



DEFECT & INVESTIGATION CENTRE

FOR ACTION BY:

Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
General Manager/Chief Executive of each Agency

Stoney Road Dundonald Belfast
Northern Ireland BT16 1US

Telephone 028 90 523714
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HN(NI) 2000/16

Date: 21 July 2000

Product	:	DRAEGER 600W RADIANT HEATER TROLLEYS (RH800) INCLUDING RADIANT HEATERS FOUND IN: BABYTHERM 8000 OPEN CARE AND RESUSCITATION UNITS, BABYTHERM 4200, RESUSCITATION UNITS PP800 AND PP8000
Manufacturer/Supplier	:	Draeger Medical
Problem	:	Hazard Notice HN(NI)2000/13 identified the problem of thermal hazard from the skin temperature probe in Draeger 8000 incubators, due to failure of the temperature sensor system. Draeger have now established that a similar sensor system is used in the 600W Radiant Heater Units, which therefore present a similar risk.
Action	:	Do not use skin temperature probes which connect directly to the Draeger 600W Radiant Heater Units. Only use these Radiant Heater Units in manual temperature control mode. Use independent temperature monitoring.

HAZARD

1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This notice should be brought to the immediate attention of all who need to know, or be aware of it including those listed below, in accordance with local procedures, and immediate action should be taken as detailed aside:

- Liaison Officers (for onward distribution)
- Medical Directors
- Nurse Executive Directors
- Directors of Midwifery
- Special Care Baby Units
- Maternity Wards
- Ambulance Service
- Paediatric Units

Boards/Trusts should ensure that if appropriate, this information is passed to **ALL** persons having the responsibility for premises registered under "THE REGISTERED HOMES (NI) ORDER 1992".



An Executive Agency of the Department of Health and Social Services and Public Safety

2. IMMEDIATE ACTION

Do not use skin temperature probes which connect directly to the Draeger 600W Radiant Heater Units. Only use these Radiant Heater Units in manual temperature control mode. Use independent temperature monitoring.

3. BACKGROUND

A disposable skin temperature probe on a Draeger 8000 incubator became very hot, causing a serious burn to a neonate. This was due to excessive current flowing through the temperature probe.

Draeger have established that the skin temperature sensor circuit lacked a means to prevent excessive current from flowing through the temperature probe when an operational amplifier failed, contrary to IEC 60601-1 which requires that a single fault condition shall not cause a hazard.

At the time of this incident Draeger Medical stated that this temperature sensor system was only found in the Draeger 8000 Incubator. Draeger have now established that a similar skin temperature sensor circuit is also used in the 600W Radiant Heater Units. Draeger intend to modify the sensor circuit in all affected models and will provide further information on the upgrading of all devices in the field in due course (See Annex A).

Babytherm 8004, 8010 and 8000 WB (Cositherm) are not affected by this action.

4. ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr Doug Sims
Quality Manager
Draeger Medical
The Willows
Mark Road
Hemel Hempstead
Hertfordshire HP2 7BW
Tel: 01442 213542
Fax: 01442 240327

Enquiries regarding this notice should be addressed as follows:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)
Health Estates
Estate Policy
Stoney Road
Dundonald
Belfast BT16 1US *marked for the attention of Mr Brian Godfrey*

Tel: 028 90 523714
Fax: 028 90 523900
Email: brian.godfrey@dhsspsni.gov.uk

Yours faithfully

BRIAN GODFREY
Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant and other medical and non medical equipment and supplies.

