## 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 187 dated 30/8/23 Regarding NCMDR Field Safety Notice of HeartMate Touch<sup>TM</sup> Communication 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





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سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

Circular No. 187/2023

14 -02-1445 H 30 -08-2023

## Field Safety Notice of HeartMate Touch<sup>TM</sup> Communication System from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19660
Product	HeartMate Touch™ Communication System.
Description	Communication System.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Model HMT1150 GTIN: 5415067032041 App Version 1.0.42
Reason	Potential of the application ('App') with the above version abruptly exiting during the log file(s) export process and users will not be able to export a PDF Log Report, that can be viewed or saved to view offline.
Action	<ol> <li>If the HeartMate Touch App closes unexpectedly during log file export, or the PDF export file is not created, the log files downloaded to the Files Folder can be saved to the Abbott-provided flash drive and sent to Abbott Customer Service for diagnostics purposes.</li> <li>A software update is anticipated to be released in or before early 2024 to resolve this issue.</li> <li>Contact the local agent for remedial action.</li> </ol>
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: <a href="Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

**Director General** 





