**HeartWare, HVAD, MVAD, PAL and the HEARTWARE logo are trademarks of HeartWare, Inc.**

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

---

**Device Operation Guidelines (continued)**

### HVAD System Overview

**HeartWare® Controller**
- Provides feedback on pump operation through text, lights, and sounds.
- Requires 2 power sources at all times.
- Contains an internal battery to run an audible "No Power" alarm.

**HeartWare® Battery**
- Lithium Ion battery used to power the pump.
- Each battery provides 4-6 hours of operation when fully charged.
- Provides feedback on pump operation through text, lights, and sounds.

**HeartWare® Monitor**
- Touch screen tablet PC.
- Used by clinicians to set and change pump parameters.
- Displays adjustable real-time and historical pump information and alarm conditions.

**HeartWare® Controller AC Adapter**
- Charges and tests up to 4 batteries simultaneously.
- Designed to support an active lifestyle.

**HeartWare® Controller DC Adapter**
- Used power from an electrical outlet in an automobile to power the controller.

**HeartWare® Controller**
- Provides feedback on pump operation through text, lights, and sounds.
- Requires 2 power sources at all times.
- Contains an internal battery to run an audible "No Power" alarm.

**HeartWare® Battery**
- Lithium Ion battery used to power the pump.
- Each battery provides 4-6 hours of operation when fully charged.
- Provides feedback on pump operation through text, lights, and sounds.

**HeartWare® Monitor**
- Touch screen tablet PC.
- Used by clinicians to set and change pump parameters.
- Displays adjustable real-time and historical pump information and alarm conditions.

**HeartWare® Controller AC Adapter**
- Charges and tests up to 4 batteries simultaneously.
- Designed to support an active lifestyle.

**HeartWare® Controller DC Adapter**
- Used power from an electrical outlet in an automobile to power the controller.

---

### Alarm Guide

#### Alarm Type

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Alarm Display</th>
<th>Action Display (line 1)</th>
<th>Action Display (line 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Flashing Red</td>
<td>Call Controller Fault</td>
<td>Call: ALARMS OFF</td>
</tr>
<tr>
<td><strong>Critical</strong></td>
<td>Flashing Yellow</td>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Flashing Yellow</td>
<td>Low Battery 1</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Solid Yellow</td>
<td>Low Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td><strong>Electrical Fault</strong></td>
<td>Flashing Red</td>
<td>Controller Failed</td>
<td>Change Controller</td>
</tr>
<tr>
<td><strong>High Watts</strong></td>
<td>Flashing Red</td>
<td>Critical Battery 1</td>
<td>Replace Battery 1</td>
</tr>
<tr>
<td><strong>Power Disconnect</strong></td>
<td>Solid Yellow</td>
<td>Critical Battery 2</td>
<td>Replace Battery 2</td>
</tr>
<tr>
<td><strong>VAD Stopped</strong></td>
<td>Flashing Red</td>
<td>VAD Stopped</td>
<td>Connect Driveline</td>
</tr>
</tbody>
</table>

---

### Pump Alarm Limits

- Set High Power alarm at 2 Watts above the average power.
- Set Low Flow alarm at 2 L/min below average flow, but no lower than 2 L/min.
- Enable Suction Response alarm once patient is stable.

---

### Pump Parameter

<table>
<thead>
<tr>
<th>Speed (rpm)</th>
<th>Power (watts)</th>
<th>Flow (L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2400</td>
<td>2.5</td>
<td>3</td>
</tr>
<tr>
<td>3200</td>
<td>8.5</td>
<td>8</td>
</tr>
</tbody>
</table>

---

**Flow Waveform Characteristics**

- **Regurgitant Region**
- **Non-regurgitant Region**
- **Low Regurgitant Region**
- **Return suction**
- **Suction**
- **Diasystole**

**Flow Pulsatility Components**

- **Beginning of systole**
- **Beginning of diastole**

---

**24-Hour Clinical Support**

- **Australia:** (61) 8-854-6801
- **Belgium:** 0800-750-012
- **Brazil:** 0800-425-030
- **Canada:** 1-888-494-6365
- **China:** 400-7998806
- **Denmark:** 8-854-6801
- **Finland:** 0800-7500111
- **France:** 0800-91-6817
- **Germany:** +49 511 676936911
- **Hungary:** 0800-750-012
- **Ireland:** 1800-7998806
- **Israel:** 180-7998806
- **Italy:** 800-875-063
- **Japan:** 03-3-304-1144
- **Korea:** 1588-8200
- **Mexico:** 800-752-4911
- **Netherlands:** 0800-750-012
- **New Zealand:** 0800-7998806
- **Norway:** 800-16825
- **Poland:** 00800-141-0046
- **Portugal:** 800-7998806
- **Sweden:** 020-790855
- **Switzerland:** +49 511 676936911
- **United Kingdom:** 0808-234-9223
- **United States:** (888) 494-6365

---

**WARNING:** Serious and life-threatening adverse events, including death, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

---

**CAUTION:** This device is intended for use in conjunction with the HVAD System. The HVAD System is a closed-loop device for use in conjunction with the HVAD System and is not compatible with other implantable cardioverter defibrillators (ICDs). Use of the HVAD System in conjunction with other implantable cardioverter defibrillators (ICDs) is not recommended. The HVAD System is a closed-loop device for use in conjunction with the HVAD System and is not compatible with other implantable cardioverter defibrillators (ICDs). Use of the HVAD System in conjunction with other implantable cardioverter defibrillators (ICDs) is not recommended.