



**Medtronic**

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

July 2008




Medtronic Reference: FA394

Dear Customer:

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 our service partner in Ireland (Oxygen Care Ltd) on 01 295 3421.

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.

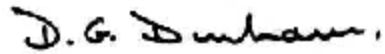
Medtronic is communicating this information to the appropriate regulatory agencies in your country.

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](http://www.physio-control-notices.com/flex).

*Alleviating Pain. Restoring Health. Extending Life*

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 service partner in Ireland (Oxygen Care Ltd) on 01 295 3421, or visit our website referenced above.

Yours sincerely

A handwritten signature in black ink that reads "D.G. Dunham," with a comma at the end.

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

Attachment: List of affected devices.

**Physio-Control LIFEPAK CR Plus FSCA. July 2008 Ref FA394. List of of affected serial numbers**

<b>Serial No</b>	<b>Serial No</b>	<b>Serial No</b>	<b>Serial No</b>	<b>Serial No</b>	<b>Serial No</b>	<b>Serial No</b>
35032243	35303827	35703659	35889473	36117042	36186725	36312948
35032244	35303828	35703661	35889475	36119165	36186727	36312949
35032245	35306911	35703662	35889482	36119198	36186728	36312950
35119317	35309744	35706605	35889483	36119202	36188960	36312951
35137532	35309745	35721098	35889484	36123000	36188961	36312952
35137534	35319505	35721105	35889485	36123001	36188962	36312969
35138238	35341220	35721106	35889486	36123002	36188968	36312970
35140683	35341221	35721107	35949965	36123003	36188969	36312971
35140684	35346014	35721108	35957892	36123004	36188970	36312972
35140685	35346019	35721109	35957893	36123005	36188971	36312973
35140686	35362977	35721110	35957894	36123006	36188972	36312974
35140687	35362978	35732206	35957895	36123007	36188973	36312976
35140688	35362979	35732207	35957897	36123008	36188986	36312977
35140689	35407222	35732208	35961662	36123009	36188989	36312987
35140690	35407223	35732209	35966024	36123010	36188990	36312994
35141703	35407224	35732210	35975434	36123011	36188991	36312997
35141704	35407225	35732211	35975435	36123012	36188992	36313002
35141790	35407226	35732212	35975436	36123016	36199268	36313009
35141791	35407227	35732213	35975437	36123017	36199269	36313029
35142122	35408663	35732214	35975990	36178655	36199270	36313038
35142123	35408664	35732215	35978858	36178656	36199271	36313039
35162578	35408721	35732217	35978859	36178657	36199461	
35172446	35408722	35732315	35978860	36178658	36199477	
35193779	35435719	35732316	35978861	36178659	36199521	
35193780	35436489	35732317	35978862	36178660	36199533	
35193788	35494575	35732319	35978863	36178661	36199539	
35193789	35566625	35732320	35978864	36178662	36199543	
35193790	35665450	35756076	35978865	36178663	36219407	
35193791	35666744	35756077	35978866	36178664	36219408	
35193792	35669646	35807436	35978867	36178665	36219409	
35193793	35673057	35820347	35978870	36178667	36219422	
35221047	35673058	35820348	35978871	36178668	36219423	
35232338	35673059	35820349	35978929	36178669	36234171	
35250790	35673060	35820350	35978930	36178670	36268540	
35267886	35673061	35868817	35978931	36186706	36268541	
35274772	35673062	35868818	35978932	36186708	36276962	
35287509	35673063	35868819	35978934	36186709	36309492	
35296270	35673067	35868820	35978936	36186711	36309497	
35296271	35673068	35868821	35987696	36186712	36309498	
35296272	35673069	35868822	35987700	36186713	36309509	
35296273	35673070	35868823	36095215	36186715	36309511	
35296274	35673071	35868824	36095216	36186716	36309512	
35296279	35703654	35868825	36095217	36186718	36309513	
35296280	35703655	35868826	36095218	36186719	36309514	
35296281	35703656	35889464	36095219	36186720	36309515	
35296282	35703657	35889471	36117038	36186723	36309517	
35296283	35703658	35889472	36117039	36186724	36309520	