

**URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

**UPDATED SAFETY ALERT**

**LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems  
Potential for Aluminum Ions to Leach into Warmed Fluids**

**Affected Device Models:** Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System

**Type of Action:** Correction

**Date:** September 2, 2021

**Attention:** Nurses, Clinicians, Physicians, Risk Managers, Field Safety Coordinators

**Affected Devices:** Level 1® Fluid Warming System disposable products listed below:

Affected Product Model Name	Affected Product Model Number
Level 1® Fluid Warmer	H-1000, H-500
Level 1® Fluid Warming System	H-1025, H-1028, H-1200
Level 1® Normothermic I.V. Fluid Administration Set	D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL, D-70, DI-70
NORMOFLO® Fluid Warmer	H-1100, H-1129
NORMOFLO® Irrigation Warming Set	IR-40, IR-500, IR-600, IRI-600, IRI-600B, IR-700

Reference Page 4 for representative pictures for some of these devices.

Dear Customer,

The purpose of this notice is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action for certain Affected Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System Disposables listed above which contain aluminum heat exchangers, due to the potential for aluminum ion leaching into warmed fluids.

**UPDATE: Our Notified Body is currently evaluating this Field Safety Corrective Action and requests that you temporarily discontinue use of the devices while they complete their assessment. This Amended Field Safety Notice is being issued at the request of our Notified Body, who may contact EU Competent Authorities with additional information upon completion of their review.**

## **REASON FOR FIELD SAFETY CORRECTIVE ACTION**

Smiths Medical has investigated the potential for aluminum ion leaching in Smiths Medical fluid warming products and is providing users with operating parameters to ensure safe operation of the devices under certain clinical use conditions.

Please note that this is an advisory notification and not a product removal. **No product return is necessary.**

This Field Safety Corrective Action is being performed with the knowledge of the Regulatory Bodies.

## **RISK TO HEALTH**

Exposure to toxic levels of aluminum could potentially lead to serious injury or possibly death, depending on the treatment being administered and the patient's condition. Symptoms of toxic levels of aluminum exposure may not be readily recognizable and exposure effects may vary including bone or muscle pain and weakness, anemia, seizures, or coma.

**Smiths Medical has identified no complaints, or reports of injury or death, associated with this issue.**

## **INSTRUCTIONS FOR ALL CUSTOMERS AND USERS**

All customers who purchased Affected Devices listed in the table on page 1 of this notice must identify any of these products within their possession and refer to the detailed instructions below. To mitigate the risk of exposure to aluminum, users must be aware of the following instructions when using affected device models. This information will also be provided in a printable placard accompanying this notice, which may be secured to or displayed near the product:

### **WARNING: USE OF THESE DEVICES UNDER CERTAIN CONDITIONS MAY RESULT IN EXPOSURE TO HARMFUL LEVELS OF ALUMINUM**

- Potentially higher aluminum leaching from these devices may occur when using lower flow rates (e.g., 30mL/min), with certain solutions and blood products, and longer duration of use.
- Normal Saline is preferred instead of balanced electrolyte solutions such as lactated Ringer's. Lactated Ringer's solution should be avoided, when clinically possible.
- The following patient populations are especially at risk: pediatric patients (particularly neonates and infants) pregnant women, elderly, patients with poor renal function or on dialysis.
- Evaluate the benefits and risks of using the device versus the patient condition.

These products are typically used in acute settings where high volumes of warmed fluids and blood are administered for clinical situations such as: trauma, post-partum hemorrhage and transplant. For patients requiring ongoing therapy at slower flow rates, Level 1® HOTLINE® products do not contain an aluminum heating element in the fluid path and may be considered as alternative devices.

Instructions to Customers:

1. Please temporarily discontinue use of the devices.
2. If you are not the actual user of the device, please ensure this notification is provided to the end users of the products.
3. Enclosed you will find a Laminated Card with the "Warning" information mentioned above. This card contains a hole in the left top corner. A Ring is provided to secure it to a pole near the device.
4. Remove the Laminated Card and Ring from the package.
5. With the open end of the Ring, attach the Laminated Card to the pole clamp on the affected fluid warmer product.

6. Proceed to the acknowledgement instructions detailed below.

**ACKNOWLEDGEMENT OF FIELD SAFETY NOTICE UNDERSTANDING – REQUIRED STEPS BELOW**

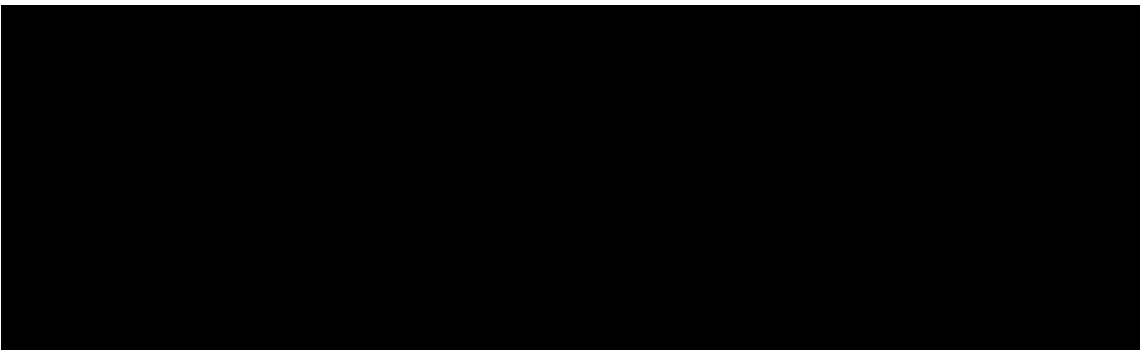
1. Locate all Affected Devices in your possession and ensure all users or potential users of these devices are immediately made aware of this notification.
2. Complete and return the attached Response Form to [smithsmedical7367@stericycle.com](mailto:smithsmedical7367@stericycle.com) to acknowledge your receipt and understanding of this Field Safety Notice within 10 days of receipt.
3. **DISTRIBUTORS:** Please immediately forward a copy of this notification and attachments to any of your customers to whom you've distributed affected product. Request that they complete the Response Form and return it to you. Please indicate your identity as the distributor and the consignees name and address.

Adverse events or quality problems experienced with the use of this product must be reported to Smiths Medical via [globalcomplaints@smiths-medical.com](mailto:globalcomplaints@smiths-medical.com).

Questions regarding this Field Safety Notice may be forwarded to [fieldactions@smiths-medical.com](mailto:fieldactions@smiths-medical.com).

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

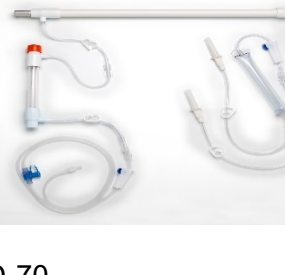
Sincerely,



Enclosures:

Attachment 1 – Field Safety Notice Response Form

Attachment 2 – Product Insert (Placard)

 <p>H-1200</p>	 <p>H-1025</p>	 <p>H-1100</p>	 <p>H-1129</p>
 <p>D-100</p>	 <p>D-300</p>	 <p>IR-700</p>	 <p>D-60HL</p>
 <p>D-70</p>	 <p>IRI-40</p>	 <p>IR-500</p>	 <p>IR-600</p>

**ATTACHMENT 1**

**MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM**

**Level 1® Fast Flow and Irrigation Fluid Warming Systems  
Potential for Aluminum Ions to Leach into Warmed Fluids**

Please acknowledge receipt of the accompanying Urgent Medical Device Field Safety Notice by completing and returning this Response Form to [smithsmedical7367@stericycle.com](mailto:smithsmedical7367@stericycle.com) within 10 days. The Response Form must be completed and returned Smiths Medical's representatives at Sedgwick even if you have no Affected Devices (refer to List of Affected Devices on page 2 of this Response Form) in your possession.

**DISTRIBUTORS – Please provide a copy of this Response Form and the accompanying Field Safety Notice to any of your customers to whom you distributed affected devices and complete the For Distributors Only table at the end of page 1.**

I certify that I have read and understand the information in the attached Field Safety Notice:

Name and Title (Please Print)	Signature and Date	Customer Number	Facility Name and Address*	Number of Devices in Inventory Requiring Placards
<b>Email Address</b>	<b>Telephone Number</b>			

\*If you are submitting a response form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

**For Distributors Only**

I have identified and notified my customers that were shipped or may have been shipped this product

Distributor Name \_\_\_\_\_

Distributor Address \_\_\_\_\_

Distributor Email Address/Phone Number \_\_\_\_\_



**Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System**

- **WARNING: USE OF THESE DEVICES UNDER CERTAIN CONDITIONS MAY RESULT IN EXPOSURE TO HARMFUL LEVELS OF ALUMINUM**
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