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

URGENT: FIELD SAFETY NOTICE

Medima P100, P200, and P300 Volumetric infusion Pumps

9th January 2025

Dear Valued Medima Infusion System Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Medima Sp. z o. o. is issuing this letter to notify you of a potential issue related to specific serial numbers of the Medima P100, P200, and P300 volumetric infusion pumps. The following information details the issue and the required steps for you to perform.

Issue:
Our stepper motor supplier informed us of a potential issue due to an error in their manufacturing process with a specific lot of the stepper motors used to load and release the Free-Flow Protection Clamp (loading and releasing the pump set line). This manufacturing issue can lead to the pump runway (shown in Figure 1 below) not opening to allow the infusion set to be inserted into the pump.

Figure 1

Potential Risk:
If the infusion set cannot be inserted into the pump, this issue could lead to a delay in the initiation of therapy. To date, Medima has not received any reports of serious injury or death related to this issue.

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Affected Product:

This issue only impacts specific serial numbers of the P100, P200, and P300 volumetric infusion pumps manufactured in 2022/2023. Please refer to the list of potentially impacted serial numbers that are at your facility (as per ICU Medical records).

Recommendations for users:

- You can continue to use your Medima volumetric pumps following the recommendations below.
- If the issue occurs, the pump displays an alarm message indicating that the pump cannot be used. The alarm is an alternating red and black animation with an audible signal, as shown in Figure 2 below.
- If this alarm occurs, please contact Medima to make arrangements to service the affected pump.

Figure 2 *– Image of alarm screens if the issue occurs*

Medima Actions:

Medima has developed a software patch to mitigate the issue described in this Field Safety Notice.

Please inform all Health professionals in your facility of this field notification

1. Ensure that all users or potential users are immediately made aware of this notification.
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 ask them to return completed response forms to you. When you have received all completed response forms from your customers, please complete a SINGLE COMPLETED form with the required details and return to EMEA-FSN@icumed.com.

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's regulatory agency has been notified of this action.

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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

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

Medima Volumetric 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:
☐ **YES** ☐ **NO**

I acknowledge receipt of this communication and confirm that I have notified users at my facility of this Field communication:
☐ **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**

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