

Medical Device **ALERT**



For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	

Issued
11/03/03 -SJH

	Further Information						
DEVICE: Medical Gas Hoses for Oxygen	*						
PROBLEM: Risk of fire from worn or damaged hoses.	*						
ACTION BY: <ul style="list-style-type: none"> Medical, nursing, technical and paramedic staff using devices incorporating oxygen hoses. Staff responsible for servicing and replacement of oxygen hoses. 							
ACTION: Ensure a system is in place for the regular inspection and replacement of hoses, in line with manufacturers' instructions.	*						
DISTRIBUTED to: <table border="0"> <tr> <td>NHS Trusts (England)</td><td>– Chief Executives</td></tr> <tr> <td>National Care Standards Commission</td><td>– Headquarters</td></tr> <tr> <td>Primary Care Trusts (England)</td><td>– Chief Executives</td></tr> </table>	NHS Trusts (England)	– Chief Executives	National Care Standards Commission	– Headquarters	Primary Care Trusts (England)	– Chief Executives	
NHS Trusts (England)	– Chief Executives						
National Care Standards Commission	– Headquarters						
Primary Care Trusts (England)	– Chief Executives						
CONTACTS: MDA contacts for technical and clinical aspects Change of address or removal from address list for services registered under the Care Standards Act 2000.	*						
FEEDBACK REQUIREMENTS: None required							

* Further information supplied in the following pages.

DEVICE:

Medical hoses designed to carry oxygen under pressure from a primary source such as a cylinder or wall mounted terminal to medical devices such as ventilators and anaesthetic machines. These hoses are normally permanently attached to the device and can only be removed by the use of a tool.

PROBLEM:

The MDA has been informed of incidents involving the rupture and ignition of oxygen hoses used beyond the lifetime or use-by date recommended by the manufacturer. Due to heavy wear and tear the risk of rupture is greatest in oxygen hoses used with transport devices. Although the incidents related to this Alert only involved oxygen hoses, there is the need for a system to regularly inspect and replace all medical gas hoses.

Many device users and their managers are not aware of manufacturers' instructions to check the hoses and their connectors regularly and the need for hose replacement, usually between 2 and 5 years. The instructions for use of a medical device incorporating an oxygen hose may not mention the care and replacement of the hose. In these cases the hose may have been supplied separately and should have its own instructions for use. Where recommended, hoses may be manufactured in-house by qualified personnel. These hoses also require care instructions and a system to monitor the replacement of each individual hose.

ACTION:

- Oxygen hoses should be regularly inspected, cleaned, stored and replaced according to the manufacturers' instructions.
- Users should be especially aware of the possibility of damage to oxygen hoses when attached to transport devices, such as ventilators.
- If there is any doubt over the age of the hose, or the time recommended by the manufacturer for its replacement, or no care instructions, then the hose must be replaced.
- Only oxygen hoses supplied, or recommended, by the manufacturer of the medical device should be attached to that device.

DISTRIBUTION:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

TRUSTS to:

- Liaison Officers (for onward distribution)
- Directors of Anaesthetics
- Medical Directors
- Nursing Executive Directors
- Theatre Managers
- Adult & Paediatric Intensive Care Units
- Special Care Baby Units
- Accident & Emergency Departments
- All Wards
- Health & Safety Officers
- Risk Managers
- Respiratory care nurse specialists
- Clinical Governance Leads

NATIONAL CARE STANDARDS COMMISSION to:

- Headquarters (for onward distribution)
- Hospices
- Hospitals in the Independent Sector
- Private Dentists

PRIMARY CARE TRUSTS to:

- Liaison Officers (for onward distribution)
- General Dental Practitioners
- Lead nurses
- Directors of Public Health
- Clinical Governance Leads
- Community hospitals

CONTACTS:

Enquiries to the MDA should quote reference number **20030207.999-001** and be addressed to:

Technical aspects

Mr Douglas McIvor or Ms Clare Fripp
Medical Devices Agency
Hannibal House
Elephant and Castle
London SE1 6TQ

Tel: 020 7972 8193 / 8277

Fax: 020 7972 8113

Emails: Douglas.McIvor@doh.gsi.gov.uk
Clare.Fripp@doh.gsi.gov.uk

Clinical aspects

Dr S Ludgate
Medical Devices Agency
Hannibal House
Elephant and Castle
London SE1 6TQ

Tel: 020 7972 8123

Fax: 020 7972 8111

Email: Susanne.Ludgate@doh.gsi.gov.uk

Change of address or removal from list for services registered under the Care Standards Act 2000.

Contact:

NCSC Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0191 233 3556

Email: enquiries@ncsc.gsi.gov.uk

HOW TO REPORT ADVERSE INCIDENTS

Incidents relating to medical devices must be reported to the Medical Devices Agency as soon as possible.

Further information about: reporting incidents; on-line incident reporting facilities (introduced during September 2001); and downloadable report forms is available from MDA's website (<http://www.medical-devices.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MDA Adverse Incident Centre
Medical Devices Agency, Hannibal House, Elephant & Castle, London SE1 6TQ
Telephone 020 7972 8080 or Fax 020 7972 8109
or e-mail: mb-md-aic@doh.gsi.gov.uk
(An answerphone service operates outside normal office hours)

From January 2000, MDA Safety Warnings have been available in full text on the MDA Internet site:
<http://www.medical-devices.gov.uk>

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