

Urgent Field Safety Notice



05.07.2023

Subject: Duplicate medication dose triggered by software error

Affected product and product versions

CGM CLINICAL Medication

- 8.0 2022CW35
- 8.0 2023CW20
- 8.0 2022CW03
- 8.0-2022CW18
- 8.0 2022CW27

Problem Description:

The problem occurs in the following temporal and functional sequence:

1. recording an open-ended medication with a periodic dosing schedule and
2. later change of the dosage and
3. time-shifted, the prescription is limited in time and
4. again staggered in time, the time limit is changed to a later date.

What can happen:

- The last valid dosage is
 - o Displayed 2 times at the same time or also
 - o Displayed again at another time.

Measures :

- **By the manufacturer CGM Software GmbH**
 - o This Urgent Security Information for affected users
 - o Hotfix planned for the next days (incl. information about it)
- **By the customer**
 - o Distribution of the Urgent Field Safety Notice to all users and their attention to it
 - o Confirmation of knowledge by the signed response form
 - o Update the system as soon as the hotfix is provided by the manufacturer.
 - o

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.

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CGM Software GmbH – Maria Trost 21, 556070 Koblenz
HISSUP-9261

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It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

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


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

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

Yours sincerely



Qualified Person (MDR)/PRRC
CGM Software GmbH

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Datum: 2023.07.11 14:59:48
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Reply form

We ask that you return this response form as soon as possible, but no later than 30 days after receipt of this letter.

Thank you for your cooperation!

Customer / Facility(impacted sites):	
Address:	
Reference:	HISSUP-9261
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Phone number:	
Date	
I confirm that I have received and understood the safety information.	
Signature	