

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

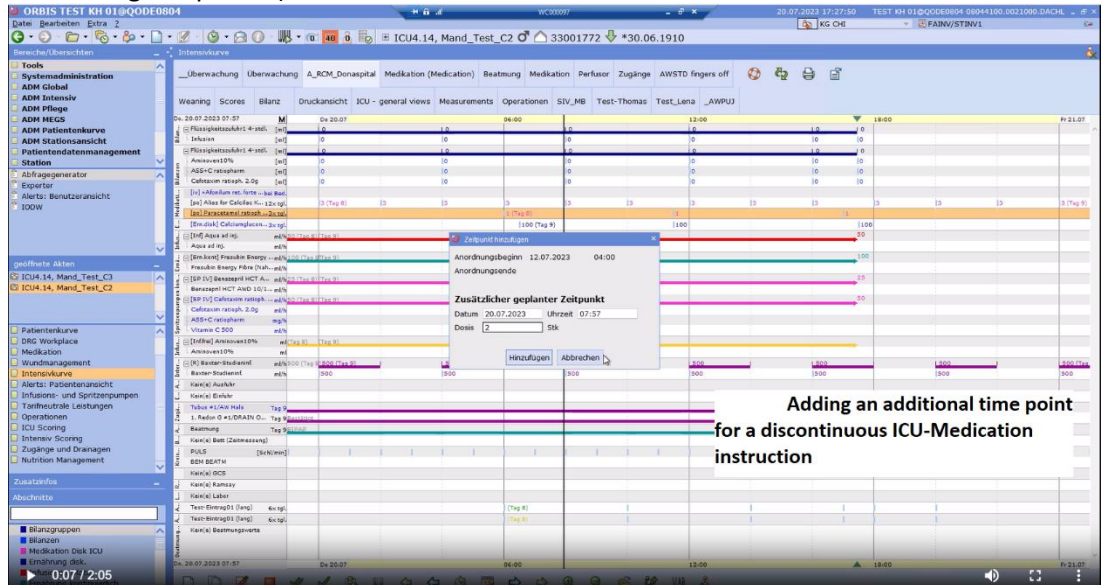
Information:

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:

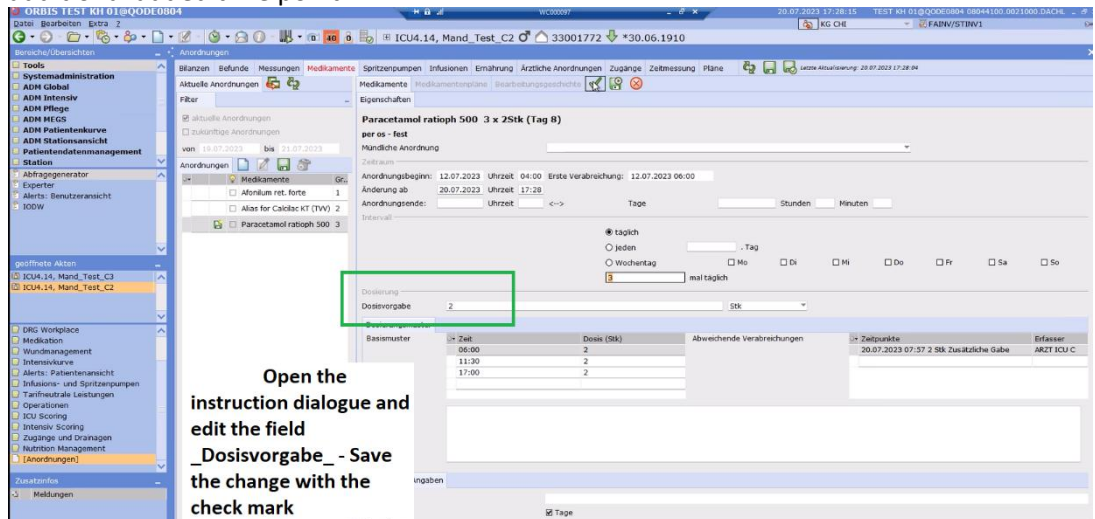
1. Prescribe an ICU-Medication with discontinued scheduling.

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

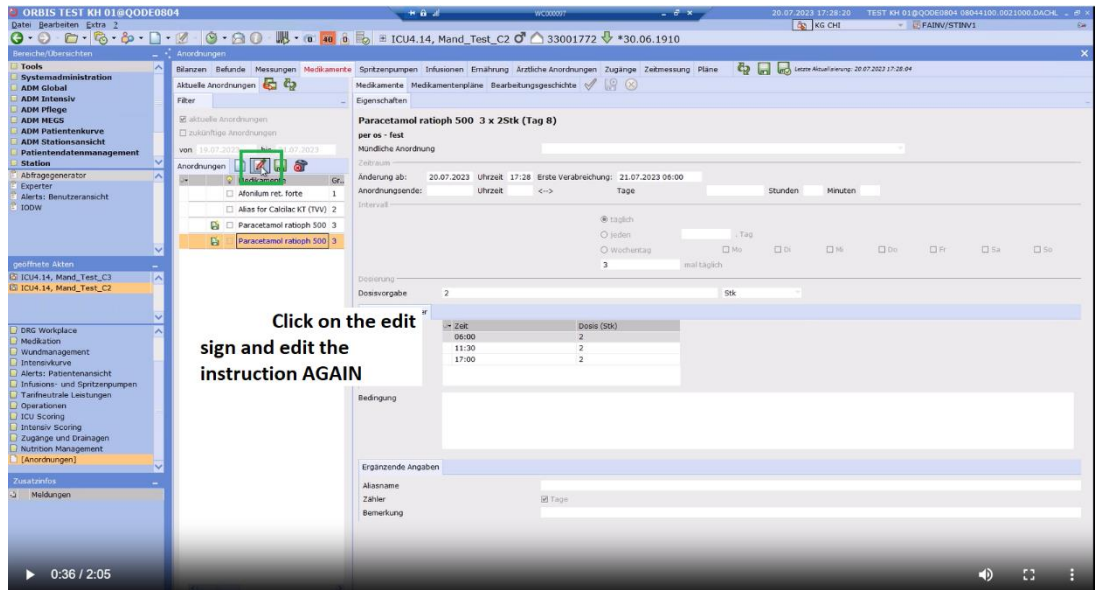


Adding an additional time point for a discontinuous ICU-Medication instruction

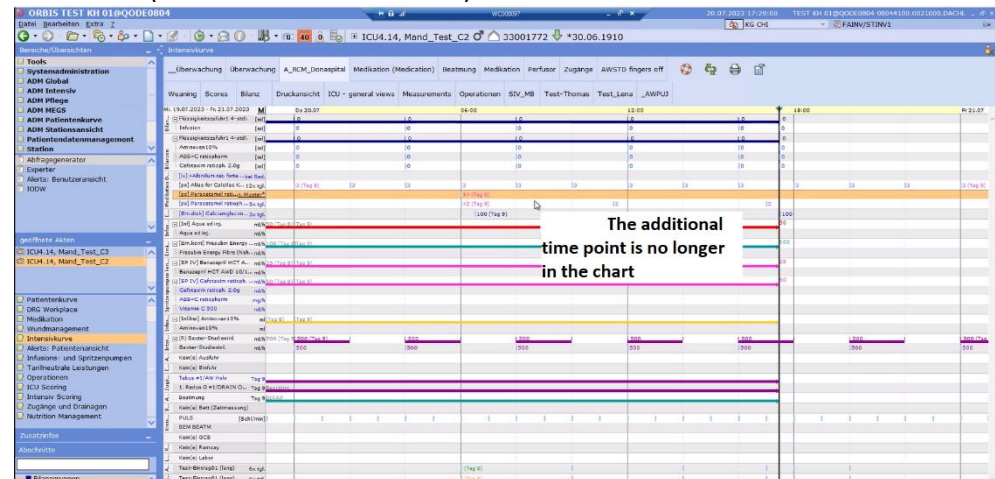
- Open the ICU instruction dialog and change the time point by selecting a time before additional added time point.



Open the instruction dialogue and edit the field Dosisvorgabe - Save the change with the check mark

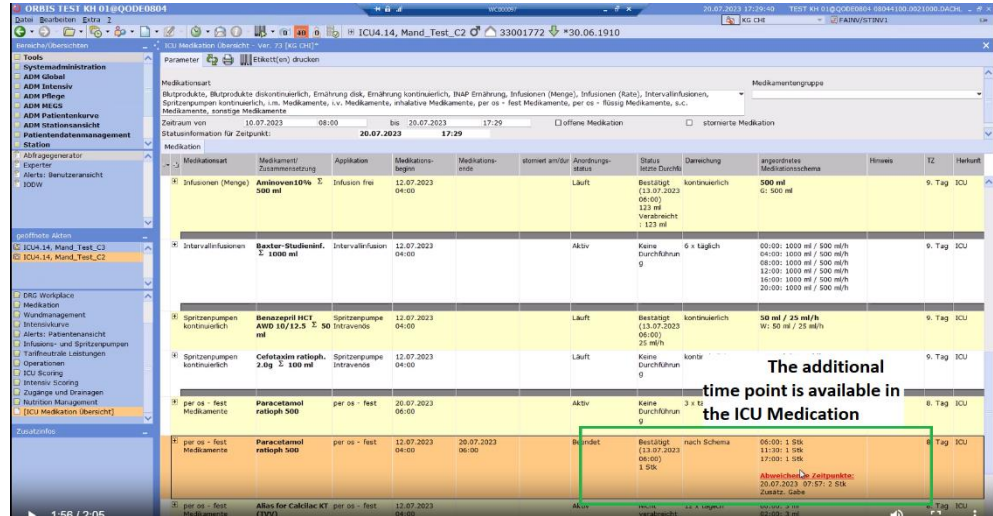


4. Click buttons "Save" or "Save and Close".
5. Check the ICU-Medication instruction in
 - a. ICU-Charts (Section "ICU-Medication")



- b. ICU instruction dialog (Section "ICU-Medication")

c. ICU Medication Overview.



Medikationsart	Medikament/ Zusammensetzung	Applikation	Medikations- beginn	Medikations- ende	storniert am/über status	Anordnungs- status	Status letzte Durchf.	Darreichung	angewordenes Medikationsschema	Hinweis	TZ	Herkunft
Infusionen (Menge)	Amivon 10% 500 ml	Infusion frei	12.07.2023 04:00			Läuft	Bestätigt (13.07.2023 05:00) 133 ml Verbracht 133 ml	kontinuierlich	500 ml i. 500 ml		9. Tag ICU	
Intervallinfusionen	Baxter-Studieninf. 1000 ml	Intervallinfusion	12.07.2023 04:00			Aktiv	Keine Durchführun g	6 x täglich	00:00: 1000 ml / 500 ml/h 04:00: 1000 ml / 500 ml/h 08:00: 1000 ml / 500 ml/h 12:00: 1000 ml / 500 ml/h 16:00: 1000 ml / 500 ml/h 20:00: 1000 ml / 500 ml/h		9. Tag ICU	
Spritzenpumpen kontinuierlich	Benzapril HCT AWD 10/12.5 50 ml	Spritzenpumpe intravenös	12.07.2023 04:00			Läuft	Bestätigt (13.07.2023 06:00) 25 ml/h	kontinuierlich	50 ml / 25 ml/h W: 50 ml / 25 ml/h		9. Tag ICU	
Spritzenpumpen kontinuierlich	Cefotaxim ratiopharm 2.0g 2 100 ml	Spritzenpumpe intravenös	12.07.2023 04:00			Läuft	Keine Durchführun g	konti			9. Tag ICU	
per os - fest Medikamente	Paracetamol ratiopharm 500	per os - fest	20.07.2023 06:00			Aktiv	Keine Durchführun g	3 x 1x			9. Tag ICU	
per os - fest Medikamente	Paracetamol ratiopharm 500	per os - fest	13.07.2023 04:00	20.07.2023 06:00		Bündelt	Bestätigt (13.07.2023 06:00) 1 Stk.	nach Schema	06:00: 1 Stk. 11:00: 1 Stk. 17:00: 1 Stk.	Abweichende Zeitpunkte: 20.07.2023 07:57: 2 Stk. Zusätz. Gabe	9. Tag ICU	
per os - fest Medikamente	Atlix für Calcilac KT 600g	per os - fest	13.07.2023 04:00			Aktiv	Keine Durchführun g				9. Tag ICU	

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: