Life-POINT

bPLUS

AED

Automatic External Defibrillator

CE
1984

IMPORTANT !!!

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

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

The Manufacturing Company, METsis Medical 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 bPLUS AED device without following the directions indicated in this manual.

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

Visit METsis Medikal Website periodically to check if there is any modification / revision in the Manual.

METsis Medical
Tech. Sys. Ltd. Comp.

Model: bPLUS AED Rev: 02 Rev Date: 25-07-2016

EC DECLRATION OF CONFORMITY

Conformity (Beyan)

The undersigned Company declares under its sole responsibility that the item of products specified below satisfies the essential requirements of the EC Medikal Devices Directive 93/42/EC with amendment 2007/47/EC directive which are apply to it.

Product Ürün	Type-Models / Tip-Model	Product Name / Ürün Adı	GMDN Code / GMDN Kodu
	Life-Point AED bPlus Defibrillator (Life-Point AED bPlus Defibrilatör)	**Automatic External Defibrillator without Monitor** (Monitörsüz Otomatik Harici Defibrilatör)	37805
	Life-Point AED mPlus Defibrillator (Life-Point AED mPlus Defibrilatör)	**Automatic External Defibrillator with Monitor** (Monitörlü Otomatik Harici Defibrilatör)	37805
	Life-Point Plus Defibrillator (Life-Point Plus Defibrilatör)	**External Defibrillator** Harici Defibrilatör	17882
	Life-Point PRO AED Defibrillator (Life-Point PRO AED Defibrilatör)	**Automatic Defibrillator** (Otomatik Defibrilatör)	35972
	Life-Point PRO Defibrillator (Life-Point PRO Defibrilatör)	**Biphasiz / Monophasic Defibrillator** (Bifazik / Monofazik Defibrilatör)	37806
	Life-Point Basic Defibrillator (Life-Point Basic Defibrilatör)	**External Defibrillator** (Harici Defibrilatör)	37806

Brand Name / Manufacturer (Marka/ Üretici)

Life Point - METsis Medikal Teknik Sistemler Elektronik Oto. İnş. Tur. ve San. Tic. Ltd. Şti.

Serial Number (Seri No)

Classification (Sınıflandırma)

Class IIb 93/42/EEC - Amd 2007/47/EC Annex IX Rule 9
(Sınıf IIb 93/42/EEC - Amd 2007/47/EC Rev.IX Kural 9)

Applicable EU Directives (Uygulanan AB Yöntemleri)

93/42/EEC Medical Devices Directive with amendment 2007/47/EC
(93/42/AT Tıbbi Cihaz Yönetmeliği, 2007/47/EC Yönetmeliği değişiklikleri ile)

EC Certificate Start Date and End Date (CE Belgesi Başlangıç ve Bitiş Tarihleri)

Start Date (Başlangıç Tarihi): 20.03.2015 **End Date** (Bitiş Tarihi): 19.03.2018

EC Certificate No (At Belgesi No)

1984-MDD-10-022 / Rev: 5

Notified Body (Onaylanmış Kurum)

KIWA MEYER BELGELENDİRME HİZMETLERİ A.Ş. **(CE-1984)**
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1- SAFETY MEASURES AND GENERAL NOTICES

- Life Point bPLUS AED must be operated by competent personnel specifically trained for such use.
- Life Point bPLUS AED should not be used for people reacting when shocked or for people with normal respiration.
- Life Point bPLUS 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 bPLUS AED is a device designed for use on unconscious and refractory people. If the patient can react or is conscious, never use Life Point bPLUS 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.
- 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.
- Life Point bPLUS 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.

❖ 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.

❖ 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 bPLUS AED device of its place.

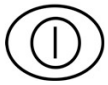
❖ Do not immerse Life Point bPLUS AED device into water or any kind of liquid. Its contact with liquid may damage the device or may lead to fire or electroshock.

❖ Do not clean Life Point bPLUS AED device with abrasive materials, detergents or acetone.

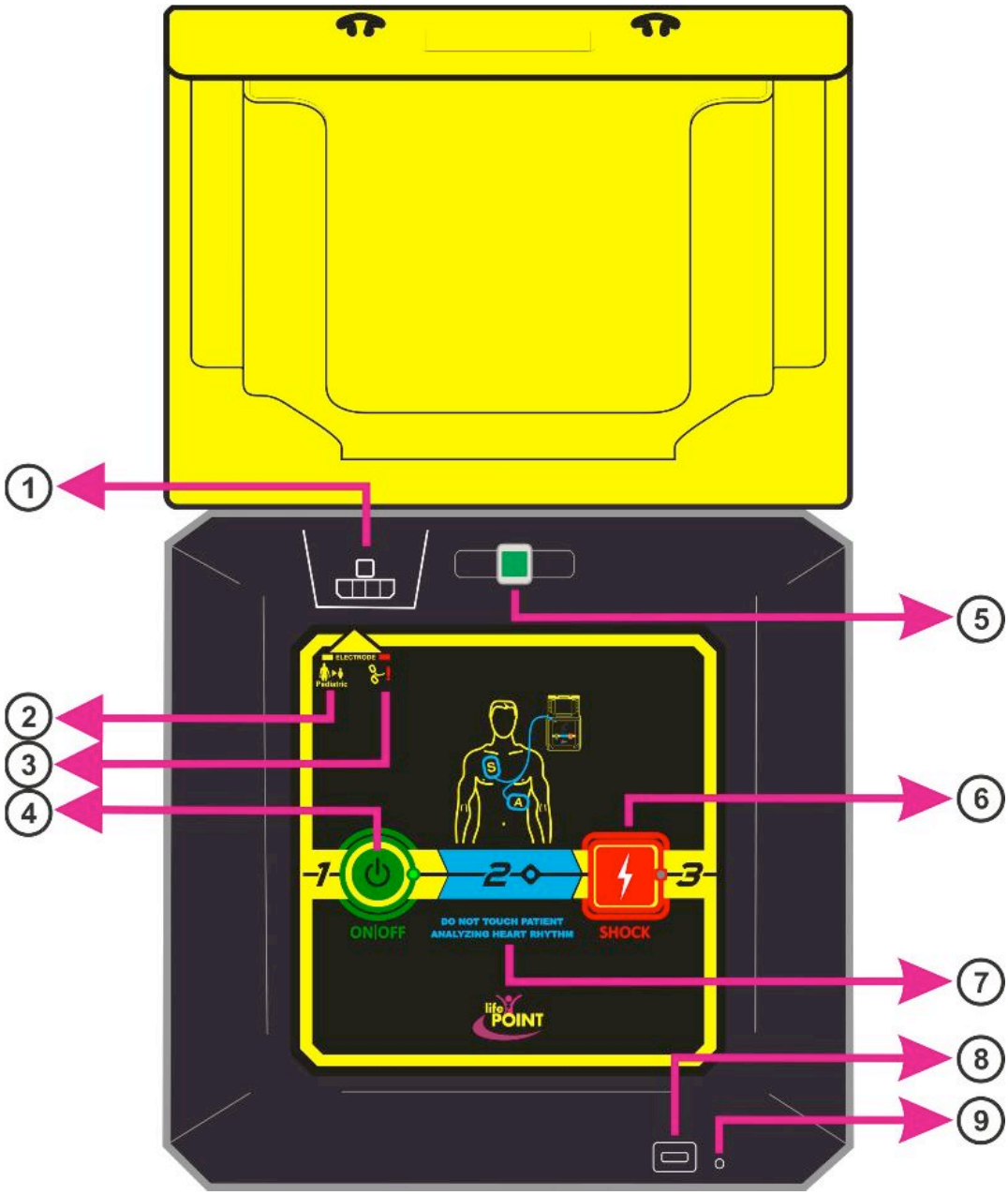
❖ The status / battery indicator at the upper right corner of the device describes that the device works when it is GREEN and there is a failure if it is RED. The GREEN status/battery indicator is somehow recommendation and it does not assure the operations of the device 100%.

- ❖ METsis Medikal recommends to calibration should be performed once a year
- ❖ 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.
- ❖ Visit METsis Medikal Website periodically to check if there is any modification / revision in the Manual

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
	Type BF

3- APPEARANCE and FUNCTIONS OF DEVICE

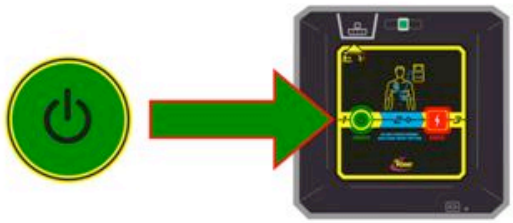


1- Disposable Electrode Input
2- Paediatric Pad Indicator
3- Electrode Warning Indicator
4- On / Off Button and Led
5- Status / Battery / Failure Warning Indicator
6- Defibrillation (shock) Button
7- Analysis Warning Indicator
8- USB Port
9- Microphone

4- DIRECTIONS FOR QUICK START

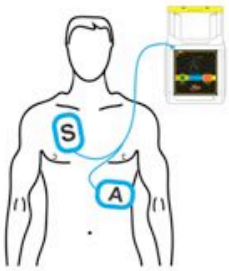
Use device only when the patient is unconscious, unresponsive and on patients with no respiration!

1



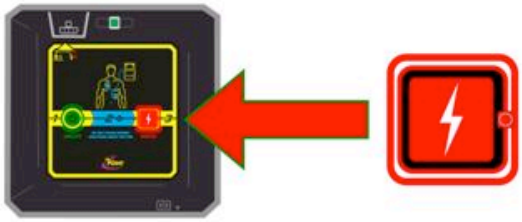
Turn the device on through pressing ON/OFF button

2



Take the sticky pads our of the package and place them on patients chest as shown in the picture

3



If defibrillation is advised press SHOCK button

5- GENERAL OPERATION AND FEATURES OF DEVICE

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 bPLUS AED defibrillator.

1st STEP
Check the patient and his / her reactions.
2nd STEP
If the patient does not react, call Emergency Service first.
3rd STEP
Put the patient's head so that he / she can breathe easily and check his / her respiration.
4th STEP
When you get AED, open the cover and turn the device on through pressing half second On / Off button.
5th STEP
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.
6th STEP
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.
P.S.: Do not place disposable pads directly over implanted pacemaker. Pacemaker signal can degrade the accuracy of ECG rhythm analyzing or the pacemaker may be damaged by defibrillation.
7th STEP
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.
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.
P.S.: If pad connector is plug in the socket already, device detects to connector and skip "insert pads plug into electrode socket" command
8th STEP
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.
9th STEP
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.

NOTE: Even if the device recommends shock, the patient continues to EKG analysis during energy re-charging. If the patient's EKG signal changes, the device cancels defibrillation and re-analyzes the patient's EKG signal. According to the new analysis result, it decides again whether or not to perform shock.

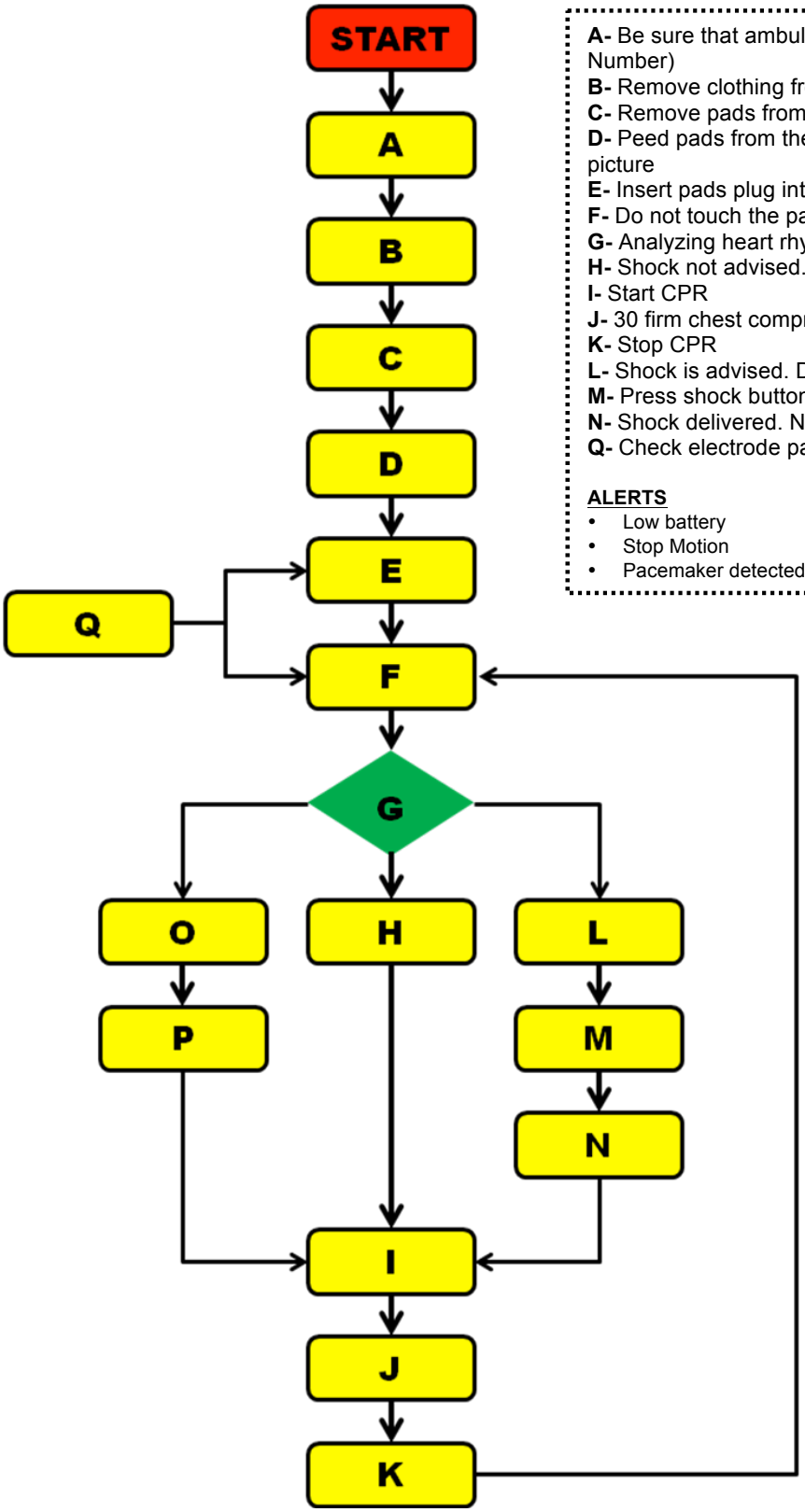
NOTE: The device has a motion sensor. If the device detects a motion that is large enough to affect the EKG analysis quality, it does not analyze and audibly warns the user with the "Motion detected, stop motion" command. When the motion gets stopped, the device automatically starts to analyze the patient's EKG signal.

10th STEP
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.

NOTE: The user can set the language / volume / energy levels / date-time settings from the SETTING option of the device.
This is accomplished by connecting the device to the computer via standard mini USB cable, requiring no special software.

6- DEFIBRILLATION FLOW CHART



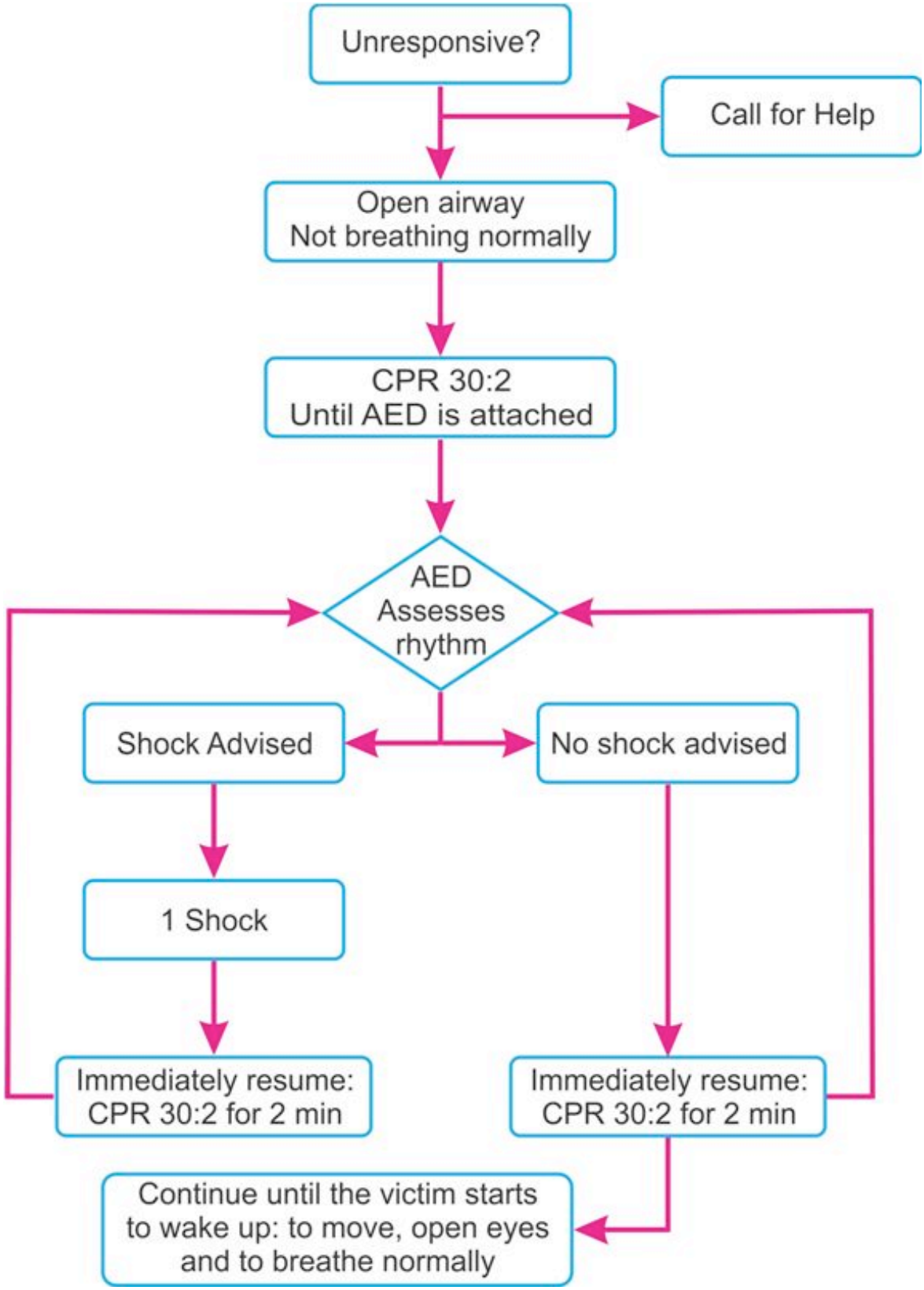
A- Be sure that ambulance has been called. (Local Emergency Number)
B- Remove clothing from patient's chest to expose bare skin
C- Remove pads from package
D- Peed pads from their liner and place exactly as shown in the picture
E- Insert pads plug into electrode socket
F- Do not touch the patient
G- Analyzing heart rhythm
H- Shock not advised. Now you can touch the patient
I- Start CPR
J- 30 firm chest compressions then give 2 breaths (x5)
K- Stop CPR
L- Shock is advised. Do not touch the patient. Preparing shock
M- Press shock button now
N- Shock delivered. Now you can touch the patient
Q- Check electrode pads (if detects any problem)

ALERTS

- Low battery
- Stop Motion
- Pacemaker detected

* The AED equipment's default mode is no pacemaker detection. if there is internal pacemaker on the patient and if AED detects shock able rhythm, even there is a pacemaker, AED will apply shock to patient. This shock can damage internal pacemaker. If you set pacemaker detect option from the settings menu, when the equipment detects internal pacemaker on the patient, it informs the user with voice about detected pacemaker and not apply shock even if there is shockable rhythm.

7- CPR (CARDIOPULMONARY RESUSCITATION) DIRECTIVE AHA / ERC 2010



8- FUNCTIONAL INSTRUCTION

8.1. General Use

Life-Point bPLUS AED device is designed to keep alive patients suffering a heart attack through directing the user with voice commands. Life-Point bPLUS AED device automatically analyses ECG signal of the patient and decides whether defibrillation is performable or not. The device performs an effective defibrillation by measuring the impedance of the patient with the biphasic waveform.

The patient's EKG waveform, BPM number, commands, time since opening, date, time and number of shocks can be monitored on the device screen.

8.2. 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.

8.3. Power Demand and Operating Conditions

Life-Point bPLUS AED operates with 12V 4500mA LiMnO2 battery pack and in environments with the temperature of 0 – 50 °C and with a relative humidity of % 10 - 95.

8.4. 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.

8.5. 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.

8.6. 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.

8.7. 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 200 typical shocking operations with a full battery.

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

8.8. Technical Characteristics and Replacement of Batteries

Remove the backside battery cover when the device is off. Take the empty battery pack out of the battery compartment carefully and then place and original 12V 4500mA LiMnO2 Life Point battery pack with the same specification into the compartment. After placing battery carefully, lock the battery pack with pin.

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

Note: Device has an internal battery for testing independently of battery pack. This self-test function battery should be changed each 6 years, even if self-test function is working normally. This process should be done in authorized technical service.

8.9. Device Software / Protocol Update

The device has been designed in compliance with the software / protocol updates and the user can obtain new software by connecting the device to a computer.
In order to load possible protocol update of AHA/ERC, contact with the dealer or the manufacturer.
For the corrections and updates which can be done by the manufacturer in addition to the protocol update, visit our webpage periodically. If there is a new software update, update the device software definitely.

8.10. Device Test Function

The device has a test circuit and it performs the self-test at every Start / Daily / Weekly / Monthly / Biannually. These periods cover the battery / hardware / software / charge – discharge / pad (adjustable) tests. The device keeps the test results in its memory. The user is also warned with the "indicator" on the device.

The status / battery indicator at the upper right corner of the device describes that the device works when it is GREEN and there is a failure if it is RED. The GREEN status/battery indicator is somehow recommendation and it does not assure the operations of the device 100%.
If the status/battery indicator is RED, please contact with an authorized service or the manufacturer as soon as possible.

Note: Device has an internal battery for testing independently of battery pack. This self-test function battery should be changed each 6 years, even if self-test function is working normally. This process should be done in authorized technical service.

9- Life-POINT bPLUS AED RHYTHM and ECG ANALYSIS PERFORMANCE

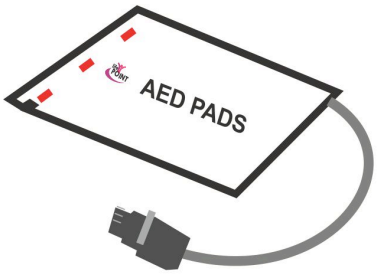
Life Point bPLUS AED analyses ECG rhythm of the patient and detects whether rhythm is suitable for electroshock.

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

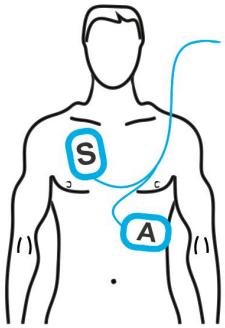
Life-POINT bPLUS AED ECG SIGNAL ANALYSIS AND DETECTION PERFORMANCE TABLE

RHYTHMS	MINIMUM TESTING SAMPLE SIZE	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

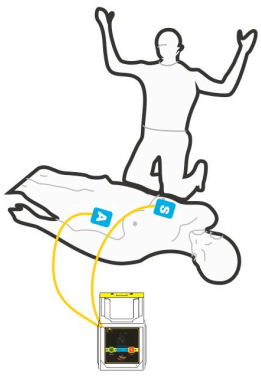
10- ATTACHING POSITIONS FOR DISPOSABLE PADS



Take the sticky pads out of the package carefully



Place the pads on the chest of the patient as shown in the picture



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

11- TROUBLESHOOTING METHODS

Technical Problem	Recommended Action
If Battery / Failure Indicator is "red"	If the device detects a fault during the manual test and continues to signal the command "call technical service" and failure/ battery indicator is "red", immediately contact Life-Point technical service.
If the failure/ battery indicator is "red"	The battery may be low. 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 failure/ battery indicator is "red"	The battery may be depleted due to energy consumption while the device issues alert signals. 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". After replacing the battery, if the device detects a fault in the manual test function, "call technical service" command will be issued. In this case, turn the device off by pressing and holding the On/Off button for 6 seconds and contact the authorized technical service.
If the failure/ battery indicator is "red"	Internal battery of self-test function may be low or empty. Self-test function battery should be changed in authorized technical service.

12- TECHNICAL SPECIFICATIONS OF DEVICE

Dimensions	11cm x 23cm x 27cm
Charging Time at 150 J	< 10 seconds
Weight	2900 gr (Battery and Accessories Included)
Operating Mode	Automatic
ECG Analysis Period	8 seconds
Wave Form	Truncated Biphasic Wave Form
Energy steps	Adult :150J 200J 200J / Child : 50J 50J 50J
Impedance Measurement	Yes
Impedance Range	25 – 175 ohm
Maximum discharging number	200 (at 20 ºC with full battery)
Derivation	II
ECG Bandwidth	2 – 25 Hz
Battery	LiMnO2 (12V 4500mA)
Self Test	Weekly, Monthly and At Each Start
Self Test	Battery, Internal Electronics, Software, Defibrillation (each 6 month)
Class (93/42/EEC)	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 (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. You can check for updates on our web page.

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METsis
ADVANCED TECHNOLOGY SYSTEMS

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