MEDIMA Sp. z o.o. ICU Medical Group
Al. Jerozolimskie 200,
02-486 Warszawa,
Poland
www.medima.pl

URGENT: FIELD SAFETY NOTICE

Medima Infusion Pump

9th January 2025

Dear Valued Medima Infusion System Customers:

Medima Sp. z o. o. is issuing this letter to notify you of a potential issue with all Medima infusion pumps with software version 3.1.87 and older

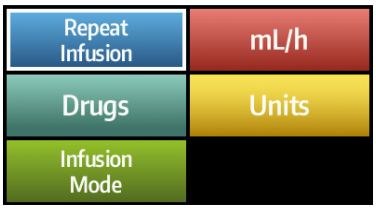
ISSUE Description:

A software issue was detected during internal testing. The issue only impacts infusions that meet both conditions below:

- The infusion is programmed using the "Profile" infusion mode with units of **mL/min** or **mL/24h**
- The user titrates the **dose rate** after the infusion is started

ICU Medical is **not** aware of any customer using the workflow detailed above, however, out of an abundance of caution we are providing the details of the specific scenario where the issue may occur as described below:

1. Select "Infusion Mode" tile on the Main Screen



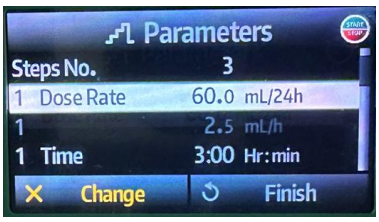
2. Select "Profile" tile on the "Infusion Mode" screen

3. Choose "Others" on the "Units" screen

4. Create mL/min or mL/24h in the "Units" window

5. Program and start a "Profile" infusion

6. Titrate the dose rate after infusion is started



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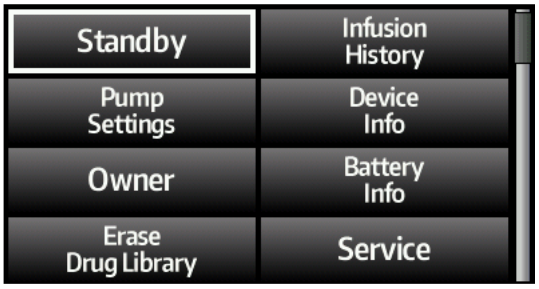
Potential Risk:
If the workflow above is used and the user changes the dose rate during a **Profile infusion using units of mL/min or mL/24h**, the flow rate will be incorrectly calculated and displayed. This will result in the incorrect amount of medication being administered to the patient. To date, no complaints or serious injuries related to this issue have been received.

Affected Product:
The issue is present in all devices with software version 3.1.87 and older.

Recommendations for users:
If you use software version 3.1.87 and older, do not use dosing units of mL/min or mL/24h with the "Profile" infusion mode and refrain from making dose rate changes when this mode is selected.
In **"Profile" infusion mode, please use only ml/h units** until you update your software version to 3.1.88 or above.

Medima Actions:
Medima has developed a new software version (3.1.88 and above) that resolves the issue described in this Field Safety Notice.

Required Actions for Users:
There is no need to return or discontinue using your Medima infusion pumps. When using the pump, all instructions, including warnings and cautions in the device User Manual, must be followed. Please select the "Device info" tile on the Options menu to identify the pump software version. Select the "Menu" button on the alphanumeric keypad when the pump is turned OFF and connected to an external power supply to access the Options menu.



1. Locate all affected pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.

2. Complete and return the attached Response Form to EMEA-FSN@icumed.com within ten days of receipt to acknowledge your understanding of this notification.

3. **DISTRIBUTORS**: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com.

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For further inquiries, please contact Medima Sp. z o. o using the information provided below.

Medima Contact	Contact Information	Areas of Support
Complaint Management	reklamacje@icumed.com	To report adverse events or product complaints
Technical Assistance	serwis@icumed.com	Additional information or assistance

Your country regulatory agency has been notified of this action.

Medima Sp. z o. o. is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Aleksandra Styczek-Grabowska
Senior Manager, Quality and Regulatory Affairs

See attachment below: *Customer Response Form*

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

Medima infusion pump

9th January 2025

Check your inventory and complete the information below, even if you do not have the affected product. Complete this form and return it to EMEA-FSN@icumed.com via email. If you have questions about this form, please contact EMEA-FSN@icumed.com , or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

I have affected product (Medima devices with version 3.1.87 or below)
☐ **YES** ☐ **NO**

I acknowledge receipt of this communication and confirm that I have notified users at my facility of this Field communication:
☐ **YES** ☐ **NO**

I am currently using the impacted **mL/min or mL/24 h with "Profile" mode** and requesting a software update:
☐ **YES** ☐ **NO**

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
- If yes, have you notified your retail customers and asked them to contact EMEA-FSN@icumed.com to obtain a response form? ☐ **YES** ☐ **NO** (if no, explain below)

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Adverse events and complaints associated with the use of these products should be reported and emailed to reklamacje@icumed.com