

# Urgent Field Safety Notice



12.11.2024.

**Subject:** Incorrect display of the medication in the timeline-prescription line and on the printed medication plan after changing the daily pattern via the user-defined field

## Affected product and product versions:

CGM CLINICAL 9.0 to 10.2, 11.1

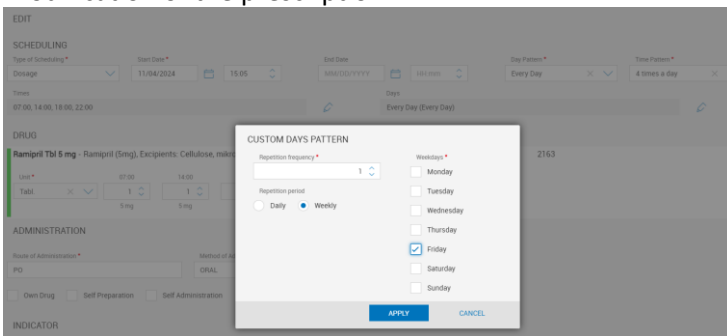
Dear Madam or Sir,

We have been made aware of a case where the following behaviour was observed:

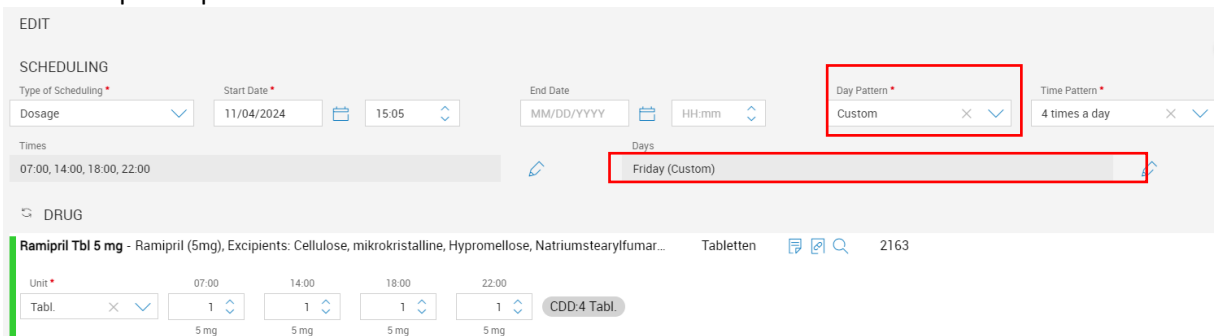
If you subsequently change the selected day pattern for a prescription, e.g. daily, using the “Days” field up to e.g. Friday (User defined), the day pattern is not displayed in the prescription line of the timeline as well on the printed medication plan. However, the day pattern is displayed correctly in the tooltip of the prescription line. The individual prescriptions are also displayed correctly in the administration line of timeline and in the work lists.

## Example illustration

Modification of the prescription



## Modified prescription



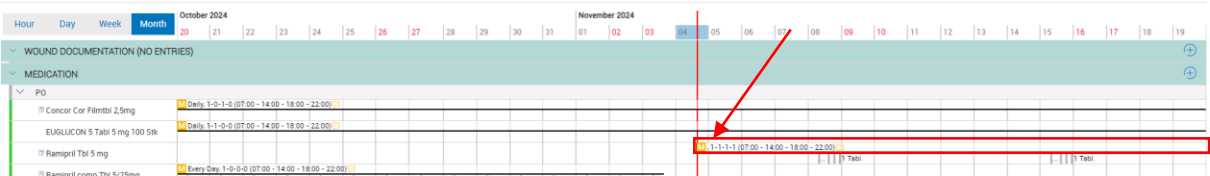
## Urgent Field Safety Notice

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HISSUP-10466

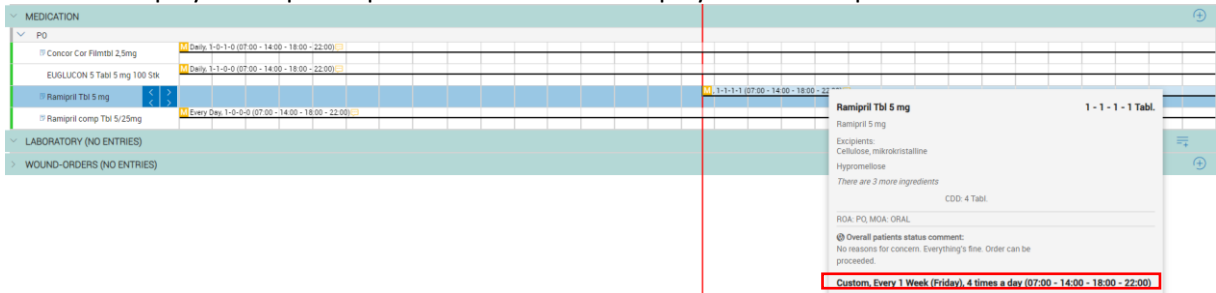
# Urgent Field Safety Notice



Incorrect display on the timeline in the prescription line:



Incorrect display in the prescription line but correct display in the tooltip:



Correct presentation in the administration line of timeline and in the work lists:

Timeline Medical Problems Clinical Stream Medications Orders and Results Documents Ward round Liquid balance OPs Progress Notes Diagnoses Procedures Medical Workplace

Home Medication **Current Medication** Recommendation Medic... Executions for Current M... Executions in Daily View Prepared to be Modified Running to change Narcotics in Daily View 01/01/1753 01:05 - 0

ROA	STATU...	DRUG DETAILS	ACTIVE INGREDIENTS	DOSE	UNIT	START/END	SCHEDULING
PO	REGULAR (4)	Concor Cor Filmtbl 2,5mg	Bisoprolol hemifumarat, Bisoprolol...	1-0-1-0	Tabl.	11/05/2022 10:00 - N/A	Daily, 4 times a day (07:00 - 14:00 - 18:00 - 22:00)
PO		EUGLUCON 5 Tabl 5 mg 100 Stk		1-1-0-0	mg	11/08/2022 09:09 - N/A	Daily, 4 times a day (07:00 - 14:00 - 18:00 - 22:00)
PO		Ramipril Tbl 5 mg	Ramipril, Excipients: Cellulose, m...	1-1-1-1	Tabl.	11/04/2024 15:05 - N/A	Custom, Every 1 Week (Friday), 4 times a day (07:00 - 14:00 - 18:00 - 22:00)

Timeline Medical Problems Clinical Stream Medications Orders and Results Documents Ward round Liquid balance OPs Progress Notes Diagnoses

Home Medication Current Medication Recommendation ... Executions for Curr... **Executions in Daily ...** Prepared to be Mo... Running to change Narcotics in Daily ... 11,

PLANNED DATE	DRUG DETAILS	ATC	FORM	ROA/MOA	DOSE	UNIT	EQUIVALENT DOSES
11/08/2024	Ramipril Tbl 5 mg - Ramipril(5 mg), Excipi...	C09AA05	Tabletten	PO, ORAL	1 - 1 - 1 - 1	Tabl.	5 - 5 - 5 - 5 mg
11/15/2024	Ramipril Tbl 5 mg - Ramipril(5 mg), Excipi...	C09AA05	Tabletten	PO, ORAL	1 - 1 - 1 - 1	Tabl.	5 - 5 - 5 - 5 mg

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Incorrect display on the printed medication plan:

Medikationsplan		Für: Vogel, X Geburtsdatum: -		Unterkunft: 01/ST.4/Station 4 (5), Fachabteilung: Urologie			
ausgedruckt am 29.10.2024 - 13:37 von cgm_mheida		Klinikname: KWA Klinik		Klinikadresse:			
Medikament	Dosiereinheit	Dosierung				Verabreichungsart	Bemerkung/Anweisung
Verordnet von 29.10.2024 - 13:32 bis n.v.							
Ramipril STADA 5mg Tabletten (Tabletten [TAB]) Ramipril (5.0 mg)	Stück	08:00	12:00	17:00	20:00	oral	Einnahme: Benutzerdefiniert
		1	1	1	1		
Verordnet von 16.10.2024 - 13:20 bis n.v.							
Fentanyl - 1 A Pharma 5 25 ugh Matrixpflaster (Pflaster Transdermal [PFT]) Fentanyl (4.2 mg)	Stück	Ab dem: 16.10.2024, 13:20 Alle 3 Tage: 2				transdermal	
Verordnet von 16.10.2024 - 13:21 bis n.v.							
Fentanyl - CT 100ugh Matrixpflaster (Pflaster Transdermal [PFT]) Fentanyl (16.5 mg)	Stück	07:00	18:00				
		1	0				
Verordnet von 11.10.2024 - 14:12 bis n.v.							
BUSCOPAN (Ueberzogene Tabletten [UTA]) Butylscopolaminium Kalium (8.19 mg), Butylscopolaminium bromid (10.0 mg)	Stück	07:00	18:00				
		1	0				
						oral	Ab dem 11.10.2024, 14:12 Benutzerdefiniert

What can happen:

If a user does not process the medications using the worklists (prescription lists / administration lists) in Medication System but only with printed version of medication plan or the timeline and only pays attention to the prescription bar and not to the administration bar, it can happen that medication is mistakenly provided for every day instead of e.g. only for 1 day a week, which could lead to a considerable overdose.

## Measures required:

- **by the manufacturer CompuGroup Medical Software GmbH**
  - This Urgent Security Information for affected users
  - An update to the system is required to resolve both issues. Once the update is available, you will be informed separately.
  
- **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
  - As a short-term solution, the functionality of the user-defined daily pattern should not be used if the prescription schedule is changed.

# Urgent Field Safety Notice



- Ensure that the prescribed medication is prepared and distributed only in accordance with the CGM CLINICAL administration list.
  - If a printout of the medication plan with a user-defined daily pattern is necessary, we recommend entering the respective daily pattern manually in the table under 'Notes' and 'Free text'. This ensures that the corresponding information is also visible on the printout of the medication plan.
- Update the system as soon as the update 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,

**Qualified Person (MDR)/PRRC  
CompuGroup Medical Software GmbH**

# Urgent Field Safety Notice



## 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-10466
Product:	CGM CLINICAL Medication
Name (contact person)	
Position	
Telephone number	
Date	
I confirm that I have received and understood the security information	
Signature	