

Urgent Field Safety Notice



14.03.2024

Subject: Interaction check shows "no interaction" (green) for preparations for which no interaction check could be carried out

Affected product and product versions:

CGM CLINICAL Medication 8.0-2023CW38; 8.0-2023CW20; 8.0-2021CW45; 8.0-2022CW03; 8.0-2022CW18; 8.0-2022 CW27; 9.1-CW44

Dear Sir or Madam,

During our market surveillance, we have become aware of cases in which the following behavior has been observed:

For a medication without a PZN, e.g. a preparation of self-manufactured drug, the interaction check shows a green result (no interaction), which is not correct from a technical point of view, as no interaction check was carried out for this medication, so that it is not known with certainty if an interaction exists or not.

What can happen:

Due to the green color for "no known interactions", the user is led to believe that an interaction check was also carried out on the self-manufactured drug and that no interactions were found, although interactions could possibly occur depending on the active ingredients in the self-manufactured medication.

Measures required:

- **by the manufacturer CGM Software GmbH**
 - This Urgent Security Information for affected users
 - Hotfix planned for the next days (incl. Information and assistance if necessary)

- **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
 - Control of the interaction check with a preparation of the company's own production, if available
 - Update the system as soon as the hotfix is provided by the manufacturer

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CGM Software GmbH – Maria Trost 21, 556070 Koblenz
HISSUP-9726

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Regardless of the situation described here, we would like to point out that practitioners must always ensure that clinically significant information, including regarding prescriptions, is clearly communicated and that verified information (e.g., from medical devices such as monitoring systems) is used that is independent of the software being used.

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,

Christoph Sperr
Qualified Person (MDR)/PRRC
CGM 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 **30 days after receipt** of this letter.

Thank you for your cooperation.

Customer/Institution (names of affected establishments):	
Address:	
Reference	HISSUP-9726
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Telephone number	
Date	
I confirm that I have received and understood the security information	
Signature	