URGENT: MEDICAL DEVICE CORRECTION UPDATE

CardioMEMS™ Patient Electronics System (CM1100),
Merlin.net™ Patient Care Network (PCN) HF Portal (MN6000)

Abbott
387 Technology Circle NW
Suite 500
Atlanta, GA 30313

November 2024

Dear Physician or Healthcare Professional,

This is a follow-up from a previous customer notification from October 2024, which is enclosed with this letter. The notification was about an issue identified from complaints after migration of the Merlin.net PCN HF Portal (MN6000) data to the cloud environment on September 30, 2024. During the migration, 3.9% of CardioMEMS™ Patient Electronics Systems (PES) CM1100 were reverted to an outdated configuration file in the cloud database that may have resulted in incorrect pulmonary artery (PA) pressure readings. Configuration files are utilized by the PES to interface with the implanted CardioMEMS™ PA Sensor and translate raw sensor data to PA pressures.

Impact and Associated Risk

For certain patients, the potential impact is not having accurate readings, and physicians may observe suspect pressure changes starting with the first reading sent after September 30, 2024. Inaccurate PA pressure readings may lead to incorrect patient management. In rare cases this may result in additional procedures or a worsening of heart failure symptoms.

Abbott Action

Abbott is recommending replacement of the affected PES that are resisting correction of their configuration file. On October 15, 2024, Abbott initiated a database correction to return affected PES to their intended configuration files. After continued monitoring, Abbott has identified a subset of units that is resisting correction and is retaining their incorrect configuration file.

New User Action Requested

To facilitate replacement of the PES units that contain configuration files that are unable to be corrected or have not taken a reading and therefore, the unit cannot be corrected, Abbott requests that clinicians take the following actions:

- Review the attached appendix to this letter which includes a complete listing of PES systems to be replaced.
- Notify the affected patients that Abbott will be contacting them about the need to replace their PES. Please ensure that the patients' mailing address is up to date within Merlin.net PCN HF Portal.
    - Patients will receive a letter asking them to call Abbott Technical Support to schedule shipment of a replacement PES.
    - Abbott will pay all postage needed to return their resistant PES.
    - When they receive their replacement PES, patients should call Abbott Technical Support to set up their new PES and arrange for pickup of their resistant PES.
- PA pressures taken between September 30, 2024 and the date their PES is replaced may still not be accurate and Abbott continues to recommend they are not used for patient management.
- Distribute this notice to those who need to be aware within your institution, complete the attached acknowledgment form included with this letter, and return it to Abbott.

Abbott
387 Technology Circle NW
Suite 500
Atlanta, GA 30313

Other Information

Should you have any questions about this notice or the status of the impacted patients, please contact your Abbott representative or Remote Care Technical Support at 1-844-MYCMEMS (692-6367) Monday – Friday, 5AM PST – 5PM PST. Another communication will be provided to you when all affected patients' PES systems associated with your clinic are sending accurate data, and you will be asked to complete an additional acknowledgement form at that time.

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. 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. Abbott is committed to providing the highest quality products and support, and we thank you for your trust as we solve this issue.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

Enclosure

- Appendix with Impacted Patients
- Acknowledgement form
- October 2024 Customer Notification
- Patient Letter