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 concerns the following devices:

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.

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.

Problem:
Adding an additional comparison study to the Clinical Side Bar in the Enterprise Imaging Diagnostics Desktop, can result in a change of the sort order of the studies in the Clinical Side Bar. The thumbnail images of the studies are no longer chronologically sorted with the most recent study at the top.

This only happens when additional comparison studies 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 thumbnail images in the clinical side bar may not appear as expected, all images are displayed correctly including dates and other visual indicators when displayed in the image area. Caution should always be taken to avoid selecting the wrong study unintentionally.

Actions:

Actions undertaken by Agfa HealthCare

1. 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/).

2. The permanent solution for this issue has been released in:

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

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

yyyy-mm-dd

Recommended actions to be taken by you:

1. 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.

2. We recommend that an upgrade be applied to correct this issue. Refer to the table for affected versions and associated correction.

Version of EI installed	Version of EI to apply
EI 8.0.0, 8.0.0 SP1 & 8.0.0 SP2.	EI 8.0.1 SP12
EI 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.	EI 8.0.1 SP12
EI 8.1, 8.1 SP1 & 8.1 SP2	EI 8.1.1 SP7

An Agfa HealthCare service representative will contact you to arrange for a date to deploy the appropriate upgrade at your facility.

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 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

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

yyyy-mm-dd

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: