



Pride in Service with Integrity

**BROWARD SHERIFF'S OFFICE
DEPARTMENT OF FIRE RESCUE
AND EMERGENCY SERVICES**



SAFETY WARNING

LP 12 Urgent Medical Device Correction

SW 08-03

**SAFETY
WARNING**

Fire Marshal's Bureau
2601 West Broward Boulevard
Fort Lauderdale, FL 33312

Phone: 954-831-8210

Fax: 954-831-8218

E-mail: FMO_Issues@sheriff.org

Date: April 30, 2008 **3 Page document**

Physio-Control is notifying customers that some LIFEPAK defibrillator/monitors have a potential to incorrectly render a shock or no shock decision during **AED analysis ONLY**.



All LP 12 units owned and operated by the BSO Fire Rescue Bureau will be updated with the appropriate software by Physio-Control as they are rotated through Logistics.

Please refer to the attached documents provided by Physio-Control regarding this issue.



Physio-Control, Inc.
11811 Williams Road, P.O. Box 57206, Redmond, WA 98073
Tel / Fax 509/400-1142 Toll-Free 800-442-1142
www.physio-control.com

April 2008

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

Dear Customer,

Physio-Control, Inc., a division of Medtronic, is notifying customers that some LIFEPAK 12 and LIFEPAK 20 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

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 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.



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