09 June 2023

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue that has already been reported to the local responsible authority:

Reference: **MST0064706 -** When "Administered" is to be confirmed by the nurse in the PTC, the error message "Patient discharged on 28/03/2023 at 10:00" appears

Product and Product versions

- ORBIS Medication 03.16.02.03 in ORBIS DACHL 84.38.03.02 and higher in Germany, Austria, Switzerland, Luxembourg – Manufacturer: DH Healthcare GmbH

Information:

After update to ORBIS Medication 03.16.02.03 in ORBIS DACHL 84.38.03.02 users have faced the following behavior:

When discharging specific inpatient cases the users are blocked in this task due to the occurrence of an error message. This leads to a continued display of administrations in the Patient chart without the ability to document them.

This behavior was caused by a software defect which has been fixed with version ORBIS Medication 03.17.03.00. However it is possible that previously affected cases still have active administrations displayed.

Depending on the number of previously recorded stays and related data, the discharge is possible after the correction of the case type from ‘current’ to ‘planned’ and back to ‘current’.

Measures:

Steps by DH Healthcare GmbH

- Information of customers with this letter.
- Release of the correction with version
  - ORBIS Medication version 03.17.03.00 in ORBIS 84.39.04.00 and higher in Germany, Austria, Switzerland, Luxembourg – Manufacturer: DH Healthcare GmbH

Steps to be taken by customers

- Immediately update to the version containing the correction, if not already performed.
- If a discharge is still not possible after the implementation of the procedure described above, please contact Dedalus to perform a correction of the affected cases.
- Check if the provided correction solves the described behavior. Please contact DH Healthcare GmbH in case you need support to correct affected cases.

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:

Support.ORBISMedizinprodukte.DACH@dedalus.com

Kind regards,

Dr. Stephan Albers
QARA Director – DH Healthcare GmbH

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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: feedbackmanagement@dedalus.com

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0064706
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: