δ LASER

DELTA LASER

MANUAL

Instructions for use

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ATTENTION:

- **READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE USE.**
- **IT IS RECOMMENDED TO SEEK THE ADVICE OF MEDICAL PERSONNEL FOR THE THERAPEUTIC INDICATIONS REQUIRED.**

Cap.1 – PRESENTATION

In 2010 New Age Italia enters the world of LASER therapy with a new aim.
To have the full control of the parameters constituting LASER therapy.
In the LASER New Age devices it is possible to set power, time, frequency from 100Hz to 20KHz, duty cycle 20%-100% (continuous).
The absolute novelty of the New Age machines is in the possibility of performing therapies simultaneously using **3** LASERS with different wave lengths: **808 nm 980 nm 1064 nm**
This unique feature enables treating different tissues and depth at the same time, concretely limiting the treatment times.
The colour display with touch-screen technology and the rotary encoder provided with push button, enable an easy and immediate approach to using the machine. The real time viewing on display of the transmitted energy, total energy and average transmitted power, guarantee full therapy control, thus supplying the operator with the best instruments.
New Age also makes available its experience in the physiotherapy field through the various programs that each appliance owns; this enables the operator to be operational and **efficient**, right from the first applications, obtaining the best results in the least possible time.
The high powers of the LASER New Age modules enabling to quickly reach the therapeutical energy dosing, thus reducing the time of each therapeutical session.
To obtain spot LASER with different diameter, the classical method envisions the use of various length interchangeable spacers, positioned between patient and knob, differently the R&D New Age department has developed an innovative knob provided with a lens system able to focus and defocus the LASER ray from a minimum spot of 8 mm to a maximum of 20 mm, simply by turning the ring nut present on the knob, thus eliminating interchangeable components and enabling a more accurate regulation of the spot.
New Age only uses first choice materials to manufacture the appliances, such to guarantee maximum efficiency and reliability to the customer.

All this translates in the utmost decision-making freedom for the operator and, therefore, the best results in shorter times.

1.1 – Biological effects of δ LASER

The LASER radiation, penetrating the tissues, causes photochemical reactions at cellular level that induce different effects.

Mitochondrial Stimulation: one of the most therapeutical effects of the LASER, consists in stimulating cellular mitochondrion. Mitochondrions are the energy generators of each cell, responsible for the production of ATP (adenosine triphosphate) that constitutes energy reserve of the cell. The **ATP** is produced by **ADP** (adenosine diphosphate) plus **Pi** (phosphate) plus **E** (energy) therefore, **ATP=ADP+P+E**.
The more ATP is present in a cell, the healthier and more energetic it is.
It has been proven that cells stimulated by LASER light increase their production of ATP and, therefore, if inflammatory or degenerative processes are in progress, they have sufficient energy to quickly recover the optimal health state.

Activation of the microcirculation: One of the effects deriving from using the high power LASER, is the distinct vasoactive effect on the microcirculation. The activation of the microcirculation entails greater oxygenation and nutritional input, as well as greater drainage of the catabolite from the tissues.

Activation of the lymphatic peristalsis: The LASER light accelerates the lymphatic peristalsis, which facilitates absorption of interstitial liquids and the reduction of oedemas of phlogistic and post-traumatic origin.

Hyperpolarisation of the membranes of the nervous fibres: Experimental studies have proven that the therapeutical LASERS determine the hyperpolarisation of the membranes of the nervous fibres. This effect appears to be linked to the closing of the membrane channels for potassium, due to amendments of the superficial lipoprotein. The hyperpolarisation causes the elevation of the excitement threshold of the pain receivers.

Transforming prostaglandin in prostacyclin: The therapeutical LASERS stimulate the forming of prostaglandin in PG12 prostacyclin, which have antiphlogistic, anti-edemigenous and analgetic action.

1.2 – Who is δ LASER for?

The medical field (especially physiotherapy) is the sector most suited for δ LASER to fully express its potentialities.

1.3 – Fields of application

The most common pathologies treated with LASER therapy are those of the locomotory apparatus and of the derma. In particular, the LASER is successfully used for treating:

- Arthralgias of various nature, rheumatic and degenerative (inflammatory and degenerative arthropathy, epicondylitis, knee pain with and without shedding, myositis, polyarthritis, arthritis, arthrosis, sciatica, lumbago).
- General traumatology articular sprains, tendonitis, tenosynovitis, muscle strains, bruises, bursitis, enthesitis, torn muscles, pathologies of overload, muscular injuries and tendon, Torn muscles and tendon, Muscular bruises
- post surgery or post forced inactivity motor rehabilitation
- Dermatology psoriasis wound healing, bedsores
- oedemas, arteriopathy;
- Circulatory deficit

We recommend consulting a doctor for the diagnosis and control of the therapy.

1.4 – Contraindications

Magnetic fields have some contraindications in common with other physical equipment which acts by means of endogenous heat production:

- Neoplasms (tumours);
- sensitivity alteration.
- area with acute haemorrhage
- photosensitivity

Cap.2 – OPERATION

<u>NOTE:</u> check the contraindications and follow indications carefully before applying LASER therapy.

2.1 – Turning device on

To activate δ **LASER**, switch-on the rear switch, check that the emergency button is released, turn the switch-on key. An initial screen appears on the display presenting the device including: the name of the appliance version, the **START** key and the **CONFIGURE** key.

2.2 – Selection of program type

δ **LASER** can operate in 3 different modes:

1- Free manual mode
2- Pre-set program mode
3- Personal program mode

2.2.1 - Free manual mode

Press **START** on the initial screen to access the manual mode area. In this area, by **TURNING THE KNOB** you can vary the value of the parameter selected, whereas by **PRESSING THE KNOB** you pass from one parameter to the next. The concerned parameters are: type of emitted wave, supplied power, therapy duration, duty cycle of the generated wave.

2.2.2 - Reset program mode

Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS (**on touch screen**)** to enter the Menu for choosing specific protocols where first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER (**touch screen**)** or else **PRESSING THE KNOB** to confirm the program selected.

2.2.3 - Personal program mode

The custom-made programs are at the bottom of the list of pre-set programs. Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS (**on touch screen**)** to enter the Menu for choosing specific protocols. At the bottom of the list first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER (**touch screen**)** or else **PRESSING THE KNOB** to confirm the program selected.

2.3 – Start of stimulation

Once selected a pre-set program or after having regulated the parameters in the manual functioning area, the display shows **START**. Press the relative **START** to begin the therapy.
After having pressed **START** , the device places itself a stand-by state; during this phase the machine will wait 30 seconds for the pedal arming the LASER to be pressed.
Having pressed the pedal once passes to **LASER ARMED** state, in this situation the LASER emits only the red pointing light.
Pressing the pedal a second time passes to EMISSION state where the therapeutical LASER also is emitted.

2.4 – Setting time and intensity of emission

The duration of the therapy and the intensity can be set at any time by rotating the encoder. **PRESS THE KNOB** repeatedly to pass from the intensity parameter to the time parameter and vice versa. The minimum density increase is of 1% and the maximum settable intensity is 100%, the minimum time increase is of 1 minute.

2.5 – Interrupt / end therapy

Treatment emission is interrupted automatically when the Timer reaches 0 and an acoustic signal is heard. If you wish to interrupt treatment before the end, press the pedal or **STOP** (on touch screen) (on the front panel). After the pause, to restart treatment press **the pedal twice**.

2.6 – Turning device off

In order to turn the device off, turn the key or press the switch on the back of the device.

2.7 – Configuration

The LASER devices can be set-up according to personal requirements.
Press **CONFIGURE** (on touch screen) to access the setting area.
This section displays the following entries:
1) language: Italian, English, French, German, Spanish, Portuguese
2) brightness of display: from 0 to 10
3) volume of buzzer: from 0 to 10

4) Operator time out: time the operator has to press the pedal after the start key has been pressed.
5) unblocking code: to enter before turning the device on the first time
6) Maximum power output: indicates the maximum power output of the device and it's given by the sum of the average powers of the waveforms delivered.

Cap.3 – PRE-SET PROGRAMS

LASER therapy has long been used for the treatment of some pathologies which can benefit from the effects of electromagnetic fields: chronic pathologies, articular problems, oedemas, etc. This chapter lists the programs pre-set inside the device.

δ LASER has 16 different pre-set programs, as well as the possibility of memorising up to 20 free protocols.

