

# PATIENT MANAGEMENT WITH THE HEARTWARE™ HVAD™ SYSTEM



**Medtronic**

# IMPORTANT KEYS TO PATIENT MANAGEMENT

## Utilize Daily Diary for the HeartWare™ HVAD™ System to record daily readings:

- Equipment: pump parameters (speed, flow and power)
- Patient: weight, INR, blood pressure (MAP), temperature

## Treating Hypertension:

MAP should not exceed 85 mm Hg (refer to Essential Physical Assessment for more information).

## Anticoagulation Medication:

Patient should be on warfarin and aspirin while supported by a VAD. Do not discontinue without discussion from implanting team. Recommendations include ASA 325 mg or multi-drug options and an INR goal of 2-3.

## Driveline and Exit Site Management:

- Monitor exit site and inspect driveline for tears, punctures or breakdowns
- Change dressing as instructed by the implanting center
- Always use aseptic technique
- Immobilize the driveline to prevent trauma to the site

## ESSENTIAL PHYSICAL ASSESSMENT

The HeartWare™ HVAD™ Pump is a continuous flow device. This means there is a narrow pulse pressure, which may make it difficult to palpate pulses, track pulse oximetry or obtain a blood pressure with an automatic cuff. A Doppler may be needed to obtain pulse and blood pressure.

Cardiac sounds may also be difficult to auscultate, as the "hum" from the device will be a prominent sound.

### 3 steps to obtain MAP using a Doppler:

1. Place a manual blood pressure cuff on the appropriate extremity.
2. Inflate the cuff and, during deflation, listen with a Doppler machine for a sound (a hum or swoosh) with blood re-entry.
3. Document the reading at which this occurs as MAP.

### Brief Statement: HeartWare™ HVAD™ System

#### Indications

The HeartWare Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

#### 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. 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 expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

#### Potential complications

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, 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](http://www.heartware.com/clinicians/instructions-use).

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

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## EMERGENCY PROCEDURES

- Patients may be defibrillated without disconnecting the pump
- Anti-arrhythmic drugs, pacemakers, and ICDs are used in conjunction with the HeartWare™ HVAD™ System
- Institute appropriate ACLS protocols
- If chest compressions have been administered, confirm function and positioning of pump


## CHANGING THE HEARTWARE™ CONTROLLER POCKET GUIDE

- 1


Sit or lie down and place new (backup) Controller within easy reach
- 2




Connect power to the new controller
- 3



Pull back the white driveline cover on the original controller
- 4




Disconnect the driveline from the original controller  
Using thumb and index finger, grasp silver portion with "ridges" and pull straight out
- 5




Connect driveline to new controller by aligning red dots, and verify pump has restarted
- 6

Step 6: Silence the no power alarm on the original controller using either option a or b




a.

a. Insert red alarm adapter into blue port on original controller




b.

b. Press and hold the alarm mute and scroll buttons for 5 seconds or until you hear a beep, then release buttons
- 7



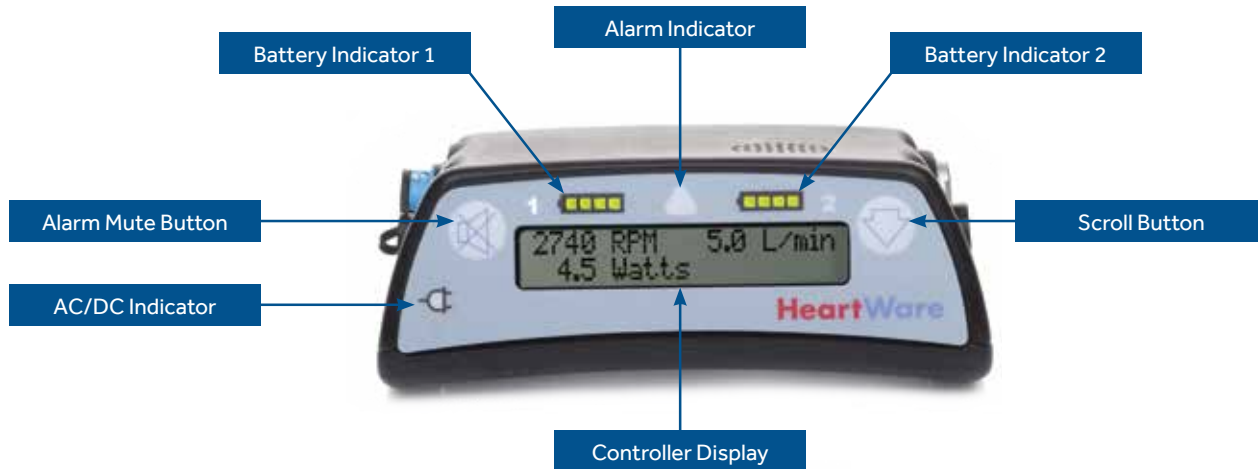
Disconnect power from the original controller
- 8



Slide white driveline cover up to cover the driveline's silver connector

NOTE: Ensure VAD Team is notified immediately that a controller exchange has been performed.

# CONTROLLER DISPLAY OVERVIEW



## EXPECTED HEARTWARE™ HVAD™ PUMP PARAMETERS

The set speed will vary from patient to patient depending a number of factors, however the recommended speed range is 2400-3200 RPMs.

The patient should have the following preset alarm parameters:




**Low Flow** – set 2 L/min below the average flow, but not lower than 2 L/min

**High Power** – set 2 watts above average power

If the patient experiences either of these alarms, the implanting center should be notified.

### Alarm Guide

*A summary of alarms that may appear on the controller*

Alarm Type	Alarm Display (line 1)	Action (line 2)
<b>"No Power" Alarm</b>	(no message)	(no message)
	When both power sources (2 batteries or 1 battery and an AC adapter or DC adapter) are removed, NO message will display on the controller. The "No Power" Alarm will sound but the Alarm Indicator on the controller WILL NOT light. This indicates the pump has stopped. You should immediately connect two power sources.	
 <b>High - Critical (Flashing Red)</b>	VAD Stopped	Connect Driveline
	VAD Stopped	Change Controller
	Critical Battery	Replace Battery 1
	Critical Battery	Replace Battery 2
	Controller Failed	Change Controller
 <b>Medium (Flashing Yellow)</b>	Controller Fault	Call
	Controller Fault	Call: ALARMS OFF
	High Watts	Call
	Electrical Fault	Call
	Low Flow	Call
	Suction	Call
 <b>Low (Solid Yellow)</b>	Low Battery 1	Replace Battery 1
	Low Battery 2	Replace Battery 2
	Power Disconnect	Reconnect Power 1
	Power Disconnect	Reconnect Power 2