URGENT: MEDICAL DEVICE RECALL

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 CardioMEMS™ HF System user,

Thank you for placing your trust in the CardioMEMS HF System. This letter is to notify you of a voluntary recall that affects your CardioMEMS™ Patient Electronics System (model number CM1100). On September 30, 2024, Abbott updated the software database your doctor uses to monitor your pulmonary artery (PA) pressure readings and help manage your heart failure. Following this update your Patient Electronics System (PES) began measuring pressures using an older configuration file, which may cause your PES to send incorrect pressure readings. Configuration files are used by the PES to talk to your implanted CardioMEMS™ PA Sensor and translate raw sensor data to PA pressures.

This issue does not affect your implanted sensor.

Abbott has notified your care team of the issue and has been working with doctors and nurses to make sure incorrect readings are not used to make care decisions.

On October 15, 2024, Abbott released a database correction designed to automatically bring affected PES back to their correct configuration file. Based on careful monitoring, we have found a group of PES that contain configuration files that are unable to be corrected. You are receiving this letter because it's recommended to replace your PES unit.

Impact and Associated Risk

Some patients with incorrect configuration files may receive inaccurate readings, and physicians may see suspect pressure changes starting after September 30, 2024. Inaccurate PA pressure readings may lead to incorrect patient management. In rare cases, this may result in additional procedures or worsening of heart failure symptoms.

Abbott Action

Abbott is recommending replacement of affected PES that contain configuration files that are unable to be corrected.

User Action Requested

In order to replace your PES, Abbott is asking you to do the following:

- Call Abbott Technical Support to arrange shipment of your replacement PES
  - 1-844-MY CMEMS (1-844-692-6367) Hours: 5AM – 5PM PST
  - Abbott will pay all necessary postage.
- Call Abbott Technical Support when your new PES arrives to set it up and to schedule pickup of your old PES.
- Abbott has notified your physician of this issue and is recommending to your physician to not use the PA pressures for patient management taken until your PES units is replaced.

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Other Information

If you have any questions about this letter, please contact Abbott 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 this issue. 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.

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- 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