

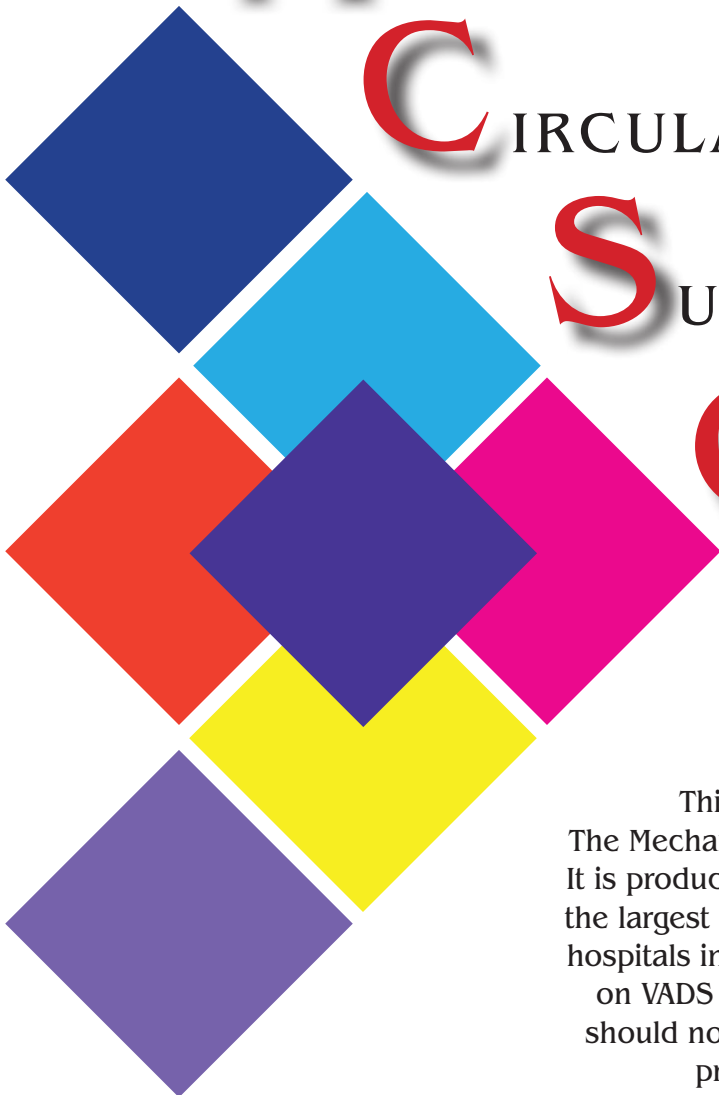
EMS Guide January 2013

M ECHANICAL

C IRCULATORY

S UPPORT

O RGANIZATION



This guide is produce by MCSO –
The Mechanical Circulatory Support Organization
It is produced by VAD Coordinators from some of
the largest and most successful VAD implantation
hospitals in the US. It has been vetted by experts
on VADS in Air Medical Transport and EMS. It
should not replace the operator manual as the
primary source of information.

Questions and Answers

What is a Ventricular Assist Device (VAD)?

A ventricular assist device (VAD) is a mechanical pump that's used to support heart function and blood flow in people who have weakened hearts.

How does a VAD work?

The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would.

What are the parts of a VAD?

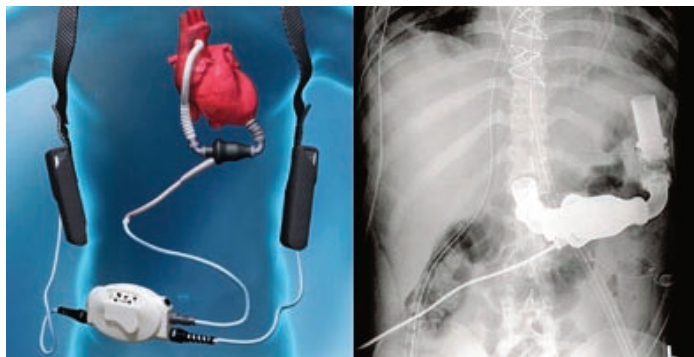
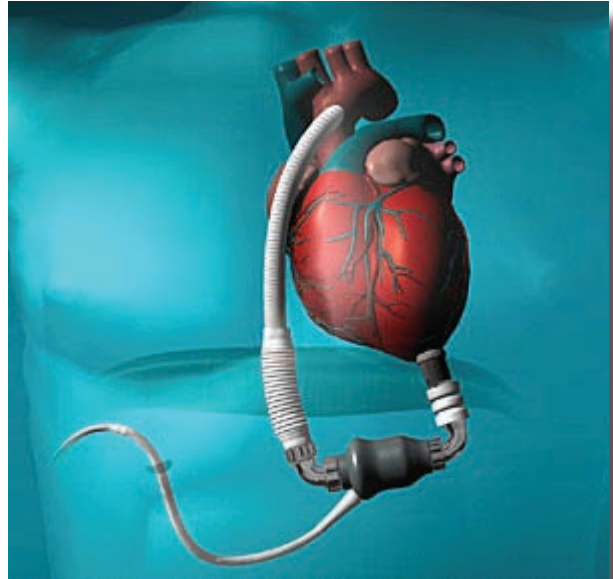
The basic parts of a VAD include: a small tube that carries blood out of your heart into a pump; another tube that carries blood from the pump to your blood vessels, which deliver the blood to your body; and a power source.

What is the power source?

The power source is either batteries or AC power. The power source is connected to a control unit that monitors the VAD's functions. The batteries are carried in a case usually located in a holster in a vest wrapped around the patients shoulders.

What does the control unit or controller do?

The control unit gives warnings, or alarms, if the power is low or if it senses that the device isn't working right. It is a computer.



The portability of the HeartMate II enables patients to resume many of their normal daily activities.

Color Coding System

MOST patients have a tag located on the controller around their waist that says what type of device it is, what institution put it in and a number to call. Most importantly is the color of the tag – it matches this EMS Field Guide and allows you to quickly locate the device you are caring for.

HEARTMATE II

HEARTWARE

JARVIK 2000

HEARTMATE XVE

THORATEC PVAD/IVAD

FREEDOM DRIVER
Total Artificial Heart

DURAHEART

Patient Management

1. **Assess the patients airway and intervene per your protocol.**
2. **Auscultate Heart Sounds to determine if the device is functioning and what type of device it is. If it is continuous flow device, you should hear a “whirling sound”.**
3. **Assess the device for any alarms.**
4. **Look on controller usually found around the waist of the patient and to see what color tag and device it is.**
5. **Match the color on the device tag to the EMS Guide.**
6. **Intervene appropriately based on the type of alarm, tag (device) and EMS Guide.**
7. **Start Large Bore IV.**
8. **Assess vital signs – Use Mean BP with Doppler – with the first sound you hear is the Mean Arterial Pressure (MAP).**
9. **If no Doppler, use the Mean on the non invasive blood pressure machine.**
10. **Transport to closest VAD center. Call the number on the device to get advice.**
11. **Bring all of the patients equipment.**
12. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

HeartMate II®

- 1. Can I do external CPR?**
Only if absolutely necessary
- 2. If not, is there a "hand pump" or external device to use?**
No.
- 3. If the device slows down (low flow state), what alarms will go off?**
A red heart alarm light indicator and steady audio alarm will sound if less than 2.5 lmp. Can give a bolus of normal saline and transport to an LVAD center.
- 4. How can I speed up the rate of the device?**
No, it is a fixed speed.
- 5. Do I need to heparinize the patient if it slows down?**
Usually no, but you will need to check with implanting center.
- 6. Can the patient be defibrillated while connected to the device?**
Yes.
- 7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
- 8. Does the patient have a pulse with this device?**
May have weak pulse or lack of palpable pulse.
- 9. What are acceptable vital sign parameters?**
MAP 70 - 90 mm Hg with a narrow pulse pressure
- 10. Can this patient be externally paced?**
Yes.

FAQs

- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to electric line exiting patient's abdominal area and is attached to computer which runs the pump.
- Pump does not affect EKG
- All ACLS drugs may be given.
- No hand pump is available.
- A set of black batteries last approximately 3 hours, gray batteries last 8-10 hours.
- 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.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

Trouble Shooting HeartMate II®

When the Pump Has Stopped

- Be sure to bring ALL of the patient's equipment with them.
- Fix any loose connection(s) 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 next page)*
- If pump does not restart, change controllers. *(see changing controllers section on next page)*

Alarms: Emergency Procedures



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

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 in the section above.



Trouble Shooting HeartMate II®

Changing Batteries

WARNING: At least one power lead 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 gray battery can be assessed by pressing the battery button on the battery. (Figures 3 and 4)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 1)
- Controller will start beeping and flashing green signals.
- Replace with new battery by lining up **RED** arrows on battery and clip. (Figure 2)
- Slide a new, fully-charged battery (Figure 4) into the empty battery clip by aligning the **RED** arrows. The battery will click into the clip. Gently tug at battery to ensure connection. If battery is properly secured, the beeping and green flashing will stop.
- Repeat previous steps with the second battery and battery clip.



Figure 1



Figure 2

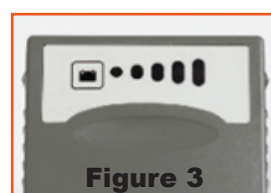


Figure 3

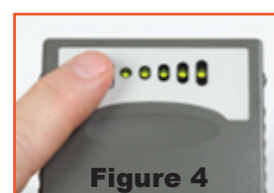


Figure 4

Changing Controllers

- 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.

- Make sure patient is sitting or lying down since the pump will momentarily stop during this procedure.

- Attach the battery clips to the spare controller by lining up the half moons and gently pushing together and attach the batteries to the spare controller by aligning the **RED** arrows. **ALARMS WILL SOUND-THIS IS OK.**



Half-Moons

- Depress the silence alarm button (upside-down bell with circle) until the alarm is silenced on the new, replacement Controller.
- Rotate the perc lock on the replacement controller in the direction of the "unlocked" icon until the perc lock clicks into the fully-unlocked position. Repeat this same step for the original Controller until the perc lock clicks into the unlocked position.



Perc Lock

- Disconnect the perc lead/driveline from the original controller by pressing the metal release tab on the connector socket. The pump will stop and an alarm will sound.

Note: The alarm will continue until power is removed from the original Controller. **Getting the replacement Controller connected and the pump restarted is the first priority.**

- Connect the replacement Controller by aligning the **BLACK LINES** on the driveline and replacement Controller and gently pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:

Step 1. Firmly press the Silence Alarm or Test Select Button to restart the pump.

Step 2. Check the powersource to assure that power is going to the controller.

Step 3. Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.



Tug gently on metal end in this direction

Perc Lead

- After the pump restarts, rotate the perc lock on the new controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position. If unable to engage perc lock to the locked position, gently push the driveline into the controller to assure a proper connection. Retry to engage perc lock.
- Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.

HeartWare® Ventricular Assist System

1. Can I do external CPR?

Chest compressions may pose a risk of dislodgment – use clinical judgment. If chest compressions are administered, confirm function and positioning of the pump.

2. If not, is there a “hand pump” or external device to use?

No.

3. If the device slows down (low flow state), what alarms will go off?

The device runs at a fixed speed. 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.

4. How can I speed up the rate of the device?

It is not possible to adjust the pump speed in the prehospital setting. Okay to give IV fluids.

5. Do I need to heparinize the patient if it slows down?

Call the accepting VAD facility for guidance.

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

Yes.

7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?

No, defibrillate per protocol.

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

The patient may not have a palpable pulse. Depending on the patient's own heart function, you may be able to feel a thready pulse.

9. What are acceptable vital sign parameters?

Goal Mean Arterial Pressure (MAP) is 75 to 90 mmHg. Use a Doppler as the first option to assess blood pressure. If that is not available, use a non-invasive BP (NIBP). 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.

10. Can this patient be externally paced?

Yes

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 computer (controller) which runs the pump.
- Pump does not affect EKG
- All ACLS drugs may be given.
- No hand pump is available. This is a rotary (continuous flow) pump with typical speed ranges of 2400 – 3200 RPMs.
- The controller draws power from one battery at a time. A fully charged battery will provide 4-6 hours of power. Both the battery and controller have status lights to indicate the amount of power remaining.
- Transport by ground to implanting facility if possible.
- Be sure to bring **ALL** of the patient's equipment with them.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

HeartWare® Ventricular Assist System Emergency Operation



CONTROLLER



BATTERY

ALARM ADAPTER

- Used to silence the internal NO POWER ALARM.
- Should only be used on a controller that is NOT connected to a patient's pump.
- Must be inserted into the blue connector 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.



DRIVELINE CONNECTION

To Connect to Controller:

- Align the two red marks and push together. An audible click will be heard confirming proper connection. (Figure A)
- The Driveline Cover must completely cover the Controller's silver driveline connector to protect against static discharge. (Figure B)
- NOTE: an audible click should be heard when connecting the Driveline or Driveline extension to the controller. Failure to use the Driveline Cover may cause an Electrical Fault Alarm.



Figure A

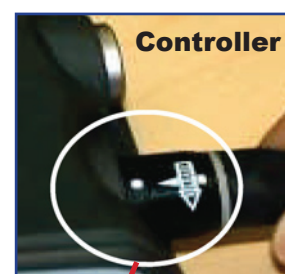


Figure B

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.



Controller



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.

HeartWare® Ventricular Assist System Emergency Operation

STEPS TO EXCHANGE THE CONTROLLER

Step 1: Have the patient sit or lie down.

Step 2: Place the new controller within easy reach.

Step 3: Connect back-up power sources (batteries or AC Power) to the new controller.

- Confirm that the power cables are properly locked on the controller by gently pulling on the cable near the connector.
- A "Power Disconnect" alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up
- A "VAD Stopped" alarm will activate if the pump driveline is not connected to the new controller within 10 seconds - this alarm will resolve once the pump driveline is connected

Step 4: Pull back the white driveline cover from the original controller's silver connector.

Step 5: Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A "VAD Stopped" alarm may activate. Don't panic. You can silence the alarm after restarting the pump, which is the priority.

Step 6: Connect the driveline to the new controller (align the two red marks and push together). If the "VAD Stopped" alarm was active on the new controller, it will now resolve.

Step 7: The pump should restart. Verify the pump is working (RPM, L/min, Watts).

Step 8: IF THE PUMP DOES NOT RESTART, CALL FOR MEDICAL ASSISTANCE IMMEDIATELY.

Step 9: Insert the Alarm Adapter into the blue connector on the original controller.

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

Step 10: Slide the white driveline cover up to cover new controller's silver connector.

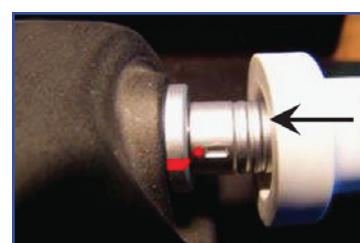
Step 11: Contact the VAD Center or Implanting hospital for a new backup controller.



Step 3



Step 4



Step 6



Step 9



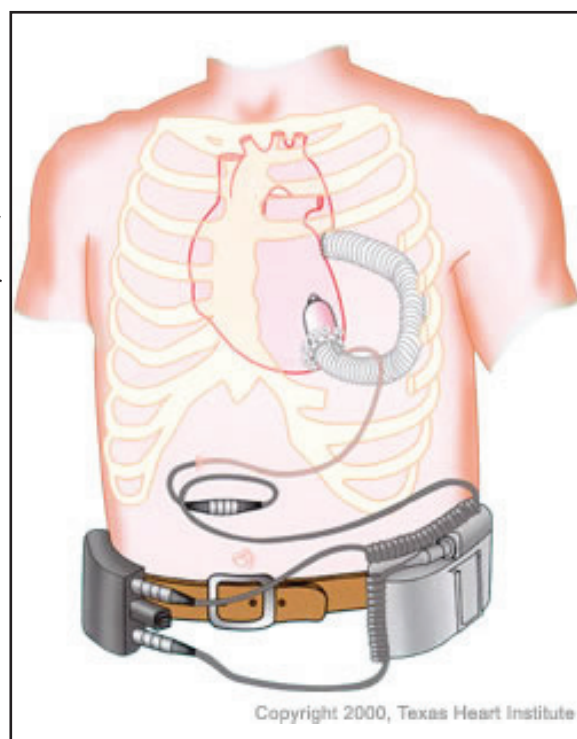
Step 10

HeartWare® Ventricular Assist System Troubleshooting

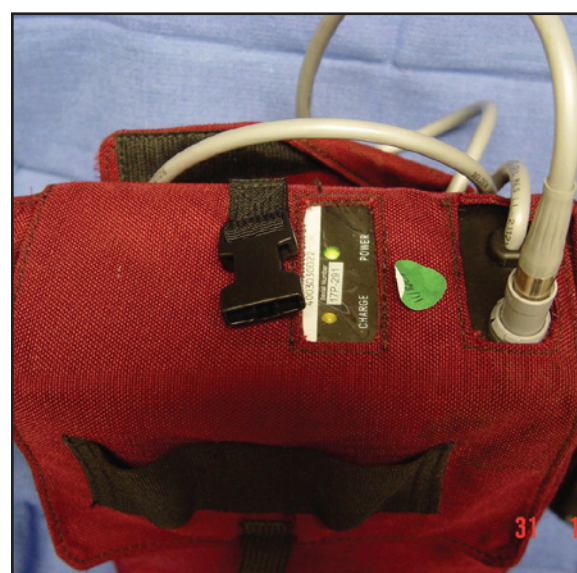
ALARM TYPE	ALARM DISPLAY (Line 1)	ACTION (Line 2)
High - Critical (FLASHING RED)	VAD STOPPED	CONNECT DRIVELINE
	VAD STOPPED	CHANGE CONTROLLER
	CRITICAL BATTERY 1	REPLACE BATTERY 1
	CRITICAL BATTERY 2	REPLACE BATTERY 2
	CONTROLLER FAILED	CHANGE CONTROLLER
MEDIUM (FLASHING YELLOW)	CONTROLLER FAULT	CALL ACCEPTING VAD HOSPITAL
	CONTROLLER FAULT	CALL: ALARMS OFF
	HIGH WATTS	CALL ACCEPTING VAD HOSPITAL
	ELECTRICAL FAULT	CALL ACCEPTING VAD HOSPITAL
	LOW FLOW	CALL ACCEPTING VAD HOSPITAL
	SUCTION	CALL ACCEPTING VAD HOSPITAL
LOW (SOLID YELLOW)	LOW BATTERY 1	REPLACE BATTERY 1
	LOW BATTERY 2	REPLACE BATTERY 2
	POWER DISCONNECT	RECONNECT POWER 1
	POWER DISCONNECT	RECONNECT POWER 2

Jarvik 2000 FlowMaker®

1. **Can I do external CPR?**
Yes.
2. **If not, is there a "hand pump" or external device to use?**
No.
3. **If the device slows down (low flow state), what alarms will go off?**
The Underspeed indicator light. If the pump is stopped you will hear a steady alarm and the pump stopped symbol will light up red. This symbol is shaped like a stop sign with a bell in it.. See next page for symbols and locations. Change to a fully charged battery or change from the reserve battery to the L-ion battery.
4. **How can I speed up the rate of the device?**
Jarvik has an indicator dial usually at a speed set at 3.
5. **Do I need to heparinize the patient if it slows down?**
No.
6. **Can the patient be defibrillated while connected to the device?**
Yes.
7. **If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
8. **Does the patient have a pulse with this device?**
Yes. Palpable pulse depends on ventricular contractility, preload and afterload.
9. **What are acceptable vital sign parameters?**
Jarvik suggest MAP 65 - 75mm Hg.
10. **Can this patient be externally paced?**
Yes.
 - All ACLS medications can be administered.
 - The Li-Ion battery can provide up to 10 hours of power when fully charged.
 - When switching to the reserve battery be sure to follow the color coding of the cables



Jarvik 2000 FlowMaker® system



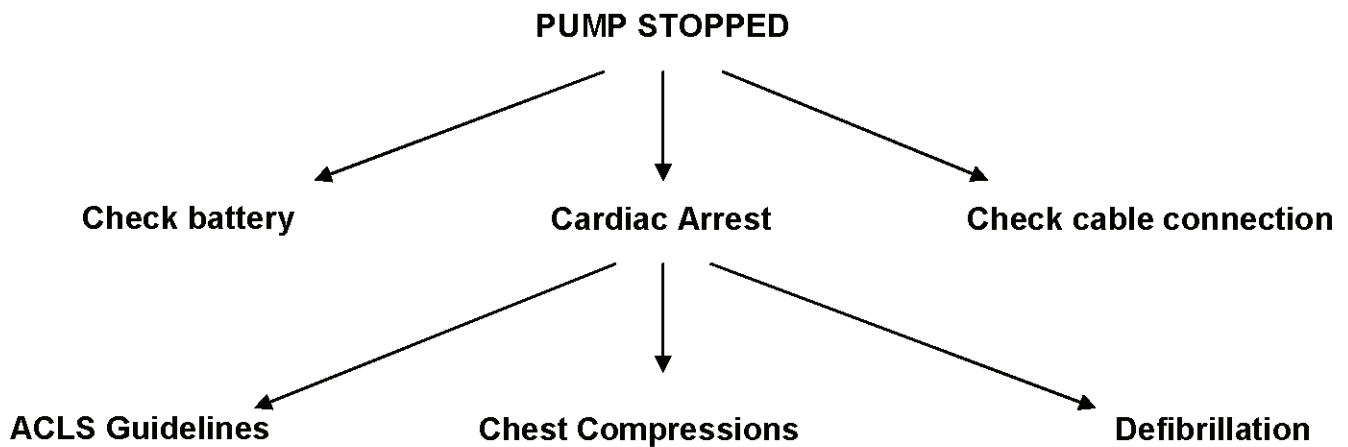
Reserve Battery Pack



Controller attached to the portable Li-ion battery.

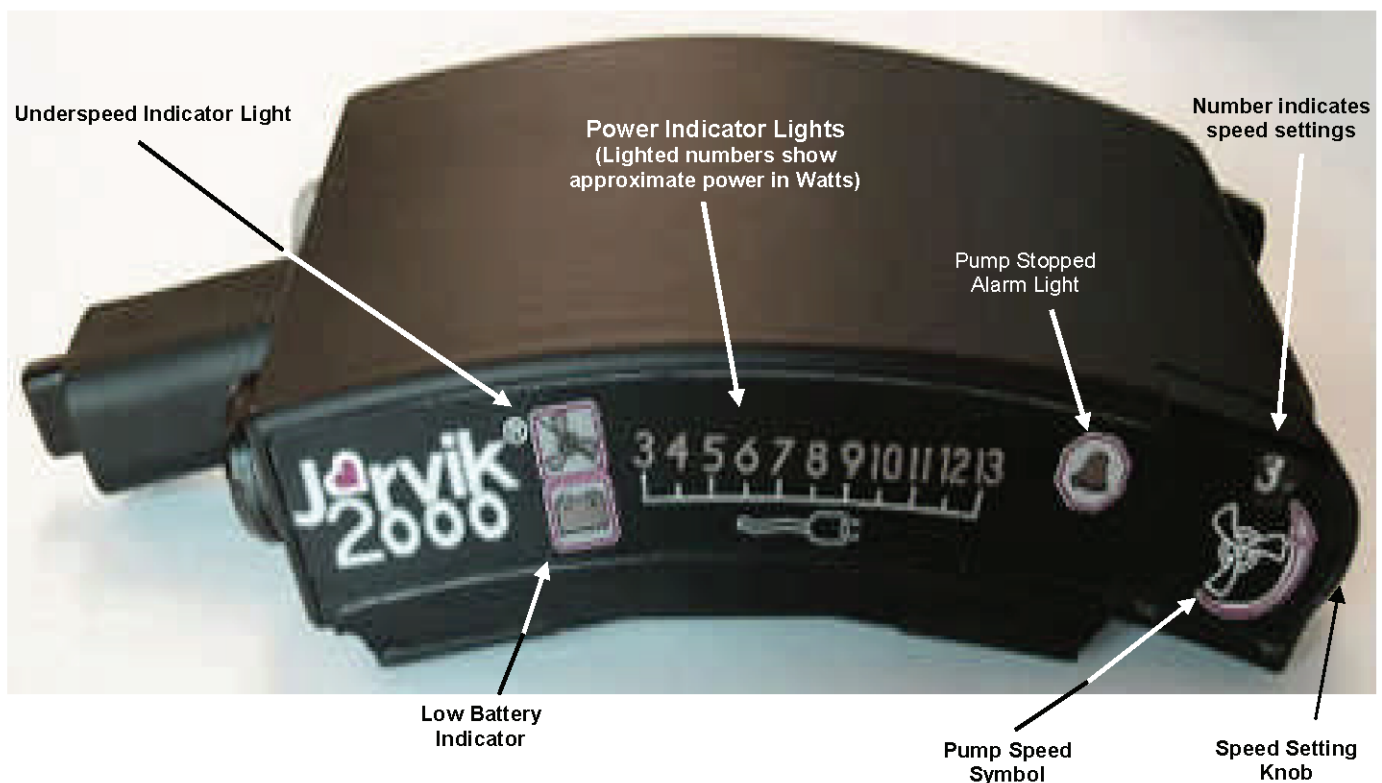
Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press. This guide does not supersede manufacturer instructions. Copy with permission only. March 2009 Jarvik 2000 FlowMaker®

Jarvik 2000 FlowMaker® Emergency Response Algorithm



If a patient does present with V-tach / V-fib, they are often conscious, but very weak and upon assessment have the classic low output signs.

Jarvik 2000 FlowMaker Controller Indicators and Troubleshooting



Jarvik 2000 FlowMaker®

The Jarvik 2000 runs ONLY on battery power (no AC adapter or console). Except during battery changes, only one battery is connected to the controller.

The only monitored parameters are pump power (in Watts) and pump speed (setting 1-5). Both are displayed on the controller. Normal ranges by speed are in the table to the left. Power > 1-2W above normal is concerning for pump thrombosis. (see chart to the left)

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

Two different battery types are used. The large Reserve battery will power the pump for at least 24 hrs; its charge status cannot be checked. The small Li-Ion battery will power it for 8-12 hrs; its charge status can be checked by pressing the black button on the top (1-5 lights indicate 20-100% charge; see photo to the left)



Cables are uniquely color-coded and keyed so that they cannot be mis-connected. Abdominal cable (driveline) connectors are black; power connections are gray or white.

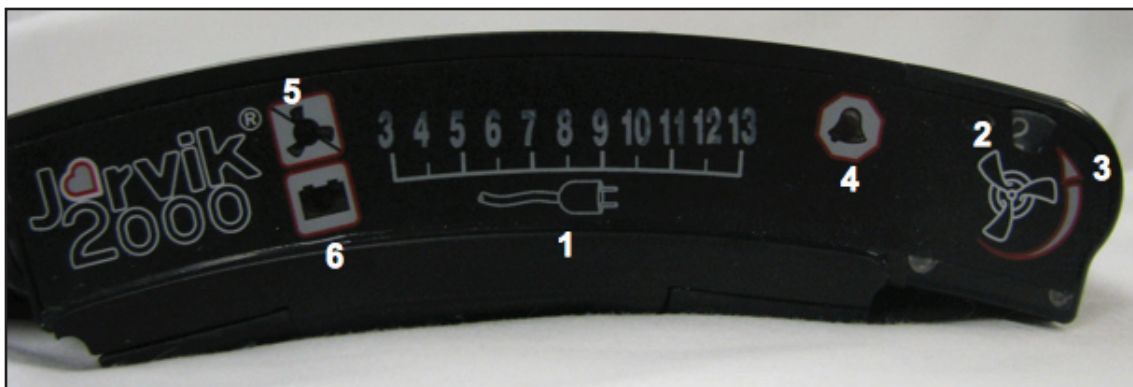
Jarvik 2000 speed is manually adjustable via a dial on the controller. The dial reads from 1 to 5, which corresponds to 8,000 (setting 1) to 12,000 (setting 5) RPM. Most patients are on setting 3 or 4.

The ILS Controller has a white "ILS" sticker on the front. On the ILS controller, the pump speed will decrease to 7,500 RPM for 8 secs every minute. During this period the pulse pressure may widen with a decreased MAP, and the pump power will decrease to 3-4 W.

Jarvik 2000 FlowMaker Controller:

1. Pump power display
2. Speed setting display
3. Speed adjustment dial (on side of controller)
4. Pump-stop alarm indicator
5. Underspeed alert indicator
6. Low battery alarm indicator.

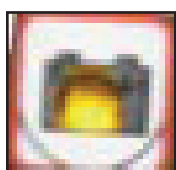
Controller attached to the protable Li-ion battery.



Jarvik 2000 FlowMaker® Controller

Jarvik 2000 FlowMaker® Troubleshooting

If unsure whether pump is working, listen near apex with stethoscope (should hear high-pitched buzz/hum).



A. Low Battery Alarm (*intermittent beep*): 5-10 min on Li-Ion; >=15 min on Reserve.

To change battery, remove blue/gray cap from unused Y-cable port.

Insert end of new battery cable into open port on Y-cable.

Disconnect old battery & put blue cap on open port.



B. Pump Stopped Alarm (*continuous alarm*): Pump not connected or running < 5,000 RPM.

1. Change to a fresh, fully charged battery;

2. If not resolved, check all cables for proper connection & for damage, including the portion of the abdominal cable that connects to the percutaneous lead at the patient's abdomen. If damaged cable, replace with backup (usually attached to patient's spare controller);

3. If not resolved, change controller & all cables. Spare controller should have back-up Y-cable & abdominal cable attached to it. If not attached & pt symptomatic, do not worry about finding them.

4. Disconnect old abdominal cable (black) from percutaneous lead at patient's abdomen. Set old system, including battery, aside. It will continue to alarm.

5. Connect new battery to Y-cable (gray to gray; or connect battery directly to gray port on spare controller if unable to locate spare Y-cable). New controller will begin to alarm.

6. Connect new controller's abdominal cable to percutaneous lead at abdomen, or connect percutaneous lead directly to black port on controller if unable to find spare abdo cable. New controller should cease alarming and pump power should be > 3W.

7. If controller continues to alarm, check all connections again. If unresolved, attempt to manipulate percutaneous lead & connector (may be lead damage). If still unresolved, transport emergently; contact implanting center to see if IV anticoagulation & inotropes are indicated.



C. Underspeed Alarm (*no audible alarm*): pump running below set speed.

If no other alarms are present, not an emergency. Change to a fully charged

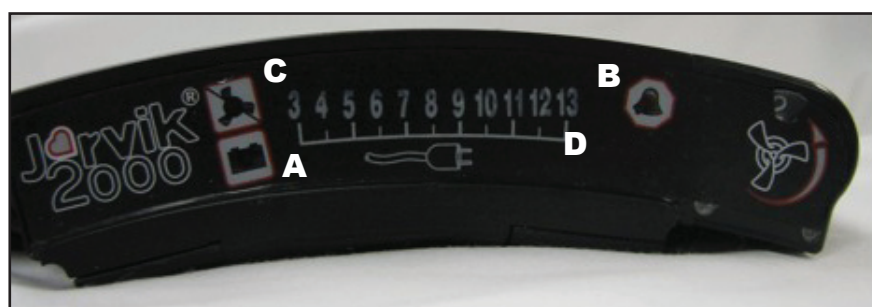
Li Ion battery. If unresolved, contact implanting center.



