27.02.2025

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: In rare cases, allergies declared for the patient might not be taken into account in the safety checks

Internal Reference: MST0097132

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

- ORBIS Medication 03.16.00.00 in ORBIS 84.38.00.00 and higher in Germany, Austria, Switzerland, and Luxembourg
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260690990026

Information:

Please note that the behaviour described below can only affect customers having ORBIS U in combination with an affected version of ORBIS Medication.

On one of our internal test systems, we recently identified rare cases where communication to the Clinical Problems module may be erroneous occasionaly. The behaviour has to our current knowledge never been observed in the field.

A physician prescribes a drug for which the patient has a declared allergy in Clinical Problems module (Patient Case > Allergies). After selection of the product, safety checks are computed by contacting the configured pharmaceutical database. In this exchange, depending on the configuration of the ORBIS environment the allergies may not be transmitted to the pharmaceutical database, therefore leading to no alert being raised regarding the prescribed product and the allergy of the patient.

If such a rare case would occur in the field and would not be identified i.e. by the physician checking the Allergies module, a patient might receive an administration of a drug to which they are allergic.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Release of correction with the update of ORBIS Medication version 03.20.05.00 in ORBIS version 84.42.08.00 or higher for DACHL (release planned for March 2025)

Recommended actions to be taken by the customer:
If you are using ORBIS U or start using ORBIS U in combination with an affected version of ORBIS Medication:

- As a physician, always check the allergies of the patient in the Allergies module before prescribing a drug.
- Install the correction when available.

If you are not using ORBIS U or are using ORBIS U in combination with a fixed version of ORBIS Medication, the described behaviour cannot occur on your environment.

Please distribute this information to all those who need to be aware of it.

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,

Dedalus

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	MST0097132 - In rare cases, allergies declared for the patient might not be taken into account in the safety checks
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: