08-01-2024

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: Not possible to withdraw an existing signature, the affected administration remains in the PTC even though it was already stopped

Internal Reference: MST0028409

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

- ORBIS Medication 03.10.00.00 in ORBIS 84.32.00.00, 85.15.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

The issue concerns the physician's signature on an administration task:
In the Patient chart, a physician enters instructions for the administration of one or more intakes. After signing off on an intake, the physician no longer has the option to cancel their instructions. Consequently, if the line is not modified or stopped and the situation is not sufficiently communicated after occuring, a potentially incorrect prescription remains in the patients' chart and could be administered to 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 planned for end of May 2024 for DACHL and second quarter 2025 for FR), 85.25.00.00 (release planned for end of July 2024).

Recommended actions to be taken by the customer:

- If the physician mistakenly documents the administration of an intake, they can modify or stop the prescription line before the intake in question and prescribe a new line.
- Special case: if the physician mistakenly documents not administering an intake, it is only possible to modify or stop the prescription line after this intake. We recommend that the

physician informs the nursing staff of the action to be taken in the event of other errors in instructions for previous doses.
- Installation of the correction when it is 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:

<provide contact details>

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: <provide contact details>
Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0028409
Product reference:	
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: