

PRODUCT UPDATE: HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM (LVAS) WITH MOBILE POWER UNIT™ (MPU) AND STATIC ELECTRICITY

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

HeartMate 3 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 listed here: 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 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) and possible pump thrombosis.

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WHAT YOU SHOULD KNOW ABOUT STATIC ELECTRICITY

Static electricity occurs when two objects come into contact. High levels of static electricity may damage or harm the HeartMate 3™ LVAS and may cause your pump to stop.

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 carpet.
- Touching the screens of older TVs or computers (LCD and LED screens are okay).

Fabrics like wool, silk and synthetic materials can build up static electricity. Use cotton fabric when possible.

Static electricity is more common when the air is dry (humidity less than 20%). Cold weather and home heating systems can make air drier. A humidifier can make air less dry and reduce static electricity.

WHAT YOU SHOULD DO TO REDUCE STATIC ELECTRICITY

When you are not sleeping or resting, it is recommended to use battery power instead of the MPU to power your HeartMate 3 LVAS. Battery power can help reduce damage or harm to your system from static electricity.

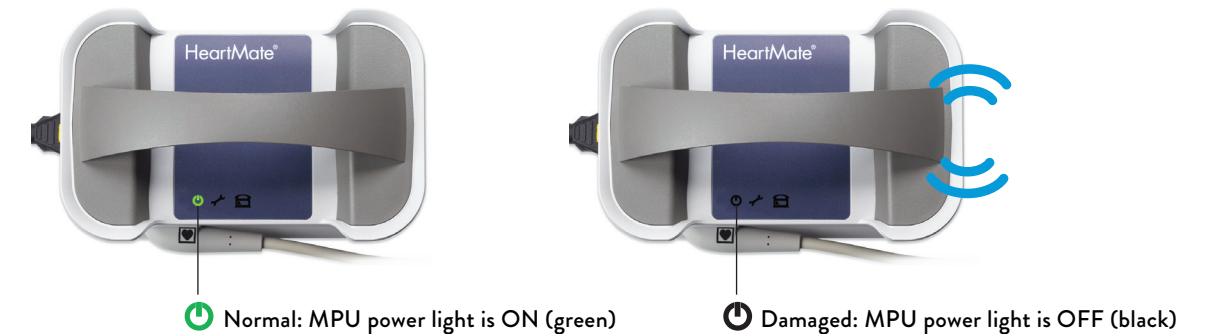
YOU CAN REDUCE STATIC ELECTRICITY WITH PRODUCTS SUCH AS:

- A humidifier to add moisture to the air.
- Dryer sheets and fabric softeners for clothes and bedsheets.
- Antistatic spray on carpets and other materials.
- Moisturizers for your skin.
- Cotton fabric clothing and bedsheets.

ALARMS YOU WOULD SEE AND HEAR

When you are using the MPU, static electricity can damage it. If this happens, the MPU is not able to supply electric power to the System Controller. Both the MPU and the System Controller will alarm to let you know.

THE MPU GREEN POWER LIGHT WILL BE OFF. YOU WILL HEAR A LOUD, CONSTANT ALARM TONE.



SCENARIO 1:

The System Controller will display the **No External Power Alarm**. You will see **flashing yellow lights** next to the power cables, a **flashing red battery** and the **pump running symbol is green**. You will hear a loud, constant alarm tone. The display screen will show two messages: Connect Power Immediately (Fig. 1) and Backup Battery (Fig. 2).

SCENARIO 2:

The System Controller will display the **No External Power Alarm**. You will see **flashing yellow lights** next to the power cables, a **flashing red battery**, a **flashing red heart** and the **pump running symbol will be off (black)**. You will hear a loud, constant alarm tone. The display screen will show two messages: Connect Power Immediately (Fig. 3) and Backup Battery (Fig. 4).

WHAT YOU SHOULD DO

Connect to battery power right away. If the alarm does not stop, call your VAD Coordinator or hospital contact immediately.



Fig. 1



Fig. 2



Fig. 3



Fig. 4