



Abbott

URGENT MEDICAL DEVICE RECALL

HeartMate™ Mobile Power Unit (Model: 107754)
Used with HeartMate 3™ LVAS and HeartMate II® LVAS

Heart Failure Division
Abbott Medical
6305 Stoneridge Dr.
Pleasanton, CA 94588




March 2025

Dear Patient,

This letter has important information about your HeartMate™ Mobile Power Unit (MPU). The MPU device connects to the wall outlet and powers your blood pump. Please read this letter carefully. Contact your clinical team at the hospital if you have any questions. Your clinical team at the hospital also has this information.


WHAT YOU NEED TO KNOW:

Some MPUs sold from April 2024 to February 2025 may not turn on. Some MPUs may suddenly shut down and/or suddenly shut down and restart. When this happens, you will have a Yellow Wrench Alarm on the MPU and a “No External Power” Alarm on the System Controller.

Alarms	
MPU Issue Alarm	System Controller Alarm
 <p>Yellow wrench sign with beeping sound</p>	 <ul style="list-style-type: none"> • Flashing Red Battery () on the user interface. • “Connect Power Immediately” and Backup Battery graphic alternate on the screen. • Yellow light near the black power cable connector is flashing. • Yellow light near the white power cable connector is flashing. • Alarm tone: Constant tone.

WHAT YOU NEED TO DO:

- Confirm if your MPU serial number is listed in Appendix A. If your serial number is not listed, this issue does not apply to your MPU.
- If the issues above occur, the Backup Battery in your System Controller can power the pump for up to 15 minutes. You must switch from the MPU to the fully charged 14V rechargeable batteries within these 15 minutes. Otherwise, your pump will stop.
- Every time you use the MPU for power, make sure your 14V rechargeable batteries are ready and available for use.
- If the yellow battery sign on the MPU is on, replace the AA batteries inside the MPU immediately. These batteries make the MPU alarms work.

Low MPU Battery Alarm
 <p>Yellow MPU battery sign with beeping sound</p>

- Do not use this MPU again. Contact Abbott Technical Support at 1-800-456-1477 (Business hours: 8 AM EST to 7 PM EST) for a new MPU.

If you need a new copy of the HeartMate 3 Patient Handbook, contact your clinical team at the hospital. You can also download it from the Abbott website:

<https://manuals.eifu.abbott/en/index.html>.

A device lookup tool with the impacted MPU devices listed in Appendix A will be available on the Abbott Product Advisories website by March 24th, 2025 at this link:

<https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/indications-safety-warnings/advisories.html>

Even if the issues above do not occur, Abbott will start to replace all affected MPU devices in June 2025. We will work with you on the replacement.

Your safety and satisfaction are important to us. Thank you for your understanding. We apologize for the inconvenience.

Sincerely,



Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure