IMPORTANT MEDICAL DEVICE CORRECTION - UPDATE

CardioMEMS™ Hospital Electronics System (CM3000),
Merlin.net™ Patient Care Network (PCN) Heart Failure Portal (MN6000)

Abbott
387 Technology Circle NW
Suite 500
Atlanta, GA 30313

December 2024

Dear Physician or Healthcare Professional,

Abbott is committed to ensuring that our customers receive the most current information to provide optimal patient care. As previously communicated, we identified an issue after the migration of the Merlin.net PCN HF Portal to the cloud environment on September 30, 2024. During the migration, some CM3000 Hospital Electronics Systems were reverted to an outdated configuration file, which may result in incorrect pulmonary artery (PA) pressure readings. Configuration files are utilized by the Hospital System to interface with the implanted sensor and translate raw sensor data to PA pressures.

Impact, Associated Risk and Abbott Action
Abbott previously communicated that a CM3000 Hospital Electronics System (HES) in your clinic was affected. If the affected HES was used only to take PA Pressure readings, those readings are potentially inaccurate. If the affected HES was used for a sensor implant or recalibration before its software configuration had been corrected, the sensor's baseline code may be imprecise and may lead to incorrect patient management. This may result in additional procedures or a worsening of heart failure symptoms.

This letter (1) confirms that the Hospital System has been returned to its correct software configuration and (2) identifies the sensor(s) that are potentially impacted because a reading(s) was taken, or an implant or calibration was performed with the affected Hospital System before its software configuration was corrected.

User Action Requested
Review the attached appendix to see patient sensors that have been impacted by the affected HES between September 30, 2024, and the HES correction date, and take action as recommended below:

- If the HES was used to take a follow-up pressure reading Abbott recommends ignoring that reading for clinical decision making or patient management. Any PA pressures taken with the HES after correction are accurate and may be used for patient management.
- If the affected HES was used for implant or recalibration, please contact your Abbott representative or Remote Care Technical Support at 1-844-MYCMEMS (692-6367) for additional information and guidance.

Other Information
Abbott has notified the United States Food & Drug Administration (FDA) about these issues. 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.

- Complete and submit the report Online (https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems)
- Regular Mail or Fax: Download form 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

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us as we resolve this issue.
Please share this notification with others in your organization, as appropriate. Should you have any questions about this notice, contact your Abbott representative or Remote Care Technical Support at 1- 844-MYCMEMS (692-6367) on Monday through Friday from 5AM PST to 5PM PST.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality Abbott Heart Failure
Enclosure
Appendix with Impacted Patients
Acknowledgement