

yyyy-mm-dd

URGENT FIELD SAFETY NOTICE

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

Attention: NX 3.0.8950 image processing software: Patient image was wrongly archived.

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 planned by Agfa HealthCare to correct the problem.

Reference: PRB0056846 – VR0000460

Device:

This Safety Notice refers to your NX workstation, specifically NX 3.0.8950 image processing software.

Problem:

Due to a memory issue a warning message about unexpected error and possible incorrect data integrity is shown to the user. A reboot of the workstation computer after having received the warning message prevents the issue from occurring. In one instance the warning instructions were not followed and resulted in the image of one patient being archived in another patient's record.

Actions:

Recommended actions to be taken by you:

- A daily reboot of NX workstation will prevent a memory issue. To perform this reboot, every day, completely turn off the computer and then restart it.
- Follow all warning instructions as indicated on your NX workstation and reboot the workstation's computer if a warning message appears.

Actions undertaken by Agfa HealthCare

Within a short time frame Agfa HealthCare will release a new version of the NX software (3.0.9000) that will provide a solution for the above mentioned issue. Your installation will be upgraded accordingly.

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:

Sincerely,
Paul Merckx, Global Head of QARA



Agfa HealthCare NV
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Belgium
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T +32 3 444 7563

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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	PRB0056846 - VR0000460
Product reference:	NX 3.0.8950

- 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: