2020-01-09

URGENT FIELD SAFETY NOTICE

Customer name

Street_Address
Zip_Code_City
Country

Dear customer,

This Urgent Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Agfa HealthCare to correct the problem

Reference: **PRB0751073** ORBIS Medication: Unintended behavior of the Drug Preparation List when prescribing drugs with a scheme

Device

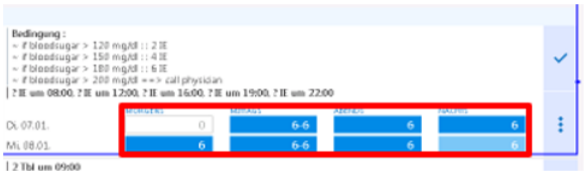
- ORBIS Medication 3.11.1 with ORBIS-version DACHL_08043300 HF01 and HF02
- ORBIS Medication 3.11.1.1 with ORBIS-version DACHL_08043301, HF01, HF02 and HF03

Problem:

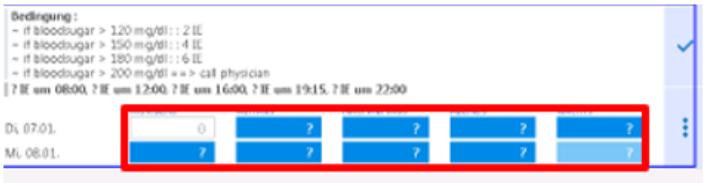
Agfa HealthCare was informed regarding the following:

When preparing a drug with a dosage schema, the highest dosage of the related schema is displayed in the *Drug Preparation List* instead of a question mark "?", as displayed in the previous versions.

This unexpected behavior is not intended and might confuse the user, potentially leading to preparation and administration of an inadequate dosage. This could result in a risk for patient safety, if the user does not consider the conditions described in the schema displayed above the tabular view of the dosages to be prepared and does not consult the patient chart before administration.

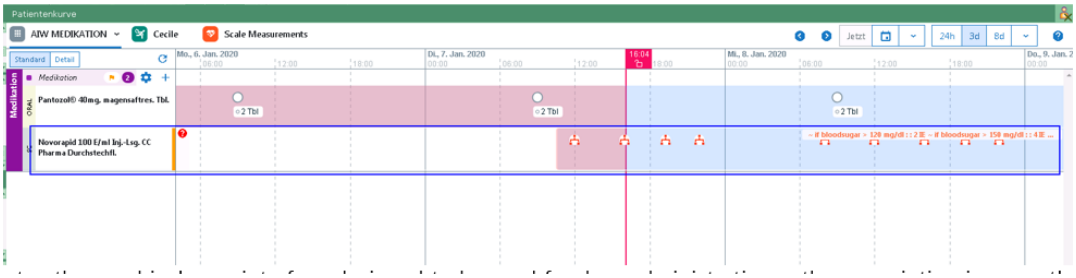


Incorrect display in the Drug Preparation List in the versions as mentioned above



Correct display in the Drug Preparation List in previous versions

Agfa HealthCare NV
Septestraat 27
B-2640 Mortsel, Belgium



In the Patient Chart – the graphical user interface designed to be used for drug administration – the prescription is correctly displayed with the question mark "?", the points in time when to administer are displayed with the icon for schema, and the conditions from the schema on the right side.

Actions:

Actions undertaken by Agfa HealthCare

- Customers are informed by this Field Safety Notice
- A correction will be provided with ORBIS Medication 3.11.1.2 in ORBIS DACHL_08043301 HF04

Recommended actions to be taken by you:

- Installation of solution provided by Agfa HealthCare with ORBIS DACHL_08043301 HF04.
- Until then, please inform your staff that the preparation of drugs with a dosage schema should only be performed out of the Patient chart /Observation Chart or Nurse task list.
- Agfa HealthCare strongly recommends training the users again, emphasizing that the Drug Preparation List is only to be used for the preparation of drugs and verification of prepared drugs, and that all displayed information must be considered before preparing the drug. For drug administration, please only use the dedicated functions, i.e. Patient Chart, Observation Chart or Nurse Task List.

Please distribute this information within your facility to all those who need to be aware of it.

Irrespective of the situation described above, care providers must always ensure that clinically important information, including that relating to prescriptions, is communicated between the care providers and verified using source information (e.g. provided by medical devices such as monitoring systems), independent from the software application in use.

It is important to take the actions detailed in this Urgent Field Safety Notification and to acknowledge receipt of this notification.

2020-01-09

Should the above information not apply to your facility or should the device have been transferred to another organization, please be so kind as to indicate this on the attached feedback form and pass this Field Safety Notice to the organization where the device has been transferred.

We apologize for the inconvenience we have caused, and we thank you for your careful attention to this issue and your continued support.

If you have any questions about this matter, please contact your local Agfa HealthCare organization:

Yasin Schwederski
- Teamlead Anwendersupport KAS -
Yasin.schwederski@agfa.com
+49 228 2668 3047

Sincerely,

Dr. Stephan Albers
QARA Director – BD HCIS

Agfa HealthCare NV
Septestraat 27
B-2640 Mortsel, Belgium

2020-01-09

URGENT FIELD SAFETY NOTICE
Feedback form

We kindly ask you to provide us this feedback form as soon as possible, latest within 30 days after receipt of this letter. Please send your feedback to the following email address: feedbackmanagement@agfa.com. Thank you for your co-operation.

Customer /Facility:	<IA_Facility_Site>
Address:	<IA_Street>
	<IA_City>, <IA_Zip_Code>, <IA_State>, <IA_Country>
Notice reference	**PRB0751073**
Product reference:	ORBIS Medication

☐ I confirm that I have received and understand the attached notice.

☐ This notice does not apply to my facility.

☐ The device has been transferred to another organization. Name and address of other organization:

_____

Customer

Name:	
Position:	
Signature:	
Date:	
Phone number:	

☐ Please correct our contact information as follows:

Customer / Facility name:

Address:

Agfa HealthCare NV
Septestraat 27
B-2640 Mortsel, Belgium