

08-08-2024

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: Decimal number automatically converted to a whole number during input

Internal Reference: MST0082701

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

- ORBIS Medication 03.16.x in ORBIS 84.38.x, ORBIS Medication 03.17.x in ORBIS 85.22.x and higher in France -Manufacturer: DH Healthcare GmbH
- ORBIS Medication 03.19.x in ORBIS 84.41.x and higher in Germany, Austria, Switzerland and Luxembourg
Manufacturer: DH Healthcare GmbH

UDI-DI: 4260693990026

Information:

While a physician is entering a dose with decimals in the prescription form, with one second pausing between each digit, then the value is automatically converted.

For the dose field in a conditional schema, the issue occurs as soon as a decimal separator is entered. E.g.: When, in the dose field of a conditional schema, the user enters the value "0." followed by "5" one second later (meaning "0.5"), then the resulting value becomes 5, as the 0 and the comma are automatically removed because of the typing delay.

For other dose or volume fields of the prescription form, the issue occurs as soon as a decimal separator is entered followed by a 0.

E.g.: When, in the main product dose field, the user enters the value "1.0" followed by "5" one second later (meaning "1.05"), then the resulting value becomes 15, as the dot and the 0 are automatically removed because of the typing delay.

This behavior occurs for all dose or volume fields available in the prescription form:

- Main product dose
- Additional product dose
- Carrier volume
- Product quantity, or volume in preparation details
- Initial bolus dose

- Additional bolus dose
- Maximum dose for administrations without scheduling (aka PRN prescription)
- Total volume dose

In a conditional schema, the user can observe that "0." is removed before he enters the decimal digit "5".

By typing more quickly a number with decimals digits (without pausing between each digit), then the correct value "0.5" is displayed without any automatic conversion when typing characters. If the user doesn't recognize that the value is automatically converted, this might lead to an overdose.

If the user enters a fraction dose, even slowly (E.g.: "1/2"), the fraction-slash "/" is not removed and the dose remains correct.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.x in ORBIS versions 84.41.00.x and 85.24.00.x and higher in France (release planned for first half of 2025).
- Release of correction with ORBIS Medication version 03.20.x in ORBIS version 84.42.x and higher (release planned for end of 2024 for DACHL).

Recommended actions to be taken by the customer:

- As a physician, enter decimal digits quickly (without pausing between each digit) and always check the value entered to correct it, if necessary.
- Install the correction when available.

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:

[<provide contact details>](#)

Sincerely,

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: [<provide contact details>](#)
Thank you for your cooperation.

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

Address:

Reference

MST008701 - Decimal number automatically converted to a whole number during input

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: