London Health Sciences Centre

Heartmate/HeartWare 2 LVAD for EMS

LHSC Cardiac Transplant and Mechanical Circulatory Support Program

Heartmate 2 Left Ventricular Assist Device

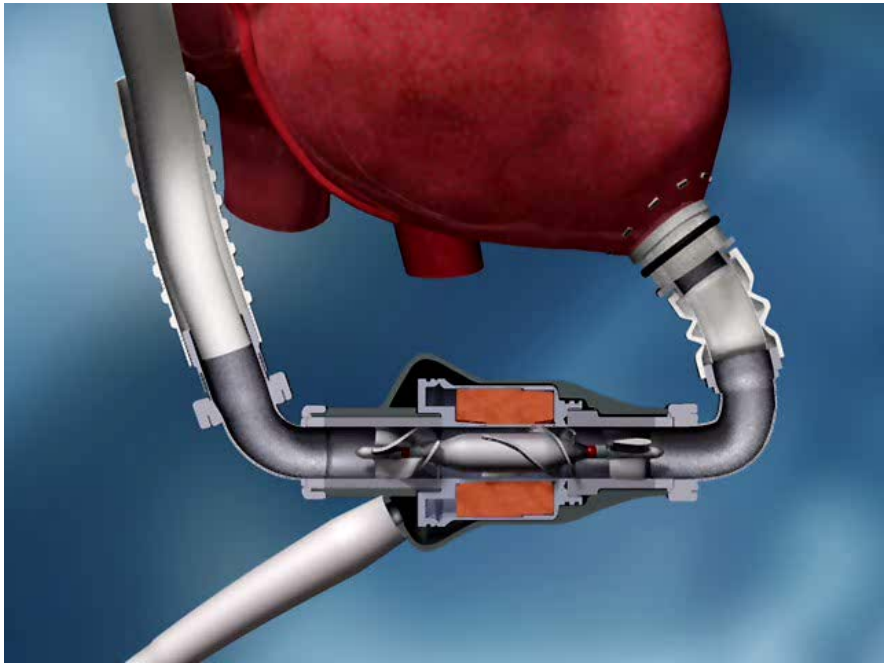
- Left Ventricular Assist Devices (LVADs) are a surgically implanted pump designed to augment the systemic flow of blood and improve patient condition
- Require a competent right ventricle (RV) to function
- Implanted as a bridge to Cardiac transplantation.
- Becoming more common as a standard of care for advanced heart failure patients
  - May soon become “Destination Therapy” in Ontario
- Major risks of device long term: 1) Infection 2) Neurological Event 3) Bleeding, especially GI

HeartMate II LVAS: Key Design Features

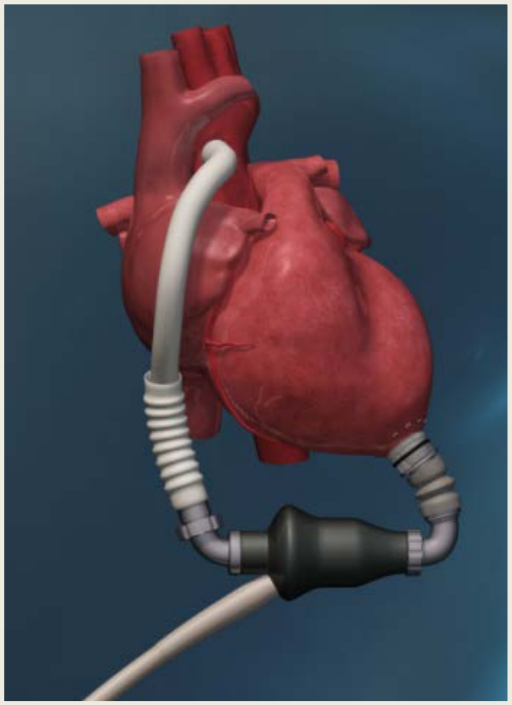
- Relatively Simple Design
  - Valveless
  - Only one moving part, the rotor
  - Blood immersed bearings designed for minimization of blood damage
  - All motor drive and control electronics are outside of the implanted blood pump
- Speed range: 6,000 to 15,000 rpm
- Flow range: 3 – 10 L/min

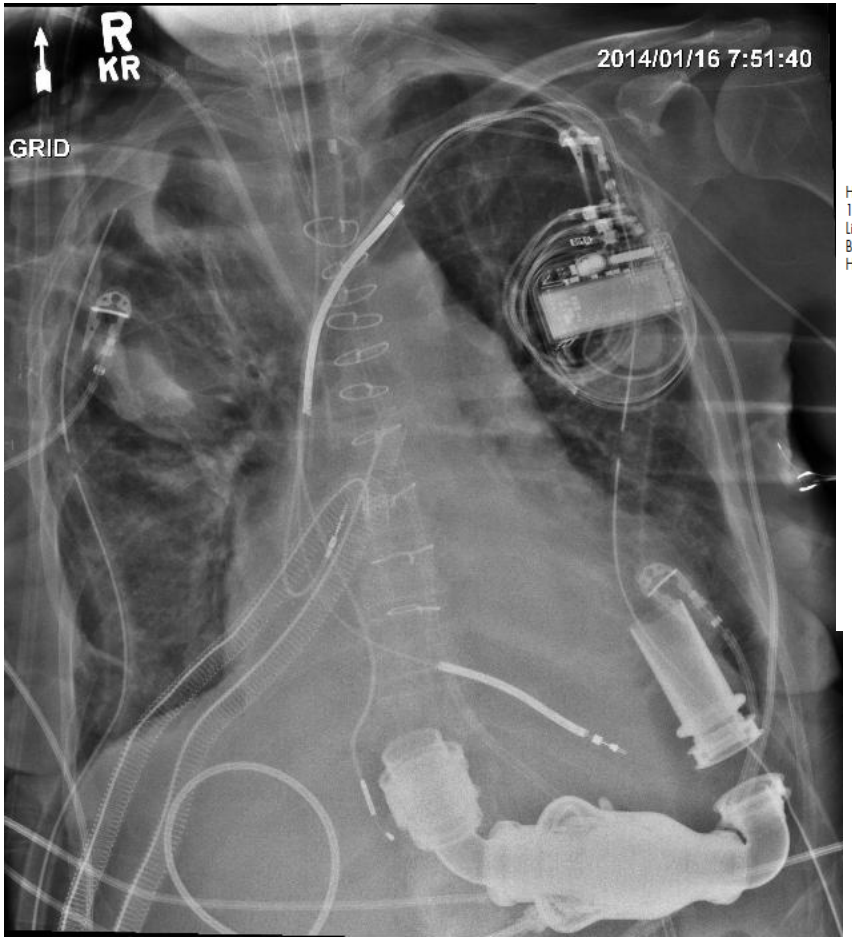
Heartmate II

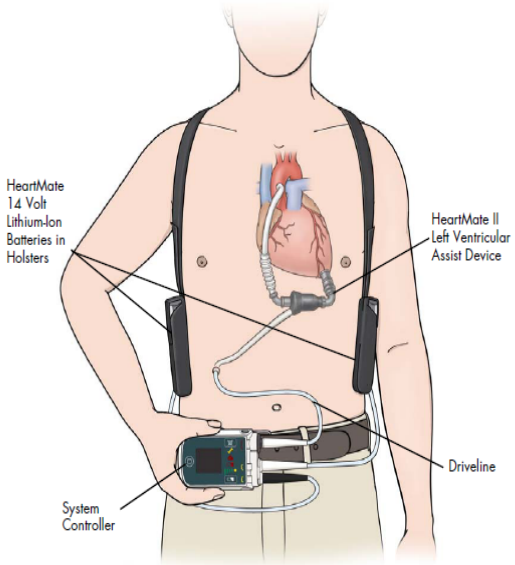
- **Flexible inflow conduit**
- **Textured surfaces**
  - Inlet cannula, inflow and outflow elbows
  - Thrombo-resistant
- **Outflow graft with bend relief**
- **Anastomosed to LV apex and ascending aorta**
- **Pump output varies over cardiac cycle**
  - Follows native pulse
  - **Afterload sensitive, Preload dependent**



Heartmate 2: Implanted components







Heartmate 2: External Components

Controller

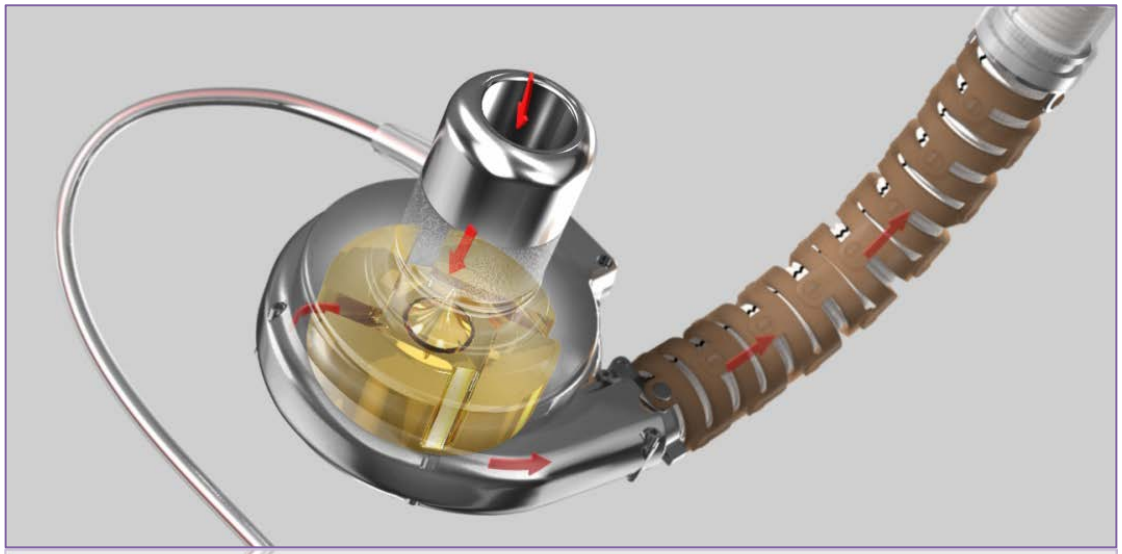
Battery & Holder

Battery Charger

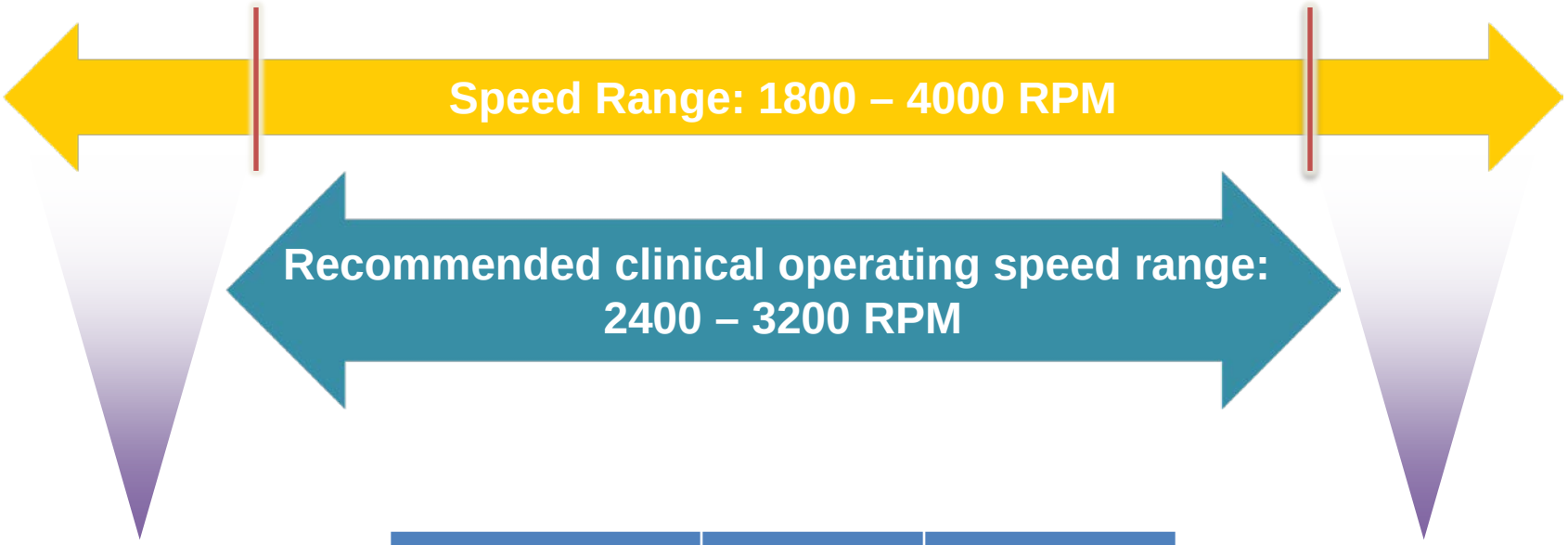
Power Module

HeartWare HVAD

- Wide-blade impeller is magnetically and hydrodynamically suspended
- Speed range: 1800-4000 RPM
- HVAD Pump flow is preload dependent and afterload sensitive



