

Medical Device/Equipment ALERT



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

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| IMMEDIATE ACTION | |
| ACTION | ✓ |
| UPDATE | |
| INFORMATION REQUEST | |

| | Section | | | | | | | | |
|--|-----------------------------------|-------------------------------|-----------------------------------|------------------------------|--------------------------------|--|------------------------|--|-----|
| Medical Device/Equipment: All Biphasic Defibrillators (all manufacturers) | ▶ ① | | | | | | | | |
| Problem: Defibrillators that use biphasic waveforms generally require lower energy levels to achieve defibrillation than those that use monophasic waveforms. There is therefore the possibility for confusion. | ▶ ② | | | | | | | | |
| Action by: All healthcare professionals using external defibrillators. | ▶ ③ | | | | | | | | |
| Action: All users of defibrillators should be made aware of the joint statement made by the Medicines and Healthcare products Regulatory Agency (MHRA) and relevant professional organisations | ▶ ④ | | | | | | | | |
| Distributed by NIAIC to: <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></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> For onward distribution see Section 5 | Chief Executive of each HSS Board | General Medical Practitioners | Chief Executive of each HSS Trust | General Dental Practitioners | Chief Executive of each Agency | | NIAIC Liaison Officers | | ▶ ⑤ |
| Chief Executive of each HSS Board | General Medical Practitioners | | | | | | | | |
| Chief Executive of each HSS Trust | General Dental Practitioners | | | | | | | | |
| Chief Executive of each Agency | | | | | | | | | |
| NIAIC Liaison Officers | | | | | | | | | |
| Contacts Details of NIAIC contacts for technical aspects. | ▶ ⑥ | | | | | | | | |
| Feedback Requirements to NIAIC None required. | ▶ ⑦ | | | | | | | | |

1. DEVICE/EQUIPMENT:

All Biphasic Defibrillators (all manufacturers)

2. PROBLEM:

There are many different models of biphasic defibrillator with a range of energy level protocols available on the UK market. The rapid uptake in biphasic technology and the differences between energy level protocols between biphasic and the more traditional monophasic devices, has caused confusion. Representatives from a range of professional organisations met to discuss this matter and have issued the joint statement in the attached Annex.

3. ACTION BY:

As outlined on page 1

4. ACTION:

As outlined on page 1

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Nursing Directors
- Directors of Anaesthetics
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Accident & Emergency Departments
- Coronary Care
- All Intensive Care units
- Resuscitation Officers
- Operating Theatre Staff
- All wards
- Directors of Public Health
- Practice Nurses
- Independent Health Care Providers including private clinics
- Clinical Governance Lead Local Health and Social Care Groups

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/04 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US, Tel: 028 9052 3714, Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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

Issued: 18 April 2003

Ref. MDEA(NI)2003/04

ANNEX TO MDEA(NI)2003/04

A joint statement from:

- The Association of Anaesthetists
- The British Association for Accident & Emergency Medicine
- The British Cardiac Society
- The Committee for the Safety of Devices
- The Department of Health's Medicines and Healthcare products Regulatory Agency (MHRA)
- The Resuscitation Council (UK)
- The Royal College of Anaesthetists
- The Royal College of Nursing
- The Royal College of Surgeons of Edinburgh Faculty of Pre-hospital Care.

Electrical defibrillation is the only possible treatment for ventricular fibrillation, the arrhythmia responsible for the great majority of cardiac arrests. The success of defibrillation depends crucially on the time between the onset of the arrhythmia and the administration of the shock.

Recent developments in defibrillator technology have led to the introduction of defibrillators that use biphasic waveforms. The majority of modern defibrillators, including Automated External Defibrillators (AEDs) use this technology. Biphasic waveforms have proved to be successful in achieving defibrillation at considerably lower energy levels than monophasic waveforms potentially reducing the frequency of adverse effects on the myocardium.

However, the 200J / 200J / 360J sequence of shocks recommended for monophasic machines is not appropriate for biphasic devices. Some AEDs deliver biphasic shocks at a fixed output with successive shocks at the same energy level. Other AEDs employ escalating levels with successive shocks but these may be considerably lower than the conventional 200J / 200J / 360J sequence. Thus where biphasic waveforms are employed, whether by a manual defibrillator or an AED / semi-automatic defibrillator used in manual mode, it is not usually possible or appropriate for users to deliver 200J or 360J shocks.

Many hospitals, ambulance services and other healthcare organisations have available both monophasic and biphasic waveform machines. Confusion has occurred particularly when both types are available in the same clinical area.

It is essential that healthcare professionals who might use a defibrillator, whether in emergency or elective clinical circumstances, are fully educated and trained to use the equipment available to them. They should understand that energy levels might differ among different defibrillators, and be confident that they can perform defibrillation without delay using the equipment that is available to them. They should also be aware that the energy levels delivered by AEDs used in automatic mode (whether monophasic or biphasic) are programmed in advance and do not require adjustment or any other input from the operator when used in a resuscitation attempt.

The Controls Assurance Standard for Medical Devices and Equipment Management requires HPSS organisations to ensure that "all professional users are trained in the safe operation of medical devices". The dual approach of device rationalisation (for instance ensuring that any one clinical area or directorate has identical equipment) and regular staff training, should be used to eliminate the risk of confusion about different energy levels employed by different biphasic defibrillators, and how these energy levels differ from those recommended for monophasic defibrillators.

As with all medical devices and equipment, if users of a medical device are concerned that it has not functioned correctly, or that there are inadequate instructions for use supplied by the medical device manufacturer, HPSS organisations and other users in Northern Ireland should report these concerns to the Northern Ireland Adverse Incident Centre (NIAIC) who work closely with the Medicines and Healthcare products Regulatory Agency (MHRA), previously MDA, in London. Details about how to report are available on the NIAIC website at www.dhsspsni.gov.uk or can be obtained by telephoning NIAIC at 028 9052 3704.