

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/31

Issued: 4th April 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: External defibrillator: Lifepak 20 defibrillator manufactured by Medtronic.</p>	▶ ①
<p>Problem: Some Lifepak 20 defibrillators may fail to deliver therapy (see appendix for list of serial numbers of affected devices). Once mains power is disconnected the defibrillators may not turn on with battery power. The display is blank and all indicator lights are off.</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"> Locate and check Lifepak 20 defibrillators against the list of serial numbers (see appendix) and take appropriate action. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<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:

External defibrillator: Lifepak 20 defibrillator manufactured by Medtronic.

2. PROBLEM:

This defibrillator may fail to work under battery power if it is turned on between 0.6 and 1.7 seconds after disconnecting it from the mains. The failure occurs up to 1 in 5 of the times that these conditions are met. Reconnecting to mains power restores normal operation.

Medtronic has developed a new system software (version 42) that corrects this problem.

Medtronic has not received any adverse incidents relating to this issue.

3. ACTION BY:

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

4. ACTION:

- Locate and check Lifepak 20 defibrillators against the list of serial numbers (see appendix).
- If you have affected devices, contact the manufacturer for a software upgrade to address this problem.
- Whilst awaiting upgrade users should:
 1. turn on the Lifepak 20 defibrillator before unplugging it from the mains
 2. immediately reconnect it to the mains to restore normal operation if the device fails to work with battery power.

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
- Dentists
- EBME departments
- Equipment stores
- Health and safety managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Intensive care units
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Paediatric intensive care units
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Theatre 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

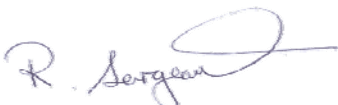
Enquires to NIAIC should quote reference number MDEA(NI)2007/31 and be addressed to:

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)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

APPENDIX to MDEA(NI)2007-31

Serial No.	Serial No.	Serial No.	Serial No.	Serial No.	Serial No.
32858894	32915363	32932742	33035362	33154555	33397601
32860140	32916293	32932749	33035375	33156307	33397627
32872430	32918043	32932760	33045023	33156361	33397640
32872434	32918133	32937970	33045042	33156390	33400415
32872437	32918144	32937971	33050876	33156919	33400419
32876449	32918189	32937976	33050907	33156921	33400426
32876450	32918250	32937977	33060658	33156934	33400428
32876452	32918260	32938007	33063515	33156935	33418104
32878860	32918263	32946057	33063519	33159925	33422379
32883064	32918272	32946058	33063520	33159932	33425114
32883065	32918304	32952117	33063524	33159934	33429351
32883072	32918355	32952128	33063527	33159935	33429373
32883102	32918360	32952129	33063530	33159936	33448738
32900306	32918363	32952131	33063531	33159938	33448741
32903858	32918375	32955172	33063532	33159945	33448742
32904724	32918382	32955175	33063533	33159946	33448746
32904739	32918397	32955176	33063536	33164833	33457077
32904751	32918401	32955178	33063538	33169237	33457078
32904757	32918607	32955180	33063539	33169302	33457085
32904758	32918714	32955185	33065294	33169303	33467676
32905332	32918771	32955186	33070500	33169307	33467685
32905348	32920853	32955187	33070501	33176569	33467694
32905349	32920854	32955188	33070503	33181890	33484326
32905350	32920855	32955189	33070504	33190270	33491201
32905356	32920856	32955191	33070506	33190275	33491211
32905357	32920858	32955195	33070508	33207287	33503225
32905358	32920859	32955198	33070514	33207299	33503316
32905359	32920860	32957396	33070527	33207306	33503904
32905360	32920862	32960344	33070532	33207311	33503907
32905363	32920863	32960350	33070536	33207312	33503908
32905364	32920864	32960388	33075327	33207320	33503909
32905397	32920865	32960389	33075328	33207322	33503910
32905398	32920871	32960392	33075331	33207327	33503911
32905399	32926090	32960395	33075332	33208119	33506680
32907954	32926091	32960396	33075339	33208120	33506708
32910896	32926644	32960397	33075340	33208141	33512164
32910897	32926645	32970452	33119944	33220981	33512172
32910898	32926648	32970454	33119945	33224579	33512173
32910899	32926661	32970455	33119952	33224585	33512221
32910900	32926663	32987153	33143696	33224589	33516458
32910901	32926664	33001372	33145961	33224615	33516462
32910902	32926665	33006114	33145965	33226763	33516467
32910903	32926666	33006120	33145968	33226819	33516468
32910904	32926667	33006121	33145970	33242796	33516476
32913779	32926668	33008366	33149644	33350353	33519794
32914939	32926672	33008370	33149649	33356452	33555287
32914940	32926674	33008371	33149653	33356538	33560876
32914941	32932724	33024655	33149655	33356541	33560915
32914944	32932728	33035344	33152176	33396500	33566623

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Serial No.	Serial No.	Serial No.
33566666	33814052	33894549
33569163	33814081	33915959
33578525	33814086	33922373
33591695	33814165	33922374
33591697	33819585	33922379
33591701	33819599	33922380
33591703	33819626	33922381
33591708	33819630	33924667
33591711	33819633	33924668
33591715	33819637	33924670
33591718	33819653	33924677
33591720	33819658	33933951
33591723	33823316	33933957
33591726	33823321	33946275
33591978	33823327	33946279
33591983	33823347	33946294
33594388	33826045	33946295
33594389	33826051	33947872
33594396	33826071	33947874
33594407	33826075	33947888
33594426	33826091	33971912
33594433	33826095	33971931
33636885	33826096	33971951
33636894	33829397	33971957
33640478	33881421	33971958
33640483	33884921	33976405
33640486	33884941	33976438
33640490	33884943	33976439
33640499	33889414	33976442
33643687	33889415	33976444
33643691	33889417	33976449
33646592	33889432	33976466
33649622	33889475	33976469
33649842	33889497	33986347
33649844	33890389	33986796
33649845	33890390	33986798
33802758	33890397	33986801
33805102	33890398	33986803
33805111	33890403	33986805
33805115	33890407	33986806
33808027	33890409	33986810
33808111	33890417	33986812
33808113	33892612	33986813
33808115	33892614	33986875
33808120	33893074	33986914
33808145	33893082	
33808195	33893086	
33808199	33893107	
33811063	33894368	