IMPORTANT MEDICAL DEVICE CORRECTION

CardioMEMS™ PA Sensor and Delivery System (Model CM2000),
CardioMEMS™ Patient Electronics System (Models CM1000, CM1010 and CM1100),
CardioMEMS™ Hospital System (Models CM3000 and CM3100)

February 2023

Dear Physician or Healthcare Professional,

Abbott is notifying clinicians of two issues with the CardioMEMS™ HF System. No increase in patient harm or adverse events have been reported as a result of these issues, 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 CM1000, CM1010, CM1100, CM3000 and CM3100). 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 and all Model CM3100 Hospital Systems 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 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**.

The Error #8 message on the CM3100 Hospital System instructs users to Contact Technical Support, and the message does not instruct the user to select another sensor. The expected course of action is to contact Technical Support before continuing the implant. Technical Support will instruct the user to select another sensor for implant. When the message appears, currently, the user can select OK and continue to the implant procedure; the new software will update the CM3100 Error #8 message to state, “Select another Sensor” and prevent implantation of a high-frequency sensor. This software is under development; all model CM3100 Hospital Systems will be updated once the software is available.

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 (cardiovascular.abbott).

CardioMEMS™ Electronics Systems (Models CM1000, CM1010, CM1100, CM3000) Radiofrequency (RF) Emissions

Abbott has identified that when the CardioMEMS Patient Electronics Systems (Models CM1000, CM1010 and CM1100) and CardioMEMS™ Hospital Electronics Systems (Model CM3000 only) are used to take a reading with the PA sensor, the radiofrequency emissions at certain frequencies are higher than levels listed in the Instructions for Use (IFU).

Impact and Associated Risks

Higher emissions have the potential to cause interference with other medical devices, such as implantable neurostimulators, pacemakers, cardiac defibrillators, continuous glucose monitors, or with biowearable sensors, when in close proximity to an active Hospital or Patient Electronics System (i.e., during readings). Interference with other medical devices

such as neurostimulators, pacemakers, or cardiac defibrillators could cause changes in the operation of those other medical devices, including possible inappropriate alarms, and/or lack or change of therapies. Since the market release of the CardioMEMS HF System in 2014, there have been two complaints reported suggesting the possibility of interference; however, no device interference has been confirmed. **No patient harm or adverse events were reported as a result of these complaints.**

Abbott has performed device testing and evaluations, which demonstrate the continued safety of device emissions. Higher emissions do not impact the ability of the device to accurately read sensor data.

User Action Requested
There is no need to change your patient management practices due to this issue. Please continue to follow CardioMEMS Instructions for Use (IFU). Abbott will notify your patients of the emissions issue; please ensure patient addresses in Merlin.net™ Patient Care Network are up to date. See Enclosure: Patient Letter.

If you suspect a CardioMEMS Electronics System has interfered with another medical device during use, report the event to Abbott Remote Care Technical Support at 1-844-MYCMEMS **(692-6367) (US).**

Abbott Action
Abbott will update emissions information in the CardioMEMS Patient Electronics Systems (Models CM1000, CM1010 and CM1100) and CardioMEMS Hospital Electronics Systems (Model CM3000) Instructions For Use (IFU) beginning in mid-2023 based on geography. IFUs will be available to physicians and patients on the Abbott website under Manuals & Technical Resources. CardioMEMS HF System Manuals & Technical Resources | Abbott (cardiovascular.abbott).

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).

Adverse reactions 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.

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
- Patient Letter

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

Please retain the following **important** information with the CardioMEMS™ Hospital Systems (Models CM3000 and CM3100).

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.

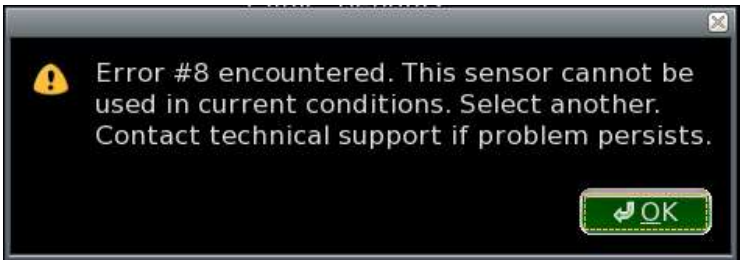
OVERVIEW

CardioMEMS™ Hospital Electronics System Model CM3000 with software version I2.2018.1105-r8829 and Hospital System Model CM3100 include 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)

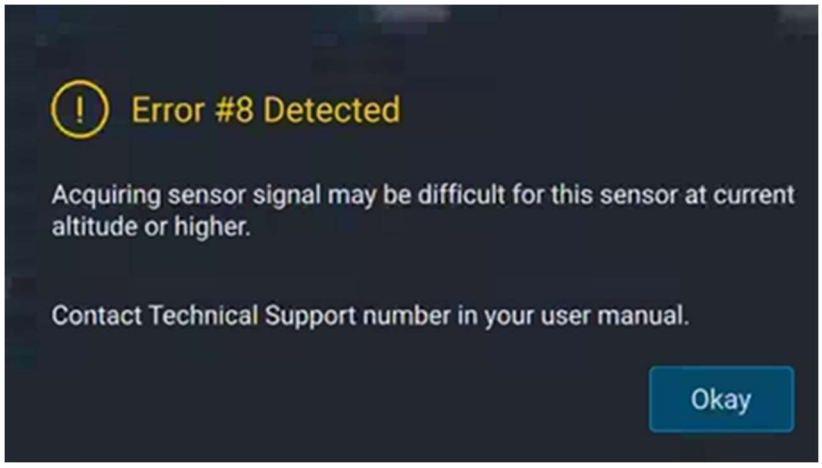
- Initiate a new implant session.
- Sensor and patient setup must be done on the Hospital System **prior to venipuncture and right heart catherization** during a sensor implant procedure.
  - Setup consists of selecting the patient or entering patient name and Date of Birth, entering the Sensor Serial 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.

PROCESS FOR CARDIOMEMS HOSPITAL SYSTEM MODEL CM3100 (software version CM3100.2022.0113)

- Initiate a new implant session.
- Sensors must be set up on the patient information screen **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, relevant physician information and inputting the Sensor Serial Number and calibration code, then selecting “Next.”
  - Once “Next” 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 “Okay,” the implant procedure may continue; however, the sensor may be subject to increased measurement inaccuracy or signal acquisition.
- **Until the software is updated, it is important for Users to select another sensor and return the out of range sensor to Abbott for exchange.**
- **Return to the patient information screen** by pressing “Edit” on the Confirm Patient Information page, clear the current Serial Number and Calibration Code, and **input a new Sensor Serial Number and Calibration Code** in order to complete the implant procedure.

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

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

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 at 1-844-MYCMEMS (692-6367) in the United States.

ELECTROMAGNETIC EMISSIONS

- Hospital Electronics Systems Instructions for Use
    - If two electronic units are proximate to each other and are used at the same time, pressure measurements may be affected due to interference between the two systems. In such isolated cases, it is recommended that operation of each electronics unit occur at separate times.
    - The use of accessories, transducers and cables, other than those specified and sold by the manufacturer of the system as replacement parts for internal components, may result in electromagnetic interference or decreased electromagnetic compatibility of the system. The use of other attachable parts other than the parts provided may result in inaccurate readings, damage to the system, or injury to the user.

Abbott is providing the following additional information for CardioMEMS™ Patient Electronic Systems (Models CM1000, CM1010 and CM1100) and CardioMEMS™ Hospital Systems (Model CM3000 only) to replace references to compliance with CISPR 11 and FCC Part 18 standards:

- The emissions characteristics of this equipment might not offer adequate protection to radio-frequency communication services when taking readings. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Abbott has performed device testing and evaluations to demonstrate continued safety of device emissions. Higher emissions do not impact the ability of the device to accurately read sensor data.

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 (cardiovascular.abbott)