

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:
**DAMAGE TO BATTERY TERMINAL CONNECTORS
IN EXTERNAL PACEMAKERS**

MANUFACTURER/SUPPLIER

Various

PROBLEM

Intermittent operation and cessation of pacing output due to inadequate battery connections in external pacemakers.

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
- Medical Directors
- Nurse Directors
- Supplies Staff
- Trauma/Accident & Emergency Units
- Surgical Units
- Operating Theatre Managers & Staff
- Coronary Care
- Cardiologists
- Cardiac Surgeons
- Intensive Care
- Biomedical Engineering
- Private Clinics
- Catheter Laboratory Managers

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. Check the battery power level (using the internal battery/power indicator) prior to each use of external pacemakers.
2. When inserting or replacing batteries in external pacemakers ensure that:
 - a) the type of battery used and the frequency of the battery replacement are in accordance with the manufacturer's instructions, and;
 - b) battery terminal connectors are:
 - not misshapen or deformed
 - secure and have an appropriate retention force
 - free from corrosion or debris.
3. Ensure that any padding material provided by external pacemaker manufacturers (to reduce battery movement and enhance battery contact) is inserted in the battery compartment in accordance with the manufacturer's instructions.
4. Ensure that periodic checks of battery terminal connectors on external pacemakers are carried out by appropriately qualified personnel in accordance with the manufacturer's instructions.
5. Ensure that all external pacemakers with suspect battery terminal connectors are inspected and/or repaired in accordance with local procedures.

SAFETY

NOTICE

BACKGROUND

The Medical Devices Agency has informed us that they have become aware of a number of incidents involving loosening of the battery terminal connectors of external pacemakers. While patient harm has not been reported, the potential exists for patient death or serious deterioration of health. The specific cause of loosening has not been determined, but may result from:

- weakening of the retention force of the battery connector over time, due to terminal deformation after repeated insertion and removal of batteries;
- attempts to insert incorrectly orientated batteries, causing deformation of battery terminals;
- replacement of batteries by inappropriate personnel;
- slight variations in battery terminal size or use of incorrect type of batteries;
- corrosion of the electrical connectors or the presence of debris.

Since the continued function of external pacemakers is critical to patient support, all battery terminal connectors should be checked for appropriate security and absence of corrosion or foreign material each time batteries are inserted.

ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2002/18 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
Aisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



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