

02.04.2026

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: In some cases additional administration tasks may be created after prescription stop

Internal Reference: MST0111121

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

- ORBIS Medication 03.21.01.02 in ORBIS version 84.43.02.00 and higher in Germany, Austria, Switzerland and Luxembourg.
- ORBIS Medication 03.21.02.01 in ORBIS version 84.43.04 and higher for UK.
- ORBIS Medication 03.21.03.00 in ORBIS version 84.43.02.00. and 85.26.02.00 and higher for France.

Manufacturer: DH Healthcare GmbH

UDI-DI: 4260693990026

Information:

In ORBIS Medication, the following issue occurs if, and only if:

- a drug is prescribed with administrations scheduled at fixed intervals, and
- this prescription contains at least one intake that is already documented as prepared, and
- no intake of this prescription has been documented as administered before, and
- the prescription is then stopped at a point of time before the first administration.

In this constellation the system generates an additional administration at the exact time the stop action is recorded. Additionally, the next prepared administration remains active in the chart. This behaviour only occurs when no intake of this prescription has been documented as administered before. As soon as one intake has been documented as administered – for instance at the end of a usual drug treatment with fixed intervals - the system behaves as usual, meaning no additional intake is created.

Illustrated scenario:

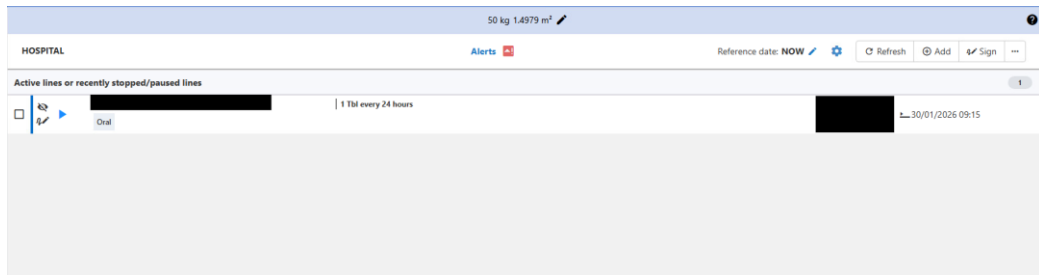
A physician prescribes a product with administrations scheduled at fixed intervals. The first administration is planned for the following day. The prescription is then signed by the physician.

1 / 5

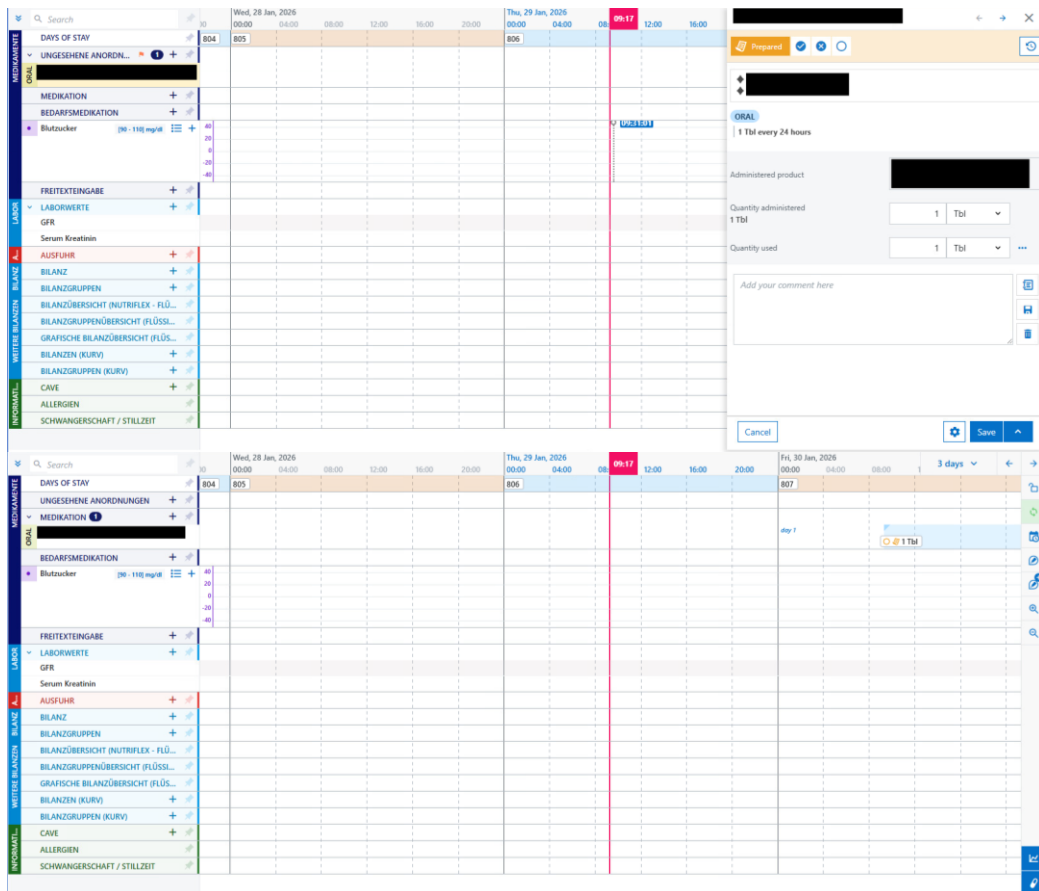
URGENT FIELD SAFETY NOTICE - MST0111121

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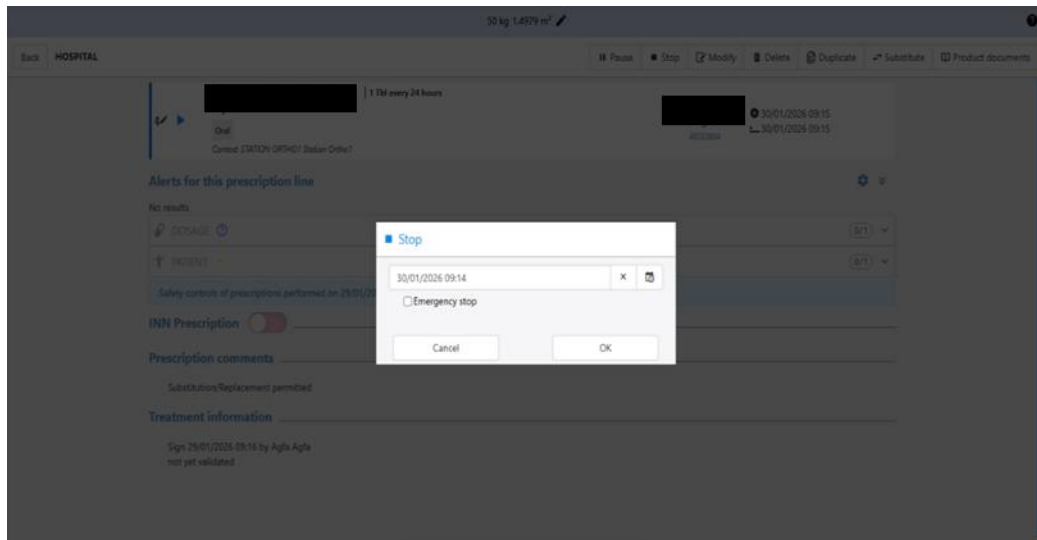
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In the Patient Chart, a nurse selects the first scheduled administration. The administration is set to “Prepared” status.

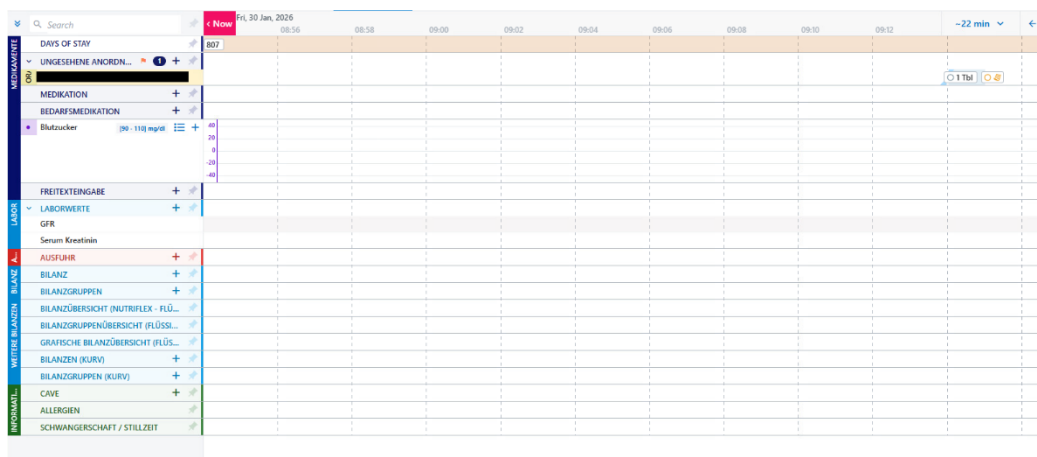
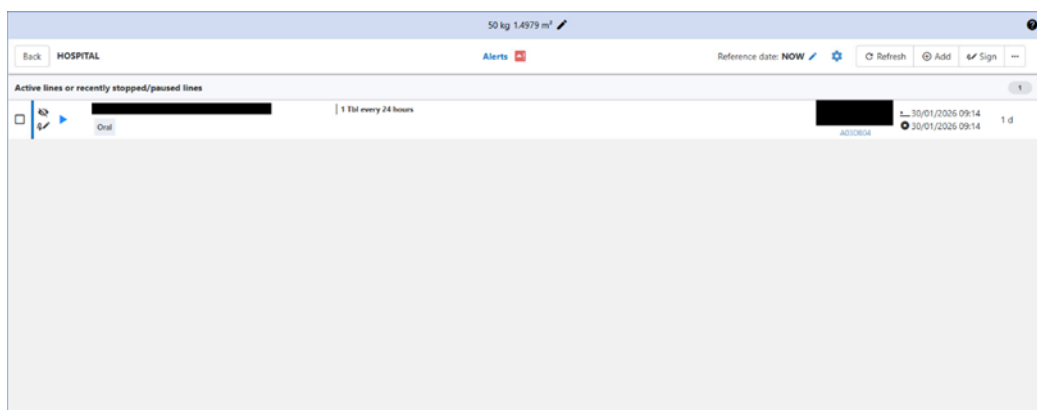


Before the first administration takes place, the physician stops the prescription. The stop date is automatically set before the first scheduled administration.



After the prescription is stopped, the actual, unexpected, result is the following:

- The next administration task previously set to **“Prepared”** remains visible in the Patient Chart.
- An **additional administration task** is created at the time the prescription is stopped.



URGENT FIELD SAFETY NOTICE - MST011121

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In the specific constellation of conditions described on page 1, this behaviour leads to an administration task, related to a stopped prescription, that may remain visible in the Patient Chart and the creation of an additional administration task. If this unintended behaviour occurs and remains undetected, both administration tasks (prepared one and additional one) may still be administered even though the prescription has been stopped before.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction for DACHL and UK with ORBIS Medication version 03.22.00.00 or higher in ORBIS version 84.44.00.00 or higher (release planned for second quarter of 2026 for DACHL and in the second half of 2026 for UK)
- Release of correction for FR with ORBIS Medication version 04.00.00.00 or higher in ORBIS version 84.44.02.00 and 85.44.02.00 or higher (release planned for first quarter of 2027 for FR).

Recommended actions to be taken by the customer:

- As a physician or nurse, in case of prescriptions scheduled with fixed intervals, with no intake documented as administered yet, and at least one intake documented as prepared, please check that the current status of the prescription in the Patient Chart is not stopped, before administering any prepared task. In particular, be cautious if you see not prepared intakes at odd times (e.g. 11:59 or 13:14) before an already prepared intake in the Patient Chart, especially for prescriptions that are usually prescribed with fixed intervals (e.g. antibiotics).
- 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

MST0111121- In some cases additional administration tasks may be created after prescription stop

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: