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

سلطنة عمان
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.179**... dated** 27/09/12 **Regarding NCMDR Field Safety Notice of Sterilizable Switched Internal Defibrillator 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**

ص . ب: ٣٩٣ مسقط ـ الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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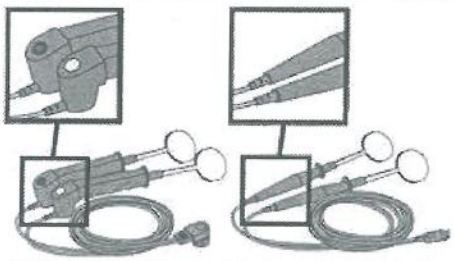
Circular No. 179/ 2020

09 -02-1442 H

27 -09-2020

Field Safety Notice of Sterilizable Switched Internal Defibrillator Paddles from Philips Healthcare.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15361
Product	Sterilizable Switched Internal Defibrillator Paddles.
Description	Rechargeable professional automated external defibrillator.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Philips Sterilizable Internal Defibrillator Paddles . Switched M4741A, M4742A, M4743A, M4744A Switchless M1741A, M1742A, M1743A, M1744A (Instructions for use only) All units manufactured and distributed January 2015 to August 2020.
Reason	The periodic Paddle Checks recommended in the Instructions for Use for Sterilizable Defibrillator Paddles may not detect one failure mode for the above Switched Internal Defibrillator Paddles.
Action	1. Addendum to IFU to add Insulation Resistance Test to Paddle Checks for Sterilizable Switched Internal Defibrillator Paddles (see attached). 2. Contact local agent for remedial action.
Product image	
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 an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 031 09 20 000 **Back**
Date submitted: 9/22/2020

Manufacturer:	Philips Healthcare
Device Type:	Sterilizable Switched Internal Defibrillator Paddles
Description:	Rechargeable professional automated external defibrillator
Medical Device Identifier:	Philips Sterilizable Internal Defibrillator Paddles . Switched M4741A, M4742A, M4743A, M4744A Switchless M1741A, M1742A, M1743A, M1744A (Instructions for use only) All units manufactured and distributed January 2015 to August 2020.
Reason of Field Safety Corrective Action:	The periodic Paddle Checks recommended in the Instructions for Use for Sterilizable Defibrillator Paddles may not detect one failure mode for the above Switched Internal Defibrillator Paddles.
Remedy Action:	Addendum to IFU to add Insulation Resistance Test to Paddle Checks for Sterilizable Switched Internal Defibrillator Paddles (see attached).
Athorized Representative/Importer/Distributor:	Philips Healthcare Saudi Arabia Ltd.
Report Source:	NCMDR
Source Ref. Number:	39FA88776F2A1
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	**Philips Healthcare.pdf**

View History

PHILIPS

URGENT - Medical Device Correction
Philips Sterilizable Defibrillator Paddles

Addendum to IFU to Add Insulation Resistance Test to Paddle Checks for Sterilizable Switched Internal Defibrillator Paddles (M4741A, M4742A, M4743A, M4744A)

ACTION TO BE TAKEN BY CUSTOMER / USER	Insert a copy of the attached Instructions for Use Addendum: *Sterilizable Defibrillator Paddles: Insulation Resistance Check for Switched Internal Paddles* to the Sterilizable Defibrillator Paddles IFU. Follow the Instructions for Use, *Paddles Checks* section. The Paddle Checks activities include: Mechanical Check, Visual Inspection, Functional Check, Continuity Check, and Insulation Resistance Check. Perform these activities to confirm the paddles are safe and ready for use. The Insulation Resistance Test is to be applied only to Switched Internal Paddles (M4741A, M4742A, M4743A, and M4744A). Continue to perform the Paddles Checks activities as recommended in the IFU, before use as this reduces the risk of a failure as the paddles age. If your Internal Paddles fail any of these Paddle Checks, the IFU directs that the paddles should be removed from service and replaced. **To acknowledge receipt of this notification, please complete and fax the Customer Reply Form to:** <Philips representative contact details to be completed by the KM / country>.
ACTIONS PLANNED BY PHILIPS	Philips is providing this Medical Device Correction Notification and IFU Addendum to customers who have received the Instructions for Use for Sterilizable Defibrillator Paddles.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative or call us at <Philips representative contact details to be completed by the KM / country>.