

10.12.2024

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: DeepUnity Viewer losing connection to the archives due to failing PACSGate container

Internal Reference: **MST0087227**

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:

The DeepUnity Viewer relies on PACSGate to manage and translate DICOM communications with multiple connected DICOM archives. In rare cases, within the PACSGate pod, the PACSGate container may fail unexpectedly—most likely due to increased memory usage—and does not automatically restart, leaving the failure unnoticed.

Consequently, the DeepUnity Viewer cannot communicate with the connected archives and hence can neither request nor display studies anymore. This affects all kinds of modalities.

To be able to use the DeepUnity Viewer again, the whole PACSGate pod needs to be restarted manually.

Technical cause:

When streaming data from the server to the DeepUnity Viewer, the PACSGate application had a memory issue that caused it to stop functioning correctly.

The system would show it as "running" but not fully operational, so it didn't restart automatically. To fix this, the way the system checks if PACSGate is working was adjusted, allowing it to restart automatically if a problem is detected.

Additionally, the PACSGate application was refactored to improve memory handling and to ensure triggering a pod restart in the event of a memory issue.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter;
- Provide a correction with DeepUnity Viewer v.2.0.5.0 (release planned for Q1 2025).

Recommended actions to be taken by the customers:

- Once the DeepUnity Viewer v.2.0.5.0 is officially released, please contact Dedalus to plan an installation window for an upgrade of the DeepUnity Viewer;
- In the meantime, we advise customers to immediately contact their responsible service department if the DeepUnity Viewer stops working, so that they can immediately restart the PACSGate pod and avoid long downtimes.

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

DeepUnity Viewer losing connection to the archives due to failing PACSGate container

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: