

FIELD SAFETY NOTICE

HeartMate 3™ Left Ventricular Assist System Catalog # 106524INT – LVAS KIT, HM 3

June 7, 2017

Dear Customer,

To ensure the safety of our patients, Abbott would like to make you aware of limited reports of errors in communication between the System Controller and pump of the HeartMate 3 Left Ventricular Assist System (LVAS). To date, there have been no patient effects related to this situation; however, there are frequent advisory alarms that need to be silenced.

We have identified the potential for a communication error between the patient's System Controller and the LVAS pump which triggers a communication fault advisory alarm on the System Controller. We have traced the issue to manufacturing variances from a single supplier that could lead to crystallization formation, which may then disrupt communication between the pump and the System Controller. Abbott has updated the specifications and manufacturing processes to ensure this issue does not occur in future lots of manufactured HeartMate 3 devices.

Importantly, the HeartMate 3 LVAS has a redundant communication line so a complete loss of communication between the System Controller and pump will only occur if *both* communication lines are affected. The HeartMate 3 LVAS has an on-board diagnostic system that monitors for these conditions several times per second. In this rare situation, the LVAS pump *will continue to operate as programmed* after the point communication is lost. Communication between the System Controller and pump, including the interface to make pump operating changes, is no longer feasible.

Estimation of Rate of Communication Errors

There have been a total of eleven (11) reports (1.29% incidence rate) of communication line faults of 850 HeartMate 3 devices subject to this advisory that have been implanted in commercial and clinical settings.

Of the 11 reports there have been:

- Eight (8) reports with a single communication line fault (*Driveline* COM Fault advisory alarm). In these instances communication between the System Controller and pump was still available.
- Two (2) reports with intermittent failures of both communication lines (COM Fault advisory alarm)
- One (1) report of failure in which both communication lines appear to be permanently affected.

In the best interest of patients, Abbott has retrieved impacted inventory from hospital shelves and replaced with HeartMate 3 devices not impacted by this field advisory.

Patient Management

Below is additional information for physicians managing patients implanted with HeartMate 3 devices subject to this field advisory:

- The loss of a *single* communication line (*Driveline* COM Fault), accompanied by an advisory alarm:
 - The *Driveline* COM Fault advisory alarm can be manually silenced on the System Controller for four (4) hours with one (1) functioning communication line or permanently silenced (at the discretion of the patient's physician) via the System Monitor (assuming the alarm persists).
- The loss of *both* communication lines (COM Fault), noted by the presence of the COM Fault advisory alarm:
 - The COM Fault advisory alarm can be manually silenced on the System Controller for four (4) hours or via the System Monitor for twenty-four (24) hours. The COM Fault advisory alarm will display even if the *Driveline* COM Fault advisory alarm has been permanently silenced.

Patients should be reminded to contact their VAD Coordinator in the event an advisory alarm appears on their System Controller.

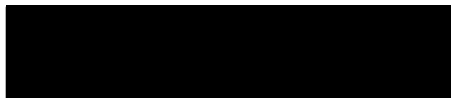
Physicians managing patients subject to an Advisory COM Fault alarm should determine patient care recommendations based on each unique clinical case.

Should you have questions regarding this notice, please contact Abbott Technical Services at +46-8474-4147, which is available 24 hours a day, 7 days a week. Alternatively, your Abbott Sales Representative is available to answer any questions you may have.

We apologize for any difficulties this may cause you and your patients. Abbott is committed to providing the highest quality products and support.

Thank you for your continued support.

Sincerely,



Susan Jezior Slane
Divisional Vice President, Quality Assurance and Compliance
Abbott Cardiovascular and Neuromodulation

CC: Chairman Medical Board and relevant Head of Department