

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/08

Issued: 1 February 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Neonatal radiant warmer: Draeger Resuscitaire, model RW82VHA-1C with variable height adjustment.</p>	▶ ①
<p>Problem: Screws that secure the column to the base of the Resuscitaire may loosen over time, allowing the support column to tilt, due to an incorrect fitting.</p>	▶ ②
<p>Action by: Neonatal special care units and EBME departments.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify Resuscitaire (model RW82VHA-1C) with an adjustable height mechanism. If the unit is tilting, contact Draeger to arrange for your unit to be corrected. Ensure that all in-house or third party service agents have access to Draeger's Technical Service Bulletin (TSB) No. 01 that was issued on 21 December 2006. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Neonatal radiant warmer: Draeger Resuscitaire, model RW82VHA-1C with variable height adjustment. The Resuscitaire is typically used in delivery rooms for resuscitation of premature babies and is designed for use in maternity units.

2. PROBLEM:

The MHRA is aware of two incidents where the screws in the main column have become loose allowing the unit to tilt.

Draeger will be updating the service test card (service requirements) for the Resuscitaire to state that when replacing the screws in the main column a specific torque and Loctite® 271 should be applied.

3. ACTION BY:

Neonatal special care units and EBME departments.

4. ACTION:

Ensure that all in-house or third party service agents have access to Draeger's Technical Service Bulletin (TSB) No. 01 that was issued on 21 December 2006.

Ensure that when the device is next serviced, by trained service engineers, the screws are replaced following the updated service guidance in TSB No. 01. This guidance has already been supplied to Draeger service engineers or hospital engineers trained by Draeger.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Clinical governance leads
- EBME departments
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- In-house maintenance staff
- Intensive care medical staff (paediatrics)
- Intensive care nursing staff (paediatrics)
- Intensive care, directors of
- Maternity units
- Medical directors
- Midwifery staff
- Neonatal nurse specialists
- Neonatologists
- Neonatology directors
- Nurse executive directors
- Obstetricians
- Obstetrics nurses
- Operating theatres
- Paediatric nurse specialists
- Risk managers
- Special care baby units

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Mr Doug Sims
Draeger Medical UK Ltd
The Willows
Mark Road
Hemel Hempstead
Herts HP2 7BW

Tel: 01442 213 542

Fax: 01442 240 327

E-mail: doug.sims@draeger.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2007/08 and be addressed to:

Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

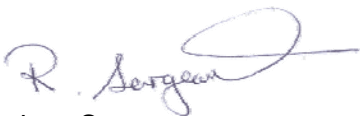
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety