EZ1 EASYONE

5W – 6W

USER AND MAINTENANCE MANUAL

CE 1370

DISCLAIMER

Level S.r.l. declines all responsibility for damage to persons or property due to improper use of this product and failure to follow the instructions, warnings, instructions and precautions described in this user manual.

This user manual is provided only in paper format and must always accompany the EZ1 EasyONE device.

EZ1 EasyONE is manufactured by:

Level S.r.l.
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SUMMARY

1 GENERAL INFORMATION

The EZ1-EASYONE device has been designed and built in a quality system complying with the specific regulations for medical devices, and following all the latest safety standards for electromedical medical equipment; is therefore an absolutely safe and reliable therapy tool both in relation to the patient and the operator.

The unique EZ1-EASYONE device allows manual mode to adjust the power of the 980 nm laser source and processing times.

The whole of the internal components is enclosed in elegant, compact bodywork mounted on an adjustable motorized stand with pivoting wheels. On the back, without further encumbrance, the bridge controls and the key of general insertion.

The electronics are of advanced type and is managed by an intelligent unit, the microprocessor that constantly controls the keyboard, processes the operator's commands visualizing them through the graphic display.

The EZ1-EASYONE device with respect to the pivot of the holder can tilt 110 degrees.

The emission occurs vertically from the part below the bodywork; it can be:

a) Point or point;
b) Horizontal and vertical scanning with output up to 30 degrees

The basic EZ1-EASYONE device consists basically of:

- a 635 nm guide diode with 3 mw power;
- an IR diode (Ga Al As) 970 - 980 nm with a maximum power of 5W (10LS21) or 6W (10LS22) in CW aligned with the 635 nm guiding diode;

1.1 END USE

The EZ1-EASYONE device is a diode laser for therapeutic use. It's used in dermatology (decubitus ulcers, skin necrosis, burns, scarring defects, etc.), aesthetic medicine, physiology, rheumatology, pain therapy. The area to be treated, chosen by the physician according to the pathology, is subjected to the emission of the laser beam for a period which usually goes from 3 to 20 minutes.

1.2 CLASSIFICATION

Classification according to Directive 93/42 / CEE Annex IX rule 9 class IIb.

ATTENZION!

THE DEVICE IS INTENDED TO BE USED BY MEDICAL AND / OR NURSING PERSONNEL SPECIFICALLY FORMED, WITHIN HOSPITALS, AMBULATORS AND PRIVATE CENTERS FOR REHABILITATION AND PHYSIOTHERAPY.

1.3 DESCRIPTION OF SYMBOLS

To make the reading of the manual more comfortable and clear, the symbols used to manage the important warnings for a correct and safe use of the device are shown below.

	**Requirement for correct use** This symbol identifies the presence of information for correct use of the device.
	**Information Requirement** This symbol identifies the presence of useful and general information whose reading guides the user to a conscious use of the device and / or to perform actions.
CE 1370	Identifies that the product is manufactured, designed and manufactured in compliance with the safety requirements (RES) of the Medical Device Directive 93/42 / EEC (Class IIb medical device, in compliance with the classification rule 9 as indicated by the Annex IX).

1.4 PRELIMINARY WARNINGS

Failure to comply with the following warnings as well as the rules and precautions described in this user manual will immediately invalidate any warranty on the EZ1-EasyONE device.
Level S.r.l. is not responsible for any damage to persons or property as a result of failure to comply with the rules or precautions listed below and described in general in this user manual.

	LACKS OR NEGLIGENCES IN THE FULFILLMENT OF THE FOLLOWING INDICATIONS MAY CAUSE THE MALFUNCTION OF THE DEVICE, DAMAGE AND INJURY TO THE USER
	WITH THE PURPOSE OF PREVENTING ELECTRIC SHOCK, CONNECT THE DEVICE ONLY TO GROUNDS WITH PROTECTIVE EARTH AND ELECTRICAL INSTALLATIONS IN ACCORDANCE WITH CEI 64-8 / 7
	DO NOT USE THE DEVICE UNTIL YOU HAVE READ AND UNDERSTAND THIS PRESENT MANUAL IN EVERY PART OF IT
	NO MODIFICATION OF THE DEVICE IS ALLOWED AND / OR ITS PARTIES
	USE OF THE DEVICE FOR PURPOSES DIFFERENT FROM THOSE INDICATED IN THIS USER MANUAL MAY EXPOSE THE PATIENT AND THE OPERATOR TO DANGERS
	IF YOU HAVE SERIOUS ACCIDENTS WITH THE DEVICE, CONTACT THE MANUFACTURER AND THE COMPETENT AUTHORITY IMMEDIATELY
	DO NOT USE THE DEVICE IN THE ENVIRONMENT WITH PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES WITH AIR OR OXYGEN OR NITROUS OXIDE. THE USE OF LASER EMISSION IN THE PRESENCE OF FLAMMABLE MATERIALS, SOLUTIONS OR GASES OR IN AN OXYGEN-RICH ENVIRONMENT MAY LEAD TO A RISK OF FIRE AND/OR EXPLOSION
	DO NOT USE IN THE PRESENCE OF EQUIPMENT OF VITAL SUPPORT OR RADIOFREQUENCY APPLIANCES
	DO NOT USE THE DEVICE ON INCLINED SURFACES, AS THE WHEELS UNDER THE BASE ARE NOT BLOCKING AND THE RISK OF OVERTURNING OR UNEXPECTED HANDLING MAY OCCUR
	IS MANDATORY FOR THE OPERATOR AND THE PATIENT TO WEAR THE PROTECTIVE GLASSES PROVIDED BEFORE STARTING THE EMISSION OF THE LASER BEAM OR THE POINTING BEAM
	DO NOT DIRECT THE LASER BEAM TO THE EYES OR THYROID GLAND

	DO NOT USE THE DEVICE IN CASES OF PREGNANCY, EPILEPSY OR NEOPLASM
	DO NOT USE THE DEVICE ON PARTS OF THE BODY WHERE AN ACTIVE IMPLANTABLE MEDICAL DEVICE IS IMPLANTED (E.G., A PACEMAKER)
	THE PATIENT MUST REMAIN ALERT AND SENTIENT THROUGHOUT THE COURSE OF TREATMENT, IN ORDER TO BE ABLE TO IMMEDIATELY STOP THE EMISSION OF THE LASER BEAM IN CASE THE PATIENT FEELS DISCOMFORT OR PAIN IN THE TREATED AREA
	THE USE OF THE DEVICE BY UNAUTHORIZED PERSONNEL IS PROHIBITED: FOR THIS PURPOSE IT IS RECOMMENDED TO REMOVE THE KEY OF THE GENERAL SWITCH WHEN THE DEVICE IS NOT IN USE AND TO STORE IT IN A SAFE PLACE
	ALWAYS CONNECT THE INTERLOCK SAFETY DEVICE PLUG BEFORE SWITCHING ON THE DEVICE
	THE USE OF CONTROLS OR ADJUSTMENTS, OR THE EXECUTION OF PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS MANUAL, MAY CAUSE EXPOSURE TO HAZARDOUS RADIATION.

1.5 COMPOSITION AND ACCESSORIES

The EZ1 EasyONE comes with the following components:

- N. 1 Power cable;
- N. 2 pairs of protective glasses;
- N. 2 Replacement fuses;
- N. 1 PVC Cover device;
- N. 1 Key for general switch;
- N. 1 Interlock connector;
- N. 1 Plastic-coated table of application points
- N. 1 Plastic-coated table of programs
- N. 1 Stiker “danger laser”

EZ1 EasyOne has the following optional accessories:

N. 1 Kit interlock system;
N. 1 Infrared viewer;
N. 1 90 degrees deflector;
N. 1 Portable power meter.

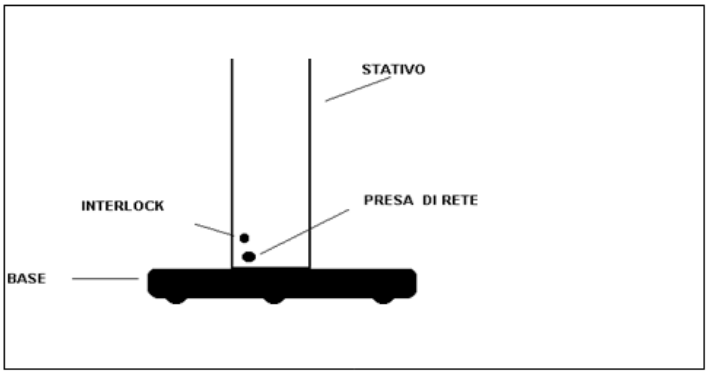
	USE OF ELEMENTS WHICH DO NOT USE THE SYSTEM ABOVE DESCRIBED OR NOT SUPPLIED TO THE DEVICE WOULD AFFECT YOUR SAFETY AND EFFECTIVENESS
	OPENING THE PACKAGING, CHECK THE TOTAL INTEGRITY OF THE CONTENT. IN CASE OF EVIDENT SIGNS OF DAMAGE, CONTACT THE MANUFACTURER IMMEDIATELY.
	If all the elements listed above have not been received, contact the manufacturer immediately

2 POWER CONNECTION AND TURNING ON THE DEVICE

⚠	BEFORE USING THE DEVICE VERIFY THAT THE ELECTRICAL SYSTEM IS IN ACCORDANCE WITH THE REQUIREMENTS OF CEI 64-8 / 7
⚠	DO NOT PLACE THE DEVICE SO THAT IT IS DIFFICULT TO DISCONNECT THE PLUG FROM THE POWER SOCKET
⚠	PLEASE NOTE THAT PRODUCTS SUCH AS SMART-PHONES, MOBILE PHONES AND OTHER RF COMMUNICATION DEVICES, MAY GENERATE DISORDERS AGAINST THE MEDICAL DEVICE
⚠	DO NOT EXPOSE THE DEVICE TO MORE THAN OTHER ELECTROMEDICAL DEVICES
⚠	VERIFY THAT THE ENVIRONMENT OF USE MEETS THAT SET FORTH IN THE FOLLOWING CHAPTER "ELECTROMAGNETIC COMPATIBILITY"
⚠	VERIFY THAT THE AIR INTAKES UNDER THE BASE OF THE DEVICE ARE FREE OF DUST OR ANY OBJECTS
⚠	WHEN MOVING THE DEVICE, PAY ATTENTION TO PIVOTING WHEELS TO AVOID THE RISK OF CRUSHING

To connect the EZ1 EasyONE to the mains and for switching on follow the instructions below:

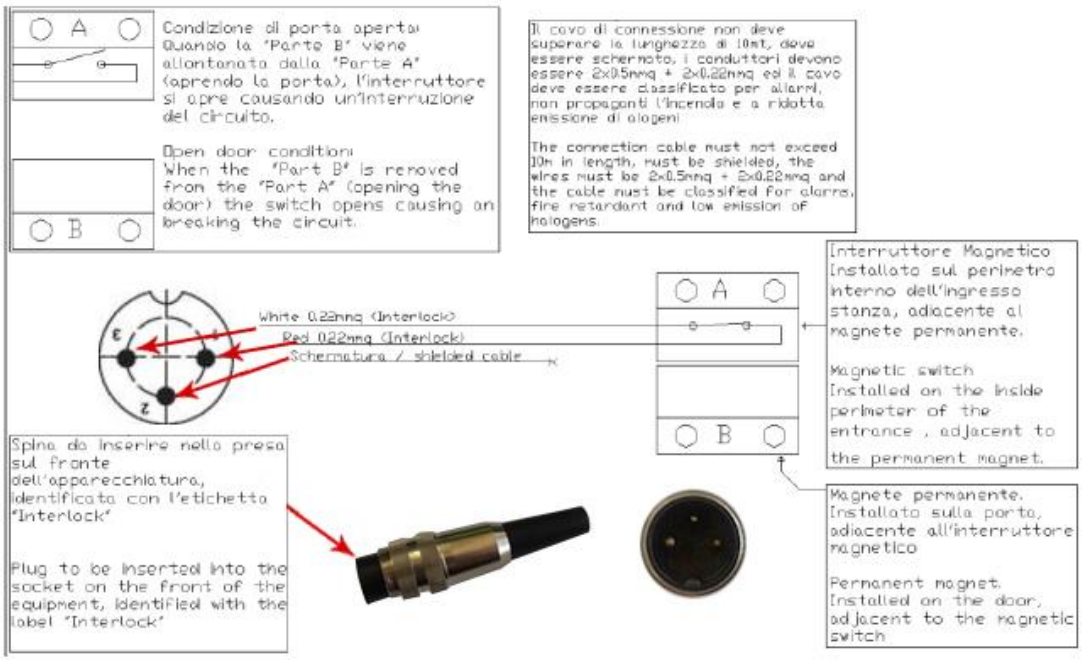
- Insert the supplied power cable into the appropriate socket.
- Connect interlock device as described in section 2.1.
- Insert the key into the general switch and turn it clockwise: the device will emit a sound signal to communicate the correct ignition .



2.1 INTERLOCK SYSTEM CONNECTION

The interlock device is a security system that blocks the laser emission every time the access door to the rooms is opened, where the treatment is carried out. Please note that the interlock device must be connected properly.
Together with the laser equipment is also provided the interlock socket to be inserted on the special socket of the laser equipment. The correct installation of the interlock device involves inserting the interlock device plug into the interlock socket of the device, as shown in the figure below. The interlock device consists of a plug connected through two electrical cables (or single cable with double conductive filament, with isolated filaments) to a normally closed switch that will be placed on the input port. The interlock plug shall be connected to the interlock socket, the two electrical cables shall be normal electrical cables and the normally closed switch shall be a magneto-electric switch, optical or mechanical with 12 Vdc and 10ma features. At the customer's request, LEVEL S.r.l. can supply the complete interlock device kit. After the operation of the device"interlock" due to the unintended opening of the access door to the room, the equipment will lock and remain locked even if the door is closed. It will then be necessary for the operator to restart the device, following the ignition instructions in the following sections.

ALWAYS CONNECT THE INTERLOCK SAFETY DEVICE PLUG BEFORE SWITCHING ON THE DEVICEUSE



3 USE MODE

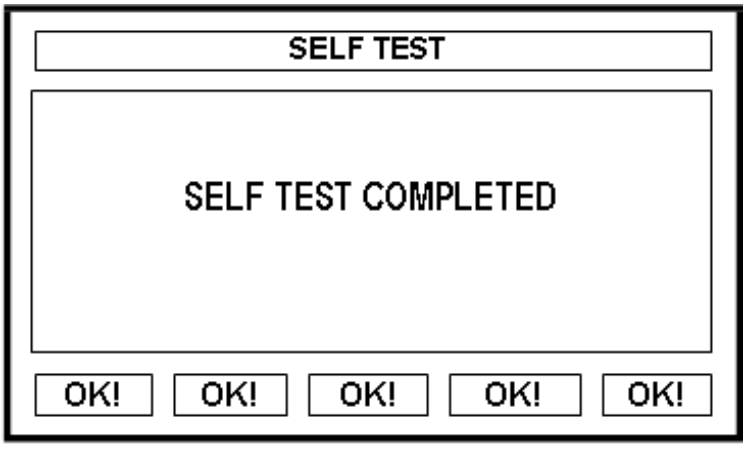
VERIFY THE INTEGRITY OF THE DEVICE BEFORE PROCEEDING TO THE NEXT STEPS

3.1 TURNING ON THE DEVICE AND AUTODIAGNOSE

After inserting and rotating the key in the general switch, the display lights up and the logo "LEVEL"is displayed. At this point, the EZ1 EasyONE Laser starts the self-testing process, where the strategic parts of the device are tested and checked for correct functioning. If a malfunction occurs at one of these stages, the device will report the problem and will not allow treatment to be initiated in any way. It will not be possible to use an apparatus that is not able to guarantee absolute reliability and safety features.

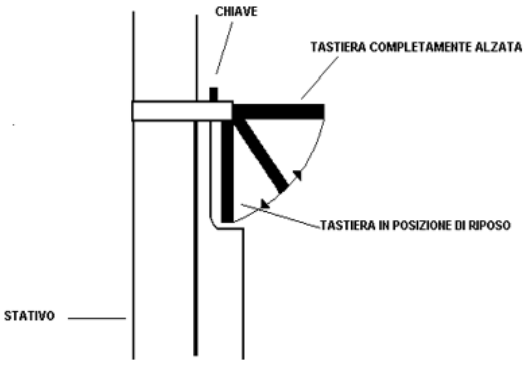
IF AN ALARM SIGNAL IS TRIGGERED DURING SELF-DIAGNOSIS, IT IS MANDATORY TO SWITCH THE DEVICE OFF IMMEDIATELY AND CONTACT TECHNICAL SUPPORT

Since it is an electromedical device, particular attention has been paid to the safety of operation, and to the possibility of identifying with extreme ease any malfunctions. To this end, the EZ1 performs a self-diagnosis procedure at each ignition in which all the main subsystems are tested in their correct functioning. If a malfunction occurs in only one of these phases, the EZ1 will stop showing a screen like that in figure 7.2, and simultaneously emitting sound signals. It will therefore not be possible to use an apparatus that is not able to guarantee absolute reliability and safety features.Most commonly, following the completion of all test steps will be confirmed by the following screen that will appear for a few seconds on the display:

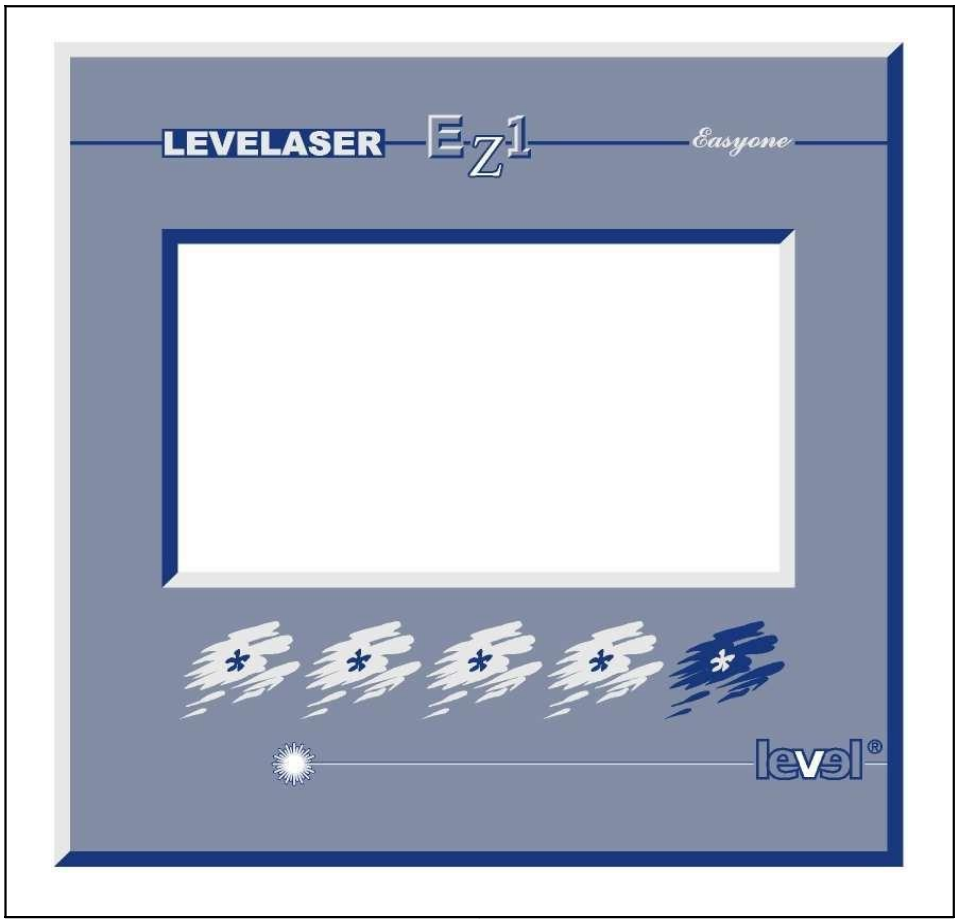


Before switching on, adjust the position of the display with integrated keyboard. The display can assume different positions starting from the rest position in which it is completely lowered.To lift it, simply rotate it upwards.

To lower it it is sufficient to pull it to the right up to the maximum and then rotate it downwards continuing to keep it pulled. The following illustration shows the positions:

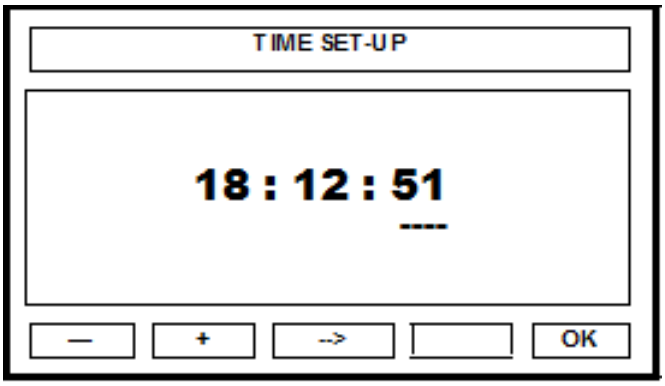


The built-in EZ1 EasyONE and' graphics display has five multifunctional keys. The functions of such keys take on different meanings depending on the operating menu of which you are intervening, and their meaning is extensively decrypted by the software labels" that appear in the last line of the same display, just above each function button.



3.2 DEVICE SETTING

Keeping the first button on the left of the keyboard pressed down, switch on the device. The following display page appears:



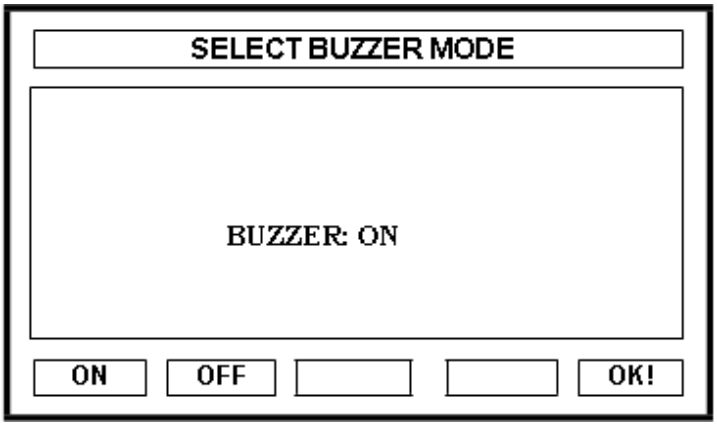
To edit the seconds value, press the buttons "–" or "+" to decrease or increase the displayed value respectively.

Press the "->" button to shift the position of the cursor onto the minutes. The editing procedure for the minutes is identical to that for the seconds.

Press the "->" button again to shift the position of the cursor onto the hour, the value of which may be edited using the – or + buttons, as for the minutes and seconds.

Press the "->" button again to take the cursor back to the seconds position. If the internal clock setup has been completed, just press the OK button to exit from the TIME SET-UP display page and to start normal operation

To select the buzzer mode (on or off) in the EZ1, just hold down the middle key of the keyboard and turn on the device. The following screen will be displayed:



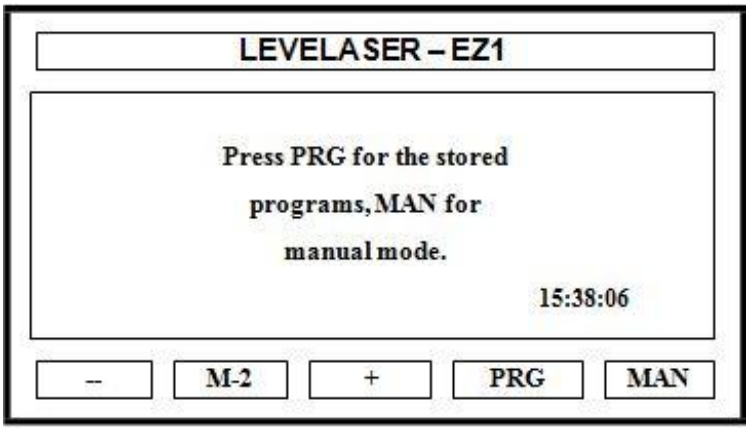
Through the ON and OFF keys you activate or deactivate the buzzer. made the selection, through the OK key! You confirm your choice and switch to the initial menu.

THE ACOUSTIC SIGNS PROVIDED BY EZ1 EasyONE ALSO HAVE A SAFETY FUNCTION, SUGGESTING TO ALWAYS LEAVE THE BUZZER IN ON MODE.

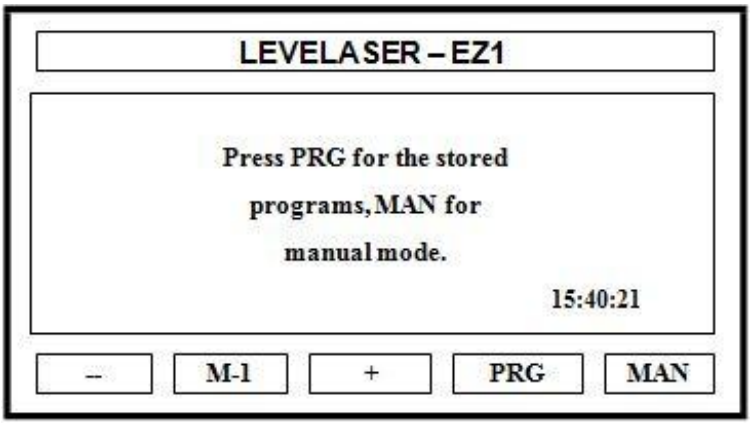
ALWAYS REMEMBER TO WEAR PROTECTIVE GLASSES DURING THE EMISSION OF THE LASER BEAM

3.3 MOTORS MANAGEMENT

After the self-diagnosis, the EZ1 EasyONE device will present the following screen:



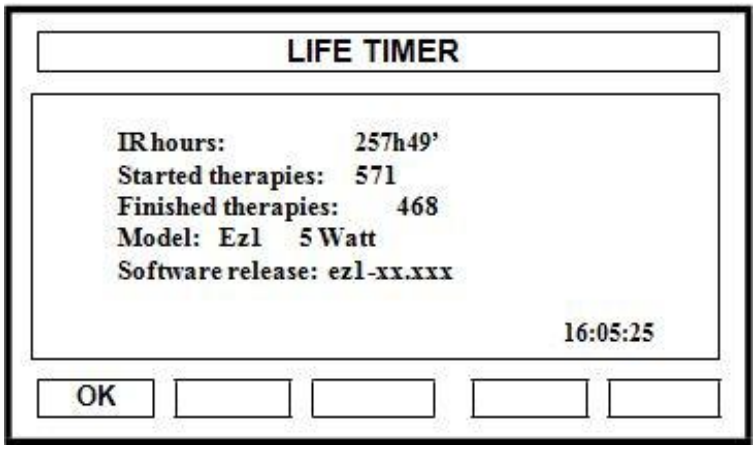
With the first three keys you can adjust the position of the head of the EZ1 EasyONE in height or inclination. Through the second button from the left (M-2) you can 'select the engine on which to go to act (swing or stand). With the keys – and + you act by moving the selected engine.
During the engine handling phase, the EZ1 EasyONE will emit a repetitive beep with two-second pauses to alert both the operator and any patient that the device is moving.
In addition, in order to prevent improper movement of the two engines, the EZ1 EasyONE and' device is equipped with four limit switches that prevent the operator from moving the tilting arm or the piston stand beyond the safety limit.
At the time of the ignition, engine 2, that is to say the one relative to the tilting arm, is the one selected by default. Pressing M-2 will then go to disable the tilting and activate the motor stand that will allow the height adjustment of the device EZ1 EasyONE. At the same time in order to alert the operator of the engine selection, the software label for the second key will change the wording, becoming M-1 as you can see in the illustration below:



Find the optimal position of the device (should always be a distance of about 30cm between the part to be treated and the exit of the laser beam) you can decide whether to operate using a preset therapy or through the manual mode.

3.4 DEVICE INFORMATIONS

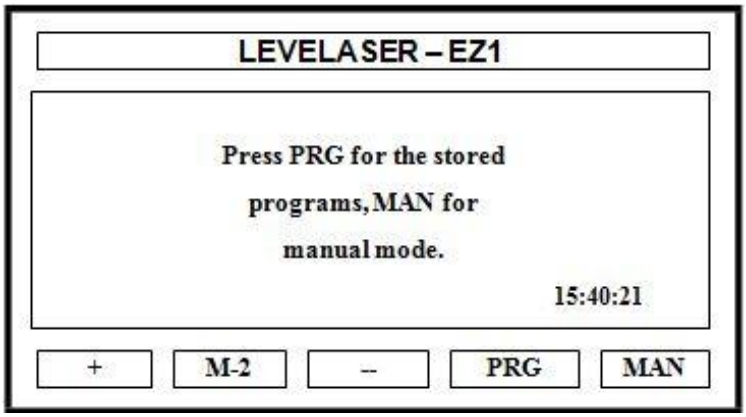
To display the EZ1 life timer, hold down the second key from the left of the keyboard and turn on the device. On the display the request for a password, and after entering the correct password (present on the service manual) the following screen will appear:



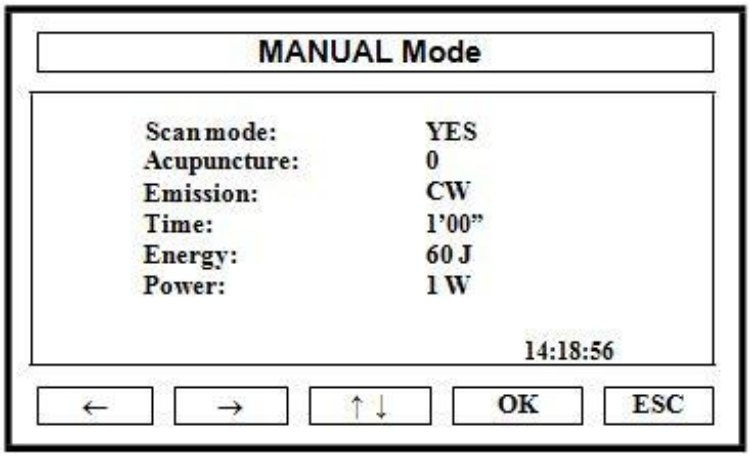
3.5 MANUAL MODE

The use of the MANUAL mode is particularly suitable for researchers, and for all experienced users who wish to embark on the path of new therapies. Through this mode, in fact, it is possible to completely customize the operation of the EZ1 generating treatment combinations not executable through the use of prememorized programs.

The access to the MANUAL mode is done by docking the MAN button. present in the function select menu.



The new window resulting from this selection will allow for the customization of the treatment through the setting of four primary parameters. In this case, it will be possible to select four primary parameters.

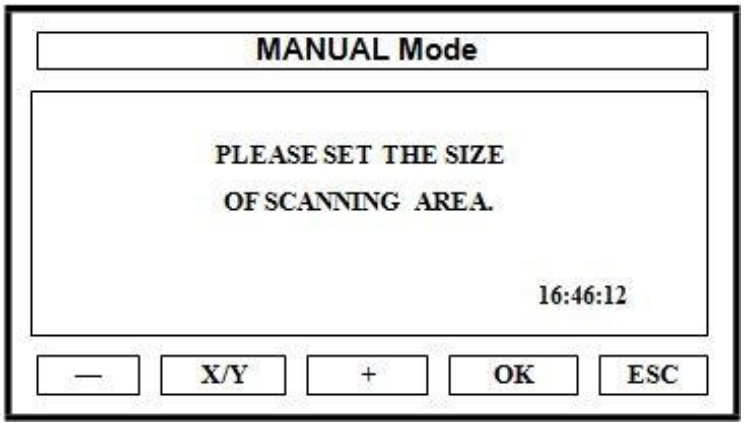


It will then be a matter of determining:

1. Whether to operate in SCANSION mode or in POINT mode (in point mode. define how many points);
2. Determine the pulse rate of the IR beam (or continuous)
3. Determine the time of treatment;
4. Determine the IR emission power.

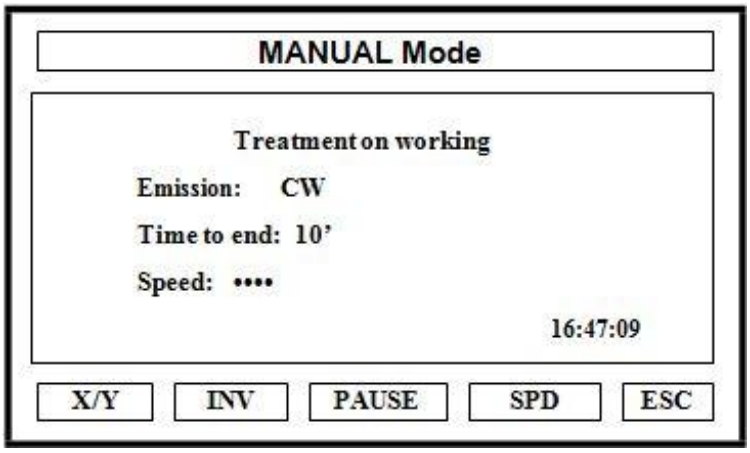
As previously the - and -> keys allow you to increase or decrease the amount of the selected field (in the case of SCANSION to decide if YES or NO). The UP and GIU key allows you to switch to the next field, the ESC key to return to the previous menu, while OK! will give the treatment away.

The activation of scanning mode immediately leads to the following screen, which is needed to adjust the scanning area. This will be done in the way described in the previous paragraph.



Clicking on OK will start the therapy and the following screen will appear

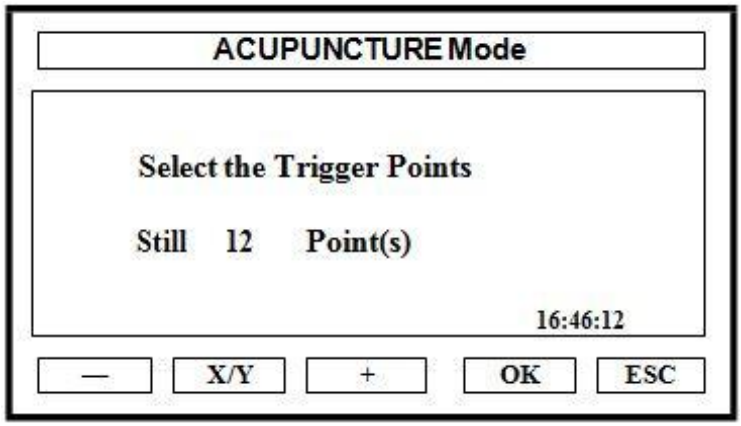
:



After starting the therapy according to the scanning mode, it is possible to modify some parameters during the treatment without interrupting the same.
In particular through the keys:

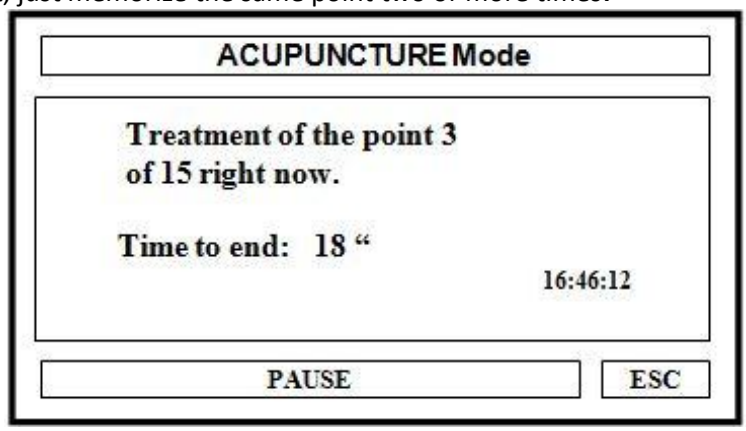
- **X/Y**: It's possible to change the fast X or Y scanning axis
- **INV**: It is possible to reverse the direction in which slow scanning takes place
- **PAUSA**: Pauses the treatment; the guide diode remains on while the IR diode is switched off.
- **VEL**: Increase the speed of slow scanning; once you have reached the maximum speed, a further pressing of this button brings the speed back to the minimum
- **ESC**: Stops treatment and returns to previous window.

If the A POINT mode is set in the menu and a number of points greater than zero are set, the location of these points on the plane should be recorded before starting the treatment. For a correct location of the"trigger point" please refer to the Atlas of Laser Therapy published by Level.



During the memorization of trigger points on the screen will always appear the writing of how many points are missing to the complete memorization.

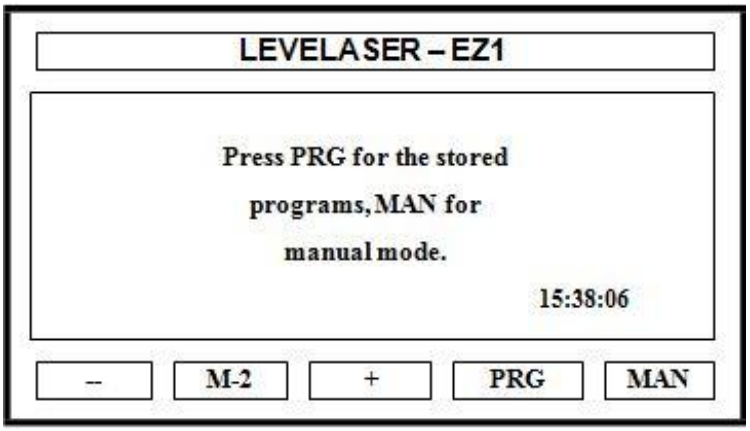
Since the treatment duration of each individual point is constant and equal to the duration of thewhole treatment divided by the number of points, where more effective action is needed at a particular point, just memorize the same point two or more times.



Given the start of treatment, it will always be possible to temporarily discontinue therapy, or possibly stop it permanently.
The passage of the treatment from one point to another will be marked by an acoustic signal.

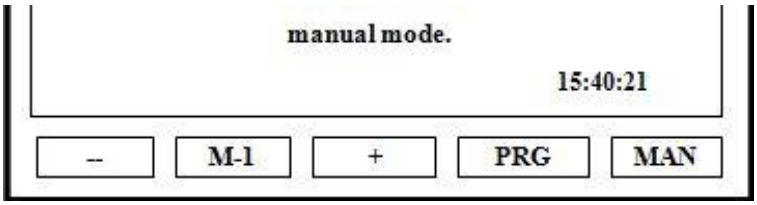
3.6 AUTO MODE

The use of prememorised programmes is indicated not only to all operators who are approaching lasertherapy for the first time, but also to the most experienced users, in order to make the operation of the EZ1 easier and more immediate.
The LEVELASER EZ1-EASYONE comes with 38 prememorized programs, suitable for 38 of the most common diseases and for which the results after treatment with lasertherapy are remarkable. To select a pre-stored program you will have to proceed as described below.
After the self-diagnosis, the EZ1 will present the following screen:



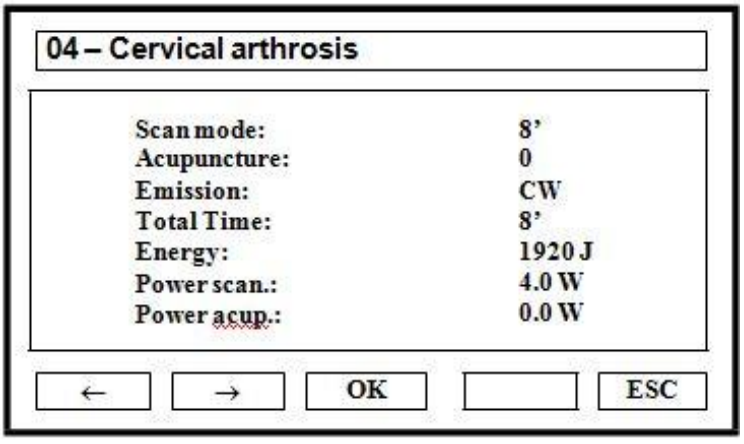
With the first three keys you can adjust the position of the head of the EZ1 in height or inclination. Through the second button from the left (M-2) you can select the engine on which to go to act (tilting or stand). With the keys “-“ and “+” you act by moving the selected engine.
During the engine handling phase, the EZ1 will emit a repetitive beep with two-second pauses to alert both the operator and any patient that the device is moving.

In addition, in order to prevent improper movement of the two motors, the EZ1 is equipped with four “limit switches” which prevent the operator from moving the tilting arm or the piston stand beyond the safety limit.
At the time of the ignition, the motor “2”, that is the one relative to the tilting arm, turns out to be the one selected of default. Pressing “M-2” will then disable the tilting and activate the motor stand that will allow the height adjustment of the EZ1. At the same time in order to alert the operator of the engine selection, the software label for the second key will become M-1. M



Finding therefore the optimal position of the EZ1 (which we remind to be of a distance of approximately 30cm between part to treat and exit of the laer beam) will be able to decide if operating using a preset therapy, or through manual mode. This selection is made using the two PRG and MAN keys, which select “Program mode” or“Manual”respectively.

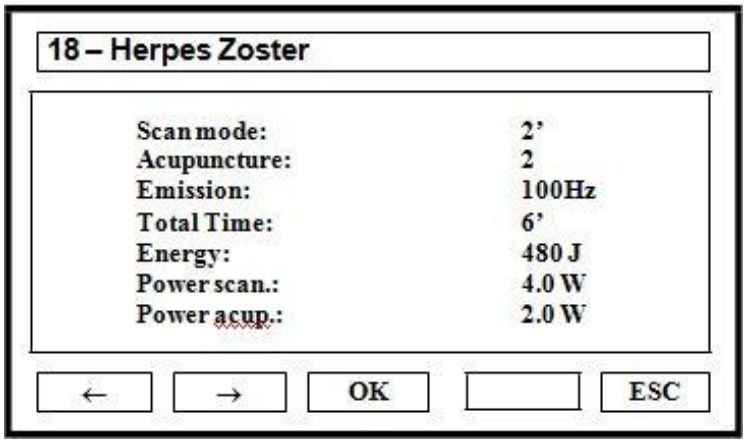
Press the button for PRG and the button -> advancing to the following screen:



This screen refers to the fourth program“cervical arthrosis”

This corresponds to the fourth of the thirty-eight pre-programmed programs within the EZ1. It is a program for the treatment of cervical arthrosis, and which operates in“scan mode” for a time of 8 minutes and never for acupuncture, providing an energy of 1920

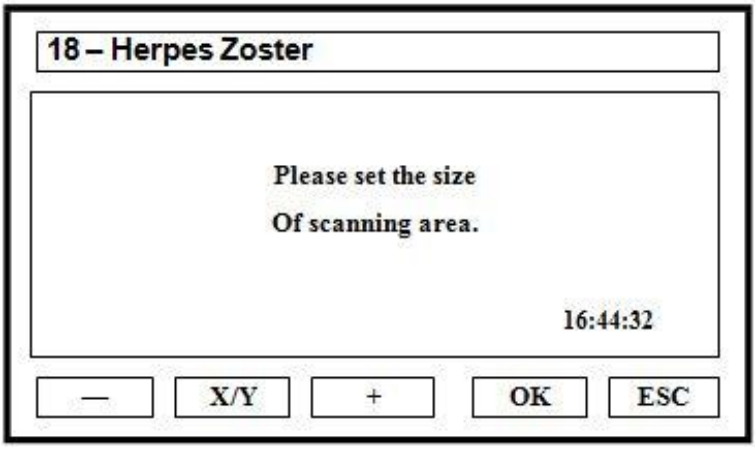
joule.
To accept this program just press the button relative to the key OK If you want instead to return to the previous window press the key ESC .
To visualize the therapies following the first, just press the button ”->”. For example, by advancing with the key ”->” you will be able to see the following screen:



This screen refers to the program“Herpes zoster”

This identifies the ninth program (Number 18) “Herpes zoster”, characterized by a scan therapy time of 2 minutes with 100hz modulated IR laser emission, and a second phase with“” with a 100hz modulated IR laser emission to provide 480 joules of energy. Overall the therapy will be characterized by a first part of“”scan treatment; and a second part of“point”treatment.

Confirmation of such treatment, happens as already said through the key “OK”that immediately projects in the window below:

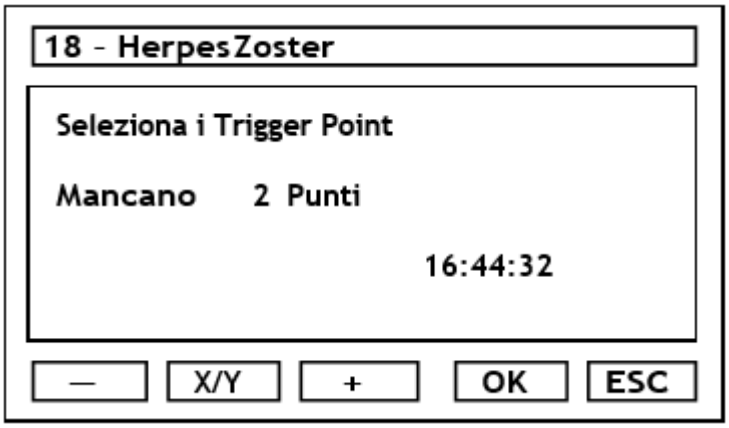


3.7 SCAN SETTINGS

IS MANDATORY FOR THE OPERATOR AND THE PATIENT TO WEAR THE PROTECTIVE GLASSES PROVIDED BEFORE STARTING THE EMISSION OF THE LASER BEAM OR THE POINTING BEAM (ALSO EMITTED DURING THE ADJUSTMENT OF THE SCAN)

The adjustment of the scan is required every time, after setting the operating parameters, both automatic and manual. This step consists in adjusting the scan X/Y so that the guiding beam covers exactly the area to be treated.
It will then be a matter of setting the operating adjustments that must be made to each therapy such as the adjustment of the scanning area and the storage of the points "trigger" on which to operate.

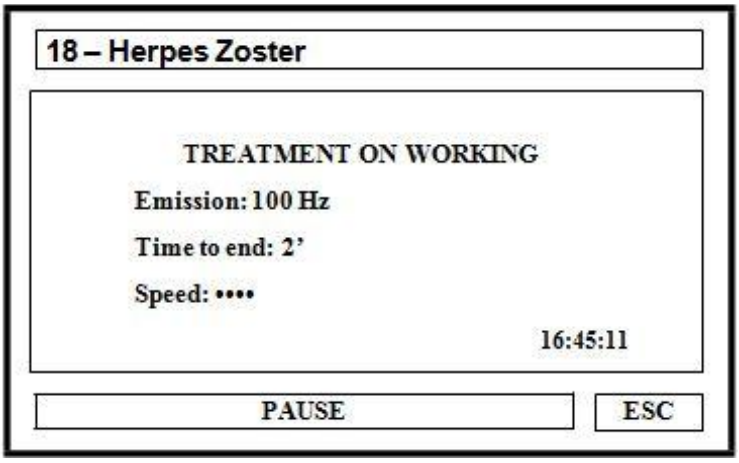
In the case of the program "Herpes zoster" it is to adjust the X/Y scan so that the guiding beam covers exactly the area to be treated. The setting happens in a similar way to what seen for the handling of the two motors. Through the buttons "-" and "+" the scanning will decrease or increase, while through the X/Y key it will be determined according to which Cartesian axis to make such adjustment. The confirmation of the adjustment is done by pressing the button "OK", while as in all operating lefasi, through the key ESC you can return to the previous menu if you have any uncertainties or second thoughts. After adjusting the area to be processed in scanning mode, the"trigger point"



Trigger point storage screen for the Herpes zoster program

3.8 STARTING TREATMENT

After entering all operating parameters and adjusting the scan, the system takes you to a pre-start screen. When this screen appears the system is fully ready for laser emission, even the mechanical shutter is disarmed and the warning lights turn on. Then memorized the trigger points, you can start the therapy, which for any reason of necessity can be temporarily suspended or permanently interrupted.
During the duration of the treatment it will be possible to read on the display not only the hour, but also the time missing at the end of the therapy.
If treatment is interrupted for more than 5 minutes, the system will automatically interrupt the treatment and a new treatment should be initiated.



Screenshot of the ongoing treatment of the Herpes zoster program

YOU CAN ALSO STOP THERAPY AT ANY TIME BY PRESSING THE EMERGENCY LOCK BUTTON. THIS OPERATION REQUIRES THE OPERATOR TO RESTART THE DEVICE

The following controls shall be in place throughout the period of the release:
• interlock security device: If the door is opened, the output is interrupted. Once the door is closed, the operator must intervene manually to resume therapy.
• Controlling the status of galvanometers: In case of a failure of galvanometers (which regulate the laser beam scan), the emission is interrupted and an error message is displayed on screen. Contact the manufacturer for technical assistance.
• Temperature control of the laser source: If the maximum temperature is exceeded, the emission is interrupted. Contact the manufacturer for technical assistance.
• Emission power control: If the emission power differs by more than 20 % from the set value, the emission is interrupted. Contact the manufacturer for technical assistance.

FUMES AND/OR BEAM VAPOUR MAY CONTAIN VITAL TISSUE PARTICLES

After the timer, the therapy is finished, the emission of the laser beam is interrupted and the shutter is reactivated. Device returns to home screen.

TABLE OF PROGRAMMES PRESENTED IN THE MEMORY OF THE DEVICE

N.	Program	SCAN MODE		POINT MODE			TOTAL TIME
		FREQ.	TIME	FREQ.	POINTS	TIME	
1	Continuos Scan	CW	10 MIN	-----	-----	-----	10MIN
2	Analgesic	-----	-----	100 HZ	1	4 MIN	4 MIN
3	Big vague	-----	-----	200 HZ	2	3 MIN	3 MIN
4	Cervical osteoartritis	CW	8 MIN	-----	-----	-----	8 MIN
5	Lumbar arthritis	25 HZ	10 MIN	25 HZ	4	6 MIN	16MIN
6	Capsulite	10 HZ	5 MIN	10 HZ	3	1 MIN	6 MIN
7	Cysts of Backer	CW	6 MIN	-----	------	-----	6 MIN
8	Muscle contracture	CW	10MIN	-----	------	-----	10MIN
9	Coxalgia-Coxartrosi	200 HZ	5 MIN	200 HZ	3	3 MIN	8 MIN
10	Cruralgia	90 HZ	6 MIN	90 HZ	2	3 MIN	9 MIN
11	Hammer toes	-----	-----	4 HZ	4	8 MIN	8 MIN
12	Post distortive oedema	200 HZ	6 MIN	200 HZ	3	6 MIN	12MIN
13	Epicondylitis	200 HZ	5 MIN	200 HZ	6	6 MIN	11MIN
14	Herniated cervical disc	4 HZ	6 MIN	4 HZ	2	2 MIN	8 MIN
15	Post-surgical wounds	CW	10MIN	-----	-----	-----	10MIN
16	Fibromyalgua	4 HZ	5 MIN	4 HZ	5	1 MIN	6 MIN
17	Gonalgia-Gonartrosi	4 HZ	6 MIN	4 HZ	3	3 MIN	9 MIN
18	Herpes zoster	100 HZ	2 MIN	100 HZ	2	4 MIN	6 MIN
19	Vascular failure	90 HZ	10MIN	90 HZ	1	1 MIN	11MIN
20	Lymph drainage	CW	20MIN	-----	------	-----	20MIN
21	Low back pain	CW	10MIN	-----	-------	-----	10MIN
22	Quervain disease	CW	10MIN	------	-------	-----	10MIN
23	Meniscal	100 HZ	5 MIN	100 HZ	1	2 MIN	7 MIN
24	Metatarsall pain	CW	10MIN	-----	------	-----	10MIN
25	Intercostal neuralgia	CW	10MIN	------	------	-----	10MIN
26	Neuritis	CW	8 MIN	------	------	-----	8MIN
27	Strain	100 HZ	3 MIN	100HZ	6	9 MIN	12MIN
28	Tarsal tunnel	100 HZ	4 MIN	100 HZ	3	6 MIN	10MIN

	syndrome						
29	Radicular compression	50 HZ	7 MIN	50HZ	1	3 MIN	10 MIN
30	Guyon syndrome	CW	10 MIN	-----	------	----	10 MIN
31	Heel spur	50 HZ	4 MIN	50 HZ	4	4 MIN	8 MIN
32	Osteochondrosis	CW	10 MIN	------	-------	----	10 MIN
33	Spondylolysis-SpondYlolisthesis	100 HZ	10 MIN	100 HZ	1	3 MIN	13 MIN
34	Tendinitis	50 HZ	10 MIN	50 HZ	2	2 MIN	12 MIN
35	Tendinitis shin splints	100HZ	5 MIN	100 HZ	2	2 MIN	7 MIN
36	Carpal tunnel	50 HZ	5 MIN	50 HZ	4	4 MIN	9 MIN
37	Decubitus ulcer	CW	10 MIN	-----	-----	----	10 MIN
38	Analgesic 2(fase 1)	200 hz	4 MIN	-----	-----	----	4 MIN
38	Analgesic 2(fase 2)	Cw	6 MIN	------	-----	-----	6 MIN

4 MANUTENZIONE

ALWAYS VERIFY THAT THE DEVICE IS DISCONNECTED FROM THE MAINS BEFORE PERFORMING ANY OF THE FOLLOWING

DO NOT DIRECT THE LASER BEAM TO THE EYES OR THYROID GLAND

The useful life of the device if correctly maintained and used is equal to 10 years

4.1 ORDINARY MAINTENANCE AND CLEANING

EZ1 EasyONE does not require special maintenance. To ensure the efficiency of the equipment make sure that the air intakes under the base of the instrument are free from dust/objects that could hinder the normal flow of air and carry out the cleaning of the device periodically. EZ1 EasyONE can be cleaned from dust using a dry soft cloth. More resistant stains can be removed using an aqueous soap solution or a sponge soaked in hydroalcoholic solution. For disinfection EZ1 EasyONE can be treated with all the devices normally used for electromedical equipment.
There is no danger of flammability of materials normally used for the cleaning of the appliance (alcohol or other detergents), given the low temperature reached by the laser emission. The device has no parts subject to sterilization.

4.2 EXTRAORDINARY MAINTENANCE AND REPAIRS

Extraordinary maintenance consists in the half-yearly control of the discharge currents to the ground by technical personnel responsible for protection against direct and indirect contacts. In addition, a periodic check is provided for the verification and calibration of the laser emission, by measuring the emission power according to the procedure described in section 3.2“Device settings”.

EZ1 EasyONE is equipped with a mechanical safety shutter that blocks any uncontrolled emissions of the Class 4 IR laser sources (CEI EN 60825-1).
For safety reasons, the user is recommended to do a check at least once a year, sending the equipment to LEVEL S.r.l., to carry out the maintenance of this shutter. This ensures the perfect functioning of the device.

In case of malfunction, the following checks are recommended:
- Check the connection to the mains socket;
- Ensure that the equipment is working in a room with room temperature below 28°C.
- Verify that the key has been correctly inserted into the safety switch;
- Check interlock plug connection;
- Check the status of mains fuses and replace them if necessary;

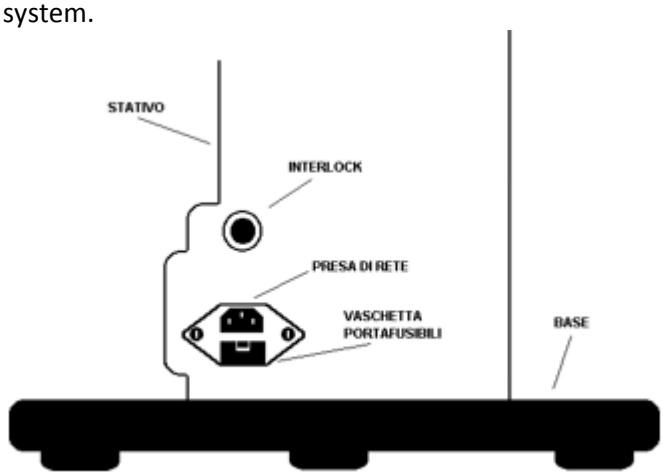
• Verify that all operations have been executed correctly;
In case the problem is not solved, call the Technical Assistance Service.

4.3 TECHNICAL ASSISTANCE

If the device needs Technical Assistance, before sending the product to our service center, you must have authorization. Therefore, please contact our office or the nearest authorized centre (see the list on www.level-laser.com) and fill in the technical assistance request form.
LEVEL S.r.l., unless otherwise indicated by the Company itself, for reasons of safety and
maintenance of the characteristics of the products even after the interventions, is the only exclusive for the assistance on its products. Any technical documentation concerning repairable parts may be provided, but only with the approval of the company and only after adequate instruction has been given to the personnel involved.
Please note that the products sent in assistance must be
and obligatorily sanitized for the protection of the health of the staff involved in the provision of the service.

4.4 FUSES REPLACEMENT

For fuse replacement, follow these instructions:
• Switch off the equipment and disconnect the mains plug;
• Pull out the fuse tray located on the mains socket acting on the appropriate tab.
• Replace fuses using spare fuses supplied to the equipment;
• re-insert the fuse tray;
• reactivate the system.



5 DISPOSAL

Do not dispose of this product and its accessories as general waste. Prepare the product for recycling or recycling in accordance with the Legislative Decree of 14 March 2014, n. 49 "Implementation of Directive 2012/19 / EU, on waste electrical and electronic equipment (WEEE)".

In case of use in hospitals, follow the internal rules for the disposal of electrical and electronic waste.

6 TECHNICAL CHARACTERISTICS

Main Voltage	230 Vac; 1.1 A Max.; 50 Hz
Current absorbed	0,8 Amax.
Motors	N°2 (stand, tilting)
Display	LCD with resolution 800x480 pixel
Mode	Continuos or pulse (Frequenza da 1 a 10000 Hz)
Frequency and scan XY angle	30 Hz, da -14° a +14° (±5%)
Dimensions	60x65x122 cm
Weight	40 Kg

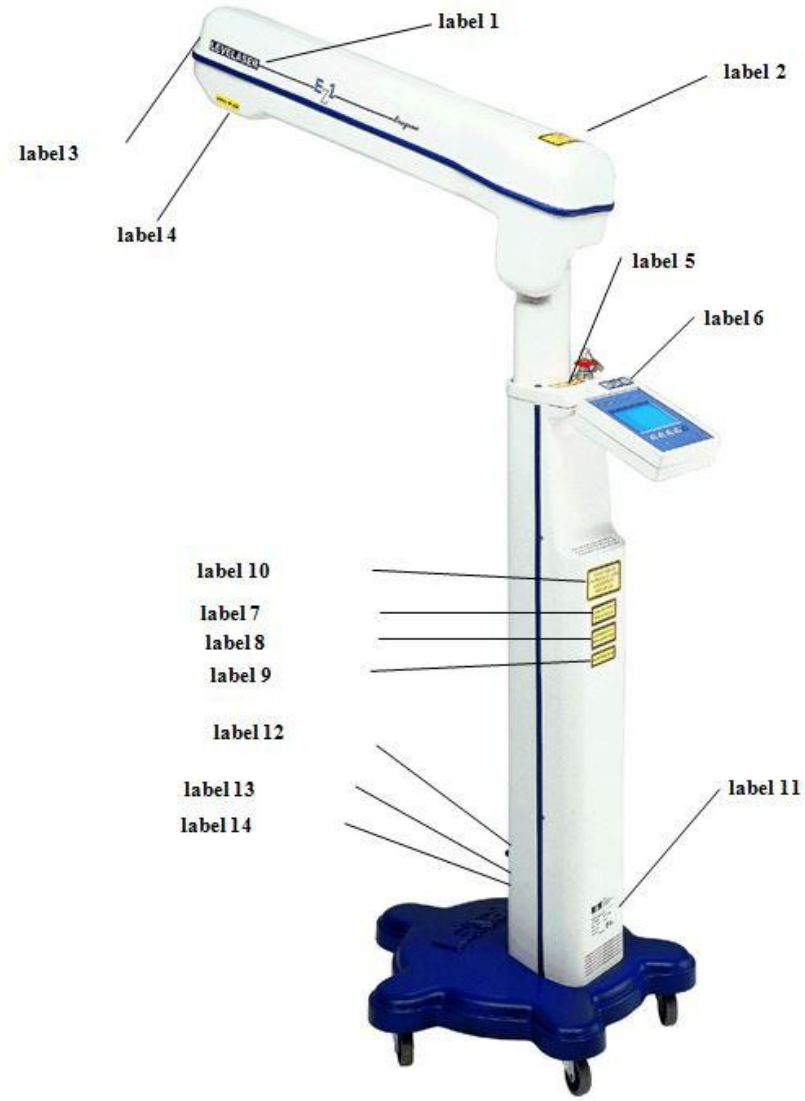
laser beam	
Diode	GaAlAs CW
Wave lenght	970 - 980 nm
Max power	5 W o 6 W ± 10%
DNRO (nominal ocular risk distance)	23.4 m ± 20%
Spot dimension	22 mm ± 20% (Diameter)
Divergence	21 x 49 milliradiant ± 20%

Point beam	
Power	<3 mW
Wave lenght	635 nm
DNRO (nominal ocular risk distance)	12.44 m ± 20%
Spot dimension	2x2 mm ± 20%
Divergence	0.3 x 0.9 milliradiant ± 20%

Enviromental conditions	Temperature	Use	+0°C - +40°C
		Storage/Transport	-40°C - +70°C
	Humidity	Use	+10 - 95% Ur without condensation
		Storage/Transport	+10 - 95% Ur
	Atmospheric pressure	Use	700 - 1060 hPa
		Storage/Transport	500 - 1060 hPa

7 LABELLING

7.1 SAFETY LABELS



7.1.1 LABEL 1

7.1.2 LABEL 2

ATTENTION
VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE
TO DIRECT OR DIFFUSE RADIATION
LASER DEVICE CLASS 4

7.1.3 LABEL 3

Meaning: warning card - Danger source laser radiation

7.1.4 LABEL 4

7.1.5 LABEL 5

7.1.6 LABEL 6

ATTENTION
TO LOWER THE KEYBOARD PULL IT
TO THE RIGHT

7.1.7 LABEL 7

Wave lenght 970 - 980 nm
Max Power 6 Watt CW
CLASSIF. CEI EN 60825-1

5W for 5w version (10LS21)

7.1.8 LABEL 8

Wave lenght 635 nm
Max Power 3 mW CW

7.1.9 LABEL 9

Classif. CEI EN 60825-1 2009-07

7.1.10 LABEL 10

ATTENTION
CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION
IN CASE OF OPENING AVOID EXPOSURE OF EYES
OR SKIN TO DIRECT OR DIFFUSE RADIATION

7.1.11 LABEL 12

INTERLOCK

7.1.12 LABEL 13

230 V. 50 HZ.

7.1.13 LABEL 14

FUSE 2X T 4A

7.2 LABEL ON THE DEVICE

5W VERSION(10LS21) use the same label with 5w write and not 6w

7.3 IDENTIFICATION OF THE SYMBOLS USED

	Identification of the Manufacturer
	Product identification code
	Serial number: identifying the production serial number
	Attention, refer to the user manual. Information concerning safety
	Consult the user manual
	Year of manufacture
	Disposal according to WEEE regulation
	Operating ambient temperature
CE 1370	Complies with Council Directive 93/42 / EEC and Council Regulations, Class IIa DM. The 4-digit code indicates the certifying body of the device.

8 ELECTROMAGNETIC COMPATIBILITY

8.1 EMC WARNINGS

L'apparecchio è conforme alla norma collaterale CEI EN 60601-1-2 Norma applicabile al prodotto e relativa alla compatibilità elettromagnetica.

THE APPLIANCE MUST BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THIS SECTION.

THE EQUIPMENT CAN BE INFLUENCED BY THE COMMUNICATION EQUIPMENT AND MOBILE PHONES.

THE EQUIPMENT CANNOT BE EQUIPPED WITH CABLES DIFFERENT FROM THOSE SPECIFIED BY THE MANUFACTURER

THE DEVICE MUST NOT BE USED NEAR OR IN OVERLAYS WITH OTHER EQUIPMENT IN ORDER TO AVOID INTERFERENCE IN THE NORMAL OPERATING CONDITION.

8.2 EVALUATION TABLES 60601-1-2

Tabella 1 (numerazione 60601-1-2)

The device is intended for use only in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 2	Device in which the RF energy in the 9kHz-400 GHz range is intentionally generated and not used in the form of electromagnetic radiation, capacitive and / or inductive coupling, for the treatment of materials or inspection.
RF emissions CISPR 11	Class A	Device suitable for all buildings except domestic ones and those connected directly to a low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	
CISPR 14	No applicable	
CISPR 15	No applicable	

Table 2 (numbering 60601-1-2)

The device is intended for use only in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ±2 kV;±4 kV;±8 kV;±15 kV air	EN 60601-1-2 Test level	Floors must be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV 100 kHz repetition frequency	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Surge EN 61000-4-5	± 0,5 kV, ± 1 kV (line-to-line) ± 0,5 kV, ± 1 kV, ± 2 kV (line-to-ground)	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2 Test level	The magnetic fields emitted at mains frequency must be at levels characteristic of a typical location in a typical commercial, hospital or domestic environment.

Table 4 (numbering 60601-1-2)

The device is intended for use only in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m EN 60601-1-2 Test level	Portable and mobile RF communications equipment should not be placed to any part of the [equipment or system], including cables, less than the separation distance calculated by the equation applicable to the transmitter frequency.**Distanza di separazione consigliata** $d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz Where P is the maximum output power of the transmitter in watt (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m). The field strength of fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V EN 60601-1-2 Test level	

The device is intended for use only in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
			marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			
a) fields generated by fixed transmitters, such as base stations for radiotelephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be accurately evaluated through calculations. To assess the electromagnetic environment generated by fixed RF transmitters, the need to make measurements in the field of application must be considered. If the measured field strength in the place where the device is used exceeds the established field strength V / m, observe the device to verify the maintenance of normal operation. In the event of abnormal operation, additional protection measures must be carried out, such as moving the device from the emitting element or using a more shielded location using RF radiation and / or using a more effective filter b) Over the frequency range 150 kHz to 80 MHz, the field strength must be less than [V1] V / m.			

Table 6 (numbering 60601-1-2)

Recommended separation distance for non-life support devices and intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters) and the device, as recommended below, based on the maximum output power of the device of communication.		
Maximum output power of the transmitter (W)	**Separation distance according to the transmitter (m)**	
	80MHz to 800MHz $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters with the maximum output power not shown in the above list, the recommended separation distance *d* in meters (m) can be estimated with the equation applicable to the transmitter frequency, where P is the maximum rated output power of the transmitter in watt (W) according to the transmitter manufacturer. Note: (1) 800 MHz, the separation distance for the highest frequency range (2) These guidelines may not be applicable in all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people NB The system has not been tested for electromagnetic immunity to radiated RF over the entire frequency range from 80 MHz to 2.5 GHz		