

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/95

Issued: 7<sup>th</sup> November 2007

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section								
<p><b>Medical Device/Equipment:</b> Automatic external defibrillator - Welch Allyn AED 20.</p>	▶ ①								
<p><b>Problem:</b> Failure to defibrillate. The manufacturer is recalling a specific batch of these defibrillators to correct a malfunction that prevents or delays the delivery of therapy, which can lead to failure to resuscitate a patient. This recall is in addition to a batch of AED 20 defibrillators recalled in July 2006 to correct a similar malfunction.</p>	▶ ②								
<p><b>Action by:</b> 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><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify affected devices using the list of serial numbers in the appendix.</li> <li>Contact the manufacturer to arrange service and upgrade as soon as possible. (See Page 2 for further action)</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></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> <p><b>For onward distribution see Section 5</b></p>	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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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> None required</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Welch Allyn AED 20 defibrillator with automated and manual mode options. The affected devices can be identified by serial numbers located on the lower right hand corner of the back of the defibrillator. Affected units were manufactured between October 2003 and January 2005.

Serial numbers of affected devices are listed in the appendix.

## 2. PROBLEM:

A malfunction is caused by an intermittent connection between a pin and socket on a circuit board inside the defibrillator. The problem develops over time and is unpredictable. The AED 20 has a self-monitoring feature that detects this problem and displays a 'Defib Comm' error message. The problem is often identified while the device is being tested before use but has also occurred while practitioners are attempting to use the device on a patient.

The manufacturer issued recall letters to their distributors on 29 August 2007.

**The manufacturer is offering loan devices whilst those affected are being upgraded free of charge.**

## 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 devices using the list of serial numbers in the appendix.
- Contact the manufacturer to arrange service and upgrade as soon as possible.
- Consider if it is appropriate to substitute alternative defibrillators for those affected devices that are in service but are awaiting upgrade.
- If affected devices awaiting upgrade are used and display a 'Defib Comm' error message, the manufacturer has advised that switching the device off and then on again may clear the error message.
- The equipment maintenance records should be updated when upgraded units are returned.

## 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
- Adult and paediatric intensive care units
- All departments
- All medical and nursing staff
- All wards
- Ambulance services directors
- Ambulance staff and paramedics
- Anaesthesia, directors of
- Anaesthetists
- Biomedical engineering staff
- Cardiology departments
- Clinical directors
- Clinical governance leads
- Coronary care departments
- Dental departments
- Equipment stores
- Health and safety managers
- Maintenance staff
- Medical directors
- Nursing executive directors
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Chris Grant  
Welch Allyn  
Navan Business Park  
Dublin Road  
Navan, Co. Meath  
Republic of Ireland

Tel: 00 353 46 906 7700

Fax: 00 353 46 906 7755

E-mail: [grantc@welchallyn.com](mailto:grantc@welchallyn.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2007/95 and be addressed to:

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

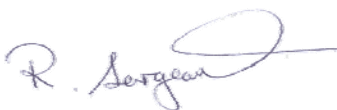
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto: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](http://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) 2007/95

### Serial numbers of affected devices

205879	206082	206103	206186	206218	206239	206331	206595	206815	206938	207161	207343
205880	206083	206104	206187	206219	206240	206332	206784	206816	206939	207214	207349
205881	206084	206105	206188	206220	206241	206333	206785	206817	206940	207215	207403
205882	206085	206106	206189	206221	206242	206334	206786	206818	206941	207216	207404
205883	206086	206107	206190	206222	206243	206335	206787	206853	206975	207217	207414
205884	206087	206108	206191	206223	206244	206336	206788	206854	207040	207218	207415
205885	206088	206109	206192	206224	206245	206337	206789	206887	207041	207219	207416
205886	206089	206110	206193	206225	206264	206338	206790	206888	207042	207220	207423
205887	206090	206111	206194	206226	206302	206339	206791	206889	207052	207221	207426
205888	206091	206112	206195	206227	206303	206340	206797	206926	207053	207222	207427
206002	206092	206113	206196	206228	206304	206341	206798	206927	207054	207223	207428
206003	206093	206125	206197	206229	206305	206342	206804	206928	207055	207224	207429
206004	206094	206126	206198	206230	206306	206343	206805	206929	207056	207225	207430
206005	206095	206127	206199	206231	206307	206344	206806	206930	207057	207226	207431
206006	206096	206128	206200	206232	206308	206345	206807	206931	207058	207228	207432
206007	206097	206129	206201	206233	206309	206346	206808	206932	207059	207230	207433
206008	206098	206130	206213	206234	206310	206347	206809	206933	207060	207331	
206009	206099	206182	206214	206235	206311	206348	206810	206934	207061	207332	
206010	206100	206183	206215	206236	206313	206379	206811	206935	207101	207340	
206011	206101	206184	206216	206237	206329	206399	206813	206936	207159	207341	
206023	206102	206185	206217	206238	206330	206477	206814	206937	207160	207342	