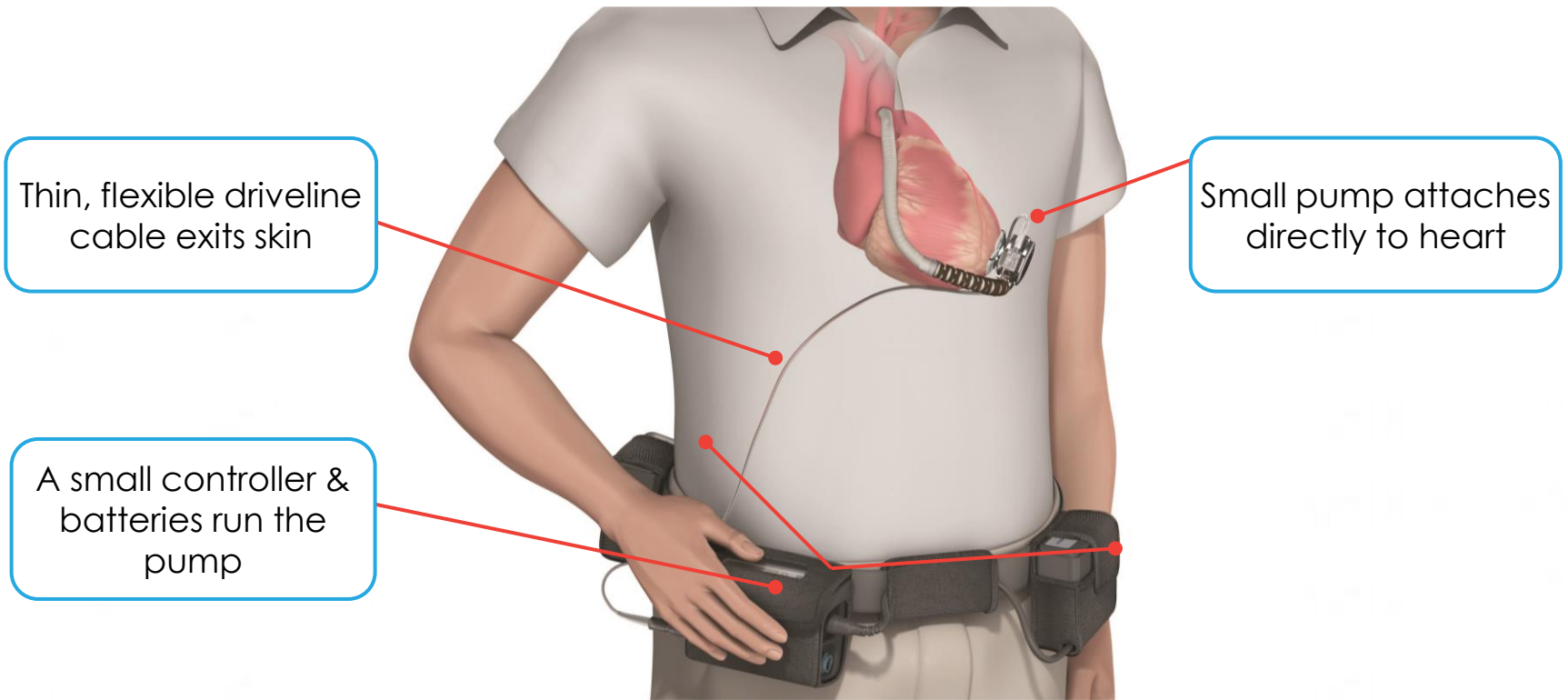




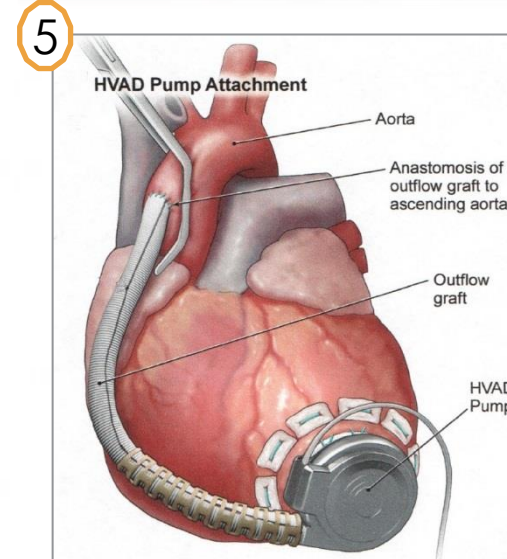
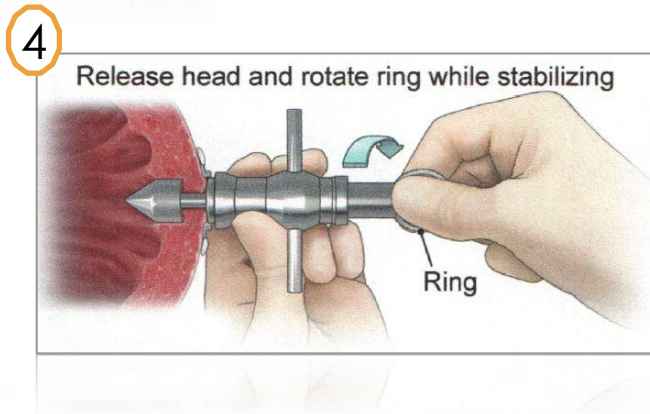
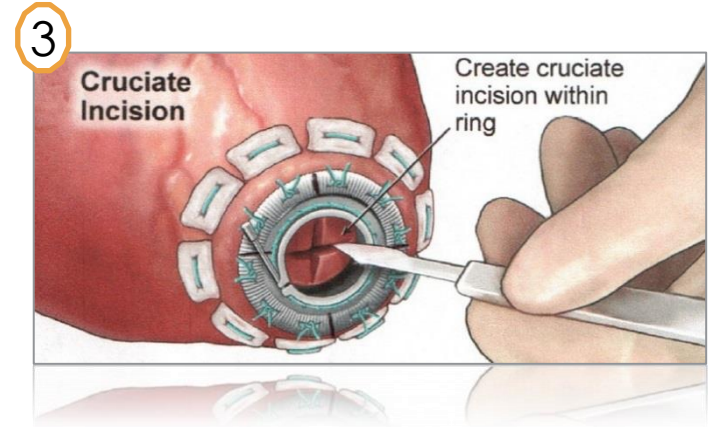
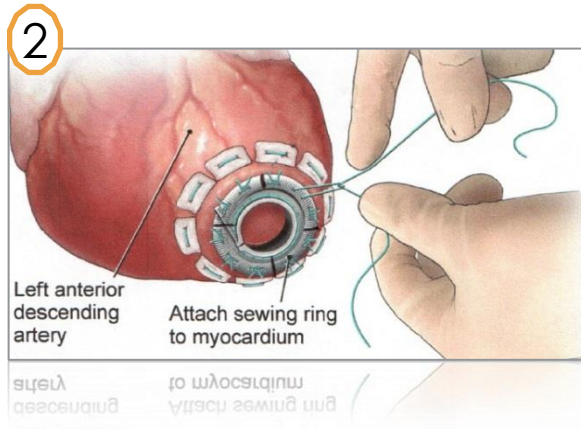
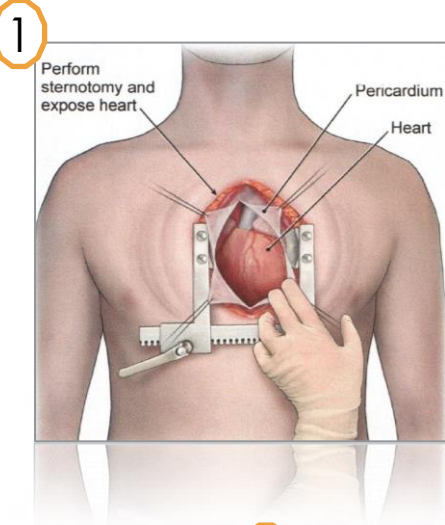
HVAD[®] System

Overview Hands-On Practicum

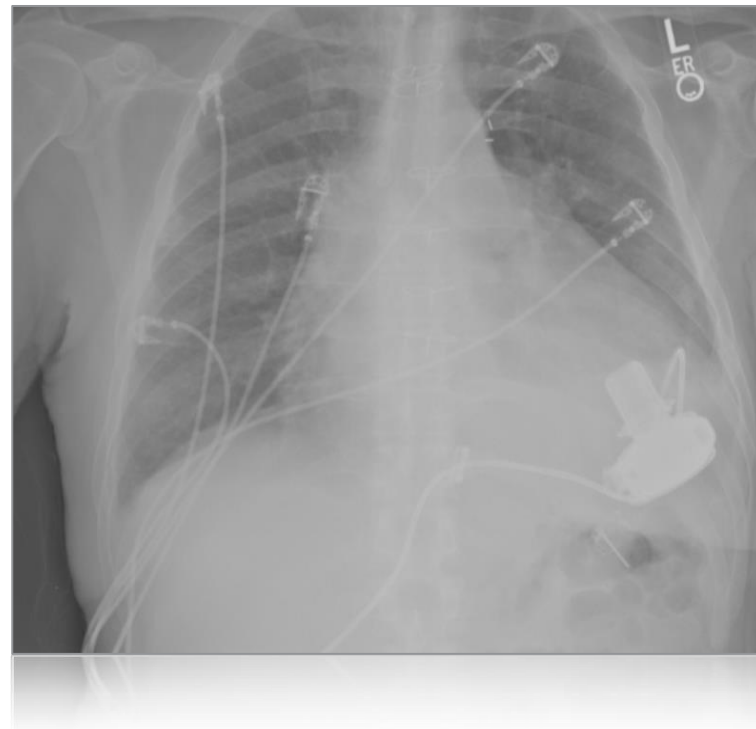
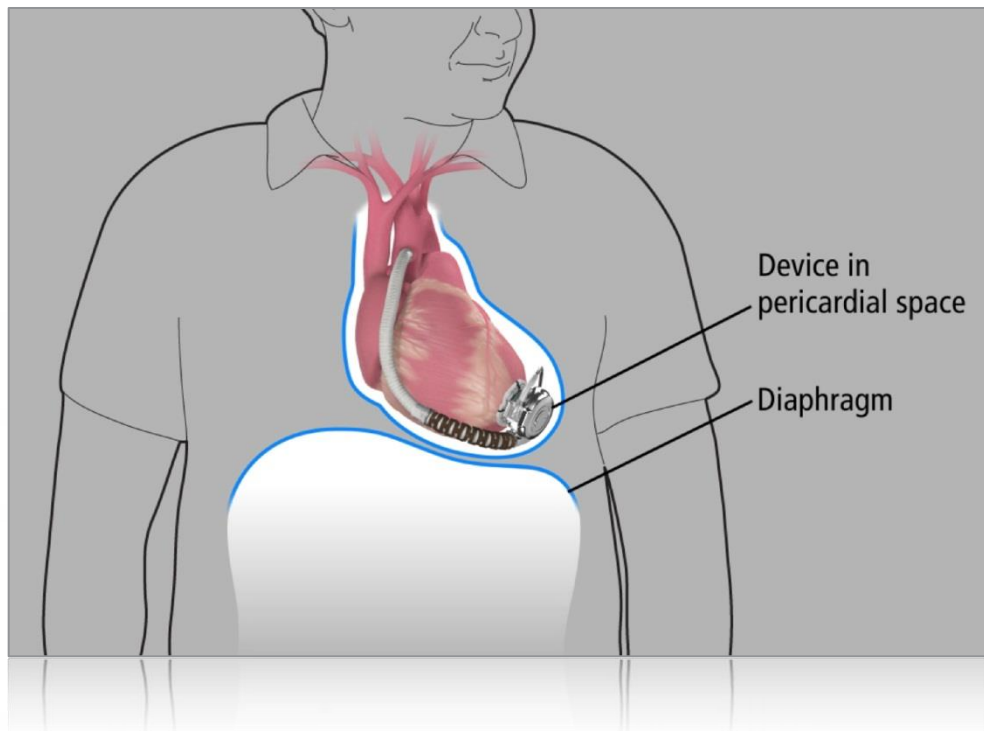
The HVAD[®] System



