

URGENT: MEDICAL DEVICE CUSTOMER NOTICE

CADD™ Medication Cassette Reservoirs

01 August 2025

Dear Valued Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

ICU Medical is issuing this letter to notify you of a potential issue with specific models and lots of 50 mL and 100 mL CADD Medication Cassette Reservoirs. This letter details the potential issue, the affected models and lots, and the required steps to perform.

Issue:

Certain CADD 50 mL and 100 mL Medication Cassette Reservoirs may exhibit weakened medication bag welds along the bag perimeter inside the plastic housing. This could result in medication leakage along the bag perimeter.

Potential Risk:

Leakage from a weakened medication bag weld could potentially result in delay or interruption of therapy, under delivery of medication, exposure to infectious or toxic agents, or air embolus.

No serious injuries or deaths have been reported to ICU Medical as a result of this issue.

Affected Models:

Out of an abundance of caution, CADD Medication Cassette Reservoir lots listed in Appendix A are considered potentially affected by this issue and in scope of this notification. All customers to whom ICU Medical distributed these products will receive a copy of this notification.

Customer Required Actions:

Please complete the following actions below.

1. Review your inventory of CADD Medication Cassette Reservoirs to confirm if any of the lots listed in Appendix A are within your possession.
2. Quarantine the affected product and destroy or discard it immediately following your institution's process for destruction or discarding.
3. **Return the attached Customer Response Form to asiaquality@icumed.com within ten (10) days of receipt to acknowledge your understanding of this notification.**

4. **DISTRIBUTORS:** Immediately forward this notice to all users to whom you distributed these products. Request that they complete the Customer Response Form and return it to asiaquality@icumed.com.

Follow up actions by ICU Medical:

ICU Medical will provide replacement products to affected customers upon receipt of a complete Customer Response Form to certify product destruction. Replacements shall be provided if the form is received within 120 days of receipt of this notification. For further inquiries, please contact ICU Medical using the following information.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Customer Service	customerservice@icumed.com 1-(800)-258-5361	Additional information or to request replacement product
Field Action Processing	asiaquality@icumed.com	Questions about this communication

Sincerely,

Leodigard Montefalcon Jr.

Senior Quality Assurance Manager – Asia

Enclosures:

Attachment 1 – Customer Response Form

Attachment 2- Frequently Asked Questions

Appendix A

Potentially Affected Product Models and Lots

Model Number	Product Name	Affected Lot Number	
21-7002-24	CADD \square Medication Cassette Reservoir with clamp and female Luer. Nonvented stopper included. 100mL	6037751	6053983