Medical Device Alert

Ref: MDA/2012/068 Issued: 25 September 2012 at 15:30

Device

ConchaTherm Neptune heated humidifiers.

Manufactured by Teleflex.

Product codes: 425–00, 425–10 and 425–30.

Specific serial numbers.

Problem

Potential for failure of the speaker. If the speaker fails, no alarm will sound in the event of a device failure, which could cause a delay in patient treatment.

The manufacturer published a Field Safety Notice (FSN), in June 2012, to notify users and prompt them to take action. The manufacturer has not received sufficient confirmation that this FSN had been received and acted upon.

Action by

All staff involved in the set-up, maintenance and use of these devices.

Action

- Locate and identify all affected devices using the list of serial numbers in the manufacturer's FSN.
- Check the speaker by following the instructions in the manufacturer's FSN.
- Return the acknowledgement form to Teleflex.
- If faulty speakers are found, contact Teleflex immediately to request replacement speakers as a priority.
- For future use, be aware that if the humidifier makes neither an audible alert nor alarm as part of the self-check on startup, there may be a fault with the speaker.

CAS deadlines

Action underway: 09 October 2012

Action complete: 26 November 2012

Note: These deadlines are for devices to be identified and arrangements made to replace the speaker.

Contact

Manufacturer
Hélène Sauvage
Teleflex Medical
Tel: 01494 532 761
Fax: 01494 524 650
Email: orders.uk@teleflex.com

Device

This heated humidification system is designed to heat and humidify respiratory gases delivered to adult and paediatric patients.

Problem

Although the speaker failure will result in no alarm sounding if there is a problem, the humidifier will continue to detect any abnormalities and take appropriate action.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- 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)
- Primary care trusts in England (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:

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Directors of nursing
- Ear nose and throat units
- EBME
- Equipment stores
- High dependency units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Medical directors
- Paediatric intensive care units
- Physiotherapists
- Respiratory nurse specialists
- Resuscitation officers and trainers

Primary care trusts

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

- Community hospitals
- Equipment libraries and stores
- Maintenance staff

Independent distribution

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

This alert should be read by:

- 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.

Contacts

Manufacturer
Hélène Sauvage
Teleflex
IDA Business & Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Tel: 01494 532 761
Fax: 01494 524 650

Email: orders.uk@teleflex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/068** or **2012/006/019/291/001**

Technical aspects
Emma Rooke and Gica Leclerc
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6609 / 6610
Fax: 020 8754 3965

Email: emma.rooke@mhra.gsi.gov.uk
gica.leclerc@mhra.gsi.gov.uk

Clinical aspects
Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ

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Fax: 020 8754 3965

Email: jonathan.plumb@mhra.gsi.gov.uk

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:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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