



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 eight (8) reported complaints received in the past 3 years with the HeartMate Touch™ Communication System (also referred to as 'HeartMate Touch') application (App) version 1.0.32 due to unintentional start/stop of the HeartMate 3™ Left Ventricle Assist Device (LVAD). Our records indicate that your institution has one or more HeartMate Touch devices with App version 1.0.32.

Our root cause investigations determined that the unintentional LVAD start/stop in these eight (8) events occurred when the "STOP PUMP" software sequence was initiated on the HeartMate Touch App and communication was lost between the HeartMate Touch System and the patient's HeartMate System Controller as a result of the user disconnecting the white cable of the HeartMate System Controller prior to completion of the "STOP PUMP" software sequence.

Three (3) of the eight events occurred during implant/explant surgery resulting in an occurrence rate of 0.02%. No patient harm has been reported for events occurring during implant/explant surgery; however, potential risks include extended procedure time. The remaining five events occurred during patient clinic/hospital visits resulting in an occurrence rate of 0.003%; unexpected pump stop during a clinic/hospital visit could result in hemodynamic compromise or syncope.

This letter contains important information on how to ensure the "STOP PUMP" sequence is completed prior to disconnecting the HeartMate System Controller or Wireless Adapter from the Power Module equipment. It is safe to continue using the HeartMate Touch device as instructed per Instructions For Use (IFU) and supplemental guidance within this letter.

Impact and Associated Risks

HeartMate Touch is part of the HeartMate 3™ Left Ventricle Assist System (LVAS) and is used in the medical facility for patient monitoring and system programming.

Disconnection of the HeartMate System Controller or Wireless Adapter from the Power Module prior to completion of the "STOP PUMP" sequence will result in a communication interruption between the HeartMate Touch App and the HeartMate System Controller. If communication is interrupted, remaining steps of the "STOP PUMP" sequence stay in the App's queue. Subsequently, when the same or a different HeartMate System Controller connects to that HeartMate Touch App version 1.0.32, the communication resumes, triggering the HeartMate Touch App to initiate the remaining "STOP PUMP" commands. This results in the LVAD starting if it was not running, or in the LVAD stopping if running at the time of connection.

Supplemental Guidance and Recommendations

The software version for the HeartMate Touch App can be confirmed by tapping "Menu" and "About" on the left-hand panel on the HeartMate Touch screen. See Figure 1.

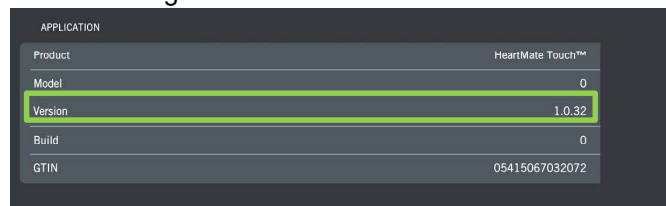


Figure 1: "About" view showing HeartMate Touch Software Version

When the "STOP PUMP" sequence needs to be performed, please follow the instructions in the Instructions For Use (IFU), Chapter 4 HeartMate Touch™ Communication System, Pages 4-58 to 4-59. The user can prevent the unintentional LVAD start/stop from occurring by following the IFU and these additional guidance and recommendations. Note that communication may also be interrupted if the Wireless Adaptor is disconnected from the HeartMate Touch system prior to completion of the "STOP PUMP" sequence.

- Do not disconnect the HeartMate System Controller white cable or the Wireless Adapter from the Power Module until “STOP PUMP” sequence screen with the red progress bar (Figure 2) is no longer visible and the “STOP PUMP” screen changes automatically as shown in Figure 3.



Figure 2: “STOP PUMP” red progress bar display on the black line indicating sequence is IN PROGRESS. Do not disconnect System Controller or Wireless Adapter.



Figure 3: Clinical view after the completion of the “STOP PUMP” sequence.

- During pump priming, do not disconnect the pump until the **timer reaches zero, the pump stops and the “Priming is complete” message appears** as instructed per the IFU¹.

The following scenarios can occur if the “STOP PUMP” sequence is not finished on a HeartMate Touch System:

- After the pump is primed, if the same HeartMate Touch System is then connected to the pump during the implant procedure, the LVAD may unexpectedly start pumping.
- When the user connects the HeartMate Touch App System to the same or a different HeartMate System Controller with a running LVAD, the pump will stop. If the pump stops the HeartMate System controller will alarm “**Pump Off Alarm**”.

Note: To resolve the “**Pump Off Alarm**” clinicians can **press any button on the System Controller to attempt pump start** as instructed in the IFU².

Abbott is in the process of developing and releasing a software update to prevent the sequence of events described above. This product correction will be included in an upcoming release of the HeartMate Touch software. An Abbott Representative will contact you for a software upgrade beginning Q2 2024.

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

Please distribute this notice to those who need to be aware within your institution and complete the attached acknowledgement form. Abbott has notified applicable regulatory agencies about this issue. Should you have any questions about this communication, please contact Abbott Technical Support at 1-800-456-1477

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. We thank you for your partnership.

Sincerely,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

¹ IFU Chapter 5 Surgical Procedure, Page 5-29

² IFU Chapter 7 Alarms, Page 7-10