carecentrix

Provider Newsflash
April 2025

FDA Recall – Abbott

Purpose of this communication:

- We are writing to inform you that there is a class I FDA recall for Abbott's HeartMate Mobile Power Unit (MPU) used with the HeartMate 3 Left Ventricular Assist System (LVAS) and HeartMate II LVAS. Abbott has received reported incidents in which the MPU experienced 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. Abbott has identified that these issues are linked to an electrical component used to manufacture certain MPUs distributed between April 2024 and February 2025. If an impacted MPU experiences a loss of power, the Backup Battery in the System Controller can support the pump for up to 15 minutes. If the 14V rechargeable batteries are not connected to the System Controller within 15 minutes, the pump will lose power and stop. This could lead to serious adverse health consequences such as hemodynamic compromise (impaired blood flow and circulation), thromboembolism (blood clot blocking a blood vessel), or death. Abbott has not reported any serious injuries or death associated with this issue.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/heart-pump-accessory-removal-abbott-removes-heartmate-mobile-power-unit-due-instances-sudden-power?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the replacement, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.