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URGENT PRODUCT DEFECT CORRECTION

CardioMEMS™ PA Sensor and Delivery System
(Model CM2000) ARTG # 236015

CardioMEMS™ Hospital System
(Model CM3000) ARTG # 236016

TGA Reference: RC-2023-RN-00121-1

February 2023

Dear Physician or Healthcare Professional,

Abbott is notifying clinicians of an product defect correction with the CardioMEMS™ HF System. No increase in patient harm or adverse events has been reported as a result of this issue, and it is safe to continue using these devices.

Select CardioMEMS™ PA Sensors (Model CM2000) Operate Outside of the Intended Frequency Range at Higher Elevations

The CardioMEMS HF System is intended to operate at frequencies between 30 and 37.5 MHz. Abbott has found that a small number (less than 1%) of implanted CardioMEMS PA sensors (Model CM2000) have operated outside of this intended radiofrequency range at least once over the life of the implant when interrogated by CardioMEMS Patient or Hospital Systems (Models CM1100, and CM3000). Operating frequency may be affected by atmospheric conditions, elevation, pulmonary artery (PA) pressure, and unique sensor and patient characteristics.

Impact and Associated Risks

When readings are taken over ~2,000 feet (610 meters) above sea level, operation outside of the intended radiofrequency range has the potential to result in inaccurate readings or sensor signal acquisition difficulties. Abbott evaluated all complaint data since commercial launch and conducted analyses related to sensors operating outside of the intended frequency range and concluded:

- There has been one reported complaint potentially related to this issue which resulted in an additional procedure (recalibration). The overall rate of recalibrations has not increased.
- There have been no incidents of incorrect patient management decisions or other harms as a result of sensors operating outside of the intended frequency range reported to Abbott.
- There has been no increase in reported sensor signal acquisition issues.
- Sensors operating above 37.5 MHz have an increased rate of inaccuracy complaints and readings identified as suspect.
- Not all sensors interrogated at these elevations will operate outside the intended radiofrequency range.

Based on complaint information, there has been no confirmed safety impact attributable to sensors operating outside of the intended radiofrequency range. While an increase in measurement inaccuracy is possible when taking readings at elevations ~2,000 feet above sea level or higher, testing has demonstrated that when readings are taken under consistent conditions (elevation, atmospheric, etc.), readings are stable and repeatable within 3.3 mmHg.

How to Recognize Sensors at Risk

Model CM3000 Hospital Electronics Systems with software version I2.2018.1105-r8829 currently evaluate the PA sensor's estimated operating frequency after its calibration code and serial number are entered. If a sensor is likely to operate outside of the intended frequency range, the systems will display an "Error #8" message. CM3000 Hospital

Electronics Systems with older software do not include the Error #8 message and will be updated as part of this device correction.

Note:

- Sensor data should be entered, and the clinician should proceed to the next screen to complete the Error #8 screening, **prior to venipuncture.**
- If your CM3000 Hospital Electronics System does not have software version I2.2018.1105-r8829, it is safe to continue use until it is upgraded.

User Action Requested

Continued use of all CardioMEMS HF System Models is safe. The current process for calibration and taking pulmonary artery pressure readings remains safe and effective.

Abbott is providing the following guidance for all users:

- **Prior to the implantation procedure, sensor data should be entered, and the clinician should proceed to the next screen to complete the Error #8 screening, prior to venipuncture.**
- **If an Error #8 message occurs, the sensor should not be implanted. Select another sensor for implant** and refer to detailed instructions for preparing sensors prior to implant and responding to an Error #8 message in **Appendix A**.
- Work with your Abbott Sales Representative to exchange the affected sensor.
- **Review Appendix B** for labeling and supplemental information related to implantation and monitoring of CardioMEMS PA Sensors.

Abbott Action

CM3000 Hospital System software updates are targeted for the first half of 2023. When the Hospital System software update is available, an Abbott representative will contact you to schedule software updates for devices that do not have Error 8 software installed. A list of your impacted CM3000 devices is included in **Appendix C**.

In addition, Abbott is updating the CardioMEMS HF System Instructions for Use. Updated Instructions for Use will be available beginning mid-2023 based on geography and will be posted on the Abbott CardioMEMS™ HF System website under Manuals & Technical Resources. CardioMEMS HF System Manuals & Technical Resources | Abbott (https://www.cardiovascular.abbott/int/en/home.html)

Abbott is initiating this action after consultation with the Australia Therapeutic Goods Administration (TGA). Please share this notification with others in your organization, as appropriate.

Adverse reactions or quality problems experienced may be reported directly to Abbott. Should you have any questions about this notice, please contact your Abbott representative.

We sincerely apologize for any difficulties or inconvenience that this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process.

Sincerely,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

Enclosures:

- Appendices