

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/07

Issued: 6 February 2006

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section		
<p>Medical Device/Equipment: BOC Ltd, CD and HX Oxygen Cylinders (only cylinders labelled with expiry dates between 18th December 2008 and 22nd January 2009) with faulty pressure gauges.</p>	▶ ①		
<p>Problem: Limited stock recall of affected cylinders due to the faulty pressure gauges leaking.</p>	▶ ②		
<p>Action by: All Trusts and ambulance Trusts supplied by BOC Ltd.</p>	▶ ③		
<p>Action: Be aware of the attached Drug Alert. (Appendix 1)</p>	▶ ④		
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5 </td> <td style="width: 50%; border: none;"> General Medical Practitioners General Dental Practitioners Community Pharmacists Hospices </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	General Medical Practitioners General Dental Practitioners Community Pharmacists Hospices	▶ ⑤
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<p>Contacts Details of BOC contact and NIAIC contact.</p>	▶ ⑥		
<p>Feedback Requirements to NIAIC</p>	▶ ⑦		

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

1. DEVICE/EQUIPMENT:

CD and HX Oxygen Cylinders with integral valves and pressure gauges. BOC has two types of gauge in service with these cylinders and only cylinders with a direct drive reading gauge are potentially affected. Photographs of the two types of gauges are included on page 6 (Appendix 2) of this Medical Device/Equipment Alert to assist in the identification of the affected cylinders.

2. PROBLEM:

A small proportion of the above cylinders are defective due to the presence of faulty gauges which may result in empty cylinders. These cylinders use an integral valve system with built in regulator and permanent live contents gauge.

3. ACTION BY:

All Trusts supplied by BOC Ltd.

4. ACTION:

Be aware of the attached Drug Alert. (See Appendix 1)

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Clinical Directors
- Directors of anaesthetics
- Nurse Directors
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Maternity Wards
- Paediatric Units
- Adult & paediatric intensive care units
- All wards
- Intensive care units
- Pharmacists
- Purchasing managers
- Respiratory care nurse specialists
- Practice Nurses
- Pharmacy Managers
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Resuscitation Officers
- Day Procedure Units
- Prison healthcare managers
- Private dentists
- Community nurses
- District nurses
- Intensive therapy units
- Medical physics/EBME
- Operating theatres

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)2006/07 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

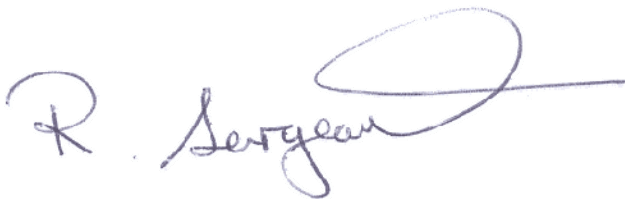
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a large loop at the end of the name.

Robert Sergeant
NIAIC Operational Manager

Appendix 1 to MDEA(NI)2006-07

From The Chief Pharmaceutical Officer
Dr Norman Morrow

Castle Buildings
Upper Newtownards Road
Belfast BT4 3SJ

Telephone: 028 90 523219
Facsimile: 028 90 522335
E-Mail: norman.morrow@dhsspsni.gov.uk
Our reference: PhC/7/06
Date: 2 February 2006

For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of H&SS Trusts

1 **DRUG ALERT** MEDICINES RECALL

CLASS 1 URGENT SAFETY INFORMATION – LIMITED STOCK RECALL

FOR IMMEDIATE ACTION

Date 2nd February 2006

EL(06)A/07

Our Ref MDR 01-02/06

Dear Sir/Madam

BOC Ltd

CD and HX Oxygen Cylinders

PL0735/5000

Cylinders distributed from 19th December 2005 until 23rd January 2006 with direct drive reading gauges.

A small proportion of the above cylinders are defective due to the presence of faulty gauges which may result in empty cylinders. These cylinders use an integral valve system with built in regulator and permanent live contents gauge.

BOC has two types of gauge in service with these cylinders and **only cylinders with a direct drive reading gauge are potentially affected**. Identification details are given below.

We understand that all of the potentially affected cylinders have an expiry date between 18th December 2008 and 22nd January 2009, AND have the direct drive reading gauge.

BOC currently has two gauge types in service and has provided images which can be found today under “What’s new” on the MHRA homepage (<http://www.mhra.gov.uk>). For future reference to this information, please visit the Drug Alerts section of the site. For those without access to the pictures we can indicate that the **DEFECTIVE gauges have no scale calibration markings**. Gauges which are NOT affected have ‘1/4 , 1/2, 3/4 and 1/1 as numerical content calibration markings and ‘315 bar’ at the top of the scale.

We understand that these cylinders are supplied to hospitals, Ambulance Trusts, Domiciliary recipients and other resuscitation users via the BOC Lifeline™ service.

BOC are telephoning all lifeline customers and plan to recover and replace the cylinders as soon as possible. Small numbers of cylinders are involved and additional support is limited at these locations.

For recipients in hospitals, Ambulance Trusts and domiciliary use there are many more cylinders in use and a recall would result in a significant supply shortage. Recipients are asked to ensure that all users are notified of this issue and cylinder contents gauges are checked daily and before use. Daily checks would provide an early indication to detect any additional failures and are recommended wherever possible. Any

cylinders which appear to be empty or for which there are serious concerns should be removed from service.

Pharmacists will need to contact patients that they may have supplied with affected cylinders distributed between 19th December 2005 and 23rd January 2006. We understand that domiciliary patients are likely to have several cylinders available.

In areas where the normal stockholding is a single cylinder, it may be advisable to redeploy cylinders or order additional supplies. **BOC is diverting resources to ensure replacement cylinders are made available. But have alerted us that supplies will be tight for weeks, it is therefore essential that only product that is identified by inspections as being defective or gives rise to serious concerns is replaces by BOC.** BOC have indicated that they will try to supply additional cylinders where there is a genuine need.

For medical, technical and general enquiries, please call BOC Customer Services centre on freephone number 0800 111 333, which is available 24 hours, 7 days a week.

Recipients of this Drug Alert should bring this information to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to bring this information to the attention of General Practitioners, Dental Practices and Community Pharmacists by copy of this letter.

Ambulance Trusts are included in the scope of this notification. Chief Executives are notified via Public Health Link and in view of the serious nature of this incident the DMRC is also faxing copies to Ambulance Trusts.

Yours sincerely



PP
DR NORMAN MORROW

Chief Pharmacist
For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist

Appendix 2 to MDEA(NI)2006-07

FAULTY DIRECT DRIVE GAUGE



NON-FAULTY GAUGE

