

نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman 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 139 dated 26/6/2023 Regarding NCMDR Field Safety Corrective Action 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



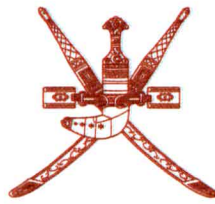
PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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](https://twitter.com/dgpa_dc) Email: dg-padc@moh.gov.om



Circular No. 139 / 2023

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26-06-2023

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

Source	NCMDR - National Center Medical Device 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

