2023-10-26

# 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: A dosage appears instead of "0.5" with a dosage of "0"

Internal Reference: MST0073458

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

- ORBIS Medication 03.17.00.00 in ORBIS 84.39.00.00 and higher in France, Germany, Austria, Switzerland, Luxembourg - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026
- ORBIS Medication 03.17.00.00 in ORBIS 85.22.00.00 and higher in France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

## Information:

After update to ORBIS Medication 03.18.02.00 or higher, an issue occurs in the new prescription form when first a multidose is filled in slowly with a zero value for one dose, and with a decimal for another dose (e.g., 1-0-0.5).
As a result, an error is displayed without explanation, and the decimal dose is considered like a zero value in the prescription summary (e.g., 1-0-0).

## Actions:

**Actions undertaken by DH Healthcare GmbH:**

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.00.00 in ORBIS version 84.41.00.00.DACHL (general release planned for mid-November 2023).
- Release of correction with ORBIS Medication version 03.17.05.00 in ORBIS version 84.39.00.x.FR and 85.22.00.x.FR (general release planned for first quarter 2024).

**Recommended actions to be taken by the customer:**

Before the fix is available:

- We can recommend using a fraction to set a multidose having a zero value and a decimal quantity (e.g., 1-0-½).

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 MST0073458

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:



DH Healthcare GmbH
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