Medical Device Alert

Action

Ref: MDA/2010/052 Issued: 28 June 2010 at 11:00

Device

Anaesthetic vaporizers used to administer volatile agents for the maintenance of anaesthesia - all manufacturers.

Problem

The MHRA has received reports where the failure to correctly attach vaporizers to the anaesthetic machine backbar has led to anaesthetic gas leakage and patient awareness.
This may be more pronounced where:

- vaporizers are attached to anaesthetic machines from an alternative manufacturer
- vaporizers are attached to the backbar during anaesthsia.

Action by

Anaesthetists, Physicians' Assistants (Anaesthsia), Operating Department Practitioners, Anaesthetic nursing staff and Clinical Perfusion Scientists.

CAS deadlines

Action underway: 12 July 2010

Action complete: 28 July 2010

Action

- Ensure that vaporizers are correctly seated on the backbar before the induction of anaesthesia and that the machine has been tested for leaks in accordance with the manufacturer's instructions and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) Guidelines.
- If a new vaporizer is attached to the backbar during anaesthesia, the machine must be checked immediately in accordance with the manufacturer's instructions and the AAGBI Guidelines.

Action

The AAGBI Guideline “Checking Anaesthesia Equipment” is under revision and can be found on: http://www.aagbi.org/publications/guidelines/docs/checking04.pdf. The testing for leaks by occluding the Common Gas Outlet may not always be appropriate, therefore always consult the instructions for use of the vaporizer and the anaesthetic machine.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

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

Trusts to:

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

- Anaesthetic nursing staff
- Anaesthetists
- Clinical perfusion scientists
- Day surgery units
- Operating department practitioners.
- Theatre managers
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector

Contacts

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/052** or **2008/012/011/401/021.**

Technical aspects
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Clinical aspects
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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

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.iric@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

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