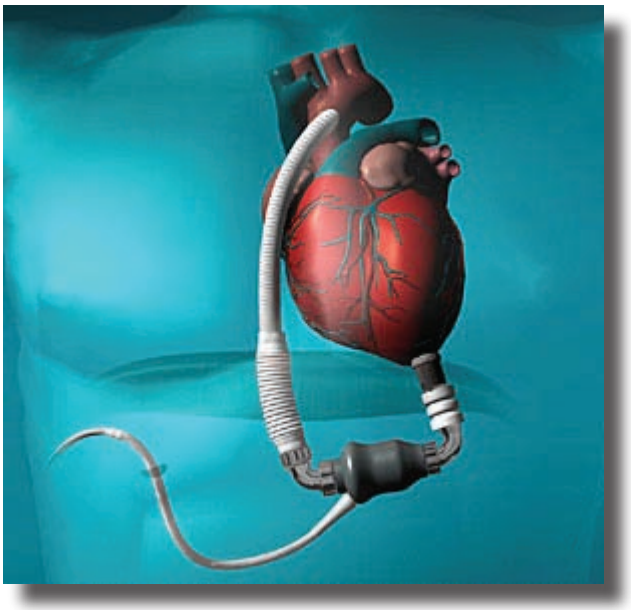
EMS Guide
January 2014

MECHANICAL
CIRCULATORY
SUPPORT
ORGANIZATION

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.

Reprinted with the permission of Thoratec Corporation

Questions and Answers
Ventricular Assist Device



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?

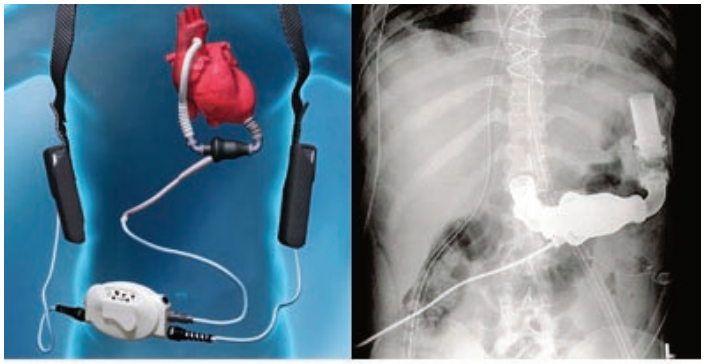
The basic parts of a VAD include: a small tube that carries blood out of your heart into a pump; another tube that carries blood from the pump to your blood vessels, which deliver the blood to your body; and a power source.

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.

Patient Management For VADs

1. Assess the patients airway and intervene per your usual 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 found around the waist of the patient or in the VAD PAK 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 patient’s equipment.

12. Allow the trained caregiver to ride in the transport vehicle if possible to act as a expert on the device in he 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 (continuos 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®

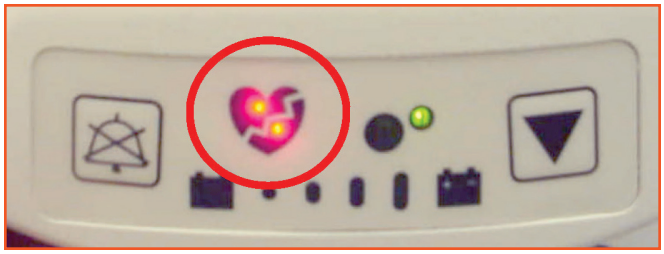
When the Pump Has Stopped

- 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.



JANUARY 2014

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.

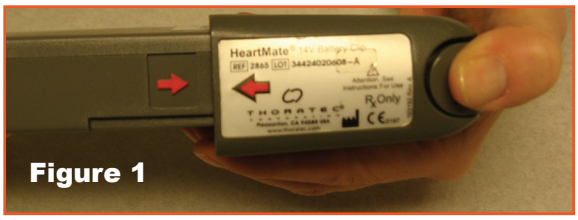


Figure 1

Figure 2

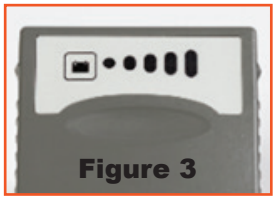


Figure 3

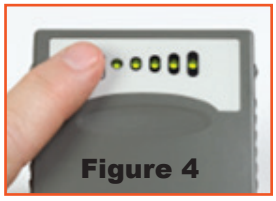


Figure 4

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.**

- 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.

- 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.

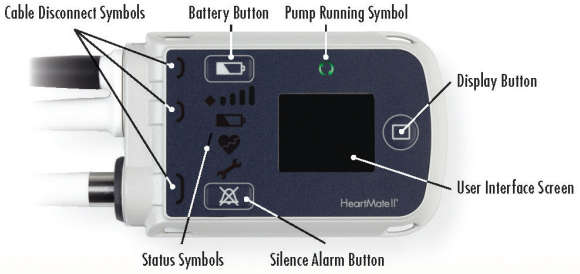
- After the pump restarts, rotate the perc lock on the new controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position. If unable to engage perc lock to the locked position, gently push the driveline into the controller to assure a proper connection. Retry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

JANUARY 2014

ORANGE ORANGE ORANGE ORANGE

HeartMate II® Controller Comparison Guide

POCKET CONTROLLER™



3 Modes: Run, Charge, Sleep
Run: Driveline + Power source connected.
Charge: Only power source connected.
Sleep: No driveline or power source connected; ready to use.

Backup Battery
An emergency backup battery is built into Pocket Controller, powering the pump for 15 minutes in the absence of an external power source. The backup battery is supplied NONSTERILE.

Event Logger
Pocket Controller includes date/time records in event history. Pocket Controller can store 240 events.

Green Pump Running Symbol
Green "pump running" symbol signifies that the pump is on and running.

Controller Buttons
Display Button: Enables viewing of pump parameters and backup battery charge status.
Silence Alarm Button: Silences hazard alarms for 2 minutes and advisory alarms for 4 hours.
Display Button + Silence Alarm Button Together: Displays previous six alarms.
Battery Button: Displays the battery power gauge when pressed. Activates a self test when held for 5 seconds then released. Enters sleep mode when driveline and external power are disconnected and button is held for 5 seconds then released.

Self Test
Press and hold the Battery Button for 5 seconds.

Low Power
Yellow Diamond Symbol: Displayed when only 15 minutes of external power is remaining.
Red Battery Symbol: Displayed when only 5 minutes of external power is remaining.
Backup Battery Mode: Entered after external power is depleted. Provides 15 minutes of internal emergency backup battery power.
Power Saver Mode: Entered when pump has run on backup battery for 15 minutes. Pump Speed is reduced to the set Low Speed Limit.

Starting the Pump
>8000 RPM: Pump starts automatically.
<8000 RPM with Backup Battery: Start pump by pressing any button on Pocket Controller.
<8000 RPM with no Backup Battery: Pump can only be started via System Monitor.

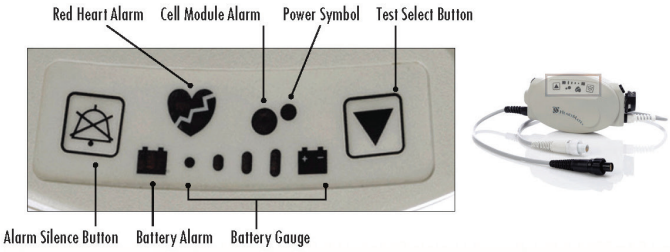
System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	PI Event
System Information:	10/04/13 01:30	4.8	6900	5.7	6.6	* System Information

Compatibility
System Monitors I and II, Power Module, Power Module Patient Cable (14 Volt), 14 Volt Lithium-Ion Batteries and Battery Clips.

Alarms
For a review of alarms and their meanings, reference HeartMate II Alarms for Clinicians, item 107526. Pocket Controller includes a yellow wrench icon to denote advisory alarms. Note that Pocket Controller includes drivelines fault detection.

EXTERNAL PERIPHERAL CONTROLLER (EPC)



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

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

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

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

Controller Buttons
Alarm Silence Button: Displays the battery fuel gauge. Also silences hazard alarms for 2 minutes and advisory alarms for 4 hours.
Test Select Button: Activates a self test when held for 3 seconds.
Note: EPC does not include a display button or user interface screen. The Display Module is used to view pump parameters and alarm events.

Self Test
Press and hold the Test Select Button for 3 seconds.

Low Power
Yellow Battery Symbol: Displayed when only 15 minutes of external power is remaining.
Red Battery Symbol: Displayed when only 5 minutes of external power is remaining.
Power Saver Mode: Entered when the battery voltage falls to a critically low level. Pump Speed is reduced to 8000 RPM.

Starting the Pump
>8000 RPM: Pump starts automatically.
<8000 RPM: Start pump by pressing Alarm Silence Button or Test Select Button on EPC.

System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	
System Information:	10/04/13 01:30	4.8	6900	5.7	6.6	*

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

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

JANUARY 2014

ORANGE ORANGE ORANGE ORANGE

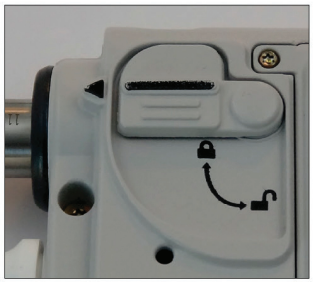
ORANGE ORANGE ORANGE ORANGE

HeartMate II Controller Comparison Guide

DRIVELINE CONNECTION

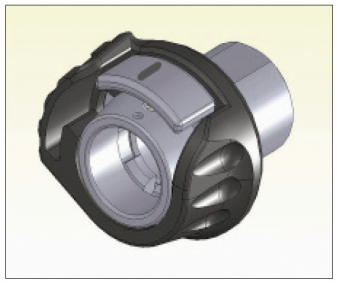
Pocket Controller:
A safety tab is located on the back of the controller.

Unlocked

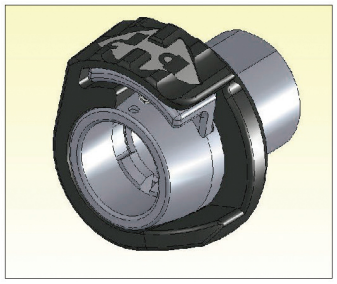


Locked

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

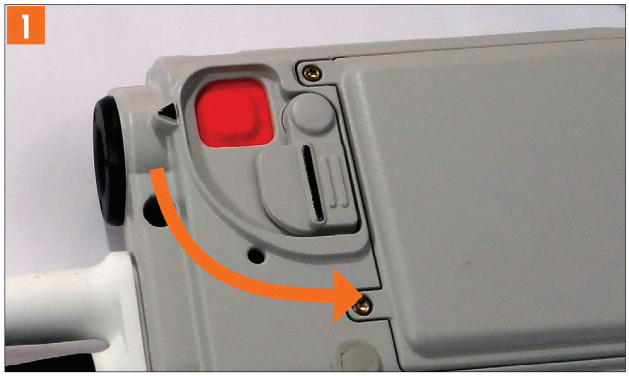


Unlocked

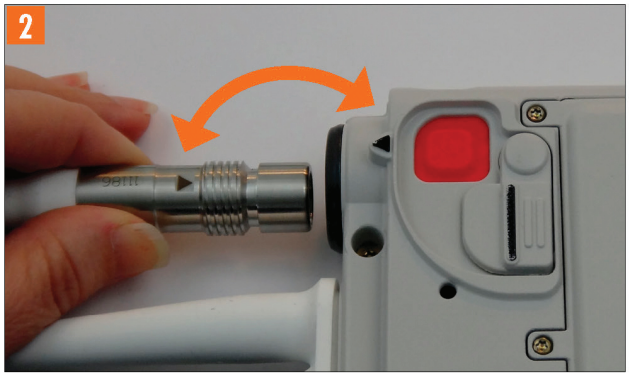


Locked

The Pocket Controller driveline connection and locking mechanism are different from the EPC. To insert and lock the driveline into Pocket Controller:

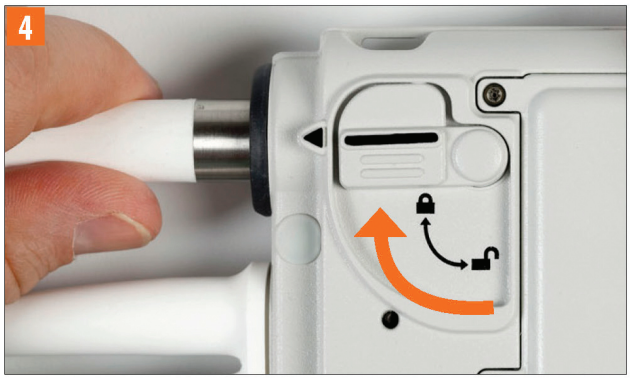


Slide the safety tab back to expose the red button.



Align the arrow on the driveline to the arrow on the Pocket Controller. Firmly insert the driveline until it snaps into place.

Tug gently on the metal portion of the driveline to ensure that it is fully engaged.



Slide the safety tab over the red button. Ensure the safety tab completely covers the red button.

Thoratec, HeartMate II, Pocket Controller, and the Thoratec logo are registered trademarks of Thoratec Corporation.
©2013 Thoratec Corporation. All rights reserved. 109816.A

THORATEC® CORPORATION for Life

JANUARY 2014

ORANGE ORANGE ORANGE ORANGE

ORANGE ORANGE ORANGE ORANGE

HeartMate II® with Pocket Controllers

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 (continuos 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® with Pocket Controllers

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.

JANUARY 2014

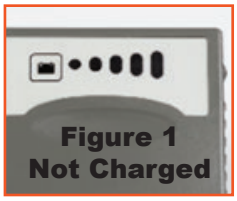
ORANGE ORANGE ORANGE ORANGE

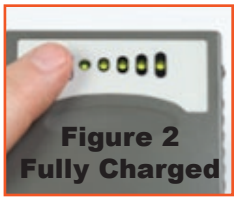
Trouble Shooting HeartMate II® with Pocket Controllers

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 1 and 2)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 3)
- Controller will start beeping, flash yellow signals and will read **power disconnect** on the front screen.
- Replace with new battery by lining up **RED** arrows on battery and clip. (Figure 4)
- Slide a new, fully-charged battery (Figure 2) 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 yellow flashing will stop.
- Repeat previous steps with the second battery and battery clip.





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.

- On the back of the replacement controller, rotate down the perc lock so the red tab is fully visible. Repeat this step on the original controller until the red tab is fully visible.
- Disconnect the drive line from the original controller by pressing down on the red tab and gently pulling on the metal end. The pump will stop and an alarm will sound. **Note:** The alarm will continue until the original controller is put to sleep. You can silence the alarm by holding down the silence button. **Getting the replacement controller connected and pump restarted is the first priority.**
- Connect the replacement Controller by aligning the BLACK ARROWS 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.

- After the pump restarts, rotate up the perc lock on the new controller so the red tab is fully covered. If unable to engage perc lock to a fully locked position, gently push the driveline into the controller to assure proper connection. Retry to engage perc lock.
- Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.
- Hold down battery symbol for 5 full seconds for complete shutdown of old controller.

JANUARY 2014

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

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?**

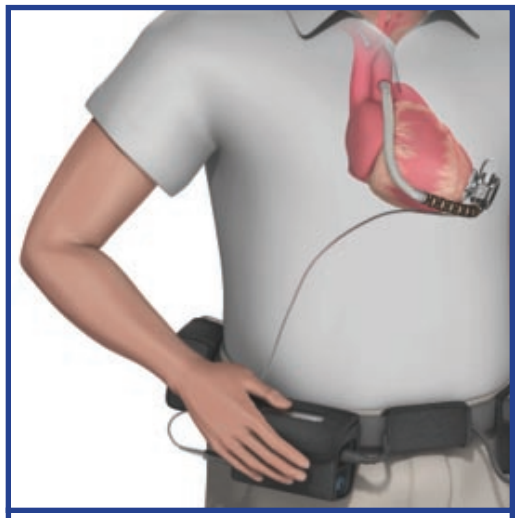
   The patient may not have a palpable pulse. Depending on the patient's own heart function, you may be able to feel a thready pulse.

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

   Goal Mean Arterial Pressure (MAP) is <85 mmHg. Use a Doppler as the first option to assess blood pressure. If you are using a Doppler, place the blood pressure cuff on the patient arm. As you release the pressure in the blood pressure cuff, the first sound you hear with the Doppler is the MAP. If that is not available, use a non-invasive BP (NIBP).

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, but patient may or may not be symptomatic even iwth ventricular arrhythmias.
- 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 patient should have back-up equipment.
- 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.

January 2014

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

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 .

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.

JANUARY 2014

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

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.

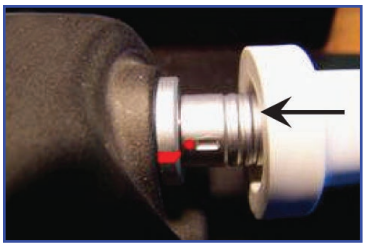
- Disconnect both power sources from the original controller.
- The controller will be turned off and all alarms silenced.

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

JANUARY 2014

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

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

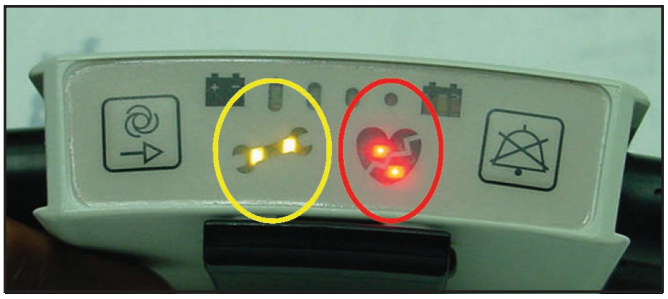
JANUARY 2014

DARK BLUE DARK BLUE DARK BLUE DARK BLUE

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 2014

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

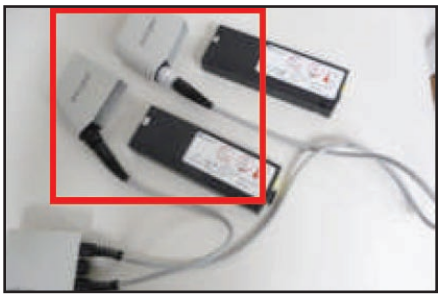


Figure 2B

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)

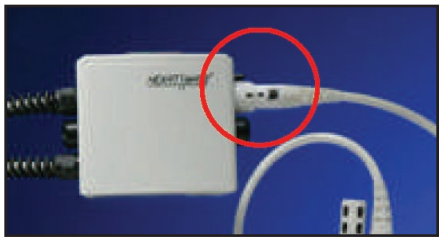


Figure 4A

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.

JANUARY 2014

Trouble Shooting HeartMate® XVE

Half Yellow Wrench
Once per second beep

- Controller inoperable
- Controller malfunction Rate control fault
- Current limit advisory

1. Check all XVE system controller connections.
2. Change vent filter, and check vent part for foreign matter.
3. Replace XVE system controller.
4. Replace the power base unit (PBU) cable.
5. Replace the PBU.
6. If the Yellow Wrench persists and the XVE LVAD remains operational, seek additional help.

Yellow Wrench
Once per second beep

- Power cable or battery is disconnected

Reconnect cable/battery or reinsert battery into battery clips

Flashing Yellow Battery
No audio tone

- XVE system controller battery module voltage low

1. Replace XVE system controller batter module.
2. Perform XVE system controller self-test to cleat alarm.

Yellow Battery
No audio tone

- Low voltage advisory **(less than 15 minutes of battery power remain)**

Change to alternate power source.

NOTE: If the XVE system controller is connected to the pecutaneous 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.

Red Heart
Continuous Audio Tone

- NO OP or LOW BEAT RATE (less than 35 BPM)
- LOW STROKE VOLUME* (less than 25ML)
- LOW FLOW* (less than 1.5 LPM)

1. Check all XVE system controller connections.
2. Change vent filter, and check vent part for foreign matter.
3. Replace XVE system controller.
4. Replace the power base unit (PBU) cable.
5. Replace the PBU.
6. If the Yellow Wrench persists and the XVE LVAD remains operational, seek additional help.

Red Battery
Continuous Audio Tone

- LOW VOLTAGE **(less than 15 minutes of battery power remain)**

1. XVE LVAD will automatically to Power Saver mode (50BPM)
2. Immediately replace batteries or connect to power base unit (PBU) cable.
3. If AC or battery power is unavailable, use emergency power pack (EPP).
4. If AC power battery power and EPP are unavailable, disconnect power and initiate emergency hand pumping.

Flashing Yellow Battery, Red Heart, & Yellow Wrench
Continuous Audio Tone

- XVE system controller disconnected from patient.

1. Check XVE system controller cable connection to XVE LVAD percutaneous tube.
2. Insure that both batteries are properly inserted into the battery clips; XVE system controller power cable are properly connected to the power base unit (PBU) Cable.
3. Ensure that PBU Cable is connected to back of PBU.
4. If condition persists, disconnect power and initiate hand pumping.
5. Seek additional help.

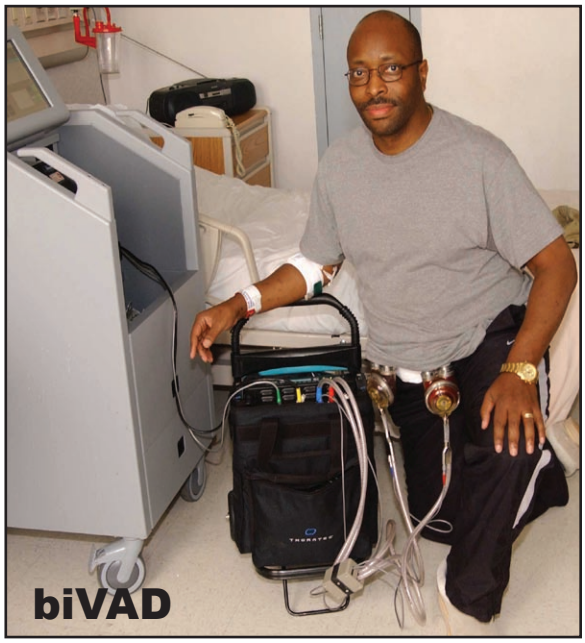
***NOTE: DO NOT HAND PUMP if there is blood in the vent port. Conditions that affect pump filling, such as hypertension, hypovolemia, or mechanical defects, may limit the restoration of normal pump flows until the conditions are resolved. Hand pumping may be ineffective under these conditions.**

JANUARY 2014

LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

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 anti coagulated 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.



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

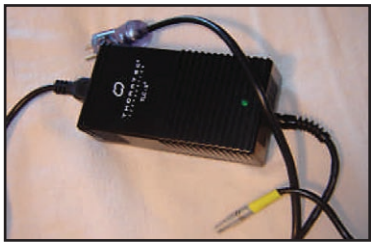
Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

- 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.

TCL-II Driver

Battery Charger

Batteries loaded into battery slots on TLC-II Driver



AC Power adapter – plug into yellow port on 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.

JANUARY 2014

LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

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 devise 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:

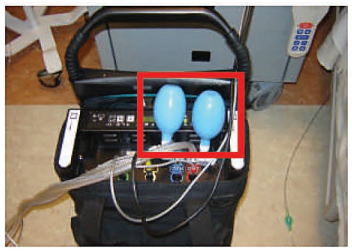
1. CPR: NO
2. Hand pump: yes called hand bulbs
3. low flow alarms: Loss of Fill alarm
4. speed up device: fluids
5. heparin: only if it stops. Patient has to be on Coumadin
6. defib: yes
7. disconnect for defib: no
8. pulse: yes
9. Vital signs: Normal BP parameters
10. externally pace: Usually in Bi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

JANUARY 2014

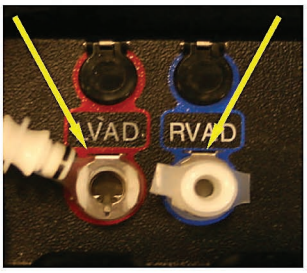
LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

Hand Pumping Instructions

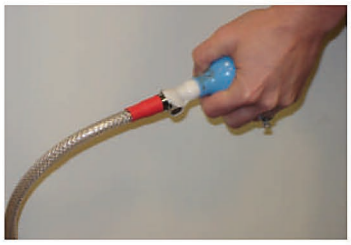


Step 1: Obtain hand pump(s) from carrying case. Note: One (1) hand pump is needed for each VAD.



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.

JANUARY 2014

LIGHT BLUE LIGHT BLUE LIGHT BLUE LIGHT BLUE

Questions and Answers for Total Artificial Heart

What Is A Total Artificial Heart?

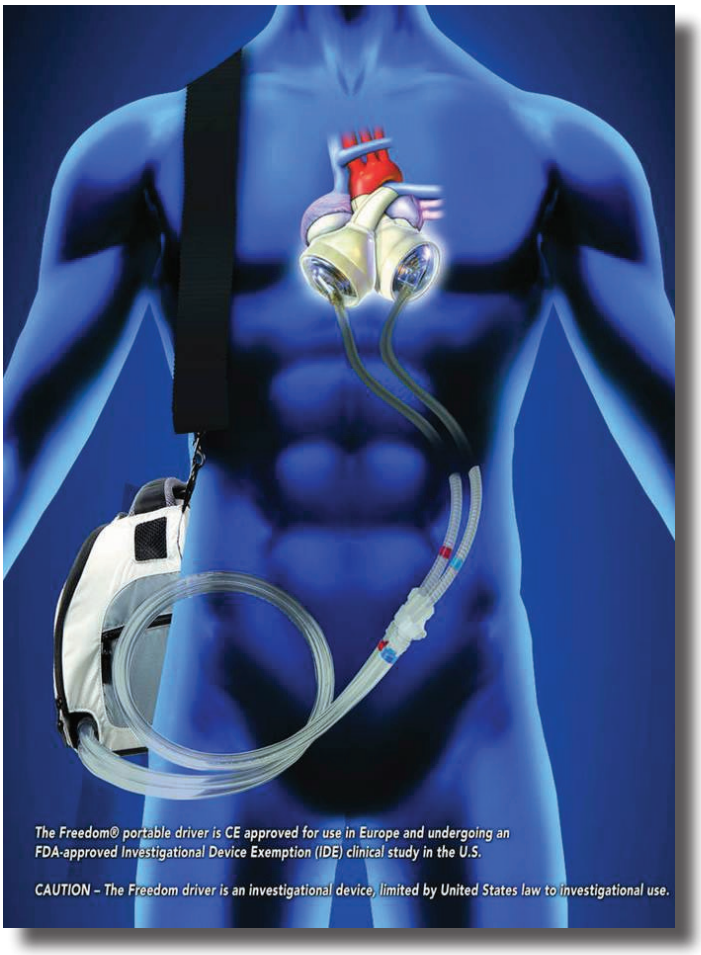
A total artificial heart (TAH) is a device that replaces the two lower chambers (ventricles) of the heart. You might benefit from a TAH if both of your ventricles don't work due to end-stage heart failure.

What are the parts of a TAH?

The SYNCARDIA has tubes that, through holes in the abdomen, run from inside the chest to an outside power source.

What is the power source?

Shortly after the TAD is implanted, the patient is switched to the Freedom driver. This is a mobile "driver" for patients to who are ambulatory. The patient considered discharge from the hospital while awaiting a transplant but ultimately received a heart transplant while still an inpatient. Higher rates of survival to transplant have already been proved with the TAH. Potential benefits for the portable Freedom driver include increased mobility, decreased cost, and improved quality of life.



The portability of the Total Artificial Heart (TAH) enables patients to resume many of their normal daily activities.

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 stetho scope. Since this is pulsatile you should hear two sounds if properly functioning.

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. The backpack or freedom driver should have a pink tag on it. It will have the type of device this is and contact information to the implantation center.

5. Match the color on the device tag to the EMS Guide. The tag on the backpack or freedom driver's colored tag should matches the ems guide. This will tell you how to manage any alarms.

6. Intervene appropriately based on the type of alarm, tag (device) and EMS Guide.

7. Start Large Bore IV.

8. Assess Vital Signs. REMEMBER THERE IS NO EKG. THE PATIENT IS ASYSTOLIC.

9. YOU SHOULD BE ABLE TO GET A SYSTOLIC AND DIASTOLIC BLOOD PRESSURE.

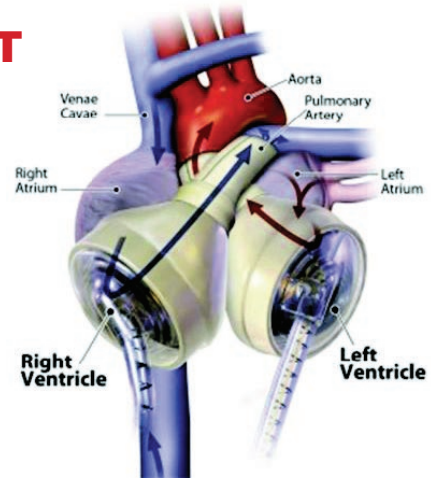
10. Transport to the closest center that can care for a TAH. Look on the PINK tag to find out this information.

11. Bring all of the patients equipment.

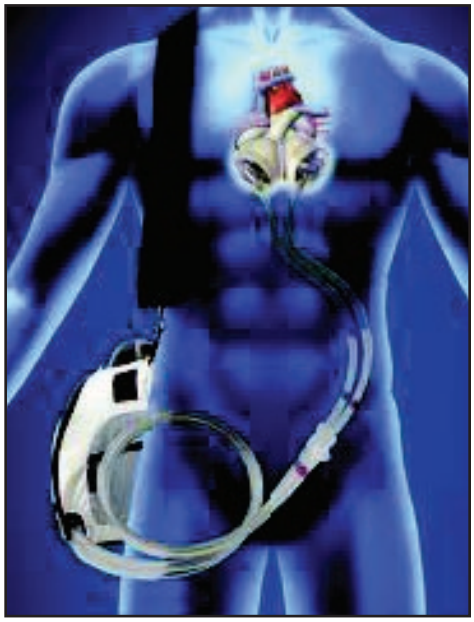
12. Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.

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 dobutimine?**
   Never give vasopressive drugs, especially epinephrine. These patients primarily have sysmptomatic 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 he 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.



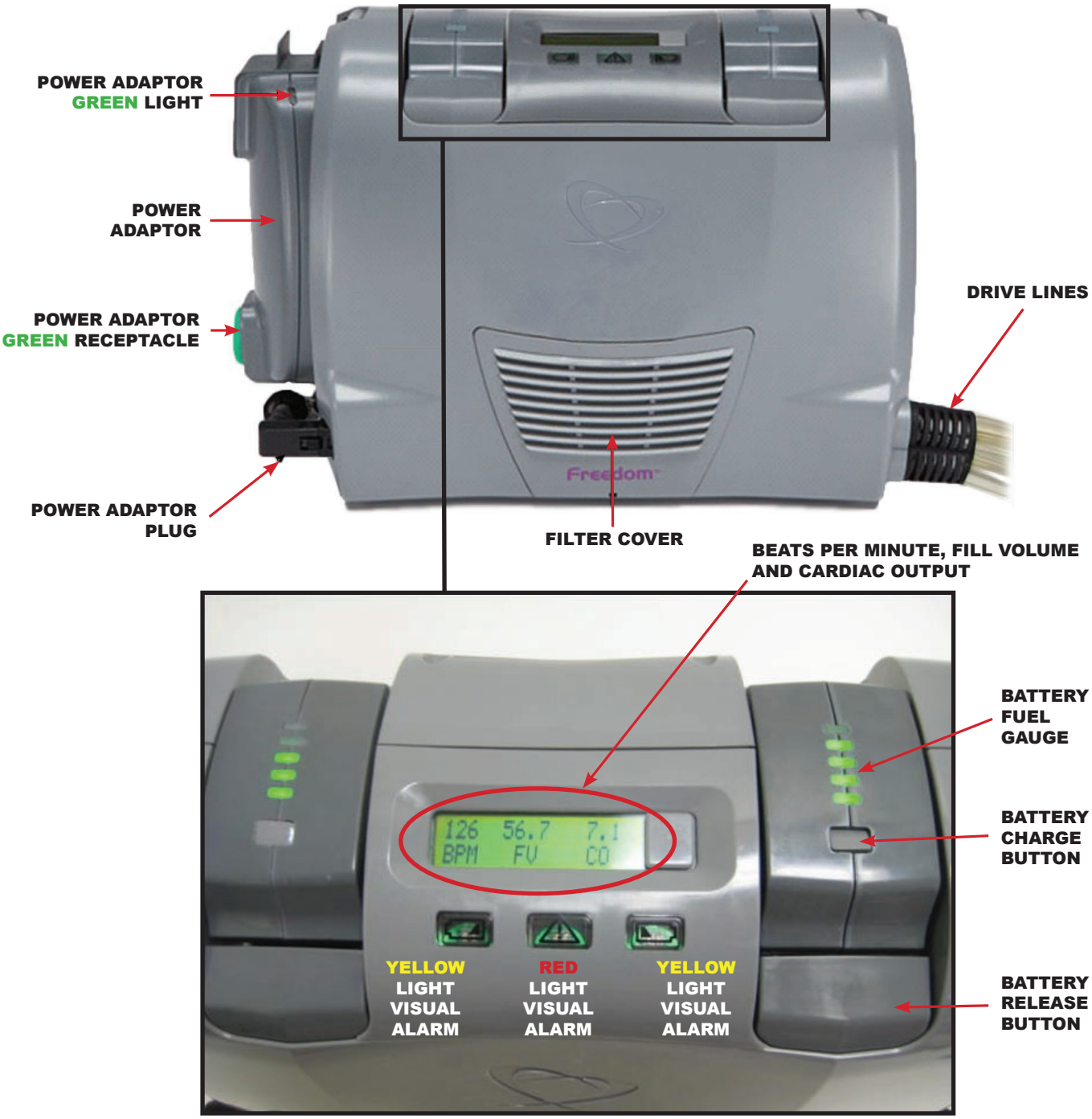
"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

JANUARY 2014

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 2014

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.

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

JANUARY 2014

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 connec to the patient.

FIGURE 1

FIGURE 2

BEATS PER MINUTE, FILL VOLUME AND CARDIAC OUTPUT

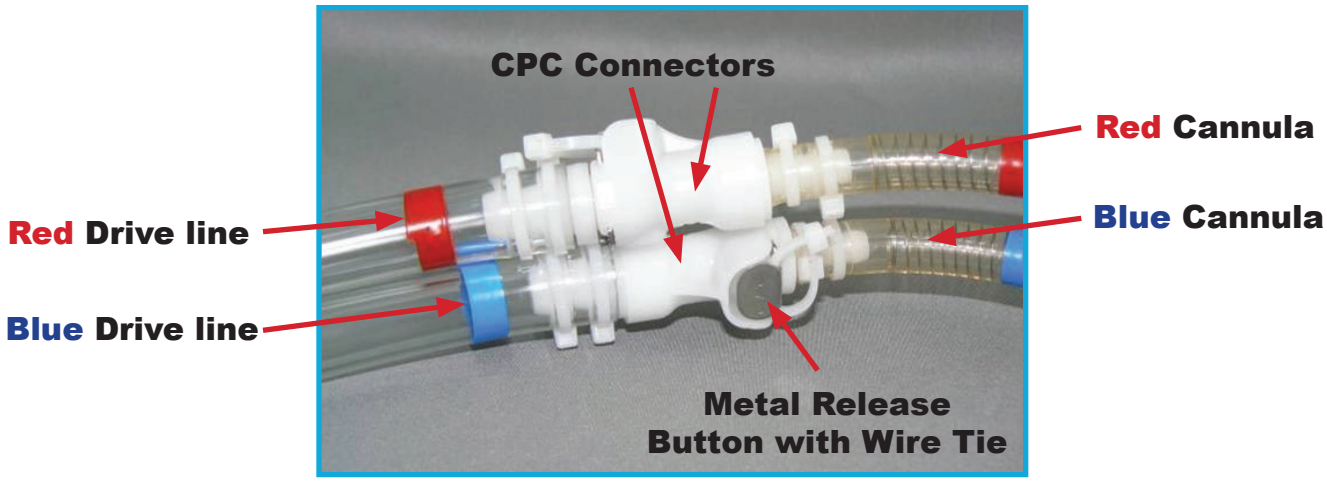
FIGURE 3

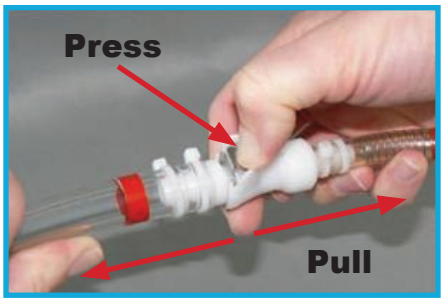
Continued on next page.

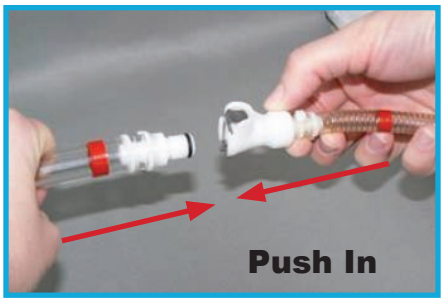
"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

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 2014

PURPLE PURPLE PURPLE PURPLE

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.

JANUARY 2014

PURPLE PURPLE PURPLE PURPLE

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.

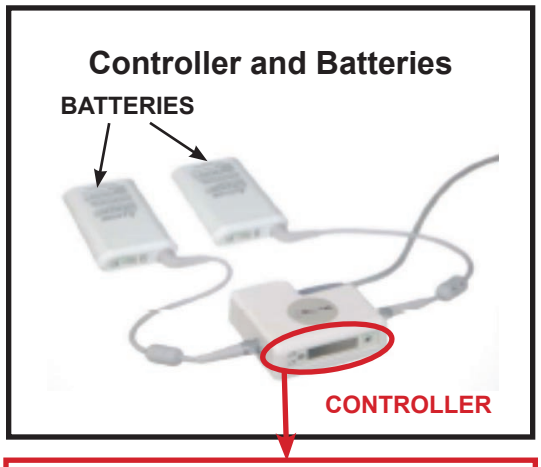
The DuraHeart™ System consists of an implantable Pump and several components that support the function of the Pump. The system is made up of seven main components (see photo below) which include:

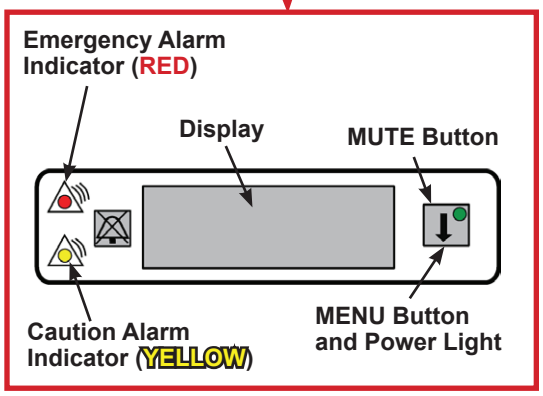
External Batteries
Li-ion batteries provide power tot the pum for untethered operation for up to 3-1/2 hours per battery. Each battery can be recharged up to 200 times.

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

DuraHeart™ System®

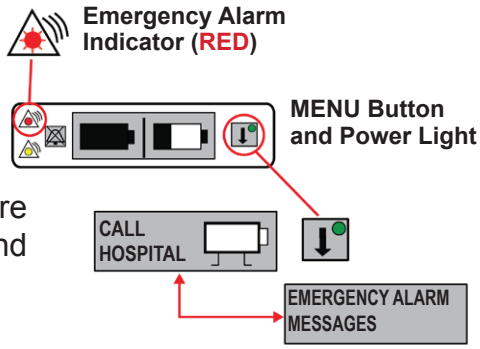
CONTROLLER





- 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 deviceTarget INR range should be between 2.0 to 3.0
Combination antiplatelet therapy of ASA 81mg daily and Persantine 25-75 mg TID

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

JANUARY 2014