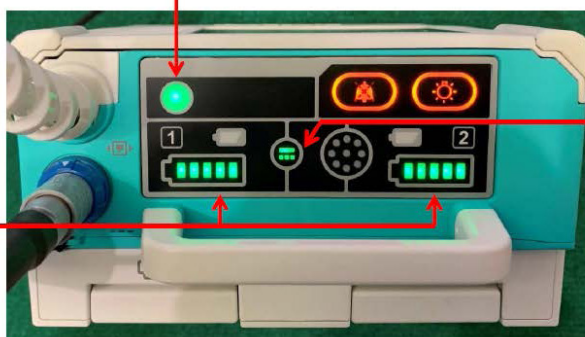
green

External battery charge indicators:

green

AC/DC adapter icon:

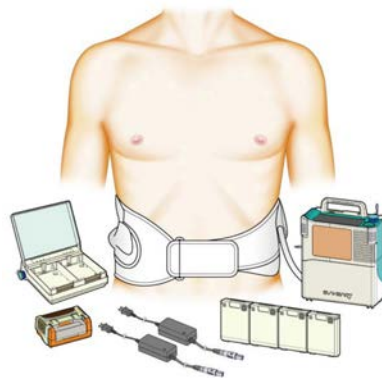
green



Patient Transport with Evaheart 2 LVAS

LVAS components to be transported with the patient to a healthcare facility

- Controller (connected to patient via driveline).
- AC power cable.
- Battery charger.
- Emergency controller.
- At least four batteries.



ALARMS & EMERGENCY PROCEDURES

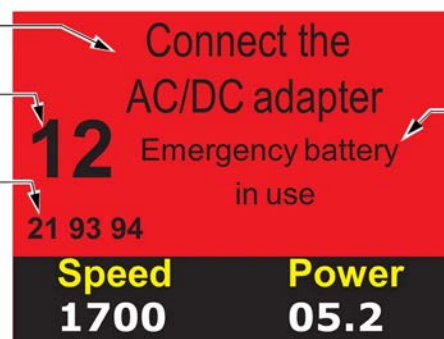
When an alarm occurs:

- Check alarm messages on controller display screen.
- Perform the corrective action as advised on the controller screen.
- Use the quick reference guide in patient's carry bag to determine next steps.
- Contact the Evaheart support line at 1(844) 432-7800.
- Contact the implant center for direction when possible.

Corrective Action

Event Code

Event Code



Condition

Speed
1700

Power
05.2

| Alarm Severity | Event Code | Description | Corrective Action |
|----------------|------------|--|---|
| Urgent | 1 | Controller communication failure | Contact your VAD team. |
| | 16 | System error | Contact your VAD team. |
| Warning | 24 | Controller temperature too high | Place the controller in cool place. |
| Critical | 20 | Low power consumption | Contact your VAD team. |
| Urgent | 21 | High power consumption | |
| Critical | 22 | Low pump speed (600 rpm below set speed) | |
| Urgent | 25 | Decrease in PI value | |
| | 30 | Blood pump stopped and restarted | |
| Critical | 32 | Blood pump stopped due to: - Disconnection of blood pump power cable - Damaged driveline | 1. Open the controller cover, and check the pump power cable connection. 2. Check for driveline damage. 3. Contact your VAD team immediately. |
| | 99 | System error | 1. Switch to emergency controller 2. Contact your VAD team immediately. |

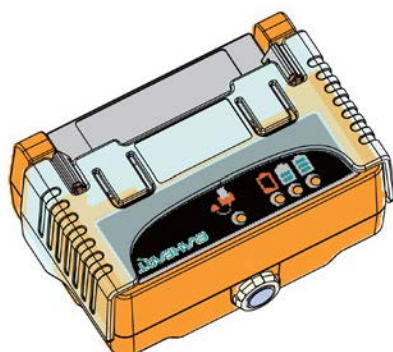
Troubleshooting Evaheart 2 LVAS

| A (critical) | | Flashing | "Beep Beep Beep - Beep Beep" + ~3 seconds of silence, repeating | | | | | | | | | | | | | |
|----------------|------------|-------------------|--|---|------------|-----|------|------|------|------|------|------|------|------|------|---|
| B (Urgent) | | Flashing | "Beep Beep Beep" + ~3 seconds of silence, repeating | | | | | | | | | | | | | |
| C (Warning) | | Solid | "Beep Beep" + ~15 seconds of silence, repeating | | | | | | | | | | | | | |
| Alarm Severity | Event Code | Component | Descriptions | Corrective Actions | | | | | | | | | | | | |
| Urgent | 1 | Controller | Controller internal communication failure. | 1. Press the alarm reset button. 2. If the alarm persists, replace the controller. | | | | | | | | | | | | |
| Warning | 11 | Emergency Battery | Emergency battery power low. | 1. Connect the AC/DC adapter to the controller and recharge the emergency battery until the emergency battery charge indicator illuminates green (up to 2 hrs.). 2. If the alarm persists after recharging, replace the emergency battery. | | | | | | | | | | | | |
| Critical | 12 | Emergency Battery | Emergency battery in use. CSU disabled and E-11 suspended. | IMMEDIATELY connect fully charged external batteries and /or AC power source. Failure to do so will result in blood pump stoppage. | | | | | | | | | | | | |
| Urgent | 13 | Emergency Battery | Emergency battery disconnected or depleted. | 1. Make sure that the emergency battery is properly connected. 2. If the alarm persists, replace the emergency battery. | | | | | | | | | | | | |
| Critical | 14 | All Power Sources | All power sources nearly depleted. | IMMEDIATELY connect fully charged external batteries and /or AC power source! Failure to do so will result in blood pump stoppage. | | | | | | | | | | | | |
| Urgent | 16 | Controller | Failure of controller's power circuit. | 1. Press the alarm reset button. 2. If the alarm persists, replace the controller. | | | | | | | | | | | | |
| Critical | 20 | Blood Pump | <p>Blood pump power consumption is low.</p> <table border="1"> <thead> <tr> <th>Speed (rpm)</th> <th>Power (<W)</th> </tr> </thead> <tbody> <tr> <td>800</td> <td>0.05</td> </tr> <tr> <td>1200</td> <td>0.27</td> </tr> <tr> <td>1600</td> <td>0.94</td> </tr> <tr> <td>2000</td> <td>2.05</td> </tr> <tr> <td>2400</td> <td>3.62</td> </tr> </tbody> </table> <p>May be due to:</p> <ul style="list-style-type: none"> • Blood Pump flow decrease • Blood circulation decrease | Speed (rpm) | Power (<W) | 800 | 0.05 | 1200 | 0.27 | 1600 | 0.94 | 2000 | 2.05 | 2400 | 3.62 | <p>Check Patient condition. Using echocardiography, check the blood pump, inflow cannula, and outflow graft for any signs of suction or blockage. Also, check for low blood flow. If any of above are present treat the patient medically or surgically.</p> |
| Speed (rpm) | Power (<W) | | | | | | | | | | | | | | | |
| 800 | 0.05 | | | | | | | | | | | | | | | |
| 1200 | 0.27 | | | | | | | | | | | | | | | |
| 1600 | 0.94 | | | | | | | | | | | | | | | |
| 2000 | 2.05 | | | | | | | | | | | | | | | |
| 2400 | 3.62 | | | | | | | | | | | | | | | |
| Urgent | 21 | Blood Pump | <p>Blood pump power consumption is high (<22.5 W)</p> <p>May be due to:</p> <ul style="list-style-type: none"> • Blood components entering mechanical seal • Increased in rotational resistance | <p>Check Patient condition. Blood pump flow may be decreasing. Apply medical emergency care as a priority. Set CSU FPour to 45kPa AND Flush CS lines every 12hrs for 5 days.</p> <p>Per flushing, use 2x 50ml syringes with sterile water and flush CS line over 8-12 seconds per syringe (i.e. total daily volume is 200 ml)</p> | | | | | | | | | | | | |
| Critical | 22 | Blood Pump | <p>Blood pump speed is low (≤600 rpm below set speed)</p> <p>May be due to:</p> <ul style="list-style-type: none"> • Blood components entering mechanical seal • Increased in rotational resistance | <p>Check Patient condition. Blood pump flow may be decreasing.</p> <p>Apply medical emergency care as a priority.</p> | | | | | | | | | | | | |
| Warning | 24 | Controller | Upper temperature limit of the pump driver circuit exceeded. | 1. Remove the controller from the carrying bag and allow to cool. 2. If the alarm has not cleared after 2 hours proceed with a controller replacement. | | | | | | | | | | | | |

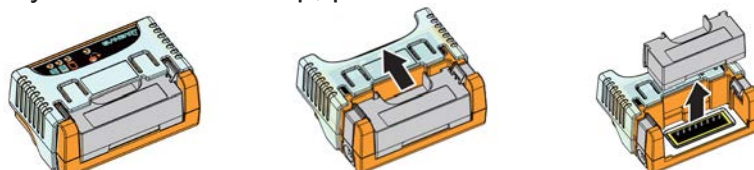
Troubleshooting Evaheart 2 LVAS

| A (critical) | | Flashing | "Beep Beep Beep - Beep Beep" + ~3 seconds of silence, repeating | |
|----------------|------------|------------------|---|---|
| B (Urgent) | | Flashing | "Beep Beep Beep" + ~3 seconds of silence, repeating | |
| C (Warning) | | Solid | "Beep Beep" + ~15 seconds of silence, repeating | |
| Alarm Severity | Event Code | Component | Descriptions | Corrective Actions |
| Urgent | 25 | Blood Pump | Decrease in P.I. (Pulsatility Index) value. Outbreak of arrhythmia. Other AE possible: impaired LV contractility, possible RHF. | Check Patient condition. Apply medical emergency care as a priority. |
| Urgent | 30 | Controller | Blood pump rotation interrupted and restarted (more than once in a 5 min. period) due to: <ul style="list-style-type: none"> • Sudden increase in the rotational resistance of the blood pump • Controller failure | Check if the patient is feeling light headed or experiences discomfort (alarm noise). If event 30 occurs more than 1 time an hour and continues for over a week then: Increase Fpout by 2kPa and monitor for the next 48 hrs. If event 30 continues, contact EVAHEART clinical support. |
| Critical | 32 | Controller | Blood pump rotation interrupted due to: <ul style="list-style-type: none"> • Disconnection of blood pump cable • Wire damage/breakage in the blood pump cable | Follow E-32 decision tree RE: Operator Manual <ul style="list-style-type: none"> • Reconnect cable connector • Use emergency controller • Urgent pump replacement |
| Warning | 40 | CSU | High Fpin pressure (>0.7 krpm). May be due to: <ul style="list-style-type: none"> • Kinked driveline / CS line • Reservoir too full | Check fluid in the CSU reservoir for any discoloration. Check for air in the reservoir and remove all while running CSU regardless of the amount. Also refill CS fluid as needed. Keep running for 30 minutes. If event 40 still remains, consider CSU replacement. |
| Warning | 41 | CSU | Low CS pump speed (>100.0 kPa). May be due to: <ul style="list-style-type: none"> • Clogged filter in the CSU • Air in reservoir | Confirm there are no kinks. If no kinks are found and the reservoir is suspected to be over filled, remove a small amount of sterile water/air from the reservoir until CS pump speed increases above 1 krpm. Check drive line CS fluid lines. Open the controller cover and confirm that the CSU and the couplers (the both red and blue) are connected correctly. |
| Warning | 43 | CSU | Low CS fluid volume (>20 mL). May be due to: <ul style="list-style-type: none"> • CS fluid leakage from the CSU, driveline, or across the mechanical seal. CSU stops and will not auto restart. | Refill the CSU reservoir and de-air if needed. Check for leaks and check the connection of the coupler (blue) or return side and re-connect if necessary. If CSU leaks inside, replace CSU. |
| Warning | 45 | CSU | CSU internal circuit failure. | Replace the CSU. |
| Warning | 48 | CSU | CSU disconnected. | Connect the CSU. |
| Warning | 93 | External Battery | External battery 1 power is low. | Replace with a fully charged external battery 1. |
| Warning | 94 | External Battery | External battery 2 power is low. | Replace with a fully charged external battery 2. |
| Critical | 99 | Controller | Blood pump rotation stopped due to: <ul style="list-style-type: none"> • Blood pump failure • Controller failure | Follow 99 decision tree RE: EVAHEART LVAS C03 IFU <ol style="list-style-type: none"> 1. IMMEDIATELY switch to the emergency controller 2. Replace emergency controller with new controller 3. If alarm is still active consider urgent blood pump replacement |

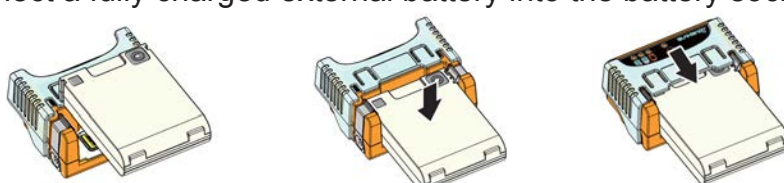
Switching To The Emergency Controller Evaheart 2 LVAS



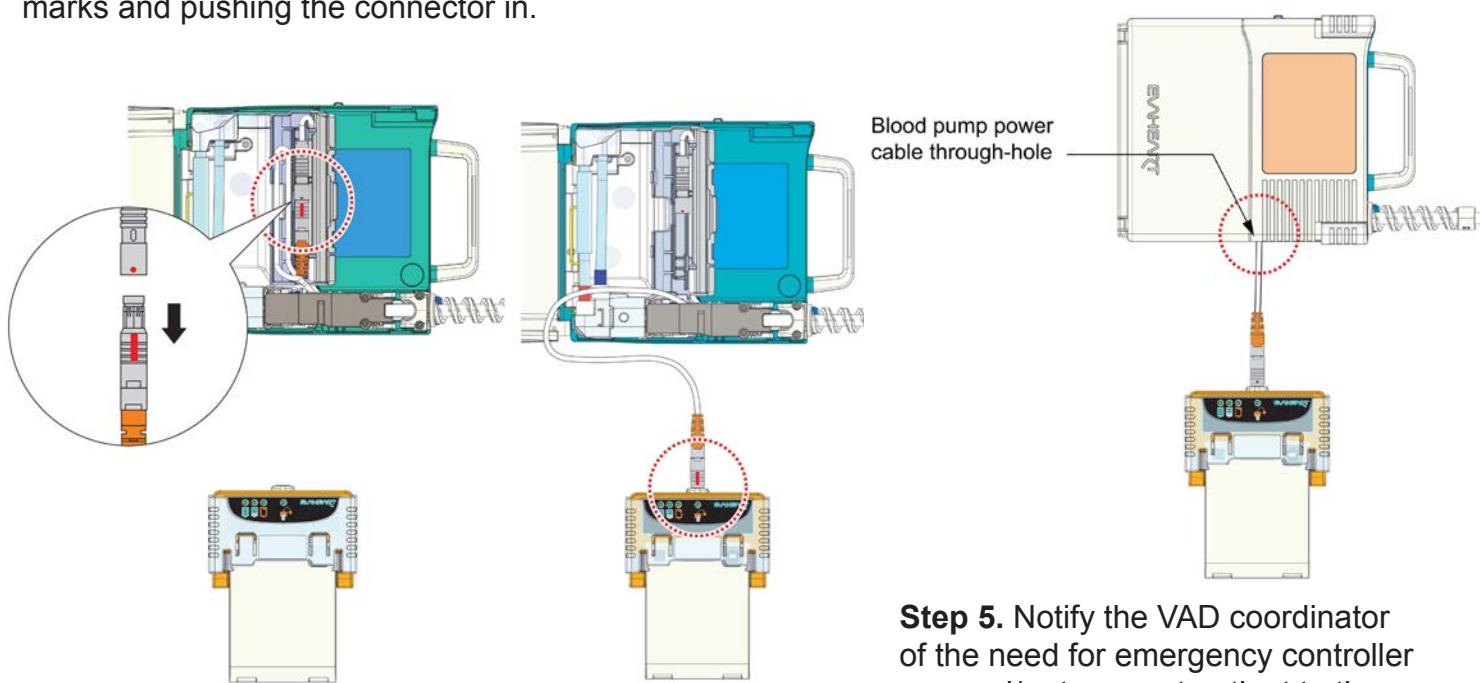
Step 1. Slide the emergency controller cover up, press the buttons on the sides of the controller and remove the dust cover.



Step 2. Connect a fully charged external battery into the battery socket.



Step 3. Disconnect blood pump power cable from inside controller cover and immediately connect the cable to the emergency controller by aligning the red marks and pushing the connector in.



Step 4. Pass the pump power cable through the through-hole and carefully close the controller cover.

Step 5. Notify the VAD coordinator of the need for emergency controller use and/or transport patient to the nearest VAD center. External battery will last approximately 4 hours; changing the battery will stop the pump.

This guide does not supersede manufacturer instructions.

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. After 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?

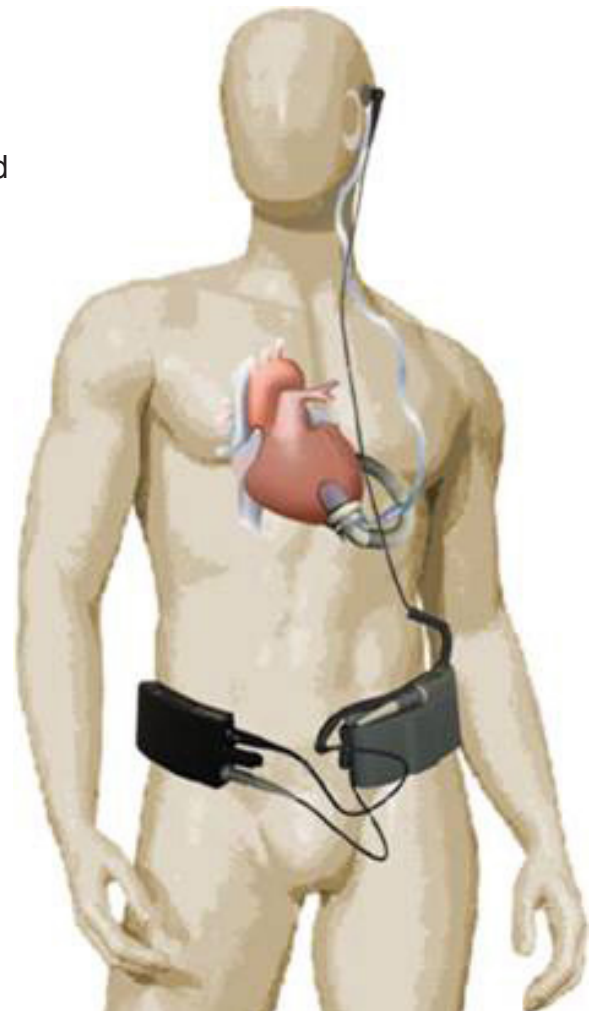
Most patients have a faint palpable pulse. If the controller is marked "ILS" (see below), the speed is automatically reduced every minute for 8 seconds & the patients pulse may increase during this time.

6. Can I change the speed of the device?

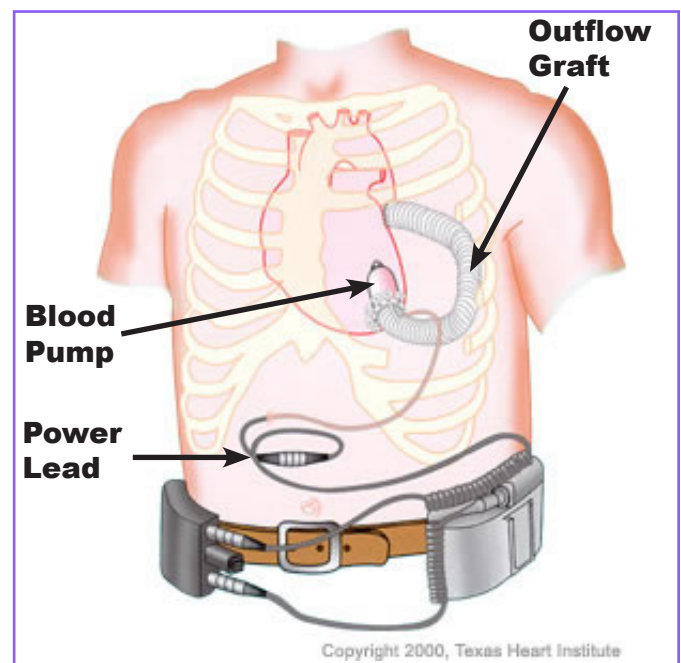
There is a speed dial on the side of the controller (see picture on page 25). Turning the dial in the direction of the arrow increases the speed. Each increment is 1,000 RPM. It is recommended not to change the speed without consulting the implanting center.

7. What are acceptable vital sign parameters?

MAP 65 - 80mmHg.

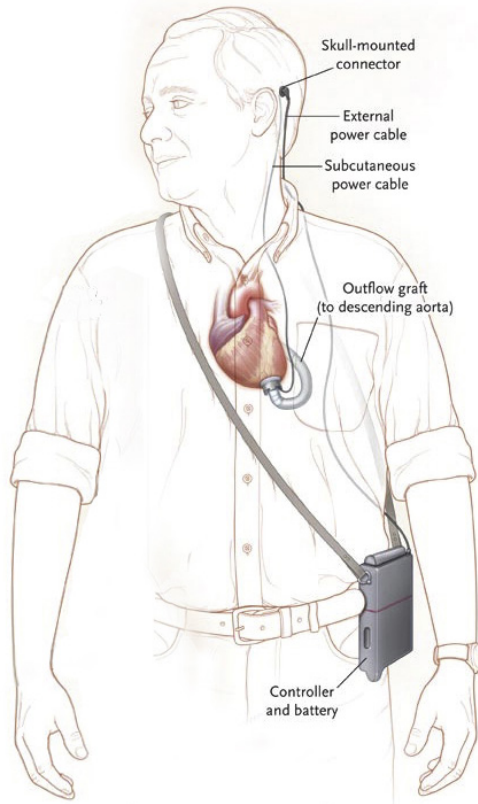


Jarvik 2000 with Post-Auricular exit site.



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.

External Equipment for Jarvik 2000® VAS, Abdominal Cable.



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



Jarvik 2000® VAS



Li-ion Battery.



FlowMaker® Controller.

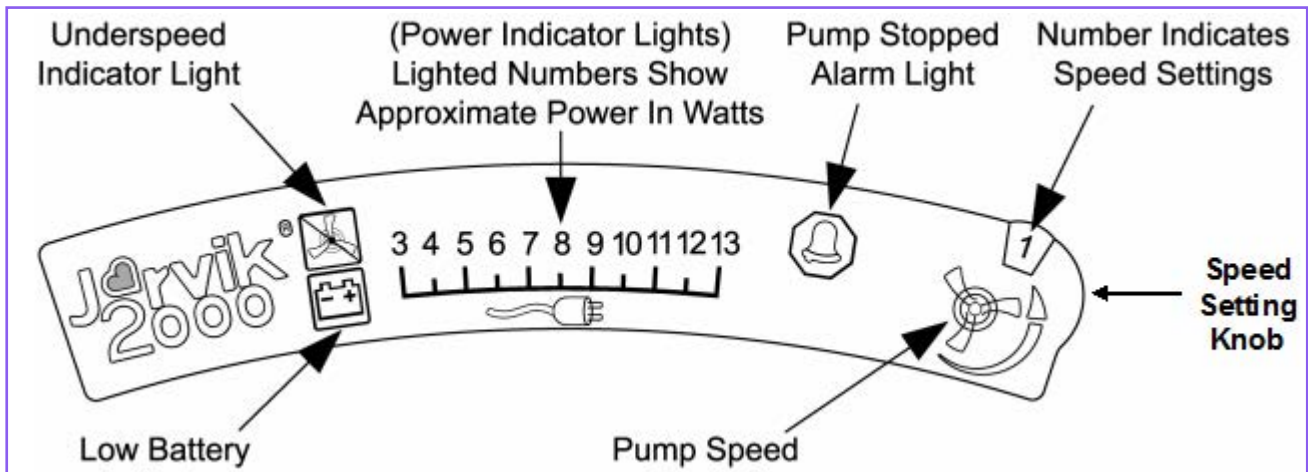


Diagram of FlowMaker® Controller Top Panel.

| 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 |

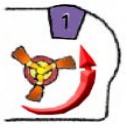
The FlowMaker Controller provides:

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.*



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 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.



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.

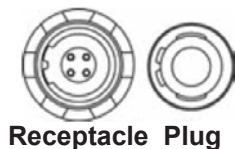
1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Extension Cable from the drive cable at the abdomen, and set 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. Red tag all components of the system that were set aside before changing to the backup components in step 2a.
4. 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.
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 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.
8. **If the Jarvik 2000® VAD (pump) is still stopped call your medical emergency number immediately.**



Jarvik® 2000

Jarvik 2000® Adult Ventricular Assist System-Quick Reference Guide

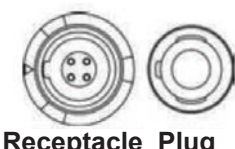
Connection from Jarvik 2000 VAD to FlowMaker Controller:



Receptacle Plug

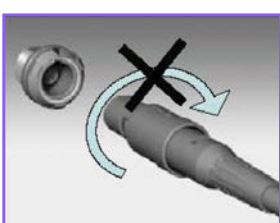
The black receptacle on the FlowMaker Controller is located above the housing for the small back-up Alarm Battery. The receptacle has double key slots for a black plug. The Extension Cable and the Pedestal Cable (depending on the model of the device used) also have double key slots.

Connection from FlowMaker Controller to Y Cable or battery:



Receptacle Plug

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.

Patient Management For TAHs

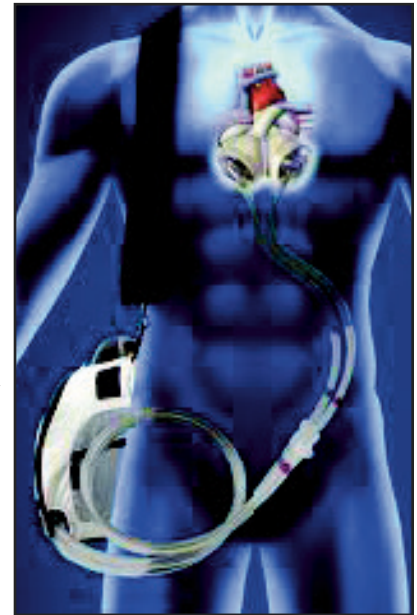
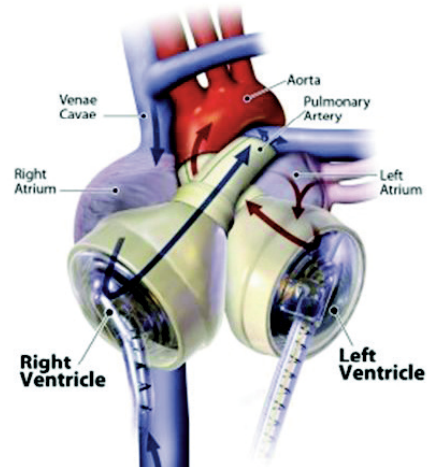
1. Assess the patients airway and intervene per your protocol.
2. Auscultate heart sounds but you can usually hear them without a stethoscope. Since this is pulsatile you should hear two sounds if properly functioning.
3. Assess the device for device information and alarms located on the driver.
4. Intervene 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 SHOULD HAVE A PALPABLE PULSE.**
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 caregiver 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)

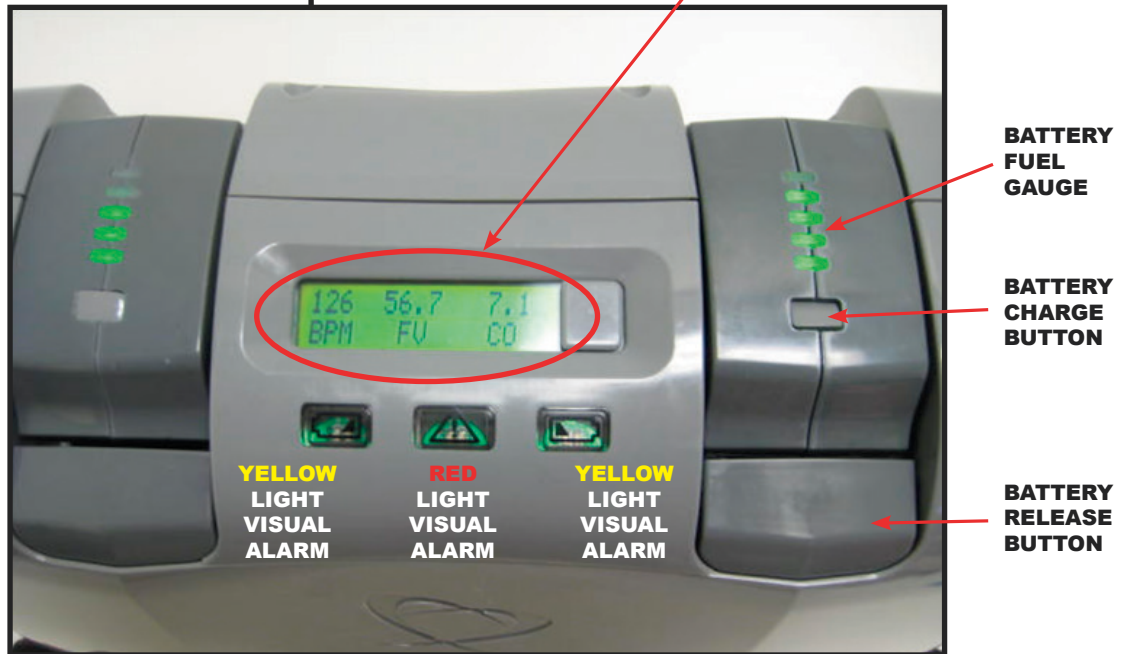
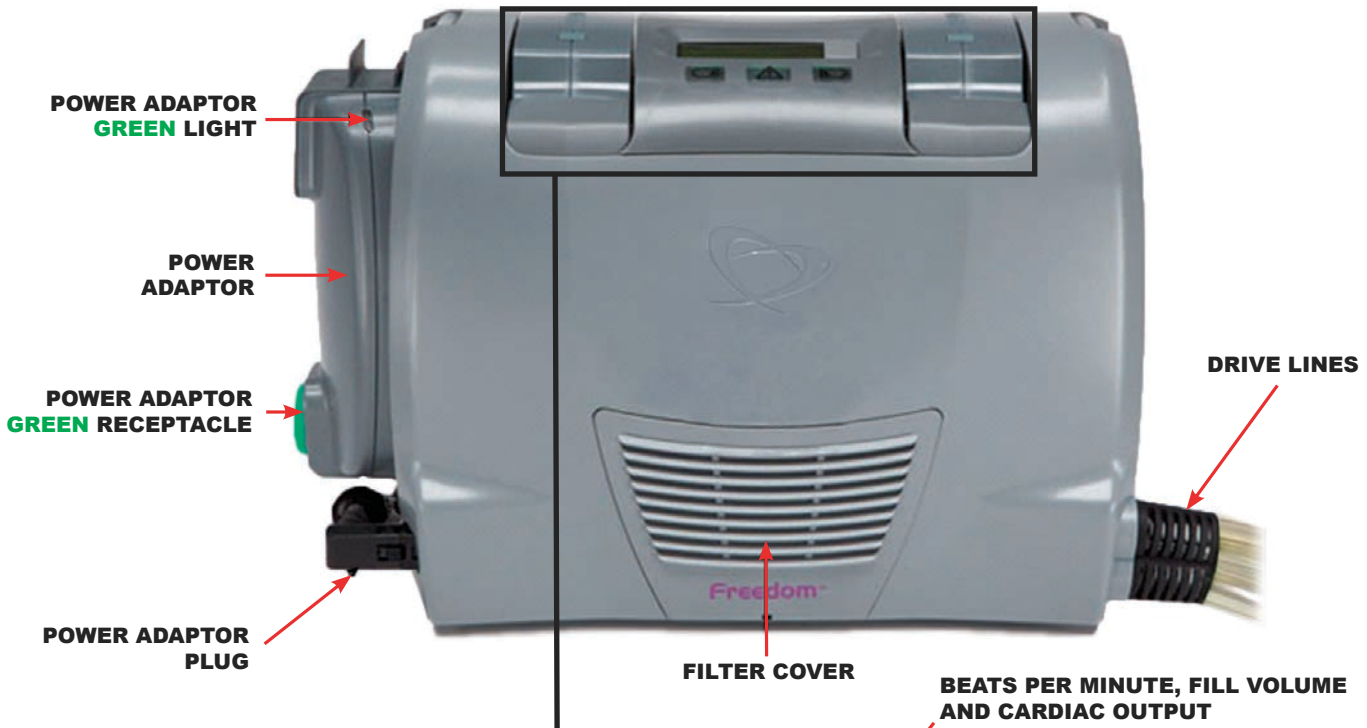
- 1. Can I do CPR?**
No. Will need to rapidly exchange to the backup driver.
- 2. Can the patient be defibrillated or externally paced?**
No, there is no native heart rhythm.
- 3. Does the patient have a pulse with this device?**
Yes. The device produces pulsatile flow. The device is pneumatically driven 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?**
NO CARDIAC RHYTHM (no native heart).
- 6. Is there a "hand pump".**
No. The priority is to secure connections to the Freedom Driver to ensure compressed air delivery.
- 7. Can I give vasopressor IV drugs like epinephrine, dopamine or dobutamine?**
Maintain patient's systolic blood pressure under 140mmHg. Avoid giving vasopressor drugs, especially epinephrine. 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 become unconscious immediately. Even when 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



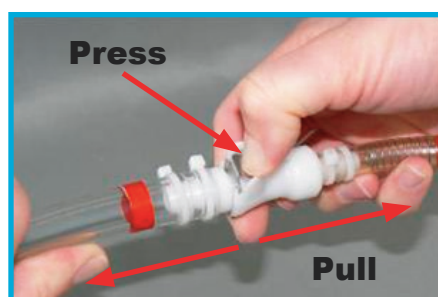
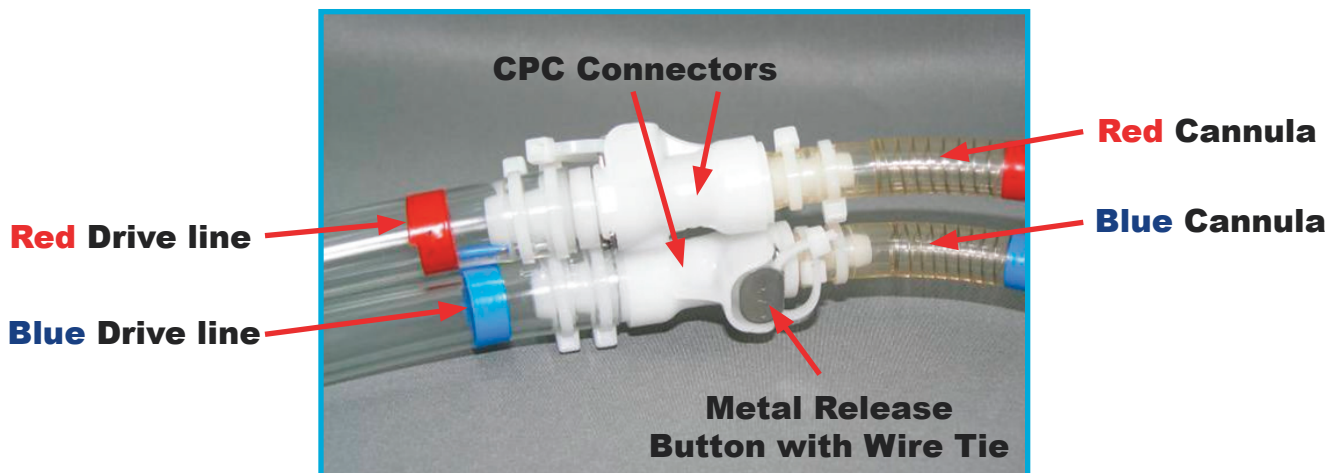
FIGURE 3

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:
 - 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. 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.