D. High Power Alarm

(13W light will be amber w/audible alarm): Power too high for any speed. Auscultate pump to check for operation.

Change all cables & controller as above. If unresolved, transport emergently. Contact implanting center to see if IV anticoagulation/inotropes are indicated. Most likely cause is pump thrombosis.



HeartMate® XVE

1. Can I do external CPR?

No.

2. If not, is there a "hand pump" or external device to use?

Yes. Pump at a rate of 60 -90 beats per minute.

3. If the device slows down (low flow state), what alarms will go off?

A red heart alarm light indicator and steady audio alarm will sound if less than 1.5 lpm. Check for hypovolemia or right heart failure and treat if red heart alarm persist after treatment consider performing a controller exchange.

4. How can I speed up the rate of the device?

Give volume of IV fluids.

5. Do I need to heparinize the patient if it slows down?

Please check with the accepting hospital.

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

No.

7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?

Yes, disconnect from power/batteries first, initiate hand pumping, disconnect controller from driveline, defibrillate the patient, remove hand pump, reattach driveline to controller, and then reattach the power source.

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

Yes, the device produces a Pulsatile flow. Heart rate is independent of pump rate.

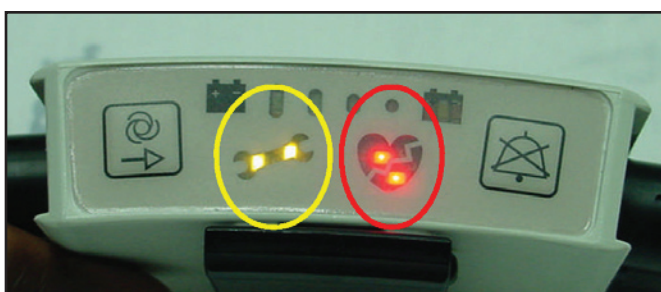
9. What are acceptable vital sign parameters?

The BP will vary. 110/80 -140/80. If greater, call the accepting hospital.

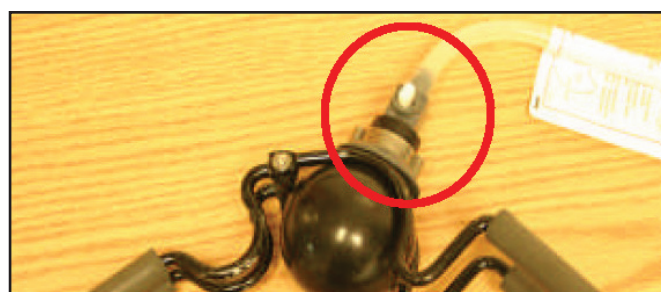
10. Can this patient be externally paced?

Yes, keep MA less than 40.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.



Heartmate XVE Controller showing Yellow Wrench & Red Heart indicator lights



Hand pump & white purge valve

HAND PUMPING PROCEDURE



Push in white purge valve



Press the black ball while holding down the white purge valve.



Release purge valve.



Count to 10, push white purge valve & black bulb should re-inflate.

JANUARY 2012

HeartMate® XVE

Steps To Exchange Controller

Step 1: Place new System Controller within easy reach. Have Hand Pump nearby.

Step 2: Disconnect Power source (Batteries, PBU, or EPP) from System Controller. The System Controller will alarm and the pump will stop. (Figure 2A and Figure 2B)



Figure 2A



Figure 2B

Step 3: Disconnect the Driveline (coming from the patient) from the System Controller by pushing down on the black release button and gently pulling the Driveline connector out of the XVE System Controller socket. (Figure 3)



Figure 3

Step 4: Connect the Driveline to the new, replacement XVE System Controller by lining up the small black arrows on the Driveline connector and System Controller socket **FIGURE 4A**. Gently push the connector into the socket until it snaps into place **FIGURE 4B**. The new System Controller will alarm if the System Controller Battery Module is NOT in place. This is normal and should stop after the System Controller Battery Module is inserted. (Figure 4A, Figure 4B and Figure 4C)



Figure 4A



Figure 4B



Figure 4C

Step 5: Connect the new System Controller to power source (Batteries, PBU, or EPP). Your pump will restart and alarm will stop.

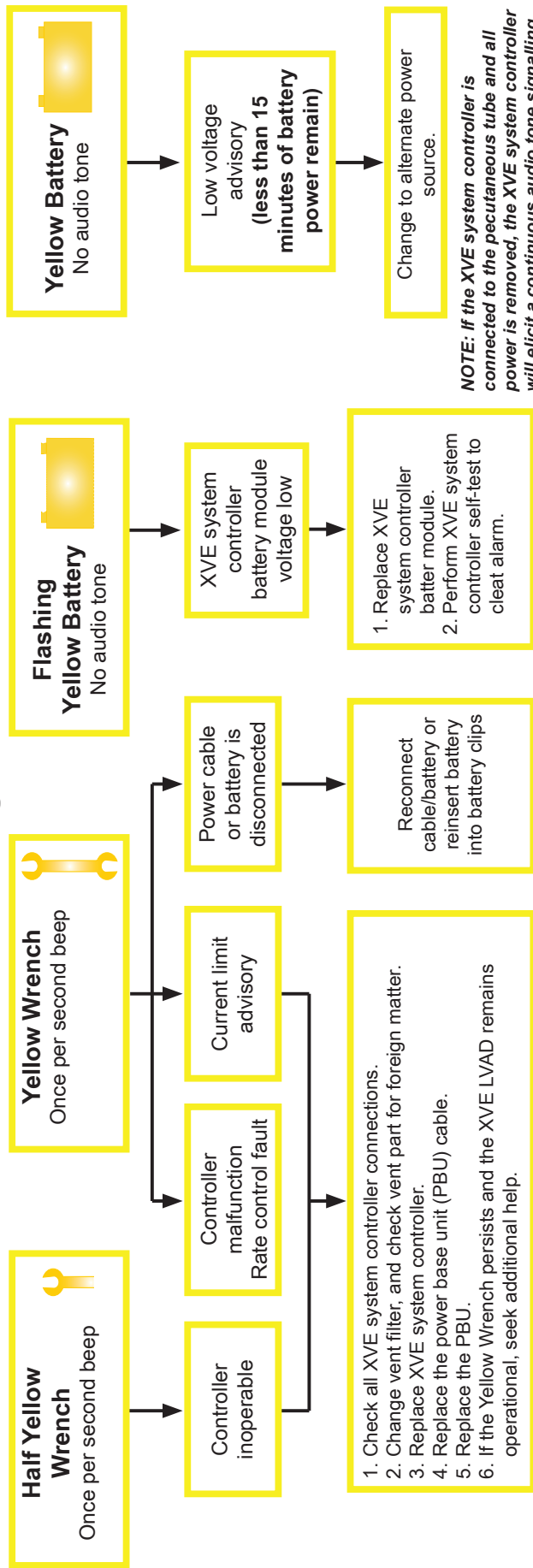
Step 6: If the pump does not restart, disconnect System Controller from power source and call for medical assistance; then immediately begin hand pumping.



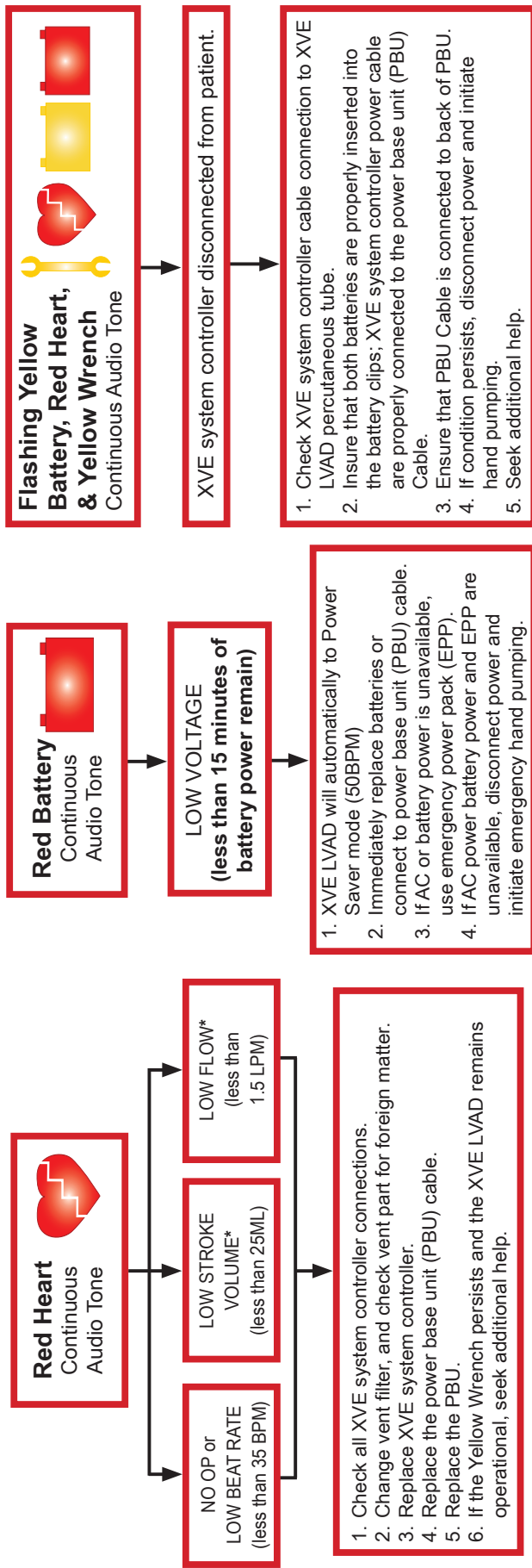
Figure 5

Air Transport Consideration: In rotor wing and fixed wing aircraft flying at heights lower than 10,000 feet-when using the hand pump for external CPR, you must re-purge the bulb every 2000 feet in ascent and 1000 feet in descent. This will assure you have consistent cardiac output.

Trouble Shooting HeartMate® XVE



NOTE: If the XVE system controller is connected to the percutaneous tube and all power is removed, the XVE system controller will elicit a continuous audio tone signalling the loss of power. This condition is not accompanied by a visual alarm.



***NOTE: DO NOT HAND PUMP if there is blood in the vent port. Conditions that affect pump filling, such as hypertension, hypovolemia, or mechanical defects, may limit the restoration of normal pump flows until the conditions are resolved. Hand pumping may be ineffective under these conditions.**

Thoratec PVAD™ w/TLC II Driver

1. **Can I do external CPR?**
No.
2. **If not, is there a "hand pump" or external device to use?**
Yes, find the blue or red hand bulbs.
3. **If the device slows down (low flow state), what alarms will go off?**
Low flow alarms: Loss of fill alarm will occur
4. **How can I speed up the rate of the device?**
Give volume of IV fluids.
5. **Do I need to heparinize the patient if it slows down?**
Only if it stops. Patient will be anticoagulated on Coumadin.
Only heparinize if the pump stops.
6. **Can the patient be defibrillated while connected to the device?**
Yes. Nothing needs to be disconnected. Patient should be placed on battery power BEFORE defibrillation.
7. **If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No. If the defibrillation is unsuccessful, disconnect pump and continue to defibrillate.
8. **Does the patient have a pulse with this device?**
Yes.
9. **What are acceptable vital sign parameters?**
Normal blood pressure parameters.
10. **Can this patient be externally paced?**
Usually in BiVAD configuration, if yes the ECG not important to treat. Because both sides of the heart are supported, there is little need to pace regardless of the rhythm seen on ECG.

- These patients have biventricular support through 2 pumps: right and left.
- EKG will NOT correlate with the patient's pulse.
- Patient may be in any arrhythmia, but because they have biventricular support — DO NOT TREAT arrhythmias. Only RVAD or LVAD patients should be treated for arrhythmias.
- Bring all extra batteries & electrical adaptor along during transport. This system is electrically driven.
- The pumps are driven by a compressor called the TLC II driver. The pneumatic hoses and cables plug into the top of the TLC II driver.
- If the Driver loses power, malfunctions, or stops, use the hand pump(s). (hand pump instructions on back of this page)
- Continue hand pumping and then, as soon as possible, replace the TLC II Driver with the backup Driver.
- Backup Driver accompanies the patient at all times. (Driver replacement instructions on back of this page)
- **WARNING:** If the pump has stopped and blood is stagnant in the device for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism. BEFORE the device is restarted or hand pumping is initiated, contact the implanting center for anticoagulation direction.



IVAD is implanted inside the abd cavity and is attached to the same TLC II driver on the outside.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.



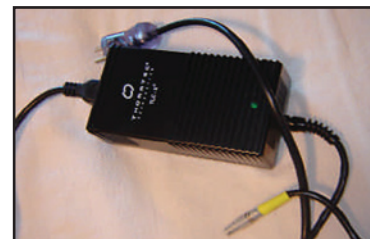
TCL-II Driver



Battery Charger



Batteries loaded into battery slots on TLC-II Driver



AC Power adapter – plug into yellow port on driver

PVAD/IVAD

Type of Device: pulsatile

What is an LVAD?

Left Ventricular Assist Devices are pumps surgically attached to patients' hearts to pump blood for the ventricle. There are three basic parts to all VAD systems. The pump, a computer with lamps and alarms, and a power source.

Why do patients get VADs?

Patient who have been treated for heart failure but in spite of optimal care continue to suffer from life limiting heart failure. Patients may be on the heart transplant list but the transplant team is worried the patient may die before a suitable donor is found, bridge to transplant. Pts who are not candidates for transplant but suffer from end stage heart failure may also be implanted as destination therapy.

How do VADs work?

Most vads implanted nationally create continuous flow. Blood comes from patients own ventricle into the pump then a turbine like spinning fan pushes the blood out into the aorta then the body. A cable connects the pump inside with the computer/controller and batteries outside the body. The pump needs a constant power supply.

biVAD



IVAD is implanted inside the abd cavity and is attached to the same TLC II driver on the outside.

Do's

1. Page the On Call Perfusionist. Call the Tower OR at 3316 to ask for the beeper number.
2. Give whatever medications you want. (no medication contraindication)
3. Defibrillate if indicated
4. Hand pump only if the device has stopped pumping, left faster than right.

Don'ts

1. NO CHEST COMPRESSIONS.
2. NO MRI.
3. Don't panic if the ECG is at one rate. The LVAD rate is at another, and the RVAD rate is a third.

Questions:

1. CPR: NO
2. Hand pump: yes called hand bulbs
3. low flow alarms: Loss of Fill alarm
4. speed up device: fluids
5. heparin: only if it stops. Patient has to be on Coumadin
6. defib: yes
7. disconnect for defib: no
8. pulse: yes
9. Vital signs: Normal BP parameters
10. externally pace: Usually in Bi VAD configuration if yes the ECG not important to treat

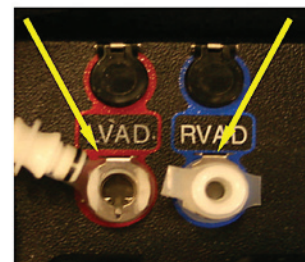
Hand Pumping Instructions



Step 1: Obtain hand pump(s) from carrying case. Note: One (1) hand pump is needed for each VAD.



Step 2: Depress metal clip(s) to disconnect the pneumatic lead(s) from the TLC II Driver.



Step 3: Connect the hand pump(s) to the pneumatic lead(s).



Step 4: Squeeze hand pump(s) once per second. Use your foot if necessary.

Note: For 2 VADs (BiVADs), squeeze each hand pump at the same rate. Never hand pump the right VAD (RVAD) faster than the left VAD (LVAD), as this may cause pulmonary edema.

Switching to Backup TLC-II Driver

Step 1: Insert a fully-charged battery (stored in carrying case) into each battery slot of backup TLC-II driver.

