### Rotational Speed
Recommended operating range is 2,400-3,200 RPM.

### Power
Recommended power limits by rotational speed listed in table at right.

<table>
<thead>
<tr>
<th>Rotational Speed (RPM)</th>
<th>Power (W)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,400</td>
<td>2.2</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>2,500</td>
<td>2.6</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>2,600</td>
<td>2.9</td>
<td>4.4</td>
<td></td>
</tr>
<tr>
<td>2,700</td>
<td>3.3</td>
<td>5.0</td>
<td></td>
</tr>
<tr>
<td>2,800</td>
<td>3.7</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>2,900</td>
<td>4.2</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>3,000</td>
<td>4.7</td>
<td>7.0</td>
<td></td>
</tr>
<tr>
<td>3,100</td>
<td>5.2</td>
<td>7.8</td>
<td></td>
</tr>
<tr>
<td>3,200</td>
<td>5.8</td>
<td>8.7</td>
<td></td>
</tr>
</tbody>
</table>

### Pulsatility
Waveform peak (systole) minus trough (diastole). Pulsatility & trough should be > 2 L/min.

### Average Flow
Calculated by controller. Low Flow Alarm should be set 2 L/min below average flow.

### Circadian Rhythm
Many patients experience a daily rise and fall in flow, power, and pulsatility. Look for breaks in consistency.
### Possible contributing factors for observed changes in logfile trends:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Mean Flow</th>
<th>Pulsatility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypovolemia</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Hypertension</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>Suction (continuous)</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>Right ventricular failure</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Pump thrombosis</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>Occlusion</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Hypervolemia</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Tamponade</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Hypotension/vasodilation</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>VF/rapid VT</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Aortic regurgitation</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>Low RPMs</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>Recovery</td>
<td>↑</td>
<td>↓</td>
</tr>
</tbody>
</table>

HVAD™ waveforms and logfiles do NOT conform to a single, classic appearance, and are not intended for diagnostic purposes. In addition to waveforms and logfiles, other measurements, as determined by the physician, are used to assess a patient's condition. Waveforms and logfiles represent pump performance, and should be considered in their clinical context.

### AUTOLOGS 1.2 INSTRUCTIONS:

1. **Download logfiles to monitor**
   - Connect controller to monitor.
   - Note patient’s ID.
   - When data download icon turns black, disconnect monitor cable from the controller.

2. **Transfer logfiles to computer**
   - Press the monitor [Log Files] button to list saved patient logs.
   - Connect a compatible USB stick.
   - Select the appropriate patient ID.
   - Press [Save to USB], [Yes], then [OK].
   - Transfer the USB stick to your computer.

3. **Request Autologs report**
   - Go to Autologs.Medtronic.com.
   - Enter the appropriate report recipients.
   - Select the desired report options.
   - Select the files to upload from the USB (Data, Alarm, and Events files for each patient).
   - Press [Submit Request].
WHAT TO KEEP IN MIND WHEN REVIEWING AN AUTOLOGS 1.2 REPORT

1. Patient information
   - Do you have the correct patient?
   - Is the data through the current date?
   - Did you select the appropriate report timeframe to capture all VAD data since the patient’s last clinic visit?

2. Current VAD parameters
   - Are speed, flow, and power at expected levels?
   - Are any parameters above average or even close to the range maximum?
   - Does the Power Consumption Summary report “Normal” power for the patient’s current VAD speed?
   - If not, is this a new trend?

3. Pump performance trends
   - Are flow, pulsatility, and power trends consistent?
   - Are there any sudden or gradual deflections in trends?
   - Can you correlate the beginning of the trend with clinical symptoms?
   - Do you see evidence of suction? Is it persistent?
   - Do any additional tests need to be considered to investigate a change in performance?

4. System settings
   - Are primary and backup controller settings appropriate for the patient?
   - Are the system settings still appropriate for the patient?

5. Alarms and events
   - Are there any unexpected alarms listed?
   - Do any alarms indicate patient error and is there an opportunity to update the patient’s training?
   - Do any alarms indicate device malfunction?

6. Battery usage
   - Are any batteries at or close to end of life (> 500 cycles or < 2-hour duration)?
   - Are there any large time gaps between use of certain batteries? Are batteries being rotated properly?
   - Has the patient kept any obsolete batteries?
References

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

**Indications for Use**
The HeartWare™ HVAD™ System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

**Contraindications:** The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

**Warnings/Precautions:** Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Serious and life threatening adverse events, including stroke, have been associated with use of this device. Blood pressure management may reduce the risk of stroke. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid devices and conditions that may induce strong static discharges as this may cause the VAD to perform improperly or stop. Magnetic resonance imaging (MRI) could cause harm to the patient or could cause the pump to stop. The HVAD™ Pump may cause interference with automatic implantable cardioverter-defibrillators (AICDs), which may lead to inappropriate shocks, arrhythmia, and death. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta — use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump post CPR.

**Potential Complications:** Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. There are numerous known risks associated with this surgical procedure and the therapy including, but not limited to, death, stroke, neurological dysfunction, device malfunction, peripheral and device-related thromboembolic events, bleeding, right ventricular failure, infection, hemolysis, and sepsis.

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.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.