



URGENT: MEDICAL DEVICE CORRECTION

CardioMEMS™ Hospital System (CM3100),
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:

The purpose of this letter is to advise you that Abbott is initiating a voluntary field action for some CardioMEMS™ Hospital Systems (model CM3100). On September 30, 2024, the Merlin.net™ PCN HF Portal (MN6000) was migrated to the cloud database and following the migration, some customers reported that their Hospital Systems were unable to transmit to the Merlin.net PCN. As of October 15, 2024, the reported rate for this issue was 6.1%.

Investigation showed that failed transmissions were caused by Hospital Systems attempting to transmit sessions using a Merlin Clinic ID number that came from the on-premise database instead of the new cloud database. This prevented the Merlin.net PCN cloud database from accepting data from these Hospital Systems.

Impact and Associated Risk

For affected Hospital Systems, the impact is an inability to transmit session data for a follow-up reading, new implant, or recalibration to the Merlin.net PCN cloud database. Due to not being able to transmit a session, the clinician may not be able to configure the CardioMEMS™ Patient Electronics System or assess the patient's hemodynamic data on Merlin.net PCN following the implant or recalibration. This could potentially lead to incorrect patient management and, in rare cases, may result in additional procedures or worsening of heart failure symptoms.

Abbott Action

On October 15, 2024, Abbott implemented a software correction to address the issue for Hospital Systems (CM3100) not transmitting sessions to the Merlin.net PCN cloud database. Abbott confirmed that the issue does not impact all CM3100 since some Hospital Systems have been able to transmit sessions.

User Action Requested

Abbott requests that clinicians take the following actions:

- The Impacted CM3100 Hospital System devices at your facility is/are listed in the enclosed Appendix.
 - For a Hospital System marked SESSIONS SENT no further correction is needed.
 - Hospital Systems marked UNSENT SESSIONS should be turned on to send unspent sessions:
 - If your Hospital System has connectivity, it will immediately attempt to send after boot-up. A spinning icon will appear to indicate that transmission is in progress, see Figure 1.

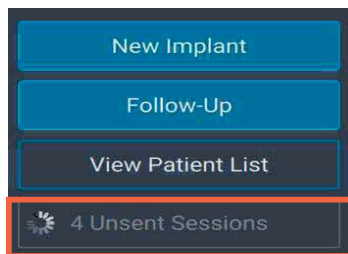


Figure 1- Spinning Icon

- If you see a button on the home screen showing “X Unsent Sessions” select the button and follow the prompts to send, see Figure 2.

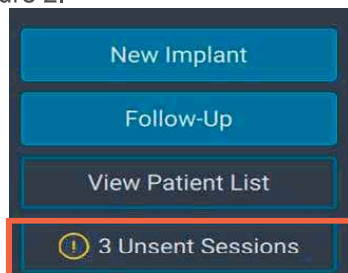


Figure 2-Unsent Sessions



Abbott

- If you are unable to send sessions, contact Abbott Remote Care Technical Support (RCTS) for assistance.
- Distribute this notice to appropriate personnel within your institution.
- Complete the included acknowledgment form and return it to Abbott.

NOTE: Hospital Systems that were not used between September 30, 2024, and October 15, 2024, are **not** impacted.

Other Information

Should you have any questions about this notice or potential patient impact, please contact your Abbott representative or Remote Care Technical Support at 1-844-MYCMEMS (692-6367) Monday – Friday, 5AM PST – 5PM PST.

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 - Impacted Serial Numbers
Acknowledgement Form