

17.08.2026

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: Moving images and/or image series from one study to another fails

Internal Reference: MST0123571

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

- DeepUnity PACSonWEB 3.4.305 in Brazil, Chile, Colombia, Costa Rica
- DeepUnity PACSonWEB 3.4.306 in Belgium, France, Switzerland
- Legal manufacturer: DH Healthcare GmbH
- UDI-DI: 04260693990125

Information:

We have discovered a defect in our DeepUnity PACSonWEB software.

In cases where a user needs to move images and/or image series from one study to another (in the DeepUnity PACSonWEB study administration) due to incorrect metadata, it can happen that the move operation fails for one or more images.

In case of such a failure, there is a chance that an image is not made available in the target study while it has been 'deleted' from the original source study. As a result, those images are no longer visible for the end user (e.g. radiologist) neither in the source nor in the target study.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Provide a correction with DeepUnity PACSonWEB 3.4.307 (planned release in August 2026);
- Affected customers will be contacted individually, with a list of affected studies;
- Recover lost images as much as possible from disk or backup (in progress)

Recommended actions to be taken by the customer:

If you have been identified by Dedalus as an affected customer

- Provide assistance to Dedalus Service teams for correcting the affected studies. This includes going through the list of flagged studies, verifying the available images and series, and – if needed – taking corrective actions.

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URGENT FIELD SAFETY NOTICE – MST0123571 – Moving images and/or image series from one study to another fails

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

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

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

MST0123571: Moving images and/or image series from one study to another fails

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: