

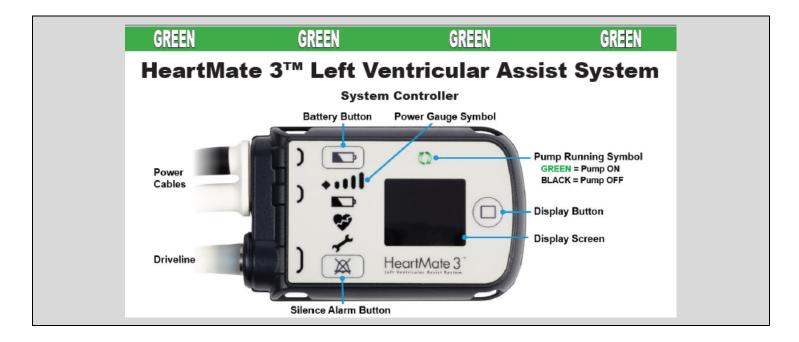
H02-LEFT VENTRICULAR ASSIST DEVICE

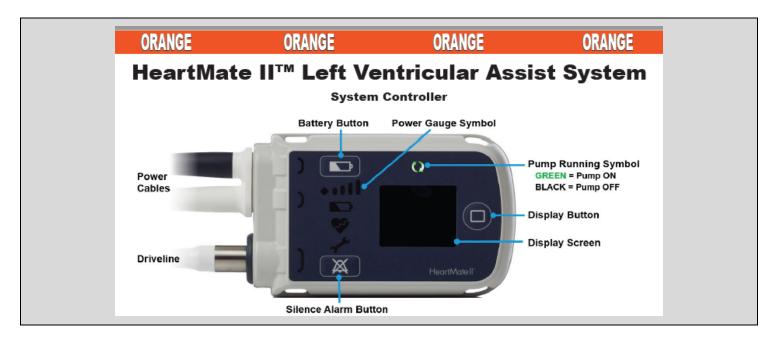
Version date: 2022-03-25 TRAINING REFERENCE

The SBH Cardiac Sciences Program currently uses the Abbot **Heartmate III (**green tag) ventricular assist device.

Paramedics may occasionally encounter a patient with an older **Heartmate II** (orange tag) unit.

2020/21 ICCAC Emergency Guide pages 1 - 14







2020-2021



International Consortium of Circulatory Assist Clinicians

This guide was created in 2008 by the innovation of VAD Coordinators from some of the largest and most successful VAD implantation hospitals in the United States. ICCAC has ensured that this document continues to be a current resource for not only emergency medical services but to all healthcare workers providing care to the mechanical circulatory support patient population. The purpose is to be a quick emergency quide and should not replace the manufacturers' Instructions For Use as the primary source of information for each device listed in this guide.

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

Questions and Answers MECHANICAL CIRCULATORY SUPPORT

Mechanical Circulatory Support Devices (MCS) are heart pumps that move blood from the heart to the body. They are temporary or permanent devices that either supplement or replace the action of a failing heart. MCS devices implanted are assisting the left ventricle (LVAD), the right ventricle (RVAD), or both ventricles (BiVAD) and the total heart (Total Artificial Heart – TAH). They consist of two major categories: Pulse generating (pulsatile) and pulseless devices (non-pulsatile/continuous flow). Patient management varies greatly between the two device categories.

Pulsatile or Non-pulsatile

Pulse generating devices have a chamber that fills with blood and ejects the blood similar to the rhythmic action of the human heart. These devices replace the majority of the heart and move the full amount of blood the patient needs. The Total Artificial Heart pump is a pulse generating device. Non-pulsatile or continuous flow devices use a motor at a fixed speed leading to a constant ejection of blood to the body. This is the reason patients with continuous flow VADs often lack a pulse upon palpation. The most common VADs are non-pulsatile/continuous flow devices.

What is a VAD?

A ventricular Assist Device (VAD) is an implantable mechanical heart pump that helps to pump blood from the lower chambers of the heart to the rest of the body in patients with advanced heart failure. The device helps move partial or full amount of blood meeting the patient needs. These devices can be attached to the Left (LVAD) or Right (RVAD) ventricles of the heart. Most patients have an LVAD and less common are RVADs and BiVADs (both left and right or Biventricular support).

What are the parts of a VAD?

All VADs have at least 4 components. (1) A heart pump unit consisting of a short tube placed inside the ventricle pulling blood thru the pump and out a tube, delivering blood to the body's great vessel; (2) A power cord called a driveline that exits the abdomen and connects to a controller and power source; (3) A controller that displays information; (4) A power source.

What does the controller do?

The controller is a computer that operates the heart pump. It provides messages and audible alarms to help monitor the pump. It gives information about pump performance such as blood flow through the pump (L/min), pump speed (RPM) and the amount of power consumed (Watts). It also gives warnings and alarms if there is an alert/problem with the pump or with the power source, such as low battery or low flow.

What is the power source?

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



HEARTMATE II Page 4



HEARTMATE 3 Page 9



HEARTWARE HVAD Page 13



JARVIK 2000 Page 18

What is a TAH?

A Total Artificial Heart (TAH) is a mechanical device that replaces the two lower ventricles of the heart. Tubes connect the TAH to a power source that is outside the body. The TAH then pumps blood through the heart's major artery to the lungs and the rest of the body. This is used for people who have inadequate function of both ventricles (biventricular failure).

What are the parts of TAH?

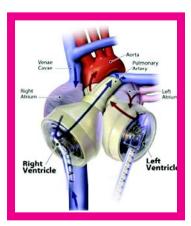
The TAH has 3 components. (1) A pump assembly consisting of 2 short tubes attached to the top of the heart and 2 chambers that fill and empty using air that pushes and pulls a membrane back and forth; (2) Air tubes that exit the body and attach to a console; (3) A power source.

What is the power source?

The TAH uses a mobile console called a Freedom Driver when patients are ambulatory. The console is powered by two batteries or AC (electricity) power. The batteries must be well charged before moving the patient and the AC plug should be brought when transporting.

The devices in this MCS Emergency Guide are color coded for quick identification. Patients may have a color matching tag or identifier on their equipment or equipment bag. Patients will also have their primary VAD team contact information for an important resource.





TOTAL ARTIFICIAL HEART (TAH) Page 25

Patient Management For VADs

- 1. Treat the patient and follow your protocols. Do not focus only on the device. Most patients do not have a primary pump malfunction. Common MCS patient problems that arise are stroke, bleeding disorders (GI, nose bleeds), arrhythmias, dehydration and right heart failure.
- 2. Assess the patients airway and intervene per your protocol.
- 3. Auscultate heart sounds to determine if the device is functioning. If it is continuous flow device, you should hear a "humming sound".
- 4. Assess vital signs. Non-pulsatile or continuous flow devices provide continuous blood flow from the heart to the aorta. This continuous flow results in a narrow arterial pulse pressure. This means it may be difficult to obtain a pulse or blood pressure reading which may be a normal state for a continuous flow device patients. To obtain a blood pressure an automated cuff or doppler method can be used. If unable to obtain with automated cuff use the mean BP with a doppler (first sound you hear MAP). Rely on other methods to assess perfusion e.g. mental status, skin color, capillary refill. The device flow shown on the controller display reflects the patient's cardiac output.
- 5. Start IV if indicated.
- 6. Assess the device for device information and alarms located on the controller display.
- 7. Intervene appropriately based on the type of alarm. See specific device alarm guides on the pages that follow.
- 8. Refer to the patient's medication list. They are typically, but not always, on anticoagulation and antiplatelet therapy.
- 9. Call the VAD Center's 24 hour emergency number on the patient's contact list, controller/equipment, or emergency bag for assistance in the management of the patient and transportation determination and location.
- 10. Bring all of the patients equipment.
- 11. Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.

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

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

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

3. Can this patient be externally paced? Yes.

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

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

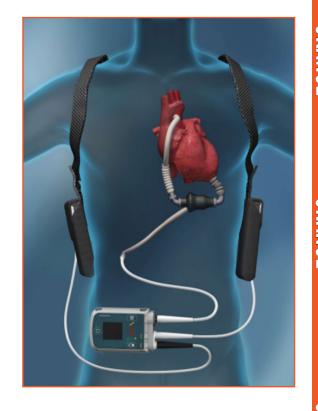
Can I change the speed of the device?No, it is a fixed speed.

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

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

7. What are acceptable vital sign parameters?

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



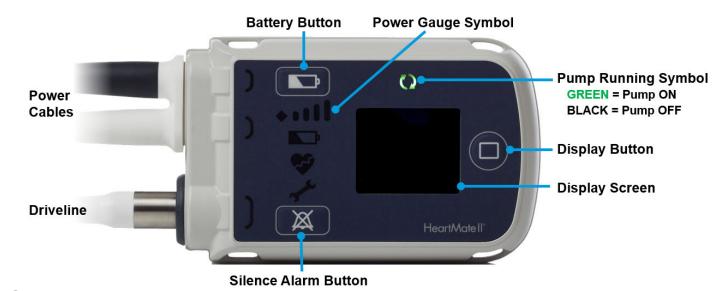
Frequently Asked Questions

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

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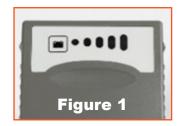
This guide does not supersede manufacturer instructions.



