Nathan Lane North
Minneapolis, MN 55442
www.icumed.com

URGENT: FIELD SAFETY NOTICE

HOTLINE™ Fluid Warming Sets

9th July 2026

Dear Valued Customers:

ICU Medical is issuing this Field Safety Notice to notify you of an issue with specific Lots of L-70 HOTLINE Fluid Warming Sets. This letter details the issue and the required actions for users to perform.

Issue:
ICU Medical became aware of an increased likelihood of leakage in specific Lots of L-70 HOTLINE Fluid Warming Sets due to potentially inadequate solvent application at the tubing to return connector bond. Four (4) Lots of L-70 HOTLINE Fluid Warming Sets have an increased likelihood of leakage due to this issue.

Refer to Figure 1 for an example of L-70 leakage from an inadequate tubing to return connector solvent bond.

Figure 1: Example of L-70 leakage at tubing to return connector bond

Potential Risk:
Delay of Therapy may occur if an L-70 set is deemed unusable during pre-use checks described in the Instructions for Use (IFU), and a replacement set is not immediately available. Interruption of Therapy may occur if leakage during use requires replacement of the set. Under delivery of medication, exposure to Infectious Agents or Toxic Agents, and Air in Line, are also possible due to leakage in sets.

ICU Medical has received zero (0) reports of death or serious injury associated with this issue.

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Affected Product:

Our records indicate your facility may have received affected products from one or more Lot in Table 1.

Table 1: List of Affected L-70 Lot Numbers

Affected List Number	Product Description	Affected Lot Number
L-70	Hotline™ Fluid Warming Set	4293568 4293569 4326087 4337724

UDI: 30695085407007

Customer Required Actions

When using the device, all instructions, including warnings and cautions contained in the Instructions for Use must be followed with heightened awareness. Please complete the following actions below

1. Locate potentially affected devices from the Lots listed in Table 1 above.
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.

Nathan Lane North
Minneapolis, MN 55442
www.icumed.com

Sincerely,

Andy Mathein
Vice President of Quality

See below:
Customer Response Form

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

HOTLINE™ Fluid Warming Sets

9th July 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.