

SN (NI) 2002/11

DATE: 14 March 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

EASTLEIGH APNOEA RESPIRATION MONITOR RE200

MANUFACTURER/SUPPLIER

Ferraris Medical Limited, previously NH Eastwood and Son Limited

PROBLEM

An apnoea monitor failed to detect that an incubated 1kg premature baby had stopped breathing, due to the sensor pad being placed on top of the mattress.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Neonatal Intensive Care Units
- Special Care Baby Units
- Maternity Wards
- Labour/Delivery Suites
- General Medical Practitioners
- Practice Nurses
- Specialist Children's Nurses
- Midwives and Community Midwives
- Health Visitors
- Private Clinics

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

ACTION

All users should ensure that: -

- The sensor pad is placed **UNDER** the mattress beneath the baby.
- If the breath light on the monitor does not indicate the baby's breathing with the sensor under the mattress, the monitor is **NOT** to be used.
- The monitor is **NOT** to be used on babies weighing less than 1kg.

BACKGROUND

The RE200 apnoea/respiration monitor is an electronic monitoring system that detects breathing movement. It alarms after a delay following cessation of these movements. The flat pressure sensitive pad detects respiration movements through the mattress (20 to 50 mm thick).

The Medical Devices Agency (MDA) was informed of an incident where an RE200 apnoea monitor failed to detect that a 1kg premature baby, being nursed in an incubator, had stopped breathing. The baby's heart rate had dropped to 60 beats per minute (bpm) at the time of discovery.

The sensor had been placed on top of the mattress under a sheepskin. In this position the sensor is less reliable being much more sensitive and likely to be affected by other non-breathing vibration.

SAFETY

NOTICE

Although the cause of the 'failure to alarm' could not be determined, a possible explanation is that the sensor may have responded to the baby's low heartbeat or other movement. Breathing had stopped and the heart rate had dropped from 160 bpm to a rate similar to normal breathing. Without the attenuation of the mattress it is possible that the sensor detected the heartbeat as breathing movement, which delayed the onset of the alarm.

As a result of this incident the manufacturer has issued revised user instructions. These instructions include the following **Important Information**:

PLEASE READ THIS INSTRUCTION LEAFLET CAREFULLY BEFORE USING THE EASTLEIGH RE200/R200C APNOEA MONITORS.

1. The monitor is for use by or under the guidance of medical and nursing professionals. When the RE200 monitor is being used in the home, it should only be with the direction and knowledge of medical personnel.
2. Care should be taken to ensure that external vibration or movement does not affect the monitor and cause spurious signals delaying the alarm. This may be achieved by ensuring that the alarm DOES sound, after installation, but prior to the baby being placed in the cot/incubator.
3. The sensor pad must be placed UNDER the mattress beneath the baby. If sensing is unachievable through mattress DO NOT USE the monitor.
4. The monitor does not prevent cessation of breathing – nor does it provide any stimulus to restore breathing, other than an audible warning alarm. Also note that this monitor is NOT recommended for use on babies less than 1 kg in weight.
5. Contact your distributor or manufacturers, Ferraris Medical Ltd. immediately, if there is any cause for concern in the operation of the monitor.
6. The Monitor is NOT suitable for cars or other transport where there is movement.

ENQUIRIES

Enquires to the manufacturer should be addressed to:

Mr Stavros Vassos, Ferraris Medical Limited, 4 Harforde Court, John Tate Road, Hertford SG13 7NW.

Tel: 01992 526 312

Fax: 01992 526 320

Enquires to the NIAIC should quote the reference number SN(NI) 2002/11 and be addressed to:

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

Tel: 02890 523714

Fax: 02890 523900

Email: brian.godfrey@dhsspsni.gov.uk

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) 2002/01. 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
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



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