

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/11

Issued: 7 February 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION	



HEALTH ESTATES

creating healing environments

This alert extends the guidance issued on 25 January 2007 in MDEA(NI)2007/07.	Section				
BOC Ltd, AZ size aluminium medical nitrous oxide cylinders fitted with a key operated pin index valve for use in MRI units.	▶ ①				
Following the issue of MDEA(NI)2007/07, regarding AZ aluminium medical oxygen cylinders, BOC have informed MHRA that a similar problem has been found in a small number of medical nitrous oxide AZ cylinders. These cylinders have also been fitted with an obsolete pin index valve containing a ferromagnetic component that makes the cylinder potentially hazardous when used in an MRI environment.	▶ ②				
Action by: Anaesthetists, operating department practitioners and anaesthetic nurses working in MRI units. Hospital pharmacists, MRI safety advisors and MRI superintendent radiographers.	▶ ③				
Action: <ul style="list-style-type: none"> Identify the affected cylinders (images of the affected valve and the two acceptable alternatives showing the relevant stamp markings are appended to this Alert) Quarantine affected cylinders outside the MRI suite and clearly label 'unsuitable for MRI use' Arrange for return to BOC Ltd MRI unit operators are advised to carry out magnetic testing of all cylinders prior to their use in an MRI environment. 	▶ ④				
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Chief Executive of each Agency</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>NIAIC Liaison Officers</td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	Chief Executive of each Agency	Chief Executive of each HSS Trust	NIAIC Liaison Officers	▶ ⑤
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Chief Executive of each HSS Trust	NIAIC Liaison Officers				
Contacts Details of supplier contact and NIAIC contact for technical aspects.	▶ ⑥				
Feedback Requirements to NIAIC See section 7 for further details on feedback requirements for HPSS Trusts	▶ ⑦				

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

1. DEVICE/EQUIPMENT:

BOC Ltd, AZ size aluminium medical nitrous oxide cylinders fitted with a key operated pin index valve for use in MRI units.

2. PROBLEM:

Over the last 15 years BOC has used three different designs of pin index valves in the AZ size cylinders. The earliest design had a ferromagnetic component, which made it unsuitable for use in an MRI environment. However, the two latest designs are acceptable for use in an MRI environment with the present generation of MRI scanners.

3. ACTION BY:

Anaesthetists, operating department practitioners and anaesthetic nurses working in MRI units. Hospital pharmacists, MRI safety advisors and MRI superintendent radiographers.

4. ACTION:

- Identify the affected cylinders (images of the affected valve and the two acceptable alternatives showing the relevant stamp markings are appended to this Alert)
- Quarantine affected cylinders outside the MRI suite and clearly label 'unsuitable for MRI use'
- Arrange for return to BOC Ltd
- MRI unit operators are advised to carry out magnetic testing of all cylinders prior to their use in an MRI environment.

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:

- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Hospital pharmacists
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Medical directors
- MRI departments
- MRI units, directors of
- Nursing executive directors
- Operating department practitioners
- Radiographer superintendents
- Radiographers, MRI
- Radiologists, MRI
- Radiology directors
- Risk managers

6. CONTACTS:

Enquiries to the supplier should be addressed to:

BOC Customer Services centre

Free phone number 0800 111 333.

This service is available 24 hours, 7 days a week.

Enquires to NIAIC should quote reference number MDEA(NI)2007/11 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

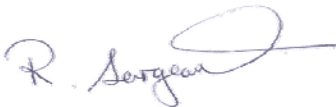
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given by HPSS Trusts **ONLY**:-

- 1. Deadline (Email received) : 9 February 2007**
- 2. Deadline (action underway) : 16 February 2007**
- 3. Deadline (action complete): 23 February 2007**



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

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety



Unacceptable
Old potentially hazardous key operated valve

Showing part number **350185** stamped on the back of the valve.

Note: The valve has a steel coloured spindle.

Appendix to MDEA(NI)2007/07

Acceptable pin index valve types for MRI use



Acceptable thumbwheel valve



Acceptable key operated valve

Note: the valve has a brass coloured spindle.



Insert showing part number **19306744** stamped around the top of the valve body.