

SN (NI) 2002/24

DATE: 20 June 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:

**VICKERS 165 RESUSCITAIRE (INTEGRATED
RADIANT WARMER AND RESUSCITATION UNIT
DESIGNED FOR USE IN DELIVERY SUITES AND
SPECIAL CARE BABY UNITS): VARIOUS AGE-
RELATED SAFETY ISSUES**

MANUFACTURER/SUPPLIER

Vickers Medical Ltd

PROBLEM

Servicing agents have reported age-related safety issues including cracks appearing in the aluminium pressure regulators (part number VS 165-29-006), problems fitting modern oxygen cylinders and displaced index pins at gas cylinder connection points.

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
- Estates Managers
- Medical Directors
- Nurse Directors
- Medical & Nursing Staff
- Special Care Baby Units
- Maternity Wards
- Paediatric Units

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

- Users should ensure that their servicing agents are aware of the potential problems outlined above.
- A protocol for inspection of these parts should be included in the regular servicing schedule and the service manual amended accordingly.
- If users wish to retain these devices for long-term use, then a full risk-assessment should be undertaken.

SAFETY

NOTICE

BACKGROUND

In 1997 Vickers Medical Ltd was broken up and some of its subsidiary companies were sold as separate entities. The rights and obligations relating to products manufactured under Vickers' own name were not sold; therefore these rights and obligations ceased to exist. However Hill-Rom and other third party service agents have been providing service support for Vickers Resuscitaires since 1997.

Although there have been no reports of patient injury from age-related failures, Hill-Rom have now identified some age-related safety issues and have announced that they will withdraw support for these devices at the end of January 2003.

As the original manufacturer has ceased trading there is no manufacturer's post-market surveillance, therefore the ongoing safety and performance of these devices is the responsibility of the user's organisation.

Advice on third party servicing and repairs can be found in NIAIC DB 2000/02 (NI), Medical Devices and Equipment Management: Repair and Maintenance Provision. This is available from our website at www.dhsspsni.gov.uk/niaic.

ENQUIRIES

Enquires regarding spare parts or servicing should be referred to the servicing agents of these devices for your organisation.

Enquires to the NIAIC should quote the reference number SN(NI) 2002/24 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

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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