N°	NAME
1	ARTHRITIS knee
2	ARTHRITIS ankle
3	ARTHRITIS elbow
4	ARTHRITIS wrist
5	ARTHRITIS shoulder
6	ARTHRITIS hip
7	TRIGEMINUS
8	FRACTURE 1cm deep
9	FRACTURE 2cm deep
10	FRACTURE 3cm deep
11	FRACTURE 4cm deep
12	FRACTURE 5cm deep
13	ARTHROSIS
14	NEURALGIA
15	POST-OPERATIVE RESULTS
16	FACIAL PARALYSIS

Cap.4 – FREE PROGRAMS

4.1 – Setting a new program

From the program section, press **NEW (**on touch screen**)** to enter the Free Program menu. By rotating the encoder you can choose which of the 20 custom-made programs available you wish to set. Press **CHANGE (**on touch screen**)** to enter the section for setting the name. **TURN THE KNOB** to change the letter and **PRESS THE KNOB** to move the letter selection cursor. Once you have chosen the name, pass on to the parameter setting phase. Press **PARAMETERS (**on touch screen**)** to move the cursor in the work phase setting section. In this zone, **ROTATE THE KNOB** to set the parameter value and **PRESS THE KNOB** to pass from one parameter to another. With δ LASER it is possible to set up to 3 consecutive work phases, where in each it is possible to use: different wave lengths, different intensity values and timing. To move from one phase to another, scroll all parameters of a phase, after passing the last parameter of a phase, the first parameter of the successive phase appears. When the parameters have been set, the name of the program can be modified once again. Press **NAME (**on touch screen**)**, save the program by pressing **SAVE (**on touch screen**)** or else exit without saving by pressing **EXIT (**on touch screen**)**.

4.2 – Use and modification of a personal program

To amend carry out the instructions in paragraph 4.1

Cap.5 – APPLICATIONS

5.1 – Therapy sessions

Apply the LASER therapy according to medical prescriptions. Applications are done every other day or 2-3 days. Use the most suitable program for the patient until the ailment disappears or considerably decreases.

5.2 – Adjusting emission power output

Intensity adjustment is a main component for the good result of the therapy. It differs based on the type of program being used, the duration of the application and the characteristics of the patient. The intensity can be changed during the program to increase its affects. It can also be decreased in case of overheating or if pain is felt.

The device is endowed with a special function that allows to have safer treatments: it's the "Maximum power output", you can find it in the configuration page, and it allows to set the maximum power output of the device. Consequently during work phase the sum of the power of the different sources cannot exceed the value set during configuration, therefore avoiding dangerous power levels during treatment.
If inadvertently the operator tries to set higher values, the device automatically limits itself.
The device shows that the threshold has been passed in two ways: if the operator is adjusting the duty cycle, the device limits the power bar and it get red; if the operator is adjusting the bar power, then the device limits the duty cycle value showing it as red.
NOTE: if the intensity set or its regulation cause excessive heating or pain in the treated zone, the intensity of the stimulation must be reduced immediately or the application must be stopped.

5.3 – Posture to be kept during the sessions

The ideal posture is to be relaxed, lying on ones back or facedown depending on the zone of application. This position must be maintained during the entire session to facilitate the effects produced by the laser beam, especially the increased the blood flow due to dilation of the blood vessels, During treatment, the knob must maintain a perpendicular position to the treated area.

– POWER SUPPLY

δ LASER must be powered by the electrical mains – Precautions for use

(1) Do not short-circuit the terminals.
(2) Do not set off sparks or flames.

Cap.6 – SYMBOLS

 BF DEVICE

 ATTENTION, CONSULT THE ATTACHED DOCUMENTATION

CE THIS DEVICE IS MARKED CE IN COMPLIANCE WITH
0476 DIRECTIVE EEC 93/42.

 DO NOT DISPOSE OF IN COMMON WASTE

Cap.7 – MAINTENANCE

7.1 – Knob

The connection cable must be periodically checked for cracks, possible cause of dispersion.

7.2 – Device

Use a cloth moistened in water and alcohol to clean the device. **Do not use liquids at all since there is not protection against their entrance (IP20)**.

7.3 – Immediate maintenance:

Immediate maintenance at New Age Italia or by authorised personnel if:

- the device has been subject to external mechanical stress (e.g.. serious drops);
- the device has been overheated excessively (e.g. if left near intense heat sources;
- you doubt that liquids may have penetrated inside;
- the power supply, the cover or other parts are damaged, broken or missing;
- it appears that the features of the device have been changed.

⚠ for safety purposes, do not operate with accessories (e.g. knobs and power supply) other than those included in the basic supply.

