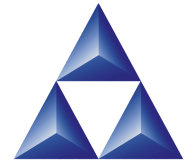


SN (NI) 2002/19

DATE: 17 May 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:

**EXTERNAL PACEMAKERS & TEMPORARY
CARDIAC PACING LEADS WITH SHROUDED
CONNECTOR PINS: CONNECTION PROBLEMS**

MANUFACTURER/SUPPLIER

Various

PROBLEM

- Incompatibility between some external pacemakers (particularly older units) and temporary cardiac pacing leads with shrouded connector pins.
- Potential for inadequate electrical connection between external pacemakers and temporary cardiac pacing leads (and patient extension cables) with shrouded connector pins when adaptors are used to facilitate connection.

This Safety Notice advises the replacement of older external pacemakers that are incompatible with temporary pacing leads having shrouded connector pins. It is a follow-up to SN(NI)2001/07 (8 February 2001) - see background.

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 | • Intensive Care Units |
| • Risk Managers | • Accident & Emergency Departments |
| • Health & Safety Officers/Advisors | • Theatre Managers |
| • Medical Directors | • Catheter Laboratory Managers |
| • Nurse Directors | • Cardiologists |
| • Cardiac/Coronary Care Units | • Cardiac Surgeons |

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

The following actions should be taken:

1. As soon as reasonably possible, replace all external pacemakers that are not fully compatible with external pacing leads having shrouded connector pins.
2. Ensure that adaptors and extension leads used with pacing leads that have shrouded connector pins are secure.
3. Take appropriate care when moving patients with external pacing systems, to avoid additional tension being placed on temporary pacing leads/extension cables/lead adaptors.
4. Check all reusable adaptors periodically for signs of wear, pin distortion or contact loosening. Discard and destroy suspect adaptors.
5. Do not reuse adaptors and extension cables designated by the manufacturer as "SINGLE USE".

When introducing the shrouded pin connector systems ensure that staff are conversant with the manufacturers' instructions for use.

SAFETY

NOTICE

BACKGROUND

In NIAIC Safety Notice SN(NI)2001/07, 8February 2001, NIAIC advised that manufacturers had begun to supply temporary cardiac pacing leads with shrouded connector pins. These leads could not be connected directly to many external pacemakers without the use of adaptors. Additionally, MDA advised that the security of adaptor connections should be checked and verified during use, especially when patients were being moved.

Prior to the issue of SN(NI)2001/07, NIAIC had been informed by the Medical Devices Agency (MDA) that they had received a small number of reports of connection integrity problems. Subsequent to the issuing of this safety notice MDA has continued to monitor connection integrity problems and has now received a total of 19 reports of incidents where connections have failed during the use of adaptors. Cardiac pacing either intermittently or completely failed where:

- the use of shrouded connector pins and adaptors resulted in connections separating (through accidental “tugging” or “snagging” of the pacing lead);
- bending and eventual loosening of the adaptor pin within the external pacemaker connector socket resulted in loss of external pacing support.

Having reviewed the risk of patient disconnection when adaptors are used with pacing leads, MDA advises NIAIC that it is now appropriate for hospitals to **replace all older external pacemakers with newer units which are directly compatible with pacing leads having shrouded connector pins.**

ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2002/19 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

*Health 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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