Surgical Implant Overview



Pericardial Placement

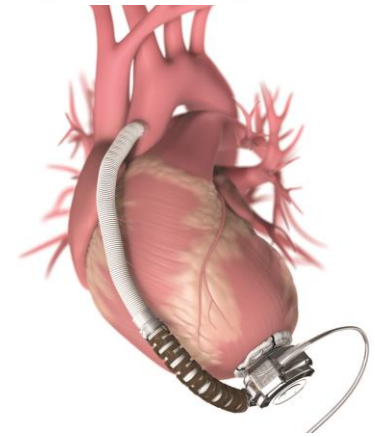


HeartWare®

HVAD® Pump

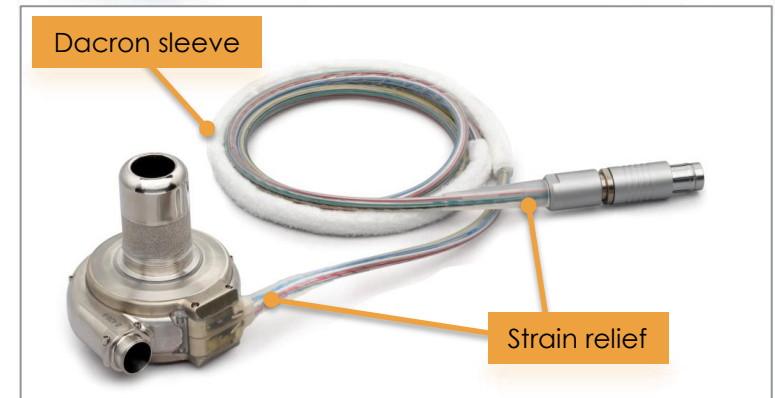
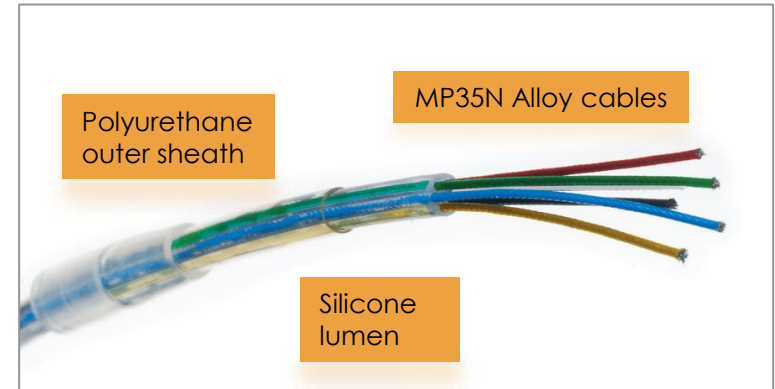
The HVAD[®] System: Pump

- 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



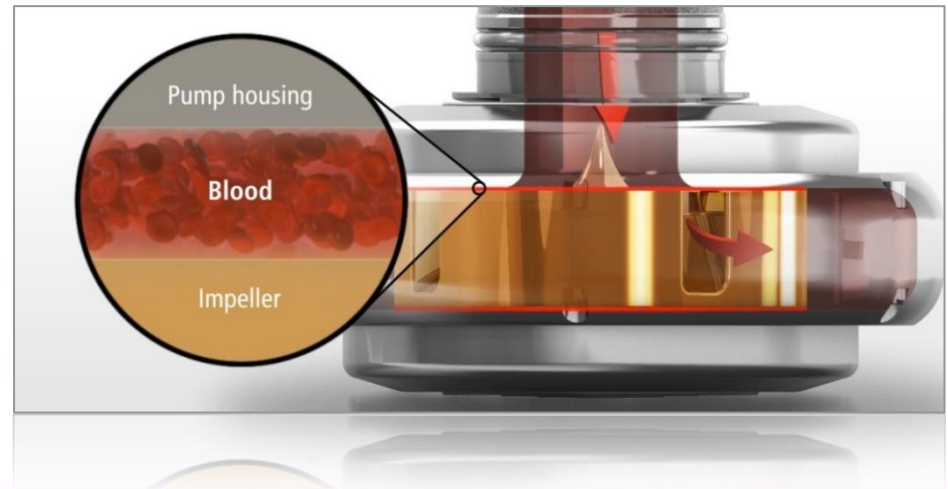
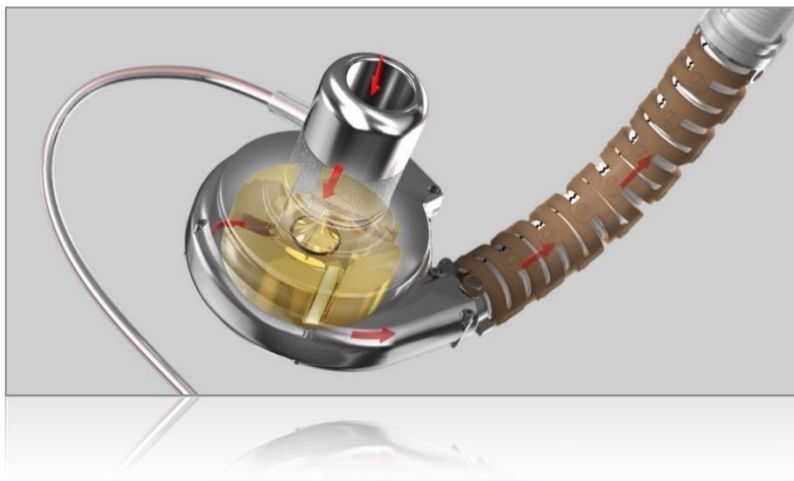
Driveline Components

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



HVAD[®] 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[®] 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

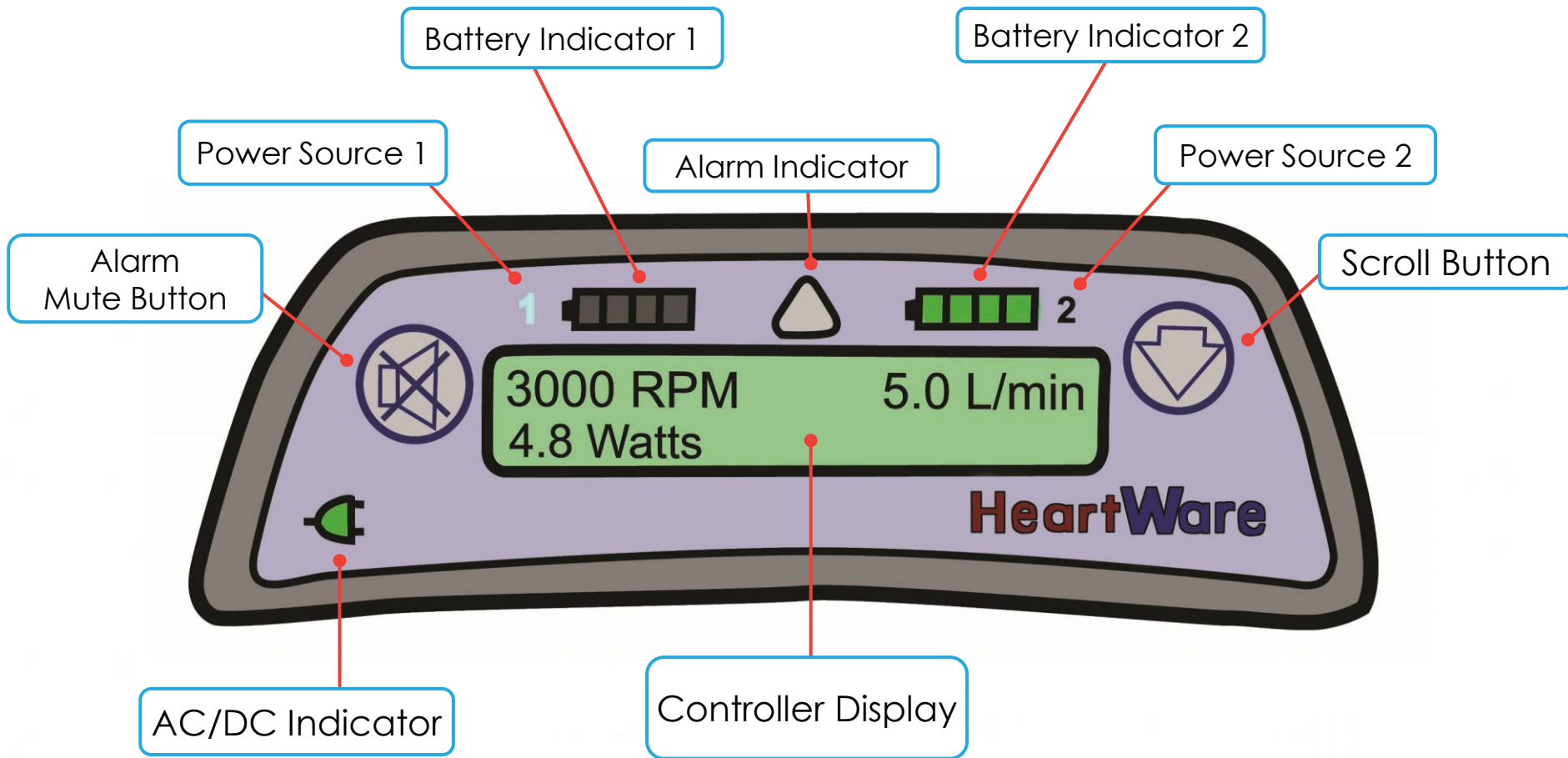
Connects the pump driveline to the controller.
Should never be removed unless performing a controller exchange.



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[®] Controller: Display Overview



HVAD[®] 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



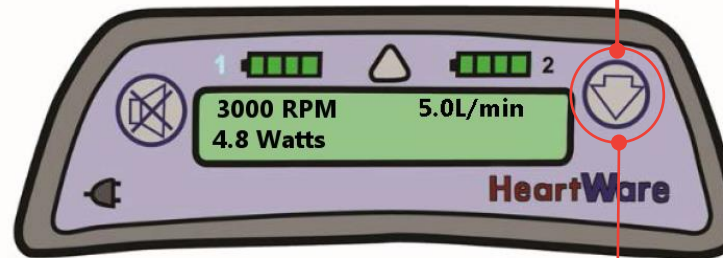
HVAD[®] Controller: Settings Screens

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[®] 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

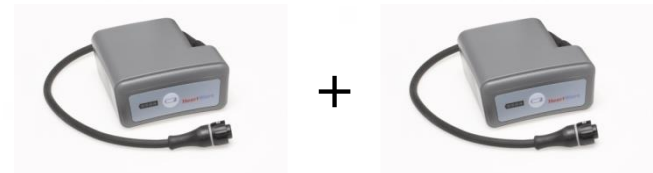
The Controller requires two power sources at all times
The Controller draws power from one power source at a time

Three Options:

1. One battery and AC adapter




2. Two batteries

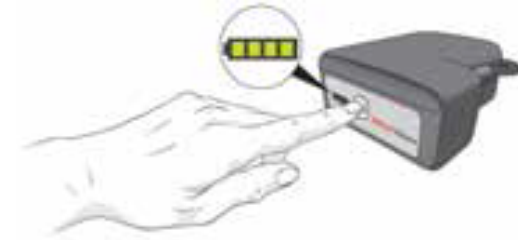






3. One battery and DC adapter



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



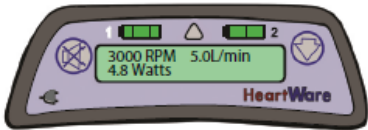
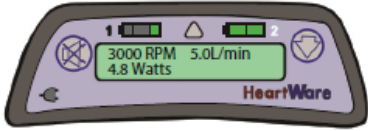
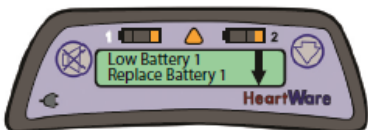
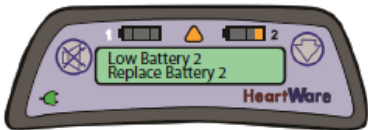

