17 March 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: **MST0063375-** ORBIS Medication - Documentation of batch number within the administration dialogue via the information field is not possible in Patient chart (PTC).

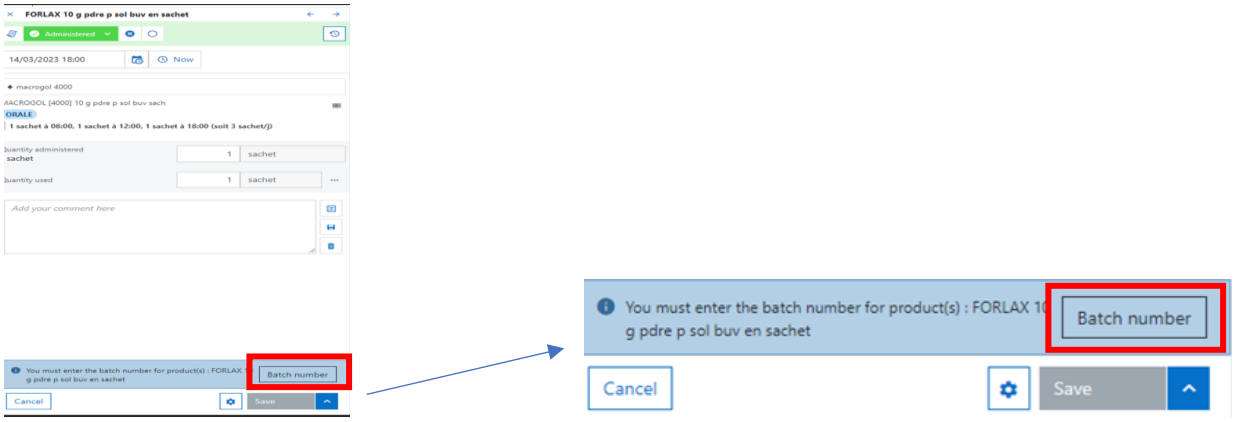
Product and Product versions

- ORBIS Medication 03.17.00.00 in ORBIS 84.39.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
- ORBIS Medication 03.17.00.00 in ORBIS 85.22.00.00 and higher in France - Manufacturer: DH Healthcare GmbH

Information:

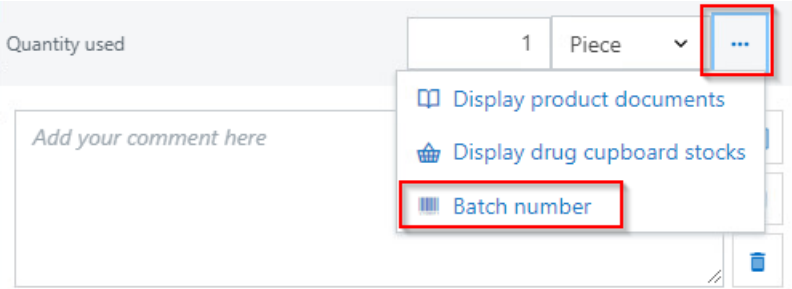
After update to ORBIS Medication 03.17.00.00, users have faced the following behavior:

For prescribed products for which the batch number documentation has been set as mandatory, the necessary documentation can be performed from within the administration dialog by clicking directly the "batch number" button within the blue information message. This button leads directly to the detailed entry screen for the batch number. After applying the entered batch number, the system returns to the actual administration dialog, where the batch number entered is displayed and the administration can be completed. However, in the case of discontinuously prescribed doses with defined composition details without carrier solution or additional product, the batch number entered is not carried over via this path. Although entered before, the respective field in the administration dialog will remain empty. Accordingly, the administration cannot be saved. This error only occurs when the batch number is entered via the button "Batch number" in the blue information message.



Workaround:

Please use the already previously existing way to document a product with a batch number: The batch number can be entered by using the "..." button that already existed before Medication 03.17 and then selecting "Batch number" (see screenshot below).



Measures:

Steps taken by DH Healthcare GmbH

- Information of customers and provision of workaround with this letter.
- Release of the correction with version
  - ORBIS Medication 03.17.04.00 in ORBIS version ORBIS 84.39.00.xx FR and ORBIS 85.22.00.xx FR (release planned for autumn 2023)
  - ORBIS Medication 03.18.00.00 in ORBIS version ORBIS 84.40.00.00 DACHL (release planned for 24 May 2023).

Steps to be taken by customers

Before the correction is provided:

- Share this information with all users who might be concerned.
- Ensure that all users are fully aware of the workaround described above in this letter.
- In case an update to one of the affected versions is planned: ensure that all users are informed – prior to the update - on the working method to document the administration of products with batch number (see section “Workaround”)…

Once the correction has been provided:

- Immediately install the provided correction of the software defect.
- Check if the provided correction solves the described behavior. Please contact DH Healthcare GmbH in case you need support.

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,

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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	MST0063375
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: