14.September 2023

# 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: Unwanted opening of previous anaesthesia documentation from the anaesthesia portal

Internal Reference: MST0073312

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

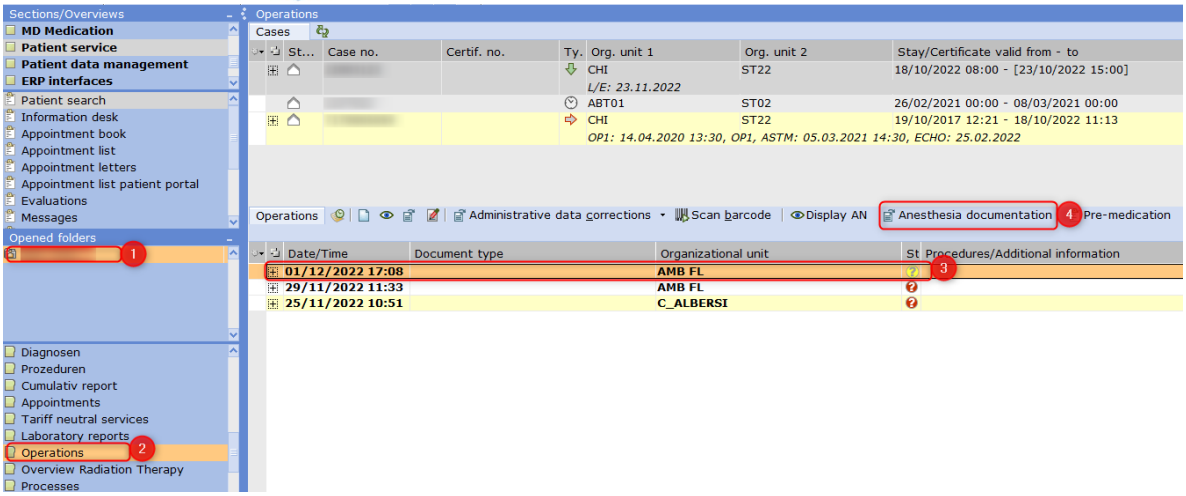
- ORBIS Anesthesia 02.10.00.00 in ORBIS 84.40.00.00 and higher in Germany, Austria, Switzerland, and Luxembourg
    - legal manufacturer: DH Healthcare GmbH
    - UDI-DI: 4260693990019

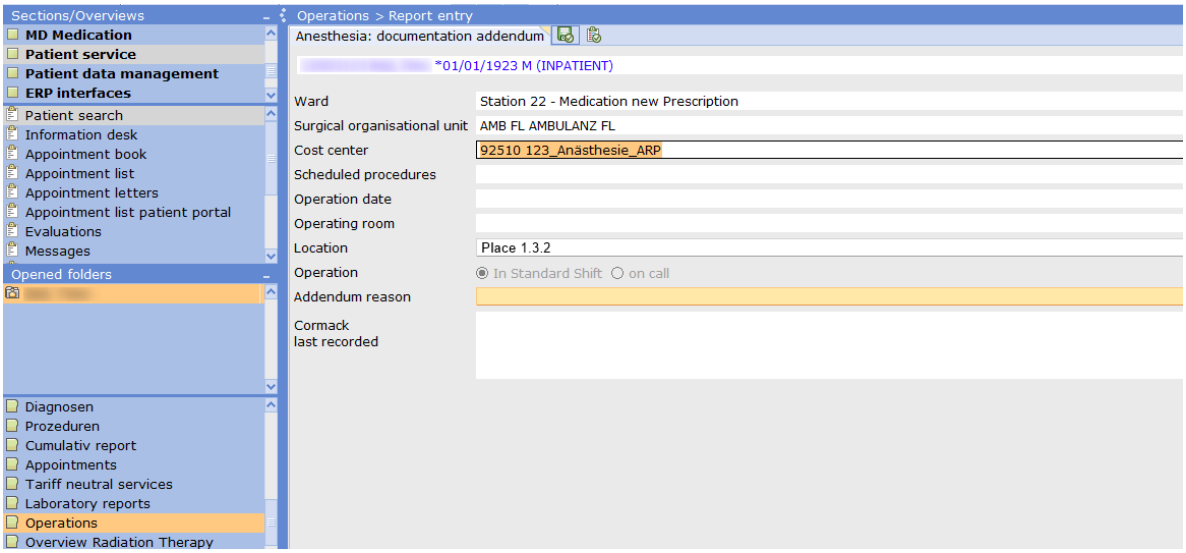
## Information:

When opening an anaesthesia document from the anaesthesia portal, it has been observed that, instead of the anaesthesia documentation relevant to the current operation being opened, a historic anaesthesia documentation was opened. This older document relates to the same patient but is not the most recent version and is connected to a previous anaesthetic / surgical procedure. This error can occur because documents are linked to the patient's location as defined in the anaesthesia portal and the location was mistakenly linked to the old, out of date, anaesthesia documentation.

This can only occur if:

a) There is an historic anaesthestic document for a patient and the same patient is placed in a location in the anaesthesia portal that is “associated” with that document.
b) The previous anaesthesia documentation is then opened from the patient's folder **Operations** using the button **Anesthesia documentation**. In that case the Anesthesia documentation is opened with addendum:



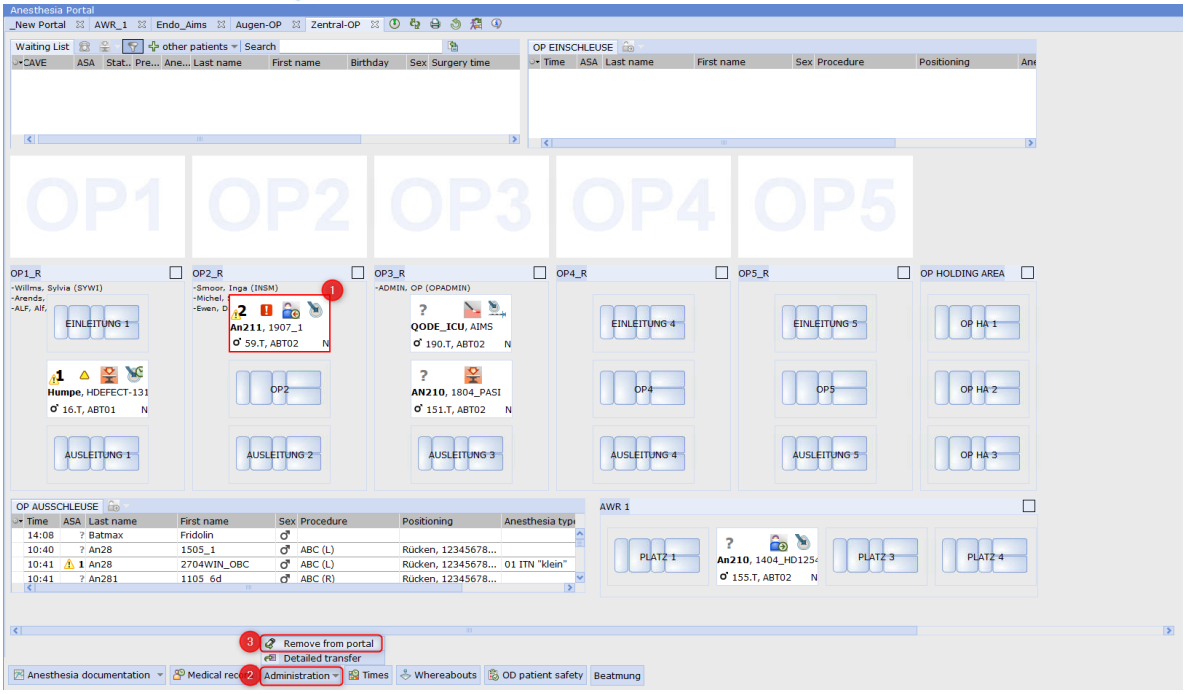




c) Once reviewed, the anaesthesia documentation is then exited with "**Save**".
d) An attempt is then made to open the current anaesthesia documentation from the anaesthesia portal at which point, the previous anaesthesia documentation is opened.

**This may result in the wrong anaesthesia documentation being used for the current anaesthesia by mistake.**

## Workaround:

- Anaesthesia documentation from the past should not be opened in the patient's folder **Operations** with the capability of editing the note ("open with addendum").
- If an older anaesthesia documentation must be viewed, this should be done via the button **Display AN.**
- If the issue has already occurred, this can be corrected by the user removing the patient from the portal (**Administration** -> **Remove from portal**):




- Then move the patient again from the waiting list to the corresponding location in the anaesthesia portal. Side effect: The relevant MEGS-protocols will then be stopped, and the user must re-prescribe them again to get the values from the medical devices.

## Actions:

### Actions undertaken by DH Healthcare GmbH:

- Informing customers and providing a workaround with this letter.
- Release of the correction with version ORBIS Anesthesia 02.10.00.04 in a HotFix of ORBIS 84.40.04 DACHL and higher in Germany, Austria, Switzerland, and Luxembourg (currently planned for end of October/beginning of November) – legal manufacturer: DH Healthcare GmbH.

### Recommended actions to be taken by the customer:

Before the correction is provided:

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

Once the correction has been provided:

- Immediately install the provided correction to the software error.
- Verify that the provided fix resolves the described behaviour.

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>

Sincerely,

<Name>

# 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: <Contact>

Thank you for your cooperation.

| | |
|---|---|
| Customer / Facility (names of all affected operational facilities): | |
| Address: | |
| Reference | MST0073312 |
| 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: