03.05.2024

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: Consecutive (or Alternate) mode abnormally available when prescribing a prescription set

Internal Reference: MST0079721

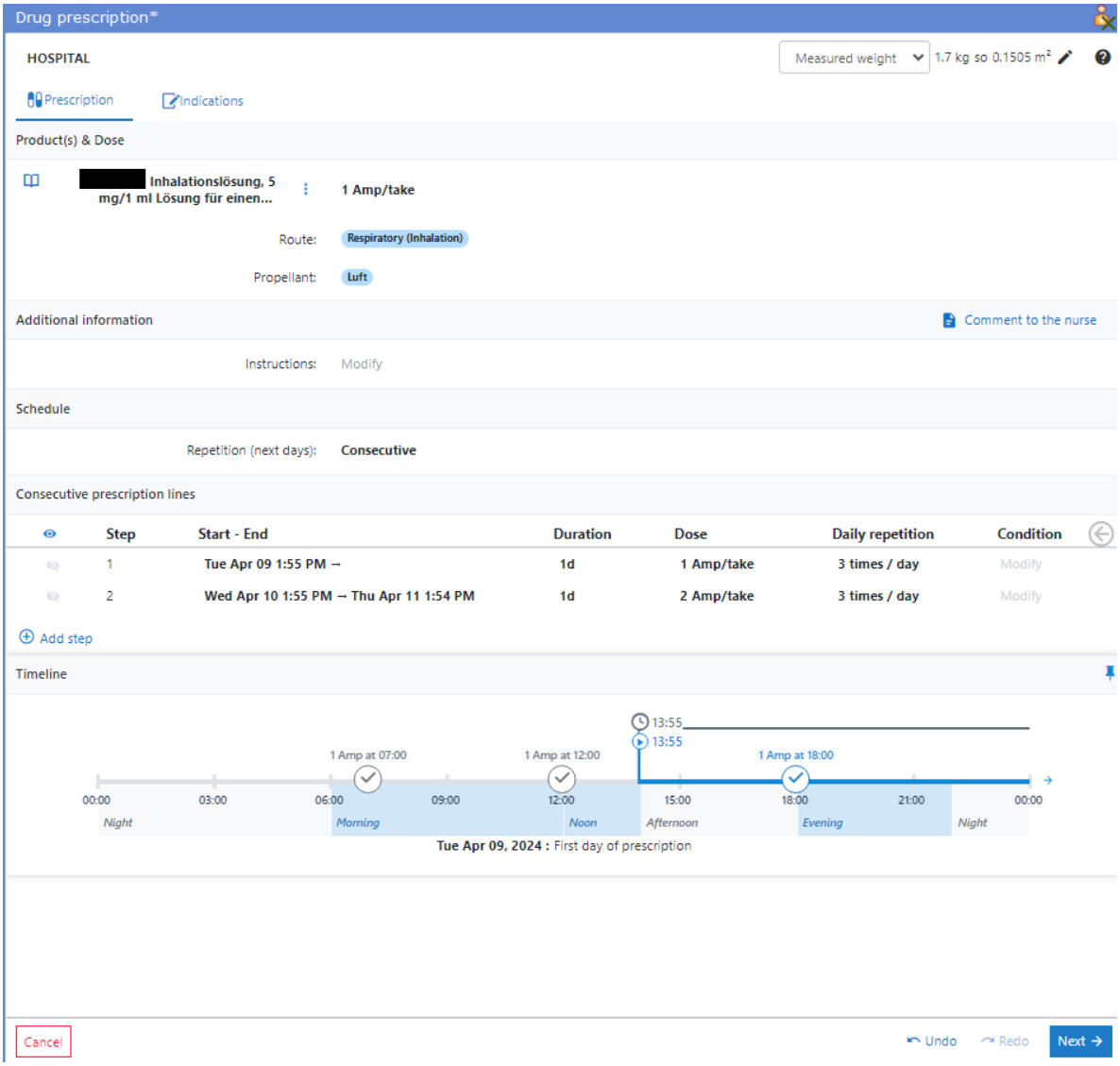
Product name and version(s) and UDI-DI:

- ORBIS Medication 03.16.07.00 in ORBIS 84.38.00.09.FR and 85.21.00.10.FR and higher in France.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

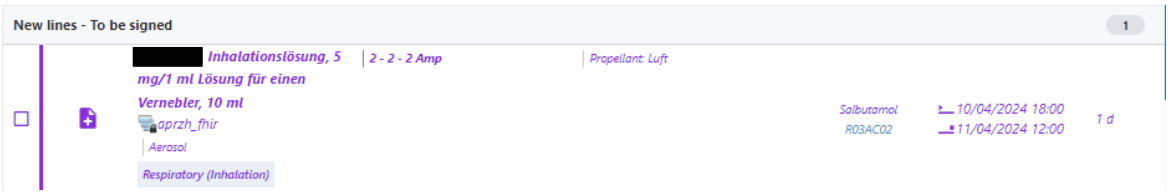
- ORBIS Medication 03.19.01.00 in ORBIS 84.41.00.00.DACHL and higher in Germany, Austria, Switzerland, Luxembourg.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The following behavior, which might occur when using ORBIS Medication, has been observed:
A physician adds a prescription set to a patient case, with a prescription line to be administered as a daily dose, with no duration.
Before signing, he modifies the prescription line and selects the Consecutive or Alternate mode. He completes the dosage for each step.



The prescription line is then only replaced by the last step defined with the Consecutive or Alternate mode The other steps are not considered.



This could lead to wrong or missing prescriptions for the patient.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.20.00.00 in ORBIS version 84.42.00.00 (release beginning of June 2024 for DACHL and planned for spring 2025 for FR) and higher, 85.25.00.00 (release planned for second half of 2025) and higher.

Recommended actions to be taken by the customer:

- As a physician, always check before signature the result of the modification of a prescription line.
- When using an affected version, if consecutive (or alternating) prescriptions are to be prescribed, add a new prescription line directly, by selecting a drug, instead of selecting a protocol.
- Installation of the correction when available.

Please distribute this information to all those who need to be aware of it and confirmation the acknowledgement by the signed response form.

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	MST0079721 - Consecutive (or Alternate) mode abnormally available when prescribing a prescription set
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: