

25.04.2025

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: Prescription in fixed intervals with a duration can be started in patient chart even if stopped before first administration

Internal Reference: MST0097252

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

- ORBIS Medication 03.20.04.00 in ORBIS 84.42.06.00 and higher in Germany, Austria, Switzerland, and Luxembourg - Manufacturer: DH Healthcare GmbH
UDI-DI: 4260693990026

Information:

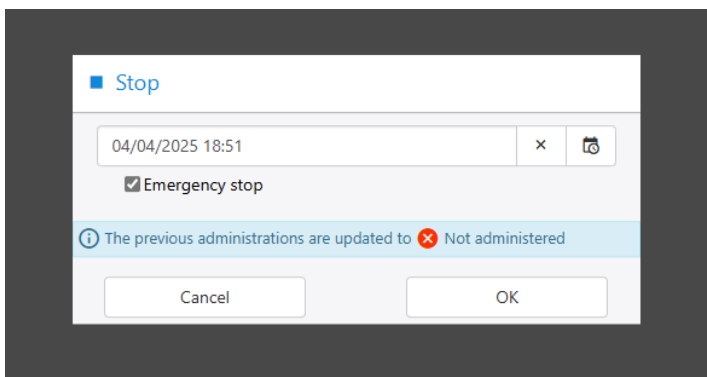
A physician prescribes a drug with duration in fixed intervals in a patient record. The first dose is automatically planned to be started at prescription start. Immediately after, the physician stops or stops with emergency the prescription line before this first administration. Despite this action, the drug is still administrable in the patient chart.

Illustrated scenario of one example with emergency stop:

- A physician prescribes a patch and signs the prescription. The first dose is planned when the prescription begins.



- Then, the physician performs an emergency stop immediately afterwards.

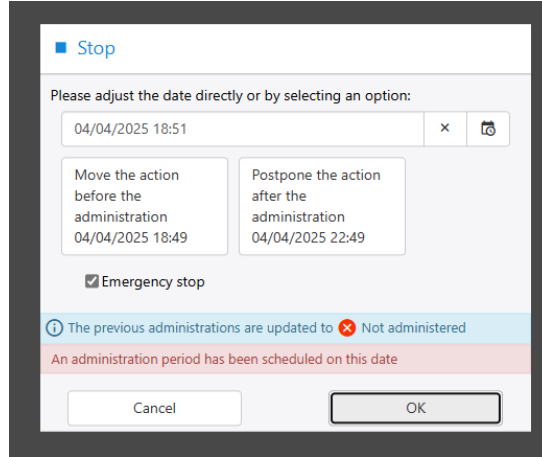


URGENT FIELD SAFETY NOTICE - MST0097252

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- The system warns the physician that the action is not possible because an administration is scheduled at the same time. The physician is invited to change his action before or after the scheduled administration.



- The physician chooses to move the action to before the administration and signs. As a result, the administration must disappear, since the stop occurs beforehand.

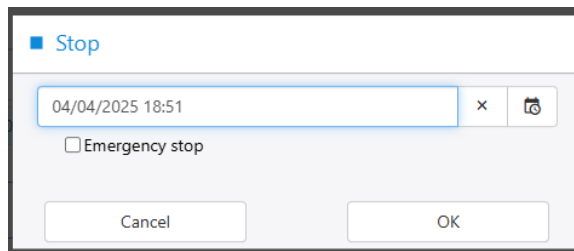


- In the patient chart, the patch can be started despite this emergency stop.



Remark: The issue can also occur

- When the physician stops normally the prescription which means stop the prescription line without selecting the emergency checkbox.



- For drugs prescribed with a duration and in fixed intervals (example: infusion with duration in fixed intervals).



Potential risk: drug could be administrated even if associated prescription is stopped.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.21.00.00 in ORBIS version 84.43.00.xx or higher (release planned for third quarter of 2025 for DACHL).

Recommended actions to be taken by the customer:

- As a physician, please delete the prescription line to delete administration task instead of doing a stop action (normal or emergency).
- 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

MST0097252: Prescription in fixed intervals with a duration can be started in patient chart even if stopped before first administration

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: