13 June 2023

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:

Reference: **MST0066878 -** UP_PRD_ORBIS21_08043901.00040: Incorrect dose displayed in the administration screen and the PTC

Product and Product versions

- ORBIS Medication 03.17.00.00 in ORBIS 84.39.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
- ORBIS Medication 03.17.00.00 in ORBIS 85.22.00.00 and higher in France - Manufacturer: DH Healthcare GmbH

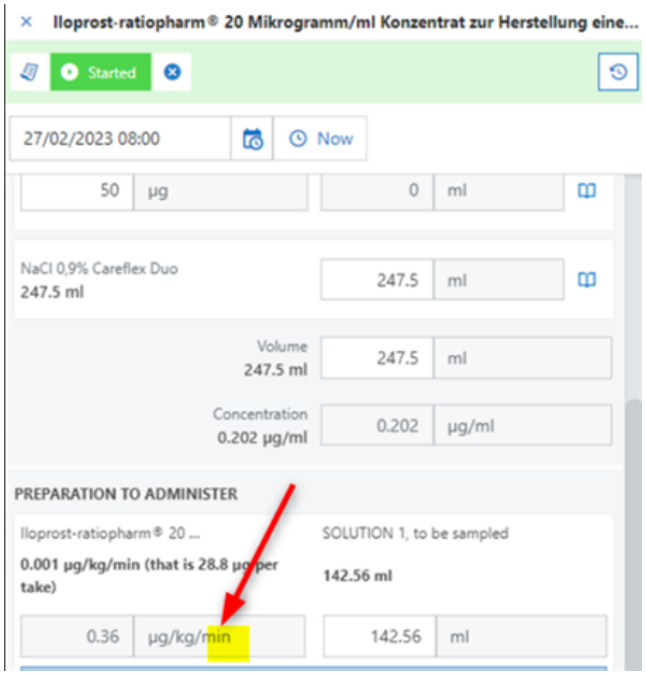
Information:

After update to ORBIS Medication 03.17.00.00, users have faced the following behaviors:

When a physician prescribes in the old prescription form, a dose/kg/minute as discontinuous with duration, the wrong unit of main product dose is displayed in the administration screen and in the Patient chart (PTC).

As an example, if the physician prescribed a 6-hour infusion as 0,001 microgram/kg/min:

In the administration screen, the preparation consists of one dose of main product 50 micrograms diluted in a solvent of 247,5 ml.
The concentration of the preparation is then 0.202 micrograms/ml.
The patient is 80 kg. He must therefore receive 28.8 micrograms per take.
For this, 142,56 ml of the preparation must be administered to the patient, which corresponds to 0,36 micrograms/kg.
The unit of the main product dose in the section 'Preparation to administer' is incorrect: It should be '0,36 microgram/kg' instead of '0,36 microgram/kg/min', and the dose displayed in the blue banner at the bottom of the screen should be in micrograms per take instead of microgram/min.
In the Patient chart the unit of the take displayed is also wrong: 'microgram/take' should be displayed instead of 'dose/minute'".



Remark: In the new prescription form, it's not possible to prescribe in 'dose/kg/minute' for a discontinuous with duration. A prescription with this unit is only possible for continuous.

Workaround:
Use the new prescription form.

Measures:

Steps by DH Healthcare GmbH

- Inform customers and provision of workaround with this letter.
- Release of the correction with version
  - ORBIS Medication 03.18.00.00 in ORBIS version ORBIS 84.40.00.00.DACHL (released on 9 June 2023)
  - ORBIS Medication 03.19.00.00 in ORBIS 84.41.00.00.FR (release planned for second quarter of 2024) and ORBIS 85.24.00.00.FR (release planned for second quarter of 2024)

Steps to be taken by customers

Before the correction is provided:

- Share this information with all users who might be concerned.
- Ensure that all users are fully aware of the workaround described above in this letter.
- In case an update to one of the affected versions is planned: ensure that all users are informed – prior to the update - on the situation described in this letter (see section "Workaround").

Once the correction has been provided:

- Immediately install the provided correction of the software defect.
- Check if the provided correction solves the described behavior. Please contact DH Healthcare GmbH in case you need support.

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>

L'équipe Support

<CONTACT>

Kind regards,

<CONTACT>

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	MST0066878
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: