

Medical Device/Equipment ALERT

Ref.

MDEA(NI)2007/107

Issued: 7 December 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: External temporary cardiac pacemaker. Bedside model 4170 serial numbers: 1 – 998. Manufactured by APC Medical Ltd.</p>	▶ ①
<p>Problem: Patients may receive inappropriate fast rate pacing when this temporary pacemaker is being switched off.</p>	▶ ②
<p>Action by: Electro-biomedical engineering (EBME) departments. All clinical staff managing patients supported by affected devices.</p>	▶ ③
<p>.Action:</p> <ul style="list-style-type: none"> • Check that the rapid pace switch is turned off before shutting down the device. • Identify all pacemakers with serial numbers 1 – 998 and return to APC Medical Ltd for a software upgrade. • Contact APC Medical Ltd customer service department for information on how to schedule the return of your device(s) for upgrade. 	▶ 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 For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturers and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The APC Bedside model 4170 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:

The APC Bedside model 4170 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.

3. ACTION BY:

Electro-biomedical engineering (EBME) departments.
All clinical staff managing patients supported by affected devices.

4. ACTION:

- Check that the rapid pace switch is turned off before shutting down the device.
- Identify all pacemakers with serial numbers 1 – 998 and return to APC Medical Ltd for a software upgrade.
- Contact APC Medical Ltd customer service department for information on how to schedule the return of your device(s) for upgrade.

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 departments
- Adult & paediatric intensive care units
- All wards
- Cardiothoracic surgeons
- Clinical governance leads
- Consultant cardiologists
- Coronary care units
- Directors of anaesthetics
- Directors of nursing
- Directors of paediatric medicine
- EBME / clinical engineering departments
- Health & safety officers
- Medical directors
- Risk managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Steven Hanson
APC Medical Ltd
68 Tewin Road
South Mundells Industrial Estate
Welwyn Garden City
Herts
AL7 1BD

Tel: 01707 327 641
Fax: 01707 333 117

E-mail: Pacemedicalpres@aol.com

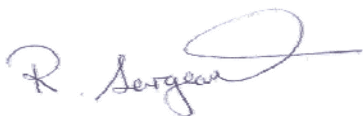
Enquiries to NIAIC should quote reference number MDEA(NI)2007/107 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 10th Dec 2007
Deadline (action underway)	: 17th Dec 2007
Deadline (action complete)	: 06th June 2008



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