URGENT MEDICAL DEVICE CORRECTION

CardioMEMS™ Hospital System (CM3100),
CardioMEMS™ Backend Web Application (MN4000)
Merlin.net™ Patient Care Network (PCN) HF Portal (MN6000)

Abbott
387 Technology Circle NW
Suite 500
Atlanta, GA 30313

February 2025

Dear Physician or Healthcare Professional,

The purpose of this letter is to inform you that Abbott is initiating a voluntary field action for the CardioMEMS™ Hospital System (model CM3100) and the Merlin.net database. Abbott has identified two issues based on customer complaints that affect Merlin.net patient profiles. These issues are very specific and only impact a small subset of patient data.

Issue 1: Merlin.net may create duplicate patient profiles after a follow-up session with certain CM3100 units. As of February 10, 2025, there are eight (8) identified duplication events, with each event involving two patients.

Issue 2: Hospital System follow-up session readings may appear in another patient's profile. As of February 10, 2025, there are twenty-six (26) events of this issue, with each event involving two patients.

These issues only occur under a specific set of circumstances, and as of February 10, 2025, your patients are not impacted. You are being contacted because you have a CM3100 system that may potentially trigger one of the issues (see Appendix A).

Potential Patient Impact and Associated Risk

In the event that your CM3100 triggers one of these issues in the future, the potential patient impacts are as follows:

Issue 1: There is distinct impact for each of the two patients involved. For one patient (Patient A), profile data including name, sensor serial number, birth date and/or phone number are overwritten into profile fields for another patient (Patient B). This means that Patient B is no longer visible in Merlin.net and Patient B's sensor is no longer associated with any patient profile. Since Patient B's sensor is no longer associated with a patient profile, any new readings that Patient B takes will not be transmitted to the Merlin.net database, and Patient A's readings may appear in Patient B's profile.

Issue 2: A reading from one patient (Patient A) from a single Hospital System session was transmitted to another patient's profile (Patient B) on Merlin.net. This means that clinicians monitoring Patient A in Merlin.net would not see Patient A's Hospital System reading, and clinicians monitoring Patient B would see an inappropriate Hospital System reading. This issue does not affect readings taken by the at home Patient System.

Due to the specific interactions between the components of the CardioMEMS HF system, the issues described are unlikely to cause adverse events given the narrow data impact. Abbott is communicating this issue because, although unlikely, a lack of awareness may lead to decisions for additional procedures or a worsening of heart failure symptoms.

User Action Requested

Even though your patients are not impacted, the CM3100 units listed in Appendix A have the potential to trigger the issues described above. Abbott is requesting that these systems be proactively powered on to complete a database synchronization and clear the CM3100 for future use.

Please work with your Abbott representative to complete these steps for all potentially affected CM3100 units listed in Appendix A:

1. Power on the CM3100 and ensure it has strong, stable network connectivity.
   Network connectivity strength is indicated by icons at the top right of the CM3100 Hospital System screen. If Wi-Fi or Cellular are disabled, they can be turned on by selecting the Gear icon to access Connection Settings.
2. Once connectivity is achieved, wait for 10 minutes without navigating away from the Main Menu screen.
3. After 10 minutes you may conduct a session or power off the device.

Abbott Action

To address any potentially affected CM3100 units, Abbott is taking the following actions:

- Notifying sites of their potentially affected CM3100 units.
- Working with each site to synchronize the database and clear any potentially affected CM3100 systems for future use.
- Monitoring Merlin.net daily for newly affected patients. If the synchronization process requested above for your CM3100 units triggers patient profile impact, Abbott will notify you with additional information within five (5) business days. Additionally, Abbott will work with you to schedule time to correct the issue in partnership with our Remote Care Technical Services team.

Abbott has notified the United States Food & Drug Administration (FDA) about these issues. Please share this notification with others in your organization as appropriate. Should you have any questions about this notice or any patients in your clinic you believe may be impacted, please contact your Abbott representative or Remote Care Technical Support at 1-844-MYCMEMS (692-6367) Monday – Friday, 5AM PST – 5PM PST.

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. 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,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

Enclosed:

- Appendix A - Potentially impacted CM3100 units
- Acknowledgment form