**URGENT MEDICAL DEVICE CORRECTION – ACTION REQUIRED**
**LIFEPAK® 1000 DEFIBRILLATOR**

Physio-Control UK | Lifesaving starts here.™

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**URGENT – Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your organisation's Automated External Defibrillators (AEDs).**

Dear Valued Customer,

As a follow-up to our previous communication in 2014, Physio-Control is conducting a **Safety Alert** and **Field Correction** for all LIFEPAK 1000 automated external defibrillators (AEDs) with software version 2.42 or earlier. This action is intended to correct a software malfunction that may contribute to defibrillator batteries not being replaced when required.

Physio-Control has been made aware of several instances where a LIFEPAK 1000 AED could not provide required patient defibrillation therapy due to depleted battery status. We have learnt that this is a result of batteries not being replaced when they have reached a low or very low state of charge as indicated on the Readiness Display in the device. Our investigation has determined that confusing Operating Instructions and a device software malfunction are contributing to batteries not being replaced as required. Other contributing factors include the absence of a spare fully charged battery contrary to the recommendation in the Operating Instructions.

This Safety Alert is intended to provide clear instructions for determining the battery status until a software update is completed. Included in this notification is a quick reference card(s) to attach to your device(s).

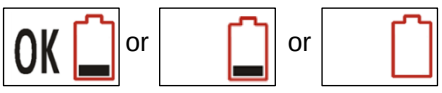
Physio-Control will be implementing a software update in all affected devices at no charge over the next few years. Updates to customer devices will be prioritised based on the age of the devices as well as the feedback provided in the response to the attached confirmation sheet. We will be contacting you in the following weeks/months in order to schedule your device updates. In the interim, please follow the instructions below to ensure readiness of your LIFEPAK 1000 device.

Our records indicate that your organisation has received one or more of the products affected by this Safety Alert and Field Correction:

**Affected Products**:

| Product | S/W |
|---|---|
| LIFEPAK 1000 Defibrillator | S/W Version 2.42 or earlier |

**Safety Information:** **WARNING Possible Device Shutdown –** Always have access to a spare, fully charged, properly maintained battery. If the Readiness Display has any of the following symbols, replace battery immediately!




**Immediate Actions:**

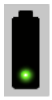
1. It is important that you forward this notification, including the confirmation sheet and quick reference cards, to all of your sites and users that may have a LIFEPAK 1000 Defibrillator. Insert this notification as an addendum to your operating instructions. You can also download copies of this notification at the following URL: www.physio-control.com/LIFEPAK1000.aspx

**Immediate Actions (continued):**

2. Check the battery status of all LIFEPAK 1000 Defibrillators for adequate battery charge:

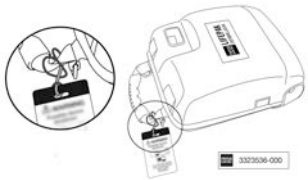
| | | |
|---|---|---|
| On the Readiness Display, if you see |   or or | Replace battery immediately! If a fully charged battery is not immediately available, take the following actions: |

A. Place an urgent order for replacement batteries, by contacting Physio-Control at 0808 258 0094 (or e-mail: Uk.customer-services@physio-control.com), 8:30 to 17:00, Monday – Friday. If you call after hours, please leave a message and you will be contacted on the next business day.
B. While the replacement batteries are in transit remove the battery from the device and check the battery status.
C. On the battery, push the grey button below the battery symbol to check the remaining charge level.


| | | |
|---|---|---|
|  | One solid LED indicates the battery is at low charge. Battery has between 5 to 25% remaining charge. | - Insert battery back into unit.<br>- Until replacement battery is received and installed, remove battery and check LED indicator daily. |
|  | One flashing LED indicates the battery is at very low charge. | ⚠ **WARNING Possible Device Shutdown, including loss of power during patient care, may occur. Remove device from service.** |

3. Please provide the status of your device(s) by completing the attached Confirmation Sheet and providing a contact for Physio-Control so that we can schedule your software update.

4. Attach the enclosed quick reference card(s) to device(s) to ensure understanding of the symbols presented on the battery status Readiness Display as shown in the following diagram:



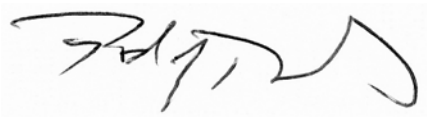
**LIFEPAK 1000 Software Update:** Physio-Control will be using the contact information you provide in the attached Confirmation Sheet to schedule the software update to your unit(s).

**Reporting issues:** Please report any product issues including the occurrence of any unexpected device shutdown or depleted battery to your local Physio-Control representative.

**Maintenance and Testing Schedule until S/W upgrade is completed**: On a weekly basis check the level of battery charge defined in Step 2 above.

Should you have any questions about this Safety Alert, please contact your local Physio-Control representative.

Sincerely,



Rod J. Rylands
Vice President, Quality
PHYSIO-CONTROL, INC.

**Attachments:**

1. Background Information/Q&A
2. Quick Reference Card(s)
3. Confirmation Sheet(s)

## BACKGROUND INFORMATION/Q&A

### Description of software malfunction being corrected:

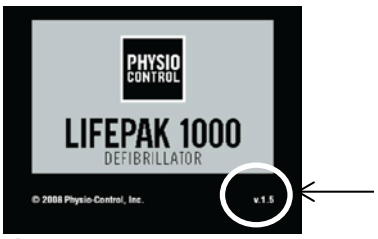
Our investigation has identified a software malfunction in the LIFEPAK 1000 defibrillator that results in the Readiness Display indicating a low battery charge when it should indicate a very low battery charge. When the battery reaches very low battery charge, the device will correctly indicate this 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.

### What if I no longer have the LIFEPAK 1000 defibrillator?

If you no longer own the LIFEPAK 1000 defibrillator(s) on the enclosed list, you are required to notify Physio-Control as soon as possible to ensure accurate tracking of the device in accordance with regulatory requirements.

### Am I affected by this issue?

All LIFEPAK 1000 defibrillators with software version 2.42 or earlier are affected by this issue, and our records indicate that one or more have been distributed to your facility. Please refer to the startup screen, shown briefly when first powering on the device to determine the software version:




Check for software version. This action applies to version 2.42 or earlier.

**Figure 1 Startup screen**