URGENT FIELD SAFETY NOTICE

CardioMEMS™ Patient Electronics System (Models CM1000 and 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 has been reported as a result of this issue, and it is safe to continue using these devices.

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

Abbott has identified that when the CardioMEMS Patient Electronics Systems (Models CM1000 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

Please provide the enclosed Patient Letter to your CardioMEMS patients to notify them of the emissions issue.

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 A** 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 1-844-692-6367**.**

Abbott Action

Abbott will update emissions information in the CardioMEMS Patient Electronics Systems (Models CM1000 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 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.

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,

Enclosures:

- Acknowledgment Form
- Appendix
- Patient Letter