03.05.2024

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: Dose quantities can be mixed-up when prescribing an infusion made of several ingredients

Internal Reference: MST0078932

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

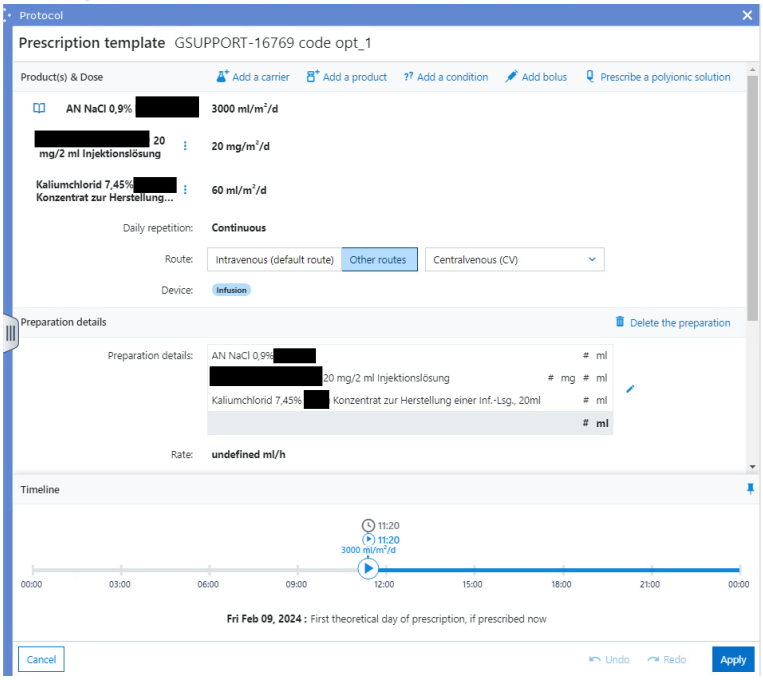
- ORBIS Medication 03.16.00.00 in ORBIS 84.38.00.00, 85.21.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The following behavior, which might occur in rare circumstances when using ORBIS Medication, has been observed:

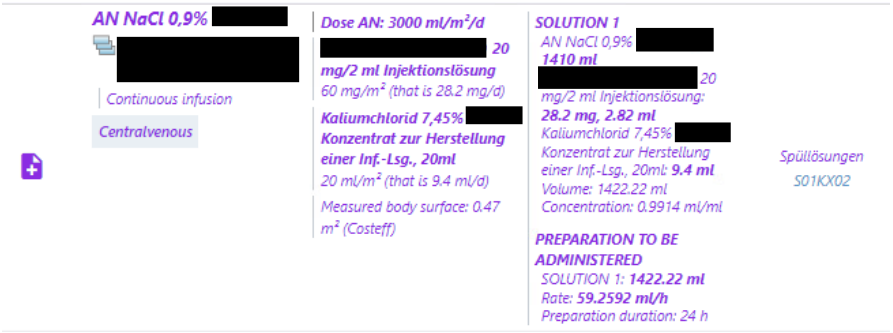
A protocol is configured with several products to be administered by continuous infusion.
The dose of each product depends on the patient's body surface area, for example:

- Product A: 3000 ml/m²/d
- Product B: 20 mg/m²/d
- Product C: 60 ml/m²/d



In rare cases it could happen, that these configured numerical values could be mixed-up when prescribing this protocol containing infusion made of several products, for example:

- Product A: 3000 ml/m²/d
- Product B: 60 mg/m²/d
- Product C: 20 ml/m²/d.



This issue could also occur at modification or duplication of a prescription line with several products. This could lead to erroneous dosages during the prescription.

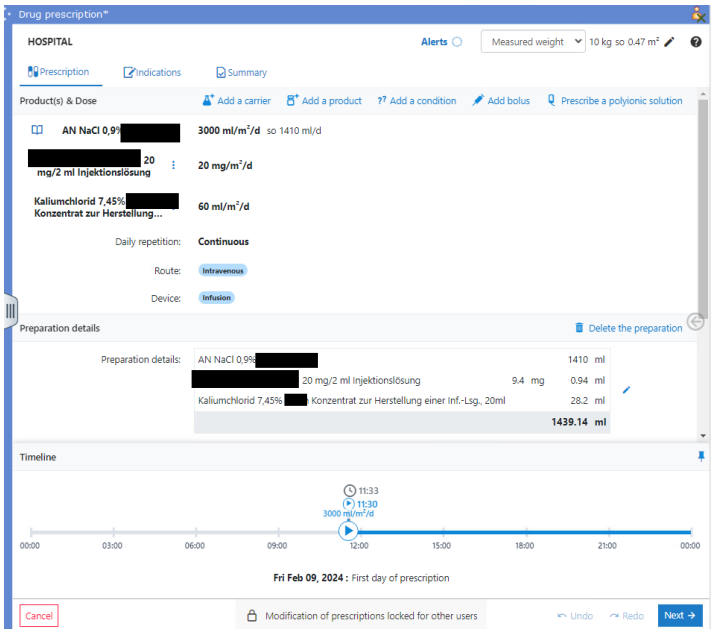
Actions:

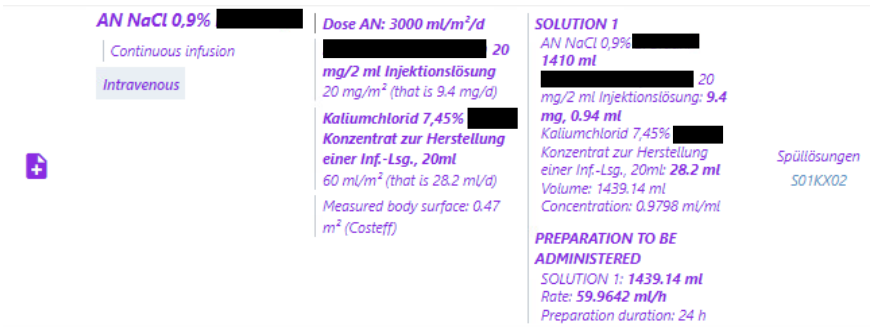
Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.Release of correction with ORBIS Medication version 03.19.02.01 in ORBIS version 84.41.02.01.DACHL (released end of February 2024 for DACHL) and higher.
- Release of correction with ORBIS Medication version 03.19.04.00 in ORBIS version 84.41.00.01.FR and 85.24.00.01.FR (release planned for end of 2024) and higher.

Recommended actions to be taken by the customer:

- As a physician, always check the dose quantities of new prescription lines before signing, and to prescribe the products without using the protocol while using an affected version of ORBIS Medication (pictures below).
- As the person in charge of the configuration of an affected prescription set, deactivate the protocol, delete and re create the prescription line then test the prescription of the protocol (the issue is related to an unwanted event during the registration of the data in the protocol, that mixes-up the products identifiers, then the issue could be resolved by the replacement by a new prescription line).
    - As from ORBIS Medication 3.19.02.01, a query SecondaryProductQuantityInversion is available in ORBIS (menu Query generator) to identify the prescription lines that have the described issue on patient cases, or on protocols.
    - For older versions than ORBIS Medication 3.19.02.01, please contact DH Healthcare GmbH's Support department to identify any prescription lines in a patient case or in existing protocols that contain this problem.
- Install correction when available.





Please distribute this information to all those who need to be aware of it and confirmation the acknowledgement by the signed response form.

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	MST0078932: Dose quantities can be mixed-up when prescribing an infusion made of several ingredients
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: