02.02.2023

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue that has already been reported to the local responsible authority:

Reference: **MST0063731-** ORBIS Medication: Incorrect dose displayed in the administration screen and the Patient Chart (PTC)

Product and Product versions

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

Information:

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

In the case of a prescription that is prescribed as “discontinuous with duration” and contains a cascaded dilution (e.g., with reconstitution), the administration documentation dialog displays an incorrect dose in the field “dose”.

Example: The prescription of Vancomycin 1000mg is aiming at a dosage of 50mg/kg bodyweight for a patient of 16kg. The main drug (Vancomycin 1000mg) is reconstituted in a solution of 10ml Aqua (solution 1). From this dilution, 8ml are taken out and diluted in 42ml sodium chloride (solution 2). This would result in a dose of 800 mg to be administered. This is correctly displayed in drug preparation dialogs, but the administration documentation dialog is showing incorrect values of 1000 mg next to the correct ones since the calculation is erroneously based on the dose of product to be reconstituted (1000mg)

There is a risk that patients would receive a wrong dose due to this inconsistent display, if administrating users would use the administration dialog to inform themselves on the required dose, instead of only documenting the administration that has already taken place according to drug preparation.

Measures:

Steps taken by DH Healthcare GmbH

- Information of customers by help of this letter
- Release of the correction with version
  - ORBIS Medication 03.17.01.02 in ORBIS version ORBIS 84.39.01.03 DACHL on 04 January 2023,

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:

Support.ORBISMedizinprodukte.DACH@dedalus.com

Kind regards,

[redacted]
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: feedbackmanagement@dedalus.com
Thank you for your cooperation.

Customer / Facility: _____

Address: _____

_____

Reference MST0063731

Product reference: ORBIS Medication

☐ 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:

Customer

_____

Name: _____

Position: _____

Signatur: _____

Date: _____

Phone number: _____

☐ Please update our contact information as follows

Customer / Facility:

Address: