

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/53

Issued: 8 September 2006



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	

	Section
<p>Medical Device/Equipment: External/temporary cardiac pacemaker: APC Medical Ltd Model 4170.</p>	▶ ①
<p>Problem: Not all model 4170 external pacemakers have been returned to the manufacturer for modification to prevent unintentional shutdown.</p>	▶ ②
<p>Action by: EBME (electro-biomedical engineering) departments, cardiologists, cardiothoracic surgeons and cardiac physiologists.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Note that the recommendations in this Update supersede the advice given in MDE(NI)2004/44 issued on 11 August 2004. Identify and withdraw from use any APC Medical 4170 pacemakers that have not yet been modified and return to the manufacturer for upgrade (including instruction manuals and APC model 5265 patient cables). Use upgraded APC Medical 4170 pacemakers in accordance with the recommendations documented in the manufacturer's instructions for use as follows: 'continuous ECG and blood pressure monitoring is necessary prior to pacing, during any pacing procedure, and in the immediate post-operative phase'. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None Required</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The APC Medical model 4170 (also referred to as the Bedside™) single chamber external/temporary cardiac pacemaker is designed in the USA by Pace Medical Inc., produced in the UK by APC Medical Ltd and supplied to UK hospitals by APC Cardiovascular.

2. PROBLEM:

This alert updates Medical Device Alert MDEA(NI)2004/44 issued in August 2004 which advised of the recall of APC Medical model 4170 external pacemakers together with APC model 5265 patient cables and instruction manuals for modification (free of charge). This action followed an investigation of reports into unintentional shutdown.

A recent reconciliation audit conducted by APC Medical indicates that 22 pacemakers were not returned for modification. Without the manufacturer's recommended modification, these 22 external pacemakers remain at risk of unintentional shutdown.

The reconciliation audit showed that units with the following serial numbers remain outstanding:

015, 025, 041, 051, 052, 053, 054, 055, 146, 204, 256, 295, 299, 301, 313, 323, 368, 434, 574, 575, 593 and 601

The original cause of unintentional shutdown could neither be identified nor characterised by the manufacturer. However, modifications were undertaken by the manufacturer following a review of the design and investigation into possible causes of shutdown.

Since the introduction of the design modification, APC Medical and MHRA have received no further reports of unintentional shutdown for the APC Medical model 4170 Bedside™ external pacemaker.

Clinicians are reminded of the recommendations documented in the instructions for use, particularly that: 'continuous ECG and blood pressure monitoring is necessary prior to pacing, during any pacing procedure, and in the immediate post-operative phase.' These recommendations are considered to be good practice for all external pacemakers.

3. ACTION BY:

EBME (electro-biomedical engineering) departments, cardiologists, cardiothoracic surgeons and cardiac physiologists.

4. ACTION:

- Note that the recommendations in this Update supersede the advice given in MDEA(NI)2004/44 issued on 11 August 2004.
- Identify and withdraw from use any APC Medical 4170 pacemakers that have not yet been modified and return to the manufacturer for upgrade (including instruction manuals and APC model 5265 patient cables).
- Use upgraded APC Medical 4170 pacemakers in accordance with the recommendations documented in the manufacturer's instructions for use as follows: 'continuous ECG and blood pressure monitoring is necessary prior to pacing, during any pacing procedure, and in the immediate post-operative phase'.

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:

- Risk Managers
- Clinical Governance Leads
- Medical Directors
- Adult and Paediatric Intensive Care Units
- Cardiothoracic Surgeons
- Consultant Cardiologists
- Accident and Emergency Units
- Nurse Directors
- Medical, Nursing and Care Staff
- All Wards
- Ambulance Staff and Paramedics
- Coronary Care Units
- Directors of Anaesthetics
- Theatre managers
- Practice Nurses
- Treatment Room Nurses
- Independent Health and Social Care Providers – Private Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Gerry Burne
APC Medical Ltd
68 Tewin Road
Haslemere Industrial Estate
Welwyn Garden City
AL7 1BD

Tel: 01707 327 641
Fax: 01707 327 117
E-mail: gerryburne@apcmedical.com

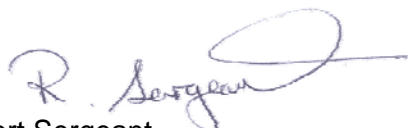
Enquires to NIAIC should quote reference number MDEA(NI)2006/53 and be addressed to:

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

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

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety