

Urgent Field Safety Notice



04.04.2024

Subject: Medication administration can be displayed twice in the administration and execution list at a scheduled time

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 internal verification, we became aware of one case in which the following behavior has been observed:

During administration documentation, a medication may be displayed twice in the administration and execution list for the planned time. In this case, the medication is displayed in the status "Planned" and administered twice for one administration time.

What can happen:

Due to the double display of the administration in the administration and execution list, the patient may be administered the corresponding medication in addition to the prescribed amount.

Measures required:

- **by the manufacturer CompuGroup Medical 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
 - Check the timeline and execution list after documenting the administration for multiple presentation of the medication
 - Update the system as soon as the hotfix is provided by the manufacturer

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CompuGroup Medical Software GmbH – Maria Trost 21, 556070 Koblenz
HISSUP-9706

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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,

Thomas Grundnig
Rep. 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 **30 days after receipt** of this letter.

Thank you for your cooperation.

Customer/Institution (names of affected establishments):	
Address:	
Reference	HISSUP-9706
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Telephone number	
Date	
I confirm that I have received and understood the security information	
Signature	