A **green** light will illuminate on adapter when correctly plugged into wall/car

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[®] Shoulder and Waist Pack Use for Patients with Pacemakers or AICDS

- HVAD[®] Shoulder Pack and HVAD[®] 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®

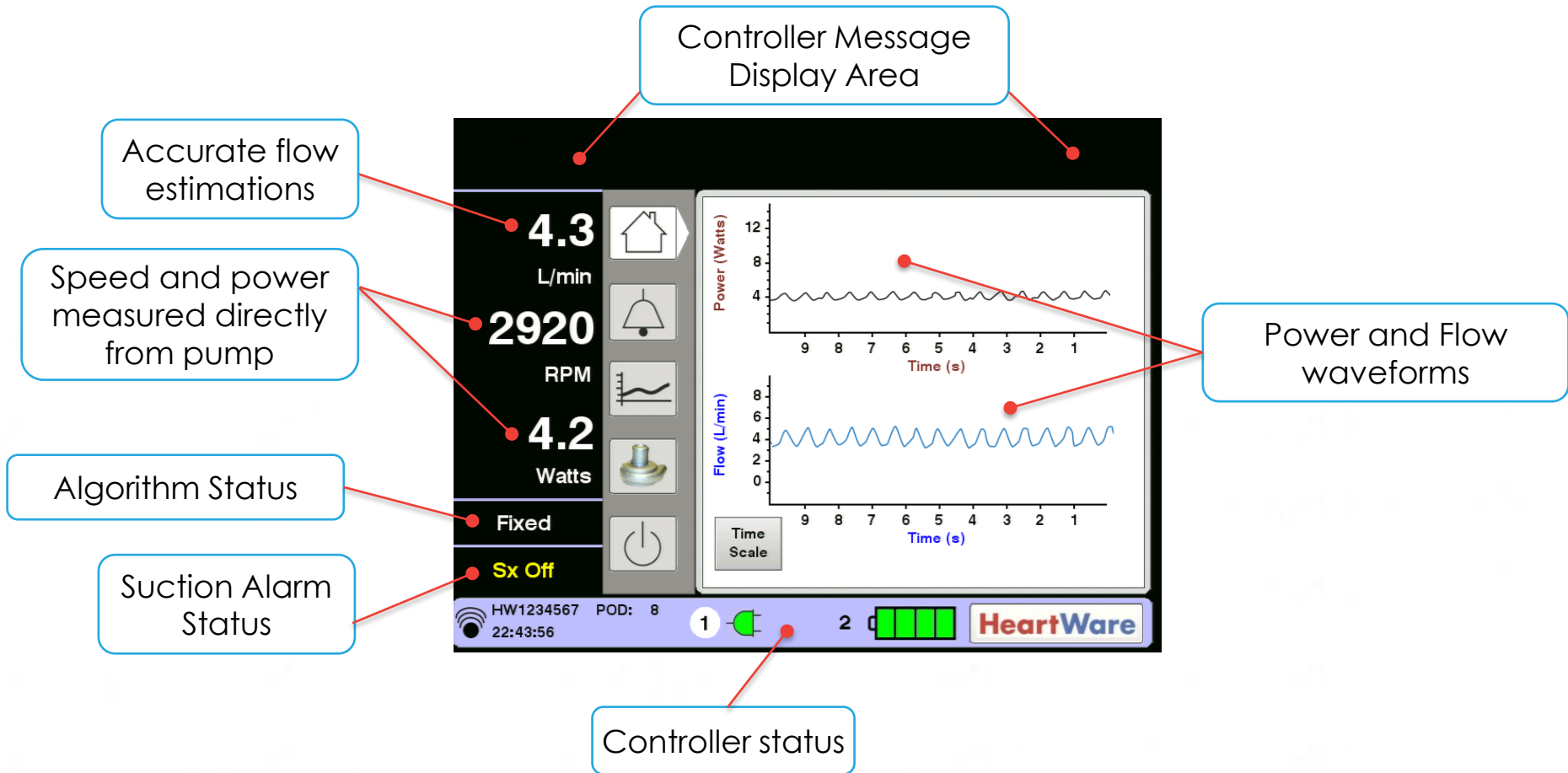
Heartware® Monitor

HeartWare® Monitor

- Touch screen tablet PC
- AC adapter or internal batteries for patient transportation (approx 2 hr battery life)
- Displays system performance
 - VAD flow
 - Pump speed
 - Watts
 - Alarms
 - Real time & historical pump values
- Pump adjustments



HVAD[®] Monitor



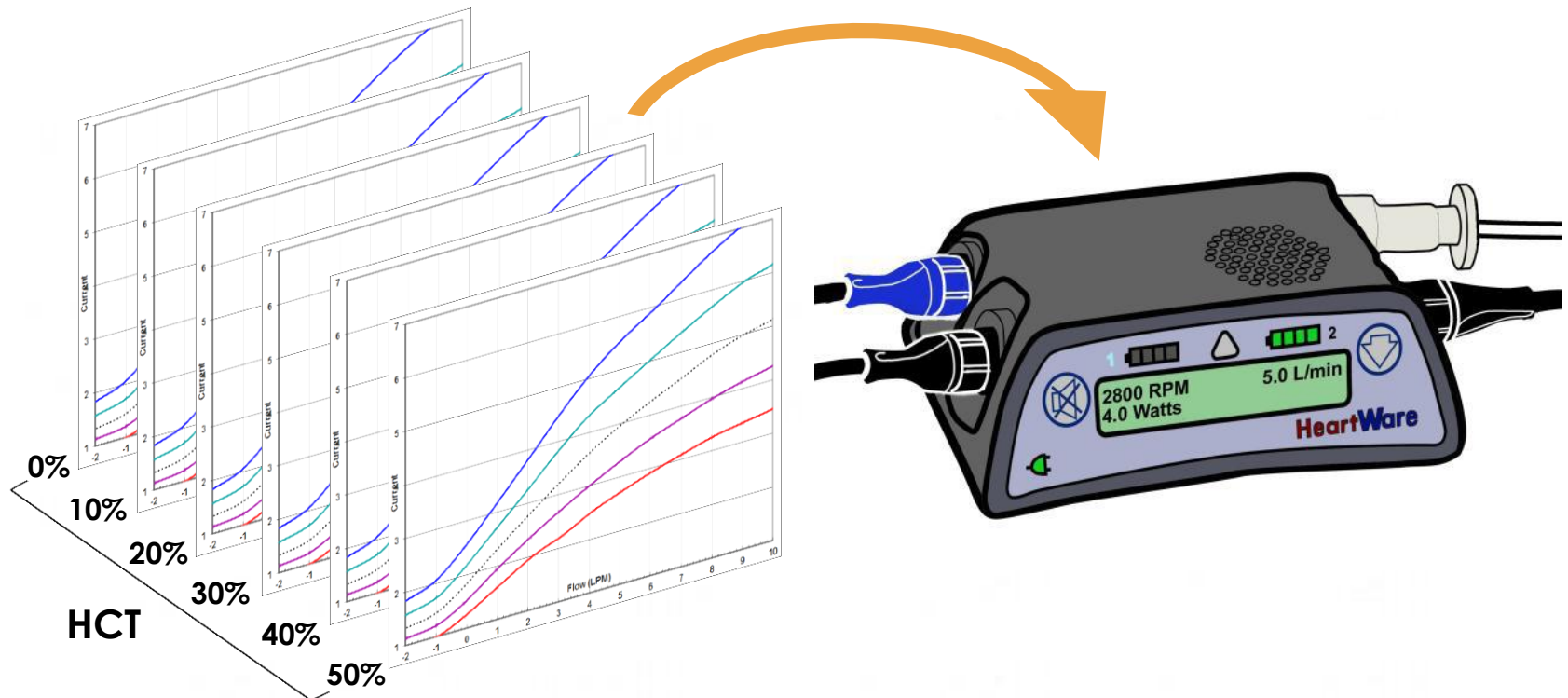
HVAD® Pump Flow Estimation

LVAD flow estimation depends upon:

- 1) Pump speed
- 2) Power
- 3) Patient's blood viscosity

HVAD[®] Pump Flow Estimation

- The HVAD Flow Estimation algorithm uses “look-up tables” to calculate flow
 - Each “look-up-table” contains corresponding speed and flow points & is gradated to correspond to a 0-50% equivalent HCT range



HVAD[®] Monitor

Monitor Icons

The main interface displays the following data points and icons:

- 4.3** L/min (with Home icon)
- 2920** RPM (with Alarms icon)
- 4.2** Watts (with Trend icon)
- Fixed** (with System icon)
- Sx Off** (with Monitor Power icon)

The central graph shows Power (Watts) and Flow (L/min) over Time (s). A 'Time Scale' button is highlighted in a red circle. To the right, three smaller graphs illustrate different timescales:

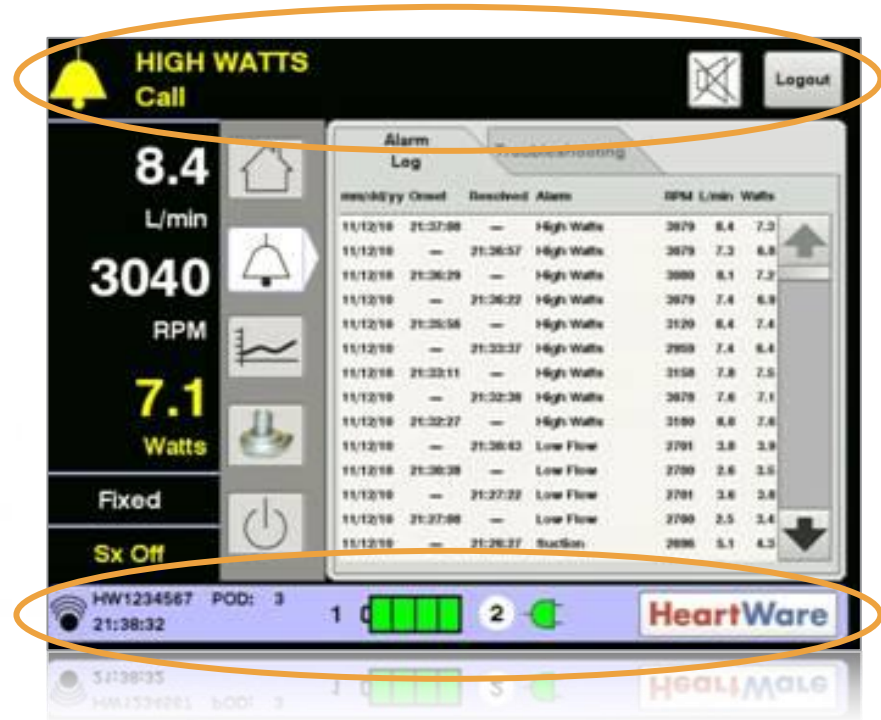
- 1 hr timescale**: Shows Flow (L/min) vs Time (min) with a legend for Peak and Trough.
- 20s timescale**: Shows Flow (L/min) vs Time (s).
- 10s timescale**: Shows Flow (L/min) vs Time (s).

At the bottom, a status bar includes: HW1234567, POD: 8, 22:43:56, 1, 2, and the HeartWare logo.

Data updated 50 times per second

HeartWare® Monitor Screen Layout

- Top of screen:
 - Alarm messages
 - Status messages
 - Alarm silence and logout buttons
- Bottom of screen:
 - Downloading data icon
 - Patient identification
 - Time
 - Postoperative day (POD)
 - Controller power supply status
 - Controller power supply source



Alarm Screen

The Alarm Screen has two tabs: [Alarm Log] and [Troubleshooting]

Alarm Log

The Alarm Log screen displays a table of alarm events. The table has columns for date, onset, resolved, alarm type, and RPM L/min Watts. The 'Alarm Log' tab is selected and circled in orange.

mm/dd/yy	Onset	Resolved	Alarm	RPM	L/min	Watts
10/05/16	---	08:40:11	VAD Stopped	0	0.0	0.0
10/05/16	08:40:00	---	VAD Stopped	0	0.0	0.0
09/28/16	---	16:27:26	VAD Stopped	0	0.0	0.0
09/28/16	16:27:19	---	VAD Stopped	0	0.0	0.0
09/16/16	05:47:31	---	VAD Stopped	2311	5.2	3.1
09/14/16	15:30:29	---	VAD Stopped	2395	9.1	5.8
05/01/10	---	20:24:04	High Watts	2499	11.9	5.7
05/01/10	20:23:35	---	High Watts	2499	11.7	5.7

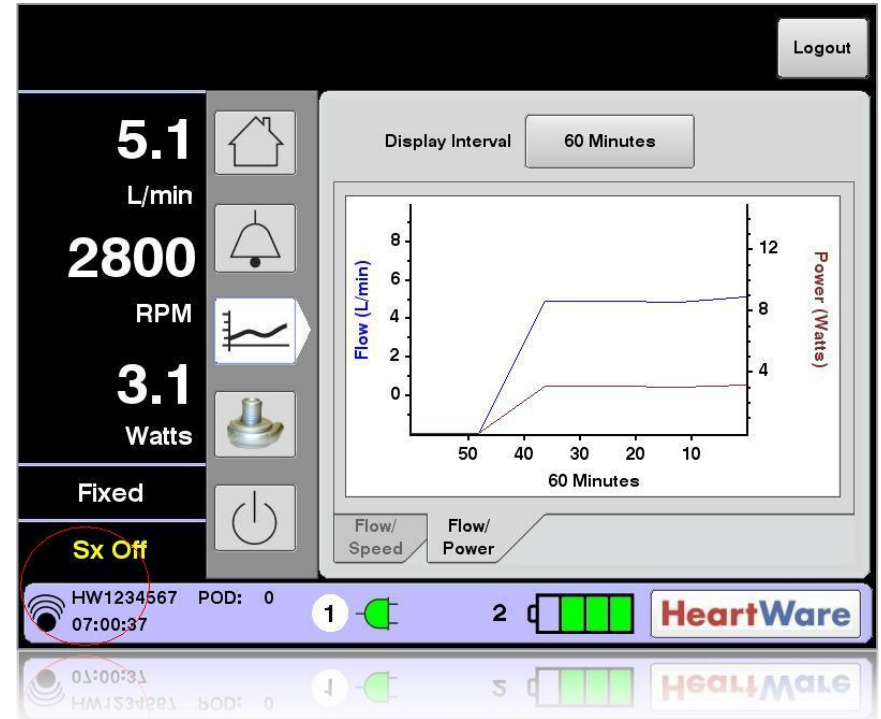
Troubleshooting

The Troubleshooting screen displays a list of error messages. The 'Troubleshooting' tab is selected and circled in orange. The error messages are: 1) Driveline Disconnect, 2) Driveline Fracture, 3) Connector Malfunction, broken, and 4) VAD Electrical Failure.

- 1) Driveline Disconnect
- 2) Driveline Fracture
- 3) Connector Malfunction, broken
- 4) VAD Electrical Failure

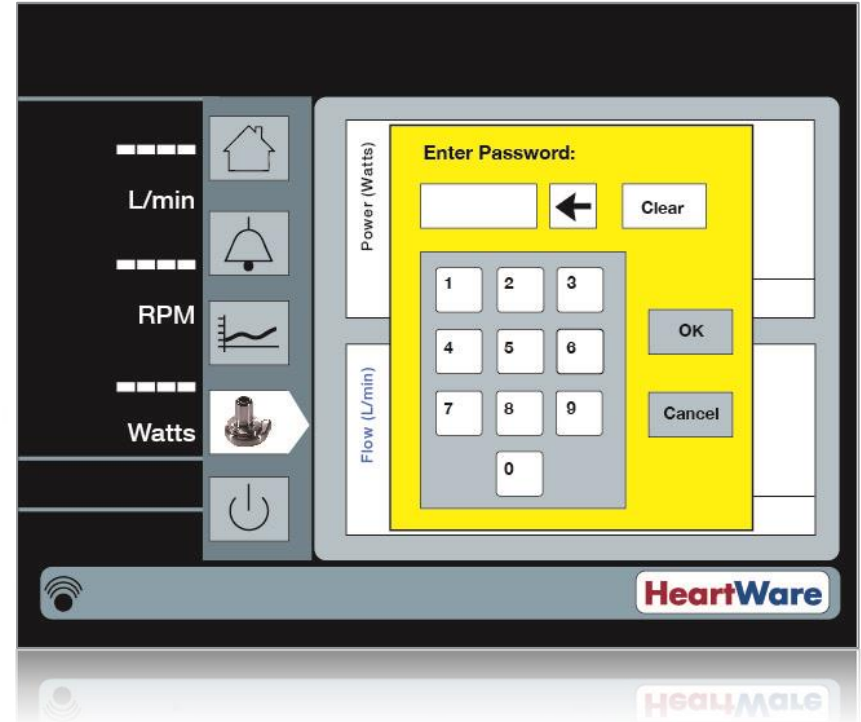
Trend Screen

- The Trend Screen has two tabs:
 - [Flow/Speed]
 - [Flow/Power]
- Displayed in intervals of
 - 60 minutes
 - 4 hours
 - 24 hours
 - 14 days
 - 30 days



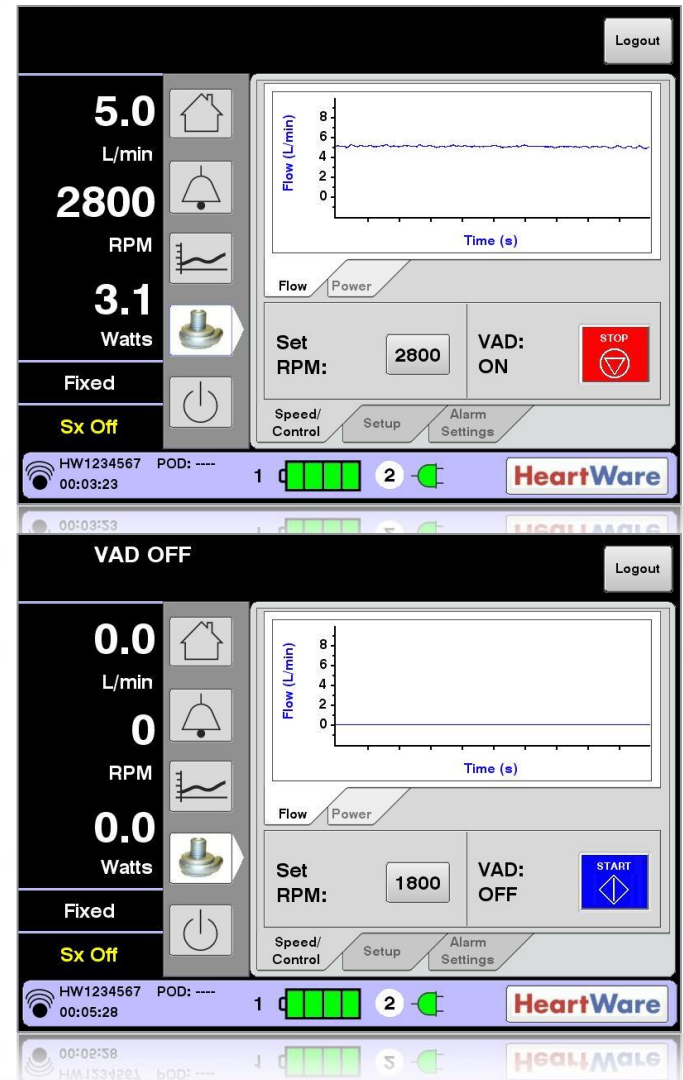
System Screen

- System Screen is accessed by pressing the HVAD® Pump icon
- System Screen provides access to 3 tabs:
 - [Speed/Control]
 - [Setup]
 - [Alarm Settings]
- System Screen is password protected
- Dialog box shown is used to enter the numeric password - 68773
- User access is timed out after 11 minutes of non-use



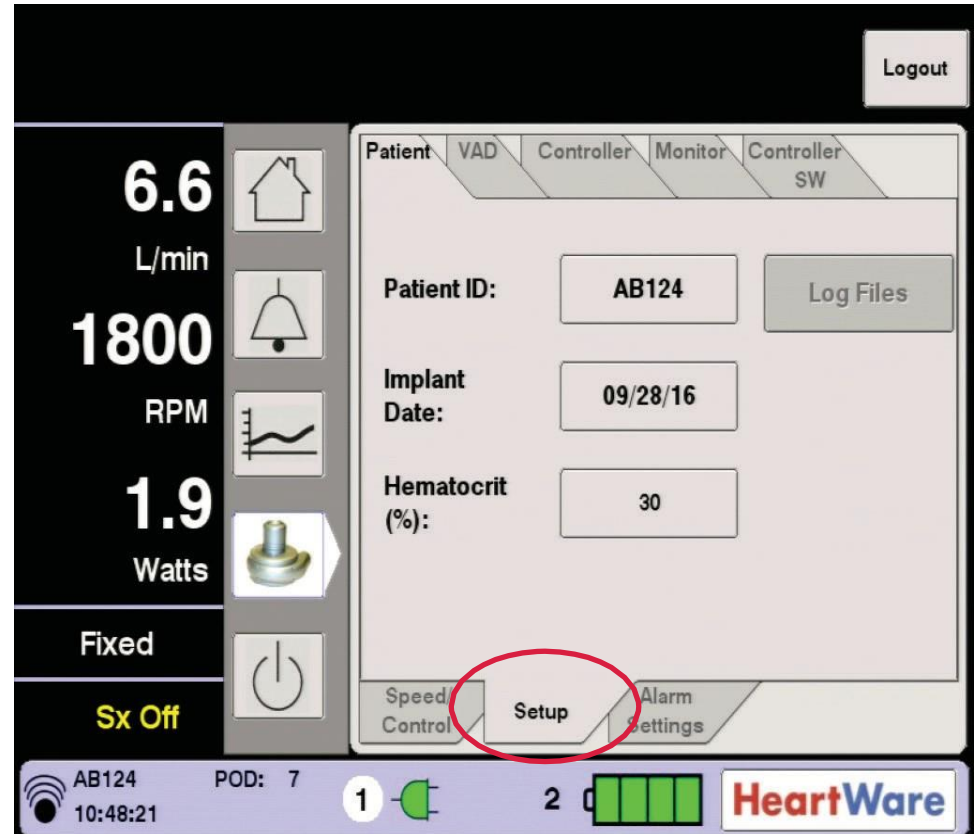
System Screen – Speed / Control Tab

- [Speed/Control] tab is used to adjust RPM and to turn the VAD “ON” or “OFF”
- [Set RPM] button is used to adjust the pump speed (RPM) from 1800 to 4000
- [VAD] button is used to turn the pump on and off
 - VAD: **ON** means the HVAD® Pump is on and the button is RED and labeled STOP
 - VAD: **OFF** means the HVAD Pump is NOT pumping; the button is BLUE and labeled START



System Screen – Setup Tab

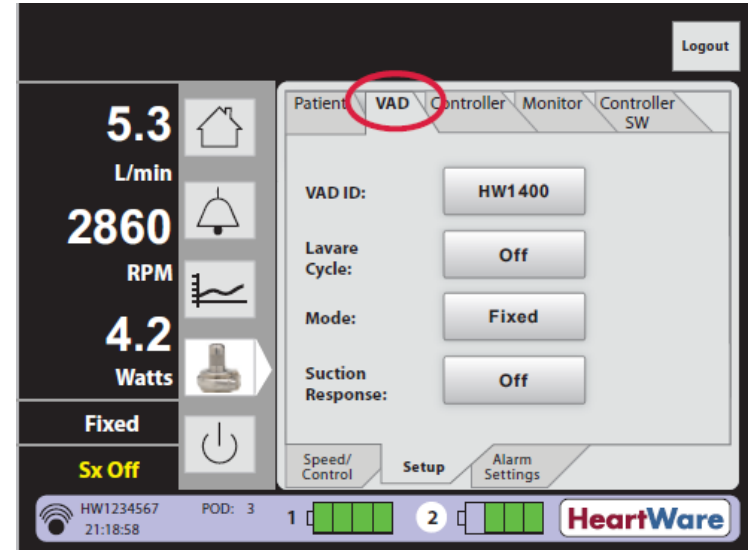
- When [Setup] tab is pressed, four tabs are displayed at top:
 - [Patient]
 - [VAD]
 - [Controller]
 - [Monitor]
 - [Controller SW]



Setup / VAD Tab: Suction Response

Two options for [Suction Response]:

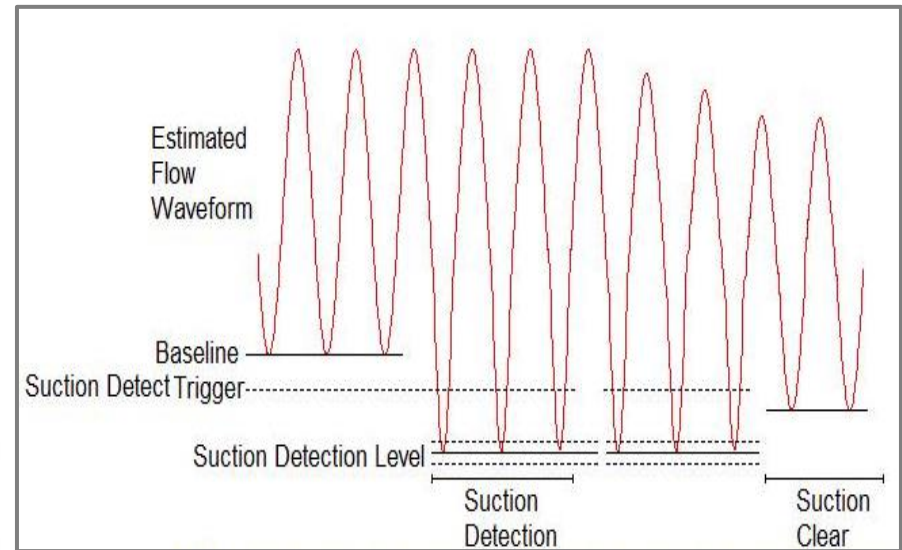
- Default Suction response is [Off]
- Suction response will say [Alarm Only] when it is enabled (on)
- Manual changes to rpm will immediately disable suction detection
- “Sx Off” or “Sx On” message will be displayed on monitor in lower left corner below “Fixed” mode display
- Suction alarm should be set after patient is hemodynamically stable



The Ventricular Suction Detection must not be turned on while the patient is in a suction condition. Patient should be hemodynamically stable prior to enabling ventricular suction detection alarm.

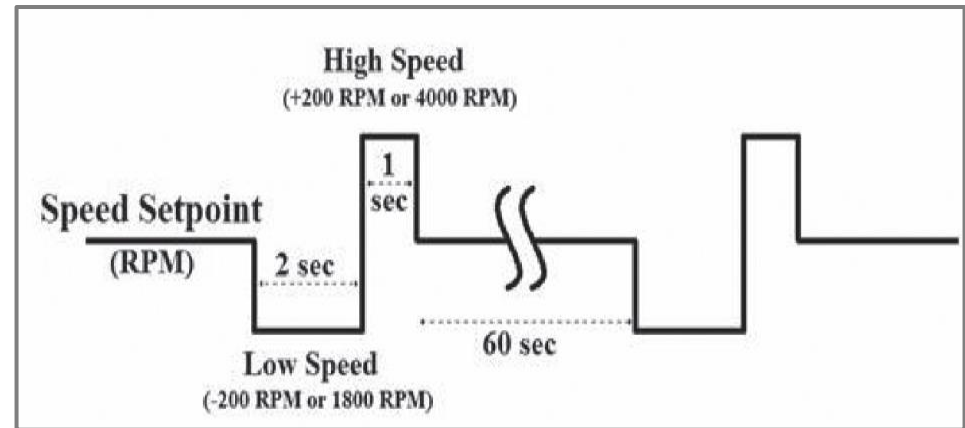
Ventricular Suction Detection

- A trigger value is established at 40% below the estimated flow baseline
- The alarm will be triggered if this condition is maintained for 10 seconds
- The suction alarm is cleared when the flow baseline is maintained above the trigger level for 20 seconds
- As the trough becomes lower, the Suction Detection Algorithm becomes more sensitive



Setup / VAD Tab: Lavare Cycle

- The Lavare Cycle is a periodic speed variation to improve flow washing in the ventricle
- Initiate the Lavare Cycle once the patient is hemodynamically stable
- The Lavare Cycle consists of
 - Decrease speed 200 RPM below set speed for two seconds
 - Increase speed 200 RPM above set speed for one second
 - Return to the set speed

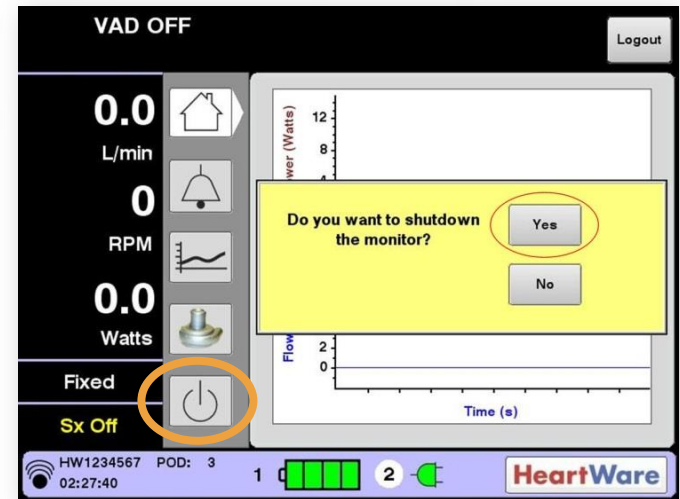
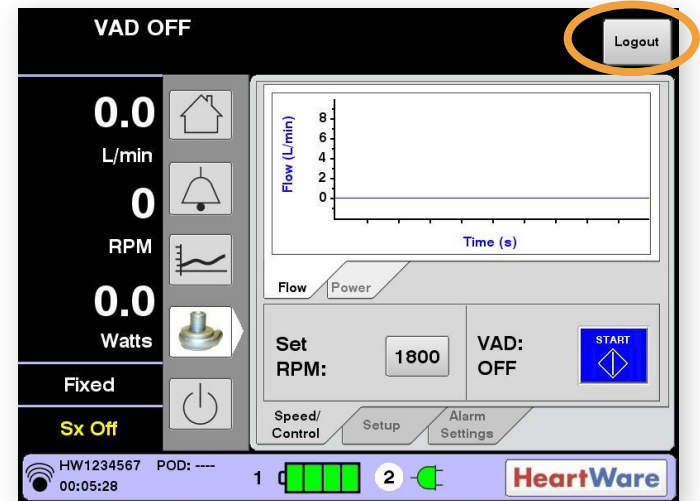


This cycle is repeated periodically every 60 seconds

NOTE: If thrombus is suspected within the device, the Lavare Cycle should be turned "Off" until the thrombus is resolved.

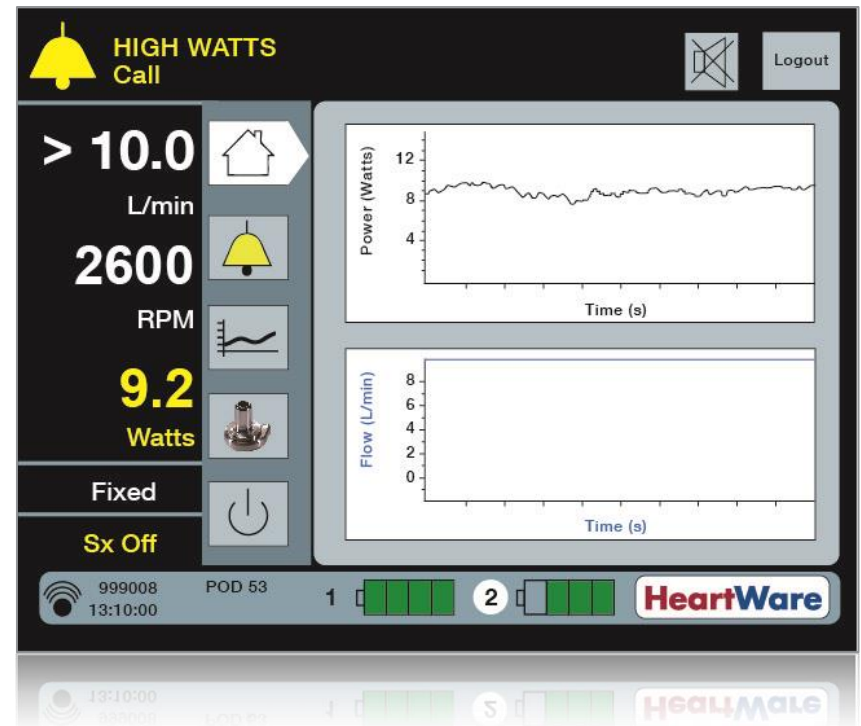
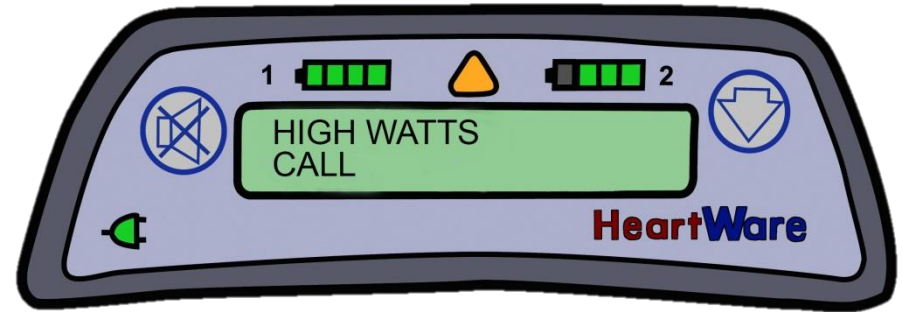
Monitor Logout and Shut Down

- [Logout] button allows user to log off password-protected System Screen after completing system adjustments
- If the System Screen is not used for 11 minutes, the user is automatically logged off
- Monitor Shut Down button may be used to turn off monitor for storage



Alarms Overview

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



HeartWare® Monitor: Alarm Settings on System Screen

- [Alarm Settings] tab is used to set [Low Flow Alarm Limit] and [High Power Alarm Limit] thresholds
- Both flow and power are “time averaged” values
- Low Flow Alarm
 - Range 1.0 to 9.9 L/min
 - Should be set 2 L/min below the average flow but no less than 2 L/min
- High Power Alarm
 - Range 1.0 to 25 Watts
 - Should be set 2 above the displayed Watts

Logout

4.9 L/min

2800 RPM

3.0 Watts

Fixed

Sx Off

Low Flow Alarm Limit (L/min): 1.0

High Power Alarm Limit (Watts): 16.0

Speed/Control Setup Alarm Settings

HW1234567 POD: 1 00:11:09

00:14:08 HW1234567 POD: 1

Default settings

- Low Flow Alarm threshold is 1.0 L/min
- High Power Alarm threshold is 16 Watts

HVAD[®] Controller: Alarm Indicator & Mute Button

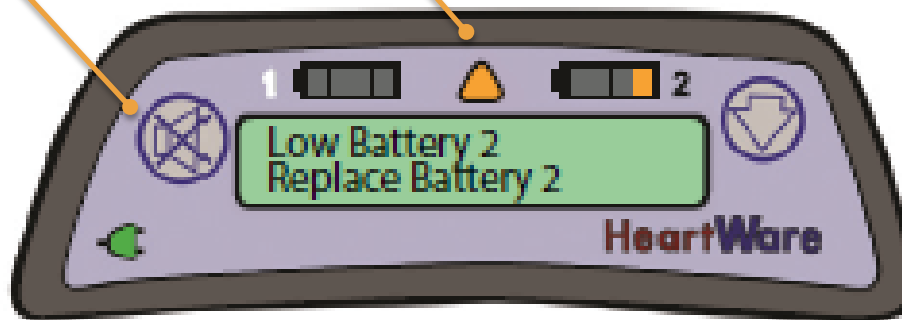


Alarm Indicator Symbol









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

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">• No power to pump• Pump has stopped	<ol style="list-style-type: none">1. Connect two new power sources2. Replace controller3. Contact Clinical Specialist

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.

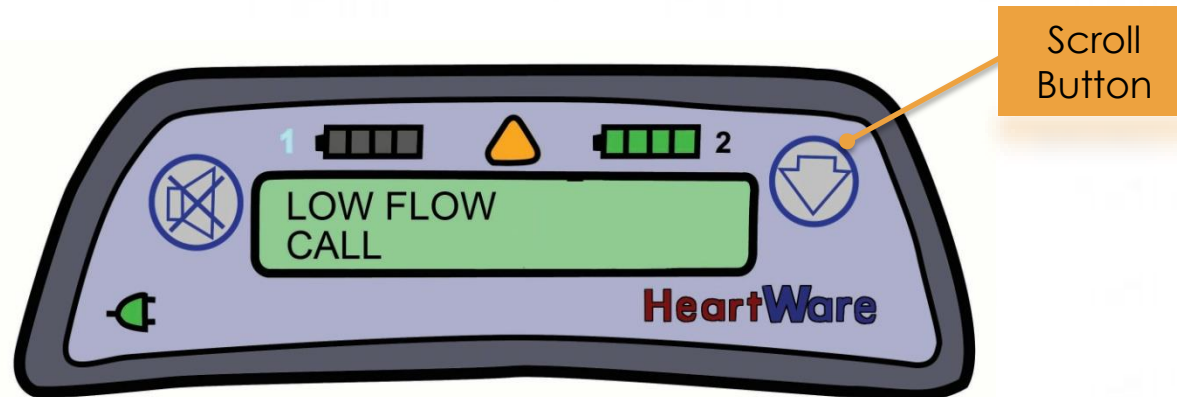
Medium Priority Alarms (Flashing Yellow)

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[®] 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 Interaction¹

PRELOAD

Low

Hypovolemia
Right Heart Failure
Tamponade

High

Hypervolemia

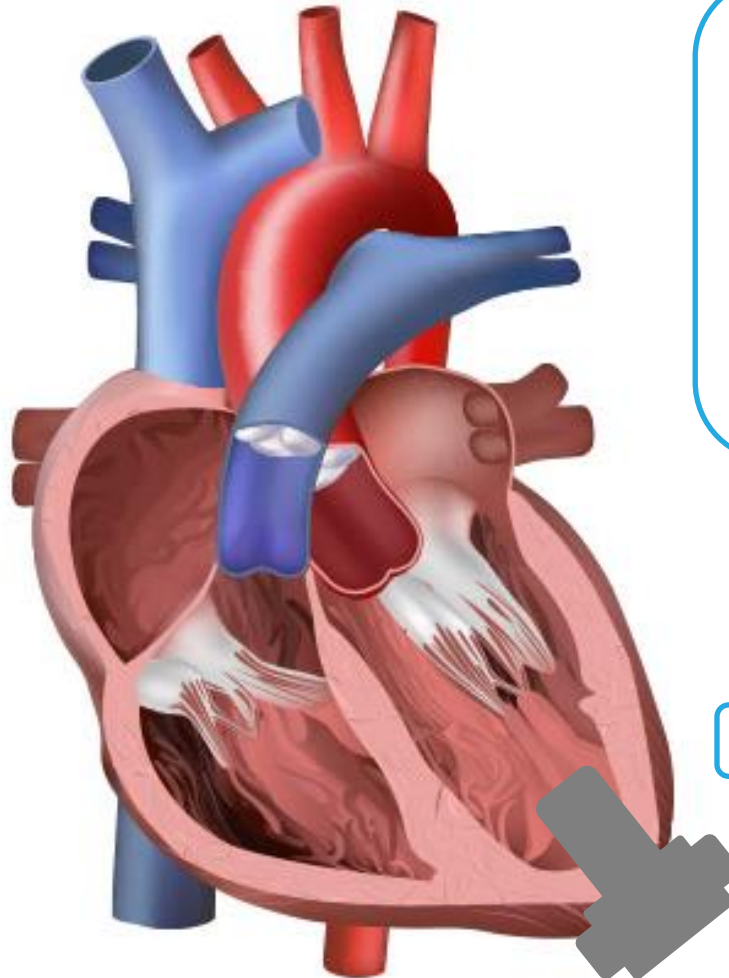
CONTRACTILITY

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

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

Postoperative Management: HVAD[®] Pump Speed

- Optimal speed is set to maintain a pump flow index between 2.0-2.6L/min/m²
- 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 collapse¹
- Amount of Aortic Valve opening is still being studied and general consensus for standard practice has not yet been reached¹

¹Slaughter, 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

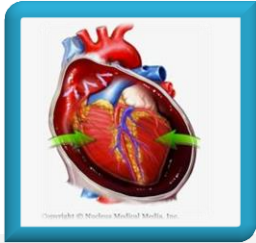
- Begins with preoperative patient management, selection and timing of implant
- Preoperative goals should include¹:
 - Improving nutritional status
 - Lowering pulmonary vascular resistance to maximize right ventricle function
 - Aggressive volume management to minimize RV work load
 - Optimization of coagulation
 - Optimization of renal, hepatic, pulmonary and neurologic function
 - Treatment of infection
 - Adequate evaluation and identification of patient support systems

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

Potential Complications*



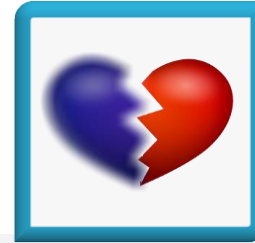
Bleeding



Tamponade



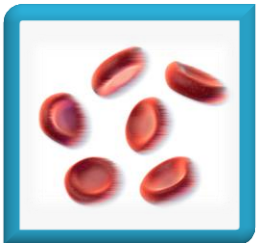
Arrhythmia



Right Heart Failure



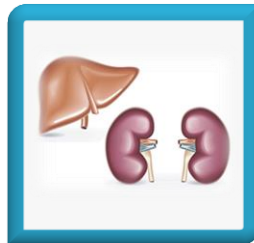
Infection



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 L/min/m² and 2.6L/min/m²

Postoperative Management: Blood Pressure

- **Mean arterial pressure should be maintained less than 85 mmHg**
- HVAD[®] 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 absent¹
- Pulse pressure is influenced by LV contractility, intravascular volume, pre-load and after-load pressure, and by pump speed¹
- Vasopressors or vasodilators may be used to maintain vascular tone

¹Slaughter, 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 include¹:
 - 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

¹Slaughter, 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: Bleeding¹

- 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

¹Slaughter, 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[®] 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[®]) 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[®] System patients
- Follow appropriate ACLS protocols
- If chest compressions have been administered, confirm function and positioning of HVAD[®] 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 infection¹



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

¹Slaughter, 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

- If attached to the HeartWare Hospital Monitor:
 - Verify hematocrit setting matches lab value
 - Ensure Low Flow alarm is set
 - Ensure High Watt alarm is set
 - Check if Suction Detection is On or Off
 - Alarm history
- Verify
 - Current Speed
 - Current Flow
 - Current Power

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

HeartWare®

Waveforms and Log Files

Disclaimer

Pump waveforms and Logfiles are provided by Medtronic for general information purposes. Each waveform has been generated by an algorithm related to pump performance and is based solely on data provided from the controller to the monitor. The waveform is imputed; it does not measure or represent a clinical condition of the patient.

Although certain variations in the waveform may correlate with one or more specific patient clinical conditions, the interpretation of a waveform must be performed by a medical professional. Similarly, although a log file may correlate with one or more specific patient clinical conditions, the data should not be considered diagnostic. Medtronic has not independently validated or verified waveforms or log files and makes no claim that a waveform or log file is indicative of a particular patient's clinical condition.

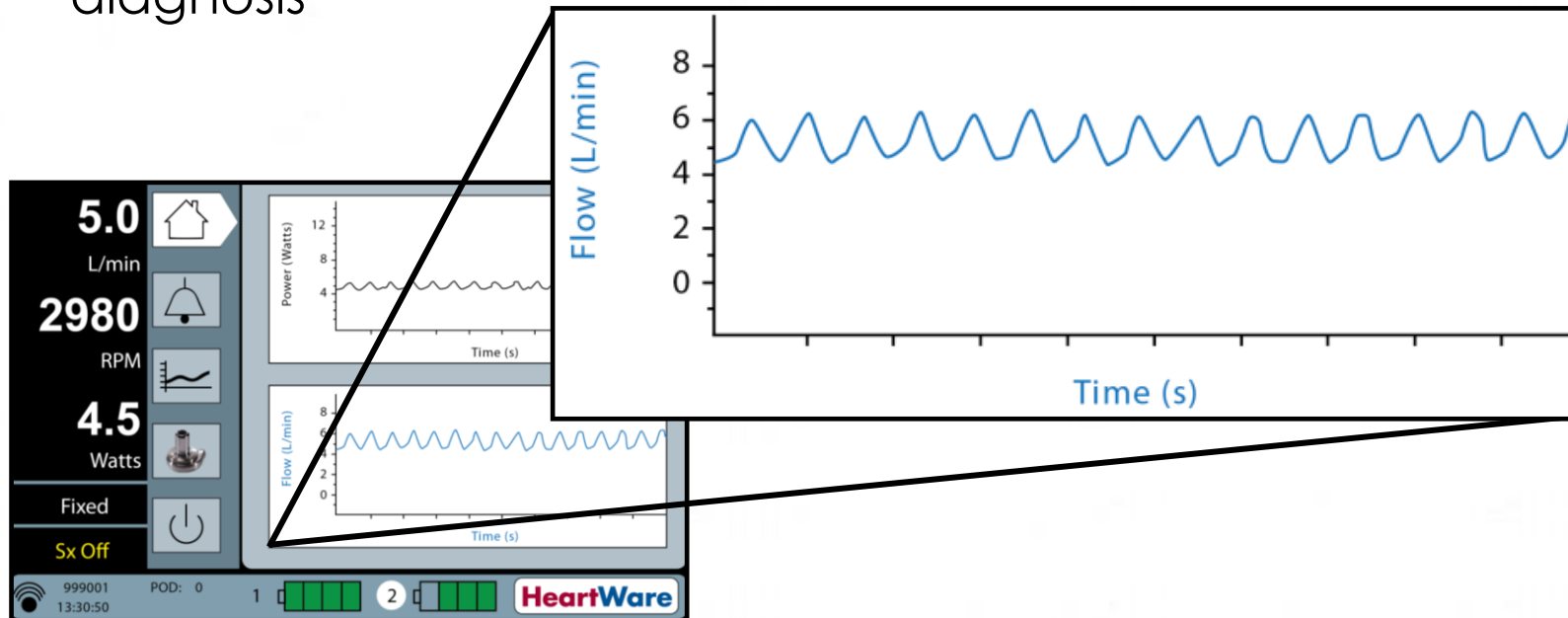
No waveform, log file, or related information provided by Medtronic is intended to constitute medical advice, nor should any of these items be used as a replacement for the advice, treatment, or diagnosis of a licensed physician. If you have questions related to the waveform or log file, please refer to HVAD System IFU or you may contact your Medtronic representative. In addition, Medtronic clinical support is available via the emergency hotline (888.494.6365). This hotline resource is available 24 hours a day, 7 days a week, 365 days a year.

Waveforms and Log Files

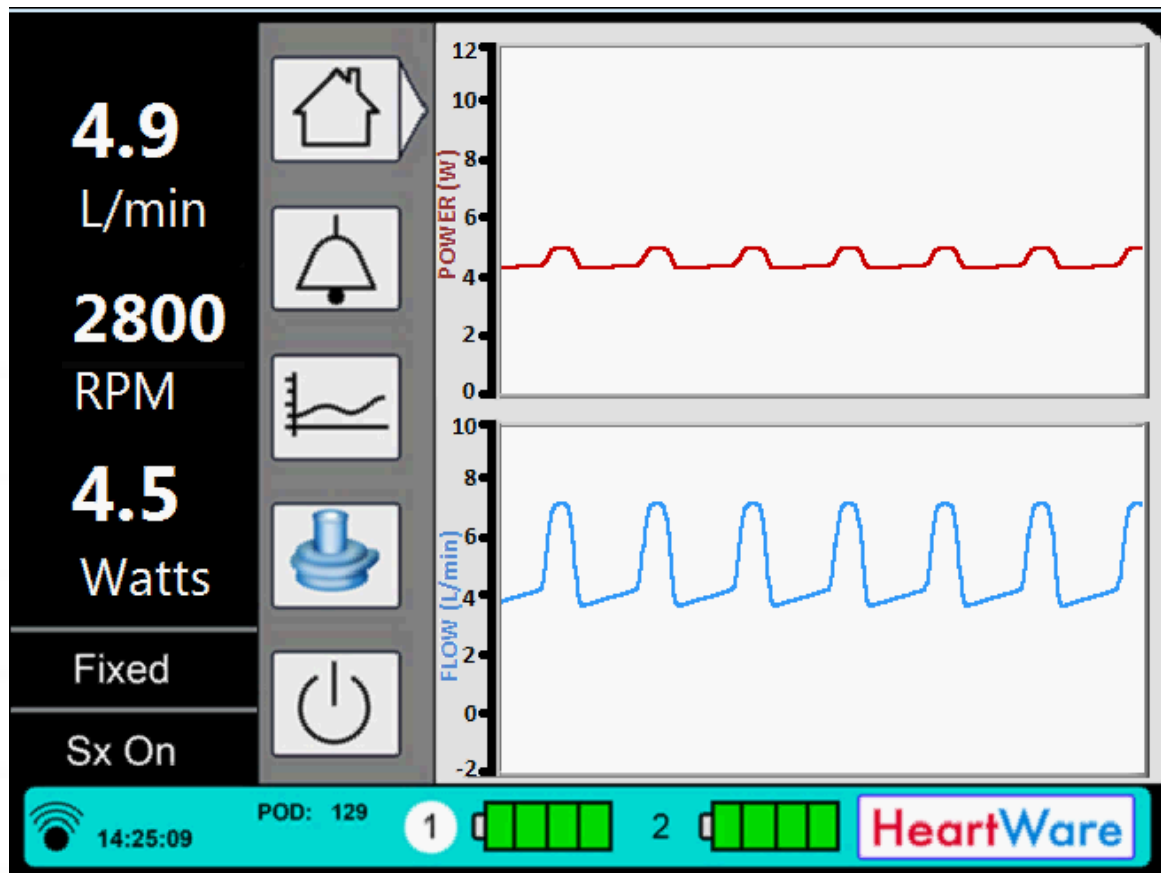
- Waveforms
 - Display the function of the HVAD[®] Pump
 - Should be correlated to physiological variables and clinical presentation
 - Use as a tool to understand the pump function and provide insight into the pump performance
- Controller log files (along with hemodynamic parameters) may provide valuable retrospective review of information

HVAD[®] Pump Performance Overview

- Waveforms are a tool to provide insight into the pump performance condition and help with patient management
- The pump flow waveform depicts the rate of blood flowing through the pump
- Simulated HVAD Pump performance. Not intended for clinical diagnosis

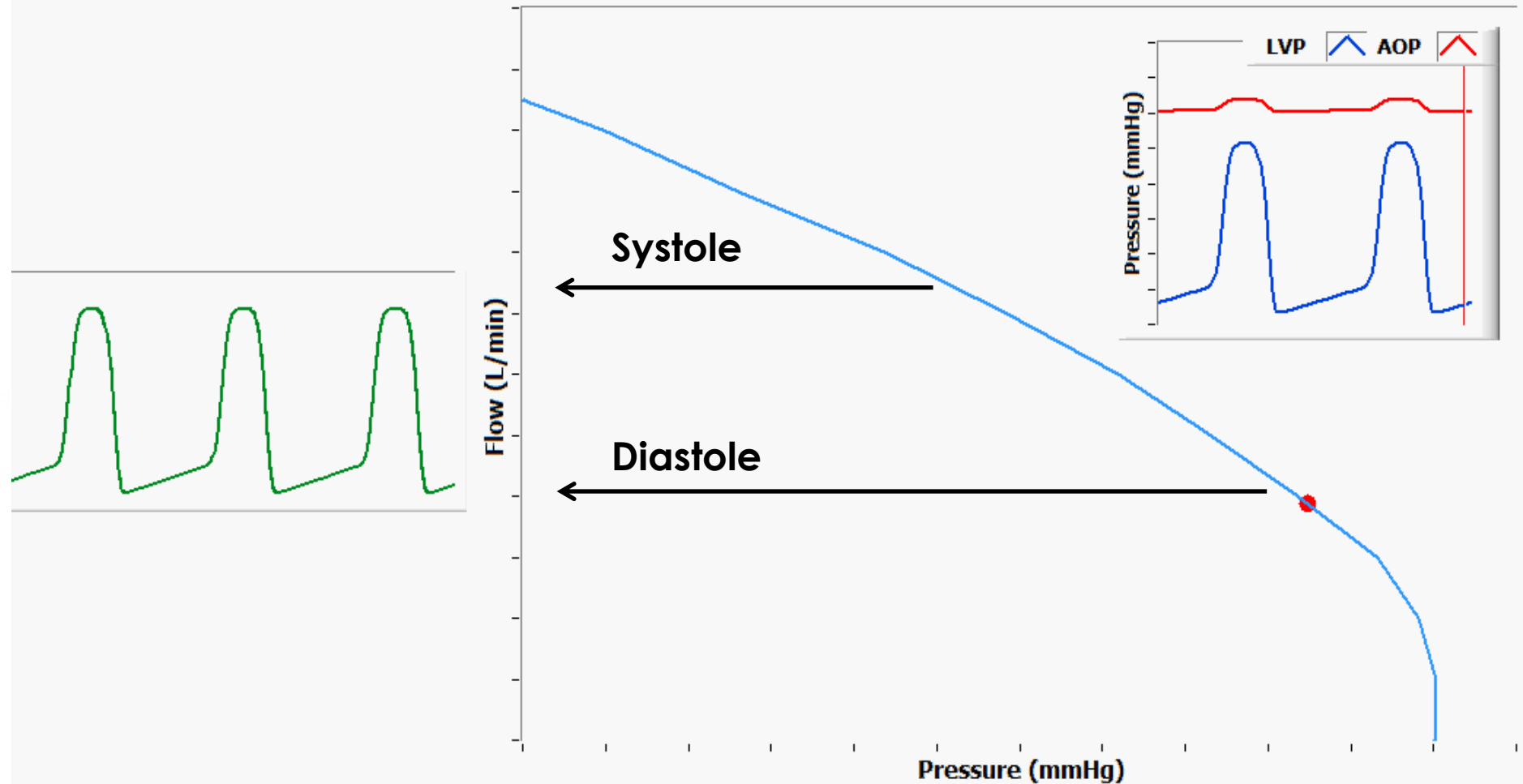


HVAD[®] Pump Waveforms: Normal Operation



Simulated HVAD Pump performance. Not intended for clinical diagnosis.

Pulsatility Is A Result Of The Changes between Flow Peak and Trough



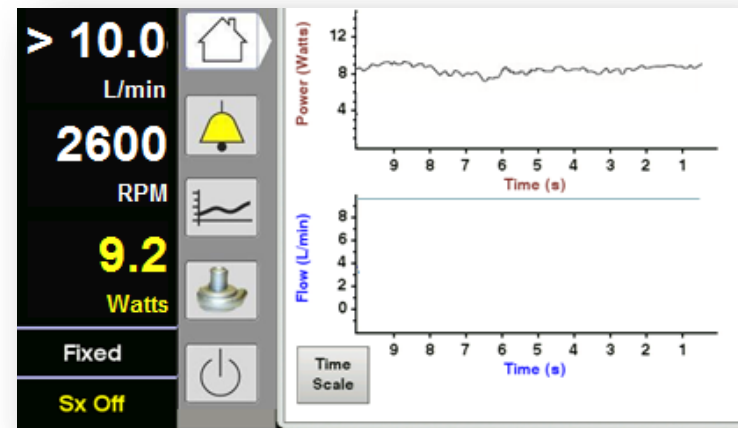
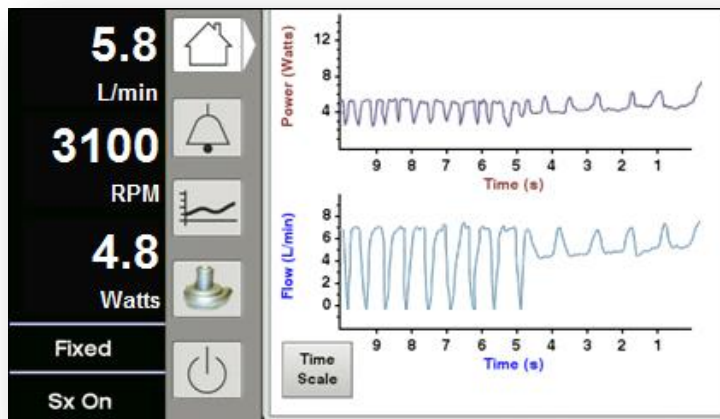
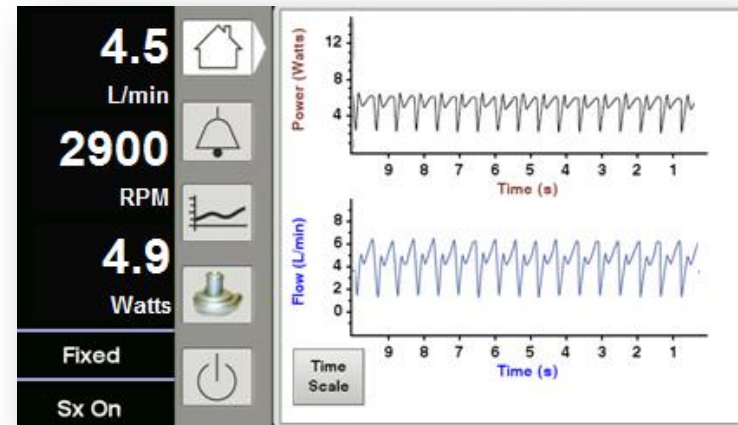
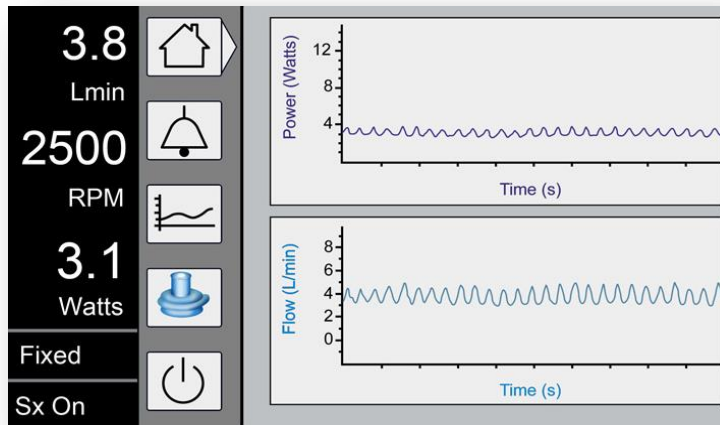
Simulated HVAD Pump performance. Not intended for clinical diagnosis.

HVAD[®] Pump Waveforms

- Pulsatility is proportional to LV stroke work and provides additional information when regulating the HVAD[®] Pump
- Pulsatility of the pump flow waveform reflects the native heart's contribution to the pump output
- Any change in native heart function may have an effect on the LVAD and the shape of the waveform¹
 - Changes in heart rate
 - Changes in LV and/or RV contractility
 - Changes in preload (PVR)
 - Changes in afterload (SVR)
 - Concomitant therapies
 - IABP
 - Ventilation
 - Right side support such as ECMO or other continuous flow pump

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

Waveform Changes: Examples



HVAD[®] Controller Log Files

- Controller logs capture data every 15 minutes
- Data is stored on a first in first out (FIFO) basis
- Log files may be transferred to the monitor from the controller then downloaded
- Send to HeartWare for analysis

	Data File	Event File	Alarm File
Content	<ul style="list-style-type: none">• Average Speed, Power and Estimated Flow• Controller & Patient ID• Battery Capacity	<ul style="list-style-type: none">• User Input Data• VAD Start• Controller Power Up, etc.	<ul style="list-style-type: none">• Onset/clear of medium and high priority alarms
Capacity	31 days of data	250 entries	200 entries

Log File Reports

Manual Logfile Report

Patient ID: 27434703
Review Date: August 5, 2015
Page 1 of 2

Logfiles

PATIENT INFORMATION	
Patient ID:	SAMPLE
Pump ID:	HW1234
Controller ID:	CON123456
Data through:	August 5, 2015

CURRENT VAD PARAMETERS	
SPEED (RPM):	2840
FLOW (LPM):	5.3
POWER (W):	5.3
Normal Power Consumption with Intermittent Suction	

VAD WAVEFORM

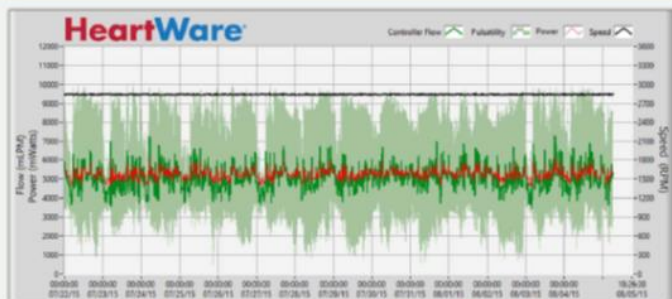


Figure 1: VAD parameters and flow pulsatility over the last 14 days

ADDITIONAL NOTES	
- No alarms have been logged in the last 14 days of available data.	

BATTERY SUMMARY	
Battery ID	Cycle Count
119655	78
119657	87
119677	95
119694	74
119724	82
119725	75

This remote analysis has been provided at your request by HeartWare for general informational purposes. It is based solely on log file data provided to HeartWare. HeartWare did not independently validate or verify these log files. This communication is not intended to be medical advice, nor should it be used as a replacement for the advice, treatment or diagnosis of a licensed physician. If you have questions related to HeartWare's log file analysis, you may contact your HeartWare representative. In addition, HeartWare Clinical Support is available via the Emergency Hotline (888.494.6365). This hotline resource is available 24 hours a day, 7 days a week, 365 days a year.

Autologs Report

Patient ID: SAMPLE_NORMAL
Review Date: October 4, 2016
Page 1 of 1

Autologs

PATIENT INFORMATION	
Patient ID:	SAMPLE
Pump ID:	HW1234
Controller ID:	CON123456
Data through:	October 4, 2016

CURRENT VAD PARAMETERS	
SPEED (RPM):	2680
FLOW (LPM):	4.5
POWER (W):	4.0

VAD PARAMETER TRENDS



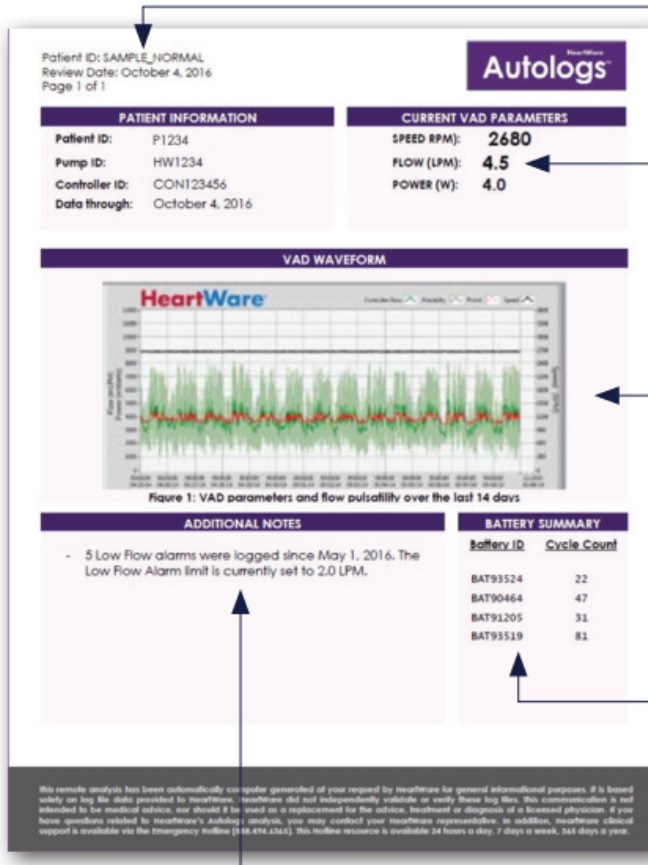
Figure 1: VAD parameters and flow pulsatility over the last 14 days

ADDITIONAL NOTES	
- 5 Low Flow alarms were logged since May 1, 2016. The Low Flow Alarm limit is currently set to 2.0 LPM.	

BATTERY SUMMARY	
Battery ID	Cycle Count
BAT93524	22
BAT90464	47
BAT91205	51
BAT93519	81

This remote analysis has been automatically computer generated at your request by HeartWare for general informational purposes. It is based solely on log file data provided to HeartWare. HeartWare did not independently validate or verify these log files. This communication is not intended to be medical advice, nor should it be used as a replacement for the advice, treatment or diagnosis of a licensed physician. If you have questions related to HeartWare's autologs analysis, you may contact your HeartWare representative. In addition, HeartWare clinical support is available via the emergency hotline (888.494.6365). This hotline resource is available 24 hours a day, 7 days a week, 365 days a year.

How To Read an Autologs Report



1 VERIFY PATIENT INFORMATION

Do you have the correct patient?
Is the data through the current date?

2 CONFIRM CURRENT VAD PARAMETERS

Are speed, flow, and power at expected levels? Consider referring to published data, such as the HVAD™ Pump Power Speed Table, for more information.

3 ANALYZE PUMP PERFORMANCE

Are flow, pulsatility, and power consistent?
Are there any gradual or sudden deflections?

4 IDENTIFY ALARMS AND TRENDS

Did you know about this alarm? Do you need clarification on an alarm or fault?
Do alarms indicate a need for more patient training?

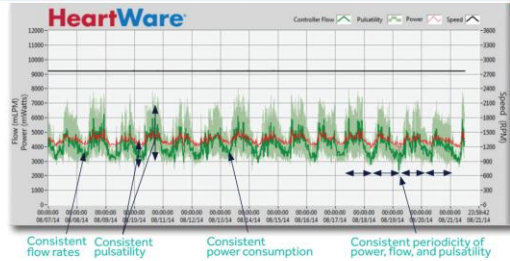
5 MONITOR BATTERY USAGE

Are any batteries above 500 cycles?
If so they should be replaced. Is the patient properly rotating batteries?

Log File Examples

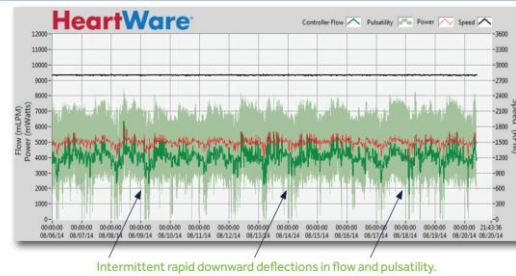
CONSISTENT PUMP PARAMETERS

In this example, the patient's system has recorded regular and consistent power, flow, and pulsatility.



RAPID DOWNWARD DEFLECTIONS IN FLOW

In this case, the system recorded a recent history of intermittent self-clearing suction conditions.



UNEVEN BATTERY USAGE

In this example, the system recorded a significant discrepancy between battery cycle counts, which was later found to be due to the patient not properly rotating batteries.

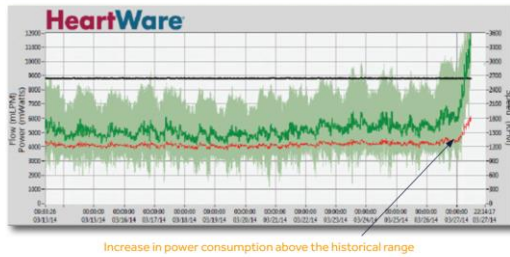
BATTERY SUMMARY

Battery ID	Cycle Count
302591	90
309877	55
309880	76
309968	64

Though all four batteries were provided to the patient at the same time, battery cycle counts are significantly dissimilar.

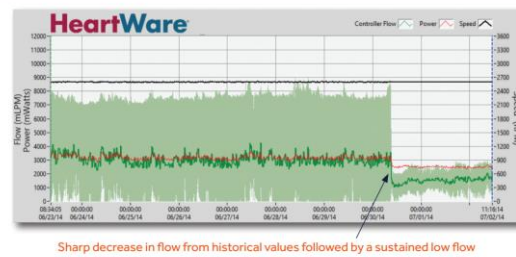
SHARP INCREASE IN POWER

In this example, the system recorded an increase in power consumption outside of the normal range. Upon further evaluation, it was noted there was thrombus in the pump.



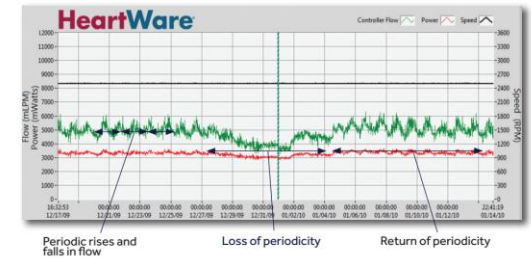
SHARP & SUSTAINED DECREASE IN FLOW

In this example, the system recorded a rapid and sustained decrease in estimated flow. Field data later confirmed the pump was occluded.



LOSS OF FLOW PERIODICITY

In this example, the system recorded a loss of periodic rises and falls in flow. Field data later confirmed an interruption of the patient's Circadian Rhythm.



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.