Medical Device Alert

Action

Ref: MDA/2010/092 Issued: 30 November 2010 at 10:30

Device

All Oxylog 3000 emergency/transport ventilators.

Manufactured by Draeger.

Problem

Insufficient ventilation of paediatric patients when using small tidal volumes (50 -100 ml).

This problem can result in gas being re-breathed and a potential dangerous rise in CO_2.

Action by

All staff using these ventilators for paediatric patients.

Action

- Ensure that all users are aware of the manufacturer's Field Safety Notice (FSN).
- Users should always consider the dead space of ventilator breathing circuits when using small tidal volumes.
- Be aware that Draeger breathing circuits for use with the Oxylog 3000 (disposable and resusable) have a dead space of 33 ml and 35 ml respectively.
- If the dead space is not suitable for the intended purpose then consider using an alternative device.

CAS deadlines

Action underway: 14 December 2010

Action complete: 29 December 2010

Contact

Manufacturer
Doug Sims
Draeger Medical UK Limited
Tel: 01442 213 542
Fax: 01442 240 327
Email: doug.sims@draeger.com

Device

The Oxylog 3000 is an emergency and transport ventilator capable of delivering tidal volumes (volume of gas inhaled and exhaled per breath) of 50 ml and upwards.

Problem

The MHRA is aware of three incidents in which the Oxylog 3000 gave insufficient ventilation to small children where a tidal volume between 50 and100 ml was used. These incidents have occurred due to the dead space volume of the entire breathing circuit being too large to cope with the small set tidal volume.

Action

Users should be aware of the additional warnings and cautions given by Draeger in the Field Safety Notice (FSN). The FSN should be added to the Oxylog 3000 Instructions for Use.

Be aware that Draeger are developing a dedicated paediatric breathing system for use with the Oxylog 3000. This should be available for purchase by the end of 2010.

Distribution

This MDA has been sent 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 relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

SABS liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Ambulance services directors
- Anaesthesia, directors of
- Clinical governance leads
- EBME departments
- Health and safety managers
- Intensive care units (adult, paediatric, neonatal)
- Intensive care, directors of
- Medical directors
- Medical physics departments
- Nursing executive directors
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- SCBU
- Supplies managers
- Theatre managers

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. 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

Manufacturer
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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/092** or **2010/008/016/081/002**

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 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