

14.01.2026

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: Anomaly when modifying a prescription line with a repeat every x days, the interval is not taken into account anymore

Internal Reference: MST0109357

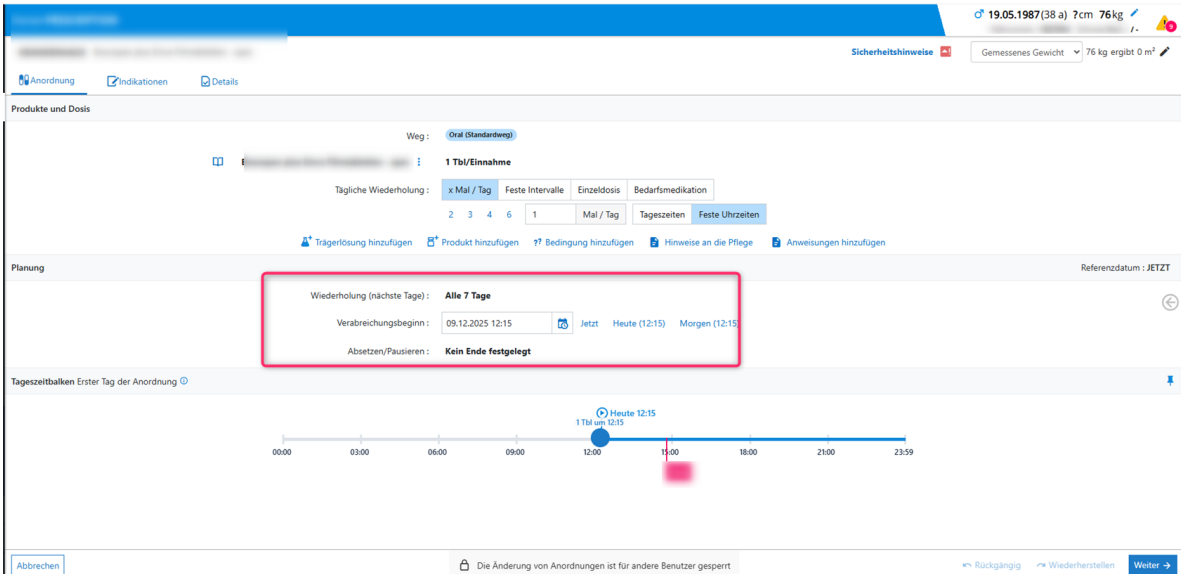
Product name and version(s) and UDI-DI:

- ORBIS Medication 03.19.00.00 in ORBIS 84.41 and higher in Germany, Austria, Switzerland and Luxembourg.- Manufacturer: DH Healthcare GmbH

Information:

A prescription line is defined with a repeat interval of every x days.

View of the prescription line:



The screenshot shows a software interface for managing prescriptions. At the top right, patient information is displayed: 19.05.1987 (38 a), 7cm, 76kg. Below this, there are tabs for 'Anordnung', 'Indikationen', and 'Details'. The main section is titled 'Produkte und Dosis' and shows a prescription for '1 Tbl/Einnahme' with a daily frequency of 'x Mal / Tag'. The 'Tägliche Wiederholung' section has tabs for 'x Mal / Tag', 'Feste Intervalle', 'Einzelosis', and 'Bedarfsmedikation'. The 'Feste Intervalle' tab is selected, showing a value of '1' and 'Mal / Tag'. Below this, there are buttons for 'Trägerlösung hinzufügen', 'Produkt hinzufügen', 'Bedingung hinzufügen', 'Hinweise an die Pflege', and 'Anweisungen hinzufügen'. The 'Planung' section shows 'Wiederholung (nächste Tage): Alle 7 Tage' highlighted with a red box. Below this, there are fields for 'Verabreichungsbeginn: 09.12.2025 12:15' and 'Absetzen/Pausieren: Kein Ende festgelegt'. At the bottom, there is a 'Tageszeitbalken' (daily time bar) showing a timeline from 00:00 to 23:59, with a blue dot at 12:15 and a red dot at 15:00. The interface also includes an 'Abbrechen' button and a footer with a lock icon and the text 'Die Änderung von Anordnungen ist für andere Benutzer gesperrt'.

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URGENT FIELD SAFETY NOTICE – MST0109357

DH Healthcare GmbH

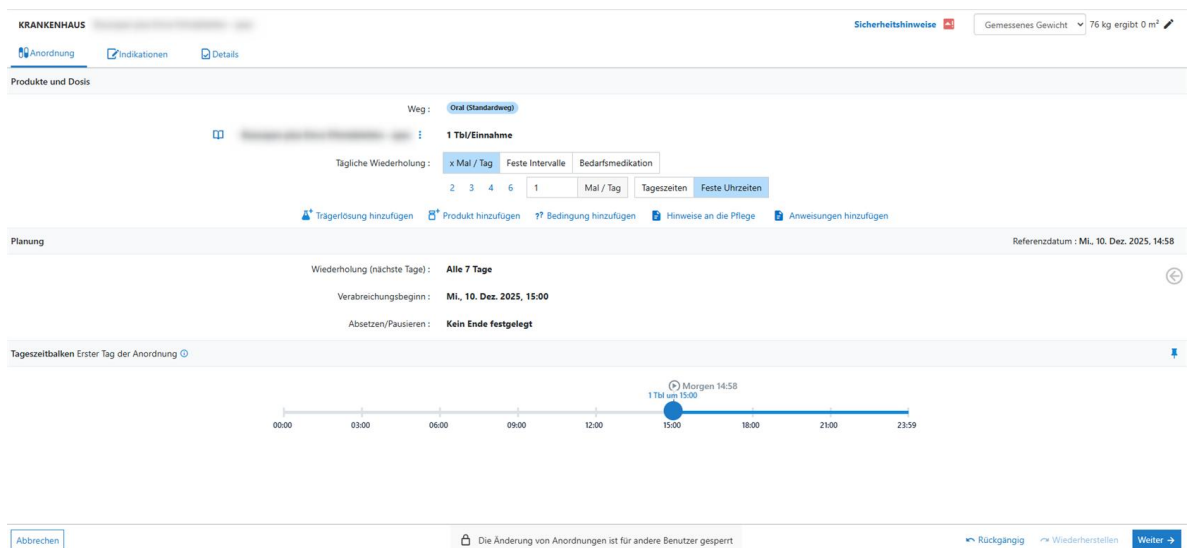
Konrad-Zuse-Platz 1-3, 53227 Bonn

View of the take in the patient chart:



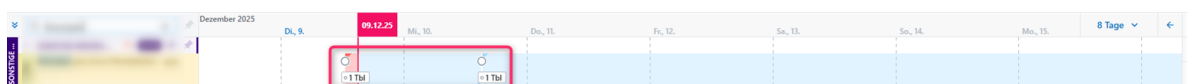
When this prescription line was modified by a physician during the interval by clicking on the button modify, the application did not correctly take this interval into account. In fact, the system incorrectly added an additional dose on the date the prescription line was modified without taking into account the interval initially prescribed.

Hypothetical view of the prescription line after clicking on modify:



This behavior can lead to a risk of overdose.

View of the takes in the patient chart after signing the modified prescription line:



Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.21.02.01 or higher in ORBIS version 84.43.06.00 DACHL or higher (release planned for first quarter of 2026).

Recommended actions to be taken by the customer:

- Avoid modifying a prescription in the middle of an interval when it uses a “every X days” repeat.
- Make adjustments at the end of the current interval.
- 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:

MST0109357 - Anomaly when modifying a prescription line with a repeat every x days, the interval is not taken into account anymore

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: