

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/43

Issued: 10 August 2004

For:

|                     |   |
|---------------------|---|
| IMMEDIATE ACTION    |   |
| <b>ACTION</b>       | ✓ |
| UPDATE              |   |
| INFORMATION REQUEST |   |



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

|  | Section |
|--|---------|
| <p><b>Medical Device/Equipment:</b><br/>Heat and moisture exchanger (HME) and heat and moisture exchanger filter (HMEF), incorporated into anaesthetic and respiratory therapy breathing systems (e.g. ventilator).</p>  | ▶ ①     |
| <p><b>Problem:</b><br/>HME components have very occasionally entered anaesthetic breathing systems and caused blockages in the breathing system with potential to cause excessive resistance.</p>  | ▶ ②     |
| <p><b>Action by:</b><br/>Anaesthetists, operating department practitioners and technicians, anaesthetic nurses, ICU staff, technicians and all staff using anaesthetic equipment and associated devices.</p>   | ▶ ③     |
| <p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• If breathing difficulties, problems with mechanical ventilation or decreases in gas exchange occur ensure that there are no blockages in the breathing system.</li> <li>• Filters and HMEs should be routinely changed according to manufacturer's instructions and local protocols pertaining to use of the equipment (i.e. intensive care).</li> <li>• Ensure an alternative method of providing oxygenation and mechanical ventilation (e.g. self-inflating bag) is immediately available at all times.</li> </ul> | ▶ ④     |
| <p><b>Distributed by NIAIC to:</b><br/>Chief Executive of each HSS Board<br/>Chief Executive of each HSS Trust<br/>Chief Executive of each Agency<br/>NIAIC Liaison Officers</p>   | ▶ ⑤     |
| <p><b>Contacts</b><br/>NIAIC contacts for technical aspects.</p>   | ▶ ⑥     |
| <p><b>Feedback Requirements to NIAIC</b><br/>None</p>  | ▶ ⑦     |

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

## 1. DEVICE/EQUIPMENT:

Heat and moisture exchangers (HME) and heat and moisture exchanging filters (HMEF) used in combination with breathing systems (e.g. anaesthetic breathing tubing, self-inflating bag) and ventilators, including those in use in ICUs.

## 2. PROBLEM:

The Medicines and Healthcare products Regulatory Agency (MHRA) have received a small number of reports of blockages arising from sub-components of breathing system filter units that have failed. For example, within the casing, the HME component next to the filter became detached and entered the breathing circuit as a result of high airway pressures and flows (probably due to coughing). These types of events can lead to blockages that have the potential to cause hypoxic brain damage or death.

These events may occur in HMEs and HMEFs which have previously been functioning normally.

## 3. ACTION BY:

Anaesthetists, operating department practitioners, anaesthetic nurses, ICU staff, technicians and all staff using anaesthetic equipment and associated devices.

## 4. ACTION:

- Be aware that filters/HMEs contained in some single-use products can fail and components may block breathing systems.
- If breathing difficulties, problems with mechanical ventilation or decreases in gas exchange occur ensure there are no blockages in the breathing system or filter/HME units. If so the breathing system or filter/HME unit should be changed.
- Before use, follow the Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines for checking anaesthetic equipment and associated breathing systems<sup>1</sup>.

<sup>1</sup> The Association of Anaesthetists of Great Britain and Ireland.

Checking anaesthetic equipment 3 (2004). Available on their website at [www.aagbi.org](http://www.aagbi.org)

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Nursing Directors
- Medical and Nursing Staff
- Adult, Paediatric/Neonatal Intensive Therapy Units
- Ambulance Service Paramedics and Technicians
- Anaesthetic Nurses
- Anaesthetists
- Day Surgery Units
- Intensive Care Units
- Operating Department Practitioners and Technicians
- Resuscitation Trainers
- Theatre Managers
- Independent Health and Social Care Providers – Private Clinics and Nursing Homes through HSS Board R&I Units

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2004/43 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:

None required.



Brian Godfrey  
NIAIC 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)2004/01. 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*