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 13 dated 29/5/23 Regarding NCMDR Field Safety Notice of MobileDiagnost wDR 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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سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

Circular No. 1/3/2023 Labate With Confidence

09 -11-1444 H

29 -05-2023

Field Safety Notice of MobileDiagnost wDR from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19550	100	3
Product	MobileDiagnost wDR.	1000	_
Description	X-ray system		7
Manufacturer	Philips Healthcare.	* B	
Local agent	Mustafa Sultan Science & Industry Co.LLC.	17	
The affected products	Model Number (REF): 712007, 712006; SW version: 2.2.0, 2.2.1, 2.2.2, 2.2.3 712004, 712002; SW version: 2.1 with Windows 10 Upgrade		
Reason	Expiration of Software Certificate Validity Preventing Users from System Lo	g In.	
Action	 Please do not reboot or log out of your system until Philips has implemented the software correction. Please refer to the attachment for more information of preventing the system from becoming inoperable. Customers will be contacted to schedule a time for a Field Service Engineer (FSE) to visit the site and implement a software solution to resolve the issue. Contact the local agent for remedial action. 		
comments	Healthcare professionals are encouraged to report any adverse events Suspe with the above device or any other medical device to Department of Med through the E-mail: Med-device@moh.gov.om		

Dr. Mohammed Hamdan Al Rubaie

Director General





