



URGENT MEDICAL DEVICE CORRECTION

HEARTMATE TOUCH™ COMMUNICATION SYSTEM

MODEL: HMT1100; HMT1100-R

GTIN: 5415067032058; 5415067033758

October 22, 2021

Dear Physician,

Abbott is writing to notify you that we have received complaints of the HeartMate Touch™ Communication System ('HeartMate Touch') Application ('App') unexpectedly closing or failing to open which will require your facility to have in addition at least one System Monitor II. The HeartMate Touch is part of the HeartMate 3™ and HeartMate II™ LVAS and is used in the medical facility for patient monitoring and system programming. There have been no reports of patient injury associated with these complaints.

Abbott has identified the potential root cause of the issue to be a previously unknown software bug in the HeartMate Touch™ App related to handling of Bluetooth connectivity interference. The HeartMate Touch™ tablet connects to the HeartMate Power Module via a HeartMate Touch™ Bluetooth Adapter. When the HeartMate Touch™ App is trying to establish Bluetooth connection with the HeartMate Touch™ Bluetooth Adapter and another Bluetooth-enabled device is nearby and is advertising for Bluetooth connection, the Bluetooth connectivity interference may cause the HeartMate Touch™ App to unexpectedly close or fail to open. This scenario is limited to the HeartMate Touch App only and does not impact any other Bluetooth-enabled devices. Once the HeartMate Touch™ is connected to the Bluetooth adaptor, barring disconnection, all functionality is unaffected, and the device will continue to operate as expected. This scenario has no impact on preset operations of the blood pump once the blood pump has started running but could delay the initiation of pump support during the implantation procedure, potentially causing harm to a patient including death. Abbott's records indicate that your facility has at least one HeartMate Touch™.

To date, Abbott has received six complaints associated with this issue from four centers. In each case, the center transitioned from the Heartmate Touch™ to the System Monitor II without patient impact. While the rate of Bluetooth connectivity issues is very low, and the risk of patient harm, if the connection is interrupted and the HeartMate Touch™ App is unable to be restarted, is remote, Abbott is communicating this information to you in the interest of patient safety.

Abbott continues to actively investigate the cause of this issue and is committed to developing and providing a resolution, which may include an update to the HeartMate Touch™ App. Abbott will provide the resolution to you as soon as it is available.

Patient Management Recommendations

Until the resolution is provided, Abbott is requesting that your facility retain or obtain the System Monitor II (Model Numbers 1286 and L1286) and ensure it is readily available for use in the event that the HeartMate Touch™ is unable to function properly. Abbott is extending the support and servicing of System Monitors II until this issue is resolved and the resolution is fully implemented in the field. If your facility does not have a System Monitor II, Abbott will provide a loaner System Monitor II at no charge until a corrective action to the HeartMate Touch™ Communication System is provided to your facility. If your facility has not previously used a System Monitor II, Abbott will provide training and implementation support to your facility. Your Abbott representative will work with you to schedule a time that is convenient for you and your staff. This interim solution does not present additional risk to patients and no specific patient intervention is needed.

Please continue to report any observations you encounter with the HeartMate Touch™ Communication System. 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.

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this may cause you and your patients, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction. If you have any questions about this communication or the recommendations, please contact your Abbott representative or Abbott Technical Support at **1-800-456-1477 (U.S.)**. Please share this notice with all those within your organization who might operate the HeartMate Touch. We ask that you maintain a record of this notice to ensure effectiveness of the communication.

Sincerely,

A handwritten signature in black ink that reads 'Elizabeth Boltz'.

Elizabeth Boltz
Divisional Vice President, Quality - Heart Failure