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 239 **dated** 28/12/2022 **Regarding NCMDR recall of Efficia External Paddles from (mfr: Philips Healthcare).**

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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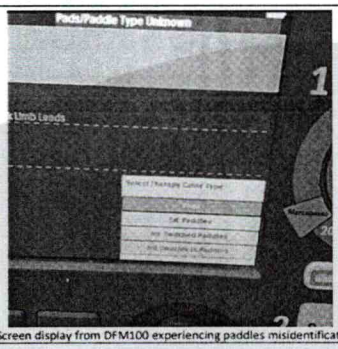
Circular No. 239 / 2022

04 -06-1444 H

28 -12-2022

Recall of Efficia External Paddles from Philips Healthcare

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18391
Product	Efficia External Paddles.
Description	External Paddles.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	All Efficia External Paddles with a date of manufacture prior to August 2022 (8/22).
Reason	The Efficia External Paddles may not be properly identified by an Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator when connected to the device. The device may display an error message reading "Pads/Paddle Type Unknown
Action	1. You can continue to use your Efficia External Paddles if you take the precautions mentioned in the attached FSN. 2. As a reminder, per the HeartStart Intrepid and Efficia DFM100 Instructions for Use, Philips recommends replacing the Efficia External Paddles every three years from the time they were initially placed into service or if they fail inspection. 3. Return all unused affected items. 4. Contact the local agent for remedial action.
Product image	 Figure 1: Screen display from DFM100 experiencing paddles misidentification issue
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
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

URGENT Field Safety Notice

Efficia External Paddles (989803196431)
Not adequately identified when connected to a Philips Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator

10-NOV-2022

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

A problem has been identified in the Philips Efficia External Paddles that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

The Efficia External Paddles are intended to be used with the Efficia DFM100 and HeartStart Intrepid Monitor/Defibrillators – by applying the external paddles to the patient's chest to deliver cardioversion and defibrillation therapy. The external paddles may also be used to obtain an ECG as a quick assessment; however, are not for continuous monitoring.

The Efficia External Paddles may not be properly identified by an Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator when connected to the device. The device may display an error message reading "Pads/Paddle Type Unknown" as shown in Figure 1. When this occurs, it is accompanied by a menu prompting the user to select a therapy cable type, also shown in Figure 1 below. The message cannot be cleared until the user either selects the cable type, disconnects and reconnects the cable, or restarts the device.

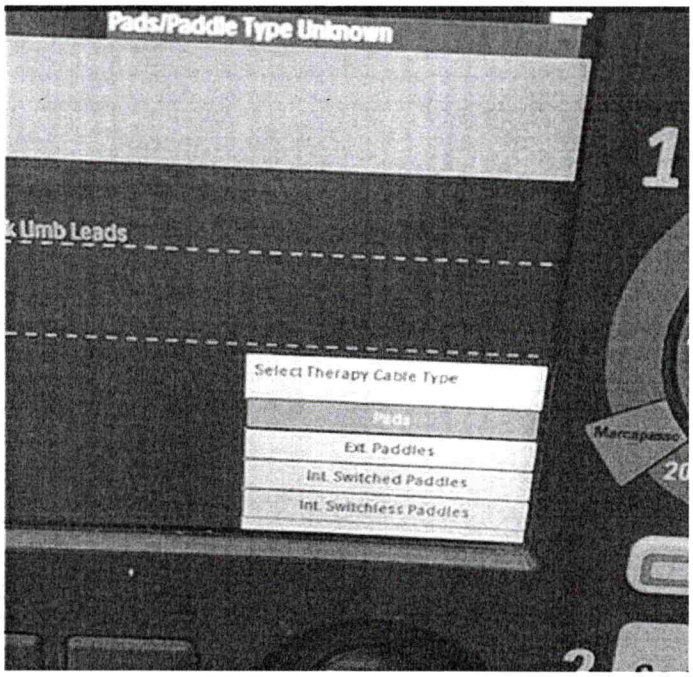


Figure 1: Screen display from DFM100 experiencing paddles misidentification issue.

2. Describe the hazard/harm associated with the issue

If an Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator is needed for clinical use and experiences these device behaviors, then that could result in a delay of therapy being delivered to a patient.

Three adverse events have been reported to Philips, which are related or may be related to this issue.

3. Affected products and how to identify them

All Efficia External Paddles with a date of manufacture prior to August 2022 (8/22), irrespective of the monitor/defibrillator they are used with, are affected by this action.

Philips has provided an example below (in Figure 2) that shows how the date of manufacture can be identified on each Efficia External Paddles set. The arrow points to the month, while the numbers inside the circle indicate the year; this example shows a date of manufacture of August 2020 (8/20):

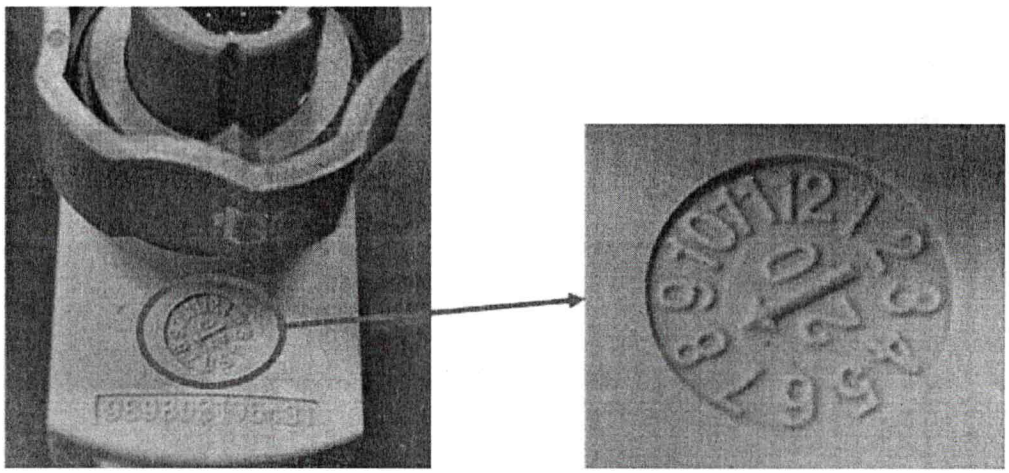


Figure 2: Example of a date of manufacture of August 2020 (8/20)

4. Describe the actions that should be taken by the customer / user to prevent risks for patients or users

You can continue to use your Efficia External Paddles if you take the following precautions:

- If the device displays an error message reading, "Pads/Paddle Type Unknown," accompanied by a menu prompting the user to select a therapy cable type, select the therapy cable type you are using. You can also remove the prompt from the display by disconnecting and reconnecting the cable or restarting the device.
- Follow the monitor/defibrillator Instructions for Use (IFU) and ensure that Operational Checks are performed to the monitor/defibrillator with the Efficia External Paddles connected. These Operational Checks will alert the user immediately upon misidentification and should be done before the device is needed for therapy.
- Continue with the recommended daily and weekly Automated Tests described in the device IFU.
- Complete and return the Urgent Field Safety Notice Response Form included at the end of this letter.

As a reminder to customers, per the HeartStart Intrepid and Efficia DFM100 Instructions for Use, Philips recommends replacing the Efficia External Paddles every three years from the time they were initially placed into service or if they fail inspection.

Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

5. Describe the actions planned by Philips Emergency Care (CN-MF-000003921) to correct the problem

Your Philips representative will contact you to arrange for replacement Efficia External Paddles to be provided, as applicable, at no cost to you.

If you need any further information or support concerning this issue, please contact your local Philips representative: met.quality@philips.com

This notice has been reported to the appropriate Regulatory Agencies, and a response form is needed by Philips from your organization upon your receipt of this notification.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya DeSchmidt
Director of Quality

Tony She
PQMS Quality & Compliance