29.01.2026

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: Inaccurate description of the workflow for discontinuing medications in ORBIS Anesthesia

Internal Reference: **MST0110479**

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

- ORBIS Anesthesia 02.09.00.00 in ORBIS 84.39.00.00 and higher in Germany, Austria, and France
  - Manufacturer: DH Healthcare GmbH
  - UDI-DI: 4260693990019

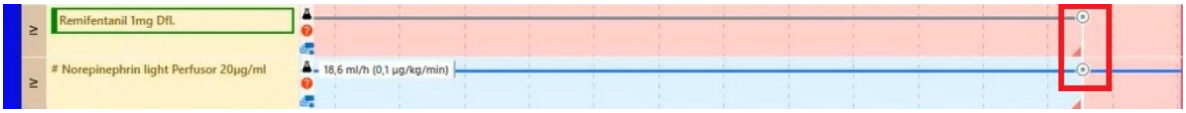
Information:

The behaviour described below can only occur when using ORBIS Anesthesia in combination with ORBIS Medication.

DH Healthcare GmbH would like to inform you that the user manual of ORBIS Anesthesia contains an inaccurate description of the workflow for terminating medications from ORBIS Medication in the context of anesthesia documentation. We are providing important information in this letter, which will be added to the next version of the user manual of ORBIS Anesthesia.

In the finalisation dialogue of ORBIS Anesthesia, you can set medications from ORBIS Medication to ‘to be stopped’. However, in order to finally document the stop of administration, it must also be confirmed in the Patient Chart. This applies in particular to continuous prescriptions: after setting them to ‘to be stopped`, the medication remains displayed in the Patient Chart with a continuous blue line, indicating an unconfirmed administration. A red background indicates that the prescription has already been stopped. With the stop of the administration the volume of the intake is confirmed.

Below you can see two variants of stopped continuous prescriptions:



1. The upper example shows an ORBIS Medication prescription where the administration was not started and the prescription was stopped.

2. The lower example shows a prescription where the administration was started. In this case the user needs to stop the administration and with this the volume of the intake is confirmed. The red background after the stop of the prescription indicates that the prescription is stopped. The blue line indicates that the administration is still running. To complete the documentation the administration has to be stopped. The stop of the administration can be earlier or later as the stop of the prescription or at the same time.

For both variants, it is important to note that none of the prescriptions are „active prescriptions“. This means that no further administrations based on these prescriptions are to be carried out. If this was overlooked, it could result in undesired administrations despite the prescription being stopped.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction (i.e. include a detailed description of the required information in the next version of the user manual of ORBIS Anesthesia) with ORBIS Anesthesia version 02.44.00.00 in ORBIS version 84.44.00.00 or higher (release planned in summer 2026 for DACHL and in Q1 2027 for FR) and ORBIS version 85.44.00.00 or higher (release planned in 2027 for FR).

Recommended actions to be taken by the customer:

- Until the user manual is updated, we kindly ask you to follow the steps described above, to ensure that nurses and phycicians stop the administration correctly.
- After release of the fix please follow the instructions as presented in the version of the user manual of ORBIS Anesthesia that is valid for your installation.

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	**MST0110479**
Product reference:	**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: