

# URGENT MEDICAL DEVICE RECALL

Heart Failure Division  
Abbott Medical  
6035 Stoneridge Dr.  
Pleasanton, CA 94588

**Product Name:** Implantable Left Ventricular Assist System (LVAS) *HeartMate II*

**Approval Number:** 22400BZI00017000

**Product Name:** Implantable Left Ventricular Assist System (LVAS) *HeartMate 3*

**Approval Number:** 23100BZI00006000

11 Volt Lithium-Ion Backup Battery

(including components bundled with System Controller 106531US and Implant Kit 106524US)

May 2026

Dear Nipro Corporation:

Abbott is writing to inform you of a voluntary 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 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.

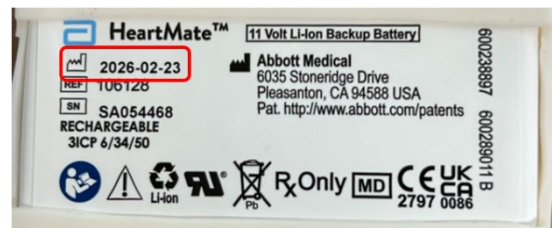
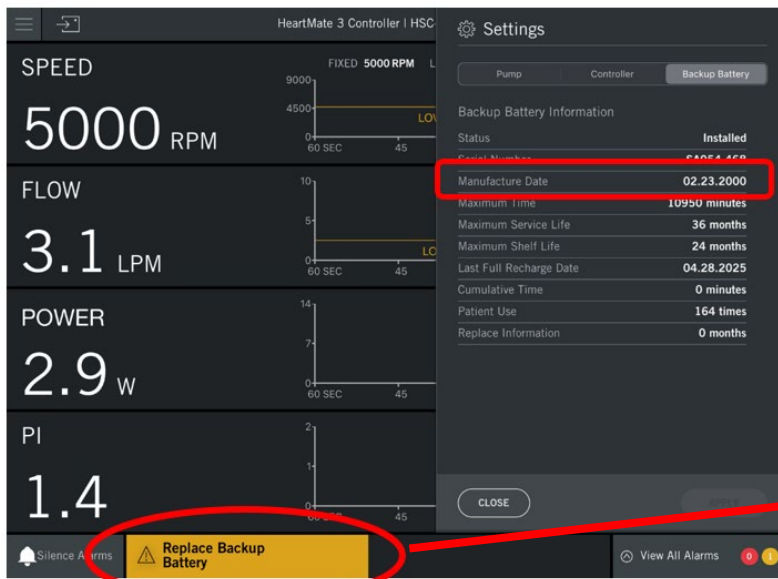


Figure 2: 2026 DOM on Battery label

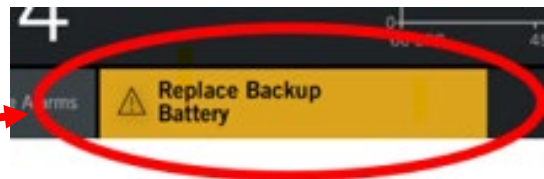


Figure 1: “Replace Backup Battery” warning and 2000 DOM as displayed in the HeartMate Touch system



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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, complete and sign the form included with this letter, acknowledging that you received and understand this information.
2. The affected products are as listed in the attached list (see Appendix 1). Please return them to Abbott Medical Japan.

### WHAT IS ABBOTT DOING

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

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

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



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Appendix 1. Affected list

Serial Number of 11 Volt Lithium-Ion Backup Battery	Model number	Serial Number
SA026245	106524US	MLP-061013
SA026247	106524US	MLP-060701
SA026248	106531US	HSC-521815
SA026251	106524US	MLP-060700
SA026252	106524US	MLP-061038
SA026253	106524US	MLP-061034
SA026254	106524US	MLP-061012
SA026257	106524US	MLP-061015
SA026258	106524US	MLP-060202
SA026259	106524US	MLP-061016

