



13.02.2026

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: Changing the patient for a procedure in a multi-procedure order does not unlink it from the report

Internal Reference: MST0112902

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

- DeepUnity PACSonWEB 3.4.203 in Austria, Belgium, Brazil, Colombia, Costa Rica, Cyprus, France, Germany, Norway, Switzerland, The Netherlands
- Legal manufacturer: DH Healthcare GmbH
- UDI-DI: 4260693990125

Information:

During planned regular testing, aimed to proactively capture defects and mitigate risks, we have discovered a defect in our DeepUnity PACSonWEB software.

The defect occurs in the following scenario:

- A single report exists for an order with multiple procedures;
- A message (e.g. HL7 ORM) is sent to DeepUnity PACSonWEB for one of the procedures linked to that order and report, linking that procedure to another patient. Such a message could be sent, for example, in the case where a second patient was not correctly administered on the modality, and hence the images from that second patient were initially still linked to the first patient that was imaged on that modality.

In this scenario, DeepUnity PACSonWEB will create an anomaly ('Patient changed via HL7') for the procedure that is linked to another patient. Such an anomaly restricts access to that study, and informs the user that action is required to resolve the anomaly.

However, the affected procedure remains linked to the original report. Also, no anomaly is created for the other procedure(s) linked to the original report.

As the original report was created for procedures belonging to different patients, this report needs to be reviewed and possibly corrected. Hence an anomaly should also be created for the procedure(s) not affected by the patient change.

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URGENT FIELD SAFETY NOTICE – MST0112902 – Changing the patient for a procedure in a multi-procedure order does not unlink it from the report

DH Healthcare GmbH

Germany, Konrad-Zuse-Platz 1-3, 53227 Bonn



Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter;
- Provide a correction with DeepUnity PACSonWEB 3.4.300 (planned release in Q2 2026);
- Affected customers will be contacted individually, with a list of affected reports;
- Perform a data clean-up for affected customers:
 - unlink the report, where the report is linked to studies of different patients, and
 - flag all studies for these reports.

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 reports. This includes going through the list of flagged studies, verifying the report content, and – if needed – taking corrective actions.

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

MST0112902: Changing the patient for a procedure in a multi-procedure order does not unlink it from the report

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: