PREVECO™

THE PREVENTION COMPANY

LIFE-POINT PRO AED

OPERATING MANUAL

LIFE-POINT PRO AED

Thank you for purchasing this life-saving device.

PLEASE READ THIS MANUAL BEFORE FIRST-TIME USE.

Read this operating manual carefully and thoroughly before operating the device for the first time.

The Guarantee is valid as long as operating instructions and warnings listed herein are followed.

The Manufacturing Company, METsis Medical and PreveCo BV shall not be responsible for any direct or indirect injury, disability injury arising from operating the device without reading the operating manual or operating the device without following the security measures specified in this manual or arising from operation, maintenance and / or repair of the device by unauthorized personnel.

The accompanying documents of the device, service manual and other technical documents shall not imply that maintenance, calibration or modification on the device is allowed.

The user shall be subject to all responsibilities arising from operation of Life-Point Pro AED device without following the directions indicated in this manual. In case of questions contact your importer/distributor.

METsis Medical and PreveCo BV shall have right to make any amendments on this operating manual.

Manufacturer:
METsis Medical
Tech. Sys. Ltd. Comp.

Importer/distributor :
PreveCo BV

DECLARATION OF CONFORMITY

METSİS MEDICAL TECHNICAL SYSTEMS ELECTRONICS
AUTO. CONS. TUR. AND IND. TRADE LTD. COMP.
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Tel: +(90) 312 395 77 70 (pbx) - Fax: +(90) 312 395 77 72
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Product List: Life-Point Pro AED Defibrillator (Class II B)
We hereby declare that the product identified above is manufactured in conformity with the norms of Medical Devices Directive - 93/42/EEC.

TOEGEPASTE NORMEN

EN 980:2003	Graphical symbols for use in the labelling of Medical
EN 1041:1998	Title Identifier, Information supplied by the manufacturer with medical devices
IEC 60601-1 :1998	Medical Electrical Equipment – General requirements for safety
IEC 60601-1-4 :1997	Medical Electrical Equipment - Particular requirements for the safety of cardiac defibrillators
IEC 60601-2-4: 2002	Medical Electrical Equipment - Particular requirements for the safety of cardiac defibrillators
ISO 14971-1: 2000	Risk Management
ISO 10993-1:1997	Biological Evaluation of Medical Devices
TS EN475:1997	Electrical Alarm Signals of Medical Devices
EN 60601-2-27:1994	Particular requirements for the safety of electrocardiographic monitoring equipment

Notified Body / Number: MEYER / 1984

Starting Date of “CE” Marking:
Ankara - Turkey

Zeki KUTLU
General Manager

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1. SAFETY MEASURES AND GENERAL NOTICES

- Life Point Pro AED must be operated by competent personnel specifically trained for such use.
- Life Point Pro AED should not be used for people reacting when shocked or for people with normal respiration.
- Life Point Pro AED is a device of electroshock for therapeutic purpose. Electroshock may bring serious damages for operators and people nearby. During electroshock, operators or people nearby must not touch the patient by no means.
- Life Point Pro AED is a device designed for use on unconscious and refractory people. If the patient can react or is conscious, never use Life Point Pro AED for therapeutic purposes.
- Touching the patient during the analysis stage of the treatment may result in failure of the diagnosis period. Do not touch patient during an ongoing analysis. Device will inform you when it is free to touch the patient.
- Life Point Pro AED must absolutely be placed suitably. It is essential to strictly follow the directions for placing PAD indicated in the label and shown during the training.
- It is of vital importance that pads are properly in contact with patient's skin. There should not be air gap between sticking pad and skin. Pads not properly in contact with skin may prevent an efficient treatment or may lead to overburn on patient's skin during electroshock for therapeutic purpose. It is normal that patients may have rashes on their skins.
- The manufacturing company shall not be deemed responsible for any intervention, maintenance, repair or modification of the device by unauthorised person and such an activity voids the guarantee.
- Metsis Medical or its official distributors shall not be obliged to make maintenance / repair operations under warranty for following cases:
    - *Unauthorized modifications on the device.*
    - *Use of non standard parts.*
    - *Operation of the device by the user not following the operating instructions or directions indicated in this manual,*
    - *Scratching, manipulating, misusing or changing the serial number of device.*
    - *Not storing or operating the device according to the environmental conditions of the device, electrodes or batteries.*

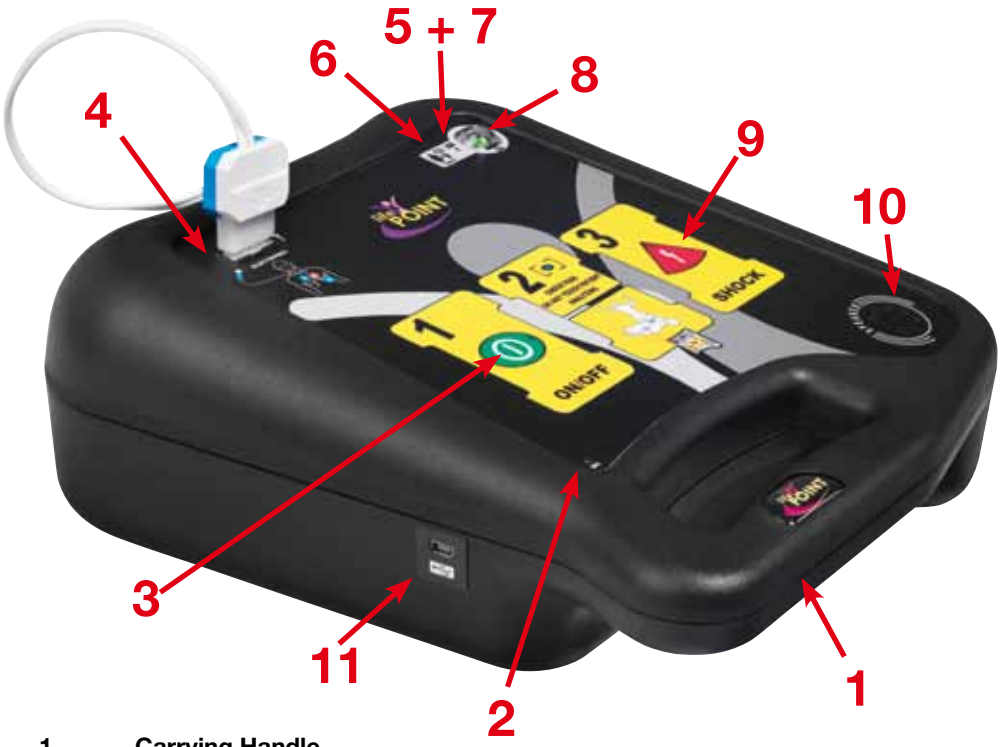
SAFETY MEASURES AND GENERAL NOTICES

- All parts must be replaced by original parts when necessary for safe operation of the device.
- It is necessary to verify that technical safety of the device conforms to the standards of the device after each maintenance or repair operation.
- A report should be kept for any maintenance, modification and testing and such reports should be filed.
- Safe operation of the medical devices requires consideration and proper maintenance. Therefore, it is recommended for the users to control the device for normal and safe functionality before each use for the safety of the user and patient.
- Using the device in environments with flammable anaesthetic materials constitutes a risk of explosion.
- Make sure the AED is placed in a heated cabinet in public areas outsite.
- The battery is sensitive for low temperatures. Make sure the battery will not go under 0° to ensure full power. Lifetime of the battery is guaranteed with a temperature of 20°.
- Do not contact the device with patient during discharge.
- Separate the devices without defibrillator protection from patients.
- This device which has a dangerous electric current output must be only operated by qualified personnel.
- There is a risk of electroshock within the device, do not open inside. Only authorized service may make interventions for the device.
- PAD centre should be kept in a secure place. Place the PAD device near a telephone in order to enable the user to call the emergency services and use PAD device without spending time.
- Make necessary arrangements for access to the device anytime. Inform the probable personnel to operate Life Point Pro AED device of its place.
- Do not immerse Life Point Pro AED device into water or any kind of liquid. Its contact with liquid may damage the device or may lead to fire or electroshock.
- Do not clean Life Point Pro AED device with abrasive materials, detergents or acetone.

2. SYMBOLS AND FIGURES

SYMBOLES	SIGNIFICATION
	On / Off Button
	Shock (Defibrillation) Button
	Error
	Battery Indicator
	Pediatric Pad Indicator
	Class II B
	Warning
	High Voltage
	Manufacturer
	CE Marking In Accordance With Medical Devices Directive

3. APPEARANCE AND FUNCTIONS OF DEVICE

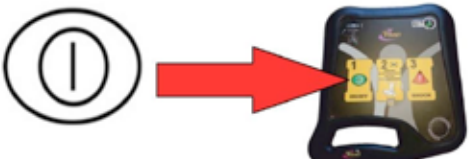


1. Carrying Handle
2. Microphone
3. On / Off Button and Led
4. Disposable Electrode Input (PED)
5. Analysis Warning Indicator
6. Paediatric Pad Alert
7. Error and Failure Warning Indicator
8. Batterijstatus indicator
9. Defibrillation (shock) Button
10. Speaker
11. USB port

4. DIRECTIONS FOR QUICK START

Use device only when the patient is unconscious, unresponsive and on patients with no respiration!

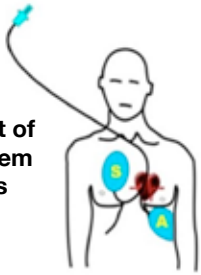
1



Turn the device on through pressing on / off button.

2

Take the sticky pads out of the packet and place them on the patient's chest as shown in the figure.



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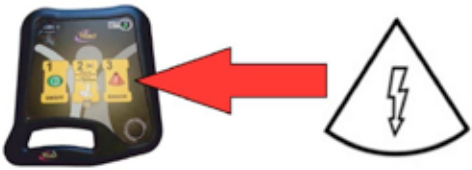


If defibrillation is suggested, press (defibrillation) schock button.

5. CPR METHOD AND FEATURES OF DEVICE

The text below is a short list of CPR guidlines 2010 following by the European Resuscitation Counsil (ERP).

Check the patient. If the person does not react but if you are not sure whether the patient suffers a cardiopulmonary arrest, use Life Point Pro AED defibrillator.

STEP 1 Make sure you are in a safe environment

STEP 2 Check the patient and his / her reactions.

STEP 3 If the patient does not react, call Emergency Service first.

STEP 4 Put the patient's head so that he / she can breathe easily and check his / her respiration.

STEP 5 When the patient is not reacting call the emergencynumber.

STEP 6 Open the patient's chest to enable easy intervention. If necessary, cut the clothing by means of scissors. Ensure that the chest of the patient is dry and clean. If not, dry and clean this part. If necessary, shave the locations where you will place the sticky pads by the means of blades.

STEP 7 Place the sticky pads on the patient's chest as shown in the figure (10- Attaching Positions For Disposable Pads). Do not attach the sticky pads inversely. Ensure that the pads are attached properly.

STEP 8 The device automatically checks whether the pads are attached properly or not. If problem is detected, red led light. If no problem is detected, device automatically analyses ECG signal of the patient. Start giving CPR (heart massge and resuscitation).

P.S.: If the user plugs the connector to the device prior to these commands and simultaneously places the pads on the patient's chest, the device shall automatically skip these steps and moves directly to the analysis step.

