12-03-2024

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: Condition on rights might not be correctly applied for bolus documentation

Internal Reference: MST0077134

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

- ORBIS Medication 03.15.00.00 in ORBIS 84.37.00.00, ORBIS 85.20.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

Prerequisites for this issue to happen:

- Having a user who can connect to 2 different wards (e.g. ward A and B)
- This user having a functional right on ward A but not on ward B (e.g. the right to document an extra bolus administration).
- The user connects to ward A and opens the start screen of a continuous administration and can administer a bolus.
  The user doesn't administer the bolus but connects to ward B and open the exact same administration.
- The user could add an additional bolus even if he doesn't have the right to, on this ward B.

This issue could also happen the other way around: when the user first connects to ward B (with no right to administer an extra bolus) and then to ward A (with the right to administer an extra bolus). In this case, he would not be able to administer the extra bolus on ward A and will have to disconnect and reconnect to ORBIS in ward A to do so.

In very rare cases, this might lead to an overdose.

This issue happens because of the technical cache that is set on the administration context.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.03.00 in ORBIS version 84.41.03.00_DACHL (release planned for March 2024).
- Release of correction with ORBIS Medication version 03.19.04.00 in ORBIS version 84.41.00.01_FR and 85.24.00.01_FR (release planned for beginning of 2025).

Recommended actions to be taken by the customer:

- Should this scenario occur, disconnect from ORBIS before reconnecting to the second ward.
- Install 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:

<provide contact details>

Sincerely,

Name of QARA Director
Title of QARA Director

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	MST0077134 - Condition on rights might not be correctly applied for bolus documentation
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: