Medical Device Alert

Ref: MDA/2011/108 Issued: 01 December 2011 at 15:30

Device

Anaesthetic machine: Auxiliary Common Gas Outlet (ACGO).

All Aestiva, Aisys, Aespire and Avance anaesthetic machines.

Manufactured by GE Healthcare.

Problem

The accidental, incorrect setting of the ACGO switch will result in no fresh gas flow to the patient.

Furthermore, if the circle breathing circuit is incorrectly attached to the ACGO, this may result in patient barotrauma.

Action by

Anaesthetic and theatre staff involved in the set-up and use of these devices.

Action

If you have these machines, ensure that:

- the position of the ACGO lever and breathing circuit connections are checked before the start of every case, as recommended by the manufacturers and in the Association of Anaesthetists of Great Britain and Ireland (AAGBI) pre-use checklist. Care is especially recommended for paediatric lists where breathing circuits are changed routinely between patients.
- relevant members of staff have been fully trained in the use of these anaesthetic machines and are aware of the manufacturer's training guidance produced in collaboration with the Safety Committee of AAGBI – **see appendix.**

CAS deadlines

Action underway: 09 December 2011

Action complete: 16 December 2011

Contact

Manufacturer
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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)
- General practitioners (for information)

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
- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Day surgery units
- Maternity units
- Operating department practitioners
- Recovery wards
- Risk managers
- 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.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/108** or **2011/006/027/401/017**

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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

Tel: 029 2082 3922

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

Appendix

Training Guidance Aestiva, Aisys, Aespire and Avance Machines

Ref: ACGO (Auxiliary Common Gas Outlet)

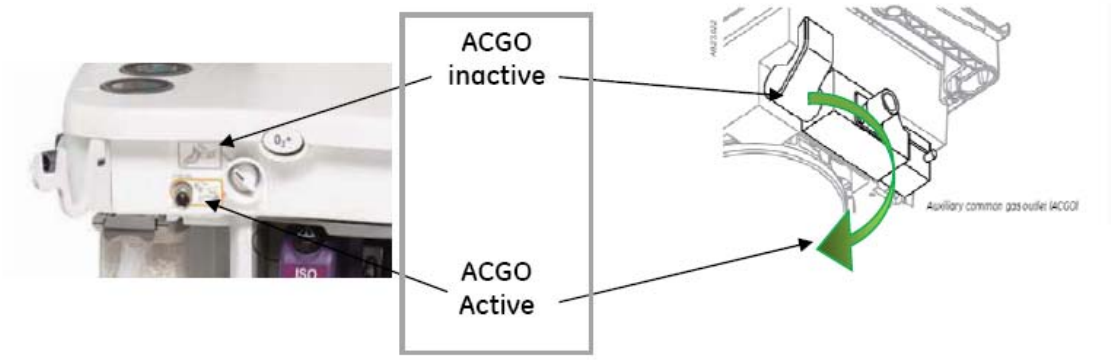
Following reports of User mis-connections regarding the ACGO, we feel it would be helpful to issue the following reminder on the use of the auxiliary common gas outlet on anaesthesia machines.
Users are also reminded to follow the Manufacturers, regulatory and training guidelines accordingly for Anaesthetic machines and the testing of breathing circuits.

1. Please ensure all relevant machine and circuit checks are carried out at the start of the list.

2. If the circuit is changed you must ensure it is configured correctly as per the user manual guidelines.

3. **Check that the ACGO switch is set appropriately for the required circuit in use.**

Aisys, Avance, Aespire Anaesthesia machines **Aestiva range of anaesthesia machines**



4. Complete Manufacturers circuit test procedure as directed in the relevant Anaesthesia machine manual before use. In conjunction with the AAGBI guidelines on the anaesthesia pre-use check out procedure.