

Medical Device Alert

Ref: MDA/2011/054 Issued: 20 May 2011 at 15:00

Device

Level 1[®] Normothermic IV fluid administration sets for use with the Level 1 fast flow fluid warmer units.

Manufactured by Smiths Medical.

All lots of model numbers DI-60HL, DI-50 and DI-100.

Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) for this device (dated 29 April 2011), but has not had sufficient confirmation from users that they have received and acted on this information.</p> <p>A copy of the FSN is in the appendix of this Alert, and it is also available on the MHRA website.</p> <p>This Alert has been issued in support of the manufacturer's actions.</p>	<ul style="list-style-type: none"> • Ensure that relevant members of staff are aware of the problem. • Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.
<h3 data-bbox="124 1391 304 1435">Action by</h3> <p>Perfusionists, operating department practitioners, theatre staff/managers and anaesthetists.</p>	
CAS deadlines	Contact
<p>Action underway: 27 May 2011</p> <p>Action complete: 07 June 2011</p>	<p>Manufacturer Customer Services Smiths Medical International Tel: 01923 241 411 Email: fluidadminsets@smiths-medical.com</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- A&E directors
- A&E nurses
- Adult and paediatric intensive care units
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- EBME departments
- Equipment stores
- Health and safety managers
- IV specialist nurses
- Medical directors
- Medical libraries
- Medical physics departments
- Midwifery departments
- Midwifery staff
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Customer Services
Smiths Medical International
Boundary Road
Hythe, Kent.
CT21 6JL

Tel: 01923 241 411

Email: fluidadminsets@smiths-medical.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/054** or **2011/005/003/291/026**.

Technical aspects

Louise Mulroy and Roopa Prabhakar
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7344 / 7293

Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
roopa.prabhakar@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix

smiths medical
bringing technology to life

Smiths Medical International
Boundary Road, Hythe, Kent.
CT21 6JL

URGENT FIELD SAFETY NOTICE

For Level 1® Normothermic IV Fluid Administration Sets

Affected Devices:	Level 1® Normothermic IV Fluid Administration Sets
Type of Action:	Urgent Field Safety Corrective Action - Recall
Date:	29 April 2011
Attention:	Risk/ Safety Managers, Clinicians, Nursing, Emergency Departments, Operating Rooms, Anaesthesia Department, Distributors and other users of these devices
Details on affected devices:	Level 1® Normothermic IV Fluid Administration Sets that are not equipped with the F-50 Gas Vent Filter Assembly, Product Reorder Numbers DI-60HL, DI-50, and DI-100, All Lot Numbers

This is in follow up to Smiths Medical's February 2011 Field Safety Corrective Action for kinking tubing for specific Lot Numbers of the Level 1® Normothermic IV Fluid Administration Set Disposables, with the Gas Vent Filter Assembly, Product Reorder Numbers DI-65HL, DI-75, and DI-150 ("F-50 Disposables"). In the February 2011, Field Safety Notice, Smiths Medical advised its customers that, because of supply issues, replacement F-50 Disposables would not be available for a period of time. One of the options available to customers during this period was to temporarily revert to use of the original Level 1® Normothermic IV Fluid Administration Sets that are **not** equipped with the F-50 Gas Vent Filter Assembly, Product Codes DI-60HL, DI-50, and DI-100 ("Non-F-50 Disposables").

Smiths Medical is conducting this Field Safety Corrective Action (Recall) because the Non-F-50 Disposables do not provide the same level of air embolism protection available in the F-50 Disposables. If a Level 1® H-1200 Fast Flow Fluid Warmer equipped with the H-30, H-31A, or the H-31B air detector is powered off when the Air Detector is in an active alarm state, the Air Detector/ Clamp will open and the Air Detector will become disabled. This could allow any air within the Patient Line to be delivered to the patient, resulting in serious injury or death.

The F-50 Disposables are now available and therefore, Smiths Medical is conducting a voluntary Field Safety Corrective Action for **all Non-F-50 Level 1® Normothermic IV Fluid Administration Sets, Product Codes DI-60HL, DI-50, and DI-100**. This voluntary Action is being conducted with the knowledge of the relevant Regulatory Agencies.

This Urgent Field Safety Notice applies to all Non-F-50 Disposables, Product Codes DI-60HL, DI-50, and DI-100, all Lot Numbers.

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Advice on Action to be Taken by the User:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers to return all unused Non F-50 Disposables for replacement with F-50 Disposables. Any product that has exceeded its expiration date should be discarded and is not part of this Action. Required actions:

- 1) Inspect your inventory and quarantine all unused Non-F-50 Disposables, Product Codes DI-60HL, DI-50, and DI-100; and
- 2) Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1303 266761 or by email to fluidadminsets@smiths-medical.com.

Advice on Action to be Taken by the Distributor:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers to return all unused Non F-50 Disposables for replacement with F-50 Disposables. Required Actions:

- 1) Immediately stop distributing and quarantine all inventory of Non-F-50 Disposables, Product Codes DI-60HL, DI-50, and DI-100;
- 2) Identify any customers in receipt of the devices covered by this Urgent Field Safety Notice;
- 3) Send a copy of this Notice, with attachments, to those customers identified as receiving Non-F-50 Disposables;
- 4) Contact Customer Services at Smiths Medical at +44 (0) 1923 241411 to confirm the mailings have been sent.; and
- 5) Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1303 266761 or by email to fluidadminsets@smiths-medical.com.

Transmission of this Urgent Field Safety Notice

This notice needs to be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this Field Safety Corrective Action.

If you should have any questions regarding this information, please contact Smiths Medical at +44 (0) 1923 241411

Smiths Medical is committed to providing quality products and service to its customers. We apologize for the inconvenience this situation may have caused.

Sincerely,



Mike Herbert
Regional Director Quality Systems UK
Smiths Medical
Email: fluidadminsets@smiths-medical.com

Enclosures:

Attachment 1 – Urgent Field Safety Notice Confirmation Form

Attachment 1

**URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
for Level 1® Normothermic IV Fluid Administration Sets that are not equipped with the F-50 Gas
Vent Filter Assembly (Product Codes DI-60HL, DI-50, and DI-100).**

Please complete and return this Form by Fax to +44 (0) 1303 266761 or by sending an electronic copy
via email to fluidadminsets@smiths-medical.com

Check the applicable boxes below:	
<input type="checkbox"/>	I DO NOT have any Non-F50 Disposables (Product Codes DI-60HL, DI-50, and DI-100) in inventory. All have been used or discarded.
<input type="checkbox"/>	I DO have unused inventory of Non-F50 Disposables (Product Codes DI-60HL, DI-50, and DI-100), which I will return for replacement with F-50 Disposables or credit. Please provide Product Reorder details on page 2 of this Form.
<input type="checkbox"/>	I no longer have any Non-F50 Disposables (Product Codes DI-60HL, DI-50, and DI-100). The Sets have been transferred to the following location:

Printed Name: _____	Department: _____
Signature: _____	Date: _____
Facility Name: _____	Facility Address: _____
	Shipping Address: _____
Phone Number (with Ext.): _____	Email: _____

