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 196 **dated** 24/9/2023 **Regarding NCMDR FSCA of Luminos Agile Max.Luminos dRF Max from (mfr: SIEMENS).**

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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Circular No. 196/ **2023**

08 -03-1445 H

24 -09-2023

Field Safety Corrective Action of Luminos Agile Max.Luminos dRF Max from SIEMENS.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=19589
Product	Luminos Agile Max. Luminos dRF Max.
Description	Interventional fluoroscopic x-ray system.
Manufacturer	SIEMENS.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Luminos Agile Max (VF10, VF11) Model: 10762472; Luminos dRF Max (VF10, VF11) Model: 10762471
Reason	Under certain unlikely circumstances during a fluoroscopic examination, the imaging system Fluorospot Compact might sporadically display an incorrect air kerma/air kerma rate related to the patient reference point, according to IEC 60601-2-43. There is no impact on workflow or diagnosis. The error can occur only in fluoroscopy systems with a second (overhead) X-ray tube.
Action	1. The affected systems with software versions VF10 and VF11 will be updated by software updates via update Instructions (UI) XP007/23/S, XP004/23/S, XP003/23/S, and XP001/23/S. 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

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

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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