26.09.2025

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: Impossible to start intermittent administration with duration

Internal Reference: MST0103364

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

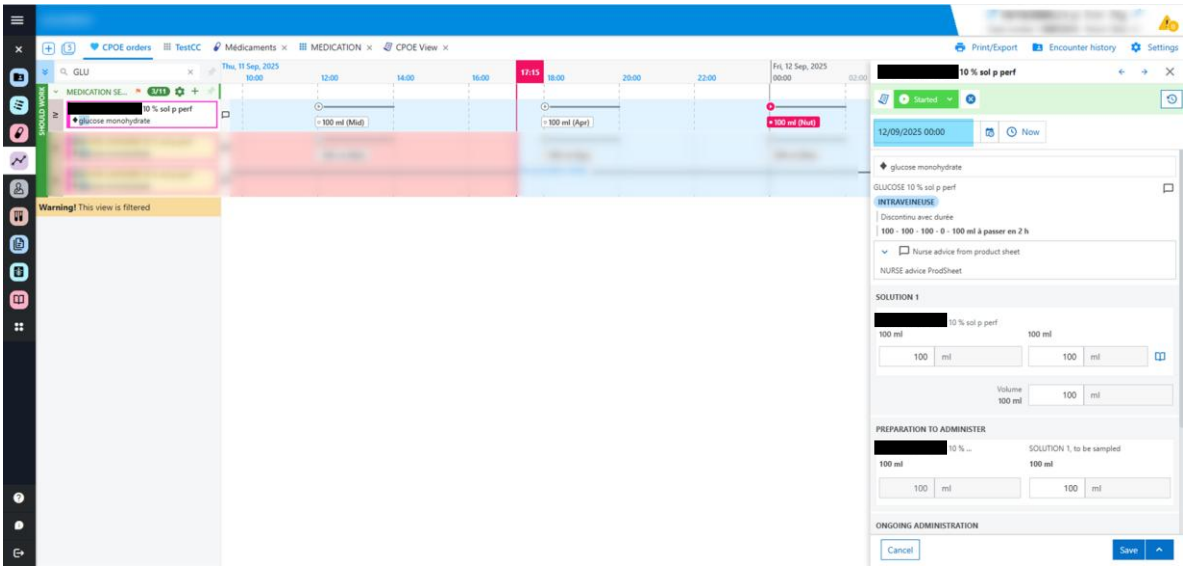
- ORBIS Medication 03.17.xx and higher in ORBIS version 84.39.00.00 and higher in Germany, Austria, Switzerland and Luxembourg.
- ORBIS Medication 03.17.xx and higher in ORBIS version 84.39.00.00 and 85.22.00.00 and higher in France.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

A discontinuous prescription with a duration is signed by the physician. Some planned takes for the present and the future have not yet been documented in the Patient Chart

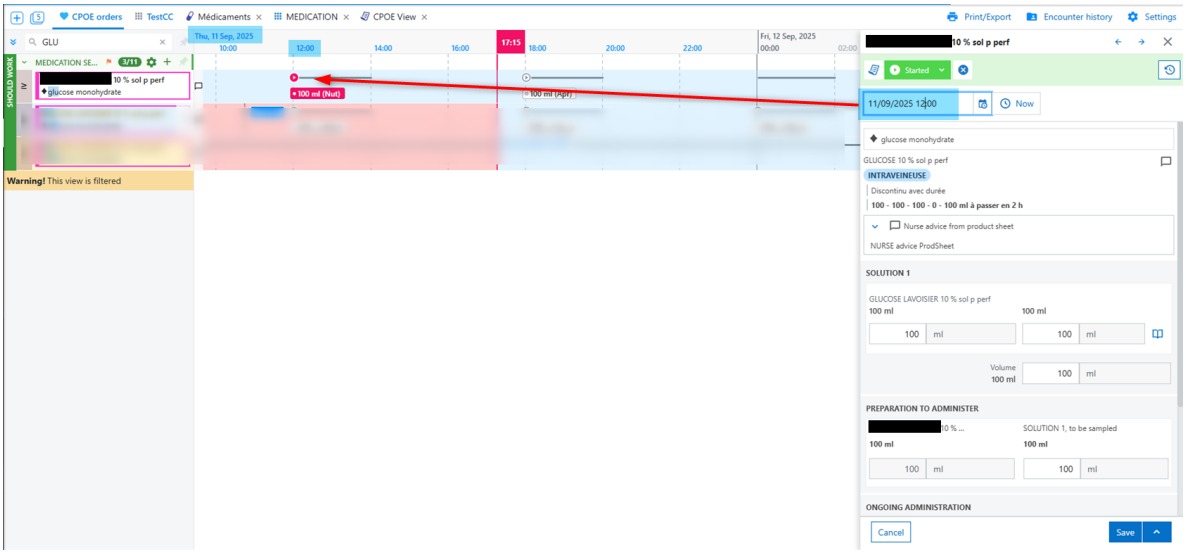
Illustrated scenario:

The nurse opens the administration screen of a take planned in the future that was initially planned after other undocumented takes, which are themselves planned for the future.

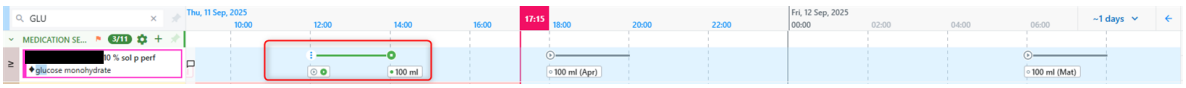


Then, the nurse changes the time of administration and records the start and the end of administration.

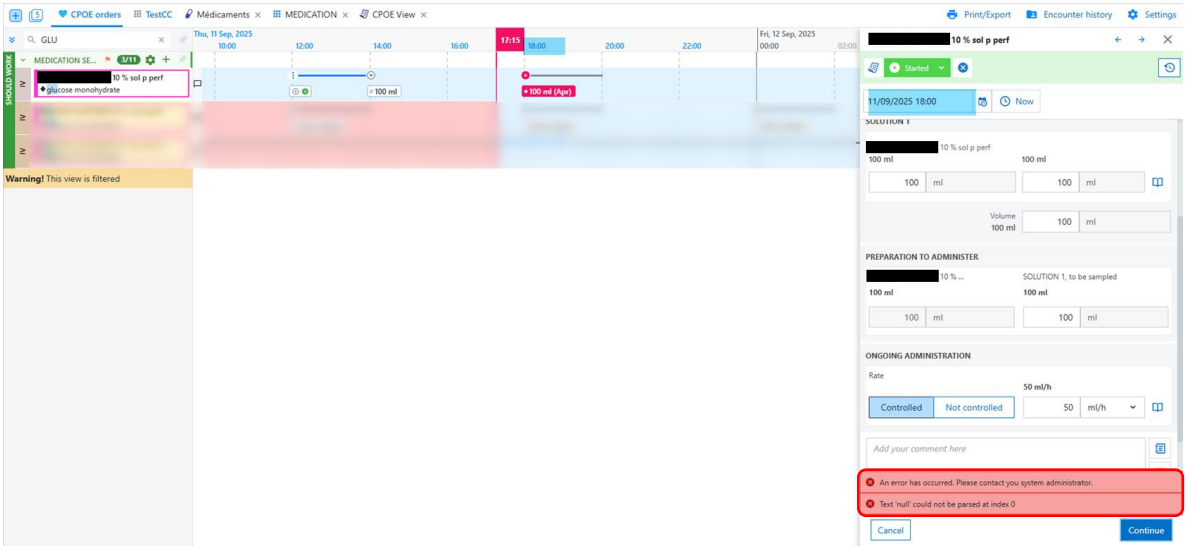
The new date and time of the just administered take coincides exactly with the start time of another take already planned.



Therefore, in the Patient Chart it can be noticed that the two takes overlap.



When the nurse wants to save the start of the next take planned right after, the following message is displayed, blocking the action from being recorded.

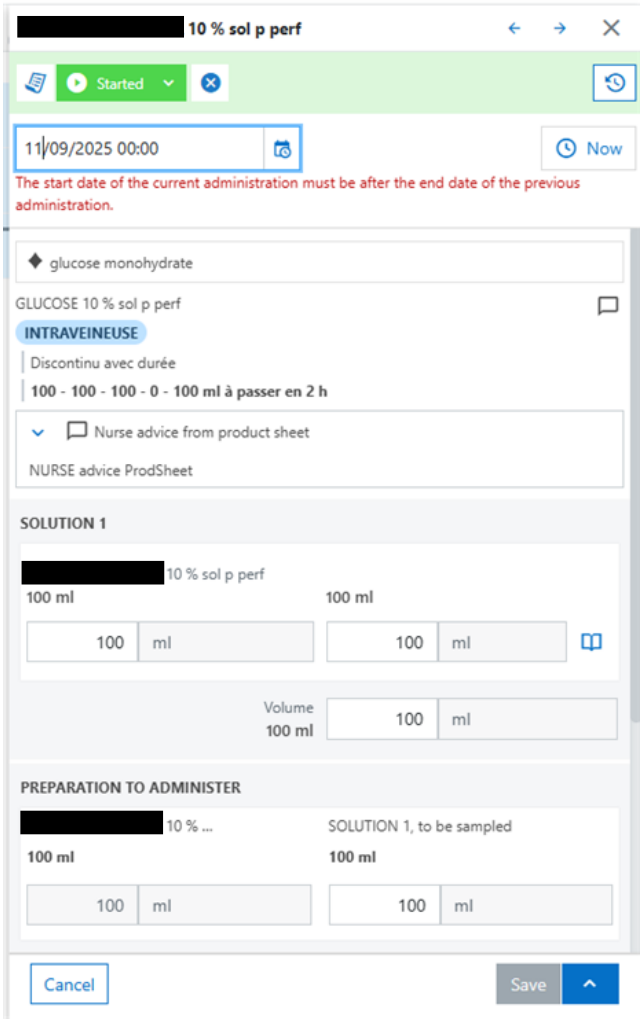


Cause identified:

The system blocks the documentation because it detects a chronological inconsistency: the take initially scheduled after the blocked one appears to have been administered before.

However, the error message displayed in this scenario does not allow the user to understand properly the real cause of the block.

Nevertheless, this message already exists when a take is rescheduled before a take that has already been started but not at the exact same time as it was described in this scenario.



Potential impact on the patient:

Obstruction of documentation of subsequent drug administrations.

- Risk of overdose.
- 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 03.22.00.00 or higher in ORBIS version 84.44.00.00 or higher (release planned for second quarter of 2026 for DACHL).
- Release of correction with ORBIS Medication version 03.22.00.00 or higher in ORBIS version 84.44.00.00 and 85.44.00.00 or higher for FR (release planned for third quarter of 2026 for FR)

Recommended actions to be taken by the customer:

- If there is an overlap of takes, delete the documentation for the take administered at the wrong date and time, then re-document the administration at the dates/times originally planned.
- Ensure that nurses have been trained in documenting drugs on the Patient Chart.
- Check that information on the use of the zoom level on the Patient Chart has been passed on and understood by users.

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	MST0103364
Product reference:	ORBIS Medication: Impossible to start intermittent administration with duration
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: