



URGENT MEDICAL DEVICE RECALL (CORRECTION)

HeartMate 3™ System Controllers
Used with HeartMate 3™ LVAS

(Model Numbers: 106524US, 106531US, 106531LF2)

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

The majority of the reports received by Abbott included anxiety, inconvenience or a replacement of the back-up battery or controller. The Kaplan Meier estimate of the rate of Backup Battery Fault Alarms that may be related to corrosion is 1.6% at 1 year, 3.2% at 2 years and 4.1% at 3 years. Between August 2020 and May 2025, there is an overall complaint rate of 5.26% for Backup Battery Fault Alarms irrespective of system controller age. A complaint rate of 0.03% was associated with patients attempting to exchange their controller without clinical support, which contributed to adverse patient outcomes, including hemodynamic compromise and death.

WHAT YOU NEED TO KNOW

When the Backup Battery Fault Alarm is active, this Advisory alarm will appear as a flashing yellow wrench on the user interface and “Call Hospital Contact; Backup Battery Fault” will appear on the screen (see Figure 2 below), accompanied by a slow beep tone. When in a clinical setting, the HeartMate Touch App will have an active alarm that reads “Replace Backup Battery.”

As a reminder, when this alarm is active and the pump is running and flow is maintained (indicated by the green arrow symbol ) , this alarm does not affect the controller or pump functionality.

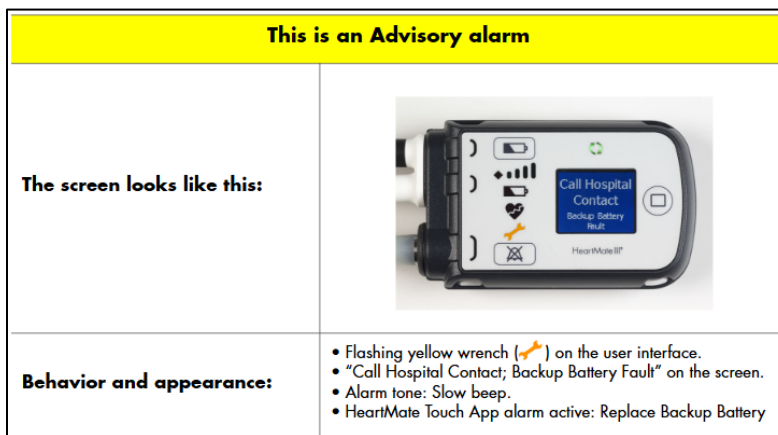


Figure 2: Backup Battery Fault Alarm, Pg. 7-21, HeartMate 3™ LVAS Clinician Instructions for Use

WHAT YOU NEED TO DO

Read this notification thoroughly, complete, sign, and return to Abbott the form included with this letter acknowledging that you received and understand this information and that you will communicate this information with other relevant staff members in your facility and to affected users, patients, and caregivers.

If further assistance is needed regarding the Backup Battery Alarm after following Instructions for Use, contact your Abbott representative for troubleshooting steps to determine if a battery or system controller replacement is required for resolution.



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This guidance is also provided in the existing Clinician Instructions for Use. The HeartMate 3™ Left Ventricular Assist System (LVAS) Clinical Instructions for Use (page 7-21) outlines that if the Backup Battery Fault Alarm is active, patients should first ensure that they remain on external power sources (e.g. 14V batteries or AC power via the Mobile Power Unit) until the issue is resolved. During this time, the pump is operating as intended and providing flow. To resolve the issue:

- Patients must call their hospital contact immediately for diagnosis and instructions.
- If a System Controller exchange is needed, remind the patient that a caregiver must be present during the exchange and that all labeling instructions on System Controller exchange must be followed.
- If a backup battery replacement is needed, advise the patient to visit your clinic and have a clinician replace the System Controller 11 Volt Lithium-Ion backup battery (see page 2-40).

WHAT IS ABBOTT DOING

Abbott is developing and qualifying a change in the System Controller Backup Battery connection interface to address this issue, which will be implemented upon receiving regulatory approvals.

Abbott is notifying the related regulatory authorities about the issue. 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. 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,

A handwritten signature in black ink, appearing to read 'C. Tabion'.

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure