URGENT MEDICAL DEVICE RECALL

HeartMate™ Mobile Power Unit (MPU)
Model Number: 107758AU
(191209-WAND-6TQSRJ & WAND 241028-WAND-74DDA2)
Used with HeartMate™ 3 LVAS Kits (Model Number 106524INT)

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Medsafe Ref: 34852

March 2025

Dear Physician or Healthcare Professional,

The purpose of this letter is to advise you that Abbott is initiating a recall action for the HeartMate™ Mobile Power Unit (MPU). Abbott has received customer complaints in which the MPU exhibited sudden, unexpected performance issues such as not turning on, unprompted shut down, or suddenly turning off and restarting, with the System Controller indicating a Yellow Wrench alarm or "No External Power" alarm. These issues have been linked to an electrical component in certain MPUs distributed between April 2024 and February 2025. This action is being initiated following consultation with Medsafe New Zealand.

Impact and Associated Risk

As of February 28, 2025, the complaint rate of MPU performance interruptions within the affected device population is approximately 4%. The reported impacts on patients included anxiety and inconvenience. Although not having been reported, this issue could also potentially lead to serious adverse health consequences such as hemodynamic compromise, thromboembolism, or death when power to the HeartMate left ventricular device is interrupted.

Root Cause

Investigation of the returned MPUs identified that an electrical component in the power supply does not meet Abbott quality standards and specifications. Not all MPUs from the identified manufacturing time frame contain the nonconforming electrical component. A list of the affected MPUs is provided in Appendix A.

How to Recognise the Issue and React

If an impacted MPU experiences a loss of power, the visual/audio alarms, as shown in Table 1, will deploy. When this happens, the Backup Battery in the System Controller can support the pump for up to 15 minutes. It is critical to switch from the MPU to the 14V rechargeable batteries immediately. If the batteries are not connected to the System Controller within 15 minutes, the System Controller Backup Battery will deplete, causing pump power loss.

Alarm Symbol	Meaning	What You Should Do
 **Advisory Alarm** Yellow wrench light with beeping audio tone	Internal malfunction detected within the MPU.	Promptly switch to two fully charged HeartMate™ 14 Volt Lithium-Ion batteries.
  • 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.	System Controller is not receiving external power.	

Table 1. Mobile Power Unit Alarm

Hospital User Action Requested

Review the enclosed Appendix A to identify potentially impacted MPUs that are either on your shelves, used in your clinic, or already assigned to patients.

- If patients **are** able to be identified using the serial number list (Appendix A), please send those patients the patient letter (Appendix B).
- If patients **are not** able to be identified using the serial number list (Appendix A), please send the patient letter (Appendix B) to all patients that have received an MPU from April 2024 to March 2025.
- For all other patients with MPUs not listed in Appendix A, they need not be notified. If the MPU is not listed in Appendix A, this device is not affected and can continue to be used.

Depending on the status of the impacted MPUs at your facility or with your patients, Abbott recommends the following:

For units that patients are currently using and have experienced MPU power issues:

- Follow the instructions provided in the Instructions for Use (IFU): If there is an MPU power failure, transfer the patient from the MPU to the 14V rechargeable batteries within 15 minutes. The Backup Battery in the System Controller will temporarily power the pump during a power source switch. Do not rely only on the System Controller's Backup Battery as a power source during power failure, as it will only power the pump for up to 15 minutes.
    - Note: MPU will continue to echo the controller alarms as long as the internal AA batteries in the MPU do not need replacement.
- Do not continue to use the MPU and immediately contact your Abbott Representative for return and replacement.

*For units currently used by patients, but **not** experiencing MPU power issues:*

- Provide the patient with the attached patient letter (Appendix B).
- As a precaution educate the patient about the issue and
    - Ensure the patient's 14V rechargeable batteries are ready and available for use at any time.
    - Prompt the patient to replace AA batteries inside the MPU immediately if the Yellow Mobile Power Unit Battery Indicator alarm is active. The internal AA batteries ensure that the MPU echoes the System Controller Alarms.
- Abbott will replace these with new units starting June 2025, even if these units continue to demonstrate expected performance.

For impacted MPU units that are currently in your clinic and have not yet been provided to a patient for use:

- Immediate return and replace units not distributed, not in use, on shelves, or that are unopened.
- Contact your Abbott Representative to arrange for product return and inventory replacement.

Please distribute this notice to those who need to be aware within your institution and to any organisation to which these devices may have been transferred. A device lookup tool with the impacted MPU devices will be available on the Abbott Product Advisories website at https://www.cardiovascular.abbott/int/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/advisories.html by March 24th, 2025.

Abbott Action

Abbott is taking the following actions:

- Notifying the clinic of patients with the impacted MPUs, and any impacted in-clinic inventory (Appendix A).
- Notifying patients with impacted MPUs through the clinics using the attached patient letter (Appendix B).
- Immediately replacing MPU devices that are demonstrating unexpected performance, and any impacted clinic inventory. Replacement of all remaining impacted MPU devices will begin in June 2025 or earlier when sufficient inventory is available. Your local Abbott representative will work with you to ensure a smooth transition.

Should you have any questions about this notice, please contact your Abbott representative.

Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

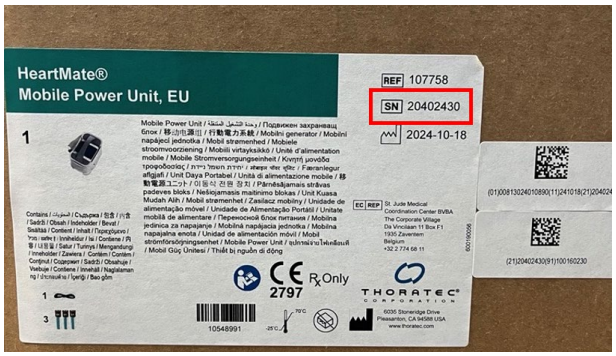
Enclosed:

- Appendix A – Reference Pictures and Listing of Potentially Impacted MPUs and Patients
- Appendix B – Patient Letter

Appendix A – Reference Pictures and Listing of Potentially Impacted MPUs

Images of location of MPU Serial Number

Product Packaging Label



Device Label

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