

Urgent Field Safety Notice



30.01.2025

Subject: Incomplete dosage display and missing scroll bar

Affected product and product versions:

CGM CLINICAL Medication: 9.1, 11.1

Dear Madam or Sir,

We have been made aware of a case where the following behaviour was observed: In the order details for an insulin-scheme, the recommendation for the dosage value is not displayed completely. The scheme pattern only shows 10 measurement corridors of the prescription. There is no scroll bar that could be used to display further values. Furthermore, there is no clear indication that more information is available than is displayed. The printout of the Federal Medication Plan (BMP) also does not display the recommendations for the dosage value beyond 10 rows. This behaviour also applies to other medications that are prescribed via a dosage schedule exceeding the dialogue window space.

This missing/incorrect information can have consequences for patient safety, such as the risk of prolonged/additional medical treatment.

Example illustration:

The screenshot shows the 'Verabreichungsschema' (Administration Scheme) window for 'Insulinschema mg/dl'. It features a table with 10 columns representing dosage ranges from 0,00 - 70,00 to 300,01 - 350,00 mg/dl, with corresponding 'Dosis (IE)' values from 16 to 34. Below the table is a 'Geplante' (Planned) section with a 'Humalog 100 E/ml Pat. x IE (x ml)' input field. Further down is a 'Messquelle' (Measurement Source) dropdown set to 'Neue Messung'. At the bottom, there is a 'Glucose (Blut)' input field with a value of '366,0' and a unit of 'mg/dl'. A red arrow points from the '366,0' value to the '300,01 - 350,00' column in the table above. The date '13.01.2025' and time '12:00' are shown at the bottom left.

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)

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CompuGroup Medical Software GmbH – Maria Trost 21, 556070 Koblenz
HISSUP-10697

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- **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
 - Update the system as soon as the hotfix is provided by the manufacturer

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
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-10697
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Telephone number	
Date	
I confirm that I have received and understood the security information	
Signature	