2024-06-26

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: Archive priority is not considered for studies stored on multiple archives

Internal Reference: MST0085667

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

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

Information:

When using the software DeepUnity Viewer, if the same study (UID) is stored on different archives with different content (e.g. it is stored with its full content on the central archive and with a subset of this content on a local archive), searching for this study returns the content from only one of these archives. However, it is unclear which archive will be chosen to display the study content. This happens when the DeepUnity Viewer is called from another application via a context-based call, as well as when the DeepUnity Viewer patient search is used.

This error could lead to images not being reviewed when making a diagnostic decision, causing a delay in diagnosis, and consequently delay in treatment or ineffective treatment.

Note: The problem only occurs when combined search over multiple archives is performed. If archives are searched separately, the returned results are correct.

Technical cause:

Searching studies via the DeepUnity Viewer is always done via the so-called “PACSGate”. It acts like a proxy forwarding the search request to all connected archives. The PACSGate collects all results and sends them back to the DeepUnity Viewer. Due to performance reasons, once an archive returns a search result, it is written into the JSON DICOM file, not waiting for the other archives to finish their requests. In consequence, the order is determined based on time and not based on priority of the archives.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter;
- Release of a correction with DeepUnity Viewer v.2.0.3.1 and higher versions (release planned for Q2 of 2024).

Recommended actions to be taken by the customers:

- Contact Dedalus to plan an installation window for upgrading to the DeepUnity Viewer fix version (2.0.3.1 or higher);
- After the installation of the fix version, verify that you are using the correct version (2.0.3.1 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: <contact Email>

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	**MST0085667**: Archive priority is not considered for studies stored on multiple archives
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: