



***URGENT MEDICAL DEVICE RECALL***  
HeartMate Mobile Power Unit™  
(Catalog #107754, UDI #00813024010883)  
HeartMate 3™ Left Ventricular Assist System (LVAS) Kit  
(Catalog #106524, #106524US, UDI #00813024013297)

December 2, 2019

Dear Clinician,

Abbott is informing customers that we have received reports of power loss to patients' HeartMate Mobile Power Unit™ (MPU) Module due to static electricity. When the HeartMate MPU Module is connected to the HeartMate 3™ Left Ventricular Assist System (LVAS), excessive static electricity can potentially cause unrecoverable power loss and damage to the MPU Module.

There is currently a 0.2% worldwide complaint rate associated with these reports. **To date, there have been two (2) reports of serious injury and zero (0) reports of death.** The serious injuries were categorized as hemodynamic compromise (no or reduced blood flow from the LVAS). Investigation of these reports have not indicated that any of the MPU Modules failed to meet manufacturing specifications.

**Patient Management Recommendations**

Abbott field personnel will be performing training of all sites on the methods to reduce generation of excessive static electricity.

- Recognition of alarms if the HeartMate 3™ LVAS when connected to the MPU Module has been impacted by excessive static electricity.
- If a patient is not sleeping or resting, battery power is recommended instead of the MPU Module to power the HeartMate 3™ LVAS in order to reduce the impact of static electricity.
- In any case of an unexpected "no external power" alarm, patients should connect to battery power to power the HeartMate 3™ LVAS before attempting to determine the cause of the alarm. If the alarm persists, the patient should call the Hospital Contact.
- To prevent the generation of excessive static electricity during daily activities, Abbott is providing clarification for static electricity management when using the MPU Module with the HeartMate 3™ LVAS. Refer to Appendix A for specific reminders and recommendations to prevent excessive static electricity.

This issue is limited to HeartMate 3™ LVAS operating with the MPU Module. HeartMate II™ LVAS devices are not affected by this notice. Contact all your HeartMate 3 patients as soon as possible and provide them with the information in Appendix A. In addition to contacting all HeartMate 3 patients, please complete the attached acknowledgement form. Clarifications will be added to the Instructions for Use and Patient Handbook in the future.

Abbott remains committed to patient safety and providing the highest quality products and services. If you have questions regarding this notice, please contact Abbott Technical Services or MCS HeartLine at 1-800-456-1477, which is available 24 hours a day, 7 days a week. Alternatively, your Abbott MCS Field Representative is available to answer any questions you may have.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online;
- Call 1-800-FDA-1088 to report by telephone; or
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages.).

Thank you for your continued support.

Sincerely,



Lance Mattoon  
Divisional Vice President, Quality  
Abbott Heart Failure

## **Appendix A: Recommendations for Patients for Prevention of Excessive Static Electricity**

**The following clarifications will be added to the Instructions for Use and Patient Handbook. Please contact all current HeartMate 3 patients and provide them with this additional information. Training should be provided to all new HeartMate 3 patients on this information until the updated IFU and Patient Handbook are available.**

### **GENERAL WARNINGS**

High levels of static electricity may damage or harm the system and cause your pump to stop. Use battery power before doing activities that can cause static electricity. High levels of static electricity can occur while:

- Folding or changing bedsheets
- Taking laundry out of a dryer
- Dragging your feet on a carpet
- Touching the screens of older TVs or computer (LCD and LED screens are less likely to cause static electricity)

Also, use a humidifier, dryer sheets, fabric softener, and skin moisturizer to reduce the buildup of static electricity.

### **Static Electricity**

When you are not sleeping or resting, it is recommended to use battery power instead of the Mobile Power Unit™ to power your system. Using battery power can reduce the risk of system damage from high levels of static electricity.

Static electricity occurs when two objects come into contact. You can receive a static shock when performing the activities listed under GENERAL WARNINGS. Fabrics like wool, silk, and synthetic materials can buildup static electricity. Use cotton fabric where possible.

Static electricity is more common when the air is dry (relative 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:**

Using battery power will help avoid system damage from static electricity. If you're on the Mobile Power Unit, switch to battery power when doing things that cause static electricity.

Reduce static electricity, with products such as:

- A humidifier to add moisture to the air
- Dryer sheets and fabric softeners to reduce the buildup of static electricity in clothes and bedsheets
- Anti-static spray on carpets and other materials to reduce the buildup of static electricity
- Skin moisturizers to make your skin less likely to build up static electricity
- Fabrics with cotton, which cause less static electricity than wool, silk and synthetic materials. Choose cotton for clothing and bedsheets instead of wool, silk, and synthetic materials.