

BIOLASER

Infrared rays Biostimulator



MANUAL

User Instructions

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WARNING:

**READ THE MANUAL CAREFULLY
BEFORE USE**

Cap.1 – INTRODUCTION

BIOLASER belongs to the new line of electromedical instruments for physiotherapy. The reduced dimensions, the facility of use and the versatility are the principal characteristics of this innovative line of products..

– What is BIOLASER

The constant research in the sector of the medical devices has brought to the creation of a new system for the infrared therapy constituted by the generator BIOLASER. In order to guarantee to the consumer the maximum reliability and safety in the respect of the actual Normative on the Safety of the Medical Devices, the generator assumes the assignments of control, while the software allows the generation of infrared light for therapeutic purpose in the treatment of the most common pathologies (muscular Contractures, Arthrosis, bedsores).

– Why use BIOLASER

BIOLASER contains inside all the technology necessary to produce the infrared light and to modulate its parameters, through the use of the presetted programs contained in its memory and the 20 free programs. Thanks to BIOLASER, therefore, it is possible to apply the infrared therapy with standard programs and to have the therapeutic sessions in relation to the demands of the patient.

– For whom is BIOLASER for

BIOLASER finds in the medical field (particularly physiotherapy) and in the home therapy the fittest environment to express completely its own potentialities. Nevertheless, for the simplicity of use, it is usable, over than from physicians and rehabilitation therapists, also from who desires to deal his own physical comfort in domiciliary circle, thanks to the facility of use and the versatility of the product.

Cap.2 – – INDICATIONS AND SIDE EFFECTS

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

– Indications

The most common pathologies which can treaten with the infraredtherapy are :

- Tendinitis (achillea, epicondylitis, pubis pain, leg of goose, bonnet of the rotators, bicepses);
- Bursitises;

- Contractures, stretchings and muscular sprain;
- Distorsions;
- Fractures;
- Hematomas and bruises;
- Arthritises and arthrosis;
- Cellulitis;
- Ulcers and bedsores;
- Acne, warts, etc.

– **Contraindications**

The infraredtherapy is not suitable on subjects with:

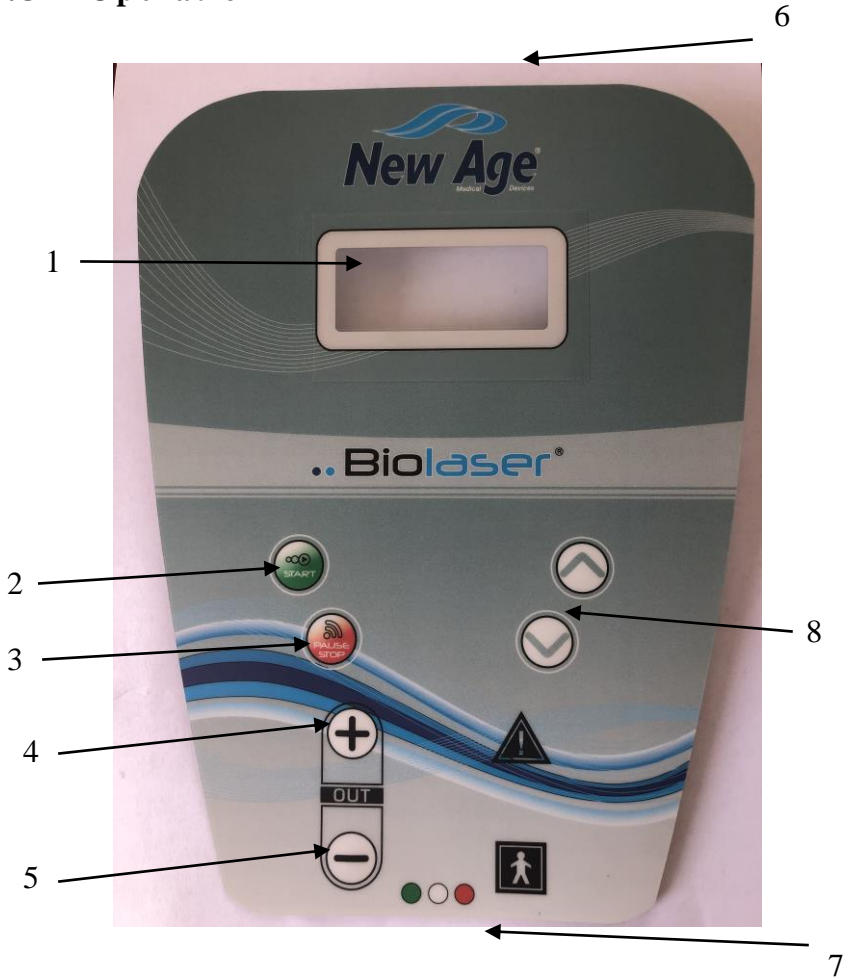
- pace-maker;
- neoplasie (tumori);
- pregnancy in progress;
- epilepsy;
- photosensitivity

children (areas of growth)

– **Side Effects**

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

Cap.3 – Operation



1 - Display LCD

2 - START: selection/start program

3 - PAUSE STOP

4 - Increase modulation

5 - Decrease modulation

6 - ON/OFF

7 - Cable output

8 - UP/DOWN: program selection / timer adjustment

– Connection to the electric net

BIOLASER can be used with battery or fed to electric current, connecting the power supply to a normal taking of tide 230V and to device through the output placed in the superior part.

– **Connection of the handle**

Before turning on the instrument, connect the handle to the output placed in the inferior part of the device through the connector of the cable. To insert the connector rotate it until the connections coincides with the output; once inserted, screw to fix well the cable to the instrument

– **Application of the handle**

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

– **Switch on of the device**

To turn on the BIOLASER press the key ON/OFF on the rear of the device. The display shows a welcome message with the software version and then the Selection Menu. It will automatically be set on first preset program.

– **Selection of the program**

Select the program with the keys UP/DOWN (see. section. Programs) and confirm with START. The programs are listed in the charts in "Preset protocols"

- **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 presetted and different in each program. It is possible to vary the dose with the keys (+) / (-) 2 (changing the dose you got a proportional adjustment of the Timer). The modulation 1/1, 1/2 ,1/4 is shown beside the dose XX.Y and it can be changed with the keys (+) / (-) 1. With the modulation you can vary the intensity of issue of the handle from the maximum one (1/1), to an intermediary value (1/2) and finally to the last one (1 / 4).

ATTENTION: in case of pain or elevated heating of the treated zone, it is necessary to remove immediately the handle and to interrupt the therapy.

– **Pause/ interrupt the therapy**

If you want to interrupt the therapy before the term , press the key (I) ON/OFF for a few seconds continue press START); twice to finish the program and to return in phase of Programs selection.

– Switch off of the device

To switch off the device hold pressed the key (The) ON/OFF for some seconds. If after the expiration of a program the instrument is not used, it switches off automatically after few minutes. At the end of the session disconnect the cables from the device and put back all the accessories in the handbag. Preserve in a cool and dry place.

Cap.4 – INFRARED THERAPY

– Programs

BIOLASER has 20 preset programs ready to be used.

4.1.1 – PRESET PROGRAMS

The preset programs are listed in the table below.

BIOLASER programs table

N° Prog.	Name on display	Pathology to be treated
P.1	Cervical	Cervical
P.2	Pubalgy	Pubalgy
P.3	Dorsalgia	Dorsalgia / Bone pain
P.4	Lumbago	Lumbago
P.5	Epicondilitis	Epicondilitis
P.6	Tunn. Carp.	Tunnel carpal
P.7	Metatarsalg.	Metatarsalgia / Fascitis
P.8	Inflammation	Inflammation / Sciatica
P.9	Contusions	Contusions / Edemas
P.10	Distorsions	Distorsions (knee/ankle)
P.11	Periarthritis	Periarthritis of shoulder
P.12	Arthritises	Arthritises / Arthrosis
P.13	Sprains	sprains / muscular Pains
P.14	Bursities	Bursities
P.15	Tendinitis	Tendinitis
P.16	Contractures	Muscular contractures
P.17	Tears	Tears / muscular Pains
P.18	Cellulitis	Cellulitis / Swelling / Sore / Acne / Scars / Warts /
P.19	Acute pains	All the acute pains
P.20	Chronic pains	All the chronic pains

– Applications

For each application press the handle directly on the skin, always to 90° in comparison to the surface to be treated (perpendicular), so that to center the precise point in which the pain or the inflamed zone are warned. If pathology is superficial or cutaneous, hold the handle at 1-2 cms of distance from the skin; if the zone to be treated is deep, press the handle against the skin so that to approach the desired point

4.1.2 – Point application

The head of the handle allows to treat a surface of some square centimeters. If the zone to be treated is more extended with diffused pain/inflammation/swelling (ex. cervical, back pain, cellulitis, etc.), apply the most proper program positioning the handle on a point of the zone to treat; at the end of the program move the handle on an adjacent point and restart the program. Repeat the operation so that to apply the therapy on the whole interested surface.

4.2 – Sessions

Apply the laser therapy 3-4 times a week at alternate days up to the disappearance or appreciable diminution of the pain. It is possible that with some particularly acute inflammations, in the first sessions the pain intensifies and the inflammation slightly increases; 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.

4.2.1

Cap.5 – POWER SUPPLY

How to use power supply

Biolaser can be supplied by power mains voltage at 230V~ 50Hz, through the external supply cable which is provided together with the device (see the section on Technical Specifications).



In order to identify the and the power supply cable provided with the device, see the chapter on “Technical Specifications”. The power supply cable must not be replaced by people who are not experts, and especially must not be replaced with any device different from those provided by the manufacturer.

Cap.6 – MAINTENANCE

6.1 – Handle

The handle and connection cable must be periodically checked for verifying that there are no cracks; to clean the handle with a moist cloth and dry with a clean and dry cloth.


