VOLUNTARY MEDICAL DEVICE RECALL

CardioMEMS™ Patient Electronics System (Model CM1100)
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.

CardioMEMS™ Electronics Systems (Models CM1100 and CM3000) Radiofrequency (RF) Emissions

Abbott has identified that when the CardioMEMS Patient Electronics Systems (Model 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

Please provide the enclosure Patient Letter to your CardioMEMS patients to notify them of the emissions issue. See Enclosure: Patient Letter. A list of CM1100 devices shipped to your facility is included in **Appendix A.**

There is no need to change your patient management practices due to this issue. Please continue to follow CardioMEMS Instructions for Use (IFU). Review **Appendix B** for labeling and supplemental information.

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)**.

Abbott Action

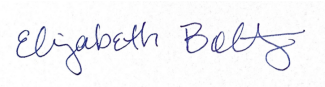
Abbott will update emissions information in the CardioMEMS Patient Electronics Systems (Model CM1100) and CardioMEMS Hospital Electronics Systems (Model CM3000) Instructions For Use (IFU) beginning in mid-2023 based on geography. IFUs will be available to physicians and patients on the Abbott website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

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 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
- Patient Letter

APPENDIX B: SUMMARY OF LABELING AND SUPPLEMENTAL INFORMATION RELATED TO ELECTRONICS SYSTEM EMISSIONS

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 (Model CM1100) and CardioMEMS™ Hospital Systems (Model CM3000) 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 (https://www.cardiovascular.abbott/int/en/home.html)

VOLUNTARY MEDICAL DEVICE RECALL

CardioMEMS™ Patient Electronics System
(Model 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 (Model CM1100), the external device that takes readings from your implanted CardioMEMS Pulmonary Artery (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 physician has been told about this issue. It is unlikely that your CardioMEMS Patient Electronics System will interfere with another medical device. If you suspect interference may be occurring during a sensor reading or any other quality issues, please contact your physician.

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 (https://www.cardiovascular.abbott/int/en/home.html)

WHAT WE HAVE DONE:

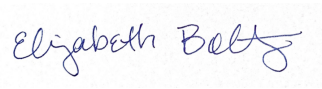
Abbott has performed device testing and evaluations, which demonstrate the continued safety of the device despite these higher emissions. Higher emissions do not impact the ability of the device to accurately read sensor data. Abbott will update the CardioMEMS Patient Electronics Systems Instructions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

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
Divisional Vice President, Quality
Abbott Heart Failure