



13.12.2024

## 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: Availability of new image studies is delayed due to server problems**

Internal Reference: MST0093604

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

- DeepUnity Viewer (all versions) in combination with DeepUnity DICOM Services (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:**

Triggered by a slow modality, the available compression capacity in DeepUnity DICOM Services may become exhausted in certain scenarios. This results in the server slowing down or even stopping the ingestion of studies from other modalities. Consequently, the availability of new image studies is significantly delayed.

### **Detailed description of the issue**

In the reported case, a slow ultrasound modality took more than 60 minutes to upload and store acquired multi-frame images. In addition, the modality attempted to send multiple studies simultaneously. This exhausted all available compression slots in DeepUnity DICOM Services. As a result, the system could no longer perform further compressions, thereby stopping or slowing down acquisitions from other modalities.

No effective workaround is known, besides pausing store requests from the slow modality.

### **Actions:**

#### **Actions undertaken by DH Healthcare GmbH:**

- Inform the potentially affected customers with this letter;

1 / 3

**URGENT FIELD SAFETY NOTICE - MST0093604**

DH Healthcare GmbH  
Konrad-Zuse-Platz 1-3, 53227 Bonn



- Provide a correction via a Service Update with DeepUnity DICOM Services v.1.1.1.4 and higher versions (release planned for Q1 2025).

**Recommended actions to be taken by the customer:**

- Contact Dedalus Support if one of your modalities triggers the problem;
- 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.

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 - MST0093604**

DH Healthcare GmbH  
Konrad-Zuse-Platz 1-3, 53227 Bonn

2 / 3



**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

**MST0093604:** Availability of new image studies is delayed due to server problems

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: