

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/17

Issued: 13 February 2007

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section
<p><b>Medical Device/Equipment:</b>            Fluid warming administration set: Smiths Medical Level 1<sup>®</sup> normothermic IV fluid administration set.            Catalogue number DI-60HL</p>	▶ ①
<p><b>Problem:</b>            A manufacturing fault in the administration set can prevent appropriate warming of the blood/fluid to be administered, leading to a delay in patient treatment. The manufacturer is recalling specific lots.</p>	▶ ②
<p><b>Action by:</b>            Perfusionists, ODPs, theatre staff/managers and anaesthetists.</p>	▶ ③
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify and quarantine affected stock. The lot numbers are listed overleaf.</li> <li>Only use devices from affected lots if an alternative is not available in an emergency situation and only until alternative stock is received.</li> <li>Contact the manufacturer (Tel: 01923 246 434) to organise the return and replacement of affected stock.</li> </ul>	▶ ④
<p><b>Distributed by NIAIC to:</b>            Chief Executive of each HSS Board            Chief Executive of each HSS Trust            Chief Executive of each Agency            NIAIC Liaison Officers</p>	▶ ⑤
<p><b>Contacts</b>            Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b>            Non required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

This device is a disposable blood and fluid warming administration set for use with the Smiths Medical Level 1<sup>®</sup> H-1200 Fast Flow Fluid Warmer unit to allow rapid infusion of warm fluids.

The affected lot numbers are:

725769	1011870	1019492	1011871
1049619	1058925	1060998	1064376
1027190	1028662	1037117	1037809
1067796	1067797	1074088	1604376
1074089			

## 2. PROBLEM:

The manufacturer has received reports of the activation of the safety mechanism on Fast Flow Fluid Warmer units. This happens following priming and at the beginning of warming the infusate (blood/IV fluid) in the administration set when connected to a fluid warmer. This has resulted in a delay in treatment.

The manufacturer has established that a manufacturing error has resulted in the restriction of the recirculating warming fluid that warms the infusate in the administration set. This causes the temperature of the recirculating warming fluid to rise above the set point temperature. When the temperature of the recirculating warming fluid reaches the over-temperature set point, the safety mechanism will activate an audible and visual over-temperature alarm. The flow and heating of the recirculating warming fluid then ceases. When this occurs, patient infusion continues but the infusate is no longer being appropriately warmed.

The manufacturer has initiated a recall of the affected lots.

## 3. ACTION BY:

Perfusionists, ODPs, theatre staff/managers and anaesthetists.

## 4. ACTION:

If a device from an affected lot is used in an emergency situation (because no alternatives are available), the manufacturer has advised that if the over-temperature alarm on the Fast Flow Fluid Warmer unit is not activated, the device is safe to use. If the over-temperature alarm is activated the use of the device must be discontinued immediately.

## 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
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Intensivists
- IV nurse specialists
- Medical directors
- Midwifery departments
- Nursing executive directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Transfusion practitioners

## 6. CONTACTS:

Enquires to manufacturer should be addressed to:

Mr Kevin Goodman  
Smiths Medical International Ltd  
Colonial Way  
Watford  
Hertfordshire  
WD24 4LG

Tel: 01923 246 434 ext 5904

Fax: 01923 237 576

Enquires to NIAIC should quote reference number MDEA(NI)2007/17 and be addressed to:

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

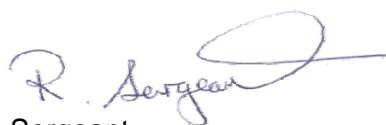
Tel: 028 9052 3868

Fax: 028 9052 3900

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

## 7. FEEDBACK:

No required



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*