600 N. Field Drive
Lake Forest, IL 60045
www.icumed.com

URGENT: FIELD SAFETY NOTICE

HOTLINE HL-90 Blood & Fluid Warmer

18th September 2025

Dear Valued Customers:

ICU Medical is issuing this letter to notify you of an issue with certain HOTLINE HL-90 Blood & Fluid Warmer devices. This letter details the issue and the required actions for users to perform.

Issue:
ICU Medical became aware of certain HOTLINE HL-90 Blood & Fluid Warmers with missing insulators on their internal Printed Circuit Boards (PCBs). PCB insulators are installed on the PCBs to shield service technicians from contact with energized points on PCBs while servicing opened devices that are plugged into an electrical outlet and powered ON. A "Line Voltage" symbol on the left side of the PCB indicates these energized areas on the PCB to technicians.

Figure 1 shows a PCB with an insulator installed. This shows the location of the transparent insulator and the energized points on the PCB, covered by the insulator.

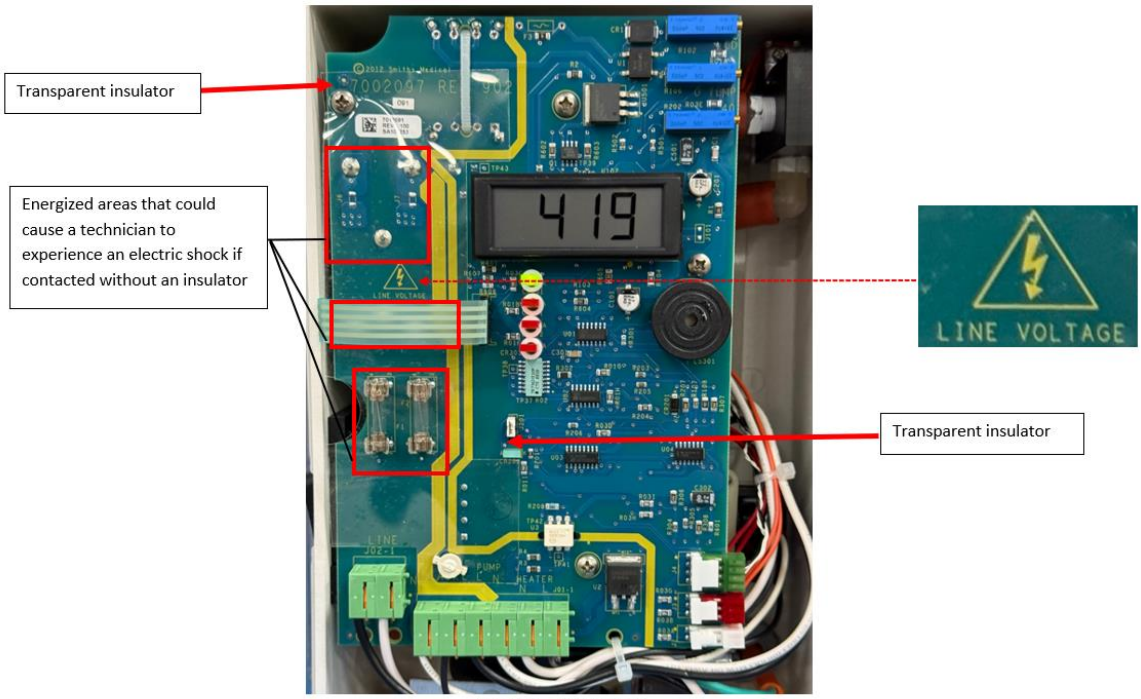

Figure 1 – HL-90 PCB

Figure 1: View of PCB inside the HOTLINE Blood & Fluid Warmer with front cover opened

Potential Risk:
A life-threatening electrical shock from 230V MAINS line voltage is possible while servicing these devices.

There is no risk of electrical shock during use in the clinical environment and a missing PCB insulator has no impact on the clinical function of the device. Clinical users are not instructed or expected to open the front cover housing of these devices under clinical use. During clinical use, the front cover remains closed and provides insulation protecting clinical users from electrical shock.

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

Affected Product:
Our records indicate that your facility may have received affected products. Refer to Table 1 for a list of affected devices and serial numbers in Denmark.

Table 1: Potentially Affected Product Models and Serial Numbers

Model Number	Product Name	Affected Serial Number
HL-90-DA-230	230V DANISH HOTLINE	S10002401

Required Actions for Users:
Please complete the following actions listed below:

1. Locate potentially affected devices from the list in Table 1
2. There is no need to discontinue using your device
3. If service technicians need to open the front cover of their HOTLINE devices before ICU Medical can schedule the repair, then users should avoid contact with any internal components as shown in Figure 1.
4. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com **within ten 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 contact customers to schedule the repairs for the affected devices.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	GlobalComplaints@icumed.com	To report adverse events or product complaints
Technical Assistance	DACHSTS@icumed.com	Additional information or assistance

Your country's regulatory agency has been notified of this action.

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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,

Andrew Mathein
Vice President of Quality and Regulatory

See below:
Customer Response Form

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

HOTLINE HL-90 Blood & Fluid Warmer

18th September 2025

Check your inventory and complete the information below, even if you do not have the affected product. Complete this form and return it to EMEA-FSN@icumed.com. If you have questions about this form please contact ICU Medical using the contact provided.

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 affected product was purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility, and I have followed the instructions provided to me (complete and return this form to EMEA-FSN@icumed.com).

Indicate the number of devices in inventory requiring updating:	
Indicate the Individual's Name, Phone, and Address to contact to schedule device inspection:	

☐ I have **NO** affected product (complete and return this form to ICU Medical)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

Adverse events and complaints associated with the use of these products should be reported and emailed to ICU Medical's Global Complaint Management Department (GlobalComplaints@icumed.com).