Patient/Family Education Teaching Protocol
HeartMate II Left Ventricular Assist System

(478) 365-0721 VAD Coordinator

(478)633-7022 AHFC

A VAD resource person is available

24 hours a day

7 days a week

HEARTMATE II LVAS SYSTEM COMPONENTS

PUMP		The pump moves blood from your heart to other parts of your body. The pump is implanted below your heart. A percutaneous lead, which is attached to the pump, passes through the skin of your abdomen. The lead connects the implanted pump to the external System Controller	Power Module (PM)	The Power Module (PM) is the other routine power source. When the PM is plugged into an electrical outlet, it provides AC electrical power to the system. See the *HeartMate Power Module IFU* (document # 103772).
Pocket Controller		The Pocket Controller is a small computer. It controls and continually checks system operation. It uses lights and sounds to tell you how the system is working	PM Patient Cable	The PM patient cable connects the PM to the System Controller. Connections are made between white-to-white and black-to-black connectors.
Batteries and Battery Clips		HeartMate batteries are a routine power source. They are used for powering the pump during mobile operation. Batteries are used in pairs. Each battery is inserted into a battery clip. The clips connect to the System Controller. They transfer battery power to the system.	Universal Battery Charger (UBC)	The Universal Battery Charger (UBC) charges and tests HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771).

POWER MODULE

Only has one function	Power Sources	Internal Back Up Battery
supplies power to controller and device	AC power(WALL) Internal battery Car charger	30 Minutes max

Cannot be attached to a adapter plug for ungrounded outlets

Cannot be attached to a multiple socket outlet (power strip)

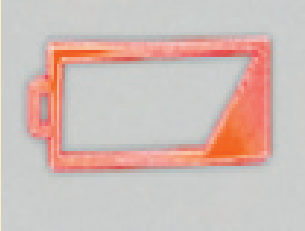Cannot attach to portable generator, uninterruptable power supply (UPS), or an extension cord

POWER ON INDICATOR

Indicator	Meaning Top right	Action
Power On Green	Power from wall	No Action Required
AC FAIL	Power from back up battery	Swap to Portable Batteries

INTERNAL BATTERY CHARGE INDICATOR

Indicator	Meaning	Action
	Middle Right	
Green Charge Lamp	Power Module Internal Back-up Battery Completely Charged	No Action Required
Yellow Charge Lamp	Power Module Internal Back-up Battery actively Charging	No Action Required

INTERNAL BATTERY ALARM

Indicator	Meaning	Action
	Bottom Right	
Red Battery	5 Minutes of Back-up battery left	Swap to Portable Batteries
Yellow Battery	15 Minutes of Back-up battery left	Swap to Portable Batteries

YELLOW WRENCH AND ALARM SILENCE

Indicator	Meaning	Action
Yellow Wrench	Need A Mechanic Left Bottom	Swap to Portable Batteries And Call Hospital
	Alarm Silence And Self Test Left Top	Press to Silence Active Alarms Press and Hold for Self Test

DAILY RESPONSIBILITIES FOR POWER MODULE

Daily Self-Test of Power Module:	Press and hold the PM Alarm Silence button for 5 seconds Listen for the continuous audio tone and watch the front of the PM to see if all the lights come on in sequence Lights should come on one-at-a-time, not all at once	If any of the following occur, there may be a problem with the PM and it should not be used: No sound Anything other than a continuous audio tone (such as beeping or broken tone) All the lights come on at once All the lights remain off One of the lights does not come on

ALARM MANAGEMENT FOR POWER MODULE

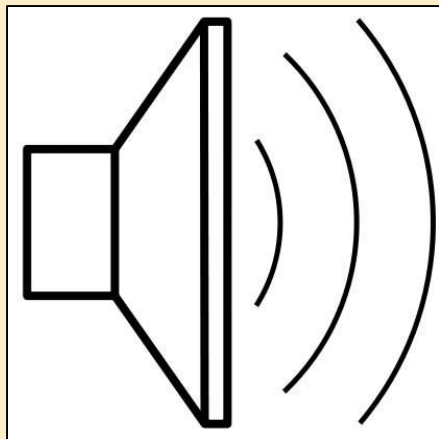|	
	VISUAL **Red – Stop, Fix it right now** **Yellow – Slow Down, has to be fixed but not emergent** **Green- Good, Go**
	AUDIBLE **Constant – Stop, Fix it right now** **Intermittent – Slow Down, has to be fixed but not emergent** **Quiet – Good, GO**

POCKET CONTROLLER

Small computer that operates the pump Monitors the function of the pump to ensure it is working correctly
Has pump and power supply warning alarms

Connects the pump to the power supply source

Cable Disconnect Symbols

Battery Button

Pump Running Symbol

Display Button

User Interface Screen

Status Symbols

Silence Alarm Button

HeartMate II®
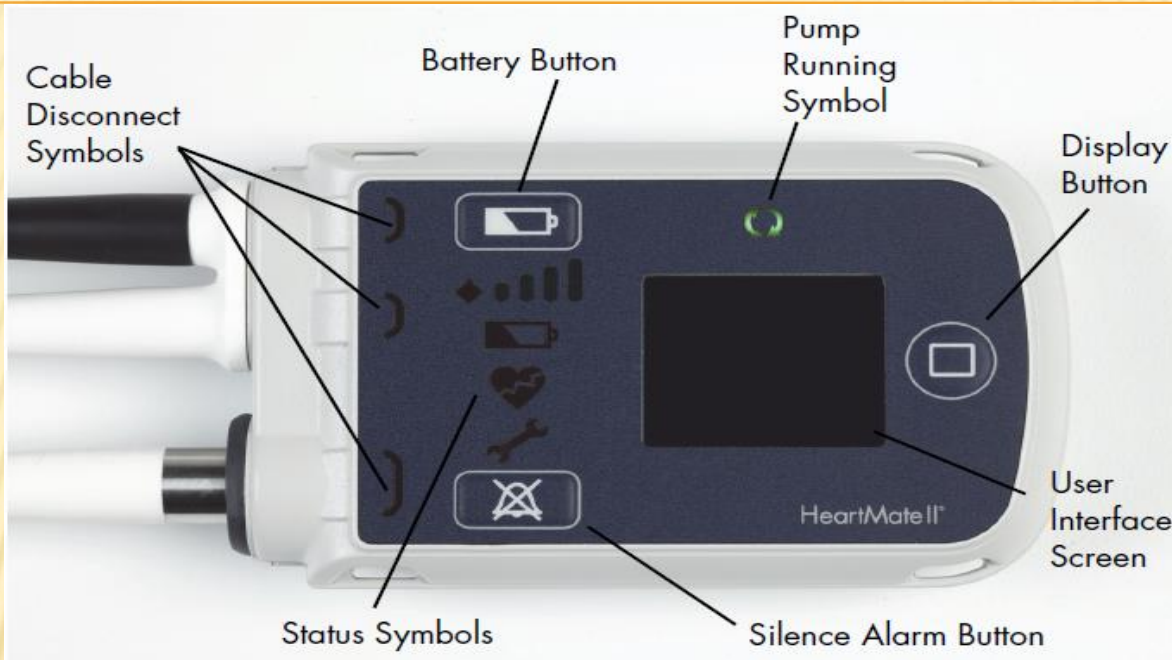
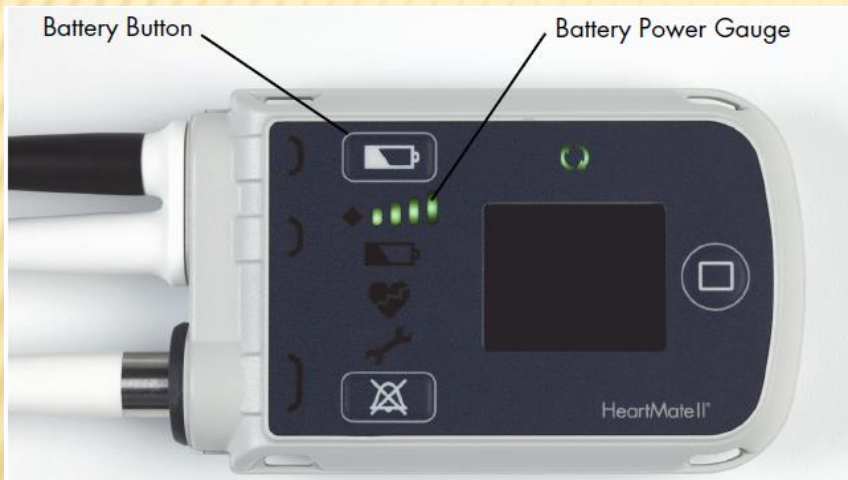| Controller Buttons		
Battery	**Silence Alarm**	**Display**

