

07/02/2025

## 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: When a physician pauses and later resumes a prescription line with a planned end date, the end date is not considered.**

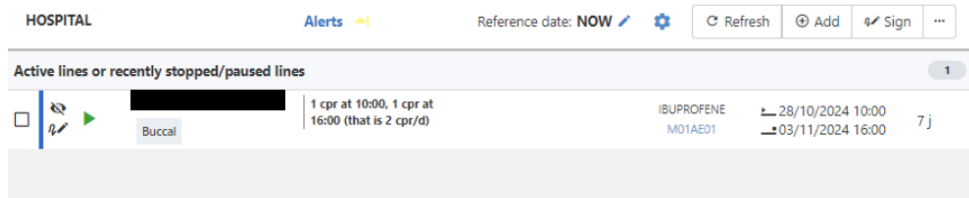
Internal Reference: MST0092440

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

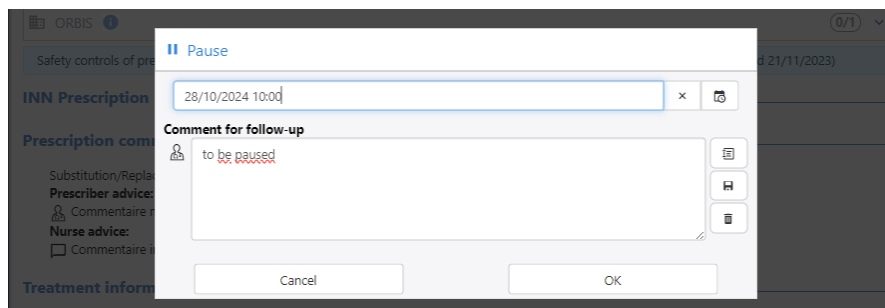
- ORBIS Medication 03.16.00.00 in ORBIS 84.38.00.00, 85.21.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH  
UDI-DI: 4260693990026

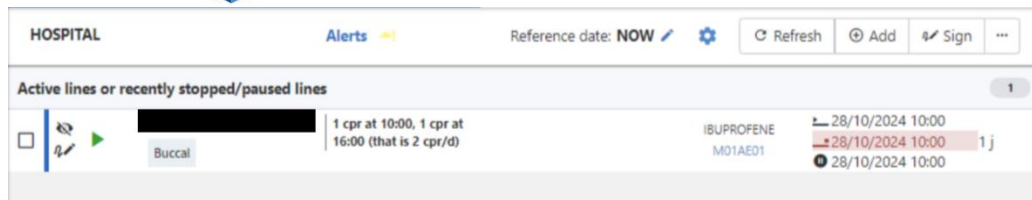
### Information:

The physician prescribes a drug during a specific period of time, i.e. with a planned end date. For example, a line is prescribed with an end date in 7 days.



Then, the physician pauses this line (e.g. due to a surgery).

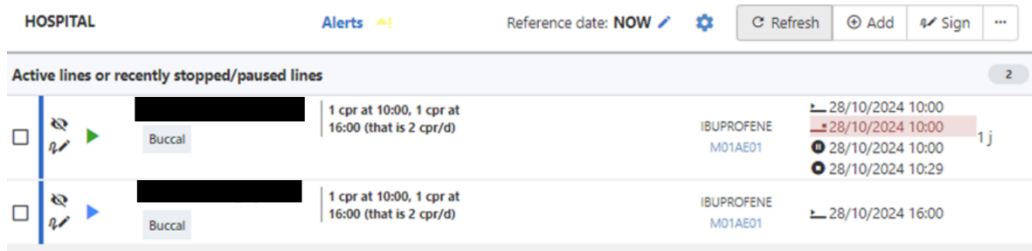




Later, the physician resumes the line (e.g. 30 min after the pause date).



Independently of the physician selecting either a continuity of treatment or not, the line is resumed without the initially planned end date. So, the line is planned without an end date.



## Actions:

### Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.20.05.00 in ORBIS version 84.42.08.00.DACHL or higher (release planned for March 2025 for DACHL), 84.43.00.00.FR or higher (release planned for Q4 of 2025 for FR) & 85.26.00.00.FR or higher (release planned for June 2025).
- In this correction, an informative message during “resume action” will be added to inform physicians that, if necessary, they should adapt the end date on a resumed line.

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

- Install the correction when available.
- Before signing the prescription, the physician should always check the ‘start date’ and ‘end date’ and adapt them if required.

Please distribute this information to all those who need to be aware of it.

**URGENT FIELD SAFETY NOTICE – MST0092440**

DH Healthcare GmbH

Konrad-Zuse-Platz 1-3, 53227 Bonn

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

MST0092440 - When a physician pauses and later resumes a prescription line with a planned end date, the end date is not considered

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: