



## **IMPORTANT MEDICAL DEVICE ADVISORY**

### **CardioMEMS™ Hospital and Patient Electronics Systems**

June 14, 2018

Dear CardioMEMS™ Physician,

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 contact patients who may have an affected unit. You may use the enclosed Patient Letter for your CardioMEMS™ patients who may have an affected unit. A list of affected units by Serial Number is attached.
- If an Error 5 message occurs, please contact your Abbott representative for troubleshooting assistance. The Abbott representative 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.

The appropriate Regulatory Agencies have been informed about this action. 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. Additional materials, can be found on [www.sjm.com/notices](http://www.sjm.com/notices).

Sincerely,



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

Enclosures:

- List of Affected Electronics Systems by Serial Number
- Patient Letter