

BACKGROUND:

Left ventricular assist devices (LVADs) are designed to assist the pumping function of the patient's left ventricle. The HeartWare HVAD®, HeartMate II®, and HeartMate III® devices attach to the apex of the left ventricle (pump inflow) and propel blood to the ascending aorta (pump outflow). These devices utilize an external wearable system that includes a small controller connected to the internal pump by an external driveline and is powered by two batteries. They may also be “plugged in” to 110 or 12 V power, depending on the device. When managing an LVAD patient, follow these general assessment guidelines.

ASSESSING PATIENT WITH LVAD:

- A. Establish airway and provide supplemental oxygen if any respiratory signs or symptoms are present.
- B. **If a patient with an LVAD is having a medical emergency, it does not necessarily mean that it is a device issue. Consider the whole clinical picture and perform a thorough patient assessment, including device function. Infection, volume depletion, stroke, bleeding, and dysrhythmias may be the cause of patient's symptoms. Most LVAD patients are anticoagulated and are at risk for bleeding complications.**
- C. Auscultate heart sounds to determine if the device is functioning. Both the HeartWare HVAD® and HeartMate II®, are continuous flow devices and you should hear a “whirring” sound”. Because these devices diminish pulsatile flow in the circulation, peripheral pulses may not be palpable. The HeartMate III®, although continuous flow, may provide artificial pulsatility (as well as a pulsatile hum) due to the addition of intermittent speed reduction which was designed into the device. Since this artificial pulse is not synchronized with the patient's heart rate, it may augment or diminish the native pulse. If a pulse is palpable, a BP can be attempted. Assess other signs of circulation—capillary refill, absence or presence of dizziness, temperature/ moisture of skin, end-tidal CO₂, and mental status to determine perfusion status.
- D. Standard blood pressure devices may not work. If unable to obtain a blood pressure consider using the following, if available, to estimate perfusion pressure:
 1. End-Tidal CO₂ - Expected values should be between 35 – 45 mmHg.
 2. Doppler cuff pressure - Estimates the mean arterial pressure. The goal range for Doppler MAP is > 60 and less than 90.
 3. Other clinical signs – Capillary refill, mental status.
- E. Locate the device to identify which type is in place and follow the device specific troubleshooting guidelines. Intervene appropriately based on the type of alarm and device.
- F. Start Large Bore IV and treat with fluids as needed.
- G. Pulse oximetry may not be accurate due to the continuous flow nature of the device. You may not get an accurate reading in the field.
- H. Your cardiac monitor **will** work, and a reliable EKG may be obtained. Because the LVAD creates continuous flow independent of left heart function, not all arrhythmias will be symptomatic, including ventricular arrhythmias. If a patient requires defibrillation, leave the pump running and all components in place. The LVAD does not interfere with electrical conduction. In general, LVAD patients also have an AICD/Pacemaker. Do not place defibrillation pads directly over the pump or AICD/Pacemaker (consider anterior/posterior placement).
- I. All ACLS medications may be administered if necessary.
- J. **If suspected cardiac arrest, proceed to following flow chart:**

Call Patient's VAD Center

- St. Vincent's: 971-678-4042
- Kaiser: 503-449-4672

Unresponsive LVAD patient

Is the patient breathing **AND**
can you hear a VAD hum?

NO

Initiate CPR and follow ACLS
protocols

YES

Doppler MAP > 50mmHg
OR ETCO₂ > 20mmHg?

NO

YES

2nd Responder available and/or trained family member assess LVAD function:

- Look/Listen for alarms
- Check driveline connection to LVAD controller
- Check power connection to LVAD controller

If any of the following true?

- Absent VAD hum
- "Pump Off" displayed
- Flow < 1 L/min
- Pulsatility < 1

Perform controller exchange

LVAD restarted AND

- Doppler MAP > 50mmHg
OR
- ETCO₂ > 20mmHg

YES

Follow standard protocols except
NO CHEST COMPRESSIONS
because the VAD is likely
providing adequate forward flow

NO

Continue CPR and follow ACLS
protocols

- Refer to the LVAD Protocol for detail instructions on the battery and controller.
- The 2 most common causes of pump failure are disconnection of the power and failure of the controller.
- Transport LVAD patient in circulatory arrest to the nearest hospital.
- Patients on LVAD support frequently do not have a palpable pulse or recognizable BP yet have adequate perfusion.
- In the non-invasive assessment of the BP, use a manual BP cuff with Doppler when available, with ETCO₂ as the second option.
- Assess and treat non-LVAD pathology:
 - 5 H's: Hypovolemia, hypoxia, hydrogen ion (acidosis), hypo/hyperkalemia, hypothermia
 - 5 T's: Toxins, tamponade, tension pneumothorax, thrombosis-heart, thrombosis-lung
- **Keep all back-up equipment with the patient during transport!**

Left Ventricular Assist Devices LVAD – 30.120

TRANSPORTING AN LVAD PATIENT:

- A. Transport the LVAD patient in circulatory arrest to the nearest hospital. **Call the number on the device and follow advice of the LVAD Coordinator on call for troubleshooting the device.**
- B. For all other concerns contact OLMC.
- C. The patient must be supported by battery power. **Remember to also transport the backup controller and the spare batteries.**
- D. The controller should be kept close to the patient, and care taken to not kink the leads.
- E. If removing or cutting patients clothing, use caution as not to sever the driveline.
- F. Do not put external pressure on any area of the LVAD system.
- G. Place gurney straps underneath the leads, and keep the batteries easily accessible.
- H. Allow the trained caregiver to ride in the transport vehicle if possible to act as an expert on the device in the absence of consciousness in the patient.
- I. Bring all of the patient's equipment.

NOTES AND PRECAUTIONS:

- A. LVAD patients who are anticoagulated have a higher risk of bleeding and hemorrhage.
- B. There are no valves on an LVAD, so there is the risk of retrograde flow and stagnation of blood if the device stops, or flow is impeded.
- C. These patients are pre-load and afterload dependent, so hypovolemia can have a profound effect.
- D. If a patient is **hypertensive**, flow through the device may be reduced.

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.

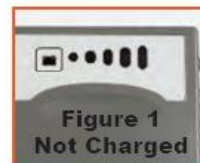


Changing Batteries

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:

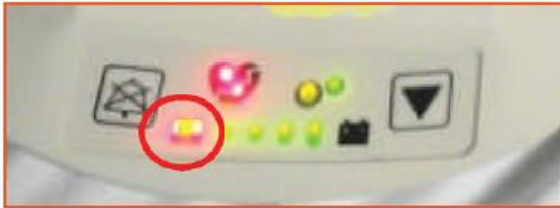


- Step 1.** Firmly press the Silence Alarm or Test Select Button to restart the pump.
- Step 2.** Check the powersource to assure that power is going to the controller.
- Step 3.** Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.
- After 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.

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.



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.



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.

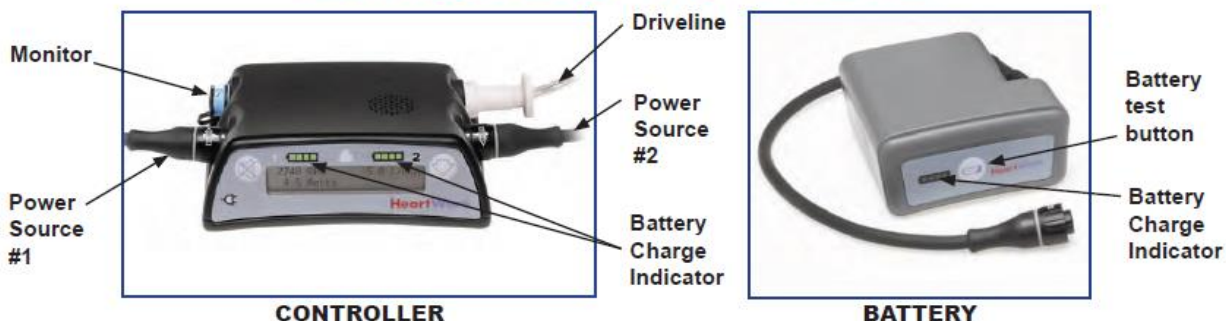
Step 2. Check the powersource to assure that power is going to the controller.

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.

HeartWare® Ventricular Assist System Emergency Operation



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

Trouble Shooting HeartMate III® 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)

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Trouble Shooting HeartMate III® 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 and flashing yellow signals and will read **POWER DISCONNECT** on the front screen. (Figure 4)
- Replace with new battery by lining up **RED** arrows on battery and clip. Gently tug on battery to ensure connection. If battery is properly secured, the beeping and yellow flashing will stop. (Figure 5)
- 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.

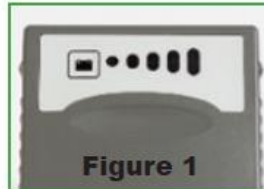


Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Trouble Shooting HeartMate III® with Pocket Controllers

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 pressing 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 power source 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.



Trouble Shooting HeartMate III[®] with Pocket Controllers Modular Cable

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

- When disconnecting a driveline, **NEVER** use the modular cable connection.
- If this section of the driveline requires replacement, this must be performed at and by the implanting center. Patients are not given a back-up modular cable.
- If the connection is loose, there will be a yellow/green line at the connection showing (Figure 2). If the line is visible, it can be retightened by turning with the arrow in the locked direction. It will ratchet and stop turning once tight.



Figure 1

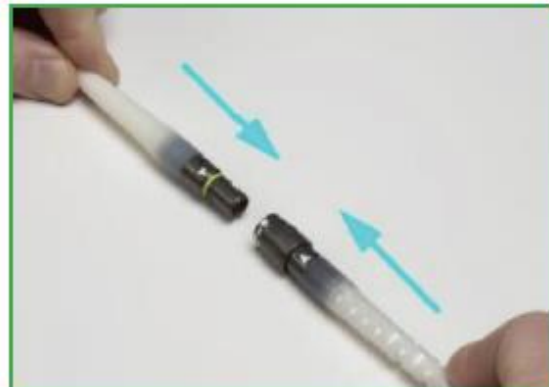


Figure 2

