IMPORTANT MEDICAL DEVICE CORRECTION

CardioMEMS™ Patient Electronics System
(Model CM1100, GTIN 05414734509800)

Abbott

October 2023

Dear Physician or Healthcare Professional,

Abbott is notifying clinicians of an issue with the CardioMEMS Patient Electronics System (PES), specifically those manufactured from December 2017 onward that include the power connector plug housed in the connector cover in the back of the device. Importantly, it is safe for patients to continue using their device when the power connector plug is undamaged and properly connected to the power adapter cable secured to the back of the PES. Examples of power connector plug damage are shown in Figure 1:

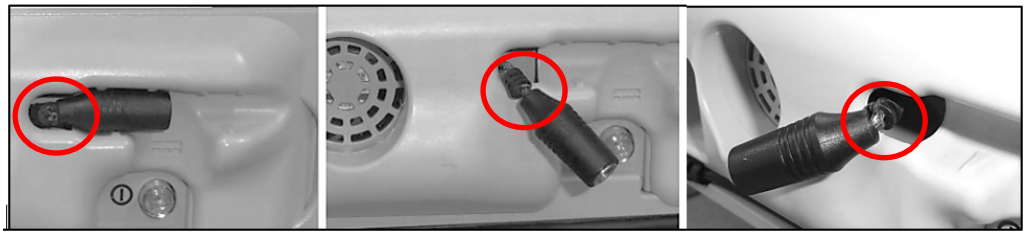

Figure 1: Example of power connector plug damage

Abbott recently observed an increase of reports (complaints) in which the power connector plug became frayed or damaged over time. Damage and fraying of the power connector plug can occur with repeated bending or manipulation beyond 90 degrees. Fraying can rarely result in wires becoming exposed. The current report (complaint) rate has remained very low.

Impact and Associated Risks

If the PES power connector plug becomes frayed and/or has exposed wiring the following may occur:

- PES does not power on. This problem is routinely reported quickly and the PES will be replaced by Abbott Technical Support. Therefore, it is not likely that this will interrupt ongoing hemodynamic-guided heart failure management long enough to result in unanticipated worsening or acute decompensation.
- Power connector plug sparking could cause fire, potentially resulting in burns. The potential for medically reversible or transient adverse health consequence is remote.
- Discomfort from mild shock or sparking resulting from exposed wiring. The potential for medically reversible or transient adverse health consequences is remote.

Should a patient's power connector plug present these issues, a replacement PES will be sent to minimize any interruption in daily readings.

User Action Requested

Please continue to instruct patients to follow the IFU and Supplemental Guidance below:

1. Continue taking readings as your Health Care Professional has recommended.
2. Inspect the Power Connector Plug for damage prior to taking your next reading.
    a. Inspect the power connector plug at the back of the PES for any damage. See examples of frayed or damaged cables/cords as shown in Figure 2.
    b. **If damage is observed do not use the device and contact Abbott Technical support.**

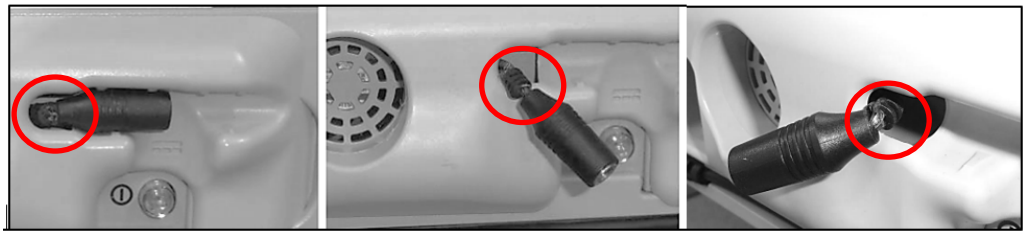

Figure 2 Examples of Damage to the connector plug

    c. After inspecting the power connector plug or when inserting the power adapter cable into the power connector plug, ensure that the connected cables are securely placed within the molded groove of the connector cover. Once the cables are connected and securely placed within the molded grooves, do not remove the cables from the molded grooves during use.
    d. When device is not in use, do not disconnect the power adapter cable from the power connector plug unless required to store the unit in the PES suitcase. The power cable should be disconnected from the wall power outlet when the device is not in use.
3. If you suspect or identify damage to the power connector plug or any other issues, call Abbott Technical Support to report the issue prior to taking a reading:

    1-844-MYCMEMS **(1-844-692-6367)**
    Monday-Friday: 8am-8pm ET

4. After the initial inspection, Abbott requests that each Patient Electronics System power connector plug is inspected monthly for damage per Step 2 above.

Existing Instructions for Use for reference:

IFU Warning:
If any of the following occurs, immediately unplug the electronics unit, and call Technical Support:
- *Any cords are noticeably frayed or damaged.*

Replacing your Patient Electronics System
There may be a time when your Patient Electronics System will need to be exchanged or replaced. Should this occur, Technical Support will assist with the replacement of your system with minimal interruption. During the exchange period, notify your doctor and follow his/her instructions

IFU Steps to connect the Power Adapter Cable with the Power Connector Plug:

[…]

1. *Place the unit where you will lie down to take your reading.*
2. *Remove the power adapter and power cable from the storage pocket in the travel case.*

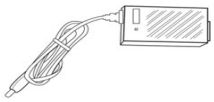

Figure 12. Power Adapter and Power Adapter Cable

Figure 13. Power Cable

3. *Insert the power cable into the power adapter.*
4. *Plug the power adapter cable into the power connector plug so they are connected all the way.* ***Press the connected plugs securely into the molded groove on the back of the electronics unit****.*

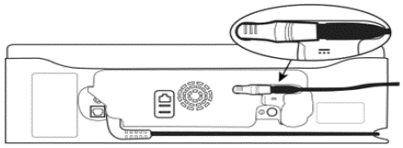

Figure 14. Plug Connections

[…]

If you or your patients learn that a CardioMEMS Patient Electronics System has a damaged power connector plug, report the event to Abbott Technical Support at 1-844-MYCMEMS (692-6367).

Abbott will notify your patients of this issue using the address listed in the Merlin.net™ Patient Care Network; please ensure all patient addresses are up to date. For a copy of the patient communication, see Enclosure: Patient Letter.

Abbott Action

Abbott will update the IFU in the appropriate language by geography to add clarity on how to connect the power adapter cable to the power connector plug. Updated IFUs will be available to patients on the Abbott website under Manuals & Technical Resources: (https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/manuals-and-resources.html). Until these updates are finalized, Abbott is reinforcing the warning in the IFU and providing supplemental guidance. See Enclosure: Patient Letter

Abbott has notified applicable regulatory agencies about this issue. Please share this notification with others in your organization as appropriate. Should you have any questions about this notice, please contact your Abbott representative or Technical Support at 1-844-MYCMEMS (692-6367).

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.

Abbott continues to plan and implement additional solutions for power cable durability.

We sincerely apologize for any difficulties or inconvenience that 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,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

Enclosures:

- Patient Letter