

# Medical Device Alert

Ref: MDA/2014/029 Issued: 22 July 2014 at 15:30

Device
<p>Ventstar disposable breathing systems. Part numbers 2M86841 and 2M86791.</p> <p>Manufactured by Draeger.</p> <p>Specific batch numbers affected.</p>

Problem	Action
<p>Risk of inhalation of foreign particles.</p> <p>Due to a manufacturing issue, there is the potential for loose adhesive residue to be inside the breathing systems. This may enter the lungs if affected devices are used.</p>	<ul style="list-style-type: none"> <li>• Identify affected devices.</li> <li>• If alternative devices from unaffected batches are available in your stocks:               <ul style="list-style-type: none"> <li>○ quarantine affected devices</li> <li>○ return them to Draeger and request replacements.</li> </ul> </li> <li>• If no alternative devices are available in your stocks:               <ul style="list-style-type: none"> <li>○ continue to use affected breathing systems</li> <li>○ carry out the check described in Draeger's <a href="#">Field Safety Notice</a></li> <li>○ exercise caution in use.</li> </ul> </li> <li>• Contact Draeger to acknowledge receipt of the Field Safety Notice.</li> </ul>
Action by	
<p>All staff who use these devices including:</p> <p>Anaesthetists Theatre practitioners Consultant intensivists</p>	
CAS deadlines	Contact
<p>Action underway: 05 August 2014</p> <p>Action complete: 22 September 2014</p> <p><b>Note: These deadlines are for staff to be made aware of the issue and affected devices to be identified.</b></p>	<p><b>Manufacturer</b> Mr Stuart Norris Draeger Medical Tel: 01442 213 542 Email: <a href="mailto:UKHealth.Safety@draeger.com">UKHealth.Safety@draeger.com</a></p>

## Device

The following products are affected by this action:

Device description	Part number	Batch number (from – to inclusive)
Packaging box set	2M86841	330384.001 - 331661.002
Hose packaging	2M86791	330384.001 - 331661.002

Affected devices were manufactured from January 2013 to April 2014 inclusive.

These breathing systems are designed for use with the Oxylog 2000 ventilator, which is an emergency and transport ventilator.

If relevant to you, the national supply codes are as follows:

England NPC: FDB675 Breathing Circuit Oxylog 2000 Disposable Circuit 1.8m

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities 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
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Operating department practitioners
- Paediatric intensive care units
- Paramedics
- Risk managers
- Theatre managers
- Theatre nurses
- 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
- Private medical practitioners

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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Mr Stuart Norris  
Draeger Medical  
The Willows  
Mark Road  
Hemel Hempstead  
Hertfordshire  
HP2 7BW

Tel: 01442 213 542

Email: [UKHealth.Safety@draeger.com](mailto:UKHealth.Safety@draeger.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/029** or **2014/005/021/081/009**

### Technical aspects

Emma Rooke and Elke Kerwick  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 6609/6826

Fax: 020 8754 3965

Email: [emma.rooke@mhra.gsi.gov.uk](mailto:emma.rooke@mhra.gsi.gov.uk)  
[elke.kerwick@mhra.gsi.gov.uk](mailto:elke.kerwick@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@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](mailto: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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

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

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Email: [improvingpatientsafety@wales.gsi.gov.uk](mailto:improvingpatientsafety@wales.gsi.gov.uk)

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