Changing Batteries

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

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









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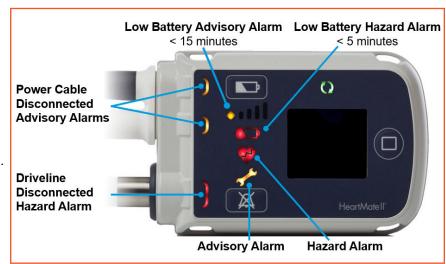
This guide does not supersede manufacturer instructions.

When an alarm occurs:

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

When the Pump Has Stopped

Check the driveline and power cable connections to the controller. Fix any loose connections to restart the pump.



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

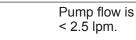
ARMS

Continuous Audible Tone









Ensure that a power source is connected to the controller. Evaluate the patient for low flow - treat the cause. Assess volume status, hypertension, arrhythmia, right heart failure, etc.







Driveline

Pump is off.

Immediately reconnect Driveline to the controller. Check modular cable connection.









Both power cables are disconnected.

Immediately connect to batteries or the Mobile Power Unit.

See above, when pump has stopped

Battery





Low Battery Power < 5 min. remaining.

Immediately replace batteries or switch to the Mobile Power Unit.

SOR LARMS

Intermittent Audible Tone







Low Battery Power <15 min. Power Unit. remaining.

Immediately replace batteries or switch to the Mobile





A power cable is disconnected.

Reconnect the power cable to power.

Check display for alarm type.



Call VAD Coordinator at implant center for direction.

This guide does not supersede manufacturer instructions.

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Troubleshooting HeartMate II™ LVAS

Changing the System Controller

- **Step 1:** Have the patient sit or lie down since the pump will momentarily stop during this procedure.
- **Step 2:** Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.
- **Step 3:** Attach the battery clips to the replacement controller by lining up half circles, firmly pushing together, and tightening connector nut. Insert the batteries into the clips by aligning the **RED** arrows.
- Step 4: On the back of the replacement controller, slide the safety lock so the red release button is fully visible. Repeat this step on the original controller.
- Step 5: Disconnect the drive-line from the original controller by pressing the red release button and pulling it out. The pump will stop and an alarm will sound. Note: The alarm will continue until the original controller is turned off. You can silence the alarm by pressing the silence alarm button.

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

- Step 6: Connect the replacement Controller by aligning the YELLOW ARROWS on the driveline and replacement Controller and firmly pushing the driveline into the replacement controller. The pump should restart, if not complete the following steps:
 - Firmly press the Silence Alarm or Battery Button to restart the pump.
 - Check the power source to ensure that power is going to the controller.
 - Ensure the driveline is fully inserted into the socket by gently tugging on the metal end.
 DO NOT pull the driveline.
- Step 7: After the pump restarts, slide the safety lock on the new controller so the red release button is fully covered. If unable to close the safety lock into fully locked position, gently push the driveline into the controller to ensure proper connection. Retry to close safety lock.
- **Step 8:** Disconnect power from the original Controller.
- **Step 9:** Hold down battery symbol for 5 full seconds to turn off the original controller.





Step 3





Step 4

Step 7



Step 5



Step 6



Step 9

This guide does not supersede manufacturer instructions.

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HeartMate II™ Left Ventricular Assist System

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



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

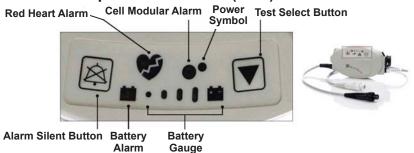
A battery clip can be attached to the EPC controller by lining up the half moons and gently pushing. Batteries can be attached



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to the battery clip by aligning the RED arrows on the battery and clip.

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 mead that the controller is receiving power. Listen over the pump pocket for confirmation that the pump is running.

CONTROLLER BUTTONS

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

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

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

SELF TEST

Press and hold the Test Select Button for 3 seconds.

LOW POWER

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

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

POWER SAVER MODE:

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

STARTING THE PUMP

>8000 RPM: Pump starts automatically.

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

SYSTEM MONITOR EVENT HISTORY SCREEN

PI Event:

System Information:

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.

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

External Peripheral Controller (EPC):

A percutaneous lock is located on the side of the controller.





Unlock

Locked

Alarms: **Emergency Procedures**

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



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



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HeartMate 3™ Left Ventricular Assist System

1. Can I do CPR?

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

Can the patient be defibrillated while connected to the device?

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

3. Can this patient be externally paced? Yes.

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

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

Can I change the speed of the device?No, it is a fixed speed.

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

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

7. What are acceptable vital sign parameters?

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

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

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





FAQs

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



Figure 1

This guide does not supersede manufacturer instructions.

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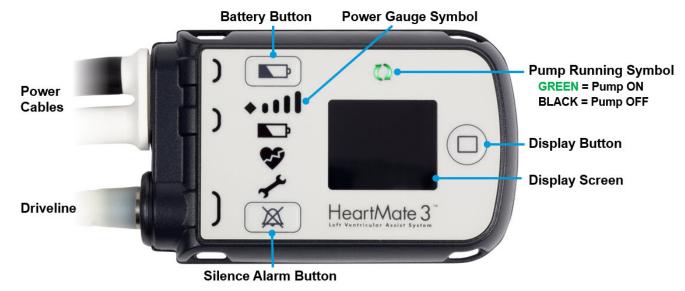
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HeartMate 3™ Left Ventricular Assist System

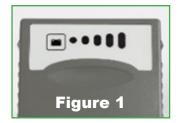
System Controller



Changing Batteries

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

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









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This guide does not supersede manufacturer instructions.

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Troubleshooting HeartMate 3™ LVAS

Alarms: Emergency Procedures

When an alarm occurs:

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

When the Pump Has Stopped

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

Low Battery Advisory Alarm Low Battery Hazard Alarm < 15 minutes < 5 minutes Power Cable Disconnected Advisory Alarms Driveline Disconnected HeartMate 3 Hazard Alarm Advisory Alarm Hazard Alarm

LARMS Continuous Audible Tone Pump is off. See above, when pump has stopped Call Hospital Low Flow Contact Pump flow is Ensure that a power source is connected to the < 2.5 lpm. controller. Evaluate the patient for low flow - treat the cause. Assess volume status, hypertension, arrhythmia, right heart failure, etc. Connect Driveline Immediately reconnect Driveline to the controller. **Driveline** Check modular cable connection. ⊕ :02 Backup Battery Connect Both power Immediately connect to batteries or the Mobile Power Immediately cables are Power Unit. disconnected. :01 ⊕ :05 Low Battery Low Replace Immediately replace batteries or switch to the Mobile Power < 5 min. Power **Battery** Power Unit. remaining. :06 SOR LARMS **Intermittent Audible Tone** Replace Low Battery Immediately replace batteries or switch to the Mobile Low Power Power <15 min. Power Unit. **Battery Immediately** remaining.

A power cable

is disconnected.

Check display for alarm type.

Connect

Power

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⊕ :02



Call VAD Coordinator at implant center for direction.

This guide does not supersede manufacturer instructions.

Reconnect the power cable to power.

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Troubleshooting HeartMate 3™ LVAS

Changing the System Controller

- **Step 1:** Have the patient sit or lie down since the pump will momentarily stop during this procedure.
- **Step 2:** Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.
- **Step 3:** Attach the battery clips to the replacement controller by lining up half circles, firmly pushing together, and tightening connector nut. Insert the batteries into the clips by aligning the **RED** arrows.
- **Step 4:** On the back of the replacement controller, slide the safety lock so the red release button is fully visible. Repeat this step on the original controller.
- Step 5: Disconnect the drive-line from the original controller by pressing the red release button and pulling it out. The pump will stop and an alarm will sound. Note: The alarm will continue until the original controller is turned off. You can silence the alarm by pressing the silence alarm button.

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

- Step 6: Connect the replacement Controller by aligning the WHITE ARROWS on the driveline and replacement Controller and firmly pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:
 - Firmly press the Silence Alarm or Battery Button to restart the pump.
 - Check the power source to ensure that power is going to the controller.
 - Ensure the driveline is fully inserted into the socket by gently tugging on the metal end.
 DO NOT pull the driveline.
- Step 7: After the pump restarts, slide the safety lock on the new controller so the red release button is fully covered. If unable to close the safety lock into fully locked position, gently push the driveline into the controller to ensure proper connection. Retry to close safety lock.
- **Step 8:** Disconnect power from the original Controller.
- **Step 9:** Hold down battery symbol for 5 full seconds for complete shutdown of old controller.





Step 3





Step 4

Step 7



Step 5



Step 6



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