HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Life-Point Pro AED / bPLUS / mPLUS defibrillator devices and Adult Electrode Pads & Paediatric Electrode Pads

Priority 1 – Immediate Action

HPRA Safety Notice: SN2016(46) **Issue Date: 21st December 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
METsis Medikal / LifePoint	V29146 / V30286

ISSUE
METsis Medikal has become aware of an issue whereby the green status indicator on the Life-Point Pro AED / bPLUS / mPLUS may not assure that the device is ready to use. A defibrillator in this condition may be inoperable and unable to deliver a shock. This may result in therapy not being delivered to a patient. The HPRA has also become aware that some METsis Medikal electrode pads produced by a specific supplier (Medeks Medikal) in 2015 may degrade prematurely, before their expiry date. Electrode Pads manufactured from the 1st of January 2015 to the 1st of June 2016 are being recalled as a result of this issue.

ACTION OR RECOMMENDATIONS
The HPRA advises the following;

All users/owners of Life-Point Pro AED / bPLUS / mPLUS AEDs should:

1) Ensure that you read and follow the instructions provided in the manufacturer's field safety notice (FSN) (see attached).

(2) Ensure that you download the software upgrade and updated user manual for these devices from the manufacturer's website or contact your distributor to arrange the software upgrade.

(3) Acknowledge receipt of the FSN if you have not already done so.

(4) Report any concerns regarding these devices to the manufacturer and the HPRA.

All users/owners of lifePOINT Adult Electrode Pads / Paediatric Electrode Pads should:

(5) Identify affected products by referring to the attached FSN.

(6) Cease use and/or distribution of stock from the affected product batches, quarantine and return to manufacturer immediately.

(7) Acknowledge receipt of the FSN if you have not already done so.

(8) Forward this HPRA safety notice and attached FSNs to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

(9) Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advises users to exercise extreme caution when using Life-Point Pro AED / bPLUS / mPLUS defibrillator devices. The HPRA is continuing to investigate both of these issues with the manufacturer.

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	Risk Managers
Emergency Medical Technicians	Schools
Fire Services	Sports clubs
Hospitals	Supplies Officers / Managers
HSE Ambulance Services	Town Councils
Medical Directors	Voluntary / Auxiliary Ambulance Services

BACKGROUND

METsis Medikal has issued a FSN advising customers that the green status indicator on the Life-Point Pro AED / bPLUS / mPLUS defibrillator devices may not signify that the device is ready to use. The status indicator of the device may be fixed "GREEN" as a result of mechanical and electrical failures.

METsis Medikal has advised in the FSN that the status indicator on the device is an advisory indicator and that the device should be checked manually by the user to determine if it is operable / functional by pushing the On/Off button as frequently as possible.

METsis Medikal, to address this issue, has revised the user manual and also developed a software upgrade which can be downloaded from the manufacturer's website free of charge.

The HPRA has also been advised that certain electrode pads produced by a specific supplier (Medeks Medikal) are being recalled due to the deterioration of certain components, which may lead to a serious operational problem. Please see the manufacturer's FSN (attached) for advice on how to identify impacted products.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to in relation to **FSN 1** should be addressed to:

METsis Medikal
2B-1 ODTU
Teknokent Binasi
Ostim
Yenimahalle / Ankara
Turkey

Telephone: +90 (312) 3862190
E-mail: info@metsismedikal.com
Website: www.metsismedikal.com

Enquiries to in relation to **FSN 2** should be addressed to:

LifePoint

Telephone: +34 619 121 295
E-mail: lifepoint@lifepoint.es
Website: www.lifepoint.es

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