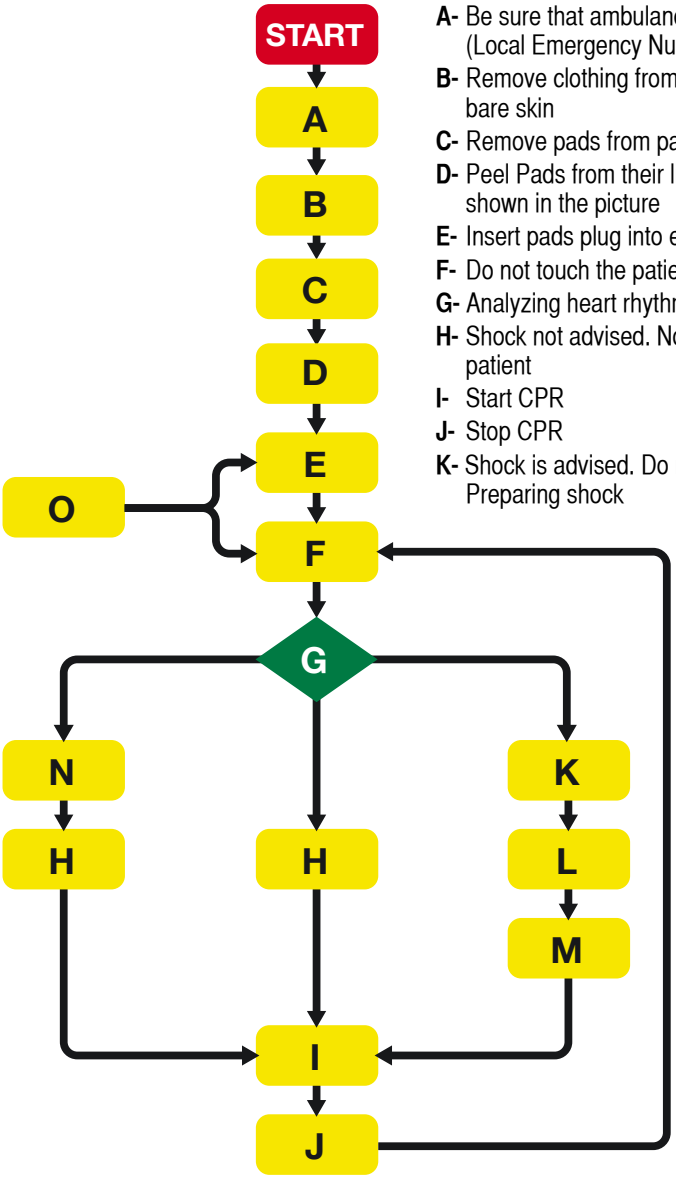
STEP 9 The device analyses ECG signal of the patient in <10 seconds and decides whether defibrillation is performable or not. At the same time, the device informs and directs the user with voice command.

STEP 10 The device warns the user not to touch the patient through voice command and informs the user if defibrillation is necessary through voice command again. Simultaneously, it starts automatic charging. When it is ready for defibrillation, the device guides the user to press the shock button. Before pressing shock button, it is ensured that the operator is not in contact with the patient. Defibrillation is performed through pressing the shock button.

STEP 11 The device analyses ECG signal of the patient again automatically after electroshock. The airway and respiration of the patient is checked if the device decides not to perform defibrillation. If necessary, CPR is performed.

NOTE: The device has internal memory. It is possible to load ECG signal and voice records into the computer through software which may be provided by the manufacturer. Upon demand, it is possible to print the date out through a printer.

6. DEFIBRALLATION FLOW CHART



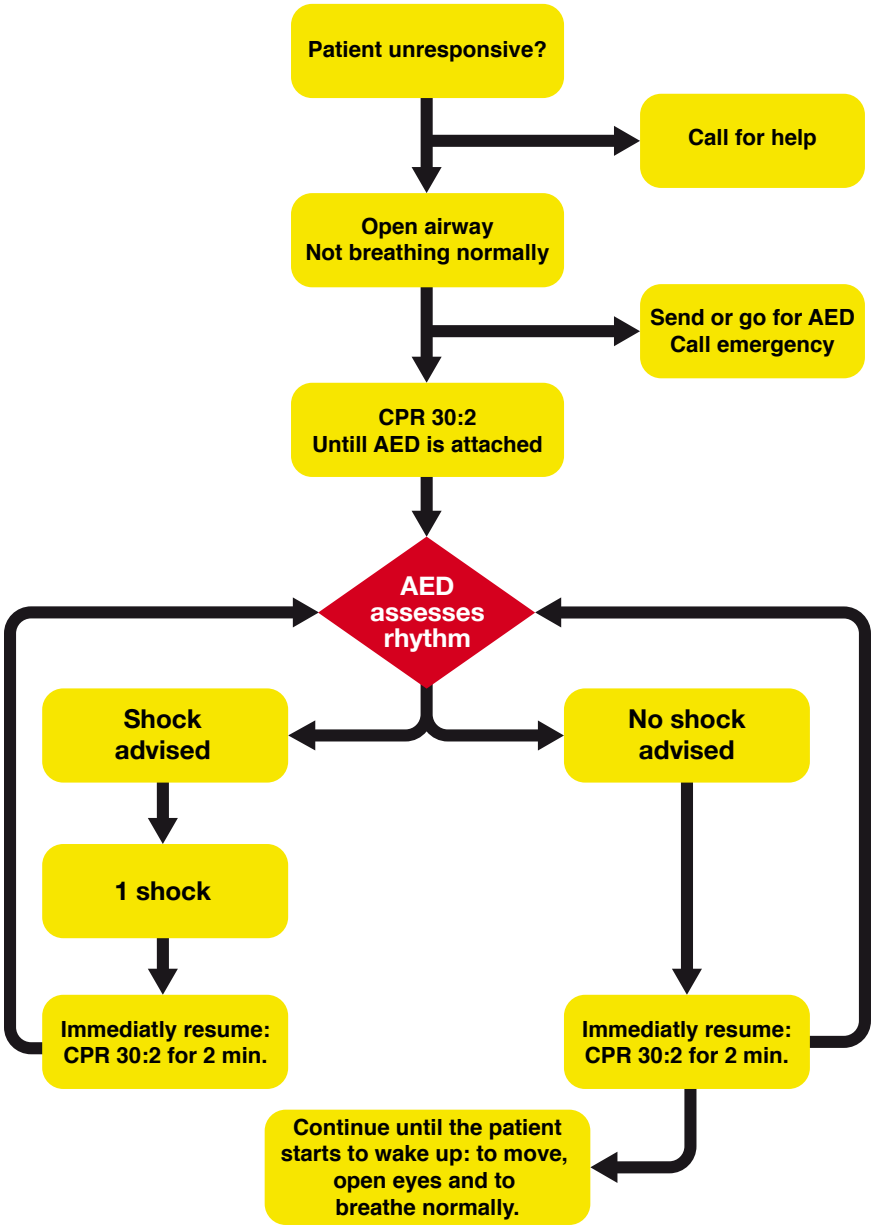
A- Be sure that ambulance has been called. (Local Emergency Number)
B- Remove clothing from patient's chest to expose bare skin
C- Remove pads from package
D- Peel Pads from their liner and place exactly as shown in the picture
E- Insert pads plug into electrode socket
F- Do not touch the patient
G- Analyzing heart rhythm
H- Shock not advised. Now you can touch the patient
I- Start CPR
J- Stop CPR
K- Shock is advised. Do not touch the patient. Preparing shock
L- Press shock button now
M- Shock delivered. Now you can touch patient
N- Pacemaker detected
O- Check electrode pads (if any problem)

ALERTS:

- **Low Battery**
- **Pacemaker detected**
- **Stop Motion**
- **Contact technical service**

Continue until the patient starts to wake up: to move, open eyes and to breathe normally.

7. CPR (CARDIOPULMONAY RESUSCITATION) DIRECTIVE AHA/ERC 2010



8. FUNCTIONAL INSTRUCTION

- **1. General Use**
  Life-Point Pro AED device is designed to keep alive patients suffering a heart attack through directing the user with voice commands. Life-Point Pro AED device automatically analyses ECG signal of the patient and decides whether defibrillation is performable or not.

- **2. Paediatric Use**
  Paediatric sticky pads must be used for child patients younger than 8 and lighter than 25 kilograms. The device automatically detects paediatric pads and performs Defibrillation at 50 – 50 – 50 Joule or a different presentable joule value.
  P.S.: If the user plugs the paediatric pad connector, device detects paediatric pad automatically and yellow led lights.

- **3. Power Demand and Operating Conditions**
  Life-Point Pro AED operates with 12V 4500mA LiMnO2 battery and in environments with the temperature of 0 – 50°C and with a relative humidity of % 10 - 95.

- **4. Device Life Cycle**
  The device has a life cycle of maximum 2500 discharging times on the condition that it is operated in line with the requirements indicated in this manual.
  The battery lifetime is 5 years. An AED with a full battery can monitor the victim for 10 hours or give 100 shocks.

- **5. Maintenance**
  The device must be cleaned with a damp – dry cloth. Do not clean the device and patient cable with abrasive / solvent solutions. The device must be cleaned in accordance with cleaning directions after each use. Do not turn the device on in case of failure detected, when the failure led is on or under a suspicious condition and contact with an authorised Life-Point technical service.

Careful: this light is a green indicator, this is not a green light.

- In case of a red indicator contact your distributor

- **6. Disinfection**
  Use non abrasive / non solvent solution for disinfection (for instance; 70% alcohol, 0,5% chlorhexidine and 29% water, acetone). Do not use disinfectants such as Fenol disinfectants, hexachlorophene since they may contaminate the next patient.

- **7. Battery Use**
  The device operates with a single use LiMnO2 battery. Its life cycle is 5 years.
  The device is programmed to test itself in daily. If the device detects a low battery level, it warns the user through the with red battery status indicator on the device. The device must be controlled upon such a warning. If necessary, contact with an authorized service. The device can monitor the patient for 10 hours or perform 100 typical shocking operations with a full battery.

If the battery is low the indicator will turn red as a warning for the user. If so please contact your Life-Point Pro distributor.

- **8. Technical Characteristics and Replacement of Batteries**
  Remove the backside battery cover when the device is off. Take the empty battery out of the battery compartment carefully and then place and original 12V 4500mA LiMnO2 Life Point battery with the same specification into the compartment. After placing battery carefully, close the cover.

Note: when battery pack is changed with new one, battery indicator turns to "green" automatically after turn on the device.

9. LIFE-POINT PRO AED RHYTHM AND ECG ANALYSIS PERFORMANCE

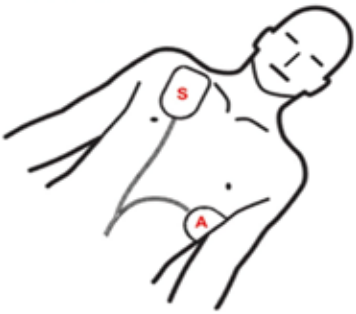
Life Point Pro AED analyses ECG rhythm of the patient and detects whether rhythm is suitable for electroshock.

This system enables the users without enough information for analysing ECG signal to make intervention for patients suffering a cardiopulmonary arrest.

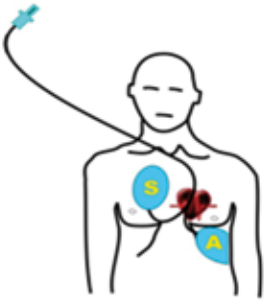
LIFE-POINT PRO AED ECG SIGNAL ANALYSIS AND DETECTION PERFORMANCE TABLE

RHYTHMS	MINIMUM TESTING SAMPLE	PERFORMANCE TARGET	OBSERVED PERFORMANCE
Shocking Rhythm VF	200	> 90 % Sensitivity	> 90 %
Shocking Rhythm VT	50	> 75 % Sensitivity	> 75 %
Non-Shocking Rhythm NSR	100 Minimum	> 99 % Sensitivity	> 99 %
Non-Shocking Rhythm AF, SB, SVT, Heart Block, PVC	30 (Optional)	> 95 % Sensitivity	> 95 %
Non-Shocking Rhythm Asystole	100 (For Security)	> 95 % Sensitivity	> 95 %
Non-Shocking Rhythm All other Rhythms	25	> 95 % Sensitivity	> 95 %

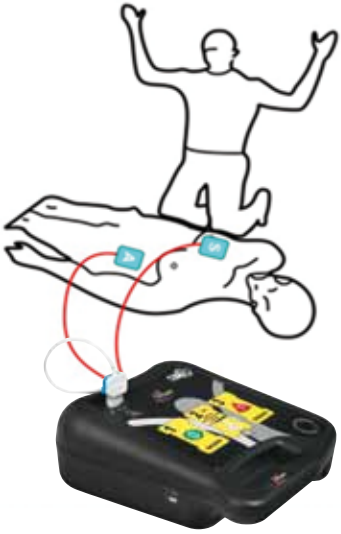
10. ATTACHING POSITIONS FOR DISPOSABLE PADS



Take the sticky pads out of the packet carefully.



Place the pads on the chest of the patient as shown in the figure.



Do not move the patient for proper analysis after attaching the pads.

11. TROUBLESHOOTING METHODS

TECHNICAL PROBLEM	RECOMMENDED ACTION
The error / fault LED indicator flashes red continuously during resuscitation. *(the red LED flashes continuously and repeatedly gives the signal "Check electrode pads".*	**Check the pads** Make sure the pads are correctly applied according to the image on the pads or review the image in Chapter 4: instructions for quick start. Make sure the plug of the pads is good attached to the socket on the AED.
If the red fault LED is on *(the red LED blinks every three seconds and the device gives the command "call technical service" every two minutes.*	**Activate the test mode:** Press and hold the On/Off button for 6 seconds to activate the manual test function, then turn the device on normally. If the device detects a fault during the manual test and continues to signal the command "call technical service" and the red LED is on, contact Life-Point technical service. P.S.: If the fault in the device is not detected for long periods, the device battery will be depleted dye to the fault alert signals and the battery indicator will turn "red".
If the battery indicator is "red" *The battery may be low.*	**Change the Battery.** While the device is switched off, open the battery cover behind the device using screwdriver and remove the battery. Remove and separate the battery from the connector. Place the new battery into the connector and place in the socket. Carefully fix the battery cover using a screwdriver. Turn the device on using the On/Off button. The "Red" battery indicator must automatically turn "green". If the AED detects a fault after replacing the battery, the red error / fault LED indicator will flash. Follow the instruction (as described above) to activate the test mode manually.

12. TECHNICAL SPECIFICATIONS OF DEVICE

Dimensions	3,7 x 11 x 9,8 inches
Charging Time at 150 J	< 10 seconden
Weight (Battery Included)	4lb 3oz
Operating Mode	Automatic
ECG Analysis Period	10 seconds
Wave Form	Truncated Biphasic Wave Form
Energy steps	Adult: 150 J -150 J -200 J / Child: 50 J-50 J -50 J
Impedance Measurement	Yes
Impedance Range	25 – 100 Ohm
Maximum discharging number	100 (at 20°C with full battery)
Derivation	II
ECG Bandwidth	2 – 25 Hz
Battery	LiMnO2 (12V 4500mA)
Autocontrol	Daily and at start
Autocontrol Scope	Battery, Internal Electronics, Software
Class (93/42/EEG)	II B
Operating Conditions	Between 0°C - 50°C and % 10 – % 95 humidity
Storage Conditions	Between -20°C and 60°C
Data Transfer	Metsis AED Software (Mini USB)
Minimum Computer Requirement	Windows XP – Windows Vista – Windows 7 Pentium or higher VGA Monitor or higher CD-ROM Driver USB Port 2 Gb Free Disk Space

*** METsis Medical has right to amend the values written above any time.**

UNPACKING AND PREPARING YOUR LIFE-POINT PRO AED

1. Open the box and take the Life-Point AED Pro and protective case out.
2. Read the instructions carefully.
3. Verify that all users are aware of the operation of the Life -Point Pro AED.
4. Check the functions of your Life-Point Pro AED ; check the battery status indicator is green, turn the AED on and listen for a English Voice command (default is Dutch). Turn the AED off again. Check the expiration date of the pads.
5. Mount the AED in an appropriate place. Your distributor provides convenient mounting brackets and indoor and outdoor cabinets.
6. Be sure the AED has the right temperature. This is important for the lifetime of the battery.

13. WARRANTY LIFE-POINT PRO AED:

The usual statury warranty period amounts five years for the battery. This is only given when the AED is stored at 20° and unused. The warranty period will start on the purchase or delivery date of the AED.

The Life-Point Pro AED is delivered with a padset for adults, the expiration date of each set is listed. Until this date unused pads are guaranteed. After this date, the pads should not be used and should be exchanged for new pads. Check your purchase contract if free pads are provided.

WARRANTY EXCLUSION:

Metsis and PreveCo BV will decline servicing, repairs or replacement of parts under warranty in the following situations:

1. If unauthorized changes or modifications have been carried out.
2. If no original parts or replacement parts are used.
3. If the device is used improperly or not according to the specifications.
4. If the serial number has been removed, is unreadable or otherwise inappropriate changes have been made.
5. If the device, the pad's or battery are stored in a wrong way (including non-heated outdoor enclosure) or used for purposes not
6. suited for the Life-Point Pro AED.
7. When the packaging material of the pad's will not be returned.
8. If the Life-Point Pro AED is tested with unapproved devices or methods.
9. If a repair during the warrantyperiod is uneconomical, or our efforts to solve the problem fail, we have the right to exchange the entire or a part of the device.

SUBMIT WARRANTY CLAIM:

Warranty claims can be submitted via your distributor.

After the proof of purchase has been submitted the warranty claim will be registered. PreveCo checks the registration of your Life-Point AED Pro in our database. Immediately afterwards we will contact you for repair or replacement.

PREVECO™

THE PREVENTION COMPANY

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