[Date]

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:

Reference: **MST0068530 –** ICU/FM: Incorrect calculation of Act. ingredient amount

Product and Product versions

- ORBIS ICU-Manager 04.12.00.03 in ORBIS 84.39.03.00 and higher in Germany, Luxembourg – Manufacturer: DH Healthcare GmbH
- ORBIS Anesthesia 02.09.00.03 in ORBIS 84.39.03.00 and higher in Germany, Austria – Manufacturer: DH Healthcare GmbH

Information:

After update to ORBIS ICU-Manager 04.12.00.03 and/or ORBIS Anesthesia 02.09.00.03, users have faced the following behavior:

When a syringe pump is instructed, the correct body weight-related active ingredient rate (in the unit µg/kg/min) is calculated when the active ingredient amount (in the unit µg) is entered. If, with a given total rate (ml/h), the standard syringe pump total volume (ml) and a given active ingredient rate (µg/kg/min), the concentration of the syringe pump is to be determined by calculating the active ingredient amount. It can happen that incorrect values are calculated.

Workaround:

Calculate the values manually and overwrite the numbers proposed by the system.

Measures:

Measures by DH Healthcare GmbH

- Inform customers and provision of workaround with this letter.
- Correction is planned to be provided with version
  - ORBIS ICU-Manager 04.13.00.02 and ORBIS Anesthesia 02.10.00.02 in ORBIS 84.40.00.xx DACHL (release planned for June 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.

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:

[contact]

Kind regards,

[signature]

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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: **[contact]**

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0068530
Product reference:	ORBIS ICU-Manager and/or ORBIS Anesthesia
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: