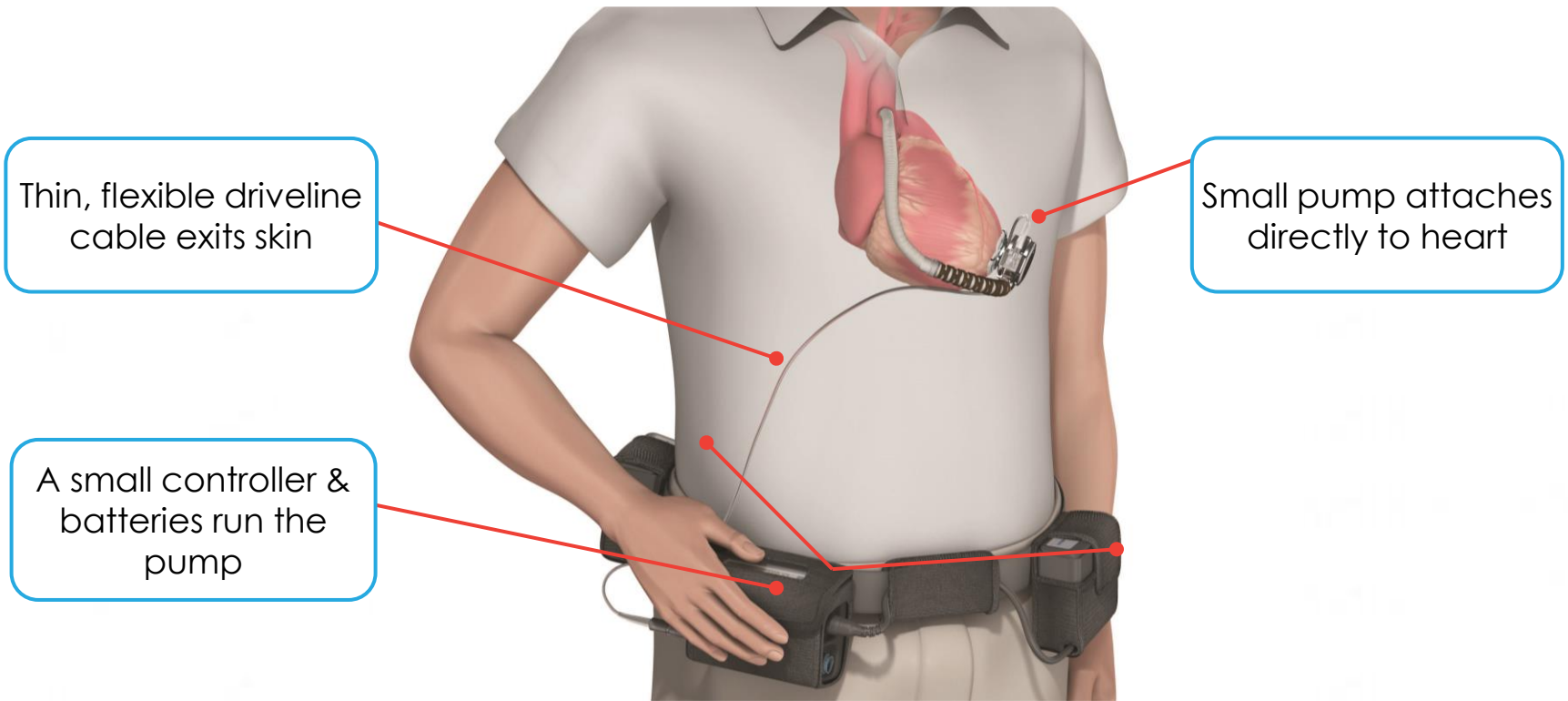




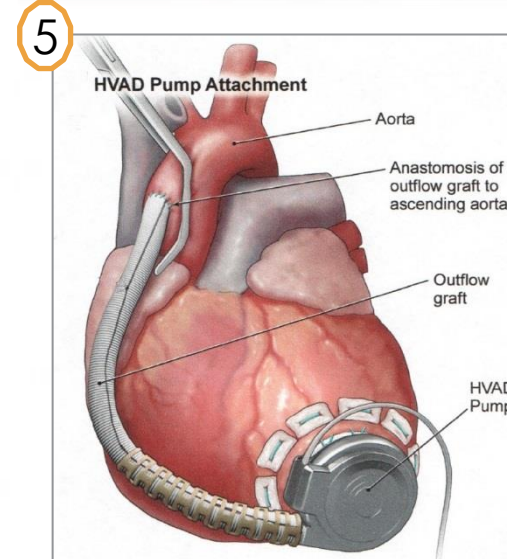
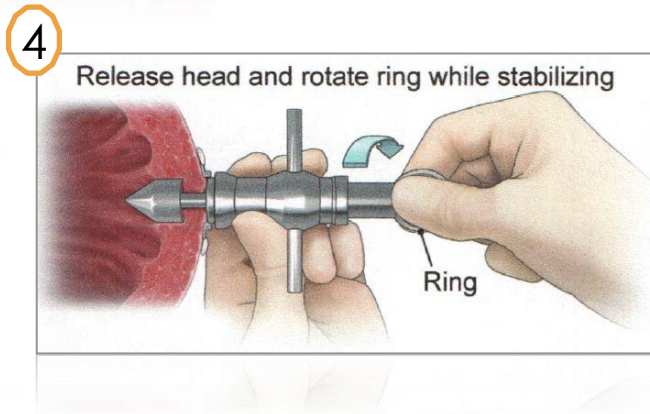
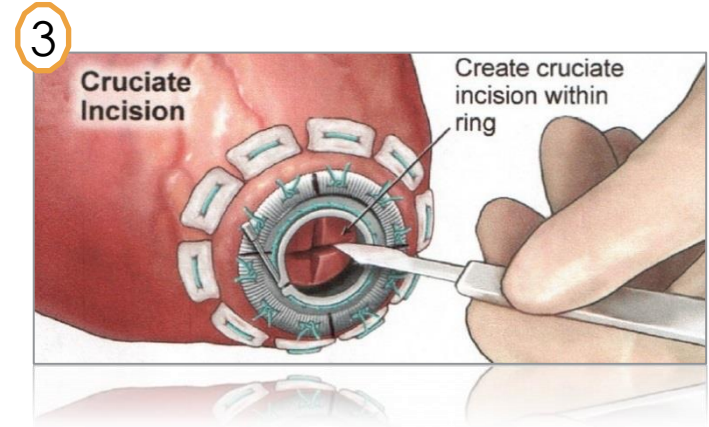
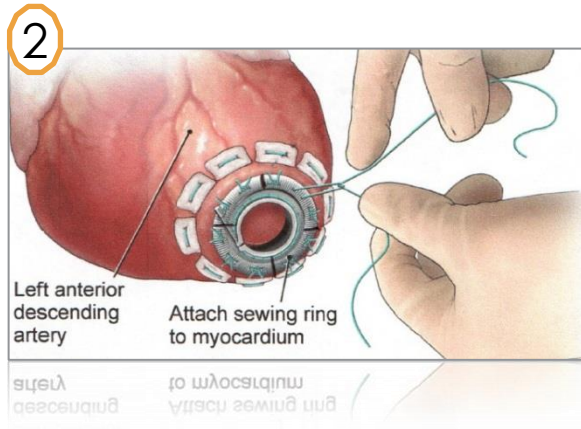
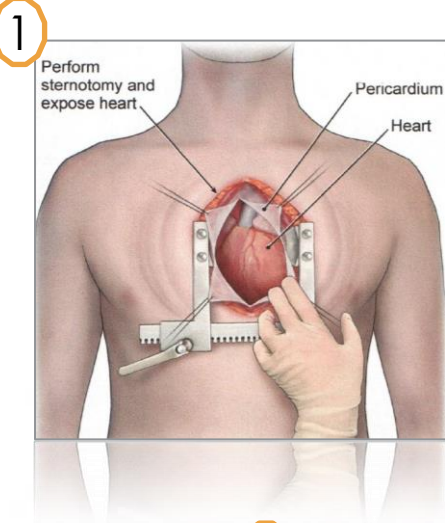
# HVAD<sup>®</sup> System

Essential Training For Healthcare Providers

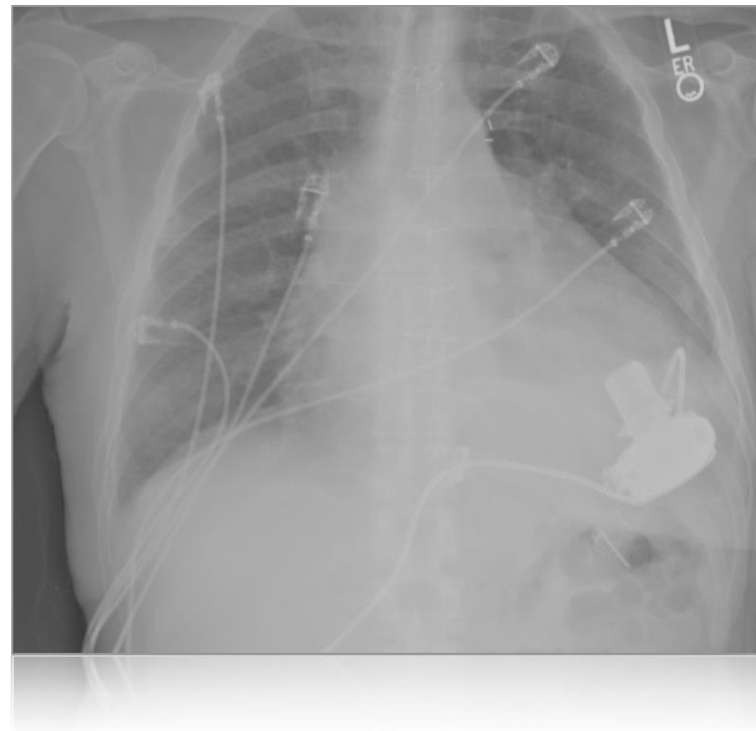
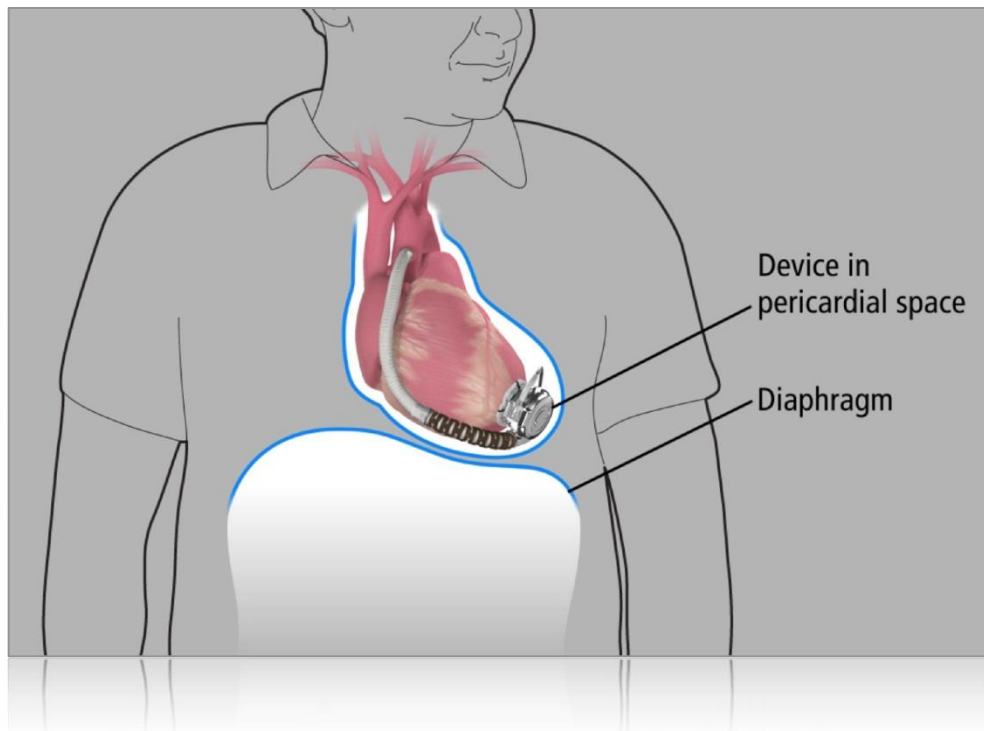
# The HVAD<sup>®</sup> System



# Surgical Implant Overview



# Pericardial Placement

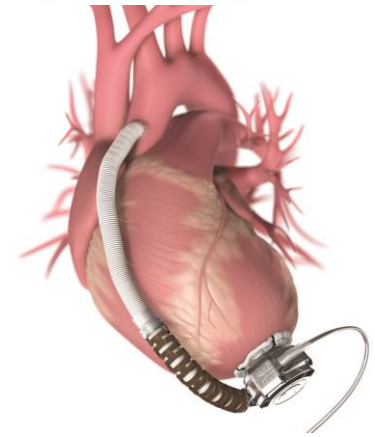


# HeartWare<sup>®</sup>

## HVAD<sup>®</sup> Pump

# The HVAD<sup>®</sup> System: Pump

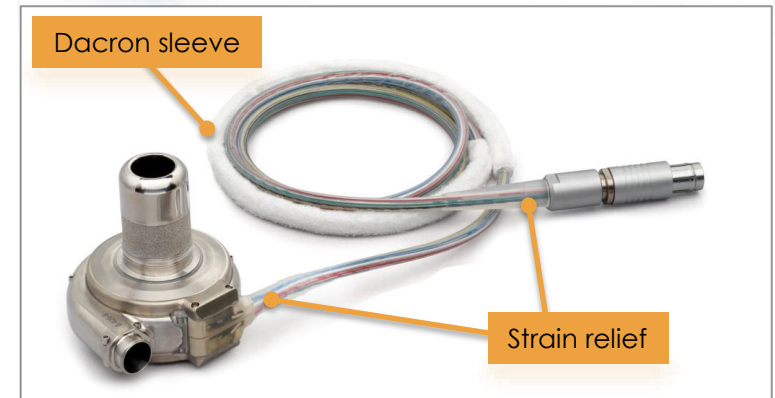
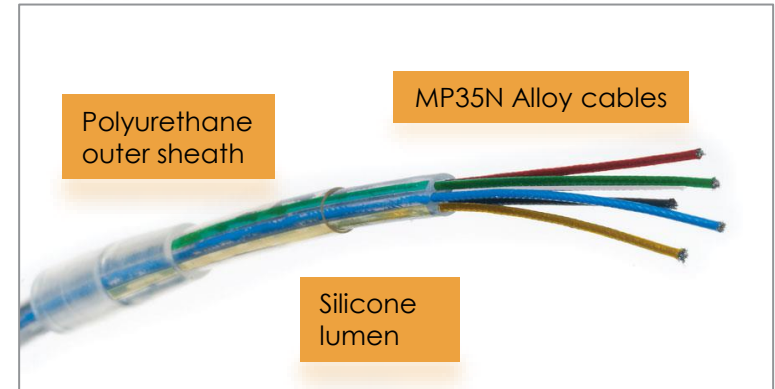
- Continuous flow, centrifugal pump
- 50cc displacement volume
- Weighs 160g
- Wide-blade impeller is the only moving part
- Hybrid magnetic / hydrodynamic suspension
- Wear-less system (no bearings)
- Dual motors designed to provide power efficiency and redundancy





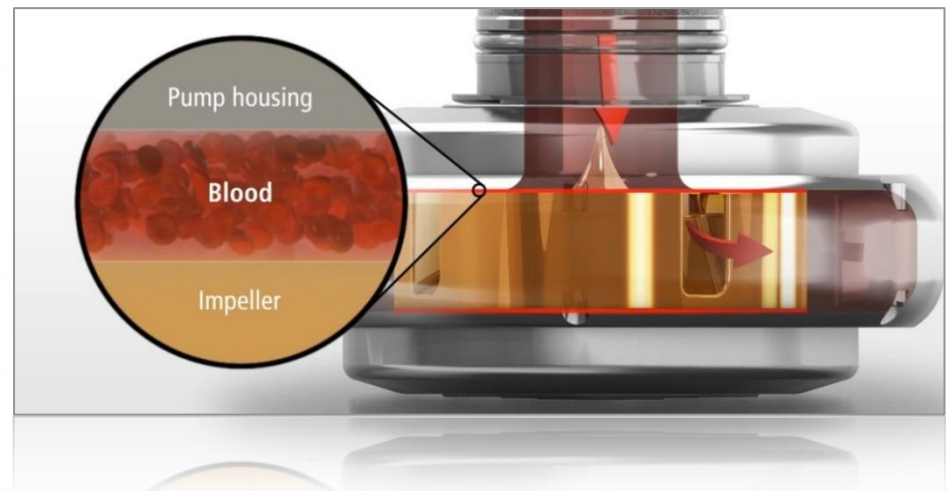
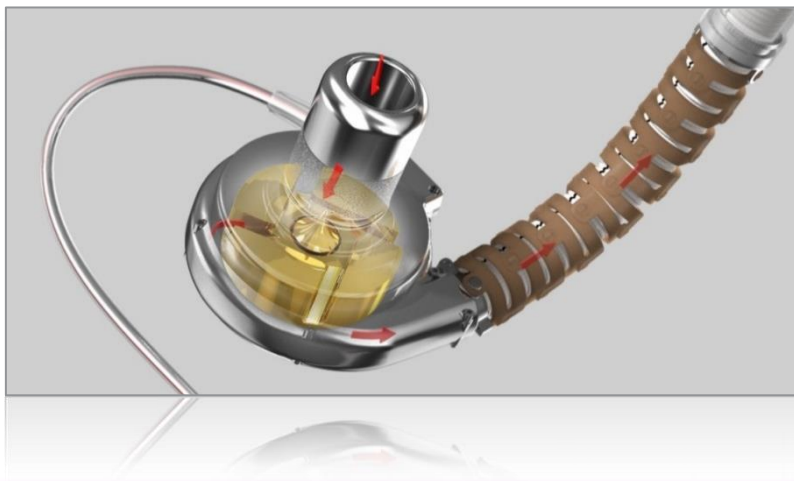
# Driveline Components

- MP35N Alloy Cables (similar to pacemaker wires)
- Silicone Lumen
- Polyurethane Outer Sheath
- Strain Relief at Connectors
- Woven Polyester Sleeve



# HVAD<sup>®</sup> Pump Suspension: Magnetic and Hydrodynamic

- Wide-blade impeller is magnetically and hydrodynamically suspended
  - Motor stators provide the active magnetic force that helps run the pump
  - Hydrodynamic thrust bearing generates a fluid film on which the rotating impeller slides (bearing “lifts” the impeller off the housing)
- HVAD Pump flow is preload dependent and afterload sensitive





**HeartWare®**

**Patient Electronics and Accessories**

# The HVAD® System: Patient Electronics and Accessories



HVAD® Controller



HVAD® Patient Pack



HVAD® Shoulder Pack



HVAD® Waist Pack



HVAD® Battery Charger and Batteries



HVAD® Controller AC Adapter



HVAD® Controller DC Adapter

# HVAD<sup>®</sup> Controller

There are 4 ports on the controller.

## Data Cable Connection

Usually covered with dust cap  
Accepts the data cable from the monitor  
Accepts the red alarm adapter

## Driveline Connection

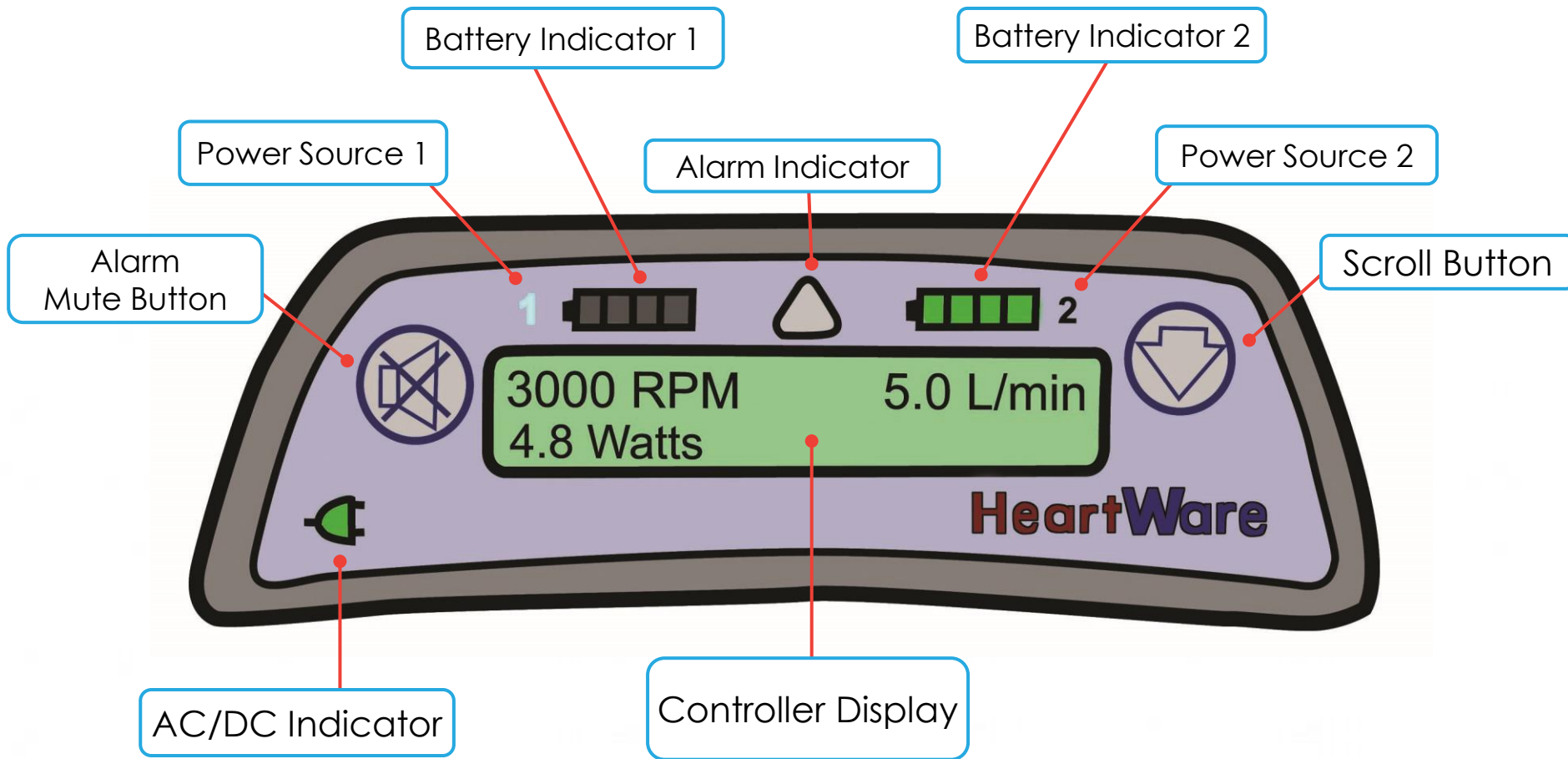
Connects the pump driveline to the controller.  
Should never be removed unless performing a controller exchange.



## Power Connections

Connects the controller to the power source  
Accepts battery, AC, or DC adapter power.  
**Never** disconnect both power sources at the same time or  
the pump will stop.

# HVAD<sup>®</sup> Controller: Display Overview



# HVAD<sup>®</sup> Controller

- Microprocessor based unit that controls and manages VAD operation
- Internal rechargeable battery used *only* to power an audible “no power” alarm
- Controller attempts to restart pump in case of a pump stop
- Controller checks the health of critical components and pump power sources



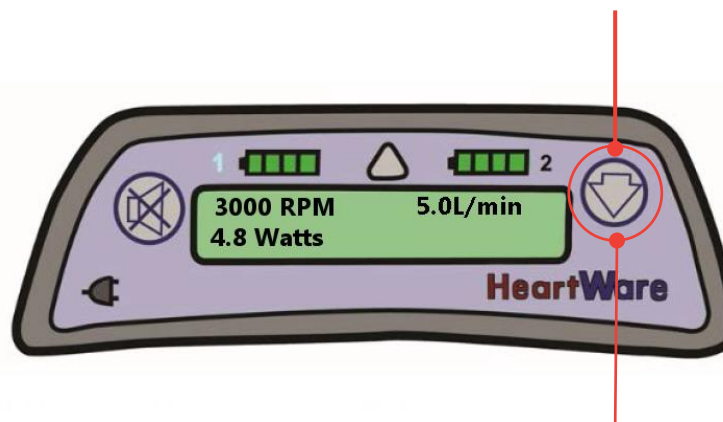
# HVAD<sup>®</sup> Controller: Settings Screens

## Order of Settings

1. Battery Cycles
2. Low Flow Alarm Limit
3. High Power Alarm Limit
4. Hematocrit
5. RPM Setting
6. Suction Response
7. Lavare Status
8. Peak
9. Trough
10. Implant Date
11. Controller Date
12. VAD ID
13. Patient ID
14. Controller Software Version

## To enter Controller settings screens

Press and hold arrow button for two seconds then tap the arrow button to scroll through the settings.  
Note: Not accessible during high priority alarm. Low and medium alarms must be acknowledged before accessing the settings screen



## To exit Controller settings screens

Press and hold arrow button for two seconds.  
Automatic exit after 60 seconds of inactivity and/or if an active alarm sounds.



# HVAD<sup>®</sup> Controller: Static Electricity

- ESD is most noticeable in dry environments and near certain materials like silk or carpeting
- To reduce the chance of ESD damage to the controller patients should:
  - Practice good power and battery connection techniques
    - Don't touch the pins in the power port on the controller
    - Don't leave the power ports on the controller open for extended periods of time
  - Be careful around electronic devices and activities that are prone to static electricity (e.g. TV and computer screens, removing clothes from the dryer, vacuuming, etc.)
  - Use anti-static dryer sheets, fabric softener and a humidifier

Note: In patients who may be at risk of cardiovascular collapse associated with pump stoppage, ESD education is particularly important.

# HVAD® System: Power Sources

**The Controller requires two power sources at all times**  
**The Controller draws power from one power source at a time**

Three Options:

1. One battery and AC adapter




2. Two batteries

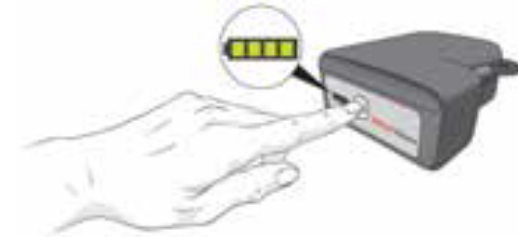






3. One battery and DC adapter



# Power Sources: Battery

- Each battery can provide 4 to 7 hours of support
- Pressing the Test Button  will light the Battery Capacity Display
- When one battery is depleted to <25%, the controller will automatically switch to the other battery



Battery Capacity	Battery Capacity Display
75-100%	4 GREEN lights 
50-74%	3 GREEN lights 
25-49%	2 GREEN lights 
less than 25%	1 GREEN light 

NOTE: The battery capacity display on the battery is similar to the battery indicator display on the controller except that only green lights are used on the batteries.

# Power Sources: AC and DC Adapters

- The AC/DC adapter will always be the primary source of power if connected

AC Adapter



DC Adapter



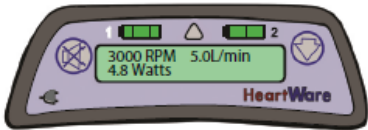
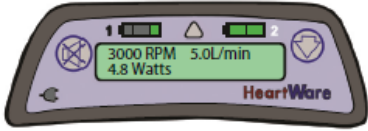
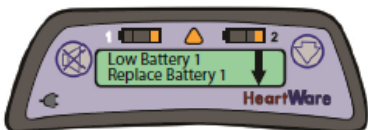
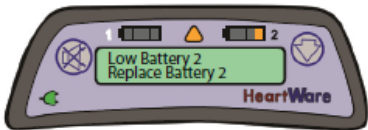

A **green** light will illuminate on adapter when correctly plugged into wall/car

NOTE: When using the AC or DC adapter, a battery should always be connected to the controller's second power connection.



CAUTION: The DC adapter is for use in vehicles only and may not fit in some vehicles

# Power Sources: Controller Indicators

If your controller shows:	It means:	You:
	<p>You have 2 fully charged batteries connected to your controller. In this example, the battery connected to Power Source 1 is providing primary power.</p>	<p>Do not need to change either battery.</p>
	<p>The battery connected to Power Source 1 has less than 25% capacity. In this example, the battery connected to Power Source 2 is fully charged and providing primary power.</p>	<p>Do not need to change either battery.</p>
	<p>Both batteries connected to your controller have less than 25% capacity. In this example, the battery connected to Power Source 1 is providing primary power. The down arrow indicates there is another alarm.</p>	<p>Should attach a full battery or AC adapter to Power Source 1.</p>
	<p>The battery connected to Power Source 2 has less than 25% capacity. In this example, an AC or DC adapter is connected to Power Source 1 and is providing primary power.</p>	<p>Should connect a fully charged battery to Power Source 2.</p>
	<p>The battery connected to Power Source 2 has limited time remaining. The battery connected to Power Source 1 has less than 25% capacity and is providing primary power.</p>	<p>Should attach a full battery or AC or DC adapter to Power Source 2. Then, attach a full battery or AC or DC adapter to Power Source 1. Never disconnect both batteries at the same time. This will stop your pump.</p>
<p>The controllers shown above are meant to be examples of the changes you might see during the day.</p>		





# Power Sources: Battery Charger

- Charges up to 4 batteries at once
- Takes up to 6 hours to fully charge a depleted battery
- Powered by AC outlet (wall) only
- Charger should remain plugged in
- Connect and disconnect charger/ battery with same action as controller/battery
- Batteries not in use should be connected and stored in the charger





# Battery Charger Status Indicators

Battery Charger “Status” Light	What it means
Yellow 	Battery being charged; NOT ready for use.
Flashing Yellow 	Battery not charging. Check battery connections. If connections are intact, switch to another battery slot. If problem persists, return battery to HeartWare.
Red 	Battery too cold or too hot; waiting to charge.
Flashing Red 	Defective battery. DO NOT use. Mark battery and return to HeartWare.

# Convertible Patient Pack



- Holds the controller and two batteries for daily use
- A viewing window allows you to see the controller display
- Velcro strips keep the bag closed and the accessories securely fastened
- It can be worn over the shoulder, around the waist or a combination of both

# Shoulder and Waist Packs

HeartWare® Shoulder Pack



HeartWare® Waist Pack



- Holds the controller and two batteries for daily use
- A viewing window allows you to see the controller display
- Magnetic snaps keep flaps closed and allow easy access to equipment

# HVAD<sup>®</sup> Shoulder and Waist Pack Use for Patients with Pacemakers or AICDS

- HVAD<sup>®</sup> Shoulder Pack and HVAD<sup>®</sup> Waist Pack contain magnetic closures
- Patients with an ICD or Pacemaker should keep these packs away from their chests
- Per guidelines from pacemaker and ICD manufacturers, magnets should be kept at least 6 inches (15 centimeters) away from the pacemaker or ICD (please refer to manufacturer guidelines for additional information)



# HVAD® Shower Bag

- Allows patients to shower with the HVAD® System
- Water resistant (not water proof) – protects the controller and batteries from direct water spray and moisture
- Instructions on proper packing, use and care can be found in the Patient Manual



# HeartWare®

## Managing HVAD System Alarms

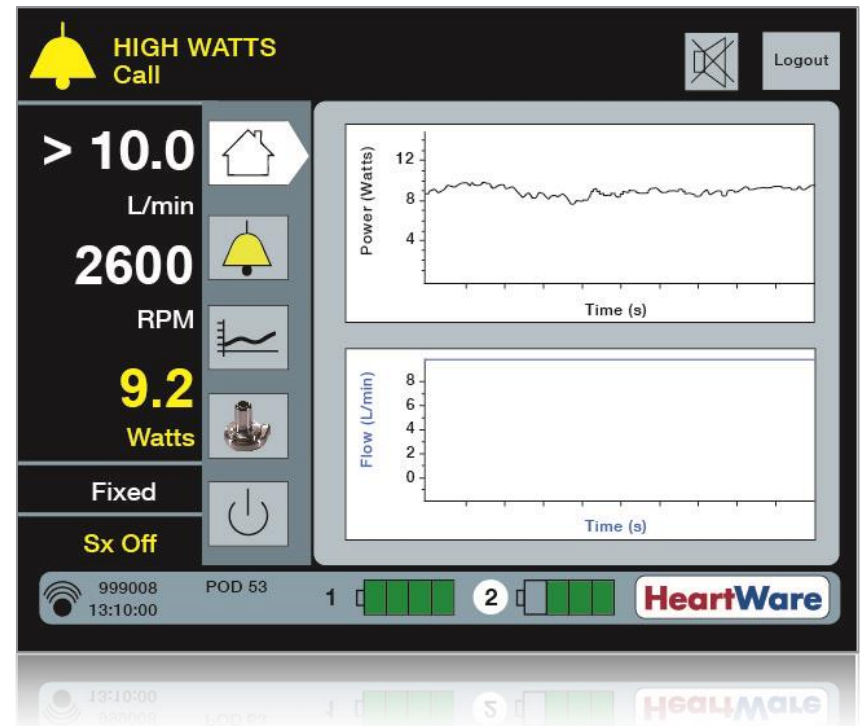
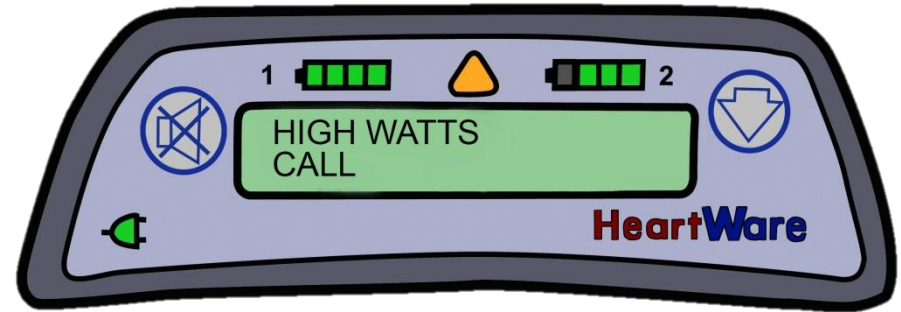
Alarm Name	Alert Type	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display
<b>HeartWare® System Alarm Troubleshooting Clinician Guide</b>										
<b>Alarm Type: Critical</b>										
<b>Base Alarm</b>	Continuous Audible Alarm	Low	High	Low	High	Low	High	Low	High	Low
<b>Flowing Stop</b>	Flow Stop	Low	High	Low	High	Low	High	Low	High	Low
<b>Alarm Type: Major</b>										
<b>Control Battery 1</b>	Control Battery 1	Low	High	Low	High	Low	High	Low	High	Low
<b>Control Battery 2</b>	Control Battery 2	Low	High	Low	High	Low	High	Low	High	Low
<b>Alarm Type: Moderate</b>										
<b>Flowing Alarm</b>	Flowing Alarm	Low	High	Low	High	Low	High	Low	High	Low
<b>High Alarm</b>	High Alarm	Low	High	Low	High	Low	High	Low	High	Low
<b>Electric Fault</b>	Electric Fault	Low	High	Low	High	Low	High	Low	High	Low

Alarm Name	Alert Type	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display	OS Display
<b>HeartWare® System Alarm Troubleshooting Clinician Guide (Continued)</b>										
<b>Alarm Type: Moderate (Continued)</b>										
<b>Flowing Alarm</b>	Flowing Alarm	Low	High	Low	High	Low	High	Low	High	Low
<b>Alarm Type: Low</b>										
<b>Low Alarm</b>	Low Alarm	Low	High	Low	High	Low	High	Low	High	Low



# Alarms Overview

- Alarm conditions are displayed on the controller and monitor
- Alarm priority
  - Low
  - Medium
  - High
- Each alarm has:
  - Unique sound
  - Visual display
  - Message



# HVAD<sup>®</sup> Controller: Alarm Indicator & Mute Button

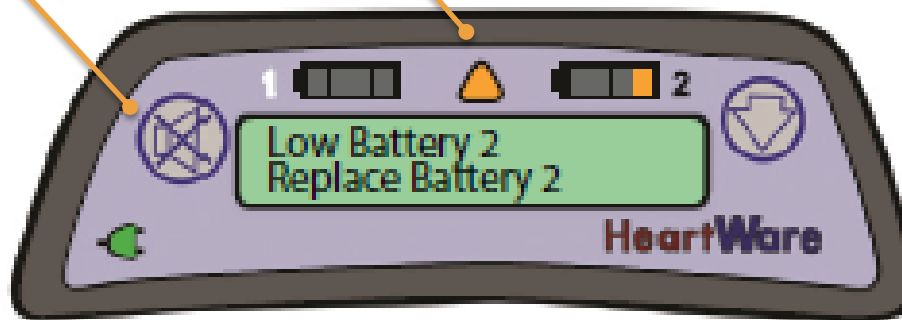


Alarm Indicator Symbol



Alarm Mute Button

- Low Priority Alarms: **Solid Yellow**
- Medium Priority Alarms: **Flashing Yellow**
- High Priority Alarms: **Flashing Red**



# HVAD<sup>®</sup> Controller: Alarm Indicator & Mute Button

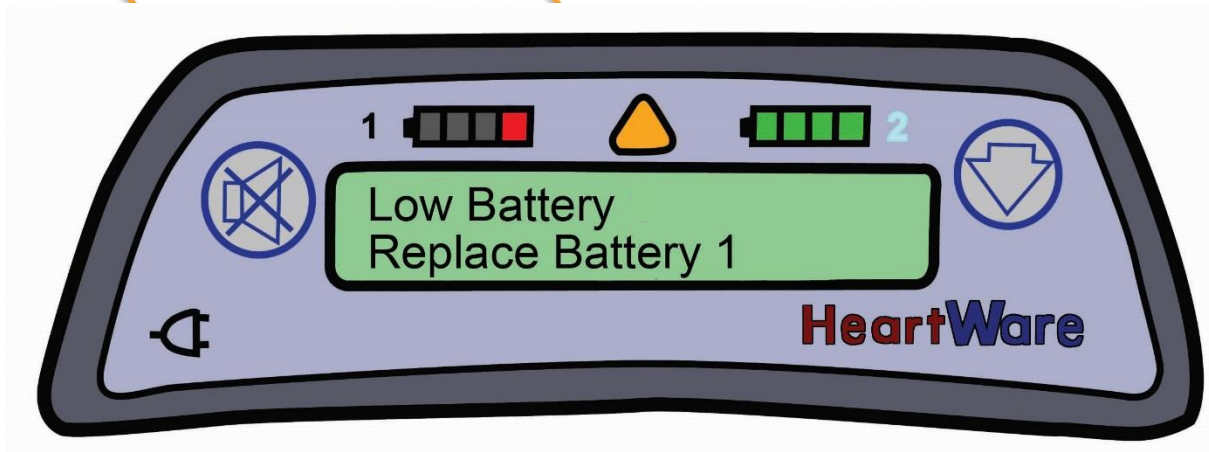


Alarm Indicator Symbol









Alarm Mute Button



- Low Priority Alarms: **Solid Yellow**
- Medium Priority Alarms: **Flashing Yellow**
- High Priority Alarms: **Flashing Red**



# Summary of Alarm Display and Audio by Alarm Type

	High	Medium	Low
Controller Display	Flashing Red Triangle 	Flashing Yellow Triangle 	Solid Yellow Triangle 
Controller Audio	<ul style="list-style-type: none"> <li>• Loudest intermittent beep</li> <li>• Cannot be silenced by the Mute Button</li> </ul> 	<ul style="list-style-type: none"> <li>• Intermittent beep that becomes louder in 1 and 5 min</li> </ul> 	<ul style="list-style-type: none"> <li>• Intermittent beep that becomes louder in 5 and 10 min</li> </ul> 
Controller Silencing	<ul style="list-style-type: none"> <li>• Cannot be silenced by the Mute Button</li> <li>• The alarm will clear once the problem is resolved</li> </ul>	<ul style="list-style-type: none"> <li>• May be silenced for 5 min or 1 hour</li> <li>• Controller and Electrical Faults may be permanently silenced</li> </ul>	<ul style="list-style-type: none"> <li>• May be silenced for 5 min</li> </ul>

# High Priority Alarms (Blank or Flashing Red)

Alarm Type	Alarm Display (line 1)	Action (line 2)
High – Critical (Blank Display) 	No Message	No Message
High – Critical (Flashing Red) 	VAD Stopped	Connect Driveline
	VAD Stopped	Change Controller
	Critical Battery	Replace Battery 1
	Critical Battery	Replace Battery 2
	Controller Failed	Change Controller


# High Priority Alarms: Blank Display



Alarm Display (line 1)	Action (line 2)	Potential Causes	Potential Actions
No Message	No Message	<ul style="list-style-type: none"><li>• No power to pump</li><li>• Pump has stopped</li></ul>	<ol style="list-style-type: none"><li>1. Connect two new power sources</li><li>2. Replace controller</li><li>3. Contact Clinical Specialist</li></ol>

**No Power (no message):** If both power sources are disconnected from the controller, a loud continuous alarm will sound and there will be NO message on the controller display. The HVAD® Pump is NOT pumping and power sources should be connected immediately. If this action does not resolve the alarm condition, replace the controller.

# Medium Priority Alarms (Flashing Yellow)

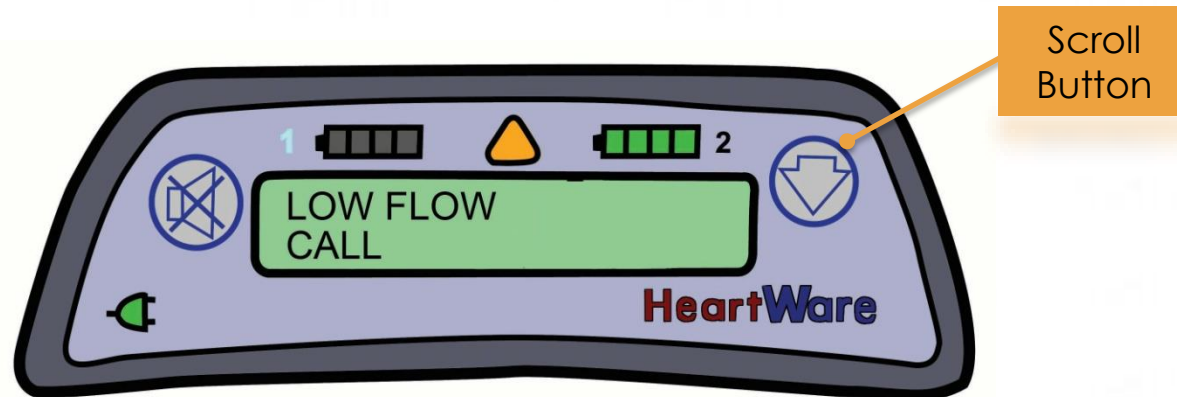
Alarm Type	Alarm Display (line 1)	Action (line 2)
Medium (Flashing Yellow) 	Controller Fault	Call
	Controller Fault	Call: ALARMS OFF
	High Watts	Call
	Electrical Fault	Call
	Low Flow	Call
	Suction	Call



# Medium Priority Alarms



- When a medium alarm self resolves there is no audible alarm or light displayed in the Alarm Indicator located on the controller
- However, the message on the controller display will remain until the message is cleared by pressing the Scroll Button
- A new alarm will also clear a resolved medium alarm from the controller display



# Medium Priority Alarms: Controller Extended Mute




**Medium alarms can be muted for one hour from the controller**

- Press and hold the ALARM MUTE BUTTON
- Then press and hold the SCROLL BUTTON
- Release the ALARM MUTE BUTTON
- Release the SCROLL BUTTON

The controller display and alarm indicator will continue to display all active alarms. Any new alarm condition will inactivate the 60-minute mute.

# Low Priority Alarms (Solid Yellow)



Alarm Type	Alarm Display (line 1)	Action (line 2)
Low (Solid Yellow) 	Low Battery 1	Replace Battery 1
	Low Battery 2	Replace Battery 2
	Power Disconnect	Reconnect Power 1
	Power Disconnect	Reconnect Power 2

# HeartWare®

## Setting Speed

# HVAD<sup>®</sup> Pump: Operating Guidelines

Total Speed Range: 1800 – 4000 RPM

Recommended clinical operating speed range:  
2400 – 3200 RPM

1800-2400 RPM  
Should only be used  
during implant  
procedure when  
weaning from CPB

Speed (RPM)	Power (watts)	Flow (L/min)
2400	2.5	3
3200	8.5	8

3200-4000 RPM  
Speeds above 3200  
increase the risk of  
suction events

# Understanding the Pump and Patient Interaction<sup>1</sup>

## PRELOAD

### Low

Hypovolemia  
Right Heart Failure  
Tamponade

### High

Hypervolemia

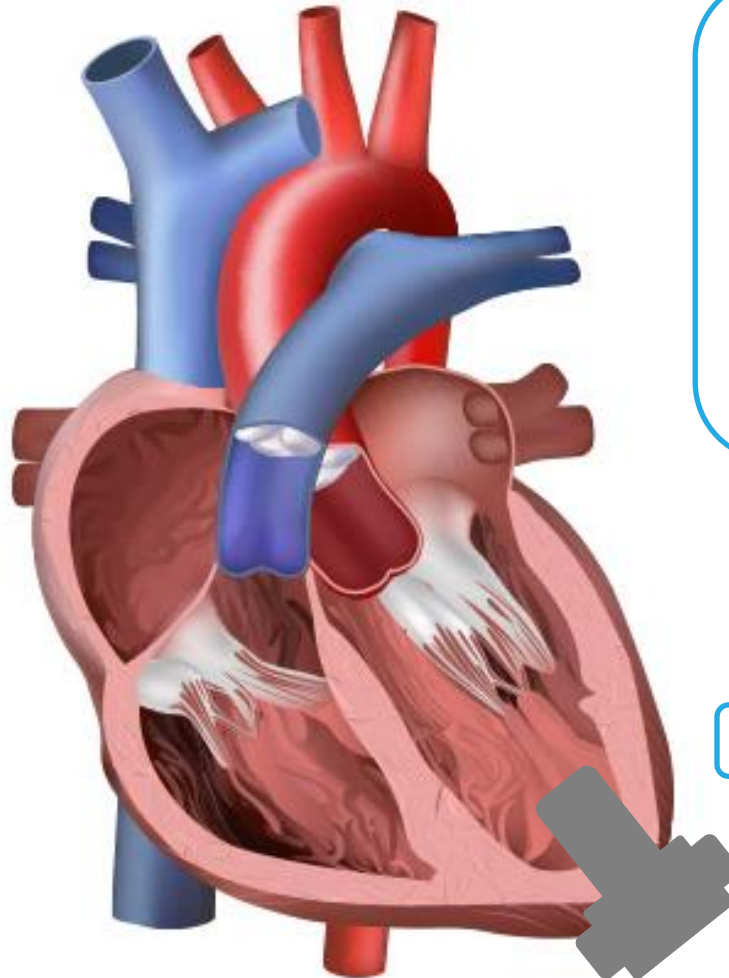
## CONTRACTILITY

### Low

Beta blockers  
Worsening heart failure

### High

Beta agonist  
LV recovery



## AFTERLOAD

### Low

Low SVR – SIRS, Sepsis

### High

High SVR – heart failure state, anesthesia

Device Set Speed

<sup>1</sup>Feldman, et.al., 2013 ISHLT MCS Guidelines. The Journal of Heart and Lung Transplantation, Vol 32, No 2, February 2013

# Postoperative Management: HVAD<sup>®</sup> Pump Speed

- Optimal speed is set to maintain a pump flow index between 2.0-2.6L/min/m<sup>2</sup>
- Echocardiography can be helpful when setting speed. It can provide detailed information on right heart function, aortic and mitral valve function, septal positioning, and inflow cannula positioning
- Avoid setting pump speed too high, this may lead to shifting of the intra-ventricular septum, arrhythmia or LV collapse<sup>1</sup>
- Amount of Aortic Valve opening is still being studied and general consensus for standard practice has not yet been reached<sup>1</sup>

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.





# Perioperative and Long Term Management

# Preoperative Considerations

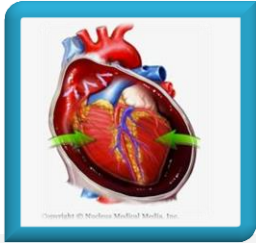
- Begins with preoperative patient management, selection and timing of implant
- Preoperative goals should include<sup>1</sup>:
  - Improving nutritional status
  - Lowering pulmonary vascular resistance to maximize right ventricle function
  - Aggressive volume management to minimize RV work load
  - Optimization of coagulation
  - Optimization of renal, hepatic, pulmonary and neurologic function
  - Treatment of infection
  - Adequate evaluation and identification of patient support systems

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.

# Potential Complications\*



Bleeding



Tamponade



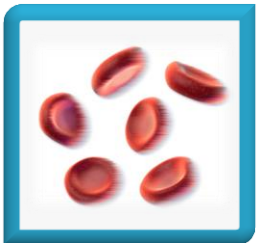
Arrhythmia



Right Heart Failure



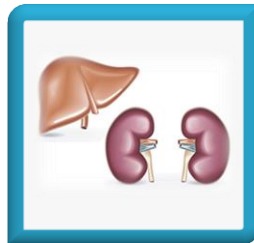
Infection



Hemolysis



Thromboembolic Events



Kidney/Liver Dysfunction



Stroke



Respiratory Failure

*\*See IFU for a full list of potential complications associated with the HVAD System*

# Postoperative Management: Hemodynamics

- After implantation, the patient is returned to the Intensive Care Unit
- Continuous flow pumps are preload dependent and afterload sensitive
- Consider clinical (patient) related changes when assessing changes in pump flow
- Patients may require inotropic assistance to improve right ventricular function
- Fluids, medications and heart rate and rhythm should be optimized to maintain a pump flow index between  $2.0 \text{ L/min/m}^2$  and  $2.6 \text{ L/min/m}^2$

# Postoperative Management: Blood Pressure

- **Mean arterial pressure should be maintained less than 85 mmHg**
- HVAD<sup>®</sup> Pump increases in speed should be done slowly and over time to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling after implant
- Because the HVAD pumps blood continuously throughout the entire cardiac cycle, aortic flow is also present during diastole when normal pulsatile flow is absent<sup>1</sup>
- Pulse pressure is influenced by LV contractility, intravascular volume, pre-load and after-load pressure, and by pump speed<sup>1</sup>
- Vasopressors or vasodilators may be used to maintain vascular tone

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.

# Postoperative Management: Right Heart Failure

- Warning signs of right heart failure include:
  - Low or decreasing HVAD flow
  - Decrease in MAP
  - Decrease in PCWP
  - Increase in CVP
  - Dilatation of right ventricle on ECHO
- Treatment may include<sup>1</sup>:
  - Adjustment of LVAD speed to decrease RV preload
  - Use volume to increase CVP to 15-18 mmHg
  - Inotropic agents
  - Use of pulmonary vasodilators (e.g., Nitric Oxide, Flolan)
  - Temporary RVAD if no response to speed change, volume, or pharmacology

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.

# Postoperative Management: Tamponade

- Usually occurs in the first 24 hours but may also occur later
- Tamponade is a consequence of bleeding and may be difficult to diagnose
- TEE can be helpful in making the differential diagnosis
- Hemodynamic changes consistent with tamponade:
  - Decreased MAP
  - Increased CVP
  - Decreased VAD flow
  - Decreased pump pulsatility



# Postoperative Management: Bleeding<sup>1</sup>

- Minimize CPB time to reduce negative effects of extracorporeal circulation on platelets
- Normothermia should be maintained
- Limit dissection and practice meticulous surgical technique for hemostasis
- Use autologous transfusions and single donor platelets when available
- Coagulation labs should be checked and normalized as much as possible both during procedure and immediately post-op

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.

# Postoperative Management: Arrhythmia

- Arrhythmias affect RV function and decrease LV preload, flow may be reduced
- Arrhythmias are common in the immediate post op period
- Anti-arrhythmic drugs, pacemakers, and ICDs are compatible with the HVAD<sup>®</sup> System

# Postoperative Management: Anticoagulation

- Anticoagulation should be individualized for each patient
- Prior to initiation of anticoagulation, chest tube drainage should be less than 40 ml/hr for approximately three hours, the HCT should be stable without the need for transfusion of blood products, and coagulation factors approaching normal
- In general, begin low-dose heparin at 10 units/kg/hr on postoperative day one to a target PTT of 40-50 seconds
- Gradually increase the heparin dosage to maintain the PTT in a range of 50-60 seconds

# Long-Term Management: Anticoagulation and Antiplatelet

- Combination of Warfarin and Aspirin
- Warfarin should be started and titrated to maintain an INR of 2.0-3.0
- In general, ASA should be started at doses >81mg/day on POD 1, if no bleeding complications
- Check for ASA resistance with a reliable test (e.g., Verify Now<sup>®</sup>) and adjust ASA monotherapy accordingly
- Other multi-drug options include
  - ASA 81mg plus Aggrenox (ASA + extended release dipyridamole)
  - ASA 81mg plus Clopidogrel

For patients who are aspirin sensitive or otherwise intolerant, clopidogrel at doses of 75-150 mg/day is a viable alternative. A clopidogrel loading dose of 300 mg followed by 75 mg/day is recommended to reduce the lag time in reaching full therapeutic.

# Postoperative Management: Infection

- After HVAD® Pump implantation, continue systemic antimicrobials prophylaxis for 48 to 72 hours
- Remove mediastinal and pleural drains as soon as appropriate
- Early extubation, removal of monitoring lines, and patient ambulation are encouraged – rapid restoration of oral nutrition should be attempted using tube feeding if necessary

# Emergency Management

- It is OK to defibrillate patients supported with HVAD<sup>®</sup> System patients
- Follow appropriate ACLS protocols
- If chest compressions have been administered, confirm function and positioning of HVAD<sup>®</sup> Pump

# Driveline Care

- Good hand-washing technique
- Always use aseptic technique
- Dressing change protocol as per institutional guidelines
- Prevention of trauma is critical for prevention of infection, so driveline should be immobilized
- Education of the patient and caregiver in the care and maintenance of the driveline is critical in the effort to prevent infection<sup>1</sup>



CAUTION: Prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine or polymixin-neomycin-bacitracin should not be used as these ointments can injure the tissue adjacent to the exit site

<sup>1</sup>Slaughter, et al. (2010). Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *JHLT*, 29 (45), S1-S39.



# Nutrition / Activity / Hygiene

- Advance diet as tolerated
- Have patient ambulate as tolerated
- Contact sports are contraindicated
- No swimming
- Patients may travel via fixed wing aircraft or helicopter
- Showering is possible with the use of a HeartWare® Shower Bag and clinician approval; until clinician approval, sponge baths only

# Daily Checks

- Ensure there are no active alarms
- Ensure tight controller cable connections
- Examine exit site dressing
- Immobilize driveline
- Ensure batteries are charged
- Ensure back-up controller is available
- Confirm monitor availability

# Indications, Safety and Warnings

## **Brief Statement: HeartWare™ HVAD™ System**

Refer to the “Instructions for Use” for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at [www.heartware.com/clinicians/instructions-use](http://www.heartware.com/clinicians/instructions-use).