

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/44

Update of MDEA(NI)2004/17

Issued: 11 August 2004



NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION REQUEST	✓

	Section		
Medical Device/Equipment: APC Medical Ltd external/temporary cardiac pacemaker (model 4170)	▶ ①		
Problem: Sudden loss of pacing without warning.	▶ ②		
Action by: Cardiothoracic Surgeons, Consultant Cardiologists, EBME (electro-biomedical engineering) departments and all other clinical staff managing patients supported by APC Medical model 4170 external pacemakers.	▶ ③		
Action: <ul style="list-style-type: none"> Note that the recommendations in this Update supersede the advice given in MDEA(NI)2004/17 issued on 7 April 2004. Note recall for modification of pacemakers and their instruction manuals, together with APC patient cables model 5265. On receipt of the modified pacemaker, use only in conjunction with an independent patient-monitoring system that has an appropriate alarm function. If subsequent 'unintentional shutdown' of the modified device occurs, turn on the pacemaker to restore pacing immediately, and then substitute with an alternative device. 	▶ ④		
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers </td> <td style="width: 50%; border: none;"> General Medical Practitioners (for information) </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners (for information)	▶ ⑤
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Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects	▶ ⑥		
Feedback Requirements to NIAIC Report all occurrences of device failure to NIAIC and APC Medical.	▶ ⑦		

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

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 MDEA/2004/17 issued in April 2004, which advised of sudden loss of pacing without warning (also referred to as 'unintentional shutdown'). That alert advised of the withdrawal from use of all APC Medical model 4170 external pacemakers unless no alternative was available. If use continued, patients were to be regularly monitored as well as independently monitored with a system that had an appropriate alarm function. This advice remains for unmodified pacemakers.

Following a review of the design and investigation into possible causes of shutdown, Pace Medical Inc. has developed a modification and is now recalling all APC Medical model 4170 devices and patient cable model 5265 for upgrading. The Medicines and Healthcare products Regulatory Agency (MHRA) has been advised that this modification will be free of charge. The recall has now started and will proceed in a phased manner, with hospitals being contacted direct by APC Medical to arrange return.

The manufacturer has been unable to reproduce the 'unintentional shutdown' failures reported in clinical practice through either in-house testing or independent laboratory testing. Therefore the root cause of failure has still not been established. However, it is thought that the shutdowns could have been the result of electromagnetic interference from a variety of unidentified sources (see APC Medical letter attached). The modifications proposed by the manufacturer are believed to greatly reduce susceptibility to shutdown through electromagnetic interference, although this cannot be guaranteed. Therefore the previous advice to use an independent patient monitoring system that has an appropriate alarm function remains.

In order to establish whether the modifications have been effective, it is important that any subsequent instances of unintentional shutdown are reported to both the manufacturer and NIIAC. Further advice will be issued as appropriate.

3. ACTION BY:

Cardiothoracic Surgeons, Consultant Cardiologists, EBME (electro-biomedical engineering) departments and all other clinical staff managing patients supported by APC Medical model 4170 external pacemakers.

4. ACTION:

- Note that the recommendations in this Update supersede the advice given in MDEA/2004/17 issued on 7 April 2004.
- Note recall for modification of pacemakers and their instruction manuals, together with APC patient cables model 5265.
- On receipt of the modified pacemaker, use only in conjunction with an independent patient-monitoring system that has an appropriate alarm function.
- If subsequent 'unintentional shutdown' of the modified device occurs, turn on the pacemaker to restore pacing immediately, and then substitute with an alternative device.

Additionally, if subsequent 'unintentional shutdown' occurs with a modified device:

- provide alternative support for the patient
- remove the defective pacemaker from service and return it to the manufacturer
- note any electrical equipment in use within the vicinity of the device at the time of shutdown (including communication devices and other non-medical appliances). Report this and any other relevant information (for example ECG strip) to NIAIC and APC Medical

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 HSS Board R&I Units

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 333 117

E-mail: gerryburne@apcmedical.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/44 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:

Report all occurrences of device failure to NIAIC and APC Medical.



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 MDEA(NI)2004/01. 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

APC Medical Ltd.

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TO: Commission for the Social Care Inspection
NHS Trusts (England)
Primary Care Trusts (England)
FROM: APC Medical Ltd.
DATE: August 2, 2004
SUBJECT: APC Medical Model 4170 Temporary Pacemaker Recall Notice

APC Medical Ltd., a wholly-owned subsidiary of Pace Medical, Inc. hereby informs you of the Recall of its Model 4170 Temporary Cardiac Pacemakers, serial numbers A001 – A024, 025 – 246, and 254 – 651. This Recall is being conducted to allow modification of devices through a “Change Protocol” to address the “unintentional” shutdown problem that has been experienced with some of these devices and to further enhance the pacemaker’s reliability and effectiveness.

The recall will be conducted in a phased manner, and you will be contacted again in the near future to confirm arrangements for return of your device(s) (including cable(s) and Instruction Manual) to APC Medical. We envisage that all pacemakers will be modified and returned by 31 December 2004. APC Medical Ltd. will do all possible to modify your pacemaker(s) in a timely manner and at no charge. When you receive your modified device, please re-acquaint yourself with the accompanying Instruction Manual.

APC Medical continues to recommend the use of an independent patient monitoring system with the Model 4170. This concurs with the current advice of the Medicines and Healthcare products Regulatory Agency (MHRA). In addition, careful observance of the “low battery” flashing red light is a MUST to avoid a shutdown due to battery depletion.

After approximately one year of extensive testing by not only Pace Medical, Inc. and APC Medical Ltd., but also independent testing laboratories, the Model 4170 pacemakers that were returned for a reported shutdown withstood any and all tests that they were exposed to. These tests included: Battery Life, Bench Testing (specifications) over a six-month period of continuous operation, Cell Phones, Conducted RFI, Defibrillation, EMI, ESD, ESIS, Magnetic Immunity, Microwave, Radiated RFI and Temperature Cycling. During EMI/RFI investigations, several suspect devices demonstrated power supply disruption at frequencies between 195MHz and 230MHz with electrical field strengths equal to or greater than 10 volts-per-meter. Follow-up testing, with patient cables incorporating ferrite cores, produced satisfactory results with electrical field strengths up to 30 volts-per-meter. We believe that the “Change Protocol” modifications, which address the ferrite core and the ON/OFF control logic, will eliminate any external electromagnetic interference signals from causing a shutdown condition.

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We trust that your confidence in the Model 4170 pacemaker's reliability and performance will be restored based on our extensive testing, positive findings, and the "Change Protocol" modifications to be performed. Also, the utilization of patient monitoring is standard clinical procedure for patients on temporary cardiac pacemakers and is recommended in our Model 4170 Instruction Manual. The loss of pacing (capture) could result from a number of conditions unrelated to the temporary pacemaker itself. In all reported cases of "unintentional" shutdown, where resetting of the Model 4170 has been performed, the results have been successful; and, the device has continued to pace the patient. Resetting simply involves pressing the green "on" switch on the front of the device.

Thank you for your patience and understanding during this period of extensive testing and evaluation. If you have any further questions regarding this recall, please contact APC Medical at 01707 327641.