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URGENT FIELD SAFETY NOTICE

Add customer address fields for mail merge if applicable (can be re-used on the feedback form)

Single Registration Number (SRN):	BE-MF-000000909

Dear customer,

This Urgent Field Safety Notice is intended to inform you about:

- a problem we have with our product and under what circumstances the issue can occur
- the actions that should be taken by the customer / user to prevent risks for patients or users
- the actions planned by Agfa HealthCare to correct the problem

1. Information on affected devices	
1.1	**Device Type(s)***
	Software for imaging, radiology and clinical information
1.2	**Commercial name(s)**
	Enterprise Imaging XERO Viewer
1.3	**Unique Device Identifier(s) (UDI-DI)**
	05400874000710
1.4	**Primary clinical purpose of device(s)***
	Agfa HealthCare Enterprise Imaging XERO Viewer is a software application used for reference and diagnostic viewing of multispecialty medical imaging and non-imaging data with associated reports and documents.
1.5	**Device model/catalogue/part number(s)***
	8.x
1.6	**Software version**
	8.x
1.7	**Affected serial or lot number range**
	All versions
1.8	**Associated devices**
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem***
	Due to a software defect, the reference/ localizer line displayed on the CT scanogram image, representing the axial CT slice position displayed on the other viewports, can have an offset from the actual correct position.

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2.2	**(Potential) hazard***
	Derived patient data wrong.
2.3	**Probability of problem arising**
	The incorrect presentation of the reference line on scout images only occurs in specific situations. We have determined the occurrence of potential harm to be very low.
2.4	**Predicted risk to patient/users**
	The worst case potential harm is defined as a serious deterioration in state of health: - Serious injury (including: life-threatening condition (even if temporary), permanent impairment of a body function, permanent damage to a body structure, or injury that requires medical or surgical intervention to prevent permanent impairment of a body function orpermanent damage to a body structure. - Any indirect harm as a consequence of incorrect diagnostic results or wrong treatment when used within the manufacturer's directions for use which led to or might have led to a serious deterioration in state of health (as defined in a-d above) o Indirect harm might be a consequence of misdiagnosis, delayed diagnosis, delayed treatment or inappropriate treatment.
2.5	**Further information to help characterize the problem**
	Whenever a reference line is incorrectly placed on the scout images in XERO, only the one patient whose images are being displayed would be impacted by each incident.
2.6	**Background on issue**
	As per today's report, 1 incident has been reported to Agfa HealthCare although the product is globally on the market for more than 10 years.
2.7	**Other relevant information to the FSCA**
	The issue only occurs in a specific non-square pixel situations and only on initial loading of the scout images.

	3. Type of action to mitigate the risk	
3.1	**Action to be taken by the user***	
	☐ Identify device ☐ Quarantine device ☐ Return device ☐ Destroy device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None	
	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.	
3.2	**Is customer reply required? ***	Yes

3.3	**Action being taken by the manufacturer** ☐ Product removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 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	
3.4	By when should the action be completed?	The anticipated completion date for the correction is December 31, 2024
3.5	Is the FSN required to be communicated to the patient/lay user?	No

	4. General information	
4.1	**FSN Type***	New
4.2	**Further advice or information already expected in follow-up FSN? ***	**No**
4.3	**Manufacturer information**	
	Company Name	Agfa HealthCare NV
	Address	Septestraat 27, B-2640 Mortsel, Belgium
	Website address	http://www.agfahealthcare.com
4.4	**The competent (regulatory) authority of your country has been informed about this communication to customers.*** Yes, they are informed.	
4.5	List of attachments/appendices:	See attached important information letter

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	5. Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (as appropriate). Please transfer this notice to other organisations on which this action has an impact (as appropriate). Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the National Competent Authority if appropriate, as this provides important feedback.*

We apologize for the inconvenience we have caused, and we thank you for your careful attention to this issue and your continued support.

If you have any questions about this matter, please contact your local Agfa HealthCare organization:

<add Agfa HealthCare Regional Contact details>

Sincerely,

Chris Ball
Head of QARA,
Person Responsible for Regulatory Compliance

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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Attachment

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.

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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.

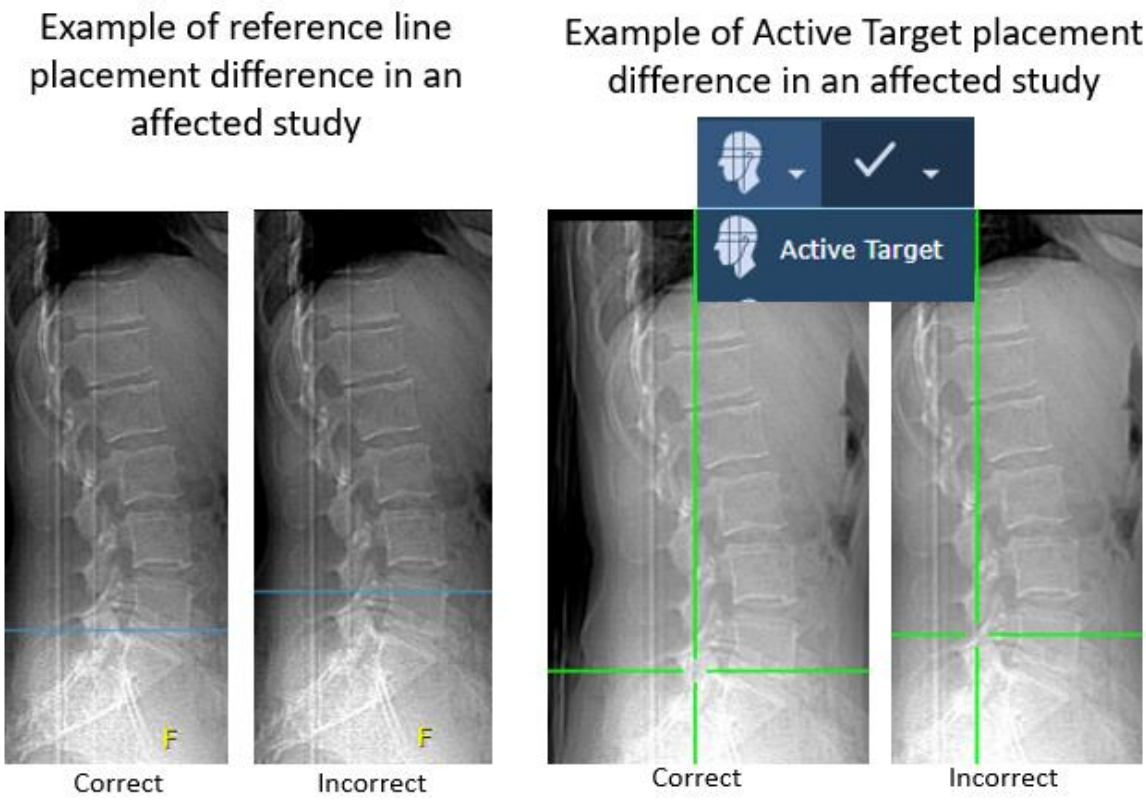

Figure 1: Example of placement difference due to incorrect initialization in XERO Viewer

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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.
Sincerely,

Rob Mayer
Chief Product Officer
AGFA HealthCare

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number* (Livelink ID) and Vigilance record number	VR0000790 PRB0762354
FSN Date*	06/09/2024
Product/ Device name*	Enterprise Imaging XERO Viewer 8.x
Product Code(s)/UDI-DI(s)	05400874000710
Batch/Serial Number(s)/Software version(s)	All versions

2. Customer Details	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I do not have any affected devices or affected software versions.	
☐	I have a query please contact me (e.g. need for replacement of the product).	
Print Name*		
Signature*		
Date*		

Mandatory fields are marked with *