URGENT: MEDICAL DEVICE CORRECTION

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

Abbott
387 Technology Circle NW
Suite 500
Atlanta, GA 30313

October 2024

Dear Physician or Healthcare Professional,

Abbott is sharing additional information regarding an issue identified from complaints after with the CardioMEMS™ HF System migration of the Merlin.net PCN HF Portal (MN6000) data to the cloud environment on September 30, 2024. During the migration, 3.9% of CM1100 Patient Electronics Systems (PES) were reverted to an outdated configuration file in the cloud database that may have resulted in incorrect pulmonary artery (PA) pressure readings.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 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 has initiated a database correction to ensure that intended configuration files are used by the affected PES systems.

User Action Requested
To ensure the impacted PES units, return to transmission of accurate data, Abbott recommends that clinicians take the following actions:

- Review the attached appendix to this letter which includes a complete listing of impacted patients' PES systems.
  - Patients with a date listed have already successfully connected and resumed sending accurate data. This date corresponds to the return of accurate PA pressures being sent by the PES. From this date forward, the data may be used for patient management.
  - Patients without a date listed have not yet resumed sending accurate data. Please encourage these patients to send daily data transmissions (PES readings) to ensure the correction can be initiated.
- PA pressures taken between September 30, 2024 and the listed date on the attachment may still not be accurate even after the database correction 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.

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 to 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.

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.

Sincerely,
Carolyn Tabion
Divisional Vice President, Quality Abbott Heart Failure

Enclosure

- Appendix with -Impacted Patients
- Acknowledge