2022-11-DD

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)**
	Agfa HealthCare 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**
	8.1.4.100 or higher; 8.2.0.000 or higher; 8.2.1.000 or higher
1.8	**Associated devices**
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem***
	Due to a software defect, 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.
2.2	**(Potential) hazard***
	Patient data/misattribution or switch
2.3	**Probability of problem arising**
	The intermittent issue may rarely occur under the following conditions: • After the startup of the Web Server and at the moment of the first image display request. • And, if at the same moment there are multiple requests within a very narrow time window. If, the first image display request completes successfully, the issue will not occur during the time the Web Server is up.
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: a) life-threatening condition (even if temporary), b) permanent impairment of a body function, c) permanent damage to a body structure, or d) 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**
	No physical harm or health damage was reported by the customers
2.6	**Background on issue**
	As soon as Agfa HealthCare was made aware of the symptoms of this issue via logged incident complaints by the customer, an urgent configuration change mechanism was identified by an Agfa HealthCare Service team to address this issue. The configuration change ensures the correct images are always displayed in the XERO Viewer. However, this configuration change results in performance degradation when viewing and interacting with the images being viewed in the XERO Viewer. Hence, Agfa HealthCare will expedite the release of defect corrected versions of the XERO Viewer software.
2.7	**Other relevant information to the FSCA**
	Clinically a diagnosis or treatment plan is rarely based upon review of a single study. Although it was never reported, a misdiagnosis or mistreatment may potentially occur if a clinician does not notice that he/she's looking at the images from another patient. The issue should be detected in situations where the imaged anatomy does not correlate with the exam requisition, gender, age, pathology or disease pattern. Xero Viewer is used outside of the Radiology department and most often the images viewed would already be reported. The report/image is only one part of the information that a medical expert is consulting before making diagnosis or treatment decisions.

	For a medical expert, the decision-making process involves reviewing the complete study, report and all additional information from other examinations.

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 Provide further details of the action(s) identified. Customers should pay special attention when viewing images in the XERO Viewer to ensure the images correspond to the study and patient being viewed.	
3.2	Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No	
3.3	**Is customer reply required? ***	Yes
3.4	**Action being taken by the manufacturer** ☐ Product removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Agfa HealthCare has determined the root cause of the problem to be a software defect and will provide the software corrections for the affected versions via the following releases:	
3.5	By when should the action be completed?	The Anticipated Completion Date for the roll out of the correction is December 31, 2022

Affected version	Version to apply for correction
XERO Viewer 8.1.4.100 or higher	8.1.4.202 (patch release that can be applied on any affected 8.1.4.x version) or 8.1.4.203 (full release build)
XERO Viewer 8.2.0.000 or higher	8.2.0.132 (patch release that can be applied on any affected 8.2.0.x version) or 8.2.0.140 (full release build)
XERO Viewer 8.2.1.000 or higher	8.2.1.020 (full release build)

3.6	Is the FSN required to be communicated to the patient/lay user?	No

4. General information		
4.1	**FSN Type***	New
4.2	For updated FSN, reference number and date of previous FSN	N/A
4.3	For Updated FSN, key new information as follows:	
	N/A	
4.4	**Further advice or information already expected in follow-up FSN? ***	No
4.5	If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4.6	Anticipated timescale for follow-up FSN	Not applicable
4.7	**Manufacturer information**	
	Company Name	**Agfa HealthCare NV**
	Address	Septestraat 27, B-2640 Mortsel, Belgium
	Website address	http://www.agfahealthcare.com
4.8	**The competent (regulatory) authority of your country has been informed about this communication to customers.*** Yes, they are informed	

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 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.

Sincerely,

Chris Ball
Head of QARA,
Person Responsible for Regulatory Compliance

2022-11-DD

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number* (Livelink ID) and Vigilance record number	Livelink ID 80858910 VR0000758 PRB0761670
FSN Date*	28/11/2022
Product/ Device name*	Enterprise Imaging XERO Viewer 8.x
Product Code(s)/UDI-DI(s)	05400874000710
Batch/Serial Number(s)/Software version(s)	8.1.4.100 or higher 8.2.0.000 or higher 8.2.1.000 or higher

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

Request customer to complete the below actions or enter N/A

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).	Customer to enter contact details if different from above and brief description of query

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Print Name*	Customer print name here
Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email	Global.vigilance.coordinator.healthcare@agfa.com
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	December 31, 2022

Mandatory fields are marked with *

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.