Medical Device ALERT



For:	IMMEDIATE ACTION	√
	1.5-1.51	
	ACHON	
	LIDEATE	
	UPDATE	
	NEORMATION REQUEST	

	Further Information	
DEVICE: Medical Gas Hoses for Oxygen		
PROBLEM: Risk of fire from worn or damaged hoses.		
 ACTION BY: 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: 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.

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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

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CONTACTS:

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

Technical aspects

London SE1 6TQ

Mr Douglas McIvor or Ms Clare Fripp Medical Devices Agency Hannibal House Elephant and Castle

Tel: 020 7972 8193 / 8277 Fax: 020 7972 8113

Emails: Douglas.Mclvor@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-mda-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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