

# Medical Device Alert

Ref: MDA/2013/002 Issued: 14 January 2013 at 14:00

## Device

Medical oxygen and medical air cylinders filled to 200 atmospheres (200 bar/20,000 kPa).

Various sizes and outlets.

Supplied by SOL SpA.



## Problem

Risk of serious injury to staff and patients.

Currently 137 bar cylinders are widely used in the UK. Connection to significantly higher pressure 200 bar cylinders may cause damage to devices such as anaesthetic machines, ventilators, incubators, respiratory support and resuscitation equipment.

## Action by

All medical, technical, nursing, pharmacy, ambulance and portering staff responsible for handling or attaching medical oxygen cylinders to medical devices.

## Action

Be aware that 200 bar medical oxygen and medical air cylinders will be entering clinical use in a pilot scheme. If this pilot is successful, the use of 200 bar cylinders is expected to become widespread across the UK.

- Before connecting these 200 bar cylinders to medical devices staff must confirm that it is safe to operate at this higher pressure by checking the instructions for use, or contacting the manufacturer.
- All users should check the cylinder label before use to ensure the cylinder gas and pressure are appropriate and that the expiry date has not been exceeded.
- Staff must seek permission to remove cylinders for use outside the hospital and ensure the above checks are carried out prior to use.

## CAS deadlines

Action underway: 28 January 2013  
Action complete: 11 February 2013

**Note: These deadlines are for all affected staff to be made aware of the issue and amended procedures to be put in place.**

## Contact

**Supplier:**  
SOL Spa / BTG Gases  
Anthony Everard  
Tel: 07725 955 697  
Email: Anthony@btgases.com

## Device

Medical oxygen at 200 bar with pin index valve in 2, 5 and 50 litre capacity cylinders.  
Medical oxygen at 200 bar with bull nose valve in 10 and 20 litre capacity cylinders.  
Medical air at 200 bar with pin index valve in 2, 5, 10, 20 and 50 litre capacity cylinders.

## Problem

A hospital trust is undertaking a pilot scheme to introduce 200 bar cylinders into clinical use. While the trust involved has ensured the safety of these cylinders within their organisation, there are concerns that these cylinders could be moved out of the trust during patient discharge, or patient transfer in ambulances for use with transport incubators and transport ventilators.

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Health and Safety Executive
- Primary care trusts in England (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Adult intensive care units
- All wards
- Ambulance staff
- Anaesthetic nurses
- Anaesthetists
- Clinical governance leads
- Clinical perfusionists
- Coronary care departments
- Day surgery units
- Dental departments
- Directors of nursing
- EBME departments
- Health and safety managers
- High dependency unit
- Hospital at home units
- Hospital pharmacists
- Intensive care units
- Maintenance staff
- Maternity units
- Medical directors
- Midwifery departments
- Neonatal units
- Operating department practitioners
- Outpatient clinics
- Paediatric intensive care units
- Paramedics
- Patient transport managers
- Pharmacists
- Post anaesthesia care unit
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatre Managers
- Theatres

### **Primary care trusts**

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Community midwives
- Community nurses
- District nurses
- General dental practitioners
- General practitioners
- Minor injury units
- NHS walk-in centres
- Palliative care teams
- Practice managers
- Walk-in centres

### **Independent distribution**

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

This alert should be read by:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Supplier**

SOL Spa / BTG Gases

Anthony Everard

Tel: 07725 955 697

Email: [Anthony@btgases.com](mailto:Anthony@btgases.com)

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/002** or **2012/011/022/291/033**

### **Technical aspects**

Douglas McIvor or Emma Rooke

Medicines & Healthcare products Regulatory Agency

Floor 4

151 Buckingham Palace Road

London SW1W 9SZ

Tel: 020 3080 7193 / 6609

Fax: 020 8754 3965

Email: [douglas.mcivor@mhra.gsi.gov.uk](mailto:douglas.mcivor@mhra.gsi.gov.uk)  
[emma.rooke@mhra.gsi.gov.uk](mailto:emma.rooke@mhra.gsi.gov.uk)

### **Clinical aspects**

Tom Clutton-Brock

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London SW1W 9SZ

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Email: [tom.clutton-brock@mhra.gsi.gov.uk](mailto:tom.clutton-brock@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

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

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

## How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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