smiths medical

6000 Nathan Lane North
Minneapolis, MN 55442

URGENT: MEDICAL DEVICE CORRECTION

Level 1® Fast Fluid Flow Fluid Warmers and Level 1® NORMOFLO® Irrigation Fluid Warmers

25 June 2024

Dear Valued Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Smiths Medical is issuing this letter to notify you of two potential issues with Level 1 Fast Fluid Flow Fluid Warmers and Level 1 NORMOFLO Irrigation Fluid Warmers. This letter details the issues, the affected models and the required actions for users to perform.

Issues:

Smiths Medical has become aware of two issues related to the Level 1 Fast Flow Fluid Warmers and Level 1 NORMOFLO Irrigation Fluid Warmers:

1. The return tube assembly inside the warmers may exhibit stress cracking that can propagate over time and potentially result in leaking recirculating fluid. Leaking recirculating fluid may potentially damage other components within the warmer, such as the printed circuit board.

2. The cable inside the warmers that connects to the external on/off switch may potentially exhibit delamination of insulation which may propagate over time and may lead to corrosion and a break in the electrical circuit.

Potential Risk:

1. Associated with return tube assembly:
   If the return tube assembly cracks, damage to other components within the warmer due to leaking recirculating fluid may lead to the device failing to power on, or audio-visual alarms getting triggered but not resolved, or device shutting down while in use, causing a delay of therapy or, interruption of therapy. A delay or interruption of therapy may result in hypothermia, hypovolemia, hypotension, prolonged clinical symptoms, underdose, or decreased visibility of affected site.

   Smiths Medical has received zero (0) reports of death and zero (0) reports of serious injuries associated to this issue.

2. Associated with the cable inside the warmers that connects to the external on/off switch:
   If the cable connecting to the on/off switch delaminates over time, potential corrosion of the cable may lead to the device failing to power on, or audio-visual alarms getting triggered but not resolved, or device shutting down while in use, causing a delay of therapy or, interruption of therapy. A delay or interruption of therapy may result in hypothermia, hypovolemia, hypotension, prolonged clinical symptoms, underdose, or decreased visibility of affected site.

   Smiths Medical has received one (1) report of death and zero (0) reports of serious injuries associated to this issue.

Affected Product:

Our records indicate that your facility may have received some of the potentially affected products. Refer to Table 1 below for a list of affected devices and serial/lot numbers.

Table 1-List of Affected Devices

Affected Product Name	Affected Models	Affected SKUs
Level 1® Fast Flow Fluid Warmer	H-1200	H-1200-EN-115V-US

Level 1® NORMOFLO Irrigation Fluid Warmer	H1100, H-1129	H1100 H-1129

Models H-250, H-500, H-1000, H-1025 and SA-1000 are also affected by the issues in this letter. However, since Smiths Medical announced the end of life for these models in 2008 and end of service in 2013, they should no longer be used for clinical care.

Required Actions for Users:
To address the described risk, users should follow the instructions below:

1. Prior to use, confirm that the device powers on and passes all the alarm tests outlined in the Setup for Use section in the Operator's Manual and described below in point A. If the device fails during these alarm tests or does not power on, remove the device from service, submit a complaint to Smiths Medical and await further instructions from Smiths Medical.
    A. Alarm Tests outlined in Set Up for Use in Operators Manual:
        i. Press and hold the Alarm Test button on the Fluid Warmer's Power and Alarm Test Panel.
            1. All Fluid Warmer visual alarm LEDs illuminate and the audible alarm signals beep.
        ii. Release the Alarm Test button; the Over Temperature alarm continues.
        iii. Clear the Over Temperature alarm condition.
            1. Turn the Fluid Warmer OFF and then back ON.
            2. The Air Detector/Clamp runs a Power On Test. (Only on the H-1200 Fast Flow Fluid Warmer)
            3. The Air Detector/Clamp goes into Automatic operation (Only on the H-1200 Fast Flow Fluid Warmer)
2. Users should have back up devices such as manual pressure cuffs or additional Level 1 Fast Flow Fluid Warmer or Level 1 Normoflo Irrigation Fluid Warmer available for emergency situations.

Please inform users of the product in your organization of this notification and complete the attached response form. Return the completed form to the fax number or e-mail address on the form within 10 days of receipt to acknowledge your understanding of this notification, even if you do not have the affected product.

Distributors: If you have distributed the product further, immediately notify your accounts that received the product identified in the Table 1 above of this notification and ask them to contact Sedgwick at 1-855-215-5836 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions by Smiths Medical:
Smiths Medical is in the process of correcting these issues and will contact customers as soon as the solutions are available for implementation onto their devices.

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

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	productcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Device Correction Inquiries	https://icumed.custhelp.com/app/market-action	For any questions regarding this action
Technical Support	1-(800)-241-4002, option 3 tsc.support@icumed.com	Additional technical information or assistance

The U.S. Food and Drug Administration (FDA) has been notified of this action.

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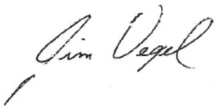
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Smiths 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,



Jim Vegel
Vice President of Quality

Enclosures:

- Response Form