Urgent Field Safety Notice

14.03.2024

Subject: Missing medication when issuing the standardized medication plan (interval logic morning-midday-evening-night may only be used for BMP handover and must be complete)

Affected product and product versions:

CGM CLINICAL Medication 8.0-2022CW27; 9.1-CW40; 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:

- When transferring the discharge medication from CGM CCLINICAL Medication to the CGM CLINICAL Federal Standardized Medication Plan module
- When creating a printout from the Current medication and discharge medication global list
- Prescription in the template "Standard medication" with planning type "Dosage"

If a standard medication is created with the "Dosage" planning type, the current medication and discharge medication printout is generated automatically in the background when the discharge medication is transferred from CGM CCLINICAL Medication to the CGM CLINICAL Standardised Medication Plan module. The dose schedule corresponds to defined intervals:

Morning   06:00-09:00
Afternoon   11:00-14:00
Evening   17:00-20:00
Night   21:00-24:00

What can happen:
For example, if the time of administration for a prescription is 9:00-14:00-21:00-24:00, two administrations overlap in one interval (21:00 and 24:00).
In the case of two or more administrations within an interval, the system only recognizes one administration when it is fed into a printout or the standardized medication plan. All other doses are not recognised.

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)

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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
  - Checking the medication in the standardized medication plan after it has been transferred from the discharge medication
  - Manual adjustment of medication in the standardized medication plan if administration times or dosages have not been transferred correctly
  - Generate a printout of the clinical medication plan via the "clinical workstation"

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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CGM CompuGroup Medical

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-9739
Product:	CGM CLINICAL Medication
Name (contact person) Position	
Telephone number	
Date I confirm that I have received and understood the security information Signature	