04.02.2025

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: Instances of data loss detected in DeepUnity PACSonWEB storage
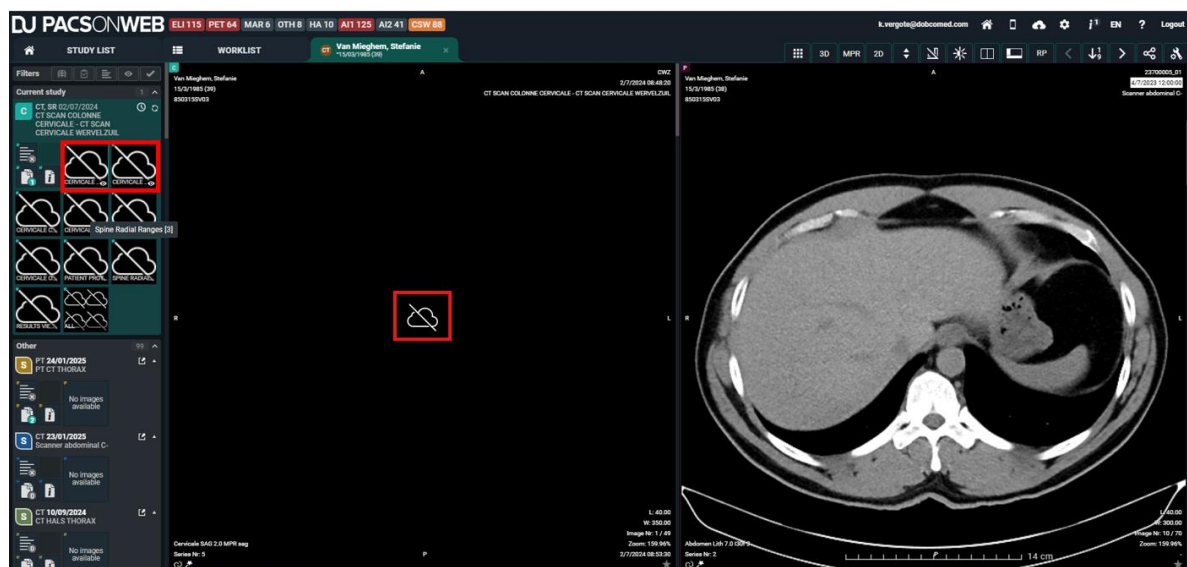
Internal Reference: **MST0096560**

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

- DeepUnity PACSonWEB in Germany, Austria, Switzerland, France, Belgium, Netherlands, Cyprus, Norway, and Brazil.
    - Manufacturer: DH Healthcare GmbH
    - UDI-DI: 4260693990125

Information:

Due to a defect in DeepUnity PACSonWEB, a partial deletion of images can occur in an edge case scenario.

In case of such unintended deletion, the missing images/series are displayed within the viewer by the "no-cloud" icon, which assures awareness for the user that images are missing.

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

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IMPORTANT: during the initial processing of the displayable DICOM files, compressed PNG images are generated for faster display in the viewer. These PNGs remain available for 3 months and are not removed as a result of the defect. Hence, the issue of missing images only occurs 3 months after the initial sending of the images. Advanced image manipulations such as Multi Planar Reconstruction and Window/Levelling will however no longer be possible as this requires the original DICOM files.

This way, the availability of all images is ensured at the time of clinical diagnosis of the impacted study.

Workaround:

For DeepUnity PACSonWEB Diagnostic and Archive+ customers:

- Restore of the images by Dedalus support from the backup of the DeepUnity PACSonWEB cloud environment.

For the DeepUnity PACSonWEB Portal customers:

- Resend all images for the impacted study from the local PACS.

Technical cause:

This issue can only occur in the highly exceptional case when a study initially contains both displayable and non-displayable DICOM files (e.g. incorrect DICOM data; unsupported SOP class), and the non-displayable DICOM files are resent on a later date with adjusted DICOM data, making them displayable.

In this scenario, the initial set of DICOM files is replaced with the resent set of DICOM files and therefore, DICOM images that have not been resent are removed from the storage.

Actions:

Actions undertaken by DH Healthcare GmbH:

Before provision of the fix:

- Inform the potentially affected customers with this letter;
- Recovery of objects, incorrectly deleted in the past, from the backup of the PACSonWEB cloud environment;
- DeepUnity PACSonWEB Diagnostic and Archive+ customers whose data has been impacted will be contacted with a detailed explanation, a listing of impacted studies and the result of the restore actions;
- Regular checking/recovery for new occurrence of the issue on the central DeepUnity PACSonWEB storage with required correction until the fix has been implemented.

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Once the fix is available:

▪ Provide a correction with an upcoming service release of DeepUnity PACSonWEB (release planned within Q1 2025).

Recommended actions to be taken by the DeepUnity PACSonWEB Portal customers:

▪ If you experience the issue and have a local PACS system, resend the data from the local PACS to DeepUnity PACSonWEB. If you need assistance, contact Dedalus Support.

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,

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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	**MST0096560:** Instances of data loss detected in DeepUnity PACSonWEB storage
Product reference:	DeepUnity PACSonWEB
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:

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