

Medical Device Alert

Immediate action

Ref: MDA/2011/031 Issued: 29 March 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-65HL, DI-75 and DI-150.

Problem	Action
<p>Design fault in the clamp position, resulting in kinking of the tube and reduced flow.</p> <p>Until a new design is available, replacement stock will be sets without an F-50 gas vent filter assembly.</p> <p>These replacement sets have an increased risk of air embolism.</p>	<p>Do not use Level 1 fluid warmers if alternatives are available.</p> <p>If no alternative fluid warmers are available follow the advice in the Field Safety Notice dated 28 February 2011 (see appendix) and ensure that:</p> <p>1. When using existing stocks of administration sets avoid moving the clamp</p> <p>Or</p> <p>2. When using replacement sets without an F-50 gas vent filter:</p> <ul style="list-style-type: none"> Do not turn off the fluid warmer when an air detection alarm is active. Ensure that the Smiths quick reference guide is attached to all Level 1 fluid warmers – copies are available from the manufacturer. <p>Return the confirmation form supplied with the Field Safety Notice.</p>
Action by	
<p>Perfusionists, operating department practitioners, theatre staff/managers and anaesthetists.</p>	
CAS deadlines	Contact
<p>Action underway: 05 April 2011</p> <p>Action complete: 12 April 2011</p>	<p>Manufacturer Customer Services, Smiths Medical International Tel: 01923 241 411 Email: fluidadminsets@smiths-medical.com</p>

Device

These sets, with the F-50 gas vent filter assembly, are for use in Smiths Medical Level 1 H-1200 fast flow fluid warmers with an integrated H-31B air detector/clamp and H-1025 fast flow fluid warmers with the optional H-31B air detector/clamp.

Problem

Smiths Medical has stopped production and supply of the affected sets and will temporarily supply an alternative set until they have resolved the design issue.

However, these alternatives are **not** equipped with the F-50 gas vent filter assembly and so there is a risk of air embolism when using these alternative non F-50 sets if the power to the fluid warmer unit is interrupted during an air detection event.

Air may also be delivered to the patient if the power to the unit is interrupted by manually switching it off or as a result of a power failure following an air detection event.

Smiths Medical issued a quick reference guide, in 2007, to alert users to this issue.

The manufacturer is modifying the design of the administration sets with the F-50 gas vent filter to address the kinking problem but these will not be available until the end of April 2011.

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
- General surgery
- General surgical units, directors of
- 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/2011/031** or **2011/002/021/291/006**.

Technical aspects

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

Tel: 020 3080 7344 or 7310

Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
nicole.small@mhra.gsi.gov.uk

Clinical aspects

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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:	February 28, 2011
Attention:	Risk/ Safety Managers, Clinicians, Nursing, Emergency Departments, Operating Rooms, Anaesthesia Department, Distributors and other users of these devices
Details on affected devices:	Product Reorder and Lot Numbers on the Attached List

Smiths Medical is conducting a voluntary Field Safety Corrective Action for a limited number of Level 1[®] Normothermic IV Fluid Administration Sets ("Sets"). This voluntary Action is being conducted with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of an increased trend in reports of kinking of the tubing on certain Sets. In some cases, the kink may lead to a decrease in the flow of fluid to the patient. A reduction in flow rate may lead to a delay of therapy, which could result in patient injury or death.

Kinking of the tubing can occur in the triple lumen tubing where the tubing connects to the aluminum tube heat exchanger (only applicable to the DI-65HL product) and in the small bore tubings – in the tube that connects from the heat exchanger to the F-50 Gas Vent Filter ("GVF") and in the tube that connects from the manifold to the F-50 GVF.

This Urgent Field Safety Notice only applies to Sets equipped with the F-50 Gas Vent Filter Assembly listed on the Attached List. While Smiths Medical has received no reports of serious injury or death, and not all Sets will experience this issue, Smiths Medical is proactively recalling all potentially affected Sets.

Advice on Action to be Taken by the User:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers with Sets listed on Attachment 2 to return all unused Sets:

1. Inspect your inventory and segregate any unused product listed on Attachment 2; 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

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Advice on Action to be Taken by the Distributor:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers with Sets listed on Attachment 2 to return all unused Sets:

1. Immediately stop distributing and quarantine all inventory listed on Attachment 2;
2. Perform a count of affected product currently in inventory, and
3. 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

As soon as we are able to resume supply for replacement product with the F50 Gas Vent Filter Assembly, we will notify you. Smiths Medical understands the critical nature of these Sets; therefore, until replacement product is available, we are providing the following options to clinicians who choose to use the affected Sets as a result of a critical clinical need:

- Set up product as described in the product's Instructions For Use. Avoid moving the position of the clamps, on the small bore tubing, located at the exit of the heat exchanger and the manifold (see Photo A). If the clamps are left in place on this tubing, as originally packaged, then the potential for a kink to diminish the flow rate is removed.



PHOTO A

- Closely monitor flow rates during use. If a diminished flow rate is observed, as a result of a kink in the tubing, the clinician can manually hold the tubing to support the tubing and establish a more normal flow (see Photo B).

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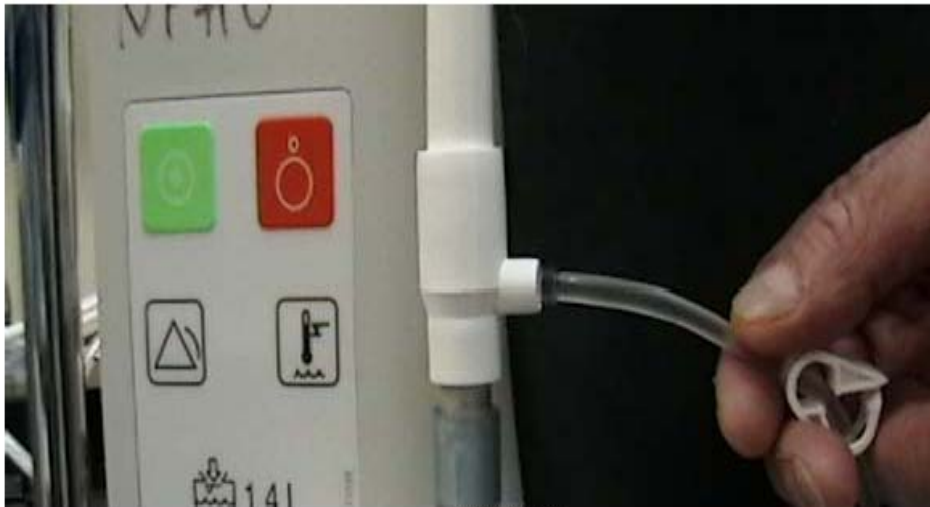


PHOTO B

Customers also have the option of temporarily reverting to use of the original Level 1[®] Normothermic IV Fluid Administration Sets that are not equipped with the F-50 Gas Vent Filter Assembly. These products are immediately available as replacements.

Product Codes <u>WITH</u> the F50 GVF Assembly	Alternative Product Codes <u>WITHOUT</u> the F50 GVF Assembly
DI-65HL	DI-60HL
DI-75	DI-50
DI-150	DI-100

If you choose to temporarily revert to use of the Level 1[®] Normothermic IV Fluid Administration Sets described above, please refer to the Quick Reference Guide attached to the Fluid Warming device for details on the safe use of these disposables. These instructions include the following warning:

Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF 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.

If you require additional copies of the Quick Reference Guides, please contact Smiths Medical at fluidadminsets@smiths-medical.com or by telephone on 01923 241411

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.

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If you should have any questions regarding this information, please contact Smiths Medical at fluidadminsets@smiths-medical.com or by telephone on 01923 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
E-Mail: fluidadminsets@smiths-medical.com

Enclosures:

- Attachment 1 – Urgent Field Safety Notice Confirmation Form
- Attachment 2 – List of All Affected Product Reorder and Lot Numbers