

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/35

Issued: 7 November 2003

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Anaesthetic vaporizers (all manufacturers).	▶ ①
<b>Problem:</b> Risk of an overdose of anaesthetic agent due to overfilling of the vaporizer.	▶ ②
<b>Action by:</b> Anaesthetists, Operating Department Practitioners, Anaesthetic Nurses and Clinical Perfusion Scientists.	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>• Precisely follow manufacturers' instructions for the filling and drainage of vaporizers.</li> <li>• When filling vaporizers do not tilt the vaporizer or switch it on.</li> <li>• Ensure the agent bottle is securely attached to its filler system.</li> <li>• If overfilling of the vaporizer is suspected, do not use and refer to the manufacturers' instructions.</li> <li>• Follow the Association of Anaesthetists of Great Britain and Ireland recommended pre-use checks and 'standards of monitoring during anaesthesia and recovery'.</li> </ul>	▶ ④
<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 <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> Feedback is necessary for this Alert. Please see specific feedback requirements in section 7.	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Agent-specific vaporizers intended for use in inhalational anaesthesia.

## 2. PROBLEM:

An incident was reported to the Medicines and Healthcare products Regulatory Agency (MHRA) where the overfilling of an anaesthetic vaporizer resulted in a serious agent overdose. Investigation revealed that tilting of the vaporizer when filling had overcome internal safety features, allowing it to be overfilled. This can result in an agent output in excess of 15% at a device setting of 2%. Additionally, very low fresh gas flows can result in no vaporizer output. Further investigation revealed that a similar outcome could result from the tilting and subsequent overfilling of all vaporizers presently on the market. Although tilting the vaporizer resulted in the greatest overfilling, it also occurred where other inappropriate methods were used, such as turning on the vaporizer or loosening the connection between the vaporizer filler system and anaesthetic agent bottle.

## 3. ACTION BY:

Anaesthetists, Operating Department Practitioners, Anaesthetic Nurses and Clinical Perfusion Scientists.

## 4. ACTION:

- Always use and store vaporizers in an upright position.
- If the vaporizer has been accidentally inverted then it should be purged before use according to the manufacturers' instructions.

The actions recommended in this Alert are endorsed by:

- Royal College of Anaesthetists;
- Association of Anaesthetists of Great Britain and Ireland;
- Association of Operating Department Practitioners;
- Society of Clinical Perfusion Scientists.

## 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
- Device Managers
- Accident & Emergency Departments
- Directors of Anaesthetics
- Anaesthetic nurses
- Anaesthetists
- Medical Directors
- Nurse Directors
- Operating Department Practitioners
- Theatre Managers
- Independent Healthcare Providers – Independent Clinics through R&I Units

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/35 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:

NIAIC Liaison Officers are requested to confirm by 20 November 2003 to e-mail address [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk) using reference MDEA(NI)2003-35 that **staff identified under “Action By” have received this Alert to enable them to take appropriate action.**  
**A NIL response is required should the subject of this Alert not apply to your organisation.**



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 Safety Notice SN (NI) 2003/01. 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*