

07.04.2025

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 unreferenced PDF reports detected in DeepUnity PACSonWEB

Internal Reference: **MST0099395**

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

- DeepUnity PACSonWEB in Germany, Austria, Switzerland, France, Belgium, and Brazil.
 - 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. When PDF reports are sent into DeepUnity PACSonWEB via HL7 ORU, only the first version of that report will be visible in the user interface. Subsequent versions of the PDF report are stored, but will not be visible in the user interface.

As such, there is a potential risk that a person looking at a PDF report in DeepUnity PACSonWEB is not seeing the latest version of the report. Depending on the nature of the changes in the subsequent versions of the PDF report, there is a potential risk that updates to clinically relevant content are not visible in the user interface.

Technical cause:

When a new plain text report is sent to DeepUnity PACSonWEB for a particular study, and a report already exists for that study, then it is checked if the new report text differs from the existing report text. If there is no difference, the new report is still stored but not referenced anymore.

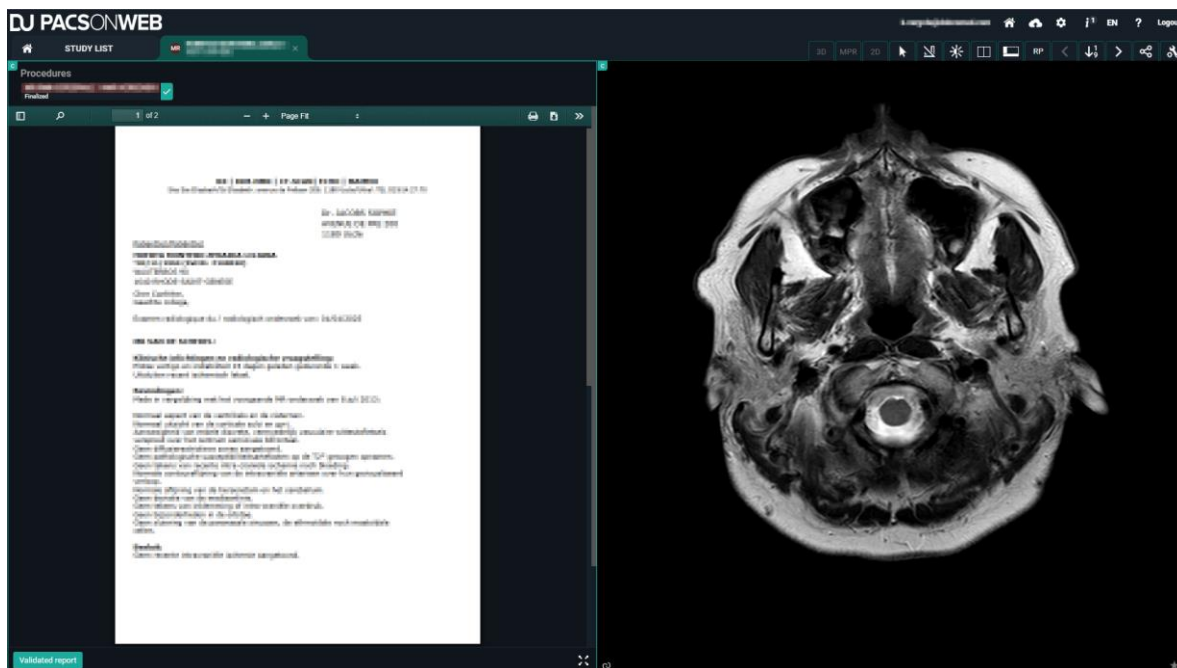
In the case of PDF reports, the report content within the PDF itself is not checked, and DeepUnity PACSonWEB always considers it as the same report. Hence the new PDF report will never replace the existing PDF report, and is stored as an unreferenced PDF report (not linked to the proper study).

This issue only affects customers using PDF reports.

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URGENT FIELD SAFETY NOTICE - MST0099395 - Instances of unreferenced PDF reports detected in DeepUnity PACSonWEB

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



Display of a PDF report within DeepUnity PACSonWEB

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter;
- Affected customers will be contacted with a detailed explanation and attempt to link unreferenced PDF reports to the correct study until the technical fix is available;
- Put on hold the provision of PDF report functionality to any additional customers until the technical fix is available;
- Provide a correction with the next hotfix of DeepUnity PACSonWEB. This release is planned for April 2025.

Recommended actions to be taken by the customer, before the correction is applied:

- In case a report is updated with any clinically relevant content, please inform the patient and/or (if known) other involved clinicians relying on this information to ensure that this information is considered for clinical decisions.

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

MST0099395: Instances of unreferenced PDF reports detected in DeepUnity PACSonWEB

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: