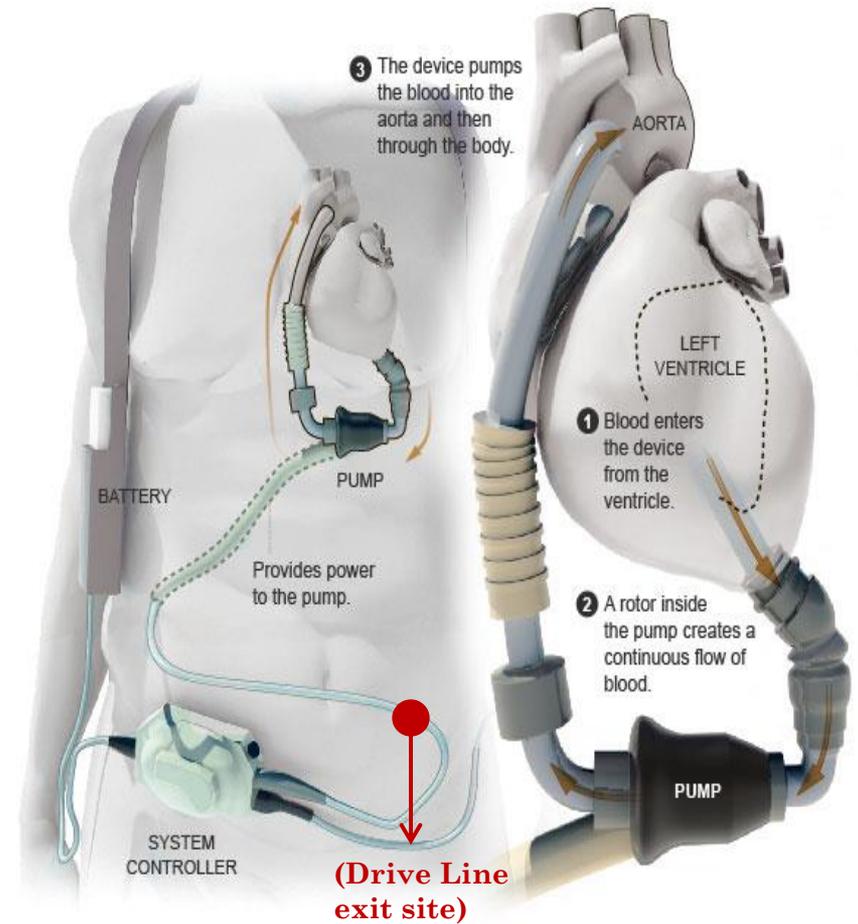


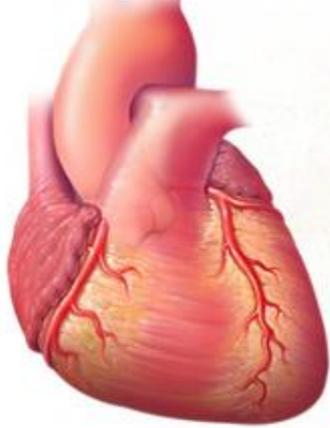
# LVAD ACADEMY

Advanced Heart Failure Center  
Piedmont Hospital, Atlanta GA

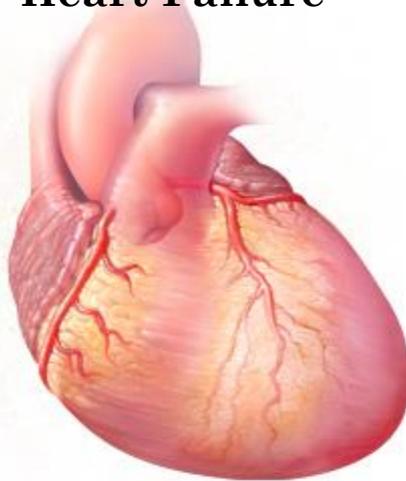


# HEART FAILURE

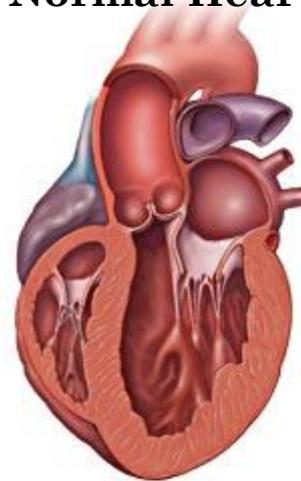
Normal Heart



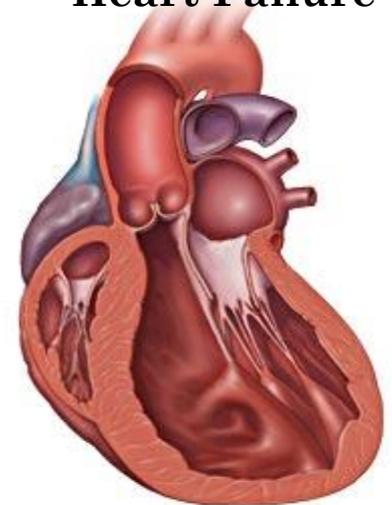
Heart Failure



Normal Heart



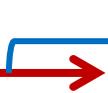
Heart Failure



## HEART FAILURE PROGRESSES OVER TIME

Possible treatment option: optimal medical management by a heart failure specialist, pacemaker &/or defibrillator

Mild  
(Class I)  
No symptoms



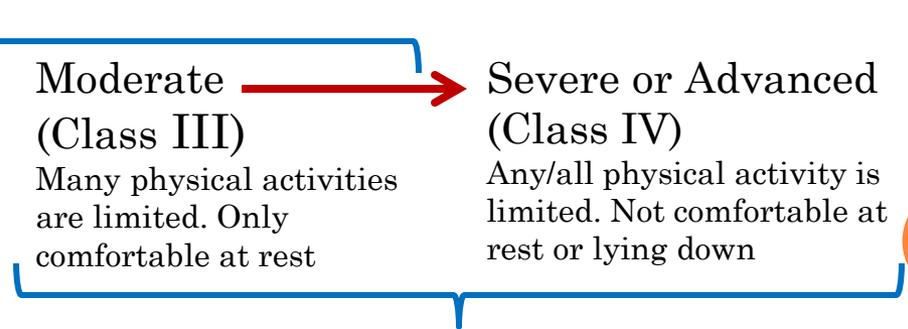
Mild  
(Class II)  
Slight symptoms that slightly limit physical activity. Comfortable at rest or with mild activity



Moderate  
(Class III)  
Many physical activities are limited. Only comfortable at rest



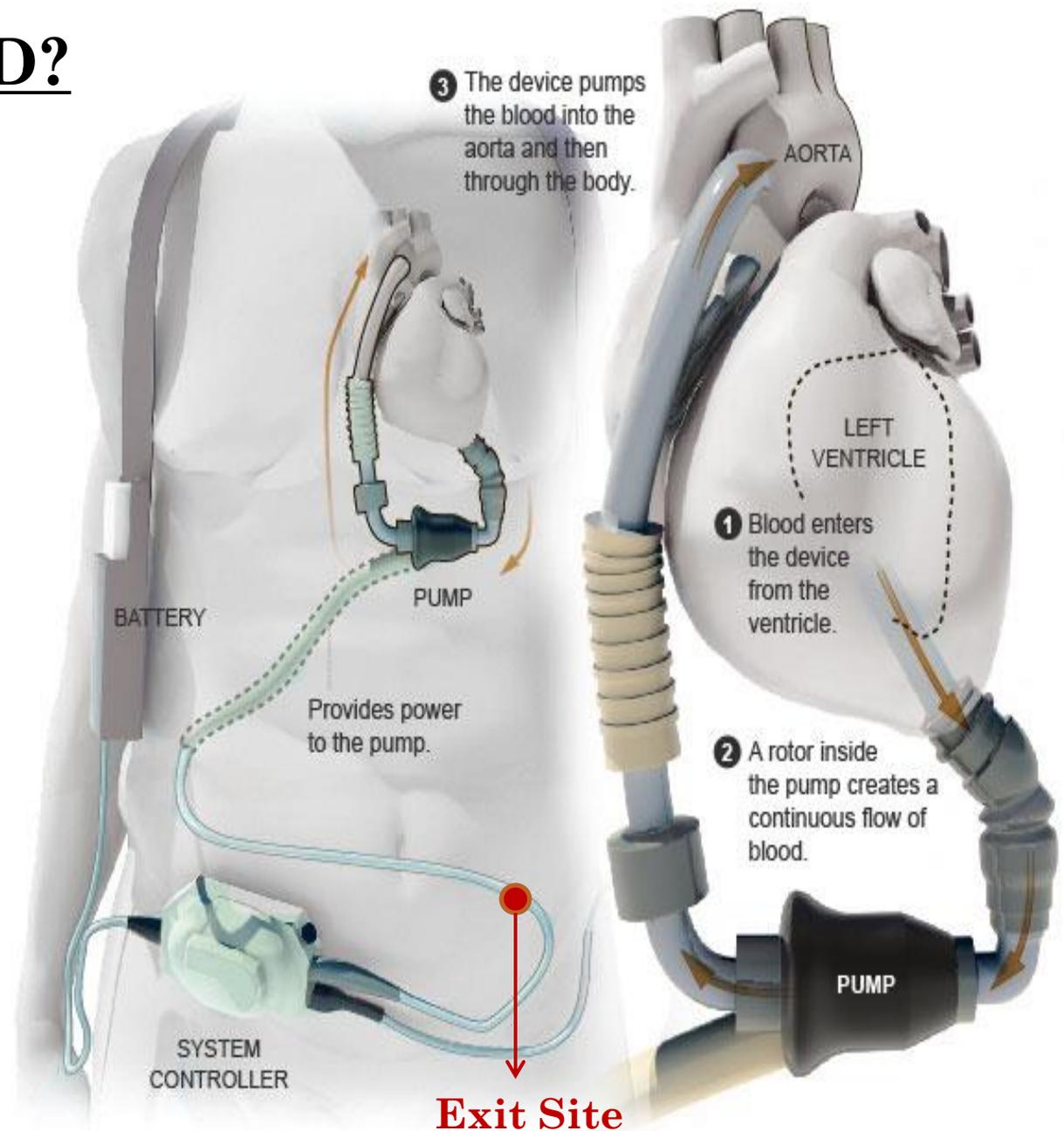
Severe or Advanced  
(Class IV)  
Any/all physical activity is limited. Not comfortable at rest or lying down



Possible treatment option: intravenous medications, VAD &/or Heart Transplant, Palliative care.

# What is a LVAD?

- A surgically implanted, rotary continuous-flow device
- Percutaneous driveline (exit site)
- Electrically powered
  - DC power (batteries)
  - AC power (wall)
- Fixed speed operating mode

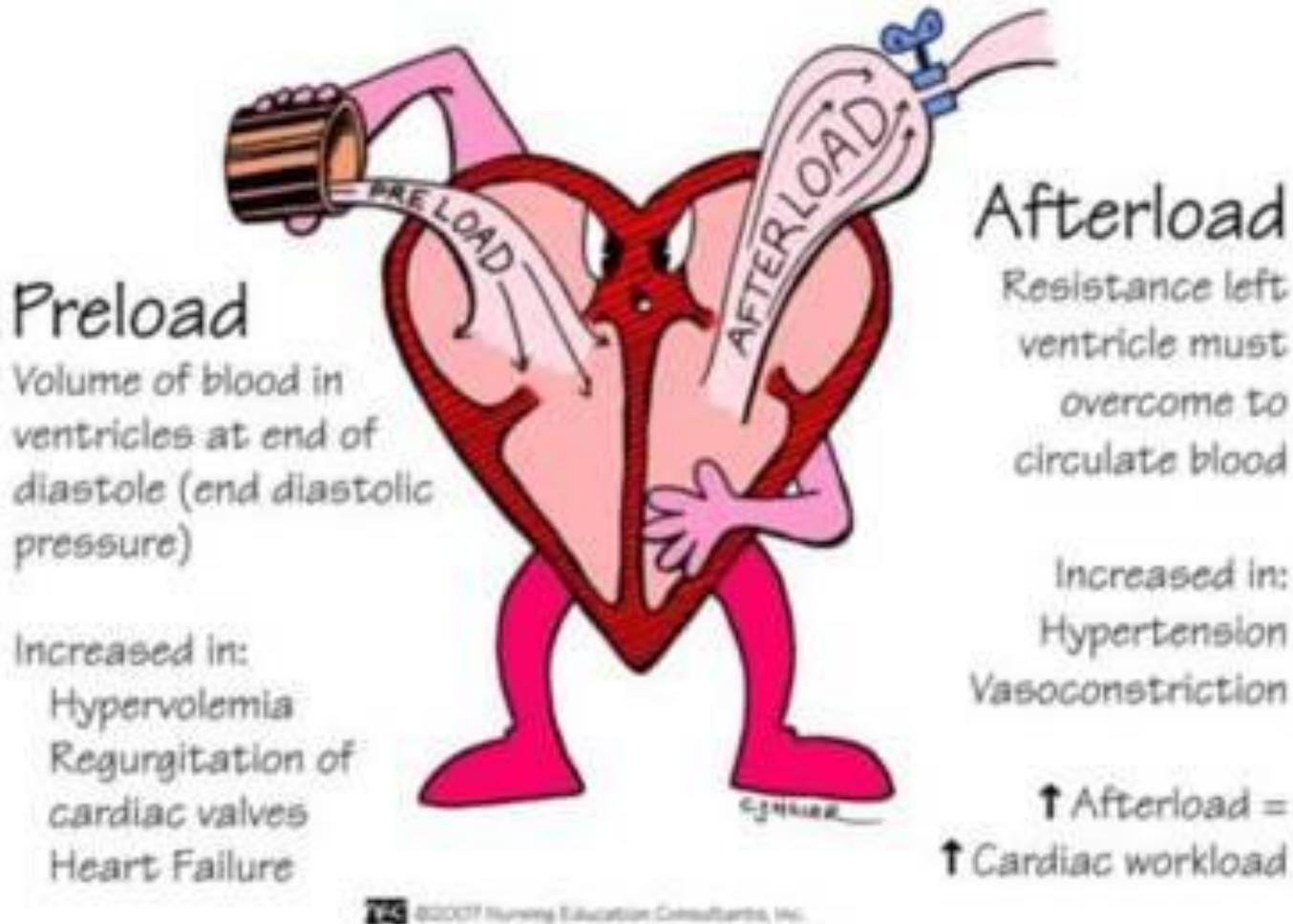


# WHAT IS A HMII LVAD?

- Replicate the function of a failing native heart while imposing as few complications as possible.
- Bridge the gap between supply and demand of donor hearts.
- Serve as a permanent therapy in patients not eligible for transplantation. (“Destination Therapy”, DT)
- Serve as a temporary therapy in patients during the decision making process. (“Bridge To Transplant”, BTT)



# PRELOAD AND AFTERLOAD



ALL Ventricular Assist Devices are:  
“Preload Driven” & “Afterload Sensitive”

# WHO NEEDS A HMII LVAD?

- Heart failure affects over 5.3M patients in the United States.<sup>1</sup>
- 300,000-800,000 Americans have advanced heart failure.<sup>2</sup>
- Over 280,000 patients die of heart failure each year.<sup>1</sup>

1 Lloyd-Jones D, Adams R, Carnethon M, et al. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics 2009 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2009;119(3):480-6.

2 Adams KF, Zannad F. Clinical definition and epidemiology of advanced heart failure. *Am Heart J* 1998;135:S204-S215.



# WHO GETS A LVAD & WHEN?

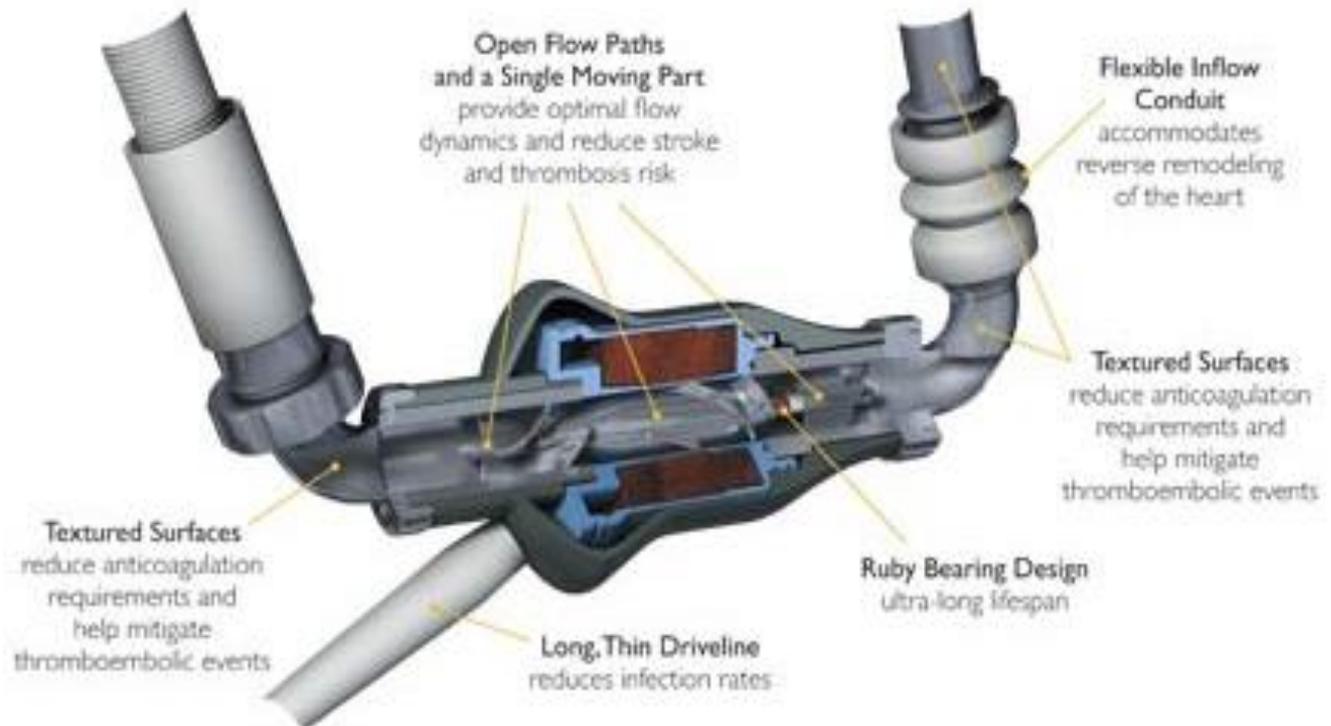
- Symptoms
    - Recurrent admissions
    - Refractory
    - At rest
  - Medications
    - Intolerance or lower doses
      - ACE-I/ARBs
      - Beta blockers
    - Increasing diuretic doses
  - Unable to carry out ADLs
  - Hypotension
  - Laboratory
    - Renal insufficiency
    - Hepatic dysfunction
    - Hyponatremia
  - Pulmonary Hypertension
  - RV dysfunction
  - Unresponsiveness to CRT (Cardiac Resynchronization Therapy)
  - Inotropes
- 

# HM II SYSTEM COMPONENTS: INTERNAL/IMPLANTED

## Technology Design

### Implanted Components:

- Inflow Conduit (attaches to LV)
- Motor Outflow Conduit (attached to aorta)
- Driveline with Velour tunneled in Abdominal Cavity



# HM II SYSTEM COMPONENTS

- Implanted Components:
  - Implantable titanium blood pump & drive line
- External Components:
  - System Controller
  - Power Module
  - Power Sources
    - Power Module
    - Batteries & Clips
  - Accessories



# HEARTMATE 3 SYSTEM COMPONENTS\*



System  
Controller

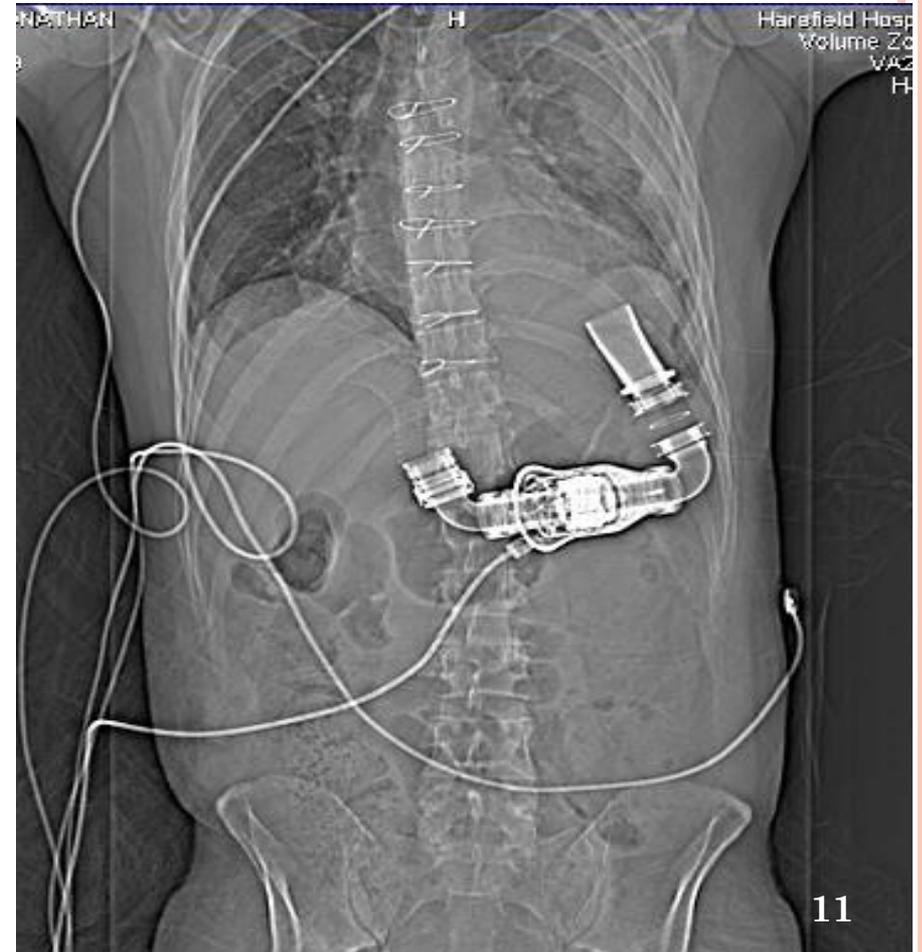
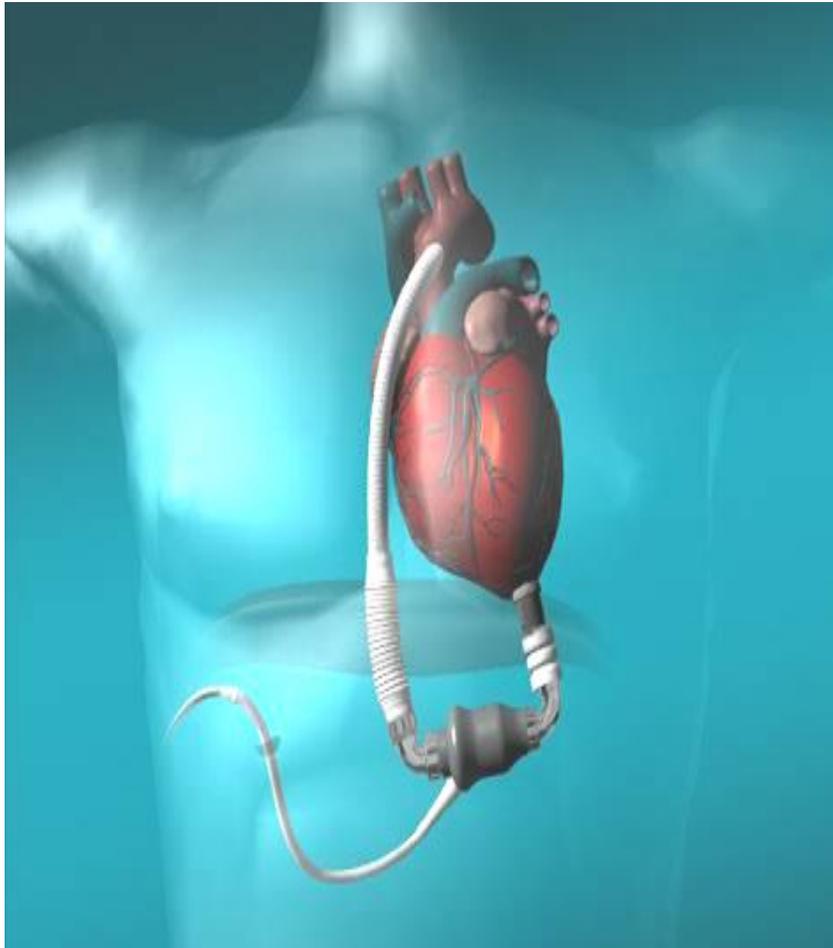


