Medical Devices Bureau, Ministry of Health Malaysia
Level 5, Block E6, Complex E,
Federal Government Administration Centre,
62590 Putrajaya, MALAYSIA.
Tel: 03-8883 2248/2249/2264
Fax: 03-8888 6184

Medical Device / Equipment ALERT: Field Corrective Action

Date Issued : 3rd June 2008 **Ref:MDB/A/2008/004**

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Lifepak 12 and Lifepak 20/20e Defibrillators/Monitors by Medtronics.**
CLASS	n/a
USE	External Defibrillators
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Field Corrective Action Letter dated 28th May 2008 from Medtronic International Ltd. - Malaysia Branch.
ALERTING / RECALLING FIRM	**Medtronic International Limited-Malaysia Branch**
REASON	The company is notifying customers that some of the above mentioned models have a potential to incorrectly render a shock or no shock decision during automated external defibrillators (AED) analysis. These defibrillators have specific software version (see attachment) and users must define the Setup Option of Auto Analyze as ON in order this to occur. The manufacturer has given out the instructions for changing the Auto Analyze Setup Options ***Please refer to the attachments for details.***
SCENARIO IN MALAYSIA	Please check whether the device is available and contact the distributor for further action.
ACTION	***Action or Recommendations For Healthcare***

	Professionals • Ensure that all relevant staff in your institution are informed of this safety alert/warning • Follow the distributor / manufacturers recommendations. • Contact the distributor for further clarifications and actions.
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and **inform the Medical Devices Bureau, Ministry of Health** providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	**Medtronic International Limited-Malaysia Branch** F-39-7 CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya Selangor Darul Ehsan. Tel:- 03-79534800 Fax:- 03- 79582202
REFERENCES	PLEASE REFER THE ATTACHMENT

Medtronic International Ltd. - Malaysia Branch
(993966-P)
F-39-7, CREST,
3 Two Square,
No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

To:

DIRECTOR OF MEDICAL DEVICE BUREAU

MINISTRY OF HEALTH MALAYSIA

ENGINEERING SERVICES DIVISION,

Level 2-5, Block E6, Parcel E, Precint 1,

Federal Government Administration Centre,

62590 Putrajaya,

Malaysia.

May 28, 2008.

Dear Sir,

FCA ON LIFEPAK® 12 AND LIFEPAK® 20/20e DEFIBRILLATOR / MONITOR.

Physio-Control, Inc., a division of Medtronic, is notifying customers that some LIFEPAK® 12 and LIFEPAK® 20/20e defibrillator/monitors have a potential to incorrectly render a shock or no shock decision during automated external defibrillator (AED) analysis.

These defibrillators have specific software versions noted in the customer communication letter, and must have a defined Setup Option of Auto Analyze ON in order for this issue to occur. No complaints or other reported events have been received due to this issue.

The Customer Communication Letter and the Instructions for Changing Auto Analyze Setup Options for both the LIFEPAK® 12 and LIFEPAK® 20/20e defibrillator/monitors are attached herewith, to provide further insights into this voluntary field action.

This field action does not have any impact on LIFEPAK® 12 for Malaysia, as the affected serial numbers were not distributed locally. Please be informed that the business of LIFEPAK is channeled in through a distributor and we have duly notified our distributor on this Field Correction.

Do consult us should you require additional information.

Thank you and kind regards.

Yours Sincerely,

Debra

Debra Anne Anthony Peter

REGULATORY AFFAIRS SPECIALIST

MEDTRONIC INTERNATIONAL, LTD.

April 2008

URGENT MEDICAL DEVICE CORRECTION
LIFEPAK® 12 and LIFEPAK 20/20e Defibrillator/Monitor

Dear Customer,

Physio-Control, Inc., a division of Medtronic, is notifying customers that some LIFEPAK 12 and LIFEPAK 20/20e defibrillator/monitors have a potential to incorrectly render a shock or no shock decision during automated external defibrillator (AED) analysis. These defibrillators have specific software versions noted below and must have a defined Setup Option of Auto Analyze ON in order for this issue to occur. No complaints or other reported events have been received due to this issue.

Our investigation indicates that under certain circumstances and with the specific Setup Option selected, the Shock Advisory System™ (SAS) analysis will start before a warning is given to the user to stand clear of the patient. As a result, the SAS may evaluate ECG noise during CPR activity or while electrodes are being applied, possibly resulting in an incorrect shock advised or no shock advised decision.

The affected defibrillator software versions are referenced below.

Software versions
LIFEPAK 12 version 130
LIFEPAK 20 versions -048, -052, and 054
LIFEPAK 20e version -058

Recommendations
- Keep the defibrillator in service.
- Check the Auto Analyze Setup Option on each of your devices. If Auto Analyze is set to ON, change the setting to one of the other two choices: OFF or After First Shock.
- Follow the enclosed instructions to confirm or change the Auto Analyze Setup Option setting.
- If you update your defibrillator with new software, confirm the Auto Analyze Setup Option is set to OFF or After First Shock.

Our records indicate you own at least one of the identified LIFEPAK 12 and/or 20/20e defibrillator/monitors. *Refer to the enclosed list for model, specific serial number, and software version for your location.*

We are continuing to investigate this issue. You will receive a follow up notification if final results determine further action is necessary.

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.

If you have any questions regarding this notification, please call Debra Anne at 603-79534800 (debra.a.anthony.peter@medtronic.com) or visit our website at www.Physio-Control-notices.com/sas. Physio-Control is committed to ensuring that our products meet the highest quality standards and that our customers are fully supported.

Sincerely,
PHYSIO-CONTROL, INC., a division of Medtronic, Inc.

Jorge Artiles
Vice President, Quality Assurance

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.

LIFEPAK 20® 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.