

SN (NI) 2002/16
DATE: 8 April 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:

**PATIENT MONITORS: SPACELABS MEDICAL
ECG PRODUCTS**

Model Numbers: 90342, 90344, 90346, 90348, 90470, 90478, 90496.

MANUFACTURER/SUPPLIER

Spacelabs Medical Ltd.

PROBLEM

An anomaly in the ECG software fails to detect low heart rates in the range 12 to 15 bpm when specific conditions occur together.

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
- Ambulance Staff and Paramedics
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Resuscitation Officers
- Resuscitation Training Officers
- 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

1. Identify all units with the above model numbers.
2. Ensure that the software is upgraded in accordance with the Spacelabs Medical Device Correction Action Notice shown in the appendix:
 - the upgrade can be carried out locally by competent personnel following instructions obtained from Spacelabs Medical (except for Model 90496)
 - users who do not wish to carry out the upgrade themselves, or have a Model 90496 unit, should contact Spacelabs Medical who will arrange for on-site installation of the upgrade by their local customer service representative.

Until units are upgraded, users must maintain awareness of the anomaly in the existing software version and exercise vigilance when monitoring patients with low heart rates. In circumstances where there is considered to be a risk of sudden drop in heart rate, an alternative monitoring device should be used.

SAFETY

NOTICE

BACKGROUND

Spacelabs Medical is carrying out a programme of corrective action to upgrade the ECG software in specific models of ECG products. Accordingly, the company has issued the 'Medical Device Corrective Action Notice' appended to this Notice (see Appendix).

Spacelabs Medical has determined from customer reports and testing that there is an anomaly in the existing ECG software which fails to detect low heart rates in the range of 12 to 15 bpm. For this to happen, it appears that three conditions must occur together:

1. the heart rate must drop suddenly within a one beat interval;
2. the heart rate must drop into the range of 12 to 15 bpm;
3. the heart rate must stay within the range of 12 to 15 bpm.

When these three conditions occur together, the software will not update, detect the change, or generate a low alarm.

Any heart rate outside this range will generate an appropriate alarm.

ENQUIRIES

Spacelabs Medical has requested that enquiries to the manufacturer should be addressed to:

Monitoring Technical Support
Spacelabs Medical
15220 N.E. 40th Street
P.O. Box 97013
Redmond
Washington 98073-9713
USA

Direct Tel: 00 1 425 882 3700 (*the telephone number stated on the appended Spacelabs Notice for customers outside the United States is incorrect*).

The UK representative is:

John Oxley
Space Labs Medical Ltd
Indigo Building
Unit 9 Mulberry Business Park
Fishponds Road
Wokingham
Berkshire
RG41 2GY

Tel: 0118 977 3100
Fax: 0118 979 8200

Enquires to the NIAIC should quote the reference number SN(NI) 2002/16 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. Serbhístí Sóisialta agus Sábháilteacht Phoiblí*



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