24.06.2026

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: Incorrect dose information on printed drugs labels when prescribing a single drug as discontinuous prescriptions with duration

Internal Reference: MST0116296

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

- ORBIS Medication 03.21.02.00 and higher in ORBIS 84.43.04.00 and higher in Germany, Austria, Switzerland, Luxembourg and UK.
- ORBIS Medication 03.21.03.00 and higher in ORBIS 84.43.02.00 and higher in France.
  - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The described issue only occurs with discontinuous prescriptions with duration for a single drug. Other prescriptions are not affected.

Under specific circumstances, outlined below, labels printed for discontinuous prescriptions with duration containing a single medication display incorrect information.

This occurs when printing labels from the Patient Chart or from the Drug Preparation List. For affected prescriptions, the printed label may display a dose corresponding to the total amount of medication in the preparation (e.g. 500 mg) instead of the prescribed dose to be administered (e.g. 400 mg). In addition, the expected preparation volume may be missing from the label.

Two scenarios have been identified:

- Printing from the Drug Preparation List, the issue occurs regardless of whether the administration has been marked as "Prepared" or not.
- Printing from the Patient Chart, the issue occurs when the administration has not yet been marked as "Prepared".

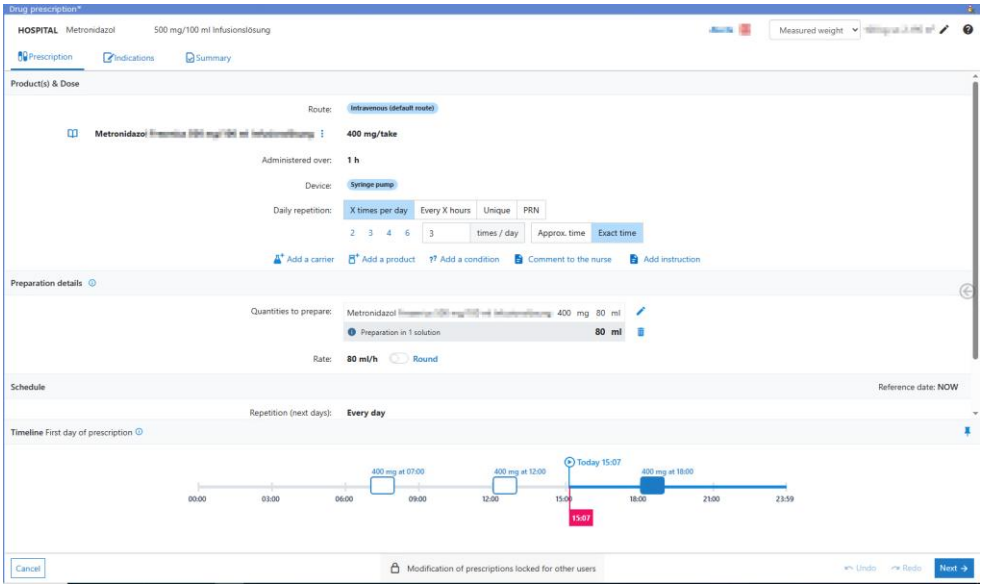

Figure 1: Discontinuous prescriptions with duration for a single drug.

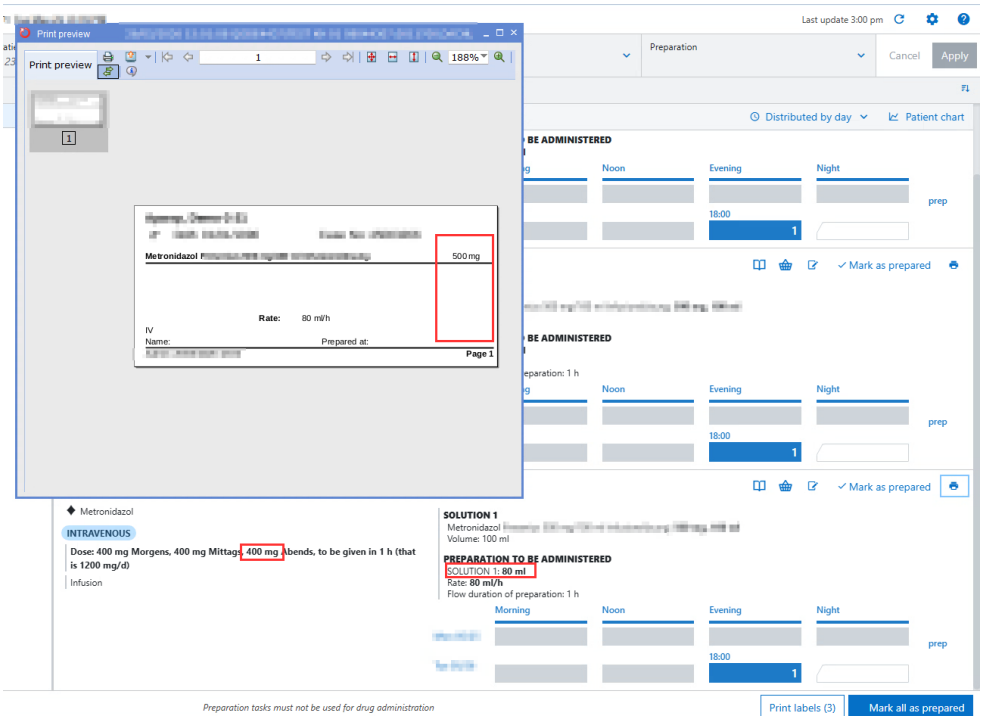

Figure 2: Label for a single drug prescribed as discontinuous prescriptions with duration printed from Drug Preparation List in the status not prepared.

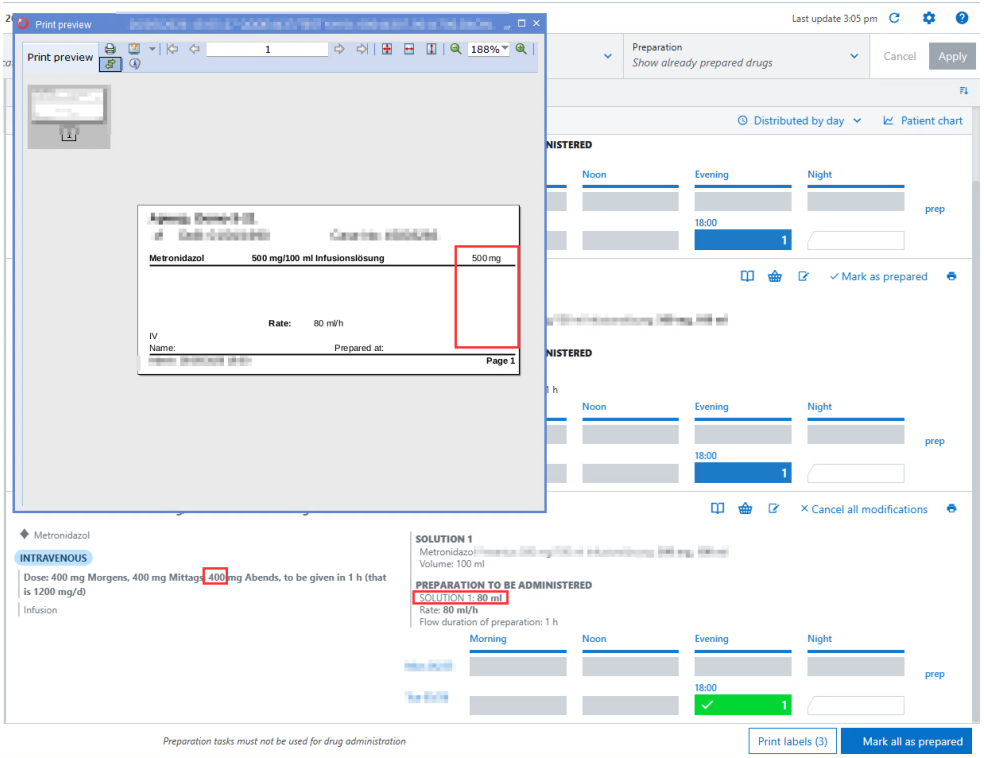

Figure 3: Label for a single drug prescribed as discontinuous prescriptions with duration printed from Drug Preparation List in the status prepared.

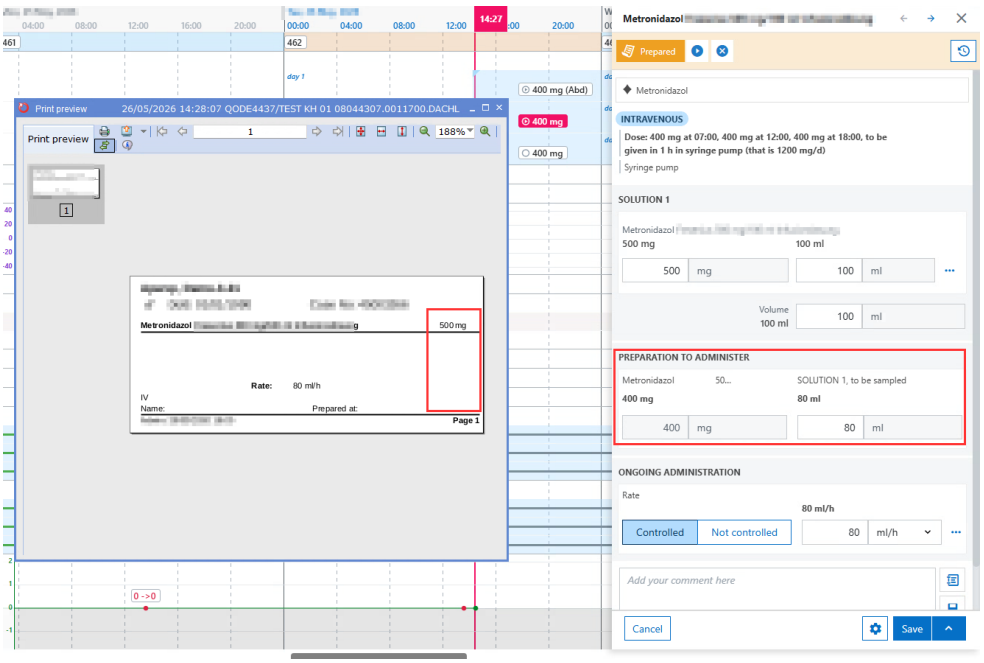

Figure 4: Label for a single drug prescribed as discontinuous prescriptions with duration printed from Patient Chart in the status not prepared.

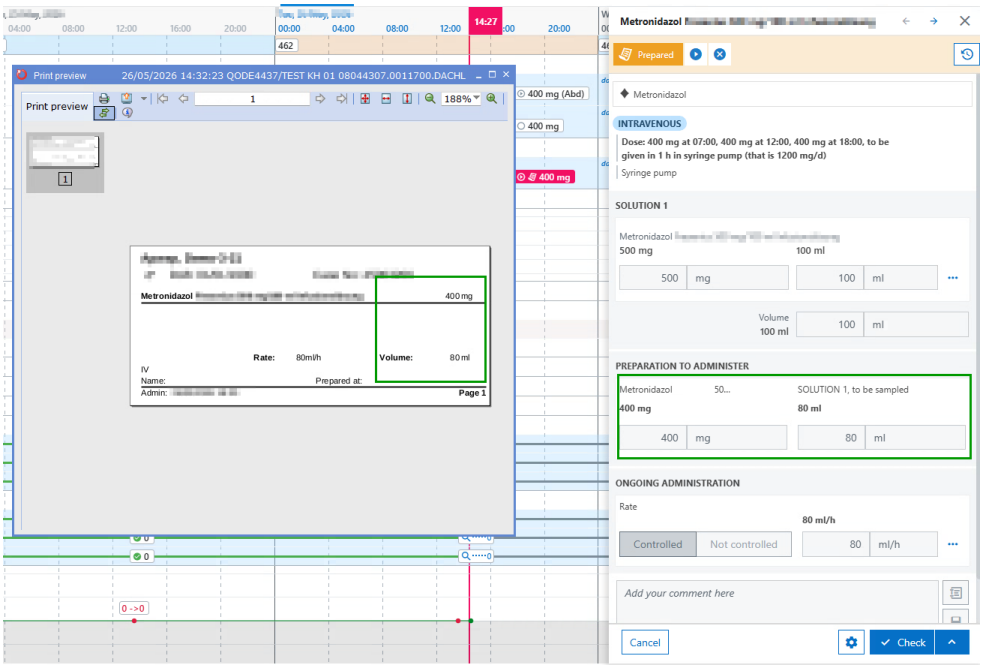

Figure 5: Label for a single drug prescribed as discontinuous prescriptions with duration printed from Patient Chart in the status prepared.

Summary:

The described issue only occurs with discontinuous prescriptions with duration for a single medication. Other prescriptions are not affected.

When printing a label from Patient chart, the issue will not occur when the administration is marked as “Prepared” before printing.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 04.00.00.00 or higher in ORBIS version 84.44.02.00 or higher for DACHL (release planned for third quarter of 2026).
- Release of correction with ORBIS Medication version 04.00.00.00 or higher in ORBIS version 84.44.02.00 or higher for UK (release planned for last quarter of 2026).

- Release of correction with ORBIS Medication version 04.00.00.00 or higher in ORBIS version 84.44.02.00 or higher for FR (release planned for first quarter 2027).

Recommended actions to be taken by the customer:

- Verify that the dose and preparation volume printed on labels for discontinuous prescriptions with duration correspond to the prescribed values before preparing or administering the medication. If needed refer to the Patient Chart and reprint the label for the prepared administration from there.
- Please pay particular attention to labels showing a dose corresponding to the total amount of medication in the preparation rather than the prescribed dose to be administered.
- If any discrepancy is identified, healthcare professionals should rely on the information displayed in the prescription summary rather than on the printed label.
- 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:	MST0116296 - Incorrect dose information on printed drugs labels when prescribing a single drug as discontinuous prescriptions with duration
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: