

Ref. MDA/2003/016
Issued: 29 May 2003

CONTACTS:

Enquiries to the MHRA should quote reference number **20030227.030-4** and be addressed to:

Technical aspects

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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 Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about: reporting incidents; on-line incident reporting facilities and downloadable report forms is available from MHRA's website (<http://www.mhra.gov.uk>).

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

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Hannibal House, Elephant and Castle, London SE1 6TQ
Telephone 020 7972 8080 or Fax 020 7972 8109
or e-mail: AIC@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

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DEVICE:

Pressure regulators and flow meters for use with gas cylinders or the wall outlets of medical gas pipeline systems. This Notice does **not** apply to pressure regulators or flow meters built in, or permanently attached, to other medical devices and serviced with these devices, e.g. anaesthetic machines, ventilators, insufflators, certain laboratory equipment and gas cylinders with integrated regulators.

PROBLEM:

The MHRA has been informed of a number of incidents involving the rupture and ignition, or gross inaccuracy, of pressure regulators and flow meters that have not been appropriately serviced as recommended by the manufacturer. Poor servicing by a third party agent contributed to a further incident of regulator ignition.

Pressure regulators and flow meters that are built in, or permanently attached, to other medical devices are not always covered by the servicing arrangements for these devices.

This Alert is intended to supplement advice given in Medical Device Alert MDA/2003/007 "Medical Gas Hoses for Oxygen" and Safety Notice 2000(07) "Medical Gas Cylinders: Risk of Fire".

ACTION:

- Ensure that devices are inspected regularly and serviced according to the manufacturers' instructions/service manuals.
- Ensure that devices have a unique inventory marking to ensure traceability for future servicing.
- If there is any doubt over the service history then ensure that these devices are serviced immediately.
- Ensure that devices on loan or rented are exchanged by the service provider on a regular basis.
- If servicing is to be undertaken by third party agents ensure that this is in line with recommendations outlined in Device Bulletin 2000(02) "Medical Devices and Equipment Management: Repair and Maintenance Provision".
- Ensure that older gas regulators without instructions for servicing, or where spare parts are no longer available, are replaced.
- Ensure that pressure regulators or flow meters that are built in, or permanently attached, to other medical devices are appropriately serviced with those devices.

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
- Health & safety officers
- Risk managers
- EBME departments,
- Medical/clinical engineering
- Medical physics departments
- Estates departments
- Respiratory care nurse specialists
- Clinical governance leads
- Pharmacy departments
- Ambulance trusts
- Chief pharmacists

NATIONAL CARE STANDARDS COMMISSION to:

- Headquarters (for onward distribution)
- Care homes providing personal care
- Care homes providing nursing care
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Community pharmacists

PRIMARY CARE TRUSTS to:

- Liaison officers (for onward distribution)
- Practice managers
- General dental practitioners
- Community hospitals