09.06.2025

# 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: Potential change in number of doses when rescheduling globally a prescription with fixed interval and end date

Internal Reference: MST0099729

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

- ORBIS Medication 03.06.00.00 in ORBIS version 84.28.00.00 and 85.11.00.00 and higher in ORBIS in Germany Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

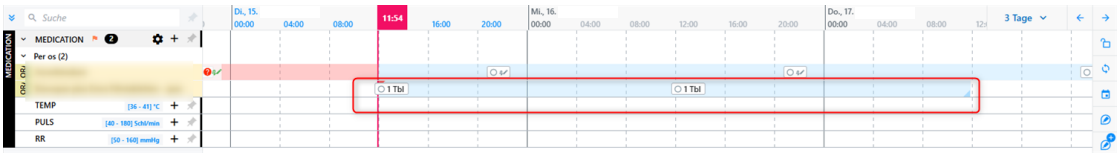
## Information:

A behavior has been identified that only occurs when a physician creates a prescription line with the following preconditions:

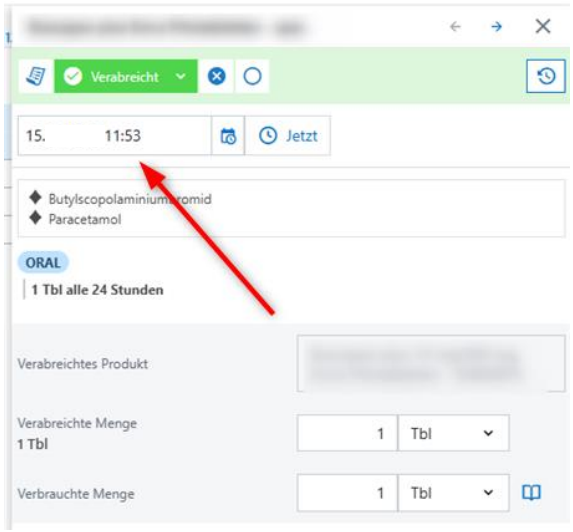
- A prescription has a defined prescription period start and prescription period end date
  - (In the example below the prescription is valid from day 15th at 11:53, for two days, to the 17th at 11:52).
- Intakes are defined on a fixed interval: (e.g. every 24 hours)
  - (Therefore, in the example the first planned administration is on the 15th at 11:53. The second planned administration is on the 16th at 11:53).

Currently the system takes the prescription period (valid from – to) to display the planned intakes. A rescheduling of the first intake before prescription start can lead to a display of an additional intake at the end of the prescription period.

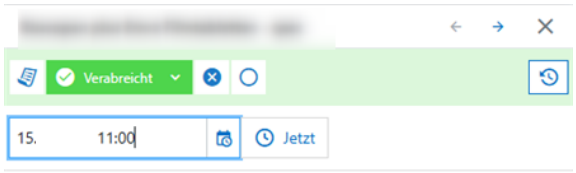
The physician signs the prescription line. At this stage, 2 intakes are displayed in the patient chart in this illustrated example: one on the first day (15th) and a second one on the second day (16th).



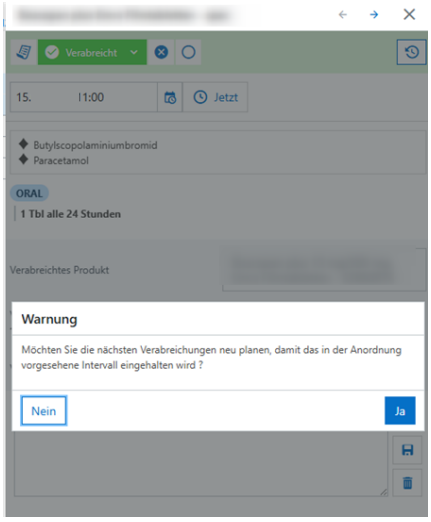

The nurse administers the first intake earlier (at 11:00 a.m.) than initially planned and to a time before the prescription start date (11:53 a.m.).




In the given example, the nurse registered that the administration was done at a different time than the one prescribed presenting a change from 11:53 a.m. to 11:00 a.m.

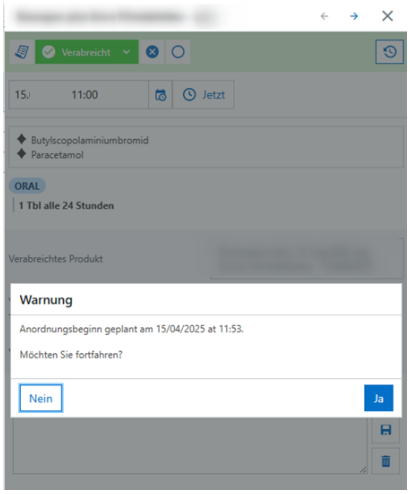



As a fixed interval has been prescribed, the nurse is asked if the following intakes have to be rescheduled to keep the fixed interval between each intake.

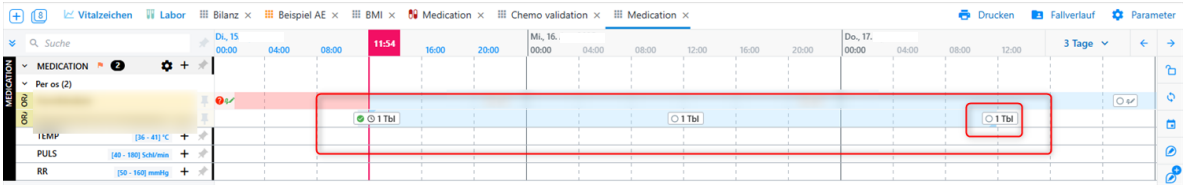



The nurse confirms that the following intakes have to be rescheduled.

The nurse confirms the upcoming warning, that the administration is changed to a time before the prescription start date (11:53 a.m.).




A third intake is then displayed on the last day (when initially no intake was planned). In case nobody notices this, it could lead to a single unplanned additional administration.




## Actions:

### Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Release of correction with ORBIS Medication version 03.21.01.00 (or higher) in ORBIS version 84.43.02.00 or higher for DACHL (release planned for latest third quarter of 2025);
- Release of correction with ORBIS Medication version 03.21.xx.xx with ORBIS versions 84.43.02.xx and 85.26.02.xx or higher for FR (release planned for first quarter of 2026).

### Recommended actions to be taken by the customer:

**When possible while using an affected version:**

- As a prescriber select the actual time of the administration so a rescheduling by the nurse can be avoided:
  - If a rescheduling to a point in time before the prescription start time is needed, please either mark the additional intake as “not administered” or deny the automatic rescheduling of the upcoming intakes and do it manually if needed.
- When prescribing at 24-hour intervals, favor daily prescriptions.
  - Check takes in the Patient chart after rescheduling: If needed mark the additional intake as “not administered”

**To avoid the described behaviour completely:**

- 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 | MST0099729 - Potential change in number of doses when rescheduling globally a prescription with fixed interval and end date |
| 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: