

# Urgent Field Safety Notice



03.12.2024.

**Subject:** Failure to check interactions in prescription sets when these contain out-of-date products

## **Affected product and product versions:**

CGM CLINICAL 8.x, 9.x to 10.2

Dear Madam or Sir,

We have been made aware of a case where the following behaviour was observed:

The interaction check shows a green result (no known interaction) for a drug that is no longer available but is still used in a prescription set. In contrast, an available drug (with identical active ingredient), prescribed directly without a set, shows an orange-colored result (moderately clinically significant) for the interaction check.

At present, we have identified the cause of this to be the retention of expired medication within the sets in the medication database.

What can happen:

If a medication from the prescription set that is no longer available is used, the result of the interaction check may be incorrect. In the worst case scenario, an avoidable interaction can be overlooked when planning medication for a patient.

## **Measures required:**

- **by the manufacturer CompuGroup Medical Software GmbH**
  - This Urgent Security Information for affected users
  - Provision of a query logic for versions of CGM CLINICAL Medication lower than 11.x, which indicates which articles are no longer available after the database has been updated so that the prescription sets can be updated in a targeted manner.
  - In this respect, the already available version 11.x is the correct software version.
  
- **by the customer**
  - Distribution of the Urgent Field Safety Notice to all users and their attention to it
  - Confirmation of acknowledgement by the signed response form
  - For versions lower than 11.x, update of all prescription sets with outdated medication by the clinic administrator
  - Preference for upgrading the system to version 11.x or higher

### **Urgent Field Safety Notice**

CompuGroup Medical Software GmbH – Maria Trost 21, 556070 Koblenz  
HISSUP-10530

## Urgent Field Safety Notice



We thank you for giving this matter the attention it deserves, as well as for your support.

**Please ensure that all users are aware of the contents of this "Urgent Security Information".**

**If you have any questions, please do not hesitate to contact the CompuGroup Service Desk.**

Yours sincerely,

Qualified Person (MDR)/PRRC  
CompuGroup Medical Software GmbH

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## Response form

We kindly ask you to return this response form as soon as possible and no later than **7 days after receipt** of this letter.

**Thank you for your cooperation.**

Customer/Institution (names of affected establishments):	
Address:	
Reference	HISSUP-10530
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Telephone number	
Date	
I confirm that I have received and understood the security information	
Signature	