

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/043

Issued: 17<sup>th</sup> June 2008

For:

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



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Medtronic Physio-Control LIFEPAK<sup>®</sup> 12, LIFEPAK<sup>®</sup> 20 and LIFEPAK<sup>®</sup> 20e external defibrillators with certain settings.</p>	▶ ①								
<p><b>Problem:</b> When used in AED mode with 'Auto Analyze' ON, the ECG analysis (Shock Advisory System™) may start before a warning is given to the user to stand clear of the patient. This can result in inappropriate shock or no shock recommendations being made by the device due to CPR or movement artefacts.</p>	▶ ②								
<p><b>Action by:</b> All those involved in the use or maintenance of these devices.</p>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify affected devices – refer to the details given on page 2.</li> <li>If AED mode is used the 'Auto Analyze' function should be set to OFF or 'After First Shock' (see appendix).</li> <li>Ensure that all users are aware of the change in operation of the device – the 'ANALYZE' button must be pressed.</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
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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>									
<p><b>Acknowledge Receipt of Alert:</b> 19<sup>th</sup> June 2008</p>	<p><b>Action Under Way:</b> 24<sup>th</sup> June 2008</p>								
<p><b>Action Complete:</b> 08<sup>th</sup> July 2008</p>	▶ ⑦								

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

## 1. DEVICE/EQUIPMENT:

LIFEPAK® 12, LIFEPAK® 20 and LIFEPAK® 20e devices are affected if AED mode follows European Resuscitation Council Guidelines for Resuscitation 2005 (i.e. a single shock, followed by 2 minutes for CPR).

Maintenance staff can confirm that a device is affected by entering the setup mode. Affected devices will have three 'Auto Analyze' options – ON, OFF, and 'After First Shock'.

Note: The device serial number **cannot** be used to identify affected devices as the software may have been updated since the device was originally supplied.

This problem **only** occurs when using AED mode with 'Auto Analyze' ON. Devices which are not configured to operate in AED mode are not affected.

## 2. PROBLEM:

When used in AED mode with 'Auto Analyze' ON, the ECG analysis (Shock Advisory System™) may start before warning is given to the user to stand clear of the patient. This can result in inappropriate shock or no shock recommendations being made by the device due to CPR or movement artefacts.

## 3. ACTION BY:

All those involved in the use or maintenance of these devices.

## 4. ACTION:

Identify affected devices from the information given above.

Devices which are configured to operate in AED mode should have the 'Auto Analyze' function set to OFF or 'After First Shock'. This requires access to the setup mode, and should only be performed by authorised persons.

Refer to the manufacturer's instructions for changing 'Auto Analyze' setup options (see appendix).

Note: Selecting 'Auto Analyze After First Shock' will cause the device to default to stacked shock protocol which is contrary to the European Resuscitation Council Guidelines for Resuscitation 2005.

Ensure that all users are aware of the change in operation of the device; once this change has been made the 'analyze' button must be pressed in order to begin ECG analysis. There will be a visual prompt to press 'analyze', and there may also be a voice prompt, depending on the options selected in the setup mode.

## 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 departments
- All intensive care units
- All outpatient departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetic departments
- EBME departments
- Medical directors
- Nursing executive directors
- Resuscitation officers and trainers
- Risk managers
- Theatre managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Community defibrillation officers
- Community hospitals
- Equipment libraries and stores

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Dave Dunham  
Regulatory Affairs Manager - UK & Ireland  
Medtronic Ltd  
Suite One, Building 5,  
Croxley Green Business Park  
Watford WD18 8WW

Tel: 01923 212 213  
Fax: 01923 202 550  
E-mail: [david.dunham@medtronic.com](mailto:david.dunham@medtronic.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/043 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)

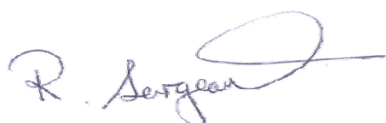
## 7. FEEDBACK:

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

**Acknowledge Receipt of Alert:**  
19<sup>th</sup> June 2008

**Action Under Way:**  
24<sup>th</sup> June 2008

**Action Complete:**  
08<sup>th</sup> July 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)2008/01. 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)2008/043

## LIFEPAK® 12 Defibrillator/Monitor

### Instructions for Changing Auto Analyze Setup Options

The following instructions are provided to assist you in confirming that the AED mode Auto Analyze setup option is not set to ON, or to change this setup option from ON, if necessary. We recommend that you have your *LIFEPAK 12 Defibrillator/Monitor Operating Instructions* available as you step through this process.

To confirm or change the Auto Analyze setup option:

1. Press and hold down the OPTIONS and EVENT buttons simultaneously and then press the ON button. Continue to hold the OPTIONS and EVENT buttons down until the Enter Setup Mode Passcode menu appears.
2. Enter the passcode for your device.  
If your site has set a passcode to enter Setup Mode, you must enter the passcode. If no passcode has been set, press the Selector four times. Do not rotate the Selector. Each time you press the Selector, a zero (0) changes to an asterisk (\*).
3. The Setup screen appears.  
Note: If you enter the passcode incorrectly, the message PASSCODE INCORRECT—TRY AGAIN appears. You have three chances to complete this correctly. If necessary, turn the device off and then on again to start over.
4. In the Setup screen, turn the Selector to scroll to and highlight the field "Advisory Mode...". Press the Selector. The Advisory Mode screen appears.
5. Check the Auto Analyze setting.  
Look at the field "Auto Analyze" and note the choice that appears to the right of it. If either "OFF" or "After First Shock" appears, you have confirmed that Auto Analyze is not ON and you can proceed to Step 8. If the "Auto Analyze" setting is ON, continue to Step 6.
6. Turn the Selector to scroll to and highlight "Auto Analyze." Press the Selector. Three choices appear. Turn the Selector to highlight either "OFF" or "After First Shock."
  - "OFF" means the user is always prompted to push the ANALYZE button to initiate analysis during patient use.
  - "After First Shock" means the user is always prompted to push the ANALYZE button to initiate analysis, with the exception of between a series of 3 stacked shocks. Between a series of stacked shocks, the device analyzes automatically.
7. After making your selection, the Advisory Mode screen appears. Confirm that your selection, either "OFF" or "After First Shock," appears to the right of "Auto Analyze."
8. Turn the device off.

Thank you for taking the time to confirm the requested change to this setup option.

# APPENDIX to MDEA(NI)2008/043

## LIFEPAK 20<sup>®</sup> Defibrillator/Monitor

### Instructions for Changing Auto Analyze Setup Options

The following instructions are provided to assist you in confirming that the AED mode Auto Analyze setup option is not set to ON, or to change this setup option from ON, if necessary. We recommend that you have your *LIFEPAK 20 Defibrillator/Monitor Operating Instructions* available as you step through this process.

To confirm or change the Auto Analyze setup option:

1. To open the door on the front of the defibrillator, press the MANUAL button on the lower left corner of the door, if necessary.
2. Press and hold down the OPTIONS and EVENT buttons simultaneously and then press the ON button. Continue to hold the OPTIONS and EVENT buttons until the Enter Passcode screen appears.
3. Enter the passcode for your device.  
If your site has set a passcode to enter Setup Mode, you must enter the passcode. If no passcode has been set, press the Speed Dial four times. Do not rotate the Speed Dial. Each time you press the Selector, a zero (0) changes to an asterisk (\*).
4. The Setup screen appears.  
Note: If you enter the passcode incorrectly, the message PASSCODE INCORRECT—TRY AGAIN appears. You have three chances to complete this correctly. If necessary, turn the device off and then on again to start over.
5. In the Setup screen, turn the Speed Dial to scroll to and highlight the field "AED Mode...". Press the Speed Dial. The AED Mode screen appears.
6. Check the Auto Analyze setting.  
Look at the field "Auto Analyze" and note the choice that appears to the right of it. If either "OFF" or "After 1st Shock" appears, you have confirmed that Auto Analyze is not ON and you can proceed to Step 9. If the "Auto Analyze" setting is ON, continue to Step 7.
7. Turn the Speed Dial to scroll to and highlight "Auto Analyze." Press the Speed Dial. Three choices appear. Turn the Speed Dial to highlight either "OFF" or "After 1st Shock."
  - "OFF" means the user is always prompted to push the ANALYZE button to initiate analysis during patient use.
  - "After First Shock" means the user is always prompted to push the ANALYZE button to initiate analysis, with the exception of between a series of 3 stacked shocks. Between a series of stacked shocks, the device analyzes automatically.
8. After making your selection, the AED Mode screen appears. Confirm that your selection, either "OFF" or "After First Shock," appears to the right of "Auto Analyze."
9. Turn the device off and close the door (if applicable).

Thank you for taking the time to confirm the requested change to this setup option.