19.08.2024

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: The process of moving a DICOM series from a study of one patient to a study of another patient during QC Fixup operation sometimes fails

Internal Reference: MST0086963

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

- DeepUnity Diagnost (all versions) in combination with DeepUnity DICOM Services versions 1.1.1.0 or 1.1.1.1 in Germany, Austria, Switzerland, and Brazil
  - Manufacturer: DH Healthcare GmbH
  - UDI-DI: 4260693990040

Information:

The issue occurs if there has been a misattribution of a study to the wrong patient and the user manually attempts to perform a correction by using a QC Fixup operation. In this case, moving a DICOM series from one patient's study to another patient's study will fail if the series (or part of it) was previously archived to a nearline location.

Technical cause:

The problem is caused by an error in the QC service module. It occurs when DICOM series are moved to another patient and the series to be moved is available in the NEARLINE storage layer (regardless of availability in the ONLINE layer).

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter;
- Release of a correction with DeepUnity DICOM Services v.1.1.1.2 and higher versions (released on 02.07.2024).

Recommended actions to be taken by the customers:

- Contact Dedalus to plan an installation window for upgrading to the DeepUnity DICOM Services (v.1.1.1.2 or higher);
- After the installation of the fix version, verify that you are using the correct version (1.1.1.2 or higher).

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

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

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	**MST0086963**: The process of moving a DICOM series from a study of one patient to a study of another patient during QC Fixup operation sometimes fails
Product reference:	DeepUnity Diagnost
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: