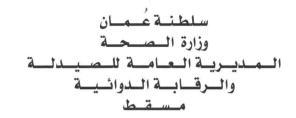
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





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 203 dated 4 11 / 2022 Regarding NCMDR Field Safety Corrective Action of DigitalDiagnost C50 1.1 from (mfr: Philips Healthcare).

Copy to:

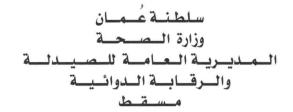
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





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





Circular No. 203/2022

20 -04-1444 H

14 -11-2022



Field Safety Corrective Action of DigitalDiagnost C50 1.1 from Philips Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=17311
Product	DigitalDiagnost C50 1.1.
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 Number 712204 Serial Number: 210182,210187,220002,210049,210051,210097,210052,210053,210055,220020.
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	 Philips will schedule an appointment with customers to install the software update. 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 A Rubaje

Director General





