

HeartMate 3[®] Left Ventricular Assist Device

Patient and Family Teaching



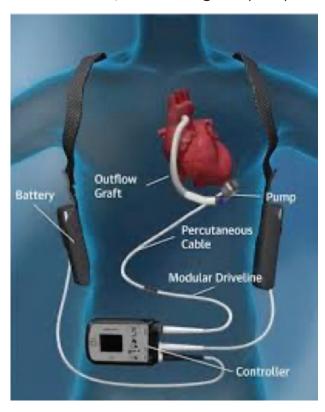
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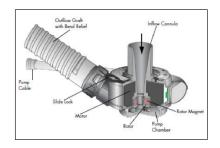
What is the Heartmate LVAD?

The HeartMate 3 Left Ventricular Assist Device (LVAD) is a mechanical heart pump used to help your heart push more blood to the rest of your body. The LVAD is implanted directly into the heart, with a percutaneous lead (driveline) exiting from the side of the abdomen, connecting the pump to

a Pocket Controller. The Pocket Controller is a computer that controls the pump operation. The Pocket Controller is worn externally and can be powered either by the Mobile Power Unit (MPU), power module when in the hospital, or by rechargeable batteries.



Components of the Heartmate System



Pump:

Moves blood from your heart to your body. The pump is implanted into the bottom of the heart. A percutaneous (through the skin) lead connects the pump to the Pocket Controller.



Pocket Controller:

Small computer, worn externally, that tells the pump how to operate. It uses lights and sounds to tell you how the system is working.



Batteries and Clips:

Used to power the pump while you are out of bed. Each battery is inserted into a clip that connects to the pocket controller.



Mobile Power Unit (MPU):

Power source used while in bed/sleeping. It plugs into an electrical outlet to provide AC power to the system. It also amplifies any alarm so you hear it when you are sleeping.

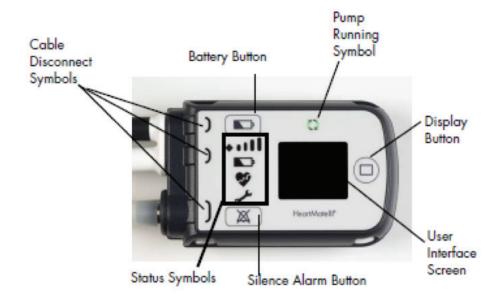


Battery Charger:

Charges and tests four batteries at a time.

Pocket Controller

- Small computer that operates the pump. It monitors the function of the pump to make sure it is working correctly.
- Connects the pump to the power supply (batteries or mobile power unit)
- Performs diagnostic monitoring via the daily Self-test
- Provides hazard and advisory alarms when necessary
- Internal backup battery runs the pump for 15 minutes when disconnected from the power source



Pocket Controller Buttons and Lights

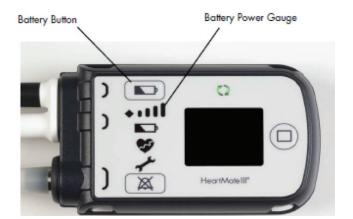
Patients who undergo LVAD implant will learn how to manage the equipment shown below.

For each device there is a controller that operates the implanted pump, batteries that hook up to and power the controller, a wall power source, and a battery charger.



- Battery power gauge
 - Press and immediately release button
- System controller self test
 - Press and hold down for 5 seconds then release button
- Puts an old controller into sleep mode when disconnected from power and driveline.
 - Press and hold
- Power Gauge:
 - Shows approximate charge status of the power sources
 - 4 bars = 75-100% battery power remains
 - 3 bars = 50-75% battery power remains
 - 2 bars = 25-50% battery power remains
 - 1 bar = less than 25% battery power remains
 - Yellow diamond with alarm= 15 mins of battery power remains

Change Batteries



Pocket Controller Buttons and Lights



Alarm Button

Silences active alarms when pressed

- Red/hazard alarm = silences for 2 min
- Yellow/advisory alarm = silences for 4 hours

Display Button

Activates the information display screen

- Pump Speed
- Flow
- Pulsatility Index (PI)
- Power
- Backup Battery Charge

^{**} Display last six alarms by pressing display button simultaneously with the alarm button. To scroll through past alarms, press the display button.

Controller Numbers

Speed

Measured in RPM (range 4800-6000)
 Your speed is set in the hospital

Flow

An estimated flow of blood through the pump

Pulsatility Index (PI)

Measures how hard the left ventricle is working

Power

- Measures how many watts the pump is using to operate
- **Press the display button to check these numbers
- **VAD numbers should all stay between 3-8 with the exception of the PI (may range 2-8)

Pocket Controller Backup Battery

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

** Backup controller must be recharged every 6 months. This is done by hooking it up to the mobile power unit or extra set of batteries. This will ensure the backup battery is charged and ready to use in case of an emergency.

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Only your VAD coordinator can remove and replace a back up battery



Battery Backup

Pocket Controller Alarms

Priority	System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
	Call Hospital Contact ©23:01 + Low Flow ©23:02	\$	2 minutes	Pump is off. The Pump Running symbol is black.	Check if the fixed speed setting is below 4000 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. Switch to the backup System Controller and attempt to restart pump. Clinically evaluate patient.
۵	Call Hospital Contact ②23:01 + Low Flow ②23:02	\$	2 minutes	Low flow, flow is less than 2.5 lpm	Ensure that the Driveline is connected to System Controller. Ensure that a power source is connected to System Controller. Clinically evaluate patient.
Z A R	Connect Driveline ② :01	😜 C - 📊	2 minutes	Driveline is disconnected. The Pump Running symbol is black.	Immediately reconnect the Driveline to System Controller and move the Driveline Safety Lock on the System Controller to the locked position. Also check that the Modular inline connector is secure. If alarm persists after reconnecting the Driveline, press any button on the System Controller to attempt pump start. If the alarm still persists, check if the fixed speed setting is below 4000 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. If Driveline is connected and alarm persists, replace System Controller with a configured backup System Controller.
ح	Connect Power Immediately ① 3:01 + Backup Battery ②23:01		2 minutes	Both power cables are disconnected.	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).
-	Call Hospital Contact Controller Fault	() **	None - the audio tone cannot be silenced	System Controller Hardware Fault (Microcontroller Failure)	No active symbols (constant audio tone). 1. Immediately switch to the backup System Controller. 2. Provide patient with a new System Controller.
	Low Battery ②23:01 + Replace Power Immediately ②23:02		2 minutes	Low Battery, Power input is extremely low with less than 5 min. remaining.	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries).

Pocket Controller Alarms

Priority	System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
	Connect Power ©23:01	OR	2 minutes	One of the two power cables is disconnected.	Promptly connect the disconnected power cable to power source (functioning Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
	Replace Power ① :02 + Low Battery ② :06	\	5 minutes	Low Battery, Power input is low with less than 15 min. remaining	Promptly connect to a working or different power source (Power Module, Mobile Power Unit, or two fully-charged HeartMate 14 Volt Lithium-Ion batteries).
R	Call Hospital Contact Controller Fault	4	4 hours	System Controller Hardware Fault	Switch to the backup System Controller. Provide patient with a new System Controller (with backup battery installed).
0	Call Hospital Contact Comm Fault	**	4 hours	Communication Fault (Comm Fault)	Contact Thoratec Corporation to determine best next steps: Use the System Monitor to silence the alarm while awaiting resolution, if needed. Note: The alarm must be active in order to access the extended alarm silence for this situation.
- S	Call Hospital Contact Backup Battery Fault	J	4 hours	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 Corporation with questions.
A D V	Call Hospital Contact Backup Bettery Fault +	4	4 hours	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 to be replaced, or additional steps may be required. Call Thoratec Corporation with questions.
	Call Hospital Contact Driveline Power Fault	gre.	4 hours	Driveline Power Fault	Contact Thoratec Corporation to determine best next steps. 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.
	Call Hospital Contact Driveline Comm Fault	y.e.	4 hours	Driveline Communication Fault (Driveline Comm Fault)	Contact Thoratec Corporation to determine best next steps. 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 7-23. Then see Fault and Driveline Communication Fault Alarm Buttons on page 4-36. Driveline Power

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

Alarm Trouble Shooting - What to Do if You Hear an Alarm

Follow On Screen Instructions

Connections

Check all 3 connections: both batteries and driveline

Power

Change power sources: have your batteries run out or is your mobile power unit not receiving power?

Help

Call your coordinator for instructions on any alarm

Controller

Consider changing out controller IF instructed to do so by coordinator

Mobile Power Unit (MPU)

Function

Provides wall power to the pump while you are sleeping

MPU contains 3 AA batteries

- Does not power VAD during power outage, only amplifies alarms
- Must be changed every 6 months

MPU can NOT be attached to:

Power strip or extension cord. Must be plugged into its own dedicated wall outlet, which can be shared with the battery charger.



Mobile Power Unit Lights and Alarms

Indicator	Meaning	Action
O	Need A Mechanic	Swap to Batteries and call VAD coordinator
(Internal Batteries Drained Right Bottom	Swap to Batteries Change the 3 AA batteries in MPU (do every 6 months)
0	MPU in Normal Operation	You may use the MPU

Static Electricity

High levels of static electricity may damage or harm the HeartMate3 and may cause your pump to stop. When you are not sleeping or resting, it is recommended to use battery power instead of the MPU to power your HeartMate3.

- Battery power can help reduce damage or harm to your system from static electricity
- You can receive a static shock when doing such things as:
 - Folding or changing bedsheets
 - Taking laundry out of the dryer
 - Dragging your feet on the carpet
 - Touching the screens of older TVs or computers
- You can reduce static electricity with products such as:
 - A humidifier to add moisture to the air
 - Dryer sheets and fabric softeners for clothes and bedsheets
 - Antistatic spray on carpets

Universal Battery Charger

- Recharges batteries used to power controller.
- It takes 4-6 hours to re-charge a set of batteries
- One pair of batteries last approximately 14-20 hrs
- Batteries are good for three years past manufacturer date (on back of each battery)
 - If batteries are past manufacturer date, notify your coordinator for replacement



UBC, Batteries and Clips

Batteries should be labeled (1-8).

You should rotate the use of your batteries: Use just four batteries at a time, two for use and two for charging/backup. Rotate each group of four on a monthly basis.

To charge battery, place in charging pocket (This should take 4-6 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 — DO NOT USE BATTERY, CALL COORDINATOR FOR REPLACEMENT.

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 previous page.

If a phone symbol or error code numbers appear on the screen, call the coordinator for further instructions.

Changing Power Sources

MPU to Batteries

Changing MPU to batteries:

- Never disconnect both cables at the same time
- Place 2 battery clips and 2 fully charged batteries within reach
- Place both batteries in clips
- Disconnect one cable from MPU and attach to battery clip
 - During this time an alarm will sound
- Disconnect the other cable from MPU and attach to battery clip

Batteries to MPU

Changing batteries to MPU:

- Never disconnect both cables at the same time
- Make sure the MPU patient cable is within reach
- Disconnect white connector from battery clip and attach to the white MPU patient cable
 - During this time alarm will sound
- Disconnect black connector from battery clip and attach to the black MPU patient cable

Heartmate 3 Emergency Procedures - Home

Red Heart

Device is Running

(Green light on)

Leave device alone

- Call VAD Coordinator 971-678-4042
- CALL 911

Device Has Stopped

(Green light is off)

Check battery and driveline connections and ensure adequate power

If OK

- Call VAD Coordinator 971-678-4042
- Prepare to replace controller
- Do NOT use mobile power unit
- Call 911

Emergency Procedures

Changing out your Pocket Controller-your coordinator should be on the phone with you during this procedure