POCKET CONTROLLER USER INTERFACE :

Battery Button

Battery Button Functions

1. Operating battery fuel gauge

2. Starting a System Controller self test

3. Putting a running System Controller into Sleep Mode

POCKET CONTROLLER USER INTERFACE :

- The battery gauge shows the approximate charge status of the power source connected to the controller: either the 14V Li-ION batteries or Power Module

- Press and release the battery button to activate the battery gauge

- Perform a System Controller Self Test daily on the running System Controller

- Press and Hold the Battery Button for 5 seconds

- Release the button

- The screen will briefly turn white then black and then "Self Test" appears on the screen

- All audible/visible indicators should remain on for 15 seconds, then all audible indicators and lights stop, the screen goes black, and the self test is complete

• To place a running System Controller into Sleep Mode disconnect the power source and driveline

• Then press and hold the Battery Button for 5 seconds.

POCKET CONTROLLER BATTERY GAUGE

On 14 Volt Lithium-Ion battery power:

4 green bars = 75–100% of battery power remains.

3 green bars = 50–75% of battery power remains.

2 green bars = 25–50% of battery power remains.

1 green bar = less than 25% of battery power remains.

POCKET CONTROLLER USER INTERFACE: ALARM BUTTON

Alarm Button

Silencing active alarms when pressed

Displays last six relevant alarms when pressed simultaneously with the Display button

Display Button

1. Activates the information display screen
   * Pump speed
   * Flow
   * Pulsatility Index
   * Power
   * Backup battery charge
   * Blank default screen

Displays last six non-transient alarms when pressed simultaneously with the Alarm button.

POCKET CONTROLLER DRIVELINE CONNECTIONS

1. To insert the driveline, slide the safety tab back to unlock and expose the red button

2. Align the arrow on the controller to the arrow on the driveline cable until they connect, and firmly insert the driveline until it snaps into place

3. Be sure to slide the safety tab back over the red button, locking the driveline in place.

4. Tug gently on the metal portion of the driveline to ensure it is fully engaged.

POCKET CONTROLLER OPERATING MODES

Run	The system is functioning and in use. The system controller automatically transitions to Run Mode when connected to the pump via the driveline and connected to a power source
Sleep	The system is not in use. It is ready to function. The Back-up system controller is primarily in Sleep Mode
Charge	The system is not connected to a driveline, but is connected to a power source to charge the internal back-up battery

Note: The back-up system controller must be placed in Charge Mode once every six months to ensure back-up battery readiness

POCKET CONTROLLER BACKUP BATTERY

- Powers the pump for at least 15 minutes during a power-loss emergency

- Charges while connected to a power source (Power Module with 14V patient cable OR 14 Volt Li-Ion Batteries)

- Expiration date: 36 months from manufacture date and/or 24 months shelf life.

BACK-UP CONTROLLER MUST BE RECHARGED EVERY 6 MONTHS

Warning: Backup battery should be used only for temporary support during a power-loss emergency. The backup battery inside the System Controller provides enough power to run the pump for at least 15 minutes. Inappropriate use of the 11 Volt Lithium Ion backup battery may result in diminished run

ALARM TROUBLESHOOTING

Follow On Screen Instructions

CONNECTIONS
Check all 3 connections

POWER
Change power sources

CONTROLLER
Consider changing controller

HELP
Call 911 and/or Vad coordinator

ALARM INDICATORS ON POCKET CONTROLLER CABLES

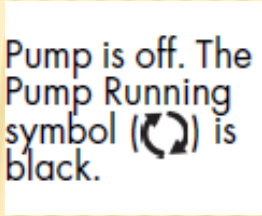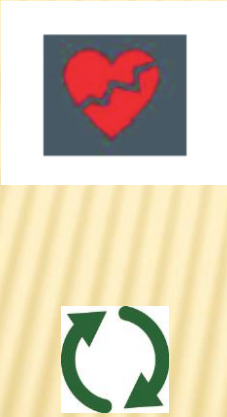|	
Black Power Cable Alarm	The yellow light near the black power cable connector illuminates when the black power cable becomes loose or disconnects from the System Controller.
	This is an **Advisory** alarm. If the black power cable disconnects or becomes loose, promptly restore the connection.
	For 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.

