



Physio-Control, Inc. | Lifesaving starts here.™

May 2014

ADDRESS
11811 Willows Road NE
Redmond, WA 98052

URGENT MEDICAL DEVICE NOTICE & CORRECTION – ACTION REQUIRED
LIFEPAK® 1000 Defibrillator

PHONE
GENERAL
425 867 4000
TOLL-FREE
800 442 1142

Dear Customer,

This communication is intended to provide you with critical information regarding the readiness of your device by ensuring proper replacement of the battery that powers your LIFEPAK 1000 defibrillator.

www.physio-control.com

What issues have been reported?

Physio-Control has become aware of incidents where customers have attempted to use their LIFEPAK 1000 defibrillator and the device has shut down unexpectedly due to a very low battery. A defibrillator in this scenario has the potential to fail to deliver a shock, with the potential result that therapy is not delivered and a patient is not resuscitated.

We have learned this to be as a result of batteries not being replaced when they have reached a low or very low state of charge as indicated in the Readiness Display on the device.

Related to this issue we have learned that the Operating Instructions provided with the device may be confusing to some customers, which has contributed to customers not replacing their battery when required. Specifically, there has been confusion regarding the readiness of the device when the OK symbol is present with a low battery charge symbol. Batteries that are at both low battery charge and very low battery charge must be replaced with a fully charged battery, whether or not the OK symbol is present.

Additionally, our investigation has identified a software malfunction in the LIFEPAK 1000 defibrillator that also contributes to some customers not replacing their battery when required. This results in the Readiness Display indicating a low battery charge when it should indicate a very low battery charge. When the battery reaches very low battery charge, the device will correctly indicate this state in the Readiness Display. However, due to the software malfunction, following the next daily auto self-test, the Readiness Display will incorrectly indicate a low battery charge. Batteries at both low and very low state of charge must be replaced with a fully charged battery.

It is important that you always carry a spare fully-charged battery, as stated in the Operating Instructions.

Am I affected by this issue?

All LIFEPAK 1000 defibrillators are impacted by this issue, and our records indicate that LIFEPAK 1000 defibrillators have been distributed to your facility. Customers with devices using batteries that are greater than 3 years of age, or who use their devices frequently are more susceptible to this issue.



What should I do?

Please refer to the enclosure on how to verify the readiness of your device and determining your battery's actual charge. We recommend customers forward this notification to all of your sites that may have a LIFEPAK 1000 defibrillator.

Physio-Control continues to investigate this issue and will have a follow up communication with you regarding this issue. This communication may include updates to Operating Instructions, software updates or additional maintenance instructions.

Important Reminders

It is critically important that you understand what the device and battery indicators mean on your defibrillator and what actions you need to take as a result. At any time the battery charge can be verified by following the instruction provided on page 2-5 of the Operating Instructions.

It is also important that you always carry a spare fully-charged battery, as stated in the Operating Instructions.

What if I no longer have the LIFEPAK 1000 defibrillator?

If you no longer own a LIFEPAK 1000 defibrillator(s), please contact Physio-Control Technical Support as soon as possible to update your account.

How can I report issues with my device?

In addition to notifying Physio-Control of any potential quality problems or adverse reactions or events associated with the use of your defibrillator, problems may be reported directly to the FDA through the MedWatch Adverse Reporting Program online, by regular mail or by fax.

If you have any questions regarding this notification, please call Physio-Control at 1-800-442-1142, 6:00 a.m. to 4:00 p.m. (Pacific), Monday – Friday.

Sincerely,
PHYSIO-CONTROL, INC.

Kathryn Janecke
Vice President, Quality

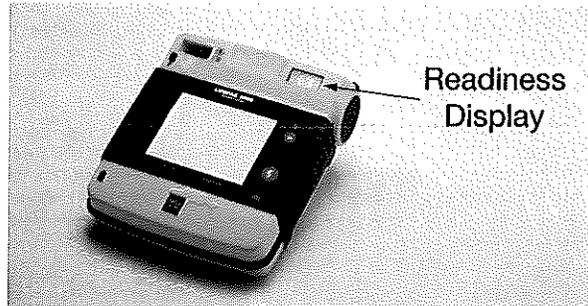
How to Verify the Readiness of Your Device

LIFEPAK® 1000 Defibrillator

URGENT MEDICAL DEVICE NOTICE & CORRECTION – ACTION REQUIRED

Please verify the readiness of your device by determining your battery's actual charge as follows:

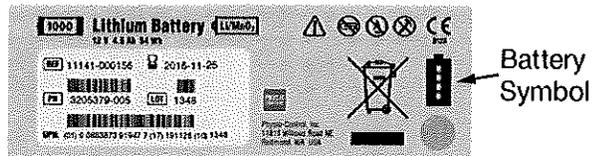
1. With the device turned off, observe the Readiness Display.



2. In the Readiness Display, if you see: **OK** and  ,  or  The battery has sufficient charge and the device is ready for use. Ensure that a spare, fully charged battery is available.

OK  or  The battery is at low or very low charge. Remove the battery from the device and proceed to step 3.

3. Push the gray button below the battery symbol on the battery to check the charge level.



One solid LED indicates the battery is at low charge.

Replace battery immediately with a fully charged battery. Contact Physio-Control at 1-800-442-1142 to obtain a replacement battery and a spare battery.



One flashing LED indicates the battery is at very low charge.

Possible defibrillator shutdown, including loss of power during patient care, may occur.

Replace battery immediately with a fully charged battery. If a fully charged battery is not immediately available, remove device from service. Contact Physio-Control at 1-800-442-1142 to obtain a replacement battery as well as a spare battery.