

POCKET LASERVIT

Infrared rays Biostimulator



USER MANUAL

Instructions

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CONTENTS:

Cap.1 – INTRODUCTION	4
1.1 – What is POCKET LASERVIT	4
1.2 – What is POCKET LASERVIT for	4
1.3 – Who can use POCKET LASERVIT	4
Cap.2 – INDICATIONS AND CONTRAINDICATIONS	5
2.1 – Indications.....	5
2.2 – Contraindications	5
2.3 – Side Effects.....	5
Cap.3 – OPERATION.....	6
3.1 – Turning on the device	6
3.2 – Connection of the handle	6
3.3 – Application of the handle.....	7
3.4 – Switch on of the device.....	7
3.5 – Selection of the program.....	7
3.6 – Starting of stimulation.....	7
3.7 – Intensity of emission	7
3.8 – Pause/ interrupt the therapy.....	7
3.9 – Switch off of the device	8
Cap.4 – INFRARED THERAPY	8
4.1 – Programs	8
4.1.1 – Preset programs.....	8
4.1.2 – Free programs	8
4.2 – Applications	9
4.2.1 – Application for points	9
4.3 – Sessions	9
Cap.5 – POWER SUPPLY	10
5.1 – Use of the power supply	10

5.1.1 Indication of the battery level.....	10
5.1.2 Recharge of the battery	10
5.1.3 Instructions to protect the battery	11
5.2 – Replacement of the battery.....	11
5.3 - Precautions for use	11
Cap.6 – MAINTENANCE.....	12
6.1 – Handle.....	12
6.2 – Device and power supply.....	12
6.3 – Immediate maintenance	12
Cap.7 – INSTRUCTIONS.....	13
Cap.8 – TECHNICAL CHARACTERISTICS	14
8.1 – Supply	14
8.2 – Output characteristics	14
8.3 – Other characteristics	14
Cap.9 – SYMBOLS.....	15
Cap.10 –STANDARD ENDOWMENT AND ACCESSORIES.....	15
10.1 – Standard endowment	15
10.2 – Accessories and consumption material.....	15
Cap.11 – BIBLIOGRAPHY.....	16

ATTENTION:

**ATTENTION: READ CAREFULLY THE
INSTRUCTIONS BEFORE USE**

Cap.1 – INTRODUCTION

POCKET LASERVIT belongs to a new generation of electromedical instruments for physiotherapy. Its main characteristics are its reduced dimensions, its ease of use and its versatility.

1.1 – What is POCKET LASERVIT

Thanks to the constant investigation and research we created a new system for the infrared therapy constituted by POCKET LASERVIT. In order to guarantee the maximum reliability and safety to the consumer, in respect of the actual Normative on the Safety of the Medical Devices, the device accomplishes the control, while the software allows the generation of infrared light for the therapeutic treatment of the most common pathologies (muscular Contractures, Arthrosis, bedsores).

1.2 – What is POCKET LASERVIT for

POCKET LASERVIT contains in its inside all the technology necessary to produce the infrared light and to modulate its parameters, through preset programs and 10 free programs. It is therefore possible to apply the infrared therapy with standard preset programs and to have the therapeutic sessions according to the patient's condition.

1.3 – Who can use POCKET LASERVIT

POCKET LASERVIT expresses its own potential in the medical field (physiotherapy particularly). Nevertheless, thanks to its ease of use and versatility, it can be used not only by physicians and therapists, but also from whoever desires to use it at home.

Cap.2 – INDICATIONS AND CONTRAINDICATIONS

The infrared therapy produces on the tissues a thermal effect which has, as secondary effects, the increasing of the metabolism of the tissues, the vasodilatation of the capillaries and of the arteries and a muscular relaxation.

2.1 – Indications

The most common pathologies which can be treated with the infrared therapy are :

- Tendinitis (achillea, epicondylitis, pubis pain, leg of goose, bonnet of the rotators, biceps);
- Bursitis;
- Contractures, stretching and muscular sprain;
- Distortions;
- Fractures;
- Hematomas and bruises;
- Arthritis and arthrosis;
- Cellulitis;
- Ulcers and bedsores;
- Acne, warts, etc.

2.2 – Contraindications

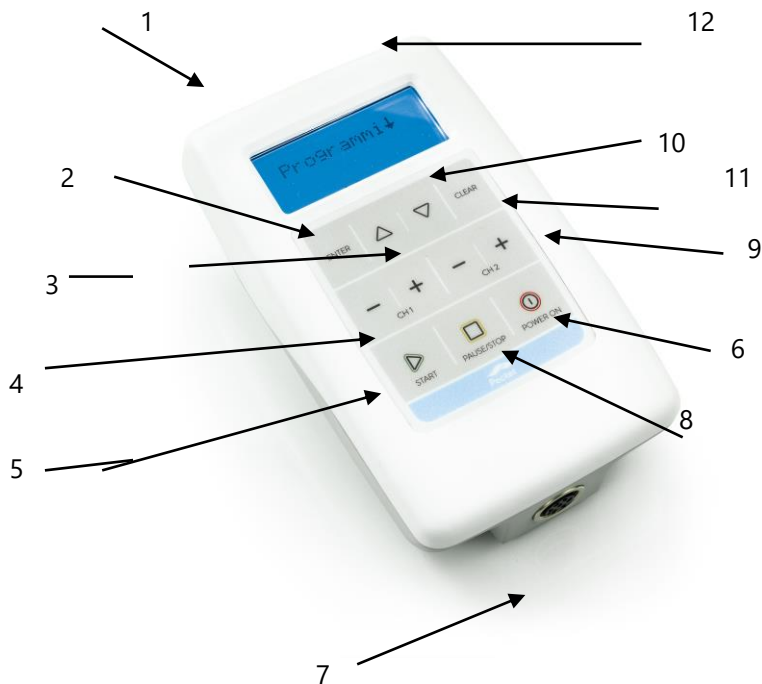
The infrared therapy is not suitable on subjects with:

- pace-maker;
- neoplasie (tumors);
- pregnancy in progress;
- epilepsy;
- photosensitivity
- children (areas of growth)

2.3 – Side Effects

- Cutaneous burns if the intensity is notable and in presence of sensitivity disorders
- Lipothimic episodes can arise in persons with a heart disease.
- Do not direct the rays on the head because there could be the possibility of heatstroke. If applications are done on the cervical spine, protect the head with a headgear.

Cap.3 – OPERATION



1 - Display LCD

2 - ENTER: it confirms selection

3 - UP: go on

4 - (+)/(-) channel 1: reg.Modulation

5 - START: beginning of the program

6 - ON/OFF: turns on / turns off

7 - output of the cable

8 - PAUSE STOP: interruption / end

9 - (+) / (-) channel 2: modulation intensity

10 - DOWN: back

11 - CLEAR: it cancels / it returns back

12 - output for the power supply

3.1 – Turning on the device

The device can be used with battery or with power supply (230V). To turn on POCKET EMAVIT, press the key (I) - ON/OFF. The display shows the version of the device and the Selection Menu.

3.2 – Connection of the handle

Before turning on the instrument, connect the handle and the output (placed in the inferior part of the device) using the connector of the cable. Insert, rotate and tighten the connector into the output

3.3 – Application of the handle

Place the head of the handle directly on the skin in a perpendicular way (90°); hold the handle during the application. For the techniques of application see chapter Applications.

3.4 – Switch on of the device

To turn on the POCKET LASERVIT press the key (I) - ON/OFF on the device board. The display shows a welcome message with the software version and then the Selection Menu. It will automatically be set on first preset program.

3.5 – Selection of the program

Select the program with the keys UP/DOWN (see. section. Programs) and confirm with ENTER.

3.6 – Starting of stimulation

To begin the therapy press START when the display visualizes > START > .

3.7 – Intensity of emission

The intensity of the emission of the handle is fixed. The dose, that is to say the total energy transferred to the body, is preset and different in each program. It is possible to vary the dose with the keys (+) / (-) 2 (changing the dose the timer will also change proportionally). The modulation 1/1, 1/2 ,1/4 is shown next to the dose XX.Y and can be changed with the keys (+) / (-) 1. With the modulation you can vary the intensity of the handle from the maximum one (1/1), to an intermediary value (1/2) and finally to the minimum one (1 / 4).

ATTENTION: in case of pain or higher temperatures in the area, remove immediately the handle and interrupt the therapy.

3.8 – Pause/ interrupt the therapy

If you want to stop the device before the program ends, press the key PAUSE STOP: once for a break (to continue press START); twice to stop the program and to get back to selection.

3.9 – Switch off of the device

To turn off the instrument press and hold the key (I) ON/OFF for some seconds. After the end of a program, if the device is not used again, it automatically turns off after a few minutes

Disconnect the cables from the device and put back all the accessories in the handbag. Keep in fresh and dry place.

Cap.4 – INFRARED THERAPY

4.1 – Programs

POCKET LASERVIT is endowed with 10 preset programs , ready to use and of 10 free programs.

4.1.1 – Preset programs

The preset programs are listed in the following chart.

Programs of POCKET LASERVIT

N° Prog.	Name on the display	Pathology to be treated
P.1	Inflammat.	Inflamations / Cervical / Backache / Sciatic
P.2	Contusion.	Contusions/ Hematomas / Edemas
P.3	Distors.	Distorsions (knee/ankle) / articular Pains
P.4	Arthritises	Arthritises / Arthrosis / Periarthritis of shoulder
P.5	Sprains	Contractures / straining / sprains / muscular Pains
P.6	Bursitises	Bursitises
P.7	Tendinitis	Tendinitis/Epicondilitis/Carpal Tunnel /Pubes pain
P.8	Cellulitis	Cellulitis / Swelling / Sore / Acne / Scars / Warts /
P.9	Acute pains	All the acute pains
P.10	Chronic pains	All the chronic pains

4.1.2 – Free programs

Select Free Program from the main Menu and press ENTER. To select a new free program, chose the icon “- - - - -” and press ENTER.

Select one Phase with the keys ARROW UP / ARROW DOWN (always begin from Phase 1) and confirm with ENTER to access to the setting of the selected phase. Every parameter can be selected with ARROW UP / ARROW DOWN. Option are selected with ARROW UP / ARROW DOWN and the desired value with the keys (+)/(-). The available values for the parameters of the free programs are in the following chart.

NAME ON THE DISPLAY	PARAMETER	ADJUSTABLE VALUE
Timer	Duration of the phase	From 1 to 60 min.
Mod.	Frequency of Modulation	CONT, 1/2, 1/4
Stop	Interruption of the phase	YES/NO

After selecting one of the memorized programs and confirming it with ENTER, you can select one of the following:

Perform + ENTER (to begin the program);

Change + ENTER (to modify the parameters and/o the Phases);

Cancel + ENTER (to cancel the program and to free memory);

4.2 – Applications

For each application press the handle directly on the skin, always 90° (perpendicular) and point exactly the area to treat. If the pathology is superficial or cutaneous, hold the handle at 1-2 cms of distance from the skin; if the area to be treated is deep, press the handle against the skin to get closer to the desired point.

4.2.1 – Application for points

The head of the handle can treat a surface of some square centimeters. If the area to be treated is bigger and the pain/inflammation/swelling (ex. cervical, back pain, cellulitis, etc.) is widespread, choose the most suitable program and place the handle in any point of the affected area; at the end of the program move the handle on an adjacent point and restart the program. Repeat the operation until you cover the whole area.

4.3 – Sessions


Apply the infrared therapy 3-4 times a week at alternate days up to the disappearance or appreciable diminution of the pain. In case of particularly acute inflammations, during the first sessions the pain may intensify and the inflammation slightly increase; in this case increase the frequency of the sessions up to 5-6 a week.

NOTE: if after 10-15 sessions pain persists, contact an expert physician.

Cap.5 – POWER SUPPLY



5.1 – Use of the power supply

POCKET LASERVIT can be powered from AC mains 230V-50Hz with the endowed power supply or from the internal rechargeable battery Ni-Mh 6V - 1,8Ah, with an autonomy of some hours under normal use conditions. The guaranteed autonomy may change depending on the program, intensity and time of application.



 For the correct identification of battery and power supply, consult the Chap. "Technical features". Neither the power supply nor the battery must be replaced from not experienced staff. Do not use spare parts which are not provided or approved by the manufacturer.

5.1.1 Indication of the battery level

When Pocket is powered by the battery on the display appears the symbol Battery.

Legenda:  - indication of charged battery  - indication of discharged battery

When the empty battery icon is displayed, please charge the device. If not, the device will automatically turn off.

 The battery symbol only appears when the instrument is disconnected from AC; otherwise the symbol  will appear when connected to AC.

5.1.2 Recharge of the battery

To charge the battery of the Pocket:

- 1- Switch off the device;
- 2- Plug the device in with power supply and to AC;
- 3- Leave the device charging (on the display the battery icon will blink while charging). When full charge is completed (approx. 3 hours), the battery charged icon will appear (Once in a while we recommend leaving the device charging for 8-10 hours)
- 4- Disconnect the device

Important:

When the battery is presenting low level of charge, but is not completely discharged yet and the battery power indicator shows 'mid charge battery' sign, the device

should be plugged into the AC mains to recharge. The user can continue using the device, whilst the battery is recharging.

If the battery is completely discharged and the battery power indicator shows 'empty battery' sign, the device will not work even when plugged into the AC mains. The user must not use the device until the battery is charged up.

5.1.3 Instruction to protect of the battery

The life of a rechargeable battery depends on the number of recharging/rundown cycles it undergoes and how these cycles are performed. In order to preserve the life of the battery:

1. If the device is not used frequently, it must be RECHARGED AT LEAST ONCE PER MONTH, under penalty of forfeiture of the guarantee on the battery.
2. Recharge the battery only when the empty battery symbol appears

5.2 – Replacement of the battery

When the battery's life is significantly lower than it used to be, we recommend replacing it. When the battery lasts less than 1 hour or does not allow performing a full program, it must be replaced by a new one. For this, please refer to an authorized New Age Italia Centre of Assistance



Never reverse the polarity of the connections of the battery, not to cause the destruction of the electronic circuits.

5.3 - Precautions for use

- (1) Do not throw the exhausted battery with the ordinary wastes. Please take them to the corresponding collection site.
- (2) Do not manipulate/ throw the battery into a fire.
- (3) Do not short-circuit the terminals.
- (4) Avoid sparks or flames, above or around the battery.
- (5) in case of direct contact with liquid leaking from the battery, wash immediately with water. In case of direct contact with eyes, wash abundantly with water and consult immediately a doctor.
- (6) in the case the inside electrolyte comes in contact with the eyes, wash abundantly and contact immediately a physician.

Cap.6 – MAINTENANCE

6.1 – Handle

The handle and connection cable must be periodically revised to check the possible presence of cracks. It is recommended to clean the handle with a damp cloth and dry with a clean and dry cloth.



6.2 – Device and power supply

Use a damp cloth to clean the device and the power supply cable. Do not use in any case liquids, because these devices are not liquid proof (IP20).

6.3 – Immediate maintenance

Immediate maintenance must be performed by New Age Italia or authorized staff if one of the followings occurs:

- external mechanical stress (eg. serious falls);
- strong overheating (eg. if the device has been left close to sources of intense heat);
- some liquids may have been penetrating the device;
- the power supply, or other parts of the device are damaged, broken or missing;
- the functionality of the instrument seems altered.

- | |
|--|
|  Use the device with the endowed accessories only |
|  Run every year a secur-tester to check the device following the legislation EN60601-1. The useful life of the device is guaranteed only if such maintenance is regularly performed. |

PLEASE NOTE: we recommend having the device checked by New Age Italia directly or through the authorized retailer where the product has been purchased.

















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Cap.7 – INSTRUCTIONS

-  Pay particular attention in the employment of the handle, not to compromise the effectiveness of the treatment.
-  Make sure that the electric system is in conformity with the actual safety norms.
-  The instrument has degree of protection IP20 (see Chap. "Technical features"). Do not use it close to liquids, because it's not liquid proof.
-  Do not use close to cellular telephones (maintain at least one meter of distance)
-  The stability of the emission can be affected when operating close (less than 1 meter) to an instrument with short waves therapy or microwaves.
-  Don't simultaneously connect the patient with the POCKET LASERVIT and with a surgical instrument HF, to avoid dangers for the patient and for the same instrument.
-  Do not use with the presence of devices to monitor the patient's vitals
-  The device works accordingly to its specifications if the environment is maintained to a temperature between the 5° and the 40° C and with humidity inferior to the 80%. The same conditions must be maintained during transportation and the storage.
-  In case of malfunctioning, do not use and request service of reparation.
-  Do not operate in proximity of inflammable substances.
-  Use only the accessories that are endowed with the device.
-  It's important to inform the patients on the type of sensation they will experience during the therapy. In case the patient perceive a different sensation, interrupt the session through the commands of the device or by removing the handle.
-  If the intensity is causing overheating or pain in the treated zone, it is necessary to reduce immediately the intensity of stimulation or eventually interrupt the treatment.
-  Keep away from children.
-  **Do not direct the handle toward the eyes**
-  **Do not use the handle on reflective areas**

Cap.8 – TECHNICAL CHARACTERISTICS

8.1 – Supply

Power supply: PRI: 230V ~ 50Hz SEC: 12V- 1A

Internal supply: rechargeable battery Ni-MH 6V-2,2 Ah

8.2 – Output characteristics

Source: 4 led infrared rays AlGaAs + 1 led Red ultrabright AllnGap and Gap

Max intensity of the Power (P): 4 x100 mW infrared + 1 x 100mW red

Wave length (λ) : Led infrared $\lambda = 940 \text{ nm}$; Led Red $\lambda = 660\text{nm}$

Frequency of the impulses (f): 100 Hz

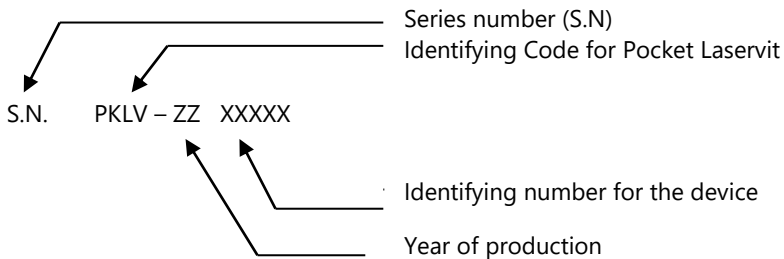
Type of emission : Continuous (1/1) o modulated ON/OFF (1/2, 1/4)

8.3 – Other characteristics

- Dimensions: 175x105x40h [mm]
- weight: 400 [g]
- Class: II Tipo: BF
- IP Classification: IP20
- Safety in presence of inflammable anaesthetic gas: it is not AP or APG category
- Type of operation of the device: continuous

Built according to the norms:

- EN 60601-1 (1998) – Electromedical devices : General norms for the safety
- EN 60601-1-2 (2003) – Collateral norm: Electromagnetic compatibility - Prescriptions and tests
- EN 60601-1-4 (1997) – Collateral norm: programmable electromedical systems
- EN 980-2003 ed EN 1041 – Symbology for electromedical instruments



Cap.9 – SYMBOLS



DEVICE TYPE BF



ATTENTION, CONSULT THE ATTACHED DOCUMENTATION



THIS DEVICE IS MARKED AT THE SENSES OF THE
DIRECTIVE CEE 93/42.



WASTE DISPOSAL FOLOWING THE CEE DIRECTIVE 2002/96 AND
2003/108

Cap.10 –STANDARD ENDOWMENT AND ACCESSORIES

POCKET LASERVIT is endowed with standard endowment for the main applications.
Consumption material and extra accessories can be bought separately.

10.1 – Standard endowment

Device
Power supply
Handle with 5 diodes
User Manual
Case
Protective glasses

10.2 – Accessories and consumption material

Handle with 5 diodes
Power supply
Protective glasses

Cap.11 – BIBLIOGRAPHY

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