

## Urgent: Important Information for Patients

HeartMate 3™ System Controller (Model: 106531INT)  
 HeartMate 3™ System Controller Low Flow 2.0 (Model: 106531LF2)

July 2024

Dear Patient,

Abbott is writing to you about important information related to the HeartMate 3 System Controller, the device that controls your Left Ventricle Assist Device (LVAD). This information was provided to your VAD Clinical Team.

Please review all the information below and reach out to your hospital contact with any additional questions about this letter.

### WHAT YOU NEED TO KNOW:

Abbott identified specific Controllers distributed since March 2024 that may have a lifted screen at the edge, near the Display Button (Figure 1). If exposed to fluid, this lift may allow fluid to enter under the screen, potentially affecting the Controller. This may result in abnormal system behavior, such as visual alarms, issues with the display LED lights, or unresponsive buttons. **Note: audible alarms are not affected.**

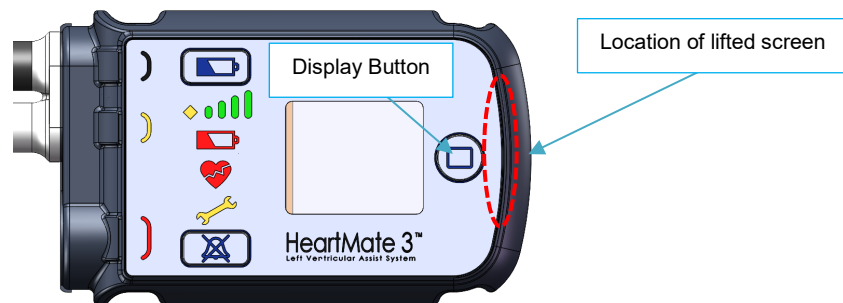
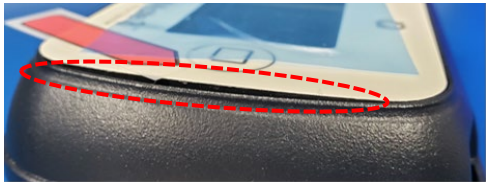





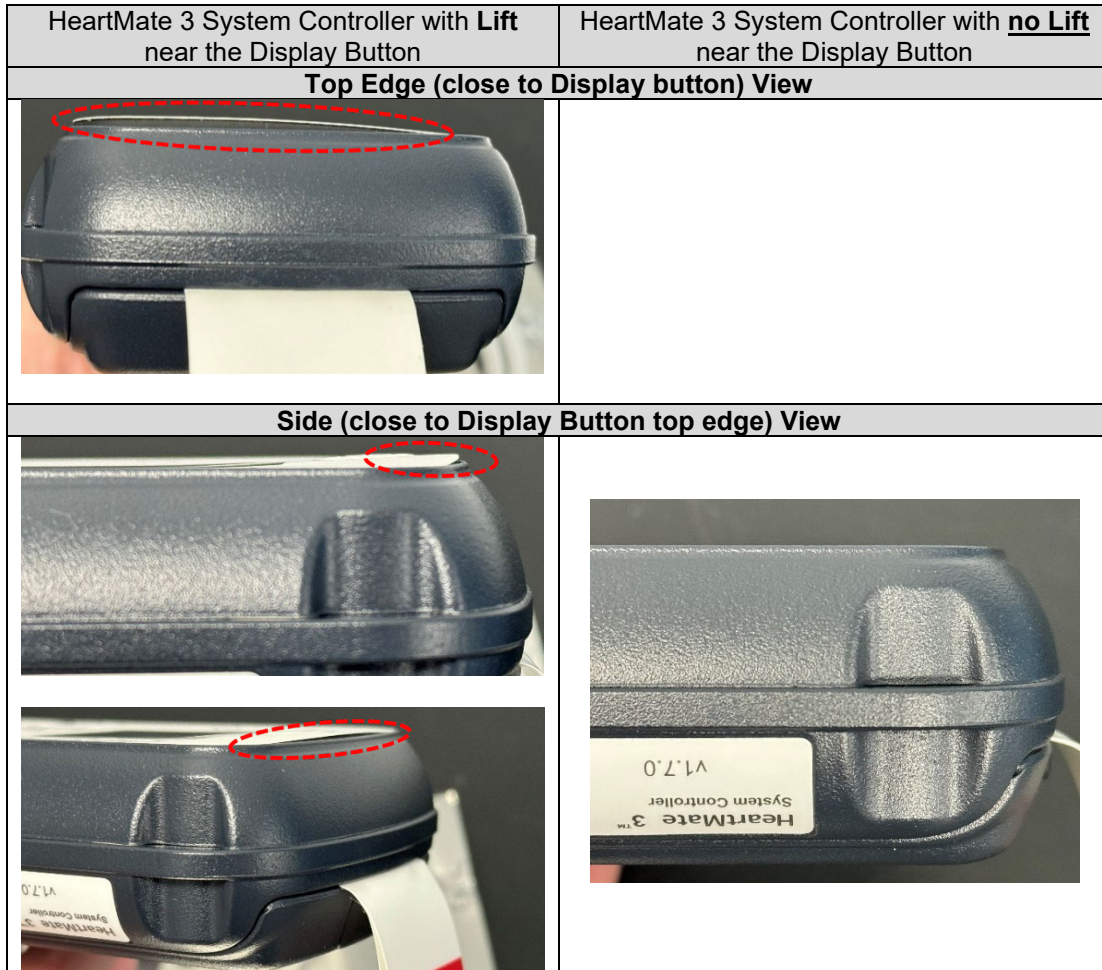
Figure 1: Location of lifted screen on the System Controller

### WHAT YOU NEED TO DO:

Abbott recommends you take the following actions:

1. **Carefully inspect your Controller** at the edge near the Display Button to confirm there is **no lift** (see below images).

HeartMate 3 System Controller with <b>Lift</b> near the Display Button	HeartMate 3 System Controller with <b>no Lift</b> near the Display Button
<b>Top Edge (close to Display button) View</b>	
	
	



2. If your controllers have a lifted screen, report it to your hospital contact.
3. **Continue to perform the Controller Self-Test** by following the instructions in your Patient Handbook on pages 2-26 and 2-27 to confirm your Controller is working. Perform the test at least once per day.
4. **Continue to protect your Controller from water or moisture** as detailed in the Patient Handbook:
  - a. Always **keep your Controller dry**.
  - b. If you are allowed by your doctor to shower, **you must use the Shower Bag for every shower**. The **Shower Bag protects the external system components from water and moisture**.
    - i. See pages 4-16 to 4-19 of the Patient Handbook on how to use the Shower Bag and the image below of a Controller stored within the Shower Bag. If a replacement shower bag is needed reach out to your hospital contact for component replacements.



c. Never swim, take tub baths, or submerge the Controller in water.

5. Report any alarms or abnormal behavior to your hospital contact.

How can you find out if your Controller may be affected?

- Your physician will inform you, if you have received a HeartMate 3™ System Controller (Model: 106531INT, 106531LF2).

Abbott implemented an additional inspection point within the manufacturing process to address this issue.

If you need a new copy of the HeartMate 3™ Patient Handbook, contact your hospital contact or download it from the Abbott Manuals website ([eLabeling | Abbott \(eifu.abbott\)](#)) at <https://manuals.eifu.abbott/en/index.html> .

Safety and satisfaction are our top priority. We appreciate the privilege to provide high quality products and support to you. Thank you for understanding; we apologize for any inconvenience this issue may have caused.

Sincerely,

Benjyna Obasuyi  
Director Quality Assurance  
Abbott Heart Failure