



METsis
ADVANCED TECHNOLOGY SYSTEMS

METsis Medikal Teknik Sistemler Elektronik Oto. İnş. Tur. ve San. Tic. Ltd. Şti.
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05.01.2017

- URGENT -

Replacement of AED Pads of Life-Point Automatic External Defibrillator

Dear Life-Point Users,

It has been identified that MEDEKS brand pads used with Life-Point Brand AED (Automatic External Defibrillator) defibrillators, which we are the manufacturer, are deformed depending on time.

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

- ❖ What is the problem and which products are involved
- ❖ 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. will replace all MEDEKS brand disposable defibrillator pads with new pads from the new supplier free of charge for the resolution of the problem as prescribed. We ask you to make this change as soon as possible through your local distributors. 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,

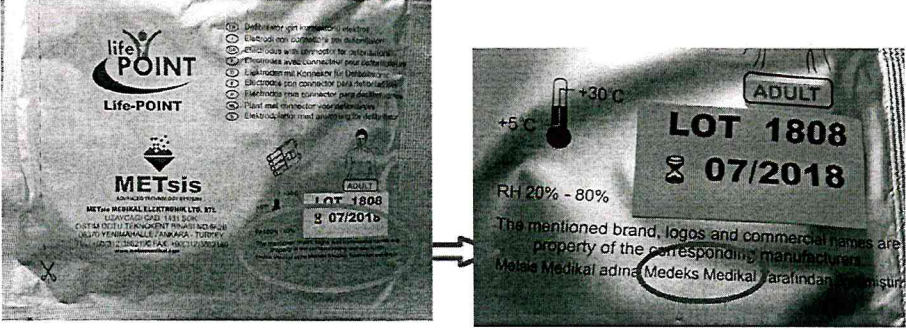
METsis Medikal Ltd. Şti.

General Director
Zeki KUTLU



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<p>1. AFFECTED PRODUCTS</p>	<p>Brand: MEDEKS Model: All MEDEKS brand disposable defibrillation pads</p> 
<p>2. AFFECTED PERIOD</p>	<p>All MEDEKS brand defibrillation pads</p>
<p>3. REMARK</p>	<p>The mentioned products are MEDEKS brand disposable defibrillation pads which do not belong to our company.</p>
<p>4. DESCRIPTION OF PROBLEM</p>	<p>MEDEKS brand disposable defibrillation pads supplied with Life-Point brand automatic defibrillator devices have been found to undergo chemical deformation depending on the time and date of expiration.</p>
<p>5. REPLACEMENT OF PADS</p>	<p>Esteemed Users,</p> <p>Although our company is not a pad manufacturer, the pads are damaging our brand-name image and reliability as they are supplied with our own Life-Point defibrillator devices. As of 18.09.2015, MEDEKS brand pads have been discontinued in our devices. By this date, we started to work with a different supplier and the confidence of our company was gained by carefully examining the bio compatibility and other test reports about the pads.</p> <p>If you have MEDEKS brand disposable defibrillation pads, replace all MEDEKS brand disposable pads with new pads from the new supplier which will be provided by our company free of charge, by contacting the local distributor.</p> <p>Please return your MEDEKS brand pads to local distributor during replacement.</p> <p>If you require additional information and support concerning the replacement procedure, please contact your local METsis Medikal Ltd. Şti. representative or call us from +90 312 386 21 90, or e-mail to the service@metsismedikal.com address. You will be provided help shortly, free of charge.</p>



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METsis Medikal declares that the mentioned problem will not be encountered with these new pads and thank you esteemed users for your understanding.

With regards,

METsis Medikal Ltd. Şti.

General Director
Zeki KUTLU