<DATE>

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: Flow rate not recalculated following modification in patient's weight

Internal Reference: MST0079694

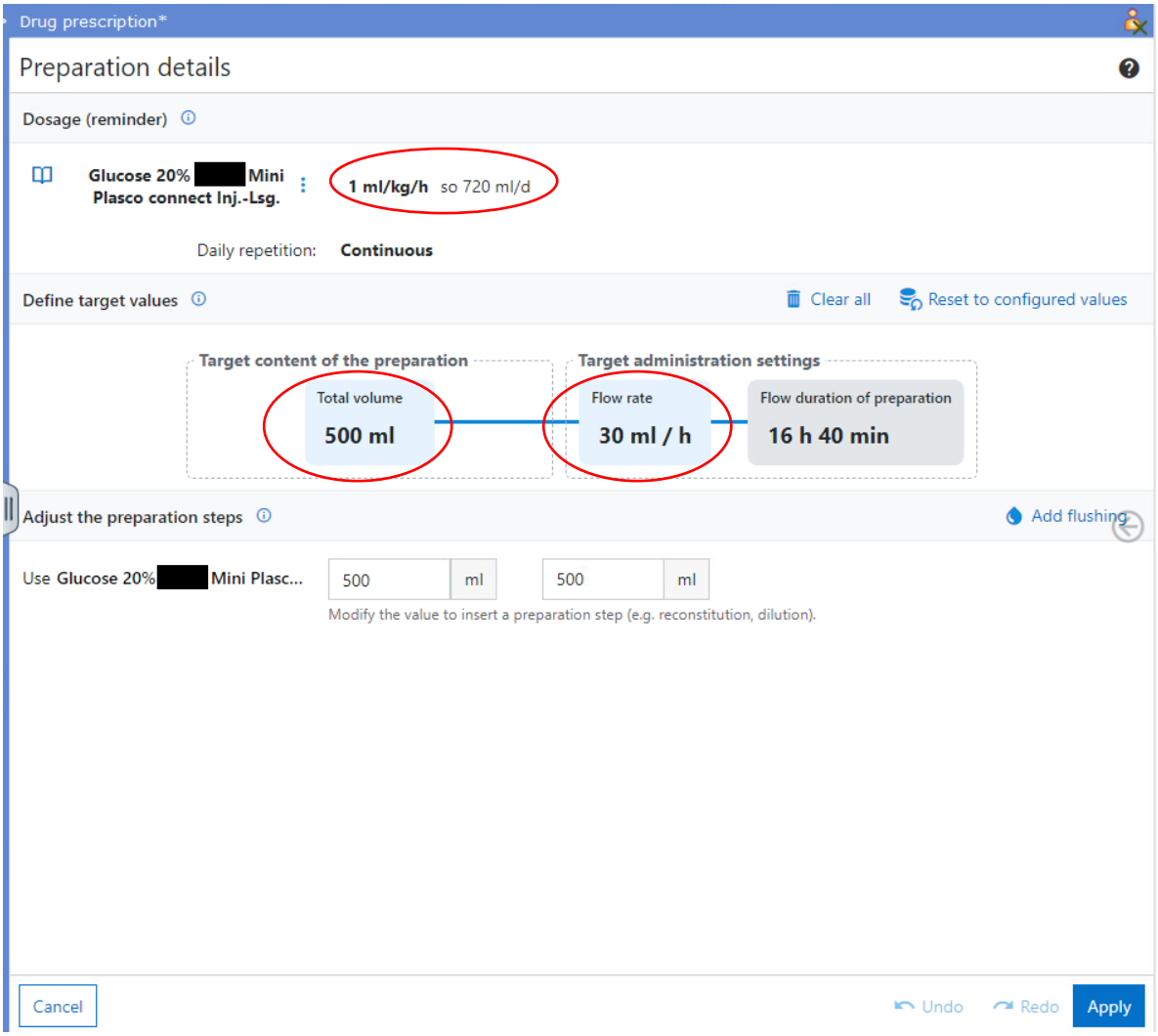
Product name and version(s) and UDI-DI:

- ORBIS Medication 03.16.07.00 in ORBIS 84.38.00.09 and 85.21.00.10 and higher in France
- ORBIS Medication 03.18.03.01 in ORBIS 84.40.04.03 and higher in Germany, Austria, Switzerland, Luxembourg - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The following behavior when using ORBIS Medication has been observed:

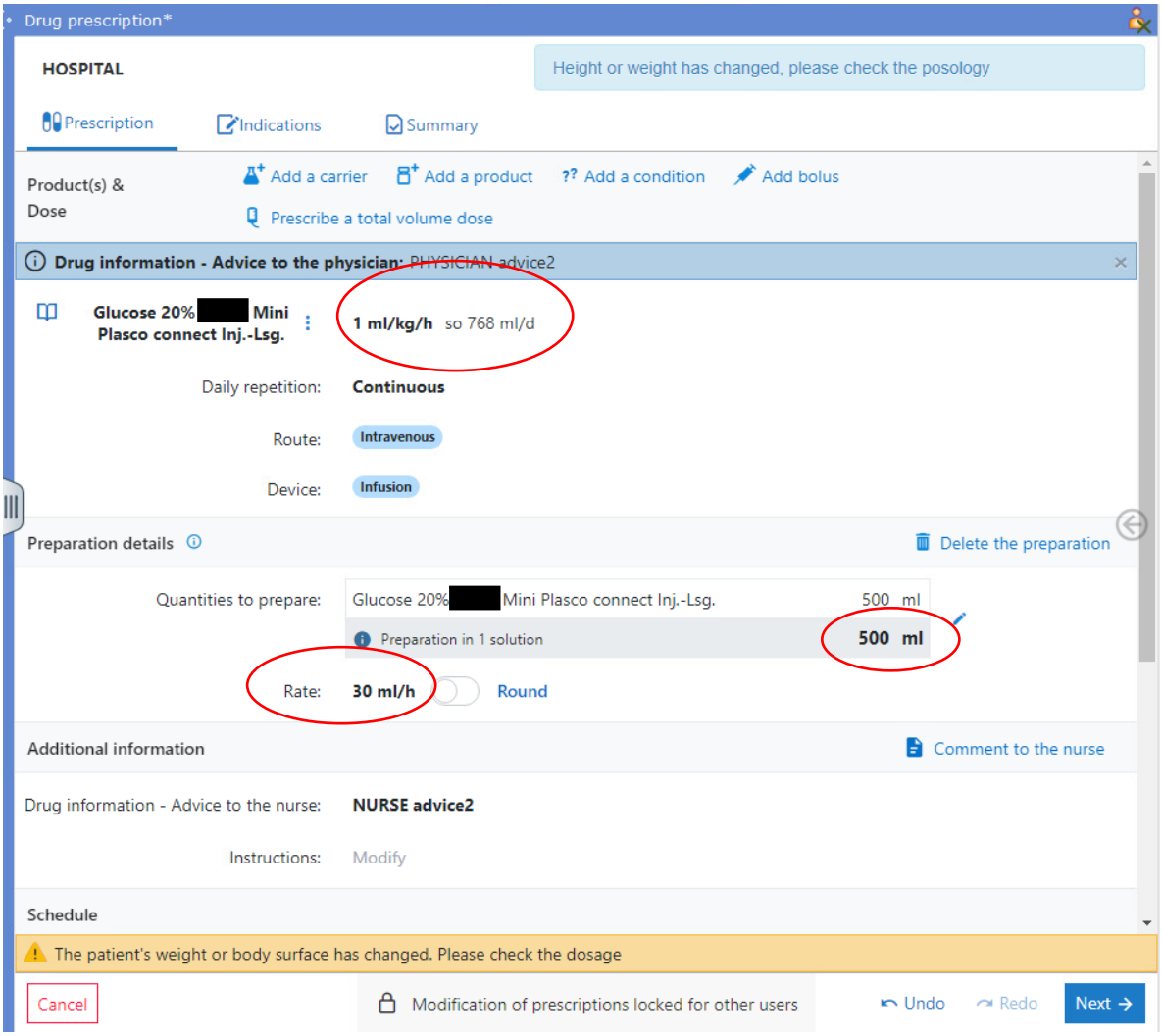
In the new prescription form, a physician prescribes a drug to be administered continuously according to the patient's weight.
He defines a preparation with a fixed quantity of product to be used for administration.



During the creation of the prescription, the patient's weight is modified.

The continuous dose quantity is recalculated according to the patient's new weight.
The flow rate though is not recalculated according to the new weight; its value remains unchanged.
In the example below, the rate value (30 ml/h) is not modified, whereas the dose is modified (was 720ml/d and is now 768 ml/d).

This could lead to prescriptions with wrong dosages.



Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.03.00 in ORBIS version 84.41.03.00 DACHL (released in March 2024) and higher.
- Release of correction with ORBIS Medication 03.19.04.x in ORBIS version 84.41.00.01 and in ORBIS version 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 flow rate obtained. In the event of an abnormal value, delete and recreate the preparation identically in the prescription form.

- 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:

<provide contact details>

Sincerely,

QARA Director – DH Healthcare GmbH

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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: <provide contact details>
Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0079694 - Flow rate not recalculated following modification in patient's weight
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: