06.08.2026

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:

When prescribing infusion pump protocols from an existing template some values may no longer match their original configuration after software update.

Internal Reference: MST0123048

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

- ORBIS Medication 03.22.00.01 in ORBIS version 84.44.00.10 and higher in Germany, Austria, Switzerland and Luxemburg.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 04260693990026

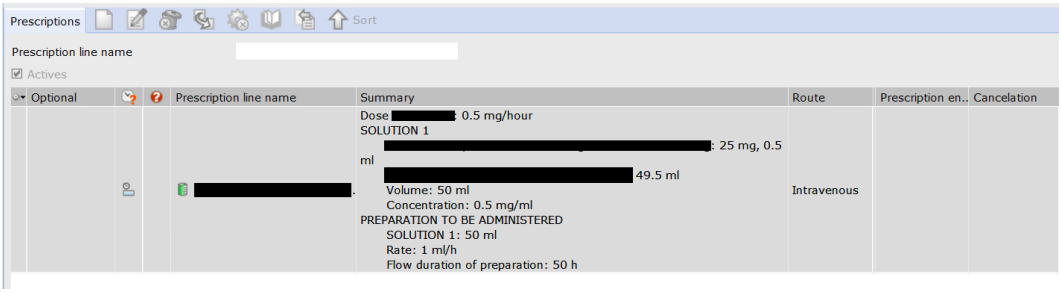
Information:

After updating to ORBIS Medication version 03.22.00.01 in ORBIS version 84.44.00.10 the following issue may occur when prescribing infusion pump protocols using an existing prescription template created before the software update. After the software update, although the prescribed dose of the main medication remains unchanged, the system may automatically modify the configured dilution steps, concentration, and infusion duration in the generated patient prescription. As a result, the prescribed protocol no longer matches its original configuration, leading to inconsistencies between the protocol definition, the administration, and the actual prescription. This may also result in unnecessary increases in fluid volume.

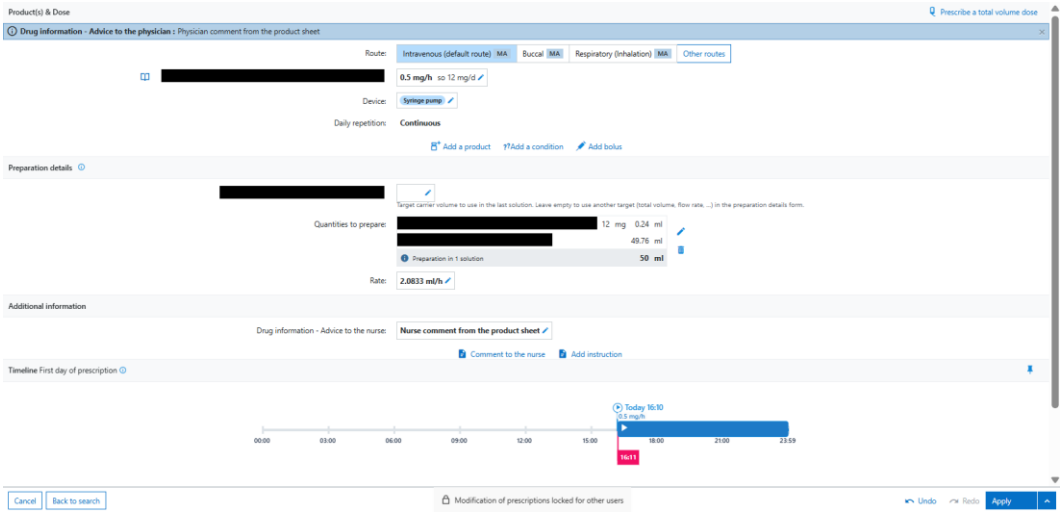
This issue only affects templates created before the update. Templates created after the update are not affected.

Illustrated scenario:

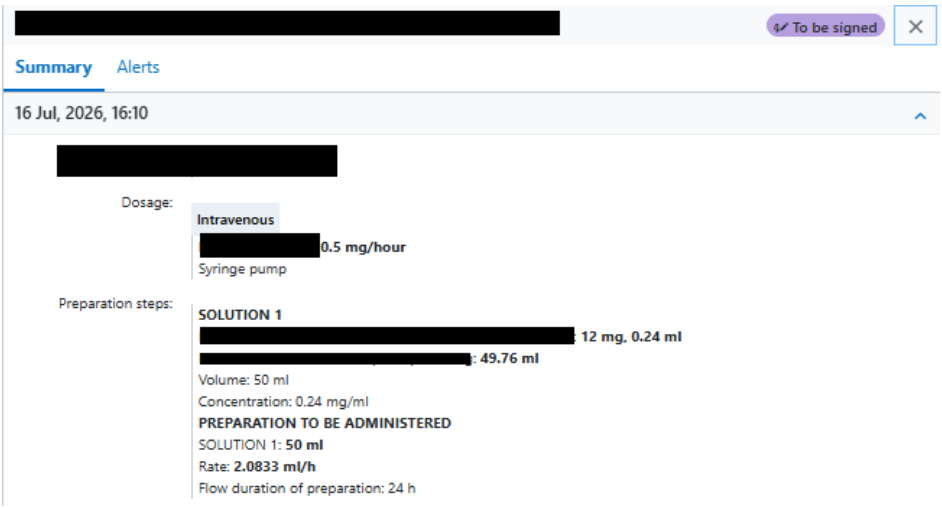
After updating to ORBIS Medication version 03.22.00.01 in ORBIS version 84.44.00.10 a physician opens the prescription screen and selects an infusion pump protocol using an existing prescription template created before the software update



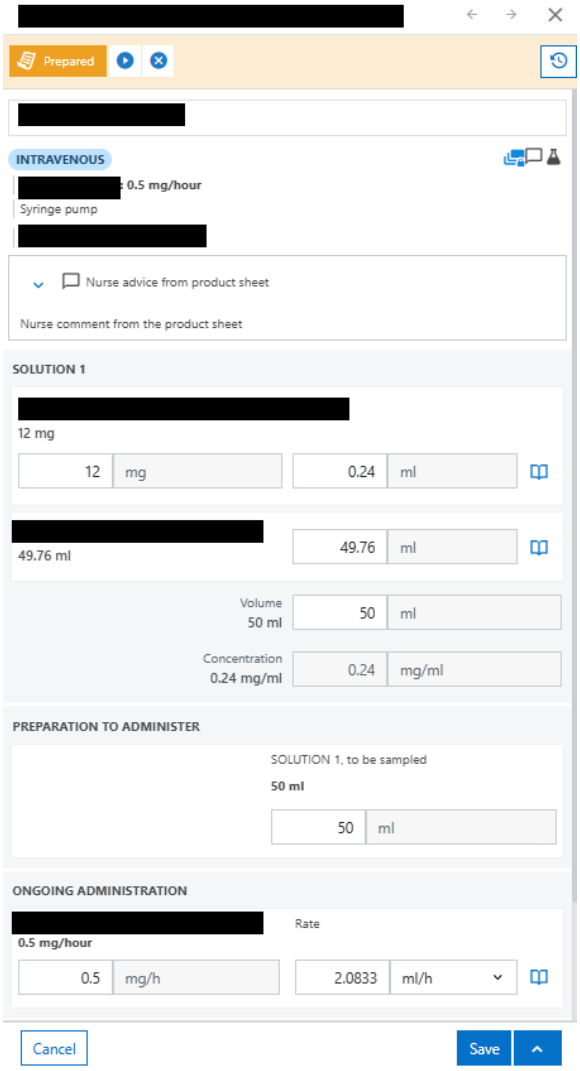
After selecting the prescription template, the prescription should be automatically filled with the protocol configuration.



Instead of applying the configuration exactly as defined in the prescription template, the system may in some cases modify some values in the infusion composition by changing the configured dilution steps, concentration, and infusion duration (not necessarily all three) while keeping the same prescribed dose of the main medication.



As a result, the prescribed infusion no longer corresponds to the configured prescription template, and the administration plan name may display a concentration that does not match the actual prescribed composition.



If the discrepancy from the template is not detected, this behaviour may lead physicians to prescribe an infusion with an incorrect dilution or incorrect amount of fluid volume. For patients requiring strict fluid management, the unintended increase in infusion volume may lead to incorrect treatment.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 04.00.00.00 or higher in ORBIS version 84.44.02.00 or higher (release planned for August 2026 for DACHL).

Recommended actions to be taken by the customer:

- Before installing the correction, create new prescription templates instead of using existing ones when configuring prescription templates.
- As a physician, check carefully and set up the correct preparation details (dilution, concentration, infusion duration, and composition as required) before prescribing.
- Install the correction when available.

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	MST0123048 - When prescribing infusion pump protocols from an existing template some values may no longer match their original configuration after software update
Product reference:	ORBIS Medication
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: