

Medical Device Alert

Ref: MDA/2014/041 Issued: 21 October 2014 at 13:00

Device
<p>Babytherm infant warmers and open infant care units for newborns.</p> <p>Manufactured by Draeger Medical.</p> <p>Model numbers: 8004, 8010 and 8000WB.</p>

Problem	Action
<p>Risk of baby falling out of the device.</p> <p>Failure to follow the instructions for use for inserting the inner safety panels and locking the outer safety side panels may result in them opening unexpectedly.</p> <p>Draeger sent a Field Safety Notice to its customers in August 2014 but hasn't had enough replies to know if users have received and acted upon this information.</p>	<ul style="list-style-type: none"> Identify affected devices. Ensure users read the important information in the Field Safety Notice (FSN) and follow the instructions (see appendix) to ensure that the inner safety panels are in place and the outer side panels are securely locked into position. If the locking mechanism is not functioning, contact Draeger. Complete the acknowledgement sheet you received with the FSN and return it to Draeger.
Action by	
<p>All those who use these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 04 November 2014</p> <p>Action complete: 22 December 2014</p> <p>Note: These deadlines are for users to be made aware of the issue and confirm that they are operating the panels correctly.</p>	<p>Manufacturer Graham Dell Draeger Medical UK Limited Tel: 01442 213 542 Email: ukhealth@draeger.com</p>

Device

This device is an open care unit for warming premature babies, neonates and infants with a body weight of up to 8 kg.

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:

- Anaesthesia, directors of
- Intensive care nursing staff (paediatric)
- Maternity units
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Special care baby units

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
- Nursing agencies
- 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 and requesting this facility.

Contacts

Draeger Medical

Graham Dell
Draeger Medical UK Limited
The Willows
Mark Road
Hemel Hempstead
HP2 7BW
Tel: 01442 213 542
Email: ukhealth@draeger.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/041** or **2014/008/022/081/003**

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
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

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

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

<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

Appendix

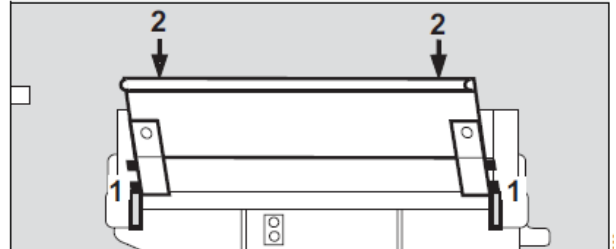
Below is part of the instructions for use provided with these models by Draeger Medical, which explains how to correctly fit both sets of side panels.

Fitting the panels

- 1 Insert the lower mounting pins of the panel hinge-pieces into the guide slots on either side.

With the panels on the long side, ensure that the handle points outwards.

- Position the panel semi-upright,
- 2 press the panel down firmly until the pins lock into position at the bottom of the slots.
- Fold the panel up into the vertical position and allow it to drop into the locking position.
- Fit all four panels in this way.



Make sure that the panels are seated correctly.

To open:

- Lift the panel all the way up until the upper pins come out of their slots, then fold the panel down.

With lively infants or older children:

- Use 230 mm high panels.

Fitting the inner panels

WARNING

**Inner panels should be used with all patients, regardless of whether the side panels are up or down!
Otherwise the patient may fall out!**

- Insert the pins into the tapered holes in the corners of the housing and press down lightly until the inner panel is firmly in place.

Make sure the panels are seated correctly.

