Kosterijland 20,
3981 AJ Bunnik,
The Netherlands

URGENT: FIELD SAFETY NOTICE

CADD™ Medication Cassette Reservoirs with NRFit

28th August 2026

Dear Valued Customers:

ICU Medical is issuing this letter to notify you of a potential issue with specific models and lots of the 100mL and 250mL CADD Medication Cassette Reservoirs with NRFit Connectors listed in Table 1. This letter details the potential issue, the affected models, and the required steps to perform.

Issue:
Certain reservoirs may exhibit fluid leakage at the joint between the connector and the tubing. See Figure 1 below.

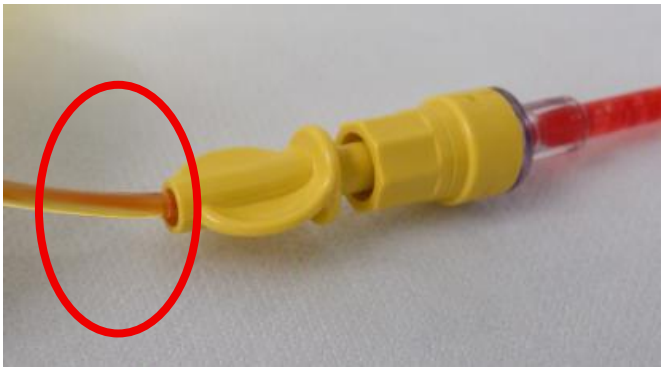

Figure 1: Leak Location

Potential Risk:
Leakage from the joint between the connector and the tubing could potentially result in the delay or interruption of therapy, under delivery of medication, exposure to infectious or toxic agents, or an air embolus. To date, ICU Medical has received zero (0) reports of serious injury and zero (0) deaths associated with this issue.

Affected Models:
The affected items and lot numbers are provided in Table 1, below:

Table 1: Affected Product

Item / SKU Number	Product Description	UDI-DI	Lot Number(s)
21-7600-24	NRFit, CASSETTE, 100ML, RESERVOIR, FS, YELLOW, 12/BX	30610586044001	6026878, 6037784, 6054015, 6062724, 6070616, 6082332, 6092886, 6108556, 6126029, 6140893, 6143454, 6147696, 6147697, 6155095, 6162769, 6171587
21-7609-24	NRFit, CASSETTE, 250ML, RESERVOIR, TOTM, FS, YELLOW, 12/BX	30610586044018	6037697, 6053978, 6077773, 6092846, 6101798, 6108514, 6108515, 6140862

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Customer Required Actions

1. Check all inventory locations within your institution for the affected products listed in Table 1 and discontinue use. Destroy all affected products following your institution's destruction process.
2. Quarantine the affected product and destroy or discard it immediately following your institution's process for destruction or discarding.
3. Share this notification with all potential users of the reservoirs to ensure they are aware of this notification. If the products are used at another location, please ensure this communication is delivered there.
4. 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.
5. **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,

Corine Broekhuizen
Director of Quality, ICU Medical BV

See below:
Customer Response Form

Kosterijland 20,
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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

CADD™ Medication Cassette Reservoirs with NRFit

28th August 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.