

28.08.2024

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: Loss of image data in DeepUnity DICOM Services

Internal Reference: MST0089990

Product name and version(s) and UDI-DI:

- DeepUnity Viewer (all versions) in combination with DeepUnity DICOM Services (all versions) in Germany, Austria, Switzerland, and Brazil
 - Manufacturer: DH Healthcare GmbH
 - UDI-DI: 4260693990071
 - Note: Only DeepUnity Viewer version 2.x and higher is a medical device

Information:

Due to a software defect in DeepUnity DICOM Services, DICOM instances that were manually moved to trash and restored again later, are deleted by the background process “Orphaned Private Files” when it is enabled.

This can lead to potentially permanent deletion of radiological images.

Detailed description of the issue:

DICOM instances which have been moved to “trash” (deleted), obtain a reference in the trash database, to be displayed and managed through the user interface.

If a user restores (recovers) an instance from trash, a reference to the restored file is incorrectly left in the trash database. This is the desired behaviour when permanently deleting instances from trash, but it shouldn’t happen in case of restored instances.

The Deleter of “Orphaned Private Files” is a background process that analyses which files referenced in the trash database need to be deleted, and then proceeds with deleting it. Typically, this deletion is performed overnight. In case of restored instances, the Deleter therefore ends up erroneously deleting files which were previously restored.

This can lead to permanent deletion of the affected radiological images and in consequence to delays in diagnosis and treatment or the need for retake of images.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Contact customers to analyse customer databases if any files were deleted and change the configuration of the *"Group Delete Orphaned Private Files Interval"* to *"NEVER"*;
- Inform the potentially affected customers with this letter;
- Provide a correction via a Service Update of DeepUnity DICOM Services (version 1.1.1.3, release planned for Q4 of 2024).

Recommended actions to be taken by the customers:

- In case you are in doubt if the configuration of *Group Delete Orphaned Private Files Interval* was changed, please contact Dedalus to review your configuration;
- Once the release of the correction is available, please contact Dedalus to plan an installation window for an upgrade of the DeepUnity DICOM Services.

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

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):

Address:

Reference

MST0089990: Loss of image data in DeepUnity DICOM Services

Product reference:

DeepUnity Viewer

Name (contact person)

Position

Phone number

Date

Signature

☐ I confirm that I have received and understood the safety information.

☐ The safety information does not apply to my facility.

☐ The device was transferred to another organization.

Name and address of the other organization: _____

☐ Please update our contact information as follows:

Customer / Facility:

Address: