



URGENT MEDICAL DEVICE RECALL

CardioMEMS™ Hospital and Patient Electronics Systems

June 14, 2018

Dear Hospital Administrator,

Abbott is advising customers that a small number of CardioMEMS™ Hospital Electronics Systems (Model CM3000) and Patient Electronics Systems (Model CM1100) may deliver a system error, known as Error 5. While this error message is intended to present if the electronics system exceeds a certain temperature, these units may deliver a false Error 5 message due to an incorrectly configured component within the device electronics.

Hospital Electronics System Impact and Associated Risks

It is safe to continue using your Hospital Electronics System until you have received a replacement System. Based on complaint information received to date, an estimated 1.3% of interrogations performed with hospital units affected by this issue will result in an Error 5 message. While there has been no patient harm reported in association with this error, if this message appears, the system cannot be used to calibrate the CardioMEMS™ Sensor or take pulmonary arterial (PA) pressure measurements until the issue is resolved through standard troubleshooting methods or the CardioMEMS Hospital Electronics System is replaced. Therefore, there is the potential for delay of procedure, or the need for an additional right heart catheterization in the event the error cannot be cleared.

Patient Electronics System Impact and Associated Risks

An estimated 0.10% of interrogations performed with patient units affected by this issue will result in an Error 5 message. There has been no patient injury or harm reported in association with this issue. If this message appears, the system is unable to take pulmonary arterial (PA) pressure measurements until the issue is resolved through standard troubleshooting methods or the CardioMEMS™ Patient Electronics System is replaced. During this time, traditional heart failure management (standard of care) should be used to guide treatment.

Action Requested

Continued use of the CardioMEMS™ Electronics Systems is considered safe. To avoid any potential disruptions resulting from this issue, Abbott is contacting physicians and patients in the coming weeks with additional details and instructions to facilitate the return and replacement of affected units. Missed transmissions should be carefully monitored to ensure that they are not related to the Error 5 message and any missed transmissions due to Error 5 should be reported to the Abbott Remote Care Technical Support team. In the meantime, Abbott recommends that you complete the following steps:

- Please complete and submit the attached Acknowledgement & Contact Form which will enable Abbott to more efficiently contact your facility regarding the return and replacement

of affected units. For units no longer at your facility, Abbott will contact associated clinics to ensure patients with affected units are informed.

- If an Error 5 message occurs, please contact Abbott Remote Care Technical Support at **1-844-MYCMEMS (692-6367) (U.S.)** for troubleshooting assistance. The Remote Care Technical Support team may be able to guide the user through steps that will remotely clear the error and reboot the unit. Please note, this process may take up to 45 minutes and unit connectivity is required for this troubleshooting process to be completed.

Adverse events 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. Additionally, please contact Abbott if you experience quality issues or adverse events related to the use of this product and/or therapy.

If you have any questions about this communication, please contact your Abbott representative or Abbott Remote Care Technical Support at **1-844-MYCMEMS (692-6367) (U.S.)**. Additional materials, can be found on www.sjm.com/notices.

Sincerely,



Melissa Owsley
Divisional Vice President, Quality
Abbott Cardiac Arrhythmia & Heart Failure

Enclosure:

- Acknowledgement & Contact Form