VOLUNTARY MEDICAL DEVICE RECALL

11 Volt Lithium-Ion Backup Battery Standalone Device and part of the HeartMate 3™ LVAS Kit, HeartMate 3™ System Controller and HeartMate II™ System Controller (Model Numbers: 106524US, 106531US (Controller) and 106128 (Standalone))

May 2026

Dear Healthcare Professional,

Abbott is writing to inform you of a voluntary medical device recall involving the 11V Lithium-Ion Backup Battery that is distributed as a standalone device, or as part of the HeartMate II™ System Controller, HeartMate 3™ System Controller, and Left Ventricular Assist System (LVAS) Kit. You are receiving this notification because your site has been identified as having an impacted battery. As part of this voluntary medical device recall, Abbott requests that all affected batteries be returned to Abbott.

As of April 27, 2026, Abbott received twenty-four (24) complaints where an advisory warning, "Replace Backup Battery," was triggered once certain 11V Backup Batteries were connected to the System Controller. This warning is displayed as a yellow banner on the HeartMate Touch Monitor and System Monitor (See **Figure 1**). This advisory alert is only visible when using HeartMate Touch or the System Monitor in the clinic, it is not visible to the patient.

Abbott's investigation has identified this issue to be limited to 11V Backup Batteries built between January 01, 2026 and April 30, 2026. It is caused by a discrepancy between the Date of Manufacture (DOM) programmed in the battery and the DOM printed on the battery label. Specifically, while the battery label indicates a year 2026 DOM, the HeartMate Touch or System Monitor Backup Battery settings menu displays a year 2000 DOM (See **Figure 2).**

In all incidents related to this recall, the battery is functioning as intended and capable of supplying power. However, battery replacement is required to clear the warning because the alert is triggered by an inaccurate DOM stored on the battery.

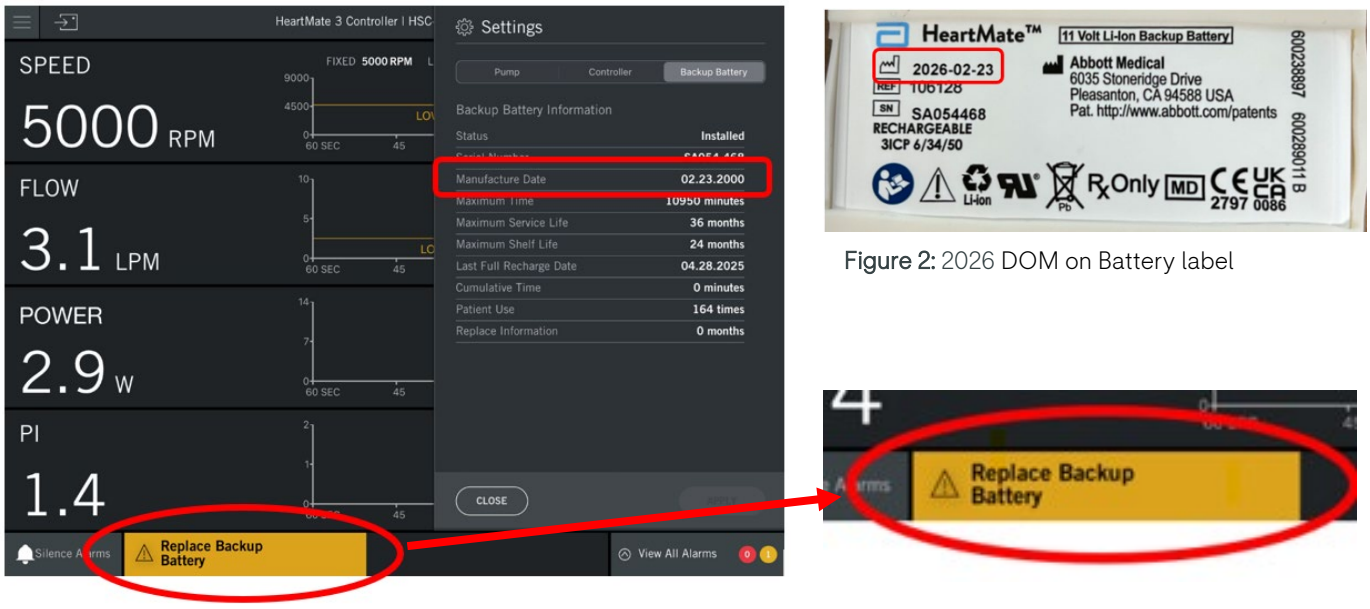

Figure 1: "Replace Backup Battery" warning and 2000 DOM as displayed in the HeartMate Touch system

Figure 2: 2026 DOM on Battery label

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IMPACT AND ASSOCIATED RISK

In all the reported complaints, the clinician replaced the 11V Lithium-Ion backup battery as instructed by the advisory warning, with no patient adverse events. Clinicians have reported anxiety/inconvenience caused by the warning immediately upon connecting the battery to the System Controller in the clinic. Abbott's medical assessment determined that this issue is unlikely to result in serious adverse health consequences.

WHAT YOU NEED TO DO

1. Read this notification thoroughly and communicate this information to those relevant in your facility.
2. Please refer to the FSCA Device Retrieval Form for the list of impacted batteries that were shipped to your site. Additionally, you may use the online lookup tool (https://www.cardiovascular.abbott/int/en/hcp/product-advisories/heartmate-batteries-2026.html) to confirm if a 11V Lithium-Ion battery at your site is an impacted one. Figure 3 shows an instruction on how to locate the serial numbers of the impacted batteries.

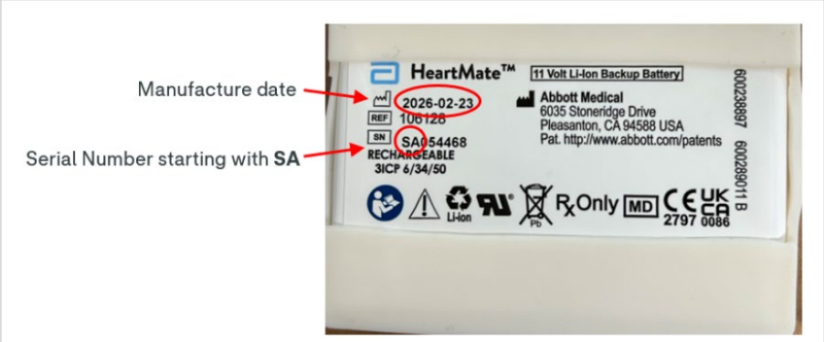

Figure 3: Affected batteries will have a combination of Serial Number that starts with the prefix SA, and a manufacture date between 01 January 2026 to 30 April 2026

3. Once the impacted batteries are identified, do not use them.
4. Review the Return Instructions included with this letter and follow the steps to ensure that all affected batteries are returned and replaced. Complete and return the signed FSCA Device Retrieval Form to Abbott. If the batteries are not able to be returned, please complete the No Return Acknowledgment Form.

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WHAT IS ABBOTT DOING

Abbott has stopped the manufacturing of devices using these impacted 11V Lithium-Ion Backup Batteries.

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. 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