VOLUNTARY MEDICAL DEVICE RECALL
URGENT

CardioMEMS™ PA Sensor and Delivery System (Model CM2000)
CardioMEMS™ Hospital System (Model CM3000)

February 2023

Dear Physician or Healthcare Professional,

Abbott is notifying clinicians of an issue with the CardioMEMS™ HF System. No increase in patient harm or adverse events have 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 evaluates 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

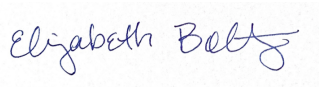
CM3000 Hospital System software updates are targeted to begin in Spring 2023. When the Hospital System software update is available, an Abbott representative will contact you to schedule software updates for devices that do not have Error 8 software installed. A list of your impacted CM3000 devices is 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 has notified applicable regulatory agencies about these issues. Please share this notification with others in your organization, as appropriate. Should you have any questions about this notice, please contact your Abbott representative or Remote Care Technical Support at 1-844-MYCMEMS (692-6367).

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:

- Acknowledgment Form
- Appendices

APPENDIX A: CARDIOMEMS™ PA SENSOR SETUP AND RESPONSE TO ERROR #8 MESSAGES

Please retain the following **important** information with the CardioMEMS™ Hospital Systems (Model CM3000).

Abbott recommends healthcare facilities ensure all personnel who are preparing the CardioMEMS PA Monitoring Sensor (Model CM2000) for implant are trained to these instructions, which supplement the Instructions for Use.

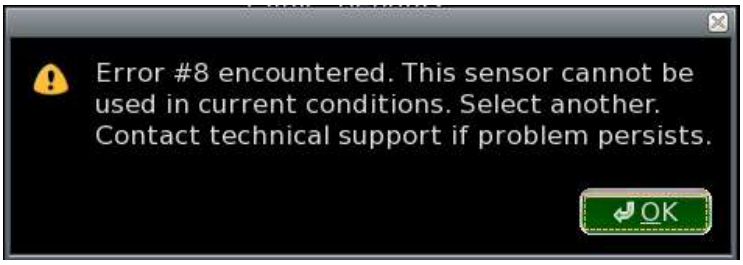
OVERVIEW

CardioMEMS™ Hospital Electronics System Model CM3000 with software version I2.2018.1105-r8829 includes an important software feature to identify CardioMEMS PA Sensors that are likely to operate above the intended radiofrequency range (between 30 and 37.5 MHz) as a result of internal sensor characteristics and current atmospheric conditions **pre-implant**. This software feature and the appropriate setup process is described below.

It is important to enter the data for CardioMEMS™ PA Sensors into the Hospital System prior to venipuncture during a sensor implant procedure**.**

PROCESS FOR CARDIOMEMS HOSPITAL ELECTRONICS SYSTEM MODEL CM3000 (software version I2.2018.1105-r8829)

- Initiate a new implant session.
- Sensor and patient setup must be done on the Hospital System **prior to venipuncture and right heart catherization** during a sensor implant procedure.
  - Setup consists of selecting the patient or entering patient name and Date of Birth, entering the Sensor Serial Number and calibration code and selecting “OK.”
  - A screen will display, asking “Is this information correct”? If yes is selected, the software process to evaluate the sensor is executed.
- If the sensor is not compatible with the current environmental conditions (i.e., the sensor may operate outside of the intended frequency range of 30 to 37.5 MHz), Error #8 will be displayed at this time.



- If an Error #8 message occurs, the sensor is not compatible with the environmental pressure conditions and **should not be implanted**. Users must **select and set up another sensor** in order to complete the implant procedure.
- Once the Error #8 message is acknowledged by selecting “OK,” the user is returned to the main system screen.
- Repeat patient and sensor information entry **prior to venipuncture and right heart catheterization**, using the **new sensor** serial number and calibration code
- Proceed to the next screen by selecting “Yes” on the “Is this information correct?” screen. This will restart the process as detailed above.

If assistance is needed with entering a new sensor, please contact Technical Support at **1-844-MYCMEMS (692-6367)**.

APPENDIX B: SUMMARY OF LABELING AND SUPPLEMENTAL INFORMATION RELATED TO CARDIOMEMS™ PA SENSOR OPERATION

SENSOR OPERATION

- The CardioMEMS™ Hospital Electronics System Instructions for Use include the following Guidelines for Management of Hemodynamic Parameters:

  The PA pressure readings should be used in addition to weights, signs and symptoms, laboratory values and other traditional markers of volume in the management of heart failure. It is important to review the trend of PA pressures. As with all other diagnostic information physicians should consider the entire medical history of each patient when initiating or modifying therapies.

- The System Instructions for Use note that "The mean pressure measurement accuracy of the system may be affected by various factors." Additional detail includes:

  - Sensor Instructions for Use:
    - An accurate right heart catheterization is required to set system baseline (mean pressure).
    - Mean pressure measurement error has been observed when the sensor was deployed in a vessel which had an inner diameter of less than 7 mm, and in cases where there was an acute bend in the vessel of >30 degrees at the location of the sensor.
    - Accuracy of the CardioMEMS HF System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. (+2 mmHg/305 meters elevation change).
    - Accuracy of the CardioMEMS™ HF System is affected by a change in body temperature (-1 mm Hg/ΔºC).
    - Signs of mean pressure measurement error include the following: (1) Gradual mean pressure changes without a corresponding proportional change in the pulse pressure (systolic-diastolic pressure) and (2) Negative mean pressures. If either feature is observed, temporarily suspend use of the pressure information for management of the patient and contact Technical Support for further assistance. A right heart catheterization may be needed to recalibrate the Baseline (mean pressure) in order to continue use of the system.

  - Hospital Electronics Systems and Patient Electronics System Instructions for Use
    - Accuracy (under typical environmental conditions): +/- 2 mmHg at baseline and +/-3% of difference between measured pressure and baseline.
    - System Accuracy: +/-4 mmHg over the range of environmental conditions.

  - Hospital Electronics Systems Instructions for Use
    - There are minimum amplitudes for the system to measure physiological signals. Operation of the equipment below the minimum amplitudes may cause inaccurate results.
    - All sensors have a unique calibration. Ensure you enter the correct sensor serial number and calibration code for each patient. Use of the incorrect calibration code information may result in an inaccurate baseline calibration and readings.
    - The serial number on the antenna and on the console must match to ensure accurate measurements.
    - A pulmonary artery or Swan-Ganz™ catheter is used to calibrate the sensor. For an accurate sensor measurement, it is important to set up the pulmonary artery or Swan-Ganz™ catheter properly.

- Signs of mean pressure measurement error include the following: (1) Gradual mean pressure changes without a corresponding proportional change in the pulse pressure (systolic-diastolic pressure) and (2) Negative mean pressures. If either feature is observed, temporarily suspend use of the pressure information for management of the patient and contact Technical Support for further assistance. A right heart catheterization may be needed to recalibrate the Baseline (mean pressure) in order to continue use of the system.

- Abbott is reinforcing existing labeling and providing supplemental information in this Field Notification:
  - Environmental and Operating Conditions:
    - When readings are taken above ~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.
    - Not all sensors interrogated at these elevations will operate outside the intended radiofrequency range.
    - While an increase in measurement inaccuracy is possible at elevations ~2,000 feet above sea level, testing has demonstrated that when readings are taken under consistent conditions (elevation, atmospheric, etc.), readings are stable and repeatable within 3.3 mmHg.
  - Sensor implant procedure:
    - Setup of patient and sensor information in the Hospital System should be done BEFORE venipuncture and right heart catheterization during a sensor implant procedure. Sensor information includes the sensor's calibration code.
  - Reviewing Pulmonary Artery (PA) Pressure Readings:
    - **Pulmonary Artery Pressure Readings** should be used in addition to weights, signs and symptoms, laboratory values and other traditional markers of volume in the management of heart failure. It is important to review the trend of PA pressures. As with all other diagnostic information, physicians should consider the entire medical history of each patient when initiating or modifying therapies.
    - **Pulmonary Artery Pressure (PAP) Changes** should be further reviewed if the pressure changes are significantly different from expected values.
      - Pressure Changes can occur due to multiple reasons, including: elevation changes, large weather changes, and physiologic PA pressure changes (*e.g.,* PA pressure optimization). All contribute to the total pressure change and may cause operation above 37.5 MHz in some sensors.
      - If readings appear inconsistent with prior pressure trends, the health care provider should consider whether the patient is or was at a significantly different elevation than where readings are typically taken.
      - Contact Technical support for unexpected variation in PAP readings at elevations above 2000 feet.
    - Review the current CardioMEMS System Precautions and Warnings for more information on evaluation of PA pressures.
    - When inaccurate readings are suspected, it is important to evaluate all available information prior to making treatment decisions. If inaccurate readings are suspected, you may request additional insight by contacting Technical Support.

Note: Instructions For Use are available to physicians 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)