29.09.2023

# 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: ICU/AIMS: Additional time point validation missing when changing discontinuous instruction

Internal Reference: MST0072414

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

- ORBIS ICU-Manager 04.10.00.00 in ORBIS 84.37.02.00 and higher in Germany and Luxembourg
    - Legal manufacturer: DH Healthcare GmbH
    - UDI-DI: 4260693990002
- ORBIS Anesthesia 02.07.00.00 in ORBIS 84.37.02.00 and higher in Germany and Austria
    - Legal manufacturer: DH Healthcare GmbH
    - UDI-DI: 4260693990019

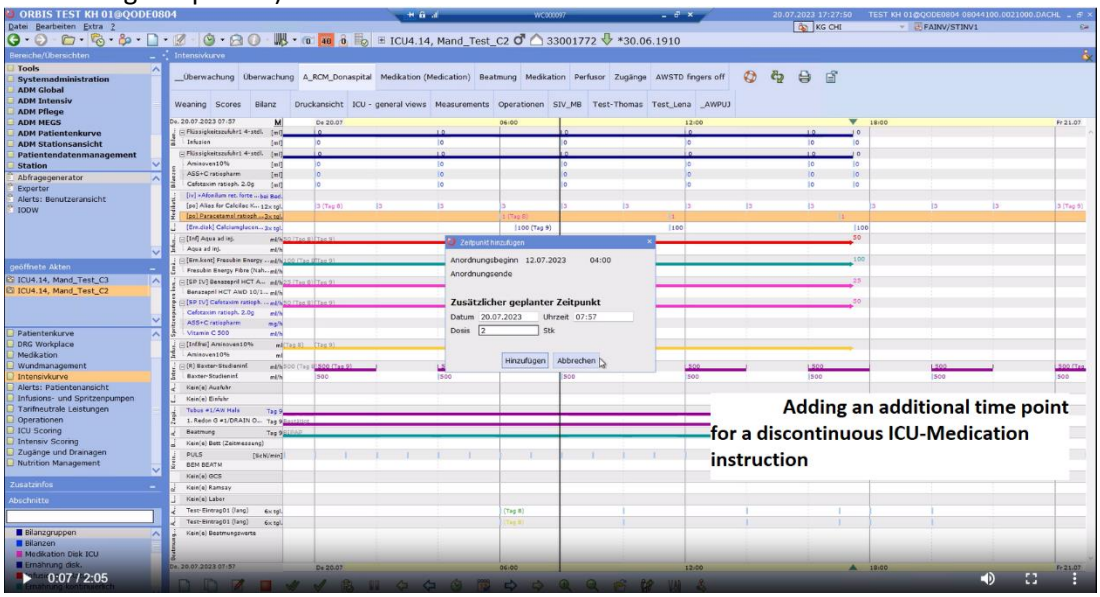
## Information:

The issue described below can occur in the validation of an instruction with additional timepoints. A validation message is not shown and the user is unaware of the additional timepoints. It affects ICU-Medication with discontinued scheduling when editing an existing instruction.

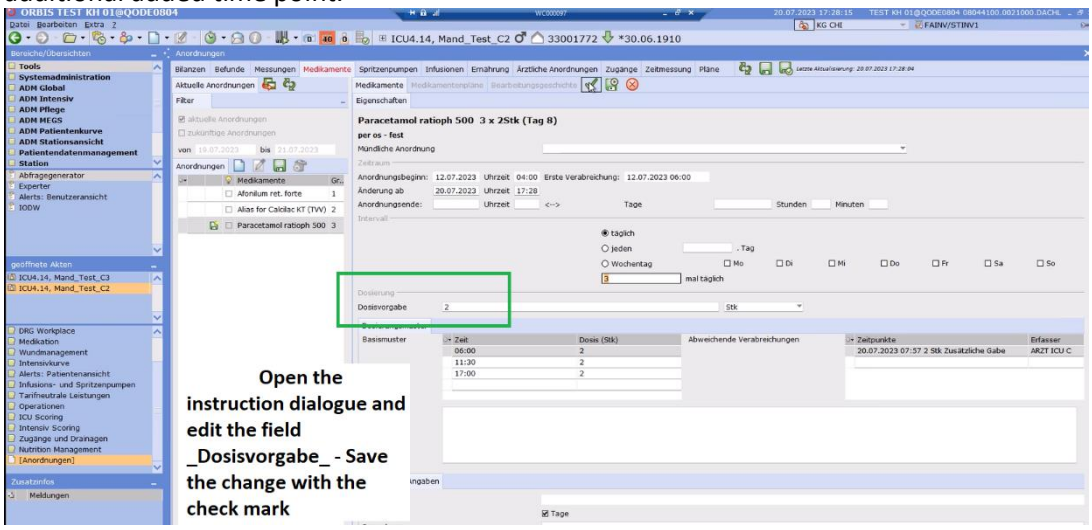
Example scenario:

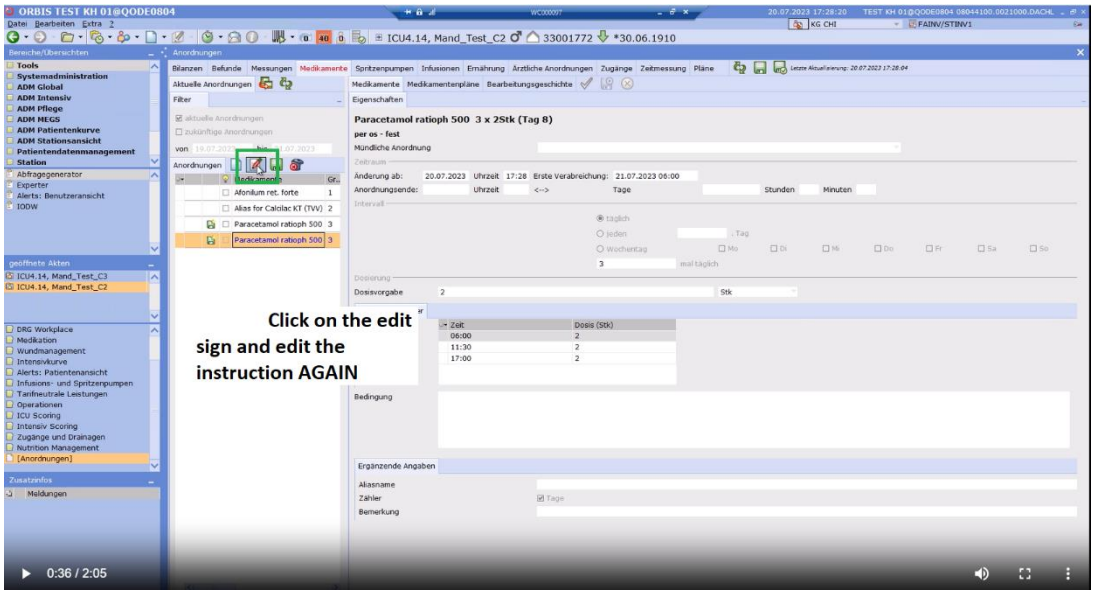
1. Prescribe an ICU-Medication with discontinued scheduling.

2. In ICU-Charts, add an additional instruction time point (“Zusätzlicher Anordnungszeitpunkt“).

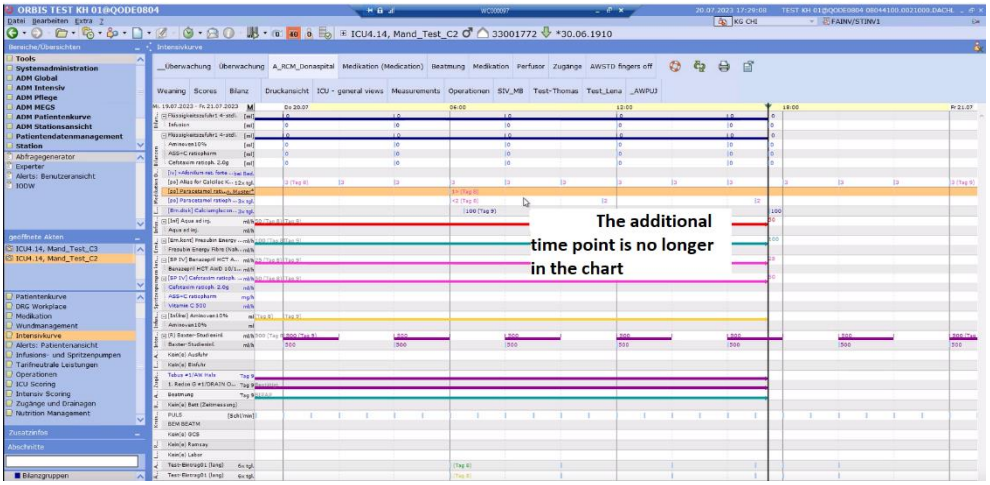



3. Open the ICU instruction dialog and change the time point by selecting a time before additional added time point.



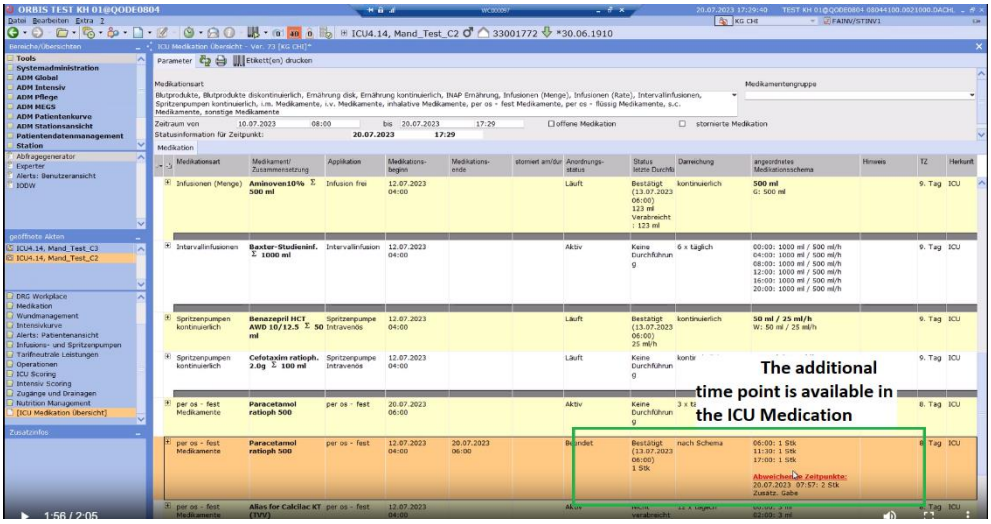



4. Click buttons “Save” or “Save and Close”.
5. Check the ICU-Medication instruction in
    a. ICU-Charts (Section “ICU-Medication”)




    b. ICU instruction dialog (Section “ICU-Medication”)

c. ICU Medication Overview.




Symptoms:

- A warning message for ICU-Medication instruction with additional time points might be not shown when the ICU-Medication instruction is edited at a later point in time.
- Therefore the user might not become aware of the existence of additional timepoints (“Zusätzliche Anordnungszeitpunkte”).
- As a result, the user has no option to take over additional timepoints (“Zusätzliche Anordnungszeitpunkte”) to the new ICU-Medication instruction.
- Finally the additional time points “Zusätzliche Anordnungszeitpunkte” are not displayed any more in ICU-Charts and instruction dialog. This could lead to a patient not receiving a planned dose of medication.
- The additional time point is still shown in the ICU Medication Overview.

Workaround:

- Do not edit ICU-medication instructions with additional timepoints.
- Note additional time points down.
- Stop existing instruction with additional timepoints and create a new instruction.
- Add the additional timepoints to the newly created instruction if necessary.

## Actions:

**Actions undertaken by DH Healthcare GmbH:**

- Informing customers with this letter.
- Release of the correction is planned with versions
  - ORBIS ICU-Manager 04.14.00.00 and ORBIS Anesthesia 02.11.00.00 in ORBIS 84.41.00.xx DACHL (release planned for end of November 2023).

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

Before the correction is provided:

- Share this information including the workaround described above with all users who might be concerned.
- 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.
- Verify that the provided correction solves the described behavior. Please contact DH Healthcare GmbH in case you need support.

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:
<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 | MST0072414 |
| Product reference: | ☐ ORBIS ICU-Manager ☐ 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: