03-07-2024

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: Possible absence of ATC code on prescription lines

Internal Reference: MST0085846

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

- ORBIS Medication 03.19.x in ORBIS 84.41 and 85.24 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

If a patient case contains an admission prescription line created from the simplified prescription form, the line might be displayed without an ATC code in the admission prescription list.

The observed issue can appear when a physician imports this admission prescription line as a hospital prescription line, and then completes the instructions.

Depending on the prescribed product (like an out of formulary product without configured default route of administration), the hospital prescription line could be displayed without an ATC code in the prescription list, and, as a result, this prescription line does not appear in a Patient Chart section filtered on the same ATC code.

If the drugs are filtered on the ATC code, and for the above reasons the concerned drug with a missing ATC code is not displayed, it might lead to the following:

- A delay in treatment must be considered until the oversight is recognised and the patient receives the appropriate drug.
- A patient could receive no or inefficient treatment if nursing staff were to overlook the error over an extended period.

In such a situation, the physician may, as a workaround, add a new hospital prescription line directly instead of importing the prescription line from admission.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.05.00 and higher in ORBIS version 84.41.00.01 FR and 85.24.00.01 FR and higher (release planned for winter 2024/25) and in ORBIS Medication 03.20.02.00 in ORBIS version 84.42.02.00 DACHL and higher (release planned for summer 2024).

Recommended actions to be taken by the customer:

- As a physician, always check the presence of the ATC code on a hospital prescription line. If no code is present, duplicate or re-prescribe the product.
- As a nurse, always check the presence of prescription lines awaiting administration in a Patient chart view, which displays all the prescription lines in the patient case.
- 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:

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	MST0085846 - Possible absence of ATC code on prescription lines
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: