DATE

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: Loss of allergy data from one patient identity during merge, causing missing alerts in prescription process

Internal Reference: MST0108017

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

- ORBIS Medication 03.21.01 in ORBIS version 84.43.02.00 and higher in Germany and Austria.
  Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

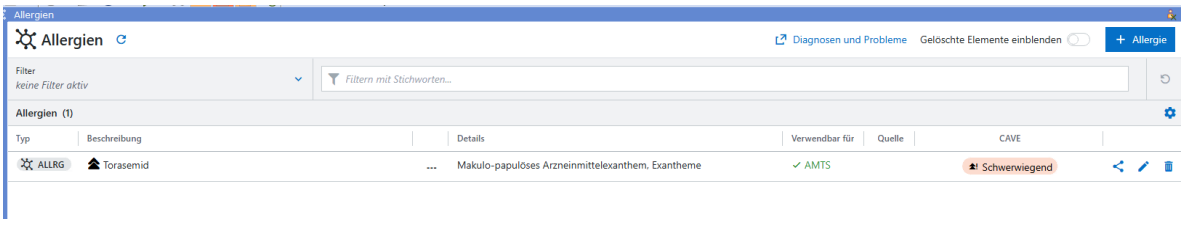
In the following scenario, a potential risk in ORBIS Medication could occur if used in combination with ORBIS Allergies: A patient was admitted. It was overlooked that this patient already had a record in the system with a specific ID, but another ID was created for this patient. Therefore, two records were created in the system for the same patient, with the same characteristics (gender, birthdate) but with a different ID.

In this FSN, the already existing patient ID will be referred to as “Pat-ID-1” and the newly created as “Pat-ID-2”.

Pat-ID-1 already has an active allergy documented. However, another allergy (different than allergy documented in Pat-ID-1) was recorded in Pat-ID-2. Both have been recorded independently of each other.

An administrative patient merge was then performed in the patient administration outside of ORBIS Allergies.

See below the view related to allergies (“Allergien”) documented in Pat-ID-1:



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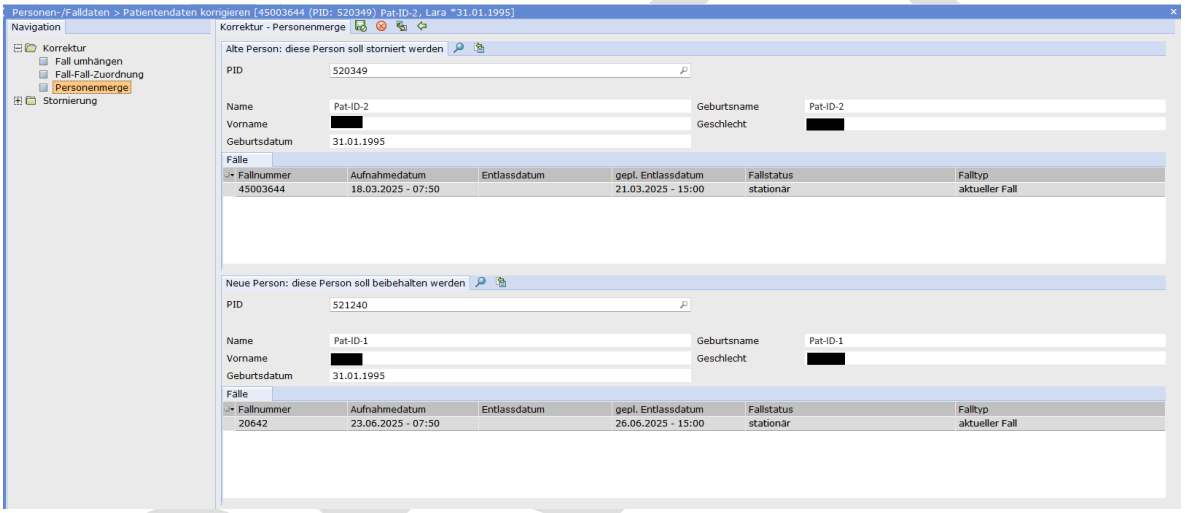
Allergies (“Allergien”) documented for Pat-ID-2:

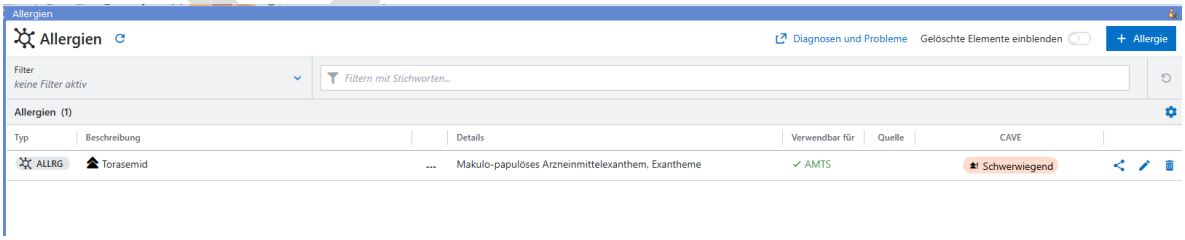
The second patient identity (Pat-ID-2) was merged into the first patient identity (Pat-ID-1) and then the patient record initially associated with Pat-ID-2 was deleted.

Following below the patient merge between Pat-ID-1 and Pat-ID-2:



Since the allergy data was linked to the patient identity and not to the case, it had no longer a valid reference and was no longer visible. As a result, the allergy from Pat-ID-2 was no longer visible for the end-user.

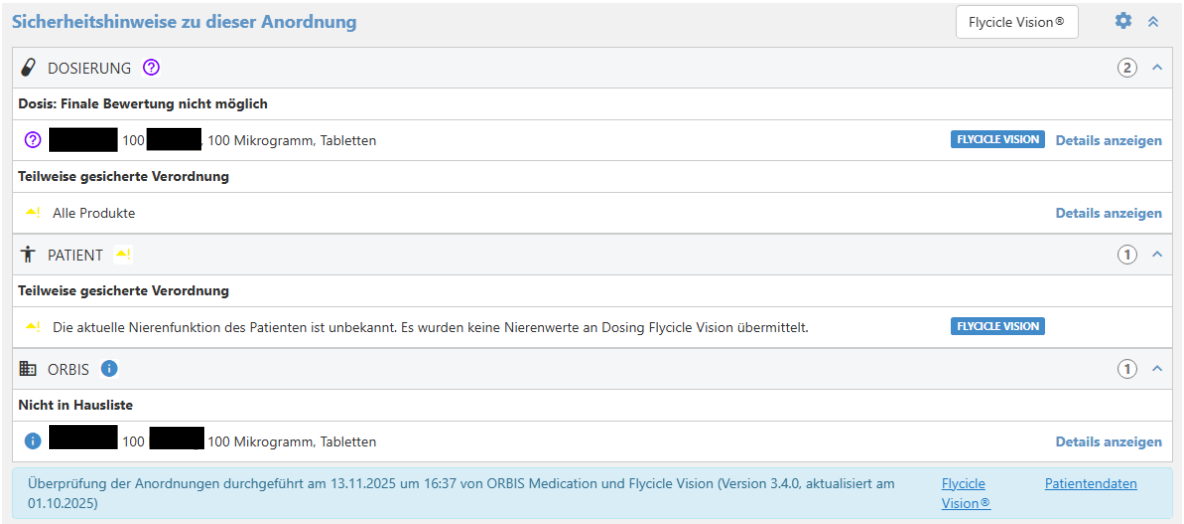
Allergies for Patient ID 1 after the merge: the medication “iodine” was not merged.



The consequence of this behavior is that, if a new drug-prescription is documented in ORBIS Medication (including the drug which the patient is allergic to) then, the AMTS-Check (Arzneimitteltherapiesicherheit) does not take the lost allergy information into account. The result is that if the physician is not aware of the lost allergy information from the calculated alerts, could

sign the prescription without the allergy information. Therefore, the patient merge could increase the potential risk of adverse drug events and compromise the safe clinical decision-making.

No allergy alert was displayed for the drug containing the substance ”iodine”:



The behavior described above can only occur with patient merges, but not with case merges. Only allergies in the discarded patient record can be lost this way.

Correction information Dedalus (ORBIS Allergies and ORBIS PAS):

When the patient merge is performed, a background routine is called that reassigns the allergies (from merged ID Pat-ID-2) to the target patient identity (Pat-ID-1).

With the correction of patient merge, all allergies from patient Pat-ID-2 will be transferred to the target patient identity Pat-ID-1 and remain visible to the end-user. In consequence, if the patient is allergic to the drug selected in the prescription, the allergy alert will be visible to the physician and the medication management checks will continue as usual.

Allergies for Pat-ID-1 after correction of patient merge:

Drug containing the substance ”iodine” after the correction in the patient merge:

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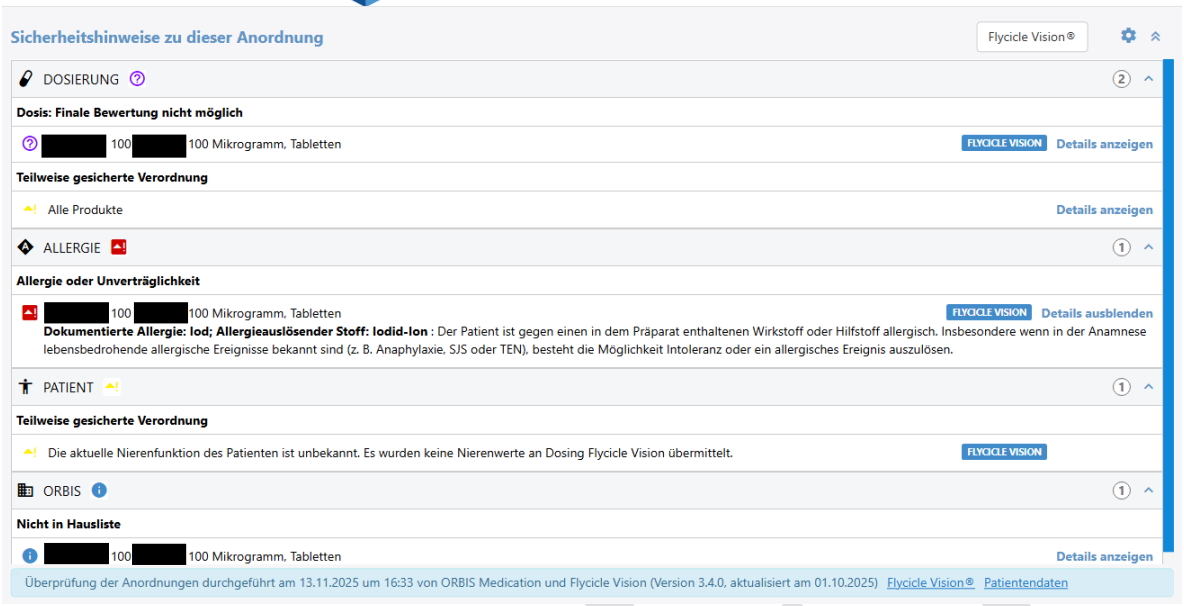

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction in ORBIS Medication 03.21.02.00 in ORBIS version 84.43.04.00 or higher (release planned for end of the 2025 year for Germany and Austria)

Recommended actions to be taken by the customer:

- As an administrative operator, before patient merge, please identify allergies in all duplicate patient profiles and fill them in the remaining one after merge action. Please review the allergies with the patient in every new admission.
- Install the correction when available.

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. They must review the allergies with the patient in every new admission and not rely on historical data, since the status of the patient may have changed since the last admission.

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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,

DRAFT

Dedalus

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	MST0108017 - Loss of allergy data from one patient identity during merge, causing missing alerts in prescription process
Product reference:	ORBIS Medication
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:

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