2023-09-19

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: ORBIS Medication: Adding value for carrier solution leads to two solutions being inserted with same value -> wrong dilution

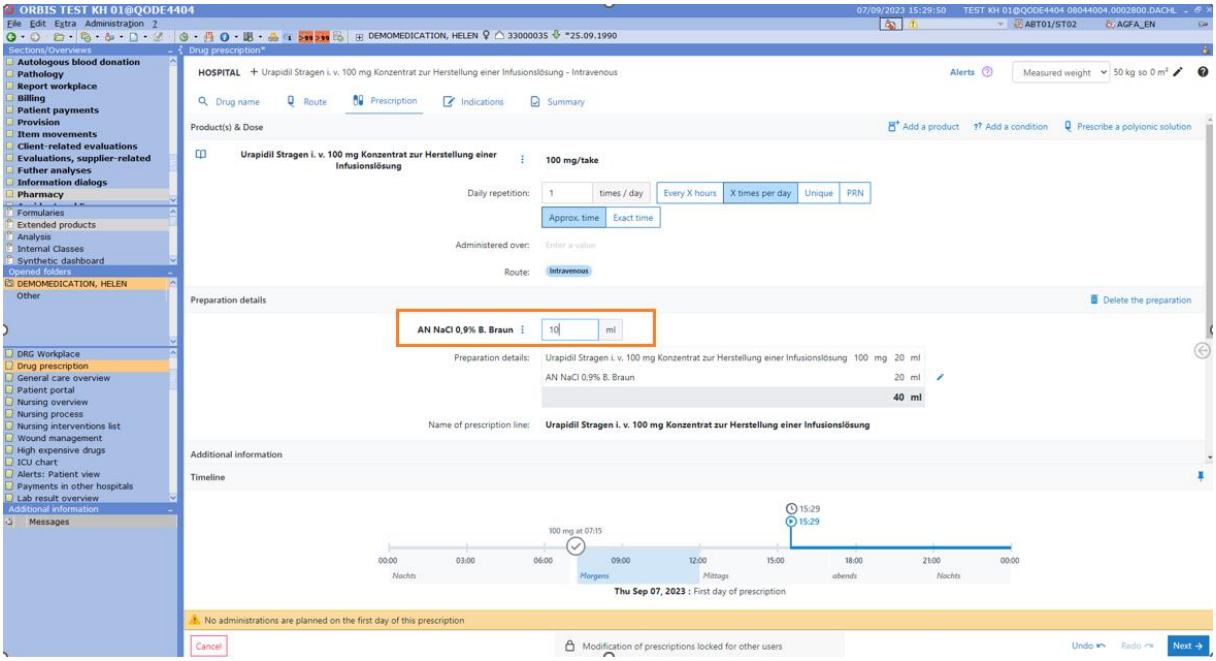
Internal Reference: MST0073175

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

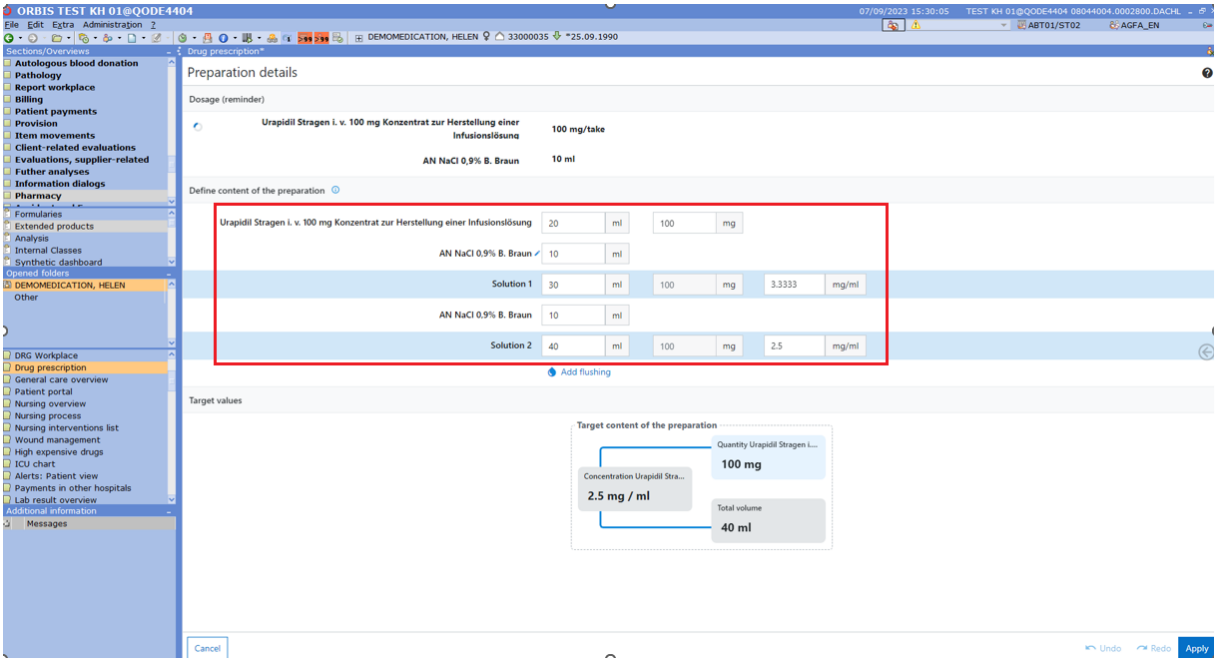
- ORBIS Medication 03.18.02.00 in ORBIS 84.40.02.00 and higher in Germany, Austria, Switzerland, Luxembourg - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

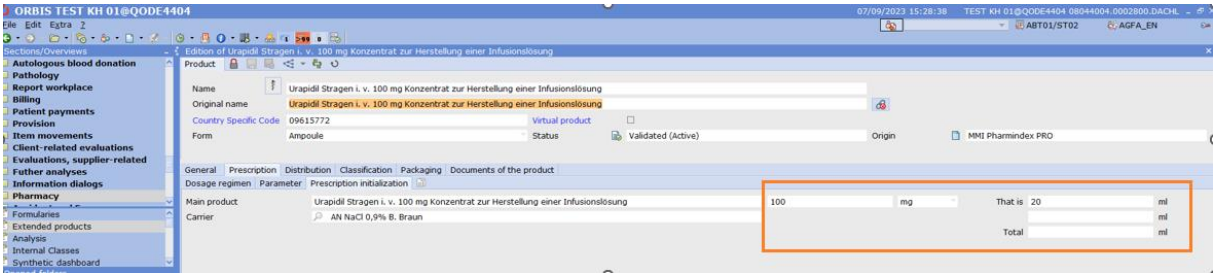
After update to ORBIS Medication 03.18.02.00 or higher , an issue occurs when a product is prescribed with a fixed carrier volume: the preparation details are wrongly initialized, and the physician cannot adapt them properly.



The issue is the following: the drug is prepared with two successive dilutions, the volume of carrier in the first dilution is different from the one defined in product configuration and there is no possibility to prepare the drug in one dilution only.



This wrong initialization of preparation details occurs when the product is configured with a quantity to prepare and (or) a volume of carrier to be used for reconstitution/dilution.



Actions:

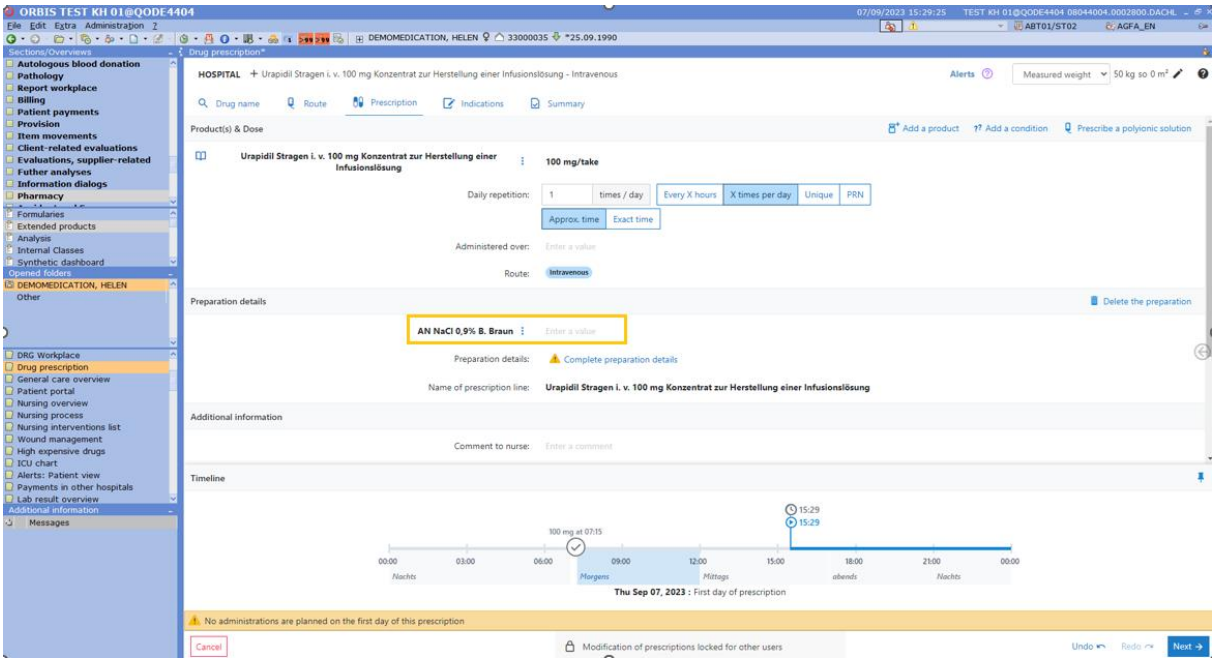
Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.18.03.01 in ORBIS version 84.40.04.03 (general release planned end of October 2023).

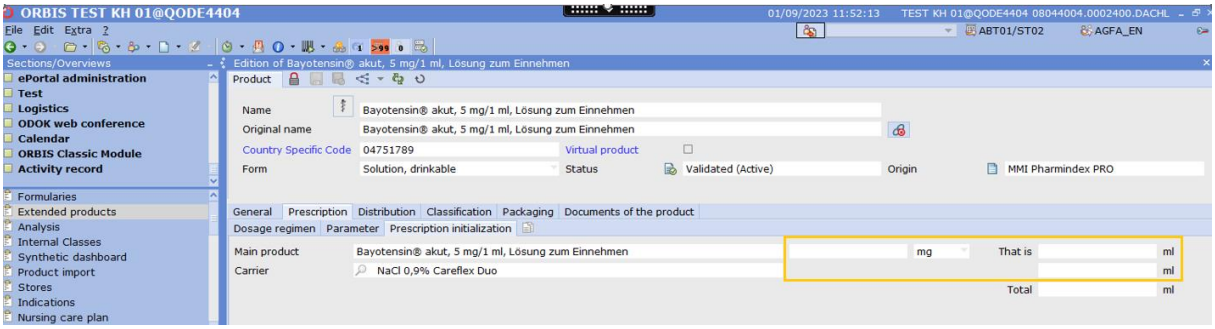
Recommended actions to be taken by the customer:

Before the fix is available:

- When prescribing a product with a configured preparation, do not enter a value for the carrier solution in the prescription "Prescription" tab, but open the preparation details screen with the "Complete preparation details" link, and enter the total volume there.



- Another workaround is to modify the product configuration, and remove all quantities set for the initialization of preparation.



After the fix is available:

- Immediately install the provided correction of the software defect.
- Check if the provided correction solves the described behavior. Please contact DH Healthcare GmbH if you need support.
- In case an update to one of the affected versions is planned: prior to the update, ensure that all users are informed.

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:

<Contact>

Sincerely,

<Name>

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: <Contact>

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities): _____

Address: _____

_____

Reference MST0073175

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: