yyyy-mm-dd

URGENT FIELD SAFETY NOTICE

«IA_Customer_Name»
«IA_Facility_Site»
«IA_Street_Address»
«IA_City», «IA_State» «IA_Zip_Code»

Dear customer,

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

- what the problem is and under what circumstances it can occur
- the actions that should be taken by you in order to prevent risks for patients or users
- the actions taken by Agfa HealthCare to ensure proper product usage

Reference: Problem PRB0056200 - The order of studies in the Clinical Side Bar may not be chronologically sorted after triggering a compare function with a new study.

Device:

- Enterprise Imaging for Radiology 8.0.0, 8.0.0 SP1 & 8.0.0 SP2.
- Enterprise Imaging for Radiology 8.0.1, 8.0.1 SP1, 8.0.1 SP2, 8.0.1 SP3, 8.0.1 SP4, 8.0.1 SP5 & 8.0.1 SP6.
- Enterprise Imaging for Radiology 8.1, 8.1 SP1 & 8.1 SP2.

Problem:

Misuse of the product can occur if the user fails to confirm the date of the image being viewed. Coupled with the problem referenced above, misuse has the potential to pose a risk to health to patients.

Problem Details: Triggering a "compare", in the Enterprise Imaging Diagnostics Desktop, with a new study can result in a change of the sort order of the studies in the Clinical Side Bar. The studies are no longer chronologically sorted with the most recent one on top.

This only happens in the specific use case where additional comparisons are added for the same patient where the primary patient ID differs, but where there is a match in one of the secondary patient IDs.

While the sort order of the images in the clinical side bar may not appear as expected, all image data is displayed correctly including dates and other visual indicators. Caution should always be taken to avoid selecting the wrong study unintentionally.

Actions:

Actions undertaken by Agfa HealthCare

Re-emphasizing the importance of the user verifying the image date via this Urgent Field Safety Notice.

Agfa HealthCare xxx
Country / regional legal address
Country / regional legal address

Please note that the solution for the problem itself has been released in

- Enterprise Imaging 8.0.1 SP7 on December 15, 2016.
- Enterprise Imaging 8.1.1 on August 18, 2017.

The issue and solution related to the problem has also been communicated via Knowledge Article KA0014395 which has been published externally and can be viewed on the Customer Service Web (https://my.agfahealthcare.com/).

Recommended actions to be taken by you:

Please instruct your users to pay extra attention when selecting a study in the Clinical Side Bar to be sure they are reporting on the active study and not on one of the comparison studies.

- The active and comparison study are clearly differentiated from each other via blue (active) and grey (comparison) icons in both the Text and Image Area.
- The images show the date the study was performed.

Please distribute this information within your facility to all those who need to be aware of it.

It is important to take the actions detailed in this Urgent Field Safety Notification and to acknowledge receipt of this notification.

Should the above information not apply to your facility or should the device have been transferred to another organization, please be so kind as to indicate this on the attached feedback form and pass this Urgent Field Safety Notice to the organization where the device has been transferred.

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:

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

Sincerely,

Christopher Ball
QARA Director IITS

yyyy-mm-dd

AGFA HealthCare

URGENT FIELD SAFETY NOTICE
Feedback form

We kindly ask you to fax back or email the attached information as soon as possible. Your reply provides Agfa HealthCare, and subsequently the Regulatory Authority, with the means to monitor the progress of the Urgent Field Safety Corrective Actions. Thanks for your co-operation.

Customer /Facility:	<IA_Facility_Site>
Address:	<IA_Street>
	<IA_City>, <IA_Zip_Code>, <IA_State>, <IA_Country>
Notice reference	<Reference ID>
Product reference:	<Lot/Unit no, Serial no./Catalog no./Model no./Version/UPC code as needed>:

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

☐ This notice does not apply to my facility.

☐ The device has been transferred to another organization. Name and address of other organization: _____

Customer

Name: _____

Position: _____

Signature: _____

Date: _____

Phone number: _____

☐ Please correct our contact information as follows:

Customer / Facility name:

Address: