IMPORTANT MEDICAL DEVICE CORRECTION

CardioMEMS™ Patient Electronics System
(Models CM1000, CM1010 and CM1100)

February 2023

Dear CardioMEMS™ HF System User,

This letter is to notify you that Abbott is initiating a voluntary medical device correction for the CardioMEMS Patient Electronics System (Models CM1000, CM1010 and CM1100), the external device that takes readings from your implanted CardioMEMS PA sensor.

WHAT YOU NEED TO KNOW:

Abbott has found that when the System is used to take a reading, the levels of radiofrequency emissions (energy) used to "talk" to your sensor may be higher than what is described in the instruction manual.

A greater level of radiofrequency emissions has the potential to interfere with other medical devices, such as neurostimulators, pacemakers, cardiac defibrillators, or continuous glucose monitors, or with biowearable sensors while you are taking a reading. 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, Abbott has received two reports suggesting possible interference, but no device interference has been confirmed, and **no patients have been harmed**.

WHAT YOU NEED TO DO:

It is safe to continue using your CardioMEMS System, and this issue will not affect your implanted sensor. **If you have not experienced issues with other medical devices when taking your daily reading, there's no need for you to do anything.** Your doctor has been told about this issue. It is unlikely that your CardioMEMS Patient Electronics System will interfere with another medical device, but if you suspect interference may be occurring during a sensor reading or any other quality issues, please report it to:

Abbott Technical Support at 1-844-MYCMEMS **(692-6367) (US);** Monday-Friday: 8am-8pm EST

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Please continue to follow the CardioMEMS Patient Electronics System Instructions for Use and provided supplemental guidance:

- If two [CardioMEMS] 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.
- **Supplemental Guidance**: 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.

  Instructions For Use are available to patients on the Abbott CardioMEMS HF System website under Manuals & Technical Resources. CardioMEMS HF System Manuals & Technical Resources | Abbott (cardiovascular.abbott).

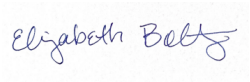
WHAT WE HAVE DONE:
Abbott has performed device testing and evaluations, which demonstrate the continued safety of the device despite these higher emissions. Higher emissions do not impact the ability of the device to accurately read sensor data. Abbott will update the CardioMEMS Patient Electronics Systems Instructions for Use to include the following:

- 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.

Again, it is safe to continue using your CardioMEMS Patient Electronics System. If you have health concerns or experience any symptoms, please contact your physician. If you have any questions about this communication, please contact Abbott Technical Support at the number provided above.

Safety and satisfaction are a top priority for Abbott. We appreciate the privilege to provide high quality products and support to you. Thank you for your understanding; we apologize for any inconvenience this issue may have caused.

Sincerely,



Elizabeth Boltz
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Abbott Heart Failure