Medtronic Emergency Response Systems
11811 Willows Road NE
P.O. Box 97048
Redmond, WA 98073-9748 USA
www.medtronic-ers.com

January 14, 2005

URGENT – MEDICAL DEVICE NOTIFICATION
LIFEPAK®12 defibrillator/monitors series with Adaptiv™ biphasic technology

Dear Customer:

This letter is to advise you that Medtronic Emergency Response Systems is voluntarily conducting a notification to all customers owning LIFEPAK®12 defibrillator/monitors series with Adaptiv™ biphasic technology. Devices that have undergone an operating software reinstallation or upgrade may have the manual default defibrillation energy setting reset to 125 joules instead of the energy settings you originally selected. The result is inappropriate energy delivery and failure of the device to escalate energy when configured to do so.

The LIFEPAK®12 defibrillator/monitors series stores many user selectable operating characteristics in software, SETUP OPTIONS. We have received two reports, one which involved a death, where it was observed that one of these settings, the default energy setting for manual mode (called PADS DEFAULT in the operating instructions), was set to a selection (i.e. 125 joules) other than the one selected by the customer. This condition may not be readily apparent to the user until the time of use, if the user is observing the displayed energy being delivered.

Recommendations

1) Check your biphasic LIFEPAK 12 defibrillator/monitor user settings. This can be accomplished by printing the current user setup defaults (reference PRINT DEFAULTS in the LIFEPAK®12 defibrillator/monitors series operating instruction, section 9). The standard factory defaults are also highlighted in this same section.
    a. Enter Setup Mode
    b. Select Print Defaults
2) Compare the current printed defaults to either the factory settings or any alternate selections you chose to support your protocol e.g. 200J, 300J, Energy Protocol, etc.
3) If the values are not in accordance with your protocol or are different than previously selected, correct them in accordance with the operating instructions in section 9. In the event you have to update the manual default defibrillation energy setting, please call the number listed below. Please have your contact information, the device serial number and the change that was made available for the call.
4) If you need assistance checking or correcting this issue, please call the number listed below.

We are communicating this information to the Food and Drug Administration and non-US Regulatory Agencies.

I sincerely apologize for any inconvenience this may cause you. We have a long-standing commitment to total quality and we recognize the importance of maintaining a close partnership with your institution and the medical community. If you have any questions regarding this action please call Technical Support at 1-877-873-7630.

Sincerely,
Medtronic Emergency Response Systems

Gary Gilliam
Vice President, Quality

When Life Depends on Medical Technology