LEFT VENTRICULAR ASSIST DEVICES IN THE COMMUNITY

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SHARP MEMORIAL HOSPITAL
Risk Factors for Mortality with HF

Guidelines for Referral of Advanced Heart Failure Therapy: >2 prompt consultation

- Class III/IV Heart Failure symptoms
- LVEF <35%
- Early End Stage Organ Dysfunction
- Rhythm instability
- Hemodynamic Instability
- Hospitalization for HF in the past 6 months
- Intolerance/withdrawal of neurohormonal blockade
- Non-responsive to CRT/Bi-V pacing
- Being considered for or currently on Inotropes
- Cardiac Cachexia
- Increasing Diuretic Dose

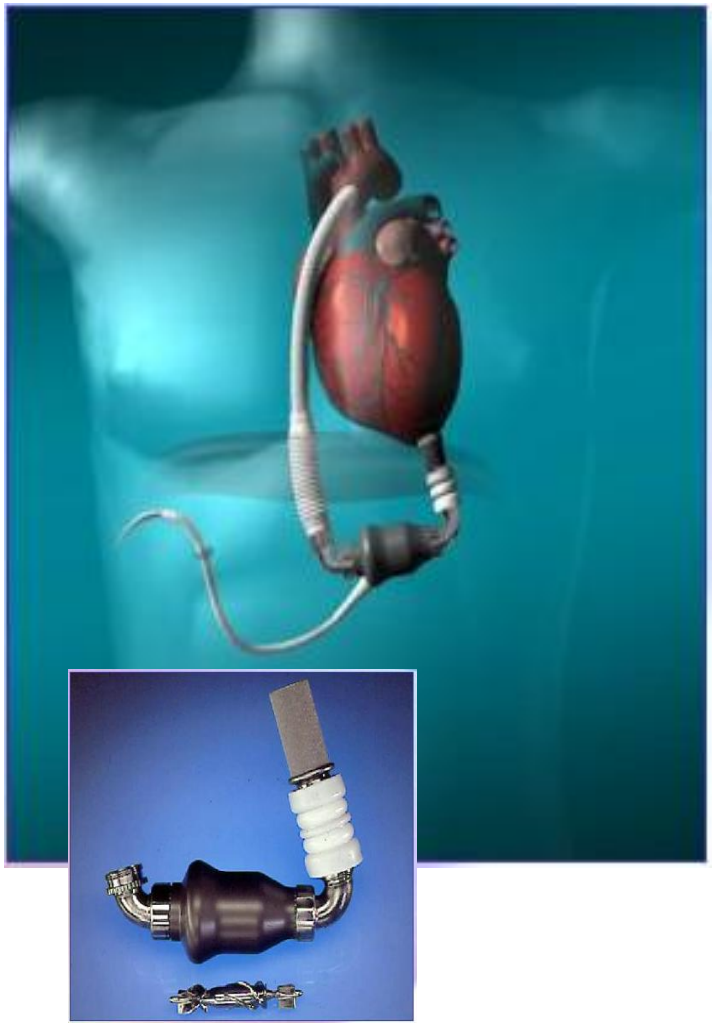
Medicare "**Destination Therapy**" Criteria

- Failed to respond to optimal medical management including beta blocker and ACE inhibitor for at least 45 of the last 60 days or IABP dependent for 7 days or IV inotrope dependent for 14 days
- EF <25%,
- MVO2 <14 (or on inotropic support),
- NY Heart Class 4

Other Option is "**Bridge to Transplant**"

- Actively listed for Heart Transplant

HeartMate II



- FDA Approved for BTT or DT
- Axial flow- they may not have a pulse and you may need a doppler to get BP (MAP)
- Manufacture suggests anticoagulation, some patients may be off all anticoagulation
- External controller and power source

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HeartMate III

- FDA Investigational use only
- Fully Magnetically Levitated Centrifugal flow
  - Large pump gaps designed to reduce blood trauma
  - Artificial pulse- but can not palpate a pulse
- Textured blood contacting surfaces- manufacturer does recommend anticoagulant
- Advanced Design for Surgical Ease
  - Engineered apical attachment
  - Modular Driveline

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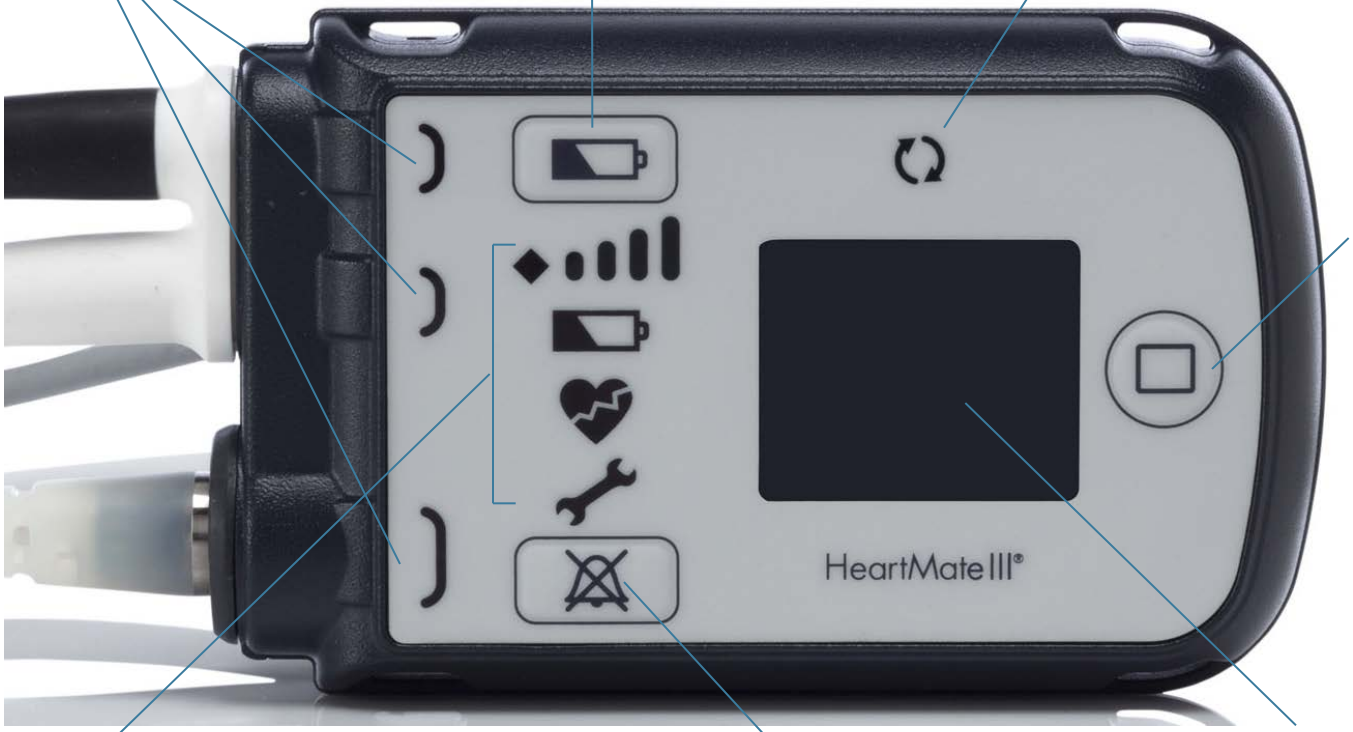
Pocket System Controller

- **Safety by Design**
  - Backup battery
  - Prioritized visual alarms with clear, actionable instructions
- **Designed for an active lifestyle**
  - Lightweight and compact with single-side cable design
  - Durable, shock-resistant outer case, cables, and electronics
  - Intuitive, discreet, and comfortable interface

HM III System Controller User Interface



Pocket System Controller Driveline Connector

- Driveline connector uses a double lock feature
  - Lowers risk of accidentally disconnecting the driveline
- Safety tab must be unlocked to connect or disconnect the driveline

Safety tab unlocked

Safety tab locked

Power Module or Mobile Power Unit

- Provides AC power to the LVAS during tethered operation (night)
- Will alarm when unplugged from wall power-press alarm silence button to quiet alarm during transport
- Bring to Hospital