Modular  
Cable

***\*New for HeartMate 3***



# WHERE IS A LVAD?: ANATOMICAL PLACEMENT



# LVAD EQUIPMENT



**System  
Controller**

**Batteries**



**Battery with  
Battery Clip**

**Battery  
Charger**



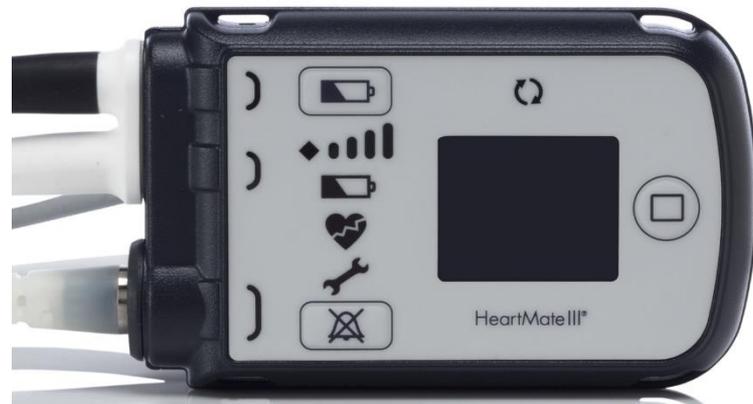
**Mobile  
Power  
Unit**

# SYSTEM CONTROLLER

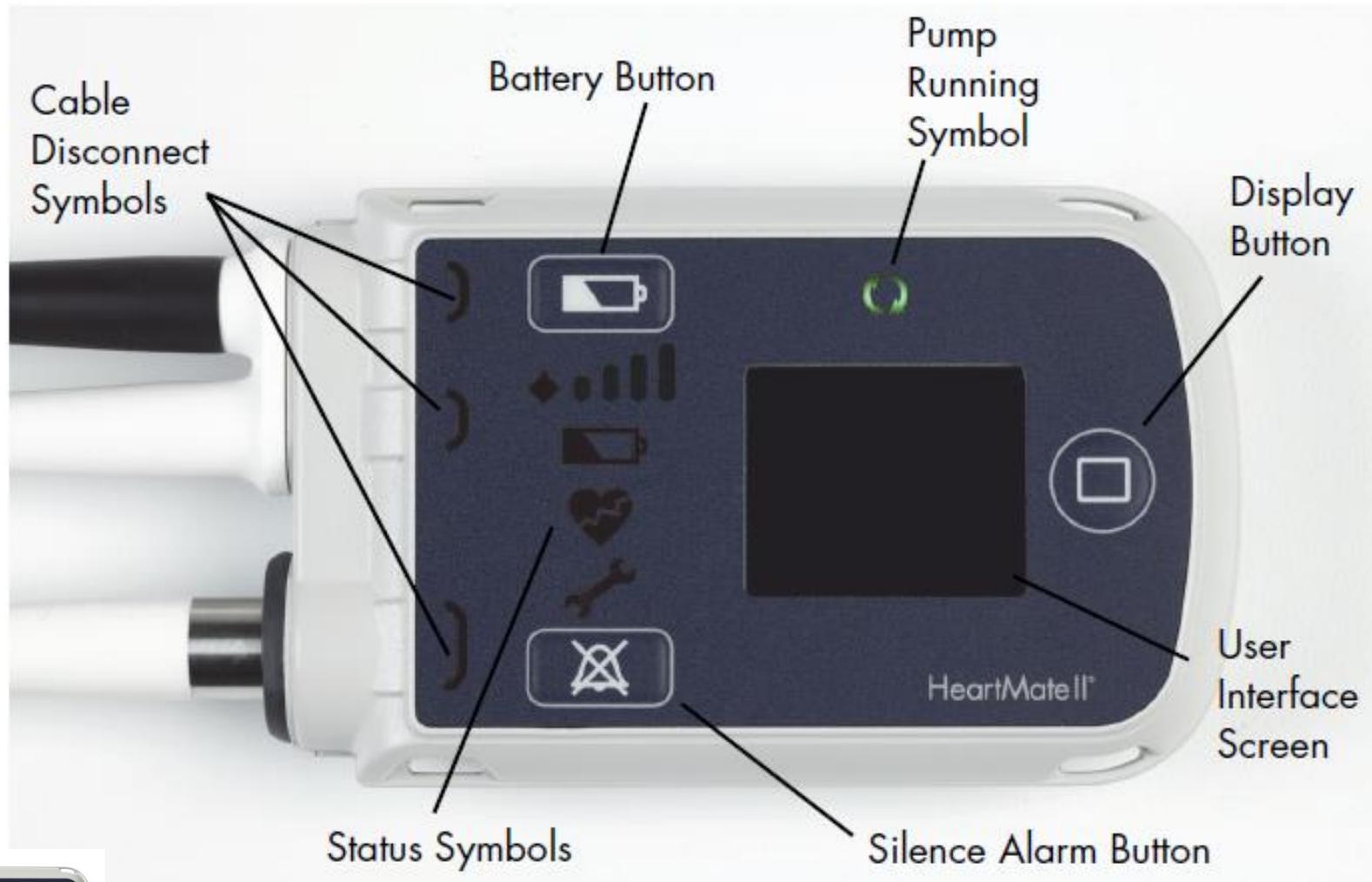
HM II



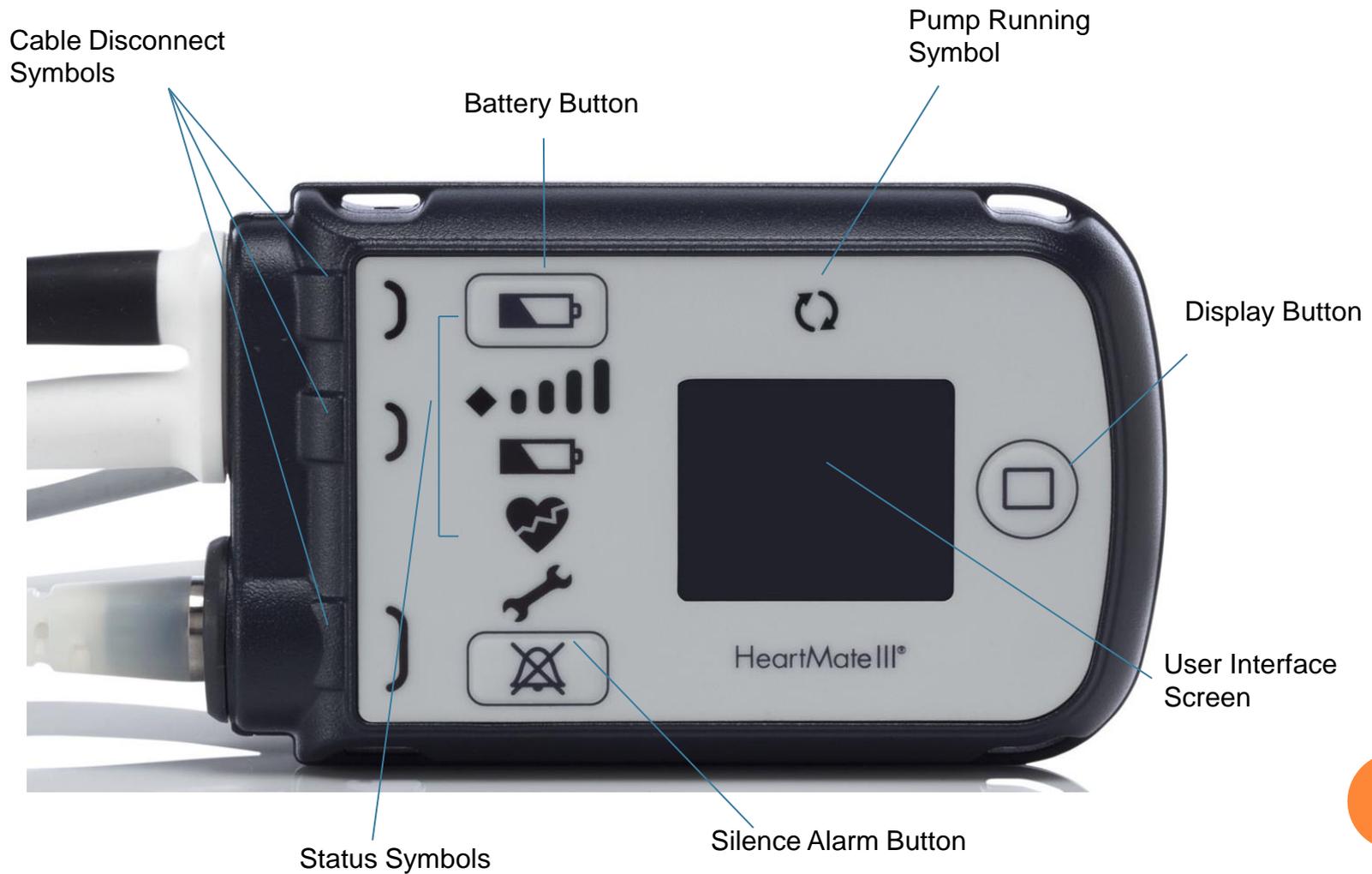
HM III



# HM II SYSTEM CONTROLLER USER INTERFACE



# HM III SYSTEM CONTROLLER USER INTERFACE



# HEARTMATE II POCKET SYSTEM CONTROLLER



- **Safety by Design**

- Backup battery
- Prioritized visual alarms with clear, actionable instructions
- Driveline diagnostic capability
- Programmed for use in 37 languages

- **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



# HEARTMATE II SYSTEM CONTROLLER



- Delivers power to the pump
- Controls and monitors system operation
- Identifies alarm conditions and initiates Hazard and Advisory Alarms
- User Interface displays the following available in 37 languages:
  - Pump parameters (Flow, Speed, Power, PI) and status of Backup Battery charge
  - Visual alarms with clear, actionable instructions
  - Accessible alarm history of last six non-transient alarms
- Display Module no longer required
- Backup battery housed within the controller
- Driveline diagnostic capability
- Records alarm data and device performance (240 events)



# SYSTEM CONTROLLER USER INTERFACE : BATTERY BUTTON

Battery  
Button



## Battery Button Functions

1. Operating battery fuel gauge
2. Starting a System Controller self test
3. Putting a running System Controller into Sleep Mode



# SYSTEM CONTROLLER BATTERY GAUGE – RUNNING ON BATTERIES

**On 14 Volt Lithium-Ion battery power:**



**4 green bars** = 75–100% of battery power remains.



**3 green bars** = 50–75% of battery power remains.



**2 green bars** = 25–50% of battery power remains.



**1 green bar** = less than 25% of battery power remains.



# SYSTEM CONTROLLER USER INTERFACE: ALARM BUTTON

## Alarm Button Functions

1. Silencing active alarms
2. Displays last six relevant alarms when pressed simultaneously with the Display button



Alarm Button



# USER INTERFACE: SILENCE ALARM BUTTON



Silence Alarm Button

## Alarm Button Functions

1. Silencing active alarms
2. Displays last six relevant alarms when pressed simultaneously with the Display button
3. Symbol below will appear on LCD if audio alarm is silenced



\*

***\*New for HM III***



# SYSTEM CONTROLLER USER INTERFACE: DISPLAY BUTTON



Display  
Button

## Display Button Functions:

1. Activates the information display screen
  - Pump speed
  - Flow
  - Pulsatility Index
  - Power
  - Backup battery charge
  - Blank default screen
2. Displays last six non-transient alarms when pressed simultaneously with the Alarm button.



# VIEWING PUMP AND SYSTEM PARAMETERS: DISPLAY BUTTON: HM II

Press the Display Button to view pump parameters and backup battery charge status on the display screen.

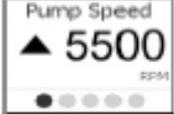
Button Press	Description	Screen Displayed (Example)	Meaning
<b>Press</b> 	Press display button <b>ONCE</b>	Pump Speed <b>9200</b> <small>RPM</small> 	Pump speed in revolutions per minute (RPM)
<b>Press</b> 	Press display button a <b>SECOND</b> time	Flow <b>4.6</b> <small>LPM</small> 	Pump flow in liters per minute (LPM)
<b>Press</b> 	Press display button a <b>THIRD</b> time	PI <b>4.2</b> 	Pulsatility Index (PI)
<b>Press</b> 	Press display button a <b>FOURTH</b> time	Power <b>5.9</b> <small>W</small> 	Power in watts (W)
<b>Press</b> 	Press display button a <b>FIFTH</b> time	Backup Battery <b>Charged</b> 	The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states: <ol style="list-style-type: none"> <li>1. Charged (ready for use).</li> <li>2. Charging (actively charging).</li> <li>3. Fault (there is a fault or problem with the backup battery that could affect its reliability).</li> </ol>
<b>Press</b> 	Press display button a <b>SIXTH</b> time		Blank screen indicates the screen is off, which is normal.

Will default back to this screen after 15 seconds



# Viewing Pump and System Parameters: Display Button: HM III

Press the Display Button to view pump parameters and backup battery charge status on the display screen.

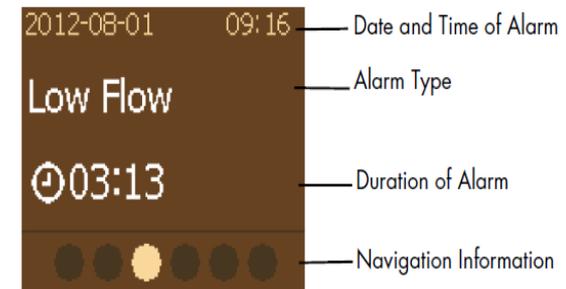
Button Press	Description	Screen Displayed (Example)	Meaning
<b>Press</b> 	Press display button <b>ONCE</b>		Pump speed in revolutions per minute (RPM) ▲ Triangle indicates that the pump is in Pulse Mode. *
<b>Press</b> 	Press display button <b>TWO</b> times		Pump flow in liters per minute (LPM)
<b>Press</b> 	Press display button <b>THREE</b> times		Pulsatility Index (PI)
<b>Press</b> 	Press display button <b>FOUR</b> times		Power in watts (W)
<b>Press</b> 	Press display button <b>FIVE</b> times		The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states: 1. Charged (ready for use). 2. Charging (actively charging). 3. Fault (there is a fault or problem with the backup battery that could affect its reliability).
<b>Press</b> 	Press display button <b>SIX</b> times		Blank screen indicates the screen is off, which is normal.

**\*New for HM III**



# VIEWING ALARM HISTORY ON SYSTEM CONTROLLER

- The last 6 alarms can be viewed on the user interface screen
  - Simultaneously press and release the silence alarm and display buttons
  - To view the next alarm, press and release the display button
- Alarms that do not appear on the System Controller alarm history screen
  - Non transient alarms that require specific action to resolve
    - Driveline Fault
    - Controller Backup Battery Fault
    - Controller Fault
  - Routine events
    - Power Cable Disconnected advisory alarm which lasts less than 30 seconds
    - Pulsatility Index (PI) Events



# VIEWING LAST SIX RELEVANT ALARMS: DISPLAY BUTTON

Button Press	Description	Alarm Screen Displayed (Example)
 <b>AND</b> 	Press display button and silence alarm button at the same time to access first alarm.	
	Press display button <b>ONCE</b> to display the second alarm.	
	Press display button a <b>SECOND</b> time to display the third alarm.	
	Press display button a <b>THIRD</b> time to display the fourth alarm.	
	Press display button a <b>FOURTH</b> time to display the fifth alarm.	
	Press display button a <b>FIFTH</b> time to display the sixth alarm.	

To view last six non-transient alarms on the display screen

1. Press the Display and the Alarm button at the same time.
2. Then press the Display button to scroll through the alarms.



# SYSTEM CONTROLLER 11 VOLT LITHIUM-ION BACKUP BATTERY



- Supplied non sterile
- Must be installed in the controller once the operating sterile field is broken
- Powers the pump for at least 15 minutes during a power-loss emergency
- Charges while connected to a power source (Power Module with 14V patient cable OR 14 Volt Li-Ion Batteries)
- The Admin and Settings Screens of the System Monitor show use of the system controller back-up battery by the patient
- Patients should not replace the 11 volt Lithium-Ion backup battery
- Expiration date: 36 months from manufacture date and/or 24 months shelf life.

**Warning:** The 11 Volt Lithium-Ion backup battery should be used only for temporary support during a power-loss emergency. The 11 Volt Lithium-Ion backup battery inside the HeartMate II System Controller provides enough power to run the implanted HeartMate II pump for at least 15 minutes if the main power source (either the Power Module or two HeartMate 14 Volt Lithium Ion batteries) is disconnected or fails. Inappropriate use of the 11 Volt Lithium Ion backup battery may result in diminished run time during a power-loss emergency.

# POWER SAVER MODE

- If external power is removed or fails, a fully charged backup battery in the system controller will provide 15 minutes of full power then enters power saver mode
- System Controller slows the pump speed to the low speed limit to save power

***IMPORTANT!*** System Controller alarms cannot be silenced when the System Controller is in power saver mode.



# LVAD SYSTEM COMPONENTS: EXTERNAL POWER SOURCES & POWER CHANGES



- AC power from Power Module (PM) or Mobile Power Unit (MPU)



- DC power from a pair of 14-volt lithium-ion batteries and clips



# POWER MODULE (PM)

- Supplies power to the LVAD when plugged into:
  - Electrical outlet
  - Automobile power outlet (e.g., cigarette lighter socket)
- Visual and audio alarm indicators provide feedback on PM system operation
  - Perform self-test daily
- Serves as the electrical interface between the System Controller and the System Monitor or Display Module
  - 20' patient cable attaches to System Controller power leads (white to white and black to black)
- Repeats alarms generated by the System Controller
  - Alarm silence button will only silence the PM alarm for 5 minutes



# POWER MODULE



# PM INTERNAL BATTERY

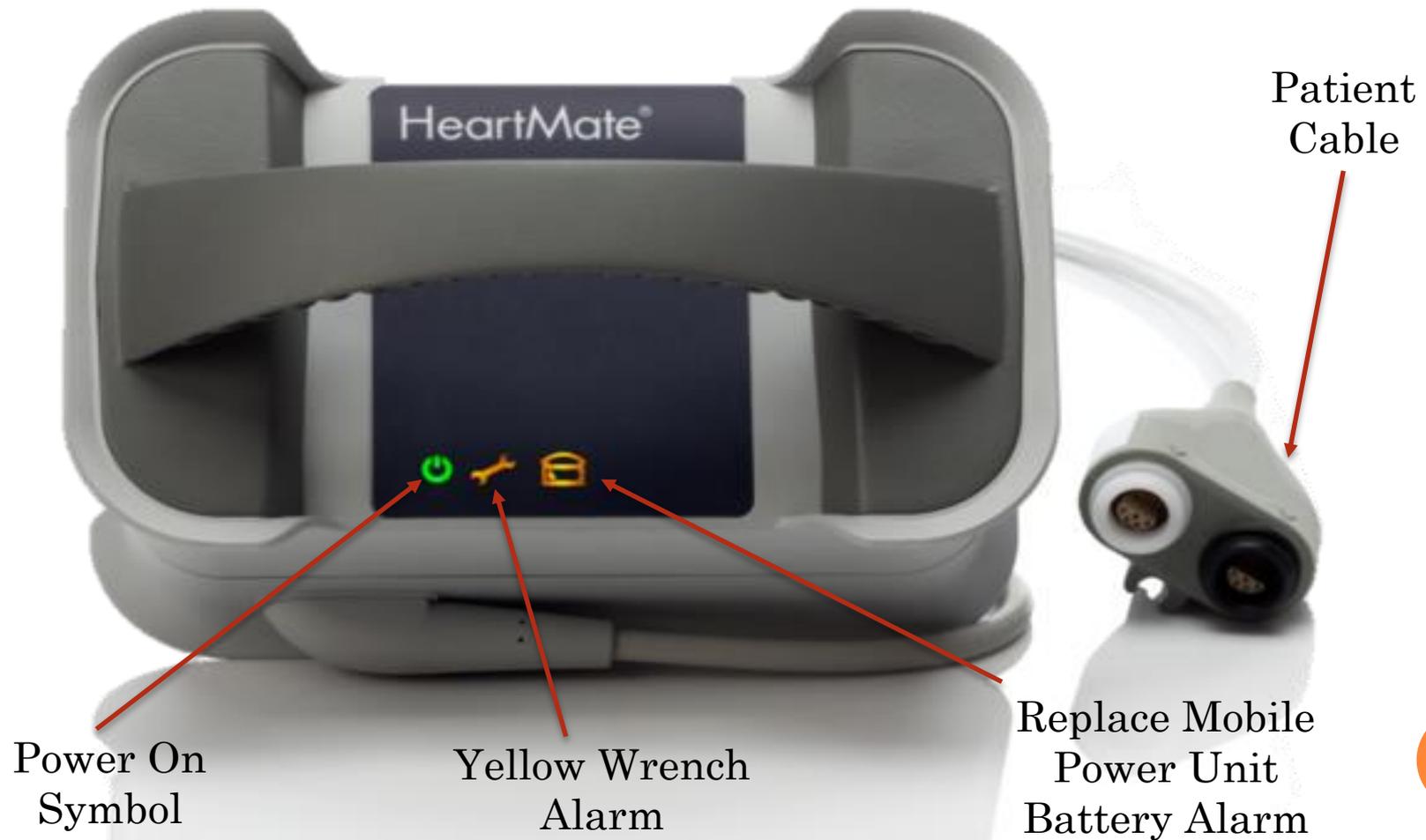
- Internal battery provides approximately **30 minutes** of backup power in the event of power interruption or failure
  - Remains charged as long as the PM remains connected to AC power or automobile DC power
  - Will operate the LVAS until the battery is depleted
  - Takes **1.5 hours to fully recharge** when depleted
- System Monitor or Display Module will lose power
- Prior to use, verify internal battery is installed and charged
  - Yellow wrench and red battery alarm with continuous tone indicates internal battery is not installed

# MOBILE POWER UNIT (MPU)

- Supplies power to the LVAD when plugged into an Electrical outlet
  - 20' patient cable attaches to System Controller power leads (white to white and black to black)
- Echoes alarms generated by the System Controller
- Alarms powered by 3 Alkaline AA batteries
  - Replaced every 6 months



# MOBILE POWER UNIT (MPU)



# MOBILE POWER UNIT (MPU)

- **Power On Symbol:** illuminated green when the Mobile Power Unit is powered and functioning properly.
- **Yellow Wrench Alarm:** illuminates when the MPU detects a mechanical, electrical, or software issue – switch to 2 fully-charged batteries
- **Replace MPU Battery Alarm:** illuminates when the Alkaline AA batteries are not installed, or are depleted and need replaced.



# MOBILE POWER UNIT ALARMS

The power symbol (🔌) is illuminated green when the Mobile Power Unit is powered and functioning properly.

Priority	Active Symbols	Alarm Means	To Resolve alarm
<b>Advisory</b>		Internal Fault	<ol style="list-style-type: none"> <li>1. Promptly connect patient to two fully-charged HeartMate® 14 Volt Lithium-Ion batteries.</li> <li>2. Call your hospital contact and replace the Mobile Power Unit.</li> </ol>
		Replace Mobile Power Unit Batteries	<p>Replace the internal AA batteries in the Mobile Power Unit.</p> 

# LVAD SYSTEM COMPONENTS: EXTERNAL POWER SOURCES & POWER CHANGES

- 14-volt, lithium ion
- Approx. 12 hours of support on a pair of batteries
  - Drains both batteries simultaneously
- On battery fuel gauge indicates charge level
- Four hours to recharge fully discharged battery
- Service life of 360 cycles or 36 months from the date of manufacturer, whichever comes first
- Dispose of expired batteries according to local, state, and federal regulations



## BATTERIES

# CLEANING BATTERY & BATTERY CLIP TERMINALS

- Clean battery terminals and interior contacts of battery clips once a week with an alcohol moistened swab
- Dirty battery terminals may prevent proper charging in the Universal Battery Charger
- Allow the alcohol to evaporate prior to use



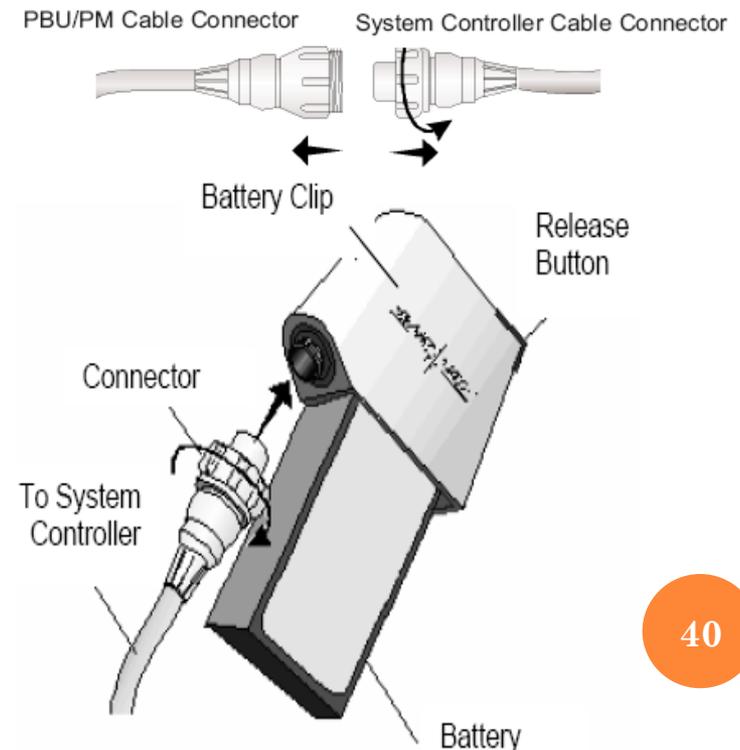
# UNIVERSAL BATTERY CHARGER

- Performs diagnostic testing and charges up to four HeartMate batteries in four hours or less
  - Provides most accurate percent of battery charge level
  - Monitors use cycles of each battery
- Pocket lights indicate battery charge status
- Monitors the need for calibration and calibrates individual HeartMate batteries
- Weighs eight pounds

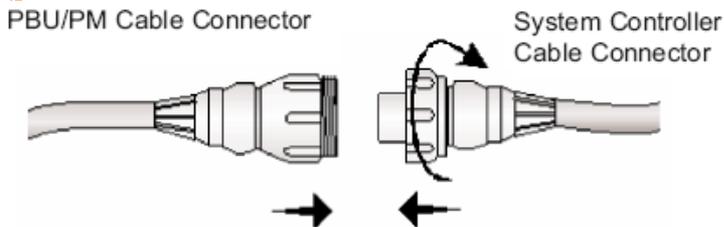
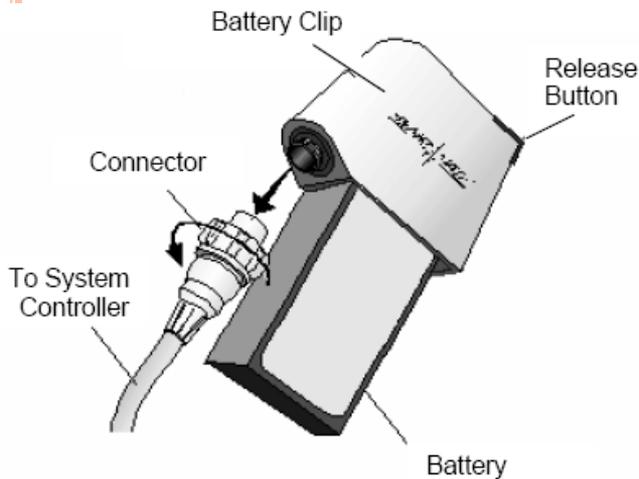


# CHANGING FROM PM TO BATTERIES

1. Place 2 fully charged batteries into battery clips by aligning arrows
2. Unscrew white power lead from PM/PBU cable & connect to battery clip
  - Power Cable Disconnected alarm will sound
3. After alarm resolves, unscrew black power lead from PM/PBU cable & connect to battery clip
4. Check battery fuel gauge
5. For SLA batteries, turn Velcro® circles from white to black
6. Place batteries in GoGear accessory



# CHANGING FROM BATTERIES TO PM



- 1a. For PBU, verify PBU plugged into outlet, turned on & PBU patient cable connected
- 1b. For PM, verify PM plugged into outlet & PM patient cable connected
2. Remove batteries & clips from GoGear accessory
3. Unscrew white power lead from battery clip & connect to white PM/PBU cable connector
  - Power cable disconnect advisory will sound
4. After alarm stops, unscrew black power lead from battery clip & attach to black PM/PBU cable connector
5. Recharge batteries if necessary
  - SLA Batteries: verify Velcro circles are black & place into PBU
  - 14 volt Li-Ion Batteries: place in UBC

# CONTROLLER COMPATIBLE WEAR AND CARRY ACCESSORIES

- Smaller and designed to be more intuitive, discreet, and comfortable



Shower Bag



Consolidated Bag

**SOLD SEPARATELY**

- Accessories kit comes with each implant kit and is sold separately. It contains:

- Belt Attachment
- Lanyard
- Protection Bag

## AVAILABLE WITH POCKET CONTROLLER



Belt Attachment



Lanyard



Protection Bag

## CURRENTLY AVAILABLE



Battery Holster



Holster Vest  
(small, medium and large)



# VITAL SIGN MONITORING

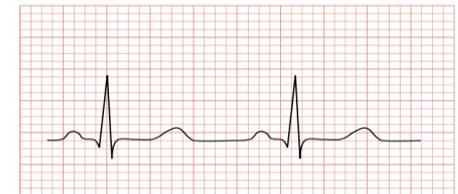
- **Temperature**

- **Blood Pressure**

- Manual Cuff and Doppler are usually required; patient may have an automated BP, however very unreliable
- Use manual cuff, pump to ~120-140mmHg. Slowly deflate cuff. First sound you hear is patients blood pressure...the sound may be a “lub”, a “dub” or a “swish”. It will be a single number. AKA Return to Flow (RTF)
- Target RTF=60-80. 90-100, look at patient trend. Is this normal? May need BP medications increased

- **Pulse oximetry**

- if obtainable, may be unreliable due to the diminished pulse pressure



# DEVICE PARAMETERS

## ○ Device parameters

- Speed: how fast the pump is going (rpms)
  - Call if speed fluctuates (up or down) by >150
- Power: how much electricity the pump is using (watts)
  - Call if power doubles or goes up to 10 watts
- Flow: how much blood is going through the pump (L/min)

PUMP



PATIENT



- PI: the patient's own heart function/contractility

## ○ Monitoring

- No single parameter is a surrogate for monitoring patient's clinical status
- NORMALLY: Speed, Power, Flow=change together & in the opposite direction of PI
- Note baseline values
  - Trends
  - Abrupt changes

# PUMP FLOW PRINCIPLES

- Pump flow is a function of:

- The speed of the rotor

↑ Speed → ↑ Flow

↓ Speed → ↓ Flow

- The difference in pressure across the pump

↑ Pressure gradient → ↓ Flow

↓ Pressure gradient → ↑ Flow

# FLOW ESTIMATOR DESIGN

- Flow measurement does not use a sensor or flow probe
- Flow range 3 – 10 liters/minute
- Derived from motor power and speed providing an estimate of pump flow
  - ↓ Power → ↓ estimated Flow
  - ↑ Power → ↑ estimated Flow
- For a given speed, pump flow is linearly related to power (over a limited range)

# PUMP POWER

- Measured in watts
- Related to pump speed and flow
- Under normal patient conditions, power should remain within a certain range for a specified speed
  - ↑ Speed → ↑ Power
  - ↓ Speed → ↓ Power
- Flow
  - ↑ Flow → ↑ Power (takes more work to move more blood)
  - ↓ Flow → ↓ Power (does not compensate for ↑ afterload)
- Monitoring
  - Normal
    - Increases or decreases with pump flow and speed without abrupt changes
    - Power fluctuations of 1-2 watts do not necessarily indicate a problem but should be closely monitored
    - Power values > 10 – 12 Watts requires further investigation
  - Fluctuations related to bearing seating
    - Some pumps exhibit high power consumption for several days post op and then drop to “normal”
    - Power will abruptly rise or fall ~2 watt
  - Monitor trends for both ↑ and ↓ in Watts
  - **Is patient symptomatic?**

# PULSATILITY INDEX (PI)

- The Pulsatility Index (PI) is a measurement of flow pulse through the pump
- It is determined by pump speed and the degree of native LV contractility
  - Pump speed determines the amount of LV unloading
    - As speed increases the PI goes down
    - As speed decreases the PI goes up

# TAKE THE GO-BAG!!!

## Contents:

- Back-Up system Controller
- Two extra batteries
- Two battery clips
- Poncho
- Alarm pamphlets
- Cell phone

# PHYSICAL THERAPY/OCCUPATIONAL THERAPY

- Must be out of bed in chair for every meal
- Ambulate 3-4 times/day every day
- Increase ambulation distance & length of time out of bed each day

# OUTPATIENT MANAGEMENT

- Weekly Clinic Visits (every Thursday in the Advanced Heart Failure Center-95 building, 3<sup>rd</sup> floor)
- Weekly INR values (may be done in home town)
- Most Frequent calls
  - Medical questions or concerns
  - Lightheaded, dizzy, dehydration
- Most frequent alarms
  - Power cable disconnected
  - Low battery advisory

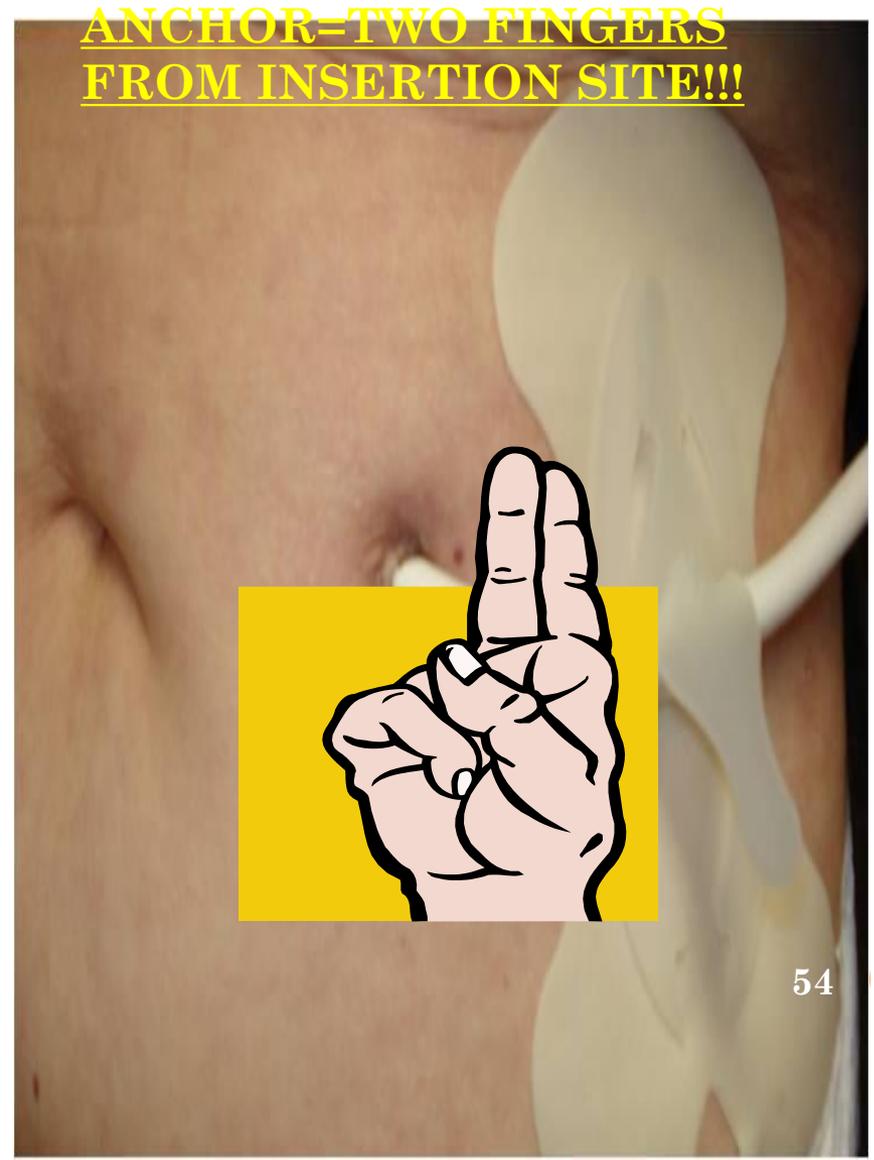
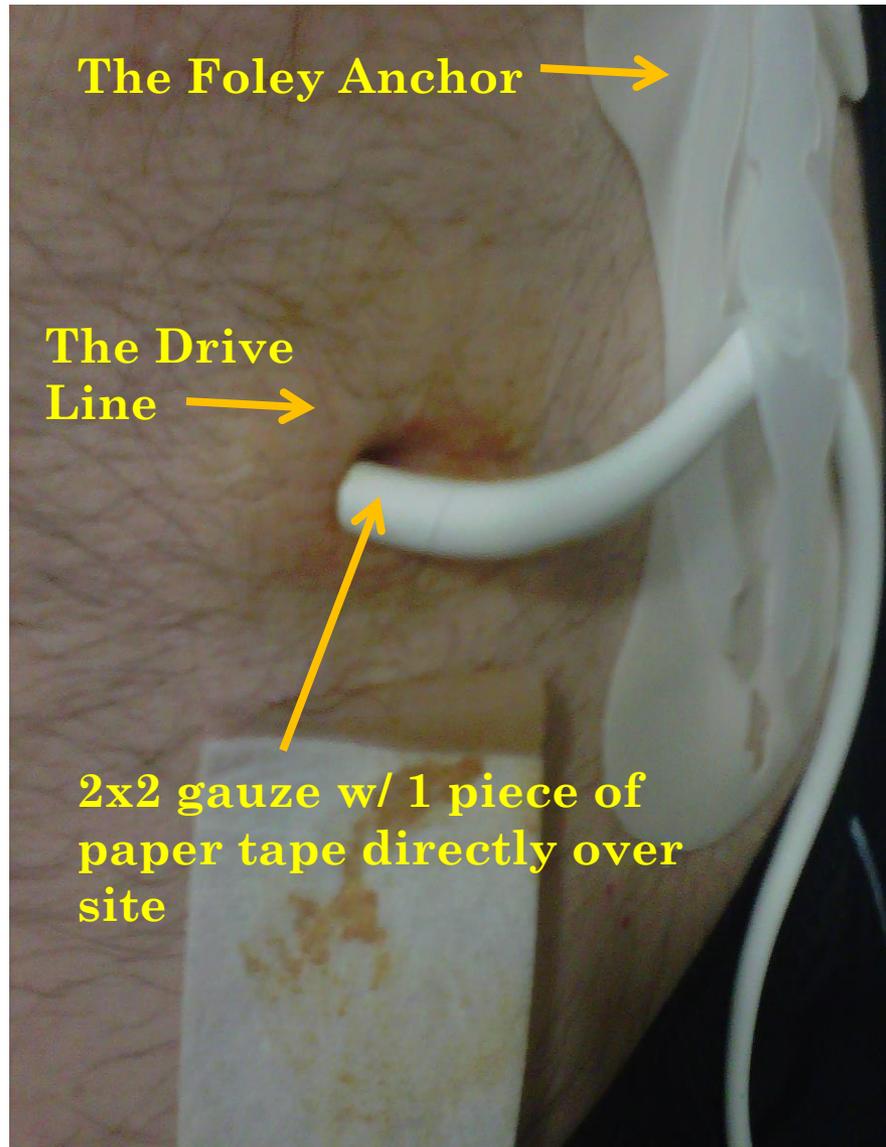
# NUTRITION & DAILY WEIGHT

- maintain adequate volume (2L/day)
  - Avoid dehydration
- Cardiac Diet=low fat, low cholesterol, low sodium
- Avoid foods rich in Vitamin K (green leafy vegetables, cranberry juice)
- Avoid herbal supplements
- Control blood glucose levels
- Daily weights and paying attention to symptoms such as orthostatic hypotension
- Call if weight fluctuates 3 – 5 pounds

# ANTICOAGULANT PROTOCOL

INR ranges	Reasons (past medical history) for being on Warfarin
<ul style="list-style-type: none"><li>▪ 1.5-2.5 (if only 1 reason to be on blood thinner)</li><li>▪ 2.0-3.0 (if 2 reasons for being on blood thinner)</li><li>▪ 2.5-3.5 (if 3 or more reasons for being on blood thinner)</li></ul>	<ul style="list-style-type: none"><li>▪ LVAD,</li><li>▪ Mechanical Mitral or Aortic valve,</li><li>▪ Atrial or Ventricular Fibrillation,</li><li>▪ DVT/PE,</li><li>▪ Stroke</li></ul>

# THE DRIVE LINE—LEFT SIDE EXIT SITE





# DRIVELINE CARE

- Daily dressing change (& as needed)
  - Use clean technique
  - Clean with Antiseptic agent such as chlorhexidine or betadine
  - Apply dry, sterile 2x2 dressing
  - Secure with 1 piece of paper tape
- Weekly Anchor Change (& as needed)
  - Use “Foley Anchor” Kit: purchase through WalGreen’s at Piedmont or through the manufacturer
  - 2 finger widths from insertion site

# CARE OF THE DRIVE LINE:

- **Do not severely bend, kink or twist the percutaneous lead**
- **Do not “catch” the percutaneous lead in a zipper**
- **Allow for a gentle curve, do not severely bend the lead multiple times or wrap it tightly**
- **Keep the percutaneous lead clean**
- **Never submerge the lead or system components in water or liquid**
- **Do not pull on or move the lead going through the skin.**
- **Gently tug on metal end of connector, NOT lead, to check connection into system controller**
- **Wear the HeartMate Stabilization Belt or immobilizing device AT ALL TIMES to prevent pulling on or moving the lead.**
- **Be mindful of where the system controller is at all times.**
  - **Protect the controller from falling or pulling on the lead.**
- **Don't allow the percutaneous lead catch or snag on anything that will pull on or move the lead**
- **Check the percutaneous lead daily for cuts, holes, tears**

# WARNINGS, PRECAUTIONS & RESTRICTIONS

- No excessive jumping or contact sports
- No swimming or bathing
- Shower using the Shower Bag (p. 106 of handbook)
- No exposure to MRI
- Avoid strong static discharge
  - Touching TV, computer screens
  - Vacuuming carpets
- No pregnancy
- No heating pads or electric blankets
- Can not sleep on stomach

# ALARMS HM II

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
H A Z A R D	<p>Low Flow</p> <p>☉ :03</p> <p>+</p> <p>Call Hospital Contact</p> <p>☉ :07</p>		Pump is off. The pump running symbol (☉) is black.	<ol style="list-style-type: none"> <li>1. Immediately connect to a working power source (Power Module or two HeartMate 14 Volt Lithium-Ion batteries).</li> <li>2. If connecting to power does not resolve the problem, press any button on the System Controller to attempt pump start and call your hospital contact immediately.</li> </ol>
	<p>Connect Driveline</p> <p>☉ :02</p>	 + 	Driveline is disconnected. The pump running symbol (☉) is black.	<ol style="list-style-type: none"> <li>1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position.</li> <li>2. If alarm persists after reconnecting the driveline, press any button on the System Controller to potentially resolve.</li> <li>3. If driveline is connected and alarm persists, replace System Controller with a programmed backup System Controller.</li> <li>4. If alarm persists, call your hospital contact immediately.</li> </ol>
	<p>Backup Battery</p> <p>☉ :01</p> <p>+</p> <p>Connect Power Immediately</p> <p>☉ :05</p>	 +  + 	Both power cables are disconnected	<ol style="list-style-type: none"> <li>1. Immediately connect to a working power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).</li> <li>2. If alarm persists, call your hospital contact immediately.</li> </ol>
	<p>Low Flow</p> <p>☉ :03</p> <p>+</p> <p>Call Hospital Contact</p> <p>☉ :07</p>		Low flow, flow is less than 2.5 lpm	Call your hospital contact immediately for diagnosis and instructions.
	<p>Replace Power Immediately</p> <p>☉ :02</p> <p>+</p> <p>Low Battery</p> <p>☉ :06</p>		Low Battery, Power input is extremely low with less than 5 min. remaining	<ol style="list-style-type: none"> <li>1. Immediately connect to a working power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).</li> <li>2. If alarm persists, call your hospital contact immediately.</li> </ol>

**Important!** The pump running (☉) symbol is always lit green when the pump is running.



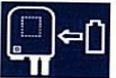
**Thoratec Corporation** 6035 Stoneridge Drive, Pleasanton, CA 94588 Tel: (925) 847-8600, Fax: (925) 847-8574, Heartline: (800) 456-1477, www.thoratec.com



**Thoratec Europe Limited** Burnett House, 3 Lakeview Court, Ermine Business Park, Huntingdon, Cambridgeshire, PE29 6UA United Kingdom, Tel: +44 (0) 1480 455200, Fax: +44 (0) 1480 454126, 24-Hr Tel: +44 (0) 7659 877901

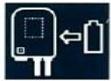
Thoratec Corporation continually strives to provide the highest quality products for mechanical circulatory support. Specifications may change without notice. Therefore, please refer to the HeartMate II Left Ventricular Assist System IFU shipped with the HeartMate II for the most current information regarding indications, contraindications, warnings, and cautions. Thoratec, the Thoratec logo, HeartMate, and HeartMate II are registered trademarks and Heartline is a trademark of Thoratec Corporation. ©2012 Thoratec Corporation. 107525.C

# ALARMS HM II

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
A D V I S O R Y	Connect Power ⊙ :04		One of the two power cables is disconnected	<ol style="list-style-type: none"> <li>Promptly connect the disconnected power cable to power source (functioning Power Module or two fully-charged HeartMate® 14 Volt Lithium-Ion batteries).</li> <li>If alarm persists, call your hospital contact.</li> </ol>
	Replace Power ⊙ :02 + Low Battery ⊙ :06		Low Battery, Power input is low with less than 15 min. remaining	<ol style="list-style-type: none"> <li>Promptly connect to a working or different power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).</li> <li>If alarm persists, call your hospital contact.</li> </ol>
	Replace Controller Controller Fault + Call Hospital Contact Controller Fault		System Controller hardware fault	Call your hospital contact as soon as possible for diagnosis and instructions.
	Call Hospital Contact Backup Battery Fault		System Controller Backup Battery fault	Call your hospital contact as soon as possible for diagnosis and instructions.
	Low Speed ⊙ :03 + Call Hospital Contact ⊙ :07		Low speed advisory warning	Call your hospital contact as soon as possible for diagnosis and instructions.
	Call Hospital Contact Driveline Fault		Driveline fault	Call your hospital contact as soon as possible for diagnosis and instructions.
			System Controller Backup Battery not installed	Call your hospital contact as soon as possible for diagnosis and instructions.
			Controller Clock not set	Call your hospital contact as soon as possible for diagnosis and instructions.

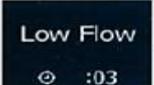
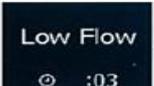
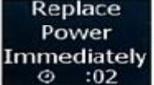
**Important!** The pump running (  ) symbol is always lit green when the pump is running.

# ALARMS HM III

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
A D V I S O R Y	Connect Power Ⓞ :04	 OR 	<b>One of the two power cables is disconnected</b>	Promptly connect the disconnected power cable to power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate® 14 Volt Lithium-Ion batteries).
	Replace Power Ⓞ :02 + Low Battery Ⓞ :06		Low voltage—power input is low, with less than 15 min remaining. <b>OR</b> System Controller Power Cables are crossed when connected to the Mobile Power Unit.	Promptly connect to a working or different power source (Mobile Power Unit, Power Module, or two fully-charged 14 Volt HeartMate® Lithium-Ion batteries).  Ensure the power cables are connected correctly—white to white, black to black. 
	Replace Controller Controller Fault + Call Hospital Contact Controller Fault		<b>System Controller hardware fault</b>	<ol style="list-style-type: none"> <li>Switch to the backup System Controller (see <i>Guide to Replacing The Running System Controller for Clinicians</i>).</li> <li>Provide patient with a new System Controller (with backup battery installed).</li> </ol>
	Call Hospital Contact Comm Fault		<b>Data communication (comm) error between LVAD and system controller</b>	<ol style="list-style-type: none"> <li>Contact Thoratec to determine best next steps.</li> <li>Use the System Monitor to silence the alarm while awaiting resolution, if needed.</li> </ol>
	Call Hospital Contact Backup Battery fault		<b>System Controller Backup Battery fault</b>	Replace the 11 Volt Lithium-Ion backup battery. <b>Note:</b> If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Thoratec with questions.
	Low Speed + Call Hospital Contact Ⓞ :03 + Ⓞ :07		<b>Low Speed advisory warning</b>	<ol style="list-style-type: none"> <li>Use the System Monitor to check that the fixed speed and low speed limit have been appropriately set.</li> <li>Replace the System Controller.</li> <li>Clinically evaluate the patient.</li> </ol>
			<b>System Controller Backup Battery not installed</b>	<ol style="list-style-type: none"> <li>Install the 11 Volt Lithium-Ion backup battery in the System Controller.</li> <li>Obtain a new backup battery replacement kit.</li> </ol> <b>Note:</b> If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Thoratec with questions.
	Call Hospital Contact LVAD Fault		<b>Internal LVAD operating parameter out of range</b>	<ol style="list-style-type: none"> <li>Contact Thoratec to determine best next steps.</li> <li>Use the System Monitor to silence the alarm while awaiting resolution, if needed.</li> </ol> <b>Note:</b> The alarm must be active in order to access the alarm silence for this situation.
	Call Hospital Contact Driveline Power Fault		<b>Driveline power wire may be damaged</b>	<ol style="list-style-type: none"> <li>Contact Thoratec to determine best next steps.</li> <li>Use the System Monitor to silence the alarm while awaiting resolution, if needed.</li> </ol> <b>Note:</b> The alarm must be active in order to access the alarm silence for this situation.
	Call Hospital Contact Driveline Comm Fault		<b>Driveline communication (comm) wire may be damaged</b>	<ol style="list-style-type: none"> <li>Contact Thoratec to determine best next steps.</li> <li>Use the System Monitor to silence the alarm while awaiting resolution, if needed.</li> </ol> <b>Note:</b> The alarm must be active in order to access the alarm silence for this situation.
			<b>Controller Clock not set</b>	Use the System Monitor to set the System Controller's internal clock. <b>Note:</b> Be sure the System Monitor clock is correct.

**Important!** The pump running (  ) symbol is lit green when the pump is running.

# ALARMS HM III

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
H A Z A R D	 + 	 + 	<b>Pump is off. The pump running symbol is black.</b>	<ol style="list-style-type: none"> <li>1. Check if the fixed speed setting is below 4,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt pump start.</li> <li>2. Switch to backup System Controller and attempt to restart pump.</li> <li>3. Clinically evaluate patient.</li> </ol>
	 + 	 + 	<b>Low flow, flow is less than 2.5 lpm</b>	<ol style="list-style-type: none"> <li>1. Ensure that the driveline is connected to System Controller.</li> <li>2. Ensure that a power source is connected to System Controller.</li> <li>3. Clinically evaluate patient.</li> </ol>
		 +  + 	<b>Driveline is disconnected. The pump running symbol is black.</b>	<ol style="list-style-type: none"> <li>1. Immediately reconnect the driveline to System Controller and move the driveline safety lock on the System Controller to the locked position.</li> <li>2. If alarm persists after reconnecting the driveline, press any button on the System Controller to attempt pump start. Otherwise, check if the fixed speed setting is below 4,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button.</li> <li>3. If driveline is connected and alarm persists, replace System Controller with a configured backup System Controller.</li> </ol>
	 + 	 +  + 	<b>Both power cables are disconnected</b>	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
		 	<b>System Controller Hardware Fault (Microcontroller Failure)</b>	No active symbols (constant audio tone). <ol style="list-style-type: none"> <li>1. Immediately switch to the backup System Controller.</li> <li>2. Provide patient with a new System Controller.</li> </ol> <b>Note:</b> The audio tone cannot be silenced.
	 + 		<b>Low Battery Power, Input Power is extremely low with less than 5 min. remaining</b>	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).

# REPLACING A SYSTEM CONTROLLER

Replace The Running System Controller with The Backup Controller and MULTIPLE Power sources		
<p>1 Set-up</p>		<ol style="list-style-type: none"> <li>Place the back up System Controller within reach.</li> <li>Have the patient sit/lie down as he or she may get dizzy if the pump briefly sops.</li> <li>Unlock the driveline safety tab on the running System controller.</li> </ol>
<p>2 Replace System Controller</p>		<p style="text-align: center;">Multiple Power Sources Available (have Power Module AND Batteries &amp; Clips)</p> <p>Important! Keep the running System Controller connected to Power.</p> <ol style="list-style-type: none"> <li>Connect both the white and black connections on the backup Controller to power.</li> <li>Promptly, move the driveline from the running controller to the backup controller.</li> </ol>
		<p>3 Finish</p>



# REPLACING A SYSTEM CONTROLLER

Replace the Running System Controller With The Backup Controller and a SINGLE Power Source		
1 Set-up		<ul style="list-style-type: none"> <li>a. Place the back up System Controller with reach.</li> <li>b. Have the patient sit/lie down (you may feel dizzy if the pump briefly stops).</li> <li>c. Unlock the driveline safety tab on the running System Controller.</li> </ul>
2 Replace System Controller	In-use Power Source Only (either Power Module OR Batteries & Clips)	
		<ul style="list-style-type: none"> <li>a. Move the white connector's power source from the running controller to the backup System Controller.</li> <li>b. Promptly move the driveline from the running controller to the backup System Controller.</li> <li>c. Move the black connector's power source from the running controller to the backup System Controller.</li> </ul>
3 Finish		<ul style="list-style-type: none"> <li>a. Lock the driveline safety tab on the backup System Controller. The safety tab cannot move to the locked position unless the driveline is fully and properly inserted. Confirm that the pump running symbol is green, pump is running.</li> <li>b. Put the old, replaced System Controller into Sleep Mode by pressing and holding the battery button for 5 seconds.</li> <li>c. Do not use the old System Controller ever again. Contact Thoratec Corp to request a new backup System Controller and for instructions on returning the old one.</li> </ul>



# SYSTEM CONTROLLER DRIVELINE CONNECTIONS



1. To insert the driveline, slide the safety tab back to unlock and expose the red button
2. Align the arrow on the controller to the arrow on the driveline cable until they connect, and firmly insert the driveline until it snaps into place
3. Be sure to slide the safety tab back over the red button, locking the driveline in place.
4. Tug gently on the metal portion of the driveline to ensure it is fully engaged.



# REPLACING A SYSTEM CONTROLLER WITH A BACKUP CONTROLLER

- If controller does not restart:
  - Check driveline connection
  - Check power sources
  - Push any button



# EMERGENCY CARE OF THE HEARTMATE II (LVAD) PATIENT

## Emergency Notification Guide

- Call 911
- After calling 911, immediately call the 24 Hour LVAD Support Line: **404.605.3066**.
- You should call the support line whether the emergency is LVAD related or not.

# EMERGENCY CARE OF THE HEARTMATE II (LVAD) PATIENT

In the event of a respiratory arrest, rescue breathing should be initiated using the American Heart Association guidelines.

- 10 to 12 breaths per minute

OR

- One breath every 5 to 6 seconds

In the event of a cardiac arrest, CPR should be initiated using the American Heart Association guidelines.

- Compressions – Airway – Ventilation
- Compression to ventilation ratio = 30:2

# PEARLS OF LVAD CARE: WHEN TO CALL: 404-605-3066

- CRITICAL INR: <1.5-3.5>
- RTF <60-90>
- ANY LVAD ALARM CONDITION
- WEIGHT GAIN OF 3-5 LBS IN 24 HOURS
- S/S of STROKE (FAST)
- S/S of INFECTION (redness, swelling, heat, pain, purulent drainage at the driveline site, fever, chills)
- PERSISTENT FRANK BLEEDING/  
DARK, TARRY STOOLS

# Re-Admission/Complications:

Complication	Signs & Symptoms
<b>Gastrointestinal Bleeding (GI Bleed)</b>	Bloody Vomit: looks like coffee grounds Bloody Bowel Movement: looks like tar (black, stringy, loose)
<b>Stroke</b>	F—(FACE) unequal smile A---(ARMS) unable to grasp or lift one S---(SPEECH) slurred or strange T---(TIME) move quickly, call 911
<b>Infection</b>	Temperature, obvious source? With white or green drainage, tender or red
<b>ICD firing/Arrhythmias</b>	Defibrillator will deliver a shock
<b>Driveline Damage</b>	Check daily for damage, nick or cuts

## TIPS

- The pump flow cannot adjust for patient activity, therefore, many patients experience dizziness or fainting.
- The patient & their caregivers are the LVAD competent individuals!!!
- The pump is very sensitive to blood volume. Hypovolemia/Dehydration can cause the pump to malfunction.
- HeartMate II patients are anticoagulated with Warfarin.
- LVAD patients have ICDs that may discharge during an abnormal heart electrical rhythm. (If external defibrillation/shock is necessary, leave the pump running. Do NOT disconnect the System Controller from the percutaneous lead before delivering the shock)

# ALWAYS CALL!!!

## ADVANCED HEART FAILURE CENTER

- Non-Urgent Needs (prescription refills, questions, appointments, etc.) **404-605-5566**
- Urgent Needs (Immediate response required) **404-605-3066**
- Emergency Needs **911**

