

Urgent safety information

FSN Reference: 137678

Version: 1.0

synedra

information technologies

synedra information technologies GmbH
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Austria

Urgent safety information

Software update concerning synedra View 22 “Niobe”¹ and synedra View 23 “Selene”

Innsbruck, October 24, 2023

From:
synedra information technologies GmbH
Feldstraße 1/13
6020 Innsbruck
Austria

To:
synedra AIM administrators
Head of Radiology Department
Head of IT Department

Dear Sir or Madam,

Please read the enclosed safety information. It contains important details for identifying specific problems and the measures to be taken.
synedra would like to confirm that this notice has been submitted to the appropriate agencies. Maintaining a high level of safety and quality is a top priority for synedra.

Thank you for your support,
synedra information technologies GmbH

¹ For older product versions, we recommend an update to 22 “Niobe” or 23 “Selene”.

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Safety issue 1: Wrong context when importing external DICOM data into synedra View

FSCA Reference: 137251

Description safety issue

When importing external data, e.g., Patient CDs, the patient context can be set incorrectly by the user. If a mismatch is not detected, this could lead to an incorrect diagnosis and resulting incorrect treatment. This may lead to serious deterioration of health or a worse prognosis. No harm related to this problem has been reported.

Products concerned

Product	concerned	Module(s)	Release [UDI-DI]*	Version(s)
synedra AIM	Yes	synedra View	22 "Niobe" [9120100700226]	all versions incl. 22.0.0.15
			23 "Selene"[9120100700233]	23.0.0.0
synedra View Professional	No	-	-	-

* For older product versions, we recommend an update to 22 "Niobe" or 23 "Selene" first.

Immediate measures for customers

Please continue to exercise the utmost care when assigning context information. Consider the inherent risk associated with assigning context information when designing and establishing corresponding workflows and educate all employees who are involved in these workflows. In addition, ensure that training is appropriate for the respective activity.

Corrective action by synedra

1. Improvement of creating context in synedra View: A new dialog has been implemented that specifically notifies the user of discrepancies when changing demographic data. If the new patient context selected for import differs from the previous context in more than just the patient ID, then a warning dialog is displayed with the differences and the user must confirm them before the import.

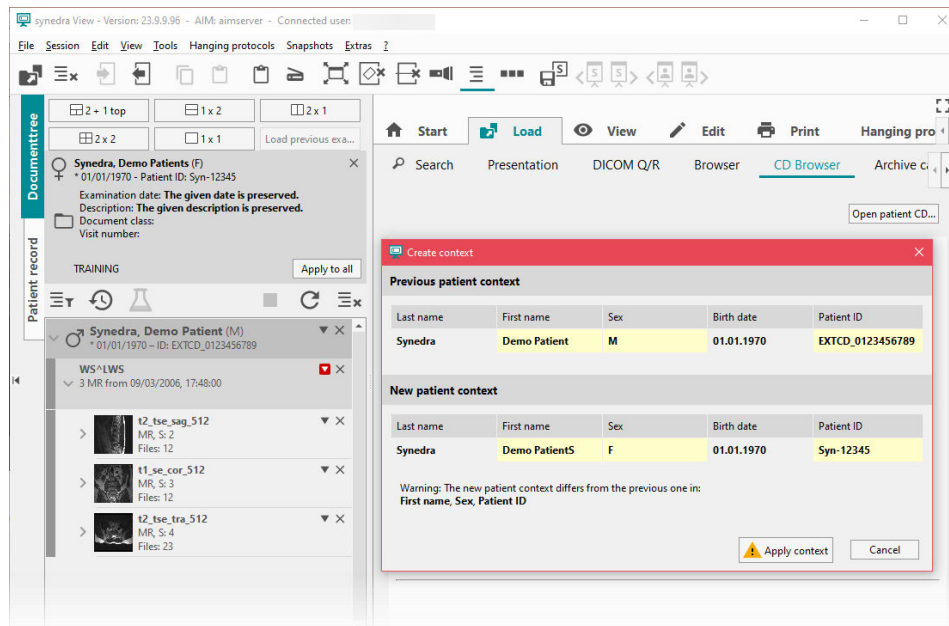


Fig. 1: New dialog for displaying deviations in the patient context

2. Addition to the documentation – best practices guide for data import: There are several available options to import external data and the best suited option depends on user context. A separate document has been created that explains and compares the workflows and provides specific recommendations. This document is attached to the letter and has been added to the documentation.

Schedule

Software updates:

- synedra View 23.0.0.2 for release 23 "Selene" and
- synedra View 22.0.0.17 for release 22 "Niobe"

are available to you, the documentation has been complemented. If your system is not yet on release 22 "Niobe", please arrange an appointment to update to 22 "Niobe" or 23 "Selene" with the synedra customer service.

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Disclosure of the information described here

This document provides you with important information about the use of your product. Please ensure that all users of the above-mentioned products within your organization are made aware of this urgent safety information and that the measures are correctly implemented. If you have passed the products on to third parties, please forward a copy of this notice or inform the contact person indicated below.


Please acknowledge this information and take corrective measures so that safety and quality of patient information can be ensured.

Contact information

If you have any questions or concerns about the safety information, please contact your account representative.

Alternatively, you are welcome to contact our support at any time.

We appreciate your understanding on this matter,


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