Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 216 **dated** 23/10/2023 **Regarding NCMDR FSCA of CardioMEMS Patient Electronics System from (mfr: Abbott).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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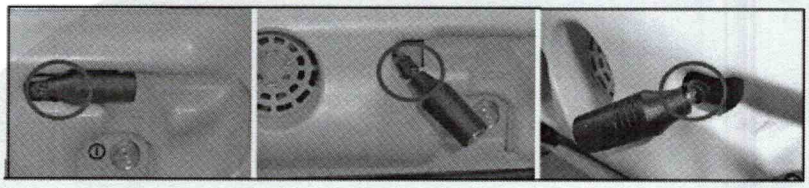
Circular No. 216/ **2023**

08 -04-1445 H

23 -10-2023

Field Safety Corrective Action of CardioMEMS Patient Electronics System from Abbott

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19731
Product	CardioMEMS Patient Electronics System.
Description	Measuring and Monitoring pulmonary artery pressure.
Manufacturer	Abbott.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Model CM1100 Specifically those manufactured from December 2017 onward.
Reason	Potentially the power connector plug housed in the connector cover in the back of the device became frayed or damaged over time.
Action	1. Please continue to instruct patients to follow the IFU and Supplemental Guidance in the attachment. 2. 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/int/en/hcp/products/heartfailure/pulmonary-pressure-monitors/cardiomems/manuals-and-resources.html). 3. Until these updates are finalised, Abbott is reinforcing the warning in the IFU and providing supplemental guidance. 4. Contact the local agent for remedial action.
Product Image	 **Figure 1: Example of power connector plug damage**
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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