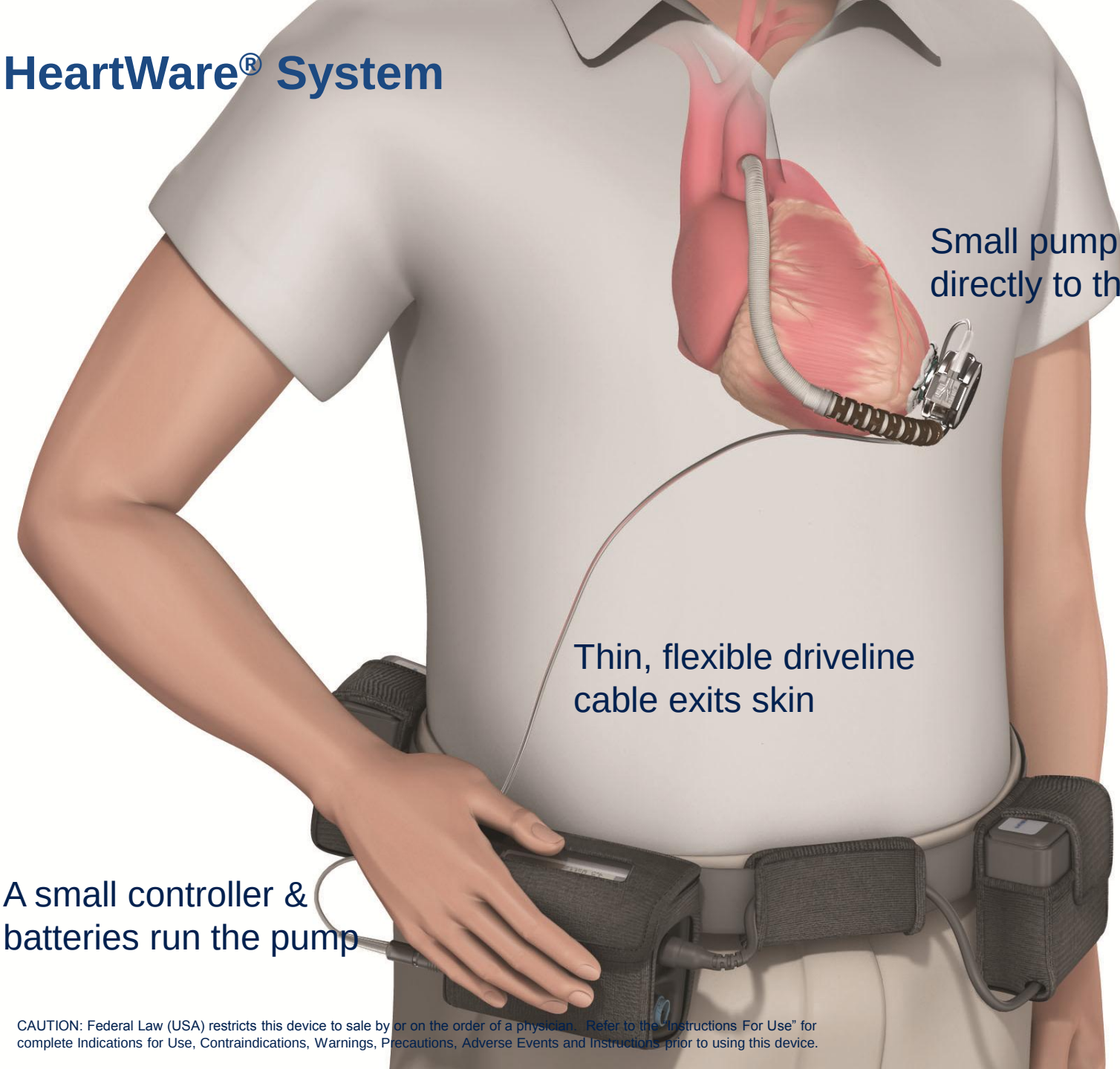
HeartWare® Ventricular Assist System

System Overview Hands-on Practicum

HeartWare
Leading a small revolution

GR00307 Rev01 11/12 Module 7/10

HeartWare® System



HVAD® Pump

Durable Driveline

Thin (4.2mm) and flexible cable with durable wires

Miniature Pump

160g centrifugal pump with integrated inflow cannula that provides up to 10 liters of flow

Only One Moving Part

No contact within pump when running

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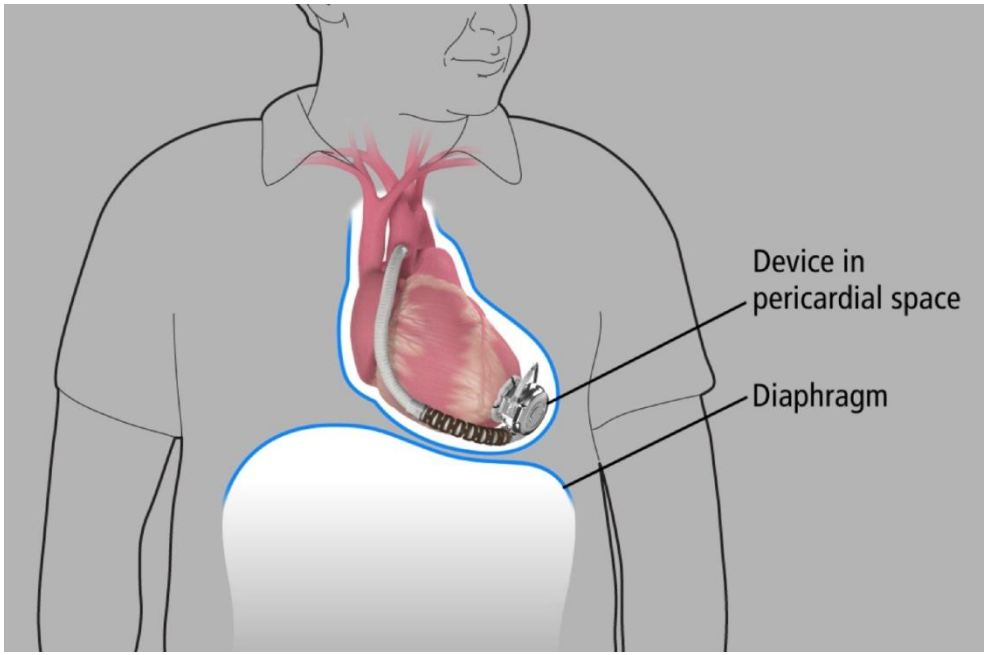
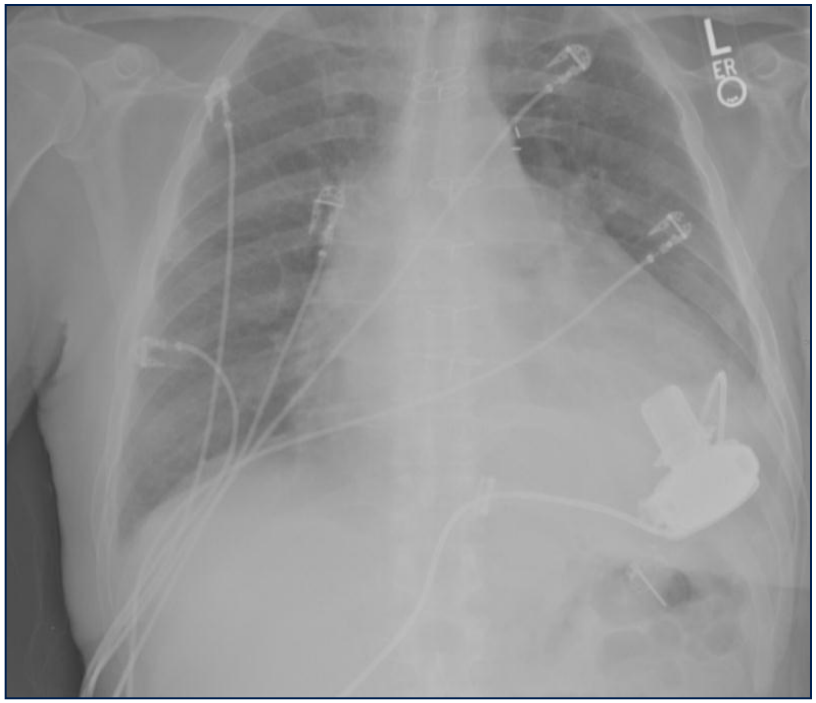
Pericardial Placement





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HeartWare Patient Peripheral Components

HeartWare® Controller: Controls and manages VAD operation

HeartWare® Power Sources: Power the controller and pump

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

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

HeartWare® Shower Bag: Holds a controller & 2 batteries while showering

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

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HeartWare® Controller

The controller sends power and operating signals to the HVAD® Pump via a percutaneous driveline. It also collects data on system operation.

Blue data connector is used by clinicians to adjust pump parameters and download pump information

Data Connection

Pump driveline is attached to silver driveline connector and must not be disconnected

Driveline Connection

Power Connection

Power Connection

2 identical power supply connectors - controller requires two power sources at all times

Controller Display

Provides information on pump parameters (flow, speed, power), power sources and alarms

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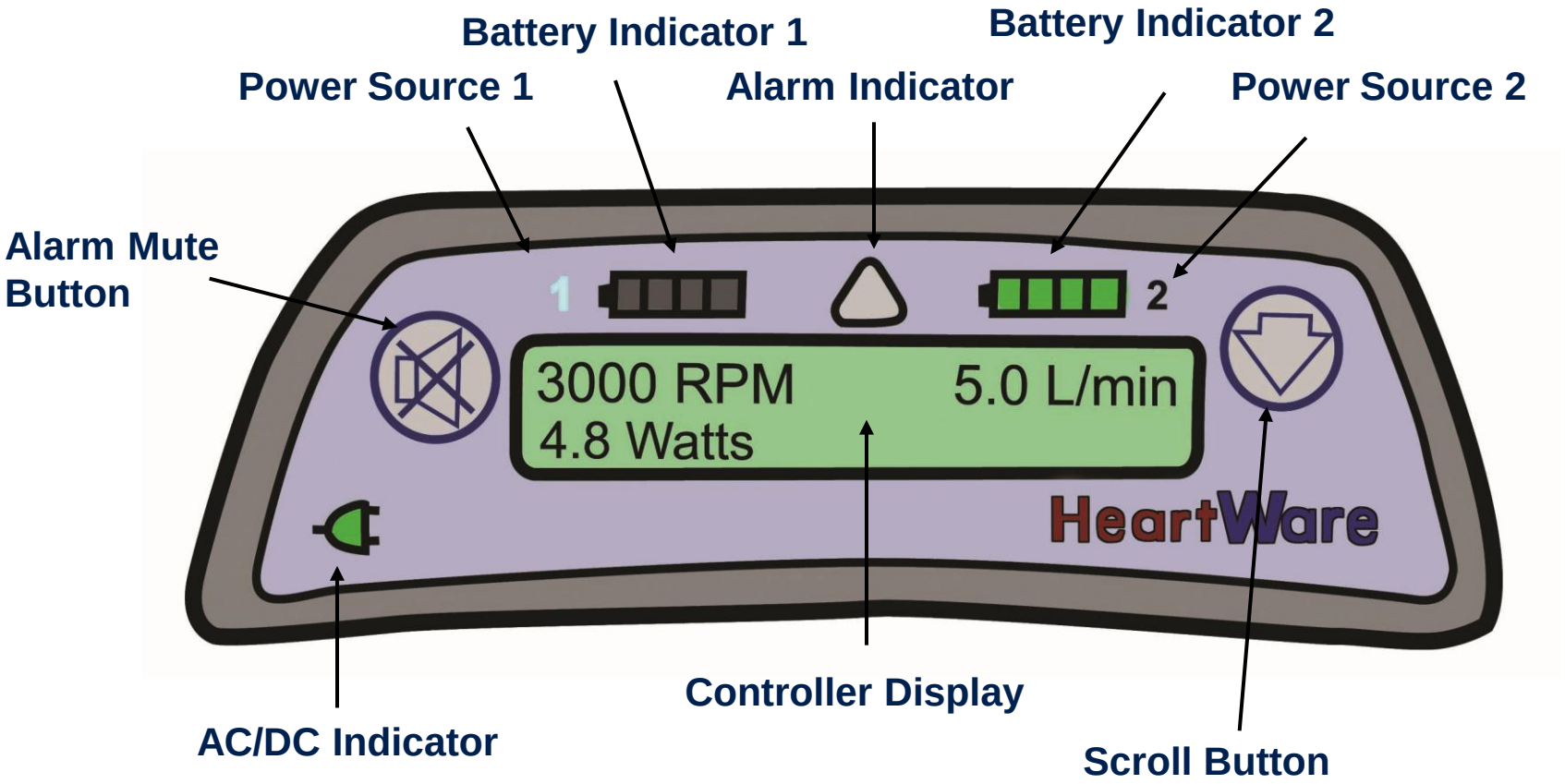
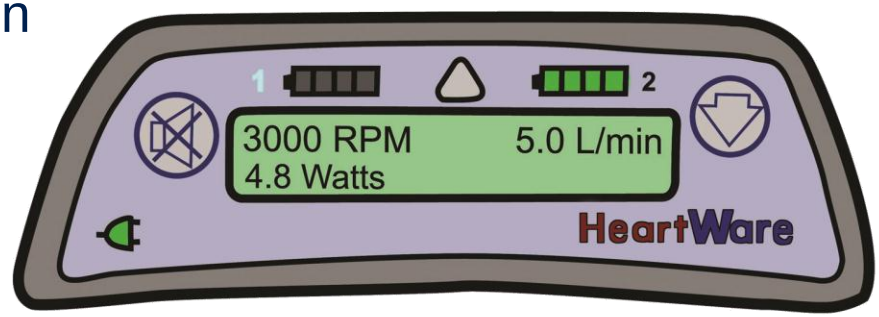
HeartWare® Controller Display Overview



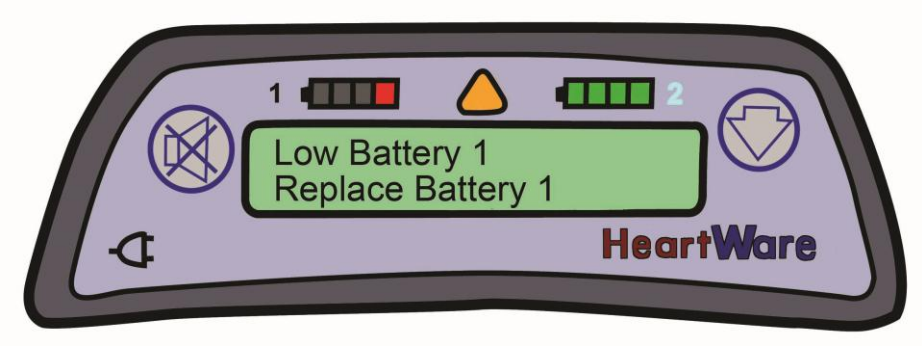
HeartWare® Controller Display Screen

- 2 line display for device status and alarms (if activated)

- Display provides pump information
  - Speed (RPM)
  - Power (Watts)
  - VAD blood flow (L/min)



- When an alarm occurs, the pump information is replaced by the alarm information



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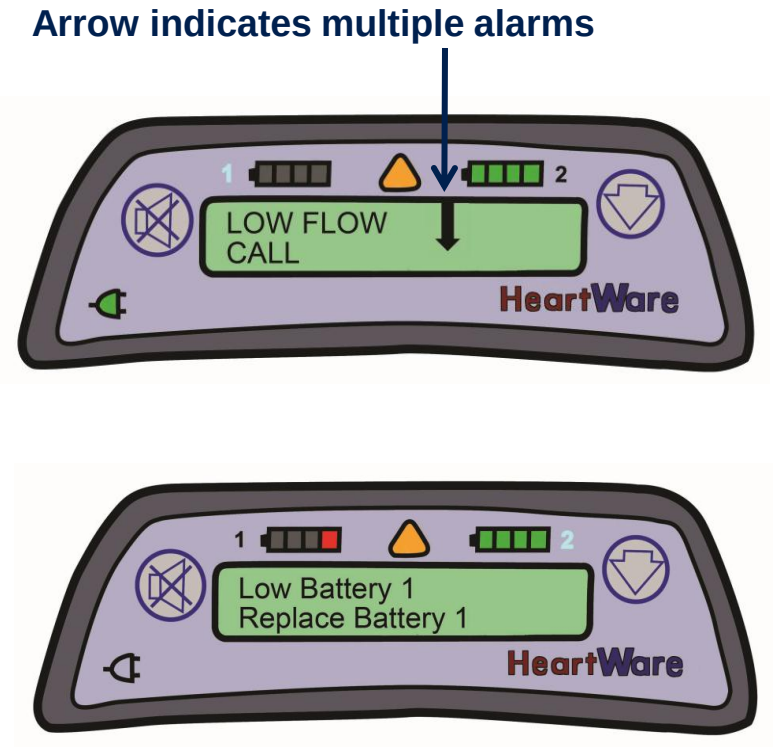
HeartWare® Controller: Buttons and Alarm Indicator

- Alarm Mute button
  - Silences medium and low priority alarms for 5 minutes
- Scroll button
  - Displays all active alarms
  - Displays pump information
  - Clears a resolved alarm condition
  - Provides a backlight
- Alarm indicator
  - Lights when 1 or more alarms occur
  - High Priority: Flashing Red
  - Medium Priority: Flashing Yellow
  - Low Priority: Solid Yellow



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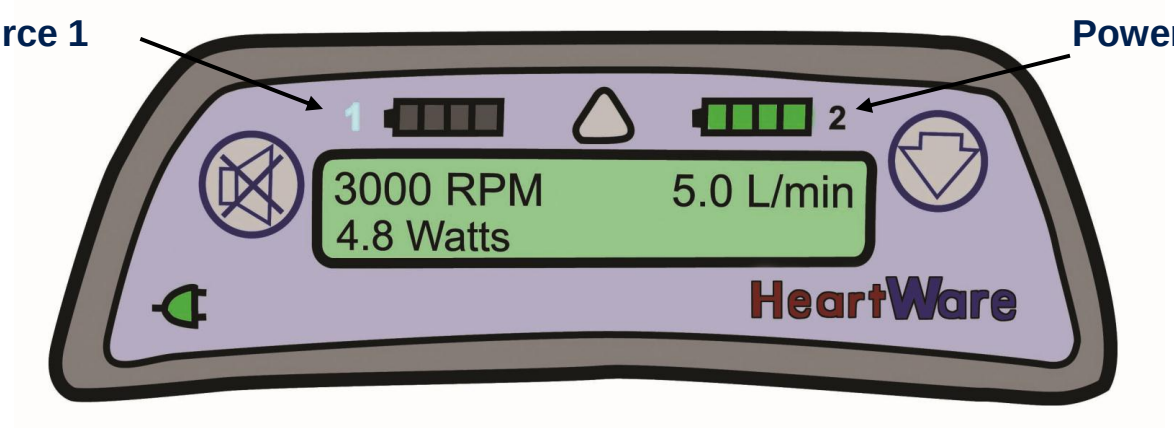
HeartWare® Controller: Power Source Indicators



- One power source indicator (labeled “1” or “2”) will light up based on which port is providing primary power (e.g. “1” in this case)
- Two battery indicators:

Battery Capacity	Battery Indicator
75-100%	4 GREEN lights
50-74%	3 GREEN lights
25-49%	2 YELLOW lights
≤24%	1 RED light

- AC/DC symbol  turns green when connected to an AC or DC adapter
- The AC/DC adapter will always be the primary source of power if connected

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Connecting the Driveline (Pump) to the HeartWare® Controller

To Connect Driveline (Pump) to Controller:

- **Align the two red marks and push together** on the silver driveline connector
- An **audible click will be heard** confirming proper connection
- Completely **cover the controller's silver driveline connector** with the driveline cover

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Disconnecting the Driveline (Pump) from the Controller

To Disconnect Driveline (Pump) From Controller:

- **Grasp** the driveline connector on the **ridged section**
- **Pull the driveline connector straight out** from the controller
- Do not disconnect by twisting or by pulling the driveline, this can damage the driveline

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Connecting Power to the HeartWare® Controller

- **Grasp** the cable of the power source at the **back end of the connector** (leaving front end of connector free to rotate)
- **Line up the solid white arrow** on the connector with the white dot on the controller
- **Gently push (but DO NOT twist) the cable into the controller until it naturally locks** into place; you should hear an audible click
- Confirm the cable is locked by gently pulling the cable near the controller power connector
- DO NOT force the cable into the controller connector without correct alignment as it may result in damaged connectors
- Repeat above steps for second power source

All power sources (batteries, AC adapter, DC adapter) use similar connectors and plug into the same controller power ports.

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Disconnecting Power from the HeartWare® Controller

- **Turn the connector sleeve ONLY counterclockwise** until it stops
- Then **pull the connector straight out** from the controller

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HeartWare® Back-up Controller

- Keep a back-up controller and extra fully charged batteries with the patient at all times in case of an emergency
- Verify that the back-up controller parameters match the primary controller parameters (e.g., pump speed, viscosity, alarm limit settings and suction detection)
- The back-up controller should be programmed:
  - Before the implant procedure
  - Upon any parameter change to the primary controller
  - When the primary controller is replaced

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HeartWare® Controller Power Sources

HeartWare® Battery

HeartWare® Controller AC Adapter

HeartWare® Controller DC Adapter

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Power Sources: AC / DC Adapters

- HeartWare® Controller AC Adapter (for wall outlet)
  - Green light will illuminate on adapter when correctly plugged into a wall outlet
- HeartWare® Controller DC Adapter (for use in car)
  - Green light will be lit on adapter when correctly plugged into a car outlet and receiving power

NOTE: When using the AC or DC adapter, a HeartWare® 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.

HeartWare Controller AC Adapter

HeartWare Controller DC Adapter

Power Sources: HeartWare® Batteries

- Contain lithium ion cells to power the HVAD® Pump.
- Each battery provides 4 to 6 hours when fully charged.
- The capacity of each battery in hours is based on:
  - Controller and pump operating power consumption
  - Number of battery charge and discharge cycles

The batteries are expected to have a useful operating life of greater than 500 charge and discharge cycles. If a battery provides only two hours of support duration, it should be replaced.

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Using the HeartWare® Batteries

- Each battery can provide 4 to 6 hours of support
- Pressing the Test Button  will light the Battery Capacity Display
- The battery will switch to other battery when <25% of power capacity remains.

Battery Capacity	Battery Capacity Display
75-100%	4 GREEN lights
50-74%	3 GREEN lights
25-49%	2 GREEN lights
≤24%	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.

- Batteries will lose capability over time; when a fully charged battery can only provide two hours of power, replace it

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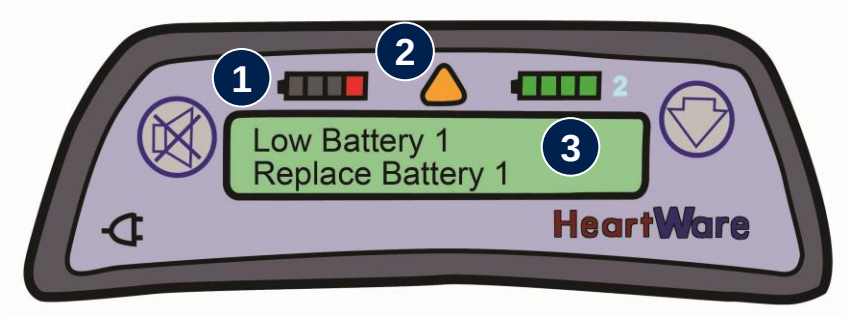
Power Sources: Battery Life

- To maintain full life of the batteries, change batteries **only when the controller instructs**
- This will occur when the battery has <24% capacity remaining
- Three indications on the controller:

1. Battery Indicator will show **1 red light**
2. Alarm Indicator will be **solid yellow**
3. Display will read **“Low Battery”** and **“Replace Battery”**



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HeartWare® Battery Charger

- Charges up to 4 batteries at a time
- Takes up to 5 hours to fully charge a depleted battery
- Connect and disconnect charger/ battery with same action as controller/battery
- Powered by AC outlet (wall) only
- Charger should remain plugged in
- Batteries not in use should be connected and stored in the charger

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HeartWare® Battery Charger Indicators

- **Battery Charger Power Light**: When **Green**, unit is plugged into wall outlet and is ready for use
- **"Ready" Light**: When **Green**, battery is fully charged and ready for use
- **"Status" Light:** Light means different things depending upon color (see table below)

Color of Light	Battery State
Yellow	Battery being charged; NOT ready for use.
Flashing Yellow	Battery not charging. Check battery connections. If connections 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.

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Patient Pack (Carry Bag)

- Patient Pack holds the HeartWare® Controller and 2 HeartWare® Batteries
- Instructions on proper packing, use, and care can be found in the Patient Manual

Additional Patient Pack Options

NOTE: These additional options are for clinical trial patients only

HeartWare® Shoulder Pack

HeartWare® Waist Pack

Instructions on proper packing, use and care can be found in the Patient Manual

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

NOTE: These additional options are for clinical trial patients only

- HeartWare® Shoulder Pack and HeartWare® 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)

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HeartWare® Shower Bag

- Allows patients to shower with the HeartWare® Ventricular Assist 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

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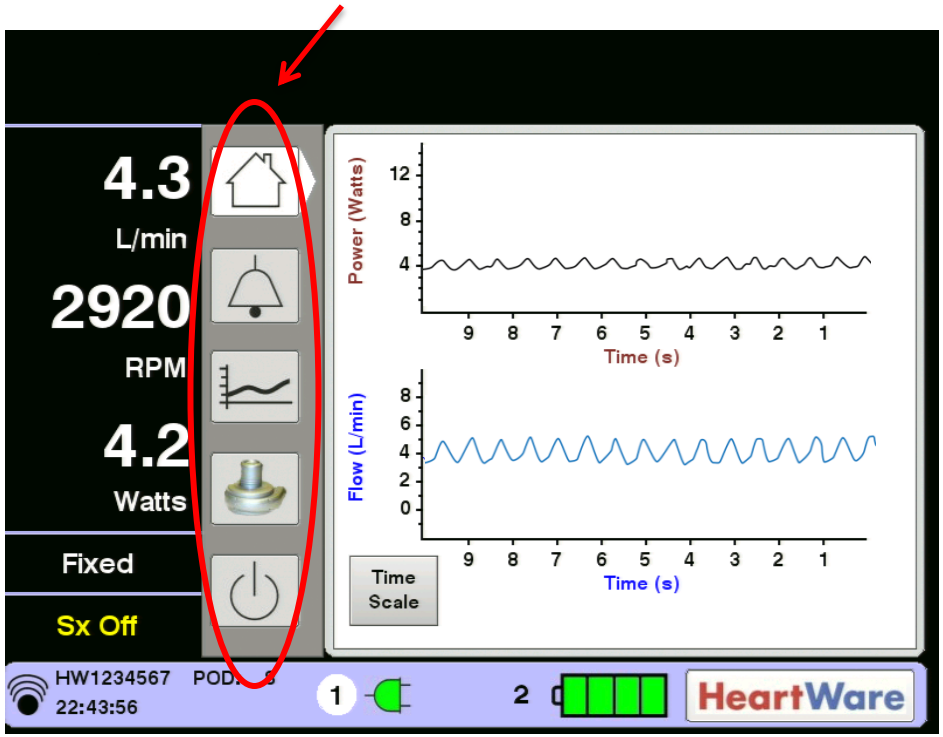
HeartWare® Monitor

There are five (5) icons on the monitor to access system information and to manage pump operation.

- Clinical (Home) Screen
- Alarm Screen
- Trend Screen
- System Screen
- Monitor Shut Down

Monitor Screen Icons



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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

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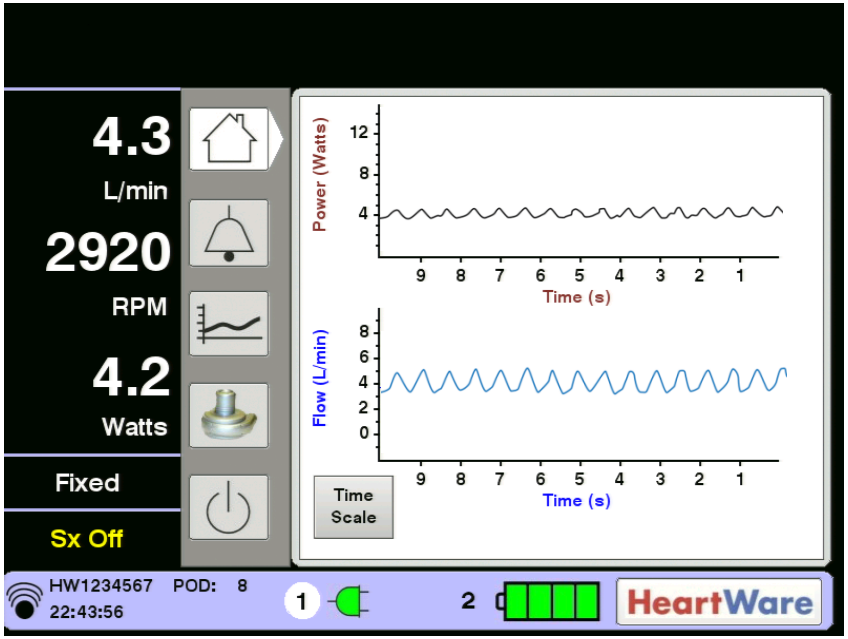
Clinical (Home) Screen

- Provides ongoing monitoring information when pump adjustment or access to other screens is not required
- Displays:
  - Real-time power (Watts) waveform
  - Real-time estimated HVAD® Pump blood flow (L/min) waveform



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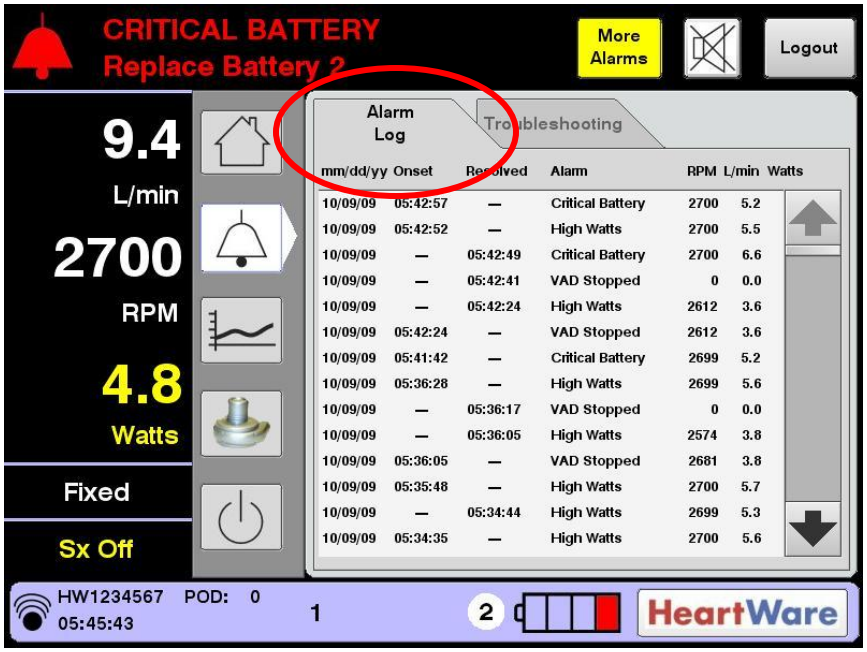
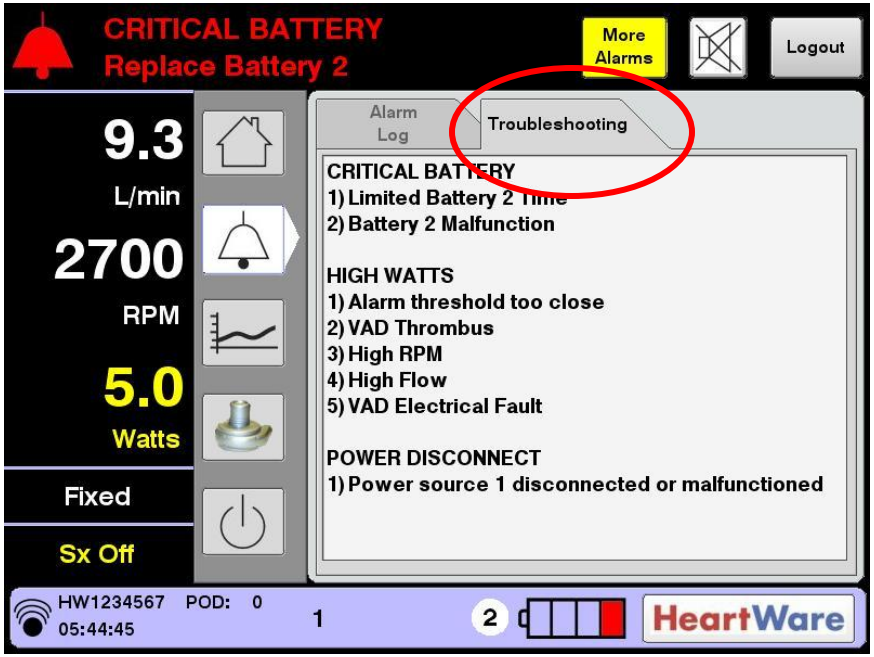
Alarm Screen

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

Alarm Log



Troubleshooting



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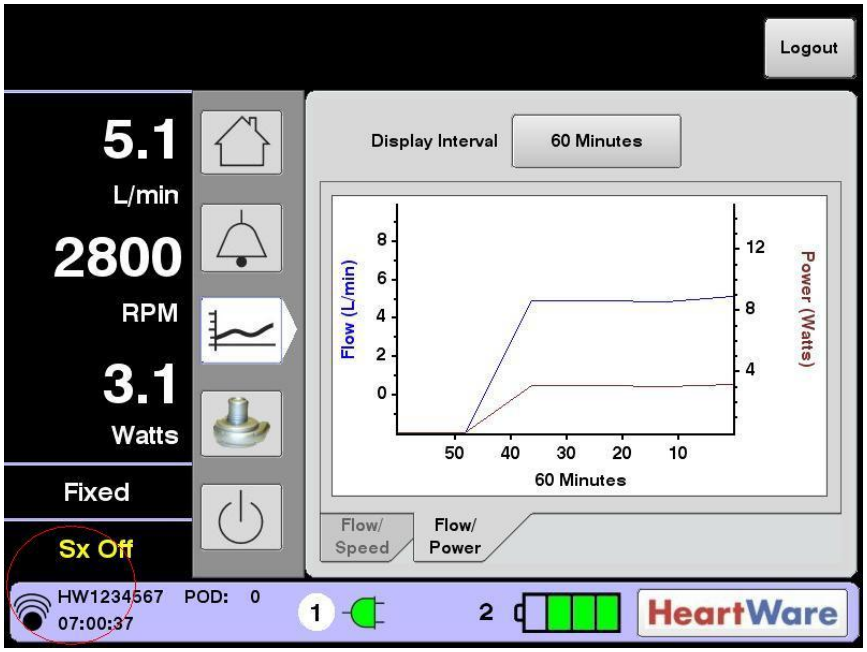
Trend Screen

The Trend Screen has two tabs:

- [Flow/Speed]
- [Flow/Power]

Displayed in Intervals of

- 60 minutes
- 4 hours
- 24 hours
- 14 days
- 30 days



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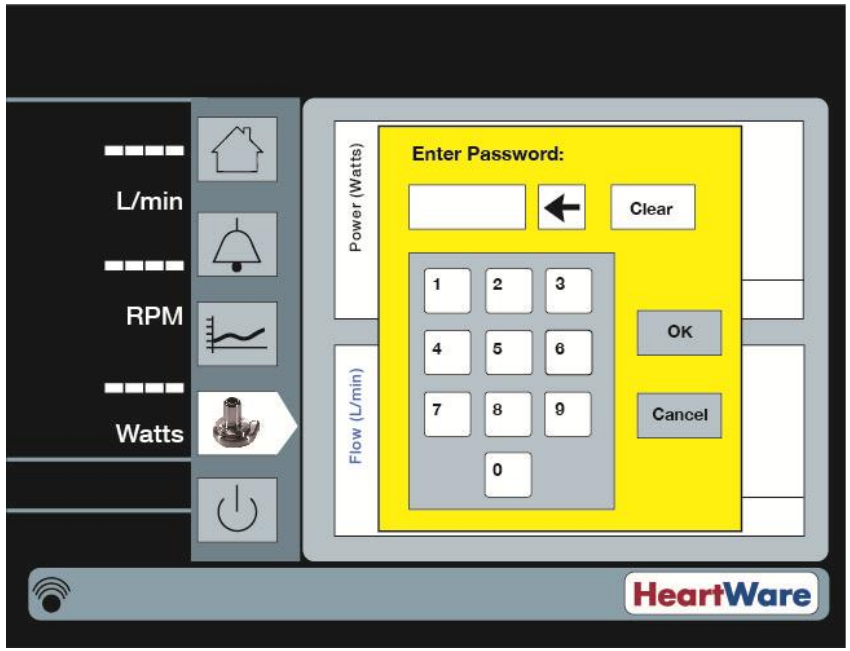
System Screen

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



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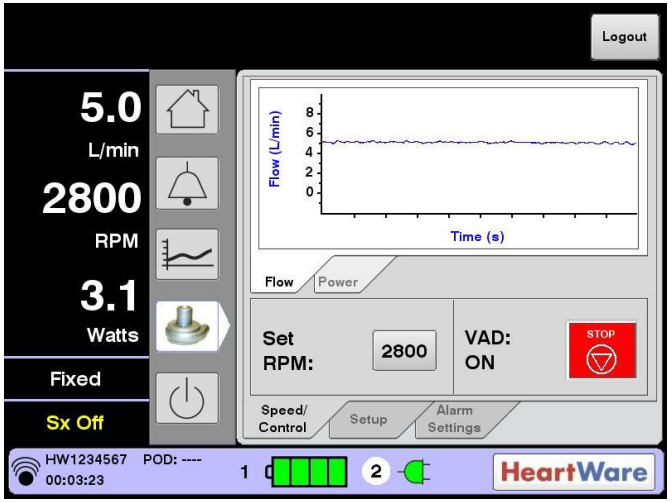
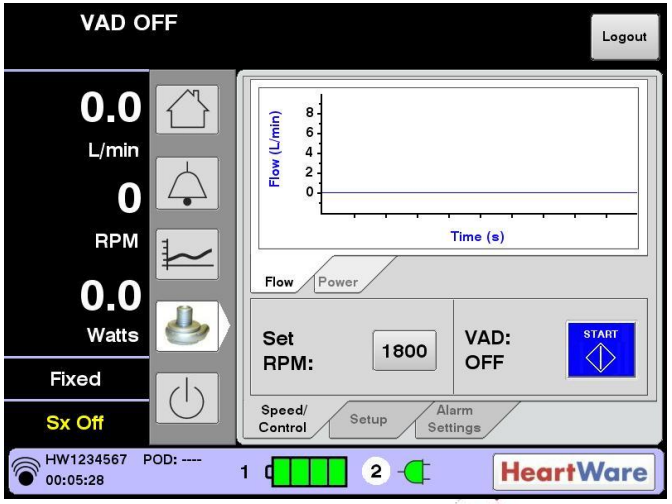
System Screen – Speed/Control Tab

- The [Speed/Control] tab is used to adjust RPM and to turn the VAD “ON” or “OFF”
- The [Set RPM] button is used to adjust the pump speed (RPM) from 1800 to 4000
- The [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





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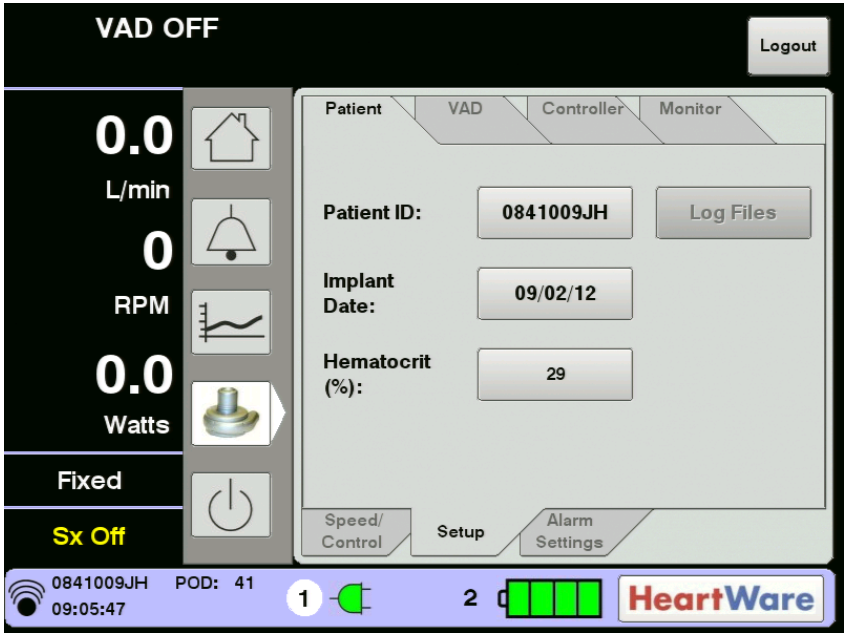
System Screen – Setup Tab

When the [Setup] tab is pressed, four tabs are displayed at the top:

- [Patient]
- [VAD]
- [Controller]
- [Monitor]



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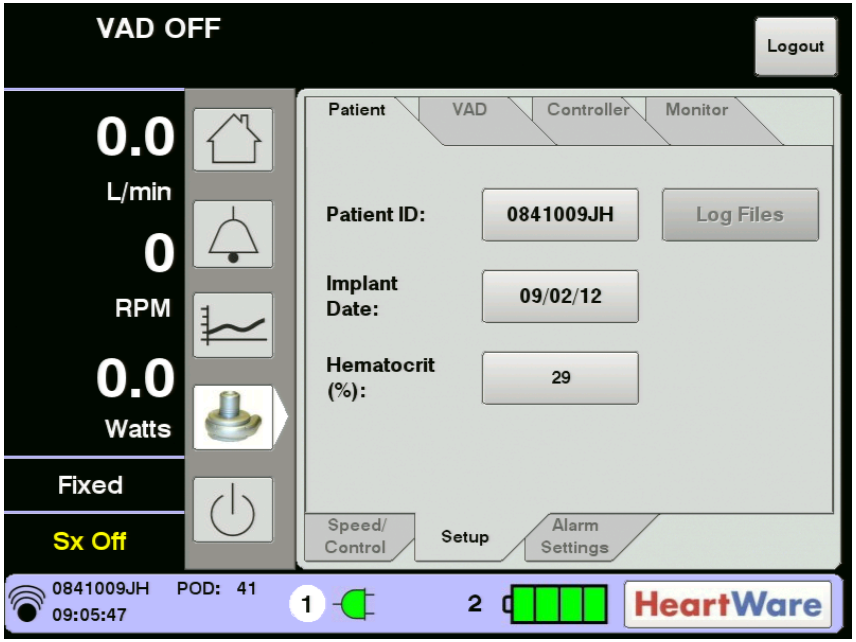
System Screen - Setup/Patient Tab

- The [Patient] tab is used to enter:
  - [Patient ID]
  - [Implant Date]
  - [Hematocrit]
- The hematocrit value is used to provide accurate flow estimation
- [Patient] tab is also used to download patient log files



Setup/Patient Tab: Patient Log Files

- This feature allows the user to obtain alarm and trend data from the controller
- Connecting a controller to the monitor initiates patient data download from the controller to the monitor
- The controller must be disconnected from the monitor serial port before the [Log Files] button is accessible
- Pressing the [Log Files] button initiates download from the monitor to a USB drive

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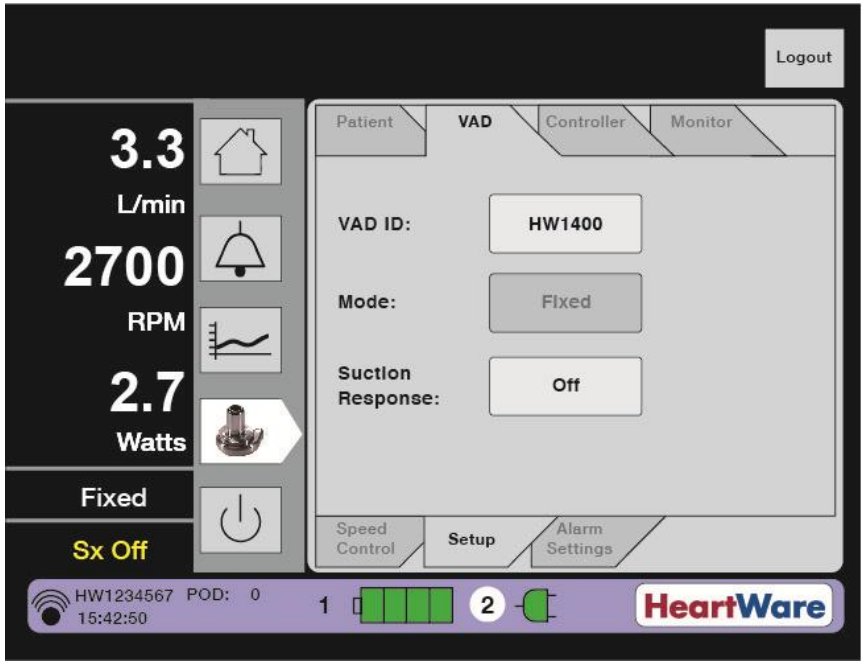
System Screen - Setup/VAD Tab

The [VAD] tab is used to:

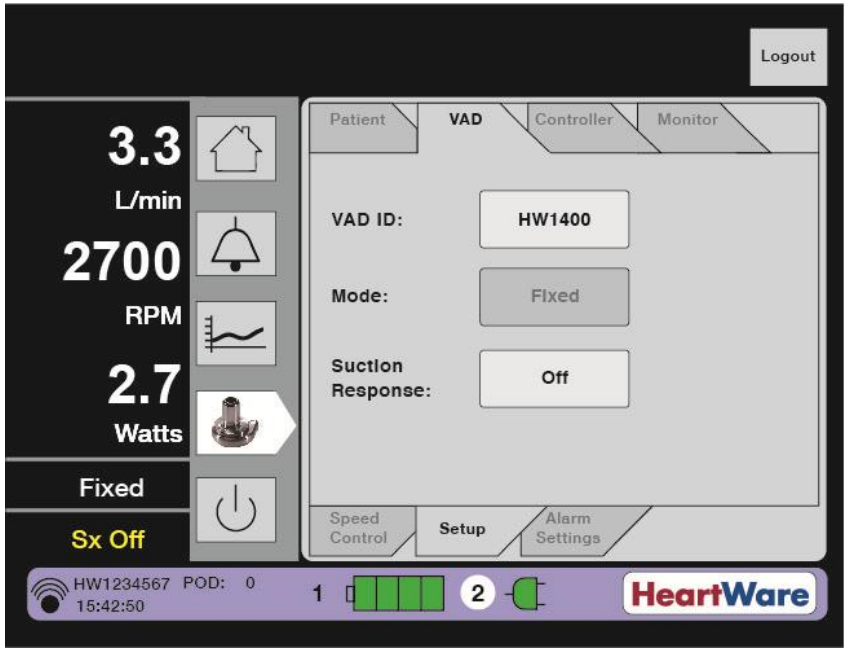
- Enter the HVAD® Pump serial number [VAD ID]
- Enable or disable the [Suction Response]
- “Fixed” mode is the only mode currently available in the US therefore this button is disabled



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 the RPM will immediately disable suction detection
- A “Sx Off” or “Sx On” message will be displayed on the Monitor in the lower left corner below the “Fixed” mode display
- Suction alarm should be set after the 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.

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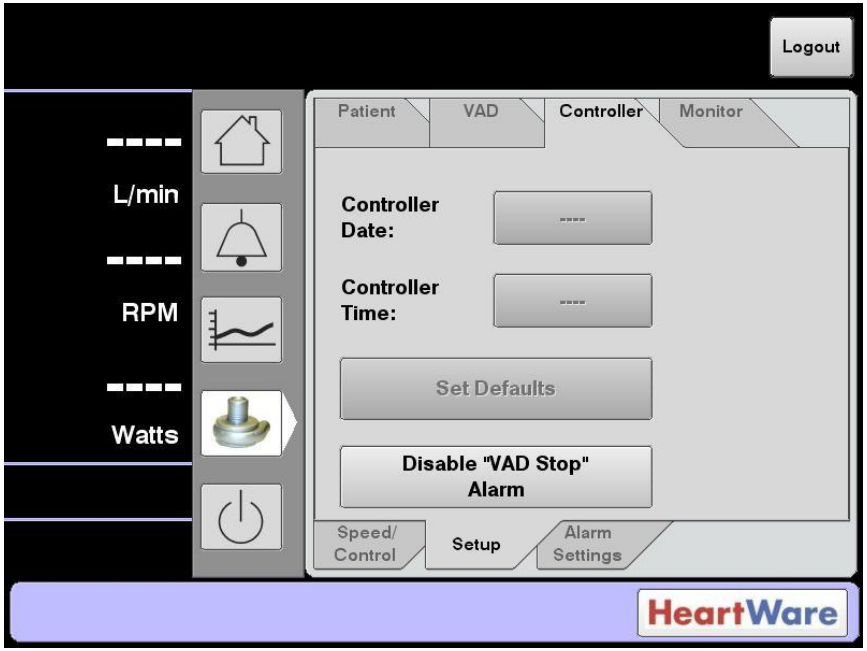
System Screen - Setup/Controller Tab

- The [Controller] tab is pressed to access [Controller Date], [Controller Time], and [Set Defaults] parameters
- [Disable “VAD Stop” Alarm] is used to silence the “VAD Stop” alarm while programming a controller not connected to a VAD
- The [Set Defaults] button sets the controller parameters to the original manufacturer settings

CAUTION: Do not use the “set defaults” button on the monitor when a controller is connected to a patient. Pressing it will erase all patient VAD parameter information from the controller.



Default settings

- Set Speed is 2500 RPM
- Low Flow Alarm threshold is 1.0 L/min
- High Power Alarm threshold is 16 Watts
- Suction Detection is “Off”
- Data Log Interval:15 minutes
- Hematocrit: 30%

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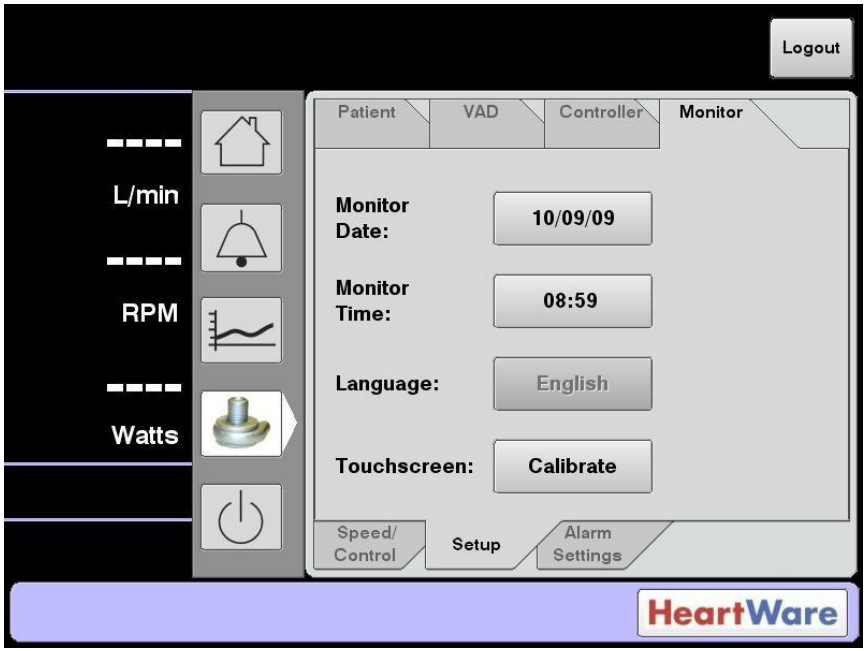
System Screen - Setup/Monitor Tab

- [Monitor Date] & [Monitor Time] buttons set the date and time on the monitor.
- [Touchscreen] button is used to initiate touch screen calibration for the monitor. The monitor will only initiate the calibration sequence if the controller is NOT connected to the monitor.



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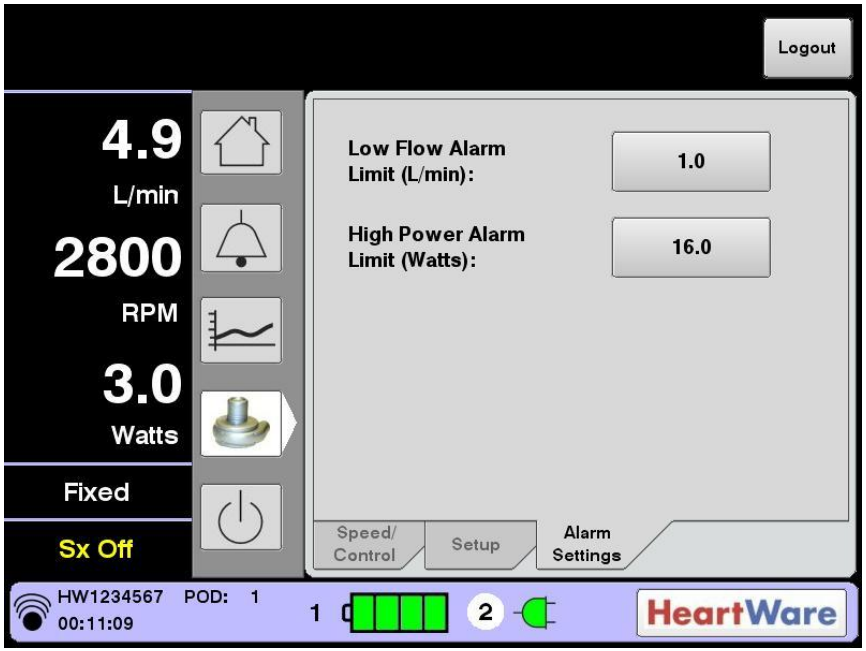
System Screen – Alarm Settings Tab

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



Default settings

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

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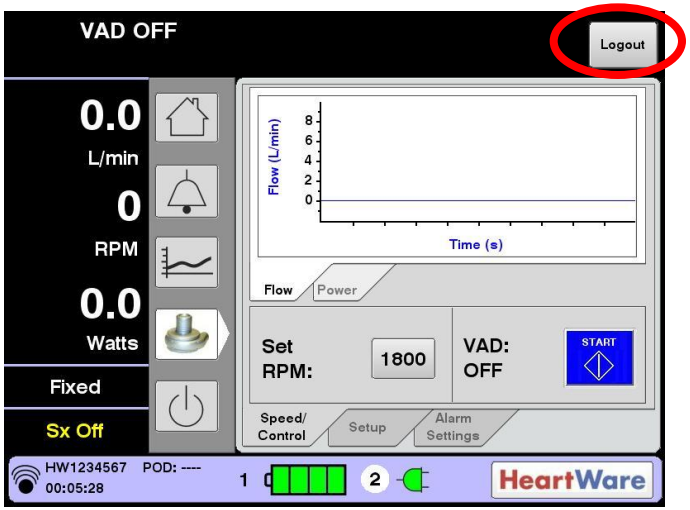
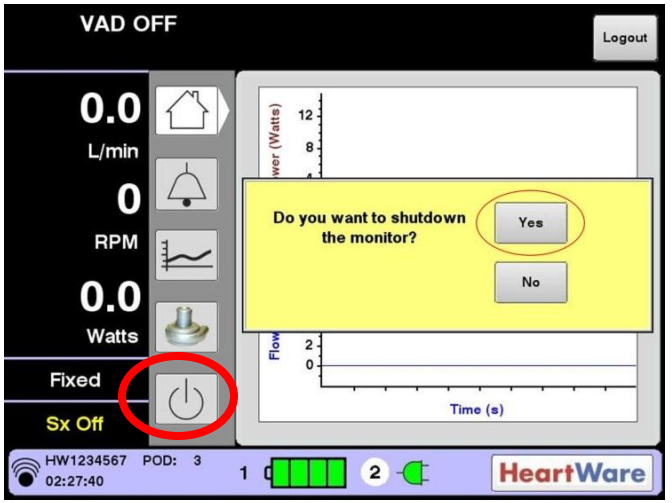
Monitor Logout and Shut Down

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





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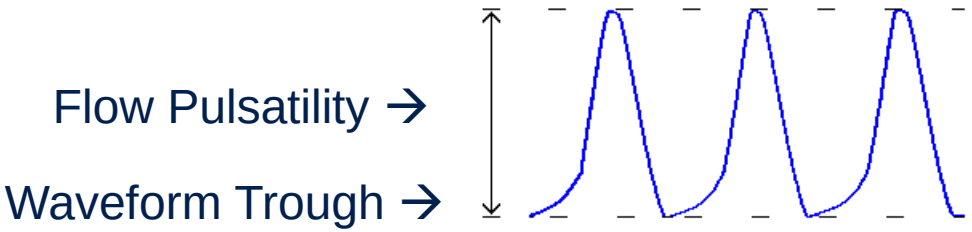
HVAD® Pump Flow Waveform Characteristics

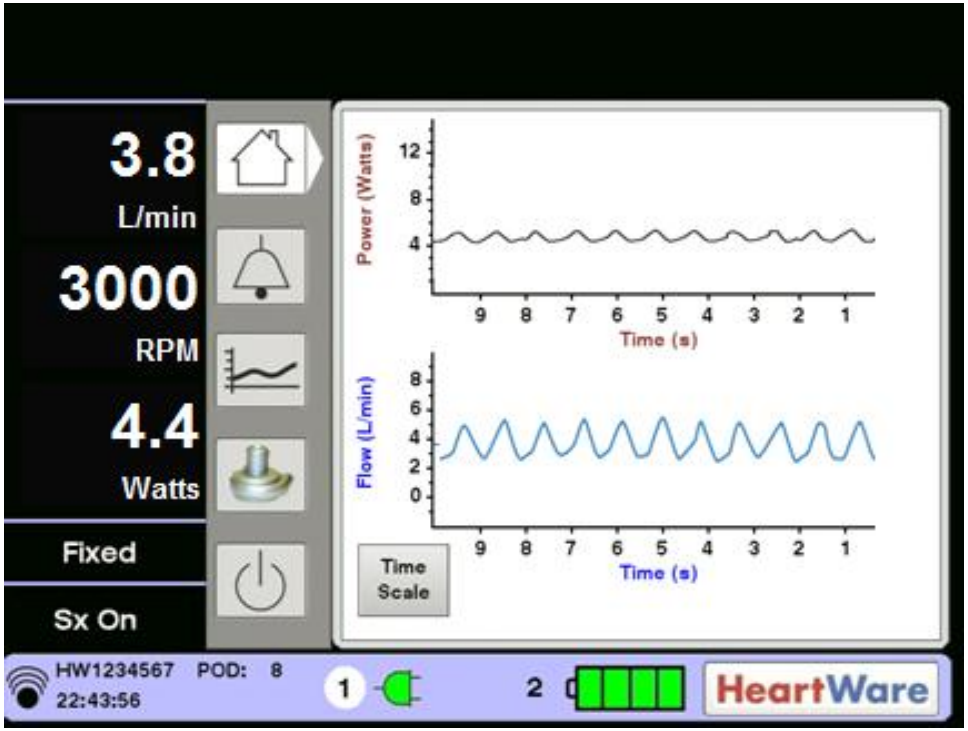
Waveform Definitions:

1. Flow Pulsatility: The difference between the minimum and maximum of the flow waveform. Pulsatility should be >2 L/min.

2. Waveform Trough: the minimum value of the VAD flow waveform. Trough should be >2 L/min.

Flow waveforms provide additional information about the patient condition and VAD performance.





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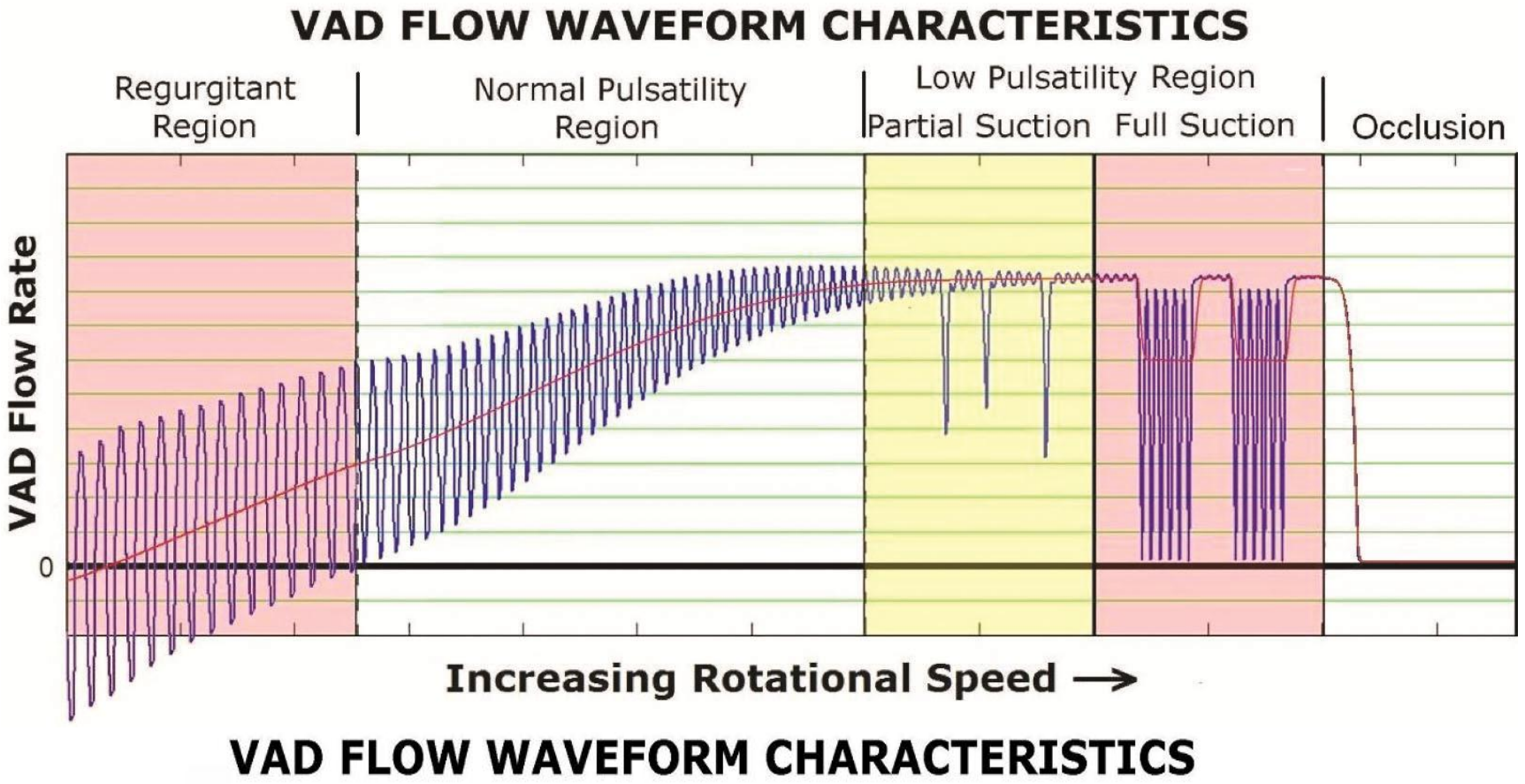
Flow Regions



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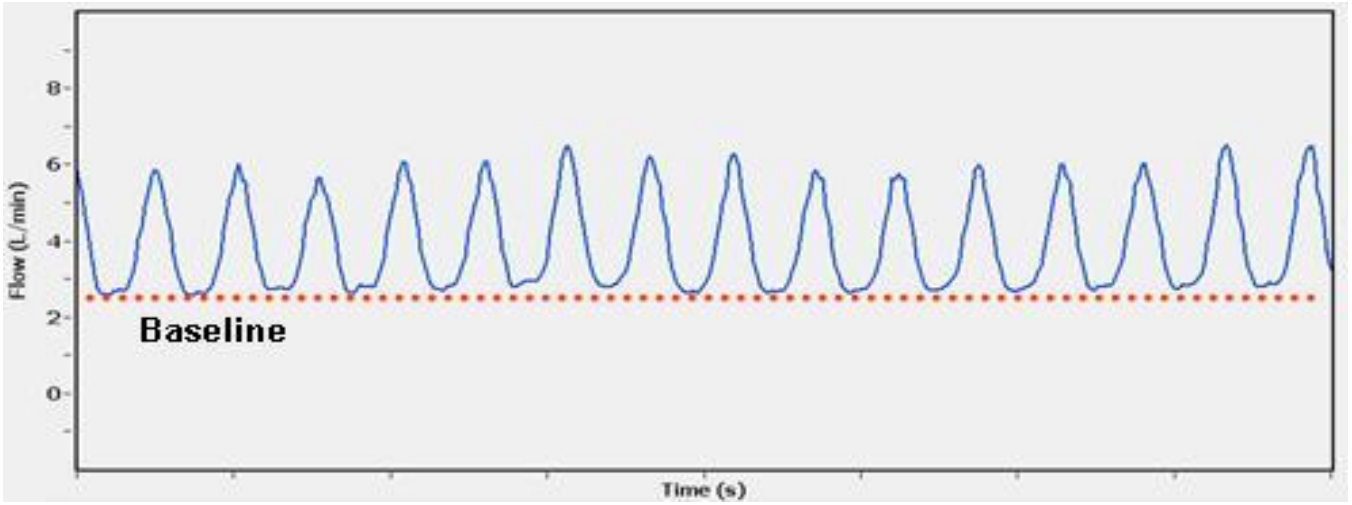
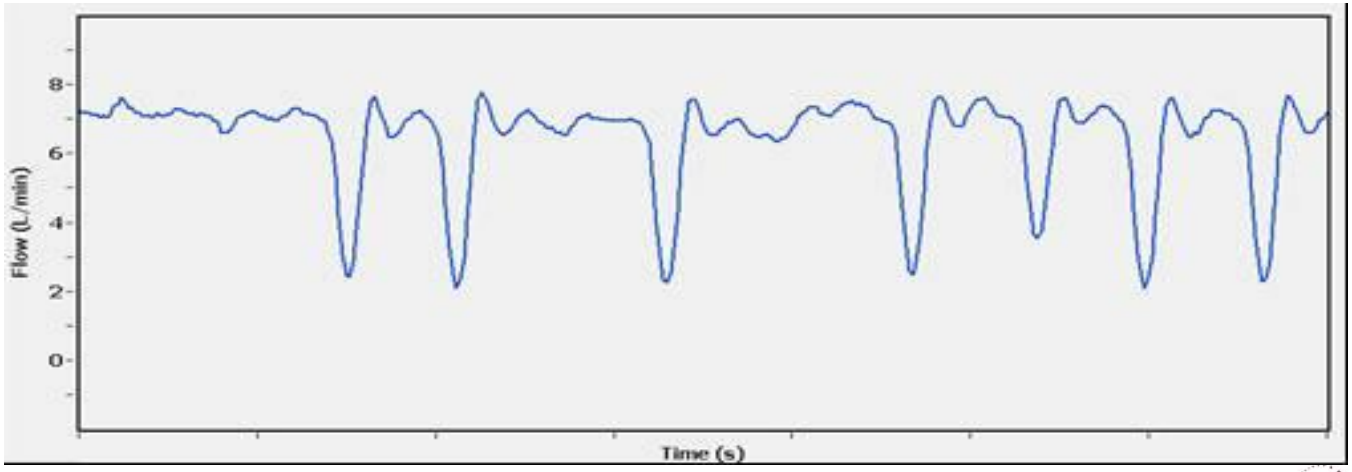
Suction Detection





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HeartWare ® Pump Operating Guidelines

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

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

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Post-Operative Management

*The following are recommended guidelines for optimal post-operative management based on industry standard of care**

- Continuous flow pumps are preload dependent and sensitive to increased afterload - consider clinical (patient) related changes when assessing changes in pump flow
- After implantation, the patient is returned to the Intensive Care Unit
- Consider clinical (patient) related changes when assessing changes in pump flow
- Fluids, medications and heart rate and rhythm should be optimized to maintain a pump flow index between **2.0 L/min/m^2 and 2.8L/min/m^2**
- Patients may require inotropic assistance of right ventricular function
- Control hypertension – **maintain MAP <85mmHg**

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

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Arrhythmias/Emergency Procedures

- Arrhythmias may occur in the post-operative period
- OK to defibrillate HeartWare® System patients
- Anti-arrhythmic drugs, pacemakers, and ICDs are compatible with the HeartWare® System
- Institute appropriate ACLS protocols as needed
- If chest compressions have been administered, confirm function and positioning of HVAD® Pump

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Postoperative Management - Anticoagulation

- Anticoagulation should be individualized for each patient
- In general, begin low-dose heparin at 10 units/kg/hr on postoperative day one to a target PTT of 40-50 seconds
- 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
- Gradually increase the heparin dosage to maintain the PTT in a range of 50-60 seconds

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Long Term Management – Anticoagulation/Antiplatelet

- A combination of Warfarin and Aspirin
- Warfarin should be started and titrated to maintain an INR of 2.0-3.0
- In general, 325mg of ASA should be started on POD 1, if no bleeding complications
- Check for ASA resistance with a reliable test (eg Verify Now) and adjust ASA monotherapy accordingly
- Other multi-drug options include
  - Aggrenox
  - ASA 81mg plus Clopidogrel

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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[1]

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

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

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Driveline Care

- Wear a cap, mask, and sterile gloves when performing exit site care
- Aseptic technique should be followed whenever the dressing is removed and the exit site exposed
- Visually inspect the driveline for tears, kinks, or any traumatic damage
- Clean exit site with antiseptic cleansing agent daily; then rinse and dry the exit site to avoid tissue injury
- Cover exit site with an occlusive dressing
- Immobilize the driveline and keep the extra length under a binder or clothing to minimize potential trauma to the exit site

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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.

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Nursing System Checks

Ongoing checks:

- Hematocrit – Verify HCT value and change as needed

Assess each shift and with EVERY speed change:

- Suction Alarm – used to detect suction events. Should be OFF for first 24-48 hours post-op and when IABP is still in. Verify ON/Alarm only after each speed change, unless physician has ordered alarm to be OFF.
- Low Flow Alarm – alarm should be set at 2 L/min below the actual flow, but no lower than 2.0 L/min
- High Power Alarm - alarm should be set 2 Watts above actual power reading

To check/change settings:

- Touch the Pump icon on monitor and enter password
- Touch [Setup] tab and [Patient] tab to change hematocrit; press [VAD] tab to turn [Suction Alarm] ON/OFF
- Touch [Alarm] tab to adjust [Low Flow Alarm] and [High Power Alarm] Limits

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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	• Loudest intermittent beep • Cannot be silenced by the Mute Button 	• Intermittent beep that becomes louder in 1 and 5 min 	• Intermittent beep that becomes louder in 5 and 10 min 
Controller Silencing	• Cannot be silenced by the Mute Button • The alarm will clear once the problem is resolved	• May be silenced for 5 min or 1 hour • Controller and Electrical Faults may be permanently silenced	• May be silenced for 5 min
Monitor Display	Red bell	Yellow bell	Yellow bell

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High Priority Alarms Summary (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 1	Replace Battery 1
	Critical Battery 2	Replace Battery 2
	Controller Failed	Change Controller

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High Priority Alarms: Blank Display

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
No Message	**No Message**	• No power to pump • Pump has stopped	1. Connect two new power sources 2. Replace controller 3. 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.

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High Priority Alarms: VAD Stopped

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
VAD Stopped	**Connect Driveline**	• Driveline disconnect • Driveline fracture • Connector malfunction/breakage • VAD electrical failure	1. **Reconnect driveline** 2. Download and email patient log files 3. Call clinical specialist
VAD Stopped	**Change Controller**	• Controller failure • VAD failure • VAD thrombus or other materials in device	1. **Exchange controller** 2. Download and email patient log files 3. Call clinical specialist

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High Priority Alarms: Controller Failed, Critical Battery

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
Controller Failed	**Change Controller**	• Controller component failed	1. Exchange controller
Critical Battery 1	**Replace Battery 1**	• Limited battery 1 or battery 2 time remaining • Critical battery malfunction without adequate secondary power source	1. Replace critical battery with fully charged battery or AC/DC adapter 2. Change controller if new power sources do not correct alarm
Critical Battery 2	**Replace Battery 2**		

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Medium Priority Alarms Summary (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: High Watt

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
High Watt	**Call**	• HVAD® pump Watts have exceeded High Power Alarm threshold • Alarm threshold too close • Thrombus or other materials in device • High RPM • High flow • LVAD electrical fault	1. Confirm correct settings for High Power Alarm and pump speed 2. Consider checking blood coagulation labs 3. Assess patient for hemolysis 4. Download and email patient log files 5. Consider ECHO to confirm unloading of heart, check for AI, thrombus, etc. 6. Contact clinical specialist

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Medium Priority Alarms: Electrical Fault

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
Electrical Fault	**Call**	• Fault in continuity of pump-to-controller electrical connections (e.g. contaminated driveline connector) • Partial driveline fracture • Connector malfunction • Controller component failure • VAD malfunction • Controller dropped	1. Ensure driveline connector is engaged 2. Patient should be seen in clinic/hospital 3. Inspect driveline for defects or the ability to reproduce the alarm 4. Download and email patient log files 5. Contact clinical specialist

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Medium Priority Alarms: Low Flow

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
Low Flow	**Call**	• Average flow dropped below Low Flow Alarm threshold • Alarm threshold too close • Suction • RPM too high or too low • Poor VAD filling (tamponade, hypovolemia, right heart failure, arrhythmias, inflow cannula obstruction, etc) • High blood pressure • Outflow graft kink	1. Confirm VAD parameters 2. Confirm correct settings for Low Flow Alarm limit and hematocrit 3. Confirm BP (MAP < 85 mmHg) 4. Attach patient to monitor and evaluate pump waveform while considering cause of poor LV filling. Consider volume resuscitation if indicated 5. Consider ECHO 6. If no potential patient cause can be identified, download and email log files 7. Contact HeartWare Clinical Support

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Medium Priority Alarms: Suction

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
Suction	**Call**	• RPM too high • Poor VAD filling (right heart failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc) • Thrombus or other materials in device	1. Confirm pump flow trends to evaluate a decrease in mean flow 2. Consider volume resuscitation and/or correct cause of poor ventricular filling 3. Consider decreasing pump speed 4. Consider ECHO 5. Download and email patient log files 6. Contact HeartWare Clinical Specialist

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Medium Priority Alarms: Controller Fault

Alarm Display (line 1)	Action (line2)	Potential Causes	Potential Actions
Controller Fault	**Call**	• Controller component malfunction but pump still working	1. Confirm frequency and duration of alarm, concurrent alarms, and pump flow, speed, and power 2. Assess patient for complaints of shortness of breath, chest pain, palpitations, dizziness, etc. 3. If isolated alarm monitor, with download at next visit
Controller Fault	**Call: ALARMS OFF**	• Controller component malfunction • Suction detection disabled • Low Flow alarm disabled • VAD Connect alarm may be disabled • High Power alarm may be disabled	1. Multiple alarms within 24 hours without other issues should be assessed at non-emergent visit 2. Multiple alarms within 1 hour with other alarms or symptoms, replace controller and assess in emergent visit 3. Download log files from original controller and new controller 4. Contact HeartWare Clinical Support

Handling an Emergency: Changing the Controller

1. Have the patient sit or lie down.

2. Place the new controller within easy reach.

3. Connect back-up power sources to the new controller.
   - Confirm that the power cables are properly locked on the controller by gently pulling on the cable near the connector
   - A “Power Disconnect” alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up
   - A “VAD Stopped” alarm will activate if the pump driveline is not connected to the new controller within 10 seconds - this alarm will resolve once the pump driveline is connected

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Handling an Emergency: Changing the Controller

4. Pull back the white driveline cover from the original controller's silver connector.

5. Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A "VAD Stopped" alarm may activate. Don't panic. You can silence the alarm after restarting the pump with the new controller, which is the priority.

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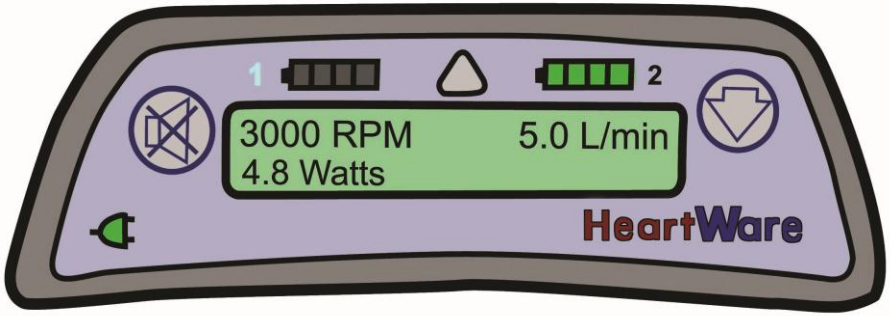
Handling an Emergency: Changing the Controller

6. Connect the driveline to the new controller (align the two red marks and push together). If the “VAD Stopped” alarm was active on the new controller, it will now resolve. The pump should restart.

Verify the pump is working (RPM, L/min, Watts). **If the pump does not restart, call for medical assistance immediately.**



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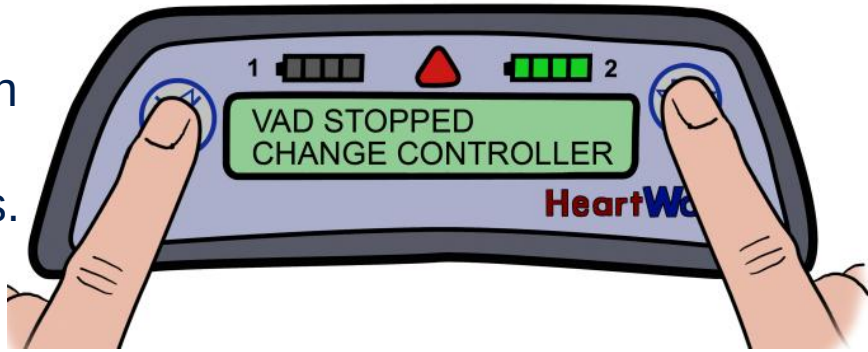
Handling an Emergency: Changing the Controller

7. To prevent the controller alarm from sounding after the power is removed:

   - If the red alarm adapter is available: before you remove power, insert it into the blue connector on the original controller.

   - If no alarm adapter is available:
     - Before you remove power, press and hold the alarm mute and scroll buttons simultaneously on the original controller until it beeps, or for at least 5 seconds.
     - Release the alarm mute and scroll buttons.



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Handling an Emergency: Changing the Controller

8. Remove both power sources from the original controller. The controller will be turned off and all alarms silenced.
9. Slide the white driveline cover up to cover new controller's silver connector.
10. Contact the VAD Coordinator or hospital to obtain a new back-up controller.

New controller

WARNING:

- Keep a spare controller and spare, fully charged batteries available at all times in case of an emergency
- The alarm adapter silences the "No Power" alarm and should only be attached to a controller that has failed or malfunctioned and one that is NOT connected to the pump.

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