

**Abbott*****IMPORTANT MEDICAL DEVICE ADVISORY***

HeartMate 3™ Modular Cables
(Catalog #106525INT and 106525)

HeartMate 3™ Left Ventricular Assist System
(LVAS) Kit (Catalog #106524INT and 106524)

December 02, 2019

Dear Clinician,

Abbott is informing physicians and VAD coordinators that we have received reports of the HeartMate 3™ modular cable being incorrectly inserted into the controller by patients during controller exchange. As you know, exchanges are required to be performed by medical professionals in the hospital setting (per the Instructions for Use); however, patients and their caregivers may need to conduct the exchange in an emergency situation and are therefore trained on the procedure. If the modular cable is incorrectly inserted at 180 degrees from the proper orientation, there is potential for erroneous electrical contact to be made, which may cause a blown fuse, confusion for the patient, and the controller to alarm with “Controller Fault.” In this case, although a physical connection appears to have been made, there is no electrical connection to power the pump.

There is currently a one percent (1%) worldwide complaint rate associated with reports of the modular cable being inserted 180 degrees from the proper orientation. The incorrect connection, as a result of patient exchanges outside of the hospital setting, may result in serious injury or death. To date, the rate of reported death is 0.05% and the rate of reported hemodynamic compromise is 0.07% associated with this issue.

Patient Management Recommendations

In the event of a “Controller Fault” alarm:

- As with any system controller exchange away from the hospital, the patient must have a caregiver present and all labeling instructions must be followed, including calling the hospital contact.
- The patient should make an exchange to their backup controller paying specific attention to the markings on the controller and driveline.

The following instructions should be reinforced for all HeartMate 3™ patients during their next clinic visit:

- A review of the HeartMate 3™ Patient Handbook, which instructs patients to contact the hospital if the System Controller alarms and displays “Call hospital contact,” and reinforce that System Controller exchanges are recommended to be performed in the hospital.

- If a system controller exchange must be done outside the hospital, ensure that the patient understands the need for having a caregiver present during System Controller exchange and that all labeling instructions are followed, including calling the hospital contact.
- Train patients on the process for exchanging controllers including the proper alignment and insertion of the modular cable, as outlined in the Clinic Visit Safety Checklist in the HeartMate 3™ Instructions for Use (IfU).

Abbott field personnel will be performing re-training of all sites on the proper method of connecting the controller cable according to the Instructions for Use.

Abbott remains committed to patient safety and providing the highest quality products and services. If you have questions regarding this notice, please contact your local Abbott MCS Clinical Specialist or the emergency MCS Hotline +32 22006645, which is available 24 hours a day, 7 days a week.

Thank you for your continued support.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lance Mattoon', with a long horizontal line extending to the right.

Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure