URGENT MEDICAL DEVICE RECALL (CORRECTION)

HeartMate II® and HeartMate 3™ System Controllers
Used with HeartMate 3™ LVAS and HeartMate II® LVAS
(Model Numbers: 106017, 106762, 107801, 106531US, 106531INT, 106531LF2)

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

October 2025

Dear Physician or Healthcare Professional,

This letter is to inform you that Abbott is initiating a voluntary medical device correction for the HeartMate II® and HeartMate 3™ System Controllers. This correction does not involve device removal from where they are used or sold.

Abbott has observed an increase in customer complaints about the controller Backup Battery Fault Alarm. This alarm is indicated by a flashing yellow wrench on the user interface of the System Controllers. When the controller is connected to an external power source (e.g., 14V batteries or AC power via the Mobile Power Unit), this is an advisory alarm and does not indicate a critical system failure or impact pump functionality.

To reduce future instances of the Backup Battery Fault Alarm, Abbott is advising that when performing Backup Battery installation or replacement, clinicians should minimize excessive handling, movement, stress and pulling at the interface between the ribbon cable and controller. An example of excessive handling would be using the ribbon cable to hold the weight of the controller.

Please remind patients and caregivers to follow the Patient Handbook: If System Controller Backup Battery Fault Alarm is active, patients should first ensure that no other alarms are active, and then they should call their hospital contact as soon as possible for diagnosis and instructions. Patients and caregivers should not immediately attempt to exchange the System Controller without clinical guidance.

CAUSE, IMPACT AND ASSOCIATED RISKS

In the confirmed complaints, Abbott identified corrosion at the connection point between the System Controller and the Backup Battery ribbon cable. This can be caused by excessive handling and movement of the ribbon during Backup Battery installation or replacement, specifically at the ribbon cable connection interface, see Figure 1.

Figure 1: Connection of Backup Battery Ribbon Cable

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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.

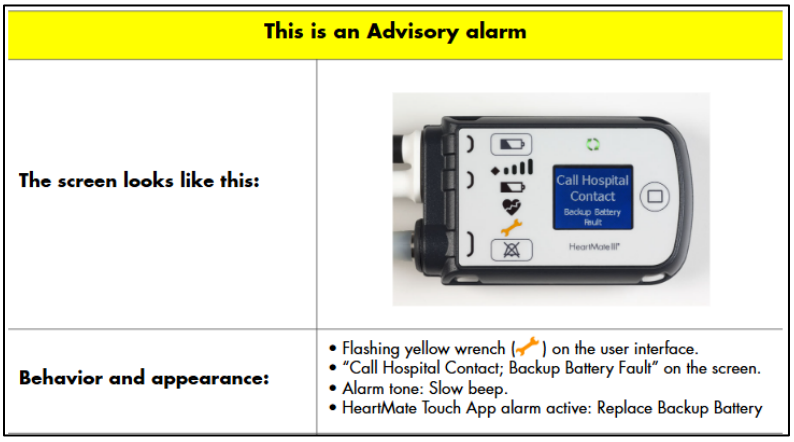

Figure 2: Backup Battery Fault Alarm, Pg. 7-21, HeartMate 3™ LVAS Clinician Instructions for Use

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 Abbott Technical Service at 1-800-456-1477 (Business hours: 8 AM EST to 7 PM EST) 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 II® and HeartMate 3™ Left Ventricular Assist System (LVAS) Clinical Instructions for Use (page 7-20 for HeartMate II®, page 7-21 for HeartMate 3™) 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 2-43 for HeartMate II® and page 2-40 for HeartMate 3™).

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 has notified the United States Food & Drug Administration (FDA) about the issue. Should you have any questions about this notice, please contact your Abbott representative or Abbott Technical Support at 1-800-456-1477 (Business hours: 8 AM EST to 7 PM EST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete the voluntary Form FDA 3500 online at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return it to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178.

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,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

URGENT MEDICAL DEVICE RECALL (CORRECTION)
Acknowledgement Form

HeartMate II® and HeartMate 3™ System Controller
Used with HeartMate 3™ LVAS and HeartMate II® LVAS

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY; RESPONSE IS REQUIRED

By entering the information requested below and signing this form, I acknowledge that I have received, read, understood and followed the directions in the contents of the customer advisory letter dated October 2025. The customer notification is related to corrosion at the Backup Battery cable interface leading to Backup Battery Fault Alarms for HeartMate II® and HeartMate 3™ System Controllers.

Name: (Print)	
Title: (Print)	
Facility Name: (Print)	
Facility Address: (Print)	
Signature:	
Date:	

PLEASE RETURN via Email: MCSHMNotices@abbott.com