



ببمودة بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Vision

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



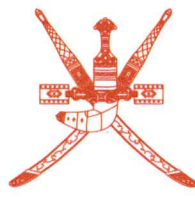
**PADC**  
المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧٨٨٨ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489

dgpa\_dc Email: dg-padc@moh.gov.om



Circular No. 184/2022

07-03-1444 H

03 -10-2022

بمقدار ثقة  
Moving Forward  
with Confidence



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

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=17284">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=17284</a>
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al-Rubai

Director General

