



Circular No. 22 / 2023

نتقدم بثقة
Moving Forward
with Confidence



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29 -01-2023

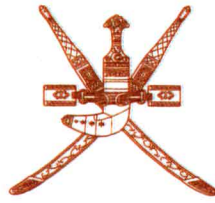
Field Safety Corrective Action of Enterprise Imaging XERO Viewer from AGFA Corp.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=18406
Product	Enterprise Imaging XERO Viewer.
Description	Software application.
Manufacturer	AGFA Corp.
Local agent	Bahwan Healthcare Center LLC.
The affected products	Software versions: 8.1.4.100 or higher, 8.2.0.000 or higher & 8.2.1.000 or higher.
Reason	Viewing images in Enterprise Imaging XERO Viewer can intermittently present images associated with an incorrect study or patient. In other cases, XERO Viewer may display the correct images but with degraded quality.
Action	1. The software corrections will be provided for the affected versions. In the interim the customers should pay special attention when viewing images in the XERO Viewer to ensure the images correspond to the study and patient being viewed. 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





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 22 dated 29/1/2023 Regarding NCMDR Field Safety Corrective Action of Enterprise Imaging XERO Viewer from (mfr: AGFA Corp).

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



Medical Devices Sector

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NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

TGA Recall

Reference Number: mdprc 044 12 22 000

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Date submitted: 12/29/2022

Manufacturer:	AGFA Corp.
Device Type:	Enterprise Imaging XERO Viewer
Description:	Software application
Medical Device Identifier:	Software versions: 8.1.4.100 or higher, 8.2.0.000 or higher & 8.2.1.000 or higher.
Reason of Field Safety Corrective Action:	Viewing images in Enterprise Imaging XERO Viewer can intermittently present images associated with an incorrect study or patient. In other cases, XERO Viewer may display the correct images but with degraded quality.
Remedy Action:	The software corrections will be provided for the affected versions. In the interim the customers should pay special attention when viewing images in the XERO Viewer to ensure the images correspond to the study and patient being viewed.
Athorized Representative/Importer/Distributor:	Gulf Medical Co.
Report Source:	https://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2022-RN-01511-1
Source Ref. Number:	RC-2022-RN-01511-1
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	No Attachments

[View History](#)

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