HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

LIFEPAK 1000 Defibrillator

Priority 2 – Warning

HPRA Safety Notice: SN2016(36) **Issue Date: 26 October 2016**

Linked to SN2014(31)

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Physio-Control, Inc.	V25493 V21326

ISSUE
Physio-Control has identified a software malfunction in the LIFEPAK 1000 defibrillator which results in the Readiness Display indicating a low battery charge when it should indicate a very low battery charge. As a result of this software malfunction Physio-Control has received incident reports 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. This issue was previously communicated by Physio Control through a Field Safety Notice (FSN) and the HPRA through a safety notice. Physio Control are now implementing a software update in all affected devices. The LIFEPAK 1000 devices with serial numbers below 42431905 are affected. .

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Ensure that all device users are aware of the information provided in the attached FSN and accompanying confirmation sheet and quick reference card.

2. Follow the actions outlined by the manufacturer in the attached FSN.

   Specifically;
   - Verify the readiness of the device and determine the battery's actual charge.
   - Always carry a spare fully-charged battery, as stated in the Operating Instructions.

3. Replace the battery immediately if the LED indicates that the battery is at low charge or very low charge.

4. Forward this Safety Notice to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred. Please maintain an awareness of this notice for an appropriate time period.

5. Contact the distributor to ensure that your device is updated with the new software.

TARGET GROUPS

Community First Responder Schemes	Nursing homes
County Councils	Paramedics / Advanced Paramedics
Clinics	Private Ambulance Services
Educations Centres	Private Medical Practitioners
Emergency First Responders / Emergency Medical Technicians	Risk Managers
Fire Services	Schools
Hospitals	Sports clubs
HSE Ambulance Services	Supplies Officers / Managers
Medical Directors	Town Councils
	Voluntary / Auxiliary Ambulance Services

BACKGROUND

Physio-Control has received incident reports where customers have attempted to use their LIFEPAK 1000 defibrillator and the device has shut down unexpectedly due to a very low battery. Physio-Control has determined 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.

When the battery reaches very low battery charge, the device will correctly indicate this state in the Readiness Display. However, due to a 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.
Physio-Control has confirmed 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. 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.

Physio-Control has developed a software upgrade which will be installed on all devices to correct this issue.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Physio-Control Operations Netherlands B.V. Keizersgacht 127 1015 CJ Amsterdam Netherlands	Telephone: +33-695-475-522 Fax: E-mail: uk.customer-services@physio-control.com Website: www.physio-control.com

Enquiries to the **distributor** should be addressed to:

Oxygen Care 2 Holfield Business Park Kilmancanogue Co. Wicklow Ireland	Telephone: +353-1-276-9700 Fax: +353-1-276-4970 E-mail: klong@oxygen-care.ie Website: www.oxygen-care.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: devicesafety@hpra.ie Website: www.hpra.ie