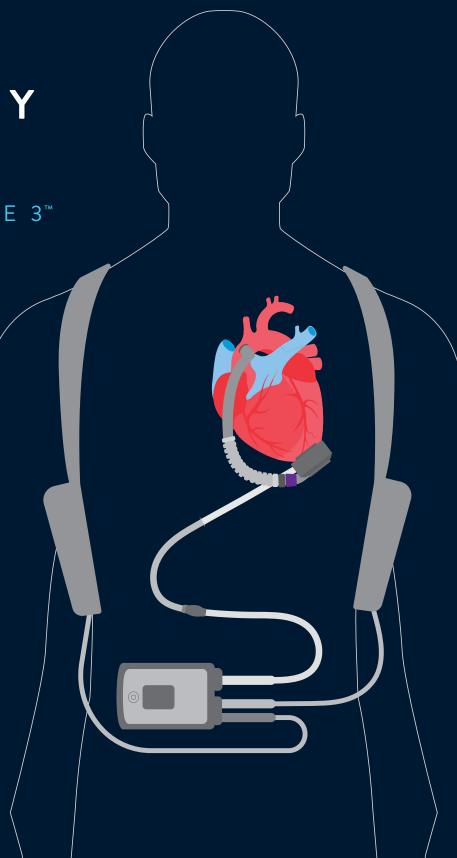




FOR THE HEARTMATE 3™ LVAD PATIENT



HEARTMATE 3™ LVAD

The HeartMate 3[™] Left Ventricular Assist Device (LVAD) is used in the treatment of end-stage heart failure, partially or completely replacing the function of the failing left ventricle. The goal of the device is to direct blood away from the failing left ventricle and provide flow to the body.

1 BLOOD PUMP

The LVAD is a centrifugal flow rotary heart pump.
The inflow cannula of the LVAD attaches to the apex of the left ventricle, and the outflow graft connects to the ascending aorta.

2 DRIVELINE

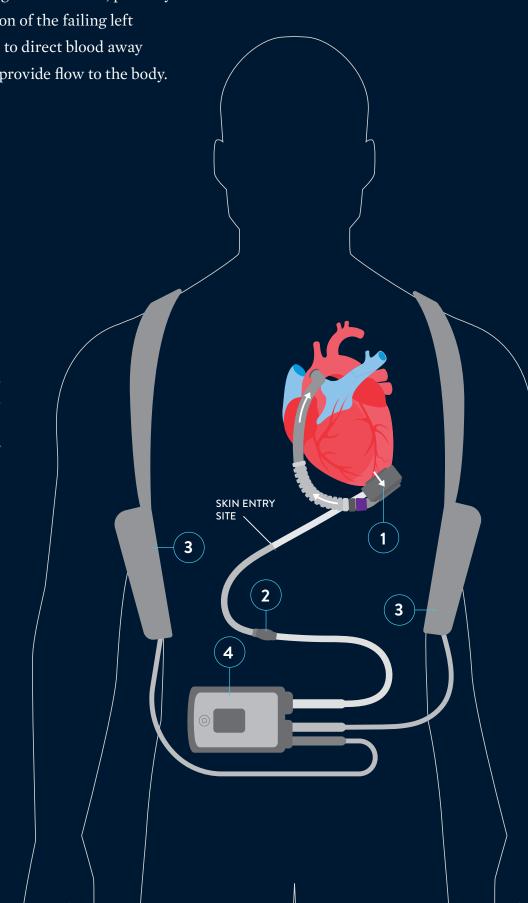
The driveline consists of two cables: the Pump Cable and the Modular Cable. The thin Pump Cable exits the abdomen and connects to the Modular Cable, which then connects the pump to the System Controller.

(3) BATTERIES AND CLIPS

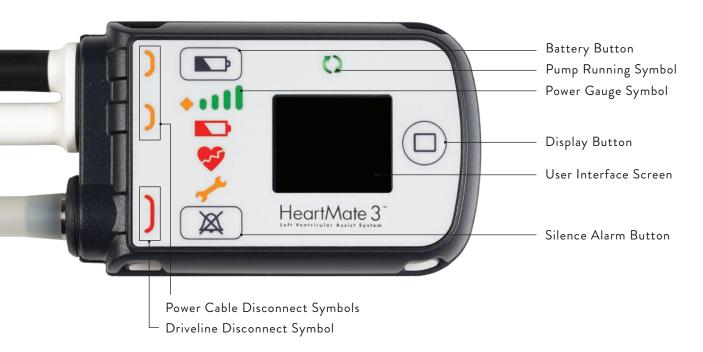
Deliver power to the system. One set of batteries will last up to 10 to 17 hours.

(4) SYSTEM CONTROLLER

Delivers power to the pump, and controls and monitors the system operation, with visual and auditory alarms that provide clear, actionable instructions.



SYSTEM CONTROLLER INTERFACE



PUMP RUNNING SYMBOL

Green arrows indicate the LVAD is running.

BATTERY BUTTON

- Displays the battery power (press and release)
- Tests the controller (press and hold for 5 seconds)
- Puts the controller into sleep mode (press and hold for 5 seconds when nothing is connected to the controller)

POWER GAUGE SYMBOL

The battery power gauge shows the approximate charge status of both batteries. Each green bar represents 25% of the charge remaining.

SILENCE ALARM BUTTON

• Silences an active alarm (press and release)

Important: The silence alarm button only silences the auditory alarm. It does not fix the underlying alarm condition.

DISPLAY BUTTON

Activates the user interface screen (press and release) to display pump readings.

ALARMS

When an alarm occurs, messages appear on the System Controller's interface screen. The screen messages indicate the alarm type and how long the alarm has been occurring.

- Yellow Diamond symbol indicates that there is less than 15 minutes of power remaining
- Red Battery symbol indicates that there is less than 5 minutes of power remaining
- Red Heart symbol indicates a hazard alarm that is urgent and requires immediate attention
- Yellow Wrench symbol indicates an advisory alarm that is not urgent

USER INTERFACE SCREEN

Displays information including pump speed, pump flow, pulsatility index, power and charge status of the backup battery.

SILENCE ALARM BUTTON WITH THE DISPLAY BUTTON

To view the last six System Controller alarms on the screen, press and release the silence alarm button and the display button at the same time. Then press the display button to scroll through the last six alarms.

EMERGENCY CARE

Emergency contact information should be located in the patient's travel case with their spare equipment.

CLINICAL CONSIDERATIONS FOR LVAD PATIENTS

- The HeartMate 3[™] LVAD is a continuous-flow device. Under normal operating conditions, patients:
 - May not have a palpable pulse
 - May not have a detectable blood pressure and therefore Doppler may be required
 - May not have a measurable pulse oximetry reading
- · Patients are anticoagulated
 - Consult the Implant Center ventricular assist device (VAD) team prior to giving
 - · Blood products
 - Thrombolytics
 - Coagulants
- MRI is contraindicated

ASSESSING AN LVAD PATIENT

- · Heart rate and rhythm
- Electrocardiogram (EKG)
 - The HeartMate 3 LVAD may create electromagnetic interference with EKG monitoring
 - Adjustment of EKG lead placement may reduce the level of interference
- Doppler blood pressure
 - Target: Mean arterial pressure < 90 mmHg
 - Confirm that the pump is running by auscultating the left chest over the apex of the heart. A continuous mechanical revving sound indicates the pump is running

