

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/45

Issued: 24<sup>th</sup> May 2007

For:

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



**HEALTH ESTATES**

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	Section
<b>Medical Device/Equipment:</b> External pacemakers and temporary cardiac pacing leads.	▶ ①
<b>Problem:</b> Potential for loss of pacing due to accidental disconnection of temporary pacing leads and lead adaptors.	▶ ②
<b>Action by:</b> Cardiologists, cardiothoracic surgeons, cardiac physiologists and biomedical engineering departments.	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>Ensure that the connectors on temporary cardiac pacing leads and external pacemaker are compatible. Do not use lead adaptors.</li> <li>Under exceptional circumstances where the use of an adaptor is unavoidable, use only an adaptor that incorporates a retention mechanism, which prevents accidental disconnection.</li> <li>Note that the recommendations in this MDEA supersede the advice given in Safety Notice SN(NI)2002(019) issued in May 2002.</li> </ul>	▶ 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	▶ ⑤
<b>Contacts</b> Details of NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None required.	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

External pacemakers and temporary cardiac pacing leads.

## 2. PROBLEM:

This alert supersedes Safety Notice SN(NI)2002(19) issued in May 2002, which outlined the risk to patients when inadequate connectors and adaptors were used to connect temporary cardiac pacing leads to external pacemakers.

Following a further report of patient asystole during temporary pacing, an MHRA investigation determined the cause to be insecure connections. Lead adaptors without a retention mechanism had been used to connect a pacing lead to an external pacemaker and the lead had become disconnected.

The MHRA is concerned that some insecure adaptor systems are still being used to connect temporary pacing leads to external pacemakers.

Direct connection (ie without an adaptor) of a temporary cardiac pacing lead to external pacemaker or patient cable will reduce the potential for disconnection and will increase the compatibility of the electrical connection.

Shrouded connectors were introduced following a non-UK incident in which an exposed connector pin was accidentally connected to a mains electrical supply. This resulted in amendments to the product safety standards governing external pacemakers and leads (IEC (60)601-1 and BS EN 60601-2-31). Subsequently external pacing leads have been supplied with shrouded connector pins.

Before purchasing a new external pacemaker, ensure that it is compatible with the types of temporary cardiac pacing leads that are used in your department.

## 3. ACTION BY:

Cardiologists, cardiothoracic surgeons, cardiac physiologists and biomedical engineering departments.

## 4. ACTION:

- Ensure that the connectors on temporary cardiac pacing leads and external pacemaker are compatible. Do not use lead adaptors.
- Under exceptional circumstances where the use of an adaptor is unavoidable, use only an adaptor that incorporates a retention mechanism, which prevents accidental disconnection.
- Note that the recommendations in this MDA supersede the advice given in Safety Notice SN2002(015) issued in May 2002.

## 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:

- A&E consultants
- Anaesthesia, directors of
- Biomedical engineering staff
- Cardiologists
- Cardiothoracic surgeons
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- EBME departments
- Equipment stores
- Health and safety managers
- Intensive care medical staff
- Intensive care nursing staff (adult and paediatrics)
- Medical directors
- Nursing executive directors
- Paediatric intensive care units
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

## 6. CONTACTS:

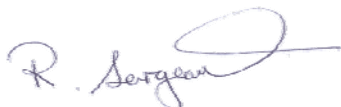
Enquires to NIAIC should quote reference number MDEA(NI)2007/45 and be addressed to:

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:

None required



Robert Sergeant  
NIAIC Operational 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 MDEA(NI)2006/01. 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*