⚠ The frequency of maintenance, functional checkups and inspection for compliance with safety standards EN60601-1 for medical devices carried out with secur-tester is yearly. The useful life span of the instrument is guaranteed by the company only if maintenance is carried out regularly.

N. B.: have inspections carried out only by New Age Italia. The device can be sent directly to company assistance workshops or delivered to the dealer where the device was purchased.

Assistance centre:

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Cap.8 – WARNINGS

⚠ Pay special attention to use of the knobs in order not to jeopardise the effectiveness of the treatment.

⚠ Use the device only with electrical systems compliant with Safety Standards in force.

⚠ The device has IP20 protection rating (see chap. "Technical features"). It must not be used in the immediate vicinity of liquids because it is not protected from their entrance.

⚠ Do not use the device in the immediate vicinity of mobile phones (keep them at least a few meters away).

⚠ Operating near (for example 1 metre away) a short wave or microwave therapy device can cause instability in the output of the stimulator.

⚠ Do not connect the patient with δ LASER and an HF surgical device at the same time, to avoid danger for the patient and for the device itself.

⚠ The device works according to its specifications if the atmosphere is kept at a temperature between 5° and 40° C and less than 80% humidity. The same conditions must be maintained during transportation and storage.

⚠ In case of malfunctioning and failures, do not use the device but send it to be repaired.

⚠ Do not operate near flammable substances.

⚠ Do not use gel and accessories other than those supplied.

⚠ It is of the utmost importance to inform the patient about the type of sensations which must be perceived during the therapy. Should he perceive that the sensation is no longer the correct one, you must intervene immediately, stopping the session by the controls and disconnecting the solenoids.

⚠ If the intensity of the output set or its regulation cause excessive heating or pain in the treated zone, the intensity must be reduced immediately or the application must be stopped.

⚠ Keep the device out of the reach of children.

⚠ Both the patient and the operator must compulsory always wear protective goggles included in the basic supply.

⚠ The device must only be used inside closed premises, adequately protected against random access of unauthorised personnel

Cap.9 – TECHNICAL FEATURES

9.1 – Power supply

Internal power supply: ROAL-MCA600

PRI: 100 - 240V ~ 47 - 63Hz SEC: 15V- 10A; 12V-12,5A; 5V-24A

9.2 – Output features

LASER:MDL4-13W980-RP-PD

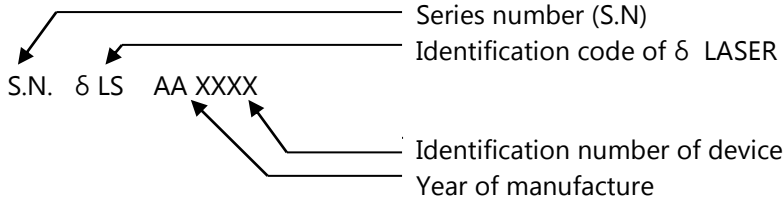
980 nm: 13W

9.3 – Other features

- Size: 44x38x21h [cm]
- Weight: 4.38 [Kg] Class: I Type: BF
- Classification for entrance of liquids: IP20
- Safety in presence of flammable anaesthetic gas: it is not category AP or APG
- Device for functioning: continuous

Manufactured according to Standards:

- EN 60601-1 (2007) – Medical electrical equipment: General safety standards
- EN 60601-1-1 (2003) – Collateral safety standard
- EN 60601-1-2 (2003) – Collateral standard: Electromagnetic compatibility – Provisions and tests
- EN 60601-1-4 (1997): Collateral standard: Programmable electrical medical systems
- EN60601-1-4/A1 (2000) General requirements for safety of programmable devices.
- EN 980-2003 and EN 1041 – Graphical symbols for labelling of electrical medical devices
- EN 60601-2-22- Safety of Laser equipment
- EN60825-1 Classification of laser equipment
- EN60601-1-6 Usability



Cap.10 – BASIC SUPPLY AND ACCESSORIES

10.1 – Basic supply

δ LASER is complete of:

N. 1 Appliance
N. 1 protective goggles for the operator
N. 1 power cable
N. 1 User manual

10.2 – Accessories and consumption material

The following is the list of accessories which can be purchased apart to increase the supply of the device or to replace worn elements:

-knob
-protective goggles for the operator
-protective goggles for the patient
-Use manual