

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/41

Issued: 9 December 2003

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Draeger Medical Babytherm 8004 and 8010 open care units for warming premature babies, neonates and infants.	▶ ①
<b>Problem:</b> Risk of inaccurate temperature monitoring resulting in minor injury or hyperthermia.	▶ ②
<b>Action by:</b> Medical, nursing and technical staff responsible for the use and servicing of these devices.	▶ ③
<b>Action:</b> As detailed in the manufacturer's instructions for use, only sensors recommended for use with the Babytherm 8004 and 8010 should be used. Users should ensure correct placement of the skin temperature sensors, and that sensor connectors are plugged in completely.	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None Required.	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Draeger Medical Babytherm 8004 and 8010 open care units for warming premature babies, neonates and infants.

## 2. PROBLEM:

NIAIC has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA) has received reports of minor injury and hyperthermia due to skin temperature measurement errors associated with Babytherm models 8004 and 8010. In July 2003, Draeger Medical issued a Safety Notice to the Chief Executives of affected trusts, highlighting their instructions for use on the correct fitting and placement of sensors. However, a sample check carried out by the MHRA showed that, within some of the trusts, the Notice had not been distributed to the appropriate departments. NIAIC and MHRA wants to ensure that the safety information within Draeger's Safety Notice is brought to the attention of all users of the Babytherm 8004 and 8010.

## 3. ACTION BY:

Medical, nursing and technical staff responsible for the use and servicing of these devices.

## 4. ACTION:

- Only recommended sensors, as stated in the manufacturer's instructions for use, should be used.
- Users must ensure correct placement of the skin temperature sensors. For the 'close to core temperature measurement', the manufacturer recommends attachment of the yellow sensor to the abdomen in the liver region if baby is lying on its back, or attachment of the sensor in the kidney region if the infant is lying on its front.
- Users must ensure that the sensor connectors are plugged in completely, with the connector pushed flush against the front panel.

Draeger Medical also advises that in cases where a temperature fluctuation alarm is given, it should be checked that the heat radiation under both heating elements can be felt; this is to ensure that heating element failures are noticed.

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Nurse Directors
- Medical and Nursing Staff
- Special Care Baby Units and Neonatal Units
- Maternity Wards
- Paediatric Intensive Care Units
- Accident and Emergency Departments
- NIAS paramedics and technicians
- NIAIS Operational Director
- Midwives
- Obstetricians
- Paediatricians

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Alan Montague  
Project Manager  
Draeger Medical UK Ltd  
The Willows  
Mark Road  
Hemel Hempstead  
Hertfordshire, HP2 7BW

Tel: 01442 292 835

Fax: 01442 240 327

E-mail: [alan.montague@draeger.co.uk](mailto:alan.montague@draeger.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2003/41 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



Brian Godfrey  
NIAIC 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 Safety Notice SN (NI) 2003/01. 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](http://www.dhsspsni.gov.uk/niaic)

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