

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/50

Issued: 5th June 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section								
<p>Medical Device/Equipment: External defibrillator batteries for the Lifepak 20 manufactured by Medtronic.</p>	▶ ①								
<p>Problem: Some Lifepak 20 defibrillators have been fitted with batteries that may have a reduced capacity. Some of the affected batteries have also been sold separately. When on battery power, a 'low battery: connect to AC power' message may be displayed. Connecting to an AC supply allows continued use of the device.</p>	▶ ②								
<p>Action by: Resuscitation officers, clinical staff and all those who maintain and service these devices.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> • Check Lifepak 20 defibrillators for batteries against the affected battery lot numbers (see page 2). • If the battery is from the affected lot and is within its two year life, contact Medtronic to have it replaced free of charge. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>General Dental Practitioners</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	General Dental Practitioners	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
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NIAIC Liaison Officers									
<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/niaic>

1. DEVICE/EQUIPMENT:

Batteries for Lifepak 20 defibrillators manufactured by Medtronic and are labelled with lot numbers.

Affected battery lot numbers:

Lot numbers less than 0539

Lot numbers 05265 and 05266

2. PROBLEM:

The reduced battery capacity is caused by a short circuit between cells. The affected batteries were manufactured prior to September 2005. The manufacturer recommends that batteries are replaced every two years of service. The two year service life starts from the date it is supplied to the customer.

3. ACTION BY:

Resuscitation officers, clinical staff and all those who maintain and service these devices.

4. ACTION:

- Check Lifepak 20 defibrillators for batteries against the affected battery lot numbers (see page 2).
- If the battery is from the affected lot and is within its two year life, contact Medtronic to have it replaced free of charge.
- If the battery is from the affected lot and is over its two year life, it should be replaced in line with the instructions for use.
- Ensure daily user tests and twice a year function tests are performed if you operate the defibrillator on battery power, as described in the operator's checklist in the operating instructions.
- If a low battery warning light illuminates while in use, connect to AC power supply.

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
- All clinical departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetists
- Biomedical engineering staff
- Cardiology, directors of
- Clinical governance leads
- Coronary care departments
- EBME departments
- Equipment stores
- Health and safety managers
- Intensive care units
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Paediatric intensive care units
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Theatre managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Equipment libraries and stores
- Minor injury units
- Practice managers

6. CONTACTS:

Enquires to manufacturer should be addressed to:

David Dunham BSc PhD
Medtronic Limited
Suite One, Sherbourne House
Croxley Business Park
Watford
WD18 8WW

Tel: 01923 212 213

Fax: 01923 241 004

E-mail: david.dunham@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/50 and be addressed to:

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

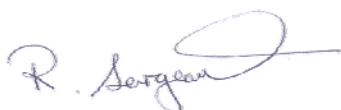
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

No 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