Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA

URGENT MEDICAL DEVICE CORRECTION

HeartMate 3™ LVAS Implant Kit (Model: 106524INT)
HeartMate 3™ System Controller (Model: 106531INT)
HeartMate 3™ System Controller Low Flow 2.0 (Model: 106531LF2)

July 2024

Dear Valued Customer,

Abbott is notifying customers of a potential issue identified with the HeartMate 3™ System Controller (Model 106531INT and 106531LF2) which is provided within the HeartMate 3™ Left Ventricular Assist System (LVAS) Implant Kit (Model 106524INT) or distributed separately. These controllers were distributed after March 2024.

Abbott has identified that there is a potential for the controllers to have a lifted User Interface (UI) membrane that when present, is observed along the edge of the controller housing, near the Display Button as highlighted in images below. The product is not being removed from the field. As of July 8, Abbott has received 4 complaints where a lifted UI membrane was observed by customer with no patient harm reported. It is unlikely that any serious adverse health consequences would occur as a result of the lifted User Interface membrane as detailed below.

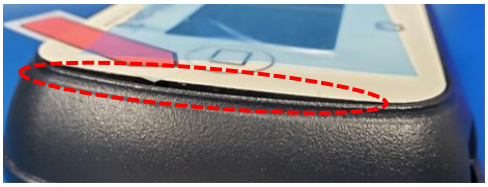
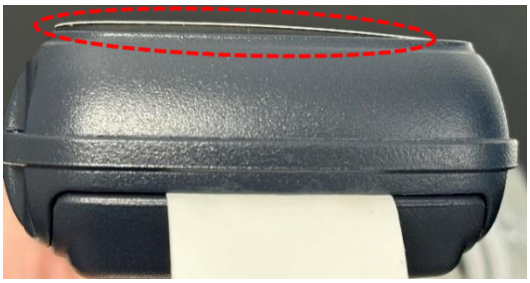
Impact and Associated Risks:

If the UI membrane is lifted and if the controller were to be exposed to fluid, there is a potential for fluid ingress into the controller which may lead to damaged Printed Circuit Board Assemblies (PCBA). This could result in unexpected and false positive alarms, as well as loss of the user interface (use of buttons, loss of visual alarms, etc.). Fluid ingress may also lead to loss of power to the pump resulting in a pump stop, however this possibility is very rare due to redundancies in the power path to the pump.

A lifted UI membrane may result in a range of harms from anxiety, hemodynamic compromise, to possibly death. The degree of harm depends on the level of fluid ingress and patient heart failure status. It is unlikely that any serious adverse health consequences would occur as a result of the lifted UI membrane. A serious adverse health consequence can only occur when both redundant power lines are equally impacted due to this issue and alarms are not addressed. There is a remote probability estimated as approximately 0.0011% that a medically reversible transient adverse health consequence (e.g., hemodynamic compromise) may occur due to the fluid ingress and subsequent degradation of controller function. In addition, degradation to one of the power paths to the pump would be detected by the controller, which would issue associated alarms while maintaining pump speed. Healthcare providers and patients are provided instructions to avoid exposing the controller to fluids per the Instructions For Use (IFU).

Recommendation:

- Carefully inspect the controller at the edge near the Display Button to confirm that the UI membrane is not lifted (refer to provided visual examples) prior to using the controller or providing the controller to your patient. Do not provide controllers with lifted UI membrane to your patients and report controllers with lifted UI membrane by contacting your local Abbott Representative. Note that controllers that do not present a lifting UI membrane will not lift over time.

HeartMate 3 System Controller with **Lift** near the Display Button	HeartMate 3 System Controller with no Lift near the Display Button
Top Edge (close to Display button) View	
	
	
	

- Use enclosed Patient Letter to explain this issue and reinforce to follow these instructions in the Patient Handbook (PHB) to patients who have received any of the serial numbers starting on March 2024.

- Reinforce requirement to patient to perform the daily Self-Test to verify the display works appropriately as listed in “Performing a System Controller Self-Test” of the IFU, and pages 2-26 and 2-27 (English version) / pages 2-25 and 2-26 (Traditional Chinese version) of the PHB . These sections can be downloaded from the Abbott Manuals website eLabeling | Abbott (eifu.abbott) which can be accessed at https://manuals.eifu.abbott/en/index.html.

- Reinforce “General Warning” and “Warnings and Cautions” within the IFU and the PHB to protect the controller from exposure to fluids and keep it dry at all times. In addition, patients who are permitted to shower by a doctor, must use the Shower Bag for every shower. The Shower Bag protects the external system components from water and moisture. Refer to Appendix A for images of Shower Bag.

Abbott has implemented an additional inspection point within the manufacturing process as an immediate action and will implement additional corrective actions to address this issue. While investigation and implementation of corrective actions is ongoing, in order to support patients who require an implant, Abbott will continue to distribute potentially affected controllers and implant kits until inventory of nonaffected controllers is available. The serial numbers affected by this notice will be continuously updated on the Abbott Product Advisory Website: Cardiovascular Product Advisories | Abbott.

Please distribute this notice to those who need to be aware within your institution and to any organization where potentially affected devices may have been transferred in the event that devices were transferred elsewhere.

Adverse reactions or quality problems experienced with the use of this product may be reported to your local Abbott Representative.

Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process. Should you have any questions about this notice, please contact your Abbott representative.

Sincerely,

Benjyna Obasuyi

Director Quality Assurance
Abbott Heart Failure

Enclosures:

- Patient Letter
- Appendix A – Image of Shower Bag

Appendix A – Image of Shower Bag

Refer to IFU and PHB pages 4-12 to 4-21 on how to use the Shower Bag and the image below of the Controller stored within the Shower Bag.

Images of Controller inside Shower Bag