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 184 **dated** 03/10/2022 **Regarding NCMDR Field Safety Corrective Action of X-Ray systems and sub systems, radiography and fluoroscopy system 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**

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

ISO 9001:2015 CERTIFIED

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**

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Circular No. 184 / 2022

07-03-1444 H

03 -10-2022

FSCA of X-Ray systems and sub systems, radiography and fluoroscopy system from Philips Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=17284
Product	DigitalDiagnost 4 High Performance. DigitalDiagnost C90 Flex/Value/Chest/ER. DigitalDiagnost C90 High Performance. DigitalDiagnost 4 Flex / Value. ProxiDiagnost N90.
Description	X-Ray systems and sub systems, radiography and fluoroscopy system.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co. LLC.
The affected products	Model:712031 Model:712035 Model:712034 Model:712032 Model:706100 Model 706110 For Serial Numbers please refer to the attached file.
Reason	An incorrect orientation of image on the first examination due to an issue in the firmware of the Wallstand VS2 board. The system will rotate the amplimat field selection by 90 degrees. The wrong amplimat field selection may cause an incorrect dose of radiation to occur.
Action	1. Philips will schedule an appointment with customers to install the software update. 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

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL