

Medical Device/Equipment ALERT



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	

	Section
Medical Device/Equipment: External Pacemakers: Models - E4162, E4164, E4165 and E4166 (manufactured by APC Medical Ltd)	▶ ①
Problem: Increase in pacing rate by 20 pulses per minute (ppm) and change in pacing mode without user intervention, under certain circumstances.	▶ ②
Action by: <ul style="list-style-type: none"> All clinicians who perform external pacing. Risk managers. 	▶ ③
Action: <ul style="list-style-type: none"> Be aware that the above external pacemakers will revert to asynchronous mode pacing at a rate of approximately 20 ppm above the pre-set pacing rate, when either the battery voltage is low or electromagnetic interference is sensed. Ensure that the above devices are not used for patients where a sudden increase in paced rate of 20 ppm, or a change from demand to asynchronous mode pacing, could compromise patient health. Consider replacing the above pacemaker models (which were designed and manufactured over 20 years ago) as soon as practicable. When the above external pacemakers are used, ensure also that mobile communication devices are not used in the vicinity, especially during patient transfer. 	▶ ④
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	▶ ⑤
Contacts Details of supplier contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC None required.	▶ ⑦

1. DEVICE/EQUIPMENT:

External Pacemakers: Models - E4162, E4164, E4165 and E4166 (manufactured by APC Medical Ltd).

2. PROBLEM:

The APC Medical E4162, E4164, E4165 and E4166 external pacemaker models incorporate a design feature whereby the pacing rate will increase by approximately 20ppm, when either the battery voltage becomes low, or when electromagnetic interference is sensed. In both instances the mode of pacing changes from demand to asynchronous pacing. The original intention of this design feature was to avoid competitive pacing and pacing on the T-wave (initiating VT/VF), by increasing the set paced rate by approximately 20ppm.

Some patients however may not tolerate such a sudden increase in pacing rate, which may be detrimental to their condition (eg open-heart surgery, valve replacement, congestive heart failure, myocardial infarction, arrhythmia etc). NIAIC has been informed that MDA became aware of an incident involving one of the above devices, where the design feature initiated an unexpected change in pacing therapy, which could be inappropriate for certain patients. In the device concerned, failure analysis determined an internal component failure in the battery monitoring circuit. This resulted in inaccurate detection of the battery voltage, which was incorrectly sensed as low. This initiated asynchronous pacing and an increase in pacing rate by an additional 20 ppm. The clinician concerned was unaware of this device feature.

The APC Medical E4162, E4164, E4165 and E4166 pacemakers were designed and manufactured over 20 years ago and therefore clinicians may not be familiar with all the instructions for use, which may not be readily accessible. The design feature common to the above models is not widely used in modern external pacemakers, which incorporate different warning systems to alert users to low battery voltage or the presence of electromagnetic interference.

NIAIC has previously advised that some external pacemakers (including APC model E4162) are susceptible to interference from mobile communications systems^{1,2,3} and care should be taken to ensure that patients supported via external pacemakers are not exposed to electromagnetic fields from mobile phones, walkie-talkies etc. NIAIC has also previously advised that older external pacemaker models should be withdrawn and replaced.^{4,5} APC Medical advises that E4162, E4164, E4165 and E4166 models have a 15-year service life expectancy and recommends their replacement at the end of that period.

Consideration should therefore be given to replacing the above models as soon as practicable. Risk Managers are advised that the new Controls Assurance Standard - Medical Devices and Equipment Management - Criterion 17⁶ (to be issued in April/May 2003), addresses the replacement of medical devices in detail, extract as follows:

"For both hospital and community devices, a stage is reached at which replacement must be considered. If any of the following seven criteria apply, the device is no longer serviceable:

- ***Worn out beyond economic repair***
- ***Damaged beyond economic repair***
- ***Unreliable (check service history)***
- ***Clinically or technically obsolete***
- ***Spare parts no longer available***
- ***More cost-effective or clinically effective devices have become available***
- ***Unable to be cleaned effectively prior to disinfection and/or sterilisation"***

References:

1. DB 9702(NI) Electromagnetic compatibility of medical devices with mobile communications.
2. DB 9903(NI) Emergency service radios and mobile data terminals: compatibility problems with medical devices.
3. SN(NI)2001(10) Update on electromagnetic compatibility of medical devices with mobile communications: TETRA (terrestrial trunked radio system) and outside media broadcasts from hospital premises.
4. SAN 97/41 Model EV4542 and EV4543 external pacemakers.
5. SN(NI)2002/19 External pacemakers & temporary cardiac pacing leads with shrouded connector pins: connection problems.
6. Controls Assurance Standard - Medical Devices and Equipment Management.

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Ref. MDEA(NI)2003/01

3. ACTION BY:

As outlined on page 1

4. ACTION:

As outlined on page 1

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
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Nurse Directors
- All wards where external pacemakers are used
- Catheter Laboratory Managers
- Accident & Emergency Departments
- Coronary Care
- Adult & Paediatric Intensive Care Units
- Cardiologists
- Cardiac Surgeons
- Biomedical Engineering

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

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

Tel: 01707 327 641
Fax: 01707 333 117

Enquires to NIAIC should quote reference number MDEA(NI)2003/01 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney
Road, Dundonald, Belfast BT16 1US, Tel: 028 9052 3714, Fax: 028 9052 3900
Email: brian.godfrey@dhsspsni.gov.uk
www.dhsspsni.gov.uk/niaic

7. FEEDBACK:

None required



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) 2003/01. 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

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