

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/78

Issued: 4 November 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Medtronic LIFEPAK[®]12 defibrillator/monitor series: QUIK-COMBO[™] cables and standard (hard) paddles.</p>	▶ ①
<p>Problem: The pins in the connectors of cables and paddles can fatigue and break with potential for a loss of external pacing and defibrillation functions. Broken pins may remain in the female connector of the defibrillator preventing treatment and further use of the defibrillator.</p>	▶ ②
<p>Action by: All medical, nursing and paramedical staff, resuscitation training officers, community defibrillation officers and technical staff responsible for the use, maintenance and purchase of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Test, as a routine, all QUIK-COMBO[™] cables and hard paddles using the 'therapy cable defibrillation check' described on page 8-7 and the 'standard paddles user test' described on page 8-3 of the instructions for use. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p>GP's General Practices Hospices</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts, 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/niaic>

1. DEVICE/EQUIPMENT:

Medtronic LIFEPAK®12 defibrillator/monitor series: QUIK-COMBO™ cables (part number xxxxxxx-006 and earlier) and standard (hard) paddles(part number xxxxxxx-013 and earlier).

2. PROBLEM:

Connector pins in older versions of QUIK-COMBO™ cables (part number xxxxxxx-006 and earlier) and standard (hard) paddles (part number xxxxxxx-013 and earlier) are constructed from a different alloy from newer cables and paddles. Under stress these older pins may break. This occurs predominantly where defibrillators are used outside the hospital environment.

There is a risk that broken pins remain lodged in the female connector of the defibrillator, preventing insertion of another accessory. Where testing reveals pins have failed, the defibrillator and the cable or paddles should be quarantined.

MHRA is aware that Medtronic sent a customer letter regarding this problem dated September 2005. However, MHRA has received further adverse event reports from centres that had received this letter but not followed its instructions.

3. ACTION BY:

All medical, nursing and paramedical staff, resuscitation training officers, community defibrillation officers and technical staff responsible for the use, maintenance and purchase of these devices.

4. ACTION:

All users:

- Test, as a routine, all QUIK-COMBO™ cables and hard paddles using the 'therapy cable defibrillation check' described on page 8-7 and the 'standard paddles user test' described on page 8-3 of the instructions for use.
- Continue to use cables and paddles that pass testing.
- Quarantine the defibrillator and any cables or paddles which do not pass testing and contact the manufacturer for service immediately.

Where devices are used outside the hospital environment:

- Identify QUIK-COMBO™ cables (part number xxxxxxx-006 or earlier) and standard (hard) paddles (part number xxxxxxx-013 or earlier). The manufacturer will contact all out-of-hospital users to arrange replacements free of charge.

Regardless of the environment in which the defibrillator is used, routine testing is recommended and can identify broken cables and paddles.

All users of the LIFEPAK®12 should carry out all routine tests advised in the instructions for use (section 8: Maintaining the Equipment).

Medtronic recommends that all users perform the 'therapy cable defibrillation check' and the 'standard paddles user test' on a routine basis. Where devices are used outside the hospital environment users should perform these tests daily. This is more critical outside the hospital environment because of the higher incidence of pin failure.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- Community Defibrillation Officers
- Coronary Care Units
- Electrical & Biomedical Engineering Departments
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Intensive Care
- All Surgical Units
- All Wards & Departments which use LIFEPAK®12 Defibrillators
- High Dependency Unit
- Paramedics
- General Practices that use LIFEPAK®12 Defibrillators
- First Responder Officers

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

David G Dunham BSc, PhD
Regulatory Affairs Manager UK & Ireland
Medtronic Ltd
Suite One
Sherbourne House
Croxley Business Centre
Watford
WD18 8WW

Tel: 01923 212 213

E-mail: david.dunham@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/78 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

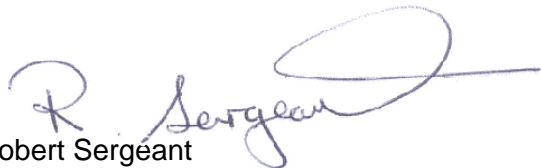
Tel: 028 9052 3868

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)2005/01. 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