Medical Device Alert

Immediate action

Ref: MDA/2010/021 Issued: 10 March 2010 at 14:00

Device

Anaesthetic gas scavenging systems (AGSS).

All manufacturers.

Problem

Risk of serious harm to the patient from excessive pressure in anaesthetic breathing systems caused by blockage of AGSS hoses.

Action by

Anaesthetic staff.

CAS deadlines

Action underway: 24 March 2010
Action complete: 07 April 2010

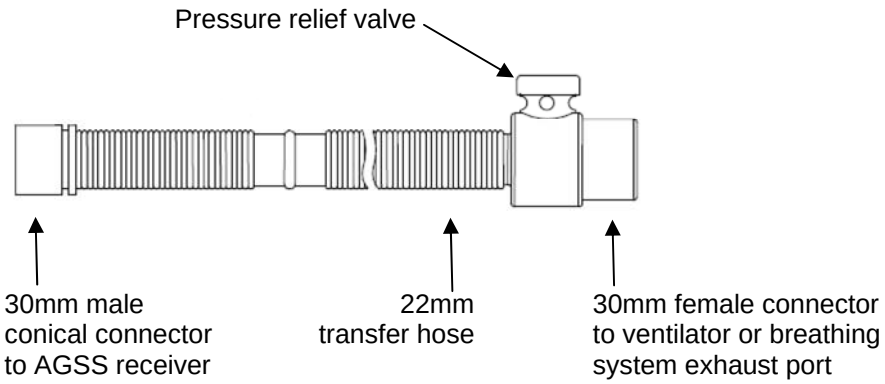
Action

- Ensure all anaesthetic staff are aware of this problem.
- Have procedures in place to ensure that:
  - a means of over-pressure relief is provided at the entry to the AGSS transfer hose when it incorporates 30mm diameter connectors to attach to either the exhaust, or adjustable pressure limiting (APL) valves of anaesthetic breathing systems or ventilators
  - pre-use checks for the anaesthetic equipment are always followed, including the anaesthetic machine, ventilator, breathing systems and the AGSS, as recommended by the Association of Anaesthetists of Great Britain and Ireland in their guidelines 'Checking Anaesthetic Equipment 3 (2004)' (www.aagbi.org).

These actions are endorsed by the Association of Anaesthetists of Great Britain and Ireland (AAGBI).

Device

Typical active AGSS transfer hose assembly incorporating pressure relief valve



Anaesthetic gas scavenging systems (AGSS) transport exhaled and waste anaesthetic gases from the exhaust valve of an anaesthetic ventilator or anaesthetic breathing system into the atmosphere at a safe location away from the operating theatre. 'Active' AGSS incorporate a mechanical pump to assist with the disposal of the waste gases. AGSS consist of transfer, receiving and disposal components. The transfer hose conveys waste gases from the breathing system to the AGSS receiving reservoir. The receiving reservoir incorporates an air break to allow entrainment of room air and prevent negative pressure being applied to the breathing system. The receiving system hose conveys the mixture of waste anaesthetic gas and room air from the receiving reservoir to the terminal unit placed at the entry to the disposal system. Interchangeable AGSS incorporate 30mm female inlet connectors to the transfer hose to prevent accidental connection to other breathing system components. This inlet connection should also incorporate a means of pressure relief to prevent the pressure within the transfer hose at this point rising above 2 kPa (20 cm H_2O) under any condition (for instance, should the transfer hose become blocked or kinked).

Some manufacturers of anaesthetic equipment have developed non-interchangeable AGSS, which do not incorporate the standard 30mm connectors. In these systems, protection against harm arising from a blockage within the AGSS transfer hose is achieved by one or both of the following: the use of kink-resistant hose or the incorporation of additional pressure-relief valves within their anaesthetic and ventilator breathing systems. Since the AGSS connectors used in these systems are incompatible with the standard 30mm AGSS connectors, the possibility of connecting the transfer hoses on these systems to a breathing system not fitted with additional pressure-relieving systems (e.g. a Bain-type system) is reduced.

GE Healthcare (formerly Datex-Ohmeda) believes only the older style machines such as Excel 210, 410 and Excel 210SE, ModSE, ModCD/CV and the Aestiva Induction may be affected by this alert.

Problem

The AAGBI and representatives from the Technical Committee of the British Standards Institution (BSI) have identified that the European and International Standard **EN ISO 8835-3 2009 Inhalational anaesthesia systems, Part 3 Transfer and receiving systems of active anaesthetic gas scavenging systems** has failed to mandate that there is a means of pressure-relief at the inlet of all interchangeable AGSS transfer hoses. This standard defines the dimensional requirements of the inlet connectors of the AGSS transfer hoses to be a 30mm female connector, to ensure compatibility and interchangeability between anaesthetic breathing systems and AGSS from different manufacturers. Consequently this transfer hose can be attached to the exhaust valve of a breathing system or an anaesthetic ventilator that may not

have integral over-pressure protection. Thus, any occlusion within the transfer hose would result in a build-up of excessive positive-pressure within the breathing system.

The technical specifications within this standard have been available to equipment manufactures since 2007; therefore these systems are now in use in the UK. Additionally some users have replaced the manufacturer's non-interchangeable inlet connector with a 30mm interchangeable type.

This latest version of the standard also mandates the use of a 30mm male connector at the outlet of the AGSS receiving reservoir (which incorporates the air-break) thereby making it possible to fit the receiving system hose directly onto the exhaust valve of the breathing system by-passing the receiving reservoir and air-break altogether. This would create a high-flow negative pressure within the breathing system.

The MHRA, AAGBI, Royal College of Anaesthetists, British Anaesthetic and Respiratory Equipment Manufacturers Association and BSI are working to amend this European and International Standard. It is estimated this Standard will be amended approximately six months after publication of this Alert.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC)
- HSC Trusts in Northern Ireland (Chief Executives)
- NHS Boards in Scotland (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:

- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Operating department practitioners
- Risk Managers
- Theatre managers

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

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/021 or 2010/001/029/081/005**

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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: 028 9052 3704
Fax: 028 9052 3900
E-mail: 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
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E-mail: nss.iric@nhs.net

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

Wales

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