- 1.) Get backup controller with attached clips
- 2.) Lay out backup controller and current controller face down
- 3.) Place one battery in a clip on the new controller
- 4.) Unlock current controller by opening latch on back
- 5.) Disconnect driveline from current controller by pressing and holding red button and pulling the driveline out of the controller at the same time
- 6.) Connect driveline to new controller by lining up black or white arrow on driveline and controller and pushing together firmly
- Lock controller by closing the latch (will not latch if driveline is not fully inserted)
- 8.) Place second battery in the other clip on the new controller
- 9.) Silence old controller by pressing the alarm button
- 10.) Ensure old controller has no batteries attached
- 11.) Put old controller to sleep by holding down battery button for a count of 5
- 12.) Retrieve new controller from coordinator

Living With Your VADDressing Change

- Infection at the driveline site can lead to serious complications or even death
- Keep your driveline site clean and dry
- Always ensure your driveline is secured with the foley anchor
- Report redness or drainage to your coordinator
- Protect your controller/bag from falling and causing a tug on your driveline. Report any pulls on your driveline to your coordinator.
- Your coordinator will teach you how to change your driveline dressing using sterile technique
- Once you leave the hospital, you or your caregiver will be responsible for caring for the driveline site
 - Never put ointment/creams on site
 - Do not pull on driveline





VAD Related Complications: Call Coordinator

Infection: See previous page

Stroke: CALL 911 for transport to nearest hospital

- F: Face drooping
- A: Arm weakness
- S: Speech
- T: Time to call 911, then VAD coordinator
- Other symptoms: sudden numbness/ confusion, vision changes, trouble walking, sudden severe headache

Bleeding: nosebleeds and gastro-intestinal bleeds are most common

- Nosebleeds: Apply pressure and gauze for 20 minutes, if unable to stop call coordinator
- GI bleeds
 - Dark tarry stools or bright red blood in stool
 - Fatigue

Thrombus in pump:

- Symptoms: Dark cola colored urine, sustained increase in pump power, return of CHF symptoms that can't be managed with medications
- Increase in lab values: LDH and/or plasma free hemoglobin

Living With Your VADBathing and Showering

- No bathing or submerging body in water
- Showering is allowed when approved by your VAD team (usually 6-8 weeks after surgery)
- VAD equipment must be placed in your shower bag
- Exit site must remain dry during showers cover your exit site with "seran wrap" or "glad press-and-seal" and secure firmly with tape
- If your driveline dressing gets wet during your shower, the dressing must be changed
- Do not shower if you are dizzy or light-headed



Living With Your VAD

Sleeping

- You should always be attached to MPU while sleeping this will help you hear any alarms that may occur
- Keep pocket controller close to you-do not allow pulling on driveline
- Keep your backup equipment close to your bed with a flashlight on your bedside table

Leaving the house

- When leaving your home, always travel with the following:
 - Travel bag with backup controller/clips
 - Two fully charged batteries do not put extra batteries in backup controller clips, this will drain the batteries
 - Alarm guide and list of emergency contact numbers

Physical Activity

- Do not lift more than 40 pounds
- No contact sports
- No repetitive bending of the drivelin
 - Stomach crunches, leg lifts
 - Anything that causes bearing down
- No total emersion in water

Dental work

- Call VAD clinic once dental work/cleaning is scheduled
- We will prescribe antibiotics to be taken 1 hour prior to dental work

Travel

- Contact the VAD team well in advance (as early as possible) so we can set you up with a nearby VAD center in case something happens while you are away
- Please bring ALL equipment with you
- Equipment must be brought on the plane with you
- You must "opt out" at the airport for a manual inspection
- The VAD team can provide you with a letter for TSA

Our Mission

As expressions of God's healing love, witnessed through the ministry of Jesus, we are steadfast in serving all, especially those who are poor and vulnerable.

Values

Compassion, Dignity, Justice, Excellence, Integrity



