

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/30

Issued: 21 October 2003

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Apnoea respiration monitor – Eastleigh RE200/RE200C	▶ ①
<b>Problem:</b> Monitor failed to alarm.	▶ ②
<b>Action by:</b> Clinical staff in neonatal intensive care units, special care baby units, maternity units and delivery suites. Staff responsible for medical devices loaned to parents for home use. Technical staff responsible for medical maintenance and medical device libraries.	▶ ③
<b>Action:</b> All units fitted with an alarm delay switch on the rear panel should be removed from use and returned to Ferraris Medical Limited for rework. If no alternative is immediately available, users should be instructed on safe use of existing monitor, pending replacement.	▶ 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 <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> Feedback is necessary for this Alert. Please see specific feedback requirements in section 7.	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Apnoea Respiration Monitor – Model Eastleigh RE200/RE200C, manufactured by Ferraris Medical Limited, previously NH Eastwood and Son Limited. The device may carry either manufacturer's name.

## 2. PROBLEM:

The manufacturer informed the Medicines and Healthcare products Regulatory Agency (MHRA) that an RE200 apnoea monitor failed to alarm due to the alarm delay switch on the rear of the device having been accidentally set in between two of the delay time settings (10, 15 or 20 seconds).

This should have caused a continuous alarm, but due to the wrong switch type being used, the apnoea alarm was disabled.

Only devices with the alarm delay switch on the rear panel are affected. The serial number ranges of the 700 affected units are listed below.

### Background

In 1991 a variant of the RE200 was introduced with an alarm delay switch that allowed the user to adjust the time taken to alarm once breathing movement ceased. It has recently become apparent that the wrong type of switch has been fitted to some units. It is not known how many of the units are affected, therefore all are being recalled. The monitors will be reworked to provide 10 and 20 second alarm delay settings with the central switch setting becoming a sounder test position.

These monitors are used to monitor the breathing movement of premature babies and those at known increased risk of apnoea. They may be used in Neonatal Intensive Care Units, Special Care Baby Units, Maternity Units and Delivery Suites. They may also be loaned to parents for use at home. Some charities also provide these monitors for use at home.

#### Serial numbers of RE200/RE200C Devices affected

1865	2393 - 2397	2782 - 2785	3082 - 3086	3395 - 3403	3614 - 3623
1889 - 1893	2403 - 2412	2623 - 2824	3106 - 3110	3405 - 3410	3644 - 3658
1974 - 1983	2428 - 2432	2833 - 2841	3131 - 3139	3420 - 3424	3723 - 3724
2034 - 2049	2463 - 2467	2902 - 2906	3155 - 3159	3435 - 3439	3735 - 3759
2103 - 2107	2503 - 2507	2927 - 2931	3155 - 3159	3445 - 3449	3780 - 3789
2154 - 2158	2544	2942 - 2951	3190 - 3209	3465 - 3474	3840 - 3849
2193 - 2202	2548 - 2551	2962 - 2966	3230 - 3239	3485 - 3489	3891 - 3899
2234 - 2238	2553	2982 - 2986	3260 - 3264	3515 - 3519	3920 - 3929
2266 - 2275	2584 - 2593	3012 - 3016	3290 - 3295	3528 - 3542	3955 - 3964
2296 - 2306	2643 - 2647	3042 - 3046	3333 - 3354	3553 - 3567	3995 - 4004
2368 - 2372	2698 - 2705	3067 - 3071	3375 - 3379	3593 - 3567	4045 - 4304

## 3. ACTION BY:

Clinical staff in neonatal intensive care, maternity units and delivery suites.

Staff responsible for equipment loaned to parents for home use.

Technical staff responsible for equipment maintenance and equipment libraries.

## 4. ACTION:

Clinical users are requested to withdraw from use devices that have the alarm delay switch on the rear panel and return them to Ferraris Medical Ltd for rework as soon as possible. If no alternative is immediately available, users should ensure the switch is set correctly and check, at least daily, that the apnoea alarm operates when the baby is lifted away from the mattress. It may be necessary to substitute the baby for an object of similar weight, e.g. telephone directory. (See Confidence Check in the User Manual).

Staff responsible for equipment loaned to parents for use at home should ensure that these units are replaced as soon as possible with an alternative. When replacements are not immediately available, parents should be instructed either by hospital or community staff on the correct use of the switch and daily check of the alarm.

Technical staff responsible for equipment maintenance and equipment libraries should check all RE200s and ensure that those fitted with the alarm delay switch are removed from use and returned for modification.

Community staff should also be aware of this notice in order to advise parents who have one of these units.

The rework will be undertaken free of charge by Ferraris Medical. Alternatively, modification kits are available for technical staff who wish to carry out the rework themselves.

## 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
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units and outpatients
- Neonatal Intensive Care Units
- Paediatricians
- Childrens Nurses
- Midwives
- Practice Nurses
- Directors of Public Health
- Community Care Staff
- District Nurses
- Health Visitors
- Independent Health Care Clinics
- Community Midwives
- Paediatric Community Nurses

## 6. CONTACTS:

Devices for rework and any enquiries 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 NIAIC should quote reference number MDEA(NI)2003/30 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](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

NIAIC Liaison Officers are requested to confirm by **29 October 2003** to e-mail address [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk) using reference MDEA(NI)2003-30 that:

1. **Staff identified under “Action By” have received this Alert to enable them to take appropriate action;**
2. **Appropriate action has been taken as outlined in section 4 of this Alert.**

A NIL response is required should the subject of this Alert not apply to your organisation.



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*