Medical Device Alert

Ref: MDA/2012/031 Issued: 06 June 2012 at 12:00

Device

Anaesthetic machines and associated devices.

All manufacturers.

Problem

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) report that 'failure to check the anaesthetic machine and/or the breathing system features as a major contributory factor in many anaesthetic misadventures, including some that have resulted in hypoxic brain damage or death'.

Action by

Anaesthetists, operating department practitioners, anaesthetic nurses and all staff using anaesthetic machines and associated devices.

CAS deadlines

Action underway: 18 June 2012

Action complete: 25 June 2012

Action

- Be aware that the AAGBI has published an updated version of 'Checking Anaesthetic Equipment' endorsed by all UK Chief Medical Officers and the Royal College of Anaesthetists. The new 'Checklist for Anaesthetic Equipment 2012' is attached to this alert.
- Always follow the manufacturer's instructions for use.
- Check anaesthetic machines and all breathing system components before use.

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)

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
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Maternity units
- Medical directors
- Nursing executive directors
- Operating department practitioners
- Risk managers
- Theatre recovery suite
- Theatres

Independent distribution

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

This alert should be read by:

- 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 and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/031** or **2012/005/022/291/017**

Technical 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 Chris Jones
Senior Medical Officer
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

Appendix

Checklist for Anaesthetic Equipment 2012

AAGBI Safety Guideline

Checks at the start of every operating session
Do not use this equipment unless you have been trained

Check self-inflating bag available	
Perform manufacturer's (automatic) machine check	
Power supply	• Plugged in • Switched on • Back-up battery charged
Gas supplies and suction	• Gas and vacuum pipelines – 'tug test' • Cylinders filled and turned off • Flowmeters working (if applicable) • Hypoxic guard working • Oxygen flush working • Suction clean and working
Breathing system	• Whole system patent and leak free using 'two-bag' test • Vaporisers – fitted correctly, filled, leak free, plugged in (if necessary) • Soda lime - colour checked • Alternative systems (Bain, T-piece) – checked • Correct gas outlet selected
Ventilator	• Working and configured correctly
Scavenging	• Working and configured correctly
Monitors	• Working and configured correctly • Alarms limits and volumes set
Airway equipment	• Full range required, working, with spares
RECORD THIS CHECK IN THE PATIENT RECORD	
Don't Forget!	• Self-inflating bag • Common gas outlet • Difficult airway equipment • Resuscitation equipment • TIVA and/or other infusion equipment

This guideline is not a standard of medical care. The ultimate judgement with regard to a particular clinical procedure or treatment plan must be made by the clinician in the light of the clinical data presented and the diagnostic and treatment options available.

CHECKS BEFORE EACH CASE

Breathing system	Whole system patent and leak free using 'two-bag' test Vaporisers – fitted correctly, filled, leak free, plugged in (if necessary) Alternative systems (Bain, T-piece) – checked Correct gas outlet selected
Ventilator	Working and configured correctly
Airway equipment	Full range required, working, with spares
Suction	Clean and working

THE TWO-BAG TEST

A two-bag test should be performed after the breathing system, vaporisers and ventilator have been checked individually

i. Attach the patient end of the breathing system (including angle piece and filter) to a test lung or bag.

ii. Set the fresh gas flow to 5 $l.min^{-1}$ and ventilate manually. Check the whole breathing system is patent and the unidirectional valves are moving. Check the function of the APL valve by squeezing both bags.

iii. Turn on the ventilator to ventilate the test lung. Turn off the fresh gas flow, or reduce to a minimum. Open and close each vaporiser in turn. There should be no loss of volume in the system.

This checklist is an abbreviated version of the publication by the Association of Anaesthetists of Great Britain and Ireland 'Checking Anaesthesia Equipment 2012'. It was originally published in *Anaesthesia*.
(Endorsed by the Chief Medical Officers)

If you wish to refer to this guideline, please use the following reference: Checklist for anaesthetic equipment 2012. *Anaesthesia* 2012; **66:** pages 662–63. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2012.07163.x/abstract