



Urgent Medical Device Correction
HeartMate Touch™ Communication System
(Models: HMT1100, HMT1100-R)
GTIN:05415067032058, 0541067033758

Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA

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Dear Valued Customer,

Abbott is notifying customers of a single reported event with the HeartMate Touch™ Communication System (also referred to as 'HeartMate Touch'). This event was not associated with patient harm. The HeartMate Touch Communication System is part of the HeartMate 3™ and HeartMate II™ Left Ventricular Assist System (LVAS) and is used in the medical facilities for patient monitoring and system programming.

During a clinic visit, the HeartMate Touch Communication System in one treatment room connected to the HeartMate Touch Wireless Adapter plugged into the Power Module in an adjacent treatment room without a user-initiated action or notification to the user. The connection to an unintended LVAS without any user interaction led to the clinician adjusting settings of another patient without the clinician's awareness. The HeartMate Touch System in the adjacent room did not have battery charge and its power cable was not plugged in prior to being used; it is unknown if the lack of battery and power connection contributed to the reported event.

Impact and Associated Risks

HeartMate Touch connection to an unintended LVAS can result in changes to LVAS settings that were not intended for the device. It can also result in the intended changes to the settings not being executed for the patient it was intended to treat. Both scenarios have the potential to result in hemodynamic compromise or discomfort to the patient based on patient conditions.

Abbott has not been able to reproduce the issue as reported. In all test scenarios, user notifications for connection and disconnection were displayed and/or prompted as expected and the HeartMate Touch Wireless Adapter auto reconnect and confirmation screen prompt function performed as expected. It is possible that a depleted charge on the HeartMate Touch in the adjacent room could have contributed to an inadvertent connection in the reported event.


This is the only reported event of this nature since the start of global commercial distribution of HeartMate Touch in 2020.

Recommendation

Continued use of all HeartMate Touch Communication Systems and HeartMate LVAS is safe when following the instructions identified in this letter. Abbott is reinforcing the existing cautions in the Instructions For Use when utilizing the HeartMate Touch Communication System:

- The HeartMate Touch Communication System should be fully charged, or its power cable should be plugged in before starting this procedure. (Pg 4-11)
- Verify that the HeartMate Touch Communication System is connected to the intended HeartMate LVAS when making changes to LVAS settings. (Pg 4-23)

The HeartMate LVAS System connects to the HeartMate Touch Communication System via connection to the Power Module and the associated HeartMate Touch Wireless Adapter that uses Bluetooth® Wireless Technology. **Prior to making any changes to pump settings**, user should confirm that they are connected to the intended LVAS System by locating the adapter as described in the ‘HeartMate Touch Communication System Interface Overview’ section (Pg 4-20) of the Instructions for Use:

- Use the ‘Locate’ feature to identify the Adapter to which the system is connected. To do this:
 - Tap on the ‘**Locate**’ icon  on the top right corner of the HeartMate Touch Communication System display.

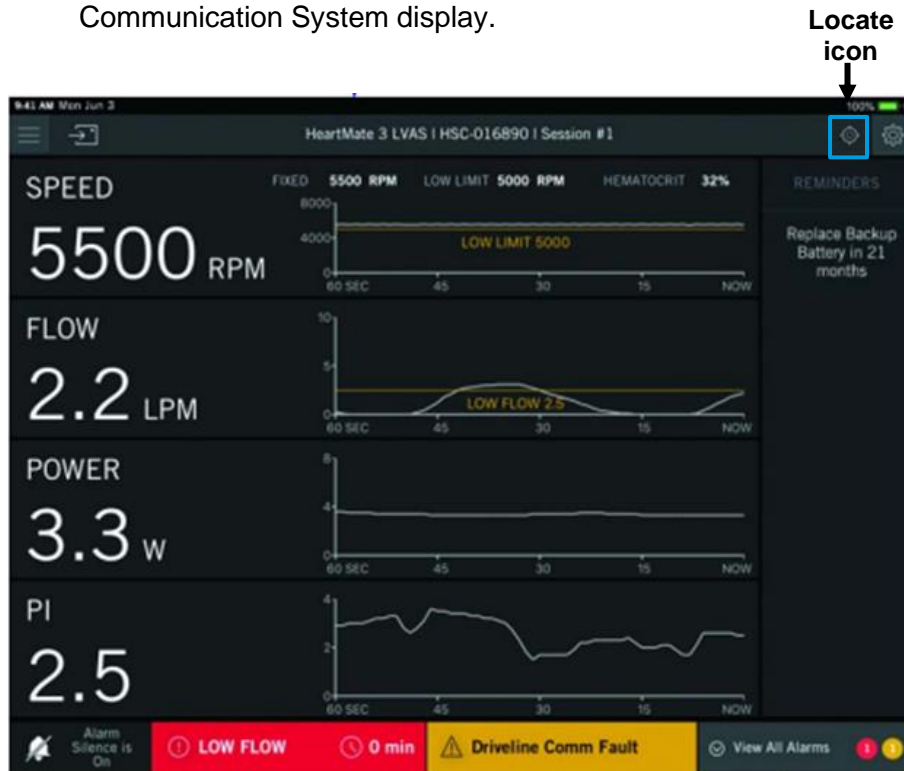


Figure 1: HeartMate Touch Communication System Display

- The HeartMate Touch Wireless Adapter to which the system is connected should blink blue and white. (Pg 4-19)

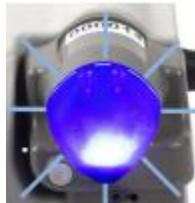


Figure 2: Blinking HeartMate Touch Wireless Adapter

In the event the HeartMate Touch is connected to an unintended LVAS, follow the existing Instructions For Use to disconnect the HeartMate Touch App from the HeartMate Touch Wireless Adapter (Pg 4-17) by:

- Tap Menu -> Disconnect HeartMate Device. A confirmation message appears asking you to confirm.

- Tap Yes to disconnect the HeartMate Touch App from the HeartMate Touch Wireless Adapter.



- Make sure to disconnect the HeartMate Touch Wireless Adapter from the Power Module before proceeding with re-establishing a connection per the Instructions For Use.

If connection to an unintended LVAS occurs, please report the event to Abbott Technical Support: 1-800-456-1477.

Abbott has notified applicable regulatory agencies about this issue. Please share this notification with others in your organization as appropriate.

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. To submit your report:

- Complete the voluntary Form FDA 3500 online
- Download form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

We sincerely apologize for any difficulties or inconvenience that 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. Should you have any questions about this communication, please contact Abbott Technical Support at 1-800-456-1477.

Sincerely,

Elizabeth Boltz
 Divisional Vice President, Quality
 Abbott Heart Failure