Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/001 Issued: 08 February 2017 at 14:30

Oxylog 3000 and Oxylog 3000 plus ventilator – risk of failure

Summary

Manufactured by Dräger – ventilator may stop working if oxide layers accumulate due to the infrequent use of the control knobs (potentiometers).

Action

- Identify all Oxylog 3000 and Oxylog 3000 plus ventilators.
- Ensure all users are aware of the Manufacturer`s Field Safety Notice (FSN) and know how to perform the pre-use check outlined in the instructions for use (IFU).
- Contact Dräger to acknowledge the FSN and schedule a time to perform the software update.
- Update the IFU with the supplement provided with the FSN or by Dräger's service engineers at the time of software installation.

Action by
All those who use these devices.

Deadlines for actions
Actions underway: 01 March 2017
Actions complete: 15 March 2017

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

This error condition (referred to by Dräger as 'Poti unplugged') which could result in the ventilator stopping, is caused by an accumulation of an oxide layer in the potentiometer when these are rarely (or never) moved. The layer develops over time, but twisting the potentiometer knobs prevents this, as described in Dräger's FSN that was sent to customers in 2015.

Dräger have now issued software which enables the ventilation to continue with the last, valid parameters (and posts the corresponding alarms). Additionally, the new software prompts turning of the potentiometer knobs in the pre-use device check, so the issue should not occur.

Manufacturer contacts

Dräger Quality Department:

Tel: 01442 292 870

Email: ukhealth@draeger.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Adult intensive care units
- Ambulance staff
- Anaesthetic medical staff
- Biomedical engineering staff
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Health and safety managers
- Intensive care units
- Medical physics departments
- Paediatric intensive care units
- Paediatric wards
- Patient transport managers
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units

Independent distribution

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

- Hospitals in the independent sector

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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/001** or **2016/012/012/291/014**.

Technical aspects
Hiten Patel or Emma Rooke, MHRA

Tel: 020 3080 6115 / 6609

Email: hiten.patel@mhra.gsi.gov.uk or emma.rooke@mhra.gsi.gov.uk

Clinical aspects
Devices Clinical Team

Tel: 020 3080 6000 (Customer Services)

Email: DCT@mhra.gsi.gov.uk

Reporting adverse incidents in England

Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).