Li-Ion Batteries and Charger

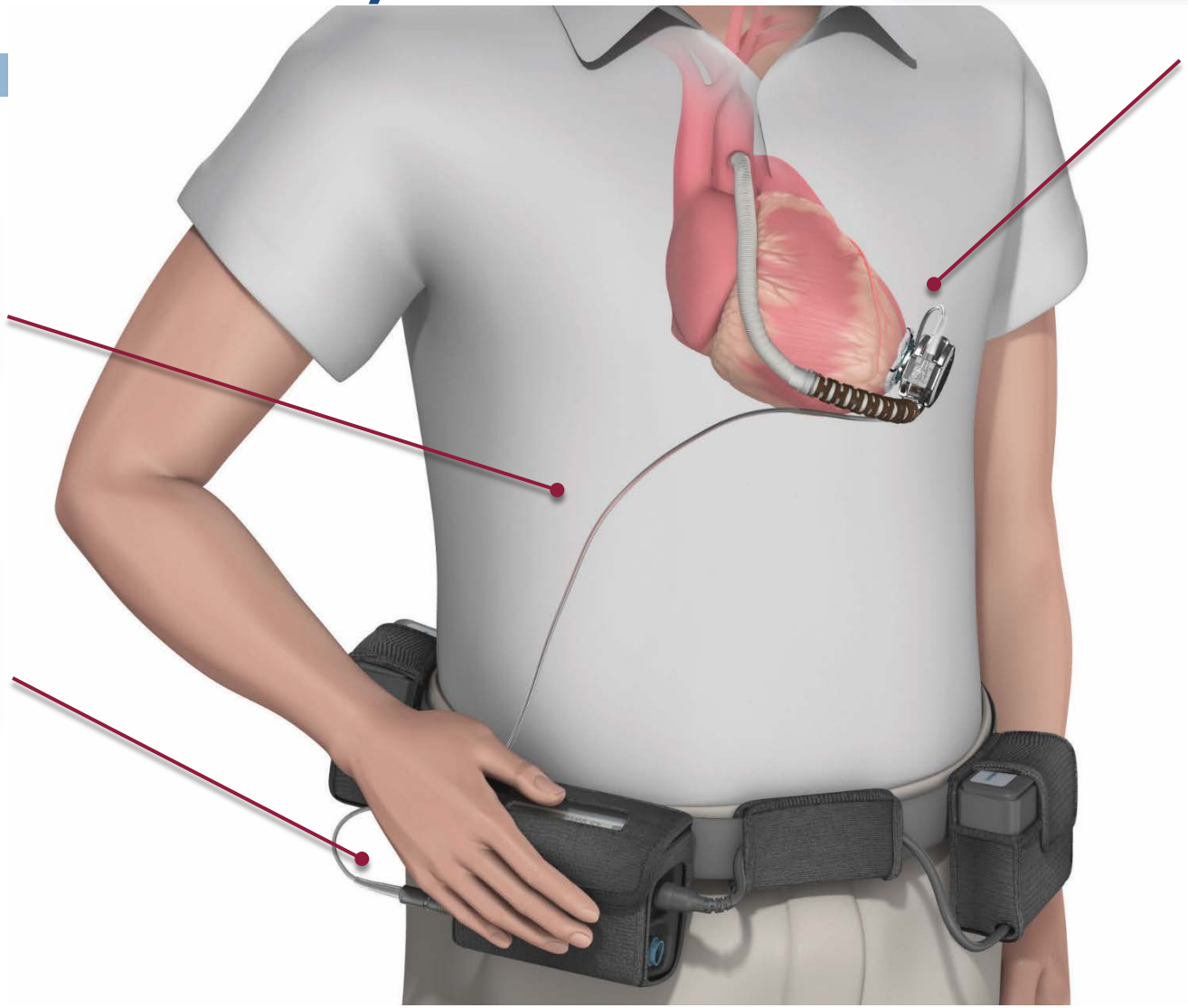
- Provide 10-12 hours of power
- Have charge indicator on each battery
- Charger will charge 4 batteries at a time
- Controller will alarm at 15 then 5 minutes of power remaining
- Bring to Hospital

HeartWare® System

Small pump attaches directly to heart

Thin, flexible driveline cable exits skin

A small controller & batteries run the pump



HeartWare Patient Peripheral Components

HeartWare® Controller: Controls and manages VAD operation

HeartWare® Power Sources: Power the controller and pump

- Batteries
- AC adapter (plugs into wall outlet)
- DC adapter (plugs into car outlet)

Patient Pack: Holds a controller & 2 batteries; may be worn around waist or over the shoulder

HeartWare® Battery Charger: Can simultaneously charge up to 4 batteries

Yellow Wrench Alarms

- System Controller Fault advisory alarm, can be silenced for 4 hours, pump will always be pumping with yellow wrench
- Action:
  - Transport to LVAD Hospital
  - Replace pocket system controller **ONLY at direction of VAD Coordinator**

NOTE: "Replace Controller, Controller Fault" is displayed. Call MCS Coordinator Immediately, do not change controller.

Red Heart Alarms

Check all connections then if possible determine if pump is pumping, by listening over chest for hum. In all cases, Red Heart Alarms must be transported to LVAD center.

- **Pump is pumping**

  "Low flow <2.5 LPM"
  - Hypovolemia
  - Arrhythmia
  - Right sided failure
  - Tamponade
  - Inflow obstruction

Treat Patient - may include electrical therapy or chest compressions

- **Pump is not pumping**
  - Notify MCS coordinator
  - Check POWER
  - Change System Controller under direction of MCS Coordinator

LVAD Treatment Algorithm
Transport **Immediately** to: Sharp Memorial Hospital
Call for MCS HELP!! 858-939-3863

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Pump pumping, Green Light On No alarms

LISTEN to Abdomen for "hum". Is pump pumping? YES /NO?

Red Heart Alarm YES-Pump Pumping

Red Heart Alarm NO-Pump Not Pumping

- **Airway,**
- **Breathing**
- **Check pulse - may not have one**
- **Check blood glucose**
- **Check controller screen for FLOW**
- **FLOW >2.5L/min with green light**
- **No compressions necessary**

- **Transport to SMH**

Please call if questions about INR or reversal

YES

Red Heart Alarm: URGENT!
CALL MCS Coordinator
Transport Immediately
Check controller screen

- **Airway, Breathing**
- **If "hum" heard: LOW FLOW <2.5L/min**
- **Check Neuro Status - Patient Responsive?**
- **Hypovolemia -give 500cc fluid bolus**
- **Hypoglycemia**
- **Check EKG Rhythm**
- **Patient will not have a pulse**
- **Check for signs of circulation**
- **Arrhythmia - Check for ICD, May shock VT / VF if patient unresponsive**
- **ACLS drugs may be given**
- **Consider CPR if patient remains unresponsive and absolutely needed**

NO

Red Heart Alarm: URGENT!
CALL MCS Coordinator
Transport Immediately
Check controller screen

- **Airway, Breathing, Circulation**
- **Check Driveline connected to Controller**
- **Change Power Source i.e. New Battery**
- **Check pulse - May not have one**
- **Change Controller under MCS Coordinator Guidance ONLY!**
- **Re-check for signs of circulation* (listen for pulse (flow), may not have one)**
- **If no signs of circulation: Perform CPR, ACLS drugs may be given.**

*****Bring All of Patient's Equipment to Hospital**

OK per Robert Adamson, MD
03/23/2017

Circulation 2017 Jun 13;135(24):e1115-1134

Cardiopulmonary Resuscitation in Adults and Children With Mechanical Circulatory Support: A Scientific Statement From the American Heart Association.

Peberdy MA, Gluck JA, Ornato JP, Bermudez CA, Griffin RE, Kasirajan V, Kerber RE, Lewis EF, Link MS, Miller C, Teuteberg JJ, Thiagarajan R, Weiss RM, O'Neil B; American Heart Association Emergency Cardiovascular Care Committee; Council on Cardiopulmonary, Critical Care, Perioperative, and Resuscitation; Council on Cardiovascular Diseases in the Young; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular and Stroke Nursing; and Council on Clinical Cardiology.

Abstract

Cardiac arrest in patients on mechanical support is a new phenomenon brought about by the increased use of this therapy in patients with end-stage heart failure. This American Heart Association scientific statement highlights the recognition and treatment of cardiovascular collapse or cardiopulmonary arrest in an adult or pediatric patient who has a ventricular assist device or total artificial heart. Specific, expert consensus recommendations are provided for the role of external chest compressions in such patients.

My LVAD.com

Color Coding System

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

- HEARTMATE III
- HEARTMATE II
- HEARTWARE
- JARVIK 2000
- HEARTMATE XVE
- THORATEC PVAD/IVAD
- FREEDOM DRIVER Total Artificial Heart

EMS Guide
January 2016/17

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.

GREEN GREEN GREEN GREEN

HeartMate III® 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 lpm. 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?**
   Likely they will not because it is a continuous flow device, however some patients may have a pulse as this pump was designed with an "artificial 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

- Pump has "artificial pulse" created by speeding up & slowing down of 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 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.
- A set of batteries last 14 – 16 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.

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)*

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.

SEPTEMBER 2016

GREEN GREEN GREEN GREEN

Common Transports

- **Trauma-** MVA, Scooter Mishap, Ladder falls, Slip and falls (broken hip)
- **Neurologic Dysfunction**- any change in LOC, check blood sugar first, transport to stroke center
- **Bleeding**- anticoagulation: ASA, Coumadin
- **Arrhythmias**- Check patient stability: drugs and/or electric therapy, as indicated
- **Equipment-** Operator Error (no backup batteries, have not had this since Li-Ion Batteries)

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Transports

- If Pump problem, patients must be taken to LVAD hospital with trained LVAD staff
- If Patient problem, may be taken to local ER only if needed to stabilize!
- Companion may go with Patient if available and can be helpful in managing equipment
- Equipment goes with patient: Batteries, Back-Up Controller, Power Module, Battery Charger,
- Depending on situation, may transport via ground or air

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This is why we do it……

Cardiac and Vascular Institute

SHARP Memorial Hospital

Quality of Life - Recreation!

HM II can withstand 6G’s of Force

Quality of Life- Returning to Work

- Depends on the Job- Underwater Arch welder not a great idea, most others ok
- Current disability laws provide patients with some protection