



## 1. DEVICE/EQUIPMENT:

Smiths Medical Level 1 fast flow fluid warmers are used to warm fluids to normothermic temperatures for rapid infusion into trauma patients and for irrigation.

All Level 1 normothermic IV fluid administration and irrigation sets with an expiry date on or before July 2011 and **not** labelled "Helium Tested" with the following catalogue REF codes are being recalled:

Catalogue Ref Codes
DI-50
DI-60HL
DI-100
DI-300
IRI-600
IRI-600B
IR-700

## 2. PROBLEM:

Smiths Medical identified a potential leakage of the inner lumen (aluminium tube) of some heat exchangers which can allow heating fluid to enter the patient fluid pathway, or vice versa. The heating fluid runs through the inside of the aluminium tube in order to heat the infusate which flows around the outside of the aluminium tube. This may result in contamination of the blood or solutions being infused. The manufacturer has introduced a helium leak test within the manufacturing process to detect the potential for leakage. Smiths Medical is only able to ship limited quantities of helium leak tested products at this time.

Smiths Medical have compiled pre-use checks which can be used to identify leaking product. They have also provided details of alternative warming methods which can be considered if the pre-use checks are unable to be used whilst replacement stock is temporarily unavailable. Once sufficient stock is available Smiths Medical will replace any affected product. The customer letter, pre-use checks and alternative warming methods are appended to this alert.

## 3. ACTION BY:

All those involved in the use of these devices including perfusionists, operating department practitioners, theatre staff/managers and anaesthetists.

## 4. ACTION:

- Identify products with an expiry date on or prior to July 2011 and **not** labelled "Helium Tested". Catalogue numbers can be found in the 'Device' section overleaf.
- Carry out pre-use checks on these devices as recommended by the manufacturer and detailed in the customer letter which can be found appended to this alert.
- If the pre-use checks cannot be followed, use the alternative methods of fluid warming, also detailed in the Appendix, until replacement stock can be provided by the manufacturer.
- Return the customer reply letter to the manufacturer with your indicated preference of action.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- Adult intensive care units
- All surgical wards
- Anaesthetic nursing staff
- Anaesthetists
- Clinical perfusionists
- Hospital pharmacies
- Intensivists
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Transfusion practitioners
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

## 6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Jon Charters  
Quality Assurance Manager  
Smiths Medical International Ltd  
Colonial Way  
Watford  
Hertfordshire WD24 4LG

Tel: +44 (0) 1923 475 809

Fax: +44 (0) 1923 237 576

E-mail: [jon.charters@smiths-medical.com](mailto:jon.charters@smiths-medical.com)

Enquires to NIAIC should quote reference number MDEA(NI)2007/70 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

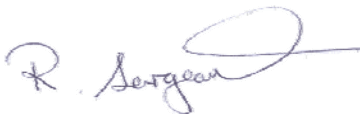
Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

<b>Deadline (Email received)</b>	<b>: 17<sup>th</sup> Aug 2007</b>
<b>Deadline (action underway)</b>	<b>: 30<sup>th</sup> Aug 2007</b>
<b>Deadline (action complete)</b>	<b>: 14<sup>th</sup> Sept 2007</b>



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

# APPENDIX to MDEA(NI)2007/070

**smiths medical**  
bringing technology to life

Smiths Medical International Ltd  
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31<sup>st</sup> July 2007

## **Urgent Product Recall**

**Level 1<sup>®</sup> Normothermic IV Fluid Administration and Irrigation Sets**  
**REF Codes: DI-50, DI-60HL, DI-100, DI-300, IRI-600, IRI-600B, IR-700**

**ALL PRODUCTS WITH AN EXPIRY DATE**  
**ON OR BEFORE JULY 2011**

Dear Valued Customer,

Smiths Medical is voluntarily issuing this product recall notification for the above referenced Level 1<sup>®</sup> Normothermic IV Fluid Administration and Irrigation Sets ("Sets"). **Product with an expiry date of July 2011 or later, and/or labeled "Helium Tested" has been Helium leak tested and are NOT affected by this recall.**

Smiths Medical has become aware that some heat exchangers in the Sets may have a leakage of the inner lumen which may allow the heating fluid to enter the patient fluid path or vice versa, which can cause contamination of the blood or solutions being infused or the recirculating solution.

Smiths Medical has conducted a thorough investigation and subsequently implemented a state-of-the-art Helium leak test within its manufacturing process that reliably detects any leakage in the inner lumen.

Smiths Medical is working diligently to establish adequate inventory of the Helium leak tested product to meet your future needs. We will be able to ship limited quantities of Helium tested product (labelled "*Helium Tested*") with an expiry date of July 2011 or later. Until sufficient inventory is available to meet all customer demands, please follow the safety measures below in using your existing inventory:

1. For products with expiration date on or before July 2011 and not labelled "Helium Tested", you should perform a pre-test of the disposable as described in the attached "Pre-Test Instructions".
2. After every use the distilled water in the reservoir should be changed.

If you are unable or unwilling to perform the pre-test, you may consider alternative warming methods until Smiths Medical can exchange your inventory. With this in mind, Smiths Medical has recommendations for alternative methods of providing warmed fluids to patients. Please see the enclosed letter, "Clinical Alternatives for Fluid Warming". Please contact any of the following for further discussion or additional information:

- **David Powlesland – Product Manager Anaesthesia – Mobile Number: 07816 650104**
- **Poonam Viridi – Marketing Manager – (01923) 475835**

**Please confirm receipt of this notification, and your willingness to pre-test by returning the attached reply letter to the Smiths Medical Regulatory Affairs Department at +44 (0) 1923 237576 as soon as possible. It is essential that you complete and return the attached form even if you no longer have the affected product in your inventory.**

We apologise for the inconvenience experienced by our customers due to this action.

Sincerely,

**SMITHS MEDICAL INTERNATIONAL LTD**



Jon Charters

Quality Assurance Manager

**Attachment: Customer Reply Letter  
Pre-Test Instructions  
Clinical Alternatives for Fluid Warming**

**URGENT: CUSTOMER REPLY LETTER**

**PRODUCT RECALL: Level 1<sup>®</sup> Normothermic I.V. Fluid Administration and Irrigation Sets with expiration dates on or before July 2011.**

Complete and Fax Immediately to: Fax No.: +44 (0) 1923 237576  
Smiths Medical International Limited – RA/QA Department

**SECTION 1 - PLEASE FILL IN REGARDLESS OF INVENTORY STATUS:**

Printed Name:		Department:	
Signature:		Date:	
Facility Name:			
Facility Address:			
Phone Number ( )	Ext:	Fax Number: ( )	

Please check one:

- We DO NOT have any affected inventory remaining in stock (Skip Section 2 and fax back)
- We DO have the affected inventory and will follow the “pre-test instructions” (Skip Section 2 and fax back)
- We DO have the affected inventory, we are unable to follow the “pre-test instructions”, and will return product to Smiths Medical for replacement or credit as indicated below (Go to Section 2)

**SECTION 2 - ANSWER ALL ITEMS BELOW**

- 1.) Returning product for  REPLACEMENTS  CREDIT  
2.) Recalled product you have on hand:

REF No.	Lot No.	Quantity (each)
REF No.	Lot No.	Quantity (each)
REF No.	Lot No.	Quantity (each)
REF No.	Lot No.	Quantity (each)

Please use additional pages or attach a list to record additional product return quantities if needed

<b>For Smiths Medical Use Only</b>		
Customer Account No.	RGA # (Rebates Dept)	<input type="checkbox"/> Copy to Returns

Normothermic Administration Sets  
Pre-Test Instructions

- 1.0 Using the Instructions for Use (IFU), Operators Manual and Figure 1 as a guide, install the D/DI-Series or IR/IRI Disposable Set onto the Fluid Warmer (Level 1® H-1000, H-1025, H-1200, H-1100 and H-1129) but **DO NOT** install the heat exchanger onto the Fluid Warmer (i.e. skip instructions referring to the #1 and #2 block). **DO NOT** turn on the Fluid Warmer.



Figure 1: **Do not** install heat exchanger onto the Fluid Warmer, but install the rest of the set. D-100 is shown. Other sets will vary in spike numbers and clamp locations.

- 2.0 **PRIME THE SYSTEM** with 0.9% Saline Solution per the IFU and using aseptic technique (use irrigating fluid with IR/IRI sets). Close the tubing clamp below the heat exchanger after the set is primed. See Figure 2.



Figure 2: Close the clamp below the heat exchanger.

- 3.0 Power on the Fluid Warmer (disregard the visible and audible alarms while conducting the test). Pressurize the priming saline by sliding the lever on the pressure chamber to the "+" position. See Figure 3. **NOTE:** If using a Model H-1100, use a manual pressure cuff to pressurize the fluid bag.

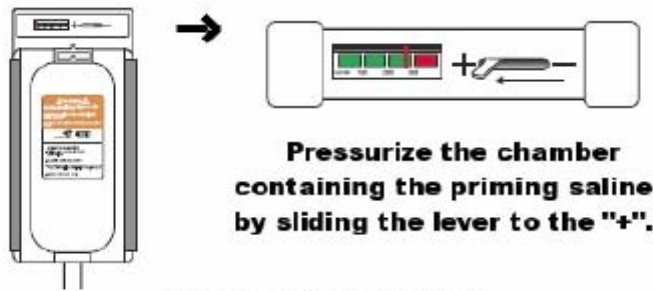


Figure 3: Pressurize the chamber.

