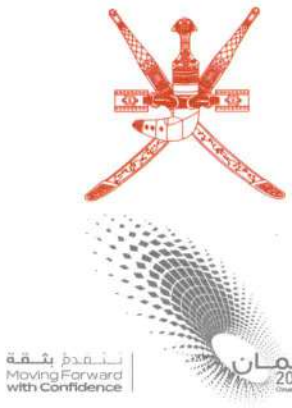
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

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 201 **dated** 24/9/2023 **Regarding NCMDR FSCA of HeartMate Touch™ 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**

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

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
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سلطنة عُمان
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مسقط

Circular No. 201 **/ 2023**

08 -03-1445 H
24 -09-2023

Field Safety Corrective Action of HeartMate Touch™ Communication System from Abbott

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19672
Product	HeartMate Touch™ Communication System.
Description	Active implantable medical devices - programming and control equipment.
Manufacturer	Abbott.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	(Model: HMT1150) GTIN: 5415067032041.
Reason	During a clinic visit, Potential of the HeartMate Touch Communication System in one treatment room to connect to the HeartMate Touch Wireless Adapter plugged into the Power Module in an adjacent treatment room without a user-initiated action or notification to the user. The connection to an unintended LVAS without any user interaction could led to the clinician adjusting settings of another patient without the clinician's awareness. This scenario could be happened when HeartMate Touch System in the adjacent room did not have battery charge and its power cable was not plugged in prior to being used.
Action	1. Please follow the instructions in the attachment for safe use of all HeartMate Touch Communication Systems and HeartMate LVAS. 2. 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

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
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

MEDICAL DEVICE NOTIFICATION

HeartMate Touch™ Communication System
(Model HMT1150)
GTIN: 5415067032041

Heart Failure
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA

August 2023

Dear Valued Customer,

Abbott is notifying affected accounts that we have received complaints of the HeartMate Touch™ Communication System ('HeartMate Touch') Application ('App') with **Version 1.0.42** abruptly exiting during the log file(s) export process. Additionally, when the user accessed the Files App to review the exported files, the controller and pump log files were exported, but the HeartMate Log Report PDF format was not exported. The HeartMate Touch Communication System is part of the HeartMate 3™ and HeartMate II™ Left Ventricular Assist System (LVAS) and is used in medical facilities for patient monitoring and system programming.

There is no impact to patient safety. This issue only affects the export of the PDF version of the Log File Report.

This event is isolated only to HeartMate Touch Model HMT1150, with the App Version 1.0.42 installed.

The investigation concluded that the HeartMate Touch App Version 1.0.42 identifies an error when patient log files contain a record logged on March 26, 2023, from 2 am to 3 am (Daylight Saving Time The error handling for this event results in the App closing unexpectedly during the Log File Export process. The issue only occurs if the log file being exported has one or more events recorded with a time stamp during the one-hour time period from 2 am to 3 am on March 26, 2023. Other software versions of the HeartMate Touch App are unaffected. The HeartMate Touch App Version 1.0.42 does not exhibit this issue when connected to LVAS systems that do not have an event recorded with a time stamp during the one-hour period from 2 am to 3 am on March 26, 2023.

Impact and Associated Risks

When the HeartMate Touch App with Version 1.0.42 is used and the HeartMate Touch system is connected to LVAS systems with events recorded with the time stamp during the one hour time period listed above, users will not be able to export a PDF Log Report that can be viewed or saved to view offline. However, the log file data is still viewable via the Historical View when the HeartMate Touch is connected to the HeartMate Controller. In addition, the log files can still be downloaded to the Files Folder and can be sent to Abbott FCS for diagnostics purposes.

Suggested Action Upon Observance Of Issue

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. Please contact local Abbott Representative.

As noted above, this issue only occurs with certain event time stamps and therefore will not affect all patient logs. If this issue is observed with a specific patient's log, you can contact your local Abbott Representative to discuss options for mitigation of future instances.

Abbott anticipates releasing a software update in or before early 2024 to resolve this issue and is committed to providing the resolution to you as soon as it is available. The observed issue is not expected to occur when Daylight Savings ends and the time returns to Standard Time on October 29, 2023 at 2:00 am.

Please share this notification with others in your organization as appropriate. Should you have any questions about this communication, please contact local Abbott Representative.

Please report any adverse reactions or quality problems experienced with the use of these products to your local Abbott representative.

We sincerely apologize for any difficulties or inconvenience that this may cause you. 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

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure