URGENT: FIELD SAFETY NOTICE

CADD™ High Volume Administration Sets

13 February 2026

Dear Valued Customers:

ICU Medical is issuing this letter to notify you of a potential issue with one lot of CADD High Volume Administration Sets and the required steps to perform.

Issue:
List Number 21-7361-24 CADD High Volume Administration Sets from Lot 6037805 may exhibit an insufficient bond that could result in medication leakage.

Potential Risk:
Leakage from a CADD High Volume Administration Set 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, all List Number 21-7361-24 CADD High Volume Administration Sets from Lot 6037805, 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

1. Review your inventory of List Number 21-7361-24 CADD High Volume Administration Sets to confirm if any sets from Lot 6037805 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
Customer Service	Regional Support | ICU Medical	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,

[redacted]

Andy Mathein
Vice President of Quality

See below:
Customer Response Form

URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

CADD™ High Volume Administration Sets

13 February 2026

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.