Reference Material Do Not Attempt To Memorize, follow On screen Directions

HAZARD ALARMS – PUMP OFF

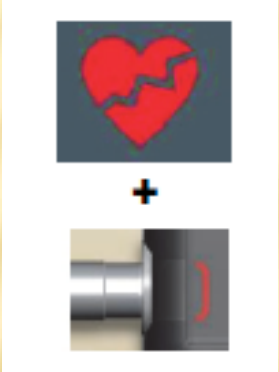| System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Low Flow ⊙ :03 ✛ Call Hospital Contact ⊙ :07	❤️	Pump is off. The Pump Running symbol (↻) is black.	Constant Tone	2 minutes

Reference Material Do Not Attempt To Memorize, follow On screen Directions

HAZARD ALARMS – 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

HAZARD ALARMS – DRIVELINE DISCONNECTED

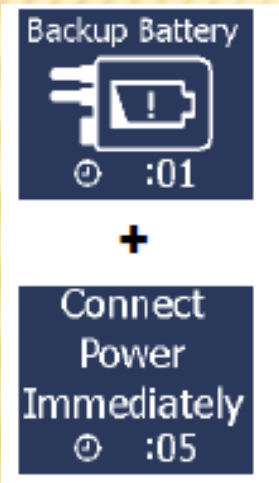| System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Connect Driveline ⊘ :02		Driveline is disconnected. The Pump Running symbol (⟳) is black.	Constant Tone	2 minutes

Reference Material Do Not Attempt To Memorize, follow On screen Directions

HAZARD ALARMS – NO EXTERNAL POWER

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Backup Battery ⊙ :01 + Connect Power Immediately ⊙ :05		Both power cables are disconnected	Constant Tone	2 Minutes

Reference Material Do Not Attempt To Memorize, follow On screen Directions

HAZARD ALARMS – 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
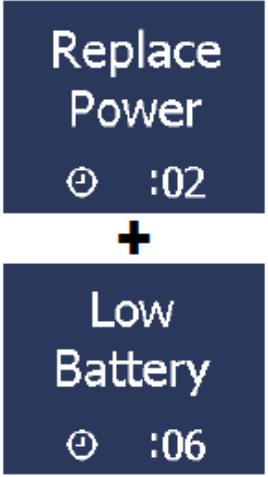
Reference Material Do Not Attempt To Memorize, follow On screen Directions

ADVISORY ALARMS – 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

Reference Material Do Not Attempt To Memorize, follow On screen Directions

ADVISORY ALARMS – 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

Reference Material Do Not Attempt To Memorize, follow On screen Directions

ADVISORY ALARMS –
POCKET CONTROLLER HARDWARE FAULT

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
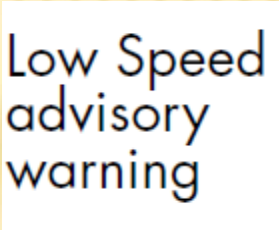
Reference Material Do Not Attempt To Memorize, follow On screen Directions

ADVISORY ALARMS – POCKET CONTROLLER BACKUP BATTERY FAULT

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

Reference Material Do Not Attempt To Memorize, follow On screen Directions

ADVISORY ALARMS –
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 hour

Reference Material Do Not Attempt To Memorize, follow On screen Directions

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ADVISORY ALARMS – DRIVELINE FAULT

System Controller Screen	Active System Controller Symbol	Alarm Means	Alarm Tone	Alarm Silence
Call Hospital Contact Driveline Fault		Driveline fault	Slow Beep	4 hours

Reference Material Do Not Attempt To Memorize, follow On screen Directions

SYSTEM CONTROLLER CHANGEOUT

DISCONNECT ONE POWER SOURCE FROM CURRENT CONTROLLER AND ATTACH TO NEW CONTROLLER

DISCONNECT DRIVELINE FROM CURRENT CONTROLLER AND CONNECT TO NEW CONTROLLER

DISCONNECT REMAINING POWER SOURCE AND CONNECT TO NEW CONTROLLER

POWER-PATIENT-POWER

UNIVERSAL BATTERY CHARGER(UBC):

	Recharges batteries used to power system controller **It Takes 4 Hours to re-charge a set of Batteries**
	Functions as Power Source For Controller when Off PM **A Pair of Batteries will last Approximately 10-12 Hours**

CARE AND MAINTENANCE

Once a week	Inspect batteries for physical damage Do not use batteries that appear damaged

Once a month	• Check manufacture date on battery
	   o If older than 3 years old, needs replaced
	   o Do not use expired batteries
	• Check the number of use/charge cycles on the batteries
	   o Place battery in charger pocket
	   o Press pocket number to display pocket number, battery symbol and percent of available charge
	   o Immediately press pocket number again
	      ▪ This will display the number of cycles. If it is greater than 360, the battery must be replaced
	• Clean the metal battery contacts and contacts inside of the battery clips using a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Do not clean batteries while using them to power the LVAS. Allow to dry before using

UBC, BATTERIES AND CLIPS

Batteries should be paired and labeled (ABCD)
To charge battery, place in charging pocket.(This Should Take 4 Hours)
•**After hearing beep, look at the three lights (yellow, green and red) next to the number on the pocket** •**If the yellow light comes on, the battery is charging. Leave in the charger until the light changes to green** ○**When the light turns green, the battery is charged** •**If the red light (or no light at all) comes on, there is a problem with the battery or charger pocket**
If the yellow light blinks and the display shows a split battery symbol with the pocket number in the middle, the battery needs calibrated. See Manual .
If a phone symbol or error code numbers appear on the screen, call for further instructions

CHANGING POWER SOURCES

PM to Batteries	**Changing PM to Batteries:** • **Never Disconnect both cables at the same time** • **Place 2 battery clips and 2 fully charged batteries within reach** • **Place Batteries in clips** • **Disconnect cable from PM and attach to battery clip** **During this time an alarm will sound** • **Disconnect cable from PM and Attach to Battery clip**

Batteries to Power Module	**Changing Batteries to PM:**
	• **Never Disconnect both cables at the same time**
	    o**Cannot be attached to a adapter plug for ungrounded outlets**
	    o**Cannot be attached to a multiple socket outlet (power strip)**
	    o**Cannot attach to portable generator, uninterruptable power supply (UPS), or an extension cord**
	•**Make sure the PM patient cable is attached to the PM and within reach**
	•**Disconnect connector from battery clip and attach to the white PM patient cable**
	•**During this time alarm will sound**
	•**Disconnect connector from battery clip and attach to the black PM patient cable**

LIFE AT HOME WITH A VAD

Dressing Changes, Exit site care and Infection Prevention	**Driveline or pump pocket infections can lead to severe complications or death** •**Keep drive line site clean and dry** •**Demonstrates proper technique for changing dressing following Dressing Change Policy** •**States signs and symptoms of driveline infection. Call VAD coordinator if these occur** •**Never severely bend or kink it** •**Do not pull or move the lead where it exits through the skin** •**Protect your controller from falling at all times** •**Report any damage to the lead to your hospital contact immediately**

BATHING AND SHOWERING	**Bathing and Showering**
	May not take tub baths
	Showering when approved by VAD Coordinator or Cardiac Surgeon
	Using shower kit for showers
	    Shower kit is water resistant
	    Can do with PM or batteries
	Exit site must remain dry during shower
	Do not get PM, batteries or battery clips wet
	Do not shower if you are dizzy or lightheaded

SLEEPING

Must always be attached to PM when sleeping or napping
Because you May not hear controller Alarms

Do not pull on percutaneous lead while you are sleeping
Keep System Controller close to your body, if not attached to your body

Do not sleep on your stomach

Keep back-up equipment close by with a flashlight

**Complete Daily log
PI,FLOW,SPEED,POWER,
WEIGHT AND TEMP**

EXCURSIONS

When Leaving Home Always Travel With:
Travel Case
Extra Batteries And Clips
Back –up Controller
Alarm Guides And List Of Emergency Contact Numbers
DO NOT leave travel case in extremely warm or cold places as this will adversely affect the batteries

WHEN TO CONTACT YOUR VAD COORDINATOR

You have questions or concerns.

You have changed the Pocket controller.

You have a fever >101, redness, Increased Tenderness, pain, and/or drainage from your driveline site.

You get a Red alarm or any alarm that you don't understand

Never Text for a vad Problem

Always Call the VAD Number
(478)365-0721
as the individual on Call is subject to change but the # will Not