6.2 – Device and power supply


To clean the device and the power supply cable we advise to use a moist cloth. Don't use in any case liquids, because they are not protected from their entry (IP20).

6.3 – Immediate maintenance

We recommend you to perform the controls only from New Age Italia or from the specialized personnel delegated if:

- the instrument has been submitted to mechanical external solicitations, as serious falls;
- the instrument has been submitted to strong overheating, for example, if left next to intense heat sources;
- you doubt that some liquids can be penetrated inside;
- the wrap or other parts of the instrument are damaged, broken or lacking; the functionality of the instrument appears altered.

 To the goals of the safety we recommend you not to operate with accessories (for example handle and power supply) different from the ones furnished as endowment of base.

 The frequency of maintenance, of functional control and verification of correspondence to the safety norms EN60601-1 for the medical devices, to perform with secur-tester, is annual. The useful life of the tool is guaranteed only from the firm if such maintenance is regularly effected.

ATTENTION: We recommend you to perform the controls only from New Age Italia or from the specialized personnel delegated by this Firm. The instrument in maintenance can be sent directly to the assistance laboratories or delivered to the reseller by which it has been purchased.


Cap.7 Assistance centre


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Cap.8 – CAUTION


 Pay particular attention in the employment of the handle for not compromising the effectiveness of the treatment.


 Use the device only with electric systems conforming to the Safety Current Regulations


 The instrument has a degree of protection IP20 (to see sec. "Technical characteristics") and it dissuades the use in the immediate proximities of liquids, because not protected from their entry.


 We would not recommend to use in the immediate proximities of cellular telephones (keep them at least to some meters of distance).


 Operate in proximity (for example 1 meter) of an instrument for short waves therapy, or microwaves, can produce instability in the output of the stimulator.

 Don't simultaneously connect the patient with the LASETRON CARD and with a surgical instrument HF, to avoid dangers for the patient and for the same instrument.


 Don't use in presence of equipments for the monitoring of vital parameters


 The tool works according to its specifications, if the environment is maintained to an inclusive temperature between the 5° and the 40° C and with an inferior humidity to the 80%. The same conditions have to be maintained during the transport and the storage.


 In case of malfunctions and breakdowns, it is opportune to send the tool exclusively to the house builder.

 We recommends not to operate in proximity of inflammable substances

 Don't use different accessories from those furnished in endowment.

 It is important to inform the patient about the type of feeling to perceive during the therapy, such as to intervene immediately, interrupting the session through the commands of the device or removing the handle, in the case the perception is not the correct one anymore.

 If the power of emission or its regulation causes elevated heating or pain in the treated zone it is necessary to reduce immediately the intensity of stimulation or eventually to interrupt the application.

 Keep away from children.

 **Don't direct the handle toward the eyes**

Cap.9 – TECHNICAL CHARACTERISTICS

– Supply

Power supply: electric power PRI: 230V~ 50Hz.

Absorption from electrical power: max 60 VA.

– Output characteristics

Source : 9 diod AlGaAs

Laser class: IV

Max intensity of power (P) : 4 ir x 225mW + 5 r x 235mW

Wavelength (λ) : Led infrared $\lambda = 940 \text{ nm}$; Led Red $\lambda = 640\text{nm}$

Frequency: 100Hz

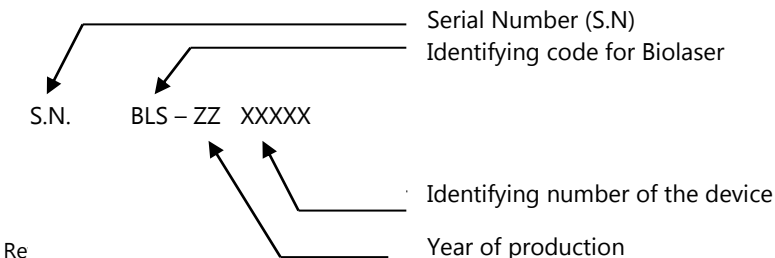
Output : Continuous (1/1) o modulated ON/OFF (1/2, 1/4)

– Other characteristics

- Dimensions: 225x170x120h [mm]
- Weight: 1000 [g] approx.
- Class: I Tipo: BF
- Class: II Tipo: BF
- Classification in comparison to the entry of liquids: IP20
- Safety in presence of inflammable anaesthetic gas: it is not of category AP or APG
- Device for operation: continuous

Built according to the norms:

- EN 60601-1 (1998) – Elettromedical 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 elettromedical systems
- EN 980-2003 ed EN 1041 – Symbology for elettromedical instruments



Cap.10 – SYMBOLS



DEVICE CLASS II



DEVICE TYPE BF



ATTENTION, CONSULT THE ATTACHED DOCUMENTATION



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

Cap.11 – STANDARD ENDOWMENT AND ACCESSORIES

– Basic endowment

BIOLASER is complete with:

Device

Handle at 9 diods

Protective goggles

Manual

Case

– Accessories and consumption material

Handle at 5 diods

Power cable

Travel bag

Cap.12 – BIBLIOGRAPHY

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