HVAD® Pump Operating Guidelines



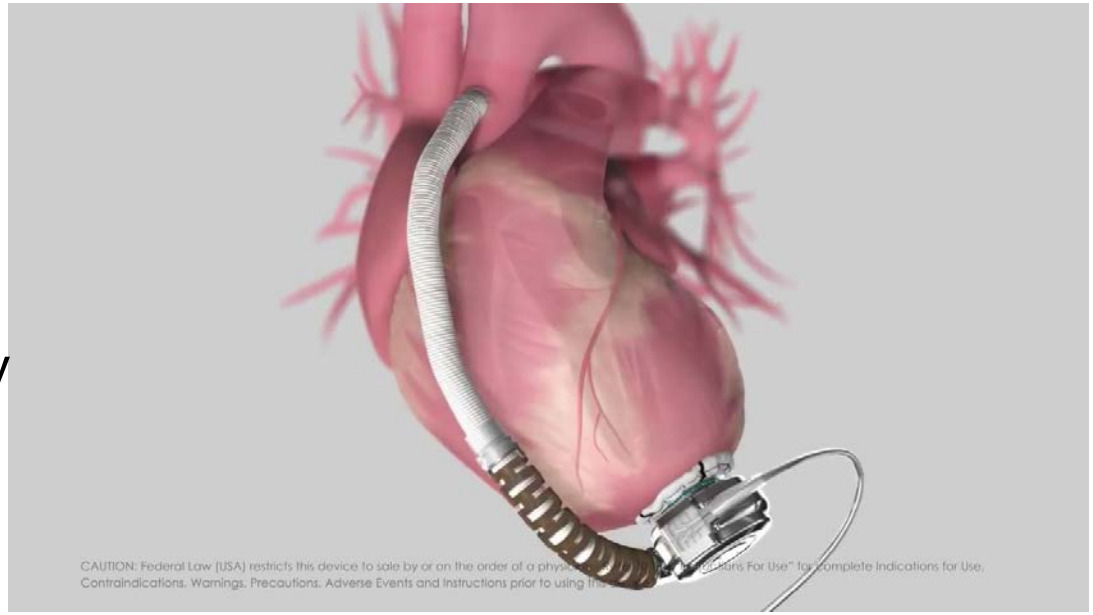
1800-2400 RPM
Should only be used during implant procedure when weaning from CPB

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

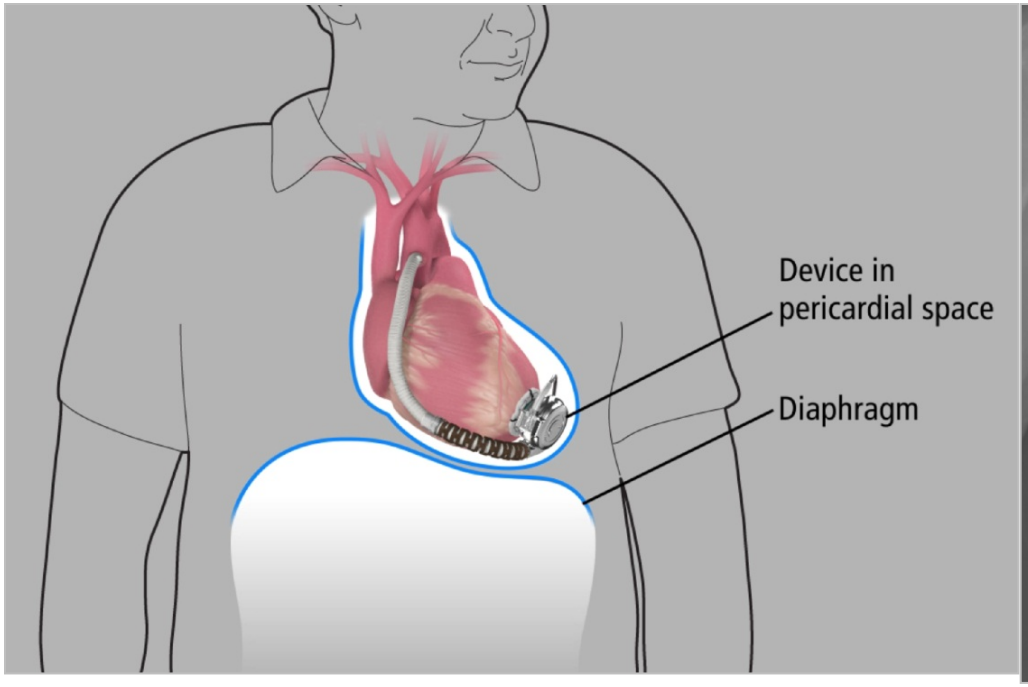
3200-4000 RPM
Speeds above 3200 increase the risk of suction events

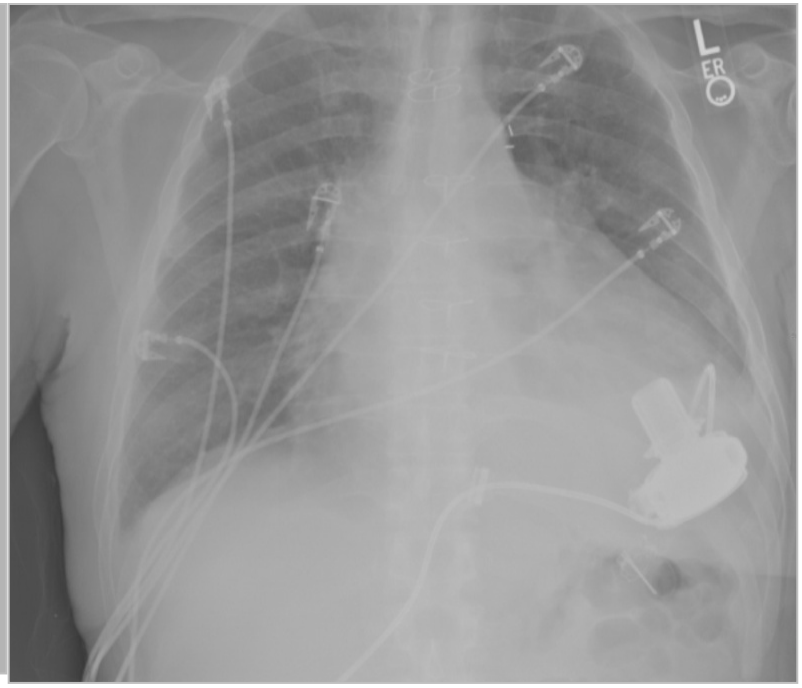
HeartWare HVAD

- Continuous flow, centrifugal pump
- 50cc / 160g, 50mm outside diameter
- Provides up to 10 liters of flow
- Wide-blade impeller is the only moving part
- Hybrid magnetic / hydrodynamic suspension
- Wear-less system
- Dual motors designed to provide power efficiency and redundancy



HeartWare: Implanted components





HeartWare External Components

Controller

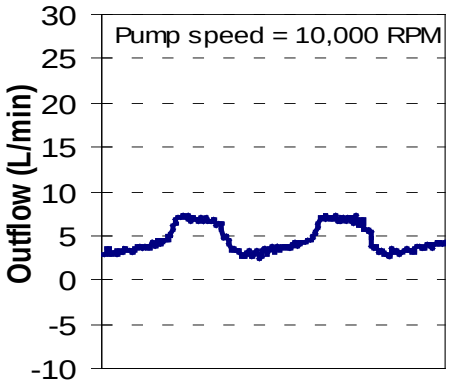
Battery

Battery Charger

AC power adapter

Important items to remember in the field

- Continual Flow devices
  - No/weak pulse
  - Difficulty obtaining traditional BP (Doppler MAP)
  - Difficulty obtaining SpO2 measurements
  - ECG not affected by pump
- Drivelines
  - External line connecting pump to controller
  - Be aware where line is-do not damage/cut/forget
  - HIGH RISK OF INFECTION
- Power
  - ALWAYS CONNECTED TO A SOURCE OF POWER
  - A/C power or Batteries
    - **Must bring extra batteries (as well as charger and base unit if possible)**



- PATIENT IS ANTICOAGULATED
  - Target INR between 2.0 and 3.0
- NO MRI
- NO IMMERSION IN WATER (baths, swimming, hot tub)

Blood pressure monitoring: FYI

Blood Pressure Monitoring

The Heartmate II/HeartWare HVAD are continuous flow support devices and therefore presents specific issues to consider in the monitoring of the patient's blood pressure post-implantation.