- 4.0 Monitor the bottom of the heat exchanger for leaking droplets of saline for at least 20 seconds according to Figure 4 below. For D/DI-60 Disposables, monitor the bottom of the plastic manifold at the bottom of the heat exchanger.

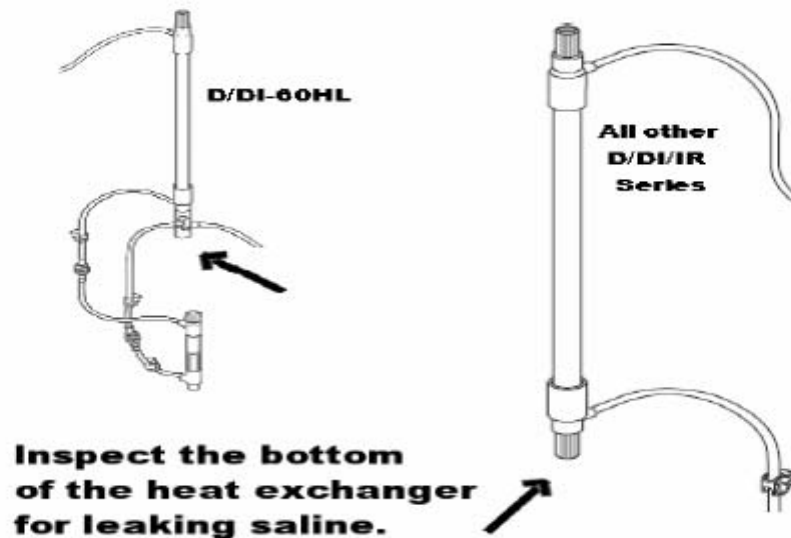


Figure 4: Inspect the heat exchanger for leaking saline.

- 5.0 **IF SALINE (or IRRIGATING FLUID) IS LEAKING** from the bottom of the heat exchanger, **DO NOT USE** as this D/DI or IR/IRI Series Disposable Set does not meet specification and by using it Severe Injury or Death may occur to the Patient or User. Contact Smiths Medical International Limited on +44 (0) 1923 246434 Ext 5913/5916 to report as a customer complaint.
- 6.0 **IF SALINE (or IRRIGATING FLUID) IS NOT LEAKING** from the bottom of the heat exchanger, the D/DI or IR/IRI Series Disposable Set has passed the pre test requirements. Insert the heat exchanger in the #1 and #2 blocks and continue with the Setup procedure as indicated in the IFU and Operator's Manual.

August 9<sup>th</sup>, 2007

To: Valued Customers

Fr: Smiths Medical Critical Care

**RE: Clinical Alternatives for Fluid Warming**

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Smiths Medical recognizes the life saving benefit Level 1® Trauma & Irrigation disposable sets provide to our patients during emergency situations. We are working to return the Level 1® Normothermic IV Fluid Administration & Irrigation Sets to normal inventory levels.

Smiths Medical has identified alternatives means to warm fluids that may be used at your facility in support of your efforts to provide vital patient care. A brief discussion of these alternatives follows.

**Alternative: Pre-Test Level 1® Normothermic IV Fluid Administration & Irrigation Sets**

Smiths Medical has validated a pre-test procedure for the Level 1® trauma & irrigation disposables identified in the recall notice with expiration dates on or before July 2011. We have included in the notification packet the pre-test instructions and you can elect to use the pre-test alternative for patient care until the new inventory of the disposable sets is shipped to your facility.

**Alternative: Use of Routine Flow Fluid Warmers**

You may elect to use the HOTLINE® (Model HL-90) with an L-70 or L-70NI set. Customers that have HOTLINE® 2 (Model HL-290) can use the L-270 disposable set. This option provides a means to infuse warm fluids into patients at gravimetric flow rates. If necessary, HOTLINE® tubing sets can be manually pressurized as long as the pressure applied does not exceed 300mmHg pressure. Under these conditions, the temperature of the fluid infused may be lower than normal body temperature.

In addition to the HOTLINE® fluid warmer, other fluid warmers available at your facility may provide a means to warm fluids at gravimetric flow rates.

**Alternative: Use of Traditional Warming Methods**

Traditional warming methods include the use of warming cabinets for IV fluid bags. After warming the fluid bags, the infusion of such fluids using gravimetric flow or pressure cuffs where the use of pressure cuffs are indicated will provide a means to infuse warm fluids to your patients.

**Smiths Medical Contact & Support Services**

In order to answer any questions that you may have and to support your decision regarding the selection of an alternative method to warm fluids we have included the contact information for our Marketing Group.

**David Powlesland**

Product Manager – Anaesthesia

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**Poonam Virdi**

Marketing Manager

T. 01923 475835

[Poonam.virdi@smiths-medical.com](mailto:Poonam.virdi@smiths-medical.com)