

VOLUNTARY MEDICAL DEVICE RECALL URGENT

CardioMEMS™ Patient Electronics System (CM1100)

October 2023

Dear CardioMEMS™ HF System User,

This letter is to notify you that Abbott is initiating a voluntary medical device recall for the CardioMEMS Patient Electronics System (PES), the external device that takes readings from your implanted PA (Pulmonary Artery) sensor. Your Health Care Professional has been made aware of this issue. **It is safe to continue using your CardioMEMS System to take readings**, and it is unlikely that the issue we highlight in this letter will interrupt your ability to take readings.

WHAT YOU NEED TO KNOW:

Abbott has identified that the power connector plug can be damaged if bent beyond 90 degrees. The power connector plug is attached to the back of the PES and housed within the connector cover. Damage can lead to the PES not powering on, exposed wires which can lead to mild shock, or in rare cases, sparking which can lead to fire in surrounding materials and potential for burns. See **Figure 1** for the overview of the back of the PES and **Figure 2** below for an example of damage on the power connector plug.

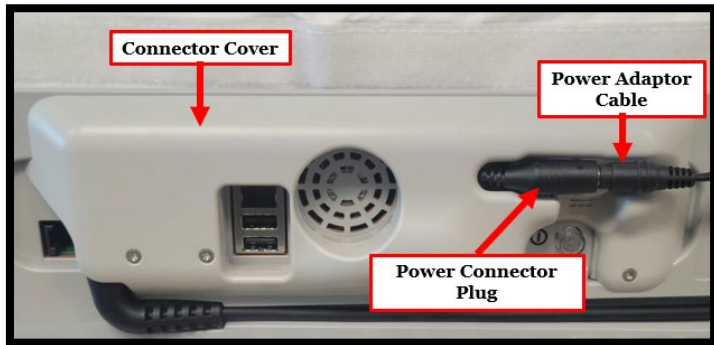


Figure 1: Back of PES

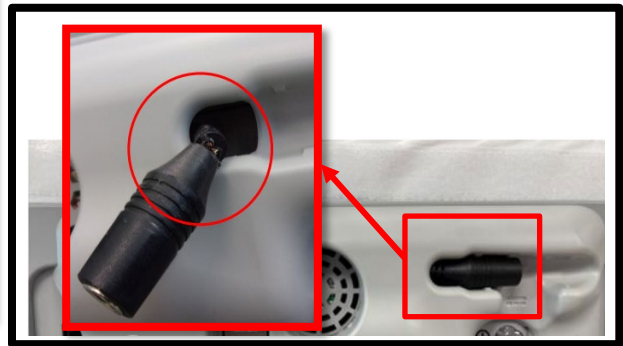


Figure 2: Example of Damage vs Acceptable Plug

WHAT YOU NEED TO DO:

Please continue to follow the Instructions for Use (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 3.
 - b. **If damage is observed do not use the device and contact your physician.**

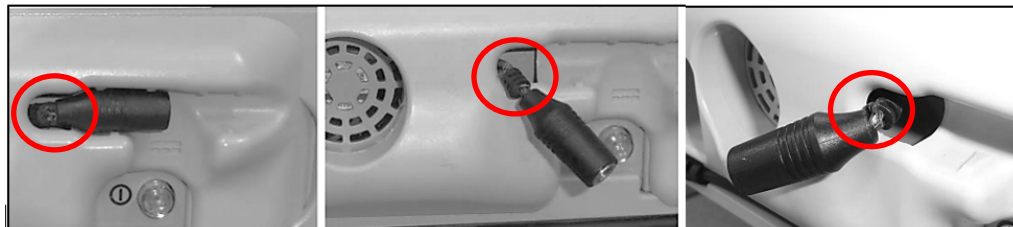


Figure 3 Examples of Damage to the connector plug

- 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 as shown in Figure 1. 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, please contact your physician to report the issue prior to taking a reading.
 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 are provided here for your 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:

[...]

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

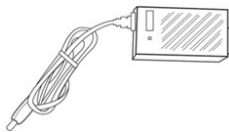


Figure 12. Power Adapter and Power Adapter Cable



Figure 13. Power Cable

4. *Insert the power cable into the power adapter.*
5. *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.***

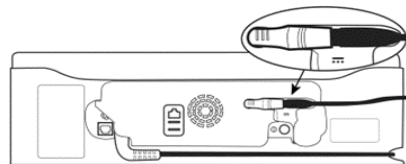


Figure 14. Plug Connections

[...]

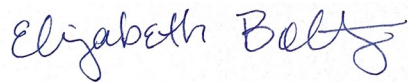
STEPS ABBOTT HAS TAKEN:

- Performed testing that shows your device is safe when the power connector plug is not damaged and instructions for use are followed to ensure the power connector plug and power adapter cable are placed in the connector cover molded grooves.
- Reminded users to follow the IFU and provided supplemental instructions above.

As noted earlier, it is safe to continue using your System when following the IFU and supplemental instructions provided in this letter. If you have any questions about this communication, please contact your physician.

Safety and satisfaction are our top priority. We appreciate the privilege to provide high quality products and support to you. Thank you for your understanding. We apologize for any inconvenience this issue may have caused.

Sincerely,

A handwritten signature in blue ink that reads "Elizabeth Boltz". The signature is written in a cursive style with a large, stylized "B" at the end.

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure