



**METsis**  
ADVANCED TECHNOLOGY SYSTEMS

**METsis Medikal Teknik Sistemler Elektronik Oto. İnş. Tur. ve San. Tic. Ltd. Şti.**  
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04.01.2017

**- URGENT -**

**Life-Point AED (Automatic External Defibrillator) Software Revision Issue**

Dear Life-Point Users,

We have identified a problem that may affect the safety and/or performance of some Life-Point Brand AED (Automatic External Defibrillator) models that we are manufacturing.

In this notification, information regarding the following issues will be provided.

- ❖ What is the problem and under which conditions it can be encountered
- ❖ Required procedures by users to prevent risks, in terms of patients and users
- ❖ Planned procedures to remedy the problem by METsis Medikal Ltd. Şti. and local distributors

**This document includes important information  
regarding the safe and proper use of your device!**

**Please review the following information with all of your employees who should have information about the content of this document. The understanding of the points to which this notification is addressed is important for the user and the patient.**

**Please keep a copy of the document together with the Operating Manual.**

METsis Medikal Ltd. Şti. has initiated a study to solve the software problem envisaged. This update and support will be available free of charge. We would like to thank you in advance for your support and understanding during the proceedings. If you need additional information or support, please contact your local METsis Medikal Ltd. Şti. representative.

With regards,

**METsis Medikal Ltd. Şti.**

General Director  
Zeki KUTLU



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<b>1. AFFECTED PRODUCTS</b>	<b>Brand:</b> Life-Point <b>Model:</b> Life-point brand PRO AED External Defibrillator Device Life-point brand bPLUS Defibrillator Device Life-point brand mPLUS Defibrillator Device
<b>2. AFFECTED PERIOD</b>	Users should perform this update if they purchased their devices <b><u>between 11th OCTOBER 2013 and 22nd DECEMBER.</u></b>
<b>3. REMARK</b>	There is one status indicator available on the Life-Point Automatic External Defibrillator devices.  This is status indicator turns to red if there are any faults identified during the low battery level or software/hardware testing process. If the battery level is normal or there is no problem at the end of the daily self-test, the indicator remains green. This green color indicates that the device is working, i.e. it is active.
<b>4. DESCRIPTION OF PROBLEM</b>	It was identified that as a result of the momentary communication interruption caused by the software of Automatic External Defibrillator devices during the self-test procedure, the device is stuck in stand-by, during this process, BIOS battery is depleted, device is locked-up due to processor being subjected to low supply voltage during depletion of BIOS battery and the warning indicator is stuck in GREEN, not switching to RED by full depletion of BIOS battery. The self-test is performed by the main processor and cannot control the indicator position in the event of possible instantaneous communication and lockup problems. This problem is not a mechanical problem, and in the case of a possible communication error between the components, the indicator that is mentioned is out of order.  <b>NOTE:</b>  This mentioned issue is caused by BIOS battery. The proposed problem results in depletion of BIOS battery. To prevent encountering this possible case, software update is sufficient.
<b>5. POTENTIAL HAZARD</b>	Despite the indicator being in GREEN, due to device not being operational, intervention during a case may be delayed or not happen.
<b>6. SOFTWARE UPDATE REQUIRED TO BE PERFORMED BY OUR USERS</b>	Esteemed Users,  <b><u>If you have the following devices purchased between 11th OCTOBER 2013 and 22nd DECEMBER;</u></b> Life-point brand PRO AED, Life-point brand bPLUS, Life-point brand mPLUS; please perform a software update as indicated below.  Software update can be found on the Metsis website (Turkish; <a href="http://www.metsismedikal.com">http://www.metsismedikal.com</a> ) and English, ( <a href="http://www.metsismedikal.com/en/">http://www.metsismedikal.com/en/</a> ) "Announcements" section.



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	<p>You can reach the announcements section directly from the link below. Turkish; <a href="http://www.metsismedikal.com/duyurular/">http://www.metsismedikal.com/duyurular/</a> English, <a href="http://www.metsismedikal.com/en/news/">http://www.metsismedikal.com/en/news/</a></p> <p>You are required to perform updating by downloading the software file found in "Life-Point Current Software" section.</p> <p>You can find the "Software Installation Visual Explanation Video" right under the software file.</p> <p>If you require additional information and support concerning the software update procedure, please contact your local METsis Medikal Ltd. Şti. representative or call us from +90 312 386 21 90, or e-mail to the <a href="mailto:service@metsismedikal.com">service@metsismedikal.com</a> address. You will be provided help shortly, free of charge.</p> <p>Following the installation of software onto the device, please contact your local user and inform them about performing the installation procedure.</p>
<b>7. Software Update Validity and Reliability</b>	<p>The mentioned software update was tested on the AED defibrillator devices.</p> <p>Tests performed are given below:</p> <ul style="list-style-type: none"><li>▪ <b>Daily Wake Up Tests:</b><ul style="list-style-type: none"><li>- Creation of file records in daily wake ups have been checked.</li><li>- Battery operating with above 10 VDC and below 10 VDC and battery, high voltage card and ecg card status have been checked.</li><li>- Pulses applied on Flip Dot were observed by oscilloscope.</li></ul>No errors were encountered in the daily wake up tests performed and validity of the data were verified.</li><li>▪ <b>Manual Starting Tests:</b><ul style="list-style-type: none"><li>- Device is operated by ON/OFF button and whether it started immediately was checked. Waiting time during starting up, buzzer sound and playing time was confirmed to be without delay.</li><li>- Battery critical levels were simulated and warning mechanisms were tested.</li><li>- Flip Dot reactions in case of removal of battery while the device is operational and operation of device without battery were tested. No problems were observed in the warning mechanisms.</li><li>- Potential communication errors related with ECG card, high voltage card and flash disk were simulated.</li></ul>Warning mechanisms were checked and validity of these were verified.</li><li>▪ <b>File Deletion Tests</b></li></ul> <p>It has been tested whether the files created in the device are changed by default or if the contents are accidentally partially or completely erased, the files are created again with default values. Flip Dot reactions were tested during these procedures. No problems were encountered during the tests performed.1</p>



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▪ **Routine Tests of the Device**

After starting the device, shockable and non-shockable rhythms were applied.

Analysis - CPR - Shocking cycle of the device was tested.

Within this cycle;

Analysis time, accuracy, duration, CPR time, number, repetition,

Operational accuracy of LEDs,

The application of different signals to both adult and pediatric pads at different amplitudes,

Humidity, temperature, vibration tests,

Charging time for 50, 150, 200 Joules,

The control and warning mechanisms of the device have been checked in the absence of shock application, motion, connectors or pads.

All possible scenarios shown above are simulated and the tests mentioned above are applied and the results are evaluated.

As a result of the tests performed, no software or hardware related problems were encountered.

As a result of these tests, it is confirmed that the device works with stability and the software update is valid.

**METsis Medikal declares that the mentioned problem will not be encountered with this software update and thanks you esteemed users for your understanding.**

With regards,

**METsis Medikal Ltd. Şti.**

General Director  
Zeki KUTLU