

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/085

Issued: 19th November 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: LIFEPAK CR Plus automatic external defibrillator manufactured by Medtronic Physio-Control. Various serial numbers.</p>	▶ ①								
<p>Problem: Failure to deliver therapy. A faulty internal cable in defibrillators manufactured between November 2006 and March 2008 means the defibrillator may fail to power on.</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"> Identify affected LIFEPAK CR Plus defibrillators (see appendix). Check the defibrillator regularly as detailed in the manufacturer's instructions and if it does not power on, contact the manufacturer immediately on 01923 234 512. If you have not already received the manufacturer's Field Safety Notice, contact Medtronic to inform them that you have an affected device. 	▶ 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
Chief Executive of each HSS Board	General Medical Practitioners								
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NIAIC Liaison Officers									
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; color: magenta;"> Acknowledge Receipt of Alert: 21st Nov 2008 </td> <td style="width: 33%; color: magenta;"> Action Under Way: 3rd Dec 2008 </td> <td style="width: 33%; color: magenta;"> Action Complete: 19th Dec 2008 </td> </tr> </table>	Acknowledge Receipt of Alert: 21 st Nov 2008	Action Under Way: 3 rd Dec 2008	Action Complete: 19 th Dec 2008	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

LIFEPAK CR Plus automatic external defibrillator manufactured by Medtronic Physio-Control.
Various serial numbers.

2. PROBLEM:

Failure to deliver therapy. A faulty internal cable in defibrillators manufactured between November 2006 and March 2008 means the defibrillator may fail to power on.

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:

- Identify affected LIFEPAK CR Plus defibrillators (see appendix).
- Check the defibrillator regularly as detailed in the manufacturer's instructions and if it does not power on, contact the manufacturer immediately on 01923 234 512.
- If you have not already received the manufacturer's Field Safety Notice, contact Medtronic to inform them that you have an affected device.

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:

- Ambulance services directors
- Ambulance staff
- Community defibrillation officers
- First responder units
- Paramedics
- Rapid responders
- Resuscitation officers and trainers
- Community dental practices
- Equipment libraries and stores
- General dental practitioners
- General practitioners
- Minor injury units
- Practice managers
- Practice nurses
- School nurses
- Independent Health and Social Care Providers –Private Hospitals & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

David Dunham or Michael Brunton
Medtronic Limited
Suite One Building
5 Croxley Green
Business Park
Watford
WD18 8WW

Tel: 01923 212 213

Fax: 01923 241 004

E-mail: david.dunham@medtronic.com
michael.brunton@medtronic.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/085 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

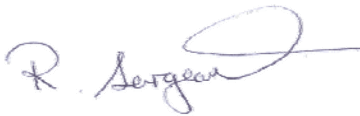
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
21st Nov 2008

Action Under Way:
3rd Dec 2008

Action Complete:
19th Dec 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)2007/01. 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

APPENDIX to MDEA(NI)2008/085



Medtronic Limited
Suite One
Building 5
Croxley Green Business Park
Watford, Herts WD18 8WW
Telephone: 01923 212213
Facsimile: 01923 241004

URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION LIFEPAK CR® Plus defibrillator / LIFEPAK EXPRESS® defibrillator

July 2008




Medtronic Ref. No. FA394

Dear

Physio-Control, Inc., a division of Medtronic, Inc. is notifying customers who own a LIFEPAK CR Plus and/or a LIFEPAK EXPRESS automated external defibrillator (AED) manufactured between November 2006 and March 2008. These AEDs may contain a specific internal flex cable that may be susceptible to failure and could potentially short, preventing the AED from powering on. Failure to power on will prevent delivery of therapy to a patient. There have been no reports of adverse events for this issue.

We have investigated three confirmed events of this shorting issue occurring during AED testing in the field. In these reports, the AED would not power on although the OK indicator was visible on the Readiness Display. Physio-Control recommends customers immediately inspect their AED for this issue by pressing the On / Off button to verify the device will power on and that voice prompts begin. See full recommendations below. An enclosed list identifies your potentially affected AEDs by serial number.

Recommendations:

- Immediately verify your AED powers on **and** voice prompts begin.
After verification, press and hold the On / Off button for approximately two seconds to turn the AED off.
- Keep your AED in use and perform monthly inspections **that include the additional AED power on test**. A monthly inspection is consistent with the LIFEPAK CR Plus/LIFEPAK EXPRESS AED Operating Instructions.
- If "OK" is visible on the Readiness Display and the AED powers on, it is ready for use.
- If, at any time, the AED does not power on or if any other indicator displays (i.e., , , or ), please immediately call 01923 234512

A Physio-Control representative will contact you within 60 days to make arrangements to correct all your potentially affected defibrillator(s) at no charge.

Please ensure this notification is appropriately forwarded to all your sites. If you no longer have the defibrillator(s) on the attached list, please notify us as soon as possible.

Medtronic is communicating this information to the appropriate regulatory agencies in your country.

If you have additional questions about whether your defibrillator is included in this notification, you can visit our website at www.physio-control-notices.com/flex.

Alleviating Pain. Restoring Health. Extending Life

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APPENDIX to MDEA(NI)2008/085

Physio-Control is committed to ensuring our products meet the highest quality standards and to fully supporting our customers. If you have any questions or would like additional information, please call our UK Service Centre on 01923 234512 or visit our website referenced above.

Yours sincerely



David G. Dunham BSc. PhD
Regulatory Affairs Manager – UK & Ireland

Attachment: List of affected devices.

APPENDIX to MDEA(NI)2008/085

Serial No	Serial No	Serial No	Serial No	Serial No	Serial No
35113211	35140835	35435767	35723205	35748941	35748995
35113212	35140836	35435768	35736955	35748943	35748996
35113213	35140838	35438284	35737235	35748944	35748997
35113214	35189992	35438287	35737237	35748945	35748998
35113215	35232582	35452838	35737239	35748946	35749000
35113216	35248566	35452839	35742128	35748947	35749001
35113217	35248965	35452840	35742129	35748948	35749002
35113221	35270549	35452841	35742130	35748949	35749003
35113222	35270550	35452842	35748891	35748950	35749004
35113223	35270551	35452844	35748892	35748951	35749005
35113262	35274765	35452845	35748894	35748953	35749006
35113263	35274766	35452846	35748895	35748954	35749007
35113264	35274767	35452860	35748896	35748955	35749008
35113265	35274768	35469945	35748897	35748956	35749009
35113266	35274769	35492467	35748898	35748957	35749010
35113267	35274770	35499326	35748899	35748958	35749011
35113268	35288235	35510640	35748900	35748959	35749012
35113269	35303838	35566908	35748901	35748960	35749013
35113270	35303839	35566911	35748902	35748961	35749014
35113271	35303840	35616846	35748903	35748962	35749015
35113272	35303841	35616849	35748904	35748963	35749016
35113273	35303842	35616850	35748906	35748964	35749017
35113274	35303843	35616856	35748907	35748965	35749018
35113275	35303844	35616857	35748908	35748966	35749020
35113276	35303845	35616858	35748909	35748967	35749021
35113277	35303846	35616862	35748910	35748968	35749022
35113278	35309738	35657443	35748911	35748969	35749023
35113279	35309739	35657444	35748912	35748970	35749024
35113280	35309740	35664521	35748913	35748971	35749025
35113281	35309741	35665447	35748915	35748972	35749026
35113282	35309742	35665452	35748916	35748973	35749027
35113283	35309743	35667739	35748917	35748974	35749028
35113284	35309746	35667740	35748918	35748975	35749029
35113285	35309747	35667805	35748919	35748976	35749031
35113286	35341223	35667807	35748921	35748977	35749032
35113287	35359282	35667809	35748922	35748978	35749033
35113288	35377871	35667820	35748923	35748979	35749034
35113290	35388155	35667822	35748924	35748980	35749035
35113291	35408792	35673066	35748925	35748981	35749036
35113292	35411337	35705660	35748926	35748982	35749037
35113293	35421717	35705662	35748927	35748983	35749039
35113294	35424159	35706601	35748929	35748984	35749040
35113295	35424160	35706602	35748930	35748985	35749041
35113296	35424161	35706607	35748931	35748986	35749043
35113297	35424162	35711122	35748932	35748987	35756180
35113298	35424163	35711123	35748933	35748988	35762755
35113299	35424164	35711134	35748934	35748989	35811187
35121350	35424165	35711141	35748936	35748990	35812900
35140669	35424166	35711144	35748937	35748991	35812901
35140672	35424167	35711145	35748938	35748992	35812902
35140831	35424168	35711148	35748939	35748993	35868799
35140833	35427195	35722023	35748940	35748994	35887148

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Serial No	Serial No	Serial No
35887149	35983070	36197524
35887152	35983071	36197527
35892100	35983072	36197537
35892107	35983073	36197540
35892111	35983074	36199080
35892112	35983075	36199457
35892113	35987947	36199464
35893568	36095254	36207657
35893581	36095255	36207659
35893582	36095256	36207660
35893583	36095257	36207662
35893584	36095258	36207663
35893585	36095259	36235067
35893586	36102013	36307120
35893587	36102014	36307121
35893588	36116265	36307122
35893589	36121032	36307130
35893590	36121408	36309510
35910115	36121410	36309516
35957829	36121414	36309518
35957832	36121428	36311286
35957884	36186710	36311291
35957885	36186714	36311295
35957886	36186721	36311300
35957924	36186726	36312545
35957926	36188486	36312546
35957968	36188487	36312567
35957969	36188488	36312568
35961664	36188489	36312572
35961670	36188490	36312574
35966063	36188491	36312575
35966068	36188492	36322488
35966154	36188493	36322489
35966155	36188494	36322492
35972387	36188495	36328427
35972399	36188496	36328429
35979480	36188497	36328430
35979996	36188498	36328431
35983054	36188499	36328434
35983055	36188500	36328435
35983056	36188935	
35983059	36188936	
35983060	36188937	
35983061	36188938	
35983062	36188939	
35983063	36188940	
35983064	36188941	
35983065	36188942	
35983066	36188943	
35983067	36188944	
35983068	36188963	
35983069	36197521	