



## URGENT MEDICAL DEVICE RECALL CardioMEMS™ Patient Electronics Systems

June 15, 2018

Dear CardioMEMS™ Patient,

Abbott is contacting you to let you know that your CardioMEMS™ Patient Electronics System (Model CM1100), the external device that connects to your implanted sensor, may experience an error when attempting to communicate with your CardioMEMS™ implant. This error, known as Error 5 would appear on your unit's screen if it occurs.

**It is important to note that this error does not impact your implanted sensor, and has no reported impact to your safety.**

Although the chance of your unit having an Error 5 is low (about 1 in 1000), Abbott intends to replace your CardioMEMS™ Patient Electronics System as soon as possible.

It is safe to continue using your Patient Electronics System until you have received a replacement System. This letter contains further information below about the error, and you may also contact Abbott Remote Care Technical Support at **1-844-MYCMEMS (692-6367) (U.S.)** to talk to an operator who will lead you through this information and answer any questions you may have.

### Action Requested

**Your continued use of the CardioMEMS™ Patient Electronics System is considered safe.** To avoid any interruption due to Error 5, your unit will be replaced. Abbott will contact you in the coming weeks with additional details and instructions to facilitate the return of the affected unit in your possession. In the meantime, Abbott requests that you complete the following steps:

- **Call the number below or fill out and return the attached form** to acknowledge you have received this notification and to provide your current contact information. This will enable Abbott to more efficiently contact you about your replacement unit.
- If an Error 5 message occurs for your unit, please contact Abbott Remote Care Technical Support at **1-844-MYCMEMS (692-6367) (U.S.)** who can provide immediate assistance which may include steps to clear the Error message and restart your unit. Additionally, you should contact your physician to inform them that your unit is not taking pressure measurement readings as expected.

### More Info on Error 5

Error 5 is an error message that is expected to display on the screen when the electronics system heats up above a certain temperature. However, your affected CardioMEMS™ Patient Electronics Systems may deliver an Error 5 message mistakenly because of a faulty component within the device electronics. There has been no patient harm reported due to this issue, and Abbott is

working to replace all affected CardioMEMS™ Patient Electronics Systems (Model CM1100) as quickly as possible.

Based on current information, about 0.10% of communications performed with affected units will result in a false Error 5 message. If the Error 5 message appears on your unit's LCD screen, the system will not be able to take pulmonary arterial (PA) pressure measurement readings until the issue is resolved or the CardioMEMS™ Patient Electronics System is replaced. During this time, please contact your physician to determine if any changes to your treatment are necessary until receiving your replacement unit.

If you have any questions or are experiencing any symptoms, please contact your physician. 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 or your 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](http://www.sjm.com/notices).

Sincerely,



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

Enclosure: Acknowledgement & Contact Form