



URGENT MEDICAL DEVICE RECALL

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HeartMate™ Mobile Power Unit (MPU)
Model Numbers: 107758AU

(191209-WAND-6TQSRJ & WAND 241028-WAND-74DDA2)
Used with HeartMate™ 3 LVAS Kits (Model Number 106524INT)

Medsafe Ref: 34852




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.



- Do not use this MPU again. Contact your hospital to organise 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>.

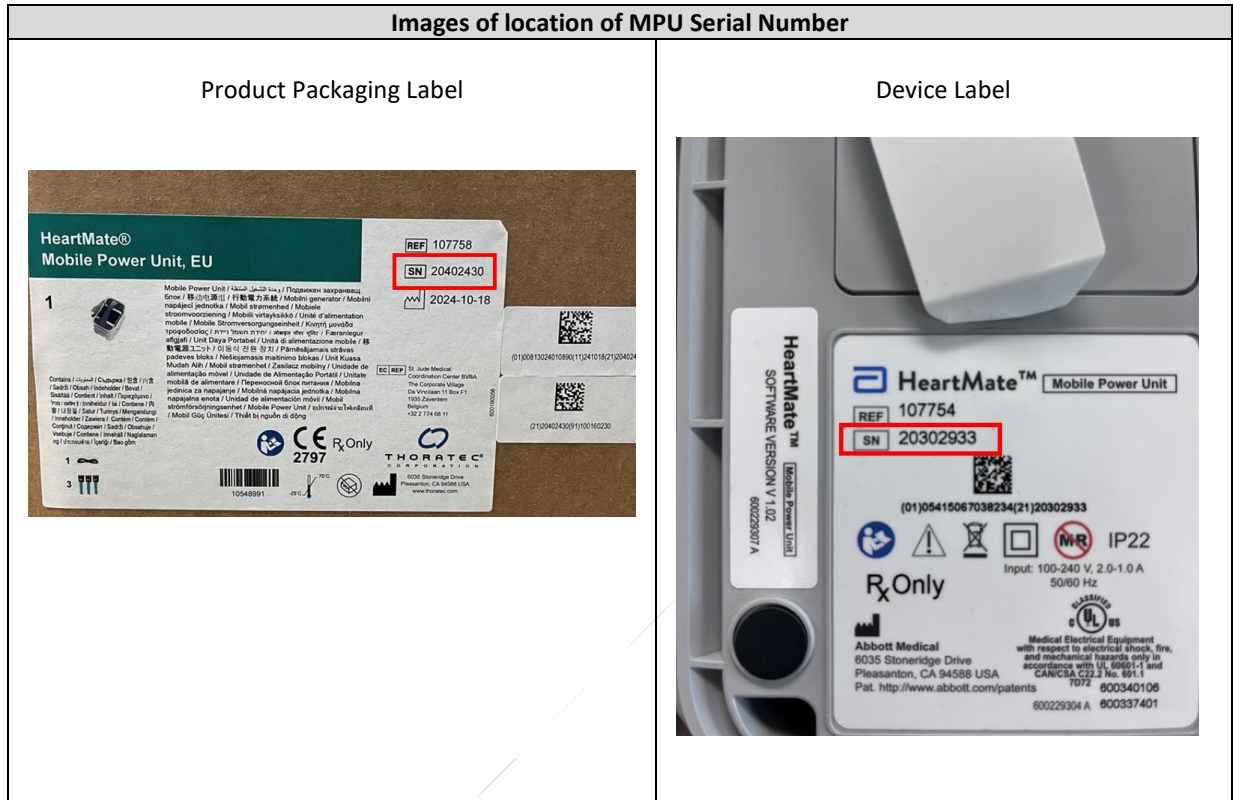
Even if the issues above do not occur, Abbott will start to replace all affected MPU devices in June 2025. We will work with you on the replacement.

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

Sincerely,

Carolyn Tabion, Divisional Vice President, Quality - Abbott Heart Failure

Appendix A – Reference Pictures and Listing of Potentially Impacted MPUs



Pictures are for reference only of the Serial Number location (pictures are of EU and US product label examples).

Potentially Impacted MPUs

MPU Model Number	MPU Serial Number
107758AU	20314706