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 45 **dated** 01/3/2023 **Regarding NCMDR Field Safety Corrective Action of CardioMEMS PA Sensor and Delivery System/CardioMEMS Hospital 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

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

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

Circular No. 45 / 2023

08-08-1444 H

01-02-2023

FSCA of CardioMEMS PA Sensor and Delivery System/CardioMEMS Hospital System from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18455
Product	CardioMEMS PA Sensor and Delivery System/CardioMEMS Hospital System.
Description	Active implantable medical devices - measuring devices and sensors.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Models CM2000, CM3000.
Reason	When the CardioMEMS Patient Electronics Systems (Models CM1000 and CM1100) and mall number (less than 1%) of implanted CardioMEMS PA sensors (Model CM2000) have operated outside of this intended radiofrequency range at least once over the life of the implant when interrogated by CardioMEMS Patient or Hospital Systems (Models CM1000, CM1010, CM1100, and CM3000).
Action	1. Continued use of all CardioMEMS HF System Models is safe. The current process for calibration and taking pulmonary artery pressure readings remains safe and effective. 2. Abbott is providing the following guidance for all users: -Prior to the implantation procedure, sensor data should be entered, and the clinician should proceed to the next screen to complete the Error #8 screening, prior to venipuncture. -If an Error #8 message occurs, the sensor should not be implanted. Select another sensor for implant and refer to detailed instructions for preparing sensors prior to implant and responding to an Error #8 message in Appendix A in the attached FSN. -Work with your Abbott Sales Representative to exchange the affected sensor. -Review Appendix B in the attached FSN for labeling and supplemental information related to implantation and monitoring of CardioMEMS PA Sensors. CM3000 Hospital System software updates are targeted to begin in Spring 2023. When the Hospital System software update is available, an Abbott representative will contact you to schedule software updates for devices that do not have Error 8 software installed. 3. Contact the local agent for remedial action.
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

Ph. Ahmed Al Harbi

Acting Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

APPENDIX A: SUMMARY OF LABELING AND SUPPLEMENTAL INFORMATION RELATED TO ELECTRONICS SYSTEM EMISSIONS

ELECTROMAGNETIC EMISSIONS

- Hospital Electronics Systems Instructions for Use
    - If two electronic units are proximate to each other and are used at the same time, pressure measurements may be affected due to interference between the two systems. In such isolated cases, it is recommended that operation of each electronics unit occur at separate times.
    - The use of accessories, transducers and cables, other than those specified and sold by the manufacturer of the system as replacement parts for internal components, may result in electromagnetic interference or decreased electromagnetic compatibility of the system. The use of other attachable parts other than the parts provided may result in inaccurate readings, damage to the system, or injury to the user.

Abbott is providing the following additional information for CardioMEMS™ Patient Electronic Systems (Models CM1000, CM1100) and CardioMEMS™ Hospital Systems (Model CM3000) to replace references to compliance with CISPR 11 and FCC Part 18 standards:

- The emissions characteristics of this equipment might not offer adequate protection to radio-frequency communication services when taking readings. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Abbott has performed device testing and evaluations to demonstrate continued safety of device emissions. Higher emissions do not impact the ability of the device to accurately read sensor data.

Note: Instructions For Use are available to physicians on the Abbott CardioMEMS™ HF System website under Manuals & Technical Resources. CardioMEMS HF System Manuals & Technical Resources | Abbott (https://www.cardiovascular.abbott/int/en/home.html)