Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 136 **dated** 26/9/2024 **Regarding Field Safety Corrective Action of Enterprise Imaging XERO Viewer from (mfr: AGFA Healthcare).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 136 / 2024

22-03-1446 H
26-09-2024

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

Source	AGFA HealthCare through their local agent Bahwan Healthcare Center.
Product	Enterprise Imaging XERO Viewer.
Manufacturer	AGFA Healthcare.
Local agent	Bahwan Healthcare Center.
The affected products	Enterprise Imaging XERO Viewer (UDI-DI: 05400874000710) All versions.
Reason	An issue related to orientation of 3D volumes using reference lines, active target localization, and series linking across multiple planes. A coding error has been identified in the initialization of pixel spacing in the XERO Viewer.
Action	1. When making any diagnosis and/or treatment decision regarding findings associated with the location of the reference line or active target in XERO Viewer, it is suggested to follow "Recommended actions to be taken" in the attachment. 2. AGFA HealthCare will provide the software corrections for the affected versions. A patch is available for each of the following XERO Viewer version streams (8.4.x, 8.3.x, 8.2.x, 8.1.4.x & 8.1.2.x), please refer to attachment for more details. 3. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

2024-09-12

IMPORTANT INFORMATION

Dear customer,

AGFA HealthCare wishes to bring to your attention the following information:

Subject: Incorrect handling of non-square Image pixel spacing in Enterprise Imaging XERO Viewer at initial load leads to incorrect placement of reference lines.

Product name and version(s) and UDI-DI:

- Enterprise Imaging XERO Viewer (UDI-DI: 05400874000710)

Versions affected:

- All versions

Information:

Agfa HealthCare has become aware of an issue related to orientation of 3D volumes using reference lines, active target localization, and series linking across multiple planes. A coding error has been identified in the initialization of pixel spacing in the XERO Viewer.

This issue only applies to XERO Viewer. It does not apply to the XERO Viewer Extended Tools (Xtend) component or the Enterprise Imaging Diagnostic Desktop Viewer.

Conditions in which this can occur:
When an image has non-square pixel spacing, the reference/localizer line is incorrectly placed on the **scout image in the XERO Viewer (offset from actual position). For example, when viewing a CT localizer** radiograph, also known as a scanogram or scout image in the sagittal plane next to an axial series, the localizer/scout line or the active target localization tool may display the incorrect crosshair/line position on the non-coplanar/scout image with respect to the axial slice location.

This misplacement occurs only initially when viewing the anatomy in the non-coplanar image within XERO Viewer. When a user scrolls through other available scout/non-coplanar images in a series, or replaces the current image in the display area with another series and then returns to the first scout image viewed, the reference/localizer line or active target crosshair will subsequently be correctly placed.

If the DICOM data sent from the modality contains the same pixel spacing for both rows and columns (square pixels), the reference lines and active target will always be placed correctly.

Impact on Clinical Use:
The reference/localizer lines and the Active Target tool to visualize areas across multiple planes are intended to accurately show where a scout or non-coplanar image intersects any series displayed on-screen, allowing clinicians to navigate to the correct anatomical location. Inaccurate placement of reference lines or crosshairs have potential risk of misdiagnosis or mistreatment due to unintended shifts in the display of anatomical locations. Prior to proceeding with medical interventions based on volumetric indications, it is recommended to review surrounding anatomical structures and the

diagnostic report to be confident in positioning. We have determined that the potential for occurrence of harm related to this defect is very low.

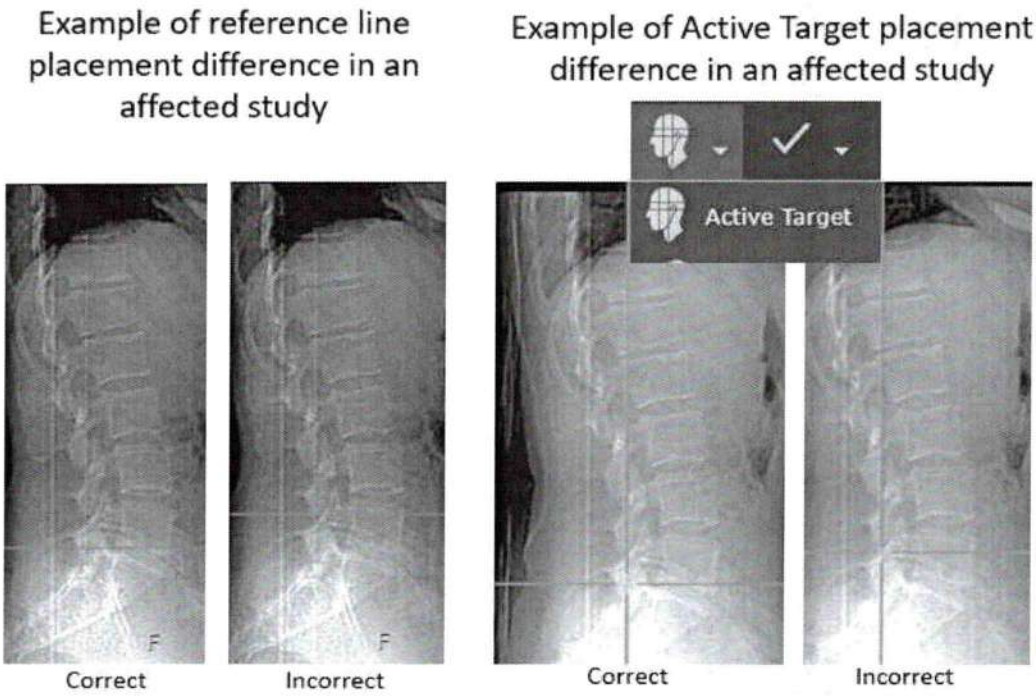

Figure 1: Example of placement difference due to incorrect initialization in XERO Viewer

Actions:

Actions undertaken by AGFA HealthCare:
AGFA HealthCare is informing all customers of this XERO Viewer issue.

Corrective actions undertaken by AGFA HealthCare:
AGFA HealthCare will provide the software corrections for the affected versions. A patch is available for each of the following XERO Viewer version streams:

- 8.4.x
- 8.3.x
- 8.2.x
- 8.1.4.x
- 8.1.2.x

Our Support organization representative will contact all customers on any of these versions and coordinate the correction activity. The patch installation will not require any downtime.

For versions of XERO Viewer prior to 8.1.2, the issue can be prevented from happening at your site by:

- Using the XERO Viewer Extended Tools component (Xtend), if enabled.
- Using the Enterprise Imaging Desktops viewer.
- There is an option to disable the features affected by this issue. This can be configured by your administrator or contact AGFA Support.

Recommended actions to be taken by you:
When making any diagnosis and/or treatment decision regarding findings associated with the location of the reference line or active target in XERO Viewer, it is suggested to:

- **Use the XERO Viewer Extended Tools component (Xtend), if enabled.**
- Use the Enterprise Imaging Desktops viewer
- Scroll through other available scout/non-coplanar images in a series, or replace the current image in the display area with another series in order to correct any potentially misplaced scout line.

Please distribute this information to all those in your organization who need to be aware of it.

We thank you for your careful attention to this issue. As your partner, we appreciate your confidence and cooperation as we work together to ensure the highest level of safety for your image management solutions.

We request that you complete and return the attached mandatory feedback form.

2024-09-12

If you have any questions about this matter, please get in touch with your local AGFA HealthCare organization:

Name of contact person
Title
Phone number
Email address@agfa.com

Sincerely,

Rob Mayer
Chief Product Officer
AGFA HealthCare

2024-09-12

AGFA HealthCare

IMPORTANT INFORMATION
Mandatory Feedback form

Please email this Feedback Form to your local AGFA representative within seven (7) business days of receipt of this Important Information Letter. Thank you for your co-operation.

Customer /Facility:	<Facility Site>
Address:	<Street>
	<City>, <Country>
Notice reference:	PRB0762354 - VR0000790
Product reference:	Enterprise Imaging XERO Viewer – All versions (UDI-DI: 05400874000710)

☐ I confirm that I have received and understand the attached notice.

☐ This notice does not apply to my facility. State reason: _____

Customer

Print Name: _____

Position: _____

Signature: _____

Date: _____

Phone number: _____

☐ Please correct our contact information as follows:

Customer / Facility name: _____

Address: _____