- There is often no palpable pulse, due to the continuous flow nature of the device, therefore automated blood pressure devices (or other monitoring devices such as oxygen saturation measuring devices) may not be able to measure accurate blood pressures. Mean Arterial Pressure (MAP) directly measured via arterial line or indirectly measured via manual blood pressure cuff and auscultation (the start of Korotkoff sounds is assumed to represent mean blood pressure) or by Doppler assessment is the primary parameter for monitoring blood pressure.

- The Heartmate II LVAD/HeartWare HVAD function is sensitive to changes in blood pressure, both increased and decreased pressure. **Hypertension** may decrease forward flow through the pump, increase the risk for right heart failure and increase the risk of bleeding and/or hemorrhagic stroke. Examples of causes can be High circulating volumes or General vasoconstriction. **Hypotension** may increase forward flow and increase the risk of a PI event (or suction event) and this may be due to Issues with low circulating volumes, issues with right sided heart failure, arrhythmias or the inability of blood to get through the device.

Blood Pressure Monitoring

- Targeting MAP with a goal of:
  - Mean ≈ 65-75 mmHg
  - Mean < 85 mmHg & SBP < 120 mmHg
- Hypertension
  - Effects on pump support
    - May decrease forward flow
    - Decrease in pump flow and power
    - Increase in PI
  - In anti-coagulated LVAD patients, a MAP > 90 increases the risk of hemorrhagic stroke
- Hypotension
  - Device requires adequate pre-load in order to function
  - Lack of volume increases risk of suction events
- Volume status very important
  - Too little-device does not function and suck down (a complete collapse of LV) can occur
  - Too much-device struggles to function and right ventricle may become compromised, leading to problems with the device: Remember-these are heart failure patients.

Device Assessment: EMS

- **Assess Environment**
- **Assess Immediate Patient Needs**
- **Assess Pump function**
  - **LISTEN**
    - Alarms? Check controller for alarm if alert is heard
    - Auscultate over Pump: Humming sound = pump working
  - **Look**
    - Controller Display will give you information
      - Pump running symbol  always green if pump is running
      - **Will display active alarms and give most common solution**
    - Pump Parameters
      - Speed, Flow, Power, Pulsitility Index (PI)
    - Connections
      - Power and driveline connected?
  - **Ask**
    - Primary caregiver for information and patient diary to compare current pump parameters with historical values

User Interface: Display Button

Display Button Functions

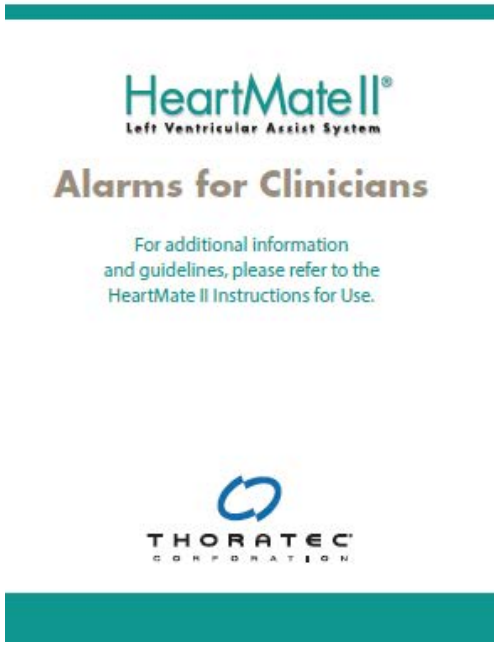
1. Activates the information display screen:
   - **Pump speed** -how fast is the pump spinning
   - **Flow**-calculated output of the pump
   - **Pulsatility Index** -proxy for volume & LV contribution
   - **Power** -how much energy needed to keep pump running (↑ or ↓ of 2 watts significant)
   - Backup battery charge
   - Blank default screen
2. Displays last six non-transient alarms when pressed simultaneously with the Alarm button.

User Interface: Display Button– Viewing Pump and System Parameters

Button Press	Description	Screen Displayed (Example)	Meaning
Press 	Press display button **ONCE**	Pump Speed 9200 RPM	Pump speed in revolutions per minute (RPM)
Press 	Press display button a **SECOND** time	Flow 4.6 LPM	Pump flow in liters per minute (LPM)
Press 	Press display button a **THIRD** time	PI 4.2	Pulsatility Index (PI)
Press 	Press display button a **FOURTH** time	Power 5.9 W	Power in watts (W)
Press 	Press display button a **FIFTH** time	Backup Battery Charged	The System Controller's backup battery (located inside the System Controller and used to temporarily run the pump during a power emergency) has three charge status states: 1. Charged (ready for use). 2. Charging (actively charging). 3. Fault (there is a fault or problem with the backup battery that could affect its reliability).
Press 	Press display button a **SIXTH** time		Blank screen indicates the screen is off, which is normal.

Press the Display Button to view pump parameters and backup battery charge status on the display screen.

Advisory & Hazard Alarms



Advisory Alarms (Yellow)

- Power Cable Disconnected
- Low Voltage
- Controller Fault
- Backup Battery Fault
- Low Speed
- Driveline Fault
- Backup Battery Not Installed
- Controller Clock Not Set

Hazard Alarms (Red)

- PUMP OFF
- DRIVELINE DISCONNECTED
- NO EXTERNAL POWER
- LOW FLOW
- LOW VOLTAGE

Alarm Guide

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
HAZARD	Low Flow :03 + Call Hospital Contact :07		Pump is off. The Pump Running symbol (🔄) is black.	1. Check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt pump start. 2. Switch to the backup System Controller and attempt to restart pump. 3. Clinically evaluate patient. **See page 7-9.**
	Connect Driveline :02		Driveline is disconnected. The Pump Running symbol (🔄) is black.	1. Immediately reconnect the driveline to System Controller and move the driveline safety tab on the System Controller to the locked position. 2. If alarm persists after reconnecting the driveline, press any button on the System Controller to attempt pump start. Otherwise, check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. 3. If driveline is connected and alarm persists, replace System Controller with a programmed backup System Controller. **See page 7-9.**
	Backup Battery :01 + Connect Power Immediately :05		Both power cables are disconnected	Immediately connect to a working power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). **See page 7-11.**
	Low Flow :03 + Call Hospital Contact :07		Low flow, flow is less than 2.5 lpm	1. Ensure that the driveline is connected to System Controller. 2. Ensure that a power source is connected to System Controller. 3. Clinically evaluate patient. **See page 7-12.**
	Replace Power Immediately :02 + Low Battery :06		Low Battery, Power input is extremely low with less than 5 min. remaining	Immediately connect to a working power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). **See page 7-13.**

Table 7.2 System Controller Hazard Alarms

IMPORTANT! The Pump Running symbol (🔄) is always green when the pump is running.

Alarm Guide

Priority	System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
ADVISORY	Connect Power :04		One of the two power cables is disconnected	Promptly connect the disconnected power cable to power source (functioning Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). **See page 7-14.**
	Replace Power :02 + Low Battery :06		Low Battery, Power input is low with less than 15 min. remaining	Promptly connect to a working or different power source (Power Module or two fully-charged HeartMate 14 Volt Lithium-Ion batteries). **See page 7-15.**
	Replace Controller Controller Fault + Call Hospital Contact Controller Fault		System Controller hardware fault	1. Switch to the backup System Controller. 2. Provide patient with a new System Controller. **See page 7-16.**
	Call Hospital Contact Backup Battery Fault		System Controller Backup Battery fault	Replace the 11 Volt Lithium-Ion backup battery. **Note:** If replacing the battery does not resolve the alarm, the System Controller may need to be replaced, or additional steps may be required. Call Thoratec with questions. **See page 7-17.**
	Low Speed :03 + Call Hospital Contact :07		Low Speed advisory warning	1. Use the System Monitor to check that the fixed speed and low speed limit have been appropriately set. 2. Replace the System Controller. 3. Clinically evaluate the patient. **See page 7-18.**
	Call Hospital Contact Driveline Fault		Driveline fault	1. Contact Thoratec to determine best next steps. 2. Use the System Monitor to silence the alarm while awaiting resolution, if needed. **Note:** The alarm must be active in order to access the alarm silence for this situation. **See page 7-19.**
			System Controller Backup Battery not installed	1. Install the 11 Volt Lithium-Ion backup battery in the System Controller. 2. Obtain a new backup battery replacement kit. **Note:** If replacing the battery does not resolve the alarm, the System Controller may need replaced, or additional steps may be required. Call Thoratec with questions. **See page 7-20.**
			Controller Clock not set	Use the System Monitor to set the System Controller's internal clock. **Note:** Be sure the System Monitor clock is correct. **See page 7-21.**

Table 7.3 System Controller Advisory Alarms

IMPORTANT! The Pump Running symbol ( ) is always green when the pump is running.

London Health Sciences Centre

Alarms: Indicators – Low Battery, Yellow Wrench, Red Heart

Low Battery Alarm

The red low battery symbol illuminates when less than 5 minutes of battery power remain (applicable only during 14 Volt Lithium-Ion battery-powered operation).

This is a **Hazard** alarm. When the red battery symbol illuminates, immediately replace the depleted batteries with a fully-charged pair, or switch to the Power Module.

For more information, see page 7-14.

Yellow Wrench Alarm

The yellow wrench symbol illuminates when the System Controller detects a mechanical, electrical, or software issue with the system.

This is an **Advisory** alarm. When the yellow wrench illuminates, check the screen for troubleshooting instructions.

For more information, see page 7-9.

Red Heart Alarm

The red heart symbol illuminates when the System Controller detects a problem that could cause serious injury or death.

This is a **Hazard** alarm. When the red heart illuminates, check the screen for instructions and take immediate action to resolve the problem.

For more information, see page 7-8.

Alarms Indicators: System Controller Cables

Black Power Cable Alarm

The yellow light near the black power cable connector illuminates when the black power cable becomes loose or disconnects from the System Controller.

This is an **Advisory** alarm. If the black power cable disconnects or becomes loose, promptly restore the connection.

For more information, see page 7-15.

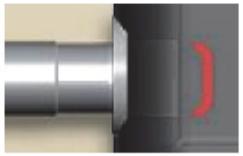
White Power Cable Alarm

The yellow light near the white power cable connector illuminates when the white power cable becomes loose or disconnects from the System Controller.

This is an **Advisory** alarm. If the white power cable disconnects or becomes loose, promptly restore the connection.

For more information, see page 7-15.

Driveline Connector Alarm



The red light near the driveline connector illuminates when the driveline becomes loose or disconnects from the System Controller.

This is a **Hazard** alarm. If the driveline loosens or disconnects from the System Controller, promptly restore the connection. If the driveline is not reconnected immediately, the pump stops.

For more information, see page 7-11.

Alarms: Hazard – Pump Off

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Alternating Low Flow :03 + Call Hospital Contact :07		Pump is off. The Pump Running symbol ( ) is black.	Constant Tone	2 minutes

1. Check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button. Otherwise, press any button on the System Controller to attempt pump start.
2. Switch to the backup System Controller and attempt to restart pump.
3. Clinically evaluate patient.

Alarms: Hazard – Low Flow

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Low Flow :03 + Call Hospital Contact :07		Low flow, flow is less than 2.5 lpm	Constant Tone	2 minutes

1. Ensure that the driveline is connected to System Controller.
2. Ensure that a power source is connected to System Controller.
3. Clinically evaluate patient.

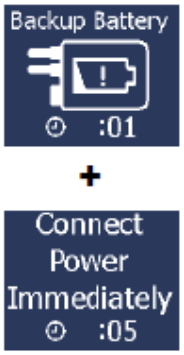
Alarms: Hazard – Driveline Disconnected

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
		Driveline is disconnected. The Pump Running symbol (🔄) is black.	Constant Tone	2 minutes

1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position.
2. If alarm persists after reconnecting the driveline, press any button on the System Controller to attempt pump start. Otherwise, check if the fixed speed setting is below 8,000 rpm AND the System Controller's backup battery is not installed. Under these conditions, the pump can only be started from the System Monitor's Clinical or Settings screen by pressing the Pump Start button.
3. If driveline is connected and alarm persists, replace the System Controller with a programmed backup System Controller.

Important! If controller stops alarming Connect Driveline, but Low Speed and Low Flow alarms persist and the pump does not ramp up to the set speed, disconnect and reconnect the driveline.

Alarms: Hazard – No External Power

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
		Both power cables are disconnected	Constant Tone	2 minutes

- Immediately connect to a working power source

Alarms: Hazard – Low Battery

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Replace Power Immediately :02 + Low Battery :06		Low Voltage, Power input is extremely low with less than 5 min. remaining	Constant Tone	2 minutes

- Refers to external power source
- Immediately connect to a working power source

Alarms: Advisory – Power Cable Disconnect

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Connect Power :04	 OR	One of the two power cables is disconnected	Fast Beep	2 minutes

- Promptly connect the disconnected power cable

Alarms: Advisory – Low Battery

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Replace Power :02 + Low Battery :06		Low Voltage, Power input is low with less than 15 min. remaining	Slow Beep	5 minutes

- Refers to external power source
- Promptly connect to a working or different power source

Alarms: Advisory – System Controller Hardware Fault 1

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Replace Controller Controller Fault + Call Hospital Contact Controller Fault		System Controller hardware fault	**Slow Beep**	**4 hours**

Controller is operating on primary system.

1. Switch to Backup System Controller
2. Provide patient with a new System Controller

Note: If LED display is affected, only “Replace Controller ,Controller Fault” will be displayed. Visual indicators and audio tones for other alarms will occur as normal. Pump parameters and alarm history cannot be viewed.

Alarms: Advisory – System Controller Hardware Fault 2

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Replace Controller Controller Fault + Call Hospital Contact Controller Fault		System Controller hardware fault	**Slow Beep**	**1 hour**

Controller is operating on backup system.

1. Switch to Backup System Controller
2. Provide patient with a new System Controller

Note: Pocket System Controller will not communicate with System Monitor – initialization screen and "Not Receiving Data" will be displayed. Events will not be recorded to log file.

Alarms: Advisory – Backup Battery Fault

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
		System Controller Backup Battery fault	Slow Beep	4 hours

- Replace 11V lithium-ion backup battery

Alarms: Advisory – Low Speed Advisory Warning

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Low Speed :03 + Call Hospital Contact :07		Low Speed advisory warning	Slow Beep	4 hours

1. Use the System Monitor to check that the fixed speed and low speed limits have been set appropriately
2. Replace system controller
3. Clinically evaluate patient

Advisory Alarms: Driveline Fault

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
		Driveline fault	Slow Beep	4 hours

1. Contact Thoratec to determine next best steps
2. Use System Monitor to silence alarm if necessary
3. See the troubleshooting algorithm

Replacing a System Controller

<table>
<tr><td colspan="3">Replace The Running System Controller with The Backup Controller and MULTIPLE Power sources</td></tr>
<tr><td>1
Set-up</td><td>  </td><td>a. Place the back up System Controller within reach.
b. Have the patient sit/lie down as he or she may get dizzy if the pump briefly sops.
c. Unlock the driveline safety tab on the running System Controller.</td></tr>
<tr><td rowspan="2">2
Replace System Controller</td><td colspan="2">Multiple Power Sources Available
(have Power Module AND Batteries & Clips)</td></tr>
<tr><td> 
  </td><td>Important! Keep the running System Controller connected to Power.

a. Connect both the white and black connections on the backup Controller to power.
b. Promptly, move the driveline from the running controller to the backup controller.</td></tr>
<tr><td>3
Finish</td><td>  </td><td>a. Lock the driveline safety tab on the backup Controller. The safety tab cannot move to the locked position unless the driveline is fully and properly inserted. Confirm that the pump running symbol is green, pump is running.
b. Put the old, replaced Controller into Sleep Mode by disconnecting from power then pressing and holding the battery button for 5 seconds.
c. Do not use the old System Controller ever again. Contact your hospital contact or Thoratec Corp to request a new backup System Controller and for instructions on returning the old one.</td></tr>
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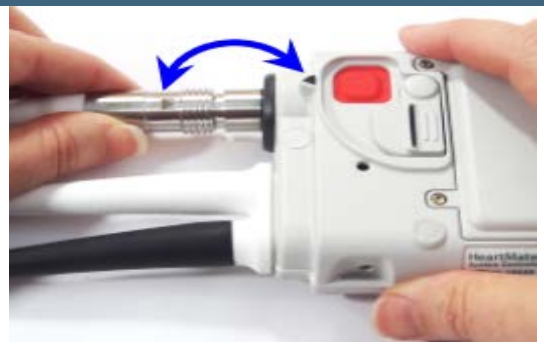
Connections: Driveline and Power



Driveline connection

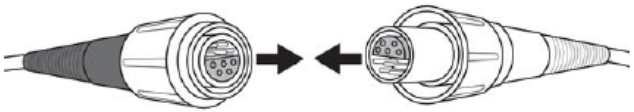


Figure 3.22 Align the Half Circles on the Connectors

Controller always connected to two power connections-AC power or 2 Batteries

Backup Equipment

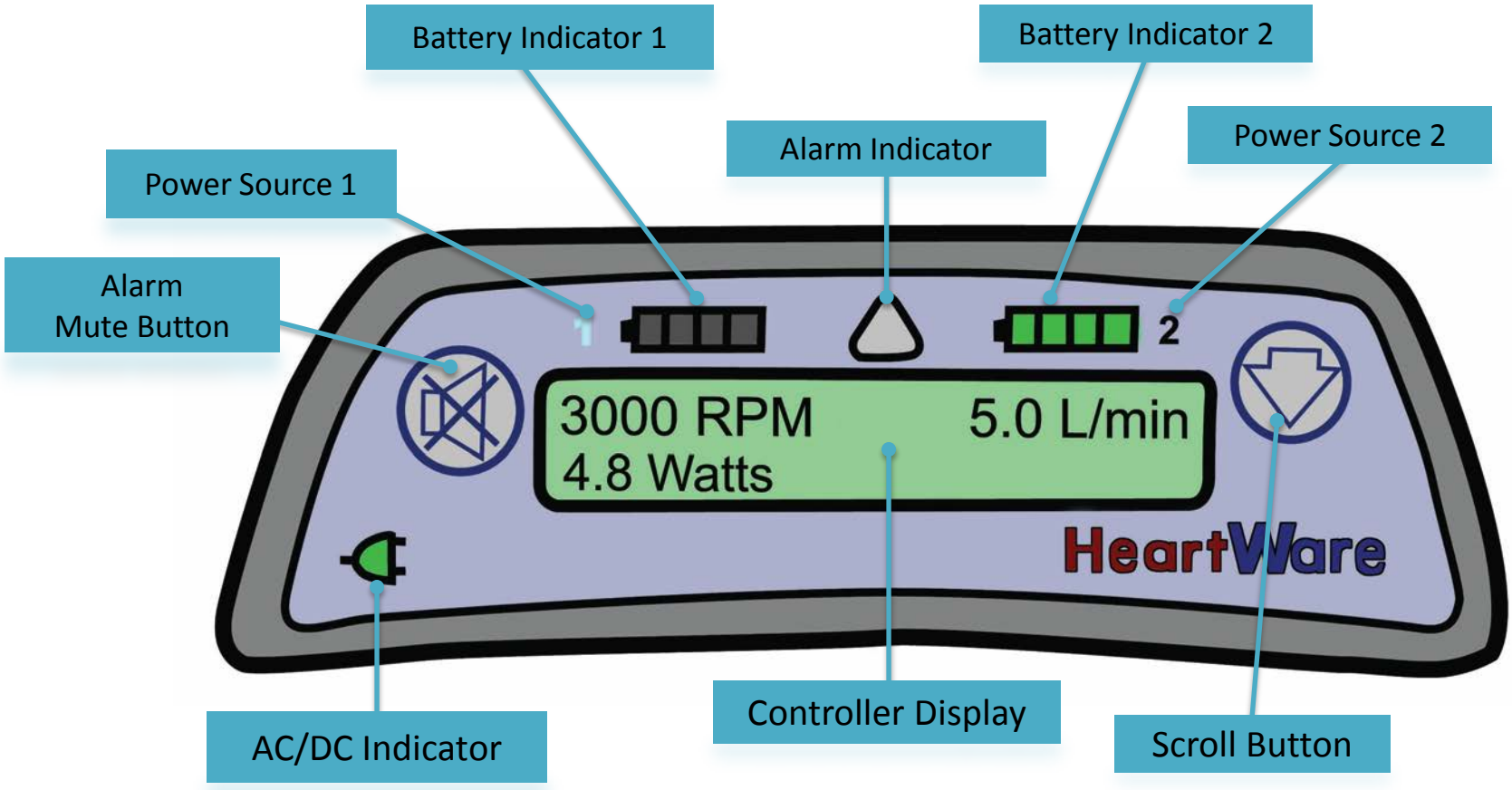
Backup controller and batteries in carrying bag

Power Module

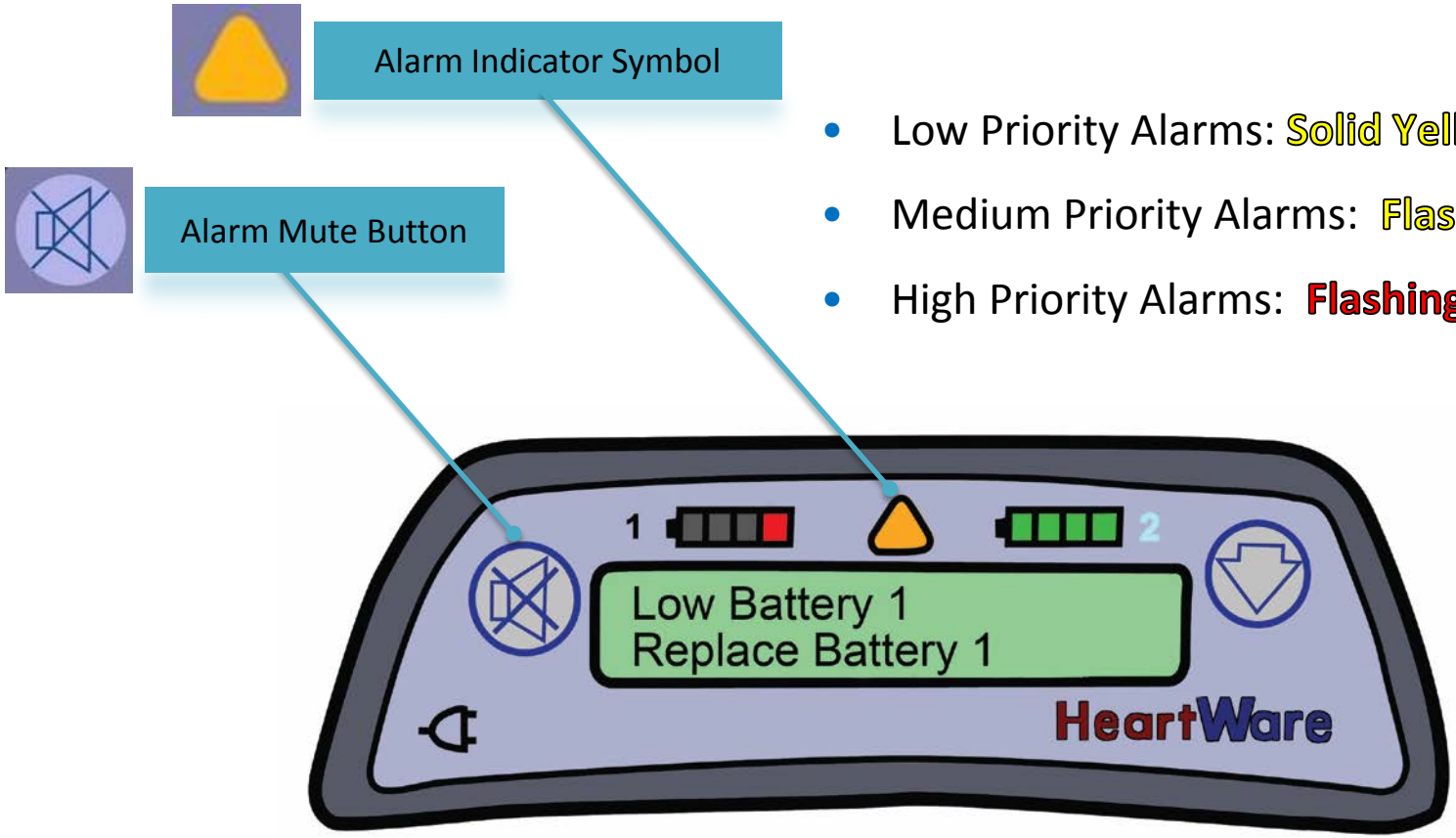
Battery charger

Ensure backup controller and extra batteries accompany patient during transport. If possible bring power module with cables and battery charger

HeartWare® Controller Display



HeartWare® Controller: Alarm Indicator & Mute Button



- Low Priority Alarms: **Solid Yellow**
- Medium Priority Alarms: **Flashing Yellow**
- High Priority Alarms: **Flashing Red**

Low Priority Alarms (Solid Yellow)

Alarm Type	Alarm Display (line 1)	Action (line 2)
Low (Solid Yellow) 	Low Battery 1	Replace Battery 1
	Low Battery 2	Replace Battery 2
	Power Disconnect	Reconnect Power 1
	Power Disconnect	Reconnect Power 2

Medium Priority Alarms (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

High Priority Alarms (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

High Priority Alarms: Blank Display

Alarm Display (line 1)	Action (line 2)	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.

High Priority Alarms: VAD Stopped

Alarm Display (line 1)	Action (line 2)	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. 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

Alarm Display (line 1)	Action (line 2)	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		

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

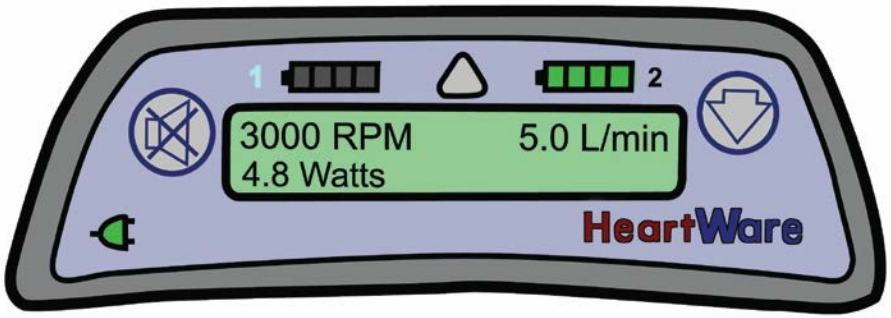
Handling an Emergency: Changing the Controller

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.

Handling an Emergency: Changing the Controller

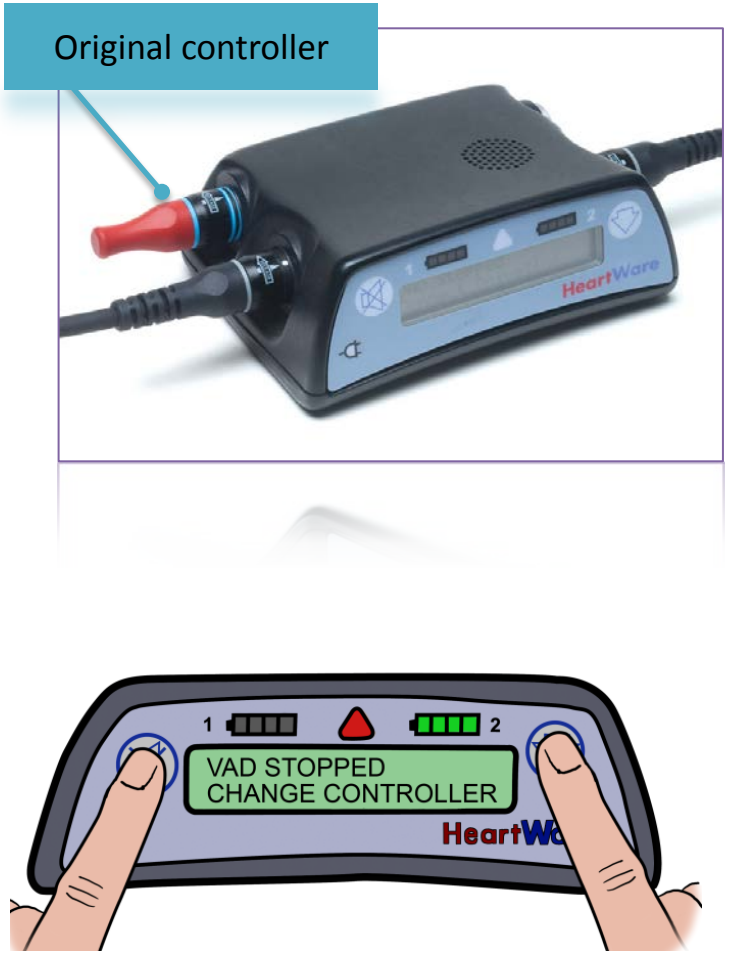
6. Connect the driveline to the **new** controller (align the two red marks and push together). If the “VAD Stopped” alarm was active on the new controller, it will now resolve. The pump should restart.

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



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



Connections: Driveline and Power

- Driveline connection is secured with a collar lock. Grasp ridged portion of silver collar and pull back
- White driveline cover prevents accidental removal

- 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

Power Source Connector with Pins

Controller Connector for Power Sources

Backup Equipment

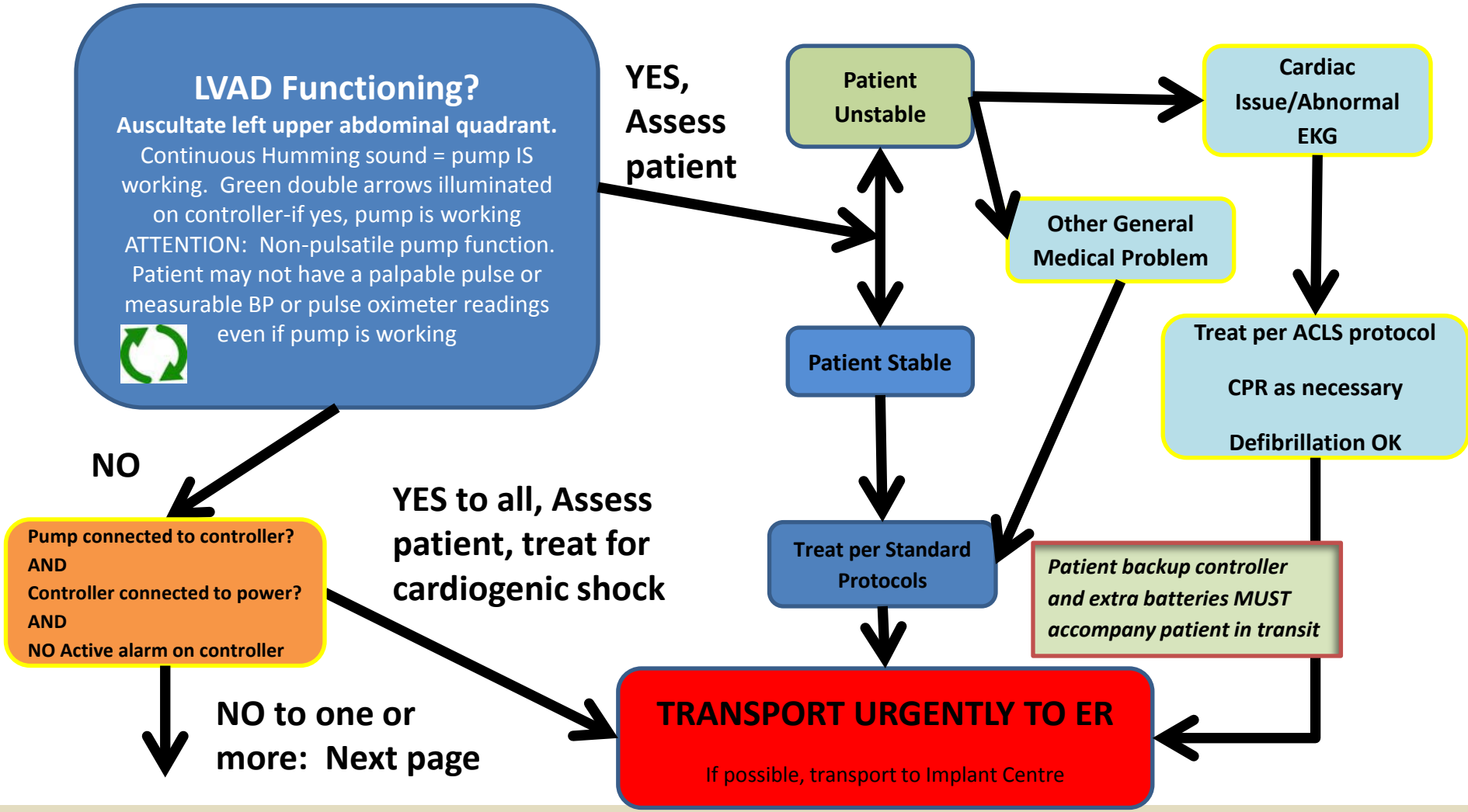
Backup controller and batteries in carrying bag

AC power adapter

Battery charger

Ensure backup controller and extra batteries accompany patient during transport. If possible bring AC power adapter and battery charger

EMS assessment protocol: Heartmate 2



London Health Sciences Centre

Implant Centre: LHSC 519-685-8500 pager 1LVAD (15823) to page Dr. Nagpal or VAD Coordinator

EMS assessment protocol: Heartmate 2

Length of time that pump has been stopped is known AND this time less than 5 minutes

YES

Give Heparin 5000u IV STAT
Connect controller to pump and/or
Connect controller to power and/or
Change controller (only if instructed)

Patient backup controller and extra batteries MUST accompany patient in transit

NO

NO

LVAD Functioning?

Auscultate left upper abdominal quadrant.
Continuous Humming sound = pump IS working. Green double arrows illuminated on controller-if yes, pump is working
ATTENTION: Non-pulsatile pump function. Patient may not have a palpable pulse or measurable BP or pulse oximeter readings even if pump is working

YES: Assess/stabilize

Give Heparin 5000u IV STAT (if not given already) Treat for cardiogenic shock
DO NOT RESTART PUMP

TRANSPORT URGENTLY TO ER

If possible, transport to Implant Centre

London Health Sciences Centre

Implant Centre: LHSC 519-685-8500 pager 1LVAD (15823) to page Dr. Nagpal or VAD Coordinator

Resources

- Questions or concerns, contact LHSC VAD team
- 519-685-8500 pager 1LVAD (15823)
- Dr. D. Nagpal 519-685-8500 x38822
- G. Fisher, VAD coordinator 519-685-8500 x33760
- On the internet: Thoratec Corporation website

http://www.thoratec.com/medical-professionals/resource-library/ifus-manuals/heartmate-ll-lvad.aspx