EMERGENCY CONSIDERATIONS

Contact the Implant Center for direction when possible

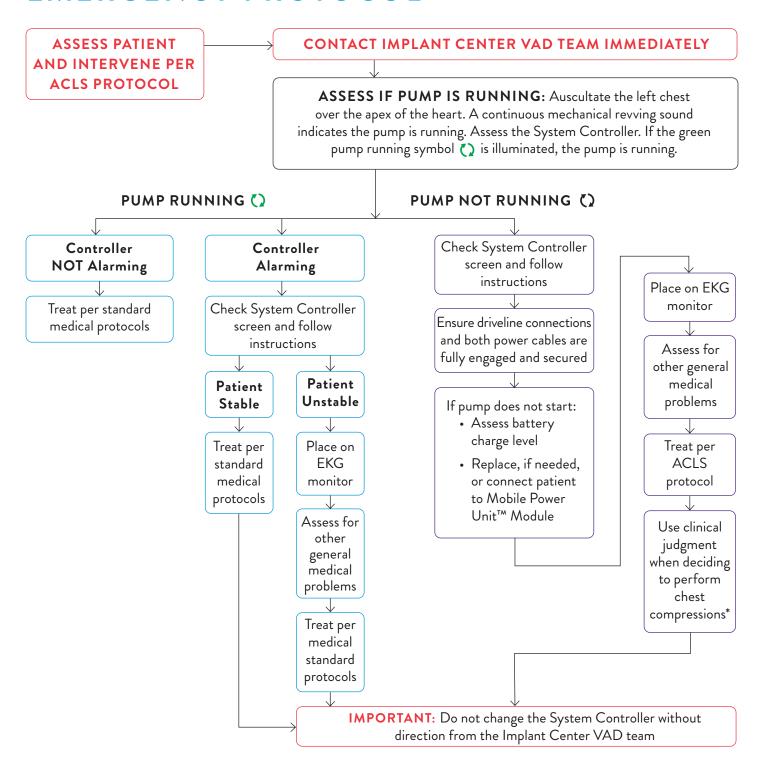
- External defibrillation, cardioversion and external pacing may be used if necessary
 - Do not stop the pump
- Use clinical judgment when deciding to perform chest compressions
- Use caution when cutting off clothing to avoid damaging the driveline

EMERGENCY TRANSPORTATION

- Any emergency mode of transportation is OK; patients are permitted to fly
- Avoid pulling, twisting or kinking the driveline when strapping the patient to a stretcher
- Be sure to bring ALL the patient's equipment with them
- Patients and their care providers have been trained to respond to LVAD emergencies; allow the care provider to remain with the patient at all times

PLACE IMPLANT CENTER CONTACT STICKER HERE

EMERGENCY PROTOCOL



IMPORTANT: The HeartMate 3[™] LVAD is a continuous-flow device. Under normal operating conditions, patients:

- · May not have a palpable pulse
- · May not have a detectable blood pressure
- · May not have a measurable pulse oximetry reading

TRANSPORT URGENTLY TO EMERGENCY ROOM

- If possible, transport to center where device was implanted
- Keep patient's companion with them
- · Bring all LVAD equipment
- Avoid pulling, twisting or kinking the driveline when strapping the patient to the stretcher

^{*}Due to the location of the LVAD and tubing connecting the LVAD to the heart, there may be risks associated with performing external chest compressions on LVAD patients during cardiac arrest. Chest compressions may dislodge tubing, resulting in fatal bleeding. Decisions on the use of chest compressions and other treatments rest with the attending physician, based on their clinical judgment and experience.

POWERING THE SYSTEM

14 V LITHIUM-ION BATTERIES

The HeartMate 3[™] LVAD uses 14 V lithium-ion batteries that provide up to 17 hours of support. The batteries drain simultaneously and require 4 hours to charge. Five lights on each battery indicate the amount of power remaining in the battery.

NUMBER OF LIGHTS ILLUMINATED		MEANING
••••	5 lights	Approximately 80%–100% of power remains
••••	4 lights	Approximately 60%–80% of power remains
•••0	3 lights	Approximately 40%–60% of power remains
••000	2 lights	Approximately 20%–40% of power remains
•0000	1 light steady	Approximately 10%–20% of power remains
• 0 0 0 0	1 light blinking	Approximately 10% or less of power remains. Do not use if battery has one blinking light. The HeartMate 3™ LVAD System Controller will indicate a power advisory

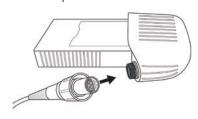




SWITCHING POWER SOURCES

From MPU to Batteries

Align the opposite half circles inside the power cables.



ACLS = advanced cardiovascular life support MPU = Mobile Power Unit

Abbott

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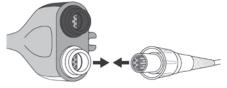
Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short-

From Batteries to MPU

Align the opposite half circles inside the power cables.



Connect

Black to black. White to white.

and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

HeartMate 3TM LVAS Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous



Scan to watch videos on powering the system

thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or pump thrombosis.

 $^{\scriptscriptstyle\mathsf{TM}}$ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

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