

URGENT: FIELD SAFETY NOTICE

CADD™ Medication Cassette Reservoirs

28 August 2025

Dear Valued Customers:

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

Issue:

Certain CADD 50mL and 100mL 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 the table below, 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

Table 1: Potentially Affected Product Models and Lots

Model Number	Product Name	Affected Lot Number				
21-7001-24	CADD™ Medication Cassette Reservoir with clamp and female Luer. Nonvented stopper included. 50mL	6022008	6022009	6037749	6062686	6062687
21-7002-24	CADD™ Medication Cassette Reservoir with clamp and female Luer. Nonvented stopper included. 100mL	4468662	6037750	6037751	6037753	6053980
		6053981	6053982	6053983	6062689	
21-7300-24	CADD™ Yellow Medication Cassette Reservoir with flow stop, clamp and female Luer. Nonvented stopper included 100mL	6037758	6053985			

Model Number	Product Name	Affected Lot Number				
21-7301-24	CADD™ Medication Cassette Reservoir with flow stop, clamp and female Luer. Nonvented stopper included. 50mL	6005584	6012462	6022022	6037765	6037768
		6037771	6062698	6092859		
21-7302-24	CADD™ Medication Cassette Reservoir with flow stop, clamp and female Luer. Nonvented stopper included. 100mL	4468670	4468677	6004936	6005593	6005601
		6012470	6012472	6037772	6037775	6037776
		6054005	6054009	6054011	6054012	6054013
		6054014	6062699	6062700	6062703	6062705
		6062710	6062712	6062714		
21-7600-24	NRFit CADD™ Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit™ connector. Yellow stopper included 100mL	6037784	6054015			

Customer Required Actions

Please note, if the cassette has been filled and if no leak is found, the user can proceed forward with using the cassette while maintaining heightened awareness based on the potential for a defect.

1. Review your inventory of CADD Medication Cassette Reservoirs to confirm if any of the lots listed in table 1 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. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.
4. **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

Follow up actions by ICU Medical:

ICU Medical will provide full credit to affected customers upon receipt of a complete Customer Response Form to certify product destruction. Full credit 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	To report adverse events or product complaints

ICU Medical Contact	Contact Information	Areas of Support
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about product replacement and/or credit.

Your country regulatory agency has been notified of this action

ICU Medical 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,



Andy Mathein
Vice President of Quality

See below:

Customer Response Form

URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

CADD™ Medication Cassette Reservoirs

28 August 2025

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com. If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
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	

Please select one:

- ☐ I have **NO** affected products (complete and return this form to the e-mail address above)
- ☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to ICU Medical's Global Complaint Management Department at globalcomplaints@icumed.com.

ADDITIONAL AFFECTED PRODUCT DESTROYED

[illegible]