20.08.2026

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:

Administration blocked by error message in some cases of rounded weight-based prescriptions.

Internal Reference: MST0122757

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

- ORBIS Medication 03.21.02.01 and higher in ORBIS 84.43.06.00 and higher in Germany, Austria, Switzerland, Luxembourg and UK.
- ORBIS Medication 03.21.03.00 and higher in ORBIS 84.43.02.00 and higher and in ORBIS 85.26.02.00 and higher in France.
  - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

Under the circumstances described below, ORBIS Medication may prevent the documentation of an administration resulting from a prescription using the weight-based dose calculation functionality when the calculated dose is manually rounded during prescribing.
This issue may occur for administrations requiring preparation using weight-based prescribing (mg/kg).

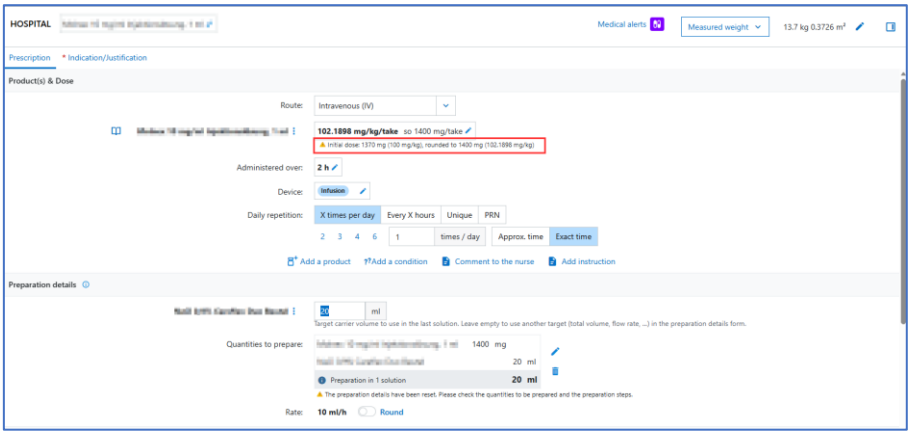

Figure 1 : Prescription line with weight-based dose calculation functionality and the calculated dose manually rounded.

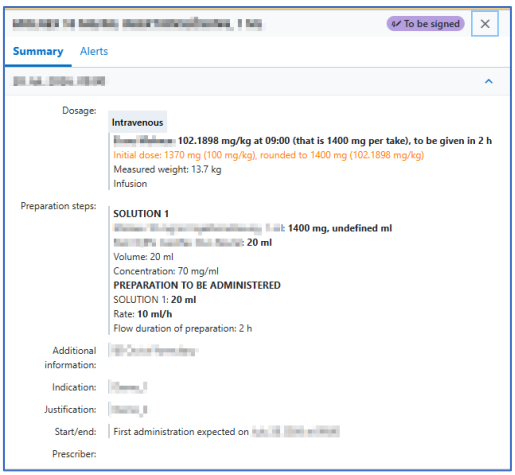

Figure 2 : Prescription summary with rounding dose information

When the administration screen is opened an error message may indicate that the administered dose exceeds the prescribed dose, preventing the administration from being started.

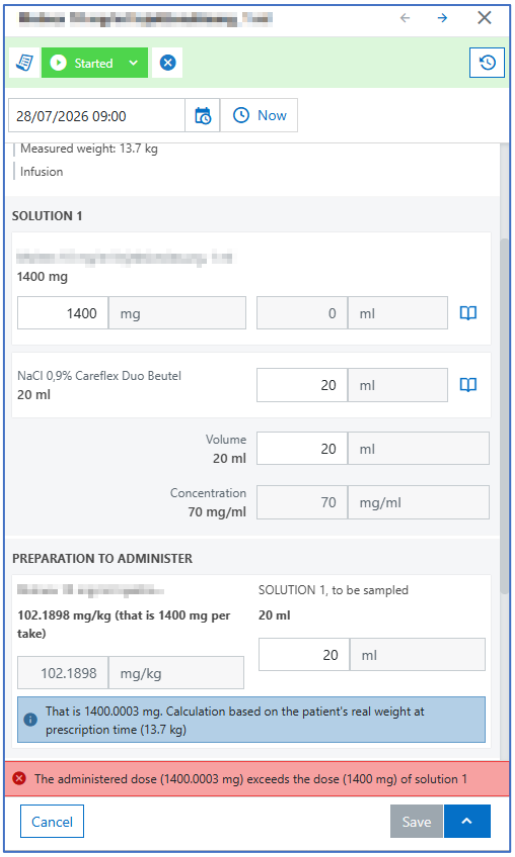

Figure 3 – Display of the blocking message at administration time.

Depending on the values, the issue may occur for this specific combination:

- Administration for a prescription with calculated weight-based dose;
- Manually rounded total prescribed dose.

The error message results from an internal calculation discrepancy related to numerical rounding, typically in the order of a few thousandths of a milligram which may be slightly higher than the prescribed dose and prevents the administration from being confirmed. This discrepancy reflects only the numerical precision of the calculation and does not represent a clinically significant overdose or underdose.

If this issue occurs, documentation of the administration in the system is delayed.
Depending on the medication, its therapeutic indication, and the patient's clinical condition, the described behavior may result in delayed patient care with potential clinical impact

The likelihood of occurrence is limited, as the issue only affects some specific combinations of patient weight calculated dose, and manually rounded prescribed dose.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 04.00.00.01 or higher in ORBIS version 84.44.02.00 or higher for DACHL (release planned for third quarter of 2026).
- Release of correction with ORBIS Medication version 04.00.01.00 or higher in ORBIS version 84.44.04.00 or higher for UK (release planned for first quarter of 2027).
- Release of correction with ORBIS Medication version 04.00.01.00 or higher in ORBIS version 84.44.02.00 or higher and in ORBIS version 85.44.02.00 and higher for FR (release planned for first quarter 2027).

Recommended actions to be taken by the customer:

- Until the software correction has been installed, healthcare professionals should be aware that this issue may occur when using the weight-based dose calculation functionality with manually rounded doses.
- If the administration cannot be started in the system because of this error, the prescribing physician should temporarily avoid using the weight-based dose calculation functionality and instead create a new prescription by manually entering the required dose in the prescription dose field.
- 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:

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:
Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference:	MST0122757 - Administration blocked by error message in some cases of rounded weight-based prescriptions.
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: