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

Circular No. 22 / 2023

07 -07-1444 H

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

PADC
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 Email: dg-padc@moh.gov.om

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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**

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

TGA Recall

Back

Reference Number: mdprc 044 12 22 000
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