Step 2: Turn on key switch

Step 3: Depress metal clip(s) to remove white occluder from pneumatic port(s) :

- LVAD port is **RED**.
- RVAD port is **BLUE**.
- Note: for BiVADS, switch LVAD first. Do NOT remove occluder caps from both ports at the same time (or from unused port during single VAD support), or system will depressurize.

Step 4: Disconnect pneumatic lead(s) from primary Driver (or hand pump) and connect to backup Driver.

Step 5: Disconnect electric lead(s) from primary Driver and connect to backup Driver.

Step 6: Place Driver in AUTO mode, if necessary. Note: Backup Drivers are preprogrammed with a patient's unique settings.

Step 7: Verify full signal(s) is/are ejecting completely.

Step 8: Remove key and place in carrying case pocket.

Step 9: Connect to external power, if available by using the AC power adapter cord.

All modes of emergency transport are acceptable for VAD patients. Aviation electronics will NOT interfere with VAD operation (and vice versa).

Air Transport Consideration: In rotor wing and fixed wing aircraft flying at heights lower than 10,000 feet-when using the hand pump for external CPR, you must re-purge the bulb every 2000 feet in ascent and 1000 feet in descent. This will assure you have consistent cardiac output.

Total Artificial Heart Freedom™ Driver System

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

1. Can I do external CPR?

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

2. Is there a “hand pump” or external backup device to use?

No.

3. Can I give vasopressive IV drugs like epinephrine, dopamine or dobutamine?

Never give vasopressive drugs, especially epinephrine. These patients primarily have symptomatic hypertension and rarely have symptoms of hypotension. Most IV vasopressive drugs can be fatal to a TAH (Total Artificial Heart) patient.

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

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

5. What is the primary emergency intervention for a TAH (Total Artificial Heart)?

Nitroglycerin sublingual for symptomatic hypertension.

6. Can the patient be defibrillated or externally paced while connected to the device?

No. There is no heart.

7. 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 when alarming, the device should continue to pump. When in doubt, immediately change out the Freedom™ Driver immediately. Then quickly check for loose or kinked connections.

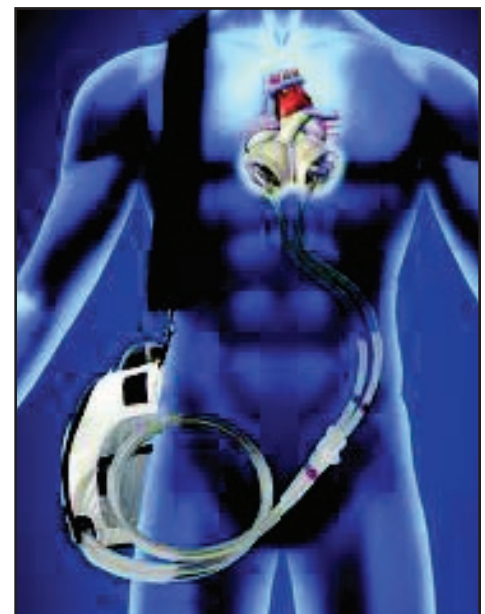
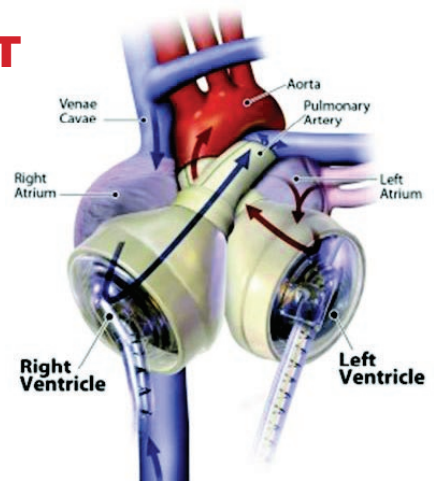
8. Does the patient have a pulse with this device?

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

9. What are acceptable vital sign parameters?

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

10. What kind of Cardiac rhythm should be displayed?
Asystole.

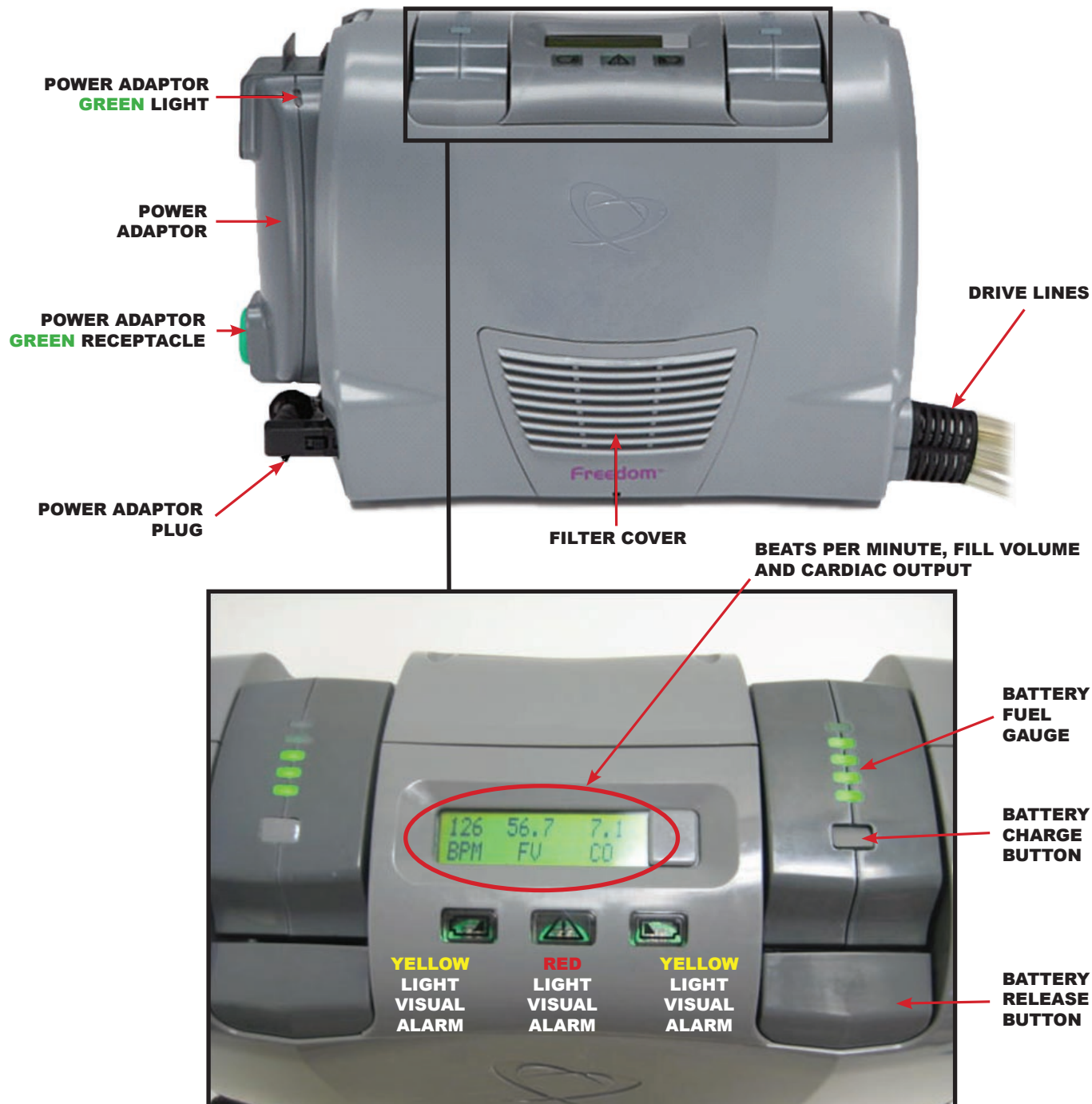


“Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010”



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.

"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

JANUARY 2013

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.

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JANUARY 2013

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



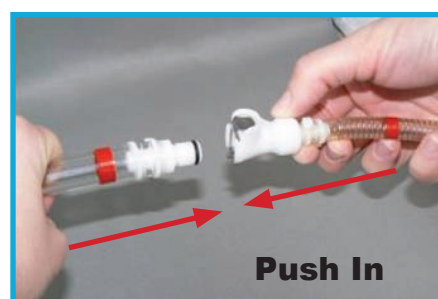
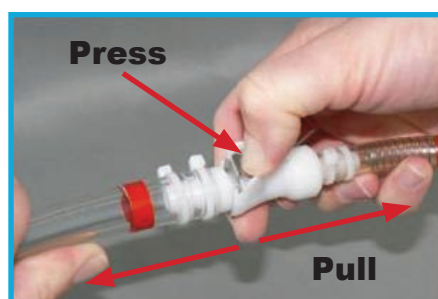
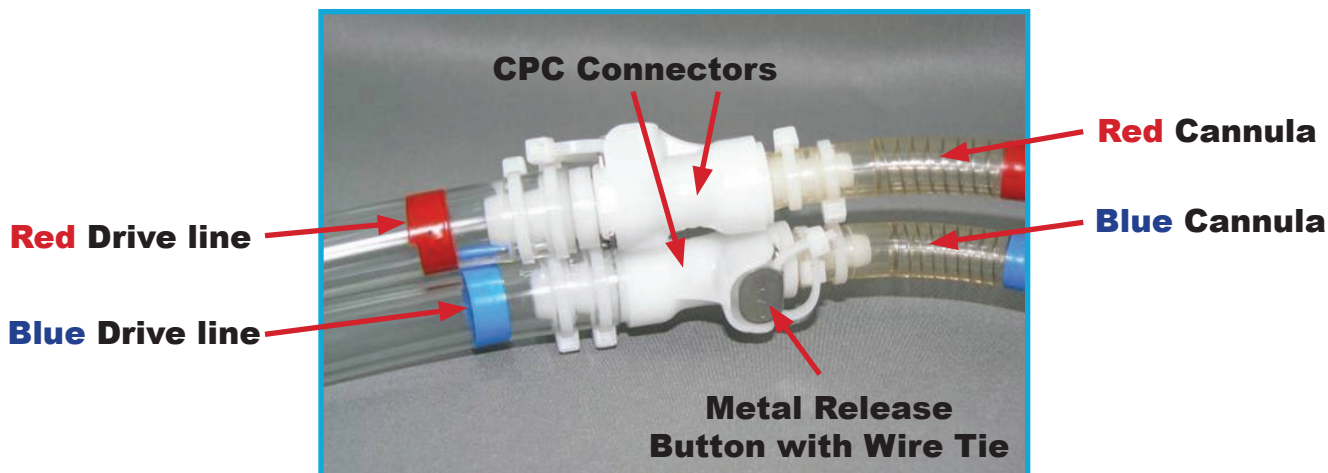
FIGURE 3

**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. 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.

JANUARY 2013

DuraHeart™ System®

1. Can I do external CPR?

- Only if necessary; treat per physician discretion.
- Closed chest CPR is contraindicated
- May be performed as needed at the discretion of the attending physician
- External chest compressions may cause the dislocation/damage of pump Inflow/Outflow conduits
- External defibrillation any be performed on a patient with the DuraHeart™ System® without disconnecting any of the system components

2. If not, is there a “hand pump” or external device to use?

No.

3. If the device slows down (low flow state), what alarms will go off?

An emergency alarm will sound and the emergency alarm indicator (RED LIGHT) will light up.

4. How can I speed up the rate of the device?

The rate of the device can only be modified in a hospital setting. For low flow rates, check for hypovolemia or RHF and treat accordingly.

5. Do I need to heparinize the patient if it slows down?

Call the accepting VAD facility for guidance.

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

Yes.

7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?

No, defibrillate per protocol.

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

If the patient's own heart has some residual function, you may be able to feel a pulse.

9. What are acceptable vital sign parameters?

Mean Arterial Pressure (MAP) 80-90 mm Hg.

10. Can this patient be externally paced?

Yes, as needed.

DuraHeart™ System®

The DuraHeart™ LVAS is the latest-generation rotary blood pump designed for long-term patient support. The system incorporates a centrifugal flow rotary pump with an active magnetically levitated impeller featuring three position sensors and magnetic coils that optimize blood flow. The impeller's magnetic levitation is designed to eliminate friction by allowing a wide gap between blood contacting surface areas, enabling blood to flow through the pump unimpeded in a smooth non-turbulent fashion.

The DuraHeart™ System consists of an implantable Pump and several components that support the function of the Pump. The system is made up of seven main components (see photo below) which include:



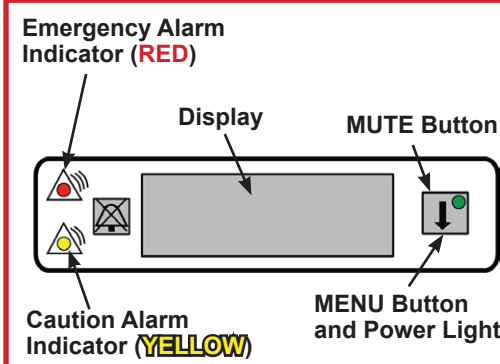
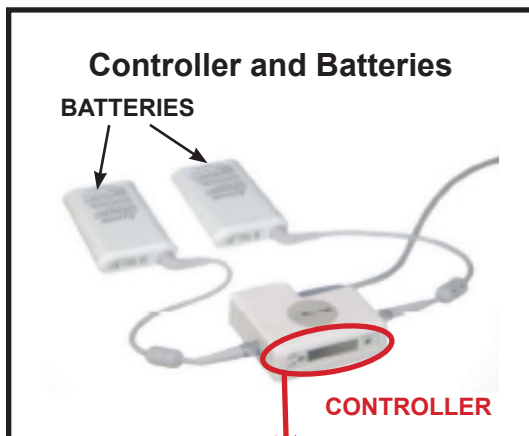
External Batteries

Li-ion batteries provide power tot the pum for untethered operation for up to 3-1/2 hours per battery. Each battery can be recharged up to 200 times.

"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010

DuraHeart™ System®

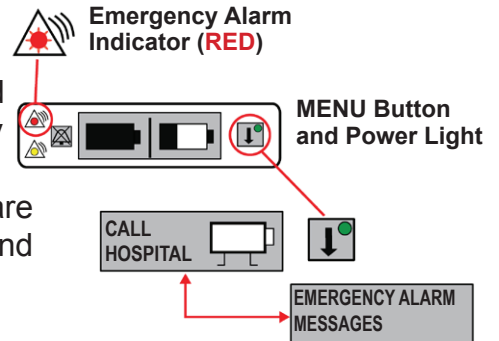
CONTROLLER



- Communicates with console for system set up, monitoring and troubleshooting
- Controls and monitors pump function, stores system data
- Interfaces with external power sources (Console, Batteries, Charger, Emergency Backup Battery)
- Displays system status – Pump Flow Rate
– Pump Rate
– Motor Current
– System alarms and Alerts
– Power Supply Status

Emergency Alarms

- High Priority.
- Flashing **RED** light and continuous Emergency Alarm tone.
- Requires immediate care by medical specialist and controller exchange.



EMERGENCY ALARMS

ALARM MESSAGE	PROBLEM
Replace Controller	The Pump may not be rotating
Connect Pump cable/Pump disconnected	The Pump cable is disconnected
Controller Error	Possible serious problem with the controller
Pump Failure	Pump motor may have serious problem
Mag-Failure	The impeller may not be levitated

SILENCING ALARMS

Emergency Alarms

- Mute button silences audible alarm for 2 minutes
- Audible alarm returns after 2 minutes

Caution Alerts

- Mute button silences audible alarm for 5

ANTICOAGULATION

Patients will be on Coumadin with this device Target INR range should be between 2.0 to 3.0
Combination antiplatelet therapy of ASA 81mg daily and Persantine 25-75 mg TID