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, the impacted patients and CM3100 units in your clinic are listed in Appendix A.

Patient Impact and Associated Risk

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

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

To reach a timely resolution related to Issue 1 the following customer action is requested:

- Review the enclosed Appendix A to identify included CM3100 Hospital Systems and affected patients.
- Work with your Abbott representative to make an appointment for an on-site visit to your site.
- Avoid performing follow-up sessions for any impacted patients (Patient A or Patient B) using any CM3100 or CM3000 Hospital System until the site visit that will enable Abbott to correct their patient profiles and the CM3100 units.
- Avoid using CardioMEMS data for patients after the profile duplication date listed in Appendix A until your Abbott representative provides you support you during the on-site visit to restore the patient profile data to accuracy.

To reach a timely resolution related to Issue 2 the following customer action is requested:

- Review the enclosed Appendix A to identify included CM3100 Hospital Systems and affected patients.
- Continue using data for Patient A. The data in Patient A's profile is accurate.
- Disregard the CM3100 session reading(s) displayed with Patient B on the specified CM3100 Session Date. All other data for Patient B is accurate and recommended for use.
- Clear any Notifications in Merlin.net for Patient B that were associated to or triggered by Hospital System readings on the same date.

Abbott Action

To address both the patients and CM3100 units already impacted, as well as those potentially affected, Abbott is taking the following actions:

- Notify the implanting site, treating clinic, and/or consulting clinic of the issues for affected patients and CM3100 units.
- Work with each site to schedule time for a site visit for Issue 1. During this visit the representative will facilitate the resolution of the duplicated profiles and identified CM3100 units in partnership with our Remote Care Technical Services team.
- Identify any additional; patient profile impact, and will notify you with additional information within five (5) business days if this occurs.

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 – Impacted CM3100 Units and Patients
- Acknowledgment Form