HVAD® System
Managing and Troubleshooting Alarms and Equipment
Objectives

1. Managing HVAD® System Alarms
   • Review possible causes of Low, Medium and High priority alarms
   • Discuss possible actions to resolve alarms
2. Troubleshooting HVAD System Equipment
   • Discuss potential equipment issues
   • Provide potential approaches to resolve equipment issues
Alarm Overview

- Alarm conditions are displayed on the controller and monitor

- There are three types of Alarms
  1. High priority
  2. Medium priority
  3. Low priority

- And each alarm has:
  1. A unique sound
  2. A visual display
  3. A message
**HVAD® Monitor: Alarm Settings on System Screen**

- The [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.

Default settings:
- Low Flow Alarm threshold is 1.0 L/min
- High Power Alarm threshold is 16 Watts
1. 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

2. High Power Alarm
   • Range 1.0 to 25 Watts
   • Should be set 2 above the average Watts
HVAD® Monitor: Alarm Screen, Alarm Log

• When connected to a HVAD Controller, the Heartware Monitor displays both active and resolved alarms

• Alarm bell in upper left indicates active alarm

• [Alarm Log] tab
  – Displays date and time of alarm start and stop as well as pump parameters
  – Only displays Medium and High Priority Alarms
HVAD® Monitor: Alarm Screen: Alarm Log

- Alarms are displayed as stored in the controller (first-in first-out basis)
- Scroll arrow is used to access additional data
HVAD® Monitor: Alarm Screen: Troubleshooting

- [Troubleshooting] tab displays active alarms and potential causes for each alarm
HVAD® Controller: Alarm Indicator & Mute Button

- Low Priority: **Solid Yellow** *as shown*
- Medium Priority: **Flashing Yellow**
- High Priority: **Flashing Red**
# Summary of Alarm Display and Audio by Alarm Type

<table>
<thead>
<tr>
<th></th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Controller Display</strong></td>
<td>Flashing Red Triangle</td>
<td>Flashing Yellow Triangle</td>
<td>Solid Yellow Triangle</td>
</tr>
<tr>
<td><strong>Controller Audio</strong></td>
<td>• Loudest intermittent beep</td>
<td>• Intermittent beep that becomes louder in 1</td>
<td>• Intermittent beep that becomes louder in 5</td>
</tr>
<tr>
<td></td>
<td>• Cannot be silenced by the Mute Button</td>
<td>and 5 min</td>
<td>and 10 min</td>
</tr>
<tr>
<td><strong>Controller Silencing</strong></td>
<td>• Cannot be silenced by the Mute Button</td>
<td>• May be silenced for 5 min or 1 hour</td>
<td>• May be silenced for 5 min</td>
</tr>
<tr>
<td></td>
<td>• The alarm will clear once the problem is resolved</td>
<td>• Controller and Electrical Faults may be permanently silenced</td>
<td></td>
</tr>
<tr>
<td><strong>Monitor Display</strong></td>
<td>Red bell</td>
<td>Yellow bell</td>
<td>Yellow bell</td>
</tr>
</tbody>
</table>

---

*HeartWare*
# High Alarms (Blank or Flashing Red)

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Controller Alarm Display (line 1)</th>
<th>(line 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High – Critical (Blank Display)</td>
<td>No Message</td>
<td>No Message</td>
</tr>
<tr>
<td></td>
<td>![blank display icon]</td>
<td></td>
</tr>
<tr>
<td>High – Critical (Flashing Red)</td>
<td>VAD Stopped</td>
<td>Connect Driveline</td>
</tr>
<tr>
<td></td>
<td>![flashing red icon]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VAD Stopped</td>
<td>Change Controller</td>
</tr>
<tr>
<td></td>
<td>Critical Battery</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td></td>
<td>Critical Battery</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td></td>
<td>Controller Failed</td>
<td>Change Controller</td>
</tr>
</tbody>
</table>
# High Priority Alarms: Blank Display

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Message</td>
<td>No Message</td>
<td>• No power to pump&lt;br&gt;• Pump has stopped</td>
<td>1. Connect two new power sources&lt;br&gt;2. Replace controller&lt;br&gt;3. Contact Clinical Specialist</td>
</tr>
</tbody>
</table>

**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.
## High Priority Alarms: VAD Stopped

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
</table>
| 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. Contact 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. Contact Clinical Specialist |
## High Priority Alarms: Controller Failed, Critical Battery

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Failed</td>
<td>Change Controller</td>
<td>• Controller component failed</td>
<td>1. Exchange controller</td>
</tr>
<tr>
<td>Critical Battery</td>
<td>Replace Battery 1</td>
<td>• Limited battery 1 or battery 2 time remaining • Critical battery malfunction without adequate secondary power source</td>
<td>1. Replace critical battery with fully charged battery or AC/DC adapter 2. Change controller if new power sources do not correct alarm</td>
</tr>
<tr>
<td>Critical Battery</td>
<td>Replace Battery 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Medium Priority Alarms (Flashing Yellow)

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium (Flashing Yellow)</td>
<td>Controller Fault</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Controller Fault</td>
<td>Call: ALARMS OFF</td>
</tr>
<tr>
<td></td>
<td>High Watts</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Electrical Fault</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Low Flow</td>
<td>Call</td>
</tr>
<tr>
<td></td>
<td>Suction</td>
<td>Call</td>
</tr>
</tbody>
</table>
## Medium Priority Alarms: High Watts

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Watt</td>
<td>Call</td>
<td>• HVAD® Pump Watts have exceeded High Power Alarm threshold</td>
<td>1. Confirm correct settings for High Power Alarm and pump speed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Alarm threshold too close</td>
<td>2. Consider checking blood coagulation labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Thrombus or other materials in device</td>
<td>3. Assess patient for hemolysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• High RPM</td>
<td>4. Download and email patient log files</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• High flow</td>
<td>5. Consider ECHO to confirm unloading of heart, check for AI, thrombus, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LVAD electrical fault</td>
<td>6. Contact Clinical Specialist</td>
</tr>
</tbody>
</table>
Medium Priority Alarms: Electrical Fault Alarm

- The Electrical Fault alarm indicates there is a fault in the continuity of the pump-to-controller electrical connection and indicates that the pump is running on a single stator.
- It occurs when there is a problem anywhere within the electrical system: pump, driveline or controller.
- Do not change controllers during an active [Electrical Fault] alarm.
## Medium Priority Alarms: Electrical Fault

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
</table>
| 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 |
## Medium Priority Alarms: Low Flow

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
</table>
| 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 clinical specialist |
## Medium Priority Alarms: Suction

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

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
</table>
| 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 the patient and download log files 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 Clinical Specialist |
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.
Permanently Silencing Controller and Electrical Fault Alarms from the Monitor

- The [Electrical Fault Audio] and [Controller Fault Audio] button appear on the monitor during an active “Electrical Fault” or “Controller Fault” alarm condition.
- The audio button can be used to permanently silence these alarms; however, the controller and monitor will continue to display the fault alarm until the condition resolves.
- If the alarm condition resolves, then occurs again, the silence command will be reset and there will be audio for the new alarm condition.

**Step 1:** Press [Controller Fault Audio] [On] button to silence alarm

**Step 2:** Confirm silence of alarm
### Low Priority Alarms (Solid Yellow)

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (Solid Yellow)</td>
<td>Low Battery 1</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td></td>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td></td>
<td>Power Disconnect</td>
<td>Reconnect Power 1</td>
</tr>
<tr>
<td></td>
<td>Power Disconnect</td>
<td>Reconnect Power 2</td>
</tr>
</tbody>
</table>
# Low Priority Alarms: Low Battery, Power Disconnect

<table>
<thead>
<tr>
<th>Controller Alarm Display (line 1)</th>
<th>Action (line 2)</th>
<th>Potential Causes</th>
<th>Potential Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Battery 1</td>
<td>Replace Battery 1</td>
<td>• Battery power is low</td>
<td>1. Replace low battery with fully charged battery or the AC or DC adapter</td>
</tr>
<tr>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power Disconnect</td>
<td>Reconnect Power 1</td>
<td>• Power source is disconnected or malfunctioning</td>
<td>1. Reconnect power source 2. Replace power source 3. Consider replacing controller (if connecting known good power sources does not clear alarm)</td>
</tr>
<tr>
<td>Power Disconnect</td>
<td>Reconnect Power 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
HVAD® System Equipment Handling, Care & Troubleshooting
HVAD® System Maintenance

- No annual maintenance requirements for the HVAD System
- Equipment should be inspected for damage and dirt, and cleaned per instructions in IFU
- Cleaning instructions for equipment can be found in the IFU

Information related to the useful life and when to replace equipment can be found in the IFU
## HVAD® Monitor Handling and Care

<table>
<thead>
<tr>
<th>Reported Issue</th>
<th>Potential Prevention / Resolution</th>
</tr>
</thead>
</table>
| Monitor plugged in, but doesn’t turn on                     | • Potentially caused by depleted internal monitor battery; keep monitor plugged into AC power when not in use  
• Call clinical specialist for instructions on advanced troubleshooting |
| Monitor displays “critical error” during boot up            | • Potentially caused by not shutting monitor down properly; press On/Off icon on monitor screen prior to pressing power button on top of monitor  
• Shut down and restart monitor  
• Replace monitor if not resolved after restart                |
| Monitor displays “critical error” message while attempting to download log files | • Shut down and restart monitor  
• Verify USB is HeartWare Monitor compatible  
• Attempt download with a different USB  
• If still not working, erase log files on monitor, then reattempt download  
• If all troubleshooting fails, replace monitor |
<table>
<thead>
<tr>
<th>Issue</th>
<th>Potential Prevention / Resolution</th>
</tr>
</thead>
</table>
| Outer sheath cracked / damaged                                       | • Potentially caused by twisting and kinking – educate patient to limit driveline trauma  
|                                                                      | • Call Clinical Specialist to repair driveline                   |
| Blood in driveline                                                  | • Generally a result of a knick in the driveline – care should be taken during device implant  
|                                                                      | • Call Clinical Specialist to repair driveline                   |
| Strain relief disconnected from driveline and/or connector           | • Take picture and send to Clinical Specialist for evaluation and potential repair (if required) |
| Loosening and disassembly of HVAD Pump driveline connector           | • Inspect during routine visits,  
|                                                                      | - Partial Separation: attempt to hand-tighten  
|                                                                      | - Complete Separation: secure connector to controller with a splint  
|                                                                      | • Take picture and send to Clinical Specialist for evaluation and potential repair (if required) |
| Physical damage to the connector and/or driveline causing electrical faults | • Ensure connector remains dry/clean during pump implant (see next slide)  
|                                                                      | • Download and send patient log files for evaluation  
|                                                                      | • Take picture and send to Clinical Specialist for evaluation and potential repair (if required) |

*Any HVAD Pump that is explanted and returned to Medtronic must have a minimum of 3 inches (7.6cm) of the driveline remaining attached to the HVAD Pump in order to perform functional testing.*
Preventing Driveline Contamination

- Care should be taken to ensure no foreign material enters the connection between the driveline and the controller.
- To prevent driveline connector contamination:
  - Utilize the driveline cap.
  - Follow the tunneling technique as outlined in the IFU.
  - Keep the connections clean and free of any foreign material.
  - Examine the driveline connection prior to connecting it to the controller – foreign substances, such as lubricants, blood or saline should not be present.

Caution! If foreign material contaminates the driveline connection, electrical fault alarms may occur.
Preventing Driveline Contamination

The following pictures illustrate connector pins as normally observed between the pump and the controller.

Controller Connector

Driveline Connector

The following pictures illustrate connectors that have been compromised due to various foreign materials.

Controller Connector

Driveline Connector

Information generated from manufacturer experience to date as documented within manufacturer’s comprehensive quality and complaint management systems.
## HVAD® Controller Handling and Care

<table>
<thead>
<tr>
<th>Issue</th>
<th>Potential Prevention / Resolution</th>
</tr>
</thead>
</table>
| Wrong date/time on controller log files   | • Verify date/time set correctly on controller  
• Elective controller exchange if patient can tolerate, return and replace                                                                                                                                                    |
| Controller software update did not complete successfully | • Be sure the power and data port connections are properly connected.  
• Power cycle the monitor by turning it off and on again.  
• Attempt the controller software update process again.  
• Ensure to power cycle the controller after completion of the update process.                                                                                                                                            |
| Controller settings defaulted to manufacturer settings | • Don't use “set defaults” button  
• Connect to monitor and re-enter parameters                                                                                                                                                                                     |

**WARNING!:** DO NOT operate the controller in temperatures less than -20°C (-4°F) or greater than 50°C (122°F) or the controller may fail.

Information generated from manufacturer experience to date as documented within manufacturer’s comprehensive quality and complaint management systems.
HVAD® Controller: Static Electricity

- Static electricity is technically referred to as electrostatic discharge (ESD)
- A mild shock to the skin will not affect the controller; however, ESD to the controller or its connectors may cause the controller to function improperly
- ESD to the controller can result in one of the following controller alarms
  - [Controller Failed]
  - High Priority Audible Alarm without accompanying text on controller screen
  - [Controller Fault]
- A controller exchange should be performed for both [Controller Failed] and high priority audible alarms without accompanying text
- If a [Controller Fault] alarm occurs and does not clear, a controller exchange should be performed

**WARNING!** Be watchful for any alarms after battery or controller changes. When possible, patients should have a caregiver nearby when changing equipment.
**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 Handling and Care

<table>
<thead>
<tr>
<th>Reported Issue</th>
<th>Potential Prevention / Resolution</th>
</tr>
</thead>
</table>
| Patient reports battery support time diminished | • Educate patient to consistently rotate batteries  
• Identify which battery(ies) are providing reduced support time  
• Download log files and send to HeartWare to verify battery life  
• Replace batteries that provide <2 hours of support |
| Broken/bent pin on power source              | • Teach patients/staff how to make good connections (see next slide)  
• Replace power source |
| Battery not charging when on charger         | • Identify whether problem is with battery or battery slot by trying different slots on battery charger  
• Replace battery if defective  
• Replace charger if defective |
| Power source doesn’t stay connected to controller | • Verify the issue is with the power source connector and not the controller  
• Replace power source if connector defective  
• Replace controller if controller connection defective |
| Green light not lit on AC/DC power adapter   | • Verify the adapter is plugged into a working outlet  
• Verify the adapter is properly attached to the power cord  
• Replace if defective |

Information generated from manufacturer experience to date as documented within manufacturer’s comprehensive quality and complaint management systems.
Making Good Connections

- Connectors for the power sources were designed to both provide power and to be securely locked once connected to the controller.
- Forcing connectors together may damage the pins.
- To prevent damage: 1) Grasp the back of the connector, 2) Align solid white arrow and white dot, 3) Gently push (DO NOT twist) until connector naturally locks in place.

Correct for snap-lock and audible feedback

Proper hold to connect

Incorrect
# HVAD® Battery Charger Handling and Care

<table>
<thead>
<tr>
<th>Reported Issue</th>
<th>Potential Prevention / Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery charger slot not charging battery</td>
<td>• Verify problem is with the battery slot and not the battery by trying another battery in same slot</td>
</tr>
<tr>
<td></td>
<td>• Replace charger if defective</td>
</tr>
<tr>
<td>Unable to connect battery to charger</td>
<td>• Determine if charger or battery has the affected connector</td>
</tr>
<tr>
<td></td>
<td>• Replace the appropriate piece of equipment (battery or charger)</td>
</tr>
<tr>
<td>Status or Ready lights not lighting</td>
<td>• Replace battery charger</td>
</tr>
</tbody>
</table>
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.

The IFU can be found at www.heartware.com/clinicians/instructions-use.