31.10.2025

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: Blocked administration documentation for discontinuous prescription with simple product and a unit not inherited from the pharmaceutical database.

Internal Reference: MST0106567

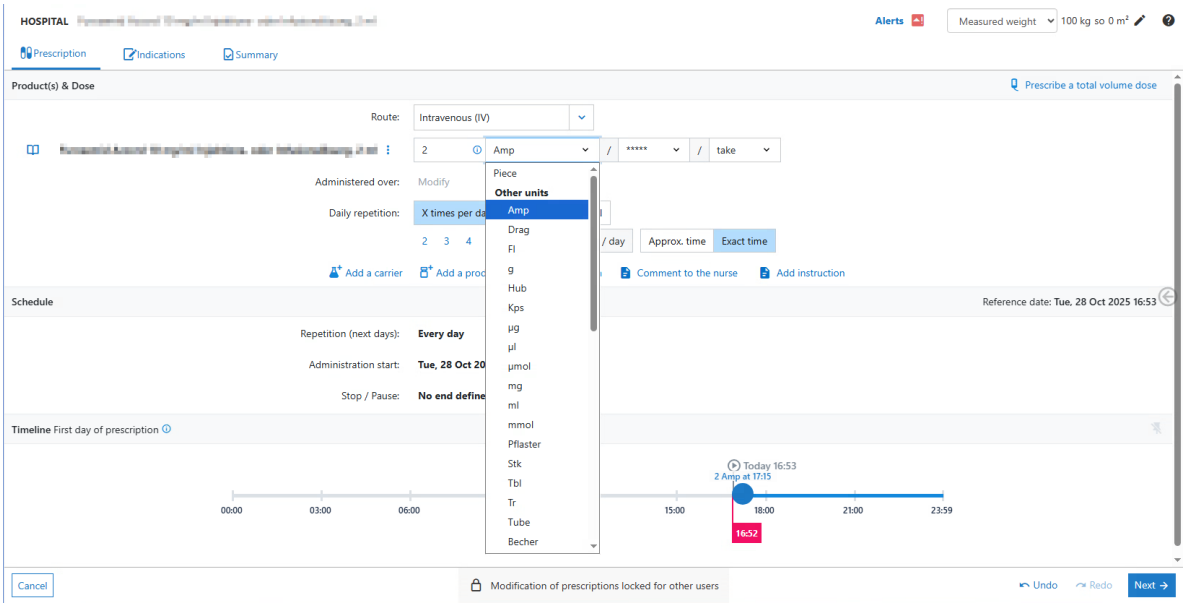
Product name and version(s) and UDI-DI:

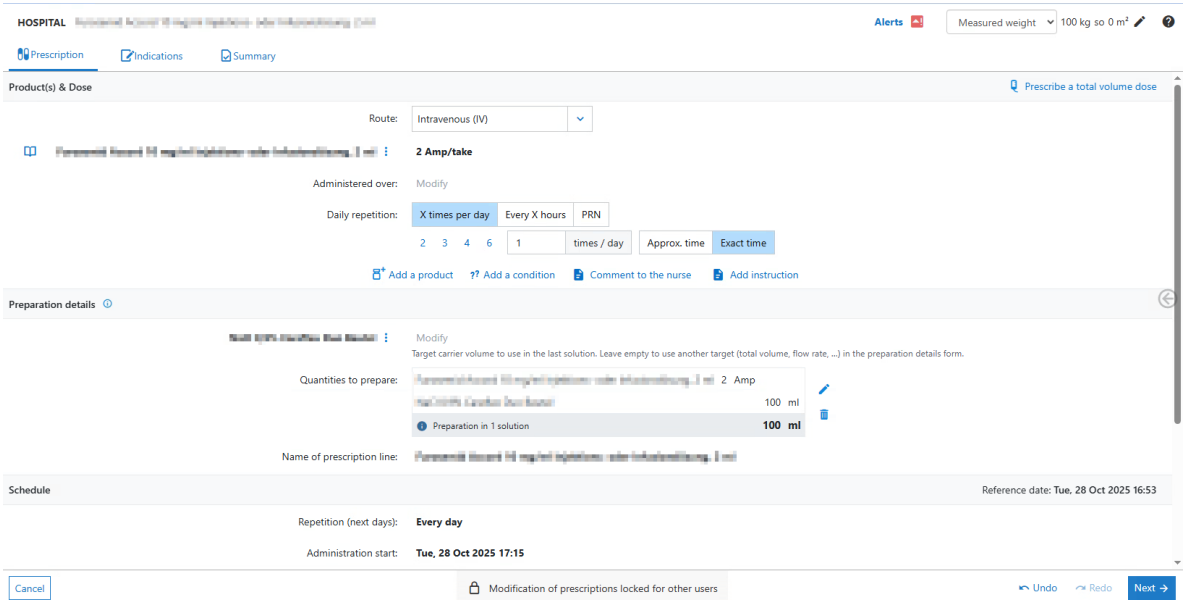
- ORBIS Medication 03.21.00.00 and higher in ORBIS 84.43.00.00 in ORBIS in Germany, Austria, Switzerland, and Luxembourg.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The system behavior occurs when a physician creates a discontinuous prescription line without duration, containing a simple product and a preparation.

During prescription entry, the physician selects a prescription unit in the section “Other units” which is a list of units not inherited by default from the pharmaceutical database **and adds a carrier**.





After the prescription line is signed by the physician, a nurse opens the administration screen to register the administration of one of the scheduled doses in the ORBIS Patient Chart.

In the “Preparation to administer” section, the main product dosage is displayed without unit.

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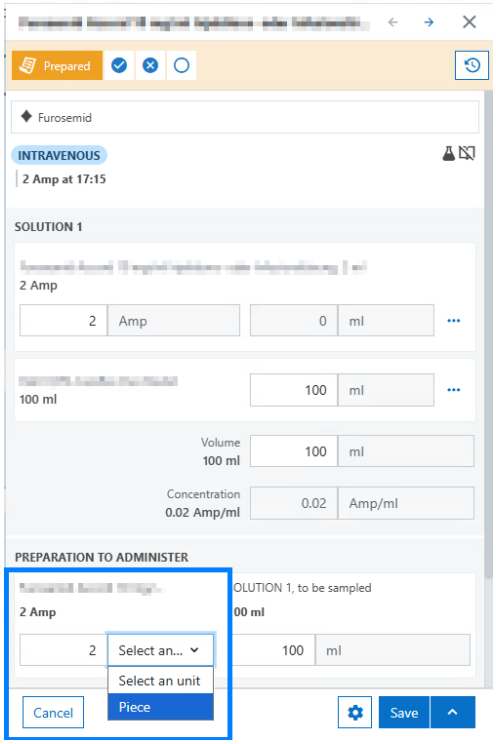
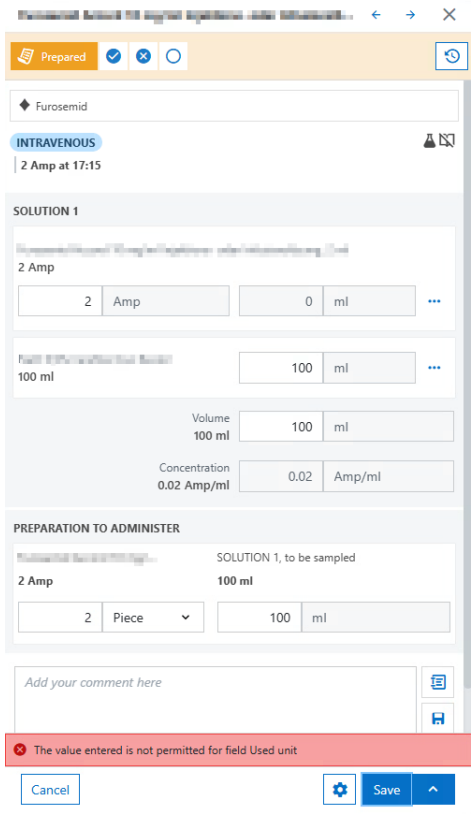


When the nurse attempts to select a unit from the dropdown list and tries to save the administration, an error message appears, preventing documentation of the administration.



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Cause identified:

The system blocks documentation because it detects a discrepancy between:

- the main product unit in the “Solution 1 section”, and
- the main product unit in the “Preparation to administer” section.

This occurs when the physician selects a prescription unit that differs from the product unit inherited by default from the pharmaceutical database for a simple product. In the given example, instead of selecting ml or mg, which are the inheritated product units, the physician selected another prescribable unit in the section “Other units”.

This is a regression introduced in ORBIS Medication 03.21.00.00, following the recent change that allows editing of the main product field in the “Preparation to administer” section for discontinuous prescriptions with a preparation.

Potential impact on the patient:

- Blockage of documentation of subsequent drugs administrations.
- Risk of errors in the traceability of drug administration.
- Potential delay in recording treatment administration.

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.21.02.00 or higher in ORBIS version 84.43.04.00 or higher (release planned for last quarter of 2025 for DACHL).

Recommended actions to be taken by the customer:

- Install the correction when available.
- For discontinuous prescriptions with a simple product and preparation, avoid to select a prescription unit different from the one inherited from the pharmaceutical database (Other units section).
- If an existing prescription is affected by this issue, cancel and recreate the prescription line using a unit provided by the pharmaceutical database (not in the “Other units” section).

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	MST0106567
Product reference:	ORBIS Medication: Blocked administration documentation for discontinuous prescription with simple product and a unit not inherited from the pharmaceutical database.
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: